No.	Function	No.	Function
⑮	ROI (region of interest) area Use the zoom function to zoom in and pan across the current image.	⑯	**End Exam** button Close the current exam for the current patient, and start a new exam for the next patient. All the value settings adjusted during this exam will be stored automatically.
⑰	• (Hig**h) Resolution**: Move the cursor to the right for a clearer yet superficial image. • (Dee**p) Penetration**: Move the cursor to the left for a deeper yet less clear image.	⑱	**PW Update** button Start/stop the PW trace.
⑲	• TGC (Time Gain Compensation) Slide any of the 8 TGC sliders to adjust the gain for the desired section of the 2D imag**e.** • **M Update** button Start/stop the M trace.	⑳	**Tuning** button Optimize the image quality during a real-time scan.
㉑	**Function** key Assign this button as a shortcut to perform a function.	㉒	Thumbnail list Thumbnails of the scanned images/clips that are saved
㉓	Touch the left/right arrow to toggle through different sets of image control settings when using duplex or triple modes.	㉔	**Freeze** button Freeze the current scan.
㉕	Open the next page of the image control settings (See page 56).	㉖	Image control settings (See page 70)
㉗	Mode selection buttons		

Imaging screen (Frozen)

During an exam, touch **Freeze** to review all the ultrasound images stored in the cine buffer frame by frame, or play back these frames in a continuous loop. The operator can also measure, calculate and add annotations to the frozen images or clips.
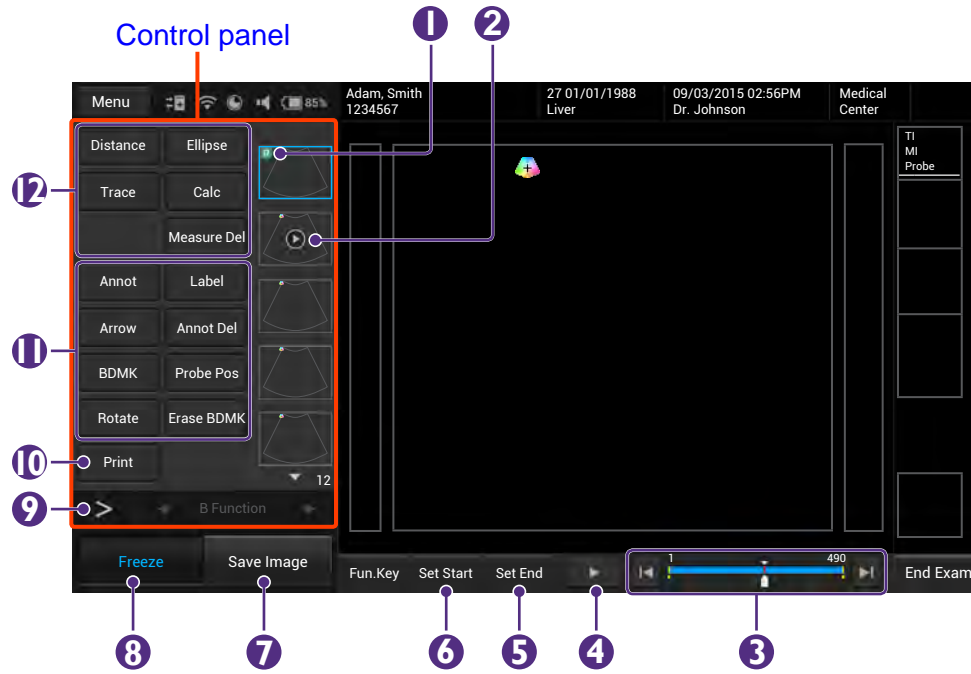
Figure 7   Frozen imaging screen (example)

No.	Function	No.	Function
❶	This image is added to a report.	❷	Cine clip
❸	The progress bar	❹	Play back the recent image frame sequence.
❺	Set the end point of the cine clip.	❻	Set the start point of the cine clip.
❼	**Save Im**age button Save a frozen image or a clip to the system hard drive.	❽	**Fre**eze button (Enabled) Touch this button again to return to the real-time scan.
❾	Open the next page of the image control settings. (See page 56)	❿	Print out the image from the thermal printer connected to the system via the USB connector.
⓫	Add annotations, including arrows, texts and body marks, to the current image using the virtual keyboard.	⓬	Perform measurements and calculations on the current image.

System tools

Touch anywhere on the system toolbar to open the system tools widget. Touch an item to adjust its setting.

Figure 8   System tool widget

No.	Function	No.	Function
❶	Manually set current date and time.	❷	Enable/Disable the Bluetooth function.
❸	Cast the system screen to an external display.	❹	Check and manage outgoing queues.
❺	Adjust the brightness.	❻	Adjust the volume.
❼	Display the percentage of the system storage used. Follow the pop-up message to free up storage space by deleting exams done in the appointed number of weeks.	❽	Manage the Ethernet settings
❾	Enable/Disable the WLAN function.		

Virtual keyboard

Whenever the operator needs to enter text in a text field, simply touch the field, and a virtual keyboard appears on the lower part of the screen.

Touch a letter to enter text; when finishing inputs, touch **Done**.

Figure 9   Virtual keyboard

Scan properties display

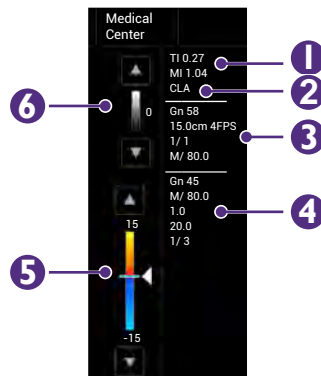The imaging window includes a text display information about the current scan.

Figure 10 Scan properties display (example)

No.	Function	No.	Function
1	Thermal index/Mechanical index	2	Transducer type
3	2D image control settings: Gain/Depth/FPS/QBeam/PWR	4	Color image control settings: Gain/PWR/PRF/Wall Filter/ Persistence
5	Color wedge	6	Grayscale wedge

Switch the control panel pages

The functions available on the control panel vary, depending on the scan mode and the transducer connected.
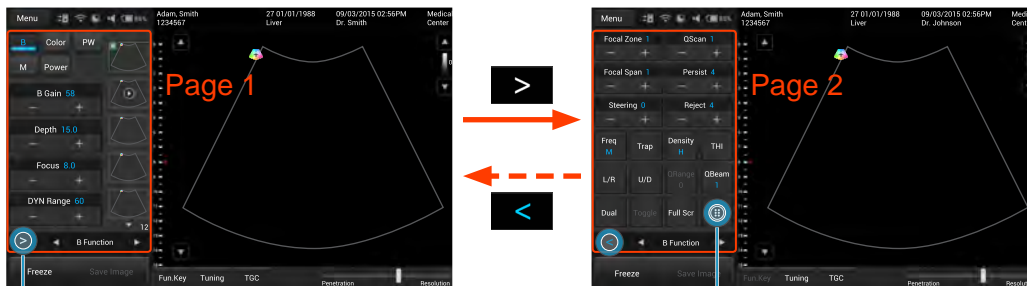
Touch to open the next page (page 2).

Touch to display more functions (page 3).

Touch to return to the first page (page 1).

Touch to return to the previous page (page 2).

Add a new patient

The system allows skipping entering patient information if the operator needs to start the ultrasound exam immediately. However, the images and cine loops cannot be saved. We recommend that the operator defines the patient within the system before scanning to avoid mix-ups and to generate reports.

1. On the imaging screen, touch **Menu** > **Patient**.

Figure 11 Patient screen

2. Touch **New Patient**. Enter the patient information as much detail as possible:
    » Touch in a text entry field, and use the virtual keyboard below to input contents.
    » Touch **Next** on the keyboard to go to the next field.
   » Touch **Done** on the keyboard.

    > To create a valid patient profile, at least the patient**'s First n**ame and **ID** number should be filled in.

3. Touch **Save**.

    To start scanning the patient, touch **Scan**.

To update patient information

1. On the patient screen, touch **Edit Patient**.

2. Enter the new information in the appropriate fields.

3. Touch anywhere on the screen, the following system message appears. Touch **Save** to save changes.
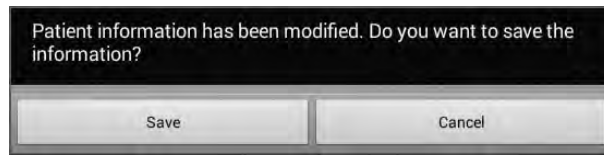
Load a work list

The system conforms with the Digital Imaging and Communications in Medicine (DICOM) standard, which is the industrial standard for the communication and management of patient data between devices in the hospital. The operator can load patient information in a work list via the DICOM server.

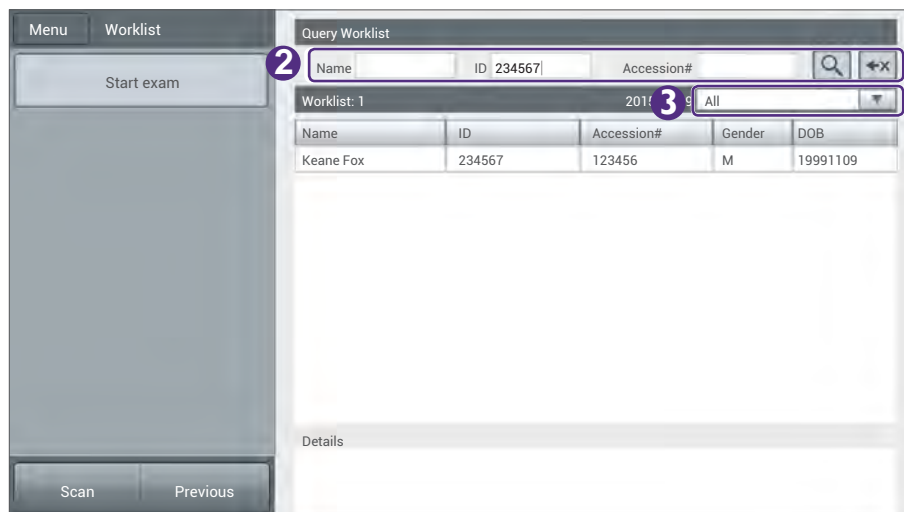1. On the imaging screen, touch **Menu** > **Work list**.

Figure 12 Work list screen

2. Enter the query criteria in any of the **Name/ID/Accession#** fields, and touch $\boxed{Q}$ to start the query. Patients matching the query will be listed on the screen.

3. Select the number of patients to scan on the worklist from the drop-down menu.

   To start scanning, select a patient, and then touch **Start exam**.

Select a preset

The system provides predefined presets for all supported transducers. Choosing an exam loads optimized presets for image control settings, based on the anatomy to be scanned, the transducer used, and the scanning mode. The presets also specify the measurements appropriate for the exams. The operator can directly use the optimized presets, or adjust any of the image control settings as necessary for the specific patient and the specific exam.

1. On the imaging screen, touch **Menu** > **Preset**. All the available presets compatible with the connected transducer displays on the preset screen.

Figure 13 Preset screen

2. Touch the exam/preset to scan, and the operator will be redirected automatically to the real-time imaging screen.

To modify current presets

1. On the preset screen, touch **Movement**.

2. Touch **Move**, and drag to re-arrange the order of the presets. To hide an unwanted preset, touch **Hide & Show Preset**, and touch **Off** on the preset.

3. Touch anywhere on the screen, the following system message appears. Touch **Save** to save changes.
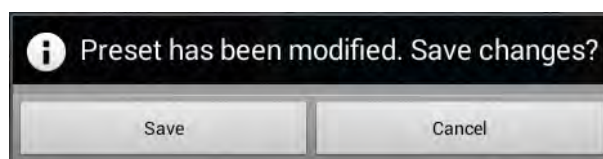
Set the transducer orientation

Upon entering all imaging modes, the orientation marker ( ) displays at the default location (usually at the top left side of the image), and suggests the operator the direction of holding the transducer. The orientation marker on the screen corresponds to the position of the orientation marking on the side of the transducer.

Orientation marker
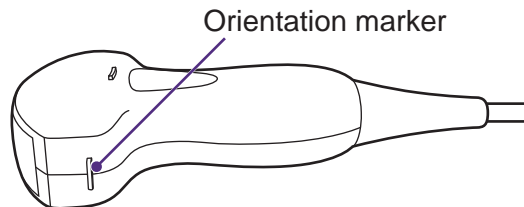
Figure 14 Transducer orientation (Example transducer-C52A)

The operator can change the left/right orientation of the image (real-time or frozen) in various imaging (single or dual) without rotating the transducer head itself.

