

Acclarix AX8

Diagnostic Ultrasound System

Version 1.4

User Manual

Basic Volume

CE₀₁₂₃



Preface

This manual contains necessary and sufficient information to use the Acclarix AX8 system safely for the purposes for which it is intended. It applies to all 1.3X releases.

Read and understand all instructions in this manual prior to using the Acclarix AX8 ultrasound system.

Disregarding instructions, particularly warnings and cautions, is considered abnormal use.

Caution: **Rx only** Federal law restricts this device to use by, or on the orders of, a physician.

Contact Information:

For sales or service information please contact your local distributor or the EDAN service department at: support@edan.com.cn

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1 Introduction

1.1 Intended Use/ Indications for Use

For the United States of America

The Edan Acclarix AX8 Ultrasound system is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include:

- Abdominal
- Gynecology (including endovaginal)
- Obstetric
- Cardiac
- Small parts (Breast, Testes, Thyroid, etc.)
- Urology
- Musculoskeletal
- Peripheral vascular
- Intra-operative

For the EU and other non-USA regions

The Edan Acclarix AX8 Ultrasound system is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include:

- Abdominal
- Gynecology (including endovaginal)
- Obstetric
- Cardiac
- Small parts (Breast, Testes, Thyroid, etc.)
- Urology
- Musculoskeletal
- Peripheral vascular
- Intra-operative
- Pediatric
- Neonatal (including abdominal and cephalic)
- Adult Cephalic*

1.2 Contra-indications

The Edan Acclarix AX8 Ultrasound system is not intended for ophthalmic use.

1.3 Device Description

The Edan Acclarix AX8 Ultrasound system consists of a main system along with associated transducers.

The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The waves are then reflected within the body and detected by the transducer, which

then converts back to an electrical signal. The Acclarix AX8 system then analyzes the returned signal to generate an image or conduct Doppler processing.










The Acclarix AX8 system gives the operator the ability to measure anatomical structures, and offers analysis packages that provide information used by competent health care professionals to make a diagnosis.

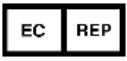










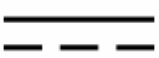

The system provides both touch screen and hard buttons for the User Interface.






*Descriptions of transducer C5-2MQ, adult cephalic application, 3D/4D function, PW one-key optimization, acoustic power control, panorama measurement and wireless function are not approved for use until finishing the related registration.

1.4 Labeling Symbols

The following labels are used on the Acclarix AX8 system:

No.	Symbol	Definition
1		Serial Number
2	P/N	Part Number
3		Date of Manufacture
4		Manufacturer
5		Operating instructions
6		Warning (Background: Yellow; Symbol & outline: Black)
7		Refer to User Manual (Background: Blue; Symbol: White)
8		Caution
9		Biological Risks
10		The symbol indicates that the device complies with the European Council Directive 93/42/EEC concerning medical devices.

11		Authorized Representative in the European Community
12		Disposal method. Indicates that the equipment should be sent to special agencies according to local regulations for separate collection after its useful life.
13		General Symbol for Recovery / Recyclable
14	Rx only	Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.
15	<p>ETL CLASSIFIED</p>  <p>Intertek 4005997</p>	<p>Conforms to AAMI Std. ES 60601-1, IEC Std. 60601-2-37</p> <p>Certified to CSA Std. No. 60601-1, No 60601-2-37</p>
16	IPX7	No harm for short time immersion
17		Type BF Applied Part
18		Transducer connector
19		Pencil Transducer connector (reserved)
20		ECG signal input connector (reserved)
21		Transducer lock
22		Transducer unlock
23		Network port
24	EDAN	Trademark
25		Direct current
26		Video Output port

27		USB 2.0 port
28		USB 3.0 port
29		Display port
30		Microphone input
31		Headphones
32	FCC ID: SMQAX8EDAN	Federal Communication Commission: FCC ID: SMQAX8EDAN

NOTE:

The user manual is printed in black and white.

2 Safety

Throughout this document the following terms are used:

- **Warning:** Advises against certain actions or situations that could result in personal injury or death.
- **Caution:** Advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.
- **Note:** Provides useful information regarding a function or a procedure.

Please read all warnings and cautions prior to using the Acclarix AX8 ultrasound system. For your convenience all warnings and cautions are provided in this section. These may be duplicated elsewhere in this document in the context of the instructions for use.

2.1 Warnings

- Only use an Edan supplied power adapter and power cord.
- Only use an Edan supplied battery. Read and understand the battery installation instructions prior to changing the battery.
- Only use Edan supplied transducer. Use of other transducers may result in electric shock or system malfunction.
- Only use a hospital grade, grounded, power outlet and plug. Do not use with an ungrounded outlet.
- The system is ordinary equipment (Sealed equipment without liquid proof). But the console panel including touch screen, track pad and hard keys is IPX1. Transducer (not including the transducer connector) is IPX7. Footswitch is IP68. Do not immerse or expose any of the parts to extended moisture. Splash resistance does not extend to transducer connectors. Keep connectors dry.
- Do not use in a wet environment or when the relative humidity exceeds 95%.
- Do not reverse the positive and negative poles when installing a battery.
- Do not use the battery near heat sources or when the ambient temperature is over 40°C. Do not heat or dispose of in fire.
- Do not destroy the battery; do not pierce or cause a strong impact to the battery.
- Do not touch the connector pins on the transducer port.
- Parts and accessories used must meet the requirements of the applicable IEC/EN60601 series safety standards, and/or the system configuration must meet the requirements of the IEC/EN60601-1.
- Use protective barriers (gloves and transducer sheaths) whenever possible. Follow sterile procedures when appropriate. Thoroughly clean Transducers and reusable accessories after each patient examination and disinfect or sterilize as needed. Refer to transducer use and care instructions. Follow all infection control policies established by your office, department or institution as they apply to personnel and equipment.

- Not intended for Ophthalmic use.
- If a sterile transducer cover becomes compromised during an intra-operative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt-Jakob disease, follow the guidelines of the U.S. Disease Control Center and this document from the World Health Organization: WHO/CDS/APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.
- Contact with natural rubber latex may lead to a severe anaphylactic reaction in persons sensitive to the natural latex protein, Sensitive users and patients must avoid contact with these items. EDAN strongly recommends that health-care professionals identify their latex-sensitive patients, and refer to the March 29, 1991 Medical Alert on Latex products. Be prepared to treat allergic reactions immediately.
- Improper operation may cause the internal lithium battery (hereinafter called battery) to be hot, ignited or exploded, and it may lead to the decrease of the battery capacity. It is necessary to read the user manual carefully and pay more attention to warning messages.
- Do not touch accessible contacts of electrical equipment and the patient simultaneously.
- This device is not suitable for intra-cardiac use or direct cardiac contact.
- The system shall not be serviced or maintained while in use with a patient.
- Install the system according the EMC guidance provided in Chapter 14
- Do not stack the system on other electronic equipment.
- The use of transducer and connecting cable not supplied by the manufacturer may result in increased emissions or decreased immunity of the equipment.
- Refer to Chapter 14 for recommended separation distances from other equipment, including portable and RF communication devices.
- The power adapter is used to isolate the system from main power. Position the system so that it is easy to disconnect the device.
- No modification of this equipment is allowed.
- The system should be maintained regularly, at least annually, by a qualified technician who has adequate training, knowledge and experience. That person should be familiar with the AX8 Service Manual (P/N: 01.54.002483), available from your Edan representative.
- Keep non-medical equipment (such as the external printer) out of the vicinity of the patient. (1.5m/6ft.)
- Use of an extension cord or multi-socket outlet setup to provide power to the ultrasound system or to the system's peripheral devices, may compromise the

system grounding and cause the system to exceed leakage current limits.

- SHOCK HAZARD – Do not connect non-isolated electrical equipment to the same circuit being used to power the system.
- Edan recommends the use of isolated connectors on any electrical equipment attached to the system, and/or using isolation transformers that complies with IEC60601-1 to power that electrical equipment.
- Always use sterile technique during a biopsy procedure. Sterilize the needle guide assembly between uses.
- Use a sterile needle with each use.
- Always confirm the clinical accuracy of the IMT result before entering it into the report.

Transducer Warnings

- To avoid infection, always use protective gloves when cleaning or disinfecting
- Read and follow all manufacturer instructions for disinfection agents.
- To avoid infection, ensure that expiration date of the disinfecting solution has not passed.
- Disinfect the transducer after each intra-cavity or intra-operative procedure. Use a new sterile sheath for each such procedure.
- Use a pyrogen-free transducer sheath for neurological intra-operative procedures.
- Unplug the transducer from the system prior to cleaning or disinfecting.
- Do not immerse the transducer beyond the point indicated in Figure 6-2.
- Do not allow the transducer connector to get wet.

2.2 Cautions

- The system contains no user serviceable components other than the battery. Do not remove any covers.
- Excessive dust and dirt could clog internal airflow and cause overheating. Do not use in a dusty environment.
- Do not use a battery that leaks, emits an odor, appears deformed, or discolored. Immediately replace it with a new Edan-supplied battery and dispose of the old battery according to local regulations. Replace a battery that has reached the end of its service life.
- Use care when storing or disposing of batteries. Do not allow the leakage to come in contact with each other. Do not dispose of them together with household garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries.
- Inspect the system regularly, at least weekly. Before use ensure there is no visible

evidence of damage to the equipment, cables, and transducers. If a component is damaged replace it before use.

- Do not use in locations subject to vibration.
- Read and understand the section *A1.2 Ultrasound Safety and the ALARA Principle* of Acclarix AX8 Advanced User Manual before using the system. Do not expose a patient to ultrasound energy longer than clinically reasonable.
- Practice ALARA principle when operating ultrasound system. Minimize the acoustic power without compromising the image quality.
- Do not use in the presence of a flammable anesthetic.
- The system generates radio frequency energy, which may cause interference with other devices in the vicinity. If interference is suspected, try re-orienting or relocating the equipment.
- The use of electrosurgical units or other devices that generate radio frequency interference may cause image distortion or other malfunction.
- During long term storage the battery should be charged at least once every 3 months to ensure battery capacity.
- The system should only be used by a qualified physician or allied health professional for ultrasound evaluations.
- Use only Edan supplied or recommended parts and accessories.
- Verify measurement results prior to entering them into a report.
- Contact your local distributor or Edan service if there is excessive noise from the system speaker or fans.
- Please read and understand cleaning instructions prior to use.
- Please read and understand maintenance instructions prior to use.
- Please read and understand instructions for system operation prior to use.
- Studies stored on the system hard drive should be archived regularly. The system is not intended for long term storage of patient information. Confirm successful archiving before deleting a study from the hard drive.
- Ensure that the system vents are clear and unobstructed.
- Confirm patient identification information prior to storing or printing any exam information.
- If you have any questions about maintenance, technical specifications, or system functionality, please contact your local distributor or Edan service at: support@edan.com.cn
- Ultrasound images occasionally have artifacts, and should only be used as one part of an overall clinical assessment.
- To avoid electrical shock, turn off and disconnect the device from the AC power

source before cleaning and disinfecting.

- The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal.

Transducer Cautions

- Do not use disinfection agents beyond their expiration date.
- Do not use sterile sheaths beyond their expiration date.
- Inspect the transducer connector, cable, and head periodically. Do not use if there is evidence of excessive wear or damage.
- Do not operate the transducer to temperatures in excess of 40°C or storage the transducer to temperatures in excess of 55°C.
- Do not kink or pull on the transducer cable.
- Broken or bent connector pins can cause image artifacts. Do not use a transducer with broken or bent pins.

3 Getting Started

3.1 System Configuration

The Acclarix AX8 system is shipped with the following components:

- ◆ Acclarix AX8 main unit
- ◆ 1 rechargeable lithium battery
- ◆ 1 UPS battery
- ◆ 1 AC adapter
- ◆ 1 bottle of coupling gel
- ◆ 1 basic user manual and 1 advanced user manual

The following options are also available (please see the Order List Appendix for details)

- ◆ Transducers: C5-2XQ, C5-2Q, L10-4Q, L12-5Q, L17-7HQ, E8-4Q, MC8-4Q, P5-1XQ, L17-7SQ, C5-2MQ*
- ◆ 1 Trolley MT-807
- ◆ Footswitch
- ◆ Suitcase
- ◆ The Acclarix AX8 supports the following external DVD drives: SAMSUNG SE-218GN, SAMSUNG SE-208GN, LENOVO DB75, ASUS SDRW-08D2S-U and PIONEER DVR-XU01C.

The Acclarix AX8 supports the following DVD disks: Philips CD-R 700MB 80min 52x, Sony CD-RW 700MB 1x-4x, Sony DVD-RW 4.7GB 120min 2x/1x, Verbatim DVD+RW 4.7GB 120min 4x.

Note: Only support DVD disk single burning.

- ◆ The Acclarix AX8 supports the following printers. Please contact the manufacturer for details.

Printer Model	Printer Type	Interface
SONY UP-25MD	Color Image	S-Video
SONY UP-D25MD	Color Image	USB
SONY UP-X898MD	B/W Image	USB
HP Officejet Pro 251dw	Color Report	USB
HP Laserjet Pro 200 M251n	Color Report	USB
HP Laserjet CP1525n Color	Color Report	USB
HP Deskjet Ink Advantage 2010	Color Report	USB
HP Deskjet 1010 Color	Color Report	USB
HP Deskjet 1510 Color	Color Report	USB
HP LaserJet 400 M401d	B/W Report	USB

Table 3-1 Printer List

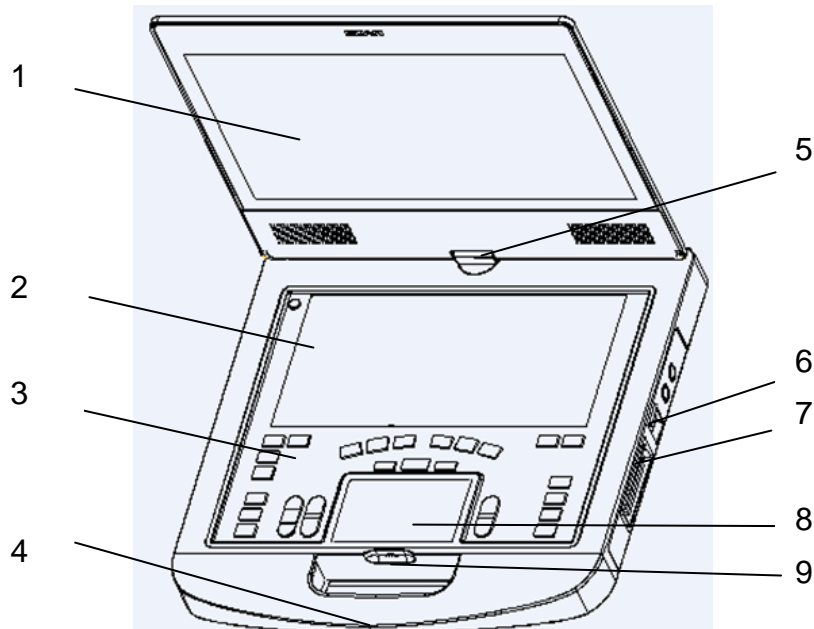
Note: For more printer models, please see: http://hplipopensource.com/hplip-web/supported_devices/combined.html . Generally, printer models with driver version 3.14.3 or lower can be supported by Acclarix AX8, but some models cannot be perfectly supported.

◆ Needle Guide Bracket Kit

Model	Name	Description
BGK-C5-2	BGK-C5-2 Needle Guide Bracket Kit	For use with the C5-2XQ/C5-2Q, Supports: 16G, 18G, 20G, 22G
BGK-L40UB	L40UB Needle Guide Bracket Kit	For use with the L10-4Q, Supports: 16G, 18G, 20G, 22G
BGK-CR10UA	CR10UA Needle Guide Bracket Kit	For use with the E8-4Q, Supports: 16G
BGK-R15UB	R15UB Needle Guide Bracket Kit	For use with the MC8-4Q, Supports: 16G, 18G, 20G, 22G
BGK-P5-1X	BGK-P5-1X Needle Guide Bracket Kit	For use with the P5-1XQ Supports: 14G-22G

Table 3-2 Needle Guide Bracket Kits

3.2 System Overview



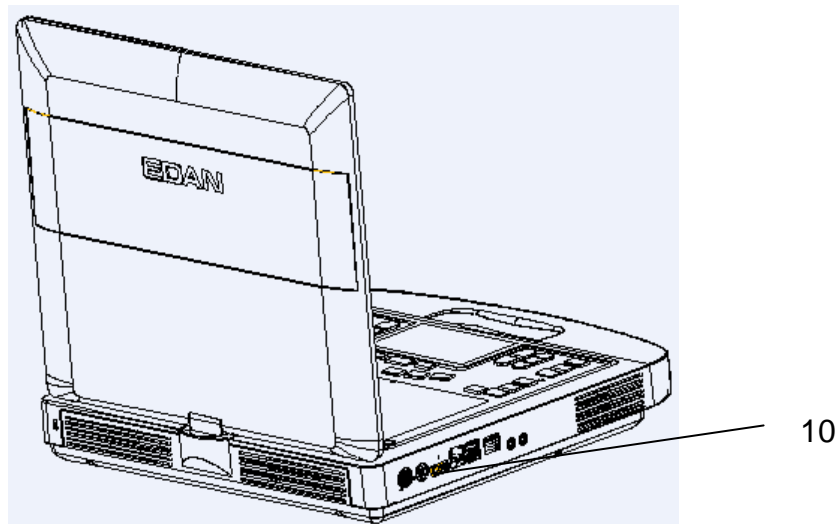


Figure 3-1 Appearance of the System

No.	Name	Description
1	Monitor	Display the images and parameters during scanning.
2	Touch Screen	Use to control operation and activate functions
3	Control panel	Use to control the operation
4	Handle	Used for carrying the system
5	Hinge	Used to rotate the monitor
6	Transducer locking lever	Use to lock or unlock the transducer
7	Transducer Port	Used for connecting a transducer to the Acclarix AX8 main unit
8	TrackPad	Use to change the cursor position
9	Battery Indicator	LEDs indicate battery charge. Each LED corresponds to 20% of battery power. The LEDs will flicker while the battery is charging. Touch the battery indicator to view the battery power.
10	I/O Ports	Use to connect the I/O extend modules

Table 3-3 Appearance of the System

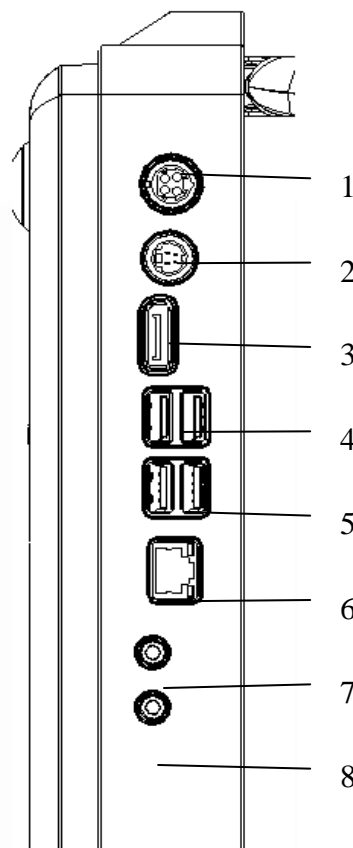
I/O Ports on the left panel:

Figure 3-2 I/O ports of the system

1. Power supply	5. USB 2.0 port
2. S-Video output port	6. Network port
3. Display port	7. Microphone input port
4. USB 3.0 port	8. Audio output port

Table 3-4 I/O Ports of the System

NOTE: If an external monitor is connected to the system via display port, configure the resolution to 1920x1080, other resolution may cause abnormal ultrasound machine display.

3.3 Battery Use

The Acclarix AX8 system comes with one lithium-ion battery. When it is fully charged it can run the system for approximately 60 minutes, depending on use. It is automatically charged when the system is plugged in.

CAUTION

1. If the system will remain unused for more than one week, charge the battery to at least 75% capacity, take the battery out and store the system and battery separately.
2. During long term storage the battery should be charged at least once every 3 months to ensure battery capacity is more than 75%.

To install the battery:

1. Turn off and unplug the Acclarix AX8 system.
2. Close the monitor, turn the system upside down and rest it on a flat stable surface.
3. Put the battery gently to battery compartment, and the button will lock the battery automatically.

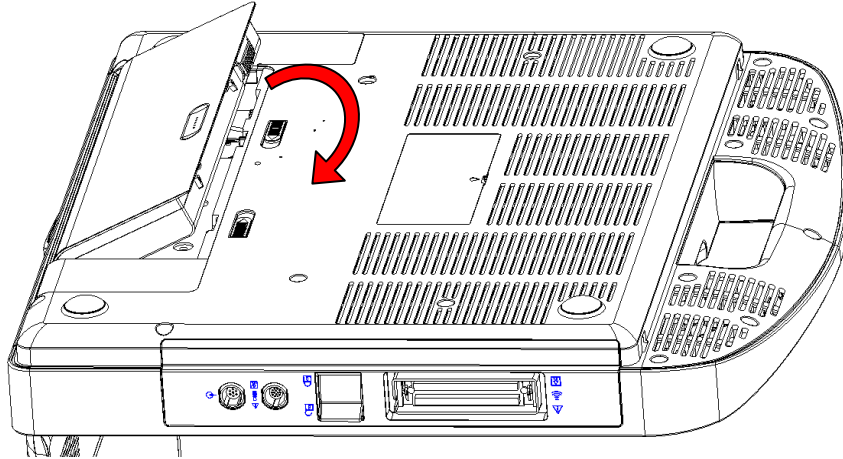


Figure 3-3 Installation of the Battery

To remove a battery:

1. Turn off and unplug the Acclarix AX8 system.
2. Close the monitor, turn the system upside down and rest it on a flat stable surface.
3. Slide the battery button to unlock the battery.
4. Take the battery out.

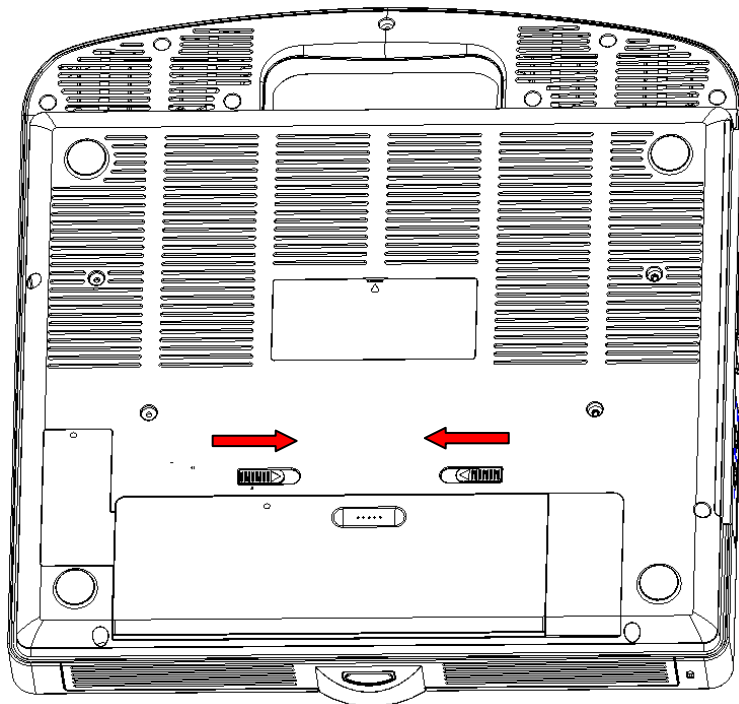


Figure 3-4 Battery Removal

To install the UPS battery:

1. Close the monitor, turn the system upside down and rest it on a flat surface.

2. Take out the UPS battery from the package.
3. Put the UPS battery gently to the UPS battery compartment.

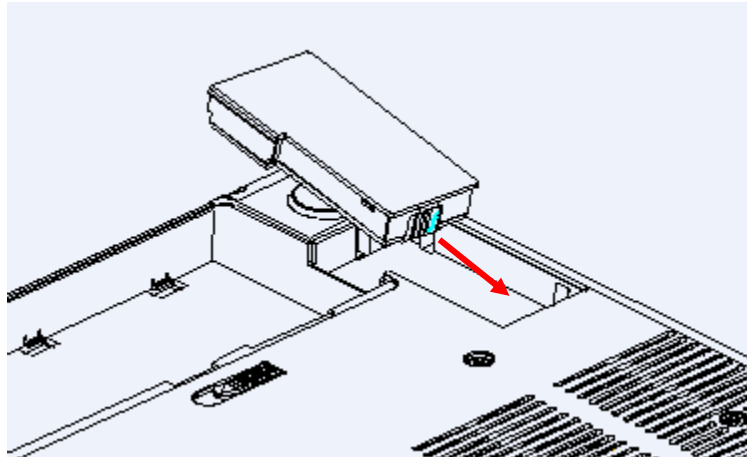


Figure 3-5 Installation of the UPS Battery

3.4 Connecting and Disconnecting a Transducer

To connect a transducer:

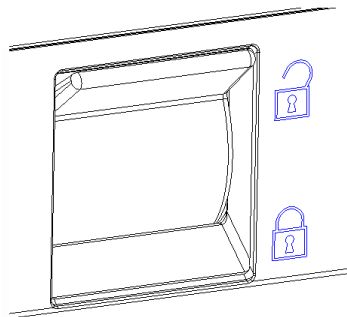


Figure 3-6 Tansducer Locking Handle

1. Align the connector with the transducer port and carefully push into place.
2. Toggle the locking handle to the bottom position.
3. Do not allow the transducer head to hang free. Impact to the transducer head could result in irreparable damage.

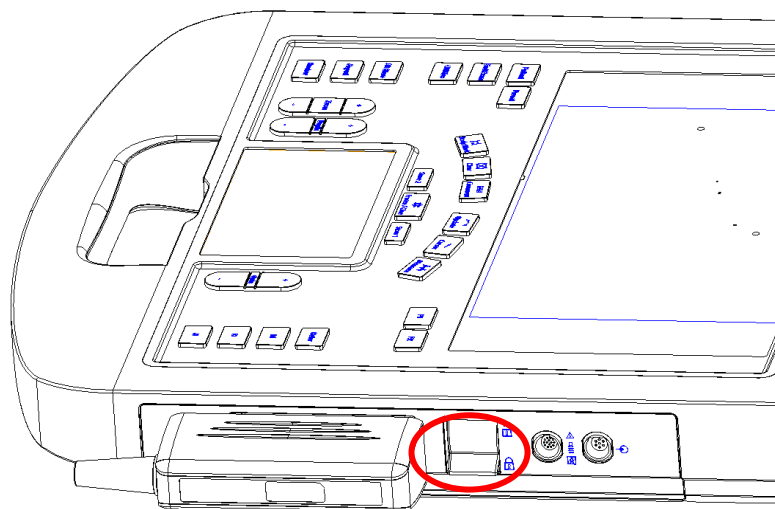


Figure 3-7 Lock the tansducer locking handle

To disconnect a transducer:

1. Toggle the locking handle to the top position to unlock the connection of the Transducer.
2. Firmly grasp the transducer connector and carefully remove it from the system port.
3. Store transducer in its protective carrying case prior to transport.

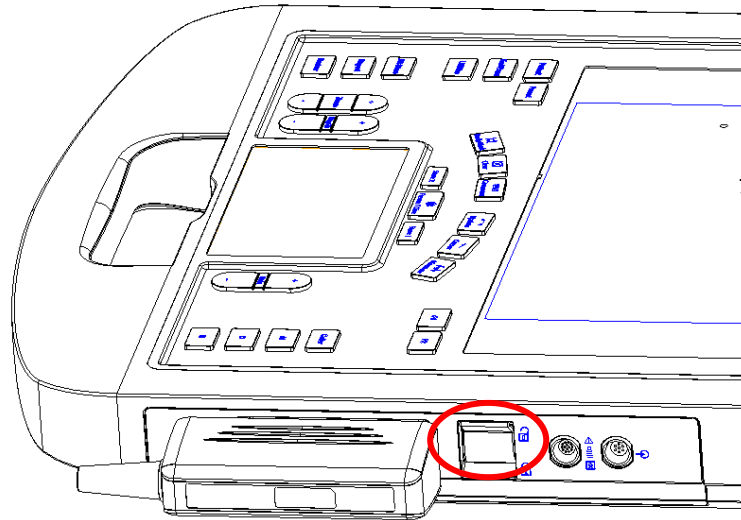


Figure 3-8 Unlock the Tansducer Locking Handle

CAUTION

1. Do not touch the pins of the transducer connector.
2. Broken or bent connector pins can cause image artifacts. Do not use a transducer with broken or bent pins.

Multi-Transducer Connector (MTC)

The Multi-Transducer Connector (MTC) is an optional addition to the AX8 that allows up to three transducers to be connected to the system. The MTC can be mounted to the optional AX8 cart, or lie flat on an adjacent table.

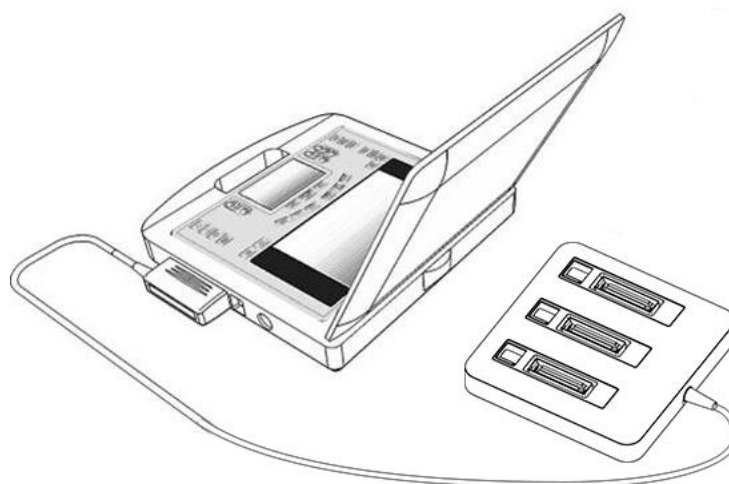


Figure 3-9 Connect to the MTC

Note:

Plugging and unplugging the MTC should be done while the system is frozen or turned off.

3.5 Powering on/ off

Please review and follow the steps described in the Section *12.1.Daily Checklist* prior to powering on the device.

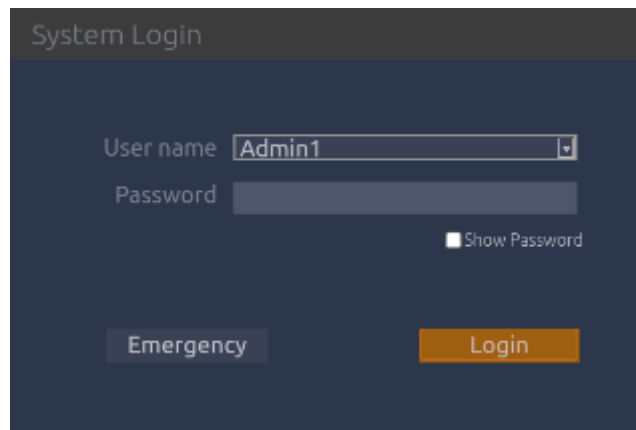
◆ To power on:

1. Connect the system to a hospital grade power supply, or use the battery as the power supply.
2. Press the power on/off key on the top left of control panel.

◆ To Login

If Password Protection is enabled (see section 9.1.5), the system displays a Login dialog when booting up the system, you can type in or select user name in the drop-down list of User name, then enter password and click **Login**.

For emergency use, you can click on **Emergency** to log on directly without entering user name and password.



Note:

When both Admin1 and Admin2 password are forgotten, please contact the serviceman for the system password reset.

◆ To power off:

1. Press the power on/off key on the top left of control panel and the system displays a confirmation dialog box.
2. Select “Shut Down” from the confirmation dialog box.

If the system is unresponsive, a long press of the power on/off key will shut down the system directly.

NOTE:

Please unplug the AC adapter from the power socket and disconnect the battery prior to storage.

◆ Sleep mode

The system will enter a sleep mode that maintains exam information while using minimal battery. There are three events that can invoke sleep mode:

- Close the cover of the system without powering-off the system.
- No user input for a configurable amount of time. Please see System Set-up to configure this time.
- Pressing the **Sleep** button on the confirmation dialog box when powering off.

