SONIVATE MEDICAL, INC.

SonicEye® Dual-Array Ultrasound System

Model# SDA-001

Part Number: 18210

SonicEye® User Manual

Version 1.0

OPERATING DOCUMENTATION

Regulatory Requirement

This manual is a reference for the SonicEye® only. This manual is a reference for the SonicEye® software release 1.0. (SonicEye® is a Registered Trademark and exclusive property of Sonivate Medical, Inc.)

i SonicEye – CONFORMANCE STANDARDS

The SONIVATE product families are tested to meet all applicable requirements. Any changes to accessories, peripheral units or any other part of the system must be approved by the manufacturer: SONIVATE MEDICAL, INC. for SonicEye Dual-Array Ultrasound System. Ignoring this advice may compromise the regulatory approvals obtained for the product.

This product complies with the regulatory requirement IEC60601-1, 3rd Edition for medical electrical equipment; general requirements for basic safety and essential performance.

This product complies with IEC60601-2-37, Edition 2.1 2015 the Medical Electrical Equipment, Part 1; General Requirements for Safety. This includes requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

This product complies with IEC60601-1-2 Medical Electrical Equipment - part 1-2. Collateral standard: Electromagnetic compatibility - Requirements and tests.

This product also complies with:

NEMA UD-2: 2004 acoustic output measurements

ISO10993-1 Biological evaluation of medical devices.

ISO 14971 application of risk management to medical devices.

ii SonicEye – COUNTRY SPECIFIC APPROVALS AND ENVIRONMENTAL REQUIREMENTS

Country Specific Approvals:
United States of America

Environmental Requirements:
NOTE: Avoid exposing the unit to saline moisture.

Requirement Temperature:
Operational 0°C to 35°C (32°F to 95°F)
Nonoperational -35°C to 65°C (-29°F to 149°F)

Humidity 30% to 75% RH non-condensing

Operating non-condensing Air Pressure 700HPA to 1060HPA

iii SonicEye – TYPE BF APPLIED PART AND CLASS II EQUIPMENT

The SonicEye is an internally powered device, type BF APPLIED PART providing a specified degree of protection against electric shock, with regard to allowable LEAKAGE CURRENT. This includes the transducer array.

Normal mode Single fault condition
Patient leakage current will normally be between 100 micro Amps and 500 micro Amps.

Class II Equipment:
Type and degree of protection against electric shock:
• SonicEye is internally powered by its battery while operated during scanning; it may also be used with the provided AC adapter.
• The AC adapter is Class II and a medical grade.

EQUIPMENT in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions.

iv SonicEye - ORIGINAL DOCUMENTATION

• The original document was written in English.

Table of Contents

Table of Contents

Chapter 1 - Introduction

CONTENTS:

GENERAL DESCRIPTION

SonicEye® Dual-Array Ultrasound System employs an innovative and unique design that combines two transducers (high frequency linear and low frequency phased arrays) into a single, finger-mounted probe connected to an image processor. The system operates in B-Mode ONLY. The image processor is connected to a tablet that contains an application that guides the user through the eFAST exam or in Manual mode accommodates other applications such as IV-line placement, musculoskeletal (MSK), nerve block, etc.

SonicEye is a battery operated, general purpose ultrasound imaging system. With the supplied, approved charger, it can be used with 100-240 VAC and the charger may be used during patient scanning.

ULTRASOUND PRINCIPLES OF OPERATION

Ultrasound for medical applications can be traced back to the 1950's with initial medical use by John Wild and John Reid. Medical ultrasound images are created by an image processor through the transmission and reception of high-frequency waves through a probe. These waves transmitted through the body, producing an echo where density changes occur. The echoes return to the probe where they are converted back into electrical signals. These echo signals are processed by the image processor into a series of digital image signals and then displayed on a monitor.

SAFETY

Read and understand all instructions in the User's Manual before attempting to use SonicEye. The manual should be accessible at all times. Periodically review the procedures for operation and safety precautions.

All information in Chapter 6 'Safety' should be read and understood before operating SonicEye.

INDICATION FOR USE

The SonicEye ultrasound unit is intended for the following applications:

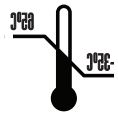
- Fetal
- Abdominal
- Peripheral vessel
- Thoracic/pleural
- Cardiac adult and pediatric
- Pediatric
- Musculoskeletal conventional and superficial
- Small parts (breast, thyroid, testes)

CONTRAINDICATION

The SonicEye ultrasound unit is not intended for intracavity, intra-operative, or ophthalmic use or any use causing the acoustic beam to pass through the eye.

CONVENTIONS USED IN THIS MANUAL

Symbols used on the SonicEye® system and associated packaging are defined here for user reference.

Symbol	Definition
SN	Designates the SonicEye® serial number assigned during manufacture.
REF	Designates the SonicEye® Part or Reference Number assigned to the system – image processor and probe.
	Indicates the legal manufacturer
	Caution, consult accompanying documents.
	Type BF patient applied part (B=body, F=floating applied part) including the transducer array
	Power On/Off Button
	Prescription only - device restricted to use by or on the order of a physician
	Not for general waste; see local disposal guidelines
	Must Reach Manual
	Relative Humidity
	Temperature
	Pressure
	Keep Dry
	Fragile

CONVENTIONS USED IN THIS MANUAL (continued)

The following conventions are also used throughout this user guide:

- **DANGER** is used to indicate a specific hazard exists that, given inappropriate conditions or actions, will cause severe or fatal personal injury with or without substantial property damage.
- WARNING is used to convey information to prevent injury or loss of life.
- CAUTION is used to convey information regarding special care to be exercised by the user for the safe and effective use of the device.

CAUTION USA only:
United States law restricts this device to sale or use by, or on the order of a physician. ℞ Only

WARNINGS
To prevent damage of the equipment or injury to yourself or others, read the following safety warnings before using the SonicEye.

- Handle SonicEye and its accessories with care. Do not subject SonicEye to mechanical shock or impact.
- Do not attempt to disassemble or alter any part of the unit including the probe, the battery, the AC/DC adapter and accessories. Disassembly or modification may result in electrical shock.
- Stop using the unit if it emits smoke or noxious fumes. Failure to do so may result in electrical shock or fire.
- Stop using the unit if the casing is damaged, including the probe. Failure to do so may result in electrical shock.
- Do not use the AC/DC adapter if showing visible damage.
- Use only the supplied power accessories (battery and charger). Failure to do so may result in electrical shock or fire or damage to unit.
- Do not immerse or expose the image processor to water.
- To reduce risk for electrical shock, do not plug or unplug the AC/DC adapter from mains socket with wet hands.
- Avoid dropping or subjecting the unit to corrosive liquid. This could result in electrical shock, and injury.
- Disconnect the image processor charger when not in use to avoid fire hazard.
- Keep the charger dry. Failure to observe this precaution may result in fire and electric shock
- Keep this unit out of reach of children.

CONTACT INFORMATION

When contacting Sonivate you will have to provide SN

Sonivate Medical, Inc.
4640 SW Macadam Ave., Suite 200
Portland, OR 97239
www.Sonivate.com
inquire@sonivate.com

Chapter 2 - Preparing the SonicEye for Use

CONTENTS:

SonicEye DUAL-ARRAY ULTRASOUND SYSTEM PACKAGE CONTENTS

Make sure all items listed below are included in the package.