- To reverse left and right

  On the imaging screen (real-time or frozen), touch ❯ > **L/R**.

- To reverse up and down

  On the imaging screen (real-time or frozen), touch ❯ > **U/D**.

Adjust the displayed image

On the real-time imaging screen, touch the corresponding mode selection button to select a scan mode. Use the image control settings to further optimize the image. For explanations and usage of these settings on specific modes, please refer to their respective chapters.

The operator can also perform the following operations to adjust the contents of the imaging window.

Enlarge an area of the image

To further examine the anatomy by enlarging a region of the image (real-time or frozen), use the zoom function.

1. On the imaging screen, touch **>** > (⠿) > **Zoom**. The ROI (Region of Interest) box appears on the center of the image.

Figure 15 Enlarge a ROI (normal image)

Touch and drag inside of the ROI box to move it to the area to enlarge. Touch on any of the box's four corners and drag to resize the ROI box.

2. Touch anywhere outside the ROI box to enlarge selected area.
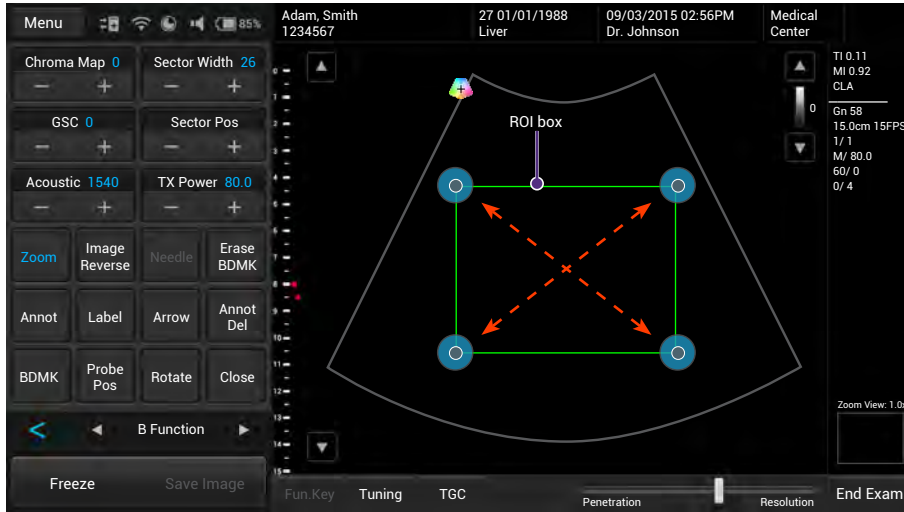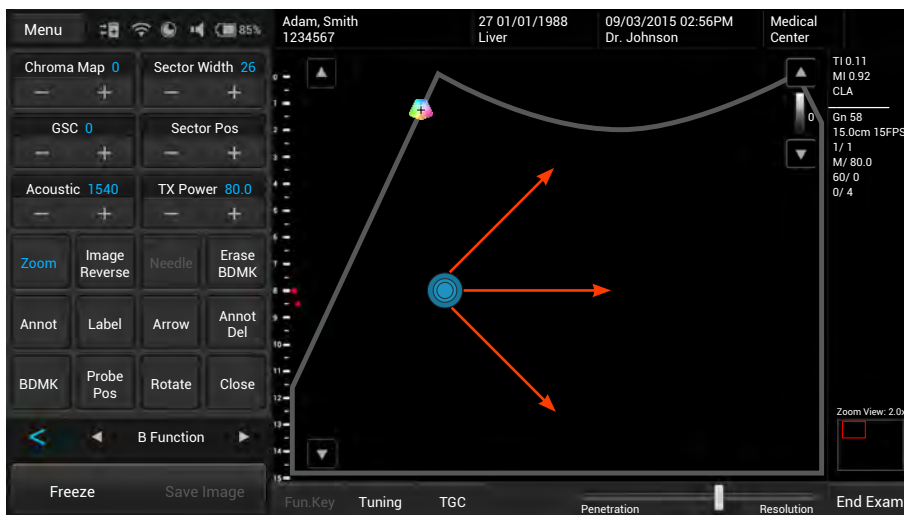

Figure 16 Enlarge a ROI (zoomed image)

The operator can still move the enlarged area by touching and dragging anywhere on the image.

Split the imaging screen

The system allows splitting the imaging screen into two sections to view two current scans for a patient. The operator can acquire one scan for the patient, enable split screen, and then acquire another scan from a different angle, location or with a different scan mode.

On the imaging screen, touch **>** > **Dual**. The ultrasound software immediately freezes the current scan, and copies the current settings for the image to the second screen.
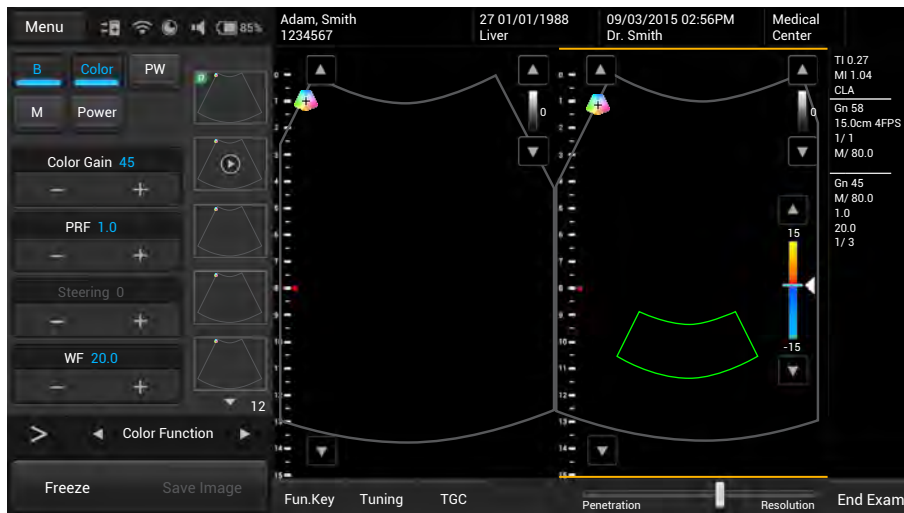
Figure 17 Dual screen

To select a screen, touch **Toggle**. Only one screen can be active at a time. The operator can then apply any image control settings and use scan modes independently to either screen. For example, the operator can acquire a 2D scan, activate dual screen, and then acquire a Color Doppler scan in the second screen.

To leave the dual screen, touch **Dual** again.

Freeze an image

During a real-time scan, touch **Freeze** to freeze live ultrasound images recorded by frame and stored temporarily in the cine buffer. Depending on the mode selected, a certain number of frames are recorded.

- To view the saved images frame by frame, touch **|◀** / **▶|** .

- To play back saved images in a continuous cine loop, touch **▶** .

- To re-start a new live scan, touch **Freeze** again.
- If no frozen image or cine loop are saved, restart live scanning erases the frame data. Make sure any needed images are saved or printed before acquiring new scan data.

Add annotations and measurements

On the frozen imaging screen, the operator can add annotations and measurements to the ultrasound images in order to explain the anatomy.

If you return to the real-time imaging screen without saving the image, all the annotations and measurements added will be cleared.

Annotations

Figure 18 Add annotations

Arrow

Touch **Arrow**. An arrow appears at the text home position. Drag the arrow to place it to the desired location **a**.

Text

1. Touch **Annot**. A virtual keyboard and a text cursor (I-beam) appear at the text home position.

2. Type the texts directly. Touch **Done** on the keyboard to finish inputs.

3. Drag the text cursor to where you want the new texts to be, and release it to place the texts **b**.

Set the text home position

The operator can choose a specified position in the image display as the starting location, which is the text home position.

1. Touch **Annot**.

2. Drag the text cursor to the desired text home position.

3. Touch Set **Home**.

Label

1. Touch **Label**. A predefined text menu and a text cursor (I-beam) appears at the text home position **C**.

2. Select a text label to place it at the current cursor position, and touch **Close**.

3. Drag the cursor/label to where you want the texts to be.

> The text labels are still editable. Touch the label to display the virtual keyboard, and start editing the texts. Touch Done on the keyboard to finish editing.

BDMK

1. Touch **BDMK** to display the body marker menu.

Figure 19 Add a body mark

2. Select a body mark. A pictogram of the body mark with a transducer indicator displays on the image.

Figure 20 Pictogram of the body mark (example)

3. Touch **Probe Pos**, Touch anywhere on the image and move to place the body marker to the desired location on the body mark.

4. Touch **Rotate**. Touch anywhere on the image and move to rotate the transducer indicator.

5. Touch and hold the pictogram, and drag to move it to the desired location on the image.

> - To delete annotations added, including texts and arrows, tou**ch Annot** Del to delete the last added annotations.
> - To delete the body mark added, tou**ch Erase B**DMK.

Measurements

Measurements accompanying ultrasound images supplement other clinical procedures available to the attending physician. The operator can perform as many measurements as needed.
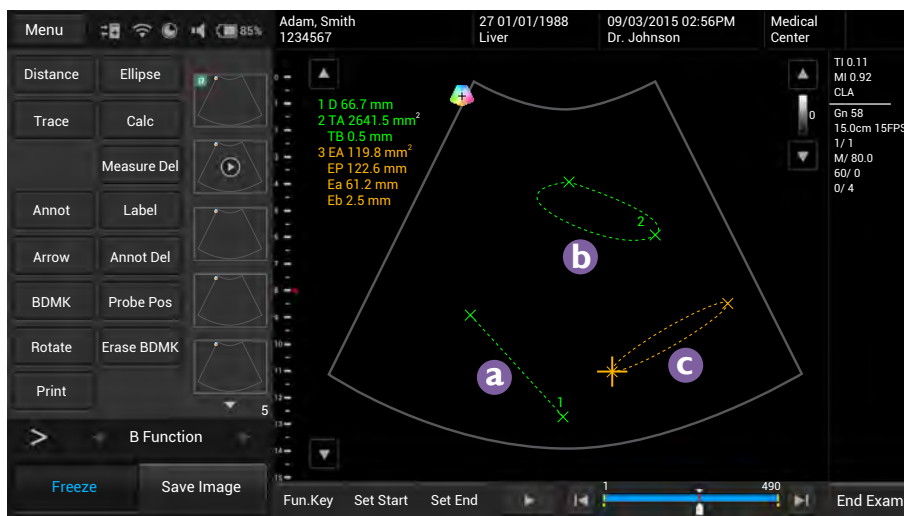
Figure 21 Perform measurements

> To delete measurements added, tou**ch Measure** Del to delete the last added measurements.

Distance

Used to measure a distance.

1. Touch **Distance**. A "cross" cursor $+$ appears on the image. Move the target cursor to where you want to start measuring and release it.

2. Drag the target cursor to where you want to finish measuring, and then release it **a**.

   The measured results (values) appear on the top left corner of the ultrasound image.

Trace

Used to trace an irregular shape.

1. Touch **Trace**. A "cross" cursor $+$ appears on the image. Move the cursor to where you want to start measuring and release it.

2. Drag the cursor along the outline of the object to trace.
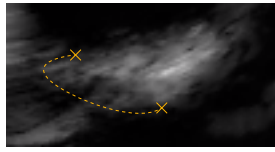
Figure 22 Trace an outline

3. When the tracing is nearly done, release your finger and the system completes the loop by drawing a line from the current cursor position to the starting point **b**.

    The measured results (values) appear on the top left corner of the ultrasound image.

Ellipse

Used to measure a circumference.

1. Touch **Ellipse**. A "cross" cursor $+$ appears on the image. Move the target cursor to one end of the area you want to measure and release it to set the start point of measurement.

2. Drag the target cursor to the other end of the desired area, and release it to set the end point of measurement. An oval area is then measured **c**.

    The measured results (values) appear on the top left corner of the ultrasound image.

Save and print the image

After adding needed annotations/measurements to the image, the operator can save or print the image.

Save an image

On the frozen imaging screen, touch **Save Image** to save the current frame as an image. The saved image will be displayed in the thumbnail list.

Save a cine clip

To save the frames as a cine clip, touch and hold **Save Image**.

Print an image

To print out the image, touch **Print**.

