



# User Guide

## Volume 2

## **Terason uSmart3300 Ultrasound System User Guide Volume 2**

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## Introduction

This volume of the *User Guide* includes safety information, technical data, and formulae required for safe and proper use of the Terason Ultrasound system.

It also includes maintenance information to help you keep your Terason system operating properly.

Not all information in this manual applies to all Terason Ultrasound systems. For instance, your system will not be equipped with every probe listed.

This manual comprises the following chapters:

- Chapter 1, [Setting Up the Ultrasound System](#), on page 7
- Chapter 3, [Terason Probes](#), on page 20
- Chapter 2, [Maintenance](#), on page 9
- Chapter 4, [System Safety](#), on page 134
- Chapter 5, [System Specifications](#), on page 192
- Chapter 6, [Electromagnetic Tables](#), on page 195

For information on how to use the Terason Ultrasound system, refer to Volume 1 of the *User Guide*.

# 1 Setting Up the Ultrasound System

To set up the system after unpacking it, refer to the *Quick Start Guide*, which is packed with the system.

If you purchased a cart, printer, or other accessory, refer to the setup instructions that came with the accessory.

The Terason Ultrasound System comes with all the required software already installed. The software upgrade information in this chapter is not needed unless you need to upgrade your system software to a newer version.

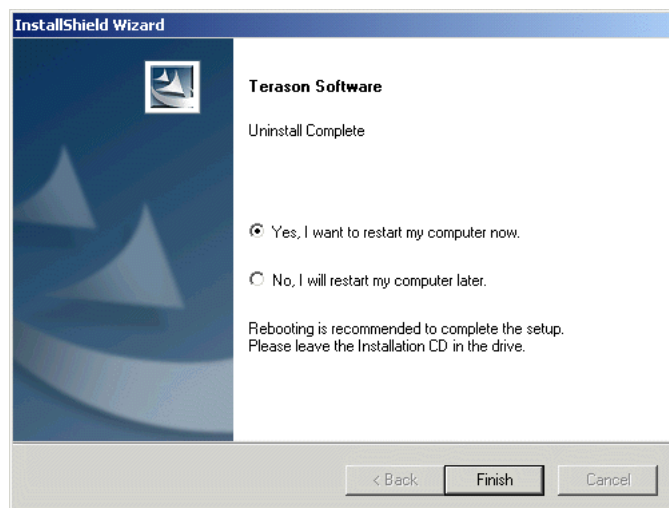
## Upgrading Terason Software

When upgrading software, the Terason installer first removes the existing version, and then installs the new version.

To upgrade to a newer version of the Terason software, complete these steps:

1. Exit all applications and **unplug** the Terason probe from the engine.
2. Insert the **Terason CD** into the CD-RW drive. The Uninstall dialog opens.
3. Click **Next>**. The Confirm Uninstall dialog box opens.
4. Click **OK** to confirm. If you see a dialog box that includes a check box, select the Don't display this message again check box and click **Yes**.

The installer removes all of the previous Terason software and displays a completion message, recommending that you reboot.



Uninstall Complete Dialog Box

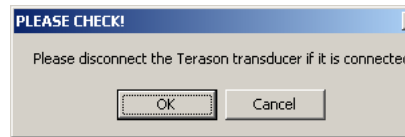
5. Click **Finish**. Keep the Terason CD in the drive and wait while the computer reboots (restarts).

After the computer finishes starting up, you may have to log on before proceeding.

When you are logged in, the Welcome dialog for the new Terason application opens.

6. Click **Next>**. The License Agreement dialog appears. Read the License Information carefully.
7. Click **Yes**. The Choose Destination Location dialog box opens.
8. Click **Next>** to install the application in the default location. You can click Browse to select a different location (not recommended).

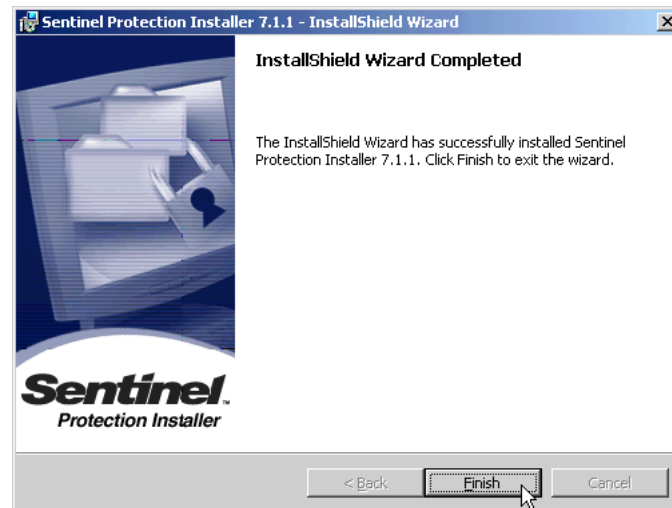
The wizard reminds you to unplug the Terason probe.



#### Reminder to Unplug the Probe

9. Click **OK**.

The installer copies the files to the selected location. When finished, the installer displays a setup complete message.



#### Installation Complete Message

If you see “Rebooting is required,” you must restart your computer before you use the Terason software.

10. Click **Finish**.

Remember to connect the probe.

## 2 Maintenance

To use the Terason Ultrasound System successfully and safely, Terason provides the following information:

- [Quarterly Inspection](#), see page 9
- [Cleaning the Ultrasound System](#), see page 10
- [Processing Terason Probes Between Uses](#), see page 13
- [Recommended Maintenance](#), see page 18



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**Warning:** To prevent patient injury, never perform any system maintenance, cleaning, or repair during a patient exam.

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### Quarterly Inspection

Besides regular cleaning of the system and probes performed by the sonographer, periodic quarterly inspection of the ultrasound system is important to assure proper performance.

**The quarterly inspection includes the following steps:**

1. Before inspection, turn the **system power off**
2. Disconnect **transducers, the power adapter, and any other devices.**
3. Remove the **battery** (see [page 10](#)).
4. Use a small computer vacuum or a household vacuum with a crevice tool to vacuum all **cooling vents**. If necessary, dust can be loosened with a stiff-bristle brush while applying the vacuum.



**Clogged Cooling Vent**

It is crucial that the cooling vents are clear. With use, these vents can become clogged with dust, lint, and hair. Clogged cooling vents cause performance issues. There are two cooling vents on the bottom of the 3300 system. It is important that both vents are clear.

5. Fully **examine all computer port openings** and the Terason probe connector port. If necessary, use compressed air to clear dust from connector ports. When cleaning the ports, check for any visible damage. Contact Tech Support if any damage is found.
6. After the quarterly inspection, proceed with a **full cleaning**, as described below. While performing a full cleaning, look for any damage or cracks in the system housing. Contact Tech Support if any damage is found.

## Cleaning the Ultrasound System

Before cleaning the system:

1. Turn the **system off**.
2. Disconnect the **probe, the power supply, and all other devices** from the system.
3. Remove the **battery**:

Turn the **system** upside down, with the side containing the battery facing you.



### Battery Latches

- a. Slide the catch on the bottom of the case (to the left of the battery) away from the battery.
- b. Slide the **catch** on the edge of the case (to the right of the battery) to the right and hold it.
- c. While holding the catch in place, pull the **battery** toward you and lift the near side up.



### Removing the Battery

**To clean the outside of the ultrasound system:**

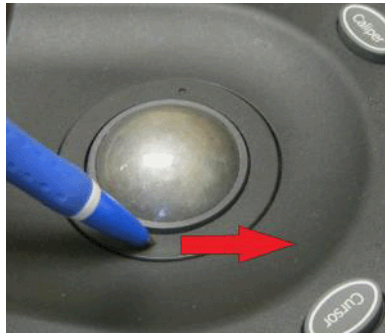
1. Wipe the case with a **soft, clean cloth** dampened slightly with isopropyl alcohol or 75% ethanol.
2. Use **compressed air** to blow dust out of the USB port, the probe port, and the other connector openings in the case.

**To clean the display screen:**

1. Blow dust off the **screen** with compressed air.
2. Slightly dampen a soft, **clean cloth** with isopropyl alcohol or 75% ethanol, and gently wipe the screen with the cloth.

**To clean the keyboard and console:**

1. Open the **cover** of the system.
2. Hold the **system** upside-down, and blow **compressed air** into the spaces around the keys to dislodge any debris.
3. Turn the system **right-side up**.
4. Use a **vacuum cleaner** crevice tool to suck dust and debris from the key openings.
5. Use a **soft clean cloth or cotton swabs** slightly dampened with isopropyl alcohol or 75% ethanol to wipe the tops and sides of the keys and the surface of the keyboard.
6. Clean the **trackball**.
  - a. Use the tip of a ball point pen or similar item to turn the **trackball locking ring** counter-clockwise until it releases from the locked position.

**Loosening the Locking Ring**

- b. Remove the **locking ring and trackball** from the console.



#### Removing the Trackball

- c. Blow any loose dust from the cavity and wipe clean the cavity and the trackball with a **soft cloth**, lightly moistened with Isopropyl alcohol or 75% ethanol.
- d. Dry the **trackball and cavity**.
- e. Replace the trackball in the cavity and position the **lock ring** with the indents at an angle to the console, as shown below.



#### Inserting Lock Ring

- f. Use the same pointed tool to turn the **lock ring** clockwise while pressing down on the ring, until it latches into position.

#### To clean the optional cart and printer:

1. Wipe the cart and printer case with a **soft, clean cloth** dampened slightly with isopropyl alcohol or 75% ethanol.
2. Use **compressed air** to blow dust out of the connector openings in the printer case.

## Processing Terason Probes Between Uses

Each probe must be processed between uses according to the type of tissue it will contact during use:

- Non-critical applications in which the device contacts only intact skin –clean the probe.
- Semi-critical use, such as endocavity applications (where the device may contact mucous membranes) – clean and high-level disinfect the probe. Use of a sheath is recommended.
- Critical use, in which the device contacts blood, compromised tissue, or is used in a sterile field – clean and high-level disinfect the probe. Use of a sheath is required.



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**Warning:** In addition to the instructions in this guide, the instructions provided by the manufacturer of cleaners and disinfectants must be strictly adhered to.

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**Warning:** Never place the probe connector on the floor when cleaning the probe. The cable connection to the system must always be higher than the lowest point of the cable, to prevent fluid from flowing down the cable to the electronics.

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**Note:** For information on cleaning and disinfecting the 8TE3 probe, refer to the *Odelift Motorized Multiplane TE Probe User Manual*, which is packaged with the probe. There is also a PDF file on the system desktop.

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## Cleaning and Disinfecting Terason Probes

### Noncritical Device Applications

After use that involves only contact with intact skin, cleaning is generally sufficient. Follow your institution's policies on infection control and ultrasound imaging. If high-level disinfection is required (as in semi-critical or critical uses), the probe must be processed using the procedure in [Semicritical Device Applications](#) on page 15.

Between patient exams, perform the following steps to clean the probe:

1. Disconnect the **probe** from the system.
2. If a **sheath** is installed on the probe, remove it.
3. Wipe all ultrasound transmission **gel** off the probe.

4. Wash the probe with a solution of **enzymatic detergent** and water. Enzymatic cleansers are generically approved for use on all Terason transducers. Follow the cleanser manufacturer's instructions for preparation and use.
  - a. Follow the manufacturer's instructions for proper **dilution** of the selected detergent.

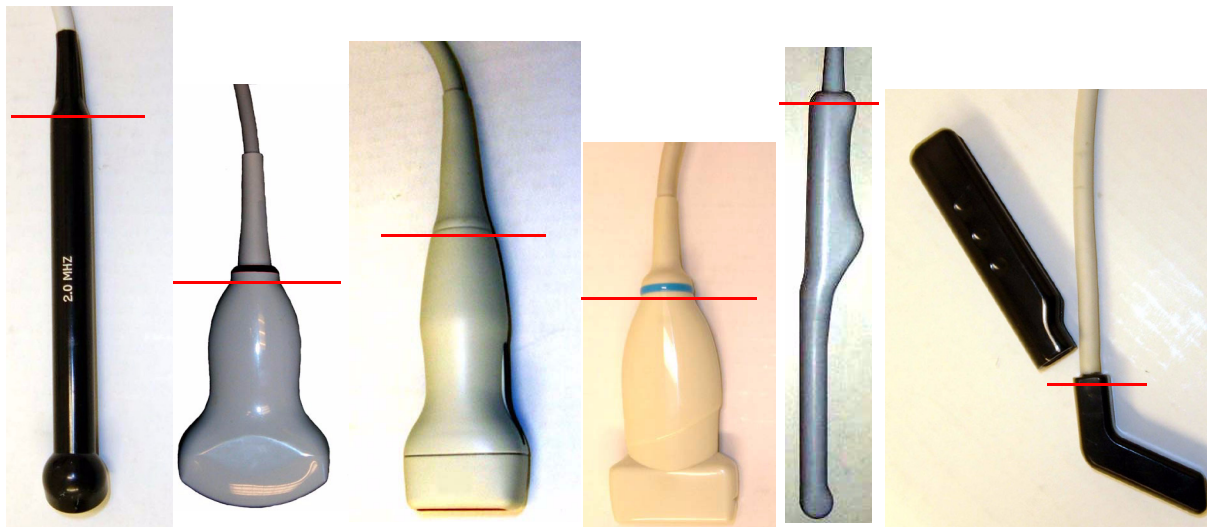


**Note:** Klenzyme detergent packaging may not include dilution instructions. If it does not, dilute Klenzyme at 1 ounce Klenzyme to 1 gallon of water (8 ml to 1 liter of water).

- b. Moisten a soft cloth with the detergent solution, and **wipe** the probe until all visible soil is removed.
  - c. Moisten a second cloth with **sterile water** and wipe all the probe surfaces to remove any detergent residue and prevent it from drying on the probe.
5. Pat the probe dry using a soft sponge, cloth, or gauze pad.



**Warning:** Some cleaning techniques can damage probes. Do not sterilize Terason probes. A sheath is required when using a probe in a sterile field. Probes can be submerged up to, but not including, the strain relief of the probe array. Do not immerse or soak any other part of a probe in any cleaning material. The following figure defines how much of the probe can be submerged.



**Do Not Submerge Probes Above Line**  
(Typical probes shown)



**Note:** The 8TE3 probe has a mark 100 cm from its end. Do not submerge the 8TE3 probe beyond that mark.



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**Warning:** The cable and connector are not waterproof. Do not immerse the cable or allow liquid to contact the connector.

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**Warning:** The Terason Ultrasound System and the AC/DC adapter are not protected from spills or splashes. Disconnect the probe from the system during cleaning.

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### Cleaners

The following cleaners have been tested and found compatible with probes used with the Terason Ultrasound System:

- Transeptic spray
- Sono wipes
- PI Spray II
- Sani Cloth (Plus & HB) wipes
- Protex wipes
- Cavi wipes

### Semicritical Device Applications

When a probe may contact infection sources such as broken skin, lesions, or post-operative wounds, always use a sterile sheath.

Probes used in surgically invasive or intraoperative applications must be enclosed in a sterile sheath marketed for the application. Probes used in such situations should always be high-level disinfected after such use.

### High Level (Immersion bath)

Note: High-Level Disinfection is required for devices that contact intact mucous membranes or non-intact skin.

As presented in the US Centers for Disease Control and Prevention (CDC) Guideline for Disinfection and Sterilization in Healthcare Facilities:

Processing Patient-Care Equipment Contaminated with Bloodborne Pathogens (HBV, Hepatitis C Virus, HIV), Antibiotic-Resistant Bacteria (e.g., Vancomycin-Resistant Enterococci, Methicillin-Resistant Staphylococcus aureus, Multidrug Resistant Tuberculosis), or Emerging Pathogens (e.g., Cryptosporidium, Helicobacter pylori, Escherichia coli O157:H7, Clostridium difficile, Mycobacterium tuberculosis, Severe Acute Respiratory Syndrome Coronavirus), or Bioterrorist Agents:

Use standard sterilization and disinfection procedures for patient-care equipment (as recommended in the CDC guideline), because these procedures are adequate to sterilize or disinfect instruments or devices contaminated with blood or other body fluids from persons infected with bloodborne pathogens or emerging pathogens, except for prions. No changes in these procedures for cleaning, disinfecting, or sterilizing are necessary for removing bloodborne and emerging pathogens other than prions.

Note: Handles of semi-critical probes that are not submerged during High-Level Disinfection require Intermediate-Level Disinfection (e.g., using wipes) to avoid cross contamination.

1. Ensure the probe has been disconnected from the console. Prepare the High-Level Disinfectant per the disinfectant manufacturer's instructions.
2. If a **sheath** is installed on the probe, remove it.
3. Wipe all ultrasound transmission **gel** off the probe.
4. Wash the **probe** with a solution of enzymatic detergent and water. See [Cleaners](#) on page 15 for a list of approved cleaners.
  - a. Follow the manufacturer's instructions for proper **dilution** of the selected detergent.
  - b. Moisten a soft cloth with the detergent solution, and **wipe** the probe until all visible soil is removed.
5. Disinfect the probe using one of the products listed in [High-Level Disinfectants](#) on page 17. Follow the disinfectant manufacturer's instructions for use of the product.



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**Caution:** Do not submerge the probe beyond the line shown in the figure labeled [Do Not Submerge Probes Above Line \(Typical probes shown\)](#) on page 14.

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- a. Submerge the probe in the high-level disinfectant up to the line shown in the figure labeled [Do Not Submerge Probes Above Line \(Typical probes shown\)](#) on page 14.
  - b. Follow the disinfectant manufacturer's instructions for duration, temperature, etc. Ensure no air bubbles are trapped. The probe must remain submerged for the minimum contact time listed on the HLD label.
6. Thoroughly rinse the probe to remove residual disinfectant. Thoroughly dry all surfaces of the probe using a soft, low-lint or lint-free wipe or cloth.
7. Store the probe in a manner that will protect and keep the probe from being recontaminated. This may be accomplished by placing the probe in a storage cabinet with filtered air flow and/or by using a disposable storage cover placed over the probe.

### High Level (Automated system)

High level disinfection can also be performed by an automated system such as trophon® and trophon2 for standard and endocavitary probes.

1. Upon completion of probe cleaning, carefully dry the probe with a clean, low-lint soft and dry cloth or wipe.
2. Visually inspect the probe to ensure the probe is visibly clean.
3. Follow the trophon instructions for probe placement and operation of the trophon system.

4. Once the Trophon High-Level Disinfection cycle is complete, don a new set of gloves and promptly remove the probe from the Trophon machine.
5. Wipe the probe from the distal end to the proximal end with a clean, lint-free soft and dry cloth or wipe.

For TEE probes, you can use an automated system such as the CS Medical TD100.

1. Upon completion of probe cleaning, carefully dry the probe by wiping with a clean, low-lint soft and dry cloth or wipe from the distal tip to the strain relief.
2. Follow the instructions for probe placement and operation of the TD100.
3. Once the TD100 High-Level Disinfection cycle is complete, don a new set of gloves and promptly remove the probe from the TD100 machine.

Wipe the probe from the distal end to the proximal end with a clean, lint-free soft and dry cloth or wipe.

### High-Level Disinfectants

The following high-level disinfectants have been tested, found compatible with probes used with the Terason Ultrasound System, and are cleared for use by the United States Food and Drug Administration (FDA):

- Cidex 2%
- Cidex OPA
- Cidex Plus
- Metricide 14
- Metricide 28
- Wavicide



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**Note:** These high-level disinfectants are for use only on endocavity and TEE probes.

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**Caution:** The 16HL7 probe can be cleaned using only the following disinfectants:

- Alkzyme
- Klenzyme
- Cidex 2%

Using other disinfectants can damage the 16HL7 probe.

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### Disinfection Systems

- The **Trophon EPR System** has been approved for use on the following probes: 4V2A, 5C2A, 8EC4A, 8L2, 8V3A, 9MC3, 15L4, 15L4A, 16L5, and 16SL5.
- The **Trophon2 system** has been approved for all probes listed for the Trophon EPR system, and for the 16HL7 probe.
- The **Steris V-Pro Sterilizer** has been approved for use on the following probes: 8BP4, 8EC4A, 10EC4, and 16HL7.



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**Caution:** When using an enzymatic cleaner, be sure to use the proper concentration and rinse thoroughly. Enzymatic cleaners are generically compatible for use.

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For more information on infection control, refer to the following articles:

- *Design Testing and Labeling of Reusable Medical Devices for Reprocessing in Healthcare Facilities: A Guide for Manufacturers*, AAMI Publishing Company, 1995
- *Disinfections and Preservation*, Block, Seymour S., Lea and Febiger, 1991
- *Sterilants and High Level Disinfectants Cleared by FDA in a 510(k)*, <http://www.fda.gov/cdrh/ode/germlab.html>

## Recommended Maintenance

Terason probes require very little maintenance. Probes should be inspected after every cleaning. If the probe is dropped, examine it immediately for signs of damage. Check for these potential problems:

- Cracks or damage to the handle, nose piece, or connector
- Cuts or gouges on lens material
- Swelling of lens material
- Cuts or cracks in the cable

Do not expose probes to direct heat such as strong sunlight or a local heat source, as heat can cause crystal aging and loss of sensitivity.

When storing the Terason Ultrasound System in environments between 0° and 50°C, the original shipping container must be used.

All components of the Terason Ultrasound System should be checked monthly for these potential problems:

- Cuts, cracks or damage to the power cables
- Dents or cracks in the electronics housing.



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**Warning:** Do not use any equipment that is cut, cracked, dented, or displays any other damage. Use of damaged equipment can create shock hazards for the operator and patient. Contact Terason Customer Support for help.

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## 3 Terason Probes

### Probe Specifications

The Terason Ultrasound System consists of the probe, electronics envelope, and the Terason software. All of the Terason probes can be used with all scan modes.

The following table describes the supported probes. Also see [Infection Control](#) on page 134, [Indications For Use](#) on page 151, [Processing Terason Probes Between Uses](#) on page 13, [Acoustic Output Reporting for Track 3](#) on page 23, and [Ultrasound System Specifications](#) on page 192.

**Terason Probe Specifications**

Probe	Elements	Description	Applications	
4V2A	64	Phased-linear array probe with a user-controllable field-of-view	Cardiac FAST	Vascular
5C2A	128	Curved linear array probe with a user-controllable field-of-view	Adult abdominal OB/GYN Fetal cardiac FAST	Abdominal vascular Renal Gynecological Obstetric
8BP4	128 X 128	Biplanar: Curvilinear and linear	Prostate (cryoablation and brachytherapy therapeutic procedures)	
8EC4A	128	Convex-linear endocavity array probe with a 130° field-of-view	General GYN Prostate Obstetric	
8L2	128	Linear wideband array probe with a user-controllable field of view	Vascular access Carotid Arterial	Venous Breast Thyroid
8TE3	64	Transesophageal Phased-array probe	Transesophageal cardiac	
8V3A	96	Phased-array-sector probe	Abdominal Cardiac Vascular access	Neonatal head Small parts Thyroid
9MC3	80	Curved-linear probe	Small organ Cardiac Neonatal cephalic Adult cephalic Peripheral vascular	Pediatric Fetal Abdominal Musculoskeletal

## Terason Probe Specifications (Continued)

Probe	Elements	Description	Applications	
10BP4	192 X 192	Biplanar: Curvilinear and linear	Prostate (cryoablation and brachytherapy therapeutic procedures)	
10EC4	192	Convex-linear endocavity array probe with a 190° field-of-view	Obstetric	Gynecological Prostate
12L5A	128	Linear wideband array probe	Breast Carotid Dialysis access Musculoskeletal Vascular access Arterial Neonatal hip	Thyroid Venous Nerve block Lung Ophthalmic Testes
14L3	128	Linear wideband array probe	Arterial Breast Carotid Dialysis access Lung Musculoskeletal	Neonatal hip Nerve block Ophthalmic Thyroid Vascular access Venous
15L4	128	Linear wideband array probe	Arterial Breast Carotid Dialysis access Lung Musculoskeletal	Neonatal hip Nerve block Ophthalmic Thyroid Vascular access Venous
15L4A	128	Linear wideband array probe	Arterial Breast Carotid Dialysis access Lung Musculoskeletal	Neonatal hip Nerve block Ophthalmic Thyroid Vascular access Venous
15WL4	192	50 mm wide linear wideband array probe	Abdominal Pediatric Small organ	Musculoskeletal Peripheral vessel
16HL7	128	Angled-head linear wideband array probe with a user-controllable field of view	Venous	Musculoskeletal
16L5	192	Linear wideband array probe	Breast Musculoskeletal Vascular access	Lung Nerve block
16SL5	128	Linear wideband array probe	Breast Musculoskeletal Vascular access	Lung Nerve block Ophthalmic
PDOF	1	Single-element CWD probe with a single-point field-of-view	Cardiac	
XY	64 X 64	Biplanar phased-array probe with a user-controllable field of view	Cardiac Vascular Lung	

## Using the 8TE3 Probe

### Temperature indication

When the 8TE3 probe is connected, the temperature of the probe tip displays in the scan properties of the Imaging Window. This temperature display shows different conditions, depending on the temperature of the probe tip:

- When the probe tip is below 20°C, the display reads <20°C.
- When the probe tip reaches 41°C, the temperature display flashes and is highlighted yellow.
- When the probe tip reaches 43°C, ultrasound transmission stops, and the temperature display is highlighted red.



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**Note:** The 8TE3 Probe must be connected directly to the ultrasound system. Do not connect it to the multiple-probe port on the optional cart.

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### Probe Steering

When the 8TE3 probe is connected, a graphic on the Imaging Window represents the orientation of the probe array, which is controlled by the steering knob on the probe handle.



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**Warning:** Remove the 8TE3 probe from the patient before applying a defibrillator.

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## Acoustic Output Reporting for Track 3

Terason follows Track 3 of the FDA's Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Probes. For ophthalmic applications, the global maximum derated  $I_{SPTA}$  must not exceed  $50 \text{ mW/cm}^2$ , and the global maximum MI must not exceed 0.23. For all other applications, the global maximum derated  $I_{SPTA}$  must not exceed  $720 \text{ mW/cm}^2$  and the global maximum MI must not exceed 1.9.

This chapter contains tables that display the Acoustic Output Reporting for Track 3. Tables are shown for the scanning modes for the following probes:

- 4V2A - see [page 24](#)
- 5C2A - see [page 30](#)
- 8BP4 (CLA) - [page 34](#)
- 8BP4 (Linear) - [page 38](#)
- 8EC4A - see [page 42](#)
- 8L2 - see [page 46](#)
- 8TE3 see [page 50](#)
- 8V3A - see [page 55](#)
- 9MC3 - see [page 60](#)
- 10BP4L - see [page 67](#)
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- 12L5A - see [page 74](#)
- 12L5A - Ophthalmic - see [page 78](#)
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## Acoustic Output Tables for Terason Probes

Acoustic Output Reporting Table for Track 3 for the 4V2A Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.57	2.04			2.04			3.98	
Index Component Value			1.57	2.04	-	-	2.04	-	-	3.98	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.62								
	P	(mW)		156.6	-		156.6	-		198.4	-
	$P_{txt}$	(mW)		130.5	-		130.5	-			
	Min of [ $P_{\alpha}(Z_s)$ , $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.9			-					
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	3.8			-					
	$Z_{MI}$	(cm)	3.6								
	$d_{eq}(Z_b)$	(cm)								-	
	$D_{eq}$	(cm)								1.25	-
	$f_{awf}$	(MHz)	2.80	3.29	-		3.29	-		1.75	-
	Dim of $A_{aprt}$	X (cm)		1.02	-		1.02	-		1.02	-
Y (cm)			1.20	-		1.20	-		1.20	-	
Other Information	Mode Components		B	B	-		B	-		B	-
	$t_d$	(usec)	0.54								
	pr	(Hz)	77.5								
	sr	(Hz)	77.5								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	36.6								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	73.3								
	$p_r$ at $Z_{pii}$	(MPa)	3.71								
	$d_{eq}$ at $Z_{pii}$	(cm)								-	
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	278.8								
	Focal Length	FLx (cm)	4.0			-				-	
		FLy (cm)	5.7			-				-	
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3									X	

Control 1: THI = off, Sector depth = 6.0 cm, Focus = 4.0 cm, Frequency = 3.0 MHz, Focus # = 1

Control 2: THI = off, Sector depth = 6.0 cm, Focus = 4.0 cm, Frequency = 4.0 MHz, Focus # = 1

Control 3: THI = on, Sector depth = 6.0 cm, Focus = 4.0 cm, Frequency = 1.71 MHz, Focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 4V2A Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan		Non-scan	Scan		Non-scan	Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.57	2.04			2.16			3.98	
Index Component Value		1.57	1.92	0.12	0.09	1.92	0.12	0.24	3.75	0.23
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.62							
	P	(mW)		147.1	9.2	147.1	9.2		186.7	11.7
	$P_{txt}$	(mW)		122.6	7.7	122.6	7.7			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			6.0					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						35.0		
	$z_s$	(cm)			1.9					
	$z_{bp}$	(cm)	1.9		1.9			1.9		
	$z_b$	(cm)						3.5		
	$Z_{pii}$	(cm)	3.8		4.2			4.2		
	$Z_{MI}$	(cm)	3.6							
	$d_{eq}(z_b)$	(cm)						0.39		
	$D_{eq}$	(cm)							1.25	1.25
	$f_{awf}$	(MHz)	2.80	3.29	3.29	3.29	3.29		1.75	1.75
Dim of $A_{aprt}$	X (cm)		1.02	1.02	1.02	1.02		1.02	1.02	
	Y (cm)		1.20	1.20	1.20	1.20		1.20	1.20	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.54							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	82.3							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	166.2							
	$p_r$ at $Z_{pii}$	(MPa)	3.71							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.36		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	278.8							
	Focal Length	FLx (cm)	4.0		4.0		4.0			
FLy (cm)		5.7		5.7		5.7				
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: THI = off, Sector depth = 6.0 cm, Focus = 4.0 cm, Frequency = 3.0 MHz, PRF = 570 Hz

Control 2: THI = off, Sector depth = 6.0 cm, Focus = 4.0 cm, Frequency = 4.0 MHz, PRF = 570Hz

Control 3: THI = off, Sector depth = 6.0 cm, Focus = 4.0 cm, Frequency = 1.71 MHz, PRF = 430Hz

Acoustic Output Reporting Table for Track 3 for the 4V2A Probe  
(Terason uSmart3300 Ultrasound System in Color M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.40	1.91			4.12			4.10	
Index Component Value		1.40	1.54	0.37	0.31	0.66	0.72	3.46	1.96	2.14
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.27							
	P	(mW)		BM = 80.3 CF = 46.3	34.6	84.3	92.2	84.3	92.2	
	$P_{txt}$	(mW)		BM = 66.9 CF = 38.6	28.9	70.3	76.9			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1cm^2$ ]	(mW)			24.3					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					475.2			
	$z_s$	(cm)			1.9					
	$z_{bp}$	(cm)	2.20		1.9			1.6		
	$z_b$	(cm)						2.8		
	$Z_{pii}$	(cm)	4.05		3.7			3.3		
	$Z_{MI}$	(cm)	3.95							
	$d_{eq}(Z_b)$	(cm)						0.41		
	$D_{eq}$	(cm)							1.08	1.08
	$f_{awf}$	(MHz)	2.65	BM = 3.29 CF = 2.65	2.65	1.99	1.99	1.99	1.99	1.99
Dim of $A_{aprt}$	X (cm)		1.02	1.02	0.76	0.76	0.76	0.76	0.76	
	Y (cm)		1.20	1.20	1.20	1.20	1.20	1.20	1.20	
Other Information	<b>Mode Components</b>		rD+M	B+rD	M	B+rD	M	B+rD	M	
	$t_d$	(µsec)	1.82							
	prr	(Hz)	140							
	srr	(Hz)	10.7							
	$n_{pps}$		6							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	498.3							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	1031.6							
	$p_r$ at $z_{pii}$	(MPa)	3.26							
	$d_{eq}$ at $z_{pii}$	(cm)						0.40		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	254.8							
	Focal Length	FLx (cm)	5.5		4.0			3.0		
FLy (cm)		5.7		5.7			5.7			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X		X		

