ULTRASONIX

SONIX CEP ULTRASOUND SYSTEM
USER MANUAL

Ultrasonix Medical Corporation

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User Manual

Ultrasonix Medical Corporation
130 – 4311 Viking Way
Richmond, BC V6V 2K9
Canada

www.ultrasonix.com

1.866.437.9508
1.604.279.8550

00.040.088, Revision C, September 25, 2008

US Patents 6,911,008 – 6,558,326 – 6,325,759

CE 0543

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CHAPTER 1: INTRODUCTION

1.1 AUDIENCE

This user manual is a reference for operators using the SONIX CEP ultrasound system. It is designed for a reader familiar with ultrasound imaging techniques; *it does not provide training in sonography or clinical practices*. Before using the system the operator must have ultrasound training.

Note: *This is not a service manual. A separate manual with SONIX CEP service details is available for qualified service personnel.*

1.2 CONVENTIONS

The following conventions are used in this manual:

- cross-references for such things as tables, page numbers, sections and chapters are in bold face, non-italic type (e.g., **Chapter 2: SONIX CEP Introduction**). When the manual is in digital format (PDF), these cross-references are links that can be followed by clicking on them
- words that are **bold** and ***italic*** refer to items on the LCD display (i.e., onscreen)
- words that are **bold** and **CAPITALIZED** refer to buttons, dials and toggle buttons located on the operator console or keyboard
- "Press" and "Turn" indicate the actions required to activate the operator console buttons, toggle buttons and dials
- "Tap" indicates the action required to activate a touch screen item
- "Select" "Check" or "Click" indicate the various actions available to choose items from onscreen pages, menus, dialog boxes, etc. The console trackball is used to position the onscreen arrow and flashing cursor
- the **SELECT** button on the operator console acts much as the "left-click" on a mouse. It will set the cursor location for text entry or select an onscreen item. Use the trackball to position the cursor
- to "right-click", as with a mouse, press the **UPDATE** button on the operator console
- a "***Warning***" describes precautions necessary to prevent injury or loss of life
- a "***Caution***" describes precautions necessary to protect the products
- a "***Note***" contains helpful information
- a highlighted "***Note***" describes helpful hidden functionality
- items marked "***IMPORTANT***" contain vital information that must be understood and followed, but which will not endanger either personnel or equipment
- when the steps in the operating instructions must be performed in a specific order, they are numbered
- instructions separated by "**>**" indicate that multiple items must be selected (e.g., "From the ***User Settings*** menu, select ***Administrator > Status Bar***" indicates that the user must first click the "***Administrator***" option, then when the next dialog is presented, click the ***"Status Bar"*** option)
- bulleted lists present information in list format, but do not imply a sequence.

1.3 UPDATES

A revised user manual or addendum will be available for all future SONIX CEP ultrasound system updates.

1.4 CEP AND E-MED SOFTWARE

CEP is the emergency ultrasound hardware platform of the SONIX series system while E-Med is the software that controls emergency ultrasound functionality. Because E-Med is available on the SONIX OP and SP platforms – minus some of the CEP hardware-specific options – the terms are **not** interchangeable. Refer to **Appendix B: System Specifications** for a listing of the various platform options.

Note: *E-Med software is only available on the SONIX OP/SP hardware platforms if an E-Med license was purchased and activated.*

1.5 CEP HARDWARE

Some hardware options are only available to users running E-Med software on the CEP hardware platform. When this occurs, headings will be followed by (CEP), e.g., section **2.6 UPS (CEP).**

Alternatively, CEP hardware options may be connected/configured differently than systems running E-Med software on an OP/SP platform. In this case, there will be sub-sections explaining the different options, e.g., section **11.6 Connecting the Barcode Reader** with subsections **11.6.1 CEP** and **11.6.2** SONIX OP/SP.

Additionally, some hardware options are available only in specific geographic locations. Where this applies, the heading will specify that the section applies only to "Canada and USA" or to "International" versions (e.g., sections **2.8.1 Retractable Power Cord or Cable Reel: Canada and USA (CEP)** and **2.8.2 Power Cord: International**).

1.6 VOLTAGE DISCLAIMER

The CEP system voltage setting is configured in the factory. Do **not** change this setting in the field.

It is the user's responsibility to ensure the SONIX CEP is used only under the electrical conditions dictated by Ultrasonix Medical Corp. Failure to comply with these conditions may result in damage to the system which is not covered by the Ultrasonix warranty.

Caution: *For users running the 120V system, always ensure the utility supply voltage is 120 VAC nominal.*

For users running the 220V–240V system, always ensure the utility supply voltage is 220-240 VAC nominal.

1.7 CONNECTIVITY DISCLAIMER

Caution: *System networking options are intended for use inside your organization's firewall. Organizations that elect to configure/use the networking functionality provided by Ultrasonix are assuming all liabilities and risks associated with that decision.*

Caution: *For details on FCC regulations as they apply to the wireless adapter, refer to the manufacturer's User Guide included with the system.*

1.8 PRIVACY DISCLAIMER

To protect patient data, Ultrasonix strongly recommends regular patient/image file back-up and purging of older patient files stored on the system. Refer to **Chapter 10: Image Storage, Review and Transfer** for details on transferring patient data.

IMPORTANT: *The contents of the system hard drive may include Personal Health Information that must be protected as per Federal privacy and Health Insurance Portability & Accountability Act (HIPAA) regulations. In order to ensure regulatory compliance, Ultrasonix will not remove the system hard drive – and the patient data it contains – from the customer site.*

In the event the hard drive must be removed from the system, it will be returned to the customer. Final disposition of the hard drive and its data will remain the customer's responsibility.

1.9 LICENSE AGREEMENT

All SONIX computer programs have been patented by Ultrasonix Medical Corporation (Ultrasonix). Such programs are licensed under the following software license agreement:

> Ultrasonix, or its suppliers, retain(s) ownership of and title to any computer program supplied with the Equipment and to the trade secrets embodied in such computer programs. Subject to the Buyer's acceptance and fulfillment of the obligations in this paragraph, Ultrasonix grants the Buyer a personal, non-transferable, perpetual, non-exclusive license to use any computer program supplied with the Equipment that is necessary to operate the Equipment solely on the medium in which such program is delivered for the purpose of operating the Equipment in accordance with the instructions set forth in the operator's manuals supplied with the Equipment and for no other purpose whatsoever. Buyer may not reverse – assemble, reverse – compile or otherwise reverse – engineer such computer programs nor may Buyer make a copy of such program or apply any techniques to derive the trade secrets embodied therein. In the event of a failure by Buyer to comply with the terms of this license, the license granted by this paragraph shall terminate. Further, because unauthorized use of such computer programs will leave Ultrasonix without an adequate remedy at law, Buyer agrees that injunctive or other equitable relief will be appropriate to restrain such use, threatened or actual. Buyer further agrees that (i) any of the Ultrasonix suppliers of software is a direct and intended beneficiary of this end-user sublicense and may enforce it directly against Buyer with respect to software supplied by such supplier, and (ii) NO SUPPLIER OF ULTRASONIX SHALL BE LIABLE TO BUYER FOR ANY GENERAL, SPECIAL, DIRECT, INDIRECT, CONSEQUENTIAL INCIDENTAL OR OTHER DAMAGES ARISING OUT OF THE SUBLICENSE OF THE COMPUTER PROGRAMS SUPPLIED WITH THE EQUIPMENT.

1.10 TRADEMARKS AND PATENTS

Ultrasonix SONIX systems are protected under US patents 6,911,008 – 6,558,326 – 6,325,759.

Windows© is a trademark of Microsoft Corporation.

DICOM® (Digital Imaging and Communications in Medicine) is the registered trademark of the National Electrical Manufacturers Association (NEMA) for its standards publications relating to digital communications of medical information.

All other products and brand names mentioned in this document are trademarks of their respective companies.

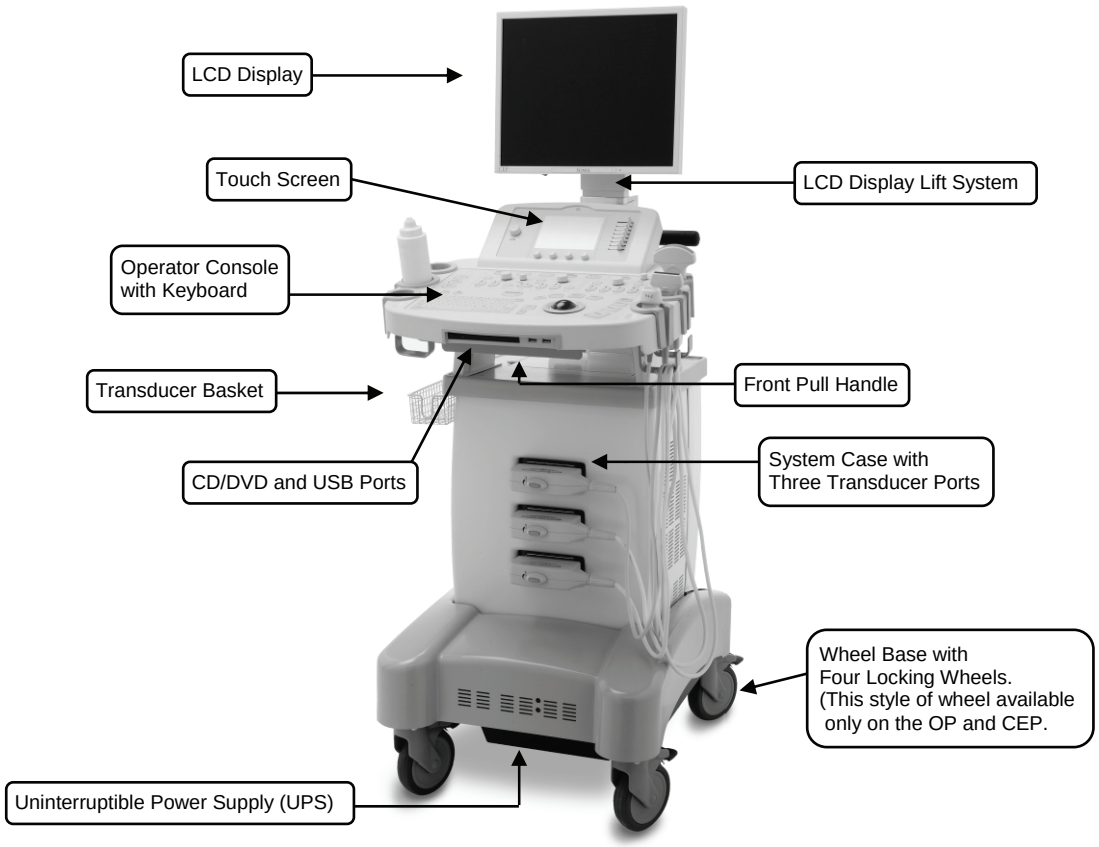
CHAPTER 2: SONIX CEP INTRODUCTION

Congratulations on your purchase of the Ultrasonix SONIX Ultrasound system. The SONIX is a high quality, easy to use diagnostic ultrasound system that is stable, highly mobile and designed to be convenient and comfortable to operate.

The various system components, including the LCD display, LCD display lift system, operator console with keyboard, base, cart, transducers, barcode reader, wireless adapter and uninterruptible power supply (UPS), may be configured to better support system use. The console soft touch controls are arranged in a manner that allows easy access.

2.1 SYSTEM COMPONENTS

Figure 2-1: SONIX System (CEP)

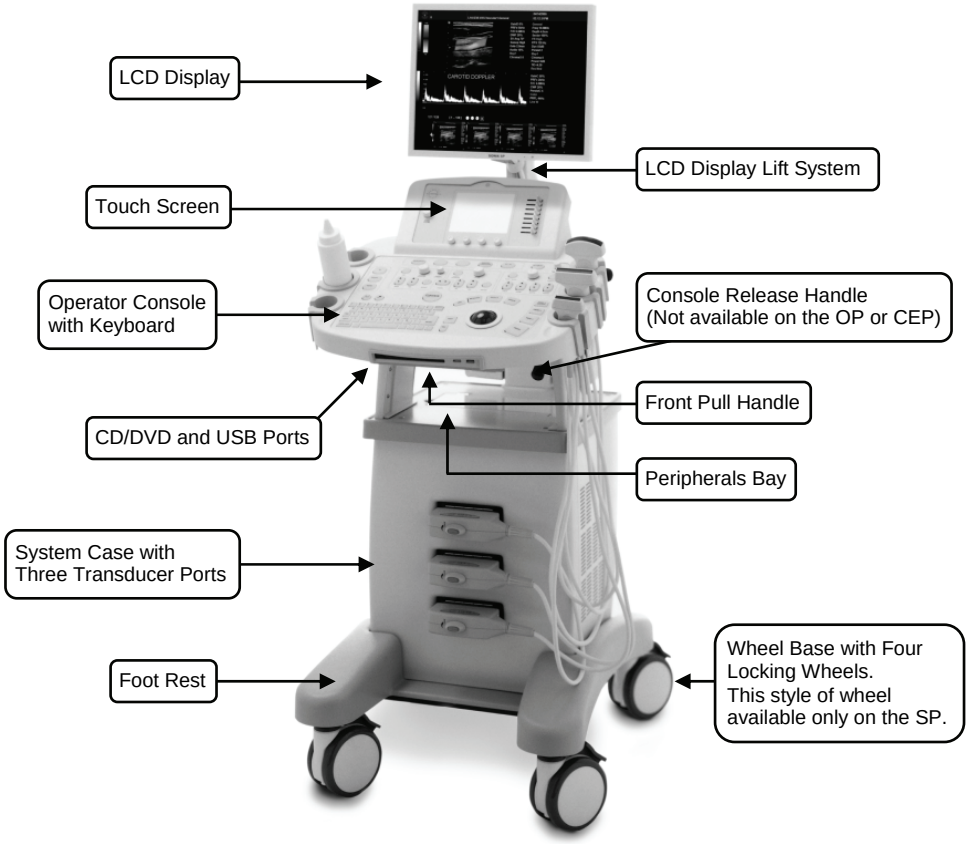


Note: *All SONIX OP and CEP wheels lock in a single position.*

Several additional features are available on the SONIX CEP but are not visible in **Figure 2-1**. Refer to the following sections for more details:

- **2.6.2 UPS EMERGENCY POWER OFF Switch (CEP)**
- **2.7 Barcode Reader** (also available for the SONIX OP/SP)
- **2.8 Power Cord**
- **2.9 Wireless Adapter** (also available for the SONIX OP/SP)
- **2.11 Cable Hooks (CEP)**

Figure 2-2: SONIX System (OP/SP)



Note: *The rear wheels on the SONIX SP are directionally locking, while the front wheels lock in a single position. Refer to* **Figure 2-1** *for details on the OP and CEP wheel style.*

2.2 OPERATOR CONSOLE

The operator console comprises a panel with patient management, system setup and ultrasound imaging controls: trackball, buttons, dials, toggle buttons, touch screen and keyboard. These operator controls enable SONIX functions such as selecting transducers, changing imaging modes, adjusting parameters like ***Time Gain Compensation*** (***TGC***), ***Depth*** and others.

Buttons light up when the feature/functionality is available for use. For instance the buttons used for adjusting the ***Color*** imaging parameter will not light up on the console until the **COLOR** imaging mode button is selected.

Figure 2-3: SONIX CEP Operator Console

Note: *Some features may not be available on all system configurations. Refer to* **Appendix B: System Specifications** *for details*

Table 2-1: SONIX Operator Console Controls

Location	System Control	Functionality
1	Power Button	Turns system ON/OFF.
2	**ID** Button	Provides access to the ***Exam Management*** page.
3	**PROBE** Button	Provides access to transducer selection keys on touch screen.
4	**MENU** Button	Provides access to setup menus.
5	**PICTOGRAM** Button	Turns on/off application-specific ***Pictogram*** graphics. Tap ***Pictogram*** and dial through the various icons. • trackball positions orientation marker • touch screen ***Rotate*** dial pivots orientation marker.
6	**ARROW** Button	Turns on/off ***Arrow*** graphic on the image field. Trackball positions and rotates the ***Arrow*** graphic.
7	Keyboard	QWERTY keyboard used for text entry (i.e., patient data, system setup, image text, etc.).
8	**QSONIX** Button	Provides: • Quick exam start-up • SONIX Operator Console Tutorial • Online support access • Training Tutorials.
9	**TEXT** Button	Activates the keyboard for ***Text*** entry and displays ***Application***-specific ***Annotation*** buttons on the touch screen.
10	**DEL** Button	Deletes the most recent ***Text*** or ***Annotation*** entry. Provides "delete character" functionality during data entry mode (***Exam Management*** page).
11	Trackball	Used to position the onscreen arrow graphic, flashing text cursor, arrow cursor, calipers, etc.
12	**DEL** Button	In ***Measure*** mode, deletes most recently saved measurement. Deletes selected thumbnail image.
13	**MEASURE** Button	Initiates/closes the ***Measurement/Calculation*** package. Removes measurements from frozen image field. ***Note:*** *If the associated* ***Worksheet*** *contains application-specific measurements, these tabs will be available for selection on the touch screen.*
14	**SELECT** Button	Provides a wide variety of functions depending on the imaging state (e.g., select and set measurements, set ***Annotation Home*** location, select onscreen keys, etc.) as well as "Left Click" mouse button functionality.
15	**UPDATE** Button	Provides a wide variety of functions depending on the imaging state (e.g., toggle between image fields on dual/quad image, toggle between ***2D*** and ***Doppler Trace*** image fields, toggles the active caliper, etc) as well as "Right Click" mouse button functionality.
16	**FREEZE** Button	Pause/resume a live image.

Print Controls	17	**PRINT 1** Button	First of three (3) programmable buttons used to auto-store/print images or CINE loops to a configured printer, archiver, etc.
	18	**PRINT 2** Button	Second of three (3) programmable buttons used to auto-store/print images or CINE loops to a configured printer, archiver, etc.
	19	**PRINT 3/ARCHIVE** Button	Third of three (3) programmable buttons used to auto-store/print images or CINE loops to a configured printer, archiver, etc. or set to provide access to the ***Exam Management/Image Review*** system.
B-Mode/2D and M-Mode Controls	20	**B-MODE/2D** Button/Dial	Activates (press dial) ***2D/B-Mode*** imaging mode and controls ***2D*** gain (turn dial) and ***M-Mode*** gain.
	21	**DUAL/QUAD** Button	Activates ***Dual*** (press once) and ***Quad*** (press twice) split screen imaging. **UPDATE** button toggles between image fields. Press **B-MODE** to return to single screen imaging.
	22	**M-MODE** Button	Activates ***M-Mode*** imaging. **B-MODE** dial controls ***M-Mode*** gain. **UPDATE** button activates ***M-Mode*** sweep.
	23	**FOCUS** Toggle Button	Adjusts the location of the image focal zone UP or DOWN on the image field.
	24	**DEPTH** Toggle Button	Adjusts the ***2D*** imaging ***Depth*** UP (less depth) or DOWN (more depth).
	25	**ZOOM** Toggle Button	Adjusts the ***2D*** magnification UP (more magnification) or DOWN (less magnification). Trackball used to pan image.
	26	**FREQ** Toggle Button	Adjusts the ***2D*** image ***Frequency*** UP or DOWN via the following options: • ***Harmonics*** (if available) • ***Resolution*** (high frequency) • ***General*** • ***Penetration*** (low frequency)
Color Doppler Controls	27	**COLOR** Doppler Button/Dial	Activates (press dial) ***Color Doppler*** imaging mode and controls ***Color Doppler Gain*** (turn dial). Controls ***Power Doppler Gain***.
	28	**INVERT** Button	Reverses the direction of the ***Color Doppler Map***.
	29	**PRF** Toggle Button	Adjusts the ***Color Doppler PRF (Pulse Repetition Frequency)*** UP (higher ***PRF***) or DOWN (lower ***PRF***).
	30	**WF** Toggle Button	Adjusts the ***Color Doppler Wall Filter*** UP (more filtering) or DOWN (less filtering).
	31	**POWER DOPPLER** Button	Activates/deactivates the ***Color Power Doppler*** imaging mode. The **COLOR DOPPLER** dial controls the ***Color Power Gain***.
	32	**STEER** Toggle Button	Adjusts the steering angle dependent on the active imaging mode: • ***Color Doppler*** Region of Interest (ROI) box • ***PW Doppler*** sample line • ***B-Mode/2D*** beam on linear transducers.

PW Doppler Controls	33	**PULSED DOPPLER** Button/Dial	Activates/deactivates (press dial) ***Pulsed Wave*** (***PW***) ***Doppler*** imaging mode and controls ***PW Doppler Gain*** (turn dial). **UPDATE** button switches between ***Trace*** and ***2D*** image. ***Note:*** *To adjust the* ***PW Gate*** *size on full screen* ***2D/Doppler*** *cursor, turn the* **PULSED DOPPLER** *dial.*
	34	**CW** Button	Not available in this release.
	35	**BASE** Toggle Button	Adjusts ***PW Doppler Trace baseline*** UP or DOWN.
	36	**PRF** Toggle Button	Adjusts ***PW Doppler PRF*** UP (higher ***PRF***) or DOWN (lower ***PRF***).
	37	**INVERT** Button	Reverses direction of ***PW Doppler trace***.
	38	**ANGLE CORRECT** Button/Dial	Activates (press dial) ***PW*** angle correct feature. Each subsequent press toggles through 0, +60, -60 degrees. Turn dial right or left to adjust angle correct in 2 degree increments up or down.
	39	**RESEARCH** Button	***Research*** option not available with CEP (E-Med) software.
	40	**WORKSHEET** Button	Activates ***Worksheets*** for the SONIX CEP. ***Note:*** *This button is available on OP and SP models that are ordered with the CEP E-Med software license.*
	41	Inactive Button	Currently inactive.
	42	**SPATIAL COMPOUND** Button	Activates/deactivates ***Spatial Compounding*** imaging mode.
	43	**3D/4D** Button	Activates/deactivates optional ***3D*** and ***4D*** imaging modes. Only ***Freehand 3D*** is available with CEP (E-Med) software.
	44	**OPTIMIZE** Button	Activates/deactivates auto-optimize feature for ***Doppler Trace***.
	45	**ACOUSTIC POWER** Button/Dial	Adjusts (turn dial) ***Acoustic Power*** and toggles (press dial) ***MI***, ***TIS***, ***TIC***, ***TIB*** display depending on the active imaging mode. ***Warning:*** *Refer to* **A.1.1 ALARA Principle and Output Displays**.
	46	**TGC** Slide Pods	Adjusts ***TGC*** (***Time Gain Compensation***) curve.
	47 – 50	Touch Screen Dials	Four (4) dials that control touch screen options which change depending on the imaging mode/state. ***Note:*** *In measure mode, if* **<<|>>** *appears on the touch screen key the measurement can be performed using different methods. Tap to select the measurement. Turn the touch screen dial directly below the desired measurement to page through the various method choices available. The method selected appears in an information bubble to the bottom right of the image screen. Refer to* **Chapter 7: Clinical Analysis** *for further details.*

51	Touch Screen	Displays touch screen menus which change depending on the imaging mode/state. ***Note:*** *The active tab on a touch screen menu will be indicated by a "dot" pattern below the tab name.*
52	**AUDIO VOLUME** Dial	Adjusts audio volume of the ***Doppler*** signal.
53	Microphone Vent	Future – voice command feature.

2.3 SYSTEM CASE

The system case contains the system PC and the System Case Connectivity Panel. Three transducer ports are available at the front of the system case.

Caution: *Access to the System Case Connectivity Panel (through the top of the system case) should be restricted to qualified service personnel only. Contact your local service representative for further information.*

Refer to the Service Manual for complete details about the system case.

Warning: *Do not touch the patient and the transducer ports simultaneously.*

2.4 BACK CONNECTIVITY PANEL

The Back Connectivity Panel is located on the tower which extends up from the back of the system case. Refer to **11.2 Back Connectivity Panel** for connectivity details.

2.5 POWER PANEL

The Power Panel is located on the back lower portion of the system case. It includes the power cord, main power switch and fuse.

Note: *If the system does not power up, ensure the power cord is plugged in and the main power switch on the back of the system case is turned to the ON position. The Main Power switch is not required for regular power shut downs and should remain in the ON position.*

2.6 UPS (CEP)

SONIX CEP is delivered with a UPS running on a lithium ion battery. The UPS, located at the bottom of the system, ensures that no data is lost when the system is *temporarily unplugged* and moved around. For more details, refer to section **11.5 UPS (CEP)**.

Warnings:

***NEVER** let liquid from any source enter the UPS. Failure to do this may result in accidental **shorts, shocks or electrocutions**.*

***DO NOT attempt to service this product yourself**. Attempting to open the UPS may cause exposure to lethal voltages within the unit even when it is apparently not operating and the input wiring is disconnected from the electrical source. Should the UPS require maintenance or replacement, only qualified Ultrasonix Service Technicians may perform service as detailed in the Service Manual.*

For UPS and battery service issues, contact Ultrasonix Technical Support.

2.6.1 UPS Use Model

The UPS is intended to facilitate system portability, i.e., a properly charged UPS can protect against the loss of data while the machine is *temporarily* unplugged and moved to a new location. Unless the system was powered down before being unplugged, make sure that it is reconnected to a power outlet within a few minutes.

When the system is running on battery power it cannot be left unplugged for long periods. For details on battery usage limitations and recharge alerts, refer to **Table 11-3** and **Table 11-4**, respectively.

***Note:** While unplugged, the rechargeable UPS battery maintains a charge for a limited time, regardless of whether the system is powered on or not. Leaving the machine plugged in while unattended will prevent automated shutdown and prolong battery life.*

Battery recharge time is exponential. Recharging for 10 to 30 minutes will only generate minutes of battery life. However, recharging – uninterrupted – for 60 minutes will generate 60 minutes of battery life.

If the battery has been completely depleted, always leave plugged in for a minimum of one (1) hour before attempting to run on battery power only.

As an added precaution, always shut down the CEP system by pressing the console POWER button for approximately one (1) second.

2.6.2 UPS EMERGENCY POWER OFF Switch (CEP)

In the event of any emergency that requires the shutdown of all power (e.g., to prevent fire or shock), the CEP is equipped with an **EMERGENCY POWER OFF** (**EPO**) switch at the bottom, rear of the system. Once the EPO switch is pressed, unplug the power cord from the wall outlet.

IMPORTANT: *Use this switch* ***only*** *in the event of an emergency. Once turned off, the CEP will be* ***completely*** *disabled until your internal service provider or a certified Ultrasonix Service Technician can reset the system.*

For more details on this switch, refer to section **11.5.2 UPS EMERGENCY POWER OFF Switch (CEP)** .

2.7 BARCODE READER

The SONIX CEP comes equipped with a configured, third-party barcode reader which allows the operator to scan certain patient data for quick and reliable data entry. The results of the scan are entered directly into the fields on the ***QSONIX Input Patient Information*** dialog and the ***Exam Management*** page – *providing* the cursor is present in the relevant field when the barcode is scanned.

Refer to **11.6 Connecting the Barcode Reader** for details on connecting the barcode reader to the SONIX CEP and OP/SP systems.

Warnings:

USE OF CONTROLS or adjustments or performance of procedures other than those specified in the manufacturer's User's Guide (delivered with system) may result in hazardous laser light exposure.

NEVER *attempt to look at the laser beam, even if the barcode reader appears to be non-functional.*

NEVER *point the laser beam in anyone's eyes.*

USE OF OPTICAL instruments with the laser equipment will increase eye hazard.

UNDER NO CIRCUMSTANCES *should users or technicians attempt to open or service the laser scanner. Attempting to open the barcode reader may cause exposure to hazardous laser light. Should the barcode reader require maintenance or replacement, contact Ultrasonix Technical Support.*

2.8 POWER CORD

2.8.1 Retractable Power Cord or Cable Reel: Canada and USA (CEP)

The nine (9) foot long (2.75m), medical grade, retractable power cord easily keeps the cable out of the way when the machine is being moved. Additionally, because it allows the user to extract only as much cable as is necessary for the space in which the system is being used, it helps to ensure a neater, and therefore safer, work environment.

Refer to **11.7.1 Unwinding/Retracting the Power Cord: Canada and USA (CEP)** for more details.

Warnings:

DO NOT *attempt to open the cable reel which houses the retractable power cord as this may cause physical injury and/or exposure to lethal voltages. It may also damage the cable reel, leading to further hazards when operating the system. Should the cable reel require maintenance or replacement, contact Ultrasonix Technical Support.*

DO NOT *use excessive force when extending or retracting the cord. This can cause the cord to separate from the reel and potentially expose anyone in the vicinity to lethal voltages.*

DO NOT *extend the cable into traffic areas as this can cause a tripping hazard.*

DO NOT *let go of the plug end of the cable while it is rewinding. Guide it gently back into its housing. If left to rewind on its own, the cable's whipping effect may cause injury.*

Cautions:

Always unwind/rewind the cable by pulling/releasing from ***behind*** *the system,* ***not*** *from the side.*

DO NOT *extend the power cord past the red warning label.*

2.8.2 Power Cord: International

International versions of the CEP are delivered with a 15 foot long (4.6m), country-specific, medical grade power cord.

2.9 WIRELESS ADAPTER

In addition to the standard, hard-wired network connection, the system supports a wireless adapter which is delivered with the system.

Refer to **11.8 Wireless** for details on connecting the wireless adapter (to either a SONIX CEP or SONIX OP/SP) and **9.2.10.3 Wireless Settings** for wireless configuration.

Caution: *System networking options are intended for use inside your organization's firewall. Organizations that elect to configure/use the networking functionality provided by Ultrasonix are assuming all liabilities and risks associated with that decision.*

Caution: *For details on FCC regulations as they apply to the wireless adapter, refer to the manufacturer's User Guide included with the system.*

Note: *The CEP wireless connection is delivered with the USB network cable hard-wired through the LCD display arm, while the OP/SP USB cable must be externally connected via the System Case Connectivity Panel.*

2.10 TRANSDUCER BASKET (CEP)

The SONIX CEP comes equipped with a factory-installed transducer basket sized to hold the Ultrasonix ***EC9-5/10 Endocavity Transducer***. The basket end-notches allow the transducer cable to hang freely.

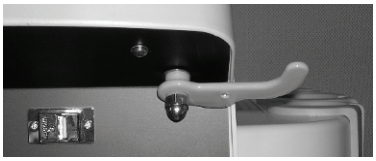
Figure 2-4: Transducer Basket

2.11 CABLE HOOKS (CEP)

There are two (2) retractable cable hooks located on the operator console, directly behind either side of the touch screen. These cable hooks are to be used at the discretion of the ***Operator*** in order to keep the various cables (barcode reader, transducers, etc) off the floor.

Figure 2-5: Cable Hooks

Retracted



Extended

2.12 CONSOLE COVER (CEP)

The CEP comes with a clear, medical grade, plastic console cover to help keep the system clean. For replacement covers and those users running E-Med software on an OP or SP platform, refer to the latest price list for details on purchasing this item.

See **11.9 Console Cover** for details on installing or replacing the console cover.

CHAPTER 3: GETTING STARTED

This chapter provides a step-by-step guide through the basic operation of the SONIX Ultrasound System.

3.1 TURNING ON SYSTEM

To Turn on the System:

1. Ensure the system is plugged in (hospital-grade electrical outlet recommended).
2. Press and hold the console **POWER** button for one (1) second. Refer to section **2.2 Operator Console** to view the button's exact location.

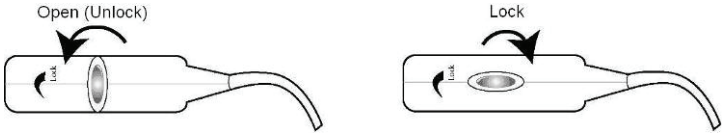
Note: *If the system does not power up, ensure the Main Power switch on the back of the system case is turned to the ON position ("—"). Refer to section* **2.5 Power Panel** *for main power switch location. The Main Power switch is not required for regular power shut downs and should remain in the ON position.*

3.2 CONNECTING TRANSDUCERS

The connection ports for SONIX transducers are located on the front of the SONIX system case (as shown in **Figure 2-1**).

To Connect/Disconnect a Transducer:

1. Turn the latch counter-clockwise to the Open or Unlock position.



2. Insert the transducer connector into the connection port with the cable directed to the right of the system.
3. Ensure the transducer is snugly in place and turn the latch clockwise to lock it in place.

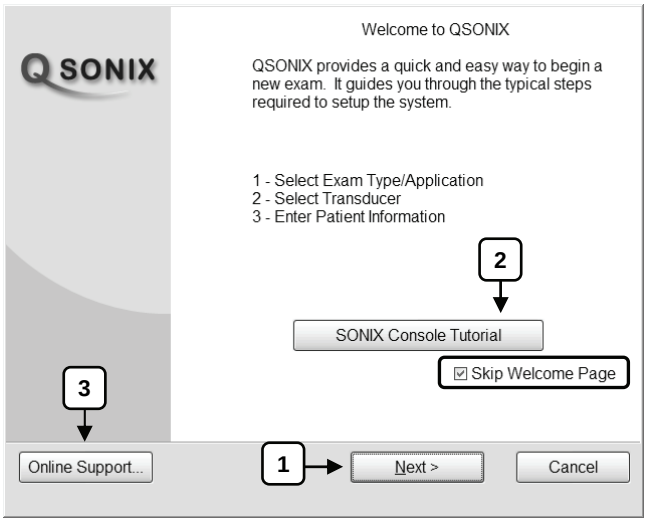
Note: *When a new exam is initiated, the transducer used in the most recent exam will still be selected if it is still connected. If it's no longer connected, the system will default to the first available transducer. This default transducer selection is not affected even if the system is turned off between exams.*

3.3 QSONIX FEATURE

The QSONIX button provides four (4) basic functions:

- Quick Exam Start-up (**1**)
- Operator Console Tutorial (**2**)
- Online Support Access (**3**)
- Training Tutorials.

Figure 3-1: Welcome to QSONIX



Note: *By default, the* ***Welcome to QSONIX*** *page will appear the first time the* **QSONIX** *button is pressed. If desired, after accessing the* ***QSONIX*** *feature, use the trackball and* **SELECT** *button to check the* ***Skip Welcome Page*** *checkbox in order to hide this page.*

3.3.1 Quick Exam Start-Up

The Quick Exam Start-up feature presents a series of dialog boxes which guide the user through the steps required to begin an exam:

1. Select the ***Exam Type/Application***.
2. Select the transducer.
3. Enter the basic patient and physician information.
4. Begin the exam.

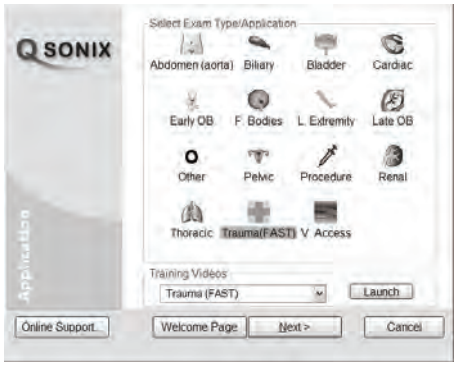
Note: Ultrasonix recommends always using the QSONIX Quick Exam Start-up feature to begin an exam.

To Begin the Quick Exam Start-up:

1. Press the console **QSONIX** button.
2. If the ***Welcome to QSONIX*** page is presented, select ***Next***.

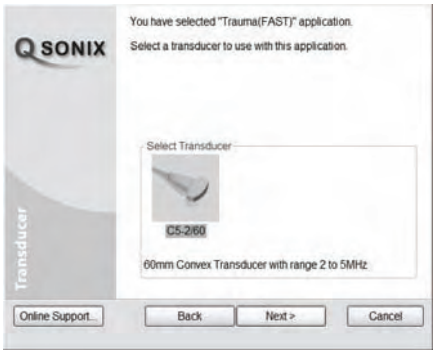
Note: *If the* ***Welcome to QSONIX*** *page has been set to "skip", it can be reset to appear by selecting the* ***Welcome Page*** *button (which is only visible when the page is skipped). Select* ***Skip*** *to prevent the* ***Welcome Page*** *from appearing the next time* **QSONIX** *button is selected.*

3. Click on the desired ***Exam Type/Application*** and the system will automatically move to the next page.



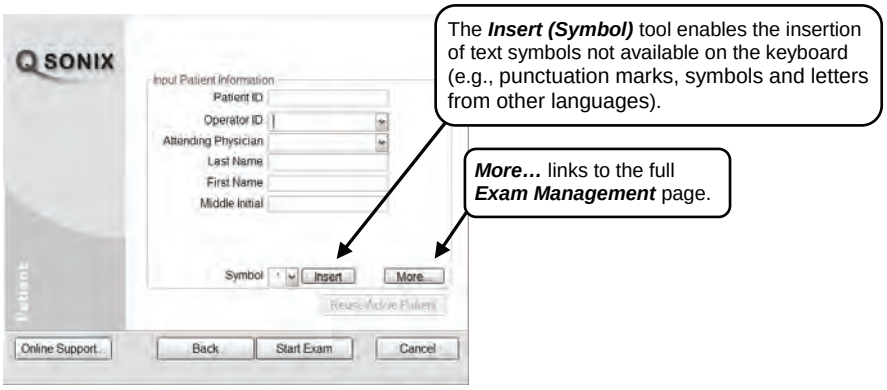
Note: *If a* ***Preset*** *has been hidden, it will not be available for selection from* ***QSONIX****. Refer to* **9.2.1.1 Show/Hide Exam Type/Applications** *for details.*

4. Click on the desired transducer and the system will automatically move to the next page.



Note: *Only transducers currently connected to the system and applicable to the previously-selected* ***Exam Type/Application*** *will be available. If the selected* ***Application*** *is not compatible with the currently connected transducers, the system will prompt for a different transducer, or select* ***Back*** *twice, to select a different* ***Application****.*

5. Use the keyboard to enter data in the ***Input Patient Information*** fields. Press **TAB** on the keyboard to move through the data fields.



Notes:

If additional patient information is required select ***More…*** *to open the full* ***Exam Management*** *data entry page. Refer to* **Chapter 4: Patient Management** *for complete details on* ***Exam Management*** *data entry.*

The ***Reuse Active Patient*** *button allows* ***Operators*** *to change* ***Applications*** *while continuing to scan the current, patient (i.e., the data acquired after switching to a different* ***Application*** *continues to be saved to the same patient).*

6. Select ***Start Exam*** to begin imaging.

Note: *During imaging, press the* **WORKSHEET** *button to access the associated* ***Worksheet****. Refer to* **7.4 Worksheets** *for details on completing and saving* ***Worksheet*** *data.*

3.3.2 Assign Exam

It is possible to begin an exam without first entering *any* patient data, either on the ***Input Patient Information*** page or using the ***More…*** button to access the ***Exam Management*** page (as described in Step 5, Section **3.3.1 Quick Exam Start-Up**). When this occurs, before being permitted to exit the exam, or begin a new exam, users will be presented with the ***Assign Exam*** dialog. This will ensure that all exams/images can be correlated to a specific patient.

Due to the urgent nature of critical care exams, the ***Assign Exam*** dialog is presented with unique, default information in the ***Patient ID***, ***Last Name*** and ***First Name*** fields. Accepting this default data can accelerate the exam/diagnostic process.

Figure 3-2: Assign Exam Dialog

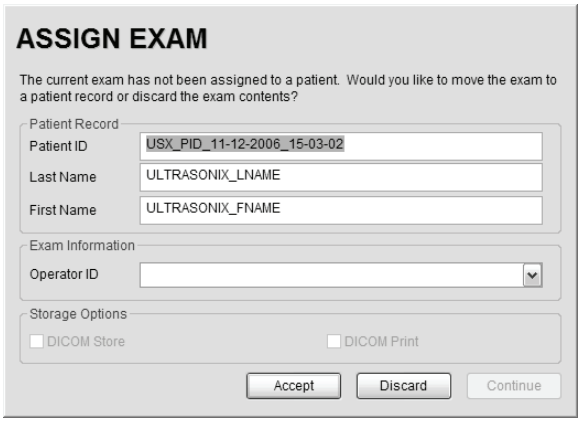


Table 3-1: Assign Exam Fields

Patient Record	***Note:*** *If the cursor is present in any of the three (3)* ***Patient Record*** *fields, data can be entered by scanning the appropriate barcode with the barcode reader.*	
	Patient ID	Enter a ***Patient ID*** here or use the unique default provided by the system. This is a required field.
	Last Name	Enter the patient's ***Last Name*** here or use the default provided by the system. Entering data in this field is optional.
	First Name	Enter the patient's ***First Name*** here or use the default provided by the system. Entering data in this field is optional.
Operator ID		Enter an ***Operator ID*** here or select an existing one from the drop-down menu. Entering data in this field is optional.
		Note: *Any new* ***Operator IDs*** *entered here will automatically become available for selection on the* ***Exam Management*** *page.*

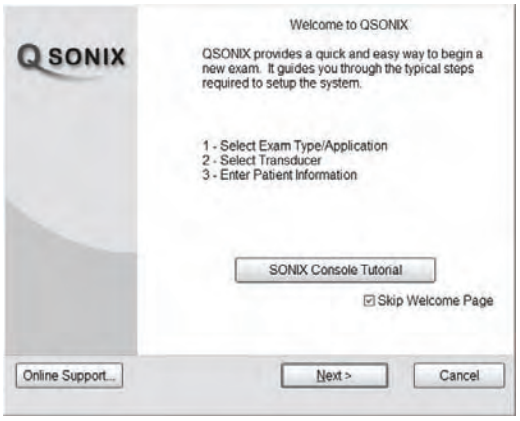
Storage Options	***Note:*** *The two (2)* ***Storage Options*** *fields are only available if the system is connected to a network and has been configured with a DICOM server.*	
	DICOM Store	If selected, all images will be sent to ***DICOM Storage***.
	DICOM Print	If selected, all images will be sent to a ***DICOM Printer***
Accept		Saves the exam and assigns the patient data (either the default data or anything edited by the ***Operator***).
Discard		Exits the exam without saving it. ***Note:*** *All unassigned images and* ***Worksheet*** *information are lost when this option is selected.*
Continue		Returns the ***Operator*** to the exam. ***Note:*** *As the exam has still not been assigned to any specific patient, the dialog will be presented again when the* ***Operator*** *next attempts to exit the resumed exam.*

3.3.3 Operator Console Tutorial

This feature provides a brief overview of the functionality of the operator console buttons, toggle buttons, dials, etc.

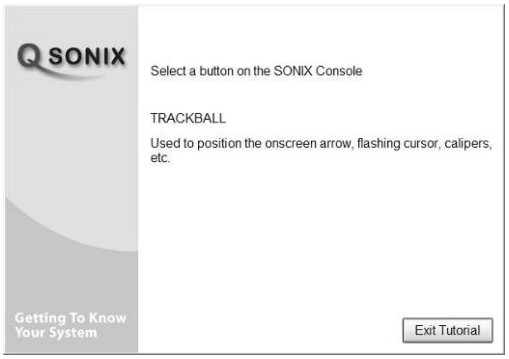
To Access the Operator Console Tutorial:

1. Press the console **QSONIX** button to access the ***Welcome to QSONIX*** page.



Note: *If the* ***Welcome to QSONIX*** *page does not appear, click the* ***Welcome Page*** *button.*

2. Select ***SONIX Console Tutorial*** and a brief, onscreen description will be presented when any console or touch screen button, dial, or knob is activated.



3. Select ***Exit Tutorial*** to return to the ***Welcome to QSONIX*** page.

3.3.4 Training Tutorials

The ***QSONIX*** button enables users to access the available ***Training Tutorials***.

While some tutorials may be delivered with the system, other topics may be made available in the future. Additionally, users have the opportunity to create and load their own tutorials, providing they are created using a specified set of file formats.

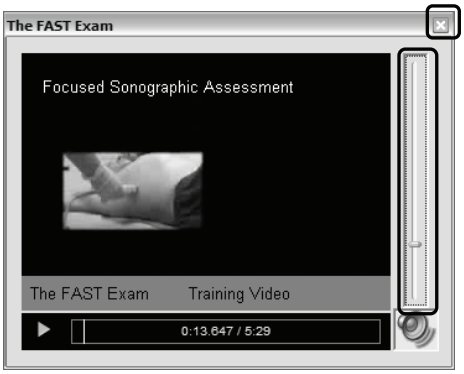
Refer to **9.2.7 Training Tutorials** for details on loading tutorials and **Table 9-14** a complete list of supported file formats for user-created tutorials.

To Access the Training Tutorials:

1. Press the console **QSONIX** button.
2. If the ***Welcome to QSONIX*** page is presented, select ***Next***.

3. Select the desired tutorial from the drop-down menu and click the ***Launch*** button.

4. The tutorial will be presented on the LCD display.



5. To reposition this window on the LCD display, move the cursor to the upper border (where the title is displayed), press and hold the **SELECT** button then move the trackball as required.
6. Press the red **X** in the top right corner of the tutorial screen to exit the tutorial.

Notes:

For files with an audio component, the volume can be adjusted with the audio slide on the right hand side of the tutorial screen. Refer to **9.2.9 System Settings** *for details on adjusting the* ***Master Volume*** *control.*

The SONIX CEP remains fully operational while the tutorial is displayed and running.

3.3.5 Online User Manual Access

Once User Manuals are present on the system, users will be able to access a cross-referenced, searchable PDF version of the User Manual by pressing a pre-mapped "hot-key" on the console keyboard.

Note: *It is not possible to view the User Manual PDF if the console* **TEXT** *button (***8.1***) is active or when a SONIX dialog (e.g.,* ***Exam Management****) or Windows dialog (****Date and Time Properties****) is open.*

To configure the system to present the PDF in the desired language, refer to **User Manual Language** in **Table 9-15: System Settings Configuration Options**.

To Access the User Manual PDF:

1. Ensure the console **TEXT** button is not active and that all Windows dialog boxes are closed.
2. Press the console keyboard "**u**" key.

To Close the User Manual PDF:

1. Click the "**X**" in the upper right corner of the PDF window.

3.3.6 Online Live Chat Support

The ***Online Support*** feature is a real-time help discussion with the Ultrasonix Technical Support team. Refer to **9.2.10 Network** to configure the system for live chat support and network connectivity.

To Access Online Live Chat Support:

1. Press the console **QSONIX** button.

   Note: Online Support *can also be accessed via* **MENU >** ***Online Support****.*

2. Select ***Online Support…*** from the bottom left side of the ***Welcome to QSONIX*** page.

3. Use the keyboard to type in the desired message in the text box.

4. Click the ***Send*** button to send the message.

5. To close the online chat window, select the "**X**" in the red box in the upper right corner of the window.

   Note: *For details on the various options available in this window, refer to the* ***Help*** *menu in the* ***Online Chat*** *dialog.*

CHAPTER 4: PATIENT MANAGEMENT

Exam Management functionality allows users to enter patient/exam-related data into the system. Entering patient-specific data automatically creates a unique file in which the patient/exam data is stored.

Note: *The actual exam can* ***only*** *be initiated through the* **QSONIX** *button.*

4.1 ENTERING PATIENT DATA

The ***Exam Management*** page is sectioned into ***Patient Information***, ***Application Information*** and ***Exam Information*** data entry areas. If applicable, data can be accessed via the storage/database tabs at the bottom right side of the page (***Patients***, ***Worklist*** and ***QA***).

SONIX systems with an attached barcode reader enable users to enter data scanned from a barcode. Any field that allows data to be entered using the keyboard will accept data scanned with a barcode reader, providing the data is encoded using one of the following barcode symbologies: UPC, EAN, Interleaved 2 of 5, Codabar, Code 3 of 9, Code 93, Code 128.

Figure 4-1: Exam Management Page

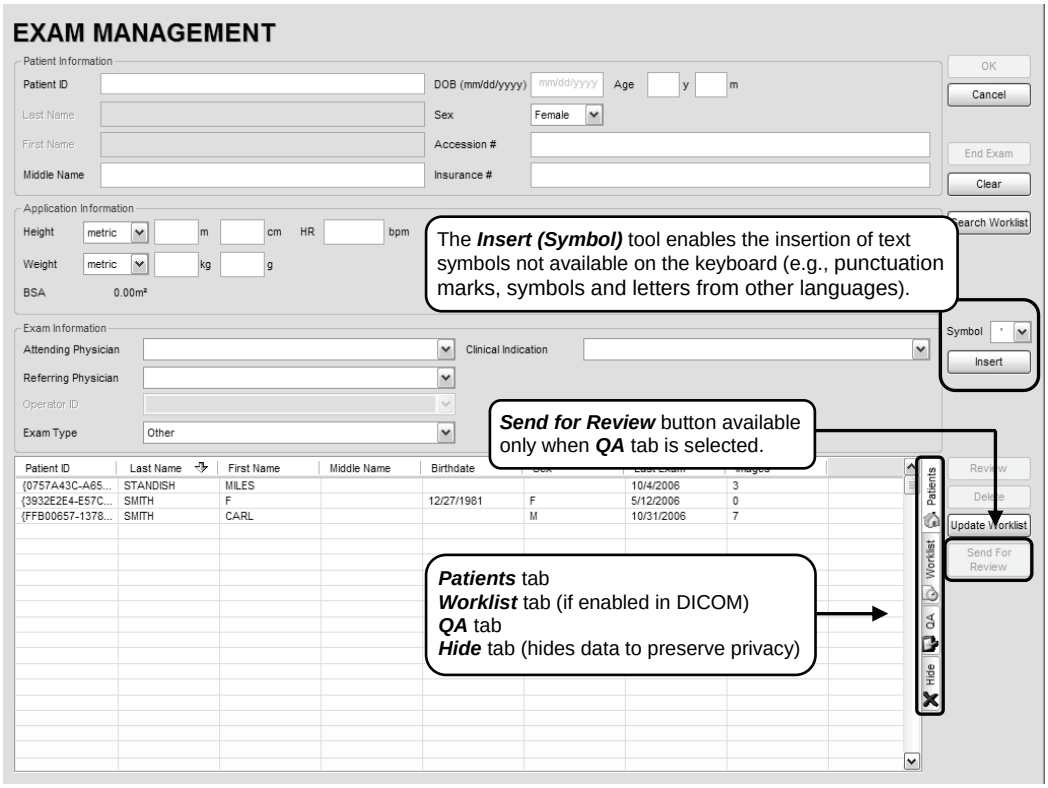


Table 4-1: Exam Management Page Options

OK	Saves the changes made to the ***Exam Management*** page and returns to imaging. ***Note:*** *If imaging is started before any Patient data is entered, the program will prompt for* ***Patient ID****,* ***Last Name*** *and* ***First Name*** *before the session can be saved.*
Cancel	Cancels any changes made to the ***Exam Management*** page and returns to live imaging. ***Cancel*** will not undo the ***End Exam*** function.
End Exam	Ends the current exam session, clears the ***Patient***, ***Application*** and ***Exam*** data fields and clears the printer queue (e.g., if printer image sheet is set for 2x2 and only two (2) images were saved, ending the exam signals the system that no more images are coming to fill up the sheet and sends the image sheet to the printer). All measurements visible on the LCD display are cleared. ***Note: End Exam*** *does not erase stored measurements.*
Clear	Clears the ***Patient*** and ***Exam*** data fields. ***Clear*** will also "end" the current exam if one is open.
Search Worklist	Use this button to search the ***DICOM®*** ***Worklist*** for a specific patient, if ***DICOM Worklist*** has been enabled (**9.2.11.3 DICOM Worklist Configuration**).
Insert (Symbol)	Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).
Review	Opens the ***Image Management*** page for the current patient or patient(s) selected from ***Patients*** file storage.
Delete	Removes the currently selected patient(s) from ***Patients*** file storage.
Update Worklist	Use to update ***Worklist*** data. ***Note:*** *This button will only be available if the system is configured for DICOM (****9.2.11.3 DICOM Worklist Configuration****). In order to actually update* ***Worklist*** *data, the system must also have an active connection to a DICOM server.*
Send for Review	***Note:*** *The* ***QA*** *tab must be selected in order to access this functionality.* Enables ***Operators*** to e-mail exams for review by qualified personnel. Refer to **9.2.10 Network** to configure ***E-Mail Setup*** and **9.2.19 QA Setup** to add ***Reviewers*** to the e-mail list. Enables ***Operators*** to print exams to a network printer ***Note:*** *The network printer should be configured during system installation. Refer to your IT department or Ultrasonix Technical support if there is an issue.*

To Access the Exam Management Page:

1. Press the console **ID** button.

4.1.1 Patient Information

Figure 4-2: Data Fields for Patient Information

Table 4-2: Patient Information Fields

Patient ID	Enter the ***Patient Identifier*** using letters and/or numbers. The system automatically creates a unique ***Patient ID*** if one is not entered manually (e.g., {C9B3F82B-BE52-4C79-8C45-28375D69F8C9}).
	Note: *The* ***Patient ID*** *cannot be changed after the patient file has been created (i.e., an exam has begun).*
Last Name ***First Name*** ***Middle Name***	Enter the patient's ***Last***, ***First*** and ***Middle Names*** - any of which can be modified at any point during the exam.
DOB ***(Date Of Birth)***	Enter the patient's ***Date of Birth*** in the required format (e.g., ***mm/dd/yyyy***), which is controlled through the ***Regional Settings*** options selected in **9.2.9 System Settings**.
	Note: *A* ***DOB*** *entry will auto-populate the* ***Age*** *field.*
Age	Rather than entering a specific ***DOB***, enter the patient's actual ***Age***.
	Note: *the* ***Age*** *field will auto-populate if a* ***DOB*** *is entered.*
Sex	Select the patient's gender: ***Female***, ***Male***, ***Other***, or ***Unknown***.
Accession #	Enter the exam's ***Accession Number***.
	Note: *This field auto-populates when the* ***DICOM Worklist*** *is used.*
Insurance #	Enter the patient's ***Insurance Number***.

Note: *During imaging, if* ***Patient ID, Name, LMP,*** *etc. are not displayed at the top of the image screen, the system may be setup to hide the patient data. For details, refer to* **General Options** *in* **Table 9-31: Patient Settings***.*

Note: *All these fields can be completed using the barcode reader. Simply ensure the cursor is in the required field and scan the relevant barcode.*

To Enter Patient Information Manually:

1. Press the console **ID** button.
2. Use the keyboard, trackball and console **SELECT** button to enter the patient information as required.

Note: *The* **TAB** *key may be used to move through the various* ***Patient Information*** *fields and the* **ENTER** *key to make drop-down menu selections.*

To Enter Patient Information with the Barcode Reader:

1. Press the console **ID** button.
2. With the cursor in the ***Patient ID*** field, scan the relevant patient barcode with the barcode reader.
3. Continue entering the patient/exam data as required.

Note: *Fields that will accept data entry via the keyboard will also accept data scanned with the barcode reader. Simply ensure that the cursor is located in the required field then scan the relevant barcode.*

4.1.2 Application Information

Use this section of the ***Exam Management*** page to select the appropriate ***Application*** (***Cardiac***, ***Gynecology***, ***Obstetrics*** or ***Other***) in order to enter application-specific data (e.g., for ***OB***, enter ***LMP***, ***Para***, ***Gravida***, ***Aborta***, etc.).

Note: *The* ***Application*** *selected here is not tied to an* ***Exam Type/Application****.*

Table 4-3: Application Information Fields

Cardiac	 • ***Height*** and ***Weight*** have both metric and imperial measurement options • ***BSA*** (***Body Surface Area***) is calculated and displayed when ***Height***/***Weight*** is entered • ***HR*** (***Heart Rate***) ***bpm*** (beats per minute) can be entered manually.
Gyn	 • ***LMP*** (***Last Menstrual Period***) • ***Exp. Ovul.*** (***Expected Date of Ovulation***) • ***Day of Cycles*** • ***Gravida***, ***Para*** and ***Aborta*** fields.

OB

- ***LMP*** auto-calculates ***GA*** and ***EDD*** (***Estimated Date of Delivery***)
- ***GA*** (***Gestational Age***) auto-calculates ***EDD***
- ***EDD*** auto-calculates ***GA***

> ***Note: LMP*** *or* ***GA*** *will display at the top of the image field in the selected Windows date format (e.g.,* ***mm/dd/yyyy****).Both weeks (****w****) and days (****d****) are used to auto-calculate* ***EDD****. If the* ***GA*** *and* ***EDD*** *are entered manually, the* ***LMP*** *entry will be removed.*

- ***Gravida***, ***Para*** and ***Aborta*** fields
- ***Fetus #*** defaults to 1. Enter up to 3 for multiple gestations

> ***Note:*** *Entering a* ***2*** *or* ***3*** *is required in order to record measurements on 2 or 3 separate fetuses (i.e., to activate multiple measurement packages (where* ***1*** *=* ***A****,* ***2*** *=* ***B*** *and* ***3*** *=* ***C*** *in reports)).*

- ***BBT*** (***Basal Body Temperature***) can be entered in ***°C*** (Celsius) or ***°F*** (Fahrenheit).