Review the image

On the frozen screen, scroll up and down on the thumbnail list to view the thumbnails of all the saved images/clips. To further examine one or a set of images/clips, touch the thumbnail(s) of the needed image or cine clip to display the review screen.
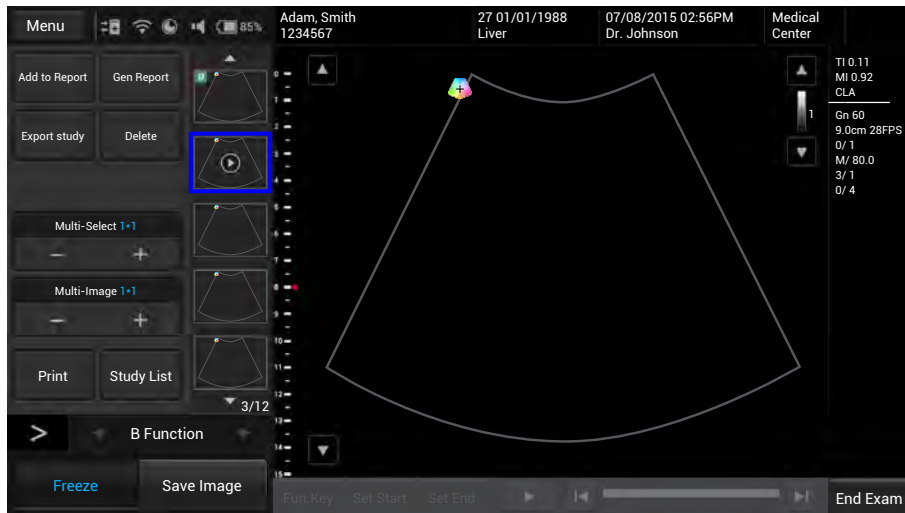
Figure 23 Review the image

Perform multiple selections

The operator can perform actions to more than one image/clip at a time.
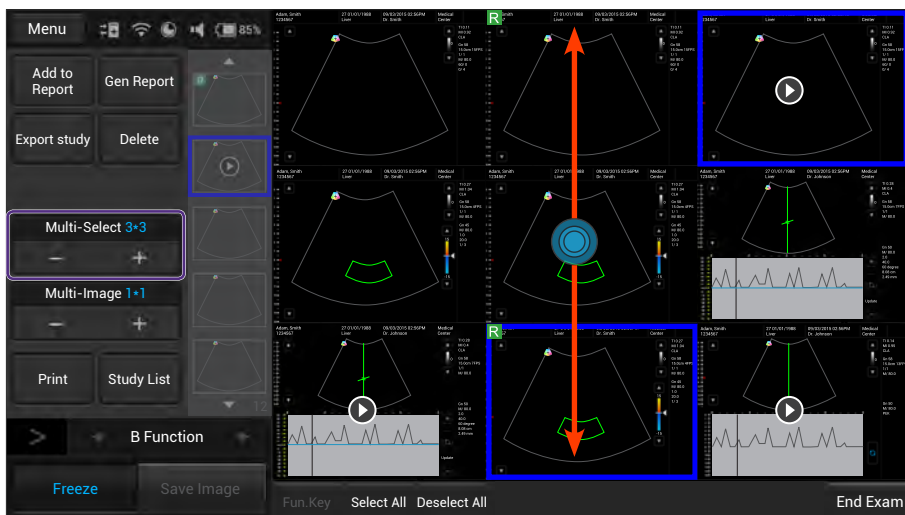
Figure 24 Perform multiple selections

1. Touch the **+** button under **Multi-Select**. Scroll up and down on the thumbnail window and touch to select up to 9 images/clips.

   - To quickly select all images, touch **Select All**.
   - To cancel all selections, touch **Deselect All**.

2. Touch an action button. For example, touch **Delete** to delete all selected images/clips.

Compare images

To compare the scanned images/clips, touch the **+** button under **Multi-Image**.
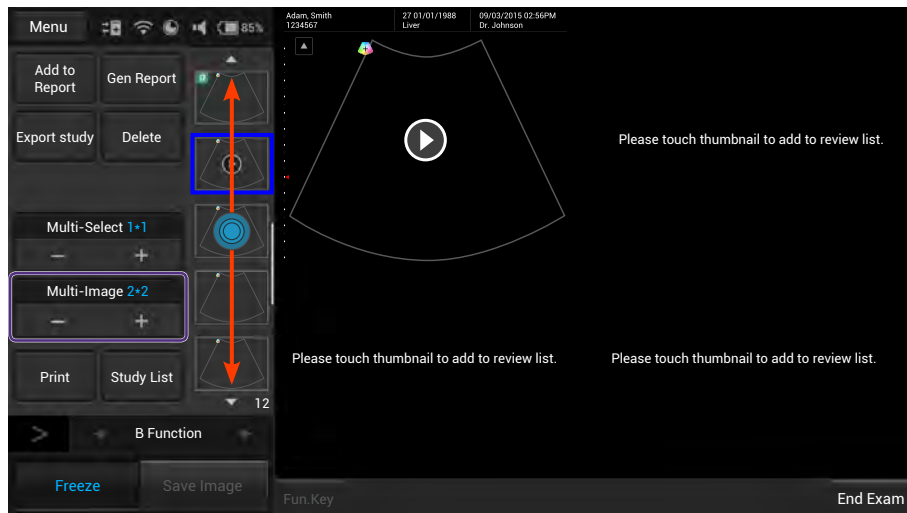
Figure 25 Compare images

Scroll up and down the thumbnail list, and touch to select up to 4 images/clips to display for comparison.

Generate a report

1. On the review screen, touch the thumbnails of the desired images and touch **Add to Report**.

2. Touch **Gen Report** to display the following screen.
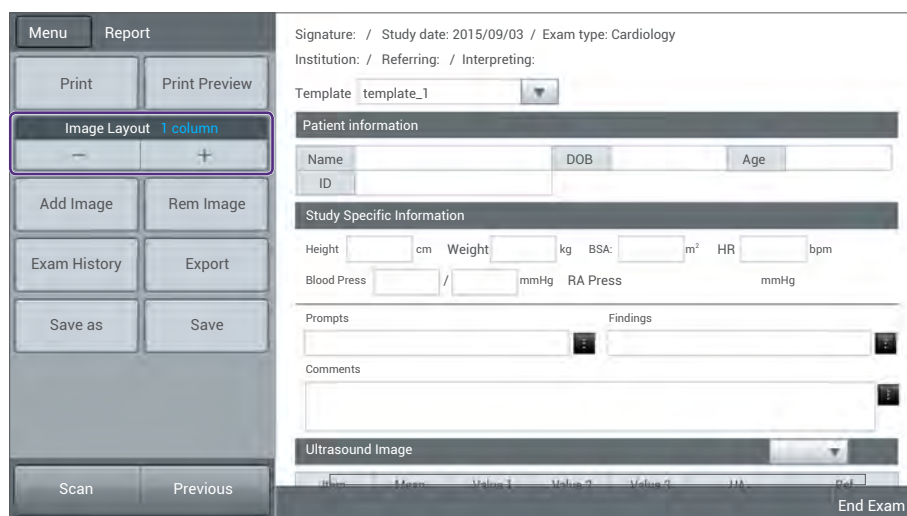
Figure 26 Report screen

3. Fill in information about the patient and the study, if not complete, and add comments using the virtual keyboard.

4. Scroll down to review the images added, and add comments to individual images, if needed.

> The operator can still add/remove images to/from the report without going back to the review screen. Touch **Add Image/Rem Image** to display the image editing screen. Check the desired images and touch **Add to Report or Remove from report**.

5. Touch the **+** button under **Image Layout** to select the numbers of columns for placing the images on a report.

6. Touch **Print Preview** to preview the report.

7. To print out the report, touch **Print**; to save the report, touch **Save as**, select the file format and directory, and then touch **Save**.

Export the exam

The operator can export exams and images to an external storage or the DICOM server. When exporting an exam, an image or a cine loop, the system creates a uniquely named subdirectory for each exam, image or loop.

The system provides three ways of exporting the exam:

- On the review screen, touch **Export study** > **Export to DICOM** or **Export to external storage**.

- On the exam history screen, check the completed exams, and touch **Export Exam** > **Export to DICOM** or **Export to external storage**.

- On the report screen, touch **Export** > **Export to DICOM** or **Export to external storage**.

> To set the default export directory, exporting to DICOM automatically after ending the exam and more, please go **to Menu > Setting**.

End the exam

An exam is not complete if the operator proceeds with a new exam without ending the previous one.

To end the exam, touch **End exam** on the imaging screen.

To check the exam status, please go to **Menu** > **Exam history**.

5 Scan modes overview

All of the information in this chapter pertains to real-time imaging. Many of the controls and functions change when the operator freeze the scan. For information on using functions when the scan is frozen, please refer to "Annotations" and "Measurements".

On the real-time imaging window:

- Touch the mode selection buttons to select a scan mode (See "Imaging screen (Real-time)").

- Touch ❯ > ⦙⦙ to switch the control panel pages to go through the available functions (See "Switch the control panel pages").

B mode overview

The system delivers 2-dimensional digital imaging using 256 digital beam-forming channels. This imaging mode delivers excellent image uniformity, tissue contrast resolution, and steering flexibility in frequencies from 2 MHz to 15 MHz.
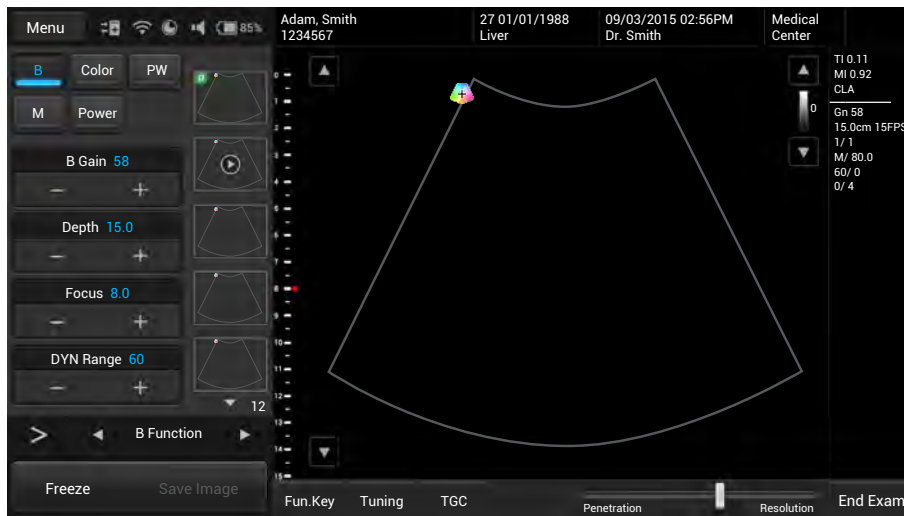
Figure 27 B mode real-time scan

B mode image controls

Use the following 2D image controls during live scanning.
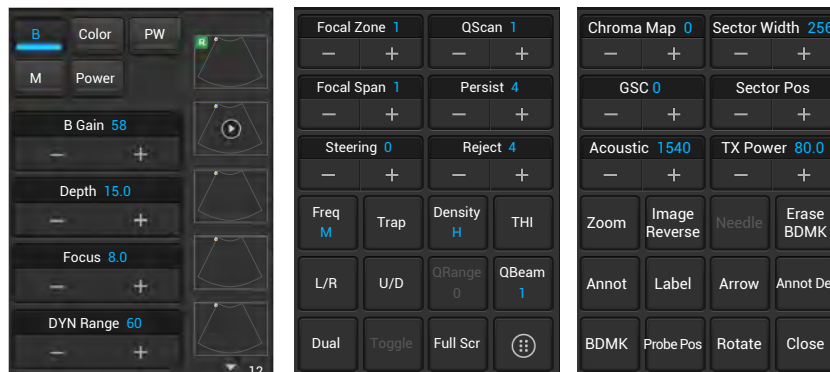
Figure 28 B mode image controls

- Gain: adjust amplification of the returning echoes, which adjust the amount of echo information displayed in an image.
- Scan depth: adjust the field of view.
- Focus depth: increase the resolution for a specific area.
- Dynamic range: control the range of acoustic levels displayed in the image, which affect the contrast of the image.
- Focal zones: select the focal number which also affect the acoustic power indices.
- Focal span: adjust the distance between the focal zones.
- QScan: allow scanning from different angles, which helps reinforce the real structures of an ultrasound image by eliminating artifacts, such as speckle, noise or refractive shadows.
- Persistence: adjust the amount of averaging (real-time) images.
- Reject: adjust the display priority of the 2D grayscale pixels.
- Frequency: change the scan frequency. As frequency increases, the resolution becomes higher while the penetration becomes lower.
- Trapezoidal imaging: increase the range of view of the ultrasound image.
- Chroma map: adjust the chroma (color tone and saturation) value with different brightness.
- Gray scale curve (GSC): change how the amplitude is converted to brightness.
- Acoustic: set the minimum acoustic output power value while still sufficient for diagnostically acceptable information.
- QBeam: permit electronic steering of the ultrasound beam to acquire scans of an ROI from several directions.