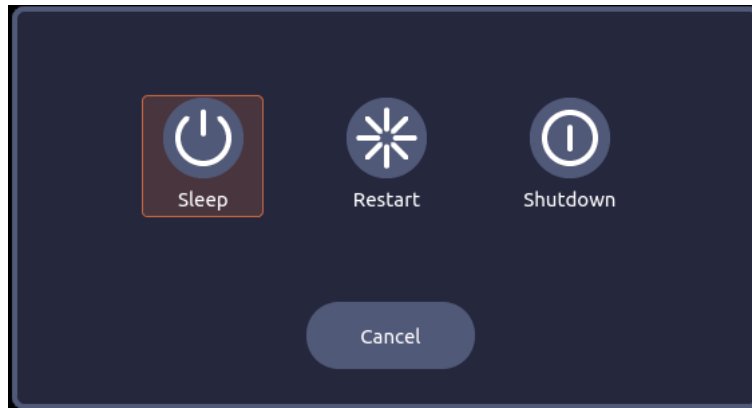


Figure 3-10 Confirmation Dialog Box When Power off

3.6 Screen Layout

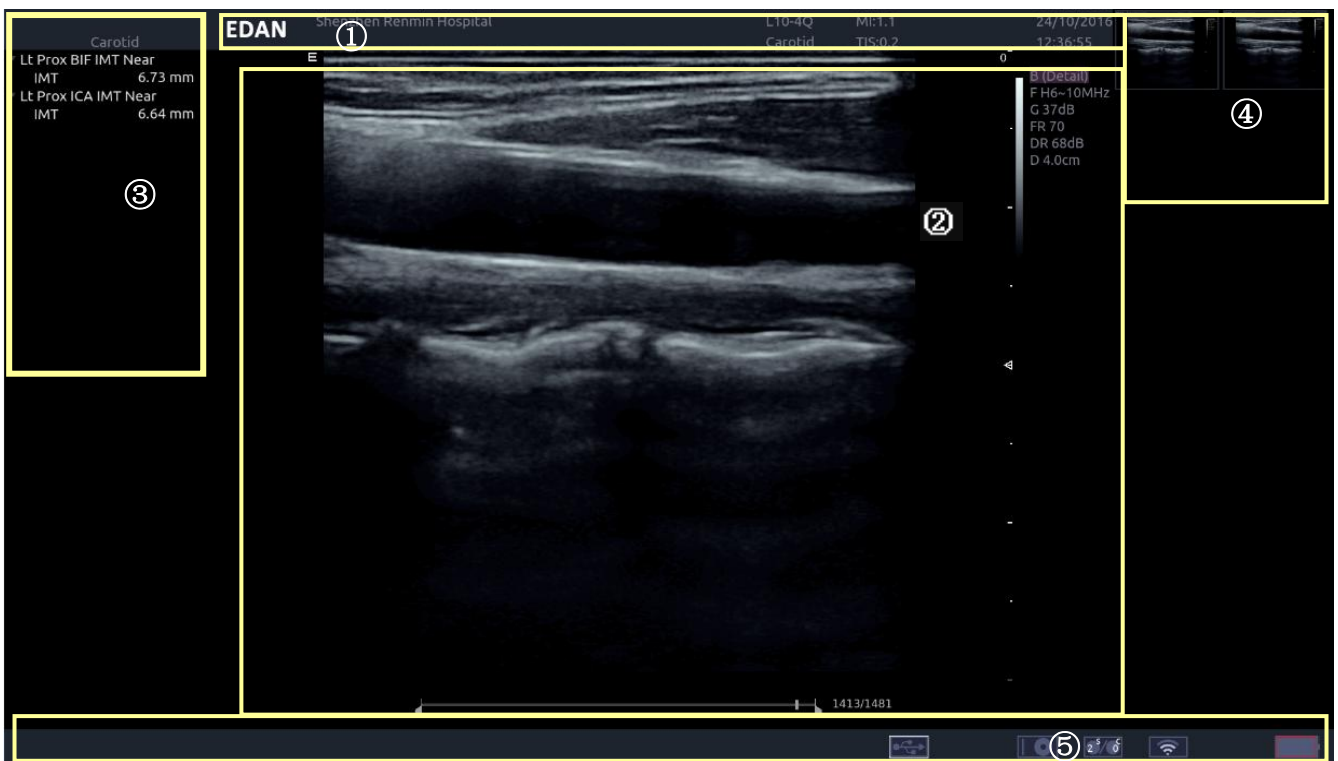


Figure 3-11 Main Screen Display

① **Information Field:**

The top line of this field contains your hospital/institution name. Please see Section 9.1. *General Set-up* for information on customizing this area.

The second line of this field contains the patient name, gender, age and ID, as entered through the Patient Information screen.

This field also contains data fields for:

- The currently active transducer

- The currently active preset
- MI, TI, current date and time.

② **Image Field:**

The ultrasound image appears in the Image Field, under the Information field. The image field also contains information typically associated with the image, such as scales, TGC, and maps. The system supports two different image sizes within the image field. See 9.1.1 for details

③ **Mini Report:**

The left side of the screen displays a “mini-report” which provides a synopsis of applications measurements performed in the current exam.

④ **Thumbnail Field:**

The right side of the screen displays thumbnail images of all statics and clips captured in the current exam.

⑤ **Status Bar:**

The bottom of the screen is used to display icons that provide system status. These include:

- Image Store icon



: Number of static images and clips in the current exam.

- Battery icon



: Battery fully charged, symbol in green.



: Battery higher than 80%.



: Battery 60%-80%.



: Battery 40%-60%.



: Battery low, symbol in red.



: Battery removed, outline in red.



: Battery charging.

- Network status icon

The network icons show the connection status of the DICOM or FTP Server. If no Network Server is defined then the icon does not show at all.



Outline in grey color: Successful connection with a Server.

Outline in green color: Data exchange with a Server.

Outline in red color: Failure to connect with a configured Server.

- Hard drive icon.



: Hard drive available



: Hard drive data exchange, symbol in green.



: Hard drive 95% full, symbol in red.



: Hard drive 95% full with data exchange, symbol in red.

- USB icon



Symbol in grey color: USB available

- DVD icon



: Symbol in grey: DVD device is connected



: Symbol in green: DVD device is connected, disc is inserted and data transmission is available.

- Printer icon



: Printer available.

- Wifi icon *



: Wi-Fi available, Subject to regulatory approval. See Connectivity (Section 9.2.1) for enabling wireless if it is licensed. Clicking on this icon shows a list of all Wi-Fi networks that are currently available.

WARNING

The system complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1) this device may not cause harmful interference, and
- 2) this device must accept any interference received, including interference that may

cause undesired operation.

NOTE:

1. 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.
2. Any changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

3.7 Control Panel

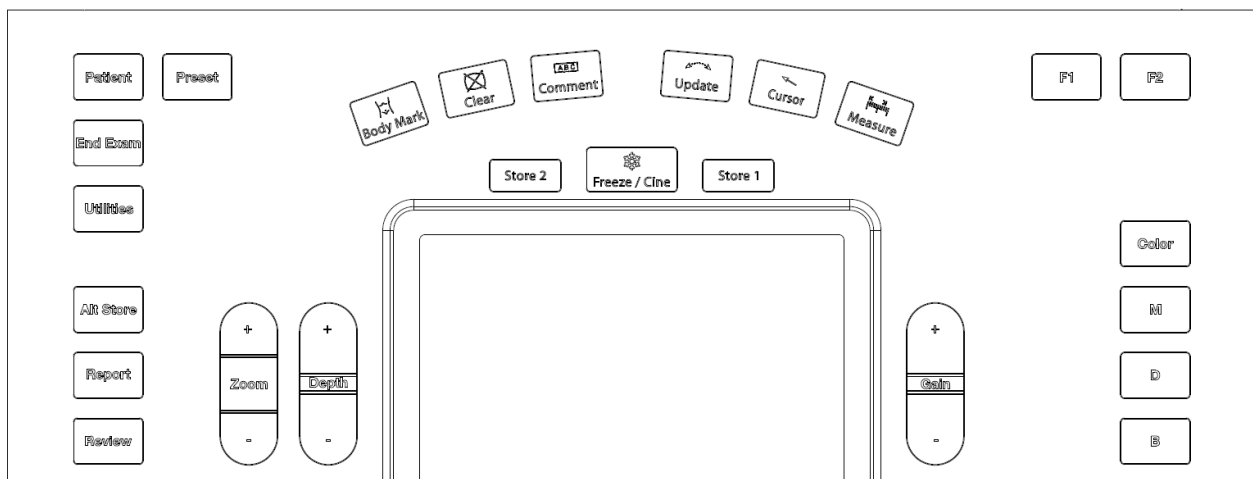






















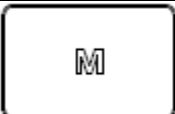
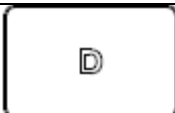


Figure 3-12 Control Panel of the System

No.	Key	Name	Description
1.		Patient	Invokes the Patient Information Screen. Typically used to start/end exams or to modify patient information during an exam. See section 4.1

2.		Preset	Allows you to change the Preset being used. See section 8 for details.
3.		End Exam	Completes an exam without invoking the Patient Information Screen for the next exam. See section 4.2
4.		Utilities	Press this button to get the Set Up, Maintenance, Connectivity and Screen Adjust keys on the touch screen.
5.		Alt Store	One of three keys that can be configured to store images or clips, or to set video printers. See section 7.4 for details.
6.		Report	Press to display the report page
7.		Review	Press to enter exam database or image review mode. See section 7.4 for details.
8.		Zoom	Press to zoom the image in or out. See section 5.1.5 for details.
9.		Depth	Press to adjust the depth of the image displayed.
10.		Body Mark	Enters or exits the Body Mark function. See section 7.2 for details.
11.		Clear	Press to clear all the measurements, calculations, comments, and body marks displayed in the current image.
12.		Comment	Enters or exits the Comment function. See section 7.1 for details.

13.		Update	In Strip Doppler this switches between acquiring the Doppler strip and the reference image. See section 5.2.3 for details.
14.		Cursor	Press to hide or display the cursor
15.		Measure	Invokes the Measure function for Generic and Application Measurements. See section 7.3 for details.
16.		Freeze/Cine	Press this key to switch between the frozen and real-time states.
17.		Store 1	One of three keys that can be configured to store or print images or clips, or to set video printers. See section 7.4 for details.
18.		Store 2	One of three keys that can be configured to store or print images or clips, or to set video printers. See section 7.4 for details.
19.		Gain	Controls the overall gain for the imaging mode that currently has the UI focus. In normal imaging the gain can also be adjusted by sliding your finger along the top of the trackpad area
20.		F1	User-defined button
21.		F2	User-defined button
22.		Color	Press to enter or exit Color Mode. See section 5.4 for details
23.		M	Press to enter or exit M Mode. See section 5.5 for details. Use the trackpad to adjust the M sample line.
24.		D	Press to get the sample line, use the trackpad to adjust the position and press the hardkey again to confirm. For other information, see section 5.2 and 5.3 for details.


25.		B	Press to return to B-mode imaging from any display or imaging mode. See section 5.1 for details.
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Table 3-4 Buttons on Control Panel

3.8 Touch Screen

The Touch Screen contains controls that vary depending on the active function.

There are several types of controls used by the touch screen, as illustrated below:

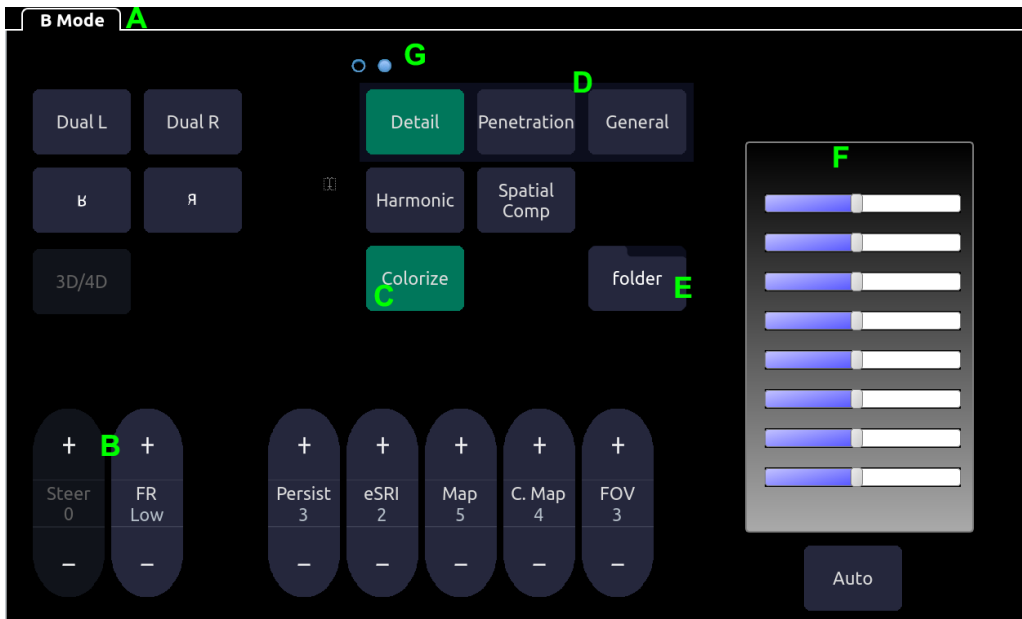


Figure 3-13 Touch screen of the System

- A. **Tabs:** Each function that is active has a tab on the touch screen. Usually the function that was most recently activated is the top tab. Pressing on any other tab will bring it to the top and provide access to that function’s controls.
- B. **Slider:** Pressing on the top or bottom of a slider changes the control setting by one value. Pressing anywhere on the control and dragging will continuously change the value.
- C. **Push button:** This can either be an on/off control (like “Colorize”) or a one-shot control that immediately performs an action (like “Auto”)
- D. **Radio Buttons:** A collection of buttons where only one is active at any time. Activating one will de-activate all others.
- E. **Folder:** Controls can be grouped together into a folder. Pressing on the folder will open it to access any of the controls in it.
- F. **TGC:** The B-mode tab has a specialized control for TGC. Each slider can be dragged horizontally and individually. Dragging vertically down across the sliders will set all sliders.
- G. **Pages:** When a tab has multiple pages of controls each page is represented by a dot at the top of the page. The current page is indicated by a filled-in dot. You can move between pages by dragging your finger horizontally across the dots. These dots do not appear when there is only one page in the current tab.

Customizing the touch screen

The touch screen can be customized to meet your needs. Press and hold any control for about a second to put the touch screen in customization mode. Continue pressing and drag the control to a new location.

- **Creating Folders:** Dragging one control on top of another control will create a folder that contains both controls. Dragging controls out of a folder until only one exists will automatically delete that folder. Folders cannot contain other folders.
- **Multiple pages:** Dragging a control to the side of the screen will move that control to the next page.
- **Radio Button Cluster:** There is no restriction on moving a single radio button. However, we suggest that they are grouped adjacent to each other. When they are grouped in this way the system will automatically draw a border around them to indicate they are a related group of radio buttons.
- **TGC:** The TGC is a special control that cannot be moved. It is always on the right side of the B-mode tab.

For most tabs there is one arrangement of controls. Whatever way they are customized will be remembered across exams and across power-ups. However, the following tabs can have multiple different arrangements:

- Comments
- Bodymarkers
- Measurements

These functions are often configured differently for different exams. For example, the measurements for an OB exam are different from those of an abdomen exam. Each configuration of these tabs is stored in an application preset (see *Chapter 8 Presets*, for details)

3.9 Trackpad

In general the Acclarix AX8 trackpad is used like a trackball or similar pointing device used on most ultrasound systems. Using a trackpad instead of a trackball helps make the console sealed, and makes the system easier to clean. In addition, there are several capabilities that the trackpad supports that would not be possible on a traditional trackball:

- The trackpad supports multi-finger gestures. For example:
 - While in B-mode a pinch-out gesture can be used to zoom the image.
 - While in Color a pinch gesture can re-size the ROI.
- Dragging along the **Swipe** button on top edge of the trackpad as a primary sliding control. For example:
 - In most live imaging modes this is Gain.
- The top right of the trackpad is reserved as a ‘Set’ button. Pressing this corner is generally equivalent to a single click on a mouse or trackball. For example:
 - In CD it is used to toggle between controlling the size and the position of the pan box.
 - In Measure it is used to toggle between controlling one side or the other side of a caliper pair.
- The top left of the trackpad is reserved as an ‘Enter’ button. Pressing this corner is

generally equivalent to a double click on a mouse. For example:

- In Measure it is used to enter a measurement into a report.

The examples provided above are a subset of how the trackpad is used. Additional examples are provided in specific feature descriptions elsewhere in this manual.

4 Exam Operation

4.1 How to Start an Exam

To start a new exam, press the **Patient** key and enter in patient information for the exam, or select a scheduled patient from the modality worklist.

If there is no previous exam this will bring you directly to the Patient Information Page (see figure 4-2 below). If a previous exam is still active you will see the following dialog:

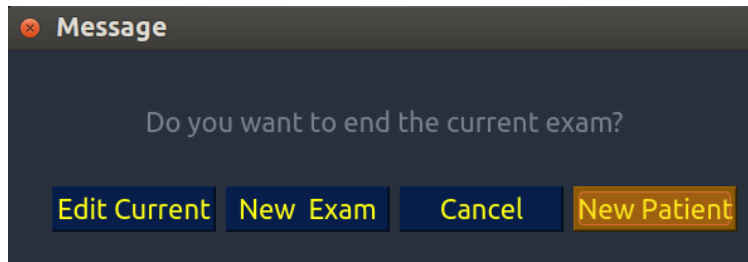


Figure 4-1 Exam Confirmation Dialog

It has the following options:

- **Edit Current:** This lets you edit the Patient Information for the current exam. It does not start a new exam.
- **New Exam:** Select this to start a new exam with the same patient. It confirms that you want to end the previous exam, and then displays the Patient Information Page with the previous patient information still displayed.
- **Cancel:** Exits the dialog without starting or ending an exam.
- **New Patient:** Select this to start a new exam. It confirms that you want to end the previous exam, and then displays a blank Patient Information Page for the new exam.

4.2 How to End an Exam

There are two ways to end an exam:

- Pressing the **Patient** key, as described above, and then selecting the **New Patient**. This both ends the exam and presents the Patient Information Page for the next exam. This is the most common way of ending the exam, especially when there are several exams in a row.
- Pressing the **End Exam** key. This brings up a dialog to confirm you want to end the exam, but does not invoke the Patient Information Page for the next exam. You might end the exam this way when there is no exam next.

When an exam is ended the associated files on the system are closed. If a DICOM server is connected successfully and **Auto-transfer when End Exam** is configured, any remaining images are transferred.

4.3 How to Restart an Exam

1. Select an exam within the time limit in Exam Database. For the setting of time limit, refer to section 9.1.2 *Patient Set-up*.
2. Press **Restart** on the touch screen to continue/edit the exam that was performed on the selected patient. You can also modify the patient information by pressing **Patient-->Edit Current**.

4.4 The Patient Information Page

The Patient Information Page is used to enter or modify patient demographic data. The following figure is an example:

Shenzhen Renmin Hospital

19/10/2016 16:35:47

Last Name First Name

ID Accession

DOB dd/mm/yyyy Age Year

Transducer Exam Preset

Gender

LMP GA EDD

G/P/A / / Fetus

Height cm Weight Kg BSA(m²)

BP / HR

PSA PPSA Coefficient

Study Description

CPT Code

Ref.Physician

Dx.Physician

Operator

Comments

Figure 4-2 Patient Information Page(OB Exam)

The top three lines are for entering the patient last name, first name, ID, exam accession number, and DOB (Date-of-Birth) or age. If a date of birth is entered the age is automatically calculated.

Note:

By default the patient name is two fields: family name and given name. It can be configured to be one field in the Patient Setup screen (See section 9.1.2 for detail).

The next line shows the current transducer, and the preset that will be used for the current exam. See section 8.3.1.2 for information on presets. The preset can be changed by clicking this drop-down and selecting one of the other presets associated with the current transducer.

The lines below the preset-selection vary depending on the current preset (see section 8.3.1.2 for detail). They show clinical information that is preset-specific.

- Gender: Select the patient's gender: "M" (Male), "F" (Female), "O" (Other), or "<blank>". "F" is default for gynecology, obstetric and breast exams; "M" is default for prostate

exam and testis exam; <blank> is default for others exam.

- LMP: Last Menstrual Period (yyyy/mm/dd), If LMP is entered then GA and EDD are calculated. Entering EDD does not impact LMP. An LMP more than 300 days ago is considered invalid.
- GA: Gestational Age (xxWyD), it is auto-calculated when LMP or EDD is entered (only in OB Exam). A GA of more than 42W6D is considered invalid and not displayed.
- EDD: Estimated Date of Delivery (yyyy/mm/dd). It is auto-calculated when LMP is entered..
- Fetus: Enter 1 up to 4, for multiple gestations.
- G/P/A: G stands for Gravida, P stands for Para and A stands for Aborta. Enter the times of them in the fields separated by slashes.
- Study Description: enter the study description.
- Height: Enter the patient's height. The units can be set in the Patient section of Setup.
- Weight: Enter the patient's weight. The units can be set in the Patient section of Setup.
- BSA: Body Surface Area, it is auto-calculated and displayed when Height/Weight is entered.
- HR: Enter the Heart Rate.
- BP: Enter the Blood Pressure.
- PSA: Prostate Specific Antigen.
- PPSA Coefficient: Predicted Prostate Specific Antigen.
- Ref. Physician: Enter the name of the Ref.Physician.
- Dx. Physician: Enter the name of the Dx.Physician.
- Operator: Enter the name of the person performing the exam. .
- CPT code: Current Procedural Terminology code.
- <Custom field 1>: Enter the user-defined data.
- <Custom field 2>: Enter the user-defined data.
- Comments: Enter any additional comments.

While the Patient Information Page is displayed the following touch screen controls are shown:

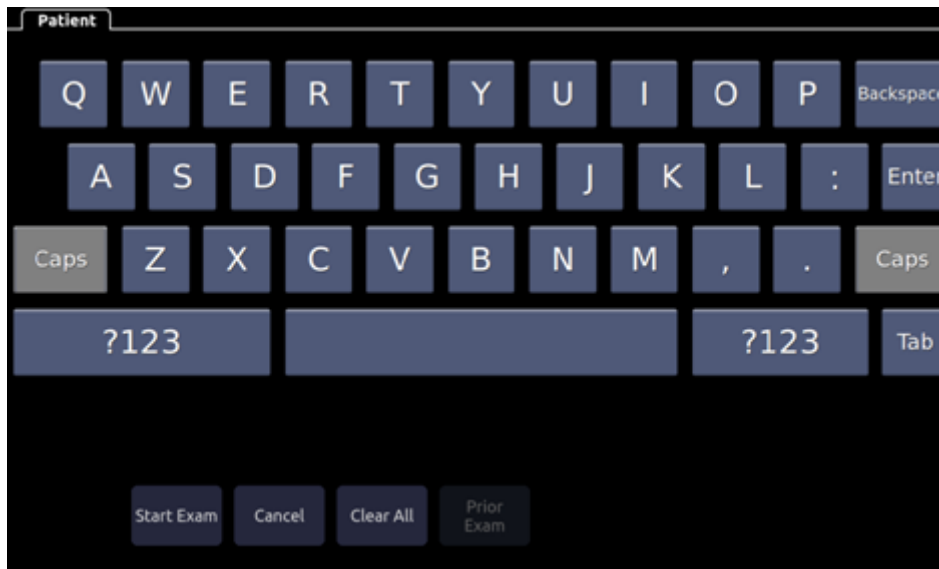


Figure 4-3 Patient Information Touch Screen

Press **Start Exam** to exit the Patient Page function and return to B-mode imaging with the newly entered demographic data entered for the active exam.

Press **Cancel** to exit the Patient Information Page without storing any of the entered data.

Press **Clear All** to clear all of the demographic fields except for name and ID.

Input LMP, and press **Prior Exam** to enable the entry of previous OB exam data for fetal trending details, it is only available when an OB preset is selected.

4.5 Modality Worklist

Modality worklist provides a list of scheduled patients derived from a DICOM server. It is available only when a DICOM server is configured and worklist is enabled.

When the modality worklist function is enabled and configured in **DICOM Connectivity** screen, the worklist is shown to the left of the Patient Information Page, as shown below.

Modality Worklist

Patient Name	ID
BEETHOVEN, LU...	BLV7346...
Chen, Xia	888
HAYDN, FRANZ J...	98765
Henderson, Rich...	6666666
Murphy, Sean	123456...
Olvera, Robbie	444444
Srinivasan, Sesh...	55555
Zhang, Renfu	777

03/06/2016 05:26:05

Patient Last Name: HAYDN First Name: FRANZ

ID: 98765 Accession: 00334

DOB: 14/09/1752 dd/mm/yyyy Age: 263 Year

Transducer: C5-2MQ Exam Preset: OB

Gender: M

LMP: 01/01/1900 GA: EDD: 01/01/1900

G/P/A: Fetus: 1

Study Description:

Ref.Physician: MILLER

Dx.Physician:

Sonographer:

Comments:

Update Hide List

Figure 4-4 Modality Worklist Display

The worklist is displayed at the left side of the Patient Information Page in two columns showing patient name and patient ID. Clicking on the header of each column will sort the list by the corresponding column.

The worklist shows all scheduled ultrasound exams within the date-range specified in the Connectivity Utility (See 9.2.2). Typing any text in the Patient Name or ID fields will filter the list to exams that contain the entered text.

Update: Press it to query the patient data and update the list manually.

Hide List: Press it to hide the list with only a **Show List** button displayed. Press the **Show List** button to display the list and other buttons.

Select one patient from the list and the detailed patient information is filled in the associated fields on the patient information page, allowing you edit or complete. Then press **Start Exam** on the touch screen to start an exam.

5 Imaging

The imaging modes are entered and exited via dedicated hard keys along the right side of the console.



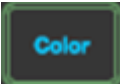

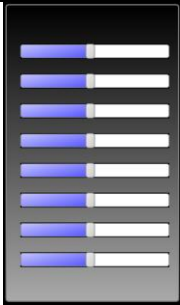

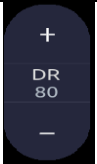
Key	Description
	The B-mode key behaves differently than the other mode keys. B-mode imaging is the baseline state of the system. Therefore, the B key returns to B-mode imaging at any time from any display on the system. See section 5.1 for B-mode controls.
	Invokes and exits strip Doppler mode. Press D button and press PW/CW on the touch screen to switch to CW mode (requires P5-1XQ transducer). See section 5.2/5.3 for Doppler controls.
	Invokes and exits color modes, including Color, Power Doppler Imaging (PDI) and Directional Power Doppler Imaging (DPDI). The default color mode is determined by the preset and can be changed while Color is active. See section 5.4 for Color controls.
	Invokes and exits M-mode. See section 5.5 for M-mode controls




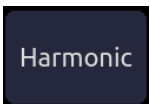




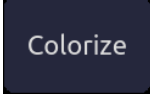


Table 5-1 Mode Control Hard Buttons




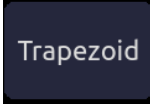
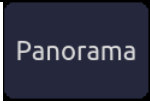
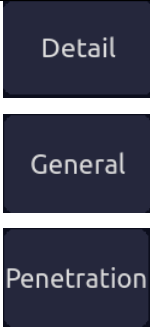




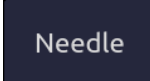
5.1 B-mode

5.1.1. B-mode Touch Screen Controls

The following touch screen controls impact the B-mode image. Touch screen controls can be located where you want them to be. See section 3.8 for details.

Name	Control	Description
TGC		The Time Gain Control (TGC) adjusts the gain of the image at different depths. Each slider can be adjusted separately, or you can drag your finger vertically to set all of the sliders to a new setting.
Auto		The Auto push button controls automatically updates the Gain and TGC. Each single press of the button renews the automatic optimization.
Dynamic Range		The Dynamic Range, or log compression, adjusts how echo intensities are converted to brightness. A high dynamic range presents a flat image, while a low dynamic range present a large range of intensities.

eSRI		eSRI is Speckle Reduction Imaging. There are 4 levels: Off, Low, Med. and High. High level provides more aggressive speckle reduction.
Persistence		Persistence averages frames together in order to reduce random noise. There are 4 options: Low, Med., High and Off. The persistence level corresponds to the number of frames averaged. The frame rate is unchanged; as each new frame is acquired it is averaged with the preceding frames.
Frequency		This determines the fundamental or harmonic (with harmonic invokes) frequencies used for imaging. It is available on live images.
Harmonic		The Harmonic control invokes and exits harmonic imaging. While in harmonic imaging the control is highlighted and 'H' in the B-mode frequency field. Depending on the transducer there may be multiple harmonic frequencies.
Spatial Compounding		Spatial Compounding combines images fired from multiple angles in order to reduce speckle, reduce shadow artifacts, and enhance contrast. Spatial compounding is an on/off control.
Foc. Num		Focus Number adjusts the number of focus positions. As the number of foci increases the frame rate will decrease, but there will be more image uniformity across depths.
Foc. Pos.		Focus Position adjusts the depth of the focus or foci. Upward presses move the focus shallower, regardless of the U/D invert status of the image.
Gray Map		Gray Map adjusts the post processing map used on the B-mode image. In general, higher map numbers correspond to more contrast in the image.
Colorize		The Colorize control adds a color tint to the B-mode image.
Tint		The Tint control changes the color tint being used. Gold, Sepia, Blue, Ice and Clear are available. If Colorize had been off, changing the Color map control will automatically activate it.
Left/Right		The Left/Right invert control is indicated by a backward R. It toggles the left/right orientation of the image. The Edan E orientation marker at the top of the image switches with the left/right invert to match the orientation marker on the transducer.

Up/Down		The Up/Down invert control is indicated by an upside-down R. It toggles the up/down orientation of the image. The TGC also swaps so the top of the TGC corresponds to the top of the image on the screen.
FOV		The Field of View control adjusts the image width. Full, Large, Med. and Small are available. As the image becomes narrower the frame rate increases.
Steer		This control is only available for linear transducers. It steers the B-mode image left or right, without moving the transducer. This can be particularly useful when visualizing needles or other objects that are enhanced by a perpendicular beam. (in Spatial Compounding, Trapezoid and Panorama states, steer function is not valid)
Trapezoid		The Trapezoid control activates the trapezoid imaging on linear transducer. It is a part of the B-mode function and available in live imaging.
Panorama		The Panorama control invokes the Panorama function. See section 5.1.4 for details.
Image Type		B-mode supports presets for Detail, General, and Penetration. See section 8.3.1.1 for more information.
Frame rate		Adjusts the tradeoff between frame rate and spatial resolution. Higher settings provide more temporal resolution.
Dual B		Press to activate dual imaging mode. Dual L activates the live image on the left side of image field, and Dual R activates the live image on the right side of image field.
Quad		Press to activate quad imaging mode. Refer to section 5.1.3 <i>Quad Imaging</i> for details.
3D/4D		Press to activate 3D/4D imaging mode. Refer to section 5.6 <i>3D/4D mode</i> for details.
Needle		Press to invoke the touch screen menu for Needle Enhancement Visualization and Needle Biopsy Guide functions. See section 7.5 and 7.6 for more information.

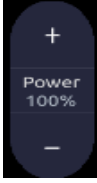
Acoustic power*		Adjusts the acoustic output power of the activated transducer. It is only available in live imaging. Higher acoustic power numbers correspond to more brightness and contrast in the image and more force of penetration, but the ALARA principle should be followed in actual situations.
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Table 5-2 B-mode Touch Screen Controls

5.1.2. Dual Imaging

Dual Imaging displays images side by side on the screen. During real-time imaging when Dual imaging is enabled, the active image is displayed in real-time and the other image is frozen.

Press the **Dual L** or **Dual R** button on the B-mode touch screen to select the left or right image for activation. With both images frozen, press the **Dual L** or **Dual R** button to toggle between the images.

Dual Exit

Dual is exited by any of the following:

- Pressing the Dual button corresponding to the currently active side.
- Pressing the Quad button.
- Pressing the B, M, D hard key.
- Pressing the 3D/4D button.
- Transducer change, preset recall, or new exam.

Color Doppler is available during dual imaging.

5.1.3. Quad Imaging

Quad Imaging displays images in four quadrants on the screen. During real-time imaging when Quad imaging is enabled, the active image is displayed in real-time and other images are frozen.

Quad imaging is invoked by pressing **Quad** button on the B-mode touch screen. **Quad** button is a one-shot button. Each single press on it during real-time imaging activates one of the four images in an order from the top left one to the top right one, then to the bottom left one and to the bottom right one. Each single press on it during frozen status switches among the four images in an order described above but does not change the frozen status of the system.

Quad Exit

Quad is exited by any of the following:

- Pressing the B, M, D hard key.
- Pressing the Dual button
- Pressing the 3D/4D button
- Transducer change, preset recall, or new exam.

Color Doppler is available during Quad imaging.

5.1.4. Panorama

Panorama constructs an extended field of view image as the transducer slides along its long axis.

Panorama is available in live B-mode imaging. To acquire a panoramic image:

- Press the **Panorama** button on the B-mode touch screen.
- Press the **Set** button on the trackpad to start acquisition.
- Slide the transducer along the long axis

The B-mode image will extend to incorporate the newly imaged anatomy.

- When the full anatomy has been acquired, press the **Enter** button on the trackpad or press the **Freeze** hard key. System also will enter the panorama review state when exceeding the default time.

After acquisition the completed Panoramic image is redisplayed to fit on the screen. Measurements*, Comments and Bodymarkers are then supported.

Note:

1. If a measurement function in panorama mode is activated, the caution information of “The accuracy of measurements in Panorama is limited and can be lower than measurements in B-image” in yellow font color appears on the bottom of the image and a caution symbol appears on the head of the measurement results.
2. IMT measurement is not available on panorama image.

Panorama is available only with linear transducers.

Speed Indicator

During an acquisition, a speed indicator bar on the screen will show the current scan speed. Keep the indicator in the green center of the graphic in order to achieve best results.



Figure 5-1 Panorama Speed Indicator

5.1.5. Zoom

Zoom is available in live or frozen B-mode and Color imaging. Press the **Zoom** hard key to zoom an image. There are 2 ways to zoom an image: The **Zoom** paddle key or a pinch-out gesture on the track pad.

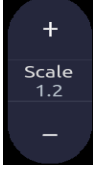
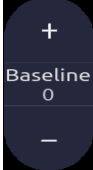
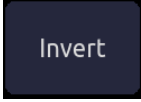
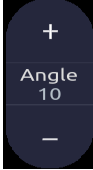
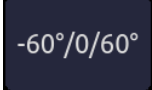
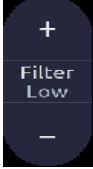
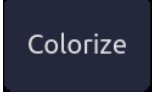

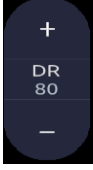
- **Zoom** Paddle key
 - Press the upper part of the **Zoom** paddle to make the image bigger.
 - Press the lower part of the **Zoom** paddle to make the image smaller, down to normal size.
- Pinch Gesture: Use two fingers on the main part of the trackpad, and move the two fingers outward from each other (“Pinch-out”). The image will enlarge.




