



National Health and Nutrition Examination Survey (NHANES)

Physician Examination Procedures Manual



August 2009

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1. OVERVIEW OF THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

This chapter provides a general history and description of the National Health and Nutrition Examination Survey (NHANES), and an overview of the tasks that staff perform during the survey.

1.1 History

The National Health Survey Act, passed in 1956, provided the legislation authorizing for a survey to provide current statistical data on the amount, distribution, and effects of illness and disability in the United States. NHANES was created to fulfill the purpose of this act. The NHANES 99 for 2004 was the eighth in a series of national examination studies conducted in the United States since 1960, but effective in 2005, NHANES has become a continuous field survey with year-round data collection.

To fulfill the purposes of this act, it was recognized that data collection would involve at least three sources: (1) direct interviews with Americans of all ages; (2) clinical tests, measurements, and physical examinations on sample persons; and (3) facilities where persons received medical care such as hospitals, clinics, and doctors' offices.

To comply with the 1956 act, the National Center for Health Statistics (NCHS), a branch of the U.S. Public Health Service in the U.S. Department of Health and Human Services, has conducted eight separate examination surveys to collect interview and physical examination data.

The first three of these national health examination surveys were conducted in the 1960s:

1. 1960-62—National Health Examination Survey I (NHES I);
2. 1963-65—National Health Examination Survey II (NHES II); and
3. 1966-70—National Health Examination Survey III (NHES III).

NHES I focused on selected chronic disease of adults aged 18-79. NHES II and NHES III focused on the growth and development of children. The NHES II sample included children aged 6-11,

while NHES III focused on youths aged 12-17. All three surveys had an approximate sample size of 7,500 individuals.

Beginning in 1970 a new emphasis was introduced. The study of nutrition and its relationship to health status gained importance as researchers began to discover links between dietary habits and disease. In response to this concern, under a directive from the Secretary of the Department of Health, Education and Welfare, the National Nutrition Surveillance System was instituted by NCHS. The purpose of this system was to measure the nutritional status of the U.S. population and changes over time. A special task force recommended that a continuing surveillance system include clinical observation and professional assessment as well as the recording of dietary intake patterns. Thus, the National Nutrition Surveillance System was combined with the National Health Examination Survey to form the National Health and Nutrition Examination Survey (NHANES). Five surveys of this type have been conducted since 1970:

1. 1971-75—National Health and Nutrition Examination Survey I (NHANES I);
2. 1976-80—National Health and Nutrition Examination Survey II (NHANES II);
3. 1982-84—Hispanic Health and Nutrition Examination Survey (HHANES);
4. 1988-94—National Health and Nutrition Examination Survey (NHANES III); and
5. 1999-05—National Health and Nutrition Examination Survey (NHANES 99).

NHANES I, the first cycle of the NHANES studies, was conducted between 1971 and 1975. This survey was based on a national sample of about 28,000 persons between the ages of 1-74. Extensive data on health and nutrition were collected by interview, physical examination, and a battery of clinical measurements and tests from all members of the sample.

NHANES II began in 1976 with the goal of interviewing and examining 28,000 persons between the ages of 6 months and 74 years. This survey was completed in 1980. To establish a baseline for assessing changes over time, data collection for NHANES II was made comparable to NHANES I. This means that in both surveys many of the same measurements were taken in the same way, on the same age segment of the U.S. population.

While the NHANES I and NHANES II studies provided extensive information about the health and nutritional status of the general U.S. population, comparable data were not available for many

of the ethnic groups within the United States. HHANES, conducted from 1982 to 1984, aimed at producing estimates of health and nutritional status for the three largest Hispanic subgroups in the United States—Mexican Americans, Cuban Americans, and Puerto Ricans—that were comparable to the estimates available for the general population. HHANES was similar in design to the previous HANES studies, interviewing and examining about 16,000 people in various regions across the country with large Hispanic populations.

NHANES III, conducted between 1988 and 1994, included about 40,000 people selected from households in 81 counties across the United States. As previously mentioned, the health status and characteristics of minority groups can be very different from that of nonminority groups. Thus, black Americans and Mexican Americans were selected in large proportions in NHANES III. Each of these groups comprised separately 30 percent of the sample. It was the first survey to include infants as young as 2 months of age and to include adults with no upper age limit. For the first time a home examination was developed for those persons who were unable or unwilling to come into the examination center but would agree to an abbreviated examination in their homes. To obtain reliable estimates, infants and young children (1-5 years) and older persons (60+ years) were sampled at a higher rate. NHANES III also placed an additional emphasis on the effects of the environment upon health. Data were gathered to measure the levels of pesticide exposure, the presence of certain trace elements in the blood, and the amounts of carbon monoxide present in the blood.

NHANES 99, conducted between 1999 and 2005, was the first of the series of surveys designed with the goal of becoming a continuous, annual survey. Each single year, and any combination of consecutive years of data collection, comprises a nationally representative sample of the U.S. population. This new design allows annual statistical estimates for broad groups and specific race-ethnicity groups as well as flexibility in the content of the questionnaires and exam components. New technologic innovations in computer-assisted interviewing and data processing result in rapid and accurate data collection, data processing, and publication of results.

The number of people examined in a 12-month period is about the same as in previous NHANES—about 5,000 a year from 15 different locations across the Nation. The data from the NHANES are used by government agencies, state and community organizations, private researchers, consumer groups, companies, and health care providers.

In addition to NHANES I, NHANES II, Hispanic HANES, and NHANES III, several other HANES projects have been underway since 1982. These projects have been a part of the HANES Epidemiological Follow-up Survey, a multiphase project that has been conducting follow-up interviews with the NHANES I survey population in order to provide a longitudinal picture of the health of the U.S. population.

1.2 Goals of the Survey

NHANES 2009, the current version of the survey, was designed to continue the collection of information about the health and diet of people in the United States. These data are used to fulfill specific goals. The overall goals of NHANES 2009 are to:

- Estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors;
- Monitor trends in the prevalence, awareness, treatment, and control of selected diseases;
- Monitor trends in risk behaviors and environmental exposures;
- Analyze risk factors for selected diseases;
- Study the relationship between diet, nutrition, and health;
- Explore emerging public health issues and new technologies; and
- Establish a national probability sample of genetic material for future genetic testing.

1.3 NHANES Data Accomplishments

NHANES data have been used to influence policy and improve the health of the U.S. population in many ways since the survey series was established. For the past 40 years, the U.S. Public Health Service has been interviewing and examining tens of thousands of Americans. Currently, teams of doctors, nutritionists, and health technologists are conducting the National Health and Nutrition Examination Survey (NHANES) in communities across the United States. Information from the survey will be updated annually.

Some of the contributions of the NHANES data include:

- **Pediatric growth charts.** Developed by the National Health and Nutrition Examination Survey, the NHANES growth charts are found on the walls of pediatricians' offices and clinics not only across the United States, but also around the world. With new information on younger babies, the current charts have been expanded and improved.
- **Vitamins and minerals.** The earlier NHANES showed that low iron levels were a serious problem for many people, including women of childbearing age, preschool children, and the elderly. As a result, the government decided to fortify grain and cereal with iron to correct this deficiency. The surveys also showed the need for folate to eliminate another deficiency and prevent birth defects. Today, we have a wealth of information at our fingertips and, indeed, on our food labels to help us make better choices about our diets. Much of that information comes directly from the National Health and Nutrition Examination Survey.
- **Cholesterol levels.** The first survey in the 1960s led public health officials to sound the alarm about the link between high cholesterol levels and the risk of heart disease. When NHANES started testing, one-third of adults had high cholesterol. Today fewer than 1 in 5 adults have high cholesterol. Changes in diet and lifestyle, all built on information from the national survey, have sharply reduced our risk of dying from a heart attack. These strategies have also helped doctors find ways to better treat heart attack patients and speed their recovery.
- **Lead-free gasoline.** It was NHANES that gave the first clear-cut evidence that Americans had too much lead in their blood. This led Congress, the Environmental Protection Agency, and others to phase out the use of lead as an additive in gasoline, and the results have been remarkable. By the 1990s, NHANES found that only 4 percent of Americans had elevated lead in their blood, but it remains a problem for certain groups, especially poor children living in old houses, in cities where lead paint was once common. The survey helps public health agencies pinpoint where lead still remains a problem.

As the NHANES survey continues to collect and update health information, there are other ways in which the information will be of use, including:

- **Osteoporosis.** This condition, in which bones get weaker as people grow old, is blamed for many of the fractures among the elderly. The National Health and Nutrition Examination Survey measures bone density of participants.
- **Environmental smoke.** Recent NHANES data found that nearly 9 out of 10 nonsmoking Americans were exposed to smoke either at home or on the job.
- **Obesity.** Despite the public health gains in recent years, more Americans are overweight than ever before. Today, more than half of the adults in the U.S. are overweight, and the number of overweight children and teens has doubled in the past

decade. This has led public health experts to look for ways to improve both diet and fitness.

- **Changes in Food/Diet.** Today consumers can find a wide range of low fat and light foods in their grocery stores, from dinner entrees to snacks. As the food we eat changes, NHANES helps monitor whether these new foods and dietary changes actually are in the best interest of our health.
- **Immunizations.** The National Health and Nutrition Examination Survey has turned up important information about the extent of hepatitis B infections, and led to the recommendation that all infants and children be vaccinated against it. Though babies and children are the primary targets for immunizations, the survey also has alerted doctors to the importance of tetanus shots for older people.

1.4 National Center for Health Statistics

The Division of Health and Nutrition Examination Surveys (DHANES) is one of the survey divisions at the CDC's National Center for Health Statistics (NCHS).

DHANES is responsible for planning, operations, informatics, analysis, and reporting activities related to the family of health and nutrition examination surveys. These surveys range from the capstone cross-sectional National Health and Nutrition Examination Survey, to longitudinal studies, and more recent efforts with community-based studies. DHANES is comprised of more than 60 Federal employees who have training and expertise in diverse areas including public health, informatics, survey methodology, and statistics. The Federal staff are augmented by contractor staff working on- and offsite.

The Division consists of four branches and the Office of the Division Director. The DHANES Office of the Director coordinates the major activities in the Division. Each of the four branches consists of a multidisciplinary team with specific duties and responsibilities.

1.5 Sample Selection

A sample is defined as a representative part of a larger group. Since it is impossible to interview and examine everyone in the United States for NHANES, a representative sample is taken of the U.S. population. By studying a representative sample of the population, it is assumed that the findings would not have been too different had every person in the U.S. been studied. Because generalizations

about the population will be made, it is extremely important that the sample be selected in a way that accurately represents the whole population. Statisticians calculate the size of the sample needed and take into consideration the geographic distribution and demographic characteristics of the population, such as age, gender, race, and income.

An introductory letter is sent to each household in the sample. A few weeks after the letter goes out, interviewers visit each listed household and use carefully designed screening procedures to determine whether any residents are eligible for the survey. If eligible residents are present, the interviewer then proceeds to introduce the study, presents the Sample Person (SP) with a survey brochure, and obtains a signed consent for the household interview. The brochure contains detailed information on the survey, the household interview, and the Mobile Examination Center (MEC) examination.

A signed consent form must be obtained from each eligible individual before the household interview can be conducted. A refusal to sign the consent form is considered a refusal to participate in the survey. After the interview is completed, the interviewer then explains the MEC exam, obtains another signed consent form for the MEC exam, and contacts the field office to schedule a MEC appointment for the SP. All SPs aged 12 years and older must sign the Examination Consent forms to participate in the MEC examination. Parental consent is also required for SPs under 18 years of age. SPs aged 7-11 years old are asked to sign the Examination Assent form. An additional consent form is required for consent to future general research and genetics testing for both adults (ages 18+) and parents of children under 18 years. This consent form gives permission to store a small sample of blood and urine for future specimen testing and to collect a sample for genetics testing. A refusal to sign the MEC consent or assent form is considered a refusal to participate in the examination phase of the survey. Examinations will not be performed on sample persons who do not sign a consent form.

1.6 Field Organization for NHANES

There are two levels of field organization for this study - the home office staff and the field staff.

- **Home Office Staff from Westat** – Project staff from Westat are responsible for overseeing the field teams and field work.

- **Field Office (FO) Staff** – For this survey, an office will be opened at every survey location (stand). Each field office will have a Study Manager (SM), Office Manager (OM), a Field Manager (FM), and one Assistant Office Manager (AOM).
 - The **Study Manager (SM)** is responsible for the overall management of operations at a stand.
 - The **Office Manager (OM)** is responsible for the stand office operations and is the main conduit for the flow of work and information between the MEC and the household interviewing staff. She or he will supervise one or more local office clerks hired to assist with office activities. The OM reports to the SM.
 - The **Field Manager (FM)** has primary responsibility for the supervision of the household interviewers. The FM also assists the SM and supervises the activities of the Assistant Office Managers. She or he will deal with administrative issues, ISIS problems, and preparations for the next stand.
 - The **Assistant Office Managers (AOMs)** are primarily responsible for data entry into the Integrated Survey Information System (ISIS), editing data collection materials, and verification of interviewer work. The AOMs report to the FM and also work closely with the OM.
- **Facilities Specialist (FES)**– One Facilities and Equipment Specialist will travel with each field office team and caravan to oversee the maintenance and operation of the trailers.
- **Household Interviewers** – These staff members are primarily responsible for identifying and enrolling the survey participants, conducting the household interviews, and appointing the study participants for the MEC exam. Specifically, household interviewers will locate occupied residential dwelling units, administer the Screener to select eligible sample persons, obtain signed consents to the household interview, conduct the interviews, set up examination appointments, obtain consents for the MEC exam, conduct field reminders for MEC appointments, and assist in rescheduling broken, cancelled, and no-show appointments.

Several times a week, household interviewers visit the field office and report to the field manager. During the course of the study, interviewers also interact on a daily basis with other field office staff and home office staff.

- **MEC Staff** – These health professionals conduct the health exams. The survey includes two exam teams. There are 16 individuals on each traveling team: 1 MEC manager, 1 MEC coordinator, 1 licensed physician, 3 medical technologists, 4 health technologists, 2 registered dental hygienists, 2 MEC interviewers, 2 dietary interviewers, and 1 phlebotomist. In addition, local assistants are recruited, trained, and employed at each stand to assist the exam staff.

The following section describes the steps that are always completed before the opening of a stand and provides an overview of the tasks that interviewers are expected to perform.

Steps completed prior to interviewing include:

1. Statisticians scientifically select certain segments in the sampling area. A segment is an area with definite boundaries, such as a city block or group of blocks containing a cluster of households.
2. Segments are listed by NHANES staff. Listing is the systematic recording on special forms of the address of every dwelling unit (DU) located within the segment. Commercial buildings and other structures not intended as living quarters are not listed.
3. A sample of dwelling units is selected from the listing forms. This sample is the group of addresses that interviewers visit in order to conduct interviews.
4. Immediately before data collection begins, an advance letter is sent to each dwelling unit with a mailing address. This letter briefly describes the study and informs the household that an interviewer will contact them in the near future.

Steps followed by the interviewers at a stand include:

1. Obtain assignment of sampled dwelling units to contact from the field manager.
2. Locate dwelling units using addresses on the Household Folders and listing/mapping materials in the Segment Folder.
3. Contact an adult who lives in the selected household (occupied residential dwelling unit) and administer the Screener using a laptop computer.
 - The Screener is an interview that lists all the individuals who live in the household, divides the household into families, and collects all the demographic characteristics necessary to immediately determine if there are persons in the household eligible for further interviewing.
 - All instructions necessary to determine eligibility and to select sample persons (SPs) are programmed in the CAPI Screener.
4. If all persons in a household are ineligible, no further work is done with the case. If eligible household members are identified, interviewers continue to conduct all the necessary tasks associated with the case.
5. In eligible households, obtain a signed interview consent form prior to completing the medical history and/or the family questionnaire.

6. Administer the appropriate medical history CAPI interview to eligible respondents. The questions asked depend on the age of the SP.
7. Administer the Family questionnaire to one adult family member from each eligible family in the household.
8. Schedule a MEC appointment for each SP, coordinating the MEC schedule and the SP schedule.
9. Obtain signed consent form(s) for each SP for the examination, confirm the examination appointment(s) with the field office, and give each SP an appointment slip.
10. If there is more than one eligible family in a household, repeat this process with each additional family.
11. Record the result of each contact or attempted contact with the household on the Call Record located in the Household Folder.

Interviewers also support the survey by conducting field reminders prior to MEC appointments and reschedule broken, cancelled, or no-show MEC appointments. When an interview has been completed, interviewers edit their work, carefully reviewing all forms for completeness and legibility. Interviewers report in person to the field manager at the stand office for regularly scheduled conferences, usually every other day. During these conferences, interviewers discuss completed cases, discuss problems with incomplete cases, receive new case assignments, and report time, expenses, and production.

To ensure the accuracy and completeness of the survey, all interviewer work is edited by the field office staff, and then validated by recontacting respondents. After this review, supervisors provide interviewers with feedback concerning the quality of the work.

1.7 Exams and Interviews in the Mobile Examination Center (MEC)

Examinations and interviews are conducted in a mobile examination center (MEC), which is composed of four specially equipped trailers. Each trailer is approximately 48 feet long and 8 feet wide. The trailers are set up side-by-side and connected by enclosed passageways. During the main survey, detachable truck tractors drive the trailers from one geographic location to another.

Exhibit 1-1 shows a floor plan for the MEC. The interior of the MEC is designed specifically for this survey. For example, the trailers are divided into specialized rooms to assure the privacy of each study participant during exams and interviews. Many customized features have been incorporated including an audiometry room that uses a soundproof booth, a wheelchair lift, and a wheelchair-accessible bathroom available to assist participants with mobility problems. Exhibit 1-2 shows the locations of the various exams within the MEC.

1.7.1 Exam Sessions

The MEC operates 5 days a week and includes weekday, evening, and weekend sessions. Two 4-hour sessions are scheduled each day with approximately 10-12 SPs per session. During a stand, workweeks rotate to offer a variety of MEC appointments on weekday mornings, afternoons, and evenings, and every weekend.

Exhibit 1-1. Floor plan of the MEC

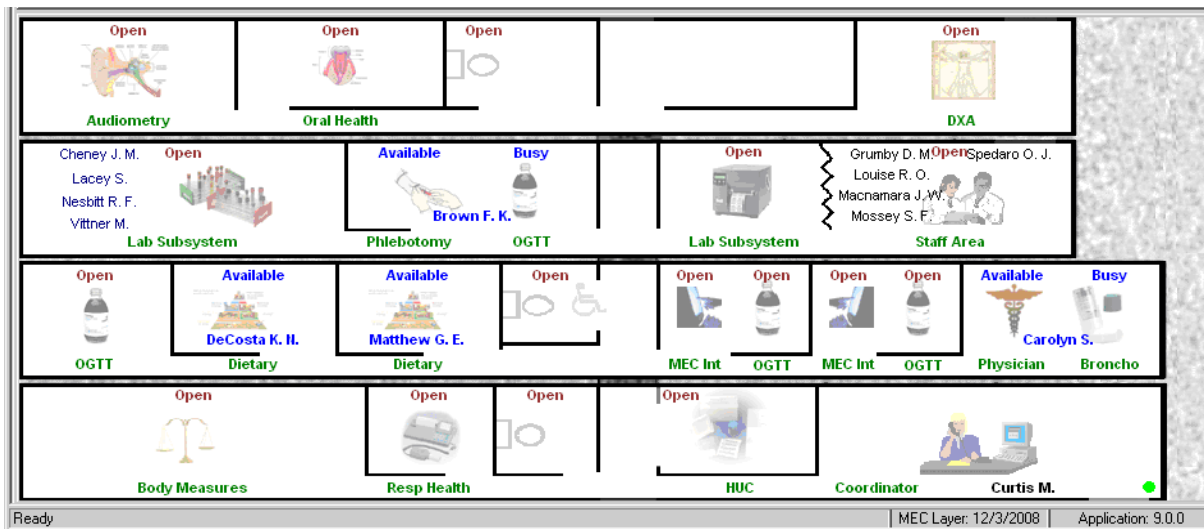


Exhibit 1-2. MEC exams and rooms

Trailer	Room	Room Use
Trailer 1	Coordinator	Welcoming and waiting area for SPs
	Proxy Room Respiratory Health	Home Urine Collection, Proxy exam Exhaled Nitric Oxide Spirometry
	Anthropometry	Body measurements
Trailer 2	Physician MEC Interview 1	Physician examination Health interview, OGTT Trutol administration, Proxy Exam
	MEC Interview 2	Health interview, OGTT Trutol administration, Proxy Exam
	Dietary Interview 1	Dietary interview
	Dietary Interview 2	Dietary interview
	Oral Glucose Tolerance Test (OGTT)	Oral glucose tolerance Trutol administration
Trailer 3	Phlebotomy/OGTT	Drawing of blood samples Oral glucose tolerance Trutol administration
	Laboratory	Processing of biological samples
	Label/shipping area	Lab area for labeling and shipping specimens
	Staff area	Staff area that houses main computer system
Trailer 4	Bone Density (DXA)	Bone Density scans
	Oral Health	Dental examination
	Audiometry	Hearing tests

1.7.2 Exam Team Responsibilities

There are 15 individuals on each exam team. In addition, a local assistant will be hired to assist the staff in managing examinee flow. The duties of the exam team members are summarized below:

- One MEC manager supervises the exam staff, oversees exam flow, and supports exam operations.
- One coordinator directs the flow of SPs through the MEC examination process. The coordinator manages all SP appointments, verifies that all components are completed for each SP, and exits SPs from the MEC.
- One physician conducts the medical examination and records results, reviews the results of the complete blood count and pregnancy test, and serves as the safety officer for the MEC.

- One registered dental hygienist conducts the oral health exam and obtains the HPV specimen.
- Two health (MEC) interviewers administer questionnaires for physical and mental health information. The interviewers are also trained to administer the proxy exam, the OGTT exam, and the home urine collection exam.
- Two dietary interviewers administer the dietary questionnaire. The interviewers record a 24-hour dietary recall of the types and amounts of foods consumed by the SP in the last 24 hours. They are also trained to administer the OGTT and home urine collection exam.
- Four health technologists (some with radiologic technology and/or other health training) take and record body measurements, conduct respiratory health exams and bone density (DXA) scans, administer hearing tests, record for the oral health exam, conduct the home urine collection exam, and administer the Trutol solution for the glucose tolerance test.
- Three medical technologists conduct clinical laboratory tests on biological and environmental specimens, record the results of the tests, and prepare and ship specimens to various laboratories.
- One phlebotomist conducts the phlebotomy interview, administers the fasting questionnaire, and draws blood for laboratory tests and special studies like the volatile organic compound special study. The phlebotomist is also responsible for administering the Trutol and drawing a second blood sample for the GTT test. They are trained as a backup examiner for other MEC components like body measures and the home urine collection.

Each staff member is part of a team of professional persons with specific assignments that must be completed in order to accomplish the overall objective of the survey. Each individual must be aware of and respect the job demands placed upon other staff members, maintain an attitude of tolerance and consideration for fellow members of the team, and willingly perform extra tasks that may be assigned to support other staff members in the performance of their duties. MEC staff members may be requested to perform tasks not directly related to their specific professional skills in order to implement the overall data collection plan.

1.7.3 Examination Components

The full examination for an adult takes approximately 3½ hours, but the actual length depends on the SP's age. Some exams are done only on certain age groups so the exam profiles vary, even among adult SPs. The exam components are described briefly below and summarized in Exhibit 1-3.

Exhibit 1-3. Examination components

Examination	Age group
Audiometry	12-19, and 70+
Bone Density (DXA)	8 +
Body Measures	All ages
Dietary Interview	All ages
Glucose Tolerance	12+
Laboratory	1+
Urine Sample	6+
MEC (Health) Interview	8 +
Home Urine Collection	6+
Oral Health	3+
Phlebotomy	1+
Physician	All ages
Blood Pressure	8+
Respiratory Health Spirometry Exhaled Nitric Oxide Bronchodilation with spirometry	6-79 Limited subsample
Volatile Organic Compounds	12+

- **Audiometry**

The goals of the hearing exam are to obtain normative data on the hearing status of the adolescent and elderly U.S. population and to evaluate certain covariates that may be related to hearing loss, such as noise exposure. The hearing component tests youth aged 12-19 years, and adults aged 70 and over, by performing pure tone air conduction audiometry and tympanometry. Because air conduction thresholds alone cannot detect middle ear disease, tympanometry is conducted to identify potentially medically-correctible conditions which may be contributing to hearing impairment.

- **Body Composition**

The DXA component will use dual energy x-ray absorptiometry to evaluate skeletal health on SP's aged 8 years and older. Two DXA scans, AP spine and femur, will be used to assess overall skeletal changes that often occur with age by measuring bone mineral content (BMC) and bone mineral density (BMD). DXA measurements can

also be used to provide information on early gender and ethnic changes in the rate of bone accretion and to determine the age when skeletal accretion ceases and when peak bone mass occurs.

- **Body Measures or Anthropometry**

All SPs will have body measurements taken. The exam will include height, weight, and other body measurements such as skinfold and arm girth, chest expansion and spine flexion. These measurements will be used to assess growth, obesity, and body fat distribution, and will provide information that can be used as a reference for later studies. Chest expansion and spinal flexion measures will provide data on the proportion of the population affected by spine disorders. Measurements of height and weight will allow for a revision of the child growth charts now in widespread use. Measuring body fat is important because it is associated with hypertension, adult diabetes, cardiovascular disease, gallstones, arthritis, and some forms of cancer. Furthermore, obesity and overweight can have an affect on the mental, physical, and social well-being of individuals.

- **Dietary Interview**

Dietary information has been collected in NHANES since the 1970s. Researchers and policymakers rely on NHANES data for detailed information about the foods and beverages that are consumed by the U.S. population. In addition to providing important national reference data on food and nutrient intakes that are obtained on all survey participants, the data help us to learn about food patterns of ethnic subgroups, the adequacy of diets consumed by young children and older persons, and the contribution of food to total nutrient intakes. Total nutrient intakes from food and dietary supplements can be computed by combining NHANES Dietary Recall data with the dietary interview supplement and antacid recall information. Many Federal agencies use NHANES data to evaluate Federal regulations in the areas of food fortification and human risk assessment analyses that are used to measure human exposure to contaminants that are found in food.

The goal of the dietary component is to estimate total intake of foods, food energy and nutrients, nonnutrient food components, and plain drinking water by the U.S. population; and assess dietary behaviors and the relationship of diet to health. Quantitative dietary intake data are obtained for all subjects by means of a 24-hour dietary recall interview using a computer-assisted dietary data entry system.

Two dietary interviews will be administered to all SPs. The primary dietary interview is administered in person in the MEC (the MEC In-person interview). At the end of the MEC dietary interview, the interviewers will schedule the SPs for a Phone Follow-up (PFU) 3-10 days later. The PFU is a follow-up dietary interview conducted by telephone by dietary interviewers from the home office. In addition, a second dietary phone interview is offered to all SPs aged 1 year and older who complete the MEC dietary interview. Proxy interviews will be conducted for children aged 1-11 years. Each household is also eligible to participate in an interview about food and food shopping. The adult who purchases the food for the household is asked to complete

the interview. This interview, called the Flexible Consumer Behavior Survey, is also conducted by the home office dietary interviewers.

- **Home Urine Collection**

Microalbuminuria, or protein excretion in the urine, is an important indicator of early kidney disease, and is a prognostic indicator for diabetes, cardiovascular disease, and mortality. Microalbuminuria is measured by the urine albumin/creatinine ratio on the specimen provided on the day of the MEC exam. A second urine specimen is collected within 10 days of the MEC exam to compare the level of protein excretion with the first urine sample obtained in the MEC. During the home urine collection exam, the SP is given the necessary instructions and materials to successfully obtain and mail a urine specimen directly to a laboratory.

- **Oral Glucose Tolerance Test (OGTT or GTT)**

The purpose of this test is to reassess the prevalence of diabetes and impaired glucose tolerance (IGT) in the U.S. population. Persons with impaired glucose tolerance (IGT) – 15.6 percent of the U.S. population – are at high risk for developing diabetes. Also, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined on the basis of an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hr value of 140-199 mg/dl are considered to have IGT. Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT.

The GTT will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts.

A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast. After the venipuncture, participants are asked to drink 75 milligrams of Trutol® and to have a second venipuncture 2 hours (plus or minus 15 minutes) after consuming the Trutol. The blood glucose level from the second venipuncture will be used to determine if an SP has IGT.

- **Laboratory**

The laboratory component includes the collection and processing of various biological and environmental specimens including blood for subjects 1 year and older, and urine for subjects 6 years and older. On-site pregnancy testing excludes pregnant women from other examination components such as DXA. Complete Blood Counts (CBCs) are also performed in the MEC laboratory. All other specimen testing is performed by Federal, private, and university-based laboratories under contract to NCHS.

Urine is collected from SPs aged 6 and older to assess kidney function, measure levels of mercury, heavy metals, iodine and arsenic, and assess environmental exposures to pesticides such as organophosphates, phthalates, polycyclic aromatic hydrocarbons, phytoestrogens, and perchlorates.

- **MEC (Health) Interview**

SPs aged 8 and older will have a health interview in the MEC. Generally, the questions asked in the MEC are considered to be more sensitive than the questions asked in the household. The MEC environment is believed to be a more appropriate setting for the administration of these questions. All eligible SPs will be asked questions in a face-to-face interview. In addition, persons who are 12–69 years old will be asked a series of more personal questions in complete privacy. The SP will listen to questions through a set of earphones and will enter responses by touching a computer screen.

Depending upon the age of the SP, the interview may consist of questions about tobacco, drug, and alcohol use, reproductive health (birth control practices, pregnancy and reproductive history, sexual activity), health behaviors (physical activity, weight history), kidney conditions and bowel health, arthritis, current health status and mental health, and exposure to certain chemicals. Children 8-11 years will only be asked questions about weight history.

- **Oral Health**

SPs aged 3 and older will receive an oral health exam conducted by registered dental hygienists. All examinees will be checked for tooth loss, cavities, restorations, and sealants. SPs 30 years and older will also be asked some questions about denture use and will be assessed for periodontal conditions; SPs aged 20–59 years will also be tested for human papilloma virus.

Oral and dental diseases affect many in the United States. Dental caries and tooth loss remain significant problems affecting the Nation's oral health. Although average dental caries rates for school-aged children have declined, nearly a half of all children still have caries. Additionally, more than 90 percent of adults in the United States have experienced caries. Dental sealants, an effective caries prevention measure, have been underutilized in the United States, with less than one-quarter of children aged 5-17 having them.

Over the past four decades, oral and dental health characteristics collected in national surveys supported by the Federal Government have been critical for monitoring health status, risk factors for disease, and access to preventive and treatment services. The 2005-06 NHANES oral health component will meet a critical need to continue monitoring trends in dental caries and tooth retention. More specifically, this NHANES will produce oral health data to monitor five oral health objectives in the Healthy People 2010 health promotion: dental caries experience, untreated dental decay, no permanent tooth loss, complete tooth loss, and dental sealants.

■ **Phlebotomy**

SPs aged 1 and older will have blood drawn. The amount drawn will depend on the person's age. It is important to draw blood from study participants for a number of reasons:

- Knowledge can be gained about how healthy a person is by measuring for various substances in his or her blood.
- Blood tests can provide early warnings of potential health problems, perhaps before physical signs appear. For example, a blood test for lead might indicate exposure to unsafe lead levels before an individual shows any physical signs of lead poisoning. Also, diabetes mellitus will be assessed by measures of plasma glucose, insulin, and glycohemoglobin in examinees ages 12 years and older. Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and more than 1 million new cases of diabetes are diagnosed each year. Alarmingly, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.
- Blood tests will also indicate the presence of STDs such as Chlamydia and gonorrhea, hepatitis, herpes, and HIV infection.
- Blood tests help in monitoring nutritional status, one of the key goals of NHANES. What researchers discover from this data can lead to health policy recommendations—the need for more vitamin fortification, for example.
- The blood testing also provides information about the levels of cholesterol and other blood lipids, another important study goal.

■ **Physician**

All SPs see the physician. The physician measures blood pressure and pulse of all participants over 8 years of age, explains to female SPs how the HPV examination will be completed and explains the meaning of the STD/HIV test results to eligible SPs. The physician explains how SPs receive the results of STD/HIV tests so that the results remain totally confidential to the SP. Beginning in 2007, the physician will screen participants who qualify for the bronchodilator with spirometry exam, obtain consent for, and administer the bronchodilator. The physician must be present on the MEC before any exams can be conducted, and the physician is in charge of any medical emergency that occurs on the MEC.

■ **Respiratory Health**

Beginning in 2007, respiratory health (RH) was incorporated in the NHANES study. RH will be collected by means of an assessment of lung function testing, or spirometry, and a measurement of exhaled nitric oxide (ENO). The objective of collecting this data is to assess the prevalence of asthma and adult chronic obstructive

pulmonary disease in the U.S. population. All SPs aged 6-79 years will be eligible to participate in the component. SP's will be excluded from the RH exam if they answer positively to any pre-exam safety exclusion questions.

RH has three subcomponents: (1) spirometry, (2) ENO measurements, and (3) repeat spirometry measurements after the administration of a bronchodilator. For the third subcomponent, a subset of SPs whose baseline spirometry results show lung function values below a certain threshold, and will be provided with an opportunity to repeat spirometry after inhaling a bronchodilator medication. The MEC physician will first evaluate the participant to determine if the participant meets the requirements for safe bronchodilator administration. The physician will then obtain written informed consent, and then instruct the SP in the administration of the bronchodilator, and then administer the medication. Results from repeat spirometry testing following the bronchodilator could potentially provide a more detailed picture of each individual's breathing problem, i.e., an indication of whether the person is likely to have asthma or chronic obstructive pulmonary disease.

ENO provides a noninvasive marker measure of airway inflammation, a factor in asthma and possibly other lung diseases. Evaluation of airway inflammation, a precursor of asthma symptoms, is important in the investigation of underlying disease. Currently, there are no U.S. population-based estimates of ENO baseline levels for normal subjects, or for those persons with asthma and chronic obstructive pulmonary disease.

■ **Volatile Organic Compounds/Perchlorate (VOC) Special Study**

The purpose of the VOC/Perchlorate study is to determine the prevalence of exposures to chemicals called Volatile Organic Compounds (VOCs) and Perchlorates. Volatile organic compounds are emitted as gases from certain solids or liquids. VOCs include a variety of chemicals, some of which may have short- and long-term adverse health effects. Concentrations of many VOCs are consistently higher indoors (up to ten times higher) than outdoors. VOCs are emitted by a wide array of products numbering in the thousands. Examples include paints and lacquers, paint strippers, cleaning supplies, pesticides, building materials and furnishings, office equipment such as copiers and printers, correction fluids and carbonless copy paper, graphics and craft materials including glues and adhesives, permanent markers, and photographic solutions.

Perchlorate is an oxidizer used in rocket fuel, explosives, and road flares, and it also occurs naturally in the atmosphere. Since the 1950s, unused amounts of the chemical have been dumped into unlined pits throughout the United States, where it has seeped into water supplies. The chemical is highly mobile and soluble in water, aiding its dispersion through the environment.

VOCs and Perchlorates are tested on a half-sample of participants over age 12; tap water from participants' homes are collected by the household interviewers, and in the MEC, blood is collected from the participant during phlebotomy.

1.7.4 Sample Person Remuneration

All examinees receive remuneration for the MEC visit as well as payment for transportation expenses. The MEC visit remuneration is age-related and may include an extra fasting incentive if the SP is eligible. SPs who complete the dietary phone interview and the Consumer Behavior Questionnaire also receive an incentive.

1.7.5 Report of Exam Findings

Examinees receive the results of many of the tests and exams conducted in the MEC, though some results are used only for research and are not reported.

One report, a Preliminary Report of Findings, is produced on the day of the SP's examination and includes results that are immediately available and require no further evaluation or interpretation. Before the examinee's departure from the MEC, the coordinator prints a report that can include height, weight, complete blood count, blood pressure and heart rate, and results from the oral health and audiometry examinations. The MEC physician reviews the blood pressure and complete blood count test results for abnormalities and discusses any problems with the SP (or his or her parent.) Approximately 12-16 weeks after the exam, NCHS mails the remainder of the examination results to the SP after appropriate clinical or quality reviews are completed. This Final Report of Findings will include all the results from the Preliminary Report of Findings and may include laboratory tests like liver and kidney function tests and lipids, bone density scan results, retinal image scan reports, and spirometry results. Seriously abnormal results are reported to the SP via telephone by NCHS before the remaining findings are mailed.

Certain tests, such as those for sexually transmitted diseases (Chlamydia, herpes simplex, and human papillomavirus) and human immunodeficiency virus (HIV) are released only to the sample person using a specially devised procedure requiring a unique password.

To further assist sample persons, an in-house NCHS survey response team is available to answer calls from NHANES participants regarding the results from the Report of Finding System. The response team effort works both as a triage mechanism and a surveillance system. A receipt and control

record is kept on all sample person inquiries. Also available at no cost to sample persons is an 800 toll-free telephone number that can be accessed during regular scheduled business hours. The response team members include a physician, a nurse with a doctorate degree, and other staff who are trained to answer specific questions.

Tests and procedures conducted in the MEC are not considered diagnostic exams and are not a substitute for an evaluation by a medical professional. No clinical treatments or health interventions of any type are performed in the MEC. If a health problem is discovered during the course of the MEC exam, the physician offers to contact the examinee's personal healthcare provider or recommend a local physician or clinic for follow-up care. If a sample person is found to have a serious condition requiring immediate attention, the local rescue squad may be summoned or the SP will be advised to seek immediate medical treatment.

1.7.6 Dry Run Day

At the beginning of the examination period, one-half day is devoted to calibrating instruments, practicing MEC procedures, and collecting biological specimens that serve as blind quality control samples. A dry run day is scheduled immediately before the first exam day of every stand to make sure that all equipment is operational, supplies are adequate, and the facility is working properly. All procedures in the dry run are completed as though the actual exam session was being conducted. The only difference is that the e

xaminees are volunteers who are not part of the sample for the survey. Volunteers may include local residents, local officials, or field employees or guests of NCHS.

1.8 Integrated Survey Information System (ISIS)

The Integrated Survey Information System (ISIS) is a computer-based infrastructure designed to support all survey operations including sample management, data collection, data editing, quality control, analysis, and delivery of NHANES data. With a collection of customized subsystems, the ISIS links the field office, mobile examination center, Westat home office, and NCHS during field operations. Each component in NHANES such as Dietary Interview has a computer application for direct data entry. Data collected in the Dietary Interview room of the mobile examination center is directly

entered in the ISIS system computers. In addition, data from biomedical equipment such as the Dual Energy X-Ray Absorptiometry (DXA) scanner for body composition is directly downloaded to the ISIS system where it is displayed on the computer screen and stored in the system database.

1.9 Confidentiality and Professional Ethics

All information regarding this study must be kept strictly confidential except as required by law. This includes location of survey sites. Since this study is being conducted under a contract with the National Center for Health Statistics, the privacy of all information collected is protected by two public laws: Section 308(d) of the Public Health Service Act (42 U.S.C.242m) and the Privacy Act of 1974 (5 U.S.C. 552a).

Each person working on the study must be continuously aware of the responsibility to safeguard the rights of all the individuals participating in the study. Each participant should be treated courteously, not as a sample number. Never divulge names or any other information about study participants except to the research team. Refrain from any discussions about study participants, in or out of the MEC, which might be overheard by people not on the survey staff. All of the members of the research team are under the same legal, moral, and ethical obligations to protect the privacy of the SPs participating in the survey. No participant names will be included in any reports prepared about the survey and neither NCHS nor the contractor is allowed to release information that would identify study participants without the consent of the participants.

Cooperation from the public is essential to the success of survey research. A great deal of effort is expended in obtaining cooperation from many national, regional, state, and local officials and the general public. It is the responsibility of every field employee to build on the integrity of the survey to encourage continued access to study participants during current and future surveys. Professional conduct, both on and off the job, is extremely important.

Each staff member has a responsibility for promoting good public relations. The Public Health Service and the contractor will be judged by the actions of the staff both on and off duty; consequently staff must be discreet in speech and action. Personal appearance and behavior must be governed by these same considerations. Please be aware of the audience at all times and avoid statements or actions that could shed an unfavorable light on the survey.

Staff will be asked to sign a pledge of confidentiality before the survey begins. This pledge states that they are prohibited by law from disclosing any information while working on the survey to anyone except authorized staff of NCHS and the contractor, and that they agree to abide by the contractor's Assurance of Confidentiality.

2. OVERVIEW OF PHYSICIAN EXAMINATION

2.1 The Role of the Physician in NHANES

Physicians function as mobile examination center (MEC) team members with the primary function of collecting blood pressure, heart rate, and pulse data. These measurements are the data source for reporting the national standard for blood pressure and heart rate from the NHANES. Clear and complete instruction for the physician aids standardized, accurate data collection across both MEC teams, and emphasizes the importance of following the protocol for the purpose of systematic, prioritized survey data collection. The physician examination is described in detail in Chapter 4, Physician Protocol.

In 2007, the physician's role was expanded to include a subcomponent of the respiratory health study. In this component, the physician conducts pre-bronchodilator study safety exclusion evaluations, and administers bronchodilator medication to selected, eligible participants, after which repeat spirometry testing is administered. The bronchodilator subcomponent of respiratory health administered by the physician is presented in the *Bronchodilator Procedures Manual* under separate cover.

The physician examination consists of:

1. Measuring blood pressure and/or heart rate or pulse depending on the age of the SP.
2. Review of exclusionary questions for male SPs 40 years of age and older who consent to have their blood tested for prostate specific antigen (PSA).
3. Discussing the STD testing done on the survey and recruiting female SPs aged 14-59 to self-collect a vaginal swab to test for Human Papillomavirus (HPV). The physician instructs the SP on how to obtain the specimen. The physicians instruct SPs about how to obtain their STD test results confidentially.
4. When physicians determine that data obtained during the MEC examination indicate a medical referral, they refer SPs to health care providers in the local community.

2.2 Medical Policy Regarding the Examination

The purpose of the NHANES study is to collect data on the health status of the United States population. The MEC is not a medical treatment facility, hence, MEC physicians do not provide diagnoses or treatment of medical conditions. It is important to emphasize that treatment is **not** within the role of the MEC physician, and any clinical findings that are of concern to physicians are documented and included in community practitioner referrals. In most instances, the examining physician will not be licensed within the state in which the examinations are being conducted. The liability insurance obtained for Westat physicians does not cover any type of treatment procedure except for medical emergency stabilization while awaiting the arrival of local paramedics.

NHANES survey teams have neither control over, nor connection with, local health care systems. Any physician involvement beyond routine referral is ineffective and interferes with the purpose of the study. Referral of examinees is included in the MEC procedures for ethical reasons, although referral is not within the purpose of the study. Before SPs depart the MEC, they are provided with a report of the findings that become available while they are in the MEC. They are provided a final report of all findings approximately 3 months after their MEC examination. These are in the form of written reports and they are mailed to the SPs.

2.2.1 Presence in MEC during MEC Examinations

Examinations do not occur in the MEC without the presence of a physician. Physicians report to the MEC at least 5 minutes before examinations are scheduled to begin. They leave the MEC only when all examination and interview protocol procedures have been completed and all SPs have left the MEC.

2.2.2 Response to Medical Emergencies

If an examinee becomes ill or disabled during the examination session, the physician renders only the level of care necessary to keep the examinee out of immediate danger. Arrangements are made to transport SPs to an appropriate medical facility. An ambulance is called if a potentially life threatening

condition develops, or if indicated for any SP. Further details about medical emergencies are included in Chapter 6.

2.2.3 Maintenance of Emergency Equipment and Supplies

Physicians maintain emergency equipment and supplies for use in the MEC. They inventory supplies, restock supplies as needed, and ensure that all emergency equipment, medications, and supplies are current and in proper working order. Emergency procedures and supplies are described in detail in Chapter 6.

2.3 Physician Examination

The physician examination is described in detail in Chapter 4, Physician Protocol. The physician examination consists of:

1. Measuring blood pressure and/or heart rate or pulse depending on the age of the SP.
2. Recruitment of female SPs aged 14-59 to self-collect a vaginal swab to test for human papillomavirus (HPV). The physician instructs the SP on how to obtain the specimen.
3. Review of exclusionary questions for male SPs 40 years of age and older who consent to have their blood tested for prostate specific antigen (PSA).

2.3.1 Measurement of Pulse and Blood Pressure

Physicians count heart rates on all SPs through 4 years of age. Radial pulse is counted on SPs from 5 years of age through age 7, and blood pressure and radial pulse is measured on all SPs 8 years of age and older.

2.3.1.1 Blood Pressure Procedures for 2009 - 2010

Accurate measurement of blood pressure (BP) is a major public health concern: it is essential for hypertension screening, as well as for disease management. In the period of 2005-2006, 29 percent of the U.S. adult population was hypertensive or taking medication for hypertension. Blood pressure has been measured with the mercury sphygmomanometer for many years but with new technologies available alternative blood pressure devices have taken center stage. The rapid pace of development of automated sphygmomanometers with improving accuracy and reliability combined with increasing affordability has meant that these devices have now replaced the mercury sphygmomanometer in many settings.

NHANES must be able to compare the measurements taken by the mercury device to those taken by a possible successor device in such a way that trends over time in blood pressure prevalence can be accurately maintained and followed. Furthermore, these results would help to better compare blood pressure values in research studies that used different blood pressure devices.

The current NHANES blood pressure protocol will be modified by adding an additional instrument to perform blood pressure - the Omron HEM 907 XL automated machine. All NHANES subjects aged 8 years and older will have blood pressure measurements taken by both the mercury sphygmomanometer and the OMRON HEM 907 XL. The physician will take all reportable blood pressure measurements using the mercury sphygmomanometer. In addition, the physician will take all Omron measurements for participants aged 8-11. For participants aged 12+ the physician will be assigned to take an Omron measurement for 50 percent of the participants. The remaining 50 percent of participants will have a mercury and Omron measurement taken by a health tech.

The specific protocol used for blood pressure measurements is described in Chapter 4, Physician Protocol.

2.3.2 Prostate Specific Antigen Testing (PSA)

Men who are 40 years of age and older are asked to have their blood tested for the PSA. The physician explains the importance of this test, the meaning of this test, and reviews of exclusionary questions with the SP. The specific protocol used for PSA testing is described in Chapter 4, Physician Protocol.

2.3.3 Counseling for STD and HIV

Physicians counsel SPs about the survey specific STD and HPV testing and inform them how to get their test results. The specific protocol used for STD/HIV and HPV counseling is described in Chapter 4, Physician Protocol.

The following four STD tests are performed:

Test	Age	Source
Chlamydia	14 – 39	Urine
Genital Herpes	14 – 49	Blood
HIV	18 – 59	Blood
HPV	14 – 59	Self-administered vaginal swab

2.3.4 Referrals

Physicians are responsible for monitoring out-of-range data values as defined by the component protocols. If data values exceed predefined limits, the ISIS system flags these data for review. Physicians are responsible for discussing out of range values with SPs and making referrals to outside physicians if necessary. Physicians' procedures for managing referrals are described in Chapter 5.

2.4 Maintenance of Physician's Examination Room

Physicians are individually responsible for the maintenance of the physician's examination room and all equipment and supplies required for their examination. At the beginning of a stand physicians inventory the required supplies and equipment. They prepare the examination room by opening and setting up all supplies and equipment needed for the physician examination. They determine that adequate supply levels are available and that all equipment is in proper working order. At the end of each examination session, physicians clean and properly store all equipment and restock supplies as

needed. At the end of each stand, physicians inventory equipment and supplies and then pack up the equipment and supplies. Details about equipment maintenance and supplies are included in Chapter 3, Equipment and Supplies.

3. EQUIPMENT AND SUPPLIES

3.1 Description of Equipment & Supplies

The physician maintains, tracks, and orders all equipment and supplies necessary for the conduct of all aspects of the physician component, including:

- Blood pressure/pulse;
- HPV testing;
- Office supplies;
- Emergency management supplies; and
- OSHA bloodborne pathogen exposure forms and kit.

3.2 Inventory

For the purposes of inventory management, equipment is designated as nonconsumable items, and supplies are those items that are depleted throughout a stand and used on a daily basis. At the beginning and end of each stand, the physician will inventory all component-specific equipment and supplies. Supplies ordered from the warehouse by the previous team during tear down should be on site when the next team arrives to set up a new stand. Physicians will check all newly received supplies against the associated packing lists before incorporating them into the existing inventory. After reconciling the supplies, the physician will stock the exam room. Any needed items should be noted on the inventory list, reported to the chief technologist and to the MEC manager, and documented in the Unusual Field Occurrence (UFO) system.

3.3 Blood Pressure

Equipment is selected that meets the requirements for obtaining the required data and creates the best opportunity for minimal data collection error. All equipment is regularly subjected to quality

control checks. Quality control procedures for physician equipment are described in detail in Chapter 8, Physician Equipment Quality Control.

3.3.1 Blood Pressure Equipment

- Baumanometer[®] calibrated mercury true gravity wall model sphygmomanometer;
- Baumanometer[®] calibrated mercury true gravity wall portable desk model sphygmomanometer (2);
- OMRON HEM-907XL Intellisense[®] Automatic Oscillatory Device digital blood pressure monitor, wall mounted;
- Oregon Scientific EMS 100 digital thermometer with digital interface to the desktop computer in the physician room;
- Baumanometer Calibrated V-Lok[®] cuffs with Latex Inflation Bulb, Air-Flo Control Valve in four sizes: child, adult, large adult, and thigh;
- Littman Cardiology III stethoscope;
- Y-tubing;
- Stop watch;
- Steel measuring tape;
- Foam foot pads;
- Calibration cylinders-small, medium, large, X-large;
- Room thermometer;
- Adjustable height chairs;
- Stainless steel scissors;
- Calculator;
- Pliers;
- Luer lock;
- Stethoscope eartips (small);

- Disposable pillow (17" X 23"); and
- Arm support pad.

3.3.2 Blood Pressure Supplies

- Cosmetic pencils – Black (2) and White (2);
- Cosmetic pencil sharpener;
- Baby oil drop dispenser bottle;
- Sani-Cloth germicidal towelettes;
- 2" x 2" gauze pads;
- Latex gloves;
- Masking tape;
- Mercury Spill Kit;
- Disposable pillow covers;
- Band-aids; and
- Black magic marker.

3.3.3 Description of Blood Pressure Equipment and Supplies

- **Baumanometer[®] calibrated mercury true gravity wall model sphygmomanometer.** The sphygmomanometer is factory calibrated to true gravity, and is guaranteed by the manufacturer to remain scientifically accurate without need for recalibration. The mercury-gravity manometer consists of a calibrated cartridge glass tube that is optically clear, easy to clean, and abrasion resistant. The mercury reservoir at the bottom of the tube communicates with a compression cuff through a rubber tube. When air pressure is exerted on the mercury in the reservoir by pumping the pressure bulb, the mercury in the glass tube rises and indicates how much pressure the cuff applies against the artery. The manometer is connected to the wall for ease of accurate visualization. See Section 3.8 of this chapter for mercury handling procedures.
- **OMRON HEM-907XL Intellisense[®] Automatic Oscillatory Device digital blood pressure monitor, wall mounted.** Developed specifically for use in the clinical office setting and other health care environments, this device determines blood pressure by

oscillometric measurement and displays systolic blood pressure, diastolic blood pressure, and pulse rate using an LCD digital monitor. It has the ability to automatically measure and store up to three sequential readings, and has a “hide” feature that hides measurements during acquisition, which is useful in this research. The pressure measurement range for this device is 0 to 280 mmHg. The OMRON is calibrated to the mercury manometer for routine quality assurance procedures.

- **Oregon Scientific EMS 100 digital thermometer.** This thermometer automatically captures the ambient room temperature, and records it directly into the ISIS physician application.
- **Baumanometer Calibrated V-Lok[®] cuffs with Latex Inflation Bulb, Air-Flo Control Valve.** These cuffs come in four sizes: child, adult, large adult, and thigh. The cuffs are used with all three blood pressure instruments: mercury, aneroid, and OMRON. The Calibrated[®] V-Lok[®] compression cuff is made of urethane-coated Dacron, an unyielding material that exerts an even pressure on the inflatable bladder inside the cuff. The compression cuffs have Velcro fasteners that adhere to them to keep the cuff in position when placed on the arm. The cuff size is determined by the circumference of the arm. The size of the cuff and the bladder used influences the accuracy of the blood pressure readings—if the cuff is too narrow, the observed blood pressure is overestimated (higher than it really is), and if it is too wide, the reading may be underestimated (lower than it really is).
- **Littman Cardiology III stethoscope.** The stethoscopes used for listening to Korotkoff sounds are Littman[™] Cardioscope III for adults and Littman[™] Classic II pediatric for children. These stethoscopes are of the very highest acoustical quality. They have a bell and diaphragm chest piece, and an acoustical rating *by the manufacturer* of 9 on a scale of 1-10, with a rating of 10 having the best acoustical attributes. The construction uses a single-lumen rubber tubing connection between the ear tubes and the chest piece. The ear tubes can be adjusted to fit the particular user at an anatomically correct angle, and the plastic ear covers come in different sizes allowing the user to match the best ear canal size to achieve an acoustically sealed ear fit. All parts of the stethoscope can be cleaned for use between SPs. The bell of the stethoscope is used to auscultate the Korotkoff sounds for blood pressure measurements. Each technologist is provided with his or her own stethoscope.
- **Y-tubing.** The Y-tubing is required for calibrating the OMRON HEM-907XL against the mercury manometer.
- **Stop watch.** The stop watch is used to measure a 60-second pulse rate during the exam.
- **Wall clock.** A 12” face clock with a second hand may be used to measure a 60-second pulse.
- **Steel measuring tape.** A retractable steel measuring tape is used to take upper arm length and circumference measurements.

- **Calibration cylinders-small, medium, large, X-large (plastic).** These cylinders are used for calibrating the sphygmomanometers and OMRON:
 - Plastic Thigh Cuff Can 20" or 51.5 cm
 - Large Arm Cuff Metal Can 13" or 33.5 cm
 - Standard Cuff Metal Can 10.5" or 26.5 cm
 - Child Cuff Metal Can 8.5" or 22 cm

- **Room thermometer.** A digital thermometer measures the ambient room temperature.

- **Adjustable height chairs.** The technologists and participant are all seated during the exam. Adjustable height chairs enable positioning of the SP so that the feet rest directly on the floor, as well as assuring that the measurement technologists can adjust their seats for optimal viewing of sphygmomanometers.

- **Footstool.** A footstool is used to adjust the SPs feet so that the feet rest directly on the floor.

- **Stainless steel scissors.** For use to cut the sleeve of the SP disposable shirt when taking blood pressure.

- **Pliers.** Pliers may be needed when changing luer locks.

- **Luer lock.** Replaces a leaking or defective luer.

- **Stethoscope eartips (small).** Replaces worn eartips for the stethoscope.

- **Disposable pillow (17" X 23").** The pillow can be used to support the SPs arm when taking pulse or blood pressure.

- **Arm support pad.** Used to elevate the SPs arm to the heart level.

3.3.4 Blood Pressure Supplies - Description

- **Cosmetic Pencil—black and white, and cosmetic pencil sharpener.** When measuring the upper arm circumference, the technologist will make any body marks on the SP using a wax-based cosmetic pencil. The health tech will use an appropriate color so that the markings are clearly visible on the SP's skin.

- **Baby oil drop dispenser bottle.** Baby oil is used for removing cosmetic pencil marks from the SP's skin. A small drop dispenser holds the oil for use during exams. Refills are obtained from a larger bottle of baby oil that is associated with the anthropometry component.

- **2" x 2" gauze pads.** The pads are used to wipe off cosmetic pencil marks with baby oil.
- **Sani-Cloth germicidal towelettes.** Disposable germicidal wipes are used to clean and disinfect the Dacron cuffs between participants.
- **Masking Tape.** Tape is used to pull together the cuts that were made on the SP outfit shirt when measuring the upper arm circumference.
- **Alcohol wipes.** Used to clean the steel measuring tape.
- **Mercury Spill Kit.** Used to control and clean a mercury spill.
- **Disposable pillow covers.** For use between SPs.
- **Band-aids.** Replace when the examiner must remove the bandaid that was applied during the phlebotomy.
- **Black magic marker.** Used to denote the size of BP cuff and arm circumference on the SP exam outfit shirt.
- **Wastebasket.**

3.3 HPV Supplies

- HPV Kits (150)
 - HPV kit contents include an Epicenter tube, plastic zip-closable bag, and instructions
- Dymo Costar label printer
- Dymo Costar labels

3.4 Office Supplies

The physician's room is equipped with a laser printer, and is stocked with the following office supplies to support the referral process:

- Envelopes (plain and NCHS return address);
- Printer paper (plain and NCHS letterhead);

- Toner cartridge; and
- Calculator.

3.5 Emergency Supplies

- Oxygen tanks (2) Size D, 415 liters
- Primary: Secured to wall above desk
- Backup: Secured to wall under desk
- Oxygen masks & tubing (kept in tank carrying case)
- Nasal Canula: 1 adult, 1 pediatric
- Oxygen Mask: 1 mask
- Extension Tubing
- Oral Airway: infant, small, medium, large
- Automatic External Defibrillator

3.5.1 Emergency Box – Contents

- Medications
 - Albuterol Inhalers
 - Ammonia Ampules
 - Aspirin, 325 mg tablets
 - Epi Pen – Junior
 - Epi Pen – Adult
 - Glucose Tube
 - Nitrostat

- Supplies
 - Protective eyewear goggles
 - Tongue depressor
 - Stethoscope (2) child & adult
 - Pocket BP aneroid cuffs – child, adult, and large adult
 - Spare AED Battery
 - Scissors
 - Pen light
 - Sterile Gloves - two pairs
 - ½” Transpore tape
 - Surgilube packets

3.6 OSHA Bloodborne Pathogen Exposure Forms

The warehouse manager provides the forms necessary to complete the exposure evaluation reporting requirements.

3.7 Inventory

At the beginning and end of each stand, the physician will inventory all component-specific equipment and supplies. Supplies ordered from the warehouse by the previous team should be on site when the next team arrives to set up a new stand. Physicians will check all newly received supplies against the associated packing lists before incorporating them into the existing inventory. After reconciling the supplies, the physician will stock the exam room. Any needed items should be noted on the inventory list, reported to the MEC manager, and documented in the Unusual Field Occurrence (UFO) system.

3.7.1 Equipment Set Up

Before setting up, the physicians should verify that all equipment and supplies are in the room. Any pieces of equipment that are missing should be reported to the home office component staff who will notify NCHS staff.

All mercury manometers on the MECs are tracked in the Equipment Tracking System (ETS) maintained by the MEC manager. Provide the MEC manager with the serial numbers present on each manometer at the beginning of each stand.

3.7.2 Teardown Procedure

At the end of each stand, prepare the equipment for transport as follows:

1. Pack up and secure all supplies and equipment into the dedicated plastic bins and store in the lower trailer compartment.
2. Secure wall-mounted mercury manometer with the padded protector. The installed wall mounted manometers do not require packing for MEC transport. See next section for more detailed manometer handling procedures.

3.8 Handling Instructions for Mercury Manometers

3.8.1 Mercury Safety Considerations

According to the manufacturer, the elemental mercury used in Baum manometers is safely contained in the reservoir and Mylar[®] Clad Calibrated Cartridge glass tube. Since February of 1995, Baum has applied several layers of very strong and crystal clear Mylar film to the glass tubes, which strengthen the tube and maintain its structural integrity even if the inner glass is broken. The Mylar sheath ends close to the tube's top end, and a fingernail can detect the change in the tube's outer diameter, which indicates that this tube has the Mylar film.

A mercury sphygmomanometer should be handled with extreme care. The instrument should not be dropped or treated in any way that could result in damage to the manometer. Regular quality

control checks are conducted to ensure that there are no leaks from the inflation system and that the manometer has not been damaged so as to cause a loss of mercury. The Baum mercury manometers are designed to minimize mercury releases from its closed system; however, there are two ways in which mercury can be released from the manometers.

One way has to do with the lever that holds the glass tube in place on top of the device only on the wall-mounted units. The lever is only supposed to be moved when the sphygmomanometer is removed from the wall and lying on its right side by a service technician. If this lever is inadvertently flipped back while the instrument is upright on the wall, the glass tube is released and the mercury spills out of the bottom of the tube. Baum has added a safety feature to this release lever, with the addition of a “set screw” that prevents an accidental movement of the lever without a tool. If the unit has not been retrofitted with the “set screw,” a safety modification is available free of charge from Baum. The “lever lock,” is simply a small piece of metal bent at a 90 degree angle that is easily slipped behind the lever to immobilize it. The lock can still be removed with no problem using a screwdriver, but spills are prevented because users cannot remove the lever lock without some effort. The lock simply eliminates the potential for anyone to accidentally flip the release lever.

The second manner in which mercury could be released is if the glass tube is damaged in some way. With the application of Mylar® to the glass tube, the incidence of glass tube damage has been drastically reduced.

Loss of mercury will occur if the glass tube is broken in either the wall-mounted or portable manometer. Care should be taken in handling and storing the manometer to prevent this. If the tube appears cracked, check for any spilled mercury near the wall-mounted manometer.

The following procedure is recommended for handling spilled or leaking mercury:

- If you discover a mercury spill, you should not attempt to clean up for yourself.
- Do not touch mercury with your bare hands or attempt to vacuum or clean up the spill.
- Leave the area in which there was a spill, taking the SP to a separate waiting area.
- Close the door to the area or room if possible.
- Obtain the Mercury Spill Kit and proceed to clean the spill.

3.8.2 Required Procedure for Handling Spilled or Leaking Mercury

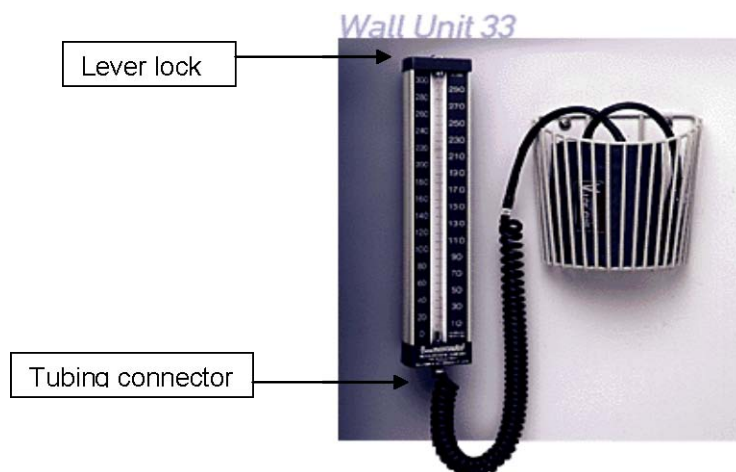
The following procedure is required for handling spilled or leaking mercury:

- Contact the MEC manager immediately to report the incident and receive instructions. The Mercury Spill Kit contains all the materials needed for clean up.
- The MEC manager will determine what action should be taken. If necessary, the local hazardous materials contact may be called to report such spills. The local hazardous materials agency may want to make a followup visit to the facility to check for levels of mercury in the exposed area.
- Do not touch the mercury with bare hands or attempt to vacuum or clean up the spill.
- The procedures for cleaning up the mercury are different depending on the surface where the spill is detected.
- If the spill is small the following procedure may be used.
 - Leakage or spillage on a hard surface (e.g., hard floor, table, etc.):
 1. Get the Mercury Spill Kit from the physician's exam room.
 2. Put on the green protective gloves.
 3. Use the mercury (Hg Absorb) sponge.
 4. Remove the sponge from the plastic zip-closable bag.
 5. Dampen the sponge with water.
 6. Wipe the area contaminated with mercury. Do this slowly to allow for complete absorption of all free mercury. The chemical layer (Hg Absorb powder) on the sponge will absorb the mercury droplets.
 7. After finishing with the Hg Absorb sponge, place it back into its plastic zip-closable bag.
 8. Place the manometer case and mercury sponge into separate plastic bags and secure with tape. Return to the MEC manager.
 9. Complete a Mercury Spill Report Form.
 10. Obtain replacement equipment.

- Leakage and/or spillage on a soft or absorbent surface (e.g., rug, etc.):
 1. Get the Mercury Spill Kit from the physician's exam room.
 2. Put on the green protective gloves.
 3. Turn off heat or air conditioning to avoid spreading vapors to other rooms in the MEC.
 4. Open a window if possible to ensure adequate ventilation to the outside for the room where the spill occurred.
 5. Use the mercury (Hg Absorb) sponge, if possible. See directions above.
 6. Wet the MERCSORB[®] powder with water. Mercury will react with powder, forming a metal/mercury amalgam.
 7. Wipe or sweep wetted powder over all cracks and hard to reach locations for maximum pickup.
 8. Pick up amalgam by sponging or by using the small sweep and dustpan provided in the Mercury Spill Kit.
 9. Complete a Mercury Spill Report Form.
 10. Obtain replacement equipment.

