National Health and Nutrition Examination Survey (NHANES)

Audiometry Procedures

December 2019

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Introduction 1

1.1 History and Overview of Hearing Examinations in NHANES

Hearing is important. Good hearing ability is an essential aspect of normal communication and plays an important role in safety and awareness in nearly every part of daily life. Hearing trouble results in a myriad of difficulties, including communication trouble, difficulty at school or work, social isolation and/or stigmatization, potentially accelerated cognitive decline, and economic ramifications at the family, community, and national level.

Our sense of hearing is truly remarkable. The smallest bones and the smallest muscles in the human body are contained within the ear. The ear can perceive vibrations that barely move the distance of an atom. It can also withstand the vibrations of much louder sounds, though sounds that are too intense can rip apart the tiny auditory structures. Our ears never rest—even when we are sleeping, our ears continue to respond to sounds (though our brains generally take a break from processing the auditory signals). Perhaps because of its delicate nature and constant function, hearing is the easiest of our five senses to lose.

Hearing loss is a widespread problem. Recent statistics indicate that 37.5 million adults aged 18 and older in the United States (U.S.) have some degree of hearing impairment (Blackwell et al., 2014). In fact, more people have hearing loss than any other disability (Huntington & Swanson, 2002). While the prevalence of hearing loss increases with age, it is not merely a problem of the elderly. Two or three out of every 1,000 children born in the U.S. are deaf or hard of hearing. Approximately 3 percent of children under age 20 have mild or worse hearing impairment (Mehra et al., 2009). Among adults, disabling hearing loss occurs in about 2 percent of those aged 45 to 54, 8.5 percent of those aged 55 to 64, nearly 25 percent of those aged 65 to 74, and in half of those who are 75 and older. For reasons that are not fully understood, hearing loss is more prevalent and more severe on average in men than in women. Less than 30 percent of adults who could benefit from a hearing aid actually use one (http://www.nidcd.nih.gov/health/statistics/quick-statistics-hearing).

Furthermore, approximately 50 million Americans report tinnitus (ringing in the ears), a condition that can be as disabling as hearing loss. Over 16 million of these individuals suffer frequent tinnitus, and about 2 million experience tinnitus so severe that it interferes with their daily life (Shagorodsky et al., 2010a; ATA, 2016). Tinnitus frequently affects children as well as adults (Mahboubi et al., 2013).

Hearing loss can be caused by a myriad of factors—age, noise exposure (occupational or recreational), developmental syndromes, infectious disease, physical trauma, ototoxic drugs, and chemicals—all of which are further influenced by genetic susceptibility. Hearing loss is an "invisible" impairment; that is, there are usually no obvious external signs of the damage that is done. In children, it often goes undetected for some time while parents, educators, or health professionals mistake the signs of hearing difficulty for behavior problems or learning disabilities. In older individuals, hearing loss usually develops gradually and insidiously over time. Because of this, individuals frequently interpret their hearing loss as "mumbling" by others or "getting used to" sounds. Others often misconstrue someone's hearing difficulty as inattentiveness or dementia. Often, extensive and irreparable damage has been done to the auditory system before it is noticed.

The National Center for Health Statistics (NCHS) has regularly included evaluations of the auditory system in its health examination surveys. These evaluations have included one or more of the following: a brief medical examination of the ear (otoscopy), interview questions regarding hearing symptoms and risk factors for hearing loss, immittance (a test of middle ear function), pure tone air conduction audiometry, pure tone bone conduction audiometry, and/or speech discrimination testing. Sometimes these evaluations have been done on all NHANES examinees, and some surveys included hearing evaluations on only a subset of examinees (such as children or adults). Table 1-1 summarizes the audiometric procedures included in each of the health examination surveys since 1960.

As the table indicates, young children (aged 6-11 years) had not been included in the audiometric NHANES sample in the 20+ years between the end of NHANES III and the 2017 NHANES survey cycle. Hearing in early childhood is critical to normal development. Children learn to talk by listening to others and imitating the sounds they hear; early childhood hearing loss can cause speech or vocabulary delays. As children enter school, poor hearing can interfere with academic achievement and inhibit social development. Children with hearing loss may have difficulty with language skills, poor reading comprehension, and lower standardized test scores. Poor academic performance can occur even in children with mild hearing impairment in early grades (Finitzo-Hieber & Tillman, 1978). Without intervention, these students can fall behind by several grade levels and often never catch up with their peers (Nelson, 1997).

Table 1-1. Summary of NHANES audiometric procedures

Survey	Years	Age	Immittance	Pure tone testing 250	500	1000	2000	3000	4000	6000	8000	Bone	Speech
NHES I*	1960-1962	18-74	✓		✓	✓	✓	✓	✓	✓			
NHES II	1963-1965	6-11		✓	✓	✓	✓	✓	✓	✓	✓		
NHES III	1966-1970	12-17		✓	✓	✓	✓	✓	✓	✓	✓		
NHANES I	1971-1974	25-74			✓	✓	✓		✓			✓	
Augmented	1974-1975	25-74			✓	✓	✓		✓				✓
NHANES II	1976-1980	4-19			✓	✓	✓		✓				
HHANES**	1982-1984	6-74	✓		✓	✓	✓		✓				
NHANES III	1988-1994	6-19	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 99-04	1999-2004	20-69	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 05-06	2005-2006	12-19, 70+	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 07-08	2007-2008	12-19	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 09-10	2009-2010	12-19, 70+	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 11-12	2011-2012	20-69	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 15-16	2015-2016	20-69	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 17-18	2017-2018	6-19, 70+	✓		✓	✓	✓	✓	✓	✓	✓		
NHANES 19-20	2019-2020	6-19, 70+	✓		✓	✓	✓	✓	✓	✓	✓		✓

* National Health Examination Survey.
**Hispanic Health and Nutrition Examination Survey.

Hearing in adolescents (aged 12-19 years) has been evaluated in NHANES approximately every 10 years (1966-1970, 1976-1980, 1988-1994, 2005-2010, 2017+). Hearing loss in this age range presents an important public health problem. Analysis of audiometric data from the 1988-1994 and the 2005-2006 survey cycles indicates that the prevalence of hearing loss in this age group rose from 3.5 percent to 5.3 percent (Shargorodsky et al., 2010b). A recent report from the World Health Organization (2015) states that nearly half of all teenagers and young adults (aged 12-35 years) in middle- and high-income countries are exposed to hazardous sounds from personal music players. Because of the alarming rate of possible noise-induced hearing loss in this subpopulation, and because hearing loss from this cause is completely preventable, it is important to continue monitoring this group so that the effectiveness of current prevention activities can be evaluated and future efforts can be properly targeted.

Older adults (aged 70+ years) have been evaluated in only two NHANES cycles prior to 2017—2005-2006 and 2009-2010. As the prevalence of hearing loss increases with age, this segment of the population is assumed to be the most affected by hearing difficulties. A recent analysis of NHANES hearing data among adults aged 20-69 years indicated a small decline in the prevalence of hearing loss among working-age adults, suggesting the onset of age-related hearing loss may be delayed until later in life (Hoffman et al., 2016). Furthermore, shifts in national demographics, diversification of the workforce and changing occupational exposures, increases in environmental noise, emergence of new illnesses, advances in clinical medicine, and development of new pharmaceuticals make it necessary to periodically re-examine the prevalence of hearing disorders among older adults. For all these reasons, the audiometric testing that will be conducted in the current NHANES cycle is very important.

A special emphasis of the NHANES hearing component since 1999 has been collection of data to assist in studies of hearing loss induced by noise and/or other ototraumatic agents. In addition to exposure to noise from personal audio devices mentioned earlier, many individuals are exposed to potentially hazardous levels of sound from other noisy activities and hobbies—including concerts, music venues such as bars or dance clubs, sporting events, motorcycles, recreational vehicles, mass transit systems, fireworks, and hunting or target shooting. An estimated 22 million U.S. workers are exposed each year to potentially hazardous noise on the job (Tak et al., 2009). As many as 26 million U.S. adults have developed a hearing loss as the result of their noise exposure—hearing losses that are nearly all preventable. Some chemicals may also damage the ear—such as lead, solvents, and carbon monoxide. The NHANES questionnaires include items about noise and other ototoxic exposures on- and off-the-job so that cohorts of exposed and unexposed individuals can be compared. These data will also be available as a comparison dataset in future studies of hearing loss, and as a baseline to monitor progress in prevention.

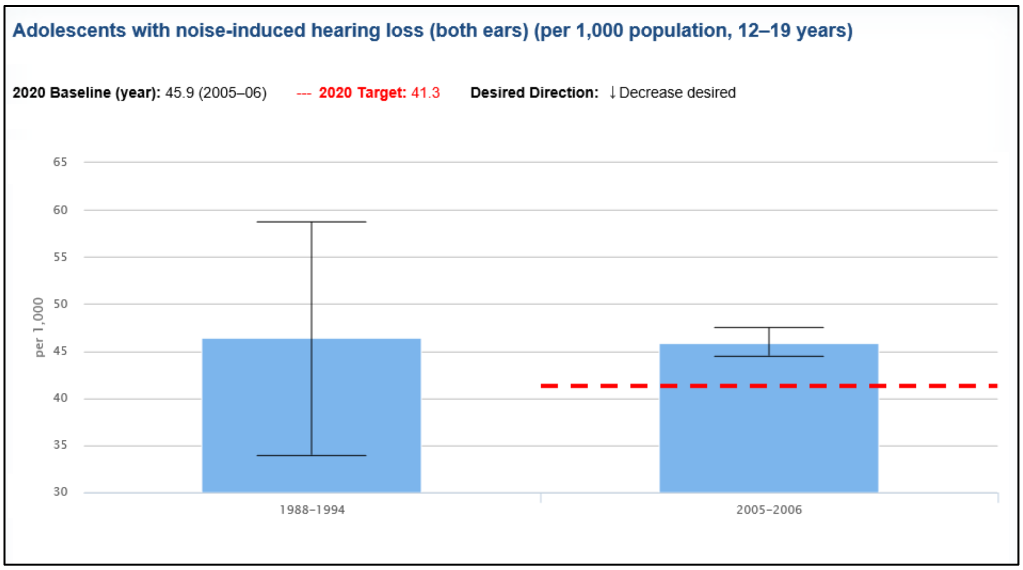
Although in the past, NHANES has been a periodic survey, it is currently authorized to run continuously. This has made it possible to use NHANES to collect data to monitor progress toward health objectives outlined in Healthy People 2020—the prevention agenda for the nation (http://www.healthypeople.gov/). Healthy People is a national health promotion and disease prevention initiative created by the Federal Government to provide a framework for monitoring progress toward identifying and reducing significant, preventable health problems, increasing the quality and years of healthy life, and eliminating health disparities. The current Healthy People program includes eleven hearing-related objectives, at least five of which rely on data collected through NHANES for baseline measurements or monitoring progress. These objectives include:

- ENT-VSL-3: Increase the proportion of persons with hearing impairments who have ever used a hearing aid or assistive listening devices or who have cochlear implants;
- ENT-VSL-4: Increase the proportion of persons who have had a hearing examination on schedule;

- ENT-VSL-6: Increase the use of hearing protection devices;
- ENT-VSL-7: Reduce the proportion of adolescents who have elevated hearing thresholds, or audiometric notches, in high frequencies (3, 4, or 6 kHz) in both ears, signifying noise-induced hearing loss; and
- ENT-VSL-8: Reduce the proportion of adults who have elevated hearing thresholds, or audiometric notches, in high frequencies (3, 4, or 6 kHz) in both ears, signifying noise-induced hearing loss.

Figure 1-1 shows progress toward reducing the prevalence of noise-induced hearing loss in adolescents (Objective ENT-VSL-7). Although the rate of noise-induced hearing loss is declining in this group, the 2020 target has not yet been met.

Figure 1-1. Progress toward reducing hearing loss among U.S. youth



The bar on the left represents the prevalence of youth aged 12-19 years with evidence of noise-induced hearing loss in NHANES III; the bar on the right shows a reduced prevalence on noise-induced hearing loss in this age group in NHANES 2005-2006. The dashed line shows the HP2020 target, which has not yet been met. (From HealthyPeople.gov; https://www.healthypeople.gov/2020/data/Chart/4420?category=1&by=Total&fips=-1.)

NHANES data are crucial to monitoring hearing health and targeting appropriate interventions. See http://www.healthypeople.gov/2020/topics-objectives/topic/hearing-and-other-sensory-or-communication-disorders/objectives for more information about Healthy People 2020 objectives and progress that has been made in meeting the hearing-related goals.

The current protocol for the hearing examination component of the NHANES was developed by NCHS in collaboration with the National Institute for Occupational Safety and Health (NIOSH) and the National Institute on Deafness and Other Communication Disorders (NIDCD) in 1999. The examination includes several parts:

- Questionnaire items – hearing-related questions included on both the household questionnaire (self-reported hearing ability; use of hearing aids and hearing protective devices; relevant medical history; noise exposure history) and in the mobile examination center questionnaire (current conditions that could affect the results of audiometric testing);
- Otoscopy – a cursory physical examination of the outer ear;
- Acoustic immittance – an objective evaluation of middle-ear function; and
- Pure tone air conduction audiometry – a basic evaluation of hearing sensitivity.

Additionally, the 2019-2020 hearing examination includes Words-In-Noise (WIN) testing for certain participants aged 70+ years. The WIN evaluates how well a person can hear speech in the presence of background noise. It is a test of the functional impact of hearing loss on listening situations often encountered in daily life.

Information obtained through the audiometric examinations conducted in the NHANES will provide valuable data that will be utilized by researchers throughout the U.S. and across the world. The data will serve as a reference for studies of hearing ability in other groups or particular U.S. subpopulations. The data will also provide a baseline from which to measure future progress in preventing hearing loss from noise, ototoxic exposures, medical conditions, and the like. Specifically, the goals of the current NHANES hearing component are to:

1. Establish technically valid and statistically representative threshold data describing the hearing sensitivity of the U.S. population aged 6-19 years and 70+ years stratified by gender, race, socioeconomic status, geographic region, and other variables;
2. Define the prevalence of hearing impairment among the noninstitutionalized U.S. population aged 6-19 years and 70+ years, and compare that prevalence to hearing loss estimates from earlier NHANES cycles;
3. Quantify the association between prevalence and risk factors such as noise exposure, medical conditions, ototoxicity from chemical exposures or pharmaceuticals, etc.;
4. Monitor the prevalence of early hearing losses consistent with overexposure to noise among U.S. youth aged 6-19 years, evaluate progress toward prevention, and identify particular subpopulations at risk for targeted prevention programs;

5. Evaluate the functional impact of hearing loss (i.e., ability to understand speech in a complex listening environment) among U.S. adults aged 70+ years; and

6. Monitor progress toward Healthy People 2020 hearing-related goals.

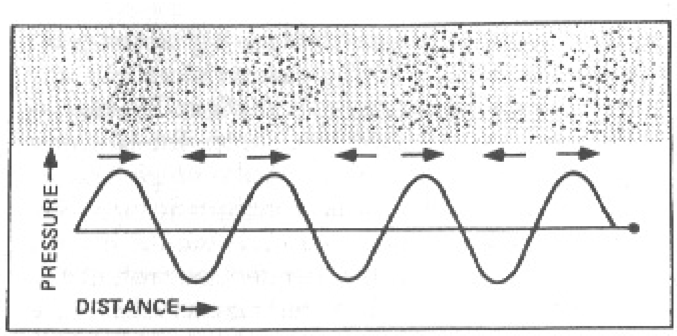
You, as a health technologist for NHANES, play a crucial role in collecting these important data. You will be responsible for conducting the examinations, monitoring the equipment calibration and test environment, maintaining the equipment and troubleshooting difficulties, and keeping relevant records. You will not be expected to interpret the test results or provide feedback to the study participants (SPs). You will receive extensive training to ensure that you understand and are able to carry out these protocols. Nationally representative surveys such as NHANES are expensive and require significant planning and oversight to ensure technically accurate information. Please always follow the standardized procedures that have been developed for the hearing component, which are outlined in this manual. While some of the procedures may appear to be simple, it is critical that you follow them exactly, so that data on each examinee are obtained in a uniform manner. If you are ever uncertain about any procedure or examinee, always ask your supervisor.

Before discussing the specific protocol for the NHANES hearing component, it is important to cover some basic information about sound and audition. A rudimentary knowledge of the physiology of hearing is essential to understanding how to test hearing.

1.2 Basic Principles of Sound

Sound can be defined in the physical sense as a series of pressure waves caused by a vibrating object and propagated through an elastic medium (see Figure 1-2). In other words, sound is initiated when an object begins to vibrate. As the object moves back and forth, it “bumps into” molecules in the surrounding area, forcing them to also move. These displaced molecules in turn put pressure on other molecules, and thus the sound wave is propagated. Because the molecules return to their original resting position following displacement, sound is said to occur in an “elastic” medium.

Figure 1-2. Schematic representation of sound propagation



The small dots in the top of the diagram represent air molecules moving back and forth from their resting position, creating pressure "waves." The lower part of the diagram depicts the pressure wave graphically. (From Suter A.H. *Hearing Conservation Manual*, 3rd Edition. Council for Accreditation in Occupational Hearing Conservation, Milwaukee, 1993.)

In the physiological sense, sound can be defined as the sensation evoked in the auditory system by these pressure changes. This will be discussed further in Section 1.3.

Sound may be characterized along three main parameters: frequency, intensity, and complexity. Frequency is the rate of the sound pressure waves, or how often the molecules are displaced in a given period. Frequency is measured in Hertz (Hz), or cycles per second, and is perceived as pitch. Lower pitched sounds (such as the rumble of traffic or a man's speaking voice) are lower in frequency; higher pitched sounds (such as a whistle or a baby's cry) have higher frequencies.

Intensity refers to the amplitude of the pressure waves, or how far the molecules are displaced from their original position. Amplitude is measured in decibels and is perceived as volume, or loudness. Low amplitude sounds (in which the molecules are displaced only a little bit) are perceived as "quiet," and high amplitude sounds (in which the displacements are larger) are perceived as "loud."

Complexity refers to the interaction of the various frequencies and intensities that make up a sound. For example, a pure tone is a sound that is made up of only one frequency and one intensity. Pure tones do not exist in nature. Most sounds are made up of many frequencies at different intensities combined to make a very complex signal. Complexity is perceived as sound quality or timbre. If a flute and violin are playing the same note at the same volume, complexity is the parameter of sound that allows us to distinguish between the two instruments.

Within the context of NHANES, we will be concerned primarily with the frequency and intensity of signals. The human ear is responsive to frequencies from about 20 to 20,000 Hz, but not equally so. It is most sensitive from about 1000 to 3000 Hz. The frequencies most necessary for understanding speech are 500 to 4000 Hz, so the human ear is really "tuned" to listen to human speech.

Audiometry conducted as part of the current NHANES will include test frequencies from 500 to 8000 Hz.

Test frequencies in audiometry are derived from the musical scale, and are generally octave intervals. An octave is a tone with a frequency that is exactly twice that of a reference tone. Therefore, the basic audiometric test frequencies are 500, 1000, 2000, 4000, and 8000 Hz. In addition, testing is often done at 3000 and 6000 Hz (sometimes called the inter-octave frequencies) because these frequencies are useful in identifying hearing losses due to noise exposure.

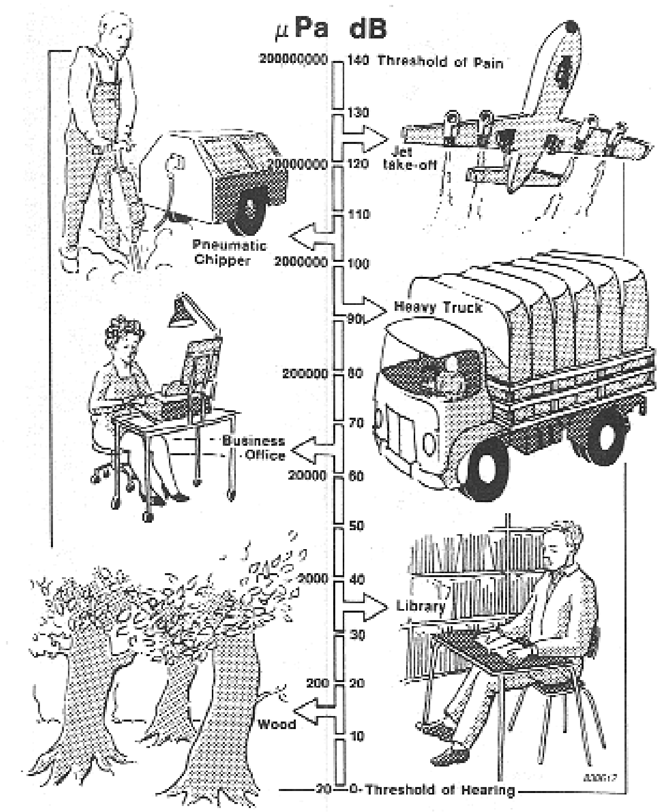
Intensity is a little more complicated. Remember that intensity refers to amplitude, or how far the molecules are displaced from their resting position by the vibrating object that is creating the sound. The farther the molecules are displaced, the greater pressure they place on neighboring molecules. Thus, intensity is measured in units of pressure; the higher the pressure, the louder the sound.

The human ear is responsive to a very wide range of pressures. The pressure of a sound that is just barely audible to a young, normal-hearing listener is approximately 20 µPa (the µPa—micropascal—is a unit for measuring pressure). The pressure of a sound that is painfully loud could be as much as 200,000,000 µPa. Because it is a bit cumbersome to use such a large range to quantify intensity, we use ratios to convert the pressure measurements to decibels. In decibels, the human ear is responsive to intensities from 0 dB to 140 dB—a much more manageable range. Figure 1-3 illustrates the sound levels of some common activities and shows the relationship between sound pressure in micropascals and sound level in decibels.

The decibel scale is logarithmic rather than linear; this means that the difference in actual sound pressure from one decibel to the next increases as the decibel level increases. For example, the increase in pressure from 20 to 40 dB is not the same as the increase in pressure from 40 to 60 dB. As you can see from the scale in Figure 1-3, pressure increases by 1800 µPa from 20 to 40 dB, but pressure increases by 18,000 µPa from 40 to 60 dB. Because of the logarithmic nature of the scale, decibels cannot be added and subtracted in the usual way. Two independent 90 dB sound sources produce a sound level of about 93 dB when they are put together, not 180 dB.

There are several different decibel scales used in measuring sound and hearing. When measuring sound levels at different frequencies in the environment (for example, when you measure the background noise levels in the test room as described in Section 2.4.2.3), the **sound pressure level** scale is used; results are recorded in **dB SPL.** When measuring an individual's hearing thresholds (for example, when doing pure tone audiometry as described in Section 3.5.3), the **hearing level** scale is used; results are recorded in **dB HL.** A measurement of 30 dB SPL is not the same as a measurement of 30 dB HL.

Figure 1-3. Sound levels of various activities



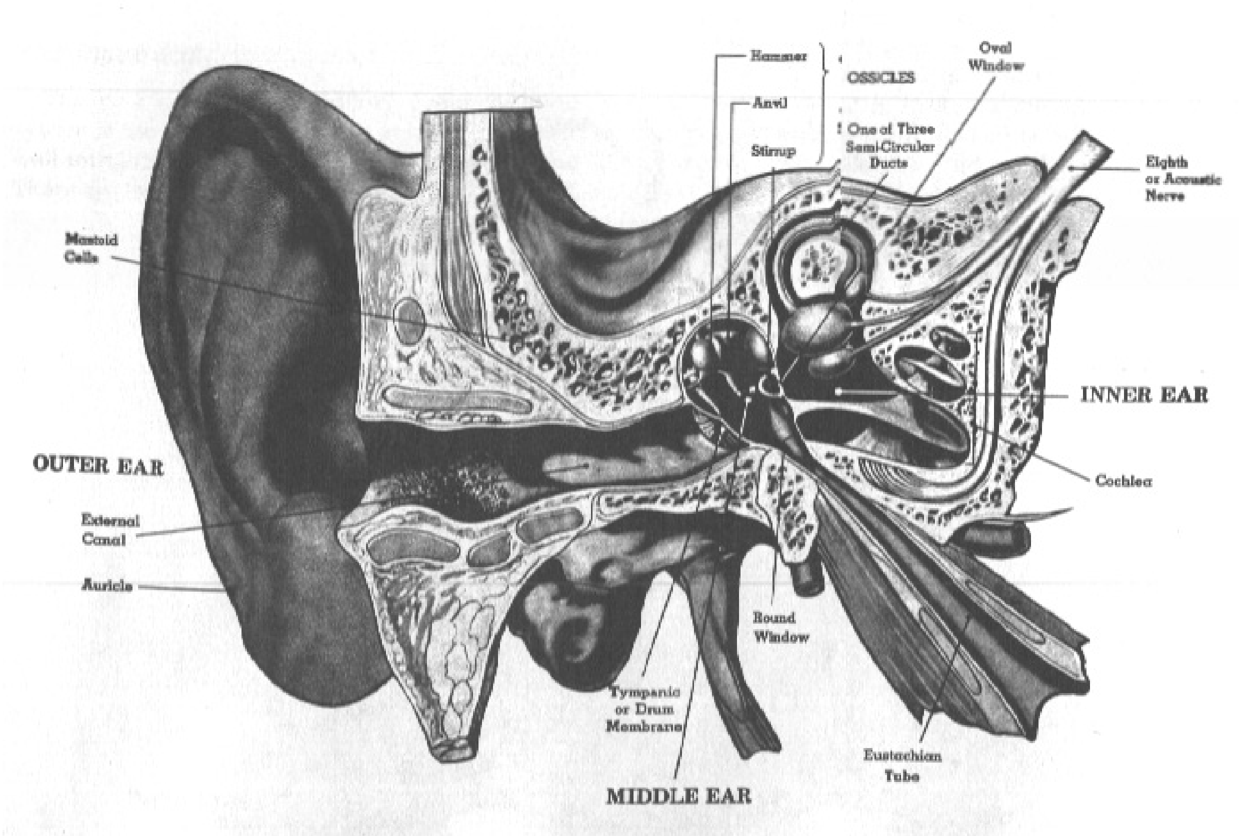
The intensity of the sound is shown in micropascals on the left and decibels on the right. (From Suter, A.H. *Hearing Conservation Manual*, 3rd Edition. Council for Accreditation in Occupational Hearing Conservation, Milwaukee, 1993).

Finally, it is important to note that a sound intensity of 0 dB does not mean that there is no sound at all—just like a temperature of 0°F does not mean that there is no heat at all. There are sounds that are quieter than 0 dB, and these sounds are measured in negative decibels in the same way that temperatures colder than 0° are measured in negative degrees.

1.3 Basic Principles of Audition

When you think of the ear, you probably think primarily of the two most visible portions of the auditory system that are located on either side of the head. However, the ear is much more than this. The ear actually has four main parts: the outer ear, the middle ear, the inner ear, and the auditory neural system (see Figure 1-4).

Figure 1-4. Schematic diagram of the ear



(From Suter A.H. *Hearing Conservation Manual*, 3rd Edition. Council for Accreditation in Occupational Hearing Conservation, Milwaukee, 1993).

The outer ear consists of the auricle (sometimes called the pinna) and the ear canal (also called the external auditory meatus). The outer ear functions primarily to funnel sound into the ear, and to modify, to some extent, the acoustic signal. The shape and size of the ear canal cause it to amplify signals with frequencies of approximately 2000-3000 Hz; this is the main reason that human hearing is most sensitive in this frequency range.

The middle ear consists of the eardrum (or the tympanic membrane); three tiny bones (or ossicles) called the malleus, the incus, and the stapes; and two small muscles. The primary function of the middle ear is to transform the acoustic signal into mechanical vibration. The middle ear muscles form part of a reflex arc (known as the acoustic reflex), which provides some small amount of protection against loud sounds. The middle ear also houses an opening to the eustachian tube, which connects this part of the ear to the back of the throat. The eustachian tube permits ventilation of the middle ear space, which maintains a balance in air pressure on either side of the eardrum; this balance is necessary for the eardrum to respond to sound most efficiently.

The inner ear consists of the cochlea, which is contained within a spiral opening in the temporal bone of the skull. The cochlea is divided into three parallel, fluid-filled ducts. The upper and lower ducts are connected at one end, and a wave is set up in them as the ossicles vibrate in response to sound. The middle duct contains rows of tiny hair cells. These hair cells bend as the wave comes to a peak; the bending of the hair cells stimulates the auditory nerve. The inner ear therefore serves to transform the mechanical vibrations from the middle ear into neural impulses.

Finally, the auditory neural system consists of the auditory nerve and the auditory areas of the cortex. This system carries the neural impulses to the brain and interprets them.

The auditory system is complete and possesses normal adult sensory function approximately half-way through prenatal development. The ability of the auditory neural system to process signals, however, continues to develop for several years. Newborns are able to discriminate sounds on the basis of frequency, intensity, and type of stimulus. (They prefer human speech!) Over the first few months, infants learn to locate the source of sounds, associate hearing with their own vocal productions, and gradually to better and better imitate the vocal sounds of others. By 1 year of age, they are able to process the meaning of approximately 50 words. By age 4, children can process and understand just about everything they hear.

Auditory sensitivity reaches its peak at adolescence and then begins a very gradual decline. Barring any insult that would accelerate the decline (such as noise or disease), the reduction in sensitivity is not generally clinically measurable until at least the third decade of life. After about age 60, hearing sensitivity decreases by an average of about 10 dB per decade. The decrease in hearing sensitivity begins at the highest frequencies and gradually progresses to include the middle and low frequencies. Hearing loss due to age-related changes is called presbycusis.

There are a number of other age-related changes that occur in the ear. The cartilage in the outer ear and the ear canal begins to deteriorate, causing the auricle and canal opening to become very soft; this can cause a condition known as "canal collapse," which can affect hearing test results (see Section 3.3.3). Additionally, the auricle gets larger and the ear canal narrows, potentially shifting the resonant characteristics of the outer ear. Cerumen becomes drier, which—in combination with narrower ear canals—can impede the natural expulsion of wax from the ear. Cerumen becomes more easily trapped, potentially partially or completely blocking the ear canal and causing a temporary loss of hearing. The tympanic membrane may become less flexible and there can be slight degenerative changes in the joints between the bones in the middle ear. However, none of these issues are typically significant enough to affect hearing sensitivity (Chisolm et al., 2003).

1.4 Basic Principles of Hearing Loss

Dysfunctions anywhere along the auditory pathway can cause hearing loss. Most hearing losses (such as age- and noise-related hearing losses) occur gradually over time, although sudden hearing losses (such as from infection or trauma) are possible. Many sudden hearing losses are idiopathic—meaning the cause remains unknown. Hearing losses can be stable (not changing over time), progressive (getting worse over time), or fluctuating (getting sometimes better and sometimes worse). Hearing losses may be divided into several categories based on where in the ear the impairment is located (the type of hearing loss), how severely the impairment affects a person's hearing sensitivity (the **degree** of hearing loss), and which ears are affected (the **laterality** of the hearing loss).

Hearing losses that are caused by a problem in the external or middle ear are called conductive hearing losses, because the difficulty lies in the conduction of sound to the cochlea. For example, excessive wax in the ear canal, fluid in the middle ear brought on by an infection, or a discontinuity between the ossicles would prevent sounds from reaching the inner ear efficiently. These types of hearing losses are often medically or surgically correctable.

Hearing losses that are caused by a problem in the inner ear or along the auditory nerve are called sensorineural hearing losses, because the difficulty lies in the ability of the cochlea to sense the sound or the ability of the nerve to carry the signal to the brain. Damage to the cochlear hair cells due to age-related deterioration, repeated noise exposure, or a tumor on the auditory nerve are examples of etiologies that would lead to sensorineural hearing impairment. These types of hearing losses are not usually medically correctable. Often, sensorineural hearing loss can be remediated to a certain extent with hearing aids. However, while hearing aid technology has improved immensely over the past few years, hearing aids do not restore normal hearing in the same sense that eyeglasses restore normal vision.

A hearing loss can also be "mixed"—that is, partly conductive and partly sensorineural. For example, if a person has a noise-induced hearing loss and then develops an ear infection, he would have a mixed hearing loss. The conductive part of the hearing loss may resolve when the infection clears up, but the sensorineural portion of a mixed hearing loss is generally permanent.

Classifying degree of hearing loss is much more complex. The severity of the handicap due to abnormal hearing thresholds depends on a number of interrelated factors, such as the age of the individual, the age at which the impairment was first sustained, the point of damage within the auditory system, the individual's communicative environment and needs, the presence or absence of other illnesses or sensory deficits, etc. For example, a person who has had significant hearing loss since birth is affected differently than someone who acquires a similar hearing loss after reaching adulthood. A person with a conductive hearing loss (which causes simply a reduction in the audibility of sounds) is affected differently than someone with a sensorineural hearing loss (which often causes a reduction in the intelligibility as well as the audibility of sounds), even if their thresholds are the same. And a person whose only sensory impairment is hearing loss is affected differently than someone with the same hearing thresholds but who also has significant visual or mobility impairments.

Nevertheless, some basic scheme for classifying severity of hearing loss is necessary. Although there is no one universally accepted method of defining degree of hearing loss, the following system is generally representative of the various schemes currently in use:

- 0-25 dB Normal hearing;
- 26-40 dB Mild hearing loss;
- 41-55 dB Moderate hearing loss;
- 56-70 dB Moderately severe hearing loss;
- 71-90 dB Severe hearing loss; and
- 91+ dB Profound hearing loss.

Quite often, an individual has different degrees of hearing loss at different frequencies. For example, normal hearing in the low frequencies and gradually worsening hearing sensitivity in the high frequencies is typical of age-related and noise-related impairments. In cases such as these, the classification scheme may be applied to each test frequency individually (for example, "normal hearing sensitivity through 1000 Hz, gradually sloping to a moderately severe hearing loss at the highest test frequencies"); or thresholds at various frequencies may be averaged and an overall hearing loss rating may be assigned. Here again, however, there is little agreement as to which frequencies ought to be averaged. The American-Speech-Language-Hearing Association (1981) and NIOSH (1996) classify hearing impairment according to the average hearing threshold at 1000, 2000, 3000, and 4000 Hz. Other recommendations include average thresholds at 500, 1000, and

2000 Hz or an average of 1000, 2000, and 3000 Hz. Some schemes even involve weighting the various frequencies included in the average. Audiometric results obtained in NHANES will be reviewed by an audiologist who will determine the scheme to be used in classifying degree of hearing loss.

Finally, hearing losses may be classified as either unilateral (affecting only one ear) or bilateral (affecting both ears). Bilateral hearing losses may be symmetric (approximately the same in each ear) or asymmetric (worse in one ear than the other). Hearing losses from environmental causes (such as noise, ototoxic chemicals, and aging) are generally bilateral and symmetric. Hearing losses from medical causes (such as ear infections, mumps, and acoustic tumors) are often unilateral or asymmetric. A substantial difference in hearing sensitivity between ears can therefore be indicative of a medically significant condition.

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Equipment 2

2.1 Description of Exam Room in the MEC

Hearing testing is conducted in the Audiometry room, located in trailer #3 of the mobile examination center (MEC). A special sound booth (manufactured by Acoustic Systems, model Delta 142) has been built into this room. This triangular-shaped booth is designed to ensure that the sound levels inside are sufficiently quiet to permit accurate hearing threshold measurements. In addition to the sound booth, the exam room has several other features designed to further reduce the sound levels in the room. These include sound dampening materials on the interior walls of the exam room and a rubber seal on the hallway door.

The area outside the sound booth includes two separate work areas for the technologist. One of the work areas is located in front of the sound booth just under the window, and consists of a small, custom-built triangular table that accommodates the audiometric testing system hardware (chassis, computer tower, monitor, keyboard, and mouse) as well as the network computer tower for the Integrated Survey Information System (ISIS). The placement of the table allows the technologist to observe the study participant (SP) during air conduction testing, yet helps ensure that the SP is unable to observe the technologist in order to prevent any inadvertent cueing that would compromise the test results. The second work area is located to the side of the booth and includes a desk area and upper and lower storage cabinets for supplies and spare equipment. There is an additional work area inside the sound booth that holds the remaining audiometric equipment as well as supplies needed during the examination. The ISIS computer display and keyboard/mouse are also located in this work area to facilitate data entry during the exam.

The entire audiometric exam is conducted with the SP seated inside the booth. SPs must step over a raised threshold to enter the sound booth. The threshold is approximately 4 inches high. A portable metal wheelchair ramp is available for SPs to facilitate their movement in and out of the booth if they are in a wheelchair or have other mobility problems. The ramp can be lifted out of the way and stored by the work area to the side of the booth when not in use. SPs who cannot get in and out of the booth safely will be excluded from the exam.

2.2 Description of Equipment and Supplies

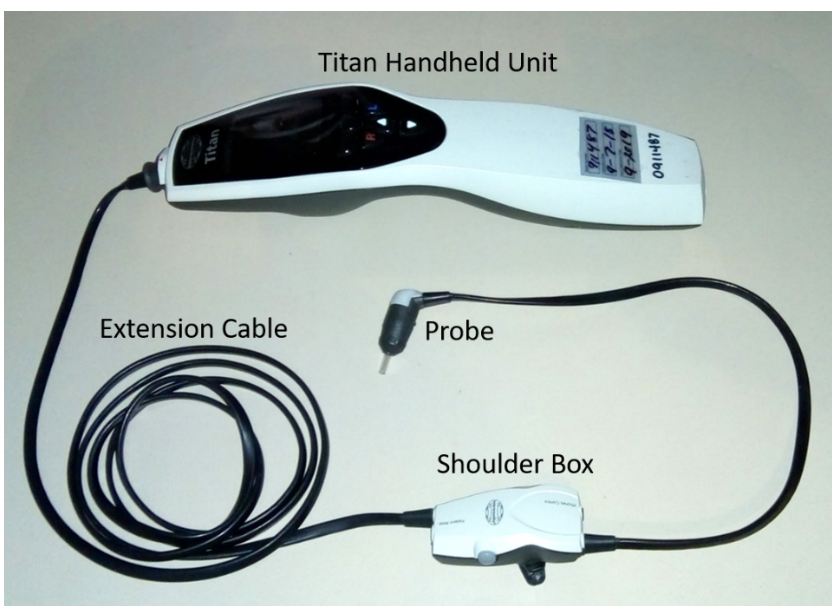
The following equipment has been supplied for the hearing component of NHANES:

- Welch-Allyn Model 25020 otoscope (Exhibit 2-1) with rechargeable handle and disposable specula in two sizes (pediatric [2.75 mm] and adult [4.25 mm]).

Exhibit 2-1. Welch-Allyn Model 25020 otoscope

- Interacoustics Titan handheld unit with probe tip and shoulder box and extension cable (Exhibit 2-2).

Exhibit 2-2. Interacoustics Titan handheld unit and cables

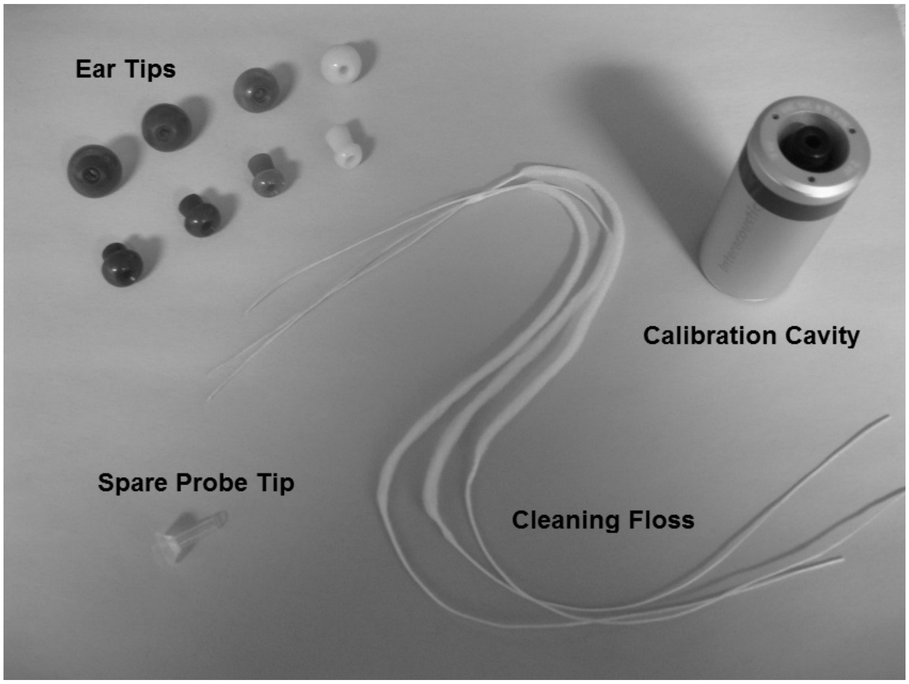


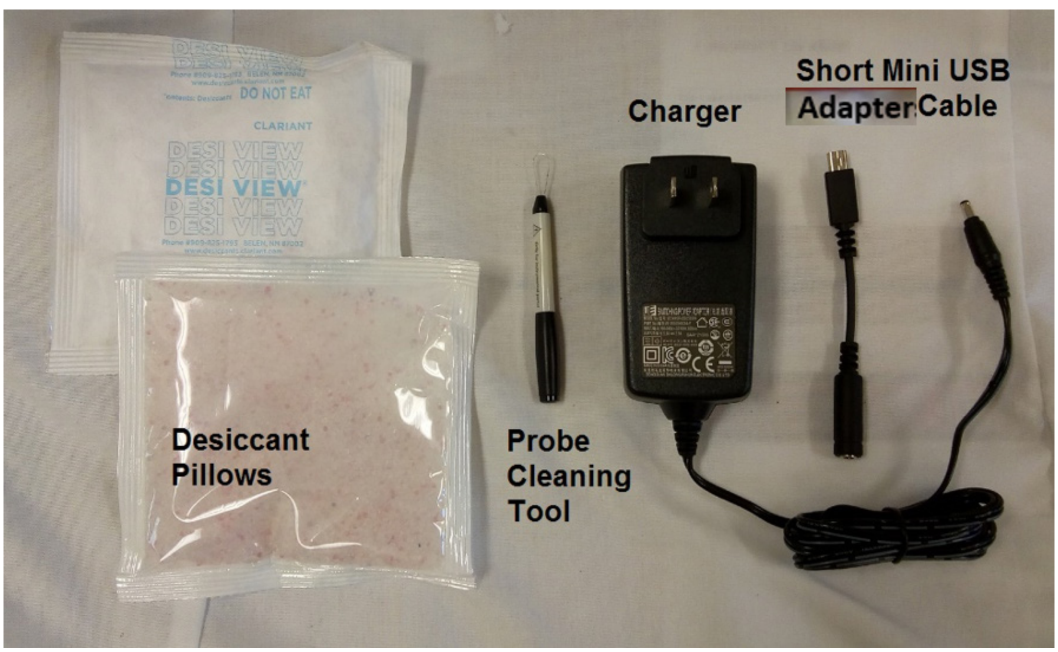
- Titan charging cradle – composed of the cradle, back plate, power cord, and USB computer cable (Exhibit 2-3).

Exhibit 2-3. Unassembled parts for the Titan cradle

- Parts and supplies for the Titan: disposable ear tips in various sizes, calibration cavity, spare probe tip, cleaning floss, external wall charger with short mini USB adapter cable, probe cleaning tool, and desiccant pillows (Exhibit 2-4).

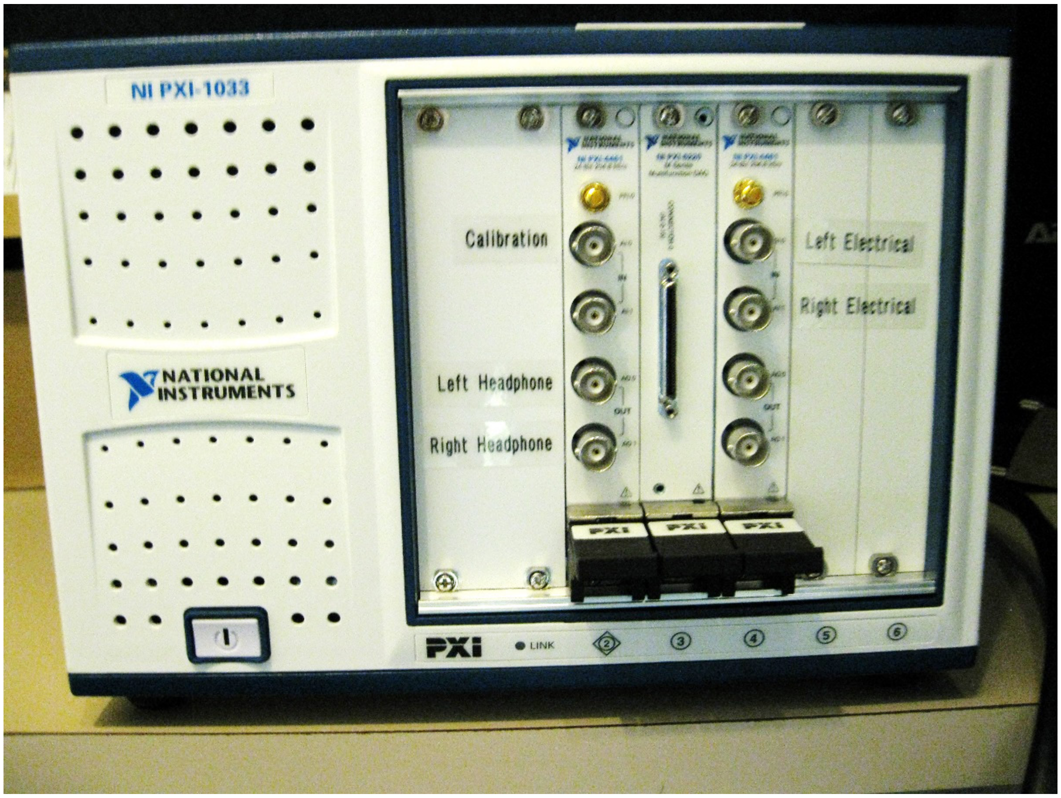
Exhibit 2-4. Parts for the Titan





- Audiometric Research Tool (ART) system (Exhibits 2-5a–2-5d) – consisting of (a) a National Instruments PXI-1033 chassis with a standard power cord, RS-232 computer cable, and two BNC headphone cables; (b) a National Instruments response switch box, ridiculously massive 42-pin cable, response switch, and patch cord; (c) a stand-alone Dell computer consisting of a tower, power cord, keyboard, mouse, and (d) a GEChic touch screen monitor with a power cable, touch screen cable, and video (HDMI) cable.

Exhibit 2-5a. Components of the Audiometric Research Tool (ART) system – National Instruments chassis and cables



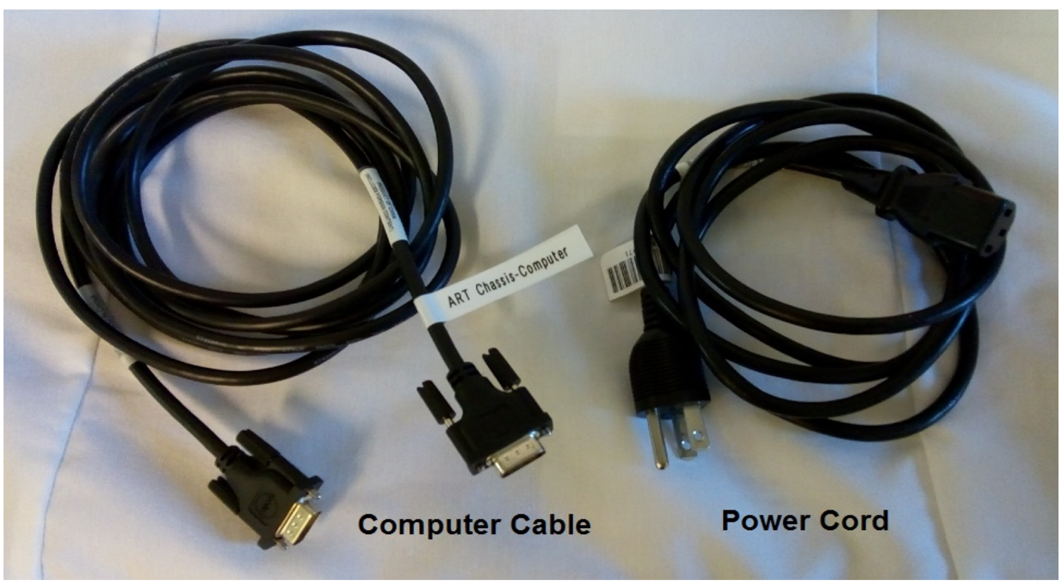


Exhibit 2-5a. **Components of the Audiometric Research Tool (ART) system – National Instruments chassis and cables (continued)**

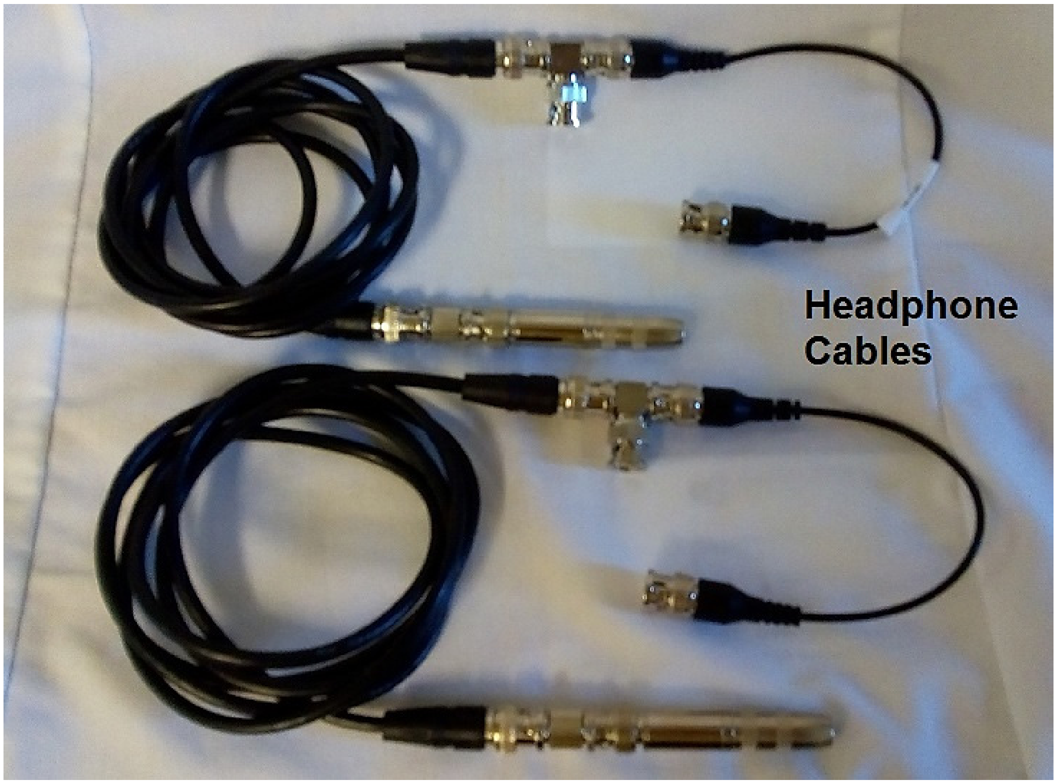


Exhibit 2-5b. **Components of the Audiometric Research Tool (ART) system – National Instruments response switch box, massive 42-pin cable, response switch, and patch cord**

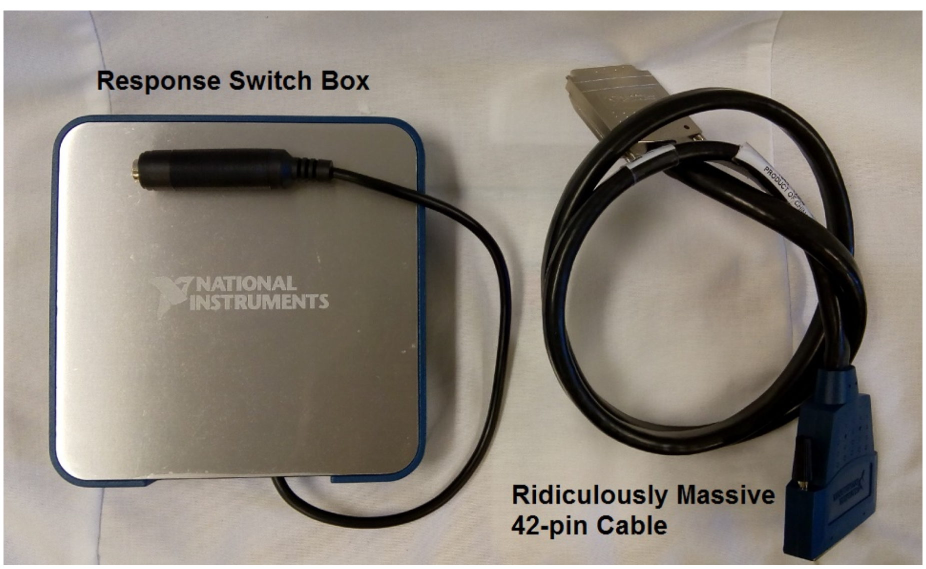


Exhibit 2-5b. Components of the Audiometric Research Tool (ART) system – National Instruments response switch box, massive 42-pin cable, response switch, and patch cord (continued)

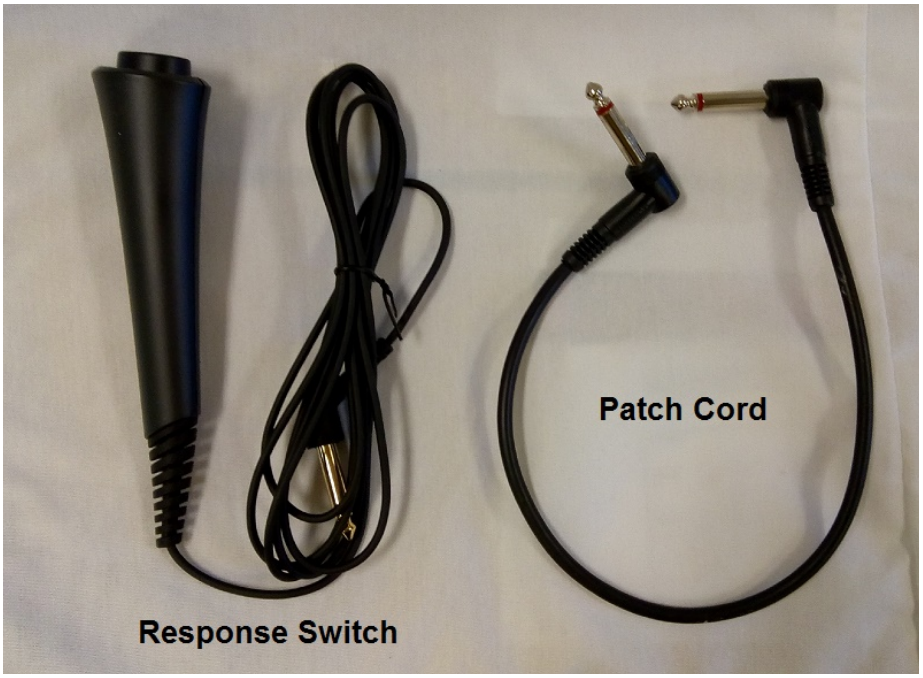
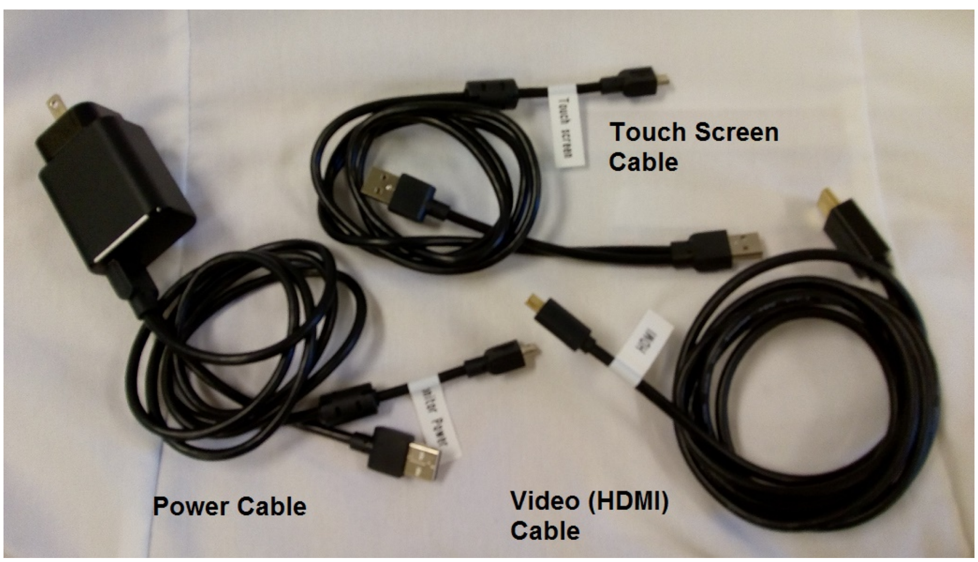


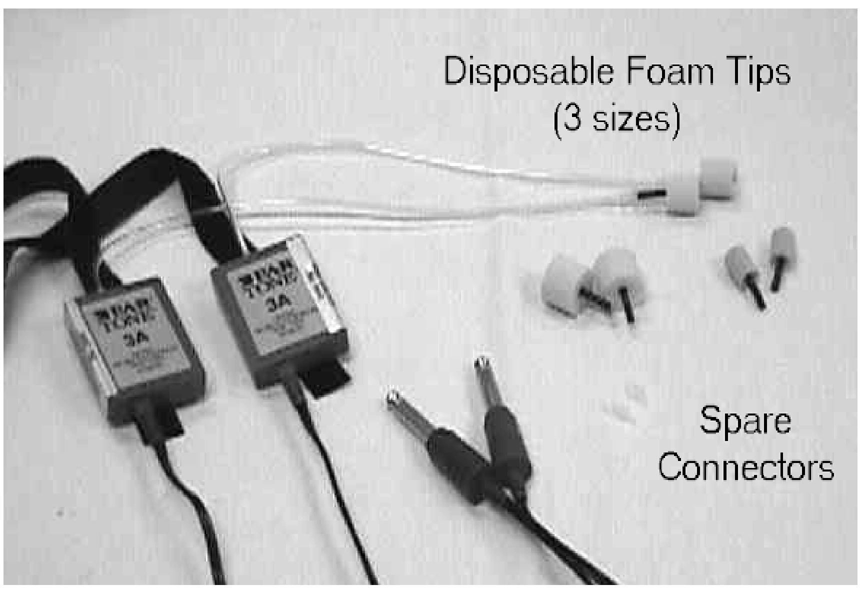
Exhibit 2-5c. Components of the Audiometric Research Tool (ART) system – Dell computer tower, power cord, keyboard, and mouse

Exhibit 2-5d. **Components of the Audiometric Research Tool (ART) system – GEChic touch screen monitor and cables (note that the touch screen cable and the power cable are actually the same; the power cable simply has a USB wall plug attached to the end of it)**



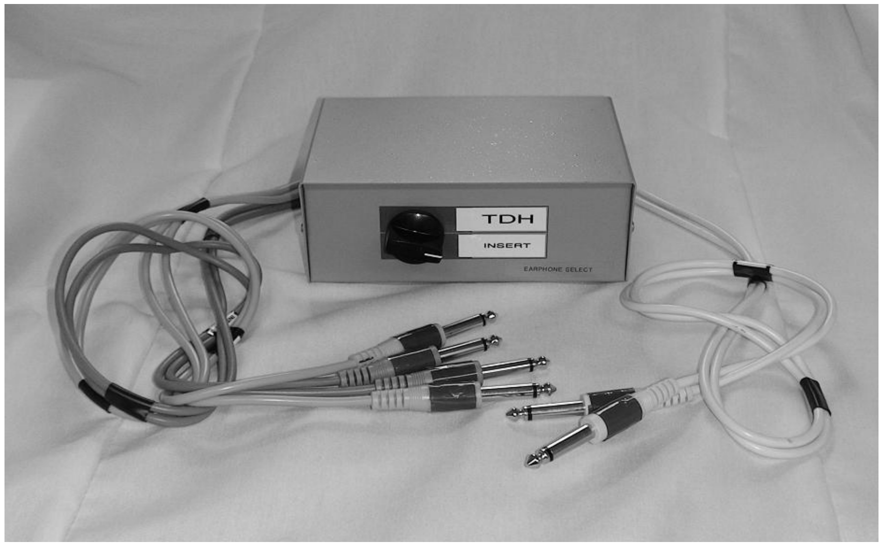
- Standard TDH-49P headphones with Phone Guard disposable hygienic covers, and E•A•Rtone 3A insert earphones with disposable foam tips in three sizes and spare plastic connectors (Exhibit 2-6).