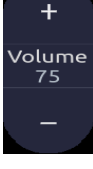

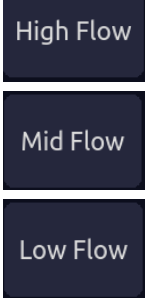

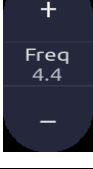

When in **Zoom** mode, use the trackpad to pan the position of zoomed image. The B image remains zoomed after entering other imaging modes.

5.2 PW-mode

5.2.1. PW Touch Screen Controls

The following touch screen controls impact the PW image. Touch screen controls can be located where you want them to be. See section 3.8 for details.

Name	Control	Description
Scale		Scale adjusts the range of velocities that are displayed. Upward presses increase scale and downward presses decrease it. Increasing scale when the PW cursor is relatively deep may result in invoking HPRF, if it is configured. See section 5.2.2 for details.
Baseline		The Baseline control adjusts the Doppler baseline. Upward presses move the baseline up on the screen and downward presses move the baseline down.
Invert		Normally signals above the baseline are positive velocities (moving toward the transducers). However, when Invert is pressed then negative velocities are above the baseline. Invert does not affect the baseline position.
Angle Correct		Adjust the Doppler scale to account for the angle between the Doppler cursor and the blood flow. Upward presses increment the angle. Downward presses decrement the angle. Angles above 80 are not allowed.
Quick-Angle		Adjusts the angle correct quickly to one of 60/0/-60.
Filter		The Filter control removes excessive noise from movement of vessel walls. Options of Low, Med. and High are available.
Colorize		Switches between grayscale and colorized (pseudo-color) postprocessing maps.
Gray Map Tint		Adjusts the current postprocessing, either grayscale or tinted
Dynamic Range		The Dynamic Range, or log compression, adjusts how signal intensities are converted to brightness. A high dynamic range presents a flat spectrum, while a low dynamic range presents a large range of spectrum brightness.

<p>SV Size/Gate Size</p>		<p>Gate adjusts the size of the sample volume gate. Upward presses increase the gate size. Downward presses decrease the gate size.</p>
<p>Sweep Speed</p>		<p>Sweep adjusts the sweep speed of the Doppler strip. Options of Slow, Low, Med., High and Fast are available. Upward presses increase sweep speed. Downward presses decrease sweep speed.</p>
<p>Strip Size</p>		<p>Format changes the relative size of the Doppler strip compared to the reference image. Full, Large, Med. and Small are available.</p>
<p>Volume</p>		<p>Volume adjusts the audio volume of the Doppler strip. This can be adjusted in pre-Doppler to set the initial volume upon invoking Doppler acquisition.</p>
<p>Duplex (Triplex)</p>		<p>This determines if the strip mode and reference image are imaging simultaneously or not. If the reference image is B-mode this is labeled "Duplex". If the reference image includes color this is labeled "Triplex".</p>
<p>Image Type</p>		<p>Strip Doppler supports image presets for Low Flow, Medium Flow, and High Flow.</p>
<p>Steer</p>		<p>This control is only available for linear transducers. It steers the Doppler cursor angle left or right.</p>
<p>Frequency</p>		<p>This determines the Doppler transmit frequency used for imaging.</p>
<p>Auto Trace</p>		<p>Press to activate the Auto Trace function on a real-time or frozen PW Doppler strip. The Auto Trace function automatically traces the spectral Doppler waveform and records several measurements on selected general imaging. See section 7.3.1 for details.</p>


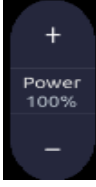

Auto Trace Direction		Press to specify which side of the Doppler baseline to take measurements from. there are 3 options: Up: traces positive portion of waveform (above baseline). Down: traces negative portion of waveform (below baseline). Both: traces waveform on both sides of baseline.
Acoustic power*		Adjusts the acoustic output power of the activated transducer. It is only available in live imaging. Higher acoustic power numbers correspond to more brightness and contrast in the image and more force of penetration, but ALARA principle should be followed in actual situations.
Auto Optimization*		The Auto push button automatically updates the PW gain, DR, baseline and PRF scale. Each single press of the button renews the automatic optimization. Whether Gain, DR or Scale/Baseline is optimized when pressing Auto button can be configured in Set-up. See section 9.1.4 for detail.

Table 5-3 PW Mode Touch Screen Controls

5.2.2. HPRF

Conventional PW Doppler scales are limited by the Nyquist limit. High Pulse Repetition Frequency (HPRF) allows the system to exceed the Nyquist limit by having multiple Doppler pulses in the body at the same time. In HPRF imaging multiple Doppler gates are displayed, since the multiple Doppler pulses could be giving information from different depths. HPRF is automatically invoked when needed to maintain the requested depth and scale. For example, if the system is at a high scale and you move the cursor deeper the system may automatically invoke HPRF. This can also happen if the cursor is deep and you increase scale.

If HPRF is active you will see multiple Doppler gates on the reference image. If you do not want to be in HPRF, decrease the scale or move the cursor to a more shallow location until only one gate is displayed.

5.2.3. Update

The **Update** hard key toggles between acquiring Doppler strip and acquiring the reference image.



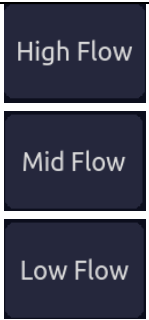
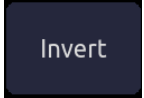

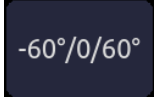
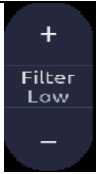
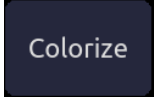

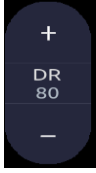
5.3 CW-mode

Depending on system configuration, CW may be available on the P5-1XQ transducer. There are two ways to invoke CW:

- Press the CW button on the Doppler touchscreen to switch between PW and CW modes.
- Configure the F1 or F2 programmable hardkey to invoke CW directly (see section 9.1 for details).

5.3.1. CW Touch Screen Controls

The following touch screen controls impact the CW image. Touch screen controls can be located where you want them to be. See section 3.8 for details.

Name	Control	Description
Scale		Scale adjusts the range of velocities that are displayed. Upward presses increase scale and downward presses decrease it.
Baseline		The Baseline control adjusts the Doppler baseline. Upward presses move the baseline up on the screen and downward presses move the baseline down.
Image Type		Strip Doppler supports image presets for Low Flow, Medium Flow, and High Flow.
Invert		Normally signals above the baseline are positive velocities (moving toward the transducers). However, when Invert is pressed then negative velocities are above the baseline. Invert does not affect the baseline position.
Angle Correct		Adjust the Doppler scale to account for the angle between the Doppler cursor and the blood flow. Upward presses increment the angle. Downward presses decrement the angle. Angles above 80 are not allowed.
Quick-Angle		Adjusts the angle correct quickly to one of 60/0/-60.
Filter		The Filter control removes excessive noise from movement of vessel walls. Options of Low, Med. and High are available.
Colorize		Switches between grayscale and tinted (pseudo-color) postprocessing maps.
Gray Tint Map		Adjusts the current postprocessing, either grayscale or tinted.
Dynamic Range		The Dynamic Range, or log compression, adjusts how signal intensities are converted to brightness. A high dynamic range presents a flat spectrum, while a low dynamic range presents a large range of spectrum brightness.


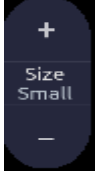

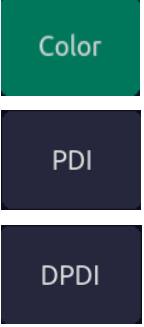

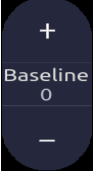
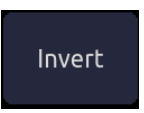
Sweep Speed		Sweep adjusts the sweep speed of the Doppler strip. Options of Slow, Low, Med., High and Fast are available. Upward presses increase sweep speed. Downward presses decrease sweep speed.
Strip Size		Format changes the relative size of the Doppler strip compared to the reference image. Full, Large, Med. and Small are available.
Volume		Volume adjusts the audio volume of the Doppler strip. This can be adjusted in pre-Doppler to set the initial volume upon invoking Doppler acquisition.

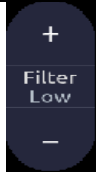
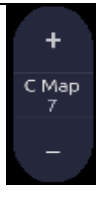
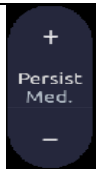
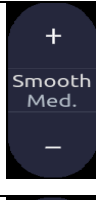
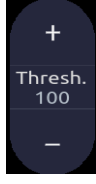
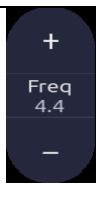

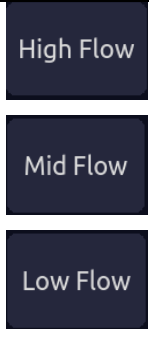

Table 5-4 CW Mode Touch Screen Controls

5.4 Color-mode

5.4.1. Color Touch Screen Controls

The following touch screen controls impact the color image. Touch screen controls can be located where you want them to be. See section 3.8 for details.

Name	Control	Description
Color Mode Variation		A set of radio-buttons display the color modes that are available on the current transducer, and let you switch between them. See section 5.4.2 for details.
Scale		Scale adjusts the range of velocities that are displayed. Upward presses increase scale and downward presses decrease it. It is available in Velocity, PDI, and DPDI. It is not available in Freeze/Cine.
Baseline		The Baseline control adjusts the Color baseline. Upward presses move the baseline up on the scale and downward presses move the baseline down. Baseline is not available in PDI mode.
Invert		Normally signals above the baseline are positive velocities (moving toward the transducers). However, when Invert is pressed then negative velocities are above the baseline. Invert does not affect the baseline position. Invert is not available in PDI mode.

Wall Filter		<p>The Filter control removes excessive noise from movement of vessel walls. Options of Low, Med. and High are available.</p>
Map		<p>Adjusts the current map for the active color variation.</p>
Persist		<p>Persistence determines the number of frames that are averaged together for display. Levels of Off, Low, Med. and High are available.</p>
Smooth Filter		<p>The smoothness filter determines the spatial filtering that is applied to the Color image. Higher filter levels create a smoother image. Upward presses increase the filter. Downward presses decrease the filter.</p>
Threshold		<p>When the system receives both B-mode and CD signal from a region the threshold determines whether to display that as grayscale or color. Higher values mean a stronger CD signal is needed to display it in color. Upward presses increase threshold. Downward presses decrease threshold.</p>
Frequency		<p>Frequency determines the transmit frequency used by color Doppler. Upward presses increase the frequency. Downward presses decrease the frequency.</p>
Steer		<p>This control is only available for linear transducers. It steers the Color ROI box angle left or right.</p>
Image Type		<p>Color Doppler supports image presets for Low Flow, Medium Flow, and High Flow.</p>
Dual Live		<p>To activate split screen with simultaneous live B/Color and live B. the live B image without color and the same live B image with color are simultaneously displayed on each side of the image field.</p> <p>Freezing the image will freeze both sides simultaneously.</p> <p>Cine review will review both sides simultaneously.</p>

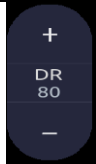
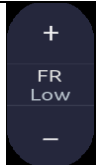
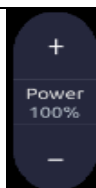
Dynamic Range		The Dynamic Range, or log compression, adjusts how echo intensities are converted to brightness. A high dynamic range presents a flat image, while a low dynamic range present a large range of intensities. Only available in PDI/DPDI mode.
Frame rate		Adjusts the tradeoff between frame rate and spatial resolution. Higher settings provide more temporal resolution.
Acoustic power*		Adjusts the acoustic output power of the activated transducer. It is only available in live imaging. Higher acoustic power numbers correspond to more brightness and contrast in the image and more force of penetration, but ALARA principle should be followed in actual situations.

Table 5-5 Color Mode Touch Screen Controls

5.4.2. Color Mode Variants

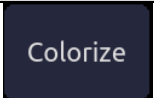

The Acclarix AX8 system supports 3 types of Color Doppler imaging:

- Color (Color Doppler): This is velocity Color Doppler that shows direction and velocity of flow. Different colors represent different velocities, and positive flow has different colors than negative flow.
- PDI (Power Doppler Imaging): PDI shows the power, or intensity, of the Doppler signal. PDI is typically more sensitive to low levels of flow, but can not distinguish the velocity or direction of the flow.
- DPDI (Directional Power Doppler Imaging): This is similar to DPI in that it shows the power of the Doppler signal instead of the velocity. However, it does map positive flow to different colors than negative flow.

5.5 M-mode

5.5.1. M-mode Touch Screen Controls

The following touch screen controls impact the M-mode image. Touch screen controls can be located where you want them to be. See section 3.8 for details.

Name	Control	Description
Colorize		Switches between grayscale and colorized (pseudo-color) postprocessing maps.
Gray Map Tint		Adjusts the current postprocessing, either grayscale or tinted.

Dynamic Range		The Dynamic Range, or log compression, adjusts how signal intensities are converted to brightness. A high dynamic range presents a flat spectrum, while a low dynamic range presents a large range of spectrum brightness.
Focus Pos		The focus position set in B-mode applies to M-mode as well. Upward presses move the focus shallower, regardless of the U/D invert status of the M-mode. Downward presses move the focus deeper.
Sweep Speed		Sweep adjusts the sweep speed of the M-mode strip. Options of Slow, Low, Med High and Fast are available. Upward presses increase sweep speed. Downward presses decrease sweep speed.
Strip Size		Format changes the relative size of the M-mode strip compared to the reference image. Full, large, Med and small are available.
Side-by-side		This is an on/off control. When On, the M-Mode strip is side-by-side with the B-mode image. When Off, the M-Mode strip is below the B-mode image
Line Persistence		The line Persistence determines how many M-mode lines are averaged together for the display, similar to persistence in B-Mode. Levels of Off, Low, Med and High are available.
Frequency		Frequency determines the transmit frequency used by M-Mode. Upward presses increase the frequency. Downward presses decrease the frequency.
Acoustic power*		Adjusts the acoustic output power of the activated transducer. It is only available in live imaging. Higher acoustic power numbers correspond to more brightness and contrast in the image and more force of penetration, but ALARA principle should be followed in actual situations.

Table 5-6 M-Mode Touch Screen Controls

5.6 3D/4D Mode*

Depending on the system configuration and regulatory approval, 3D/4D may be available on the C5-2MQ* transducer. The first step in using 3D or 4D is to activate pre-3D mode. There are two ways to activate pre-3D mode:

1. Press the 3D/4D button on the touch screen in B-mode.
2. Configure the **F1** or **F2** hard key to invoke 3D/4D. There are two options to do so, one labeled '3D' and the other '4D'. These both invoke pre-3D, but with different defaults for 3D

and 4D.

NOTE: Measurement function is not available in 3D/4D.

5.6.1. Pre-3D

The Pre-3D mode supports defining the 3D/4D acquisition location and settings.

Figure 5-2 shows an example of the pre-3D image. The ROI (Region of Interest) indicates the portion of the image that will be used for 3D/4D. The position/size of the ROI can be adjusted using the trackpad and **Set** key. Also note that there is a horizontal line going across the ROI near the top and it can be adjusted to a curved line upwards and downwards by using the trackpad. This is the clip plane. The initial volume rendering will show everything below this line.

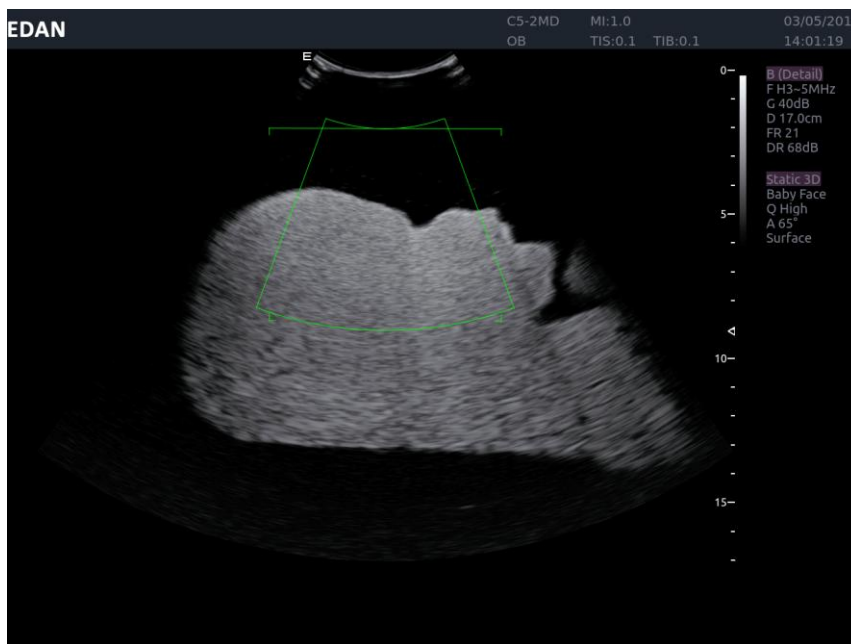





Figure 5-2 Pre-3D Image

The touch screen controls in pre 3D interface:

Name	Control	Description
Image quality		Adjusts the trade-off between speed and quality of the acquisition. Settings include High (quality), Medium, and Fast.
Angle		Adjusts the angle of the volume acquisition. Upward presses increment the angle. Downward presses decrement the angle. Angle range is from 5° to 70° in increments of 5°.
Baby Spine/ Baby Face		These two radio buttons determine if the acquisition is optimized for looking at a Baby Spine (Maximum Intensity Projection), or a Baby Face (Surface Render). Thresh (only in surface render mode), bright and contrast will be adjusted




		automatically.
3D/4D		These two radio buttons determine if the acquisition will be 3D or 4D.
Start		Start an acquisition. If 3D was highlighted then a single volume is acquired. If 4D was highlighted then continuous acquisitions are started.
Exit		Exit 3D/4D

Table 5-7 Pre-3D Touch Screen

5.6.2. 3D Volume Sweeping

During the process of 3D volume sweeping, the images swept in ROI box are displayed in the image area.

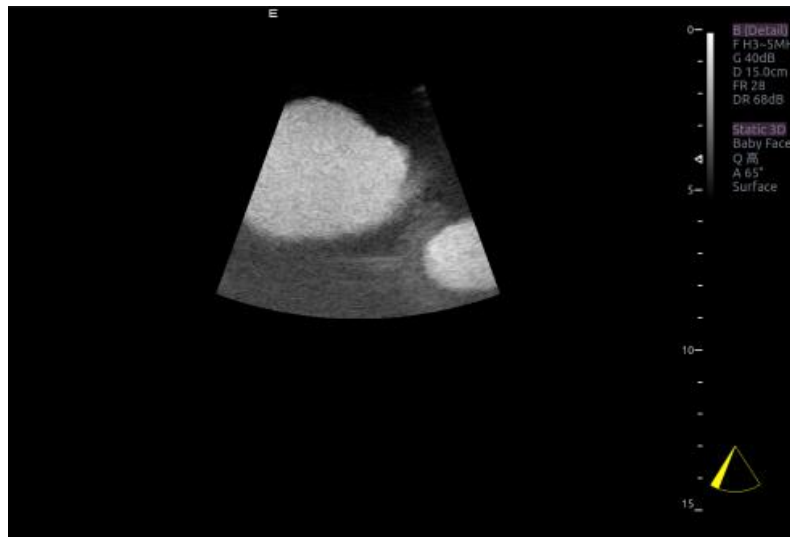



Figure 5-3 3D Image Scanning

While scanning, the sector  in the right bottom is filled gradually, and no buttons on the control panel and touch screen can be activated.

5.6.3. 3D Image Review

If 3D was selected, then the system will enter to the 3D review status after finishing one sweep.

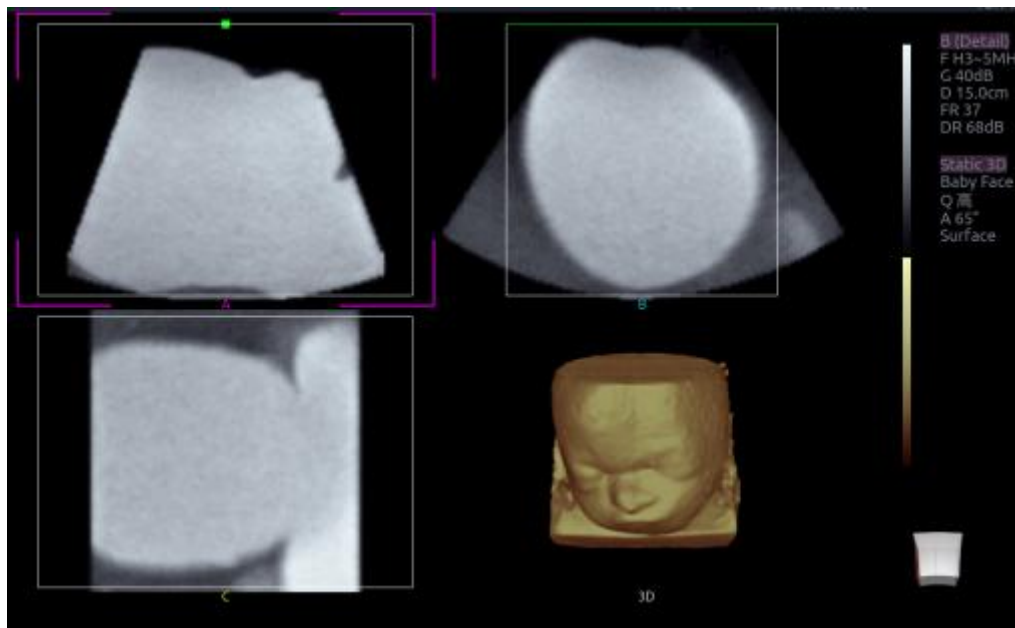


Figure 5-4 3D Image Review





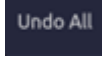
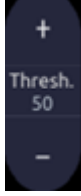
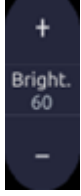


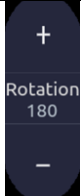
- There are two image modes: Volume imaging mode and multi-slice imaging mode. Figure 5-4 shows Volume Imaging Mode in quad screen with a Baby Face volume rendering.
- Quadrant A shows a slice through the data that mimics the original ultrasound image.
- Quadrant B is orthogonal to A, as if the transducer had been rotated 90 degrees.
- Quadrant C is orthogonal to A and B, showing a slice that is parallel to the transducer face.



The icon at the bottom-right shows the position of each slice with respect to the full 3D data set.

The following table shows the controls that are available in Volume Imaging Mode

Name	Control	Description
Volume	<input type="radio"/> Volume <input checked="" type="radio"/> Multi-Slice	These two radio buttons toggle between the Volume display and the Multi-Slice display.
A/B/C/3D	<input type="radio"/> A <input type="radio"/> B <input type="radio"/> C <input type="radio"/> 3D	These four radio buttons select which quadrant is the focus of the navigation/panning controls. A/B/C are three orthogonal slices through the volume, while '3D' is the rendered image.
Single, Dual, Quad	<input type="radio"/> Single <input type="radio"/> Dual <input checked="" type="radio"/> Quad	These three radio buttons switch the display to show 1, 2, or 4 images at once. Single shows the 3D image, dual shows the A slice and 3D image, Quad shows three MPR slices and 3D image.
Reset	<input type="button"/> Reset	Reset the operation of pan, rotate and zoom to the initial condition.
Pan	<input type="button"/> Pan	Pan image along the x-axis or y-axis of the activated window. Use the trackpad to pan image along x-axis and

		y-axis.
VOI		Press to activate the function of adjusting VOI or clip plane. Use the trackpad to adjust and press Set to switch between VOI and clip plane.
Cut		Function of cut. After activating this button, the 3D image is selected, press Set to locate the start point, use trackpad to trace and second press Set to locate the end point The region within these two points will be cut. The system will draw a straight line between the start and end point to enclose the cut region.
Undo		Undo the previous cut operation
Redo		Redo the previous undo operation
Undo All		Return to the condition before cutting
Threshold		Adjust the threshold of surface render mode, Upward presses increase threshold. Downward presses decrease threshold.
Bright.		Adjust the bright of 3D image
Contrast		Adjust the contrast of 3D image.
3D Smooth/ MPR Smooth		Adjust smoothness of A\B\C slices and 3D images. Higher filter levels create a smoother image. Upward presses increase the filter. Downward presses decrease the filter.
Rotation		Quickly rotate the image. Available angles are: 0° /90° /180 ° /270° .

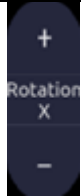

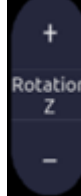



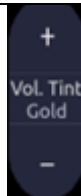

Rotation X		Rotate the image by the X-axis of the activated window.
Rotation Y		Rotate the image by the Y-axis of the activated window.
Rotation Z		Rotate the image by the Z-axis of the activated window.
New Volume		End the 3D volume sweeping and return to the pre-3D interface
Exit		Exit 3D/4D
MPR Review		MPR (multi-planar reconstruction) review function. After this button is activated, the 3D image is hidden, two perpendicular lines appear on the selected quadrant. These two lines are color matched with the other 2 MPR quadrants, and show where the three planes intersect. Left/right trackpad movement moves one of these lines while up/down moves the other line.
3D Tint		Select 3D tint, options of Clear, Candle, Copper, Sepia, Gold.
MPR Tint		Select MPR tint, options of Gold, Sepia, Blue, Ice and Clear are available.

Table 5-8 Volume imaging Mode Touch Screen

Image area and touch screen controls in multi-slice imaging mode:

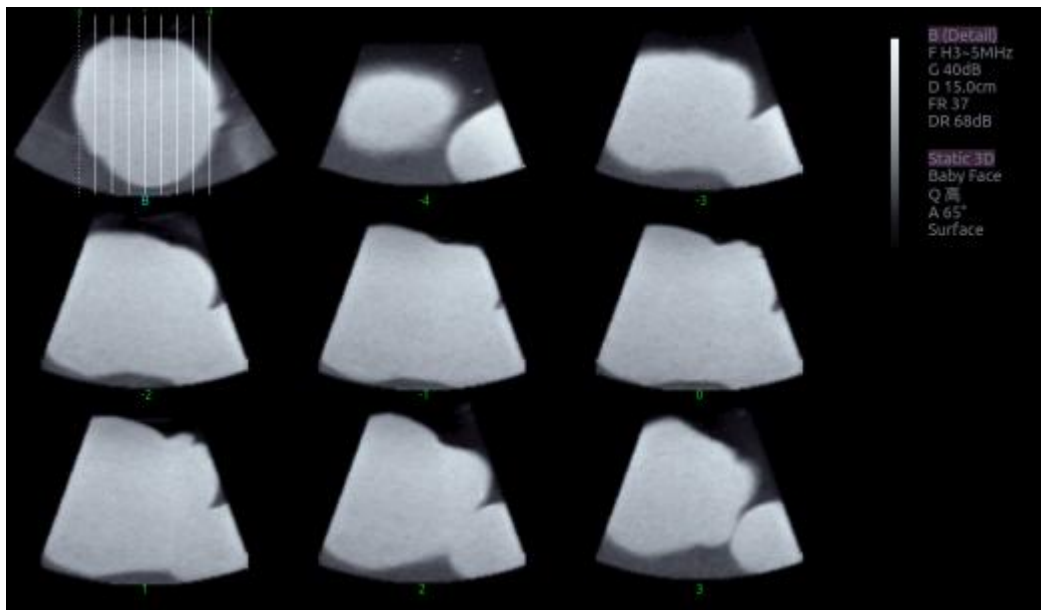


Figure 5-5 Multi-slice Imaging Mode

In figure 5-5, the first image shows the basis slice, other images are orthogonal to the basis slice and parallel to each other. Lines on the basis slice indicate the locations of the parallel slices. If there are more slices than images then the un-displayed slices are shown with a dotted line. A number below each parallel slice shows the slice location in the basis slice, with 0 being the middle slice.

Control	Name	Description
A/B/C	<input type="radio"/> A <input type="radio"/> B <input type="radio"/> C	These three radio buttons determine which slice is the required parallel slice. These three choices are the same as on the Volume display in quad mode.
3*3, 2*2, 3*2	<input type="radio"/> 3*3 <input type="radio"/> 3*2 <input type="radio"/> 2*2	These three radio buttons determine the layout of the display.
Pan	<input type="button" value="Pan"/>	Pan the basis slice along the x-axis or y-axis of the activated window. Use the trackpad to pan the basis slice along x-axis y-axis. Parallel slices change with the pan operation.
Reset	<input type="button" value="Reset"/>	Reset the operation of pan, rotate and zoom to the initial condition.
Number	<input type="button" value="+"/> Number 3 <input type="button" value="-"/>	Select how many slices to use


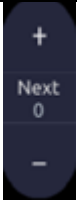

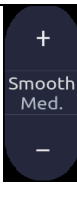
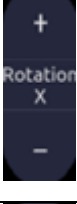


Distance		Adjust the distance between slices.
Next		When there are more slices than can be displayed at once this control cycles through the subset of slices displayed.
Tint		Select multi-slice tint, options of Gold, Sepia, Blue, Ice and Clear are available.
Smooth		Adjust smoothness of A\B\C slices. Higher filter levels create a smoother image. Upward presses increase the filter. Downward presses decrease the filter.
Rotation X		Rotate the basis slice by the X-axis of the activated window. Parallel slices change with the rotation operation.
Rotation Y		Rotate the basis slice by the Y-axis of the activated window. Parallel slices change with the rotation operation.
Rotation Z		Rotate the basis slice by the Z-axis of the activated window. Parallel slices change with the rotation operation.

Table 5-9 Multi-slice Mode Touch Screen

5.6.4. 4D Volume Acquisition

Press 3D/4D button on the touch screen in B-mode to enter pre-3D, select 4D, select **Baby Spine** or **Baby Face** fist and use the ROI box to set the region. Only ROI will be stored during the volume sweep. Use the trackpad to set the size and location of the ROI box. Press **Set** to confirm. Use the trackpad to set the edge of VOI (Volume of interest) and press **Start** button on the touch screen or the **Enter** button on the trackpad to begin sweep.

5.6.5. 4D Live Volume

4D Live volume continuously sweeps and displays successive 3D volumes. During live 4D imaging the following controls are available: activate any window of A/B/C/3D, Single/Dual/Quad, VOI, Threshold, Bright, Contrast, 3D Smooth/ MPR Smooth, 3D Tint/ MPR Tint, Rotation, Rotation X, Rotation Y, Rotation Z, Zoom and Gain in B mode.

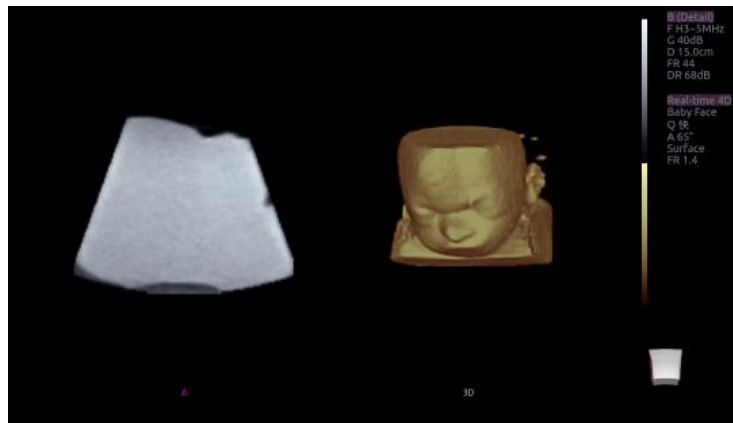


Figure 5-6 4D Volume Sweeping Image

As shown in figure above, image in the left is A slice and image in the right is the live 4D volume rendering.

5.6.6. 4D Cine

During the process of 4D live volume imaging; press the **Freeze** button on the control panel to enter the 4D cine mode. A cine replay scroll bar appears below the images. Use the trackpad to replay the reset 3D images. For the selected frame, user can execute all operations that are available 3D review status. Press **Freeze** again to return to the live image.

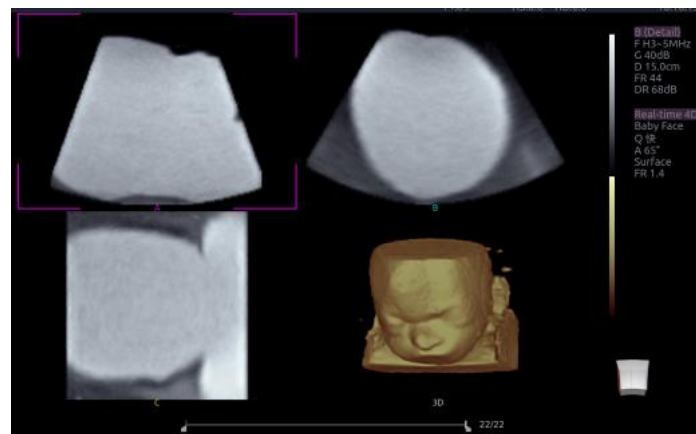


Figure 5-7 4D Cine

Touch screen controls are the same as that of static 3D except for Cine button.


Name	Control	Description
cine		Switch between 3D and 4D review state

Table 5-10 4D Touch Screen

6 Transducers

6.1 Transducer Model

No.	Model	Type	Application
1	C5-2XQ/ C5-2Q	Convex	Abdomen Fetal / Obstetrics Urology Gynecology Musculo-skeletal Nerve
2	E8-4Q	Endocavity	Fetal / Obstetrics Endo-vaginal Endo-rectal : Urology
3	L10-4Q	Linear	Small Parts (Thyroid, Testes, Breast) Peripheral Vascular Musculo-skeletal Neurology
4	L12-5Q	Linear	Small parts (Thyroid, Testes, Breast) Vascular Musculoskeletal Neurology
5	L17-7HQ	Linear	Small Parts (Thyroid, Testes, Breast) Peripheral Vascular Musculo-skeletal Neurology
6	L17-7SQ	Linear	Intra-operative Musculo-skeletal Nerve Vascular
7	MC8-4Q	Micro Convex	Pediatric Neonatal (including abdominal and cephalic) Neurology Vascular
8	P5-1XQ	Phase array	Adult Cardiac Abdomen Pediatric Cardiac Adult cephalic*
9	C5-2MQ*	Convex	Fetal / Obstetrics

Table 6-1 Transducer Model & Application

6.2 Name and Function of Each Part of the Transducer

Figure 6-1 shows an example of a transducer.

