SONIVATE MEDICAL

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SonicEye® Diagnostic Ultrasound Transducer

Model# HFL-FKDS-01

User Guide

For use with Fukuda UF-760AG Ultrasound System

Manufactured By:

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Patent Information	The SonicEye Probe is protected by US Patent 8211026 and other pending and international patents.

Caution	United States federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

NOTE: SonicEye® is a registered trademark of Sonivate Medical, Inc.

Contents

Introduction

This user guide provides instructions for using the SonicEye® ultrasound transducer. This guide is intended for a user familiar with standard ultrasound technique. See the Fukuda UF-760AG Ultrasound Imaging System User Guide for information on preparation, use, and maintenance of the ultrasound system, as well as additional safety information.

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

Symbol	Definition
	Designates the SonicEye® serial number assigned during manufacture.
	Designates the SonicEye® part number assigned to the probe.
	Indicates date of manufacture.
	Indicates the name of the manufacturer.
Rx only	Prescription only - device restricted to use by or on the order of a physician
	Caution, consult accompanying documents.
	Type BF patient applied part (B=body, F=floating applied part)
	Not for general waste.
	Indicates the SonicEye® has been tested to ensure protection of the equipment inside the enclosure against harmful ingress of water when immersed at 1 meter for a 30 minute duration.

The following conventions are used throughout this user guide:

- A **WARNING** is used to convey information to prevent injury or loss of life.
- A **CAUTION** is used to convey information regarding special care to be exercised by the user for the safe and effective use of the device.

Technical Support

For technical support for the SonicEye® transducer, contact Sonivate Medical at the following:

Phone: **(971) 238-3767**

E-mail: **inquire@sonivate.com**

Website: **www.sonivate.com**

For technical support for the Fukuda UF-760AG Ultrasound Imaging System, refer to the manufacturer's user guide.

Environmental Conditions

Operating Conditions:	**10°C to 40°C** **30-75% R.H.** **800hPa to 1060hPa**
Shipping and Storage Conditions:	**-10°C to 60°C** **10 to 95% RH** **800hPa to 1060hPa**

SonicEye® Indications for Use

The SonicEye® ultrasound transducer is a general-purpose transducer intended for use by a qualified clinician for diagnostic ultrasound imaging or fluid flow analysis of the human body in the following applications: Pediatric, Small Organ (breast, thyroid, testicles, prostate), Musculo-skeletal (conventional and superficial), and Peripheral Vessel.

SonicEye® Contraindications

There are no known contraindications for use of the SonicEye®.

Caution

The SonicEye® probe is not intended for intracavity use, such as the following:

- Transesopohageal Use
- Transvaginal Use
- Transrectal Use

The SonicEye® probe is not indicated for therapeutic use and is not indicated for use through surgical openings in the skin.

The SonicEye® is not intended to be used in intraoperative applications. Refer to the Ultrasound System's User Guide for additional safety information.

Observe the ALARA (As Low As Reasonably Achievable) Principle when scanning to limit patient ultrasound exposure to the minimum required to achieve diagnostic image quality. Refer to the Ultrasound System's User Guide for additional information about how to optimize image quality while still practicing the ALARA Principle.

Using the SonicEye®

Connect the SonicEye®

1. Inspect the SonicEye® and system connectors. Ensure no foreign material is present.
2. Remove the probe connector protection from the probe receptacle.
3. Connect the probe connector to the probe receptacle.
4. Turn the lever on the probe connector clockwise 90° to lock the probe connector.

(See Fukuda UF-760AG Ultrasound System's User Guide for drawings and pictures for attaching the probe).

Confirm proper connection of the SonicEye® to the Fukuda UF-760AG Ultrasound System, following instructions outlined in the Ultrasound System's User Guide.

Inspect the SonicEye®

1. Examine the SonicEye® lens, housing, cable, and strain relief before each use.
2. Inspect for cracks, tears, sharp edges, or exposed wiring.
3. Confirm the probe is intact and is not damaged.

Warning	Do not use a damaged or defective probe. Failure to follow these precautions may result in injury to the operator or patient.

Use the Ultrasound System

Refer to the Ultrasound System's User Guide for information on how to:

- Power on the system
- Start an exam
- Acquire or optimize an image
- Perform measurements
- Execute other system-related tasks

Caution	See the Ultrasound System's User Guide for additional safety information.