1. SonicEye Cradle
2. SonicEye Image Processor unit with Dual-Array probe
3. 1 USB cable
4. 1 charging adapter for SonicEye (Model GSM36B05-P1J)
5. Tablet (Model B01J67JHK), charger (Model AW018WR-0500300UH) and the SonicEye App preinstalled
    a. SonicEye User and Reference Guide preinstalled on the tablet
    b. ALARA Brochure preinstalled on the tablet

SYSTEM DESCRIPTION

System overview

The SonicEye device (Figure 2.1a):

1. SonicEye Cradle (storage and display accessory)
2. Image Processor (6.18” L x 4.17” W x 1.14” H) with Dual-Array Probe (2.50” L x 1.15” W x 1.25” H) weight in total is less than 16 oz.
    a. Image Processor charger
    b. Two port covers for the data and power outlets when system is not in use
3. Operates in B-Mode only.
4. Approved Vanquisher 8-inch Industrial Rugged Tablet PC by Sinicvision Technologies (8” L x 5.8” W x 0.7” H).
5. Vanquisher Tablet charger
6. One USB cable; one end is USB-A (larger) and one end is USB-C (smaller)

NOTE: SonicEye Dual-Array Ultrasound System has a Reference Number or **REF** and each manufactured unit has a unique Serial Number or **SN** More details can be found in Chapter 6, Device Labels.

REGISTRATION

Prior to charging the tablet and Image Processor go to www.Sonivate.com and register the product. Go to “Registration” and follow the directions to input the Reference Number REF of the system, the Serial Number SN along with other requested data.

CRADLE ASSEMBLY

The SonicEye cradle holds the tablet and Image Processor in the shipping case (Figure 2.01). Detach the Image Processor by sliding it out of the cradle and insert the handles into the slots (Figure 2.02) on the tablet holder to form a kick stand (Figure 2.02). The fan exhaust should allow for proper ventilation (Arrow).

Figure 2.01

Figure 2.02

Figure 2.03

CHARGING THE SYSTEM

Charge the Tablet and Image Processor: The batteries are not fully charged at shipment. Plug the Tablet adapter into an AC electrical outlet and then plug the BLACK colored adapter cord into the tablet (Figure 2.1b). Plug the Image Processor adapter into an AC electrical outlet and then plug the WHITE colored adapter cord into the Power Input for the Image Processor. Do not turn on either unit.

CAUTION Only use the AC/DC adapters supplied.

SonicEye AC/DC Adapter: Mean Well, Model GSM36B05-P1J, AC/DC Medical Adapter; Input: 100-240 VAC, 50-60 Hz, 0.9-0.45A; Output: 5Vdc, 4.5A, 22.5W Max (Smaller, USB-C, connector to be inserted into the Power Input i.e. Figure 2.1c - to the Image Processor for charging). The Power input is adjacent to the On/Off light on the right side of the Image Processor.

Figure 2.1b

Figure 2.1c

Tablet AC Adapter: Model AW018WR-0500300UH; Input: 100-240V, 50/60Hz, 0.5A; Output: 5V, 3A.

To achieve maximum charging capacity with your SonicEye Tablet and Image Processor batteries, you should allow the battery to be fully charged and then fully discharged at least three times. The unit can be used as normal during these cycles. Once these initial charging/discharging cycles are performed, the following is applicable without reducing the life time of the battery:

- It is not necessary to completely discharge the battery before re-charging it.
- It is possible to stop charging the battery before it is fully charged, but the battery will then be discharged more rapidly.
- It is possible to charge the battery several times each day, if needed.

Item Specification

- Charging time about 1.5 hour
- Capacity about 1 hour and 30 minutes active use*
- Lifetime At least 300 charges

* Assuming a new battery. Batteries generally degrade by aging and number of recharging cycles and will have reduced capacity over time.

Once charged, the tablet and Image Processor can run off of their battery power or operate using the chargers.

SONICEYE ACTIVATION

Once both the tablet and Image Processor are charged, SonicEye is ready to be connected to the tablet. The USB connection will transmit the data from the Image Processor to the tablet. The small, USB-C, connection to be inserted into the Image Processor (left side of Image Processor and adjacent to Power On button- Figure 2.1d); the larger end, USB-A, to be inserted into the tablet (located adjacent to the charger input). After the two are connected, then turn the tablet on by pushing the Power On button . Hold down until red power

Figure 2.1d

CRADLE ASSEMBLY

The SonicEye cradle holds the tablet and Image Processor in the shipping case (Figure 2.01). Detach the Image Processor by sliding it out of the cradle and insert the handles into the slots (Figure 2.02) on the tablet holder to form a kick stand (Figure 2.02). The fan exhaust should allow for proper ventilation (Arrow).

CAUTION Once initialized, the system will ask for a Password. The initial Password is 1 2 3 4. The Password should be modified in the tablet settings.

SonicEye AC/DC Adapter: Mean Well, Model GSM36B05-P1J, AC/DC Medical Adapter; Input: 100-240 VAC, 50-60 Hz, 0.9-0.45A; Output: 5Vdc, 4.5A, 22.5W Max (Smaller, USB-C, connector to be inserted into the Power Input i.e. Figure 2.1c - to the Image Processor for charging). The Power input is adjacent to the On/Off light on the right side of the Image Processor.

The Image Processor is initialized by pushing the Power On icon. The power light will turn GREEN to indicate it is on and then turn to RED to indicate the system is running off of the battery. Once the tablet and Image Processor are initialized, DOUBLE TAP the SONICEYE ICON (Figure 2.2a). The system will begin initiating the hardware (Figure 2.2b).

Figure 2.2a

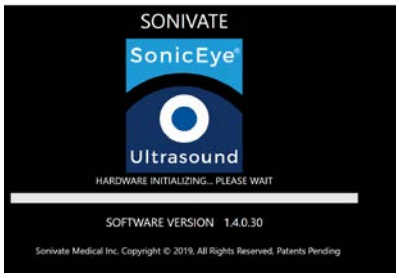


Figure 2.2b

GRAPHICAL USER INTERFACE OVERVIEW

Once the system is initialized, the HOME SCREEN (Figure 2.3) will appear. This is the Main Menu from which all activities are accessed. ONE TAP any icon to open that section or “X” to Exit or Log Off from the system.

A more detailed description about each section’s operation is contained in Chapter 3.

Figure 2.3

The Settings section (Figure 2.4a) is where SonicEye can be customized to each user. Enter the Organization and User using a pop-up keyboard. The system will always operate in Landscape. The User may adjust left or right handed, in Operation as well as being to set the system on "Tactical" light mode (Figure 2.4b).

The system will start with the installed pre-set including: Starting View (Landscape), Operation (LEFT), and Tactical (Off). Changes need to be manually inputted.

Figure 2.4a

Figure 2.4b

The Patient section (Figure 2.5) is where the individual data (Name, Male/Female, Social Security Number, Date of Birth, ID and UTA – "Unable To Attain") is recorded. This creates a patient record containing those scans that were conducted and saved for each patient. Observations can be included per patient. See Chapter 3 for more detail.

When observations are desired to be added, ONE TAP the NOTES icon and a pop-up menu will appear.