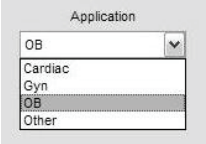
> ***Note: BBT*** *is only available if it was selected in* **9.2.15 Patient Settings**.

Other

- ***Height*** and ***Weight*** have both metric and imperial measurements options
- ***BSA*** is calculated and displayed when ***Height/Weight*** is entered.

To Enter Application-Specific Data:

1. Press the console **ID** button.
2. Tab to the ***Application*** drop-down menu on the right side of the ***Application Information*** section.
3. Select the desired ***Application*** from the drop-down menu.



Note: *The* **TAB** *key may be used to move through the various data fields and the* **ENTER** *key to make drop-down menu selections.*

4. The application-related data entry fields to the left side of the ***Application Information*** section change with the selection of the various applications.

Note: *The* ***Application*** *selected here is not tied to an* ***Exam Type****.*

4.1.3 Exam Information

Figure 4-3: Data Fields for Exam Information

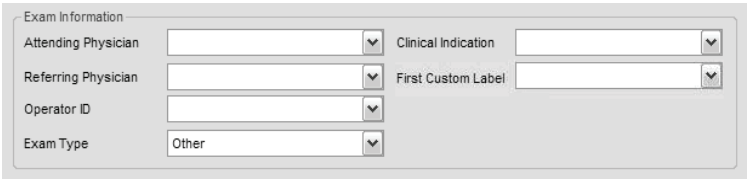


Table 4-4: Exam Information Fields

Attending Physician	Enter name of the ***Attending Physician*** manually or select from drop-down menu of previously entered and currently active physician names.
Referring Physician	Enter name of the ***Referring Physician*** manually or select from drop-down menu of previously entered and currently active physician names. ***Referring Physician*** auto-populates when the patient is selected from ***DICOM Worklist***.
Operator ID	Enter name or initials of the ***Operator*** or select from drop-down menu of previously entered and currently active ***Operator IDs***. ***Operator ID*** appears at the top of the screen during imaging.
Exam Type	Enter ***Exam Type*** manually or select from drop-down menu of previously entered and currently active ***Exam Types***. ***Exam Type*** auto-populates based on the ***Exam Type/Application*** chosen when starting an exam via the **QSONIX** button. It will also auto-populate when the patient is selected from ***DICOM Worklist***. In either case, the selection can be modified.
Clinical Indication	Enter ***Clinical Indication*** manually or select from drop-down menu of previously entered and currently active ***Clinical Indications***. ***Clinical Indication*** auto-populates when the patient is selected from ***DICOM Worklist***, but can be modified.
Custom Label 1, 2, 3	Enter user-defined data manually or select from drop-down menu of previously entered and currently active data.

Note: *Refer to* **9.2.15 Patient Settings** *for details on adding, editing and maintaining data for the following fields:* ***Reporting Physician***, ***Referring Physician, Operator ID*** *and* ***Custom Label 1***, ***2***, *and* ***3***.

Attending Physicians, ***Referring Physicians*** *and* ***Operator IDs*** *can be added via* **3.3.1 Quick Exam Start-Up**.

Operator IDs *can also be added through* **3.3.2 Assign Exam**.

Note: *All these fields can be completed using the barcode reader. Simply ensure the cursor is in the required field and scan the relevant barcode.*

To Enter Exam Information Manually:

1. Press the console **ID** button.
2. Enter the ***Exam Information*** as required. Once entered, the text is available for recall from the drop-down menu.

Note: *Use the* **TAB** *or* **ENTER** *key to move around the* ***Exam Information*** *fields. Drop-down menu selections can be made with the trackball and* **SELECT** *button.*

To Enter Exam Information with the Barcode Reader:

1. Press the console **ID** button.
2. With the cursor in the ***Attending Physician*** field, scan the relevant patient barcode with the barcode reader.
3. Continue entering the patient/exam data as required.

Note: *Fields that will accept data entry via the keyboard will also accept data scanned with the barcode reader. Simply ensure that the cursor is located in the required field then scan the relevant barcode.*

4.2 SELECTING A TRANSDUCER

Each transducer is restricted to a specific set of ***Exam Type/Applications***. Refer to section **C.3 Ultrasound Indications for Use Tables** for ***Clinical Application*** details on each transducer type.

To Select/Change a Transducer:

1. Press the console **PROBE** button.
2. Up to three (3) options are presented on the touch screen listing the transducers connected to the system.

Note: *If an* ***Exam Type/Application*** *is active at the time the* **PROBE** *button is pressed, any connected transducer that does not support the active* ***Application*** *will be shown with a line through the transducer name – temporarily removing it from the pool of currently selectable transducers.*

3. Tap the name of the transducer required for the exam and the system will move to live imaging.

4.3 BEGINNING AN EXAM FOR A NEW PATIENT

Note: Ultrasonix recommends always using the QSONIX Quick Exam Start-up feature to begin an exam.

To Begin an Exam for a New Patient (Manual Entry):

1. Press the console **ID** button.
2. The ***Exam Management*** page will be presented on the LCD display.

   Note: *The text cursor defaults to the* ***Patient ID*** *field unless a current exam is open. To end the current exam session, click the* ***End Exam*** *button near the top right corner of the page.*

3. Enter ***Patient Information*** as required.

   Note: *The* ***Patient ID*** *cannot be edited once the exam is underway.*

4. Under ***Application Information***, select the appropriate ***Application*** in order to access the ***Application***-specific data fields (e.g., for ***Cardiac***, complete the ***Height***, ***Weight***, ***BSA*** and ***HR*** fields).

   Note: *The* ***Application*** *selected here is not tied to* ***Exam Type/Application****.*

5. Enter ***Exam Information*** as required.
6. To save the changes and move to live imaging, select ***OK*** on the ***Exam Management*** page or tap ***OK*** on the touch screen.

   Note: *The* ***Patient ID, Name*** *and* ***Operator ID*** *details appear at the top of the image field during an exam. When applicable,* ***LMP*** *and* ***GA*** *will also be presented.*

   If the above-listed fields are relevant to the imaging session but are not displayed, the system may be configured to hide patient data. Refer to ***General Options*** *in* **Table 9-31** *for details.*

To Begin an Exam for a New Patient (Barcode Reader):

1. Press the console **ID** button.
2. The ***Exam Management*** page will be presented on the LCD display.
3. With the cursor in the ***Patient ID*** field, scan the relevant patient barcode with the barcode reader.
4. Continue entering the patient/exam data as required.

   Note: *Fields that will accept data entry via the keyboard will also accept data scanned with the barcode reader. Simply ensure that the cursor is located in the required field then scan the relevant barcode.*

4.4 ENDING AN EXAM

To End the Current Exam Session:

1. Press the console **ID** button.
2. Tap ***End Exam*** on the touch screen or select ***End Exam*** from the ***Exam Management*** page.

Note: End Exam *ends the current exam session, clears the* ***Patient*** *and* ***Exam*** *data fields and clears the printer queue (i.e., if printer image sheet is set for 2x2 and only two (2) images were saved,* ***End Exam*** *signals the system that no more images are coming to fill up the sheet).*

All exam measurements visible on the LCD display are cleared.

4.5 STORAGE/DATABASE TABS

To the bottom right of the ***Exam Management*** page is a series of up to four (4) vertical ***Storage*** tabs.

Table 4-5: Storage/Database Tabs

Patients	Select this tab to display a list of patients stored in local memory.
Worklist	Select this tab to display the patient list recently retrieved from the ***DICOM Worklist*** server. ***Note:*** *This tab is available only when the system is configured for* ***DICOM Worklist****.*
QA	Select this tab to access the available ***Exams***. At the Operator's discretion, these ***Exams*** can be ***Reviewed*** on the system, e-mailed to a ***Reviewer*** or sent to the network printer.
Hide	Select this tab to blank out the patient data on the ***Exam Management*** page. This feature provides data privacy.

4.5.1 Patients

Using data entered in section **4.1.1 Patient Information**, the system maintains and displays a database containing patient details.

Figure 4-4: Patients Database

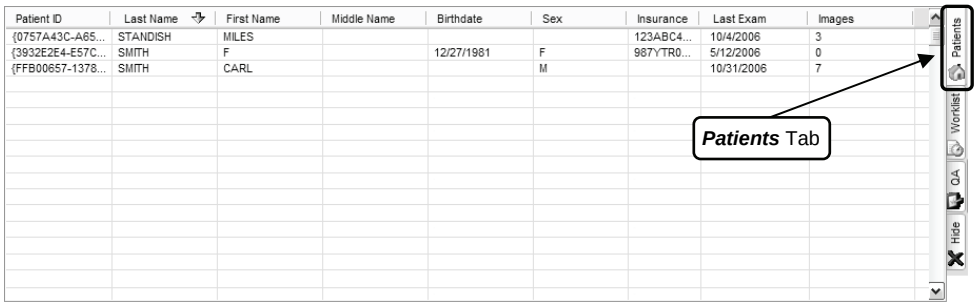


Table 4-6: Patient Database Fields

Patient ID	***Patient Identifier*** as entered in the ***Patient Information*** section.
Last Name ***First Name*** ***Middle Name***	Patient's ***Last***, ***First*** and ***Middle Names*** as entered in the ***Patient Information*** section.
Birthdate	Patient's ***Birthdate*** as entered in the ***Patient Information*** section.
Sex	Patient's ***Sex*** as entered in the ***Patient Information*** section.
Insurance #	Patient's ***Insurance #*** (if applicable) as entered in the ***Patient Information*** section.
Last Exam	Date of the ***Last Exam*** performed on the patient (if applicable).
(Number of) Images	Total number of ***Images*** stored for the patient's most recent exam.

4.5.1.1 Manipulating the Patients Database

To Manually Select a Previously Stored Patient from the Patients Database:

1. Press the console **ID** button.
2. Select the ***Patients*** tab near the bottom of the ***Exam Management*** page to display a list of locally stored (on the system hard drive) patients.

3. Use the trackball and **SELECT** button to select a patient and auto-populate the data fields.
4. Modify patient and exam data fields as required.

Note: *The (**Patient**) **ID** cannot be modified.*

5. Select ***OK*** to save the data and move to live imaging.

Note: *When a new exam is initiated, the transducer used in the most recent exam will still be selected **if** it is still connected. If it's no longer connected, the system will default to the first available transducer. This default transducer selection is not affected even if the system is turned off between exams.*

To Search the Patients Database for a Previously Stored Patient:

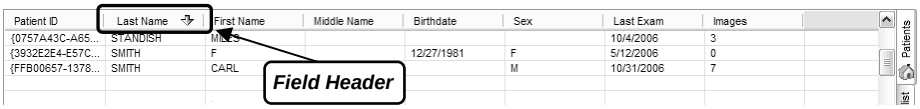
1. Press the console **ID** button.
2. Select the ***Patients*** tab near the bottom of the ***Exam Management*** page to display a list of locally stored (system memory) patients.
3. Use the keyboard and trackball to enter the patient search data in ***Patient Information*** (***Patient ID*** or ***Name***, etc.).

   Note: *The* ***Patients Database*** *narrows the list of patients to those that match entered search criteria.*

4. When the list has been narrowed sufficiently (e.g., to one ***Patient ID*** or all patients with the desired ***Last Name***), use the trackball and **SELECT** button to choose the desired patient. Press **ENTER**.

To Change the Layout of the Patient Data Columns:

1. Press the console **ID** button.
2. Use the trackball to position the arrow cursor over the ***Field Header*** to be moved.



3. Hold down the **SELECT** button and simultaneously use the trackball to drag the column to the desired location.

   Note: *To change the order of the list (e.g., from numerical by* ***Patient ID*** *number to alphabetical by* ***Last Name****), position the cursor over the relevant* ***Field Header*** *and press* **SELECT**. *To reverse the order press* **SELECT** *again.*

4.5.2 DICOM Worklist

The system must be configured for ***DICOM Worklist*** and connected to a DICOM server in order for the ***Worklist*** database feature to function. For setup instructions, refer to **9.2.11 DICOM Configuration**.

Note: *The data in the fields available on the actual search page are dependant upon the data entered into DICOM:* ***Patient ID***, ***Last Name***, ***First Name***, ***Accession #***, ***Start Date (mm/dd/yyyy)***, ***End Date (mm/dd/yyyy)***, ***Exam Type***, ***Procedure ID***, ***Station AE Title***, ***Station Location*** *and* ***Modality Type****.*

Figure 4-5: Exam Management Page (Worklist)

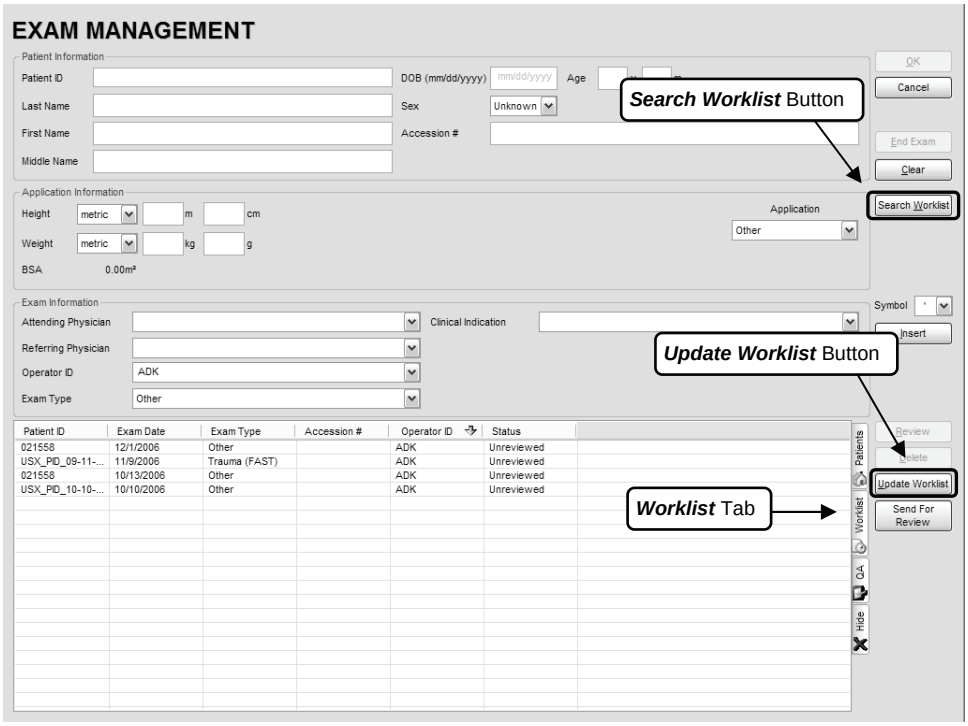


Figure 4-6: DICOM Worklist Search Page

4.5.2.1 Manipulating the Worklist Database

To Perform a Worklist Search:

1. Press the console **ID** button.
2. Select ***Search Worklist*** from the ***Exam Management*** page.
3. When the ***Worklist Search Criteria*** page appears on the screen, enter the patient search data (***Patient ID*** or ***Name***, etc.).

Note: Worklist *text fields can be searched with wildcards, e.g., entering* ***SMI**** *in the* ***Last Name*** *field will find all names beginning with* ***SMI****.*

4. Select ***Search*** to update the ***Worklist*** with the results of the advanced search.

Note: *The parameters from the last search will be retained for the duration of the current (computer-defined) date.*

Note: Worklist Search *results are limited to a maximum of 100 records. Any result list longer than 100 records will be truncated.*

To Select a Patient from the Worklist:

1. Press the console **ID** button.
2. Select the ***Worklist*** tab to display the ***DICOM Worklist*** database.
3. If the desired patient is not available on the list, select ***Update Worklist*** to refresh the data.

   Note: *Updates will be based upon the last search performed.*

4. Select the desired patient and the patient data fields will auto-populate.
5. Modify patient and exam data fields as required.

   Note: T*he* ***Patient ID*** *cannot be modified.*

   Modifications to auto-populated ***Worklist*** *fields (****Name*** *and* ***Accession #****) are not recommended.*

6. Select ***OK*** to save the data, create a patient in the ***Patient*** database and move to live imaging.

   Note: *The patient file is automatically deleted at the end of the exam if no images or measurements are stored to the system for this patient.*

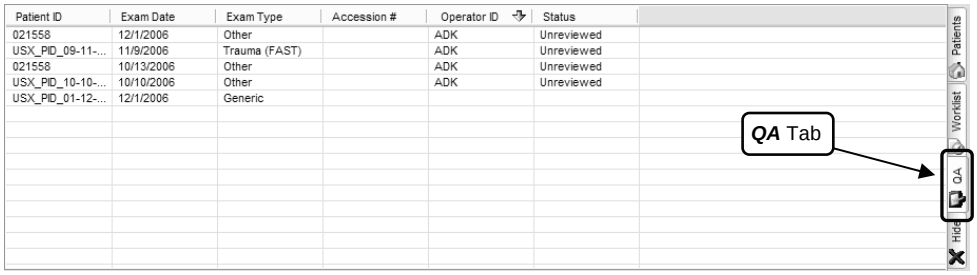
   Note: *When a new exam is initiated, the transducer used in the most recent exam will still be selected* ***if*** *it is still connected. If it no longer connected, the system will default to the first available transducer. This default transducer selection is not affected even if the system is turned off between exams.*

4.5.3 QA

Selecting the ***QA*** tab enables users to view the ***Review Status*** of all exams. For security purposes, each organization has the option of password protecting access to this database (see ***QA Password…*** in **9.2.9 System Settings** for details).

For a complete list of the options available and directions on reviewing actual exams, refer to **4.6 QA – Exam Review**.

Figure 4-7: QA Database



4.5.4 Hide

Selecting the ***Hide*** tab will instantly blank all patient data visible in the ***Patient*** or ***Worklist*** database. This is very useful when an ***Operator*** needs to quickly protect the privacy of patient data that would otherwise be visible to anyone within viewing distance.

To reveal patient data, simply click another database tab.

Figure 4-8: Hide Tab

4.5.5 User-Defined Presets/Imaging Parameters

User-defined ***Presets*** affect *only* the imaging parameters of a given ***Exam Type/Application*** on a per transducer basis. Because each type of transducer for a given ***Exam Type/Application*** can have only one (1) set of imaging parameters at any given moment, saving a ***Preset*** overwrites either the factory settings or the existing user-defined imaging parameters. Deleting a ***Preset*** will restore the factory imaging parameters. Refer to **9.2.1.2 Delete User-Defined Presets/Imaging Parameters (Non-Freehand 3D Format)** for details.

In addition to standard ***Presets***, the SONIX also allows users to create and save user-defined ***Freehand 3D Presets***. Because a ***3D*** image must be acquired before a user-defined ***3D Preset*** can be created, refer to **6.6 User-Defined Presets for Freehand 3D** for more details.

To Save User-Defined Presets (Imaging Parameters Only):

1. Use the **QSONIX** feature to start an exam.
2. Adjust the imaging parameters (e.g., ***Depth***, ***Dynamic Range***, ***Gain***, ***Sector Size***, ***Default Color Direction***, etc…) as required.
3. Tap the touch screen ***Presets*** tab.
4. Tap ***Save…*** and the imaging parameters will automatically be saved to the current ***Exam Type/Application*** – based on the current transducer type.

Note: *For details on deleting user-defined imaging parameters, refer to* **9.2.1 Presets***.*

4.6 QA – EXAM REVIEW

In an emergency room situation, not all personnel will be qualified to scan and/or diagnostically interpret the images that result from an exam. This situation is addressed by the ***Send for Review*** button – available via the ***Exam Management*** page – thus enabling an "oversight" option for qualified personnel. When this option is used, it is the responsibility of each institution to determine how the ***Reviewer's*** feedback is recorded.

In order for ***Send for Review*** to function, the system must: be connected to a network and a network printer and have ***E-Mail Setup*** and ***Reviewers*** configured (**9.2.10 Network** and **9.2.19 QA Setup**).

As a security precaution, ***Send for Review*** can be password protected to limit access to approved ***Reviewers*** only (refer to ***QA Password***… under **9.2.9 System Settings)**.

There are two (2) other methods for reviewing an exam:

- if a ***Reviewer*** is conducting/present during the exam, approval can be entered into the ***Worksheet*** before the exam is completed
- after an exam has been completed, by opening it using the ***Review*** button process and accessing the ***Worksheet***, a ***Reviewer*** can record their approval (refer to **10.2 Image Review** for more details).

Figure 4-9: Exam Management - Review

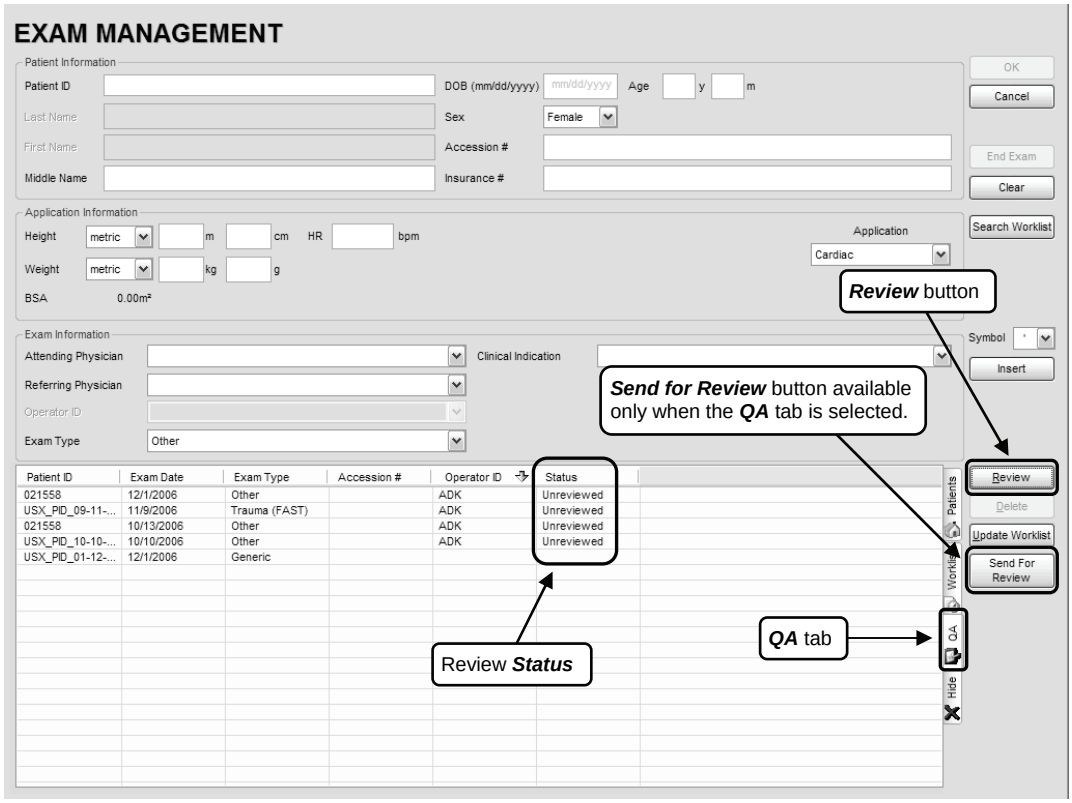


Table 4-7: "Review" Status Options for Exams

Unreviewed	The exam has not been reviewed, nor has it been sent for review.
Sent for Review	Exam has been sent to a ***Reviewer***(s) (via e-mail or print option) but the ***Worksheet*** has not been updated.
Agree	Exam has been reviewed and the ***Worksheet*** has been updated stating that the ***Reviewer Agrees*** with the results.
Disagree	Exam has been reviewed and the ***Worksheet*** has been updated stating that the ***Reviewer Disagrees*** with the results.
TP (True Positive)	Exam has been reviewed via the ***Worksheet*** and marked as a ***True Positive***.
TN (True Negative)	Exam has been reviewed via the ***Worksheet*** and marked as a ***True Negative***.
FP (False Positive)	Exam has been reviewed via the ***Worksheet*** and marked as a ***False Positive***.
FN (False Negative)	Exam has been reviewed via the ***Worksheet*** and marked as a ***False Negative***.
TLS (Technically Limited Study)	Exam has been reviewed via the ***Worksheet*** and marked as a ***Technically Limited Study***.

Note: *The last seven (7)* ***Status*** *options are dependant upon selections made in the* ***QA Review*** *section of the* ***Worksheet*** *attached to the relevant* ***Patient/Exam****.*

4.6.1 Send for Review (and Print)

Figure 4-10: Send for Review Dialog

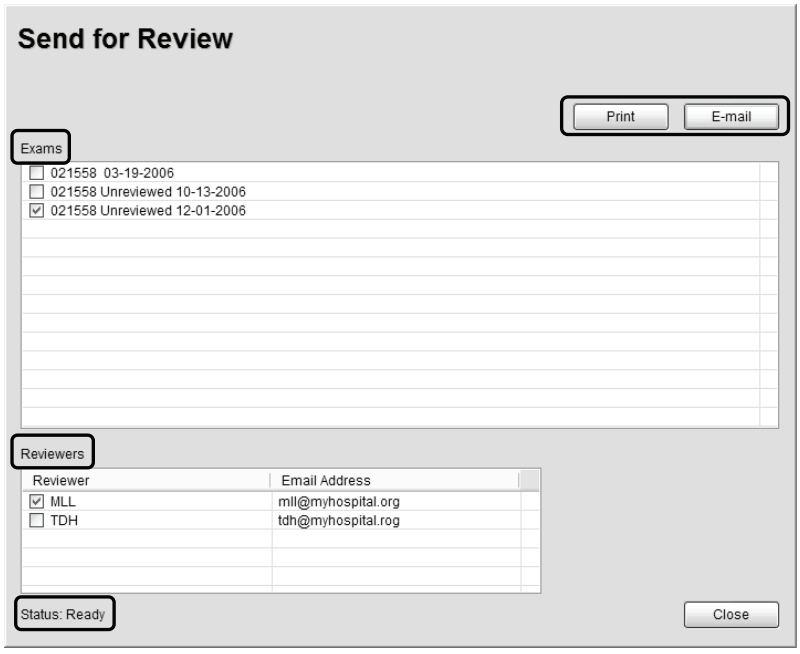


Table 4-8: Send for Review Options

Exams		The ***Exams*** presented here are selected on the ***Exam Management*** page before selecting the ***Send for Review*** button.
Reviewers	***Reviewer***	***Reviewer*** names and ***E-Mail Addresses*** must be added through **9.2.19 QA Setup**.
	E-Mail Address	
Status		In order to send an ***Exam*** to the printer or to a ***Reviewer***, the status must be set to ***Ready***. ***Note:*** *If* ***Status*** *is not set to* ***Ready****, ensure:* • *there is a* ***Network*** *connection and* ***E-Mail Setup*** *options are configured (***9.2.10 Network***)* • ***Reviewers*** *have been configured properly (***9.2.19 QA Setup***).*

Print	Press to send a PDF (Portable Document Format) version of the selected ***Exam(s)*** to the printer. ***Note:*** *The* ***Reviewer*** *will need a PDF reader to open the PDF. Free downloads of such products as Adobe® Reader® software are available from the Internet.*
E-Mail	Press to e-mail a PDF version of the selected ***Exam(s)*** to the selected ***Reviewer(s)***.

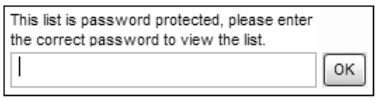
Note: *During* ***Print*** *or* ***E-Mail****, the system will present a variety of messages indicating the status of the job. Most of these messages are simply informational.*

If the ***Print*** *or* ***E-Mail*** *function fails, make note of the message in order to help your IT department or Ultrasonix Technical Support diagnose the exact nature of the problem.*

*Example messages: "****PDF generation failed****", "****Could not send message****", "****Failed to connect to the internet****".*

To Print or Send an Exam for Review:

1. Press the console **ID** button.
2. Select the ***QA*** database tab.
3. If prompted, enter the ***QA Password*** and select ***OK***.



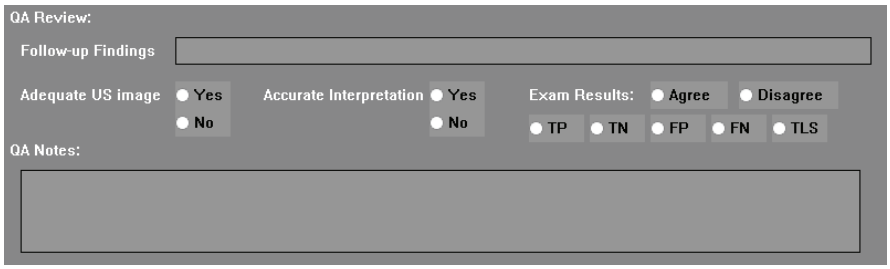
Note: *This password is controlled via the* ***QA Password…*** *option in* **9.2.9 System Settings**.

4. Select the relevant ***Patient***.
5. Click the ***Send for Review*** button.
6. Select/deselect the appropriate ***Exams*** and ***Reviewers***.
7. Click the ***Print*** or ***E-mail*** button to send the selected ***Exam(s)*** to the printer or the selected ***Reviewer(s)***, respectively.

4.6.2 Attending Review

When a ***Reviewer*** is available to oversee and/or conduct the exam, this section can be completed before the ***Worksheet*** is closed – in which case the ***Send for Review*** option (**4.6.1**) will not be required.

Figure 4-11: Review Approval via the Worksheet during an Exam



Note: *Refer to* **9.2.4 Presets – Worksheets** *for details on the fields available here.*

4.6.3 Exam Review from the Image Review Page

It is also possible to access a ***Worksheet*** – and therefore the ***Worksheet's QA Review*** fields – from the standard ***Review*** option on the ***Exam Managements*** page.

To Review an Exam via the Image Review Page:

1. Press the console **ID** button.
2. Select the ***Patients*** tab.
3. Select the relevant exam from the ***Patient*** database.
4. Click the ***Review*** button.
5. Press the console **WORKSHEET** button to access the associated ***Worksheet***.

   Note: *If no* ***Worksheet*** *was completed for the exam in question, the following message will be presented:*

6. Move to page three (3) of the ***Worksheet*** and complete the ***QA Review*** section.
7. Press the console **WORKSHEET** button to exit the ***Worksheet***.
8. Press the "**X**" in the top right corner to exit the ***Image Review*** page.

CHAPTER 5: IMAGING

The SONIX buttons controlling key imaging modes are organized into specific sections on the operator console (i.e., **2D**, **Color**, **Doppler**, **Print**, etc.). Refer to section **2.2 Operator Console** for layout details.

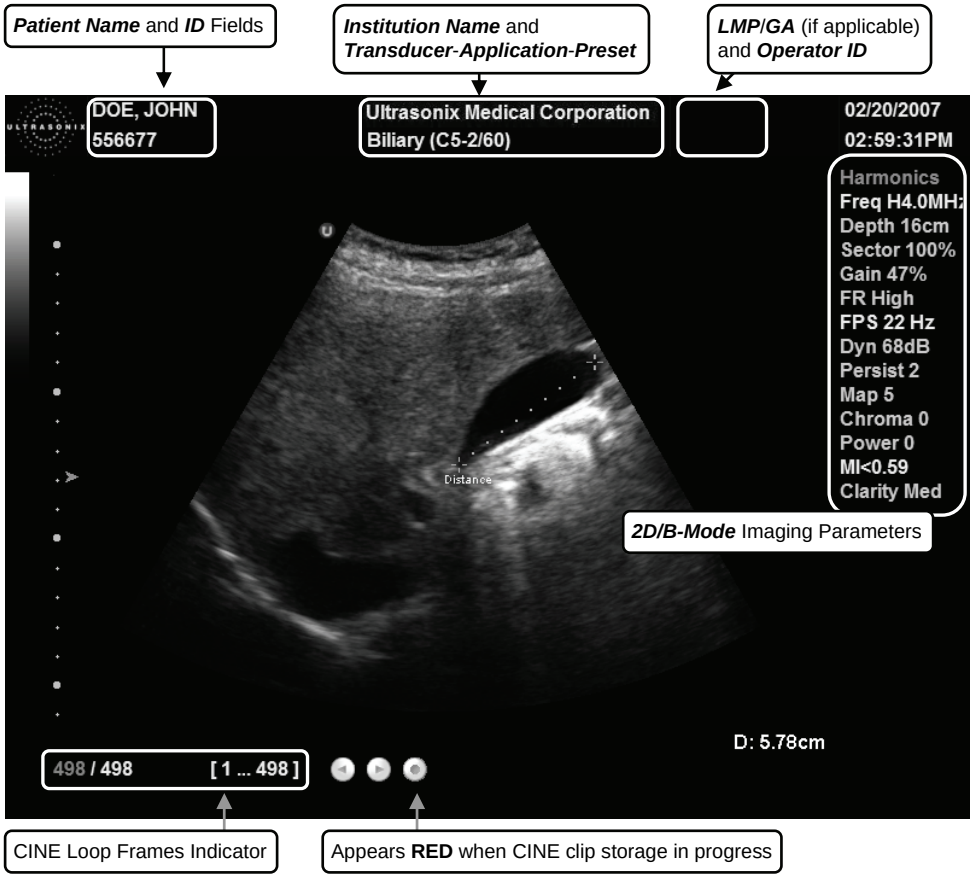
Additional imaging controls are accessible on the touch screen when a specific imaging mode is active. Touch screen imaging controls are organized by tabs for each active imaging mode.

5.1 2D/M-MODE

5.1.1 2D (B-Mode)

2D or ***B-Mode*** is the default imaging mode on the SONIX system. The key ***2D*** imaging controls are located to the upper right portion of the operator console with the exception of the ***2D*** **STEER** button which is located between the Color and Doppler controls:

Figure 5-1: 2D/B-Mode Field Locations During Imaging



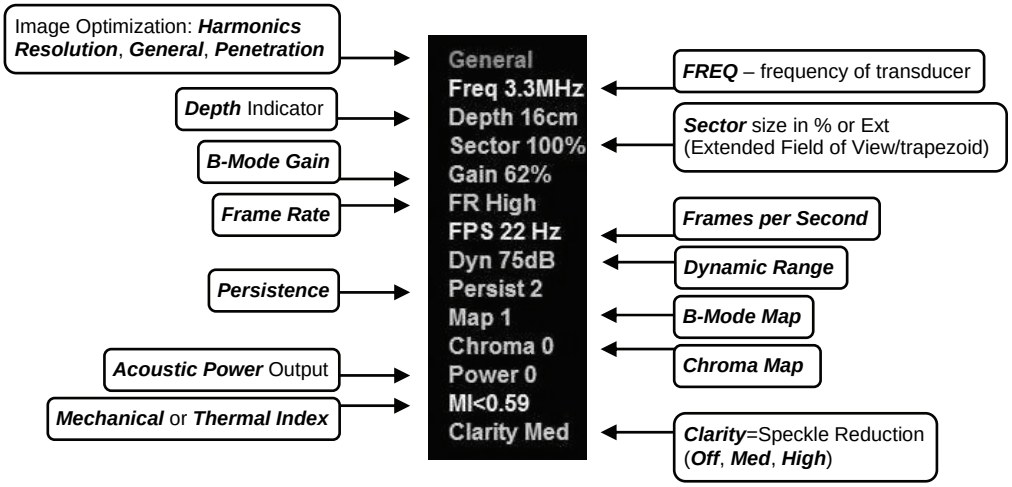
Note: *Refer to* **9.2.15 Patient Settings** *for details on* ***LMP*** *vs.* ***GA*** *selection.*

Any onscreen ***Measurements*** *taken using the* ***Master Worksheet*** *(***9.2.4***) for either* ***Early*** *or* ***Late OB Presets*** *will include* ***Gestational Age*** *(****GA****). If the user creates their own* ***Worksheet*** *(***9.2.4.1*** *and* **9.2.4.2***) for these* ***Presets*** *or deletes any default* ***Measurements*** *from the* ***Master Worksheet****,* ***GA*** *will not be visible.*

The SONIX broadband transducers provide a range of imaging ***Frequencies***:

- ***Harmonics***: provides artifact reduction (not available with all transducers)
- ***Resolution***: provides highest frequency
- ***General***: standard imaging frequency
- ***Penetration***: provides lowest frequency.

Figure 5-2: 2D/B-Mode Onscreen Imaging Parameters



Additional ***2D*** imaging parameters are available on the touch screen under the ***B-Mode*** tab.

Table 5-1: 2D Imaging Console Controls

B-MODE button/dial	Turn to adjust overall ***Gain***. Press to exit other imaging modes and return to ***2D*** imaging.
FREQ toggle button	Press up or down to adjust the transducer ***Frequency***: ***Penetration***, ***General***, ***Resolution*** and ***Harmonics.*** ***Note:*** *The* ***Harmonics*** *setting is not supported by all transducers.*
ZOOM toggle button	Press up or down to ***Zoom*** the image in or out. Press **B-Mode** to exit ***Zoom***.
DEPTH toggle button	Press up or down to adjust the imaging ***Depth*** up or down.
FOCUS toggle button	Press up or down to adjust focal zone position up or down.
DUAL/QUAD button	Press once to activate **DUAL** and twice to activate **QUAD** imaging.
M-MODE button	Press to activate **M-Mode** imaging.
STEER toggle button	Press to steer the ***2D*** beam on linear transducers. This function is not available when **COLOR** or **DOPPLER** imaging modes are active.

The **TGC** slide pods located to the right of the touch screen are used to adjust the ***Time Gain Compensation*** .

Note: *Press the* **B-MODE** *button/dial to exit other imaging modes (****Color****, ****PW Doppler****, ****M-Mode****, ****Panoramic****, ****3D****, etc.) at any time during the imaging session and return to* ***2D*** *imaging.*

Table 5-2: 2D/B-Mode Touch Screen Controls (tap to activate)

Reverse	Tap to ***Reverse*** the image orientation right/left.
Invert	Tap to ***Invert*** the image orientation up/down.
Biopsy	Tap to display ***Biopsy*** guidelines. ***Note:*** *This option is only available for the following transducers: C5-2/60, EC9-5/10, L9-4/38 and L14-5/38.* *For details on* ***Biopsy*** *use, refer to the instructions included with the Biopsy Starter Kits.*
Pano	Tap to activate the ***Panoramic*** imaging mode.

Table 5-3: 2D/B-Mode Touch Screen Controls: (tap to activate, dial to adjust)

Fr Rate	Adjusts the ***Frame Rate,*** up to 60 ***Frames per Second*** (***FPS***)
Sector	Adjusts the image ***Sector*** size. ***Note:*** *Extended* ***Field of View*** *(****FOV****) and trapezoid imaging if available.*
Focus Span	Adjusts the distance between focal zones.
Focus #	Adjusts the number of transmit focal zones on the screen. The maximum number of focal zones varies depending on which transducer is selected. ***Note:*** *Increasing the number of focal zones may reduce the* ***Frame Rate****.*
Clarity	Adjusts the level of Speckle Reduction: ***Off***, ***Med***, ***High***.
Dyn (Dynamic Range)	Adjusts the overall image contrast resolution in 1 dB increments. Displayed ***Dynamic Range*** varies from 45dB to 105dB. Complete system ***Dynamic Range*** is 262dB ***Note:*** *An increase in dB increases the level of grays displayed.*
Chroma	Adjusts the color ***Maps*** of the ***2D*** image: 0 to 4.
Persist	Adjusts the level of visual smoothing of the ***2D*** image.
Map	Adjusts the grayscale ***Map***: 1 to 10.

To Adjust the Imaging Frequency (Image Optimization):

1. Press the console **FREQ** toggle button.
2. Press up/down on the toggle button to increase/decrease the ***2D*** imaging transmit frequency.

Note: *To increase the* ***Frequency****, press the toggle button up once for* ***Resolution*** *and twice for* ***Harmonics.*** *(The latter option is transducer dependent.)*

To decrease the ***Frequency****, press the toggle button down for* ***Penetration****.*

To Select/Adjust Touch Screen 2D Imaging Parameters:

1. Tap the ***B-***Mode tab on the touch screen.
2. Tap the desired touch screen selection (e.g., ***Persistence***) .
3. Use the touch screen dial below the column containing the desired selection to make the adjustment to the imaging parameter (e.g., turn dial left to decrease ***Persistence*** or turn dial right to increase ***Persistence***).

5.1.2 Clarity (Speckle Reduction)

Clarity imaging mode enhances the ***2D*** image by performing adaptive filtering of the image. ***Clarity*** provides improved visibility of real structures with various levels of speckle reduction: ***Off***, ***Medium***, ***High***. The default ***Clarity*** level for most imaging ***Presets*** is ***Medium***.

To Adjust the Clarity (Speckle Reduction) Imaging Mode:

1. Tap the ***2D/B-Mode*** tab on the touch screen.
2. Tap ***Clarity*** on the touch screen menu.
3. Use the touch screen dial below ***Clarity*** to adjust the level of speckle reduction. The ***Clarity*** level is stated at the bottom of the ***2D*** imaging parameters listed to the right of the image field.

5.1.3 Spatial Compound Imaging

To Activate Real Time Spatial Compound Imaging:

1. Press the console **SPATIAL COMPOUND** button.
2. To exit spatial compound imaging, press **SPATIAL COMPOUND**.

Note: Spatial Compound *imaging is available as an option with some transducers, but is not available during* ***Color*** *imaging modes.*

5.1.4 2D Zoom Imaging

To Activate the Zoom Feature:

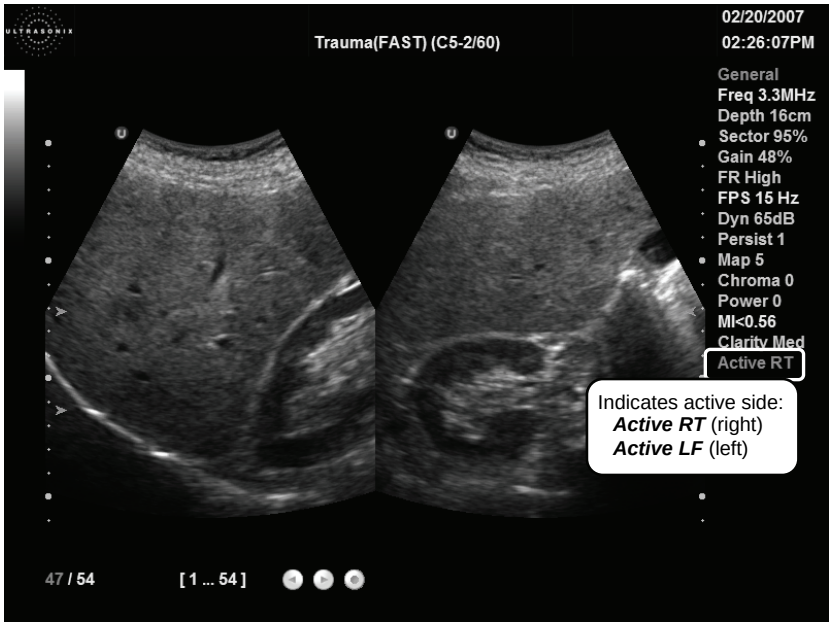
1. On a live or frozen image, press the console **ZOOM** toggle button up to the desired level of magnification.
2. Use the trackball to reposition the magnified field of view.

Note: *Repositioning of the* ***Zoom*** *field of view is only possible after the image is magnified off the image field.*

3. To reduce the level of magnification, press the **ZOOM** toggle button down to the desired level.
4. To exit the ***Zoom*** feature, press the **B-MODE** button to return to ***2D*** imaging.

5.1.5 Dual Imaging Format

Figure 5-3: Dual Image



To Activate Dual Imaging:

1. Press the console **DUAL/QUAD** button once.
2. When a live image appears on the left side of the LCD display (***Active LT***), press **UPDATE** to freeze the ***Active LT*** image and unfreeze (i.e., make active) the ***Active RT*** image, in one step.

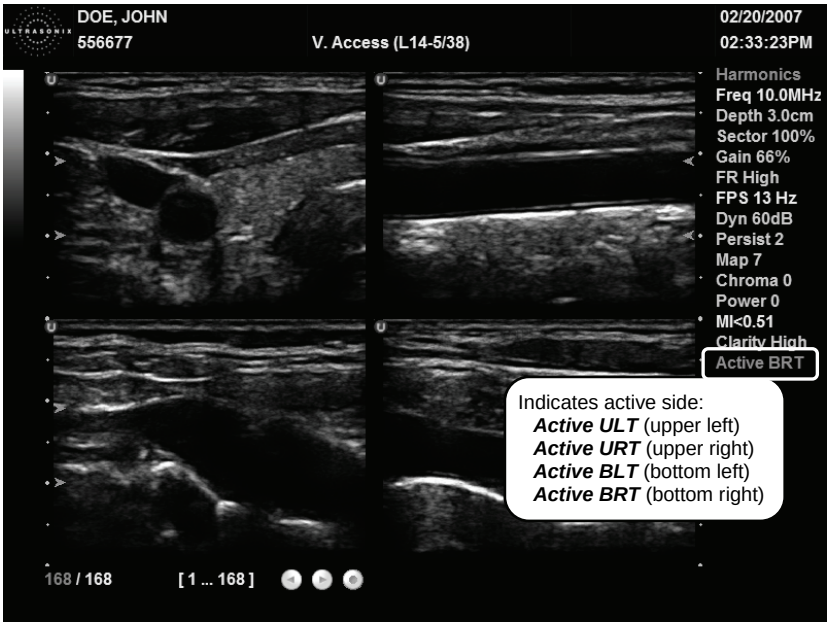
   Note: *As an alternative, press* **FREEZE** *to freeze the active image. Pressing* **UPDATE** *will then toggle between the frozen images. Press* **FREEZE** *again at any time to activate the current image.*

3. Press **UPDATE** to toggle back and forth between the dual images, freezing the inactive image and unfreezing the newly active image.
4. Press **B-MODE** to exit ***Dual*** imaging.

   Note: Color Doppler *is available during* ***Dual*** *but not* ***Quad*** *imaging.*

5.1.6 Quad Imaging Format

Figure 5-4: Quad Image



To Activate Quad Imaging:

1. Press the console **DUAL/QUAD** button twice.
2. When a live image appears on the upper left side of the LCD display (***Active ULT***), press **UPDATE** to freeze the ***Active ULT*** image and unfreeze (i.e., make active) the upper right (***URT***) quadrant, in one step.

   Note: *Instead of pressing* **UPDATE***, press* **FREEZE** *to freeze the active image. Press* **UPDATE** *to move to the next quadrant which will also contain a frozen image. Press* **FREEZE** *to activate it or* **UPDATE** *to move to the next quadrant.*

3. Press **UPDATE** again to freeze the current image and move to the next quadrant.

   Note: **UPDATE** *toggles through the images sequentially:* ***ULT***, ***URT***, ***BLT***, ***BRT****.*

4. Continue pressing **UPDATE** to move through the four (4) images as required. Depending on the method selected above (**UPDATE** only or **FREEZE** and **UPDATE**), the images will be active or frozen, respectively.
5. Press **DUAL/QUAD** or **B-MODE** to exit ***Quad*** imaging.

   Note: Color Doppler *is available during* ***Dual*** *but* <u>*not*</u> ***Quad*** *imaging.*

5.1.7 M-Mode Imaging Mode

The following ***M-Mode*** imaging parameters are available on the touch screen during active ***M-Mode*** imaging.

Table 5-4: M-Mode Touch Screen Controls (tap to activate, dial to adjust)

Sweep	Adjusts the speed of ***M-Mode Sweep***: ***Low***, ***Medium*** or ***High***.
M Zoom	Adjusts the amount of ***M-Mode*** magnification. Use the trackball to reposition ***M-Zoom*** location.
Chroma	Adjusts the color of the ***M-Mode Sweep***: 0 to 5.
Map	Adjusts the grayscale ***Map***: 1 to 3.

To Activate M-Mode Imaging:

1. Press the console **M-MODE** button.
2. A live full screen ***2D*** image appears with an ***M-Mode*** cursor.

   Note: *Refer to section* **9.2.14 Display Settings** *to customize the* ***M-Mode*** *display settings (****Side by Side****, etc.)*

3. Press **UPDATE**.
4. On the touch screen, tap/dial ***M Zoom***, ***Sweep***, ***Chroma*** and ***Map*** to make any required adjustments.
5. Press **M-MODE** or **B-MODE** to exit ***M-Mode*** imaging and return to ***2D*** imaging.

To Select/Adjust Touch Screen M-Mode Imaging Parameters:

1. Tap the touch screen ***M-Mode***.
2. Tap desired selection (e.g., ***Chroma***).
3. Use the touch screen dial below the column containing the desired selection to make the adjustment to the imaging parameter.

5.1.8 CINE Clip Storage and Thumbnail Image/Clip Review

5.1.8.1 CINE Clip Storage

To Store a 2D or 2D/Color CINE Clip:

1. Press the console **FREEZE** button.
2. The image field will freeze and display the ***CINE*** touch screen controls.
3. If not currently active, tap the touch screen ***CINE*** tab.

The following ***CINE clip*** storage controls are available on the touch screen with a frozen ***2D*** image.

Table 5-5: CINE Touch Screen Controls (tap to activate)

Play Fwd	Select to ***Play Forward*** the available ***CINE*** frames.
Play Rev	Select to play in reverse the available ***CINE*** frames.
Stop	Select to ***Stop*** the ***CINE*** frames from playing.
Record	Select to store the selected ***CINE*** frames to the system.

Table 5-6: CINE Touch Screen Controls (tap to activate, dial to adjust)

FrmByFrm Fast	Use to select currently displayed frame, 10 frames at a time.
FrmByFrm	Use to select currently displayed frame, one (1) frame at a time.
Start Fast	Use to select start frame for ***CINE Clip***, 10 frames at a time.
Start	Use to select start frame for ***CINE Clip***, one (1) frame at a time.
End Fast	Use to select end frame for ***CINE Clip***, 10 frames at a time.
End	Use to select end frame for ***CINE Clip***, one (1) frame at a time.
Play Speed	Use to select ***CINE Play Speed*** (⅛, ¼, ½, full (1) or double (2)).

Notes:

CINE clip *storage is not available for* ***M-Mode*** *and* ***PW****.*

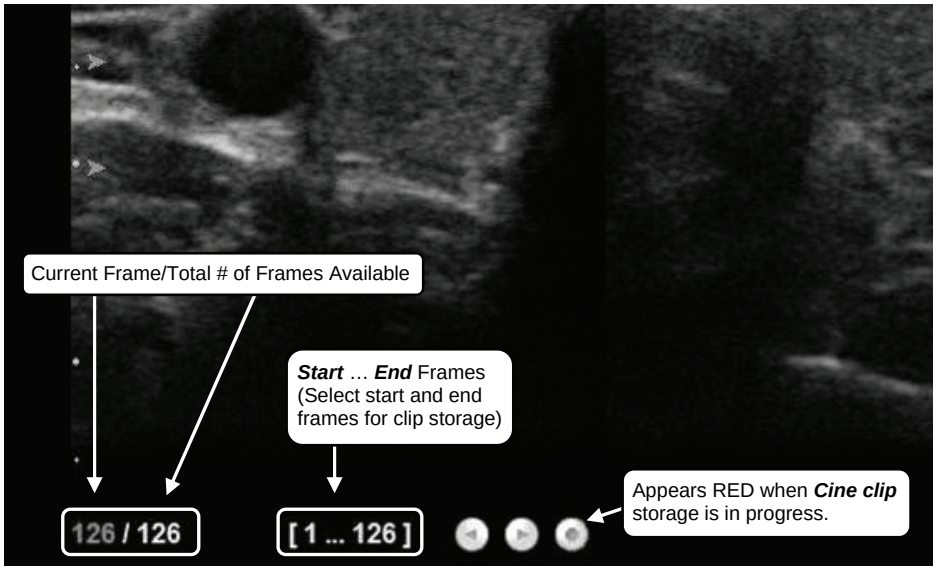
Changes made to ***Depth****,* ***Gain****, etc., will reset the number of frames available for review or storage.*

CINE loop *storage is a retrospective acquisition.*

To Select/Adjust Touch Screen CINE Controls:

1. Tap the touch screen ***CINE*** tab.
2. Tap desired selection (e.g., ***Start Fast***).
3. Use the touch screen dial below the column containing the desired selection to make the adjustment to the ***CINE clip***.

Figure 5-5: CINE Frame Indicators (located at bottom left of the image field on frozen image)



5.1.8.2 Stored Thumbnail Review

The Stored Thumbnail Review is displayed at the bottom of the LCD display.

To Review a Thumbnail Image/CINE Clip:

1. Move the trackball arrow over the desired thumbnail and press the console **SELECT** button.
2. Press **SELECT** again to return to imaging mode.

Note: *If the trackball arrow is not available, it may be occupied by other imaging or measurement modes. To retrieve it, press the* **SELECT** *button to release the cursor from the active mode.*

The following ***CINE Clip Review*** controls are available on the touch screen.

Table 5-7: CINE Review Touch Screen Controls (tap to activate)

Toggle Repeat	Select to toggle between two methods of reviewing the stored loop: • repeat clip over/loop (indicated by curved arrow) • stop clip at end (indicated by straight arrow).
Exit	Select to ***Exit*** the clip review and return to ***2D*** imaging.
Play	Select to ***Play*** the clip forward.
Pause	Select to ***Pause*** the stored clip.

Table 5-8: CINE Review Touch Screen Controls (tap to activate, dial to adjust)

FrmByFrm	Use to select currently displayed frame, one (1) frame at a time.
Speed	Use to select ***CINE*** review play ***Speed*** (⅛, ¼, ½, full (1) or double (2)).

To Select/Adjust Touch Screen CINE Review Controls:

1. Tap the touch screen ***Review*** tab.
2. Tap desired selection (e.g., ***Speed***).
3. Use the touch screen dial below the column containing the desired selection to make the adjustment to the ***CINE Review***.

5.2 COLOR/POWER DOPPLER

Color Doppler is used to detect blood flow and determine flow direction. ***Power Doppler*** is more sensitive to low flow rate in small vessels, but offers no directional information. ***Color Power Doppler*** is ***Power Doppler*** with a red/blue color map providing directional flow information.

Figure 5-6: Color Doppler Image

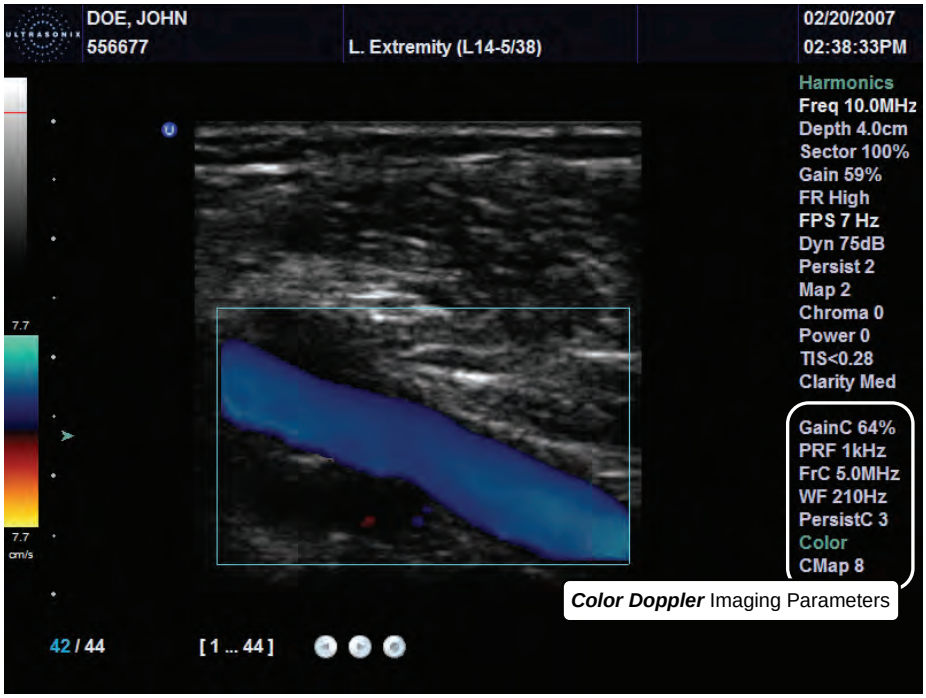
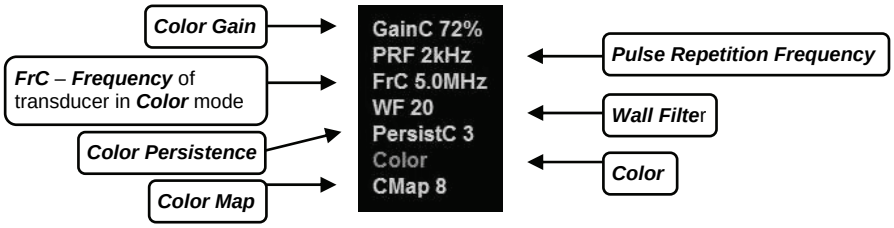


Figure 5-7: Color Doppler Imaging Parameters



The key ***Color/Power Doppler*** imaging controls are located in the upper center position of the operator console.