Follow these instructions for packing, unpacking, storing and/or shipping a wall-mounted mercury manometer.

Wall-mounted Units

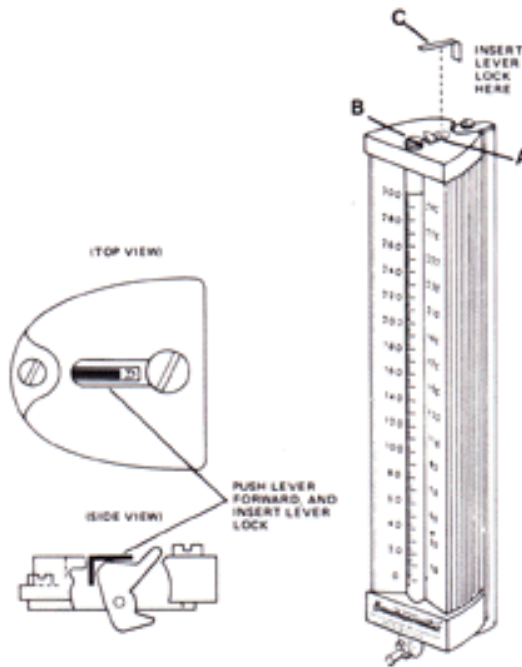


1. Remove the coiled tubing from the instrument.
2. Attach a red cap firmly to the tubing connector on the instrument to seal.
3. Check that the lever lock is in place on top of instrument. If not, see attached instructions for inserting a lever lock.
4. Remove the instrument from the wall unit.
5. Place instrument in a zip-closable bag and seal closed.
6. Place the instrument (in bag) into storage box.
7. Place storage box into zip-closable bag and seal closed.
8. Wrap manometer box with bubble wrap.
9. Place in storage container in physician's room for storage, or if shipping back to the warehouse, pack the manometer securely with bubble wrap in a box. The amount of mercury contained in a manometer does not require special shipping procedures in compliance with the regulations pertaining to hazardous materials.

Unpacking Manometers (wall-mounted units):

1. Carefully inspect outer bag for mercury droplets. If no mercury is seen, open bag and remove manometer box.
2. Open box and remove manometer. Inspect inner bag for mercury droplets. If no mercury is seen, open bag and remove manometer.
3. Check that the lever lock is in place on top of instrument. If not, see attached instructions for inserting a lever lock.
4. Reattach manometer to wall mount.
5. Remove red cap from tube connector and reconnect tubing.

Lever Lock Insertion Instructions



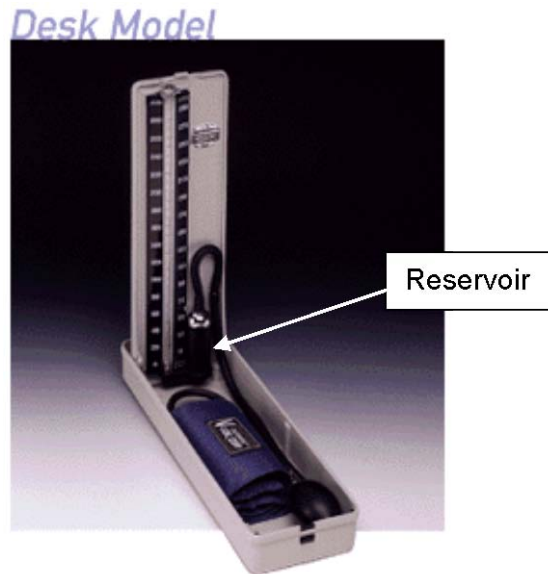
Purpose

To prevent tampering with the cartridge tube release lever and accidental release of mercury.

Procedure

Push lever 'A' forward (toward the chrome plated cap 'B') and insert lever lock 'C' as shown in diagram.

Desk-top Models



Packing Desk-top manometers:

1. Remove tubing from top of reservoir.
2. Tilt manometer onto reservoir-side. Mercury should be contained in reservoir.
3. Place red cap firmly on reservoir opening while manometer is on its side.
4. Stand manometer up. Close.
5. Place manometer in zip-closable bag and seal closed.
6. Place manometer (in bag) into storage box.
7. Place storage box into zip-closable bag and seal closed.
8. Wrap manometer box with bubble wrap.
9. Place in storage container in physician's room for transport to next stand.

Unpacking Manometers (Desk-top model):

1. Carefully inspect outer bag for mercury droplets. If no mercury is seen, open bag and remove manometer box.
2. Open box and remove manometer. Inspect inner bag for mercury droplets. If no mercury is seen, open bag and remove manometer.
3. Open manometer and place upright on table.
4. Remove red cap from reservoir and reconnect tubing.

4. PHYSICIAN PROTOCOL

General Overview

The physician examination consists of:

1. Measuring blood pressure (BP) and/or heart rate or pulse depending on the age of the SP. See Section 4.1.
2. The physician may ask “Shared Exclusion” questions, which are asked by the first person to examine the SP. The purpose of having questions that are shared between examiners is to minimize examination time by excluding questions from any component that have already been asked in another examination component. This process saves time in each component and prevents replication of questions for SPs. These questions are asked to determine whether SPs should be included or excluded from bone density scanning. See Section 4.2.
3. Review of exclusionary questions for male SPs 40 years of age and older who consent to have their blood tested for prostate specific antigen (PSA). See Section 4.3.
4. Discuss the STD testing done on the survey and recruit female SPs aged 14-59 to self-collect a vaginal swab to test for Human Papillomavirus (HPV). The physician instructs the SP how to obtain the specimen. The physicians instruct SPs about how to obtain their STD test results confidentially. See Section 4.4.
5. When physicians determine that data obtained during the MEC examination indicate a medical referral, they refer SPs to health care providers in the local community. See Section 4.5 and Chapter 5.
6. The ISIS physician application supports many features for the physician protocol, and a thorough review of these functionalities are found in Section 4.6.

Physicians collect the SPs blood pressure, heart rate, and pulse measurements for the survey. The protocol for these measurements is described in detail in Section 4.1 of this chapter. As noted in Chapter 2, Overview of Physician Examination, physicians also perform the bronchodilator administration subcomponent of respiratory health described under separate cover. The physician examination does, however, exclude SPs from the bronchodilator component based on blood pressure, and pulse findings. Physicians are the only MEC examiners who discuss sexually transmitted diseases, human papillomavirus, and human immunodeficiency virus testing with SPs. The SP examination profile differs by age groups. MEC physicians are the designated examiners to discuss pregnancy results with

SPs who are less than 17 years of age. Physicians also review examination data results to determine the need for referrals. The referral procedure, including referral for pregnancy, is described in detail in Chapter 5, Referrals.

4.1 Heart Rate, Pulse, and Blood Pressure Measurements

Physicians count heart rates on all SPs through 4 years of age. Radial pulse is counted on SPs from 5 through 7 years of age and blood pressure and pulse are measured on all SPs 8 years of age and older. Physicians record the survey blood pressure measurements. The protocol for blood pressure measurement follows procedures developed by the American Heart Association. Physicians and backup physicians are certified in blood pressure measurement through a training program provided by SHARED Care, Inc, that includes didactic information, video practice, listening to and recording Korotkoff sounds, and practice listening to blood pressures of volunteers with a certified instructor. Certification is achieved when physicians meet all requirements of the training program. Recertification is accomplished quarterly.

4.1.1 SPs Included for Blood Pressure, Heart Rate, and Pulse Measurements

Heart rates are measured on all children up to and including 4 years of age. Radial (brachial if necessary) pulses are measured on SPs 5 years of age and older. Blood pressures and radial pulses are measured on all SPs 8 years of age and older.

Age	
0 – 4	Apical heart rate
5 – 8	Radial pulse
8 – 11	Radial pulse; Hg Blood Pressure, and Omron blood pressure
12 +	Radial pulse; Hg Blood Pressure, and 50% of Omron blood pressures

The new protocol for blood pressure as noted in Chapter 2 will employ the use of both auscultatory (mercury sphygmomanometer) and oscillatory (Omron) measures. The physician will continue to take all blood pressures on SPs age 8 and above using the mercury manometer. The physician will also be responsible for taking all Omron measures on children ages 8 – 11, and 50 percent of SPs age 12 and above using a randomized assignment scheme in ISIS to determine the order of the device to be used, i.e., mercury first or Omron first. The remaining 50 percent of the comparison blood pressure measurements will be taken by health technicians.

The results obtained by the Omron device will not be mentioned or discussed with the sample participant. During the Omron measurements, the display monitor will be hidden using a HIDE feature and will not be visible to the physician taking the measurement or the SP. The data entry of the

Omron measurements will be performed by a “recorder” assigned by the coordinator. The blood pressure recorder will enter the Omron results on the “Omron Data Capture Screen” as detailed later in this chapter.

4.1.2 Scripts

4.1.2.1 Talking Points

- “The NHANES program is testing devices to take blood pressure measurements. We are currently doing research on how well other devices measure blood pressure. In this exam we will be taking your blood pressure with two different devices. The repeated measurements may cause slight discomfort in your arm and tingling in your hand for 1 or 2 minutes. You will only receive a report of the blood pressure results taken with the manual device, the mercury manometer.”
- First, I will be taking your pulse and then I will be measuring your blood pressure.
- We are going to take a series of three measurements with each device.
- Before taking your first blood pressure reading there will be a 5-minute waiting period.
- When I inflate the cuff it may feel tight and you will feel some pressure.
- While we are taking your BP, we ask you not to talk and I will not talk either because talking and moving changes your BP.
- The results from the machine will not be given to you. The readings taken by the manual method are the results that will be given to you on your Report of Findings.
- Do you have any questions?
- Proceed to the next screen “Five Minute Timer” starts now (read screen from top to bottom).

4.1.3 SPs Excluded from Blood Pressure, Heart Rate, and Pulse Measurements

SPs are excluded from blood pressure measurement if they have any condition that could potentially cause them harm or discomfort or would prevent accurate blood pressure measurement. Specifically, BP measurements are not done when both arms have a rash, gauze/adhesive dressings, casts, are withered, puffy, have tubes, open sores, hematomas, wounds, arteriovenous (AV) shunt, or any other intravenous access device. Also, women who have had an axillary nodal biopsy or resection, or a unilateral radical mastectomy do not have their blood pressure measured in the affected arm. If there is a condition with both arms, the blood pressure is not taken.

Some conditions that may affect BP are noted, but these conditions do not exclude SPs from BP measurement. SPs are asked if they have had any food, coffee, cigarettes, or alcohol in the past 30 minutes. Although intake of coffee and cigarettes could affect blood pressure, this information is not used to exclude SPs from blood pressure measurement. There are no protocol specific reasons for excluding SPs from heart rate or pulse measurement.

4.1.4 Procedures for Measuring Blood Pressures, Heart Rates, and Pulses

These are the instructional procedures for physicians to follow when measuring BPs, heart rate, and pulse. Physicians are taught during training to follow these protocol specific procedures exactly when measuring blood pressures, listening to heart rates, and counting pulses.

4.1.4.1 Selecting the Arm for BP and Pulse Measurement

For the purpose of standardization, both pulse and blood pressure are measured in the right arm unless specific SP conditions prohibit the use of the right arm, or, if SPs self-report any reason that the blood pressure procedure should not use the right arm. If the measurements cannot be taken in the right arm, they are taken in the left arm. In all cases, if there is a problem with both arms, the blood pressure is not taken.

4.1.4.2 Position SP for Pulse and Blood Pressure Measurements

Ask the SP to sit all the way to the back of the chair so that the spine is straight. Instruct the SP to rest quietly for 5 minutes prior to blood pressure measurement. The arm and back should be supported and the legs should be uncrossed with both feet flat on the floor. The arm should be bared and unrestricted by clothing with the palm of the hand turned upward and the elbow slightly flexed. The arm should be positioned so that the midpoint of the upper arm is at the level of the heart. The location of the heart is the junction of the fourth intercostal space and the lower left sternal border.

Small or short SPs may need the chair position raised or lowered to correctly position for the BP measurement. If necessary, place SP's feet on a foot stool to correctly stabilize the feet. Very tall SPs may need to place their arm on an arm rest or pillow to bring their upper arm to the correct position. During the 5 minute resting phase, the pulse/heart rate can be measured after 4 minutes.

4.1.4.3 Locating the Pulse Points

Locating the Radial Pulse: Position SP with the right palm upward. Palpate the radial pulse on the flexor surface of the wrist, laterally, with the pads of the index and middle fingers.

Locating the Brachial Pulse in the upper arm (for BP cuff placement): Position SP with the right palm turned upward and the arm slightly bent at the elbow. Palpate the brachial pulse in the groove between the bicep and tricep muscles above the elbow with the pads of the index and middle fingers. Using an eyeliner pencil, mark the spot where the pulse is most strongly palpated. **The center of the cuff bladder is placed at this point.**

Locating the Brachial Pulse at the Antecubital Space: The brachial pulse is traced from the bicep and tricep space until palpated in the medial aspect of the antecubital fossa. Mark the spot using the eyeliner pencil. This is the point where the bell of the stethoscope is placed to listen for the BP. If the pulse cannot be felt in the arm, check the radial pulse. If no radial or brachial pulse is palpable on the right arm, use the left arm unless contraindicated. If a radial pulse is apparent, whether or not the brachial pulse can be felt, the blood pressure measurement should be attempted.

4.1.4.4 Heart Rate Measurements for SPs through Age 4

For all SPs through the age of 4 years, only the apical heart rate is recorded. Count the heart rate by listening to the heart at approximately the 4th intercostal space, midclavicular line. Use the bell device of the pediatric stethoscope.

- Remove all clothing over the left chest wall.
- The heart rate should be recorded after the child rests for 4 minutes.
- If the SP is extremely active or crying, allow an additional maximum of 2 minutes for the child to become quiet before counting the heart rate.
- If the child can sit in a chair without an adult, have the child sit quietly in the chair until the heart rate is counted.
- If the child needs to be held, ask the adult who accompanies the child to hold the child in an upright position, without “squeezing” any portion of the body, especially the abdomen.
- Count the rate for 30 seconds and record the rate in the **ISIS Heart Rate Field**.
- Note regularity and record in the **ISIS Regular Field**.

4.1.4.5 Pulse Measurements for All SPs Aged 5 and above

For all SPs 5 years of age and above, a palpated radial pulse rate is recorded.

- The pulse may be taken after the SP has been seated and resting quietly for approximately 4 minutes.
- With the elbow and forearm resting comfortably on a table and the palm of the hand turned upward, find the radial pulse and count for 30 seconds.
- The number of beats in 30 seconds is recorded.
- The **rhythm field** is defaulted to “Regular.” If there is an irregular rhythm, click on the radio button indicating regular, and check the box to specify “Irregular.”
 - If the SP is between the ages 6 through 79, the system will enable a space to enter the number of irregular beats that occurred in 60 seconds.

- Count the pulse again for 60 seconds and record the number of missed beats during that period. Enter this number in the appropriate box. If there are 4 or more missed beats in 60 seconds, the system will block the SP from the bronchodilator component.

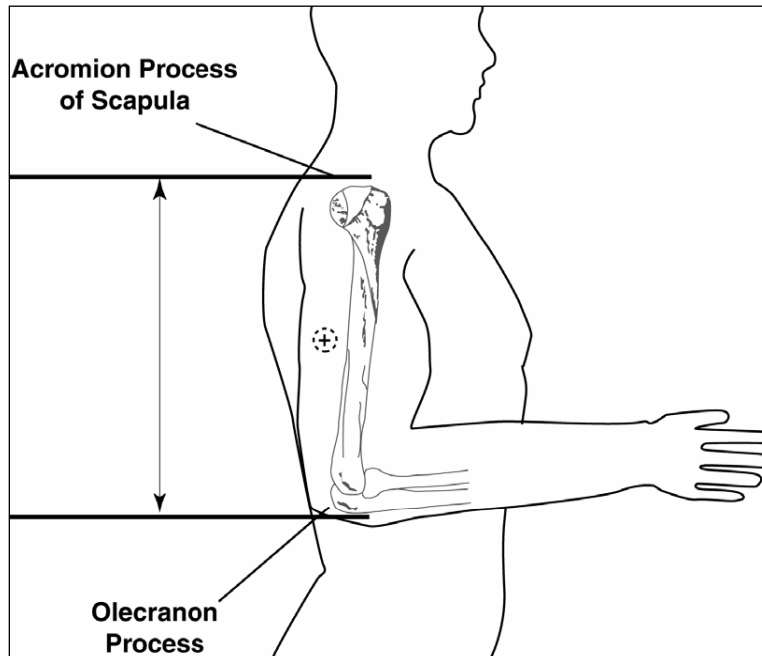
4.1.5 Blood Pressure Cuff Size and Application

The first step to obtain an accurate BP is to use an accurate cuff bladder size. The length and width of the cuff's bladder should encircle at least 80 percent of the length of the arm, and 40 percent of the width of an adult's arm. The length and width of the cuff should encircle 100 percent of the arm in children less than 13 years old. The index lines found on most BP cuffs are not used to guide cuff application in this study. Arm length and circumference measurement are specified in detail below per the NHANES anthropometry procedures manual.

4.1.5.1 Arm Circumference Protocol to Determine Cuff Size

To reliably measure circumferences on the arm, upper arm length must first be measured and the midpoint located and marked. Stand behind the SP and have the SP stand erect with feet together and the right arm flexed 90° at the elbow with the palm facing up. On the right scapula, locate and mark with a horizontal line the uppermost edge of the posterior border of the acromion process (see Exhibit 4-1). Hold the zero end of the measuring tape at this mark and extend the tape down the posterior surface of the arm to the tip of the olecranon process (the bony part of the mid-elbow). Note the length of the upper arm and record to the nearest 0.1 cm, keeping the tape in position. Make a horizontal mark with a cosmetic pencil at the midpoint at the posterior aspect of the arm. Cross this mark (+) with another mark that lies in a plane extending from the acromion to the olecranon process. This point defines the site at which both the mid-arm circumference is measured.

Exhibit 4-1. Upper arm bony landmarks



Using a centimeter tape, determine the midpoint of the upper arm by measuring the length of the arm between the acromium and olecranon process (between the shoulder and elbow).*

Mark the midpoint of this measurement with a cosmetic pencil.*

Measure the circumference of the bare upper arm at the midpoint. *

Find the arm circumference under column 4 in Table 4-1, Arm circumference and acceptable cuff size.

Table 4-1. Arm circumference and acceptable cuff size

Cuff size	Bladder width (cm)	Bladder length (cm)	Arm circumference ¹
Child	9	17	17-21.9
Adult	12	22	22-29.9
Large adult	15	32	30-37.9
Adult thigh	18	35	38-47.9

¹ Adapted from Human Blood Pressure Determination by Sphygmometry, American Heart Association.

* These measurement instructions are available in more detail in the *NHANES Anthropometry Procedures Manual*.

Application of the cuff:

1. Use the cuff size from column 1 associated with the arm circumference in column 4. (Example: If the arm circumference at midpoint is 36 cm, use the large adult cuff.)
2. Position the *rubber bladder* over the brachial artery at least **1” above the crease of the elbow**. For long thin arms, the cuff should be placed in the middle of the arm. Place the marker on the inner part of the cuff directly over the brachial artery.
3. Wrap the cuff in a circular manner taking care not to wrap the cuff in a spiral direction so that any part overlaps with another part.
4. Check the fit of the cuff to ensure that it is secure but not tight.

4.1.5.2 Determine the Maximum Inflation Level (MIL)

NOTE: The MIL will be obtained by palpation before any blood pressure is taken, regardless of the order in which the devices are assigned. For the individuals randomized to the Omron/mercury condition, the MIL will first be obtained using the mercury device even if Omron is the first randomized method of measurement.

Determine the maximum inflation level (MIL) after the SP has been seated and resting quietly for **approximately 4 minutes**. The MIL or palpatory method provides an approximation of the systolic blood pressure. The MIL is the highest level to which the cuff should be inflated when the actual measurement is made. The MIL is determined as follows:

- The mercury manometer should be positioned at the eye level of the examiner so the mercury meniscus can be easily read without parallax.
- Locate the radial pulse in the right arm;
- Inflate the cuff quickly to a pressure of 70 – 80 mm Hg;
- Then inflate the cuff in increments of 10 mm Hg until the radial pulse is no longer palpable (palpated systolic);
- Continue inflating the cuff in increments of 10 mm Hg to a final measure that is 30 mm Hg above the pressure where the pulse was last palpated. This number is the MIL. Note this measurement and record in the application;

- Rapidly deflate the cuff, confirm the return of the pulse, and disconnect the tubing between the cuff and the manometer; and
- If unable to obtain the MIL on the first attempt, wait 1 minute and repeat the process. Enter the MIL in the **MIL Field** in the ISIS system.

4.1.5.3 Mercury Manometer Blood Pressure Readings

Three consecutive blood pressure readings are obtained, using the same arm. If a blood pressure measurement is interrupted or you are unable to get one or more of the readings, a fourth attempt may be made.

Pressure Readings for the Mercury Condition

The following procedures are used for seated blood pressure readings using the mercury manometer:

- Place earpieces of the stethoscope into the ear canals;
- Confirm that the stethoscope head is in the low-frequency (bell) position. The bell is recommended because it may be better suited to hear the low frequency sounds;
- Position the bell of the stethoscope over the brachial artery and hold it firmly in place, making sure that the head makes contact with the skin around its entire circumference. If possible, avoid allowing the cuff, tubing, or bell to come in contact with each other;
- Position the bell of the stethoscope over the brachial artery pulsation just above and medial to the antecubital fossa;
- Rapidly and steadily, inflate the cuff to the MIL;
- When the MIL is reached, open the thumb valve and smoothly deflate the cuff at a constant rate near 2-mm Hg per second (one mark or dial tick per second) while listening for systolic and diastolic blood pressure sounds;
- Keep the center of the manometer at eye level;
- Watch the top of the mercury column (meniscus) as the pressure in the bladder falls and note the level of the manometer pressure when the first repetitive sounds are heard (Phase I) and when they disappear (Phase V);

- Continue steady deflation at 2 mm Hg per second for at least another 10 mm Hg past where the last sounds were heard;
- Rapidly deflate the cuff and disconnect the manometer tubing from the inflation cuff between measurements to ensure the cuff deflates completely to zero (begin 30 second-count);
- Wait 30 seconds between readings with the SP resting quietly;
- While waiting for the 30-second count between measurements, record Phase I (the level of the pressure on the manometer at the first appearance of repetitive sounds) as the systolic blood pressure reading;
- Record Phase V (the point at which the last muffled sound is heard) as the diastolic blood pressure reading;
- If Phase I or Phase V occurs between the millimeter marks on the glass column, round upward to the nearest digit;
- Take a second set of measurements and record the systolic and diastolic pressures in the system;
- Disconnect the manometer tubing and wait 30 seconds between readings with the SP resting quietly; and
- Take the third measurement and record the systolic and diastolic pressures in the system.

If enhancement techniques were needed (see Section 4.3.2), enter this in the system for that reading. If you are unable to get a blood pressure reading for some reason, deflate the cuff and enter this in the system as “Could Not Obtain.”

4.1.6 Procedures to Enhance the Brachial Pulse Sounds

If an SP’s blood pressure sounds are difficult to hear, two methods can be used to increase the intensity and loudness of the sounds:

1. Elevate the SP’s arm before and during inflation, and then lower the arm after the cuff has been inflated. Blood pressure is then determined in the usual manner. **Or,**
2. Inflate the cuff, and then have the subject open and close his or her fist several times (6 to 8 times). Blood pressure is then determined in the usual manner.

When an enhancement method is used to measure blood pressures (BP), check “**enhancement**” field on the data entry screen for that measurement.

4.1.7 Additional Blood Pressure Measurement Guidelines

If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the bell headpiece directly over the pulse point. See the procedures in the above section for enhancing the sounds at the brachial pulse. Check enhancement techniques in the box on the blood pressure screen.

- If a BP measurement was interrupted, use the following guidelines:
 - The maximum number of cuff inflations for each SP in the mercury measurement is **five**, counting all MIL attempts and blood pressure attempts. The rationale for this is twofold: to minimize the discomfort to the SP of frequent cuff inflations and to accomplish data collection for this measurement within the time allowed.
 - If the blood pressure sounds are not heard during the first measurement, review your technique, check stethoscope position for loose connections or tubing kinks, and maintain a quiet environment. Relocate the brachial pulse and apply the bell headpiece directly over the pulse point. See the procedures in the above section for enhancing the Korotkoff sounds at the brachial pulse. Check enhancement techniques in the box on the Blood Pressure screen.
 - If the difference between the MIL and the 1st systolic measurement is less than 10 mm Hg or greater than 50 mm Hg, the system will prompt the examiner to obtain a new MIL. In this case, return to the first screen, do another estimate of the MIL, and record the new MIL in the system. The first and second BP measures are then obtained in the usual manner. Due to the limit of five inflations, the third BP measure (and the subsequent 4th measurement) should be marked as “Could not Obtain.”

4.1.7.1 Hard Edit Limits for Blood Pressure

A hard edit is a limit imposed by the system that prevents data entry above or below the specified instrument or measurable limits. When entries are recorded that are outside these limits, the system displays a message that the value is out of range and sends a “popup message” asking that the

value be reentered. The system will not allow entries that are outside the specified hard edit limits. The hard edits imposed by the system are listed below:

- Systolic blood pressure and maximum inflation level cannot be greater than 300 mm Hg. This is the upper range of the measurement device. The mercury manometer has a minimum and maximum scale of 0 to 300, respectively. It is impossible to get a reading above or below this level.
- Systolic and diastolic blood pressure and maximum inflation level can be even numbers only. This is a function of the measurement device. The manometer displays the readings in increments of 2.
- Systolic blood pressure must be greater than diastolic blood pressure.
- If there is no systolic blood pressure, there can be no diastolic blood pressure. (There can be a systolic measurement without a diastolic measurement.)
- Systolic blood pressure cannot be zero (diastolic blood pressure can be zero).

4.1.7.2 Soft Edit Limits for Blood Pressure

A soft edit is a limit imposed by the system if a value is outside the predefined edit limits for the SP being measured. The predefined edits are based on NHANES III data. When measures outside these values are recorded, the system displays a “popup message” warning that the limit is out of range, and asks if the measurement is correct. The person entering the data has the option of editing or accepting that data value. Soft edits are placed on heart rate, pulse, and on systolic and diastolic blood pressures. The soft edits applied by the system are listed below.

- The difference between systolic BP and diastolic BP cannot be less than 20 mm Hg or greater than 100 mm Hg.
- Maximum inflation level should be greater than systolic blood pressure.
- Systolic BP minimum and maximum ages 8-19 76 to 130 mm Hg
- Diastolic BP minimum and maximum ages 8-19 20 to 85 mm Hg
- Systolic BP minimum and maximum ages 20-49 86 to 160 mm Hg
- Diastolic BP minimum and maximum ages 20-49 50 to 100 mm Hg

- Systolic BP minimum and maximum ages 50+ 90 to 200 mm Hg
- Diastolic BP minimum and maximum ages 50+ 50 to 106 mm Hg
- Pulse minimum and maximum all ages, males and females
40 to 190 beats/minute

4.1.7.3 Averaging Rules for Determining Mean Blood Pressure

- ISIS calculates the blood pressure average using the following protocol:
 - If only one blood pressure reading was obtained, that reading is the average.
 - If there is more than one blood pressure reading, the first reading is always excluded from the average.
 - If only two blood pressure readings were obtained, the second blood pressure reading is the average.
 - If all diastolic readings were zero, then the average would be zero.
- Exception: If there is one diastolic reading of zero and one (or more) with a number above zero, the diastolic reading with zero is not used to calculate the diastolic average.
 - If two out of three are zero, the one diastolic reading that is not zero is used to calculate the diastolic average.

4.1.8 Procedure for Omron HEM-907XL

This protocol is written for use with the Omron HEM-907XL automated blood pressure monitor. Special attention must be placed on assessment and maintenance of the instrument's accuracy as per the manual that accompanies the instrument.

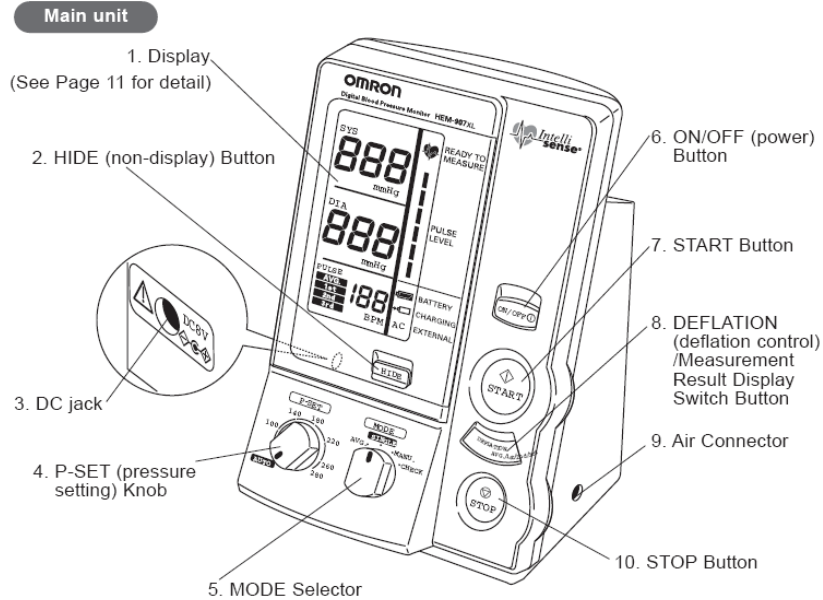
The design and operation of the Omron HEM-907XL are based upon the combined principles of compression of the brachial artery under an elastic, inflatable cuff and estimation of the systolic and diastolic blood pressure levels by oscillometric methods. **The Omron will be in HIDE mode during the entire blood pressure measurements.**

4.1.8.1 Setting the Omron

Below is a diagram and description of the features and functions of the Omron HEM-907XL.

FEATURES AND FUNCTIONS

Names of the Parts



1. **Display:** Displays blood pressure and, pulse rate readings, and oscillation pulse level.
2. **HIDE Button:** Switches display and non-display of measured results.
3. **DC jack:** Connects the AC adapter.
4. **P-SET (pressure setting) Knob:** In the AUTO position, inflation level is automatically set. Otherwise, inflation level can optionally be set manually between 100 and 280 mmHg.
5. **MODE Selector:** Selects the operation mode.
 - One-time Measurement Mode (SINGLE Mode): Measurement with automatic inflation.
 - Average Mode (AVG Mode): Automatically measures two (or three) times consecutively.
 - Auscultation Mode (MANU Mode): Automatic inflation, automatic deflation, and pressure display for auscultation (does not measure blood pressure).
 - Check Mode (CHECK Mode): Checks the accuracy of pressure display. Displays only pressure.
6. **ON/OFF (power) Button:** Turns on or off the unit.
7. **START Button:** Starts the measurement.
8. **DEFLATION (deflation control) /Measurement Result Display Switch Button:**
 - In the MANU Mode, deflates the cuff by approximately 5 to 10 mmHg with each push during deflation.
 - In the AVG Mode, switches the display of average values and the measurement results with each push.
9. **Air Connector:** Connects the air tube.
10. **STOP Button:** Stops the measurement and deflates air rapidly.

At a start of each session:

- Check that the monitor is attached to the AC adapter and to the DC jack and plugged in (see Exhibit 4-2) and that the AC sign (see Exhibit 4-3) is visible in the lower window.

Exhibit 4-2. The Omron showing plugged in DC jack




Confirm that the battery level is displayed for the operable level—see Exhibit 4-3 below.

Exhibit 4-3. AC sign visible in lower window




Battery level

Displays  for the operable level.

Blinks  for a low charged level

Displays  for the inoperable level.

Charging

Displays  when the battery pack is being charged.

External power source

Displays **AC** when the unit is connected to the external power source via the AC adapter.

4.1.8.2 Procedures to Set the Values for the Omron Protocol

A total of five settings must be selected for the Omron Protocol. For this protocol, the Omron will be set to three consecutive inflations (measures), 0 seconds waiting time to start the first inflation, and 30 seconds between inflations. Follow the steps below:

Omron Set Up Procedure

1. Start with the Omron in the “off” position
2. P-Set (inflation limit setting) = AUTO
3. MODE setting = AVG
4. Function Settings:

Function Number	Definition	Set Value
F1	Number of inflations	3
F2	Waiting time to start the first inflation	0 seconds
F3	Inflation interval	30 seconds

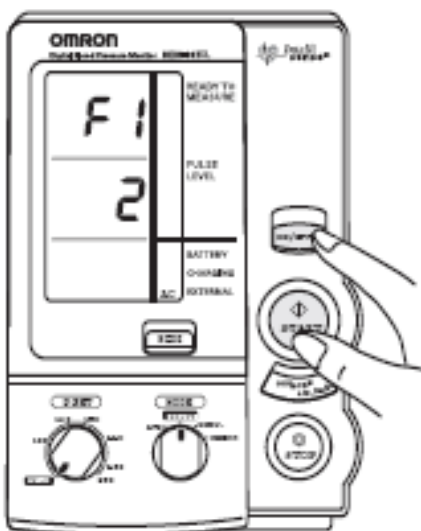
5. To access the function settings, the Omron must be off.
 - a. Press the On/Off button together with the START button simultaneously for 3 seconds. F1 is displayed in the top window.
 - b. F1 is the number of readings/inflations you want the Omron to conduct. If you need to change the setting, push the deflation button to change the set value to 3 inflations. The “3” appears in the middle window.
 - c. To move to F2, push the START button. All values should be 00. If you need to change the setting, push the deflation button to change the set value to 00.
 - d. To move to F3, push the START button. Note that the middle window indicates minutes, the bottom window indicates seconds. Ensure that the middle window indicates 00, and the bottom window indicates 30. Use the deflation button to change the set value to 30 seconds if necessary.
6. The Omron is now set. Turn off machine to save the settings.

Table 4-2. Summarizes the needed setting for the exam

Function number	Items to set	Set value
F1	Number of inflations	3 times
F2	Waiting time to start the first inflation	0 sec
F3	Inflation interval	30 sec

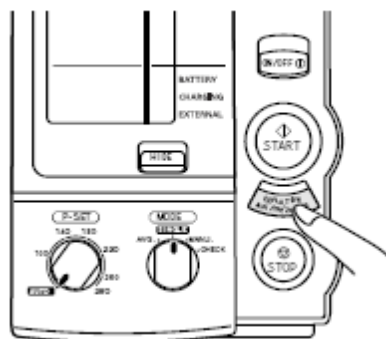
Function Setting 1: Number of Inflations (F1)

When power is OFF, Push the ON/OFF (power) button for more than 3 seconds while holding the START button simultaneously: F1 is displayed in the top window. Make sure that 3, (denoting three inflations) is displayed in the middle window (see Exhibit 4-4).



In the above diagram, the middle window denotes 2 inflations. To change the setting:

- Push the DEFLATION button (the deflation button also functions as a display switch) to change the set value to three inflations as indicated in the photo below.



Deflation /Result Display Switch Button

Press the deflation button until you see “3” displayed in the middle window (Exhibit 4-4).

Exhibit 4-4. F1 setting, indicating 3 inflations



Function Setting 2: the waiting time until the start of the 1st measurement (F2)

To set F2, push the START button; each time you push the START button, the functions change in the order of F1→F2→F3, then back to F1.

- Push the START button and F2 function is displayed in the first window and 0 waiting time is displayed in the middle window (see Exhibit 4-5).

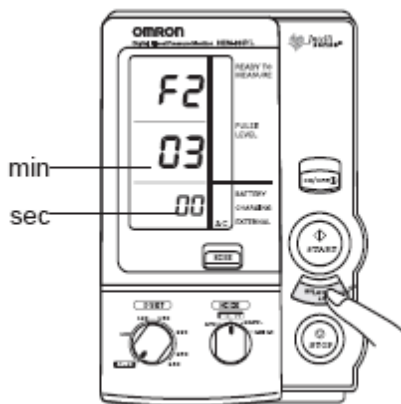
Exhibit 4-5. The F2 function setting to 0 seconds waiting time until the first measurement



If the display in the middle window is not 00, push the DEFLATION button and change the set value to 0 seconds waiting time.

Function Setting 3: the Measurement Interval (F3) to 30 Seconds between inflations

- Push the START button to access the F3 function, which is displayed in the top window.



Note that the display shows the setting in the top row, Minutes in the second row, and seconds in the third row.

Exhibit 4-6. The F3 function and inflation interval



To change the value to 30 seconds, push the DEFLATION/Measurement Result Display Switch Button and change the set value to 30 sec measurement interval.

Saving the Function Settings

Turn off the Omron by pushing the ON/OFF button; this will save the settings, and the settings will be saved when the machine is turned on again. At the beginning of every session, confirm that the F1, F2, and F3 settings are correctly designated.

Setting the Mode Selector Switch to measure BP in Average mode:

- Push the ON/OFF button to turn on the power; and
- Set the MODE selection to AVG (see Exhibit 4-7).

Exhibit 4-7. Settings for BP in AVG mode



Setting the P-SET Switch--Inflation Level Setting

In the AUTO position, the inflation level is automatically set. Set the P-SET (inflation level) knob to **AUTO** (see Exhibit 4-7).

Setting the Non-Display Function (HIDE)

Finally, place the Omron in the “HIDE” mode by pressing the “HIDE” button. push the HIDE button. The word “Hid” will appear in the top window.



Summary of the Settings

The Omron is now set to take 3 measurements at 30 second intervals with no waiting time before the first inflation; the Omron will determine the inflation level, and the average mode will enable the display to reflect all three measurements, as well as the average of the three measurements. Ensure that:

1. F1 = 3
2. F2 = 0
3. F3 = 30
4. MODE = Avg.
5. P-SET = AUTO
6. Non-Display Function = HIDE

4.1.8.3 Taking the Omron Blood Pressure Measurements

- Connect the air tube to the cuff that was used to determine the MIL:
 - For all cuff sizes small, medium, large, and thigh, connect the air tube to the main unit by attaching the air plug to the base of the air connector; and
 - Connect the cuff to the air tube attached to Omron unit.
- **Make absolutely sure that the inflation control valve is closed;**
- Confirm that the Omron is set to the HIDE mode;
- Press START button.
- Monitor the display to ensure that that the machine is inflating properly and there is no error (ERR) message displayed on the monitor, particularly during the first 10 seconds after pressing the start button. **The ERR message is usually the results of the inflation valve not tightly closed.** Keep the HIDE condition on for all three inflations.
- If you want to stop measurement, push the STOP Button. The unit will rapidly deflate.

- If an error occurs during measurement, the monitor will automatically start measurement again. If a second error occurs, measurement will automatically stop.
- Do not push the START Button without wrapping the cuff around the arm.

4.1.8.4 Omron Inflation Error Troubleshooting Procedures

- If you notice that the Omron is not completing the cycle of 3 inflations, take the Omron out of the HIDE mode to determine if there is an error code displayed on the Omron LED.
- Troubleshoot the error using the guidelines on the laminated pages from the Omron Manufacturer manual.
- If you can correct the problem, turn off Omron, turn it back on, place in HIDE mode, and attempt to get the Omron readings a second time.
- If you can not correct the problem, discontinue the Omron measurement for that SP, and continue to the end of the Physician exam.
- When you reach the Omron Data Capture Screen, and no Omron measurements were taken, a recorder is not needed for this outcome. The physician will hit the “Enter” key on the keyboard. A dialogue box will appear asking “Do you wish to skip due to time constraints?” Answer yes (this will take you to the Omron Status Screen.) The Omron Status screen will appear as “Not Done,” and you will enter a comment such as “Equipment Failure,” and finish the exam.

When the Omron has completed the measurements, disconnect the air tube from the cuff, remove the cuff from the SP’s arm, maintain the setting in the HIDE mode, and continue with the remainder of physician exam. **Do not turn off the Omron.** When the end of the physician exam is reached in the ISIS application, the Omron recording screen will appear before the “Finish Exam” screen. At this point, the coordinator will have assigned an observer, a trained technician, to stand by to be ready to enter the physician’s room to record the Omron measurements after the physician releases the SP. It is imperative to maintain efficient MEC flow that the recorder enters the physician’s room in a timely manner and record the Omron results.

4.1.8.5 Recording the Omron Results in the Omron Data Capture Screen—The BP Recorder

The BP recorder will push the HIDE button and unhide the Omron results. Results captured by the Omron device will include fields for 8 separate entries, four systolic entries, and four diastolic entries. The observer will type in the results twice on two separate screens (double keying the entries). Extreme care must be taken when transcribing these measurements. The ISIS application will recognize a discrepancy if the data entered on the two screens is not consistent.

4.1.9 Data Entry Screens for Pulse and Blood Pressure

The following sections instruct physicians about how to carry out the data entry for the physician component. The ISIS screens are displayed as a visual reference.

4.1.9.1 Child Heart Rate, Pulse

Heart rate (0-4 years of age) or pulse (5-7 years of age) is counted for 30 seconds and the number of beats in a 30-second period is entered in the heart rate field. The system calculates this rate and displays the number of beats in 60 seconds on the screen. The 60-second heart rates are stored in the database.

Exhibit 4-8. Child heart rate/pulse

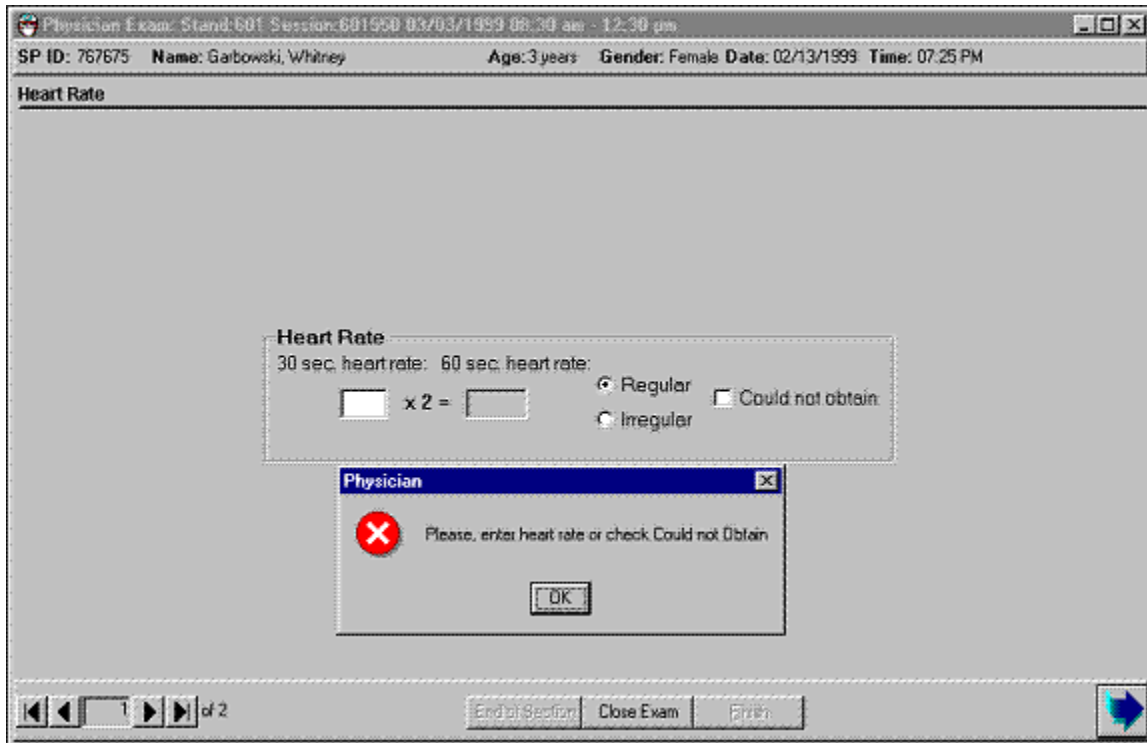
The screenshot shows a software window titled "Physician Exam: Stand:601 Session:601550 03/03/1999 08:30 am - 12:30 pm". Below the title bar, patient information is displayed: "SP ID: 767675 Name: Gerbowski, Whitney Age: 3 years Gender: Female Date: 02/13/1999 Time: 07:15 PM". The main area is titled "Heart Rate". In the center, there is a form with the following fields and options:

- 30 sec. heart rate: x 2 =
- 60 sec. heart rate:
- Radio buttons for "Regular" (selected) and "Irregular".
- A button labeled "Could not obtain".

At the bottom of the window, there are navigation controls: "End of Section", "Close Exam", and "Print". A status bar at the very bottom shows "1 of 2" and a blue arrow icon.

- Enter the 30-second heart rate or pulse in the field. The system calculates the 60-second heart rate and displays it in the **60-second heart rate field**.
- When taking the heart rate and pulse, note whether it is regular or irregular. The default is regular. If the heart rate is irregular, click the **irregular field option** box.

Exhibit 4-9. Child heart rate: Required data entry



- If the next button is pressed before the heart rate is entered, a message is displayed: “Please enter heart rate or check Could not Obtain.”
- Click OK to this message and enter the number of beats in the **30-sec. heart rate** field.
- Click the Next arrow button to advance to the Component Status screen.

Exhibit 4-10. Component status for child heart rate/pulse

The screenshot shows a software window titled "Physician Exam: Stand:601 Session:601550 03/03/1999 08:30 am - 12:30 pm". The header bar contains patient information: "SP ID: 767675 Name: Garbowski, Whitney Age: 3 years Gender: Female Date: 02/13/1999 Time: 07:25 PM". The main content area is titled "Heart Rate Status" and contains a "Status" section with three radio buttons: "Complete" (selected), "Partial", and "Not Done". Below this is a "Comments" dropdown menu and an "Other text" input field. The bottom of the window features navigation controls, including a page indicator "2 of 2" and buttons for "End of Section", "Close Exam", and "Finish".

- If the heart rate was entered, the component status defaults to “complete.”
- If the heart rate was not done, the status defaults to “partial.”
- Select an appropriate comment from the drop-down list.
- Select the Finish button to close the examination.

4.1.10 Blood Pressure Data Entry

Exhibit 4-11. Default blood pressure screen

- A timer on the right side of the screen starts a 5-minute count when this screen is opened. The timer is used to help determine when the pulse, MIL, and blood pressure measurements are to be made.
- The room temperature will be automatically captured into the ISIS application from the Oregon Scientific Wireless Indoor/Outdoor Thermometer connected via USB to the physician's computer. Confirm that the data capture is present.
- Ask if the SP has had food, alcohol, coffee, or cigarettes in the last 30 minutes. Check all that apply. Answering "Yes" does not exclude SPs from any of the physician's examination.

- The pulse should not be taken until the SP has been resting quietly for **at least 3** minutes. The SP should be seated quietly during this time to allow the heart rate and blood pressure measurements to stabilize to a standard resting state.
- The MIL should not be taken until the SP has been resting quietly for **at least 4** minutes.
- The blood pressure should not be taken until the SP has been resting for **at least 5** minutes.
- The default for “Arm/cuff” is the right arm. If the left arm is used, click on left.
- If “Could not Obtain” is selected, the cuff size, MIL, and blood pressure fields are disabled.

Exhibit 4-12. Blood pressure cuff size

- Check which arm is being used for the BP. The system defaults to the right arm.
- Select the BP cuff size from the drop-down menu. The sizes of cuffs are child, adult, large adult, and adult thigh.

- If the cuff size is not selected before the Next button is pressed, a message is displayed with a reminder to select cuff size.
- The default site for taking the pulse is radial. If the radial pulse is not palpable, try the brachial. If a brachial pulse is obtained, select and record brachial from the drop-down menu of the “Pulse Type” field.
- Enter the 30-second pulse in the “30-sec pulse” field. The system will automatically calculate the 60-second heart rate and display it on the screen.
- Note whether the heart rate was regular or irregular. If the heart rate was irregular, click the box indicating irregular.
- The default pulse type is radial. If the pulse type was brachial, use the drop-down menu to change the pulse type to brachial.

Exhibit 4-13. Required pulse entry

Physician: Stand:505 Session:505070 12/30/1999 08:30 am - 12:30 pm
 SP ID: 535881 Name: SMITH, SAMMY Age: 20 years Gender: Male Date: 07/06/20

Blood Pressure

Meal
 Have you had any of the following in the past 30 minutes? (check all that applies)

Arm/Cuff
 Arm selected: Right Left Could not obtain Cuff size: adult

Pulse/MIL
 30 sec pulse: 60 sec pulse:
 x 2 =
 Regular Irregular
 Pulse type: Radial

Physician
 Please, enter Pulse or check Could not Obtain
 OK

1 of 3
 End of Section Close Exam EXIT

- If the physician tries to exit from this screen before recording the pulse measurement, a system message is displayed: “Please, enter Pulse or check Could not Obtain.”
- Click OK to this message and record the 30-sec pulse in the “30-sec pulse” field.

Exhibit 4-14. Select Irregular pulse, missed beats box enabled

Meal
Have you had any of the following in the past 30 minutes? (check all that apply) food
 alcohol
 coffee
 cigarettes

Arm/Cuff
Arm selected: Right Left Could not obtain Cuff size: child
Timer, min. 1 2 3 4 5

Pulse/MIL
30 sec pulse: 60 sec pulse:
48 x 2 = 96 Regular Irregular Missed beats:
Pulse type: Radial
Room temperature: 73 °F
Maximum inflation level: mm Hg
 Could not obtain

- Enter the number of missed beats into the Missed Beats Box

4.1.10.1 Exclusion from Bronchodilator Based on Pulse and Irregular Beats

Exhibit 4-15. Irregular rhythm exclusion from Bronchodilator

SP ID: 196300 Name: HARRIS_3, PENNY Age: 8 years Gender: Female Date: 03/09/2009 Time: 10:58 AM

Blood Pressure

Meal
Have you had any of the following in the past 30 minutes? (check all that apply) food
 alcohol
 coffee

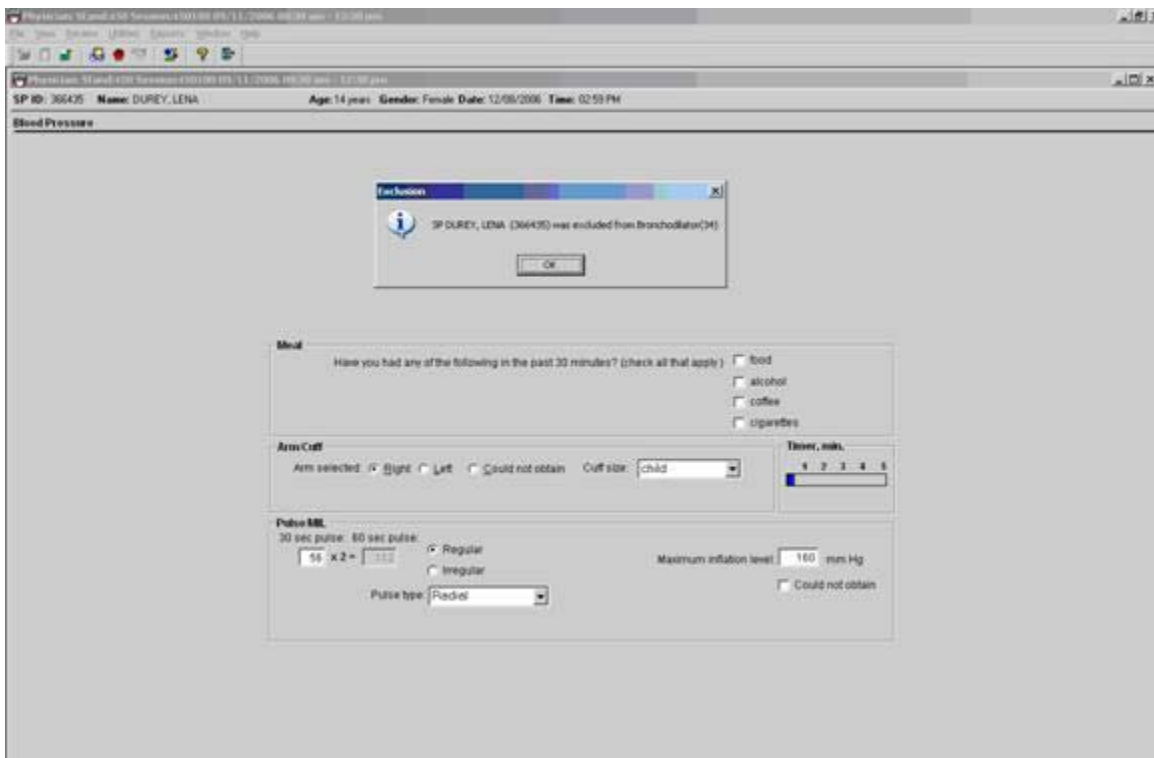
Arm/Cuff
Arm selected: Right Left Could not obtain Cuff size: child
Timer, min. 1 2 3 4 5

Pulse/MIL
30 sec pulse: 60 sec pulse:
56 x 2 = 112 Regular Irregular Missed beats:
Pulse type: Radial
Room temperature: 73 °F
Maximum inflation level: 140 mm Hg
 Could not obtain

Exclusion
SP HARRIS_3, PENNY (196300) was excluded from Bronchodilator(34)
OK

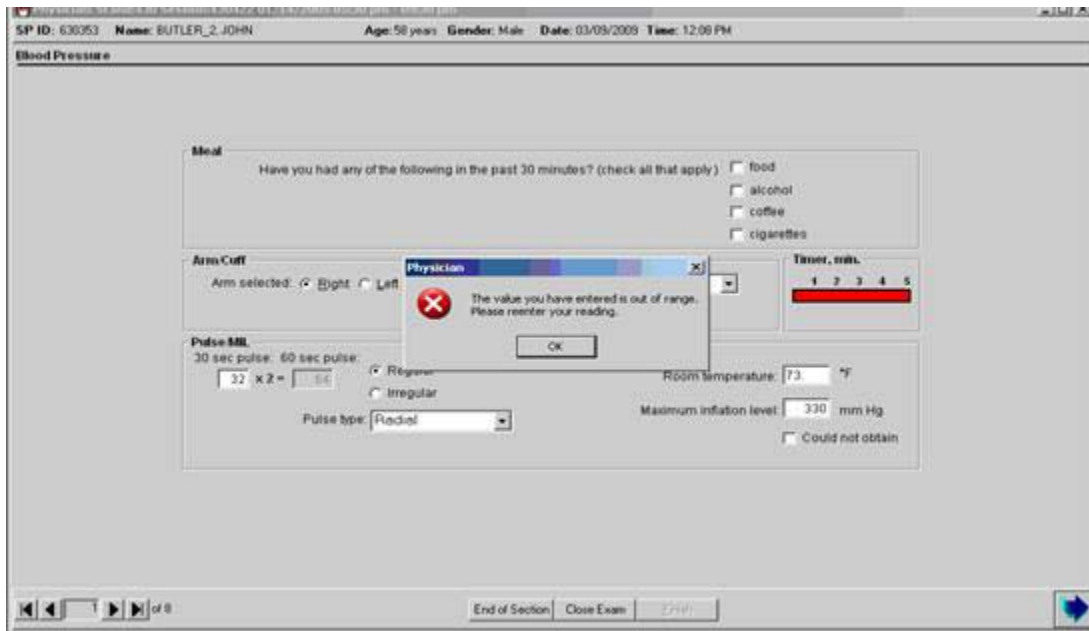
- If the pulse is irregular, SPs are excluded from the bronchodilator subcomponent. A message is displayed: “SP [name] was excluded from Bronchodilator.” Click OK to this message.
- The SP is excluded from the Bronchodilator safety exclusion questions and the subcomponent.

Exhibit 4-16. Heart rate exclusion from Bronchodilator



- If the pulse is greater than the rates for specified age ranges, SPs are excluded from the Bronchodilator subcomponent. A message is displayed: “The SP was excluded from Bronchodilator.” Click OK to this message.
- The SP is excluded from the Bronchodilator safety exclusion questions and from the Bronchodilator subcomponent.

Exhibit 4-17. Out of range maximum inflation level



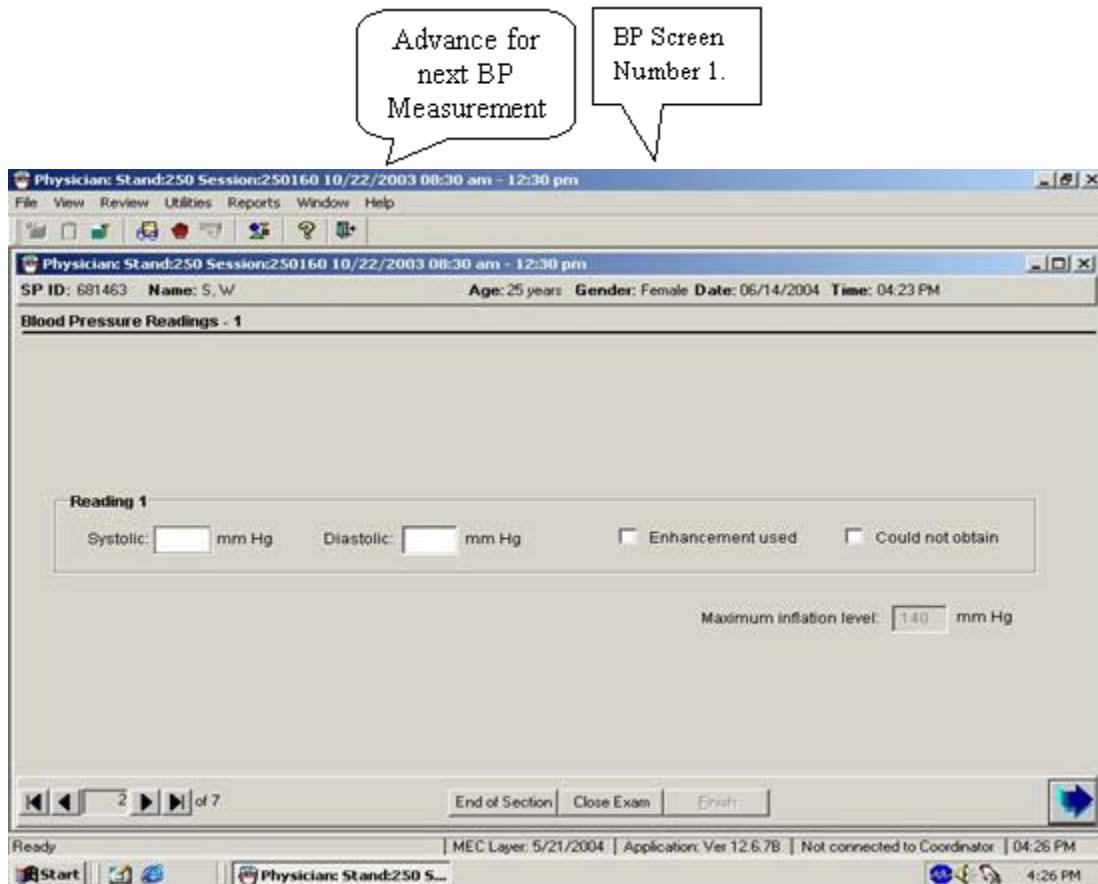
- Get the maximum inflation level (MIL) and enter this in the “Maximum inflation level” data entry field. If a number greater than 300 is entered a message is displayed: “The value you entered is out of range. Please reenter your reading.” The mercury manometer does not register numbers greater than 300.
- Alternatively, if the MIL is too low, the application will display the same hard edit alert.

Exhibit 4-18. MIL data entry required

- If the Next button is entered before the MIL is entered, the system will display a message: “Please enter MIL or check “Could not Obtain.” If “Could not Obtain” is selected for MIL, an attempt should be made to get a blood pressure measurement.

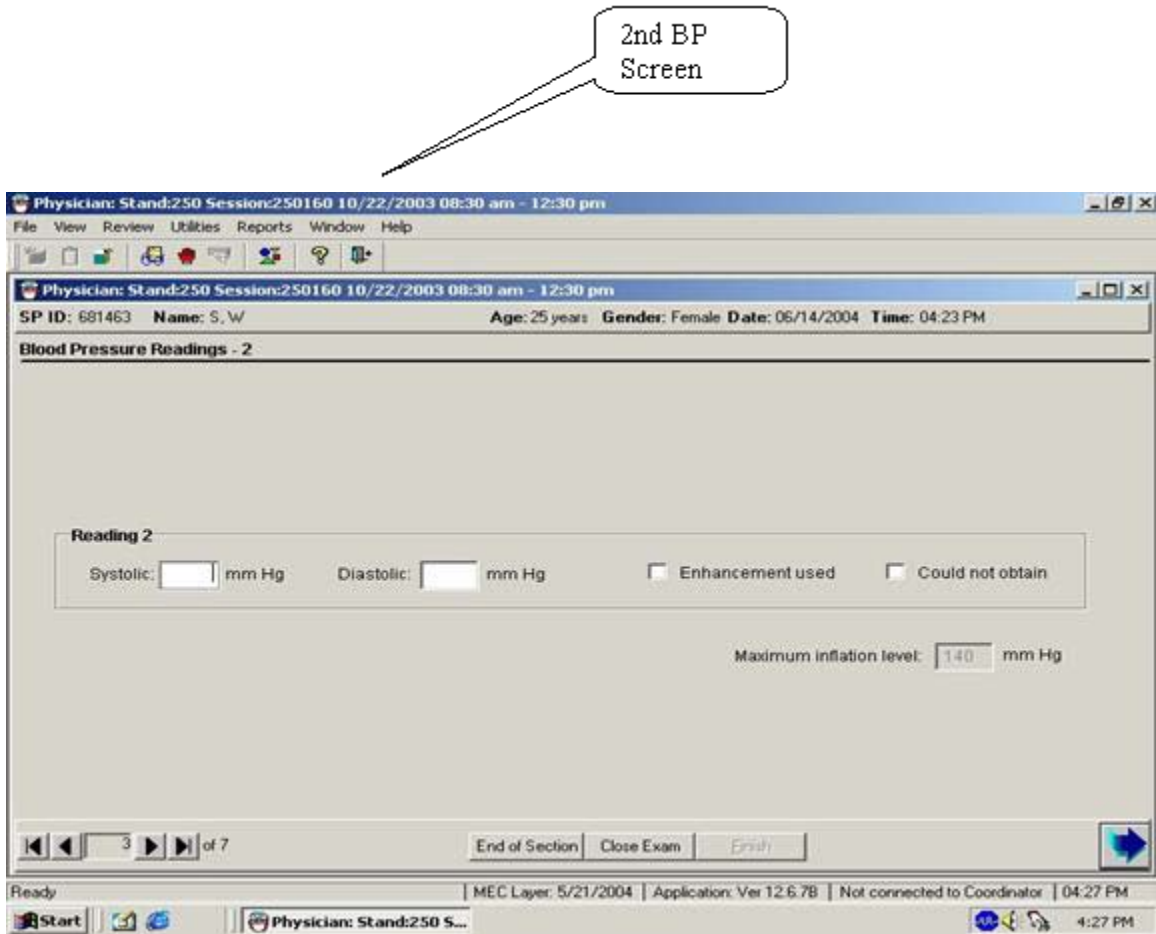
4.1.11 Blood Pressure Measurement Screens

Exhibit 4-19. Default blood pressure data entry screen



- Blood pressures are measured 3 times with a 30-second pause between each successive measurement.
- If you are unable to get a blood pressure measurement, check "Could not Obtain" for that measurement.
- If the blood pressure is difficult to hear, enhancement methods may, and should, be used. See Section 4.2.3.11 for a description of these methods. If the enhancements are used, click on the "Enhancement" button for that measurement.
- **Each BP measurement is recorded on a new screen. Advance the screen after each successive BP measurement. Do not go back to review previous BPs before taking the next measurement.**

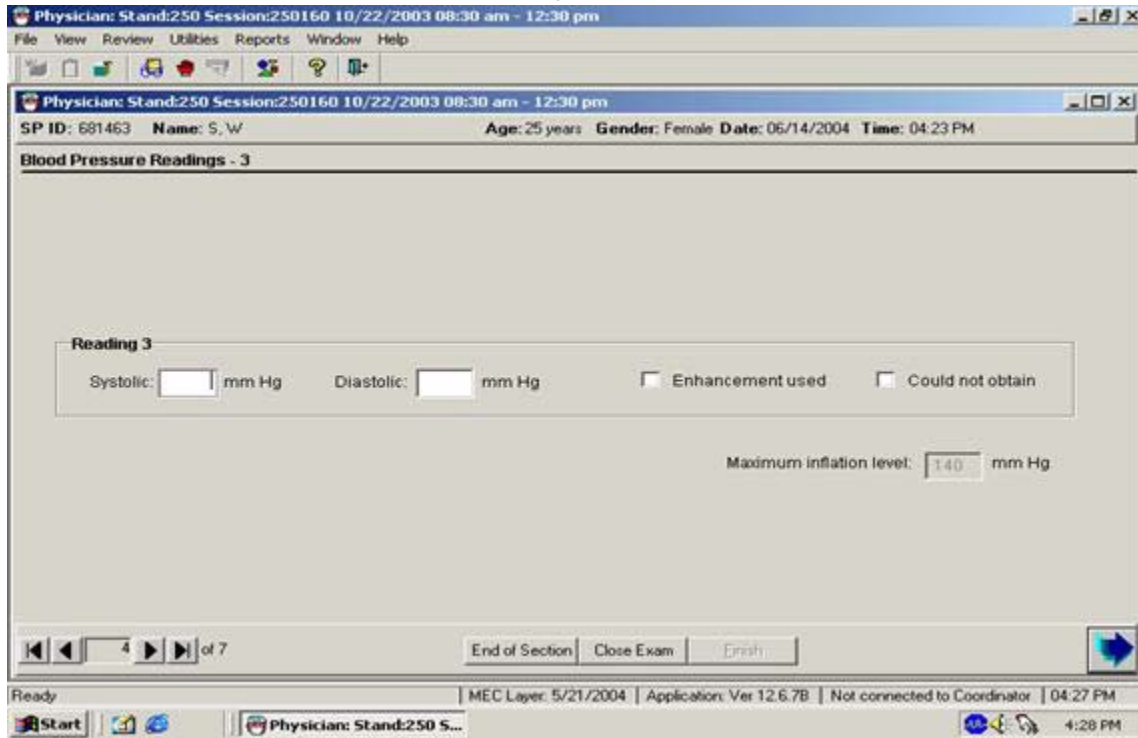
Exhibit 4-20. Blood Pressure Readings screen 2



- Take the second BP using the same techniques as BP 1.
- Record the 2nd BP, and advance the screen.