Control 1: B-Mode Frequency = 2.0 MHz, sector depth = 18.0 cm, focal depth = 16.5 cm, Color Doppler frequency = 2.7 MHz, Color Doppler focus = 5.5 cm, Frame Rate = 10.7 Hz, Color ROI = 0.83 cm, Packet size = 6, transmit pulses = 5, PRF = 2250 Hz, Dual Beam on, Sweep Speed = 50 mm/s

Control 2: B-Mode Frequency = 4.0 MHz, sector depth = 6.0 cm, focal depth = 4.0 cm, Color Doppler frequency = 2.7 MHz, Color Doppler focus = 4.0 cm, Frame Rate = 46.7 Hz, Color ROI = 0.73 cm, Packet size = 5, transmit pulses = 4, PRF = 10220 Hz, Dual Beam on, Sweep Speed = 100 mm/s

Control 3: B-Mode Frequency = 1.67 MHz, sector depth = 6.0 cm, focal depth = 3.0 cm, Color Doppler frequency = 2.0 MHz, Color Doppler focus = 3.0 cm, Frame Rate = 5.3 Hz, Color ROI = 4.76 cm, Packet size = 12, transmit pulses = 10, PRF = 9230 Hz, Dual Beam on, Sweep Speed = 150 mm/s

Acoustic Output Reporting Table for Track 3 for the 4V2A Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.56	1.96			1.96			4.22	
Index Component Value		1.56	1.96	-	-	1.96	-	-	4.22	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.21							
	P	(mW)		B-M=118.0 CF= 40.3	-	B-M=118.0 CF= 40.3	-		266.2	-
	$P_{txt}$	(mW)		B-M= 98.4 CF= 33.6	-	B-M= 98.4 CF= 33.6	-			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )								
	$z_s$	(cm)								
	$z_{bp}$	(cm)	2.4							
	$z_b$	(cm)								
	$Z_{pii}$	(cm)	4.8							
	$Z_{MI}$	(cm)	4.6							
	$d_{eq}(z_b)$	(cm)								
	$D_{eq}$	(cm)							1.58	-
	$f_{awf}$	(MHz)	1.99	B-M= 3.29 CF= 2.65	-	B-M= 3.29 CF= 2.65	-		1.99	-
	Dim of $A_{aprt}$	X (cm)		1.02	-	1.02	-		1.63	-
Y (cm)			1.20	-	1.20	-		1.20	-	
Other Information	Mode Components		rD	B+rD	-	B+rD	-	B+rD	-	
	$t_d$	(µsec)	1.91							
	prr	(Hz)	7540							
	srr	(Hz)	45.4							
	$n_{pps}$		4							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	331.9							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	627.5							
	$p_r$ at $z_{pii}$	(MPa)	3.0							
	$d_{eq}$ at $z_{pii}$	(cm)								
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	255.5							
	Focal Length	FLx (cm)	7.0							
		FLy (cm)	5.7							
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: B-Mode Frequency = 2.5 MHz, sector depth = 30.0 cm, focal depth = 16.5 cm, Color Doppler frequency = 2.0 MHz, Color Doppler focus = 7.0 cm, Frame Rate = 45.4 Hz, Color ROI = 1.30 cm, Packet size = 5, transmit pulses = 4, PRF = 7540 Hz, Dual Beam on  
 Control 2: B-Mode Frequency = 2.0 MHz, sector depth = 6.0 cm, focal depth = 4.0 cm, Color Doppler frequency = 2.7 MHz, Color Doppler focus = 4.0 cm, Frame Rate = 46.3 Hz, Color ROI = 0.49 cm, Packet size = 5, transmit pulses = 4, PRF = 13120 Hz, Dual Beam off  
 Control 3: B-Mode Frequency = 1.67 MHz, sector depth = 7.0 cm, focal depth = 7.0 cm, Color Doppler frequency = 2.0 MHz, Color Doppler focus = 7.0 cm, Frame Rate = 4.5 Hz, Color ROI = 7.28 cm, Packet size = 14, transmit pulses = 10, PRF = 7720 Hz, Dual Beam on

Acoustic Output Reporting Table for Track 3 for the 4V2A Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.57	1.87			5.06			4.14	
Index Component Value		1.57	-	1.53	1.87	-	1.30	5.06	0.24	3.90
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.43							
	P	(mW)		-	241.8	-	246.2	10.6	237.9	
	$P_{txt}$	(mW)		-	134.3	-	136.8			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			164.3					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					511.4			
	$z_s$	(cm)			2.3					
	$z_{bp}$	(cm)	2.0		2.3			2.3		
	$z_b$	(cm)						4.9		
	$Z_{pii}$	(cm)	3.9		5.6			5.8		
	$Z_{MI}$	(cm)	3.8							
	$d_{eq}(z_b)$	(cm)						0.56		
	$D_{eq}$	(cm)							1.08	1.53
	$f_{awf}$	(MHz)	2.40	-	2.39	-	1.99	2.43	1.99	
Dim of $A_{aprt}$	X (cm)		-	1.52	-	1.52	0.76	1.52		
	Y (cm)		-	1.20	-	1.20	1.20	1.20		
Other Information	<b>Mode Components</b>		D	-	D	-	D	B	D	
	$t_d$	( $\mu$ sec)	3.18							
	prr	(Hz)	700							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	576.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	973.1							
	$p_r$ at $Z_{pii}$	(MPa)	3.31							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.53		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	259.1							
	Focal Length	FLx (cm)	5.5		13.0		16.5			
FLy (cm)		5.7		5.7		5.7				
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				
	Control 4							X		

- Control 1: Sector depth = 24.0 cm, Focus = 3.0 cm, B-Mode Frequency = 3.0 MHz, PWD Frequency = 2.4 MHz, SV Size = 2.5 mm, SV Depth = 5.5 cm, PRF = 700 Hz, Update = off
- Control 2: Sector depth = 24.0 cm, Focus = 3.0 cm, B-Mode Frequency = 3.0 MHz, PWD Frequency = 2.4 MHz, SV Size = 2.5 mm, SV Depth = 12.0 cm, PRF = 5100 Hz, Update = off
- Control 3: Sector depth = 24.0 cm, Focus = 3.0 cm, B-Mode Frequency = 2.0 MHz, PWD Frequency = 2.0 MHz, SV Size = 5.0 mm, SV Depth = 16.5 cm, PRF = 2000 Hz, Update = off
- Control 4: Sector depth = 24.0 cm, Focus = 3.0 cm, B-Mode Frequency = 2.5 MHz, PWD Frequency = 2.0 MHz, SV Size = 5.0 mm, SV Depth = 16.5 cm, PRF = 1500 Hz, Update = on

Acoustic Output Reporting Table for Track 3 for the 4V2A Probe  
(Terason uSmart3300 Ultrasound System in CWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.10	0.87			4.38			3.17	
Index Component Value		0.10	-	0.86	0.87	-	1.03	4.38	-	3.17
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.13							
	P	(mW)		-	129.7	-	129.7	-	129.7	
	$P_{txt}$	(mW)		-	108.1	-	108.1			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)			109.2					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					501.2			
	$z_s$	(cm)			1.5					
	$z_{bp}$	(cm)	1.5		1.5			1.5		
	$z_b$	(cm)						2.7		
	$Z_{pii}$	(cm)	3.2		3.2			3.2		
	$Z_{MI}$	(cm)	2.8							
	$d_{eq}(z_b)$	(cm)						0.50		
	$D_{eq}$	(cm)							-	1.02
	$f_{awf}$	(MHz)	1.67	-	1.67	-	1.67	-	1.67	
Dim of $A_{aprt}$	X (cm)		-	0.69	-	0.69	-	0.69		
	Y (cm)		-	1.20	-	1.20	-	1.20		
<b>Mode Components</b>		cwD	-	cwD	-	cwD	-	cwD		
Other Information	$t_d$	( $\mu$ sec)	-							
	prr	(Hz)	-							
	srr	(Hz)	-							
	$n_{pps}$		-							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	514.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	709.6							
	$p_r$ at $z_{pii}$	(MPa)	0.16							
	$d_{eq}$ at $z_{pii}$	(cm)						0.49		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	-							
	Focal Length	FLx (cm)	4.0		16.0		16.0			
FLy (cm)		5.7		5.7		5.7				
Operating Control Conditions	Control 1		X							
	Control 2			X		X		X		
	Control 3									

Control 1: Sector depth = 18.0 cm, Focus = 3.0 cm, B-Mode Frequency = 2.5 MHz, CWD Frequency = 1.7 MHz, SV Depth = 4.0 cm, Update = off  
 Control 2: Sector depth = 18.0 cm, Focus = 3.0 cm, B-Mode Frequency = 2.5 MHz, CWD Frequency = 1.7 MHz, SV Depth = 16.0 cm, Update = off

Acoustic Output Reporting Table for Track 3 for the 5C2A Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.48	0.46			0.46			Note 1	
Index Component Value		1.48	0.46	-	-	0.46	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.22							
	P	(mW)		216.8	-	216.8	-	-	-	-
	$P_{txt}$	(mW)		43.2	-	43.2	-	-	-	-
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	2.2		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	4.4		-			-		
	$Z_{MI}$	(cm)	4.3							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	2.24	2.26	-	2.26	-	-	-	-
Dim of $A_{aprt}$	X (cm)		4.35	-	4.35	-	-	-	-	
	Y (cm)		1.30	-	1.30	-	-	-	-	
Other Information	<b>Mode Components</b>		B	B	-	B	-	-	-	
	$t_d$	(μsec)	0.94							
	prr	(Hz)	24.8							
	srr	(Hz)	24.8							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	49.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	96.9							
	$p_r$ at $Z_{pii}$	(MPa)	3.01							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	264.8							
	Focal Length	FLx (cm)	6.0		-			-		
FLy (cm)		4.3		-			-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq. = 2.21 MHz, sector depth = 11 cm, focus = 6.0 cm, focus # = 1, sector width = L

Control 2: Freq. = 2.21 MHz, sector depth = 4 cm, focus = 2.5 cm, focus # = 1, sector width = S

**Acoustic Output Reporting Table for Track 3 for the 5C2A Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.48	0.61			1.12			Note 1	
Index Component Value		1.48	0.31	0.12	0.30	0.32	0.14	0.80	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.22							
	P	(mW)		150.5	50.2	149.4	21.9		-	-
	$P_{txt}$	(mW)		29.7	12.1	29.7	13.0			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			29.0					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						139.0		
	$Z_s$	(cm)			3.6					
	$Z_{bp}$	(cm)	2.2		3.6			2.2		
	$Z_b$	(cm)						4.1		
	$Z_{pii}$	(cm)	4.4		15.2			4.4		
	$Z_{MI}$	(cm)	4.3							
	$d_{eq}(Z_b)$	(cm)						0.32		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	2.24	2.15	2.15	2.26	2.24		-	-
Dim of $A_{aprt}$	X (cm)		6.40	3.60	4.35	1.30		-	-	
	Y (cm)		1.30	1.30	1.30	1.30		-	-	
<b>Mode Components</b>			B+M	B	M	B	M	-	-	
Other Information	$t_d$	( $\mu$ sec)	0.94							
	prr	(Hz)	570							
	srr	(Hz)	71.3							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	212.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	419.6							
	$p_r$ at $Z_{pii}$	(MPa)	3.01							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.31		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	264.8							
	Focal Length	FLx (cm)	6.0		16.0			6.0		
FLy (cm)		4.3		4.3			4.3			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq. = 2.21 MHz, sector depth = 11 cm, focus = 6.0 cm, sector width = L, PRF = 570 Hz

Control 2: Freq. = 2.21 MHz, sector depth = 26 cm, focus = 16.0 cm, sector width = L, PRF = 570 Hz

Control 2: Freq. = 2.21 MHz, sector depth = 14 cm, focus = 6.0 cm, sector width = S, PRF = 570 Hz

**Acoustic Output Reporting Table for Track 3 for the 5C2A Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.53	1.17			1.17			Note 1	
Index Component Value			1.53	1.17	-	-	1.17	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.30								
	P	(mW)		139.7	-	-	139.7	-	-	-	-
	$P_{txt}$	(mW)		87.6	-	-	87.6	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	2.2			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	4.2			-			-		
	$Z_{MI}$	(cm)	4.1								
	$d_{eq}(Z_b)$	(cm)								-	
	$D_{eq}$	(cm)									-
	$f_{awf}$	(MHz)	2.27	2.81	-	-	2.81	-	-	-	-
Dim of $A_{aprt}$	X (cm)		1.50	-	-	1.50	-	-	-	-	
	Y (cm)		1.30	-	-	1.30	-	-	-	-	
<b>Mode Components</b>			rD	B+rD	-	-	B+rD	-	-	-	
Other Information	$t_d$	( $\mu$ sec)	1.23								
	prr	(Hz)	250								
	srr	(Hz)	14.2								
	$n_{pps}$		16								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	296.0								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	568.6								
	$p_r$ at $Z_{pii}$	(MPa)	3.09								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	380.7								
	Focal Length	FLx (cm)	6.0			-			-		
FLy (cm)		4.3			-			-			
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 4.0 MHz, sector depth = 6.0 cm, focal depth = 6.0 cm, Color Doppler frequency = 2.3 MHz, Color Doppler focus = 6.0 cm, Frame Rate = 14.2 Hz, Color ROI = 1.43 cm, Packet size = 16, transmit pulses = 3, PRF = 250 Hz  
 Control 2: B-Mode Frequency = 4.97 MHz, sector depth = 4.0 cm, focal depth = 1.0 cm, Color Doppler frequency = 2.8 MHz, Color Doppler focus = 1.0 cm, Frame Rate = 24.0 Hz, Color ROI = 1.37 cm, Packet size = 14, transmit pulses = 10, PRF = 22210 Hz

Acoustic Output Reporting Table for Track 3 for the 5C2A Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.53	1.35			3.45			Note 1	
Index Component Value			1.53	-	0.76	1.35	-	0.84	3.45	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.30								
	P	(mW)		-	188.4		-	90.8		-	-
	$P_{txt}$	(mW)		-	57.0		-	69.9			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				101.7					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							419.9		
	$Z_s$	(cm)				3.2					
	$Z_{bp}$	(cm)	2.2			3.2				1.4	
	$Z_b$	(cm)								1.4	
	$Z_{pii}$	(cm)	4.2			12.0				4.1	
	$Z_{MI}$	(cm)	4.1								
	$d_{eq}(Z_b)$	(cm)								0.46	
	$D_{eq}$	(cm)									-
	$f_{awf}$	(MHz)	2.27	-	2.79		-	2.54		-	-
Dim of $A_{aprt}$	X (cm)		-	2.90		-	0.50		-	-	
	Y (cm)		-	1.30		-	1.30		-	-	
Mode Components			D	-	D	-	D	-	-	-	
Other Information	$t_d$	( $\mu$ sec)	2.88								
	prf	(Hz)	350								
	srr	(Hz)	-								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	397.3								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	765.1								
	$p_r$ at $Z_{pii}$	(MPa)	3.10								
	$d_{eq}$ at $Z_{pii}$	(cm)							0.40		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	394.3								
	Focal Length	FLx (cm)	6.0			13.0			2.5		
FLy (cm)		4.3			4.3			4.3			
Operating Control Conditions	Control 1		X								
	Control 2				X						
	Control 3						X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 21.0 cm, Focus = 4.0 cm, B-Mode Frequency = 4.0 MHz, PWD Frequency = 2.3 MHz, SV Size = 2.5 mm, SV Depth = 6.0 cm, PRF = 350 Hz, Update = off

Control 2: Sector depth = 21.0 cm, Focus = 4.0 cm, B-Mode Frequency = 4.97 MHz, PWD Frequency = 2.8 MHz, SV Size = 3.5 mm, SV Depth = 13.0 cm, PRF = 4000 Hz, Update = off

Control 3: Sector depth = 21.0 cm, Focus = 4.0 cm, B-Mode Frequency = 4.47 MHz, PWD Frequency = 2.6 MHz, SV Size = 4.0 mm, SV Depth = 2.5 cm, PRF = 2250 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 8BP4 (CLA) Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.60	0.32			0.32			Note 1	
Index Component Value			0.60	0.32	-	-	0.32	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.46								
	P	(mW)		21.7	-	-	21.7	-	-	-	-
	$P_{txt}$	(mW)		11.8	-	-	11.8	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.1			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	2.6			-			-		
	$Z_{MI}$	(cm)	2.4								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	5.85	5.78	-	-	5.78	-	-	-	-
	Dim of $A_{aprt}$	X (cm)		2.52	-	-	2.52	-	-	-	-
Y (cm)			0.70	-	-	0.70	-	-	-	-	
Mode Components			B	B	-	B	-	-	-	-	
Other Information	$t_d$	( $\mu\text{sec}$ )	0.20								
	prr	(Hz)	150								
	srr	(Hz)	150								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	16.8								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	44.6								
	$p_r$ at $Z_{pii}$	(MPa)	2.27								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	165.5								
	Focal Length	FLx (cm)	2.5			-				-	
FLy (cm)		2.6			-				-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 6.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, lines = 90, Sector Width = S, focus# = 1

Control 2: Freq = 6.0 MHz, sector depth = 4.0 cm, focus = 3.5 cm, lines = 180, Sector Width = S, focus# = 1

Acoustic Output Reporting Table for Track 3 for the 8BP4 (CLA) Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.60	0.29			0.31			Note 1	
Index Component Value		0.60	0.27	0.02	0.01	0.27	0.02	0.04	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.46							
	P	(mW)		18.0	0.8	18.0	0.8		-	-
	$P_{txt}$	(mW)		9.8	0.8	9.8	0.8			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)			0.4					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						31.0		
	$z_s$	(cm)			1.2					
	$z_{bp}$	(cm)	1.1		1.2			1.2		
	$z_b$	(cm)						2.5		
	$Z_{pii}$	(cm)	2.6		2.9			2.9		
	$Z_{MI}$	(cm)	2.4							
	$d_{eq}(z_b)$	(cm)						0.16		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	5.85	5.78	5.78	5.78	5.78		-	-
Dim of $A_{aprt}$	X (cm)		2.52	0.68	2.52	0.68		-	-	
	Y (cm)		0.70	0.70	0.70	0.70		-	-	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M		-	-
	$t_d$	(usec)	0.20							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	25.7							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	69.7							
	$p_r$ at $z_{pii}$	(MPa)	2.00							
	$d_{eq}$ at $z_{pii}$	(cm)						0.15		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	121.0							
	Focal Length	$FL_x$ (cm)	2.5		3.5			3.5		
$FL_y$ (cm)		2.6		2.6			2.6			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 6.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, lines = 90, Sector Width = S, PRF = 570 Hz

Control 2: Freq = 6.0 MHz, sector depth = 4.0 cm, focus = 3.5 cm, lines = 90, Sector Width = S, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 8BP4 (CLA) Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.51	0.69			0.69			Note 1	
Index Component Value			0.51	0.69	-	-	0.69	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.11								
	P	(mW)		33.4	-	-	33.4	-	-	-	-
	$P_{txt}$	(mW)		30.1	-	-	30.1	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.1			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	2.4			-			-		
	$Z_{MI}$	(cm)	2.3								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	4.77	4.77	-	-	4.77	-	-	-	-
Dim of $A_{aprt}$	X (cm)		1.41	-	-	1.41	-	-	-	-	
	Y (cm)		0.70	-	-	0.70	-	-	-	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	-	-
	$t_d$	( $\mu$ sec)	0.98								
	prf	(Hz)	13500								
	srr	(Hz)	82.5								
	$n_{pps}$		5								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	199.2								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	425.4								
	$p_r$ at $Z_{pii}$	(MPa)	1.58								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	75.1								
	Focal Length	FLx (cm)	2.5			-			-		
FLy (cm)		2.6			-			-			
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 6.0 MHz, sector depth = 6.0 cm, focal depth = 2.5 cm, Color Doppler frequency = 4.8 MHz, Color Doppler focus = 2.5 cm, Frame Rate = 82.5 Hz, Color ROI = 0.81 cm, Packet size = 12, transmit pulses = 5, PRF = 13500 Hz  
 Control 2: B-Mode Frequency = 6.0 MHz, sector depth = 12.0 cm, focal depth = 1.5 cm, Color Doppler frequency = 4.8 MHz, Color Doppler focus = 1.5 cm, Frame Rate = 27.9 Hz, Color ROI = 2.71 cm, Packet size = 12, transmit pulses = 10, PRF = 22210 Hz

Acoustic Output Reporting Table for Track 3 for the 8BP4 (CLA) Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.91	0.67			1.54			Note 1	
Index Component Value		0.91	-	0.67	0.45	-	0.60	1.54	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.00							
	P	(mW)		-	29.6	-	26.4	-	-	-
	$P_{txt}$	(mW)		-	29.6	-	26.4			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			19.9					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						495.7		
	$Z_s$	(cm)			1.2					
	$Z_{bp}$	(cm)	1.1		1.2			1.2		
	$Z_b$	(cm)						2.4		
	$Z_{pii}$	(cm)	2.4		3.0			2.6		
	$Z_{MI}$	(cm)	2.3							
	$d_{eq}(Z_b)$	(cm)						0.18		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.77	-	4.76	-	4.77	-	-	-
Dim of $A_{aprt}$	X (cm)		-	0.78	-	0.68	-	-	-	
	Y (cm)		-	0.70	-	0.70	-	-	-	
<b>Mode Components</b>		D	-	D	-	D	-	-	-	
Other Information	$t_d$	(µsec)	1.77							
	prr	(Hz)	1250							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	526.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	1138.7							
	$p_r$ at $Z_{pii}$	(MPa)	2.85							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.17		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	238.3							
	Focal Length	FLx (cm)	2.5		4.5			3.5		
FLy (cm)		2.6		2.6			2.6			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 9.0 cm, Focus = 2.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 1.5 mm, SV Depth = 2.5 cm, PRF = 1250 Hz, Update = off

Control 2: Sector depth = 9.0 cm, Focus = 2.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 3.5 mm, SV Depth = 4.5 cm, PRF = 4500 Hz, Update = off

Control 3: Sector depth = 9.0 cm, Focus = 2.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 4.0 mm, SV Depth = 3.3 cm, PRF = 15200 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 8BP4 (Linear) Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.84	0.31			0.31			Note 1	
Index Component Value			0.84	0.31	-	-	0.31	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.06								
	P	(mW)		51.3	-	-	51.3	-	-	-	-
	$P_{txt}$	(mW)		12.8	-	-	12.8	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.9			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.6			-			-		
	$Z_{MI}$	(cm)	1.6								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	6.02	5.10	-	-	5.10	-	-	-	-
	Dim of $A_{aprt}$	X (cm)		5.38	-	-	5.38	-	-	-	-
Y (cm)			0.50	-	-	0.50	-	-	-	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	-	
	$t_d$	( $\mu$ sec)	0.14								
	prr	(Hz)	121.4								
	srr	(Hz)	121.4								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	28.8								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	57.7								
	$p_r$ at $Z_{pii}$	(MPa)	2.81								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	417.2								
	Focal Length	FLx (cm)	2.5			-			-		
		FLy (cm)	1.5			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 6.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, lines = 128, focus# = 1

Control 2: Freq = 6.0 MHz, sector depth = 8.0 cm, focus = 8.0 cm, lines = 128, focus# = 1

Acoustic Output Reporting Table for Track 3 for the 8BP4 (Linear) Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.84	0.29			0.31			Note 1	
Index Component Value		0.84	0.25	0.02	0.04	0.25	0.02	0.06	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.06							
	P	(mW)		41.9	3.5	41.9	3.5		-	-
	$P_{txt}$	(mW)		10.5	0.9	10.5	0.9			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)						1.5		
	$I_{spta a}$ at $Z_b$	(mW/cm <sup>2</sup> )						5.1		
	$Z_s$	(cm)			2.4					
	$Z_{bp}$	(cm)	0.9		2.4			2.4		
	$Z_b$	(cm)						2.4		
	$Z_{pii}$	(cm)	1.6		8.1			8.1		
	$Z_{MI}$	(cm)	1.6							
	$d_{eq}(Z_b)$	(cm)						0.63		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	6.02	5.10	5.10	5.10	5.10		-	-
	Dim of $A_{aprt}$	X (cm)		5.38	4.03	5.38	4.03		-	-
Y (cm)			0.50	0.50	0.50	0.50		-	-	
<b>Mode Components</b>		B+M	B	M	B	M		-	-	
Other Information	$t_d$	( $\mu$ sec)	0.14							
	prr	(Hz)	570							
	srr	(Hz)	95.0							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	57.2							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	114.6							
	$p_r$ at $Z_{pii}$	(MPa)	2.81							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.47		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	417.2							
	Focal Length	FLx (cm)	2.5		8.0			8.0		
FLy (cm)		1.5		1.5			1.5			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 6.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, lines = 144, PRF = 570 Hz

Control 2: Freq = 6.0 MHz, sector depth = 8.0 cm, focus = 8.0 cm, lines = 72, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 8BP4 (Linear) Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.66	0.59			0.59			Note 1	
Index Component Value			0.66	0.59	-	-	0.59	-	-	-	-
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	1.44								
	P	(mW)		35.7	-	-	35.7	-	-	-	-
	$P_{txt}$	(mW)		25.9	-	-	25.9	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.9			-					
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.55			-				-	
	$Z_{MI}$	(cm)	1.50								
	$d_{eq}(Z_b)$	(cm)								-	
	$D_{eq}$	(cm)									-
	$f_{awf}$	(MHz)	4.78	4.78	-	-	4.78	-	-	-	-
Dim of $A_{aprt}$	X (cm)		5.38	-	-	5.38	-	-	-	-	
	Y (cm)		0.50	-	-	0.50	-	-	-	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	-	-
	$t_d$	(µsec)	0.79								
	prf	(Hz)	20520								
	srr	(Hz)	100.1								
	$n_{pps}$		4								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	343.9								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	567.2								
	$\rho_r$ at $Z_{pii}$	(MPa)	1.81								
	$d_{eq}$ at $Z_{pii}$	(cm)								-	
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	111.9								
	Focal Length	FLx (cm)	2.5			-				-	
FLy (cm)		1.5			-				-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 6.0 MHz, sector depth = 4.0 cm, focal depth = 2.5 cm, Color Doppler frequency = 4.8 MHz, Color Doppler focus = 2.5 cm, Frame Rate = 100.1 Hz, Color ROI = 0.63 cm, Packet size = 14, transmit pulses = 4, PRF = 20520 Hz

Control 2: B-Mode Frequency = 6.0 MHz, sector depth = 4.0 cm, focal depth = 1.5 cm, Color Doppler frequency = 4.8 MHz, Color Doppler focus = 1.5 cm, Frame Rate = 43.5 Hz, Color ROI = 1.31 cm, Packet size = 14, transmit pulses = 10, PRF = 22210 Hz

Acoustic Output Reporting Table for Track 3 for the 8BP4 (Linear) Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.21	0.79			1.81			Note 1	
Index Component Value		1.21	-	0.43	0.79	-	0.64	1.81	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.64							
	P	(mW)		-	76.9	-	32.8		-	-
	$P_{txt}$	(mW)		-	19.2	-	28.1			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			35.0					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					384.4			
	$Z_s$	(cm)			2.40					
	$Z_{bp}$	(cm)	0.90		2.40			1.30		
	$Z_b$	(cm)						1.30		
	$Z_{pii}$	(cm)	1.55		8.10			3.05		
	$Z_{MI}$	(cm)	1.50							
	$d_{eq}(Z_b)$	(cm)						0.26		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.78	-	4.74	-	4.77		-	-
Dim of $A_{aprt}$	X (cm)		-	4.03	-	1.18		-	-	
	Y (cm)		-	0.50	-	0.50		-	-	
Other Information	<b>Mode Components</b>		D	-	D	-	D	-	-	
	$t_d$	( $\mu$ sec)	1.77							
	prr	(Hz)	700							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	426.9							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	709.3							
	$p_r$ at $Z_{pii}$	(MPa)	3.31							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.20		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	344.2							
	Focal Length	FLx (cm)	2.5		8.0		3.5			
FLy (cm)		1.5		1.5		1.5				
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

- Control 1: Sector depth = 9.0 cm, Focus = 2.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 1.5 mm, SV Depth = 2.5 cm, PRF = 700 Hz, Update = off
- Control 2: Sector depth = 9.0 cm, Focus = 2.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 2.0 mm, SV Depth = 10.4 cm, PRF = 6400 Hz, Update = off
- Control 3: Sector depth = 9.0 cm, Focus = 2.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 1.0 mm, SV Depth = 3.5 cm, PRF = 10000 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 8EC4A Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.47	0.55			0.55			Note 1	
Index Component Value			1.47	0.55	-	-	0.55	-	-	-	-
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	3.86								
	P	(mW)		25.1	-	-	25.1	-	-	-	-
	$P_{txt}$	(mW)		22.8	-	-	22.8	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.9			-					
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.6			-					
	$Z_{MI}$	(cm)	1.5								
	$d_{eq}(Z_b)$	(cm)								-	
	$D_{eq}$	(cm)									-
	$f_{awf}$	(MHz)	6.93	4.94	-	-	4.94	-	-	-	-
	Dim of $A_{aprt}$	X (cm)		1.33	-	-	1.33	-	-	-	-
Y (cm)			0.50	-	-	0.50	-	-	-	-	
<b>Mode Components</b>			B	B	-	B	-	-	-	-	
Other Information	$t_d$	( $\mu\text{sec}$ )	0.21								
	prf	(Hz)	150.0								
	srr	(Hz)	150.0								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	55.4								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	116.2								
	$\rho_r$ at $Z_{pii}$	(MPa)	5.19								
	$d_{eq}$ at $Z_{pii}$	(cm)								-	
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	590.9								
	Focal Length	FLx (cm)	1.5			-					-
		FLy (cm)	2.0			-					-
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 11.0 cm, Focus = 1.5 cm, Frequency = 7.5 MHz, Sector size = 16 lines, Focus # = 1

Control 2: Sector depth = 4.0 cm, Focus = 2.5 cm, Frequency = 5.0 MHz, Sector size = 64 lines, Focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 8EC4A Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.47	0.52			0.58			Note 1	
Index Component Value		1.47	0.45	0.07	0.04	0.45	0.07	0.13	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.86							
	P	(mW)		22.6	2.8	22.6	2.8		-	-
	$P_{txt}$	(mW)		19.2	2.8	19.2	2.8			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)						1.9		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						31.4		
	$Z_s$	(cm)			1.2					
	$Z_{bp}$	(cm)	0.9		1.2			1.2		
	$Z_b$	(cm)						2.3		
	$Z_{pii}$	(cm)	1.6		2.6			2.6		
	$Z_{MI}$	(cm)	1.5							
	$d_{eq}(Z_b)$	(cm)						0.23		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	6.93	4.92	4.92	4.92	4.92		-	-
Dim of $A_{aprt}$	X (cm)		1.62	0.96	1.62	0.96		-	-	
	Y (cm)		0.50	0.50	0.50	0.50		-	-	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M		-	-
	$t_d$	( $\mu$ sec)	0.21							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	72.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	153.0							
	$p_r$ at $Z_{pii}$	(MPa)	5.19							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.22		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	590.9							
	Focal Length	FLx (cm)	1.5		3.5			3.5		
FLy (cm)		2.0		2.0			2.0			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 6.0 cm, Focus = 1.5 cm, Frequency = 7.5 MHz, Sector size = 16 lines, PRF = 570 Hz

