



National Health and Nutrition Examination Survey (NHANES)

Liver Ultrasound Transient Elastography Procedures Manual



January 2020

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1. Overview of Liver Ultrasound Elastography

1.1 Background

Chronic liver disease and cirrhosis are significant contributors to morbidity and mortality. Combined, they are the 12th leading cause of death overall in the United States, accounting for 36,427 deaths in 2013 (CDC/NCHS, 2013). The prevalence of cirrhosis is on the rise due to aging persons living with hepatitis C, and the reported increase in fatty liver disease is related to the obesity epidemic (Ruhl and Unalp-Arida, 2015; Everhart, 2008; Ogden et al., 2014; Feldstein et al., 2014; Wong et al., 2015). Health disparities for liver conditions also exist in the U.S. population. The incidence of viral hepatitis, nonalcoholic fatty liver disease (NAFLD), and survival associated with hepatocellular carcinoma disproportionately affect populations by sex, race, and socioeconomic status (Ruhul and Unalp-Arida, 2015). The burden of liver disease is estimated to increase substantially in the next several decades due to the obesity epidemic and increasing prevalence of diabetes in the United States (Everhart, 2008; Ogden et al., 2014; Feldstein et al., 2014). In addition, the prevalence of NAFLD is rising with an increasing trend for end-stage liver disease. Recently, nonalcoholic steatohepatitis has become the second leading etiology of liver disease among adults awaiting liver transplantation in the United States, followed by alcoholic liver disease (Wong et al., 2015). Viral hepatitis remains the most common condition leading to liver transplantation.

1.2 Justification for the Study

Understanding the epidemiology of fatty liver disease in the general population is an important first step to monitor the progression of this epidemic nationwide, and to develop interventions that will reduce the public health burden. Obtaining population estimates for liver fibrosis will contribute to the understanding of alcoholic and nonalcoholic liver disease etiologies. A hip circumference body measure will also be obtained, which will be used to help assess metabolic measures and liver disease.

In 2016, a successful National Center for Health Statistics (NCHS) Ethics Review Board–approved pilot study of the liver ultrasound elastography examination demonstrated the following:

1. This non-invasive exam was safe and acceptable to over 400 NHANES participants who received it.

2. The exam performed well in the mobile examination centers (MECs).
3. Valid findings were obtained, namely the prevalence estimates of steatosis and fibrosis were similar for the two teams at two MEC locations and were similar to estimates in smaller communities published by others in the literature.
4. Valid findings were reported to approximately 90 percent of the participants who agreed to the examination.

1.3 Objectives for the Study

This study aims to:

1. Estimate the prevalence of hepatic steatosis (i.e., fatty liver) and hepatic fibrosis (i.e., fibrotic liver) by transient ultrasound elastography. In the United States, most hepatic steatosis can be classified as NAFLD, but hepatic steatosis can also be attributed to other factors such as alcohol consumption. Hepatic fibrosis, which can follow NAFLD, is a more advanced stage of liver damage that can also result from liver infections.
2. Explore demographic and clinical features of those with hepatic steatosis or fibrosis.
3. Determine the population attributable fraction of hepatic steatosis and fibrosis risk factors, (e.g., alcohol, metabolic factors/diabetes, and viral hepatitis) as potentially preventable contributors to cirrhosis progression.
4. Measure related health and risk factors in order to accurately categorize the results of the liver ultrasound elastography. Specifically, a hip circumference will be obtained to identify people with central obesity as determined by a hip/waist ration; laboratory measures of iron stores in the body will be obtained to identify people whose liver changes may be due to iron overloads; C-reactive protein will be measured to determine if those with liver changes have evidence of an inflammatory process occurring; and information on gall bladder conditions will be collected because previous NHANES data suggested that gall bladder surgery may be a risk factor for nonalcoholic fatty liver disease (Pang et al., 2015).

1.4 Liver Ultrasound Elastography

Ultrasound exams have been used to evaluate liver health for years, especially in Europe. The method that will be used is Vibration-Controlled Transient Elastography (VCTE™). This involves an ultrasound machine (FibroScan model 502 V2 Touch) with a handheld transducer that taps, in rapid succession, on the participant's abdomen. The dissipation of the vibrations caused by the tapping is recorded by the ultrasound machine, and the values can be interpreted to estimate the

amount of fat tissue in the liver and the extent of liver fibrosis, if any. The FibroScan Model 502 Touch has been approved by the Food and Drug Administration (FDA).

1.5 Hip Circumference

Metabolic factors, including body fat distribution, are known to be related to changes in the liver (Pang et al., 2015). To assess abdominal body fat distribution, the study plans to assess the participant's waist-to-hip ratio using the same method to measure hip circumference that was used in NHANES III.

References

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2. Equipment

2.1 Description of the Exam Room in the MEC

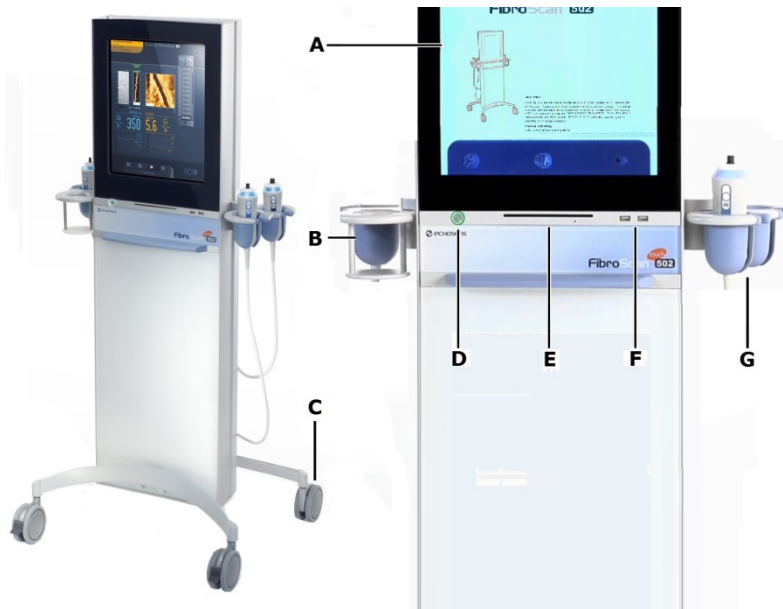
The Liver Ultrasound Transient Elastography (LUTE) test will be conducted in trailer 3 of the mobile examination center (MEC). The room will be equipped with features designed to facilitate accurate and efficient examinations. This chapter describes the LUTE equipment and supplies and explains the procedures for the set-up, operation, and pack-up of the LUTE component.

2.2 Equipment and Supplies

2.2.1 FibroScan 502 Touch

The FibroScan system (Exhibits 2-1 and 2-2) is an active, noninvasive medical device that measures liver stiffness. Liver stiffness is calculated by measuring the velocity of a 50-Hz shear wave as it passes through the liver. The shear wave velocity can then be converted into liver stiffness, which is expressed in kilopascals. In addition to liver stiffness, the FibroScan system uses the ultrasound acquisitions to assess the Controlled Attenuation Parameter (CAP). CAP and liver stiffness are simultaneously measured in the same liver volume, and CAP is only calculated if the liver stiffness measurements are valid.

Exhibit 2-1. FibroScan 502 Touch – Front view

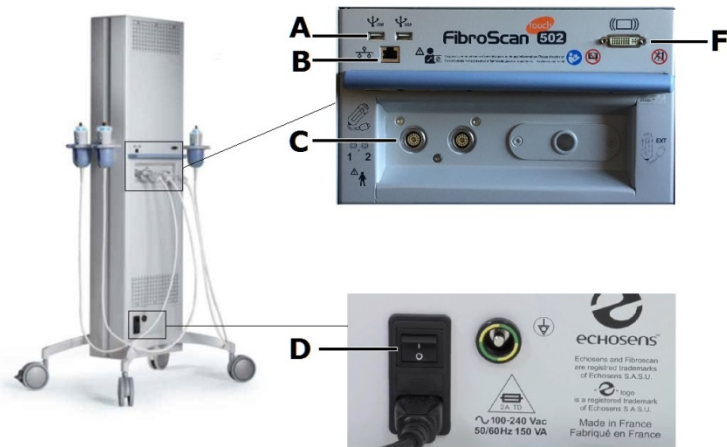


- A 17” color LCD touch screen
- B Gel holder
- C Casters and brakes. The two front casters are fitted with a brake. The brake is locked by pressing the toggle. The caster is released by lifting this same toggle.
- D “Standby” button. This button is active only if the main switch is in the “On” position. The button flashes when power is on.

Pressing this button once loads the application, and the cut-on indicator light runs green. After a few seconds, the home window is displayed.

Pressing the button a second time closes the application; the built-in indicator light and monitor are both turned off. This is the usual position when the FibroScan has not been in use for a short time (between study participants [SPs]).
- E CD-ROM/DVD-ROM drive. This drive is used to install software applications. Only CD-ROMs or DVDs authorized by Echosens should be inserted into the drive.
- F Two USB 2.0 connectors
- G Wand holder

Exhibit 2-2. FibroScan 502 Touch – Rear view



- A Two USB 2.0 sockets to connect an external hard disk for backups, a USN key, or a USB printer
- B Ethernet connector: also used for connectivity.
- C Two wand connectors
- D Main switch. This switch has two positions.

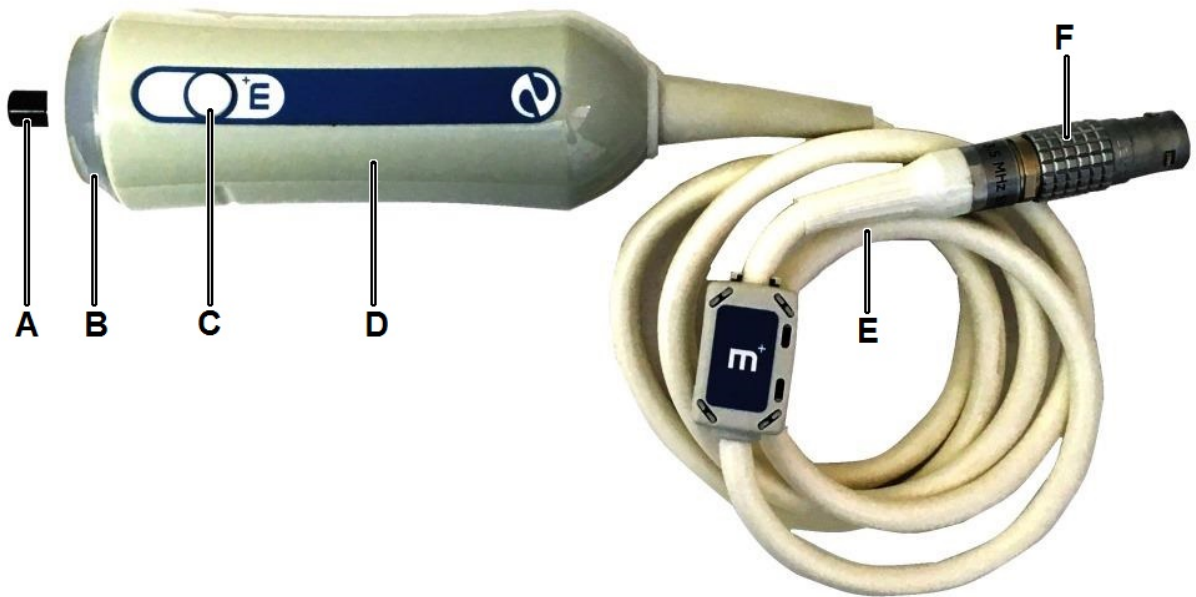
Position 0. No voltage is present in the internal circuits of the system. This is the position when the FibroScan is no longer to be used.

Position |. The internal electrical circuits of the FibroScan are powered by the AC power supply. This is the FibroScan’s working position.
- F DVI-I output. This output is used to connect an additional monitor.

2.2.2 M+ and XL+ Wands

Each wand contains an electrodynamic transducer, an ultrasound transducer, and a measurement trigger button (Exhibit 2-3).

Exhibit 2-3. FibroScan wands



- A Ultrasound transducer
- B Indicator light. The indicator light displays a status as follows:
- On during FibroScan startup and when standing by to launch an exam.
 - Flashing lights for the wand selected when an exam starts.
 - Switched off during an exam when the examiner is applying incorrect pressure to the SP's body.
 - On during an exam when the examiner is applying the correct pressure to the SP's body.
- C “Measurement” button. As soon as this button is pressed, the vibrator activates the electrodynamic transducer, which in turn generates a shear wave that painlessly impacts the SP's skin. The ultrasound transducer performs a series of acquisitions to measure the propagation speed of the shear wave. Acquisition lasts less than one-tenth of a second.
- D Electrodynamic transducer
- E Connection cable. Connects the wand to the FibroScan by means of a multi-pin jack.
- F Connection jack. The wand jack has a red dot that should be aligned with the red dot on the FibroScan socket before insertion.

2.2.2.1 Connecting and Disconnecting the Wands

- Locate the wand connector (Exhibit 2-4).
- Align the wand connection jack's red dot with the socket's red dot (Exhibit 2-4).
- Insert the wand's jack.
- To disconnect the wand jack, first pull the jack's splined sleeve back to unlock it and pull the whole jack back.
- When the wand is not in use, it must be positioned on the wand holder.

NOTE: The wand connectors are fragile. When connecting and disconnecting the wands, do not twist the connection jack.

Exhibit 2-4. Connecting the wand



2.2.3 Description of Additional Equipment and Supplies

A brief description of additional equipment and supplies is provided below. At the beginning and end of each stand, the health technologist will take an inventory of all component-specific equipment and supplies. Any needed items should be noted on the inventory sheet, reported to the MEC manager, and documented in the Unusual Field Occurrence (UFO) system.

Equipment

- **Exam table.** An exam table with a weight capacity of 600 pounds for SPs to lie down (Exhibit 2-5).
- **Step stool.** A metal step stool will be used to assist SPs in stepping on and off the table.

- **Aegis Secure Key.** Encrypted secure USB drive used to manually export exam files from the FibroScan to the ISIS computer (Exhibit 2-6).
- **Shear Wave Liver Fibrosis Phantoms.** The CIRS Model 039 Liver Fibrosis Phantoms provide a set of reference standards for performing quantitative measurements of tissue stiffness. The Model 039 consists of four phantoms; each is housed in a cylinder with a Sara-based scan surface and is filled 10-cm deep with Zerdine gel and 2-cm with an acoustic absorbing layer. The phantoms are stored and shipped in a rugged carrying case (Exhibit 2-7).
 - Phantom 1 – PH1
 - Phantom 2 – PH2
 - Phantom 3 – PH3
 - Phantom 4 – PH4
- **Wand support stand.** A cast iron support stand with a zinc-plated steel rod that screws into the base support will be used to hold the three-finger clamp during the phantom quality control (QC) scans (Exhibit 2-8).
- **Phantom jack.** An aluminum jack will be used to adjust the height of the phantoms during the phantom QC scans (Exhibit 2-8).
- **Three-finger clamp.** The three-finger clamp is an industrial three finger, rubber-coated extension clamp that will be use to hold the wand during the phantom QC scans (Exhibit 2-8).