- Sector width and position: adjust the imaging area of both the sector and the transducer to the ROI. A smaller sector width increases the frame rate.

- Image reverse: reverse the image orientation horizontally and vertically.

Color/Power Doppler mode overview

Color Doppler mode is used to detect the presence, direction, and relative velocity of blood flow by assigning color-coded information to these parameters. The color is depicted in a region of interest (ROI) that is overlaid on the 2D image. Non-inverted flow towards the transducer is assigned shades of red, and flow away from the transducer displays in shades of blue. The mean Doppler shift is then displayed against a grayscale scan of the structures.

All forms of ultrasound-based imaging of red blood cells are derived from the received echo of the transmitted signal. The primary characteristics of this echo signal are its frequency and its amplitude (or power). The frequency shift is determined by the movement of the red blood cells relative to the transducer – flow towards the transducer produces a higher-frequency signal than flow away from the transducer. Amplitude depends on the amount of moving blood within the volume sampled by the ultrasound beam. The operator can also apply a high frame rate or high resolution to control the quality of the scan. Higher frequencies generated by rapid flow are displayed in lighter colors, and lower frequencies in darker colors.

Figure 29 Color Doppler mode real-time scan

In Power Doppler Mode, low flow rate in small vessels are clearly observed. Colors are carried out only to demonstrate the blood flow, but contain no velocity information, thus, offers no directional information.

Both Color and Power Doppler modes can work with other scan modes to form duplex and triplex modes.

Color/Power Doppler mode image controls

Use the following Color/Power Doppler mode image controls during live scanning.
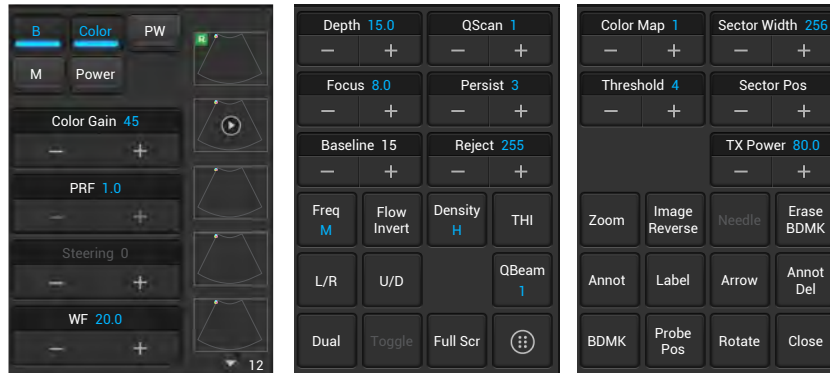
Figure 30 Color Doppler mode image controls

- Pulse Repetition Frequency (PRF): adjust the velocity range of the display, which manifests as a scale.
- Wall filter (WF): adjust the wall filter setting to reduce or eliminate unwanted low-frequency, high-intensity signals generated by movements of blood vessel walls.
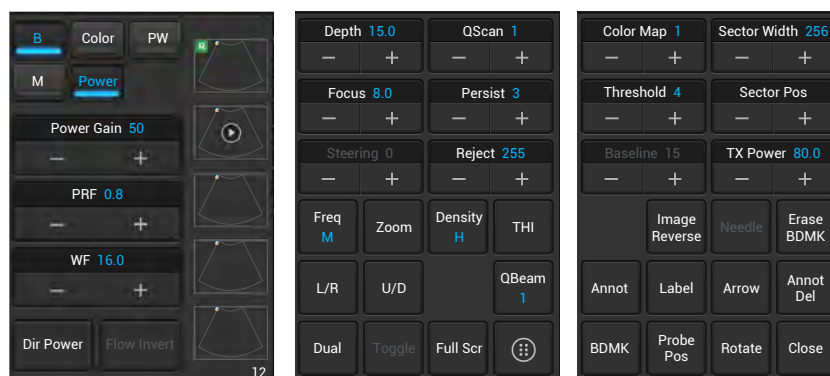
Figure 31 Power Doppler mode image controls

- Dir Power: activate Directional DPI with the DPI indicator displaying the direction of flow for use in applications where sensitivity and directional information are both required.

M mode overview

M mode imaging is used simultaneously with 2-dimensional (B mode) imaging, to determine patterns of motion for objects within the ultrasound beam. M mode displays scan data of the anatomy in the 2D Imaging window **a**, and the motion scan in the Time Series window **b**. Typically, this mode is used for viewing motion patterns of the heart.
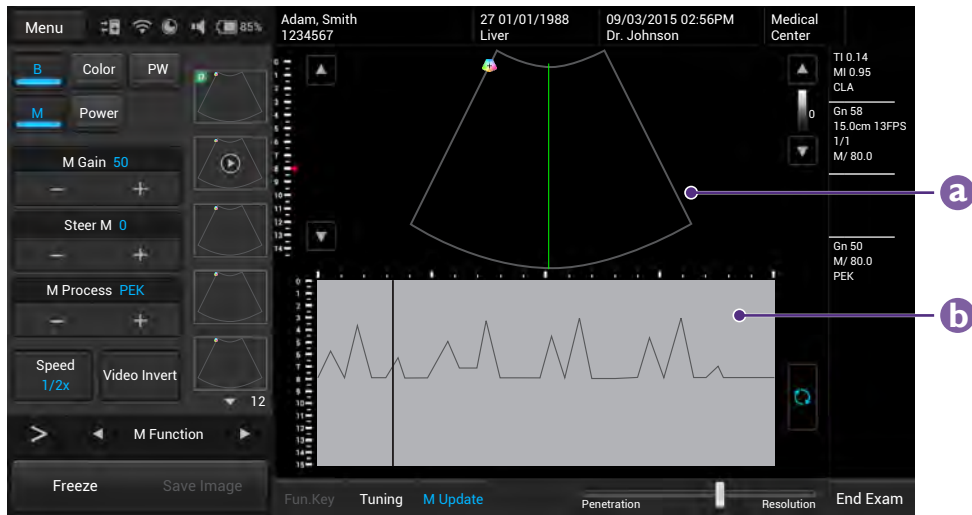
Figure 32 M mode real-time scan

M mode image controls

Use the following M mode image controls during live scanning.
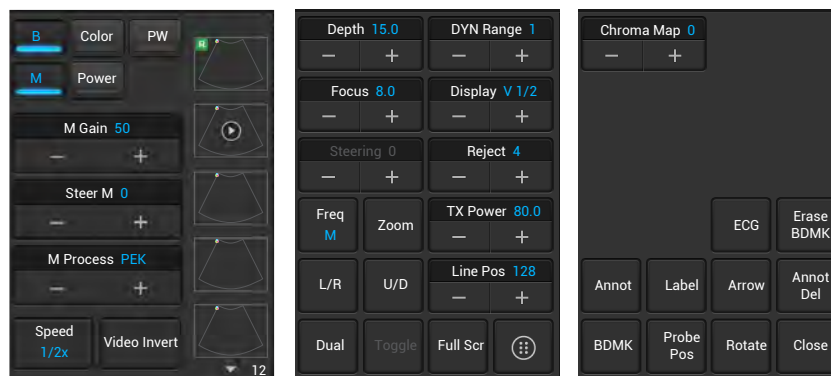
Figure 33 M mode image controls

- M process: select the method for detection processing the M trace display.
- Steer M: adjust the M mode cursor line (M-line) position.
- Sweep speed: adjust how fast the timeline is scanned across the Time Series window.
- Video invert: invert the M trace display in relation to brightness.
- Scan lined position: adjust the scan line position.

- Display format: adjust the layout of the B+M mode ultrasound image.

Pulsed-Wave (PW) Doppler mode overview

A pulsed-wave Doppler scan produces a series of pulses used to study the motion of blood flow selectively in a small region along a desired ultrasound cursor, called the Doppler Range Gate (RG) located on the spectral Doppler cursor. A short line across the sample volume is called the Flow Direction cursor. This cursor line should be aligned to the blood flow direction when measuring the flow velocity.
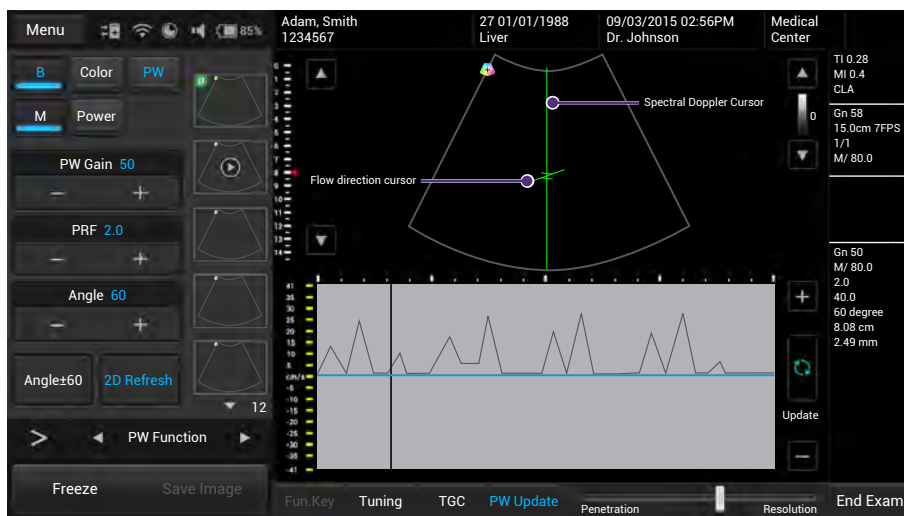
Figure 34 PW Doppler mode real-time scan

PW Doppler mode image controls

Use the following PW mode image controls during live scanning.
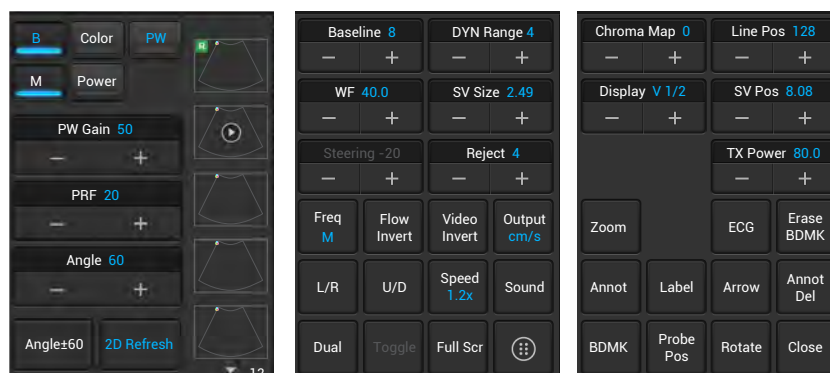
Figure 35 PW Doppler mode image controls

- Baseline: adjust the zero baseline up or down in the Time Series window.
- Sample Volume (SV) size: adjust the SV size which controls the size of the Doppler region being examined.

- Reject: adjust noise rejection which controls rejection of low-level returned signals.
- Sound: adjust the volume of the Doppler signal.
- PW update: select whether or not to continue scanning the anatomy (displayed in the 2D imaging window) while acquiring PW Doppler scan data (displayed in the Time Series window).

6 IT Network

Introduction

To exchange ultrasound images and patient data, the system conforms with the Digital Imaging and Communications in Medicine (DICOM) standard and can therefore be connected to Picture Archiving and Communication System (PACS) and Modality Worklist (MWL). The former allows the system to store the acquired examination data (static images or cine clips) in PACS, while the latter allows the system to query examination orders from the MWL server and start the examinations. In order to achieve the purposes above, the system offers two ways of connecting to the IT network, hard-wired LAN and wireless LAN connections, for DICOM communication.