Control 2: Sector depth = 4.0 cm, Focus = 3.5 cm, Frequency = 5.0 MHz, Sector size = 32 lines, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 8EC4A Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.19	0.71			0.71			Note 1	
Index Component Value			1.19	0.71	-	-	0.71	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.89								
	P	(mW)		30.5	-	-	30.5	-	-	-	-
	$P_{txt}$	(mW)		29.7	-	-	29.7	-	-		
	Min of [ $P_a(z_s)$ , $I_{ta, a}(z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$z_s$	(cm)				-					
	$z_{bp}$	(cm)	0.9			-			-		
	$z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.5			-			-		
	$Z_{MI}$	(cm)	1.4								
	$d_{eq}(z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	5.93	4.97	-	-	4.97	-	-	-	-
Dim of $A_{aprt}$	X (cm)		1.19	-	-	1.19	-	-	-	-	
	Y (cm)		0.50	-	-	0.50	-	-	-	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	-	-
	$t_d$	(µsec)	0.64								
	prr	(Hz)	1250								
	srr	(Hz)	8.6								
	$n_{pps}$		7								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	42.4								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	75.0								
	$p_r$ at $z_{pii}$	(MPa)	3.74								
	$d_{eq}$ at $z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	330.5								
	Focal Length	FLx (cm)	1.5			-			-		
FLy (cm)		2.0			-			-			
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 9.0 MHz, sector depth = 14.0 cm, focal depth = 1.5 cm, Color Doppler frequency = 6.0 MHz, Color Doppler focus = 1.5 cm, Frame Rate = 8.6 Hz, Color ROI = 0.84 cm, Packet size = 7, transmit pulses = 4, PRF = 1250 Hz  
 Control 2: B-Mode Frequency = 7.5 MHz, sector depth = 4.0 cm, focal depth = 0.8 cm, Color Doppler frequency = 5.0 MHz, Color Doppler focus = 0.8 cm, Frame Rate = 28.8 Hz, Color ROI = 1.4 cm, Packet size = 14, transmit pulses = 10, PRF = 22220 Hz

**Acoustic Output Reporting Table for Track 3 for the 8EC4A Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.46	0.65			1.82			Note 1	
Index Component Value		1.46	-	0.65	0.44	-	0.43	1.82	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.56							
	P	(mW)		-	27.3	-	22.5		-	-
	$P_{txt}$	(mW)		-	27.3	-	22.5			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			18.4					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						431.7		
	$Z_s$	(cm)			1.55					
	$Z_{bp}$	(cm)	0.9		1.15			.60		
	$Z_b$	(cm)						.60		
	$Z_{pii}$	(cm)	1.7		1.65			1.45		
	$Z_{MI}$	(cm)	1.6							
	$d_{eq}(Z_b)$	(cm)						0.24		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	5.93	-	4.99	-	4.00		-	-
Dim of $A_{aprt}$	X (cm)		-	0.90	-	0.27		-	-	
	Y (cm)		-	0.50	-	0.50		-	-	
Other Information	<b>Mode Components</b>		D	-	D	-	D	-	-	
	$t_d$	( $\mu$ sec)	1.14							
	prr	(Hz)	800							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	425.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	820.4							
	$p_r$ at $Z_{pii}$	(MPa)	4.80							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.21		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	468.2							
	Focal Length	FLx (cm)	2.5		4.5			0.8		
FLy (cm)		2.0		2.0			2.0			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

- Control 1: Sector depth = 9.0 cm, Focus = 3.5 cm, B-Mode Frequency = 9.0 MHz, PWD Frequency = 6.0 MHz, SV Size = 1.0 mm, SV Depth = 2.5 cm, PRF = 800 Hz, Update = off  
Control 2: Sector depth = 9.0 cm, Focus = 3.5 cm, B-Mode Frequency = 7.5 MHz, PWD Frequency = 5.0 MHz, SV Size = 7.0 mm, SV Depth = 4.5 cm, PRF = 4500 Hz, Update = off  
Control 3: Sector depth = 12.0 cm, Focus = 3.5 cm, B-Mode Frequency = 4.0 MHz, PWD Frequency = 4.0 MHz, SV Size = 4.5 mm, SV Depth = 0.8 cm, PRF = 11000 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 8L2 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.92	0.82			0.82			1.48	
Index Component Value			0.92	0.82	-	-	0.82	-	-	1.48	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.13								
	P	(mW)		79.6	-	-	79.6	-	-	101.1	-
	$P_{txt}$	(mW)		32.5	-	-	32.5	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.2			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	2.4			-			-		
	$Z_{MI}$	(cm)	2.2								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.71	-
	$f_{awf}$	(MHz)	5.36	5.32	-	-	5.32	-	-	5.07	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.60	-	-	0.60	-	-	0.60	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-
	$t_d$	( $\mu$ sec)	0.20								
	prr	(Hz)	47.3								
	srr	(Hz)	47.3								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	27.3								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	61.7								
	$p_r$ at $Z_{pii}$	(MPa)	2.98								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	378.1								
	Focal Length	FLx (cm)	2.4			-			-		
		FLy (cm)	4.0			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3									X	

Control 1: Freq. = 5.33 MHz, sector depth = 5 cm, focus = 2.4 cm, focus # = 1

Control 2: Freq. = 5.33 MHz, sector depth = 7 cm, focus = 6.5 cm, focus # = 1

Control 3: Freq. = 5.33 MHz, sector depth = 10 cm, focus = 10.0 cm, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 8L2 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.92	0.81			0.82			1.40	
Index Component Value		0.92	0.79	0.02	0.02	0.79	0.02	0.03	1.36	0.04
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.13							
	P	(mW)		76.4	1.9	76.4	1.9		92.9	2.9
	$P_{txt}$	(mW)		31.2	0.8	31.2	0.8			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)						0.9		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						2.9		
	$Z_s$	(cm)			2.0					
	$Z_{bp}$	(cm)	1.2		2.0			2.0		
	$Z_b$	(cm)						2.1		
	$Z_{pii}$	(cm)	2.4		6.4			6.4		
	$Z_{MI}$	(cm)	2.2							
	$d_{eq}(Z_b)$	(cm)						0.63		
	$D_{eq}$	(cm)							1.71	1.64
	$f_{awf}$	(MHz)	5.36	5.32	5.32	5.32	5.32		5.13	5.13
	Dim of $A_{aprt}$	X (cm)		3.84	2.31	3.84	2.31		3.84	3.51
Y (cm)			0.60	0.60	0.60	0.60		0.60	0.60	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	(µsec)	0.20							
	prr	(Hz)	280							
	srr	(Hz)	70.0							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	48.9							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	110.9							
	$p_r$ at $Z_{pii}$	(MPa)	2.98							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.32		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	378.1							
	Focal Length	FLx (cm)	2.4		6.5		6.5			
		FLy (cm)	4.0		4.0		4.0			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 5.33 MHz, sector depth = 3 cm, focus = 2.4 cm, PRF = 280 Hz  
 Control 2: Freq. = 5.33 MHz, sector depth = 7 cm, focus = 6.5 cm, PRF = 210 Hz  
 Control 3: Freq. = 5.33 MHz, sector depth = 9 cm, focus = 8.6 cm, PRF = 210 Hz

Acoustic Output Reporting Table for Track 3 for the 8L2 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.79	0.92			0.92			1.85	
Index Component Value			0.79	0.92	-	-	0.92	-	-	1.85	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.63								
	P	(mW)		110.9	-	-	110.9	-	-	126.7	-
	$P_{txt}$	(mW)		45.3	-	-	45.3	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.2			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	2.2			-			-		
	$Z_{MI}$	(cm)	2.2								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.71	-
	$f_{awf}$	(MHz)	4.28	4.28	-	-	4.28	-	-	3.78	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.60	-	-	0.60	-	-	0.60	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	B+rD	-
	$t_d$	( $\mu$ sec)	2.34								
	prr	(Hz)	250								
	srr	(Hz)	14.5								
	$\eta_{pps}$		14								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	365.5								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	689.1								
	$p_r$ at $Z_{pii}$	(MPa)	2.13								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	150.8								
	Focal Length	FLx (cm)	2.4			-			-		
		FLy (cm)	4.0			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3									X	

Control 1: B-Mode Frequency = 10.0 MHz, sector depth = 4.0 cm, focal depth = 2.4 cm, Color Doppler frequency = 4.3 MHz, Color Doppler focus = 2.4 cm, Frame Rate = 14.5 Hz, Color ROI = 0.41 cm, Packet size = 14, transmit pulses = 10, PRF = 250 Hz  
 Control 2: B-Mode Frequency = 10.0 MHz, sector depth = 7.0 cm, focal depth = 6.5 cm, Color Doppler frequency = 4.3 MHz, Color Doppler focus = 6.5 cm, Frame Rate = 5.1 Hz, Color ROI = 3.81 cm, Packet size = 14, transmit pulses = 10, PRF = 10430 Hz  
 Control 3: B-Mode Frequency = 8.87 MHz, sector depth = 10.0 cm, focal depth = 10.0 cm, Color Doppler frequency = 3.8 MHz, Color Doppler focus = 10.0 cm, Frame Rate = 3.6 Hz, Color ROI = 3.81 cm, Packet size = 14, transmit pulses = 10, PRF = 7130 Hz

**Acoustic Output Reporting Table for Track 3 for the 8L2 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.40	1.22			1.98			1.88	
Index Component Value		1.40	-	0.70	1.22	-	0.89	1.98	-	1.88
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.50							
	P	(mW)		-	129.1	-	81.9		-	129.1
	$P_{txt}$	(mW)		-	34.3	-	43.5			
	Min of [ $P_{ra}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)			59.9					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						225.9		
	$z_s$	(cm)			2.6					
	$z_{bp}$	(cm)	1.2		2.6			1.8		
	$z_b$	(cm)						2.15		
	$Z_{pii}$	(cm)	2.1		10.2			5.4		
	$Z_{MI}$	(cm)	2.1							
	$d_{eq}(z_b)$	(cm)						0.50		
	$D_{eq}$	(cm)							-	1.71
	$f_{awf}$	(MHz)	3.19	-	4.27	-	4.28		-	4.27
	Dim of $A_{aprt}$	X (cm)		-	3.84	-	1.92		-	3.84
Y (cm)			-	0.60	-	0.60		-	0.60	
Other Information	<b>Mode Components</b>		D	-	D	-	D	-	D	
	$t_d$	( $\mu$ sec)	2.37							
	prr	(Hz)	400							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	364.0							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	593.5							
	$p_r$ at $z_{pii}$	(MPa)	3.15							
	$d_{eq}$ at $z_{pii}$	(cm)						0.30		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	409.0							
	Focal Length	FLx (cm)	2.4		10.0			5.6		
FLy (cm)		4.0		4.0			4.0			
Operating Control Conditions	Control 1		X							
	Control 2			X				X		
	Control 3					X				

Control 1: Sector depth = 11.0 cm, Focus = 1.8 cm, B-Mode Frequency = 5.33 MHz, PWD Frequency = 3.2 MHz, SV Size = 2.0 mm, SV Depth = 2.4 cm, PRF = 400 Hz, Update = off

Control 2: Sector depth = 11.0 cm, Focus = 1.8 cm, B-Mode Frequency = 10 MHz, PWD Frequency = 4.3 MHz, SV Size = 2.5 mm, SV Depth = 9.6 cm, PRF = 7100 Hz, Update = off

Control 3: Sector depth = 11.0 cm, Focus = 1.8 cm, B-Mode Frequency = 10 MHz, PWD Frequency = 4.3 MHz, SV Size = 1.5 mm, SV Depth = 5.7 cm, PRF = 11200 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 8TE3 probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.62	0.20			0.20			Note 1	
Index Component Value			0.62	0.20	-	-	0.20	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.31								
	P	(mW)		9.1	-	-	9.1	-	-	-	-
	$P_{txt}$	(mW)		9.0	-	-	9.0	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.4			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	2.8			-			-		
	$Z_{MI}$	(cm)	2.4								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	4.41	4.78	-	-	4.78	-	-	-	-
	Dim of $A_{aprt}$	X (cm)		1.02	-	-	1.02	-	-	-	-
Y (cm)			0.91	-	-	0.91	-	-	-	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	-	
	$t_d$	(µsec)	0.15								
	prr	(Hz)	150								
	srr	(Hz)	150								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	14.4								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	29.8								
	$p_r$ at $Z_{pii}$	(MPa)	1.79								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	126.9								
	Focal Length	FLx (cm)	3.0			-			-		
		FLy (cm)	5.0			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq. = 5.0 MHz, sector depth = 6 cm, focus = 3.0 cm, B-Mode lines = 20, focus # = 1  
Control 2: Freq. = 5.0 MHz, sector depth = 9 cm, focus = 8.5 cm, B-Mode lines = 128, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 8TE3 probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.62	0.21			0.21			Note 1	
Index Component Value		0.62	0.20	0.01	0.00	0.20	0.01	0.01	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.31							
	P	(mW)		9.0	0.3	9.0	0.3		-	-
	$P_{txt}$	(mW)		8.9	0.3	8.9	0.3			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)						0.2		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						1.0		
	$Z_s$	(cm)			1.6					
	$Z_{bp}$	(cm)	1.4		1.6			1.6		
	$Z_b$	(cm)						4.0		
	$Z_{pii}$	(cm)	2.8		4.6			4.6		
	$Z_{MI}$	(cm)	2.4							
	$d_{eq}(Z_b)$	(cm)						0.31		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.41	4.75	4.75	4.75	4.75		-	-
Dim of $A_{aprt}$	X (cm)		1.02	1.02	1.02	1.02		-	-	
	Y (cm)		0.91	0.91	0.91	0.91		-	-	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M		-	-
	$t_d$	( $\mu$ sec)	0.15							
	prr	(Hz)	210							
	srr	(Hz)	52.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	9.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	19.2							
	$p_r$ at $Z_{pii}$	(MPa)	1.79							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.27		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	126.9							
	Focal Length	FLx (cm)	3.0		13.0			13.0		
		FLy (cm)	5.0		5.0			5.0		
	Operating Control Conditions	Control 1		X						
Control 2				X		X				
Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses..

Control 1: Freq. = 5.0 MHz, sector depth = 6 cm, focus = 3.0 cm, B-Mode lines = 54, PRF = 210 Hz

Control 2: Freq. = 5.0 MHz, sector depth = 13 cm, focus = 13.0 cm, B-Mode lines = 128, PRF = 140 Hz

Acoustic Output Reporting Table for Track 3 for the 8TE3 probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.57	0.22			0.22			Note 1	
Index Component Value			0.57	0.22	-	-	0.22	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.04								
	P	(mW)		13.8	-	-	13.8	-	-	-	-
	$P_{txt}$	(mW)		13.5	-	-	13.5	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.6			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	2.9			-			-		
	$Z_{MI}$	(cm)	2.6								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	3.33	3.33	-	-	3.33	-	-	-	-
	Dim of $A_{aprt}$	X (cm)		1.02	-	-	1.02	-	-	-	-
Y (cm)			0.91	-	-	0.91	-	-	-	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	-	-
	$t_d$	(µsec)	1.43								
	prr	(Hz)	2780								
	srr	(Hz)	14.7								
	$\eta_{pps}$		6								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	20.1								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	36.2								
	$p_r$ at $Z_{pii}$	(MPa)	1.37								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	43.4								
	Focal Length	FLx (cm)	4.0			-			-		
		FLy (cm)	5.0			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 8.85 MHz, sector depth = 17 cm, focal depth = 4.0 cm, Color Doppler frequency = 3.3 MHz, Color Doppler focus = 4 cm, Frame Rate = 14.7 Hz, Color ROI = 0.55 cm, Packet size = 6, transmit pulses = 5, PRF = 2780 Hz  
 Control 2: B-Mode Frequency = 8.85 MHz, sector depth = 6 cm, focal depth = 4.0 cm, Color Doppler frequency = 3.3 MHz, Color Doppler focus = 4 cm, Frame Rate = 6.3 Hz, Color ROI = 4.08 cm, Packet size = 14, transmit pulses = 10, PRF = 12290 Hz

Acoustic Output Reporting Table for Track 3 for the 8TE3 probe  
(Terason uSmart3300 Ultrasound System in Pulsed-wave Doppler Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.02	0.23			0.75			Note 1	
Index Component Value		1.02	-	0.23	0.16	-	0.23	0.75	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.85							
	P	(mW)		-	14.4	-	14.4		-	-
	$P_{txt}$	(mW)		-	14.2	-	14.2			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			10.0					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						175.2		
	$Z_s$	(cm)			1.6					
	$Z_{bp}$	(cm)	1.6		1.6			1.6		
	$Z_b$	(cm)						2.6		
	$Z_{pii}$	(cm)	2.9		2.9			2.9		
	$Z_{MI}$	(cm)	2.6							
	$d_{eq}(Z_b)$	(cm)						0.24		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	3.33	-	3.33	-	3.33		-	-
Dim of $A_{aprt}$	X (cm)		-	1.02	-	1.02		-	-	
	Y (cm)		-	0.91	-	0.91		-	-	
Other Information	<b>Mode Components</b>		D	-	D	-	D		-	-
	$t_d$	(µsec)	2.29							
	prr	(Hz)	500							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	167.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	313.9							
	$p_r$ at $Z_{pii}$	(MPa)	2.44							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.24		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	145.7							
	Focal Length	FLx (cm)	4.0		4.0			4.0		
FLy (cm)		5.0		5.0			5.0			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 6.0 cm, Focus = 2 cm, B-Mode Frequency = 8.85 MHz, PWD Frequency = 3.3 MHz, SV Size = 2.0 mm, SV Depth = 4.0 cm, PRF = 500 Hz, Update = off  
 Control 2: Sector depth = 6.0 cm, Focus = 2 cm, B-Mode Frequency = 8.85 MHz, PWD Frequency = 3.3 MHz, SV Size = 4.5 mm, SV Depth = 4.0 cm, PRF = 600 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 8TE3 probe  
(Terason uSmart3300 Ultrasound System in Continuous-wave Doppler Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.04	0.24			0.91			Note 1	
Index Component Value		0.04	-	0.24	0.19	-	0.24	0.91	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.07							
	P	(mW)		-	16.7	-	16.7	-	-	-
	$P_{txt}$	(mW)		-	16.7	-	16.7			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1cm^2$ ]	(mW)			13.4					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						153.1		
	$Z_s$	(cm)			1.05					
	$Z_{bp}$	(cm)	1.05		1.05			1.05		
	$Z_b$	(cm)						1.05		
	$Z_{pii}$	(cm)	1.05		1.05			1.05		
	$Z_{MI}$	(cm)	1.05							
	$d_{eq}(Z_b)$	(cm)						0.34		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	3.00	-	3.00	-	3.00	-	-	-
	Dim of $A_{aprt}$	X (cm)		-	0.43	-	0.43	-	-	-
Y (cm)			-	0.91	-	0.91	-	-	-	
<b>Mode Components</b>		cwD	-	cwD	-	cwD	-	-	-	
Other Information	$t_d$	(µsec)	-							
	prr	(Hz)	-							
	srr	(Hz)	-							
	$\eta_{pps}$		-							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	153.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	190.3							
	$p_r$ at $Z_{pii}$	(MPa)	0.07							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.34		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	-							
	Focal Length	FLx (cm)	4.0		4.0			4.0		
		FLy (cm)	5.0		5.0			5.0		
Operating Control Conditions	Control 1		X	X	X					
	Control 2									
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 6.0 cm, Focus = 2 cm, B-Mode Frequency = 5 MHz, CWD Frequency = 3.0 MHz, SV Depth = 4.0 cm

Acoustic Output Reporting Table for Track 3 for the 8V3A Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.57	1.68			1.68			2.71	
Index Component Value		1.57	1.68	-	-	1.68	-	-	2.71	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.88							
	P	(mW)		107.1	-		107.1	-	82.0	-
	$P_{txt}$	(mW)		105.5	-		105.5	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )								
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	1.4							
	$Z_b$	(cm)								
	$Z_{pii}$	(cm)	2.6							
	$Z_{MI}$	(cm)	2.6							
	$d_{eq}(Z_b)$	(cm)								
	$D_{eq}$	(cm)							0.76	-
	$f_{awf}$	(MHz)	3.27	3.34	-		3.34	-	3.36	-
	Dim of $A_{aprt}$	X (cm)		1.02	-		1.02	-	0.56	-
Y (cm)			0.80	-		0.80	-	0.80	-	
Other Information	<b>Mode Components</b>		B	B	-	B	-	B	-	
	$t_d$	( $\mu$ sec)	0.43							
	prr	(Hz)	150							
	srr	(Hz)	150							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	356.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	653.5							
	$p_r$ at $Z_{pii}$	(MPa)	3.86							
	$d_{eq}$ at $Z_{pii}$	(cm)								
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	653.5							
	Focal Length	FLx (cm)	4.0							
FLy (cm)		3.0								
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 3.33 MHz, sector depth = 4 cm, focus = 4.0 cm, B-Mode lines = 22, focus # = 1

Control 2: Freq. = 3.33 MHz, sector depth = 6 cm, focus = 5.5 cm, B-Mode lines = 24, focus # = 1

Control 3: Freq. = 3.33 MHz, sector depth = 4 cm, focus = 3.0 cm, B-Mode lines = 44, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 8V3A Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label				MI	TIS			TIB			TIC	
					Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
					At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value				1.57	1.68			2.05			2.70	
Index Component Value				1.57	1.56	0.12	0.09	1.38	0.28	0.67	2.47	0.23
Associated Acoustic Parameter	$p_{r,3}$	$p_{ra}$ at $Z_{MI}$	(MPa)	2.88								
	$W_o$	P	(mW)		99.2	7.8		88.5	18.0		74.7	7.0
	$W_{o1}$	$P_{txt}$	(mW)		97.7	7.6		87.1	17.7			
	$\min$ of [ $W_{.3}(Z_1)$ , $I_{TA,3}(Z_1)$ ]	$\min$ of [ $P_{\alpha}(Z_s)$ , $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				5.5					
	$I_{spta\ 3}$ @ $Z_{sp}$	$I_{spta\ a}$ at $Z_b$	(mW/cm <sup>2</sup> )							125.6		
	$Z_1$	$Z_s$	(cm)				1.5					
	$Z_{bp}$	$Z_{bp}$	(cm)	1.4			1.5			1.5		
	$Z_{sp}$	$Z_b$	(cm)							3.1		
	$z@P_{II\max}$	$Z_{pii}$	(cm)	2.6			3.3			3.3		
	$z@P_{II3\max}$	$Z_{MI}$	(cm)	2.6								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.29		
	$D_{eq}$	$D_{eq}$	(cm)								0.76	0.76
	$f_c$	$f_{awf}$	(MHz)	3.27	3.34	3.34		3.34	3.34		3.36	3.36
Dim of $A_{aprt}$	Dim of $A_{aprt}$	X (cm)		1.02	1.02		1.02	1.02		0.56	0.56	
		Y (cm)		0.80	0.80		0.80	0.80		0.80	0.80	
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	$t_d$	( $\mu$ sec)	0.43								
	PRF	prf	(Hz)	210								
	SRF	srf	(Hz)	30								
		$n_{pps}$		1								
	$I_{spta\ 3}$ @ $Z_{pii\ 3}$ or $Z_{sii\ 3}$	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	130.2								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	238.6								
	$pr@P_{II\max}$	$p_r$ at $Z_{pii}$	(MPa)	3.86								
	$d_{eq}@P_{II\max}$	$d_{eq}$ at $Z_{pii}$	(cm)							0.29		
	$I_{PA3}$ @ $MI_{\max}$	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	653.5								
Focal Length	Focal Length	FLx (cm)	4.0			5.5			5.5			
		FLy (cm)	3.0			3.0			3.0			
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				
	Control 4										X	

Control 1: Freq. = 3.33 MHz, sector depth = 4 cm, focus = 4.0 cm, B-Mode lines = 128, PRF = 210 Hz  
 Control 2: Freq. = 3.33 MHz, sector depth = 6 cm, focus = 5.5 cm, B-Mode lines = 64, PRF = 280 Hz  
 Control 3: Freq. = 3.33 MHz, sector depth = 20 cm, focus = 5.5 cm, B-Mode lines = 64, PRF = 570 Hz  
 Control 4: Freq. = 3.33 MHz, sector depth = 4 cm, focus = 3.0 cm, B-Mode lines = 64, PRF = 430 Hz

Acoustic Output Reporting Table for Track 3 for the 8V3A Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.06	1.66			1.66			2.79	
Index Component Value		1.06	1.66	-	-	1.66	-	-	2.79	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.84							
	P	(mW)		106.8	-	106.8	-		139.3	-
	$P_{txt}$	(mW)		105.1	-	105.1	-			
	Min of [ $P_a(z_s), I_{ta, a}(z_s) \times 1 \text{ cm}^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$z_s$	(cm)			-					
	$z_{bp}$	(cm)	1.4		-			-		
	$z_b$	(cm)						-		
	$Z_{pii}$	(cm)	2.7		-			-		
	$Z_{MI}$	(cm)	2.6							
	$d_{eq}(z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.25	-
	$f_{awf}$	(MHz)	2.99	3.31	-	3.31	-		3.31	-
	Dim of $A_{aprt}$	X (cm)		1.02	-	1.02	-		1.54	-
Y (cm)			0.80	-	0.80	-		0.80	-	
Other Information	<b>Mode Components</b>	rD	B+rD	-	B+rD	-		B+rD	-	
	$t_d$	( $\mu$ sec)	1.55							
	prr	(Hz)	2000							
	srr	(Hz)	30.6							
	$n_{pps}$		6							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	349.0							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	599.0							
	$p_r$ at $z_{pii}$	(MPa)	2.38							
	$d_{eq}$ at $z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	218.7							
	Focal Length	FLx (cm)	4.0		-			-		
FLy (cm)		3.0		-			-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: B-Mode Frequency = 5.96 MHz, sector depth = 20 cm, focal depth = 4.0 cm, Color Doppler frequency = 3.0 MHz, Color Doppler focus = 4 cm, Frame Rate = 30.6 Hz, Color ROI = 0.46 cm, Packet size = 6, transmit pulses = 5, PRF = 2000 Hz

Control 2: B-Mode Frequency = 3.3 MHz, sector depth = 6 cm, focal depth = 5.5 cm, Color Doppler frequency = 3.3 MHz, Color Doppler focus = 5.5 cm, Frame Rate = 4.1 Hz, Color ROI = 4.06 cm, Packet size = 12, transmit pulses = 10, PRF = 9960 Hz

Control 3: B-Mode Frequency = 3.3 MHz, sector depth = 17 cm, focal depth = 16.5 cm, Color Doppler frequency = 3.3 MHz, Color Doppler focus = 16.5 cm, Frame Rate = 3.6 Hz, Color ROI = 4.19 cm, Packet size = 12, transmit pulses = 10, PRF = 4340 Hz

**Acoustic Output Reporting Table for Track 3 for the 8V3A Probe  
(Terason uSmart3300 Ultrasound System in CWD Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan		Non-scan	Scan		Non-scan	Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.07	0.75			2.79			2.50	
Index Component Value			0.07	-	0.75	0.64	-	0.75	2.79	-	2.50
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.12								
	P	(mW)		-	52.7		-	52.7		-	52.7
	$P_{txt}$	(mW)		-	52.7		-	52.7			
	Min of [ $P_{\alpha}(Z_s)$ , $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				44.6					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							436.3		
	$Z_s$	(cm)				0.8					
	$Z_{bp}$	(cm)	0.8			0.8			0.8		
	$Z_b$	(cm)							0.8		
	$Z_{pii}$	(cm)	0.8			0.8			0.8		
	$Z_{MI}$	(cm)	0.8								
	$d_{eq}(Z_b)$	(cm)							0.36		
	$D_{eq}$	(cm)								-	0.79
	$f_{awf}$	(MHz)	3.00	-	3.00		-	3.00		-	3.00
Dim of $A_{aprt}$	X (cm)		-	0.27		-	0.27		-	0.27	
	Y (cm)		-	0.80		-	0.80		-	0.80	
Other Information	<b>Mode Components</b>		cwD	-	cwD		-	cwD		-	cwD
	$t_d$	( $\mu$ sec)	-								
	prr	(Hz)	-								
	srr	(Hz)	-								
	$n_{pps}$		-								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	436.3								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	514.9								
	$p_r$ at $Z_{pii}$	(MPa)	0.13								
	$d_{eq}$ at $Z_{pii}$	(cm)							0.36		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	-								
	Focal Length	FLx (cm)	4.0			4.0			4.0		
FLy (cm)		3.0			3.0			3.0			
Operating Control Conditions	Control 1		X	X			X			X	
	Control 2										
	Control 3										

Control 1: Sector depth = 18.0 cm, Focus = 4 cm, B-Mode Frequency = 5.0 MHz, CWD Frequency = 3.0 MHz, SV Depth = 4.0 cm, Update = off

Acoustic Output Reporting Table for Track 3 for the 8V3A Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.37	1.51			3.87			2.93	
Index Component Value		1.37	-	1.51	1.30	-	1.32	3.87	-	2.93
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.49							
	P	(mW)		-	121.6	-	141.9		-	146.7
	$P_{txt}$	(mW)		-	95.8	-	93.1			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)			82.5					
	$I_{spta a}$ at $Z_b$	(mW/cm <sup>2</sup> )					460.2			
	$Z_s$	(cm)			1.7					
	$Z_{bp}$	(cm)	1.1		1.7			1.9		
	$Z_b$	(cm)						2.7		
	$Z_{pii}$	(cm)	2.4		4.3			5.3		
	$Z_{MI}$	(cm)	2.2							
	$d_{eq}(Z_b)$	(cm)						0.47		
	$D_{eq}$	(cm)							-	1.25
	$f_{awf}$	(MHz)	3.32	-	3.31	-	2.98		-	2.99
	Dim of $A_{aprt}$	X (cm)		-	1.28	-	1.54		-	1.54
Y (cm)			-	0.80	-	0.80		-	0.80	
<b>Mode Components</b>		D	-	D	-	D		-	D	
Other Information	$t_d$	( $\mu$ sec)	2.28							
	prr	(Hz)	600							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	457.0							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	776.9							
	$p_r$ at $z_{pii}$	(MPa)	2.96							
	$d_{eq}$ at $z_{pii}$	(cm)						0.43		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	334.7							
	Focal Length	FLx (cm)	3.0		7.0			8.5		
FLy (cm)		3.0		3.0			3.0			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				
	Control 4							X		