Exhibit 2-6. Headphones and accessories



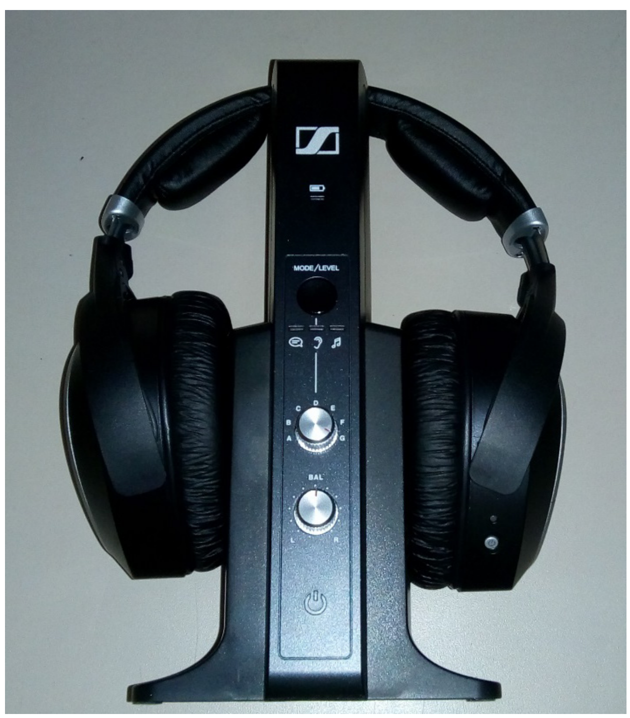
- Headphone selector box (Exhibit 2-7).

Exhibit 2-7. Headphone selector box



- Sennheiser RS 195 headphones and large headphone covers (Exhibit 2-8).

Exhibit 2-8. Sennheiser RS 195 headphones

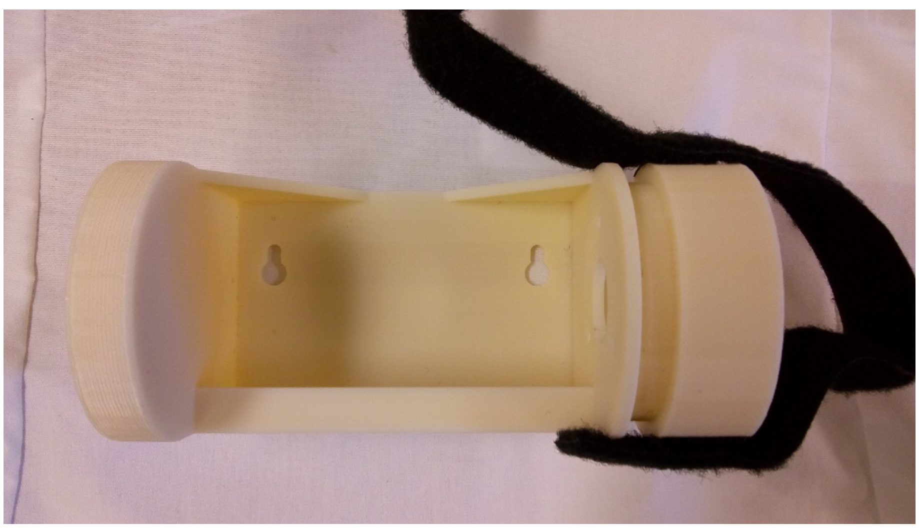


- Vidpro XM-L lavalier microphone (Exhibit 2-9).

Exhibit 2-9. Vidpro XM-L lavalier microphone

- G.R.A.S. calibration system, including the plastic calibration fixture, calibration base, standard headphone coupler, insert earphone coupler, ½-inch microphone (called the "coupler microphone"), pre-amp, and microdot cable (Exhibit 2-10).

Exhibit 2-10. G.R.A.S. calibration system

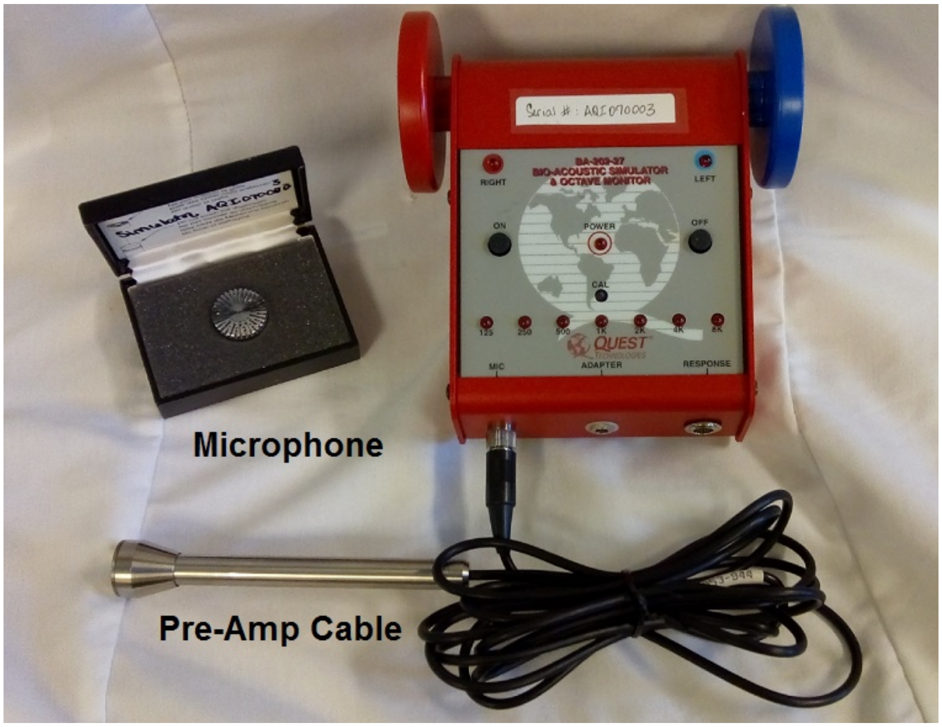


- Quest Model QC-20 calibrator with adapter for ½-inch microphone (Exhibit 2-11).

Exhibit 2-11. Quest Model QC-20 calibrator with adapter

- Quest Model BA-202-27 bioacoustic simulator and accessories (Exhibit 2-12) with built-in octave band monitor with microphone and pre-amp cable.

Exhibit 2-12. Quest Model BA-202-27 bioacoustic simulator and accessories



- Flathead screwdriver (for removing standard headphones from headphone band)
- Hex key set (for adjusting sound booth door height [done only by outside contractor])
- Lighted magnifying glass (for cleaning Titan probe, if needed)
- Audiowipes (for cleaning audiometry equipment)
- Alcohol prep pads (for cleaning audio jacks)
- Gauze pads (for removing used otoscope specula and Titan ear tips)
- Purell waterless hand sanitizer
- Touch screen stylus
- Touch screen cleaning cloth

2.2.1 Otoscope

The Welch-Allyn 25020 otoscope is a small, handheld instrument with a light that is directed through a funnel-like tip to illuminate the ear canal for examination. The funnel-like tip is called a "speculum." The specula are disposable and come in two sizes – pediatric (2.75 mm), for younger children and others with very small ear canals, and adult (4.25 mm), for older children and adult ear canals. The otoscope is powered by a rechargeable battery in the handle; the handle detaches and can be plugged into a standard wall outlet for recharging. There is a spare otoscope on each MEC.

2.2.2 Middle Ear Analyzer

The Interacoustics Titan is a device used to evaluate the functional health of the middle ear system. Known as an "immittance unit" or "middle ear analyzer," it conducts traditional tympanometry, wideband reflectance, and a variety of acoustic reflex tests through a probe with a soft rubber tip that is used to seal off the entrance to the ear canal. The Titan unit comes with a supply of disposable rubber ear tips in different sizes, ranging from 7 to 15 mm and 19 mm (for some completely unknown reason, probe tips from 16-18 mm are not available). Other Titan accessories include a cylindrical cavity that is used for calibration and tools and floss for cleaning the probe tip. A charging cradle holds the Titan while allowing it to charge continuously – even while running tests. Two Titans on each MEC are rotated between stands and provide a backup unit in the event one malfunctions during a stand. Due to storage limitations, only one Titan cradle is kept on each MEC; backups are available if needed.

2.2.3 The ART System

The Audiometric Research Tool (ART) system is a comprehensive, highly configurable audiometer designed for research applications. ART is used to obtain air conduction thresholds on all SPs. The ART system is capable of performing the audiometric threshold test automatically (which will be the general protocol) or allowing you to perform the test manually (which will be the protocol under special circumstances as described in Section 3.5.3.3). The ART system consists of a chassis (which contains the system hardware), a dedicated computer (which runs the ART software), and associated peripherals. Each MEC has one chassis that is equipped with two boards, one of which provides a backup in case one malfunctions during a stand.

ART is supplied with both standard audiometric headphones and insert earphones, which are used in cases where ear canal collapse is suspected or when there is a large difference in hearing thresholds between ears (see Sections 3.3.4 and 3.5.5). The standard headphones should be covered with disposable Phone Guard fabric earphone covers (which are acoustically transparent) for hygienic purposes; the insert earphones come with disposable tips in three sizes to prevent contamination between SPs.

Headphones are assigned to sets consisting of one standard and one insert earphone. Headphone sets must stay together (i.e., you cannot use the standard headphones from one set and the insert earphones from another set). Each MEC is supplied with two headphone sets that should be rotated between stands. Two additional headphone sets (for a total of eight sets) are available if needed.

Words-in-Noise (WIN) testing is also conducted using the ART system. A set of Sennheiser RS 195 headphones is provided for monitoring SP responses during the WIN test. Large headphone covers can be used to cover the headphone cushions for hygienic purposes. The Vidpro lavalier microphone allows the health technician to talk to SPs through the audiometric headphones during WIN testing (note that this function is currently available in the WIN software but not the ART software).

ART contains an integrated calibration system. A G.R.A.S. calibration kit – consisting of the calibration base, microphone, pre-amp, and microdot cable – is used in conjunction with ART to monitor calibration. The kit contains couplers for each type of headphone that connects the headphone to the microphone to measure ART and WIN signal output. The Quest QC-20 calibrator generates a reliable signal that is used to check the function of the microphone prior to conducting calibration checks.

2.2.4 Bioacoustic Simulator

The Quest Model BA-202-27 continuously measures the background noise levels in the audiometric test room. Whenever the noise levels in the test room exceed the standards that have been programmed into the unit, one or more lights will come on to alert the tester to the problem. Audiometric testing cannot be accomplished when the monitor indicates that background noise levels are too high (see Section 2.5.2).

There are two simulators on each MEC that should be rotated between stands and provide a backup in case one stops functioning during a stand.

2.2.5 Inventory Procedures

An inventory of the audiometric equipment and supplies is conducted at the beginning and end of each stand, using the form illustrated on pages A-1 and A-2. Please note the following when conducting the inventory:

- Supply counts refer to unused (i.e., spare) items only. Supplies currently in use (for example, batteries currently in equipment, light bulbs currently in the otoscope, headbands currently attached to headphones) are not to be counted on the inventory sheet.
- When otoscope batteries expire, return them to the warehouse instead of throwing them way.

Supplies will be sent to a MEC prior to its next stand opening. Malfunctioning or missing equipment should be reported to the MEC manager and health technologist assigned to Audio for the stand.

2.3 Start of Stand Procedures

2.3.1 Room Setup

Unpack the Quest BA-202-27 bioacoustic simulator that was not used at the previous stand and insert a 9-volt battery into the battery compartment (see Section 2.7.1). Slide the simulator over the screws on the sound booth wall, making sure it is secure on both screws. Insert the pre-amp cable into the MIC jack at the bottom left of the unit, lining up the pins and notches, and screw the cable securely in place. Unpack the microphone from its case and remove the white plastic cover. Gently screw the microphone onto the other end of the preamp cable. Run the microphone cable up the wall and across the ceiling through the magnetic hooks and suspend it above the subject chair. Use a twist-tie to secure the extra cord length; the microphone should be as close to the ceiling as possible. The simulator is not used for any quality control (QC) checks. It does not need to be powered on at set-up except to ensure that it is working.

Unpack the otoscope and rechargeable handle and plug the handle into a wall outlet. The handle should be charged for 8 hours before examinations begin at each stand.

Check the Serial Number Register and unpack the Titan unit that was NOT used at the previous stand. Place it on the table inside the sound booth. Assemble the Titan cradle following the steps below:

1. Insert the wall charger cable into the port on the back of the cradle labeled "power." Insert the USB computer cable into the port labeled "USB." The connections are shown in the photos in Exhibit 2-13.

Exhibit 2-13. Charging cradle connections

2. Slide the back plate into place and stand the cradle up (Exhibit 2-14).

Exhibit 2-14. Cradle back plate in position, covering the USB and power cord connections

3. Insert the spare Titan battery into the cradle holder (Exhibit 2-15). ***Make sure the gold plates on the bottom of the battery line up with the gold pins in the cradle.*** Don't rely on the printing on the battery to know which way to place it—some of them are printed on the front and some on the back. Installing it incorrectly will break the pins.

Exhibit 2-15. Spare Titan battery in cradle holder

4. Slide the handheld unit into the cradle as shown below (Exhibit 2-16). Hang the cable on a hook on the booth wall. It is important that this cable be kept looped up and out of the way as it contains an air line, microphone, and speaker wires that can be easily damaged by stepping on or rolling over the cable with a chair.

Exhibit 2-16. Handheld unit in cradle holder

5. Plug the wall charger into the outlet inside the booth and the USB cable into the side of the ISIS computer monitor inside the booth. The "Power" light in the bottom right corner of the cradle should light up and remain on. The "Charge" lights to the left of the power indicator will flash whenever the handheld unit and/or spare battery is charging.

Note: A short USB adapter cable can be used to charge the Titan independently of the cradle if for any reason the cradle is not working and does not maintain a sufficient charge from the computer (see Section 2.7.3.4).

Unpack the headphone selector box and affix it to the VELCRO® strips on the wall outside the booth. Remove the ART headphone cables from the cable holder on top of the table. Plug the white cables from the selector box labeled "AUDIO" into the ART cables labeled "RIGHT" and "LEFT"; the white selector box cable with the red tip goes into the ART cable labeled "RIGHT HEADPHONE" and the white selector box cable with the blue tip connects to the ART cable labeled "LEFT

HEADPHONE." Drop the cables behind the back of the table to get them out of the way. Plug the yellow cables from the headphone selector box labeled "TDH" into jack 5 (blue-tipped cable) and jack 6 (red-tipped cable) on the sound booth jack panel. Plug the gray cables from the headphone selector box labeled "INSERT" into jack 9 (blue-tipped cable) and jack 10 (red-tipped cable) on the sound booth jack panel. Plug the black cable labeled "Calibration" into jack 7.

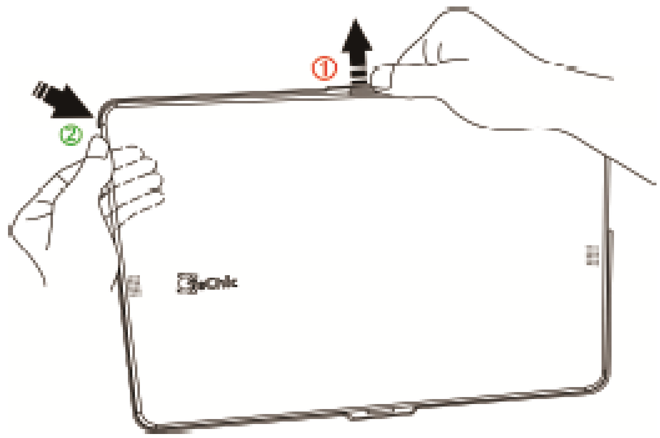
Note: Some headphone selector boxes have all black cables. When this is the case, refer to the labels on the cables to make the appropriate connections.

Check the Serial Number Register and unpack the headphone set that was NOT used at the previous stand. Plug the standard headphones into the jack panel **inside** the booth, connecting the cable with the blue tip into jack 5 and the cable with the red tip into jack 6 on the jack panel **inside** the sound booth. Plug the insert earphones into the panel inside the booth as well, connecting the blue-tipped cable into jack 9 and the red-tipped cable into jack 10. Plug the patient response switch into jack 3 **inside** the sound booth; plug one end of the black patch cord into jack 3 **outside** the sound booth and the other end into the cable from the response switch box. Cover the unused audio input jacks both inside and outside the sound booth with the protective blue covers.

Note: Actual jack numbers have been assigned arbitrarily. If a jack is broken or if the equipment will fit more conveniently into a different jack, it is perfectly fine to use jacks other than those indicated here. However, **each component MUST be plugged into the same numbered jack both inside and outside the booth.** For example, if you decide to use jack 1 for the left standard headphone cable outside the booth, be sure to plug the left standard headphone (i.e., TDH) cable into jack 1 inside the booth.

Unpack the ART touch screen monitor. Take the monitor out of the protective cover/stand by holding both sides of the cover's rim with the thumbs and pushing the monitor out from the back with your fingers (Exhibit 2-17).

Exhibit 2-17. Unpacking the ART monitor



Unpack the monitor stand. Slide the "X" stand support into the slot on the back of the monitor holder in the horizontal position (Exhibit 2-18).

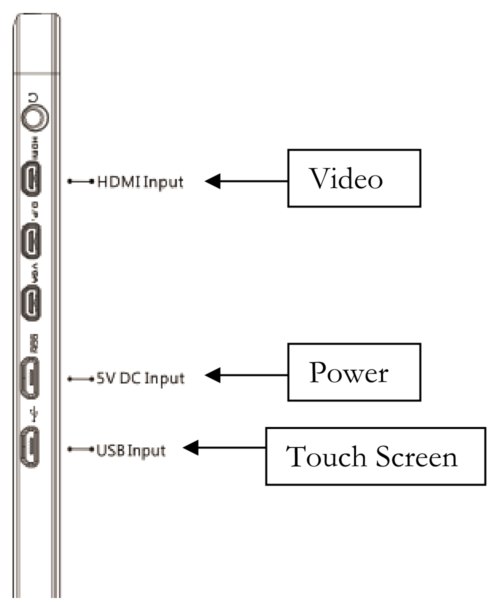
Exhibit 2-18. ART monitor stand

Place the monitor on the stand, as shown in Exhibit 2-19.

Exhibit 2-19. Monitor on monitor stand

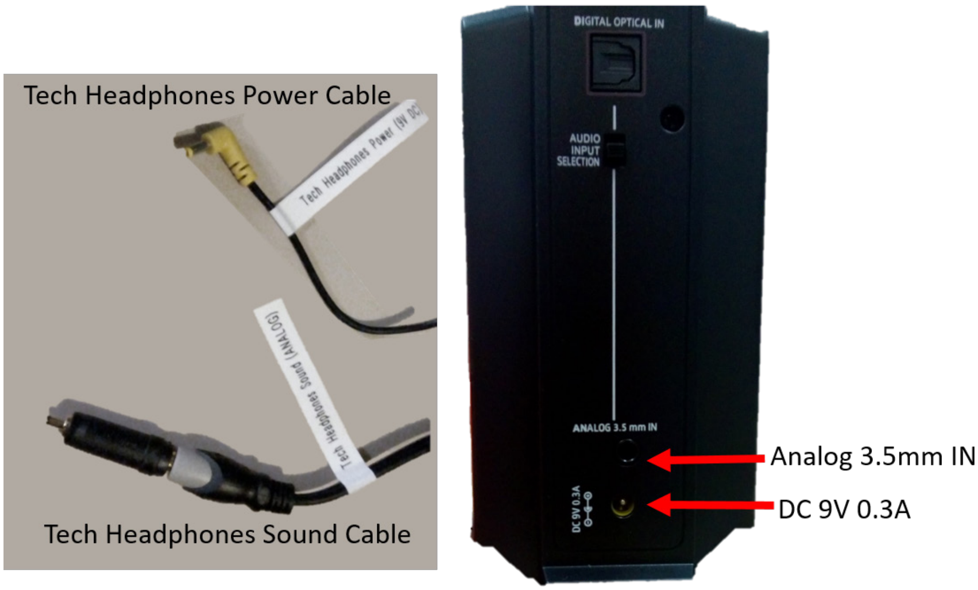
Remove the three monitor connections from the cable holder on top of the table outside the sound booth. Plug the cable labeled "HDMI" into the port on the left side of the monitor labeled "HDMI" (second port from the top). Connect the cable labeled "Monitor Power" into the port labeled "DCIN" (second port from the bottom). Connect the cable labeled "Touch Screen" to the bottom port on the left side of the monitor (labeled with a USB icon). Monitor connections are shown in Exhibit 2-20.

Exhibit 2-20. ART monitor connections



Unpack the Sennheiser RS 195 headphones used for monitoring WIN responses. Plug the cable labeled "Tech Headphones Power" into the port on the back of the charging stand labeled "DC 9V 0.3A" and the cable labeled "Tech Headphones Sound" into the port labeled "ANALOG 3.5 mm IN" (Exhibit 2-21).

Exhibit 2-21. Sennheiser RS 195 headphone charging stand and cables



Place the headphones on the charging stand and press the "Power" button on the front of the stand to turn it on (Exhibit 2-22).

Exhibit 2-22. Headphones on charging stand

Unwrap the Vidpro lavalier microphone from its protective pouch (Exhibit 2-23). Hang the microphone on the hook on the outside of the sound booth. Put a fresh battery in the microphone (see Section 2.7.4.2).

Exhibit 2-23. Microphone protective pouch

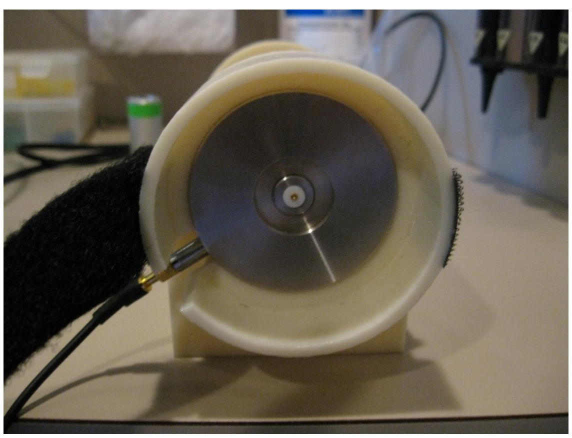
Place the following items on the table outside the booth:

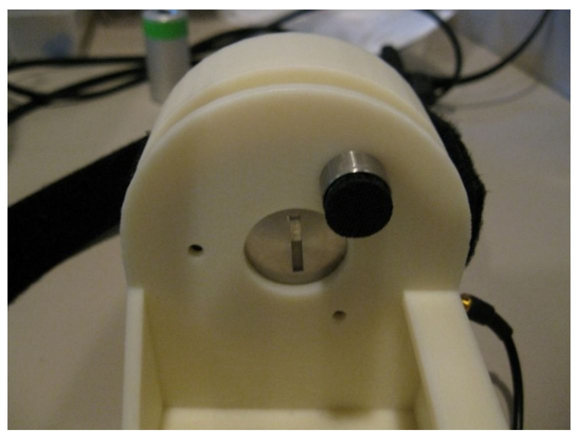
- monitor,
- keyboard,
- mouse and mousepad,
- wrist pad,
- a pad of Post-It notes.

VELCRO® the "test tube" pen holder onto the wall outside the booth in a convenient location. Put the stylus and a pen in the holder.

Remove the calibration fixture from the drawer inside the booth. Make sure the coupler base is inserted into the right "ear" of the fixture, with the pre-amp cable exiting through the slot, and it is secured to the fixture with at least one of the three base screws (Exhibit 2-24).

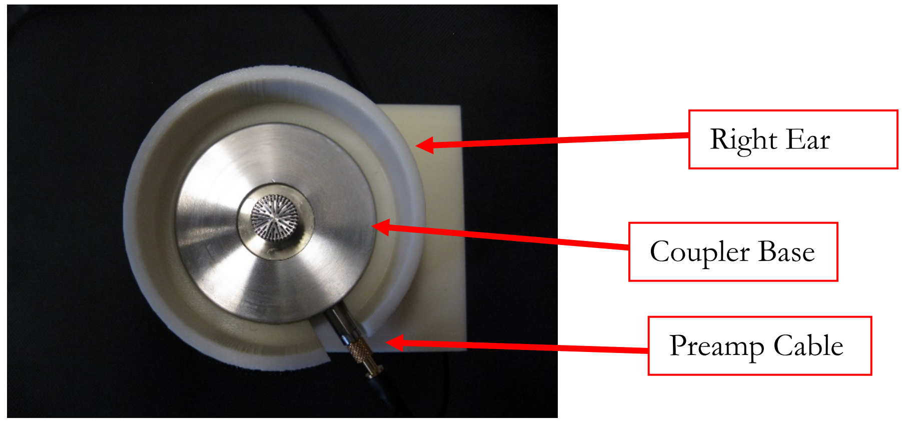
Exhibit 2-24. Coupler base secured to the calibration fixture





Unpack the black plastic calibration kit case. Remove the standard and insert earphone couplers and place them on the table inside the booth. Unscrew the microphone from its case, and gently screw it to the coupler base (Exhibit 2-25). Store the calibration case under the table inside the booth.

Exhibit 2-25. Microphone on coupler base



Untape the black cable labeled “Calibration” from the top of the table and plug it into jack 7 inside the booth.

Mount the specula dispenser on the wall and fill it as needed. Unpack the tympanometer ear tips and insert earphone tips and place them in containers on the table inside the sound booth. Fill the headphone cover dispenser with Phone Guard covers.

Hang the reminder cards and help sheets in convenient locations. Cards should be hung as follows:

- **Inside the booth.** Cards with SP instructions, the reminder for SPs to turn off their cell phones, help sheet with incomplete exam codes, and guidelines for positive/negative noise exposures.
- **Outside the booth.** Help sheets for daily calibration and unusual test situations and reminders about test differences and output limits of each type of headphone.
- **On the hallway side of the door to the Audiometry room.** “Quiet Please. Hearing Evaluations in Progress” sign.

Exhibit 2-26 shows the Audiometry room after set-up is complete.

Exhibit 2-26. Audiometry room with set-up complete

2.3.2 Powering Up and Configuring the ART System

2.3.2.1 Turning on ART and Establishing a Connection with ISIS

In order for all of the equipment to communicate, the ART components and the ISIS computer must be powered up in a specific order.

Power up order:

1. Turn on the ART chassis by pressing the “Power” button in the lower left corner of the front of the chassis.
2. Wait at least 30 seconds.
3. Turn on the ART computer tower by pressing the “Power” button in the top left corner of the front of the tower.
4. Turn on the ART monitor by pressing the top button on the right side of the monitor.
5. Swipe the screen and enter the password.
6. Reboot the ISIS computer.

On set-up day, if the equipment has already been turned on by the Facilities Equipment Specialist (FES), turn everything off and then power it up in the specified order.

2.3.3 Start of Stand Calibrations and Checks

A complete calibration check of all the audiometric equipment that will be used during a stand must be completed at set-up. Following the instructions provided in Section 2.4, conduct calibrations and checks of the following equipment in the order shown below:

- Bioacoustic simulator;
- ART system (Trident calibration, background noise measurement, earphone acoustic check [output, linearity, and distortion] and listening check); and
- Middle ear analyzer.

At the start of a stand, one set of earphones (standards and inserts) and one middle ear analyzer should undergo complete calibration checks. If either of the earphones do not pass calibration checks, contact Christi Themann before moving on to the back-up set of earphones. If the middle ear analyzer does not pass calibration checks, conduct the calibration checks on the backup Titan and refer to the flow chart in Appendix B for guidelines about when a Titan should or should not be used when the calibration checks are out-of-range. If any equipment is determined to be non-functional, notify the Westat component specialist and Audiometry consultant so that arrangements can be made to return it for repair.

Record the results of start of stand calibrations and checks in the Start of Stand tab in the ISIS QC application, as explained in the individual calibration instructions in Section 2.4. The six subtabs correspond to the following results:

QC 1: Audiometer Acoustic Calibration Check (Standard Phones)

QC 2: Audiometer Acoustic Calibration Check (Insert Phones)

QC 3: Audiometer Listening Check (Standard Phones)

QC 4: Audiometer Listening Check (Insert Phones)

QC 5: Titan Calibration Check

QC 6: Equipment Serial Numbers

2.4 Calibration Checks

In order for audiometric test results to have any validity, it is necessary to know that all the equipment associated with the tests was properly calibrated. Calibration checks will therefore be conducted as the audiometric equipment is set up at the start of each stand, daily throughout the stand, and again at the end of each stand to ensure that the accuracy has not shifted.

2.4.1 Bioacoustic Simulator Check

The Quest BA-202-27 bioacoustic simulator is only used to monitor noise in the booth during exams. To check the bioacoustic simulator, press the ON button on the bioacoustic simulator and check the power indicator to verify that the light is flashing "brightly" (compare the brightness of the power indicator light to the brightness of the octave monitor lights to determine whether the light is flashing "brightly.") If the light is flashing dimly or does not flash at all, replace the battery as described in Section 2.7.1.1.

The microphones and sound measurement function of the bioacoustic simulators will be checked by a certified laboratory annually or whenever unresolvable problems are discovered.

2.4.2 ART System Calibration Checks

The ART system requires two levels of QC checks. The first type of check is an acoustic calibration check, which measures output of the audiometric testing system to verify that the test signals meet standard specifications. The audiometer acoustic check consists of three parts:

- **Output Check.** This check ensures that the system generates sounds at the intensities that it should; for example, the audiometer produces 70 dB HL of sound when it is set for 70 dB HL.
- **Distortion Check.** This check makes sure that the test signals contain only the frequencies that they should; for example, a 1000 Hz tone contains only sound at 1000 Hz and not at any other frequencies.
- **Linearity Check.** This check makes sure that the test signals change in volume the amount that they should; for example, if the intensity is reduced from 70 dB to 60 dB, the change in system output is truly 10 dB.

The second type of audiometer check is a functional (or listening) check. This involves listening to the output through the earphones to ensure that the signals are being routed properly and there are no extraneous sounds. The listening check looks for problems that a sound measurement system may not pick up, but which a human listener can hear.

The ART system is also used to measure the background noise in the audiometric booth to ensure that the environment is quiet enough for accurate threshold testing.

In addition to these calibration checks, each ART system will receive an exhaustive calibration once a year, or whenever unresolvable problems are discovered during the calibration checks.

2.4.2.1 Opening the ART Calibration System and Choosing a Config File

The ART system is driven by configuration (config) files, which store information about how the test will be conducted (e.g., the order of test ears and frequencies), the way the signals will be played (e.g., steady tones or pulsed tones), the length of time the SP will have to indicate that he or she heard a signal presentation (i.e., the response window), the type of earphones that will be used (e.g., standards or inserts), and many other things. In addition, the config files hold the calibration levels specific to a particular set of earphones. Because calibration levels are stored in the config files and not the ART hardware, any set of earphones can be used with any ART system, provided the config files for that set of earphones are loaded into the system.

ART configuration settings are stored in three different types of configuration files:

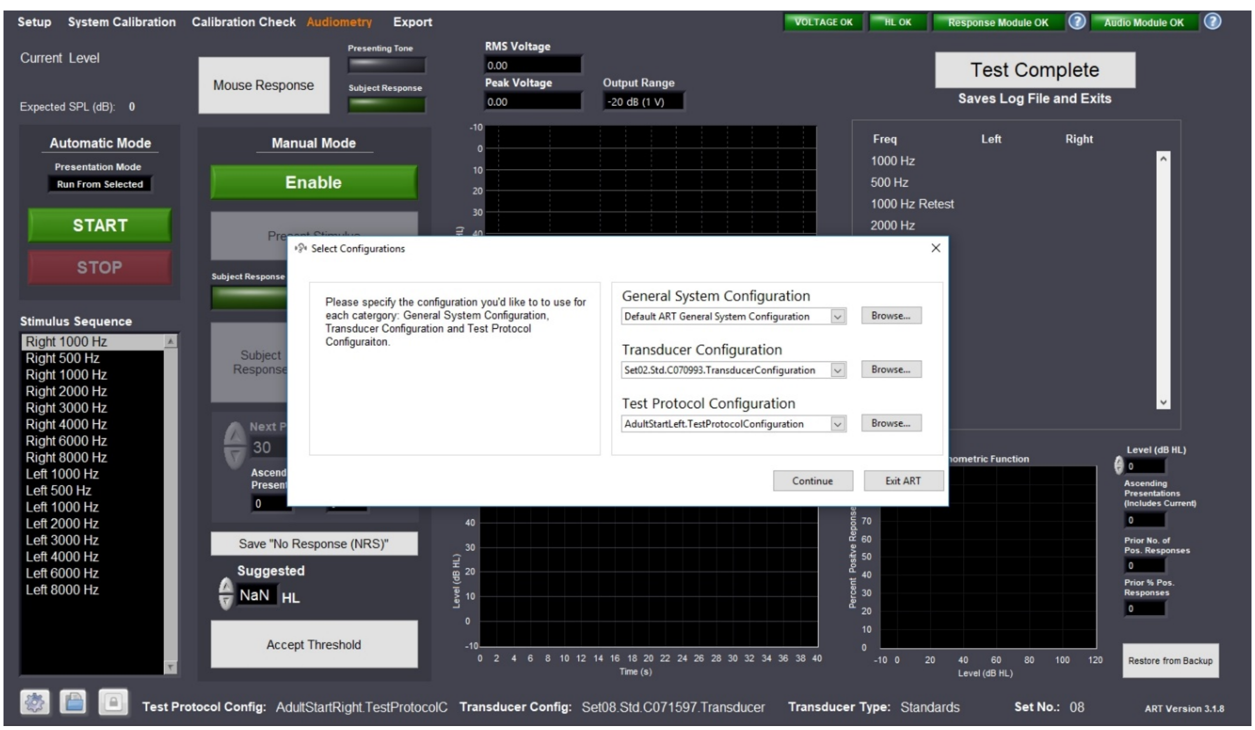
- **General system configuration** – This file describes stimulus parameters such as how test signals are routed, how long tones will play, rules for establishing thresholds, calibration settings for Trident, etc. This file is the same for all ART and WIN tests.
- **Transducer configuration** – This file contains the calibration levels for each headphone. It also allows minimum and maximum output levels to be set for individual frequencies. Each set of headphones has its own transducer configuration file, for a total of 16 files. Transducer configuration files are named according to the headphone set number, headphone type, and right headphone serial number – for example, “Set08.Std.C071597.” You can use the set number and headphone type to identify the correct transducer configuration file. ISIS uses the right headphone serial number to identify the correct file.

- **Test protocol configuration** – This file specifies how the test will proceed for a particular SP. In ART, this file identifies the order of test frequencies (adult or child – see Section 3.5.2.1) and the first test ear, for a total of 4 test protocol configuration files. File names reflect frequency order and first test ear – for example, “AdultStartRight” – to make it confirm or select the appropriate file.

During exams, ISIS chooses the correct config files for each SP based on the set of headphones stored in the QC application, and information gathered during the audiometry test (such as headphone type, first test ear, and adult or child frequency order). If ISIS does not pre-load the correct config files, you can select them manually in ART. During QC checks, however, you will need to manually select config files.

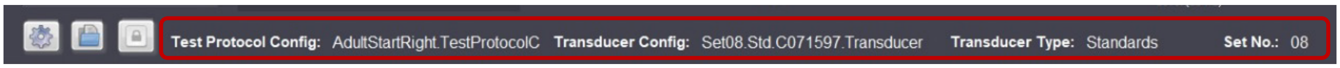
Double click the ART icon to open the program. To select the correct config files, click the blue file folder icon in the lower left corner of the ART screen. A pop-up window will open to allow you to browse for and select each of the three types of configuration files. **All default file names shown in the pop-up window should be changed.** The General System Configuration file will always be the same (but you need to browse and select it). Choose the transducer config file that matches the set number and earphone type you are checking (during start and end of stand QC, check the standard earphones first, then the inserts). Any test protocol config file is suitable for QC; it is simplest to select “AdultStartLeft” just because it is the first file in the list. See Exhibit 2-27.

Exhibit 2-27. Selecting config files for QC checks



Click the “Continue” box in the pop-up window to return to ART. Check the bottom of the ART screen and confirm that the correct config files have been selected, as shown in Exhibit 2-28.

Exhibit 2-28. Confirming the calibration config files



Set the headphone selector box for the type of headphones you are checking. The system will not pass calibration if the wrong config files or wrong set of earphones are chosen.

2.4.2.2 Calibrate Trident (Daily)

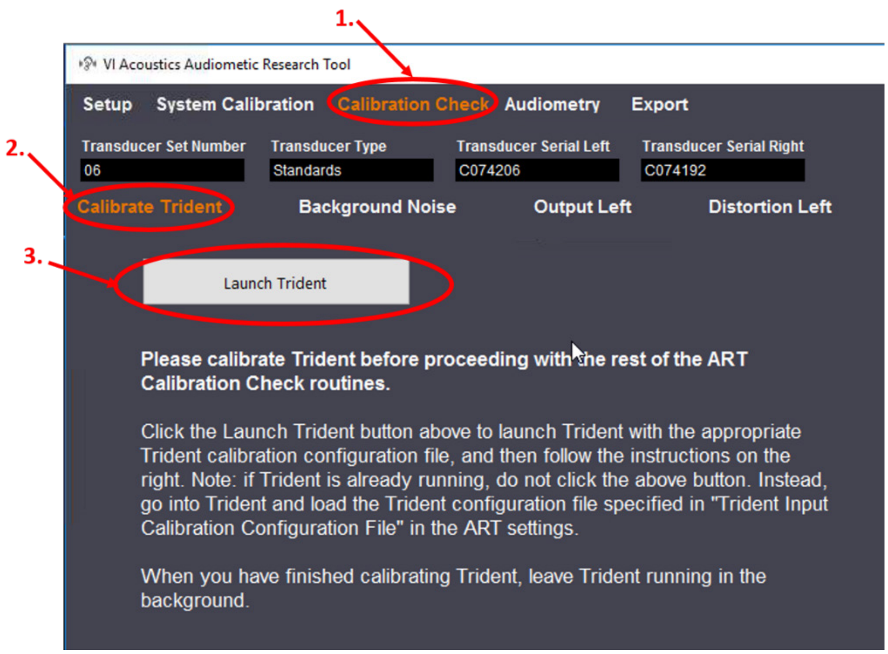
The ART system uses a separate software package called Trident to measure the sound levels put out by the system. Although Trident is a separate software package, it is (almost) fully integrated into the ART calibration routines. The only time you have to open Trident independently is to calibrate the Trident software. This is the first step in the acoustic calibration check process. Before you can use Trident to check the calibration of ART, you have to calibrate Trident itself.

Once the correct calibration config files have been selected, click the Calibration Check tab in the top left corner of the ART screen. A new window will appear with nine tabs:

- Calibrate Trident
- Background Noise
- Output Left
- Distortion Left
- Linearity Left
- Output Right
- Distortion Right
- Linearity Right
- Results/Export

The software should open with the "Calibrate Trident" tab selected; if it does not, click the tab to activate it. When you are on the "Calibrate Trident" screen, click the "Launch Trident" button in the middle, left side of the screen to open Trident (see Exhibit 2-29).

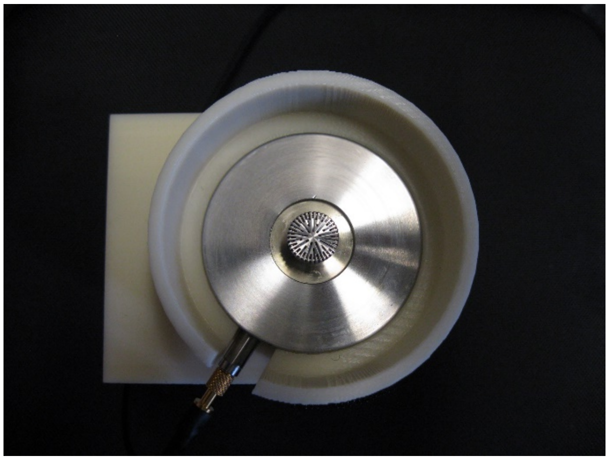
Exhibit 2-29. Opening Trident



You only need to calibrate Trident once a day. For example, on set-up day, you will run through the whole calibration routine for standard headphones, then close ART and re-open it to repeat the calibration for insert earphones. When re-opening ART to test the insert earphones, you do not need to re-calibrate Trident. Similarly, should the ART system lock up during a calibration check and you need to close and re-open it, you can just pick up where you left off without re-calibrating Trident.

Stand the calibration fixture up vertically on the table inside the booth, having the side with the microphone facing up. Remove any couplers from the calibration base if necessary. Exhibit 2-30 shows how the calibration fixture should appear.

Exhibit 2-30. Setting up the calibration fixture to calibrate Trident

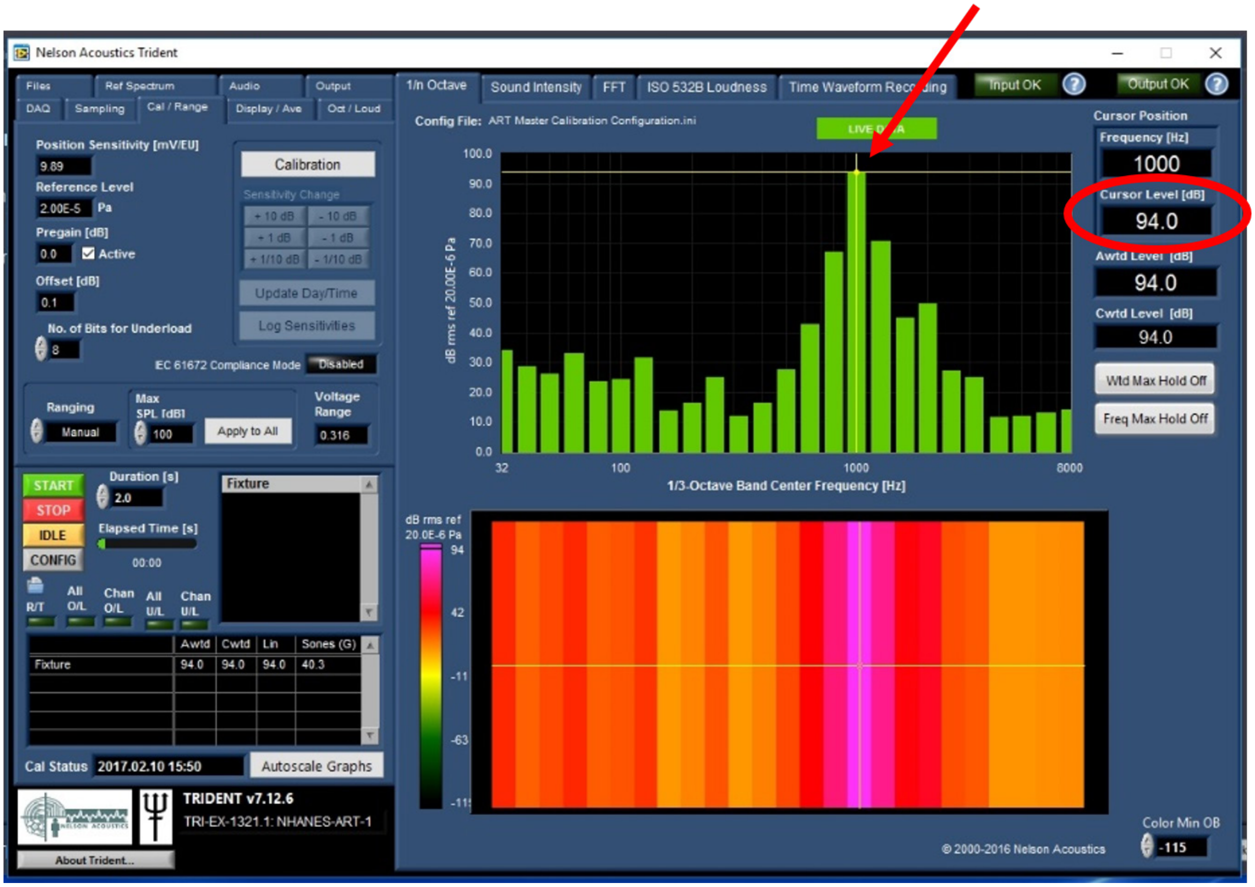


Turn on the QC-20 calibrator. Make sure it is set to 1 KHz and 94 dB, and the ½-inch adapter is in place. Slide the calibrator over the microphone. Use the VELCRO® strap to hold it in place if necessary. (See Exhibit 2-31.)

Exhibit 2-31. Calibrator on the coupler base

Look at the green bar graph on the right side of the Trident window. Make sure the cursor (thin yellow vertical line) is hovering on the 1000 Hz bar; if it is not, move it by "grabbing" the line with the mouse and dragging it until it is over the 1000 Hz bar on the graph. Check the "Cursor Level [dB]" reading to the right of the bar graph. It should read 94.0 dB (Exhibit 2-32).

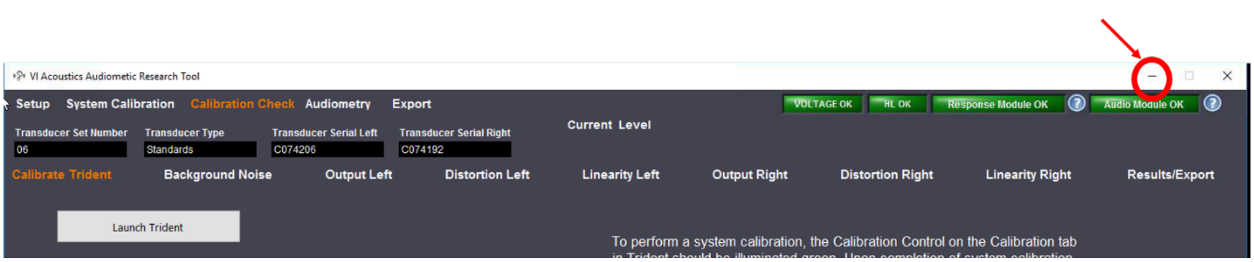
Exhibit 2-32. Trident screen – "Cursor Level [dB]" reading



If it does, click the "Minimize" button in the top right corner of the Trident screen to move the calibration screen out of the way and return to ART.

Note: Make sure you only minimize Trident; do not close the program completely (Exhibit 2-33)!

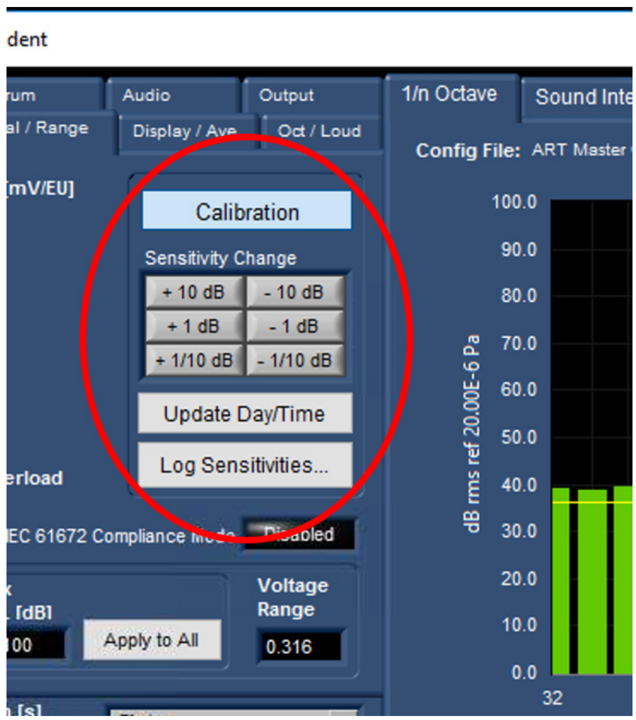
Exhibit 2-33. Minimizing the Trident screen



If the “Cursor Level [dB]” reading does not read 94.0 dB, click the “Calibration” button to the left of the bar graph (Exhibit 2-34). Click the “Sensitivity Change” buttons to adjust the level as needed.

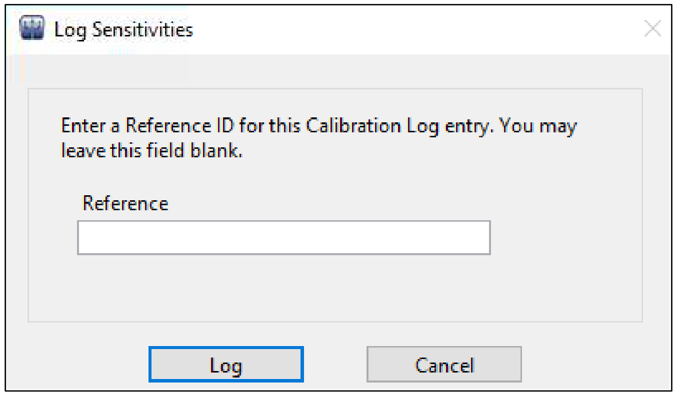
Note: If the Cursor Level [dB] reading is less than 92.0 or more than 96.0, call the Audiometry consultant before making any adjustments.

Exhibit 2-34. Buttons to adjust the cursor level reading



When the “Cursor Level” reads 94.0, click the “Log Sensitivities” button below the “Calibration Adjustment” buttons. A pop-up window will ask for a reference name (see Exhibit 2-35). You do not need to enter a reference name; just click “Log” to close the window. Click the “Calibration” button again to exit the calibration adjustment function and then minimize the Trident screen to return to ART.

Exhibit 2-35. Log Sensitivities pop-up window for file name



When Trident has been calibrated, remove the calibrator from the microphone and turn the calibrator off.

2.4.2.3 Check Background Noise (Daily)

To obtain valid hearing threshold measurements, the background noise levels in the test environment (called the ambient noise) must be quiet enough for the SP to hear the very low intensity test tones that will be presented to him or her. If the ambient noise is too high, the SP might be unable to hear signals that his auditory system is capable of sensing, simply because the test environment is inadequate.

Because the sound room used in NHANES is mobile, the ambient noise levels must be checked each time the MEC is moved to a new location. Therefore, a sound survey must be done as part of the setup procedure at the beginning of a new stand. Additionally, since the sound environment around the MEC is subject to change, the sound survey will be repeated daily during the stand to verify that the ambient noise has not changed. Finally, if at any point you notice a change in the background environment (for example, if any of the background noise indicators on the bioacoustic simulator light up consistently or if operations using heavy equipment begin adjacent to the MEC), the background noise levels should be measured again to check for any problems that would interfere with accurate testing.

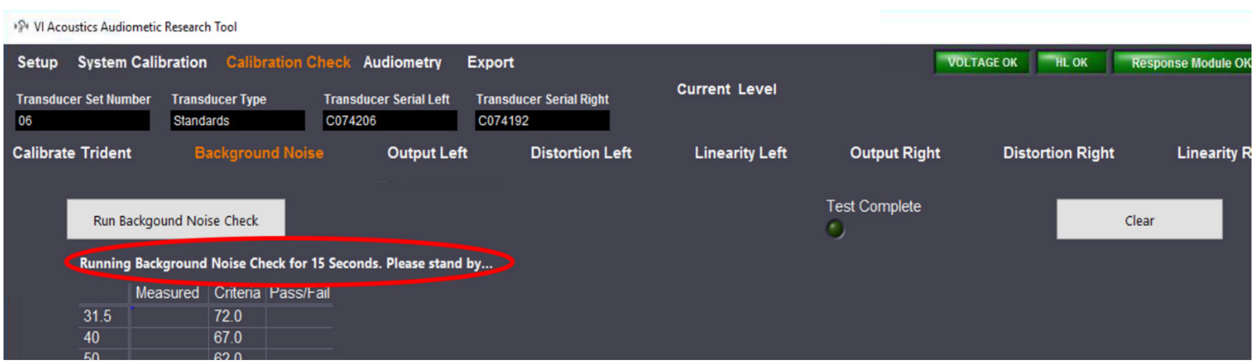
The background noise levels in the sound room should be measured insofar as possible under the same conditions as will exist during actual audiometric testing. Therefore, prior to conducting the ambient noise survey, set up the test environment as follows:

- ISIS computer, ART system, and Titan turned on;
- Lights turned on inside the booth; lights turned off outside the booth;
- Ventilation system turned on inside the test booth; and
- Sound room and hallway doors closed.

To conduct the background noise check, leave the calibration fixture with the microphone (uncovered by the calibrator or any couplers) standing vertically on the table inside the booth (refer to Exhibit 2-31). Leave the sound booth and close the booth door.