> To ensure the data security, use an IT network isolated from the external environment by a firewall.

Specifications

Hardware

    802.11 a/b/g/n, Gigabit Ethernet

Software

- The system is connected to PACS and MWL by DICOM standard.

> Please refer to the system's DICOM Conformance Statement for detailed instructions.

- The system connects to the network time server at startup when available.

Security

The system has no listening ports open to the WLAN interface. So a network entity cannot initiate a connection to the system from the WLAN. However, the system can initiate a connection to servers on the WLAN, Gigabit Ethernet and beyond.

Use the USB port ONLY to export data to a USB memory stick. Computer access to the system through the USB port is blocked.

The system allows connection via Bluetooth with limited devices (HID) only.

Use the following TCP/IP ports for outgoing communication to the WLAN and Gigabit Ethernet.

- Port for DICOM communication (typically port 104, 2762 or 11112; to specify the port, on the system's imaging screen, touch **Menu** > **Setting** > **DICOM**.)
- Port 80 for HTTP web servers (not supported by the system)
- Anti-virus software is not installed on the system

Information flow

From\To	Worklist server	UH100	PACS
Worklist server	X	DICOM worklist responses	X
UH100	DICOM worklist queries	X	1. Study data (DICOM Storage) 2. Ping/Echo request
PACS	X	Ping and Echo response	X

Table 8 Information flow

Please refer to the system's DICOM Conformance Statement for detailed instructions.

IT network failure recovery measures

IT network connection stability depends on many factors. Unreliable connection may later lead to failure and cause the following hazardous situations.

IT Network failure	Impact on the equipment	Hazard	System countermeasures
IT network becomes unstable	Unable to transmit exam data to a PACS	Delay of diagnosis	Exam data is stored in the system's internal storage. After the IT network has resumed stability, the operator can re-initiate the data transfer.
	Delay of transmission to a PACS		
	Incorrect data transmitted to a PACS	Misdiagnosis	The system uses the TCP/IP and DICOM protocols to ensure the integrity of the data.
	Unable to retrieve order data from an MWL server.	Delay of exam	The operator can initiate/create a new exam from the system
	Delay of retrieving order data from an MWL server.		
	Incorrect data from a MWL server	Incorrect exam	The system uses the TCP/IP and DICOM protocols to ensure the integrity of the data.
Firewall has broken down	Attack via network	Manipulation of the exam data	The system closes unnecessary network ports.
	Infection by computer virus	Exam data leakage	The system forbids installation of any software by any user.

Table 9 IT network failure recovery measures

Any connection of the equipment, this system (UH100) or/and other systems, to the IT network risks the unidentified data leakage of the patients, operators or third parties. Therefore, the operator must evaluate and identify all potential risks as well as prepare suitable countermeasures before connecting the equipment to an uncontrolled IT network. For guidance addressing these risks, please refer to IEC 80001-1:2010.

Even when the connection to an IT network is trusted, any change of the network settings requires immediate checkup and possible measures taken. Should any of the changes below occur, perform additional evaluation to the IT network.

- Changes in the network configuration (IP address, router, proxy, and so on)
- Connection of additional items

- Disconnection of items
- Equipment update
- Equipment upgrade

7 Maintenance

System maintenance

To maintain the best performance of the system and extend its life, please clean the ventilation slots, all connection ports/sockets and the touchscreen regularly or whenever the operator observes dust or other particles.

Before cleaning the system, perform the following operations to avoid the risk of electric shock.

1. Turn off the system power.

2. Unplug the power cord from both the system and the power outlet.

⚠️ Running the system for a period of time may generate excessive heat. Do not clean the system until it completely cools down.

Clean the ventilation slots and connection ports/sockets

Use a suitable dust blower or a can of compressed air to blow off the dust accumulated in and around the slots/sockets.

Clean the touchscreen

1. Gently wipe the screen with a lint-free, non-abrasive and dry cloth.

2. If any smear or spots remain, apply a small amount of monitor specific cleaning solution to the cloth, and gently wipe it across the screen in one direction. Repeat the application and cleaning process several times until the spots are dissolved.

⚠️ Moving the cloth back and forth will damage the screen.

3. Wipe off any excess moisture and then leave the screen completely dry before powering the system back on.

Transducer precautions and maintenance

The transducers provided with the system are durable and have reliable performance. Inspect these precision instruments daily and handle with care. Please observe the following precautions:

- Do not drop the transducer on the hard surface, as this will damage the transducer elements and compromise the electrical safety of the transducer.
- Avoid kinking or pinching the transducer cable.
- Use only the approved ultrasound coupling gels.
- Do not immerse the transducer into liquids beyond its binding line, and must not immerse the transducer connector into any liquids at all times.
- Do not use damaged or flawed transducers.
- Use only couplants specifically designed for ultrasound examinations. Do not use mineral-oil or vegetable-based couplants, which can damage transducers.
- Do not expose transducers to direct heat such as strong sunlight or local heat sources. Heat ages the crystal and causes loss of sensitivity.

⚠️
- Transducers are highly-sensitive instruments and are easily damaged due to improper operations. Use the transducers with extra care and avoid damages when not in use.
- A recommendation calling the operator's attention to the need for regular testing and periodic maintenance including inspection of the transducer assembly for cracks that allow the ingress of conductive fluid shall be provided.

Inspect the transducer

- Inspect the transducer's acoustic lens, outer cover, the cable, and the transducer connector before each use. Check the transducer carefully and see if there are cracks, cuts, or any other damages which may admit fluids. Do not use the transducer if it is damaged.
- If the transducer is dropped accidentally, examine it immediately for signs for damage. Perform a sample scan to make sure it operates correctly. Contact the Qisda dealer for service or replacement if any abnormalities are found.

⚠️ To avoid any possibilities of hurting the patient, check if the transducer has a smooth edge and an even surface before each use.

Cleaning and disinfection

- Clean the transducer and the transducer handle after use.
- For surface transducers, disinfect the transducer periodically.
- Keep a log of maintenance (inspection, cleaning and disinfection) and malfunction.

Transducer immersion level

When using surface transducers, do not immerse the transducer beyond its immersion line.
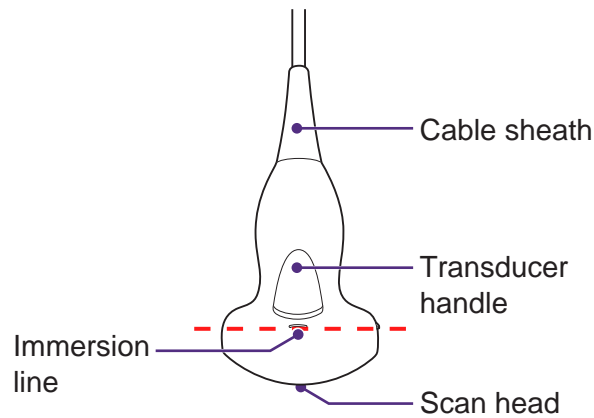
Figure 3   Surface transducer (Example transducer-C52A)

⚠️	• Do not use solutions containing alcohol, mineral oil for cleaning or disinfecting transducers. • Wear medical sterile gloves to prevent potential disease transmission. Wear protective goggle if necessary. • Do not apply solutions containing ethyl oxides on the transducer.

Cleaning instructions

1. Disconnect the transducer from the system.

2. Remove all the coupling gel and clean the transducer with soft cloth and flowing potable water.

3. If the transducer surface carries too much residue, remove all visible residue with wet cloth soaked in mild soap water. Use wet soft cloth to scrub the surface if dried residue exists. Remove all soap water residue with damp cloth soaked in potable water.

4. Air dry or dry with a soft cloth.

⚠️	Take extra care when cleaning the transducer surface. Avoid causing damages to the transducer by excessive and forceful cleaning.

Disinfection instructions

The level of disinfection is directly related to the duration of contact with the germicide. Legally marketed liquid chemical germicides (e.g. Cidex) are highly recommended. Prepare use the germicides following the manufacturer's instructions.

The following statement from AIUM outlines instructions for cleaning the intracavitary transducer:

AIUM Guidelines for Cleaning and Preparing Endocavitary Ultrasound Transducers between Patients

Approved June 4, 2003

The purpose of this document is to provide guidance regarding the cleaning and disinfection of transvaginal and transrectal ultrasound transducers.

All sterilization / disinfection represents a statistical reduction in the number of microbes present on a surface. Meticulous cleaning of the instrument is the essential key to an initial reduction of the microbial / organic load by at least 99%. This cleaning is followed by a disinfecting procedure to ensure a high degree of protection from infectious disease transmission, even if a disposable barrier covers the instrument during use.

Medical instruments fall into different categories with respect to potential for infection transmission. The most critical levels of instruments are those that are intended to penetrate skin or mucous membranes. These require sterilization. Less critical instruments (often called "semi-critical" instruments) that simply come into contact with mucous membranes such as fiber optic endoscopes require high-level disinfection rather than sterilization.

Although endocavity ultrasound transducers might be considered even less critical instruments because they are routinely protected by single use disposable transducer covers, leakage rates of 0.9 % to 2 % for condoms and 8 % to 81 % for commercial transducer covers have been observed in recent studies. For maximum safety, one should therefore perform high-level disinfection of the transducer between each use and use a transducer cover or condom as an aid in keeping the transducer clean.

There are four generally recognized categories of disinfection and sterilization.

Sterilization is the complete elimination of all forms or microbial life including spores and viruses.

Disinfection, the selective removal of microbial life, is divided into three classes:

- High-level disinfection includes destruction / removal of all microorganisms except bacterial spores.
- Mid-level disinfection includes inactivation of Mycobacterium Tuberculosis, bacteria, most viruses, fungi, and some bacterial spores.

- Low-Level Disinfection includes destruction of most bacteria, some viruses and some fungi. Low-level disinfection will not necessarily inactivate Mycobacterium Tuberculosis or bacterial spores.

The following specific recommendations are made for the use of endocavity transducers. Operators should also review the Centers for Disease Control and Prevention document on sterilization and disinfection of medical devices to be certain that their procedures conform to the CDC principles for disinfection of patient care equipment.

Procedures for cleaning

1. After removing the transducer cover, use running water to remove any residual gel or debris from the transducer.

2. Use a damp gauze pad or other soft cloth and a small amount of mild non-abrasive liquid soap (household dishwashing liquid is ideal) to thoroughly cleanse the transducer.

3. Use a small brush especially for crevices and areas of angulations depending on the design of your particular transducer.

4. Rinse the transducer thoroughly with running water, and then dry the transducer with a soft cloth or paper towel.

Procedures for disinfection

1. Follow the above cleaning procedures to clean the transducer first with a detergent/water solution, and ensure all visible residues are removed from the transducer.

2. Use high-level disinfectant to ensure further statistical reduction in microbial load. Because of the potential invisible disruption of the transducer sheath, additional high level disinfection with chemical agents is necessary.

Examples of such high level disinfectants include but are not limited to:
- 2.4% to 3.2% Glutaraldehyde products (a variety of available proprietary products including "Cidex", "Metricide", or "Procide")
- Non-glutaraldehyde agents including Cidex OPA (o-phthalaldehyde), Cidex PA (hydrogen peroxide & peroxyacetic acid).
- 7.5% Hydrogen Peroxide solution
- Common household bleach (5.25% sodium hypochlorite) diluted to yield 500 parts per million chlorine (10 cc in one liter of tap water). This agent is effective, but generally not recommended by transducer manufacturers because it can damage metal and plastic parts.

- Other agents such as quaternary ammonium compounds are not considered high level disinfectants and should not be used. Isopropanol is not a high level disinfectant when used as a wipe and transducer manufacturers generally do not recommend soaking transducers in the liquid.

- The FDA has published a list of approved sterilant and high level disinfectants for use in processing reusable medical and dental devices. Consult the list to find agents that may be useful for transducer disinfection.

3. Operators should follow the instructions of proprietary products to prepare, store and use the disinfectant. Regarding the compatibility of these agents with transducers, consult the manufacturers. Many of the chemical disinfectants are potentially toxic and many require adequate precautions, such as proper ventilation, personal protective devices (gloves, face/eye protection, etc.) and rinsing before reusing the transducer.