Control 1: Sector depth = 7.0 cm, Focus = 4 cm, B-Mode Frequency = 8.85 MHz, PWD Frequency = 3.3 MHz, SV Size = 2.0 mm, SV Depth = 3.0 cm, PRF = 500 Hz, Update = off  
 Control 2: Sector depth = 18.0 cm, Focus = 4 cm, B-Mode Frequency = 8.85 MHz, PWD Frequency = 3.3 MHz, SV Size = 3.0 mm, SV Depth = 6.4 cm, PRF = 8400 Hz, Update = off  
 Control 3: Sector depth = 18.0 cm, Focus = 4 cm, B-Mode Frequency = 5.96 MHz, PWD Frequency = 3.0 MHz, SV Size = 6.0 mm, SV Depth = 7.9 cm, PRF = 7000 Hz, Update = off  
 Control 4: Sector depth = 18.0 cm, Focus = 4 cm, B-Mode Frequency = 5.96 MHz, PWD Frequency = 3.0 MHz, SV Size = 1.5 mm, SV Depth = 16.5 cm, PRF = 900 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 9MC3 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.57	0.92			0.92			1.22	
Index Component Value			1.57	0.92	-	-	0.92	-	-	1.22	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.28								
	P	(mW)		47.2	-	-	47.2	-	-	68.2	-
	$P_{txt}$	(mW)		44.4	-	-	44.4	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$z_s$	(cm)				-					
	$z_{bp}$	(cm)	1.1			-			-		
	$z_b$	(cm)							-		
	$Z_{pii}$	(cm)	2.1			-			-		
	$Z_{MI}$	(cm)	2.0								
	$d_{eq}(z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.40	-
	$f_{awf}$	(MHz)	4.34	4.37	-	-	4.37	-	-	4.37	-
Dim of $A_{aprt}$	X (cm)		1.28	-	-	1.28	-	-	2.57	-	
	Y (cm)		0.60	-	-	0.60	-	-	0.60	-	
Other Information	<b>Mode Components</b>		B	B	-	B	-	-	B	-	
	$t_d$	( $\mu\text{sec}$ )	0.44								
	prr	(Hz)	150								
	srr	(Hz)	150								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	299.3								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	549.9								
	$p_r$ at $Z_{pii}$	(MPa)	4.31								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	621.0								
	Focal Length	FLx (cm)	2.5			-			-		
FLy (cm)		2.2			-			-			
Operating Control Conditions	Control 1		X								
	Control 2			X			X				
	Control 3								X		

Control 1: Freq = 4.3 MHz, sector depth = 3.0 cm, focus = 2.5 cm, focus# = 1, Omni off

Control 2: Freq = 4.3 MHz, sector depth = 6.0 cm, focus = 0.8 cm, focus# = 1, Omni off

Control 3: Freq = 4.3 MHz, sector depth = 4.0 cm, focus = 0.8 cm, focus# = 1, Omni off

**Acoustic Output Reporting Table for Track 3 for the 9MC3 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.57	0.90			1.00			1.24	
Index Component Value			1.57	0.85	0.04	0.04	0.85	0.04	0.15	1.12	0.11
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.28								
	P	(mW)		43.5	2.1		43.5	2.1		63.0	2.0
	$P_{txt}$	(mW)		40.8	2.1		40.8	2.1			
	Min of [ $P_{\alpha}(Z_s)$ , $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				1.7					
	$I_{spta a}$ at $Z_b$	(mW/cm <sup>2</sup> )							32.6		
	$z_s$	(cm)				0.7					
	$z_{bp}$	(cm)	1.1			0.7			0.7		
	$z_b$	(cm)							0.7		
	$Z_{pii}$	(cm)	2.1			1.8			1.8		
	$Z_{MI}$	(cm)	2.0								
	$d_{eq}(z_b)$	(cm)							0.26		
	$D_{eq}$	(cm)								1.40	0.44
	$f_{awf}$	(MHz)	4.34	4.37	4.37		4.37	4.37		4.37	4.37
Dim of $A_{aprt}$	X (cm)		1.28	0.26		1.28	0.26		2.57	0.26	
	Y (cm)		0.60	0.60		0.60	0.60		0.60	0.60	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M		
	$t_d$	( $\mu\text{sec}$ )	0.44								
	prr	(Hz)	210								
	srr	(Hz)	52.5								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	128.8								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	185.2								
	$p_r$ at $Z_{pii}$	(MPa)	4.31								
	$d_{eq}$ at $Z_{pii}$	(cm)							0.25		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	621.0								
	Focal Length	FLx (cm)	2.5		0.8			0.8			
FLy (cm)		2.2		2.2			2.2				
Operating Control Conditions	Control 1		X								
	Control 2			X			X				
	Control 3								X		

Control 1: Freq = 4.3 MHz, sector depth = 3.0 cm, focus = 2.5 cm, B-Mode Lines = 80, PRF = 210 Hz

Control 2: Freq = 4.3 MHz, sector depth = 3.0 cm, focus = 0.8 cm, B-Mode Lines = 102, PRF = 570 Hz

Control 3: Freq = 4.3 MHz, sector depth = 3.0 cm, focus = 0.8 cm, B-Mode Lines = 256, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 9MC3 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.94	0.96			0.96			1.36	
Index Component Value			0.94	0.96			0.96	-	-	1.36	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.99								
	P	(mW)		51.2			51.2	-		29.6	-
	$P_{txt}$	(mW)		47.1			47.1	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.1						-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.9						-		
	$Z_{MI}$	(cm)	1.8								
	$d_{eq}(Z_b)$	(cm)								-	
	$D_{eq}$	(cm)									0.54
	$f_{awf}$	(MHz)	4.46	4.29			4.29	-		4.29	-
	Dim of $A_{aprt}$	X (cm)		1.32			1.32	-		0.26	-
Y (cm)			0.60			0.60	-		0.60	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-		B+rD	-		B+rD	-
	$t_d$	( $\mu$ sec)	0.85								
	prr	(Hz)	3000								
	srr	(Hz)	33.7								
	$n_{pps}$		5								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	101.9								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	181.0								
	$p_r$ at $z_{pii}$	(MPa)	2.64								
	$d_{eq}$ at $z_{pii}$	(cm)								-	
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	251.0								
	Focal Length	FLx (cm)	2.5							-	
		FLy (cm)	2.2							-	
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3										X

Control 1: B-Mode Frequency = 9.0 MHz, sector depth = 15.0 cm, focal depth = 2.5 cm, Color Doppler frequency = 4.5 MHz, Color Doppler focus = 2.5 cm, Frame Rate = 33.7 Hz, Color ROI = 0.60 cm, Packet size = 5, transmit pulses = 4, PRF = 3000 Hz

Control 2: B-Mode Frequency = 4.3 MHz, sector depth = 3.0 cm, focal depth = 0.8 cm, Color Doppler frequency = 4.3 MHz, Color Doppler focus = 0.8 cm, Frame Rate = 20.1 Hz, Color ROI = 1.53 cm, Packet size = 12, transmit pulses = 10, PRF = 22220 Hz

Control 3: B-Mode Frequency = 7.5 MHz, sector depth = 3.0 cm, focal depth = 0.8 cm, Color Doppler frequency = 4.3 MHz, Color Doppler focus = 0.8 cm, Frame Rate = 88.1 Hz, Color ROI = 0.16 cm, Packet size = 12, transmit pulses = 10, PRF = 22220 H

Acoustic Output Reporting Table for Track 3 for the 9MC3 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.53	0.73			1.77			1.61	
Index Component Value		1.53	-	0.73	0.52	-	0.52	1.77	-	1.61
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.97							
	P	(mW)		-	38.5	-	25.5		-	28.5
	$P_{txt}$	(mW)		-	35.9	-	25.5			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1cm^2$ ]	(mW)			25.5					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						378.9		
	$Z_s$	(cm)			1.4					
	$Z_{bp}$	(cm)	1.1		1.4			0.7		
	$Z_b$	(cm)						0.7		
	$Z_{pii}$	(cm)	2.0		3.5			1.7		
	$Z_{MI}$	(cm)	2.0							
	$d_{eq}(Z_b)$	(cm)						0.26		
	$D_{eq}$	(cm)							-	0.44
	$f_{awf}$	(MHz)	3.77	-	4.28	-	4.29		-	3.77
	Dim of $A_{aprt}$	X (cm)		-	1.22	-	0.26		-	0.26
Y (cm)			-	0.60	-	0.60		-	0.60	
<b>Mode Components</b>		D	-	D	-	D		-	D	
Other Information	$t_d$	( $\mu$ sec)	1.75							
	prr	(Hz)	400							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	407.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	693.5							
	$p_r$ at $Z_{pii}$	(MPa)	3.75							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.25		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	582.1							
	Focal Length	FLx (cm)	2.5		4.5		0.8			
		FLy (cm)	2.2		2.2		2.2			
Operating Control Conditions	Control 1		X							
				X						
	Control 3					X				
	Control 4							X		

Control 1: Sector depth = 15.0 cm, Focus = 2.5 cm, B-Mode Frequency = 5.0 MHz, PWD Frequency = 3.75 MHz, SV Size = 1.5 mm, SV Depth = 2.5 cm, PRF = 400 Hz, Update = off  
 Control 2: Sector depth = 15.0 cm, Focus = 2.5 cm, B-Mode Frequency = 7.5 MHz, PWD Frequency = 4.3 MHz, SV Size = 1.5 mm, SV Depth = 4.5 cm, PRF = 900 Hz, Update = off  
 Control 3: Sector depth = 15.0 cm, Focus = 2.5 cm, B-Mode Frequency = 7.5 MHz, PWD Frequency = 4.3 MHz, SV Size = 6.0 mm, SV Depth = 0.8 cm, PRF = 10000 Hz, Update = off  
 Control 4: Sector depth = 15.0 cm, Focus = 2.5 cm, B-Mode Frequency = 5.0 MHz, PWD Frequency = 3.75 MHz, SV Size = 9.0 mm, SV Depth = 0.8 cm, PRF = 600 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 10BP4 (CLA) Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.51	0.75			0.75			Note 1	
Index Component Value		1.51	0.75	-	-	0.75	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.36							
	P	(mW)		52.8	-		52.8	-		-
	$P_{txt}$	(mW)		22.2	-		22.2	-		
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)				-				
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$z_s$	(cm)				-				
	$z_{bp}$	(cm)	0.60			-				
	$z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.10			-				
	$Z_{MI}$	(cm)	1.05							
	$d_{eq}(z_b)$	(cm)						-		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.91	7.05	-		7.05	-		-
Dim of $A_{aprt}$	X (cm)		3.15	-		3.15	-		-	
	Y (cm)		0.42	-		0.42	-		-	
Other Information	<b>Mode Components</b>		B	B	-	B	-	-	-	
	$t_d$	(μsec)	0.30							
	prr	(Hz)	135.2							
	srr	(Hz)	135.2							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	128.9							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	184.3							
	$p_r$ at $z_{pii}$	(MPa)	3.95							
	$d_{eq}$ at $z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	626.9							
	Focal Length	FLx (cm)	2.5			-			-	
FLy (cm)		1.2			-			-		
Operating Control Conditions	Control 1		X							
	Control 2				X		X			
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 5.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, lines = 122, focus# = 1

Control 2: Freq = 8.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, lines = 122, focus# = 1

Acoustic Output Reporting Table for Track 3 for the 10BP4 (CLA) Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.51	0.72			0.82			Note 1	
Index Component Value		1.51	0.65	0.07	0.05	0.65	0.07	0.17	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.36							
	P	(mW)		46.4	2.1	46.4	2.1		-	-
	$P_{txt}$	(mW)		19.3	2.1	19.3	2.1			
	Min of [ $P_{\alpha}(z_s)$ , $I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)				1.2				
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						56.4		
	$z_s$	(cm)			0.60					
	$z_{bp}$	(cm)	0.60		0.60			0.60		
	$z_b$	(cm)						1.05		
	$Z_{pii}$	(cm)	1.10		1.15			1.15		
	$Z_{MI}$	(cm)	1.05							
	$d_{eq}(z_b)$	(cm)						0.16		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.91	7.05	7.05	7.05	7.05		-	-
	Dim of $A_{aprt}$	X (cm)		3.15	0.32	3.15	0.32		-	-
Y (cm)			0.42	0.42	0.42	0.42		-	-	
Mode Components		B+M	B	M	B	M		-	-	
Other Information	$t_d$	( $\mu\text{sec}$ )	0.30							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	213.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	306.7							
	$p_r$ at $z_{pii}$	(MPa)	3.95							
	$d_{eq}$ at $z_{pii}$	(cm)						0.15		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	626.9							
	Focal Length	FLx (cm)	2.5		2.5			2.5		
FLy (cm)		1.2		1.2			1.2			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 5.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, B-Mode lines = 90, PRF = 570

Control 2: Freq = 8.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, B-Mode lines = 90, PRF = 570

Acoustic Output Reporting Table for Track 3 for the 10BP4 (CLA) Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.91	1.05			1.05			Note 1	
Index Component Value		0.91	1.05	-	-	1.05	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.93							
	P	(mW)		56.3	-	56.3	-	-	-	-
	$P_{txt}$	(mW)		49.2	-	49.2	-	-	-	-
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					-			
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	0.60		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.10		-			-		
	$Z_{MI}$	(cm)	1.00							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.47	4.48	-	4.48	-	-	-	-
Dim of $A_{aprt}$	X (cm)		1.30	-	1.30	-	-	-	-	
	Y (cm)		0.42	-	0.42	-	-	-	-	
Mode Components		rD	B+rD	-	B+rD	-	-	-	-	
Other Information	$t_d$	(μsec)	1.03							
	prr	(Hz)	1250							
	srr	(Hz)	57.4							
	$n_{pps}$		12							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	468.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	638.1							
	$p_r$ at $Z_{pii}$	(MPa)	2.20							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	171.1							
	Focal Length	FLX (cm)	2.5		-			-		
FLY (cm)		1.2		-			-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 6.0 MHz, sector depth = 4.0 cm, focal depth = 2.5 cm, Color Doppler frequency = 4.5 MHz, Color Doppler focus = 2.5 cm, Frame Rate = 57.4 Hz, Color ROI = 0.46 cm, Packet size = 12, transmit pulses = 5, PRF = 1250 Hz

Control 2: B-Mode Frequency = 6.0 MHz, sector depth = 5.0 cm, focal depth = 1.5 cm, Color Doppler frequency = 4.5 MHz, Color Doppler focus = 1.5 cm, Frame Rate = 19.6 Hz, Color ROI = 2.07 cm, Packet size = 14, transmit pulses = 10, PRF = 22210 Hz

Acoustic Output Reporting Table for Track 3 for the 10BP4 (Linear) Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.45	0.58			0.58			Note 1	
Index Component Value		1.45	0.58	-	-	0.58	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.14							
	P	(mW)		84.7	-	84.7	-	-	-	-
	$P_{txt}$	(mW)		17.6	-	17.6	-	-	-	-
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)			-					
	$I_{spta a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	0.8		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.35		-			-		
	$Z_{MI}$	(cm)	1.30							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.93	6.96	-	6.96	-	-	-	-
Dim of $A_{aprt}$	X (cm)		7.10	-	7.10	-	-	-	-	
	Y (cm)		0.50	-	0.50	-	-	-	-	
Other Information	<b>Mode Components</b>		B	B	-	B	-	-	-	
	$t_d$	(µsec)	0.32							
	prr	(Hz)	150							
	srr	(Hz)	150							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	82.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	126.6							
	$p_r$ at $z_{pii}$	(MPa)	3.92							
	$d_{eq}$ at $z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	549.2							
	Focal Length	FLx (cm)	2.5		-			-		
FLy (cm)		1.5		-			-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 5.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, lines = 96, focus# = 1

Control 2: Freq = 7.5 MHz, sector depth = 8.0 cm, focus = 8.0 cm, lines = 96, focus# = 1

Acoustic Output Reporting Table for Track 3 for the 10BP4 (Linear) Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.45	0.63			0.63			Note 1	
Index Component Value		1.45	0.50	0.12	0.13	0.50	0.12	0.13	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.14							
	P	(mW)		72.4	12.1	72.4	12.1		-	-
	$P_{txt}$	(mW)		15.1	3.5	15.1	3.5			
	Min of [ $P_{\alpha}(z_s)$ , $I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)						4.0		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						11.1		
	$z_s$	(cm)			2.3					
	$z_{bp}$	(cm)	0.8		2.3			2.3		
	$z_b$	(cm)						2.3		
	$Z_{pii}$	(cm)	1.35		2.3			2.3		
	$Z_{MI}$	(cm)	1.30							
	$d_{eq}(z_b)$	(cm)						0.69		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.93	6.96	6.96	6.96	6.96		-	-
Dim of $A_{aprt}$	X (cm)		7.10	3.55	7.10	3.55		-	-	
	Y (cm)		0.50	0.50	0.50	0.50		-	-	
Mode Components		B+M	B	M	B	M		-	-	
Other Information	$t_d$	( $\mu\text{sec}$ )	0.32							
	prr	(Hz)	570							
	srr	(Hz)	143							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	164.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	254.4							
	$p_r$ at $z_{pii}$	(MPa)	3.92							
	$d_{eq}$ at $z_{pii}$	(cm)						0.69		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	549.2							
	Focal Length	FLx (cm)	2.5		8.0			8.0		
FLy (cm)		1.5		1.5			1.5			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 5.0 MHz, sector depth = 4.0 cm, focus = 2.5 cm, B-Mode lines = 72, PRF = 570

Control 2: Freq = 7.5 MHz, sector depth = 8.0 cm, focus = 8.0 cm, B-Mode lines = 72, PRF = 570

Acoustic Output Reporting Table for Track 3 for the 10BP4 (Linear) Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.94	0.73			0.73			Note 1	
Index Component Value		0.94	0.73	-	-	0.73	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.10							
	P	(mW)		45.0	-	45.0	-	-	-	-
	$P_{txt}$	(mW)		30.6	-	30.6	-	-	-	-
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	0.8							
	$Z_b$	(cm)								
	$Z_{pii}$	(cm)	1.30							
	$Z_{MI}$	(cm)	1.25							
	$d_{eq}(Z_b)$	(cm)								
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.98	4.98	-	4.98	-	-	-	-
Dim of $A_{aprt}$	X (cm)		2.18	-	2.18	-	-	-	-	
	Y (cm)		0.50	-	0.50	-	-	-	-	
Mode Components		rD	B+rD	-	B+rD	-	-	-	-	
Other Information	$t_d$	(µsec)	0.79							
	prr	(Hz)	900							
	srr	(Hz)	81.7							
	$n_{pps}$		7							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	368.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	559.4							
	$p_r$ at $Z_{pii}$	(MPa)	2.58							
	$d_{eq}$ at $Z_{pii}$	(cm)							-	
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	228.6							
	Focal Length	FLX (cm)	2.5							-
FLY (cm)		1.5							-	
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 7.5 MHz, sector depth = 4.0 cm, focal depth = 2.5 cm, Color Doppler frequency = 5.0 MHz, Color Doppler focus = 2.5 cm, Frame Rate = 81.7 Hz, Color ROI = 0.84 cm, Packet size = 7, transmit pulses = 4, PRF = 900 Hz

Control 2: B-Mode Frequency = 7.5 MHz, sector depth = 5.0 cm, focal depth = 4.5 cm, Color Doppler frequency = 5.0 MHz, Color Doppler focus = 4.5 cm, Frame Rate = 28.8 Hz, Color ROI = 0.79 cm, Packet size = 14, transmit pulses = 10, PRF = 14470 Hz

**Acoustic Output Reporting Table for Track 3 for the 10EC4 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.32	1.37			1.37			Note 1	
Index Component Value		1.32	1.37	-	-	1.37	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.72							
	P	(mW)		58.2	-	58.2	-	-	-	-
	$P_{txt}$	(mW)		48.9	-	48.9	-	-	-	-
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	0.9					-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.9					-		
	$Z_{MI}$	(cm)	1.8							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.23	5.90	-	5.90	-	-	-	-
Dim of $A_{aprt}$	X (cm)		1.58	-	1.58	-	-	-	-	
	Y (cm)		0.60	-	0.60	-	-	-	-	
Other Information	<b>Mode Components</b>		B	B	-	B	-	-	-	
	$t_d$	( $\mu$ sec)	0.45							
	prr	(Hz)	150							
	srr	(Hz)	150							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	149.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	251.7							
	$p_r$ at $Z_{pii}$	(MPa)	3.54							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	323.3							
	Focal Length	FLx (cm)	3.5					-		
FLy (cm)		2.2					-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 4.0 MHz, sector depth = 9.0 cm, focus = 3.5 cm, lines = 40, focus# = 1

Control 2: Freq = 6.0 MHz, sector depth = 4.0 cm, focus = 3.5 cm, lines = 104, focus# = 1

**Acoustic Output Reporting Table for Track 3 for the 10EC4 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.32	1.04			1.06			Note 1	
Index Component Value		1.32	0.96	0.08	0.05	0.96	0.08	0.10	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.72							
	P	(mW)		50.9	3.1	50.9	3.1		-	-
	$P_{txt}$	(mW)		35.0	3.1	35.0	3.1			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)						2.0		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						19.8		
	$Z_s$	(cm)			1.1					
	$Z_{bp}$	(cm)	0.9		1.1			1.1		
	$Z_b$	(cm)						2.1		
	$Z_{pii}$	(cm)	1.9		2.6			2.6		
	$Z_{MI}$	(cm)	1.8							
	$d_{eq}(Z_b)$	(cm)						0.29		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.23	5.73	5.73	5.73	5.73		-	-
Dim of $A_{aprt}$	X (cm)		2.12	0.69	2.12	0.69		-	-	
	Y (cm)		0.60	0.60	0.60	0.60		-	-	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M		-	-
	$t_d$	( $\mu$ sec)	0.45							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	164.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	279.7							
	$p_r$ at $Z_{pii}$	(MPa)	3.54							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.26		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	323.3							
	Focal Length	FLx (cm)	3.5		5.0		5.0			
FLy (cm)		2.2		2.2		2.2				
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq = 4.0 MHz, sector depth = 4.0 cm, focus = 3.5 cm, B-Mode lines = 16, PRF = 570 Hz

Control 2: Freq = 6.0 MHz, sector depth = 5.0 cm, focus = 5.0 cm, B-Mode lines = 66, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 10EC4 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.77	1.53			1.53			Note 1	
Index Component Value			0.77	1.53	-	-	1.53	-	-	-	-
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	1.69								
	P	(mW)		71.0	-	-	71.0	-	-	-	-
	$P_{txt}$	(mW)		67.2	-	-	67.2	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.9			-					
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.8			-			-		
	$Z_{MI}$	(cm)	1.7								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	4.76	4.76	-	-	4.76	-	-	-	-
Dim of $A_{aprt}$	X (cm)		1.22	-	-	1.22	-	-	-	-	
	Y (cm)		0.60	-	-	0.60	-	-	-	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	-	-
	$t_d$	(µsec)	0.79								
	prr	(Hz)	1500								
	srr	(Hz)	22.9								
	$n_{pps}$		7								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	67.3								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	117.6								
	$\rho_r$ at $Z_{pii}$	(MPa)	2.16								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	180.3								
	Focal Length	FLx (cm)	3.5			-			-		
		FLy (cm)	2.2			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 6.0 MHz, sector depth = 14.0 cm, focal depth = 3.5 cm, Color Doppler frequency = 4.8 MHz, Color Doppler focus = 3.5 cm, Frame Rate = 22.9 Hz, Color ROI = 1.12 cm, Packet size = 7, transmit pulses = 4, PRF = 1500 Hz

Control 2: B-Mode Frequency = 6.0 MHz, sector depth = 4.0 cm, focal depth = 1.5 cm, Color Doppler frequency = 4.8 MHz, Color Doppler focus = 1.5 cm, Frame Rate = 31.3 Hz, Color ROI = 1.68 cm, Packet size = 12, transmit pulses = 10, PRF = 22210 Hz

Acoustic Output Reporting Table for Track 3 for the 10EC4 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.41	1.16			2.15			Note 1	
Index Component Value		1.41	-	1.16	0.76	0.05	0.62	2.10	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.09							
	P	(mW)		-	51.4	3.1	27.5		-	-
	$P_{txt}$	(mW)		-	51.4	1.6	27.5			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)			33.6					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						487.4		
	$z_s$	(cm)			1.3					
	$z_{bp}$	(cm)	0.9		1.3			0.6		
	$z_b$	(cm)						0.6		
	$Z_{pii}$	(cm)	1.8		3.2			1.7		
	$Z_{MI}$	(cm)	1.7							
	$d_{eq}(z_b)$	(cm)						0.25		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.76	-	4.74	6.05	4.77		-	-
Dim of $A_{aprt}$	X (cm)		-	0.92	1.99	0.23		-	-	
	Y (cm)		-	0.60	0.60	0.60		-	-	
Other Information	<b>Mode Components</b>		D	-	D	B	D		-	-
	$t_d$	( $\mu$ sec)	1.79							
	prr	(Hz)	500							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	489.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	879.2							
	$p_r$ at $z_{pii}$	(MPa)	3.95							
	$d_{eq}$ at $z_{pii}$	(cm)						0.23		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	548.7							
	Focal Length	FLx (cm)	3.5		6.5			1.5		
FLy (cm)		2.2		2.2			2.2			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 9.0 cm, Focus = 3.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 1.5 mm, SV Depth = 3.5 cm, PRF = 500 Hz, Update = off

Control 2: Sector depth = 9.0 cm, Focus = 3.5 cm, B-Mode Frequency = 6.0 MHz, PWD Frequency = 4.8 MHz, SV Size = 1.0 mm, SV Depth = 6.5 cm, PRF = 9100 Hz, Update = off

Control 3: Sector depth = 9.0 cm, Focus = 8.5 cm, B-Mode Frequency = 6.0 MHz, B-Mode lines = 48, PWD Frequency = 4.8 MHz, SV Size = 7.0 mm, SV Depth = 1.5 cm, PRF = 700 Hz, Update = on

Acoustic Output Reporting Table for Track 3 for the 12L5A Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.04	0.53			0.53			1.09	
Index Component Value			1.04	0.53	-	-	0.53	-	-	1.09	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.68								
	P	(mW)		44.8	-		44.8	-		61.1	-
	$P_{txt}$	(mW)		18.3	-		18.3	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)									
	$Z_{bp}$	(cm)	0.85								
	$Z_b$	(cm)									
	$Z_{pii}$	(cm)	1.50								
	$Z_{MI}$	(cm)	1.50								
	$d_{eq}(Z_b)$	(cm)									
	$D_{eq}$	(cm)								1.40	-
	$f_{awf}$	(MHz)	6.67	6.07	-		6.07	-		5.88	-
	Dim of $A_{aprt}$	X (cm)		3.84	-		3.84	-		3.84	-
Y (cm)			0.40	-		0.40	-		0.40	-	
Other Information	<b>Mode Components</b>		B	B	-		B	-		B	-
	$t_d$	( $\mu$ sec)	0.19								
	prr	(Hz)	31.0								
	srr	(Hz)	31.0								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	23.9								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	47.8								
	$p_r$ at $Z_{pii}$	(MPa)	3.73								
	$d_{eq}$ at $Z_{pii}$	(cm)									
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	657.8								
	Focal Length	FLx (cm)	1.8								
		FLy (cm)	1.4								
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3									X	

Control 1: Freq. = 7.5 MHz, sector depth = 5 cm, focus = 1.8 cm, B-Mode lines = 256, focus # = 1

Control 2: Freq. = 7.5 MHz, sector depth = 7 cm, focus = 6.5 cm, B-Mode lines = 128, focus # = 1

Control 3: Freq. = 7.5 MHz, sector depth = 8 cm, focus = 8.0 cm, B-Mode lines = 128, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 12L5A Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.04	0.52			0.55			1.05	
Index Component Value		1.04	0.47	0.04	0.05	0.47	0.04	0.08	0.99	0.06
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.68							
	P	(mW)		39.6	3.4	39.6	3.4	55.3	3.5	
	$P_{txt}$	(mW)		16.2	1.5	16.2	1.5			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			1.7					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						79.2		
	$Z_s$	(cm)			1.60					
	$Z_{bp}$	(cm)	0.85		1.60			1.60		
	$Z_b$	(cm)						1.60		
	$Z_{pii}$	(cm)	1.50		6.30			6.30		
	$Z_{MI}$	(cm)	1.50							
	$d_{eq}(Z_b)$	(cm)						0.48		
	$D_{eq}$	(cm)							1.40	1.35
	$f_{awf}$	(MHz)	6.67	6.07	6.07	6.07	6.07	5.88	5.88	
Dim of $A_{aprt}$	X (cm)		3.84	2.31	3.84	2.31	3.84	3.60		
	Y (cm)		0.40	0.40	0.40	0.40	0.40	0.40		
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.19							
	prr	(Hz)	570							
	srr	(Hz)	71.3							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	104.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	208.6							
	$p_r$ at $Z_{pii}$	(MPa)	3.73							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.38		
	$I_{pa, a}$ at $Z_{pii, a}$		(W/cm <sup>2</sup> )	657.8						
		Focal Length	$FL_x$ (cm)	1.8		6.5		6.5		
	$FL_y$ (cm)	1.4		1.4		1.4				
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 7.5 MHz, sector depth = 4 cm, focus = 1.8 cm, B-Mode lines = 128, PRF = 570 Hz  
 Control 2: Freq. = 7.5 MHz, sector depth = 7 cm, focus = 6.5 cm, B-Mode lines = 128, PRF = 430 Hz  
 Control 3: Freq. = 7.5 MHz, sector depth = 8 cm, focus = 8.0 cm, B-Mode lines = 128, PRF = 280 Hz

Acoustic Output Reporting Table for Track 3 for the 12L5A Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.07	0.99			0.99			2.12	
Index Component Value		1.07	0.99	-	-	0.99	-	-	2.12	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.42							
	P	(mW)		99.5	-		99.5	-	118.7	-
	$P_{txt}$	(mW)		40.7	-		40.7	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1cm^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	0.85		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.45		-			-		
	$Z_{MI}$	(cm)	1.35							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.40	-
	$f_{awf}$	(MHz)	5.12	5.10	-		5.10	-	5.09	-
	Dim of $A_{aprt}$	X (cm)		3.84	-		3.84	-	3.84	-
Y (cm)			0.40	-		0.40	-	0.40	-	
Other Information	<b>Mode Components</b>	rD	B+rD	-		B+rD	-		B+rD	-
	$t_d$	(µsec)	0.75							
	prr	(Hz)	3000							
	srr	(Hz)	9.7							
	$\eta_{pps}$		10							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	108.7							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	173.6							
	$p_r$ at $z_{pii}$	(MPa)	2.86							
	$d_{eq}$ at $z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	341.3							
	Focal Length	FLx (cm)	1.8		-			-		
		FLy (cm)	1.4		-			-		
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: B-Mode Frequency = 12.0 MHz, sector depth = 11 cm, focal depth = 1.8 cm, Color Doppler frequency = 5.14 MHz, Color Doppler focus = 1.8 cm, Frame Rate = 9.7 Hz, Color ROI = 0.51 cm, Packet size = 10, transmit pulses = 4, PRF = 3000 Hz  
 Control 2: B-Mode Frequency = 10.0 MHz, sector depth = 7 cm, focal depth = 6.5 cm, Color Doppler frequency = 5.0 MHz, Color Doppler focus = 6.5 cm, Frame Rate = 2.7 Hz, Color ROI = 3.81 cm, Packet size = 14, transmit pulses = 10, PRF = 10360 Hz  
 Control 3: B-Mode Frequency = 12.0 MHz, sector depth = 8 cm, focal depth = 8.0 cm, Color Doppler frequency = 5.14 MHz, Color Doppler focus = 8.0 cm, Frame Rate = 2.3 Hz, Color ROI = 3.81 cm, Packet size = 14, transmit pulses = 10, PRF = 9110 Hz