Exhibit 4-21. Blood Pressure Readings screen 3

BP measurement 3



- Take the third BP using the same techniques as BPs 1 and 2.
- Record the 2nd BP, and advance the screen.

Exhibit 4-22. Blood Pressure Readings screen 4

Take the 4th BP only if one of the 1st 3 was recorded as a "Could Not Obtain".

Physician Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

File View Review Utilities Reports Window Help

Physician Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

SP ID: 601463 Name: S, W Age: 25 years Gender: Female Date: 06/14/2004 Time: 04:23 PM

Blood Pressure Readings - 4

Reading 4

Systolic: mm Hg Diastolic: mm Hg Enhancement used Could not obtain

Maximum inflation level: mm Hg

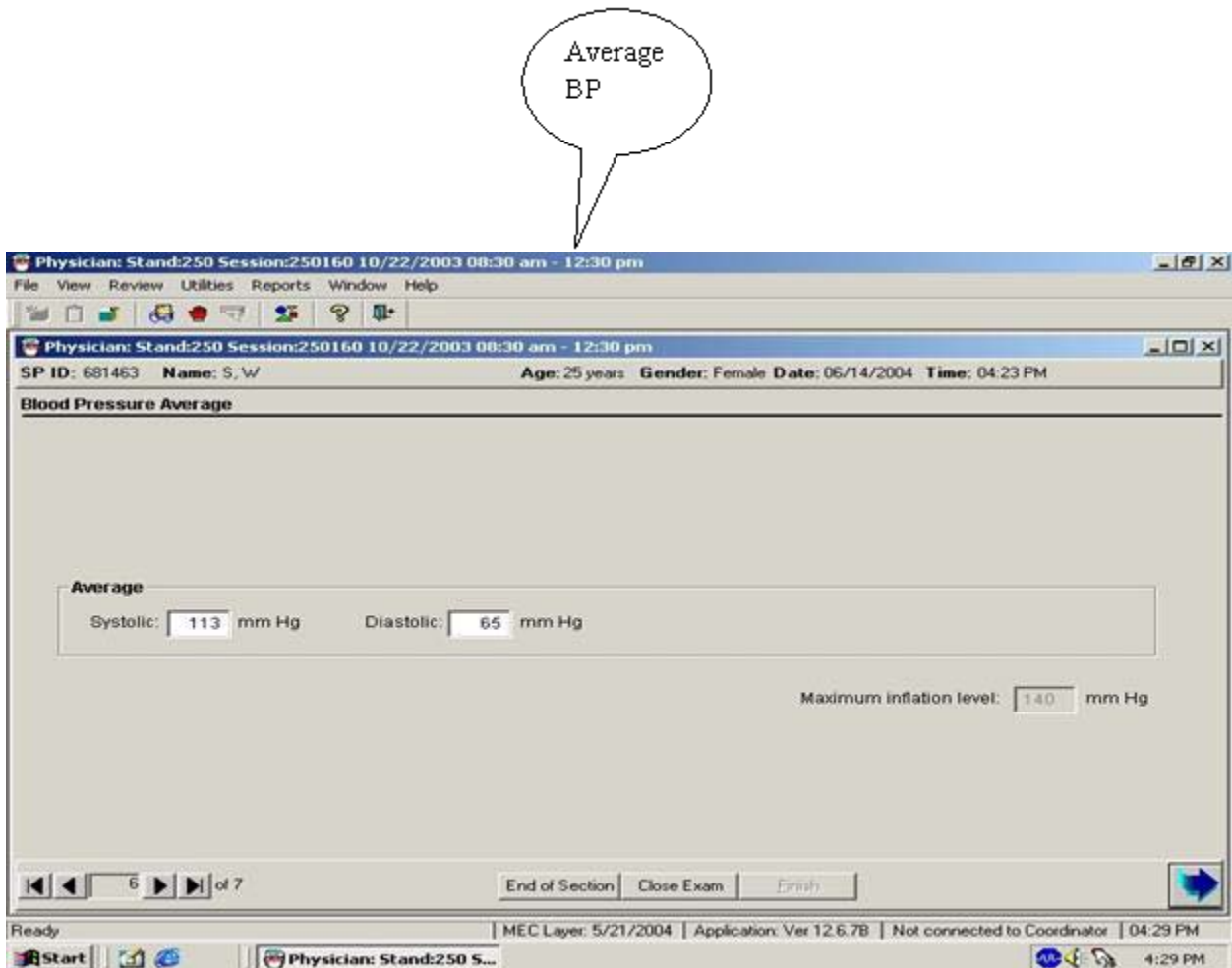
End of Section Close Exam Finish

Ready | MEC Layer: 5/21/2004 | Application: Ver 12.6.7B | Not connected to Coordinator | 04:28 PM

Physician Stand:250 S... 4:29 PM

- If any of the first three measurements are checked as "Could not Obtain," the BP section of the application will open up another field to allow a fourth measurement.
- Take the fourth measurement and record the results.
- The maximum number of times the cuff should be inflated for blood pressure measurements is five including all MIL measurements.
- The increment of the mercury manometer markings are in 2-millimeter intervals. All end digit BP measurements should be recorded as even numbered digits. If an odd number is entered as the end digit for either the systolic or diastolic measurement, a message is displayed: "**Number must be even!**"
- Click OK to this message. Reenter the correct measurement and continue with data entry or measurement.
- If the systolic BP entered is greater than the MIL, a message is displayed: "SBP should be less than MIL. Please, redo your MIL."
- Redo the MIL and record. The maximum number of times the cuff can be inflated is five.

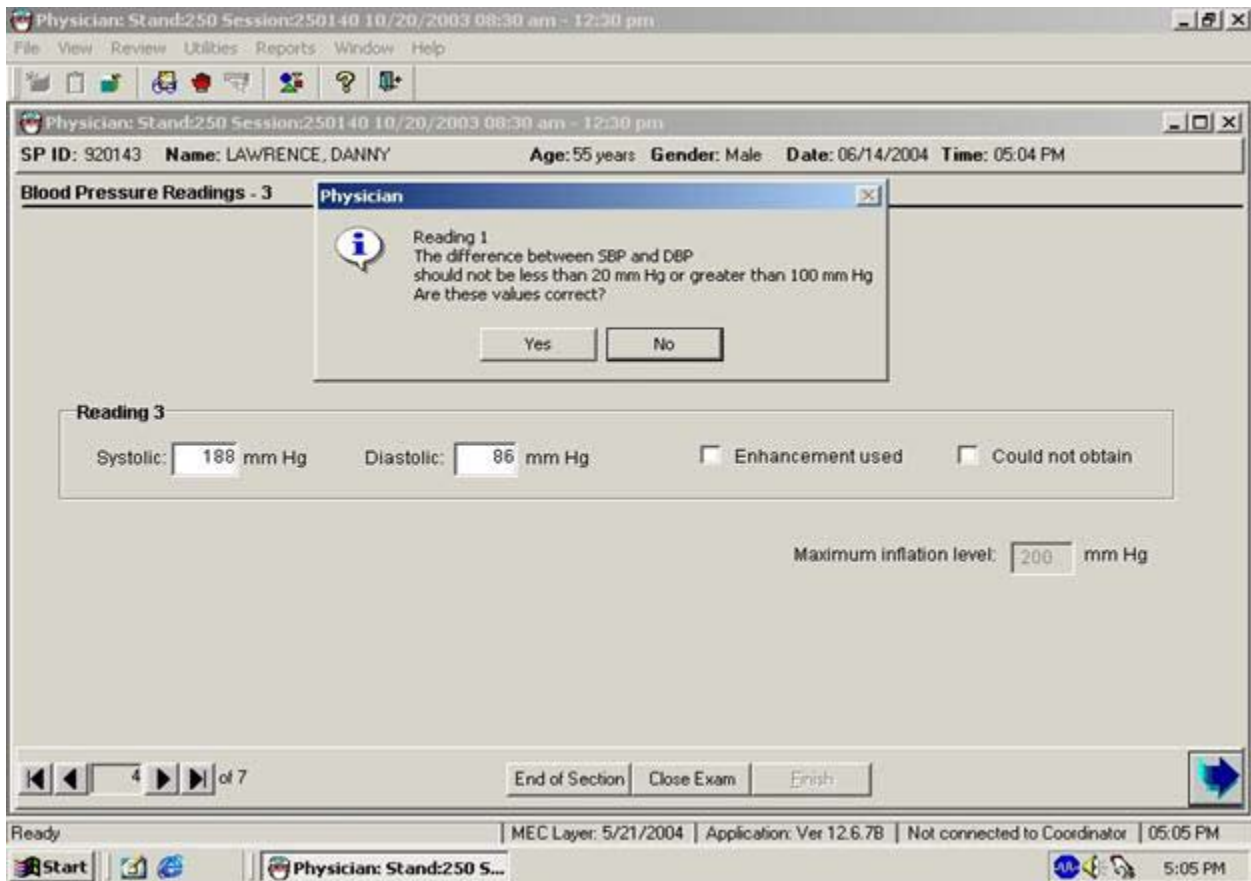
Exhibit 4-23. Averaging systolic blood pressure



- There must be a MIL recorded for every SP.
- Ideally, every SP has three blood pressure measurements recorded.
- When three systolic blood pressure readings are recorded, the systolic average is calculated by the system as the average of the **last two systolic measurements**.
- When only one systolic blood pressure reading can be obtained, the one systolic reading is calculated by the system as the average.
- When only two systolic blood pressure readings can be obtained, the first systolic reading is discarded and the second systolic blood pressure measurement is calculated by the system as the systolic average.
- If all diastolic readings are zero, the average diastolic BP is calculated by the system as zero (0).

- If there is one diastolic reading of zero and one or more readings with a diastolic above zero (0), the system uses only the nonzero diastolic readings to calculate the average diastolic BP.
- If two out of three diastolic readings are zero (0), the system uses the one nonzero diastolic reading to calculate the average diastolic BP.
- When the average BP appears, tell the SP his or her BP.

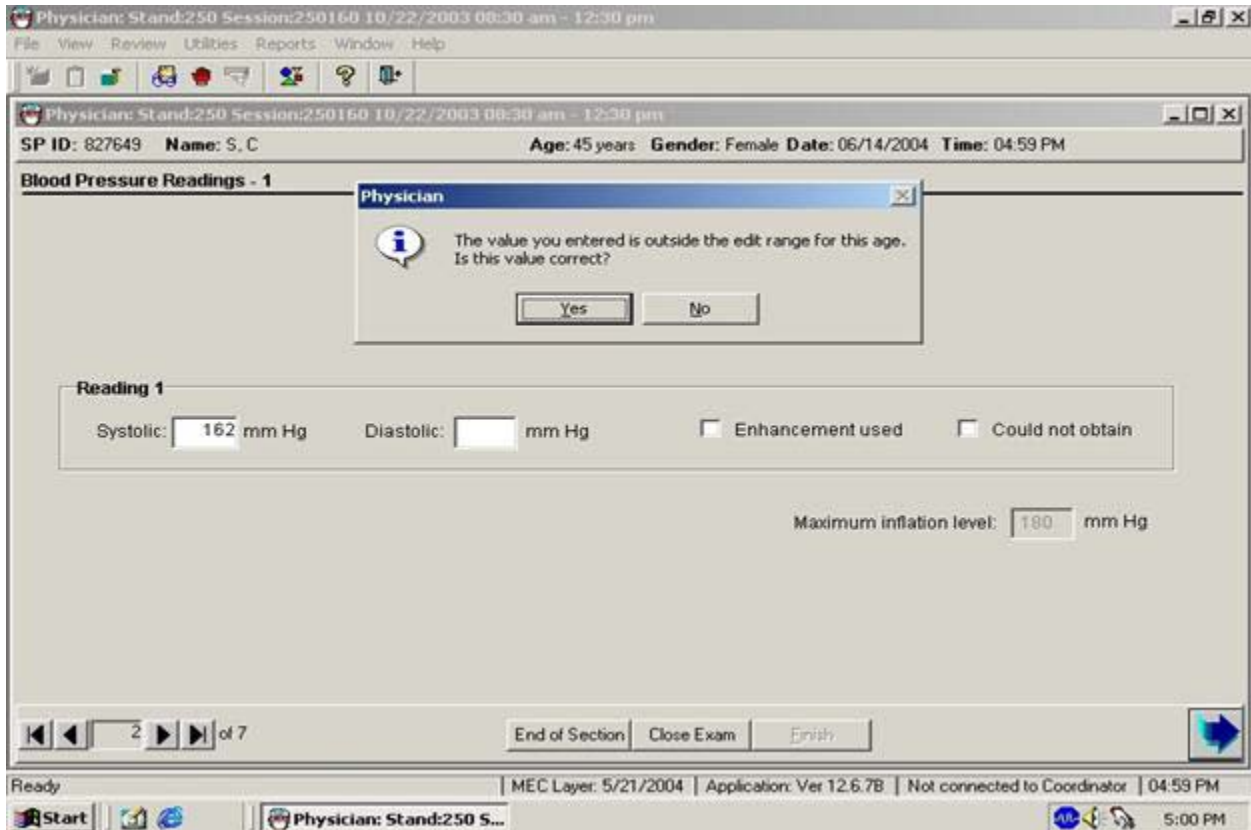
Exhibit 4-24. Edit allowable systolic and diastolic blood pressure



- If the systolic and diastolic BP are less than 20 mm Hg or more than 100 mm Hg, the application edits asks for verification of accuracy.
- If the measurements are correct, click “Yes.”
- If the measures are incorrect, click “No,” and reenter the measurements.

4.1.12 Blood Pressure Edit Limits

Exhibit 4-25. Edit range limits for blood pressure



- If a systolic or diastolic value is outside the edit range for that SP, (age specific) the system displays a message: “The value you entered is outside the range for this age. Is this value correct?”
- If the value entered is correct, click “Yes,” and proceed with the data entry.
- If the response is not correct, click on “No” and reenter the value, then proceed with the examination.

4.1.13 Blood Pressure Component Status and Comments

Exhibit 4-26. Comments in blood pressure component

Physician: Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

File View Review Utilities Reports Window Help

Physician: Stand:250 Session:250160 10/22/2003 08:30 am - 12:30 pm

SP ID: 681463 Name: S, W Age: 25 years Gender: Female Date: 06/14/2004 Time: 04:23 PM

Blood Pressure Status

Status

Complete
 Partial
 Not Done

Comments [dropdown menu]

Other text [input field]

End of Section Close Exam Finish

Ready | MEC Layer: 5/21/2004 | Application: Ver 12.6.7B | Not connected to Coordinator | 04:30 PM

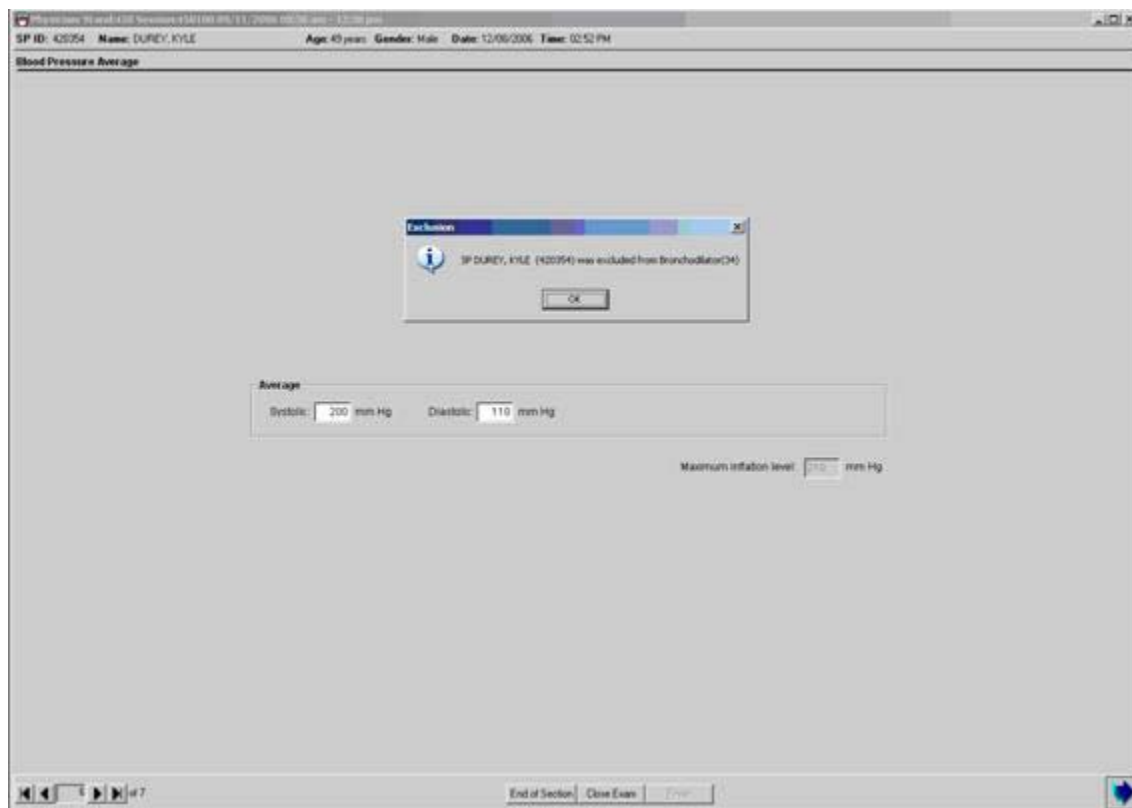
Start | Physician: Stand:250 S... | 4:30 PM

- If all the measurements were entered, the system sets the default last screen for the component status to “Complete.”
- If one or more of the measurements were not recorded, the system sets the component status to “Partial.”
- If the Component Status is partial, select the appropriate comment from the drop-down menu.
- The comments in the menu are:
 - Safety exclusion: SP is excluded due to a situation that may cause him or her harm or discomfort such as applying or inflating a cuff on an arm with visible edema, lesions, or other conditions.
 - SP refusal: SP refuses all or part of the examination.
 - No time: SP is unable to complete the examination due to time restrictions.

- Physical limitation: SP has a physical limitation that prevents examination completion.
- Communication problem: Physician is unable to communicate instructions for the examination adequately.
- Equipment failure: There is a malfunction of the equipment.
- SP ill/emergency: SP became ill while in the middle of the examination.
- Interrupted: Session was interrupted due to natural phenomena or other event.
- Poor cuff fit: If cuff does not fit properly, the blood pressure measurements should not be taken.
- Other, specific: If none of the standard comments apply, select “Other” and specify the reason for the status in the open text field.

4.1.14 Exclusion from Bronchodilator Based on Blood Pressure

Exhibit 4-27. Blood pressure exclusion from Bronchodilator



- If the systolic BP exceeds specific age criteria, the SP is excluded from the Bronchodilator subcomponent and from the safety exclusion questions in the physician’s examination.
- A message is displayed: “SP [name] was excluded from Bronchodilator.”
- Click “OK.”

4.1.15 Omron Data Capture Screen

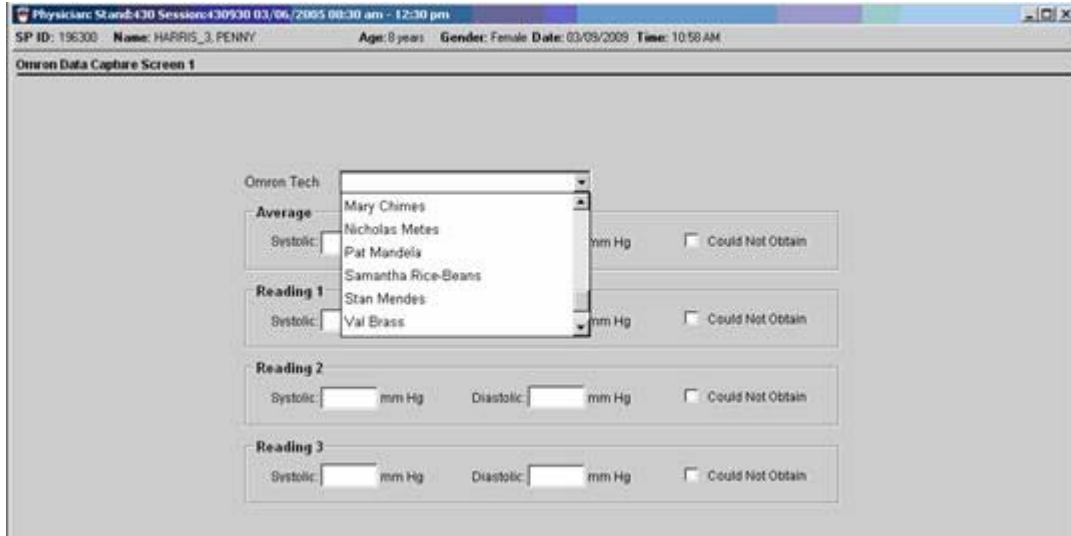
The physician will not perform this function under any circumstance; the BP recorder is the only person assigned with completing this portion of the physician exam data entry.

Exhibit 4-28. Omron Data Capture Screen 1

- This screen will appear at the end of the physician exam. When the physician sees this screen, the recorder will have been assigned by the coordinator, and will be standing by to enter the physician’s room.

- The physician will release the SP from the room, and at that time the recorder may enter the physician's exam room.
- The recorder must transcribe the readings from the Omron into the ISIS application in the physician exam.

Exhibit 4-29. Omron Tech drop-down box

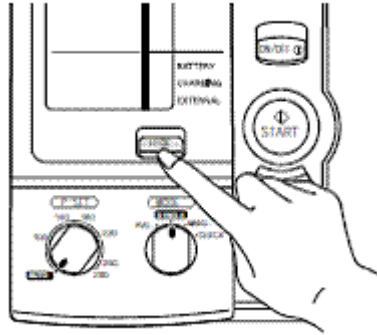


- Select the appropriate name from the Omron Tech drop-down box as in Exhibit 2.

The Omron Tech will only be required to use two buttons on the Omron to access the BP readings: the HIDE button and the DEFLATION button. The DEFLATION button is a dual function switch that toggles through the 3 BP measurements when the Omron is set in the AVG mode.

1. Press the HIDE button to take the display out of the HIDE mode.

Exhibit 4-30. Omron hide button



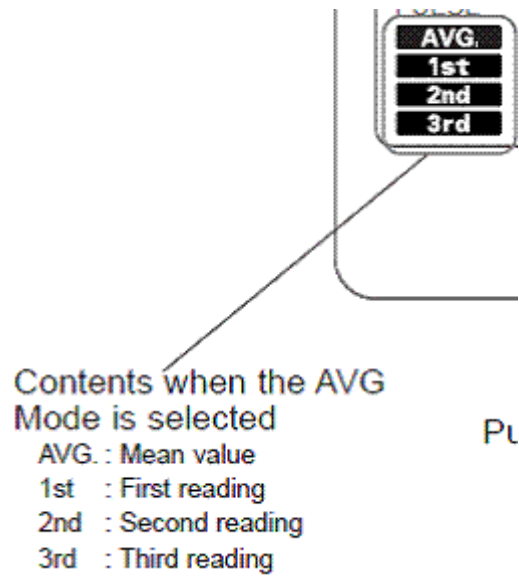
2. The first BP reading to appear on the Omron display is the calculated average of the three measures. Record these numbers into the first line of the Omron Data Capture Screen.
3. To move on to the value of the first BP reading, press the DEFLATION button:

Exhibit 4-31. Deflation button



Each time the DEFLATION button is pushed, the results for each reading will be displayed associated with the bottom window indicating the current reading, either Avg, 1st, 2nd, or 3rd, as in the exhibit below:

Exhibit 4-32. AVG Mode reading indicator



4. To obtain the value of the second BP result, press the DEFLATION button, and record.
5. To obtain the value of the third BP result, press the DEFLATION button to advance to the third reading, and record.

Note** ISIS will not allow an entry field to be advanced if the block is blank; the cursor will remain in the empty block until something is entered into the field. Therefore, there is no possibility to have a partial entry into any Omron Data Capture field.

Exhibit 4-33. Completed Omron Data Capture Screen 1

Physician: Stand-430 Session:430930 03/06/2005 08:30 am - 12:30 pm
SP ID: 196300 Name: HARRIS_3, PENNY Age: 8 years Gender: Female Date: 03/09/2009 Time: 10:58 AM
Omron Data Capture Screen 1

Omron Tech: Nicholas Metes

Average
Systolic: 119 mm Hg Diastolic: 72 mm Hg Could Not Obtain

Reading 1
Systolic: 127 mm Hg Diastolic: 74 mm Hg Could Not Obtain

Reading 2
Systolic: 114 mm Hg Diastolic: 76 mm Hg Could Not Obtain

Reading 3
Systolic: 117 mm Hg Diastolic: 76 mm Hg Could Not Obtain

End of Section Close Exam Error

- When reading 3 is recorded, thus completing all the fields, advance to the next screen (Exhibit 4-34).

Exhibit 4-34. Omron Data Capture Screen 2

Physician: Stand-430 Session:430951 03/08/2005 01:30 pm - 05:30 pm
Omron Data Capture Screen 2

Average
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 1
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 2
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

Reading 3
Systolic: mm Hg Diastolic: mm Hg Could Not Obtain

End of Section Close Exam Error

- Continue to toggle through the BP readings using the DEFLATION button to record the readings a second time.

Exhibit 4-35. Completed Omron Data Capture Screen 2

The screenshot displays a software window titled "Omron Data Capture Screen 2". At the top, a status bar shows patient information: "Physician: Stand:430 Session:4309151 03/10/2005 01:30 pm - 05:30 pm", "SP ID: 543848", "Name: CLEAVER_6, THEODORE", "Age: 12 years", "Gender: Male", "Date: 03/10/2009", and "Time: 03:25 PM". The main area contains four sections for blood pressure data:

Category	Systolic (mm Hg)	Diastolic (mm Hg)	Could Not Obtain
Average	119	72	<input type="checkbox"/>
Reading 1	127	74	<input type="checkbox"/>
Reading 2	114	76	<input type="checkbox"/>
Reading 3	117	76	<input type="checkbox"/>

At the bottom left, there are navigation arrows and a "2 of 4" indicator. At the bottom right, there are buttons for "End of Section", "Close Exam", and "Print", along with a blue arrow icon.

- When reading 3 is recorded, using the advance arrow in the right corner, advance to the next screen, Omron Data Capture Screen 3. If the readings were entered the same on Data Capture Screens 1 & 2, the Omron Data Capture Screen 3 will appear as below; all fields will be grayed out, and the Omron tech will be unable to change anything on the screen.

Exhibit 4-36. Omron Data Capture Screen 3: No errors made in data entry

The screenshot displays the Omron Data Capture Screen 3 interface. At the top, a status bar shows patient information: "Physician: Stand-430 Session: 430921 03/05/2005 01:30 pm - 05:30 pm", "SP ID: 651757 Name: HOLLAND_5, USA", "Age: 30 years Gender: Female Date: 03/09/2009 Time: 11:53 AM". The main area contains four sections for data entry:

Section	Systolic (mm Hg)	Diastolic (mm Hg)	Could Not Obtain
Average	117	79	<input type="checkbox"/>
Reading 1	114	71	<input type="checkbox"/>
Reading 2	118	84	<input type="checkbox"/>
Reading 3	120	81	<input type="checkbox"/>

At the bottom, there are navigation controls: "End of Section", "Close Exam", and "Exit" buttons, along with a status indicator "3 of 4" and a blue arrow icon.

Data Capture Screen Edits

The “double keying” of the BP readings minimizes user data entry error, and the system has several features to detect errors when the readings do not agree. These features prompt the recorder to review the data entered to ensure the correct transcription of the Omron readings into ISIS. Common mistakes to avoid while entering the data include:

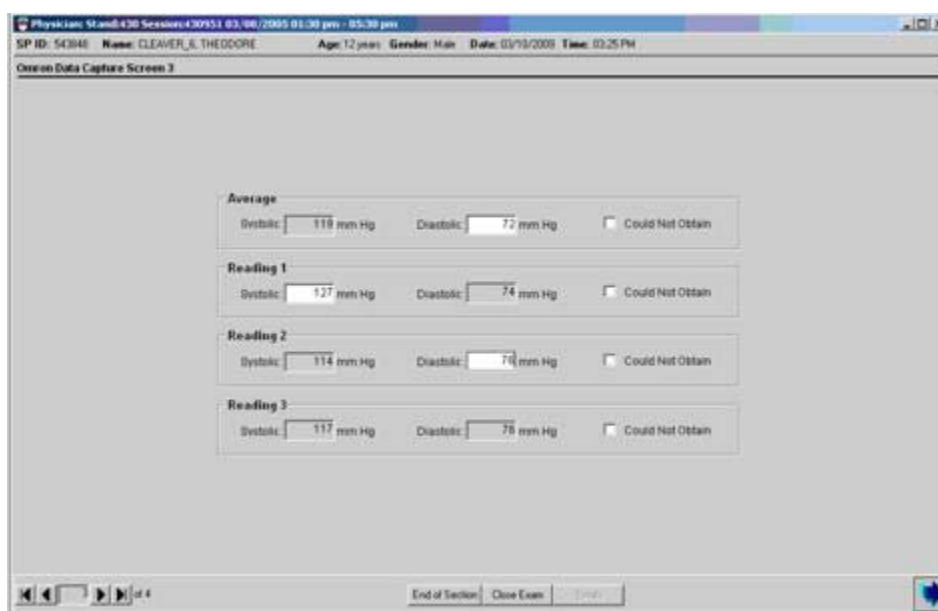
- Rushing through the data entry. If you take your time, and carefully move through the measurements, it will ultimately save time if you transcribe the results correctly the first time.
- Pressing the On/Off button prematurely—if the On/Off button is accidentally pushed, the data is permanently lost. **Do Not** touch the off/on button until you have exited the Omron Data Capture Screen.

Data Entry Error Edit Alerts

If a data entry error is detected by ISIS, the Omron Data Capture Screen 3 will appear with the fields that need to be corrected as enabled; the entries that do not need corrected will appear grayed-out. See below:

You do not have to reverse through the screens to correct the entries. What is required is to review the Omron displays for the enabled fields, toggle through the displays, and re-enter the data into Omron Data Capture Screen 3.

Exhibit 4-37. Corrected Data Capture Entries on Screen 3



The screenshot shows a software window titled "Physician: Stand:430 Session:430451 03/19/2009 01:30 pm - 05:30 pm". The patient information is: "SP ID: 543848 Name: CLEAVER, S. THEODORE Age: 12 years Gender: Male Date: 03/19/2009 Time: 02:25 PM". The screen is labeled "Omron Data Capture Screen 3". It displays four rows of data entry fields for blood pressure readings:

Category	Systolic (mm Hg)	Diastolic (mm Hg)	Status
Average	118	72	Could Not Obtain
Reading 1	127	74	Could Not Obtain
Reading 2	114	70	Could Not Obtain
Reading 3	117	78	Could Not Obtain

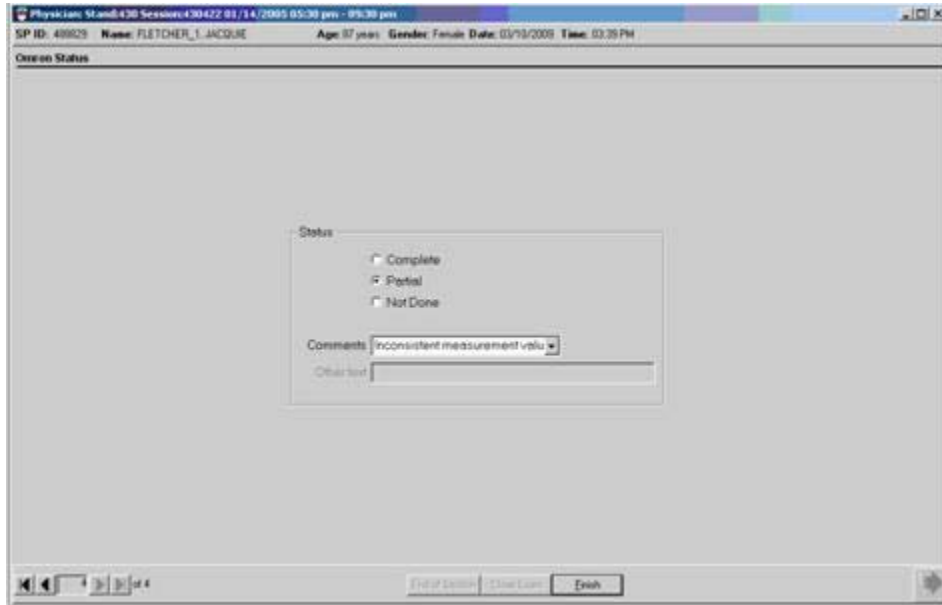
At the bottom of the screen, there are navigation arrows and buttons for "End of Section" and "Close Exam".

This is the only opportunity to correct the data entry errors. If the Omron tech enters another error, the following status screen will appear: the Omron Status will be marked as a partial exam, and automatically inserted comment will indicate "Inconsistent measurement values".

The goal as data collectors is to never see this Omron Status. At this point if this message is displayed, it is still possible to back up using the lower left hand arrows to the first Omron Data Capture screen and re-enter all the readings, proceed to the second Omron Data Capture Screen and re-enter the data. This is not an ideal scenario because of the length of time that is being added to the exam to re-enter

all of the readings, but it is an option if the recorder gets the “inconsistent measurement values” message. The primary objective is to transcribe the Omron readings precisely.

Exhibit 4-38. Inconsistent measurement values



The ISIS application will impose no hard or soft edit alerts for any values in the Omron Data Capture screens. This will allow an unlimited range of values to be measured by the Omron, but the recorder must be aware that the application will accept a digit such as 0, or 999. It is impossible to over-emphasize the care that must be taken when entering the data. Inconsistent values will result in lost data.

Exhibit 4-39. No digit high/low edits



Exhibit 4-40. Omron Data Capture Screen: Skip due to time constraints

The screenshot shows the 'Omron Data Capture Screen 1' interface. At the top, it displays patient information: 'SP ID: 936916 Name: HARTLEY, WILL Age: 23 years Gender: Male Date: 03/09/2009 Time: 11:30 AM'. Below this is a header 'Omron Data Capture Screen 1'. The main area contains a form with the following elements:

- 'Omron Tech' dropdown menu.
- 'Average' section with input fields for 'Systolic: [] mm Hg' and 'Diastolic: [] mm Hg', and a checkbox for 'Could Not Obtain'.
- 'Reading 1' section with 'Systolic: [] mm Hg' and 'Diastolic: [] mm Hg' fields, and a 'Could Not Obtain' checkbox.
- 'Reading 2' section with 'Systolic: [] mm Hg' and 'Diastolic: [] mm Hg' fields, and a 'Could Not Obtain' checkbox.
- 'Reading 3' section with 'Systolic: [] mm Hg' and 'Diastolic: [] mm Hg' fields, and a 'Could Not Obtain' checkbox.

A modal dialog box is overlaid on the 'Reading 1' section. It has a title bar 'Physician' and a red 'X' icon. The text inside reads 'Do you wish to skip due to time constraints?'. Below the text are two buttons: 'Yes' and 'No'. The dialog box is positioned over the 'Systolic' and 'Diastolic' input fields of the 'Reading 1' section.

At the bottom of the screen, there are navigation controls: a set of arrows and '1 of 4', and buttons for 'End of Section', 'Close Exam', and 'Finish'.

In the rare event that the Omron readings were not completed during the physician exam, this screen will appear if the advance screen arrow is clicked when no data were entered into the Omron Data Capture Screen. The physician will notify the coordinator that the recorder will not be needed, and the physician may indicate that Omron readings were not done. If Yes is selected in this dialogue box and the screen is advanced, the Omron Status Screen will appear. The physician will enter a comment code that explains the reason the Omron was not done in the drop-down box in the Omron Status Screen.

Exhibit 4-41. Omron status screen

The screenshot shows the 'Omron Status' screen. It has a header 'Omron Status'. The main area contains a form with the following elements:

- 'Status' section with three radio buttons: 'Complete', 'Partial', and 'Not Done'. The 'Not Done' option is selected.
- 'Comments' dropdown menu.
- 'Other text' input field.

4.1.16 Summary of Omron Data Entry Procedure

Omron

1. Reveal BP readings by pressing the “HIDE” button.



2. The reading numbers are displayed in the box on the left lower corner of the LED display of the Omron.



The first BP reading to appear on the Omron display is the calculated mean of the three measures, denoted in the left lower corner as AVG.

3. To move to the 1st BP reading, press the “DEFLATION” button. The DEFLATION button acts as a toggle switch between the 4 BP readings.



4. Repeat step 3 to advance to the 2nd and 3rd readings.

ISIS Application

1. Access Omron Tech dropdown box, and select your name.
2. Carefully enter the data into Omron Data Capture Screen 1.
3. Advance to Omron Data Capture Screen 2 and enter data.
4. Advance to Omron Data Capture Screen 3
5. Review Screen 3. If all entries are grayed-out, there is no disagreement in the entries on Screens 1 & 2, and you may advance to the Exam Status (final) screen, and close exam.
6. If the screen contains enabled fields, do not reverse back in the application. Toggle through the readings on the Omron to the desired reading, and carefully re-enter the data on Screen 3.
7. Advance to the Exam Status (final) screen, and close exam.

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4.2 Shared Exclusion Questions

The phlebotomy, GTT, bone density (DXA), oral health and respiratory health components include questions designed to exclude SPs based on safety reasons. The questions are component specific and they are asked in the component for all SPs aged 16+, but there are two safety exclusion questions that are asked of all SPs for several exams, and these are referred to as shared exclusion questions. They are:

- Do you have a pacemaker or automatic defibrillator?
- Are you currently pregnant?

Safety exclusion questions that were not answered during the household interview are asked during the MEC examination and are asked at the first opportunity when the SP begins the exam. In the case of children, parents or guardians answer the exclusion questions (proxy exam) as soon as they arrive on the MEC, with the exception of the pregnancy question. The proxy exam is conducted either by the MEC manager or the MEC interviewers. Each question is asked only once, even when the question is relevant for more than one component—this eliminates wasting time during exams to repeat questions that the SP has all ready answered. It is important to note that answers to the safety exclusion questions provided during previous components will appear on the screen for the next examiner to see, but the field for data entry is disabled. Once answered, they cannot be changed.

The pregnancy question is administered to all female SPs between the ages of 12 through 59 years. The question is also addressed to SPs aged 8 through 11 years if they reported during the household interview that menarche had begun. The physician is the only MEC examiner who asks this question.

They physician will see two questions on the Shared Exclusion Screen:

Exhibit 4-42. Shared Exclusion Questions females aged 12 to 59

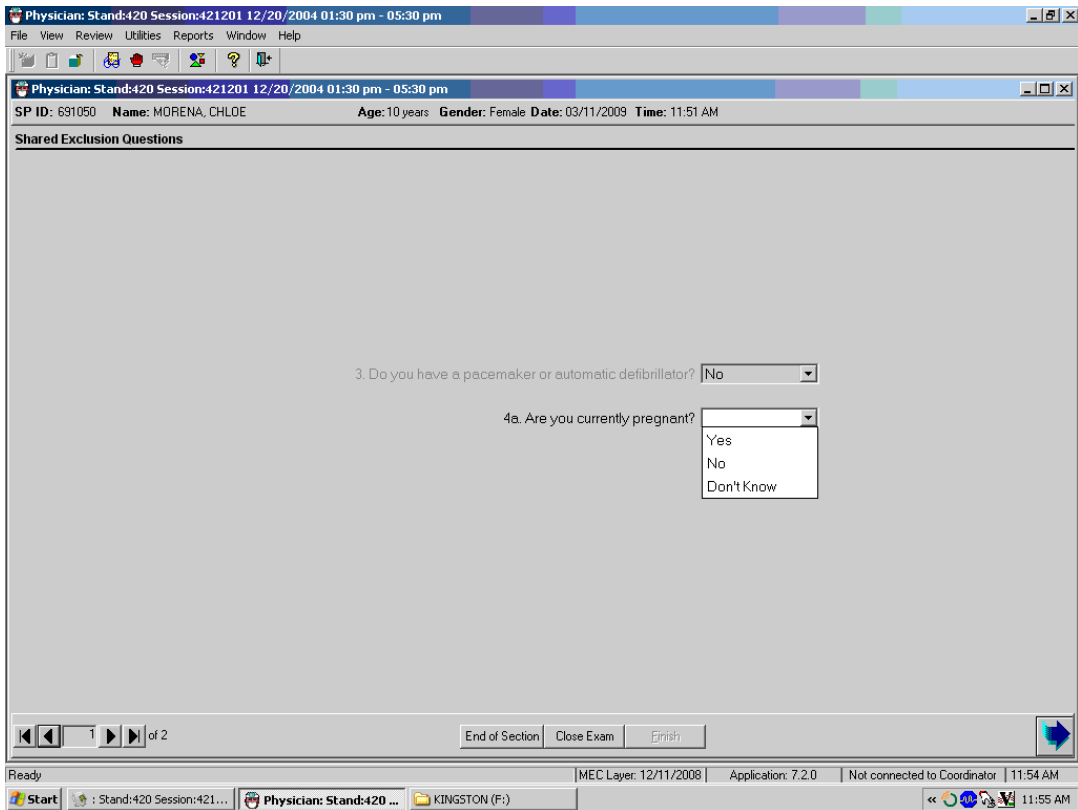
The screenshot shows a software interface for a Shared Exclusion Screen. At the top, a status bar displays: "Physician: Stand-450 Sessions:450100 09/11/2006 09:30 am - 12:30 pm". Below this, patient information is shown: "SP ID: 798037 Name: DUREY, KATE Age: 10 years Gender: Female Date: 12/08/2006 Time: 02:56 PM". The main area is titled "Shared Exclusion Questions" and contains two questions, each with a dropdown menu:

- 3. Do you have a pacemaker or automatic defibrillator? [dropdown menu]
- 4a. Are you currently pregnant? [dropdown menu]

At the bottom of the screen, there are navigation controls: a left arrow, a right arrow, and "1 of 2". To the right of these are three buttons: "End of Section", "Close Exam", and "Exit".

- If the SP is female, there are shared exclusion questions on self-reported pregnancy.
- If the shared exclusion questions are answered in the household examination, the questions will appear answered and disabled. These responses cannot be changed in the MEC.
- If the responses excluded the SP from Bronchodilator, the SP would not be sent to the Bronchodilator subcomponent.

Exhibit 4-43. Shared Exclusion Questions answered during a previous exam



- This slide represents the condition in which a parent would have answered the pacemaker or automatic defibrillator question during the proxy exam, but the pregnancy question is asked by the physician during the physician exam.

- If the pregnancy question is answered Yes, a dialogue box will appear with a message that the SP is excluded from DXA as well as bronchodilator. See the following screen (Exhibit 4-44):

Exhibit 4-44. Shared Exclusion Questions: Exclusion

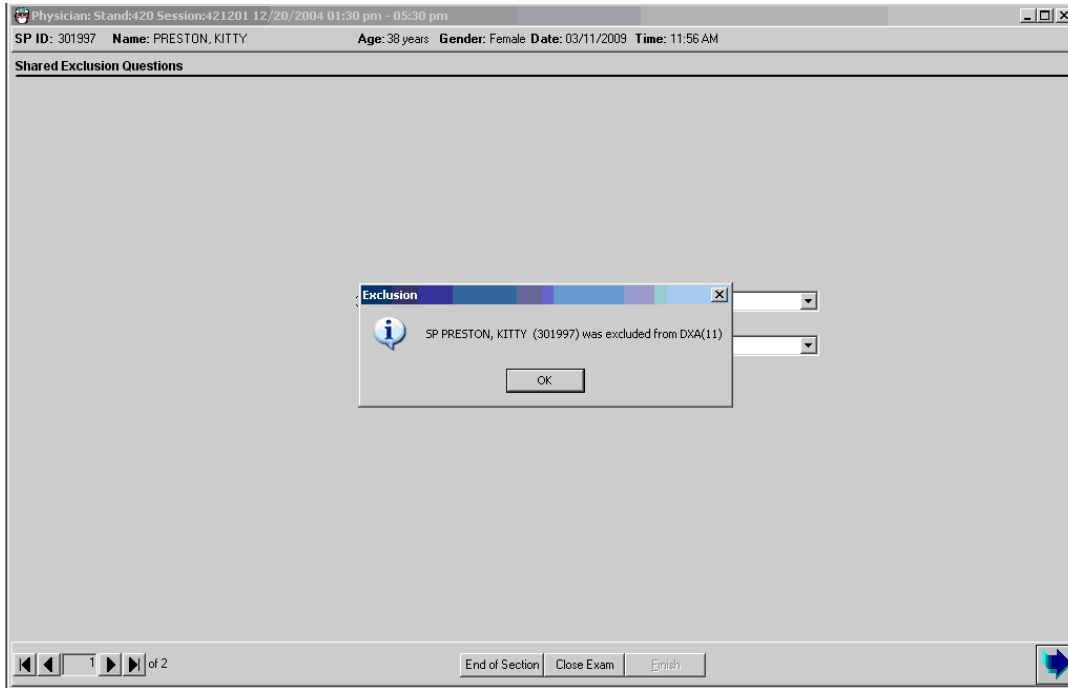
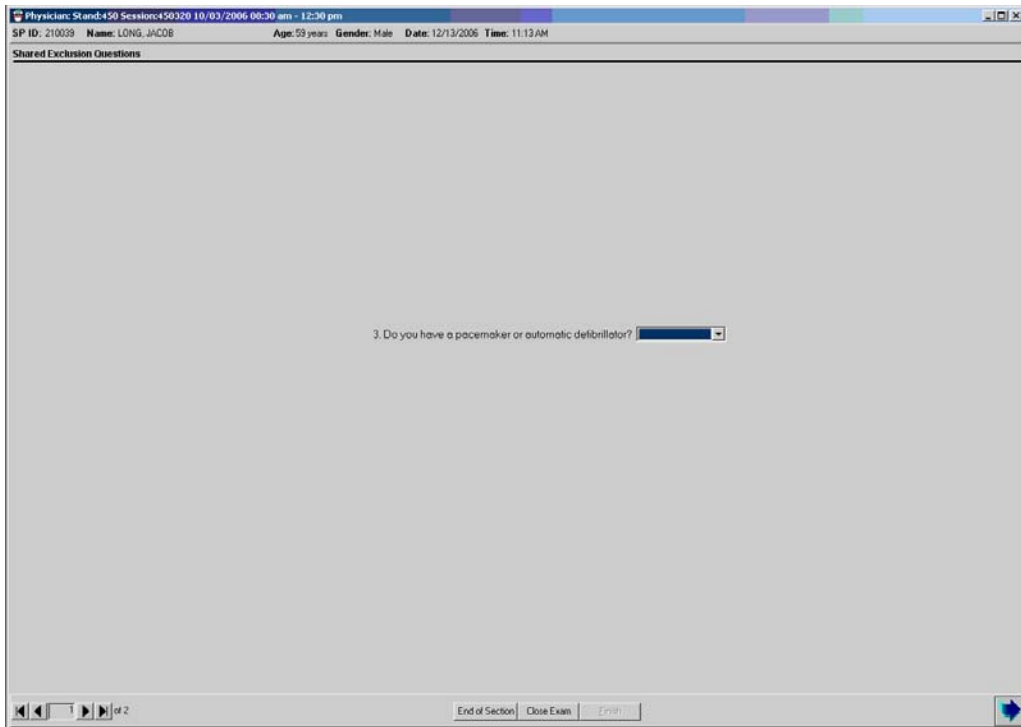
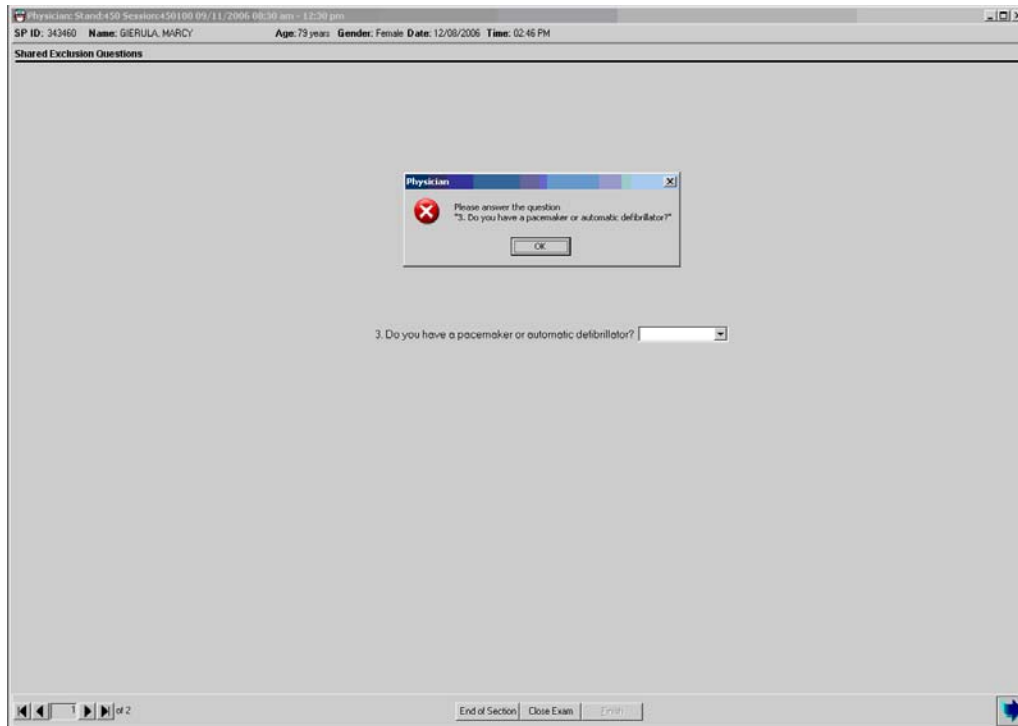


Exhibit 4-45. Shared Exclusion Questions: Pacemaker/Automatic Defibrillator



- This is the only Shared Exclusion question for SPs who are male, and females who are not of childbearing age.
- If the response to the above question is “Yes,” the SP is excluded from the Bronchodilator subcomponent.

Exhibit 4-46. Shared Exclusion Questions: Required data entry



- If the Next button is pressed to go to the next screen, a message is displayed: “Please answer the question.” The specific question that was not answered will also be part of this message.
- Click “OK” to this message and answer the question, then go to the next screen.

Exhibit 4-47. Component completion status for shared exclusions

Physician Exam: Stand:601 Session:601480 02/24/1999 08:30 am - 12:30 pm

SP ID: 305781 Name: Washington, George Age: 43 years Gender: Male Date: 02/13/1999 Time: 07:54 PM

Shared Exclusion Status

Status

Complete

Partial

Not Done

Comments

Other text

2 of 2

End of Section Close Exam Finish

- If all the shared exclusion questions are answered, the component status for shared exclusions defaults to “Complete.”
- If all questions were not answered, the status defaults to partial. The examination is closed with the “Close Examination” button.
- If the SP was excluded by any of the shared exclusion questions, the system displays a series of messages to indicate the other components that are blocked for this SP.
- The SP is excluded from DXA if the response to the question on pacemaker or defibrillator is “Yes.”
- The SP is excluded from DXA if the weight is greater than 300 pounds, so the pacemaker/defibrillator question might be disabled if the SP is sent to body measures first.

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4.3 Prostate Specific Antigen Testing

Men who are 40 years of age and older are asked to have their blood tested for prostate specific antigen. The exclusion criteria is first addressed, because if the SP reports any condition/s that would exclude the SP from PSA testing, the test will not be offered; however, the data pertaining to prostate health is also important to the survey. If the SP remains eligible for PSA testing after completing the exclusion questions, the physician explains the importance of this test, recruits the SP, and informs the SP when the results will be received and what they mean. It is important that the physician fully explain that for PSA, a positive test does not mean that the SP has cancer, or that a negative result does not mean that the SP does not have cancer.

4.3.1 Introduction to Exclusion Questions

“I am now going to ask you some questions about your prostate health.” The physician introduces the SP to the prostate health section of the physician exam with this statement, and proceeds to ask the exclusion questions. They are:

1. Do you have an infection or inflammation of the prostate gland at the present time?
2. Have you had a rectal exam in the last 7 days?
3. Have you had a prostate biopsy or other prostate surgery in the last 4 weeks?
4. Have you had a cystoscopy in the last 4 weeks?
5. Have you ever been told by a doctor or health professional that you had prostate cancer?

SP ID: 472495 Name: JONES_1, JIMMY Age: 68 years Gender: Male Date: 03/11/2009 Time: 04:53 PM

PSA Testing Exclusion Questions

{Do you/does SP} have an infection or inflammation of the prostate gland at the present time?

{Have you/Has SP} had a rectal exam in the last 7 days?

{Have you/Has SP} had a prostate biopsy or other prostate surgery in the last 4 weeks?

{Have you/Has SP} had a cystoscopy in the last 4 weeks?

(Cystoscopy is an internal examination of the prostate and bladder using a flexible tube-like instrument with a lens inserted through the penis.)

{Have you/Has SP} ever been told by a doctor or health professional that {you/he} had prostate cancer?

How old {were you/was SP} when {you were/he was} first told that {you/he} had prostate cancer?

{Have you/Has SP} ever had surgery on {your/his} prostate?

{Have you/Has SP} had surgery for prostate cancer?

{Have you/Has SP} ever had radiation treatments for prostate cancer?

{Have you/Has SP} ever taken prescribed medicines for prostate cancer?

1 of 3

End of Section Close Exam Finish

If any one of these 5 questions is answered “Yes,” the SP will be excluded from PSA testing; however, all five of the questions remain enabled so that the physician may complete the prostate health questionnaire.

SP ID: 127189 Name: BUTLER_3, JOHN Age: 58 years Gender: Male Date: 04/02/2009 Time: 02:30 PM

PSA Testing Exclusion Questions

I am now going to ask you some questions about your prostate health.

{Do you/does SP} have an infection or inflammation of the prostate gland at the present time?

{Have you/Has SP} had a rectal exam in the last 7 days?

{Have you/Has SP} had a prostate biopsy or other prostate surgery in the last 4 weeks?

{Have you/Has SP} had a cystoscopy in the last 4 weeks?

(Cystoscopy is an internal examination of the prostate and bladder using a flexible tube-like instrument with a lens inserted through the penis.)

{Have you/Has SP} ever been told by a doctor or health professional that {you/he} had prostate cancer?

How old {were you/was SP} when {you were/he was} first told that {you/he} had prostate cancer?

{Have you/Has SP} ever had surgery on {your/his} prostate?

{Have you/Has SP} had surgery for prostate cancer?

{Have you/Has SP} ever had radiation treatments for prostate cancer?

{Have you/Has SP} ever taken prescribed medicines for prostate cancer?

1 of 3

End of Section Close Exam Finish

If the SP responds “No” to the question regarding prostate cancer, the following five questions remain disabled. If the SP responds Yes, these prostate cancer followup questions are asked:

1. How old were you when first told that you had prostate cancer?
2. Have you ever had surgery on your prostate?
3. Have you had surgery for prostate cancer?
4. Have you ever had radiation treatments for prostate cancer?
5. Have you ever taken prescribed medicines for prostate cancer?

SP ID: 127189 Name: BUTLER_3,JOHN Age: 58 years Gender: Male Date: 04/02/2009 Time: 02:30 PM

PSA Testing Exclusion Questions

I am now going to ask you some questions about your prostate health.

{Do you/does SP} have an infection or inflammation of the prostate gland at the present time?

{Have you/Has SP} had a rectal exam in the last 7 days?

{Have you/Has SP} had a prostate biopsy or other prostate surgery in the last 4 weeks?

{Have you/Has SP} had a cystoscopy in the last 4 weeks?

(Cystoscopy is an internal examination of the prostate and bladder using a flexible tube-like instrument with a lens inserted through the penis.)

{Have you/Has SP} ever been told by a doctor or health professional that (you/he) had prostate cancer?

How old {were you/was SP} when {you were/he was} first told that {you/he} had prostate cancer?

{Have you/Has SP} ever had surgery on {your/his} prostate?

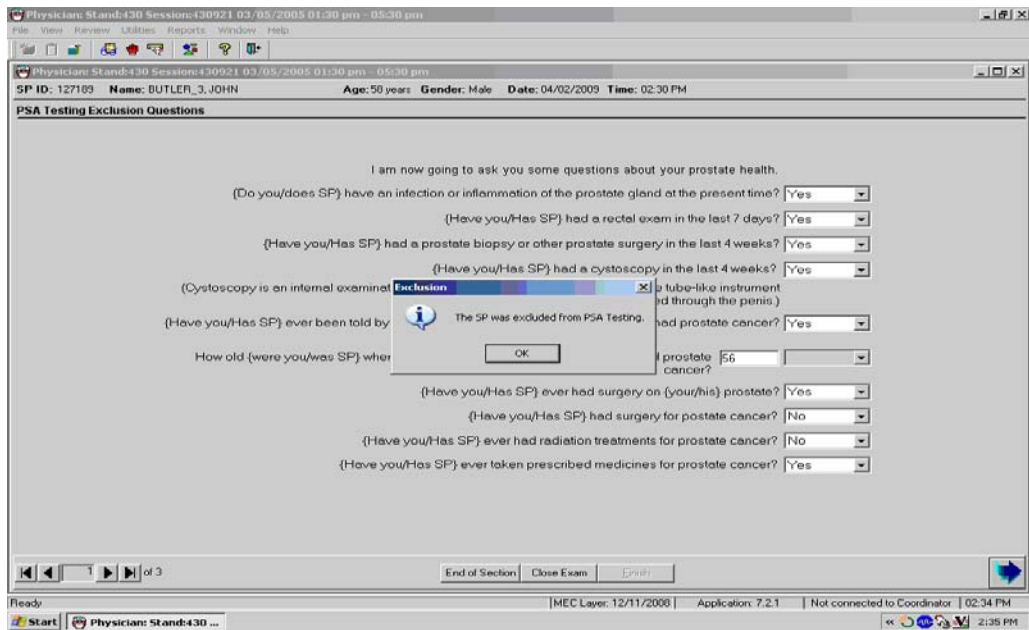
{Have you/Has SP} had surgery for prostate cancer?

{Have you/Has SP} ever had radiation treatments for prostate cancer?

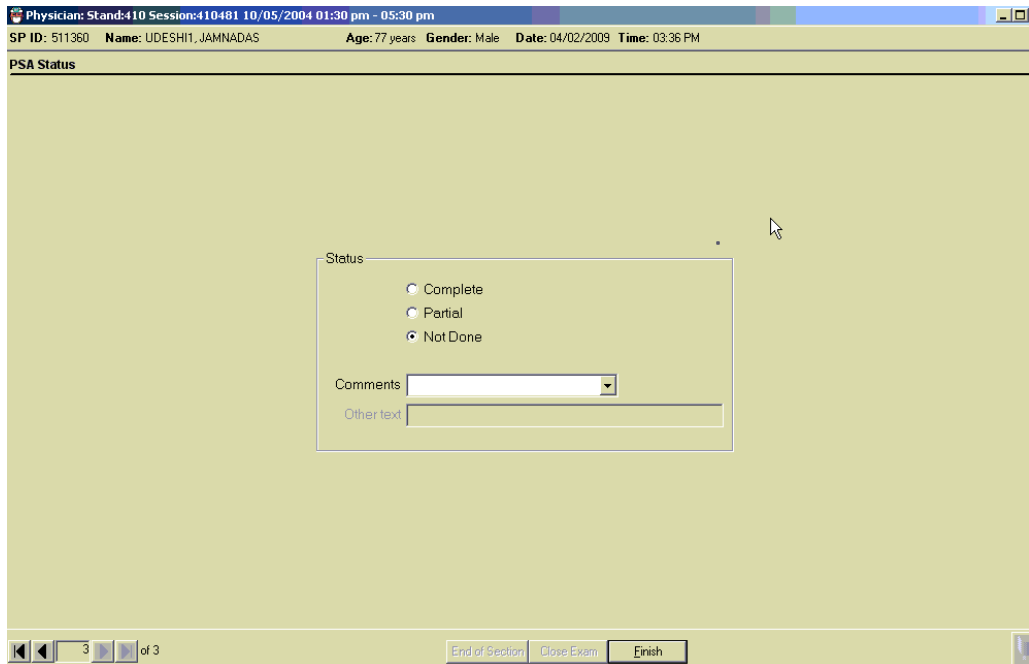
{Have you/Has SP} ever taken prescribed medicines for prostate cancer?

1 of 3

End of Section Close Exam Finish



Answer the remaining followup questions, and advance to the next screen. If the SP answered “Yes” to any of the exclusion criteria, the PSA Status Screen will appear.



Explain to the SP that he is not eligible for blood PSA testing due to the exclusion criteria, and that the test cannot be accurately done. The PSA section status screen defaults to “Not Done,” but the application needs a reason. Select “Other,” and type in Excluded from exam.

If the SP answered “No” to the five exclusion questions, the SP will be eligible for PSA testing, and the following screen will appear when the screen is advanced from the exclusion questions.

SP ID: 127188 Name: BUTLER_3,JOHN Age: 58 years Gender: Male Date: 04/02/2009 Time: 02:30 PM

PSA Testing

Are you willing to have your blood tested for PSA?

Some medical procedures and prostate conditions will result in a high PSA. Because the survey is interested in learning about normal levels of PSA in the population, participants will be excluded if they have a condition or recent procedure that may affect the PSA result. Moreover, if you have had some of these conditions or procedures, a PSA test may not be useful to detect if you currently have prostate cancer.

2 of 3

End of Section Close Exam Finish

The physician will recruit the SP for PSA testing at this point in the exam, and will use the following recommended scripts:

“Some medical procedures and prostate conditions will result in a high PSA. Because the survey is interested in learning about normal levels of PSA in the population, participants will be excluded if they have a condition or recent procedure that may affect the PSA result. Moreover, if you have had some of these conditions or procedures, a PSA test may not be useful to detect if you currently have prostate cancer.”

4.3.2 Physician Script for Prostate Specific Antigen (PSA)

“I would like to provide you with some information on the blood test for prostate specific antigen, or PSA. This test is commonly used by doctors along with a digital rectal exam for early detection of prostate cancer. Prostate cancer is a major public health problem among men, especially those with increasing age and in certain racial/ethnic groups. This testing will help us to do national-level planning to control this problem.

We will not do a rectal examination, but would like to test your blood for PSA to help us determine what the levels or concentrations are in men in the United States. Before we proceed, here are some facts you should know:

The PSA test measures a protein produced by the prostate gland. When prostate cancer is present, the PSA tends to rise. It is important to note that an elevated PSA does not necessarily mean cancer is present. Other problems such as prostate enlargement or an infection of the prostate may cause the PSA test result to be high.

Another fact to consider is that a normal PSA test does not guarantee that prostate cancer is not present. Certain medications and supplements are also known to affect the PSA test value.

You will receive the result of your PSA test in the Final Report of Findings sent to your home 12-16 weeks after the exam. If your PSA level is high, you will receive a letter from the survey program about your PSA level in approximately 3 weeks. You should discuss your PSA results with your doctor. If you have an elevated PSA test, your doctor or health care provider will want to do other tests to see whether prostate cancer is present or not present.

If the SP does not want to have the PSA test done, mark the PSA status section as “Not done, refused.” This will block the lab from shipping blood for PSA. If the SP agrees, the specimen is tagged and the blood is shipped to the lab for PSA.

Proceed to the PSA Status screen, select “Finish,” and proceed to the next section.