Exhibit 2-5. Exam table



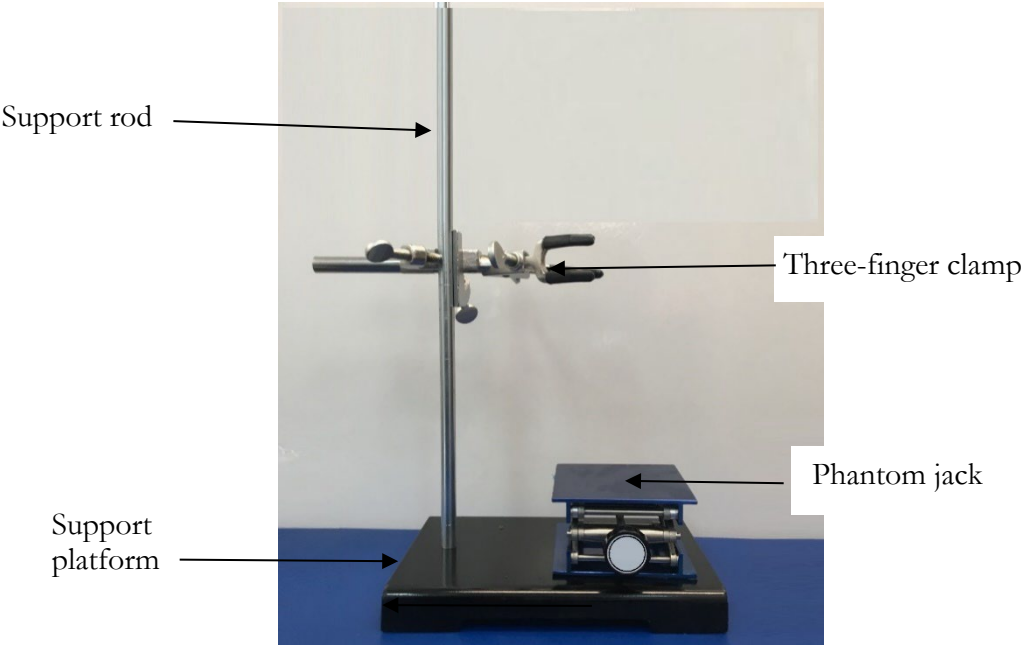
Exhibit 2.6. Aegis Secure Key



Exhibit 2-7. Shear Wave Liver Fibrosis Phantoms



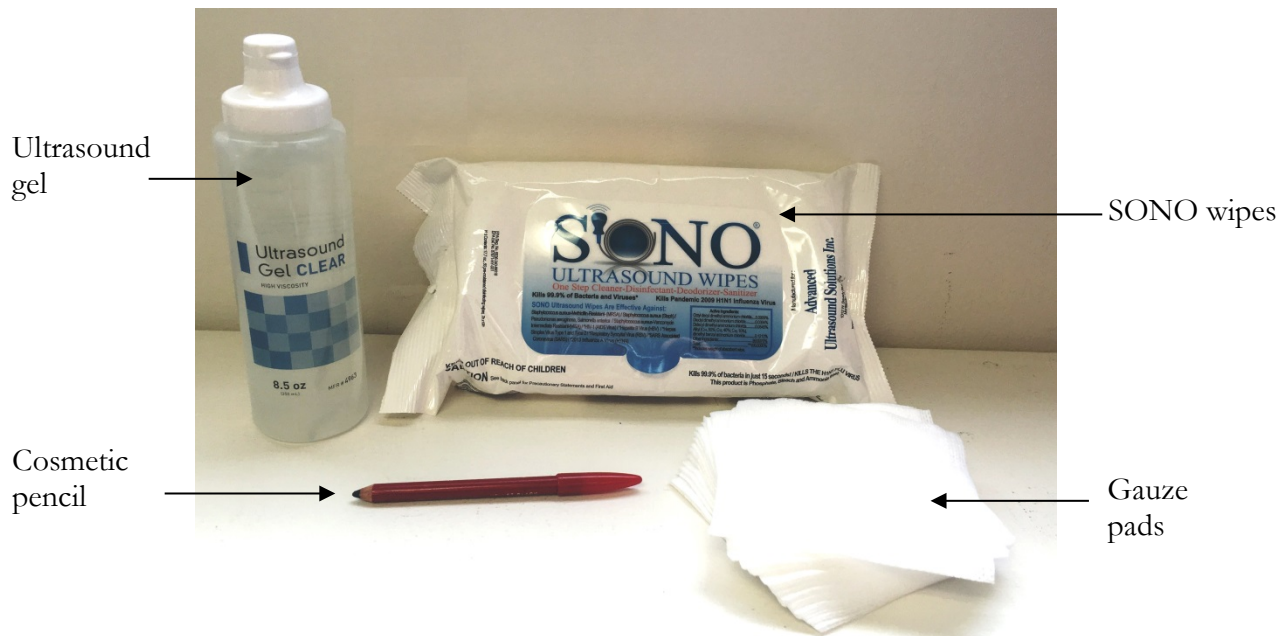
Exhibit 2-8. Phantom QC equipment



Supplies

- **Black/white cosmetic pencil.** The technologist will use a wax-based cosmetic pencil to mark the examination starting site on the SP's skin (Exhibit 2-9).
- **Ultrasound gel.** The ultrasound gel is a conductive, greaseless, water soluble contact medium for ultrasound transmission. It is salt, alcohol, and fragrance free (Exhibit 2-9).
- **SONO ultrasound wipes.** Fast-acting, broad spectrum, disinfectant disposable wipes. These wipes deliver effective biocidal action against a number of bacteria, fungi, and viruses. SONO ultrasound wipes are used to disinfect and sanitize the FibroScan, wands, cables, and the examination table (Exhibit 2-8).
- **Examination gloves.** To be used as needed.
- **Gauze pads.** The gauze pads are used to remove the gel from the SPs and to clean and disinfect the wands (Exhibit 2-9).
- **Terry wipes.** Terry wipes (WyPall) are used to clean and dry equipment as needed.
- **Exam paper.** Disposable exam paper is used for all SPs. A clean layer of the paper is placed on the exam table between each SP.

Exhibit 2-9. Supplies







2.2.4 FibroScan Software

The software loaded when the FibroScan unit is started up is used to perform examinations, manage the archives, and export the results of the examinations. When the unit is switched on, the Home screen is displayed (Exhibit 2-10). When a user is logged in, a Status bar located at the top of the Home screen gives information about the device (Table 2-1).

Exhibit 2-10. FibroScan Home screen



Table 2-1. Status bar

 99%	Percentage disk space available
 2	Results of FibroScan exam waiting for network transfer
	Options enabled: CAP and Clinical Mode
	Profile type: Default to MEC operator

The Home menu is located at the bottom of the Home screen (Table 2-2) and allows access to the FibroScan configuration, SP files, and SP Record screen (Exhibit 2-11).

Table 2-2. Home menu





	Use this button to shut down or power off the FibroScan. After the FibroScan is shut down, main components are powered down, although some internal components, such as the internal clock, may retain power.
	Access to FibroScan Configuration mode
	Access to the exam archive files
	Access to the SP Record screen

Exhibit 2-11. SP Record screen

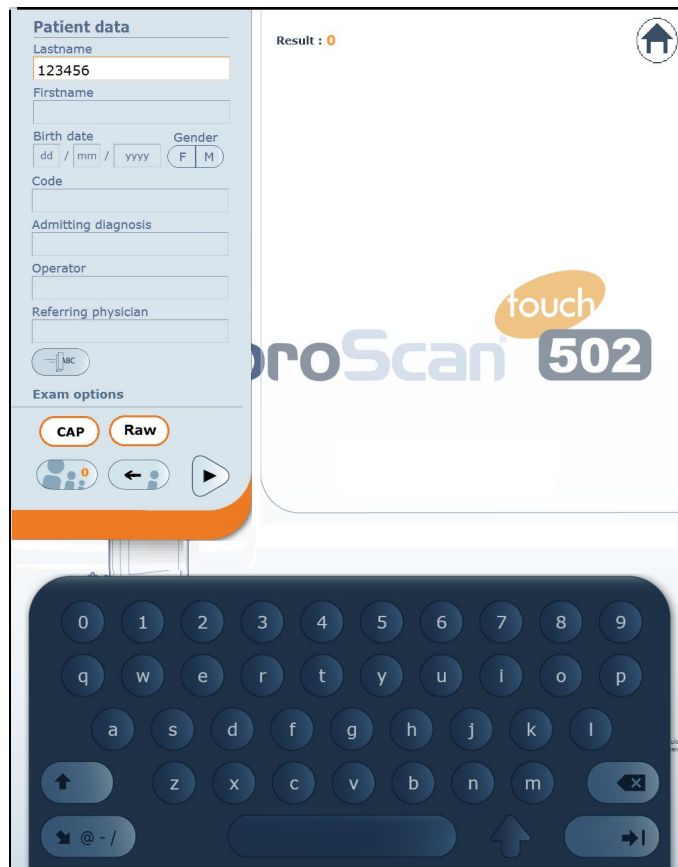









Table 2-3 presents the menu for the Record Screen shown earlier.

Table 2-3. Record Screen menu

	Deletes the content of the fields
	Enables/disables the “CAP” option for the exam about to start
	Enables/disables the saving of raw data for the exam about to start
	Shows/hides the SP waiting list (not being used)
	Add the selected SP to the list of SPs waiting for an exam. An examination can be performed on this SP later (not being used).
	Starts the examination
	Cancels the SP entry and returns to the Home screen

2.2.5 Acquisition Screen

The main screen to manage the examination is the Acquisition screen (Exhibit 2-12). It contains the following elements:

- SP data
- Ultrasound images
- Pressure indicator
- Shear wave propagation map
- Counter: valid and invalid measurements
- Shear wave speed results area
- Stiffness results area
- Deleting measurements
- Message area
- Exam type selection area
- Save and exit the examination

NOTE: After 5 minutes of idle time during an acquisition, a message will let the user know that he or she has 5 additional minutes before the exam is automatically paused. Beyond this time, if no action has been taken, the exam is saved and then stopped.

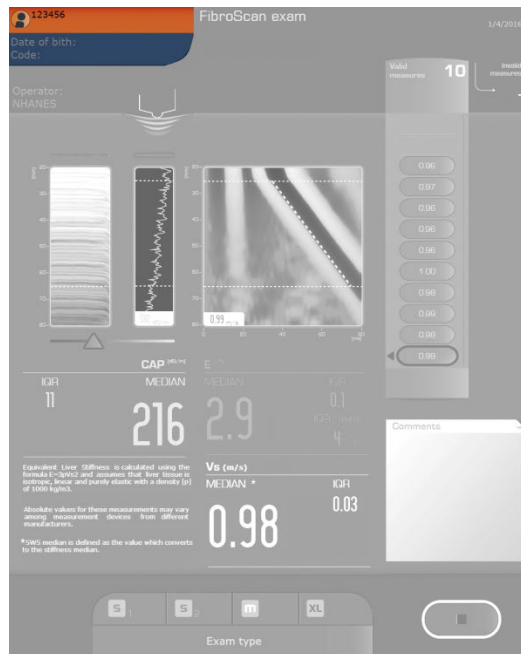
Exhibit 2-12. Acquisition screen



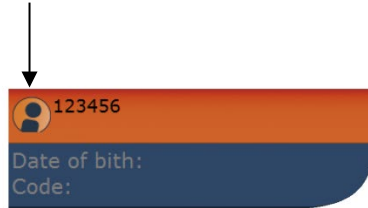
2.2.5.1 SP Data

This area on the Acquisition screen displays the SP ID. Click on the icon to show or hide the SP ID (Exhibit 2-13).

Exhibit 2-13. SP data



Click to show/hide
the SP ID



2.2.5.2 Ultrasound Images

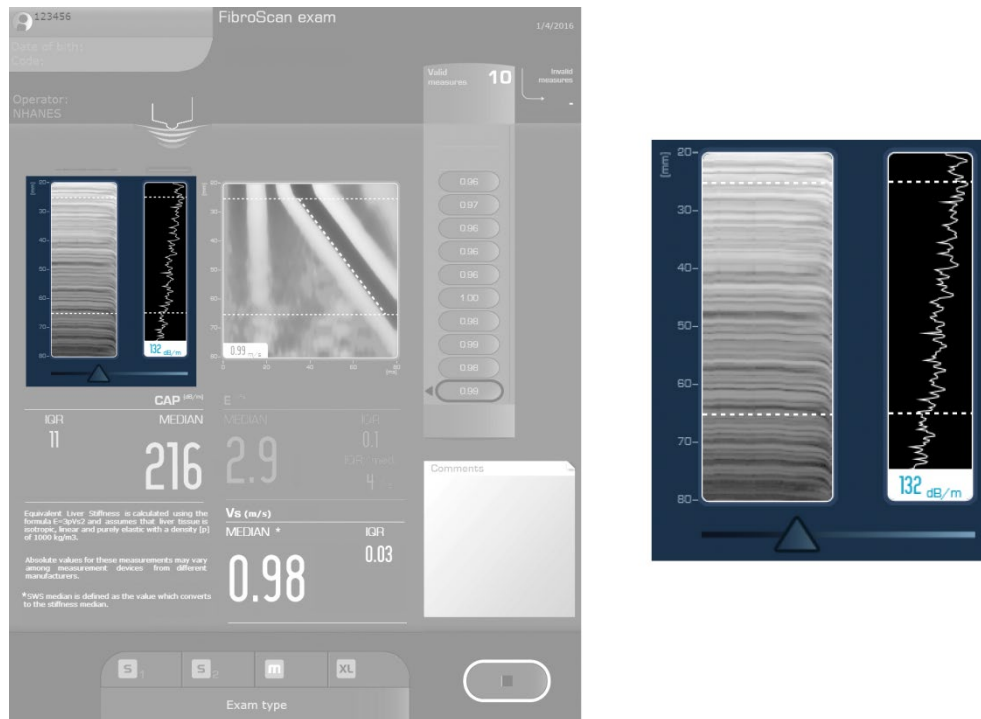
As soon as the wand makes contact with the skin, when a pressure change is detected, the ultrasound transducer makes ultrasound acquisitions (Exhibit 2-14).

The system displays two ultrasound images used to locate a zone that satisfies the measurement criteria:

- Time-Motion (TM) mode, two-dimensional grayscale image; and
- Amplitude (A) mode, ultrasound signal amplitude.

The gain on the display of both modes can be adjusted using the cursor under the ultrasound images. These two modes serve to confirm that the wand is correctly positioned to perform a measurement on a sufficiently thick position of liver, visible throughout the explored depth. This also allows the operator to ensure that the measurement will not be disrupted by the presence of structures that are not of interest, such as blood vessels.

Exhibit 2-14. Ultrasound images



The liver targeting tool (Exhibit 2-15) is used to position the wand at an appropriate point for measuring the liver stiffness and CAP. As soon as the wand is in contact with the SPs skin, the liver targeting tool illustrates the quality of the ultrasound signals propagating in the liver using the following color scale:

- **Black.** The quality of the ultrasound signals is low.
- **Green.** The quality of the ultrasound signals is high. The greener the liver indicator, the higher the quality of the ultrasound signals, and the better the position of the measurement point.

Exhibit 2-15. Liver targeting tool

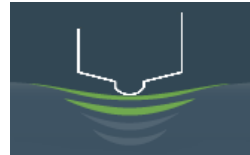


A: Liver indicator history
 B: Real-time liver indicator

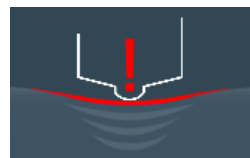
2.2.5.3 Pressure Indicator

The wand contains a sensor that measures the pressure the examiner applies to the SP (Exhibit 2-16). The software pressure indicator (green/orange/red) and the wand's blue LED gives the pressure level. Measurements may be made only when the pressure indicator is in the green zone.

Exhibit 2-16. Pressure indicator



- Correct pressure
- Indicator green
- Wand LEDs ON
- Measurement possible



- Pressure too low
- Indicator orange
- Wand LEDs OFF
- Measurement impossible

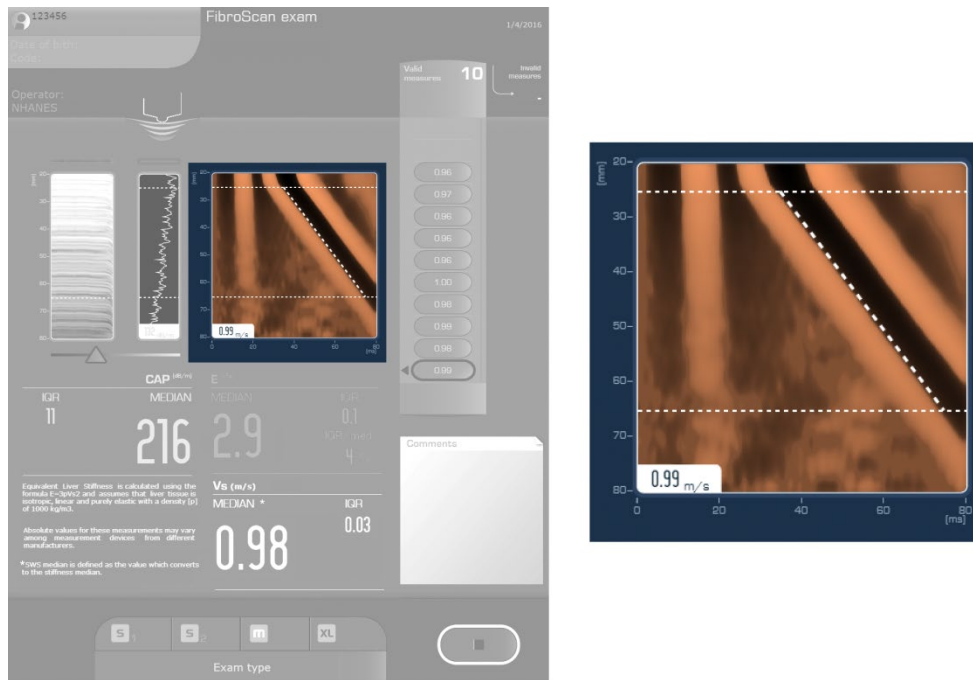


- Pressure too high
- Indicator red
- Wand LEDs OFF
- Measurement impossible

2.2.5.4 Shear Wave Propagation Map

The shear wave propagation map is displayed once the measurement is complete. It represents the levels of liver deformation generated by the propagation of the shear wave as a function of time and depth (Exhibit 2-17). The color scale indicates the sign of the compression or expansion. Black areas correspond to negative deformation, and pale areas correspond to positive deformation. The black strip through the image represents deformation associated with the passage of the shear wave, which penetrates progressively deeper with time.

Exhibit 2-17. Shear wave propagation map



2.2.5.5 Counter of Valid and Invalid Measurements

This area of the Acquisition screen displays the number of valid and invalid measurements (Exhibit 2-18). Valid measurements are displayed from first (top of the list) to bottom (last of the list) in kilopascals (kPa). When the number of valid measurements is equal to 1, the interquartile range (IQR) and the IQR/median (IQR/M) ratio are undefined and therefore are not displayed.

Invalid measurements are automatically rejected by the algorithms if the pulse sent out by the transducer could not be delivered successfully and/or the shear wave propagation maps are not satisfactory. The message “Invalid measurement” is then displayed above the shear wave propagation map (Exhibit 2-19).