Prepare the SonicEye® for Use

For General Use:

1. Ensure the probe fits snugly on your finger. Adjust the fit by inserting a finger cot (S, M, L) into the probe opening (See Figure 1).
2. Place the probe on your finger.
3. Route the cable up your arm and over your shoulder.
4. If desired, secure the cable at your wrist, shoulder, and/or belt (See Figure 2).
5. Apply gel to the transducer.

Figure 1

Figure 2

Caution	Proper fitting is important: A snug fit is required so probe doesn't rotate on finger. If probe is too tight, discomfort or reduced blood circulation can occur.

Warning	Cable attached to user can snag on objects, causing damage to probe or host system.

Caution	Sonivate Medical recommends the use of Aquasonic gel or equivalent to ensure suitable acoustic coupling without damaging the SonicEye®. Some gels may be incompatible with transducer materials. Sterile gel must be used for sterile procedures. Sonivate Medical recommends cleaning the SonicEye® after each use.

Warning	Ultrasound can produce harmful effects and may result in injury to the patient. Use the lowest exposure time and ultrasound levels necessary to minimize negative effects on the patient. Observe the ALARA (As Low As Reasonably Achievable) principle and increase output only when necessary to achieve diagnostic image quality. Refer to the Ultrasound System's User Guide for additional information about how to optimize image quality while still practicing the ALARA principle.

Scanning with the SonicEye®

Use the probe on the finger in the same manner as you would use a normal probe to scan. By wearing the probe on the finger, you can use the same hand to assist in performing the scanning by stabilizing the region or body part being imaged, or feeling tactilely with the finger or hand doing the scanning. Keep the hand relaxed during scanning as only sufficient force to adequately couple the probe to the body being imaged is required. By not having to "grip" a hand-held probe you should be able to relax your arm and shoulder while scanning. When performing ultrasound needle guided procedures, wear the probe on your non-dominant hand, reserving your dominant hand to perform the actual procedure. You may need to move the patient or reorient yourself to the patient to change the probe orientation during scanning. Other than ergonomic factors in using the SonicEye®, all traditional techniques of ultrasound scanning apply to the probe.

Transducer Orientation

The distal end (tip) of the transducer corresponds to the side of the screen marked with the Medical Application Icon on the Imaging System screen. The scan orientation can be reversed by using the F1 button beneath the screen. Verify proper screen orientation by placing finger or instrument on tip of transducer and viewing image on screen before draping.

Caution	See the Ultrasound System's User Guide for additional information on body mechanics and healthy scanning guidelines.

SonicEye Optional Parts

Sonivate Medical supplies 2 packs of Finger Cots and 2 packs of Probe Caps with the probe. Additional optional parts are available to order separately. Contact Distributor for Ordering Information.

Use of SonicEye with Finger Cot

NOTE: Finger Cots are optional and provided to allow secure fit for fingers of multiple sizes. Larger fingers may not require the use of a finger cot, but can be used for increased comfort, if desired.

1. Hold the probe in one hand and the finger cot of desired size in the other hand.
2. Insert the finger cot into the opening of the rear of the probe, with the ribs facing towards the lens (or bottom of probe). (See Figure 3).

Figure 3

3. Insert finger into probe. If necessary, adjust finger cot placement or size for best fit and/or comfort.
4. Finger cots may be used with or without probe cap, and during sterile or non-sterile procedures.

Use of SonicEye® with Probe Cap

NOTE: Cap (and finger cot, if used) should be placed on probe ***prior*** to insertion into sterile glove or sheath.

Figure 4

1. Hold the probe in one hand and the probe cap in the other hand. (See Figure 5).

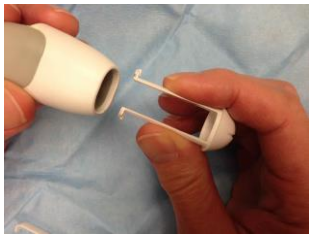

Figure 5

2. Gently squeeze the plastic latches of the probe cap together to allow insertion in the finger cavity of the probe. (See Figure 6).