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4.4 Sexually Transmitted Diseases (STD), Human Immunodeficiency Virus (HIV), and Human Papillomavirus (HPV)

SPs consent to have blood drawn for STD and HIV testing. Female SPs who consent to self-collect vaginal swabs have the swabs tested for human papillomavirus (HPV). The specific tests are determined by age categories:

All SPs aged 14-59	Herpes type 2
All SPs aged 18-59	Human Immunodeficiency Virus (HIV)
Female SPs aged 14-59	Human papillomavirus (HPV)

SPs consent to these tests during the household interview, but may change their mind prior to the examination. Some SPs agree during the home interview, but decide not to be tested when they arrive at the MEC. Other SPs do not agree to be tested during the home interview, but change their mind and want to be tested when they arrive for the examination. In either case, the examiner is responsive to the decision of the SP. The physicians' role in STD, HIV, and HPV testing is to discuss these tests with SPs. The objective of the physician's STD and HIV pretest discussion is to educate eligible participants about the STD, HIV, and HPV testing and to explain the mechanism for getting their personal test results. The confidential nature of the test result reports is explained.

4.4.1 Guidelines Affecting STD, HIV, and HPV Test Result Reporting

Two guidelines affect the confidential reporting of STD, HIV, and HPV test results to participants in NHANES. First, NHANES is not subject to state laws that require reporting STD results to state health departments. Second, adolescents in the United States can consent to the confidential diagnosis and treatment of STDs. Medical care for these conditions can be provided to adolescents without parental consent or knowledge. Therefore, there is no legal obligation to disclose findings to anyone other than the participant (CDC, 1993 *Sexually Transmitted Diseases Treatment Guideline*, MMWR 42 RR-14).

STD, HIV, and HPV test results are confidential and are **not disclosed to anyone**, including the participant's doctor, insurer, family or friends, except at the SP's specific request, and **only** after the SP properly provides the password selected during the examination. Everyone working with the

NHANES signs a legal document making them subject to the Privacy Act, the Public Health Service, and other laws.

Because of the medical, social, and emotional consequences of positive STD, HIV, or HPV tests, disclosure of results are always handled in a sensitive, respectful, and confidential manner. SPs can only obtain their results when they call the toll-free telephone number provided to them during the examination. STD, HIV, and HPV results are the only NHANES SP health examination results that are provided verbally. All other findings from the health examination are reported to persons in a written report that is mailed to them. The methods for reporting results of these tests differ slightly for adolescents and adults. These methods are described in the following sections.

4.4.1.1 Procedures for Reporting STD, HIV, and HPV Results

During the physician's examination, eligible participants are informed about the STD, HIV, and HPV tests conducted during the MEC examination. To assure that these results are only provided to the SP for whom the results are specified, SPs are asked to provide their own password. Physicians record the password in the ISIS at the time of the physician component examination. Physicians inform participants that they must call a toll-free number in order to get their individual results. SPs use their personally selected password to confirm their identity when they call for their results. The physician encourages SPs to keep their password to themselves and not share the information with anyone. Physicians also encourage SPs to call for their results after the designated date. This self-initiated request for test results is the most foolproof method of ensuring that test results will go only to the tested individual. All SPs receive a reminder notice (Exhibit 4-48, Reminder form to get STD and HIV results) that includes the toll-free number, the date after which the results will be available, and their password.

Adult participants (aged 18 and older) receive their reminder notice from the coordinator as they leave the MEC. The reminder notice is in an envelope that is handed directly to the SP.

Minors (SPs 14-17 years of age) receive the same reminder notice, but instead of receiving it at checkout from the coordinator, the physician personally places the form in a sealed envelope marked with a number that was previously placed on the SP's examination gown. (When SPs change into an examination gown at the beginning of the session, they are given a numbered basket in which to store clothing. The assistant coordinator marks the number of the basket on their gown for subsequent

identification). The physician gives the envelope to the assistant coordinator who places it in the SP's numbered basket. The physician reminds the SP to retrieve the envelope from the basket when changing clothes to leave the MEC.

Exhibit 4-48. Reminder form to get STD, HIV, and HPV results

National Health and Nutrition Examination Survey	
STD AND HIV CALLBACK REMINDER	
How to get results for sexually transmitted diseases and HIV	
Call toll free:	1-888-301-2360
When:	anytime after 8/3/1999
Hours:	Monday – Friday, 8:30 am – 6:00 pm Eastern Time
When calling for results, you will need to provide the following information:	
Sample Number:	955543
Password:	Picture
We will only give results to the person tested.	

Participants who do **not** call for their report are sent a letter reminding them to call the toll-free number to receive their special test results. If they do not call the survey, staff from NCHS will contact them by phone and tell them their results, whether positive or negative. If a health problem is identified, the participant is informed and referred for treatment in their area.

4.4.2 Informing SPs of STD, HIV, and HPV Results

SPs call the National Center for Health Statistics personnel for STD, HIV, and HPV reports. When SPs call to obtain their test results, they provide their password. Test results are not provided unless the caller correctly states the password. Under no circumstances are STD test results put in writing with a respondent's name, address, or any other personal identifiers. Test results are only communicated by telephone specifically and solely to the SP.

4.4.3 Vaginal Swab

Women within the ages of 14-59 are being asked to self-collect a vaginal swab for human papillomavirus (HPV) testing. The swab is self-collected by the women in the privacy of the bathroom after receiving instructions from the physician. The next sections instruct the physician in the vaginal swab protocol.

4.4.3.1 Gaining Cooperation for the HPV Swab

The physician will explain the HPV assessment after discussing the tests for sexually transmitted diseases and HIV, and obtaining participant's password. The following is the suggested physician script.

Instructions

“Additionally we ask all girls and women your age to participate in a test for human papillomavirus. You may not have heard about these conditions. Human papillomavirus is sexually transmitted and many women who are infected do not have any symptoms. Here is some additional information about these diseases. You will find a sheet like this in your packet when you leave. [Show Reproductive Health/Sexually Transmitted Diseases Chart.]

We will test for HPV using vaginal fluid. I will explain how to collect a vaginal specimen yourself. Here is a kit that contains one vaginal swab, smaller than a tampon. You will do this in the

bathroom where you will have complete privacy. I recommend that you wash your hands before starting and after completing the collection. Also, because you will be inserting a swab into your vagina, you may want to undress partially before starting. Once you are ready to begin, first twist the top off the clear soft plastic tube. Do not discard the top. Place the top on a clean surface. Remove the swab from the plastic tube. Hold the stick at the end and do not touch the foam part of the swab. Hold the lips of the vagina open with one hand. Insert the swab fully into the vagina (like a tampon) with your other hand. Turn the foam swab against the walls of your vagina as you count to ‘ten.’ Carefully remove the swab without touching the skin or hair outside of the vagina. Place the swab into the soft plastic tube and replace the cover onto the tube. When you are done, you can give the tube to the staff person who will be waiting outside the bathroom. There are written instructions in English and Spanish inside the package if you need a reference.”

Instructions for women in the third trimester of pregnancy vary in that the SP is instructed to insert the swab halfway into the vaginal area by holding the swab at about halfway from the end of the swab.

“Do you have any questions about this test?”

“How do you feel about taking part in this test?”

(If participant indicates she is uncomfortable, you can probe “you seem unsure about doing this, what are you thinking about?” Remember the participant has the right to refuse this test. If the participant refuses this test, explain, “This will not affect your participation in the rest of the study.”) If the participant agrees to the test, explain:

“Like the blood and urine tests that are being done, these results are very private, and we will give these results only to you. We will not put the results in the report that is mailed to your home. We will give you a toll-free number to call in 4 weeks, and results will be reported only after you provide the password which you gave me a few minutes ago <*password provided during STD/HIV pre-test counseling*>.”

Persons 18-59:

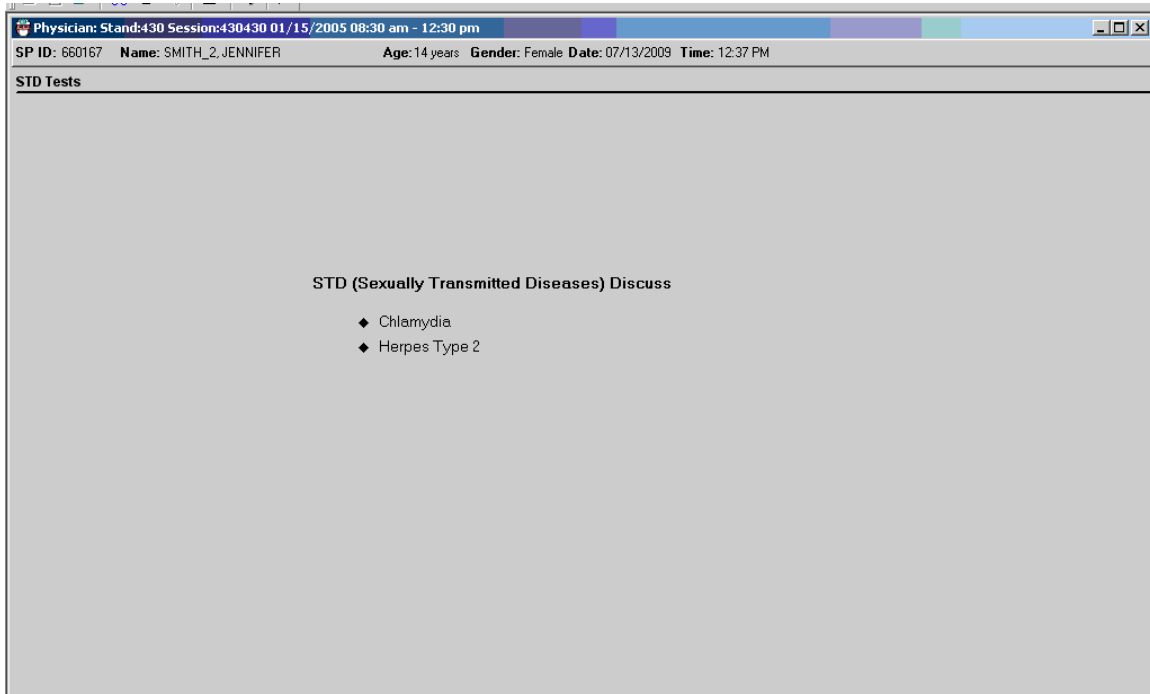
“When you leave, you will have a piece of paper in your packet with a toll-free number, the dates to call, and the password you just gave me. Please be sure to call for your STD and HPV test results during those dates.”

Youth under 18 years:

“Here is a piece of paper with a toll-free number, the dates to call, and the password you just gave me. Please be sure to call for your STD and HPV results during those dates.”

4.4.4 Discussing STD & HIV Testing and Instructing the SP How to Obtain Results

Exhibit 4-49. STD Tests for SPs 14-17 years old



- If the SP is 14-17 years of age, the physician discusses the method for the SP to receive STD results.
- The physician asks the SP to give a password to use when calling to get his or her test results. If the SP cannot think of a password, the physician will give the SP a password by clicking on "Generate." The system will generate a password and display it in the password field.

Exhibit 4-50. STD password field

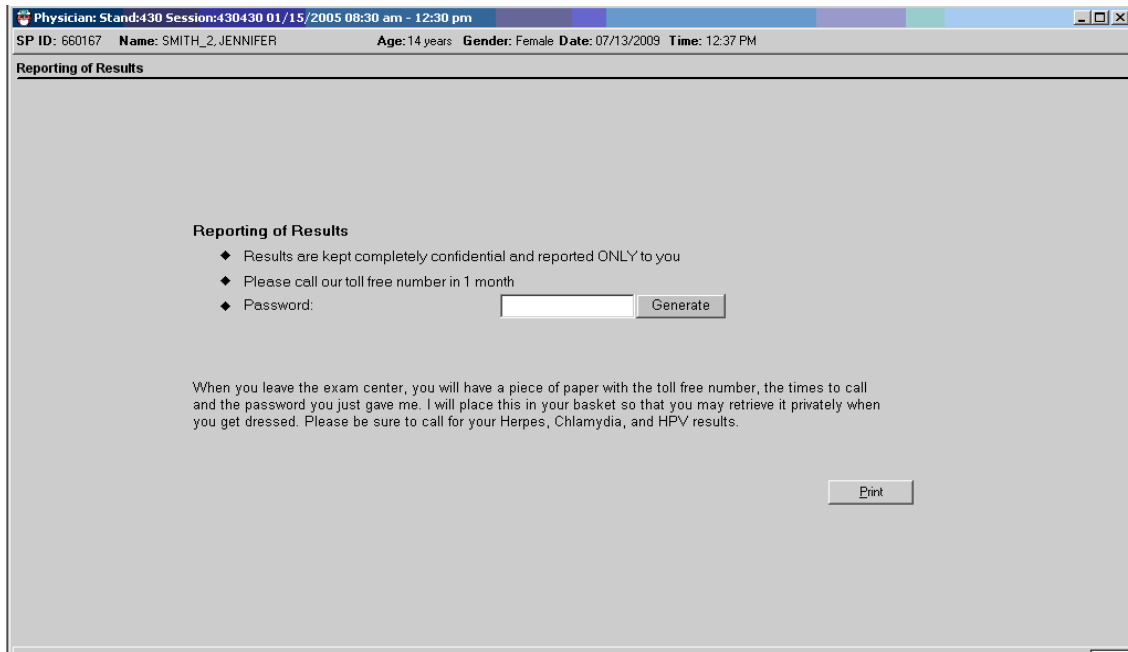
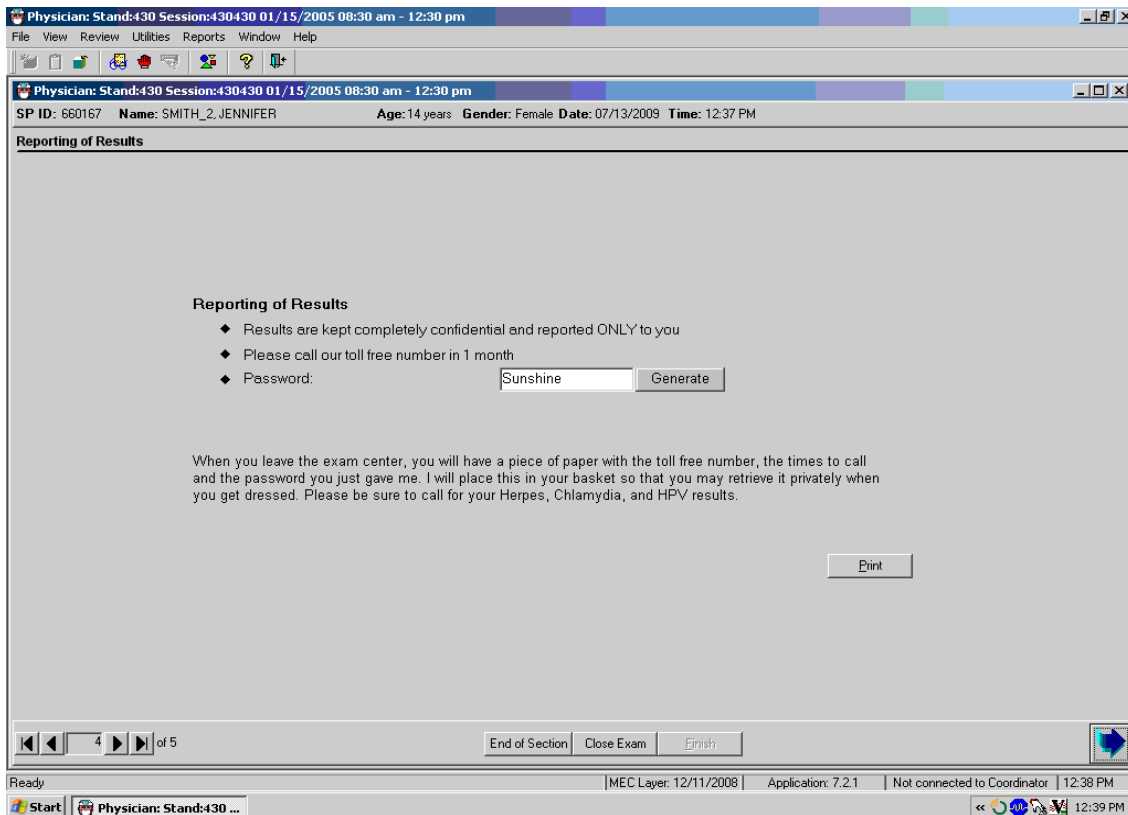
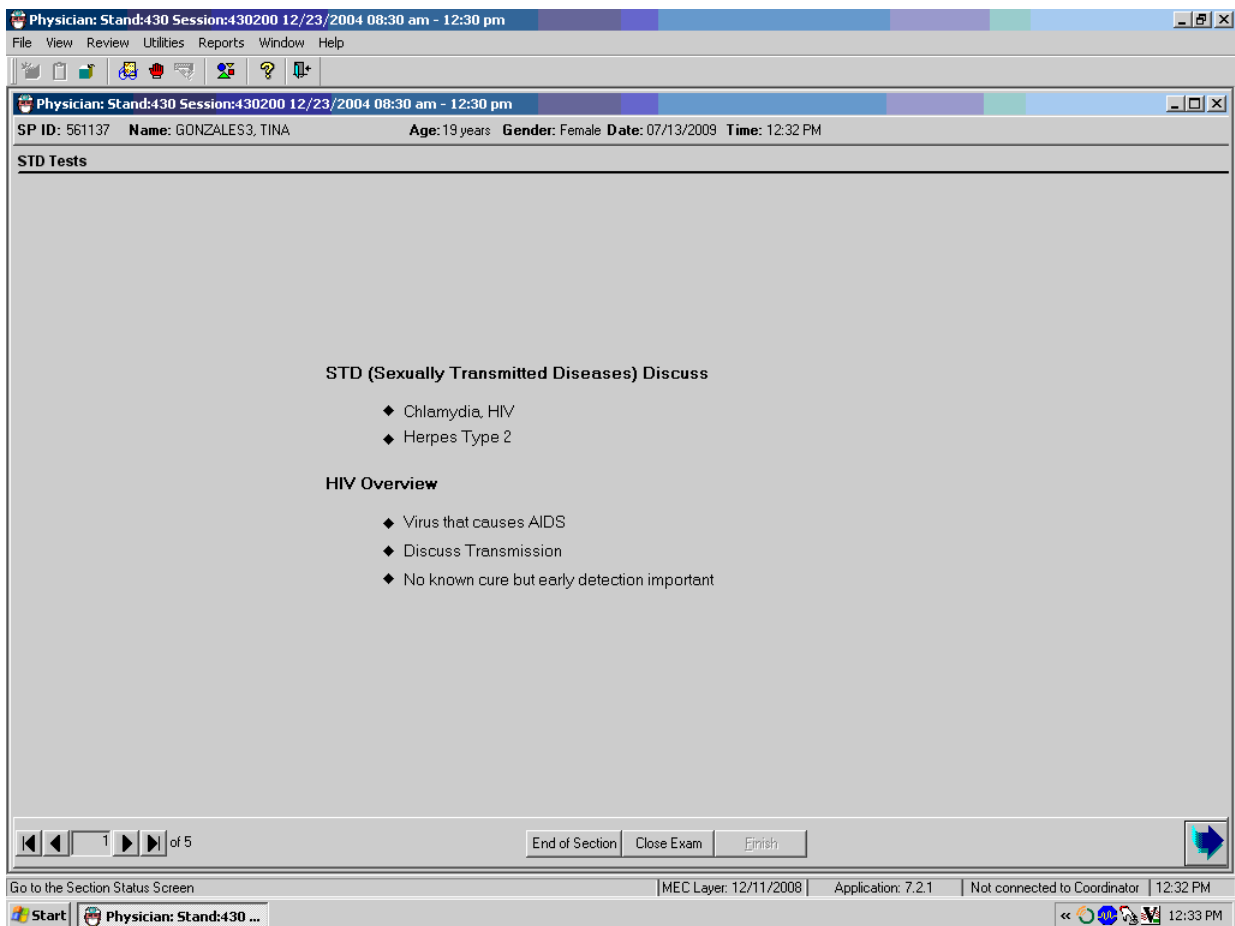


Exhibit 4-51. STD password automatically generated



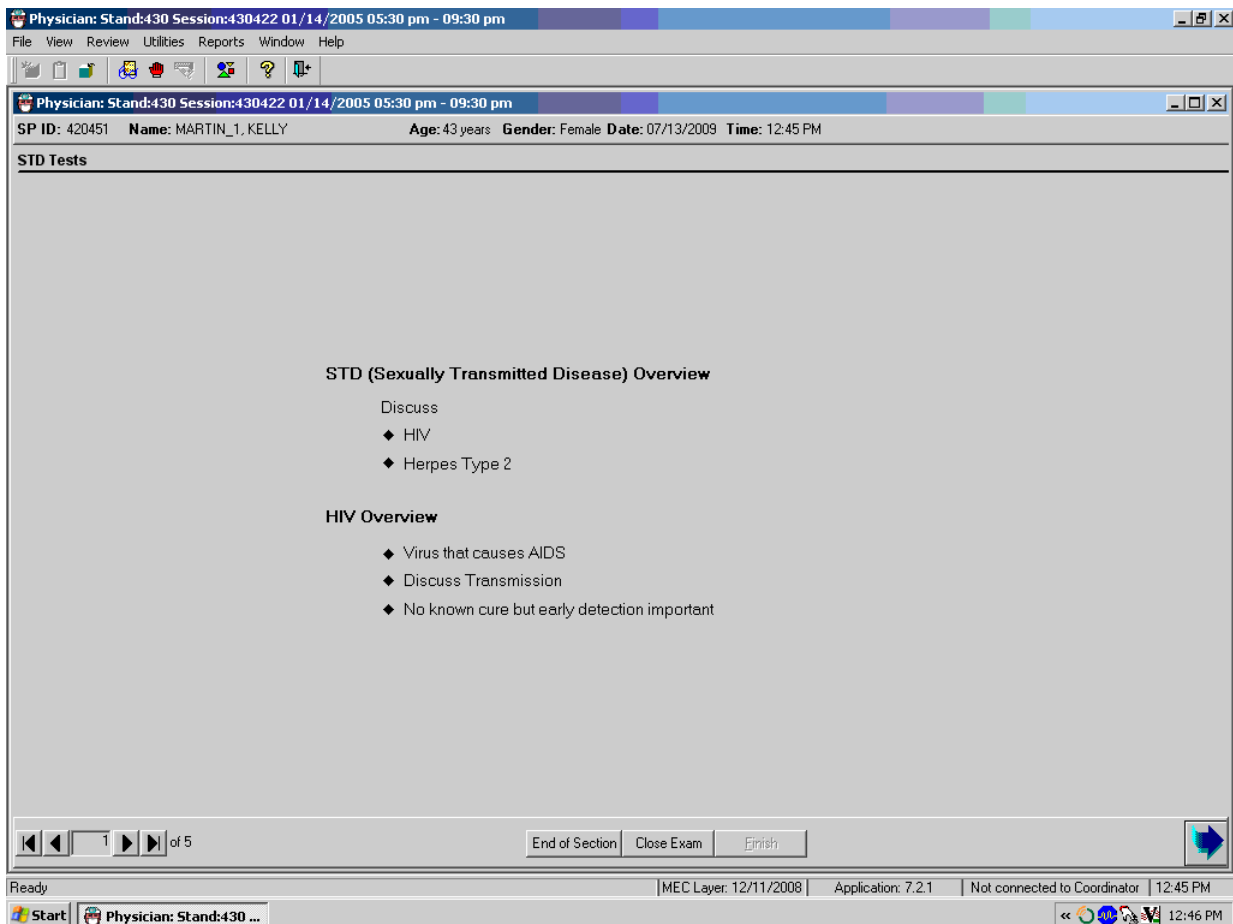
- Other SP information on minors is given to the parents at the time of checkout from the MEC. Due to the sensitive and confidential nature of STD results, the information reports for 14- to 17-year-olds are printed in the physician’s room. These test results are given only to the SP.
- Click on the “Print” button to print the information form for the SP. After discussing the mechanism for obtaining test results, put the STD and HIV information form in a sealed envelope.
- On the envelope, write the number on the SP’s examination gown (the number corresponding to the number on the basket containing the SP’s clothes). Put the envelope in your mailbox or give it directly to the assistant coordinator, who will put the envelope in the basket corresponding to the number on the envelope.

Exhibit 4-52. STD and HIV for SPs 18-39 years old



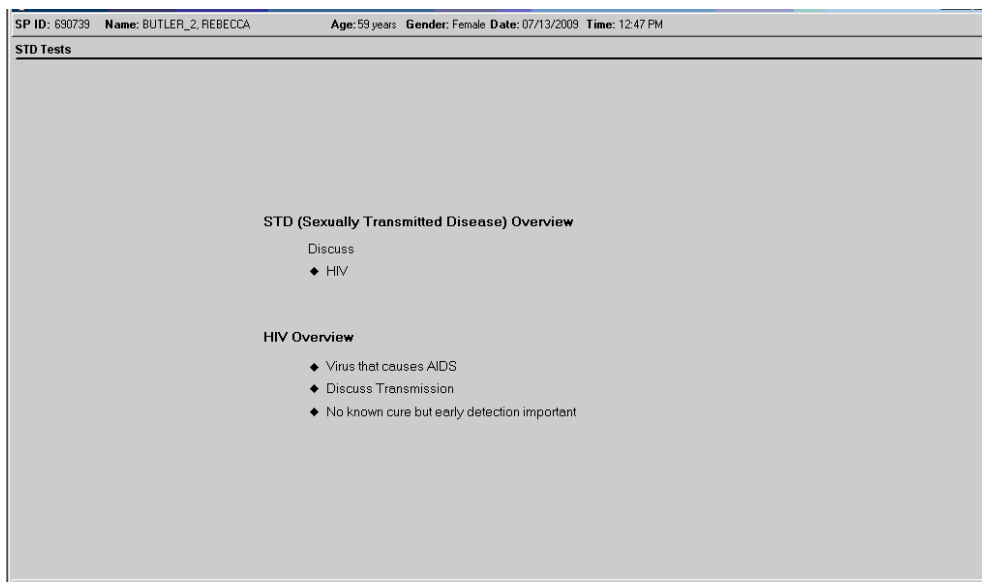
- If the SP is 18-39 years of age, the physician discusses the method for the SP to receive results for STD and HIV.
- The physician asks the SP to give a password to use when calling to get the test results.
- If the SP cannot think of a password, the physician will give the SP a password by clicking on “Generate.”
- The system generates a password and displays it in the password field.
- The SP is given a printout during MEC checkout with the information needed to call for test results. The information printout form is printed at the coordinator station and placed with the SP’s information packet.

Exhibit 4-53. STD and HIV for SPs 40-49 years old



- If the SP is 40-49 years of age, the physician discusses the method for the SP to receive STD and HIV results.
- The physician asks the SP to give a password to use when calling to get test results.
- If the SP cannot think of a password, the physician will give the SP a password by clicking on “Generate.”
- The system generates a password and displays it in the password field.
- The SP is given a printout at the time of MEC checkout with the information needed to call for test results. This information printout is printed at the coordinator station and placed with the SP’s information packet.

Exhibit 4-54. STD and HIV for SPs 50 - 59 years old



- If the SP is 50 – 59 years of age, the physician discusses the method for the SP to receive HIV results.
- The physician asks the SP to give a password to use when calling to get test results.
- If the SP cannot think of a password, the physician will give the SP a password by clicking on “Generate.”
- The system generates a password and displays it in the password field.
- The SP is given a printout at the time of MEC checkout with the information needed to call for test results. This information printout is printed at the coordinator station and placed with the SP’s information packet.

4.4.5 Informed Consent Designation in ISIS

SPs may refuse the STD and/or the HIV tests. They may do this at the household interview or in the phlebotomy room. The SP can also be excluded for STD and or HIV during the physician’s examination, or at any time during their visit to the MEC. If the SP determines that they want to refuse any or all of these tests, the physician accesses the “Utilities” menu from the toolbar and selects “IC Exclusions” (Informed Consent exclusions).

Exhibit 4-55. Utilities menu for informed consent exclusions

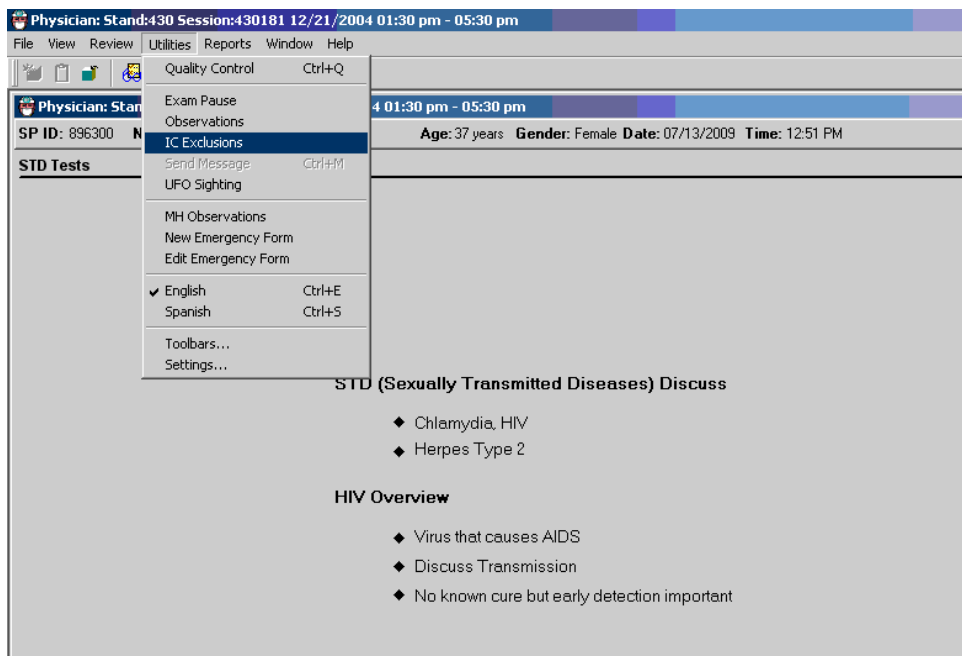
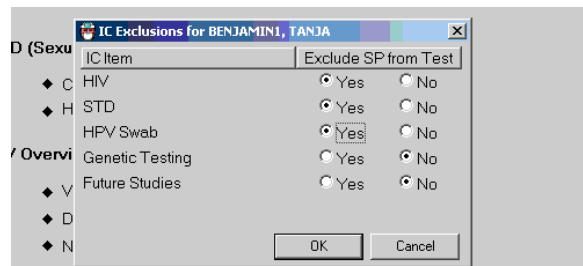


Exhibit 4-56. STD and HIV – Informed consent exclusions



- If the SP had previously agreed to these tests and later decided to refuse these test after discussion with the physician, the specimens can be still be excluded. Select “Yes” to exclude the SP from HIV, STD, or HPV swab tests. This sends a message to the phlebotomy and laboratory examination component to exclude the SP from these tests.
- The SP could refuse these tests initially and later change his or her mind after talking with the physician or phlebotomist. In this situation, the informed consent exclusion should be unchecked. This will remove the exclusion for these tests in the laboratory.

Exhibit 4-57. SP refusal for STD and HIV testing

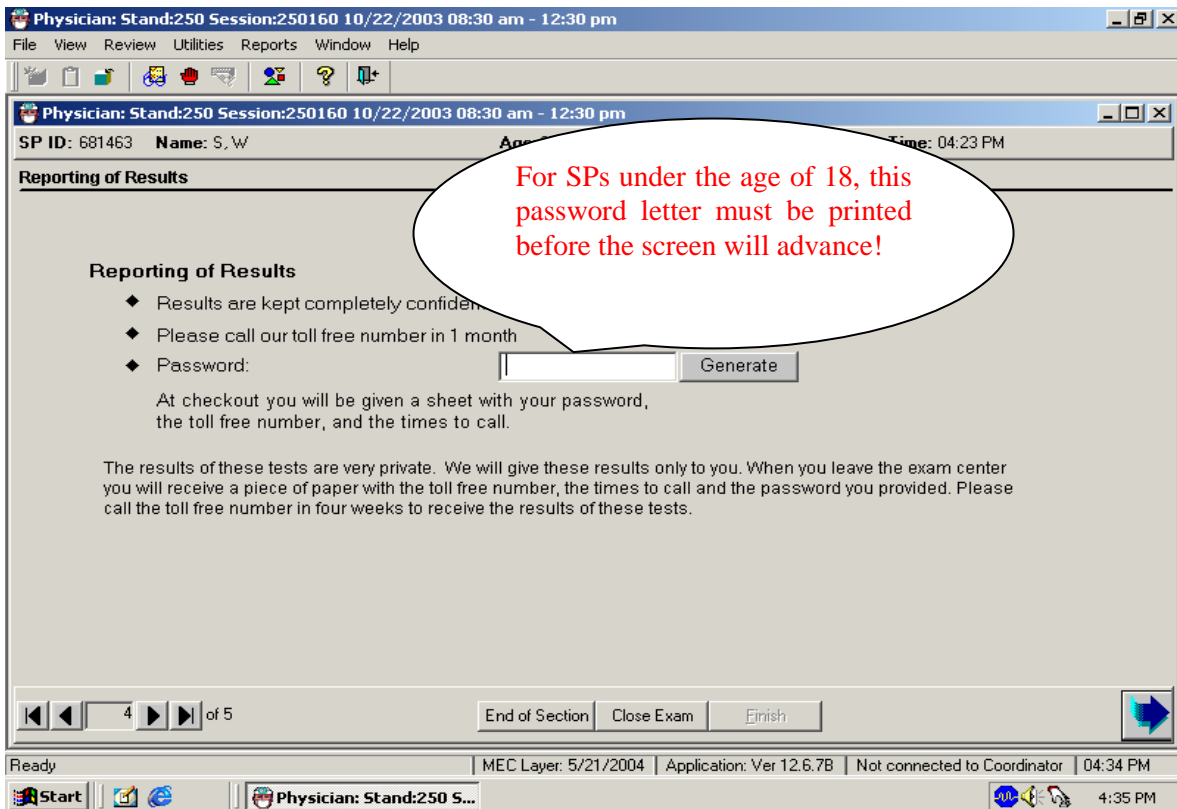
The screenshot shows a software interface for a physician's examination. At the top, a status bar displays: "Physician: Stand:505 Session:505071 12/30/1999 01:30 pm - 05:30 pm". Below this, patient information is shown: "SP ID: 751065 Name: TERMANA, SISCO Age: 30 years Gender: Male Date: 07/07/2000 Time: 10:38 AM". The main content area is titled "STD Tests" and contains three sections:

- STD (Sexually Transmitted Disease) Overview:** A message box states "Participant has refused STD Testing".
- HIV Overview:** A message box states "Participant has refused HIV Testing".
- Reporting of Results:** Text reads "Results kept completely confidential and reported only to you. Please call our toll free number in 1 month." Below this is a "Password:" label, an empty text input field, and a "Generate" button. A note at the bottom says "At checkout you will be given a sheet with your password, the toll free number, and the times to call."

At the bottom of the screen, there are navigation controls: a set of arrows and a "1 of 2" indicator, buttons for "End of Section", "Close Exam", and "Finish", and a blue arrow icon.

- If the SP refused to have STD and HIV testing either during the consent process or in the phlebotomy room, the screen in the physician’s examination appears with a message over each section that was refused: “Participant has refused STD and HIV testing.”
- If the SP refuses the testing, it is not necessary to discuss the mechanism for getting results.
- It is not necessary to have the SP select a password.
- Select the “Next” button to go to the component status.

Exhibit 4-58. Password entry requirement for STD and HIV



- If a password is not entered, a message is displayed: “Please enter the Password.”
- Click “OK” to this message.
- Generate a password if one is needed.
- Select the “Next” button to go to the next screen.

Exhibit 4-59. STD and HIV test completion status

The screenshot shows a software window titled "Physician: Stand:505 Session:505071 12/30/1999 01:30 pm - 05:30 pm". Below the title bar, a header bar contains the following information: "SP ID: 751065 Name: TERMANA, SISCO Age: 30 years Gender: Male Date: 07/07/2000 Time: 10:38 AM". The main content area is titled "STD Tests Status" and contains a form with the following elements:

- A "Status" section with three radio buttons: "Complete" (selected), "Partial", and "Not Done".
- A "Comments" section with a text input field and a dropdown arrow.
- An "Other text" section with a text input field.

At the bottom of the window, there is a navigation bar with the following elements:

- Navigation icons: back, forward, and a page indicator showing "2 of 2".
- Buttons: "End of Section", "Close Exam", and "Finish".
- A right-pointing arrow icon.

- The STD and HIV test completion status defaults to “Complete.”
- Select “Finish” to close the examination.

4.5 The Physician Examination Application and Utilities

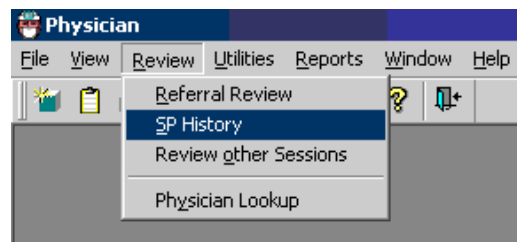
4.5.1 Review Functionalities

The Review menu allows the user to access four functions: (1) Referral Review; (2) SP History; (3) Review Other Sessions; and (4) Physician Lookup. The SP History review functionality of the physician application will be described in this section; the Referral Review function, Review Other Sessions, and Physician Lookup functionalities are described fully in Chapter 5, as these options are specific to the referral review procedures.

4.5.2 SP History

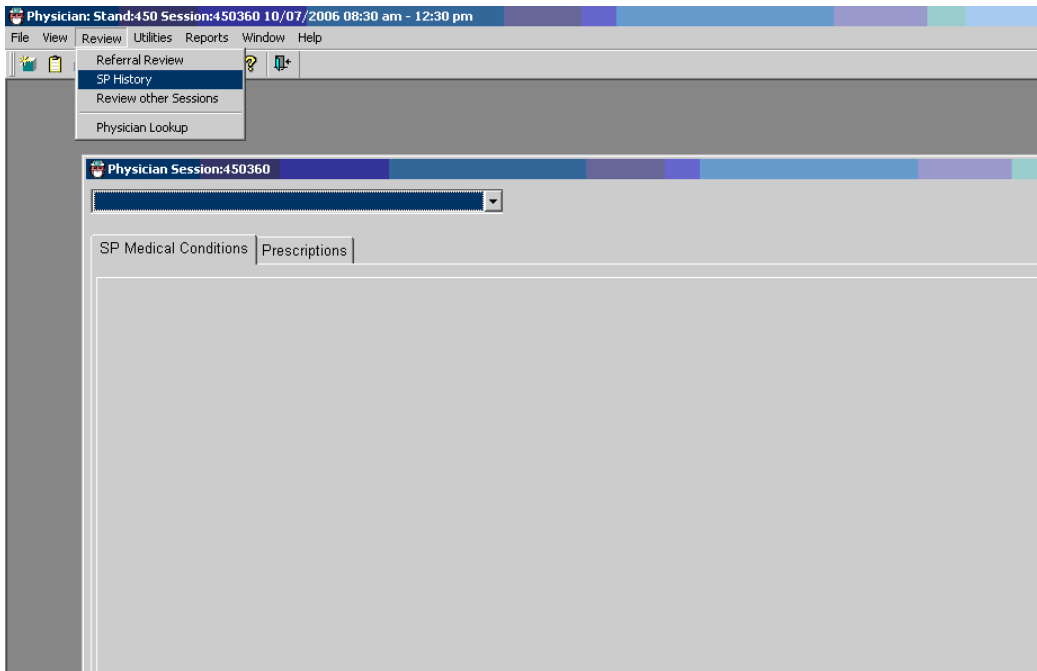
Medical conditions and medications reported during the home interview for all SPs in the session can be reviewed in the physician’s examination under “SP History.”

Exhibit 4-60. Review menu to select SP History



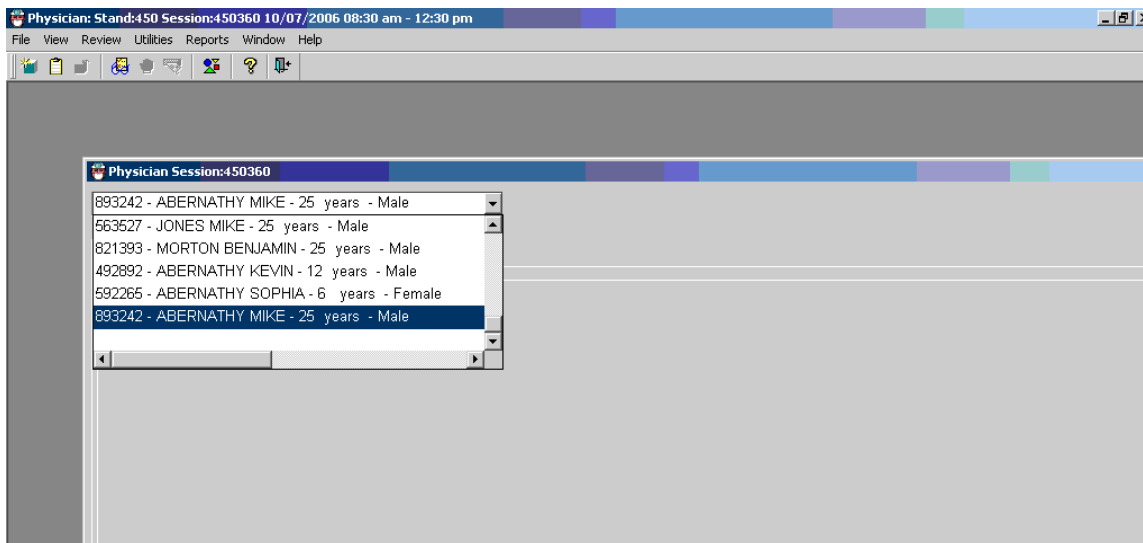
- To access “SP History,” select “Review” from the toolbar and then choose “SP History.”
- The “SP History” box is displayed.

Exhibit 4-61. SP History screen



- A drop-down menu will appear to access individual SP information from the current session only.
- Two Tabs appear on the screen - SP Medical Conditions and Prescriptions. Medical conditions include self-reported illnesses, as well as pregnancy status. The Medications tab displays only those medications that were reported during the home interview.

Exhibit 4-62. SP History drop-down menu to select SP from current session



- Each SP's ID number, name, age, and gender is displayed.
- Highlight the name of the SP to view the medical conditions, medications, and self-reported pregnancy history.
- Switch between the tabs to review medications and medical conditions.
- If no medications or medical conditions have been reported, the screens will indicate this to alert the user that the application is functional, and that the screen is blank because nothing was reported during the interview.

Exhibits 4-63 and 4-64 show no data available under SP Medical Conditions and Prescriptions Tabs.

Exhibit 4-63.
No data available under SP Medical Conditions tab

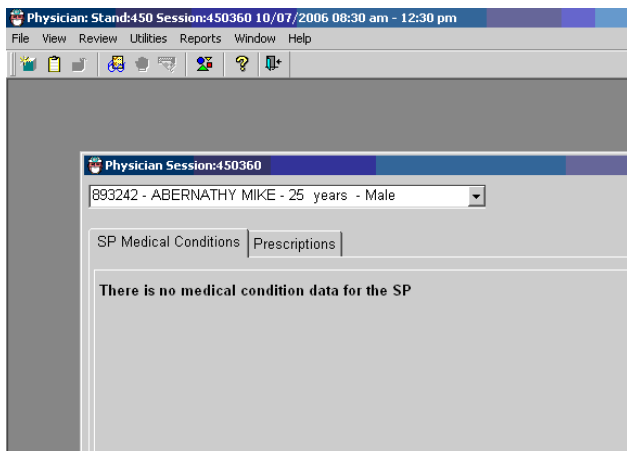


Exhibit 4-64.
No data available under Prescriptions tab

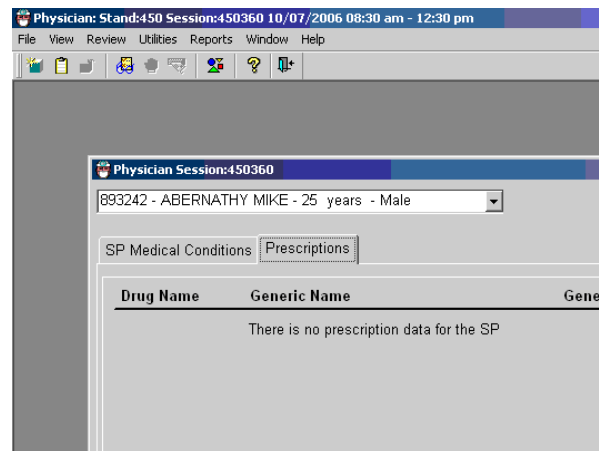


Exhibit 4-65 below illustrates the appearance of numerous medical conditions, and Exhibit 4-66 illustrates the appearance of reported medications.

Exhibit 4-65. SP History medical data appearance

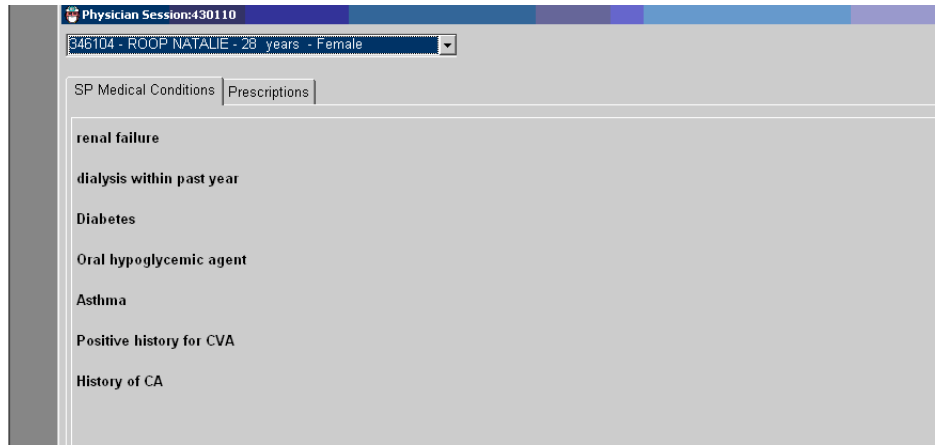
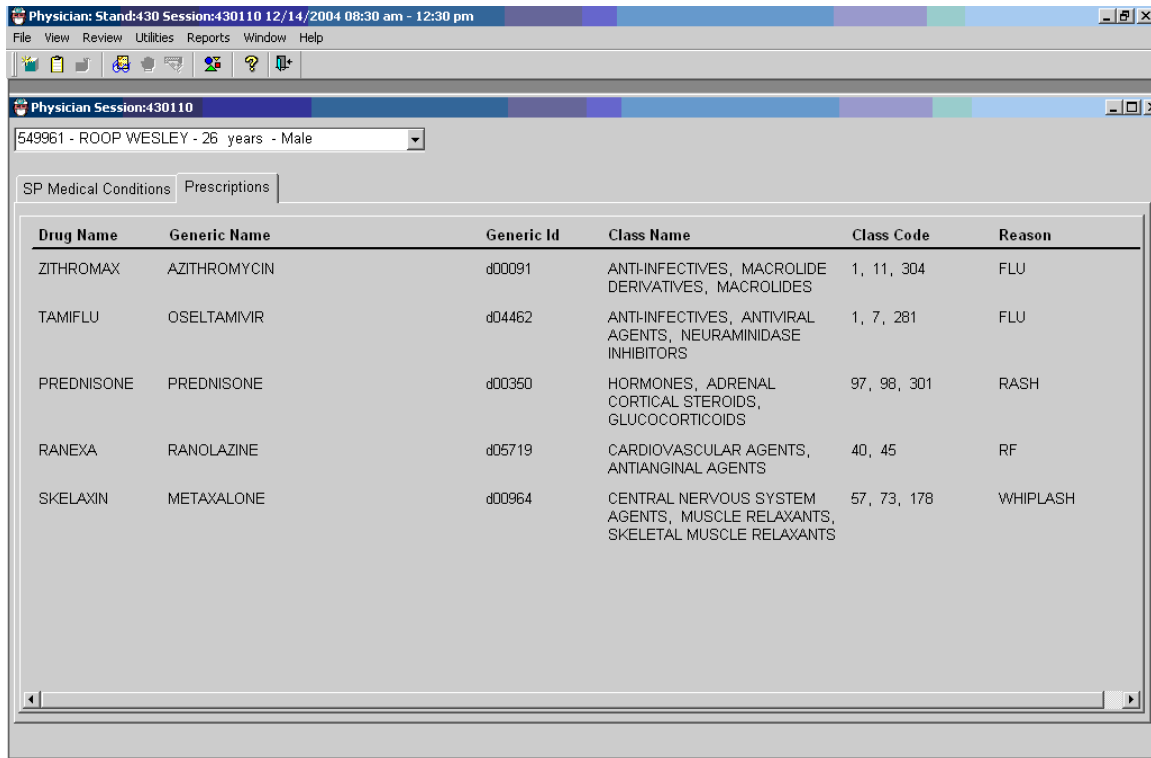


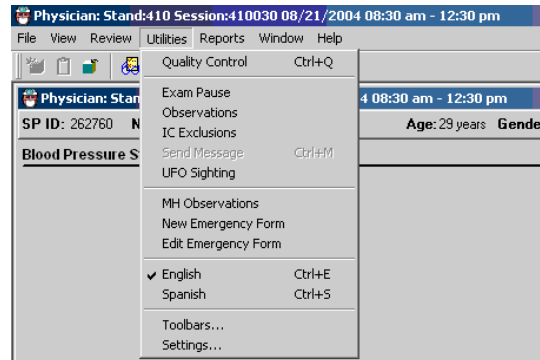
Exhibit 4-66. SP History reported medications appearance



It is important to bear in mind that the field interviewers who gather this information record only the medication information provided by the SP, and the indication for the medication as the SP understands it. Therefore, if the physician observes a medication and has any further questions about the medication, the physician may ask the SP during the physician exam.

4.5.3 Utilities Menu

Exhibit 4-67. Utilities drop-down menu



The utilities menu consists of:

- Exam Pause (This functionality is also present on the icon toolbar below the menus.)
- Observations
- IC Exclusions
- Send Message
- UFO Sighting
- MH Observations
- New Emergency Form
- Edit Emergency Form
- English
- Spanish

Quality Control

This option opens the quality control dialog box to initiate quality control procedures. See Chapter 8 for quality control procedures.

Exam Pause

This pauses the exam temporarily to stop the exam timer; when the user selects this, a message to the coordinator is sent (exam paused). This should be used in case of an emergency in the MEC.

Observation

The observation field allows the user to document any additional information that could inform the data collection process. See Chapter 5.

IC (Informed Consent) Exclusions

The status of SP informed consent for HIV, STD, HPV, Genetic Testing, and Future Studies is displayed in the box for IC items. The physician can change the status either way if the SP changes her or his mind regarding these lab tests at any time during the SP's visit to the MEC. For specific guidance on the IC exclusion procedure, see Section 4.4.5 of this chapter.

Send Message

This function allows the physician to send a message to the coordinator.

UFO Sighting

This feature allows the user to document any unusual occurrence that is observed during the operation of a stand. All MEC staff use the UFO utility to document issues relating to: equipment, software, protocols, SPs, trailer facility, supplies, and inventory.

MH (Mental Health) Observation

See Chapter 5 for specific guidance related to documenting MH observations and referrals.

New Emergency Form

Select this utility when documenting a new Incident/Emergency Form. Refer to Chapter 6.

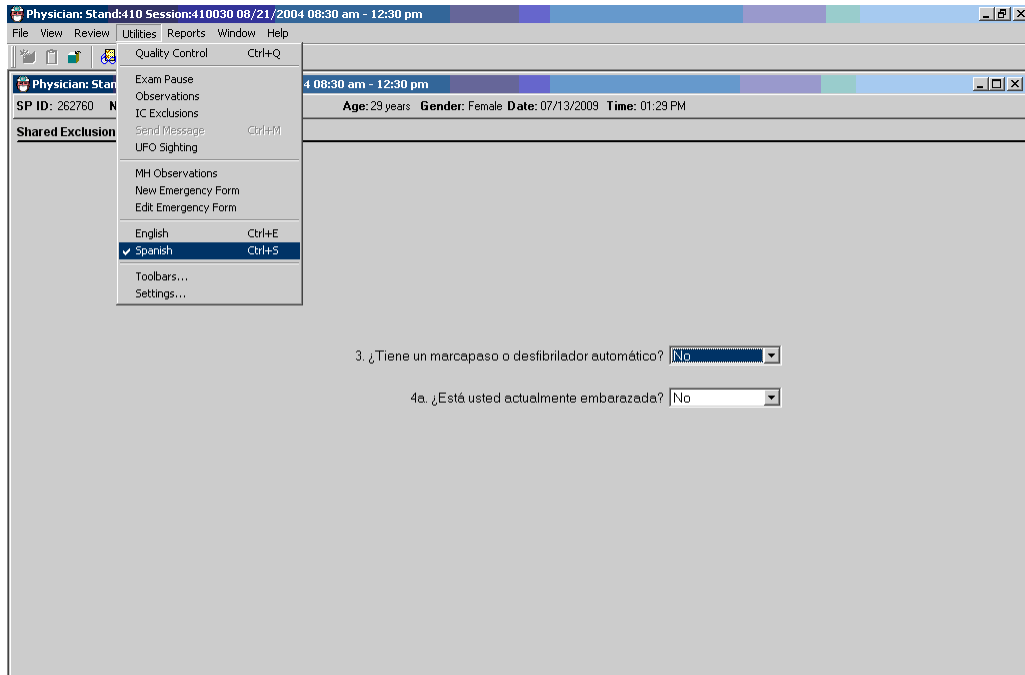
Edit Emergency Form

Additional or follow up information may be added to an existing Incident/Emergency Form using this utility.

English/Spanish

The default setting for language is English, but this utility allows the user to switch between English and Spanish. The physician, when using an interpreter for a Spanish speaking SP, will switch the application to Spanish for the interpreter's benefit.

Exhibit 4-68. Spanish screen: Example – Shared Exclusion questions

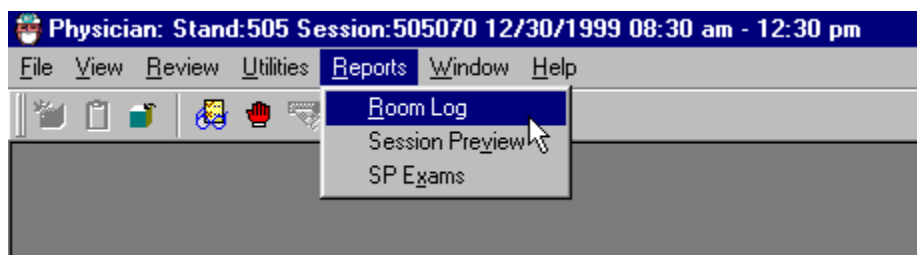


4.6 Report Utility

The Reports utility displays three different reports: (1) The Room Log, (2) Session Preview, and (3) SP Exams.

Room Log

Exhibit 4-69. Menu for selecting Room Log



The physician application tracks the status of the examinations and displays the information under the physician room log.

Exhibit 4-70. The Physician Room Log

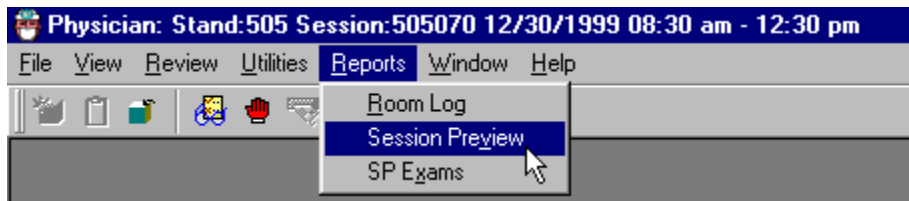
A screenshot of a software application window displaying a report titled "Physician Room Log". The title bar reads "Physician: Stand:410 Session:410030 08/21/2004 08:30 am - 12:30 pm". The menu bar includes "File", "View", "Review", "Utilities", "Reports", "Window", and "Help". The report header shows "Stand: 410" and "07/13/2009 01:43 PM". Below the header, the session information is "Session: 410030 08/21/2004 08:30 AM - 12:30 PM" and "Total: 8 SPs". The main content is a table with the following data:

SP ID	SP Name	Gender	Age	Component Status
704440	Harland Quinn	Male	33	partial
778641	Bailey Quinn	Male	65	partial
990444	Stuart Quinn	Male	52	partial
262760	Madison Quinn	Female	29	partial
780832	Laila Quinn	Female	24	partial
769558	Stacey Quinn	Female	17	partial
315773	Katherine Quinn	Female	57	complete
686762	Emily Quinn	Female	48	complete

- The room log displays a list of the SPs who are eligible for this examination. All SPs are eligible for the physician’s examination. The SP examination status report displays all SPs in the session along with the status and status comment.
- Choose “Reports” from the toolbar and select “Room Log.”

Session Preview

Exhibit 4-71. Session preview



- To preview a list of SPs in the current session, select “Reports” from the toolbar.
- Select “Session Preview.”

Exhibit 4-72. Session Preview Report

 A screenshot of a window titled "Physician Stand:505 Session:505070". The window displays a "Session Preview Report" for "Stand: 505" on "07/07/00 12:02". The report details "Session: 505070 12/30/1999 08:30 AM - 12:30 PM". Below this is a table with the following columns: "SP ID", "SP Type", "SP Name", "Age", "Gender", "Special Considerations", and "Consent Comments".

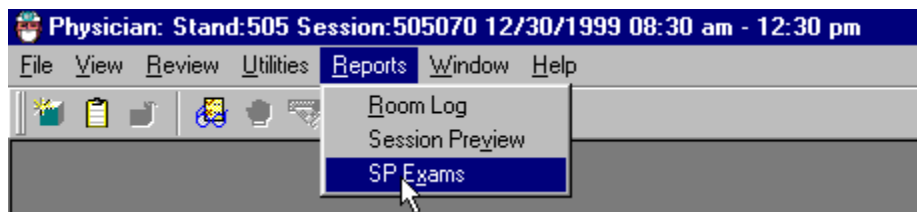
SP ID	SP Type	SP Name	Age	Gender	Special Considerations	Consent Comments
312510	Primary	TARA DUSTY	4 years	Female		
312601	Primary	SALY DUSTY	2 years	Female		
341421	Primary	LUKE COSIMAND	40 years	Male		
354508	Primary	FELIX DUSTY	11 months	Male		
414345	Primary	BOBBY MCGEE	12 years	Male		
460193	Primary	SUSAN SULLY	50 years	Female		

Page 1 of 4

- The “Session Preview Report” displays a list of SPs in the current session.
- The ID, SP Type, SP Name, Age, Gender, Special Considerations, and Consent Comments are displayed.
- This report provides information about special needs or consideration for each SP, such as wheelchair used for mobility, disabilities, and consent issues.

4.6.1 SP Examinations

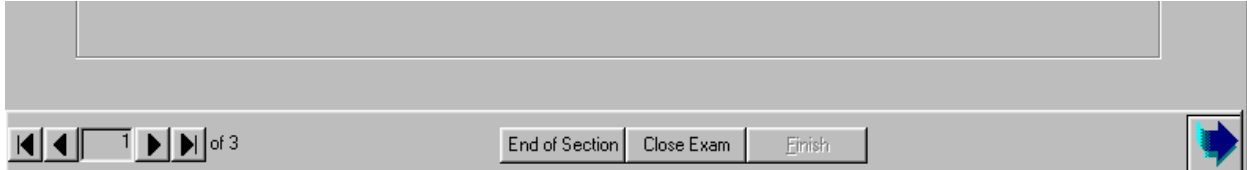
Exhibit 4-73. SP examination



- To preview the status of the SP examinations in the current session, select “Reports” from the toolbar.
- Select “SP Exams” from the menu.
- The SP examination status report can be viewed for each SP in the session.
- The first column lists the components for which the SP is eligible.
- The second column displays the examination status: complete, partial, not done.
- The status remains blank until the SP has been to that component.
- If applicable, the status comment and “Other” comment are also listed.
- Scroll up and down to view all SPs in the session. Page up and page down may also be used.

4.6.2 End of Section

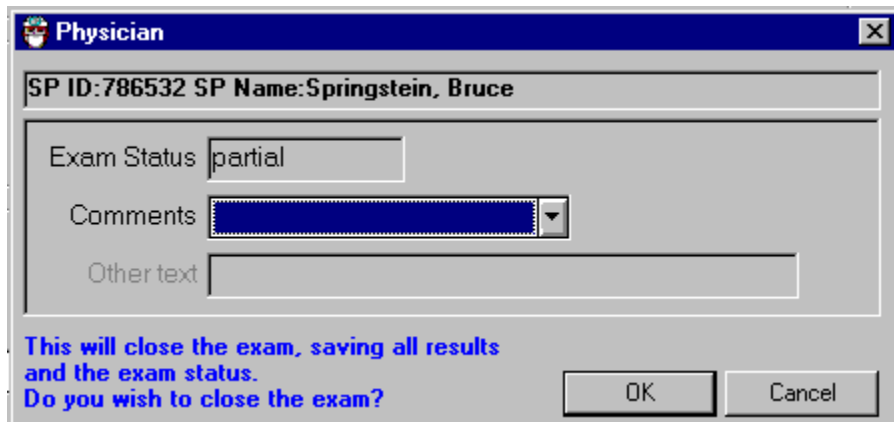
Exhibit 4-74. End of section



- The “End of Section” button is used to advance to the end of the current section without entering data in the required fields.
- The status defaults to “Not Done” and a comment is required. Select the appropriate comment for the situation.
- One potential situation is when there is not enough time at the end of a session to complete the entire examination, but the SP needs the STD and HIV information sheet to be able to obtain test results. The physician opens the examination, selects “End of Section” for the blood pressure and CV exclusion questions. The appropriate comment for both sections would be “No Time.”
- The “End of Section” button can be selected from each section.
- This allows the screens to advance through each section until the STD and HIV results screen appears.

4.6.3 Close Examination Button

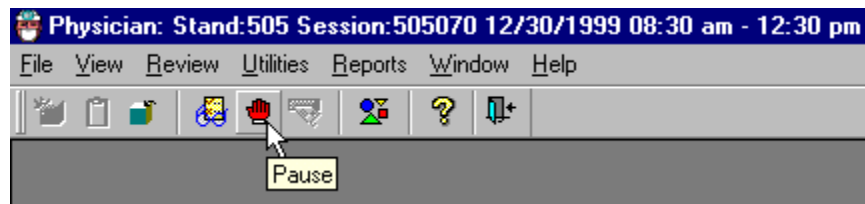
Exhibit 4-75. Prematurely closing examination



- The correct method of closing an examination is to select the “Finish” button after all the data have been entered.
- If there is a need to end the examination prematurely, the “Close” button can be selected at the bottom of the screen next to the “End of Section” button.
- When the “Close” button is selected, a pop-up box is displayed. The examination status defaults to “Not Done” or “Partial” depending on the stage of the examination when the “Close” button was pressed.
- Select the appropriate comment from the drop-down list.

4.6.4 Pausing an Examination

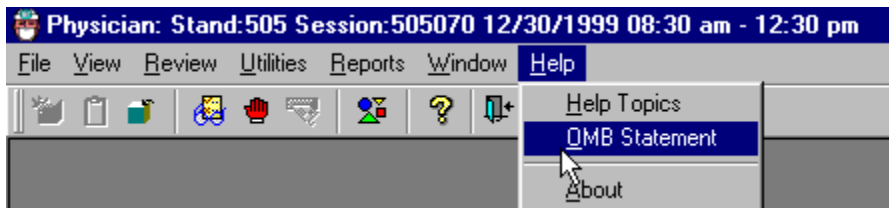
Exhibit 4-76. Pause an examination



- There may be situations where the physician is needed in another room in the MEC. If this occurs during an examination, select the icon with the red hand (the Pause icon).
- Clicking this icon pauses the examination in the physician’s room. The timer for the examination stops.
- The Pause icon acts as a toggle and the timer will not start again until the Pause icon is clicked again.
- Examination pause may also be accessed from selecting “Utilities” from the Toolbar and then selecting “Examination Pause” from the menu.

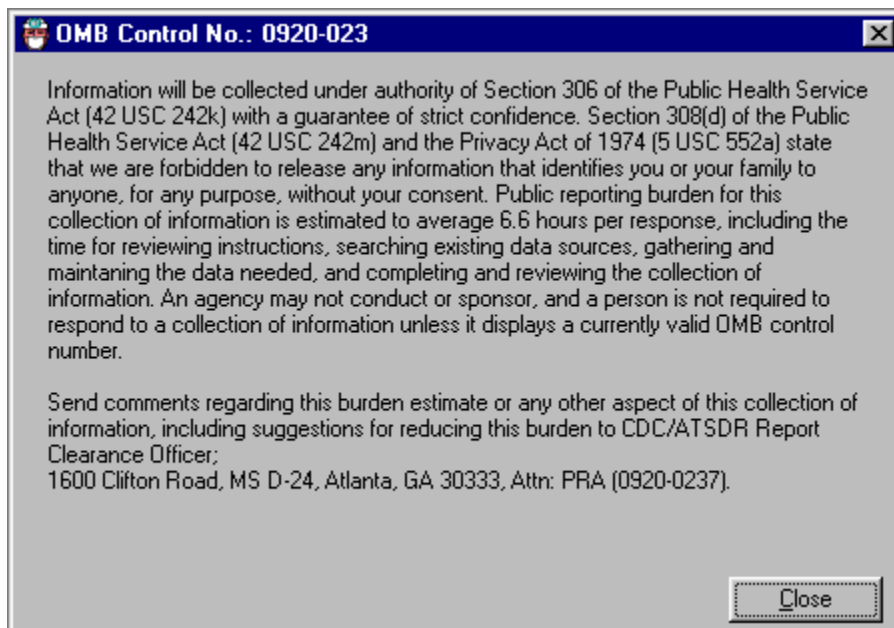
OMB Statement

Exhibit 4-77. Menu to select OMB statement



- The OMB statement is found under the Help menu on the toolbar. Choose “Help,” and then select OMB statement from the menu.