Exhibit 2-18. Counter of valid and invalid measurements

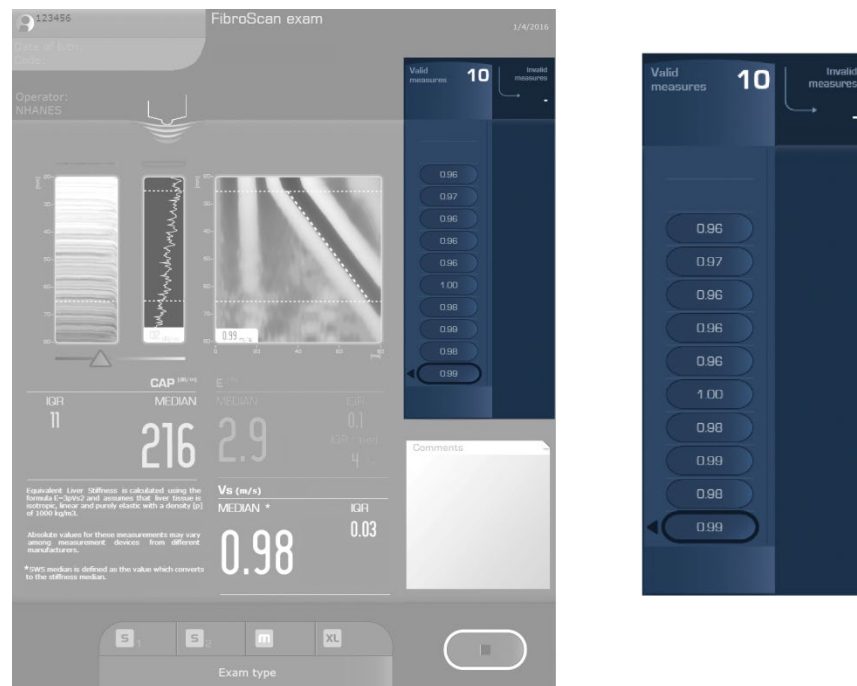
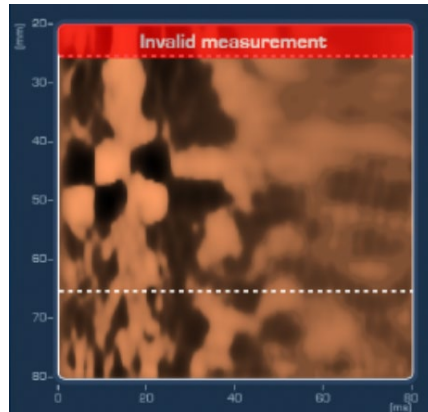


Exhibit 2-19. Invalid shear wave propagation map



2.2.5.6 Stiffness and Shear Wave Speed Results Area

The stiffness results area is located in the Acquisition screen and displays the following values (Exhibit 2-20):

- Median.** Stiffness is expressed in kPa. This value is the median of all valid measurements performed during the examination. If the repeat measurement is invalid, the median is not recalculated. To obtain a reliable and representative liver stiffness measurement, at least 10 valid measurements must be made.

- **IQR.** Is expressed in kPa and represents the interval around the median within which 50 percent of all valid measurements will fall. This value is recalculated after each new valid measurement.
- **IQR/M.** This value, expressed as a percentage, is the ratio of the IQR to the median stiffness. This value is recalculated after each new valid measurement.

Exhibit 2-20. Stiffness and shear wave speed results area



2.2.5.7 Controlled Attenuation Parameter (CAP) Result Zone

The CAP values include the median and the IQR (Exhibit 2-21).

- **Median.** The CAP is expressed in decibels per meter (dB/m). This value is the median of all valid measurements performed during the examination. The CAP value is calculated when the stiffness measurement is valid.
- **IQR.** The IQR for the CAP is expressed in dB/m. It represents the interval around the median within which 50 percent of all valid measurements will fall. It is recalculated after each new measurement.

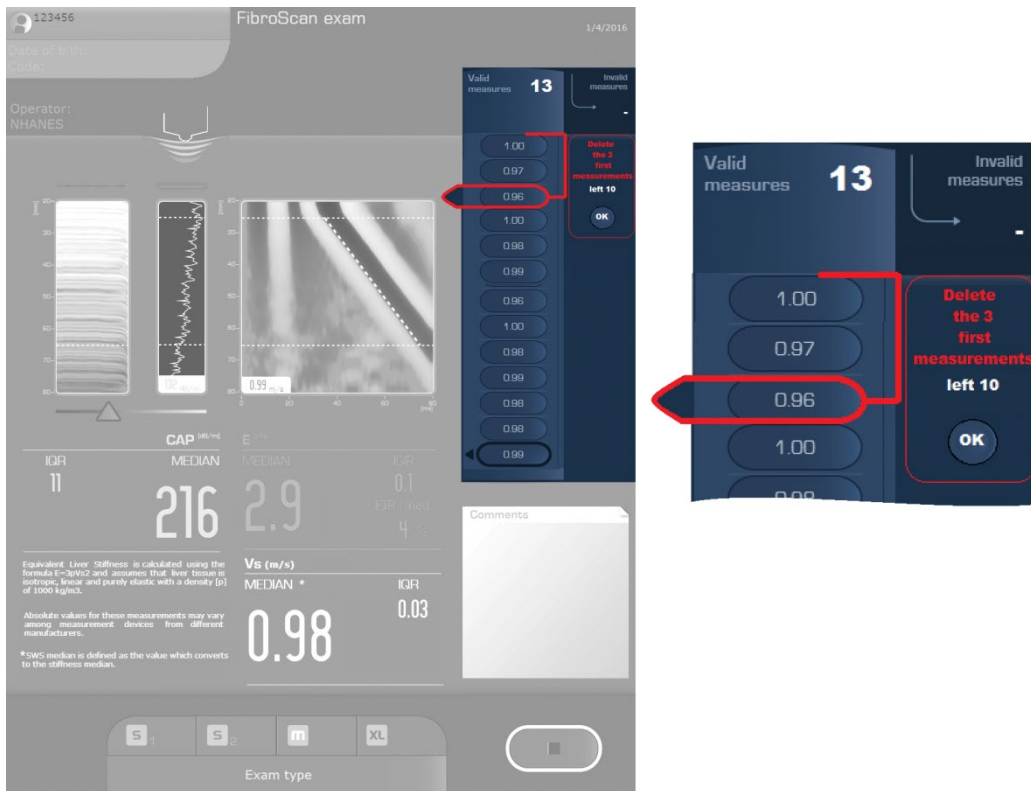
Exhibit 2-21. Controlled attenuation parameter result zone



2.2.5.8 Deleting Measurements

Some or all of the measurements in the current examination may be deleted at any time during the examination (Exhibit 2-22). To delete a measurement, select the last measurement to be deleted and then press the “X” button. A confirmation request is displayed that indicates the number of measurements remaining if deletion is confirmed. Note that all measurements taken before the one chosen for deletion will be eliminated from the exam after confirmation.

Exhibit 2-22. Deleting measurements



2.2.5.9 Message Area

The area above the shear wave propagation map (Exhibit 2-23) is used to display messages.

Exhibit 2-23. Message area



Connect the wand.

Replace the wand.

Calibrate the wand.

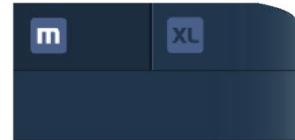
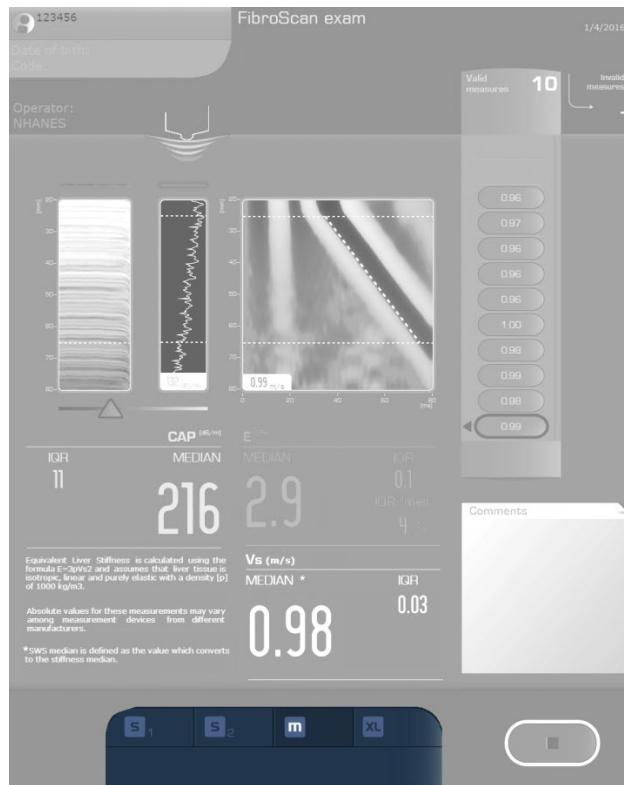


Electromagnetic disturbances

2.2.5.10 Exam Type Selection Area

Two types of examinations are available, M and XL (Exhibit 2-24), which correspond to specific measurement depths that take into account the liver's depth beneath the skin. If only the M+ or XL+ wand is plugged, the corresponding exam type is selected automatically by the machine software. If both wands are plugged, the examiner will always start with the M wand.

Exhibit 2-24. Exam type selection area



2.2.5.11 Automatic Wand Recommendation

The automatic wand recommendation tool is based on the skin-to-capsule distance (SCD) measurement using ultrasound signals received by the machine's wand. This feature operates in real time as the wand detects ultrasound signals. The result of the automatic wand recommendation tool is displayed at the bottom of the screen. If the tool is able to recommend a wand and it matches the wand being used, the examiner can confirm the wand choice by pressing the icon of the exam type and continue using the same wand until the end of the exam. If the wand being used does not match the recommendation, the examiner will need to switch wands.

Change of Wand During an Exam

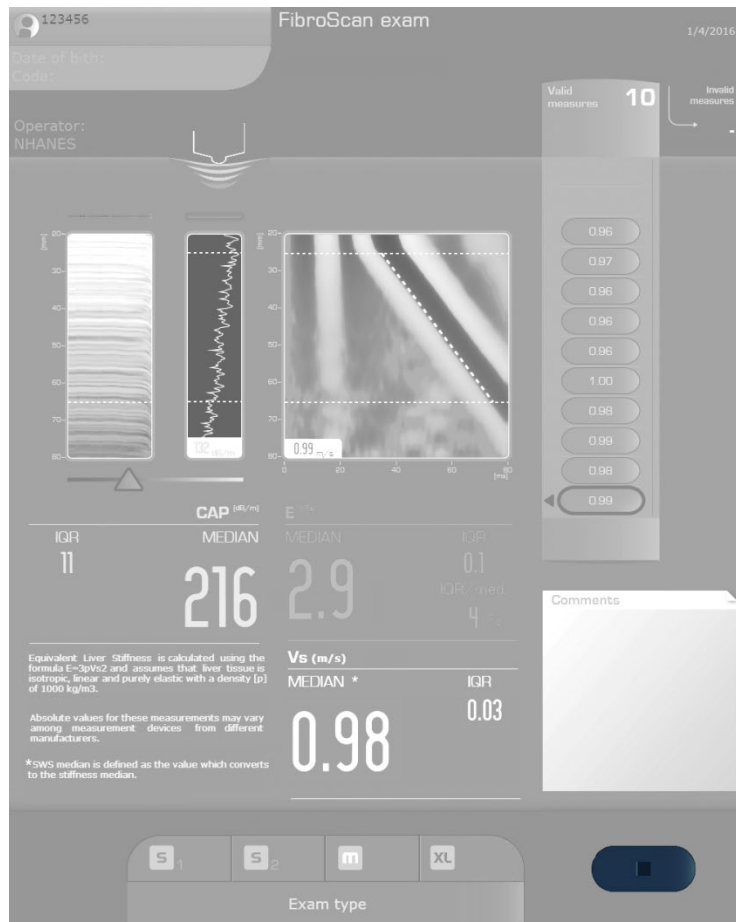
Changing wands during an exam will delete all measurements taken using the previous wand. To change wands during an exam, follow the steps below:

1. Select the new wand type. The following message is displayed:
2. “Change of exam type. Changing exam type causes all previous measurements to be definitively erased.”
3. Click OK. The following message is displayed: “Exam type has changed.”
4. Plug in the appropriate wand if necessary and resume the exam.

Save and Exit the Examination

The FibroScan machine has been configured to automatically save the results at the end of an examination. To end the exam, press the button located next to the exam type selection area (Exhibit 2-25).

Exhibit 2-25. Save and exit the examination



2.3 Equipment Care and Maintenance

The equipment and room supplies need to be checked on a regular basis. Some checks are completed daily and others need to be completed at the beginning and end of each session or stand. These checks include cleaning, inspection of equipment and supplies, and preparation of the room and equipment for the session exams. Follow the procedures below to ensure that the liver ultrasound elastography equipment functions properly and remains hygienic throughout the stand. Always use personal protective equipment to prevent injury. The specific timeframes for equipment QC are as follows: start of stand, start of session, between examinations, end of day, and end of stand.

2.3.1 Start of Stand

At the beginning of each stand, count all component-specific equipment and supplies. Supplies ordered from the warehouse by the previous team should be on site when the next team arrives to set up a new stand. Check all newly received supplies against the associated packing lists before incorporating them into the existing inventory. Any needed items should be noted on the inventory list, reported to the MEC manager and home office component specialist, and documented in the UFO system.

Equipment Setup

Before setting up the LUTE room, verify that all equipment and supplies are in the room. The FibroScan and both wands on the MECs are tracked in the Equipment Tracking System (ETS) maintained by the MEC manager. Provide the MEC manager with the serial numbers present on the FibroScan and wands at the beginning of each stand.

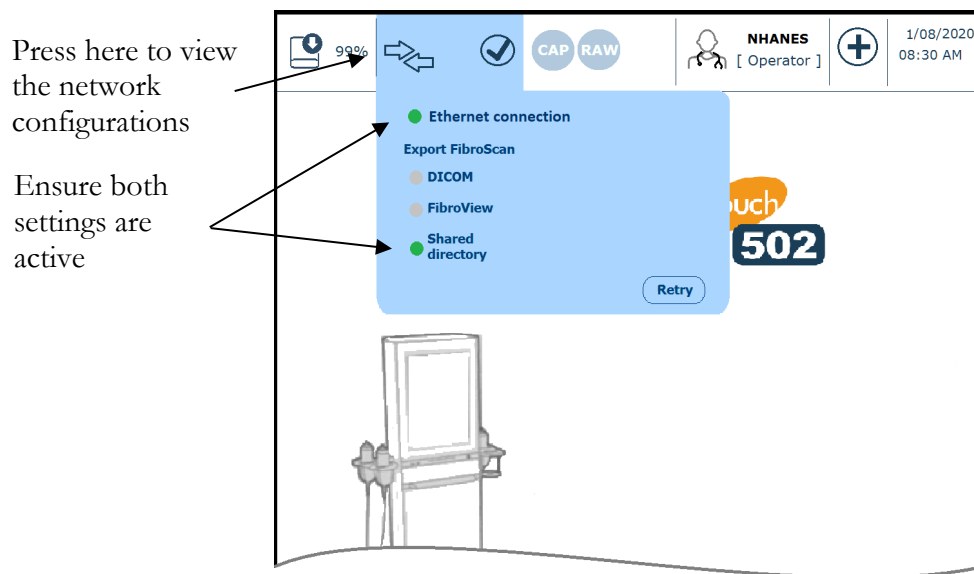
FibroScan

1. Remove the FibroScan from its protection box.
2. Connect the power cable to the back of the FibroScan (Exhibit 2-2/D).
3. Connect the FibroScan power cable to the UPS power supply receptacle.
4. Connect the additional monitor to the DVI-I output.
5. Ensure that the network cable is connected to the Ethernet connector on the back of the FibroScan.
6. Remove the M+ and XL wands from their protection cases and place them on the wand holders (Exhibit 2-1/G).
7. Connect both wands to the wand connectors; the connectors are not wand specific.
8. Connect the barcode gun to one of the USB 2.0 sockets located on the front of the FibroScan.
9. Wipe the surface using a SONO disinfectant wipe. Use multiple wipes if necessary to achieve contact time.
10. Turn the FibroScan on; the main switch located at the rear of the machine should be in the “I” position.

11. Press the “Standby” button once to load the application; the built-in indicator light turns green. After a few seconds, the home window is displayed.
12. Ensure the ISIS computer is ON.
13. Attach the two clear plastic baskets to the front of the FibroScan.
14. Complete the Start of Stand QC checks.
15. Check the network configuration on the FibroScan machine.

To check the network configuration, press the two arrows on the Status bar located on the top of the Home screen (Exhibit 2-26). Ensure that the network (Ethernet) configuration and shared directory are active (green circle). If they are not active, check the network connections and press “Retry.” If they continue to be inactive (grey circle), call ISIS support.

Exhibit 2-26. Network configuration



Start of Stand QC Checks

- **FibroScan.** Wipe the surface using a SONO disinfectant wipe. Use multiple wipes if necessary to achieve contact time.
- **Wands.** Wipe the surface using a SONO disinfectant wipe.
- **Wands.** Using a magnifying glass, examine the housing for any damage such as cracks, breakage, or liquid leakage. If any damage is observed, stop using the wand, submit a UFO, and contact the facilities and equipment specialist (FES).

- **Wands.** Examine the cables and jacks for any damage. If any damage is observed, stop using the wand, submit a UFO, and contact the FES.
- **FibroScan.** Check and update the time and time zone.
- **FibroScan.** Delete old exam files.
- **FibroScan.** Complete all Phantom QC Scans.

2.3.1.1 Updating Date and Time

The date and time on the FibroScan machine can be modified in Configuration mode. To enter Configuration mode, press the “Configuration” button in the Home screen and select NHANES (Exhibit 2-27). Select the Localization tab and press “Modify” to enter the system date and time, and press “Save” to save the data (Exhibit 2-28).