On the ART Calibration Checks screen, click the “Background Noise” tab. Click “Run Background Noise Check.” A message will tell you to stand by while the background noise is measured for 15 seconds (Exhibit 2-36).

Exhibit 2-36. Run Background Noise Check message



A pop-up window will tell you when the background noise check is complete. Click OK. If the background noise levels are within acceptable limits, the box next to each frequency in the table will be green and will read “Pass” (Exhibit 2-37).

Exhibit 2-37. All tested frequencies indicate "Pass"

	Measured	Criteria	Pass/Fail
31.5	44.7	72.0	Pass
40	49.2	67.0	Pass
50	49.4	62.0	Pass
63	44.0	58.0	Pass
80	43.7	52.0	Pass
100	38.9	48.0	Pass
125	31.7	44.0	Pass
160	24.6	39.0	Pass
200	15.8	34.0	Pass
250	15.4	30.0	Pass
315	18.5	26.0	Pass
400	18.8	21.0	Pass
500	13.2	16.0	Pass
630	9.8	17.0	Pass
800	10.3	19.0	Pass
1000	10.7	21.0	Pass
1250	10.9	23.0	Pass
1600	10.5	25.0	Pass
2000	11.6	29.0	Pass
2500	10.7	31.0	Pass
3150	11.2	33.0	Pass
4000	11.7	32.0	Pass
5000	12.5	32.0	Pass
6300	13.4	32.0	Pass
8000	14.1	32.0	Pass
10000	15.2	32.0	Pass

If any frequencies fail the check, click "Clear" to delete the results. Try to locate and correct the source of the noise, then click "Run Background Noise Check" to repeat the measurement. If the noise levels are still too high after three measurements, inform the MEC manager immediately. **Pure tone audiometric testing can NEVER be done when the ambient noise levels in the test room exceed the levels shown on the screen above.** Thresholds obtained in high background noise are invalid and useless.

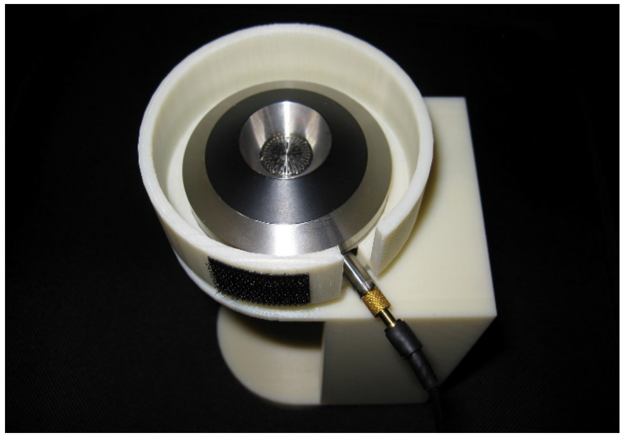
2.4.2.4 Check Earphone Output (Daily)

Checking headphone output involves measuring each test frequency at one intensity level to ensure that the volume of the test signal is accurate. The right and left earphones of both the standard and insert earphones must be checked individually. At the start and end of stand (as well as anytime a set of earphones is swapped in), output is checked for both the standard headphones and insert earphones. Daily throughout the stand, one set of earphones is checked on an alternating basis (i.e., standard headphones one day, inserts the next). ISIS will prompt you which set of earphones should be checked on a given day.

To conduct the output calibration check, place the appropriate coupler (for standards or inserts as prompted by ISIS) over the microphone on the coupler base.

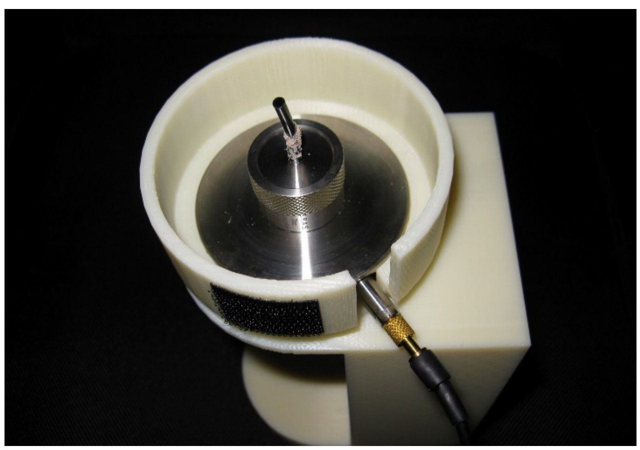
- For standard headphones, gently screw the large, round, silver disk around the microphone (make sure it is screwed all the way down, but do NOT overtighten!). Place the black plastic ring over the silver disk (Exhibit 2-38).

Exhibit 2-38. Standard coupler on the coupler base



- For inserts, slide the small, silver cylinder over the microphone until it clicks into place (Exhibit 2-39).

Exhibit 2-39. Insert coupler over the microphone on the coupler base



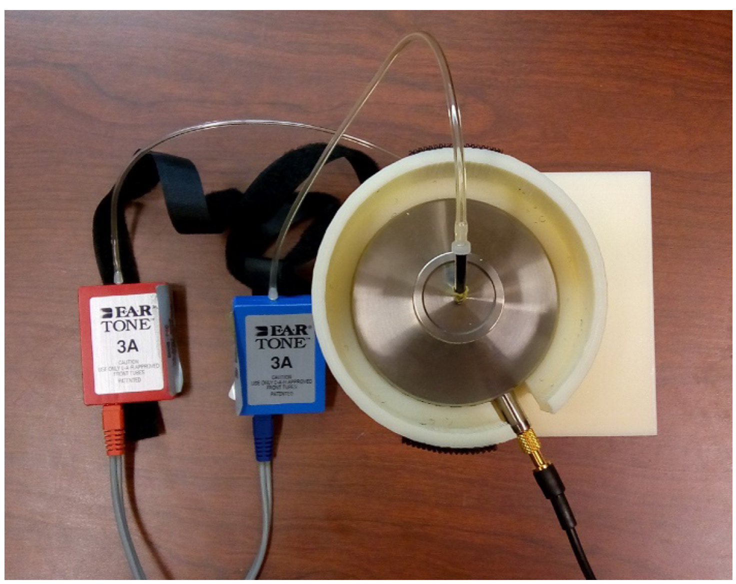
Place the earphones on the calibration fixture. Put the earphone to be tested on the side of the fixture with the coupler (for example, as the ART system is set up to check the left output first, attach the left earphone to the coupler).

- For standard headphones, extend the headband to its full height. Lay the calibration fixture horizontally on the table in the sound booth (or hang it on the sound booth wall) and place the headphones on the fixture as if it were a "head." Make sure the headphone cushions rest completely within the cylinders on either side of the fixture. See Exhibit 2-40.

Exhibit 2-40. Standard headphones mounted to calibration fixture

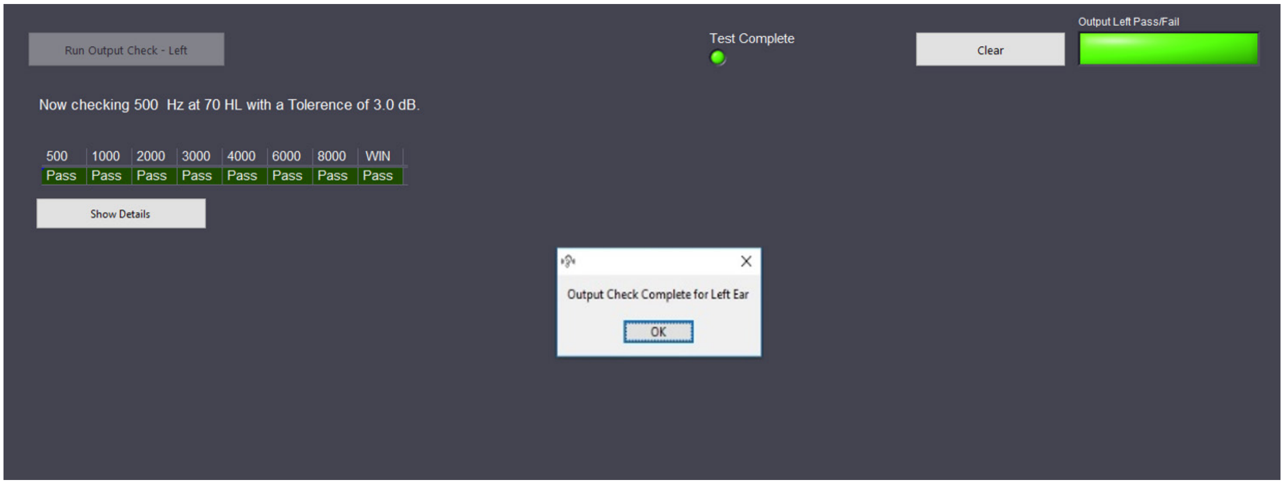
- For insert earphones, insert the white plastic connectors into the black tubing at the top of the coupler, just as though you were inserting it into a foam insert earphone tip. Make sure the connector is inserted all the way to the nub. Lay the opposite earphone gently on the table (or let it dangle carefully from the fixture if it is hung on the wall). See Exhibit 2-41.

Exhibit 2-41. Insert earphones mounted to calibration fixture



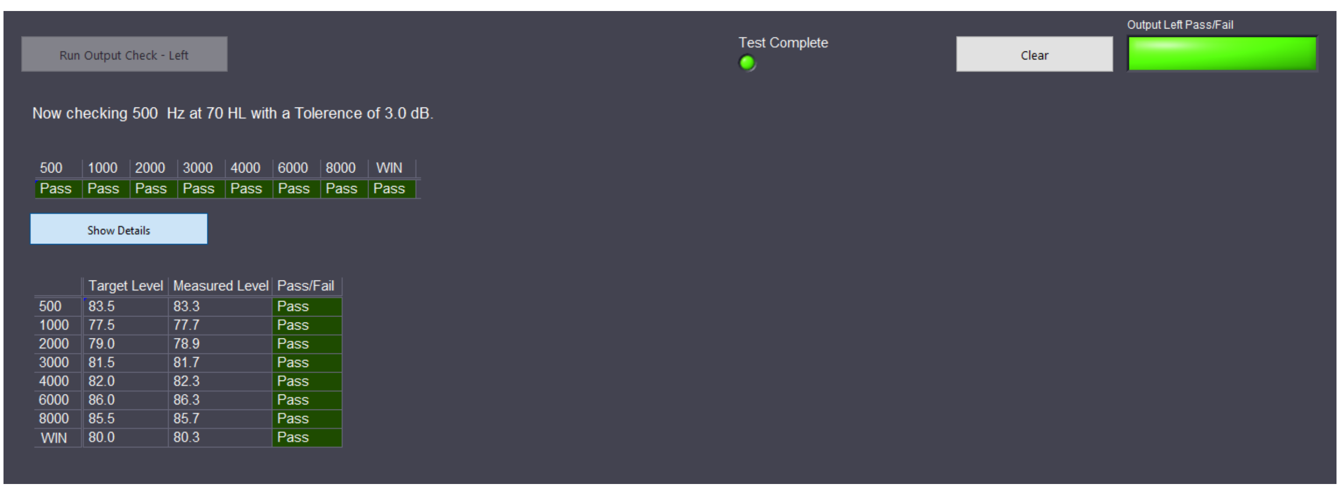
On the ART screen, select the "Output Left" tab, then click the "Run Output Check – Left" button. Messages above the table will update as the output check progresses through each frequency. When all frequencies and the WIN calibration stimulus have been checked, a pop-up window will inform you that the check is complete (Exhibit 2-42). Click OK.

Exhibit 2-42. Output check complete message



If the earphones pass at all frequencies, each box in the table will be green and will read "Pass" (Exhibit 2-43). If any checks fail, you can click the "Show Details" button to troubleshoot the problem. To rerun the output check, click "Clear," then click the "Run Output Check" button again.

Exhibit 2-43. Output results showing overall and detailed results

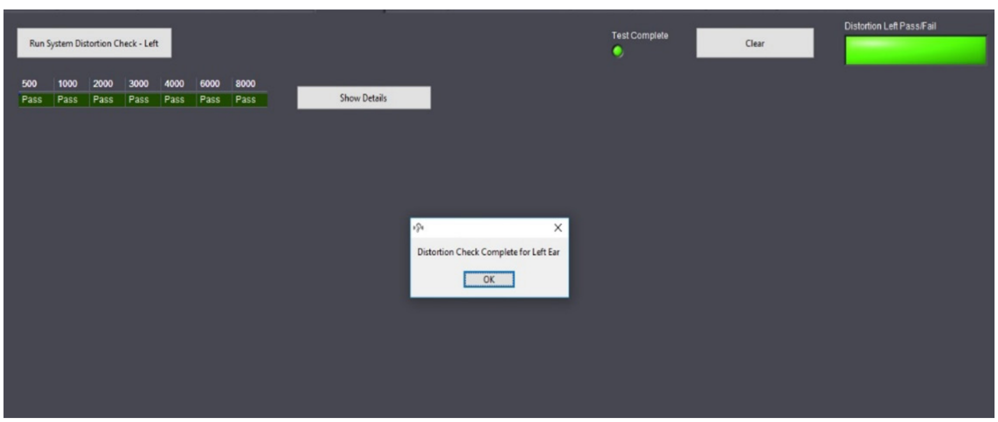


2.4.2.5 Check Distortion (Daily)

Distortion measures the frequency content of each test signal to ensure that it truly is a pure tone and is not contaminated by other frequencies (the presence of other frequencies makes the tone sound "fuzzy"). Distortion is checked at each of the audiometric test frequencies. As with the output check, the right and left earphones of both the standard and insert earphones must be checked individually. Also, as with the output check, distortion is checked on both the standard and insert earphones at start and end of stand (or if a headphone set is swapped mid-stand); however, on a daily basis, only one or the other set of earphones is checked.

To run the distortion test, keep the earphones mounted on the calibration fixture and the booth door closed. Click the "Distortion Left" tab in ART, then click the "Run System Distortion Check – Left" button. Messages in the top center section of the screen will update as the distortion check progresses. When all frequencies have been checked, a pop-up window will inform you that the check is complete (Exhibit 2-44). Click OK.

Exhibit 2-44. Distortion results



If the earphones pass at all frequencies, each box in the table will be green and will read "Pass." If any checks fail, you can click the "Show Details" button to troubleshoot the problem. To rerun the output check, click "Clear," then click the "Run Output Check" button again.

2.4.2.6 Check Linearity (Start and End of Stand Only)

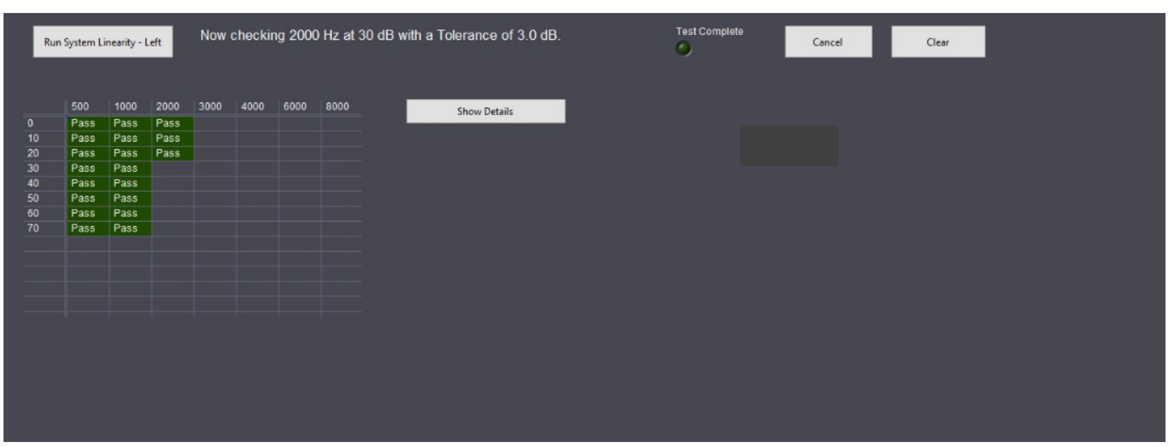
Whereas checking the output of the audiometric test system measures signals at a single intensity, linearity measures signals across the range of intensities that we test in NHANES. Because linearity involves so many individual measurements (eight intensity levels at each frequency), it takes several minutes to complete the test in each ear. Therefore, linearity is only tested at the start and end of each stand, or when a set of earphones is swapped out mid-stand.

Conduct the linearity test with the earphones mounted to the calibration fixture and the sound booth door closed, as with the other acoustic calibration checks. Click the “Linearity Left” tab on the ART screen, then click the “Run System Linearity – Left” button. Initially, a message to the right of the “Run Linearity” button will indicate that system noise levels are being checked. The message will update as it checks the output from 0 to 70 dB at each test frequency. The table will fill in with “Pass” or “Fail” messages as the test progresses.

Note: The linearity check takes several minutes to run. You can work on other tasks aside from ART (for example, inventory) while the linearity check is running.

If the earphones pass at all frequency/intensity combinations, each box in the table will be green and will read “Pass” (Exhibit 2-45). If any checks fail, you can click the “Show Details” button to troubleshoot the problem. To rerun the output check, click “Clear,” then click the “Run Output Check” button again.

Exhibit 2-45. Linearity results



Note: When viewing details for the linearity check, some results may be displayed as "BGND" instead of a decibel level. This indicates that the background noise is too high to reliably make a measurement. "BGND" results are considered equivalent to "Pass."

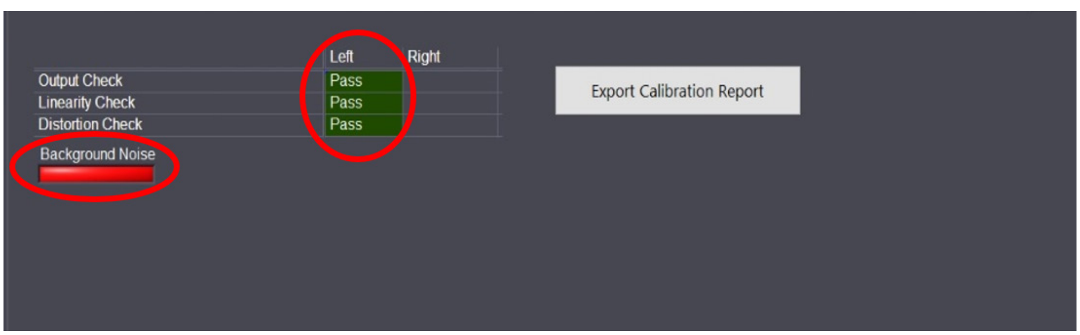
2.4.2.7 Check the Right Earphone

When you have completed the acoustic calibration checks on the left earphone, reverse the earphones on the calibration fixture so that the right earphone is attached to the coupler. Click the "Output Right," "Distortion Right," and "Linearity Right" (if required) tabs and repeat the tests on this earphone.

2.4.2.8 Saving the Results

When all of the calibration checks have been completed for a set of earphones, click the "Results/Export" tab on the far right side of the ART screen. The summary table will indicate which checks were run and whether each test passed or failed. If you missed a check or need to repeat one of the tests, you can return to that tab and do it. For example, in Exhibit 2-46, you can see that the right earphones have not been checked and the background noise check failed.

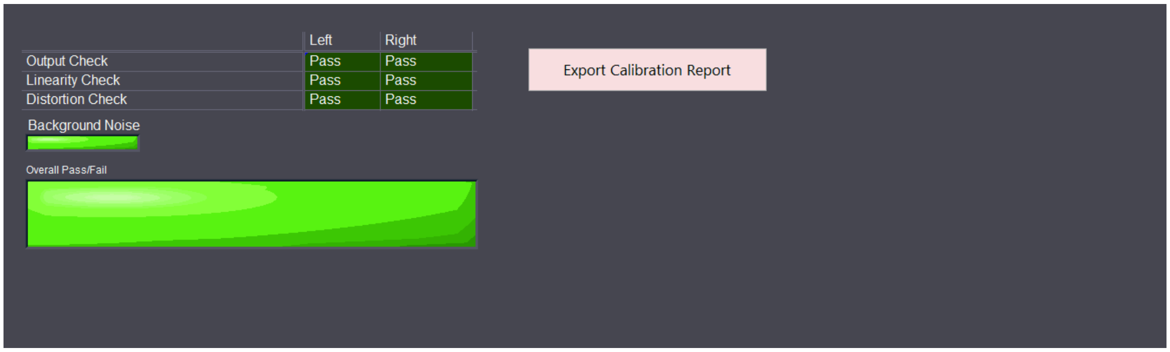
Exhibit 2-46. Incomplete/failed results



Note: Background noise is checked only once, so there are no separate "right" and "left" indicators as there are for the other calibration checks.

When everything is complete (as shown in Exhibit 2-47), click the "Export Calibration Report" button. A pop-up window will indicate that the report has been exported successfully. Click OK.

Exhibit 2-47. Complete results, ready to be exported



Click the Windows "X" to close ART. A pop-up window will verify that you really want to exit. Click "Exit" to finish. Click "Cancel" if you want to return to the program.

Note: If you click the Windows "X" without exporting the calibration report, the results will not be saved.

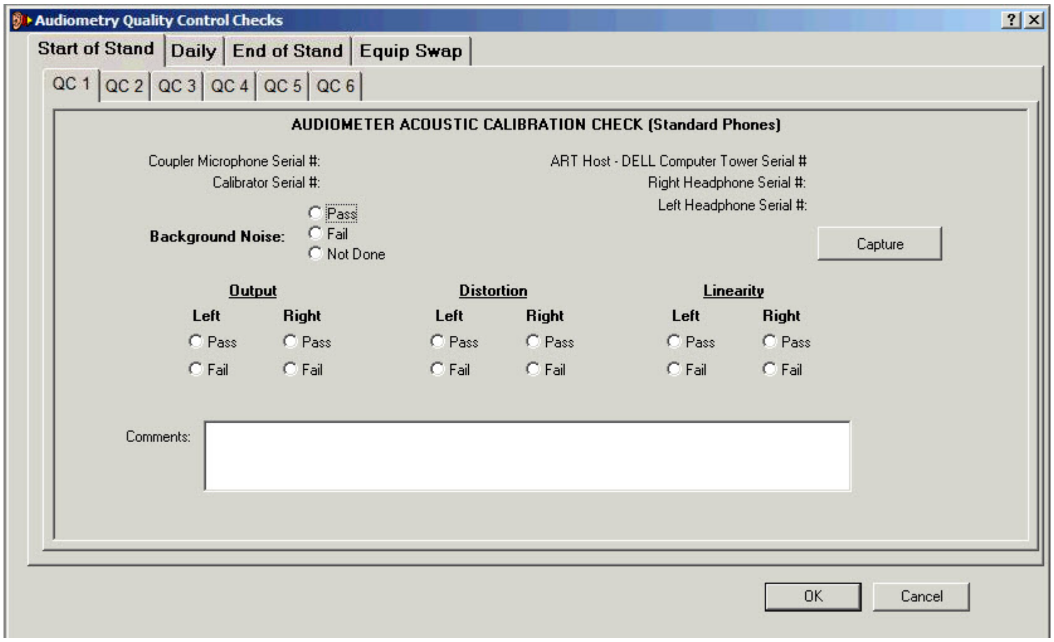
Remove the coupler from the calibration fixture and pack it in the black case. Check the microphone to be certain it did not become loose in the process of removing the coupler.

At start and end of stand (and any time a set of earphones is swapped during the stand), calibration checks must be conducted on both the standard and insert earphones in the set you will be using. When you are ready to start calibrations on the next set of earphones, reopen ART and select the correct config file as described in Section 2.4.2.1. Attach the approriate coupler, following the instructions in Section 2.4.2.4. Conduct the output, distortion, and linearity checks as before. When the checks have been completed in both ears, use the Results/Export tab to save the results; then exit ART again.

Note: Just as you do not have to recalibrate Trident when you begin the acoustic calibration checks on the second set of earphones, you also do not have to repeat the background noise check.

Enter the results of the acoustic calibration check into ISIS (Exhibit 2-48). To record the standard headphone results, go to the QC 1 tab under the Start of Stand tab (the insert earphone results will be entered under the QC 2 tab). Select "Pass" or "Fail" for background noise, output, distortion, and linearity for the left and right. **Be sure to use the correct ISIS tab when recording and capturing results for each earphone (standard or insert). Note:** It is important to record and capture the results for standard headphones (QC 1) before beginning QC procedures in ART on the insert earphones.

Exhibit 2-48. Entering results of acoustic calibration check



2.4.2.9 Listening Check

The object of the listening check (also called a functional check) is to verify that the unit is functioning properly and the test signals are being generated and routed to the appropriate earphone without distortion, extraneous sounds (such as clicks or hum), or loss of signal. A listening check is conducted at the beginning of each stand for both standard and insert earphones. Throughout the stand, standard and insert earphones are checked on alternate days following the same schedule as for the acoustic checks. ISIS will prompt you regarding which earphones to check on a particular day. A listening check of both sets of earphones is also conducted if earphones are swapped during a stand, and again at the end of each stand.

Note: Technologists must have normal hearing (i.e., thresholds better than or equal to 25 dB HL from 500-8000 Hz bilaterally) to conduct the listening check. If you do not have normal hearing, we will work out an accommodation that allows you to conduct as much of the checks as possible without risk of missing a potential problem. For example, if your hearing is better in one ear than the other, you may be able to conduct the listening check for each side of the earphones in your better ear.

There are six components to the functional check:

- Checking the function of the response switch;
- Listening to the quality of the test tones and verifying the adjustment of the attenuator;
- Checking the integrity of the earphone cords;
- Ensuring the proper routing of signals between the right and left earphones;
- Ensuring the function of the system used to talk to the SP (the Talk Forward microphone) during WIN testing; and
- Ensuring the function of the system used to hear the SP responses during WIN testing.

To conduct the listening check, click the "Audiometry" tab at the top of the ART screen. Make sure the correct earphones are selected on the headphone selector box. Put on the earphones that you are checking, making sure the right earphone is on your right ear and the left is on your left ear (or making sure you are certain which earphone is coupled to your better ear, if you are using an accommodation to conduct the check).

Check the response switch:

- Press the SP's "Response" button.
- Verify that the response light illuminates the two "Subject Response" light bars on the ART screen. Also make sure that pressing the response switch does not produce any sound in the earphones.

Check tonal quality and attenuator accuracy:

- While still on the Audiometry tab, select "Right 1000 Hz" from the Stimulus Sequence list.
- Click "Start" to begin an automated test.
- Allow the test signal to climb to a comfortable listening level (i.e., do not respond until the signal reaches 50 dB or a level that is comfortably loud for you). Press the "Response" button or click on the "Mouse Response" button toward the top of the screen.

- Listen to the signals and examine the ART presentation history exhibit to ensure that the signal level drops by 10 dB.
- Run through a single threshold sequence. Allow the tone to climb back to the level at which you initially clicked the button, then respond again. Repeat this two more times.
- Listen to the tones to ensure that they pulse appropriately, that there are no extraneous sounds (e.g., clicks, static), and that the level becomes louder and softer as it should.
- Click "Stop."
- Select "Left 1000 Hz" from the Stimulus Sequence list and repeat the procedure.

Check the earphone cords:

- Click the "System Calibration" tab in the upper left corner of the ART screen.
- Set the controls as follows:
  - Select the right ear
  - Set the stimulus frequency to 1000 Hz
  - Adjust the level to 50 dB HL or a level that is comfortably loud for you.
- Click "Play." You should hear a steady tone in the right earphone.
- Wiggle the earphone cords, especially where they enter the earphones and where they are plugged into the jacks inside the test room. Also wiggle the cables between the headphone selector box and the NI chassis and the sound booth. Listen for any interruption in the test signal, changes in the signal level, or static or other noise in the earphones as the cords are flexed.
- Click "Playing" to turn off the signal.
- Select the left earphone. Keep the stimulus at 1000 Hz and the intensity at 50 dB HL and repeat the procedure.

Check for crossover:

- With the left earphone still selected and the stimulus set for 1000 Hz, adjust the intensity to 70 dB HL. You should hear a loud signal in the left earphone.
- Unplug the left earphone from the sound booth jack panel. Listen through the earphones; there should be no tone in either ear.

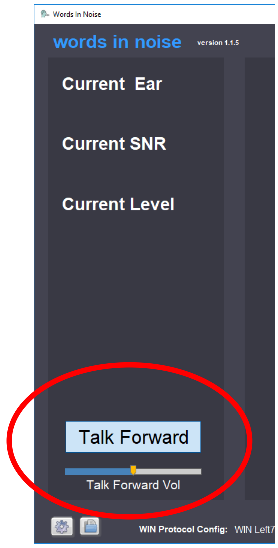
- Plug the left earphone jack back into the booth jack panel. Verify that you can again hear the loud tone in the left earphone.
- Click "Playing" to turn off the sound.
- Select the right earphone. Ensure that the stimulus is still set for 1000 Hz and the intensity is still at 70 dB HL. There should be a loud signal in the right ear.
- Unplug the right earphone from the booth jack panel. Listen through the earphones; there should be no signal in either ear.
- Plug the right earphone jack back into the booth jack panel. Verify that you can again hear the loud tone in the right earphone.
- Click "Playing" to turn off the test tone.

Do not save the listening check results. When the listening check is complete, close the ART by clicking the "X" in the upper right corner. A pop-up box will warn you that the data will not be saved; click "Exit."

Check the Talk Forward system:

- Verify that ART and Trident have been closed. Note the setting of the earphone selector box so that you listen through the correct earphones.
- Turn on the Quest QC-20 calibrator and place it within approximately 2 inches of the Talk Forward microphone.
- Open the WIN software. It does not matter which configuration files are loaded when doing the listening check.
- Press the "Talk Forward" button in the lower left corner of the WIN screen (Exhibit 2-49).

Exhibit 2-49. Talk forward on the WIN screen

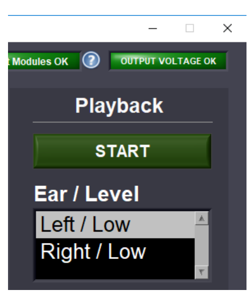


- Place the earphones on your ears and listen for the tone from the QC-20 calibrator. It should be equally loud through both earphones.
- Move the yellow Talk Forward Volume marker to the right edge of the slider range and listen through the earphones again. The QC-20 calibrator tone and any background noise should be louder and should still be equally loud through both earphones.
- Turn off and return the QC-20 calibrator to storage.

Check the Talk Back system:

- Determine which ear is to be tested first based on the WIN configuration file that loaded when you opened WIN. This is the ear displayed as black letters against a gray background in the "Ear / Level" box in the upper right corner of the WIN software screen (Exhibit 2-50).

Exhibit 2-50. First test ear on WIN screen



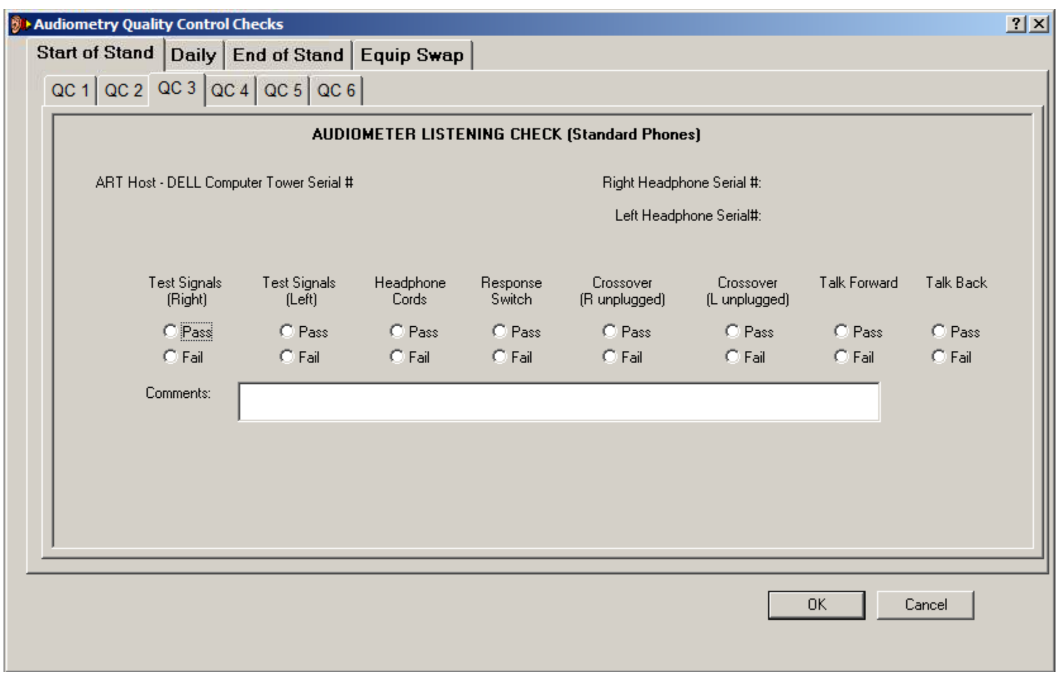
- Place the selected earphone over the G.R.A.S. coupler.
- Verify that the wireless Sennheiser earphones and the charging dock are turned on. Place the wireless Sennheiser earphones over your ears.
- Press the WIN "Start" button to begin playing the speech stimulus into the G.R.A.S. coupler. Listen for the combined speech and babble signals.

At start and end of stand (and any time a set of earphones is swapped during the stand), listening checks must be conducted on both the standard and insert earphones in the set you will be using.

Enter the results in ISIS:

Results of the listening check are recorded as Pass/Fail in ISIS. Standard headphone results are recorded under tab QC 3 (Exhibit 2-51) and insert earphone results are entered under tab QC 4 in the Start of Stand section. If any problems are noted, explain the problems in the "Comments" box and notify the MEC manager and the health technologist assigned to Audio for the stand.

Exhibit 2-51. Results of the listening check



2.4.3 Middle Ear Analyzer (Titan) Calibration Check

A simple check of the Titan's physical volume calibration must be conducted daily, including the beginning and end of stand as well as each day throughout the stand. The calibration will be affected by changes in temperature, so make sure that the temperature of the unit has stabilized prior to turning on the unit. In addition, a sample test should be run each day to evaluate the overall function of the Titan system and ensure that the unit is producing clear, normal graphs.

Note: If there is a loss of power during a session, or if the Titan is turned off completely between sessions, the physical volume calibration should be rechecked once the unit is powered up again. It is not possible to capture the repeat check in the ISIS QC system; the result should simply be recorded on the hard-copy log, with a note explaining the purpose of the recheck.

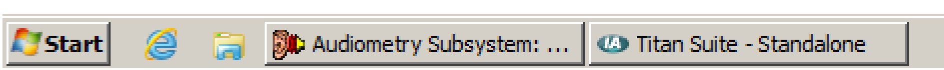
2.4.3.1 Titan Physical Volume Check

Physical volume must be calibrated on the Titan system each day. This is accomplished by running a test in a hard-walled cavity that has a known volume, and verifying that the volume measurement (V) reported by the Titan matches the known volume of the cavity.

Conduct the Titan physical volume check in the following way:

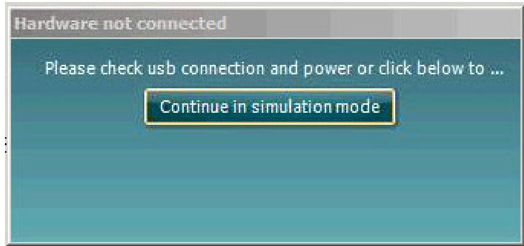
- Turn on the Titan handheld unit by pressing the R or L button on the handheld unit (the unit can remain in the storage cradle).
- The Titan Suite automatically launches when the ISIS QC utility is first opened. When you are ready to conduct the Titan physical volume check, toggle to the Titan Suite by clicking on the Titan Suite icon in the task bar at the bottom of the screen (Exhibit 2-52).

Exhibit 2-52. Task bar with Audiometry application and Titan Suite open



Note: If the unit is off or "sleeping," you will get a message that the hardware is not connected (Exhibit 2-53). Turn the unit on to make the message go away.

Exhibit 2-53. Hardware not connected message



- Select the IMP tab in the upper right corner of the Titan Suite window.

Note: It does not matter if the Titan is set to test the left or right ear for the physical volume calibration check.

Insert the Titan probe (without an ear tip) into the 2.0 cc calibration cavity (the side marked with green tape) until the black probe cap touches the black rubber gasket on the cavity (see Exhibit 2-54). The probe light should turn green, indicating that the Titan is able to test.

Note: The lower left corner of the cradle contains a built-in 2cc calibration cavity that you can use for the daily volume check in lieu of the cylindrical calibration cavity. You can use whichever you prefer for conducting this check; however, it may be easier to see how fully the Titan tip is inserted if you use the silver cylinder to do the check rather than the calibration cavity built into the charging cradle.

Exhibit 2-54. Probe tip inserted in calibration cavity

Press the laptop space bar or "Shoulder Box" button to start the test. The Titan will run through both the entire test sequence (tympanometry, wideband reflectance, and acoustic reflexes); however, only the tympanometry results are necessary for the physical volume calibration.

When the probe flashes white and the test is complete, remove the probe from the calibration cavity.

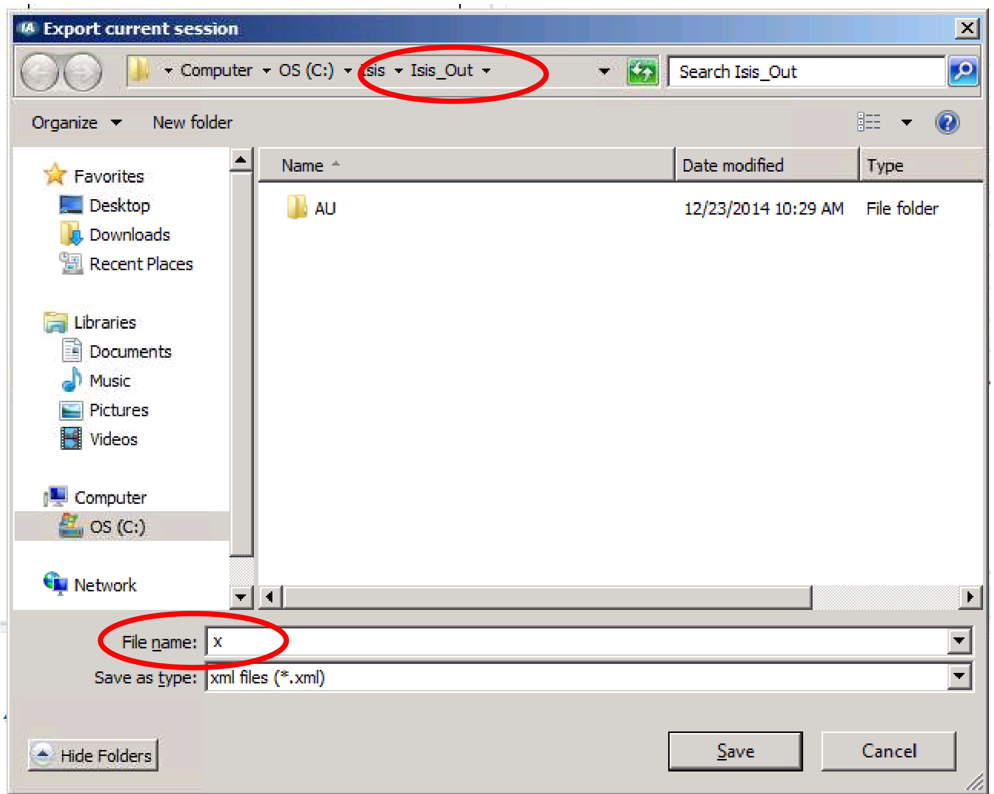
Verify that the V (volume) value reported on the Titan display is between 1.90 and 2.10 ml, as shown in Exhibit 2-55.

Exhibit 2-55. Physical volume calibration result

Press ALT-M, ALT-E, ALT-X (think "ALT-MEX") to save the Titan results to ISIS. The Titan Export window will pop up.

Confirm that the path at the top of the window indicates the ISIS_Out folder, as shown below, type "x" for the file name, and click SAVE (Exhibit 2-56).

Exhibit 2-56. ISIS_Out folder

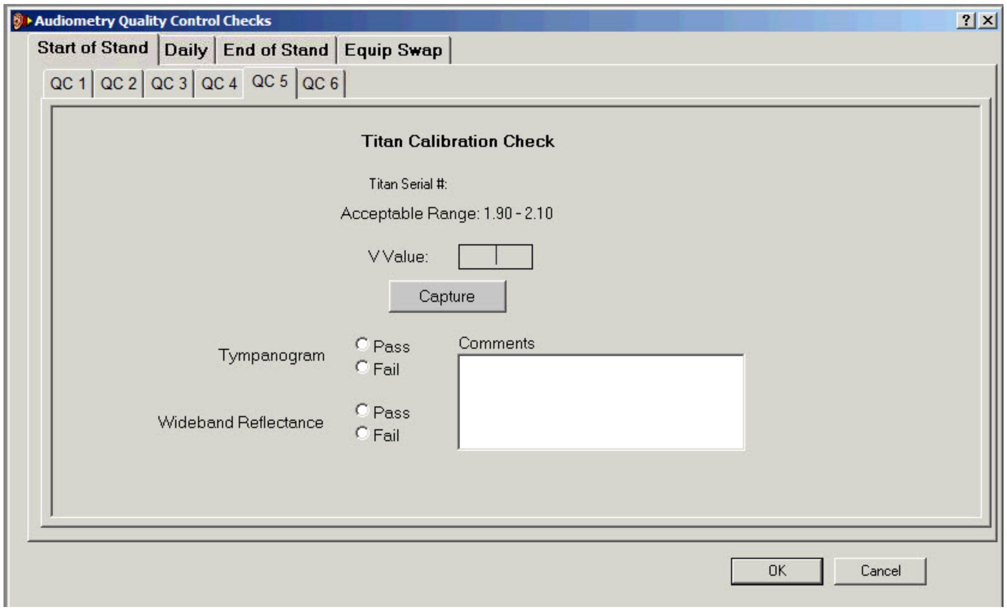


Note: If an x.xml file is already in the ISIS_Out folder when you try to save the calibration result, do not save over it. Save the current file with the SPID instead of "x." When the exam is over, contact the component lead and send a UFO immediately and notify the health technologist assigned to Audio for the stand.

Toggle back to the ISIS QC utility by clicking the audiometry icon in the task bar at the bottom of the screen.

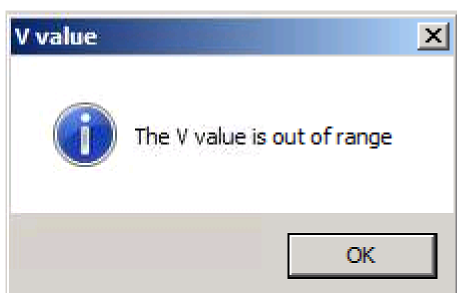
Go to the QC 10 tab under the Start of Stand tab. Click the "Capture" button to capture the tympanometry QC data (Exhibit 2-57).

Exhibit 2-57. Tympanometry Calibration Check screen



If the physical volume measurement does not fall within the required range, ISIS will display a notification message (Exhibit 2-58). (The notification will not prevent you from continuing or saving.) Repeat the calibration, making sure to insert the probe completely into the cavity and hold the probe very still (ambient movement results in "noisy" immittance measurements). Placing the probe on a piece of foam or other soft surface during the calibration may be helpful.

Exhibit 2-58. Out of Range notification



If the physical volume is still out of calibration limits, clean and reseal the probe tip as described in Section 2.7.3.2. If this fails to correct the problem, notify the health tech assigned to Audio for the stand.

Note: Recheck the Titan volume calibration no more than three times per exam day. If the volume calibration does not fall into the 1.9-2.1 range after three attempts, contact the Audiometry consultant. Once the Audiometry consultant has been notified of a Titan volume issue at a particular stand, continue to use the current Titan unit unless the daily calibration falls below 1.8 or above 2.2. Notify the Audiometry consultant if the volume calibration either falls outside this wider range or eventually falls within the actual target range (1.9 – 2.0).

2.4.3.2 Titan Sample Tympanogram and Wideband Reflectance Checks

The physical volume measurement only checks the calibration part of the middle ear measurement system. To evaluate the overall function of the system, you need to run a sample test on yourself to ensure that the unit is producing clear, normal graphs.

Run the Titan middle ear test sequence on yourself just as you would during a test (see Section 3.4.3.2). Make sure the Titan is set to test the same ear that the physical volume check was run on (your results will overwrite the results from the physical volume check in the Titan Suite window). Run a sample middle ear test sequence on one of your ears; it does not matter which ear you test, but try to test the same ear each day. You will not be able to monitor the probe lights while testing yourself, but you will know when you have obtained a seal when you feel the pressure build up in your ear canal. You can also monitor the progress of the test by watching the Titan Suite display on the computer screen. If you do not have a seal, the pressure indicator (∨) below the horizontal axis will waver back and forth; once you obtain a seal, the tympanogram will plot on the display and the wideband reflectance (WBR) test will immediately follow.

Once the test is completed, evaluate the tympanogram for smoothness and symmetry, as during a hearing evaluation (see Section 3.4.3.3). Also evaluate your WBR results just as you would during a hearing evaluation (see Section 3.4.3.3). Make sure the graph crosses the vertical axis below the 40 percent point, and check that the plot looks similar to your usual WBR result. Verify that the acoustic reflexes were tested as they should; do not worry about the specific acoustic reflex results.

You do not need to save the results from the sample test. On the ISIS QC screen, click “Pass” to indicate that you obtained normal sample tests on the ISIS screen.

If any part of the sample test does not look normal, follow the troubleshooting guide in Section 2.4.5 and try repeating the test (overwriting your initial results). If you cannot obtain a normal tympanogram or WBR result on your usual ear, try running the test on your other ear or on another team member. If you still do not get an acceptable tympanogram or WBR result, record "Fail" on the ISIS QC screen and describe the problem and your troubleshooting efforts in the "Comments" box. Notify the MEC manager and health technologist assigned to Audio for the stand.

2.4.4 Recording Serial Numbers

Serial numbers of the equipment used at each stand must be recorded on the Serial Number Register (a hard-copy log) and in ISIS. The Serial Number Register should be kept in the Audiometry room in the MEC. If there is no hard copy available, it can be obtained from the "blank forms" folder on the computer in the staff lounge.

To enter the serial numbers in ISIS, open the QC application on the computer in the Audiometry room and go to the Start of Stand tab. Click on the QC 6 tab (Exhibit 2-59) and enter the serial number for each piece of equipment in the "Serial Number" column. Click the "Done" box next to each piece of equipment as you enter each serial number. Use the scroll bars to move up and down the screen and enter numbers for all the equipment listed.

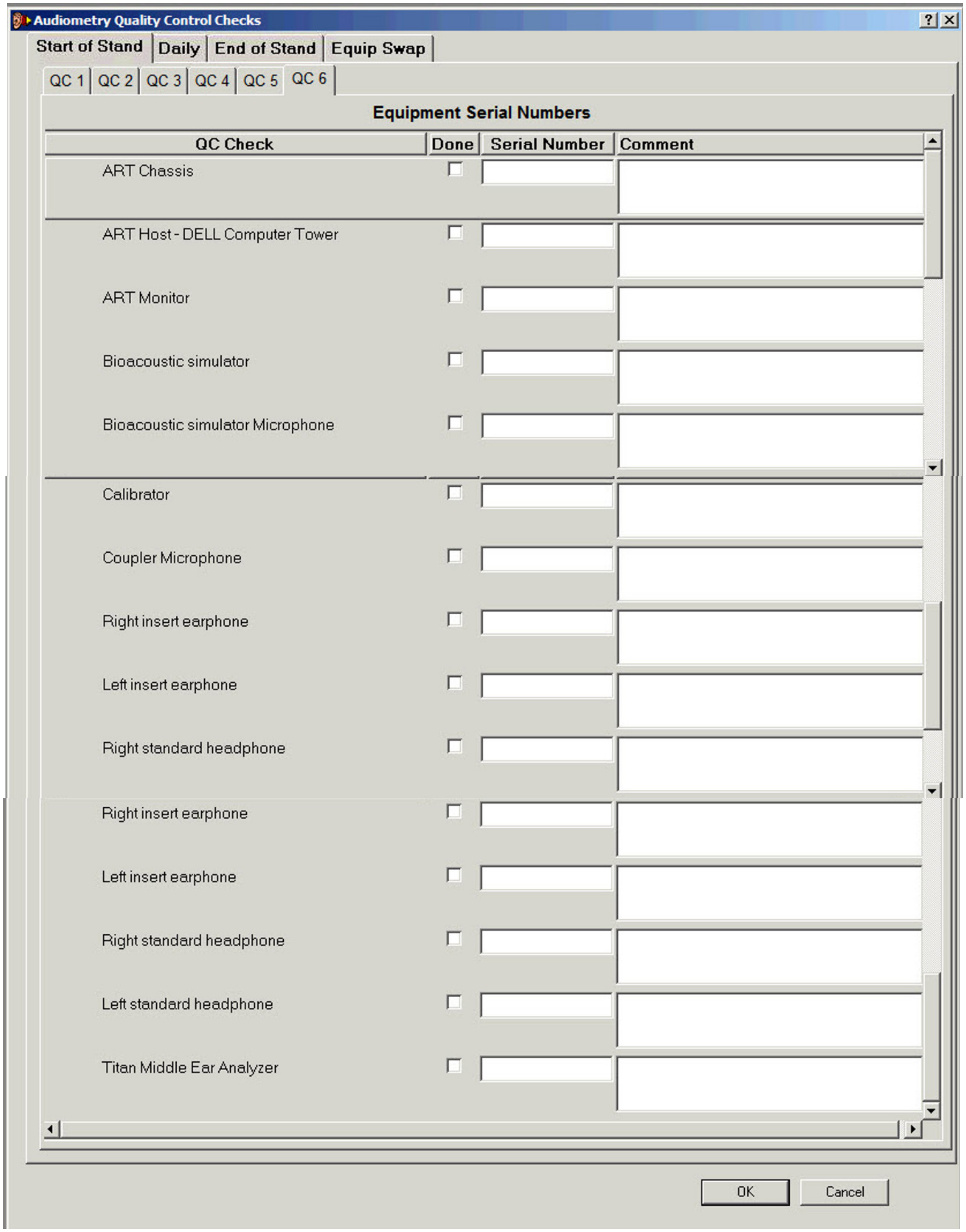
Note: Be sure to enter the manufacturer's serial number for each piece of equipment. Do NOT enter the DHHS/PHS barcode number or the NHANES equipment identification number. You will know you are recording the correct number if it has exactly the same number of characters as there are spaces for that item number on the hard-copy serial number log.

Another Note: Be certain to enter the serial numbers in the "Serial Number" field and NOT the "Comment" field.

You can find the serial number for each piece of equipment in the locations listed below:

- **Bioacoustic simulator:** Serial number is taped to the front of the unit. All serial numbers currently begin "AQI" and are followed by six numbers.
- **Titan:** Serial number is handwritten on the front of the handheld unit along the bottom edge. The serial numbers are seven digits and all begin with the numbers "091."
- **Audiometer:** Each ART system has several serial numbers associated with it (e.g., the National Instruments chassis, Dell computer, etc.). These serial numbers are long and unwieldy. Since the components of each system stay together, the serial numbers of the

Exhibit 2-59. Entering equipment serial numbers in ISIS



individual pieces have been entered into the Equipment Tracking System (ETS). You need only enter the number of the ART system you are using (for example “ART4”). The number of the system is printed on a label at the top of the chassis as well as on the top of the computer tower.

- **Standard headphones:** The serial number for each headphone is printed on the outside of each speaker. The serial numbers are seven characters, typically a “C” followed by six digits.

- **Insert earphones:** The serial number for each side of the earphones is printed at the top of the red and blue boxes on the earphones. They consist of five digits.

- **Calibrator:** The serial number of the Quest QC-20 calibrator is one metal barcoded tag at the base of the calibrator. The serial numbers consist of two letters followed by seven numbers.

  Note: If you are using the smaller (B&K) type of calibrator, you have to slide the unit partially out of its leather case to find the serial number. The serial numbers of the B&K calibrators are seven digits.

- **Microphone:** The serial number of the microphone has been printed on a label on the top of the microphone box; the serial number is also located underneath the mic. The number is the six digits after “40AO.”

After completing all of the Start of Stand procedures, click the daily tab in the QC utility. Since you have already completed all of the QCs under the daily tab during your SOS QC, you do not need to repeat them. Simply fill out each tab based on the results from your SOS procedures.

2.4.5 Troubleshooting Calibration Problems

The following problems may be encountered during audiometric calibration checks. Potential solutions are listed for each problem to assist in troubleshooting these difficulties.

- Acoustic calibration values out of range:
  - Make sure the standard or insert coupler is seated all the way onto the microphone on the coupler base.
  - Ensure that the earphones are seated all the way onto the standard or insert coupler.
  - Verify that the correct CALIBRATION config file is selected.

  - Make sure the switch box is set to the proper headset.

  - Verify that all headphone jacks are plugged in completely.

  - "Clean" the audio jacks and sound booth inputs by inserting/removing the jack in and out of the panel several times, twisting it around a bit in the jack panel each time.

- Sound stops coming through the earphones in the middle of QC:

  - Reboot the chassis, ART computer, and ISIS computer and resume QC. (Power up the chassis, ART computer, and ISIS computer in the order indicated in Section 2.3.2.1.) Pick up the calibration where you left off; you do not need to repeat checks that have already been completed.

If it takes more than two attempts to pass the background noise or more than one attempt to pass anything else (unless it is a clear mistake, like accidentally choosing the wrong config file or selecting the wrong earphones), please call Christi or the Westat component person.

- Titan V value outside range:

  - Repeat calibration, holding the probe very still or placing it on a piece of soft foam.

  - Clean or replace probe tip, as explained in Section 2.7.3.2.

  - Check the volume using the alternate cavity (i.e., the silver cylindrical cavity or the cavity on the Titan storage cradle).

- Sample tympanogram flat:

  - Repeat tympanogram in your other ear.

  - Run a tympanogram on another team member.

  - Clean probe tip as explained in Section 2.7.3.2

- Sample tympanogram "noisy":

  - Repeat tympanogram, holding the probe very still.

  - Repeat tympanogram on another team member.

- Sample WBR crosses vertical axis above 40 percent mark:

  - Repeat WBR, pressing the probe more firmly in the ear.`

2.5 Daily Procedures

2.5.1 Setup and Calibration

Prior to beginning the daily calibration procedures, turn on the ART monitor by pressing the "Power" button on the top of the left side of the monitor (under normal circumstance, the ART chassis and computer tower are kept running throughout the stand). Turn on the Titan middle ear analyzer and allow it to warm up for at least 10 minutes. Unplug the otoscope base from the electric outlet and screw the top portion onto it. Turn on the otoscope and verify that it works. Turn on the Talk Forward microphone by sliding the switch to the "green" position. Turn on the ventilation switch inside the sound booth and open the door. Keep the door to the booth open as often as possible to keep the temperature inside at a comfortable level.

Run daily ART system calibration checks as indicated in Section 2.4. Conduct a listening check of the earphones, as described in Section 2.4.2.9. Standard and insert earphones should be checked on alternate days, as prompted by ISIS.

Calibrate Titan physical volume measurement as described in Section 2.4.3.1. Remember that the calibration will be affected by changes in temperature; if a large change in temperature occurs in the test room over the course of the day, turn the power off, wait 3 seconds, and turn the unit on again. Also, if the Titan is turned off completely at any point during the day (e.g., between sessions or due to a power outage), recheck the physical volume calibration before conducting the next exam.

Conduct a sample middle ear test on yourself as described in Section 2.4.3.2.

2.5.2 Daily Monitoring of Ambient Noise Levels

The Quest BA-202-27 is equipped with an octave band monitor that monitors the ambient noise in the sound room continuously. The octave band monitor is activated simply by turning on the simulator. If the background noise levels exceed the maximum levels that have been programmed into the unit, one or more of the red indicators will light up.

Whenever pure tone testing is conducted, the monitor should be observed. If the indicator lights remain on for more than a few seconds, the hearing test should be suspended until the noise problem is resolved.

2.5.3 Changing Equipment After Start of Stand

If equipment is changed for any reason during a stand, the replacement equipment must go through the start of stand calibration procedures. All calibration checks done on replacement equipment will be entered into ISIS under the Equip Swap section. The QC tabs in the Equip Swap section are identical to the tabs in the Start of Stand section. The serial number of the new piece of equipment must be entered on the hard-copy serial number log and in the QC 6 tab in ISIS. Appropriate calibration checks must be conducted as indicated below.

If the bioacoustic simulator is swapped, conduct the following QC checks:

QC 6: Enter the serial number of the replacement bioacoustic simulator.