Exhibit 4-78. OMB statement



- The OMB statement is displayed. Click on “Close” to close this box.

5. REFERRALS

5.1 Medical Referrals

Although the primary purpose of the MEC examination is data collection, not diagnosis or treatment, the examination may produce findings that warrant further medical attention. There is an obligation to inform SPs of any abnormal results from the examinations and to refer SPs to appropriate providers for treatment. MEC physicians are responsible for referrals. Each examination component has a referral process built into the ISIS system. This automatic process alerts examining physicians to findings that may require a referral. SPs and their providers may already be aware of some findings, but others may have been revealed for the first time during the MEC exam. MEC physicians review the data provided and the categories set forth by the Physicians Advisory Group (PAG) to determine what type of referral, if any, is needed.

MEC physicians can arrange for a referral to a care provider for SPs who do not have a local provider. The local providers agree to accept referrals from the MEC examination prior to the arrival of the mobile examination team and prior to any examinations being carried out in the MEC. These advance arrangements are made through an advance arrangement team that includes a physician from the National Center for Health Statistics.

5.2 Referral Levels

The MEC physician examiner makes decisions about referring SPs for additional care based on a system rated by three levels. This is important, because different MEC examinations generate various categories of urgent information that are often different, one from the other. Findings that are outside the normal limits should be reviewed by a qualified medical professional to determine if additional followup care is needed. These three levels of referral apply across all MEC examinations. The Physician's Advisory Group (PAG) at the National Center for Health Statistics (NCHS) defined the action required for each referral level. The edit limits or ranges for referrals in each component were defined by the component specialists and consultants and subsequently reviewed and approved by the PAG. Based on the results of any component of the MEC examination, physicians place SPs in one of three referral categories. They provide guidance to the MEC physician regarding the urgency of an

examination finding. The highest, most urgent referral is a Level 1 referral. Level 3 represents an examination finding that the physician reviews, but does not refer the SP for further care. This method of referral assures that physicians from both exam teams review all findings that appear out of the standardized norm, and that there is a record made that the physician reviewed the findings and made an informed decision, based from their medical background, about whether the SP should be referred.

5.2.1 Level 1 Referrals

These referrals are generated when there are major medical findings that warrant immediate attention by a health care provider, such as a dangerously high blood pressure, and life threatening emergencies. SPs determined to need a Level 1 referral usually terminate further MEC examinations. SPs are transferred out of the MEC and into a hospital or other care facility. SPs who refuse treatment from this level of referral are asked to sign a release stating that they are aware of the examination findings, but they are refusing treatment against the advice of the MEC physician. SPs must sign the release form before leaving the MEC. The release is available in both English and Spanish.

5.2.2 Level 2 Referrals

The MEC physician generates these referrals when there are major medical findings that require attention by a health care provider in the next 2 weeks because they are expected to cause adverse effects within this time. Level 2 referrals allow SPs to continue MEC examinations; however, they are advised to see their primary care provider within 2 weeks following the examination. A high, but not dangerously high blood pressure is an example of a level 2 referral.

5.2.3 Level 3 Referrals

Level 3 referrals consist of either no out-of-range medical findings or minor medical findings that an examinee already knows about, is under care for, or does not require prompt attention by a medical provider. Level 3 findings do not necessarily generate referrals. Examinees receive a report of the findings from many of the examination components before leaving the MEC. In addition, a detailed

Report of Findings is sent from NCHS approximately 2 to 4 months after completion of the examination. The latter report contains the results of some findings that are not available before SPs leave the MEC.

Table 5-1. Table of referral levels

Referral level	Category	Action
1	4	Indicates major medical findings that warrant immediate attention by a health care provider.
2	3	Indicates major medical findings that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period and they have previously been undiagnosed, unattended, nonmanifested, or not communicated to the examinee by his or her personal health care provider.
3	1 & 2	Indicates no major negative medical findings, or minor medical findings that an examinee already knows about, and is under care for, or findings that do not require prompt attention by a medical provider.

5.3 Basis for Referrals

Referrals may be based on data collected during MEC examination components (examination data-related referrals) or based on subjective or objective observations made by any MEC examiner (observation referrals). These two types of referrals are described in detail in this section.

5.3.1 Examination Data-Related Referrals

Examination data-related referrals are based on predefined criterion levels from the examination data. These criterion levels were defined by the physician advisory group and are built into the ISIS system such that when the limits are exceeded, the system automatically flags this information to the physician for the specific SP. The flag occurs when component data that are above or below the predefined limits are recorded. The examination components that send data-related referrals to the physician system are the laboratory (pregnancy and complete blood count), mental health (from the MEC Interviewer health examination), blood pressure from the physician’s examination, and spirometry results.

5.3.2 Laboratory Referrals

Pregnancy Referrals

A positive test for pregnancy activates a system notification to the physician for all SPs. Urine pregnancy tests are done on all SPs between the ages of 12 through 59 years. In addition, pregnancy tests are done on SPs aged 8 through 11 years if they reported during the household interview that menarche had begun. The physician is the person who informs the SP of these results since some SPs may be unaware of their pregnancy at the time of the test. The physician discloses results of positive pregnancy tests to the SP, unless the SP is 18 or over and had already reported the pregnancy during the interview. SPs under 18 years of age always see the physician when a positive pregnancy test is reported. Negative pregnancy test results are provided to SPs only upon the SP's specific request. Physicians discuss the importance of prenatal health care in situations where SPs have not seen a health care provider when they have a positive pregnancy test. Referrals are facilitated if appropriate. SPs with no source of prenatal care are referred to a local public health clinic or primary care provider.

5.3.3 Age Specific Pregnancy Referral Requirements

SPs 18 years and over who have a positive pregnancy test are referred as described in Section 5.3.2 above. There are referral requirements based on child abuse laws for SPs under 18 years of age. While counseling the pregnant minor, physicians take a brief history to determine whether the pregnancy may have resulted from sexual abuse. The index of suspicion for sexual abuse is based solely on what a minor discloses, rather than a full medical evaluation. Young women may refuse to provide information surrounding their pregnancy. If the information provided by a minor leads the physician to be concerned about possible, probable, or definite sexual abuse, **the parent/guardian is informed** and a report is filed with Child Protective Services (CPS). If the physician is unsure whether to report, the physician discusses the case with a social worker at Child Protective Services. When presenting the case, MEC physicians do not use the minor's name or any other identifier. If the social worker and physician agree that the referral to CPS should be made, the physician may provide the name and address of the minor. Physicians may followup the verbal reporting with a written documentation of findings relevant to the reporting. **These written reports are private, and are not collected in the NHANES database.** The age specific requirements are described in Section 5.3.4.

5.3.4 Unmarried Minors Pregnancy Referrals

Federal law requires physicians to report child abuse. The finding of a positive pregnancy test in an unmarried minor (under age 18) requires physicians to conduct a brief evaluation to determine the level of counseling and referral necessary. The physician discloses a positive pregnancy test result directly to the minor.

If the minor is under 14 years of age, physicians discuss the circumstances of the pregnancy with the child, inform the parent, and report the case to Child Protective Services (CPS). Pregnancy in such a young age is probable child abuse. If the physician is informed that the child is already receiving prenatal care, the physician verifies this information directly with the provider. In cases where the child is already receiving prenatal care and has received a full medical evaluation, no report to CPS is indicated.

If the minor is 14 years and older, physicians disclose results directly to the minor and assesses (a) whether the minor is already receiving prenatal care or pregnancy counseling, (b) whether minor's parent/guardian is aware of the pregnancy, and (c) whether the pregnancy is a result of child sexual abuse. If a minor who is 14 years or older is already receiving prenatal health care, physicians confirm this with the local provider. No further referral or parental notification is necessary unless other examination findings meet the criteria for referral. If the minor is not receiving prenatal care, the physician discusses the importance of a medical evaluation and pregnancy counseling for the SP, and facilitates a referral. SPs with no source of care are referred to a local public health clinic or primary care provider. Because a parent/guardian should be informed of a minor's pregnancy if she is not receiving prenatal care, the physician will offer to help the minor tell her parent/guardian before leaving the MEC. **If the minor strongly opposes the disclosure of the pregnancy test results to a parent or guardian, the physician respects the minor's confidentiality.**

5.4 Laboratory Values

Urine and blood are collected for various laboratory tests on all SPs 1 year old and over. A complete and detailed description of these tests can be found in the *NHANES Laboratory Procedures Manual*, January 2009. Some laboratory findings are available prior to SPs leaving the mobile examination center. These findings are provided to the SPs, and when these findings are outside the

predetermined criterion levels for referral, physicians decide whether a referral is needed. When a referral is indicated, the physician provides the information to the SP. The laboratory findings and the parameters that generate referral advice to the physician are shown in Tables 5-2 and 5-3.

Reference ranges for normal values were calculated from the NHANES III data set using 95 percent reference interval(s) determined nonparametrically, through ranking the observations and determining the lower (2.5th percentile) and the upper (97.5th percentile) reference limits. The nonparametric (ranking) method was used because most measured hematology parameters have a skewed, non-Gaussian distribution.

Action Limits. Action limits are a guide to inform the physician that a CBC result(s) is/are abnormal. Since all specimens are run in duplicate, there is no reason to retest the sample.

- WBC male and female (all ages) < or = to $3 \times 10^3 \mu\text{L}$ or > or = to $16.0 \times 10^3 \mu\text{L}$
- Hgb male and female (<6 years) <6.5 g/dL or >14.5 g/dL
- Hgb female (>6 years) <6.5 g/dL or >16.0 g/dL
- Hgb male (>6 years) <6.5 g/dL or >18.0 g/dL
- PLT male and female (all ages) < $50 \times 10^3 \mu\text{L}$ or > $800 \times 10^3 \mu\text{L}$

Table 5-2. Complete Blood Count Reference Ranges—Males

Age in years	1-5		6-18		19-65		66+	
White blood cell count (SI)	4.3	14.6	3.6	11.5	3.9	11.8	3.8	12.1
Red cell count (SI)	3.98	5.3	4.14	5.78	4.18	5.86	3.57	5.67
Hemoglobin (g/dL)	10.7	14.2	11.9	16.9	13.1	17.5	11.4	17.1
Hematocrit (%)	32.1	41.7	35.3	49.9	38.7	51.4	33.9	50.9
Mean cell volume (fL)	68.2	88.8	75.6	94.6	79.8	99.1	81.4	102.7
Mean cell hemoglobin (pg)	22.3	30.6	25	32.3	26.3	34	26.3	35
MCHC (g/dL)	32.3	35.6	32.3	35.3	32.3	35.3	32.1	35.1
Red cell distribution width (%)	11.4	15.8	11.4	14	11.4	14.5	11.8	16.2
Platelet count (%) SI	212	546	179	439	152	386	124	384
Mean platelet volume (fL)	6.1	8.9	6.6	10	6.8	10.1	6.6	10.2
Lymphocyte percent (%)	22.8	68.4	17.5	54.3	16.1	47.9	12.3	46.4
Monocyte percent (%)	4.6	15.2	4.8	13.7	4.4	13.5	4.6	14
Segmented neutrophils percent (%)	17.6	67.1	30.3	72.8	37.8	74.6	39.5	78.1
Eosinophils percent (%)	0.7	11.3	0.7	11.5	0.7	8.5	0.6	8.8
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.6	0.1	1.6

Table 5-3. Complete Blood Count Reference Ranges—Females

Age in years	1-5		6-18		19-65		66+	
White blood cell count (SI)	4.3	14	3.9	12.2	4.1	12.9	4	11.6
Red cell count (SI)	3.96	5.28	3.84	5.24	3.64	5.2	3.51	5.34
Hemoglobin (g/dL)	11	14.2	11.2	15.1	10.6	15.6	10.9	15.9
Hematocrit (%)	32.5	41.9	33.5	44.6	32	45.9	32.8	47
Mean cell volume (fL)	70.2	89.1	74.7	94.9	74.6	98.2	80.3	100.6
Mean cell hemoglobin (pg)	23.3	30.8	24.5	32.6	24.3	33.8	26.4	34.5
MCHC (g/dL)	32.4	35.5	32.3	35.3	32.1	35.3	32.3	35.1
Red cell distribution width (%)	11.3	15.4	11.3	14.8	11.4	16.3	11.6	16.3
Platelet count (%) SI	215	547	190	446	168	441	155	428
Mean platelet volume (fL)	6.1	8.9	6.6	10	6.8	10.2	6.7	10.5
Lymphocyte percent (%)	21.6	68.8	17.2	54.7	14.1	47.6	13.7	46.9
Monocyte percent (%)	4.2	14.4	4.3	12.7	3.8	11.6	4.4	12.8
Segmented neutrophils percent (%)	19.4	69.5	31.9	74.3	39.8	78.1	40.9	78.1
Eosinophils percent (%)	0.6	9.9	0.6	9.9	0.6	7.3	0.6	7.5
Basophils percent (%)	0.1	2.5	0.1	1.6	0.1	1.7	0.1	1.7

Possible causes of abnormal parameters:

- High RBC, Hgb, or HCT—dehydration, polycythemia, shock, chronic hypoxia
- Low RBC, Hgb or HCT—anemia, thalassemia and other hemoglobinopathies
- Low MCV—microcytic anemia
- High MCV—macrocytic anemia, liver disease
- Low WBC—sepsis, marrow hypoplasia
- High WBC—acute stress, infection, malignancies
- Low platelets—risk of bleeding
- High platelets—risk of thrombosis

5.5 Complete Blood Count (CBC)

The Beckman Coulter MAX® generates the CBC report. This machine directly measures the red blood count (RBC), white blood count (WBC), hemoglobin (Hgb), and differential percentage. The mean corpuscular volume (MCV), red cell distribution (RDW), platelets (PLT), and mean platelet volume (MPV) are derived from histograms while other values are calculated. The reference ranges for normal values were calculated from the NHANES III data set, using 95 percent reference interval. The following values are transmitted to the physician for review:

- **Red Blood Count** – Elevated RBC may reflect primary polycythemia (polycythemia rubra vera) or secondary causes of polycythemia (stress erythrocytosis, diseases associated with low oxygen, certain renal disorders, etc.) Decreased RBC count may indicate anemia.
- **Hemoglobin** – Abnormal Hgb measurements usually reflect the same conditions as the RBC count and can define the type of anemia.
- **Hematocrit** – Abnormal hematocrit values usually reflect the same conditions as the RBC and can help define the type of anemia.
- **White Blood Count** – High values (leukocytosis) may indicate a primary condition such as leukemia or a secondary condition such as infection. Low values (leukopenia) may indicate the presence of autoimmune, neoplastic, drug-induced, congenital, or other conditions. See below.
- **Lymphocytes** – Elevated counts (lymphocytosis) may be primary (leukemias, lymphomas, monoclonal B cell lymphocytosis) or secondary (viral infection, acute physical stress, pertussis, and chronic disorders such as autoimmune disease and cancer). Depressed counts (lymphopenia) can reflect a variety of uncommon inherited disorders or the more frequent acquired conditions such as viral and certain bacterial infections, the effects of immunosuppressive agents, and some chronic diseases.
- **Monocytes** – These cells, derived from the bone marrow are the precursors of tissue macrophages. Monocytosis is often seen in chronic infections (TB, brucellosis), acute protozoan and rickettsial diseases, and in neutropenia. Uncommon malignant disorders (monocytic leukemia, histiocytic lymphoma) and nonmalignant conditions (hemophagocytic syndromes) can also cause it.
- **Neutrophils** – Elevated neutrophils (granulocytosis) are seen in both primary (myelocytic leukemias, polycythemia rubra vera) and, more commonly, in secondary conditions (bacterial infections, chronic inflammation, corticosteroid use, cigarette smoking, etc.). Hereditary neutrophilia is rare. Decreased neutrophils (leukopenia) can also result from primary (myeloid malignancies, congenital disorders) and secondary (drug effect, viral infection, splenomegaly, autoimmune, and hereditary disorders) conditions.

- **MCH** – The mean corpuscular hemoglobin, in picograms, is calculated from the ratio of Hgb to RBC. This measure of hemoglobin per RBC is used in conjunction with the MCV and the MCHC to further define anemias. For example, the MCH is elevated in macrocytic anemias and depressed in microcytic, hypochromic anemia.
- **MCHC** – The mean corpuscular hemoglobin concentration is derived from the ratio of the Hgb to the VPRC. It is also used to help define anemias, being elevated in macrocytic anemias and depressed in hypochromic anemias.
- **RDW** – The red cell distribution width is a measure of the homogeneity of the RBC population. It is analogous to anisocytosis seen on microscopic examination. Most macrocytic and microcytic anemias, especially with reticulocytosis, will cause an increased RDW. There is no known pathological cause of a decreased RDW.
- **Platelets** – A decreased platelet count (thrombocytopenia) can be caused by production abnormalities (radiation, drug-induced, cancer, folate or B12 deficiency, myelodysplasia syndromes, HIV, alcohol abuse, etc.), accelerated removal (ITP, SLE, drug antibodies, certain infections, etc.), and hypersplenism. Elevated counts (thrombocytosis) can be primary (myeloproliferative disorders such as CML and PRV, essential thrombocythemia) or secondary (acute trauma, chronic iron deficiency, inflammatory disease, cancer, splenectomy, etc.).

When the values from the Beckman Coulter® report are interpreted, various interfering substances and conditions may affect these parameters:

- Abnormal BUN, glucose, or sodium levels could affect the MCV.
- Abnormal WBCs could affect lymphocytes, monocytes, and granulocytes.
- Abnormally small WBCs could affect white count, lymphocytes, monocytes, and granulocytes.
- Clumped platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Cryofibrinogen and cryoglobulin crystals could affect white count, lymphocytes, monocytes, granulocytes, RBC, hemoglobin, platelet count, and MPV.
- An elevated WBC could affect RBC, hemoglobin, MCV, RDW, platelet count, and MPV parameters.
- Fragile WBCs could affect white count, lymphocytes, monocytes, granulocytes, platelet count, and MPV.
- Giant platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Hemolyzed specimens could affect RBC, hemoglobin, platelet count, and MPV.

- Lipemic specimens could affect MCV.
- Severely icteric plasma causes increased hemoglobin. Evaluate CBC result carefully and report all parameters except the hemoglobin result.
- Nucleated RBC's could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.

In rare circumstances a result from the complete blood count may be an extreme value that would be considered a “panic” value in clinical practice. An example is severe thrombocytopenia. The physician may repeat the complete blood count if the participant reports no history of nosebleeds or prolonged bleeding and the physician verifies that the site of the first venipuncture clotted normally. The second complete blood count will overwrite the first results in ISIS and will be used for reporting and referrals. Please follow the procedures below when it is determined that a repeat CBC must be drawn.

If the physician feels a repeat blood count is needed, then he or she has the discretion to discuss this with the SP and have the phlebotomist draw a 3-ML EDTA tube for a repeat CBC if the SP agrees. Prior to a second phlebotomy, the physician should visually inspect the site of the first venipuncture to rule out prolonged bleeding. If the puncture site looks normal, then a second phlebotomy can be requested. The SP always has the right to refuse the blood draw. The need for this action should be rare as evidenced by the four total low platelet counts in the last 2 years.

After the physician reviews the findings with the SP, and the SP agrees to a repeat CBC phlebotomy:

- The physician should consult with the MEC manager and chief med tech to arrange to have the blood drawn at the next earliest opportunity.
- If the SP is eligible for the second GTT blood draw, we currently require the phlebotomist to draw any tubes that might not have been collected during the first blood draw. The second 3-mL EDTA tube could be drawn at that time but the phlebotomist will need to be alerted because the tube will not display on the GTT blood draw protocol screen.
- If the SP is not eligible for the GTT blood draw then he or she will need to be walked to phlebotomy to have the blood drawn.
- This additional blood draw will not be supported by the laboratory and phlebotomy applications.

- As long as the SP has not checked out of the MEC or if the Report of Findings has **not** been printed, the lab application will allow the med techs to overwrite the existing CBC data with the new data and the new data will become the final result of record.
- The physician will document this event under observations in the physician application.

5.6 Blood Pressure Referrals

5.6.1 Blood Pressure Referrals – Adults

The MEC physician takes the BP on all SPs 8 years old and over. Tables 5-4 through 5-7 provide the matrix of combinations of systolic and diastolic blood pressure results and the referrals that are generated when these BPs are present for adults. The left column specifies the minimum and maximum systolic pressure groupings. The first row specifies the minimum and maximum diastolic blood pressure (DBP) categories. The matrix cells specify the BP category severity for the SBP and the DBP combination. The category severity defines the MEC referral level.

Table 5-4. Referral levels for blood pressure (adults)¹

Systolic	Diastolic				
	<80	80-89	90-99	100-119	>/=120
<120	1	2	3	4	5
120-139	2	2	3	4	5
140-159	3	3	3	4	5
160-209	4	4	4	4	5
>/= 210	5	5	5	5	5

¹Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.

Table 5-5. Blood pressure referral levels, category, and action guideline (adults)

Referral level	BP Category	Physician guideline referral action
1	5	Indicates major medical findings (BP) that warrant immediate attention by a health care provider.
2	3 & 4	Indicates major medical findings (BP) that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period and they have previously been undiagnosed, unattended, nonmanifested, or not communicated to the examinee by his/her personal health care provider.
2	2	Indicates prehypertensive blood pressure, minor medical findings that an examinee already knows about, and is under care for, or findings that do not require prompt attention by a medical provider prior to a month.
3	1	Indicates no abnormal BP findings.

Table 5-6. Adults BP referral letter comments

BP Category	BP Referral level	Referral statement
5	1	The participant's blood pressure today is severely high.
4	2	The participant's blood pressure today is very high based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.
3	2	The participant's blood pressure today is high. Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.
2	2	The participant's blood pressure today is above normal and is in the prehypertensive range. Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.
1	3	The participant's blood pressure today is within the normal range. Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.

Table 5-7. Table of blood pressure report of findings comment (adults)

Report of findings level BP category	Report of findings message – English	Report of findings message – Spanish
1	Your blood pressure today is within the normal range . Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.	Su presión de sangre hoy está dentro del rango normal . Basado en el Séptimo Informe del Comité Conjunto Nacional de Prevención, Detección, Evaluación y Tratamiento de la Alta Presión Sanguínea. Publicación del NIH, 2003.
2	Your blood pressure today is above normal and is in the prehypertensive range . Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.	Su presión de sangre hoy es por encima de lo normal y está dentro del rango de prehipertensión . Basado en el Séptimo Informe del Comité Conjunto Nacional de Prevención, Detección, Evaluación y Tratamiento de la Alta Presión Sanguínea. Publicación del NIH, 2003.
3	Your blood pressure today is high . Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.	Su presión de sangre hoy es alta . Basado en el Séptimo Informe del Comité Conjunto Nacional de Prevención, Detección, Evaluación y Tratamiento de la Alta Presión Sanguínea. Publicación del NIH, 2003.
4	Your blood pressure today is very high . Based on the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. NIH Publication, 2003.	Su presión de sangre hoy es muy alta . Basado en el Séptimo Informe del Comité Conjunto Nacional de Prevención, Detección, Evaluación y Tratamiento de la Alta Presión Sanguínea. Publicación del NIH, 2003.
5	Your blood pressure today is severely high .	Su presión de sangre hoy es severamente alta .

(Note: ROF level number 5 should **not** have the NIH Publication referenced.)

5.6.2 Blood Pressure Referrals – Children

Children’s normal blood pressures vary by age, weight, and height. The table for children’s blood pressures is found at Appendix A, Child Blood Pressure Values.

Table 5-8. Referral comments for blood pressure (children)

BP Category	Referral level	Referral statement*
4	1	The participant’s blood pressure is very high based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents. *
3	2	The participant’s blood pressure is high based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents. *
2	3	The participant’s blood pressure is normal but at the high end of normal based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents. *
1	3	The participant’s blood pressure is normal based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents. *

* National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. *Pediatrics*. 1996; 11:649-658.

Table 5-9. Table of blood pressure report of findings comment (children)*

Report of findings level BP Category	Report of findings message
1	Your child’s blood pressure today is within the normal range .*
2	Your child’s blood pressure today is normal but at the high end of normal range .*
3	Your child’s blood pressure today is high .*
4	Your child’s blood pressure today is very high .*

* National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. *Pediatrics*. 1996; 11:649-658.

5.7 Observation Referrals

Observation referrals are not related to specific examination data. An observation referral includes any observation by the technician or other examination staff about an SP's nonemergency condition that may require attention by the physician. An observation referral is sent through the ISIS process from any examination component examiner and may be initiated during the examination, but is sent after the component examination is completed and the SP has left the component room. The examiner initiating the observation enters a message in the observation box and sends it electronically to the physician. The observation sets a flag in the physician component and coordinator applications and SPs are not checked out of the MEC until the physician reviews and acts on this observation. Examples of observations include information from a dietary interviewer when children or adult SPs are thought to be malnourished, or mental health observations from a MEC interviewer. The physician will discuss the issue with the SP and refer as deemed medically necessary.

5.7.1 Mental Health Observation Referrals

The MEC interviewer asks the physician to see any SP who meets criteria for a potential mental health problem. The instructions to the MEC interviewer are included in this section to inform the physician with regard to the reasons and circumstances that the MEC interviewer may ask the physician to see an SP. In addition to the reasons stated in these instructions, the MEC interviewer may ask the physician to see an SP to evaluate a potential MH issue at other times.

5.7.1.1 MEC Interviewer Mental Health Observation Process

Certain information volunteered or reported during the mental health interview should prompt an observation from the MEC interviewer to the MEC physician. These are listed below. MEC interviewers will complete an observation from their Utility screen. This observation goes to the physician Referral Review inbox screen. The physician is responsible for assessing the mental health concern and facilitating a referral when needed. If no referral is needed, the physician completes a MH observation from the physician menu bar Utility option.

5.7.1.2 MEC Interviewer Mental Health Referrals

SPs 12 years and older are administered a Depression Screener questionnaire. Certain information volunteered or reported during the mental health interview should initiate an observation from the MEC interviewer to the MEC physician. These observations should be sent to the physician prior to the SP leaving the MEC interviewer examination and prior to the SP leaving the MEC. The question asked by the MEC interviewer that would prompt an observation to the physician for mental health assessment is:

DPQ090: Over the **last 2 weeks**, how often have you been bothered by the following problem: Thoughts that you would be better off dead or hurting yourself in some way?

Response categories for DPQ090 – Not at all; several days; more than half the days; nearly everyday.

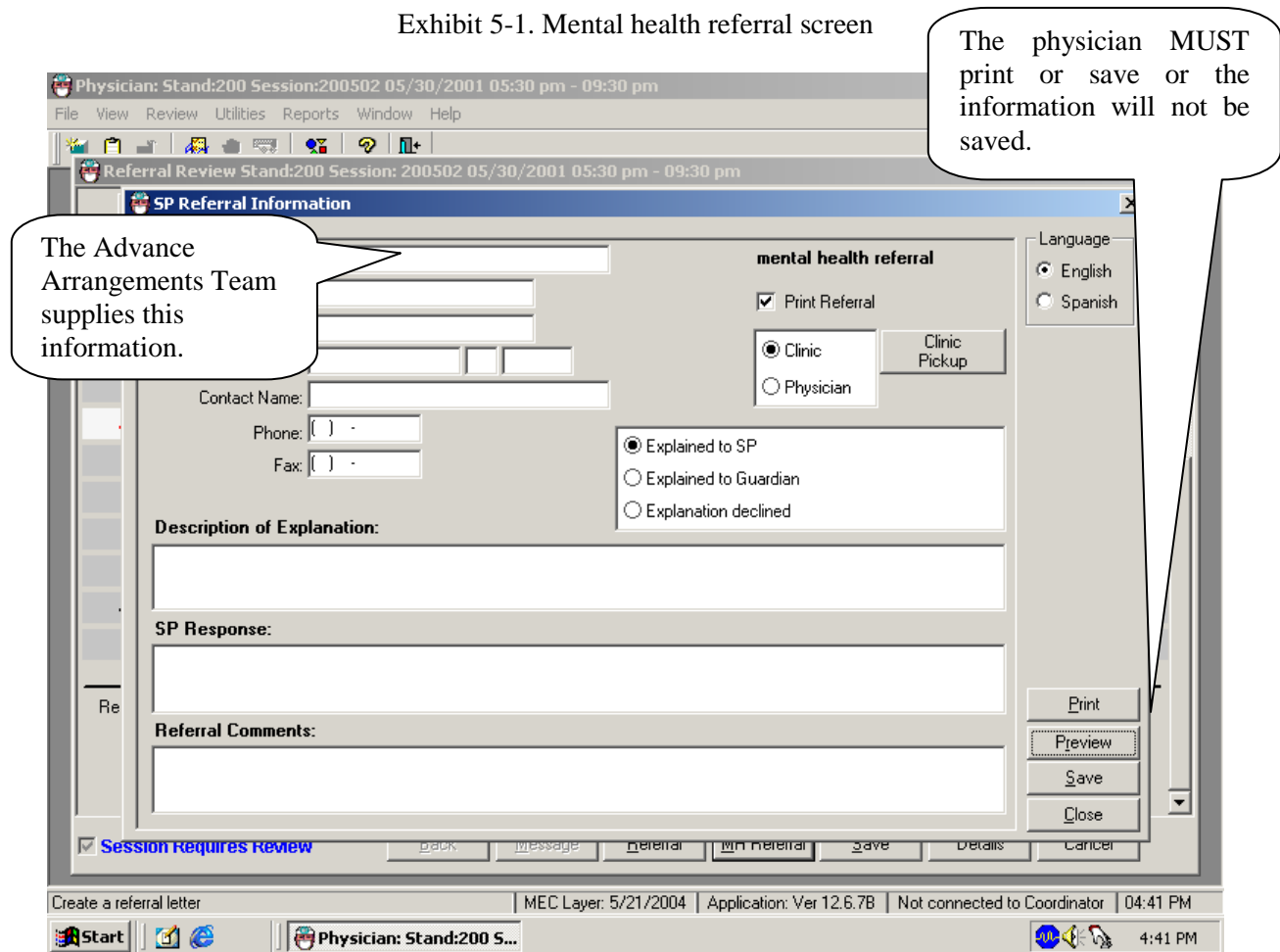
Responses of several days, more than half the days, and nearly everyday require a physician observation. If the SP says he or she thought about it only one time in the last 2 weeks, the answer is coded as “several days.”

When the MEC interviewer determines that an SP meets the criteria, the interviewer will generate a mental health observation in the ISIS system. The observation will appear on the MD referral screen for review by the physician. The physician will code the observation as “action required,” which will cause ISIS to alert the coordinator that the physician needs to meet with the SP. The physician is responsible for assessing the mental health problem and facilitating a referral, if needed. The Mental Health Referral is a separate referral screen, as shown in Exhibit 5-1, below.

5.7.2 MEC Physician

The MEC physician should document the encounter with an SP by either entering information describing the reason no referral was given in the physician MH Observation box, or by completing a MH referral.

Exhibit 5-1. Mental health referral screen



5.7.3 Suicidal Ideation

The MEC physician is not responsible for making psychiatric diagnoses; however, thoughts and plans for suicide should be considered seriously. The MEC physician should assess the need for a mental health referral for those who have either reported or voluntarily disclosed recent suicidal ideations or attempts.

Protocol for a MEC physician receiving an observation from the mental health interview:

- Assess if the SP is currently suicidal. Ask the SP if she or he is depressed or thinking about suicide now. If so, then probe as to whether she or he has a plan and/or set a time for doing this. A person who is suicidal with a plan to kill at a definite time is a **psychiatric emergency**, and a level 1 referral.

Protocol for a participant who is in imminent danger:

- If the SP is currently under psychiatric care, ask the SP for permission to call the mental health care provider. The physician should negotiate a followup with the provider. If the participant does not have a provider, call the **referral center provided by the advance arrangements team.**

Protocol for a participant who is not in imminent danger:

- If the SP is under the care of a psychiatrist or other mental health care provider, there may be no need to refer unless the participant provides some indication that his or her symptoms are worsening.
- If the SP has not seen a health professional for suicidal thoughts, then refer him or her to the specific clinics or crisis hotline **provided by the advance arrangements team.**

For minors under 18 years of age, the initial assessment should be done with the youth in private. If a referral is necessary, the participant's parent/guardian must be notified.

5.7.4 Homicidal Ideations/Threats

Threats to kill a person or person(s) should be considered seriously. The MEC physician should judge the mental stability of the participant. The physician should ask about the specific plan for carrying out the threat and the timeframe. A homicidal threat with a lethal weapon and plan must be reported to the 911 system.

5.7.5 Reporting Child Abuse

If a minor reports that he or she has been abused, the MEC physician should document the nature of the abuse. If warranted, the MEC physician should call **Child Protective Services at the number provided by the NHANES Advance Arrangements Team.** If the physician is unsure whether or not to refer, the physician should discuss the case with a social worker at Child Protective Services. When presenting the case, the MEC physician should not use the child's name or any other identifier. If the social worker and physician agree that the referral to CPS should be made, the physician may provide the name and address of the child.

5.8 Level II Referral Evaluations

5.8.1 Level II Referral Evaluation for Participants with FEV1/FVC% \leq 50% Predicted

There is an obligation to inform participants of abnormal results from the examinations and to refer participants to local medical providers when appropriate. MEC physicians are responsible for such referrals. All participants completing spirometry will routinely be sent a summary of their examination findings by mail. In these reports, abnormal results will be highlighted. In addition, all spirometry examination participants with an FEV1/FVC% \leq 50% of predicted **in baseline spirometry testing regardless of whether they are eligible for bronchodilator testing** will be referred to the MEC physician for counseling and evaluation for Level II Referral. Persons with an FEV1/FVC% \leq 50% predicted have an increased likelihood of severe obstructive lung disease, and constitute the group that may benefit most from physician counseling and Level II referral.

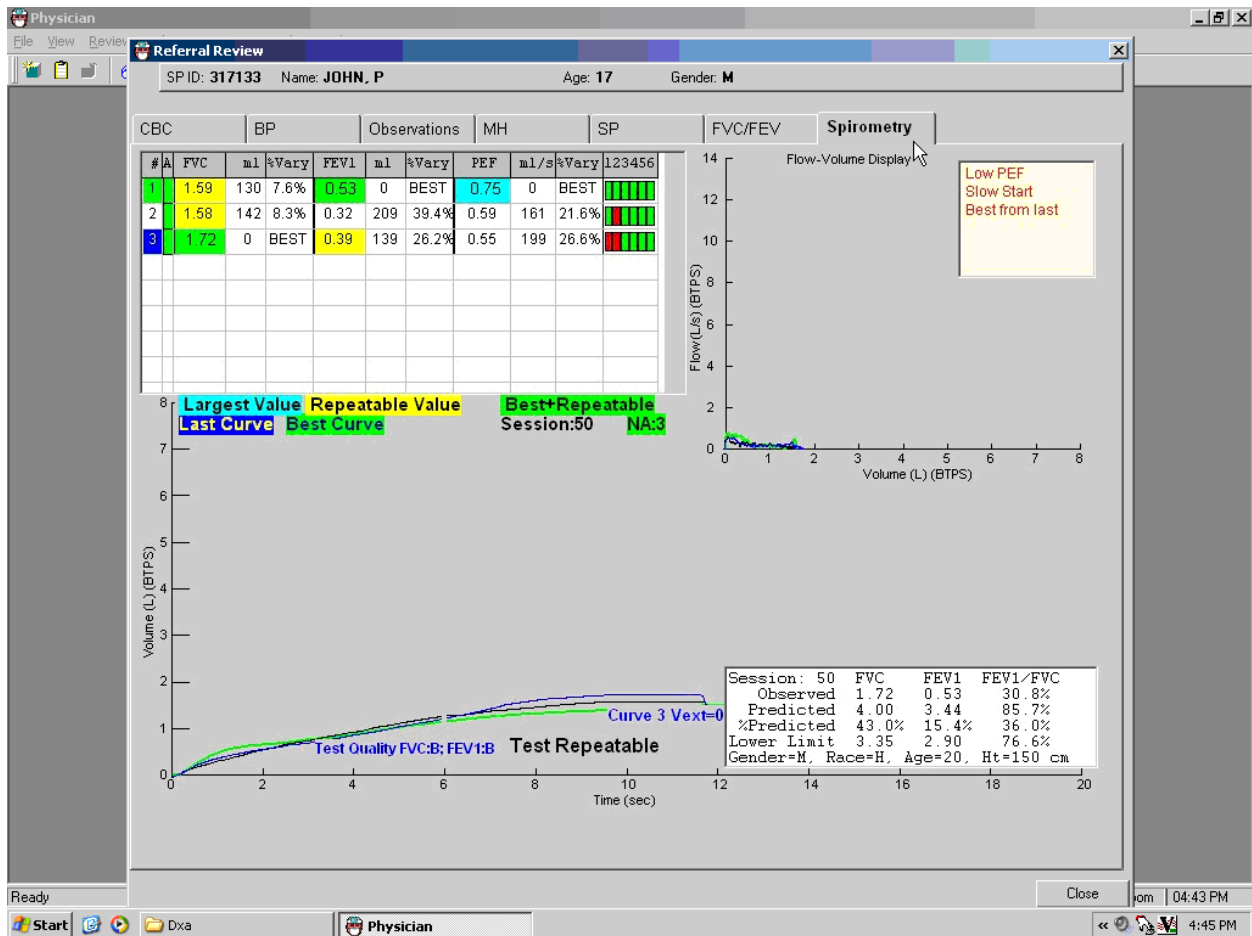
At the completion of baseline spirometry, the ISIS software will compare the participant's results to the values for the standard prediction equations to determine whether the participant's FEV1/FVC% \leq 50% of predicted. If this is the case, then a physician observation message will be generated by the ISIS system. The MEC physician will receive the following message:

“The baseline Spirometry results for this participant indicate the possibility of severe obstructive lung disease (asthma or chronic bronchitis). The FEV1/FVC% is \leq 50% of predicted. A referral to the MEC physician is being made.”

The MEC physician will then see the participant in follow up. Generally speaking, it is not necessary to delay the Level II referral evaluation until after all spirometry studies are complete: i.e., it is not necessary to wait to see the results of the post-bronchodilator studies. This is because the finding of such abnormal results at baseline spirometry is a potentially significant finding in and of itself: such a finding would result from either severe obstructive lung disease (fixed COPD), or from more severe cases of asthma (i.e., either undiagnosed or untreated, severe cases or cases under the case of a physician but with loss of treatment control). The MEC physician, however, has the option to counsel these participants either at the time baseline spirometry is completed or at the completion of bronchodilator testing, at his or her discretion. (Typically all participants with obstructive airflow limitation of this magnitude would be eligible for post-bronchodilator spirometry, however some may be excluded for safety reasons.)

The MEC physician should speak with the participant and review the spirometry results. The possibility that the abnormal findings could result from poor participant effort or poor quality tracings should be evaluated, and the SP's spirometry test results summary and the graphic display of the spirometry curves can be reviewed (Exhibit 5-2). The MEC physician can also consult with the Spirometry Technician who performed the test. If the observed abnormality appears simply due to a poor quality effort or tracing, then a Level II referral is not necessary. However, it should be kept in mind that persons with severe obstructive lung disease can often have a more difficult time performing spirometry, and in general are less likely to produce high quality tracings.

Exhibit 5-2. Spirometry flow curves



The following guidelines can be used by the MEC physician as a basis for Level II referrals:

- If the participant is **not** under the care of a physician, a Level II referral should be made. In this case, the participant may have either asthma or COPD, or both, and requires expedited medical evaluation to determine the diagnosis and therapy that may be indicated.
- If the participant is known to have fixed COPD (chronic bronchitis or emphysema), **and** is currently under the regular care of a physician, then a Level II referral is not generally necessary. The results of the spirometry test should be reviewed with the participant and the participant should be instructed to give a copy of these to his or her medical provider at their next office visit.
- If the participant is known to have COPD, and is **not** currently under the care of a physician, then a Level II referral **is** generally necessary. This potential degree of airways obstruction requires regular medical monitoring.
- If the participant shows significant improvement from the abnormal baseline after bronchodilator administration, then this is an indication of poorly controlled asthma, and the participant **should** have a Level II referral to see their treating physician for re-evaluation of therapy.

Generally speaking, the MEC physician should counsel the participant selected for Level II referral evaluations that their NHANES spirometry test results were abnormal as compared to national standards. The participant should be informed that this finding raises the question of whether a participant has potentially serious degree of lung disease such as asthma or COPD. However, because it is primarily a screening test, the NHANES spirometry examination cannot by itself diagnose any disease. The participant's spirometry test result makes it very likely there is a problem, but as a research evaluation, NHANES testing cannot say for certain whether a problem exists, or how severe it is. Occasionally, screening tests may give abnormal results even when there is not an actual problem; however, NHANES sets its criteria such that this possibility is minimized, so it is important to get further, proper medical evaluation.

The participant should be counseled that in order to make a diagnosis of a disease such as asthma or COPD, a physician must be consulted and take a more extensive history, perform a physical examination, additional laboratory tests, and possibly x-rays. A more complete lung function test should be done of the type available in hospitals. This type of evaluation is the only way the participant can learn their true status. It is important for the participant to make sure to follow through and get medical evaluation, because if asthma or COPD was actually present, it is potentially a serious health problem, and could cause major health problems if ignored or not properly treated.

Level II referrals should be made to the participant's own personal treating physician, if they have one. If not, the MEC physician would advise on a new referral.

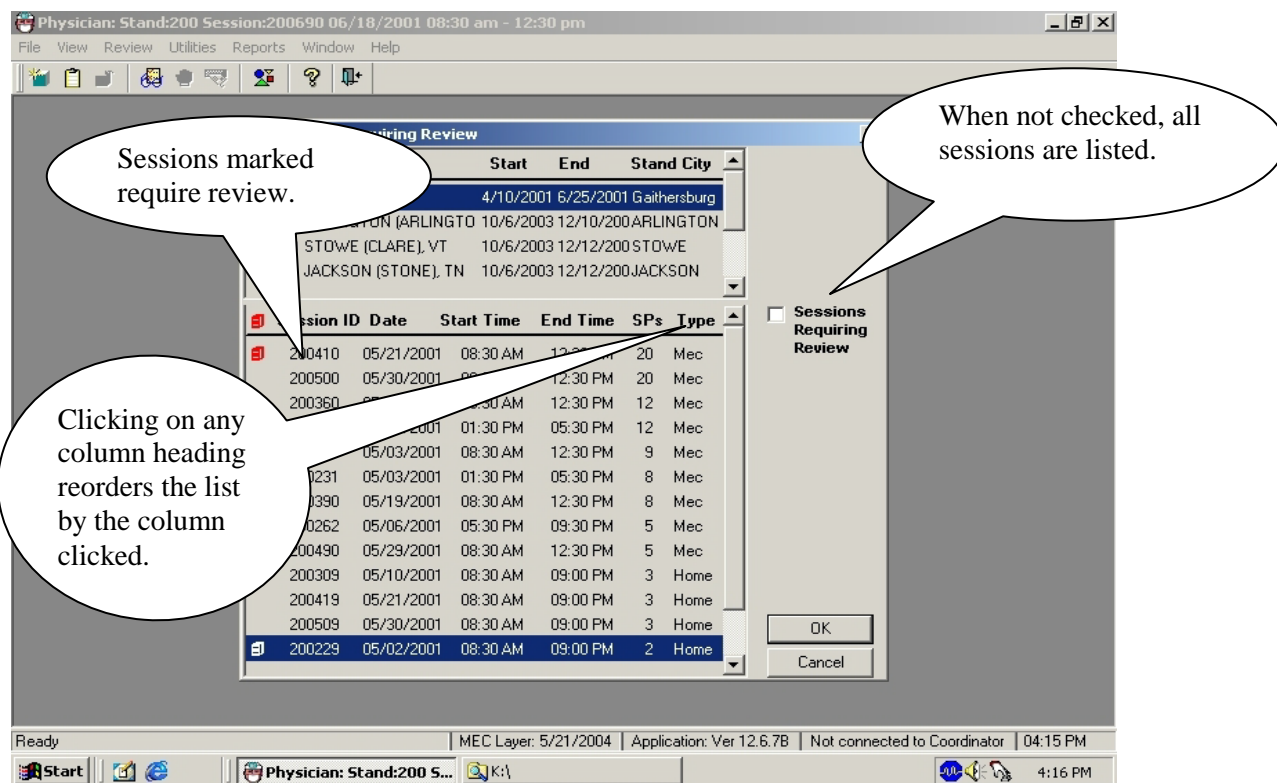
5.8.2 Level II Referral Evaluation for Participants with FEV1/FVC% Lower Limits of Normal

All participants with an FEV1/FVC% less than or equal to the lower limits of normal are referred to the physician for the bronchodilator. The physician can at that point review the flow curves for all participants referred. Those participants who have abnormal pulmonary function testing who are not currently under the care of a physician specifically for their breathing problem should be referred to a community provider on an elective basis for evaluation and treatment. Also, those participants who are currently under medical treatment for asthma who also have a low FEV1/FVC% should be referred to their treating physicians because their asthma may not be properly controlled on their current therapy. Finally, at their discretion, the MEC physician may also refer other participants whose FEV1/FVC% is very low if they feel there is a medical need, based on the participant's information.

5.9 Sessions Requiring Review

All MEC sessions with an SP requiring a physician's review for referral determination must be reviewed. The "Sessions Requiring Review" box is displayed every time the physician logs on to the application, and the physician must review these sessions. When the ISIS application first opens for the physician component, the "Sessions Requiring Review" screen opens by default. The purpose of this screen is to prompt the physician to complete reviews for SPs in all previous sessions. The physician can select which sessions to review.

Exhibit 5-3. Review all MEC sessions in the current stand



- When the physician’s application is opened, the “Sessions Requiring Review” pick list is displayed. If the physician does not want to review referrals at this time this screen may be closed by clicking on the “x” in the upper right corner or by clicking cancel in the lower right corner.
- The top part of the screen displays the current stand.
- The lower part of the screen displays the Sessions Review.
- To view all sessions in the current stand leave the box for “Sessions Requiring Review” unchecked. All sessions in the current stand will be displayed.
- To review a specific session, highlight and double click on that session and that session will be displayed.
- Click “Cancel” to exit without viewing any sessions.
- Close the screen when completed.

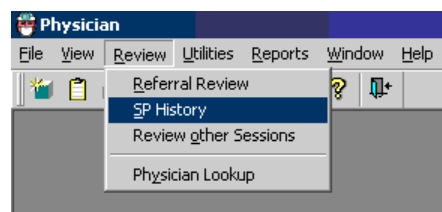
5.10 Data Entry Screens for Referrals

The following sections describe the ISIS screens and data entry process related to physician referrals. There are three types of screens related to referral: “Sessions Requiring Review,” “Review in Box” and “Referral Review.”

5.10.1 Review Menu

The review toolbar selection (Exhibit 5-4) has several review options: CV Medication Review, Referral Review, SP History, Review Other Sessions, and Physician Lookup. Each of these options is described in the following sections.

Exhibit 5-4. Review menu for selecting referral review

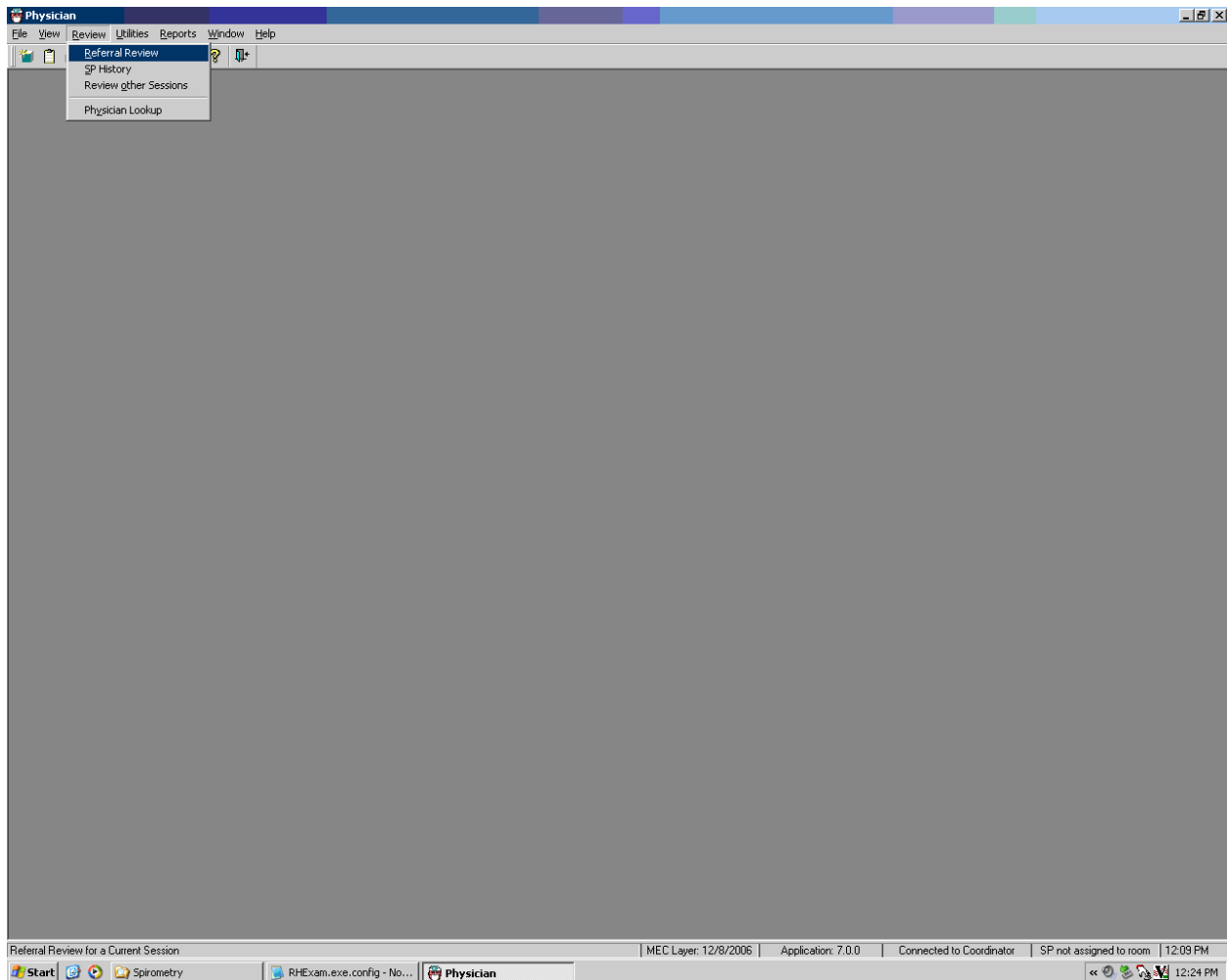


- Use this drop-down list to select the desired activity.
- Highlight the activity by pointing to it with the pointer.
- Click the activity to access the screens.

5.10.2 Review Box

- The Referral Review box option is the screen where all SPs who require an assessment of the need for a referral can be viewed.
- To access the Review Inbox box, first access the desired session (see Exhibit 5-3), then select “Review” (see Exhibit 5-4) from the toolbar, and last, select “Referral Review” from the drop-down list (see Exhibit 5-5).
- This will access the referral review requirements for the current session.

Exhibit 5-5. Referral Review selection screen

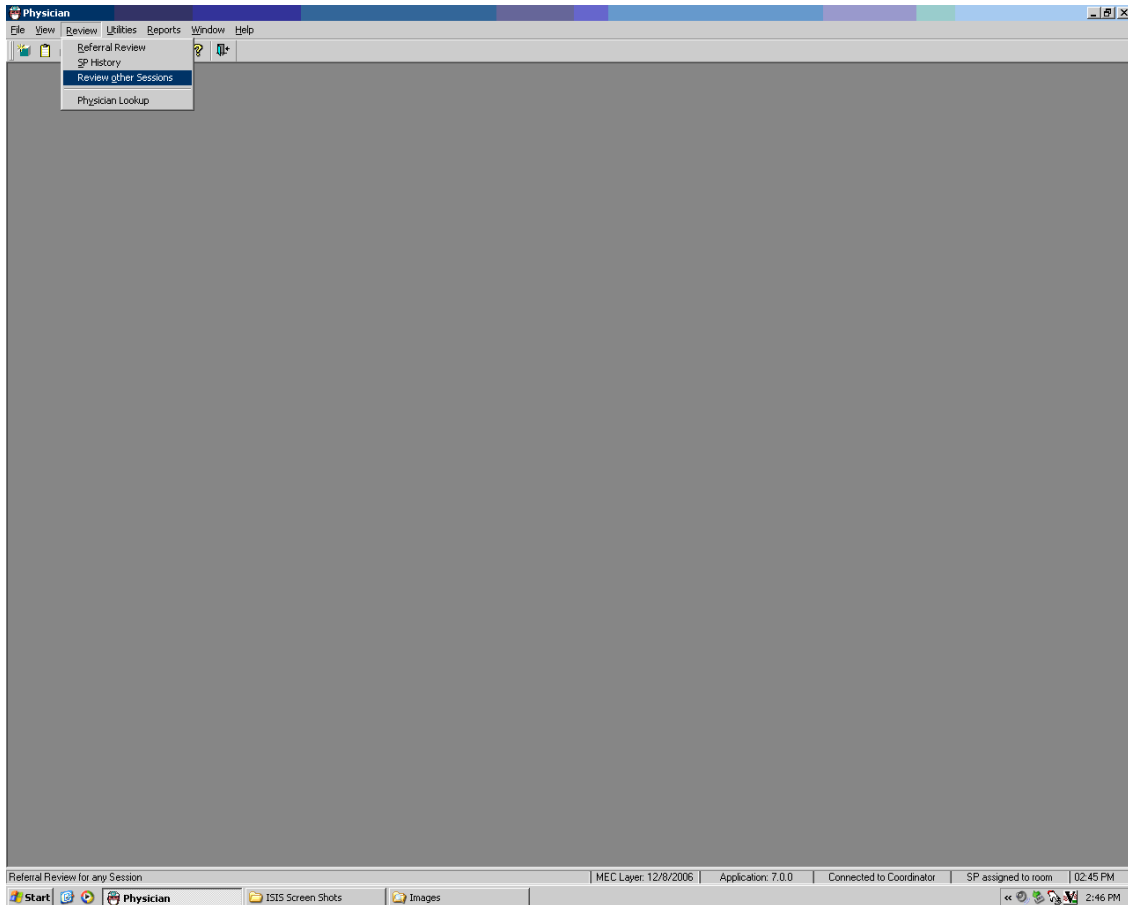


5.10.3 Review Other Sessions

The “Sessions Requiring Review” is accessed from the “Review Other Sessions” drop-down list under the “Review” selection on the toolbar. The “Sessions Requiring Review” screens inform physicians which MEC sessions remain to be reviewed. The purpose of the review is to assure that all referrals are completed. This is especially important since some referrals may not be able to be completed while SPs are still available on the MEC. Physicians mark appropriate boxes about their referral decision for each SP.

Exhibit 5-6 shows the review selection, and drop-down selection list for “Review Other Sessions” option that accesses the Sessions Requiring Review.

Exhibit 5-6. Review other sessions

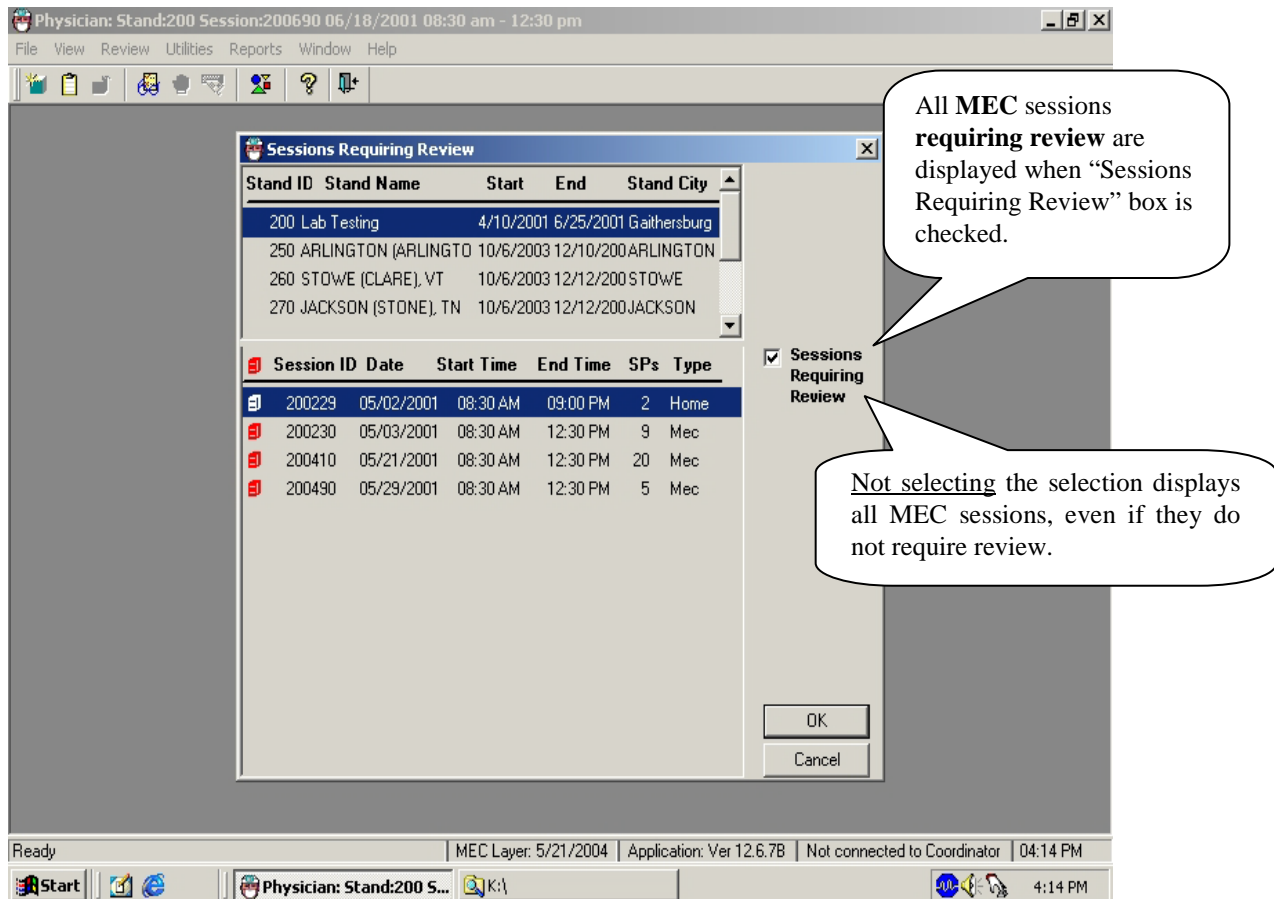


- When the “Review Other Sessions” option is clicked, the “Sessions Requiring Review” screen drop-down list is accessed. From this screen, physicians make choices about which sessions need to be reviewed.

5.10.4 Sessions Requiring Review

The top part of the “Sessions Requiring Review” screen (Exhibit 5-7) displays the current stand location and number. The bottom part of the screen displays various sessions in the stand, depending on how they are selected by the physician.

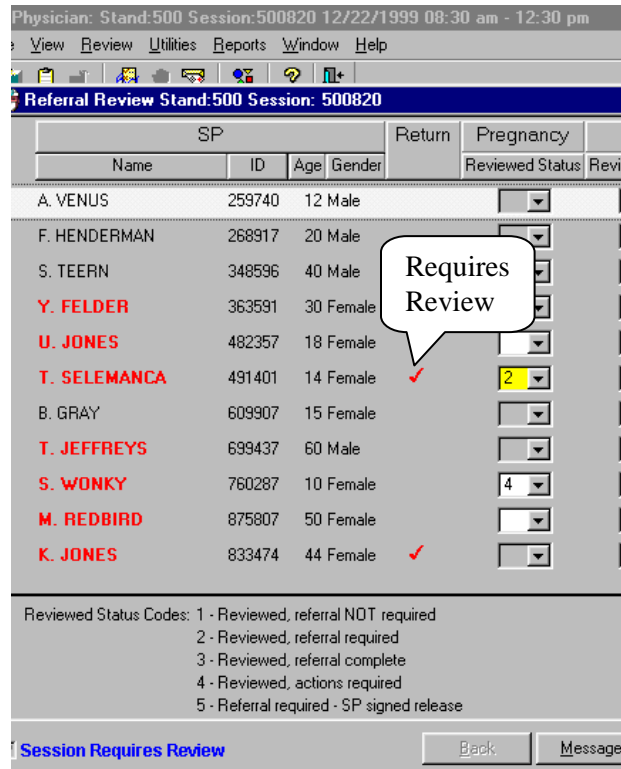
Exhibit 5-7. MEC Sessions requiring review



- When the “Sessions Requiring Review” box is checked, all MEC sessions that require review are displayed.
- Referrals posted in the “Review Box” that the physician has not reviewed causes the application screen to display a **red marking beside the session indicating that the session requires review**.
- The **red mark remains** beside this session until the physician reviews all referrals in the session.
- When all referrals are completed or reviewed, the system removes the red flag.

5.10.5 Referral Review Inbox Screen

Exhibit 5-8. SPs referred back to MD for review for referral determination



- The “Referral Review” box (Exhibit 5-8) has the stand and session numbers on the top bar.
- Names of SPs requiring review are highlighted in red. The boxes for components requiring review are enabled. All other boxes are disabled or “grayed out.”
- Note also that the SPs name is in red when a review is required.

5.10.6 Selecting SP for Detailed Referral Review

To complete the referral, the physician selects each SP in turn who has an indication that a review for referral determination is needed. The selection is made from the Referral Review screen.

Exhibit 5-9. SP Selection from review in box

U. JONES	482357	18 Female						
T. SELEMANCA	491401	14 Female	✓	2				
B. GRAY	609907	15 Female						
S. WINK	89437	60 Male			3			
S. WINK	760287	10 Female		4				
M. REDBIRD	875807	50 Female						
K. JONES	833474	44 Female	✓				2	

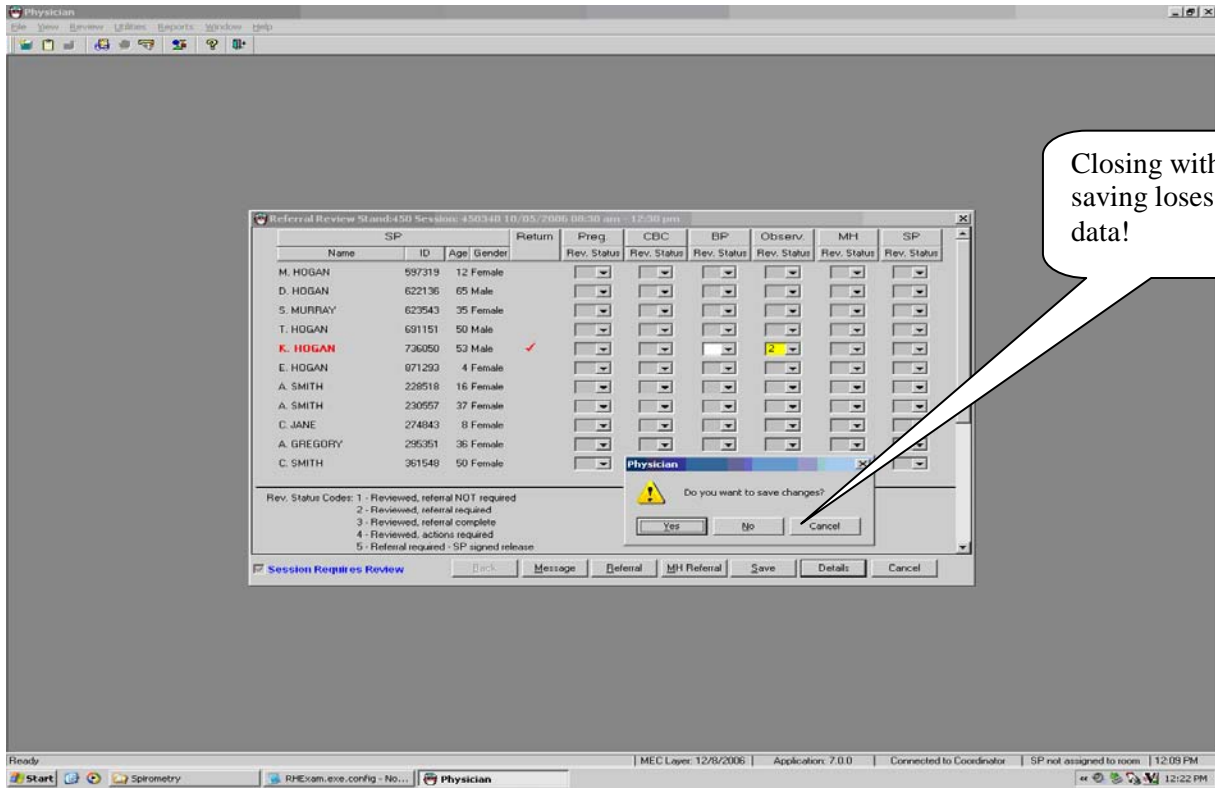
Reviewed Status Codes: 1 - Reviewed, referral NDT required
2 - Reviewed, referral required
3 - Reviewed, referral complete
4 - Reviewed, actions required
5 - Referral required - SP signed release

Session Requires Review

Back Message Save Referral **Details** Cancel

- To select the SP for review, move the cursor over the desired name.
- Highlight the name of the SP to be reviewed.
- Double click on the SP name, or, click the “Details” radio button.