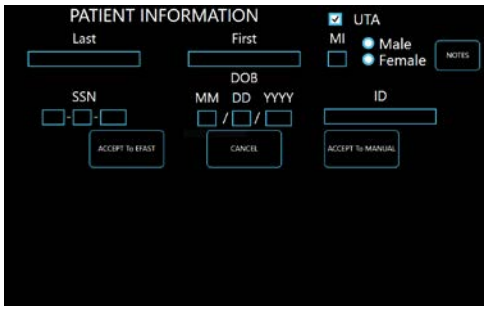


Figure 2.5

The Scan: eFAST section (Figure 2.6a & 2.6b) is the heart of the Sonivate system for the novice ultrasound user. These screens guide one through the nine views of the eFAST exam, indicates approximate location for the probe to be placed and pre-sets frequency, depth and brightness depending upon the exam location. The guide is color coded: **GREEN** = Completed; **BLUE** = Being Conducted; and **RED** = Incomplete/To be Done. Figure 2.6a shows a view (RUQ1) with the Phased Array (views 1-7) and Figure 2.6b shows a view with the High Frequency Linear Array (8-9). For each view the user can save up to four images or clips. ONE TAP the VIEW icon to raise or lower the eFAST placement views. To advance to the next View, the Views must be in the raised position (Figure 2.6b). To access Settings, Patient Records, etc. ONE TAP the DOCK icon (Figure 2.6b)

Figure 2.6a

Figure 2.6b

The **Scan: Manual** section (Figure 2.7 shown in Tactical View) is for the more experienced user and it allows the freedom to switch back and forth between the phased array and the high frequency array with ONE TAP. It also provides up to nine specific ultrasound scan views, each with one scan or clip saved. For each scan view, a pop-up menu is available to identify the scan type/location.

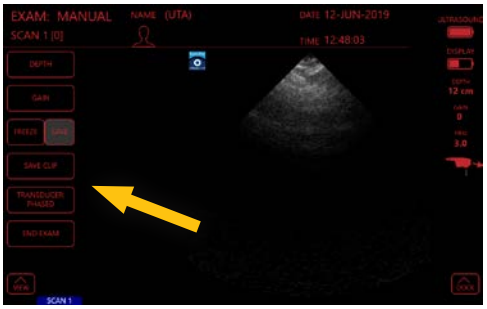


Figure 2.7

Learn section (Figure 2.8) is a refresher tutorial for the eFAST exam and an introduction to using the SonicEye finger probe. No internet is needed to view either.

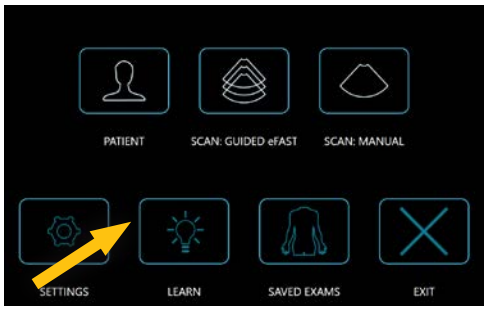


Figure 2.7

Image display on SonicEye is dependent of the ambient light, IF POSSIBLE, avoid direct sun light on the display when scanning and reviewing images.

ONE TAP “X” to Exit (Figure 2.9) the Home Screen to return to the main tablet screen.

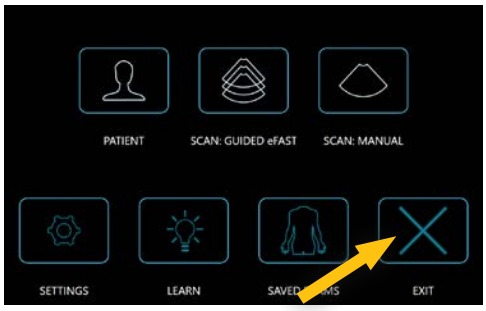


Figure 2.9

Then to exit the system ONE TAP the YES button or NO if EXIT was tapped accidently (Figure 2.10)

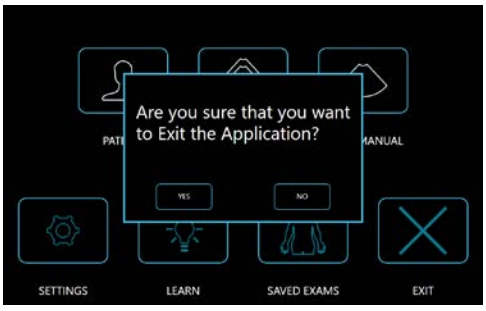


Figure 2.9

THE SONICEYE IS READY FOR USE.

When SonicEye is not planned on being used for scanning within 10 minutes, it is recommended to EXIT the system and return to the tablet home screen.

Chapter 3 - Using SonicEye

CONTENTS:

PATIENT DATA ENTRY:

ONE TAP on the Patient ICON located on the HOME SCREEN. The Patient screen will appear. TOUCH the location of the Patient's Last Name and a key board will appear. Touch each letter or number as needed. Move to the next data field. NOT ALL OF THE DATA FIELDS NEED TO BE ENTERED. If none of the information is available, the UTA button is the default. Close the keyboard using the "X". and then ONE TAP "Accept eFAST". Or "Accept Manual" and the system will go to the desired exam. The Patient record is complete, and all saved images will be assigned to this Patient or UTA by date and time.. (Figure 3.1)

Figure 3.1

CAUTION When scanning several patients make sure to create a new patient record for each.

SCANNING:

General Scanning Recommendations:
Before each use:
• Inspect the probe (see Inspecting the probe- Chapter 5).

CAUTION If any damage is found on the probe or its cable, DO NOT use SonicEye.

After each use:
- Inspect the probe (see Inspecting the probe – Chapter 5)
- Clean the probe (see Disinfection – Chapter 5).

Use of Gel:
To assure optimal transmission of energy between the patient and the probe, a conductive gel must be applied on the probe lens.

WARNING Do not apply gel to the eyes. If there is gel contact to the eye, flush eye thoroughly with water.

The following gels have been tested to be compatible with the Dual-Array probe:
Aquasonics 100; Parker Laboratory, Inc.
Clear Image; Sonotech, Inc.

CAUTION Coupling gels should not contain the following ingredients as they are known to cause probe damage:
- Methanol, ethanol, isopropanol, or any other alcohol-based product
- Mineral and Olive Oils
- Iodine
- Lotions including Aloe Vera, Lanoline, etc.

Other Considerations:
Like most high frequency computing devices, the electronic components of SonicEye will generate some heat while operating normally and as intended. SonicEye is equipped with safety mechanisms which will automatically reduce computing speed (frame rate), and ultimately shut down the device, before any risk of overheating occurs.

SonicEye can be operated by battery or through its supplied chargers. The supplied adapter should always have a 100-240 ACV plug nearby for connection or disconnection. There is no on/off switch for the adapters, to completely disconnect them, they must be removed from the outlet.

Probe Orientation:
The probe is provided with an orientation notch. This mark correlates to the first channel on the array and is generally pointed in the direction of the head or right side of the patient.

Probe Orientation:
The probe is provided with an orientation notch for image position, one for each array. These marks correlates to the  icon on the screen during scans.

Probe Overview:
The Dual-Array Probe has two probes built into one. It contains both a low frequency phased transducer array and a high frequency linear transducer array (Figure 3.2).

Low Frequency Phased Array: The phased array is located on the “fingertip” position of the dual-array. The phased array is used for deep body scans and best suited to determine internal bleeding when conducting the eFAST exam. It is designed to function at a low frequency (MHZ) and the ultrasound wave is transmitted in a triangular shape.