Acoustic Output Reporting Table for Track 3 for the 12L5A Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.42	1.40			2.20			2.15	
Index Component Value		1.42	-	0.80	1.40	-	1.00	2.20	-	2.15
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.18							
	P	(mW)		-	116.6	-	46.1	-	116.6	
	$P_{txt}$	(mW)		-	33.0	-	41.3			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)			57.7					
	$I_{spta a}$ at $Z_b$	(mW/cm <sup>2</sup> )					401.6			
	$z_s$	(cm)			2.00					
	$z_{bp}$	(cm)	0.85		2.00		1.15			
	$z_b$	(cm)					1.20			
	$Z_{pii}$	(cm)	1.65		8.00		2.80			
	$Z_{MI}$	(cm)	1.60							
	$d_{eq}(z_b)$	(cm)					0.31			
	$D_{eq}$	(cm)							-	1.35
	$f_{awf}$	(MHz)	5.01	-	5.09	-	5.11	-	5.09	
Dim of $A_{aprt}$	X (cm)		-	3.60	-	1.14	-	3.60		
	Y (cm)		-	0.40	-	0.40	-	0.40		
<b>Mode Components</b>		D	-	D	-	D	-	D		
Other Information	$t_d$	( $\mu$ sec)	1.13							
	prr	(Hz)	600							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	482.7							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	858.5							
	$p_r$ at $z_{pii}$	(MPa)	4.14							
	$d_{eq}$ at $z_{pii}$	(cm)					0.21			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	718.8							
	Focal Length	FLx (cm)	2.4		8.0		3.2			
FLy (cm)		1.4		1.4		1.4				
Operating Control Conditions	Control 1		X							
	Control 2			X				X		
	Control 3					X				
	Control 4		1.42	1.40		2.20		2.15		

Control 1: Sector depth = 9.0 cm, Focus = 2.4 cm, B-Mode Frequency = 10.0 MHz, PWD Frequency = 5.0 MHz, SV Size = 1.0 mm, SV Depth = 2.4 cm, PRF = 600 Hz, Update = off  
 Control 2: Sector depth = 9.0 cm, Focus = 2.4 cm, B-Mode Frequency = 12.0 MHz, PWD Frequency = 5.14 MHz, SV Size = 0.5 mm, SV Depth = 8.0 cm, PRF = 8400 Hz, Update = off  
 Control 3: Sector depth = 9.0 cm, Focus = 2.4 cm, B-Mode Frequency = 12.0 MHz, PWD Frequency = 5.14 MHz, SV Size = 2.0 mm, SV Depth = 3.2 cm, PRF = 17000 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 12L5A (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.18	0.02			0.02			0.04	
Index Component Value			0.18	0.02	-	-	0.02	-	-	0.04	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.49								
	P	(mW)		2.5	-	-	2.5	-	-	2.5	-
	$P_{txt}$	(mW)		0.7	-	-	0.7	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.90			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	3.40			-			-		
	$Z_{MI}$	(cm)	1.60								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.40	-
	$f_{awf}$	(MHz)	7.75	7.75	-	-	7.75	-	-	7.75	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.40	-	-	0.40	-	-	0.40	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-
	$t_d$	( $\mu$ sec)	0.16								
	prr	(Hz)	64.2								
	srr	(Hz)	64.2								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	4.4								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	10.6								
	$p_r$ at $Z_{pii}$	(MPa)	0.72								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	12.7								
	Focal Length	FLx (cm)	5.0			-			-		
		FLy (cm)	1.4			-			-		
Operating Control Conditions	Control 1		X	X			X			X	
	Control 2										
	Control 3										

Control 1: Freq. = 12.0 MHz, sector depth = 2 cm, focus = 5.0 cm, B-Mode lines = 256, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 12L5A (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.18	0.03			0.03			0.04	
Index Component Value		0.18	0.022	0.003	0.002	0.022	0.003	0.004	0.040	0.004
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.49							
	P	(mW)		2.2	0.09	2.2	0.09	2.2	0.08	
	$P_{txt}$	(mW)		0.6	0.09	0.6	0.09			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			0.05					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						1.0		
	$Z_s$	(cm)			0.90					
	$Z_{bp}$	(cm)	0.90		0.90			0.90		
	$Z_b$	(cm)						1.30		
	$Z_{pii}$	(cm)	3.40		3.40			3.40		
	$Z_{MI}$	(cm)	1.60							
	$d_{eq}(Z_b)$	(cm)						0.24		
	$D_{eq}$	(cm)							1.40	0.62
	$f_{awf}$	(MHz)	7.75	7.75	7.75	7.75	7.75	7.75	7.75	7.75
	Dim of $A_{aprt}$	X (cm)		3.84	0.75	3.84	0.75	3.84	0.75	
Y (cm)			0.40	0.40	0.40	0.40	0.40	0.40	0.40	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.16							
	prr	(Hz)	570							
	srr	(Hz)	114							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	5.2							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	13.5							
	$p_r$ at $Z_{pii}$	(MPa)	0.72							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.18		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	12.7							
	Focal Length	FLx (cm)	5.0		5.0		5.0			
		FLy (cm)	1.4		1.4		1.4			
Operating Control Conditions	Control 1		X	X		X		X		
	Control 2									
	Control 3									

Control 1: Freq. = 12.0 MHz, sector depth = 2 cm, focus = 5.0 cm, B-Mode lines = 128, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 12L5A (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.17	0.16			0.16			0.35	
Index Component Value		0.17	0.16	-	-	0.16	-	-	0.35	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.38							
	P	(mW)		19.5	-		19.5	-	19.5	-
	$P_{txt}$	(mW)		6.4	-		6.4	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )								
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	1.40							
	$Z_b$	(cm)								
	$Z_{pii}$	(cm)	4.80							
	$Z_{MI}$	(cm)	4.65							
	$d_{eq}(Z_b)$	(cm)								
	$D_{eq}$	(cm)							1.40	-
	$f_{awf}$	(MHz)	5.12	5.12	-		5.12	-	5.12	-
	Dim of $A_{aprt}$	X (cm)		3.84	-		3.84	-	3.84	-
Y (cm)			0.40	-		0.40	-	0.40	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-		B+rD	-	B+rD	-
	$t_d$	(µsec)	0.74							
	prr	(Hz)	22220							
	srr	(Hz)	10.8							
	$\eta_{pps}$		10							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	28.7							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	47.1							
	$p_r$ at $Z_{pii}$	(MPa)	0.85							
	$d_{eq}$ at $Z_{pii}$	(cm)								
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	10.1							
	Focal Length	FLx (cm)	5.0							
		FLy (cm)	1.4							
Operating Control Conditions	Control 1		X							
	Control 2			X		X		X		
	Control 3									

Control 1: B-Mode Frequency = 12.0 MHz, sector depth = 6 cm, focal depth = 5.0 cm, Color Doppler frequency = 5.14 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 10.8 Hz, Color ROI = 3.81 cm, Packet size = 10, transmit pulses = 4, PRF = 22220 Hz  
 Control 2: B-Mode Frequency = 12.0 MHz, sector depth = 2 cm, focal depth = 5.0 cm, Color Doppler frequency = 5.14 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 4.5 Hz, Color ROI = 3.81 cm, Packet size = 12, transmit pulses = 10, PRF = 22220 Hz

**Acoustic Output Reporting Table for Track 3 for the 12L5A (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic PWD Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.17	0.07			0.15			0.12	
Index Component Value			0.17	-	0.07	0.07	-	0.07	0.15	-	0.12
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.38								
	P	(mW)		-	4.5		-	4.5		-	4.5
	$P_{txt}$	(mW)		-	2.7		-	2.7			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			2.8						
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						19.4			
	$Z_s$	(cm)			1.40						
	$Z_{bp}$	(cm)	1.40		1.40			1.40			
	$Z_b$	(cm)						1.40			
	$Z_{pii}$	(cm)	4.80		4.80			4.80			
	$Z_{MI}$	(cm)	4.65								
	$d_{eq}(Z_b)$	(cm)						0.42			
	$D_{eq}$	(cm)								-	0.93
	$f_{awf}$	(MHz)	5.12	-	5.12		-	5.12		-	5.12
	Dim of $A_{aprt}$	X (cm)		-	1.71		-	1.71		-	1.71
Y (cm)			-	0.40		-	0.40		-	0.40	
Other Information	<b>Mode Components</b>		D	-	D		-	D		-	D
	$t_d$	( $\mu$ sec)	1.84								
	prr	(Hz)	1500								
	srr	(Hz)	1								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	28.1								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	149.8								
	$p_r$ at $Z_{pii}$	(MPa)	0.85								
	$d_{eq}$ at $Z_{pii}$	(cm)						0.19			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	10.2								
	Focal Length	FLx (cm)	5.0		5.0			5.0			
		FLy (cm)	1.4		1.4			1.4			
Operating Control Conditions	Control 1		X								
	Control 2			X		X		X			
	Control 3										

Control 1: Sector depth = 9.0 cm, Focus = 5.0 cm, B-Mode Frequency = 12.0 MHz, PWD Frequency = 5.14 MHz, SV Size = 1.5 mm, SV Depth = 5.0 cm, PRF = 1500 Hz, Update = off

Control 2: Sector depth = 2.0 cm, Focus = 5.0 cm, B-Mode Frequency = 12.0 MHz, PWD Frequency = 5.14 MHz, SV Size = 1.5 mm, SV Depth = 5.0 cm, PRF = 2500 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 14L3 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan		Non-scan	Scan		Non-scan	Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.45	0.84			0.84			2.46	
Index Component Value			1.45	0.84		-	0.84		-	2.46	
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.17								
	P	(mW)		113.4		-	113.4		-	145.8	
	$P_{txt}$	(mW)		40.6		-	40.6		-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)									
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )									
	$Z_s$	(cm)									
	$Z_{bp}$	(cm)	0.85								
	$Z_b$	(cm)									
	$Z_{pii}$	(cm)	1.50								
	$Z_{MI}$	(cm)	1.35								
	$d_{eq}(Z_b)$	(cm)									
	$D_{eq}$	(cm)								1.48	
	$f_{awf}$	(MHz)	4.76	4.33		-	4.33		-	4.09	
Dim of $A_{aprt}$	X (cm)		3.84		-	3.84		-	3.84		
	Y (cm)		0.45		-	0.45		-	0.45		
Other Information	Mode Components		B	B		-	B		-	B	
	$t_d$	(µsec)	0.27								
	prr	(Hz)	150								
	srr	(Hz)	150								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	71.6								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	112.0								
	$p_r$ at $Z_{pii}$	(MPa)	3.77								
	$d_{eq}$ at $Z_{pii}$	(cm)									
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	478.8								
	Focal Length	FLx (cm)	1.8								
		FLy (cm)	1.5								
Operating Control Conditions	Control 1		X								
	Control 2			X			X				
	Control 3								X		

Control 1: Freq. = 4.5 MHz, sector depth = 2 cm, focus = 1.8 cm, 96 lines, focus # = 1  
 Control 2: Freq. = 5.1 MHz, sector depth = 9 cm, focus = 8.0 cm, 96 lines, focus # = 1  
 Control 3: Freq. = 5.0 MHz, sector depth = 11 cm, focus = 10.6 cm, 96 lines, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 14L3 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.45	0.87			0.94			2.36	
Index Component Value		1.45	0.77	0.07	0.10	0.77	0.07	0.17	2.28	0.08
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.17							
	P	(mW)		104.5	8.9	104.5	8.9		135.0	4.8
	$P_{txt}$	(mW)		37.4	3.2	37.4	3.2			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			5.0					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						15.0		
	$Z_s$	(cm)			1.90					
	$Z_{bp}$	(cm)	0.85		1.90			1.90		
	$Z_b$	(cm)						1.90		
	$Z_{pii}$	(cm)	1.50		8.10			8.10		
	$Z_{MI}$	(cm)	1.35							
	$d_{eq}(Z_b)$	(cm)						0.64		
	$D_{eq}$	(cm)							1.48	1.48
	$f_{awf}$	(MHz)	4.76	4.33	4.33	4.33	4.33		4.12	4.12
Dim of $A_{aprt}$	X (cm)		3.84	2.85	3.84	2.85		3.84	3.84	
	Y (cm)		0.45	0.45	0.45	0.45		0.45	0.45	
Other Information	<b>Mode Components</b>		B	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.27							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$n_{pps}$		2							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	178.0							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	283.5							
	$p_r$ at $Z_{pii}$	(MPa)	3.77							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.48		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	478.8							
	Focal Length	FLx (cm)	1.8		8.0		8.0			
FLy (cm)		1.5		1.5		1.5				
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 4.5 MHz, sector depth = 4 cm, focus = 1.8 cm, PRF = 570 Hz  
 Control 2: Freq. = 5.1 MHz, sector depth = 8 cm, focus = 8.0 cm, PRF = 570 Hz  
 Control 3: Freq. = 5.1 MHz, sector depth = 11 cm, focus = 10.6 cm, PRF = 210 Hz

**Acoustic Output Reporting Table for Track 3 for the 14L3 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan		Non-scan	Scan		Non-scan	Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.15	1.57			1.57			3.11	
Index Component Value			1.15	1.57	-	-	1.57	-	-	3.11	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.60								
	P	(mW)		73.3	-	-	73.3	-	-	184.6	-
	$P_{txt}$	(mW)		66.1	-	-	66.1	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)									
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$z_s$	(cm)									
	$z_{bp}$	(cm)	0.85						-		
	$z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.35						-		
	$Z_{MI}$	(cm)	1.30								
	$d_{eq}(z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.48	-
	$f_{awf}$	(MHz)	5.09	4.97	-	-	4.97	-	-	4.25	-
Dim of $A_{aprt}$	X (cm)		1.32	-	-	1.32	-	-	3.84	-	
	Y (cm)		0.45	-	-	0.45	-	-	0.45	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	B+rD	-
	$t_d$	( $\mu$ sec)	0.74								
	prr	(Hz)	600								
	srr	(Hz)	34.4								
	$n_{pps}$		14								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	425.7								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	674.8								
	$p_r$ at $Z_{pii}$	(MPa)	3.26								
	$d_{eq}$ at $z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	454.4								
	Focal Length	FLx (cm)	1.8			-			-		
FLy (cm)		1.5			-			-			
Operating Control Conditions	Control 1		X								
	Control 2			X			X				
	Control 3								X		

Control 1: B-Mode Frequency = 5.1 MHz, sector depth = 2.0 cm, focal depth = 1.8 cm, Color Doppler frequency = 5.1 MHz, Color Doppler focus = 1.8 cm, Frame Rate = 34.4 Hz, Color ROI = 0.51 cm, Packet size = 14, transmit pulses = 4, PRF = 600 Hz

Control 2: B-Mode Frequency = 10.0 MHz, sector depth = 2.0 cm, focal depth = 0.6 cm, Color Doppler frequency = 5.0 MHz, Color Doppler focus = 0.6 cm, Frame Rate = 22.1 Hz, Color ROI = 1.08 cm, Packet size = 14, transmit pulses = 10, PRF = 22220 Hz

Control 3: B-Mode Frequency = 6.0 MHz, sector depth = 11.0 cm, focal depth = 10.06 cm, Color Doppler frequency = 4.3 MHz, Color Doppler focus = 10.06 cm, Frame Rate = 2.2 Hz, Color ROI = 3.84 cm, Packet size = 14, transmit pulses = 10, PRF = 7100 Hz

Acoustic Output Reporting Table for Track 3 for the 14L3 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.54	2.13			2.96			3.39	
Index Component Value		1.54	-	2.13	1.08	-	1.31	2.96	-	3.39
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.47							
	P	(mW)		-	201.2	-	85.2	-	201.2	
	$P_{txt}$	(mW)		-	53.4	-	64.4			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)			105.5					
	$I_{spta}$ at $Z_b$	(mW/cm <sup>2</sup> )					406.8			
	$z_s$	(cm)			2.20					
	$z_{bp}$	(cm)	0.85		2.20			1.30		
	$z_b$	(cm)						1.55		
	$Z_{pii}$	(cm)	1.35		10.80			3.65		
	$Z_{MI}$	(cm)	1.30							
	$d_{eq}(z_b)$	(cm)						0.41		
	$D_{eq}$	(cm)							-	1.48
	$f_{awf}$	(MHz)	5.09	-	4.25	-	4.27	-	4.25	
Dim of $A_{aprt}$	X (cm)		-	3.84	-	1.35	-	3.84		
	Y (cm)		-	0.45	-	0.45	-	0.45		
Other Information	<b>Mode Components</b>		D	-	D	-	D	-	D	
	$t_d$	(μsec)	1.48							
	prr	(Hz)	450							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	515.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	826.9							
	$p_r$ at $Z_{pii}$	(MPa)	4.35							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.30		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	775.5							
	Focal Length	FLx (cm)	1.8		10.6		4.0			
FLy (cm)		1.5		1.5		1.5				
Operating Control Conditions	Control 1		X							
	Control 2			X				X		
	Control 3					X				

Control 1: Sector depth = 12.0 cm, Focus = 1.8 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.1 MHz, SV Size = 1.5 mm, SV Depth = 1.8 cm, PRF = 450 Hz, Update = off  
 Control 2: Sector depth = 12.0 cm, Focus = 1.8 cm, B-Mode Frequency = 6 MHz, PWD Frequency = 4.3 MHz, SV Size = 4.0 mm, SV Depth = 10.6 cm, PRF = 6000 Hz, Update = off  
 Control 3: Sector depth = 12.0 cm, Focus = 1.8 cm, B-Mode Frequency = 6 MHz, PWD Frequency = 4.3 MHz, SV Size = 1.0 mm, SV Depth = 4.2 cm, PRF = 14100 Hz, Update = off

**.Acoustic Output Reporting Table for Track 3 for the 14L3 (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.19	0.03			0.03			0.06	
Index Component Value			0.19	0.03	-	-	0.03	-	-	0.06	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.52								
	P	(mW)		3.4	-	-	3.4	-	-	3.4	-
	$P_{txt}$	(mW)		0.9	-	-	0.9	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.0			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	3.55			-			-		
	$Z_{MI}$	(cm)	1.55								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.48	-
	$f_{awf}$	(MHz)	7.51	7.51	-	-	7.51	-	-	7.51	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.45	-	-	0.45	-	-	0.45	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-
	$t_d$	( $\mu$ sec)	0.19								
	prr	(Hz)	86.8								
	srr	(Hz)	86.8								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	4.4								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	10.4								
	$p_r$ at $Z_{pii}$	(MPa)	0.95								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	8.0								
	Focal Length	FLx (cm)	4.5			-			-		
		FLy (cm)	1.5			-			-		
Operating Control Conditions	Control 1		X	X			X			X	
	Control 2										
	Control 3										

Control 1: Freq. = 7.2 MHz, sector depth = 2 cm, focus = 4.5 cm, 256 lines, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 14L3 (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic M-Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.19	0.03			0.03			0.05	
Index Component Value			0.19	0.026	0.003	0.002	0.026	0.003	0.004	0.047	0.003
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.52								
	P	(mW)		2.8	0.09		2.8	0.09		2.8	0.09
	$P_{txt}$	(mW)		0.7	0.09		0.7	0.09			
	Min of [ $P_{\alpha}(Z_s)$ , $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				0.05					
	$I_{spta a}$ at $Z_b$	(mW/cm <sup>2</sup> )						0.77			
	$z_s$	(cm)			1.0						
	$z_{bp}$	(cm)	1.0		1.0			1.0			
	$z_b$	(cm)						1.4			
	$Z_{pii}$	(cm)	3.55		3.55			3.55			
	$Z_{MI}$	(cm)	1.55								
	$d_{eq}(z_b)$	(cm)						0.25			
	$D_{eq}$	(cm)								1.48	0.66
	$f_{awf}$	(MHz)	7.51	7.51	7.51		7.51	7.51		7.51	7.51
Dim of $A_{aprt}$	X (cm)		3.84	0.75		3.84	0.75		3.84	0.75	
	Y (cm)		0.45	0.45		0.45	0.45		0.45	0.45	
Other Information	<b>Mode Components</b>		B	B	M	B	M	B	M		
	$t_d$	( $\mu\text{sec}$ )	0.19								
	prr	(Hz)	142.5								
	srr	(Hz)	570								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	4.6								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	13.5								
	$p_r$ at $Z_{pii}$	(MPa)	0.95								
	$d_{eq}$ at $z_{pii}$	(cm)						0.16			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	8.0								
	Focal Length	FLx (cm)	4.5		4.5			4.5			
FLy (cm)		1.5		1.5			1.5				
Operating Control Conditions	Control 1		X	X		X		X			
	Control 2										
	Control 3										

Control 1: Freq. = 7.2 MHz, sector depth = 2 cm, focus = 4.5 cm, 128 lines, PRF = 570 Hz

**Acoustic Output Reporting Table for Track 3 for the 14L3 (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic Color Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.18	0.80			0.80			0.87	
Index Component Value			0.18	0.80	-	-	0.80	-	-	0.87	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.48								
	P	(mW)		33.1	-		33.1	-		51.4	-
	$P_{txt}$	(mW)		23.9	-		23.9	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	1.3			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	4.30			-			-		
	$Z_{MI}$	(cm)	4.15								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.48	-
	$f_{awf}$	(MHz)	7.02	7.02	-		7.02	-		7.02	-
	Dim of $A_{aprt}$	X (cm)		1.92	-		1.92	-		3.81	-
Y (cm)			0.45	-		0.45	-		0.45	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-		B+rD	-		B+rD	-
	$t_d$	( $\mu$ sec)	0.56								
	prr	(Hz)	35.2								
	srr	(Hz)	35.2								
	$n_{pps}$		14								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	29.8								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	221.9								
	$p_r$ at $Z_{pii}$	(MPa)	1.30								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	14.7								
	Focal Length	FLx (cm)	4.5			-			-		
		FLy (cm)	1.5			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3									X	

Control 1: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 4.5 cm, Color Doppler frequency = 7.2 MHz, Color Doppler focus = 4.5 cm, Frame Rate = 35.2 Hz, Color ROI = 0.51 cm, Packet size = 14, transmit pulses = 4, PRF = 22220 Hz

Control 2: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 4.5 cm, Color Doppler frequency = 7.2 MHz, Color Doppler focus = 4.5 cm, Frame Rate = 21.2 Hz, Color ROI = 0.51 cm, Packet size = 14, transmit pulses = 10, PRF = 22220 Hz

Control 3: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 4.5 cm, Color Doppler frequency = 7.2 MHz, Color Doppler focus = 4.5 cm, Frame Rate = 4.7 Hz, Color ROI = 3.81 cm, Packet size = 14, transmit pulses = 10, PRF = 22220 Hz

**Acoustic Output Reporting Table for Track 3 for the 14L3 (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic PWD Mode)**

Index Label			MI	TIS			TIB			TIC		
				Scan		Non-scan	Scan		Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface	
Maximum Index Value			0.19	0.17			0.19			0.19		
Index Component Value			0.19	-	0.17	0.12	-	0.17	0.19	-	0.19	
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.51									
	P	(mW)		-	6.9		-	6.9		-	6.9	
	$P_{txt}$	(mW)		-	5.1		-	5.1				
	Min of [ $P_{\alpha}(Z_s)$ , $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				3.6						
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							26.4			
	$z_s$	(cm)				1.35						
	$z_{bp}$	(cm)	1.35			1.35			1.35			
	$z_b$	(cm)							1.35			
	$Z_{pii}$	(cm)	4.30			4.30			4.30			
	$Z_{MI}$	(cm)	4.15									
	$d_{eq}(z_b)$	(cm)							0.39			
	$D_{eq}$	(cm)								-	0.89	
	$f_{awf}$	(MHz)	7.02		-	7.02		-	7.02		-	7.02
Dim of $A_{aprt}$	X (cm)			-	1.38		-	1.38		-	1.38	
	Y (cm)			-	0.45		-	0.45		-	0.45	
Other Information	<b>Mode Components</b>		D	-	D		-	D		-	D	
	$t_d$	( $\mu\text{sec}$ )	1.26									
	prr	(Hz)	1750									
	srr	(Hz)	-									
	$n_{pps}$		1									
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	34.3									
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	262.2									
	$p_r$ at $Z_{pii}$	(MPa)	1.38									
	$d_{eq}$ at $Z_{pii}$	(cm)							0.18			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	15.6									
	Focal Length	FLx (cm)	4.5			4.5			4.5			
FLy (cm)		1.5			1.5			1.5				
Operating Control Conditions	Control 1		X									
	Control 2			X			X			X		
	Control 3											

Control 1: Sector depth = 5.0 cm, Focus = 4.5 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 7.2 MHz, SV Size = 1.0 mm, SV Depth = 4.5 cm, PRF = 1750 Hz, Update = off

Control 2: Sector depth = 5.0 cm, Focus = 4.5 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 7.2 MHz, SV Size = 1.0 mm, SV Depth = 4.5 cm, PRF = 2500 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 15L4 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.34	1.01			1.01			1.87	
Index Component Value			1.34	1.01	-	-	1.01	-	-	1.87	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.54								
	P	(mW)		44.4	-	-	44.4	-	-	104.8	-
	$P_{txt}$	(mW)		30.9	-	-	30.9	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.70			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.25			-			-		
	$Z_{MI}$	(cm)	1.15								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.40	-
	$f_{awf}$	(MHz)	7.03	6.86	-	-	6.86	-	-	4.85	-
	Dim of $A_{aprt}$	X (cm)		2.07	-	-	2.64	-	-	3.84	-
Y (cm)			0.40	-	-	0.40	-	-	0.40	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-
	$t_d$	( $\mu$ sec)	0.16								
	prr	(Hz)	103.4								
	srr	(Hz)	103.4								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	27.1								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	47.2								
	$p_r$ at $Z_{pii}$	(MPa)	4.35								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	690.5								
	Focal Length	FLx (cm)	1.3			-			-		
		FLy (cm)	1.4			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3								X		

Control 1: Freq. = 7.5 MHz, sector depth = 5 cm, focus = 1.3 cm, focus # = 1

Control 2: Freq. = 7.5 MHz, sector depth = 4 cm, focus = 4.0 cm, focus # = 1

Control 3: Freq. = 5.0 MHz, sector depth = 10 cm, focus = 8.0 cm, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 15L4 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.34	0.91			0.95			1.88	
Index Component Value			1.34	0.82	0.09	0.07	0.82	0.09	0.13	1.76	0.11
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.54								
	P	(mW)		40.4	4.0		40.4	4.0		98.6	6.2
	$P_{txt}$	(mW)		25.1	2.9		25.1	2.9			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				2.2					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							18.1		
	$Z_s$	(cm)				1.25					
	$Z_{bp}$	(cm)	0.70			1.25			1.25		
	$Z_b$	(cm)							1.25		
	$Z_{pii}$	(cm)	1.25			3.95			3.95		
	$Z_{MI}$	(cm)	1.15								
	$d_{eq}(Z_b)$	(cm)							0.41		
	$D_{eq}$	(cm)								1.40	1.35
	$f_{awf}$	(MHz)	7.03	6.86	6.86		6.86	6.86		4.85	4.85
Dim of $A_{aprt}$	X (cm)		2.64	1.44		2.64	1.44		3.84	3.60	
	Y (cm)		0.40	0.40		0.40	0.40		0.40	0.40	
Other Information	<b>Mode Components</b>		B+M	B	M		B	M		B	M
	$t_d$	( $\mu$ sec)	0.16								
	prr	(Hz)	570								
	srr	(Hz)	142.5								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	65.1								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	114.5								
	$p_r$ at $Z_{pii}$	(MPa)	4.35								
	$d_{eq}$ at $Z_{pii}$	(cm)							0.34		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	690.5								
	Focal Length	FLx (cm)	1.3			4.0			4.0		
FLy (cm)		1.4			1.4			1.4			
Operating Control Conditions	Control 1		X								
	Control 2			X			X				
	Control 3									X	

Control 1: Freq. = 7.5 MHz, sector depth = 2 cm, focus = 1.3 cm, PRF = 570 Hz

Control 2: Freq. = 7.5 MHz, sector depth = 4 cm, focus = 4.0 cm, PRF = 570 Hz

Control 3: Freq. = 5.0 MHz, sector depth = 8 cm, focus = 8.0 cm, PRF = 430 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.06	0.99			0.99			2.07	
Index Component Value			1.06	0.99	-	-	0.99	-	-	2.07	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.40								
	P	(mW)		99.4	-	-	99.4	-	-	116.1	-
	$P_{txt}$	(mW)		40.6	-	-	40.6	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.85			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.50			-			-		
	$Z_{MI}$	(cm)	1.50								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.40	-
	$f_{awf}$	(MHz)	5.00	4.99	-	-	4.99	-	-	5.07	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.40	-	-	0.40	-	-	0.40	-	
Other Information	<b>Mode Components</b>		rD	B+rD	-	-	B+rD	-	-	B+rD	-
	$t_d$	(µsec)	0.78								
	prr	(Hz)	350								
	srr	(Hz)	30.7								
	$n_{pps}$		10								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	324.7								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	544.6								
	$p_r$ at $Z_{pii}$	(MPa)	3.07								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	307.3								
	Focal Length	FLx (cm)	1.8			-			-		
		FLy (cm)	1.4			-			-		
Operating Control Conditions	Control 1		X								
	Control 2			X			X				
	Control 3								X		

Control 1: B-Mode Frequency = 10.0 MHz, sector depth = 4.0 cm, focal depth = 1.8 cm, Color Doppler frequency = 5.0 MHz, Color Doppler focus = 1.8 cm, Frame Rate = 30.7 Hz, Color ROI = 0.48 cm, Packet size = 10, transmit pulses = 4, PRF = 350 Hz  
 Control 2: B-Mode Frequency = 10.0 MHz, sector depth = 7.0 cm, focal depth = 6.5 cm, Color Doppler frequency = 5.0 MHz, Color Doppler focus = 6.5 cm, Frame Rate = 3.2 Hz, Color ROI = 3.81 cm, Packet size = 12, transmit pulses = 10, PRF = 10360 Hz  
 Control 3: B-Mode Frequency = 12.0 MHz, sector depth = 8.0 cm, focal depth = 8.0 cm, Color Doppler frequency = 5.14 MHz, Color Doppler focus = 8.0 cm, Frame Rate = 2.8 Hz, Color ROI = 3.81 cm, Packet size = 12, transmit pulses = 10, PRF = 8960 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.36	1.40			2.15			2.16	
Index Component Value		1.36	-	0.80	1.40	-	0.93	2.15	-	2.16
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.82							
	P	(mW)		-	117.1	-	65.2	-	117.1	
	$P_{txt}$	(mW)		-	33.2	-	38.2			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)			58.1					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					149.2			
	$Z_s$	(cm)			2.00					
	$Z_{bp}$	(cm)	0.70		2.00		1.40			
	$Z_b$	(cm)					1.40			
	$Z_{pii}$	(cm)	1.15		8.10		4.65			
	$Z_{MI}$	(cm)	1.05							
	$d_{eq}(Z_b)$	(cm)					0.42			
	$D_{eq}$	(cm)							-	1.35
	$f_{awf}$	(MHz)	4.29	-	5.07	-	5.09	-	5.07	
Dim of $A_{aprt}$	X (cm)		-	3.60	-	1.74	-	3.60		
	Y (cm)		-	0.40	-	0.40	-	0.40		
Mode Components		D	-	D	-	D	-	D		
Other Information	$t_d$	( $\mu$ sec)	1.77							
	prr	(Hz)	500							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	280.7							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	395.4							
	$p_r$ at $Z_{pii}$	(MPa)	3.39							
	$d_{eq}$ at $Z_{pii}$	(cm)					0.34			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	337.8							
	Focal Length	FLX (cm)	1.8		8.0		4.8			
FLY (cm)		1.4		1.4		1.4				
Operating Control Conditions	Control 1		X							
	Control 2			X				X		
	Control 3					X				