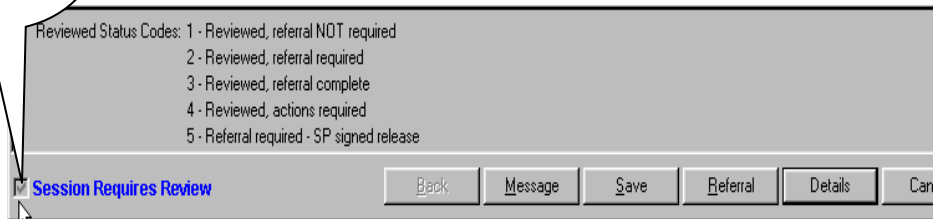
Exhibit 5-10. Warning to save changes



- If you want to close a session before saving the results, a message will be displayed: “Do you want to save changes?”
- Click “Yes” to save and close this box. If all status codes are 1 and 3, the “Session Requires Review” box will be unchecked and the red flag will be removed from the session requiring review list.

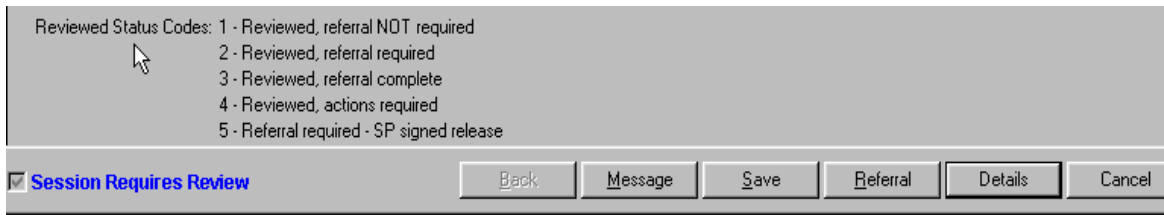
“Session Requires Review”

Exhibit 5-11. Session Requires Review indicator



- A box at the bottom left of the screen is checked if the session requires review. The box is unchecked if no review is required.
- This box is especially useful if there is a long list of SPs. If the box is not checked, there is no need to scroll through the SP list.

Exhibit 5-12. Reviewed Status Codes legend



- The “Reviewed Status Codes” are listed at the bottom left of the screen.
- Code 1 – “Reviewed, referral not required”: If findings were reviewed but the situation does not require a referral, select Code 1 from the drop-down menu.
- Code 2 – “Reviewed, referral required”: If a referral is required but there is not enough time to do it or if the SP is in another exam, check Code 2. This keeps the referral session active. A referral Code 2 turns the physicians examination progress box on the coordinator’s screen (for that SP) to green. This alerts the coordinator that the SP must return to see the physician before checking out of the MEC. (If the SP has not completed the physicians exam component, the box does not turn green. When the SP checks into the physicians exam the box turns green). The box remains green as long as there are referrals for that SP with a referral Code 2. After the code is changed from 2 to another code, the box turns blue.
- Code 3 – “Reviewed, referral complete”: After the physician reviews the referral, sees the SP, and completes the referral letter, Code 3 is checked. If no other referrals are needed, the session will be considered complete.
- Code 4 – “Reviewed, action required”: This is similar but not the same as Code 2. This code is marked when the SP has been reviewed and a referral generated; however, the physician wants to take further action but has not been able to complete the action at this time. This situation could occur when the physician needs to

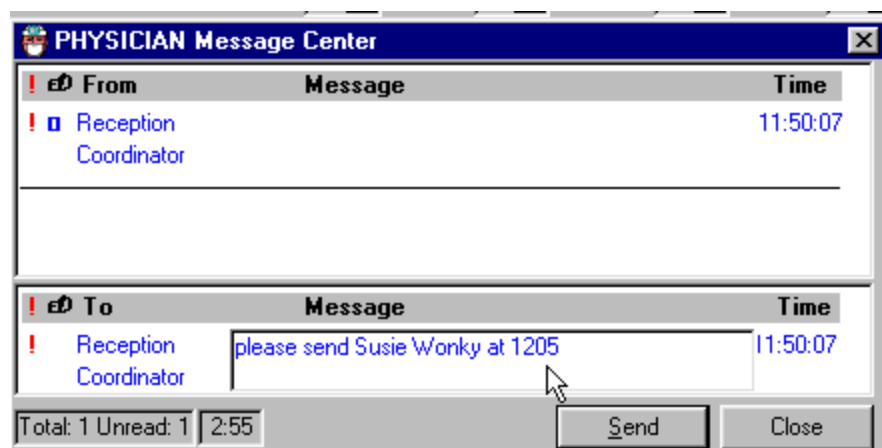
telephone a health care provider but has been unable to complete the process. This may be carried over to the next day, or the next session. When Code 4 is checked, the SP may be checked out of the MEC but this session continues to be flagged, requiring review until this and other referrals are coded as 1 or 3.

- Code 5 – “Referral required – SP signed release”: When SPs refuse to accept a required referral, they sign a release form. The physician checks Code 5 which removes the red flag on the session if all other referrals are complete.

5.10.7 ISIS Message

To assure that SPs see the physician prior to leaving the MEC, the physician can send a message to the coordinator to specify a time to send the SP to the physician examination room to complete the referral.


Exhibit 5-13. Message to coordinator



- Notify the coordinator when it is a good time to complete this referral.
- Click “Message” from the tool bar utilities, type a message, and send to the coordinator.

5.10.8 NHANES Release Form for SPs Refusing Referrals

Exhibit 5-14. NHANES Release Form

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Public Health Service Centers for Disease Control and Prevention
		National Center for Health Statistics 6525 Belcrest Road Hyattsville, Maryland 20782

**NHANES
RELEASE FORM**

Date: _____

Stand: _____

This is to certify that against the advice of the staff doctor I:

(Check one)

am leaving the Mobile Exam Center

am removing _____
(name of sample person)
from the Mobile Exam Center

choose no further medical referral or immediate follow-up.

By so doing, I assume all responsibilities for my act.

Signed _____

Relationship _____

Witness _____

- SPs who decline or refuse a medical referral, are asked to sign the NHANES Release Form (Exhibit 5-14). The date and stand number must be completed. The form is available in English and Spanish.

- This form is available for printing in the “Forms” directory.
- Ask the SP to place a check mark next to the correct ending for the reference sentence:

“This is to certify that against the advice of the staff doctor, I:”

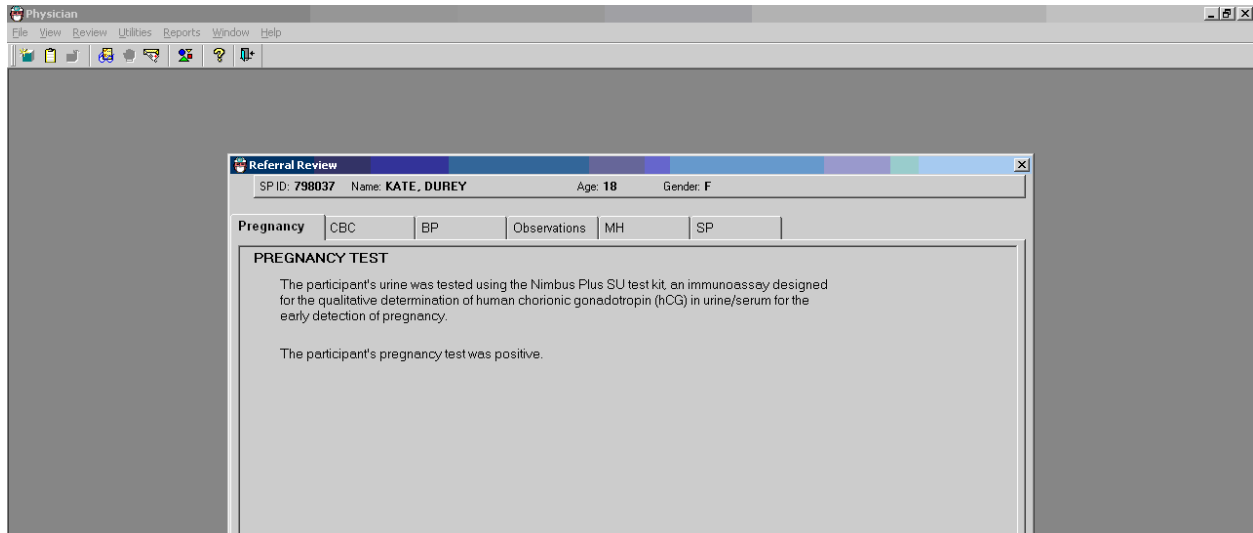
- am leaving the Mobile Exam Center
- am removing (name of sample person)
- choose no further medical referral or immediate followup.”

- Ask the SP to sign this form.
- Obtain a witness signature for the form.

5.10.9 Review in Box for Pregnancy Details

The potential data for referral are selected from tabs for each SP that is referred: Pregnancy, CBC, BP, LED, and Observations.

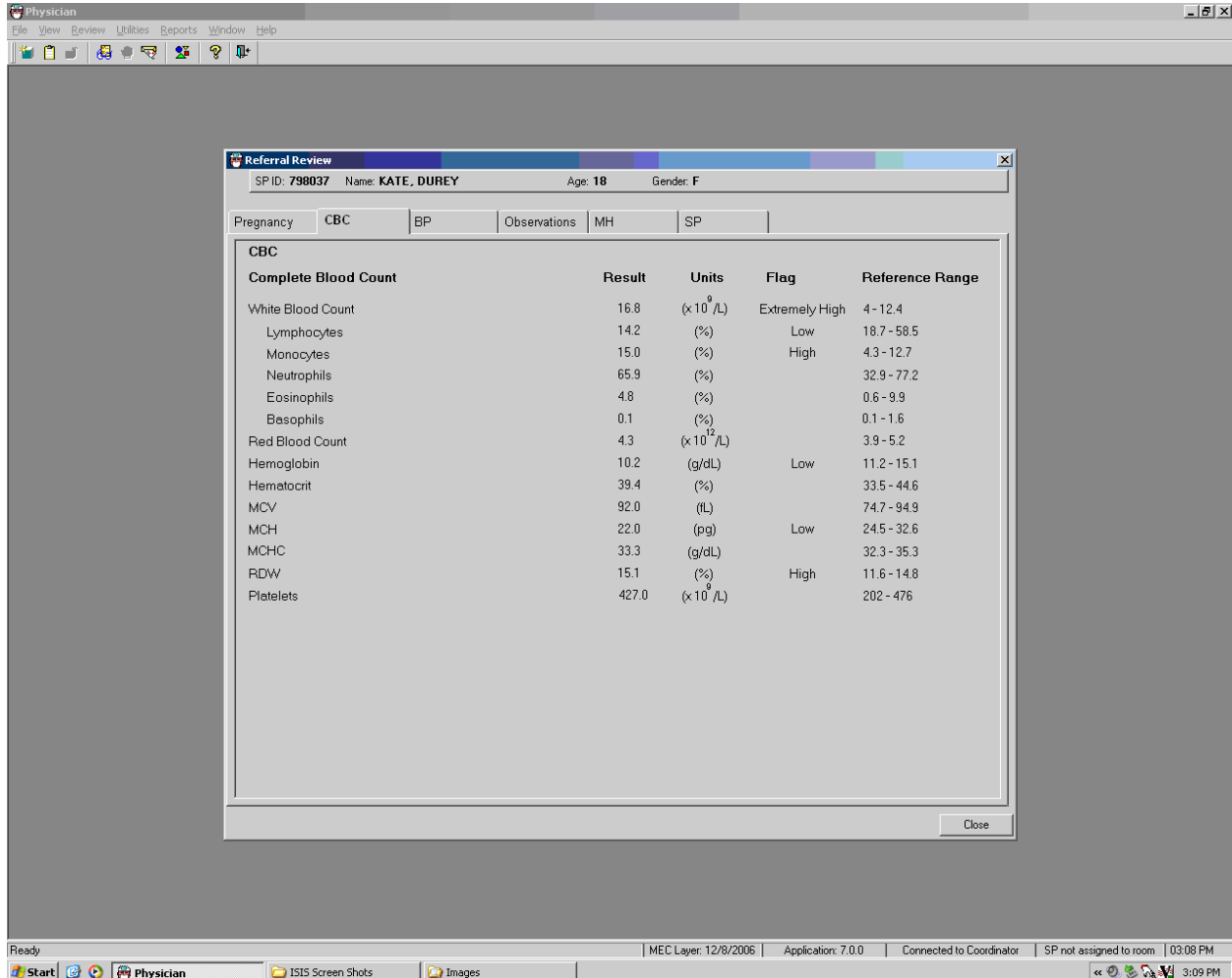
Exhibit 5-15. Details for pregnancy referral



- If the “Pregnancy” tab is checked, the results of the pregnancy test in the lab are displayed. The results can only be one of the following for pregnancy:
 - The pregnancy test is negative;
 - The pregnancy test is positive; or
 - The pregnancy test is invalid.
- Complete the referral as appropriate.

5.10.10 Review in Box for CBC Details

Exhibit 5-16. Details of complete blood count referral (1)



Physician

File View Review Utilities Reports Window Help

Referral Review

SP ID: 798037 Name: KATE, DUREY Age: 18 Gender: F

Pregnancy CBC BP Observations MH SP

CBC

Complete Blood Count	Result	Units	Flag	Reference Range
White Blood Count	16.8	($\times 10^9/L$)	Extremely High	4 - 12.4
Lymphocytes	14.2	(%)	Low	18.7 - 58.5
Monocytes	15.0	(%)	High	4.3 - 12.7
Neutrophils	65.9	(%)		32.9 - 77.2
Eosinophils	4.8	(%)		0.6 - 9.9
Basophils	0.1	(%)		0.1 - 1.6
Red Blood Count	4.3	($\times 10^{12}/L$)		3.9 - 5.2
Hemoglobin	10.2	(g/dL)	Low	11.2 - 15.1
Hematocrit	39.4	(%)		33.5 - 44.6
MCV	92.0	(fL)		74.7 - 94.9
MCH	22.0	(pg)	Low	24.5 - 32.6
MCHC	33.3	(g/dL)		32.3 - 35.3
RDW	15.1	(%)	High	11.6 - 14.8
Platelets	427.0	($\times 10^9/L$)		202 - 476

Close

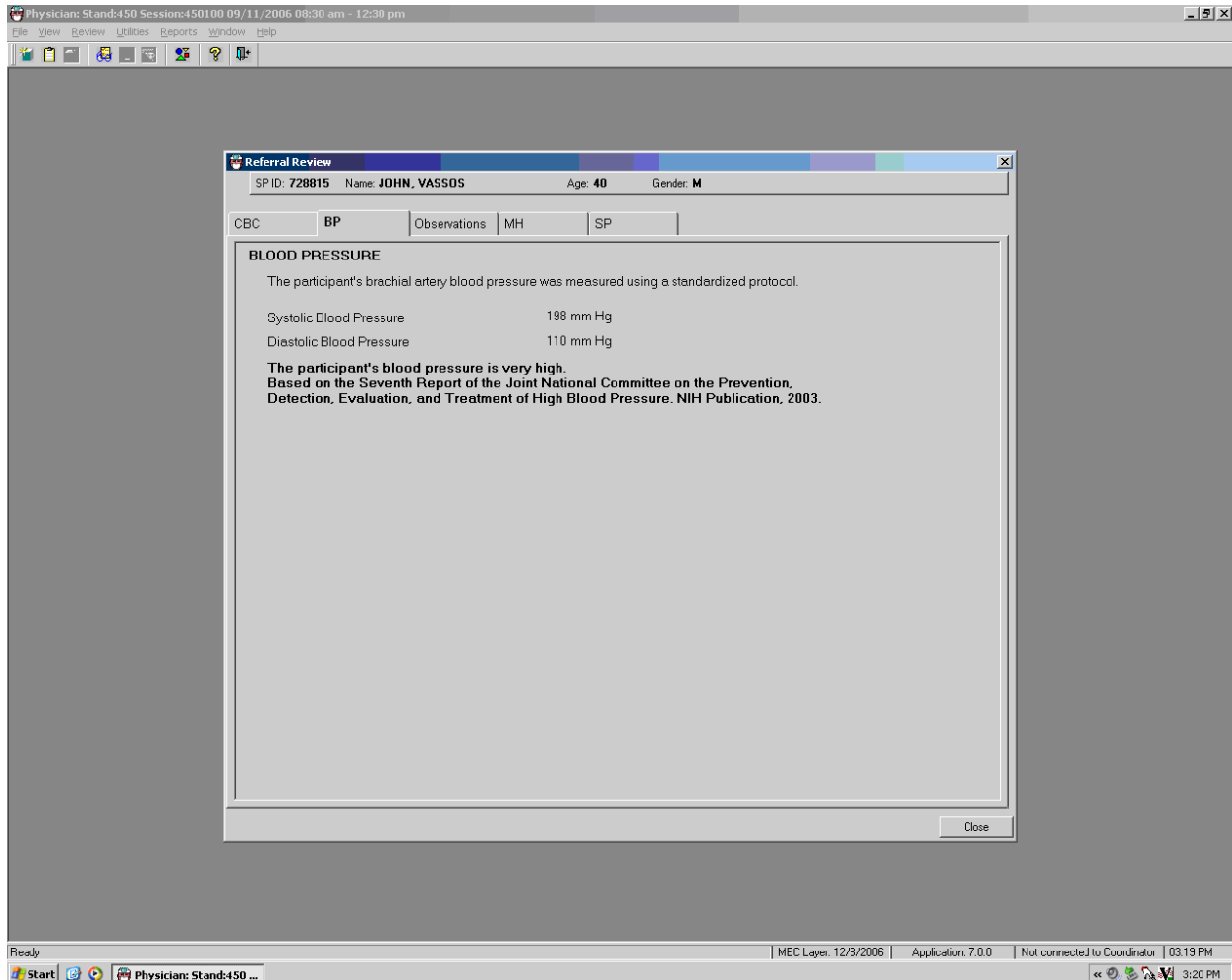
Ready | MEC Layer: 12/8/2006 | Application: 7.0.0 | Connected to Coordinator | SP not assigned to room | 03:08 PM

Start | Physician | 1515 Screen Shots | Images | 3:09 PM

- Click on the CBC tab to review the results of the MEC laboratory CBC.
- The names of the tests are displayed in the left columns along with the units of measurement.
- The reference ranges are displayed in the far right column.
- The results and units of measurement are displayed in the next two columns.
- The flagged items are displayed as “low, high, and extremely high.”
- Complete the referral as necessary.

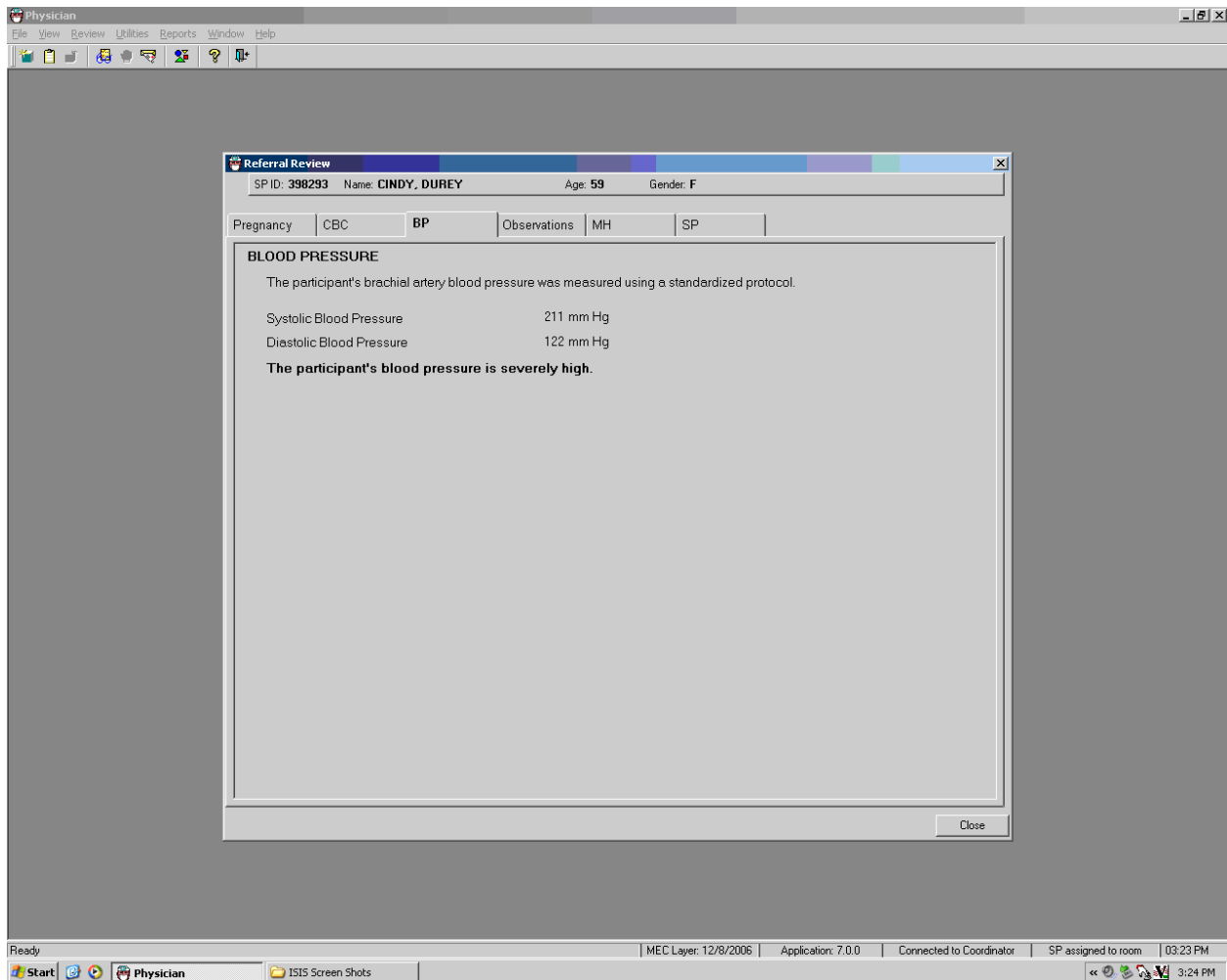
5.10.11 Review in Box – Blood Pressure Details

Exhibit 5-17. Details of very high blood pressure referral



- Click on the blood pressure tab to view the BP results.
- Complete the referral if necessary and enter the appropriate code.
- The blood pressure in the above example is very high for the age group and is a Level 2 referral. These results are discussed with the SP and the physician gives a Level 2 referral letter to the SP. The SP may take this letter to his or her health care provider.
- Click on the “Close” button to exit from this screen.

Exhibit 5-18. Details of severely high blood pressure referral

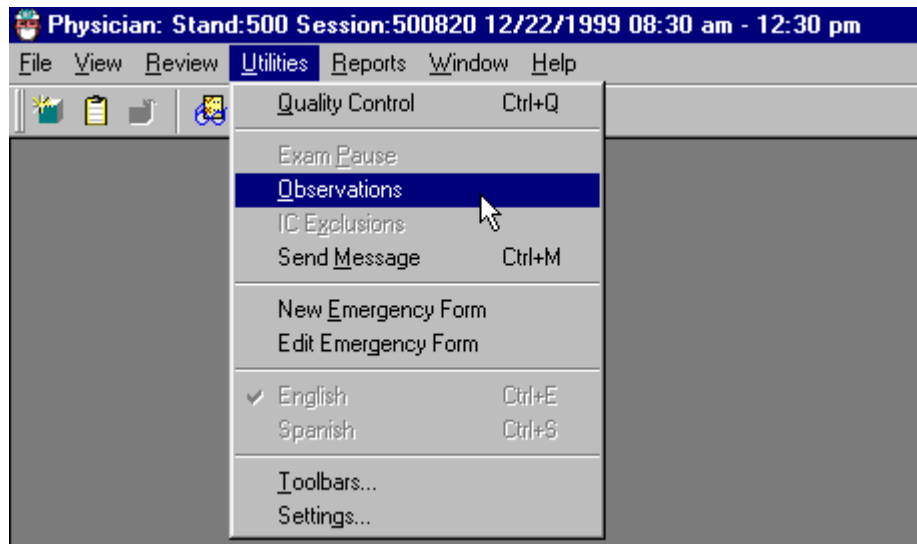


- The blood pressure in the above exhibit is severely high. This is a Level 1 referral. The physician should try to get an immediate referral to the SP's health care provider or to a local clinic.
- Complete the referral as necessary.
- Click on the "Close" button to exit this screen.

5.10.12 Observation Referrals

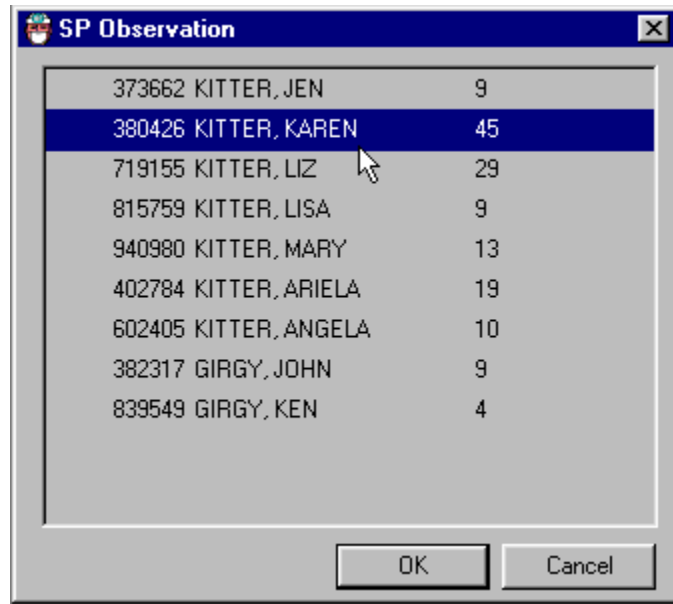
Observation referrals can be displayed by selecting “Observations” from the Utilities toolbar menu. This allows the physician to select any SP from the list of SPs referred for observation. The physician can also select the “Observations” tab from the Review in Box screen for the specific SP being reviewed.

Exhibit 5-19. Utilities menu for selecting observations referrals



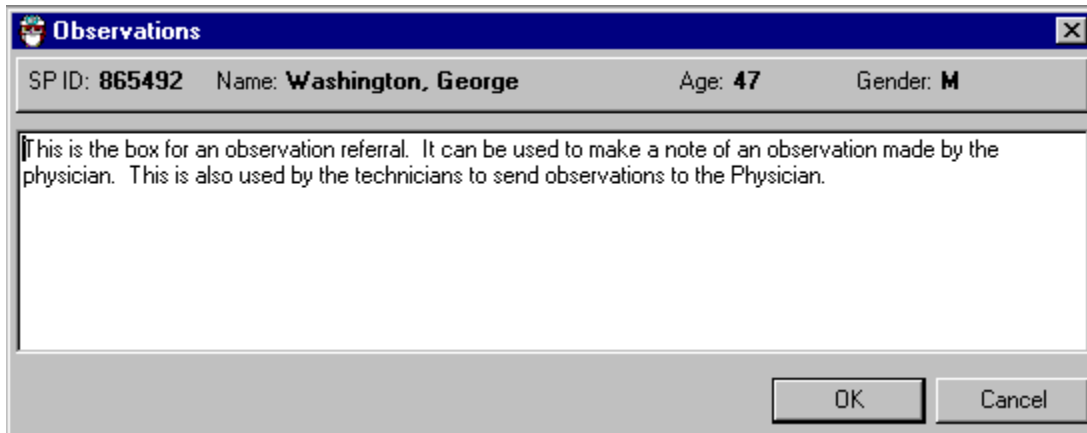
- Select the “Utilities” menu from the toolbar to access the Observations Referral window and then select Observations from the menu.

Exhibit 5-20. SP observation picklist



- The SP Observation picklist will appear with a list of all the names and ages of the SPs in the current session.
- Select the name of the SP for whom the observation referral is needed.

Exhibit 5-21. Observations referral box



- This is the Observations referral box that will be displayed in the other components. The technician will open this box, write the information in the referral information box, and send it to the physician.
- This will be flagged in the physicians exam system and the SP will not be able to leave the MEC until the physician has reviewed this referral.

5.10.13 Referral Letter

Exhibit 5-22. Clinic pick-up medical referral screen

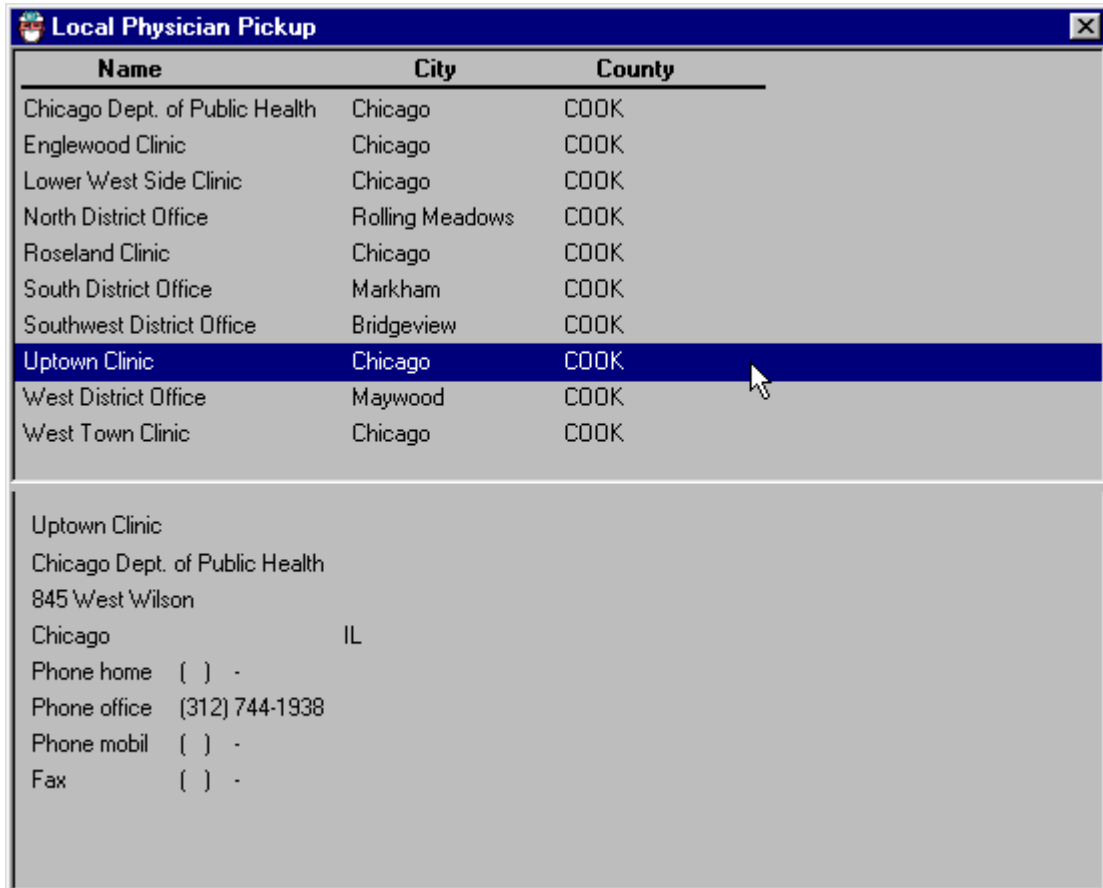
The screenshot shows a software window titled "SP Referral Information" with the following elements:

- Form Fields:** Clinic/Physician Name, Addr.1, Addr.2, City, State, Zip, Contact Name, Phone, Fax.
- medical referral Section:** Includes a checked "Print Referral" checkbox and radio buttons for "Clinic" (selected) and "Physician". A "Clinic Pickup" button is also present.
- Explanation Options:** Radio buttons for "Explained to SP" (selected), "Explained to Guardian", and "Explanation declined".
- Text Areas:** "Description of Explanation", "SP Response", and "Referral Comments".
- Language Selection:** Radio buttons for "English" (selected) and "Spanish".
- Buttons:** Print, Preview, Save, Close.
- Status Bar:** "Create a referral letter", "MEC Layer: 5/21/2004", "Application: Ver 12.6.7B", "Not connected to Coordinator", "04:40 PM".

- When the “Medical Referral” button is clicked, the above box is displayed. Click on “Clinic Pickup” to view a list of local clinics. Click on “Physician” to see a list of local providers.
- The address and phone number will appear in the appropriate boxes.
- Enter a description of your explanation of the referral to the SP, and how the SP responds.
- The box at the bottom of the screen (Referral Comments) is for entering physician comments. These comments will appear on the second page of the referral letter.

5.10.14 Local Physician Pickup

Exhibit 5-23. Local physician and clinic pickup referral letter addresses



Name	City	County
Chicago Dept. of Public Health	Chicago	COOK
Englewood Clinic	Chicago	COOK
Lower West Side Clinic	Chicago	COOK
North District Office	Rolling Meadows	COOK
Roseland Clinic	Chicago	COOK
South District Office	Markham	COOK
Southwest District Office	Bridgeview	COOK
Uptown Clinic	Chicago	COOK
West District Office	Maywood	COOK
West Town Clinic	Chicago	COOK

Uptown Clinic
Chicago Dept. of Public Health
845 West Wilson
Chicago IL
Phone home () -
Phone office (312) 744-1938
Phone mobil () -
Fax () -

- Select the name of the clinic or health care provider.

5.10.15 Referral Address Information

Exhibit 5-24. Local physician and clinic pickup data entered for referral letter information

The screenshot shows a software window titled "SP Referral Information" with a menu bar (File, View, Review, Utilities, Reports, Window, Help) and a toolbar. The form contains the following fields and options:

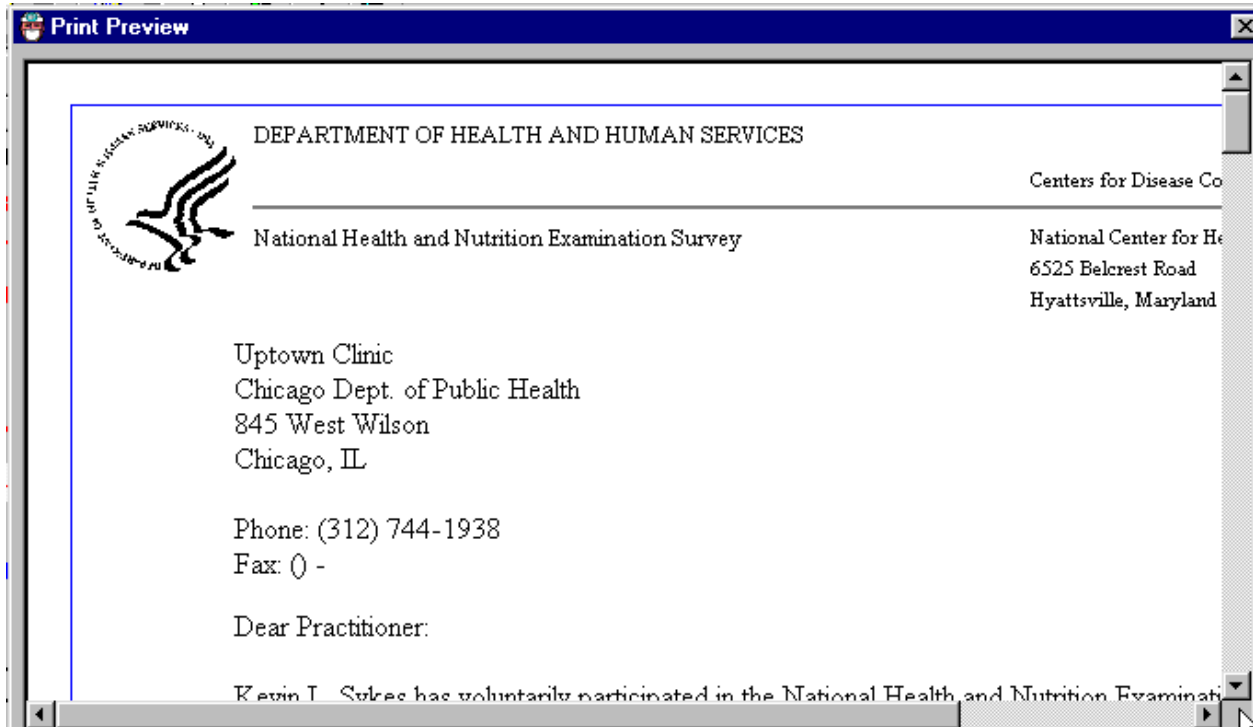
- Clinic/Physician Name:** Text input field.
- Addr.1:** Text input field.
- Addr.2:** Text input field.
- City, State, Zip:** Text input field with dropdowns for state and zip.
- Contact Name:** Text input field.
- Phone:** Text input field with area code dropdown.
- Fax:** Text input field with area code dropdown.
- medical referral:** Section containing:
 - Print Referral**
 - Clinic** (with **Clinic Pickup** button)
 - Physician**
- Description of Explanation:** Text area with radio buttons:
 - Explained to SP
 - Explained to Guardian
 - Explanation declined
- SP Response:** Text area.
- Referral Comments:** Text area.

On the right side, there is a **Language** section with **English** and **Spanish**. Below the form are buttons for **Print**, **Preview**, **Save**, and **Close**. At the bottom of the window, there is a status bar with a **Session Requires Review** checkbox and buttons for **Back**, **Message**, **Referral**, **Print Referral**, **Save**, **Details**, and **Cancel**. The taskbar at the bottom shows the Start button, taskbar icons, and system tray with the time 4:41 PM.

- Describe the explanation given to the SP and the SP response in the appropriate fields. These entries will not appear on the referral letter.
- The “Referral Comments” field may be used to enter comments to the referral physician.

5.10.16 Referral Letter Review


Exhibit 5-25. Preview referral letter



- Select “Preview” from the Session Review in Box screen.
- A preview of the referral letter will be displayed. Use the scroll bar to view all areas of the letter.

5.10.17 Referral Letter

Exhibit 5-26. Referral letter mock-up

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Public Health Service Centers for Disease Control and Prevention
		National Center for Health Statistics 6525 Belcrest Road Hyattsville, Maryland 20782

<Insert Clinics Name> or <SPs Physician>
<Insert Clinic Address>
<Insert Clinic City, ST, Zip>
<Insert Point of Contact>
<Insert Phone Number>

Dear Doctor:

<SP Name> has voluntarily participated in the fourth National Health and Nutrition Examination Survey conducted at special facilities of the U.S. Public Health Service. The objectives of the survey are to obtain information on the health and nutrition status of the U.S. population. As a result of the testing that was done, it was noted that on <Exam Date>, a finding was revealed that was outside the survey's medically acceptable range. This finding is described on the attached Referral Comments page.

<Insert the following paragraph for SPs with Blood Pressure Level 1>
As indicated on the Referral Comments page the participant's blood pressure measurements were severely high. The measurements were taken three times; and the values indicated are the average of the last two measures. All survey participants with severely high blood pressure are instructed to see their doctor or clinic the same day, or go to a hospital emergency room to have their blood pressure rechecked.

This examination is intended to collect health measures for research. It is not a complete physical exam. No attempt has been made to diagnose or treat medical conditions of the participants. The findings disclosed to you are done so with the participant's permission.

Should you have any questions, you may contact me at the Mobile Exam Center. The phone number is <MEC Physician Phone> until <MEC Stand End Date>. After that date you may contact Dr. Kathryn Porter at the National Center for Health Statistics, Monday through Friday 9 AM to 6PM, EST. The toll free number is 1-800-452-6115.

Cordially,

<MEC Physician Name>, M.D.

- The data display for this referral letter includes all areas for referral in a single letter.
- See the next exhibit for the second page that will be attached to this referral.

6. SAFETY ISSUES AND EMERGENCY PROCEDURES

6.1 Safety in the Mobile Examination Center (MEC)

The best approach to emergency situations in the MEC is to prevent problems from developing into emergencies whenever possible, and to be well prepared for those emergencies that cannot be avoided. It is the responsibility of all examination staff members to participate in maintaining safety in the MEC by staying alert for potentially unsafe conditions or unusual sample person (SP) behavior, and by being thoroughly familiar with the current NHANES procedures for emergencies.

Promotion of safety and prevention of accidents and emergencies in the MEC is of particular concern in NHANES in view of the proportion of elderly sample persons that will be participating in the survey. The number of elderly respondents will be significant as a result of an intentional oversampling and removal of the upper age limit on the examination.

6.1.1 Elderly Sample Persons

Care should be taken with all elderly sample persons to minimize confusion and ensure the safe completion of the examination. Elderly SPs should be escorted when moving between exam procedures and the coordinator's area, and should not be left alone for more than a few minutes, such as when changing clothes.

Instructions to elderly SPs should be provided in a clear, calm manner, and repeated as needed. It should not be assumed that the directions are understood until the SP offers an appropriate response. It may be necessary to guide SPs through each step required, such as providing a urine specimen or changing into a gown, to successfully complete a task. If the SP has difficulty understanding or performing tasks, try to offer one instruction or direction at a time and wait until the SP understands before proceeding.

Exam staff should be particularly alert to complaints or concerns from elderly SPs, as elderly SPs may not clearly communicate the extent of their discomfort or concern. Staff members will need to further investigate SP complaints and to refer all potential problems to the MEC physician.

6.1.2 Sample Persons in Wheelchairs

Some SPs may arrive for the examination in wheelchairs, and the exam staff will have to facilitate the SPs' entry into the MEC and their progress through the examination. The field office will alert the MEC manager and coordinator that an examinee uses a wheelchair for mobility so that the handicap lift in trailer #1 can be prepared .

SPs in wheelchairs will enter the MEC through the handicapped access hydraulic lift in Trailer #1, and then will be taken to the reception area where the coordinator will check them in and initiate the exam. The MEC trailers are large enough to allow passage of most wheelchairs. In the event a SP's wheelchair cannot move easily through the MEC, the SP may be transferred to the MEC wheelchair located in the wheelchair-accessible bathroom. If the SP can bear sufficient weight on at least one leg or can otherwise support him or herself during the transfer, the physician and another exam staff member should assist him or her into the MEC wheelchair to facilitate movement throughout the MEC.

Sample persons who cannot bear most of their weight on one leg and need assistance in transferring to the MEC chair should not be lifted or moved out of their wheelchairs. Lifting or moving SPs without their assistance could result in injury to a SP or staff member, and is unwarranted. SPs should remain in their wheelchairs and receive the exams that can be conducted in that position. When the transfer of a SP raises questions, the physician should make the decision to transfer or not transfer a SP.

6.1.3 Children in the MEC

Children in the MEC should be monitored at all times when not participating in an exam component. Young children should not be permitted to walk through the MEC unescorted, and should not interfere with the performance of any examinations.

When waiting for an exam, young or unruly children should remain in the reception area under the supervision of the MEC coordinator and assistant coordinator. Other staff members, when available, may be asked to assist the MEC coordinator and assistant coordinator during particularly busy sessions. A limited collection of small toys are available to entertain young children.

Staff members should be alert to the presence of children in the MEC, and always investigate the behavior of young children walking unattended through the exam center.

6.2 Safety Precautions

A number of precautions have been taken to promote safety in the exam center.

6.2.1 Mobile Exam Center Preparation

- Fire extinguishers have been placed throughout the MEC to allow rapid response to fire. Exit doors are present in every trailer.
- A drug kit, an automated external defibrillator, 2 portable oxygen tanks, and portable blood pressure equipment is kept in one box in the physician's exam room in each caravan. All staff must be able to recognize and locate this equipment without delay.
- Pocket masks for CPR are in the following areas: the coordinator's station, vision room, respiratory health room, body measures room, physician's exam room, MEC interview room #2, dietary interview room #1, the staff room, phlebotomy room, body composition room, dental exam room, and the audiometry room.
- The phone number "911" is to be used to activate EMS if applicable for the MEC location. The telephone number and address of the local fire and rescue squad will also be posted at the coordinator's station and in the staff room by the telephone.
- The address of the MEC will be posted in the coordinator's station and staff room so that the location can be reported correctly to EMS.
- The MEC is a "NO SMOKING" facility. Neither staff nor SPs may smoke in the exam center. Should a staff member or SP have the need to smoke, she or he should step outside the MEC.

6.2.2 Mobile Examination Staff Preparation

- All examination staff members are certified in cardiopulmonary resuscitation, Course Level C, and recertified biannually.
- A physician is required to be present when SPs are in the MEC.

- All examination staff are required to be in the MEC while a session is in progress, and whenever SPs are in the MEC.
- All staff are required to be thoroughly familiar with the safety issues and emergency procedures.
- Mock emergency drills will be held periodically in the mobile exam center to simulate a medical emergency and permit practice of emergency procedures.

6.2.3 On-Site Preparations at Each Stand

- The field office or the advance arrangements team will contact and meet with local fire and rescue representatives to orient them to the location and structure of the MEC.
- The field office will provide advance notice to the MEC coordinator of any SPs who will require assistance entering or moving through the exam center. The coordinator will inform the MEC manager so that appropriate preparations can be made.
- The physician will review the medication history from the household interview for each SP prior to the examination session in which the SP's appointment is scheduled. The SP medication information can be accessed by the physician in the ISIS Physician's Exam application.

6.3 Reporting SP Problems to the MEC Physician

SPs who report feeling ill or who appear to feel ill should be reported to the MEC physician at the earliest opportunity. At times SPs may have nonspecific complaints such as viral illnesses, joint pain, or fatigue that do not appear to warrant an emergency response. Exam staff members should offer to have the physician speak with a SP who has a particular complaint. If the SP is reluctant or refuses, and there is any question about the health or safety of the SP, staff members should consult the physician for recommendations on how to proceed through the exam.

6.4 Medical Management and Referrals

6.4.1 Medical Referrals

Although the primary purpose of the MEC examination is data collection, not diagnosis or treatment, the exam may produce findings that warrant further medical attention. There is an obligation to inform the SP of any abnormal results from the exams, and to refer the SP to the appropriate provider for treatment. The MEC physician is responsible for the referral process. Each exam component has a referral process built into the ISIS system, which will alert the physician to findings that may require a referral. Some of the exam findings may already be known to the SPs and their providers, but others may have been unknown up until the day of the MEC exam. Based on the results of any component of the MEC examination, the physician will place the examinee in one of three categories:

- Level I Major medical findings that warrant immediate attention by a health care provider, e.g., dangerously high blood pressure, emergencies.
- Level II Major medical findings that warrant attention by a health care provider in the next 2 weeks because they are expected to cause adverse effects within this time period.
- Level III Minor medical findings that an examinee and his or her physician already know about. Medical findings that do not require prompt attention by a medical provider.

A Level I referral usually results in termination of the MEC exam, with a transfer of the SP out of the MEC and into a hospital or other care facility. If a SP refuses treatment, she or he must sign a release stating that she or he is aware of the exam findings and is refusing treatment against the advice of the MEC physician. The SP must sign the release form before leaving the MEC.

An SP with a Level II referral can continue the MEC examination, and will be advised to see his or her primary care provider within the 2 weeks following the exam. If the SP does not have a care provider, the MEC physician can arrange for the SP to see a local provider who has previously agreed to accept referrals from the MEC exam. See Chapter 5 of this manual for information on the referral process.

6.4.2 Medical Management

The following section describes some medical scenarios that may occur during the MEC examination and actions to be taken by the MEC physician. The section also provides guidance in determining the level of referral for an examinee.

6.4.2.1 Allergic Reactions

Examinees that experience allergic reactions will be treated according to the procedures adopted from Phil Lieberman, M.D., *Conn's Current Therapy*, 1981, which states: "the therapy of anaphylaxis and anaphylactic reactions is subdivided into those procedures which are to be performed immediately and those which require a more detailed evaluation of the patient prior to transfer to the institution." Procedures that should be instituted immediately are:

1. The administration of epinephrine is the most important single therapeutic measure. Epinephrine should be administered at the first appearance of symptoms. Early administration can prevent more serious manifestations. The route of administration should be intramuscular or subcutaneous. Intravenous administration should be avoided if possible, being reserved only for those rare instances in which there is loss of consciousness and obvious severe cardiovascular collapse.

The dose of intramuscular or subcutaneous epinephrine is 0.3 to 0.5ml of a 1:1000 concentration. Injections may be administered every 10 to 15 minutes until an effect is achieved or until tachycardia or other side effects supervene.

The aforementioned subcutaneous and intramuscular dose is for adults. Children should receive a dose of 0.01 ml per kg of 1:1000 epinephrine to a maximum of 0.3 ml.

2. The airway should be checked immediately. Laryngeal edema and angioedema of the tissue surrounding the airway is the most rapid cause of death.
3. The SP should be placed in a recumbent position and his or her feet elevated.
4. Nasal oxygen should be started.
5. Vital signs should be obtained and monitored every 10 to 15 minutes for the duration of the attack.

After the procedures noted above have been done, a more extensive evaluation can be performed. The injection of epinephrine may be sufficient to prevent further symptoms. If, however, the SP continues to have difficulty, other measures are instituted as deemed appropriate according to the patient's evaluation.

6.4.2.2 First Aid for Choking

Infants, children, and adults who are choking as a result of a foreign body obstruction should be treated according to the guidelines recommended in basic life support courses.

For adults and children older than 1 year, the Heimlich maneuver is the treatment of choice. A series of six to ten rapid, upward abdominal thrusts can be performed until the foreign body is expelled. If the obstruction is not relieved using the Heimlich maneuver, the victim's airway should be opened using the tongue-jaw lift. If the object can be visualized, it can be removed with a finger sweep. If the object cannot be visualized, blind finger sweeps can be attempted on adults. Blind finger sweeps can cause further airway obstruction and should never be done on children.

For choking infants, place the infant face down on the rescuer's forearm in a 60-degree head-down position with the head and neck stabilized. A series of back blows and chest thrusts should be performed until the airway obstruction is relieved.

For further information on treatment of choking victims, both conscious and unconscious, consult the *Emergency Medicine Manual*.

6.4.2.3 Seizures

Examinees who experience a seizure while in the MEC should receive immediate attention from the physician. The following steps should be taken to secure the safety of the examinee:

- Step 1. Position the examinee on the ground.
- Step 2. Insert an oral airway if the jaw is relaxed (do not **force** any object into the mouth).
- Step 3. Remove glasses and loosen collar.

Step 4. Remove objects from vicinity of examinee to prevent injury.

Step 5. Monitor vital signs.

The MEC physician must use his or her clinical judgment based on the examinee's past medical history, the type and duration of the seizure, the cause of the seizure, and current seizure medication to determine whether or not the person needs emergency medical care or can be sent home. The MEC physician is also responsible for maintaining an airway, giving any indicated medications, and directing care of a seizing examinee until an ambulance arrives or the seizure is over.

6.4.2.4 Hypoglycemia

Most conditions of hypoglycemia can be treated while the subject is conscious with the simple administration of juice and other first aid measures. If hypoglycemia is suspected in the case of an unconscious examinee, the following steps may be taken after emergency assistance is summoned:

Step 1. Recognition of hypoglycemia based on available history:

- Bizarre behavior and other clinical signs of possible glucose insufficiency should lead the physician to think of hypoglycemia. Hypoglycemia may develop in both diabetic and nondiabetic individuals.

Step 2. Basic life support:

- Immediate management includes positioning (supine), airway maintenance, oxygen administration, and monitoring of vital signs. The hypoglycemic examinee will not regain consciousness until the blood glucose level is elevated.

Step 3. Definitive management:

- An unconscious person with a prior history of diabetes mellitus is always presumed to be hypoglycemic unless other causes of unconsciousness are present. Definitive management of the unconscious diabetic usually entails the administration of a carbohydrate by the most effective route available. The most effective route is usually intravenous administration of 50 percent dextrose solution. The unconscious examinee must **never** be given anything by mouth, since this may add to the possibility of airway obstruction or pulmonary aspiration. In the absence of intravenous fluids, definitive management must await the arrival of local emergency assistance.

6.4.2.5 Use of Oxygen

When the oxygen tank is used in the MEC, the flow rate should be set between 3-6 liters/minute unless the person has Chronic Obstructive Pulmonary Disease (COPD). With the use of the nasal cannula, a flow range of 3-6 liters/minute produces a forced inspiratory oxygen of 40 to 50 percent.

If the SP has COPD, the flow rate should be set at 2 liters per minute. At this rate, there is little to no danger of interfering with the hypoxic-breathing stimulus present in COPD.

6.5 Emergency Procedures

6.5.1 Medical Emergencies Overview

Before examinations begin at a stand, the facility and equipment specialist (FES) will have obtained information from the advance team about the types and availability of emergency medical services in the area where the MEC is located. The FES will also invite the emergency medical service to tour the MEC prior to the start day of SP examinations. Emergency medical services can include those available at nearby hospitals, hospital ambulance services, and emergency services available from police and fire rescue squads as well as from other county or local rescue squads. The phone number “911” is to be used if applicable for the MEC location. However, the telephone numbers of the nearest police, fire, and rescue squads will also be posted. Execution of emergency procedures and the proper use of all emergency equipment will be the responsibility of the MEC physician. The primary response of the MEC physician should be to stabilize the examinee’s condition and to expedite a safe transfer to the nearest emergency medical treatment facility.

The MEC examinations are designed to be safe for examinees. To ensure maximal safety, the physician must be able to handle the initial management of an examinee in distress.

The response of the physician is limited by a number of factors. There are no nurses, respiratory therapists, physician’s assistants, or other specialized staff that are necessary for a high level emergency response. The MEC is not a diagnostic or treatment center, and the liability insurance obtained for Westat physicians does not cover any type of treatment procedure (except emergency stabilization). Within these restrictions, the appropriate response of the physician should be, as previously stated, to

stabilize the examinee in distress and facilitate a safe and expedited transfer to the nearest medical facility.

The physician is responsible for directing the care of a patient in the event of an emergency. Staff members are responsible for the tasks assigned to them under the direction of the MEC manager and the physician.

The best overall approach to medical emergencies is prevention. The physician may be called upon to decide if some procedures should not be administered to certain examinees to avoid potential medical problems if the examinee does not fit easily into the preexisting medical exclusion categories for that procedure. The examining physician can at his or her discretion proscribe certain procedures such as respiratory health and other tests if he or she believes the test may endanger an examinee's health. The specific reasons for excluding the examinee should be recorded in the system in the comment drop-down list.

Standard first aid approaches are to be followed for common problems such as faints, minor seizures, falls, and other minor injuries. The MEC physician will determine the level of treatment and referral based on the circumstances of each case. Caution should be exercised and there should be no hesitation to send an examinee to an emergency room when circumstances warrant.

The physician is to be notified immediately of any situation involving an examinee whose safety is of concern. Any questionable situation should be considered an emergency and evaluated by the physician. In addition to the equipment and supplies that are transported to the site at the time of the emergency, a list of the medications (prescription and nonprescription) that the examinee is currently taking will be available. The medication list may provide pertinent medical history information to the physician so that a more accurate assessment of the examinee can be made and the appropriate emergency treatment given. The medication list is the one obtained by the interviewer in the household questionnaire, and is available in the Physician's Exam ISIS application.

When ambulance personnel trained in emergency medical care arrive to transport an examinee in distress (Level I referral) the physician should make an assessment of whether he or she should accompany the examinee to the emergency room. The decision should be based on maximizing safety for the examinee. If the physician determines that he or she should accompany the examinee to the hospital, the MEC must be closed. The field office will contact the examinee's family as soon as possible

to inform them of the incident and the medical facility to which the examinee was taken. The physician may also contact the examinee's designated primary health care providers as soon as possible to inform them of the occurrence and name of the medical facility to which the examinee was taken.

6.5.1.1 Emergency Supplies and Equipment

A limited number of emergency supplies are located in the physician's room, described below.

Emergency cardiac and respiratory care supplies located in the physician room:

- Oxygen tanks (2)
 - Primary: Secured to wall above desk
 - Backup: Secured to wall under desk
- Oxygen masks & tubing (kept in oxygen tank carrying case)
 - Nasal Canula: 1 adult, 1 pediatric
 - Oxygen Mask: 1 mask
 - Extension Tubing
- Automatic External Defibrillator
- Emergency Kit - medications
 - Ammonia Ampules
 - Aspirin, 325 mg tablets
 - Epi Pen – Adult
 - Epi Pen – Junior
 - Glucose Tube
 - Nitrostat
 - Albuterol adult and child

- Emergency Kit – supplies
 - Spare AED Battery
 - Pocket BP cuffs – child, adult, & large adult
 - Stethoscope (2) child & adult
 - Protective eyewear
 - Tongue depressor
 - Scissors
 - Pen light
 - Sterile gloves - Two pairs
 - ½” Transpore tape
 - Surgilube packets
 - Oral airways: infant, small, medium, large

The drugs in the emergency kit are described in more detail below in Table 6–1.

Table 6–1. Drugs in emergency kit

Medication	Form supplied	Dose	Route administered
Albuterol (17g)	Metered dose canister	90 mcg/puff	Inhaled
Ammonia	Ammonia Aspirol	0.3 ml	Inhaled
Asprin	Unit dose package	325 mg	Oral
Epinephrine-adult	EpiPen	0.3 mg 1:1000	IM injection
Epinephrine-peds	EpiPen Jr.	0.15 mg 1:2000	IM injection
Glucose – tube	Insta-Glucose 31 gm	1-2 tbsp	Oral
Nitroglycerin (25 tabs)	Nitrostat	0.4mg 1/150gr	Sublingual

Please note the drug kit does not contain antiarrhythmic medications or narcotics. Only the physician should administer emergency procedures and use the contents of the emergency supplies other than the stethoscope and blood pressure cuff.

Oxygen Cylinders and Supplies

There are two size D aluminum oxygen cylinders on the mobile examination center (MEC). The cylinders are 15.27” long by 4.38” diameter with an oxygen capacity of 415 liters. The **PRIMARY** oxygen cylinder is kept in the physician’s room, on top of the leftmost table in the corner, and is secured between the two perpendicular corner walls. The regulator must be attached at all times. The cylinder and regulator are encased in a soft nylon padded carrying bag with a shoulder strap for ease of carrying it during an emergency. Oxygen administration supplies are stored in the external pockets of the bag. The physician is responsible for conducting an inventory of all oxygen administration supplies at stand setup and teardown, and ordering replacements through the inventory management system.

The **BACK-UP** oxygen cylinder is secured to the wall under the desk in the physician’s room. This cylinder and regulator are also encased inside a soft carry bag. When the primary cylinder is off the MEC, the back-up cylinder should be moved to the primary cylinder location until the primary cylinder is returned. The oxygen administration supplies should remain on the MEC at all times.

Oxygen Administration

The **PRIMARY** oxygen cylinder should be used first in all emergencies. If oxygen is depleted from this cylinder, then the **BACK-UP** cylinder should be used. A full cylinder will vary in clinically effective usage time, but an estimate of usage time is approximately 25 minutes when running at 8L/min.

Oxygen is regarded as a medication and should only be administered by or with the direction of a qualified health care provider. On the mobile examination center, the physician is the staff member designated to determine the necessity of oxygen administration, and will provide other MEC staff with instructions regarding method of administration and the flow rate. Whenever oxygen is administered *for any length of time*, the physician is responsible for recording all information regarding the oxygen administration on the Oxygen Usage Log (Attached, Oxygen Usage and Record Form). Any administration of oxygen constitutes an emergency or incident, and the physician must also complete the emergency forms on the MEC.

The back-up oxygen cylinder should be used for all instructional and training purposes. The primary cylinder should never be used for this purpose.

Oxygen Cylinder Monitoring

The MEC manager and the physician are responsible for monitoring the supply of oxygen for both the primary and the back-up cylinders. The regulator readings should be recorded on the **Oxygen Cylinder Monitoring Log** at the following times throughout each stand: on set up day, **every Monday** during the afternoon or evening session, and at teardown. If the team is not working on Monday, then the supply level should be checked the next session worked. Both the MEC manager and the physician are responsible for signing the form when the oxygen level is checked. The completed forms are sent to the home office at the end of the stand with all other end of stand mailings.

Oxygen Tank Refilling/Replacement

When either cylinder is less than one-half full, the facility and equipment specialist is responsible for refilling the cylinder. During SP sessions, one cylinder must be present on the MEC, even if only half full. Never remove both cylinders for refilling at the same time during the stand when SPs will be present. NCHS provides Westat with a prescription letter to be kept with the FES, and a copy of the letter will be retained at the Westat home office. Oxygen suppliers almost always require a prescription for oxygen; however this depends on the laws of individual states. At this time, we do not switch out the cylinder, as is the practice with most oxygen replenishment practices—the cylinders on the MECs are refilled, so that we can provide standardization of the regulators and tanks as the MEC travels across the country.

Automatic External Defibrillator

The Automatic External Defibrillator (AED) requires one battery to function during use. The par level for defibrillator batteries on each MEC is 2. This par level assures that if the primary battery fails, becomes outdated, or is totally discharged during use, that there will be a back-up battery for the AED. The expiration date for each battery is set by the manufacturer, and is recorded on the battery, as

well as on the Physician Examination start of stand and end of stand inventory forms. The importance of assuring the availability of these critical inventory items cannot be overemphasized. This is a start of stand, weekly, mid stand, and end of stand QC check requirement.

Reference Materials in the Physician Exam Room

Reference materials available to the physician include:

1. *The Merck Manual of Diagnosis and Therapy*, 18th Edition. Mark H. Beer, Robert S. Porter, Thomas V. Jones. April 2006. Wiley Publishers;
2. *Physician's Desk Reference 2008*; Thompson Healthcare.
3. *Emergency Medicine Manual*, 6th Edition. O. John Ma, David M. Cline, Judith E. Tintinalli, Gabor D. Kelen, J. Stephan Stapczynski 2004, McGraw-Hill Companies, Inc.

6.5.1.2 MEC Standard Medical Emergency Protocol

Due to the limited space in the MEC trailers, congregations of more than three or four people in one room are almost impossible. Subsequently, staff response to an emergency has been designed to limit the number of people needed to be together at one time. For example, a true cardiac or respiratory arrest requires only three people to be close to the patient for an extended period of time; two staff members to perform CPR and one physician. Two staff members will act as a runner and a recorder, but will be required to do so without hindering the performance of CPR or the physician's access to the patient. Once an ambulance arrives, the path to the victim must be clear to allow transfer to EMS staff. If possible, the closest emergency exit door should be opened for EMS personnel to transfer the patient to an ambulance. Other types of emergencies, such as a fall or a seizure, will require the presence of the physician and only one or two staff as requested by the physician and the MEC manager. There should be no spectators in the vicinity that may inhibit care of a patient.

6.5.1.3 Staff Roles in an Emergency

First Responder

The first responder is the person who either discovers the victim or is with the victim at the time of the event. Do not leave the victim alone at any time. Call for another staff member to alert the coordinator and the physician of the situation immediately and initiate CPR if needed. The first person who responds to your call will be the runner for the event. If another staff member is immediately available, call for that person to assist you with CPR. If no one is available, continue one-person CPR until someone arrives to assist you. Once the physician arrives, explain briefly what happened and she or he will direct care of the patient while you and your partner continue CPR. The physician will also ensure that there is a designated recorder for the event. If the physician is the first person on the scene, she or he should call for help to alert the coordinator and MEC manager immediately and then initiate CPR if needed. The physician should continue one-person CPR until two other staff members arrive to take over CPR while the physician directs care of the patient. The MEC manager will confirm that all roles in the emergency response have been filled, and that all unneeded staff are clear of the area. If the coordinator has taken on a role in the emergency, the MEC manager will assign another staff member to take over for the coordinator. The coordinator will then return to the reception area to manage the SPs in the MEC. If the MEC manager is not in the MEC at the time of the event, the chief health technologist should be notified to follow the MEC manager's emergency protocol responsibilities.