If the middle ear analyzer is changed, conduct the following calibration checks:

QC 5: Check the volume calibration of the replacement Titan and run a sample test on yourself.

QC 6: Enter the serial number of the replacement Titan.

If earphones are swapped, conduct the following calibration checks:

QC 1: Conduct a complete acoustic calibration check of the standard earphones.

QC 2: Conduct a complete acoustic calibration check of the insert earphones.

QC 3: Do a listening check of the standard earphones.

QC 4: Do a listening check of the insert earphones.

QC 6: Enter the serial numbers of the right and left standard earphones and right and left insert earphones.

If the calibration kit is swapped, conduct the following QC checks:

QC 6: Enter the serial number of the replacement coupler microphone.

If the calibrator is swapped, conduct the following QC checks:

QC 6: Enter the serial number of the replacement calibrator.

Note: If equipment is changed at the beginning of a test day, you may need to enter the results into the daily QC section as well.

2.5.4 Procedures at the End of an Exam Day

At the end of each test day, turn off the ART monitor by pressing the "Power" button on the top of the left side of the monitor. Leave the ART chassis and computer tower running.

Power down the Titan handheld unit by pressing both the R and L buttons until the globe appears.

Turn off the Talk Forward microphone by sliding the switch to the "red" position.

Recharge the otoscope as explained in Section 2.7.2.2.

Note: Do **not** recharge the otoscope if the MEC will be closed the following day.

2.6 Weekly Procedures

Clean the viewing window on the otoscope as described in Section 2.7.2.3, and the Titan probe tip as described in Section 2.7.3.2.

2.7 Equipment Care and Maintenance Procedures

The equipment selected for the study was chosen in part because it is rugged and durable enough to withstand field testing conditions. Nonetheless, like all medical equipment, it must be handled with care to ensure that it stays in good working order and the calibration of the instruments do not change.

The exterior housing of the calibrator, bioacoustic simulator, chassis, computer tower, and Titan handheld unit may be cleaned as necessary by wiping them with a damp cloth or an Audiowipe. Do not use any other cleaners or a cloth that is so damp that fluids can seep into the interior of the housing. Maintenance and care of the specific instruments are described in the following sections.

2.7.1 Bioacoustic Simulator

2.7.1.1 Changing the Battery

The bioacoustic simulator requires one 9-volt alkaline battery. The battery compartment is located at the top of the unit. Lift the left side of the gray battery door upward. Snap the battery onto the connector, slide it into the battery compartment, and close the battery door. Battery life is approximately 24-32 hours, or 3-4 days, assuming 8 hours of daily use. As the battery weakens, the power light indicator will flash less brightly. When the light flashes dimly or does not flash at all, the battery must be replaced.

Because the battery must be changed so frequently, the battery connector on the bioacoustic simulator suffers a lot of "wear and tear." **Be particularly careful when removing and replacing the battery so that the battery connector is not damaged.**

2.7.1.2 Calibration

The bioacoustic simulator should receive a comprehensive calibration annually (or sooner if problems are encountered). The calibration should be accomplished by the manufacturer (Quest Technologies) or by another laboratory that is a member of the National Association of Special Equipment Distributors, to ensure that the calibrations are traceable to National Institute of Standards and Technology (NIST).

2.7.2 Otoscope

2.7.2.1 Assembling the Otoscope

The otoscope consists of two parts: the head (which contains the lamp and the eyepiece) and the handle (which holds the batteries). The handle itself also contains two parts: the upper part (which connects to the head) and the lower part (which contains the battery). Assemble the two parts of the handle by screwing them together. Then, slide the head over the top of the handle, lining up the notches on the head with the protrusions on the handle, and turn it clockwise until it locks into place.

2.7.2.2 Charging the Battery

The otoscope contains a rechargeable battery in its base, which can be charged simply by unscrewing the top of the handle and plugging the base into any standard wall outlet (see Exhibit 2-60). The otoscope should be charged for 8 hours at the start of each stand; and overnight during the stand. Do not charge the battery if the MEC will be closed the following day.

Exhibit 2-60. Charging the otoscope

Note: It is not necessary to remove the head of the scope to charge the handle.

2.7.2.3 Cleaning the Eyepiece

The eyepiece on the head of the otoscope slides out for easy cleaning (see Exhibit 2-61). Gently push the window to the right with your thumb. The window may be cleaned with alcohol or standard glass cleaner. The eyepiece should be cleaned about once a week, or as often as necessary. Do **not** clean the window without first removing it, as the cleaning solutions could damage the otoscope.

Exhibit 2-61. Cleaning the eyepiece

2.7.2.4 Changing the Otoscope Lamp

The light source for the otoscope is a small, fiber optic bulb located at the base of the otoscope head. To change the lamp, disconnect the otoscope head from the handle. Remove the old bulb by gently pulling it out using your fingernails or a small nail file to lift it out of place (the bulb is held in by friction only). Taking care not to touch the glass surface of the replacement bulb, gently insert it into the receptacle and push it in as far as it will go. (The base of the bulb should be slightly below the metal base of the otoscope head.) Replace the head on the handle.

2.7.3 Middle Ear Analyzer

2.7.3.1 General Handling

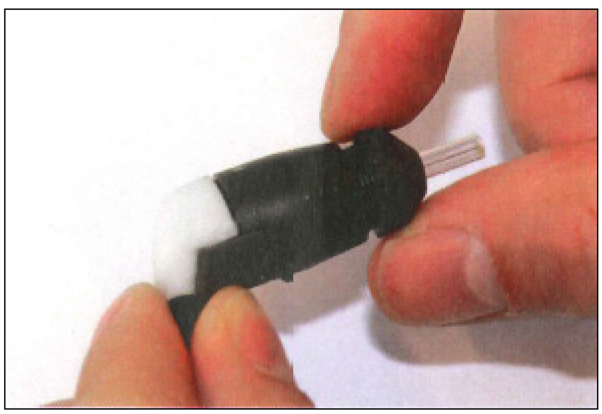
Calibration data for the Titan is stored in the probe tip and shoulder box. Be especially careful not to bang or drop the extension cable to which these parts are attached, as this may affect the function or calibration of the Titan. In addition, take care not to kink or step on the extension cable, as this could damage the internal air line and make it impossible to conduct the middle ear tests. Coil this cable loosely when hanging it in the exam room or when packing equipment, to avoid potential damage to the air line or wires.

2.7.3.2 Cleaning the Probe Tip

The clear tip at the end of the Titan probe must be cleaned regularly to ensure proper functioning of the Titan. It should minimally be cleaned once a week and at the end of each stand, and more often if cerumen or other debris is evident, if the Titan repeatedly reports a block when attempting to conduct immittance testing, or if the physical volume measurement is repeatedly low during calibration.

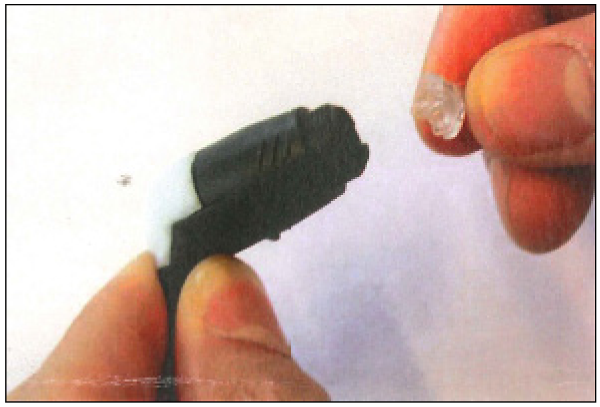
Clean the probe as follows: Unscrew the probe cap, as shown in Exhibit 2-62 below.

Exhibit 2-62. Unscrew the probe cap from the probe tip



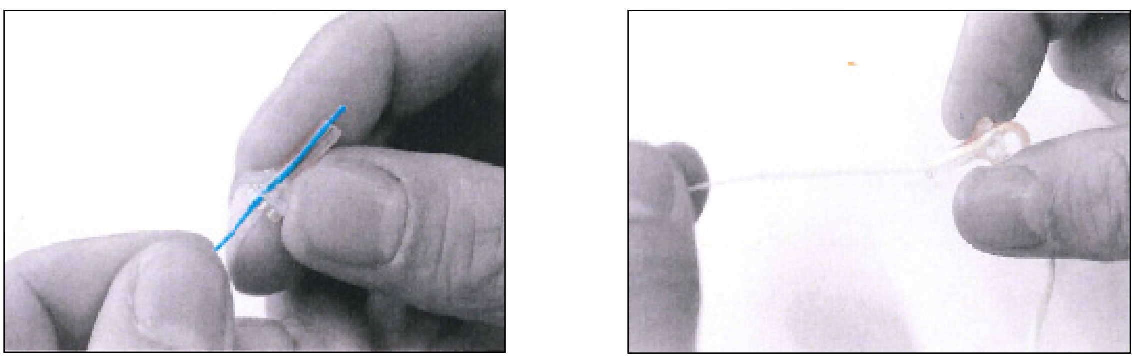
Next, take off the probe tip by pulling it gently straight out, as shown in Exhibit 2-63.

Exhibit 2-63. Pull the probe tip directly off the probe



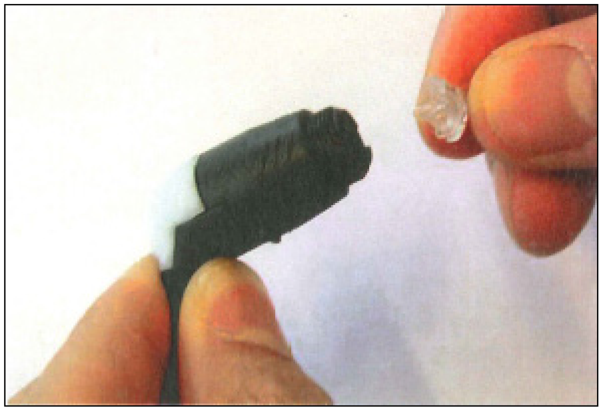
Use the probe cleaning tool to remove any debris from the probe tip. You can also use cleaning floss. Thread the stiff end of the cleaning floss through the probe tip tube and then pull the cleaning floss completely through, as shown in Exhibit 2-64. Discard the floss.

Exhibit 2-64. Cleaning the probe tip with floss



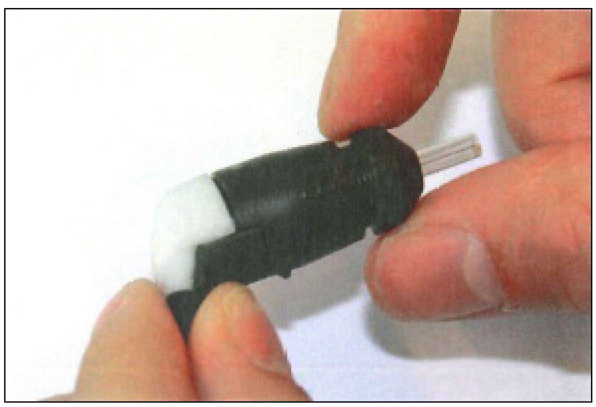
Replace the tip onto the probe by lining up the two small holes and one large hole; there is also a notch between the two small holes to guide placement (see Exhibit 2-65). Press gently until the tip snaps into place.

Exhibit 2-65. Snap the tip back onto the probe



Screw the cap back onto the probe, as shown in Exhibit 2-66.

Exhibit 2-66. Screw the cap back onto the probe



A spare probe tip is provided with your supplies so that you can quickly swap the tip if it becomes clogged while conducting an evaluation. The clogged tip can be cleaned later when time permits.

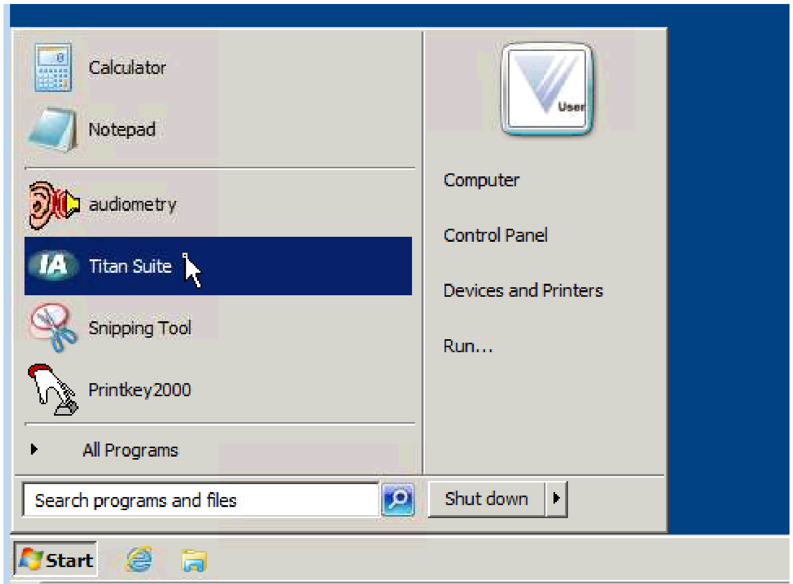
Note: Do **not** attempt to clean the probe tip while still attached to the housing.

And Another Note: Do **not** attempt to remove debris that may be evident on the probe itself. A block at the level of the probe itself must be cleaned by an authorized laboratory and the Audiometry consultant would arrange this service.

If it is necessary to clean the probe tip or switch the probe tip after the daily QC has been conducted, you must recalibrate the middle ear analyzer. This can be done outside of the ISIS QC utility by clicking on the "Start Menu" button in the toolbar and selecting "Titan Suite"

(Exhibit 2-67). Check the volume calibration and run a sample test on yourself using the instructions in Section 2.4.3.1; however, you do not need to save the results.

Exhibit 2-67. Opening Titan Suite outside of ISIS



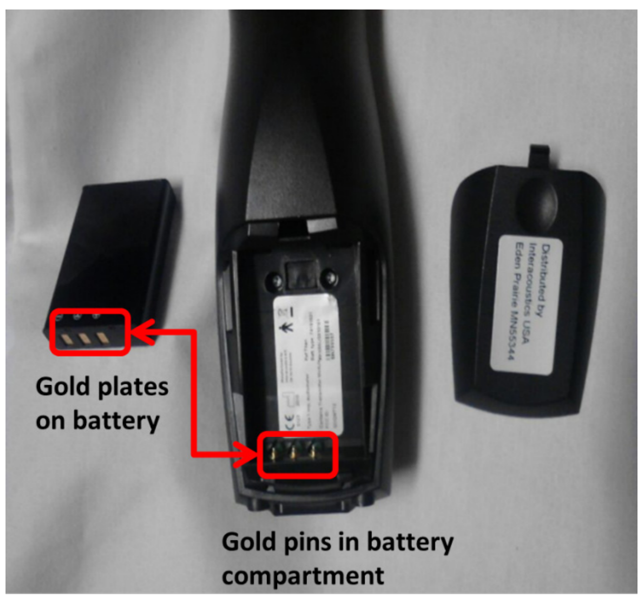
2.7.3.3 Changing the Titan Battery

The Titan operates from a rechargeable battery, which is continually charged through the Titan storage cradle. However, if for some reason the battery becomes fully discharged and must be replaced, remove the battery cover from the back of the handheld unit by pressing gently on the indentation near the bottom of the unit and gently sliding the cover downward (see Exhibit 2-68).

Exhibit 2-68. Removing the battery cover from the Titan handheld unit

Place the new battery in the compartment, making sure that the gold plates on the bottom of the battery line up with the gold pins in the battery compartment, as shown in Exhibit 2-69.

Exhibit 2-69. Gold plates on Titan battery lined up with the gold pins in the battery compartment



Note: Do not rely on the printing on the battery to know which way to place it; some batteries are printed differently than others. Always double check how you are placing the battery in the unit, as installing it incorrectly will break off the pins.

Replace the battery door by sliding it up over the compartment until it clicks into place.

2.7.3.4 Charging the Titan Outside the Cradle

The Titan can be charged independently of the storage cradle in two ways. The handheld unit can be connected directly to the ISIS computer using a USB cable (with a mini USB connection on one end and regular USB connector on the other end). Insert the mini USB connector into the bottom of the handheld unit and the regular USB connector into any available USB port on the ISIS computer monitor. If the battery is fully charged, this type of connection is usually sufficient to run tests for a day.

The Titan, however, does not always maintain a sufficient charge over time when charged via a computer USB port, and it takes a long time to recharge a low battery through the computer connection. Therefore, when you are not using the Titan cradle, the handheld unit should be charged overnight using a wall outlet. Connect the mini USB end of the short USB adapter cable into the bottom of the handheld unit and the other end to the plug on the wall charger cable. Plug the charger into a wall outlet (see Exhibit 2-70).

Exhibit 2-70. Setting up the Titan to charge directly from a wall outlet

Do not charge the Titan overnight on evenings when no exams are scheduled for the following day.

2.7.3.5 Controlling Humidity

The Titan probe (the small part at the end of the cable, which lights up) contains a filter that is very sensitive to humidity. Desiccant packs are used to try to keep humidity out of this filter. There are two different types of desiccant packs – large pillows for use when the Titan is in storage in its black case and smaller packs for when the Titan is unpacked for use during a stand.

Desi View desiccant pillows should be used in the black Titan storage case whenever the Titan is packed in this case. This would include:

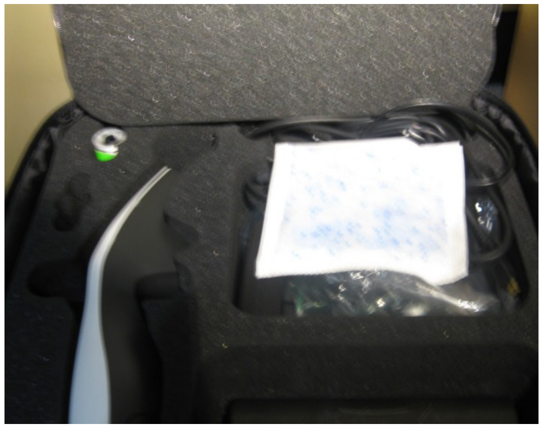
- When the Titans are packed up between stands;
- When shipping a Titan for calibration or service; and
- When storing the spare Titan during a stand.

The pillows are filled with blue and white silica gel (Exhibit 2-71). When the silica crystals turn from blue to pink, they have reached their absorbance capacity and should be changed.

Exhibit 2-71. Desiccant pillows

When packing the desiccant pillows in the black cases, try to keep them as close to the probe as possible (Exhibit 2-72).

Exhibit 2-72. Probe packed near desiccant pillows

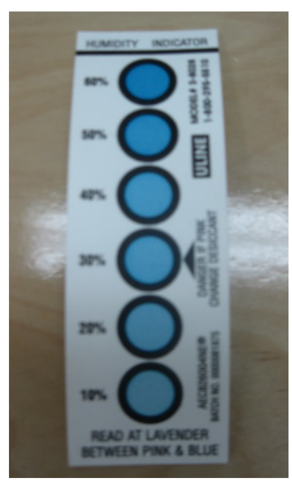


Spare desiccant pillows should be kept in a Ziploc bag to prevent them from absorbing moisture until they are needed.

Please check the desiccant pillow packed with the spare Titan at the start and end of each stand and replace it if necessary. It isn't necessary to monitor the desiccant for the spare Titan during a stand.

Small desiccant packs should be used during the stand to prevent humidity from affecting the probe tip of the Titan in use for that stand. These desiccant packs have silica crystals that do not change color when their moisture capacity is reached. Therefore, a humidity indicator strip is needed to monitor how much moisture has been absorbed. The humidity strips are supplied in an airtight can and have dots that will successively turn pink as more moisture is absorbed (Exhibit 2-73).

Exhibit 2-73. Humidity strips and can



At the end of each exam day, put the Titan probe tip in a Ziploc bag each evening with five of the small white desiccant packs and the dot strip (Exhibit 2-74).

Exhibit 2-74. Titan probe tip storage

Change the desiccants and the strip when the 30 percent dot changes from blue to pink.

Store the spare desiccant packs in a Ziploc bag to prevent them from absorbing moisture until they are needed.

2.7.3.6 Annual Calibration

The Titan must receive a comprehensive calibration annually (or sooner if problems are encountered). The calibration must be accomplished by the manufacturer (Interacoustics) or a laboratory that is a member of the National Association of Special Equipment Distributors, to ensure that all calibrations are traceable to NIST.

2.7.4 Vidpro XM-L Lavalier Condenser Microphone

2.7.4.1 General Handling

Like all microphones, the Vidpro Talk Forward microphone is sensitive to hard knocks, so be careful not to drop the head of the microphone or bang it against hard surfaces such as the sound booth door or top of the table. Keep the foam over the top of the microphone to protect it. Loosely coil up the excess cord length, secure it gently with a twist-tie, and hang it over the hook on the booth door to avoid stepping on it or getting the cord pinched in the door.

As needed, the Vidpro mic can be wiped clean with an Audiowipe. Do not spray any cleaner on the microphone itself or allow any moisture to get into the openings at the top of the microphone.

2.7.4.2 Changing the Microphone Battery

The battery for the Talk Forward microphone is located inside the adapter. To access it, twist the adapter in the center near the "rough" portion (Exhibit 2-75). The battery can be found on the back side of the adapter. A tiny black ribbon behind the battery can be pulled to help remove the battery. When placing the new battery in the adapter, make sure the battery is turned in the correct direction and the tiny black ribbon is behind it as it is inserted in the slot.

Exhibit 2-75. Microphone adapter and battery

2.7.5 Care and Maintenance of the ART System

2.7.5.1 General Handling of the Chassis and Accessories

While the chassis is a fairly rugged instrument designed to provide accurate and reliable service even under field testing conditions, the earphones are more susceptible to damage. Be very careful not to bang or drop the headphones or insert earphones, as this may alter the calibration. If either earphone is accidentally dropped, recheck the calibration (see Section 2.4.2.2).

Sound measurement and signal generation systems – such as those used for audiometric testing and calibration – are very precise instruments that require careful handling. Always use the following precautions when handling the National Instruments chassis and its accessories:

- Handle the microphone very carefully. Never touch the diaphragm of the microphone; try to keep dust and other objects from touching the diaphragm as well.
- Store the microphone in its case between stands.
- Make sure the power is turned off on the National Instruments chassis and the audiometric testing computer before connecting or disconnecting any cables.
- Attach all cable connections very gently. Never try to force a connection. If something does not seem to be attaching easily, remove it and try again.
- Do not expose the National Instrument chassis or the audiometric testing system computer to excessive heat, cold, or dampness. Allow the instruments to adjust to the ambient temperature of the environment before using them.

2.7.5.2 ART Monitor

Because the ART monitor is a touch screen, special care must be taken in its use and care.

- Do not use sharp objects to touch the screen. Gently use the finger or stylus to touch or swipe on the screen.
- Use your finger pad, not your fingertip or fingernail, to touch the screen.
- Keep fingers clean and dry when touching the screen. Wet or damp fingers can make it difficult for the screen to determine touch location.

- Clean the monitor screen with the special cloth provided. Make sure the power is turned off before cleaning. If necessary, the cloth may be dampened with water to remove tough spots on the screen. Do not use chlorine, alcohol, ammonia, detergent, or any other cleaner; these solvents may damage the screen or leave residue.

- Do not place the touch monitor near light bulbs, electrical wires, or other items that generate an electromagnetic field; this can cause touch functions to respond abnormally.

- Do not apply heavy pressure on the screen. Always place the monitor in its protective cover when moving it or packing it for transport.

2.7.5.3 Annual Calibration

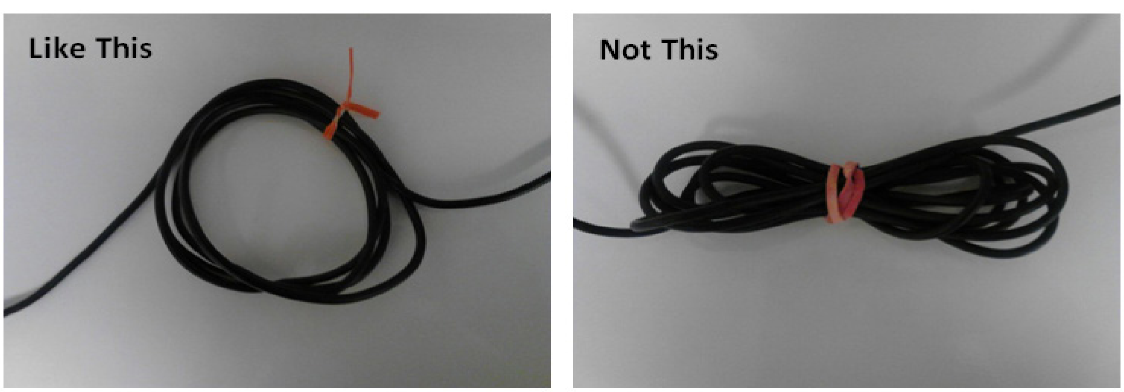
The ART system must receive a comprehensive calibration annually (or sooner, if problems are encountered). The calibration must be accomplished by a certified laboratory to ensure that all calibrations are traceable to NIST.

2.7.6 Cable Management

As you have noticed by now, the equipment for the audiometry component involves a lot of cables. Cables are often the weakest link in electronic systems. Follow these simple precautions to avoid damage to the cables and subsequent problems with the hearing test equipment:

- Coil cables loosely when packing equipment to avoid potential damage to the internal wires. Do not pinch or crimp cables tightly. See the examples in Exhibit 2-76.

Exhibit 2-76. Correct and incorrect ways to secure cables



Keep attachment points loose to avoid stress where the cable meets the equipment. For example, when packing up the headphones, allow a bit of the cord to hang directly down from the earpiece before coiling up the rest of the cord, as shown in Exhibit 2-77.

Exhibit 2-77. Correct and incorrect ways to protect cables at attachment points to equipment

- Use twist-ties to loop up extra length to reduce the amount of dangling cord (Exhibit 2-78).

Exhibit 2-78. Correct and incorrect ways to manage extra cable length

- Group cables together as much as possible to make it easier to avoid stepping or tripping over them.

2.8 End of Stand Procedures

2.8.1 End of Stand Calibrations

Conduct final calibration checks in the order indicated below. Only the equipment used during the stand needs to be rechecked at the end (it is not necessary to check the spares at the end of a stand). Refer to Section 2.4 for directions on calibration.

- Background noise measurement;
- Acoustic check (output, distortion, and linearity) and listening calibration check of both standard and insert earphones; and
- Middle ear analyzer.

Enter the results in ISIS as described in Section 2.4.2. If any equipment fails the end of stand QC check, notify the health technologist assigned to Audio for the stand or the MEC manager so that arrangements can be made for repair of the equipment prior to the next stand.

Conduct an inventory of equipment and supplies, as described in Section 2.2.5.

2.8.2 Room Teardown

Inside the sound booth:

Make sure the bioacoustic simulator is turned off. Unscrew the microphone from the preamp, put the protective white plastic cover over it (do not cover up the hole in the cover when placing it on the microphone), and pack it in its case. Disconnect the microphone cable from the bottom of the bioacoustic simulator. Take the simulator down from the sound room wall and remove the battery. Wrap the simulator and the cable and pack everything carefully into the packing box. Put the box in the lower cabinet to the right of the sound booth.

Disconnect the otoscope head from the rechargeable handle. Clean the eyepieces if necessary, as explained in Section 2.7.2.3. Check the dates on the rechargeable batteries and replace if required. Wrap each part of the otoscope in bubble paper and pack them in the small green packing boxes. Place the boxes in one of the drawers outside the sound room.

Remove the Titan handheld unit (and spare battery, if applicable) from the cradle. Inspect and clean the probe as necessary, as described in Section 2.7.3.2. Pack the Titan handheld unit, USB cable, calibration cavity, and spare battery (if applicable) into the special zippered carrying case. **Do <u>not</u> coil the extension cable too tightly or the air line may be damaged!** Put a large desiccant pack in the case in the section with the probe. Label the case with a note stating "Used at Stand ###" to facilitate setup at the next stand. Disassemble the Titan cradle and pack it in its box. Put the Titan case and cradle box in the lower cabinet outside of the sound booth.

Unplug the calibration cable from the jack panel and tape it to the table. Remove the microphone from the calibration fixture (if possible) and gently screw it into its case. Since the coupler base fits snuggly into the calibration fixture, it is not necessary to remove the coupler and pack it in the case. With the coupler base still in the fixture and the cord still running behind the desk, wrap the calibration fixture in bubble wrap and put it in the drawer inside the booth with the cable coming out of the hole in the drawer. Pack the standard and insert earphone couplers into the calibration case (Exhibit 2-79). Put the case in the lower cabinet outside of the sound booth.

Exhibit 2-79. Calibration case with standard and insert earphone couplers

Note: If you are unable to remove the microphone from the coupler base, leave it in place, cover it with several gauze pads to protect it (see Exhibit 2-80), and pack it along with the fixture inside the drawer.

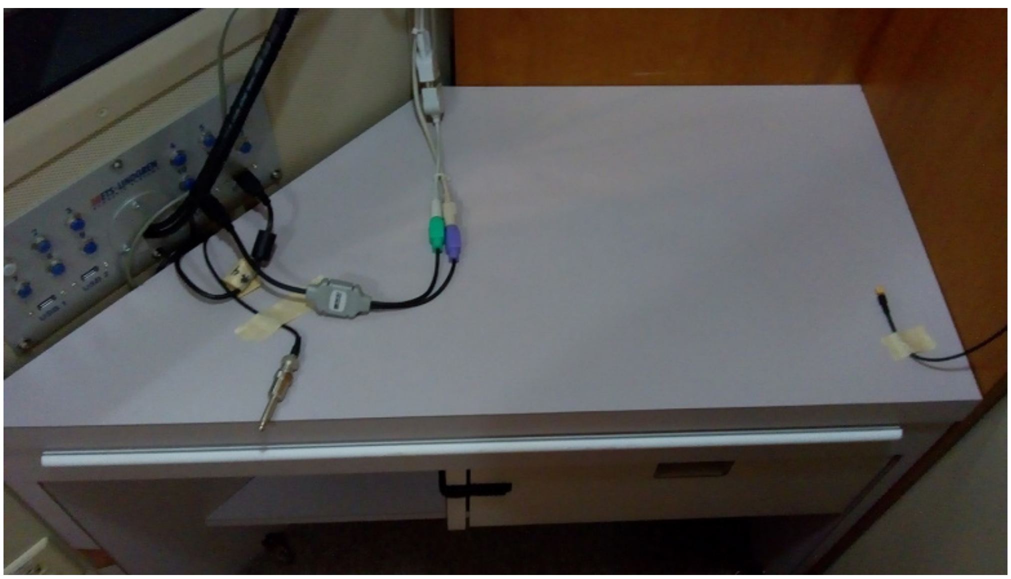
Exhibit 2-80. Microphone covered with gauze pads

Remove the Phone Guard headphone covers from the dispenser and pack them in their original box in the upper cabinet outside the booth. Remove the specula dispenser from the wall and pack it in a drawer. Place the tympanometer ear tips in the large, lidded, plastic container, and place the container in the cabinet outside the booth. Place the foam insert earphone tips in zip closable bags and place them in the drawer inside the booth. Secure other small items in the drawer also, including the screwdriver(s), batteries, and pipe cleaners. Tape or VELCRO® the drawer shut for transit.

Cover all of the audio jacks with protective covers.

Once all of the cords are disconnected and the equipment is packed, the desk and jack panel inside of the booth should appear approximately as shown in Exhibit 2-81.

Exhibit 2-81. Jack panel and work station inside the audiometric booth prepared for transport



<u>Outside the booth</u>:

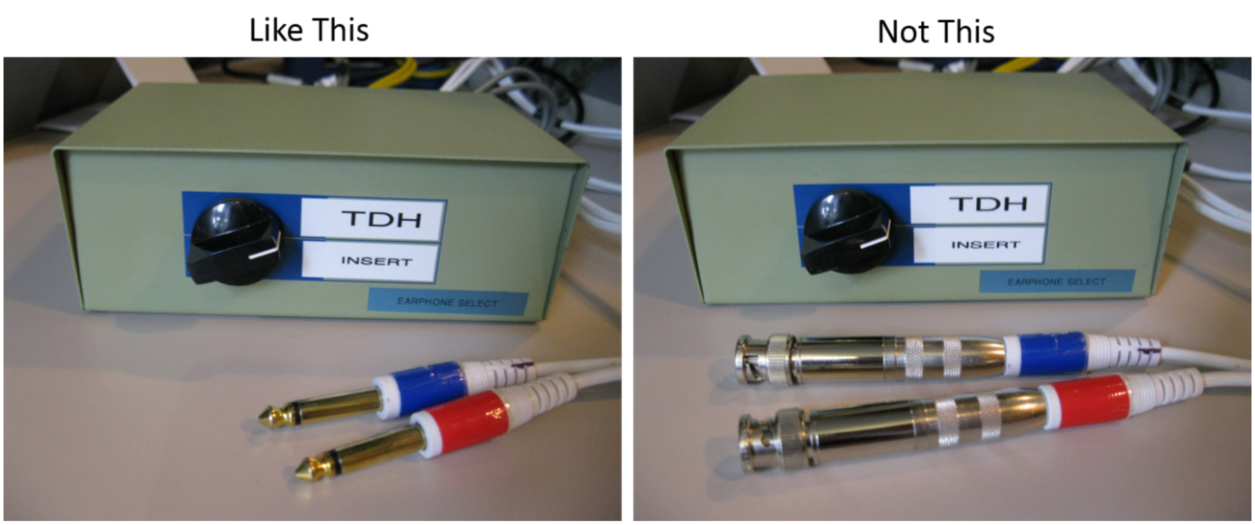
Power down all ART equipment before disassembly (see Section 2.5.4). The power down order does not matter. Disconnect the power, HDMI, and touch cables from the right side of the ART monitor and put them in the cable station on the table. Remove the monitor from its stand. Put the monitor into the protective metal cover with the screen side against the cover and the controls and connection ports fitting into the notched sections on the side. Put the bottom edge of the monitor in place first, then gently push the top part of the monitor into the cover. Pack the monitor in its box – slide it into the brown protective sleeve and then place it between the two foam sheets in the box. Put the cloth used to clean the monitor screen in the box with the monitor. Put the box in the storage cabinet.

Remove the "X" stand support from the back of the monitor stand. Pack the stand and the support in its box and put the box in the storage cabinet.

Place the keyboard and mouse in the mailbox on the wall or secure them to the top of the table with VELCRO® or tape.

Disconnect the ART cables from the switch box cables (Exhibit 2-82) and secure the ART cables in the cable station on the table. Disconnect the remaining switch box cables from the jack panel. Pack the switch box for transport and put it in one of the drawers in the cabinet outside the booth.

Exhibit 2-82. Disconnect the switchbox cables from the ART cables



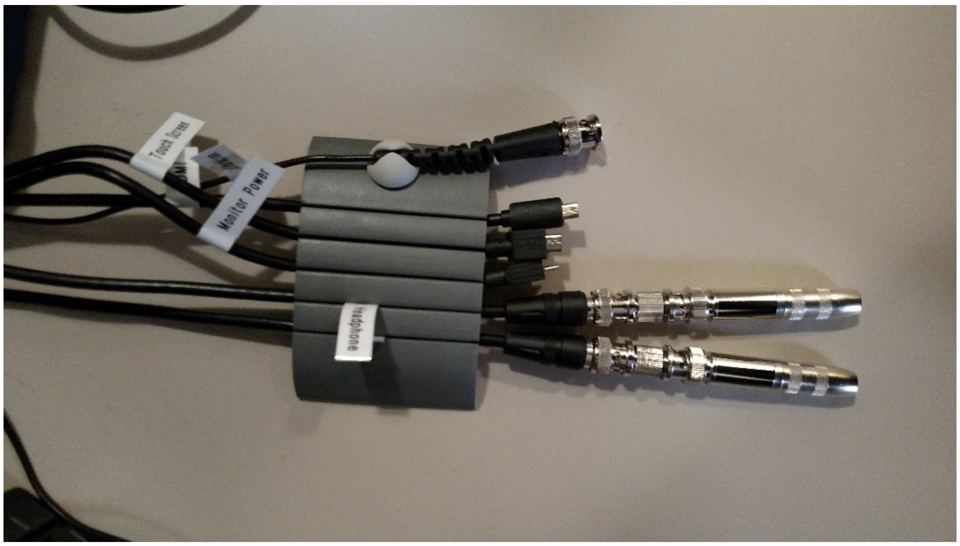
Disconnect the calibration cable from the jack panel and put it in the cable station on the table.

Unplug the patch cord from the ART response switch box and the jack panel. The ART response switch box can remain Velcroed to the table during transport. Put the patch cord in a ziploc bag and put it in one of the cabinet drawers.

Disconnect both sets of earphones and the response switch from the jack panel inside the booth. Pack the earphones, the response switch, and the patch cord securely in their box. Put the box in the storage cabinet.

Unplug the calibration cable from the jack panel outside the booth and put it in the cable station on the table (Exhibit 2-83).

Exhibit 2-83. Cords in cable station



Disconnect the power and sound cables from the back of the Sennheiser headphones charging tower. Secure them in the cable holder or tape them to the top of the table. Pack the Sennheiser headphones in a box and put them in the storage cabinet.

Remove the Vidpro Talk Forward microphone from the hook on the sound booth door. Pack it in its protective pouch or wrap it in bubble wrap. Tape the microphone securely to the top of the table.

Once all of the cords are disconnected and the equipment is packed, the desk and jack panel outside of the booth should appear approximately as shown in Exhibit 2-84.

Exhibit 2-84. Outside the sound booth prepared for transit

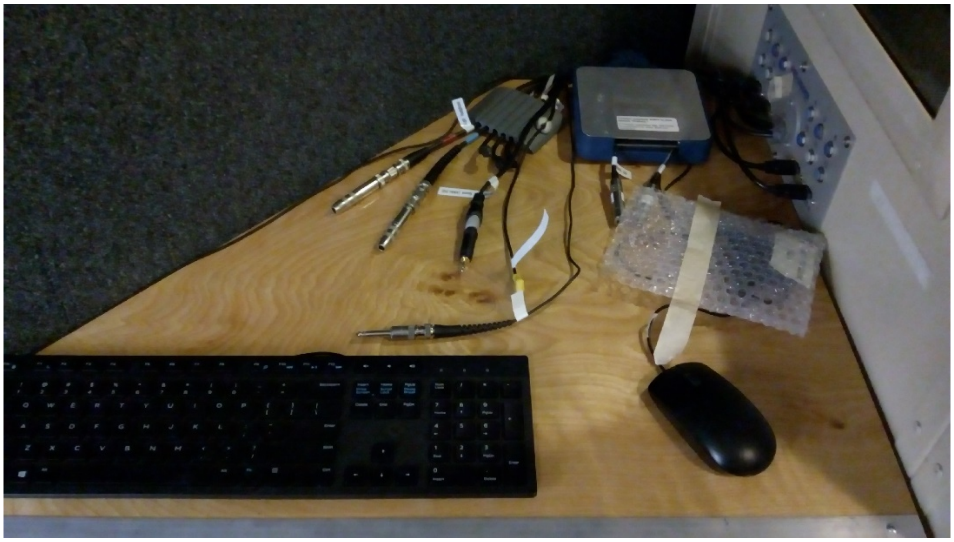


Exhibit 2-84. Outside the sound booth prepared for transit (continued)

Ensure that the ART chassis and ART computer are properly secured for transport.

Secure the wheelchair ramp outside the booth. Secure the outside cabinets and drawers with VELCRO® fasteners and a long board. Overturn the SP chair and technologist stool inside the sound booth and tightly close the doors to both the sound booth and the exam room.

2.8.3 Guidelines for Packing Audio Equipment

When packing equipment at the end of stand, or to ship out at other times (e.g., for annual calibration), each unit must be packed up **neatly** and **carefully** in its own packing box with **all necessary components** for that piece of equipment and **no additional components.**

Bioacoustic simulators can be shipped in any available box, with whatever secure packaging is available. Be certain to ship the microphone in its case, with the white protective cover over the mic. When shipping a bioacoustic simulator, components should include:

- Simulator;
- Microphone; and
- Pre-amp cable.

Titans should be shipped in their black zipper case, which can then be packed in any available box. With each middle ear analyzer, include the following components:

- Titan handheld unit and attached probe cable;
- USB computer cable;
- Calibration cavity; and
- Desiccant pillow.

Note: Do **NOT** send Titan charging cradle with the Titan when sending the Titan away from the MEC, **unless** the charging cradle needs repair. Also, keep the Titan wall charger and short mini USB adapter cable on the MEC unless these are specifically requested.

When an ART system needs to be shipped out, special cases for the chassis and the computer tower will be shipped to you. When packing the ART system, please follow the specific instructions provided in Appendix C. The following components should be included:

- Chassis;
- Computer tower;
- ART chassis-computer cable;

- Keyboard and mouse;
- Response switch box; and
- Massive 42-pin cable.

Note: Unless specifically requested, do NOT send any of the cables attached to the front of the chassis or the power cables for the chassis or computer tower; tape these cables to the top of the table or the chassis shelf as appropriate. Also, do NOT send SP earphones, health tech headphones, the earphone switch box, or the Talk Forward mic unless requested.

When shipping the ART system, you may or may not need to also ship the monitor. If you are shipping the monitor, please pack it in its box and include it in the special box sent for the computer tower. Just send the monitor itself (no cables), unless otherwise requested.

Earphones are handled separately from the ART audiometer, as any set of earphones can be used with any of the ART systems. When returning a set of earphones, they should be packed in their storage case and shipped in any available box. Please include:

- Standard headphones;
- Insert earphones;
- Response switch; and
- Patch cord.

Health tech headphones can be shipped in any available box, with any available packing materials. When shipping these headphones, include the following components:

- Headphones;
- Charging stand; and
- Power cord.

Note: Do **NOT** send the headphone sound input cable(s) unless specifically requested. Tape this cable to the top of the audiometry cable to secure it.

The calibration kit should be packed in its black case, which can then be packed in any available box. Be sure to remove the microphone from the coupler base and screw it into its plastic storage box for shipping. Please include the following items with the calibration kit:

- Microphone;
- Coupler base, pre-amp, and pre-amp cable;
- Standard headphone coupler;
- Insert earphone coupler; and
- Screw(s) for securing coupler base into the plastic calibration fixture.

Note: Do **NOT** send the plastic calibration fixture unless specifically requested OR unless you cannot remove the microphone from the coupler base. In the event you cannot remove the microphone, keep the coupler base in the calibration fixture (secured with at least one screw). Cover the microphone with bubble wrap, foam, or some other protective material to prevent damage during shipping.

Hearing Test Protocol 3

3.1 Eligibility Criteria

All study participants (SPs) aged 6-19 and 70+ years are eligible to participate in the audiometry component. Although a few screening questions are asked of the SP prior to testing, these are designed only to ascertain whether alternate test methods are necessary and to provide information that may assist with later analysis of the data. There are no precluding conditions for any part of the audiologic exam (otoscopy, middle ear testing, or audiometry). All three tests may be performed on all eligible, consenting SPs. SPs can refuse any part of the evaluation without affecting other components of the hearing test (for example, if an SP declines middle ear testing, he or she can still participate in threshold testing).

All testing in this protocol is done unaided (i.e., without the benefit of hearing aids, personal sound amplification devices, cochlear implants, or any other device the SP might ordinarily use for assistance in hearing).

3.2 Pre-Examination Procedures

3.2.1 Preliminary Activities

A few preliminary procedures should be accomplished before beginning an audiometry exam. If possible, complete these activities before bringing the SP to the Audiometry room:

- Wash your hands;
- Put fresh phone guards on the audiometric headphones; and
- Verify that the ventilation system and lights are turned on inside the audiometric booth. The lights outside the sound booth should be turned off while hearing testing is conducted in order to make it easier to observe the SP during the test.

When the coordinator assigns an SP to the audiometry component, introduce yourself and ask the SP to have a seat **inside** the sound booth; warn the SP to watch their step as they enter the booth.

Follow standard Integrated Survey Information System (ISIS) logon procedures. Click on the audiometry icon. Click on the logon SP button. Log on using your ID and password.

Each participant wears an identification bracelet with the participant's identification number bar-coded on it. Enter the participant's identification number into the ISIS system by "reading" the barcode with the wand. ISIS will automatically pull up the Identification screen for that SP. Verify that the SP's information is correct. Click "OK" to proceed with the examination.

Check to see if the SP is wearing hearing aids. If so, provide as much instruction/explanation as possible before asking the SP to remove his or her hearing aid(s) for the examination. Be aware that the SP may need to reinsert at least one hearing aid between various portions of the exam in order to hear instructions for the next segment.

Note: If an SP cannot remove his or her own hearing aid(s) (or is not accompanied by a family member or other person who can assist in removing the hearing aid[s]), the SP will skip the audiometry component. Close the exam and enter "Physical Limitation" as the reason the exam was not done.

Have the SP remove eyeglasses, chewing gum, earrings, hair ornaments, hats, or anything else that may interfere with your ability to manipulate the ear and/or properly place the audiometric headphones on the subject. These items may be placed on the table inside the sound booth during the test.

3.2.2 Pre-Exam Questionnaire

Prior to beginning the hearing examination procedures, the SP is asked a series of questions to identify conditions that may affect either how the test will be conducted or how the results will be interpreted. The wording of some of the questions has been simplified for children aged 6-11 years. Based on the SP's age, ISIS will load the screens with the appropriate questions for the SP you are testing.

Responses are entered directly into the computer (Exhibits 3-1 and 3-2). In most cases, responses are entered from drop-down menus.

Exhibit 3-1. Audiometry Interview (1) screen, SPs 12+

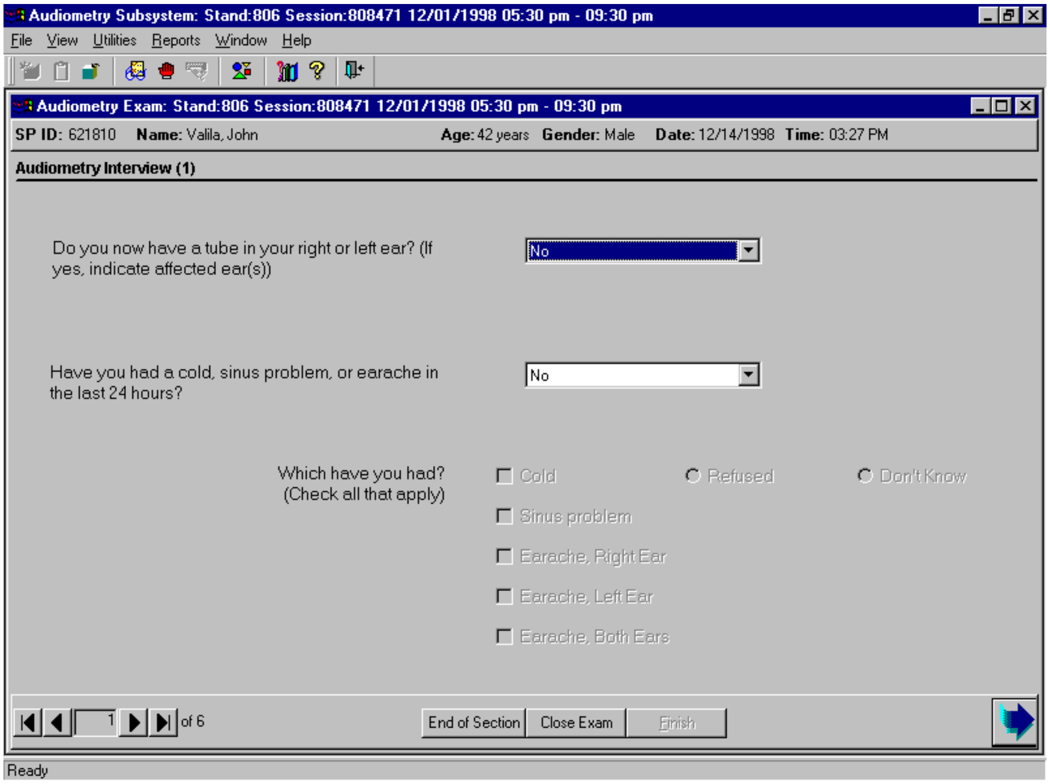
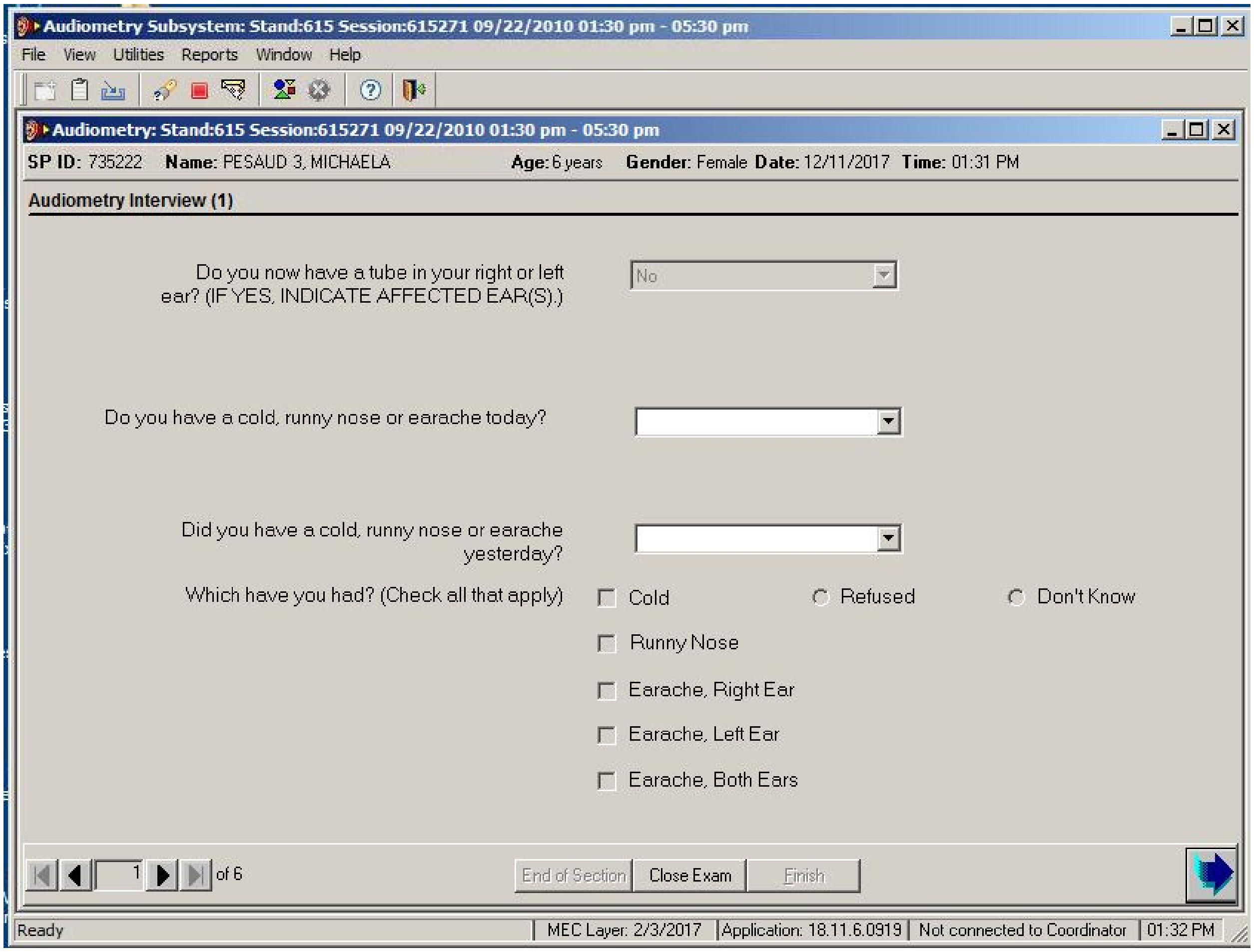


Exhibit 3-2. Audiometry Interview (1) screen, SPs 6-11



Be certain to ask the questions **exactly** as they appear on the screen. Do not omit or add anything. If the SP is unsure how to answer, use the explanations provided in this section to help the SP determine the answer. Listen carefully to the SP's responses, and make certain he or she is providing the information the question is seeking. If you think the SP has misunderstood the question, probe to clarify by repeating the question with a preface such as "Just to make sure I have this correct…"

Individual questions and guidelines for explaining them and coding the responses are provided below.

Question 1: Presence of Pressure Equalization Tubes (see Exhibits 3-1 and 3-2)

Adult (aged 12+ years) and Child (aged 6-11 years) versions are the same.

Do you now have a tube in your right or left ear? (If yes, indicate affected ear[s].)

Yes, right ear	No
Yes, left ear	Refused
Yes, both ears	Don't know

Pressure equalization (p.e.) tubes are frequently placed in the eardrums of persons who are prone to chronic ear infections. Although more common in children, they are also used in the adult population. If an SP reports the presence of a p.e. tube in one or both ears, you should expect to visualize it during otoscopy. It should appear as a round, plastic disk with an opening in the center. Additionally, you should expect a flat, high volume tympanogram and unusual wideband reflectance results during middle ear testing (see Section 3.4.3).

Parents of SPs aged 6-11 years answer this question during the Automated Proxy interview. The response from the Automated Proxy interview will appear in a read-only format on the Audiometry screen for these SPs (see Exhibit 3-2). You do not need to ask the question again.

Question 2: Upper Respiratory Issues in the Past 24 Hours (see Exhibits 3-1 and 3-2)

Adult (aged 12+ years) version:

Have you had a cold, sinus problem, or earache in the last 24 hours?

YES	REFUSED
NO	DON'T KNOW

(If Yes) Which have you had? (Check all that apply)

Cold	REFUSED
Sinus problem	DON'T KNOW
Earache, Right Ear	
Earache, Left Ear	
Earache, Both Ears	

Child (aged 6-11 years) version:

Do you have a cold, runny nose, or earache today?

YES	REFUSED
NO	DON'T KNOW

(If No, Refused, or Don't know) Did you have a cold, runny nose, or earache yesterday?

YES	REFUSED
NO	DON'T KNOW

(If Yes) Which have you had? (Check all that apply)

Cold	REFUSED
Sinus problem	DON'T KNOW
Earache, right ear	
Earache, left ear	
Earache, both ears	

A cold refers to a disorder of the upper respiratory tract. A sinus problem refers to an inflammation of the sinuses. Allergies are included if they have resulted in a reaction within the upper respiratory system or sinuses. If the SP is unsure if he or she has had either of these, probe for any of the following conditions: runny nose, stuffy head, slight temperature, chills, sinus headache, or sinus pain when pushed on or when bending over. **Focus on symptoms from the neck up.** If the SP has had any of these symptoms in the past 24 hours, record a positive answer.

An earache refers to any pain **within** the ear, regardless of severity. It does **not** include pain on the external ear.

Question 3: Noise Exposures in the Past 24 Hours (see Exhibits 3-3 and 3-4)

Adult (aged 12+ years) version:

In the past 24 hours, have you been exposed to noise so loud that you would have had to raise your voice to speak to someone an arm's length away?

YES	REFUSED
NO	DON'T KNOW

(If Yes) What time did the noise end?

|___|___|:|___|___|	REFUSED
	DON'T KNOW

Child (aged 6-11 years) version:

Have you listened to sounds today that were so loud you would have to shout so someone close by could hear you?

YES	REFUSED
NO	DON'T KNOW

(If No) Did you listen to any sounds that were that loud yesterday?

YES	REFUSED
NO	DON'T KNOW

(If Yes) What time did the noise end?

|___|___|:|___|___|	REFUSED
	DON'T KNOW

This question looks for exposure to sounds loud enough to cause a temporary hearing loss. Sounds are loud enough to cause a temporary shift in hearing if either (1) someone would have had to raise their voice to be heard 3 feet (an arm's length) away; **or** if (2) ringing in the ear was noticed after the noise ended. Record the response exactly as the SP provides it. If there is any question in determining whether or not an exposure counts as "loud," refer to the two rules of thumb. For reference, some examples are shown below:

Types of Sounds That DO Count	Types of Sounds That DO NOT Count
Very loud TV or radio	People yelling
Very loud music	Dogs barking
Sporting events	Recess
Motorbikes	School bells
Lawnmowers	Sounds that last less than 5 minutes
Firecrackers	(EXCEPT for firecrackers, gunfire, or
Gunfire	other "impulse" type noises)

If the SP indicates that he or she was exposed to loud noise, record what time the noise ended and select AM or PM from the dropdown box. The hour must be entered in two digits. For example, 3:00 must be entered 0300. You do not have to type the colon punctuation mark. If the SP cannot remember, encourage him or her to make the best estimate possible; only enter "DON'T KNOW" if the SP cannot make a guess after you have encouraged him or her to do so.