Control 1: Sector depth = 9.0 cm, Focus = 1.8 cm, B-Mode Frequency = 7.5 MHz, PWD Frequency = 4.29 MHz, SV Size = 1.5 mm, SV Depth = 1.8 cm, PRF = 500 Hz, Update = off  
 Control 2: Sector depth = 9.0 cm, Focus = 1.8 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.14 MHz, SV Size = 2.5 mm, SV Depth = 8.0 cm, PRF = 700 Hz, Update = off  
 Control 3: Sector depth = 9.0 cm, Focus = 1.8 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.14 MHz, SV Size = 2.5 mm, SV Depth = 4.8 cm, PRF = 600 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 15L4 (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.18	0.05			0.05			0.08	
Index Component Value			0.18	0.05	-	-	0.05	-	-	0.08	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.52								
	P	(mW)		4.6	-	-	4.6	-	-	4.6	-
	$P_{txt}$	(mW)		1.2	-	-	1.2	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.90			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	3.50			-			-		
	$Z_{MI}$	(cm)	1.70								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.40	-
	$f_{awf}$	(MHz)	8.64	8.64	-	-	8.64	-	-	8.64	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.40	-	-	0.40	-	-	0.40	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-
	$t_d$	( $\mu$ sec)	0.15								
	prr	(Hz)	86.8								
	srr	(Hz)	86.8								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	5.4								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	15.0								
	$p_r$ at $Z_{pii}$	(MPa)	0.84								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	12.7								
	Focal Length	FLx (cm)	5.0			-			-		
		FLy (cm)	1.4			-			-		
Operating Control Conditions	Control 1		X	X			X			X	
	Control 2										
	Control 3										

Control 1: Freq. = 12.0 MHz, sector depth = 2 cm, focus = 5.0 cm, B-Mode lines = 256, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 15L4 (Ophthalmic)Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.18	0.05			0.05			0.07	
Index Component Value		0.18	0.041	0.005	0.003	0.041	0.005	0.004	0.068	0.005
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.52							
	P	(mW)		3.8	0.1	3.8	0.1		3.8	0.1
	$P_{txt}$	(mW)		1.0	0.1	1.0	0.1			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			0.1					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						2.3		
	$Z_s$	(cm)			0.90					
	$Z_{bp}$	(cm)	0.90		0.90			0.90		
	$Z_b$	(cm)						1.40		
	$Z_{pii}$	(cm)	3.50		3.50			3.50		
	$Z_{MI}$	(cm)	1.70							
	$d_{eq}(Z_b)$	(cm)						0.27		
	$D_{eq}$	(cm)							1.40	0.62
	$f_{awf}$	(MHz)	8.64	8.64	8.64	8.64	8.64		8.64	8.64
Dim of $A_{aprt}$	X (cm)		3.84	0.75	3.84	0.75		3.84	0.75	
	Y (cm)		0.40	0.40	0.40	0.40		0.40	0.40	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.15							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	5.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	16.6							
	$p_r$ at $Z_{pii}$	(MPa)	0.84							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.20		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	12.7							
	Focal Length	FLx (cm)	5.0		5.0			5.0		
FLy (cm)		1.4		1.4			1.4			
Operating Control Conditions	Control 1		X	X		X		X		
	Control 2									
	Control 3									

Control 1: Freq. = 12.0 MHz, sector depth = 2 cm, focus = 5.0 cm, B-Mode lines = 64, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4 (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.15	0.21			0.21			0.46	
Index Component Value		0.15	0.21	-	-	0.21	-	-	0.46	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.33							
	P	(mW)		25.5	-	25.5	-	25.5	-	
	$P_{txt}$	(mW)		8.4	-	8.4	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					-			
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	1.40		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	4.95		-			-		
	$Z_{MI}$	(cm)	4.80							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.40	-
	$f_{awf}$	(MHz)	5.12	5.12	-	5.12	-	5.12	-	
Dim of $A_{aprt}$	X (cm)		3.84	-	3.84	-	3.84	-		
	Y (cm)		0.40	-	0.40	-	0.40	-		
Other Information	<b>Mode Components</b>	rD	B+rD	-	B+rD	-	B+rD	-		
	$t_d$	(µsec)	0.77							
	prr	(Hz)	22220							
	srr	(Hz)	8.4							
	$n_{pps}$		14							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	32.8							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	53.8							
	$p_r$ at $Z_{pii}$	(MPa)	0.75							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	8.1							
	Focal Length	FLx (cm)	5.0		-			-		
		FLy (cm)	1.4		-			-		
Operating Control Conditions	Control 1		X							
	Control 2			X		X		X		
	Control 3									

Control 1: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 5.0 cm, Color Doppler frequency = 5.14 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 9.7 Hz, Color ROI = 3.81 cm, Packet size = 14, transmit pulses = 4, PRF = 22220 Hz  
 Control 2: B-Mode Frequency = 12.0 MHz, sector depth = 10.0 cm, focal depth = 5.0 cm, Color Doppler frequency = 5.14 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 5.0 Hz, Color ROI = 3.81 cm, Packet size = 12, transmit pulses = 10, PRF = 10130 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4 (Ophthalmic) Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic PWD Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.17	0.09			0.18			0.16	
Index Component Value			0.17	-	0.09	0.09	-	0.09	0.18	-	0.16
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.40								
	P	(mW)		-	5.9		-	5.9		-	5.9
	$P_{txt}$	(mW)		-	3.5		-	3.5			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				3.6					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							22.9		
	$Z_s$	(cm)				1.40					
	$Z_{bp}$	(cm)	1.40			1.40			1.40		
	$Z_b$	(cm)							1.40		
	$Z_{pii}$	(cm)	4.95			4.95			4.95		
	$Z_{MI}$	(cm)	4.80								
	$d_{eq}(Z_b)$	(cm)							0.44		
	$D_{eq}$	(cm)								-	0.93
	$f_{awf}$	(MHz)	5.12	-	5.12		-	5.12		-	5.12
	Dim of $A_{aprt}$	X (cm)		-	1.71		-	1.71		-	1.71
Y (cm)			-	0.40		-	0.40		-	0.40	
Other Information	<b>Mode Components</b>		D	-	D		-	D		-	D
	$t_d$	( $\mu$ sec)	1.92								
	prr	(Hz)	1500								
	srr	(Hz)	-								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	33.8								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	187.9								
	$p_r$ at $Z_{pii}$	(MPa)	0.89								
	$d_{eq}$ at $Z_{pii}$	(cm)							0.20		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	11.7								
	Focal Length	FLx (cm)	5.0			5.0			5.0		
		FLy (cm)	1.4			1.4			1.4		
Operating Control Conditions	Control 1		X								
	Control 2				X			X		X	
	Control 3										

Control 1: Sector depth = 12.0 cm, Focus = 5.0 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.14 MHz, SV Size = 1.5 mm, SV Depth = 5.0 cm, PRF = 1500 Hz, Update = off

Control 2: Sector depth = 12.0 cm, Focus = 5.0 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.14 MHz, SV Size = 4.0 mm, SV Depth = 5.0 cm, PRF = 700 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 15L4A Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.42	0.47			0.47			0.96	
Index Component Value			1.42	0.47	-	-	0.47	-	-	0.96	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.18								
	P	(mW)		38.4	-	-	38.4	-	-	55.4	-
	$P_{txt}$	(mW)		15.7	-	-	15.7	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.90			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.65			-			-		
	$Z_{MI}$	(cm)	1.55								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.44	-
	$f_{awf}$	(MHz)	5.03	6.28	-	-	6.28	-	-	4.86	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.425	-	-	0.425	-	-	0.425	-	
<b>Mode Components</b>			B	B	-	-	B	-	B	-	
Other Information	$t_d$	( $\mu$ sec)	0.28								
	prr	(Hz)	79.2								
	srr	(Hz)	79.2								
	$n_{pps}$		2								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	47.8								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	81.8								
	$p_r$ at $Z_{pii}$	(MPa)	4.15								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	280.3								
	Focal Length	FLx (cm)	1.8			-			-		
FLy (cm)		1.4			-			-			
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3								X		

Control 1: Freq. = 4.3 MHz, sector depth = 3 cm, focus = 1.8 cm, focus # = 1

Control 2: Freq. = 7.5 MHz, sector depth = 7 cm, focus = 6.5 cm, 128 lines, focus # = 1

Control 3: Freq. = 6.0 MHz, sector depth = 8 cm, focus = 8.0 cm, 256 lines, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 15L4A Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.42	0.48			0.51			0.96	
Index Component Value		1.42	0.42	0.05	0.06	0.42	0.05	0.9	0.86	0.10
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	3.18							
	P	(mW)		34.0	4.1	34.0	4.1	49.4	5.6	
	$P_{txt}$	(mW)		13.9	1.8	13.9	1.8			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)			2.0					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						10.3		
	$z_s$	(cm)			1.60					
	$z_{bp}$	(cm)	0.90		1.60			1.60		
	$z_b$	(cm)						1.60		
	$Z_{pii}$	(cm)	1.65		6.50			6.50		
	$Z_{MI}$	(cm)	1.55							
	$d_{eq}(z_b)$	(cm)						0.52		
	$D_{eq}$	(cm)							1.44	1.40
	$f_{awf}$	(MHz)	5.03	6.28	6.28	6.28	6.28	4.86	4.86	
	Dim of $A_{aprt}$	X (cm)		3.84	2.31	3.84	2.31	3.84	3.60	
Y (cm)			0.425	0.425	0.425	0.425	0.425	0.425	0.425	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.28							
	prf	(Hz)	570							
	srr	(Hz)	114							
	$n_{pps}$		2							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	92.8							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	161.1							
	$\rho_r$ at $z_{pii}$	(MPa)	4.15							
	$d_{eq}$ at $z_{pii}$	(cm)						0.43		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	280.3							
	Focal Length	FLx (cm)	1.8		6.5		6.5			
		FLy (cm)	1.4		1.4		1.4			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 4.3 MHz, sector depth = 4 cm, focus = 1.8 cm, PRF = 570 Hz

Control 2: Freq. = 7.5 MHz, sector depth = 12 cm, focus = 6.5 cm, PRF = 570 Hz

Control 3: Freq. = 6.0 MHz, sector depth = 8 cm, focus = 8.0 cm, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4A Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.08	0.78			0.78			1.26	
Index Component Value		1.08	0.78	-	-	0.78	-	-	1.26	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.45							
	P	(mW)		33.7	-		33.7	-	72.8	-
	$P_{txt}$	(mW)		31.6	-		31.6	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	0.90		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.50		-			-		
	$Z_{MI}$	(cm)	1.45							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.44	-
	$f_{awf}$	(MHz)	5.12	5.13	-		5.13	-	5.09	-
Dim of $A_{aprt}$	X (cm)		1.17	-		1.17	-	3.84	-	
	Y (cm)		0.425	-		0.425	-	0.425	-	
Other Information	<b>Mode Components</b>	rD	B+rD	-		B+rD	-	B+rD	-	
	$t_d$	(μsec)	0.74							
	prr	(Hz)	500							
	srr	(Hz)	38.6							
	$n_{pps}$		10							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	261.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	435.9							
	$p_r$ at $Z_{pii}$	(MPa)	3.05							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	345.5							
	Focal Length	FLx (cm)	1.8		-			-		
FLy (cm)		1.4		-			-			
Operating Control Conditions	Control 1	X								
	Control 2			X		X				
	Control 3							X		

Control 1: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 1.8 cm, Color Doppler frequency = 5.1 MHz, Color Doppler focus = 1.8 cm, Frame Rate = 38.6 Hz, Color ROI = 0.48 cm, Packet size = 10, transmit pulses = 4, PRF = 500 Hz  
 Control 2: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 0.3 cm, Color Doppler frequency = 5.1 MHz, Color Doppler focus = 0.3 cm, Frame Rate = 67.2 Hz, Color ROI = 0.99 cm, Packet size = 12, transmit pulses = 10, PRF = 21000 Hz  
 Control 3: B-Mode Frequency = 12.0 MHz, sector depth = 8.0 cm, focal depth = 8.0 cm, Color Doppler frequency = 5.1 MHz, Color Doppler focus = 8.0 cm, Frame Rate = 6.3 Hz, Color ROI = 3.81 cm, Packet size = 12, transmit pulses = 10, PRF = 8970 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4A Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.55	0.93			1.59			1.39	
Index Component Value		1.55	-	0.53	0.93	-	0.71	1.59	-	1.39
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.52							
	P	(mW)		-	77.7	-	32.7		-	77.7
	$P_{txt}$	(mW)		-	22.0	-	29.3			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1cm^2$ ]	(mW)						38.5		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						301.4		
	$z_s$	(cm)			2.00					
	$z_{bp}$	(cm)	0.70		2.00			1.15		
	$z_b$	(cm)						1.25		
	$Z_{pii}$	(cm)	1.30		8.00			2.90		
	$Z_{MI}$	(cm)	1.20							
	$d_{eq}(z_b)$	(cm)						0.30		
	$D_{eq}$	(cm)							-	1.40
	$f_{awf}$	(MHz)	5.13	-	5.09	-	5.11		-	5.09
	Dim of $A_{aprt}$	X (cm)		-	3.60	-	1.14		-	3.60
Y (cm)			-	0.425	-	0.425		-	0.425	
Mode Components		D	-	D	-	D		-	D	
Other Information	$t_d$	( $\mu$ sec)	1.83							
	prr	(Hz)	350							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	450.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	702.8							
	$p_r$ at $z_{pii}$	(MPa)	4.18							
	$d_{eq}$ at $z_{pii}$	(cm)						0.20		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	705.4							
	Focal Length	FLx (cm)	1.8		8.0			3.2		
FLy (cm)		1.4		1.4			1.4			
Operating Control Conditions	Control 1		X							
	Control 2			X					X	
	Control 3					X				
	Control 4									

Control 1: Sector depth = 12.0 cm, Focus = 1.8 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.1 MHz, SV Size = 1.5 mm, SV Depth = 1.8 cm, PRF = 350 Hz, Update = off  
 Control 2: Sector depth = 12.0 cm, Focus = 1.8 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.1 MHz, SV Size = 3.5 mm, SV Depth = 8.0 cm, PRF = 900 Hz, Update = off  
 Control 3: Sector depth = 12.0 cm, Focus = 1.8 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.1 MHz, SV Size = 1.5 mm, SV Depth = 3.2 cm, PRF = 15000 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 15L4A Ophthalmic Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic 2D Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.19	0.07			0.07			0.10	
Index Component Value		0.19	0.07	-	-	0.07	-	-	0.10	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.56							
	P	(mW)		6.0	-	6.0	-	6.0	-	
	$P_{txt}$	(mW)		1.6	-	1.6	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					-			
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	0.95		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	3.60		-			-		
	$Z_{MI}$	(cm)	1.70							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.44	-
	$f_{awf}$	(MHz)	9.10	9.10	-	9.10	-	9.10	-	
	Dim of $A_{aprt}$	X (cm)		3.84	-	3.84	-	3.84	-	
Y (cm)			0.425	-	0.425	-	0.425	-		
<b>Mode Components</b>		B	B	-	B	-	B	-		
Other Information	$t_d$	( $\mu$ sec)	0.12							
	prr	(Hz)	86.8							
	srr	(Hz)	86.8							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	2.0							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	7.6							
	$p_r$ at $Z_{pii}$	(MPa)	0.91							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	15.9							
	Focal Length	FLx (cm)	5.0		-			-		
FLy (cm)		1.4		-			-			
Operating Control Conditions	Control 1		X	X		X		X		
	Control 2									
	Control 3									

Control 1: Freq. = 12.0 MHz, sector depth = 2 cm, focus = 5.0 cm, B-Mode lines = 256, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 15L4A Ophthalmic Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.19	0.06			0.06			0.09	
Index Component Value		0.19	0.057	0.007	0.004	0.057	0.007	0.005	0.086	0.006
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	0.56							
	P	(mW)		5.0	0.2	5.0	0.2	5.0	0.2	
	$P_{txt}$	(mW)		1.3	0.2	1.6	0.2			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			0.1					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					1.0			
	$Z_s$	(cm)			0.95					
	$Z_{bp}$	(cm)	0.95		0.95			0.95		
	$Z_b$	(cm)						1.40		
	$Z_{pii}$	(cm)	3.60		3.60			3.60		
	$Z_{MI}$	(cm)	1.70							
	$d_{eq}(Z_b)$	(cm)						0.29		
	$D_{eq}$	(cm)							1.44	0.64
	$f_{awf}$	(MHz)	9.10	9.10	9.10	9.10	9.10	9.10	9.10	9.10
	Dim of $A_{aprt}$	X (cm)		3.84	0.75	3.84	0.75	3.84	0.75	
Y (cm)			0.425	0.425	0.425	0.425	0.425	0.425	0.425	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu\text{sec}$ )	0.12							
	prf	(Hz)	570							
	srr	(Hz)	142.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	6.0							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	18.4							
	$\rho_r$ at $Z_{pii}$	(MPa)	0.91							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.22		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	15.9							
	Focal Length	FLx (cm)	5.0		5.0			5.0		
		FLy (cm)	1.4		1.4			1.4		
Operating Control Conditions	Control 1		X	X		X		X		
	Control 2									
	Control 3									

Control 1: Freq. = 12.0 MHz, sector depth = 2 cm, focus = 5.0 cm, B-Mode lines = 128, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4A Ophthalmic Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.17	0.22			0.22			0.48	
Index Component Value		0.17	0.22	-	-	0.22	-	-	0.48	-
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	0.39							
	P	(mW)		27.5	-	27.5	-	27.5	-	
	$P_{txt}$	(mW)		9.1	-	9.1	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					-			
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	1.45		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	5.00		-			-		
	$Z_{MI}$	(cm)	4.80							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.44	-
	$f_{awf}$	(MHz)	5.13	5.13	-	5.13	-	5.13	-	-
Dim of $A_{aprt}$	X (cm)		3.84	-	3.84	-	3.84	-	-	
	Y (cm)		0.425	-	0.425	-	0.425	-	-	
<b>Mode Components</b>		rD	B+rD	-	B+rD	-	B+rD	-	-	
Other Information	$t_d$	( $\mu$ sec)	0.74							
	prr	(Hz)	300							
	srr	(Hz)	11.4							
	$n_{pps}$		10							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	31.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	56.5							
	$\rho_r$ at $Z_{pii}$	(MPa)	0.88							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	9.2							
	Focal Length	FLx (cm)	5.0		-			-		
FLy (cm)		1.4		-			-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X		X		
	Control 3									

Control 1: B-Mode Frequency = 12.0 MHz, sector depth = 12.0 cm, focal depth = 5.0 cm, Color Doppler frequency = 5.1 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 11.4 Hz, Color ROI = 0.51 cm, Packet size = 10, transmit pulses = 4, PRF = 300 Hz  
 Control 2: B-Mode Frequency = 12.0 MHz, sector depth = 12.0 cm, focal depth = 5.0 cm, Color Doppler frequency = 5.1 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 4.6 Hz, Color ROI = 3.81 cm, Packet size = 12, transmit pulses = 10, PRF = 10730 Hz

Acoustic Output Reporting Table for Track 3 for the 15L4A Ophthalmic Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.19	0.09			0.20			0.16	
Index Component Value		0.19	-	0.09	0.09	-	0.09	0.20	-	0.16
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.44							
	P	(mW)		-	6.3	-	6.3	-	6.3	
	$P_{txt}$	(mW)		-	3.8	-	3.8			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			3.8					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						26.2		
	$Z_s$	(cm)			1.45					
	$Z_{bp}$	(cm)	1.45		1.45			1.45		
	$Z_b$	(cm)						1.45		
	$Z_{pii}$	(cm)	5.00		5.00			5.00		
	$Z_{MI}$	(cm)	4.80							
	$d_{eq}(Z_b)$	(cm)						0.43		
	$D_{eq}$	(cm)							-	0.96
	$f_{awf}$	(MHz)	5.13	-	5.13	-	5.13	-	5.13	
	Dim of $A_{aprt}$	X (cm)		-	1.71	-	1.71	-	1.71	
Y (cm)			-	0.425	-	0.425	-	0.425		
<b>Mode Components</b>		D	-	D	-	D	-	D		
Other Information	$t_d$	( $\mu$ sec)	1.85							
	prr	(Hz)	1250							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	29.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	165.3							
	$p_r$ at $Z_{pii}$	(MPa)	0.99							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.21		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	12.8							
	Focal Length	FLx (cm)	5.0		5.0			5.0		
FLy (cm)		1.4		1.4			1.4			
Operating Control Conditions	Control 1		X							
	Control 2			X		X		X		
	Control 3									

Control 1: Sector depth = 12.0 cm, Focus = 5.0 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.1 MHz, SV Size = 1.5 mm, SV Depth = 5.0 cm, PRF = 1250 Hz, Update = off

Control 2: Sector depth = 12.0 cm, Focus = 5.0 cm, B-Mode Frequency = 12 MHz, PWD Frequency = 5.1 MHz, SV Size = 3.5 mm, SV Depth = 5.0 cm, PRF = 900 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 15WL4 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.34	0.66			0.66			Note 1	
Index Component Value		1.34	0.66	-	-	0.66	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.89							
	P	(mW)		82.4	-	82.4	-	-	-	-
	$P_{txt}$	(mW)		22.5	-	22.5	-	-	-	-
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	0.85					-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.45					-		
	$Z_{MI}$	(cm)	1.40							
	$d_{eq}(Z_b)$	(cm)							-	
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.68	6.15	-	6.15	-	-	-	-
Dim of $A_{aprt}$	X (cm)		5.49	-	5.49	-	-	-	-	
	Y (cm)		0.40	-	0.40	-	-	-	-	
<b>Mode Components</b>		B	B	-	B	-	-	-	-	
Other Information	$t_d$	( $\mu\text{sec}$ )	0.31							
	prr	(Hz)	86.8							
	srr	(Hz)	86.8							
	$n_{pps}$		2							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	38.2							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	59.9							
	$p_r$ at $Z_{pii}$	(MPa)	3.55							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	242.9							
	Focal Length	FLx (cm)	1.8					-		
FLy (cm)		1.5					-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq. = 4.3 MHz, sector depth = 2 cm, focus = 1.8 cm, focus # = 1

Control 2: Freq. = 7.5 MHz, sector depth = 9 cm, focus = 8.0 cm, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 15WL4 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.34	0.70			0.68			Note 1	
Index Component Value		1.34	0.59	0.07	0.11	0.59	0.07	0.09	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.89							
	P	(mW)		73.5	8.5	73.5	8.5		-	-
	$P_{txt}$	(mW)		20.1	2.3	20.1	2.3			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)						3.7		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						5.9		
	$Z_s$	(cm)			2.0					
	$Z_{bp}$	(cm)	0.85		2.0			2.0		
	$Z_b$	(cm)						2.0		
	$Z_{pii}$	(cm)	1.45		8.1			8.1		
	$Z_{MI}$	(cm)	1.40							
	$d_{eq}(Z_b)$	(cm)						0.91		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.68	6.15	6.15	6.15	6.15		-	-
Dim of $A_{aprt}$	X (cm)		5.49	3.66	5.49	3.66		-	-	
	Y (cm)		0.40	0.40	0.40	0.40		-	-	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M		-	-
	$t_d$	( $\mu\text{sec}$ )	0.31							
	prf	(Hz)	570							
	srr	(Hz)	71.3							
	$n_{pps}$		2							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	74.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	117.3							
	$p_r$ at $Z_{pii}$	(MPa)	3.55							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.63		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	242.9							
Focal Length	FLx (cm)	1.8		8.0			8.0			
	FLy (cm)	1.5		1.5			1.5			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq. = 4.3 MHz, sector depth = 2 cm, focus = 1.8 cm, PRF = 570 Hz

Control 2: Freq. = 7.5 MHz, sector depth = 12.0 cm, focus = 8.0 cm, PRF = 570 Hz

**Acoustic Output Reporting Table for Track 3 for the 15WL4 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.01	0.98			0.98			Note 1	
Index Component Value		1.01	0.98	-	-	0.98	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.09							
	P	(mW)		47.4	-	47.4	-	-	-	-
	$P_{txt}$	(mW)		40.2	-	40.2	-	-	-	-
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	0.70		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.05		-			-		
	$Z_{MI}$	(cm)	0.95							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	4.30	5.07	-	5.07	-	-	-	-
Dim of $A_{aprt}$	X (cm)		1.29	-	1.29	-	-	-	-	
	Y (cm)		0.40	-	0.40	-	-	-	-	
<b>Mode Components</b>		rD	B+rD	-	B+rD	-	-	-	-	
Other Information	$t_d$	( $\mu$ sec)	0.89							
	prf	(Hz)	15800							
	srr	(Hz)	50.0							
	$n_{pps}$		14							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	321.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	422.4							
	$p_r$ at $Z_{pii}$	(MPa)	2.33							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	160.2							
	Focal Length	FLx (cm)	1.3		-			-		
		FLy (cm)	1.5		-			-		
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 10.0 MHz, sector depth = 7.0 cm, focal depth = 1.3 cm, Color Doppler frequency = 4.3 MHz, Color Doppler focus = 1.3 cm, Frame Rate = 50.0 Hz, Color ROI = 0.36 cm, Packet size = 14, transmit pulses = 4, PRF = 15800 Hz

Control 2: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 0.3 cm, Color Doppler frequency = 5.1 MHz, Color Doppler focus = 0.3 cm, Frame Rate = 52.4 Hz, Color ROI = 1.09 cm, Packet size = 14, transmit pulses = 10, PRF = 22220 Hz

Acoustic Output Reporting Table for Track 3 for the 15WL4 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.45	1.48			1.86			Note 1	
Index Component Value		1.45	-	0.80	1.48	-	0.92	1.86	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.27							
	P	(mW)		-	124.1	-	59.6		-	-
	$P_{txt}$	(mW)		-	33.9	-	38.6			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)						62.6		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						230.3		
	$Z_s$	(cm)			2.00					
	$Z_{bp}$	(cm)	0.85		2.00			1.35		
	$Z_b$	(cm)						1.35		
	$Z_{pii}$	(cm)	1.40		8.10			4.50		
	$Z_{MI}$	(cm)	1.40							
	$d_{eq}(Z_b)$	(cm)						0.46		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	5.10	-	4.95	-	4.97		-	-
	Dim of $A_{aprt}$	X (cm)		-	3.66	-	1.54		-	-
Y (cm)			-	0.40	-	0.40		-	-	
<b>Mode Components</b>		D	-	D	-	D		-	-	
Other Information	$t_d$	( $\mu$ sec)	1.11							
	prf	(Hz)	600							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	394.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	636.6							
	$p_r$ at $Z_{pii}$	(MPa)	4.18							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.43		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	593.3							
	Focal Length	FLx (cm)	1.8		8.0			4.8		
FLy (cm)		1.5		1.5			1.5			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 12.0 cm, Focus = 2.4 cm, B-Mode Frequency = 12.0 MHz, PWD Frequency = 5.1 MHz, SV Size = 1.0 mm, SV Depth = 1.8 cm, PRF = 600 Hz, Update = off

Control 2: Sector depth = 12.0 cm, Focus = 2.4 cm, B-Mode Frequency = 10.0 MHz, PWD Frequency = 5.0 MHz, SV Size = 0.5 mm, SV Depth = 8.0 cm, PRF = 5000 Hz, Update = off

Control 3: Sector depth = 12.0 cm, Focus = 2.4 cm, B-Mode Frequency = 10.0 MHz, PWD Frequency = 5.0 MHz, SV Size = 1.0 mm, SV Depth = 4.8 cm, PRF = 1500 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 16HL7 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.11	0.38			0.38			Note 1	
Index Component Value		1.11	0.38	-	-	0.38	-	-	-	-
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	3.38							
	P	(mW)		21.2	-	21.2	-	-	-	-
	$P_{txt}$	(mW)		8.3	-	8.3	-			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$z_s$	(cm)			-					
	$z_{bp}$	(cm)	0.60		-			-		
	$z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.05		-			-		
	$Z_{MI}$	(cm)	1.00							
	$d_{eq}(z_b)$	(cm)						-		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	9.28	9.58	-	9.58	-	-	-	-
	Dim of $A_{aprt}$	X (cm)		2.56	-	2.56	-	-	-	-
Y (cm)			0.35	-	0.35	-	-	-	-	
Mode Components		B	B	-	B	-	-	-	-	
Other Information	$t_d$	( $\mu$ sec)	0.13							
	prf	(Hz)	76.9							
	srr	(Hz)	76.9							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	15.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	29.2							
	$\rho_r$ at $z_{pii}$	(MPa)	4.51							
	$d_{eq}$ at $z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	571.2							
	Focal Length	FLx (cm)	1.2					-		
		FLy (cm)	1.0					-		
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq. = 10.0 MHz, sector depth = 4 cm, focus = 1.2 cm, focus # = 1

Control 2: Freq. = 10.0 MHz, sector depth = 6 cm, focus = 5.8 cm, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 16HL7 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.11	0.38			0.38			Note 1	
Index Component Value		1.11	0.34	0.04	0.03	0.34	0.04	0.04	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.38							
	P	(mW)		13.8	1.4	13.8	1.4		-	-
	$P_{txt}$	(mW)		7.6	0.9	7.6	0.9			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)						0.6		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						5.1		
	$z_s$	(cm)			1.25					
	$z_{bp}$	(cm)	0.60		1.25			1.25		
	$z_b$	(cm)						1.25		
	$Z_{pii}$	(cm)	1.05		1.25			1.25		
	$Z_{MI}$	(cm)	1.00							
	$d_{eq}(z_b)$	(cm)						0.40		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	9.28	9.45	9.45	9.45	9.45		-	-
Dim of $A_{aprt}$	X (cm)		2.56	1.62	2.56	1.62		-	-	
	Y (cm)		0.35	0.35	0.35	0.35		-	-	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	-	-	
	$t_d$	( $\mu$ sec)	0.13							
	prr	(Hz)	570							
	srr	(Hz)	81.4							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	44.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	83.9							
	$p_r$ at $z_{pii}$	(MPa)	4.51							
	$d_{eq}$ at $z_{pii}$	(cm)						0.40		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	571.2							
	Focal Length	FLx (cm)	1.2		4.4		4.4			
FLy (cm)		1.0		1.0		1.0				
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Freq. = 10.0 MHz, sector depth = 3 cm, focus = 1.2 cm, PRF = 570 Hz