Table 5-9: Color Doppler Console Controls

COLOR button/dial	Press to select ***Color Doppler*** imaging/turn to adjust ***Color*** gain.
POWER DOPPLER button	Press to activate ***Power Doppler*** imaging.
WF toggle button	Press up or down to adjust the ***Color Wall Filte***r higher or lower.
PRF toggle button	Press up or down to adjust the ***Color Doppler Pulse Repetition Frequency*** up or down.
INVERT button	Press to ***Invert*** the direction of the ***Color Map***.
STEER toggle button	Press to ***Steer Color*** ROI box right or left.

Additional ***Color/Power Doppler*** image optimization controls are available on the touch screen ***Color*** tab when the ***Color*** imaging mode is active:

Table 5-10: Color Doppler Touch Screen Controls (tap to activate)

Simult 2D/Col	Tap to activate/deactivate simultaneous side-by-side split screen: • left side: ***live 2D/Colo***r • right side: ***live 2D***.

Table 5-11: Color Doppler Touch Screen Controls: (tap to activate, dial to adjust)

Baseline	Adjusts the ***Color Doppler Baseline***.
Priority	Adjusts the ***Color Doppler 2D Priority***.
Persistence	Adjusts the ***Color Doppler Persistence***.
Map	Adjusts the ***Color Doppler Map***. Choose from any of 10 different ***Color Maps***.
Freq	Adjusts the ***Frequency*** of the ***Color Doppler***.
Box Height	Adjusts the size of the ***Color*** ROI box vertically.
Fr Rate	Adjusts the image ***Frame Rate***. ***Note:*** *Decreasing the* ***Frame Rate*** *increases color quality providing higher color line density. Increasing the* ***Frame Rate*** *decreases color quality.*
Box Width	Adjusts the size of the ***Color ROI*** box horizontally.

To Select/Adjust Touch Screen Color Imaging Parameters:

1. Tap the touch screen ***Color*** tab.
2. Tap the desired selection (e.g., ***Persistence***).
3. Use the touch screen dial below the column containing the desired selection to make the adjustment to the imaging parameter (e.g., turn dial left to decrease the amount of ***Persistence***/turn dial right to increase the amount of ***Persistence***).

5.2.1 Color Doppler Imaging Mode

To Activate Color Doppler Imaging Mode:

1. Press the console **COLOR** button. A live, full screen ***2D*** image with ***Color*** ROI box is displayed.
2. Use the trackball to position the ***Color*** ROI box to the area of interest.
3. Press **SELECT** to toggle control of the trackball to resize the ***Color*** ROI box.
4. Use the trackball to resize the ***Color*** ROI box or use the touch screen controls to make the horizontal and vertical ***Color*** ROI box adjustments.

   Note: *During multiple mode imaging (i.e.,* ***2D/Color/PW Doppler****) use the* **SELECT** *button to toggle control of the trackball for* ***Color*** *ROI box positioning,* ***Color*** *ROI box resizing and* ***PW*** *cursor/****Gate*** *positioning. Alternate controls are available on the* ***Color*** *tab to resize the* ***Color*** *ROI box. The* ***Color*** *ROI box moves with the* ***PW*** *cursor.*

5. Press **COLOR** to exit ***Color Doppler*** imaging.

5.2.2 Color Power Doppler Imaging Mode

To Activate Color Power Doppler Imaging Mode:

1. Press the **POWER DOPPLER** button. A live, full screen ***2D*** image with ***Color Power*** ROI box is displayed.
2. Use the trackball to position the ***Color Power*** ROI box to the area of interest.
3. Press **SELECT** to toggle control of the trackball to resize the ***Color Power*** ROI box.
4. Use the trackball to resize the ***Color Power*** ROI box or use the touch screen controls to make the horizontal and vertical ***Color Power*** ROI box adjustments.

   Note: *During multiple mode imaging (i.e., **2D/Color/PW Doppler**) use the* **SELECT** *button to toggle control of the trackball for **Color** ROI box positioning, **Color** ROI box resizing and **PW** cursor/**Gate** positioning. Alternate controls are available on the **Color** tab to resize the **Color** ROI box. The **Color** ROI box moves with the **PW** cursor.*

5. Press **POWER DOPPLER** to exit ***Color Doppler*** imaging.

5.2.3 Simultaneous 2D/Color and 2D

To Activate Split Screen with Simultaneous Live 2D/Color and Live 2D:

1. Activate ***Color*** imaging mode.
2. Tap the touch screen ***Color*** tab.
3. Tap ***Simult 2D/Color***.

   Note: *The live, **2D** image with **Color** is displayed on the left side of the image field and the same live, **2D** image without **Color** is simultaneously displayed on the right side of the image field. Freezing the image will freeze both sides simultaneously.*

4. To exit the simultaneous ***2D/Color*** and ***2D*** imaging mode, tap ***Simult 2D/Color*** located under the touch screen ***Color*** tab.

5.3 PULSED WAVE (PW) DOPPLER AND TRIPLEX

Figure 5-8: Pulsed Wave Doppler Image

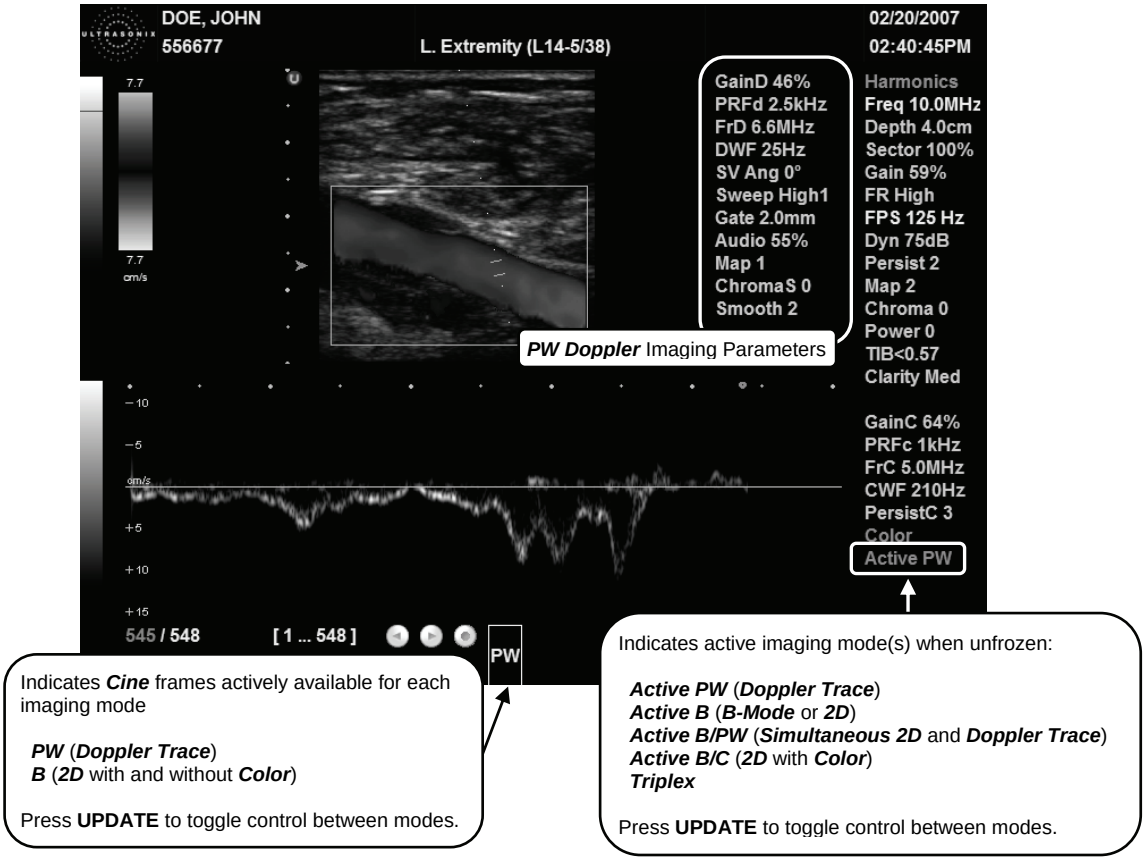
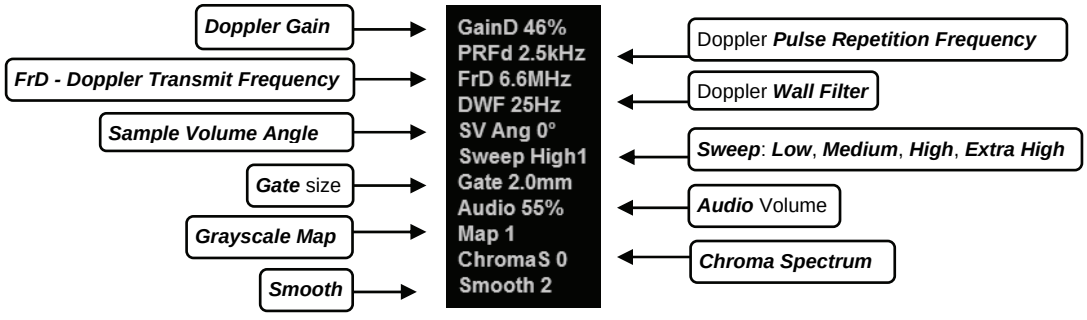


Figure 5-9: PW Doppler Imaging Parameters



The key ***PW Doppler*** imaging controls are positioned to the upper left portion of the operator console:

Table 5-12: Doppler Console Controls

PW button/dial	Press to activate ***PW Doppler*** mode/turn to adjust ***PW Doppler Gain***.
CW button	Not available.
BASE toggle button	Press up or down to adjust the ***Doppler Trace Baseline*** up or down.
PRF toggle button	Press up or down to adjust the ***Doppler PRF*** up or down.
INVERT button	Press to ***Invert*** the direction of the ***Doppler Trace***.
ANGLE CORRECT button/dial	Press to toggle between +60, -60 and 0 degree ***Doppler*** **ANGLE CORRECT** selections. Turn the dial to make angle corrections in 2 degree increments.
STEER button	Press to ***Steer Doppler*** cursor angle right or left. Also used to steer ***Color*** ROI box and ***2D*** linear image field.

The ***Doppler Volume*** control dial is located to the left of the touch screen on the operator console.

Additional ***PW Doppler*** imaging parameters are available on the touch screen to optimize the Live ***Doppler Trace***.

Table 5-13: Doppler Touch Screen Controls (tap to activate, dial to adjust)

Trace On/Off	Activates/deactivates live spectral ***Doppler Trace*** display with measurement values.
Triplex	Available when ***Color*** and ***Pulsed Doppler*** imaging modes are activated. Tap to activate/deactivate ***Triplex*** imaging mode.
Sweep	Adjusts the sweep speed of ***Doppler Trace*** (***Low***, ***Medium***, ***High***, ***Extra High***)
Reject	Adjusts the ***Doppler*** spectrum threshold.
Gate (Sample Volume)	Adjusts the ***PW Sample Volume Gate*** size. ***Note:*** *To adjust the* ***Gate*** *size in full screen* ***2D/PW*** *cursor, turn the* **PULSED DOPPLER** *dial.*
Map	Adjusts the grayscale ***Map*** of the ***Doppler Trace***.
Chroma	Adjusts the color ***Map*** of the ***Doppler Trace*** (0 to 7).
Freq	Adjusts the ***Doppler*** transmit ***Frequency***.
WF (Wall Filter)	Adjusts the ***Doppler Wall Filte***r

To Select/Adjust Touch Screen PW Doppler Imaging Parameters:

1. Tap the touch screen ***PW Doppler*** tab.
2. Tap the desired selection (e.g., ***PW Gate*** size).
3. Use the dial below the relevant touch screen column to adjust the imaging parameter (e.g., turn dial left to decrease ***Gate*** size/turn dial right to increase ***Gate*** size).

5.3.1 Pulsed Wave (PW) Doppler Imaging Mode

To Activate PW Doppler Imaging Mode:

1. Press the console **PULSED DOPPLER** button.

Note: *The default* ***Doppler*** *display settings are* ***⅓ – 2D || ⅔ – Trace*** *(****Large Spectrum****) with full screen* ***2D/Doppler*** *cursor upon initial activation. Refer to* **9.2.9 System Settings (Imaging Modes)** *to customize the* ***Doppler*** *display settings.*

Note: *To adjust the* ***Sample Volume Gate*** *size in full screen* ***2D/PW*** *cursor, turn the* ***PW*** *button/dial.*

2. Use the trackball to position the ***Doppler*** cursor/***Gate*** to the area of interest.
3. Press **UPDATE** to display a live ***Doppler Trace*** and a frozen ***2D*** image/cursor.
4. Press **UPDATE** to toggle back and forth between ***PW Trace*** and ***2D***/cursor.
5. Press **B-MODE** to exit ***PW*** imaging mode.

5.3.2 Triplex Imaging Mode

Triplex imaging mode combines live ***2D/Color Doppler*** with live ***PW Doppler*** imaging modes, allowing the user to image with ***2D/Color*** and ***PW Doppler*** modes simultaneously.

Caution: Triplex *imaging may diminish the quality of the* ***2D/Color*** *image and may cause* ***Doppler*** *artifacts.*

Table 5-14: Triplex Touch Screen Controls (tap to activate)

Triplex	Tap to activate/deactivate ***Triplex*** imaging mode.
	Note: *Once* ***Triplex*** *is active, press the console* **UPDATE** *button to toggle through* ***Active PW***, ***Active B/C*** *and* ***Triplex*** *imaging modes.*

To Activate Triplex Imaging Mode:

1. Activate ***Color*** and ***Pulsed Doppler*** imaging modes.
2. Press the console **UPDATE** button.
3. Tap ***Triplex*** on the touch screen.

   Note: *Once* ***Triplex*** *is active, press the console* **UPDATE** *button to toggle through* ***Active PW***, ***Active B/C*** *and* ***Triplex*** *imaging modes.*
4. To return to ***Duplex*** imaging, tap ***Triplex*** on the touch screen.

5.4 PANORAMIC IMAGING MODE

Panoramic imaging enables the user to generate a panoramic view of the 2D ultrasound image field, which is much wider than the typical transducer field of view.

Panoramic images are composed of several standard ultrasound images acquired as the transducer is moved along the anatomical area of interest in a direction parallel to the transducer array. The resulting compound or composite image displays a large cross section of the area of interest which can then be viewed, measured, labeled and archived.

Figure 5-10: Panoramic Image

Caution: *Measurements performed on the acquired **Panoramic** image may be inaccurate as the accuracy of the geometric re-composition is very user-dependent. Measurements performed on the acquired **Panoramic** image should be used for informational purposes only.*

To Activate Panoramic (Pano) Imaging Mode:

1. While in ***B-Mode***, tap the ***B*** tab on the touch screen.
2. Tap the ***Pano*** button and a progress bar with the message "***Loading Panoramic Tables…***" will appear on the screen.

   Note: *This may take a few seconds. The panoramic feature is ready to use when a white* ***Pano*** *ROI box appears on the* ***2D*** *image.*

3. To begin acquiring a ***Panoramic*** image, position the left side of the anatomical area of interest within the ***Pano*** ROI box.
4. Press **UPDATE** or tap ***Start/Stop*** on the touch screen to begin the ***Panoramic*** acquisition.
5. Move the transducer along a path parallel to the transducer array along the area of interest. For best results move the transducer at a slow and steady pace.
6. When a suitable ***Pano*** image is acquired, press the **FREEZE** or **UPDATE** button on the operator console or tap ***Start/Stop*** on the touch screen.
7. The generated ***Panoramic*** image appears in the image field.

   Note: Pano *parameters to rotate or enlarge the image are available on the touch screen.*

8. Tap ***Exit*** to exit the ***Panoramic*** imaging mode and return to ***2D*** imaging.

   Caution: *Measurements performed on the acquired* ***Panoramic*** *image may be inaccurate as the accuracy of the geometric re-composition is very user-dependent. Measurements performed on the acquired* ***Panoramic*** *image should be used for informational purposes only.*

CHAPTER 6: FREEHAND 3D IMAGING

Configuration for ***Freehand 3D*** imaging is controlled through **9.2.8 3D Settings**. The ***3D Config*** dialog box may be configured to appear after image acquisition or not to display at all. In the latter case the freehand imaging parameters are controlled via the touch screen, before image acquisition.

The following ***3D*** image optimization parameters are available on the touch screen.

Table 6-1: 3D Main Touch Screen Controls (tap to activate, dial to adjust)

VR	Displays only the ***Volume Rendering*** of the 3D image.
A|VR	Displays side-by-side, split-screen view of the ***Acquisition Plane (A)*** image with a ***3D VR*** image.
C|VR	Displays side-by-side, split-screen view of the ***Coronal Plane (C)*** image with a ***3D VR*** image.
A|B ***C|VR***	Displays the ***A***, ***B (Transverse)*** and ***C*** planes images along with a ***3D VR*** image.
Save Volume	Tap to save the volume data. This allows ***Operators*** to reopen the ***3D*** image (and manipulate its settings) during the exam so long as it remains the ***Current*** exam. It can also be reopened later using the ***Review*** option on the ***Exam Management*** page.
Reset	Returns many settings to their default.
Exit	***Exits 3D*** imaging.
Threshold	Tap/dial to suppress image artifacts or noise with a ***Threshold*** adjustment. ***Reset*** applies to this option. ***Note:*** *The* ***Dynamic Range*** *of the image will be optimized automatically based on the selected* ***Threshold*** *setting.*
Transp	Adjusts image ***Transparency*** settings on the LCD display. ***Reset*** applies to this option.
X-axis	Rotates the selected image about the ***X-axis***.
Y-axis	Rotates the selected image about the ***Y-axis***.
Z-axis	Rotates the selected image about the ***Z-axis***.
VR Orient	Sets the ***Orientation*** of the ***VR***. ***Reset*** applies to this option. ***Note:*** *This setting is tracked under* ***Current Display*** *on the right side of the LCD display.*

***Note: 3D Advanced**, **Sculpt…** options (below) cannot be applied during image acquisition.*

Table 6-2: 3D Advanced Touch Screen Controls (tap to activate, dial to adjust)

Sculpt…	***Lasso (inside)***	Traces a freehand ***Lasso*** around the desired area and deletes all items inside the shape.
	Lasso (outside)	Traces a freehand ***Lasso*** around the desired area and deletes all items outside the shape.
	Rect (inside)	Traces a ***Rectangle*** around the desired area and deletes all items inside the shape.
	Rect (outside)	Traces a ***Rectangle*** around the desired area and deletes all items outside the shape.
	Ellipse (inside)	Traces an ***Ellipse*** around the desired area and deletes all items inside the shape.
	Ellipse (outside)	Traces an ***Ellipse*** around the desired area and deletes all items outside the shape.
	Undo All	Undoes all the edits made during the session. ***Note:*** *A session is considered ended once the user exits **Sculpt…**. Re-entering **Sculpt…** is considered a new session even if the same image is being edited.*
	Undo Last	Undoes the edits made during the session, one at a time, in reverse order.
	Exit	***Exits Sculpt…***.
	VR Orient	Sets the ***Orientation*** of the selected image. ***Note:*** *This setting is tracked under **Current Display** on the right side of the LCD display.*
X-axis		Rotates the selected image about the ***X-axis***.
Y-axis		Rotates the selected image about the ***Y-axis***.
Z-axis		Rotates the selected image about the ***Z-axis***.

Table 6-3: 3D Display Touch Screen Controls (tap to activate, dial to adjust)

Slice Lines	Displays the actual slices of the ***3D*** image as determined by the ***A***, ***B*** and ***C Planes***. To view their position without ***Slice Lines*** selected, turn on ***Reference Planes***.
Reference Planes	Displays the positioning of the three-dimensional planes as they would appear in the ***VR*** or ***MPR Rendering***, without actually "slicing" the planes through the image. To view the actual slices, turn on ***Slice Lines***.
Boundary Box	Inserts a yellow, 3D box that represents the outer edges of the 3D data.
Axes	Displays the color-coded ***Axes*** markers through the ***VR*** image.
Save Preset	Once the settings have been adjusted as desired, tap to save as a user-defined ***3D Preset***.
Background	Tap/dial to adjust the color of the LCD display ***Background***. This setting has a range of 1 to 101, inclusive, where 1 is the darkest and 101 is the lightest. ***Note:*** *This setting is tracked under* ***Current Display*** *on the right side of the LCD display. This setting is not affected by* ***Reset****.*
Contrast	Adjusts ***VR*** image ***Contrast*** settings on the LCD display. ***Reset*** applies to this option.
VR Map	Tap/dial to adjust the coloration of the ***VR*** image using pre-defined color maps. The range for this setting is 01 to 19, inclusive. ***Reset*** applies to this option. ***Note:*** *This setting is tracked under* ***Current Display*** *on the right side of the LCD display.*
MPR Map	Tap/dial to adjust the coloration of the ***MPR*** images using pre-defined color maps. The range for this setting is 01 to 34, inclusive. ***Reset*** applies to this option. ***Note:*** *This setting is tracked under* ***Current Display*** *on the right side of the LCD display.*
VR View	Tap/dial to adjust the position from which the ***VR*** is viewed. There are six (6) positions available: ***Top***, ***Bottom***, ***Left***, ***Right***, ***Front*** and ***Back***. ***Reset*** applies to this option. ***Note:*** *This setting is tracked under* ***Current Display*** *on the right side of the LCD display.*

6.1 ACQUIRING FREEHAND 3D IMAGES

Freehand 3D images are acquired by moving the transducer in either a ***Parallel*** or ***Fan*** motion.

Table 6-4: Freehand 3D Image Configuration Options (touch screen/dial or dialog box)

Paral (Parallel)	Select ***Paral*** as the ***Scan Type*** to measure the ***Length*** of a linear path in centimeters. The selection range is 1 cm to 25 cm, with adjustments available in 1 cm increments.
	Note: *Slide the transducer along a linear path.*
Fan	Select ***Fan*** as the ***Scan Type*** to measure a pivot ***Angle*** in degrees. The selection range is 5º to 90º, with adjustments available in 5º increments.
	Note: *Pivot the transducer in a rocking motion.*

To Obtain a Freehand 3D Image with Configuration BEFORE Acquisition:

1. Press the console **3D/4D** button.
2. On the touch screen, tap the desired ***Preset*** name.
3. Turn the dial below ***Scan Type*** to select either ***Paral*** or ***Fan***.
4. The associated value option will automatically change to the appropriate measurement type: ***Length*** for ***Parallel*** or ***Angle*** for ***Fan*** .
5. Turn the dial below the associated value until it reaches the desired setting.
6. Position the transducer to one side of the anatomical area of interest.
7. Press **UPDATE** to begin the acquisition.
8. Move the transducer over the area of interest in a motion relevant to the ***Scan Type*** selection made in Step 3, above (***Parallel*** or ***Fan).***
9. Press the console **FREEZE** button to complete the acquisition.

Note: *If the process takes too long, the system will complete the image automatically before the* **FREEZE** *button is pressed and present the following message bubble.*

10. The acquired image will be rendered to the LCD display in the ***A|B|C|VR*** format.

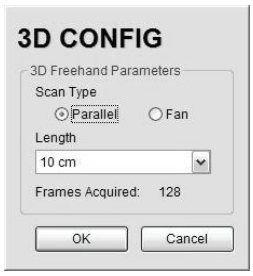
Note: *Use the* ***3D Main*** *touch screen selections to change the viewing format.*

To Obtain a Freehand 3D Image with Configuration AFTER Acquisition:

1. Press the console **3D/4D** button.
2. On the touch screen, tap the desired ***Preset*** name.
3. Position the transducer to one side of the anatomical area of interest.
4. Press **UPDATE** to begin the acquisition.
5. Move the transducer over the area of interest in either a ***Parallel*** or ***Fan*** motion.
6. Press the console **FREEZE** button to complete the acquisition.

Note: *If the process takes too long, the system will complete the image automatically before the* **FREEZE** *button is pressed and present the following message bubble.*

7. Select the freehand ***Scan Type*** from the ***3D Config*** dialog box: ***Parallel*** or ***Fan***.



Note: *The* ***Scan Type*** *selected should match the motion used to acquire the image:* ***Parallel*** *or* ***Fan****.*

8. Select the appropriate ***Length*** or ***Angle*** setting from the drop-down menu.
9. Select ***OK*** to complete the configuration.
10. The acquired image will be rendered to the LCD display in the ***A|B|C|VR*** format.

Note: *Use the* ***3D Main*** *touch screen selections to change the viewing format.*

6.2 LCD DISPLAY EDITING PARAMETERS FOR FREEHAND 3D IMAGES

Once a ***3D*** image has been captured, there are several editing parameters available on the LCD display.

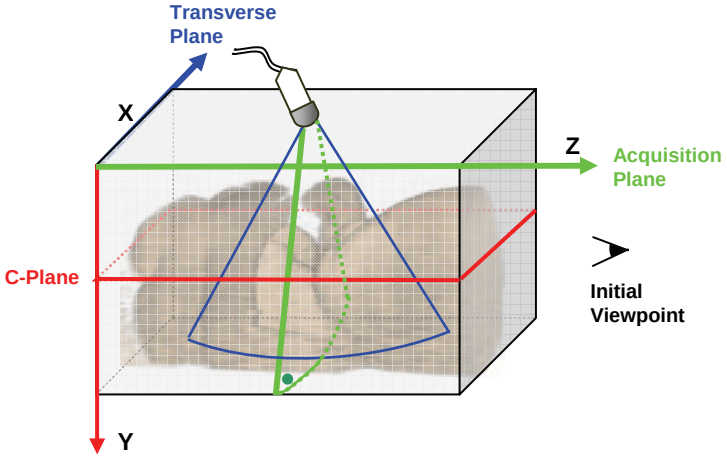
Figure 6-1: Sample Freehand 3D Image Display

Table 6-5: Image Quadrants

Green: ***Acquisition Plane (A)***	**Blue:** ***Transverse Plane (B)*** Perpendicular to the ***Acquisition Plane***
Red: ***Coronal Plane (C)***	***Volume Rendering*** **(*VR*)** **AND/OR** ***MPR Rendering***

Note: *For more information on adjusting the items in* ***Current Display****, refer to the appropriate fields in the tables beginning on page* **6-1***.*

Figure 6-2: Acquisition Diagram



This diagram demonstrates the various planes and axes of a ***3D*** image once it has been acquired and before any changes are made to it. Remember that once an image has been edited (e.g., the ***MPR ROI*** has been altered) the positions of the planes shown here will have been altered as well. Once changes have been made, use the touch screen ***Reset*** button on ***3D Main*** to return the image to its original geometric position.

Note: *Using* ***Reset*** *will also return other settings to their original positions, including:* ***Threshold***, ***VR View*** *and* ***Contrast****.*

Table 6-6: 3D Visualization options (edit using trackball and console SELECT button)

3D Rendering	***Enable MPR ROI***	Select to view the Region of Interest (ROI) in each view of the image. By default, this field will be selected after every image capture.
		Note: Enable MPR ROI *cannot be selected at the same time as* ***Section Plane****.*
		Select the radio button for ***Position*** to adjust the positioning of the image in relation to the ROI (which will display as solid lines during ***Position*** adjustment).
		Select the radio button for ***Size*** to adjust the size of the ROI (which will display as dotted lines during ***Size*** adjustment).
Section Planes	***Show VR***	Select ***Section Planes*** to view to the intersection point of all planes on the ***VR*** or ***MPR Rendering***.
		Note: Section Planes *cannot be selected at the same time as* ***Enable MPR ROI****.*
		Select ***Show VR*** to adjust the intersection point of all planes on the ***VR*** or ***MPR Rendering***.
Exit		Select to ***Exit*** the current editing session.

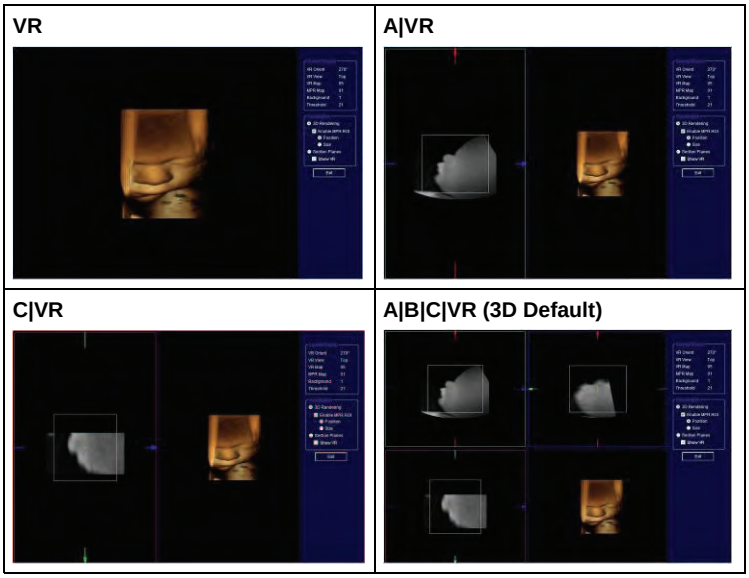
Note: *To move a selected item (e.g., the* ***Acquisition Plane*** *ROI) use the trackball to position the cursor, press the console* **SELECT** *button and use the trackball to drag the desired item to its new position. Press* **SELECT** *again to complete the action.*

6.3 3D IMAGE FORMATS FOR THE LCD DISPLAY

There are four (4) different image formats available for the LCD display: ***VR***, ***A|VR***, ***C|VR*** and ***A|B|C|VR***.

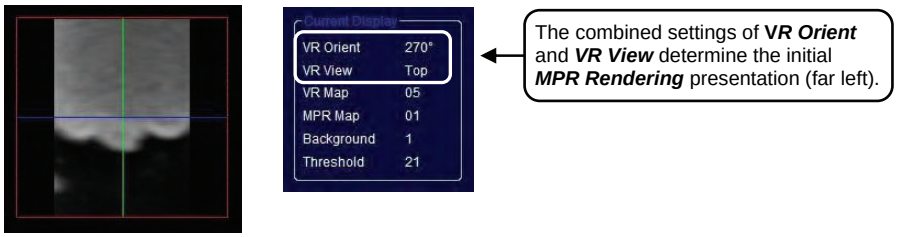
After acquiring a ***Freehand 3D*** image, the LCD display will default to the ***A|B|C|VR*** option.

Figure 6-3: 3D Image Presentation Formats



Note: *If the **Show VR** radio button is not selected in the **Visualization** menu on the LCD display, then the **MPR Rendering** will be displayed in place of the **VR** image.*

Figure 6-4: MPR Rendering Presentation Settings



To Change the Format of a Rendered Freehand 3D Image on the LCD Display:

1. Tap the **3D** touch screen tab.
2. Make the appropriate selection on the ***3D Main*** touch screen panel: ***VR***, ***A|VR***, ***C|VR*** or ***A|B|C|VR***.

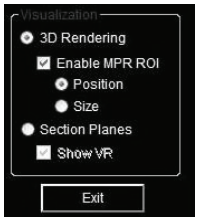
6.4 OPTIMIZING A FREEHAND 3D IMAGE

A ***Freehand 3D*** image can only be optimized after it has been acquired. Both the image and its environment can be optimized in several ways, including: ***Threshold***, ***Transparency***, ***VR Orient***, ***Background***, ***Contrast***, ***VR Map***, ***MPR Map*** and ***VR View***.

For a comprehensive list of options for editing a ***Freehand 3D*** image and its environment, refer to the tables beginning on page **6-1**.

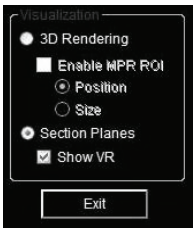
To Optimize a Freehand 3D Image:

1. Acquire an image using the instructions in section **6.1 Acquiring Freehand 3D Images**.
2. Once the image has been rendered to the screen, tap ***3D Main*** on the touch screen.
3. Tap the desired image presentation format: ***VR***, ***A|VR***, ***C|VR*** or ***A|B|C|VR***.
4. Tap the desired tab on the touch screen: ***3D Main***, ***3D Advanced*** or ***3D Display***.
5. Tap/dial to make the necessary changes, tapping page tabs to move through the touch screens as necessary.
6. To adjust the ***Visualization*** options on the LCD display, check the ***3D Rendering*** radio button.
7. Check ***Enable MPR ROI***, then the ***Position*** radio button to adjust the location of the ROI rectangle (solid line).



8. Press the console **SELECT** button, then use the trackball to drag the image to the desired position (in either the ***A***, ***B*** or ***C Plane***).
9. Press **SELECT** again to lock in the ***Position*** of ROI rectangle.
10. To change the size of the ROI rectangle (dotted line), check the ***Size*** radio button.
11. Press the console **SELECT** button, then use the trackball to drag the ROI rectangle to the desired size (in either the ***A***, ***B*** or ***C Plane***).
12. Press **SELECT** again to lock in the ***Size*** of ROI rectangle.

13. To view/edit the intersection point of all planes on the image, check the ***Section Planes*** radio button on the LCD display (***Visualization*** option).



Note: *Select the* ***Show VR*** *checkbox or not as desired.*

The plane shown is controlled by the combined settings of ***VR View*** *and* ***VR Orient*** *which are listed to the right under* ***Current Display*** *(e.g.,* ***VR Orient*** *= 270º and* ***VR View*** *= Top).*

14. To adjust the intersection point of the ***Section Planes***, move the cursor over the right hand (or bottom right hand) image on the LCD display.

15. Press and hold the console **SELECT** button then use the trackball to drag the image's ***Section Planes*** to the desired intersection point.

Note: *To make it easier to determine the location of the intersection point, tap* ***3D Display*** *and turn on/off any combination of* ***Slice Lines****,* ***Reference Planes****,* ***Axes*** *or the* ***Boundary Box****.*

16. Release the **SELECT** button once the desired effect has been achieved.

Note: *If desired, the image can be set to rotate freely. Refer to* **6.5 Freehand 3D Active Rotation** *for details on this functionality.*

17. To undo the changes made to the image, tap ***Reset*** on ***3D Main***.

Note: Reset *will return many, but not all, settings to their original positions.*

6.5 FREEHAND 3D ACTIVE ROTATION

If desired, the ***VR*** or ***MPR Rendering*** can be set to rotate the ***Freehand 3D*** image.

To Initiate/End 3D Active Rotation

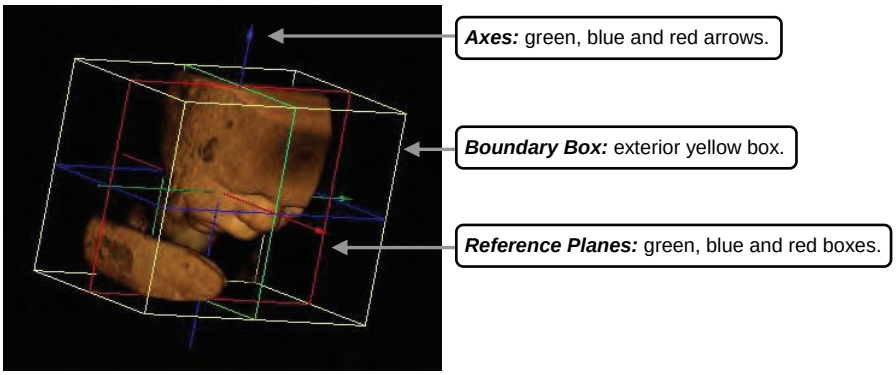
1. Acquire an image using the instructions in section **6.1 Acquiring Freehand 3D Images**.
2. Tap ***3D Main*** on the touch screen.
3. Tap the desired presentation image format: ***VR***, ***A|VR***, ***C|VR*** or ***A|B|C|VR***.
4. Tap the desired tab on the touch screen: ***3D Main***, ***3D Advanced*** or ***3D Display***. Once the touch screen page presents the available options, tap/dial to make the necessary changes.
5. To initiate ***Active Rotation***, press and hold the console **SELECT** button.
6. Keep the trackball moving when releasing the console **SELECT** button.

Note: *The trackball's speed and angle of movement will determine the rotation's speed and angle of movement.*

7. To end ***Active Rotation***, position the cursor over the rotating image and press the console **SELECT** button.
8. Ensure that the trackball is stationary, then release the **SELECT** button.
9. The image will once again be stationary, however, the image will remain in whatever position it was in just prior to freezing it. It will <u>not</u> return to its original position unless the ***3D Main Reset*** button is tapped.

Note: Reset *will return many, but not all, settings to their original positions.*

Figure 6-5: Sample VR Image with Axes, Boundary Box and Reference Planes



6.6 USER-DEFINED PRESETS FOR FREEHAND 3D

As with other imaging formats, user-defined ***3D Presets*** can be designed/saved for future use.

Note: *Unlike other user-defined* ***Presets****, renaming or deleting user-defined* ***3D Presets*** *is handled through* **9.2.8 3D Settings.**

It doesn't matter if ***Freehand 3D*** *image configuration is done before or after the image is acquired.*

To Save a User-Defined 3D Preset

1. Acquire an image using either set of instructions in section **6.1 Acquiring Freehand 3D Images**.
2. To save the image configurations as a ***Preset***, tap the ***3D Display*** tab.
3. Tap ***Save Preset***.

4. Use the keyboard to type in a ***Preset Name***.

Note: *Duplicate* ***Preset Names*** *are not allowed. If a duplicate name is entered, the system will present the* ***Invalid Preset Name*** *message bubble. If this happens, click* ***Cancel*** *to exit, or type in a different name and select* ***OK*** *to accept it.*

5. Select ***Ok*** to save the ***Preset Name*** or ***Cancel*** to exit without saving.

CHAPTER 7: CLINICAL ANALYSIS

Measurements provide the user with the functionality to perform clinical analysis on an ultrasound image. They range from simple measurements that calculate length, circumference, area, volume, etc., to measurement packages that use calculation formulas to determine fetal age.

The ***Worksheet*** feature records patient/exam-specific data and can be printed as a report that includes patient and facility information, labeled measurement values, calculation results and QA and billing details.

Note: *Only those measurement types programmed into the* ***Worksheet*** *will be recorded automatically. Any additional measurements must be entered manually in the* ***Worksheet Notes*** *section.*

The SONIX CEP provides ***Basic***, and application-specific measurement/calculation packages: ***Abdomen (Aorta)***, ***Biliary***, ***Bladder***, ***Cardiac***, ***Early OB***, ***F(oreign) Bodies***, ***L(ower) Extremities***, ***Late OB***, ***Other***, ***Pelvic***, ***Procedure***, ***Renal***, ***Thoracic***, ***Trauma (FAST)*** and ***V(ascular) Access***.

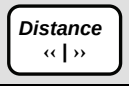
The measurement/calculation package defaults to the ***Exam Type/Application*** selected. For example, the Obstetrical calculation package is the default when an OB ***Application*** (***Early*** or ***Late OB***) is selected.

Note: *When multiple sets of measurements are recorded onscreen, the active set will always be at the bottom.*

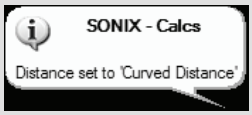
Table 7-1: Console Measurement Buttons

MEASURE	On a frozen image, use to activate the ***Measurements*** package. On a frozen image with ***Measurements*** already recorded, use to remove all the measurements on the frozen image screen ***Note:*** *Pressing* **MEASURE** *does not delete the measurements from the* ***Worksheet****.*
WORKSHEET	Press to access the ***Worksheet*** associated with the current Exam ***Measurement***. Press it again to exit the ***Worksheet***.
DEL	Use the console **DEL** button (to the left of the **MEASURE** button) to remove measurements from the screen. If saved to the ***Worksheet***, **DEL** will remove the measurement from the ***Worksheet***. Continue to press **DEL** for each of the measurements to be deleted. ***Note:*** *To delete one specific measurement when more than one is visible onscreen, move the cursor closest to the one to be deleted and press the console* **UPDATE** *button to select it.*
SELECT	Selects, sets and activates calipers, ellipse, etc.
UPDATE	Toggles between the calipers prior to finalizing (setting) the measurement.
BACKSPACE	Corrects an incorrect move on a trace measurement.

Note: *When several methods of performing a measurement are available a "***<<|>>***" appears on the touch screen button. Tap the selected measurement button and turn the dial beneath the selection to choose the preferred method. The method selected appears in a message bubble on the lower right corner of the LCD display and becomes the default.*

e.g., for ***Distance*** 

Distance *measurements set to* ***Curved****.*

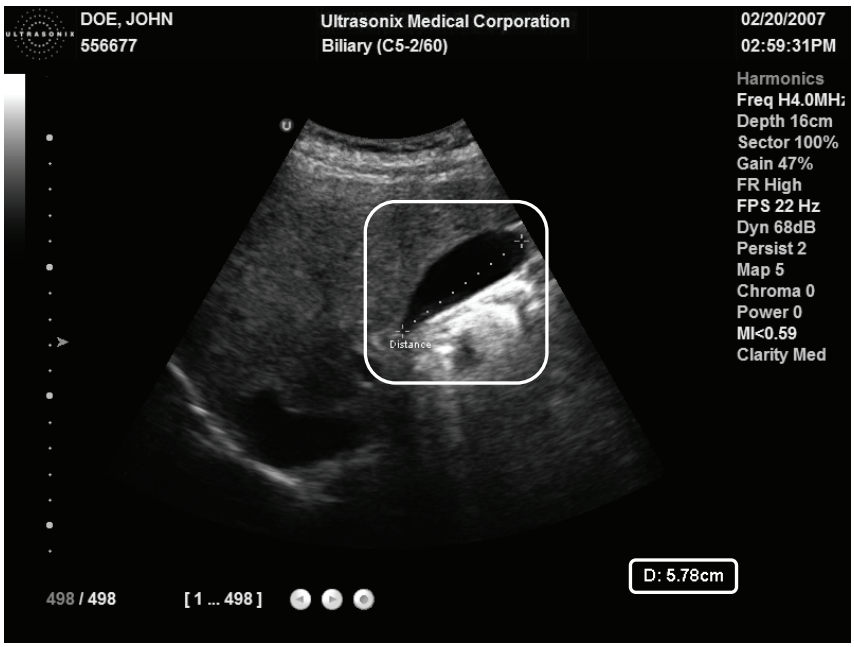


7.1 2D BASIC MEASUREMENTS

2D Basic measurements are accessible by tapping ***Basic*** on the touch screen when the ***Measurement*** feature is active.

7.1.1 2D Linear (B-Distance) Measurement

Figure 7-1: 2D Image with Linear Measurement



To Perform a Linear Measurement:

1. With a frozen ***2D*** image, press the console **MEASURE** button.
2. A caliper will appear on the image on the LCD display. Use the trackball to position the first caliper.
3. Press **SELECT** to set the first caliper and activate the second caliper.
4. Use the trackball to position the second caliper.

   Note: *To reposition the first caliper, press* ***UPDATE*** *to toggle control between the two calipers.*

5. Press **SELECT** to set the measurement. The measurement value will appear on the bottom of the LCD display.

To Perform a Curved Distance Measurement:

1. With a frozen ***2D*** image, press the console **MEASURE** button.
2. A caliper will appear on the image on the LCD display. Use the trackball to position the first caliper.
3. Press **SELECT** to set the first caliper.
4. Use the trackball to trace the ***Curved Distance***.

   Note: *To reposition the first caliper press* **UPDATE** *to toggle control between the two calipers.*

5. Press **SELECT** to set the measurement. The measurement value will appear on the bottom of the LCD display.

7.1.2 Area or Circumference (Area/Circ) Measurement

There are three (3) methods of performing the ***Area/Circumference*** measurement: ***Ellipse***, ***Trace*** and ***Point by Point***.

7.1.2.1 Trace Method Area or Circumference Measurement

To Perform a Trace Method Area or Circumference Measurement:

1. With a frozen ***2D*** image, press the console **MEASURE** button.
2. To select the desired method, tap ***Area <<\|>>*** on the touch screen and turn the dial directly below it until the desired method flashes on the lower right portion of the LCD display (e.g., ***Area set to "Continual"***).
3. Use the trackball to position the caliper at the start position.
4. Press **SELECT** to set the first caliper.

   Note: *Use the keyboard* **BACKSPACE** *key to delete the trace.*

5. Use the trackball to trace the ***Circumference*** of the area of interest.
6. Press **SELECT** to set the trace.
7. The ***Area*** and ***Circumference*** values will appear on the bottom right of the LCD display.

7.1.2.2 Ellipse Method Area or Circumference Measurement

To Perform an Ellipse Method Area or Circumference Measurement:

1. With a frozen ***2D*** image, press the console **MEASURE** button.
2. To select the desired method, tap ***Area <<\|>>*** on the touch screen and turn the dial directly below it until the desired method flashes on the lower right portion of the LCD display (e.g., ***Area set to "Ellipse"***).
3. Use the trackball to position the first caliper.
4. Press **SELECT** to set the caliper position and activate the second caliper of the ***Ellipse***.
5. Use the trackball to position the second caliper.
6. Press **SELECT** to set the second caliper position and activate the ***Ellipse*** sides.
7. Use the trackball to increase/decrease the sides of the ***Ellipse***.

   Note: *Press* **UPDATE** *to toggle control of the calipers/****Ellipse*** *prior to completion of the measurement.*

8. Press **SELECT** to complete the ***Ellipse*** measurement.
9. The ***Area*** and ***Circumference*** values will appear on the bottom right of the LCD display.

7.1.2.3 Point by Point Method Area or Circumference Measurement

To Perform a Point by Point Method Area or Circumference Measurement:

1. With a frozen ***2D*** image press, the console **MEASURE** button.
2. To select the desired method, tap ***Area <<\|>>*** on the touch screen and turn the dial directly below it until the desired method flashes on the lower right portion of the LCD display (e.g., ***Area set to "Point by Point"***).
3. Use the trackball to position the caliper at the start position.
4. Press **SELECT** to set the caliper.

   Note: *Use the keyboard* **BACKSPACE** *key to delete the previous trace move/position. Press* **BACKSPACE** *several times to undo several previous positions.*

5. Use the trackball to move the cursor to the next ***Point***.
6. Press **UPDATE** to set the marker.
7. Repeat Steps 4 to 6 as many times as necessary to complete the ***Area***.
8. Press **SELECT** to finish the measurement.
9. The ***Area*** and ***Circumference*** values will appear on the bottom right of the LCD display.

7.1.3 Volume Calculation

To Perform a Volume Calculation:

1. With a frozen ***2D*** image, press the console **MEASURE** button.
2. A caliper will appear on the image on the LCD display.
3. If the ***Basic*** measurement tab is not active on the touch screen, tap ***Basic*** to activate it.
4. Tap ***3 Dist Volume***.
5. Use the track ball to position the first caliper.

   Note: *The* ***Volume*** *calculation will always assume the measurements are made in the following order:* ***Length***, ***Height***, ***Width****. Additionally, all three (3) linear measurements must be completed in order to calculate the* ***Volume****.*

6. Press **SELECT** to set the caliper position and activate the second caliper.

   Note: *Press* **UPDATE** *to toggle control of the calipers prior to completion of each linear measurement.*

7. Use the trackball to position the second caliper.
8. Press **SELECT** to set the second caliper position and complete the measurement.

   Note: *On the touch screen, a number in brackets appears at the beginning of the touch screen button name, indicating the number of completed measurements. Measurements that are deleted from the LCD display remain part of the count as they are still part of measurement history.*

9. Repeat steps 5 through 8 until all three (3) linear measurements have been completed. The three (3) measurement values with auto-calculated ***Volume*** results will be presented on the bottom right of the LCD display.

   Note: *The seven (7) most recent* ***Volume*** *measurements will be displayed on the screen.*

7.2 M-MODE BASIC MEASUREMENTS

7.2.1 M-Mode Heart Rate Measurement

To Perform an M-Mode Heart Rate Measurement:

1. With a frozen ***M-Mode*** image, press the console **MEASURE** button.
2. On the touch screen, tap ***Basic***.
3. Tap ***HR*** to activate the caliper.
4. Use the trackball to position the caliper on the ***M-Mode Sweep*** to the first beat.
5. Press **SELECT** to set the first caliper and activate a second caliper.
6. Use the trackball to position the second caliper to the next beat.

   Note: *The default* ***Heart Rate*** *measurement requires one heart beat. Refer to section* **9.2.6 Measurements** *to change the number of beats required for the* ***HR*** *calculation.*

7. To reposition either cursor, press **UPDATE** to toggle control between the two calipers.
8. Press **SELECT** to set the measurement. The ***Heart Rate*** value will be presented on the bottom right of the LCD display.

7.2.2 M-Mode Slope Measurement (Time, Slope and Distance)

To Perform an M-Mode Slope Measurement:

1. With a frozen ***M-Mode*** image, press the console **MEASURE** button.
2. On the touch screen, tap ***Basic***.
3. Tap ***Time/Slope <<\|>>*** and turn the associated touch screen dial to select ***Time/Slope set to "Time/Slope"*** to activate the caliper.
4. Use the trackball to position the first caliper on the ***M-Mode Sweep***.
5. Press **SELECT** to set the first caliper and activate a second caliper.
6. Use the trackball to position the second caliper to the desired location.
7. Press **SELECT** to set the measurement. The ***Time***, ***Distance*** and ***Slope*** values will be presented on the bottom right of the LCD display.

7.2.3 M-Mode Distance Measurement

To Perform an M-Mode Distance Measurement:

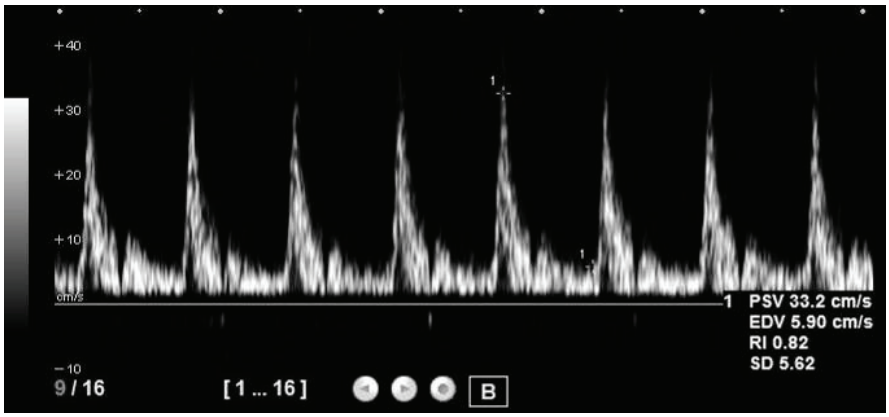
1. With a frozen ***M-Mode*** image, press the console **MEASURE** button.
2. On the touch screen, tap ***Basic***.
3. Tap ***Distance <<\|>>*** and turn the associated touch screen dial to select ***Distance set to "M Distance"***.
4. Use the trackball to position the caliper on the ***M*** display section of the screen.
5. Press **SELECT** to set the first caliper and activate a second caliper.
6. Use the trackball to position the end of the measurement.
7. Press **SELECT** to set the measurement. The ***M Distance*** value will be presented on the bottom right of the LCD display.

7.3 PW DOPPLER BASIC MEASUREMENTS

7.3.1 Velocity Measurement(s)

To Perform a Velocity Measurement:

1. With a frozen ***Doppler Trace***, press the console **MEASURE** button.
2. A ***Measurements*** tab appears on the touch screen. By default the caliper appears on the ***Doppler Trace***.
3. Use the trackball to position the caliper.



4. Press **SELECT** to set the caliper.

7.3.2 Doppler Heart Rate Measurement

To Perform a Doppler Heart Rate:

1. With a frozen ***Doppler Trace***, press the console **MEASURE** button.
2. Tap ***HR*** on the touch screen.
3. Use the trackball to position the caliper on the ***Doppler Trac***e to the first beat.

Note: *The default* ***Heart Rate*** *measurement requires one heart beat. Refer to section* **9.2.6 Measurements** *to change the number of beats required for the* ***HR*** *calculation.*

4. Press **SELECT** to set the first caliper and activate a second caliper. Use the trackball to position the second caliper to the desired next beat.
5. Press **SELECT** to set the measurement. The ***Heart Rate*** value will be presented on the screen.

7.4 WORKSHEETS

Worksheets have been created as an electronic documentation tool for emergency ultrasound. Each ***Exam Type/Application*** is linked to a ***Worksheet*** for use during an exam. While it is possible to create multiple ***Worksheets*** per ***Exam Type/Application***, only one (1) can be active at any given time.

Each ***Exam Type/Application*** is linked with a default ***Master Worksheet***. This ***Master Worksheet*** cannot be edited, but it can be used as the basis for creating a new ***Worksheet***. Alternatively, a new ***Worksheet*** can be created completely from scratch.

For details on managing ***Worksheets***, refer to **9.2.4 Presets – Worksheets**.

Warning: *Ultrasonix does not endorse user-defined measurements for diagnostic purposes. All user-defined measurements are used at the operator's discretion and risk only.*

7.4.1 Accessing Worksheets during an Exam

At any point during imaging, press the console **WORKSHEET** button to access the ***Worksheet*** for the currently selected ***Exam Type/Application***. Note that the touch screen options will reflect the fact that a ***Worksheet*** is now open.

Table 7-2: Worksheet Touch Screen Options

Print	Sends the ***Worksheet*** to the printer if the system ***Print*** functions have been configured.
Close	Saves and closes the ***Worksheet***, returning the user to the still-active exam. ***Note:*** *It is not possible to cancel changes to a* ***Worksheet****. Any incorrect information must be edited/deleted in order to ensure accuracy.*
Pages	Turn the dial below ***Pages <<|>>*** to move the ***Worksheet*** from page to page. ***Note:*** *The digital* ***Worksheet*** *on the system comprises three (3) pages, but generally prints as a single page, depending on the volume of data recorded.*

To Access a Worksheet During an Exam:

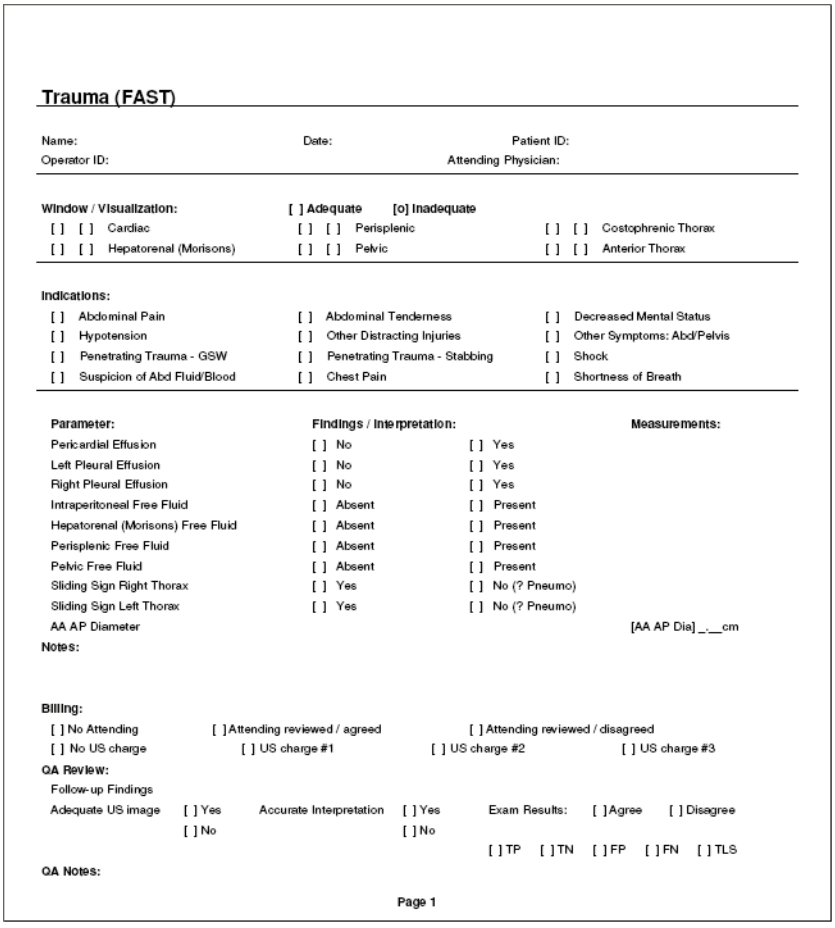
1. During an exam, press the console **WORKSHEET** button.
2. Use the touch screen ***Page <<|>>*** dial to cycle through the ***Worksheet*** pages.
3. Press the console **WORKSHEET** button again to close the ***Worksheet***.

Note: *This will not end the current exam.*

To Access a Worksheet for a Completed Exam:

1. Press the console **ID** button.
2. On the ***Exam Management*** page, select the ***Patients*** or ***QA*** tab.
3. Highlight the relevant exam/patient.
4. Click the ***Review*** button.
5. When the ***Image Review*** screen is presented, press the console **WORKSHEET** button.
6. Use the touch screen ***Page <<\|>>*** dial to cycle through the ***Worksheet*** pages.
7. Press the console **WORKSHEET** button again to close the ***Worksheet***.