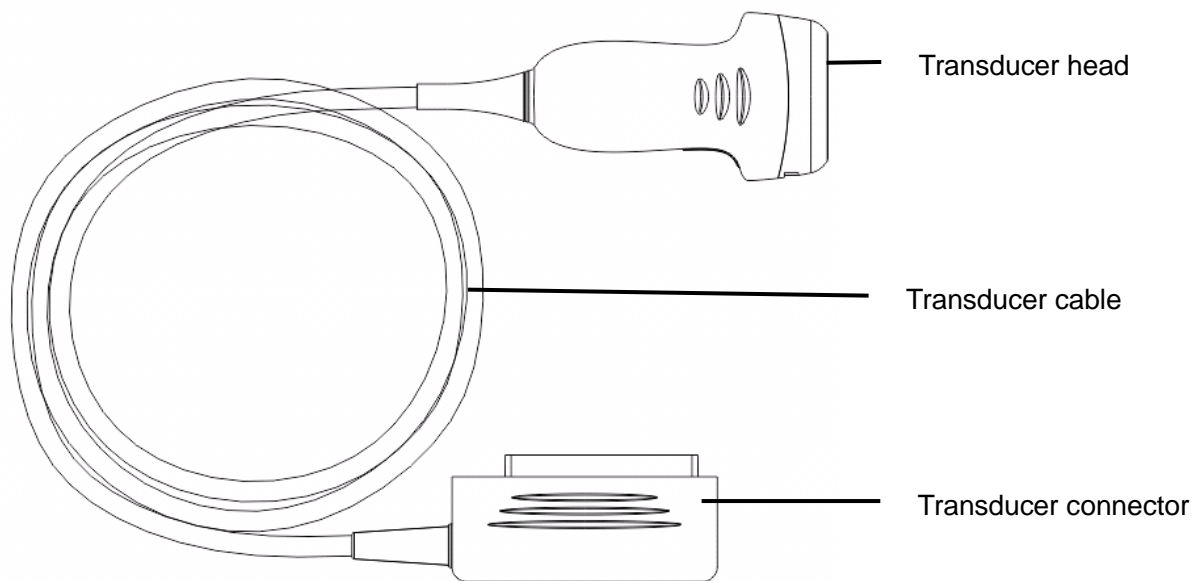


Figure 6-1 Typical transducer

Name	Function
Transducer head	Converts electrical signals to sound waves, and then converts received echoes back to electrical signals. The tip of the transducer is the acoustic lens.
Transducer cable	Transmits electrical signals between the transducer head and the transducer connector.
Transducer connector	Connects the transducer to the ultrasonic diagnostic system

6.3 Transducer Cleaning and Disinfecting

Transducers should be cleaned and/or disinfected as necessary or between use with a recommended cleanser or disinfectant. Disconnect the transducer from the system prior to cleaning and disinfecting.

The validated cleaning agents for cleaning the transducers are:

- Mild near neutral detergent
- Ethanol (75%)
- Isopropanol (70%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

The validated disinfectants for transducer are:

- Ethanol (75%)

- Isopropanol (70%)
- OPA (0.55%)

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required for the disinfection step.

WARNING

1. Unplug the transducer from the system prior to cleaning or disinfecting.
 2. To avoid infection, always use protective gloves when performing cleaning and disinfecting procedures.
 3. To avoid infection, ensure that expiration date of the disinfecting solution has not passed.
-
-

To clean the transducers:

1. Disconnect the transducer from the system.
2. Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
4. Wipe off with a dry cloth to remove residual moisture.
5. Leave the transducer to air dry.

NOTE: A single-use sheath should be used on E8-4Q transducer. Before cleaning the transducer, remove the sheath gently and discard it. Put on a new single-use sheath before using the transducer.

CAUTION

1. Always wear gloves to perform the following steps.
 2. To minimize the disease transmission, use of legally marketed, sterile transducer and sheath is strongly recommended for intra-cavitary and intra-operative procedures. Legally marketed, sterile, pyrogen free transducer sheath is required to use for neurological intra-operative procedures.
 3. **DO NOT** use an expired transducer sheath. Check whether the term of validity has expired prior to using transducer sheaths.
 4. The single-use sheath should comply with the local regulations.
-
-

To install transducer sheath:

1. Place an adequate amount of sterile coupling gel on the acoustic window of the transducer;
2. Insert the transducer into the sheath;
3. Pull the sheath over the transducer and cable until the sheath is fully extended;
4. Secure the sheath using the bands or clips supplied with the sheath;
5. Check and eliminate bubbles between the face of the transducer and the sheath. Bubbles between the face of transducer and the sheath may affect the ultrasound imaging.
6. Inspect the sheath to ensure that there are no damages (i.e. holes or tears).

There are two methods to disinfect the transducer (use the immersion method for the E8-4Q and L17-7SQ):

Non-immersion:

1. Disconnect the transducer from the system.
2. Prepare the disinfectant solution (75% ethanol or 70% isopropanol).
3. Spray the solution to the transducer interface or wipe it with a soft cloth dampened with the disinfectant solution.
4. Rinse the transducer according to the disinfectant instructions. Wipe the transducer with a dry cloth or leave the transducer to air dry.
5. Inspect the transducer to ensure that there is no damage.

Immersion:

1. Prepare the disinfectant solution (Cidex OPA)
2. Place the cleaned and dried transducer in contact with the disinfectant (refers to figure 6-2 for the contacting area) for the time specified by the disinfectant manufacturer.
3. Rinse the transducer according to the disinfectant instructions. Wipe the transducer with a dry cloth or leave the transducer to air dry.
4. Inspect the transducer to ensure that there is no damage.

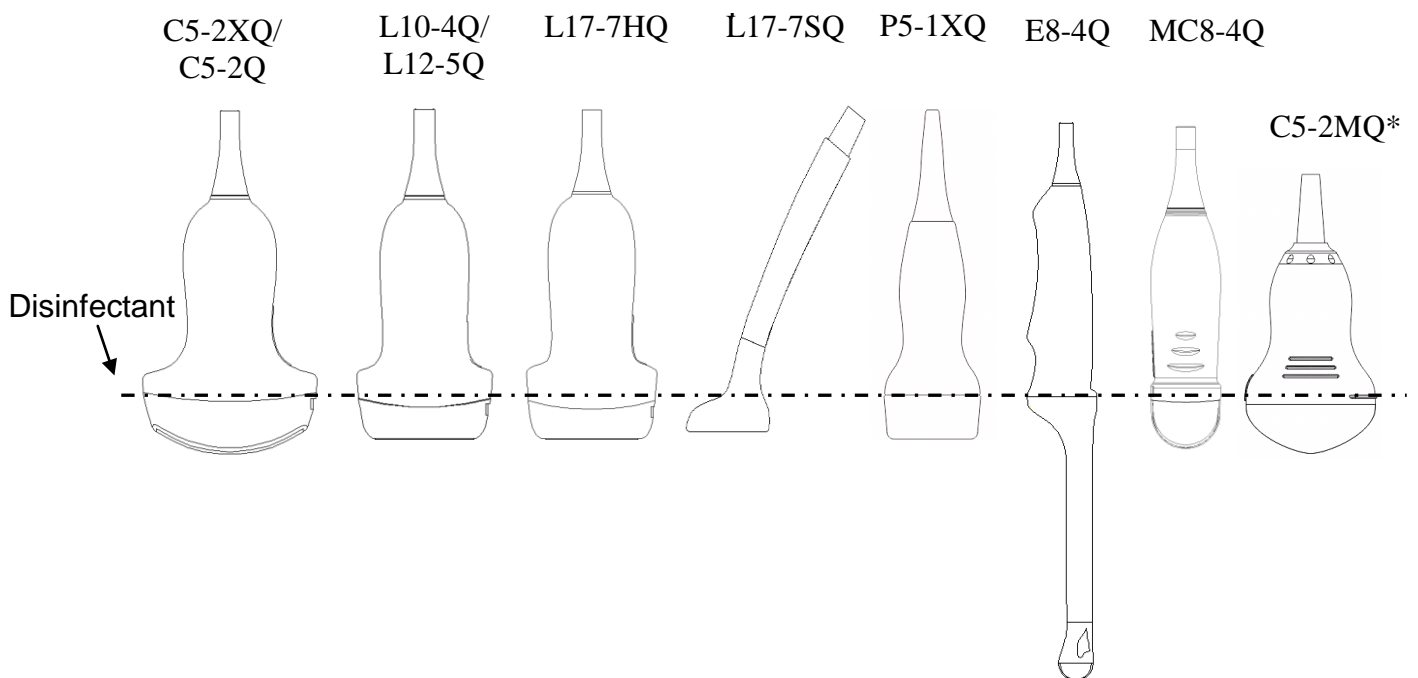


Figure 6-2 Depth of the Transducer Immersed into Disinfectant

WARNING

1. Do not immerse the transducer connector. If the cable connector is immersed, do not plug the connector into the system. Rinse the connector under running water and dry it thoroughly. If necessary, contact EDAN for service.

2. Prohibit infiltration of any type of liquid into the device or the transducer.
3. Do not sterilize the transducer using techniques such as autoclave, ultraviolet, gamma radiation, gas, steam, or heat. Severe damage May result.
4. Use only ultrasound coupling gel that complies with local regulations.
5. Do not immerse the AC adapter and connector of the transducer into solutions. Transducers can be submerged to, but not including, the strain relief of the transducer array. Do not immerse or soak any part of a transducer in any cleaning material not listed in the recommended list of disinfectant.
6. Use the Cidex OPA immersion method to disinfect the endocavity transducer.
7. Only non-immersion method can be used with solution of ethanol or isopropanol. The solution concentration should not exceed the value provided above.
8. The immersion time should not exceed the time that is specified by the disinfectant manufacturer.
9. Patient contact area should be immersed into the solution while using the immersion method, but should not exceed the depth shown in figure 6-2.

Proper Use of Transducers

In order to extend the service life and to obtain optimum performance of the transducer, please operate as follows:

Inspect AC adapter, socket and acoustical window of the transducer periodically.

Shut down the machine before connecting or disconnecting the transducer.

Do not drop the transducer onto the floor or collide with hard objects. Otherwise it will be damaged easily.

Do not heat the transducer.

Do not pull or bend the transducer cable.

Coupling gel can only be used on the head of the transducer, and it should be wiped off after use.

Clean and disinfect the transducer after every use.

The acoustical window and the shell of the transducer should be examined frequently.

CAUTION

1. Do not disinfect or clean transducers under high temperature, and the temperature should be below 45°C.
 2. In order to avoid damaging the device, the disinfection method is limited to regular maintenance of devices in hospitals. Disinfecting instruments should be cleaned first.
-

7 Features

7.1 Comments

The Comments function lets you add annotation to an image. The Comment function is invoked by pressing the **Comment** hard key on the console. Figure 7-1 shows an example touch screen for Comments. The top portion of the screen shows comments that are pre-defined in pre-sets. See section 8 for details on how to configure these. The bottom portion of the screen shows controls available while the Comment function is active. Table 7-1 gives an overview of these controls.

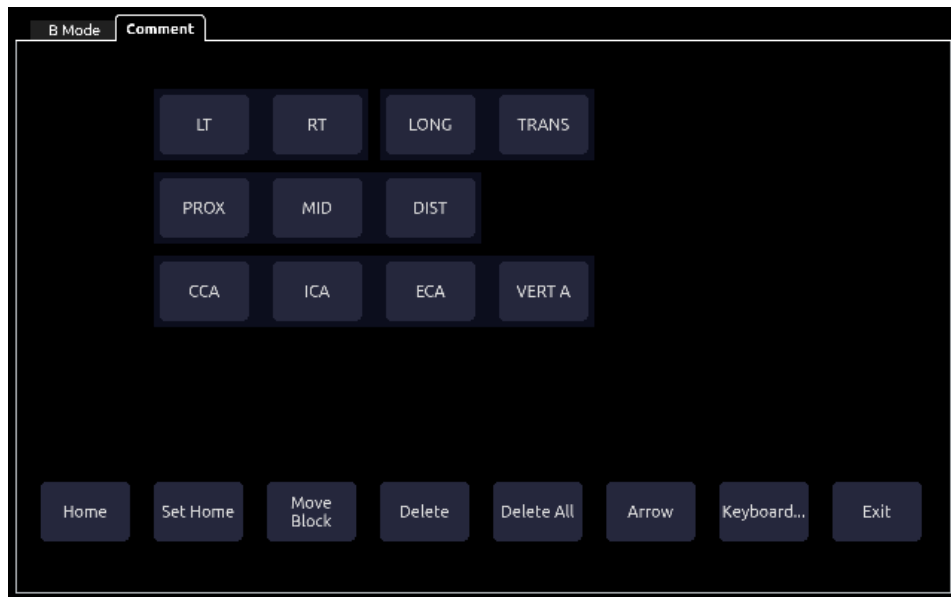


Figure 7-1 Comment Touch Screen

Button	Description
Home	Set the cursor in a pre-defined location.
Set Home	Set the current cursor location as the new Home location
Move Block	Select comments for moving to desired locations
Delete	Delete a whole text or text group or an arrow
Delete All	Clear all comments on the image area
Arrow	Create a new arrow for annotating
Keyboard	Toggle between showing pre-defined comments(comment library) or a touch screen keyboard

Table 7-1 Comment Touch Screen Description

Adding comments

You can add either pre-defined comments or use a keyboard.

Adding comments using the keyboard

1. Invoke the Comment function.
2. Press the “**Keyboard**” touch screen key to display a keyboard on the touch screen.
3. Move the cursor to the desired location and enter the desired text.

Adding comments using pre-defined comments

1. Invoke the Comment function
2. Move the cursor to the desired location and press the desired pre-defined comment.

Some of the pre-defined comments may be grouped together with a border surrounding them (such as 'Rt' and 'Lt' in figure 7.1). These are special keys that let you quickly replace one term with another, regardless of where the cursor is within a block of text. For example, if you had entered "Rt. Kidney" as a block of text, pressing the "Lt." button would change that block to "Lt. Kidney" even if the cursor is not at the specific location.

Adding arrows

1. Invoke the Comment function
2. Press **Arrow** button on the touch screen to display an arrow at the current cursor location.
3. Move the arrow to the desired location. Note that while the arrow is being moved the orientation of the arrow is fixed.
4. Press the **Pos/Angle** button to set the tip of the arrow in its current location and toggle adjusting the angle of the arrow. The trackpad can now be used to rotate the arrow. The **Pos/Angle** button can be used to toggle between moving the head of the arrow and moving the tail of the arrow. The selected button is yellow colorized in the background.
5. Press the **Enter** button to complete the arrow. You can now enter text at the end of the arrow.

Modifying comments

1. Move the cursor to a desired comment, notice that an insert cursor appears in the text as the cursor moves over an existing block of text.
Enter text using either the keyboard or pre-defined comments. The new comments will be added to the old text.

Deleting comments

There are several ways to delete comments:

- ◆ Move the cursor to the desired block of comments and press the **Delete** button on the touch screen to delete that block of comments.
- ◆ Press the **Delete All** button on the touch screen to remove all comments.
- ◆ Press the **Clear** hard key on the console to remove all comments, bodymarkers, and measurements.

7.2 Body Mark

The Body Mark lets you add a bodymarker graphic to an image and indicate the location of the transducer using a transducer icon on that graphic. The Body Mark function is invoked by pressing the **Body Mark** hard key on the console. Figure 7.2 shows an example touch screen for Body Mark. The main portion of the screen shows a grid of bodymarkers that are pre-defined in pre-sets. See section 8 for details on how to configure these. The bottom portion of the screen shows controls available while the Comment function is active. Table 7-2 gives an overview of these controls.



Figure 7-2 Body Mark Touch Screen

Button	Description
Delete	Delete the graphics on the image area
Angle	Rotates the transducer icon on the bodymarker graphic.

Table 7-2 Body Mark Touch Screen Description

Adding a body mark:

1. Invoke the **Body Mark** function
The default bodymarker graphic appears on the main screen, with the transducer icon shown in the default position.
2. Select a desired bodymarker graphic on the touch screen, that graphic replaces the default.
3. Move the transducer icon as needed. The orientation of the transducer icon can be changed with the Angle touch screen key.

Moving the transducer icon:

1. Press **Probe/Graphic** to toggle moving the transducer icon.
The transducer icon can not be moved outside of the bodymarker graphic area.
2. Press **Probe/Graphic** to confirm the new position of the transducer icon and toggle moving the bodymarker graphic.
Probe/Graphic button can be used to toggle between moving the transducer icon and moving the bodymarker graphic. The selected button is yellow colorized in the background.

Deleting a body mark:

There are two ways of deleting a bodymarker graphic:

- ◆ Press **Delete** on the touch screen to delete the graphics on the image area.
- ◆ Press the **Clear** hard key to delete all bodymarkers, comments, and measurements.

7.3 Measurements

NOTE: This section provides general introduction of generic and application measurements. For details about specific application measurements and calculations, please refer to the Acclarix AX8 Advanced Manual.

The Measure function lets you perform measurements on a live or frozen image. The Measure function is invoked by pressing the **Measure** hard key on the console. Figure 7-3 shows an example touch screen for Measure.

There are two types of measurements:

Generic Measurements: These are simple tools like Distance or Area. There is no specific anatomy associated with these measurements and they do not appear in a report.

Application Measurements: These are measurements for specific anatomy or clinical conditions. The results can be entered into a report that can be printed later.

On the Measure touch screen the lower part of the touch screen shows Generic Measurements. These are different for each imaging mode, but are the same for all presets. The upper part of the touch screen shows Application Measurements. These are different for each imaging mode and each preset. See section 8 for details on how to configure these.

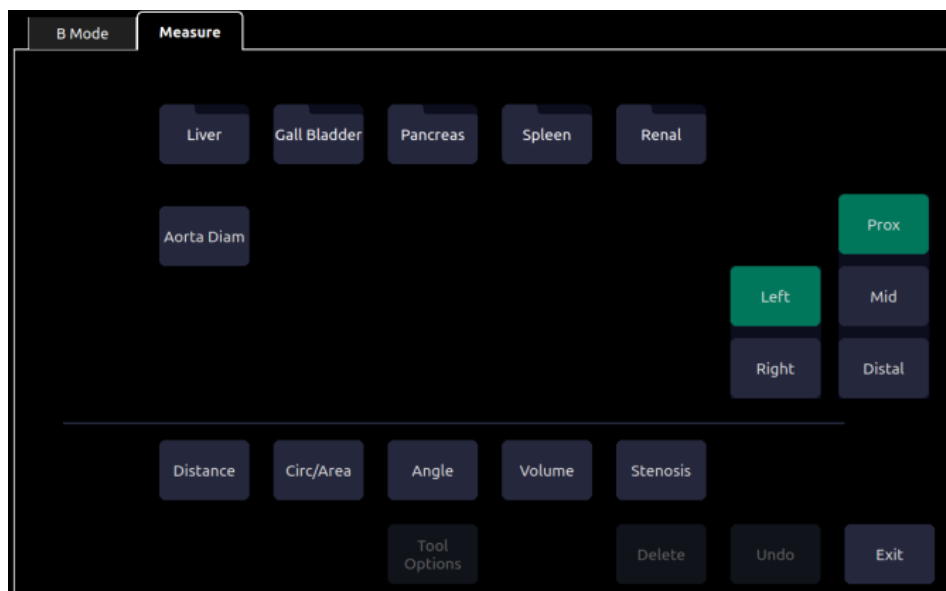


Figure 7-3 Measure Touch Screen

Tool Options

Some measurements can be done with a choice of different tools, and each tool has a choice of multiple output result items. The users can configure the default tool and result items for these measurements by **Tool Options**. For result options, at least one item should be selected.

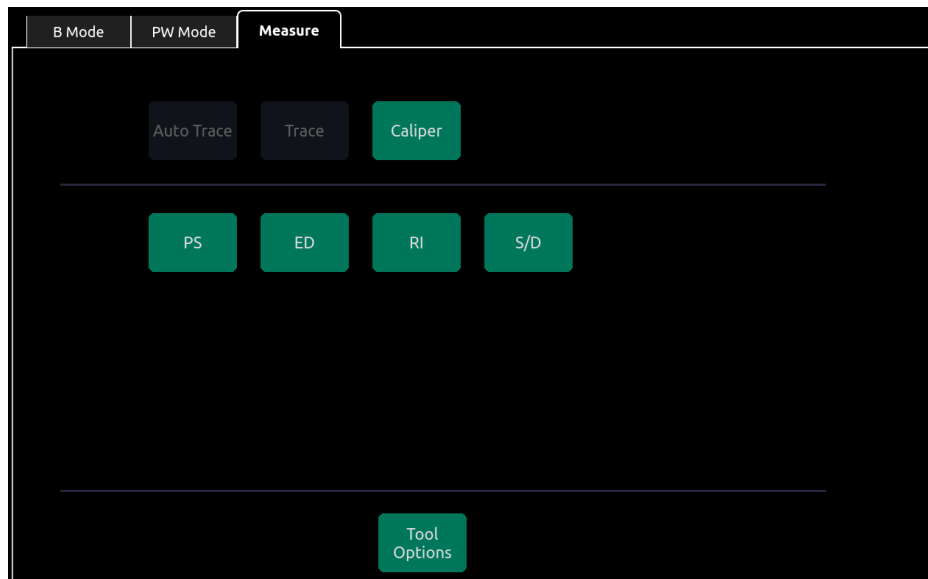


Figure 7-4 Tool Options Touch Screen

Moving the measurement result window

The measurement result window is displayed on the top left corner of the image field by default, the system supports changing the display position of the result window by dragging it.

To change the display position of result window:

1. Press **Cursor** hard key to invoke a cursor after a measurement is done.
2. Move the cursor over the result window, and press **Set** key, the result window will turn green.
3. Move on the track pad to locate a desired position within the image field for the result window.
4. Press **Set** key again to fix the result window on the new position.

The system supports a different result window position for each image mode.

Note:

The measurement result window cannot be moved when measure in review state.

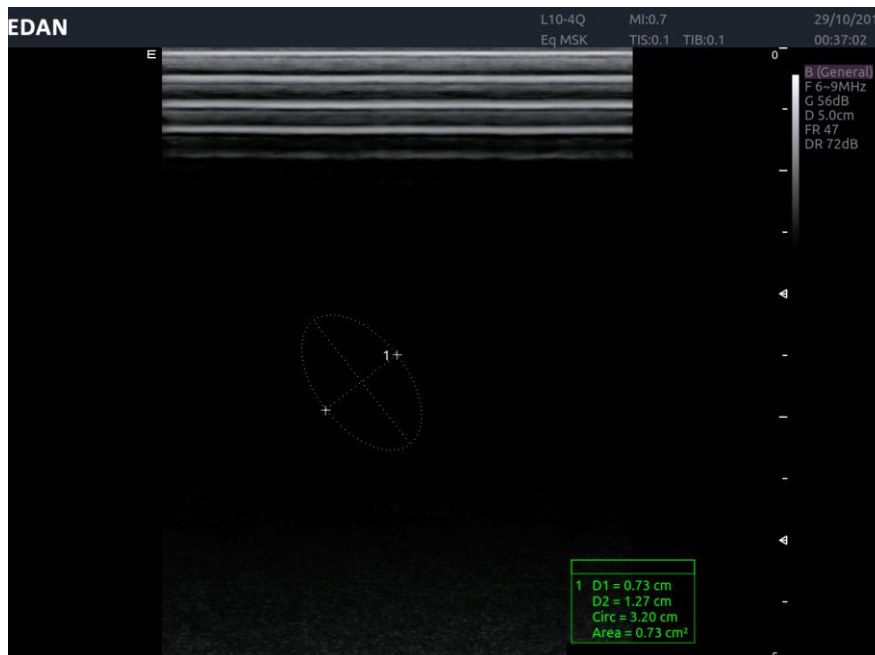


Figure 7-5 Moving the Measurement Result Window

7.3.1. Generic Measurements

A default generic measurement is automatically started when Measure is invoked. Each imaging mode supports several types of measurements, as described below. You can switch between these types using the touch screen buttons along the bottom of the touch screen. Some generic measurements have options, for the method to perform the measurement. When the current generic measurement has options available you can view and change those options through the **Tool Options** touch screen buttons.

7.3.1.1. B-mode Generic Measurements

The Acclarix AX8 supports the following types of generic B-mode measurements:

- Distance
- Circ/Area
- Angle
- Volume
- Stenosis

Distance: The distance measurement is always done with a caliper pair.

To measure Distance with a caliper pair:

1. Invoke the measure function on a B-mode image.
2. If Distance is not the default measurement, select **Distance** from the touch screen.
3. Move the caliper to the desired location.
4. Press the **Set** key to place that caliper and add the second half of the caliper pair.

Further presses of the **Set** key toggle which side of the caliper can be moved. Pressing the **Enter** key completes the caliper and allows you to create another tool.

Circ/Area: Area and Circumference can be measured with an Ellipse or Trace

To measure Area or Circumference with an Ellipse:

1. Invoke the measure function on a B-mode image.
2. If Area is not the default measurement, select **Area** from the touch screen.
If Ellipse is not the default tool, press **Tool Options** to switch to Ellipse
3. Move the caliper to the desired location.
4. Press the **Set** key to place that caliper and add the second half of the caliper pair.
5. Press the **Set** key to place the second half of the caliper. An ellipse appears and can be adjusted with the trackpad.
Further presses of the **Set** key toggle between controlling each side of the ellipse caliper and the ellipse diameter. Pressing the **Enter** key completes the caliper and allows you to create another tool.

To measure Area or Circumference with a Trace:

1. Invoke the measure function on a B-mode image.
2. If Area is not the default measurement, select **Area** from the touch screen.
If Trace is not the default tool, press **Tool Options** to switch to Trace. Trace can be done with a Draw option. Draw will follow your movements.
3. Move the caliper to the desired location.
4. Press the **Set** key to place the caliper and start drawing the trace.
5. Moving the caliper now leaves behind a trail of dots to mark the trace outline
6. Press the **Enter** key to complete the trace.

Angle: The Angle measurement is always done with an angle tool.

To measure Angle:

1. Invoke the measure function on a B-mode image.
2. If Angle is not the default measurement, select **Angle** from the touch screen.
3. Move the caliper to the vertex of the angle you are measuring.
4. Press the **Set** key to place that point and create a new caliper. Move that to one end of the angle.
5. Press the **Set** key to place that end and create a new caliper. Move that to the other end of the angle. Further presses of the **Set** key toggle between controlling each of the three points that make up the angle. Pressing the **Enter** key completes the angle and allows you to create another tool.

Volume: Volume can be measured with 3 Distance.

To measure Volume with 3 Distance:

1. Invoke the measure function on a B-mode image.
2. If Volume is not the default measurement, select **Volume** from the touch screen.
Move the caliper to the desired location.

3. Press the **Set** key to place that caliper and add the second half of the first caliper pair.
4. Further presses of the **Set** key toggle which side of the caliper can be moved. Pressing the **Enter** key completes the first caliper pair and creates the second caliper pair.
5. Repeat step 3~5 to complete the second caliper pair and create the third caliper pair.
6. Repeat step 3~5 to complete the third caliper pair and allow you to create another tool.

Stenosis: Stenosis can be measured with Caliper Pairs, Ellipses, or Traces

To measure Stenosis with Caliper Pairs:

1. Invoke the Measure Function on a B-mode image.
2. If Stenosis is not the default measurement, select **Stenosis** from the touch screen. If Caliper is not the default tool, press **Tool Options** to switch to Caliper.
3. Move the caliper to the desired location.
4. Press the **Set** key to place that caliper and add the second half of the caliper pair.
5. Further presses of the **Set** key toggle which side of the caliper can be moved. Pressing the **Enter** key completes the caliper and creates the second caliper pair tool.
6. Repeat step 3~5 to complete the second caliper pair and allow you to create another tool.

To measure Stenosis with Ellipses:

1. Invoke the Measure Function on a B-mode image.
2. If Stenosis is not the default measurement, select **Stenosis** from the touch screen. If Ellipse is not the default tool, press **Tool Options...** to switch to Ellipse.
3. Move the caliper to the desired location.
4. Press the **Set** key to place that caliper and add the second half of the caliper pair.
5. Press the **Set** key to place the second half of the caliper. An ellipse appears and can be adjusted with the trackpad.
6. Further presses of the **Set** key toggle between controlling each side of the ellipse caliper and the ellipse diameter. Pressing the **Enter** key completes the first Ellipse and creates the second Ellipse tool.
7. Repeat step 3~6 to complete the second Ellipse and allow you to create another tool.

To measure Stenosis with Traces:

1. Invoke the Measure Function on a B-mode image.
2. If Stenosis is not the default measurement, select **Stenosis** from the touch screen. If Traces is not the default tool, press **Tool Options** to switch to Traces.
3. Move the caliper to the desired location.
4. Press the **Set** key to place the caliper and start drawing the trace.
5. Moving the caliper now leaves behind a trail of dots to mark the trace outline
6. Press the **Enter** key to complete the trace.
7. Repeat step 3~6 to complete the second trace and allow you to create another tool.

7.3.1.2. Strip Doppler Generic Measurements

The Acclarix AX8 supports the following types of generic strip Doppler measurements:

- Caliper
- Trace
- Auto Trace
- HR (Heart Rate)
- RI (Resistive Index)

Caliper: The Caliper measurement can provide a wide range of results.

To use the Caliper measurement:

1. Invoke the Measure Function on a Doppler strip.
2. If Caliper is not the default measurement, select **Caliper** from the touch screen.
3. Move the caliper to the desired location. At this point the measurement can display the following results (the actual results shown will depend on the preset):
 - Vel
 - PG
4. If you want a caliper pair, press the **Set** key to place the caliper and add the second half of the caliper pair. At this point the measurement may display the following results (the actual results shown will depend on the preset):
 - V1
 - V2
 - RI
 - S/D
 - Time
 - ΔV
 - Accel
 - PG1
 - PG2
 - PHT

Further presses of the **Set** key toggle which side of the caliper can be moved. Pressing the **Enter** key completes the caliper and allows you to create another tool. The S/D, PI, and PHT results assume that the first caliper is placed on the peak systolic point.

Trace: The Trace measurement can provide a wide range of results.

To use the Trace measurement:

1. Invoke the Measure Function on a Doppler strip.
2. If Trace is not the default measurement, select **Trace** from the touch screen.
3. Trace can be done with a Draw. Draw will follow your movements
4. Move the caliper to the desired start point.

5. Press the **Set** key to place the start point and start drawing the trace.
6. Moving the caliper now leaves behind a trail of dots to mark the trace outline. Press the **Set** key to adjust the positions of the PS or ED points in the trace.
7. Press the **Enter** key to complete the trace.
8. At this point the trace measurement may display the following results (the actual results shown will depend on the preset):
 - PS
 - ED
 - MD
 - TAMax
 - PGmax
 - PGmean
 - PI
 - RI
 - S/D
 - VTI
 - Time
 - AT
 - DT

NOTE: Measure trace can only be active in image frozen status.

Auto Trace: Auto Trace is capable of determining the maximum and/or mean blood flow in freeze mode. Each result that it calculates is associated with either the maximum or the mean value. For activate auto trace in real time mode, press **Auto Trace** button in PW touch screen.

To use the Auto Trace measurement:

1. Invoke the Measure Function on a Doppler strip.
2. If Auto Trace is not the default measurement, select **Auto Trace** from the touch screen.

The trace waveform(s) automatically appear. If any maximum-related results are enabled then the maximum value waveform is displayed on the Doppler strip. If any mean-related results are enabled then the mean value waveform is displayed.

3. The Trace measurement may display the following results (the actual results shown will depend on the preset):
 - PS
 - ED
 - MD
 - TAMax
 - TAMean
 - PGmax
 - PGmean
 - PI
 - RI
 - S/D
 - VTI
 - Time
 - AT
 - DT

- HR

NOTE: Measure Auto trace can only be active in image frozen status. Live auto trace is available as a separate feature from the Doppler touch screen.

HR: The HR measurement can provide the heart rate calculation by measured the time of the heart beat cycles.

To use the HR measurement:

1. Invoke the Measure Function on a Doppler strip.
2. If HR is not the default measurement, select HR from the touch screen.
3. Move the caliper to position the first heart beat. Press the **Set** key to activate a second caliper.
4. Move the second caliper to position the next beat.
5. Press the **Enter** key to complete or press the **Set** key to switch moving the first caliper.
6. The HR measurement can display the following result(the actual results shown will depend on the preset):

- HR

RI: The RI measurement can measure the PS and ED to calculate the result of RI and S/D.

To use the RI measurement:

1. Invoke the Measure Function on a Doppler strip.
2. If RI is not the default measurement, select RI from the touch screen.
3. Move the caliper to position the PS point. Press the **Set** key to activate a second caliper.
4. Move the second caliper to position the ED point.
5. Press the **Enter** key to complete or press the **Set** key to switch moving the first caliper.
6. The RI measurement can display the following results (the actual results shown will depend on the preset):

- PS
- ED
- RI
- S/D

7.3.1.3. M-mode Generic Measurements

The Acclarix AX8 supports the following types of generic M-mode measurements:

- Caliper
- HR (Heart Rate)

Caliper: The Caliper measurement can provide a wide range of results.

To use the Caliper measurement:

1. Invoke the Measure Function on an M-mode strip. A caliper measurement is automatically invoked. It displays the Depth at the current location.
2. Move the Caliper to the desired location.