High Frequency Linear Array (HFL): The high frequency linear array is located underneath the “fingertip” position of the dual-array. The HFL array is used for near field scans and best suited to determine pneumothorax (PTX) or collapsed lung when conducting the eFAST exam. Because of its near field clarity, it is also suited for musculoskeletal (MSK) evaluations, biopsies, line placements, etc. It is designed to function at a relative high frequency (MHZ) and the ultrasound wave is transmitted in a rectangular shape.

The probe is ergonomically designed to be gripped like a traditional probe or stabilized using the finger insert. The finger insert is elastomeric and will conform to 95% of finger diameters.

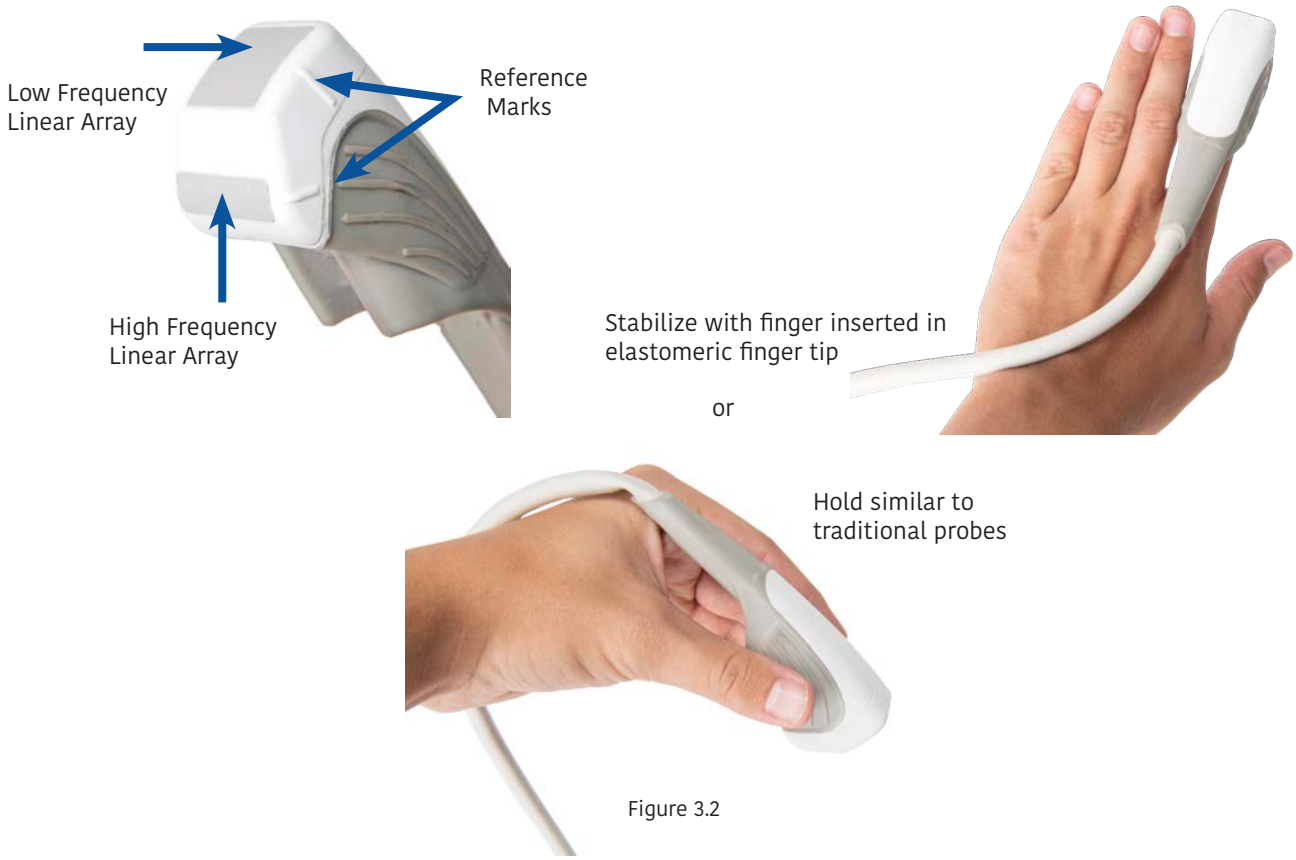


Figure 3.2

Pre-sets:
SonicEye comes with already established pre-sets for frequency, depth and contrast (brightness). Only Depth and Contrast may be adjusted by the user within an eFAST exam. In Manual scanning, the transducer can be selected by the user.

Array Type: During the eFAST exam the SonicEye system automatically pre-sets which array is in use depending upon the exam location. For all internal bleeding exams (Views 1-7) the Phased Array will be used. For PTX, the HFL will be used (Views 8-9). The Array in use is also shown on the Probe ICON on the screen. Manual Mode will always begin with the Phased Array.

Frequency: The Phased or 90 sector Array is pre-set at 3.0 MHZ with a footprint of 18 mm X 18 mm and the High Frequency Linear Array is set at 7.5 MHZ with a footprint of 7 mm X 22 mm. The frequencies are indicated on the operating screens during an exam (Figure 3.3a and b). THERE IS NO FREQUENCY ADJUSTMENT.

Depth Default Setting and Adjustment: In eFAST Mode, depth is pre-set for the phased array at 16 cm (with the PLAX pre-set at 12 cm) and the HFL is pre-set at 4 cm. These can then be adjusted accordingly by ONE TAP on the “Depth” button and then ONE TAP on the desired depth. (Figure 3.3a). In Manual Mode, depth is pre-set for the phased array is at 12 cm and the HFL is pre-set at 4 cm.

The Dual-Array Probe has two probes built into one. It contains both a low frequency phased Gain Default Setting and Adjustment (Image Brightness/Contrast): Regardless of which mode the system is in, gain is pre-set for both arrays at "0". These can then be adjusted accordingly by ONE TAP on the "Gain" button and then ONE TAP on the increase or decrease position. (Figure 3.3b)

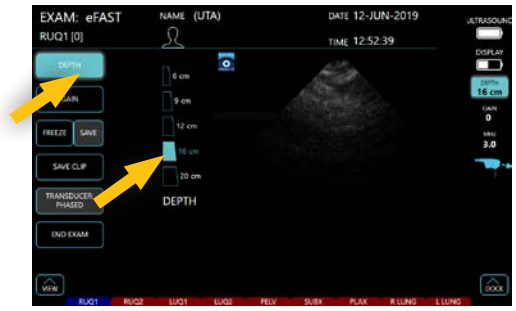


Figure 3.3a

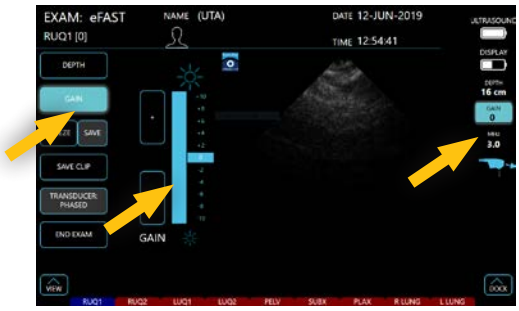


Figure 3.3b

BATTERY LEVEL INDICATORS:
There are two battery level indicators on both the eFAST and Manual screens in the upper right corner. When the Image processor goes below 25% it will blink (Figure 3.3b). There is also a battery level light on the Image Processor as well.