Figure 7-2: Example (Printed) Worksheet



Trauma (FAST)

Name: Date: Patient ID:
Operator ID: Attending Physician:

Window / Visualization: [ ] Adequate [o] Inadequate

[ ] [ ] Cardiac	[ ] [ ] Perisplenic	[ ] [ ] Costophrenic Thorax
[ ] [ ] Hepatorenal (Morisons)	[ ] [ ] Pelvic	[ ] [ ] Anterior Thorax

Indications:

[ ] Abdominal Pain	[ ] Abdominal Tenderness	[ ] Decreased Mental Status
[ ] Hypotension	[ ] Other Distracting Injuries	[ ] Other Symptoms: Abd/Pelvis
[ ] Penetrating Trauma - GSW	[ ] Penetrating Trauma - Stabbing	[ ] Shock
[ ] Suspicion of Abd Fluid/Blood	[ ] Chest Pain	[ ] Shortness of Breath

Parameter:	Findings / Interpretation:		Measurements:
Pericardial Effusion	[ ] No	[ ] Yes	
Left Pleural Effusion	[ ] No	[ ] Yes	
Right Pleural Effusion	[ ] No	[ ] Yes	
Intraperitoneal Free Fluid	[ ] Absent	[ ] Present	
Hepatorenal (Morisons) Free Fluid	[ ] Absent	[ ] Present	
Perisplenic Free Fluid	[ ] Absent	[ ] Present	
Pelvic Free Fluid	[ ] Absent	[ ] Present	
Sliding Sign Right Thorax	[ ] Yes	[ ] No (? Pneumo)	
Sliding Sign Left Thorax	[ ] Yes	[ ] No (? Pneumo)	
AA AP Diameter			[AA AP Dia] _.__cm

Notes:

Billing:

[ ] No Attending [ ] Attending reviewed / agreed [ ] Attending reviewed / disagreed
[ ] No US charge [ ] US charge #1 [ ] US charge #2 [ ] US charge #3

QA Review:

Follow-up Findings
Adequate US image [ ] Yes [ ] No Accurate Interpretation [ ] Yes [ ] No Exam Results: [ ] Agree [ ] Disagree
[ ] TP [ ] TN [ ] FP [ ] FN [ ] TLS

QA Notes:

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CHAPTER 8: TEXT, ANNOTATIONS AND PICTOGRAMS

Text, ***Annotation*** and ***Pictograms*** enable the user to label the image prior to image transfer and storage.

8.1 TEXT AND ANNOTATIONS

The SONIX system enables users to add ***Text*** (via the keyboard) or ***Preset Annotations*** (listed on the touch screen) to the image field. ***Annotations*** are predefined by ***Exam Type/Application***, but can also be customized by users (**9.2.2 Presets – Annotations**). An ***Annotation*** arrow is available as well as an ***Auto Complete Text*** feature that anticipates the word being entered (**9.2.5 Annotations**).

8.1.1 Keyboard Text

To Enter Keyboard Text:

1. Press the console **TEXT** button.
2. A ***Text*** cursor appears on the image screen.
3. Use the trackball to position the ***Text*** cursor as required.
4. Use the keyboard to enter the desired text.

   Note: *When the* ***Auto Complete*** *function is active (***9.2.5 Annotations***), enter the first letter(s) of the preset word and the rest of the word will be presented in blue. If more than one preset word with the same first letter exists, use the* **TAB** *key to cycle through all the preset words beginning with that letter. To set the selected preset word, press* **ENTER** *on the keyboard.*

5. Use the trackball to relocate the ***Text*** cursor as required.
6. Use the keyboard backspace arrow to remove the letter(s) to the left of the ***Text*** cursor.
7. Press **TEXT** to exit ***Text/Annotation*** mode.

8.1.2 Set Text Home Position

Once a ***Text/Annotation*** cursor ***Home Position*** has been set, it will remain until/unless it is reset.

To Set the Text Home Position:

1. Press the console **TEXT** button.
2. Use the trackball to position the cursor in the desired ***Home Position***.
3. Tap ***Set Home*** on the touch screen to set the ***Home Position***.

Note: *Tap* ***Home Position*** *on the touch screen to automatically reposition the cursor to the previously defined* ***Text Home Position****.*

8.1.3 Application-Specific Annotations

To Enter Application-Specific Annotations:

1. Press the console **TEXT** button.
2. Once the ***Text/Annotation*** cursor location is presented on the screen, use the trackball to reposition the cursor as required.
3. Tap the desired ***Annotation*** from the selection presented on the touch screen.

Note: *To modify the preset* ***Annotations****, refer to section* **9.2.2 Presets – Annotations.**

4. Repeat steps 2 and 3 as many times as required.
5. Press **TEXT** to exit ***Text/Annotation*** mode.

8.1.4 Deleting Text/Annotation

To Delete All Text/Annotations:

1. Press the console **TEXT** button.
2. Press **DEL** (below the console **TEXT** button) to delete all user-entered ***Text/Annotations*** from the image field.

Note: *Alternatively, move the cursor to the desired position and use the keyboard back space arrow to remove the letter(s) to the left of the* ***Text*** *cursor.*

To remove the most recently entered annotation, select ***Delete Last*** *from the touch screen while in* ***Text*** *mode. Repeating this action will delete each subsequent entry in reverse order.*

---

3. Press **TEXT** to exit ***Text/Annotation*** mode.

8.1.5 Text Arrow

To Enter the Text Arrow:

1. Press the console **ARROW** button.

2. When the arrow appears on the image screen, use the trackball to position/rotate it.
3. Press the console **SELECT** button to place the positioned arrow on the image.
4. Repeat steps 2 and 3 as many times as necessary.
5. Archive the image (**PRINT 1**, **2**, or **3**) to save it with the arrows visible.
6. Press **ARROW** to remove the ***Text*** arrow(s).

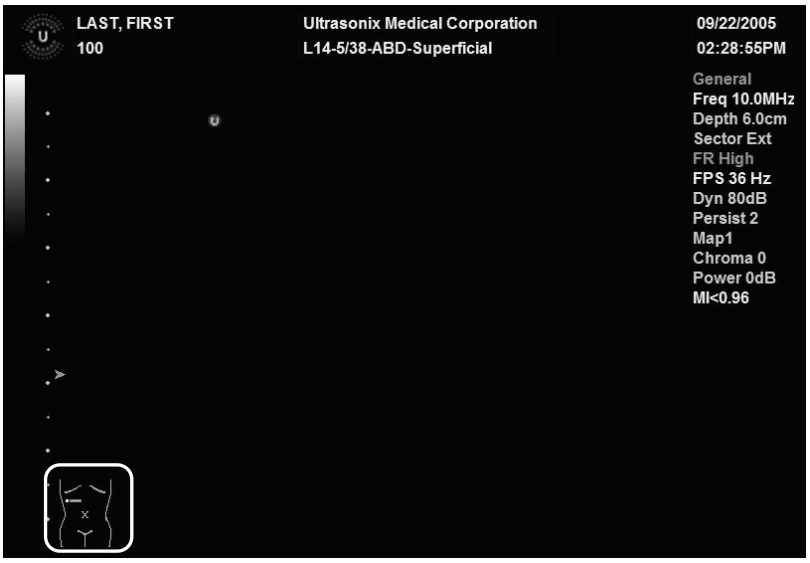
8.2 PICTOGRAMS

Pictograms are predefined, ***Application***-specific icons that enable users to visually label the imaging feature. Customizing the availability of specific ***Pictograms*** within ***Presets*** is controlled through **9.2.3 Presets – Pictograms**.

To Activate a Pictogram:

1. Press the console **PICTOGRAM** button.

2. Rotate the knob below the ***Pictogram*** heading on the touch screen to move through the various ***Pictograms*** available.
3. Once the desired ***Pictogram*** is located, press **PICTOGRAM** again.



4. Press **SELECT,** then use the trackball to position the ***Pictogram*** orientation marker to the desired location on the ***Pictogram***.
5. To rotate the ***Pictogram*** orientation marker, tap ***Rotate*** on the touch screen and turn the associated knob until the desired position is reached.
6. Once positioned as required, press **SELECT** again.
7. To re-access the ***Pictogram*** functions after performing other imaging functions, press ***Pictogram*** again and repeat Steps 2 to 6.
8. To hide the ***Pictogram*** from view, tap the ***Hide*** button on the touch screen.

CHAPTER 9: SYSTEM SETUP

The various features and settings of the SONIX CEP ultrasound system can be customized via one of the three (3) System Setup menus: User, Administrator and Service. Menu-level password protection applies as follows:

- ***Users Settings***: no password protection
- ***Administrator Settings***: optional password protection, with additional password protection available for the settings that govern access to the ***QA*** tab on the ***Exam Management*** page

  Caution: *Refer to* ***QA Password… in*** **9.2.9 System Settings** *for important information regarding this additional level of password protection.*

- ***Service Settings***: always password protected. Only qualified Ultrasonix Medical Corporation service personnel can access this menu.

The following tables provide a quick overview of the system's setup menus. Refer to the related sections later in this chapter for further details on any particular setup option.

Table 9-1: User Settings Menu

Setup	***SONIX Live***	Activate/deactivate ***Video Streaming***.
	Administrator	Access the ***Administrator Settings*** menu.
Support	***Remote Support***	Access the ***Remote Suppor***t option.
		Note: Remote Support *is configured via* **9.2.10 Network**.
	Online Support	Access the ***Online Support*** option.
		Note: Online Support *is configured via* **9.2.10 Network**.

Note: *The software version number is displayed across the bottom of this menu.*

Table 9-2: Administrator Settings Menu

Application Setup	***Presets***	View, create and edit ***Presets*** (***Annotations***, ***Pictograms*** and ***Worksheets***) for each ***Exam Type/Application***.
	Annotations	Toggle on/off the three (3) global ***Annotation*** settings.
		Note: *Customization of* ***Preset****-specific* ***Annotations*** *is handled through* ***Presets***.
	Measurements	Configure graphic settings, including connection points, text and caliper sizes as well as colors for connection points and calipers. Set ***Pregnancy Weeks*** and ***Heart Rate Beats***.
	Training Tutorials	Download, copy or view SONIX CEP training materials in a variety of file formats.
	3D	Set default configuration for ***Freehand 3D*** image acquisition. Set display timing for ***3D Config*** dialog box.

System Setup	***System***	Customize the ***Institution Name***. Configure ***Regional*** options, ***Shutdown Options, Auto-Freeze*** and ***User Data***. Reset system to ***Factory Defaults***. Set the system's ***Master Volume***. Set ***QA*** and ***Administrator Passwords***. ***Caution: Administrative*** *and* ***QA passwords*** *are provided to protect clinical system setups from being changed and sensitive patient data from being viewed by unauthorized personnel.* *Ultrasonix highly recommends applying a unique* ***QA Password…*** *(i.e., Ultrasonix does not recommend using the same password for both* ***QA*** *and* ***Administration)****.*
	Network	Configure settings for connecting to the ***Network*** (Local Area Network (LAN) or dialup), ***TCP/IP*** (***Transmission Control Protocol/Internet Protocol***), ***E-mail*** and ***Online Support***. ***Caution:*** *System networking options are intended for use inside your organization's firewall. Organizations that elect to configure/use the networking functionality provided by Ultrasonix are assuming all liabilities and risks associated with that decision.*
	DICOM	Enable and configure ***DICOM Storage***, ***Print*** and ***Worklist***.
	Print Keys	Set the ***Store***, ***Print***, ***Archive*** parameters for the three (3) console **PRINT** buttons.
	Peripherals	Configure ***Peripherals***: ***Paper Printer***, ***LCD Display***, ***VCR/Photo***, ***Footswitch*** and (***Image***) ***Brightness/Contrast***.
	Display	Set options for the LCD display and touch screen.
	Patient	Customize entry of ***Patient*** information using a variety of options, including: show/hide fields, create new fields, allow/disallow editing of specific fields, and selection of gender and application defaults.
	Status Bar	Configure which ***Status Bar*** icons are visible on the LCD display.
	Capture	Configure the ***Capture*** settings for still images, video output and ***CINE*** loop storage.
	Imaging Modes	Configure a variety of ***Imaging Mode*** options including ***Split Imaging*** and ***Screen Layouts***.
	QA	Create/edit settings for ***Reviewers*** using the ***QA Review*** process.
System Maintenance	***Software Updates***	Update system software via the Internet, CD/DVD or a USB memory stick.
	Licensing	View and add ***License*** details.
	Service	Access the ***Service Mode Password*** dialog.

Table 9-3: Service Settings Menu

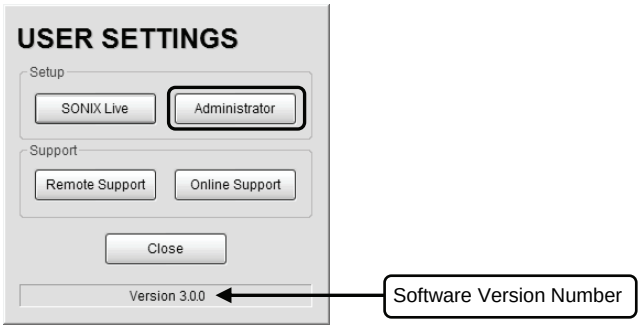
Service Mode	The system is delivered with this option under ***Password*** protection.
	Note: *Only qualified Ultrasonix Medical Corporation service personnel can access this menu.*

Note: *Use the trackball and* **SELECT** *button to close each menu and exit the menu system, one menu at a time. To exit the entire menu system in one step, press the console* **MENU** *button.*

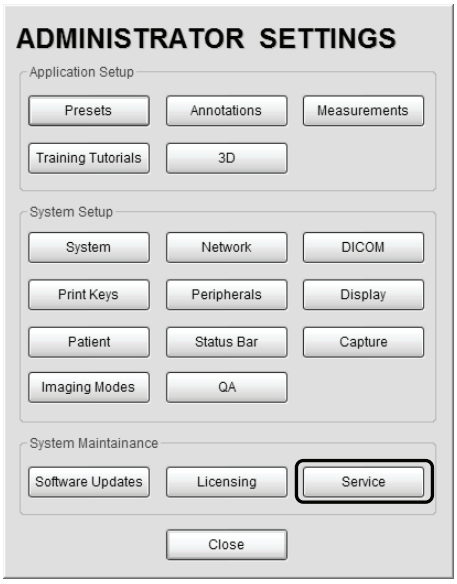
Be sure to save whatever edits are in progress before exiting, otherwise changes may be lost.

To Access the System Menus:

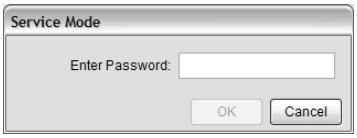
1. Press the console **MENU** button and the ***User Settings*** menu will be presented.



2. From the ***User Settings*** menu, select ***Administrator*** to access ***Administrator Settings***.



3. From the ***Administrator Settings*** menu, select ***Service*** to access the ***Service Mode Password*** dialog.



Note: *To exit the entire menu system in one step, press the console* **MENU** *button.*

9.1 USER SETTINGS

9.1.1 SONIX Live

SONIX Live allows remote users to view live imaging as ***Streaming Video*** using ***Windows Media Player*** (***WMP***). When both ***SONIX Live*** and the ***Status Bar*** icon are activated and ***Streaming Video*** is underway, the ***SONIX Live*** icon will appear on the imaging screen (refer to **9.2.16 Status Bar** for details on the ***SONIX Live*** icon).

Note: *Because* ***Streaming Video*** *may cause a noticeable decrease in overall system performance, Ultrasonix recommends activating* ***SONIX Live*** *only when video streaming is required.*

Figure 9-1: SONIX Live Setup

Note: *A network connection (***9.2.10***) must be configured and active in order to use* ***SONIX Live****.*

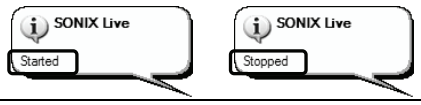
To Configure SONIX Live Streaming Video on the SONIX – PART 1:

1. Press the console **MENU** button.
2. Select ***SONIX Live.***
3. Check the ***Activate SONIX Live*** option.

   Note: *The* ***SONIX Live*** *icon will only be visible if it has been enabled (refer to the instructions below or* **9.2.16 Status Bar** *for more details).*

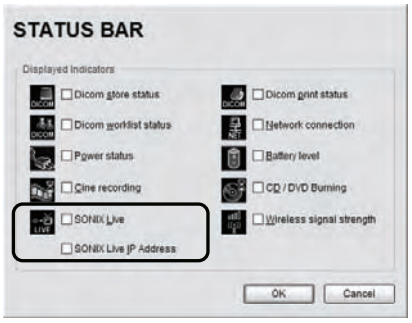
4. Select ***OK*** to accept the changes or ***Cancel*** to exit without saving.

   Note: *Relevant message bubbles will be displayed whenever* ***SONIX Live*** *is activated or deactivated.*



To Configure SONIX Live Streaming Video on the SONIX – PART 2:

1. Press the console **MENU** button.
2. Select ***Administrator > Status Bar***.



3. Check the ***SONIX Live*** and ***SONIX Live IP Address*** options.

Note: *Selecting the* ***SONIX Live IP Address*** *will write the actual* ***IP Address*** *to the LCD display. If privacy/security is a concern, do not select this option. To determine the relevant* ***IP Address****, refer to the* ***Local IP Address*** *field in* **9.2.10 Network**.

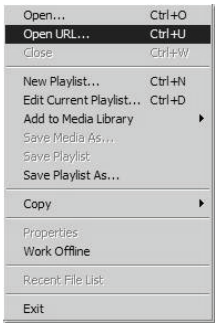
4. Select ***OK*** to accept the changes or ***Cancel*** to exit without saving.

To Configure SONIX Live Streaming Video on the Remote Computer**:**

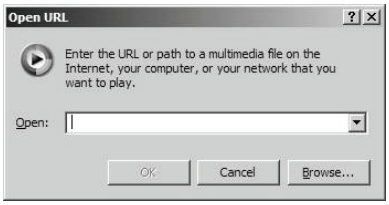
***Note:** Be sure to have the **SONIX Live IP Address** handy before beginning this process.*

1. After turning on the remote computer, open the ***Windows Media Player*** program.

2. From the ***File*** menu, select ***Open URL…***.



3. In the ***Open URL*** dialog, enter the ***SONIX Live IP Address*** followed by "`:8080`". For example, if the relevant ***IP Address*** is 127.0.0.1, type in `http://127.0.0.1:8080`.



4. Click the ***OK*** button and the ***SONIX Live*** video stream will be displayed in the ***Windows Media Player***.

9.1.2 Remote Support

In order to use ***Remote Support***, the ***Network*** must be configured in **9.2.10 Network**.

To Access Remote Support:

1. Press the console **MENU** button.
2. Select ***Remote Support*** and follow the onscreen instructions.

Note: *If* ***Remote Support*** *does not appear to be available, contact your IT Department and have them check to make sure the network connection is active and the* ***Remote Support*** *option has been configured for use.*

9.1.3 Online Support

In order to use ***Online Support***, it must first be configured in **9.2.10 Network**.

To Access Online Support:

1. Press the console **MENU** button.
2. Select ***Online Support***.
3. Follow the directions in **3.3.6**.

Note: *If* ***Online Support*** *does not appear to be available, contact your IT Department and have them check to make sure the network connection is active and that the* ***Online Support*** *option has been configured for use.*

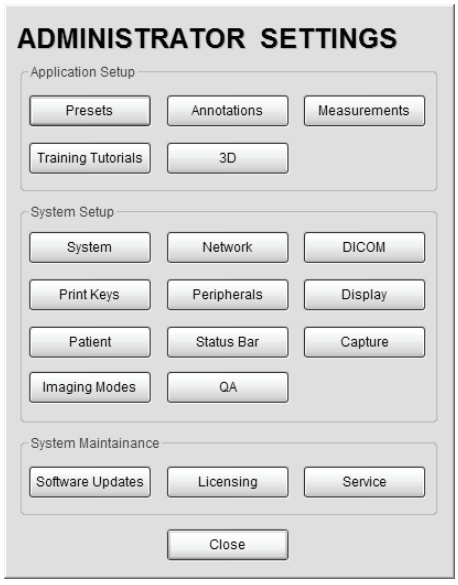
9.2 ADMINISTRATOR SETTINGS

Administrator Settings allow the system administrator to configure high level ***Application*** and ***System*** settings as well as perform certain ***System Maintenance*** functions.

Typically, the ***System*** parameters are set during initial installation and only require limited access and adjustment. By default, ***Administrator Settings*** are not delivered with an active ***Password***, however, at their discretion, each institution has the option to apply ***Password*** protection (see page **9-41** for details).

Warning: *SONIX CEP* ***Application*** *parameters should be configured by a qualified medical practitioner.*

Figure 9-2: Administrator Settings Menu



To Access Administrator Settings:

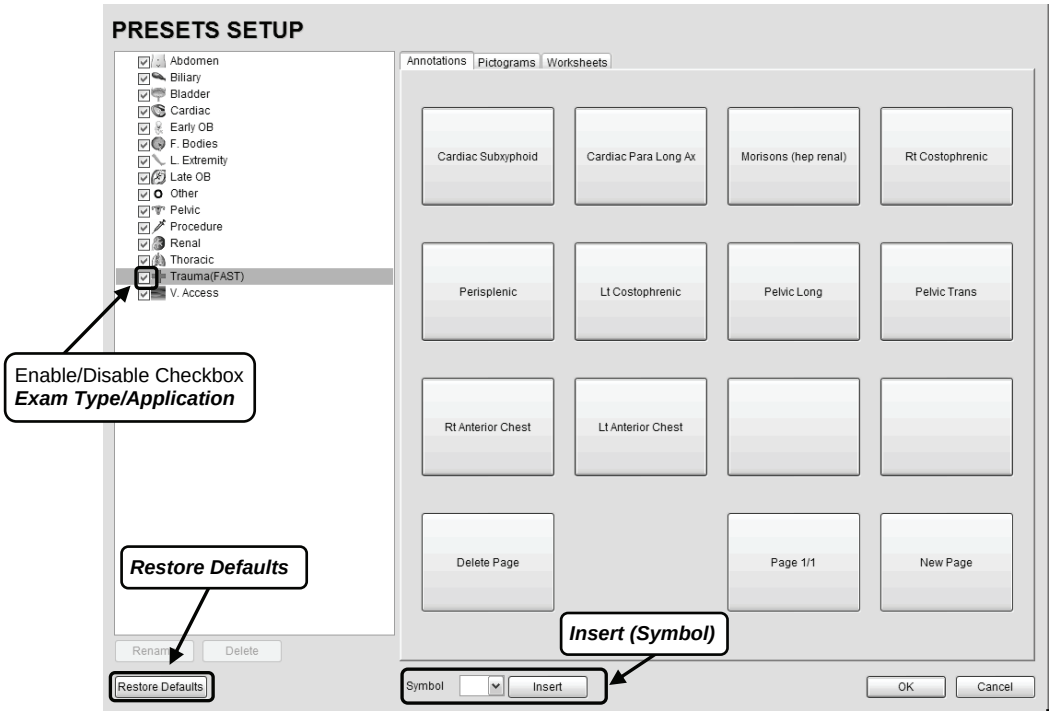
1. Press the console **MENU** button.
2. Select ***Administrator*** to access the ***Administrator Settings*** menu.

9.2.1 Presets

SONIX CEP allows users to choose from a set of factory-defined ***Exam/Type/Applications*** and corresponding ***Presets (Annotations, Pictograms and Worksheets)***.

Exam Type/Applications can be selected/deselected via the ***Preset*** menu.

Figure 9-3: Preset Setup



To Access Presets Setup:

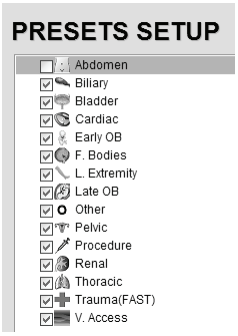
1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.

9.2.1.1 Show/Hide Exam Type/Applications

Exam Type/Application availability can be controlled using its associated checkbox. When selected, as indicated by the presence of the green check mark, they will be available via ***QSONIX*** for selection as the ***Exam Type/Application***. When deselected, they will not be available for selection and therefore will not be available for use in an exam.

To Show/Hide an Exam Type/Application on the Touch Screen:

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. Select/deselect the relevant checkbox.



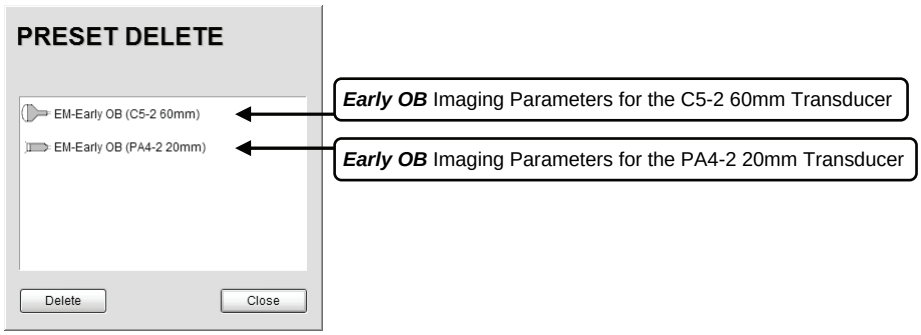
4. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.1.2 Delete User-Defined Presets/Imaging Parameters (Non-Freehand 3D Format)

The creation of user-defined imaging parameters overrides the factory default settings that were delivered with each ***Exam Type/Application*** – transducer combination. To reset the imaging parameters to the factory defaults, simply delete them.

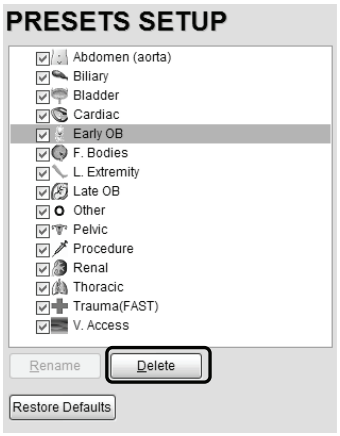
Note: *Refer to* **4.5.5 User-Defined Presets/Imaging Parameters** *for creation details.*

Figure 9-4: Preset Delete



To Delete User-Defined Presets/Imaging Parameters:

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. Highlight the relevant ***Exam Type/Application***.



Note: *The* ***Delete*** *button will only be available if there are user-defined imaging parameters attached to the highlighted* ***Exam Type/Application****.*

4. Select ***Delete*** to access the ***Presets Delete*** dialog.

5. Highlight the imaging parameter(s) to be deleted and click the ***Delete*** button.
6. Click ***Close*** to exit the dialog.

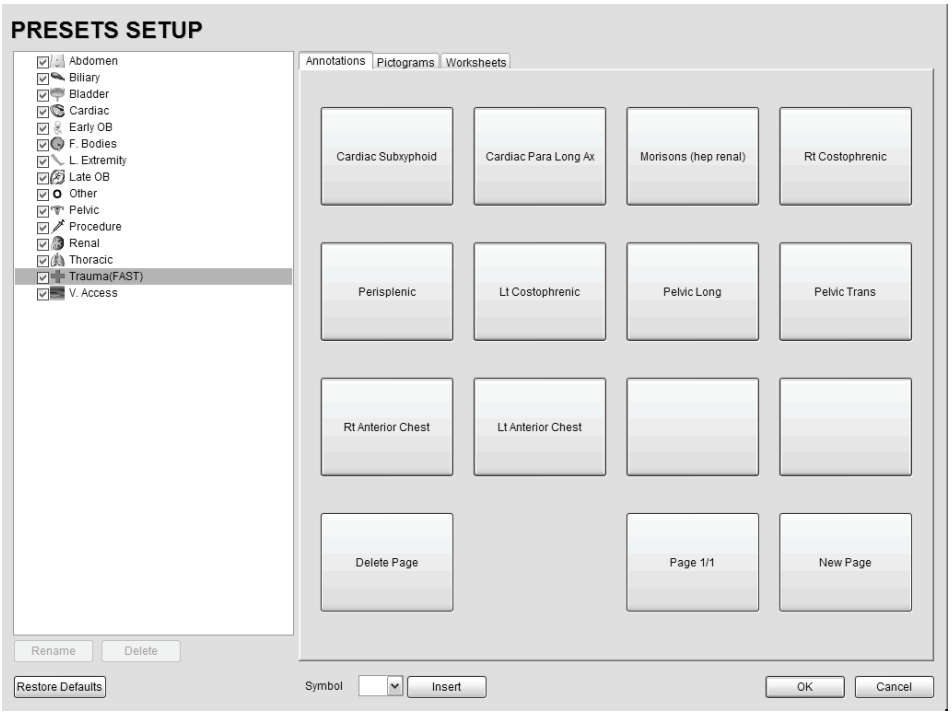
9.2.2 Presets – Annotations

Note: *Refer to* **9.2.5 Annotations** *for details on global* ***Annotation*** *settings.*

The ability to manipulate the text of a specific ***Annotation*** attached to an ***Exam Type/Application*** is handled through the ***Annotations*** tab on the ***Presets Setup*** page. ***Annotation*** text appears by ***Application*** on the console touch screen.

Note: *Not all* ***Exam Type/Applications*** *have pre-defined* ***Annotations****.*

Figure 9-5: Preset **Setup – Annotations**



Note: *The order in which* ***Annotations*** *appear here is matched on the touch screen during* ***Text*** *entry (***8.1 Text and Annotations***).*

9.2.2.1 Modify Annotations

Changes can only be made to the ***Annotations*** of one ***Exam Type/Application*** at a time. Additionally, the system allows users to define/change the ***Home Position*** for the ***Annotation*** cursor. Once set, whenever the ***Home Position*** touch screen button is tapped, the ***Text*** cursor will move directly to that spot.

Note: *Refer to* **8.1.2 Set Text Home Position** *to define the* ***Text/Annotation*** *cursor* ***Home Position****.*

To Modify an Exam Type/Application's Annotations:

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. Highlight the relevant ***Exam Type/Application*** from the left hand menu.
4. Highlight the relevant ***Annotation*** space on the right hand side of the LCD display.
5. Use the keyboard to type in the new ***Annotation***.

   Note: *If multiple pages of* ***Annotations*** *are required, press the* ***New Page*** *button as often as necessary to create the desired number of* ***Annotation*** *spaces.*

   Alternatively, if multiple pages already exist, move through them using the onscreen page selection button, making changes as required.

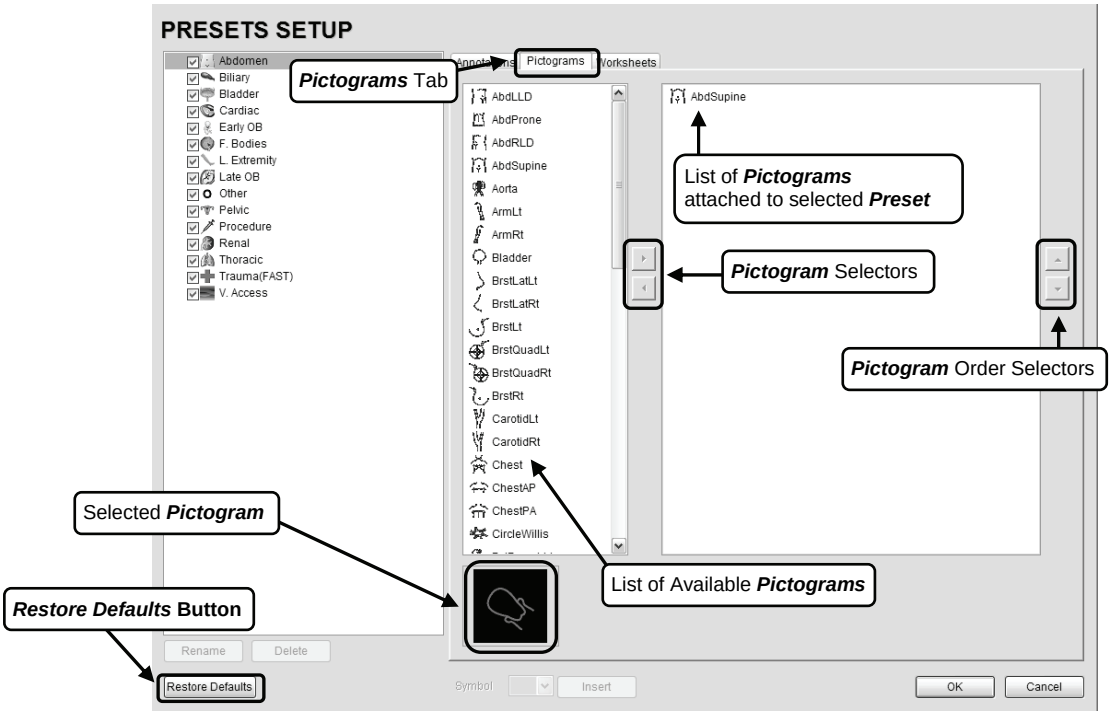
6. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.3 Presets – Pictograms

The ability to attach/detach specific ***Pictograms*** to ***Exam Type/Application*** is handled via the ***Pictograms*** tab in ***Presets Setup***. Re-ordering the sequence in which they will appear on the touch screen during a scanning session is managed here as well.

Note: *Not all* ***Exam Type/Applications*** *have pre-defined* ***Pictograms****.*

Figure 9-6: Preset – Pictograms



9.2.3.1 Modifying Pictograms Attached to Presets

To Add Pictograms to an Exam Type/Application:

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. On the ***Presets Setups*** page, click the ***Pictograms*** tab.
4. Highlight the relevant ***Exam Type/Application*** in the left hand column.
5. From the list of available ***Pictograms***, highlight the relevant ***Pictogram***.
6. Use the right facing selector button to move the item to the list of selected ***Pictograms***.
7. Repeat Steps 5 and 6 as many times as required.
8. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

To Delete Pictograms from an Exam Type/Application:

1. Press the console **MENU** button.
2. From the ***User Settings*** menu, select ***Administrator > Presets***.
3. On the ***Presets Setups*** page, click the ***Pictograms*** tab.
4. Highlight the relevant ***Exam Type/Application*** in the left hand column.
5. Highlight the relevant ***Pictogram*** in the list of selected ***Pictograms***.
6. Use the left facing selector button to delete the item from the list of selected ***Pictograms***.
7. Repeat Steps 5 and 6 as many times as required.
8. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

To Reorder Selected Pictograms Attached to an Exam Type/Application:

1. Press the console **MENU** button.
2. From the ***User Settings*** menu, select ***Administrator > Presets***.
3. On the ***Presets Setups*** page, click the ***Pictograms*** tab.
4. Highlight the relevant ***Exam Type/Application*** in the left hand column.
5. Highlight the relevant ***Pictogram*** in the list of selected ***Pictograms***.
6. Use the order (up/down) selector buttons to move the item to another place in the list of selected ***Pictograms***.
7. Repeat Steps 5 and 6 as many times as required.
8. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

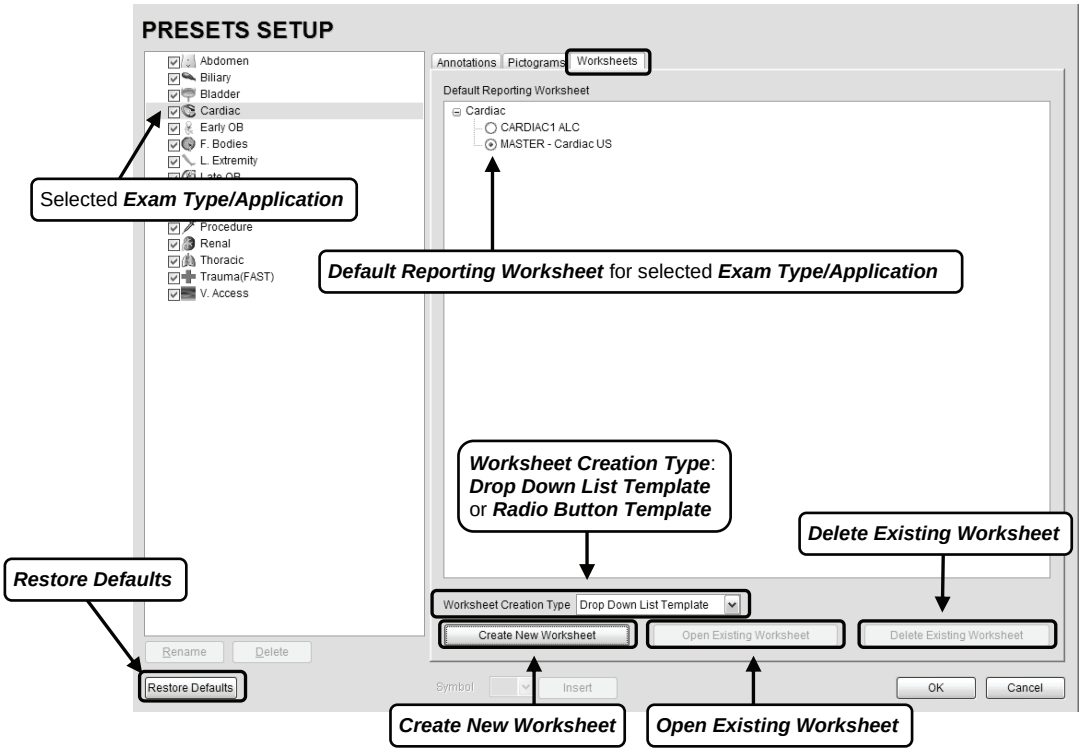
9.2.4 Presets – Worksheets

Worksheets have been created as an electronic documentation tool for emergency ultrasound. Each ***Preset*** (***Exam Type/Application)*** is linked to a ***Worksheet*** for use during an exam. While it is possible to create multiple ***Worksheets*** per ***Exam Type/Application***, only one (1) can be active at any given time.

Each ***Exam Type/Application*** is linked to a default ***Master Worksheet***. This ***Master Worksheet*** cannot be edited, but it can be used as the basis for creating a new ***Worksheet***. Alternatively, a new ***Worksheet*** can be created completely from scratch.

Note: *A* ***Worksheet*** *can be a maximum of three (3) pages long.*

Figure 9-7: Preset – Worksheets

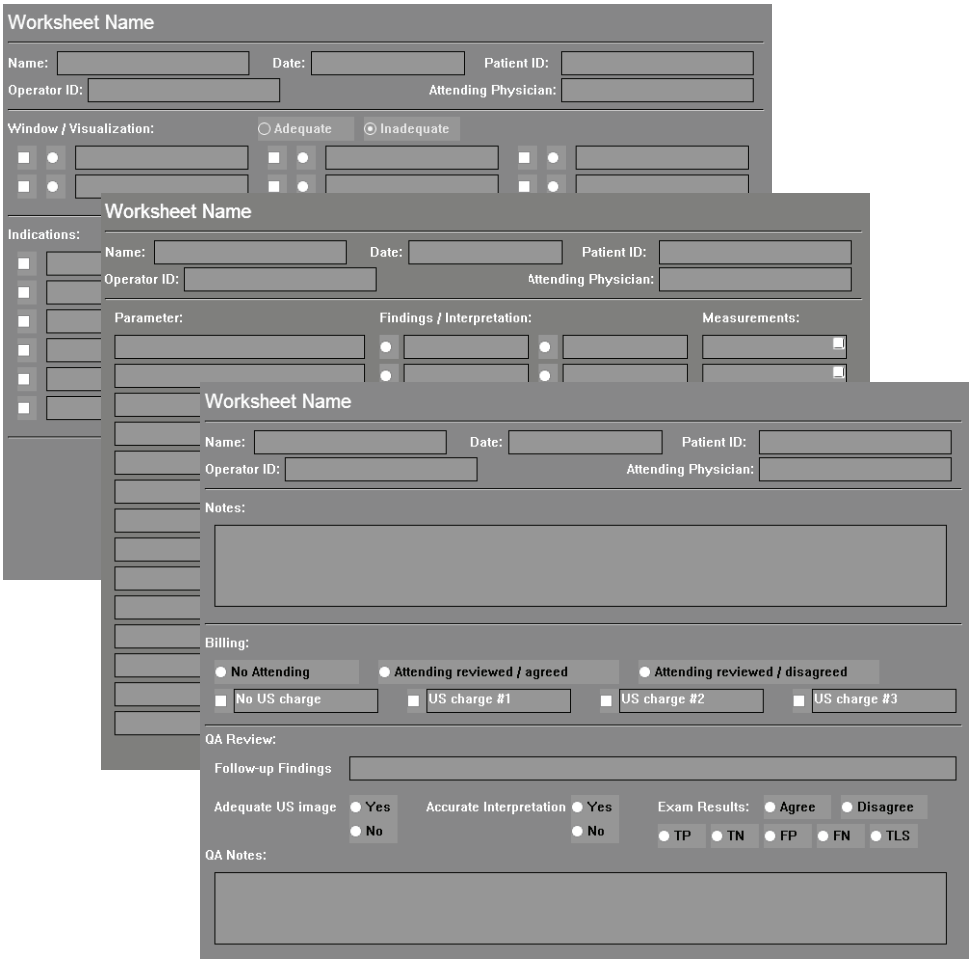


Note: Open Existing Worksheet *and* ***Delete Existing Worksheet*** *will be available only if the* ***MASTER Worksheet*** *is not selected.*

9.2.4.1 Worksheet Templates

A ***Worksheet Template*** is essentially a blank, three (3) page ***Worksheet*** that can be configured – based on the associated ***Exam Type/Application*** – to meet the specific requirements of each institution. When it is presented, each page will be labeled ***Worksheet Name*** until it has been saved. If this saved ***Worksheet*** is subsequently edited, ***Worksheet Name*** will be replaced by whatever ***Template Title*** was chosen by the creator.

Figure 9-8: Worksheet Template (Radio Button Style)



Notes: *When creating a* ***Worksheet*** *using the* ***Drop-down List*** *style, the structure of page two (2) will be somewhat different from a* ***Radio Button*** *style* ***Worksheet****.*

Figure 9-9: Worksheet Patient Data (Pages 1, 2 and 3)

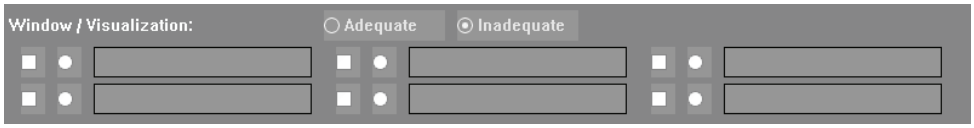
Each page of the ***Worksheet Template*** repeats the data shown in **Figure 9-9**, above. *These fields are not editable during* ***Worksheet*** *creation*.

During imaging, these fields will auto-populate with patient and physician-specific data when a ***Worksheet*** is opened and/or when ***Assign Exam*** data is accepted (refer to **3.3.2 Assign Exam** for details on this option). The ***Worksheet (Template) Name*** will also be included.

Table 9-4: Worksheet Patient Data Fields (Pages 1, 2 and 3)

Name	The patient's ***Name*** as entered for the exam in progress.
Date	The current ***Date*** (based on the system date).
Patient ID	The ***Patient ID*** as entered for the exam in progress.
Operator ID	The ***Operator ID*** as entered for the exam in progress.
Attending Physician	The ***Attending Physician*** as entered for the exam in progress.

Figure 9-10: Worksheet Window/Visualization (Page 1)

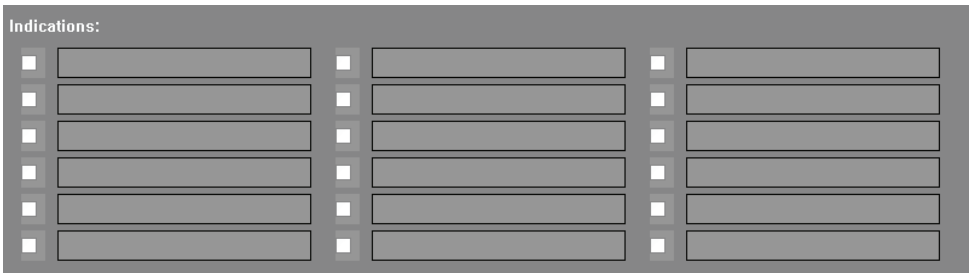


These options enable each institution to customize sonographic views for each ***Exam Type/Application***.

Table 9-5: Worksheet Window/Visualization Fields (Page 1)

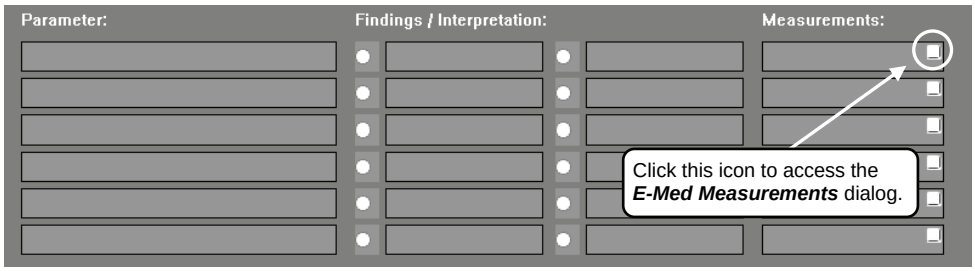
Window/Visualization	There are two options for each entry. Select the checkbox if that sonographic ***Window*** was used for imaging. Select the radio button to mark that the ***Visualization*** through the sonographic ***Window***/view was ***Inadequate***.
	Note: *When the radio button is left unmarked, the* ***Visualization*** *is deemed to be* ***Adequate****.*

Figure 9-11: Worksheet Indications (Page 1)



Use the ***Indications*** section to enter up to 18 different clinical indications.

Figure 9-12: Worksheet Parameters (Page 2)



Parameter settings are used to control the ***Findings***/***Interpretation*** and ***Measurements*** for each ***Parameter*** being tracked.

In a ***Radio Button*** style ***Worksheet***, it's possible to link several ***Parameter*** rows together when more than two (2) ***Findings/Interpretation*** options are required. For example, if instead of a ***Yes/No*** answer, the ***Parameter*** requires the ability to select from three (3) or more options, linking two or more ***Parameter*** rows would enable this functionality (i.e., one (1) row has two (2) options, two (2) linked rows have four (4) options, three (3) linked rows have six (6) options, etc.).

To link ***Radio Button*** style ***Parameter*** rows, enter identical ***Parameter*** descriptions in two (2) or more consecutive ***Parameter*** rows. This will link the ***Parameter*** rows together, resulting in only one ***Parameter*** description and linking the multiple rows of ***Findings/Interpretation*** radio buttons. If two (2) ***Parameters*** were linked, enter up to four (4) ***Findings/Interpretation*** options. If a ***Measurement*** is required, enter it only in the first linked row.

Table 9-6: Worksheet Parameter Fields (Page 2)

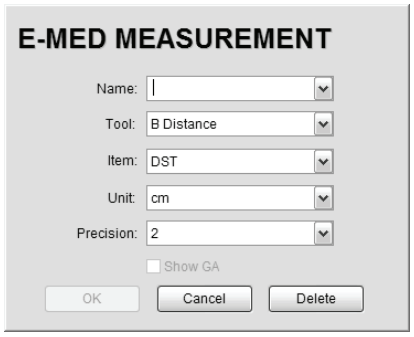
Parameter	A maximum of 14 ***Parameters*** can be entered.
Findings/Interpretations	A ***Finding*** or ***Interpretation*** is a response to the ***Parameter***.

Notes:

*Case sensitivity applies when entering identical **Radio Button** style **Parameter** descriptions on multiple lines.*

*If entering **Drop-Down** style **Findings/Interpretations**, one line will automatically be blank. This should be left alone for those **Exams** where it might be useful to leave the **Findings/Interpretations** blank. If a blank line is not required, simply select it during the **Worksheet** creation/edit process and click the **X** (delete button) in the **Findings/Interpretations** field.*

Figure 9-13: Worksheet E-Med Measurement Dialog



***Note:** On the **Parameters** page, click the icon on the right side of the **Measurements** field to access the **E-Med Measurement** dialog.*

Table 9-7: Worksheet E-Med Measurement Dialog Fields (Page 2)

Name	Enter a relevant ***Measurement Name*** or select one from the drop-down menu.
Tool	Select an appropriate ***Measurement Tool*** from the drop-down menu (e.g., ***Acceleration*** or ***3 Dist. Volume***). ***Note:** The list of available **Tools** will be limited to a specific subset if the **Measurements Name** (above) was selected from the drop-down menu, rather then entered via the keyboard.*

Item	Select an appropriate ***Measurement Item*** from the drop-down menu. ***Note:*** *The list of available* ***Items*** *will be limited to a specific subset based on the* ***Tool*** *selected (above). For example, if* ***3 Dist. Volume*** *was chosen as the* ***Tool****, then the* ***Item*** *choices will be limited to* ***H****,* ***L****,* ***Vol*** *and* ***W****.*
Unit	Select an appropriate ***Measurement Unit*** from the drop-down menu. ***Note:*** *The list of available* ***Units*** *will be limited to a specific subset based on the* ***Item*** *selected (above). For example, if* ***Vol*** *was chosen as the* ***Item****, then the* ***Unit*** *choices will limited to* ***ml*** *and* ***cc****.*
Precision	Select the appropriate ***Precision*** level, i.e., the decimal place setting. There are five (5) choices: ***0***, ***1***, ***2***, ***3***, or ***4***.

Note: *When taking OB measurements, those specific to* ***Gestational Sac*** *will use the Hansmann tables, while all other OB measurements will use the Hadlock tables.*

Any onscreen ***Measurements*** *taken using the* ***Master Worksheet*** *for either* ***Early*** *or* ***Late OB Presets*** *will include* ***Gestational Age*** *(****GA****). If the user creates their own* ***Worksheet*** *for these* ***Presets*** *or deletes any default* ***Measurements*** *from the* ***Master Worksheet****,* ***GA*** *will not be visible.*

Warning: *Ultrasonix does not endorse user-defined measurements for diagnostic purposes. All user-defined measurements are used at the* ***Operator's*** *discretion and risk only.*

Figure 9-14: Worksheet Notes (Page 3)

Table 9-8: Worksheet Notes (Page 3)

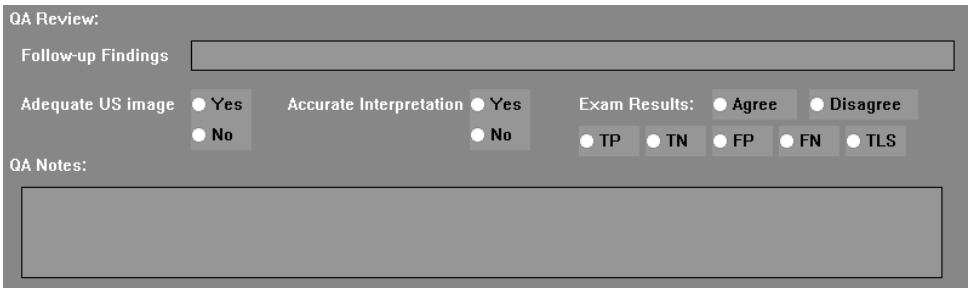
Notes	Enables ***Operators*** to add whatever additional information they feel is necessary.
	Note: *This field will accept approximately 400 characters.*

Figure 9-15: Worksheet Billing (Page 3)

Table 9-9: Worksheet Billing Fields (Page 3)

No Attending	Select if no ***Attending Physician*** is present during the exam.
Attending Reviewed/Agreed	Select when an ***Attending Physician*** is present during the exam and ***Agrees*** with the ***Operator***.
Attending Reviewed/Disagreed	Select when an ***Attending Physician*** is present during the exam and ***Disagrees*** with the ***Operator***.
No US Charge	The names of these four (4) ***Ultrasound*** (***US***) fields can be edited to reflect billing codes relevant to the ***Exam Type/Application*** and/or individual institutions.
US Charge #1	
US Charge #2	***Note:*** *Ultrasonix recommends "blanking out" any unused billing code fields.*
US Charge #3	

Figure 9-16: Worksheet QA Review (Page 3)



This section enables a ***Reviewer*** to make note of any ***Follow-up Findings***, record their ***QA*** results and ***Agree/Disagree*** with the results determined by the ***Operator*** associated with the exam in question.

If a ***Reviewer*** is available to oversee the exam this section can be completed before the ***Worksheet*** is closed – in which case ***Send for Review*** (**4.6.1**) will not be required. If a qualified ***Reviewer*** is not immediately available, this section can be completed at a later date – whether or not ***Send for Review*** (**4.6.1**) was utilized.

Note: *If a qualified* ***Reviewer*** *is also the current* ***Operator****, it would be appropriate for this section to be completed during the exam.*

Table 9-10: Worksheet QA Review Fields

Follow-up Findings		Enables ***Reviewers*** to comment on ***Follow-up Findings*** as necessary. ***Note:*** *This field will accept approximately 75 characters.*
Accurate Interpretation		Accepts a ***Yes*** or ***No*** answer.
Exam Results	When one of the following options is selected by a ***Reviewer*** it will be saved and displayed in the ***Status*** column of the ***QA Database*** on the ***Exam Management*** page (**4.6 QA – Exam Review**).	
	Agree/Disagree	Allows ***Reviewers*** to ***Agree/Disagree*** with the ***Operator's*** results.
	TP	***True Positive***
	TN	***True Negative***
	FP	***False Positive***
	FN	***False Negative***
	TLS	***Technically Limited Study***
QA Notes		Enables ***Reviewers*** to add whatever review comments they feel are necessary. ***Note:*** *This field will accept approximately 400 characters.*

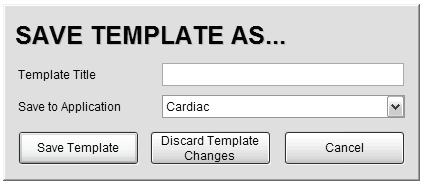
9.2.4.2 Manipulating Worksheets

To Create a Worksheet Template:

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. The ***Presets Setups*** page will be presented with the ***Worksheet*** tab selected.
4. Highlight the desired ***Exam Type/Application***.
5. Select ***Drop-down List Template*** or ***Radio Button Template*** as the ***Worksheet Creation Type***.
6. Select the ***Create New Worksheet*** button.
7. Complete page one as required.
8. Turn the ***Page <<\|>>*** touch screen dial to move to the second page of the template.
9. Complete page two (2) as required.

> ***Warning:*** *Ultrasonix does not endorse user-defined measurements for diagnostic purposes. All user-defined measurements are used at the operator's discretion and risk only.*

10. Turn the ***Page <<\|>>*** touch screen dial to move to the third page of the template.
11. Complete page three (3) as required
12. Once the edits are complete, press the "close" button (**X**) in the top right hand corner or press **WORKSHEET**.
13. In the ***Save Template As…*** dialog, enter a ***Template Title***.



14. From the drop-down menu, make the appropriate ***Save to Application*** selection.
15. Select ***Save Template*** to save the changes and exit to the ***Presets Setup*** page, ***Discard Template Changes*** to exit without saving or ***Cancel*** to continue editing the ***Worksheet*** without saving the ***Template Title***/***Application*** information.

To Create a Worksheet Template Based on an Existing Template:

Note: *When creating a new* ***Worksheet*** *based on an existing one, it is not possible to select a* ***Worksheet Creation Type****. Instead, the new* ***Worksheet*** *will default to the* ***Worksheet Creation Type*** *used by the selected* ***Worksheet****.*

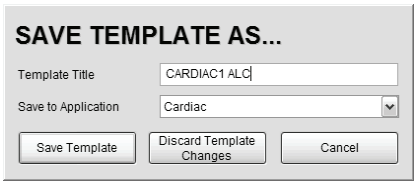
1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. The ***Presets Setups*** page will be presented with the ***Worksheet*** tab selected.
4. Highlight the desired ***Exam Type/Application***.
5. Select the existing ***Worksheet*** to be used as the basis for a new ***Worksheet***.

   Note: *This can be either a user-created* ***Worksheet*** *or the* ***Master Worksheet****.*

6. Select the ***Open Existing Worksheet*** button.
7. Edit the settings from the existing ***Worksheet*** as required, turning the touch screen dial beneath ***Page <<\|>>*** to move to through the ***Worksheet*** pages.

   Warning: *Ultrasonix does not endorse user-defined measurements for diagnostic purposes. All user-defined measurements are used at the operator's discretion and risk only.*

8. Once the edits are complete, press the "close" button (**X**) in the top right hand corner or press **WORKSHEET**.
9. In the ***Save Template As…*** dialog, enter a new ***Template Title***.



10. From the drop-down menu, make the appropriate ***Save to Application*** selection.
11. Select ***Save Template*** to save the changes and exit to the ***Presets Setup*** page, ***Discard Template Changes*** to exit without saving or ***Cancel*** to continue editing the ***Worksheet*** without saving the ***Template Title***/***Application*** information.