Control 2: Freq. = 10.0 MHz, sector depth = 6 cm, focus = 4.4 cm, PRF = 570 Hz

**Acoustic Output Reporting Table for Track 3 for the 16HL7 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.70	0.49			0.49			Note 1	
Index Component Value			0.70	0.49	-	-	0.49	-	-	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.88								
	P	(mW)		15.3	-	-	15.3	-	-	-	-
	$P_{txt}$	(mW)		12.9	-	-	12.9	-	-		
	Min of [ $P_a(z_s), I_{ta, a}(z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$z_s$	(cm)				-					
	$z_{bp}$	(cm)	0.55			-			-		
	$z_b$	(cm)							-		
	$Z_{pii}$	(cm)	0.80			-			-		
	$Z_{MI}$	(cm)	0.75								
	$d_{eq}(z_b)$	(cm)							-		
	$D_{eq}$	(cm)								-	-
	$f_{awf}$	(MHz)	7.16	7.91	-	-	7.91	-	-	-	-
	Dim of $A_{aprt}$	X (cm)		1.46	-	-	1.46	-	-	-	-
Y (cm)			0.35	-	-	0.35	-	-	-	-	
Other Information	<b>Mode Components</b>		rD	B	-	-	B	-	-	-	
	$t_d$	( $\mu$ sec)	0.52								
	prr	(Hz)	1000								
	srr	(Hz)	36.0								
	$\eta_{pps}$		10								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	187.8								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	273.4								
	$p_r$ at $z_{pii}$	(MPa)	2.23								
	$d_{eq}$ at $z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	190.3								
	Focal Length	FLx (cm)	0.90			-			-		
		FLy (cm)	1.0			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3										

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: B-Mode Frequency = 12.0 MHz, sector depth = 2.0 cm, focal depth = 0.9 cm, Color Doppler frequency = 7.2 MHz, Color Doppler focus = 0.9 cm, Frame Rate = 36.0 Hz, Color ROI = 0.35 cm, Packet size = 10, transmit pulses = 4, PRF = 1000 Hz  
Control 2: B-Mode Frequency = 13.3 MHz, sector depth = 7.0 cm, focal depth = 3.0 cm, Color Doppler frequency = 8.0 MHz, Color Doppler focus = 3.0 cm, Frame Rate = 7.5 Hz, Color ROI = 0.34 cm, Packet size = 14, transmit pulses = 10, PRF = 3000 Hz

Acoustic Output Reporting Table for Track 3 for the 16HL7 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.29	0.59			0.94			Note 1	
Index Component Value		1.29	-	0.59	0.37	-	0.47	0.94	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.44							
	P	(mW)		-	17.3	-	12.4	-	-	
	$P_{txt}$	(mW)		-	15.7	-	12.4			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			9.9					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						291.0		
	$Z_s$	(cm)			1.05					
	$Z_{bp}$	(cm)	0.55		1.05			0.80		
	$Z_b$	(cm)						0.90		
	$Z_{pii}$	(cm)	0.80		2.80			1.65		
	$Z_{MI}$	(cm)	0.75							
	$d_{eq}(Z_b)$	(cm)						0.19		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	7.16	-	7.91	-	7.93	-	-	-
	Dim of $A_{aprt}$	X (cm)		-	1.10	-	0.66	-	-	-
Y (cm)			-	0.35	-	0.35	-	-	-	
<b>Mode Components</b>		D	-	D	-	D	-	-	-	
Other Information	$t_d$	( $\mu$ sec)	1.17							
	prr	(Hz)	500							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	380.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	566.8							
	$p_r$ at $Z_{pii}$	(MPa)	4.08							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.14		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	647.6							
	Focal Length	FLx (cm)	0.90		3.0			2.0		
FLy (cm)		1.0		1.0			1.0			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: Sector depth = 7.0 cm, Focus = 0.9 cm, B-Mode Frequency = 12.0 MHz, PWD Frequency = 7.2 MHz, SV Size = 1.0 mm, SV Depth = 0.9 cm, PRF = 500 Hz, Update = off

Control 2: Sector depth = 7.0 cm, Focus = 0.9 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 8.0 MHz, SV Size = 5.5 mm, SV Depth = 3.0 cm, PRF = 2000 Hz, Update = off

Control 3: Sector depth = 7.0 cm, Focus = 0.9 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 8.0 MHz, SV Size = 1.5 mm, SV Depth = 2.0 cm, PRF = 19000 Hz, Update = off

Acoustic Output Reporting Table for Track 3 for the 16L5 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC		
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan	
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface	
Maximum Index Value			1.34	0.70			0.70			1.11		
Index Component Value			1.34	0.70	-	-	0.70	-	-	1.11	-	
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.26									
	P	(mW)		53.4	-	-	53.4	-	-	57.9	-	
	$P_{txt}$	(mW)		15.4	-	-	15.4	-	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-						
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-			
	$Z_s$	(cm)				-						
	$Z_{bp}$	(cm)	0.65			-			-			
	$Z_b$	(cm)							-			
	$Z_{pii}$	(cm)	1.20			-			-			
	$Z_{MI}$	(cm)	1.20									
	$d_{eq}(Z_b)$	(cm)							-			
	$D_{eq}$	(cm)								1.31	-	
	$f_{awf}$	(MHz)	5.94	5.94	9.55	-	-	9.55	-	-	7.76	-
	Dim of $A_{aprt}$	X (cm)			3.84	-	-	3.84	-	-	3.84	-
Y (cm)				0.35	-	-	0.35	-	-	0.35	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-	
	$t_d$	( $\mu$ sec)	0.22									
	prr	(Hz)	86.8									
	srr	(Hz)	86.8									
	$\eta_{pps}$		1									
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	35.7									
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	58.8									
	$p_r$ at $Z_{pii}$	(MPa)	4.16									
	$d_{eq}$ at $Z_{pii}$	(cm)							-			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	275.5									
	Focal Length	FLx (cm)	1.4			-			-			
		FLy (cm)	1.5			-			-			
Operating Control Conditions	Control 1		X									
	Control 2				X			X				
	Control 3								X			

Control 1: Freq. = 5.0 MHz, sector depth = 2 cm, focus = 1.4 cm, focus # = 1

Control 2: Freq. = 10.0 MHz, sector depth = 6 cm, focus = 5.8 cm, focus # = 1

Control 3: Freq. = 7.5 MHz, sector depth = 4 cm, focus = 3.5 cm, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 16L5 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.34	0.70			0.70			1.11	
Index Component Value			1.34	0.70	-	-	0.70	-	-	1.11	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.26								
	P	(mW)		53.4	-	-	53.4	-	-	57.9	-
	$P_{txt}$	(mW)		15.4	-	-	15.4	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	0.65			-			-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.20			-			-		
	$Z_{MI}$	(cm)	1.20								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.31	-
	$f_{awf}$	(MHz)	5.94	9.55	-	-	9.55	-	-	7.76	-
	Dim of $A_{aprt}$	X (cm)		3.84	-	-	3.84	-	-	3.84	-
Y (cm)			0.35	-	-	0.35	-	-	0.35	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-
	$t_d$	( $\mu$ sec)	0.22								
	prr	(Hz)	86.8								
	srr	(Hz)	86.8								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	35.7								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	58.8								
	$p_r$ at $Z_{pii}$	(MPa)	4.16								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	275.5								
	Focal Length	FLx (cm)	1.4			-			-		
		FLy (cm)	1.5			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X			X			
	Control 3								X		

Control 1: Freq. = 5.0 MHz, sector depth = 2 cm, focus = 1.4 cm, focus # = 1

Control 2: Freq. = 10.0 MHz, sector depth = 6 cm, focus = 5.8 cm, focus # = 1

Control 3: Freq. = 7.5 MHz, sector depth = 4 cm, focus = 3.5 cm, focus # = 1

Acoustic Output Reporting Table for Track 3 for the 16L5 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.34	0.68			0.68			1.09	
Index Component Value		1.34	0.60	0.08	0.05	0.60	0.08	0.06	1.02	0.07
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.26							
	P	(mW)		45.6	2.6	45.6	2.6		53.4	2.1
	$P_{txt}$	(mW)		13.2	1.7	13.2	1.7			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			1.2					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						7.3		
	$Z_s$	(cm)			1.20					
	$Z_{bp}$	(cm)	0.65		1.20			1.20		
	$Z_b$	(cm)						1.20		
	$Z_{pii}$	(cm)	1.20		1.30			1.30		
	$Z_{MI}$	(cm)	1.20							
	$d_{eq}(Z_b)$	(cm)						0.48		
	$D_{eq}$	(cm)							1.31	0.72
	$f_{awf}$	(MHz)	5.94	9.55	9.55	9.55	9.55		7.76	7.76
Dim of $A_{aprt}$	X (cm)		3.84	1.54	3.84	1.54		3.84	1.16	
	Y (cm)		0.35	0.35	0.35	0.35		0.35	0.35	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.22							
	prr	(Hz)	570							
	srr	(Hz)	95.0							
	$n_{pps}$		2							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	65.7							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	108.2							
	$p_r$ at $Z_{pii}$	(MPa)	4.16							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.47		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	275.5							
	Focal Length	FLx (cm)	1.4		5.8		5.8			
FLy (cm)		1.5		1.5		1.5				
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 5.0 MHz, sector depth = 2 cm, focus = 1.4 cm, PRF = 570  
 Control 2: Freq. = 10.0 MHz, sector depth = 6 cm, focus = 5.8 cm, PRF = 570  
 Control 3: Freq. = 7.5 MHz, sector depth = 4 cm, focus = 3.5 cm, PRF = 570

Acoustic Output Reporting Table for Track 3 for the 16L5 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.81	1.09			1.09			1.51	
Index Component Value		0.81	1.09	-	-	1.09	-	-	1.51	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.00							
	P	(mW)		40.4	-	40.4	-		78.7	-
	$P_{txt}$	(mW)		34.0	-	34.0	-			
	Min of [ $P_a(z_s), I_{ta, a}(z_s) \times 1 \text{ cm}^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$z_s$	(cm)			-					
	$z_{bp}$	(cm)	0.70		-			-		
	$z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.10		-			-		
	$Z_{MI}$	(cm)	1.10							
	$d_{eq}(z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.31	-
	$f_{awf}$	(MHz)	6.02	6.64	-	6.64	-		6.65	-
	Dim of $A_{aprt}$	X (cm)		1.36	-	1.36	-		3.84	-
Y (cm)			0.35	-	0.35	-		0.35	-	
Other Information	<b>Mode Components</b>	rD	B+rD	-	B+rD	-		B+rD	-	
	$t_d$	(µsec)	0.63							
	prr	(Hz)	13000							
	srr	(Hz)	63.1							
	$n_{pps}$		10							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	369.6							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	582.6							
	$p_r$ at $z_{pii}$	(MPa)	2.48							
	$d_{eq}$ at $z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	201.5							
	Focal Length	FLx (cm)	1.4		-			-		
		FLy (cm)	1.5		-			-		
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: B-Mode Frequency = 7.5 MHz, sector depth = 2.0 cm, focal depth = 1.4 cm, Color Doppler frequency = 6.0 MHz, Color Doppler focus = 1.4 cm, Frame Rate = 63.1 Hz, Color ROI = 0.34 cm, Packet size = 10, transmit pulses = 4, PRF = 13000 Hz  
 Control 2: B-Mode Frequency = 10.0 MHz, sector depth = 7.0 cm, focal depth = 0.8 cm, Color Doppler frequency = 6.6 MHz, Color Doppler focus = 0.8 cm, Frame Rate = 20.8 Hz, Color ROI = 1.06 cm, Packet size = 12, transmit pulses = 10, PRF = 18140 Hz  
 Control 3: B-Mode Frequency = 13.3 MHz, sector depth = 7.0 cm, focal depth = 5.8 cm, Color Doppler frequency = 6.6 MHz, Color Doppler focus = 5.8 cm, Frame Rate = 4.4 Hz, Color ROI = 3.82 cm, Packet size = 12, transmit pulses = 10, PRF = 9000 Hz

Acoustic Output Reporting Table for Track 3 for the 16L5 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.48	1.22			1.69			1.66	
Index Component Value			1.48	-	1.22	0.86	-	1.22	1.69	-	1.66
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.62								
	P	(mW)		-	44.8		-	44.8		-	55.0
	$P_{txt}$	(mW)		-	38.6		-	38.6			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)				27.1					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							275.3		
	$z_s$	(cm)				1.10					
	$z_{bp}$	(cm)	0.70			1.10			1.10		
	$z_b$	(cm)							1.20		
	$Z_{pii}$	(cm)	1.10			3.20			3.20		
	$Z_{MI}$	(cm)	1.10								
	$d_{eq}(z_b)$	(cm)							0.36		
	$D_{eq}$	(cm)								-	0.83
	$f_{awf}$	(MHz)	6.02	-	6.63		-	6.63		-	6.65
Dim of $A_{aprt}$	X (cm)		-	1.16		-	1.16		-	1.54	
	Y (cm)		-	0.35		-	0.35		-	0.35	
Mode Components			D	-	D	-	D	-	D		
Other Information	$t_d$	( $\mu$ sec)	1.26								
	prr	(Hz)	500								
	srr	(Hz)	-								
	$n_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	417.4								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	658.0								
	$p_r$ at $z_{pii}$	(MPa)	4.50								
	$d_{eq}$ at $z_{pii}$	(cm)							0.28		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	662.3								
	Focal Length	FLx (cm)	1.4			3.5			3.5		
		FLy (cm)	1.5			1.5			1.5		
Operating Control Conditions	Control 1		X								
	Control 2			X		X					
	Control 3								X		

Control 1: Sector depth = 7.0 cm, Focus = 2.5 cm, B-Mode Frequency = 7.5 MHz, PWD Frequency = 6.0 MHz, SV Size = 1.0 mm, SV Depth = 1.4 cm, PRF = 500 Hz, Update = off  
 Control 2: Sector depth = 7.0 cm, Focus = 2.5 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 2.0 mm, SV Depth = 3.3 cm, PRF = 17600 Hz, Update = off  
 Control 3: Sector depth = 7.0 cm, Focus = 2.5 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 5.0 mm, SV Depth = 5.8cm, PRF = 300 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in 2D Mode)**

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			1.58	0.73			0.73			0.92	
Index Component Value			1.58	0.73	-	-	0.73	-	-	0.92	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.73								
	P	(mW)		27.8	-	-	27.8	-	-	39.2	-
	$P_{txt}$	(mW)		15.0	-	-	15.0	-	-		
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)									
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							-		
	$Z_s$	(cm)									
	$Z_{bp}$	(cm)	0.70						-		
	$Z_b$	(cm)							-		
	$Z_{pii}$	(cm)	1.20						-		
	$Z_{MI}$	(cm)	1.05								
	$d_{eq}(Z_b)$	(cm)							-		
	$D_{eq}$	(cm)								1.07	-
	$f_{awf}$	(MHz)	5.59	10.23	-	-	10.23	-	-	6.88	-
	Dim of $A_{aprt}$	X (cm)		2.56	-	-	2.56	-	-	2.56	-
Y (cm)			0.35	-	-	0.35	-	-	0.35	-	
Other Information	<b>Mode Components</b>		B	B	-	-	B	-	-	B	-
	$t_d$	( $\mu$ sec)	0.37								
	prr	(Hz)	112.2								
	srr	(Hz)	112.2								
	$\eta_{pps}$		1								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	64.7								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	98.5								
	$p_r$ at $Z_{pii}$	(MPa)	4.56								
	$d_{eq}$ at $Z_{pii}$	(cm)							-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	347.4								
	Focal Length	FLx (cm)	1.4			-			-		
		FLy (cm)	1.2			-			-		
Operating Control Conditions	Control 1		X								
	Control 2				X		X				
	Control 3								X		

Control 1: Freq. = 5.0 MHz, sector depth = 6 cm, focus = 1.4 cm, 96 lines, focus # = 1

Control 2: Freq. = 13.3 MHz, sector depth = 7 cm, focus = 5.8 cm, 96 lines, focus # = 1

Control 3: Freq. = 6.64 MHz, sector depth = 2 cm, focus = 0.8 cm, 128 lines, focus # = 1

**Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.58	0.74			0.74			0.88	
Index Component Value		1.58	0.69	0.05	0.03	0.69	0.05	0.03	0.77	0.11
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	3.73							
	P	(mW)		26.0	1.6	26.0	1.6	32.9	2.1	
	$P_{txt}$	(mW)		14.1	1.1	14.1	1.1			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			0.7					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					4.1			
	$Z_s$	(cm)			1.2					
	$Z_{bp}$	(cm)	0.70		1.2			1.2		
	$Z_b$	(cm)						1.2		
	$Z_{pii}$	(cm)	1.20		1.3			1.3		
	$Z_{MI}$	(cm)	1.05							
	$d_{eq}(Z_b)$	(cm)						0.53		
	$D_{eq}$	(cm)							1.07	1.07
	$f_{awf}$	(MHz)	5.59	10.23	10.23	10.23	10.23	6.90	6.90	
Dim of $A_{aprt}$	X (cm)		2.56	1.54	2.56	1.54	2.56	0.46		
	Y (cm)		0.35	0.35	0.35	0.35	0.35	0.35	0.35	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.37							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	134.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	303.5							
	$p_r$ at $Z_{pii}$	(MPa)	4.56							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.53		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	347.4							
	Focal Length	FLx (cm)	1.4		5.8		5.8			
FLy (cm)		1.2		1.2		1.2				
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 5.0 MHz, sector depth = 6 cm, focus = 1.4 cm, 64 lines, PRF = 570Hz

Control 2: Freq. = 13.3 MHz, sector depth = 6 cm, focus = 5.8 cm, 64 lines, PRF = 570Hz

Control 3: Freq. = 6.64 MHz, sector depth = 2 cm, focus = 1.4 cm, 64 lines, PRF = 570Hz

Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in Color Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.89	0.92			0.92			1.11	
Index Component Value		0.89	0.92	-	-	0.92	-	-	1.11	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	2.18							
	P	(mW)		30.4	-	30.4	-	47.4	-	
	$P_{txt}$	(mW)		28.9	-	28.9	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	0.70					-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.05					-		
	$Z_{MI}$	(cm)	1.00							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.07	-
	$f_{awf}$	(MHz)	6.04	6.67	-	6.67	-	6.66	-	
Dim of $A_{aprt}$	X (cm)		1.16	-	1.16	-	2.56	-		
	Y (cm)		0.35	-	0.35	-	0.35	-		
<b>Mode Components</b>		rD	B+rD	-	B+rD	-	B+rD	-		
Other Information	$t_d$	( $\mu$ sec)	0.64							
	prr	(Hz)	8000							
	srr	(Hz)	49.4							
	$n_{pps}$		12							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sij, a}$	(mW/cm <sup>2</sup> )	297.3							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sij}$	(mW/cm <sup>2</sup> )	455.8							
	$p_r$ at $Z_{pii}$	(MPa)	2.58							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	240.5							
	Focal Length	FLx (cm)	1.4		-			-		
FLy (cm)		1.2		-			-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: B-Mode Frequency = 10.0 MHz, sector depth = 7.0 cm, focal depth = 1.4 cm, Color Doppler frequency = 6.0 MHz, Color Doppler focus = 1.4 cm, Frame Rate = 49.4 Hz, Color ROI = 0.34 cm, Packet size = 12, transmit pulses = 4, PRF = 8000 Hz, Dual Beam on  
Control 2: B-Mode Frequency = 6.6 MHz, sector depth = 2.0 cm, focal depth = 0.4 cm, Color Doppler frequency = 6.6 MHz, Color Doppler focus = 0.4 cm, Frame Rate = 13.1 Hz, Color ROI = 1.00 cm, Packet size = 14, transmit pulses = 10, PRF = 22220 Hz, Dual Beam off  
Control 3: B-Mode Frequency = 13.3 MHz, sector depth = 6.0 cm, focal depth = 5.8 cm, Color Doppler frequency = 6.6 MHz, Color Doppler focus = 5.8 cm, Frame Rate = 5.4 Hz, Color ROI = 2.54 cm, Packet size = 14, transmit pulses = 10, PRF = 11650 Hz, Dual Beam off

Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.57	0.84			1.40			1.14	
Index Component Value		1.57	-	0.84	0.59	-	0.78	1.40	-	1.14
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	4.05							
	P	(mW)		-	30.8	-	24.8	-	37.8	
	$P_{txt}$	(mW)		-	26.5	-	24.8			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1cm^2$ ]	(mW)			18.6					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					334.8			
	$Z_s$	(cm)			1.10					
	$Z_{bp}$	(cm)	0.70		1.10			0.90		
	$Z_b$	(cm)						1.15		
	$Z_{pii}$	(cm)	1.05		3.25			2.10		
	$Z_{MI}$	(cm)	1.05							
	$d_{eq}(Z_b)$	(cm)						0.24		
	$D_{eq}$	(cm)							-	0.83
	$f_{awf}$	(MHz)	6.66	-	6.63	-	6.64	-	6.66	
	Dim of $A_{aprt}$	X (cm)		-	1.16	-	0.84	-	1.54	
Y (cm)			-	0.35	-	0.35	-	0.35		
Other Information	<b>Mode Components</b>		D	-	D	-	D	-	D	
	$t_d$	(µsec)	1.15							
	prr	(Hz)	500							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	522.4							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	847.7							
	$p_r$ at $Z_{pii}$	(MPa)	4.98							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.20		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	908.1							
	Focal Length	FLx (cm)	1.4		3.5			2.5		
FLy (cm)		1.2		1.2			1.2			
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3				X					
	Control 4							X		

Control 1: Sector depth = 7.0 cm, Focus = 1.4 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 1.0 mm, SV Depth = 0.8 cm, PRF = 500 Hz, Update = off  
 Control 2: Sector depth = 7.0 cm, Focus = 3.5 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 1.0 mm, SV Depth = 3.1 cm, PRF = 18200 Hz, Update = off  
 Control 2: Sector depth = 7.0 cm, Focus = 2.5 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 1.0 mm, SV Depth = 2.0 cm, PRF = 22000 Hz, Update = off  
 Control 3: Sector depth = 7.0 cm, Focus = 5.8 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 1.0 mm, SV Depth = 4.9 cm, PRF = 900 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic 2D Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.20	0.19			0.19			0.22	
Index Component Value		0.20	0.19	-	-	0.19	-	-	0.22	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.66							
	P	(mW)		9.3	-	9.3	-	9.3	-	
	$P_{txt}$	(mW)		3.6	-	3.6	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	0.80					-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	1.70					-		
	$Z_{MI}$	(cm)	1.40							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.07	-
	$f_{awf}$	(MHz)	10.74	10.74	-	10.74	-	10.74	-	
	Dim of $A_{aprt}$	X (cm)		2.56	-	2.56	-	2.56	-	
Y (cm)			0.35	-	0.35	-	0.35	-		
<b>Mode Components</b>			B	B	-	B	-	B	-	
Other Information	$t_d$	( $\mu$ sec)	0.13							
	prr	(Hz)	88.2							
	srr	(Hz)	88.2							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	10.8							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	31.2							
	$p_r$ at $Z_{pii}$	(MPa)	1.12							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	20.0							
	Focal Length	FLx (cm)	5.0			-			-	
		FLy (cm)	1.2			-			-	
Operating Control Conditions	Control 1		X	X		X		X		
	Control 2									
	Control 3									

Control 1: Freq. = 13.3 MHz, sector depth = 2 cm, focus = 5.0 cm, 252 lines

**Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic M-Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.20	0.16			0.16			0.19	
Index Component Value		0.20	0.15	0.012	0.007	0.15	0.012	0.007	0.18	0.01
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.66							
	P	(mW)		7.6	0.2	7.6	0.2	7.6	0.2	
	$P_{txt}$	(mW)		3.0	0.2	3.0	0.2			
	Min of [ $P_{\alpha}(z_s), I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$ ]	(mW)						0.1		
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						1.3		
	$z_s$	(cm)			0.80					
	$z_{bp}$	(cm)	0.80		0.80			0.80		
	$z_b$	(cm)						1.20		
	$Z_{pii}$	(cm)	1.70		1.70			1.70		
	$Z_{MI}$	(cm)	1.40							
	$d_{eq}(z_b)$	(cm)						0.30		
	$D_{eq}$	(cm)							1.07	0.56
	$f_{awf}$	(MHz)	10.74	10.74	10.74	10.74	10.74	10.74	10.74	10.74
Dim of $A_{aprt}$	X (cm)		2.56	0.70	2.56	0.70	2.56	0.70		
	Y (cm)		0.35	0.35	0.35	0.35	0.35	0.35	0.35	
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu$ sec)	0.13							
	prr	(Hz)	570							
	srr	(Hz)	142.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	9.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	30.8							
	$p_r$ at $z_{pii}$	(MPa)	1.12							
	$d_{eq}$ at $z_{pii}$	(cm)						0.26		
	$I_{pa, a}$ at $z_{pii, a}$	(W/cm <sup>2</sup> )	20.0							
	Focal Length	FLx (cm)	5.0		5.0			5.0		
		FLy (cm)	1.2		1.2			1.2		
Operating Control Conditions	Control 1		X	X		X		X		
	Control 2									
	Control 3									

Control 1: Freq. = 13.3 MHz, sector depth = 2 cm, focus = 5.0 cm, 128 lines, PRF = 570Hz

**Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic Color Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.18	0.28			0.28			0.37	
Index Component Value		0.18	0.28	-	-	0.28	-	-	0.37	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.47							
	P	(mW)		16.0	-	16.0	-	15.9	-	
	$P_{txt}$	(mW)		8.3	-	8.3	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)								
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					-			
	$Z_s$	(cm)								
	$Z_{bp}$	(cm)	1.20				-			
	$Z_b$	(cm)					-			
	$Z_{pii}$	(cm)	4.90				-			
	$Z_{MI}$	(cm)	1.10							
	$d_{eq}(Z_b)$	(cm)					-			
	$D_{eq}$	(cm)							1.07	-
	$f_{awf}$	(MHz)	6.65	6.65	-	6.65	-	6.65	-	
Dim of $A_{aprt}$	X (cm)		2.56	-	2.56	-	2.56	-		
	Y (cm)		0.35	-	0.35	-	0.35	-		
Other Information	<b>Mode Components</b>	rD	B+rD	-	B+rD	-	B+rD	-		
	$t_d$	( $\mu$ sec)	0.43							
	prr	(Hz)	9600							
	srr	(Hz)	15.8							
	$\eta_{pps}$		16							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	32.8							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	59.5							
	$p_r$ at $Z_{pii}$	(MPa)	0.76							
	$d_{eq}$ at $Z_{pii}$	(cm)					-			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	8.4							
	Focal Length	FLx (cm)	5.0		-		-			
		FLy (cm)	1.2		-		-			
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: B-Mode Frequency = 13.3 MHz, sector depth = 7.0 cm, focal depth = 5.0 cm, Color Doppler frequency = 6.6 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 15.8 Hz, Color ROI = 0.94 cm, Packet size = 16, transmit pulses = 3, PRF = 9600 Hz, Dual Beam on  
 Control 2: B-Mode Frequency = 13.3 MHz, sector depth = 4.0 cm, focal depth = 5.0 cm, Color Doppler frequency = 6.6 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 36.7 Hz, Color ROI = 2.56 cm, Packet size = 5, transmit pulses = 4, PRF = 21060 Hz, Dual Beam on  
 Control 3: B-Mode Frequency = 13.3 MHz, sector depth = 2.0 cm, focal depth = 5.0 cm, Color Doppler frequency = 6.6 MHz, Color Doppler focus = 5.0 cm, Frame Rate = 38.5 Hz, Color ROI = 2.56 cm, Packet size = 5, transmit pulses = 5, PRF = 22220 Hz, Dual Beam on

**Acoustic Output Reporting Table for Track 3 for the 16SL5 Probe  
(Terason uSmart3300 Ultrasound System in Ophthalmic PWD Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.19	0.14			0.23			0.21	
Index Component Value		0.19	-	0.14	0.13	-	0.14	0.23	-	0.21
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.48							
	P	(mW)		-	6.9	-	6.9	-	6.9	
	$P_{txt}$	(mW)		-	4.6	-	4.6			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			4.0					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						34.1		
	$Z_s$	(cm)			1.20					
	$Z_{bp}$	(cm)	1.20		1.20			1.20		
	$Z_b$	(cm)						1.20		
	$Z_{pii}$	(cm)	4.90		4.90			4.90		
	$Z_{MI}$	(cm)	1.10							
	$d_{eq}(Z_b)$	(cm)						0.38		
	$D_{eq}$	(cm)							-	0.82
	$f_{awf}$	(MHz)	6.65	-	6.65	-	6.65	-	6.65	
	Dim of $A_{aprt}$	X (cm)		-	1.50	-	1.50	-	1.50	
Y (cm)			-	0.35	-	0.35	-	0.35		
Other Information	<b>Mode Components</b>		D	-	D	-	D	-	D	
	$t_d$	( $\mu$ sec)	1.16							
	prr	(Hz)	3000							
	srr	(Hz)	-							
	$\eta_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	30.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	177.3							
	$p_r$ at $Z_{pii}$	(MPa)	0.79							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.22		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	8.8							
	Focal Length	FLx (cm)	5.0		5.0		5.0			
		FLy (cm)	1.2		1.2		1.2			
Operating Control Conditions	Control 1		X							
	Control 2			X		X		X		
	Control 3									

Control 1: Sector depth = 7.0 cm, Focus = 5.0 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 1.0 mm, SV Depth = 5.0 cm, PRF = 3000 Hz, Update = off

Control 2: Sector depth = 7.0 cm, Focus = 5.0 cm, B-Mode Frequency = 13.3 MHz, PWD Frequency = 6.6 MHz, SV Size = 1.5 mm, SV Depth = 5.0 cm, PRF = 2250 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the PDOF Probe  
(Terason uSmart3300 Ultrasound System in CWD Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.08	0.79			3.54			Note 1	
Index Component Value		0.08	-	0.79	0.78	-	0.79	3.54	-	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.11							
	P	(mW)		-	100.0	-	100.0		-	-
	$P_{txt}$	(mW)		-	83.4	-	83.4			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			81.9					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						417.7		
	$Z_s$	(cm)			1.45					
	$Z_{bp}$	(cm)	1.45		1.45			1.45		
	$Z_b$	(cm)						2.10		
	$Z_{pii}$	(cm)	2.75		2.75			2.75		
	$Z_{MI}$	(cm)	2.30							
	$d_{eq}(Z_b)$	(cm)						0.47		
	$D_{eq}$	(cm)							-	-
	$f_{awf}$	(MHz)	2.00	-	2.00	-	2.00		-	-
	Dim of $A_{aprt}$	X (cm)		-	0.69	-	0.69		-	-
Y (cm)			-	1.38	-	1.38		-	-	
<b>Mode Components</b>		cwD	-	cwD		-	cwD		-	-
Other Information	$t_d$	( $\mu$ sec)	-							
	prr	(Hz)	-							
	srr	(Hz)	-							
	$\eta_{pps}$		-							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	417.0							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	580.9							
	$p_r$ at $Z_{pii}$	(MPa)	0.13							
	$d_{eq}$ at $Z_{pii}$	(cm)						0.46		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	-							
	Focal Length	FLx (cm)	8.0		8.0			8.0		
		FLy (cm)	8.0		8.0			8.0		
Operating Control Conditions	Control 1		X	X		X				
	Control 2									
	Control 3									

NOTE 1: Information need not be provided regarding TIC for any probe ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Control 1: CWD Frequency = 2.0 MHz, SV Depth = 8.0 cm