Scanning in Guided eFAST Exam Mode:

The guided eFAST exam interface option provides novice sonographers with an interactive graphical display of the windows required to complete the eFAST exam. Upon selecting this mode, the machine will default to the Phased Array probe, and the Right Upper Quadrant #1 ("RUQ1") window will be highlighted in **BLUE** (Figure 3.4a). The user can proceed with scanning the right upper quadrant or, if desired, select the anatomical region which he/she prefers to scan first. The **BLUE** window represents the current window in which the user is scanning. **RED** windows represent windows in which the user has not saved images or clips. To advance to the next desired window, the user must select the window to be scanned. Selecting the lung windows will automatically activate the HFL for scanning. (Figure 3.4b). Observations can be added by ONE TAP to the Patient icon and returning to the Patient Record (Figure 3.4a)

**Note 1 – RUQ1 and RUQ2 windows are included to prompt the user to ensure they are considering the two primary potential spaces where free fluid to collect. These include the hepatorenal interface (Morison's Pouch) and the paracolic gutter (tip of liver, inferior pole of kidney)

**Note 2 – LUQ1 and LUQ2 windows are included to prompt the user to ensure they are considering the two primary potential spaces where free fluid to collect. These include the splenorenal recess and space between diaphragm and spleen.

Figure 3.4a

Figure 3.4b

Saving Images – Still images can only be saved after the image is frozen. To freeze an image while scanning your target structure, ONE TAP the "Freeze" button. While the image is frozen, the user can opt to "Unfreeze" the image and continue scanning, or ONE TAP to "Save" the image. Once an image is saved in a window, that window will turn to **GREEN** (Figure 3.5) alerting the user that an image was saved and that window has been completed. The number of images stored in each window will be annotated at the top left of the window. A maximum of 4 still images can be saved in each window.

Saving CineLoops or "Clips" – While scanning, the user can select the "Save Clip" tab. Once the "Save Clip" tab is selected, the machine will then record the following 3 seconds of scanning and automatically store the clip in the window in which you are scanning. The number of video clips stored in each window will also be displayed on the window. See Figure 3.6

Figure 3.6

Reviewing Images – The user may review the stored images at any time during an exam. To do so, the user can open the eFAST window bar, select which window's images is to be reviewed. The available images will pop up and allow the user to select which image to review (Figure 3.7).

Figure 3.7

Once an image is selected, it will be displayed on the main screen (Figure 3.8). Users can opt to discard it by ONE TAP the "trash" icon or select another image within that window to review. When finished reviewing, users may return to scanning by ONE TAP of the "return" option.

Figure 3.8

When the user has completed the exam, ONE TAP the “End Exam” button. This will prompt a pop-up window that will allow the user to confirm the exam is complete, and provide options to continue the exam, save and exit, or abort the exam and exit, which will result in the exam not being saved. (Figure 3.9)

Figure 3.9

Scanning in Manual Mode:
Manual Mode option offers the user the flexibility to perform exams at his/her own discretion. Depth and gain can be modified in the same manner noted in “Scanning Section” previously. The user can select which transducer is active by ONE TAPPING the transducer tab (Figure 3.10). The transducer that is currently active will be annotated by the icon at the right of the image.

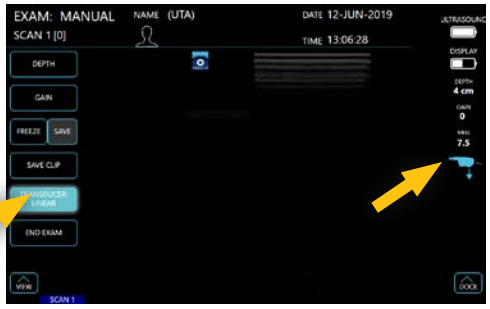


Figure 3.10

Labeling the Scan in Manual Mode – The title of each window will default to “scan #” but can be renamed by Taping the Scan Icon, which prompts a pop-up keyboard which allows the user to title each window as desired (less than 8 characters). Figure 3.11. A maximum of 1 still images or clip can be saved in each scan or view window.

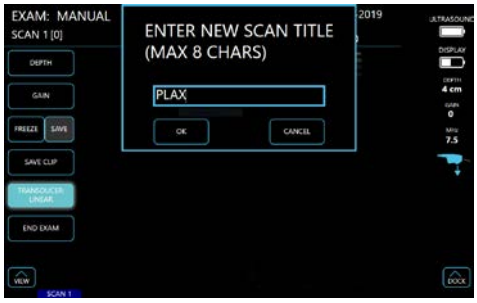


Figure 3.11

Saving Images – Still images can only be saved after the image is frozen. To freeze an image while scanning your target structure, ONE TAP the “Freeze” tab. While the image is frozen, the user can opt to “Unfreeze” the image and continue scanning, or ONE TAP to “Save” the image. Once an image is saved, it will be displayed at the bottom of the screen within a panel of windows. The number of images stored in each window will be annotated at the top left of the window. (Figures 3.12a and 3.12b)

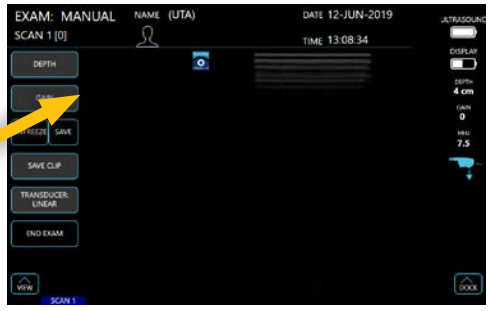


Figure 3.12a

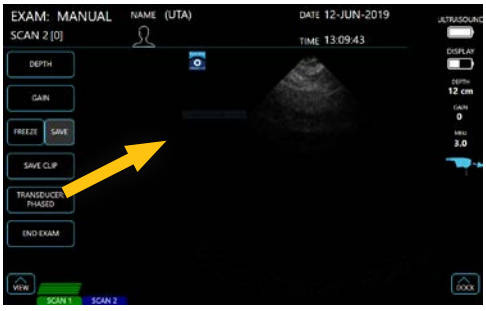


Figure 3.12b

Saving CineLoops or "Clips" – While scanning, the user can ONE TAP the "Save Clip" tab. Once the "Save Clip" tab is selected, the machine will then record the following 3 seconds of scanning and automatically store the clip in the window in which you are scanning. The number of video clips stored in each window will also be displayed on the window.

Reviewing Images – The user may review the stored images at any time during an exam. To do so, the user can open the scan window bar at the bottom of the screen, select which window's images he/she desires to review. The available images will pop up and allow the user to ONE TAP which image to review (Figure 3.14).

Figure 3.14

Once an image is selected, it will be displayed on the main screen. Users can opt to discard it by ONE TAP of the "trash" icon or select another image within that window to review. When finished reviewing, users may return to scanning by ONE TAP of the "return" option. (Figure 3.15)

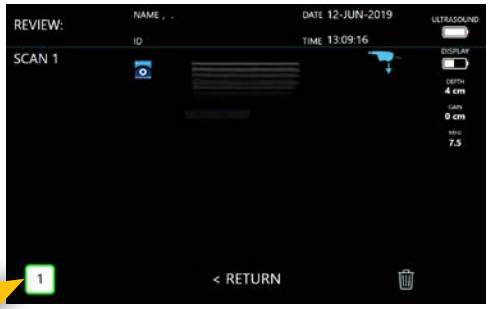


Figure 3.15

When the user has completed the exam, ONE TAP the "End Exam" button. This will prompt a pop-up window that will allow the user to confirm the exam is complete, and provide options to continue the exam, save and exit, add patient data or abort the exam and exit, which will result in the exam not being saved. (Figure 3.16)

CAUTION When the SonicEye Image Processor reaches 25% of its battery life it is recommended that it be recharged. Battery life is reported both on the GUI (upper right-hand corner) and on the Image Processor. The system can function properly while the charger is plugged in.