Figure 6

3. Insert the probe cap until it is securely in place and the latches lock into place in the recess cavity on the rear of the probe. (See Figure 7 and 8).

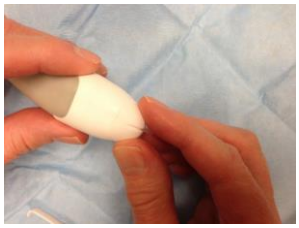

Figure 7

Figure 8

4. If desired, place a finger cot inside the probe. (See Figure 9).

Figure 9

5. Insert preferred finger into probe. To allow your finger to more easily fit into probe with a finger cot, hold the tab of the cot in place with your thumb as you insert your finger into the probe.
6. The probe and cap are now ready for insertion into a glove or sheath. (See Figures 10 and 11).
7. Scan with the SonicEye as described in section “Scanning with the SonicEye”.

   NOTE: The groove on the cap serves as an alignment indicator for the center of the array (See Figures 10 and 11.

Figure 10

Figure 11

Use of SonicEye® with Sterile Probe Cover

NOTE: Sonivate Medical suggests the use of a 3.5" (9 cm) wide sterile probe cover (e.g. CIVCO 610-637)

1. Prepare for ultrasound-guided procedure using approved sterile protocols.

2. Apply ultrasound gel to the lens of the probe.

3. Insert and place the probe at one corner of the sterile cover. The lens should face outward. (See Figure 12).

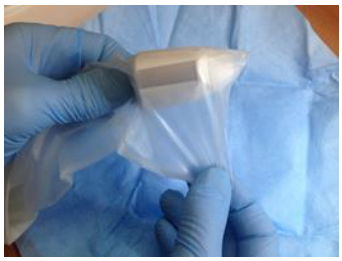

Figure 12

4. Take the opposite corner of the cover and wrap it behind the probe, leaving the sheath tightly wrapped around the lens area of the probe. (See Figures 13 and 14).

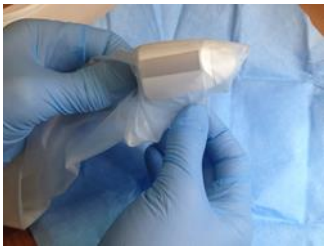

Figure 13

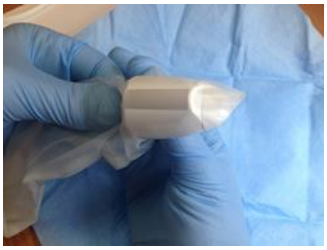

Figure 14

5. Pinch the sheath approximately 1.5" behind the probe and push the sheath and finger through the probe opening. (See Figures 15 and 16).

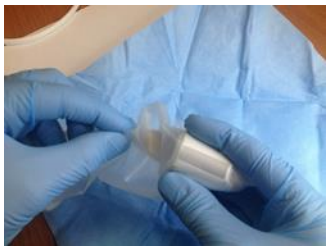

Figure 15

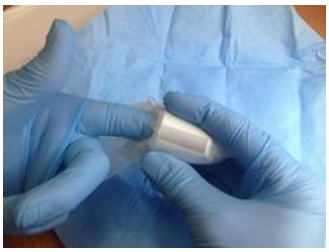

Figure 16

6. Ensure there are no air bubbles or wrinkles over the lens.

7. Wrap the finger and head of probe with a sterile elastic band. (See Figures 17 and 18).

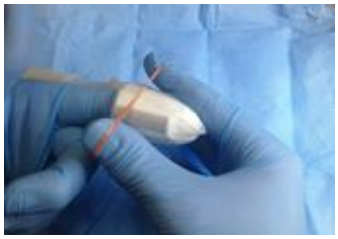

Figure 17

Figure 18

8. Extend the probe cover to its full length.

9. Apply sterile ultrasound gel to the outside of the sheath over the covered lens.

Use of SonicEye® with Sterile Glove

NOTE: Sonivate Medical suggests using size Large (8) or greater sterile gloves (e.g. Biogel Skinsense 31480-00). Materials such as polychloroprene or latex will more readily stretch over the probe.