Exhibit 3-3. Audiometry Interview (2) screen, SPs 12+

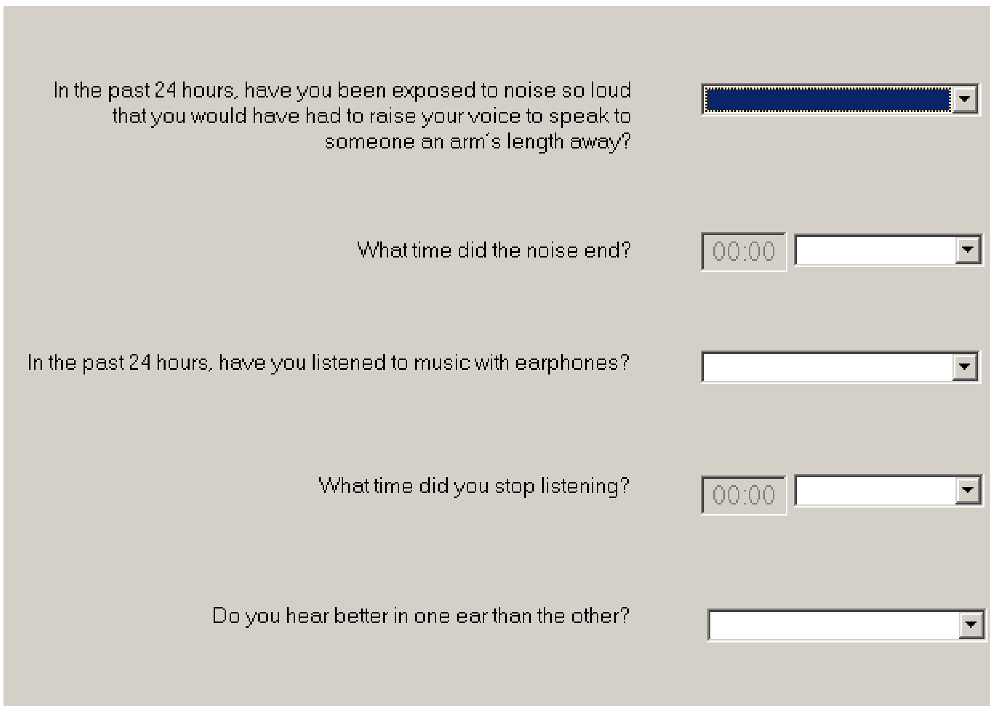


Exhibit 3-4. Audiometry Interview (2) screen, SPs 6-11

Question 4: Music with Earphones in the Past 24 Hours (see Exhibits 3-3 and 3-4)

Adult (aged 12+ years) version:

In the past 24 hours, have you listened to music with earphones?

YES	REFUSED
NO	DON'T KNOW

(If Yes) What time did you stop listening?

|___|___|:|___|___|	REFUSED
	DON'T KNOW

Child (aged 6-11 years) version:

Have you listened to music with earphones today?

YES	REFUSED
NO	DON'T KNOW

(If No) Did you listen to music with earphones yesterday?

YES	REFUSED
NO	DON'T KNOW

(If Yes) What time did you stop listening?

|___|___|:|___|___|	REFUSED
	DON'T KNOW

Any listening to music with earphones should be recorded as a positive response – regardless of whether the SP considers that the music was "loud." Listening to other sounds through headphones (for example, radio programs that are primarily speech [such as news programs or "talk radio"] or talking on the telephone through a headset) should be recorded as a negative response.

If the SP indicates that he or she listened to music with earphones, record what time he or she stopped listening to music with earphones and select AM or PM from the dropdown box. Some children, (especially those in the 6-11 age range) may not be able to report a time. If this is the case, ask questions to try to figure out the approximate time frame (for example, "Was it in the morning or the afternoon?" or "Was it before or after dinner?"). Once you have identified the time as best you can, enter it on the ISIS screen.

As with the noise exposure question, the hour must be entered in two digits. If the SP cannot remember, encourage him or her to make the best estimate possible; only enter "DON'T KNOW" if the SP cannot make a guess after you have encouraged him or her to do so.

Question 5: Hearing Symmetry (see Exhibits 3-3 and 3-4)

Adult (aged 12+ years) version:

Do you hear better in one ear than the other?

YES, RIGHT EAR	REFUSED
YES, LEFT EAR	NO/DON'T KNOW

Child (aged 6-11 years) version:

Is it easier for you to hear out of one ear than the other?

YES, RIGHT EAR	REFUSED
YES, LEFT EAR	NO/DON'T KNOW

When an SP indicates that they have a better ear, follow up by inquiring specifically which ear is **better.** There seems to be a tendency for people to report the ear that they think has trouble rather than the ear that they think is better. **Therefore, it is important to always verify that the SP is telling you which is the better ear. Always double check the SP's response by asking, "So, your left[right] ear is <u>better</u>?"**

Note that some children (and even some adults!) may have difficulty remembering left from right. It is fine for the SP to point to the ear that is better. Still confirm that the ear the SP indicates is the ear in which they hear **<u>better</u>.**

If an SP reports better hearing in one ear than the other, air conduction testing should begin in that ear. If the SP indicates that his or her hearing is about the same in both ears or doesn't know, then the first test ear will be alternated between SPs as described in Section 3.5.3.1.

When responses to all the questions have been entered, click the forward arrow on the navigation bar to advance to the Otoscopy screen.

3.3 Otoscopy

3.3.1 Purpose of Otoscopy

Otoscopy refers to the visual examination of the outer ear—including the auricle, ear canal, and eardrum. Otoscopy has two purposes in NHANES:

1. To identify abnormalities that may require alternate audiometric procedures or influence the results obtained; and

2. To identify conditions that may require medical referral.

It is important to note that otoscopy in the context of NHANES has only the two purposes noted above; it is **not** a diagnostic procedure.

3.3.2 Instrumentation for Otoscopy

As described briefly in Section 2.2.1, the otoscope is a small, hand-held instrument with a light that is directed through a funnel-like tip to illuminate the ear canal for examination. The funnel-like tip is called a "speculum." Directions for assembling the otoscope are given in Section 2.7.2.1. To turn the otoscope on, press the green button down and rotate the black ring clockwise. To turn it off, rotate the black ring counterclockwise until the green button pops back up.

3.3.3 Procedure for Otoscopy

Explain to the participant that you are "just going to take a quick look in his or her ear." For young children, it may be helpful to show them your "special flashlight" – even turning it off and on once so they can see that it is just a light. Then, generally inspect the auricle for skin changes or other gross abnormalities. While these conditions should not affect the results of the hearing test (unless they prevent proper placement of the headphones or cause such discomfort that the subject cannot tolerate the hearing test), they may warrant medical referral. If such a significant abnormality is noted, send an observation to the MEC physician.

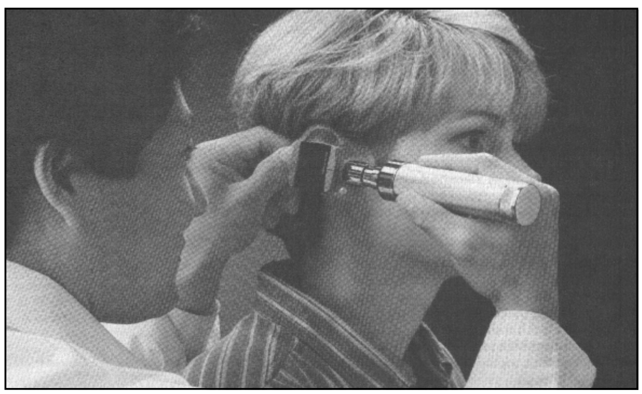
Begin with either ear. Select the proper size speculum. The pediatric size speculum will usually be the best fit for children aged 6-11 years; the adult size speculum will be appropriate for most subjects aged 12 and older. However, ear canal sizes vary widely. Use the largest speculum that will fit comfortably in the opening to the SP's ear canal; larger specula allow more light to enter the canal, making it easier to visualize the ear drum. Place the speculum on the otoscope and turn it on.

Hold the otoscope like a pen, between the thumb and index/middle fingers, having the speculum end of the scope where the writing tip of the pen would be (see Exhibit 3-5). Brace the hand holding the otoscope against the cheek or mastoid bone (behind the ear) of the SP—depending on which ear you are examining; bracing your hand will help prevent jabbing the wall of the ear canal if the participant moves suddenly. With your other hand, grasp the helix (upper portion) of the auricle and gently pull on it to straighten the ear canal. For younger children, you will typically need to pull down and back; for older children and adults, you will usually need to pull up and back.

Carefully insert the speculum just into the entrance of the ear canal and direct it toward the eardrum. The eardrum should appear pearly gray in color. Look closely for any evidence of perforation, inflammation (redness), drainage or discharge, presence of a p.e. tube, small objects in the canal, etc. Move the otoscope around slightly to examine the canal walls for any evidence of irritation or swelling.

Exhibit 3-5 presents the proper method of holding the otoscope during otoscopy (from Suter, A.H. *Hearing Conservation Manual*, 3rd Edition. Council for Accreditation in Occupational Hearing Conservation, Milwaukee, 1993).

Exhibit 3-5. Proper method of holding otoscope



Look also for excessive cerumen (earwax). Most people have some amount of wax in their ear canals, and this is normal. Even an excessive amount of wax (such that less than half the eardrum is visible) will not have too great an effect on the audiometric thresholds; it will, however, preclude the use of insert earphones. If there is so much earwax that no part of the eardrum can be visualized at all, the ear is said to be "impacted" with cerumen; this condition can cause a significant reduction in hearing thresholds, and also precludes the use of insert earphones.

Make a mental note of the size and direction of the ear canal; this information will be important when you are conducting the middle ear tests.

Remove the otoscope from the ear. On each ear, gently press the auricle against the mastoid bone behind the ear using your index and middle fingers in the form of a "V" (see Exhibit 3-6), imitating the pressure that will be caused by the headphone when it is placed on the ear. Direct the light of the otoscope toward the opening of the ear canal and look for any sign of "canal collapse"; that is, a closing off of the entrance to the ear canal. This problem is more common among the elderly; however, canal collapse can be present in any individual. It is particularly likely in persons who have small ear canals or whose pinna feels "soft" when you pull on the outer ear. Collapsed canals can cause elevated thresholds because the test signals cannot enter the ear canal effectively. When this condition is noted, the participant should be tested with insert earphones rather than headphones, provided there are no precluding conditions for the use of inserts. (See Section 3.5.3.1 for instructions.)

Exhibit 3-6. Checking for collapsed ear canal

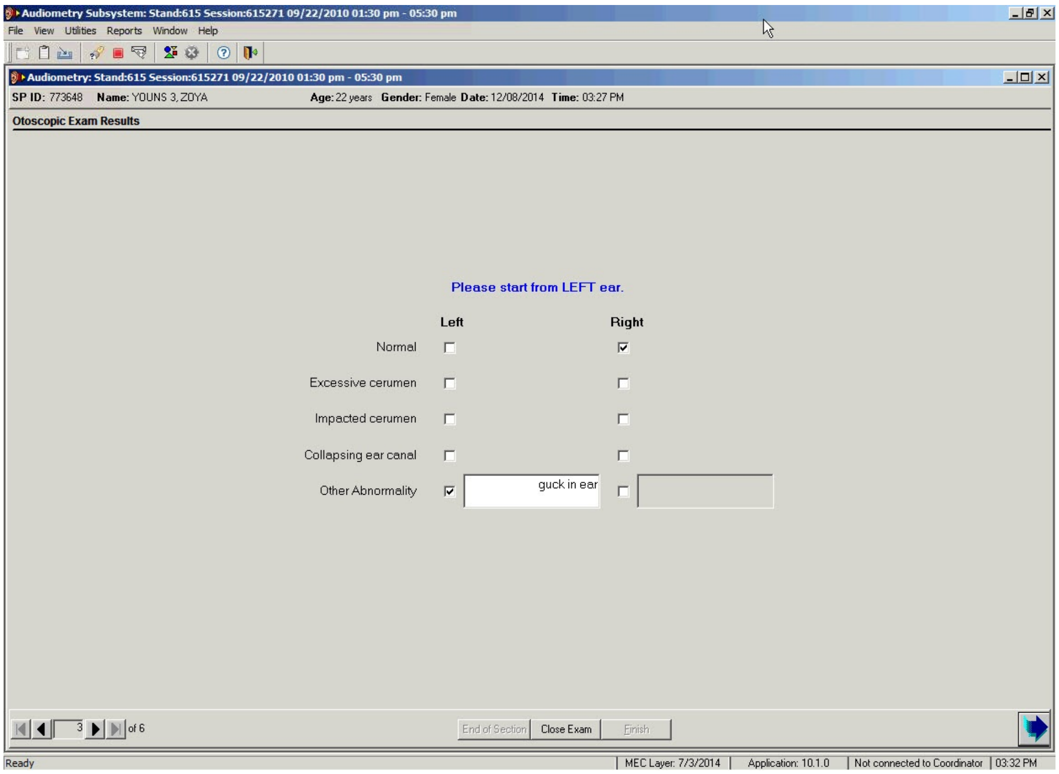
Record the results in the ISIS program as described in Section 3.3.4. Repeat the examination in the other ear and record the results in ISIS. Remove the speculum from the otoscope and throw it away.

Note: Be very careful not to make any mention to the SP of what you observe in otoscopy, as you are not conducting this check for diagnostic purposes. If the SP inquiries about the otoscopic results, simply say that you are only checking to see which earphones to use.

3.3.4 Recording Results of Otoscopy

The Otoscopy Exam Results screen (Exhibit 3-7) presents a list of possible outcomes and corresponding check boxes for each ear. ISIS defaults to "normal" for both ears. If otoscopy is not normal in one or both ears, simply record the results by clicking in the appropriate box(es) as described below. A checkmark will appear in the box(es) you select. If you make an error, simply click in the same box again, and the checkmark will be removed.

Exhibit 3-7. Otoscopy Exam Results screen

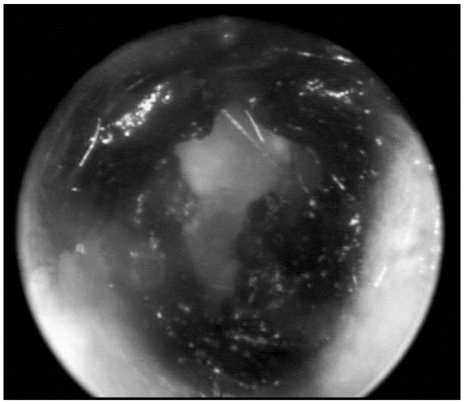


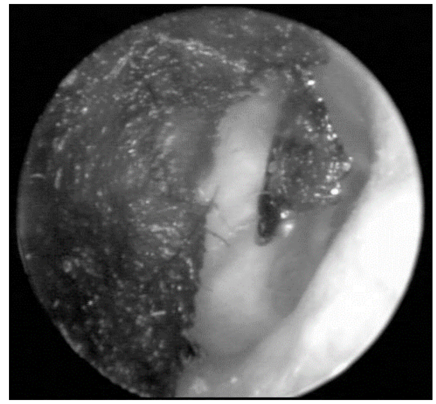
Note: On this screen and all subsequent screens, results for the left ear are always recorded in the left column and results for the right ear are always recorded in the right column, regardless of which ear is evaluated first.

- **Normal.** At least half the eardrum can be clearly visualized, and it appears pearly gray in color. No other abnormalities are noted. A "normal" result excludes any other result in that ear, **except** for collapsed canals.

- **Excessive Cerumen (Exhibit 3-8).** Significant accumulation of earwax in canal, such that view of the eardrum is partially (but not completely) blocked. If less than half the tympanic membrane is visible due to wax, it is considered excessive. This condition precludes the use of insert earphones during audiometry.

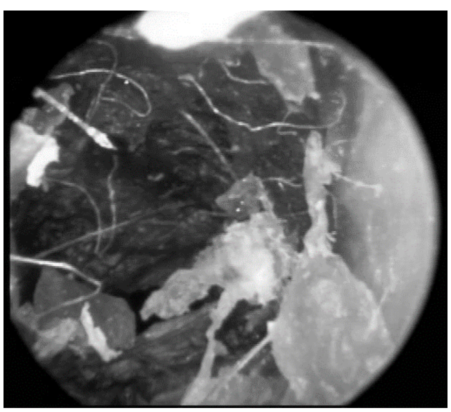
Exhibit 3-8. Examples of excessive cerumen during otoscopy (From Sullivan, R.F. *Audiology Forum: Video Otoscopy*)

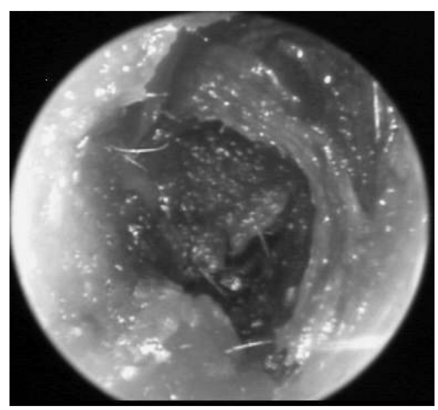




Impacted cerumen (Exhibit 3-9)—Even greater accumulation of earwax in the ear canal, such that no part of the eardrum can be visualized. This condition precludes the use of insert earphones during audiometry. In addition, SPs with impacted cerumen should be seen by the MEC physician for examination and possible referral. **Note:** Excessive cerumen and impacted cerumen cannot both be recorded in the same ear. If you try to mark one after the other has already been marked, the first result will be deleted. If you **can see any part** of the eardrum, record the result as "excessive cerumen." If you **cannot see any part** of the eardrum, record "impacted cerumen" as the finding.

Exhibit 3-9. Examples of impacted cerumen during otoscopy (From Sullivan R.F. *Audiology Forum: Video Otoscopy*)





- **Other Abnormality (Describe).** Any other observation that does not appear normal (Exhibit 3-10). This could include drainage (fluid) in the ear canal; blood; a foreign body (e.g., bugs, cotton, a p.e. tube that has ejected itself from the eardrum, etc.); a perforation in the eardrum; a growth in the ear canal; significant skin abnormalities; or anything else that you feel may be cause for concern. Describe the abnormality briefly in the field provided. This finding precludes the use of insert earphones. In addition, SPs with abnormalities should be referred to the MEC physician.

Exhibit 3-10. Examples of other findings during otoscopy

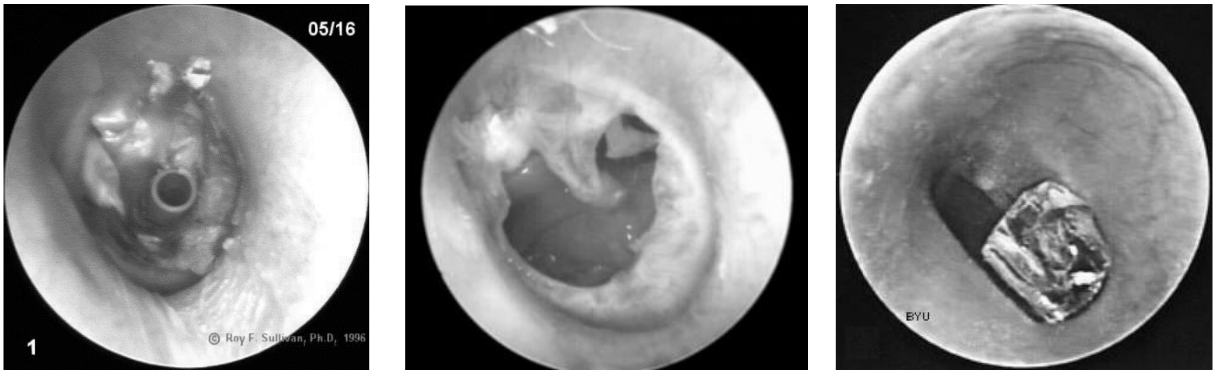
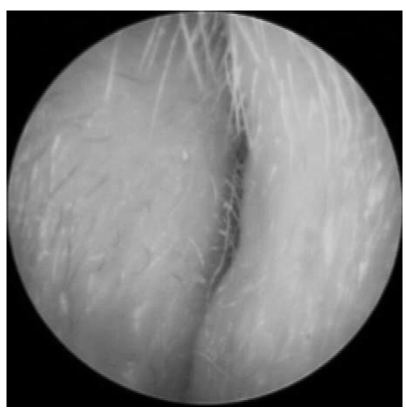


Illustration 1 shows a p.e. tube placed in the eardrum. Illustration 2 (center) depicts a large perforation in the eardrum; the entire center portion of the membrane is missing. Illustration 3 (right) shows a small piece of glass lodged in the ear canal. (From Sullivan, R.F. *Audiology Forum: Video Otoscopy.)*

- **Potential canal wall collapse (Exhibit 3-11).** This condition requires the use of insert earphones during audiometry, provided no other conditions preclude their use.

Exhibit 3-11. Example of a collapsed ear canal (From Sullivan, R.F. *Audiology Forum: Video Otoscopy*)

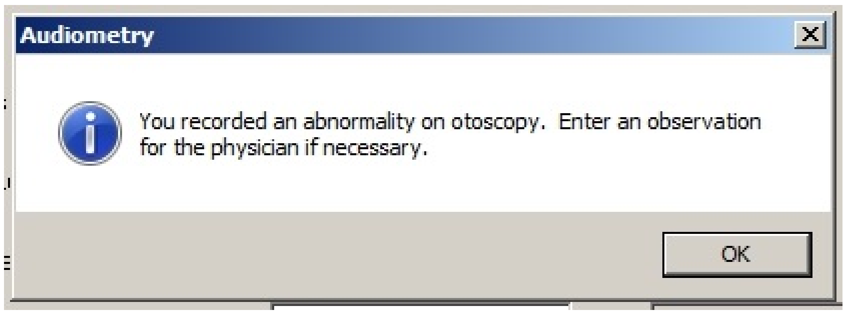


3.3.5 Referral

SPs who have impacted cerumen and/or other abnormalities in at least one ear should be referred to the MEC physician. Observations to the physician are not sent automatically, and the physician cannot see any comments you may have entered on the Otoscopy screen. You must re-enter the finding using the standard physician observation procedures within ISIS.

If "impacted cerumen" or "other abnormality" is checked for the left or right ear on the Otoscopy Exam screen, you will receive a pop-up reminder to send the observation (Exhibit 3-12) when advancing from the Otoscopy screen to the Tympanometry screen.

Exhibit 3-12. Physician Observation Reminder message



You may enter the observation right away or at any time before completing the exam.

When you have completed otoscopy in both ears (and sent any necessary observations to the physician), click the forward arrow on the navigation bar to advance to the Middle Ear Testing screen.

3.4 Middle Ear Testing

3.4.1 Purpose of Middle Ear Testing

Middle ear testing, sometimes called acoustic immittance, is a collective term which refers to measurements of eardrum compliance. From such measures, we can make inferences about the health of the middle ear system—including the eardrum, the three ossicles, the Eustachian tube, and the two middle ear muscles. Note that middle ear testing evaluates the physiological status of the middle ear; that is, whether or not it is working as it should. While these tests can point out problems with how the ear is functioning—which of course may impact hearing sensitivity—they do not directly indicate how well a person can hear. A person can have normal middle ear function and yet be completely deaf.

The hearing examination in NHANES includes three middle ear tests: tympanometry, wideband reflectance (WBR), and acoustic reflex threshold screening. Both tympanometry and WBR measure the movement of the eardrum. Tympanometry measures how much sound is delivered through the middle ear system at a single frequency (226 Hz) across a range of pressures. WBR measures how much sound is transferred through the middle ear across a range of frequencies at a single pressure (ambient air pressure). Both tests are conducted by placing a probe with a rubber tip into the entrance of the ear canal, playing calibrated signals (a 226 Hz tone for tympanometry and broadband clicks for WBR) into the canal, and measuring how much sound bounces back. Because tympanometry involves varying the pressure in the ear canal, it requires that the rubber tip form an airtight seal. Because WBR makes measures just at the background room air pressure, it does not require an airtight seal. However, the rubber tip blocks out room noise and keeps a certain amount of air in the ear canal.

The acoustic reflex is an involuntary contraction of the two muscles in the middle ear—the stapedius and the tensor tympani—in response to loud sounds. When these muscles contract, the ossicles pull the eardrum slightly back; the middle ear system "stiffens up" and sound is not transmitted as efficiently. This affords the sensitive inner ear a small bit of protection against potentially damaging sounds. The acoustic reflex is tested by sending a brief tone into the middle ear loud enough to elicit the reflex, and looking for a resultant change in eardrum mobility as the muscles contract and pull back on the eardrum. Acoustic reflex test results are useful in clarifying questionable tympanograms, verifying degree of hearing loss, and distinguishing between sensorineural hearing losses caused by damage to the cochlea versus the auditory nerve.

All three middle ear tests have the advantage of being objective, meaning that they do not require any response or feedback from the SP. The equipment for these tests is automated; once the probe is correctly placed in the ear, it performs the tests and records the results without any further intervention from the tester.

3.4.2 Instrumentation for Middle Ear Testing

The Interacoustics Titan, which was described briefly in Section 2.2.2, will be used to conduct middle ear testing. The Titan consists of the "hand-held" unit (though you will not be holding it in your hands to run the test) with a long cable and a probe. The probe contains three tiny openings – one of these openings sends air pressure into the ear canal, one delivers the test signals (tones or clicks) to the ear, and one contains a microphone to measure the amount of the signal that is reflected from the eardrum. The end of the probe is fitted with rubber tips of various sizes, which are used to seal off the entrance to the ear canal in order to block out background noise and control the air pressure in the canal when needed. The Titan Suite software that runs the middle ear tests interprets the amount of sound reflected from the eardrum and converts it to a measure of the stiffness of the eardrum.

Between the handheld unit and the probe is the "shoulder box" (see Exhibit 3-13). On the back of the shoulder box is a clip that can be clipped to the SP's clothing to help keep the probe in place. On the side of the shoulder box is a "Control" button that can be used to send commands to the Titan system.

Exhibit 3-13. Titan shoulder box and Control button

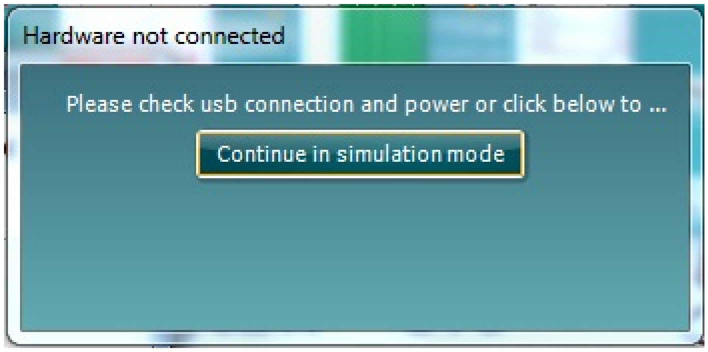
3.4.3 Procedure for Middle Ear Testing

3.4.3.1 Opening Titan Suite and Operating the Titan

When you advance to the Middle Ear Testing screen by clicking on the "Forward arrow" button after otoscopy, ISIS will automatically launch the Titan Suite software. ISIS will remain running in the background. You will be able to switch back and forth between ISIS and Titan Suite if necessary by clicking the appropriate buttons on the task bar.

If you have not used the Titan for some time, you may also receive a pop-up window on top of the opening screen with the following message (see Exhibit 3-14).

Exhibit 3-14. Hardware Not Connected message box



This usually indicates that the Titan is in "sleep" mode. Press the R or L button (see Exhibit 3-15) on the handheld unit to re-activate the Titan and the message window will close automatically. You will not be able to proceed in Titan Suite until this message disappears.

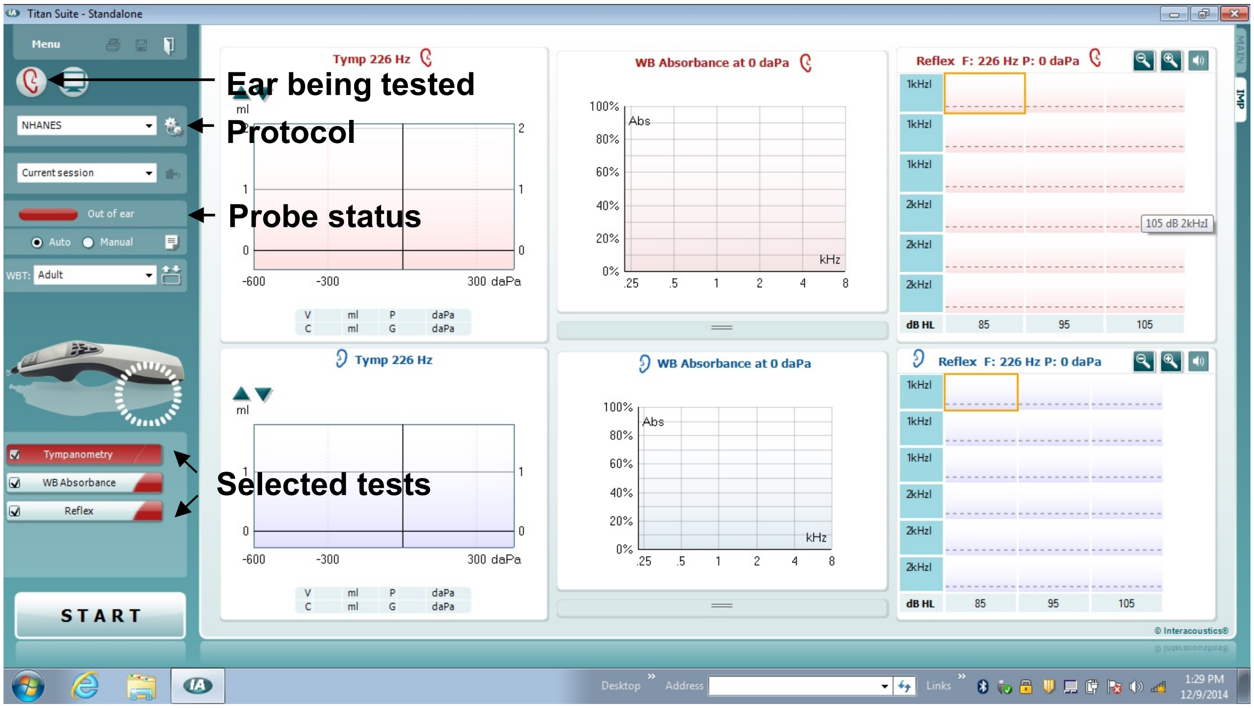
Exhibit 3-15. R and L buttons on the Titan handheld unit

The Titan Suite software will open to the window shown in Exhibit 3-16. Click the IMP tab in the upper right corner of the Titan Suite window to open the NHANES Middle Ear Testing screen.

Exhibit 3-16. Opening Titan Suite screen. Click IMP (as shown by the arrow) to proceed

Once you have clicked the IMP tab, Titan Suite will open the NHANES Testing screen (see Exhibit 3-17).

Exhibit 3-17. NHANES Middle Ear Testing screen



The left panel of the Titan Suite screen indicates the following, as shown by the captions above:

- The ear selected for testing (a red ear icon indicates the right ear; a blue ear icon indicates the left ear);
- The selected test protocol (this should always read "NHANES");
- The probe status (the probe is "out of ear" in the example above); and
- The tests in the protocol that will be run (indicated by checked boxes).

The main panel of the Titan Suite screen shows the test results for the right (top) and left (bottom) ears. (There are no results displayed on the screen shown above.)

You can begin the middle ear tests with either ear. The Titan Suite defaults to testing the right ear first. You can select a different test ear in any of the following ways:

- Press the R or L button on the handheld unit.
- Click the ear icon in the top left corner of the Titan Suite screen (the selection will toggle back and forth between the right and left ear).
- Press the "Control" button on the shoulder box.

Note: The "Control" button method only works if the probe is out of the ear. If the probe is in the ear, the "Control" button starts and stops the test.

If everything functions normally, the Titan Suite will close between each SP, and any data for that SP will be deleted from the Titan software (it will have been saved in a separate location). Therefore, the Titan Suite should always open to a blank Results screen. **If there is any data from a previous SP in the Titan Suite window when you start a new test, notify the ISIS staff before proceeding with the middle ear tests.**

3.4.3.2 Instructions and Probe Placement

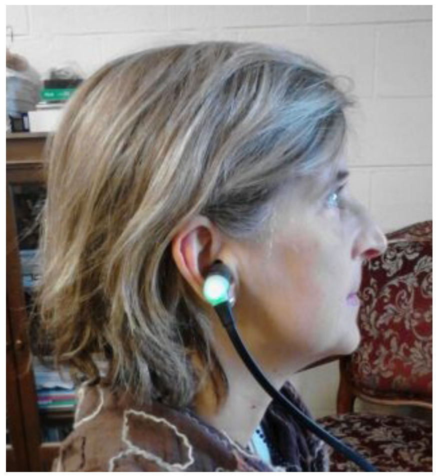
When you are ready to begin middle ear testing, explain the procedure to the SP. You may use your own words, but please include all the points in the sample instructions below:

> **Instructions for Adults and Older Children.** "This is a test to measure how well your eardrum is able to move. It is a completely automatic test, so you will not need to respond in any way. I am going to place a probe snugly into the opening of your ear canal. You will hear a continuous "hum" and feel a little pressure; then you will hear some clicks and several loud beeps. The test will only take about 30 seconds. It is important that you sit very still, and try not to move, speak, or swallow from the time I insert the probe until I tell you the test is finished. Do you have any questions?"
>
> **Instructions for Younger Children.** "This test takes a little picture of how well your eardrum moves. It is completely automatic, so all you have to do is sit very still. I am going to put this button right up against your ear. You will hear a humming sound and some clicks and then some loud beeps. You might feel a little puff of air. It may feel a little funny – like your ears are going to pop – but it won't hurt. The test will only take a few seconds. Again, all you have to do is sit still while the machine takes the picture. Do you have any questions?"

Select a disposable rubber Titan tip of the appropriate size to seal off the entrance to the ear canal, keeping in mind the size of the ear canal, which you noted during otoscopy. **Note that bigger is not always better!** It is just as difficult to obtain a good seal with a tip that is too large as it is with a tip that is too small. Slide the tip onto the probe, making sure that the base of the tip goes all the way down. If you like, clip the shoulder box to the SP's clothing.

Move away any hair or other items (e.g., hats, hair ornaments) from the ear. For best results, position yourself at eye level with the SP's ear canal. With your nondominant hand, gently pull the auricle up and back (down and back for younger children) slightly to straighten out the ear canal. With your dominant hand, place the Titan probe gently into the entrance of the ear canal (see Exhibit 3-18). If you have an appropriately sized tip, the probe should stay in place without having to hold it there; however, it is OK to hold the probe during the test as long as you keep it very still.

Exhibit 3-18. Correct placement of the Titan probe



The Titan probe lights will help you know whether you have placed the probe correctly (you can also refer to the probe status indicator on the left panel of the Titan Suite screen). Whenever the handheld unit is active (i.e., the Titan has not reverted to "sleep" mode), the probe will be lit with one of the following colors:

- **Red Light.** The right ear is selected, but the probe is either out of the ear or not sufficiently inserted into the ear to conduct the test.
- **Blue Light.** The left ear is selected, but the probe is either out of the ear or not sufficiently inserted into the ear to conduct the test.
- **Green Light.** The probe is inserted into the ear canal and the Titan is ready to conduct the test. **Note that a green light does not necessarily mean an airtight seal has been obtained.** You may have a sufficient fit for WBR but not for tympanometry.
- **Yellow Light.** The probe tip is blocked or leaking. This could indicate that the probe is directed toward the wall of the ear canal rather than toward the eardrum; that the probe itself is blocked by cerumen or other debris, or that the seal has been lost.

  If the yellow light changes to red or blue when you remove the probe from the ear, the problem is with probe fit or direction. Re-insert the probe into the ear canal, making sure to direct it toward the eardrum; you may need to re-examine the ear with the otoscope to assist in properly directing the probe.

If the yellow light remains lit when the probe is removed from the ear canal, the probe itself is blocked. Clean the probe tip as described in Section 2.7.3.2.

- **White Light (Solid).** The probe status is unknown.
- **White Light (Flashing).** The Titan has finished the current test. If another test is programmed to run automatically, the Titan will immediately proceed to conduct the next test. If no further tests are programmed, the probe can be removed from the ear.

3.4.3.3 Running and Evaluating the Middle Ear Tests

Confirm that all three middle ear tests (tympanometry, WBR, and acoustic reflex thresholds) are selected (checked) on the left panel of the Titan Suite screen. Start the test in one of the following ways:

- Press the space bar on the computer keyboard;
- Click the START button in the lower left corner of the Titan Suite screen; or
- Press the “Control” button on the shoulder box.

Note: The “Control” button method only works if the probe is in the ear. If the probe is not in the ear, the “Control” button changes the selected test ear (left or right). Also note that the Titan determines whether or not the probe is in the ear… although the probe may be in the ear from your perspective, if the Titan doesn’t detect the probe placement, the “Control” button will change test ears. Therefore, **always check that the Titan is set for the ear you expect just before starting the test.**

The Titan will run each test automatically. Results will be displayed on the Titan Suite screen as they are obtained. Tympanometry is conducted first. Recall that tympanometry requires an airtight seal. If the seal is sufficient, the sliding arrow at the bottom of the tympanometry display (on the Titan Suite screen) will slide all the way to the right, and then slide back to the left as the graph is traced on the screen. If the seal is not airtight, the sliding arrow will pause and hover on the way to the right, indicating that the system cannot build up sufficient pressure.

If you do not have a seal, adjust the probe. Note that (as you have started the test sequence) Titan will run the tympanogram as soon as a seal is obtained. If you are still moving the probe at that point, the result will be noisy. Alternatively, you can press the “Control” button or space bar to stop the test while you re-seat the probe, and then begin the test again.

When tympanometry has been completed in the first test ear, the Titan will proceed automatically to WBR. As WBR does not require an airtight seal, a probe that was successfully placed for tympanometry will nearly always be appropriately placed for WBR. The WBR test involves averaging results for several seconds. You will notice the results "jump around" a bit on the Titan Suite screen while the test is running. When the WBR graph stops moving, the test is finished.

When WBR has been completed, the Titan will begin the acoustic reflex screening. The Titan will test for an acoustic reflex six times in each ear – at 85 dB, 95 dB, and 105 dB at the 1000 Hz level and 2000 Hz level. As each stimulus is delivered, the Titan will display a tiny graph on the reflex grid. If the Titan believes a reflex was measured, the graph for that stimulus will have a green background. When all six frequency/intensity combinations have been tested, the middle ear test is complete. A sample results screen is shown in Exhibit 3-19.

Exhibit 3-19. Sample Titan Suite screen showing a completed test in the right ear

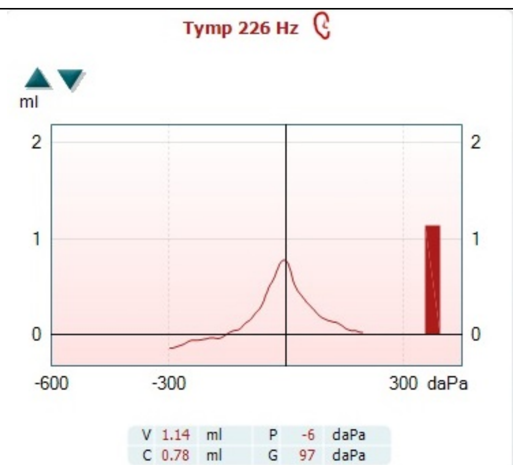
Check the results displayed on the screen. Tympanometry results will include a graphed curve and numbers in four fields below the graph. The numbers indicate the following:

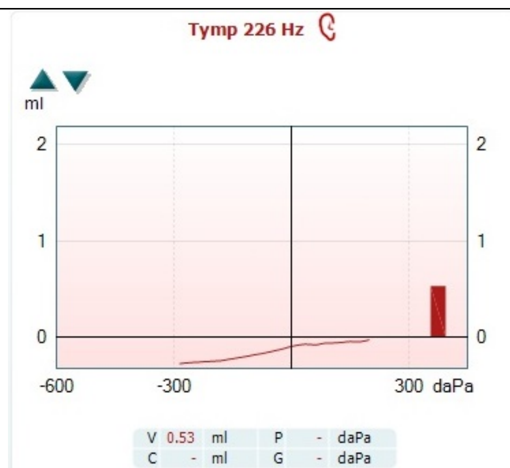
- V: the volume of the ear canal in milliliters (ml);
- C: the compliance, or flexibility, of the eardrum;
- P: the air pressure in the middle ear space in decaPascals (daPa); and
- G: the gradient, or width of the curve at half its height.

You do not need to evaluate the meaning of the numbers; only confirm that they are there. If the V value is missing, you should rerun the test. Do not rerun the test if any of the other values are missing.

You do need to judge the adequacy of the tympanometric curve. Tympanograms should be evaluated on the basis of smoothness and symmetry. A normal tympanogram will have a peak located near the vertical line near the center of the graph. However, the peak may occur in other places if the SP has an early or resolving infection. In some cases, the tympanogram will be flat, with no peak evident at all. Such cases include people who have impacted cerumen, perforated eardrums, or p.e. tubes. As long as the results are clear and consistent, abnormality is not a reason to reject a tympanogram. Examples of good and poor tympanograms are shown in Exhibit 3-20.

Exhibit 3-20. Examples of good, questionable, and poor tympanograms

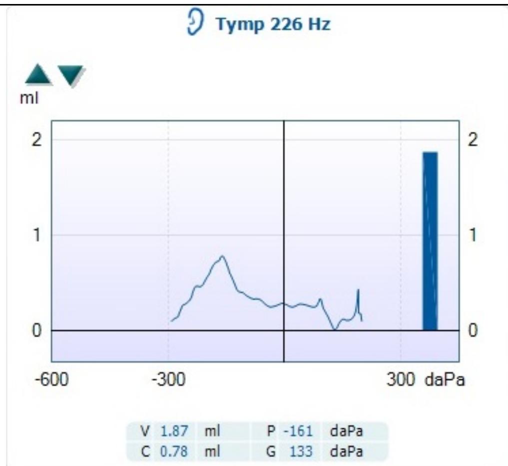


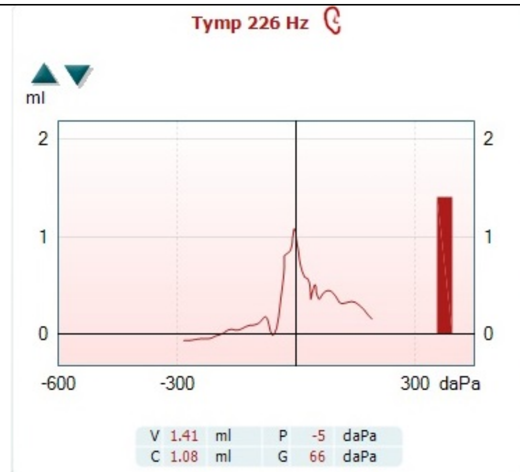


The left tympanogram is good; it is smooth and symmetrical.

The right tympanogram is questionable; it may be a valid flat tympanogram or it may be the result of a technical error; it should be rerun to verify.

Exhibit 3-20. Examples of good, questionable, and poor tympanograms (continued)





The two results are "noisy" and should be redone.

Wideband reflectance results include only a graph. It should also be evaluated for adequacy. WBR graphs may take many shapes. A good graph will have at least some part of the curve above the 60 percent point on the vertical axis and will cross this axis below 40 percent. Examples of good and poor WBR results are provided in Exhibit 3-21.

Exhibit 3-21. Examples of good, questionable, and poor WBR results

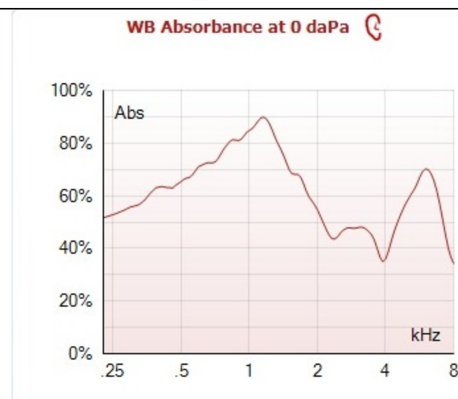
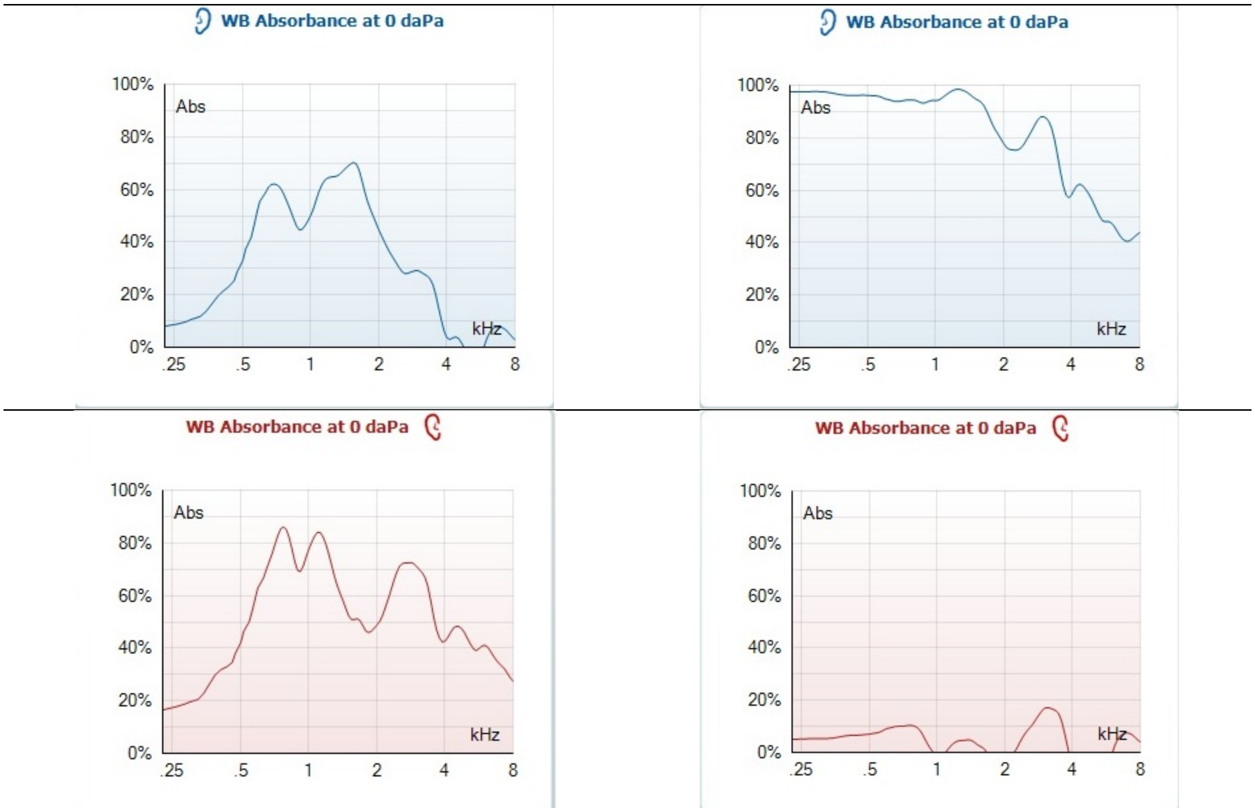


Exhibit 3-21. Examples of good, questionable, and poor WBR results (continued)



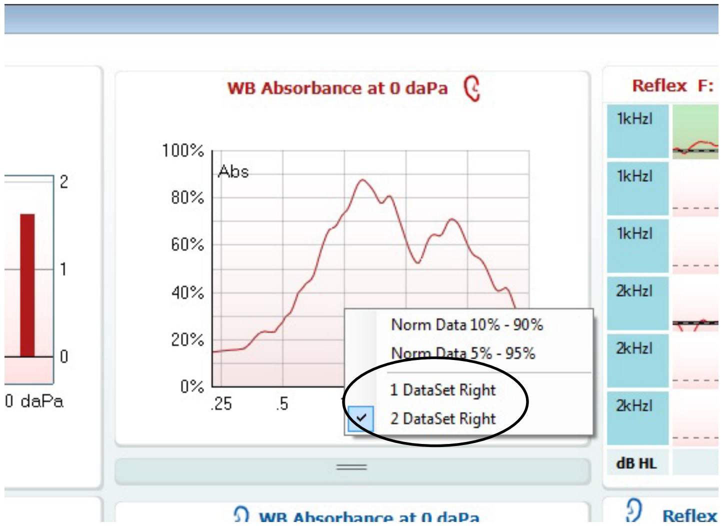
The three graphs on the left are good; each of them have part of the graph that exceeds 60 percent and they all cross the vertical axis below 40 percent.

The three graphs on the right are questionable or poor. The top and middle graphs cross the vertical axis above the 40 percent point; the bottom graph does not have any part that exceeds 60 percent.

Verify that the acoustic reflex results are displayed for each of the six test stimuli. You do not need to evaluate the acoustic reflex results in any way; simply confirm that they have been obtained.

If either the tympanogram or the WBR are unacceptable, or if all or part of the acoustic reflex results are missing, rerun that test once to try to obtain a better result (or, at least, to confirm the poor result). Check the box(es) in the lower left corner of the Titan Suite screen to select the test(s) that you want to rerun (by default, Titan only selects the last test run). Re-seat the probe in the SP's ear, then start the test as before. Titan Suite will display the second set of results, but the results of the first test are not overwritten. You can select whether to save the first or second result of each middle ear test by right-clicking on the graph of the result and selecting Data Set 1 or 2 in the pop-up window, as illustrated in Exhibit 3-22. You can toggle back and forth between the results if needed to select the better result. Only the result that is displayed on the Titan Suite screen when you save the data will be saved.

Exhibit 3-22. Pop-up window allowing the display of the first or second test results



Regardless of the results of the second trial, move on to the next ear. To keep the test time within specified limits, middle ear testing will not be repeated more than once in each ear.

Note: If you cannot obtain an airtight seal for tympanometry for a particular ear, de-select the tympanometry test in the lower left corner of the Titan Suite screen and just run WBR on that ear.

When you have completed testing the first ear, select the next test ear as described earlier. **Note that the Titan Suite software cannot catch a mistake if you accidentally select the wrong test ear.** If you forget to select a new test ear, the Titan will replace your results from the first ear with the results from the second ear (you can go back and select the results for the correct ear by right-clicking each graph as described above). Also, if you are supposed to test the right ear and you correctly set the Titan for testing the right ear but inadvertently put the probe in the left ear, the software cannot catch this (and you cannot correct this in the field; if you accidentally test the ears in reverse, submit a back-end edit request to reverse the results in the data set). **Always double-check that you have selected the correct ear and that you are testing the ear you selected.**

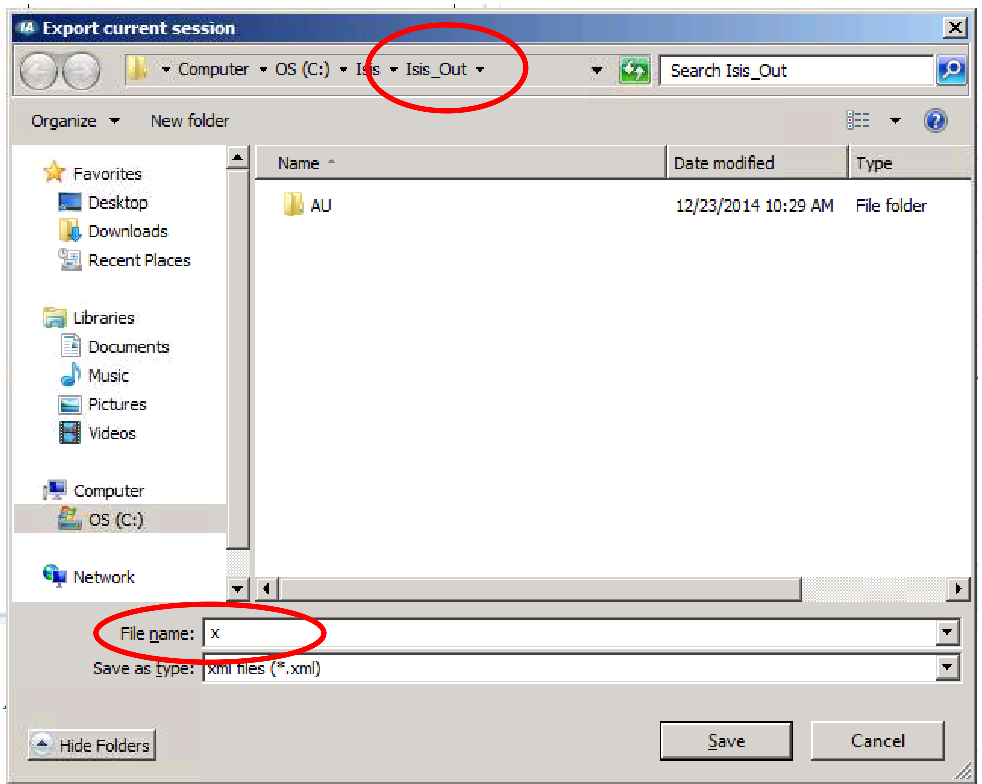
Place the probe in the other ear (you will probably need to move the shoulder box as well, if you are clipping it to the SP's clothing). Often, you will be able to use the same probe tip in both ears; however, some SPs will require a different size tip in each ear. Also, if the tip becomes contaminated with wax, drainage, or any other substance while testing the first ear, change to a clean tip before testing the next ear. Run the tests in the second ear, evaluate the graphs, and repeat any poor or questionable results once. The Titan Suite screen should now show complete results for both ears, as shown in Exhibit 3-23:

Exhibit 3-23. Completed middle ear test results in both ears

3.4.4 Recording Results of Middle Ear Testing

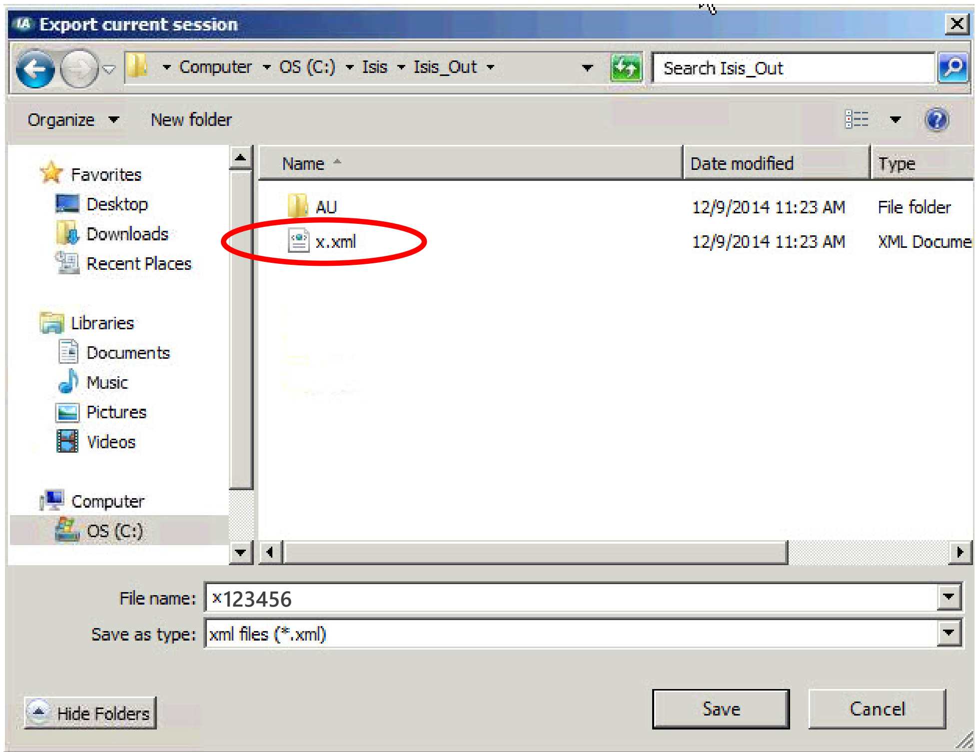
After both ears have been tested, press ALT-M, ALT-E, ALT-X (think "ALT-<u>MEX</u>") to save the Titan results. The Titan Export window will pop up. Confirm that the path at the top of the window indicates the ISIS_Out folder, as shown in Exhibit 3-24. Also check that the only item in this folder is a folder called "AU." Type "x" for the file name and click SAVE.