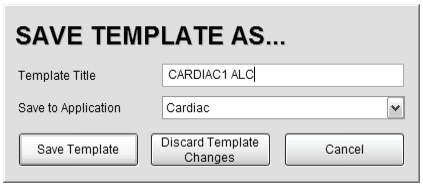
To Edit an Existing Worksheet Template:

Note: *It is not possible to edit any of the* ***Master Worksheets****.*

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. The ***Presets Setups*** page will be presented with the ***Worksheet*** tab selected.
4. Highlight the desired ***Exam Type/Application***.
5. Select the ***Worksheet*** to be edited
6. Select the ***Open Existing Worksheet*** button.
7. Edit the settings from the existing ***Worksheet*** as required, turning the touch screen dial beneath ***Page <<\|>>*** to move to through the ***Worksheet*** pages.
8. Once the edits are complete, press the "close" button (**X**) in the top right hand corner or press **WORKSHEET**.

Warning: *Ultrasonix does not endorse user-defined measurements for diagnostic purposes. All user-defined measurements are used at the operator's discretion and risk only.*

9. In the ***Save Template As…*** dialog, leave the ***Template Title*** as is.



10. If required, from the drop-down menu, make a new ***Save to Application*** selection.
11. Select ***Save Template*** to save the changes and exit to the ***Presets Setup*** page, ***Discard Template Changes*** to exit without saving or ***Cancel*** to continue editing the ***Worksheet*** without saving the ***Template Title***/***Application*** information.

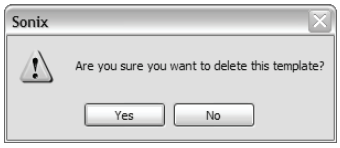
To Set the Default Reporting Worksheet Template:

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. The ***Presets Setups*** page will be presented with the ***Worksheet*** tab selected.
4. Highlight the desired ***Exam Type/Application***.
5. In the right hand column, select the radio button next to the relevant ***Worksheet***.
6. Select ***OK*** to save the new default ***Reporting Worksheet*** or ***Cancel*** to exit without saving.

To Delete a Worksheet Template:

Note: *It is not possible to delete any of the* ***Master Worksheets****. If the* ***Master Worksheet*** *is selected, the* ***Delete Existing Worksheet*** *button will be grayed out.*

1. Press the console **MENU** button.
2. Select ***Administrator > Presets***.
3. The ***Presets Setups*** page will be presented with the ***Worksheet*** tab selected.
4. Highlight the desired ***Exam Type/Application***.
5. Click the ***Worksheet*** tab.
6. Highlight the ***Worksheet*** to be deleted.
7. Select the ***Delete Existing Worksheet*** button.
8. The program will present a deletion confirmation dialog box. Select ***Yes*** to continue with the deletion or ***No*** to cancel it.



9.2.5 Annotations

There are three (3) global ***Annotation*** settings available.

Figure 9-17: (Global) Annotations Dialog

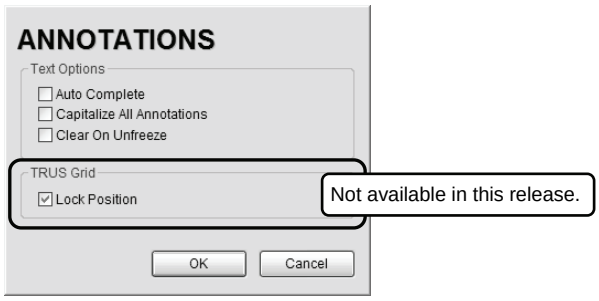


Table 9-11: (Global) Annotations Settings

Text Options	***Auto Complete***	When selected, this feature automatically fills in a word when the first letter(s) is entered on the LCD display. If more than one ***Preset*** begins with the same letter use the **TAB** key to move through the list or continue typing the ***Preset*** name. When enough of the name has been completed in order to jump to the correct entry, the desired ***Preset*** name will appear onscreen and can be selected.
	Capitalize All Annotations	When selected, this feature will automatically force the first letter of each word in the ***Annotation*** to be typed as an upper case character.
	Clear On Unfreeze	When selected, this feature will automatically clear the ***Annotations*** from the image field with un**FREEZE**. If this option has not been selected, the text will remain on the image field until the user deletes it.
TRUS Grid Lock Position		Not available in this release.

To Access the Global Annotations Settings Dialog:

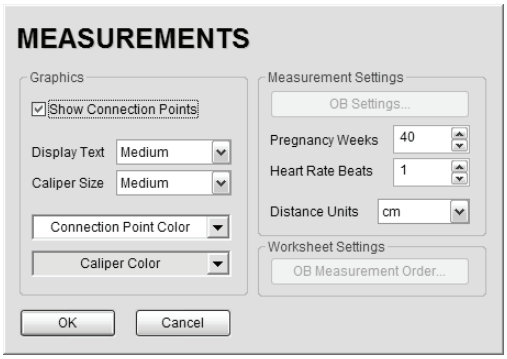
1. Press the console **MENU** button.
2. Select ***Administrator > Annotations***.

Note: *Refer to* **9.2.2 Presets – Annotations** *for details on configuring* ***Exam Type/Application****-specific* ***Annotations****.*

9.2.6 Measurements

The ***Measurements*** dialog enables users to configure certain display details of the measurement/calculation packages. When the **MEASURE** button is selected, ***Measurements*** are available on the touch screen based on clinical ***Application***.

Figure 9-18: Measurements Settings



To Access the Measurements Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > Measurements***.

9.2.6.1 Modify Caliper/Caliper-Text Graphics

The following settings enable the user to customize the onscreen appearance of calipers, caliper labels and measurement values.

Table 9-12: Graphics Settings for Measurement Calipers and Caliper Text

Graphics	***Show Connection Points***	Select to display the connection points (dotted line) between the linear calipers.
	Display Text	Allows the selection of one (1) of three (3) measurement label font size options: ***Small***, ***Medium*** and ***Large***.
	Caliper Size	Allows the selection of one (1) of three (3) caliper size options: ***Small***, ***Medium*** and ***Large***.
	Connection Point Color	Allows the selection of the color of the caliper connection points (dots) between the linear calipers. The default is turquoise.
	Caliper Color	Allows the selection of the color of the caliper end points. The default is turquoise.
	Caution: *Some caliper sizes/colors, font sizes or dot colors may not appear clearly on the image screen, stored image or printed/recorded image. To ensure clear visualization of the caliper, label font and connection points, Ultrasonix recommends setting the caliper graphics to at least* ***Medium****.*	
	Note: *To ensure the caliper modifications have been activated, switch imaging modes after exiting the* ***Setup*** *menus.*	
Other	***OB Settings…***	CEP software does not support this option.
	Pregnancy Weeks	Defines the number of weeks used to calculate the ***EDD*** based on ***LMP***. Range: 35 – 45 weeks.
	Heart Rate Beats	Number of beats used to measure the ***HR*** and ***FHR*** on an ***M-Mode*** and ***Doppler Trace***. Range: 1 – 7 beats.
	Distance Units	Unit used to display ***Distance*** calculation: ***mm***, ***cm***, ***m***, ***in*** or ***µm.***
	OB Measurement Order…	CEP software does not support this option.

9.2.7 Training Tutorials

This option enables organizations to load and view a variety of different video, audio or PowerPoint files on the SONIX CEP system in order to provide training to their staff.

The training files may be provided by Ultrasonix, but they can also be created by each organization, as long as they are created in one of the accepted digital formats.

For details on viewing ***Training Tutorials*** via the **QSONIX** button, refer to **3.3.4 Training Tutorials**.

Figure 9-19: Training Tutorials Dialog

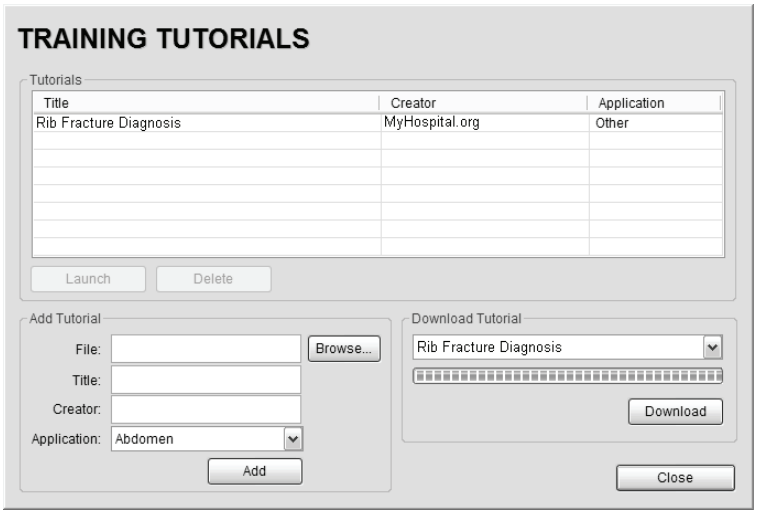


Table 9-13: Training Tutorial Options

Tutorials	The ***Tutorials*** section lists files that have already been downloaded and are ready for viewing.	
	Title	Lists the ***Titles*** of the available ***Tutorials***.
	Creator	Lists the ***Creator*** of the specific ***Title***.
	Application	Lists the ***Clinical Application*** associated with the specific ***Title***.
	Launch	Plays the selected ***Title***.
	Delete	***Deletes*** the selected ***Title***.

Add Tutorial	***Add Tutorial*** enables organizations to add user-created ***Tutorials***.	
	File	Displays the name of the ***File*** selected with the ***Browse*** button.
	Title	Enter a descriptive ***Title*** that will immediately reveal the ***Tutorial's*** purpose.
	Creator	Enter the name of the ***File's Creator***. This might be an individual, an outside company or the name of the host organization.
	Application	Select an ***Application*** which best describes the clinical relevance of the ***Tutorial***.
Download		Launches the ***Download*** sequence for the ***Title*** selected from the drop-down menu.

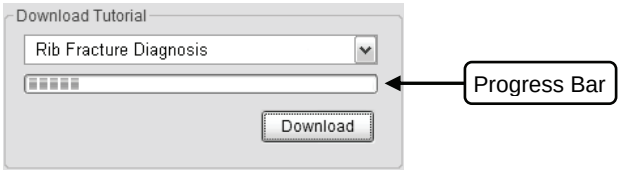
Table 9-14: Supported Training Tutorial File Formats

Video	***AVI***, ***MPG***, ***MPEG*** and ***WMV***.
Audio	***MP3*** and ***WMA***.
PowerPoint	***PPT***
	Note: *Video files embedded in PowerPoint presentations are not supported.*

9.2.7.1 Manipulating Training Tutorials

To Download a Training Tutorial from the Network:

1. Press the console **MENU** button.
2. Select ***Administrator > Training Tutorials***.
3. Select a file from the drop-down menu in the ***Download Tutorial s***ection of the dialog.

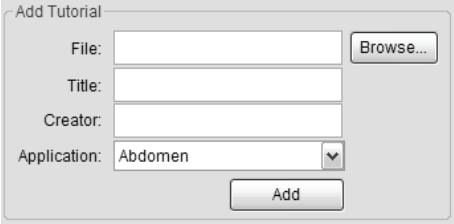


4. Click the ***Download*** button.
5. Follow the status of the progress bar to see how far along the download is.
6. When the download is complete, the ***Title*** will be added to the list of available tutorials.

To Add a Training Tutorial from External Media:

Note: *External media includes: USB key, CD and DVD. When using this type of media, ensure that the relevant item is loaded into the appropriate device.*

1. Press the console **MENU** button.
2. Select ***Administrator Settings > Training Tutorials > Browse…***.



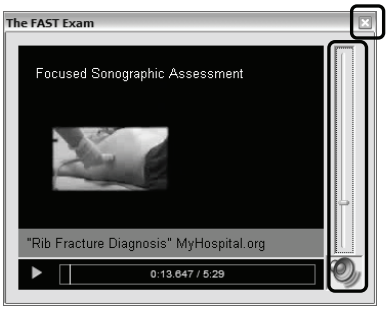
3. From the dialog presented, find and select the relevant ***File*** to be added.
4. Enter a ***Title*** and ***Creator*** in the fields provided.
5. Select a clinically relevant ***Application*** type from the drop-down menu.
6. Click the ***Add*** button.
7. Once the addition is complete, the ***Title*** will be added to the list of available ***Tutorials***.

To Launch a Training Tutorial:

Note: *The primary method of viewing a* ***Training Tutorial*** *is via the* **QSONIX** *button (***3.3.4 Training Tutorials***), but they can also be viewed from here as well.*

As a precaution, it's a good idea to test each file after it is downloaded/added in order to ensure it views properly.

1. Press the console **MENU** button.
2. Select ***Administrator > Training Tutorials***.
3. Highlight a ***Title*** from the list of ***Tutorials***.
4. Click the ***Launch*** button and the tutorial will be presented on the LCD display.



5. Press the red **X** in the top right corner of the tutorial screen to stop/exit the tutorial.

Note: *For files with an audio component, the volume can be adjusted with the audio slide on the right hand side of the tutorial screen.*

Master Volume *control is adjusted from the* **System Settings** *dialog (***9.2.9***).*

9.2.8 3D Settings

3D Settings enables users to configure the ***3D Config*** parameters (available during ***Freehand 3D*** imaging) and to manage user-defined ***3D Presets***.

The ***3D Config*** dialog can be configured to appear after ***Freehand 3D*** image acquisition or only when requested (via the touch screen during an exam). This setting applies to all ***3D Presets*** used during freehand image acquisition.

Additionally, user-defined ***3D Presets*** (marked with a key icon) can be renamed or deleted here.

Note: *Default* ***Presets*** *are marked with a lock icon adjacent to the* ***Preset*** *name. They cannot be renamed or deleted.*

Figure 9-20: 3D Settings

To Configure 3D Settings for Freehand Image Acquisition:

1. Press the console **MENU** button.
2. Select ***Administrator > 3D***.
3. Select/deselect the ***Provide 3D Freehand Options After Acquisition*** checkbox.

   Note: *This is a global option and applies to all* ***3D Presets****.*

4. Select ***OK*** to accept the change and exit or ***Cancel*** to exit without saving.

To Rename User-Defined 3D Presets:

1. Press the console **MENU** button.
2. Select ***Administrator > 3D***.
3. Highlight the user-defined ***3D Preset*** to be renamed.

   Note: *User-defined* ***Presets*** *are marked with a key icon.*

4. Click the ***Rename*** button.
5. Use the keyboard to enter a new name in the ***Save Preset*** dialog box.

   Note: *The system will not allow duplicate* ***Preset*** *names. If a duplicate name is entered, a message bubble will prompt for a different name.*

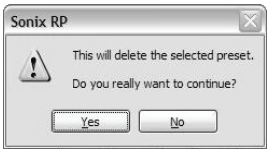
6. Select ***OK*** to accept the ***Preset Name*** and exit or ***Cancel*** to exit without saving.

To Delete User-Defined 3D Presets:

1. Press the console **MENU** button.
2. Select ***Administrator > 3D***.
3. Highlight the user-defined ***3D Preset*** to be deleted.

   Note: *User-defined* ***Presets*** *are marked with a key icon.*

4. Click the ***Delete*** button.
5. Select ***Yes*** to accept the deletion and exit or ***No*** to exit without deleting the ***Preset***.



9.2.9 System Settings

System Settings are used to configure: ***Institution Name***, ***Regional*** parameters, ***Shutdown Options***, ***Auto-Freeze***, ***Auto-Shutdown***, ***User Data*** settings, ***Master Volume***, ***QA Password*** and ***Admin Password***.

Figure 9-21: System Settings

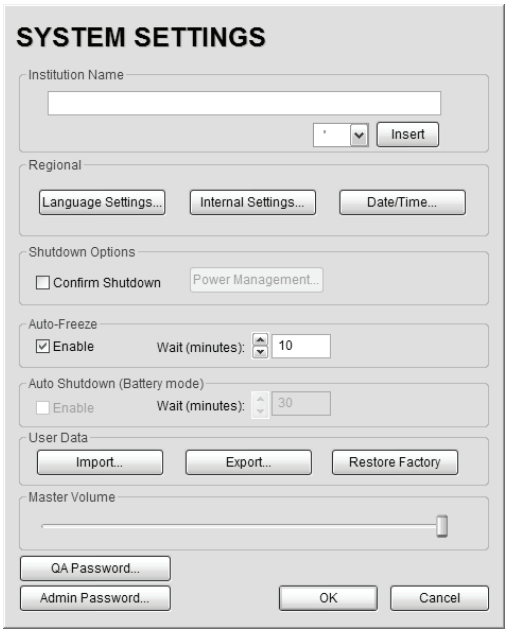


Table 9-15: System Settings Configuration Options

Institution Name		Enter the ***Institution Name*** using the keyboard. The text entered here appears at the top of the image field.
Insert (Symbol)		Use to insert text symbol(s) not available on console keyboard (e.g., punctuation marks, symbols and letters from other languages).
Regional	***Language Settings…***	Select the desired language for the user interface.
	User Manual Language	Select the default PDF ***User Manual Language***. Refer to **3.3.5** for details on accessing the PDF User Manual. ***Note:*** *If no* ***User Manuals*** *are available on the system, then this option will inaccessible (grayed out).*
	Internal Settings…	Select country-specific parameters, including ***Date*** and ***Time*** formats and ***Number*** display modes.
	Date/Time…	Configure the actual ***Date*** and ***Time*** (based on the ***Date/Time*** format selected in ***Internal Settings…***).

Shutdown Options	***Confirm Shutdown***	Forces the system to request confirmation when powering down. ***Note:*** *If the system powers down under* ***Auto-Shutdown*** *parameters (***below***), the* ***Confirm Shutdown*** *request will not be presented.*
	Power Management	Not in use.
Auto-Freeze	***Enable***	Enables ***Auto-Freeze***, which deactivates any transducer that is connected but not currently in use.
	Wait (minutes)	Once ***Auto-Freeze*** is ***Enabled***, ***Wait*** controls the number of minutes a stationary transducer will remain active before ***Auto-Freeze*** is triggered. Deactivating/freezing transducer usage will help to prolong its life span. Select a setting of 5 to 120 minutes. The default is ***Auto-Freeze Enabled***, with a 10 minute ***Wait*** time. ***Note:*** *To reactivate (or unfreeze) the transducer/imaging session, simply press the console* **FREEZE** *button.*
Auto-Shutdown (Battery Mode)	***Enable***	Checking ***Auto-Shutdown*** will automatically shutdown the system after it has remained inactive for the amount of time specified in the ***Wait*** field, providing the system is running on UPS battery power. By default, ***Enable*** is not selected. ***Note:*** *Because* ***Auto-Shutdown*** *is designed for those situations when the system has been left unattended and running on battery power, if both* ***Auto-Shutdown*** *and* ***Confirm Shutdown*** *(***above***) have been enabled,* ***Confirm Shutdown*** *will be ignored by* ***Auto-Shutdown****. This means that when* ***Auto-Shutdown*** *reaches the end of the predefined* ***Wait*** *period, the system will automatically shutdown without requesting confirmation, even though* ***Confirm Shutdown*** *has been checked.* *Additionally, if the battery charge falls to the lowest allowable level (***Alert Level 1***) before* ***Auto-Shutdown*** *reaches its* ***Wait*** *time limit, then the low battery shutdown procedure will take precedence over the* ***Auto-Shutdown*** *settings. Refer to* **Table 11-4** *for details on* ***Battery Recharge Alerts****.*
	Wait (minutes)	Once ***Auto-Shutdown*** is ***Enabled***, ***Wait*** controls the number of minutes the system must remain inactive before ***Auto-Shutdown*** is triggered. The range is 5 to 120 minutes.

User Data	***Import…***	Imports user-configured system settings from a USB storage device. Settings must have been previously exported from a SONIX system. Data imported: user-defined ***Imaging Presets***, ***Worksheet Templates***, user-configured ***Annotations*** and ***Pictograms***, and ***DICOM*** and ***Network*** configurations setups. ***Note:*** *Ultrasonix does not recommend importing user-defined* ***Presets*** *created with a previous software version as they may not be compatible for use with a more recent software update.*
	Export…	Exports user-configured system settings to a USB storage device. Data exported: user-defined ***Imaging Presets***, ***Worksheet Templates***, user-configured ***Annotations*** and ***Pictograms***, ***DICOM*** and ***Network*** configurations setups and ***System Logs***.
	Restore Factory	Resets the system to the default settings installed during manufacturing.
Master Volume		Controls the master setting for SONIX audio volume.
QA Password…		Creates/removes a ***QA Password*** in order to protect access to the ***QA*** tab/database on the ***Exam Management*** page. ***Caution:*** *If no password is set, all users will have access to the* ***QA*** *tab.*
Admin Password…		Creates/removes a global, administration level ***Password*** in order to protect ***Administrator Settings*** configuration.

To Password Protect Administrator Settings Access:

1. Press the console **MENU** button.
2. Select ***Administrator > System > Admin Password…***.
3. Enter a ***Password*** when prompted by the dialog.

4. Select ***OK*** to accept the ***Password*** and exit or ***Cancel*** to exit without saving.

To Password Protect QA Tab/Database Access (Exam Management Page):

1. Press the console **MENU** button.
2. Select ***Administrator > System > QA Password…***.
3. Enter a ***Password*** when prompted by the dialog.
4. Select ***OK*** to accept the ***Password*** and exit or ***Cancel*** to exit without saving.

To Configure PDF User Manual Language:

1. Press the console **MENU** button.
2. Select ***Administrator > System > Language Settings…***.
3. From the ***User Manual Language*** drop-down menu, select the desired language.

   Note: *If this option is inaccessible (grayed out), there are no PDF User Manuals available on the system.*

4. Select ***Close*** to accept the language selection and exit.

9.2.10 Network

The ***Network*** setup dialog allows users to configure the system's network, either through a hard-wired LAN or dialup connection or via a wireless network.

Note: *Refer to* **Appendix B: System Specifications** *for wireless availability on the various system configurations.*

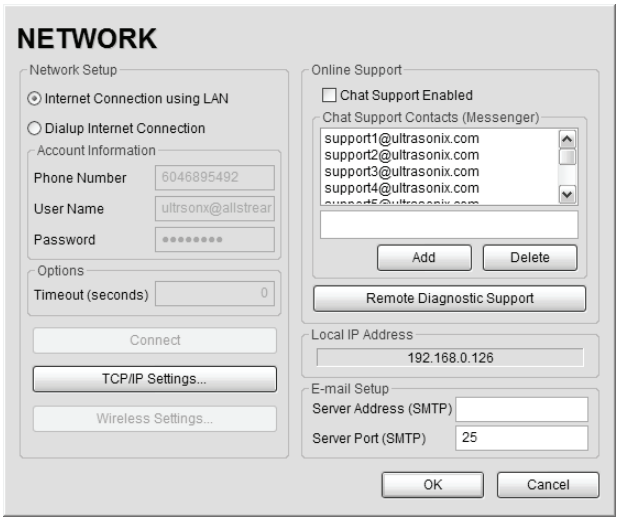
The ***Remote Diagnostic Support*** button is used to connect with an online Ultrasonix technician. Ultrasonix Technical Support will help configure this option should it ever be required.

Additionally, for those organizations wishing to use the ***Exam Review*** process, it will be necessary to configure the ***E-Mail Setup*** fields and/or configure a network printer.

Caution: *System networking options are intended for use inside your organization's firewall. Organizations that elect to configure/use the networking functionality provided by Ultrasonix are assuming all liabilities and risks associated with that decision.*

Caution: *For details on FCC regulations as they apply to the wireless adapter, refer to the manufacturer's User Guide included with the system.*

Figure 9-22: Network Dialog



Note: *A network connection is required to use any of the following:* ***DICOM, Online Support****,* ***Remote Diagnostic Support****,* ***Exam Review*** *and* ***SONIX Live*** *(video streaming).*

Table 9-16: Network Settings

Network Setup	***Internet Connection Using LAN*** ***OR*** ***Dialup Internet Connection***		Select ***Internet Connection*** type: ***LAN*** or ***Dialup***.
	Account Information	***Phone Number***	If ***Dialup*** was selected in the previous step, enter the telephone number for the Internet Service Provider (ISP).
		User Name	Enter the ***User Name*** for the dialup ISP account.
		Password	Enter the ***Password*** that will protect the ***Dialup*** connection to the Internet.
	Timeout (seconds)		Enter the ***Timeout*** limitation (in number of seconds). ***Note:*** *If the system fails to connect within the proscribed time limit, it will stop trying.*
	Connect		Click to ***Connect*** using the ***Dialup*** settings.
	TCP/IP Settings…		Click to configure ***TCP/IP Settings***. Refer to **9.2.10.1 Ethernet (LAN) Network Configuration** for details.
	Wireless Settings…		Click to configure ***Wireless Settings***. Refer to **9.2.10.3 Wireless Settings** for details.
Online Support	***Chat Support Enabled***		Select this checkbox to enable online ***Chat Support***.
	Add		Use this option to add extra (i.e., non-Ultrasonix) online ***Chat Support*** addresses. ***Note:*** *Ultrasonix* ***Online Support*** *addresses are added automatically.*
	Delete		After selecting an address from the ***Chat Support Contacts*** list, click the ***Delete*** button to remove it.
	Remote Diagnostic Support		After receiving a PIN from Ultrasonix, use this option to connect to the Internet. This will allow an Ultrasonix Support technician to remotely access the system to resolve any issues that may have arisen.
Local IP Address			When using ***Streaming Video***, it is necessary to advise the recipient of the system's ***Local IP Address***. ***Note:*** *During* ***Streaming Video****, this* ***Local IP Address*** *can be accessed temporarily by clicking on the* ***Streaming Video*** *icon on the LCD display.* *For details on* ***Streaming Video*** *and its associated icon, refer to* **9.1.1 SONIX Live***.* *If the system is not connected to a network, instead of a* ***Local IP Address****, the field will read* ***No Network Connection****.*

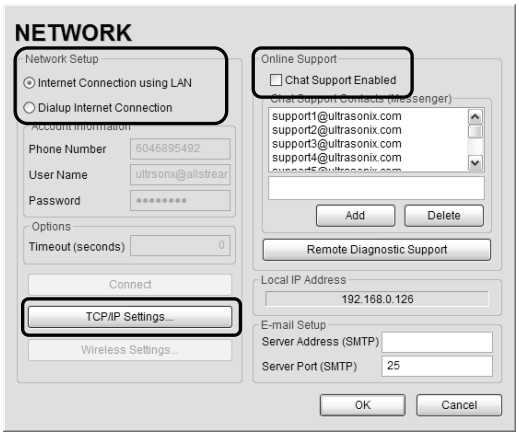
E-Mail Setup	***Server Address (SMTP)***	Enter the ***Outgoing (SMTP) Server Address*** here.
	Server Port	Enter the ***Outgoing Server Port*** number here.

Note: *Ultrasonix recommends that* ***Network*** *connections be configured using the settings provided by your IT Department.*

9.2.10.1 Ethernet (LAN) Network Configuration

To Configure an Ethernet (LAN) Connection (If Available):

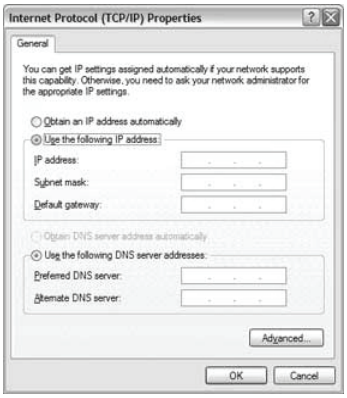
1. Connect an RJ45 cable to the NET or LAN port located on the Back Connectivity Panel.
2. Press the console **MENU** button.
3. Select ***Administrator > Network > Internet Connection using LAN***.



4. Under ***Online Support***, ensure the ***Chat Support Enabled*** check box has been selected.

Note: *Do not select the* ***Chat Support Enabled*** *checkbox unless there is an Internet connection available.*

5. Click ***TCP/IP Settings…***.
6. Under ***General***, select ***Obtain an IP address automatically*** or ***Use the following IP address*** and enter the assigned static ***IP address***, ***Subnet mask***, and ***Default gateway***.



7. Select ***OK*** and press the console **MENU** button to exit the menu system.

Note: *It may be necessary to restart in order for the changes to take affect.*

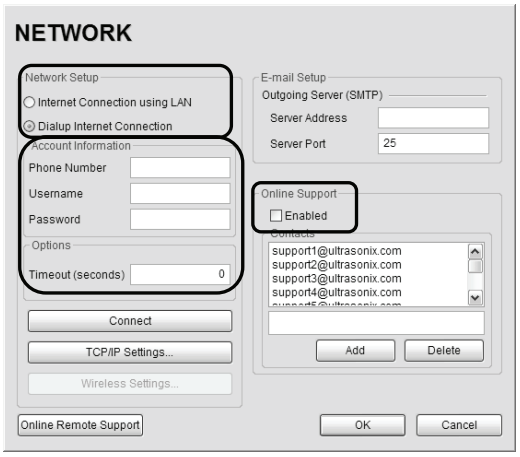
9.2.10.2 Dialup Network Configuration

To Configure a Dial-up Connection (If Available):

1. Connect an RJ11 cable to the **PHONE** port located on the Back Connectivity Panel.
2. Press the console **MENU** button.
3. Select ***Admin… > Network > Dialup Internet Connection***.
4. Under ***Online Support***, ensure the ***Enabled*** checkbox has been selected.

Note: *Do not select the* ***Chat Support Enabled*** *checkbox unless there is an Internet connection available.*

5. Complete the ***Account Information*** and ***Options*** sections: ***Phone Number***, ***Username***, ***Password*** and ***Timeout***.



6. Select ***OK*** and press the console **MENU** button to exit the menu system.

Note: *While the system is dialing out, the current dialing status to the ISP will be displayed.*

9.2.10.3 Wireless Settings

Figure 9-23: Wireless Network Connection Setup

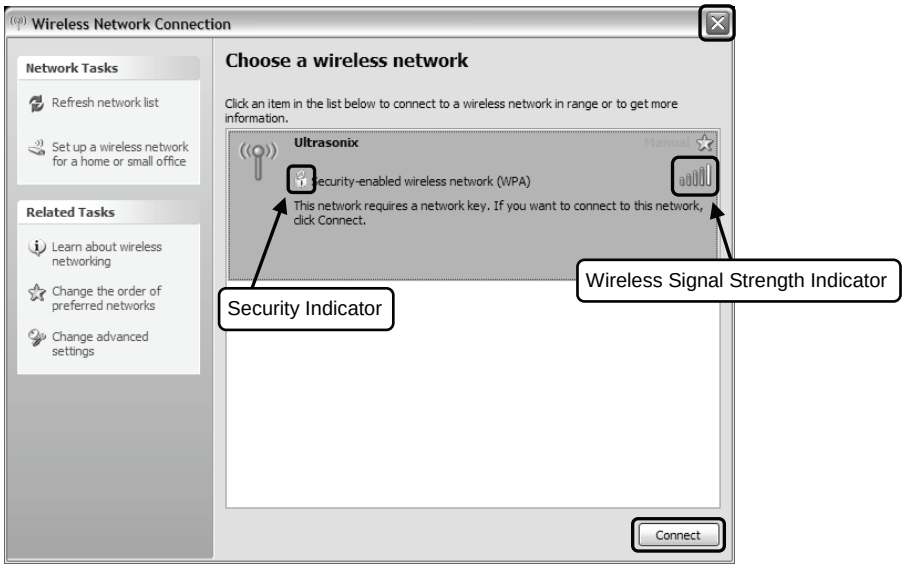


Table 9-17: Wireless Network Connection Options

Wireless Signal Strength Indicator  100% 75% 50% 25% 0%	Denotes the strength of the wireless signal (%). If selected in **9.2.16 Status Bar**, this icon will also appear on the LCD display.
Security Indicator	This indicator is dependant upon the type of wireless network in use. If no ***Lock*** icon is present, then the wireless network has no security. A ***Lock*** icon will be present for ***WEP*** (***Wired Equivalent Privacy***) and ***WPA*** (***Wi-Fi Protected Access***) wireless networks, indicating that wireless security has been configured. When a wireless network is in place, it will be necessary to obtain your institution's ***Network Key*** in order to login. ***Note:*** *Ask your IT department for the* ***Network Key****.*
Connect/Disconnect	Used to ***Connect***/***Disconnect*** from the wireless network.

To Configure Wireless Network Connection Options:

Note: *Always consult with your IT department when configuring a wireless connection.*

1. Press the console **MENU** button.
2. Select ***Administrator*** > ***Network*** > ***Wireless Settings…***.
3. Configure the wireless connection following the onscreen directions in the ***Wireless Network Connection*** dialog.

   Note: Wireless Network Connection *options are controlled by MS Windows, not Ultrasonix.*

9.2.10.4 Online (Chat) Support

Note: *A network connection is required for online* ***Chat Support****.*

To Add Extra Online Chat Support IP Addresses:

1. Press the console **MENU** button.
2. Select ***Administrator > Network***.
3. Ensure the ***Online Support Enabled*** box is checked.
4. Enter the ***Contact*** IP address (above ***Add*** and ***Delete***).
5. Click ***Add***.
6. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

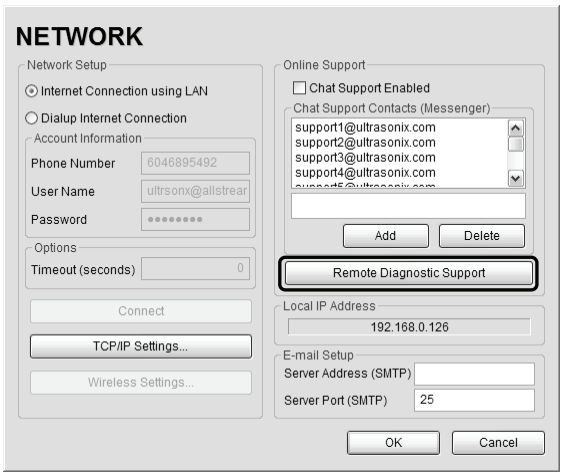
9.2.10.5 Remote Diagnostic Support

Remote Support allows Ultrasonix Technical Support to view and control the SONIX system for remote diagnostic purposes.

Note: *A network connection is required for* ***Remote Support****.*

To Configure Remote Diagnostic Support:

1. Press the console **MENU** button.
2. Select ***Administrator > Network.***
3. Under ***Online Support***, ensure the ***Enabled*** check box has been selected.
4. Click ***Remote Diagnostic Support***.



Note: *A network connection is required for* ***Remote Support****.*

5. Enter the ***PIN*** (***Personal Identification Number***) provided by Ultrasonix Technical Support.

Note: *The* ***PIN*** *is valid for 20 minutes only, so be sure to use it right away.*

6. When prompted, select ***Download > Run > Run*** in order to install the required programs.
7. The SONIX can now be remotely controlled.

9.2.11 DICOM Configuration

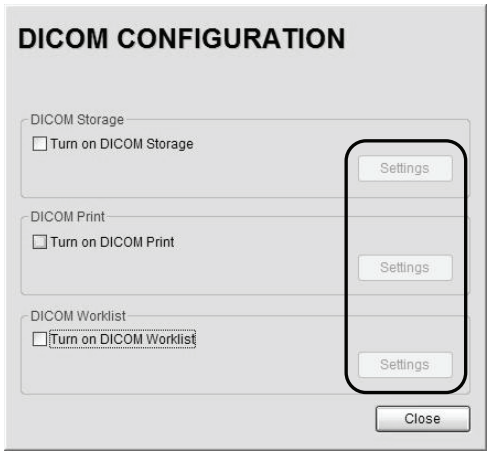
The system uses the *Digital Imaging and Communications in Medicine* (***DICOM***) standard to share medical information with other digital imaging systems. The SONIX system, by means of the ***DICOM*** protocol, communicates with ***Storage***, ***Print*** and ***Modality Worklist Service Class Providers***.

Refer to **9.2.10 Network** to configure the system for network connectivity.

To Configure for DICOM Connectivity:

1. Press the console **MENU** button.
2. Select ***Administrator > DICOM***.
3. To activate/deactivate access to a ***DICOM*** feature, select/deselect the appropriate ***Turn on…*** checkbox beside the desired feature (***Storage***, ***Print*** or ***Worklist***).

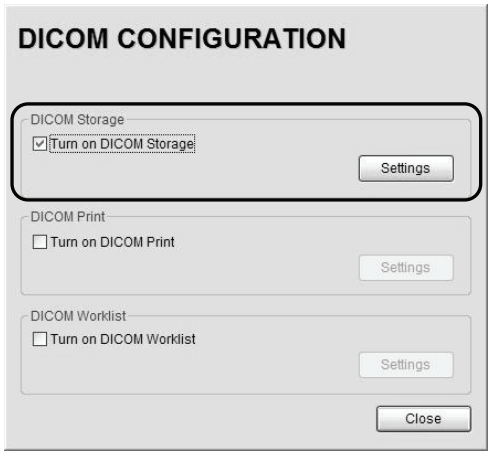
Note: *Each* ***Settings*** *button (on the right side of the dialog) becomes available when that particular* ***DICOM*** *feature is activated.*



9.2.11.1 DICOM Storage Configuration

The ***DICOM Storage Settings*** dialog offers basic and advanced settings for configuring the SONIX system for ***DICOM*** image storage.

Figure 9-24: DICOM Configuration – DICOM Storage



To Configure the DICOM Storage Setting:

1. Press the console **MENU** button.
2. Select ***Administrator > DICOM***.
3. Check ***Turn on DICOM Storage***, then select the associated ***Settings*** button.
4. An onscreen dialog with four (4) tabs will be presented: ***AE (Application Entity) Configuration***, ***Storage Settings***, ***Brightness/Contrast*** and ***Storage Commitment***.
5. Configure the four (4) dialogs as required.

The ***DICOM Storage AE Configuration*** dialog enables configuration of ***AE*** properties.

Figure 9-25: DICOM Storage Settings – AE Configuration

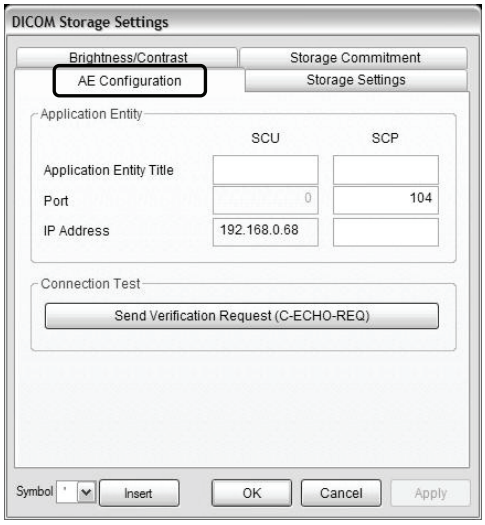


Table 9-18: DICOM Storage Settings – AE Configuration Settings

Local Host Properties – Service Class User(SCU) – SONIX system	
Application Entity Title	***AE Title*** of the SONIX system.
Port	Listening ***Port*** of the SONIX system (unused).
IP Address	Unique identifier of the SONIX system (informational only).
Remote Host Properties – Service Class Provider (SCP) – DICOM Storage Server	
Application Entity Title	***AE Title*** of the ***Storage SCP***.
Port	Listening ***Port*** of the ***Storage SCP***.
IP Address	Unique identifier of ***Storage SCP***.
Connection Test	Select to send verification request to ***DICOM Storage*** device (ping to verify connection).
Insert (Symbol)	Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).

The ***DICOM Storage Settings*** dialog specifies how images are stored.

Figure 9-26: DICOM Storage Settings – Storage Settings

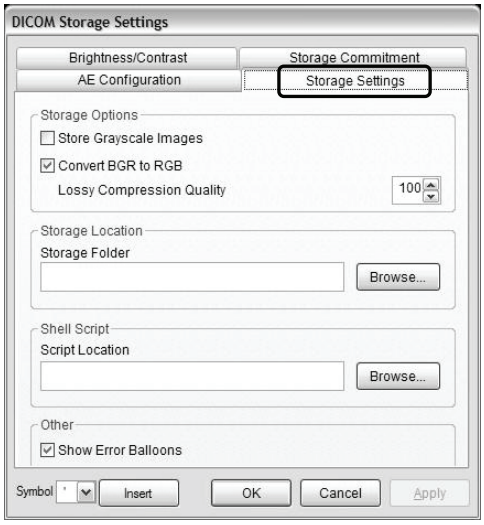


Table 9-19: DICOM Storage Settings – Storage Settings

Storage Options	***Store Grayscale Images***	Select to store images in grayscale format.
	Convert BGR to RGB	Select to swap the color components of the image pixel data – the blue colors are swapped with the red colors.
	Lossy Compression Quality	Select the quality (1% – 100%) of image compression.
Storage Folder		Select the location (local or remote) where the images will be stored. ***Note:*** *If a value is specified, the* ***AE Configuration*** *and* ***Storage Commitment*** *dialogs are disabled – images can not be stored to an* ***SCP****.*
Script Location		Select the location of the script that will be run immediately before images are stored (e.g. a script to run filters on images before storing them).
Show Error Balloons		Select to enable the display of ***DICOM Storage*** error messages (e.g., ***Failed to connect to DICOM***).
Insert (Symbol)		Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).

The ***DICOM Storage Brightness/Contrast*** dialog changes the ***Brightness*** and ***Contrast*** settings. These settings are applied to the images that are sent to the ***SCP***, not the images stored locally.

The effects of these settings can be seen in the ***Before*** and ***After*** images.

Figure 9-27: DICOM Storage Settings – Brightness/Contrast

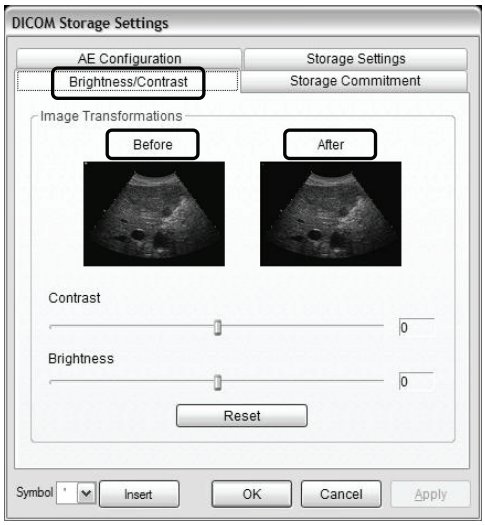


Table 9-20: DICOM Storage Settings – Brightness/Contrast

Contrast	Adjusts the level of ***Contrast*** applied to the images.
Brightness	Adjusts the level of ***Brightness*** applied to the images.
Reset	***Resets*** the values of ***DICOM Storage Brightness*** and ***Contrast*** back to zero.
	Note: *To adjust the* ***Brightness/Contrast*** *settings, position the trackball arrow over the* ***Brightness*** *or* ***Contrast*** *slider. Press and hold the* **SELECT** *button while moving the trackball left or right to the desired position.*

The ***DICOM Storage Commitment*** dialog enables configuration of the ***Storage Commitment AE***.

Check ***Turn on Storage Commitment*** to enable the ***Storage Commitment*** feature.

Figure 9-28: DICOM Storage Settings – Storage Commitment

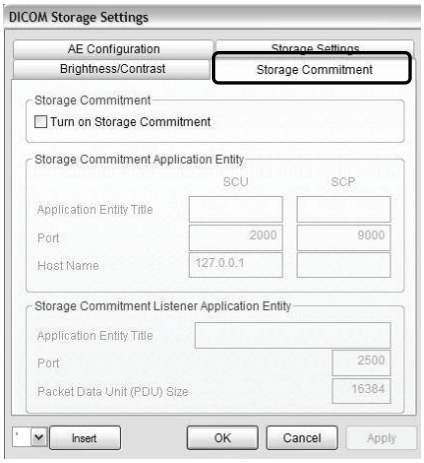


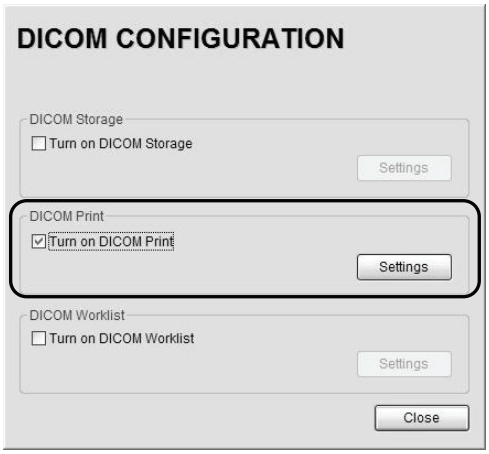
Table 9-21: DICOM Storage Settings – Storage Commitment

Turn on Storage Commitment	Select to enable ***Storage Commitment*** functionality.
Local Host Properties of Storage Commitment - SCU (SONIX System)	
SCU AE Title	***AE Title*** of the SONIX system.
SCU Port	Listening ***Port*** of the SONIX system.
SCU Host Name	***Host Name*** of the SONIX system ***SCU*** (informational only).
Remote Host Properties – SCP – DICOM Storage Server	
SCP AE Title	***AE Title*** of the ***Storage Commitment SCP***.
SCP Port	Listening ***Port*** of the ***Storage Commitment SCP***.
SCP Host Name	***Host Name*** of the ***Storage Commitment SCP***.
Storage Commitment Listener AE	
AE Title	***AE Title*** of the ***Storage Commitment Listener SCU***.
Port	Listening ***Port***.
Packet Data Unit (PDU) Size	***PDU*** size in bytes.
Insert (Symbol)	Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).

9.2.11.2 DICOM Print Configuration

DICOM Print Settings offer basic and advanced settings for configuring the SONIX system for ***DICOM Print***.

Figure 9-29: DICOM Configuration – DICOM Print



To Configure DICOM Print Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > DICOM***.
3. Check ***Turn on DICOM Print***, then select the associated ***Settings*** button.
4. An onscreen dialog with four (4) tabs will be presented: ***AE Configuration***, ***Print Settings***, ***Advanced Print Settings*** and ***Brightness/Contrast***.
5. Configure the four (4) dialogs as required.

The ***DICOM Print AE Configuration*** dialog enables configuration of ***AE*** properties.

Figure 9-30: DICOM Print Settings – AE Configuration

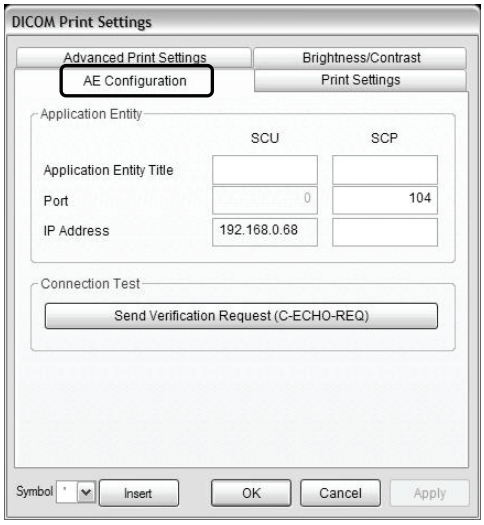


Table 9-22: DICOM Print Settings – AE Configuration

Local Host Properties – SCU – SONIX System	
Application Entity Title	***AE Title*** of the SONIX system.
Port	Listening ***Port*** of the SONIX system (unused).
IP Address	Unique identifier of the SONIX system (informational only).
Remote Host Properties – SCP – DICOM Print Server	
Application Entity Title	***AE Title*** of the ***Print SCP***.
Port	Listening ***Port*** of the ***Print SCP***.
IP Address	Unique identifier of ***Print SCP***.
Connection Test	Select to send verification request to ***DICOM Print*** device (ping to verify connection).
Insert (Symbol)	Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).

The ***DICOM Print Settings*** dialog enables configuration of general print properties.

Figure 9-31: DICOM Print Settings – Print Settings

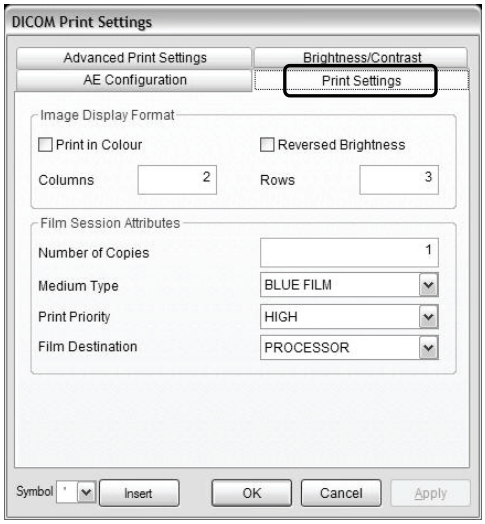


Table 9-23: DICOM Print Settings – Print Settings

Image Display Format	***Print in Color***	Select to print images in color. Deselect to print in grayscale (default).
	Reversed Brightness	Select to print images in ***Reversed Brightness***.
	Columns	Select the number of ***Columns*** per page.
	Rows	Select the number of ***Rows*** per page.
Film Session Attributes	***Number of Copies***	Select the ***Number of Copies*** of each page to be printed.
	Medium Type	Select the type of medium on which the images will be printed: ***Paper***, ***Clear Film*** or ***Blue Film***.
	Print Priority	Select the print job priority: ***High***, ***Medium*** or ***Low***.
	Film Destination	Select the location to which the print job will be sent: ***Processor*** or ***Magazine***.
Insert (Symbol)		Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).

The ***Advanced Print Settings*** dialog enables configuration of advanced printing options.

Figure 9-32: DICOM Print Settings – Advanced Print Settings

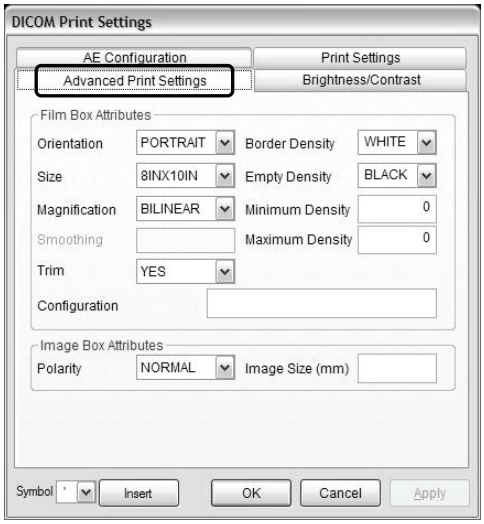


Table 9-24: DICOM Print Settings – Advanced Print Settings

Film Box Attributes	***Orientation***	Select the ***Orientation*** of the print page.
	Size	Select the ***Size*** of the print page.
	Magnification	Select the method of ***Magnification*** used.
	Smoothing	Select the ***Smoothing***. ***Note:*** *This option is printer-specific and only available if* ***Cubic Magnification*** *is selected in the previous field.*
	Trim	Select ***Yes*** or ***No*** to use a border (Trim) on each page.
	Border Density	Enter the ***Border Density*** in hundredths of ***OD*** (***Optical Density***).
	Empty Density	Enter the ***Empty Density*** in hundredths of ***OD*** (***Optical Density***).
	Minimum Density	Enter the minimum image density.
	Maximum Density	Enter the maximum image density.
	Configuration	Enter printer-specific ***Configuration*** information.
Image Box Attributes	***Polarity***	Enter the type of ***Polarity*** to be used.
	Image Size	Enter the printer-specific ***Image Size*** in mm.
Insert (Symbol)		Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).

The ***DICOM Print Brightness/Contrast*** dialog changes the ***Brightness*** and ***Contrast*** settings. These settings are applied to the images that are sent to the ***SCP***, not the images stored locally.

The effect of these settings can be seen in the ***Before*** and ***After*** images.

Figure 9-33: DICOM Print Settings – Brightness/Contrast

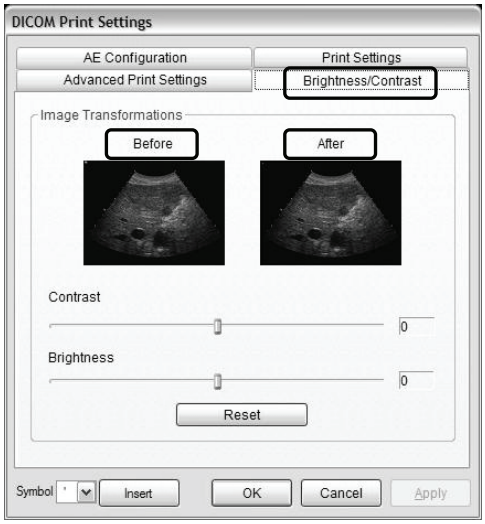


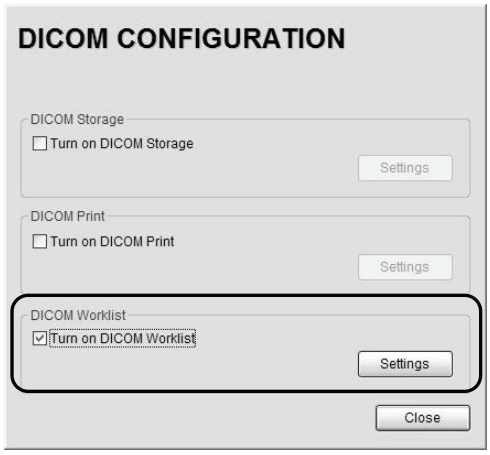
Table 9-25: DICOM Print Settings – Brightness/Contrast

Contrast	Adjusts the level of ***Contrast*** applied to the images.
Brightness	Adjusts the level of ***Brightness*** applied to the images.
Reset	Resets the values of ***DICOM Print Brightness*** and ***Contrast*** to zero.
	Note: *To adjust the* ***Brightness/Contrast*** *settings, position the trackball arrow over the* ***Brightness*** *or* ***Contrast*** *slider. Press and hold the* **SELECT** *button while moving the trackball left or right to the desired position.*

9.2.11.3 DICOM Worklist Configuration

DICOM Worklist Settings offer advanced settings for configuring the ***DICOM Worklist SCU***.

Figure 9-34: DICOM Configuration – DICOM Worklist



To Configure DICOM Worklist Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > DICOM***.
3. Check ***Turn on DICOM Worklist***, then select the associated ***Settings*** button.
4. An onscreen dialog with one (1) tab will be presented: ***AE Configuration***.
5. Configure the dialog as required.

The ***DICOM Worklist AE Configuration*** dialog enables configuration of ***AE*** properties.

Figure 9-35: DICOM Worklist Settings– AE Configuration

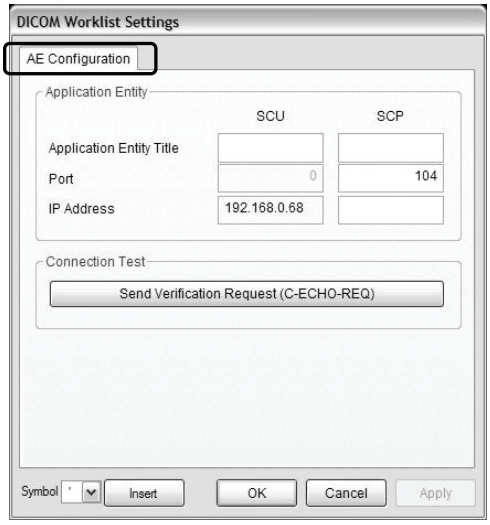


Table 9-26: DICOM Worklist Settings – AE Configuration

Local Host Properties – SCU – SONIX System	
Application Entity Title	***AE Title*** of the SONIX system.
Port	Listening ***Port*** of the SONIX system (unused).
IP Address	Unique identifier of the SONIX system (informational only).
Remote Host Properties – SCP – DICOM Worklist Server	
Application Entity Title	***AE Title*** of the ***Worklist SCP***.
Port	Listening ***Port*** of the ***Worklist SCP***.
IP Address	Unique identifier of ***Worklist SCP***.
Connection Test	Select to send verification request to ***DICOM Worklist*** device (ping to verify connection).
Insert (Symbol)	Use to insert text symbol(s) not available on the console keyboard (e.g., punctuation marks, symbols and letters from other languages).

9.2.12 Print Keys

Print Keys allows users to configure the three (3) console **PRINT** buttons.

There are three (3) ***Print Keys*** setup dialogs that correspond to the three (3) console **PRINT** buttons. Once configured, pressing the console button **PRINT 1**, **PRINT 2** or **PRINT 3/ARCHIVE** will produce the configured action.