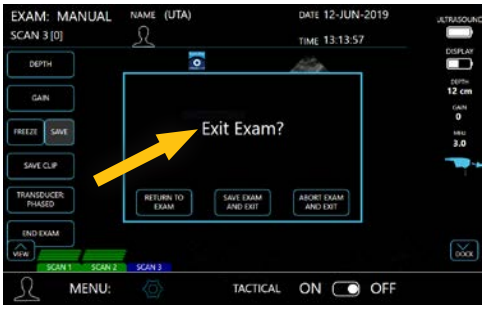


Figure 3.16

Recall Stored Patient Data

Patient data can be accessed by ONE TAP the Saved Exam icon on the Home screen (Figure 3.17). The last 4 Saved Exams are displayed (Figure 3.18). A SEARCH (by Last Name) capability can be used if the desired exam is not seen. The records can also be accessed using the scroll bar right of the records. UTA exams are saved by Date and Time. Once a Patient is highlighted, Patient Data for that individual can be reviewed by ONE TAP the Review button (Figure 3.18). This will include the ability to review images, clips or add comments. Then ONE TAP the Return button to return to Saved Exams. To exit Saved Exams, ONE TAP the Exit button.

Deletion of Saved Patient Data
The SonicEye system will automatically delete saved exams after 30 days from the date of examination. It will also delete the last saved exam by date and time when 30 exams are saved.

An individual exam may be deleted using the TRASH icon.

Shut Down
The tablet shuts down by holding the Power On button down and then scrolling down the pop-up panel to power down the tablet. The Image Processor is shut down by holding the Power Button until the light goes off.

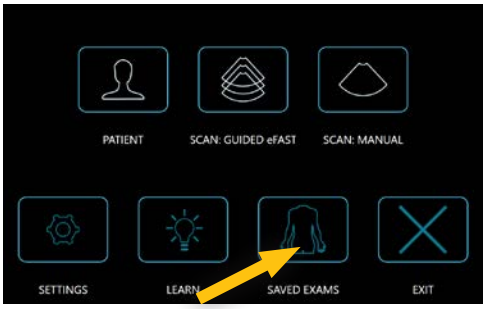


Figure 3.17

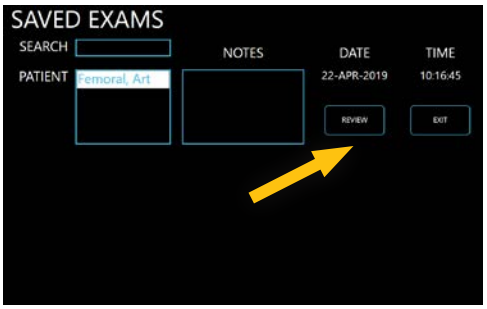


Figure 3.18

Chapter 4 - SonicEye GUI/App

CONTENTS:

TABLET REQUIREMENTS:

The supplied tablet is a Sinicvision Technologies, 8-inch Rugged Tablet PC or equivalent (Model # B01J67BJHK); 9” L x 5.8” W x 0.7” H.

NOTE: Password protection should be used on the tablet running SonicEye software, since the software is handling patient information (e.g. patient name, ID and birthdate). Initial Password is set at: 1 2 3 4. Password may be re-set in Settings on the tablet.

The tablet is pre-set for “30 minutes” run time before the screen saver is initiated. The pc tablet is pre-set to “Never” shut down the pc operation unless the operator pushes the On/Off button and then slides downward the “shut down” screen. The operator may adjust both settings in “Power”.

SonicEye GUI PRE-INSTALLED

The SonicEye GUI (graphical user interface) App will be installed on the supplied tablet.

Sonivate Medical, Inc. User and Reference Manual are pre-installed in a PDF format. Updates may be attained through the Sonivate Medical, Inc. website.

The SonicEye App is configured so that an update to the Microsoft operating system will not normally interfere with its operation. Future upgrades to Microsoft cannot predict non-interference. Microsoft Office and Internet Explorer are turned off and not recommended.

Chapter 5 - SonicEye Maintenance

CONTENTS:

SYSTEM CARE AND MAINTENANCE

The SonicEye requires regular care and maintenance to function safely and properly. To ensure that SonicEye consistently operates at maximum efficiency we recommend that the following procedures be observed as part of the customer's internal routine maintenance program.

CAUTION Only trained persons should perform the safety inspections mentioned below.

INSPECTING THE SONICEYE IMAGE PROCESSOR

Examine the following monthly (or whenever there is a reason to assume that any issue may have occurred):
- Connectors on cables, for any mechanical defects
- Entire length of electrical cables, for cuts or abrasions
- Equipment, for loose or missing hardware

INSPECTING THE DUAL-ARRAY PROBE BEFORE EACH USE

1. Inspect the lens, the probe housing and the cable.
2. Look for damage that might allow liquid into the probe.
3. Test the functionality of the probe.

WARNING: To avoid electrical shock hazard, do not remove covers from the SonicEye.

CAUTION: If any defects or damages are found on the image processor, the probe or its cable, DO NOT use the SonicEye.

CAUTION: If any defects or damages are found on the probe or its cable, DO NOT use the SonicEye.

CLEANING AND DISINFECTION

Cleaning the probe
1. Remove the coupling gel by wiping the probe lens with a soft cloth.
2. Wipe the probe and cable with a soft cloth moisten in a warm soap and water solution (<80o F/27o C).
3. Wipe the probe and cable with a soft cloth moisten in clean water (<80o F/27o C). until all soap is removed.
4. Wipe dry with a soft towel.
5. Disinfect probe per instruction below

CAUTION Do not spray any liquid directly onto the Image Processor

DISINFECTING THE DUAL-ARRAY PROBE

Ensure all solids are removed. After cleaning, the probe and cable may be wiped accordingly with a recommended disinfectant.

Although a necessary step in protecting patients and employees from disease transmission, liquid chemical germicides must also be selected to minimize potential damage to the transducer. The following disinfectants can be used on the SonicEye and its probe:

T-Spray, Pharmaceutical Innovations
T-Spray II, Pharmaceutical Innovations
CaviWipes, Metrex
Cleanisept wipes, Dr. Schumacher GmbH
Sani-Cloth HB PDI
Septiwipes, Dr. Schumacher GmbH

NOTE: Follow the manufacturer's instructions for storage, use and disposal of the disinfection solution.

Disinfecting the Image Processor:
WARNING: Use only compatible disinfects. In addition, refer to the local /national regulations. Never use thinner, benzene, alcohol (ethanol, methanol, or isopropyl alcohol), abrasive cleaners, or other strong solvents, or solutions containing alcohol, bleach, ammonium chloride compounds or hydrogen peroxide s these may cause damage to the Image Processor or the probe.

WARNING: Use additional precautions (e.g. gloves and gown) when decontaminating an infected unit. The unit should be exposed to the disinfectant longer than specified to achieve the desired effect.

DO NOT: Soak or saturate the Image Processor, use only a moistened cloth if needed to disinfect the unit.

SonicEye LIMITED WARRANTY

SonicEye has a 1-year limited warranty. See Limited Warranty documents on the Sonivate website for details.

SONICEYE DISPOSAL

SonicEye should be disposed in accordance with local guidelines for disposing of electronic equipment.