3. Press the **Set** key to place that caliper and add the second half of the caliper pair. Further presses of the **Set** key toggle which side of the caliper can be moved. Pressing the **Enter** key completes the caliper and allows you to create another tool
4. The Caliper measurement can display the following results:
 - Distance
 - Time
 - Slope

HR: The HR measurement can provide the heart rate calculation by measured the time of the heart beat cycles.

To use the HR measurement:

1. Invoke the Measure Function on a Doppler strip.
2. If HR is not the default measurement, select HR from the touch screen.
3. Move the caliper to position the first heart beat. Press the **Set** key to activate a second caliper.
4. Move the second caliper to position the next beat.
5. Press the **Enter** key to complete or press the **Set** key to switch moving the first caliper.
6. The HR measurement can display the following result(the actual results shown will depend on the preset):

7.3.2. Application Measurements and Calculations

Application Measurements have a pre-defined meaning and can be entered into a report. Acclarix AX8 supports the following application packages, each with its own set of measurements, calculations and report:

- OB (including multiple fetuses)
- Abd
- Vascular
- Cardiac
- Gynecology
- Small Parts
- Urology
- Pediatric(including Neonatal)

Please see the Advanced User Manual for the complete content of each package.

When you select an application measurement from the touch screen it will automatically invoke the type of measurement it needs. For example, if you select “BPD” from the OB application it will automatically invoke a distance measurement. These measurements generally behave as described above for generic measurements. However, a final press of the **Enter** key after the measurement is complete will enter the result into the report.

Some application measurements can have multiple variations. For example, in a twin OB exam the OB measurements can be done on either fetus. As another example, in Vascular exams several measurements can be done in a Proximal, Mid, or Distal location. When a measurement has

multiple variations you will see buttons on the touch screen that let you pick which variation you are measuring.

7.3.2.1. Auto IMT

(Note: Auto-IMT is not available in the USA and some other countries.)

Intima-media thickness (IMT) is a measurement of the thickness of tunica intima and tunica media. The system provides an automatic measurement of the Carotid IMT.

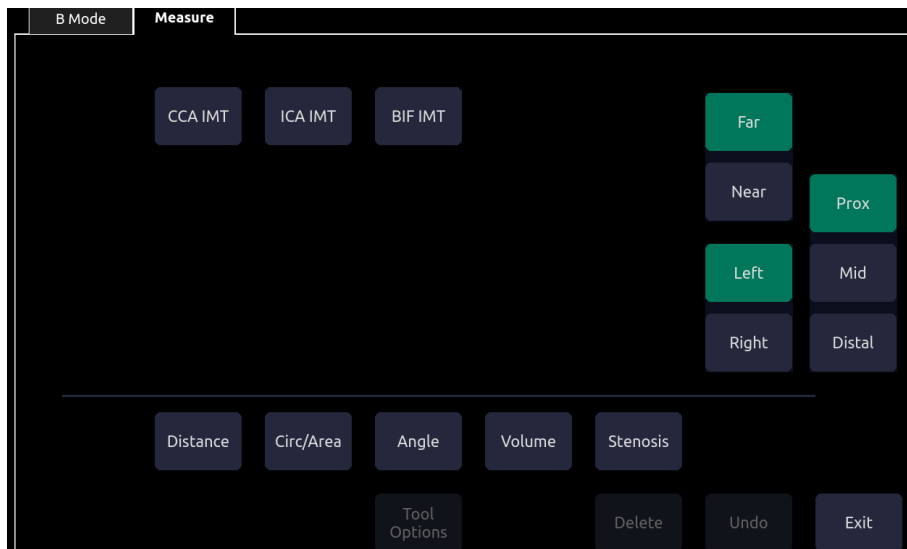


Figure 7-6 IMT Touch Screen

To measure IMT:

1. Invoke the B-mode Measure Function in Carotid Preset.
2. Select an IMT measurement on the touch screen. A ROI box will be displayed on the image field.
3. Select the buttons on right side of the touch screen to measure a different position of carotid artery.
4. Press **Set** key to resize the ROI box, move the ROI box to locate the measure position.
5. Press **Enter** key to complete and get the Auto IMT measure results. Press **Enter** Key again to save the results in the worksheet.
6. If you are not satisfied with the measurement result, press Undo key to restart the IMT measurement.
7. The IMT measurement can display the following result:
 - Max (the maximum value of the IMT results)
 - Min (the minimum value of the IMT results)
 - Avg (the average value of the IMT results)
 - Width (the width of the ROI box)
 - SD (the Standard Deviation of the IMT results)
 - Points (the number of valid points in the IMT results)

NOTE: IMT measurement can only be active in image frozen status.

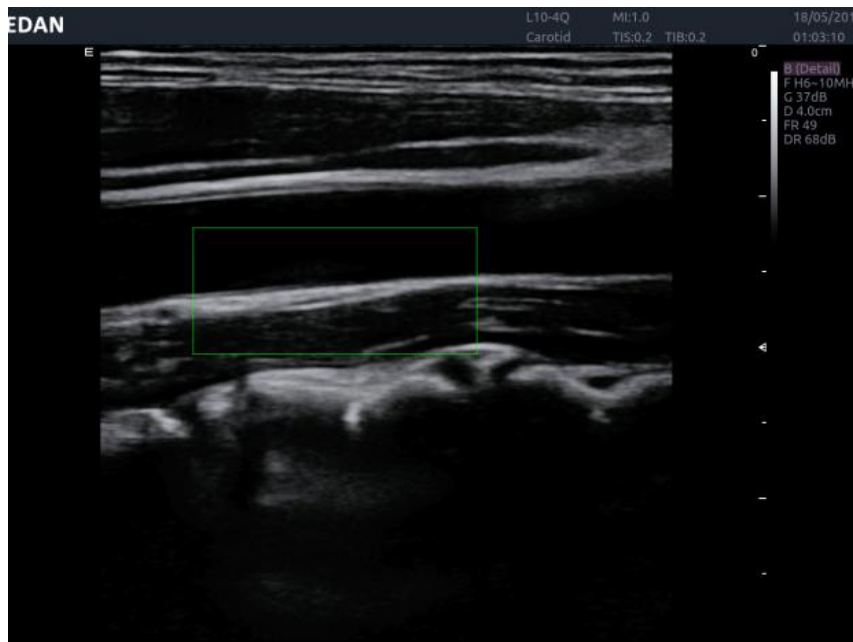


Figure 7-7 ROI Box of Auto IMT

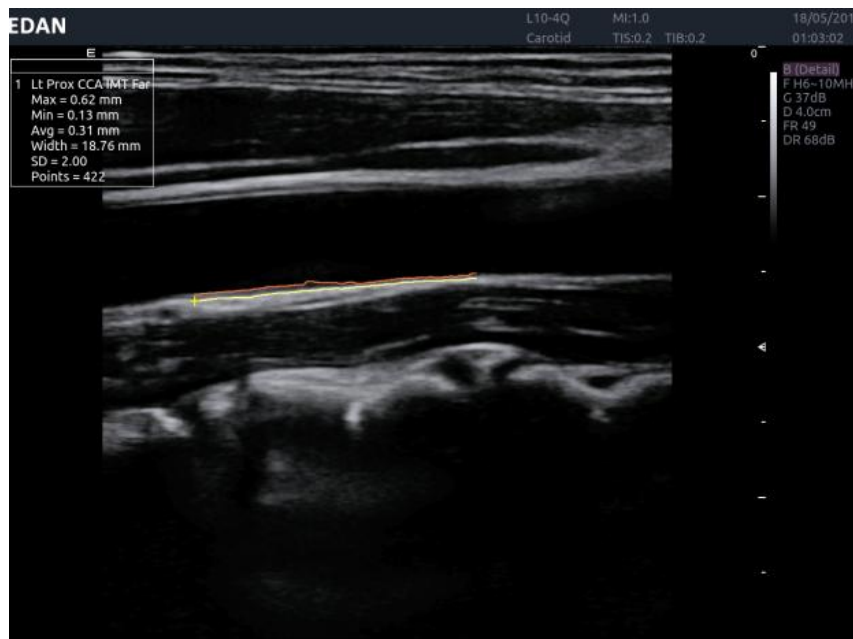


Figure 7-8 Measure Result of Auto IMT

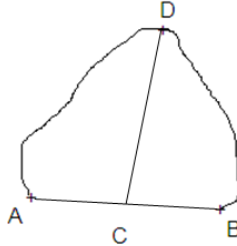
7.3.2.2. Simpson's (Method of Disks)

Simpson is a tool in Cardiac presets used to determine LV diastolic and systolic volumes, and from that derive an ejection fraction.

To use the Simpson measurement:

1. Invoke the B-mode Measure function.
2. Select **LV Simpson** measurement on the touch screen and then select one measurement label from **A4C Dias.**, **A4C Sys.**, **A2C Dias.**, and **A2C Sys.**. A single caliper will be displayed on the image field.
3. Move the caliper and press **Set** key to position the start point A at one end of left ventricular long axis.

4. Draw the trace along the endocardium of left ventricular.
5. Press **Set** key to fix the end point B and complete the trace. A new caliper positions automatically at the apex (Point D) of the trace, connecting the Point C (Midpoint of point A and B). This distance between point C and D is the longest detected by the system, as shown below:



6. Move the caliper(Point D) to a new desired position if necessary.
7. Press **Enter** key to complete the measurement.

See Chapter 6 Cardiac in advanced manual for the detailed Simpson measurement and calculation results and equations.

7.3.2.3. PISA

PISA (Proximal Isovelocity Surface Area) is a tool in Cardiac presets used for quantitative analysis of regurgitation. It is only available in Color and Doppler mode.

To use PISA measurement in Color mode:

1. Adjust the color image until the aliasing appears. Invoke the Measure function.
2. Select **PISA** measurement on the touch screen and then select a measurement label from **MR Rad**, **MR Als. Vel**, **AR Rad**, **AR Als. Vel**, **TR Rad**, **TR Als. Vel**, **PR Rad** and **PR Vls. Vel**. A single caliper will be displayed on the image field.
3. Move the caliper and press **Set** key to position the caliper as the center of the semicircular.
4. Move the trackpad to adjust the radius length and orientation of the semicircular.
5. Press **Enter** key to fix the semicircular and then a dialog box of “Color Aliasing Velocity” pops up.
6. Select “Top aliasing velocity”, “Bottom aliasing velocity”, or manually enter the aliasing velocity from 0 cm/s to 500 cm/s.
7. Click OK and then measurement results are shown.

To use PISA measurement in Doppler mode:

1. Freeze a strip image. Invoke the Measure function.
2. Select **PISA** measurement on the touch screen and then select a measurement label from **MR Trace**, **AR Trace**, **TR Trace** and **PR Trace**.
3. Use the Doppler trace tool to get the measurement results.

When all the measurements described above have been completed, the system automatically calculates the Flow Rate, Flow and EROA(Effective Regurgitant Orifice Area). See Chapter 6 Cardiac in advanced manual for the detailed PISA measurement and calculation results and related equations.

7.4 Patient Information Management

7.4.1. Storing Images

The control panel has three store keys: **Store 1**, **Store 2**, and **Alt Store**. Each store key can be separately configurable to support any of the following functions:

- Store a static image.
- Store a clip.
- Video print function

For details about the configuration of store keys, please refer to Section 8.

Storing an image:

1. If a **Store** key is configured to store a static image it will always capture what is on the imaging area of the screen. This includes live, frozen, or Cine images. It also includes reports or other GUI screens and review.

Storing a clip:

1. If a **Store** key is configured to store a clip image it will capture the moving image in live or auto cine play. If the image is frozen or a non-image screen is displayed then a static image is stored.
2. The store starts with the press of the button and continues for the configured length of the clip or until the clip store is interrupted. The following events can cause the clip store to stop:
 - A second press of the store button
 - Display of a GUI screen or dialog
 - Mode change
 - Reaching a pre-defined clip duration (refer to **System Setup**)
 - Image parameters change (depth and zoom in B/C mode, M cursor, sweep speed, strip size and depth in M mode, angle, scale, baseline, invert, strip size and sweep speed in Strip Doppler mode.)
 - Cine play pause (press **Freeze** button, **Set** button or dragging left along the **Swipe** button)

7.4.2. Reviewing Images

If Static or Clip images have been stored for the current exam then they can be reviewed by pressing the **Review** hard key on the console.

NOTE: If nothing has been stored in the current exam then the **Review** hard key will invoke the Patient Database function (see the next section).

Figure 7-9 shows an example touch screen for Review. The following table explains the action of each button in Review.

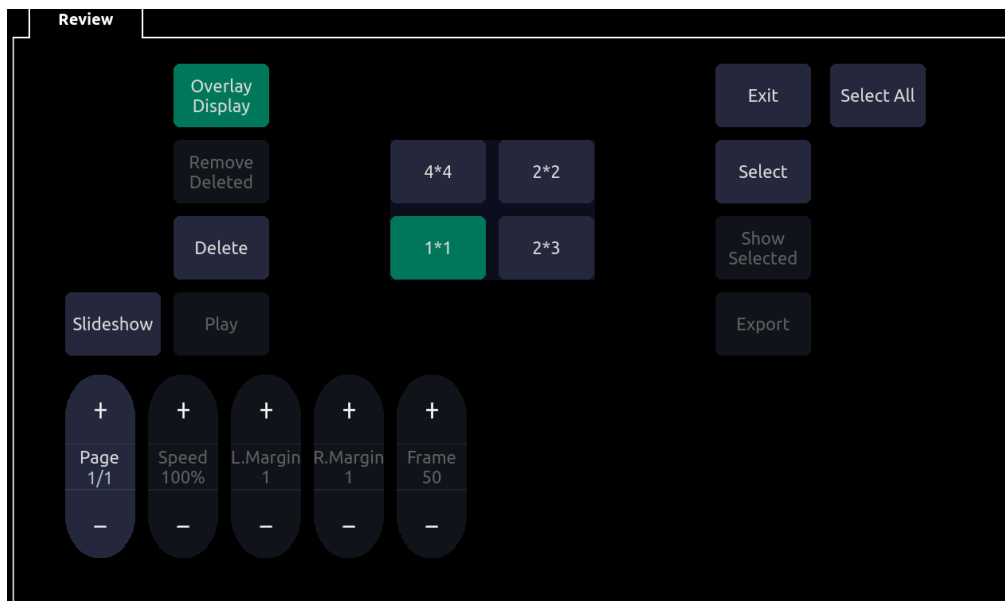
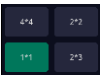


Figure 7-9 Review Screen

Button	Description
Page	Change the display one page at a time.
Speed	Change the playing speed of the highlighted clip; the speed range is 12.5%-100%, in increments of 12.5%.The default speed is 50%.
L.Margin	Change the left margin of a highlighted clip
R.Margin	Change the right margin of a highlighted clip
Frame	Scroll the paused clip frame by frame
Play	Plays/Stops the highlighted clip. This can also be done with the Set key on the trackpad.
Overlay Display	Show or hide overlay icons on thumbnail images
Remove Deleted	Permanently remove all deleted images
Delete	Delete the highlighted image. A deleted image is marked by a deleted icon. To cancel the delete, press this button while the deleted image is highlighted
	Change the displayed layout: 4*4, 2*2, 1*1, 2*3
Show Selected	Toggle between showing all images and only showing the selected images
Select	Toggle the highlighted image in/out of the selected images
Select All	Select all the images in the current exam.
Slideshow	Play all the images as a slideshow.
Export	Export selected images to a removable media currently available. Plug in a USB disk, select a image, press this button and the following confirmation dialog pop-up:

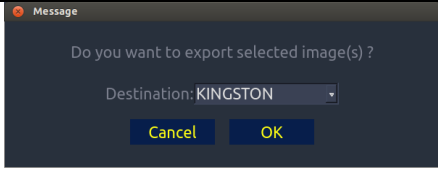

	 <p>Select the export path from destination drop list menu and click OK to confirm. If there is only one removable media then this field is a read-only field. Static images export as .bmp files. Clip images export as .avi files.</p> <p>While export in progress the dialog is displayed as bellow. Cancel button is used to stop the export. The dialog disappears when export finishes.</p>  <p>If there is no USB plugged in, the message “The images cannot be exported because no USB flash drive is inserted” is displayed and no export work to do.</p>
Exit	Exit review function

Table 7-3 Review Touch Screen Controls

Select Set:

By default, Review displays all Static and Clip images stored for the current exam in the order they were stored. Images can be placed into the Select Set by highlighting them and pressing the **Select** key on the touchscreen. Pressing the **Show Selected** button will then display the selected images in the order they were selected.

Reviewing Clips:

By default stored clips playback at half speed. You can adjust the playback rate Review will show Static and Clip images intermixed in the order they were stored.

Exiting Review:

In review state, press **Review** or **B** hard key on the control panel, or press the **Exit** button on the touch screen to exit the review function.

Measurement in Review State:

Measurements in review state are supported for the current exam (including restarted). Review a clip or static image for current active exam (please pause the clip when a desired image is got) and then press **Measure** hardkey on the console to start measurements.

Note:

- 1) PISA, Auto IMT and Auto Trace measurements are disabled in review state.
- 2) Measurements on stored panorama image are not available in review state.

7.4.3. Patient Database

The Patient Database provides a list of recently performed studies. It can be accessed by pressing the **Review** hard key on the console when there is no active exam. Figure 7-10 shows an example

screen shot from the Patient Database screen.

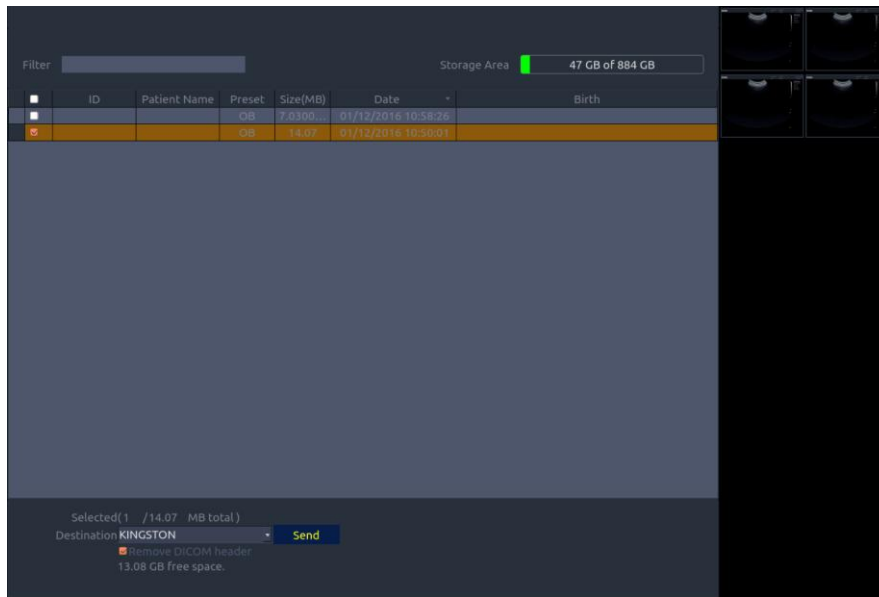


Figure 7-10 Patient Database screen

The main part of the display shows a list of studies. Clicking on the header of a field will sort the list by that field. Fields can be displayed or hidden.

Filter:

The database filter field at the top-left of the screen provides a powerful tool to find the study of interest. It filters the list based on whatever text is typed in this field. The filter applies to all fields. For example, typing “Ab” into the filter will show exams that either have that text in either the patient name or in the Exam preset. By default the filter is set to blank, so the default list shows all exams.

Storage Size: There is a box displaying current disk usage. It contains text with the current usage and is filled with a solid color to the extent that the current capacity is used. The text shows “<current usage> of <total capacity>”. The units are “Mb” for values less than 1 Gb, and “Gb” for anything larger. The solid color fill is green when usage is less than 75% of capacity, yellow for usage between 75% and 95%, and red when disk usage is above 95%.

Destination: The location where the highlighted exam(s) shall be exported, including all configured network locations and any writable USB disk or DVD drive currently available. This includes:

- DICOM server location(s) defined in the DICOM section of Connectivity. (See 9.2.2)
- FTP server location(s) defined in the Network Store section of Connectivity. (See 9.2.3)
- Any inserted USB drive or DVD drive.

Remove DICOM Header: If this item is checked, static images will be exported as bmp format, and clips will be exported as avi format. Otherwise all the images will be exported as DICOM format. This interaction is only available when exporting to USB or DVD.

Send/Burn: Pressing this will send/burn the highlighted exam(s) to the destination. This button is available when one or more exams are selected.

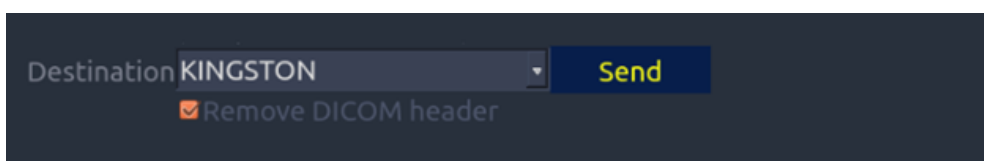


Figure 7-11 Send database

Working with one study:

A study is selected by clicking on it. When a study is selected thumbnail images from that study are shown on the right side of the screen.

A study can also be send to a DICOM server, saved to a USB device or DVD drive, or deleted. If the study has been copied to either a server or to a USB device or DVD drive a small disk icon appears next to it, indicating that it has been saved.

CAUTION:

- Studies stored on the system hard drive should be archived regularly. The system is not intended for long term storage of patient information. Confirm successful archiving before deleting a study from the hard drive.

Working with multiple studies:

Multiple studies can be selected by clicking the small box at the left of each listed study. Multiple studies can be stored to a DICOM server, saved to a USB device or DVD drive, or deleted. Only one study can be reviewed at a time.

7.4.4. Archiving Studies

All Clips and Static images stored on the Acclarix AX8 are stored internally in DICOM format.

They may be converted to .bmp and .avi as described below.

The AX8 supports many methods to export an exam for long-term storage:

- The study can be sent to a DICOM server. In this case the images are in DICOM (.dcm) format.
- The study can be send to an FTP server. In this case the images are in .bmp and .avi format.
- The study can be saved to a USB or DVD. In this case the images can be stored as either DICOM or .bmp/.avi format.

Sending a study to a DICOM server:

There are three ways to send a study to a DICOM server. See section 9 for details on configuring a DICOM server and choosing one of the following options

1. From the patient database screen, you can select a study or multi-studies and send it to a configured server.
2. You can configure the system to automatically send the study at the end of the exam. With this option the study is sent in the background while you continue to use the system for the next exam.
3. You can configure the system to automatically send each image and clip as it is stored. This has the advantage that the images and clips are available on the server sooner. Note that if you have it configured this way you can still delete stored images and clips on the system, but that will not delete them on the server if they have already been sent.

Sending a study to FTP Server

Please see section 9 for details on configuring a FTP server. Once an FTP server is configured the exam can be sent to the server from the patient database screen. Select the exam(s) from the list shown, and select the FTP server from the list of currently configured destinations.

Saving a study to USB or DVD

If a USB flash drive or DVD is plugged in then studies can be archived to them in either DICOM or .avi/bmp format. Plug the device into a USB port prior to invoking the patient database

screen, select the exam(s) from the list shown, and select the device from the list of currently configured destinations.

7.5 Needle Biopsy Guide

NOTE: Use proper sterile technique at all times when performing a biopsy.

Always follow these basic precautions:

WARNING

1. Disinfect the needle guide kit before the first use and after each subsequent use.
2. Calibrate the needle guide kit (see section 7.5.3) under any of the following conditions:
 - a) The first time that each bracket/transducer combination is used.
 - b) If the bracket or transducer head is dropped or struck, or has evidence of wear.
 - c) If previous use has shown some drift of the needle from the center of the guidelines.
3. The displayed needle guide pathway on the EDAN video monitor is intended for reference during biopsy procedures. A variety of factors outside EDAN's control, such as changing tissue density, bending of the needle, off-axis pressure by the person holding the transducer, etc., may cause deflection of a needle outside of the displayed video pathway even when the transducer, needle guide, and the system software are all performing as intended and within manufacturing specification. The specialist performing a biopsy procedure must be aware of potential external factors when performing an invasive procedure.
4. Do not freeze the system when performing a biopsy.
5. EDAN needle guides are designed and manufactured to attach firmly to designated transducers and should not require excessive force to assemble or disassemble. Do not use a needle guide that requires excessive force or manipulation to assemble or disassemble.
6. A single-use sheath should be used on transducer when performing a biopsy.

7.5.1. Installing Needle Guide Bracket

The needle guide bracket kit consists of the needle guide bracket and between 1 to 4 interchangeable guides for different gauge needles (see table 3-2 for details)

Step 1: Take the needle guide bracket kit out of the package. Check to make sure it is the correct kit for the transducer being used (see table 3-2) and inspect it carefully for any damage. See figure 7-12 for a typical needle guide bracket kit.

WARNING

The needle guide bracket kits are not disinfected or sterilized before delivery. Disinfect the needle guide kit before the first use and after each subsequent use. For detailed operations, see 12.4.2 Needle Guide Bracket Cleaning and Sterilization.

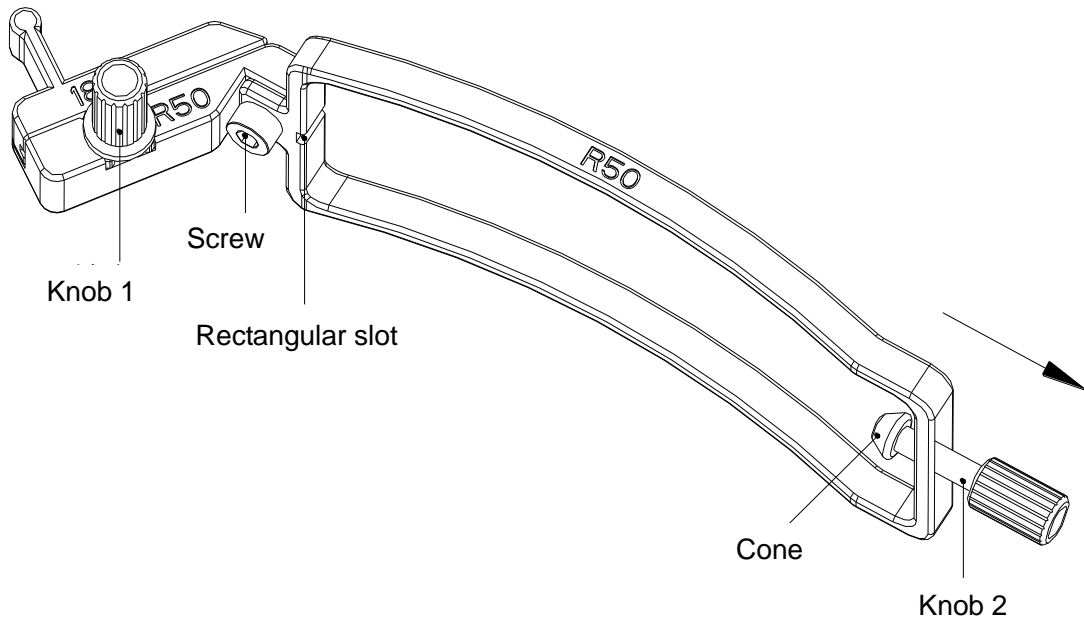


Figure 7-12 Structure of Needle Guide Bracket Kit

Step 2: Select the correct size guide for the gauge of needle to be used, and secure it to the needle guide holder by tightening knob 1. If the needle guide holder is loose tighten the screw with an allen wrench. Loosen knob 2 all the way prior to installing the bracket on the transducer.

Step 3: The transducer has a small circular dimple on one side of the transducer, and a rectangular ridge on the other side. Place the needle guide bracket over the transducer such that knob 2 tightens into the circular dimple and the ridge sits inside the corresponding slot on the bracket. (see figures 7-13 through 7-16).

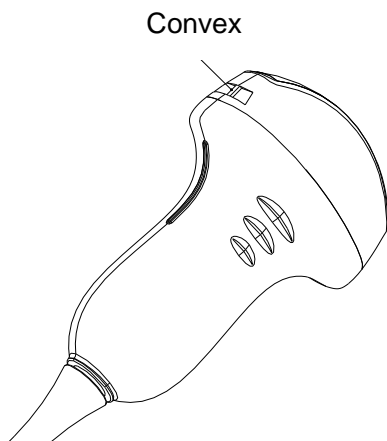


Figure 7-13 Convex slot of Probe

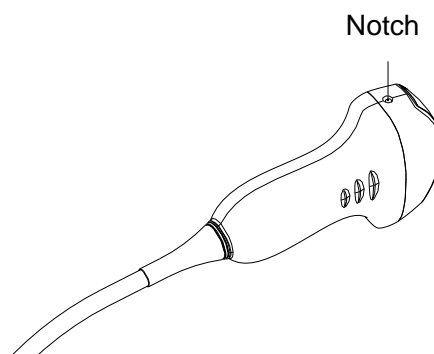


Figure 7-14 Notch of Probe

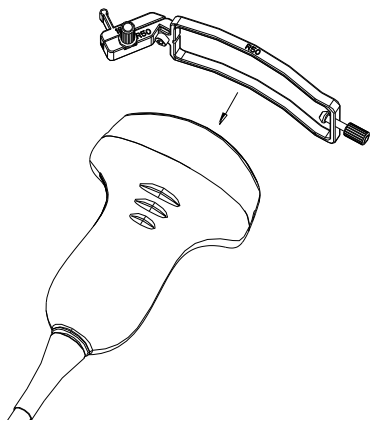


Figure 7-15 Attaching Bracket Kit to Probe

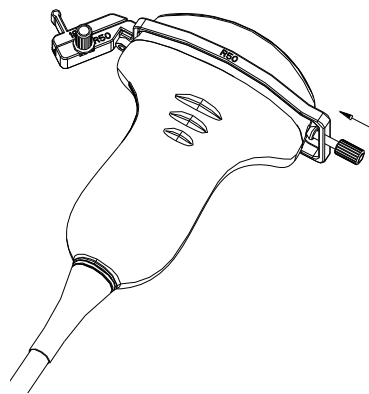


Figure 7-16 Turning Knob 2 Clockwise

Step 4: Insert the needle into the rectangular hole, as shown in [Figure 7-17](#).

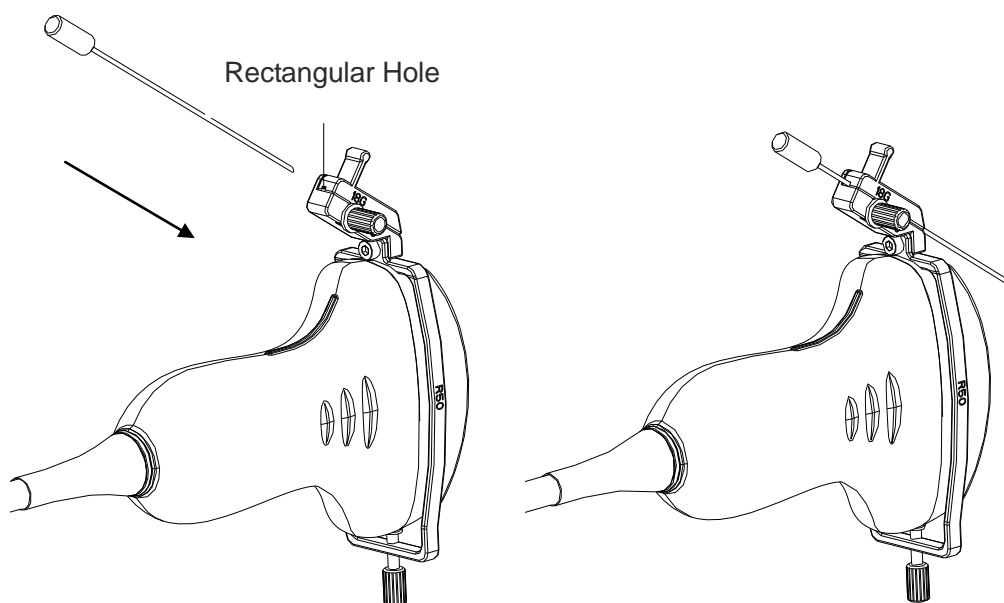


Figure 7-17 Inserting Needle into Rectangular Hole

Installing needle guide bracket of endocavity probe:

Step 1: Take the needle guide bracket kit out of the package. Check to make sure it is the correct kit for the endocavity transducer (see table 3-2) and inspect it carefully for any damage. See figure 7-18 for an endocavity needle guide bracket kit.

WARNING

The needle guide bracket kits are not disinfected or sterilized before delivery. Disinfect the needle guide kit before the first use and after each subsequent use. For detailed operations, see [12.4.22 Needle Guide Bracket Cleaning and Sterilization](#).

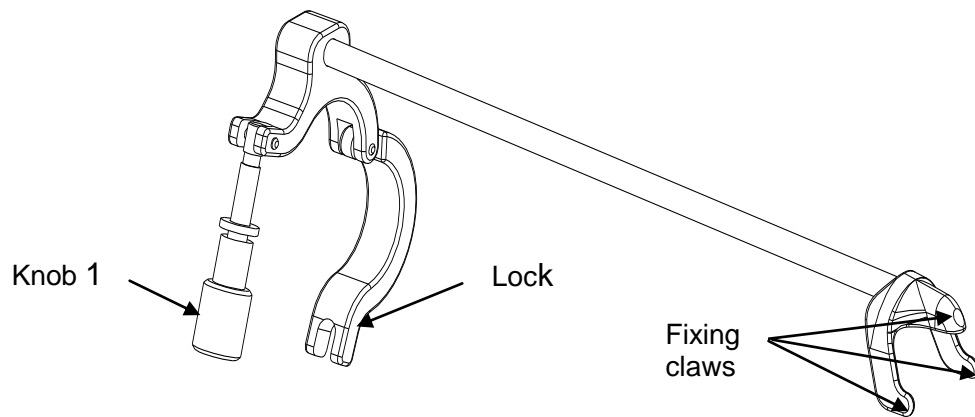


Figure 7-18 Structure of Needle Guide Bracket Kit

Step 2: Attach the needle guide bracket kit to the transducer by placing the bracket over the head of the probe, ensure that the three fixing claws of the bracket catch in the notches at the probe tip, turn the lock clockwise as the arrow direction shown in *Figure 7-21*, and then turn knob 1 clockwise until it locks in place, as shown in *Figure 7-22*.