Coordinator

The coordinator's responsibilities in the event of an emergency are as follows:

1. Activate the Emergency Medical Services (EMS) system by calling 911 or other emergency number posted at the coordinator station. Request an ambulance for a medical emergency and give the location of the MEC, which will be posted at the coordinator's station.
2. Notify the MEC manager of the emergency and provide any information you have regarding the need for staff assignments. If the MEC manager is not in the MEC at the time of the event, notify the chief health technologist who will then follow the MEC manager's emergency protocol responsibilities.
3. Retrieve any SPs left unattended in exam rooms while staff members are assisting with the emergency. Staff should remain in the exam rooms with the SPs if they are

not called upon to assist in the emergency. All other SPs should remain in the reception area with the coordinator. If the event occurs in the reception area, SPs in the reception area should be escorted to other exam rooms.

4. Remain in the reception area with the SPs or designate another staff member to do so. Maintain calm and assure SPs the situation is under control.

MEC Manager

The MEC manager's responsibilities in the event of an emergency are as follows:

1. Check that the following staff are on the scene: 1 runner, 1 recorder, 2 people performing CPR, and the physician.
2. Check that all other staff members are clear of the area.
3. Post the assistant coordinator or other available staff member outside the MEC to direct EMS to the site of the emergency.
4. If possible, open the emergency exit closest to the site of the emergency to facilitate transfer of the patient to EMS.
5. Contact the field office immediately after the SP has left the MEC to inform the field office manager of the emergency. The field office will notify the SP's family of the event if the SP came alone to the MEC.

If the MEC manager is not available at the time of the emergency, the chief health technologist will follow the protocol for the MEC manager's responsibilities.

Assistant Coordinator

The assistant coordinator, when available, will be stationed outside the entrance to the MEC and will direct EMS into the MEC and to the site of the emergency. If an emergency exit door has been opened, the assistant coordinator will direct EMS to the emergency exit door to facilitate transfer of the victim. If the assistant coordinator is not available, another staff member can be designated to guide the EMS team.

MEC Physician

The MEC physician is responsible for directing care of the SP until EMS arrives. Once the emergency equipment is on the scene, the physician should ensure that a staff member is recording events on the MEC Incident/Emergency Report form. The physician should not perform tasks such as CPR unless the physician is the first person on the scene. If the physician is the first responder, she or he should begin CPR until two other staff members arrive. The physician is also responsible for the operation of the automated external defibrillator and the administration of medications. The physician will follow the ACLS algorithm and emergency protocols as outlined in the physician manual. When ambulance personnel trained in emergency medical care arrive to transport a SP in distress (Level I referral) the physician should make an assessment of whether she or he should accompany the SP to the emergency room. The decision whether or not to provide an escort to the hospital should be based on maximizing safety for the SP. If the physician determines that she or he should accompany the SP to the hospital, the MEC must be closed. If possible, the physician should obtain consent from the SP or the SP's family to contact the SP's designated primary health care provider as soon as possible to report the occurrence and give the name of the medical facility to which the SP was taken.

Recorder

Any staff member could be called upon to act as recorder for the event. The recorder will be responsible for documenting the time of the emergency and the sequence of events that follow the initiation of emergency care on the MEC Incident/Emergency Report form (Exhibit 6-3).^{*} The order of the events and time sequence are the critical elements in documentation. MEC Incident/Emergency Report forms will be kept in the physician's emergency kit and are available on ISIS by clicking on the ambulance icon in the Toolbox. Instructions for completing this form are found in Exhibit 6-4 of this manual.

^{*} All exhibits are located at the end of this chapter.

Runner

Generally, the first person to respond to the call for help will be the runner for the event. The runner's first responsibility is to notify the physician, the coordinator, and the MEC manager of the event. Once the appropriate people have been notified, the runner is responsible for retrieving supplies and equipment, and making phone calls as directed by staff at the scene.

Other staff members should remain clear of the site and assist in keeping order in the MEC unless asked to help. No SPs should be left alone in the MEC. If a staff member has a role in the emergency and is in the process of examining a SP, the SP will be returned to the reception area while the staff member is in the emergency. All other staff will remain in the exam rooms with SPs until the crisis has passed. The coordinator is responsible for managing SPs in the reception area. The MEC manager is responsible for managing the MEC staff. In the absence of the MEC manager, the chief technologist will manage the MEC staff response during the emergency.

6.5.1.4 The Physician's Role and AED Operation

As explained previously, the MEC is not a diagnostic or treatment center, and the liability insurance obtained for Westat physicians does not cover any type of treatment procedure (except emergency stabilization). The primary response of the MEC physician should be to stabilize the examinee's condition and to expedite a safe transfer to the nearest emergency medical treatment facility. MEC physicians are required to be BLS certified. The physician is the only person responsible for the operation of the automated external defibrillator (AED), and the administration of oxygen and medications (Exhibit 6-1). The AED can be placed on a patient for the purpose of monitoring a heart rhythm, but only one lead will be displayed. The physician is not expected to make a diagnosis based on the AED monitor. The AED should be used only for monitoring a heart rate, or when ventricular tachycardia or ventricular fibrillation is suspected or imminent. Any patient who is unconscious is a candidate for application of the AED. The AED will advise a shock only in the event of ventricular tachycardia or fibrillation. The AED does not have cardioversion capability, nor will the physician be able to deliver a shock if the AED does not advise a shock. As there are no antiarrhythmic medications in the emergency drug kit, the response to a cardiac emergency is basic life support with defibrillation if indicated.

6.5.1.5 Documentation

After the SP has left the MEC, the physician should make sure that the incident and outcome are documented in the automated system in the physician's ISIS application. The physician will also complete a full report on a separate form, the MEC Incident/Emergency Report form, described below. The recorder will also use this form to record events on the scene. The recorder's notes of the event will be especially important in the completion of the physician's report, and should be kept with the physician's documentation of the incident. The MEC manager should review the final report prepared by the physician and add any information not included in the physician's report. The MEC manager's addendum should include only information about the event that is not in the physician's report. Any discrepancies in reports should be brought to the attention of the Director of MEC Operations before being made final. Notification and documentation of the emergency incident should be directed to Catherine Novak, Director of MEC Operations, as soon as possible.

6.5.1.6 MEC Incident/Emergency Report Form

A hard copy form titled "MEC Incident/Emergency Report" will be utilized for recording the sequence of events or actions that are taken during the emergency response. An example of the form is shown in Exhibit 6-3. Guidelines for completion of the form are in Exhibit 6-4. During the emergency, the recorder will use the form to record vitals, treatments, and some patient outcomes. The physician will then use the recorder's notes to complete a final official MEC Incident/Emergency Report form. The MEC manager will then review the final form with the physician and make any necessary additions.

The NHANES Emergency Protocol Checklist (Exhibit 6-2), and the MEC Incident/Emergency Report Form Documentation Guidelines (Exhibit 6-4) are located in the emergency kit in the physician's exam room. The NHANES Emergency Protocol Checklist is also located in the major hallways of the MEC.

6.6 Psychiatric/Behavioral Problem Procedures

There are situations that may arise regarding SP behavior that will require special handling. They include:

- Previous psychological injuries, deterioration, and/or deprivation – Due to changes in mental status, the SP may seem confused or may actually have dementia.
- Intoxication due to alcohol and/or drugs – The SP will be less able to grasp ideas, reason, problem-solve, calculate, and attend to the tasks at hand. Therefore, the potential for injury, trauma, and violence is present.
- Belligerence – This will include SPs with noncompliant or abusive behavior.
- Suicidal/Homicidal Ideation – If a SP expresses intent to harm him/herself or someone else, the SP should be referred to the physician. The physician will evaluate the SP and determine the need for a referral to a psychiatric facility.

If the SP is so demented, confused, intoxicated, or belligerent that it is impossible to continue the examination, the MEC manager should calmly terminate the MEC examination and have the examinee leave the center without delay. For those examinees who require assistance going home, have a family member escort them home or call a cab.

Suicidal and homicidal ideation are considered psychiatric emergencies and are generally handled by referral. Guidelines for handling SPs who express suicidal or homicidal intent are included in the physician's manual.

For any psychiatric emergency, an incident form should be completed, and the incident reported by telephone to the Director of MEC Operations as soon as possible.

6.7 Natural Disaster Procedures

In the event of an unforeseeable occurrence (i.e., hurricane, tornado, fire, etc.), certain procedures should be followed depending on whether the event happens prior to or during an examination session.

6.7.1 Disaster Prior to an Examination Session (Predicted Event)

- The stand coordinator should contact the home office for instructions regarding whether to cancel the session. If the session is canceled, the stand coordinator will then notify the MEC manager, who in turn will notify the MEC staff.
- If residents of mobile homes and trailers have been notified to evacuate, the stand coordinator should make the decision to cancel the session. She or he should then call the home office to report the occurrence and cancellation of the session and notify the MEC manager. The MEC manager should notify the MEC staff.
- The stand coordinator and MEC manager may place the staff on stand-by procedures, with instructions to be ready to work but accessible by phone at home awaiting orders from the MEC manager regarding status of operations.

6.7.2 Disaster During an Examination Session

If an examination session is underway and SPs are in the MEC when the MEC manager or coordinator is notified by the field office of a pending natural event, the following procedures should be followed:

- The MEC manager and the physician should make a joint decision regarding closing the MEC and/or canceling the session. The first priority should be the safety of the SPs and staff.
- The MEC staff and SPs should evacuate the MEC as soon as possible and go directly to a safe haven, such as a building close by or the staff hotel. The staff and SPs should remain at this site until the impending event is over and it is safe to proceed outside.
- After the event, the MEC manager and the physician should decide whether or not to continue the exam session if the SPs are willing to stay for the rest of the session.
- If either the decision is made to cancel the session or the SPs decline to remain, the appointments for those SPs will need to be rescheduled by the field office.
- It is essential for the MEC manager to notify the stand coordinator of the outcome of events. The stand coordinator should then notify the home office immediately.
- Examiners who were conducting an exam or interview at the time evacuation of the MEC was ordered should interrupt the exam in the ISIS system. The reason for interruption of the exam must be accurately documented in ISIS and in room logs as soon as possible after the MEC is reopened.
- The MEC coordinator should be sure to document the reason for exam components omitted because of the closure of the MEC.

Exhibit 6-1. AED Algorithm

Automated External Defibrillation (AED) Treatment Algorithm
Emergency cardiac care pending arrival of EMS personnel

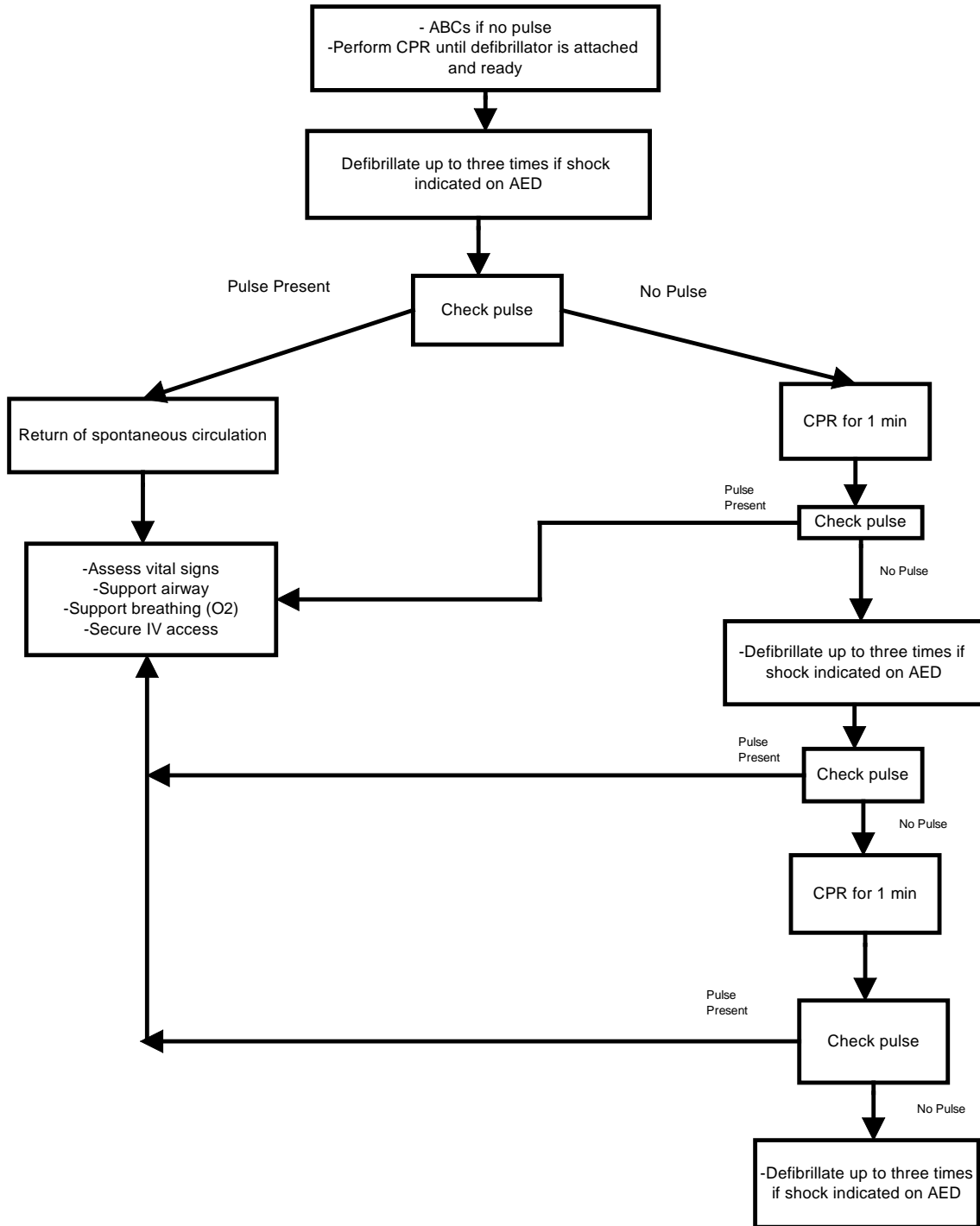


Exhibit 6-2. NHANES Emergency Protocol Checklist

Mobile Examination Center Emergency Management Protocol	
First responder	<ul style="list-style-type: none"> ✎ Call for help and assess victim for A-B-C, and initiate CPR ✎ Send closest staff to notify physician, MEC manager, and coordinator of the emergency; this person assumes the role of runner
Physician:	<ul style="list-style-type: none"> ✎ Direct the care of victim until EMS arrives ✎ Operate automated external defibrillator (AED) ✎ Give medications ✎ Instructs recorder about what to document ✎ Determine if victim needs a physician escort to the hospital
Coordinator:	<ul style="list-style-type: none"> ✎ Activate EMS by calling 911 when advised ✎ Retrieve unattended SPs and return them to the reception area ✎ Remain with SPs in reception area, and provide reassurance ✎ Confer with MEC manager regarding the continuation of exams
MEC manager: <i>In the absence of the MEC manager, the chief health tech will assume this role</i>	<ul style="list-style-type: none"> ✎ Ensure appropriate number of staff for emergency response; assign as necessary ✎ Traffic control ✎ Ensure clear access to the emergency exit door closest to the scene ✎ Post assistant coordinator or other staff member outside the MEC to greet ambulance personnel ✎ Notify the field office of the event once the SP has left
Runner:	✎ Obtain equipment and supplies as directed
Recorder:	✎ Record events on the MEC Emergency/Incident Report Form
Assistant coordinator:	✎ Posted at the door to direct ambulance personnel to emergency site

Staff not requested to be involved in the emergency must stay away from the scene, remain in the exam rooms with SPs, and assist in maintaining order in the MEC.

Exhibit 6-3. MEC Incident/Emergency Report form



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782

MEC INCIDENT/EMERGENCY REPORT

Incident/Emergency

Incident Emergency

Person Type

SP Tech Other

General Information

Physician Name:		Recorder Name:
Emergency Date:		Runner Name(s):
Start Time:	End Time:	Who Called 911:
Location:		Who Found:
Description:		

Personal Information

Person ID:		Age:	Gender:
Last Name:	First Name:	Middle Name:	

DEPARTMENT OF HEALTH & HUMAN SERVICES



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782

Vitals

Time	Heart Rate	Systolic BP	Diastolic BP	Respiratory Rate	Comments

Treatment

Time	Medication/Equipment	Comment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782

Symptoms

Empty text box for recording symptoms.

Observation

Empty text box for recording observations.

Assessment

Empty text box for recording assessment.

Plan

Empty text box for recording the plan.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782

Urgent Care

<input type="checkbox"/> Transported to Hospital	Hospital Name:	
Ambulance Arrival Time:		Ambulance Departure Time:
Emergency Service Name:		
<input type="checkbox"/> Physician Accompanied SP to Hospital		

Notification

<input type="checkbox"/> Family Member Notified	Name:	Date/time:
Relation:		
<input type="checkbox"/> Family Physician Notified	Family Phys Named:	Date/time:

Signature: _____

Date: _____



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782

Vitals

Time	Heart Rate	Systolic BP	Diastolic BP	Respiratory Rate	Comments

Exhibit 6-4. MEC Incident/Emergency Form Documentation Guidelines

The Vitals and Treatment sections on page 2 should be completed first during the emergency. If the spaces on page 2 are insufficient, the last page should be used for recording vital signs. The “comments” section of the last page can be used to record treatments. The remaining sections should be completed as soon as the emergency is over. The recorder should collect most of the information requested on page 1 before turning the notes over to the physician for compilation of the final report. The following information is to be documented:

Page 1:

- Check either Incident or Emergency, depending on the event. The difference is to be determined by the physician and the MEC manager;
- Check whether the person was a SP, a tech, or other (such as a guest or someone who has accompanied a SP to the exam);
- Names of the physician, runner, recorder, person who called 911, and person who found the victim;
- Date of the emergency response;
- Time that the emergency response started, beginning from the time the victim was found;
- Time that the emergency response ended, i.e., time the ambulance arrived or time the victim left the MEC;
- Location of the emergency in the MEC;
- Description of the victim upon discovery; and
- If the victim is a SP, escort, or guest, the sample number, age, gender, and first and last names should be recorded. If the victim is a staff member, the first and last names are sufficient.

Page 2:

- Vitals and Treatment sections to be recorded at the time of the event by the recorder.

Page 3:

- The sections Symptoms, Observation, Assessment, and Plan are to be completed by the physician after the event.

Exhibit 6-4. MEC Incident/Emergency Form Documentation Guidelines (continued)

Page 4:

- The section Urgent Care is to be completed by the physician if the SP is transported to a hospital;
- The section Notification will be completed by the MEC manager after notifying the field office of the emergency; and
- If the physician has obtained consent from the SP or the SP's family to contact the SP's care provider, the physician must record the name of the physician and the date and time the physician was notified of the SP's status.

7. DOCUMENTATION OF INCIDENTS AND EMERGENCIES

7.1 Incident Forms

If an incident occurs in the MEC, the physician is called to assess the SP. The physician completes an Incident Form as soon as possible after the incident has occurred. Blank Incident/Emergency Forms are kept in the emergency kit in the Physician Exam Room. Blank Incident/Emergency Forms may also be printed directly from the ISIS system using the following steps:

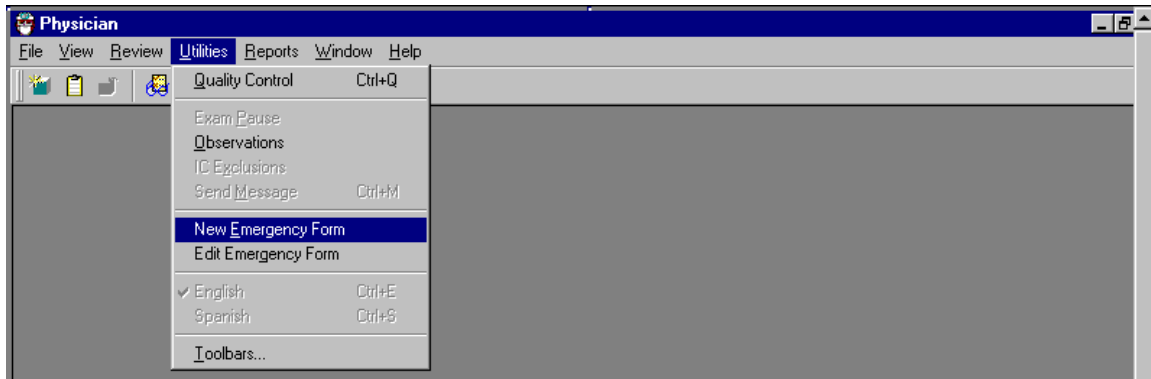
- At the Desktop, open Microsoft Word.
- Select “File.”
- Select “Open.”
- Go to the network drive.
- Select MEC STAFF “H.”
- Select “Blank Forms.”
- Select “Incident/Emergency Forms.”
- A blank form will be opened in “Read-only” mode.
- Select “Print” and click “OK” to print a hard copy of the blank form.

The blank form can be used to temporarily record the details of the incident if it is not convenient to enter the information directly into the system.

At a convenient time, the information is entered directly into the system.

See Exhibit 7-1 for the “Utilities” menu. Exhibit 7-2 is a blank Incident Form. Exhibit 7-3 shows an Incident Form with the vitals completed.

Exhibit 7-1. Utilities menu for Incident/Emergency Form



At the “Utilities” menu, select “New Emergency Form” and press “Enter.”

Exhibit 7-2. Incident Form – blank

A screenshot of the "Incident/Emergency Form" window. At the top, there are radio buttons for "Incident" (selected) and "Emergency". To the right, there is a "Person Type" section with radio buttons for "SP" (selected), "Tech", and "Other". Below this, there are several input fields: "Phys. ID:" (1221), "Recorder Name:" (dropdown), "Emergency Date:" (05/22/06), "Runner Name(s):" (dropdown), "Start Time:" (02:03 PM), "End Time:" (00:00 AM), "Who Called 911:" (dropdown), "Location:" (text), and "Who Found:" (dropdown). A "Description:" text area is below these. A "Personal Info" section contains fields for "Person ID:", "Age:", "Gender:", "Last name:", "First name:", and "Middle name:". Below the form is a tabbed interface with tabs for "Vitals", "Symptoms", "Observation", "Assessment", "Plan", "Misc.", "Treatment", "Urgent Care", and "Notification". The "Vitals" tab is active, showing a table with columns for "Time:", "Heart Rate:", "Systolic:", "Diastolic:", "Respiratory Rate:", and "Comments:". At the bottom, there are buttons for "Insert", "Delete", "Print", "Close", and "Save".

- Select “Incident” or “Emergency” as appropriate.
- Select the “Person Type.” The choices are “SP,” “Staff,” or “Other.” “Other” may include visitors or guests.

- The “Date” is automatically entered as the current date. If the incident occurred on an earlier date, the date entered should be the date the incident occurred. The date is a required field.
- The “Start Time” is automatically entered as the time the form was opened. If the incident occurred at an earlier time, the time entered should be the time the incident started. The start time is a required field. Please pay careful attention to this field in order to document the incident/emergency accurately.
- **NOTE:** “AM” is changed to “PM” by pressing “Shift-P” (press the Shift key and the P key) and “PM” is changed to “AM” by pressing “Shift A” (press the Shift key and the “A” key).
- The “End Time” is the time the incident was resolved. This is a required field.
- Enter the location where the incident occurred in the “Location” field.
- Enter a brief description of the incident in the “Description” field.
- Enter the SP’s (or staff) ID in the ID field and press the Tab key. The remainder of the “Personal Information” will be automatically entered.

Exhibit 7-3. Incident Form – vitals

The screenshot shows a software window titled "Incident/Emergency Form". It has two tabs: "Incident" (selected) and "Emergency". Under "Person Type", there are radio buttons for "SP" (selected), "Tech", and "Other".

The form contains several input fields:

- Phys. ID: 1221
- Recorder Name: Brown, Francesca K
- Emergency Date: 05/22/06
- Runner Name(s): Brown, Francesca K
- Start Time: 03:26 PM
- End Time: 03:36 PM
- Who Called 911: [empty]
- Location: Mec1
- Who Found: [empty]
- Description: fghggihghgig

Below these fields is a "Personal Info" section with:

- Person ID: 123456
- Age: 22
- Gender: Male
- Last name: koon
- First name: Jack
- Middle name: [empty]

At the bottom of the form are several tabs: "Vitals" (selected), "Symptoms", "Observation", "Assessment", "Plan", "Misc.", "Treatment", "Urgent Care", and "Notification".

The "Vitals" tab contains a table with the following data:

Time:	Heart Rate:	Systolic:	Diastolic:	Respiratory Rate:	Comments:
03:26 AM	80	102	78	10	conscious, orientated x3, no injuries
03:36 AM	76	106	76	10	alert, orientated, wants to continue with exams

At the bottom of the window are buttons for "Print", "Close", "Save", "Insert", and "Delete".

- To add a line to enter “Vitals” information, right click (click the right button on the mouse) and select “Add” or “Insert.” This may also be used to delete a line.
- Enter the time the vital signs were taken and then enter the heart rate/minute, systolic and diastolic blood pressure, and respiratory rate/minute.
- Enter a comment to describe the SP’s condition at the time the vital signs were taken. Add additional lines as necessary.

Exhibit 7-4. Incident Form – observations

Click on the Symptoms, Observation, Assessment, Plan, or the miscellaneous (Misc.) tab to open the appropriate field. Information for each of the fields is entered as free text (Exhibit 7-4).

Exhibit 7-5. Incident Form – save

Incident/Emergency Form

Incident/Emergency
 Incident Emergency

Person Type
 SP Tech Other

Phys. ID: 1221 **Recorder Name:** Brown, Francesca K
Emergency Date: 05/23/06 **Runner Name(s):** Brown, Francesca K
Start Time: 08:25 AM **End Time:** 10:00 AM **Who Called 911:**
Location: phlebotomy **Who Found:** Carolyn, Stevens
Description: fainted after blood draw

Personal Info
Person ID: 123456 **Age:** 39 **Gender:** Female
Last name: sommere **First name:** simone **Middle name:**

Physician
 Do you want to close without save changes?

Vitals | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification

Time:	Heart Rate:	Systolic:	Diastolic:	Respiratory Rate:	Comments:
10:30 AM	80	102	78	10	conscious, orientated x3, no injuries
10:40 AM	76	106	76	10	alert, orientated, wants to continue with exams

- Select “File” and choose “Save” to close and save the form.
- If you close without saving, a message will be displayed “Do you want to save changes?” (See Exhibit 7-5.)
- Click “Yes” if you want to close and save the form or changes made to the form.
- Click “No” if you want to close without saving the form or changes made to the form.
- Click “Cancel” if you do not want to close the form at this time.

Exhibit 7-6. Incident Form – required fields

Physician Stand-410 Session:410001 06/16/2006 01:30 pm - 05:30 pm

Incident/Emergency Form

Incident/Emergency: Incident Emergency

Person Type: SP Tech Other

Phys. ID: 1221 Recorder Name: Brown, Francesca K

Emergency Date: 05/23/06 Runner Name(s): Brown, Francesca K

Start Time: 08:25 AM End Time: 00:00 AM Who Called 911: Physician

Location: phlebotomy Who Found: Carolyn, Stevens

Description: wanted after blood draw

Personal Info: Person ID: 123456 Age: 39 Gender: Female
Last name: sommore First name: simone Middle name:

Vitals Symptoms Observation Assessment Plan Misc. Treatment Urgent Care Notification

Time	Heart Rate	Systolic	Diastolic	Respiratory Rate	Comments
10:30 AM	80	102	78	10	conscious, orientated x3, no injuries
10:40 AM	76	106	76	10	alert, orientated, wants to continue with exams

Save changes | MEC Layer: 5/12/2006 | Application: 6.1.10 | Not connected to Coordinator | 08:31 AM

If you try to close the form without entering an “End Time,” a message will be displayed “Please enter a valid time.” (See Exhibit 7-6.) Click “OK” and enter the time the incident/emergency was completed.

If you try to close the form and the “End Time” is not valid (end time must be later than start time), the above message will be displayed. Click “OK” and enter the correct time.

Exhibit 7-7. Incident Form tab marks – vitals

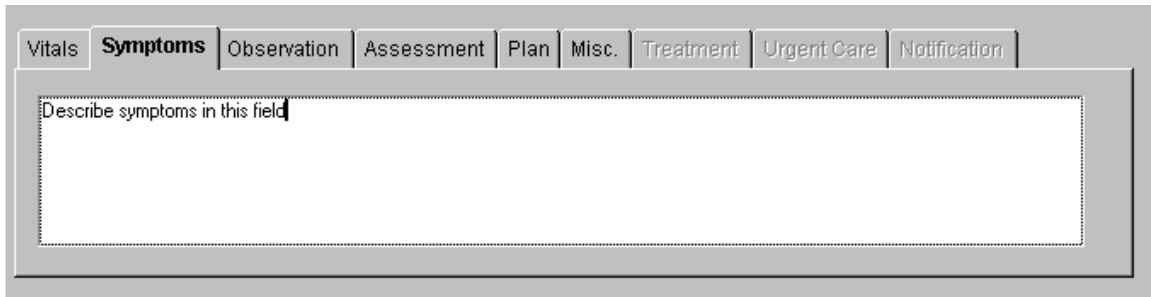
Vitals Symptoms Observation Assessment Plan Misc. Treatment Urgent Care Notification

Time	Heart Rate	Systolic	Diastolic	Respiratory Rate	Comments
10:30 AM	80	102	78	10	conscious, orientated x3, no injuries
10:40 AM	76	106	76	10	alert, orientated, wants to continue with exams

Insert Delete

Exhibit 7-7 shows the tab for “Vitals” for both the Incident and Emergency Forms.

Exhibit 7-8. Incident Form – symptoms



The screenshot shows a web-based form interface with a horizontal tabbed menu at the top. The tabs are labeled: Vitals, **Symptoms**, Observation, Assessment, Plan, Misc., Treatment, Urgent Care, and Notification. The 'Symptoms' tab is highlighted with a dark background and white text. Below the tabs is a large, empty rectangular text area with a dotted border. The text 'Describe symptoms in this field' is positioned at the top left of this area.

Exhibit 7-8 shows the tab for “Symptoms” for both Incident and Emergency Forms.

Exhibit 7-9. Incident Form – observation



The screenshot shows the same web-based form interface as Exhibit 7-8. In this view, the 'Observation' tab is selected and highlighted. The text area below the tabs is empty, with the text 'Describe observations in this field' at the top left. A vertical scrollbar is visible on the right side of the text area.

Exhibit 7-9 shows the tab for “Observations” for both Incident and Emergency Forms.

Exhibit 7-10. Incident Form – assessment



The screenshot shows the same web-based form interface. The 'Assessment' tab is selected and highlighted. The text area below the tabs is empty, with the text 'Describe assessment in this field' at the top left. A vertical scrollbar is visible on the right side of the text area.

Exhibit 7-10 shows the tab for “Assessment” for both Incident and Emergency Forms.

Exhibit 7-11. Incident Form – plan

Vitals	Symptoms	Observation	Assessment	Plan	Misc.	Treatment	Urgent Care	Notification
Describe plan in this field								

Exhibit 7-11 shows the tab for “Plan” for both Incident and Emergency Forms.

Exhibit 7-12. Incident Form – miscellaneous

Vitals	Symptoms	Observation	Assessment	Plan	Misc.	Treatment	Urgent Care	Notification
Use this field for miscellaneous comments.								

Exhibit 7-12 shows the tab for “Miscellaneous” for both Incident and Emergency Forms.

7.1.1 Incident Report Hard-Copy Form

Exhibit 7-13. Incident Report hard-copy form

Incident Report for Bobby Simone						02/14/1999
General Information						
Person Type: SP	Recorder Name: Trumbore, Steve					
Emergency Date: 02/14/1999	Runner Name(s):					
Start Time: 10:25 AM	End Time: 10:50 AM	Who Called 911:				
Location: phlebotomy	Who Found: Edwards, Philessia					
Description: fainted after blood draw						
Personal Info						
Person ID: 589231	Age: 39		Gender: Male			
Last name: Simone	First name: Bobby			Middle name:		
Symptoms						
Describe symptoms in this field						
Vitals						
Time:	Heart Rate:	Systolic:	Diastolic:	Respiratory Rate:	Comments:	
10:30 AM	80	102	78	10	conscious, orientated x3, no injuries	
10:40 AM	76	106	76	10	alert, orientated, wants to continue with exams	
Observations						
Describe observation in this field						
Assessment						
Describe assessment in this field.						
Plan						
Describe plan in this field						
Miscellaneous						
Use this field for miscellaneous comments.						

Exhibit 7-13 is a hard-copy printout of an Incident Report Form.

7.2 Emergency Forms

Exhibit 7-14. Emergency Form – blank

The screenshot shows a software window titled "Incident/Emergency Form". At the top, there are two sections: "Incident/Emergency" with radio buttons for "Incident" and "Emergency" (selected), and "Person Type" with radio buttons for "SP", "Tech", and "Other" (selected). Below these are several input fields: "Phys. ID:" (10), "Recorder Name:" (dropdown), "Emergency Date:" (02/14/1999), "Runner Name(s):" (dropdown), "Start Time:" (10:39 AM), "End Time:" (00:00 AM), "Who Called 911:" (dropdown), "Location:" (text), and "Who Found:" (dropdown). A "Description:" text area is also present. A "Personal Info" section includes "Person ID:", "Age:", "Gender:", "Last name:", "First name:", and "Middle name:". Below this is a tabbed interface with tabs for "Vitals", "Symptoms", "Observation", "Assessment", "Plan", "Misc.", "Treatment", "Urgent Care", and "Notification". The "Vitals" tab is active, showing a table with columns for "Time:", "Heart Rate:", "Systolic:", "Diastolic:", "Respiratory Rate:", and "Comments:". The table is currently empty.

The data entry for the Emergency Form (Exhibit 7-14) is similar to data entry for the Incident Form.

- Select "Incident" or "Emergency" as appropriate.
- Select the "Person Type." The choices are "SP," "Staff," or "Other." "Other" may include visitors or guests.

The "Date" is automatically entered as the current date. If the incident occurred earlier, the date entered should be the date the incident occurred. The date is a required field.

The "Start Time" is automatically entered as the time the form was opened. If the incident occurred earlier, the time entered should be the time the incident started. The "Start Time" is a required field. Please pay careful attention to this field in order to document the emergency accurately.

NOTE: "AM" is changed to "PM" by pressing "Shift-P" (press the Shift key and the P key) and "PM" is changed to "AM" by pressing "Shift A" (press the Shift key and the A key).

Exhibit 7-15. Emergency Form – data

Incident/Emergency Form

Incident/Emergency
 Incident Emergency

Person Type
 SP Tech Other

Phys. ID: 1221
Recorder Name: Brown, Francesca K
Emergency Date: 05/23/06
Runner Name(s): Brown, Francesca K Cheney, Jillian May
Start Time: 08:48 AM **End Time:** 00:00 AM
Who Called 911: Carolyn, Stevens
Location: Bathroom, trailer 4
Who Found: DeCosta, Kelley N.
Description: found unconscious in bathroom

Personal Info
Person ID: 123456 **Age:** 16 **Gender:** Male
Last name: koon **First name:** rascal **Middle name:**

Vitals | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification

Time:	Heart Rate:	Systolic:	Diastolic:	Respiratory Rate:	Comments:
08:50 AM	60	90	54	8	unconscious, shallow respirations, weak pulse
09:00 AM	62	96	68	10	conscious, confused

Insert Delete

Exhibit 7-15 shows a completed Emergency Form. The “End Time” is the time the incident was resolved. This is a required field.

- Enter the location where the incident occurred in the “Location” field.
- Enter a brief description of the incident in the “Description” field.
- Enter the SP’s (or staff) ID in the ID field and press the Tab key. The remainder of the “Personal Information” will be automatically entered.
- To add a line to enter “Vitals” information, right click (click the right button on the mouse) and select “Add” or “Insert.” This may also be used to delete a line.
- Enter the time the vital signs were taken and then enter the heart rate/minute, systolic and diastolic blood pressure, and respiratory rate/minute.
- Enter a comment to describe the SP’s condition at the time the vital signs were taken.
- Add more lines as necessary.

- Enter free text information in the Vitals, Symptoms, Observation, Assessment, Plan, and Miscellaneous fields.
- To add a line to enter “Treatment” information, right click (click the right button on the mouse) and select “Add” or “Insert.” This may also be used to delete a line.
- Enter the time the treatment was administered.
- Select the “Medication” administered or “Equipment” used by clicking on the arrow to pull down the menu with the list of medications.
- Highlight the appropriate medication.

The medications in the emergency kit are displayed in Exhibits 7-16 and 7-17.

Exhibit 7-16. Emergency Report Form – treatment 1

Vitals	Symptoms	Observation	Assessment	Plan	Misc.	Treatment	Urgent Care	Notification
Time:		Medication/Equipment:				Comment:		
12:10 AM		<div style="border: 1px solid black; padding: 5px;"> Glucose - tube 1-2 tbsp PO (Insta-Glucose 31 gm.) Ringers Lactate - 1000 ml IV Nitroglycerin - 0.4 mg 1/150gr SL (Nitrostat) Oxygen - nasal canula Oxygen - Mask Defibrillator </div>						
						Insert	Delete	

Exhibit 7-17. Emergency Report Form – treatment 2

Vitals	Symptoms	Observation	Assessment	Plan	Misc.	Treatment	Urgent Care	Notification
Time:		Medication/Equipment:				Comment:		
12:10 AM		<div style="border: 1px solid black; padding: 5px;"> Albuterol - 90 mcg/puff - inhalation (metered dose canister) Ammonia - 0.3 ml - inhalation (ammonia aspirol) Dextrose - 5% 500 ml IV Dextrose - adult - 50% 50 ml 500 mg/ml IV (prefilled) Dextrose - child - 25% 10 ml 250 mg/ml IV (prefilled) Epinehprin - adult - 0.3 mg 1:1000 - IM (EpiPen) </div>						
						Insert	Delete	

Additional medications or equipment in the pick list for Emergency Medications/Equipment.

Exhibit 7-18. Emergency Report Form – urgent care

The screenshot shows the 'Urgent Care' tab selected in a software interface. The form contains the following elements:

- Transported to hospital
- Hospital Name:
- Ambulance arrival time:
- Ambulance departure time:
- Emergency Service Name:
- Physician accompanied SP to Hospital

- If the SP needs to be transported to a hospital or clinic, click on the “Urgent Care” tab (Exhibit 7-18).
- Check the box labeled “Transported to hospital.”
- Enter the name of the hospital in the “Hospital Name” field.
- Enter the arrival and departure time of the ambulance.
- Enter the name of the Emergency Service.
- Check the appropriate box if the physician accompanied the SP to the hospital.

Exhibit 7-19. Emergency Report Form – notification

The screenshot shows the 'Notification' tab selected in a software interface. The form contains the following elements:

- Family Member Notified
- Name:
- Relation:
- Date/time:
- Family Physician Notified
- Physician Name:
- Date/time:

- Click on the “Notification” tab and enter information about notification of family member and/or physician (Exhibit 7-19).

7.2.1 Emergency Report Hard-Copy Form

An example of the hard-copy printout of the Emergency Report Form is displayed in Exhibits 7-20 and 7-21.

Exhibit 7-20. Emergency Report hard-copy form (page 1)

Emergency Report for Thomas Jefferson

02/14/1999

General Information

Person Type: SP Recorder Name: Braddock, Ivy
 Emergency Date: 02/14/1999 Runner Name(s): Guerrero, Olga Pinkerton, Ronald
 Start Time: 10:44 AM End Time: 11:30 AM Who Called 911: Trumbore, Steve
 Location: Bathroom, trailer 4 Who Found: Maples, Sean
 Description: found unconscious in bathroom,

Personal Info

Person ID: 705142 Age: 46 Gender: Male
 Last name: Jefferson First name: Thomas Middle name:

Symptoms

Vitals

Time	Heart Rate:	Systolic:	Diastolic:	Respiratory Rate:	Comments:
10:45 AM	52			8	unconscious, shallow respirations, weak pulse
10:50 AM	58	96	68	10	conscious, confused,

Observations

Describe observations in this field.

Assessment

Describe assessment in this field.

Plan

Describe plan in this field.

Miscellaneous

Additional field for miscellaneous comments.

Treatment

Time:	Medication/Equipment:	Comment:
10:45 AM	Oxygen - nasal canula	

Exhibit 7-21. Emergency Report hard-copy form (page 2)

Emergency Report for Thomas Jefferson		02/14/1999
Urgent Care		
<input type="checkbox"/> Transported to hospital	Hospital Name:	
Ambulance arrival time: 00:00 AM	Ambulance departure time: 00:00 AM	
Emergency service name:		
<input type="checkbox"/> Physician accompanied SP to Hospital		
Notification		
<input checked="" type="checkbox"/> Family Member N	Name: Mary	Date/time: 02/14/99 11:00 AM
	Relation: wife	
<input checked="" type="checkbox"/> Family Physician Notified	Family Physician Name: Comstock	Date/time: 02/14/99 11:30 AM

8. QUALITY CONTROL

8.1 Elements of the Quality Control Program

To ensure complete and accurate data collection, the quality control program for this study will take place in mobile examination centers (MECs) and will consist of the following major elements:

- Training and calibrating of the physicians with gold standard expert;
- Monitoring equipment and equipment repair, and verifying weekly calibrations; and
- Site visit observations by NCHS and Westat.

8.2 Training and Calibrating of Physicians with Gold Standard Expert

The protocol for blood pressure measurement follows procedures developed by the American Heart Association. The physicians underwent initial training and certification in blood pressure measurement through a training program provided by an independent expert consultant. This certification process included didactic presentations, video presentations that included listening to and recording Korotkoff sounds, and practice listening to blood pressures of volunteers with a certified instructor. Certification is achieved when all requirements of the training program are met, as well as quarterly monitoring by the consultant. Ongoing training needs as identified by the home office staff and NCHS will be assessed and scheduled.

8.3 Monitoring Equipment and Equipment Repair

The equipment and room supplies need to be checked on a regular basis. Some checks are completed daily and others need only be completed on a weekly basis or at the beginning and end of each stand. These checks include calibration checks, maintenance inspection of equipment and supplies, and preparation of the room and equipment for the session exams. The specific timeframes for equipment QC are as follows: start of stand, daily, weekly, and end of stand.

All of the Quality Control (QC) processes are recorded into the computer application, which reminds the physicians to perform the time sensitive QC procedures. If the QC procedures have not been completed for that time period, this message will be displayed at each logon until the QC procedures have been completed for that time period. The home office component staff monitors the equipment QC completion rates, and provides feedback and/or retraining as warranted.

Each time you log onto the application, the system will remind you to do Quality Control (QC) checks if the checks have not been completed for that time period. The specified QC checks performed at the beginning of stand, daily, weekly, and end of stand are selected by the physician. If you do not have time to do the checks when you logon, you can bypass this message and complete the checks at a later time. However, this message will be displayed each time you logon until you have completed the checks for that time period. After you have completed the checks and entered this in the system, the message box with the remainder will not be displayed again until the appropriate time period has passed.

8.3.1 Maintenance of Equipment

Physicians maintain all equipment used in their component. The following sections specifically state the requirements that physicians follow to check equipment and maintain equipment used for the BP measurements. The following items are checked on a routine basis.

8.3.2 Inflation System (BP cuffs)

1. Cuff material is clean, intact.
2. Clean all cuffs with a disinfectant wipe.
3. Velcro is functional and free of lint/debris.
4. Rubber tubing and inflation bulb is smooth, has no cracks or tears.
5. Pressure control valve opens and closes smoothly without sticking.

8.3.3 Littmann Cardiology III Stethoscopes

1. Check the stethoscope for cracks in the tubing.
2. Earpieces are securely attached.
3. Head of stethoscope is securely attached to tubing.
4. Diaphragm is secure, no cracks.

8.3.4 Mercury Sphygmomanometer

1. The shape of the meniscus (top of the column of mercury) should be a smooth, well-defined curve. If not, replace the equipment. This is usually caused by dirt/oxidation in the mercury or the glass tube.
2. Check that the mercury rises easily in the tubing and mercury does not bounce noticeably when inflated. If the mercury does not rise easily in the tube, or if the mercury column bounces noticeably as the valve is closed, replace the equipment.
3. Disconnect the inflation system from the cuff and confirm that the meniscus of the mercury in the glass manometer tube is zero.
4. Check for cracks in the glass tube.
5. Check the screw at the top of the calibrated glass tube to make sure it is securely in place.
6. Check the coiled air tube for cracks, tears.
7. Inflation system testing protocol to test for air leaks (test all BP cuffs in this manner):
 - Connect each size cuff to the inflation system and wrap it around the corresponding calibration cylinder;
 - Inflate to 250 mm Hg;
 - Open valve and deflate to 200 mm Hg and close valve;
 - Wait for 10 seconds; if mercury column drops more than 10 mm Hg, there is an air leak in the system; and
 - If a leak is detected, change the cuff, check the coiled tubing and repeat the test.

8.3.5 Omron HEM-907XL

1. Wipe the monitor with a soft, damp cloth.
2. Confirm function settings: (F1 = 3 inflations, F2 = 0 waiting before 1st inflation, and F3 = 30 second interval between inflations).
3. Mode setting = average, P-Set = AUTO.
4. Make sure that the AC adapter cord of the OMRON unit is securely plugged in (it has a tendency to get disconnected from the unit).
5. Check the air tube for cracks, and confirm that the tube is securely attached to the Omron.
6. Omron calibration protocol:
 - Connect the mercury manometer, adult cuff, and the Omron air tube with the T-tube;
 - Tightly wrap the adult cuff over the calibration cylinder;
 - Release the valve of inflation bulb to remove the air inside the cuff completely;
 - Push the ON/OFF button to turn on the monitor;
 - Set the MODE selector to "CHECK;"
 - Close the valve of inflation bulb and inflate the cuff to 300, 250, 200, 150, 100, 60, and 0 mm Hg;
 - Compare the pressure values displayed on the monitor to the one on the mercury manometer and record the OMRON reading at each level;
 - The Omron should be validated to be ± 3 mmHg of the manometer reading; and
 - If the Omron readings are not falling within ± 3 mm Hg, re-check the inflation system, and repeat the Omron calibration; if the Omron continues to fail the calibration procedure, replace the Omron, send the unit back to the NHANES warehouse, and submit a UFO that explains what was observed during the calibration procedure.

8.4 Frequency of QC Procedures

The designated intervals for the BP QC procedures are: start of stand, daily checks, weekly checks, and end of stand checks.

8.4.1 Daily QC Checks

1. Check to see if the level of mercury in glass tube is zero.
2. Check the shape of the meniscus.
3. Check that the mercury rises easily in the tubing and does not bounce noticeably.
4. Check for cracks in the glass tube.
5. Check that the cap at the top of the calibrated glass tube is secure.
6. Check pressure control valve for sticks or leaks.
7. Wipe both sides of BP cuffs with disinfectant wipes.

8.4.2 Weekly QC Checks

1. Complete daily checks.
2. Check functioning of all emergency equipment.
3. Complete inventory of emergency medications.
4. Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears.
5. Check stethoscope diaphragm for cracks.
6. Inflation system testing protocol to test for air leaks with the mercury manometer.
7. Perform the Omron calibration protocol with the mercury manometer at 300 mm, 250 mm, 200 mm, 150 mm, 100 mm, 60 mm, and 0 mm Hg.

8.4.3 Start of Stand Checks

1. Complete daily checks.
2. Complete weekly checks.
3. Perform Omron calibration protocol with the mercury manometer at 300 mm, 250 mm, 200 mm, 150 mm, 100 mm, 60 mm, and 0 mm Hg.

8.4.4 End of Stand Checks

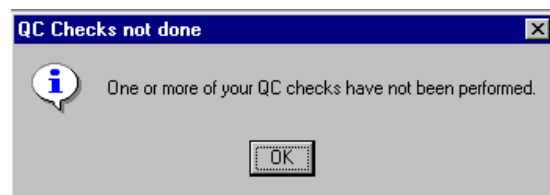
Perform the Omron calibration protocol with the mercury manometer at 300 mm, 250 mm, 200 mm, 150 mm, 100 mm, 60 mm, and 0 mm Hg.

8.5 ISIS Data Entry Screens for QC on Equipment

8.5.1 Data Entry Screens for QC on Equipment

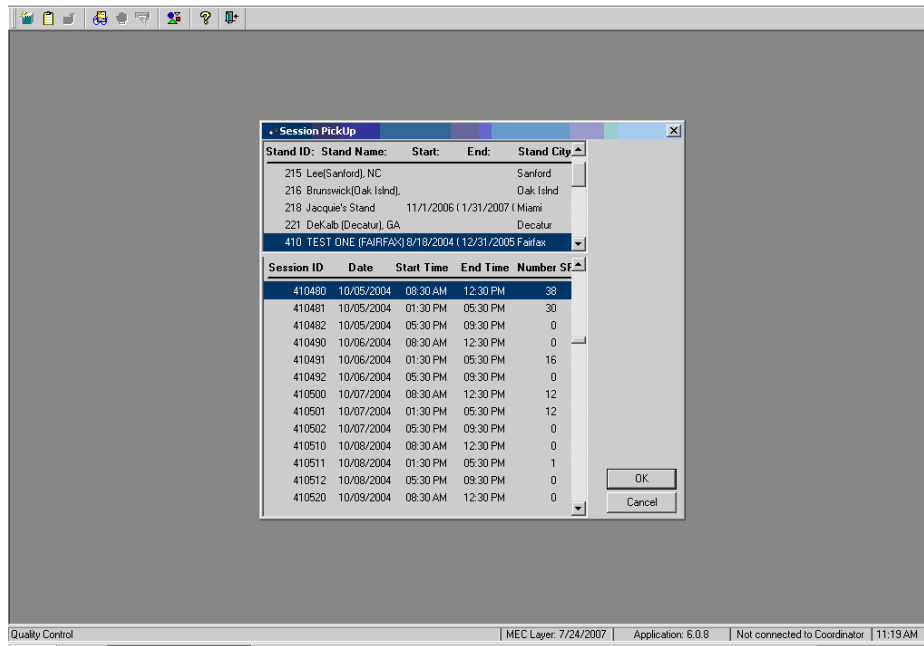
When you log onto the application (Exhibit 8-1) before the Quality Control checks are performed, the system displays a message: “One or more of your QC checks have not been performed.”

Exhibit 8-1. Quality control logon with reminder message



Click “OK” to this message. When you want to complete the QC checks, select “Utilities,” then select Quality Control from the menu (Exhibit 8-2). Clicking on the QC icon from the Toolbar can also access the QC screens. When QC is selected from the Utilities menu, the Session Pick-Up box will be displayed. Select the current session.

Exhibit 8-2. Session Pick-Up Box

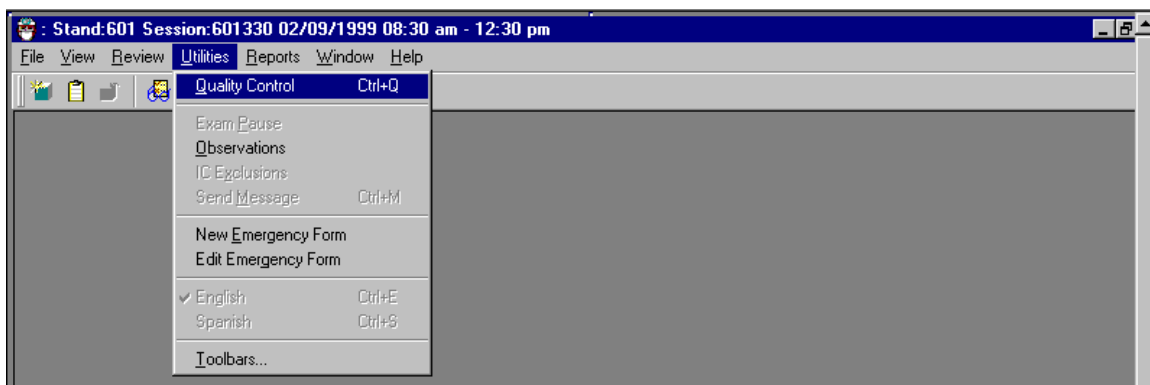


Each physician will have a personal ID. This ID will be used to identify the person who completed the QC checks for this time period. Enter your User ID and click “OK.” If you do not want to do the QC checks at this time, click “Cancel.” You will still be able to conduct the exam:

When you want to complete the QC checks, select “Utilities,” then select Quality Control from the menu (Exhibit 8-3).

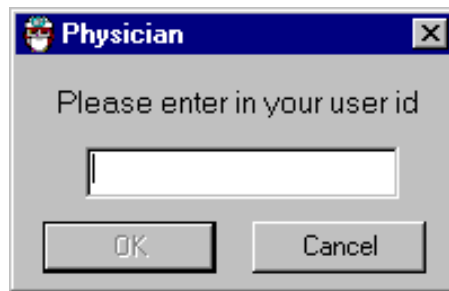
Clicking on the QC icon from the Toolbar can also access the QC screens.

Exhibit 8-3. Utilities menu to select Quality Control



When QC is selected from the Utilities menu, the User ID entry box (Exhibit 8-4) will be displayed.

Exhibit 8-4. Quality Control log-on



A dialog box titled "Physician" with a close button (X) in the top right corner. The text inside reads "Please enter in your user id". Below the text is a single-line text input field. At the bottom of the dialog are two buttons: "OK" and "Cancel".

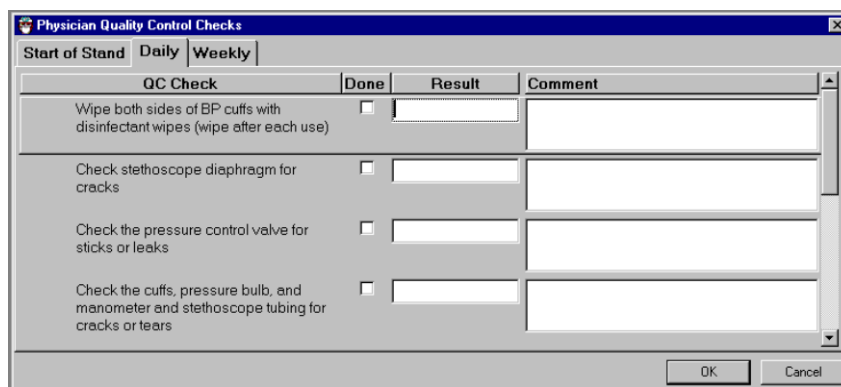
Each physician will have a personal ID. This ID will be used to identify the person who completed the QC checks for this time period.

Enter your User ID and click "OK."

If you do not want to do the QC checks at this time, click "Cancel."

On the QC screens, check "Done" for the listed items when that item has been completed (Exhibit 8-5).

Exhibit 8-5. Example of a Quality Control screen



A screenshot of a software window titled "Physician Quality Control Checks". At the top, there are three tabs: "Start of Stand", "Daily", and "Weekly", with "Daily" selected. Below the tabs is a table with four columns: "QC Check", "Done", "Result", and "Comment". The table contains four rows of checks, each with a checkbox in the "Done" column and an empty text box in the "Result" column. At the bottom right of the window are "OK" and "Cancel" buttons.

QC Check	Done	Result	Comment
Wipe both sides of BP cuffs with disinfectant wipes (wipe after each use)	<input type="checkbox"/>		
Check stethoscope diaphragm for cracks	<input type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input type="checkbox"/>		
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input type="checkbox"/>		

You are not required to enter anything in the “Result” or “Comment” fields unless there is a problem with the equipment. The “Result” field is used to enter values for selected QC items if required. The “Comments” field is used to enter information about problems encountered with the QC item check.

8.5.2 Daily Checks

On the QC daily checks screens, check “Done” for the listed items when that item has been completed (Exhibits 8-6 to 8-9).

Exhibit 8-6. Quality Control daily checks (1)

QC Check	Done	Result	Comment
Check to see that the level of mercury in glass tube is zero	<input checked="" type="checkbox"/>		
Check the shape of the meniscus	<input checked="" type="checkbox"/>		
Check that the mercury rises easily in the tubing and does not bounce noticeably	<input checked="" type="checkbox"/>		
Check for cracks in the glass tube	<input checked="" type="checkbox"/>		

Exhibit 8-7. Quality Control daily checks (2)

QC Check	Done	Result	Comment
Check for cracks in the glass tube	<input checked="" type="checkbox"/>		
Check that the cap at the top of the calibrated glass tube is secure	<input type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input type="checkbox"/>		
Wipe both sides of BP cuffs with disinfectant wipes (wipe after each use)	<input type="checkbox"/>		

Use the scroll bar to move to the next item on the list.

Exhibit 8-8. Quality Control daily checks (3)

The screenshot shows a dialog box titled "Physician Quality Control Checks" with tabs for "Start of Stand", "Daily", "Weekly", and "End of Stand". The "Daily" tab is selected. Below the tabs is a table with the following structure:

QC Check	Done	Result	Comment
Check for cracks in the glass tube	<input checked="" type="checkbox"/>		
Check that the cap at the top of the calibrated glass tube is secure	<input type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input type="checkbox"/>		
Wipe both sides of BP cuffs with disinfectant wipes (wipe after each use)	<input type="checkbox"/>		

At the bottom right of the dialog box are "OK" and "Cancel" buttons.

Exhibit 8-9. Quality Control daily checks (4)

The screenshot shows a dialog box titled "Quality Control Checks" with tabs for "Start of Stand", "Daily", "Weekly", and "End of Stand". The "Daily" tab is selected. Below the tabs is a table with the following structure:

QC Check	Done	Result	Comment
Mercury: Glass manometer tube has no cracks	<input checked="" type="checkbox"/>		
Mercury: Glass manometer tube is clean	<input checked="" type="checkbox"/>		
Mercury: Cap at the top of the calibrated glass tube is securely in place	<input checked="" type="checkbox"/>		
Check the pressure control valve for sticks or leaks	<input checked="" type="checkbox"/>		

At the bottom right of the dialog box are "OK" and "Cancel" buttons.

When you are finished with the daily item checks, click "OK" to close the QC box.

8.5.3 Weekly Checks

Exhibit 8-10. Quality Control weekly checks (1)

The screenshot shows a software window titled "Physician Quality Control Checks". It has a menu bar with "Start of Stand", "Daily", "Weekly", and "End of Stand". The "Daily" option is selected with a checkmark. Below the menu bar is a table with three columns: "QC Check", "Done", "Result", and "Comment". The table contains four rows of checks, each with a checked "Done" box and empty "Result" and "Comment" boxes. At the bottom right are "OK" and "Cancel" buttons.

QC Check	Done	Result	Comment
Complete daily checks	<input checked="" type="checkbox"/>		
Check functioning of all emergency equipment	<input checked="" type="checkbox"/>		
Complete inventory of emergency medications	<input checked="" type="checkbox"/>		
Check the cuffs, pressure bulb, and manometer and stethoscope tubing for cracks or tears	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 8-11. Quality Control weekly checks (2)

The screenshot shows the same software window as Exhibit 8-10, but the table is scrolled down to show items 5 through 8. Each item has a checked "Done" box and empty "Result" and "Comment" boxes.

QC Check	Done	Result	Comment
Check stethoscope diaphragm for cracks	<input checked="" type="checkbox"/>		
Mercury reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		

Exhibit 8-12. Quality Control weekly checks (3)

The screenshot shows the same software window as Exhibit 8-10, but the table is scrolled down to show items 9 through 12. Each item has a checked "Done" box and empty "Result" and "Comment" boxes.

QC Check	Done	Result	Comment
OMRON reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 8-13. Quality Control weekly checks (4)

QC Check	Done	Result	Comment
OMRON reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

When you are finished with the weekly item checks, click “OK” to close the QC box .

8.5.4 Start of Stand Checks

The start of stand checks consist of screens in Exhibits 8-14 to 8-18.

Exhibit 8-14. Quality Control start of stand checks (1)

QC Check	Done	Result	Comment
Complete daily checks	<input checked="" type="checkbox"/>		
Complete weekly checks	<input checked="" type="checkbox"/>		
Remove all BP cuffs from bladder and clean cuffs.	<input checked="" type="checkbox"/>		
Mercury reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 8-15. Quality Control start of stand checks (2)

The screenshot shows a window titled "Physician Quality Control Checks" with tabs for "Start of Stand", "Daily", "Weekly", and "End of Stand". The "Start of Stand" tab is active. Below the tabs is a table with columns "QC Check", "Done", "Result", and "Comment". The first four rows are visible, each with a checked "Done" box and empty "Result" and "Comment" fields.

QC Check	Done	Result	Comment
OMRON reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		

Buttons for "OK" and "Cancel" are located at the bottom right of the window.

Use the scroll bar to move to the remaining items.

Exhibit 8-16. Quality Control start of stand checks (3)

The screenshot shows the same window as Exhibit 8-15, but the scroll bar has been moved down. The visible rows in the table are items 3 through 5.

QC Check	Done	Result	Comment
OMRON reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		

Buttons for "OK" and "Cancel" are located at the bottom right of the window.

Use the scroll bar to move to the remaining items.

Exhibit 8-17. Quality Control start of stand checks (4)

The screenshot shows the same window as Exhibit 8-15, but the scroll bar has been moved further down. The visible rows in the table are items 5 through 8.

QC Check	Done	Result	Comment
OMRON reading 5 at 100 mm Hg	<input type="checkbox"/>		
Mercury reading 6 at 60 mm Hg	<input type="checkbox"/>		
OMRON reading 6 at 60 mm Hg	<input type="checkbox"/>		
Mercury reading 7 at 0 mm Hg	<input type="checkbox"/>		

Buttons for "OK" and "Cancel" are located at the bottom right of the window.

Use the scroll bar to move to the remaining items.

Exhibit 8-18. Quality Control start of stand checks (5)

The screenshot shows a software window titled "Physician Quality Control Checks" with a tabbed interface. The "Start of Stand" tab is selected. Below the tabs is a table with three columns: "QC Check", "Done", "Result", and "Comment". There are four rows of checks. The first three rows have their "Done" checkboxes checked, while the fourth is unchecked. Each row has a corresponding empty text box for the "Result" and "Comment" columns. At the bottom right of the window are "OK" and "Cancel" buttons.

QC Check	Done	Result	Comment
Mercury reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 7 at 0 mm Hg	<input type="checkbox"/>		

Use the scroll bar to move to the remaining items.

8.5.5 End of Stand Checks

The end of stand checks consist of the calibrations screens as in Exhibits 8-19 – 8-22.

Exhibit 8-19. Quality Control end of stand checks (1)

The screenshot shows the same software window as Exhibit 8-18, but with the "End of Stand" tab selected. The table now contains four rows of checks, all with their "Done" checkboxes checked. Each row has an empty text box for the "Result" and "Comment" columns. The "OK" and "Cancel" buttons are still present at the bottom right.

QC Check	Done	Result	Comment
Mercury reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 1 at 300 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 2 at 250 mm Hg	<input checked="" type="checkbox"/>		

Use the scroll bar to move to the remaining items.

Exhibit 8-20. Quality Control end of stand checks (2)

The screenshot shows a window titled "Physician Quality Control Checks" with tabs for "Start of Stand", "Daily", "Weekly", and "End of Stand". The "End of Stand" tab is active. A table lists four QC checks, each with a checked "Done" box, an empty "Result" box, and an empty "Comment" box. The items are:

QC Check	Done	Result	Comment
Mercury reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 3 at 200 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 4 at 150 mm Hg	<input checked="" type="checkbox"/>		

Buttons for "OK" and "Cancel" are at the bottom right.

Use the scroll bar to move to the remaining items.

Exhibit 8-21. Quality Control end of stand checks (3)

The screenshot shows the same window as Exhibit 8-20, but the scroll bar has moved down. The table now shows items 5 and 6:

QC Check	Done	Result	Comment
Mercury reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 5 at 100 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		

Buttons for "OK" and "Cancel" are at the bottom right.

Use the scroll bar to move to the remaining items.

Exhibit 8-22. Quality Control end of stand checks (4)

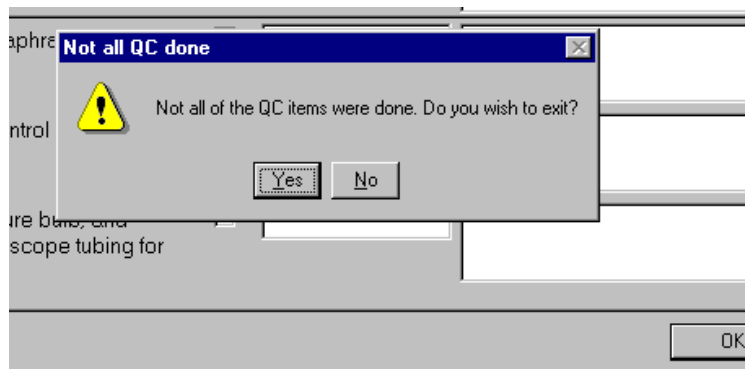
The screenshot shows the same window as Exhibit 8-21, but the scroll bar has moved down further. The table now shows items 6 and 7:

QC Check	Done	Result	Comment
Mercury reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 6 at 60 mm Hg	<input checked="" type="checkbox"/>		
Mercury reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		
OMRON reading 7 at 0 mm Hg	<input checked="" type="checkbox"/>		

Buttons for "OK" and "Cancel" are at the bottom right.