Transducer sheath

When using E94A endocavity transducers, the transducers must be protected with a transducer sheath. If condoms are used, they should be non-lubricated and non-medicated. Operators should be aware that condoms have been shown to be less prone to leakage than commercial transducer covers, and have a six-fold enhanced AQL (acceptable quality level) when compared to standard examination gloves. They have an AQL equal to that of surgical gloves. Operators should be aware of latex-sensitivity issues and have available nonlatex-containing barriers.

Aseptic technique

For the protection of the patient and the health care worker, all endocavitary examinations should be performed by the operator wearing gloves properly throughout the ultrasound diagnostic process. Gloves should be used to remove the condom or other barrier from the transducer and to wash the transducer as mentioned above. As the transducer sheath is removed, care should be taken not to contaminate the transducer with secretions from the patient. At the completion of the procedure, hands should be thoroughly washed with soap and water.

⚠️
- Do not use high pressure steam to disinfect the transducer.
- Do not use thermal disinfection. Temperatures higher than 66°C or 150°F will damage the transducer.

- Obvious disruption in condom integrity does not require modification of this protocol. These guidelines take into account possible transducer contamination due to a disruption in the barrier sheath.
- In summary, routine high-level disinfection of the endocavity transducer between patients, plus the use of a transducer cover or condom during each examination is required to properly protect patients from infection during endocavitary examinations.
- Ensure that all visible residues have been removed.
- Prepare the germicide solutions according to the manufacturer's instructions. Please also follow the manufacturer's instructions for storage and disposal of the germicide.
- Immerse the transducer head into the germicide for time interval specified by the germicide manufacturer. The immersion level should be kept below the binding line. Note that you may need to rotate and shake the transducer in order to remove the air bubbles between the transducer surface and germicide solution.
- After removing the transducer from the germicide solution, rinse it thoroughly with clean, potable water to remove all visible germicide. Dry the transducer with a soft cloth.

8 Appendix

Acoustic output Reporting for Track 3

Qisda Corporation follows Track 3 of the FDA's information for manufacturers seeking marketing clearance of diagnostic ultrasound systems and transducers. Track 3 does not require evaluation of acoustic output on an application-specific basis, but the global maximum derated ISPTA must not exceed 720 mW/cm2 and the global maximum MI must not exceed 1.9.

Acoustic output tables for UH100 Transducers

Acoustic output reporting table for Track 3 for the C52A transducer UH100 Diagnostic Ultrasound System in B mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1\ cm^2$	TIS Non-scan $A_{aprt} > 1\ cm^2$	TIB	TIC
Global maximum index value			0.0282	0.088	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.053					
	W_0	(mW)		24.4	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	5.9					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	3.5	3.5	#	#	#	#
	Dim of A_{aprt} — X (cm)			2.25	#	#	#	#
	Dim of A_{aprt} — Y (cm)			1.1	#	#	#	#
Other information	PD	(microsec)	0.37					
	PRF	(Hz)	5900					
	$p_r@PII_{max}$	(MPa)	0.109					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length — FLx (cm)			7	#	#		#
	Focal length — FLy (cm)			7	#	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	0.09					
Operating control conditions	Control 1		B	B	#	#	#	#
	Control 2		7 cm	7 cm	#	#	#	#
	Control 3		5917	5917	#	#	#	#
	Control 4		100%	100%	#	#	#	#

- \# No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the C52A transducer UH100 Diagnostic Ultrasound System in CFM-B mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1$ cm^2	$A_{aprt} > 1$ cm^2		
Global maximum index value			0.132	0.138	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.209					
	W_0	(mW)		58	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	4.6					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.5	2.5	#	#	#	#
	Dim of A_{aprt}	X (cm)		2.25	#	#	#	#
		Y (cm)		1.1	#	#	#	#
Other information	PD	(microsec)	1.5					
	PRF	(Hz)	5000					
	$p_r@PII_{max}$	(MPa)	0.303					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		5	#	#		#
		FLy (cm)		7	#	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	2.96					
Operating control conditions	Control 1		CFM	CFM	#	#	#	#
	Control 2		5 cm	5 cm	#	#	#	#
	Control 3		5 KHz	5 KHz	#	#	#	#
	Control 4		100%	100%	#	#	#	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the C52A transducer UH100 Diagnostic Ultrasound System in B/M mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1\ cm^2$	TIS Non-scan $A_{aprt} > 1\ cm^2$	TIB	TIC
Global maximum index value			0.133	#	#	0.0199	0.077	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.246					
	W_0	(mW)		#	#		37	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)]$	(mW)				1.23		
	z_1	(cm)				5		
	z_{bp}	(cm)				2.66		
	z_{sp}	(cm)					4.5	
	$z@PII_{.3max}$	(cm)	5					
	$d_{eq}(z_{sp})$	(cm)					3.4	
	f_c	(MHz)	3.4	#	#	3.4	3.4	#
	Dim of A_{aprt} X (cm)			#	#	2.25	2.25	#
	Dim of A_{aprt} Y (cm)			#	#	1.1	1.1	#
Other information	PD	(microsec)	1.2					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.47					
	$d_{eq}@PII_{max}$	(cm)					3.2	
	Focal length FLx (cm)			#	#	7		#
	Focal length FLy (cm)			#	#	7		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	3.4					
Operating control conditions	Control 1		M	#	#	M	M	#
	Control 2		7 cm	#	#	7 cm	7 cm	#
	Control 3		250	#	#	250	250	#
	Control 4		100%	#	#	100%	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the C52A transducer UH100 Diagnostic Ultrasound System in PW mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1\ cm^2$	TIS Non-scan $A_{aprt} > 1\ cm^2$	TIB	TIC
Global maximum index value			0.127	#	#	0.209	0.52	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.241					
	W_0	(mW)		#	#		165	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				12.1		
	z_1	(cm)				5		
	z_{bp}	(cm)				2.66		
	z_{sp}	(cm)					4.2	
	$z@PII_{.3max}$	(cm)	5					
	$d_{eq}(z_{sp})$	(cm)					2.22	
	f_c	(MHz)	3.6	#	#	3.6	3.6	#
	Dim of A_{aprt} X	(cm)		#	#	2.25	2.25	#
	Dim of A_{aprt} Y	(cm)		#	#	1.1	1.1	#
Other information	PD	(microsec)	1.08					
	PRF	(Hz)	3000					
	$p_r@PII_{max}$	(MPa)	0.43					
	$d_{eq}@PII_{max}$	(cm)					2.1	
	Focal length FLx	(cm)		#	#	7		#
	Focal length FLy	(cm)		#	#	7		#
	$I_{pa.3}$ at MI_{max}	(W/cm²)	2.84					
Operating control conditions	Control 1		PW	#	#	PW	PW	#
	Control 2		7 cm	#	#	7 cm	7 cm	#
	Control 3		3000	#	#	3000	3000	#
	Control 4		100%	#	#	100%	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the L115A transducer

UH100 Diagnostic Ultrasound System in B mode

Index label		MI	TIS			TIB	TIC
			Scan	Non-scan			
				$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
Global maximum index value		0.055	0.07	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$ (MPa)	0.142					
	W_0 (mW)		1.4	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)]$ (mW)				#		
	z_1 (cm)				#		
	z_{bp} (cm)				#		
	z_{sp} (cm)					#	
	$z@PII_{.3max}$ (cm)	1.79					
	$d_{eq}(z_{sp})$ (cm)					#	
	f_c (MHz)	6.7	6.7	#	#	#	#
	Dim of A_{aprt} — X (cm)		0.6	#	#	#	#
	Dim of A_{aprt} — Y (cm)		0.6	#	#	#	#
Other information	PD (microsec)	0.183					
	PRF (Hz)	9800					
	$p_r@PII_{max}$ (MPa)	0.209					
	$d_{eq}@PII_{max}$ (cm)					#	
	Focal length — FLx (cm)		1.5	#	#		#
	Focal length — FLy (cm)		1.9	#	#		#
	$I_{pa.3}$ at MI_{max} (W/cm^2)	1.13					
Operating control conditions	Control 1	B	B	#	#	#	#
	Control 2	1.5 cm	1.5 cm	#	#	#	#
	Control 3	9804	9804	#	#	#	#
	Control 4	100%	100%	#	#	#	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the L115A transducer

UH100 Diagnostic Ultrasound System in CFM-B mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1$ cm^2	TIS Non-scan $A_{aprt} > 1$ cm^2	TIB	TIC
Global maximum index value			0.107	0.188	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.237					
	W_0	(mW)		32	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	2.57					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	4.9	4.9	#	#	#	#
	Dim of A_{aprt} X (cm)			3.8	#	#	#	#
	Dim of A_{aprt} Y (cm)			0.6	#	#	#	#
Other information	PD	(microsec)	0.81					
	PRF	(Hz)	3000					
	$p_r@PII_{max}$	(MPa)	0.37					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length FLx (cm)			1.5	#	#		#
	Focal length FLy (cm)			1.9	#	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	5.6					
Operating control conditions	Control 1		CFM	CFM	#	#	#	#
	Control 2		3 cm	3 cm	#	#	#	#
	Control 3		3 KHz	3 KHz	#	#	#	#
	Control 4		100%	100%	#	#	#	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the L115A transducer

UH100 Diagnostic Ultrasound System in B/M mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
Global maximum index value			0.13	#	0.36	#	0.047	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.35					
	W_0	(mW)		#	10.7		10.7	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					2.01	
	$z@PII_{.3max}$	(cm)	2.11					
	$d_{eq}(z_{sp})$	(cm)					1.85	
	f_c	(MHz)	7.1	#	7.1	#	7.1	#
	Dim of A_{aprt}	X (cm)		#	0.71	#	0.71	#
		Y (cm)		#	0.6	#	0.6	#
Other information	PD	(microsec)	0.68					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.58					
	$d_{eq}@PII_{max}$	(cm)					1.82	
	Focal length	FLx (cm)		#	1.5	#		#
		FLy (cm)		#	1.9	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	7.7					
Operating control conditions	Control 1		M	#	#	M	M	#
	Control 2		3 cm	#	#	3 cm	3 cm	#
	Control 3		250	#	#	250	250	#
	Control 4		100%	#	#	100%	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the L115A transducer

UH100 Diagnostic Ultrasound System in PW mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1\ cm^2$	TIS Non-scan $A_{aprt} > 1\ cm^2$	TIB	TIC
Global maximum index value			0.1	#	1.18	#	0.38	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.27					
	W_0	(mW)		#	34		34	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)]$	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					2.06	
	$z@PII_{.3max}$	(cm)	2.15					
	$d_{eq}(z_{sp})$	(cm)					0.71	
	f_c	(MHz)	7.3	#	7.3	#	7.3	#
	Dim of A_{aprt} X (cm)			#	0.41	#	0.41	#
	Dim of A_{aprt} Y (cm)			#	0.6	#	0.6	#
Other information	PD	(microsec)	1.03					
	PRF	(Hz)	4000					
	$p_r@PII_{max}$	(MPa)	0.46					
	$d_{eq}@PII_{max}$	(cm)					0.69	
	Focal length FLx (cm)			#	1.5	#		#
	Focal length FLy (cm)			#	1.9	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	6.4					
Operating control conditions	Control 1		PW	#	PW	#	PW	#
	Control 2		3 cm	#	3 cm	#	3 cm	#
	Control 3		4000	#	4000	#	4000	#
	Control 4		100%	#	100%	#	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the P42A transducer UH100 Diagnostic Ultrasound System in B mode