Exhibit 2-27. Entering Configuration mode

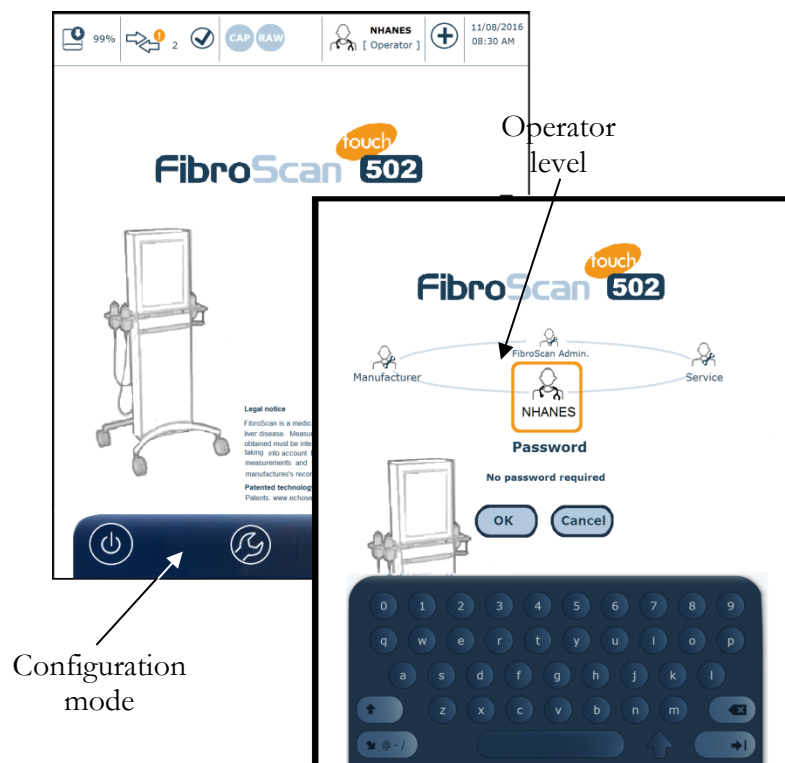


Exhibit 2-28. Localization tab



2.3.1.2 Exporting Files

To export exam files, in FIBX format, from the Fibroscan to ISIS follow the steps listed below:

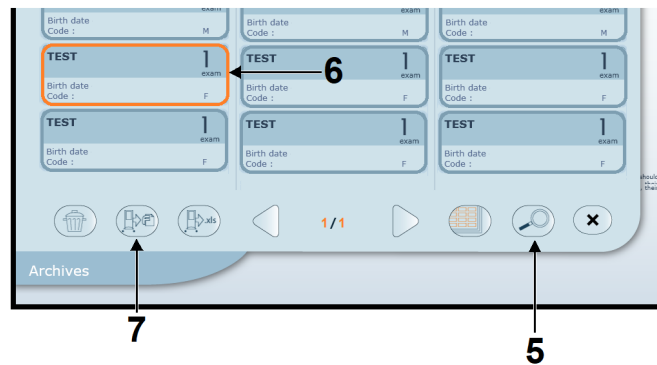
1. To unlock the Aegis Secure key (Exhibit 2-6), press the Key button. Both LED lights will blink together.
2. Wait 10 seconds, enter the password and press the key button. The green light will blink for a correct PIN, red will blink for an incorrect PIN entry.
3. Connect the Secure key to a USB port on the FibroScan within 30 seconds. The green light will be on and the blue on or blink for activity.
4. Search for the exam file to be exported by pressing the “Exam Archive Files” button (Exhibit 2-29).

Exhibit 2-29. Exam Archive Button



5. Access the advanced file search by pressing the magnifying glass icon (Exhibit 2-30).
6. Select the SP file; the selected file will have an orange border (Exhibit 2-30).
7. Export the FIBX file (Exhibit 2-30).

Exhibit 2-30. Exporting exam files



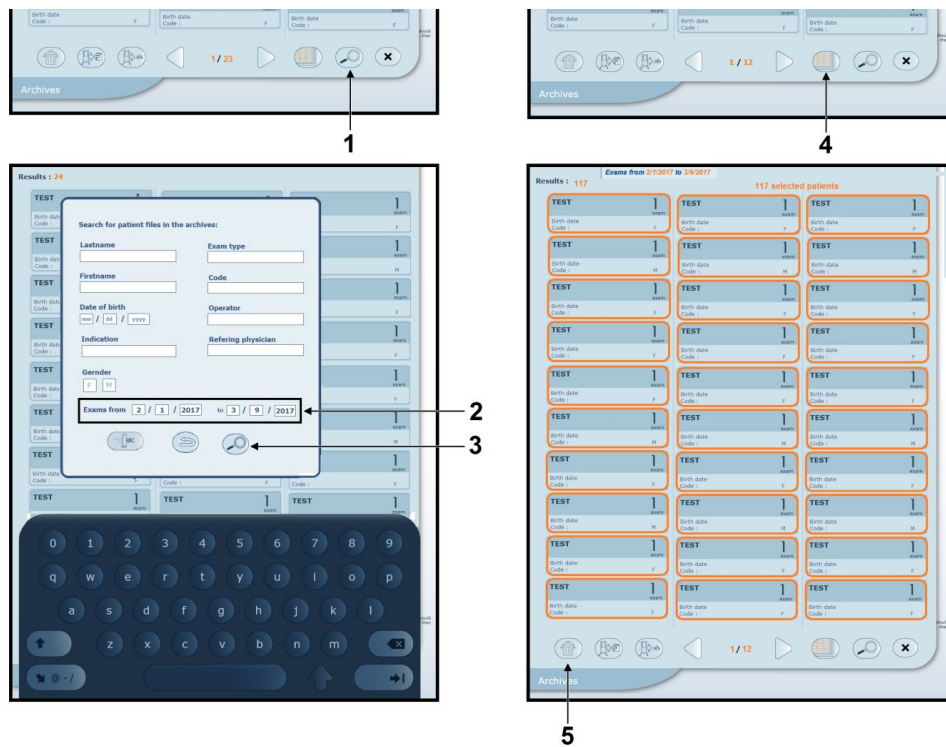
8. If there is more than one file, the FibroScan will ask if you want to transfer all the files and if you want them normalized, select yes for both.
9. After the files have been exported, wait 10 seconds before unplugging the Secure Key.

2.3.1.3 Deleting Old Exam Files

FibroScan. Delete all of the exam files from the stand previous to the last. Keep all exam files from the previous stand (for example, for MEC 1 at Stand 375, delete files from Stand 369 and keep files from Stand 372). See Exhibit 2-31 for an illustration of the steps listed below.

1. To display the exam archive files, press the “Access to the exam archive files” button (Table 2-2) in the Home menu.
2. Access the advanced file search by pressing the magnifying glass icon.
3. Enter the date range “Exam from mm/dd/yyyy to mm/dd/yyyy” and close the advance file search by pressing the magnifying glass icon.
4. Press the “Select all” icon to highlight all selected exam files.
5. Press the trash can icon to delete all the selected files.

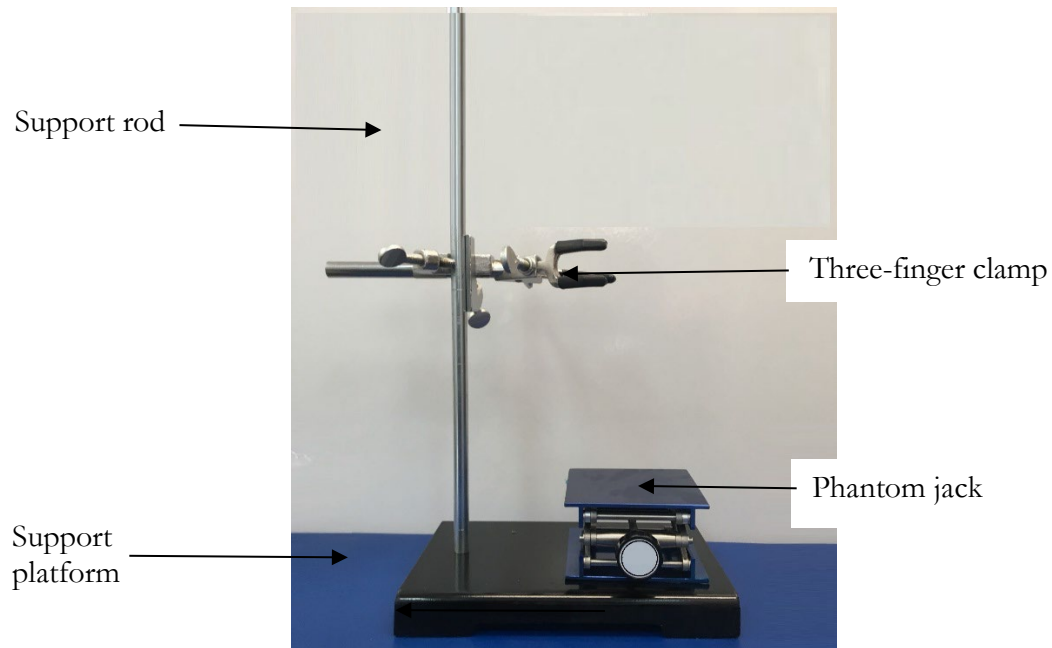
Exhibit 2-31. Deleting exam files



2.3.1.4 Liver Phantom QC Scans

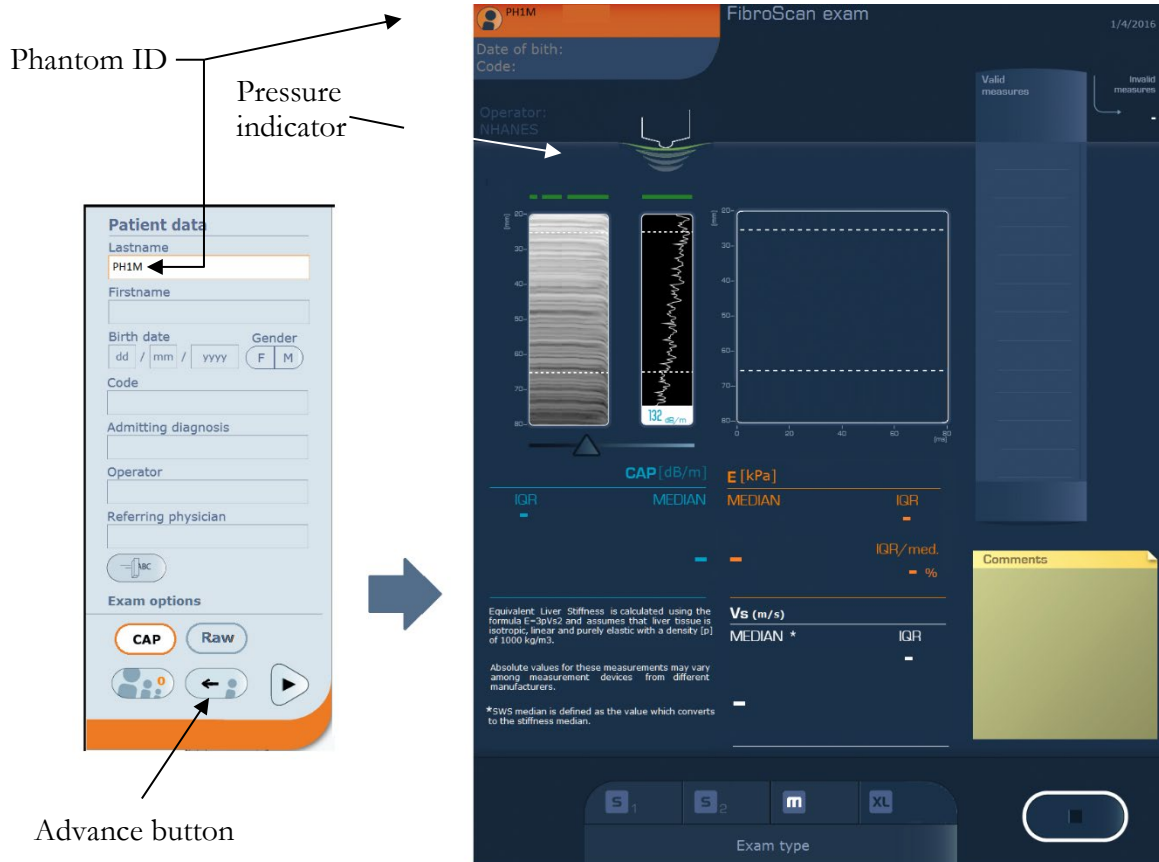
1. Attach the support rod to the support platform; ensure the rod is securely fastened to the platform.
2. Connect the three-finger clamp to the middle of the rod; inspect the rubber-coated fingers to ensure they are in good condition before attaching the wand.
3. Carefully attach the M wand to the clamp. Use the clamp's adjustment screws to secure the wand. Do not overtighten the screws; doing so may damage the wand.
4. Place the phantom jack on the support platform; see Exhibit 2-32 for a picture showing the assembled set-up.

Exhibit 2-32. Phantom QC set-up



5. Apply ultrasound gel to the scanning surface of the first phantoms (PH1).
6. Enter the first phantom ID number, PH1M (Phantom 1 with the M wand), on the “Lastname” field by “reading” the barcode (Exhibit 2-33).
7. Go to the FibroScan Home screen and access the SP Record screen.
8. Place PH1 on the center of the phantom jack platform. Ensure the center of the scanning surface is directly above the wand’s ultrasound transducer (Exhibit 2-34).

Exhibit 2-33. Phantom QC Record and Acquisition screen



9. Verify that the “Raw” option is disabled.
 10. Press the “Advance” button to move to the Acquisition screen.
 11. On the Acquisition screen, select or confirm the exam type (M).
 12. Raise the phantom jack platform until the ultrasound transducer comes into contact with the scanning surface of the phantom (Exhibit 2-35–2-36). Check that the pressure indicator has no more than two bars of pressure.
- Note: The scanning surface is the most important item on the phantom to protect. It can withstand normal scanning pressure but do not apply excessive pressure with the wand, fingernails or any other sharp object. If the scanning surface becomes damaged, seal the phantom in an airtight container, submit a UFO, and return the damaged phantom to the component lead.
13. Perform 50 valid measurements (Exhibit 2-37).

Exhibit 2-34. Phantom QC set-up with a resting phantom platform

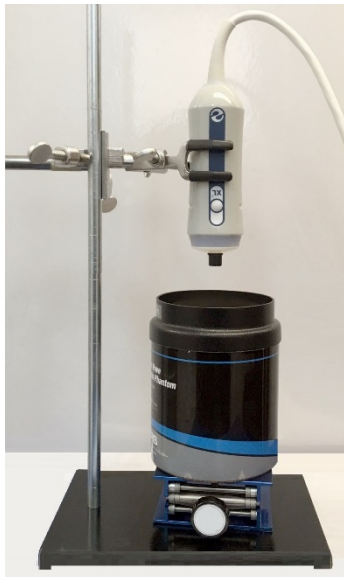


Exhibit 2-35. Phantom QC set-up with a raised phantom platform



Exhibit 2-36. Screening surface with transducer

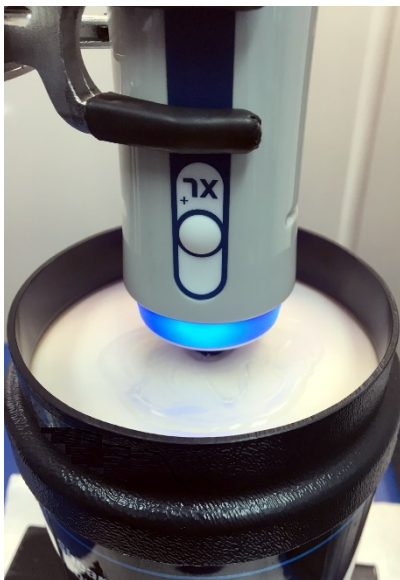


Exhibit 2-37. Acquisition screen with valid QC measurements



14. Quickly review the measurements and end the exam by pressing the “End” button.
15. Import the results from the FibroScan system into ISIS by clicking the “Done” box beside the appropriate QC check (i.e., PH1M, PH2M, PH3M, PH4M).
 - If the file is successfully imported, the name of the file will appear under “Results” (Exhibit 2-38).

- If you are unable to import the file or complete the test, enter the reason in the Comment field. If a file is missing for a phantom, text is required in the Comment field to continue.
16. Repeat steps 5-15 with phantoms 2, 3, and 4 (PH2, PH3, and PH4).
 17. Remove the M wand from the clamp. Wipe the ultrasound gel from the wand, wrap a SONO wipe around it and place it in its corresponding holder.
 18. Carefully attach the XL wand to the clamp. Use the clamp's adjustment screws to secure the wand. Do not overtighten the screws; doing so may damage the wand.
 19. Repeat steps 5-15 using the XL wand on all four phantoms.
 20. Remove the XL wand from the clamp. Wipe ultrasound gel from the wand, wrap a SONO wipe around it and place it in its corresponding holder.
 21. Remove any ultrasound gel from the scanning surface of the phantoms with a SONO wipe and store them in their airtight case.

Exhibit 2-38. Start of Stand Phantom QC checks

QC Check	Done	Result	Comment
Phantom 1 - M wand (PH1M)	<input checked="" type="checkbox"/>	PH1M	
Phantom 2 - M wand (PH2M)	<input checked="" type="checkbox"/>	PH2M	
Phantom 3 - M wand (PH3M)	<input checked="" type="checkbox"/>	PH3M	
Phantom 4 - M wand (PH4M)	<input type="checkbox"/>		
Phantom 1 - XL wand (PH1XL)	<input type="checkbox"/>		
Phantom 2 - XL wand (PH2XL)	<input type="checkbox"/>		
Phantom 3 - XL wand (PH3XL)	<input type="checkbox"/>		
Phantom 4 - XL wand (PH4XL)	<input type="checkbox"/>		

2.3.2 Start of Session

- **FibroScan.** Wipe the surface using a SONO disinfectant wipe. Use multiple wipes if necessary to achieve contact time.
- **Wands.** Wipe the surface using a SONO disinfectant wipe.
- **Wands.** Using a magnifying glass, examine the housing for any damage such as cracks, breakage, or liquid leakage. If any damage is observed, stop using the wand, submit a UFO, and contact the FES.
- **Wands.** Examine the cables and jacks for any damage. If any damage is observed, stop using the wand, submit a UFO, and contact the FES.
- **Wands.** Wrap a new SONO disinfectant wipe around each wand and leave them in their corresponding holders.
- **Wands.** At the end of a work week, store them in their corresponding storage case.

2.3.3 QC Checks Between SPs

At the end of the exam, remove the cosmetic pencil marks with a gauze pad. Remove the paper from the table and wipe it with a Purell wipe. Place a new sheet of paper for the next SP and clean the wands.

Wands

The following steps describe how to clean the wand. (See Exhibit 2-39).