Exhibit 3-24. ISIS_Out folder



Note: When you close the ISIS application at the end of the hearing test, ISIS will find the x.xml file and move it to another location with a specific file name that identifies the result with that SP. Therefore, when you save the Titan results for the next SP, there should no longer be an x.xml file in the ISIS_Out folder. If you ever find a previous x.xml file in the ISIS_Out folder when saving an SP's results, do not overwrite it! Instead, name the file you are saving with the current SP ID (for example, "123456" instead of "x," as shown in Exhibit 3-25) and notify the ISIS staff as soon as possible.

Exhibit 3-25. ISIS_Out folder when an x.xml file is already present

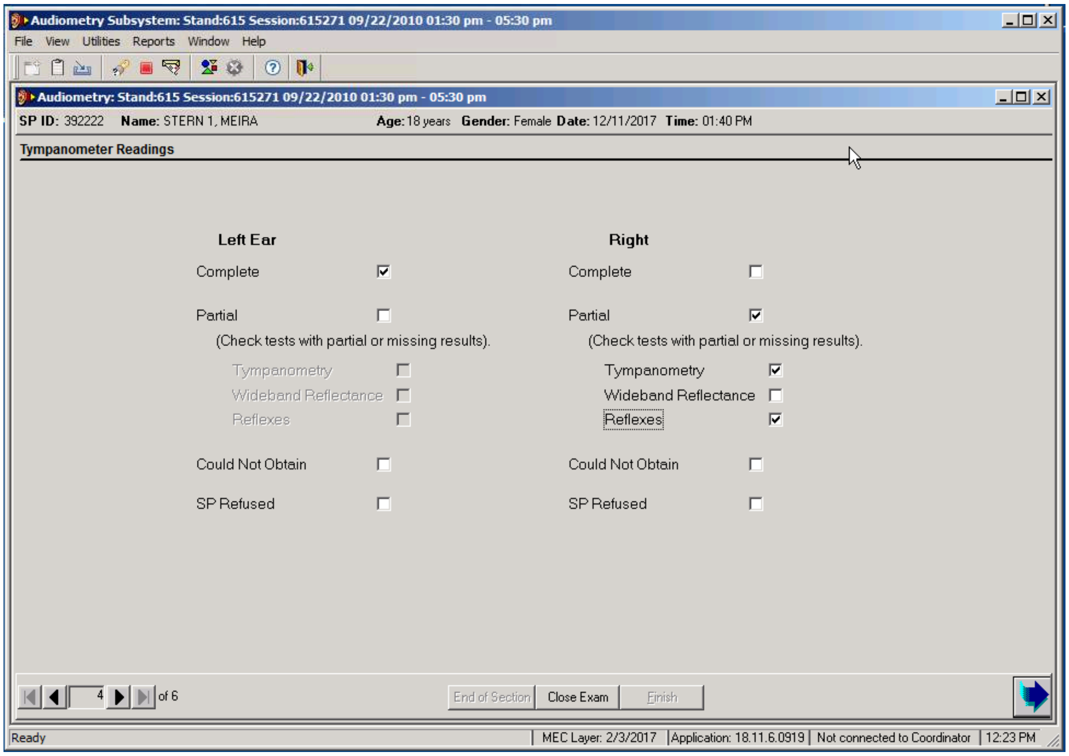


Toggle back to the ISIS Audiometry application by clicking the audiometry icon in the task bar at the bottom of the screen. You will receive a pop-up message indicating whether the data were successfully stored or if some data are missing, etc. (Exhibit 3-26).

Exhibit 3-26. Pop-up window indicating data were successfully stored

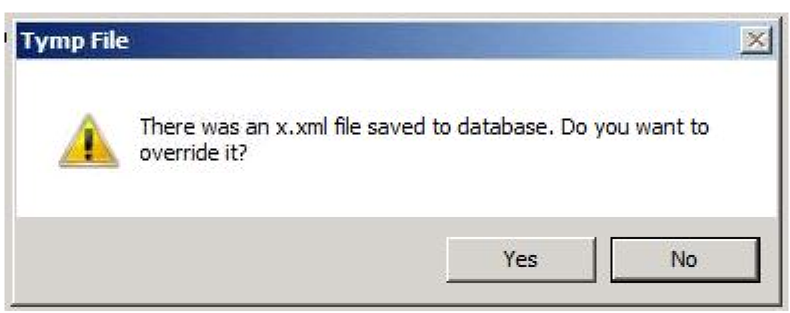
On the Middle Ear Testing screen, indicate whether results were complete or partial in each ear. If the test was partial in one or both ears, click the boxes to indicate which subtests (tympanometry, wideband absorbance, or acoustic reflexes) were missing or partial. If one or both ears were not able to be tested at all, click COULD NOT OBTAIN or SP REFUSED, as appropriate (Exhibit 3-27). Titan Suite will automatically close when the screen advances.

Exhibit 3-27. ISIS Middle Ear Test Results screen



If you back up after advancing past the Middle Ear Test Results screen, you will receive a warning message (Exhibit 3-28). If you previously saved an x.xml file and do not want to save over it, click "No," and ISIS will proceed to the Audiometry screen. (If you want to save over your original x.xml file for some reason, the application will allow that if you select "Yes.")

Exhibit 3-28. Override x.xml file message



3.4.5 Troubleshooting Middle Ear Testing

The following are some common problems that may be encountered during middle ear testing, and a list of possible solutions that may correct the difficulty.

- Difficulty obtaining a sufficient seal to conduct the test:
  - Pull the probe completely away and reset the probe tip in the ear.
  - Pull up and back a little more (or down and back for younger children) on the ear to straighten the ear canal.
  - Use a different size tip.
- Probe indicates blockage when running the test (indicated by a yellow probe light):
  - Verify that the probe cuff is in the entrance to the ear canal and is pointing toward the ear drum, not up against another part of the ear.
  - Check that the probe tip is not blocked by wax, etc. If necessary, replace the clear plastic probe tip.
  - Recall the direction of the ear canal noted on otoscopy and try to direct the probe appropriately.
- Titan takes an abnormally long time to begin tympanometry:
  - Typically, this means that an airtight seal has not been obtained.
  - Remove the probe and begin again.
- Results are “noisy”:
  - Try to seat the probe so that you do not have to hold it during the test. If you must hold the probe in place, hold it very still.
  - Remind the SP to be as still and quiet as possible (yawning, swallowing, talking, or chewing during the test will result in “noisy” graphs).
- ISIS will not capture data:
  - Make sure you have saved the file in the correct location (the ISIS_Out folder).

If you are ever unsure whether the Titan is malfunctioning, test it by placing your finger over the tip of the probe (the probe status indicator in the left panel of the Titan Suite screen should read

"Blocked") or by running a calibration. If the Titan can calibrate or gives the "Blocked" message, it is not malfunctioning; reseat the probe, try a different size probe cuff, etc.

3.5 Audiometry

3.5.1 Purpose of Audiometry

Audiometry is the measurement of hearing sensitivity. The NHANES hearing component includes pure tone air conduction audiometry, which tests the hearing sensitivity of the entire auditory system by presenting pure tone signals (sounds that have one frequency and one intensity) to the ear through earphones and varying the intensity of the signals until the level is identified at which the person is just able to hear the sound. This level is known as the person's threshold; clinically, threshold is usually defined as the level at which the subject will be able to detect the signal 50 percent of the time that it is presented. Pure tones are presented at frequencies across the range of human hearing. Because the tones are presented at the external ear, and processing of those signals through the auditory neural system is necessary for the subject to be aware and respond that the signal was heard, this type of testing evaluates the auditory system as a whole and is capable of identifying hearing problems at almost any level within the auditory system.

3.5.2 Instrumentation for Audiometry

Pure tone air conduction threshold testing is done using an audiometer – an electronic device capable of generating pure tone signals, which can be adjusted in both frequency and level. NHANES uses dedicated National Instruments hardware and Audiometric Research Tool (ART) software as an audiometer. The ART software has been programmed to conduct the threshold test automatically. It is capable of presenting the tones, recording the subject's responses, adjusting the level of the tone accordingly, and determining when the threshold has been found. The ART software can also be used to conduct the threshold test manually, which means the frequencies and levels of the test signals are controlled by the tester, who also presents the tones and makes the threshold determination.

The NHANES audiometric test system consists of a National Instruments chassis, which holds the system hardware, and a dedicated Dell computer that runs the ART software. In addition, the system is supplied with standard supra-aural (i.e., "on the ear") headphones, EARtone 3A insert earphones, and a response switch control box and "Response" button. Standard and insert earphones are paired in sets and are not interchangeable; if one set of the pair develops problems, a new set of both standard and insert earphones must be swapped in. However, all of the earphone sets can be used with any of the audiometric testing systems. Response switch boxes and "Response" buttons are completely interchangeable.

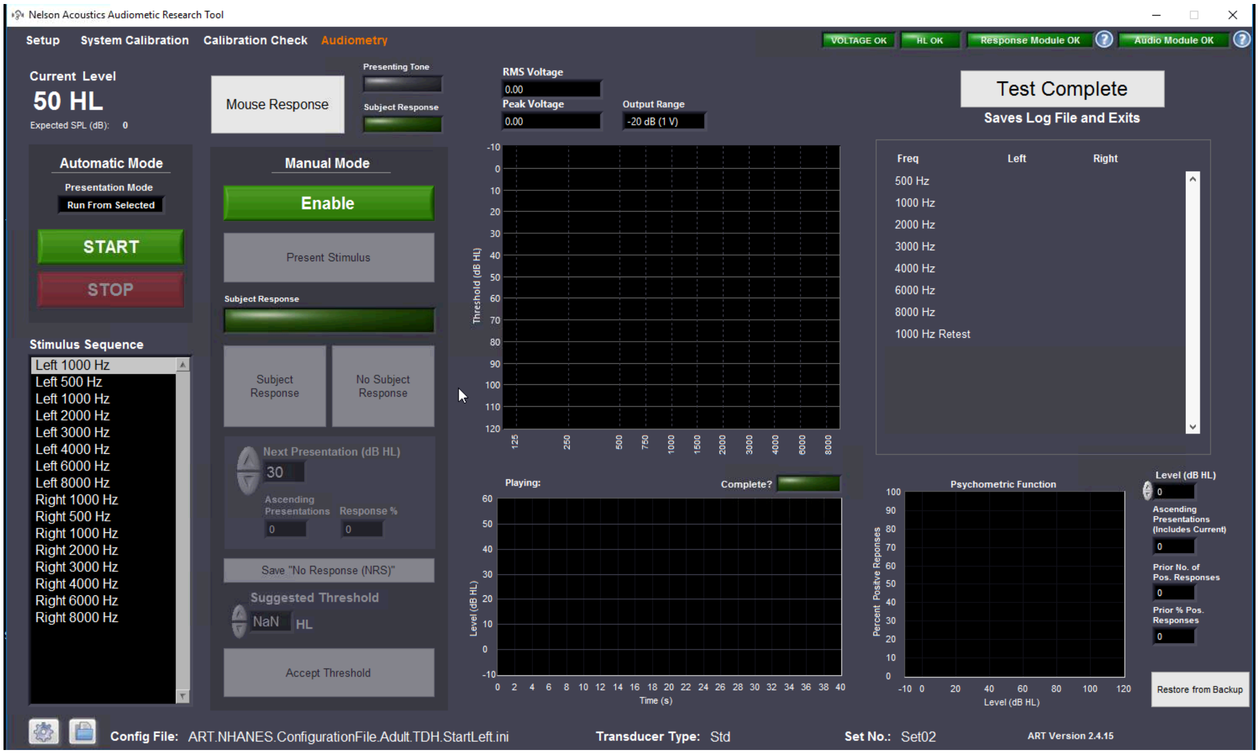
3.5.2.1 Audiometric Research Tool (ART) Software

The ART software is capable of automated and manual testing of pure tone hearing thresholds. The ART screen has four menu options, represented by tabs across the top left part of the screen:

- **Setup.** This tab shows the test settings – for example, at what level the automated test will start, the length of the test signals, the specifications for determining threshold, etc. The values on this screen are controlled by the configuration files that run the test (discussed in Chapter 2, Section 2.4.2.1). It should seldom (if ever) be necessary to access this tab.
- **System Calibration.** This screen is used to calibrate headphones to the ART system (not to check the calibration, but to make adjustments to the calibration as needed). Headphone calibration will generally be done by the consulting audiologist. You will need to use this tab to conduct part of the daily listening check (see Chapter 2, Section 2.4.2.9)
- **Calibration Check.** This tab is used to measure the background noise levels in the room and to conduct most of the audiometry calibration checks (checking output, distortion, and linearity).
- **Audiometry.** This tab is used to conduct audiometric testing and is part of the daily listening check.

The currently selected tab is indicated by the orange font color (see Exhibit 3-29). By default, ART opens to the Audiometric Testing screen; this screen can also be accessed at any time by clicking the Audiometry tab.

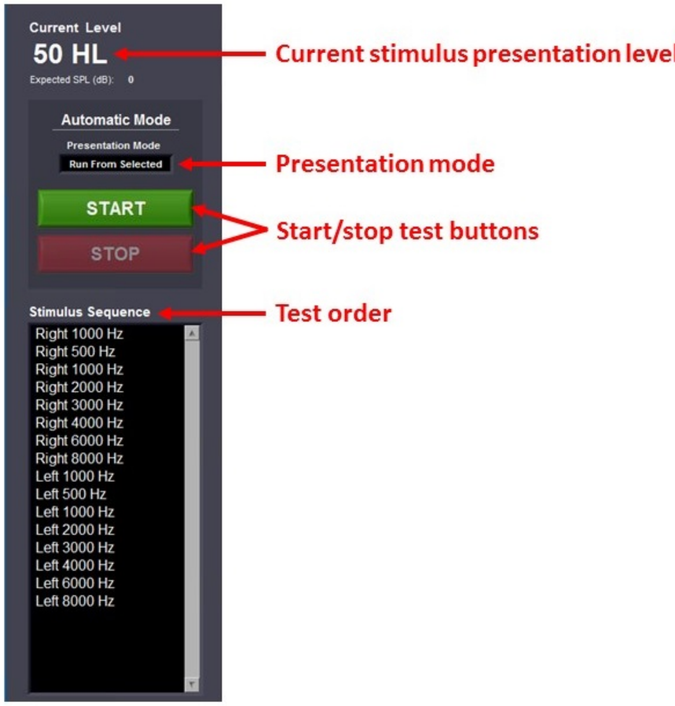
Exhibit 3-29. ART Audiometry screen



The Audiometric Testing screen is divided into four vertical sections. The two sections on the left are used to control the test and the two sections on the right display responses.

The section of the Audiometry screen on the far left is for conducting a test in automatic mode (see Exhibit 3-30). This section had four main parts.

Exhibit 3-30. ART Automatic Mode screen section



The Current Level field at the top of this panel displays the current presentation level in dB HL. This level updates as each new test signal is played. It is updated by the software itself; it cannot be manually changed by the tester.

Below the Current level field, in the panel labeled "Automatic Mode" is the Presentation Mode field. This setting determines which signals will be presented for testing. In the "Run from Selected" mode, the test will begin with the ear/frequency that is highlighted in the Stimulus Sequence box and will proceed automatically in order through the remaining frequencies in that box. In the "Single Stimulus" mode, only the highlighted ear/frequency will be tested; this mode is used if only a single frequency is to be tested. ART defaults to "Run from Selected" mode. To select "Single Stimulus" mode, click on "Run from Selected" and "Single Stimulus" will appear. Click "Single Stimulus" to select it.

Just beneath the Presentation Mode field are the Start/Stop buttons. These buttons start and end an automated test. If no test is currently running, only the "Start" button is clickable and the "Stop" button is grayed out. If a test is running, then only the "Stop" button is active and the "Start" button is grayed out. The "Start" button initiates the testing in the presentation mode that is shown on the screen. The "Stop" button stops the current test sequence, which allows continuation of the test in manual mode or closing the program via the "Test Complete" button. In automated testing mode, the test will stop on its own when the final stimulus has been tested; you do not need to click "Stop" unless you want to interrupt or end the test sooner.

The lower section of this panel contains the Stimulus Sequence box. This displays the order of the test frequencies. The test order is driven by the configuration file. The stimulus sequence order will change based on the ear to be tested first and the age of the SP.

SPs aged 12+ will be tested in the following order:

Ear 1: 1000, 500, 1000 (repeat), 2000, 3000, 4000, 6000, 8000 Hz
Ear 2: 1000, 500, 1000 (repeat), 2000, 3000, 4000, 6000, 8000 Hz

Children aged 6-11 will be tested in the following frequency order, so that data may be obtained for more important frequencies first in case the child's attention wanes before all frequencies can be completed:

Ear 1: 1000, 2000, 1000 (repeat), 4000, 8000 Hz
Ear 2: 1000, 2000, 1000 (repeat), 4000, 8000, 6000, 3000, 500 Hz
Ear 1: 6000, 3000, 500 Hz

ISIS will send information to ART so that the correct stimulus test order will be loaded for each SP.

The second panel from the left on the Audiometric Testing screen is shown in Exhibit 3-31. At the top of this section are indicator lights that show when tones are presented and when SP responses are made. When test signals are presented, the Presenting Tone indicator light will "illuminate" (change from black to gray). The presentation of a stimulus has a maximum duration (four beeps); the stimulus is stopped after four beeps are presented or when the SP activates the response switch – whichever comes first.

To the left of the indicator lights is a button labeled "Mouse Response." It is used when the operator wants to indicate a response without pressing the SP response switch. This is used during the daily listening check. It can also be used to register responses from SPs who cannot operate the response switch during automated testing.

Exhibit 3-31. ART Manual Mode screen section

This section of the screen also contains the controls for conducting audiometric testing manually. When necessary, all or part of a test can be conducted manually. Manual mode is activated by clicking the green "Enable" button. When manual mode is enabled, this button changes to a red button labeled "Disable." Clicking the "Disable" button will exit manual mode.

In manual mode, tones are presented by clicking the "Present Stimulus" button. Just as in the automatic testing mode, the "Presenting Tone" indicator light will change from black to gray after the "Present Stimulus" button has been clicked. Once the "Present Stimulus button has been activated, another stimulus cannot be presented until the prior presentation is finished. The "Present Stimulus" button is disabled during this presentation period, as indicated by the temporary darkening of the button after it has been clicked.

Responses from the SP are detected automatically via the response switch. The two green indicator lights labeled "Subject Response" on the Audiometry screen will illuminate when the response switch is activated. In the event that the SP responded by some means other than the response switch (e.g., by raising a hand), a response can also be recorded by clicking the "Subject Response" button.

Manual testing requires an indication of whether there was or was not a response to the stimulus at a particular presentation level. If the SP does not respond to a presentation, the tester must indicate that. This is done by clicking the "No Subject Response" button. The tester cannot indicate that the SP did not respond to the stimulus until the stimulus presentation is complete. The "No Subject Response" button is disabled during the presentation period.

If the SP does not respond due to a distraction or if the tester is unsure whether a response was valid, a stimulus presentation can be repeated by pressing the "Present Stimulus" button again.

Once ART detects that the response switch or "Subject Response" button has been clicked, the presentation level is automatically decreased by 10 dB. If the "No Subject Response" button has been clicked, the presentation level is automatically increased by 5 dB. The tester can override these automatic adjustments in presentation level, although this should not be necessary often.

The "Next Presentation Level" field indicates the recommended level for the next stimulus that will be presented. It is updated as soon as a positive or negative subject response is recorded (unlike the "Current Level" field in the left panel, which is not updated until the next stimulus is presented). Detailed information about the number and percentage of SP responses from prior ascending presentations (i.e., presentations made after an ascending step) are displayed below the "Next Presentation Level" field.

The number in the "Current Level" field can be adjusted in 5 dB steps while in manual mode, but this is not normally necessary. The current level can be increased by pressing the up arrow next to the indicated level or decreased by pressing the down arrow. It is also possible to enter the current level into the box directly to present a stimulus at an arbitrarily chosen level, but this should not be necessary except in very rare circumstances.

If the SP does not hear the selected stimulus at the maximum output of the audiometer, the threshold is stored as "No Response" using the "Save "No Response (NRS)" button. When the "Save No Response (NRS)" button is pressed, a "NaN" code will appear in the threshold table for the selected stimulus and ear. "NaN" means "not a number" and is different from an empty cell, which means no threshold information was collected at all.

The ART software tracks all stimulus presentations. Once the necessary number of responses to ascending stimulus presentations has been reached, the "Suggested Threshold" section of the screen will become visible. Unless the "Next Presentation Level" has been modified by the tester, the numeric value indicated in the "Suggested Threshold" section of the screen represents the threshold for the selected stimulus. The numeric value for the selected threshold can be modified if the tester determines that the suggested threshold is incorrect, but this should be done with care. The SP threshold for the selected stimulus can be recorded by clicking the "Accept Threshold" button, which will add the appropriate symbol to the audiogram form and the appropriate value to the threshold table.

The two right vertical sections of the ART screen (Exhibit 3-32) monitor the progress of the test. These sections together have four main parts.

Exhibit 3-32. ART Audiometry screen, including response information

In the top left area is the SP's audiogram – which is a graphical display of their hearing thresholds. Stimulus frequencies are arranged in ascending order from left to right, and threshold levels are arranged in ascending order from top to bottom. Results from the left ear are represented with blue Xs and results from the right ear are represented with red Os. Better hearing sensitivity is indicated by smaller threshold values, and lower threshold values appear at the top of the form.

The NHANES protocol includes a repeated threshold test at 1000 Hz to confirm reliability. In Exhibit 3-32, the thresholds for the left ear at 1000 Hz were the same, so the symbol for the retest threshold is on top of the original threshold, making it look as though there were only one symbol. In the right ear, the thresholds differed by 5 dB, so two symbols appear at that stimulus frequency for the left ear.

To the right of the audiogram is a table displaying the thresholds numerically.

Beneath the audiogram form is a graph of the presentation history. This displays all of the presentations for the selected stimulus in the sequence. During audiometry, this history can help the tester keep track of the SP responses to help in determining when threshold is reached. The horizontal axis of the presentation history represents time since the onset of the first presentation of this frequency. The vertical axis represents presentation levels with softer levels at the bottom of the graph and louder levels at the top (the reverse of how levels are displayed on the audiogram). Each presentation of the tones is represented by a white line segment. If an SP does not respond to a test signal, the line for the next presentation will be higher on this chart. If the SP did respond to the signal, the next line will be lower on the chart.

The record of the presentation history also provides information about the certainty with which a threshold can be interpreted (i.e., how consistent and reliable the SP's responses were). In automated mode, the length of the line indicates how long it took for the SP to respond; shorter line segments indicate a faster response from the SP. In manual mode, the lines are all the same length. The scaling of the horizontal axis is dynamic and will be adjusted to accommodate longer searches for threshold as necessary.

The top of the presentation history (Exhibit 3-32) provides ongoing information about test execution. The text labeled "Playing:" indicates the frequency that is currently being tested (2000 Hz in Exhibit 3-32). During automated testing, yellow text will appear above the presentation history chart after each signal presentation to indicate the status of the response to that presentation. The text will report one of the following:

- On Time Response – the response was detected during the allowable time window.
- No Response – the SP did not respond by the end of the defined time window.
- Early Response – the SP responded too early for the response to be considered valid.

To the right of the presentation history chart is a graph labeled Psychometric Function. This graph tracks the percentage of positive SP responses to ascending presentations at various levels (from lower levels to the left of the chart and higher levels to the right). For example, in Exhibit 3-32, the SP has responded to 100 percent of the ascending presentations at 45 dB and 50 dB HL. The percentage of positive responses can help the tester determine whether threshold has been reached. To the right of the graph are the numeric values from this chart for the level currently being tested (in Exhibit 3-32, at the current presentation level of 50 dB HL, there has been one prior ascending presentation and one positive response, resulting in a positive response rate of 100 percent).

In the top right corner of this section of the Audiometry screen is the "Test Complete" button, which is used to save the test information to an output file and exit the program. This button is the only route by which the program should be closed when testing an SP. If you try to close the ART software program in any other manner (for example, by clicking the Windows "X" in the top right corner of the screen), the data will not be saved. A warning message will pop up, asking if you are sure you want to exit without saving the data.

In addition, the upper section of this part of the Audiometry screen has four small tabs labeled "Voltage," "HL," "Response Module," and "Audio Module," which indicate whether the system is functioning properly. All four of these lights should be green during normal operation of the software. If any of the tabs turn red, a problem exists, which must be resolved before testing can continue. The help items (question marks with a blue background) next to these tabs are currently disabled.

The bottom edge of the ART Audiometry screen contains information about the configuration file selected for the current test (see Exhibit 3-33). The configuration file tells ART which earphones are being used (standards or inserts), which ear is to be tested first (right or left), and what frequency order to use (adult [aged 12+] or child [aged 6-11]). In addition to the configuration file name, the type of headphones and the headphone set number are displayed along the lower edge of the ART screen.

Exhibit 3-33. ART configuration file display

During audiometric testing, ISIS sends information to ART so that the correct configuration file is automatically selected (the file name will read "ISIS.ini"). You can confirm that the correct config file has been selected by checking the threshold order under "Stimulus Sequence" on the ART screen (adults test all frequencies in one ear before switching to the other ear) and the "Transducer Type" at the bottom of the ART screen ("STD" indicates standard headphones and "INS" indicates insert earphones).

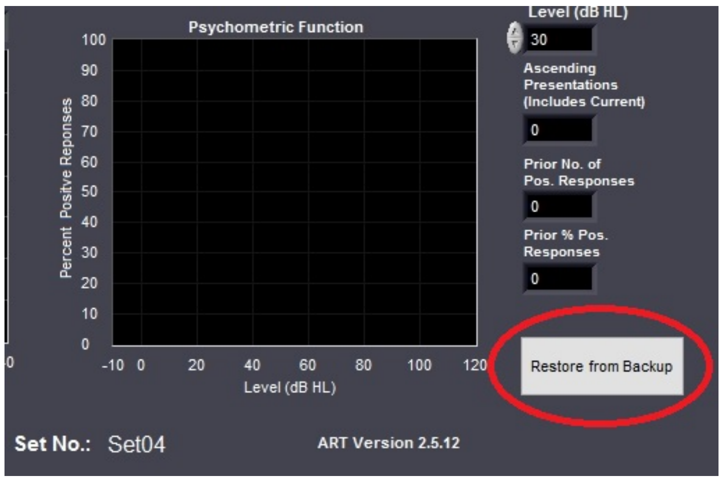
If for any reason you need to choose a different file (for example, if the SP would normally have been tested with insert earphones but the inserts are not working), you can override the ISIS-selected configuration file by clicking the blue file icon and choosing another. If ISIS loses communication with the ART system and is not able to "tell" ART which config file to use, no thresholds will appear in the "Stimulus Sequence" field. You can select the appropriate config file by clicking the blue file icon and choosing the correct config file from the list. Whenever you select a config file from the list, the config file name (i.e., "ART.NHANES.ConfigurationFile.Adult.TDH. StartLeft.ini") will appear beside "Config File" at the bottom of the screen instead of "ISIS.ini."

Note: If ISIS loses communication with ART, you can manually select a config file and conduct the Audiometry exam but the results will not be captured by ISIS. Enter the results manually on the ISIS screen. When the exam is complete and the SP leaves the room, power down all equipment and power it back up as indicated in Chapter 2 to re-establish communication between ART and ISIS.

The gear icon to the left of the config file selection icon takes you to the settings menu where changes can be made to the config file. You should never make changes to the config file settings unless you are specifically instructed to do so. On the far right of the lower edge of the screen, the version of the ART software is displayed.

One other very useful button is located in the bottom left corner of the ART Audiometric Testing screen. This is the "Restore from Backup" button (see Exhibit 3-34). This button brings back the results of the most recent test. If you should accidentally exit the ART system without saving the results, or if ISIS cannot find the results, you can use this button to restore the most recent test and try to save it again.

Exhibit 3-34. Restore from Backup button



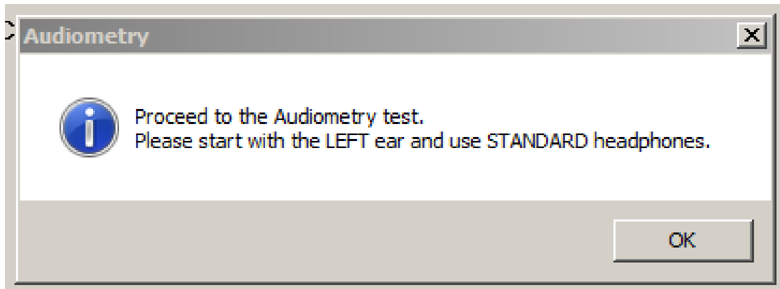
Finally, the ART Audiometry screen has several small fields above the audiogram display (RMS Voltage, Peak Voltage, and Output Range). These values provide technical information that might be used during troubleshooting, but do not require constant attention during routine use of ART.

3.5.3 Procedure for Audiometry

3.5.3.1 Preliminary Procedures and Instructions

The SP will remain in the sound room for pure tone audiometry. The ear to be tested first will be varied to prevent biasing the data. The fifth digit of the sample person identification number (SPID) will be used to identify which ear should be tested first; if the fifth digit is 5-9, the right ear will be tested first, and if the fifth digit is 0-4, the left ear will be tested first. For example, SP# 448937 will have his left ear tested first, and SP# 879592 will have her right ear tested first. However, if the SP indicated that he or she has better hearing in one ear than the other, the ear with the better sensitivity should be tested first. The ISIS program will display a message to indicate which ear to test first and which earphones to use for audiometry when you advance to the Audiometry screen (Exhibit 3-35). **Pay close attention to this message.** Click OK to close the message.

Exhibit 3-35. Audiometry pop-up box



Note: You MUST advance to the ISIS Audiometry screen before launching the ART software. ISIS assigns the config files for the SP as you advance to this screen. If you launch ART without having advanced to the ISIS Audiometry screen, the correct config files will not be pre-loaded into ART.

Be certain that the SP has removed eyeglasses, earrings, chewing gum, hair ornaments, hats, or anything else that might interfere with proper placement of the headphones. Hair should be pushed away from the entrance to the ear canal. Also, verify that any hearing aids have been removed. If the SP must wear his or her hearing aid to hear the test instructions, remember to have the SP remove it before testing begins.

Explain the test and instruct the SP in the following manner:

> **Instructions for Adults and Older Children.** "This next test measures how well you can hear certain sounds. I am going to place these earphones on your head and you will hear a series of short beeping sounds through them. They will have various pitches, both low and high, and will gradually become softer and softer until you can't hear them anymore. Each time you think you hear the tones, no matter how quiet they seem, push down on this button. You will have to listen very carefully. You will hear sets of beeping sounds like this – beep beep beep. You only have to push the button once for each set. As soon as you think you hear the first beep, press and release the button right away. We will be starting in your right/left ear. Do you have any questions?"

> **Instructions for Younger Children (Aged 6-11).** "This test checks to see how well you can hear. I am going to place these earphones on your ears. You will hear groups of beeping sounds through them. Some of the beeps will sound low like this – beep beep beep [*in a low-pitched voice*] and some will sound high like this – beep beep beep [*in a high-pitched voice*]. The beeps will get softer and softer until you can't hear them anymore. Whenever you think you hear the beeps, no matter how quiet they are, I want you to [*age 6-8* "raise your hand"*;*

age 9-11 "push down on this button"]. You will have to listen very carefully. Whenever you hear the beeps, *[age 6-8 "raise your hand"; age 9-11 "push the button"]*. Sometimes the beeping sounds will be in your right ear and sometimes they will be in your left ear. You should [raise your hand/push the button] whenever you hear them, no matter which ear they are in. Do you have any questions?"

Place the appropriate earphones on the SP. **The RED earphone goes on the RIGHT ear and the BLUE earphone goes on the LEFT ear.** Proper placement of the earphones is essential to obtain accurate hearing thresholds. Do not permit the SP to place the headphones on herself or himself, although it is OK to allow the SP to adjust the headphones if needed after you have initially placed them.

- Standard headphones:

  Standard headphones will be the default, unless the potential for collapsing canals was noted on the otoscopic exam.

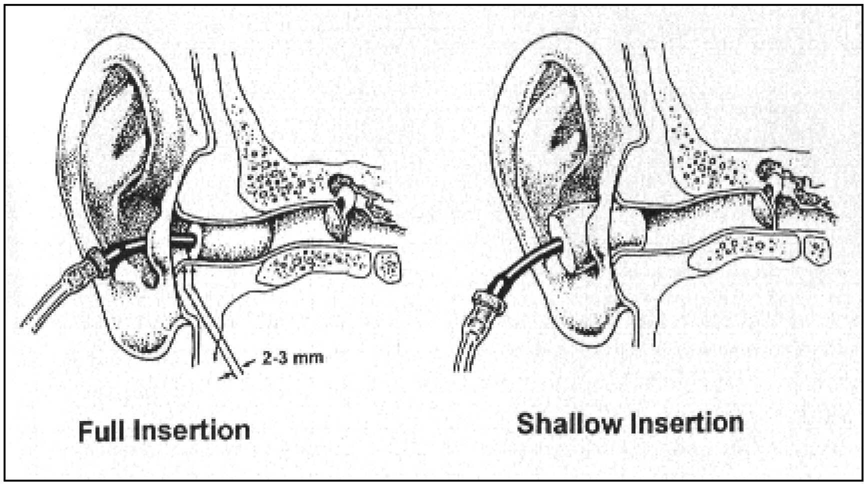
  To place the headphones on the SP, fully extend the height of the headset. Position the headphones such that the diaphragm of the headphone is aimed directly at the opening of the ear canal, pushing aside any hair from over the ear. When the headphones have been positioned, hold them in place and slide the top of the headset down so that it rests solidly on the top of the SP's head. (This step may disturb the SP's hairstyle but it is important for proper use of the headphones.) Make sure that the headphones exert firm pressure on each ear and form a good seal.

- Insert earphones:

  Insert earphones will be used when the potential for collapsing canals was noted on otoscopy, and for any retests when there is a significant difference in threshold between the right and left ears at the same frequency. Insert earphones **may not** be used when excessive or impacted cerumen was noted in either ear, or when there was another abnormality noted in either ear at otoscopy.

  Particular care must be taken in proper insertion, as improper insertion will result in inaccurate threshold levels. Drape the VELCRO® strip behind the SP's neck to support the earphones. Determine which size foam tip is needed; the tip should be larger than the opening of the SP's ear canal, but able to be rolled down smaller than the opening of the canal. Slowly roll (do **not** squeeze) the foam tip into as small a diameter as possible; there should be no creases or wrinkles in the compressed foam. Pull up and back (down and back for young children) on the helix (upper part) of the outer ear to straighten the ear canal, and quickly insert the foam tip to a point such that the outer edge of the tip is flush with the entrance to the ear canal. Hold the foam plug in place with a fingertip until the foam has completely expanded (approximately 10 seconds). Correct insertion is shown in the first illustration in Exhibit 3-36. Incorrect (i.e., shallow) insertion is shown in the second illustration. If the foam tip is not inserted properly, remove it and try again.

Exhibit 3-36. Proper insertion depth for earphones



After placing the earphones on the SP, make sure the SP is seated in such a way that you can observe him or her during the test protocol, but the SP cannot observe what you are doing or how the equipment is being operated. Generally, it is best to have the SP facing the back wall of the room. Explain to the SP that you are asking him or her to face this way to prevent distraction. It may be necessary to have young children face toward you so you can see them raise their hand and help maintain their attention by watching them through the glass in the sound booth door. A mirror has been installed on the shelf inside the booth to help observe SPs who provide visual responses.

Close both the door to the sound room and the exterior door to the audiometry exam room prior to the start of testing. Assure the SP that, although the door must be closed during testing, you will be observing the test through the window and he or she should signal if anything is needed.

3.5.3.2 Automated Audiometry Procedures

Automated audiometry is the procedure in which the frequency, stimulus level, presentation of test signals, and determination of threshold are controlled by a computer program. The ART software is capable of conducting the hearing test in much the same way as you would conduct the test manually (as described in the next section). Automated audiometry will be the standard test procedure in NHANES, except for SPs aged 6-8 years and under certain conditions (see Section 3.5.3.3). Children aged 6-8 years old will be tested manually by default, responding by raising their hand.

Once the preliminary procedures have been completed and the SP is ready to begin the test, double-click the ART icon to launch the software. ISIS will send information to ART to load the appropriate configuration file based on the SP's age, the earphones to be used for the test, and the first ear to be tested. Check the settings on the ART Audiometric Testing screen to confirm that the correct file has loaded.

Select the appropriate headset on the headphone selector box by turning the knob toward "TDH" (standards) or "Inserts."

Click the "Start" button in the left panel of the Audiometric Testing screen to begin testing. The ART automatic test mode controls the presentation of stimuli and monitors for responses. Monitor the test as it is conducted. The PRESENTING TONE light will flash green when a test signal is being presented to the SP; the SUBJECT RESPONSE lights will flash when the SP presses the response switch to indicate that he or she heard the tone.

The amount of time between presentations varies to prevent the SP from developing a response rhythm. The software has a defined "response window" in which SP responses are considered valid. If the SP presses the "Response" button too early, the response is considered an early response and is ignored by the software. If the SP presses the "Response" button after the response window has closed, the software will also ignore the response and continue the test as if it had not happened. Subjects who can respond consistently but cannot respond within the response window require manual testing.

ART uses a modified Hughson-Westlake procedure to establish thresholds. After an initial presentation at a comfortable listening level, test signals are decreased in 10 dB steps when the SP hears the tones, and increased in 5 dB steps when the SP does not. This is known as the **UP 5, DOWN 10** procedure. Responses made following an **increase** in stimulus intensity are called "ascending presentations" and count toward threshold; responses made following a **decrease** in stimulus intensity are called "descending presentations" and do **not** count toward threshold. ART is programmed to establish threshold at the lowest intensity at which the tone has been heard by the SP at least 50 percent of the time following a minimum of three ascending presentations at that level (e.g., at least 2 out of 3, 2 out of 4, 3 out of 5, etc.).

As you are monitoring the test, watch for the following:

- SP attention:

  Periodically observe the SP to verify that everything is well and that he or she is not watching the audiometer for cues to the presentation of test signals. If you need to communicate with the SP, you can pause the test (by pressing STOP) and open the sound booth door.

- Frequent false positive responses:

  A false positive occurs when the subject responds to a signal that was not presented. False positives are indicated by a flash of the SUBJECT RESPONSE light that does not immediately follow a flash of the PRESENTING TONE light. In other words, the SP indicated that he or she heard the tone, but the tone was not presented. In automatic mode, false positives are also noted by an "Early Response" message above the presentation history chart on the ART screen. If more than three false positives are noted at a given test frequency, press STOP to pause the test and reinstruct the participant (see Section 3.5.8 on Difficult Test Situations). Press START again to resume testing (ART will pick up at the frequency at which the test was paused and start a new series of presentations). If false positives persist, the SP should be tested manually.

- Long searches for threshold at a given frequency:

  A long search for threshold can occur when the subject has difficulty distinguishing the test signal from tinnitus, when the subject becomes fatigued, etc. If the SP spends an inordinate amount of time at a given frequency, you may want to remind the SP of the tone by pressing STOP and START in quick succession (which will restart the test at that frequency at a comfortable listening level) or by pausing the test (by pressing STOP), reinstructing the SP, and then starting to test that frequency again. If the situation does not improve, the test should be completed manually (see Section 3.5.8 on Difficult Test Situations). You can also skip the problem frequency temporarily and try it again at a later point in the test. To do this, click STOP to pause the test, highlight the next frequency, and then click START. To go back and test the frequency you skipped later, choose the SINGLE STIMULUS presentation mode, highlight the skipped frequency, and click START. ART will obtain an automated threshold at that frequency only.

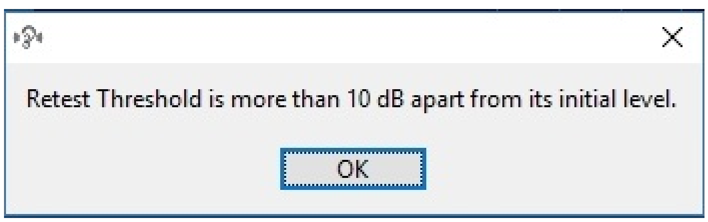
- Slow response time or inability to operate the response switch:

  If the SP has limited dexterity, he or she may be unable to operate the response switch or may not be able to respond in the time window programmed into the audiometer for a valid response. In such cases, the SP should be tested using a different response mechanism—such as raising his or her hand or nodding his or her head. It may still be possible to conduct the test in automated mode for these SPs. You can enter the SP's responses by clicking the "Mouse Response" button at the top of the center left panel of the ART Testing screen. The response window of the system could be a limitation, however. If you cannot observe the SP's response and click the "Mouse Response" button within the time window, you will need to test the SP manually (see Section 3.5.3.3 on Manual Audiometry Procedures and Section 3.5.8 on Difficult Test Situations).

- Test/retest consistency at 1000 Hz:

  The ART test protocol tests 1000 Hz twice in each ear as a measure of the reliability of the subject's responses. It is important to pay attention to both 1000 Hz thresholds in a given ear and make sure that there is no more than a 10 dB difference between them (both thresholds will be displayed on the audiogram form and in the threshold table on the testing screen). If the test/retest thresholds differ by more than 10 dB **in the same ear,** the ART system will pause the test and display the message saying "Retest Threshold is more than 10 dB apart from its initial level," (see Exhibit 3-37). When this happens, reinstruct the SP—emphasizing that he or she only press the response switch when fairly certain that the test tone is heard (remind him or her that the tones will be pulsed). Begin the test in that ear again by highlighting the initial 1000 Hz in the Stimulus Sequence list. ART will overwrite the original thresholds as it retests.

Exhibit 3-37. Pop-up message indicating that the two thresholds at 1000 Hz do not meet the criterion for test/retest consistency



  If the test/retest at 1000 Hz fails a second time in the same ear, end the test by clicking STOP and the TEST COMPLETE button to save the data and exit ART.

  Note: The ART notification of mismatched 1000 Hz thresholds works in both automated and manual testing modes.

- Excessive ambient room noise:

  Observe the Quest bioacoustic simulator from time to time throughout the test to verify that the power light is still flashing and that the ambient room noise is within acceptable limits. If the power light is not flashing, change the battery in the simulator after you finish the examination. If the noise monitor lights remain on for more than a few seconds, press STOP to pause the test until the noise goes away; when ambient levels have quieted sufficiently, press START again to resume testing.

When all frequencies have been tested, the test will stop. Click TEST COMPLETE to save the thresholds.

3.5.3.3 Manual Audiometry Procedures

Manual audiometry is the procedure in which the technologist controls the frequency, stimulus level, and presentation of test signals and makes the determination as to when threshold has been identified. It is essential that hearing tests that are given manually follow the same protocol as hearing tests done automatically by the audiometer in order to obtain comparable results. Therefore, it is very important that the procedures outlined in this section be followed exactly.

Manual audiometry is done in lieu of automated audiometry when any of the following circumstances exists:

- The SP is aged 6-8 years.
- The SP lacks the dexterity necessary to operate the response switch and it is not possible to record the SP's responses within the response time window using the Mouse Response function;
- The SP appears confused by or unable to "keep up with" the automated test (i.e., he or she responds to the signal slowly – outside the defined response window – and therefore the response is not counted by the audiometer);
- More than three false positive responses are noted at any given test frequency during the automated procedure; and
- A threshold exceeds 90 dB HL.

In situations in which the automated test has already determined threshold at some test frequencies when a circumstance arises that dictates the need for manual testing, the technologist should pick up the manual procedure where the automated procedure left off. It is not necessary to go back and begin the audiometry all over. However, as soon as manual testing has begun, the remainder of the test should be done manually. At the end of the test, note on the Audiometry Results screen in which ear and at which frequency the manual procedure was begun.

To conduct the manual test, verify that the correct earphones are selected on the switchbox. Make sure the frequency at which you want to start testing is highlighted in the STIMULUS SEQUENCE list. Click ENABLE on the Manual Mode panel of the Audiometric Testing screen.

ART will automatically start to test the first frequency at 30 dB HL. Click PRESENT STIMULUS to present the tone. If the SP responds using the "Response" button, ART will automatically record the response and will adjust the next presentation level down by 10 dB. If the SP is using another response mode (e.g., raising his or her hand) or if the SP does not respond to the tone, you will need to record the result by clicking SUBJECT RESPONSE or NO SUBJECT RESPONSE as appropriate. Either way, ART will adjust the presentation level for the next tone accordingly (decreasing the next presentation by 10 dB when a response is recorded and increasing the next presentation by 5 dB when you indicate the SP did not respond) and will wait for you to present the next stimulus. **If no response is obtained by 75 dB HL** and the SP did not seem to have a lot of trouble hearing, stop the test and listen to the output of the earphone yourself to verify that the equipment is working properly.

ART will continue to guide you through the manual testing process, adjusting the tone up or down as appropriate depending on whether the SP heard the test signal or not, according to the **UP 5, DOWN 10** method of threshold search. ART will count only ascending responses toward threshold. When ART determines that threshold has been reached, the software will display the suggested threshold and enable the ACCEPT THRESHOLD button at the bottom of the Manual Mode panel. If you agree with ART's determination, click ACCEPT THRESHOLD and ART will move on to the next test frequency. If you do not agree, you may continue testing. Although ART will continue to suggest the next presentation level based on the SP's response, you can manually override the suggested level if you feel it is warranted.

As each threshold is saved, ART will automatically move on to the next frequency in the Stimulus Sequence table. When all thresholds have been obtained (or if you decide it is necessary to end the test before all thresholds have been obtained), click the TEST COMPLETE button to save the results and exit ART.

Should you reach the maximum output of the audiometer, the green VOLTAGE OVER and/or HL OVER buttons in the upper right corner of the screen will become red and a pop-up message indicating "Max HL Exceeded" will be displayed. Click "OK" to clear the message, decrease the signal intensity by 10 dB, and present the test signals in increasing 5 dB steps until the SP responds or the maximum output is reached again. If the SP does not respond to at least 50 percent of the signal presentations at the maximum output, click "Save "No Response (NRS)"" to record the threshold as No Response. No Response thresholds are not displayed on the audiogram form; they are listed in the threshold table as "NaN" (not a number).

The output limit of the audiometer varies by headphone and frequency. Some earphones produce slightly higher output than others. Exhibit 3-38 summarizes the approximate audiometer output constraints for both standard and insert earphones.

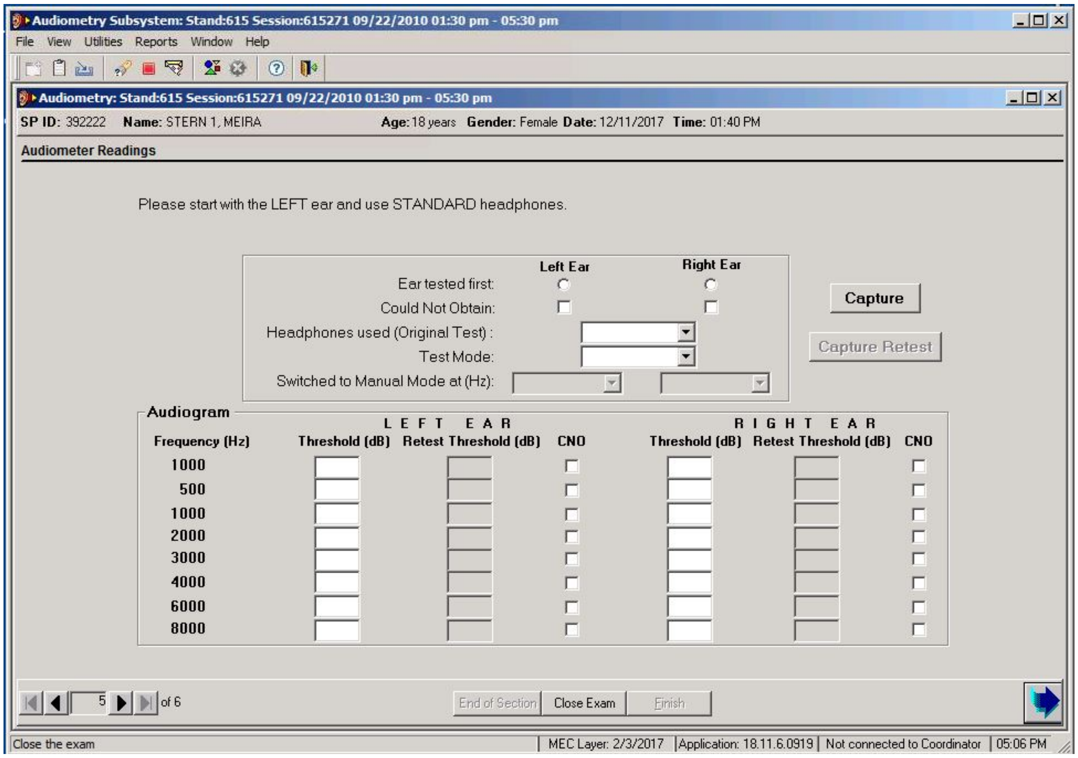
Exhibit 3-38. Audiometer output constraints for standard and insert earphones

	Standard headphones	Insert earphones
Frequency	Max output	Max output
500 Hz	100	100
1000 Hz	100	100
2000 Hz	100	100
3000 Hz	100	100
4000 Hz	100	100
6000 Hz	100	100
8000 Hz	90	90

3.5.4 Recording Audiometry Results in ISIS

When thresholds have been obtained at all frequencies in both ears, transfer the results to ISIS by clicking the "Capture" button on the Audiometry Results screen. Verify that ISIS displays results in the THRESHOLD (dB) column for each frequency in each ear. Also record the earphones used for the test, the test mode (automated, manual, or mixed), and (if mixed mode) the ear and frequency at which you switched from automated to manual testing. See Exhibit 3-39.

Exhibit 3-39. Audiometer Readings screen



If an entire ear could not be tested, click the COULD NOT OBTAIN (CNO) box in the upper portion of the screen for that ear. If a particular threshold could not be obtained, click the CNO box for the appropriate ear and frequency in the lower part of the screen. A threshold, NRS, or CNO result must be recorded for each frequency or ISIS will not advance to the Final Exam screen.

If one or more frequencies were accidentally skipped, ISIS will permit you to go back and test those frequencies. You will need to manually launch ART from the desktop icon; the configuration file used previously will load automatically. Test individual frequencies by selecting the Single Stimulus option in the Presentation Mode box in the left panel of the ART screen. When you have obtained the missing thresholds, click the “Capture” button again to transfer the thresholds to the Results screen.

3.5.5 Retesting with Insert Earphones

3.5.5.1 Crossover Principles

There are times during audiometric testing that the signal presented to the test ear is loud enough that it can actually be heard by the other ear (i.e., the nontest ear). When this occurs, it is difficult to determine if the threshold obtained is truly the threshold of the test ear, or an artifact of the nontest ear (which is the ear with better hearing).

How does the test signal get to the nontest ear? In basic audiometric testing, this generally occurs when the signal in the headphone is so intense that its vibration causes the bones of the skull to vibrate as well. Because the cochleas are enclosed within the skull, they can be stimulated by the vibratory motion of the head.

There is a law of physics, which states that when a vibratory source is applied to a solid mass, the vibrations set up within the mass have the same intensity throughout the object, regardless of where on the object the vibratory source is applied. For example, imagine that a vibrating tuning fork is placed on one end of a table. If you were to place your ear against the table at the end opposite the tuning fork, the sound you would hear would be just as loud as if you were to place your ear against the table at the end nearest the tuning fork. There is essentially no loss of vibratory energy across the table, and therefore no attenuation (loss) of the audible signal.

Because the human skull is essentially one solid bone, both cochleas are stimulated equally by any vibration of the bone. Therefore, if the signal being presented to the test ear is sufficiently intense to set the skull in motion, it has the potential to stimulate the cochlea of the opposite ear.

The stimulus intensity required to set the skull in motion varies across individuals and across the range of test frequencies. However, it is not possible to know in advance how loud the stimulus must be for crossover to occur in a particular individual; and it would be very difficult to remember a different intensity level for each audiometric test frequency. Therefore, to simplify things, clinicians choose a conservative value that represents the minimum level that might cause the skull to vibrate and the test signal to "cross over" and be heard in the nontest ear—regardless of individual differences or test frequency. The value generally chosen is 25 dB for low frequencies and 40 dB for mid-to-high frequencies when testing with standard headphones.

Whenever the threshold at any given frequency is poorer in one ear than the other by 25 dB (at 500 and 1000 Hz) or 40 dB (at 2000-8000 Hz) or more (i.e., whenever there is a 25 or 40 dB difference between ears at a given frequency), the nontest ear could be responding to the test signal. The threshold in the test ear is therefore questionable.

Because insert earphones are smaller, and less mass is in direct contact with the head, a louder stimulus is required before there is the potential for crossover to occur. The value generally agreed upon as the minimum level, which might cause the skull to vibrate when testing with insert earphones is 60 dB, regardless of frequency. Therefore, whenever there is the potential for crossover using standard headphones, those frequencies will be retested using insert earphones.

3.5.5.2 Procedure for Retesting with Insert Earphones

Retesting with insert earphones will be accomplished in NHANES whenever testing with standard headphones results in a difference in threshold between the right and left ears at the same frequency of 25 dB or more at 500 or 1000 Hz, or 40 dB or more at 2000 Hz up (provided, of course, that inserts are not contraindicated for that SP based on otoscopy findings). After pure tone test results are captured, the ISIS system will prompt you if retesting is necessary. The boxes in the RETEST THRESHOLD (dB) column will be highlighted to indicate which ear must be retested, and at which frequency(s).

Remove the standard headphones from the SP and instruct the SP that he or she will now be listening to some tones through a different headset, but should continue to respond as before. Insert the earphone tips as explained in Section 3.5.3.1.

Note: Even though only one ear will be retested with inserts, it is necessary to insert the earphone tips into both of the SP's ears.

Double click the ART icon to re-launch the software. Verify that the correct config file has been selected by ISIS ("INS" will appear beside "Transducer Type" on the ART screen). You must make sure to switch the headphone selector box to inserts; if you do not, the SP will not hear any test signals.

If all frequencies must be retested, conduct the test in the automated mode as usual. If only certain frequencies must be retested, select the SINGLE STIMULUS presentation mode and click START to test the individual frequencies as needed. You can also conduct the retest with inserts manually. When retesting with inserts, it is not necessary to obtain a second 1000 Hz threshold unless you are retesting the entire ear in automated mode.

When you have tested all of the required frequencies, click the TEST COMPLETE button to exit ART and save the results.

3.5.6 Recording Retest Results in ISIS

When all required frequencies have been retested and the results have been saved in ART, click the CAPTURE RETEST button on the ISIS Audiometry screen to transfer the retest thresholds to ISIS. If any frequencies that required retest were omitted, ISIS will prompt you to go back and obtain those thresholds. (Click CAPTURE RETEST again to transfer the missing thresholds to ISIS.) If a particular threshold could not be obtained, click the CNO box for the appropriate ear and frequency. ISIS will not advance to the final screen if results are missing at any frequency.

3.5.7 Considerations to Ensure Threshold Accuracy

Accurate pure tone testing sounds very simple, but a number of precautions are necessary to ensure that threshold measurements are accurate:

- Vary the interval between stimulus presentations; stimuli that are presented too consistently may permit the SP to develop a response rhythm, which can lead to false positive responses.
- Avoid giving visual cues that might indicate stimulus presentations (e.g., looking at the subject each time a tone is presented; using excessive arm movement in the operation of the audiometer).
- Avoid excessive activity, which may distract the SP.
- If responses to tones at the same frequency show large inconsistencies (i.e., more than 10 dB), reinstruct the SP and begin that frequency again.

- If difficulty is encountered in determining threshold at a particular frequency, continue with other test frequencies and return to the problem frequency later. Spending too much time on one frequency will tire and/or frustrate the SP and exacerbate the problem.
- Make periodic checks for false positives by not presenting the tone for 8-10 seconds and verifying that the subject does not respond.
- Count only ascending presentations when determining threshold.
- Avoid being influenced by the initial threshold at 1000 Hz when performing the recheck.
- Always double-check the ART settings (particularly that you are using the correct config file) and headphone selector switch.

In addition, keep in mind that pure tone audiometry is a **subjective** test, which means that it relies on the perception of the subject. Therefore, the accuracy of the results can be affected by a number of subject variables, including motivation, attention, familiarity with the task, etc. Your rapport with the SP can be an important factor in encouraging him or her to complete the test well.

3.5.8 Difficult Test Situations

Obtaining accurate pure tone thresholds can be a challenge under some circumstances. Listed below are some of the most common difficulties encountered in audiometric testing and suggestions for overcoming them.