1. Prepare for ultrasound-guided procedure using approved sterile protocols.

2. Place SonicEye probe on finger. (See Figure 19 below).

Figure 19

3. Apply ultrasound gel to the lens of the probe.

4. Cover the probe hand with a sterile glove. (See Figure 20).

Figure 20

5. Place sterile glove on your other hand, then adjust the glove on the probe hand as needed. Ensure there are no bubbles or wrinkles over the lens and there is adequate ultrasound gel inside the glove. (See Figure 21).

Figure 21

6. Apply sterile ultrasound gel outside of the glove over the covered lens.

Warning	The SonicEye® is not intended to be used for intraoperative or intracavitary applications. To prevent contamination during procedures requiring sterile technique, the use of sterile transducer sheaths or gloves and sterile coupling gel is required. Do not apply the sheath and gel until you are ready to perform the procedure.

Caution	Some gloves and/or transducer sheaths may contain natural rubber latex which can cause allergic reactions in some humans. Certain types of gloves, including textured gloves, do not transmit ultrasound energy efficiently. User must confirm adequate image quality before initiating any procedure.

Cleaning and Disinfecting the SonicEye®

To Clean:

1. Disconnect the SonicEye® from the ultrasound system.
2. Remove any transducer sheath or glove used.
3. Remove all coupling gel and other debris from probe by wiping with a soft, damp cloth or gently washing with lukewarm water, until all visible particulates or residues have been removed.

To Disinfect – Wipe Method:

1. Ensure the SonicEye® is thoroughly cleaned prior to disinfection.
2. Use a Sani-Cloth Plus Germicidal Disposable Cloth or Isopropyl Alcohol (IPA) to wipe the probe and cable.
3. Thoroughly wet the probe and cable with a wipe.
4. Allow the treated surface to remain visibly wet for 5 minutes.
5. Use additional wipes if needed to assure the full 5 minute wet contact time.
6. Allow to air dry or dry with a clean, soft cloth before storage. Store in a manner to minimize recontamination.

Caution

The SonicEye® must be cleaned after every use. Proper cleaning is necessary for effective disinfection. Use your hospital or clinic standard cleaning guidelines for ultrasound transducers.

Clean the SonicEye® as soon as practical after use (e.g., at the point of use) to minimize soiled materials drying onto the probe.

Users should follow OSHA Bloodborne Pathogens Universal Precautions when handling and cleaning a soiled SonicEye®.

Avoid damage to the SonicEye®; do not use hot water.

Warning

The SonicEye® can easily be damaged by contact with certain chemicals. Failure to follow Sonivate Medical recommendations and precautions can result in serious injury or equipment damage.

Avoid electrical shock; disconnect the SonicEye® from the system before cleaning.

Avoid injury; always wear the appropriate personal protective equipment when cleaning or disinfecting the SonicEye®.

The SonicEye® cannot be sterilized using steam, ethylene oxide gas, Steris®, or Sterrad® processes.

Avoid infection; use only the recommended disinfection solution strength and duration of contact.

Sonivate Medical does not endorse disinfection efficacy claimed by the disinfectant manufacturer.

Acoustic Output Reporting Table for Track 3 – B Mode

index table FDA			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
global maximum index value			1.22	0.59	-	-	-	(b)
associated acoustic parameters	$p_{r.3}$	Mpa	3.06					
	W_0	mW		18.5	-		-	#
	min of [$W_{0.3}(z_1)$, $I_{ta.3}(z_1)$]	mW				-		
	z_1	cm				-		
	z_{bp}	cm				-		
	z_{sp}	cm					-	
	z at $PII_{.3max}$	cm	1.1					
	$d_{eq}(z_{sp})$	cm					-	
	f_c	MHz	6.32	7.08	-	-	-	#
	dim of A_{aprt} in X	cm		0.51	-	-	-	#
	dim of A_{aprt} in Y	cm		0.5	-	-	-	#
other information	PD	µs	0.3					
	PRF	Hz	640					
	p_r at max PII_{max}	MPa	3.85					
	d_{eq} at max PII_{max}	cm					-	
	focal length in X	cm		1.2	-	-		#
	focal length in Y	cm		1.7	-	-		#
	$I_{pa.3}$ at MI_{max}	W/cm^2	286.5					
operating control conditions	Application	-	Vascular / Artery	Vascular / Artery	-	-	-	#
	Depth	cm	9	6	-	-	-	#
	Frequency	MHz	High H	High H	-	-	-	#
	Focus	cm	2	5	-	-	-	#