Note: *Multiple actions can be configured and performed per* **PRINT** *button.*

Figure 9-36: Print Keys

Table 9-27: Print Keys Settings

Store Locally	This setting is always selected by default and can only be deselected (or reselected) if: • ***Trigger*** is selected. • No other ***Print Keys*** options are selected. When selected, regardless of other settings, images will always be saved to the system's local storage. ***Note:*** *Access to locally stored images is through Patient Management – Image Review.*
DICOM Store	Sends images to a ***DICOM*** archiver. Refer to **9.2.11.1 DICOM Storage Configuration** for more setup details.
Printer	Sends output to a ***Paper Printer***. Refer to **9.2.13 Peripherals** for details on printer setup.
Trigger (Photo Printer/VCR)	Sends a ***Trigger*** signal to attached video printers (e.g., ***Thermal Printer***). ***Note:*** *To select* ***Store Locally*** *(above), all other options must be deselected.*

DICOM Print	Sends images to a ***DICOM*** printer. Refer to **9.2.11.1 DICOM Storage Configuration** for more setup details.
Record CINE	Enables the system to be configured to record a CINE loop. Loop duration is configured **9.2.17 Capture Settings**.
DICOM Store CINE	Enables the user to send animated ***DICOM*** to a ***DICOM*** archiver (**9.2.11.1 DICOM Storage Configuration**).
Archive	Toggles access between imaging and the Patient Review screen. ***Note:*** *This function is only accessible via the console* **PRINT 3/ARCHIVE** *button (**Print 3** tab).*

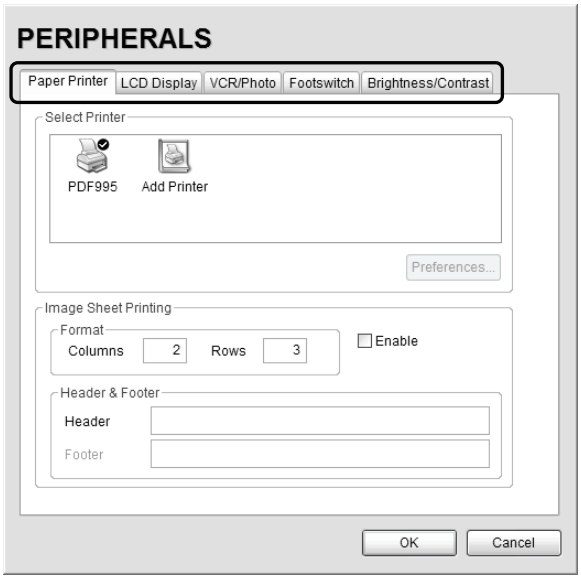
To Configure Print Keys:

1. Press the console **MENU** button.
2. Select ***Administrator > Print Keys***.
3. Select the desired tab: ***Print 1***, ***Print 2*** or ***Print 3***.
4. Configure the individual ***Print Keys*** as required.
5. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.13 Peripherals

The ***Peripheral*** setup dialogs enable software configuration for the various peripherals that are approved for connection to the SONIX system. For installation details of the specific connections involved, refer to **Chapter 11: Connectivity and Peripherals**.

Figure 9-37: Peripherals



To Access the Peripherals Dialog:

1. Press the console **MENU** button.
2. Select ***Administrator > Peripherals***.
3. Select the relevant ***Peripherals*** dialog tab: ***Paper Printer***, ***LCD Display***, ***VCR/Photo***, ***Footswitch*** or ***Brightness/Contract***.

9.2.13.1 Paper Printer

The ***Paper Printer*** dialog is used to configure a laser or inkjet paper printer connected to the system. If the printer is connected via a parallel or USB port, the system will recognize the printer and subsequently list it as a recognized printer in the ***Select Printer*** section of the dialog.

Figure 9-38: Peripherals – Paper Printer

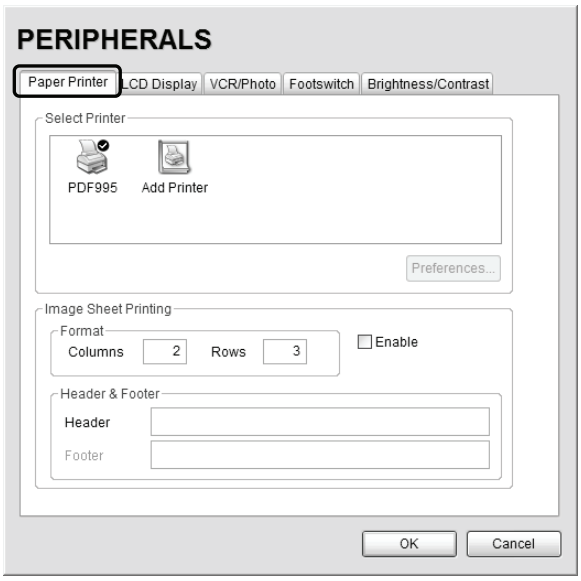


Table 9-28: Paper Printer Settings

Select Printer			Select a ***Paper Printer*** from the options presented.
Preferences			Click this button to configure ***Preferences*** for the selected printer.
Image Sheet Printing	***Format***	***Columns***	Select the number of print ***Columns***.
		Rows	Select the number of print ***Rows***.
		Enable	Select to allow ***Image Sheet Printing***.
	Header & Footer	***Header***	Enter text to be printed in each ***Header***.
		Footer	***Note:*** *This field is always disabled.*

To Configure the System for a Paper Printer:

1. Press the console **MENU** button.
2. Select ***Administrator > Peripherals***.
3. Select the ***Paper Printer*** tab.
4. Select the printer from the list of recognized printers. For multiple printers, press the console **UPDATE** button and select ***Set as Default Printer*** from the onscreen menu.

   Note: *The selected printer can be a network or a local printer and can be configured for specific formats by selecting* ***Preferences****.*

5. To select/deselect ***Image Sheet Printing*** (e.g., 2x3 image sheets) check/uncheck the ***Enable*** box.
6. Enter the number of ***Columns*** and ***Rows*** desired in the text boxes provided.
7. To add an optional ***Header*** to the image sheet (or to supply special commands, as required), enter the desired text in the space provided.

   Note: *To configure a console* **PRINT** *button to send images to the default printer, refer to section* **9.2.12 Print Keys***.*

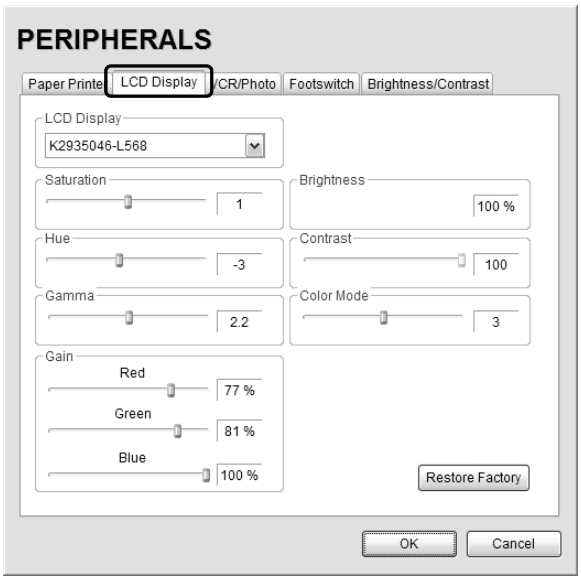
   To send partial print pages (e.g., 3 images remaining on a 4 image/sheet format) at the end of an exam, press the console **ID** *button and select* ***End Exam****.*

9.2.13.2 LCD Display

Adjust the following LCD display settings as required: ***Saturation***, ***Hue***, ***Gamma***, ***Brightness***, ***Contrast***, ***Color Mode*** and ***Gain*** (***Red***, ***Green*** and ***Blue***).

Note: *Click the* ***Restore Factory*** *button to reconfigure the LCD display to factory settings.*

Figure 9-39: Peripherals – LCD Display



To Adjust the LCD Display Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > Peripherals***.
3. Select the ***LCD Display*** tab.
4. Position the trackball arrow over the desired setting slider.
5. Press and hold the **SELECT** button while moving the trackball to the desired position.

   Note: *Click the* ***Restore Factory*** *button to reconfigure the LCD display to factory settings.*
6. Repeat steps 4 and 5 as many times as required.
7. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.13.3 VCR/Photo

Output video includes only the image area (or full screen when a dialog such as the ***Exam Management*** or ***Image Review*** pages are displayed on the screen). The output video does not include the thumbnail images.

Use the ***VCR/Photo*** dialog to enable/disable the live output video (***Video Out***).

Figure 9-40: Peripherals – VCR/Photo

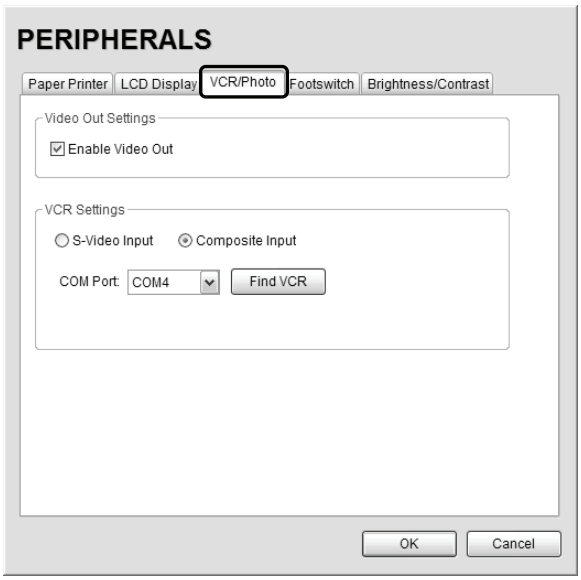


Table 9-29: Peripherals – VCR/Photo Fields

Enable Video Out	Enables/disables ***Video Out***.
VCR Settings	Enables the selection and ***COM Port*** configuration of the ***Video Input*** format: ***S-Video*** or ***Composite***. ***COM Port*** options: ***N/A*** and ***COM1*** to ***COM8***.

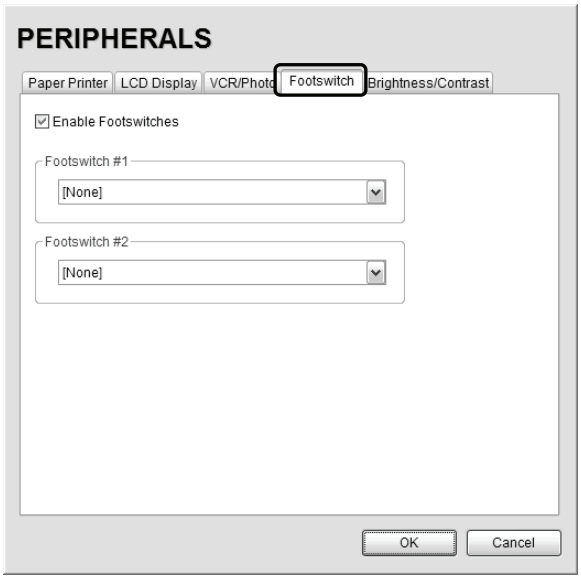
To Enable VCR/Photo Functionality:

1. Press the console **MENU** button.
2. Select ***Administrator > Peripherals***.
3. Select the ***VCR/Photo*** tab.
4. Configure the settings as required.
5. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.13.4 Footswitch

The ***Footswitch*** configuration dialog allows the user to configure the desired operation for either or both ***Footswitch*** connections. There are three (3) settings: ***None***, ***Print*** or ***Freeze***.

Figure 9-41: Peripherals – Footswitch



To Configure the Footswitch Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > Peripherals***.
3. Select the ***Footswitch*** tab.
4. Check ***Enable Footswitches***.
5. Select the desired action from the drop-down menu for either or both footswitches, as required.
6. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.13.5 Brightness/Contrast

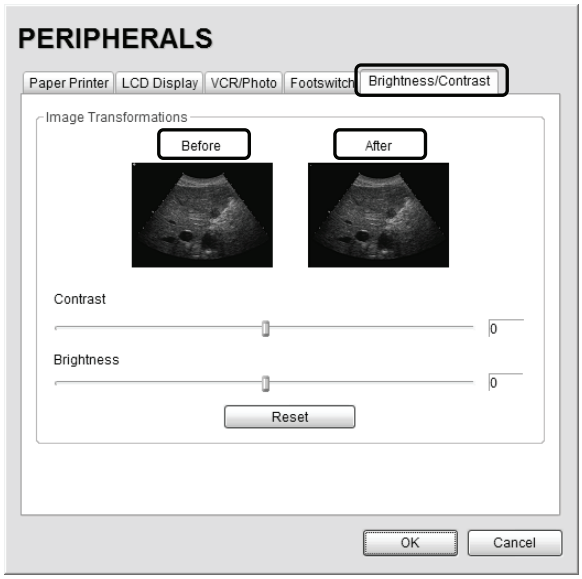
The ***Brightness/Contrast*** dialog allows users to change the ***Brightness/Contrast*** of images transferred to peripherals to ensure optimum quality.

Note: *The* ***Brightness/Contrast*** *values set on this tab are not applied to the image on the screen or images stored to the system.*

The effects of the ***Brightness/Contrast*** settings are seen in the ***Before*** and ***After*** images.

Note: *Click the* ***Reset*** *button to restore* ***Brightness/Contrast*** *settings to factory defaults.*

Figure 9-42: Peripherals – Brightness/Contrast



To Adjust the Brightness/Contrast Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > Peripherals***.
3. Select the ***Brightness/Contrast*** tab.
4. Position the trackball arrow over the ***Brightness*** or ***Contrast*** slider.
5. Press and hold the **SELECT** button while moving the trackball to the desired position.
6. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.14 Display Settings

The ***Display Settings*** dialog allows the adjustment of various LCD display parameters:

Figure 9-43: Display Settings

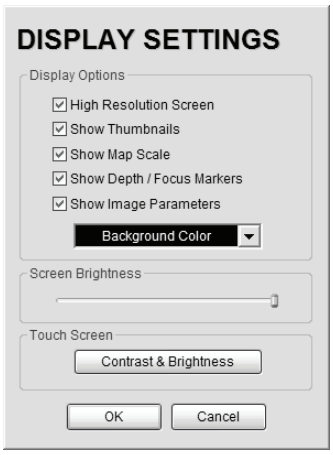


Table 9-30: LCD Display Settings

Display Options	***High Resolution Screen***	Select the optimal settings for the LCD display: ***Note:*** *Ultrasonix recommends checking all five (5) options.*
	Show Thumbnails	
	Show Map Scale	
	Show Depth/Focus Markers	
	Show Image Parameters	
	Background Color	Enables the selection of a ***Background Color***. Choose the actual color from the table presented in the drop-down menu.
Screen Brightness		Adjusts the overall brightness of the LCD display.
Contrast & Brightness		Opens the ***Contrast & Brightness*** adjustment controls on the console touch screen.

To Configure the Display Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > Display***.
3. Configure the ***Display Settings*** as required.
4. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.15 Patient Settings

Patient Settings allows users to configure options for the ***Exam Management*** page, onscreen display of patient data and exam ***Review*** settings.

Figure 9-44: Patient Settings

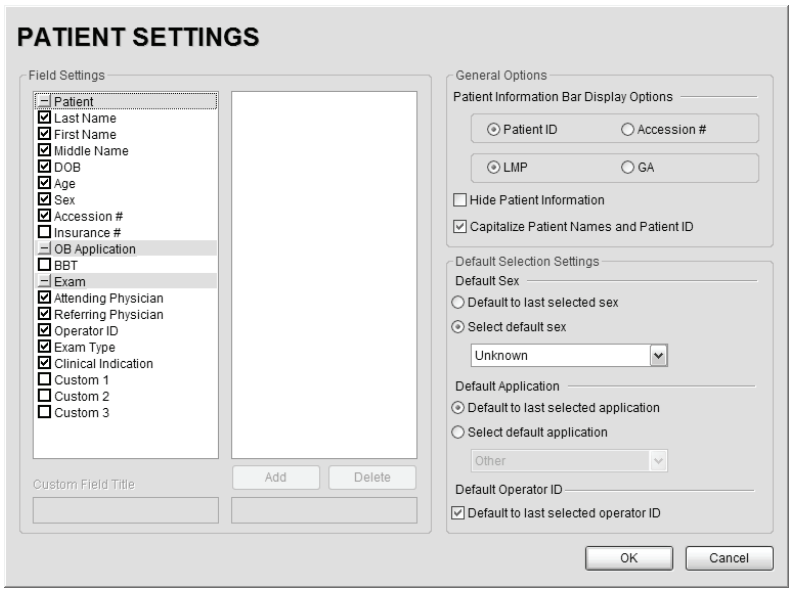


Table 9-31: Patient Settings

Field Settings	***Last Name*** ***First Name*** ***Middle Name*** ***DOB*** ***Age*** ***Sex*** ***Accession #*** ***Insurance #*** ***BBT*** ***Attending Physician*** ***Referring Physician*** ***Operator ID*** ***Exam Type*** ***Clinical Indication*** ***Custom 1, 2, 3***	Select/deselect these data entry fields as required. Selected fields will appear on the ***Exam Management*** page and, where applicable, in the relevant databases (as described in **4.5 Storage/Database Tabs**). There are three (3) user-defined data entry fields. Select ***Custom 1***, ***2*** and/or ***3*** and create the desired label in the ***Field Title*** text entry box (e.g., Nationality). The customized label appears as one of the data entry fields on the ***Exam Management*** page. ***Note:*** *Entries in* ***Attending Physician***, ***Referring Physician***, ***Operator ID***, ***Clinical Indication*** *and the* ***Custom 1***, ***2*** *and* ***3*** *fields can be edited/maintained from this dialog without affecting existing patient data.* *Deleting data from any of these fields (e.g., an* ***Operator's ID****) does not affect existing patient data. It simply removes that data from the drop-down menu on the* ***Exam Management*** *page.* *Deleted data can always be added again at a later date, either here or when filling in details on the* ***Exam Management*** *page.*

General Options	***General Options*** control the ability to include/exclude or display/hide certain fields in the Patient Bar on the imaging screen.		
	Patient Information Bar Display Options	***Patient ID*** ***OR*** ***Accession #***	The option selected here (***Patient ID*** or ***Accession*** #) will be displayed in the Patient Information Bar along the top of the screen during an exam.
		LMP ***OR*** ***GA***	The option selected here (***LMP*** or ***GA***) will be displayed in the Patient Information Bar along the top of the screen during an exam – providing ***LMP*** and/or ***GA*** data was entered for the patient in question. ***Note:*** *If **GA** is chosen, it will only be visible if an **OB Exam Type** is selected.*
	Hide Patient Information		Select/deselect this field to display/hide the ***Patient Information*** during an exam.
	Capitalize Patient Names and Patient ID		Select this option to capitalize <u>all</u> letters in a patient's name or identification number.
Default Selection Settings	***Default Sex***	***Default to last selected sex*** ***OR*** ***Select default sex***	When ***Default to last selected sex*** is chosen, opening a fresh ***Exam Management*** page will result in the ***Sex*** field being populated with the same gender that was selected in the last ***Exam Management*** page. When ***Select default sex*** is chosen, the user must select a specific ***Sex*** from the drop-down menu. The ***Sex*** selected will then become the default and be automatically entered in the ***Sex*** field of every new patient record that is created. There are four (4) choices available: ***Female***, ***Male***, ***Other*** and ***Unknown***.
	Default Application	***Default to last selected application*** ***OR*** ***Select default application***	When ***Default to last selected application*** is chosen, opening a fresh ***Exam Management*** page will result in the ***Application*** field being populated with the same ***Application*** that was selected in the last ***Exam Management*** page. When ***Select default application*** is chosen, the user must select a specific ***Application*** from the drop-down menu. The ***Application*** selected will then become the default and be automatically entered in the ***Application*** field of every new patient record that is created. There are four (4) choices available: ***Cardiac***, ***OB***, ***Gyn*** and ***Other***
	Default Operator ID	***Default to last selected Operator ID***	When ***Default to last selected Operator ID*** is chosen, opening a fresh ***Exam Management*** page will result in the ***Operator ID*** field being populated with the same ***Operator*** that was selected in the last ***Exam Management*** page. ***Note:*** *This option is especially useful if the same **Operator** will be using the system for an extended period of time.*

To Access the Patient Settings Dialog:

1. Press the console **MENU** button.
3. Select ***Administrator > Patient***.

To Configure Patient Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > Patient***.
3. Configure the ***Patient Settings*** as required.
4. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.16 Status Bar

When ***Status*** indicators are enabled, the system will present the relevant icons at the bottom right of the LCD display. Read the definitions carefully as not all icons will always be visible – even if the relevant option has been activated.

By default, all ***Status Bar*** options are unchecked.

Figure 9-45: Status Bar

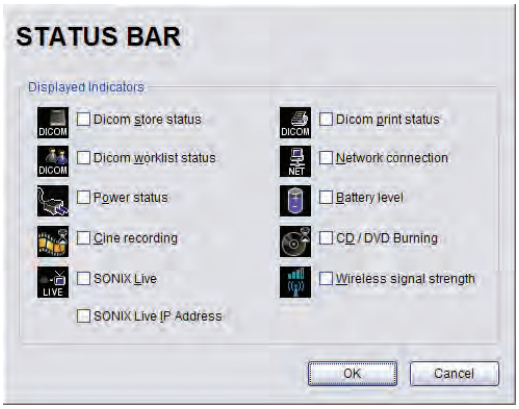


Table 9-32: Status Bar – Displayed Indicators

DICOM Store status Active Success Failure	Indicates the system is connected to a ***DICOM Storage*** server. This icon will be visible for only a short period of time. When a user accesses the ***DICOM Storage*** server, the icon will be presented while the operation is underway. ***Note:*** *A* ***Network connection*** *must exist in order to have access to a DICOM network.*
DICOM Print status Active Success Failure	Indicates the system is connected to a ***DICOM Print*** device. This icon will be visible for only a short period of time. When the ***DICOM Print*** device is in use, the icon will be presented while the job is printing. ***Note:*** *A* ***Network connection*** *must exist in order to have access to a DICOM network.*
DICOM Worklist status Success Failure	Indicates the system is connected to a ***DICOM Worklist*** server. This icon will be visible only when the ***DICOM Worklist*** server is being accessed. ***Note:*** *A* ***Network connection*** *must exist in order to have access to a DICOM network.*

Network connection

Connected

Not Connected

Indicates whether or not a hard-wired network connection is available.

Power status


Wall Plug


Battery

Specifies the power source in use: ***Wall Plug*** (AC power) or ***Battery***.

Note: *If* ***Battery*** *power is available, the icon displayed will be the appropriate* ***Battery Level*** *icon (see below).*

Ultrasonix recommends selecting this option so users will always be aware of the power source in use.

Battery level


≥80%


79%≤


59%≤


39%≤


19%≤

Displays the approximate amount of ***Battery*** power remaining.

Note: *The level will rise over time when the system is connected to an AC power source or fall when it is running solely off the UPS battery.*

CINE recording

When ***CINE Recording*** is underway, this icon will be visible during the recording process.

CD/DVD Burning

Indicates that a CD or DVD is being burned.

Wireless signal strength


100%


75%


50%


25%


0%

Denotes the strength of the wireless signal (%).

Note: *If a wireless network is not available and active, the relevant icon will not be presented – even if this option is enabled.*

SONIX Live

Connected

Not Connected

When ***Streaming Video*** is underway, the ***Connected*** icon will be visible during the streaming process.

SONIX Live IP Address

When ***Streaming Video*** is underway, clicking the icon will display the ***IP Address*** at which remote users can view the video.

Note: *If the relevant staff has been informed of a fixed* ***IP Address****, activating this option is unnecessary.*

If a dynamic ***IP Address*** *is used, enable this option to access the address from the LCD display during* ***Streaming Video****.*

Alternatively, to maintain data privacy, do not enable this option and direct staff to view the current ***Local IP Address*** *(fixed or dynamic) via* **MENU > *Administrator* > *Network*** *dialog.*

To Access Status Bar Indicators:

1. Press the console **MENU** button.
2. Select ***Administrator > Status Bar***.

To Configure Status Bar Indicators:

1. Press the console **MENU** button.
2. Select ***Administrator > Status Bar***.
3. Select/deselect ***Displayed Indicators*** as required.
4. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.17 Capture Settings

The ***Capture Settings*** dialog allows the user to select between image and full screen for image storage and to configure the loop storage record time.

Figure 9-46: Capture Settings

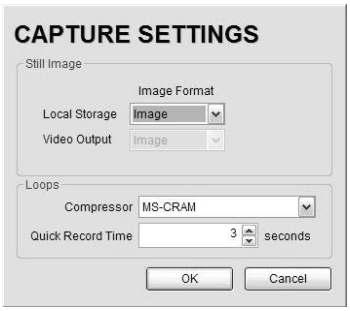


Table 9-33: Capture Settings

Still Image	***Local Storage***	Select between ***Full Screen*** and ***Image*** for still image storage. ***Note:*** *Image includes image field, imaging parameters and patient data bar. Thumbnail images are not included.* *"Full screen" includes the entire display, including the thumbnails.*
	Video Output	Unused.
Loops	***Compressor***	Select the AVI movie ***Compressor*** type. ***MS-CRAM*** is the default. ***Caution:*** *This setting should not be changed without a thorough understanding of* ***Compressor*** *types.*
	Quick Record Time	Select the ***Quick Record Time*** (1 to 30 seconds) for post recording (retrospective acquisition). Refer to section **9.2.12 Print Keys** to configure the console **PRINT** button for ***Quick Record***. ***Quick Record*** is only available for ***2D*** or ***2D/Color*** imaging. ***Note: Selecting a*** *longer record time may slow down system performance.*

To Configure Capture Settings:

1. Press the console **MENU** button.
2. Select ***Administrator > Capture***.
3. Configure ***Capture Settings*** as required.
4. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.18 Imaging Modes

The ***Imaging Modes*** dialog allows the configuration of a variety of ***Imaging Mode*** options.

Figure 9-47: Imaging Modes

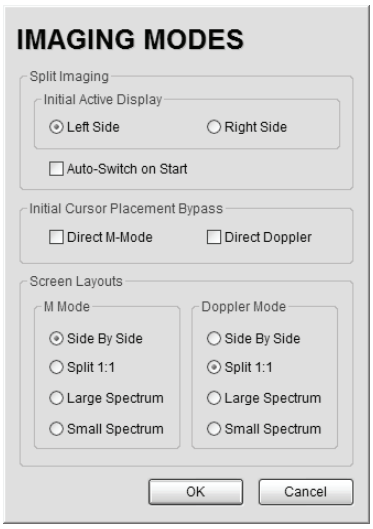


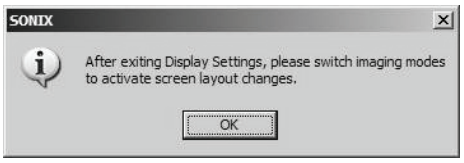
Table 9-34: Imaging Mode Options

Split Imaging	***Initial Active Display***	Select as active either the ***Left Side*** or ***Right Side*** of the LCD display when first entering a ***Split Image***.
	Auto-Switch on Start	During dual (or split) imaging, once the image is frozen the cursor will automatically switch to the previously inactive side of the display.
Initial Cursor Placement Bypass	***Direct M-Mode***	Selecting ***Direct M-Mode*** automatically displays split screen ***2D/M-Mode*** sweep immediately after pressing **M-MODE**. Deselecting ***Direct M-Mode*** displays a full screen ***2D*** with an ***M-Mode*** cursor line immediately after pressing **M-MODE**. Pressing the **UPDATE** button to activate ***M-Mode Sweep***.
	Direct Doppler	Selecting ***Direct Doppler*** automatically displays split screen ***2D/Doppler Trace*** immediately after activating **DOPPLER** mode. Deselecting ***Direct Doppler*** displays a full screen ***2D*** with ***Doppler SV*** (***Sample Volume***) cursor immediately after pressing **DOPPLER**. Press the **UPDATE** button to activate the ***Doppler Trace***.

Screen Layouts	***M-Mode***	• ***Side by Side*** (Display) • ***Split 1:1*** .....(½ 2D – ½ Trace) • ***Large Spectrum***.....(⅓ 2D – ⅔ Trace) • ***Small Spectrum***.....(⅔ 2D – ⅓ Trace)
	Doppler	• ***Side by Side*** (Display) • ***Split 1:1*** .....(½ 2D – ½ Trace) • ***Large Spectrum***.....(⅓ 2D – ⅔ Trace) • ***Small Spectrum***.....(⅔ 2D – ⅓ Trace)

To Configure Imaging Modes:

1. Press the console **MENU** button.
2. Select ***Administrator > Imaging Modes***.
3. Configure ***Imaging Modes*** as required.
4. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.
5. If ***OK*** is selected in Step 4, the following message will be presented.



6. Select ***OK*** to continue.

9.2.19 QA Setup

In order to e-mail exams to ***Reviewers*** (**4.6.1**), ***QA Setup*** details must be configured.

Figure 9-48: QA Setup

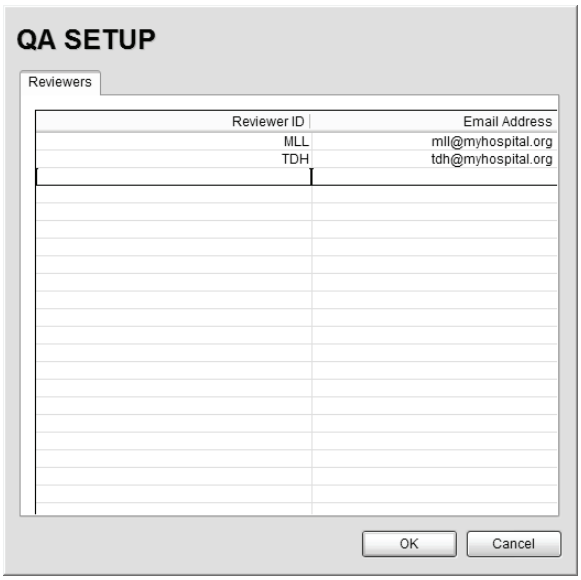


Table 9-35: QA Setup Options

Reviewer ID	Enter an ***ID*** for each ***Reviewer***.
E-Mail Address	Enter an ***E-Mail Address*** for each ***Reviewer***.

To Create Reviewers for the Exam Review Process:

1. Press the console **MENU** button.
2. Select ***Administrator > QA***.
3. Enter a new ***Reviewer***(s).
4. Enter an ***E-Mail Address*** for the ***Reviewer(s)***.
5. Select ***OK*** to accept the changes and exit or ***Cancel*** to exit without saving.

9.2.20 Software Update

This option allows users to install software updates via the Internet, from a CD, DVD or a USB key.

Note: *Access to* ***Software Update*** *is available only with a valid warranty license.*

Figure 9-49: Software Updates

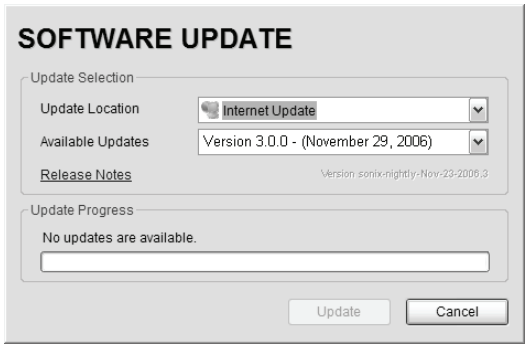


Table 9-36: Software Updates

Update Selection	***Update Location***	***Internet Update***	If the system is connected to the Internet, an automatic search for available software updates occurs. If successful, the ***Available Updates*** drop-down menu auto-populates with the software revisions available for download. The latest revision is automatically selected but older software revisions may also be available.
		DVD-RAM Drive (E:)	If the update is located on a CD or DVD, it can be accessed via the ***DVD-RAM Drive*** which can be selected from the ***Available Updates*** drop-down menu.
		Removable Disk	If a removable disk (e.g., USB key or thumb drive) containing the update has been inserted in a USB port on the Front Connectivity Panel, it will be available for selection from the ***Available Updates*** drop-down menu.
	Available Updates		Select to choose the appropriate update. Options in this drop-down menu are limited by the selection made in the ***Update Location*** drop-down menu.
	Release Notes		Click to view the ***Release Notes*** associated with the ***Available Updates*** selection.
Update Progress			Lets the user know when the update is complete or ***Ready***.

To Perform a Software Update:

1. Press the console **MENU** button.
2. Select ***Administrator > Software Updates***.
3. Select an ***Update Location*** from the drop-down menu:

   Note: *In order to be available in the* ***Update Location*** *drop-down menu, the CD and/or USB must be inserted prior to selecting the* ***Software Update*** *option from the* ***Administrator Settings*** *menu.*

4. Select ***Release Notes*** to view the selected software's revision history.

   Note: *An internet connection is required to access* ***Release Notes****.*

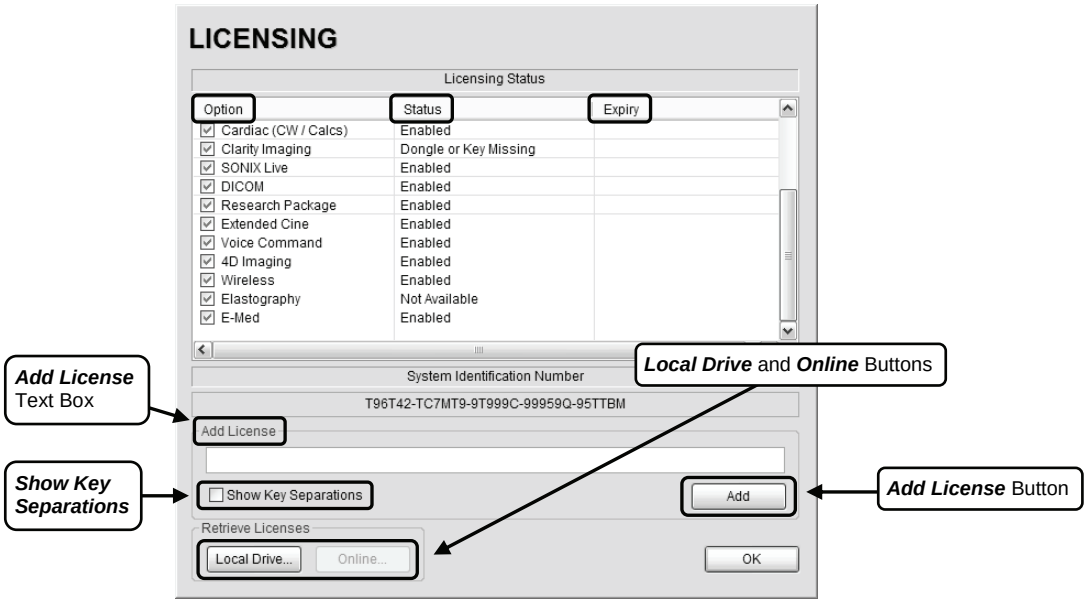
5. Select ***Update*** to begin the update process or ***Cancel*** to exit without updating.

   Note: *The* ***Update Progress*** *bar displays the download progress. Upon completion, the* ***Software Update*** *will be auto-installed and the system will restart automatically.*

9.2.21 Licensing

Licensing displays the ***Options*** available on the system. ***Status*** and ***Expiry*** dates (when applicable) of enabled features are also displayed. The checkbox in the ***Option*** column must be selected in order to enable a specific, available feature.

Figure 9-50: Licensing



Note: *Contact your Ultrasonix representative for details on obtaining a new license key and enabling additional features.*

To Access the Licensing Dialog:

1. Press the console **MENU** button.
2. Select ***Administrator > Licensing***.

To Enter a New Licensing Key:

1. Press the console **MENU** button.
2. Select ***Administrator > Licensing***.

Notes:

*An **Option** that has its **Status** listed as "**Enabled**" but has no entry in the **Expiry** field will never expire.*

*The **Licensing Status** list details the specifics of the system's **Options**, their **Status** (**Active**, **Expired**, etc.) and the applicable **Expiry** date.*

3. Enter the new license key in the ***Add License*** text box.

Notes:

*If the new license key is being entered manually, select the **Show Key Separations** checkbox to enable the entry of the key block-by-block.*

If it is typed in as one long text string, the dashes ("-") will also have to be entered in order to ensure the license key format conforms to the required standard.

*If the new license key has been received in an electronic format that lends itself to the standard "copy and paste" method, do not select the **Show Key Separations** checkbox. Simply copy the key and paste it into the **Add License** text box as one long string, with the formatting intact.*

*If the new license key is available on the local hard drive, click the **Local Drive…** button and choose the appropriate file (*.key) to import/enable the new license.*

4. Click ***Add*** to add the new license key.
5. Check to ensure the new license has been added then click ***Close*** to exit the ***Licensing*** dialog.

9.3 SERVICE MENU

Access to ***Service*** is password protected and restricted to certified, Ultrasonix service representatives.

CHAPTER 10: IMAGE STORAGE, REVIEW AND TRANSFER

The ***Exam Management*** option includes a local patient/exam management system with image storage, review and transfer.

10.1 IMAGE STORAGE

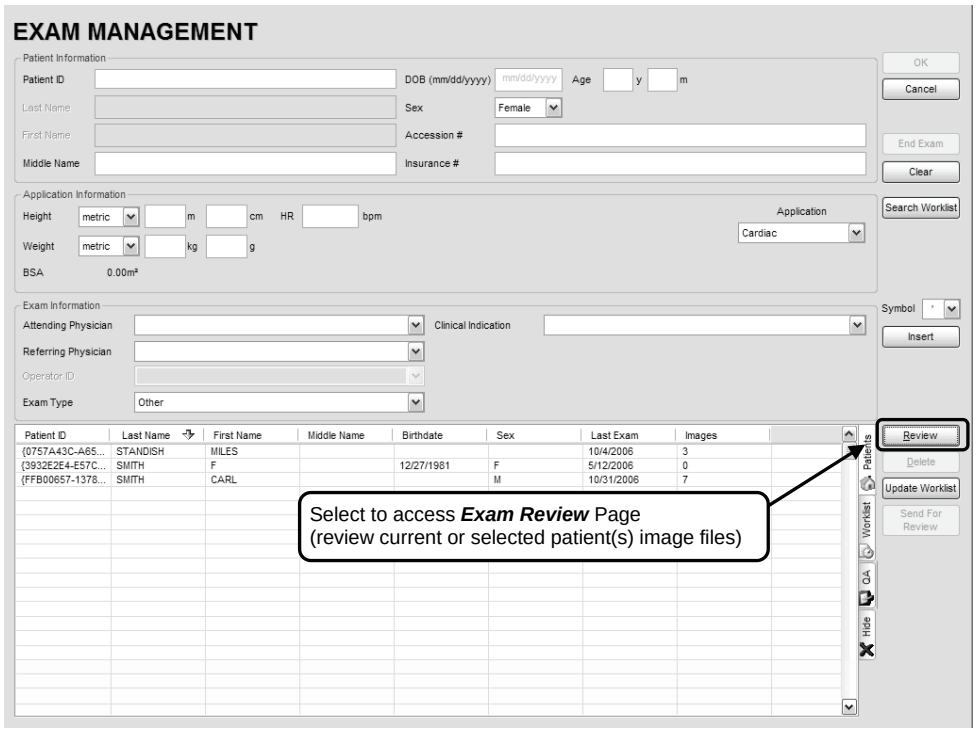
Each time a new patient is entered into the system, a local file is created for that patient. All saved images and CINE clips are stored in the patient file and organized by exam date and type. This image/CINE data may be retrieved at any time and transferred to a printer, ***DICOM*** archiver, etc.

Hard drive capacity for patient data storage is 160Gb. Depending on the specific number/type of images involved, the system can store more than 50,000 exams.

Note: *Ultrasonix recommends regular patient/image file back-up and purging of older patient files stored on the system.*

10.2 IMAGE REVIEW

Figure 10-1: Exam Management/Image Review



To Access the Image Review Page (Method 1 – Current Patient):

1. Press the console **PRINT3/ARCHIVE** button to view the current exam images.

Note: *Refer to section* ***9.2.12*** *to configure* ***Print Keys****.*

To Access the Image Review Page (Method 2 – Active Patient Exam):

1. During a patient exam, press the **ID** button on the console to open the ***Exam Management*** page.
2. Select ***Review*** from the onscreen menu to view the current exam images.

To Access the Image Review Page (Method 3 –Patient Database):

1. Press the console **ID** button.
2. Click the ***Patients*** tab.
3. Select the desired ***Patient(s)*** from the ***Patient*** database.

Note: *To select multiple* ***Patients*** *at the same time press and hold the console* **SHIFT** *key, then use the trackball and* **SELECT** *button to highlight the relevant* ***Patients****.*

To select all ***Patients*** *at the same time, tap the touch screen* ***Select All*** *button.*

4. Click ***Review*** and the ***Image Review*** page will be presented with the exam files for the selected ***Patient(s)***.

Note: *Regardless of the Image Review method selected, press the* **WORKSHEET** *button to access the associated* ***Worksheet****.*

Figure 10-2: Image Review

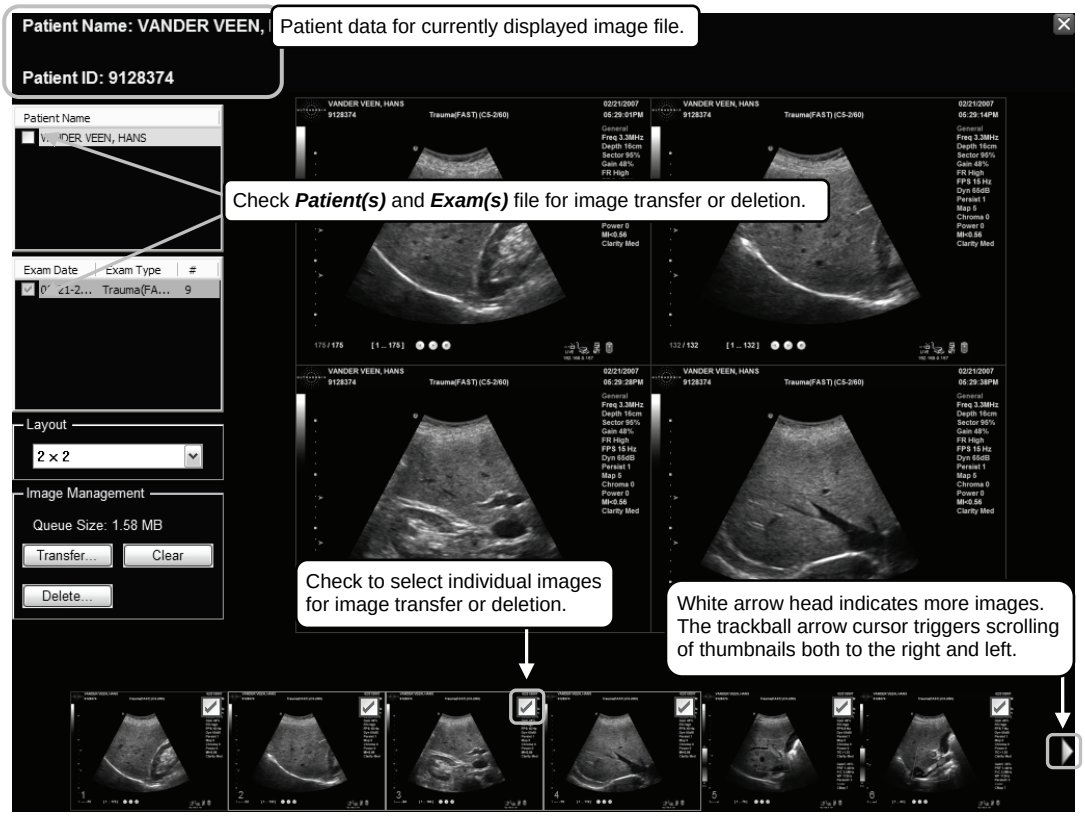


Table 10-1: Image Review Screen

Patient Name	Patient(s) selected from the ***Exam Management*** page.
Exam Date/Exam Type	Displays the exam files/images for the ***Patient*** selected (above). The number of images and CINE clips stored appears in the far right column of this section. By default, if only one patient file is listed under ***Patient Name***, the system will display the images from that patient's most recent exam. If multiple ***Patient Names*** are listed, select each patient individually to access a list of exam dates for that patient.
Layout	Sets up the image display area: ***1x1*** (single), ***2x2***, ***3x3***, ***4x4***, ***5x5***, ***6x6***. The default is ***2x2***.
Image Management	Enables the transfer and/or deletion of images and exams. The ***Queue Size*** lists the total size (in Mb) of images/exams selected for transfer/deletion.

Note: *Stored CINE clips are identified by a small "movie" symbol on the lower right of the image thumbnail. Once selected, the movie will replay in the* ***Review*** *window.*

The image thumbnails on the bottom of the screen represent all the available images for the exam under review. To scroll through the thumbnails, use the trackball to move the cursor over to the right or left side of the thumbnails. The thumbnails will scroll automatically.

Table 10-2: Image Management Touch Screen Controls (tap to activate)

Exit	Tap to ***Exit*** the ***Exam Review*** page.
Select All	Tap to ***Select All*** the lists patients/patient files/images for image transfer or deletion.
Transfer	Tap to initiate image transfer and display the ***Select Storage Destination*** page.
Delete	Tap to ***Delete*** the patient(s), patient exam file(s) and/or image(s) selected via checkboxes.
Add Patient	Tap to add the next patient to the queue (selected via checkboxes).
Add Exam	Tap to add the next exam file to the queue (selected via checkboxes)
Add Image	Tap to add the next image to the queue (selected via checkboxes).
Clear Queue	Tap to uncheck (deselect) all the selected patient(s), patient exam file(s) and image(s).

Table 10-3: Image Management Touch Screen Controls (tap to activate, dial to adjust)

Image	Tap ***Image*** then use the associated touch screen dial to select the image(s) displayed. Dial right to select the next image available. Dial left to select the previous image.
Thumbnail	Tap ***Thumbnail*** then use the associated touch screen dial to move through the thumbnail images. Dial right to select the next thumbnail. Dial left to select the previous thumbnail.
Layout	Tap ***Layout*** then use the associated touch screen dial to change the display ***Layout***: (***Single***, ***2x2***, ***3x3***, etc.).
Patient	Tap ***Patient*** then use the associated touch screen dial to page through the list of available patients. Press **SELECT** to select the highlighted patient.
Exam	Tap ***Exam*** then use the associated touch screen dial to page through the list of available exams. Press **SELECT** to select the highlighted exam file.

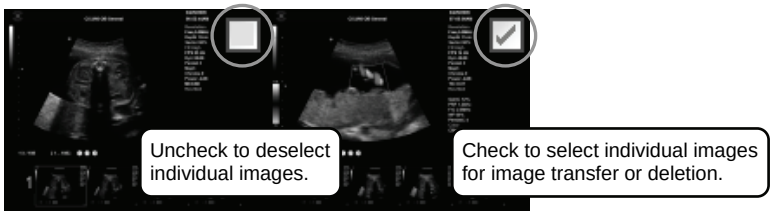
Table 10-4: CINE Review Touch Screen Controls (tap to activate)

Toggle Repeat	Select to toggle between two methods of reviewing the stored loop • repeat the clip/loop, as indicated by curved arrow • stop clip at end as indicated by straight arrow.
Exit	Select to ***Exit*** the clip review and return to 2D imaging.
Play	Select to view the clip.
Pause	Select to ***Pause*** viewing of the stored clip.

Table 10-5: CINE Review Touch Screen Controls (tap to activate, dial to adjust)

FrmByFrm	Use to select currently displayed frame, one (1) frame at a time.
Speed	Use to select CINE review play speed (⅛, ¼, ½, full (1/1) or double (2/2).

Figure 10-3: Image Selection/Deselection



To Select/Adjust the CINE Review Controls:

1. Tap ***Review*** on the touch screen menu.
2. Tap the desired selection on the touch screen menu (e.g., ***Speed***).
3. Use the dial below the selected touch screen button to make the adjustment to the CINE review.

10.2.1 Deleting Image(s)/Exam(s)

To Delete Individual Images:

1. Select the desired patient and exam date to display the images.
2. To select the desired image(s), use the trackball and **SELECT** button to place a check in the associated box(s) as shown in **Figure 10-3.**
3. Select ***Delete*** from the menu on the LCD display.

Note: *Select* ***Clear*** *to reset the screen and deselect the patient(s), exam(s) and image(s).* ***Clear*** *does not delete the images, it simply resets the screen by unchecking the selections.*

To Delete a Complete Exam:

1. Select the desired ***Patient*** and ***Exam Date***.
2. Select ***Delete*** from the menu on the LCD display or tap ***Delete*** on the touch screen.

Note: *Select* ***Clear*** *to reset the screen and deselect the patient(s), exam(s) and image(s).* ***Clear*** *does not delete the exams, it simply resets the screen by unchecking the selections.*

10.3 IMAGE TRANSFER

The image management system enables users to transfer stored images and CINE clips to a storage medium: DICOM Archiver or Printer, CD, USB key, DVD. ***Worksheets*** are converted to PDF before being transferred to a digital storage medium.

Notes:

To select an entire exam, check the checkbox for the desired exam.

To select all exams for a patient, check the checkbox for the desired patient.

To select only desired images, open each exam and check the checkbox for the desired images.

Figure 10-4: Select Storage Destination Dialog

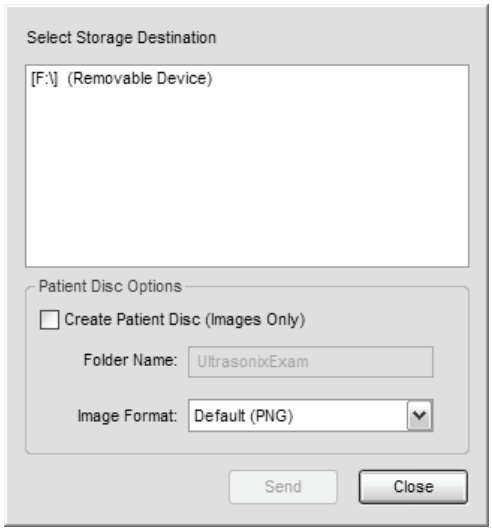
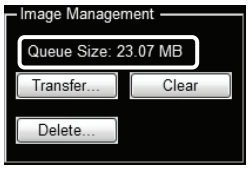


Table 10-6: Select Storage Destination Options

Storage Destination			All available storage options will be listed here, including all printers currently attached to the system, either locally or via the network: ***DICOM Archiver*** or ***Printer***, CD, USB key or DVD. ***Note:*** *A USB key, CD or DVD must be connected to the system in order to have it appear in the list of* ***Storage Destinations****.*
Patient Disc Options	***Create Patient Disc (Images Only)***		Creates a CD/DVD with just images (database and measurement data are not included). If multiple patients are selected with this option, all images will be in one file.
	Folder Name		Images written to a CD/DVD will be written into the ***Folder Name*** entered here. The default is ***UltrasonixExam***.
	Image Format	Enables the selection of four (4) different image formats.	
		Default (PNG) (Portable Network Graphics)	Selecting anything other than ***Default (PNG)*** will extend the image transfer time as ***.PNG*** images will have to be converted to the new format. The average ***.PNG*** image size is 100Kb.
		JPEG	***Joint Photographic Experts Group*** image format.
		Bitmap (BMP)	Converting the image to a ***Bitmap (BMP)*** increases the image size as follows: • 800 x 600 ***Bitmap*** image = approximately 2Mb • 1024 x 768 ***Bitmap*** image = approximately 3Mb.
		GIF	***Graphics Interchange File*** or ***Format*** image.

To Transfer Patient Exams:

1. Select the desired ***Patient(s)***, ***Exam Date*** and/or images.

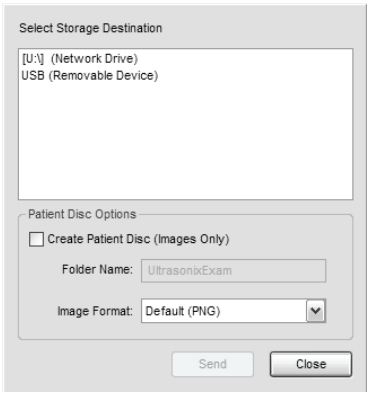


Note: *The amount of space required is listed under* ***Image Management*** *as* ***Queue Size****.*

2. Select ***Transfer…***.

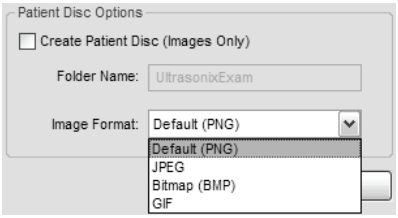
Note: *Select* ***Clear*** *to reset the screen and deselect the patient(s), exam(s) and image(s).* ***Clear*** *does not delete the images, it simply resets the screen by unchecking the selections.*

3. Select the desired ***Storage Destination***.



Note: *All connected Ultrasonix-approved digital storage peripherals will appear in the list of* ***Storage Destinations****.*

4. If required, select ***Create Patient Disc (Images Only)***.
5. If required, change the default ***Folder Name*** (***UltrasonixExam***) using the console keyboard.
6. Select the desired ***Image Format*** (***Default (PNG)***, ***JPEG***, ***Bitmap (BMP)***, ***GIF***, ***DCM***, ***DCM JPEG*** or ***DCM JPEG lossless***).



7. Select ***Send*** to transfer the files and/or images or ***Close*** to exit without transferring.

Note: *The original files will remain unchanged on the local hard drive.*

Note: *If the* ***Queue*** *jams during transfer/print, press* **SHIFT+ID**. *This will display the relevant* ***Queue****, enabling the user to delete the job and release the function.*

CHAPTER 11: CONNECTIVITY AND PERIPHERALS

The system includes a wide range of connectivity features that allow the user to simultaneously connect a variety of peripherals. Refer to section **9.2.13** and the *SONIX CEP Service Manual* for further details on peripheral connectivity.

Warning: *Do not touch the patient and the transducer ports simultaneously.*

11.1 SYSTEM CASE CONNECTIVITY PANEL

The System Case Connectivity Panel is accessible from the top of the system case.