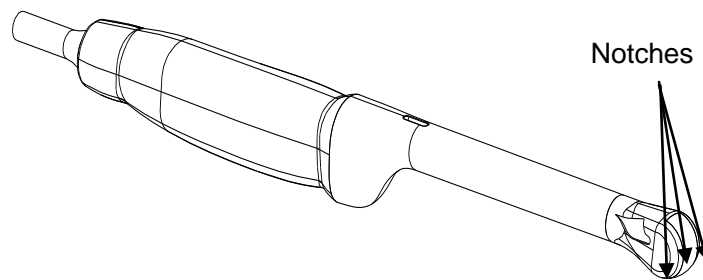


Figure 7-19 Notches at the Probe Tip

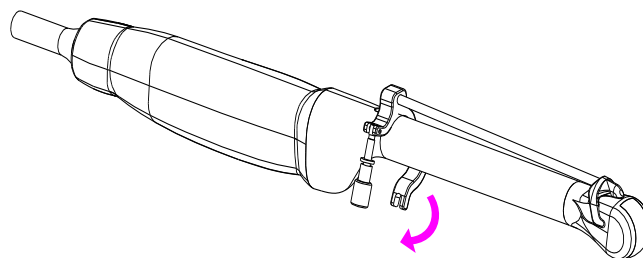


Figure 7-20 Turning the Lock Clockwise

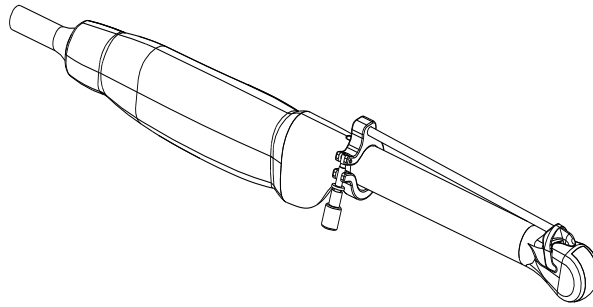


Figure 7-21 Turning the Knob 1 Clockwise

Step 3: Insert the needle into the round hole, as shown in *Figure 7-22*.

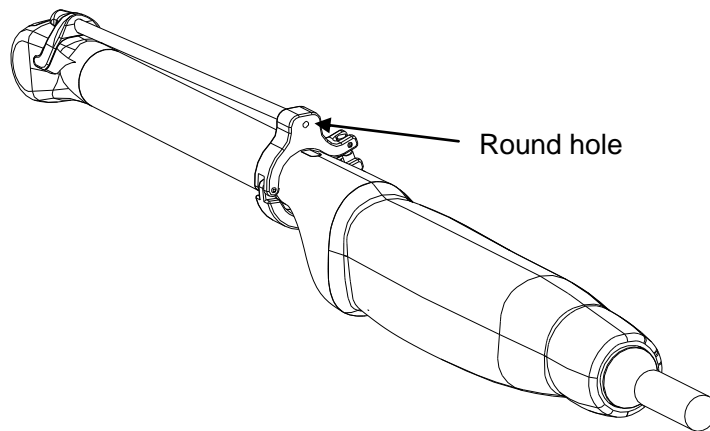


Figure 7-22 Insert the Needle into the Round Hole

7.5.2. Activating Needle Guide Function

To enable the needle guide function:

1. In the B mode imaging, press **Needle** button on touch screen, A needle touch screen UI is displayed, Press **Enable** button to active the Needle Guide function.
2. Press **Double Line** button to switch double line and single line as the Needle guide Line graphics.
3. Some needle guide brackets support multiple (up to 3) angles. If the current transducer supports such a guide then the **Angle** button appears. Pressing it cycles through the available angles.

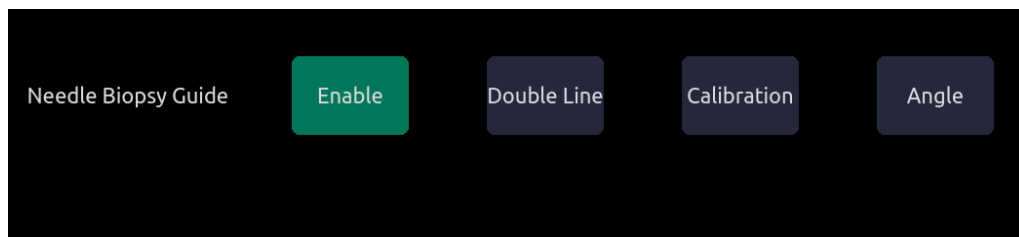


Figure 7-23 Needle Guide Touch Screen

NOTE:

The distance between each dot of the needle guide line indicates 0.5 cm.

7.5.3. To Adjust the Needle Guide Line

The needle guide bracket was calibrated during manufacture. However, certain events may cause the bracket alignment to shift, and new calibration required.

WARNING

1. Calibrate the needle guide under any of the following conditions:
 - a) The first time a needle guide is used with a given transducer.
 - b) Any time the needle guide or transducer has been dropped or struck against a hard surface.
 - c) After repeated use.
2. Do not use the needle guide bracket if the needle does not track with the guide during calibration.

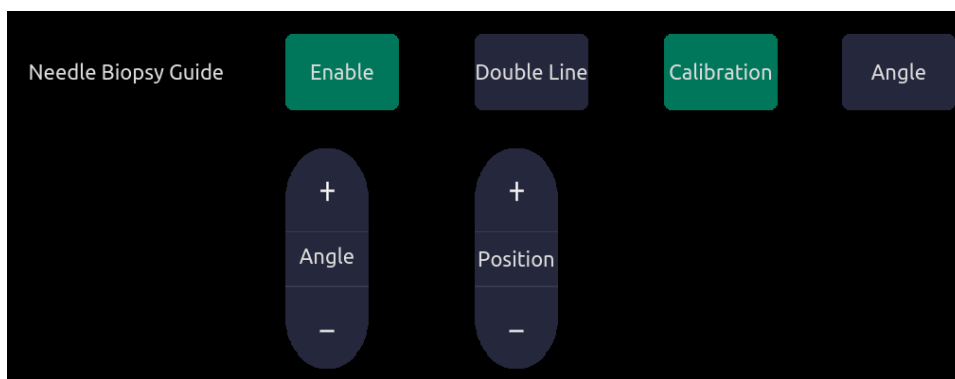


Figure 7-24 Needle Guide Calibration Touch Screen

To calibrate the guide line

1. Assemble the needle guide bracket on the transducer, and use the transducer to image a water bath or needle guide phantom.
2. From the Needle function on the B-mode touch screen, press the **Calibration** button on the touch screen to display the **Angle** and **Position** paddle button.
 - Use the **Position** paddle to adjust the line horizontally until the origin aligns with the actual needle.
 - Use the **Angle** paddle to adjust the angle of the line until the entire line aligns with the actual needle.
 - Any changes will be saved as the default value automatically.

7.6 Needle Visualization

Needle Visualization is an image processing technology that enhances needle visibility. It is available in B-mode for all linear transducers.



Figure 7-25 Needle Enhancement Visualization

Needle Visualization is invoked by pressing the **Needle** button on B-mode touch screen, and then the **Enable** button in the Needle Visualization section of the Needle touch screen. The following parameters can be adjusted when it is active.

- **Enable:** Enables or disables Needle Visualization.
- **L/R:** press to display the angle line on left side or right side of the image field.
- **Medium/Steep:** press to enhance the needle visibility for different needle inserted angles: 24° (**Medium**) and 40° (**Steep**). For best results use the angle line that is closest to perpendicular to the needle path.

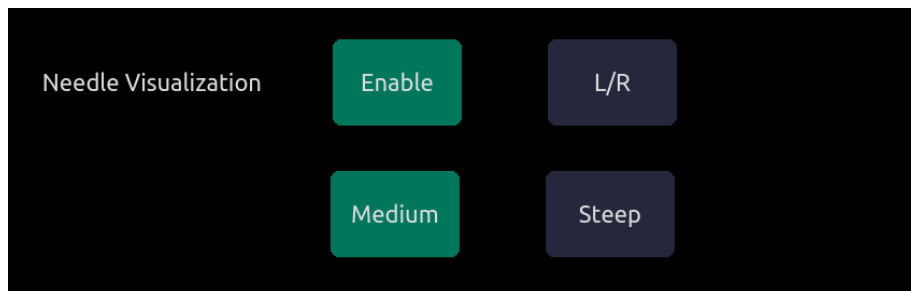


Figure 7-26 Touch Screen for Needle Enhancement Visualization

8 Presets

8.1 Preset Organization

The Acclarix AX8 Presets are divided into two levels: the Exam Presets and Application Presets.

Exam Preset: Each transducer has its own set of Exam Presets. Each Exam Preset contains:

- The image parameters that optimize its transducer for an intended use.
- The list of data fields displayed on the patient demographic page.
- Pointers to Application Presets for Comments, Measurements, and BodyMarkers.

Application Preset: The Application Presets are independent from the transducer. Application Presets are used to select Comments, BodyMarkers and Measurements. Since they are independent from the transducer, several Exam Presets can use the same Application Preset.

Figure 8-1 shows an example of how Transducers, Exam Presets, and Application Presets are related. For simplicity, this shows just a few of the items that are on the real system. In this example the C5-2XQ and the E8-4Q both have an OB Exam Preset. The C5-2XQ OB Exam Preset optimizes the C5-2XQ imaging for OB while the E8-4Q OB Exam Preset optimizes the E8-4Q for the same use. The parameters used for each transducer can be different, and changing one Exam preset does not change the other.

However, both OB Exam Presets point to the same OB Measurement Preset as the Application Preset. This means you can, for example, just configure OB measurements once, and both the C5-2XQ and E8-4Q will have updated OB measurements.

This example just shows a single kind of Application Preset. The Acclarix AX8 actually has separate Application presets for Comments ,Bodymarkers and Measurements. The same principle applies to each of these: application presets can be shared across exam presets and transducers.

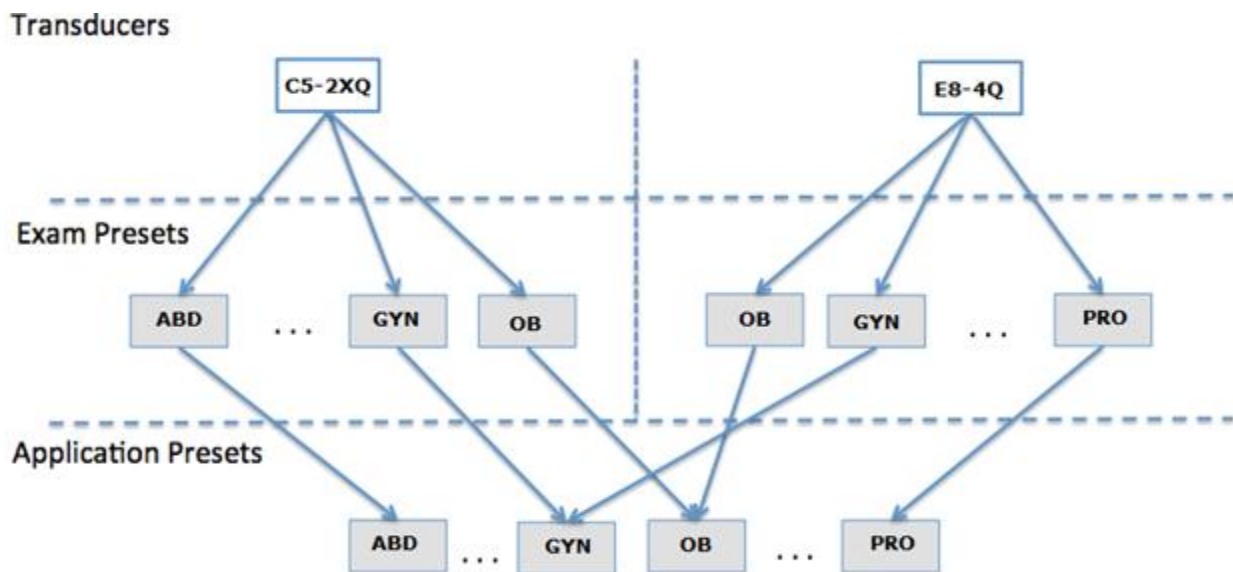


Figure 8-1 Preset Organization

8.2 Selecting a Preset

There are two ways to select a preset

The Preset Function: The preset function is invoked by pressing the Preset button in the upper left corner of the console. See figure 8-2 for an example preset touch screen. The currently active transducer is shown at the top of the touch screen. Below it are all the presets associated with that transducer. Pressing any preset button selects that preset, recalling its parameters for system use. If the system is configured with the optional Multi-Transducer Connector (MTC) this screen will show a top row of all connected transducers, allowing you to switch to any one of these and then select the preset to be used with that transducer.



Figure 8-2 Example Preset Screen

The Patient Page: An exam preset can also be selected from the patient page, typically at the beginning of an exam. A drop-down list of presets associated with the current transducer is shown near the top of the screen. Select from that drop down to change the preset. This will also change the demographic fields that are displayed.

8.3 Storing a Preset

There are two ways to store or modify an exam preset: Snapshot and Editing.

Snapshot:

- Select the exam preset you want to modify or use as the basis for a new preset.
- Make any changes you want to system settings using the standard imaging UI.
- Press the **Preset** hard key on the console.
- Press the **Save** button on the touch screen to update the current exam preset with the new setting.
- Press the **Save As** button to create a new preset and rename the preset.

Editing:

You can directly view and change the settings for any preset using the Set-up function.

- Press the **Utilities** hard key on the console.
- Press the **Set-up** button on the touch screen to invoke setup.

The screen shown in Figure 8-3 appears.

- Press **System** to edit overall system settings unrelated to presets. See section 9 for details.
- Press **Presets** to do any of the following:
 - Edit the imaging parameters of an exam preset.
 - Configure the demographic fields that appear for that preset
 - Configure which Comment, Measure, or Bodymarker presets are associated with each exam preset.
- Press **Comments** to configure the pre-defined text of each comment preset.
- Press **Bodymarker** to configure which bodymarker graphics appear with each bodymarker preset.
- Press **Measure** to configure measurement options of each measure preset.

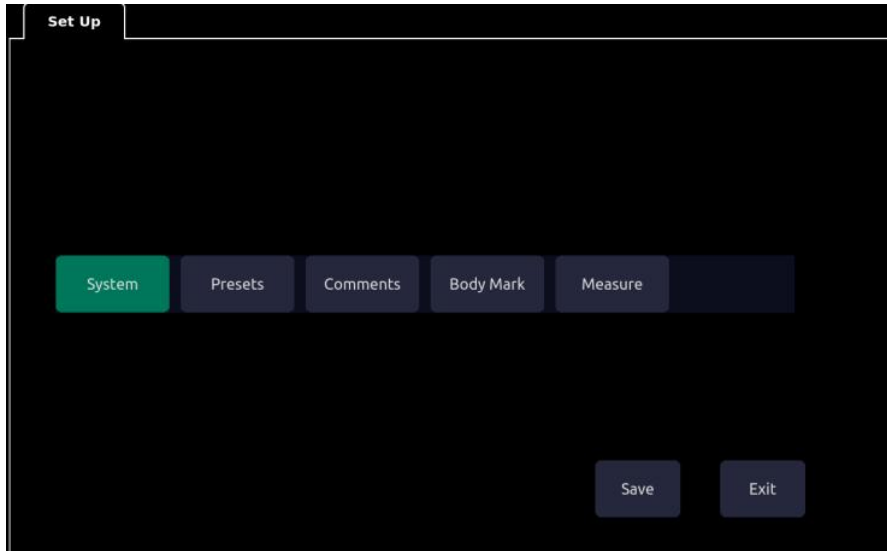


Figure 8-3 Top level Touch Screen for the Setup Function

8.3.1. Presets

Figure 8-4 shows an example of the presets page.

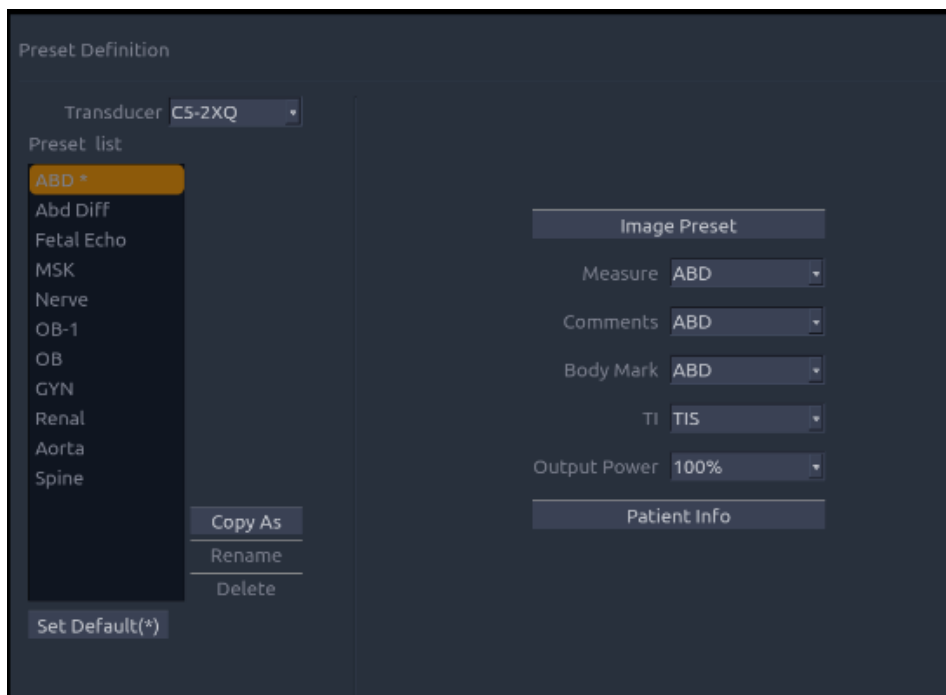


Figure 8-4 The Preset Definition Page

8.3.1.1. Editing Image Settings

Figure 8-5 shows an example imaging set-up screen for imaging parameters. This example shows the screen for editing the B-mode settings for the C5-2XQ Abdomen exam preset.



Figure 8-5: Example Set-up Screen for Imaging Parameters

Transducer and Exam Preset: There are drop-downs at the top of the screen for selecting the transducer and Exam Preset you want to edit. Each transducer has its own set of exam presets, and these two drop-downs let you select which exam preset, on which transducer, you want to edit.

Image Modes: The next row of controls show tabs for each imaging mode. These let you select which imaging mode you want to edit for the current exam preset. The example shows the B-mode tab selected.

The image mode is divided into two sections. Parameters that have one value for each preset are shown on the left. Parameters that are associated with Image Types are shown on the right.

Image Type: Each imaging mode has a set of image types. For example in B-mode the types are Detail, General, and Penetration. While imaging, the image type lets you quickly change the aesthetic look of the image without changing settings like depth or invert status. The right side of the preset set-up screen shows a tab for each image look. The parameters shown below those tabs let you customize that image type for the current preset.

8.3.1.2. Configuring Patient Info

Figure 8-6 shows an example of the Patient information configuration page. This page allows you to configure which demographic fields are shown for each exam preset.

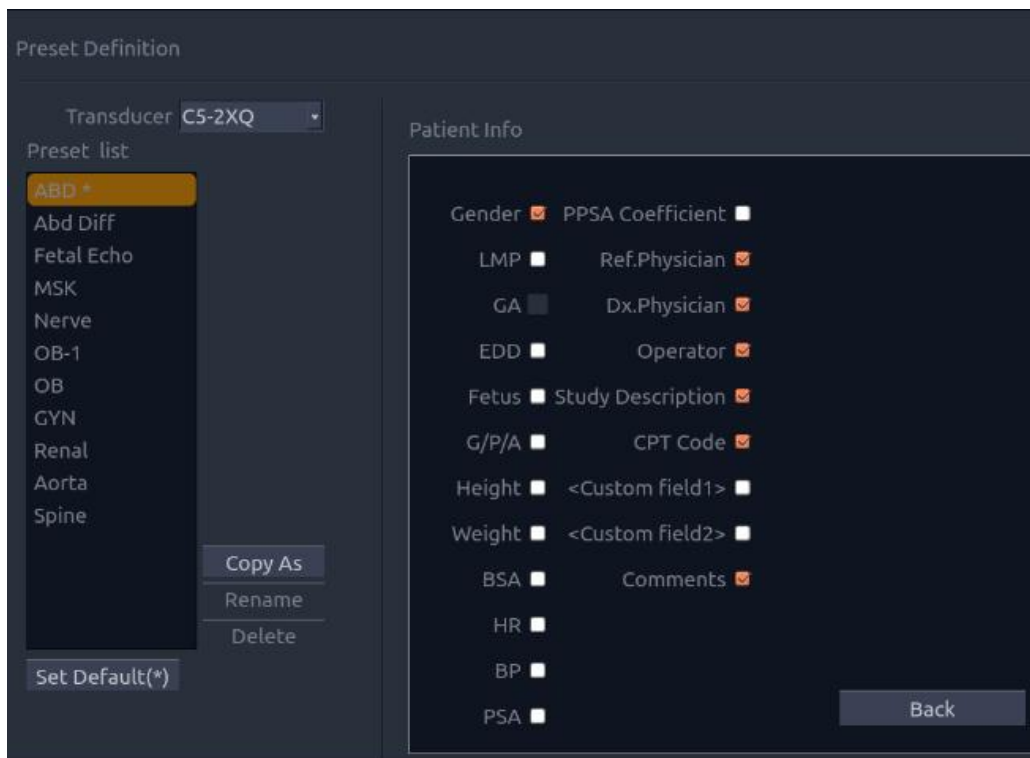


Figure 8-6 Example Patient Information Configuration Page

To change the demographic fields shown with any preset:

- Select the preset you want to configure. This can either be done at the Preset Definition level before invoking the Patient Information Configuration page, or it can be done directly on this page.
- Click the check box on any field you want to display.

8.3.1.3. Selecting Default Measurement Package

Measure: Select one of the pre-defined application measurement packages to be the default measure for the preset.

8.3.1.4. Selecting Default Comments Preset

Comments: Select one of the pre-defined comments presets to be the default comments for the preset.

8.3.1.5. Selecting Default Bodymark Preset

Bodymark: Select one of the pre-defined bodymark presets to be the default bodymark for the preset.

8.3.1.6. Selecting Default TI

TI: Select one of the pre-defined TI presets to be the default preset.

TI here includes: TIS (Soft Tissue Thermal Index), TIB(Bone Thermal Index) and TIC (Cranial Bone Thermal Index)

8.3.1.7. Selecting Default Output Power

Output Power: Select one of the pre-defined acoustic output power.

8.3.2. Comments Presets

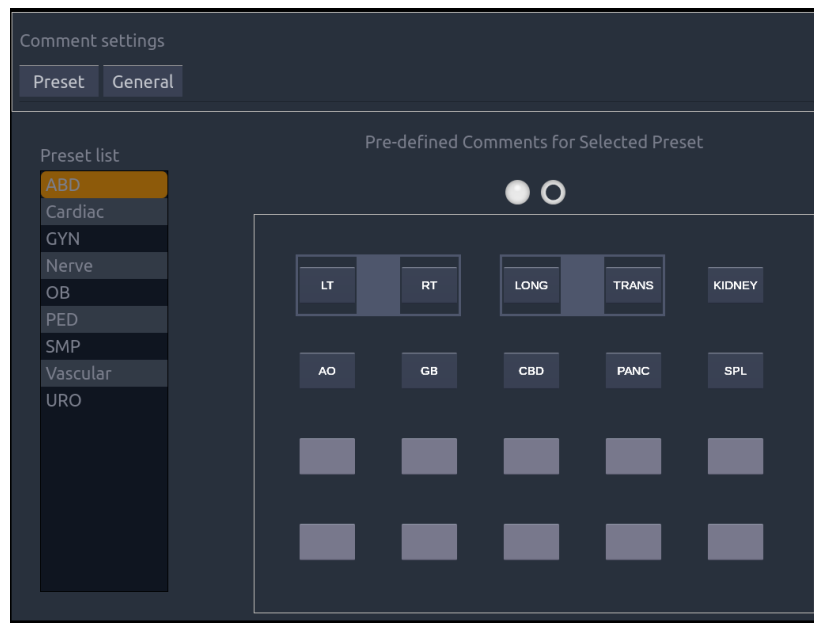


Figure 8-7 Comments Preset

Adding a new Comment:

1. Move the cursor to a blank field in the comments area and press **Set**.
2. Enter a new comment through keyboard and press **Enter** to finish editing.

Editing an Exist Comment in Comment Preset:

1. Move the cursor to a comment in the comments area and press **Set**.
2. Edit the selected comment through keyboard and press **Enter** to finish editing.

Deleting an Exist Comment in Comment Preset:

1. Move the cursor to a comment in the comments area and press **Set**.
2. Press **Delete** in touch screen to delete the selected comment.

Creating a Group of Comments:

1. Move the cursor over the intended comment then press-and-hold the **Enter** button. The selected comment will pop-up.
2. Drag the selected comment on top of an adjacent comment or insert it into an adjacent group, then Press **Set**. The selected comments are joined as one group.

Moving out a Comment from a Comment Group:

1. Move the cursor over the intended comment then press the **Set** button.
2. Press **Delete** button on touch screen. The selected comment is removed from the group.

The rest of the comments in the group will be re-ordered. If there is only one comment in the group, then the group is disbanded.

General Settings:

- **Auto-erase comments when the image is unfrozen:** If this option is enabled, the comments will be erased when the image is unfrozen, otherwise the comments will only be erased on demand or at the start of a new exam.

- **Suppress Comment on Unfreeze:** If this option is enabled the Comment function goes away when the system is unfrozen, and comes back again with the next freeze. Manually exiting the function causes it to remain inactive until manually activated.

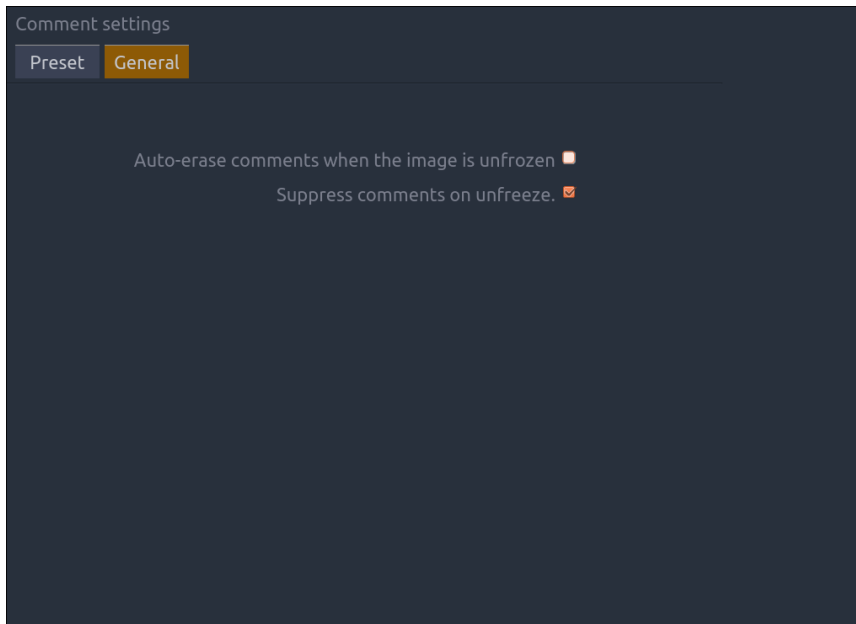


Figure 8-8 Comment Setting

8.3.3. Bodymarker Presets

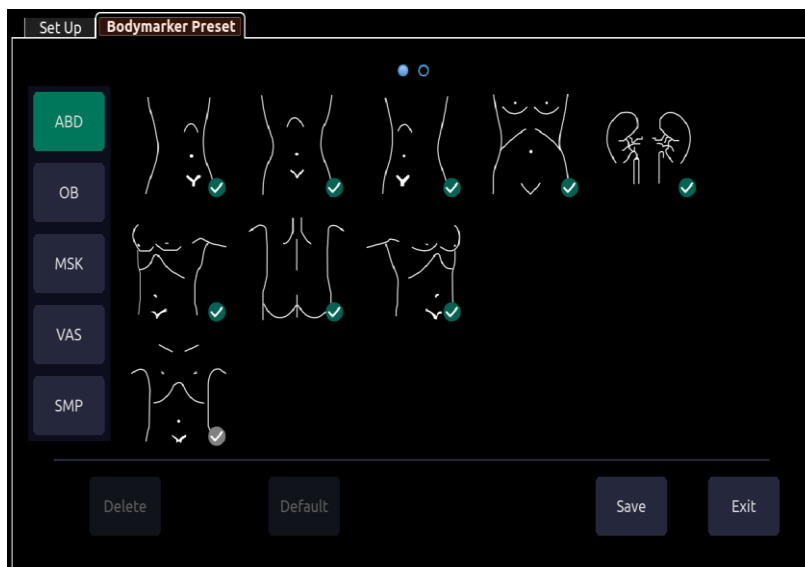


Figure 8-9 Bodymarker Preset Touch Screen

Enabling/Disabling a Bodymarker to a Preset:

Press a bodymarker on touch screen to switch it as checked or not, the bodymarker is enabled or disabled to current preset.

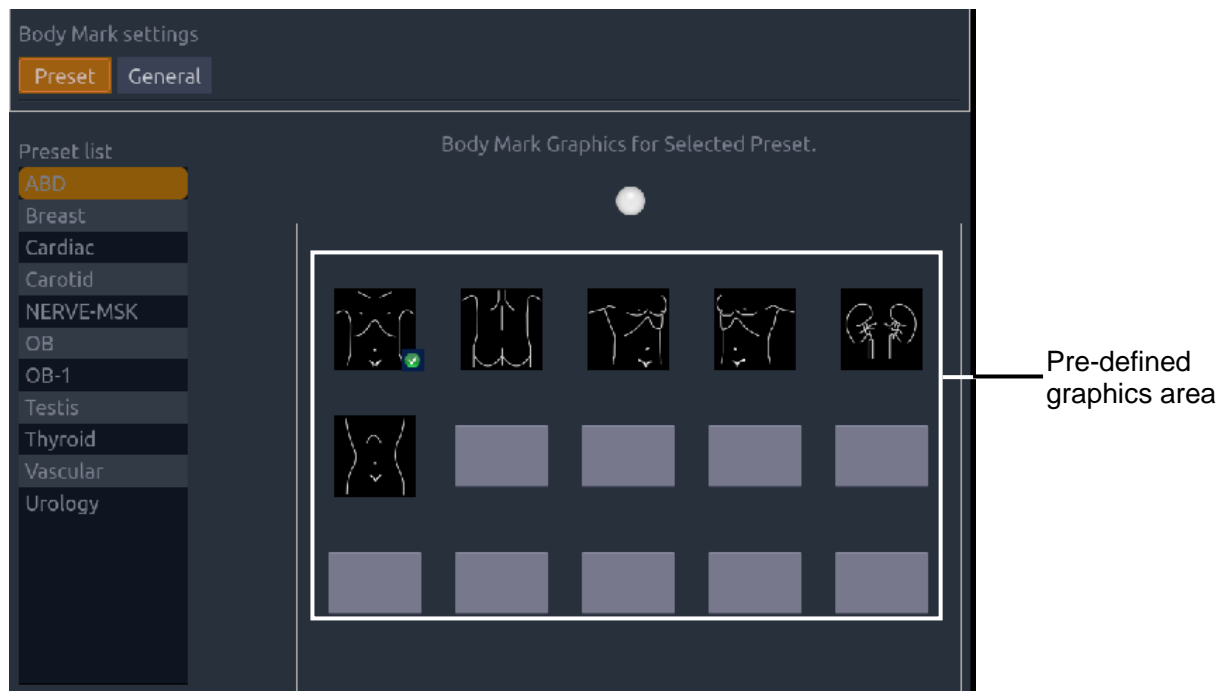


Figure 8-10 Bodymarker Preset

Deleting a Bodymarker from a Preset:

If the selected bodymarker is from a user-defined which does not point to any exam preset, you can delete it with the **Delete** button.

If the selected bodymarker is from a user-defined which points to an exam preset, or the selected bodymarker is from a default preset, the **Delete** button will be unavailable.

1. Select a bodymarker from pre-defined graphics area.
2. Press **Delete** on the touch screen.

Moving a Bodymarker in Pre-Defined Graphics Area:

1. Move the cursor over a bodymarker in pre-defined graphics area and click **Enter**.
A green box displays outside of the bodymarker.
2. Move the trackpad to a desired position and click **Enter**. To move it to another page, move the trackpad over page up or down icons.

Set a Default Bodymarker for a Preset:

Select a bodymarker from pre-defined graphics area and click **Default**, the bodymarker is set as a default bodymarker to select preset.

The default bodymarker can not be deleted from a preset until another bodymarker is selected as a default one.

General Settings:

- **Auto-erase bodymarker when the image is unfrozen:** If this option is enabled, the bodymarkers will be erased when the image is unfrozen, otherwise the bodymarkers will only be erased on demand or at the start of a new exam.
- **Suppress Body Mark on Unfreeze:** If this option is enabled the bodymarkers function goes away when the system is unfrozen, and comes back again with the next freeze. Manually exiting the function causes it to remain inactive until manually activated.