- Significant pre-existing hearing loss:

  Some SPs with significant hearing loss will actually be quite experienced with audiometric testing procedures, and may not present much of a challenge at all. But others will not be familiar with the threshold testing procedure and may have difficulty hearing the test instructions. If the SP wears a hearing aid, have him or her put it back on between each test while the explanations and directions are being given. Face the person when you speak, and talk a little more slowly than usual (but don't exaggerate your facial expressions). Use motions to help augment your message. If the SP has sufficient vision and reading skills, have him or her read the test instructions from the card kept in the sound booth.

- False positives/inconsistent responses:

  Responses that continuously vary over a range of more than 10 dB are too inconsistent to accurately determine threshold. In such cases, the best course of action is to reinstruct the SP, indicating that he or she should only respond when fairly certain that a tone is heard. Remind the SP that the signals will be a series of three or four pulses; instructing the SP to wait until he or she has heard at least two of the pulses may also help resolve the problem.

If the false positives/inconsistent responses are only at one frequency, try skipping that frequency and coming back to it later. Sometimes the SP just needs a break from listening to the same signal.

- Tinnitus:

  Tinnitus (the presence of ringing or other sounds in the ear) can make it difficult for the SP to distinguish the test tones from the other noises he or she hears. The use of pulsed tones should alleviate this problem somewhat. It may be necessary to skip the frequency corresponding to the SP's tinnitus.

- Fatigue:

  Listening for signals near threshold level is a difficult and demanding task. An SP may weary of it quickly; if the SP arrives fatigued, he or she may have difficulty staying on task. Verbal reinforcement may help keep the SP alert.

- Poor coordination/long tone-response latency:

  Some SPs may be slow to respond when they hear the test tones due to poor dexterity or other reasons. Reinstructing the SP to respond **as soon as** he or she hears the signal may help the situation. Otherwise, try to get a feel for the "rhythm" of the SP's response pattern so that you will better know when a response is valid and when it is random. If another method of responding is more workable (e.g., raising a hand or finger, nodding the head, etc.), use it.

- Comprehension or language difficulties:

  If an SP has difficulty understanding the test instructions, try another mode of communication. Use motions to demonstrate the test directions while you explain them. If the SP has sufficient vision and reading skills, have him or her read the test instructions from the card kept in the sound room. If a family member or friend accompanied the SP to the MEC and is available, ask him or her to help you explain the procedures to the SP. If you do not think the SP understands the directions well enough to provide valid test results, skip the pure tone testing and note "Communication Problem" as the reason for the incomplete test.

- Anxiety:

  Some SPs may be anxious about the test, for various reasons. Perhaps the most common is claustrophobia. Try to put the SP at ease as much as possible. SPs who are claustrophobic may be more comfortable facing the window in the sound booth door than the back of the booth; that is perfectly acceptable, though it requires careful testing techniques to avoid cuing the SP to tone presentations. In some cases, it may be possible to conduct the test with the door to the sound room partly or completely open…but only if the octave monitor on the Quest BA-202-27 indicates that the noise levels in the sound room are still sufficiently quiet. If the ambient noise in the room is too high with the sound booth door open, and the SP is unable to complete the test with the door closed, skip pure tone testing and record "Physical Limitation" as the reason for the incomplete test.

Reinstructing the SP can sometimes help to alleviate a difficult test situation or improve the accuracy and efficiency of the threshold test. Reinstruction is helpful in situations that involve a **misunderstanding of test instructions.** For example:

- SP pushes the button for each beep in the series;
- SP waits for all beeps to play before responding; and
- SP fails test/retest at 1000 Hz once.

However, reinstructing the SP does not help when the situation involves an **inability to follow test instructions.** For example:

- SP repeatedly fails test/retest at 1000 Hz;
- SP continues to respond with more than three false positives per frequency; and
- SP's dexterity is too poor to press the "Response" button in a timely manner.

When reinstructing the SP, be certain to tailor the reinstruction to the specific circumstance. Repeating the same directions initially given to the SP does not help. If the SP did not understand the first time, a verbatim recitation of the same instructions is not likely to be successful the second time. If the SP fails the test/retest at 1000 Hz or if the SP has more than three false positives at one frequency, emphasize that he or she should only respond when <u>sure</u> that tones have been heard. If the SP responds outside the time window of the audiometer, emphasize that he or she should respond <u>as soon as</u> tones are heard.

Finally, if for any reason you feel that the SP is unable to provide reliable thresholds, end the test. No data is preferable to poor data; and there is no mechanism for indicating reliability. Thresholds recorded in ISIS will be assumed to be valid; therefore, if you feel they are not, discontinue testing and enter the reason for the partial exam on the Status screen (see Section 3.6.1).

3.5.9 Troubleshooting Audiometry

The following are some problems that may be encountered in operating the audiometer or conducting pure tone threshold testing, and a list of possible solutions that may be used for troubleshooting.

- Earphones are out of calibration on daily check:
  - Correct config file selected. In addition to selecting the config file for the appropriate set of headphones, the config file used for daily QC must be the "CALIBRATION" config file;
  - Correct earphones selected on headphone selector box; and
- No tones in earphone:
  - Proper headphone selected on headphone box;
  - All earphones plugged into appropriate booth jacks; and
  - Correct ear selected.
- Patient response light does not come on or stays on and does not turn off:
  - Check that the response switch is plugged **all the way** into booth jack;
  - Make sure SP is pressing button all the way down.
- ISIS does not capture thresholds.
  - Re-open ART. Click the "Restore from Backup" button in the lower left corner of the screen and verify that the test results that load are those for the SP you just tested. Click TEST COMPLETE to save the results and to try capturing the results in ISIS again.
  - If ISIS still does not find the results, close the exam in ISIS, saving it as a partial. Send an Unusual Field Occurrence (UFO) to notify ISIS staff at the home office that the results were not picked up. After the SP has left the room, power down all the equipment (including rebooting ISIS) and power it back up as indicated in Chapter 2 to re-establish communication between ART and ISIS.

3.6 Post-Examination Procedures

3.6.1 Closing the Hearing Exam in ISIS

Click the forward arrow to advance to the Audiometry Component Status screen. If any part of the examination was incomplete (or if the exam was not done at all), ISIS will prompt you to enter an explanation code. The codes are standardized across all exam components. Refer to the guidelines below in assigning codes for incomplete hearing examinations:

- **Safety Exclusion.** Refers to an exclusion based on precluding conditions as outlined in the protocol. As there are no precluding conditions for the hearing component, there should seldom, if ever, be a time to select this code.
- **SP Refusal.** Refers to circumstances in which all or part of the exam was omitted because the SP refused, was uncooperative, etc. but was physically able to undertake the component.
- **No Time.** Indicates that the session ended and the exam could not be conducted or had to be terminated before it was completed.
- **Physical Limitation.** Refers to the physical inability of the SP to complete all or part of the exam; for example, the SP could not remove his or her hearing aids unassisted, had ear pain so great he could not tolerate the earphones, was claustrophobic and could not sit in the sound booth; had no external ear canals, etc.
- **Communication Problem.** Indicates that the exam could not be accomplished because the SP could not understand the test instructions for reasons other than a language barrier (e.g., a cognitive deficit or other communication impairment).
- **Language Barrier.** Indicates that the exam could not be accomplished because of a language barrier; the SP did not speak English and an interpreter was not available.
- **Equipment Failure.** Refers to a problem with test equipment or the ISIS system, or high ambient noise that precluded pure tone testing.
- **SP Ill/Emergency.** SP had to leave abruptly due to a serious, unforeseen circumstance.
- **Interrupted.** Exam interrupted for a reason not covered in another code, for example outside noise interfered with administering the exam.
- **SP Unable to Comply.** Indicates that the exam could not be accomplished because the SP could not respond consistently to the test tones or lost focus or was distracted during the exam.
- **Other (Specify).** For use when the reason cannot be coded with any of the other categories. A brief explanation (40 characters or less) in the accompanying comment field is required. Use of this category should be limited as much as possible.

If the SP needs a referral to the MEC physician and you have not yet entered the observation into ISIS, do so now before exiting the component. When everything is complete, click the "Next" button to exit the component.

3.6.2 Conducting the WIN Test (When Indicated)

Most SPs aged 70+ will move on to the Words in Noise Test following audiometry. Complete the Audiometry Completion screen as described in the preceding section. If the SP is eligible for WIN testing, ISIS will prompt you to conduct it. Refer to Chapter 4 for instructions on conducting the WIN test.

Note: If you will be moving on to the WIN test, it is not necessary to remove the headphones from the SP unless you need to do so for them to hear the questions and instructions for the WIN.

3.6.3 Directions to SP

When the entire test has been completed and the SP has been closed out of the component, return any items that the SP may have removed at the beginning of the exam (e.g., hearing aids, eyeglasses, earrings, hair ornaments, etc.). Wait a few moments for a message from the coordinator indicating which station the SP should be directed to next. Thank the SP and direct him or her to the next station.

If the SP inquires about the results of any of the hearing examination procedures, explain to him or her that you simply conduct the tests and the results will be given to him or her with some explanatory materials at the end of the exam.

NEVER, NEVER, NEVER interpret the results of the hearing exam for the SP or give any indication of the test results!

3.6.4 Final Procedures

If time permits following the exam, reset the test room for the next SP. Discard the otoscope speculum, Titan ear tips, headphone covers, and foam ear tips if you have not already done so. **(Be very careful not to throw away the white, plastic connectors on the insert earphones between the foam tips and earphone tubing.)** Reset the headphone selector box to standard headphones, if applicable.

Words in Noise Test 4

4.1 Hearing Loss, Distortion, and New Research

Although the pure tone audiogram remains the gold-standard test of hearing ability, it has long been known that persons with similar pure tone audiometric thresholds can have very different functional hearing ability. As far back as 1951, Carhart suggested that hearing loss could be divided into two types: a loss of "acuity," which primarily involves a reduction in volume that can be compensated by increasing the intensity level of sounds; and a loss of "clarity," which involves a distortion of signals that cannot be corrected simply by turning up the volume. Subsequent research has confirmed these observations over and over (e.g., Ward, 1964; Stephens, 1976). This distinction is recognized and applied clinically; for example, a typical evaluation for hearing aid candidacy includes tests to determine whether increasing volume leads to improved auditory performance.

While the two types of hearing disability have been understood for decades, the underlying physiological damage that leads to a reduction in volume versus a reduction in clarity has not. However, recent research has found that substantial, irreversible auditory damage can occur at the synapse between auditory neurons and cochlear hair cells (Kujawa & Liberman, 2006; Liberman & Kujawa, 2017). This damage – termed synaptopathy – creates a "hidden" hearing loss that is not evident on the pure tone audiogram. The degradation in auditory neural processing likely affects speech intelligibility and could explain the range of functional impairment across similar audiograms. It could furthermore explain the many individuals who report some level of hearing trouble, but have no measurable hearing loss based on pure tone audiometry.

The discovery of synaptic damage at the cochlear neurons has led to a flurry of research in search of a clinical test to identify this damage. Speech-in-noise testing has been proposed as a sensitive measure of synaptopathic damage (Liberman et al., 2016). Recognizing speech in the presence of background noise challenges the auditory system and has been used for years as a method of distinguishing between hearing losses that involve only "acuity" and those that involve "clarity." Speech-in-noise testing is non-invasive and easy to administer, making it suitable for NHANES.

4.1.1 Speech-in-Noise Testing

As Liberman and colleagues explain (2016), one hypothesis for the insensitivity of pure tone audiometry to cochlear synaptopathy is that the neurons most susceptible to damage are those with high thresholds and low spontaneous discharge rates. These neurons are not necessary for detection of low-level signals in quiet, but they are essential for decoding signals when high levels of background noise overwhelm the response of more sensitive neurons with high, spontaneous, discharge rates. Pure tone threshold testing does not evaluate the response of neurons most at risk for synaptic damage. However, understanding speech in noise requires the normal function of these susceptible nerve fibers for detection of the speech signal in the presence of a constant masker.

In addition to the biologic plausibility of speech-in-noise testing as a marker of cochlear synaptopathy, evaluation of speech intelligibility in background noise possesses face validity; spoken language is among the most common auditory signals, and human communication frequently takes place in the presence of competing signals (Zecker et al., 2013).

A number of speech intelligibility in noise tests have been developed for clinical and research use over the past several decades. Of the tests available, the Words in Noise Test (WIN) is the best suited for NHANES implementation. The test was developed nearly 15 years ago (Wilson, 2003) and has been extensively tested (e.g., Wilson & Burks, 2005; Wilson & McArdle, 2007) and validated in various populations (e.g., Wilson et al., 2010; Zecker et al., 2013), including older populations which are the target population for NHANES 2019-2020 (e.g., Wilson, 2011). It is available in both English and Spanish. The WIN test has been recommended as part of the NIH Toolbox (www.nihtoolbox.org), making it readily available to other researchers who might want to use the same test in their studies in order to make use of the NHANES reference population. It is designed to be administered separately to each ear and under headphones, minimizing the effect of background noise and variability in the test environment. It uses pre-recorded materials and has automated functions for recording responses and calculating results. Test items are single words that reduce the impact of listener attention, memory, and cognitive function. The test takes a maximum of 2.5 minutes per ear.

4.1.2 The Words in Noise (WIN) Test

The Words in Noise Test measures a person's ability to hear and understand single words presented in background noise. The background noise is multi-talker babble – a complex noise composed of speakers talking simultaneously. The babble is presented at a constant average sound level based on the pure tone thresholds of the person being tested. While the babble remains at a constant level, the level of the test words is gradually reduced during the test. The test words start at a level 24 dB above the background babble (i.e., a signal-to-noise ratio [SNR] of +24) and are gradually reduced in 4 dB steps until the words are presented at the same level as the background noise (i.e., 0 dB SNR).

All of the test words in the English version are one syllable and have a consonant sound – vowel sound – consonant sound format (for example, "kick," "wheat," "cool"). The words for the English version of the WIN test are drawn from the Northwestern University Auditory Test No. 6 (NU-6) word lists, which are widely used word lists for testing speech understanding in quiet in clinical audiology. The words in the English version are phonetically balanced – meaning that individual speech sounds occur in the lists in the same proportions that they occur in spoken American English speech. Common, familiar, two-syllable Spanish words are used in the Spanish version.

The test words are presented in one ear at a time with the background in the same ear. Five words are presented at a maximum of seven different SNRs (i.e., 24, 20, 16, 12, 8, 4, and 0 dB greater than the multi-talker babble). If at any point during the test, the listener misses all five words at a given SNR, the test is stopped in that ear; the remaining words are counted as incorrect.

The test is scored as the SNR at which the listener is able to hear 50 percent of the words correctly. Scores can range from -2 dB SNR to 26 dB SNR. The score is calculated according to the following formula:

WIN Score = 26 – (0.8 * number of words repeated correctly)

Don't worry, though… in NHANES, the score will be automatically calculated by the equipment.

4.2 WIN Equipment and Software

4.2.1 Equipment and Supplies

Equipment and supplies used for WIN testing are briefly summarized below. See Chapter 2 for full descriptions and images.

The NHANES WIN test uses the following components of the Audiometric Research Tool (ART) system:

- ART computer tower and chassis-computer cable
- Standard supra-aural headphones (Telephonics TDH-49P)
- Insert earphones (EAR-3A)
- Headphone selector box
- G.R.A.S. calibration system

Additional equipment used for the WIN test includes:

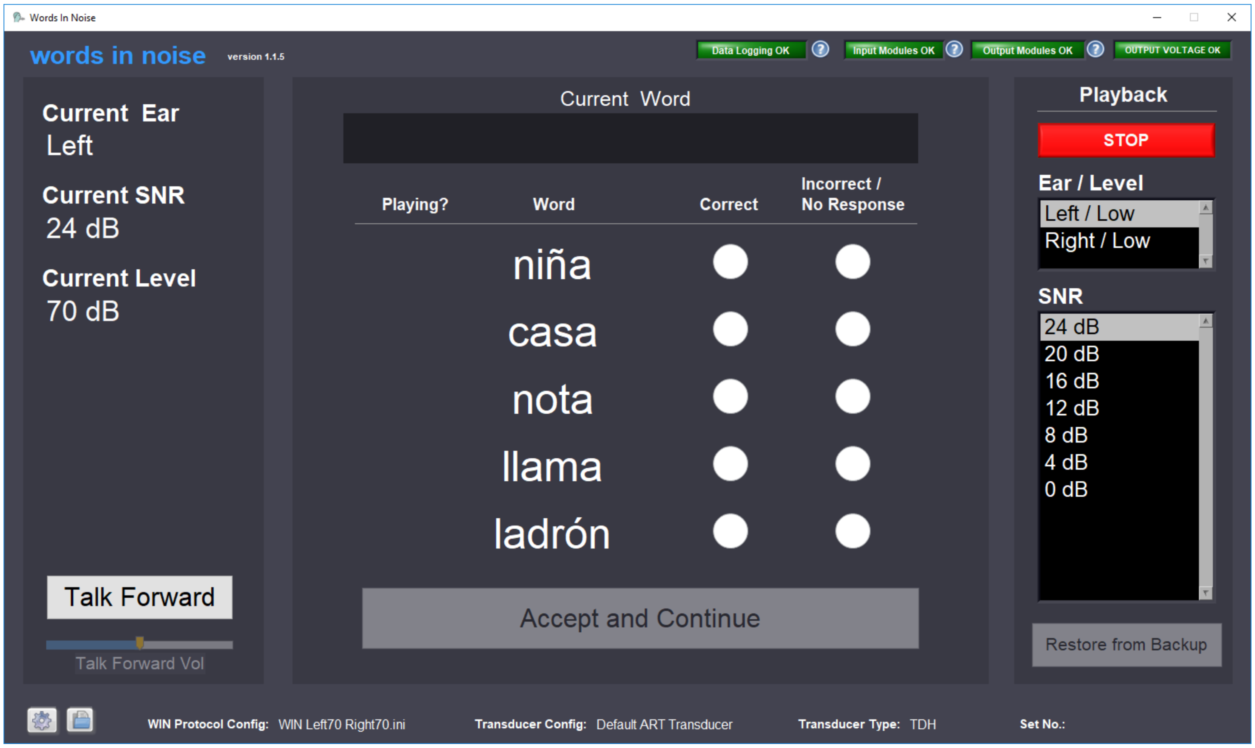
- Talk-over microphone for communicating with the SP (Vidpro XM-L)
- Headphones for listening to SP responses (Sennheiser RS 195)

4.2.2 The WIN Software

The WIN software is designed to conduct Words in Noise testing using the ART hardware. The ear(s) tested, the sound levels of the speech materials, the type of earphone used (TDH or inserts), and the language (English or Spanish) are determined by ISIS based on the results of the threshold tests obtained using ART. The software also relays the words repeated by the SP to the tester through the G.R.A.S. calibration microphone in the booth to the wireless Sennheiser earphones, which are to be worn by the tester. The words repeated by the SP are also recorded (provided the SP consents) to permit scoring at a later time by a different listener.

The WIN software screen is divided into three vertical sections (see Exhibit 4-1). The left section contains a display of the current ear under test, the current SNR, the current level of the babble signal that is mixed with the speech, and the test language. The "Talk Forward" button is also in the left section. This button can be used to speak to the SP using the Vidpro microphone located outside the sound booth. The volume of the sound heard by the SP can be increased or decreased by sliding the yellow indicator arrow to the left (to turn it down) or right (to turn it up). Sliding the yellow indicator arrow all the way to the left reduces the loudness of the sound, but does not turn the sound off. Similarly, sliding the yellow indicator arrow all the way to the right does not increase the loudness of the sound to the maximum that the system can provide.

Exhibit 4-1. WIN software screen



The middle section is used to display the word that is currently being played, the list of words in the current SNR, and is also used to enter the tester's judgment about whether the SP repeated the word correctly. This section also contains a button to indicate that the tester is ready to accept the current judgments about the SP's responses and continue to the next part of the test.

The right section contains the controls to start, stop, and restart the test, and displays the combinations of ears and babble sound levels to be tested and the SNRs that could be included in the current test. The order of the ears to be tested is the same as the prior audiometry test, and the babble sound levels are determined by the results obtained using the ART software. For a given combination of ear and babble level, testing begins at the 24 dB SNR and continues with a presentation of 5 words at each SNR until the SP repeats zero words in an SNR correctly or all words at the 0 dB SNR have been presented, whichever comes first. In the event of a software crash, this section also contains a button that can be used to restore prior test results from the current SP.

4.2.3 WIN Configuration Files

4.3 Set-Up and Calibration

Refer to Chapter 2 for instructions on setting up (Section 2.3.1) and tearing down (Section 2.8.2) WIN equipment.

Output levels of the WIN system are checked during the same output check that verifies the output of the ART system (see Section 2.4.2.4). Listening checks of the Talk Forward system and health tech headphones for monitoring SP responses are described in Section 2.4.2.9.

4.4 Conducting the WIN Test

SPs aged 70+ who can speak and understand English or Spanish and who complete threshold testing in at least one ear will be eligible for speech-in-noise testing, unless the pure-tone average threshold (PTA) across 500, 1000, and 2000 Hz ≥ 60 dB HL is in both ears. If thresholds are elevated above a PTA of 60 dB HL, the SP will not be able to hear the WIN test signals sufficiently to provide interpretable results.

The SP will be tested with the set of headphones last used for audiometry (for example, if the audiometry test required re-testing with inserts, the SP will do the WIN test with insert earphones).

Note: Currently, it is not possible to change the transducer configuration file in WIN. Therefore, the test must be conducted using the headphones automatically assigned by ISIS. If it is not possible to use the headphones assigned by ISIS, do not conduct the WIN test.

The WIN will be conducted in the language in which the audiometry exam was conducted. SPs who speak English or Spanish will be tested in the same language that was used for the preceding parts of the Audio exam. SPs who required an interpreter for any other language for the Audio test will be excluded from the WIN.

The ear tested first during audiometry will also be tested first for the WIN. The test will be conducted without hearing aids or other assistive devices. SPs can refuse WIN testing without affecting other components of the hearing exam.

4.4.1 Determining Eligibility and Test Level

After completing audiometry (including any retesting with inserts), close ART and capture the thresholds in ISIS as usual. ISIS will determine the SP's eligibility for the WIN test based on age (SPs 70+ years) and hearing thresholds (pure tone average threshold at 500, 1000, and 2000 Hz ≤ 60 dB HL in at least one ear).

ISIS will automatically determine the first test ear, test language, and test level based on information collected during the hearing component. Test level is based on the average pure tone threshold at 500, 1000, and 2000 Hz in each ear, using the following criteria:

- If the average 500, 1000, and 2000 Hz pure tone threshold is ≤ 40 dB HL, the WIN test will be conducted at the SOFT babble level in that ear.
- If the average 500, 1000, and 2000 Hz pure tone threshold is > 40 dB HL but ≤ 60 dB HL, the WIN test will be conducted at the LOUD level in that ear.
- If the average 500, 1000, and 2000 Hz pure tone threshold is > 60 dB HL, the WIN test will not be conducted in that ear.

ISIS will send a message to the WIN software instructing it to load the appropriate configuration files. A message will also pop up on the ISIS screen identifying the Test Protocol configuration file to be used for each SP so that you can confirm that the correct files have loaded. Exhibit 4-2 lists the WIN protocol configuration files and ISIS screen messages for each combination of average threshold and first test ear.

Exhibit 4-2. WIN test protocol configuration files and ISIS screen messages based on average pure tone thresholds and first ear

Left ear average threshold	Right ear average threshold	Ear tested first	WIN protocol config file	ISIS screen message
≤40 dB	≤40 dB	left	LeftLow.RightLow.ini	Conduct the WIN test starting in the LEFT ear at the LOW level, then the RIGHT ear at the LOW level
≤40 dB	≤40 dB	right	RightLow.LeftLow.ini	Conduct the WIN test starting in the RIGHT ear at the LOW level, then the LEFT ear at the LOW level
≤40 dB	>40 and ≤60 dB	left	LeftLow.RightHigh.ini	Conduct the WIN test starting in the LEFT ear at the LOW level, then the RIGHT ear at the HIGH level
≤40 dB	>40 and ≤60 dB	right	RightHigh.LeftLow.ini	Conduct the WIN test starting in the RIGHT ear at the HIGH level, then the LEFT ear at the LOW level

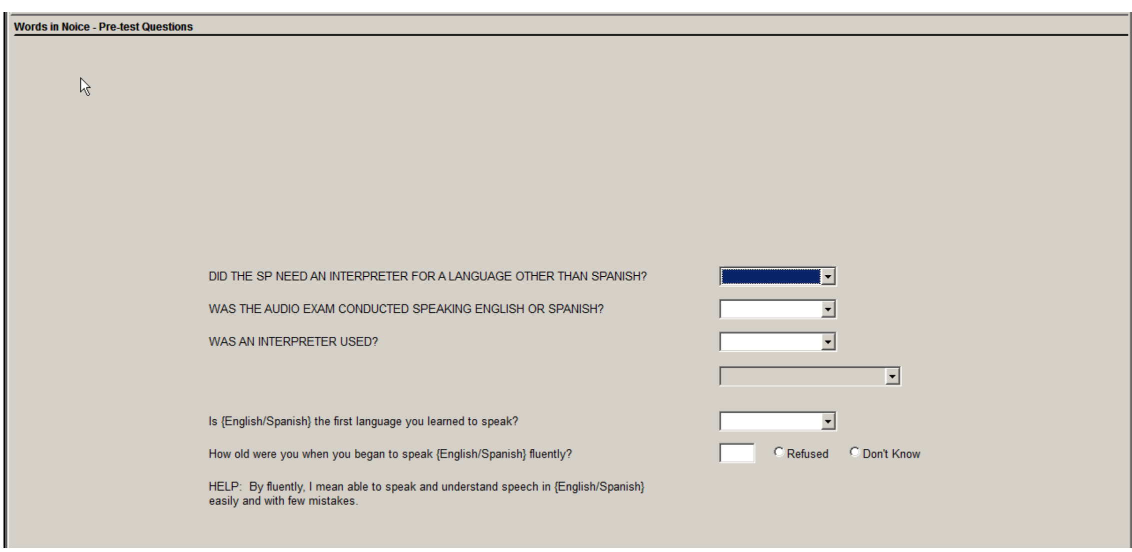
Exhibit 4-2. WIN test protocol configuration files and ISIS screen messages based on average pure tone thresholds and first ear (continued)

Left ear average threshold	Right ear average threshold	Ear tested first	WIN Protocol Config file	ISIS screen message
>40 and ≤60 dB	≤40 dB	left	LeftHigh.RightLow.ini	Conduct the WIN test starting in the LEFT ear at the HIGH level, then the RIGHT ear at the LOW level
>40 and ≤60 dB	≤40 dB	right	RightLow.LeftHigh.ini	Conduct the WIN test starting in the RIGHT ear at the LOW level, then the LEFT ear at the HIGH level
>40 and ≤60 dB	>40 and ≤60 dB	left	LeftHigh.RightHigh.ini	Conduct the WIN test starting in the LEFT ear at the HIGH level, then the RIGHT ear at the HIGH level
>40 and ≤60 dB	>40 and ≤60 dB	right	RightHigh.LeftHigh.ini	Conduct the WIN test starting in the RIGHT ear at the HIGH level, then the LEFT ear at the HIGH level
≤40 dB	>60 dB	left or right	LeftLow.RightSkip.ini	Conduct the WIN test in the LEFT ear only at the LOW level
>40 and ≤60 dB	>60 dB	left or right	LeftHigh.RightSkip.ini	Conduct the WIN test in the LEFT ear only at the HIGH level
>60 dB	≤40 dB	left or right	RightLow.LeftSkip.ini	Conduct the WIN test in the RIGHT ear only at the LOW level
>60 dB	>40 and ≤60 dB	left or right	RightHigh.LeftSkip.ini	Conduct the WIN test in the RIGHT ear only at the HIGH level

4.4.2 Pre-Test Questions

Advance ISIS to the next screen, shown below:

Exhibit 4-3. WIN Pretest Questions screen



Complete the first three fields based on the audiometry test. ISIS will use this information to determine the language in which WIN will be conducted. WIN will always be conducted in the same language as the rest of the audiometry component.

To properly interpret an SP's WIN scores, we need to know how well the SP understands the language in which they were tested. Therefore, all SPs who qualify for WIN testing will be asked one or two questions about their familiarity with the test language prior to starting the WIN. ***These questions do not exclude anyone from the WIN**…* they are just for use later in interpreting the results.

If the SP can hear you with the headphones still in place, you do not need to remove them to continue on to the WIN test; if the SP cannot hear you very well, remove the headphones while you ask the following questions and explain the test; then put the headphones back on the SP.

Tell the SP:

> "Now we are going to do one more test where you will be listening to words instead of beeps. Before we start, I need to ask you one or two questions."

Ask the SP the questions that follow, reading them word-for-word from the ISIS screen.

IS ENGLISH [SPANISH] THE FIRST LANGUAGE YOU LEARNED TO SPEAK?

Yes	Refused
No	Don't know

If the SP responds "NO" to this question, ask the following follow-up question:

HOW OLD WERE YOU WHEN YOU BEGAN TO SPEAK ENGLISH [SPANISH] FLUENTLY?

______ (age in years)	Refused
	Don't know

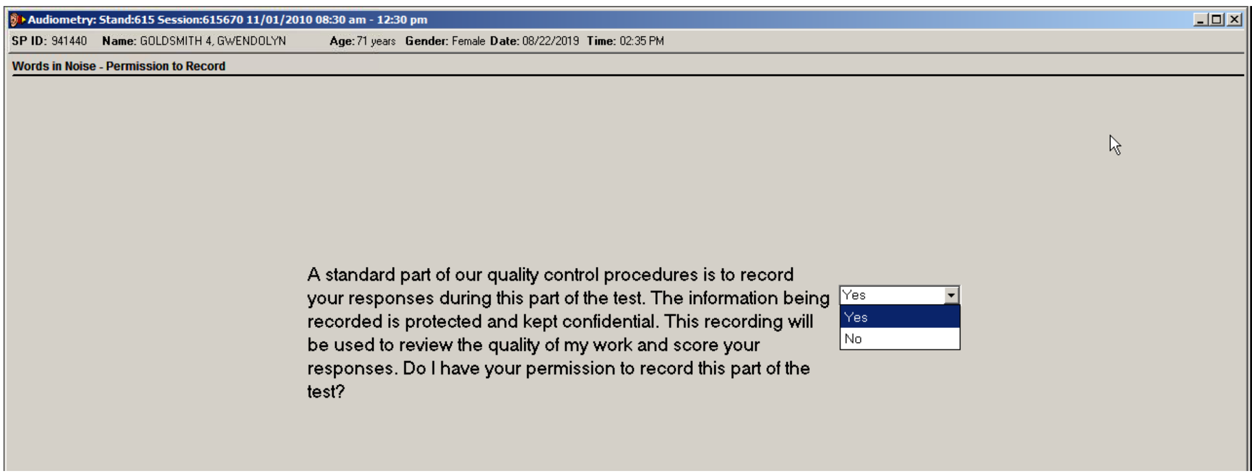
By "fluently," we mean able to speak and understand speech in English [Spanish] easily and with few mistakes.

Advance to the next ISIS screen.

4.4.3 Consent to Record SP Responses

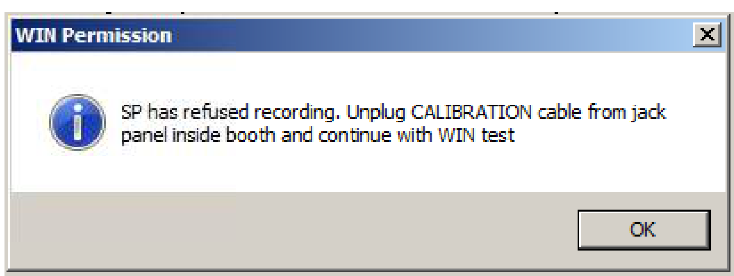
If the SP permits, we would like to record their responses on the WIN test to allow second scoring for quality assurance purposes (see Section 4.5). Read the consent text to the SP **word-for-word** from the ISIS screen (Exhibit 4-4) or the WIN instructions card to ask permission to make this recording. Record the SP's response.

Exhibit 4-4. WIN Permission to Record screen



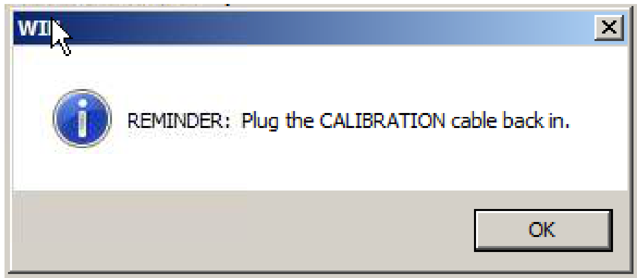
<u>If the SP does not want their responses recorded</u>, you will receive a pop-up box instructing you to unplug the calibration cable inside the test booth (Exhibit 4-5). Drape the cable over the ISIS keyboard.

Exhibit 4-5. Refused recording pop-up box



Remember to plug the cable back in at the end of the test so that it will be in place for daily QC checks and other WIN tests. You will receive a pop-up box reminding you to plug the cable back in when the test is complete (Exhibit 4-6).

Exhibit 4-6. Plug in cable reminder



4.4.4 Conducting the WIN Test

Advance to the next ISIS screen. A message window will pop up telling you which ears should be tested at which level.

Instruct the SP as follows:

> "This test checks how well you can hear speech when there is background noise. I'm going to put the headphones back on you. You will hear a woman asking you to repeat various words. All you have to do is repeat out loud the words she asks; for example, if you hear her say "Say the word dog," say "dog."
>
> "You will also hear people talking in the background during the test. Do your best to ignore them and just repeat the words you are asked to say. If you are not sure what the word was, please make your best guess. The words and noise will be in the same ear – one ear at a time.
>
> "I will be able to hear you on the other side of the booth. Try to repeat the words loudly and clearly, so I can make sure I hear you correctly.
>
> "The test will take about 5 minutes. Do you have any questions?"

Turn the SP so s/he is facing the table in the booth. Close the booth door.

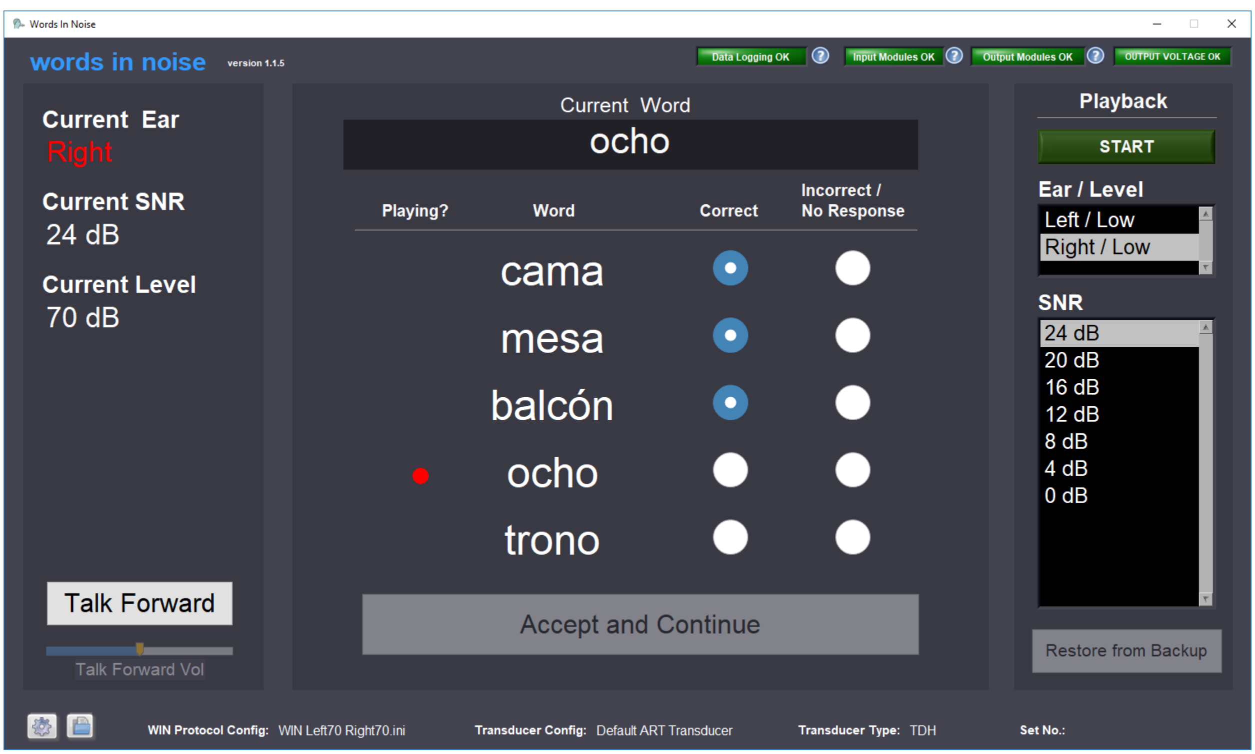
Outside the booth, put the monitoring headphones on yourself. Launch the WIN application on the ART computer. ISIS will load the correct headphone config files based on the ART config file used in the audiometry exam. ISIS also should pre-load the correct configuration files based on the SP's thresholds in each ear and the language to be used for the test. ***Always double-check that the correct config files have loaded.***

If for any reason you need to change the WIN configuration files, click the blue file folder in the lower left corner of the screen. A pop-up window will allow you to browse and select the correct WIN protocol (based on the level at which each ear should be tested) and the language for the test. Note that once you click the blue file folder, you must re-specify both the WIN protocol and the language for the test. These must be changed from the default entries displayed on the screen. Click "Continue" to return to the main WIN screen.

The WIN stimuli begin after the "START" button is pressed. Following the onset of babble noise, the talker will present each word as part of a sentence "Say the word _____." The "Current Word" text and a red circle in the "Playing?" column of the middle section can be used to track progress within the SNR. The text in the left column and the highlighted (i.e., black text on a gray background) SNR in the right column can be used to track progress across SNRs.

The tester listens to the responses from the SP and judges whether the response was correct or incorrect (Exhibit 4-7). These judgments must be made based solely on the SP's response, and a response must be judged "Incorrect" if the SP's response does not match the target word precisely. Note also that an erroneous response is incorrect even if the error does not affect the word's meaning (e.g., peso versus pesos).

Exhibit 4-7. WIN software screen - scoring



After you have entered responses to all five words at a particular SNR, click the "Accept and Continue" button to move to the next test level. If an SP misses all of the words at a given SNR, the remaining words in that ear are skipped. At that point (or when the 0 dB SNR is completed), the test will automatically move to the next test ear (if applicable).

4.4.5 Pausing and Restarting the WIN Test

To pause or stop the test, click the stop button in the top right corner of the screen. The button's text will change to read "Restart." When you are ready to resume the test, click "Restart."

When the test is restarted, WIN will go back to the beginning of the 5-word set for that SNR (even if several words have already been played). However, do not re-score any words already scored unless you think they were affected by the reason you paused the test.

4.4.6 Guidelines for Scoring SP Responses

The accuracy of the WIN test results depends on many factors, including how well the SP articulates their responses and how accurately the health technician hears the SP responses. Do not hesitate to ask the SP to speak louder or more clearly if you cannot hear them well. Moving the SP closer to the microphone may also improve audibility.

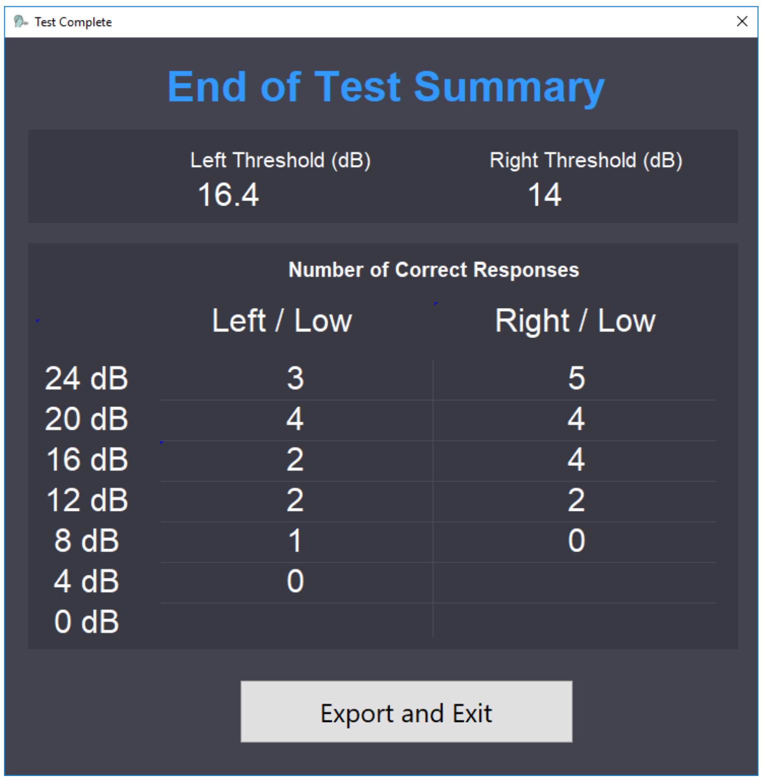
To make sure that everyone scores the test in a consistent way, please follow the guidelines below in determining whether the SP has repeated a word correctly.

- Score the first word the SP says. For example, if an SP says "Cap. No, cat" score their response as "cap."
- Score mispronunciations that do not change the meaning as correct. For example, if the SP does not pronounce the final "l" in shawl (a common mispronunciation), score the word as correct.
- Score mispronunciations that change the meaning of the word (such as plurals and tense differences) as incorrect. For example, if the target word is "dodge" and the SP responds "dodged," score the response as incorrect.

4.4.7 Saving WIN Test Results

After testing is complete, clicking "Accept and Continue" will bring up the End of Test window (Exhibit 4-8). This window displays the WIN threshold in each ear (in dB SNR – representing how much louder than the background noise the words had to be for the SP to repeat 50% of them correctly). The window also includes a table indicating the numbers of correct responses at each SNR for each ear. Empty locations in this table represent SNRs that were not tested in that ear.

Exhibit 4-8. WIN End of Test window



Following review of the summary information, press the "Export and Exit" button, which will produce output files for import into ISIS and are saved for later scoring by a second listener. The WIN application will automatically close once all the files are saved.

SPs will receive their WIN scores and a general explanation in their Report of Findings when they leave the MEC. As usual, please do not provide any feedback to SPs regarding their results.

4.4.8 Conducting the WIN Test with an Interpreter

Bilingual MEC staff have been trained to conduct the WIN test as interpreters. They understand the pre-test questions, the consent to record responses, the operations of the WIN software, and the guidelines for scoring SP responses. They have not been trained to place the headphones on the SP, to situate the SP toward the microphone, confirm that the correct config files are in place, capture the results in ISIS, or respond to SP questions about the test or its results.

When an interpreter will be conducting the test, you should remove the SP headphones (if necessary) and then have the interpreter explain the purpose of the test, ask the pre-test question(s), and obtain consent to record the responses. If the SP does not consent to recording, you should unplug the microphone cable.

The interpreter should then give the SP instructions for the WIN test. Once the SP understands the test, you should put the headphones on the SP and turn the SP to face the microphone.

Launch the WIN software for the interpreter and confirm that the correct config files have loaded. The interpreter will then conduct the test, running the WIN software and scoring the responses. When the test is complete, the WIN software will close as usual. You should capture the results in ISIS and remove the SP headphones. Complete the final ISIS screens. If the SP has any questions, provide the responses for the interpreter to translate back to the SP.

4.5 A Few Additional Procedures…

Be careful about showing facial expression during the conduct of the test. Because they are facing more forward during the WIN test, SPs may be able to observe you through the window in the booth door. Some responses may be comical, but be careful not to show it. We've told the SPs to make their best guess, so don't laugh if their best guess is way off target!

Turn the Talk Back mic on every morning and turn it off each night. The mic battery lasts 600+ hours, so a single battery should last an entire stand even if you forget to turn it off a few times. Put a fresh battery in at each set up.

4.6 Scoring Application

4.6.1 The Scoring Application

The WIN test is conducted separately in each ear of participants using 35 pre-recorded words presented in a background noise. Target words are initially presented at a level of 24 decibels above the background noise; after every five words, the level of the target words is reduced 4 decibels until they are presented at the same decibel level as the background noise. The test on each ear stops when the SP cannot repeat any of the target words correctly or when the SP reaches the lowest decibel level.

The WIN responses are scored in real-time during the exam. A second scoring of the WIN responses is complete by listening to a recording of the SP's responses given during the exam. In this chapter, "Scorer 1" refers to the staff member who scored the exam in real-time and "Scorer 2" refers to the staff member who completes the scoring of the exam by listening to the recording. Scorer 1 and Scorer 2 are never the same person. When a bilingual staff member scores the WIN exam in real-time, he/she will be Scorer 1, not the health tech.

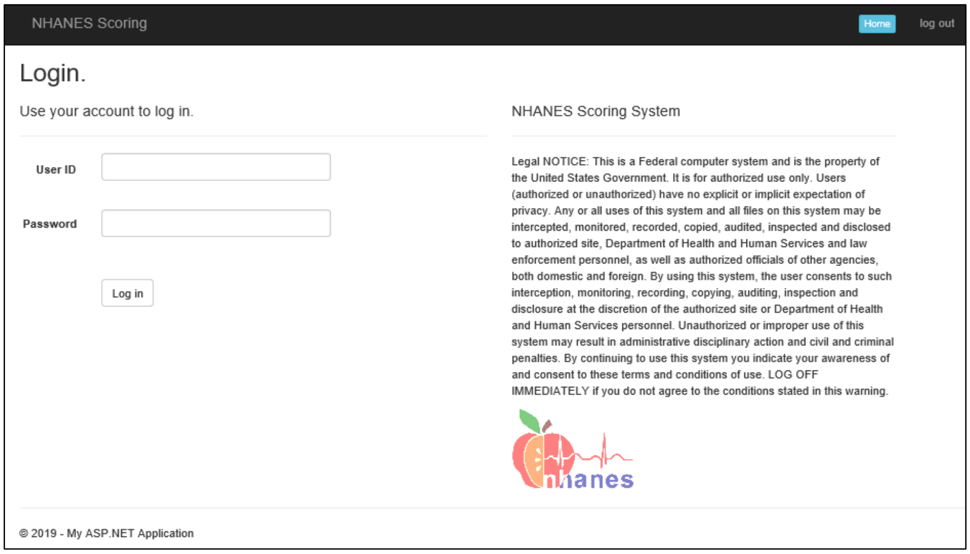
4.6.2 Log In

There is a shortcut icon to the scoring application on the desktop of both Dietary Interview computers, both MEC Interview computers, and the computer in the room behind the coordinator (Exhibit 4-9). Double click the icon to open the scoring application.

Exhibit 4-9. Scoring application shortcut icon

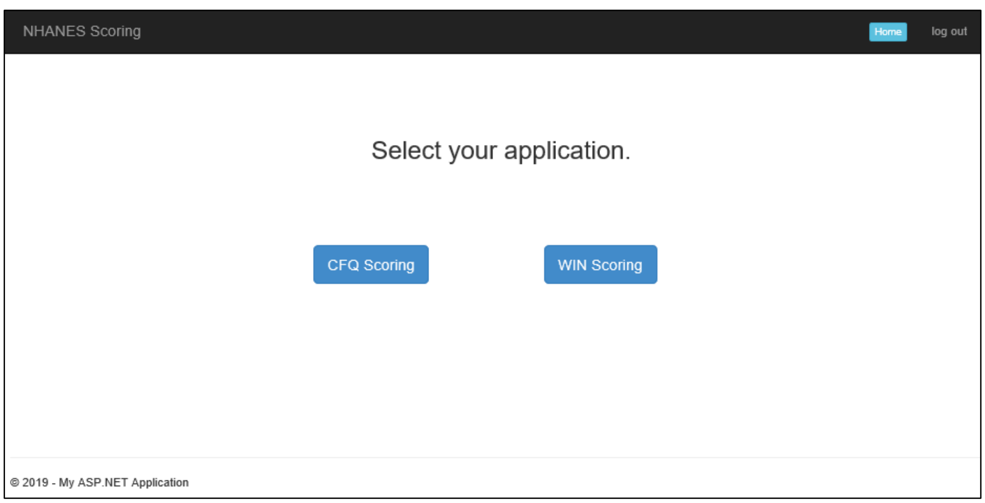
When the scoring application opens, you will need to enter your username and password and click the "Login" button (Exhibit 4-10).

Exhibit 4-10. Login screen



If you have permissions for both the Cognitive Functioning Scoring application and the WIN Scoring application, you will be prompted to select the application you wish to access (Exhibit 4-11). If you don't have permissions for both applications, you will bypass this screen.

Exhibit 4-11. Select application screen

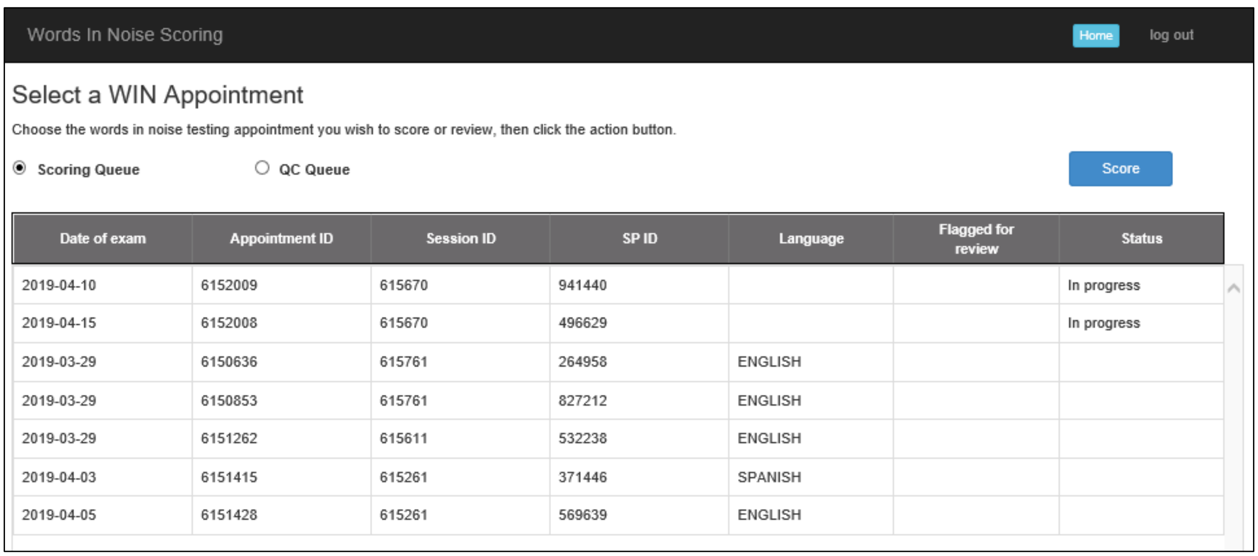


4.6.3 Main Menu

The Appointment screen, the first screen seen upon logging in to the scoring application, is a queue of all of the WIN tests that are available to score (Exhibit 4-12). WIN cases will appear in the queue of all trained staff members except the person who scored the case in real-time. The first person to select a case from the queue becomes Scorer 2 for that case and that case will then only appear in Scorer 2's queue.

The Appointment screen has seven sortable columns – date of the exam, appointment ID, session ID, SP ID, language, flagged for review, and status. The "flagged for review" column will indicate if a case has been flagged for home office review by the scorer. The "status" column will show "In Progress" if a case has been started but not finished, and "Mismatch" if a case has been scored by both scorers but the scores do not match. Cases with a status of "In Progress" or "Mismatch" will appear at the top of the queue. To sort the columns, click on the column header. To open a case in the queue to start the scoring process, select a case from the list and click the "Score" button.

Exhibit 4-12. Appointment screen



Date of exam	Appointment ID	Session ID	SP ID	Language	Flagged for review	Status
2019-04-10	6152009	615670	941440			In progress
2019-04-15	6152008	615670	496629			In progress
2019-03-29	6150636	615761	264958	ENGLISH		
2019-03-29	6150853	615761	827212	ENGLISH		
2019-03-29	6151262	615611	532238	ENGLISH		
2019-04-03	6151415	615261	371446	SPANISH		
2019-04-05	6151428	615261	569639	ENGLISH		

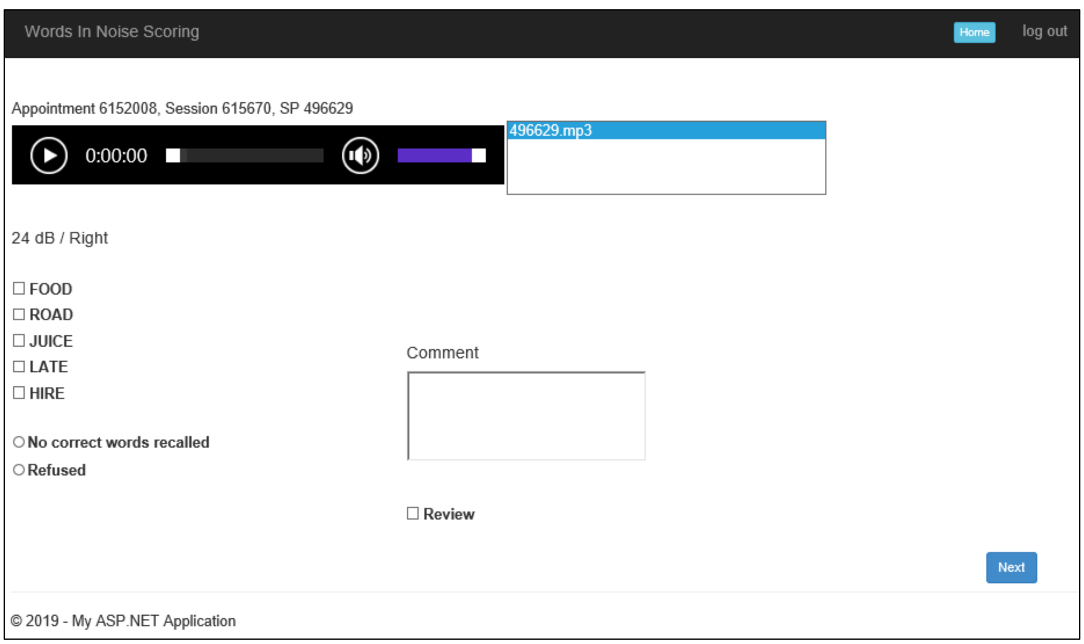
During busy sessions, there may not be time to score tests, however, whenever time allows, trained staff should check the WIN scoring queue and score cases that are there. All cases should be completed before the stand closes. That means, if WIN exams are done on the last day of exams, those cases will need to be scored the same day. Prompt scoring not only prevents backlog at the end of a stand but if there are technical issues with the recording that may impact subsequent recordings, the ISIS staff and component lead can be notified.

There is currently no notification system when a scorer has a case that needs scoring. Staff will have to log in to the scoring application periodically to check their queue. Every effort should be made to complete scoring of all cases in the queue before the stand closes. Any unscored or mismatched cases in the scorer's queues when the stand closes will be scored or adjudicated by home office staff. **Health techs will only score cases in their queue that are marked as a mismatch.**

4.6.4 Scoring the WIN Exam

The WIN test consists of a maximum of 14 screens. Each screen contains a list of the five words that the SP was asked to say at each decibel level (Exhibit 4-13). You will be recording the results from each recording. As you listen to the recording, click the checkbox for each word the SP repeats that appears in the list. You may hear the SP say words that do not appear in the list or the SP may not say anything at all. You are only recording correct words. If the SP does not repeat any correct words, select "No correct words recalled" on the screen.

Exhibit 4-13. Example of a scoring screen



Make sure you listen to the recording until it stops. Occasionally, the examiner will stop and restart the test. When the test is restarted, WIN will go back to the beginning of the 5-word set for that decibel level. When this happens, you may hear the SP repeat words that they have already repeated. Do not re-score any words already scored unless you hear something on the recording that you think interfered with the SP hearing the target word (i.e., SP had a coughing fit). After recording the results from the recording on each screen, click the "Next" button to save the results and continue to the next screen.

4.6.4.1 Common Screen Features

The scoring screens have certain features in common. These include a "review" check box, a comment box, and a recording control box.

Scorers may flag a test for review by the component lead if there are questions or concerns about a recording or item, by checking the "Review?" check box on the screen. Items flagged for review will be reviewed by the component specialist.

All screens have a comment box, which allows the interviewer to record comments about the exam or recording. The component lead will review these comments during QC or adjudication. Please note that these comments are not reviewed immediately, so anything that needs urgent attention should be relayed to home office staff using another method.

Each screen has a recording control box that allows the interviewer to control the recording (Exhibit 4-14). The volume of the recording can also be adjusted by dragging the volume button left or right. When listening to recordings, make sure the volume on the computer is also turned up.