1. Clean off gel using the SONO disinfectant wipe that was covering the wand.
2. Use a new SONO disinfectant wipe to clean the ultrasonic transducer, surrounding surfaces of the transducer, and the wand's housing. Wrap the wipe around the wand and leave it in the holder to keep the transducer surface wet.
3. Leave the wrapped wand in the holder until the next SP.
4. Wipe any other surface that may have come into contact with the SP. Use multiple wipes if necessary to achieve contact time.

Exhibit 2-39. Cleaning the wand



2.3.4 End of Stand

- **FibroScan.** Wipe the surface using a SONO disinfectant wipe. Use multiple wipes if necessary to achieve contact time.
- **FibroScan.** Press the “Standby” button to close the application; both the built-in indicator light and monitor will be turned off.
- **Wands.** Disconnect both wands. To disconnect the wand jack, first pull the jack’s splined sleeve back to unlock it, and then pull the whole jack back.
- **Wands.** Wipe the surface using a SONO disinfectant wipe.
- **Wands.** Using a magnifying glass, examine the housing for any damage such as cracks, breakage, or liquid leakage. If any damage is observed, submit a UFO and contact the FES.
- **Wands.** Examine the cables and jacks for any damage. If any damage is observed, submit a UFO and contact the FES.

- **Wands.** Store them in their corresponding storage case.
- **FibroScan.** Turn the machine off. Ensure the main power switch is in the “0” position.

Equipment Packup Procedures

FibroScan

1. Complete all the “End of Stand” QC checks.
2. Remove and store the clear plastic basket from the front of the FibroScan.
3. Disconnect the additional monitor from the DVI-I output.
4. Unplug and store the power cable from the back of the FibroScan.
5. Slide the FibroScan into its protective box (Exhibit 2-40).
6. Place the extra foam pads to protect the screen and the base of the FibroScan (Exhibit 2-41).
7. Secure the protective box to the wall (Exhibit 2-42).
8. Engage the two front casters of the FibroScan by pressing the tongue.
9. Place the protective blanket over the examination table.

Exhibit 2-40. FibroScan machine inside its protective box



Exhibit 2-41. FibroScan machine inside its protective box with protection foams



Exhibit 2-42. FS protective box secured to the wall



2.3.5 Equipment Malfunctions

All equipment malfunctions or repair must be reported to the health technologist assigned to the LUTE component, MEC manager, and home office component lead. All repairs to the FibroScan and/or wands must be performed by an Echosens authorized technician. When contacting Echosens Technical Support, you must provide the model information and serial number of the Fibroscan and/or wand, which are presented in Table 2-4. The Echosens Technical Support number and email address are also listed below:

Echosens Technical Support: 866-905-4837 or ESNAservice@echosens.com

Table 2-4. FibroScan and wand: Item codes, model information, and serial numbers for the three MECs

	Item Code	Product	Serial Number
FibroScan #1 (MEC #1)	K502T22	FibroScan 502 Touch +M+XL	
	P800019	FibroScan 502 Touch	F62173
	P800010	Probe (wand) M+	S72154
	P800008	Probe (wand) XL+	S90969
	S200048	CAP module	
FibroScan #2 (MEC #2)	K502T22	FibroScan 502 Touch +M+XL	
	P800019	FibroScan 502 Touch	F62333
	P800010	Probe (wand) M+	S72596
	P800008	Probe (wand) XL+	S92033
	S200048	CAP module	
FibroScan #3 (MEC #3)	K502T22	FibroScan 502 Touch +M+XL	
	P800019	FibroScan 502 Touch	F62334
	P800010	Probe (wand) M+	S72598
	P800008	Probe (wand) XL+	S72598
	S200048	CAP module	
Back-up probes	P800010	Probe (wand) M+	S75206
	P800008	Probe (wand) XL+	S92258

2.3.6 Troubleshooting

The following table (2-5) may be used to troubleshoot some common problems with the FibroScan and wands.

Table 2-5. Troubleshooting problems with the FibroScan and wands

Problem	Solution
The “Standby” button is not working	Check that the FibroScan is plugged into a correctly powered AC supply socket and the main switch is in the “I” position. Have the main switch’s fuses checked by the FES.
Automatic wand recommendation is not working	Be sure to use enough pressure to get the tool functioning properly.
The probe is no longer calibrated	Contact the home office component specialist.
Frozen FibroScan monitor	Perform a system reboot. Press and hold down the power button “Standby” until the system turns off. Once the system is off, wait a few seconds, then turn it back on and let it start as normal.
Unable to switch between wands	Perform a system reboot.
Unable to transfer files to ISIS	Ensure that the network configuration and shared directory are active. Verify the SP ID is in the correct format (e.g. 123456). See section 2.3.1.2 for instructions on how to export an exam file from the FibroScan to a Secure Key.
Suspected damage to the wand (i.e., a wand is accidentally dropped)	Contact the home office component lead. A backup wand will be sent.

3. Examination Protocol

3.1 Eligibility Criteria

The liver ultrasound transient elastography (LUTE) exam will be conducted on study participants (SPs) 12 years and older. Participants are excluded if they (1) are unable to lie down on the exam table, (2) are currently pregnant, (3) have an implanted electronic medical device, or (4) are wearing a bandage or have lesions on the right side of their abdomen by the ribs.

3.2 Pre-Examination Procedure

When the coordinator assigns an SP to the LUTE room, a “Communication dialog” box will appear on the Integrated Survey Information System (ISIS) computer screen. This will inform you that an SP has been assigned to the component. If possible, prepare the room for the exam before the SP enters the room. Confirm that all supplies needed for the exam are available and accessible. Wand the barcode on the SP’s identification (ID) bracelet or type the SP’s ID number to log the SP into the ISIS LUTE application, select your name from the list of users in the FibroScan machine, and enter your password. Go to the FibroScan Home screen and access the SP Record screen (Exhibit 3-7). Enter the participant’s identification number by “reading” the barcode on the ID bracelet label with the barcode gun. Verify that the “CAP” and “Raw” options are enabled, and advance to the Acquisition screen. It is important to log the SP onto the computer data entry system and FibroScan as soon as you can after entering the examination room.

Below is an introductory script; this is a standard script, but you may adjust the explanation to the level of understanding of the SP. The exam will be explained in more detail as each step is being conducted. The objective of the introduction is to inform the SP about the exam and position the SP as quickly as possible. Make frequent eye contact with the SP when you are explaining the test and make sure he or she is listening and understands what you are saying. Refer to Appendix A for a copy of the script in Spanish.

“In this room, we are going to be doing an exam that will attempt to check the health of your liver. For this exam, you will be lying on this exam table on your back. I will ask you to raise your gown top slightly to locate your breastbone in the middle of your abdomen. This machine does not take an

image of your liver. It just measures the speed that the ultrasound waves travel once they reach your liver, which can indicate the stiffness of your liver. During this examination, I will hold this wand [show wand] next to your ribs and the wand will quickly tap you on the skin, sending ultrasound waves to your liver and recording the waves coming back from your liver. If the machine doesn't record the information correctly, it will notify me and I will need to repeat this process to get accurate results. You should not feel any discomfort during this exam. I will help to position you on the table so valid measurements can be obtained. This will help me position the ultrasound wand in the correct location, on your right side, to take measurements of your liver. Do you have any questions?"

After introducing the LUTE examination, ask the SP to gather his or her shirt gown above the waist and, using a hair clip, clip it on the front so it will not interfere with the measurements. Then, direct the SP to lie down on the examination table and go through the safety exclusion questions in ISIS (Exhibit 3-1).

3.2.1 Shared Exclusion Question

The Shared Exclusion Questions may be answered in several components in the mobile examination center (MEC). If these questions have been answered in a previous component in the MEC, the questions and responses will be displayed in read-only format. If the SP is excluded from this exam based on his or her answers to the Shared Exclusion Questions in another component, the SP will be blocked from the liver ultrasound exam by the Coordinator System and will not be sent to this exam. The exclusion questions that block SPs from the LUTE are listed below:

1. Are you currently pregnant? *(If the SP is male, or a female older than 60 years, the shared exclusion pregnancy question will not be displayed.)*
2. Do you have a pacemaker or automatic defibrillator?
3. Are you using an insulin pump or have insulin lines now?
4. Are you using any implanted electronic device?

If the response to any of the Exclusion Questions is "Yes," "Don't Know," or "Refused," the SP will be excluded from the exam. The component status for the liver ultrasound exam will be set to "Not Done" with a comment specific to the reason for exclusion (SP pregnant, physical limitation, etc.). See Exhibit 3-1 for a copy of the ISIS screen with the exclusion question.

Exhibit 3-1. Liver ultrasound Safety Exclusion Questions screen

Liver Ultrasound: Stand:615 Session:615261 09/21/2010 01:30 pm - 05:30 pm

SP ID: 185868 Name: LIU 3, TANGELA Age: 32 years Gender: Female Date: 01/18/2016 Time: 03:59 PM

Exclusion Questions

Are you currently pregnant?

Do you have a pacemaker or automatic defibrillator?

Are you using an insulin pump or have insulin lines now?

Are you using any implanted electronic device?

[HT Help: examples include implantable cardioverter defibrillator (differs from pacemaker), cochlear implants (for hearing) neurostimulators, lower esophageal stimulators, medication delivery devices, etc.]

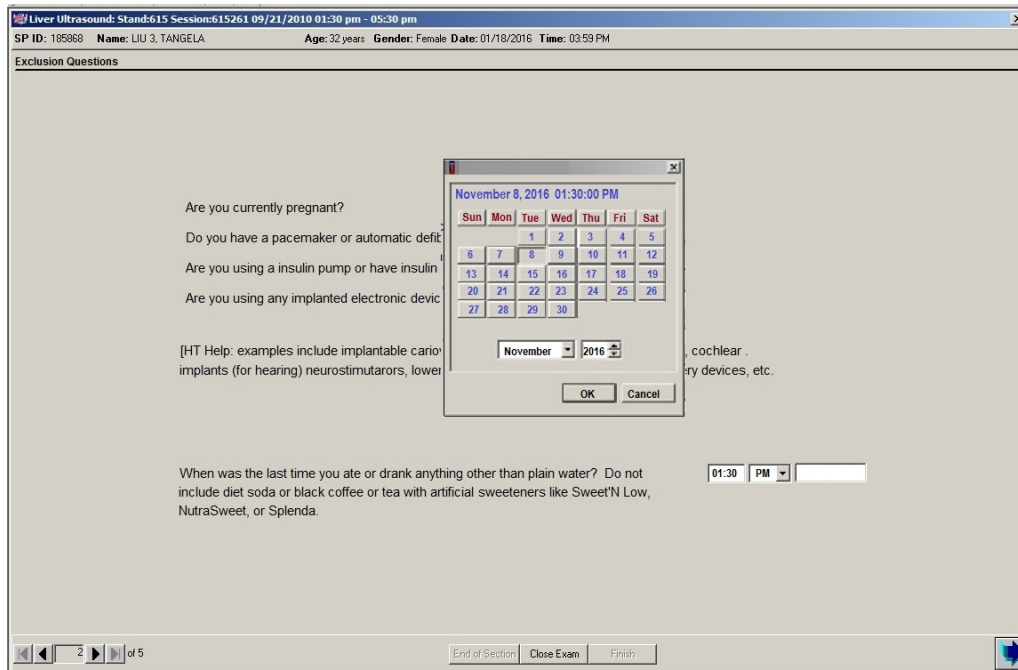
When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, or Splenda.

2 of 5 End of Section Close Exam Finish

3.2.2 Administering the Fasting Questionnaire

Fasting data are required for the correct interpretation of the liver ultrasound results. The technologist administers the fasting questionnaire to all eligible SPs, and the application calculates the fasting time in number of hours and minutes. This question elicits the last time the SP ate or drank anything, and determines fasting time. SPs are allowed to consume diet soda, black coffee, or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. To administer the fasting questionnaire, read the text exactly and record the date and time (Exhibit 3-2).

Exhibit 3-2. Liver Ultrasound Fasting Questions screen



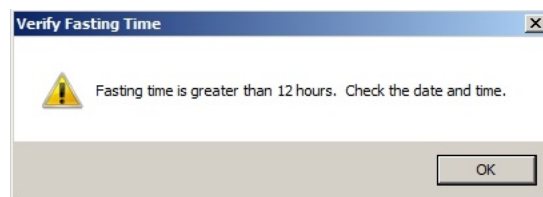
To enter the reported time, use the numeric keys and press Tab to move to the AM/PM space. Type in A for times between midnight and 11:59 AM or P for times between noon and 11:59 PM and then press Tab. Alternatively, to select AM or PM, direct the mouse arrow to the drop-down arrow on the right side of the text box, left-click, drag the mouse arrow to AM or PM and left-click.

To enter the date, use the keyboard's numeric keys and the mm/dd/yyyy format and press Tab, or use the calendar to enter the date. To access the calendar, select [F2]. To select the correct month, direct the mouse arrow to the drop-down list, drag the arrow to the correct month (use the Scroll bar if necessary), and left-click. To select the correct day, direct the mouse arrow to the correct day on the displayed month and left-click. To correct the year, direct the mouse arrow to the up-down controls on the spin box and toggle the number up and down. To transfer this date into the date space, direct the mouse arrow to the "OK" button and left-click, or press Enter. To exit the

calendar function, direct the mouse arrow to the “Cancel” button and left-click. After the fasting questionnaire has been answered, continue with the examination.

- If the calculated fasting time is greater than 12 hours, a message will be displayed to confirm whether or not the date and time entered is correct (Exhibit 3-3)
 - If the fasting time entered was incorrect, select “OK” and enter the correct fasting time.
 - If the fasting time was correct, select “OK” and advance to next screen.

Exhibit 3-3. Edit Check – Fasting time greater than 12 hours



- If the calculated fasting time is less than 3 hours, the message “Fasting time is less than 3 hours. Would you like to proceed” will be displayed (Exhibit 3-4).
 - If there is enough time left in the session and the SP is willing to wait, select “No” and close the exam. The exam will be coded as “Partial”, select “Waiting to meet fast” as the comment for the Partial exam (Exhibit 3-5).
 - If the SP will not meet the 3-hour fast during the session and or he/she is not willing to wait, select “Yes” and proceed with the exam.

Exhibit 3-4. Edit Check – Fasting time less than 3 hours

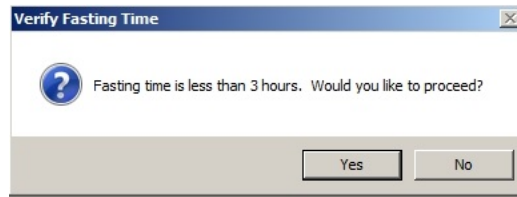
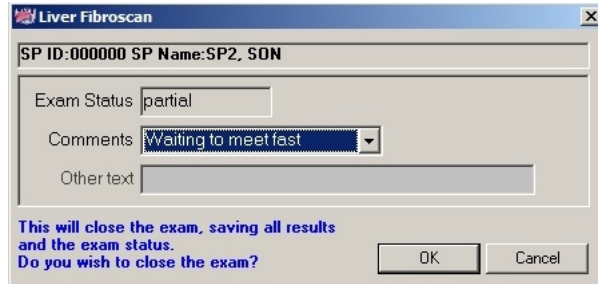


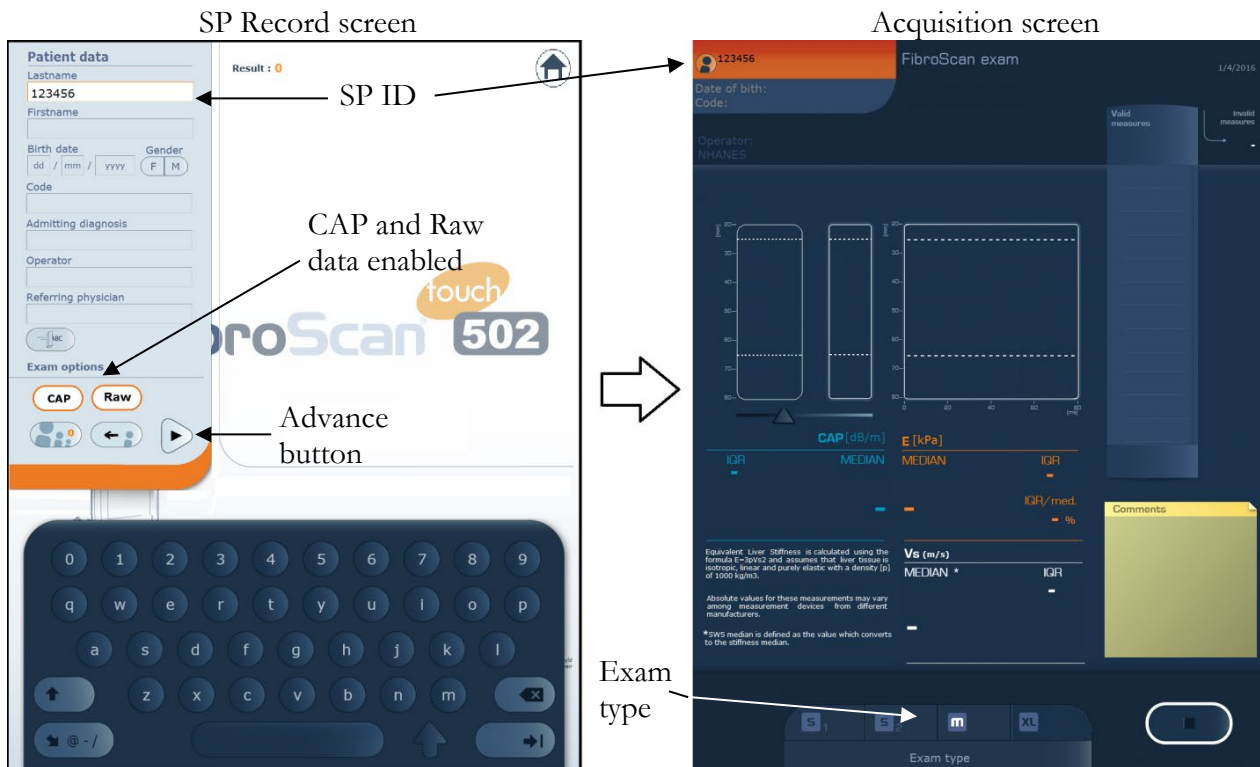
Exhibit 3-5. Partial Exam – Waiting to meet fast



3.2.3 FibroScan Setup

- Go to the FibroScan Home screen and access the SP Record screen (Exhibit 3-6).
- Enter the participant’s identification number by “reading” the barcode on the ID bracelet label with the barcode gun.
- Verify that the “CAP” and “Raw” options are enabled.
- Press the “Advance” button to move to the Acquisition screen.