TROUBLESHOOTING:

Problem	Possible Cause	Solution
Image Processor has no power	Battery not charged	Charge battery with supplier adaptor or use with power via adaptor
Battery defect or end of life		Contact SONIVATE Service
Defect AC adapter or charger		Contact SONIVATE Service
Temperature is outside the specified limits	Ensure the ambient temperature is within the specified limits	To help keeping the SonicEye operating temperature at an optimal functional level, and to ensure longer scanning time with maximum frame rate, it is recommended to hold the SonicEye so that there is good contact between the device and the hand
When opening the display, the screen is white and nothing is happening		Restart the SonicEye to enable normal frame rate again
Connection broken during software loading		Restart the SonicEye to enable normal frame rate again
Parts of the image is missing when scanning		Restart the SonicEye to enable normal frame rate again
Channels are missing		Contact SONIVATE Service
Noise when moving the probe cable		Contact SONIVATE Service
Defect probe cable		Contact SONIVATE Service
No image displayed when scanning		Battery needs recharging; using supplied adaptor, plug into "power" on image processor and continue
Defect probe		Contact SONIVATE Service
No connection between SonicEye and SonicEye software	SonicEye is not turned on	Ensure that the SonicEye is turned on
USB cable is not connected		Make sure the USB cable is properly connected in both ends.
SonicEye movies are not playing in SonicEye software		The display adapter requirements are not met
SonicEye display is flashing while scanning	Automatic reduction of the frame rate due to increase of the operating temperature after extended scanning	Restart the SonicEye to enable normal frame rate again. To help keeping the SonicEye operating temperature at an optimal functional level, and to ensure longer scanning time with maximum frame rate, it is recommended to hold the SonicEye so that there is good contact between the device and the hand

Contact Sonivate Service at inquire@sonivate.com

Chapter 6 - Safety

CONTENTS:

INTRODUCTION

Owner Responsibility

It is the responsibility of the owner to ensure that anyone operating the SonicEye reads and understands this section of the manual. However, there is no representation that the act of reading this manual renders the reader qualified to operate, inspect, test, align, calibrate, troubleshoot, repair or modify the system. The owner should make certain that only properly trained, fully-qualified service personnel undertake the installation, maintenance, troubleshooting, calibration and repair of the equipment.

The owner of the SonicEye should ensure that only properly trained, fully qualified personnel are authorized to operate the system. Before authorizing anyone to operate the system, it should be verified that the person has read, and fully understands, the operating instructions contained in this manual. It is advisable to maintain a list of authorized operators. Should the system fail to operate correctly, or if the SonicEye does not respond to the commands described in this manual, the operator should contact SONIVATE.

For information about specific requirements and regulations applicable to the use of electronic medical equipment, consult the local, state and federal agencies. Never modify this product, including system components, labels, and so on. User modification may cause safety hazards.

For USA only:
Federal law restricts this device to use by, or on the orders of, a physician. 

Important Safety Considerations

This section includes safety considerations for the following:

- Patient Safety
- Personnel and Equipment Safety

The information contained in this section is intended to familiarize the user with the hazards associated with the use of the SonicEye, and to alert them to the extent to which injury and damage may occur if the precautions are not observed. Users are obligated to familiarize themselves with these safety considerations and to avoid conditions that could result in injury or damage.

PATIENT SAFETY

Patient Identification
Always include proper identification with all patient data. Identification errors could result in an incorrect diagnosis. It is the user's responsibility that all the patient information is deleted from the tablet if the tablet is no longer being used for ultrasound purposes or returned to the manufacturer.

WARNING The concerns listed in this section can seriously affect the safety of the patient undergoing a diagnostic ultrasound examination.

Diagnostic Information
The images provided by the system are intended for use by competent users, as a diagnostic tool. They are explicitly not to be regarded as the sole, irrefutable basis for clinical diagnosis. Users are encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of the system. The user should be aware of the product specifications and of the system accuracy and stability limitations. The user must become thoroughly familiar with the operation of the SonicEye in order to optimize its performance and to recognize possible malfunctions.

Mechanical Hazards
A damaged probe may result in injury or increased risk of infection. Inspect the probe frequently for sharp, pointed or rough surface damage that could cause injury or tear protective barriers (gloves and sheaths).

Electrical Hazard
A damaged probe may increase the risk of electric shock if conductive solutions come in contact with internal live pads. Inspect the probe often for cracks or openings in the housing and holes in and around the acoustic lens, or other damage that could allow moisture to enter. Become familiar with the probe's care precautions outlined in 'SonicEye Maintenance'.

Explosion Hazard
Never operate the equipment in the presence of flammable or explosive liquids, vapors or gases. Malfunctions in the SonicEye, or sparks, can electrically ignite these substances. Operators should be aware of the following points to prevent such explosion hazards.

- If flammable substances are detected in the environment, do not plug in or turn on the system.
- If flammable substances are detected after the system has been turned on, do not attempt to turn off the SonicEye, or to unplug it.
- If flammable substances are detected, evacuate and ventilate the area before turning off the SonicEye.

Latex Alert
When protective sheaths or gloves are used during a patient exam, is it recommended that they be Latex-Free. Due to reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA advises health-care professionals to identify latex-sensitive patients and be prepared to treat allergic reactions promptly. Latex is a component of many medical devices, including surgical and examination gloves and probe sheaths. Patient reaction to latex has ranged from contact urticaria, to systemic anaphylaxis. For more details regarding allergic reaction to latex, refer to FDA Medical Alert MDA91-1.

CONTENTS:

Personnel and Equipment Safety

DANGER
The hazards listed below can seriously affect the safety of personnel and equipment during a diagnostic ultrasound examination.

The internal circuits of the AC/DC adapter use high voltages, capable of causing serious injury or death by electrical shock.

General Safety and to Avoid Injury
- Do not remove the SonicEye's protective covers. No user-serviceable parts are inside. If servicing is required, contact SONIVATE.

Pacemaker Hazard
The possibility of the system interfering with pacemakers is minimal. However, as this system generates high frequency electrical signals, the operator should be aware of the potential hazard this could cause.

Electromagnetic Compatibility (EMC) Safety
All types of electronic equipment may characteristically cause electromagnetic interference with other equipment, transmitted either through air or connecting cables. The term Electromagnetic Compatibility (EMC), indicates the capability of the equipment to curb electromagnetic influence from other equipment, while at the same time not affecting other equipment with similar electromagnetic radiation. Radiated or conducted electromagnetic signals can cause distortion, degradation, or artifacts in the ultrasound image which may impair the ultrasound unit's essential performance

The SonicEye has been tested and complies with existing standards for EMC. However, there is no guarantee that interference will not occur in a particular installation. If this equipment is found to cause or respond to interference, attempt to correct the problem by one or more of the following measures:
- Re-orient or re-locate the affected device.
- Increase the separation between the unit and the affected device.
- Power the equipment from a source other than that of the affected device.

The manufacturer is not responsible for any interference or responses caused by the use of interconnecting cables other than those recommended, or by unauthorized changes or modifications to this unit. Unauthorized changes or modifications could void the user's authority to operate the equipment.

When the ultrasound unit is used adjacent to or in close proximity to other equipment the user should be attentive to unexpected device behavior which may be caused by such radiation.

MEDICAL ULTRASOUND SAFETY

ALARA
Ultrasound procedures should be performed using output levels and exposure times As Low As Reasonably Achievable (ALARA) while acquiring clinical information.