(a): index not required for this operating mode
(b): this probe is not intended for transcranial or neonatal cephalic use
: no measurement data reported due to (a) or (b)
Remark: (Peripheral) Vascular application is equivalent to Peripheral Vessel application

Acoustic Output Reporting Table for Track 3 – M & B+M Mode

index table FDA			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
global maximum index value			1.22	0.69	< 0.4	-	< 0.4	(b)
associated acoustic parameters	$p_{r.3}$	Mpa	3.06					
	W_0	mW		14.7	3.2		3.2	#
	min of [$W_{0.3}(z_1)$, $I_{ta.3}(z_1)$]	mW				-		
	z_1	cm				-		
	z_{bp}	cm				-		
	z_{sp}	cm					1.20	
	z at $PII_{.3max}$	cm	1.1					
	$d_{eq}(z_{sp})$	cm					0.27	
	f_c (B/M)	MHz	6.32	7.08/6.35	6.35	-	6.35	#
	dim of A_{aprt} X (B/M)	cm		0.5	0.51	-	0.5	#
	dim of A_{aprt} Y	cm		0.5	0.5	-	0.5	#
other information	PD	µs	0.3					
	PRF	Hz	640					
	p_r at max PII_{max}	MPa	3.85					
	d_{eq} at max PII_{max}	cm					0.27	
	focal length in X	cm		1.7	1.2	-		#
	focal length in Y	cm		2.0	2.0	-		#
	$I_{pa.3}$ at MI_{max}	W/cm²	286.5					
operating control conditions	Application	-	Vascular / Artery	Vascular / Artery	Vascular / Artery	-	Vascular / Artery	#
	depth	cm	9	6	6	-	6	#
	frequency	MHz	High H	High H	High H	-	High H	#
	focus	cm	2	5	5	-	5	#

(a): index not required for this operating mode
(b): this probe is not intended for transcranial or neonatal cephalic use
: no measurement data reported due to (a) or (b)
Remark: (Peripheral) Vascular application is equivalent to Peripheral Vessel application

Acoustic Output Reporting Table for Track 3 – PWD & B+PWD Mode

index table FDA			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
global maximum index value			0.79	0.95	0.58	-	1.12	(b)
associated acoustic parameters	$p_{r.3}$	Mpa	2.06					
	W_0	mW		14.7	17.9		17.9	#
	min of [$W_{0.3}(z_1)$, $I_{ta.3}(z_1)$]	mW				-		
	z_1	cm				-		
	z_{bp}	cm				-		
	z_{sp}	cm					1.3	
	z at $PII_{.3max}$	cm	1.2					
	$d_{eq}(z_{sp})$	cm					0.2	
	f_c (B/PW)	MHz	6.8	7.08/6.8	6.81	-	6.8	#
	dim of A_{aprt} X (B/PW)	cm		0.5/0.33	0.51	-	0.5	#
	dim of A_{aprt} Y	cm		0.5	0.5	-	0.5	#
other information	PD	µs	1.25					
	PRF	Hz	1000					
	p_r at max PII_{max}	MPa	2.68					
	d_{eq} at max PII_{max}	cm					0.2	
	focal length in X	cm		1.7/1.7	1.5	-		#
	focal length in Y	cm		2	2.0	-		#
	$I_{pa.3}$ at MI_{max}	W/cm²	159.5					
operating control conditions	Application	-	Vascular / Artery	Vascular / Artery	Vascular / Artery	-	Vascular / Artery	#
	B depth [cm]	cm	-	6	-	-	-	#
	Frequency (B/PW)	MHz	-/6.8	High H/6.8	6.8	-	6.8	#
	Gate size	mm	6	6	6	-	6	#
	Focus (B/PW)	cm	-/2	5/2.5	4	-	4	#
	Velocity Range	kHz	1	1	1	-	1	#
	Energy	dB	0	0	0	-	0	#
	Steering	-	no	no	no	-	no	#

(a): index not required for this operating mode
(b): this probe is not intended for transcranial or neonatal cephalic use
: no measurement data reported due to (a) or (b)
Remark: (Peripheral) Vascular application is equivalent to Peripheral Vessel application