Exhibit 3-6. SP Record and Acquisition screen



- On the Acquisition screen (Exhibit 3-6), select or confirm the exam type.

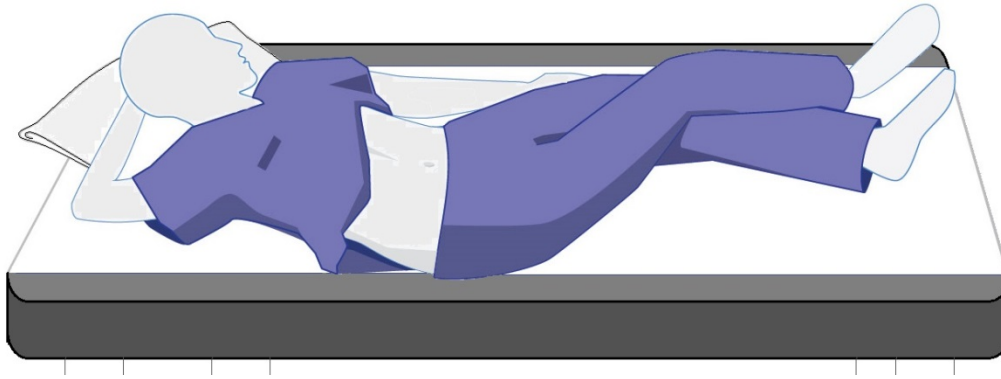
3.2.4 Preparing the SP

Study participants should be in the supine position, with the right arm in maximum abduction, the right leg over the left, and the torso slightly curved to increase the intercostal space around the upper-right area of the abdominal cavity (Exhibit 3-7). Below is a script for marking the examination site; this is a standard script, but you may adjust the explanation to the level of understanding of the SP.

“Now, I will start by feeling for your breastbone and placing a small mark on your right side with a cosmetic pencil. I will apply a small amount of water-based gel to the tip of this wand and place it against your skin with a slight pressure.”

Refer to Appendix A for a copy of the script in Spanish.

Exhibit 3-7. SP position on table



Find the xiphoid process and palpate the intercostal space located at the intersection of the mid-axillary line and a transverse line at the level of the xiphoid process (Exhibit 3-8). Mark this site with a wax-based cosmetic pencil. Exhibit 3-9 shows the measurement site correctly marked for the LUTE examination.

Exhibit 3-8. Abdominal landmarks

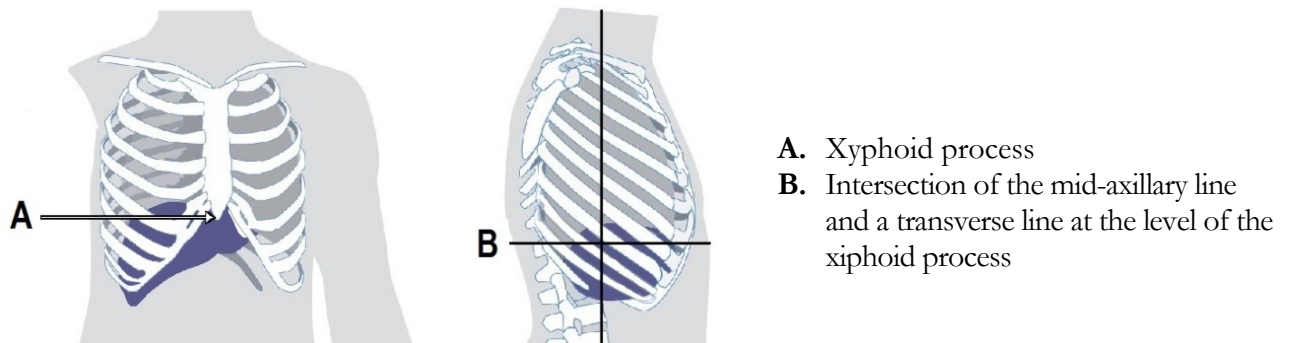
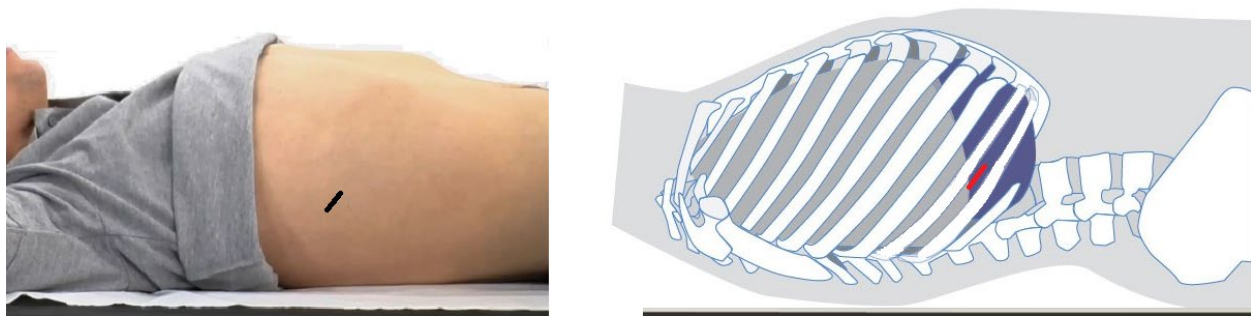


Exhibit 3-9. Measurement mark



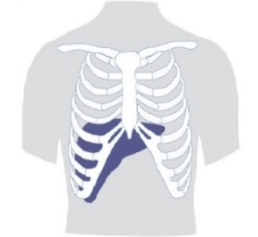



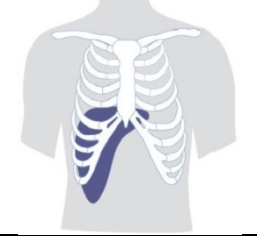



NOTE: If it is difficult to find the measurement site, such as on SPs with large breasts or skinfolds that cover the area, ask the SP to use his or her left hand to lift and hold themselves. If it is difficult to find an intercostal space, start by following the rib cage from the xiphoid process to the mid-axillary line and palpate until you find an intercostal space at the level of the xiphoid process.

3.2.4.1 Body Habitus

Depending on the SP's body habitus (Hypersthenic, Sthenic, Hyposthenic, or Asthenic) the position and size of the liver can vary. Refer to Table 3-1 for examples of expected liver location between these major body types.

Table 3-1. Body habitus

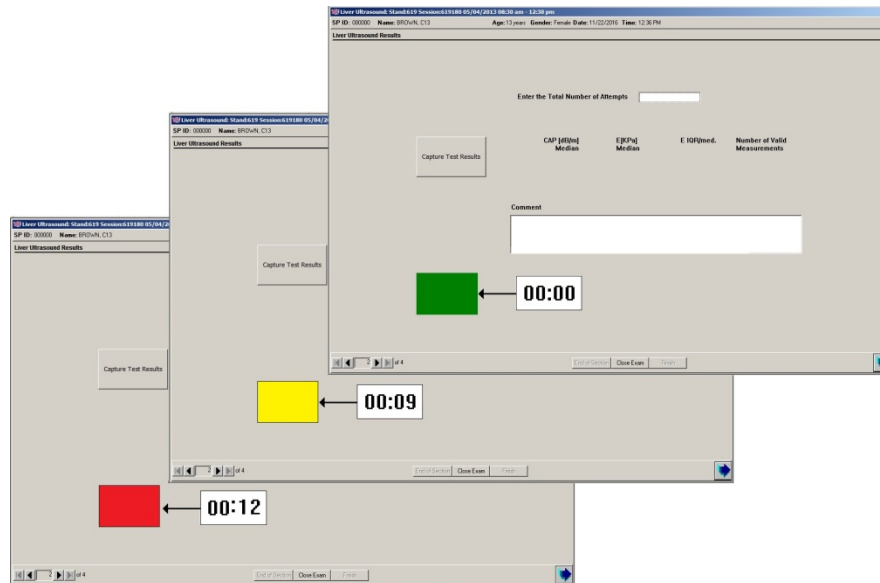
Body habitus	Front view	Side view
<p><u>Sthenic</u> Means active or strong. The sthenic body is the one we usually associate with the athletic type. The body is rather heavy with large bones.</p>		
<p><u>Hyposthenic</u> Slender and light in weight with the stomach and liver situated high in the abdomen.</p>		
<p><u>Hypersthenic</u> The hypersthenic body is of massive build with a broad and deep thorax. The diaphragm is high and the stomach and liver also occupy high positions.</p>		
<p><u>Asthenic</u> Extremely slender, light build, with a narrow, shallow thorax, and the gallbladder and stomach situated low in the abdomen.</p>		

3.3 Examination Procedure

Make sure all shared exclusion and fasting questions in ISIS have been answered and saved.

Advance to the Liver Ultrasound Result screen in ISIS before proceeding with the exam. The Liver Ultrasound Result screen in ISIS (Exhibit 3-10) has a built-in visual timer to monitor the length of the examination. On entry to this screen, the visual timer will be green. It will turn yellow after 9 minutes, and then red after 12.

Exhibit 3-10. Liver Ultrasound Result screen



3.3.1 FibroScan Premeasurement Data

Premeasurement data includes the (A) Liver Targeting Tool, (B) Wand Pressure Indicator, (C) Time-Motion mode, and (D) Amplitude mode (Exhibit 3-11).

- A. **Liver targeting tool.** This tool characterizes the quality of the ultrasound signals propagating in the liver using a color scale. The greener the liver indicator, the higher the quality of the ultrasound signals, and the better the position of the measuring site.
- B. **Wand pressure indicator.** The wands contain a sensor that measures the pressure the operator applies to the SP.
- C. **Time-Motion (TM) mode.** An ultrasonic display mode in which the motion of structures is seen on the vertical axis of the display. This tool can also be used to ensure that the measurement will not be disrupted by the presence of structures not of interest, such as blood vessels.

- D. **Amplitude (A) mode.** A display of ultrasonic echoes in which the horizontal axis of the visual display represents the time required for the return of the echo and the vertical axis represents the strength of the echo.

Exhibit 3-11. Premeasurement data



3.3.2 Liver Ultrasound Transient Elastography Exam

Verify that the SP is in the correct position (Exhibit 3-12), apply ultrasound gel to the tip of the M+ wand, and place a small amount of gel on a gauze pad. Place the M+ wand against the SP's skin. As soon as the wand makes contact with the skin (i.e., when a pressure change is detected), the ultrasound transducer will start making ultrasound acquisitions. Hold the wand perpendicular to the skin surface and move it up an intercostal space and down an intercostal space using the premeasurement data—Liver targeting tool, Time Motion mode (TM) and Amplitude mode (A)—to ensure the wand is positioned in the center of the liver. Exhibit 3-13 shows the wand perpendicular to the skin; whereas Exhibit 3-14 shows the wand incorrectly positioned on the SP's skin.

Exhibit 3-12. SP position

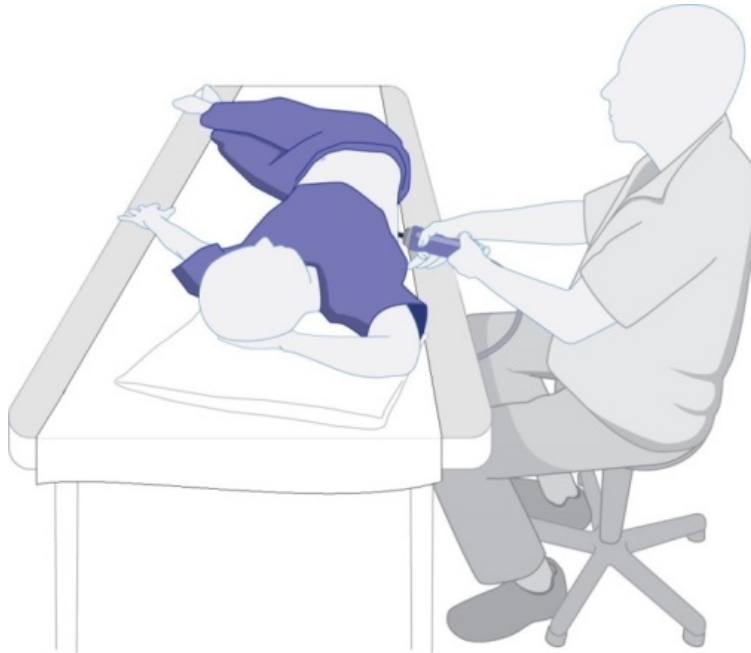


Exhibit 3-13. Correct wand placement



Exhibit 3-14. Incorrect wand placement



3.3.2.1 Wand Selection Criteria

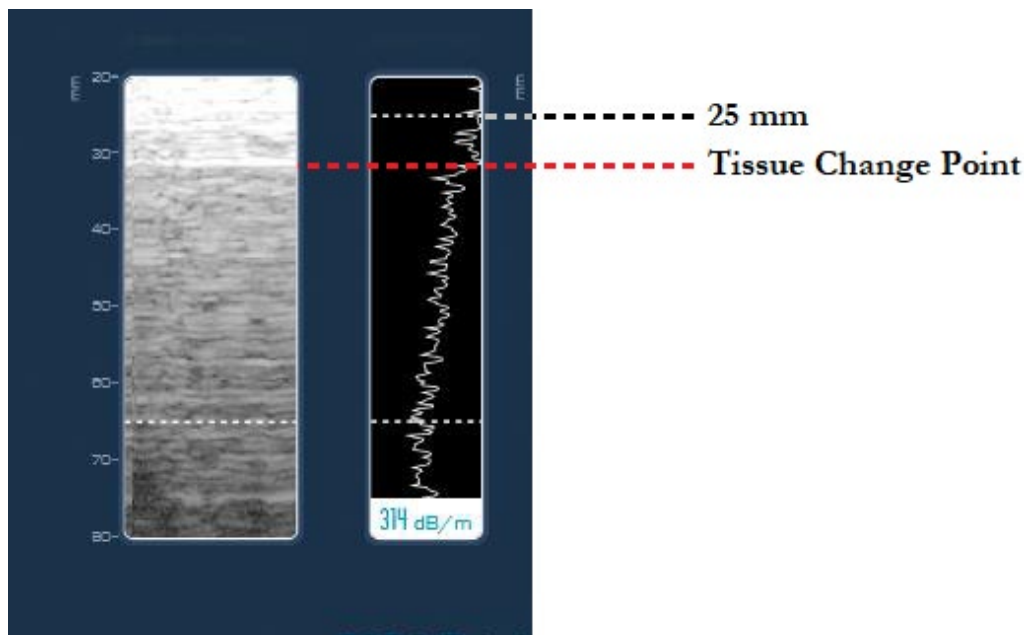
The FibroScan has a built-in automatic wand recommendation tool that operates in real time as the wand detects ultrasound signals. The result of the automatic wand recommendation tool is displayed at the bottom of the screen. Always start with the M+ wand regardless of the body habitus of the SP. If the automatic wand recommendation tool suggests the XL wand, move the M+ wand to at least three different sites before switching wands. Do not switch wands based off one measurement site. If the skin-to-capsule-distance (SCD) exceeds 25 mm in three different location then switch to the XL wand. See Exhibit 15 for an example of an SCD that exceeds 25 mm. Note that changing

wands during an exam will delete all measurements taken using the previous wand. To change wands during an exam, follow the steps below:

1. Select the new wand type. The following message is displayed:
2. “Change of exam type. Changing exam type causes all previous measurements to be definitively erased.”
3. Click OK. The following message is displayed: “Exam type has changed.”
4. Resume the exam.

NOTE: The sight of the wand may make some SPs frightened and anxious. To make them feel more relaxed, demonstrate the use of the wand on your palm or the SP’s palm.

Exhibit 3-15. Probe Selection Guidance

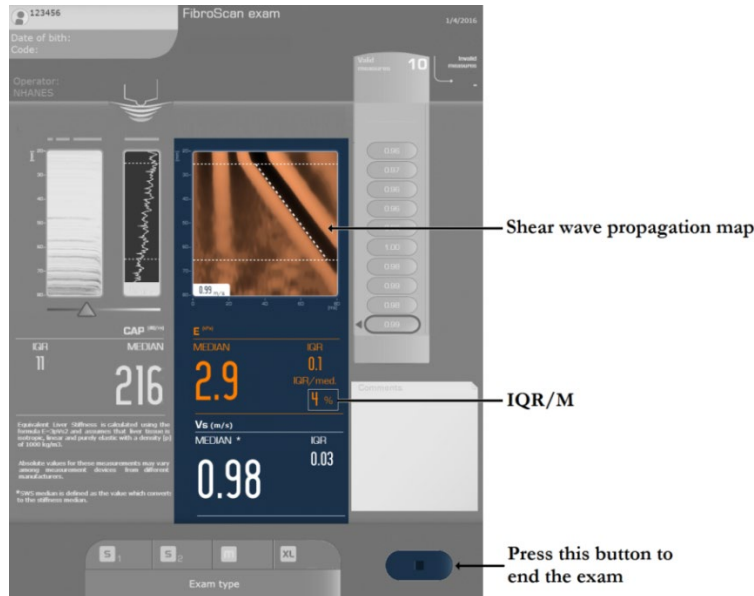


3.3.2.2 Examination Procedure

After selecting the correct wand and confirming that is correctly positioned in the center of the liver, take 10 valid measurements. If the first measurement is equal or greater than 12 Kilopascals (KPa), reposition the wand and take additional measurements in at least three different sites and select the site with the lowest stiffness value to obtain the 10 valid measurements. A measurement is considered valid when the shear wave propagation map is displayed with parallel margin shear waves

and the interquartile range/median (IQR/M) is less than 30% (Exhibit 3-16). If you have to reposition the wand for any reason, ensure that the valid measurements are from the same location.