Caution: *The system case contains the system PC and internal connectivity panel. Access to the internal connectivity panel (through the top of the system case) should be restricted to qualified service personnel only. Contact your local service representative for further information.*

Figure 11-1: System Case Connectivity Panel (CEP SX3.0)

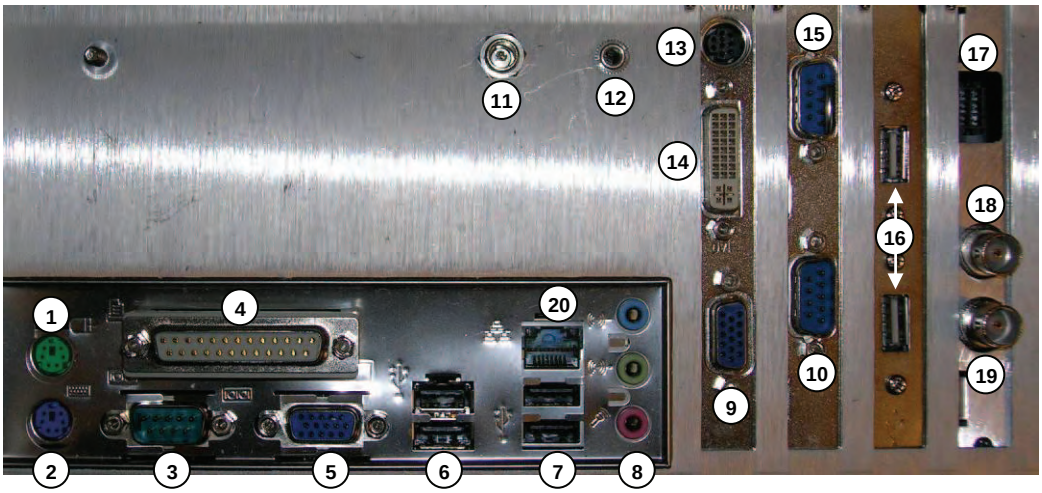


Figure 11-2: System Case Connectivity Panel (CEP SXmod 3.1)

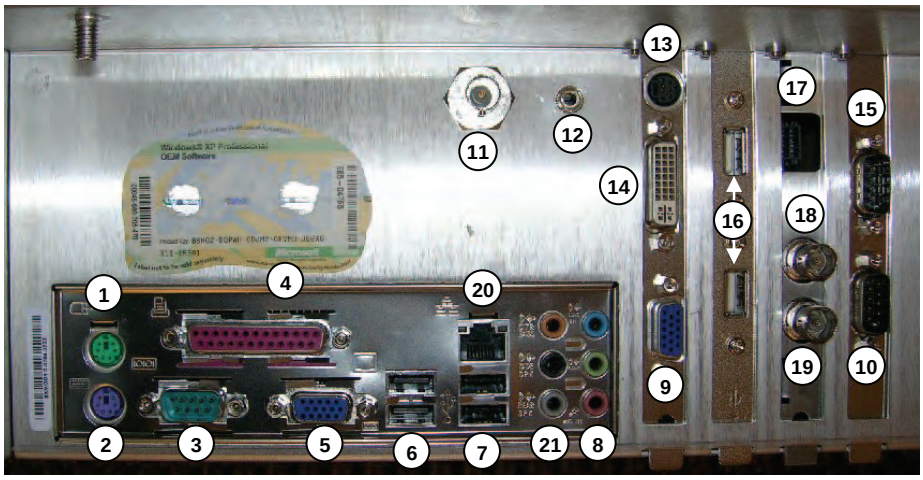


Figure 11-3: System Case Connectivity Panel (CEP SX3.2/3.3-FI)

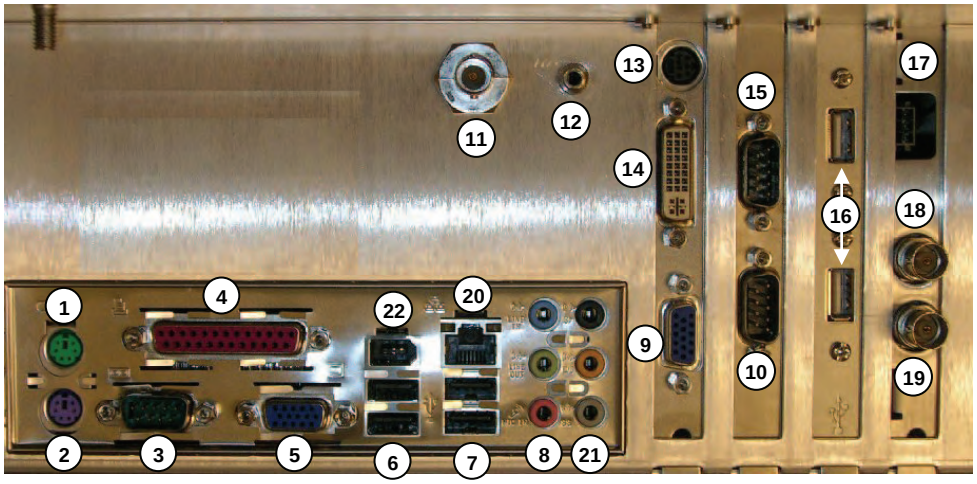


Figure 11-4: System Case Connectivity Panel (CEP SX3.2/3.3-F)

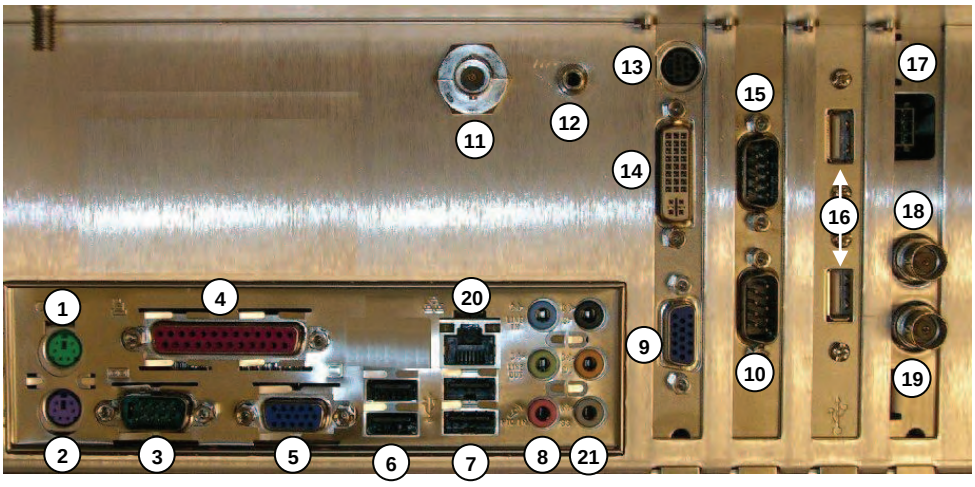


Figure 11-5: System Case Connectivity Panel (CEP SX3.4)

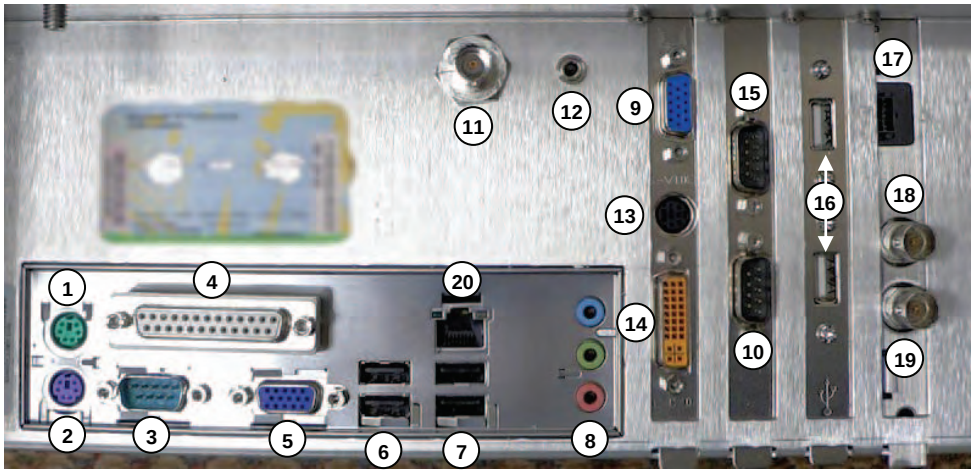


Figure 11-6: System Case Connectivity Panel (OP/SP SX1.0)

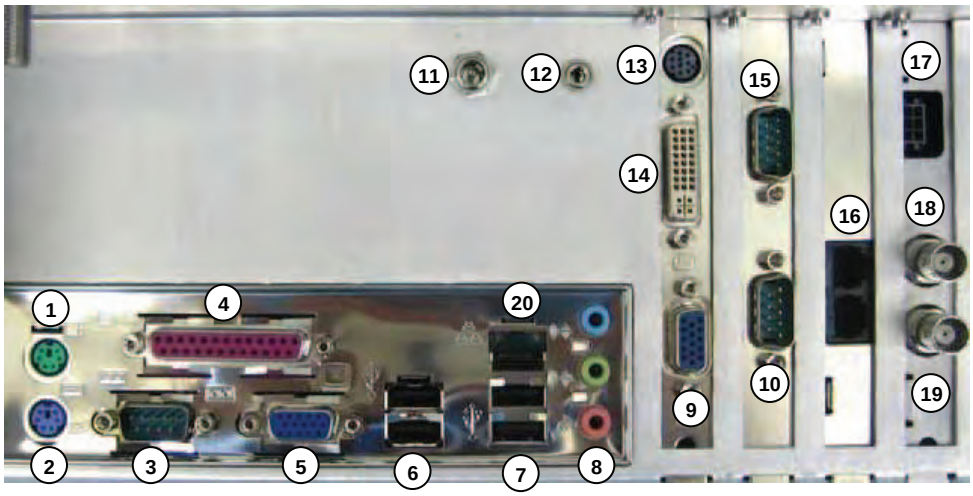


Figure 11-7: System Case Connectivity Panel (OP/SP SX1.1)

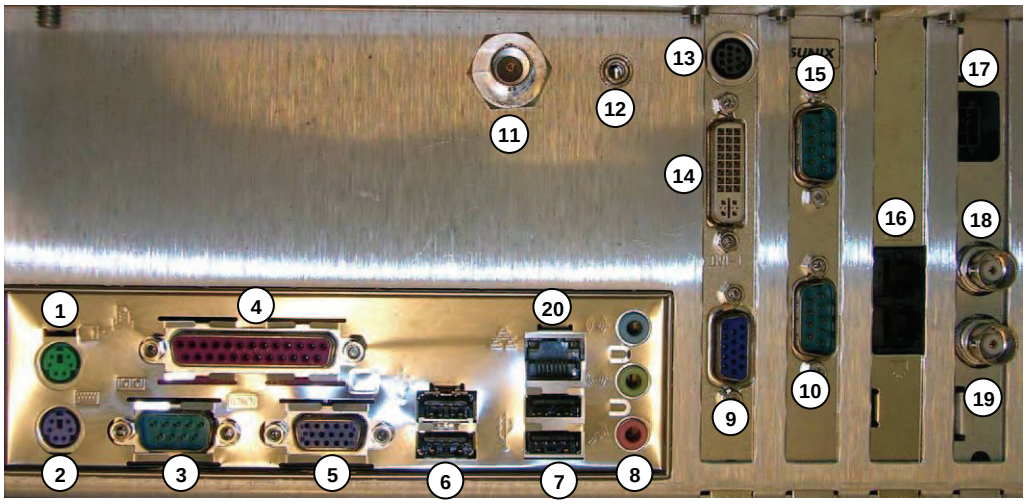


Figure 11-8: System Case Connectivity Panel (OP/SP SX1.1 mod)

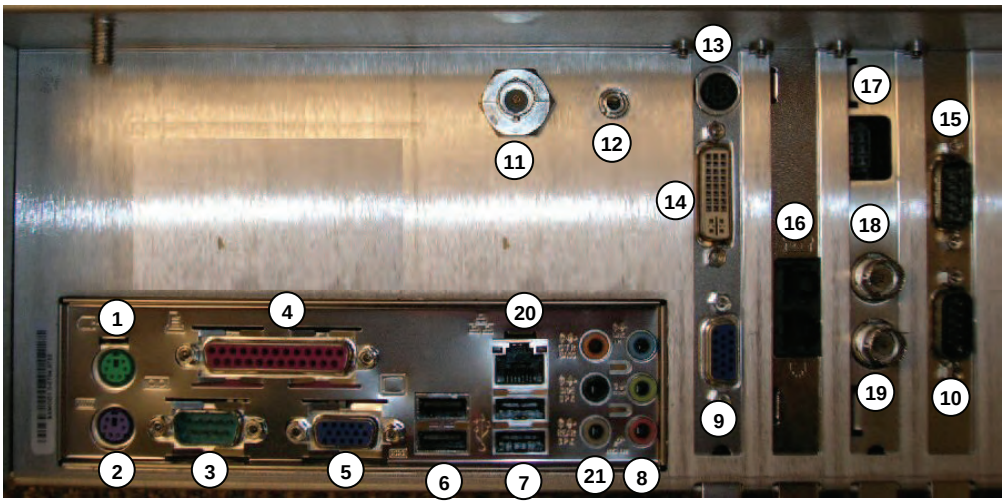


Figure 11-9: System Case Connectivity Panel (OP/SP SX1.2/1.3-FI)

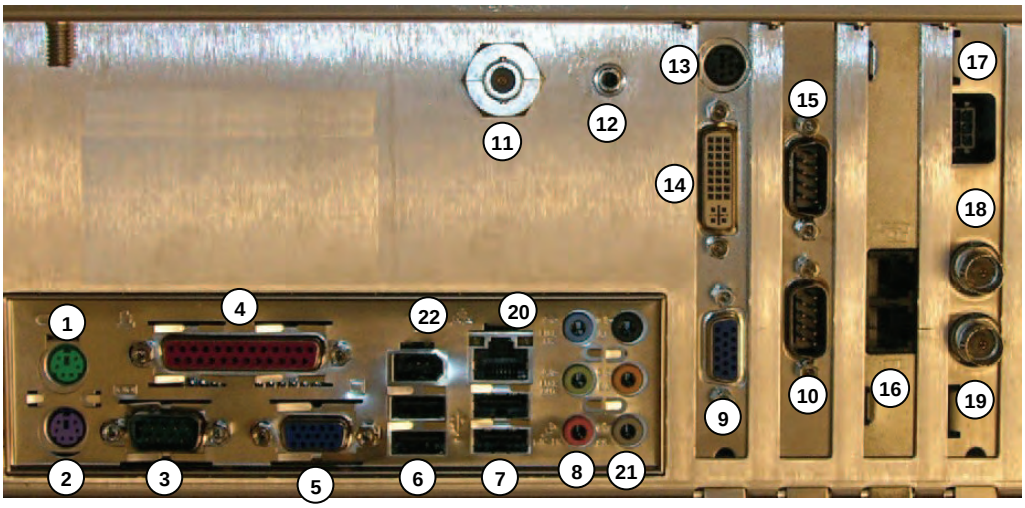


Figure 11-10: System Case Connectivity Panel (OP/SP SX1.2/1.3-F)

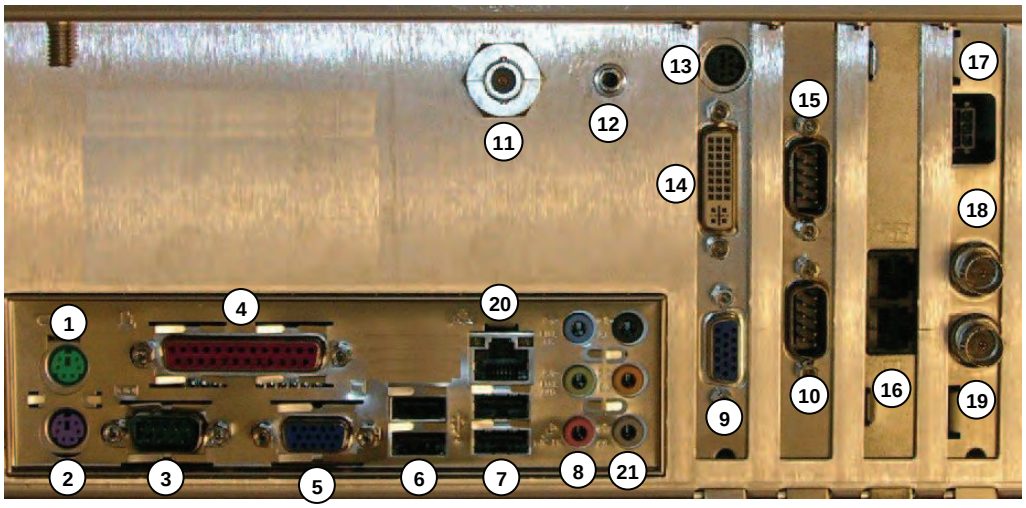


Figure 11-11: System Case Connectivity Panel (OP/SP SX1.4)

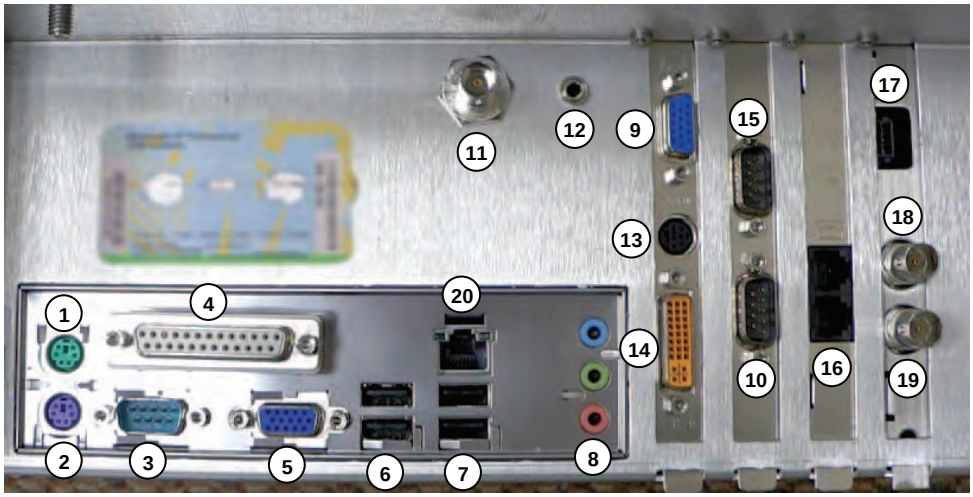
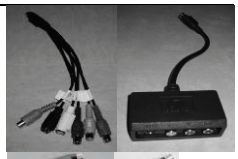


Table 11-1: System Case Connectivity Panel

1	PS2 Mouse port	Used by the operator console trackball.
2	PS2 Keyboard port	Used by the operator console keyboard.
3	RS232 Serial port	Used by the operator console.
4	Parallel port	A factory installed dongle connected to this port is required to activate selected system features. Additionally, this port may be used to connect an Ultrasonix-approved parallel-port printer.
5	Video output port	Disabled.
6	USB ports (2) **OP/SP:** **CEP:**	 Used by the two (2) USB ports at the front of operator console and the USB connector from the LCD display. Used by the two (2) USB ports at the front of the operator console and the USB port on the rear of the CEP operator console (barcode reader connection).
7	USB ports (2) **OP/SP:** **CEP:**	 Two (2) additional USB ports. These ports may be used to connect printers and other Ultrasonix-approved USB peripherals. Use to connect the barcode reader and wireless adapter. Used by the LCD display and wireless adapter.
8	Sound connections	Line-in (blue): may be used to connect an Ultrasonix-approved audio input device. System Speaker connection (green). System Microphone connection: Disabled.
9	Video VGA output **OR** Digital Video DVI video output	Not in use. Refer to item **14**, below.
10	RS232 Serial Port **OP/SP:** **CEP:**	 May be used to connect an Ultrasonix-approved RS232 serial device. Used by the UPS.
11	Speaker power connector	Used by the system speakers.
12	System Power Switch **OP/SP** **CEP:**	 Used as the ON/OFF switch by the operator console. Used as ON/OFF switch by the operator console and UPS.

13	Video outputs	Connected to a video splitter module that outputs Black & White (B&W) and Color video. It will look like one of these four (4) photos.  ***Note:*** *The B&W and Color video outputs are typically routed to the Back Connectivity Panel. These may also be connected directly to a video output device. Refer to* **11.2 Back Connectivity Panel** *for details.*  In the event that an S-Video connector is required (e.g., the four (4) wire video output cable pictured to the right) but has not been supplied, contact Ultrasonix Technical Support.
14	Digital Video DVI video output **OR** Video VGA output	Used by the system's LCD display. A DVI splitter may be used to connect additional Ultrasonix-approved DVI Video output devices. Refer to item **9**, above.
15	RS232 Serial port	Used by the operator console.
16	**OP/SP:** Two (2) modem connections **CEP:** Two (2) USB ports	The modem line is typically routed directly to the Back Connectivity Panel. It may also be connected directly to a phone/fax line from this location. Used by the internal modem (where applicable). The second USB port is unused.
17	Console power connector	Used by the operator console.
18	Freeze Bayonet Neill Concelman (BNC)	May be used to trigger a freeze or print function by connecting directly to an Ultrasonix-approved switching device, such as a ***Footswitch***. Refer to **9.2.13 Peripherals** to configure the trigger action of the switching device.
19	Print BNC	Port may be connected directly to an Ultrasonix-approved triggered device, such as a video printer. Refer to **9.2.12 Print Keys** to configure the **PRINT** keys.
20	Ethernet	The Ethernet connection is typically routed to the Back Connectivity Panel. It may also be connected directly to the Ethernet from this location. This port supports 10/100Mb.
21	Additional audio connections	Not in use.
22	IEEE 1394 Port	Not in use.

11.2 BACK CONNECTIVITY PANEL

The Back Connectivity Panel can be accessed from the back of the system. The connectors are routed internally to the system case connectivity panel which enables easy configuration.

Table 11-2: Back Connectivity Panel (Standard Configuration)

B&W OUT or B&W VIDEO	Use to connect an Ultrasonix approved video output device such as a B&W video printer or a frame grabber.
COL OUT or COL VIDEO	Use to connect an Ultrasonix approved video output device such as a color video printer, VCR or a frame grabber.
NET (Network) or LAN	Use to connect the system to a network. This port supports 10Mb/100Mb.
PHONE	Use to connect the modem to a phone line. This will allow the system to be configured for ***Chat Support*** (refer to **9.2.10 Network** for details on configuring a dialup connection).

Figure 11-12: Back Connectivity Panel

11.3 FRONT CONSOLE CONNECTIVITY

Figure 11-13: Console Front

The system provides two (2) USB ports and a CD/DVD writer at the front of the operator console. These USB ports can be used to connect Ultrasonix-approved USB devices (such as a USB thumb drive) for image file transfer.

Note: *Below and to the left side of the CD/DVD slot is a black button. Press this to release the CD/DVD from the drive.*

11.4 ULTRASONIX-APPROVED DEVICES

Warning: *Refer to the Service Manual for connection of AC power for third-party peripherals. The internal AC connector should only be used with Ultrasonix-certified, third-party peripherals.*

The power drawn from the internal AC peripheral power cable ***must not exceed 150W****.*

The following peripherals have been approved for use with the system:

- USB thumb drive connected to USB port
- SONY B&W Video printer connected to B&W Video and Trigger output
- SONY VCR and SONY DVD Recorder connected to RGB-Sync
- Canon i80 Inkjet Printer connected to Parallel Port.

Note: *Refer to the most recent Ultrasonix price list to determine the exact makes/models of Ultrasonix-approved devices.*

11.5 UPS (CEP)

When the SONIX CEP arrives, the UPS battery will be turned off and may be completely drained of power. During installation, the technician will ensure that the system – and therefore the UPS – is left plugged in, allowing it to completely charge the battery. This will take approximately 3.5 hours.

As a data safety measure, Ultrasonix has configured the UPS alert system to ensure an optimal warning time for UPS battery recharging.

Warnings:

NEVER *let liquid from any source enter the UPS. Failure to do this may result in accidental* ***shorts, shocks or electrocutions****.*

DO NOT attempt to service this product yourself*. Attempting to open the UPS may cause exposure to lethal voltages within the unit even when it is apparently not operating and the input wiring is disconnected from the electrical source. Should the UPS require maintenance or replacement, only qualified Ultrasonix Service Technicians may perform service as detailed in the Service Manual.*

For UPS and battery service issues, contact Ultrasonix Technical Support.

Caution: *In order to effectively protect exam data for the current patient, pay particular attention to the details in* **Table 11-3** *and* **Table 11-4***, respectively.*

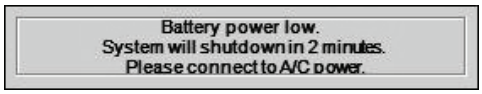
The system is delivered with a built-in screen saver utility. If it remains inactive for a predetermined period of time, the LCD display will enter screen saver mode and the phrase "***Always Plug in AC Power"*** will scroll continuously across the screen.

Although the Battery Recharge Alerts (**Table 11-4**) will continue to function, it will not be possible to see the onscreen warnings. The screen saver's message "***Always Plug in AC Power***" serves to remind users of the intent of the Battery Recharge Alerts' audible alarm.

Table 11-3: Battery Usage Limitations

Scanning Time Limit (Active and Frozen Imaging)	Ultrasonix does not recommend leaving the system unplugged even when imaging is frozen. ***Caution:*** *The system should only be unplugged (without shutting down) for the few moments it takes to move it to a new location.* ***Ignoring these instructions may result in data loss and battery failure.***
Recharge Time	To fully charge the battery, Ultrasonix recommends keeping the system plugged in continuously for 3.5 hours. ***Note:*** *If required, the system can continue to be used while the battery is charging. However, if the system is unplugged and moved during the recharge cycle, it may require more than 3.5 hours to fully charge.*

Table 11-4: Battery Recharge Alerts

Alert Level 2	While unplugged, if the battery charge falls below a predetermined level, the system will emit an audible alarm and present the following message on the ***Status Bar*** (bottom right of the LCD display). Both the message and the alarm will continue so long as the system remains unplugged. **Urgent: Plug in AC Power.** ***Caution:*** *To protect patient data and prolong battery life, connect the system to an AC power source immediately.*
Alert Level 1	If ***Alert Level 2*** is ignored (i.e., if the system is not connected to an AC power source), after a predetermined time the tone of the audible alarm will alter and the following message will be presented onscreen – *in front of any imaging that may be underway*:  There will also be a ***Status Bar*** message that will count down the two (2) minute warning (in seconds). If the counter reaches zero (0) before the system is plugged into an AC power outlet, the system will automatically shutdown. Shutting down in xx seconds. Before restarting the system, connect the power cord to an AC outlet. If the system is not plugged in before it is turned on, it will simply shut itself down again. Additionally, because the UPS remains in ***Standby*** mode even when it is powered off, the battery will continue to drain so it must be plugged in immediately after the shutdown process. ***Caution: Ignoring these instructions may result in data loss and battery failure.*** *To fully charge the battery after an* ***Alert Level 1*** *automated shutdown, leave the system plugged in continuously for 3.5 hours. If the charging cycle must be interrupted, Ultrasonix recommends leaving the system plugged in for a minimum of one (1) hour before unplugging it. Once the system has been moved, it should be reconnected to a power source immediately and allowed to continue charging for the full 3.5 hours.* *Failure to follow these recommendations may result in premature battery failure which is not covered by the system warranty.*

Note: *Battery Recharge Alerts are pre-programmed and cannot be edited or deleted by the user.*

11.5.1 UPS Battery Sleep Mode (CEP)

There are two (2) circumstances under which the UPS battery will automatically enter sleep mode:

- if an ***Alert Level 1*** is ignored and the system is not plugged in to recharge, after a short period of time the battery will drain to the point where it automatically enters sleep mode
- if the system is powered off and left *unplugged* for an extended period of time, the battery will continue to drain even though the system is not in use. If the battery charge falls *below* the level at which an ***Alert Level 1*** would occur, the battery will automatically enter sleep mode.

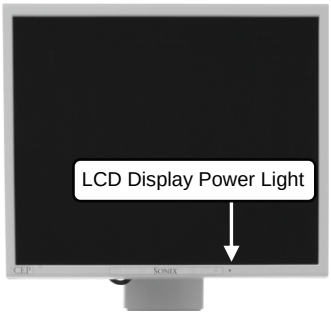
Proper use of the system, as discussed in **2.6.1 UPS Use Model** and **11.5 UPS (CEP)** will ensure that neither of these circumstances ever applies.

To Wake the UPS Battery from Sleep Mode:

1. Plug the system in to a power outlet that is known to be working.

   Note: *If the power light on the LCD display is not lit, then battery is likely in sleep mode.*

2. Press the console **POWER** button for approximately 1 second to wake the battery from "sleep" mode (a clicking sound may be heard).



   Note: *If the battery is in sleep mode, the power light on the LCD display will light up.*

3. Press the console **POWER** button a second time and the CEP should begin the boot process.
4. If the CEP fails to wake, the EPO switch may have been pressed and the UPS breakers will need to be reset. Contact your internal service provider or Ultrasonix Technical Support.
5. If the CEP boots correctly, leave the system plugged in and recharging – uninterrupted – for at least 60 minutes to attain approximately 60 minutes of battery life. (To attain a full battery charge, leave the unit plugged in for an uninterrupted period of approximately 3.5 hours).

   Note: *If desired, the system can be powered off and left plugged in to recharge or it can be used – without being unplugged – during the recharging period.*

11.5.2 UPS EMERGENCY POWER OFF Switch (CEP)

In the event of any emergency that requires the shutdown of all power (e.g., to prevent fire or shock), the CEP is equipped with a red, **EMERGENCY POWER OFF** (**EPO**) switch at the bottom, rear of the system. Once the EPO switch is pressed, unplug the power cord from the wall outlet.

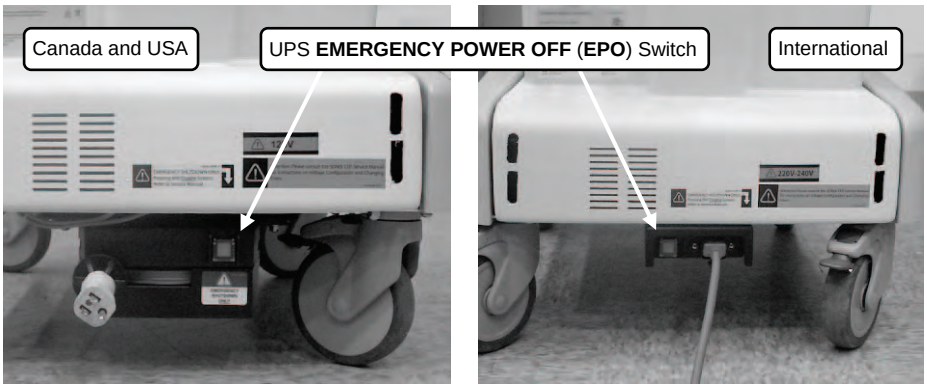
Caution: DO NOT use the EPO switch as a regular shutdown option.

Use this switch only in the event of an emergency (e.g., to prevent fire or shock). *Once the EPO switch has been pressed, the CEP will be completely disabled until your internal service provider or a certified Ultrasonix Service Technician can reset the system.*

Service calls that result from misuse of the EPO switch are not covered under the system Warranty and may not be covered by the Service Contract.

To Activate an Emergency Shutdown:

1. At the bottom, rear of the system, lift the clear plastic protective cover and press the red **EPO** switch.



2. Unplug the power cord from the wall outlet.
3. Call your internal service provider or Ultrasonix Technical Support.

IMPORTANT: *Use this switch **only** in the event of an emergency. Once turned off, the CEP will be **completely** disabled until your internal service provider or a certified Ultrasonix Service Technician can reset the system.*

If the **EMERGENCY POWER OFF** *switch is pressed, contact your internal service provider or Ultrasonix Technical Support immediately.*

11.6 CONNECTING THE BARCODE READER

The barcode reader comes standard with CEP hardware and is available as an option for OP/SP platforms running CEP software.

Figure 11-14: Barcode Reader

Warnings:

USE OF CONTROLS or adjustments or performance of procedures other than those specified in the manufacturer's User's Guide (delivered with system) may result in hazardous laser light exposure.

***NEVER** attempt to look at the laser beam, even if the barcode reader appears to be non-functional.*

***NEVER** point the laser beam in anyone's eyes.*

USE OF OPTICAL instruments with the laser equipment will increase eye hazard.

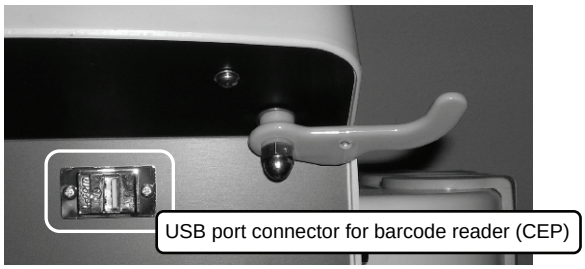
***UNDER NO CIRCUMSTANCES** should users or technicians attempt to open or service the laser scanner. Attempting to open the barcode reader may cause exposure to hazardous laser light. Should the barcode reader require maintenance or replacement, contact Ultrasonix Technical Support.*

Caution: Do not apply ultrasound gel to the barcode reader.

11.6.1 CEP

Simply plug the barcode reader's USB connector into the USB port on the back of the operator console. To keep it handy, store the barcode reader in one of the smaller transducer holders.

Figure 11-15: Rear Console USB Port Connection for the Barcode Reader (CEP)



11.6.2 SONIX OP/SP

Plug the barcode reader's USB connector into one of the USB ports at connection point **7** on the System Case Connectivity Panel (refer to the figures and table in section **11.1 System Case Connectivity Panel** for details on this connection). To keep it handy, store the barcode reader in one of the smaller transducer holders.

11.7 POWER CORD

11.7.1 Unwinding/Retracting the Power Cord: Canada and USA (CEP)

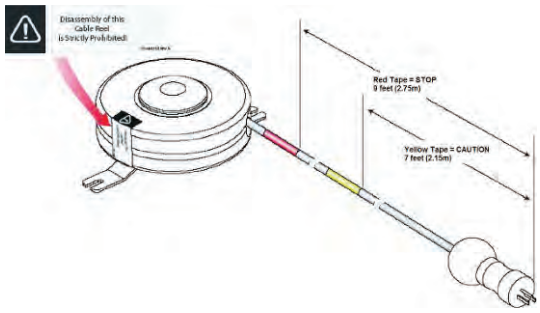
Before plugging in the retractable power cord, move the SONIX into the desired position. Gently pull the cord from its housing until it is long enough to comfortably reach the power connection. There should be a small amount of slack so that the cord is not under tension, but not so much that it pools on the floor, causing a possible tripping hazard or interfering with the smooth operation of the system wheels.

Two (2) colored labels on the power cord mark the maximum lengths to which the cord should be extended. The first label (yellow) is at 7' (2.15m) and indicates that the user should exercise caution as the cord is approaching its maximum length. The second label (red) is at 9' (2.75m) and indicates that the cord should not be extended any further.

To retract the cord back into its housing, grasp the cable plug firmly in one hand, then pull gently on the cable end nearest the base of the system until one (1) click is heard/felt. At this point, release the cable – but not the plug – and it will automatically retract until it encounters the resistance caused by retaining hold of the plug.

Figure 11-16: Retractable Power Cord

Figure 11-17: Power Cord Warning Labels



Warnings:

DO NOT *attempt to open the cable reel which houses the retractable power cord as this may cause physical injury and/or exposure to lethal voltages. It may also damage the cable reel, leading to further hazards when operating the system. Should the cable reel require maintenance or replacement, contact Ultrasonix Technical Support.*

DO NOT *use excessive force when extending or retracting the cord. This can cause the cord to separate from the reel and potentially expose anyone in the vicinity to lethal voltages.*

DO NOT *extend the cable into traffic areas as this can cause a tripping hazard.*

DO NOT *let go of the plug end of the cable while it is rewinding. Guide it gently back into its housing. If left to rewind on its own, the cable's whipping effect may cause injury.*

Cautions:

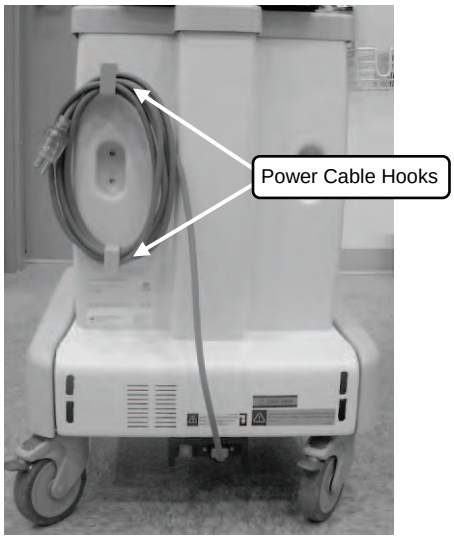
Always unwind/rewind the power cord by pulling/releasing from behind the system, not from the side.

DO NOT *extend the power cord past the red warning label.*

11.7.2 Power Cord: International (CEP)

When the system is unplugged, the power cord on the International CEP model can be wrapped around the power cable hooks to keep it tidy yet easily accessible.

Figure 11-18: Retractable Power Cord



11.8 WIRELESS

The SONIX CEP is delivered with a wireless adapter (for installation on the back of the LCD display) which should be configured during installation (**9.2.10.3 Wireless Settings**).

The wireless option can also be ordered pre-installed on the OP/SP platforms. When purchased at a later date (i.e., for a non-factory installed wireless adapter), refer to **11.8.2** for connection details.

Caution: *System networking options are intended for use inside your organization's firewall. Organizations that elect to configure/use the networking functionality provided by Ultrasonix are assuming all liabilities and risks associated with that decision.*

Caution: *For details on FCC regulations as they apply to the wireless adapter, refer to the manufacturer's User Guide included with the system.*

Each adapter is delivered with a bracket and two (2) set screws which are used to gently tighten the adapter in the bracket so it cannot move once it is secured to the system.

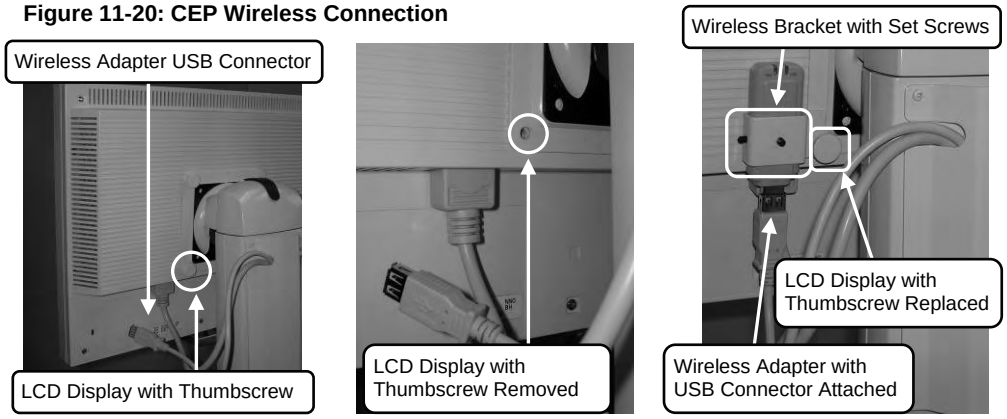
Note: *Use the set screws to secure the wireless adapter in the bracket after attaching it to the LCD display.*

Figure 11-19: Wireless Bracket with Set Screws

11.8.1 CEP

To attach the bracket to the back of the LCD display, remove the bottom left thumbscrew then reattach it in the same place, making sure to first thread the thumbscrew through the wireless adapter bracket.

Figure 11-20: CEP Wireless Connection

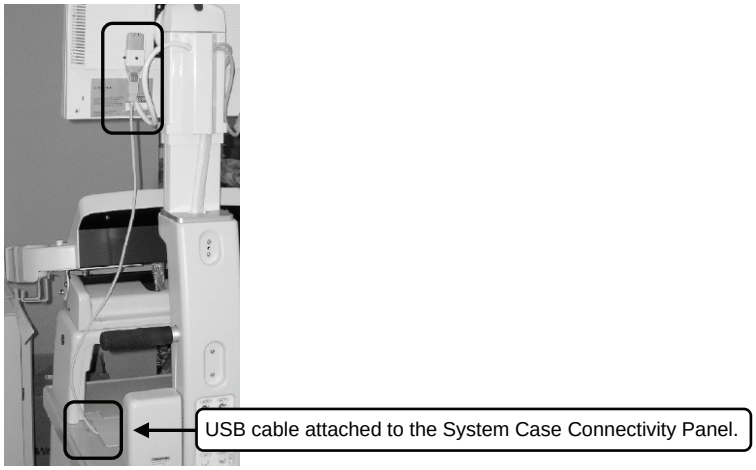


Note: *Before making the USB connection, be sure that the cover protecting the wireless adapter's USB connector has been removed.*

11.8.2 SONIX OP/SP

To attach the bracket to the back of the LCD display, remove the bottom left thumbscrew, thread the thumbscrew through the wireless adapter bracket and reattach it in the same place. Connect the other end of the cable to a spare USB port on the System Case Connectivity Panel.

Figure 11-21: CEP Wireless Connection



11.9 CONSOLE COVER

The SONIX CEP comes with the console cover installed, however, if a replacement cover is ever purchased, it will have to be installed. Users running E-Med software on an OP or SP who purchase a console cover will need to install this item.

To Install the First Console Cover:

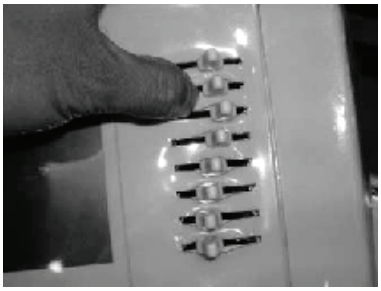
1. Place the console cover over the console, taking the time to align it properly.

2. Gently lift the front section of the cover and remove the paper backing from the Velcro.

3. Press the Velcro into place, taking care to ensure that exposed glue is positioned correctly.

4. Repeat steps 2 and 3 for the top of the console.

5. Make sure the cover sits behind the **TGC SLIDE PODS**.



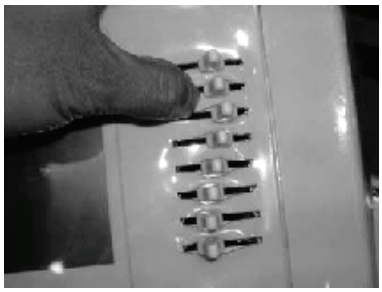
6. Repeat steps 2 and 3 for the left and, then the right hand side of the console until the console cover is snugly attached.

To Install a Replacement Console Cover:

1. Remove the old console cover.
2. Place the new console cover face down on a table.
3. Taking care not to put any pressure on the plastic itself, gently peel apart all the Velcro fastenings, discarding the excess strip of fastening.
4. Place the console cover over the console – without pressing together any of the Velcro strips.

Note: *Be sure to take the time to align the cover properly.*

5. Gently smooth all the Velcro fasteners into place, starting across the bottom, then moving to the top and the sides.
6. Make sure the cover sits behind the **TGC SLIDE PODS**.



APPENDIX A: SAFETY

A.1 SAFETY

This section contains important information about the safe use of the SONIX ultrasound system. Much of the information is required by various regulatory agencies and should be read prior to using the SONIX ultrasound system.

A.1.1 ALARA Principle and Output Displays

The Acoustic Power Output Display for the SONIX ultrasound system meets FDA requirements and the guidance standards set out by AIUM and NEMA – "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment".

The SONIX system provides real-time Mechanical Index (MI) and Thermal Index (TI) acoustic power output display values depending on the transducer and imaging mode.

- MI – Mechanical Index (2D imaging)
- TIB – Bone Thermal Index
- TIC – Cranial Thermal Index
- TIS – Soft Tissue Thermal Index

To Change the Index Value Displayed:

1. Press the console **ACOUSTIC POWER** button/dial.
2. Press several times to toggle through the MI, TIS, TIC and TIB values available to display depending on the imaging mode.

Note: *The MI and TI values are displayed to the right of the image field. The MI and TI values are updated as changes are made to the system, which affect the acoustic power output.*

The ALARA principle, provided by AIUM in "Ultrasound Medical Safety – Implementing ALARA", guides the ultrasound user on the prudent use of diagnostic ultrasound. Display of the acoustic power output value enables the ultrasound user to better implement the ALARA principle. The ultrasound user can determine the right balance of ultrasound exposure benefits to risks by using acoustic power output levels that are As Low As Reasonably Achievable (ALARA). Without compromising diagnostic quality, patient ultrasound exposure should be kept to a minimum while using the lowest output power possible.

A.2 BASIC PRECAUTIONS

DO NOT operate the SONIX Ultrasound System in the presence of flammable anesthetics.

NEVER allow water or other liquids onto the keyboard, operator console or interior of the system case.

ALWAYS handle transducers with care. Dropping the transducer or allowing it to strike a hard surface can damage the transducer elements and the acoustic lens. Such a collision can also crack the transducer housing and destroy its electrical safety features.

To avoid the risk of electrical shock, before using the transducer, inspect the transducer face, housing and cable. DO NOT use the transducer if the transducer or cable is damaged.

ALWAYS turn off the system before cleaning or changing fuses.

To avoid the risk of electrical shock and fire hazard, inspect the power supply, AC power cord and plug on a regular basis. Ensure they are not damaged.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components.

Keep the system clean. Carefully follow the procedures described in **Appendix D: Maintenance and Cleaning** for cleaning the system and transducers.

ALWAYS FREEZE the system when not imaging to prevent the transducer from overheating.

Ensure the LCD display and operator console are secure when imaging is being done or when the system is left unattended.

ALWAYS choose the appropriate transducer and parameters for the type of clinical application.

When scanning subjects, always work to use As Low As Reasonably Achievable (ALARA) acoustic scanning energies. Refer to section **A.1.1 ALARA Principle and Output Displays** before using the SONIX. Do not use more than the minimum energy necessary to conduct an ultrasound exam. This is especially necessary where fetal and cephalic scans are being conducted.

DO NOT remove panels or covers from the system base.

ALWAYS power the system from a grounded outlet.

Ultrasonix does not recommend the use of transducer covers containing natural rubber latex and talc as these ingredients are known to cause an allergic reaction in some individuals. Refer to "21 CFR 801.437" user labeling for more details on latex use.

Where intracavity transducers are used in clinical applications of a semi- critical nature (e.g., trans-rectal, trans-vaginal, trans-esophageal), any covers/sheaths used will be STERILE and have received regulatory clearance for use.

Warning: *The SONIX ultrasound system may produce physiological effects of ultrasound which may cause danger to the patient and operator.*

Caution: *Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy.*

Caution: *Contact Ultrasonix if repairs are needed on the system. Repairs and components maintenance must be carried out by Ultrasonix authorized personnel only.*

A.3 UPS PRECAUTIONS

Warnings:

NEVER *let liquid from any source enter the UPS. Failure to do this may result in accidental* ***shorts, shocks or electrocutions****.*

DO NOT attempt to service this product yourself*. Attempting to open the UPS may cause exposure to lethal voltages within the unit even when it is apparently not operating and the input wiring is disconnected from the electrical source. Should the UPS require maintenance or replacement, only qualified Ultrasonix Service Technicians may perform service as detailed in the Service Manual.*

For UPS and battery service issues, contact Ultrasonix Technical Support.

A.4 SYMBOL DEFINITIONS

Table A-1: SONIX CEP System Symbols

Symbol	Location	Meaning
	On the serial plate that indicates the serial number and electrical rating.	Alternating current
	On transducers.	Patient applied part meets the isolation requirements for type B applied part.
	On inputs of ECG module.	Patient applied part meets the isolation requirements for type BF applied part.
	On the warning/caution labels (rear of system).	Caution: Dangerous Voltages. Do not remove cover or back. Refer servicing to qualified service personnel.
	On the warning/caution labels.	Attention: Consult accompanying documents

A.5 ELECTRICAL SAFETY REQUIREMENTS

A.5.1 SONIX CEP System

The SONIX Ultrasound System is classified in accordance with the IEC 60601-1, the standard for Medical Electrical Equipment as follows.

Table A-2: SONIX CEP System Electrical Safety

Standard	IEC 60601-1
Type of protection against electrical shock	Class I
Degree of protection against electrical shock	Type B
Degree of protection against ingress of water	Ordinary

Warning: *Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If you have any additional questions, contact your Ultrasonix Customer Engineer.*

Warning: *If the SONIX CEP utility supply voltage exceeds the acceptable range, the internal circuitry protection feature will not allow the system to power up nor will it allow the battery to charge.*

The system voltage setting is configured in the factory. Do **not** change this setting in the field.

It is the user's responsibility to ensure the SONIX CEP is used only under the electrical conditions dictated by Ultrasonix Medical Corp. Failure to comply with these conditions may result in damage to the system which is not covered by the Ultrasonix warranty.

Caution: *For users running the 120V system, always ensure the utility supply voltage is 120 VAC nominal.*

For users running the 220V–240V system, always ensure the utility supply voltage is 220-240 VAC nominal.

A.5.2 CEP Hardware

Table A-3: Barcode Reader Electrical Safety

UL (Underwriter's Laboratory)	UL listed for US and Canada UL 60950 C22.2 No. 60950
Laser Class	CDRH and IEC Laser Class 1 – In accordance with IEC 60825-1:1993 + A1:1997 + A22001 Class 1

Note: *For details on the wireless adapter, refer to the manufacturer's User Guide included with the system.*

A.6 EMC (ELECTRO-MAGNETIC COMPATIBILITY) REQUIREMENTS

A.6.1 SONIX CEP System

The SONIX Ultrasound System has special precautions regarding EMC. Always install and use according to the EMC information provided in the relevant Service Manual.

Portable and mobile RF communications equipment can affect the SONIX Ultrasound System.

Transducer cables have to be raised above the ground during scanning.

Warning: *The use of accessories, transducers and cables other than those specified by Ultrasonix may result in increased emissions or decreased immunity of the SONIX.*

A.6.2 CEP Hardware

Table A-4: Barcode Reader

Electro-Magnetic Compatibility	Class B: FCC Part 15 ICES-003 European Union Directive 89/336/EEC

Note: *For details on the wireless adapter, refer to the manufacturer's User Guide included with the system.*

A.7 ENVIRONMENTAL CONDITIONS

Table A-5: SONIX System Operating Environment

Ambient Operational Temperature	61º to 95º F (16º to 35º C)
Internal Operational Temperature	61º to 131º F (16º to 55º C)
Internal Operational Humidity	10% to 80% (non-condensing)
Storage Conditions	+5º to +122º F (-15º to +50º C)
Storage Humidity	10% to 90% (non-condensing)

Warning: *Operate in an indoor environment only, free from moisture, flammable liquids, gases, corrosive substances, strong electrical or magnetic fields and equipment that generates high frequency waves.*

Ultrasonix cannot guarantee the proper performance of the SONIX CEP if used in the above-listed conditions.

Table A-6: Barcode Reader

Operating Temperature	32º to 104º F (0º to 40º C)
Storage Temperature	-40º to 140º F (-40º to 60º C)
Humidity	5% to 95% relative humidity, non-condensing
Light Levels	Up to 4842 Lux (footcandles)
Shock	Designed to withstand 1.5 m (5') drops
Contaminants	Sealed to resist airborne particulate contaminants
Ventilation	None required

Table A-7: Wireless Adapters

Operating Temperature	32º to 104º F (0º to 40º C)
Storage Temperature	-4º to 158º F (-20º to 70º C)
Humidity	80% maximum, non-condensing

Note: *For more details on the wireless adapter, refer to the manufacturer's User Guide included with the system.*

A.8 LIMITING TRANSDUCER SURFACE HEATING

Ultrasonix has ensured that the transducer surface temperature in still air does not exceed 50°C and applied on tissue does not exceed 43°C.

Surface heating may be created by transmitting energy on the same area of a transducer at a high rate. This heating may occur, for example, during Pulsed Wave Doppler or Color Doppler imaging. The only SONIX transducer where this surface heating issue could be an issue is the EC9-5/10 transducer. To limit the surface heating, SONIX software conditions are used to prevent the same area on the transducer from being excited to a rate of less than 100us. Thorough testing has shown no noticeable EC9-5/10 transducer surface heating. For added security the SONIX system high voltage excitation power circuit contains "Polyswitches" that ensure no more than a specified current can be drawn from these high-voltages circuits.

A.9 LATEX

Ultrasonix does not recommend the use of transducer covers containing natural rubber latex and talc as these ingredients are known to cause an allergic reaction in some individuals. Refer to "21 CFR 801.437" user labeling for more details on latex use.

APPENDIX B: SYSTEM SPECIFICATIONS

Note: *Optional features may not be available on all system configurations. Ultrasonix Medical Corporation reserves the right to alter system specifications at any time.*

SONIX OP and SP as described here are running E-Med software, not standard OP or SP software.

✓ – Standard ♦ – Optional Blank – Not Applicable

Table B-1: SONIX Series System Specifications

	SONIX OP	SONIX SP	SONIX CEP
EXAM TYPE/APPLICATIONS			
Abdomen/Aorta	✓	✓	✓
Biliary	✓	✓	✓
Bladder	✓	✓	✓
Cardiac	✓	✓	✓
Early OB	✓	✓	✓
F(oreign) Bodies	✓	✓	✓
L(ower) Extremity	✓	✓	✓
Late OB	✓	✓	✓
Other	✓	✓	✓
Pelvic	✓	✓	✓
Procedure	✓	✓	✓
Renal	✓	✓	✓
Thoracic	✓	✓	✓
Trauma (FAST)	✓	✓	✓
V(ascular) Access	✓	✓	✓
IMAGING MODES			
B, Dual B, Quad B	✓	✓	✓
B/M mode	✓	✓	✓
Color, Power and Directional Power Doppler	✓	✓	✓
Split B/Color mode	✓	✓	✓
Pulsed Wave Doppler (mono and duplex)	✓	✓	✓
Continuous Wave	✓	✓	✓
Triplex mode	✓	✓	✓
Clarity (adaptive image adjustment)	✓	✓	✓
Real-time Spatial Compound Imaging	✓	✓	✓
Tissue Harmonic Imaging (THI)	✓	✓	✓
Trapezoidal imaging (linear transducers)	✓	✓	✓
Tint (chroma)	✓	✓	✓
Panoramic Imaging	✓	✓	✓
Freehand 3D	✓	✓	✓
BROADBAND TRANSDUCERS			
P4A-2/20 broadband (2-4MHz), 20mm, 75" (1m90) cable, phased array	♦	♦	♦
C5-2/60 broadband (2-5MHz), 60mm radius, 75" (1m90) cable, curved array	♦	♦	♦
EC9-5/10 broadband (5-9MHz), 10mm radius, 75" (1m90) cable, endocavity microconvex array	♦	♦	♦
L9-4/38 broadband (4-9 MHz), 38mm, 75" (1m90) cable, linear array	♦	♦	♦
L14-5/38 broadband (5-14MHz), 38mm, 75" (1m90) cable, linear array	♦	♦	♦

	SONIX OP	SONIX SP	SONIX CEP
SYSTEM PARAMETERS			
Digital broadband channels	512	1024	1024
Maximum frames/sec	223	223	223
Maximum Display Size	1024 x 768	1024 x 768	1024 x 768
Dynamic range (Internal)	262dB	262dB	262dB
Dynamic range (Display)	45 - 105dB	45 - 105dB	45 - 105dB
PHYSICAL CHARACTERISTICS			
Footprint: 53cm x 71cm (21" x 28")	✓	✓	✓
Height (with adjustable LCD display) : 142cm – 155 cm (56" – 61")	✓	✓	✓
Weight:	75 kg (166 lbs)	75 kg (166 lbs)	108 kg (238lbs)
ErgoMetrics console		✓	
TFT (Active Matrix) 17" LCD display	✓	✓	✓
Three (3) Transducer connectors	✓	✓	✓
Peripherals Bay	✓	✓	✓
Presets and Worksheets			
Default Presets	✓	✓	✓
Default (Master) Worksheets (only 1 active Worksheet per Application)	✓	✓	✓
User-Defined Worksheets (only 1 active Worksheet per Application)	✓ Unlimited	✓ Unlimited	✓ Unlimited
USER INTERFACE			
QSONIX			
Quick Exam Start-up	✓	✓	✓
Operator Console Tutorial	✓	✓	✓
Online Support Access	✓	✓	✓
Training Tutorials	✓	✓	✓
Universal language option	✓	✓	✓
TGC, B mode gain	✓	✓	✓
Color gain, Spectral gain	✓	✓	✓
Depth selection from 2 to 24 cm (transducer dependent)	✓	✓	✓
Focus (up to 5 transmit zones with span)	✓	✓	✓
Persistence (B Mode)	✓	✓	✓
Persistence (Color and Spectral Doppler)	✓	✓	✓
Acoustic Power	✓	✓	✓
Dynamic range	✓	✓	✓
Sector size	✓	✓	✓
Zoom	✓	✓	✓
Color maps	✓	✓	✓
Line density (B Mode)	✓	✓	✓
Line density (Color and Spectral Doppler)	✓	✓	✓
Steer (B Mode)	✓	✓	✓
Steer (Color and Spectral Doppler)	✓	✓	✓
Baseline, PRF (Color and Spectral Doppler)	✓	✓	✓
Display method (scroll or moving bar, Spectral Doppler, B/M)	✓	✓	✓
Sweep Speed (M Mode, PW)	✓	✓	✓
Automatic optimization key (Spectral Doppler)	✓	✓	✓
Easy-to-use Interface	✓	✓	✓
LCD touch screen command centre	✓	✓	✓
User-programmable Print keys	✓	✓	✓
Text, Annotations, Pictograms	✓	✓	✓

	SONIX OP	SONIX SP	SONIX CEP
REMOTE SUPPORT			
Real-time live chat support	✓[1]	✓[1]	✓[1]
Ultrasonix remote system diagnostic capability	✓[1]	✓[1]	✓[1]
1-Step Software upgrades (CD-ROM or Internet)	✓[1]	✓[1]	✓[1]
CINE MEMORY			
Up to 4 minutes of data (Transducer/sector size dependant)	✓	✓	✓
Total available memory	>2048 fr	>2048 fr	>2048 fr
STORAGE AND CONNECTIVITY			
DICOM service classes (Print/Store/Worklist)	♦	♦	♦
Hard-drive storage	✓	✓	✓
Still image storage (PNG, JPEG, BMP, GIF)	✓	✓	✓
CINE loop storage & trim (AVI)	✓	✓	✓
Front-load integrated CD and DVD-Writer	✓	✓	✓
Front-load USB 2.0 ports (2)	✓	✓	✓
Rear Console USB Port (1) for Barcode Reader Hookup			✓
Built-in Firewall	✓	✓	✓
Video output – Composite Color	✓	✓	✓
Video output – Composite B&W	✓	✓	✓
Video output – Separate VGA output	✓	✓	✓
Video output – S-Video out	✓	✓	✓
Video output – Digital video DVI output	✓	✓	✓
Video input – S-Video	✓	✓	✓
Serial connector	✓	✓	✓
Parallel and USB standard inkjet or laser printer output	✓	✓	✓
Integrated modem and Network connection	✓	✓	✓
Wireless networking	♦	♦	✓
Streaming video (SONIX Live)	♦	♦	✓
MEASUREMENTS AND ANALYSIS			
Default Worksheets	✓	✓	✓
User-Defined Worksheets	✓	✓	✓
User-Defined Measurements	✓	✓	✓
Data Management	✓	✓	✓
Patient Database	✓	✓	✓
QA Review Process/QA Status	✓	✓	✓

	SONIX OP	SONIX SP	SONIX CEP
PERIPHERALS			
Color Video Printer	♦	♦	♦
B/W Video Printer	♦	♦	♦
VHS Video Cassette recorder	♦	♦	♦
Footswitch	♦	♦	♦
Uninterruptible Power Supply (UPS)			✓
Barcode Reader (Pre-programmed to support the following barcode symbologies: UPC, EAN, Interleaved 2 of 5, Codabar, Code 3 of 9, Code 93, Code 128)	♦	♦	✓
Power Cord Canada and USA: Medical Grade Retractable Power Cord/Cable Reel, 9' (2.75m) International: Medical Grade, Country-Specific Power Cord, 15' (4.6m)	 ✓	 ✓	 ✓
Wireless Adapter (802.11b/g compatible)	♦	♦	✓
Transducer Basket			✓
Cable hooks			✓
Console cover	♦	♦	✓

[1] Where available. Requires Internet connection and ISP.