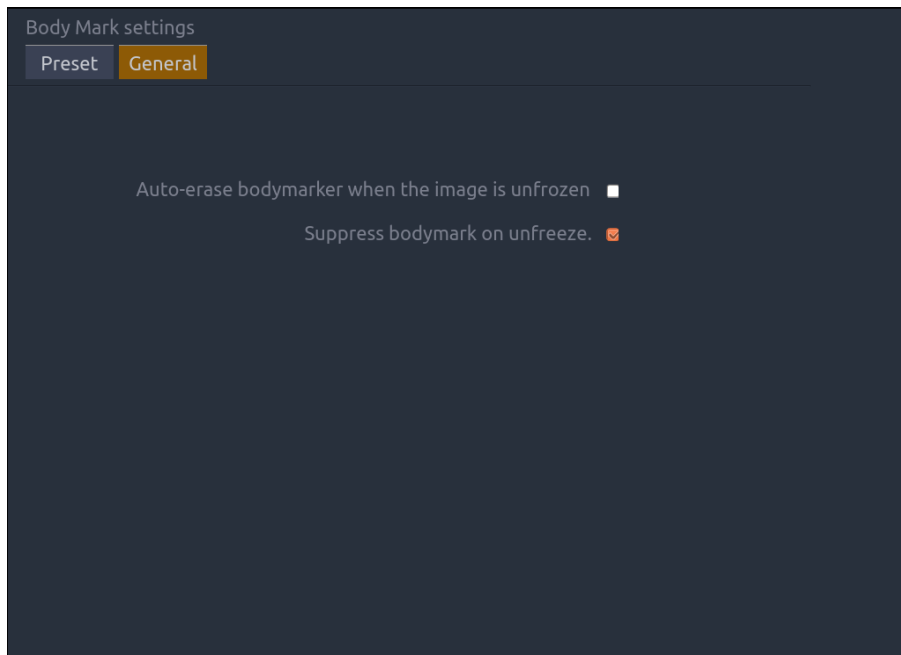


Figure 8-11 Bodymaker Preset

8.3.4. Measure Presets

The Preset UI of the Measure Presets set-up page is divided into the main screen display and the touchscreen display.

The main screen display shows the current measure presets. The list of presets is shown along the left side, and the grid of buttons to the right show the current content of the selected preset.

The touch screen display shows a library of all possible measurements that can be added to or deleted from any measure preset. The column along the left shows different clinical application types and the grid of buttons to the right show all the supported content for that application. You can add a measurement from any application to any preset.

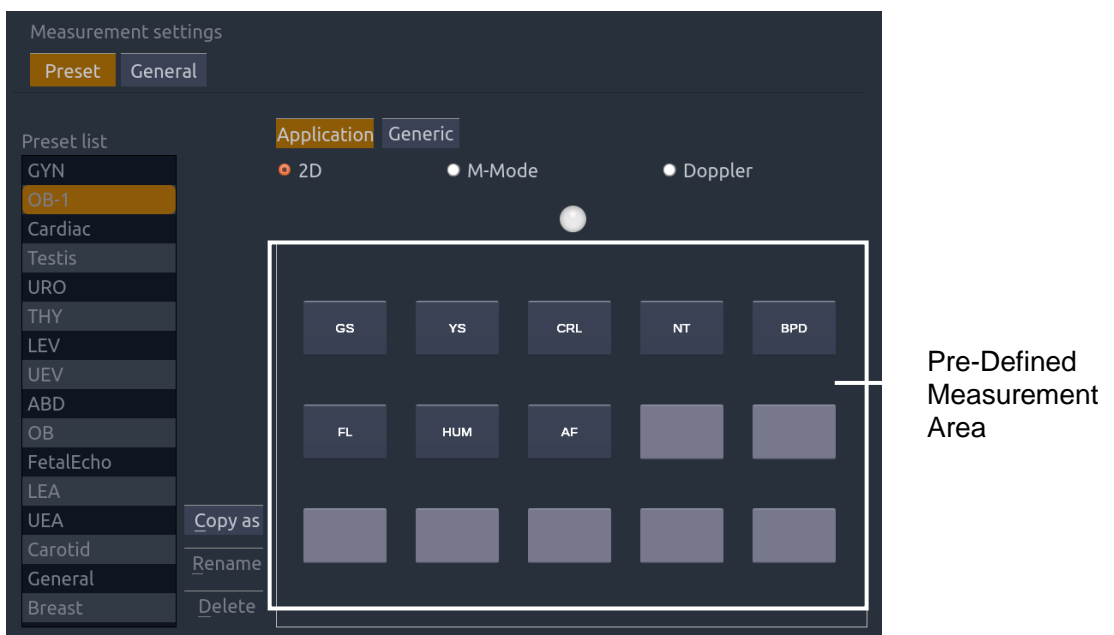


Figure 8-12 Measure Preset

Adding a new Measure Preset:

A new measure preset can be added by copying an existing preset. The new measure preset contains the same measurements as the copied preset. Select a preset from the list along the left, and then press the **Copy As** button.

Enabling/Disabling a measurement in a Preset

Select the preset you want to configure from the list along the left side of the main screen. The current contents show in the grid along the right of the main screen. Press a measurement from the measurement library on the touch screen to toggle it in or out of the selected preset.



Figure 8-13 Measure Preset touch screen

Editing an Existing Measurement in a Measure Preset

1. Select the preset you want to customize from the list along the left of the main screen.
2. Select the measurement you want to customize from the grid along the right of the main screen.
3. Press the Option button on the touch screen to customize the selected measurement.
4. If the selected measurement can be performed by different tools (Caliper, Trace, etc.) select the tool you want from the tabs provided, and check the default box.
5. Check the boxes for the results that you want to derive from this measurement.

For a Generic measurement, press **Default** button on the touch screen to configure it as a default measurement for the current selected image mode in a preset.

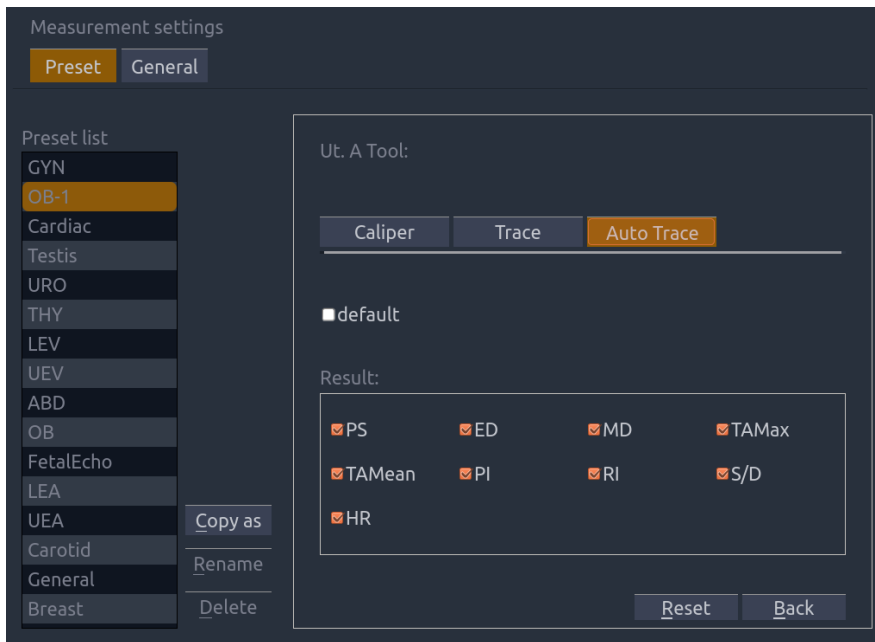


Figure 8-14 Measurement Option

8.3.4.1. General Settings

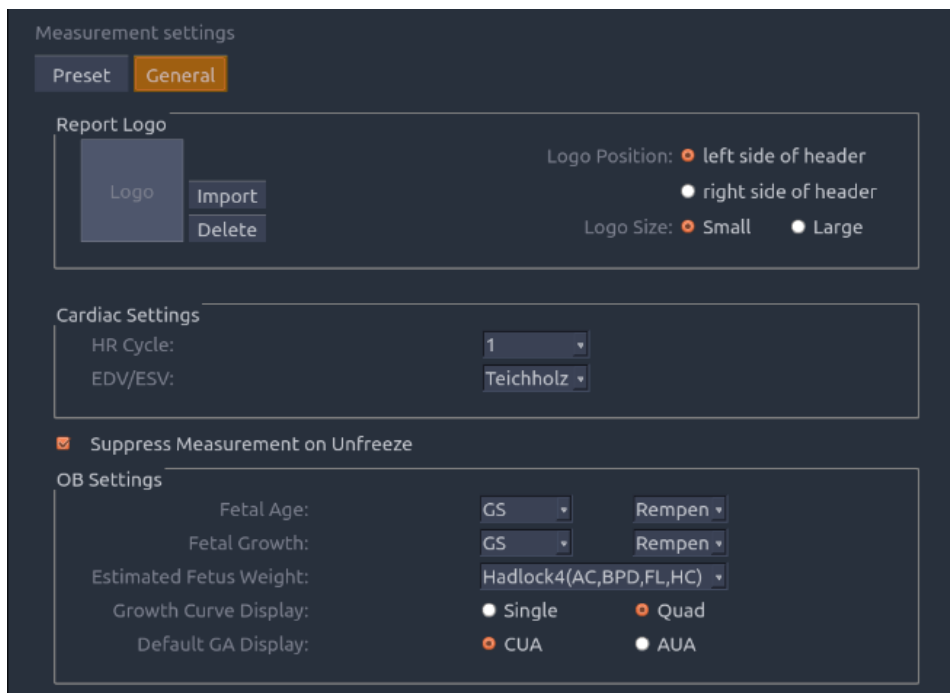


Figure 8-15 Measurement General Settings

- Report Logo

The system supports a user-defined report header by importing a logo and setting the logo’s position and size.

Report logo settings are as follows:

- Import: import a bmp format logo from USB disk.
- Delete: delete the imported logo.

- Logo Position: set the logo position to locating at the left or right side of report header.
- Logo Size: set the logo size to Small or Large.
- OB Settings

The system supports the following OB measurement settings:

 - Fetal Age: select the author / measurement options for Fetal age calculation.
 - Fetal Growth: select the author / measurement options for Fetal Growth calculation.
 - Estimated Fetus Weight: select an equation for the Estimated Fetus Weight calculation.
 - Growth Curves Display: set single or quad curves as the default display format for the Growth Curves.
 - Default GA display: set the CUA (Composite Ultrasound Age) or AUA (Average Ultrasound Age) as a default result displayed in the worksheet.
- Cardiac Settings

The system supports following Cardiac measurement settings:

 - **HR Cycle**: set the number of heartbeats that are assumed in the HR or FHR measurement calculation. Range: 1-8.
 - **EDV/ESV**: set the author of the formula that is used in EDV/ESV calculation. There are three options: Teichholz, Gibson and Cube.
- **Suppress Measurement on Unfreeze** If this option is enabled the Measure function goes away when the system is unfrozen, and comes back again with the next freeze. Manually exiting the function causes it to remain inactive until manually activated.

9 Utilities

The **Utilities** hard key provides access to setup, screen adjust, connectivity and maintenance software. Each of these is described in separate sections below.

9.1 Set-up

The Set-up function is divided into several sections, accessed by separate touch screen buttons

- System Set-up: Described in the remainder of this section.
- Presets: Supports edits of preset organization and image preset. See section 8.3.1
- Comments: Supports edits of comment presets. See section 8.3.2
- Body Mark: Supports edits of Body Mark presets. See section 8.3.3
- Measure: Support edits of Measure presets. See section 8.3.4

System setup is used to configure parameters that are unrelated to presets. Generally, there is one value of each system setup parameter that is shared across all presets.

Entering/exiting Setup:

Press **Utilities** on the control panel, the **Setup** touch screen button, and then the **System** touch screen button to access system setup.

Reloading Factory Default Set-up:

1. Press “Restore Factory Settings” on the Set-up screen, you are prompted Restore System Setting to factory default? This will erase all current system setting.
2. Press **Yes** to restore to factory default, and press **Cancel** to cancel.

9.1.1. General Set-up

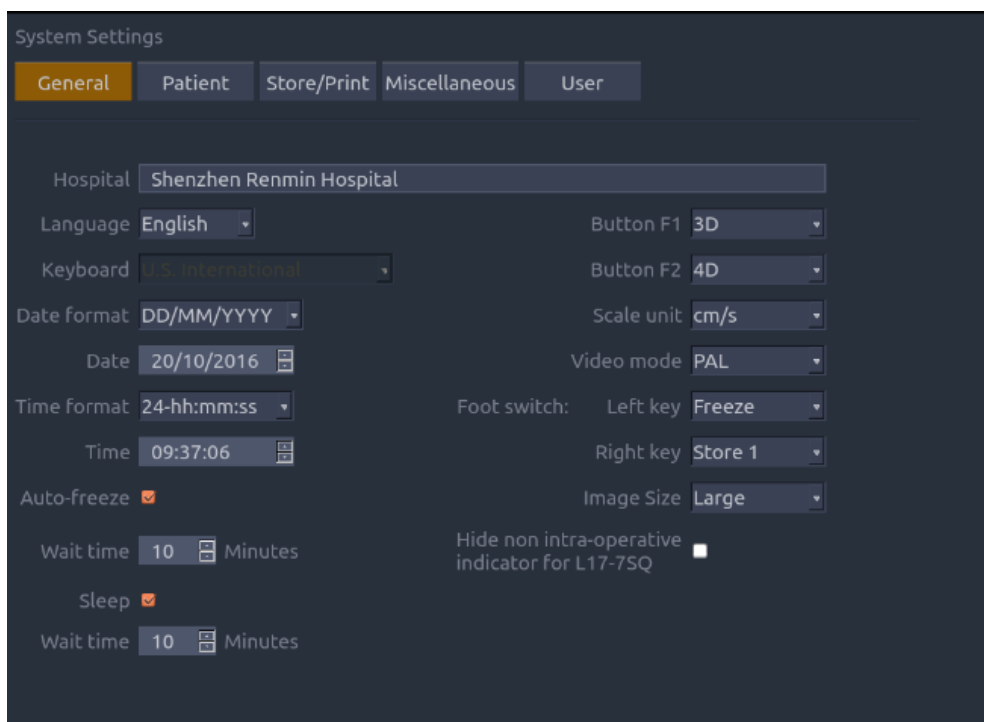


Figure 9-1 General Set-up Screen

Item	Options	Description
Hospital	Input freely	Set hospital name displayed on the top left of the screen and diagnosis report
Language	Chinese, English, German, French, Italian, Spanish, Russian, Turkish	Set the system language (new language is effective after reboot the system)
Keyboard	U.S International	Set the keyboard layout
Date Format	YYYY/MM/DD/ MM/DD/YYYY DD/MM/YYYY	Set the date format Note: If the license is invalidated because of changing the system date, please contact EDAN serviceman.
Date	Set freely	Set the system date
Time Format	12-AM/PM, 24-hh:mm:ss	Set the time format
Time	Set freely	Set the system time, format: H/M/S
Auto-Freeze& Waiting Time	√/× 1-999 min	Set whether to turn on auto-freeze function by default or not; and set the waiting time to perform auto-freeze
Sleep& Waiting time	√/× 1-999 min	Set whether to turn on system sleep function by default or not; and set the system waiting time to enter sleep mode
Button F1/F2	Color PDI DPDI CW Needle 3D 4D	Define the F1/F2 keys, select one of the pull-down options. The options that are available will depend on what functions are enabled on the system.
Scale Unit	cm/s, kHz	Set the velocity units of spectrum scale
Video Mode	PAL/NTSC	Set the output video mode, the selected video mode should be the same as that of the s-video printer, otherwise the printer can not work.
FootSwitch	Freeze/Store1/Store2/Alt Store	Set a function for the left key or right key of Footswitch. If the physical footswitch only has one button then the Left button selection applies.
Image Size	Large/Small	Set the image area size.
Hide non intra-operative indicator for L17-7SQ	√/×	Set whether to hide the hint of "non intra-operative" while using transducer L17-7SQ.

Table 9-1 General Set-up Description

9.1.2. Patient Set-up

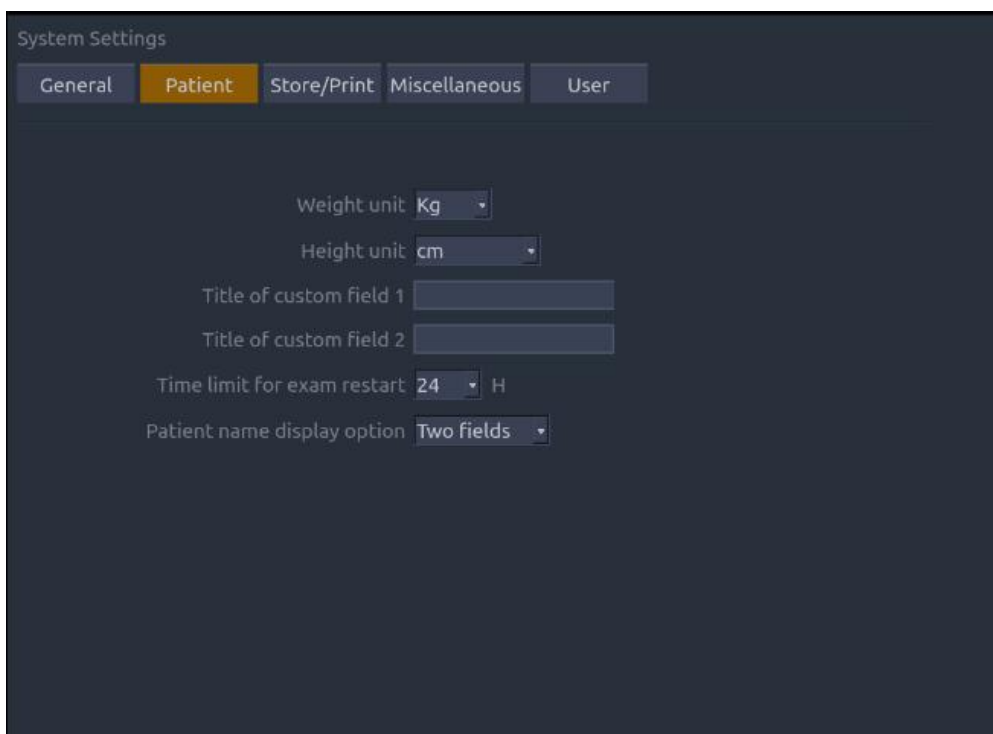


Figure 9-2 Patient Set-up Screen

Item	Options	Description
Weight Unit	kg, lbs	Set the weight unit of patients
Height Unit	cm, ft/in	Set the height unit of patients
Title of custom field 1/2	/	You can define two additional fields for data entry on the Patient Information screen
Time Limit for Exam Restart	0/12h/24h/48h/72h	You can define the time limit for restarting exam. Only exams within the time limit can be restart. If 0 is selected, no exam can be restart.
Patient Name Display Option	One field/Two fields	You can define the patient name display format. The patient information page displays “Patient Name” for one field and displays “Last Name” and “First Name” for two fields.

Table 9-2 Patient Set-up Description

9.1.3. Store/Print Set-up

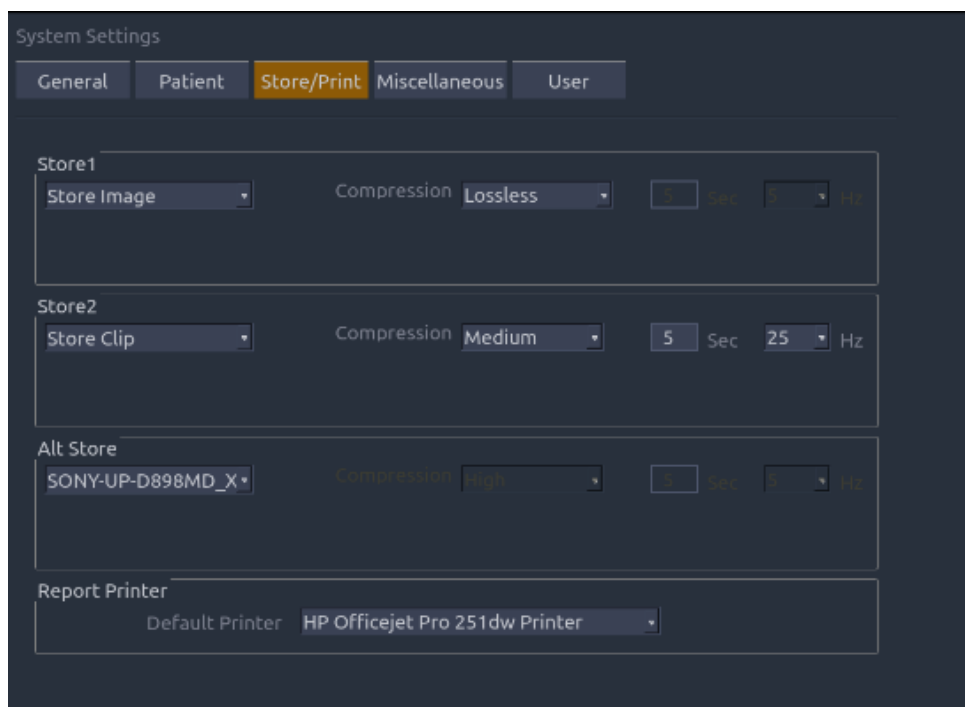


Figure 9-3 Store/Print Set-up Screen

Item	Options	Description
Store1/Store2/ Alt Store	Store Image	Store static image to internal hard disk
	Store Clip	Store clip to internal hard disk
	SONY-UP-D25MD, SONY-UP-D898MD_X898MD	Connect the corresponding printer to print the current image.
Compression	Lossless/Low/Medium/High	Set the image compression type
Duration	≤10 seconds	Set the clip capture duration
Target Frame Rate	5/10/15/20/25 Hz	Set the clip capture frame rate
Report Printer	Printer Model	Set the default report printer from the supported printers list (System supports generic HP printer models, select Generic HP printer if you cannot find the printer models in the drop-down list)

Table 9-3 Store/Print Set-up Description

9.1.4. Miscellaneous Set-up

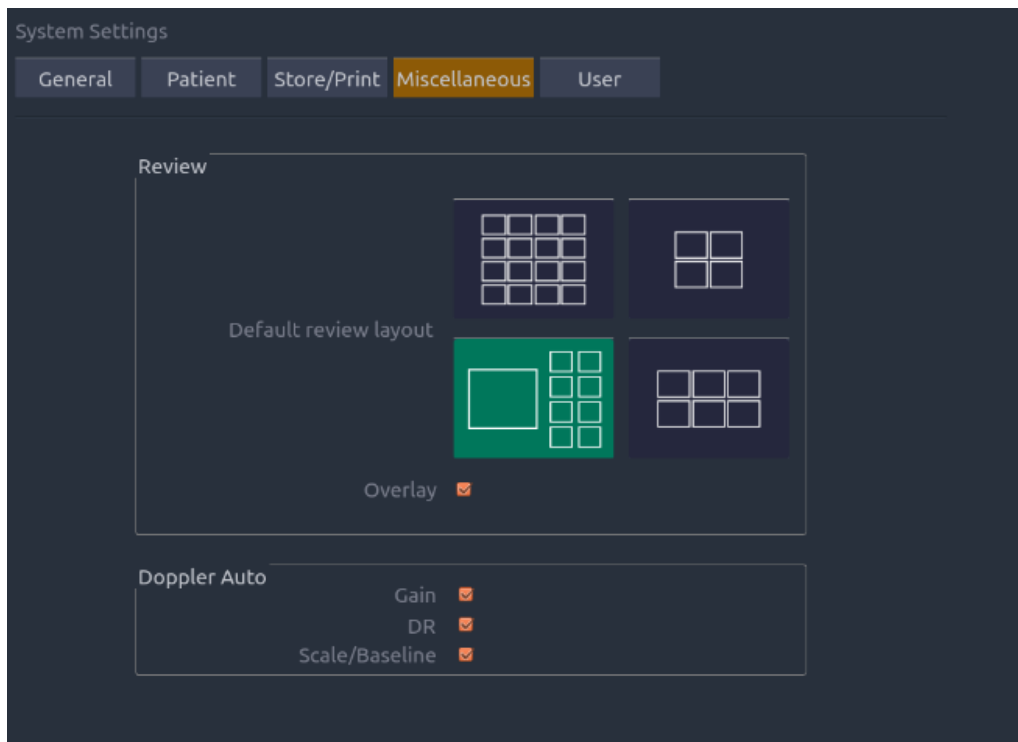


Figure 9-4 Miscellaneous Set-up Screen

Item	Options	Description
Default review layout	4*4, 2*2, 1*1, 2*3	Set the default review layout
Overlay	√/×	Show or hide overlay icons on thumbnail images
Gain	√/×	Optimize Gain or not when press auto button in PW mode.
DR	√/×	Optimize Dynamic Range or not when press auto button in PW mode.
Scale /Baseline	√/×	Optimize scale/Baseline or not when press auto button in PW mode.

Table 9-4 Miscellaneous Set-up Information

9.1.5. User Set-up

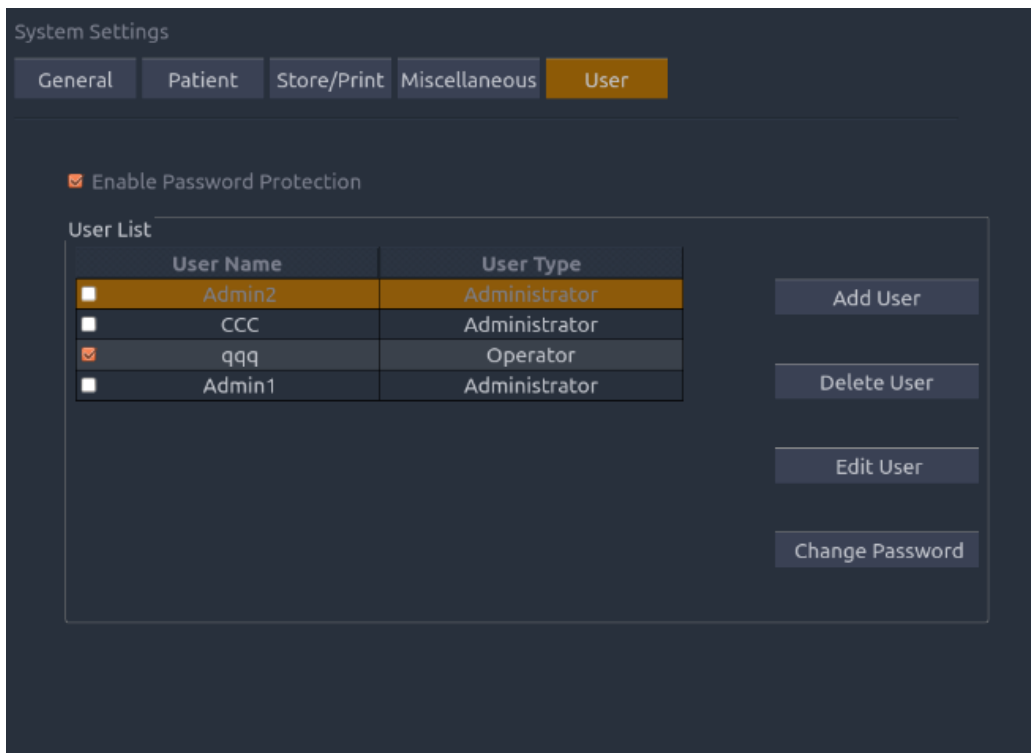


Figure 9-5 User Set-up Screen

Item	Options	Description
Enable Password Protection	√/×	Show or hide the login dialog when booting up the system.
User List	√/×	Show all users displaying user name and user type. Click the dialog before the user to select this user for edit operation.

Table 9-5 User Set-up Information

User type includes Administrator and Operator.

- Administrator users have authority to enable/disable password protection, add/delete/edit users and can view all exams in the patient database. There are two pre-defined administrator users called Admin1 and Admin2.
- Operator users can only edit their own user information, change their own password, and view exams that they created. There's one pre-defined operator user called Emergency for Emergency login without entering password described below.

There's a couple of buttons for different user edit operation. It includes Add User, Delete User, Edit User, and Change Password.

Add User: Click it to add user in the user list.

Change Password: Click it to change the password of the users.

Delete User: Click it to delete the highlighted user in user list.

Edit User: Click it to modify the user information.

9.2 Connectivity

The Connectivity screens support configuration of network access and services. It is divided into 3 tabs:

- **TCP/IP:** Configures access to the network from the AX8.
- **DICOM:** Configures network DICOM services.
- **Network Store:** Configures non-DICOM storage to a network via FTP.

9.2.1. TCP/IP

This screen configures access to a network. Access can be either wired or wireless*.

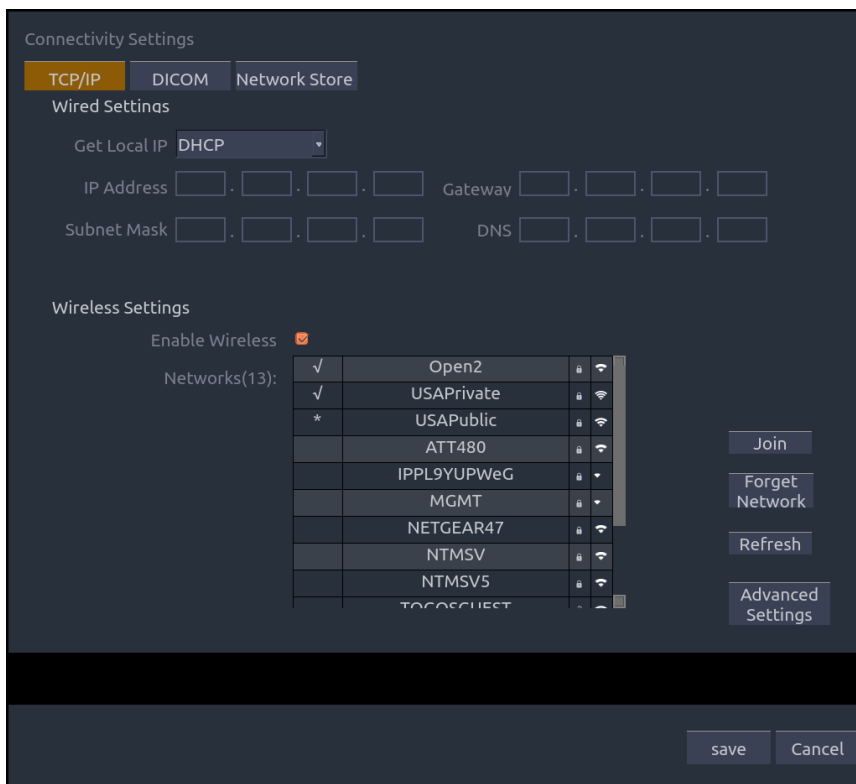


Figure 9-6 TCP/IP settings

Wired Settings:

The following settings apply when connecting an AX8 to a wired network via the network port on the side of the system.

Get Local IP: Either Manually entered (Static) or DHCP. The correct setting will depend on how your DICOM network is administrated. If you are unsure, try DHCP first. Generally a Static IP is only needed if the target PACS system requires it. If it is needed, contact your network IT manager.

IP Address, Subnet Mask, Gateway, DNS: These settings determine how the AX8 communicates with your network. If you chose DHCP then your network router will set these automatically. If you chose Manually Entered IP then contact your network IT manager for the appropriate settings.

Wireless Settings:* (*note: availability of this feature will depend on local regulatory status*)

Enable Wireless: This will turn the wireless radio on/off. No wireless networks are

displayed when this is disabled.

Networks: When wireless is enabled the system will search for wireless networks that are available and display them in this list. Networks that have been previously accessed will show up with a checkmark (“√”). If there is currently an active network it will show up with an asterisk (“*”). If the network requires a password it shows up with a lock icon. Each displayed network shows the strength of the wireless signal.

Refresh: Clicking on this button updates the list of displayed networks.

The following controls require that a wireless network has been selected from the network list. Click on the name of a network to select it.

Join: This joins the selected network. If a password is needed a dialog box will be displayed to enter it.

Forget Network: This forgets any password of the selected network that had been entered, but the network is still shown in the list.

Advanced Settings: This brings up a dialog box with additional settings for the selected wireless network. The dialog box includes the following:

- **Password:** This is useful when the network password has changed.
- **Method:** Either Manually entered (Static) or DHCP. Generally wireless networks use DHCP, and a Static address is only needed if required by the target PACS system.
- **IP Address, Subnet Mask, Gateway, DNS:** If you chose DHCP then your network router will set these automatically. If you chose Manually Entered IP then contact your network IT manager for the appropriate settings.

9.2.2. DICOM

This screen configures DICOM services, including Store and Modality Worklist.

Local Settings:

These settings determine how the AX8 communicates with other DICOM devices. These are required for both Store and for Modality Worklist.

Figure 9-7 DICOM Settings

Local AE Title: Any 16 characters that uniquely identify this system on your DICOM network. The default “EDAN_STR_SCU” will work unless you have multiple Edan systems on your network.

Time Out, Transfer Syntax: These determine how the DICOM messages are configured. The AX8 default settings are common, and you will typically not have to change them. If Ping works, but Verify does not, you may need to review the conformance statement of your server to determine the proper settings for these.

DICOM Store: Determines when DICOM images and clips are sent to the server. The options are:

- **Transfer on demand:** Images and clips are only sent when you manually send them. When there is no exam in progress the Review hard key will show a list of all exams on the hard drive. Select an exam and press the Send button at the bottom of the screen.
- **Auto-Transfer when Store:** Each image or clip is sent automatically when it is captured. This has the advantage that images and clips are immediately available for review at the server while the exam is in progress. It has the disadvantage that, due to the nature of DICOM, images that are already sent can not be deleted from the server from the AX8.
- **Auto Transfer when End Exam:** Images and clips are sent automatically when the exam is ended. This is the most common setting.