Acoustic Output Reporting Table for Track 3 – B+Color & B+Color+PWD

index table FDA			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1cm^2$	$A_{aprt} > 1cm^2$		
global maximum index value			1.22	0.91	0.36	-	0.93	(b)
associated acoustic parameters	$p_{r.3}$	Mpa	3.06					
	W_0	mW		13.9	11.2		11.2	#
	min of [$W_{0.3}(z_1)$, $I_{ta.3}(z_1)$]	mW				-		
	z_1	cm				-		
	z_{bp}	cm				-		
	z_{sp}	cm					1.6	
	z at $PII_{.3max}$	cm	1.1					
	$d_{eq}(z_{sp})$	cm					0.1	
	f_c	MHz	6.32	7.08/6.8/6.8	6.8	-	6.8	#
	dim of A_{aprt} in X	cm		0.6/0.3/0.3	0.3	-	0.3	#
	dim of A_{aprt} in Y	cm		0.5	0.5	-	0.5	#
other information	PD	µs	0.3					
	PRF	Hz	640					
	p_r at max PII_{max}	MPa	3.85					
	d_{eq} at max PII_{max}	cm					0.1	
	focal length in X	cm		1.6/1.9/1.45	1.7	-		#
	focal length in Y	cm		2	2	-		#
	$I_{pa.3}$ at MI_{max}	W/cm²	286.5					
operating control conditions	Application	-	Vascular	Vascular	Vascular	-	Vascular	#
	Subapplication	-	Artery	Artery	Artery	-	Artery	#
	Depth	cm	9	6	-	-	-	#
	Frequency (B/C/PW)	MHz	High H/6.8/6.8	High H/6.8/6.8	6.8	-	6..8	#
	Focus (B/C/PW)	cm	2/6/2	5/4/2.5	2.5	-	2.5	#
	Energy	dB	0	0	0	-	0	#
	Gatesize	mm	-	6	6	-	6	#
	Velocity Range	kHz	-	1	1	-	1	#
	Resolution	-	-	High	-	-	-	#
	CFM Window width	-	-	standard	-	-	-	#
	CFM Window height	-	-	standard	-	-	-	#
	Steering	-	no	no	no	-	no	#

(a): index not required for this operating mode
(b): this probe is not intended for transcranial or neonatal cephalic use
: no measurement data reported due to (a) or (b)
Remark: (Peripheral) Vascular application is equivalent to Peripheral Vessel application

The ALARA Principle

The Fukuda UF-760AG Ultrasound System's Operator manual contains a complete description of the ALARA (As Low As Reasonably Achievable) principal and outlines specific steps an operator can take to minimize exposure to ultrasound energy while still obtaining a diagnostic image. For the SLA probe, specific steps can be taken by the operator to reduce ultrasound energy including increasing the depth setting (all modes), increasing the box depth in color Doppler mode, reducing the PRF setting in color Doppler mode, and reducing the PRF in PW Doppler. In addition the system displays in real-time the MI or appropriate TI numbers for all conditions, allowing the operator to see the effect of changing any settings, which may affect output.

The SonicEye® probe's output in the worst case output settings are reflected by the real-time display within the measurement and display uncertainty. Changes to the operator settings may affect the acoustic output of the probe. Users of the SonicEye® probe should refer to the ALARA principle as outlined in the Ultrasound System's user manual and adjust the operator settings, as needed.

Miscellaneous Cautions and Warnings

Caution

The SonicEye® can easily be damaged by rough or improper handling. A damaged probe may result in patient injury or equipment failure.

Do not drop; avoid mechanical shock or impact to the SonicEye®.

Do not apply excessive bending or pulling force to the cable.

Do not allow the cable, when attached to the user, to snag on an object.

Do not use with a defibrillator. The SonicEye® is not a defibrillation approved applied part.

Ultrasound use may be linked to musculoskeletal disorders, such as tendonitis or carpal tunnel syndrome. Unusual user fatigue when using the SonicEye® may require discontinued use.

Warning

There are no user-serviceable or user-repairable parts in the SonicEye®. Refer all such issues to service personnel only.

Avoid risk of explosion; do not use near flammable gases or anesthetics.

Avoid patient injury due to burns; do not use with high frequency surgical equipment.