Index label		MI	TIS			TIB	TIC
			Scan	Non-scan			
				$A_{aprt} \leq 1$ cm^2	$A_{aprt} > 1$ cm^2		
Global maximum index value		0.149	0.39	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$ (MPa)	0.235					
	W_0 (mW)		44	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)]$ (mW)				#		
	z_1 (cm)				#		
	z_{bp} (cm)				#		
	z_{sp} (cm)					#	
	$z@PII_{.3max}$ (cm)	5.7					
	$d_{eq}(z_{sp})$ (cm)					#	
	f_c (MHz)	2.48	2.48	#	#	#	#
	Dim of A_{aprt} X (cm)		1.92	#	#	#	#
	Dim of A_{aprt} Y (cm)		1.4	#	#	#	#
Other information	PD (microsec)	0.53					
	PRF (Hz)	5600					
	$p_r@PII_{max}$ (MPa)	0.35					
	$d_{eq}@PII_{max}$ (cm)					#	
	Focal length FLx (cm)		6	#	#		#
	Focal length FLy (cm)		8	#	#		#
	$I_{pa.3}$ at MI_{max} (W/cm^2)	2.14					
Operating control conditions	Control 1	B	B	#	#	#	#
	Control 2	6 cm	6 cm	#	#	#	#
	Control 3	5555	5555	#	#	#	#
	Control 4	100%	100%	#	#	#	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the P42A transducer UH100 Diagnostic Ultrasound System in CFM-B mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1$ cm^2	$A_{aprt} > 1$ cm^2		
Global maximum index value			0.205	1.74	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.32					
	W_0	(mW)		207	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	5.1					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	2.48	2.48	#	#	#	#
	Dim of A_{aprt}	X (cm)		1.92	#	#	#	#
		Y (cm)		1.4	#	#	#	#
Other information	PD	(microsec)	1.46					
	PRF	(Hz)	2000					
	$p_r@PII_{max}$	(MPa)	0.49					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length	FLx (cm)		6	#	#		#
		FLy (cm)		8	#	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	5.5					
Operating control conditions	Control 1		CFM	CFM	#	#	#	#
	Control 2		7 cm	7 cm	#	#	#	#
	Control 3		2 KHz	2 KHz	#	#	#	#
	Control 4		100%	100%	#	#	#	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the P42A transducer UH100 Diagnostic Ultrasound System in B/M mode

Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
Global maximum index value			0.242	#	#	0.043	0.207	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.38					
	W_0	(mW)		#	#		67	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				3.6		
	z_1	(cm)				4.8		
	z_{bp}	(cm)				2.77		
	z_{sp}	(cm)					4.6	
	$z@PII_{.3max}$	(cm)	4.8					
	$d_{eq}(z_{sp})$	(cm)					3.2	
	f_c	(MHz)	2.48	#	#	2.48	2.48	#
	Dim of A_{aprt}	X (cm)		#	#	1.92	1.92	#
		Y (cm)		#	#	1.4	1.4	#
Other information	PD	(microsec)	1.49					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.56					
	$d_{eq}@PII_{max}$	(cm)					3.12	
	Focal length	FLx (cm)		#	#	6		#
		FLy (cm)		#	#	8		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	9.5					
Operating control conditions	Control 1		M	#	#	M	M	#
	Control 2		7 cm	#	#	7 cm	7 cm	#
	Control 3		250	#	#	250	250	#
	Control 4		100%	#	#	100%	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the P42A transducer UH100 Diagnostic Ultrasound System in PW mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1$ cm^2	TIS Non-scan $A_{aprt} > 1$ cm^2	TIB	TIC
Global maximum index value			0.248	#	#	0.77	2	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.39					
	W_0	(mW)		#	#		340	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				65		
	z_1	(cm)				4.8		
	z_{bp}	(cm)				2.77		
	z_{sp}	(cm)					4.5	
	$z@PII_{.3max}$	(cm)	4.8					
	$d_{eq}(z_{sp})$	(cm)					1.72	
	f_c	(MHz)	2.48	#	#	2.48	2.48	#
	Dim of A_{aprt} X (cm)	X (cm)		#	#	1.92	1.92	#
	Dim of A_{aprt} Y (cm)	Y (cm)		#	#	1.4	1.4	#
Other information	PD	(microsec)	1.53					
	PRF	(Hz)	4000					
	$p_r@PII_{max}$	(MPa)	0.59					
	$d_{eq}@PII_{max}$	(cm)					1.69	
	Focal length FLx (cm)	FLx (cm)		#	#	6		#
	Focal length FLy (cm)	FLy (cm)		#	#	8		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	10.9					
Operating control conditions	Control 1		PW	#	#	PW	PW	#
	Control 2		7 cm	#	#	7 cm	7 cm	#
	Control 3		4000	#	#	4000	4000	#
	Control 4		100%	#	#	100%	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the E94A transducer UH100 Diagnostic Ultrasound System in B mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1\ cm^2$	TIS Non-scan $A_{aprt} > 1\ cm^2$	TIB	TIC
Global maximum index value			0.109	0.069	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.266					
	W_0	(mW)		4.1	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	2.47					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6	6	#	#	#	#
	Dim of A_{aprt} X	(cm)		1.75	#	#	#	#
	Dim of A_{aprt} Y	(cm)		0.6	#	#	#	#
Other information	PD	(microsec)	0.216					
	PRF	(Hz)	7000					
	$p_r@PII_{max}$	(MPa)	0.44					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length FLx	(cm)		3.5	#	#		#
	Focal length FLy	(cm)		2.6	#	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	3.9					
Operating control conditions	Control 1		B	B	#	#	#	#
	Control 2		3.5 cm	3.5 cm	#	#	#	#
	Control 3		6973	6973	#	#	#	#
	Control 4		100%	100%	#	#	#	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the E94A transducer UH100 Diagnostic Ultrasound System in CFM-B mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1\ cm^2$	TIS Non-scan $A_{aprt} > 1\ cm^2$	TIB	TIC
Global maximum index value			0.113	0.195	#	#	#	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.284					
	W_0	(mW)		13.2	#		#	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					#	
	$z@PII_{.3max}$	(cm)	2.02					
	$d_{eq}(z_{sp})$	(cm)					#	
	f_c	(MHz)	6.3	6.3	#	#	#	#
	Dim of A_{aprt} X	(cm)		1.75	#	#	#	#
	Dim of A_{aprt} Y	(cm)		0.6	#	#	#	#
Other information	PD	(microsec)	0.48					
	PRF	(Hz)	3010					
	$p_r@PII_{max}$	(MPa)	0.43					
	$d_{eq}@PII_{max}$	(cm)					#	
	Focal length FLx	(cm)		2.5	#	#		#
	Focal length FLy	(cm)		2.6	#	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm²)	7.6					
Operating control conditions	Control 1		CFM	CFM	#	#	#	#
	Control 2		2.5 cm	2.5 cm	#	#	#	#
	Control 3		3 KHz	3 KHz	#	#	#	#
	Control 4		100%	100%	#	#	#	#

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- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the E94A transducer UH100 Diagnostic Ultrasound System in B/M mode

Index label			MI	TIS Scan	TIS Non-scan $A_{aprt} \leq 1\ cm^2$	TIS Non-scan $A_{aprt} > 1\ cm^2$	TIB	TIC
Global maximum index value			0.15	#	#	0.049	0.034	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.37					
	W_0	(mW)		#	#		4	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				1.64		
	z_1	(cm)				1.96		
	z_{bp}	(cm)				1.73		
	z_{sp}	(cm)					1.82	
	$z@PII_{.3max}$	(cm)	1.96					
	$d_{eq}(z_{sp})$	(cm)					3.4	
	f_c	(MHz)	6.3	#	#	6.3	6.3	#
	Dim of A_{aprt} X	(cm)		#	#	1.75	1.75	#
	Dim of A_{aprt} Y	(cm)		#	#	0.6	0.6	#
Other information	PD	(microsec)	0.62					
	PRF	(Hz)	250					
	$p_r@PII_{max}$	(MPa)	0.55					
	$d_{eq}@PII_{max}$	(cm)					1.14	
	Focal length FLx	(cm)		#	#	2.5		#
	Focal length FLy	(cm)		#	#	2.6		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	12.3					
Operating control conditions	Control 1		M	#	#	M	M	#
	Control 2		2.5 cm	#	#	2.5 cm	2.5 cm	#
	Control 3		250	#	#	250	250	#
	Control 4		100%	#	#	100%	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Acoustic output reporting table for Track 3 for the E94A transducer UH100 Diagnostic Ultrasound System in PW mode

| Index label			MI	TIS			TIB	TIC
				Scan	Non-scan			
					$A_{aprt} \leq 1\ cm^2$	$A_{aprt} > 1\ cm^2$		
Global maximum index value			0.153	#	0.84	#	0.32	(b)
Associated acoustic parameter	$P_{r.3}$	(MPa)	0.38					
	W_0	(mW)		#	28.1		28.1	#
	Min of $W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				#		
	z_1	(cm)				#		
	z_{bp}	(cm)				#		
	z_{sp}	(cm)					1.82	
	$z@PII_{.3max}$	(cm)	1.93					
	$d_{eq}(z_{sp})$	(cm)					0.86	
	f_c	(MHz)	6.3	#	6.3	#	6.3	#
	Dim of A_{aprt}	X (cm)		#	1.14	#	1.14	#
		Y (cm)		#	0.6	#	0.6	#
Other information	PD	(microsec)	0.62					
	PRF	(Hz)	3000					
	$p_r@PII_{max}$	(MPa)	0.56					
	$d_{eq}@PII_{max}$	(cm)					0.84	
	Focal length	FLx (cm)		#	2.5	#		#
		FLy (cm)		#	2.6	#		#
	$I_{pa.3}$ at MI_{max}	(W/cm^2)	11.4					
Operating control conditions	Control 1		PW	#	#	PW	PW	#
	Control 2		2.5 cm	#	#	2.5 cm	2.5 cm	#
	Control 3		3000	#	#	3000	3000	#
	Control 4		100%	#	#	100%	100%	#

- # No data are reported for this operating condition since the global maximum index value is not reported for the reason listed.
- (a) This index is not required for this operating mode.
- (b) This transducer is not intended for transcranial or neonatal cephalic uses.
- (c) This formulation for TIS is less than that for an alternate formulation in this mode.
- (d) Control 1: Mode
- (e) Control 2: Focal distance
- (f) Control 3: PRF
- (g) Control 4: Power