When you have completed all checks, click “OK” to close the QC box. If you do not check that all items are complete, the system will display this message: “Not all the QC items were done. Do you wish to exit?”

Exhibit 8-23. Quality Control incomplete entry



If you want to complete the items before exiting, click “No” to this message and complete the items. If you do not wish to complete all QC checks, click “Yes” to this message. If all QC items were not complete, the system will remind you each time you logon that the QC checks are not complete.

Appendix A

Child Blood Pressure Values

APPENDIX A. CHILD BLOOD PRESSURE VALUES

Girls – Age 6

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<68	68 - 71	72 - 85	≥ 86
< 104	1	2	3	4
104 - 107	2	2	3	4
108 - 120	3	3	3	4
≥ 121	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<68	68 - 71	72 - 85	≥ 86
< 105	1	2	3	4
105 - 108	2	2	3	4
109 - 121	3	3	3	4
≥ 122	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<69	69 - 72	73 - 85	≥ 86
< 106	1	2	3	4
106 - 109	2	2	3	4
110 - 122	3	3	3	4
≥ 123	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<70	70 - 73	74 - 86	≥ 87
< 108	1	2	3	4
108 - 110	2	2	3	4
111 - 124	3	3	3	4
≥ 125	4	4	4	4

**Child Blood Pressure Values
Girls - Age 6 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<70	70 - 73	74 - 87	≥ 88
< 109	1	2	3	4
109 - 112	2	2	3	4
113 - 125	3	3	3	4
≥ 126	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 88	≥ 89
< 110	1	2	3	4
110 - 113	2	2	3	4
114 - 126	3	3	3	4
≥ 127	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 88	≥ 89
< 111	1	2	3	4
111 - 114	2	2	3	4
115 - 127	3	3	3	4
≥ 128	4	4	4	4

**Child Blood Pressure Values
Girls - Age 7**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<69	69 - 72	73 - 86	≥ 87
< 106	1	2	3	4
106 - 109	2	2	3	4
110 - 122	3	3	3	4
≥ 123	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<70	70 - 73	74 - 86	≥ 87
< 107	1	2	3	4
107 - 110	2	2	3	4
111 - 123	3	3	3	4
≥ 124	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<70	70 - 73	73 - 87	≥ 88
< 108	1	2	3	4
108 - 111	2	2	3	4
112 - 124	3	3	3	4
≥ 125	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 87	≥ 88
< 109	1	2	3	4
109 - 112	2	2	3	4
113 - 125	3	3	3	4
≥ 126	4	4	4	4

**Child Blood Pressure Values
Girls - Age 7 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 88	≥ 89
< 111	1	2	3	4
111 - 114	2	2	3	4
115 - 127	3	3	3	4
≥ 128	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 89	≥ 90
< 112	1	2	3	4
112 - 115	2	2	3	4
116 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 89	≥ 90
< 113	1	2	3	4
113 - 115	2	2	3	4
116 - 129	3	3	3	4
≥ 130	4	4	4	4

**Child Blood Pressure Values
Girls - Age 8**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 87	≥ 88
< 108	1	2	3	4
108 - 111	2	2	3	4
112 - 124	3	3	3	4
≥ 125	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 87	≥ 88
< 109	1	2	3	4
109 - 111	2	2	3	4
112 - 125	3	3	3	4
≥ 126	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 88	≥ 89
< 110	1	2	3	4
110 - 113	2	2	3	4
114 - 126	3	3	3	4
≥ 127	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 88	≥ 89
< 111	1	2	3	4
111 - 114	2	2	3	4
115 - 127	3	3	3	4
≥ 128	4	4	4	4

**Child Blood Pressure Values
Girls - Age 8 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 89	≥ 90
< 113	1	2	3	4
113 - 115	2	2	3	4
116 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 90	≥ 91
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

**Child Blood Pressure Values
Girls - Age 9**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 88	≥ 89
< 110	1	2	3	4
110 - 113	2	2	3	4
114 - 126	3	3	3	4
≥ 127	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 88	<89
< 110	1	2	3	4
110 - 113	2	2	3	4
114 - 126	3	3	3	4
≥ 127	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 89	≥ 90
< 112	1	2	3	4
112 - 114	2	2	3	4
115 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 89	≥ 90
< 113	1	2	3	4
113 - 116	2	2	3	4
117 - 129	3	3	3	4
≥ 130	4	4	4	4

**Child Blood Pressure Values
Girls - Age 9 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 90	≥ 91
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 91	≥ 92
< 116	1	2	3	4
116 - 118	2	2	3	4
119 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 116	1	2	3	4
116 - 119	2	2	3	4
120 - 132	3	3	3	4
≥ 133	4	4	4	4

**Child Blood Pressure Values
Girls - Age 10**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 89	≥90
< 112	1	2	3	4
112 - 115	2	2	3	4
116 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 89	≥90
< 112	1	2	3	4
112 - 115	2	2	3	4
116 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 90	≥91
< 114	1	2	3	4
114 - 116	2	2	3	4
117 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 115	1	2	3	4
115 - 118	2	2	3	4
119 - 131	3	3	3	4
≥ 132	4	4	4	4

**Child Blood Pressure Values
Girls - Age 10 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 91	≥ 92
< 116	1	2	3	4
116 - 119	2	2	3	4
120 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 92	≥ 93
< 118	1	2	3	4
118 - 120	2	2	3	4
121 - 134	3	3	3	4
≥ 135	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥ 94
< 118	1	2	3	4
118 - 121	2	2	3	4
122 - 134	3	3	3	4
≥ 135	4	4	4	4

**Child Blood Pressure Values
Girls - Age 11**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 90	≥ 91
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 90	≥ 91
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 116	1	2	3	4
116 - 118	2	2	3	4
119 - 131	3	3	3	4
≥ 132	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 117	1	2	3	4
117 - 120	2	2	3	4
121 - 133	3	3	3	4
≥ 134	4	4	4	4

**Child Blood Pressure Values
Girls - Age 11 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 92	≥ 93
< 118	1	2	3	4
118 - 121	2	2	3	4
122 - 134	3	3	3	4
≥ 135	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 93	≥ 94
< 119	1	2	3	4
119 - 122	2	2	3	4
123 - 135	3	3	3	4
≥ 136	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 120	1	2	3	4
120 - 123	2	2	3	4
124 - 136	3	3	3	4
≥ 137	4	4	4	4

**Child Blood Pressure Values
Girls - Age 12**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 91	≥ 92
< 116	1	2	3	4
116 - 118	2	2	3	4
119 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 91	≥ 92
< 116	1	2	3	4
116 - 119	2	2	3	4
120 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 117	1	2	3	4
117 - 120	2	2	3	4
121 - 133	3	3	3	4
≥ 134	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥94
< 119	1	2	3	4
119 - 122	2	2	3	4
123 - 135	3	3	3	4
≥ 136	4	4	4	4

**Child Blood Pressure Values
Girls - Age 12 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 93	≥ 94
< 120	1	2	3	4
120 - 123	2	2	3	4
124 - 136	3	3	3	4
≥ 137	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 94	≥ 95
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 137	3	3	3	4
≥ 138	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 138	3	3	3	4
≥ 139	4	4	4	4

**Child Blood Pressure Values
Girls - Age 13**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 92	≥ 93
< 117	1	2	3	4
117 - 120	2	2	3	4
121 - 133	3	3	3	4
≥ 134	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 92	≥ 93
< 118	1	2	3	4
118 - 121	2	2	3	4
122 - 134	3	3	3	4
≥ 135	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥ 94
< 119	1	2	3	4
119 - 122	2	2	3	4
123 - 135	3	3	3	4
≥ 136	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 120	1	2	3	4
120 - 123	2	2	3	4
124 - 137	3	3	3	4
≥ 138	4	4	4	4

**Child Blood Pressure Values
Girls - Age 13 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 94	≥ 95
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 138	3	3	3	4
≥ 139	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 95	≥ 96
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 139	3	3	3	4
≥ 140	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 127	2	2	3	4
128 - 140	3	3	3	4
≥ 141	4	4	4	4

**Child Blood Pressure Values
Girls - Age 14**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 93	≥ 94
< 119	1	2	3	4
119 - 122	2	2	3	4
123 - 135	3	3	3	4
≥ 136	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 93	≥ 94
< 120	1	2	3	4
120 - 122	2	2	3	4
123 - 136	3	3	3	4
≥ 137	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 137	3	3	3	4
≥ 138	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 138	3	3	3	4
≥ 139	4	4	4	4

**Child Blood Pressure Values
Girls - Age 14 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 95	≥ 96
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 140	3	3	3	4
≥ 141	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 96	≥ 97
< 120	1	2	3	4
120 - 128	2	2	3	4
129 - 141	3	3	3	4
≥ 142	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 97	≥ 98
< 120	1	2	3	4
120 - 128	2	2	3	4
129 - 141	3	3	3	4
≥ 142	4	4	4	4

**Child Blood Pressure Values
Girls - Age 15**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 94	≥ 95
< 120	1	2	3	4
120 - 123	2	2	3	4
124 - 136	3	3	3	4
≥ 137	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 94	≥ 95
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 137	3	3	3	4
≥ 138	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 138	3	3	3	4
≥ 139	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 83	84 - 96	≥ 97
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 139	3	3	3	4
≥ 140	4	4	4	4

**Child Blood Pressure Values
Girls - Age 15 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 97	≥ 98
< 120	1	2	3	4
120 - 128	2	2	3	4
129 - 141	3	3	3	4
≥ 142	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 97	≥ 98
< 120	1	2	3	4
120 - 129	2	2	3	4
130 - 142	3	3	3	4
≥ 143	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 98	≥ 99
< 120	1	2	3	4
120 - 130	2	2	3	4
131 - 143	3	3	3	4
≥ 144	4	4	4	4

**Child Blood Pressure Values
Girls - Age 16**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 137	3	3	3	4
≥ 138	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 138	3	3	3	4
≥ 139	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 95	≥ 96
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 139	3	3	3	4
≥ 140	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 96	≥ 97
< 120	1	2	3	4
120 - 127	2	2	3	4
128 - 140	3	3	3	4
≥ 141	4	4	4	4

**Child Blood Pressure Values
Girls - Age 16 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 97	≥ 98
< 120	1	2	3	4
120 - 129	2	2	3	4
130 - 142	3	3	3	4
≥ 143	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 98	≥ 99
< 120	1	2	3	4
120 - 130	2	2	3	4
131 - 143	3	3	3	4
≥ 144	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 85	86 - 98	≥ 99
< 120	1	2	3	4
120 - 131	2	2	3	4
132 - 144	3	3	3	4
≥ 145	4	4	4	4

**Child Blood Pressure Values
Girls - Age 17**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 138	3	3	3	4
≥ 139	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 95	≥ 96
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 138	3	3	3	4
≥ 139	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 139	3	3	3	4
≥ 140	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 96	≥ 97
< 120	1	2	3	4
120 - 128	2	2	3	4
129 - 141	3	3	3	4
≥ 142	4	4	4	4

**Child Blood Pressure Values
Girls - Age 17 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 97	≥ 98
< 120	1	2	3	4
120 - 129	2	2	3	4
130 - 142	3	3	3	4
≥ 143	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 85	86 - 98	≥ 99
< 120	1	2	3	4
120 - 130	2	2	3	4
131 - 143	3	3	3	4
≥ 144	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 85	86 - 98	≥ 99
< 120	1	2	3	4
120 - 131	2	2	3	4
132 - 144	3	3	3	4
≥ 145	4	4	4	4

**Child Blood Pressure Values
Boys - Age 6**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<68	68 - 71	72 - 85	≥ 86
< 105	1	2	3	4
105 - 108	2	2	3	4
109 - 121	3	3	3	4
≥ 122	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<68	68 - 71	72 - 85	≥ 86
< 106	1	2	3	4
106 - 109	2	2	3	4
110 - 122	3	3	3	4
≥ 123	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<69	69 - 72	73 - 86	≥ 87
< 108	1	2	3	4
108 - 111	2	2	3	4
112 - 124	3	3	3	4
≥ 125	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<70	70 - 73	74 - 87	≥ 88
< 110	1	2	3	4
110 - 113	2	2	3	4
114 - 126	3	3	3	4
≥ 127	4	4	4	4

**Child Blood Pressure Values
Boys - Age 6 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 88	≥ 89
< 111	1	2	3	4
111 - 114	2	2	3	4
115 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 90	≥ 91
< 113	1	2	3	4
113 - 116	2	2	3	4
117 - 129	3	3	3	4
≥ 130	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 89	≥ 90
< 113	1	2	3	4
113 - 116	2	2	3	4
117 - 130	3	3	3	4
≥ 131	4	4	4	4

**Child Blood Pressure Values
Boys - Age 7**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<70	70 - 73	74 - 87	≥ 88
< 106	1	2	3	4
106 - 109	2	2	3	4
110 - 122	3	3	3	4
≥ 123	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<70	70 - 73	74 - 87	<88
< 107	1	2	3	4
107 - 110	2	2	3	4
111 - 121	3	3	3	4
≥ 122	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 88	≥ 89
< 109	1	2	3	4
109 - 112	2	2	3	4
113 - 125	3	3	3	4
≥ 126	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 89	≥ 90
< 111	1	2	3	4
111 - 114	2	2	3	4
115 - 127	3	3	3	4
≥ 128	4	4	4	4

**Child Blood Pressure Values
Boys - Age 7 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 90	≥ 91
< 113	1	2	3	4
113 - 116	2	2	3	4
117 - 129	3	3	3	4
≥ 130	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 115	1	2	3	4
115 - 118	2	2	3	4
119 - 131	3	3	3	4
≥ 132	4	4	4	4

**Child Blood Pressure Values
Boys - Age 8**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<71	71 - 74	75 - 88	≥ 89
< 107	1	2	3	4
107 - 110	2	2	3	4
111 - 124	3	3	3	4
≥ 125	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 89	≥ 90
< 109	1	2	3	4
109 - 111	2	2	3	4
112 - 125	3	3	3	4
≥ 126	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 76	77 - 90	≥ 91
< 110	1	2	3	4
110 - 113	2	2	3	4
114 - 127	3	3	3	4
≥ 128	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 77	78 - 91	≥ 92
< 112	1	2	3	4
112 - 115	2	2	3	4
116 - 128	3	3	3	4
≥ 129	4	4	4	4

**Child Blood Pressure Values
Boys - Age 8 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 78	79 - 92	≥ 93
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 115	1	2	3	4
115 - 118	2	2	3	4
119 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥ 94
< 116	1	2	3	4
116 - 119	2	2	3	4
120 - 132	3	3	3	4
≥ 133	4	4	4	4

**Child Blood Pressure Values
Boys - Age 9**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<72	72 - 75	76 - 89	≥ 90
< 109	1	2	3	4
109 - 112	2	2	3	4
113 - 125	3	3	3	4
≥ 126	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 90	<91
< 110	1	2	3	4
110 - 113	2	2	3	4
114 - 126	3	3	3	4
≥ 127	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 112	1	2	3	4
112 - 115	2	2	3	4
116 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

**Child Blood Pressure Values
Boys - Age 9 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 79	80 - 86	≥ 87
< 115	1	2	3	4
115 - 118	2	2	3	4
119 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥ 94
< 117	1	2	3	4
117 - 120	2	2	3	4
121 - 133	3	3	3	4
≥ 134	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 118	1	2	3	4
118 - 120	2	2	3	4
121 - 134	3	3	3	4
≥ 135	4	4	4	4

**Child Blood Pressure Values
Boys - Age 10**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 76	77 - 90	≥ 91
< 111	1	2	3	4
111 - 114	2	2	3	4
115 - 127	3	3	3	4
≥ 128	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<73	73 - 77	78 - 91	≥ 92
< 112	1	2	3	4
112 - 115	2	2	3	4
116 - 128	3	3	3	4
≥ 129	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 78	79 - 91	≥ 92
< 114	1	2	3	4
114 - 116	2	2	3	4
117 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 79	80 - 93	≥ 94
< 115	1	2	3	4
115 - 118	2	2	3	4
119 - 132	3	3	3	4
≥ 133	4	4	4	4

**Child Blood Pressure Values
Boys - Age 10 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 80	81 - 93	≥ 94
< 117	1	2	3	4
117 - 120	2	2	3	4
121 - 133	3	3	3	4
≥ 134	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 119	1	2	3	4
119 - 121	2	2	3	4
122 - 135	3	3	3	4
≥ 136	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 119	1	2	3	4
119 - 122	2	2	3	4
123 - 135	3	3	3	4
≥ 136	4	4	4	4

**Child Blood Pressure Values
Boys - Age 11**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 113	1	2	3	4
113 - 116	2	2	3	4
117 - 129	3	3	3	4
≥ 130	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 114	1	2	3	4
114 - 117	2	2	3	4
118 - 130	3	3	3	4
≥ 131	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 115	1	2	3	4
115 - 118	2	2	3	4
119 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥ 94
< 117	1	2	3	4
117 - 120	2	2	3	4
121 - 134	3	3	3	4
≥ 135	4	4	4	4

**Child Blood Pressure Values
Boys - Age 11 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 119	1	2	3	4
119 - 122	2	2	3	4
123 - 135	3	3	3	4
≥ 136	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 123	2	2	3	4
124 - 137	3	3	3	4
≥ 138	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 137	3	3	3	4
≥ 138	4	4	4	4

**Child Blood Pressure Values
Boys - Age 12**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<74	74 - 77	78 - 91	≥ 92
< 115	1	2	3	4
115 - 118	2	2	3	4
119 - 131	3	3	3	4
≥ 132	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 116	1	2	3	4
116 - 119	2	2	3	4
120 - 132	3	3	3	4
≥ 133	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 79	80 - 93	≥ 94
< 118	1	2	3	4
117 - 121	2	2	3	4
122 - 134	3	3	3	4
≥ 135	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 80	81 - 94	≥ 95
< 119	1	2	3	4
119 - 122	2	2	3	4
123 - 136	3	3	3	4
≥ 137	4	4	4	4

**Child Blood Pressure Values
Boys - Age 12 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 138	3	3	3	4
≥ 139	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 139	3	3	3	4
≥ 140	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 140	3	3	3	4
≥ 141	4	4	4	4

**Child Blood Pressure Values
Boys - Age 13**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 117	1	2	3	4
117 - 120	2	2	3	4
121 - 133	3	3	3	4
≥ 134	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 78	79 - 92	≥ 93
< 118	1	2	3	4
118 - 121	2	2	3	4
122 - 135	3	3	3	4
≥ 136	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥ 94
< 120	1	2	3	4
120 - 123	2	2	3	4
124 - 136	3	3	3	4
≥ 137	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 138	3	3	3	4
≥ 139	4	4	4	4

**Child Blood Pressure Values
Boys - Age 13 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 127	2	2	3	4
128 - 140	3	3	3	4
≥ 141	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 128	2	2	3	4
129 - 141	3	3	3	4
≥ 142	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 129	2	2	3	4
130 - 142	3	3	3	4
≥ 143	4	4	4	4

**Child Blood Pressure Values
Boys - Age 14**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<75	75 - 79	80 - 92	≥ 93
< 120	1	2	3	4
120 - 123	2	2	3	4
124 - 136	3	3	3	4
≥ 137	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 79	80 - 93	≥ 94
< 120	1	2	3	4
120 - 124	2	2	3	4
125 - 137	3	3	3	4
≥ 138	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 139	3	3	3	4
≥ 140	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 127	2	2	3	4
128 - 141	3	3	3	4
≥ 142	4	4	4	4

**Child Blood Pressure Values
Boys - Age 14 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 129	2	2	3	4
130 - 143	3	3	3	4
≥ 144	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 83	84 - 97	≥ 98
< 120	1	2	3	4
120 - 131	2	2	3	4
132 - 144	3	3	3	4
≥ 145	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 97	≥ 98
< 120	1	2	3	4
120 - 131	2	2	3	4
132 - 145	3	3	3	4
≥ 146	4	4	4	4

**Child Blood Pressure Values
Boys - Age 15**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<76	76 - 80	81 - 93	≥ 94
< 120	1	2	3	4
120 - 125	2	2	3	4
126 - 139	3	3	3	4
≥ 140	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<77	77 - 80	81 - 94	≥ 95
< 120	1	2	3	4
120 - 126	2	2	3	4
127 - 140	3	3	3	4
≥ 141	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 82	83 - 95	≥ 96
< 120	1	2	3	4
120 - 128	2	2	3	4
129 - 141	3	3	3	4
≥ 142	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 130	2	2	3	4
131 - 143	3	3	3	4
≥ 144	4	4	4	4

**Child Blood Pressure Values
Boys - Age 15 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 97	≥ 98
< 120	1	2	3	4
120 - 132	2	2	3	4
133 - 145	3	3	3	4
≥ 144	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 98	≥ 99
< 120	1	2	3	4
121 - 133	2	2	3	4
134 - 147	3	3	3	4
≥ 148	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 98	≥ 99
< 120	1	2	3	4
120 - 134	2	2	3	4
135 - 147	3	3	3	4
≥ 148	4	4	4	4

**Child Blood Pressure Values
Boys - Age 16**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 81	82 - 95	≥ 96
< 120	1	2	3	4
120 - 128	2	2	3	4
129 - 141	3	3	3	4
≥ 142	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<78	78 - 82	83 - 95	≥ 96
< 120	1	2	3	4
120 - 129	2	2	3	4
130 - 142	3	3	3	4
≥ 143	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<79	79 - 82	83 - 96	≥ 97
< 120	1	2	3	4
120 - 131	2	2	3	4
132 - 144	3	3	3	4
≥ 145	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 97	≥ 98
< 120	1	2	3	4
120 - 133	2	2	3	4
134 - 146	3	3	3	4
≥ 147	4	4	4	4

**Child Blood Pressure Values
Boys - Age 16 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 98	≥ 99
< 120	1	2	3	4
120 - 134	2	2	3	4
135 - 148	3	3	3	4
≥ 149	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 85	86 - 99	≥ 100
< 120	1	2	3	4
120 - 136	2	2	3	4
137 - 150	3	3	3	4
≥ 151	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 86	87 - 99	≥ 100
< 120	1	2	3	4
120 - 136	2	2	3	4
137 - 150	3	3	3	4
≥ 151	4	4	4	4

**Child Blood Pressure Values
Boys - Age 17**

Percentile of height = Less than 10%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 83	84 - 97	≥ 98
< 120	1	2	3	4
120 - 130	2	2	3	4
131 - 144	3	3	3	4
≥ 145	4	4	4	4

Percentile of height = 10 - 24%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 84	85 - 98	≥ 99
< 120	1	2	3	4
120 - 131	2	2	3	4
132 - 145	3	3	3	4
≥ 146	4	4	4	4

Percentile of height = 25 - 49%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 85	86 - 98	≥ 99
< 120	1	2	3	4
120 - 133	2	2	3	4
134 - 146	3	3	3	4
≥ 147	4	4	4	4

Percentile of height = 50 - 74%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 86	87 - 99	≥ 100
< 120	1	2	3	4
120 - 135	2	2	3	4
136 - 148	3	3	3	4
≥ 149	4	4	4	4

**Child Blood Pressure Values
Boys - Age 17 (continued)**

Percentile of height = 75 - 89%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 86	87 - 100	≥ 101
< 120	1	2	3	4
120 - 137	2	2	3	4
148 - 150	3	3	3	4
≥ 151	4	4	4	4

Percentile of height = 90 - 94%

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 87	88 - 101	≥ 102
< 120	1	2	3	4
120 - 138	2	2	3	4
139 - 151	3	3	3	4
≥ 152	4	4	4	4

Percentile of height = 95% and higher

Systolic(mm Hg)	Diastolic (mm Hg)			
	<80	80 - 88	89 - 102	≥ 103
< 120	1	2	3	4
120 - 139	2	2	3	4
140 - 152	3	3	3	4
≥ 153	4	4	4	4

Appendix B
Child Blood Pressure References

APPENDIX B. CHILD BLOOD PRESSURE REFERENCES

Blood Pressure - Children

Referral Levels:

Level 1 (category 4)	Indicates major medical findings that warrant immediate attention by a health care provider.
Level 2 (category 3)	Indicates major medical findings that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period and they have previously been undiagnosed, unattended, nonmanifested, or not communicated to the examinee by his or her personal health care provider.
Level 3 (categories 1 & 2)	Indicates no medical findings; minor medical findings that an examinee already knows about, and is under care for; or findings that do not require prompt attention by a medical provider.

Referral Comments for Blood Pressure (Children)

Referral Comments:

Statement for blood pressure in category 4	Level 1 referral	The participant's blood pressure is very high based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents.*
Statement for blood pressure in category 3	Level 2 referral	The participant's blood pressure is high based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents.*
Statement for blood pressure in category 2	Level 3 no referral	The participant's blood pressure is normal but at the high end of normal based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents.*
Statement for blood pressure in category 1	Level 3 no referral	The participant's blood pressure is normal based on the 1996 update of the Task Force Report on High Blood Pressure in Children and Adolescents.*

Report of Findings Comments:

- Category 4 Your child's blood pressure today is **very high**.
- Category 3 Your child's blood pressure today is **high**.
- Category 2 Your child's blood pressure today is **normal but at the high end of the normal range**.
- Category 1 Your child's blood pressure today is **normal**.

* National High Blood Pressure Education Program Working Group on Hypertension Control in Children and Adolescents. Update on the 1987 Task Force Report on High Blood Pressure in Children and Adolescents: A Working Group Report from the National High Blood Pressure Education Program. *Pediatrics*. 1996;11:649-658.

Appendix D

Exclusions Based on Medical Conditions and Medication Listings for Bronchodilator

APPENDIX D. EXCLUSIONS BASED ON MEDICAL CONDITIONS

From Responses to Household Questionnaire

Respiratory Health (RDQ) -

- RDQ.080 (if 12 or more attacks, 77, or 99 exclude) Wheezing in past 12 months
- RDQ.110 (if 1, 7, or 9, exclude) Wheezing that limits speech (last 12 months)

Vision (VIQ) -

- VIQ.020 (if 1,7, or 9, exclude) Blind
- VIQ.030 (if 5,7, or 9, exclude) Very poor eyesight

DSQ.240

- Medications will be available in SP History in Physician's Exam. Physician will check this list and exclude based on medication on the Exclusion list.

See Exclusionary Medication List:

The household interviewer will have the participant get his or her medication bottles and will enter the complete product name of the medication in CAPI. This list of medications will be compared to the medications on the Exclusion list - see p. D-2. Participants taking a medication that is on the Exclusion Medication list will be excluded from the bronchodilator subcomponent.

MEDICATION LISTINGS FOR MEC PHYSICIAN'S DRUG REVIEW AND BRONCHODILATOR TYPE EVALUATION

Potassium Lowering Drugs

These include the Loop Diuretics, Thiazides and Derivatives.

Loop Diuretics:

- Bumetanide
- Ethacrynate Sodium
- Ethacrynic Acid
- Torsemide

Thiazide Diuretics and Derivatives:

- Bendroflumethiazide
- Chlorothiazide
- Chlorthalidone
- Hydrochlorothiazide
- Hydroflumethiazide
- Indapamide
- Methyclothiazide
- Metolazone
- Polythiazide,
- Trichlormethiazide

Potassium Raising Drugs

These include Potassium Supplements, Angiotensin Converting Enzyme Inhibitors, Angiotensin II Receptor Antagonists, Potassium Sparing Diuretics, and Combination drugs of which contain a potassium raising drug:

Angiotensin Converting Enzyme Inhibitors:

- Benazepril HCl
- Captopril
- Enalapril Maleate
- Fosinopril Sodium
- Lisinopril
- Moexipril HCl
- Perindopril Erbumine
- Quinapril HCl
- Ramipril
- Trandolapril

Angiotensin II Receptor Antagonists:

Candesartan Cilexetil
Eprosartan Mesylate
Irbesartan
Losartan Potassium
Olmesartan Medoxomil
Telmisartan, Valsartan

Potassium Sparing Diuretics:

Amiloride
Acetazolamide
Dichlorphenamide
Methazolamide
Sironolactone
Tiamterine

Combination Diuretics Designed to be Potassium Sparing:

Dyazide
Maxizide
Moduretic

Tricyclic Antidepressants:

<u>Generic Name</u>	<u>Brand Name</u>
Amoxapine	Asendin
Amitriptyline	Elavil
Clomipramine HCl	Anafranil
Desipramine	Pertofrane
Doxepin	Sinequan
Imipramine	Norfranil
Nefazodone	Nefazodone
Nortriptyline	Pamelor
Protriptyline	Vivactil
Trimipramine	Surmontil

Anticonvulsants:

Carbamazepine
Clonazepam
Divalproex Sodium EC
Diazepam
Ethosuximide
Ethotoin
Felbamate
Fosphenytoin Sodium

Gabapentin
Levetiracetam
Lamotrigine
Methsuximide
Oxcarbazepine
Phenacemide
Phenytoin
Primidone
Tiagabine HCl
Topiramate
Valproic Acid
Zonisamide

Long Acting β 2-Agonist Bronchodilators:

Advair
Advair Diskus (combines Serevent and an anti-inflammatory drug)
Serevent
Serevent discus (salmeterol)
Foradil

(These drugs take longer to begin to work, but their benefits last longer, even up to 12 hours. Serevent and Foradil are the only inhaled, long-acting beta 2-agonists available. They are used twice a day to maintain open airways for long term-control. Serevent and Foradil are available in dry powder inhaler (DPI) form.)

Short Acting β 2-Agonist Bronchodilators:

Albuterol (Proventil HFA, Ventolin HFA, Accuneb)
Alupent
Combivent (combines a beta 2-agonist and an anticholinergic)
Duoneb (combines a beta 2-agonist and an anticholinergic)
Maxair
Xopenex
Bitolterol Mesylate
Clenbuterol HCl
Formoterol Fumarate
Isoetharine HCl Nebulizer Solution
Isoproterenol HCl
Levalbuterol HCl Nebulizer Solution
Levalbuterol HCl Nebulizer Solution
Metaproterenol Sulfate
Pirbuterol
Terbutaline Sulfate

Short Acting Anti-Cholinergic Inhalers:

Atrovent (ipratropium)
Tiotropium (Spiriva)

(Short-acting beta 2-agonists or anticholinergics are also called "quick acting," "reliever," or "rescue" medications because they relieve asthma symptoms very quickly by opening the airways. These inhalers are the best for treating sudden and severe or new asthma symptoms. They work within 20 minutes and last four to six hours).

MAO Inhibitors:

Isocarboxazid (Marplan)
Phenelzine Sulfate (Nardil)
Tranylcypromine Sulfate (Parnate)

Class 1 Antiarrhythmics:

Amiodarone (Cordarone)
Bretylum (Bretylol)
Bretylol (Bretylum)
Cardioquin (Quinidine, Quinalan, Quinidex, Quinaglute)
Cordarone (Amiodarone)
Disopyramide (Norpace)
Dofetilide
Enkaid (Encainide)
Ethmozine (Moricizine)
Flecainide (Tambocor)
Ibutilide
Lidocaine (Xylocaine, Xylocard)
Mexiletine (Mexitil) Mexitil (Mexilitine)
Moricizine (Ethmozine)
Norpace (Disopyramide)
Procainamide (Pronestyl, Procan SR)
Procan SP (Procainamide, Pronestyl)
Pronestyl (Procan SP, Procainamide)
Propafenone (Rhythmol)
Rhythmol (Propafenone)
Tambocore (Flecainide)
Tocainide (Tonocard)
Tonocard (Tocainide)
Quinaglute (Cardioquin, Quinidine, Quinora, Quinalan, Quinidex)
Quinidine (Quinora, Quinalan, Cardioquin, Quinidex, Quinaglute)
Quinalan (Quinora, Cardioquin, Quinidex, Quinaglute, Quinidine)
Quinora (Quinidine, Quinalan, Cardioquin, Quinidex, Quinaglute)
Xylocaine (Lidocaine, Xylocard)
Xylocard (Lidocaine, Xylocaine)

Long-acting Beta 2-agonists:

- Advair, Advair Diskus (combines Serevent and an anti-inflammatory drug)
- Serevent, Serevent discus (salmeterol)
- Foradil

(These drugs take longer to begin to work, but their benefits last longer, even up to 12 hours. Serevent and Foradil are the only inhaled, long-acting beta 2-agonists available. They are used twice a day to maintain open airways for long term-control. Serevent and Foradil are available in dry powder inhaler (DPI) form.)

Short-acting Beta 2-agonists include:

- Albuterol (Proventil HFA, Ventolin HFA, Accuneb)
- Alupent
- Combivent (combines a beta 2-agonist and an anticholinergic, see below)
- Duoneb (combines a beta 2-agonist and an anticholinergic, see below)
- Maxair
- Xopenex

Short-acting Anti-Cholinergic Inhalers Include:

- Atrovent (ipratropium)

(Short-acting beta 2-agonists or anticholinergics are also called "quick acting," "reliever," or "rescue" medications because they relieve asthma symptoms very quickly by opening the airways. These inhalers are the best for treating sudden and severe or new asthma symptoms. They work within 20 minutes and last 4 to 6 hours.)

Appendix E
STD Information Sheets and Role Plays

MEC INFORMATION SHEETS

INFECTIONS WITH HERPES SIMPLEX VIRUS TYPE 2

Mode of infection

- Almost always sexual

Laboratory assay used in NHANES

- Type specific immunodot assay using sera, which measures antibodies specific for HSV-2. This test result is an indicator of past infection.

Frequency

- Approximately 1 in 10 adolescents
- Increases with age among white adults to over 1 in 4 adults
- Increases with age among black adults to over 1 in 2 adults

Location of the initial infection and of symptoms

- Women
 - Skin around the vagina, urethra, and rectum
 - Skin of inner thighs and on the buttocks
 - In the vagina and on the cervix
- Men
 - Skin on and around the penis
 - Skin of inner thighs
 - Rectum and skin around the rectum and on the buttocks

Latent infection

- Most of the time, the virus remains dormant in nerve cells connected to the lower spinal cord.

- Symptoms occur when the virus begins to replicate in skin cells around the nerve endings.

Symptoms of uncomplicated infection

- Most infected individuals report no symptoms.
- Blisters that break to form multiple small tender sores that heal spontaneously within a week.
- Episodes recur with highly variable frequency, symptom-free intervals ranging from days to months.

Complications

- Occasionally, the sores are sufficiently painful to interfere with urination.
- Rarely, infection of the brain occurs.
- Rarely, babies born to infected women contract serious infections.

Diagnosis

- Blood tests to detect antibody.
 - In NHANES, a special blood test is used that is not yet available to most physicians. The blood test detects antibody and is usually correct, but no test is 100% accurate.
 - Physicians can order blood tests, but they do not reliably distinguish between the type 2 herpes simplex virus infection and type 1 infection that is the infection that most commonly causes fever blisters of the mouth and is not usually sexually transmitted.
- Cultures and other tests detect the virus in blisters and sores, except during the later stage of healing.
- Frequently, the blisters, sores, and history of recurrences are characteristic, and the physician requires no laboratory test to make the diagnosis.

NOTE: Except by using the NHANES type of blood test, the infection cannot be detected unless blisters or ulcers are present.

Treatment

- No treatment is curative.
- Antiviral drugs suppress symptoms, which usually recur after the drug is stopped.
- Treatment of each recurrence, separately, is not usually worthwhile, because healing occurs before the drug can act.

Preventing infection of others

- Transmission-related factors
 - Intimate, usually sexual, contact is required.
 - Infected individuals are most infectious when they have sores, but they most often infect others when they are asymptomatic.
 - Infected individuals, who never have symptoms, often shed herpes virus, but how many are infectious is unknown.
- Prevention measures should be taken, but they are not entirely effective.
 - Visit a physician, who can help the infected person determine when a herpes outbreak is occurring.
 - Avoid intercourse during outbreaks.
 - Use condoms.
 - Make sex partners aware of need for preventive measures and residual risks.

MEC INFORMATION SHEETS

INFECTIONS WITH HUMAN IMMUNODEFICIENCY VIRUS

Mode of infection

- Sexual transmission and percutaneous blood exposure (IV drug use, needle sticks in health care workers, etc.).

Laboratory assay used in NHANES

- Serum is screened for HIV-1 antibody using an FDA-licensed enzyme immuno assay kit. Repeatedly reactive specimens are then tested by an FDA-licensed Western blot assay.

Frequency

- Approximately 3 in 1,000 adults
- Approximately 2 in 1,000 white adults
- Approximately 11 in 1,000 black adults
- Approximately 4 in 1,000 Mexican American adults

Diagnosis

- Blood tests to detect antibody

Incubation (infection to AIDS diagnosis)

- Median 8-10 years in untreated individual, but varies by age.
- Treatment with HAART (highly active antiretroviral therapy) is altering the median incubation time.

Treatment

- HAART, if given early, can slow or stop disease progression.
- Treatment of opportunistic infections as they occur.

Preventing infection of others

- Condom use has been demonstrated to be effective against transmission.
- Only abstinence or monogamous relationship (between two HIV negative partners) is totally effective in preventing exposure.

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Reproductive Health/Sexually Transmitted Diseases

STD	Symptoms	Treatment	Things to Know
HIV/AIDS (virus)	<p>None or mild flu-like symptoms early in infection.</p> <p>With onset of AIDS many years after infection, persistent cough, unexplained weight loss, diarrhea, fever, etc.</p>	<p>Treatment is available to slow or stop disease progression.</p> <p>Many serious AIDS-related infections can be prevented by medications.</p>	<p>Early treatment can delay serious complications.</p> <p>Treatment of pregnant HIV positive women can reduce transmission to the baby.</p>
Gonorrhea (clap, drip, GC) (bacterium)	<p>Most women and many men have no symptoms.</p> <p>Women: Abnormal vaginal discharge, burning on urination or lower abdominal pain. Men: Discharge of pus from penis; burning on urination.</p>	<p>Can be cured with antibiotics. Sex partners need to be treated.</p>	<p>If not treated, can lead to more serious problems. Gonorrhea can lead to infertility in women. A mother can pass the infection on to her baby.</p>
Chlamydia (bacterium)	<p>Most women and many men have no symptoms.</p> <p>Women: Mild or no symptoms; vaginal discharge; burning on urination or lower abdominal pain. Men: Discharge from penis; burning or pain on urination.</p>	<p>Can be cured with antibiotics. Sex partners need to be treated.</p>	<p>If not treated, Chlamydia can lead to more serious problems. Reproductive organs can be damaged (Pelvic Inflammatory Disease). A mother can pass the infection on to her baby.</p>

Reproductive Health/Sexually Transmitted Diseases (continued)

STD	Symptoms	Treatment	Things to Know
Genital Herpes (virus)	Most women and many men have no symptoms. Painful blisters. Painful urination. Swollen glands in groin area and fever.	Herpes cannot be cured but medication can reduce symptoms.	Symptoms disappear and may recur at any time. Infected persons are most likely to transmit the infection when they have symptoms, but they can also transmit when they don't have symptoms. In rare instances a mother can give herpes to her infant during childbirth.
Bacterial Vaginosis (BV) (bacterial growth)	Women: Most women have no symptoms. Others have a gray, thin vaginal discharge with an odor.	Can be cured with antibiotics. May recur and require repeat or long-term treatment.	If not treated, can lead to more serious problems. It is very important for pregnant women to get treated. Women who have never had sexual intercourse can get BV.
Trichomonas (protozoan)	Many women have no symptoms. Some women have a yellow gray or green vaginal discharge with an odor. Burning, irritation of the vaginal area.	Can be cured with antibiotics. Sex partners need to be treated.	It is very important for pregnant women to get treated.
Syphilis (bacterium)	Many women and men have no symptoms. Painless ulcers in the genital area. New infection may produce sore genitals, an unusual rash, fever, or swollen lymph nodes.	Can be cured with antibiotics.	If not treated, syphilis can lead to long-term health problems including heart disease and nerve problems. It is very important for pregnant women to get treated.

Reproductive Health/Sexually Transmitted Diseases (continued)

STD	Symptoms	Treatment	Things to Know
Human Papillomavirus (virus)	<p>Many people have no symptoms.</p> <p>Symptoms and signs of infection are genital warts, abnormal Pap smear, cervical lesions, and cervical cancer.</p>	HPV is not cured with medicine, but symptoms can be treated.	<p>Some types of HPV are linked to cervical cancer, others to genital warts.</p> <p>HPV infection can resolve on its own.</p>

For information and/or test results, call the NHANES Health Educator: 1-888-301-2360, Monday – Friday 9 AM to 6 PM Eastern Standard Time.

Your participation is giving researchers valuable information about the number of people in this country who are infected with sexually transmitted diseases (STDs). In order to get accurate numbers, we test all survey participants in your age group, even if you are not at risk for getting these diseases.

Your test results are completely confidential and will not be reported to your family, employers, insurers, or intimate contacts. Your doctor can receive results only with your permission. Test results are given only to you. Four weeks after the exam, you may call our health educator toll free at 1-888-301-2360 for your STD results (including HIV testing for those aged 18-49 years). You must provide your password before any results are given out. Please make sure you remember this password when you call. If a health problem is identified, you will be told how to get evaluated and treated.

Other phone numbers you can call:
 National STD Hotline
 1-800-227-8922

and the AIDS Hotline
 1-800-342-AIDS

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ROLE PLAY—SCENARIO 1:

Client

Sam is a 45-year-old divorcé who left his former wife about a year ago. He was married for 20 years and has two children. He has never had an STD, just a urinary tract infection once. He has heard much about HIV/AIDS and is worried how to date safely in the '90s. He is a sample person for the NHANES survey and is willing to be tested for STDs. He is in general good health and looks forward to developing a new romantic relationship.

Counselor

You will be counseling Sam a 45-year-old divorcé who has recently rejoined the dating scene. He is worried about HIV/AIDS and wants to become romantically involved again but safely. He is not very aware of the various types of STDs and the associated symptoms.

You will need to provide a smooth segue into this part of the physician's exam. Discuss the purpose of testing for STD/HIV and why these special tests have a different mechanism for reporting. Assure confidentiality of the survey and test results. If asked, explain and educate Sam on the various STDs, risk behaviors associated with transmission, complications, testing methods, and possible treatments available if found to be infected. In closing, you will arrange for Sam to call to obtain his results if he wishes, in a confidential manner.

Observer

As the observer, you are not to interrupt or engage in the counseling session. Take side notes of the counselor's ability to cover the major points listed:

- Smooth segue into STD/HIV component of physician's exam;
- Assure confidential manner of testing and obtaining results;

- When asked, explain the various types of STDs, risk behaviors, testing methods, associated symptoms, and treatments available if found to be infected; and
- Mechanisms for client to obtain results.

Did the counselor listen to the client to assess risk and knowledge level of the client about STDs?

Did the counselor use open-ended questions to better assess the client's level of understanding?

Did the client appear to understand the level of communication that the counselor was speaking from?

Did the counselor adequately cover the bullets highlighted above?

ROLE PLAY—SCENARIO 2:

Client

Julie is a 19-year-old college student. She has never had an STD and has recently become sexually involved with her boyfriend, Bob, whom she has been dating for 1 year. She has heard about STDs but is not very familiar with symptoms or ways to be tested for them. She is in general good health and looks forward to a happy and healthy future with Bob when she finishes college.

Counselor

You will be counseling Julie, a 19-year-old college student, who has recently become sexually active with her boyfriend Bob. She is not very aware of the various types of STDs and the associated symptoms.

You will need to provide a smooth segue into this part of the physician's exam. Discuss the purpose of testing for STD/HIV and why these special tests have a different mechanism for reporting. Assure confidentiality of the survey and tests methods involved. If asked, explain and educate Julie on the various STDs, risk behaviors associated with transmission, sequelae, testing methods, and possible treatments available if found to be infected. In closing, you will arrange for Julie to call to obtain her results if she wishes, in a confidential manner.

Observer

As the observer you are not to interrupt or engage in the counseling session. Take side notes of the counselor's ability to cover the major points listed:

- Smooth segue into STD/HIV component of physician's exam;
- Assure confidential manner of testing and obtaining results;

- When asked, explain the various types of STDs, risk behaviors, testing methods, associated symptoms, and treatments available if found to be infected; and
- Mechanisms for client to obtain results.

Did the counselor listen to the client and address specific questions about STDs?

Did the counselor use open-ended questions to better assess the client's level of understanding?

Did the client appear to understand the level of communication that the counselor was speaking from?

Did the counselor adequately cover the bullets highlighted above?

ROLE PLAY—SCENARIO 3:

Client

Jack Williams is 42-years-old and married with two children. He has been married for 12 years and works for a new car dealer. He spent 4 years in the Navy and was once infected with gonorrhea while on leave in Japan. While in the Navy he had to attend presentations about STD/HIV and is familiar with their symptoms and treatment.

Counselor

You will be talking to Jack about the NHANES project and seeking his permission to test him for STDs and HIV.

You will provide a smooth segue into this part of the examination, assure him that everything is confidential, and explain the test procedures. Explain why he is being tested, the purpose of the project, and what your role is with the project. If Jack agrees to be tested, make arrangements for him to call back for his test results.

Observer

Do not interrupt the session. Take notes of the following:

- Smooth segue into STD/HIV component of physician's exam;
- Assure confidential manner of testing and obtaining results;
- When asked, explain the various types of STDs, risk behaviors, testing methods, associated symptoms, and treatments available if found to be infected; and
- Mechanisms for client to obtain results.

Did the counselor address the above checklist?

Did the counselor address questions the client may have asked?

Appendix F

Procedures for Handling Mercury Manometers

APPENDIX F

PROCEDURES FOR HANDLING MERCURY MANOMETERS

F.1 Background

The elemental mercury in the Baum mercury manometer is encased in a closed system composed of a glass tube and reservoir, and unless exposed to the atmosphere, is harmless. Elemental mercury is a shiny, silver-gray metal that is a liquid at room temperature and which gives off a toxic vapor when exposed to the atmosphere. Although it is less toxic than the organic compound of methylmercury, elemental mercury, Hg(0), can cause tremors, gingivitis, and excitability when vapors are directly inhaled over a long period of time. Temperature, ventilation, and sunlight affect the level of the vapor's concentration, and the vapors can permeate the skin surface and are easily inhaled. If elemental mercury is ingested, it is absorbed relatively slowly and may pass through the digestive system without causing damage.

According to the manufacturer, the elemental mercury used in Baum manometers is safely contained in the reservoir and Mylar® Clad Calibrated Cartridge glass tube. Since February of 1995, Baum has applied several layers of very strong and crystal clear Mylar® film to the glass tubes, which strengthen the tube and maintain its structural integrity even if the inner glass is broken. The Mylar® sheath ends close to the tube's top end, and a fingernail can detect the change in the tube's outer diameter, which indicates that this tube has the Mylar film.

A mercury sphygmomanometer should be handled with extreme care. The instrument should not be dropped or treated in any way that could result in damage to the manometer. Regular quality control checks are conducted to ensure that there are no leaks from the inflation system and that the manometer has not been damaged so as to cause a loss of mercury. The Baum mercury manometers are designed to minimize mercury releases from its closed system; however, there are two ways in which mercury can be released from the manometers.

The glass tube release lever at the top of the wall mounted manometers is one potential source of mercury spillage. If this lever is inadvertently flipped back while the instrument is upright on the wall, the glass tube is released and the mercury spills out of the bottom of the tube. The lever should only be moved by a service technician when the sphygmomanometer is removed from the wall and lying

on its right side. Baum has added a safety feature to this release lever, with the addition of a “set screw” that prevents an accidental movement of the lever without a tool. If the unit has not been retrofitted with the “set screw” during routine maintenance, a safety modification, a “lever lock” is available free of charge from Baum. The “lever lock” is simply a small piece of metal bent at a 90 degree angle, which is easily slipped behind the lever to immobilize it. Once installed, the lever lock can be removed with a screwdriver. Spills are prevented because users cannot remove the lever lock without some effort; the lock simply eliminates the potential for anyone to idly flip the release lever.

The second manner in which mercury could be released is if the glass tube is damaged in some way. With the application of Mylar® to the glass tube, the incidence of glass tube damage has been drastically reduced. According to Baum, the mercury within the tube is contained within the Mylar coating.

F.2 Mercury Sphygmomanometer Procedures

The mercury devices maintained in the physician component are:

- One (1) wall-mounted unit model 33 Baum manometer;
- One (1) backup wall-mounted unit; and
- One (1) backup desktop unit.

At this time, physicians alone have the responsibility for installing the wall-mounted manometers, and this includes the blood pressure methodology study room.

The backup units should be kept in boxes in sealed plastic double bags in their own dedicated plastic bins.

All mercury manometers are periodically sent for cleaning and maintenance to Baum. The wall manometers in use should be taken down and sent back to the warehouse twice per year for servicing following the last day of exams prior to the summer and winter holiday vacations. Install the backup manometer, and send an inventory UFO that alerts the warehouse manager to send a replacement wall-mounted manometer to the field.

If a defect or irregularity is observed during a routine QC check, never attempt to repair the equipment yourself. Notify the MEC manager and package the manometer in preparation for shipping to the NHANES warehouse. The MEC manager will inform the warehouse manager that a replacement backup manometer is required. Packing, shipping, and installing these manometers require specific procedures to be followed.

F.2.1 Wall-Mounted Unit Model 33

Unpacking and mounting the unit



The manometers are sent to the MEC in a sealed box, and are stored on the MEC in dedicated plastic bins. The wall mount bracket is in place on the wall in the physician component room, as well as the blood pressure methodology room.

1. Remove the manometer from the box. ******IMPORTANT: Save the box—do not discard******; the box is required for safely storing and shipping the manometer back to the warehouse.
2. Carefully inspect the outer bag for mercury droplets. If no mercury is seen, remove contents from the outer bag.
3. Inspect inner bag for mercury droplets. If no mercury is seen, open bag and remove manometer.

4. To remove the blue shipping seal, place the instrument on its side and hold it securely. Grasp the blue shipping seal and pull it out. Important: you must remove the blue shipping seal before the instrument is mounted on the wall or pressurized.
5. Inspect the cartridge tube release lever located at the top of the manometer casing in front of the swivel screw. This lever releases the glass tube cartridge, *which should never be released under any circumstances on the MEC*. If the lever is not secured with a factory installed “set screw,” Baum has supplied us with L-shaped lever lock inserts designed to prevent tampering with the cartridge tube release lever and accidental release of mercury. See the following section for Lever Lock insertion instructions.
6. Remove the red cap from the metal connector at the bottom of the instrument. *******IMPORTANT: Save the red cap—do not discard*******; the red cap is required for storing and shipping the manometer. Tape the red cap to the box, and place the box inside the plastic bags.
7. Attach the instrument onto the mounting bracket attached to the wall. Tighten the chrome plated swivel screw at the top of the bracket, securing the manometer to the bracket with a flat head screw driver.
8. Attach the coiled Extendex® tubing to the metal connector at the bottom of the instrument.
9. Note the serial number located at the top right face of the manometer, just above the number 290, and give this to the MEC manager to be entered into the equipment tracking system.
10. Continue with equipment QC procedures.

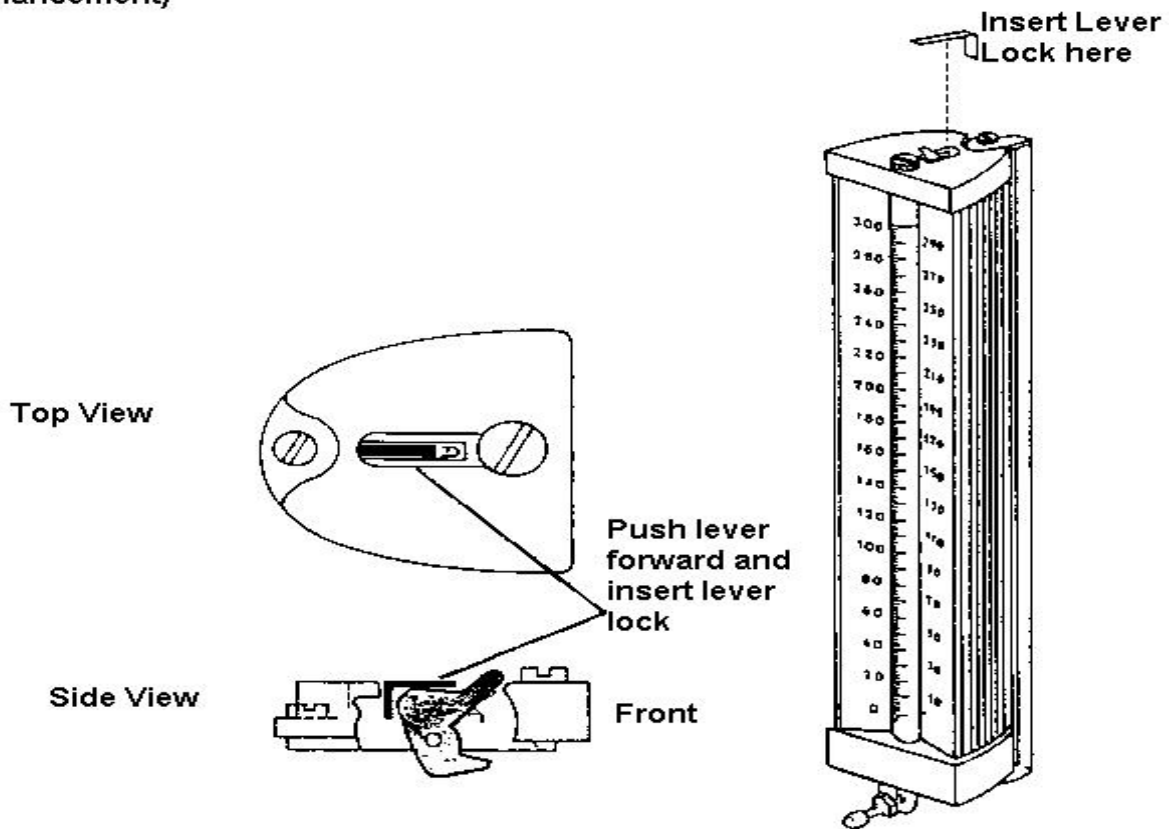
Lever Lock Insertion Instructions:

Although Baumanometer wall units sold in the last few years come equipped with a glass tube release lever secured with a “set screw” that keeps the lever in place, older models without these set screws are still common. While the manometers that are being sent to Baum for servicing return with the set screws, the survey does have the older models that do not have this safety feature. See the following instructions for inserting the lever locks provided by Baum.

Purpose

To prevent tampering with the cartridge tube release lever and accidental release of mercury.

Lever Lock Insertion Instructions (after-factory safety enhancement)



Teardown Procedures for Wall-Mounted Manometers

Installed wall-mounted manometers:

The installed wall-mounted manometers are left in place during MEC transport.

1. Complete the end-of-stand QC procedures for the manometer.
2. Observe that the swivel screw at the top of the manometer that secures the manometer to the wall bracket is sufficiently tight.
3. Place the cushions provided securely around the manometer.

Backup wall-mounted manometers:

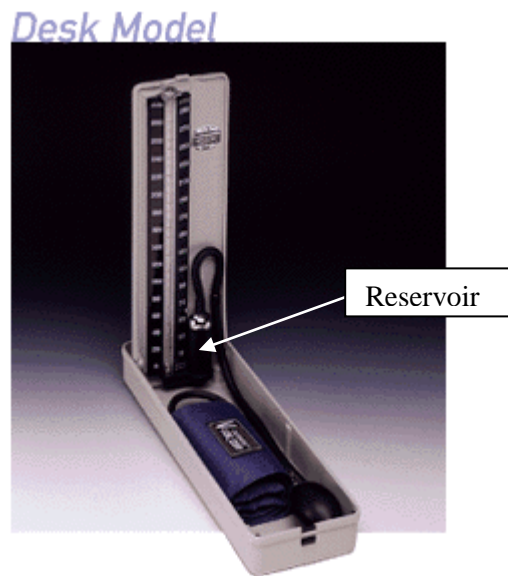
1. Keep the manometer in the packing--double plastic bags and box.
2. Store in the bin used for the manometers and pack in the black storage box.
3. Place in storage container in physician's room for transport to next stand.

*******Important: Do not store the mercury-containing manometers in the belly compartment during transport.*******

Packing Wall-Mounted Manometers for Shipping

1. Remove the coiled Extendex ® tubing from the instrument.
2. Attach the red cap firmly to the tubing connector on the instrument to seal.
3. Check that the lever lock, if needed, is in place on top of the instrument. If not, see attached instructions for inserting a lever lock.
4. Remove the instrument from the wall unit.
5. Place instrument in a plastic bag and seal closed with adhesive tape. Repeat this process with another plastic bag so that the unit is double bagged.
6. Wrap manometer box with bubble wrap.
7. Place the wrapped manometer into a box for shipping.
8. Give the boxed manometer to the MEC manager.
9. The MEC manager will enter the transfer of the equipment from the MEC to the warehouse in the equipment tracking system, and send the unit to the warehouse.

F.2.2 Desk-top Mercury Manometer



One Baum Desk Model mercury manometer is maintained as a backup manometer in the physician component. It is intended for use as a backup instrument for both the physician component as well as the blood pressure methodology study. The desk model weighs 2.7 pounds. Unlike the wall-mounted Baum manometer, the desk model does not require a safety enhancement like the lever lock.

Unpacking Desk Model Manometers :

1. Open box and remove manometer.
2. Carefully inspect outer bag for mercury droplets. If no mercury is seen, open bag and remove contents.
3. Carefully inspect the inner bag for mercury droplets. If no mercury is seen, open bag and remove the manometer box.
4. Open manometer and place upright on table.
5. Remove red cap from reservoir and reconnect tubing.

Packing Desk Model Manometer:

1. Tilt manometer onto reservoir-side. Mercury should be contained in reservoir.
2. Remove tubing from top of mercury reservoir.
3. Place red cap firmly on reservoir opening while manometer is on its side.
4. Stand manometer up, and close the unit.
5. Place instrument in a plastic bag and seal closed, then fold the end of the bag over and seal it with adhesive tape. Repeat this process with another plastic bag so that the unit is double bagged.
6. Wrap manometer box with bubble wrap.
7. Place the wrapped manometer into a box for shipping.
8. Place in storage container in physician's room for transport to next stand.

Appendix G

OMRON IntelliSense[®] Blood Pressure Monitor User Manual

The OMRON Model HEM-907XL instruction Manual is available at:

<http://www.omronhealthcare.com/img/shop/hem-907xl---2007-1628519-0b.pdf>

Appendix H

Oregon Scientific
Wireless Indoor and Outdoor Thermometer
User Manual

FIG. 1

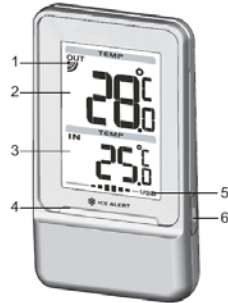


FIG. 2

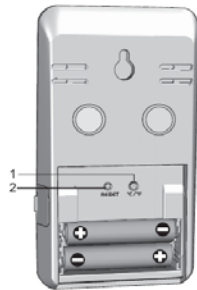
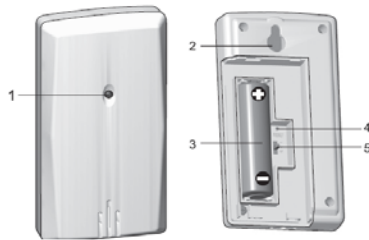


FIG. 3



**Wireless Indoor and Outdoor Thermometer
with USB
Model: EMS100
USER MANUAL**

EN

OVERVIEW

FRONT VIEW – FIG. 1

1. Remote sensor reception indicator
2. Outdoor temperature
3. Indoor temperature
4. Ice alert LED indicator
5. USB status indicator
6. USB port (at the side)

BACK VIEW – FIG. 2

1. °C / °F: Select temperature unit
2. **RESET**: Reset unit to default settings

REMOTE SENSOR – FIG. 3

1. **LED** status indicator
2. Wall mount hole
3. Battery compartment
4. **RESET** hole
5. **CHANNEL** switch

GETTING STARTED

INSERT BATTERIES

1. Remove the battery compartment.
2. Insert the batteries, matching the polarities (see FIG 2).
3. Press **RESET** after each battery change.

LOCATION	MEANING
Indoor temperature area	Main unit batteries low
Outdoor temperature area	Sensor batteries low

REMOTE SENSOR

To set up the sensor:

1. Open the battery compartment (see FIG 3).
2. Select channel 1 then press **RESET**.
3. Close the battery door.
4. Place the sensor within 30 m (98 ft) of the main unit using the table stand or wall mount.

NOTE Use alkaline batteries for longer usage and consumer grade lithium batteries in temperatures below freezing.

SENSOR DATA TRANSMISSION

To search for a sensor:

Reset the unit.

The sensor reception icon in the remote sensor area shows the status:

ICON	DESCRIPTION
OUT →	Main unit is searching for sensor(s).
OUT →	A channel has been found.
OUT	The sensor cannot be found.

TIP The transmission range may vary depending on many factors. You may need to experiment with various locations to get the best results.

ICE ALERT


If the temperature falls between 3°C to -2°C (37°F to 28°F), the green ice alert LED indicator will flash continuously, and will stop flashing once the temperature is out of this range.

CONNECTION TO PC

Temperature readings can be uploaded to the computer by connecting the main unit to the computer.

To upload the temperature data to the computer:

1. Install the PC software.
2. Follow instructions in the software programme.
3. Plug one end of the USB cable into the USB port and the other end into the computer.

4. If data upload is completed, the display will show  "USB".

NOTE Computer system requirements:

- Operating system: Microsoft Windows XP SP2 or Vista
- Processor: Pentium III or IV (recommended)
- RAM: Min. 256 MB or 512 MB (recommended)
- Hard disk free space: Min. 256 MB or 512 MB (recommended)
- CD-ROM or DVD drive

NOTE The USB is only used for uploading temperature data. It cannot be used for charging battery power.

RESET

Press **RESET** to return to the default settings.

PRECAUTIONS

- Do not subject the unit to excessive force, shock, dust, temperature or humidity.
- Do not cover the ventilation holes with any items such as newspapers, curtains etc.
- Do not immerse the unit in water. If you spill liquid over it, dry it immediately with a soft, lint-free cloth.
- Do not clean the unit with abrasive or corrosive materials.
- Do not tamper with the unit's internal components. This invalidates the warranty.
- Only use fresh batteries. Do not mix new and old batteries.
- Images shown in this manual may differ from the actual display.
- When disposing of this product, ensure it is collected separately for special treatment and not as normal household waste.
- Placement of this product on certain types of wood may result in damage to its finish for which Oregon Scientific will not be responsible. Consult the furniture manufacturer's care instructions for information.
- The contents of this manual may not be reproduced without the permission of the manufacturer.
- Do not dispose old batteries as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.
- Please note that some units are equipped with a battery safety strip. Remove the strip from the battery compartment before first use.

NOTE The technical specifications for this product and the contents of the user manual are subject to change without notice.

SPECIFICATIONS

TYPE	DESCRIPTION
MAIN UNIT	
L x W x H	63 x 23 x 115 mm (2.48 x 0.91 x 4.53 in)
Weight	80 g (2.8 oz) without battery
Temperature range	-5°C to 50°C (23°F to 122°F)
Resolution	0.1°C (0.2°F)
Signal frequency	433 MHz
Power	2 x UM-4 (AAA) 1.5 V batteries
REMOTE UNIT (THN132N)	
L x W x H	96 x 50 x 22 mm (3.78 x 1.97 x 0.87 in)
Weight	62 g (2.22 ounces)
Transmission range	30 m (100 ft) unobstructed
Temperature range	-20°C to 60°C (-4°F to 140°F)
Power	1 x UM-3 (AA) 1.5 V batteries

ABOUT OREGON SCIENTIFIC

Visit our website (www.oregonscientific.com) to learn more about Oregon Scientific products. If you're in the US and would like to contact our Customer Care department directly, please visit: www2.oregonscientific.com/service/support

OR

Call 1-800-853-8883.

For international inquiries, please visit:

www2.oregonscientific.com/about/international

EU-DECLARATION OF CONFORMITY

Hereby, Oregon Scientific, declares that this Wireless Indoor and Outdoor Thermometer with USB (Model: EMS100) is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC. A copy of the signed and dated Declaration of Conformity is available on request via our Oregon Scientific Customer Service.



COUNTRIES RTTE APPROVED COMPLIED
All EU countries, Switzerland  and Norway 

FCC STATEMENT

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

WARNING Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio / TV technician for help.

DECLARATION OF CONFORMITY

The following information is not to be used as contact for support or sales. Please call our customer service number (listed on our website at www.oregonscientific.com, or on the warranty card for this product) for all inquiries instead.

We
Name: Oregon Scientific, Inc.
Address: 19861 SW 95th Ave., Tualatin,
Oregon 97062 USA
Telephone No.: 1-800-853-8883

declare that the product
Product No.: EMS100
Product Name: Wireless Indoor and Outdoor
Thermometer with USB
Manufacturer: IDT Technology Limited
Address: Block C, 9/F, Kaiser Estate,
Phase 1, 41 Man Yue St.,
Hung Hom, Kowloon,
Hong Kong

is in conformity with Part 15 of the FCC Rules. Operation is subject to the following two conditions: 1) This device may not cause harmful interference. 2) This device must accept any interference received, including interference that may cause undesired operation.