APPENDIX C: TRANSDUCER SPECIFICATIONS

Table C-1: Transducer Type/Applications

Transducer Name	Type	Application
PA4-2/20	Phased Array	Abdomen, Cardiac (Adult), OB/Gyn
C5-2/60	Convex	Abdomen, Obstetrics, Gyn/Fertility
EC9-5/10	Endocavity	Transvaginal, Transrectal
L9-4/38	Linear	Breast, Small parts, Vascular, Vein Care
L14-5/38	Linear	Small parts, Superficial, Msk, Vascular, Superficial Abd

C.1 TRANSDUCER MEASUREMENT ACCURACY

Table C-2: Measurement Accuracy Test Results

		System Error		Range			
Test Parameter	Probe	Best System Setting	Worst System Setting	Min	Max	Test Method	Estimated uncertainty between the Best and Worst System Settings
2D MEASUREMENT TEST							
Axial Distance	Linear	± 0.55%	± 1.00%	0.07mm	90.20 mm	Multipurpose Phantom***	
	Convex	± 0.50%	± 0.20%	0.14mm	240.98 mm	Multipurpose Phantom***	
	Phase Array	± 0.45%	± 0.90%	0.12mm	240.33 mm	Multipurpose Phantom***	
	Max. Value Among Probes	± 0.55%	± 1.00%	0.07mm	240.98 mm	Multipurpose Phantom***	± .45% {1%}
Lateral Distance	Linear §	± 1.10%	± 1.07%	0.07mm	84.26 mm	Multipurpose Phantom***	
	Convex §	± 1.30%	± 1.20%	0.14mm	383.02 mm	Multipurpose Phantom***	
	Phase Array #	± 2.10%	± 1.77%	0.12mm	334.11 mm	Multipurpose Phantom***	
	Max. Value Among Probes	± 2.10%	± 1.77%	0.07mm	383.02 mm	Multipurpose Phantom***	± 0.33% {1%}
Diagonal Distance	Linear ^	± 1.79%	± 0.45%	0.10mm	97.69 mm	Multipurpose Phantom***	
	Convex ^	± 0.89%	± 2.23%	0.21mm	282.12 mm	Multipurpose Phantom***	
	Phase Array^^	± 1.50%	± 1.53%	0.16 mm	47.91 mm	Multipurpose Phantom***	
	Max. Value Among Probes	± 1.79%	± 2.23%	0.10 mm	282.12 mm	Multipurpose Phantom***	± 0.44% {1%}

2D MEASUREMENT TEST – Cont'd							
Area (Ellipse)	Linear	± 1.66%	± 2.08%	0.00 cm^2	114.01 cm^2	Multipurpose Phantom***	
	Convex	± 1.80%	± 1.40%	0.00 cm^2	836.3 cm^24	Multipurpose Phantom***	
	Phase Array	± 2.56%	± 2.69%	0.00 cm^2	717.80 cm^2	Multipurpose Phantom***	
	Max. Value Among Probes	± 2.56%	± 2.69%	0.00 cm^2	836.34 cm^2	Multipurpose Phantom***	± 0.13% {1%}
Area (Continual Trace)	Linear	± 1.66%	± 2.08%	1.76 cm^2	145.64 cm^2	Multipurpose Phantom***	
	Convex	± 1.80%	± 1.40%	0.00 cm^2	1084.84 cm^2	Multipurpose Phantom***	
	Phase Array	± 2.56%	± 2.69%	0.00 cm^2	925.54 cm^2	Multipurpose Phantom***	
	Max. Value Among Probes	± 2.56%	± 2.69%	0.00 cm^2	1084.84 cm^2	Multipurpose Phantom***	± 0.13% {1%}
Circumference (Ellipse)	Linear	± 1.56%	± 1.51%	1.47 mm	384.89 mm	Multipurpose Phantom***	
	Convex	± 1.84%	± 1.70%	2.95 mm	1039.46 mm	Multipurpose Phantom***	
	Phase Array	± 2.97%	± 2.50%	2.34 mm	962.29 mm	Multipurpose Phantom***	
	Max. Value Among Probes	± 2.97%	± 2.50%	1.47 mm	1039.46 mm	Multipurpose Phantom***	± 0.47% {1%}
Circumference (Continual Trace)	Linear	± 1.56%	± 1.51%	1.76 mm	483.98 mm	Multipurpose Phantom***	
	Convex	± 1.84%	± 1.70%	1.91 mm	1326.17 mm	Multipurpose Phantom***	
	Phase Array	± 2.97%	± 2.50%	1.86 mm	1225.97 mm	Multipurpose Phantom***	
	Max. Value Among Probes	± 2.97%	± 2.50%	1.76 mm	1326.17 mm	Multipurpose Phantom***	± 0.47% {1%}
M-MODE TEST							
Heart Rate (HR)	Linear	± 1.65%	± 2.13%	8.58 bpm	15000.00 bpm	Ultrasonix Test Equipment	
	Convex	± 1.08%	± 4.81%	8.58 bpm	15000.00 bpm	Ultrasonix Test Equipment	
	Phase Array	± 1.88%	± 3.40%	8.58 bpm	15000.00 bpm	Ultrasonix Test Equipment	
	Max. Value Among Probes	± 1.88%	± 4.81%	8.58 bpm	15000.00 bpm	Ultrasonix Test Equipment	± 2.93% {3%}
Distance (D)	Linear	± 0.65%	± 0.15%	0.04 mm	88.70 mm	Multipurpose Phantom***	
	Convex	± 2.15%	± 2.15%	0.04 mm	237.98 mm	Multipurpose Phantom***	
	Phase Array	± 2.55%	± 2.00%	0.04 mm	237.98 mm	Multipurpose Phantom***	
	Max. Value Among Probes	± 2.55%	± 2.15%	0.04 mm	237.98 mm	Multipurpose Phantom***	± 0.40% {1%}
Time (Tm)	Linear	± 0.00%	± 4.00%	0.00 s	7.00 s	Ultrasonix Test Equipment	
	Convex	± 1.00%	± 4.00%	0.00 s	7.00 s	Ultrasonix Test Equipment	
	Phase Array	± 3.00%	± 4.00%	0.00 s	7.00 s	Ultrasonix Test Equipment	
	Max. Value Among Probes	± 3.00%	± 4.00%	0.00 s	7.00 s	Ultrasonix Test Equipment	± 1.00% {1%}

PW MODE TEST							
Velocity Calipers (V)	Linear	± 9.63%	± 9.31%	0.00 cm/s	240.63 cm/s	**Doppler Phantom*	
	Convex	± 5.18%	± 2.74%	0.00 cm/s	481.25 cm/s	**Doppler Phantom*	
	Phase Array	± 2.59%	± 6.62%	0.00 cm/s	481.25 cm/s	**Doppler Phantom*	
	Max. Value Among Probes	± 9.63%	± 9.31%	0.00 cm/s	481.25 cm/s	**Doppler Phantom*	± 0.32% {1%}
Heart Rate	Linear	± 0.15%	± 0.43%	7.92 bpm	15000.00 bpm	Doppler Phantom*	
	Convex	± 1.33%	± 2.13%	7.92 bpm	15000.00 pbm	Doppler Phantom*	
	Phase Array	± 0.47%	± 0.30%	7.92 bpm	15000.00 bpm	Doppler Phantom*	
	Max. Value Among Probes	± 1.33%	± 2.13%	7.92 bpm	15000.00 bpm	Doppler Phantom*	± 0.80% {1%}
Time (Tm)	Linear	± 0.00%	± 0.00%	0.00 s	7.57 s	Doppler Phantom*	
	Convex	± 2.00%	± 2.00%	0.00 s	7.57 s	Doppler Phantom*	
	Phase Array	± 1.00%	± 1.00%	0.00 s	7.57 s	Doppler Phantom*	
	Max. Value Among Probes	± 2.00%	± 2.00%	0.00 s	7.57 s	Doppler Phantom*	± 0.00% {0%}

* Optmizer, RMI 1425 A, Doppler Phantom.
** The errors of the PW velocity measurements are based on the reference measured value obtained from the GE Voluson 730 PRO with Probe: RAB 4-BP.
*** Gammex, Model 403 GS LE, Multipurpose Phantom.
§ Horizontal Pins were located at a depth of 2cm in the multipurpose phantom.
# Horizontal Pins were located at a depth of 12cm in the multipurpose phantom.
^ Pin targets were located between a depth of 2 to 4 cm in the multipurpose phantom.
^^ Pin targets located between a depth of 10 and 12 cm in the multipurpose phantom.
{ } The estimated uncertainty that is rounded towards infinity.

Table C-3: Field Definitions

Best System Setting	Test was performed so the ROI filled as much of the measurement screen as possible.
Worst System Setting	Test was performed using the maximum setting of the measurement axis.
Max. Value Among Probes	Maximum error or range among all probes (except in the lower range where the minimum values were used) was chosen to be presented.
Estimated Uncertainty	Difference between the **Worst Setting** and **Best Setting** errors. Indicates the possible uncertainty when taking measurements using different scales of the axis.

Table C-4: Transducers Used for Measurement Accuracy Tests

Linear	L14-5/38
Convex	C5-2/60
Phase Array	PA4-2/20

C.2 ACOUSTIC OUTPUT REPORTING TABLES

Below are copies of the **Acoustic Output Reporting Tables for Track 3** for all transducers and all modes (provide data where global maximum displayed index exceeds 1.0)

The following notes apply to **ALL** Acoustic Output Reporting Tables for **ALL** transducers/modes:

a) This index is not required for this operating mode; see section 4.1.3.1 of the *Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment* (AIUM/NEMA 1998b)

b) This probe is not intended for trans-cranial or neonatal cephalic uses.

c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

Table C-5: Transducer Model PA4-2/20 (Operating Mode: B Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.66	(a)	(a)	(a)	(a)	(a)
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.04					
	W_o	[mW]		(a)	(a)		(a)	(a)
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(a)		
	Z_1	[cm]				(a)		
	z_{bp}	[cm]				(a)		
	z_{sp}	[cm]	4.47				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	2.50	(a)	(a)	(a)	(a)	(a)
	Dim of A_{aprt}	Elev (Y) [cm]		(a)	(a)	(a)	(a)	(a)
		Azi. (X) [cm]		(a)	(a)	(a)	(a)	(a)
Other Information	PD	[µsec]	0.71					
	PRF	[Hz]	22					
	$p_r@PII_{max}$	[MPa]	1.53					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(a)	(a)	(a)		(a)
		Y [cm]		(a)	(a)	(a)		(a)
	$I_{PA.3}@MI_{max}$	[W/cm^2]	65					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 1

Table C-6: Transducer Model PA4-2/20 (Operating Mode: Color Flow)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.45	0.75	(c)	(c)	(a)	1.11
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.79					
	W_o	[mW]		53	(c)		(a)	76
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	5.26				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	3.00	3.00	(c)	(c)	(a)	3.00
	Dim of A_{aprt}	Elev (Y) [cm]		1.20	(c)	(c)	(a)	1.20
		Azi. (X) [cm]		1.00	(c)	(c)	(a)	1.92
Other Information	PD	[µsec]	1.09					
	PRF	[Hz]	135					
	$p_r@PII_{max}$	[MPa]	1.36					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		5.00	(c)	(c)		5.00
		Y [cm]		5.00	(c)	(c)		5.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	32					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 4.71

Table C-7: Transducer Model PA4-2/20 (Operating Mode: M Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.70	0.56	(c)	(c)	(c)	0.93
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.11					
	W_o	[mW]		39	(c)		(c)	64
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	4.47				(c)	
	$d_{eq}(z_{sp})$	[cm]					(c)	
	f_c	[MHz]	2.50	3.00	(c)	(c)	(c)	3.00
	Dim of A_{aprt}	Elev (Y) [cm]		1.20	(c)	(c)	(c)	1.20
		Azi. (X) [cm]		1.00	(c)	(c)	(c)	1.92
Other Information	PD	[µsec]	0.73					
	PRF	[Hz]	3125					
	$p_r@PII_{max}$	[MPa]	1.64					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		5.00	(c)	(c)		5.00
		Y [cm]		5.00	(c)	(c)		5.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	61					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 139.07

Table C-8: Transducer Model PA4-2/20 (Operating Mode: PW Doppler)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} \leq$		
Global Maximum Index Value			0.17	(c)	0.86	(c)	0.51	1.60
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.26					
	W_o	[mW]		(c)	72		72	72
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	4.47				4.90	
	$d_{eq}(z_{sp})$	[cm]					1.15	
	f_c	[MHz]	2.50	(c)	3.00	(c)	3.00	3.00
	Dim of A_{aprt}	Elev (Y) [cm]		(c)	1.20	(c)	1.20	1.20
		Azi. (X) [cm]		(c)	0.84	(c)	0.84	0.84
Other Information	PD	[µsec]	2.22					
	PRF	[Hz]	1250					
	$p_r@PII_{max}$	[MPa]	0.39					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(c)	8.00	(c)		8.00
		Y [cm]		(c)	8.00	(c)		8.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	1					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 26.45

Table C-9: Transducer Model C5-2/60 (Operating Mode: B Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.66	(a)	(a)	(a)	(a)	(a)
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.20					
	W_o	[mW]		(a)	(a)		(a)	(a)
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(a)		
	Z_1	[cm]				(a)		
	z_{bp}	[cm]				(a)		
	z_{sp}	[cm]	3.66				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	3.33	(a)	(a)	(a)	(a)	(a)
	Dim of A_{aprt}	Elev (Y) [cm]		(a)	(a)	(a)	(a)	(a)
		Azi. (X) [cm]		(a)	(a)	(a)	(a)	(a)
Other Information	PD	[µsec]	0.67					
	PRF	[Hz]	22					
	$p_r@PII_{max}$	[MPa]	1.83					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(a)	(a)	(a)		(a)
		Y [cm]		(a)	(a)	(a)		(a)
	$I_{PA.3}@MI_{max}$	[W/cm^2]	39					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 1

Table C-10: Transducer Model C5-2/60 (Operating Mode: Color Flow)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.46	1.60	(c)	(c)	(a)	1.78
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.86					
	W_o	[mW]		96	(c)		(a)	223
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	2.22				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	3.50	3.50	(c)	(c)	(a)	3.50
	Dim of A_{aprt}	Elev (Y) [cm]		1.20	(c)	(c)	(a)	1.20
		Azi. (X) [cm]		1.00	(c)	(c)	(a)	6.40
Other Information	PD	[µsec]	1.12					
	PRF	[Hz]	144					
	$p_r@PII_{max}$	[MPa]	1.12					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		5.00	(c)	(c)		5.00
		Y [cm]		5.00	(c)	(c)		5.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	39					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 6.32

Table C-11: Transducer Model C5-2/60 (Operating Mode: M Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.50	1.53	(c)	(c)	(c)	1.40
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.92					
	W_o	[mW]		96	(c)		(c)	175
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	3.66				(c)	
	$d_{eq}(z_{sp})$	[cm]					(c)	
	f_c	[MHz]	3.33	3.33	(c)	(c)	(c)	3.33
	Dim of A_{aprt}	Elev (Y) [cm]		1.20	(c)	(c)	(c)	1.20
		Azi. (X) [cm]		1.00	(c)	(c)	(c)	6.40
Other Information	PD	[µsec]	0.70					
	PRF	[Hz]	4000					
	$p_r@PII_{max}$	[MPa]	1.40					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		5.00	(c)	(c)		5.00
		Y [cm]		5.00	(c)	(c)		5.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	34					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 95.24

Table C-12: Transducer Model C5-2/60 (Operating Mode: PW Doppler)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.33	(c)	(c)	0.43	1.30	1.96
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.60					
	W_o	[mW]		(c)	(c)		97	97
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				26		
	Z_1	[cm]				3.70		
	z_{bp}	[cm]				1.85		
	z_{sp}	[cm]	3.70				3.70	
	$d_{eq}(z_{sp})$	[cm]					0.69	
	f_c	[MHz]	3.50	(c)	(c)	3.50	3.50	3.50
	Dim of A_{aprt}	Elev (Y) [cm]		(c)	(c)	1.20	1.20	1.20
		Azi. (X) [cm]		(c)	(c)	1.00	1.00	1.00
Other Information	PD	[µsec]	1.09					
	PRF	[Hz]	1250					
	$p_r@PII_{max}$	[MPa]	0.94					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(c)	(c)	8.00		8.00
		Y [cm]		(c)	(c)	8.00		8.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	19					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 117.68

Table C-13: Transducer Model EC9-5/10 (Operating Mode: B Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.66	(a)	(a)	(a)	(a)	(a)
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.48					
	W_o	[mW]		(a)	(a)		(a)	(a)
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(a)		
	Z_1	[cm]				(a)		
	z_{bp}	[cm]				(a)		
	z_{sp}	[cm]	2.00				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	5.00	(a)	(a)	(a)	(a)	(a)
	Dim of A_{aprt}	Elev (Y) [cm]		(a)	(a)	(a)	(a)	(a)
		Azi. (X) [cm]		(a)	(a)	(a)	(a)	(a)
Other Information	PD	[µsec]	0.47					
	PRF	[Hz]	49					
	$p_r@PII_{max}$	[MPa]	2.09					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(a)	(a)	(a)		(a)
		Y [cm]		(a)	(a)	(a)		(a)
	$I_{PA.3}@MI_{max}$	[W/cm^2]	74					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 2

Table C-14: Transducer Model EC9-5/10 (Operating Mode: Color Flow)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.28	0.33	(c)	(c)	(a)	0.34
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.63					
	W_o	[mW]		14	(c)		(a)	21
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	1.54				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	5.00	5.00	(c)	(c)	(a)	5.00
	Dim of A_{aprt}	Elev. (Y) [cm]		0.70	(c)	(c)	(a)	0.70
		Azi. (X) [cm]		1.00	(c)	(c)	(a)	2.62
Other Information	PD	[µsec]	0.80					
	PRF	[Hz]	204					
	$p_r@PII_{max}$	[MPa]	0.83					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		5.00	(c)	(c)		5.00
		Y [cm]		5.00	(c)	(c)		5.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	14					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 2.33

Table C-15: Transducer Model EC9-5/10 (Operating Mode: M Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.46	0.07	(c)	(c)	(c)	0.08
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.04					
	W_o	[mW]		3	(c)		(c)	5
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	1.54				(c)	
	$d_{eq}(z_{sp})$	[cm]					(c)	
	f_c	[MHz]	5.00	5.00	(c)	(c)	(c)	5.00
	Dim of A_{aprt}	Elev. (Y) [cm]		0.70	(c)	(c)	(c)	0.70
		Azi. (X) [cm]		1.00	(c)	(c)	(c)	2.62
Other Information	PD	[µsec]	0.49					
	PRF	[Hz]	7875					
	$p_r@PII_{max}$	[MPa]	1.35					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		5.00	(c)	(c)		5.00
		Y [cm]		5.00	(c)	(c)		5.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	47					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 178.87

Table C-16: Transducer Model EC9-5/10 (Operating Mode: PW Doppler)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.16	(c)	0.12	(c)	0.07	0.17
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.36					
	W_o	[mW]		(c)	5		5	5
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	1.54				4.90	
	$d_{eq}(z_{sp})$	[cm]					0.28	
	f_c	[MHz]	5.00	(c)	5.00	(c)	5.00	5.00
	Dim of A_{aprt}	Elev. (Y) [cm]		(c)	0.70	(c)	0.70	0.70
		Azi. (X) [cm]		(c)	0.57	(c)	0.57	0.57
Other Information	PD	[µsec]	1.26					
	PRF	[Hz]	1250					
	$p_r@PII_{max}$	[MPa]	0.47					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(a)	4.00	(c)		4.00
		Y [cm]		(a)	4.00	(c)		4.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	4					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 14.97

Table C-17: Transducer Model L9-4/38 (Operating Mode: B Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.56	(a)	(a)	(a)	(a)	(a)
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.24					
	W_o	[mW]		(a)	(a)		(a)	(a)
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(a)		
	Z_1	[cm]				(a)		
	z_{bp}	[cm]				(a)		
	z_{sp}	[cm]	1.86				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	5.00	(a)	(a)	(a)	(a)	(a)
	Dim of A_{aprt}	Elev (Y) [cm]		(a)	(a)	(a)	(a)	(a)
		Azi. (X) [cm]		(a)	(a)	(a)	(a)	(a)
Other Information	PD	[µsec]	0.46					
	PRF	[Hz]	49					
	$p_r@PII_{max}$	[MPa]	1.72					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(a)	(a)	(a)		(a)
		Y [cm]		(a)	(a)	(a)		(a)
	$I_{PA.3}@MI_{max}$	[W/cm^2]	73					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 2

Table C-18: Transducer Model L9-4/38 (Operating Mode: Color Flow)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.32	0.35	(c)	(c)	(a)	0.35
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.65					
	W_o	[mW]		11	(c)		(a)	26
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	2.50				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	4.00	6.66	(c)	(c)	(a)	6.66
	Dim of A_{aprt}	Elev (Y) [cm]		0.70	(c)	(c)	(a)	0.70
		Azi. (X) [cm]		1.00	(c)	(c)	(a)	3.84
Other Information	PD	[µsec]	1.02					
	PRF	[Hz]	182					
	$p_r@PII_{max}$	[MPa]	0.92					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		5.00	(c)	(c)		5.00
		Y [cm]		5.00	(c)	(c)		5.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	19					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 3.46

Table C-19: Transducer Model L9-4/38 (Operating Mode: M Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.56	0.29	(c)	(c)	(c)	0.46
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.25					
	W_o	[mW]		12	(c)		(c)	34
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	1.85				(c)	
	$d_{eq}(z_{sp})$	[cm]					(c)	
	f_c	[MHz]	5.00	5.00	(c)	(c)	(c)	5.00
	Dim of A_{aprt}	Elev (Y) [cm]		0.70	(c)	(c)	(c)	0.70
		Azi. (X) [cm]		1.00	(c)	(c)	(c)	3.84
Other Information	PD	[µsec]	0.50					
	PRF	[Hz]	7875					
	$p_r@PII_{max}$	[MPa]	1.72					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		2.00	(a)	(a)		2.00
		Y [cm]		2.00	(a)	(a)		2.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	81					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 317.11

Table C-20: Transducer Model L9-4/38 (Operating Mode: PW Doppler)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.18	(c)	0.32	(c)	0.49	0.49
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.36					
	W_o	[mW]		(c)	17		17	17
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	3.17				3.17	
	$d_{eq}(z_{sp})$	[cm]					0.33	
	f_c	[MHz]	4.00	(c)	4.00	(c)	4.00	4.00
	Dim of A_{aprt}	Elev (Y) [cm]		(c)	0.70	(c)	0.70	0.70
		Azi. (X) [cm]		(c)	0.84	(c)	0.84	0.84
Other Information	PD	[µsec]	1.24					
	PRF	[Hz]	1250					
	$p_r@PII_{max}$	[MPa]	0.56					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(a)	4.00	(a)		4.00
		Y [cm]		(a)	4.00	(a)		4.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	7					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 84.38

Table C-21: Transducer Model L14-5/38 (Operating Mode: B Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.63	(a)	(a)	(a)	(a)	(a)
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.62					
	W_o	[mW]		(a)	(a)		(a)	(a)
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]				(a)		
	Z_1	[cm]				(a)		
	z_{bp}	[cm]				(a)		
	z_{sp}	[cm]	1.26				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	6.67	(a)	(a)	(a)	(a)	(a)
	Dim of A_{aprt}	Elev (Y) [cm]		(a)	(a)	(a)	(a)	(a)
		Azi. (X) [cm]		(a)	(a)	(a)	(a)	(a)
Other Information	PD	[µsec]	0.39					
	PRF	[Hz]	36					
	$p_r@PII_{max}$	[MPa]	2.17					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(a)	(a)	(a)		(a)
		Y [cm]		(a)	(a)	(a)		(a)
	$I_{PA.3}@MI_{max}$	[W/cm^2]	138					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 2

Table C-22: Transducer Model L14-5/38 (Operating Mode: Color Flow)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.28	0.38	(c)	(c)	(a)	0.32
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.55					
	W_o	[mW]		12	(c)	(c)	(a)	24
	min of $[W_{.3}(z_1) : I_{TA.3}(z_1)]$	[mW]						
	Z_1	[cm]						
	z_{bp}	[cm]						
	z_{sp}	[cm]	3.68				(a)	
	$d_{eq}(z_{sp})$	[cm]					(a)	
	f_c	[MHz]	4.00	6.66	(c)	(c)	(a)	6.66
	Dim of A_{aprt}	Elev. (Y) [cm]		0.70	(c)	(c)	(a)	0.70
		Azi. (X) [cm]		1.00	(c)	(c)	(a)	3.84
Other Information	PD	[µsec]	0.40					
	PRF	[Hz]	156					
	$p_r@PII_{max}$	[MPa]	0.92					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		4.00	(c)	(c)		4.00
		Y [cm]		4.00	(c)	(c)		4.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	11					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 1.42

Table C-23: Transducer Model L14-5/38 (Operating Mode: M Mode)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.63	0.39	(c)	(c)	(c)	0.31
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	1.63					
	W_o	[mW]		12	(c)		(c)	23
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	1.26				(c)	
	$d_{eq}(z_{sp})$	[cm]					(c)	
	f_c	[MHz]	6.67	6.67	(c)	(c)	(c)	6.67
	Dim of A_{aprt}	Elev. (Y) [cm]		0.70	(c)	(c)	(c)	0.70
		Azi. (X) [cm]		1.00	(c)	(c)	(c)	3.84
Other Information	PD	[µsec]	0.37					
	PRF	[Hz]	7875					
	$p_r@PII_{max}$	[MPa]	2.17					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		2.00	(c)	(c)		2.00
		Y [cm]		2.00	(c)	(c)		2.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	150					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 442.97

Table C-24: Transducer Model L14-5/38 (Operating Mode: PW Doppler)

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} >$		
Global Maximum Index Value			0.27	(c)	0.49	(c)	0.66	0.43
Assoc. Acoustic Param.	$P_{r.3}$	[MPa]	0.69					
	W_o	[mW]		(c)	15		15	15
	min of $[W_3(z_1) : I_{TA.3}(z_1)]$	[mW]				(c)		
	Z_1	[cm]				(c)		
	z_{bp}	[cm]				(c)		
	z_{sp}	[cm]	1.71				1.71	
	$d_{eq}(z_{sp})$	[cm]					0.19	
	f_c	[MHz]	6.66	(c)	6.66	(c)	6.66	6.66
	Dim of A_{aprt}	Elev. (Y) [cm]		(c)	0.70	(c)	0.70	0.70
		Azi. (X) [cm]		(c)	0.84	(c)	0.84	0.84
Other Information	PD	[µsec]	1.10					
	PRF	[Hz]	1250					
	$p_r@PII_{max}$	[MPa]	1.02					
	$d_{eq}@PII_{max}$	[cm]						
	Focal Length	X [cm]		(c)	4.00	(c)		4.00
		Y [cm]		(c)	4.00	(c)		4.00
	$I_{PA.3}@MI_{max}$	[W/cm^2]	20					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

ISPTA.3 [mW/cm2] = 193.19

C.3 ULTRASOUND INDICATIONS FOR USE TABLES

Table C-25: SONIX Ultrasound Scanner – Diagnostic Ultrasound Indications for Use Form

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P(*1)	P(*2)
Abdominal		P	P	P	P	P	P	P	P(*1)	P(*2)
Intraoperative (specify)		P	P	P		P	P	P	P(*1)	P(*2)
Intraoperative Neurological		P	P	P		P	P	P	P(*1)	P(*2)
Pediatric		P	P	P	P	P	P	P	P(*1)	P(*2)
Small Organ (specify)		P	P	P		P	P	P	P(*1)	P(*2)
Neonatal Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Adult Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Cardiac		P	P	P	P	P	P	P	P(*1)	P(*2)
Transesophageal		P	P	P		P	P	P	P(*1)	P(*2)
Transrectal		P	P	P		P	P	P	P(*1)	P(*2)
Transvaginal		P	P	P		P	P	P	P(*1)	P(*2)
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P(*1)	P(*2)
Laparoscopic										
MSK Conventional		P	P	P		P	P	P	P(*1)	P(*2)
MSK Superficial		P	P	P		P	P	P	P(*1)	P(*2)
Other (specify) (*3)		P	P	P		P	P	P	P(*1)	P(*2)

N = **N**ew indication; **P** = **P**reviously cleared

Additional Comments:

Small Organ: Breast, Thyroid, testicle

Intraoperative: Abdominal organs and vascular

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Freehand 3D imaging, live 3D imaging, Directional Power Doppler (DPD)
*3. Transcranial Doppler

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Table C-26: PA4-2/20 phased array 2.8 MHz transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P	P	P(*1)	P(*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P	P	P	P	P	P(*1)	P(*2)
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Adult Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Cardiac		P	P	P	P	P	P	P	P(*1)	P(*2)
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify) (*3)		P	P	P		P	P	P	P(*1)	P(*2)

N = **N**ew indication; **P** = **P**reviously cleared

Additional Comments:

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Freehand 3D imaging, Directional Power Doppler (DPD)
*3. Transcranial Doppler

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Table C-27: C5-2/60 convex 3.2 MHz 60mm radius transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P(*1)	P(*2)
Abdominal		P	P	P		P	P	P	P(*1)	P(*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P(*1)	P(*2)
Small Organ (specify)		P	P	P		P	P	P	P(*1)	P(*2)
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P(*1)	P(*2)
Laparoscopic										
MSK Conventional		P	P	P		P	P	P	P(*1)	P(*2)
MSK Superficial		P	P	P		P	P	P	P(*1)	P(*2)
Other (specify)										

N = **N**ew indication; **P** = **P**reviously cleared

Additional Comments:

Small Organ: Breast, Thyroid, testicle

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Freehand 3D imaging, Directional Power Doppler (DPD), Imaging for guidance of biopsy

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Table C-28: EC9-5/10 microconvex endocavity 6.6 MHz 10mm radius transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		**P**	**P**	**P**		**P**	**P**	**P**	**P(*1)**	**P(*2)**
Transvaginal		**P**	**P**	**P**		**P**	**P**	**P**	**P(*1)**	**P(*2)**
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
MSK Conventional										
MSK Superficial										
Other (specify)										

N = **N**ew indication; **P** = **P**reviously cleared

Additional Comments:

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Freehand 3D imaging, Directional Power Doppler (DPD), Imaging for guidance of biopsy

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Table C-29: L9-4/38 linear 6.5 MHz 38mm transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P(*1)	P(*2)
Abdominal		P	P	P		P	P	P	P(*1)	P(*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P(*1)	P(*2)
Small Organ (specify)		P	P	P		P	P	P	P(*1)	P(*2)
Neonatal Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Adult Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P(*1)	P(*2)
Laparoscopic										
MSK Conventional		P	P	P		P	P	P	P(*1)	P(*2)
MSK Superficial		P	P	P		P	P	P	P(*1)	P(*2)
Other (specify)										

N = **N**ew indication; **P** = **P**reviously cleared

Additional Comments:

Small Organ: Breast, Thyroid, testicle

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Freehand 3D imaging, Directional Power Doppler (DPD), Imaging for guidance of biopsy

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

Table C-30: L14-5/38 linear 8 MHz 38mm transducer

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Doppler	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal		P	P	P		P	P	P	P(*1)	P(*2)
Abdominal		P	P	P		P	P	P	P(*1)	P(*2)
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P	P		P	P	P	P(*1)	P(*2)
Small Organ (specify)		P	P	P		P	P	P	P(*1)	P(*2)
Neonatal Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Adult Cephalic		P	P	P		P	P	P	P(*1)	P(*2)
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P	P	P(*1)	P(*2)
Laparoscopic										
MSK Conventional		P	P	P		P	P	P	P(*1)	P(*2)
MSK Superficial		P	P	P		P	P	P	P(*1)	P(*2)
Other (specify)										

N = **N**ew indication; **P** = **P**reviously cleared

Additional Comments:

Small Organ: Breast, Thyroid, testicle

*1. B/M, B/PWD, B/CWD, B/CFM/PWD, B/AD/PWD, B/DPD/PWD, B/CFM/CWD, B/AD/CWD, B/DPD/CWD
*2. Freehand 3D imaging, Directional Power Doppler (DPD), Imaging for guidance of biopsy

APPENDIX D: MAINTENANCE AND CLEANING

D.1 TRANSDUCERS

D.1.1 Guidelines

Ultrasonix recommends inspecting the SONIX transducers prior to each use:

- Ensure the transducers are always clean before they are used. There must be no ultrasound gel (from previous imaging), any debris, films or unusual odors present.
- Ensure there are no cracks or other damage to the transducers before they are used. Inspect the transducer surfaces for cracks and feel for cracks with finger tips as well.

Where endocavity transducers are being used in clinical applications of a semi-critical nature (e.g., trans-rectal or trans-vaginal), ensure the transducer is covered with the appropriate STERILE transducer cover/sheath which has received regulatory clearance for use.

D.1.2 Ultrasound Coupling Gels

The following ultrasound coupling gels are recommended for use with SONIX transducers:

Table D-1: Recommended Ultrasound Coupling Gels

Gel Name	Manufacturer	Address
Aquasonic 100	Parker Laboratories, Inc	286 Eldridge Road Fairfield, NJ, 07004 USA Ph (800) 631-8888 Fax (973) 276-9510
Clear Image	Sonotech, Inc.	774 Marine Drive Bellingham, WA 98225 USA Ph (360) 671-9121 Fax (360) 671-9024
Echo-Oil®	Echo Ultrasound	R.D.#2. Box 118 Reedsville, PA 17084 USA
Echotrack®	Echo Ultrasound	R.D.#2. Box 118 Reedsville, PA 17084 USA
Ecogel 100& 200	Echo-Med Pharmaceutical Inc.	7050 Bramalea Road Unit C58 Mississauga, ON L5S 1S9 Canada Ph (905) 405-1050 Fax (905) 405-0775

Do not use gels that contain any of the following solutions:

- Acetone
- Methanol
- Denatured ethyl alcohol
- Mineral oil
- Iodine
- Any lotions or gels that contain perfume.

If there are any questions, contact Ultrasonix Medical Corporation.

D.1.3 Cleaning/Disinfecting Recommendations and Warnings for all Non-Invasive Transducers

Warnings:

Never sterilize the transducer with sterilization techniques such as autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result using the above sterilization techniques.

Use of precleaning solutions should be restricted to the external transducer face. DO NOT get solution on any other areas or surfaces of the transducer. This includes transducer connectors and contacts.

Some chemicals such as phenol, benzothonium chloride, pHisohex, benzoyl peroxide, hydrogen peroxide are commonly found in clinic and hospital settings, while others are found in antibacterial skin cleaners or lotions. ***Use of these chemicals will cause damage to your transducer.***

DO NOT use sterilization or disinfection methods that have not been recommended by Ultrasonix. Severe damage will result. Contact Ultrasonix if you have any doubt about sterilization or disinfection methods.

Warning: *Any transducer suspected of being contaminated with* ***Creutzfeld Jacob*** *disease material cannot be cleaned or sterilized.*

Contact Ultrasonix Medical Corporation to obtain instructions on the proper disposal of these transducers.

Remove the ultrasound transmission gel with a dry or water-moistened soft cloth. It is recommended that transducers are reprocessed as soon as is reasonably practical following use.

Note: *Repeated processing has minimal effect on these transducers. End of life is normally determined by wear and damage due to use. Disassembly is not required.*

D.1.3.1 Cleaning (Non-Invasive Transducers)

To Clean a Non-invasive Transducer:

1. After every patient exam, wipe the ultrasound transmission gel off the transducer.
2. Wipe the transducer and cable with a soft, dry or water-moistened cloth.
3. Wipe the transducer with either:
   - a recommended disinfectant (refer to **Table D-2**)
   - Metrizyme
   - Klenzyme
4. Remove any residue with a soft cloth moistened in water. Do not allow cleaning solutions or isopropyl alcohol to air dry on the transducer.

Table D-2: Recommended Disinfectants for Cleaning Non-Invasive Transducers

High level disinfectants	Low level disinfectants
• Cidex plus TM	• Sani-Cloth
• Wavicide®-01	• T-spray
• Omnicide TM	

D.1.3.2 Disinfecting (Non-Invasive Transducers)

The disinfectant solution may be used in accordance with the label instructions.

Table D-3: Recommended Disinfectants for Disinfecting Non-Invasive Transducers

High level disinfectants	Low level disinfectants
• Cidex plus ™	• Sani-Cloth
• Wavicide®-01	• T-spray
• Omnicide ™	

D.1.3.3 Sterilization (Non-Invasive Transducers)

Sterilization of transducers is not possible. Follow the instructions for disinfection (above) instead.

D.1.3.4 Maintenance (Non-Invasive Transducers)

Cautions:

DO NOT drop the transducers.

DO NOT hit the transducers against any surface that can dislodge or damage any of the transducer components.

DO NOT pinch or kink the transducer cable.

DO NOT use a brush to clean the transducer. (Use a soft cloth.)

DO NOT immerse the transducer scan head past the first seam in any liquid.

DO NOT soak the transducer for extended periods of time.

DO NOT rinse or immerse near the strain relief.

DO NOT use coupling gels and cleaning agents that have not been recommended by Ultrasonix.

DO NOT use sterilization or disinfection methods that have not been recommended by Ultrasonix. Severe damage will result. Contact Ultrasonix if you have any doubt about sterilization or disinfection methods. Use of non-recommended cleaning agents may cause damage to the housing and will void transducer warranties.

DO NOT use chemicals such as phenol, benzothonium chloride, pHisohex, benzoyl peroxide, hydrogen peroxide – commonly found in hospitals or clinics. These chemicals will damage the transducer.

D.1.3.5 Inspection and Testing (Non-Invasive Transducers)

Inspect the transducers prior to each use:

- always ensure the transducers are clean before they are used. There must be no ultrasound gel (from previous imaging), debris, films, or unusual odors present
- ensure there are no cracks or other damage to the transducers before they are used. Inspect the transducer surfaces for cracks and feel for cracks with finger tips as well.

Cautions:

DO NOT use transducers if they are found to be cracked, damaged or broken.

DO NOT use the transducer if the transducer cable insulation is damaged, thereby exposing the wiring.

D.1.3.6 Storing and Packaging (Non-Invasive Transducers)

Always ensure the transducer is clean and disinfected before storing/packing it. This will help to avoid contaminating the transducer holders or the foam lining of the carrying case.

- store in one of the transducer holders
- avoid storing the transducer in areas with extreme temperatures or in direct sunlight.

After placing a transducer in its carrying case, wrap the case in bubble wrap and place the wrapped case in a cardboard box.

D.1.4 Cleaning/Disinfecting Recommendations and Warnings for all Invasive Transducers

Warnings:

Never sterilize the transducer with sterilization techniques such as autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe damage will result using the above sterilization techniques.

Use of precleaning solutions should be restricted to the external transducer face. DO NOT get solution on any other areas or surfaces of the transducer. This includes transducer connectors and contacts.

Some chemicals such as phenol, benzothonium chloride, pHisohex, benzoyl peroxide, hydrogen peroxide are commonly found in clinic and hospital settings, while others are found in antibacterial skin cleaners or lotions. ***Use of these chemicals will cause damage to your transducer.***

Avoid transducer contact with strong solvents such as acetone, freon and other industrial cleansers.

DO NOT use sterilization or disinfections methods that have not been recommended by Ultrasonix. Severe damage will result. Contact Ultrasonix if you have any doubt about sterilization or disinfection methods.

Warning: *Any transducer suspected of being contaminated with* ***Creutzfeld Jacob*** *disease material cannot be cleaned or sterilized.*

Contact Ultrasonix Medical Corporation to obtain instructions on the proper disposal of these transducers.

Remove the ultrasound transmission gel with a dry or water-moistened soft cloth. It is recommended that transducers are reprocessed as soon as is reasonably practical following use.

Note: *Repeated processing has minimal effect on these transducers. End of life is normally determined by wear and damage due to use. Disassembly is not required.*

D.1.4.1 Cleaning (Invasive Transducers)

Disinfect the transducer prior to the first exam and following each exam thereafter.

To Clean an Invasive Transducer:

1. Unplug the transducer.
2. Wash the transducer head and cable with soap and water to remove any protein buildup; however do not rinse or immerse the transducer near the strain relief.
3. Disinfect the transducer with one of these disinfectants:
   - Cidex plus ™
   - Wavicide®-01
   - Omnicide ™
4. Remove the transducer from the disinfectant and rinse it thoroughly with sterile water.
5. Check the transducer for any residual organic material. If the residual glutaraldehyde is higher than 10ppm, disinfect the transducer again.

Note: *Where endocavity transducers are being used in clinical applications of a semi-critical nature (e.g., trans-rectal or trans-vaginal), ensure the transducer is covered with the appropriate sterile transducer cover/sheath which has received regulatory clearance for use.*

D.1.4.2 Disinfecting (Invasive Transducers)

The disinfectant solution may be used in accordance with the label instructions.

Table D-4: Recommended Disinfectants for Invasive Transducers

High level disinfectant
• Cidex plus ™
• Wavicide®-01
• Omnicide ™

D.1.4.3 Sterilization (Invasive Transducers)

Sterilization of transducers is not possible. Follow the instructions for disinfection (above) instead.

D.1.4.4 Maintenance (Invasive Transducers)

Cautions:

DO NOT drop the transducers.

DO NOT hit the transducers against any surface that can dislodge or damage any of the transducer components.

DO NOT pinch or kink the transducer cable.

DO NOT use a brush to clean the transducer. (Use a soft cloth.)

DO NOT immerse the transducer scan head past the first seam in any liquid.

DO NOT soak the transducer for extended periods of time.

DO NOT rinse or immerse near the strain relief.

DO NOT use coupling gels and cleaning agents that have not been recommended by Ultrasonix.

DO NOT use sterilization or disinfection methods that have not been recommended by Ultrasonix. Severe damage will result. Contact Ultrasonix if you have any doubt about sterilization or disinfection methods. Use of non-recommended cleaning agents may cause damage to the housing and will void transducer warranties.

DO NOT use chemicals such as phenol, benzothonium chloride, pHisohex, benzoyl peroxide, hydrogen peroxide – commonly found in hospitals or clinics. These chemicals will damage the transducer.

D.1.4.5 Inspection and Testing (Invasive Transducers)

Inspect the transducers prior to each use:

- always ensure the transducers are clean before they are used. There must be no ultrasound gel (from previous imaging), debris, films, or unusual odors present
- ensure there are no cracks or other damage to the transducers before they are used. Inspect the transducer surfaces for cracks and feel for cracks with finger tips as well.

Cautions:

DO NOT use transducers if they are found to be cracked, damaged, or broken.

DO NOT use the transducer if the transducer cable insulation is damaged, thereby exposing the wiring.

D.1.4.6 Storing and Packaging (Invasive Transducers)

Always ensure the transducer is clean and disinfected before storing/packing it. This will help to avoid contaminating the transducer holders or the foam lining of the carrying case.

- store in one of the transducer holders
- store the transducer separately from other instruments to avoid inadvertent transducer damage
- if storing the transducer in the original case or in a drawer, make sure the transducer is thoroughly dry.
- avoid storing the transducer in areas with extreme temperatures or in direct sunlight.

After placing a transducer in its carrying case, wrap the case in bubble wrap and place the wrapped case in a cardboard box.

D.2 SHIPPING TRANSDUCERS FOR SERVICE

It is the customer's responsibility to ensure:

- each transducer is disinfected prior to shipping (**D.1.3** and **D.1.4**)
- the transducer is properly packaged for shipment (**D.1.3.6** and **D.1.4.6**)
- all shipping waybills/paperwork is completed as per the relevant regulations and laws.

D.3 SYSTEM COMPONENTS

Ultrasonix recommends the following cleaning instructions for all external surfaces, including the cart, cables and connectors.

Cautions:

Power off and unplug the system before cleaning.

Do not spill or spray water on the controls, transducer connection receptacle, or transducer ports.

D.3.1 LCD Display

Cautions:

Power off and unplug the system prior to cleaning the LCD display.

DO NOT apply cleaning solutions directly to any surface of the LCD display.

DO NOT scratch the LCD display.

DO NOT use paper towels to clean the LCD display as they may cause damage and scratches.

NEVER use cleaning products containing any of the following on either the cabinet or the screen:

- *Abrasives*
- *Acetone*
- *Alcohol (Ethanol, Methanol or Isopropyl)*
- *Ammonia*
- *Benzene*
- *Solvents*
- *Wax.*

D.3.1.1 LCD Display Cabinet

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe down the cabinet:

- Water
- Mild detergent (PH level at or near 7) and water solution.

D.3.1.2 LCD Display Screen

Apply a small amount of water to a soft, non-abrasive cloth. Stroke the cloth across the display in one direction, moving from the top to the bottom.

Caution: *Computer wipes may be used only if they specifically state they are designed for LCD displays.*

D.3.2 Touch Screen

Cautions:

Power off and unplug the system prior to cleaning the touch screen on the operator console.

DO NOT apply the cleaning solution directly to the touch screen.

DO NOT scratch the touch screen.

DO NOT use paper towels to clean the console touch screen as they may cause damage and scratches.

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe the touch screen:

- Water
- 1% Isopropyl Alcohol.

D.3.3 Operator Console

Cautions:

Power off and unplug the system prior to cleaning the operator console.

DO NOT apply cleaning solutions directly to the operator console.

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe down the console:

- Water
- Mild detergent (PH level at or near 7) and water solution.

D.3.4 Operator Console Cover

Cautions:

Power off and unplug the system prior to cleaning the console cover.

DO NOT apply cleaning solutions directly to the console cover.

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe the console cover:

- Water
- Mild detergent (PH level at or near 7) and water solution.

D.3.5 Barcode Reader

Warning: *Disconnect the barcode reader prior to cleaning.*

Caution: *DO NOT apply cleaning solutions directly to the barcode reader.*

Note: *Barcode reader usage should not entail patient contact.*

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe the barcode reader:

- Water
- Mild detergent (PH level at or near 7) and water solution.

D.3.6 Power Cord

D.3.6.1 Retractable Power Cord or Cable Reel: Canada and USA (CEP)

Cautions:

Power off and unplug the system prior to cleaning.

DO NOT apply cleaning solutions directly to the retractable power cord.

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth. Pull the retractable power cord out to its maximum extension and wipe:

- Water
- Mild detergent (PH level at or near 7) and water solution.

D.3.6.2 Power Cord: International

Cautions:

Power off and unplug the system prior to cleaning.

DO NOT apply cleaning solutions directly to the power cord.

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe the power cord:

- Water
- Mild detergent (PH level at or near 7) and water solution.

D.3.7 Wireless Adapter

Warning: *Disconnect the wireless adapter and remove it from the bracket prior to cleaning.*

Caution: *DO NOT apply cleaning solutions directly to the wireless adapter.*

Note: *Wireless adapter usage should not entail patient contact.*

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe the wireless adapter:

- Water
- Mild detergent (PH level at or near 7) and water solution.

D.3.8 Transducer Basket

Caution: *Disconnect the transducer basket from the system prior to cleaning as per the directions on the label affixed to the system (below).*

Apply a small amount of one of the following recommended cleaning solutions to a soft, non-abrasive cloth and wipe the transducer basket:

- Water
- Mild detergent (PH level at or near 7) and water solution.

Reinstall the transducer basket when cleaning is complete.

APPENDIX E: REFERENCES

E.1 OB REFERENCES

E.1.1 Gestational Age Tables

AC (Abdominal Circumference)

Hadlock, F., et al. "Estimated Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152: (1984), 497-501.

BPD (Biparietal Diameter)

Hadlock, F., et al. "Estimated Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152 : 1984), 497-501.

CRL (Crown Rump Length)

Hadlock, F., et al. "Fetal Crown-Rump Length: Re-evaluation of Relation to Menstrual Age (5-18 weeks) with High-Resolution, Real-Time Ultrasound." Radiology, 182: (February 1992), 501-505.

FL (Femur Length)

Hadlock, F., et al. "Estimated Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152:(1984), 497-501.

GS (Gestational Sac)

Hansmann, M., et al. Ultrasound Diagnosis in Obstetrics and Gynecology. New York: Springer-Verlag, (1986)

HC (Head Circumference)

Hadlock, F., et al. "Estimated Fetal Age: Computer-Assisted Analysis of Multiple Fetal Growth Parameters." Radiology, 152:(1984), 497-501.

E.2 GENERAL REFERENCES

ACC (Acceleration)

Zwiebel, W.J. Introduction to Vascular Ultrasonography. 4th ed., W.B. Saunders Company, (2000), 52.

AT (Acceleration Time) & DT (Deceleration Time)

Oh, J.K., J.B. Seward, A.J.Tajik. The Echo Manual. 2nd ed., Lippincott, Williams, and Wikins, (1999), 219.

APPENDIX F: GLOSSARY

F.1 ABBREVIATIONS AND ACRONYMS

% A Red ..... Percent Area Reduction

% Area Red .. Percent Area Reduction

% D Red ..... Percent Diameter Reduction

% Diam Red . Percent Diameter Reduction

2D ..... Two Dimensional

3D ..... Three Dimensional

4D ..... Four Dimensional (Live 3D)

4DC ..... 4D Curved Array Transducer

Abd ..... Abdomen

AC ..... Abdominal Circumference

AC ..... Alternating Current (power supply)

ACC ..... Acceleration

AD ..... Angio Doppler

Admin ..... Administrative/Administrator

AE ..... Application Entity (DICOM)

AFI ..... Amniotic Fluid Index

AFV ..... Amniotic Fluid Volume

AIUM ..... American Institute of Ultrasound in Medicine

ALARA ..... As Low As Reasonably Achievable

Ao ..... Aorta

AO/LA ..... Aorta/Left Atrium

AoV ..... Aortic Valve

AP ..... Anterior Posterior

APD ..... Anterior Posterior Diameter

APTD ..... Anterior Posterior Thorax Diameter

AR ..... Area

AT ..... Acceleration Time

AUA ..... Average Ultrasound Age

AV ..... Aortic Valve

AVI ..... Audio Video Interleave

AVm ..... Mean Average Velocity

AVp ..... Peak Average Velocity

B/M Mode ..... 2D and M-Mode

Base ..... Baseline (i.e., Doppler Baseline)

BBT ..... Basal Body Temperature

BGR ..... Blue Green Red

BMP ..... Bitmap

BNC ..... Bayonet Neill Concelman

BPD ..... Biparietal Diameter

BLT ..... Bottom Left

BRT ..... Bottom Right

BSA ..... Body Surface Area

Calcs ..... Calculations

Card ..... Cardiology

CCA ..... Common Carotid Artery

CD ..... Compact Disc

Cereb ..... Cerebellum

CEREB ..... Cerebellum

CFM ..... Color Flow Mode

CI ..... Cephalic Index

CIR ..... Circumference

COR ..... Coronal

CRL ..... Crown Rump Length

CSA ..... Cross Sectional Area

CW ..... Continuous Wave

CWD ..... Continuous Wave Doppler

DEL ..... Delete

DICOM ..... Digital Imaging and Communications in Medicine

DIST ..... Distal

Dist ..... Distance

DPD.....Directional Power Doppler

DT.....Deceleration Time

DVD.....Digital Video Device

Dyn .....Dynamic Range

EC .....Endocavity

ECA.....External Carotid Artery

EDD.....Estimated Date of Delivery

EDV.....End Diastolic Velocity

EDVPG .....EDV Pressure Gradient

EF.....Ejection Fraction

EFW .....Estimated Fetal Weight

EMC .....Electro-Magnetic Compatibility

EPO.....Emergency Power OFF

EPSS .....E Point Septal Separation

ET.....Elapsed Time

EV.....Endovaginal

FDA.....U.S. Food and Drug Administration

FHR.....Fetal Heart Rate

FL .....Femur Length

FOV.....Field Of View

FP.....False Positive

FPS .....Frames per second

FN.....False Negative

FR.....Frame Rate

FrD .....Doppler Transmit Frequency

Freq .....Frequency

FrRate.....Frame Rate

FTA .....Fetal Trunk Area

GA.....Gestational Age

Gb .....Gigabyte

Gen .....General

GIF .....Graphics Interchange File or Format

GS .....Gestational Sac

Gyn .....Gynecology

HC .....Head Circumference

HIPAA.....Health Insurance Portability & Accountability Act

HL.....Humeral Length

HR .....Heart Rate

ICA .....Internal Carotid Artery

ICT.....Intracavity Transducer

IP .....Internet Protocol

ISP.....Internet Service Provider

IT .....Information Technology (e.g., IT Department)

IVS.....Interventricular Septum

IVSd .....Interventricular Septum diastole

IVSs .....Interventricular Septum systole

JPEG.....Joint Photographic Experts Group

Kb.....Kilobyte

LA.....Long Axis

LA.....Left Atrium

LAT .....Lateral

LCD.....Liquid Crystal Display

LMP.....Last Menstrual Period

LONG.....Longitudinal

LOV.....Left Ovary

LT .....Left

LVDd.....Left Ventricular Diameter diastole

LVDs .....Left Ventricular Diameter systole

LVOT.....Left Ventricular Outflow Tract

LVPWd .....Left Ventricular Posterior Wall diastole

LVPWs.....Left Ventricular Posterior Wall systole

Mb .....Megabyte

MCA.....Middle Cerebral Artery

MED .....Medial

MGr.....Mean Gradient

MI .....Mechanical Index

M-M.....Motion Mode

MP3..... Moving Picture (Experts Group Audio Layer) 3
MPEG ..... Moving Picture Experts Group
MPG..... Moving Picture (Experts) Group
MPR..... Multiplanar Reconstruction
Msk..... Musculoskeletal
MV..... Mean Velocity
MV..... Mitral Valve
NEMA ..... National Electrical Manufacturers Association
NF ..... Nuchal Fold
NT ..... Nuchal Thickness
NTSC ..... National Television Standards Committee
OB..... Obstetrics
OD..... Optical Density
OEM..... Original Equipment Manufacturer
OFD ..... Occipital-Frontal Diameter
OOD..... Outer Orbital Diameter
PA ..... Phased Array
PAL..... Phased Alternating Line
Pano ..... Panoramic Imaging Mode
PDF..... Portable Document Format
Pel..... Pelvis
Pen ..... Penetration
Persist..... Persistence
PGr ..... Pressure Gradient
PHT..... Pressure Half Time
PI..... Pulsatility Index
PIN..... Personal Identification Number
Picto ..... Pictogram
PNG ..... Portable Network Graphics
PostV Blad ... Post Void Bladder
PPT..... Power Point (Windows)
PreV Blad ..... Pre Void Bladder
PRF..... Pulse Repetition Frequency
PROX..... Proximal
PSV..... Peak Systolic Velocity
PSVPG ..... PSV Pressure Gradient
PV ..... Peak Velocity
PV ..... Pulmonary Valve
PW ..... Pulsed Wave Doppler
PWD..... Power Doppler
Q ..... Quadrant (e.g., AFI)
Rad ..... Radius
Rect ..... Rectangle
Res ..... Resolution
RF ..... Radio Frequency
RGB..... Red Green Blue
RI..... Resistive Index
ROI..... Region of Interest
ROV ..... Right Ovary
RT ..... Right
RVDd ..... Right Ventricular Dimension diastole
RVDs ..... Right Ventricular Dimension systole
RVOT..... Right Ventricular Outflow Tract
RVWd ..... Right Ventricular Wall diastole
RVWs ..... Right Ventricular Wall systole
SA ..... Short Axis
SAG ..... Sagital
SCP..... Service Class Provider
SCU ..... Service Class User
SD ..... Standard Deviation
SD ..... Systolic/Diastolic Ratio
SDK ..... Software Development Kit
SEL..... Select
Simult..... Simultaneous
SMTP..... Simple Mail Transport Protocol
SV ..... Sample Volume
SV ..... Stroke Volume
TCP..... Transfer Control Protocol

TCP/IP .....Transmission Control Protocol/Internet Protocol

TFT.....Thin Film Technology

TGC.....Time Gain Compensation

THI.....Tissue Harmonic Imaging

TI .....Thermal Index

TIB.....Thermal Index – Bone

TIC.....Thermal Index – Cranial

TIS.....Thermal Index – Soft Tissue

TL .....Tibia Length

TLS .....Technically Limited Study

TN.....True Negative

TP.....True Positive

TRANS.....Transverse

Transp.....Transparency

TRUS .....Transrectal Ultrasound

TTD .....Transverse Trunk Diameter

TV.....Tricuspid Valve

UI.....User Interface

UL.....Ulnar Length

UL.....Underwriter's Laboratory

ULT .....Upper Left

Umb A .....Umbilical Artery

UPS.....Uninterruptible Power Supply

URL.....Uniform Resource Locator

URT.....Upper Right

US .....Ultrasound

USB.....Universal Serial Bus

VAC.....Volts Alternating Current

VCR.....Video Cassette Recorder

Vel.....Velocity

Vol.....Volume

VPS.....Volumes per Second

VR .....Volume Rendering

VTI.....Velocity Time Integral

WEP.....Wired Equivalent Privacy

WF.....Wall Filter

WMA .....Windows Media Audio

WMV .....Windows Media Video

WPA.....Wi-Fi Protected Access

WWW.....World Wide Web

YS.....Yolk Sack