Exhibit 3-16. Acquisition screen with valid measurements



NOTE: The IQR/M is recalculated after each new valid measurement. When the number of valid measurements is equal to 1, the IQR/M ratio is undefined and therefore not calculated.

If you have at least 10 valid measurements taken at the same location, and an IQR/M <30%, quickly review each measurement for the following:

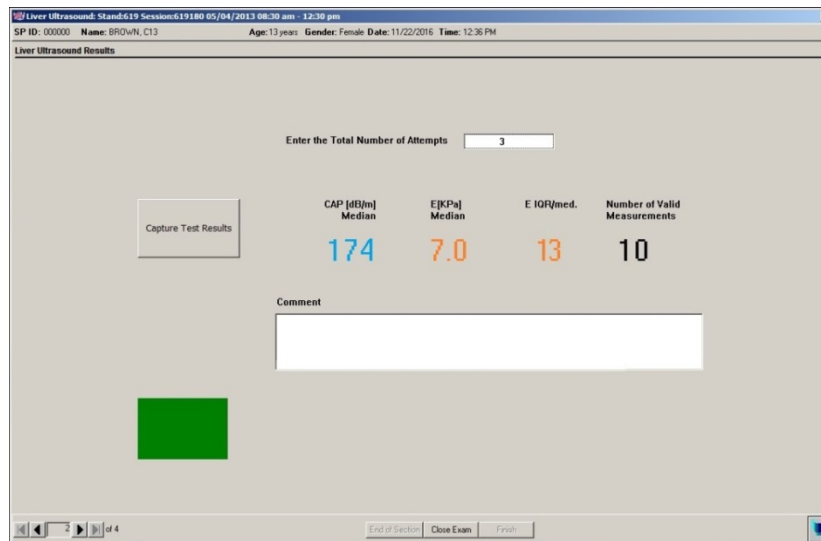
- TM mode visually uniform and nicely layered,
- TM and A mode display the tissue change point above the upper dotted line,
- Liver targeting tool green,
- A mode displays a linear decrease with depth,
- Propagation map displays parallel margin shear waves.

NOTE: As long as most of the valid measurements meet the requirements listed above (a-e), no more than 15 measurements, taken from the same location, should be imported into ISIS.

End the exam by pressing the “End” button (Exhibit 3-16).

- Import the results from the FibroScan system into ISIS by clicking the “Capture Test Results” button on the ISIS Liver Ultrasound Results screen (Exhibit 3-17).
- Enter the number of attempts into ISIS. An attempt consists of at least one valid or invalid measurement on the same measuring site. If the skin indentations made by the ultrasonic transducer overlap, consider the measurements as made on the same measuring site. If the skin indentations don’t overlap, count them as separate attempts.
- Wipe the ultrasound gel from the SP, remove the cosmetic pencil marks, and ask the SP to sit up.
- Clean off the gel from the wand using a gauze pad and wipe it using a SONO disinfectant wipe.
- Wrap a new SONO wipe around the wand and leave it in the holder to keep the surface wet.

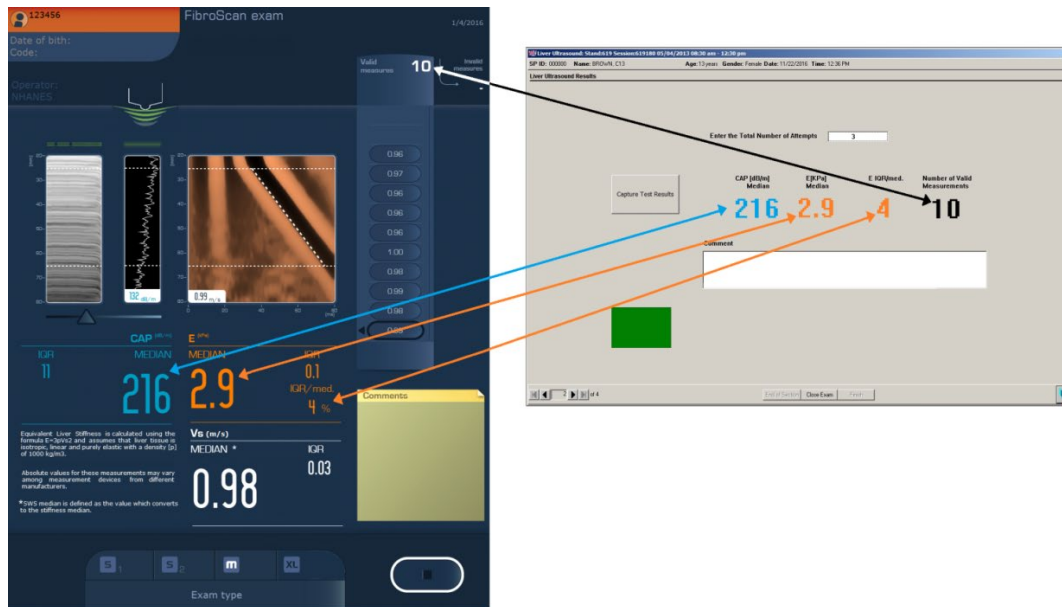
Exhibit 3-17. Liver Ultrasound Results screen



Verify that the following fields are populated (Exhibit 3-18):

- Number of valid measures;
- CAP median (blue font);
- Stiffness median (orange font); and
- IQR/M (orange font).

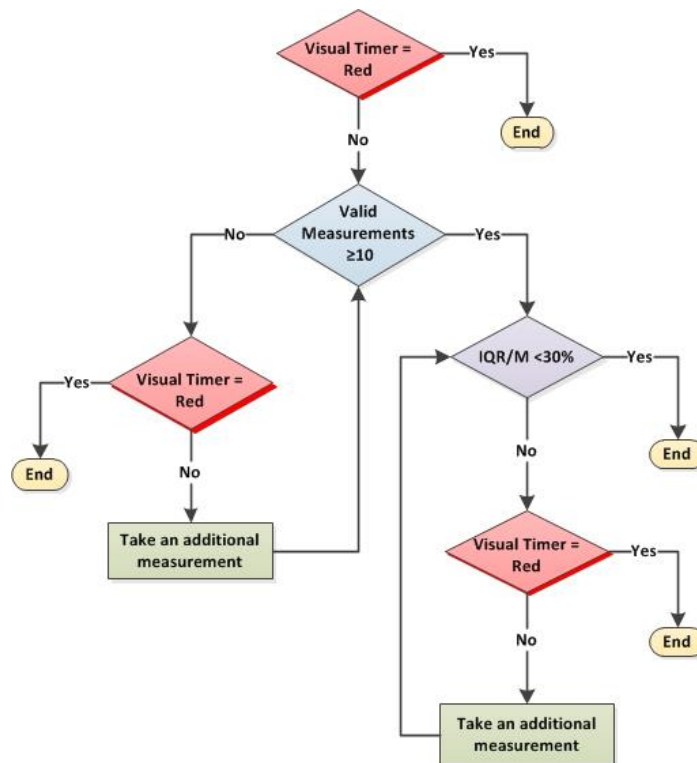
Exhibit 3-18. Data verification



3.3.2.4 Procedure for Less Than 10 Valid Measurements and or an IQR/M \geq 30%

If the visual timer is not red and you have less than 10 valid measurements with an IQR/M \geq 30%, continue taking measurements until you have at least 10 valid measurements with an IQR/M $<$ 30%. To lower the IQR/M you might have to delete measurements from the list of valid measurements. Do not delete valid measurements unless you have taken additional ones to replace them. Valid measurements are listed first to last (top to bottom). To delete a measurement, select the last measurement to be deleted and then press the “X” button. (Refer to Chapter 2 for instruction on how to delete measurement.) A confirmation request is displayed that indicates the number of measurements remaining if deletion is confirmed. Note that all measurements taken before the one chosen for deletion will be eliminated from the exam after confirmation (Exhibit 3-19.)

Exhibit 3-19. Less than 10 valid and or IQR/M \geq 30%

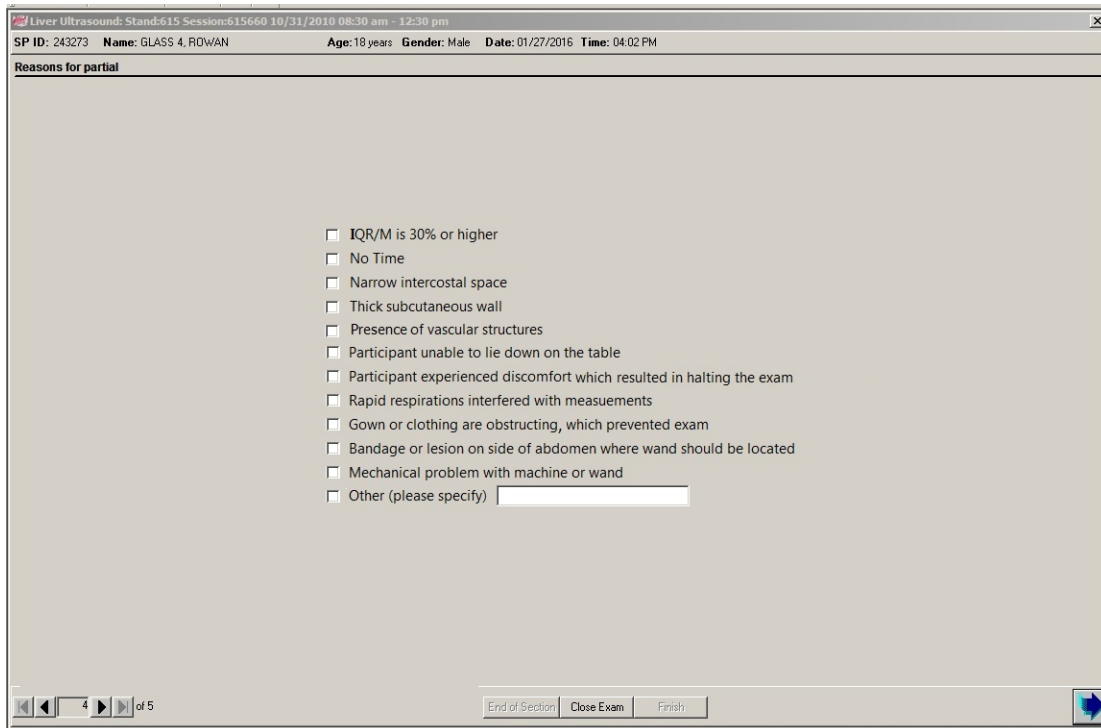


If you are unable to obtain at least 10 valid measures and/or the IQR/M remains greater or equal to 30%, a Comment screen (Exhibit 3-20) will be displayed when the “Next” button is pressed. This screen allows you to check more than one reason or choose the “Other, specify” box and enter a description.

1. IQR/M is 30% or higher;
2. No time;
3. Narrow intercostal space;
4. Thick subcutaneous wall;
5. Presence of vascular structures;
6. Participant unable to lie down on the table;
7. Participant experienced discomfort which resulted in halting the exam;
8. Rapid respirations interfered with measurements;
9. Gown or clothing are obstructing, which prevented exam;

10. Bandage or lesion on side of abdomen where wand should be located;
11. Mechanical problem with machine or wand; and;
12. Other (please specify)

Exhibit 3-20. Reasons for Partial screen



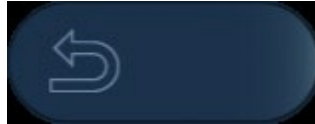
3.4 Procedure to End the Examination

After verifying the correct information was transferred into ISIS, select the “Return” button (Exhibit 3-21) on the FibroScan system to go back to the home window (Exhibit 3-13). Press the “Next” button on the ISIS Liver Ultrasound Result screen. When the “Next” button is pressed and you have at least 10 valid measurements with an IQR/M less than 30%, the ISIS system will advance to the Component Status screen. If the number of valid measurements is less than 10 and/or the IQR/M is greater or equal to 30%, the ISIS system will advance to the Reasons for Partial screen. Select one or more applicable reasons or enter a description under “Other, specify” and press the “Next” button. Then:

- Clean and disinfect the wands,
- Remove the cosmetic pencil marks,

- Assist the SP into a sitting position and off the examination table,
- Remove the paper from the table and wipe it with a SONO wipe, and
- Place a new sheet of paper for the next SP.

Exhibit 3-21. Return button



3.4.1 LUTE Component Status Screen

The LUTE Component Status marks the final ISIS screen. The purpose of this screen is to document the overall status of the LUTE examination: Complete, Partial, or Not Done. As with all other MEC exam components, ISIS will automatically default to one of these codes.

- **Complete:** 10 or more valid measurements with an IQR/M < 30% (Exhibit 3-22);
- **Partial:** Less than 10 valid measurements (Exhibit 3-23) and/or an IQR/M \geq 30% (Exhibit 3-24); or
- **Not Done:** No required measurements were captured in ISIS (Exhibit 3-25).

For Partial and Not Done exams, use the drop-down menu beside the “Comments” box to select from a list of reasons. If you choose the “Other, specify” comment, you must enter a description. Only select “Other, specify” if the comment does not fit into one of the defined comments.

Below is a script for ending the examination. This is a standard script, but you may adjust the explanation to the level of understanding of the SP.

“Thank you, we are done with the exam, you can sit up when you are ready. After your liver stiffness values are reviewed for accuracy by NHANES staff and determined to be valid, the results will be sent to you with your final report of findings. If you are interested in additional information about this exam, you will receive a list of questions and answers that are commonly asked.”

To end the component click the Finish button on the ISIS screen. This signals the coordinator to make the next assignment for that SP. Do not click Finish until the SP is ready to be escorted out of the room and the room is ready for the next SP.

Exhibit 3-22. LUTE Component Status screens – Complete

The screenshot shows a software window titled "Liver Ultrasound: Stand:615 Session:615261 09/21/2010 01:30 pm - 05:30 pm". The header bar contains patient information: "SP ID: 185868 Name: LIU 3, TANGELA Age: 32 years Gender: Female Date: 01/18/2016 Time: 03:59 PM". The main area is titled "Liver Ultrasound Status". A central form titled "Status" contains three radio buttons: "Complete" (selected), "Partial", and "Not Done". Below the radio buttons are two text input fields: "Comments" and "Other text". At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish".

Exhibit 3-23. LUTE Component Status screens – Partial < 10

The screenshot shows the same software window as Exhibit 3-22. The header bar contains the same patient information. The "Status" form has the "Partial" radio button selected. The "Comments" field contains the text "Less than 10 valid measurements" and the "Other text" field contains "expected 10 or higher valid measurements comm". The navigation buttons at the bottom are the same as in Exhibit 3-22.

Exhibit 3-24. LUTE Component Status screens – Partial IQR/M \geq 30%

The screenshot shows a software window titled "Liver Ultrasound: Stand615 Session:615261 09/21/2010 01:30 pm - 05:30 pm". The patient information at the top includes "SP ID: 195868", "Name: LIU J, TANGELA", "Age: 32 years", "Gender: Female", "Date: 01/18/2016", and "Time: 03:59 PM". The main area is titled "Liver Ultrasound Status". A central form has a "Status" section with three radio buttons: "Complete", "Partial" (which is selected), and "Not Done". Below this is a "Comments" dropdown menu with the text "IQR/M is 30% or higher" and an "Other text" field containing "expected the IQR/M is 30% or higher comm". At the bottom of the window are navigation buttons: "End of Section", "Close Exam", and "Finish".

Exhibit 3-25. LUTE Component Status screens – Not done

The screenshot shows the same software window as Exhibit 3-24. The patient information is identical. In the "Status" section, the "Not Done" radio button is selected. The "Comments" dropdown menu now shows "Select a reason". The "Other text" field is empty. The navigation buttons at the bottom remain the same.

3.4.2 Special Consideration

Obtaining complete and accurate data can be more challenging under some circumstances. The following situations may require certain modifications to the procedures that would be followed under routine conditions.

SPs in Street Clothes. Some SPs refuse to change into the shirt and/or pants provided to them as part of the standard survey examination gown. If a participant enters the exam room wearing his or

her street clothes, ask if the shirt or blouse can be raised to expose their right side above the waist and below the breastbone. Use a terry wipe (WyPall) to protect SP's clothing from the ultrasound gel.

Comprehension or Language Difficulties. Some SPs may have difficulty understanding the examination instructions. Exam staff should use extreme caution when attempting to conduct the liver ultrasound transient elastography component on these participants. If the SP cannot understand your instructions due to a developmental disability or other type of physical or mental impairment, ask if a family member or friend accompanied the SP to the MEC who can help explain your directions to the SP. Regardless, if you believe the SP cannot comprehend well enough for you to safely and accurately carry out the examination protocol, then on the Reasons for Partial screen choose the “Other, specify” option and enter a description. On the ISIS Component Status screen select “Communication Problem” as the reason for the Partial.

For many SPs, language barriers are a common cause of difficulty in understanding examination instructions. For Spanish-speaking SPs, if the examiner is not English-Spanish bilingual, a Spanish interpreter will be assigned to interpret for the SP and the examiner during the exam. If the SP speaks a language other than English or Spanish, arrangements will be made ahead of the exam to identify an appropriate interpreter. Nevertheless, as in the case of other forms of comprehension difficulties, if you cannot safely and accurately perform the exam on the SP, code the exam as Could Not Obtain (CNO) on the ISIS screen and select “Communication Problem” as the reason for the Partial or Not Done exam status.