Server Settings:

Server list: The main interaction in this section is a list of configured servers. It starts off as an empty list, and grows as servers are added. Most sites will only use one server, but if the system is moved between locations then multiple servers may be entered. Clicking in any field in this list will select that server. Depending on the exact level of software a second click may be needed to edit that field. The fields are:

- **Default:** A check mark on the left side indicates which server is the default for Auto-Transfer.
- **Name:** The name of the server that appears in the drop-down list of the patient database
- **AE Title, IP Address, Port, Max PDU:** These are the settings of the destination DICOM server; it's how the AX8 finds the DICOM server on your network. The AE title and IP Address are unique to your network; contact your network IT manager for these settings. The most common setting of Remote Port for DICOM servers is 104, although your server may be different.

Testing the server: There are two tests to ensure that the server information is entered correctly. Click on any field for a given server to make that server selected, then:

- **Ping:** A successful Ping means that the AX8 can communicate with the server at a low-level; basically that the two computers 'see' each other. As a security measure, some servers on the Internet may be configured to not respond to a Ping even if the connection is successful.
- **Verify:** A successful Verify means that the AX8 can communicate with the server at a DICOM level; basically that the DICOM on both computers understand each other. A successful Verify will typically mean that your DICOM configuration is correct.

Other controls:

- **Add:** Adds another line in the list of servers.
- **Delete:** Deletes the selected server.
- **Default:** Makes the selected server the default for Auto-transfer.

Modality Worklist: Modality Worklist will query the configured server for a list of all ultrasound exams scheduled within the configured date range.

Enable: Turns Modality Worklist on/off.

Update Worklist: Determines when the worklist is updated. Choices are:

- **On Demand:** Updates only when the Update button is pressed from the patient page.
- **Every 15 Minutes:** Updates on power-up and then regularly every 15 minutes.
- **Every hour:** Updates on power-up and then regularly every hour.
- **On Start of Exam:** Updates when the patient page is displayed at the start of each exam.

Comment Source: Modality Worklist can fill the ultrasound comments section from the server. Depending on

- **Patient Comments:** Obtains comments from DICOM tag (0x0010,0x4000);
- **Scheduled Procedure Description:** Obtains comments from DICOM tag (0x0040,0x0007)
- **Comments on Schedule Procedure:** Obtains comments from DICOM tag (0x0040,0x0400)

Worklist Server: Selects the server to query for the worklist. Options include any server configured in Server Settings (see previous section).

Date Range: The range of dates for the worklist query. Note, the option of "Yesterday and Tomorrow" includes today's exams.

9.2.3. Network Store

This screen configures the system to connect to an FTP server on the local network. This allows the system to store .avi and .bmp files to a local server without using DICOM. To use this, a PC or server needs to be configured as an FTP server on the local network. The mechanism to do this depends on the operating system used. Please contact your local IT support for assistance.

Once configured, studies can be sent to the FTP server from the Exam Database shown in Review. Studies are sent to the configured folder, where each study appears in a separate folder with the name of the patient and the study date.

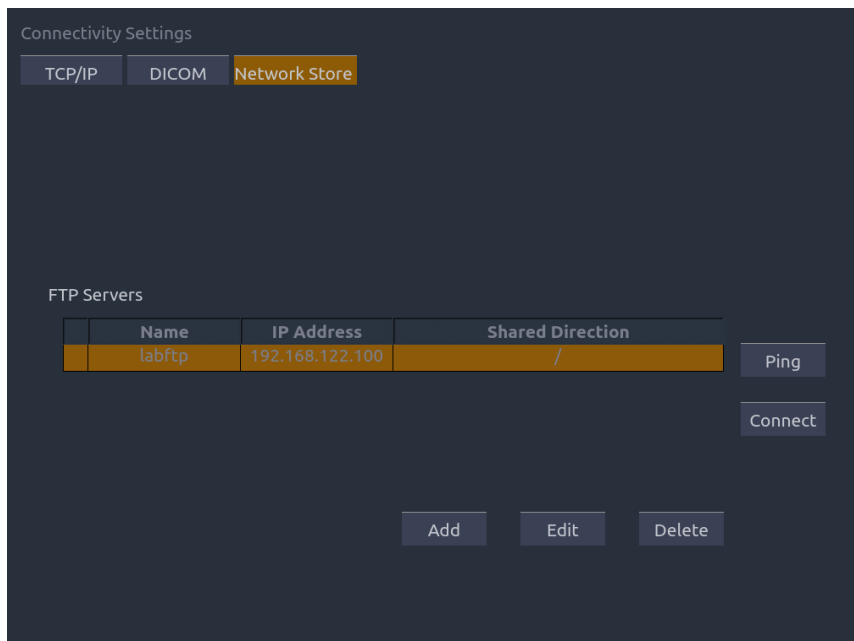


Figure 9-8 Network Store Settings

FTP Server list: The main interaction in this section is a list of configured servers and directories. It starts off as an empty list, and grows as servers are added. Most sites will only use one, but if the system is moved between locations then multiple entries may be useful. Clicking in any field in this list will select that server.

- **Name:** The name of the server that appears in the drop-down list of the patient database
- **IP Address, Shared Directory:** These are the address of the FTP server and the directory used on that server.

Testing the server: There are two tests to ensure that the server information is entered correctly. Click on any field for a given server to make that server selected, then:

- **Ping:** A successful Ping means that the AX8 can communicate with the FTP server at a low-level; basically that the two computers ‘see’ each other. As a security measure, some servers on the Internet may be configured to not respond to a Ping even if the connection is successful.
- **Connect:** A successful Connect means that the AX8 can communicate with the FTP server, and FTP transfers will work. If this fails but Ping works it could mean:
 - The destination computer is not correctly configured as an FTP server.
 - The password on the server has changed. Use Edit to re-enter the password.
 - The Shared Directory does not exist. Use Edit to confirm the directory.

Add: Adds another line in the list of servers. This automatically invokes Edit.

Edit: Available when an FTP Server has been selected. This invokes a dialog that edits the IP address, name, directory, and password.

Delete: Available when an FTP Server has been selected. This deletes the selected server.

9.3 Maintenance

The Maintenance screens provide access to controls that are not typically needed during normal operation of the system.

9.3.1. License

The **License** page displays which features are currently licensed for use on the system. At the top of the screen is displayed the current license key. Below that is a list of all licensable features, along with its current status. The system supports temporary trial licenses. If a feature is so licensed the expiration date is also shown.

- Press **Import** button to import a license file from a USB external storage device.
- Press **Revert** button to restore the previous license if the imported license is not correct.

Please contact your distributor or Edan service engineer to obtain a new license key.

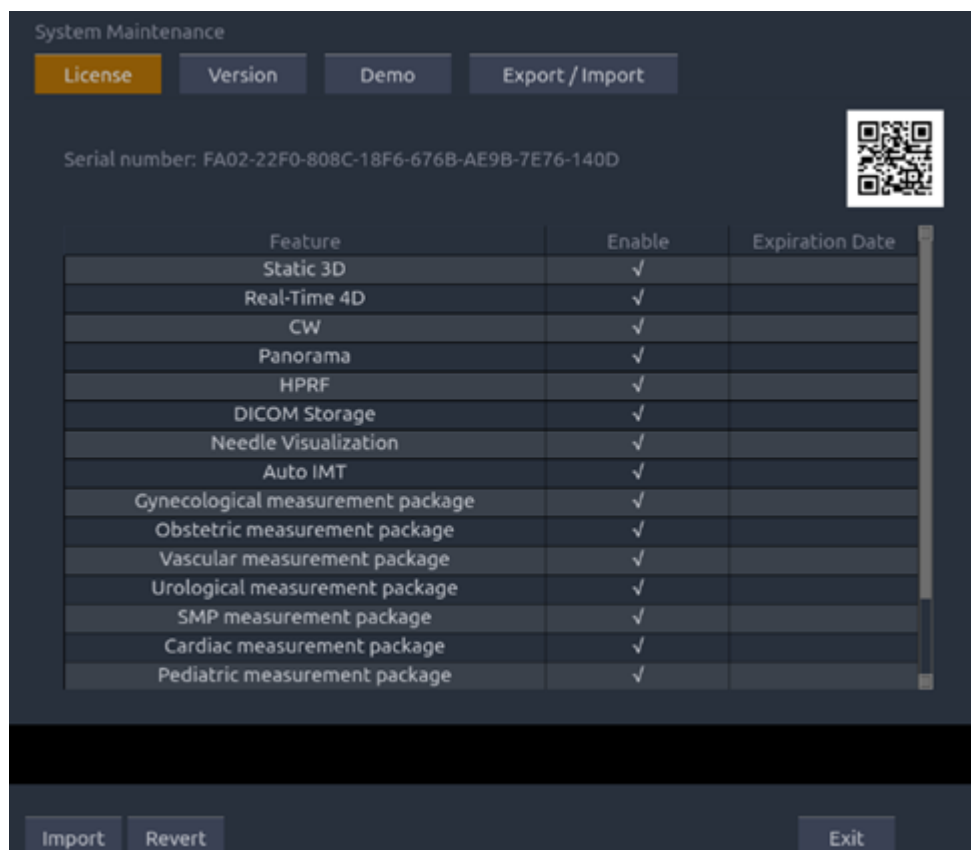


Figure 9-9 System License Screen

9.3.2. Version

The **Version** screen shows the current version of software, firmware, and selected hardware for the system. This information is only needed if requested by an Edan service engineer. This page also includes an **Upgrade**, **Import Config** and **Show Config** button. Any released

upgrade will include instructions regarding use of these buttons.

9.3.3. Demo

A Demo exam is a special exam with a patient name of “Demo”. It allows you to collect any set of images from multiple exams. To create a Demo exam:

1. Export the images you want as DICOM format from the system to a USB external storage device. (See section 7.4.3)
2. Using a computer, create a folder named “Demo” under the folder “Edan_Image” on the USB external storage device.
3. Move the exported images to the “Demo” folder.
4. Connect the USB external storage device to a system, Press **Utilities** hard key, select **Maintenance** → **Demo**.
5. Press **Import** button, and select the USB device.
6. Press **OK** to start copying the images from the USB device to the Demo exam.

If “Show Demo exam in Exam Database” is enabled the imported Demo exam will show up in the Exam Database list.

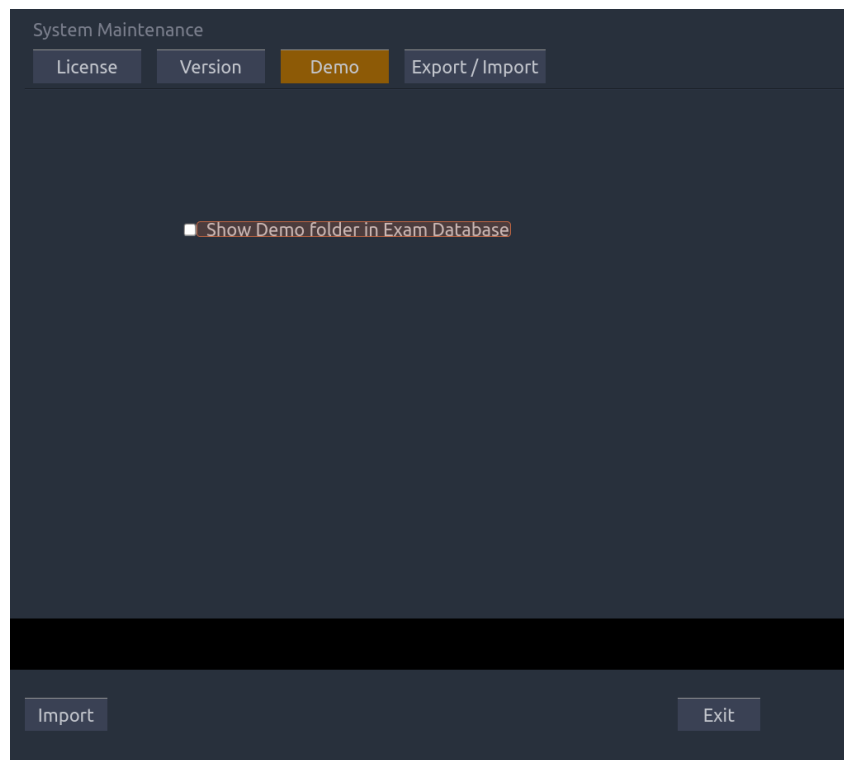


Figure 9-10 System Demo Screen

9.3.4. Export/Import

The system supports export/import of user-configured presets and settings to an external storage device. This same UI supports the export of system log files.

To export user data:

1. Press **Utilities** hard key, select **Maintenance** → **Export/Import** → **Export**.
2. Select an external USB storage device.
3. Check the items to be exported: **Image Presets, Comment Presets, Body Mark Presets, User Settings, System Log, Findings**. The Preset items can be expanded to select a specific preset.
 - Each type of preset can be expanded using the arrow graphics on the left side. This allows you to export/import any subset of any type of preset.
4. Press **Export** button to begin the export process.

The **User Settings** includes all system setting data described in section 9.1. It also contains the links between layers of presets. For example, suppose a system has a user-created comment preset that was named 'my_ABD_comments' that was linked to the Abdomen exam preset on that system. Exporting those presets and then importing them to a different system would not link 'my_ABD_comments' to the Abdomen exam preset on the new system, unless the User Settings were also exported/imported.

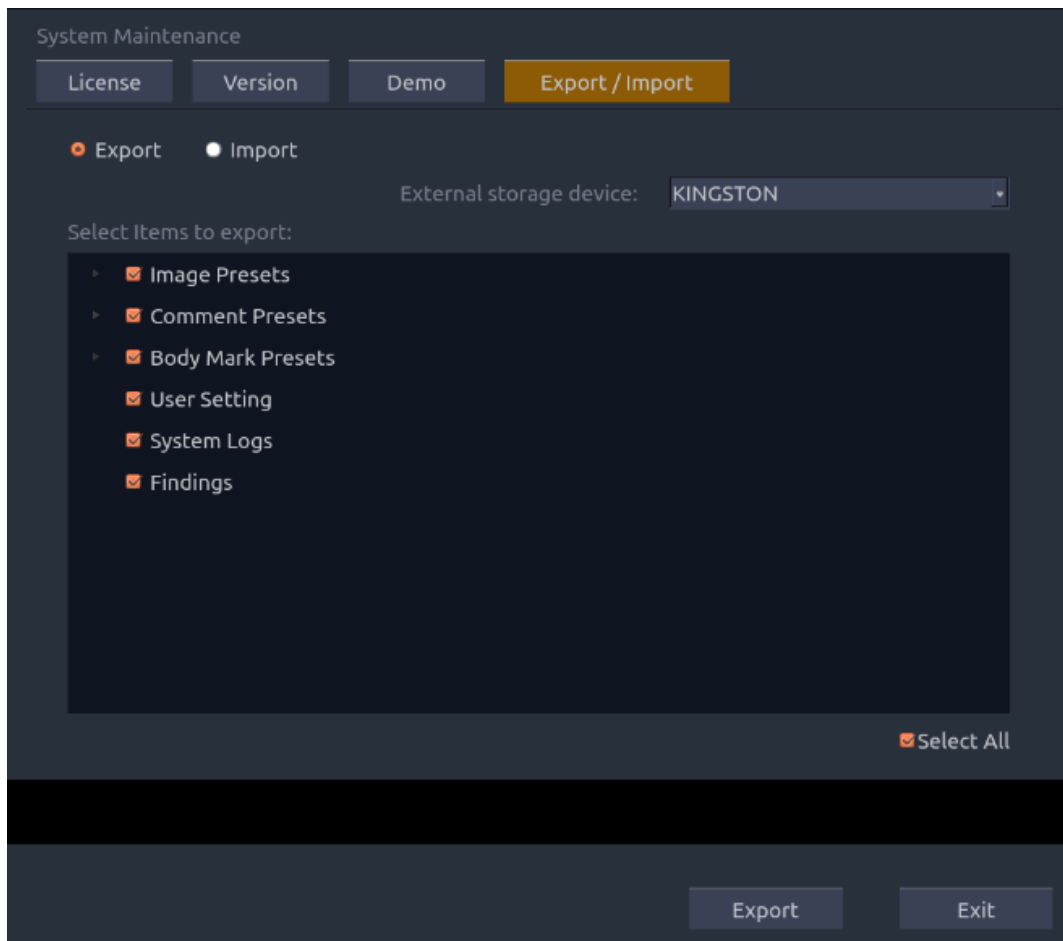


Figure 9-11 System Export Screen

To import user data:

1. Press **Utilities** hard key, select **Maintenance** → **Export/Import** → **Import**.
2. Select an external USB storage device, all the presets on it will be loaded and displayed. The Presets must have been previously exported from a system.

3. Check the items to be imported: **Image Presets, Comment Presets, Body Mark Presets, User Settings, Findings**. The Preset items can be expanded to select a specific preset.
4. Press **Import** button to begin the import process.

Note: Import of **System Logs** is not supported.

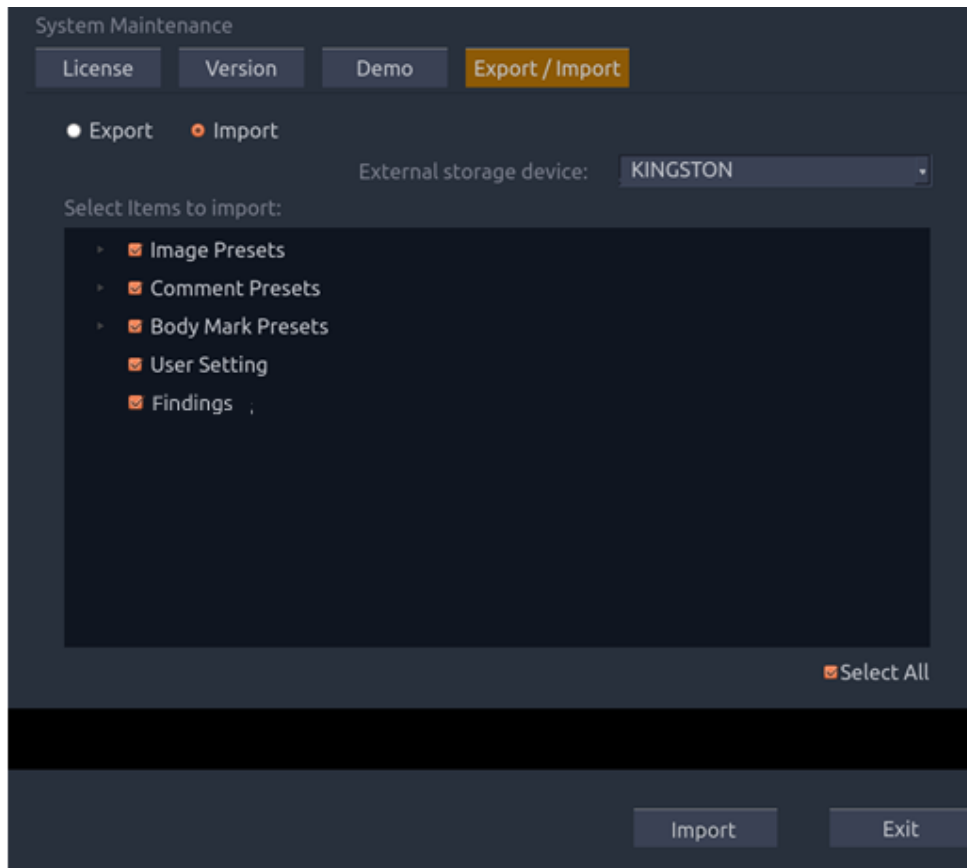


Figure 9-12 System Import Screen

9.4 Screen Adjust

The brightness and contrast of the monitor and touch screen in the system can be customized. Press **Utilities** hard key, select **Screen Adjust** to customize the brightness and contrast:

- **Main Screen Brightness:** adjusts the brightness value of the monitor.
- **Main Screen Contrast:** adjusts the contrast value of the monitor.
- **Touch Screen Brightness:** adjusts the brightness value of the touch screen.
- **Touch Pad Brightness:** adjusts the brightness value of the touch pad.

Press **Restore Default** button to restore the factory settings for all the brightness and contrast values.



Figure 9-13 Screen Adjust Screen

10 In Between Exams

10.1 Unpacking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage. After unpacking the device, you should follow the packing list to check the product carefully and to make sure that no damage has occurred during transportation. Then, install the device according to the installation requirements and methods.

WARNING

1. Do not use the device if it is found to be damaged or defective.
 2. Do not drop or collide with the transducer. Otherwise you shall give up using it.
 3. Make sure the AC power supply complies with the following specifications:
100V-240V~, 50Hz/60Hz.
-
-

10.2 Transport

The system is designed to be portable and easily transported. Power off the system and secure all accessories before moving it to another location.

CAUTION

- 1 Switch off the ultrasound system. Unplug the AC adapter from the power source and secure the power cable.
 - 2 Remove the transducer and place them in a safe place.
 - 3 Disconnect and secure the connecting cable.
 - 4 Connect optional system accessories.
 - 5 Secure the system and complete the system setup, and then perform all the daily checking before using it.
-
-

To prepare the system for shipment over long distances or rough terrain, repack the system in the factory packing

To prepare the system for transport over distances: load the system into a vehicle using a lift gate.

To prevent lateral movement of the system, secure the system with cargo straps. To prevent sudden jarring of the system during transport, provide anti-shock cushions beneath the system.

It is suitable for transportation by air, railway, highway and ship. Protect the system from inversion, collision, and splashing with rain and snow.

10.3 Storage

- ◆ Do not place the device near the ground, walls or the roof.
- ◆ Keep good indoor ventilation. Avoid strong and direct sunlight, and erosive gas.

11 Order List

The following accessories are recommended for use on the Acclarix AX8.

WARNING

Only accessories supplied or recommended by EDAN can be used, the battery and transducers of EDAN can be only used on EDAN's systems. Otherwise, the performance and electric shock protection cannot be guaranteed. If electrical or mechanical equipment from other companies need to be connected to the device, please contact EDAN or authorized representatives before connection.

Part Name	Part Number
Transducer C5-2XQ	02.01.211389
Transducer L10-4Q	02.01.211855
Transducer L17-7HQ	02.01.211856
Transducer E8-4Q	02.01.211392
Transducer P5-1XQ	02.01.211391
Transducer L17-7SQ	02.01.211857
Transducer C5-2Q	02.01.212622
Transducer MC8-4Q	02.01.212625
Transducer L12-5Q	02.01.212623
Transducer C5-2MQ*	02.01.211474
BGK-C5-2 Needle Guide Bracket Kit	02.01.211006
L40UB Needle Guide Bracket Kit	02.01.210407
CR10UA Needle Guide Bracket Kit	02.01.102963
R15UB Needle Guide Bracket Kit	02.01.210618
BGK-P5-1X Needle Guide Bracket Kit	02.01.210985
Main Lithium-Ion battery	21.21.064246
UPS Battery	01.21.064353
Adapter	21.21.064243
Power Cable, European Standard	01.13.036638
Power Cable, American Standard	21.13.036384
Ultrasound Gel	01.57.78008

USB Disk	11.18.052245
Trolley MT-807	83.63.560199
Footswitch(single button)	01.10.000910
Fottswitch(doule button)	01.10.027323
Suitcase	01.56.466102
Multi-Transducer Connector(MTC)	83.63.560232

NOTE: The part name may vary depending on context, but the part number is constant.

12 Troubleshooting and Maintenance

In order to ensure proper system operation and function, a maintenance and inspection plan should be established to periodically check the safety of the system. If any system malfunction is experienced, contact EDAN or authorized representatives.

12.1 Daily Checklist

Check before the system is switched on, if any system malfunction is experienced, eliminate the malfunction before use, or contact EDAN or authorized representatives for service if needed.

- ◆ Visually inspect all the transducers. Do not use any damaged transducer.
- ◆ Visually inspect all the transducer assembly cables and associated connectors.
- ◆ Visually inspect all the cords. Do not turn on the power if a cord is frayed or split, or shows signs of wear.
- ◆ Verify that the controls are clean and free from gel or contaminants.

Check after the system is switched on:

- ◆ Visually check the on-screen display and lighting. Verify that the monitor displays the current date and time and there isn't any error message.
- ◆ Verify that the transducer identification and indicated frequency on the screen are correct for the activated transducer.
- ◆ Ensure that there isn't obvious abnormal noise, discontinuous image or dark area.
- ◆ Ensure that it isn't smelly or too hot.
- ◆ Ensure that the ultrasound window isn't too hot, checking with your hand.
- ◆ Verify that the buttons on the keyboard are good to operate.
- ◆ Ensure that there isn't obvious abnormal noise from the loudspeakers.
- ◆ Ensure that there isn't obvious abnormal noise from the air fan.

12.2 Troubleshooting

If any persistent system malfunction is experienced, e.g. an onscreen error message, blank imaging screen, absent menus, please refer to the following table below. If the failure cannot be eliminated, please contact EDAN or authorized representatives.

Item	Problem	Solution
1	When the power switch is on, there isn't any image displayed.	<ol style="list-style-type: none"> 1. Check power supply. 2. Check wires and plugs.

2	Strip-shape or snowflake-shape disturbance occurs on the display screen.	<ol style="list-style-type: none"> 1. Inspect the power supply. 2. Check whether it is disturbed by the ignition action of any other device. 3. Check the disturbance of electric or magnetic field in the surrounding environment. 4. Check whether the plug and socket of power supply and transducer are properly connected.
3	Image is not displayed clearly on the screen.	<ol style="list-style-type: none"> 1. Adjust overall gain (Gain). 2. Adjust eight TGC slide controls. 3. Adjust focus (the number and the position).
4	Image window is dark.	<ol style="list-style-type: none"> 1. Adjust the brightness and slide the TGC controls on the touch screen. 2. Check whether the transducer is connected correctly.
5	The button is no response	<ol style="list-style-type: none"> 1. Check the control panel to see whether the button is blocked and press it several times to release it. 2. Clean the button

12.3 Maintenance

The system should be maintained regularly, at least annually, by a qualified technician who has adequate training, knowledge and experience. That person should be familiar with the AX8 Service Manual (P/N 01.54.002483), available from your Edan representative.

12.4 Cleaning the System

Use only the EDAN-approved substances and methods listed in this chapter to clean the system. The warranty does not cover damage caused by using unapproved substances or methods.

Edan Instruments has validated the cleaning and disinfection instructions included in this User Manual. It is the responsibility of the healthcare professional to ensure that the instructions are followed so as to ensure adequate cleaning and disinfection.

General Points:

Keep your monitor, cables and accessories free of dust and dirt. To prevent the device from damage, please follow the procedure:

- Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.
- Always dilute according to the manufacturer's instructions.
- Unless otherwise specified, do not immerse any part of the equipment or any accessories in liquid.
- Do not pour liquid onto the system.
- Do not allow liquid to enter the case.
- Never use abrasive material (such as steel wool or silver polish).
- Inspect the monitor and reusable accessories after they are cleaned and disinfected.

WARNING

The console (including touch screen, track pad and hard keys) of system is splash resistant (IPX 1) but not waterproof. Do not immerse or expose to extended moisture. Splash resistance does not extend to transducer connectors. Keep connectors dry.

For cleaning agents and disinfectants, refer to section 6.3 Transducer Cleaning and Disinfection

12.4.1.Cleaning the System Surface

To clean the system surface:

1. Switch off the system and unplug it.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain.
3. Wipe off the cleaning solution with a fresh cloth or towel, dampened with tap water after cleaning until no visible cleaning agent remains.
4. Dry the system in a ventilated and cool place.

NOTE:

1. Make sure the system is free of gel and any other visible residue.
2. Use a soft dry cloth without chemicals for cleaning. The monitor surface is easily scratched.

12.4.2.Needle Guide Bracket Cleaning and Sterilization

NOTE:

1. Use proper sterilization technique at all times when performing a biopsy.
 2. Ensure that protective gloves are worn.
-
-

WARNING

The needle guide bracket kits are not disinfected or sterilized before delivery. The operators must clean and sterilize the needle guide bracket kits before and after each use.

Cleaning

Clean the needle guide assembly using a mild detergent prior to sterilizing.

Sterilization

Sterilize the Needle Guide Assembly by autoclaving for at least four minutes at 132°C

13 Specifications

13.1 Electrical Safety Classifications

According to the type of protection against electric shock	Internally powered equipment, Class I equipment
According to the degree of protection against electric shock	Type BF
According to the degree of protection against harmful ingress of liquid	Whole device: IPX0 Console (including touch screen, track pad and hard keys): IPX1 Transducer (not including the transducer connector): IPX7; Footswitch: IP68
According to the degree of safety of application in the presence of a flammable gas	Equipment not suitable for use in the presence of a flammable gas
According to the mode of operation	Continuous operation
According to the grade of EMC	CISPR 11 Group 1, Class A
Standards Compliance	EN 60601-1:2006 idt IEC 60601-1: 2005 +A1:2012 EN 60601-1-2: 2007 idt IEC 60601-1-2: 2007 IEC/EN 60601-2-37 NEMAUD 2 NEMAUD 3
Imaging Compliance	The AX8 is a portable diagnostic ultrasound system. Compliant with : Essential Performance : EN60601-2-37. 2D Imaging: GB10152-2009. Color Flow Imaging: YY 0767-2009. Spectral Doppler Imaging: YY 0767-2009.

13.2 Power Supply

Operating Voltage	100 -240 V~
Operating Frequency	50 Hz/60 Hz
AC Input Current	2.5A-1.5A
DC Input Current	19V ===7.8A MAX
Lithium battery	
Capacity	6150 mAh
Voltage	14.4V
Average working time	1 Hours
Charging time	3 hours with system power-on; 2.5 hours with system power-off
Cycle life	300

13.3 Machine Specifications

Main unit dimensions	38.8cm(W)x 40.7cm (D) x 7.7cm (H)
Net weight	9.25kg including battery (not including power adaptor or transducer)

13.4 Display Specifications

Display	TFT-LCD
Diagonal Size	15.6 inches
View Angle	Right 80, Left 80, Up 80, Down 80 (min)
Pixel Number	1920x1080
White Luminance	300 cd/m ² (typ)
Contrast Ratio	700 (typ)

13.5 General Technical Specifications

Display Modes	<p>B Mode: B, 2B,4B</p> <p>C Mode: B/C (Single, Dual, Quad) ; B+B/C(Dual Live); B/C/PW (triplex mode)</p> <p>PDI/DPDI Mode: B/PDI(DPDI) (Single, Dual, Quad) ; B+B/PDI(DPDI) (Dual Live); B/PDI(DPDI)/PW (triplex mode)</p> <p>PW Mode: B/PW;(Update) B/PW; (duplex, simultaneous) B/C/PW(Update) B/C/PW, B/PDI(DPDI)/PW; (triplex mode)</p> <p>CW Mode: B/CW; B/C/CW, B/PDI(DPDI)/CW;</p> <p>M Mode: B/M (Display layout: Up/down, Left/right,1:1)</p>
Image Gray Scale	256 levels
Image Magnification	In area Real time: x1.0, x1.3, x1.5, x1.8, x2.0. Frozen: x1.0, x1.3, x1.5, x1.8, x2.0.
Hard Drive Storage	500 GB
Depth Adjustment	Adjustable in real time in all modes

Image Conversion	Up/Down flip, Left/Right flip
Language Display	Chinese, English, German, French, Italian, Spanish, Russian, Turkish
Focus Number	Max. 3
Report Packages	Abdomen, Obstetrics, Small Parts, Vascular, Cardiac, Gynecology, Urology, Pediatric
B/Color mode Generic measurement	Distance, Circ/Area, Angle, Volume, Stenosis
M mode generic measurement	Distance, Slope, Time, HR
D mode generic measurement	Velocity, PG(Pressure Gradient), Heart Rate, Time, Acceleration, PI, RI, Auto trace
Annotations	Patient name, age, sex, time, date, hospital name, doctor name, comment (full-screen character editing)
Body Mark	100 types
USB Port	Two USB 3.0 and two USB 2.0 ports.

13.6 Operating, Storage and Transportation Environment

13.6.1. Operating Environment

Temperature	0 °C ~ +40 °C(+32 °F~+104 °F)
Relative humidity range	15% RH ~ 95% RH(non-condensing)
Atmospheric pressure range	860 hPa ~ 1060 hPa

13.6.2. Storage and Transportation Environment

Temperature	-20 °C ~ +55 °C(-4 °F~+131 °F)
Relative humidity range	15% RH ~ 95% RH(non-condensing)
Atmospheric pressure range	700 hPa ~ 1060 hPa

14 EMC Information


Electromagnetic emissions

Electromagnetic emission		
The Acclarix AX8 is intended for use in the electromagnetic environment specified below; The customer or the user of the Acclarix AX8 should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Acclarix AX8 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Acclarix AX8 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	

Electromagnetic immunity

Electromagnetic immunity			
The Acclarix AX8 is intended for use in the electromagnetic environment specified below. The customer or the user of Acclarix AX8 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2KV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Acclarix AX8 requires continued operation during power mains interruptions, we recommend that the Acclarix AX8 be powered from an uninterruptible power supply or a battery.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Electromagnetic immunity

Electromagnetic immunity			
The Acclarix AX8 is intended for use in the electromagnetic environment specified below. The customer or the user of the Acclarix AX8 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment -guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Acclarix AX8, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P} \quad 150\text{kHz} \sim 80 \text{ MHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P} \quad 80 \text{ MHz} \sim 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz} \sim 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Acclarix AX8 is used exceeds the applicable RF compliance level above, the Acclarix AX8 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Acclarix AX8</p> <p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

**Recommended separation distances between portable and mobile
RF communication equipment and the EQUIPMENT or SYSTEM**

Recommended separation distances between portable and mobile RF communications equipment and the Acclarix AX8			
The Acclarix AX8 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Acclarix AX8 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Acclarix AX8 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ~ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

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