Ultrasound validation

1. Set up the phantom for validation. Make sure the notch is filled with some water.


2. Insert the transducer for ultrasound validation.

3. Initiate the ultrasound software. Confirm Ultrasound software has scanned images as below photos. You can see the bright dot on Phantom, and the background should be the same speckle without any particular dark lines or streaks.
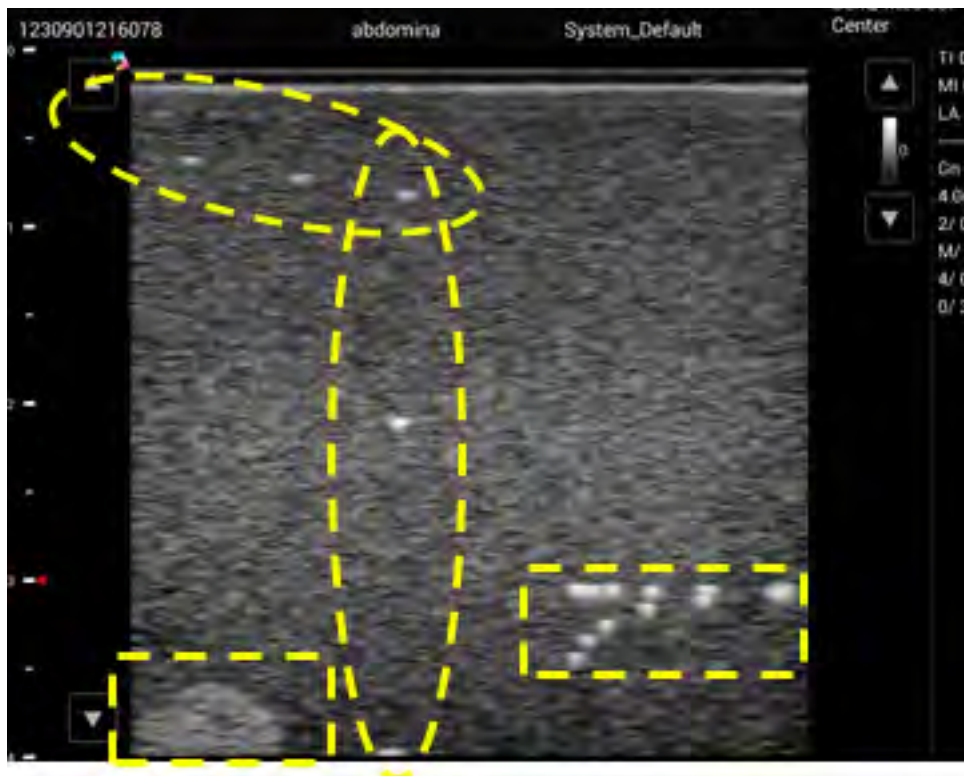
The actual scan area of the phantom is shown as the image below.
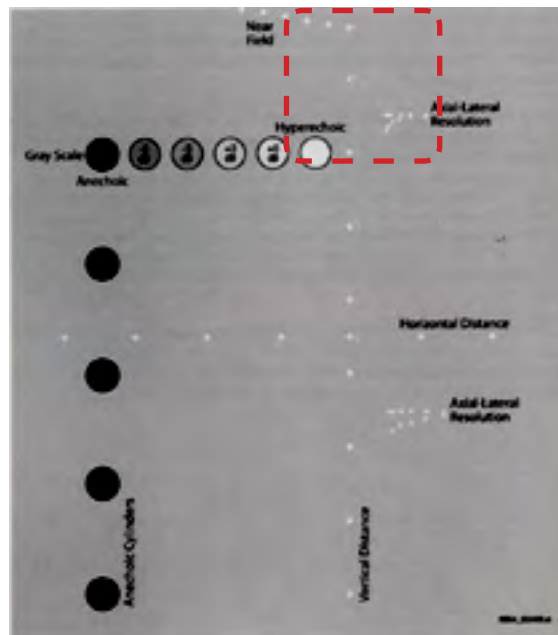
4. Touch **Color** to switch to Color Doppler mode and keep the transducer stationary. Confirm there is no stationary color image signal in the Green block area as the photo below.
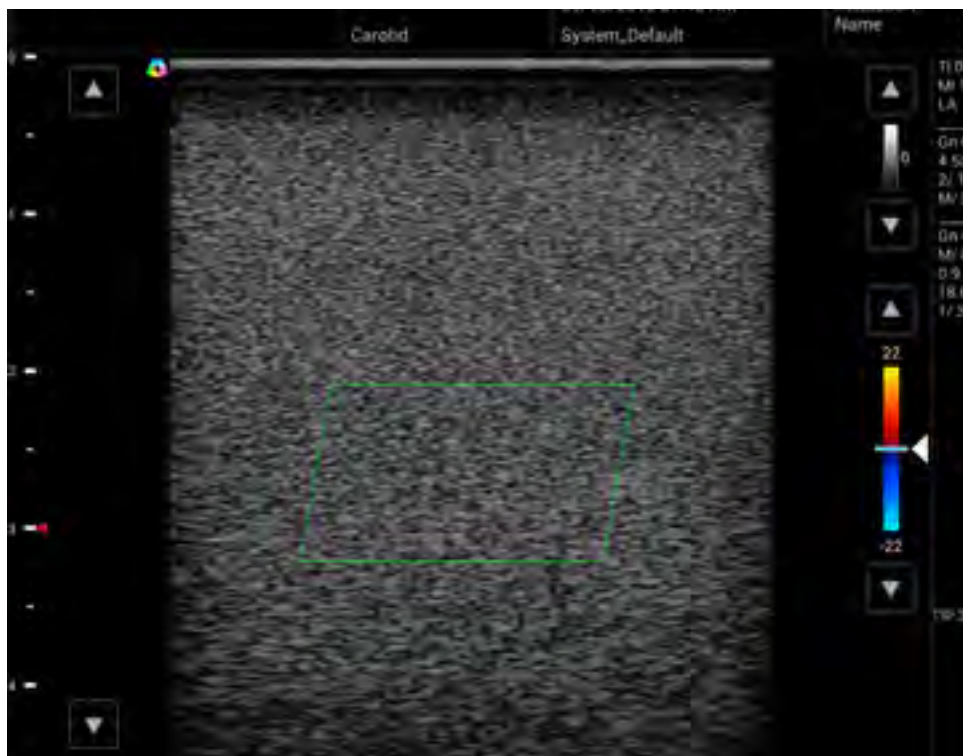
5. Touch **PW** to switch to PW Doppler mode and keep the transducer stationary. Confirm the picture is evenly distributed without any particular waveform signal as the photo below.
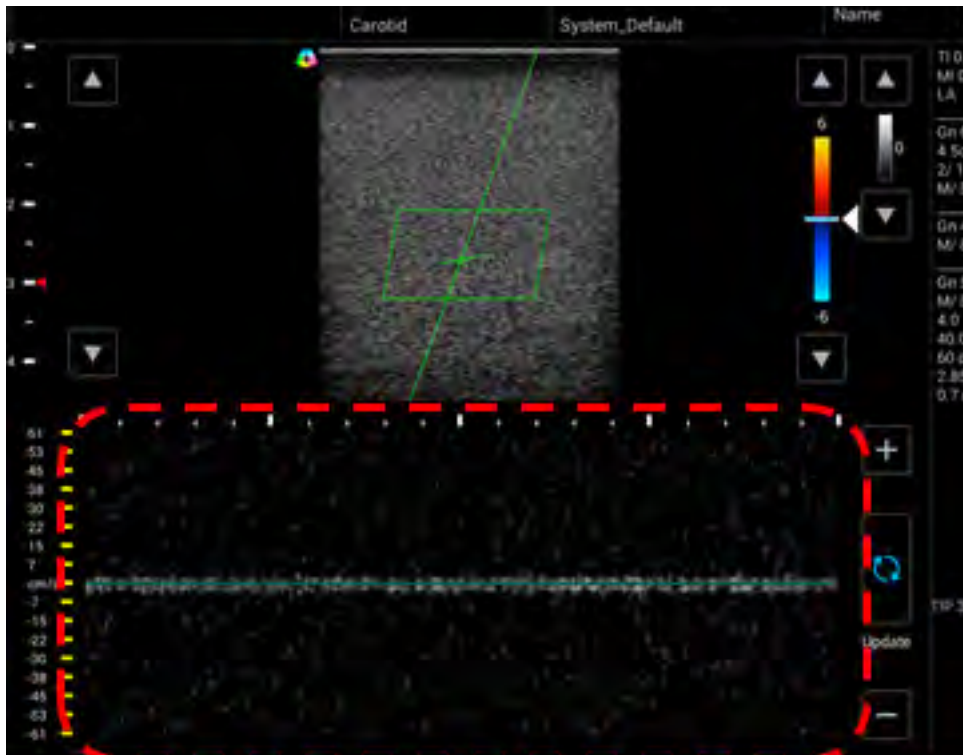
6. Remove the transducer.

Troubleshooting

Item	Error description	Possible root cause	Possible swap parts
System - Power on	System can't power on	1. SOM board damage 2. Carrier board damage 3. Screen off / Screen cable damage 4. Battery no power (can charge Battery) / Battery damage (can use adapter to check) 5. Disconnect gauge cable 6. Disconnect bottom cable / bottom board damage	1. SOM board 2. Carrier board 3. LCD / LCD cable 4. Battery 5. Connect gauge cable 6. Bottom cable/ board
System - Charging	System can't charge	1. Power supply damage 2. Adapter damage 3. Carrier board damage 4. Gauge cable / connector damage	1. Power supply 2. Adapter 3. Carrier board 4. Gauge cable / connector

Item	Error description	Possible root cause	Possible swap parts
System - eMMC	Can't read and write date from eMMC	SOM board damage	SOM board
System - SD card	Can't read and write data from SD card	1. SOM board damage 2. Carrier board damage	1. SOM board 2. Carrier board
System - USB 2.0	Can't read and write data from USB 2.0	1. SOM board damage 2. Carrier board damage	1. SOM board 2. Carrier board
System - USB 3.0	Can't read and write data from USB 3.0	1. SOM board damage 2. Carrier board damage	1. SOM board 2. Carrier board
System - mSATA	Can't read and write data from mSATA	1. SOM board damage 2. Carrier board damage 3. mSATA module damage	1. SOM board 2. Carrier board 3. mSATA
System - System fan	System fan can't work	1. System fan damage 2. Carrier board damage	1. System fan 2. Carrier board
System - Engine fan	Engine fan can't work	1. Engine fan damage 2. Carrier board damage	1. Engine fan 2. Carrier board
System - Ethernet	Ethernet not function	1. SOM board damage 2. Carrier board damage	1. SOM board 2. Carrier board
System - OTG	OTG not function	1. SOM board damage 2. Carrier board damage	1. SOM board 2. Carrier board
System - LCD	LCD screen abnormal or no display	1. LCD damage 2. LCD cable damage 3. SOM board damage 4. Carrier board damage	1. LCD module 2. LCD cable 3. SOM board 4. Carrier board
System - Touch	Touch not function or abnormal	1. Touch module damage 2. Touch control board damage 3. Touch cable disconnect or damage 4. SOM board damage 5. Carrier board damage	1. LCD (including touch module) 2. Touch control board 3. Touch cable 4. SOM board 5. Carrier board
System - Camera	Camera not function or display abnormally	1. Camera PCBA damage 2. Camera cable disconnect or damage 3. SOM board damage 4. Carrier board damage	1. Camera PCBA 2. Camera cable 3. SOM board 4. Carrier board
System - HDMI	HDMI not function or abnormal	1. HDMI cable damage 2. SOM board damage 3. Carrier board damage	1. LCD cable 2. SOM board 3. Carrier board
System - MIC	Recording no sound or unclear	1. The received voice hole of Mic is covered by something 2. SOM board damage 3. Carrier board damage	1. Remove anything that covered the hole of mic 2. SOM board 3. Carrier board

Item	Error description	Possible root cause	Possible swap parts
System - Speaker	Speaker no sound or noise when playing sound	1. Speaker damage 2. SOM board damage 3. Carrier board damage	1. Speaker 2. SOM board 3. Carrier board
System - Headset	Headset no sound or noise when playing sound	1. Headset damage 2. SOM board damage 3. Carrier board damage	1. Headset 2. SOM board 3. Carrier board
System - Power button	Power button not function	1. Power button damage 2. SOM board damage 3. Carrier board damage	1. Power button 2. SOM board 3. Carrier board
System - RTC	RTC not function	1. Coin cell damage 2. SOM board damage 3. Carrier board damage	1. Coin cell 2. SOM board 3. Carrier board
System - Temperature	Temperature does not show or abnormal	1. SOM board damage 2. Carrier board damage	1. SOM board 2. Carrier board
System - LED	LED indicator not function	1. SOM board damage 2. Carrier board damage	1. SOM board 2. Carrier board
System - Wi-Fi	Wireless not response or no connection	1. Antenna cable disconnect or damage 2. Antenna board damage 3. SOM board damage	1. Antenna cable 2. Antenna board 3. SOM board
System - Bluetooth	Bluetooth not response or no connection	1. Antenna cable disconnect or damage 2. Antenna board damage 3. SOM board damage	1. Antenna cable 2. Antenna board 3. SOM board
Engine	Can't open ultrasound app	1. SOM board damage 2. Carrier board damage 3. USB 3.0 cable (for engine) damage 4. Power cable (for engine) damage	1. SOM board 2. Carrier board 3. USB 3.0 cable 4. Power cable

FCC statement

Federal Communications Commission (FCC) Statement

15.21

You are cautioned that changes or modifications not expressly approved by the part responsible for compliance could void the user's authority to operate the equipment.

15.105(b)

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation.

This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. This device may not cause interference and

2. This device must accept any interference, including interference that may cause undesired operation of the device.

RF Radiation Exposure Statement:

1. This Transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

2. This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

*CE

Statement regarding the disposal of UH100 products containing electronic components:

As a company, UH100 is committed to sustainable business practices, which are aimed to preserve, protect and improve the quality of the environment. We apply these to product technologies, design and the selection of the materials used in our products. Adhering to corresponding environmental laws, directives and guidelines are a core element of our sustainability principles. Since the UH100 concept is equipped with electronic components, we will ensure that it complies with actual or planned directives and laws, which are mandatory for electronic products and may require specific measures regarding labeling, collection and recycling.

NOTE: If not disposed of properly, batteries can be harmful. Protect the environment by taking exhausted batteries to authorized disposal stations.

European Commission (CE) Statement

European Union Regulatory Notice

This device bearing the CE marking is compliance with the essential requirements and other relevant provisions of Directive 2004/108/EC, 2014/53/EU, 2011/65/EU, 2012/19/EU and 93/42/EEC.

This device complies with the following harmonized European standards,

EMC: EN55022, EN55024

Radio: EN300328,EN301893,EN301489-1,EN301489-17, EN62311

Medical: IEC 60601-1, EN60601-1-2, IEC 60601-1-6, IEC 60601-2-37, IEC 62304, EN ISO10993-1, EN ISO10993-5, EN ISO10993-10, EN ISO 14971

ROHS: EN50581

The following CE marking is valid for EU harmonized telecommunications products.

$C\epsilon$