Training
During each ultrasound examination the user is expected to weigh the medical benefit of the diagnostic information that would be obtained against the risk of potential harmful effects. Once an optimal image is achieved, the need for increasing acoustic output or prolonging the exposure cannot be justified. It is recommended that all users receive proper training in applications before performing them in a clinical setting.

Track 3 ALARA Educational Program
The user should be familiar with the document "Medical Ultrasound Safety", published by AIUM (American Institute of Ultrasound in Medicine). This document is acceptable to FDA as meeting the content of the ALARA educational program. This document is preinstalled on the SonicEye tablet.

To contact the AIUM for additional publications:
American Institute of Ultrasound in Medicine
14750 Sweitzer Lane, Suite 100
Laurel, Maryland
20707-590

Phone: 301-498-4100 or 800-638-5352
Fax: 301-498-4450

Device Labels
The following two labels (Figures 6.1a and 6.1b) are attached to each device.

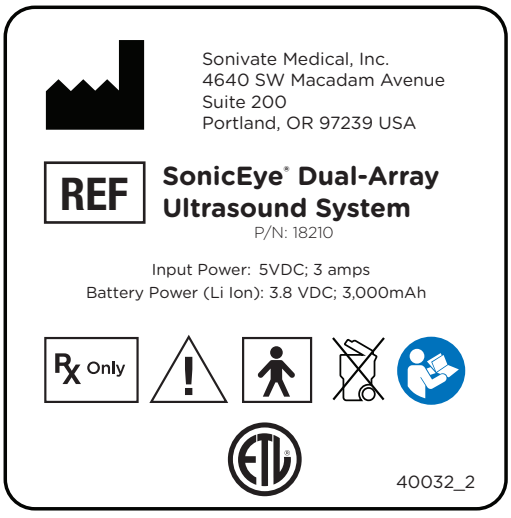


Figure 6.1a

Figure 6.1b

Device Labels

The following are attached to each secondary shipping container (Figure 6.2a and 6.2b):

Figure 6.2a

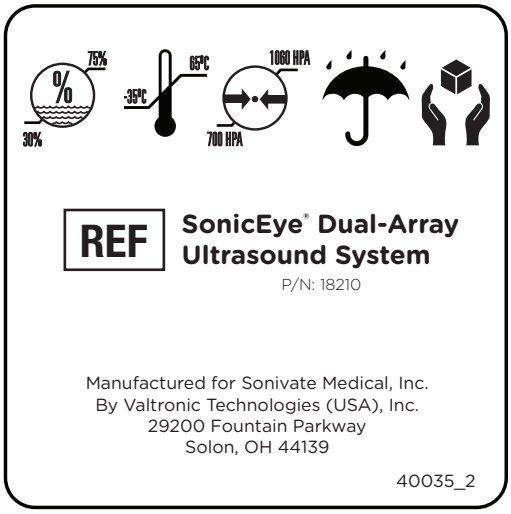


Figure 6.2b

The following label (Figure 6.3) is attached to the back of the Sinicvision Technologies, 8-inch Rugged Tablet PC to ensure it is kept with the system:

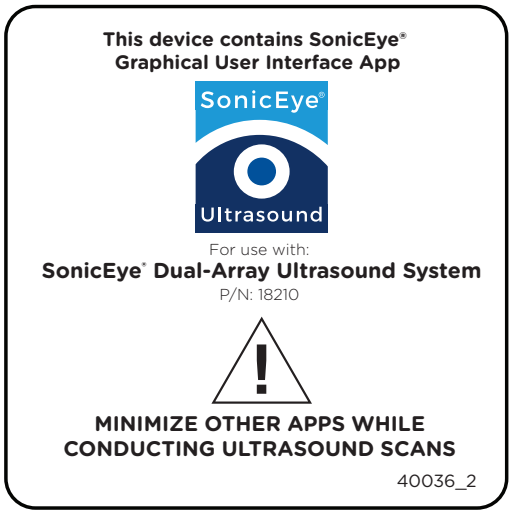


Figure 6.3

Chapter 7 - Appendix

CONTENTS:

Acoustic Output Reporting Tables

These tables show the highest possible acoustic intensity for a given mode, obtainable only when the maximum combination of control settings is selected. Most settings result in a much lower output. It is important to note the following:

- The duration of an ultrasound examination is as important as the acoustic output, since patient exposure to output is directly related to the exposure time.
- Better image quality yields faster clinical results, making it possible to complete the relevant ultrasound examination more rapidly. Therefore, any control that improves the quality of the examination can help to reduce patient exposure, even though it may not directly affect acoustic output.

Selecting the application appropriate to a particular ultrasound examination automatically provides acoustic output limits within FDA guidelines for that application. Other parameters which optimize performance for the selected application are also set.

TRACK 3 SUMMARY

It should be noted that the SonicEye system is a B-mode imaging system only and in no cases can the system exceed global maximum index values (MI/TI) of 1.0.

Acoustic Power data for both the 3.0 MHz Phased and the 7.5 MHz Linear arrays are shown in the table below.

System: SonicEye® Dual-Array Ultrasound System

Transducer Model	I SPTA.3	TI Type	TI Value	MI	I PA.3@MI max
3.0MHz Phased (LFP)	9.17mW/cm2	TIS	0.4	0.72	113W/cm2
7.5MHz Linear (HFL)	0.71mW/cm2	TIS	0.11	.066	127W/cm2

Measurement Uncertainties

The uncertainties in the measurements were predominantly systematic in origin. The non- negligible overall systematic uncertainties were determined as the following standard deviations ( ):

1. Voltage: = ±1.2 %

2. The two contributing sources were the stated DC gain accuracy and digitization error of the Tektronix TDS3012B digital oscilloscope.

3. ML - Hydrophone Pressure Sensitivity: = ±3.6 %

4. The principal source of this uncertainty is the stated uncertainty of the NPL calibration. Additional variance is introduced by the stated temperature range of the water bath.

5. Spatial Averaging: = ±1.3 %
   See section 1.6.1.5 for full discussion.

1. Acoustic Impedance: = ±0.8 %
2. Variance is introduced by the stated temperature range of the water bath.
3. 5. Derating: = ±0.6 %
4. The contributing factor is error in the mechanical positioning of the hydrophone. The estimate is worst case by assuming a high frequency probe.
5. 6. Power Factor (PF): = ±1.7 %
6. The contributing factor is error in the mechanical positioning of the hydrophone.
7. 7. Zsp – Spatial-peak depth: = ±1.2 %
8. If the exact spatial peak depth is missed due to the step size the PII and related values will be systematically incorre m the spatial variability for worst case historic
9. 8. Non-linear Distorti
10. The uncertainty of the from [5], and subsequent discussion with FDA p
11. Uncertainties were all tion from their original probability distributio they may be added on a Root Sum Square (RSS g calculated values:
12. 1. PII: = ±17.4 %
13. = √22 2 Vol
14. 2. Ispta.3: .3 = ±17.4 %
15. spta = √ 2 + 2
16. 3. Power: = ±17.5 %
17. = √ 2 + 2 + 2
18. 4. Thermal Index: = ±17.5 %
19. 5. Mechanical Index: = ±8.8 %
20. = = √ 2 + 2 + 2 + 2 + 2 + 2

WORKING ON TRANSLATING FORMULAS TO THIS FORMAT ON PAGES 32-33

Probe Temperature Data

TBD

Terms and Conditions

See Terms and Conditions document on the Sonivate website (www.sonivate.com) for details.