Use the "Play/Pause" buttons to start and stop the recording as necessary. A play bar moves along as the recording plays. If you need to hear a word in the recording again, it is best to let the recording finish playing and start the recording again by clicking the Play icon. The WIN recording is one long recording of all of the words from the WIN exam. The scoring application is programmed to start and stop the recording in the appropriate spot for each screen. If you click or drag the play bar to rewind or fast-forward the recording, you may end up hearing a set of words for a different screen. If this happens, the easiest way to get back to the correct spot is to back up to the previous screen and advance forward again.

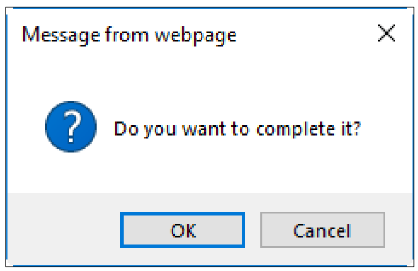
Exhibit 4-14. Recording control box

4.6.4.2 Exiting and Saving Scores

If you need to exit a case before you finish scoring, you can save the scoring you have done on one screen by advancing to the next screen. To exit a case early, click the "Home" or "Logout" button. Partially scored cases will appear at the top of the scoring queue.

When you click "complete" on the last screen, a pop-up message appears to confirm that you want to complete the case (Exhibit 4-15). Clicking "OK" will remove the case from your queue and it will only return if there is a mismatch.

Exhibit 4-15. Complete scoring confirmation pop up



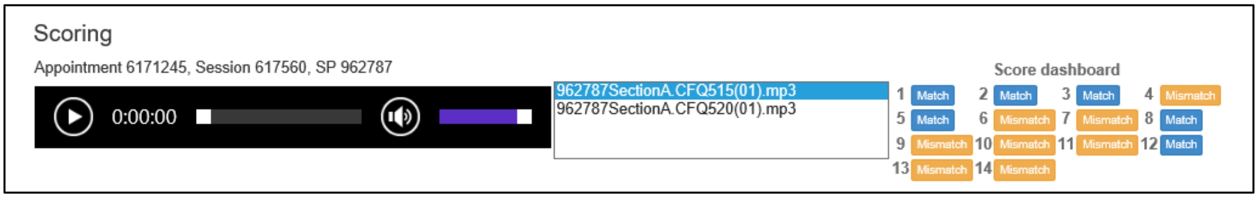
The scoring application automatically logs the user out after an extended period of inactivity.

4.6.4.3 Mismatches

If there is a score discrepancy (i.e., the score by Scorer 1 does not match the score by Scorer 2), the test will be put back into the queue for Scorer 2 and will also appear in the queue for Scorer 1 for rescoring. The case will be marked as a mismatch in the status column on the Appointment screen and will appear at the top of the scoring queue.

Only one attempt to resolve a mismatch will be made. If a case is marked as "mismatch," only the mismatch screens will display when the case is opened. In the top right corner of the screen is a score dashboard (Exhibit 4-16). The score dashboard indicates which screens have matching results and which screens do not have matching results.

Exhibit 4-16. Score dashboard



Scorers should carefully listen to the recordings on each screen and rescore the case. After this attempt, the case will permanently be removed from the queue even if the mismatch still exists. If a mismatch still exists, the responses coded in real-time will be saved as the final results.

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Appendix A

Inventory of Audiometric Equipment and Supplies

Appendix A
Inventory of Audiometric Equipment and Supplies

Consumable

Site ID: MEC 3

Part #	Description	Par	Unit	Count
EXAM SUPPLIES				
8012972	10mm Mushroom Style Eartip	40	each	
8012974	11mm Mushroom Style Eartip	40	each	
8012976	12mm Mushroom Style Eartip	50	each	
8012978	13mm Mushroom Style Eartip	100	each	
8012980	14mm Mushroom Style Eartip	80	each	
8012982	15mm Mushroom Style Eartip	75	each	
8120347	19mm Mushroom Style Eartip	20	each	
8013002	7mm Mushroom Style Eartip	20	each	
8013004	8mm Mushroom Style Eartip	20	each	
8012970	9mm Mushroom Style Eartip	50	each	
58-104	Alcohol Wipes	1	box	
STO-01302	Audiowipes - 160 wipe canister	1	bottle	
2865460	Cleaning Floss 3 in1 - 200 pc box	2	box	
2860744	Cleaning Floss Bridge & Implant - 30 pc box	2	box	
SO-EPG	Ear Phone Guards, Paper	2	box	
RAS-420-2006	EarLink 3A Tips (Foam, Small)	50	each	
RAS-420-2005	EarLink 3A Tips (Foam, Standard)	75	each	
RAS-420-2028	EarLink 3A Tips (Foam, X-Large)	20	each	
9022	Gauze Pads (2 x 2)	2	pack	
GOJ-3639-12CT	Handsoap-Waterless (Purrell) -	1	bottle	
STH-100	Kids Cartoon Sticker - Hearing Tested	1	roll	
PJZ49-04	Large Black Earphone Covers - Stretch	1	bag	
52432	Otoscope Specula (Kleenspec - 2.5 mm)	3	sleeve	

52434	Otoscope Specula (Kleenspec - 4.25 mm)	6	sleeve	
793578	Purell Sanitizing Wipes - 270 Pack Bottle	1	bottle	
OFFICE SUPPLIES				
EVEEN22	Batteries, 9-Volt - do not count what is in equip.	15	each	
EVEEN91	Batteries, AA Cell - (spares, do not count what is	4	each	
EVE357BPZ3	Battery, 1.5 Volt Button - Energizer 357	1	each	
UNV43671	Markers, Dry Erase (Black) - Fine Tip	2	each	
SPARE PARTS & TOOLS				
72300	Otoscope Battery, 3.5 volt - DO NOT count what is in equip	2	each	
	Lot: 2017-03 Exp DT: 06/30/2019			
	Lot: 2017-10 Exp DT: 01/31/2020			
	Lot: 2018-08 Exp DT: 11/30/2020			
03100	Otoscope Bulbs (Halogen 12v/20watt) - do not count bulbs in equip.	2	each	
COMPONENT TOOLS				
S-8028	Humidity Indicator Strips - 10 - 60% Read-Out	1	can	
S-20191	Large Desiccant Pack, 5 x 5 pack - Do Not Count Ones In Use	6	each	
S-3902	Small 1 Gram Desiccant Pack	25	each	
871701	Zip-Lock Sandwich Bags	1	box	
MEC SUPPLIES				
PC720891	Tissues - Facial	2	box	

* Expired Lot

Non-Consumable

Site ID: MEC 3

Part #	Description	Par	Unit	Count
EXAM SUPPLIES				
ER3-04	Eartip Connectors (white) - do not count tips on equip.	10	each	
SO-HB	Headband for Standard Headphones	2	each	
OFFICE SUPPLIES				
UNV40304	Clipboard	2	each	
SPARE PARTS & TOOLS				
41005	Hex Key Set, Standard, Buck Bros. 7 pc.	1	each	
62-104	Screwdriver, Straight Head	1	each	
EMERGENCY SUPPLIES				
COMPONENT TOOLS				
Int. Manual	Asian Interpreter Manual - Audio	1	each	
9688K221	Audio Jack Cover - 1/4 Inch Plastic Cap	25	each	
LM-20	Deskbrite 200 Lighted Magnifier - Battery Powered	1	each	
	Desktop Eartip Storage Box - Infinite Divider System Box	1	each	
IVR51506	MicroFiber Cleaning Cloth - 6" x 7" Gray	1	each	
WBB2057872	Mini Gel Wrist Pad - Black	1	each	
8011348	Probe Cleaning Tool	2	each	
8122239	Probe Tip - For Sanibel Eartip	2	each	
226207	SP Jewelry Container - 250mL Plastic Box with Lid	1	each	
6942629250333	Storage Box - Mushroom Eartips - Locking Plastic Organizer	1	each	
226207	Storage Box - Small Eartips - 250mL Box with Lid	1	each	
226206	Storage Box - Standard Eartips - 500mL Box with Lid	1	each	
226206	Storage Box - XLarge Eartips - 500mL Box with Lid	1	each	
14J24E	Touchscreen Stylus - Insignia Slim Model	1	each	

* Expired Lot

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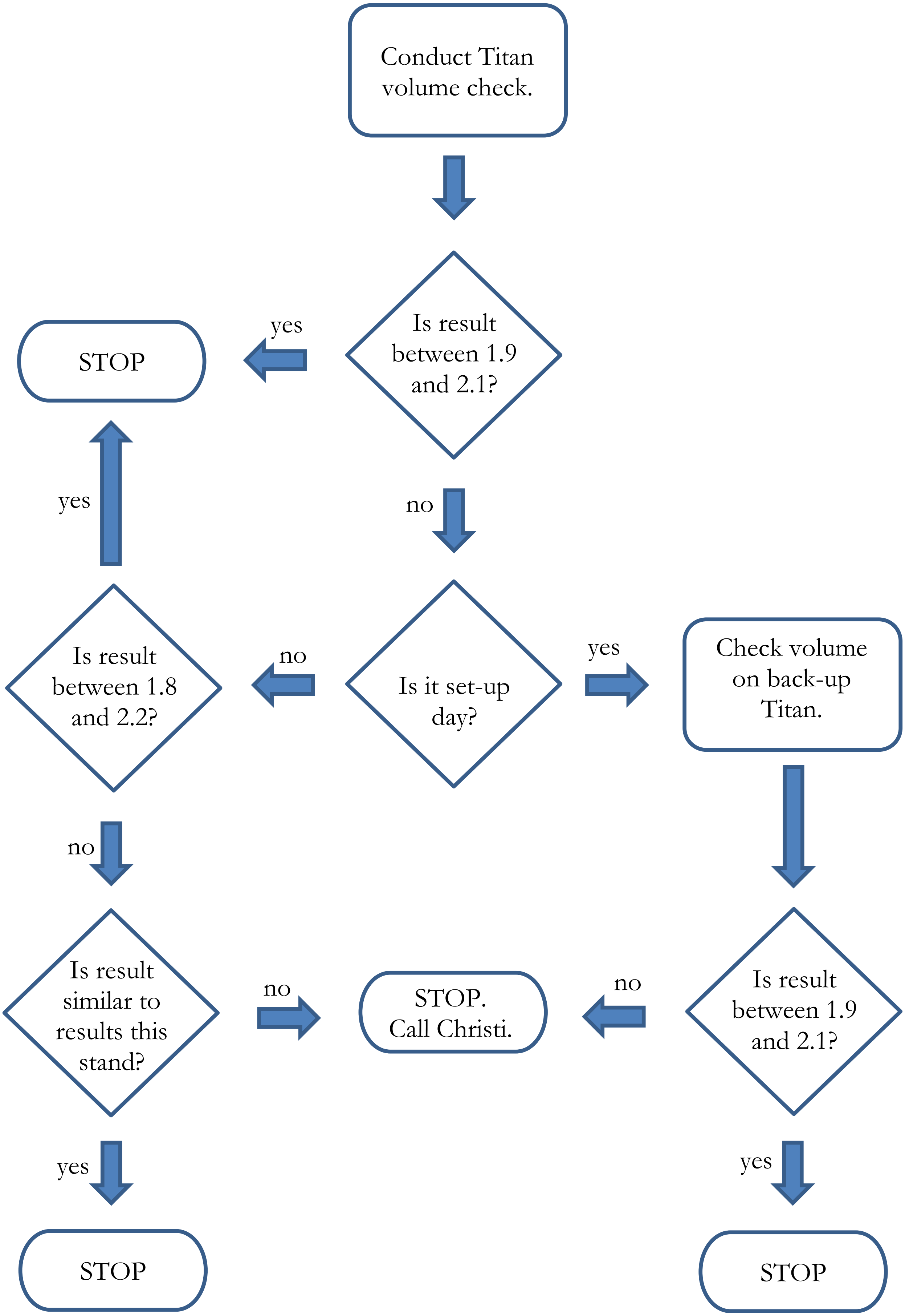
Appendix B

Titan Flow Chart


Conduct Titan volume check.
Is result between 1.9 and 2.1?
yes
STOP
no
Is it set-up day?
yes
Check volume on back-up Titan.
no
Is result between 1.8 and 2.2?
yes
STOP
no
Is result similar to results this stand?
no
STOP. Call Christi.
yes
STOP
Is result between 1.9 and 2.1?
no
yes
STOP

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Appendix C

Assembling and Disassembling the ART System

Appendix C
Assembling and Disassembling the ART System

C.1 Assembling the ART System

Unpack the ART chassis (be aware… it is HEAVY) and response switch box, along with all of the accompanying cords and cables. These include:

- the power cable for the chassis (see NOTE below)
- the ART Chassis-Computer cable
- two BNC headphone cable assemblies
- the ridiculously massive response switch cable

Note: Whenever possible, we will leave ART cables that have to be fed through tight locations (such as behind the table) in place. If a required cable is not packed with the system, check to see if the cable is already in place in the room.

On the back of the chassis, plug in the power cable and screw either end of the ART Chassis-Computer cable into the appropriate connections. See Exhibit C-1:

Exhibit C-1. Connections on the back of the ART chassis

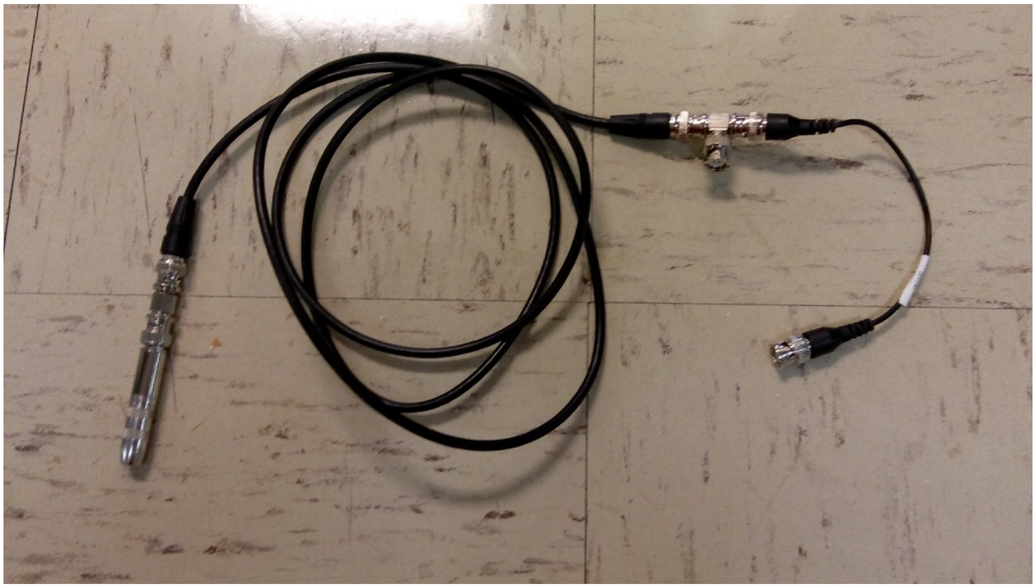
Turn the chassis forward and set it on the top left shelf of the table outside the sound booth. If necessary, feed the power cable behind the back of the shelf and plug it into the power strip plugged into the outlet to the right of the table. Feed the other end of the Chassis-Computer cable behind the shelf; it will connect to the back of the ART computer tower. Slide the chassis as far back as possible on the shelf. Try to leave a little space on either side of the chassis for air to circulate through the side vents.

On the front of the chassis, connect the "T" connector of the left BNC headphone assembly (the one marked with blue tape) to the connection labeled "Left Electrical." To do this, line up the notch on the T-connector with the pin on the chassis connection and spin the ridged ring on the T-connector to the right until it locks in place. Exhibit C-2 shows a close up of BNC-type connectors.

Exhibit C-2. BNC-style connectors. The ridged ring will spin right or left to lock or unlock the connection, respectively. The connector disconnects when the square notch is lined up with the connection pin and locks in place when the round notch is lined up with the connection pin

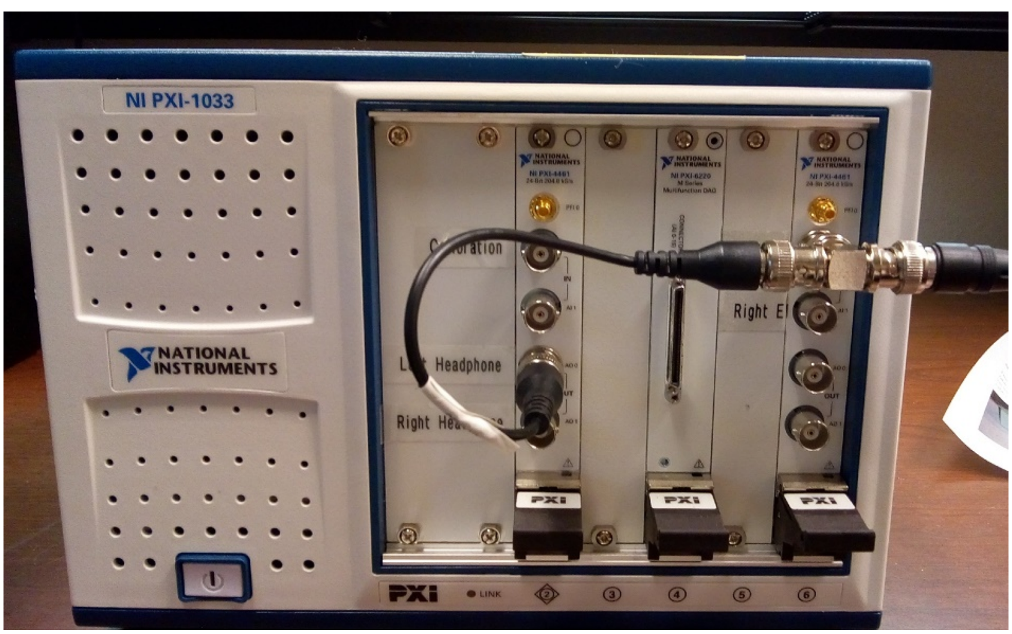
Note: Each headphone assembly is made of three parts – a T-connector; a long, heavier cable; and a very short, thin cable (see Exhibit C-3). If it is easier to make connections to the chassis by taking them apart, that is fine. For example, if you need to temporarily disconnect the thin cable from the right side of the left headphone connection while you screw in the ridiculously massive response switch cable, that's fine. Just reconnect it when you are finished.

Exhibit C-3. **Headphone cable assembly illustrating the three parts: a long, heavy cable (left part of cable assembly); a T-connector (center); and a short, thin cable (right part of assembly)**



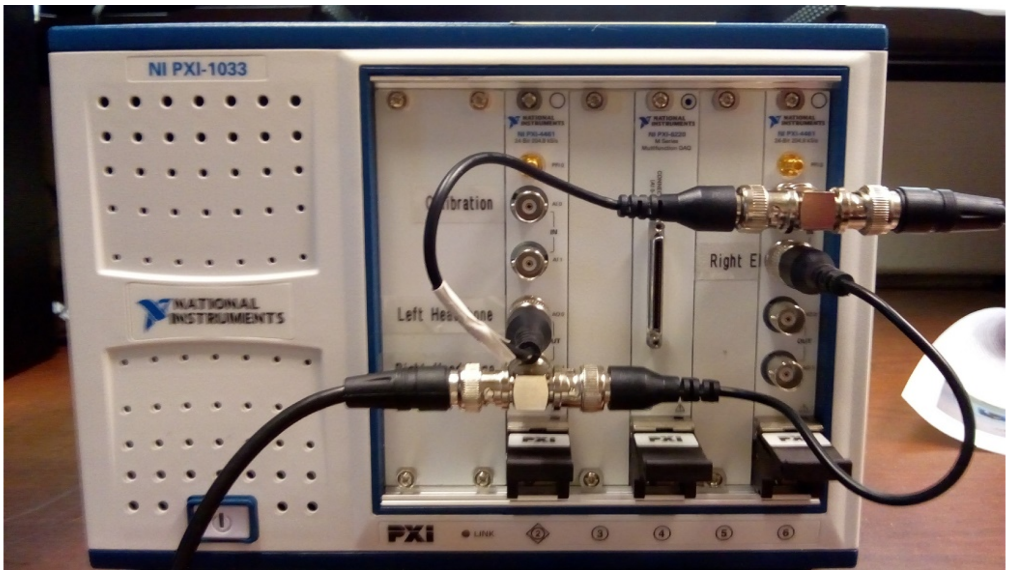
Connect the other end of the short, thin cable on the headphone assembly to the input on the front of the chassis labeled “Left Headphone.” The other end of the long, heavy cable will be connected to the “Audio” cables from the headphone selector box. The front of the chassis should now look as shown in Exhibit C-4.

Exhibit C-4. **Left BNC headphone assembly attached to the front of the chassis**



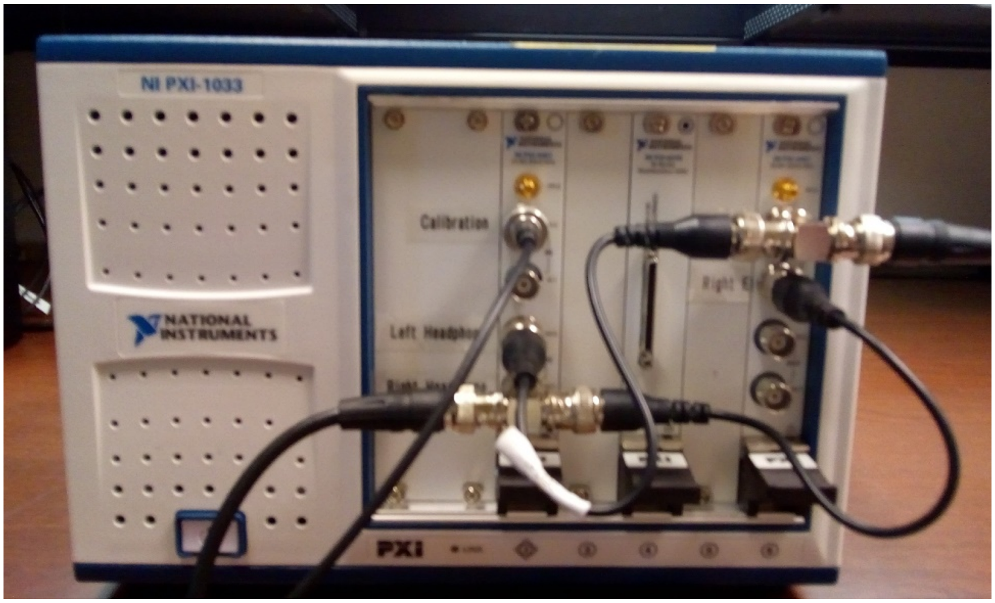
Now connect the "T" connector of the right BNC headphone assembly (the one marked with red tape) to the connection labeled "Right Headphone." Connect the other end of the short, thin cable to the input labeled "Right Electrical." The front of the chassis should look as shown in Exhibit C-5.

Exhibit C-5. Right BNC headphone assembly attached to the front of the chassis



Connect the long, thin cable labeled "Calibration" to the connection also labeled "Calibration," just as you do when setting up at Start of Stand. The front of the chassis should now appear as shown in Exhibit C-6.

Exhibit C-6. Calibration cable attached to the front of the chassis

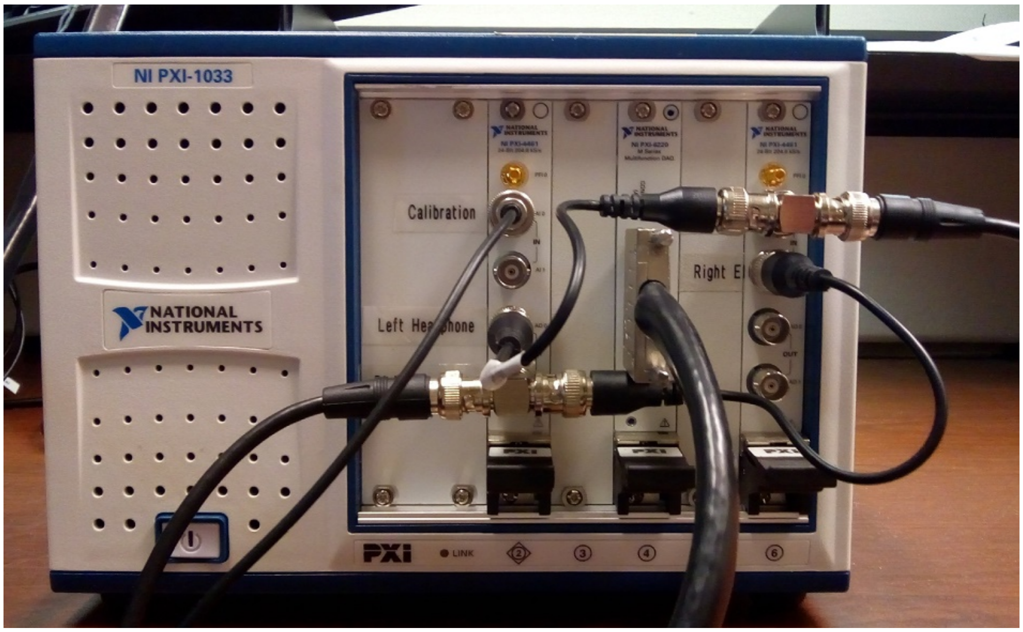


Connect the blue end of the ridiculously massive response switch cable to the square National Instruments response switch box and tighten the screws. See Exhibit C-7.

Exhibit C-7. Ridiculously massive response switch cable attached to the National Instruments response switch box

Connect the silver end of the ridiculously massive response switch cable to the front of the chassis and tighten the screws. The connections on the front of the chassis are now complete, and it should look as shown in Exhibit C-8.

Exhibit C-8. Front of ART chassis with all connections in place

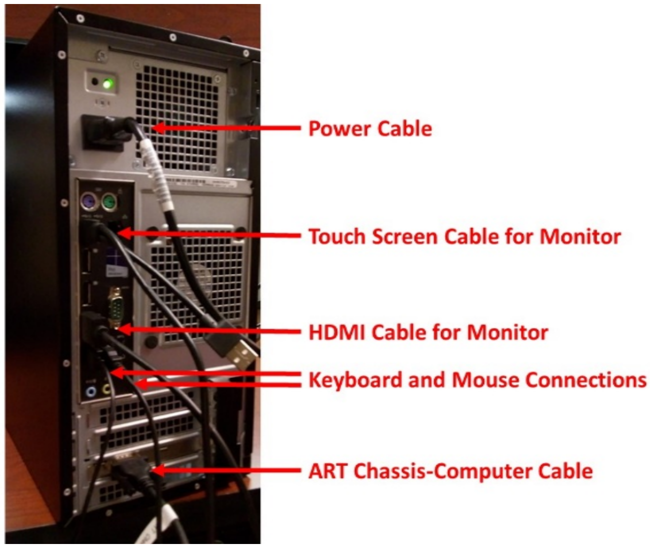


Unpack the ART computer tower, keyboard, mouse, and power cord (if necessary… with any luck, it will still be in place, dangling behind the table in front of the sound booth). Set the keyboard and mouse on the top of the table and drop the cables down at the back of the table.

Connect the following seven cables to the back of the computer tower, using Exhibit C-9 as a guide.

- Connect the power cable to the connection toward the top of the tower.
- Connect the HDMI cable from the monitor (which is probably in the cable holder on the table) to the connection labeled "HDMI" toward the center of the tower.
- Connect the Touch Screen cable from the monitor (which is also likely to be in the cable holder on the table) to any available USB port.
- Connect the keyboard and the mouse cables to any available USB port.
- Connect the ART Chassis-Computer cable to the connection near the bottom of the tower. Tighten the pins.
- Connect the ISIS computer cable to the network port just above the Windows logo tag (see the Facilities Equipment Specialist [FES] for assistance if needed).

Exhibit C-9. Back of ART computer tower showing all connections in place



Turn the ART computer tower around and slide it in place on the floor in the space under the ART chassis.

Congratulations! The ART system should now be all set and ready to go. Plug in the monitor, headphones, and response switch as you normally do when setting up the Audiometry room at the Start of Stand (see Chapter 2, Section 2.3) Power the system up as usual, following the instructions in Section 2.3.2. Conduct the same calibration checks you would at Start of Stand (see Section 2.4.2) to verify that the system is working properly.

C.2 Disassembling the ART System

Power down the ART system as usual, turning off each component in the following order:

- Turn off the ART computer tower by clicking the Power icon on the task bar on the monitor, then selecting “Shut down.”
- Turn off the monitor by pressing the “Power” button on the top of the left side.
- Turn off the ART chassis by pressing the “Power” button in the top left corner of the front of the unit.

If you are disassembling any other part of the ART system for shipment (for example, the monitor, headphone selector, box, etc.), follow the teardown procedures described in Chapter 2, Section 2.8.2 for those components.

Some cables for the ART system run behind the table in front of the sound booth and are difficult to put in place. These cables are summarized in Exhibit C-10 and are noted in the instructions that follow. Unless you are specifically requested to pull these cables, leave them in place. If possible, secure them to a convenient place with tape or in the cable holder so they are easy to retrieve when the system is re-installed.

Exhibit C-10. Cables that should be left in place when disassembling the ART system, unless specifically requested to do otherwise

ART chassis cables	ART computer cables	Monitor cables
Power Cable	Power Cable	Power Cable
	ISIS Computer Cable	Touch Screen Cable
		HDMI (Video) Cable

Disconnect the white cables labeled "AUDIO" coming from the selector box from the ART headphone cables.

Note: Be sure to disconnect the cables at the point that the switch box cable connects to the jack on the ART cable; do not leave the jack connectors on the switchbox cables. Refer to Exhibit C-11.

Exhibit C-11. Correct (left) and incorrect (right) point of disconnection between the headphone selector box cables and the ART headphone cables

On the front of the ART chassis, disconnect the BNC headphone cable assemblies where they are attached to the right headphone, left headphone, right electrical, and left electrical inputs. To do this, turn the ridged part of the silver connector to the left; the connection will slide along a track until it reaches a point where you can gently pull it straight out. Pull the cables out and set them aside for packing.

Also disconnect the BNC cable labeled "Calibration" from the front of the chassis. Unless specifically requested to send it, tape the cable to the chassis shelf.

Note: It may be difficult to get your fingers in the right place to unscrew the BNS connections. If it is easier, you can disconnect the cables from either side of the T-connector, remove the T-connector from the chassis input, then reconnect the cables to the T-connector.

Unscrew the ridiculously massive 42-pin cable for the response switch box from the front of the ART chassis from the square response switch box.

Pull the chassis forward (it is HEAVY). On the back of the chassis, unplug the power cord and unscrew the two pins that hold in the ART Chassis-Computer cable. Unless specifically instructed to pull out the power cable, leave it in place and tape it to the shelf where the chassis sits. Set the chassis and the headphone assembly cables aside for packing.

Unscrew the other end of the ridiculously massive 42-pin cable from the response switch box. Set the cable and the box aside for packing.

On the back of the ART computer tower, unplug the power cable at the top of the tower. Unless specifically requested to send it, tape the power cord to the vertical table support (or some other convenient place). Disconnect the HDMI cable and also tape it to the vertical table support. Disconnect the USB connections for the keyboard and mouse. Pull the keyboard and mouse out and set them aside to ship back with the tower. Unscrew the two pins for the ART Chassis-Computer cable and pull the cable out. Disconnect the ISIS computer cable (see FES for assistance, if needed); tape the cable to the vertical table support. Set the ART computer tower and the ART Chassis-Computer cable aside to ship back.

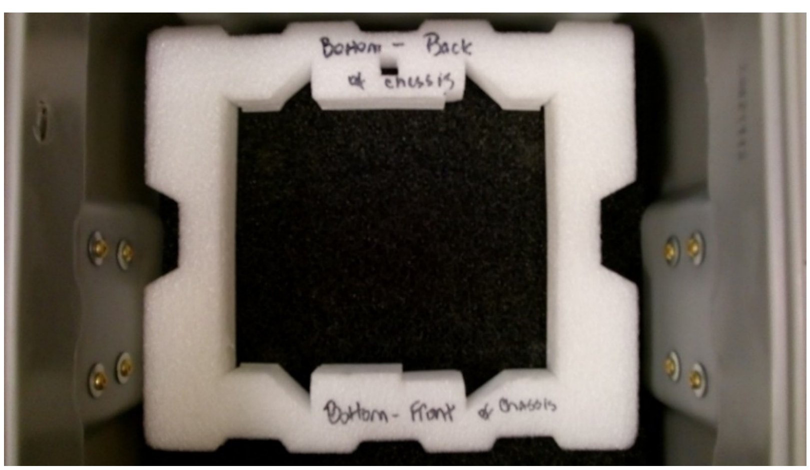
C.3 Packing the ART System for Shipment

The ART chassis and associated cables should be packed in the square, dedicated Pelican case. Inside the Pelican case is a cardboard box labeled “NI Accessories” for the ART cables and response switch box. Put the response switch box and the massive cable in separate bubble wrap pouches in this box. Also put the two headphone cable assemblies and the ART Chassis-Computer cable in this box. If you need to, use the extra bubble wrap in the box to keep things from sliding around too much. See Exhibit C-12. Close the box and set it aside.

Exhibit C-12. Response switch box and cables packed in the cardboard “NI Accessories” box

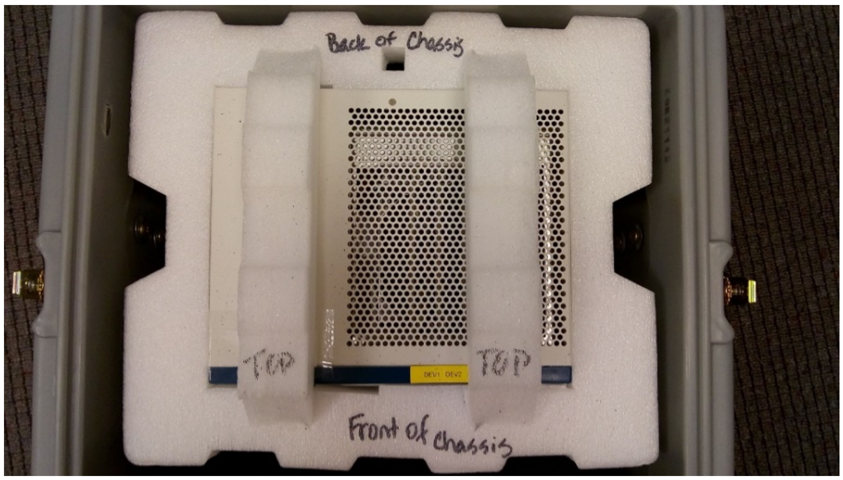
Inside the Pelican case are two white foam braces for the chassis. Pull the top one out of the Pelican case; leave the foam labeled “Bottom” in the case with the handwritten words facing up, as shown in Exhibit C-13.

Exhibit C-13. Bottom foam brace for chassis in the Pelican case



Set the chassis into this foam brace, with the front of the chassis toward the side labeled front. Slide the top foam brace over the chassis, again with the handwritten lettering facing up and following the labeled front and back of chassis guides. It should look like the image shown in Exhibit C-14.

Exhibit C-14. ART chassis in the Pelican case with foam braces



Slide the accessories box in the remaining space. Slide the lid of the Pelican case over everything (note that the lid has one side with the foam cut back to accommodate the accessories box). It may be easier to slide the accessories box into the case lid first, then slide the whole thing over the base of the Pelican case. Close all eight latches of the Pelican case.

Pack the ART computer tower and its accessories in the Dell cardboard box. Inside the computer box are two foam braces that are labeled a bit cryptically. On one corner of each brace is either an "F" (indicating that it is the brace for the front of the tower) or a "B" (indicating that it is the brace for the back of the tower). There is also an arrow showing you which end of the brace is the top. See Exhibit C-15.

Exhibit C-15. Foam braces for ART computer tower

Using these cryptic labels to help you (the foam is also cut differently for the front and back and only fits nicely one way), slide the foam braces onto the front and back of the computer tower. Once you have them in place, lay the tower in the bottom of the computer box on its side, as shown in Exhibit C-16.

Exhibit C-16. ART computer tower placed in Dell computer box

If you are shipping the monitor as well, the monitor box will fit between the two foam braces, as shown in Exhibit C-17.

Exhibit C-17. ART monitor packed on top of computer tower

Put the keyboard in its box, and place this on top of the monitor (or directly on top of the tower, if you are not shipping the monitor). Wrap the mouse and the computer tower power cord in bubble wrap and slide them alongside the tower wherever they fit. Put the extra bubble wrap over the top of everything to fill the box to the top, then seal the box.

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Appendix D

Monitoring ART System Temperatures

Appendix D
Monitoring ART System Temperatures

D.1 Background

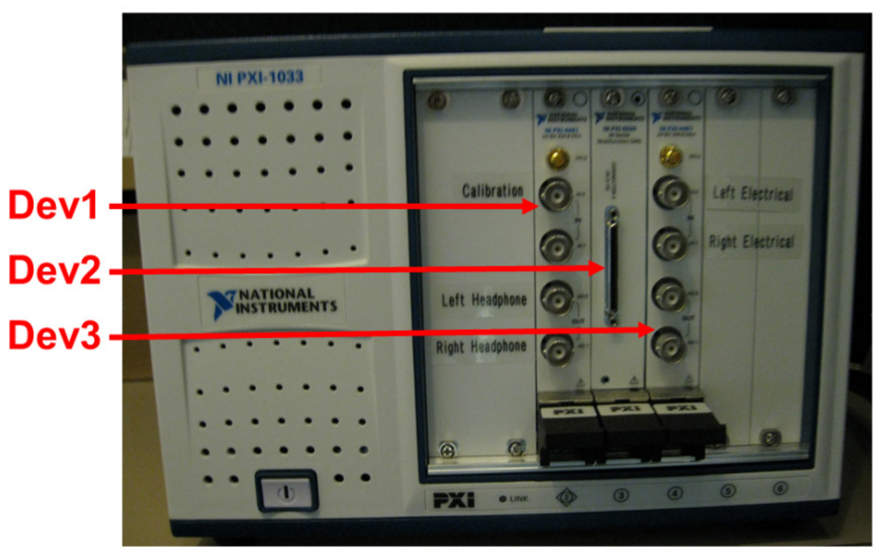
Like all electronic devices, the circuitry in the ART system generates a certain amount of heat. If the ART chassis becomes too warm, signal processing times can increase, reducing system performance. In addition, system components can wear out more quickly. If the temperature becomes high enough, the system will stop working altogether. Under normal conditions, the ART system should operate below 40°C (about 100°F). Temperatures above 50°C (about 120°F) are cause for concern, and temperatures above 60°C (140°F) can cause the system to fail.

Checking ART temperatures is done on an as-needed basis. At times, you may be requested to check the ART temperatures as a way of troubleshooting problems or on a particular schedule for a certain period. If you are ever concerned about the temperature of the ART system, please check it yourself… it only takes about a minute to do.

D.2 Checking ART System Temperatures

The ART chassis contains three boards, as shown in Exhibit D-1.

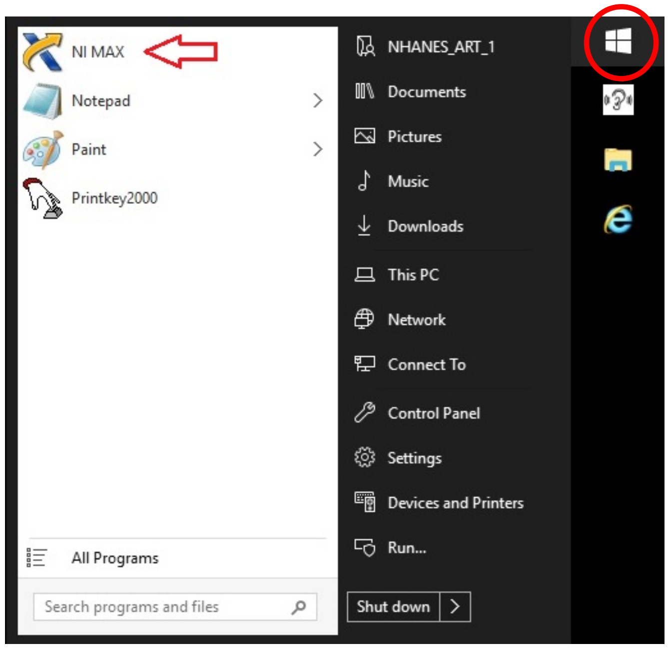
Exhibit D-1. Boards inserted into the ART chassis



The board on the left (Dev1) runs the testing and calibration, the center board (Dev2) runs the SP's response switch, and the board on the right (Dev3) is a duplicate of Dev1 and is there primarily as a back-up should Dev1 fail.

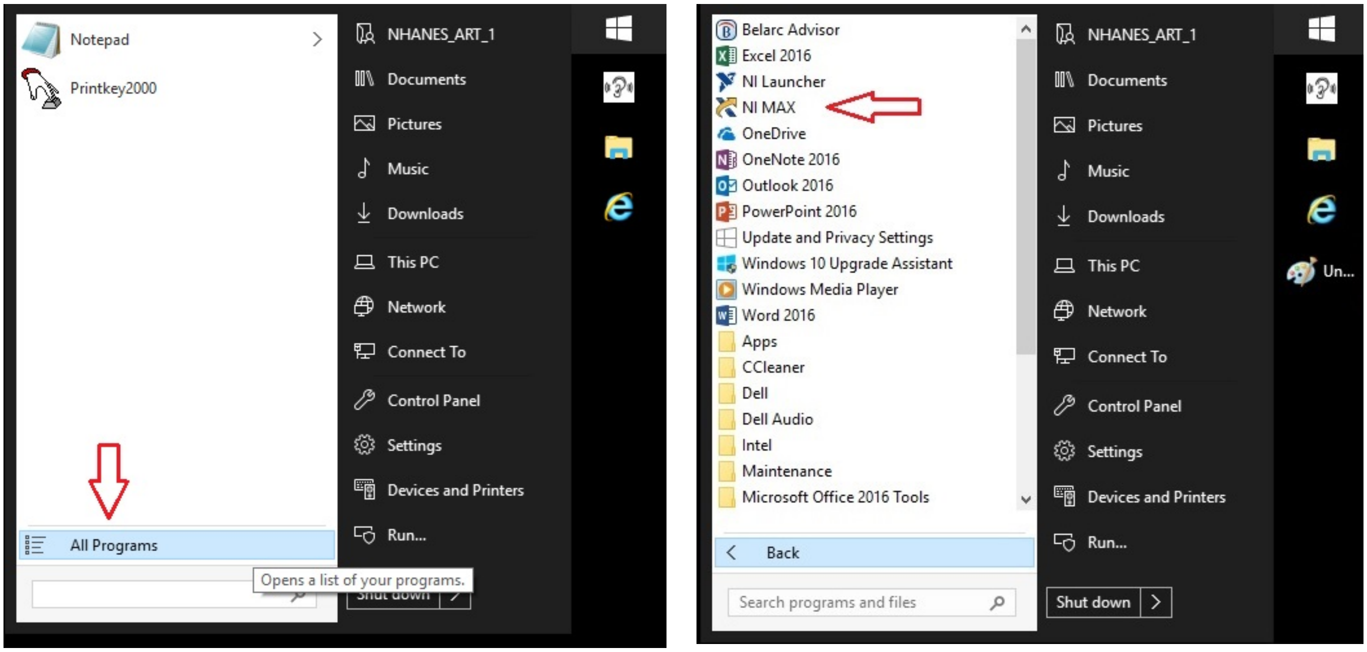
The ART system has a separate program called NI MAX (National Instruments Measurement and Automation Explorer) that is used to test the internal functions of the system. This program can check the operating temperature of each ART component. To open NI MAX, click the Windows icon in the top right corner of the ART computer screen (circled in Exhibit D-2). Look for a program called "NI MAX" in the list to the left (see arrow). If you see it, click to open it.

Exhibit D-2. Opening the NI MAX program



If you do not see NI MAX in the left menu, click "All Programs" at the bottom of the list, then look for it in the new list that pops up on the left side of the window, as the arrows in Exhibit D-3 show. Click to open NI MAX.

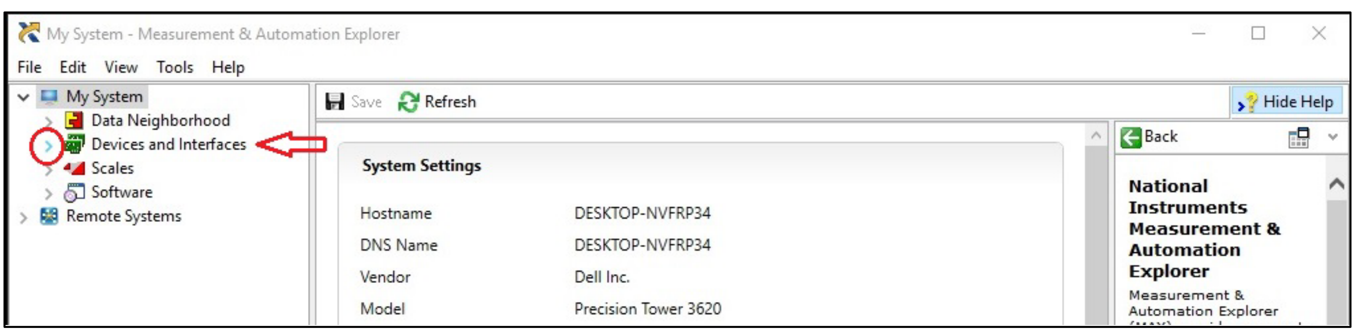
Exhibit D-3. Finding NI MAX in the list of all programs



Note: Once you've opened NI MAX once, Windows should "remember" it and put it in the program list in the future, as shown in the first image.

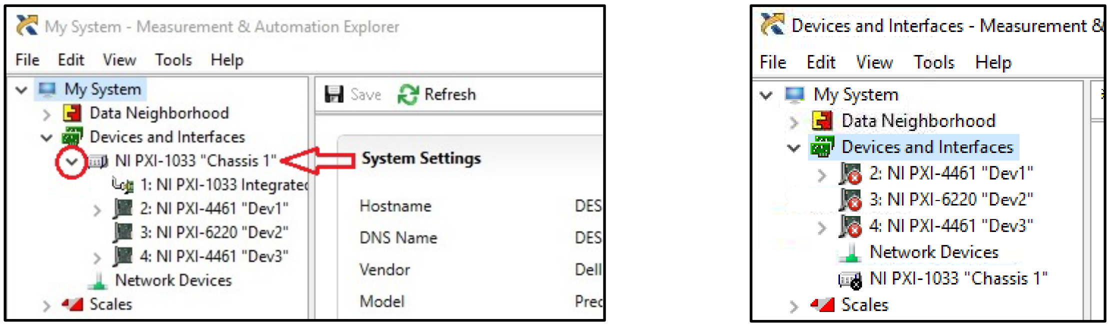
In the left panel of the main NI MAX window, click the **>** next to "Devices and Interfaces" to expand the list (see Exhibit D-4).

Exhibit D-4. Expanding the list of devices and interfaces in NI MAX



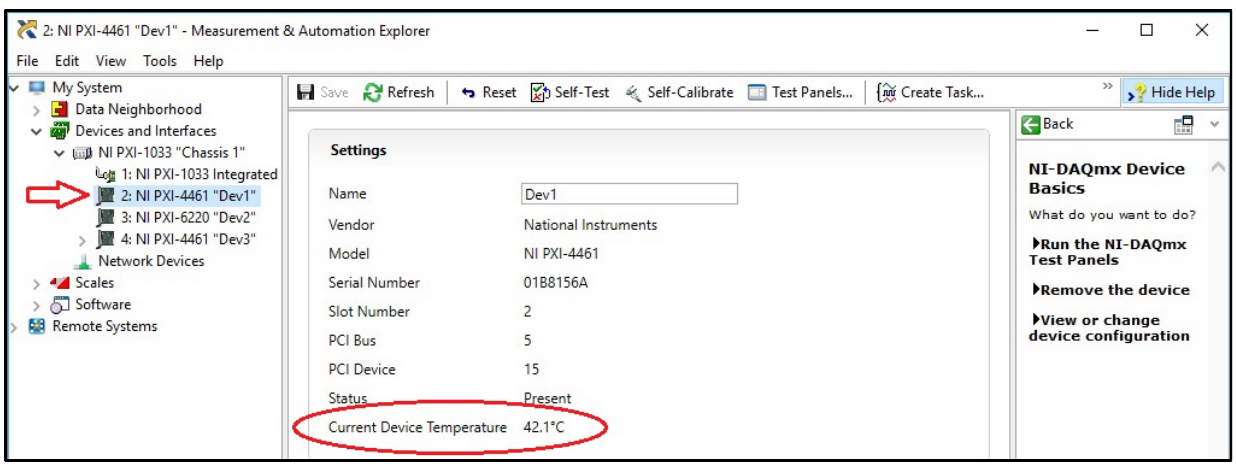
Then click the **>** next to "NI PXI-1033 Chassis 1" to view the list of boards in the chassis. The list of boards may appear in a different order on each system (as shown in the two images in Exhibit D-5), but you should see a Dev1, Dev2, and Dev3.

Exhibit D-5. Viewing the three ART boards in NI MAX



Click on the device called NI PXI-4461 "Dev1" from the list. Record the "Current Device Temperature" shown at the bottom of the "Settings" box (see Exhibit D-6).

Exhibit D-6. Finding the current ART board temperature in NI MAX



Repeat for NI PXI-6220 "Dev2" and NI PXI-4461 "Dev3."

Click the **X** in the top right corner of the screen to close the program.

D.3 Recording ART System Temperatures

Temperatures should be recorded on a hard-copy log (see Exhibit D-7). This form is stored as "ART Temperatures Form" in the Audiometry MEC blank forms directory.

Exhibit D-7. Form for recording ART temperatures

ART CHASSIS TEMPERATURE CHECKS *NHANES AUDIOMETRY 2017-2018*

ART System: ART_____ Stand: ________________________

If any temperature ever exceeds 50° C, please notify Christi.

Date	Time	Tech ID	Temperatures Dev1	Dev2	Dev3
			°C	°C	°C
			°C	°C	°C
			°C	°C	°C
			°C	°C	°C
			°C	°C	°C
			°C	°C	°C
			°C	°C	°C
			°C	°C	°C

If any temperature ever exceeds 50° C, please call Christi right away. You do not have to stop testing, but please let Christi know as soon as possible.

The hard-copy log is the only record of ART temperatures. Please send the form back to Christi whenever requested. If any ART temperature forms are still on the MEC at the end of a stand, please send them to Christi when you tear down.

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Appendix E

Examples of Report of Findings

Appendix E
Examples of Report of Findings

A preliminary and final Report of Findings will be provided to participants after the MEC exam. The results are explained and tailored to each participant's results. There are many variations of the messages that participants receive. Below are only a few examples of the types of messages SPs may receive.

Examples of the Preliminary Report of Findings

6-19 years old with normal hearing

The softest sounds {you are/your child is} able to hear are called hearing thresholds. {Your/Your child's} thresholds at different frequencies (pitches) are reported in the table below. The lower pitched sounds are toward the left of the table and the higher pitched sounds are toward the right. Smaller numbers mean quieter sounds, and therefore indicate better hearing. Values of 20 dB or less are considered normal hearing for children and young adults.

Hearing Levels by Ear and Frequency (Air Conduction)

	Frequency (Hz)						
Ear (dB HL)	500	1000	2000	3000	4000	6000	8000
Right Ear (dB HL)	5	10	0	0	5	5	5
Left Ear (dB HL)	15	5	15	5	10	0	10

Print legend only if "***" or "NRS" appears in table:
*** = threshold could not be determined
NRS = no response at limits of equipment.

{Your/Your child's} hearing was tested by a trained examiner. Results indicate that your [your child's] hearing is entirely within normal limits in {your/his/her} right ear. In {your/his/her} left ear, results indicate that your [your child's] hearing is entirely within normal limits.

6-19 years old without normal hearing

The softest sounds {you are/your child is} able to hear are called hearing thresholds. {Your/Your child's} thresholds at different frequencies (pitches) are reported in the table below. The lower pitched sounds are toward the left of the table and the higher pitched sounds are toward the right.

Smaller numbers mean quieter sounds, and therefore indicate better hearing. Values of 20 dB or less are considered normal hearing for children and young adults.

Hearing Levels by Ear and Frequency (Air Conduction)

Ear (dB HL)	Frequency (Hz)						
	500	1000	2000	3000	4000	6000	8000
Right Ear (dB HL)	*999*	*999*	*999*	*999*	*999*	*999*	*999*
Left Ear (dB HL)	*999*	*999*	*999*	*999*	*999*	*999*	*999*

Print legend only if "***" or "NRS" appears in table:
*** = threshold could not be determined
NRS = no response at limits of equipment.

{Your/Your child's} hearing was tested by a trained examiner. Results indicated a slight hearing loss (a few thresholds marginally outside normal limits) in {your/his/her} right ear. In {your/his/her} left ear, results indicated normal, low frequency hearing but a mild, high frequency hearing loss. This kind of hearing loss could cause {you/your child} to miss some speech sounds. The audiometry test can identify a hearing problem but cannot determine the cause of a hearing loss. We recommend that {you/your child} see a doctor regarding {your/his/her} hearing loss if {you have/he has/she has} not already done so.

70+ year old with normal hearing and high WIN scores

The softest sounds you are able to hear are called hearing thresholds. Your thresholds at different frequencies (pitches) are reported in the table below. The lower pitched sounds are toward the left of the table and the higher pitched sounds are toward the right. Smaller numbers mean quieter sounds, and therefore indicate better hearing. Values of 25 dB or less are considered normal hearing.

Hearing Levels by Ear and Frequency (Air Conduction)

Ear (dB HL)	Frequency (Hz)						
	500	1000	2000	3000	4000	6000	8000
Right Ear (dB HL)	*999*	*999*	*999*	*999*	*999*	*999*	*999*
Left Ear (dB HL)	*999*	*999*	*999*	*999*	*999*	*999*	*999*

Print legend only if "***" or "NRS" appears in table:
*** = threshold could not be determined
NRS = no response at limits of equipment

Your hearing was tested by a trained examiner. Results indicate that your [your child's] hearing is entirely within normal limits in your right ear. In your left ear, results indicate that your [your child's] hearing is entirely within normal limits.

You also participated in the Words in Noise (WIN) test. The score (shown below) indicates how much louder words must be than the background noise for you to understand at least half of the words. It does NOT assess your hearing thresholds that are shown above. Many factors influence how well a person understands speech in noise – such as hearing ability, native language, and memory. We recommend that you see a hearing health professional for a full evaluation if you have not already done so.

Words in Noise Scores*			
Right Ear	_____dB SNR	Left Ear	_______dB SNR

*WIN scores represent "signal-to-noise" ratio (SNR) hearing ability
Scores can range from -2 dB SNR to 26 dB SNR.
A higher score indicates more difficulty with hearing words in noise.

70+ year old without normal hearing and normal WIN scores

The softest sounds you are able to hear are called hearing thresholds. Your thresholds at different frequencies (pitches) are reported in the table below. The lower pitched sounds are toward the left of the table and the higher pitched sounds are toward the right. Smaller numbers mean quieter sounds, and therefore indicate better hearing. Values of 25 dB or less are considered normal hearing.

Hearing Levels by Ear and Frequency (Air Conduction)

	Frequency (Hz)						
Ear (dB HL)	500	1000	2000	3000	4000	6000	8000
Right Ear (dB HL)	999	999	999	999	999	999	999
Left Ear (dB HL)	999	999	999	999	999	999	999

Print legend only if "***" or "NRS" appears in table:
*** = threshold could not be determined
NRS = no response at limits of equipment.

Your hearing was tested by a trained examiner. Results indicated a severe hearing loss in the low frequencies and a profound hearing loss in the high frequencies in your right ear. In your left ear, results indicated a profound hearing loss across most test frequencies. This kind of hearing loss could make it very difficult for you to hear speech and other sounds. The audiometry test can identify a hearing problem but cannot determine the cause of a hearing loss. We recommend that you see a doctor regarding your hearing loss if you have not already done so.

You also participated in the Words in Noise (WIN) test. The score (shown below) indicates how much louder words must be than the background noise for you to understand at least half of the words. It does NOT assess your hearing thresholds that are shown above. Many factors influence how well a person understands speech in noise – such as hearing ability, native language, and memory. Talk to your health care provider if you think you have trouble understanding speech in noise.

Words in Noise Scores*			
Right Ear	_____dB SNR	Left Ear	_______dB SNR

*WIN scores represent "signal-to-noise" ratio (SNR) hearing ability
Scores can range from -2 dB SNR to 26 dB SNR.
A higher score indicates more difficulty with hearing words in noise.