Close Exam. Any exam may be terminated at any point during the exam (SP becomes ill, changes his or her mind about completing the test). To close the exam, press the “Close Exam” button. This will end the exam abruptly without going through the remaining screens. Select a comment and click on “Close” to end the exam.

3.5 Post-Examination Procedure

To end the component, click the “Finish” button on the ISIS screen. This signals the coordinator to make the next assignment for that SP. **Do not click Finish until the SP is completely ready to be escorted out of the room.** Wait for a message from the coordinator indicating where to direct the

SP. Thank the SP for participating and accompany him or her to the next exam room or the reception area.

3.6 Report of Findings for LUTE

A list of questions and answers that are commonly asked (Appendix B) will be generated by the coordinator and given to the participants during check out. The final Report of Findings for LUTE will be sent from NCHS after the liver stiffness values are reviewed for accuracy and determined to be valid.

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4. Quality Control

4.1 Introduction to Quality Control

Quality control procedures ensure the collection and documentation of accurate, reliable data. The procedures were developed to reduce interexaminer variability, reduce error, and ensure data quality. The quality control (QC) program for this component will take place in mobile examination centers (MECs) and will consist of the following major elements:

- Training;
- Monitoring equipment and equipment repair, and verifying daily and weekly calibrations; and
- Site visit observations by NCHS and Westat.

4.2 Training

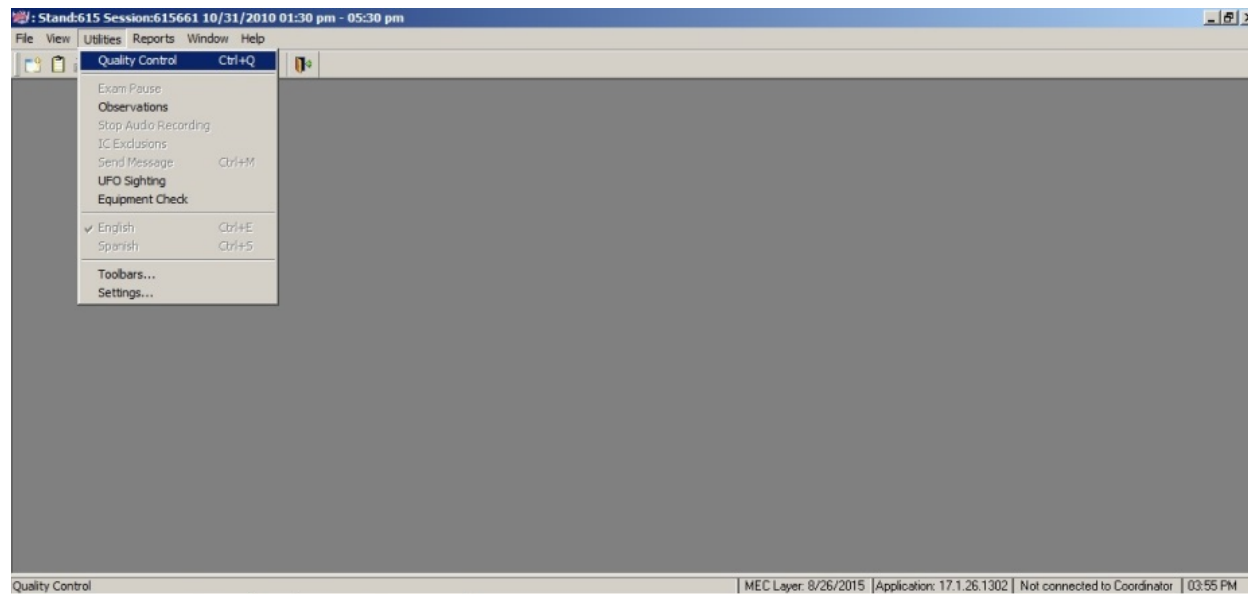
Training will be provided by NCHS personnel, Westat, and an Echosens expert trainer. This training process includes didactic presentations and practice sessions with volunteers. Ongoing training needs, as identified by the home office staff, consultants and NCHS, will be assessed and scheduled. Retraining sessions will be arranged by Westat in coordination with the NCHS project officer and the Echosens consultants when major protocol changes are introduced or a lack of standardization is observed among the technologists.

4.3 Monitoring Equipment

Routine cleaning of the liver ultrasound transient elastography equipment is an essential QC measure to ensure optimal operation. Specifically, the FibroScan machine and wands must be cleaned and disinfected according to the schedule outlined in this section. The technologist will complete these procedures using the Liver Ultrasound Quality Control Checks dialog box that contains designated tabs for the start of stand, start of session, and end of stand. To access this dialog box, select the “Quality Control Checks” option from the toolbar menu at the top of the screen (Exhibit 4-1). Click the “Done” box beside each of the checked items listed to record completion of the procedure. If the QC procedures have not been completed for that period, a

message will be displayed at each logon until the QC procedures have been completed. The home office component staff monitors the equipment QC completion rates, and provides feedback and/or retraining as warranted.

Exhibit 4-1. Quality control checks



4.3.1 Quality Control Checks Screens

The schedule for equipment cleaning is provided in the following screens of the Quality Control Checks dialog box.

4.3.2 Start of Stand

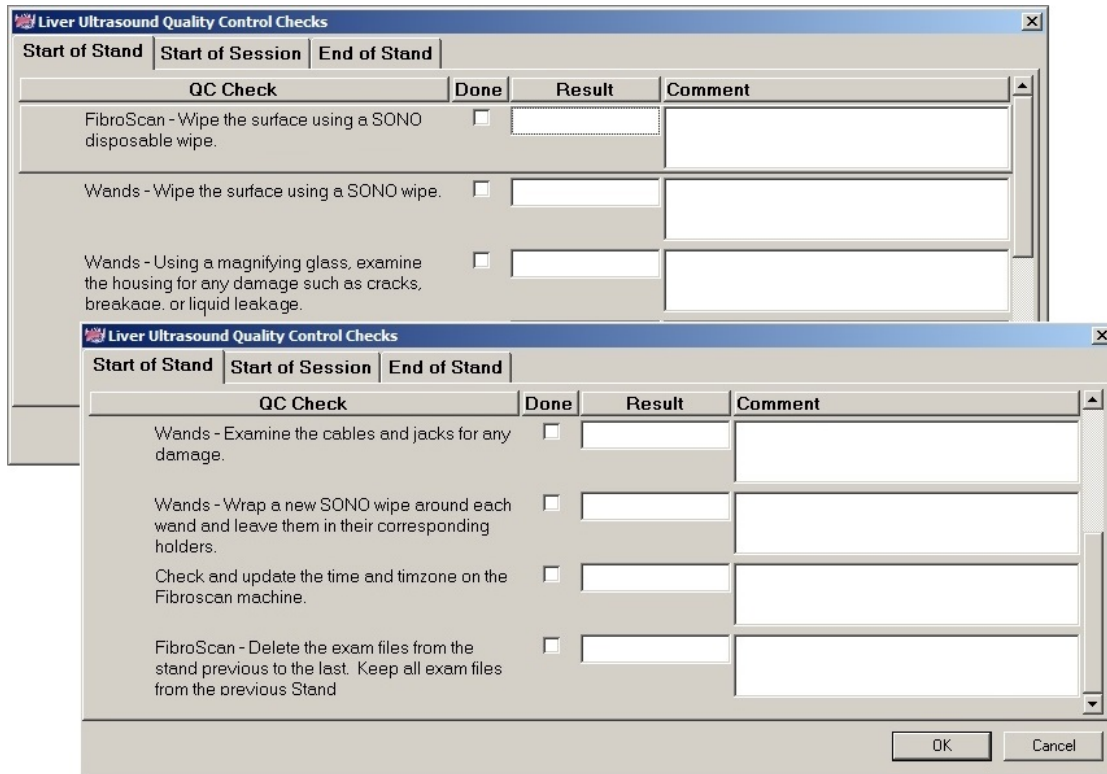
Check and update the time and time zone on the FibroScan machine (Exhibit 4-2). The date and time on the FibroScan machine can be modified in Configuration mode. For detailed information on how to complete the Start of Stand QC checks, refer to Chapter 2, Section 2.3.1.

- **FibroScan.** Wipe the surface using a SONO disinfectant wipe. Use multiple wipes if necessary to achieve contact time.
- **Wands.** Wipe the surface using a SONO wipe.
- **Wands.** Using a magnifying glass, examine the housing for any damage such as cracks, breakage, or liquid leakage. If any damage is observed, stop using the wand, submit an

Unusual Field Occurrence (UFO), and contact the facilities and equipment specialist (FES).

- **Wands.** Examine the cables and jacks for any damage. If any damage is observed, stop using the wand, submit a UFO, and contact the FES.
- **Wands.** Wrap a new SONO wipe around each wand and leave each wand in its corresponding holder.
- **FibroScan.** Check and update the time and time zone.
- **FibroScan.** Delete old exam files.
- **FibroScan.** Complete all Phantom QC Scans.

Exhibit 4-2. Start of stand QC checks



4.3.3 Start of Session

The following is detailed instruction on the start of session QC checks (Exhibit 4-3).

- **FibroScan.** Wipe the surface using a SONO wipe. Use multiple wipes if necessary to achieve contact time.

- **Wands.** Wipe the surface using a SONO wipe.
- **Wands.** Using a magnifying glass, examine the housing for any damage such as cracks, breakage, or liquid leakage. If any damage is observed, stop using the wand, submit a UFO, and contact the equipment specialist.
- **Wands.** Examine the cables and jacks for any damage. If any damage is observed, stop using the wand, submit a UFO, and contact the FES.
- **Wands.** Wrap a new SONO wipe around each wand and leave each wand in its corresponding holder.
- **Wands.** At the end of a work week, store them in their corresponding storage cases.

Exhibit 4-3. Start of session QC checks

The image displays two screenshots of the 'Liver Ultrasound Quality Control Checks' software interface. The top screenshot shows the 'Start of Stand' tab with two rows of checks: 'FibroScan - Wipe the surface using a SONO disposable wipe.' and 'Wands - Wipe the surface using a SONO wipe.' The bottom screenshot shows the 'Start of Session' tab with four rows of checks: 'Wands - Using a magnifying glass, examine the housing for any damage such as cracks, breakage, or liquid leakage.', 'Wands - Examine the cables and jacks for any damage.', 'Wands - Wrap a new SONO wipe around each wand and leave them in their corresponding holders.', and 'Wands - At the end of a work week, store them in their corresponding storage case.' Both screenshots include 'Done', 'Result', and 'Comment' columns and 'OK' and 'Cancel' buttons.

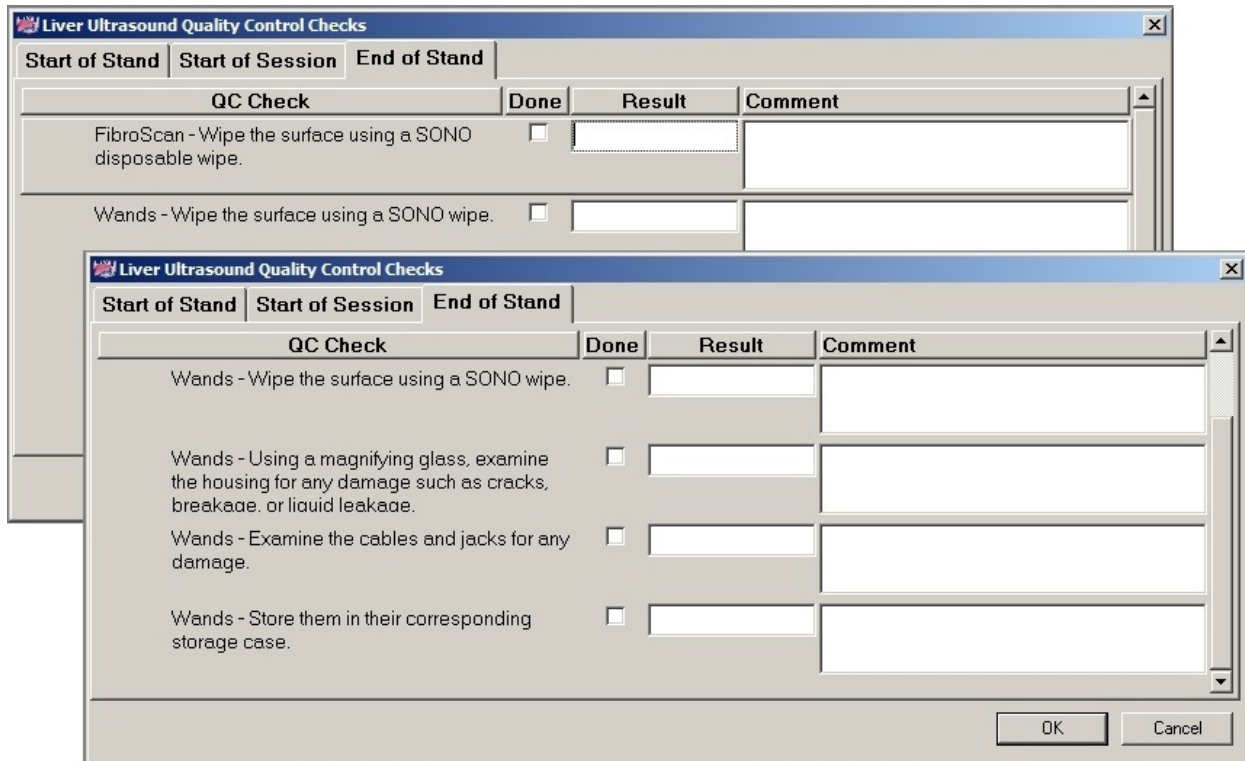
4.3.4 End of Stand

The following is detailed instruction on the end of stand QC checks (Exhibit 4-4).

- **FibroScan.** Wipe the surface using a SONO wipe. Use multiple wipes if necessary to achieve contact time.
- **Wands.** Wipe the surface using a SONO wipe.

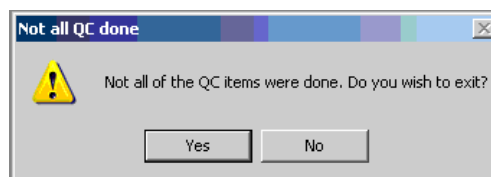
- **Wands.** Using a magnifying glass, examine the housing for any damage such as cracks, breakage, or liquid leakage. If any damage is observed, submit a UFO and contact the FES.
- **Wands.** Examine the cables and jacks for any damage. If any damage is observed, submit a UFO and contact the FES.
- **Wands.** Store them in their corresponding storage cases.

Exhibit 4-4. End of stand QC checks



When finished completing the required Quality Control Checks, click OK to exit the dialog box and return to the Main Component screen. However, if you have not checked the “Done” box beside all of the required checks, clicking OK will open the following pop-up window (Exhibit 4–5).

Exhibit 4-5. Quality control checks: Not all QC done



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Appendix A

**Suggested Introduction Script
(Spanish Translation)**

Appendix A

Suggested Introduction Script (Spanish Translation)

En esta sala vamos a hacer un examen que intentará ver el estado de su hígado. Para este examen tendrá que acostarse bocarriba en esta camilla. Voy a pedirle que se levante la bata un poco para encontrar el esternón (este hueso plano ubicado aquí, en la parte delantera del pecho) a la mitad del abdomen.

Esta máquina no toma imágenes del hígado. Únicamente mide la velocidad a la cual viajan las ondas de ultrasonido cuando llegan al hígado, lo cual puede indicar la rigidez del hígado. Durante este examen voy a ponerle este aplicador [SHOW WAND] a un lado de las costillas. El aplicador va a vibrar contra la piel, enviará ondas de ultrasonido al hígado y grabará las ondas que regresan del hígado. Si la máquina no graba la información correctamente, me lo notificará y tendré que repetir el procedimiento para obtener resultados correctos. No sentirá ninguna incomodidad durante este examen. Lo ayudaré a ponerse en la posición correcta en la camilla para que podamos obtener las mediciones válidas. Esto me ayudará a poner el aplicador en el lugar correcto, en el costado derecho, para medir la rigidez de su hígado. ¿Tiene alguna pregunta?

Ahora, comenzaré por palparle hasta encontrar el esternón y le voy a hacer una pequeña marca en el costado derecho con un lápiz cosmético. Voy a aplicar un poco de gel a base de agua en la punta de este aplicador y se lo voy poner contra la piel, presionando muy suavemente. ¿Está listo?

(If necessary to get a good measurement, ask the participant to hold his or her breath briefly.)

Ahora, necesito que tome aire lentamente, déjelo salir despacio y haga una pausa.

Muy bien. Ahora puede respirar normalmente.

Gracias. Hemos terminado el examen. Se puede sentar cuando esté listo(a). Después de que el personal de NHANES revise la precisión de los valores de rigidez de su hígado y determine que son válidos, le enviarán su informe final con los resultados. Si desea más información sobre este examen, recibirá una lista de preguntas y respuestas frecuentes.

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Appendix B

Frequently Asked Questions

Appendix B

Frequently Asked Questions

Why is this Test Being Done? This test is designed to measure the stiffness of your liver. A healthy liver is usually soft and flexible, but a person with liver disease tends to have a liver that is stiff. The information obtained from this exam will be used to determine how many people in the United States have liver stiffness and what may have caused this liver change.

How Does this Test Work? The liver ultrasound test uses a technology called transient elastography. A wand placed on the skin on the right side of your chest sends ultrasound waves through your liver, and the machine records the speed of waves as they pass through the liver.

Was I Exposed to Radiation Like an X-Ray? No, the test used ultrasound waves and did not give off radiation like an x-ray machine.

Will I Receive my Liver Results? After reviewing the liver elastography measurements, if it is determined your test results are accurate, we will send them to you in the mail along with your final report of findings in the coming weeks.

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