**Acoustic Output Reporting Table for Track 3 for the XY Probe  
(Terason uSmart 3300 Ultrasound System in 2D Mode)**

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.38	0.64			0.64			1.94	
Index Component Value		1.38	0.64	-	-	0.64	-	-	1.94	-
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.89							
	P	(mW)		79.5	-	79.5	-		107.9	-
	$P_{txt}$	(mW)		44.2	-	44.2	-			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )						-		
	$Z_s$	(cm)			-					
	$Z_{bp}$	(cm)	3.0		-			-		
	$Z_b$	(cm)						-		
	$Z_{pii}$	(cm)	6.3		-			-		
	$Z_{MI}$	(cm)	6.1							
	$d_{eq}(Z_b)$	(cm)						-		
	$D_{eq}$	(cm)							1.39	-
	$f_{awf}$	(MHz)	1.88	3.03	-	3.03	-		1.74	-
Dim of $A_{aprt}$	X (cm)		0.84	-	0.84	-		0.84	-	
	Y (cm)		1.80	-	1.80	-		1.80	-	
<b>Mode Components</b>		B	B	-	B	-		B	-	
Other Information	$t_d$	( $\mu$ sec)	0.76							
	prr	(Hz)	150							
	srr	(Hz)	150							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	249.2							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	553.7							
	$p_r$ at $Z_{pii}$	(MPa)	2.76							
	$d_{eq}$ at $Z_{pii}$	(cm)						-		
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	281.1							
	Focal Length	FLx (cm)	7.0		-			-		
		FLy (cm)	7.5		-			-		
Operating Control Conditions	Control 1		X							
	Control 2			X		X				
	Control 3							X		

Control 1: Freq. = 1.88 MHz, sector depth = 17 cm, focus = 7.0 cm, 16 lines, focus # = 1

Control 2: Freq. = 3.19 MHz, sector depth = 6 cm, focus = 3.0 cm, 78 lines, focus # = 1

Control 3: Freq. = 1.71 MHz, sector depth = 12 cm, focus = 3.0 cm, 36 lines, focus # = 1

Acoustic Output Reporting Table for Track 3 for the XY Probe  
(Terason uSmart 3300 Ultrasound System in M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.38	0.65			1.12			1.95	
Index Component Value		1.38	0.60	0.04	0.05	0.30	0.08	0.82	1.74	0.22
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	1.89							
	P	(mW)		74.4	5.3	105.4	30.1	96.4	12.0	
	$P_{txt}$	(mW)		41.3	3.0	32.9	9.4			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			3.4					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					116.1			
	$z_s$	(cm)			2.1					
	$z_{bp}$	(cm)	3.0		2.1		3.0			
	$z_b$	(cm)					5.7			
	$Z_{pii}$	(cm)	6.3		2.3		6.3			
	$Z_{MI}$	(cm)	6.1							
	$d_{eq}(z_b)$	(cm)					0.30			
	$D_{eq}$	(cm)							1.39	1.39
	$f_{awf}$	(MHz)	1.88	3.03	3.03	1.88	1.88	1.74	1.74	
Dim of $A_{aprt}$	X (cm)		0.84	0.84	1.79	1.79	0.84	0.84		
	Y (cm)		1.80	1.80	1.80	1.80	1.80	1.80		
Other Information	<b>Mode Components</b>		B+M	B	M	B	M	B	M	
	$t_d$	( $\mu\text{sec}$ )	0.76							
	prr	(Hz)	430							
	srr	(Hz)	107.5							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	270.1							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	603.6							
	$\rho_r$ at $Z_{pii}$	(MPa)	2.76							
	$d_{eq}$ at $z_{pii}$	(cm)					0.38			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	281.1							
	Focal Length	FLx (cm)	7.0		3.0		7.0			
FLy (cm)		7.5		7.5		7.5				
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				
	Control 4							X		

Control 1: Freq. = 1.88 MHz, sector depth = 17 cm, focus = 7.0 cm, 16 lines, PRF = 430 Hz

Control 2: Freq. = 3.19 MHz, sector depth = 6 cm, focus = 3.0 cm, 56 lines, PRF = 570 Hz

Control 3: Freq. = 1.88 MHz, sector depth = 25 cm, focus = 7.0 cm, 14 lines, PRF = 570 Hz

Control 4: Freq. = 1.71 MHz, sector depth = 12 cm, focus = 3.0 cm, 96 lines, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the XY Probe  
(Terason uSmart 3300 Ultrasound System in Color M-Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		0.72	0.73			2.07			1.89	
Index Component Value		0.72	0.29	0.33	0.44	0.27	0.36	1.80	1.71	0.18
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.14							
	P	(mW)		51.2	57.5	45.6	62.8	94.9	10.0	
	$P_{txt}$	(mW)		25.6	28.7	22.8	31.4			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1cm^2$ ]	(mW)			38.6					
	$I_{spta}$ at $Z_b$	(mW/cm <sup>2</sup> )					212.8			
	$z_s$	(cm)			2.4					
	$z_{bp}$	(cm)	2.4		2.4		2.4			
	$z_b$	(cm)					3.0			
	$Z_{pii}$	(cm)	3.2		3.1		3.1			
	$Z_{MI}$	(cm)	3.1							
	$d_{eq}(z_b)$	(cm)					0.52			
	$D_{eq}$	(cm)							1.39	1.39
	$f_{awf}$	(MHz)	2.50	2.40	2.40	2.40	2.40	1.74	2.39	
Dim of $A_{aprt}$	X (cm)		1.12	1.12	1.12	1.12	0.84	0.84		
	Y (cm)		1.80	1.80	1.80	1.80	1.80	1.80		
Other Information	<b>Mode Components</b>		rD+cM	B+rD	M+cM	B+rD	M+cM	B+rD	M+cM	
	$t_d$	( $\mu$ sec)	2.27							
	prr	(Hz)	140							
	srr	(Hz)	28							
	$n_{pps}$		6							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	166.5							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	288.7							
	$p_r$ at $Z_{pii}$	(MPa)	1.47							
	$d_{eq}$ at $z_{pii}$	(cm)					0.51			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	59.2							
	Focal Length	FLx (cm)	4.0		4.0		4.0			
FLy (cm)		7.5		5.7		5.7				
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3					X				
	Control 4							X		

- Control 1: B-Mode Frequency = 3.75 MHz, sector depth = 13.0 cm, focal depth = 4.0 cm, Color Doppler frequency = 2.5 MHz, Color Doppler focus = 4.0 cm, Frame Rate = 28.0 Hz, Color ROI = 0.65 cm, Packet size = 6, transmit pulses = 5, PRF = 5090 Hz, Dual Beam on, Sweep Speed = 50 mm/s
- Control 2: B-Mode Frequency = 2.4 MHz, sector depth = 6.0 cm, focal depth = 4.0 cm, Color Doppler frequency = 2.4 MHz, Color Doppler focus = 4.0 cm, Frame Rate = 18.7 Hz, Color ROI = 1.15 cm, Packet size = 12, transmit pulses = 10, PRF = 8410 Hz, Dual Beam on, Sweep Speed = 150 mm/s
- Control 3: B-Mode Frequency = 2.4 MHz, sector depth = 6.0 cm, focal depth = 4.0 cm, Color Doppler frequency = 2.4 MHz, Color Doppler focus = 4.0 cm, Frame Rate = 22.6 Hz, Color ROI = 0.63 cm, Packet size = 14, transmit pulses = 10, PRF = 9180 Hz, Dual Beam on, Sweep Speed = 150 mm/s
- Control 4: B-Mode Frequency = 1.71 MHz, sector depth = 6.0 cm, focal depth = 3.0 cm, Color Doppler frequency = 2.4 MHz, Color Doppler focus = 3.0 cm, Frame Rate = 35.0 Hz, Color ROI = 0.44 cm, Packet size = 5, transmit pulses = 4, PRF = 7570 Hz, Dual Beam on, Sweep Speed = 50 mm/s

Acoustic Output Reporting Table for Track 3 for the XY Probe  
(Terason uSmart Ultrasound 3300 System in Color Mode)

Index Label			MI	TIS			TIB			TIC	
				Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value			0.72	0.62			0.62			1.94	
Index Component Value			0.72	0.62			0.62			1.94	
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	1.14								
	P	(mW)		108.8			108.8			107.4	
	$P_{txt}$	(mW)		54.4			54.4				
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				-					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )									
	$Z_s$	(cm)				-					
	$Z_{bp}$	(cm)	2.4								
	$Z_b$	(cm)									
	$Z_{pii}$	(cm)	3.2								
	$Z_{MI}$	(cm)	3.1								
	$d_{eq}(Z_b)$	(cm)									
	$D_{eq}$	(cm)								1.39	
	$f_{awf}$	(MHz)	2.50	2.40			2.40			1.74	
	Dim of $A_{aprt}$	X (cm)		1.12			1.12			0.84	
Y (cm)			1.80			1.80			1.80		
Other Information	<b>Mode Components</b>		rD	B+rD	-		B+rD	-		B+rD	-
	$t_d$	( $\mu$ sec)	2.27								
	prr	(Hz)	6000								
	srr	(Hz)	41.1								
	$n_{pps}$		6								
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	106.7								
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	183.9								
	$p_r$ at $Z_{pii}$	(MPa)	1.47								
	$d_{eq}$ at $Z_{pii}$	(cm)									
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	59.1								
	Focal Length	FLx (cm)	4.0								
		FLy (cm)	7.5								
Operating Control Conditions	Control 1		X								
	Control 2			X			X				
	Control 3								X		

Control 1: B-Mode Frequency = 3.75 MHz, sector depth = 10.0 cm, focal depth = 4.0 cm, Color Doppler frequency = 2.5 MHz, Color Doppler focus = 4.0 cm, Frame Rate = 41.1 Hz, Color ROI = 0.65 cm, Packet size = 6, transmit pulses = 5, PRF = 6000 Hz  
 Control 2: B-Mode Frequency = 2.4 MHz, sector depth = 6.0 cm, focal depth = 4.0 cm, Color Doppler frequency = 2.4 MHz, Color Doppler focus = 4.0 cm, Frame Rate = 14.2 Hz, Color ROI = 1.16 cm, Packet size = 14, transmit pulses = 10, PRF = 11700 Hz  
 Control 3: B-Mode Frequency = 1.71 MHz, sector depth = 6.0 cm, focal depth = 3.0 cm, Color Doppler frequency = 2.4 MHz, Color Doppler focus = 3.0 cm, Frame Rate = 30.3 Hz, Color ROI = 0.29 cm, Packet size = 4, transmit pulses = 5, PRF = 18490 Hz

Acoustic Output Reporting Table for Track 3 for the XY Probe  
(Terason uSmart 3300 Ultrasound System in CWD Mode)

Index Label			MI	TIS			TIB			TIC		
				Scan		Non-scan	Scan		Non-scan		Scan	Non-scan
				At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface	
Maximum Index Value			0.06	0.69			2.50			1.80		
Index Component Value			0.06	-	0.50	0.69	-	0.50	2.50	-	1.80	
Associated Acoustic Parameter	$p_{ra}$ at $Z_{MI}$	(MPa)	0.09									
	P	(mW)		-	94.7		-	94.7		-	94.7	
	$P_{txt}$	(mW)		-	52.6		-	52.6				
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)				72.4						
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )							233.4			
	$z_s$	(cm)				2.0						
	$z_{bp}$	(cm)	2.0			2.0			2.0			
	$z_b$	(cm)							2.5			
	$Z_{pii}$	(cm)	6.6			6.6			6.6			
	$Z_{MI}$	(cm)	2.5									
	$d_{eq}(z_b)$	(cm)							0.62			
	$D_{eq}$	(cm)								-	1.32	
	$f_{awf}$	(MHz)	1.99	-	1.99		-	1.99		-	1.99	
	Dim of $A_{aprt}$	X (cm)		-	0.76		-	0.76		-	0.76	
Y (cm)			-	1.80		-	1.80		-	1.80		
Other Information	<b>Mode Components</b>		cwD	-	cwD		-	cwD		-	cwD	
	$t_d$	(μsec)	-									
	prr	(Hz)	-									
	srr	(Hz)	-									
	$n_{pps}$		-									
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	233.8									
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	331.6									
	$p_r$ at $Z_{pii}$	(MPa)	0.11									
	$d_{eq}$ at $Z_{pii}$	(cm)							0.62			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	198.1									
	Focal Length	FLx (cm)	4.0			3.0			4.0			
FLy (cm)		7.5			7.5			7.5				
Operating Control Conditions	Control 1		X	X			X			X		
	Control 2											
	Control 3											

Control 1: CWD Frequency = 2.0 MHz, SV Depth = 4.0 cm, Update = off

Acoustic Output Reporting Table for Track 3 for the XY Probe  
(Terason uSmart 3300 Ultrasound System in PWD Mode)

Index Label		MI	TIS			TIB			TIC	
			Scan	Non-scan		Scan	Non-scan		Scan	Non-scan
			At Surface	At Surface	Below Surface	At Surface	At Surface	Below Surface	At Surface	At Surface
Maximum Index Value		1.29	0.78			2.77			1.90	
Index Component Value		1.29	-	0.40	0.78	-	0.52	2.77	1.75	0.15
Associated Acoustic Parameter	$\rho_{ra}$ at $Z_{MI}$	(MPa)	2.04							
	P	(mW)		-	111.9	-	91.7	97.1	8.3	
	$P_{txt}$	(mW)		-	35.0	-	45.9			
	Min of [ $P_{\alpha}(Z_s), I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$ ]	(mW)			68.2					
	$I_{spta, a}$ at $Z_b$	(mW/cm <sup>2</sup> )					343.0			
	$z_s$	(cm)			3.0					
	$z_{bp}$	(cm)	2.4		3.0		2.4			
	$z_b$	(cm)					3.0			
	$Z_{pii}$	(cm)	3.2		6.5		3.1			
	$Z_{MI}$	(cm)	3.1							
	$d_{eq}(z_b)$	(cm)					0.45			
	$D_{eq}$	(cm)						1.39	1.39	
	$f_{awf}$	(MHz)	2.50	-	2.39	-	2.40	1.74	2.39	
Dim of $A_{aprt}$	X (cm)		-	1.79	-	1.12	0.84	0.84		
	Y (cm)		-	1.80	-	1.80	1.80	1.80		
Other Information	Mode Components		D	-	D	-	D	B	D	
	$t_d$	( $\mu\text{sec}$ )	3.02							
	prr	(Hz)	600							
	srr	(Hz)	-							
	$n_{pps}$		1							
	$I_{spta, a}$ @ $Z_{pii, a}$ or $Z_{sii, a}$	(mW/cm <sup>2</sup> )	359.2							
	$I_{spta}$ @ $Z_{pii}$ or $Z_{sii}$	(mW/cm <sup>2</sup> )	625.8							
	$\rho_r$ at $Z_{pii}$	(MPa)	2.63							
	$d_{eq}$ at $z_{pii}$	(cm)					0.45			
	$I_{pa, a}$ at $Z_{pii, a}$	(W/cm <sup>2</sup> )	198.1							
	Focal Length	FLx (cm)	4.0		7.0		4.0			
FLy (cm)		7.5		7.5		7.5				
Operating Control Conditions	Control 1		X							
	Control 2			X						
	Control 3				X					
	Control 4						X			

Control 1: Sector depth = 17.0 cm, Focus = 7.0 cm, B-Mode Frequency = 3.75 MHz, PWD Frequency = 2.5 MHz, SV Size = 2.5 mm, SV Depth = 4.0 cm, PRF = 600 Hz, Update = off  
 Control 2: Sector depth = 17.0 cm, Focus = 7.0 cm, B-Mode Frequency = 2.4 MHz, PWD Frequency = 2.4 MHz, SV Size = 10.5 mm, SV Depth = 7.0 cm, PRF = 900 Hz, Update = off  
 Control 3: Sector depth = 17.0 cm, Focus = 7.0 cm, B-Mode Frequency = 3.0 MHz, PWD Frequency = 2.4 MHz, SV Size = 14.0 mm, SV Depth = 4.0 cm, PRF = 450 Hz, Update = off  
 Control 4: Sector depth = 6.0 cm, Focus = 3.0 cm, B-Mode Frequency = 1.71 MHz, B-Mode lines = 192, PWD Frequency = 2.4 MHz, SV Size = 0.5 mm, SV Depth = 3.0 cm, PRF = 200 Hz, Update = on

## 4 System Safety

To use the Terason Ultrasound System successfully and safely, Terason provides the following information:

- [Infection Control](#) on page 134
- [Safety Cautions and Warnings](#) on page 136
- [Labels](#) on page 146
- [Safety Standards](#), see page 149
- [Indications For Use](#), see page 151
- [Acoustic Output Indices](#), see page 174
- [Relationship of Index to Display Accuracy](#), see page 182
- [Acoustic Output Tables](#), see page 185
- [Accuracy Measures](#), see page 186
- [Compliance and Approvals](#), see page 188
- [Environmental Protection](#), see page 188

### Infection Control

Proper infection control procedures are essential for preventing the spread of disease between patients. This section contains information on the following related topics:

- [Sterile Probe Covers](#) on page 134
- [Disinfection](#) on page 135

### Sterile Probe Covers

When performing intraoperative studies or scanning patients with open wounds, you must use a sterile sheath on the probe.

The following table lists the appropriate sheath for each Terason probe:

**Sterile Probe Sheaths**

Probe	Sheath
4V2A	Civco # 610-044
5C2A	Civco # 610-044
8BP4	Civco # 610-006
8EC4A	Civco # 610-006
8L2	Civco # 610-044
8V3A	Civco # 610-044
9MC3	Civco # 610-002

## Sterile Probe Sheaths (Continued)

Probe	Sheath
10BP4	Civco # 610-006
10EC4	Civco # 610-006
12L5A	Civco # 610-044
14L3	Civco # 610-044
15L4	Civco # 610-044
15L4A	Civco # 610-044
15WL4	Civco # 610-637
16HL7	Civco # 610-797
16L5	Civco # 610-044
16SL5	Civco # 610-044
PDOF	Refer to the <a href="#">Civco Website</a>
XY	Civco # 610-044



**Caution:** When installing a sheath on a probe, always follow the sheath manufacturer's instructions.

## Disinfection

It is very important that appropriate infection-prevention measures are taken. The type of use a probe is put to determines what level of disinfection should be used. See [Noncritical Device Applications](#) on page 13 and [Semicritical Device Applications](#) on page 15 for disinfection procedures.



**Warning:** System operators must take measures to prevent the transfer of infection between persons.



**Warning:** Special infection-control precautions must be taken when scanning patients with open wounds.



**Warning:** Probes must be enclosed in a sterile sheath during intraoperative studies. See [Sterile Probe Covers](#) on page 134 for recommended sterile covers for each type of probe. Follow the manufacturer's instructions for use of sheaths.



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**Warning:** To prevent cross-contamination and transmission of infectious disease, high-level disinfection of probes is required after scanning patients with open wounds. High-level disinfection is required even if a sterile sheath is used during the study.

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**Warning:** Operators should identify their latex-sensitive patients, and be prepared to treat allergic reactions promptly. Refer to the FDA's March 29, 1991 Medical Alert on Latex products.

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For an overview of infection control, refer to the following publication:

Block, S.S., *Disinfection, Sterilization, and Preservation*, Chemical Disinfection of Medical and Surgical Materials, Chapter 35, Lea & Febiger, Philadelphia, 1991.

## Safety Cautions and Warnings

### Cautions

Closely review the following cautions before using the Terason Ultrasound System for the first time.

### Sale and Use

The Terason Ultrasound System is designed for medical ultrasound imaging. Federal law restricts this device to sale by or on the order of a physician. The Terason system should only be used in a medical facility under the supervision of a trained physician.



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**Caution:** Do not use the Terason Ultrasound System during an MRI exam, when using a defibrillator, or near other strong sources of EMI.

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### Terason Probes

Each probe model has indications for use (see [Indications For Use](#) on page 151) concerning specific applications.

### Ultrasound System

Always position the ultrasound system on a stable surface where it cannot fall on the patient.



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**Warning:** To prevent patient injury or equipment damage, do not lift the ultrasound system by the power cable or probe. If either disconnects, the ultrasound system could fall on the patient.

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**Caution:** To prevent system overheating, do not block or obstruct any cooling vents or openings in the system case.

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### Allergies

Metals used in some of the decorative exterior plates may contain nickel. If persons using the system are allergic to nickel, avoid handling the exterior decorative metal.

### System Covers

Do not remove any system covers or cables. Only qualified Terason personnel should service the Terason Ultrasound System.



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**Warning:** Do not open any part of the system, or remove any screws or covers, or modify the Terason Ultrasound System, probes, or power supplies in any way. Modifying the system can produce hazardous conditions. If any part of the system is modified or tampered with, contact Terason Support immediately and do not use the system.

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### Electrical Shock Hazard

Probe cables have strain relief at terminations. Inspect cables regularly, to detect damaged, frayed, or broken cables that might contact a patient.



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**Warning:** To avoid the risk of electric shock, this equipment must only be connected to supply mains that incorporate protective earth.

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**Caution:** Do not use a probe if the probe or cable is damaged. Return damaged equipment to Terason for replacement. See “Contacting Terason” in Volume 1 of the *User Guide* for instructions on contacting Terason Support.

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Shock hazards exist if the AC power adapter is damaged or is not properly grounded. Use only the supplied medical grade power cord and power adapter, and connect the adapter only to a receptacle marked “Hospital Only”, “Hospital Grade,” or equivalent.



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**Caution:** Do not remove or try to circumvent the grounding wire. If the protective grounding of the system is questionable, disconnect the ultrasound system from the power source and run it on its internal battery.

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**Warning:** If the ultrasound system is purchased with the cart and printer option, an integrated multiple-outlet power strip (MSO) is mounted on the cart for connecting the ultrasound system and the printer to an AC wall outlet. Connecting equipment to an MSO creates an ME system, and may produce a reduced level of safety.

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**Warning:** To avoid the risks of electric shock and circuit overload, never exceed the maximum load rating of 12 A at 50/60 Hz for the ultrasound cart power strip.

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**Warning:** To avoid the risks of electric shock and circuit overload, never connect any type of multiple-outlet power cord or connector to the ultrasound cart power strip.

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Before cleaning the system, always disconnect the AC power adapter from the system.

The Terason Ultrasound System is a Type BF Class I product suitable for continuous operation when connected as a system to a Medical Grade AC/DC Power Adapter or operated from the ultrasound system battery.



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**Caution:** Use only Medical-Grade peripherals in the patient environment. See [Patient Environment](#) on page 144 for a diagram of the patient environment.

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**Caution:** Failure to follow the warnings in this guide may cause the system to no longer comply with regulatory requirements.

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**Caution:** Do not block or otherwise obstruct access to the power plug at the wall. operators must have must be able to quickly unplug the AC cord at the wall in case of emergency.

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### **Electrical Fast Transients (EFT)**

The Terason ultrasound system complies with the IEC 60601-1-2:2001 standard for susceptibility to electrical fast transients (EFT) on the power line (see Chapter 6, [Electromagnetic Tables](#), on page 195 for specific test and compliance levels). However, if

the ultrasound system experiences EFT on the power line, artifacts (vertical lines, excessive noise in image, etc.) may appear on the ultrasound image. To eliminate these artifacts caused by an EFT condition the user should either:

- Remove the power source by unplugging the DC power cord from the ultrasound system, causing the system to run on battery power.

or

- Unplug the AC power cord from the wall and move to a different AC power source that is not experiencing this condition.

### Surges to AC Power Mains

If the system is powered from AC mains that could experience surges above 1 CV (for example, from extreme lightning conditions), additional surge suppression is recommended.

### RF Interference

The unit should be operated in a location that is no closer than listed in [Non-Life-Supporting Equipment](#) on page 198 to any part of RF communications equipment that may disturb its functions. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment. The Terason Ultrasound System should be separated by at least the distances specified in the table referenced above.

The Terason Ultrasound System is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or the user of the Terason Ultrasound System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Terason Ultrasound System according to the maximum output power of the communications equipment. See Chapter 6, [Electromagnetic Tables](#), on page 195 for recommended separation distances.

### Protection From Liquid Spills, etc.

This equipment has a degree of protection from ingress of water and particulate matter, but the system is not approved for use where it would be exposed to liquids. If it is used in environments where it might be exposed to liquids, the system must be covered by a drape, such as a Civco #610-1037. These environments include, but are not limited to outpatient and private office procedures such as biopsies, office visits, and other traditional, non-invasive scanning.

The following table lists the applied parts and their levels of protection.

#### Spill Protection of System and Non-Applied Parts

Component	Manufacturer	Mfr. Part No.	Use	IPX Level <sup>1</sup>
Ultrasound system	Terason	10-3821-01	Ultrasound system	IPX-0 <sup>3</sup>
DC power adapter	Protek	PMP120-13-2	Power source and battery charger for ultrasound system	IPX-0 <sup>3</sup>

**Spill Protection of System and Non-Applied Parts**

Component	Manufacturer	Mfr. Part No.	Use	IPX Level <sup>1</sup>
Power supply cord - North America	Interpower	86610820	AC line cord	IPX-0
Power supply cord - Europe	Interpower	86230060	AC line cord	IPX-0
Footswitch	Kinessis	FS20A-USB-UL	Footswitch programmed for image freeze and image save	IPX-1
Printer	Sony	UP-D897	B/W thermal printer	IPX-0
Cart	Terason	15-30083	Cart for ultrasound system	N/A

1. IPX-0 = No protection  
 IPX-1 = Protection against dripping water  
 IPX-7 = Protection against immersion

The following table lists the applied parts and their levels of protection.

**Spill Protection of Applied Parts**

Component	Manufacturer	Mfr. Part No.	Use	IPX Level <sup>1</sup>
Ultrasound system	Terason	10-3360	Ultrasound system	IPX-0 <sup>3</sup>
4V2A probe	Terason	10-3216	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
5C2A probe	Terason	10-3278	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
8BP4 probe	Terason	10-3075	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
8EC4A probe	Terason	10-3374	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
8L2 probe	Terason	10-3593	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
8TE3 probe	Terason	10-3283	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
8V3A probe	Terason	10-3319	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
9MC3	Terason	10-3255	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>

## Spill Protection of Applied Parts (Continued)

Component	Manufacturer	Mfr. Part No.	Use	IPX Level <sup>1</sup>
10BP4 probe	Terason	10-3818	Ultrasound probe	IPX-7 <sup>3</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
10EC4	Terason	10-3514	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
12L5A probe	Terason	10-3276	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
14L3	Terason	10-3397	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
15L4 probe	Terason	10-3512	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
15L4A probe	Terason	10-3512	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
15WL4 probe	Terason	10-3390	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
16HL7 probe	Terason	10-3599	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
16L5	Terason	10-3389	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
16SL5 probe	Terason	10-3595	Ultrasound probe	IPX-7 <sup>4</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
PDOF probe	Terason	10-3282	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
XY probe	Terason	10-3393	Ultrasound probe	IPX-7 <sup>2</sup> (at probe head); IPX-0 for connector. See Chapter 2 - <a href="#">Maintenance</a>
DC power adapter	Sinpro	15-33101	Power source and battery charger for ultrasound system	IPX-0
Power supply cord	Webber Electronics	6-2054	AC line cord	IPX-0
ECG module	Terason	10-3306	3-lead ECG module to connect to ultrasound system	IPX-0

1. IPX-0 = No protection  
IPX-1 = Protection against dripping water  
IPX-7 = Protection against immersion
2. Refer to Chapter 2 - [Maintenance](#) for detailed description of how much of the probe can be immersed during cleaning.
3. A drape is available (Civco #610-1037) to protect the computer screen and underlying electronics.
3. Refer to Chapter 2 - [Maintenance](#) for detailed description of how much of the probe can be immersed during cleaning.
3. A drape is available (Civco #610-1037) to protect the computer screen and underlying electronics.
4. Refer to Chapter 2 - [Maintenance](#) for detailed description of how much of the probe can be immersed during cleaning.
3. A drape is available (Civco #610-1037) to protect the computer screen and underlying electronics.

### Explosive

This equipment is not suitable for use in the presence of FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.



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**Caution:** Do not use the Terason Ultrasound System in an oxygen-rich environment. Do not use the Terason Ultrasound System if flammable anesthetics are in use in the patient environment.

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### Battery Pack Usage/Disposal

Lithium-ion battery packs are labeled with cautions indicating that the device could present a fire or chemical burn hazard if mistreated.



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**Caution:** Do not disassemble, heat above 60°C (140°F), crush, puncture, short external contacts, or incinerate the battery pack.

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**Caution:** Keep the battery pack away from children. Dispose of used battery packs according to the manufacturer's instructions.

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### Recycling/Disposal After Useful Life

This equipment can contain environmentally hazardous materials such as, but not limited to: heavy metals, general recyclable metals, and plastics. This product should be recycled according to local and national guidelines for recycling electronic equipment.

### Warnings

Observe the following safety precautions when using the Terason Ultrasound System.

## Intended Use

The Terason Ultrasound System is designed for use as a diagnostic tool and should only be operated by someone who has received proper training in the use and operation of an ultrasound system. This system produces images derived from sound echoes; those images must be interpreted by a qualified medical professional. This system in no way interprets these images or provides a medical diagnosis of the patient being examined.

The Terason Ultrasound System has successfully completed compliance tests for IEC 60601-1, IEC 60601-1-1 2nd edition, IEC 60601-1-2, and IEC 60601-2-37 medical standards for the configuration as originally installed. To maintain compliance with the stated safety and EMI standards, Terason recommends use of MEDICAL GRADE PERIPHERALS ONLY. Use of non-medical grade peripherals will result in non-compliance of safety and EMI standards. Non-conformance to these standards can produce risks to the patient and operator of this equipment. Terason cannot be held liable for changes to the system topology that no longer conform to the stated safety and EMI standards. Changes to the system topology may make it necessary to retest the complete system for compliance to these standards. The *Terason Ultrasound System User Guide* refers to the potential for connecting the Terason Ultrasound System to peripherals such as VCRs, TVs, and printers. Note that Terason has not performed compliance tests to the stated standards with these types of devices connected to the system. Any peripheral device, such as a network connection, etc. connected to the Terason Ultrasound System must conform to the IEC standards outlined above (i.e., IEC 60601-1, IEC 60601-1-1 2nd edition, IEC 60601-1-2, and IEC 60601-2-37).

During scanning, the patient is typically lying on an exam table with the ultrasound technician sitting or standing to one side. There are usually no other persons in the exam room.

The Terason Ultrasound System (without peripherals) is suitable for use within the patient environment, as defined by the following:

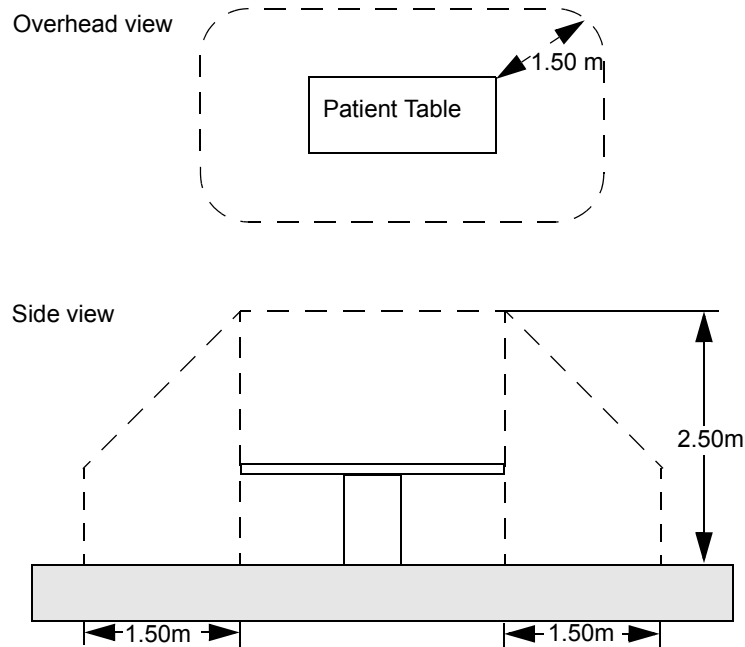


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**Warning:** The user should never simultaneously make contact with the patient and the inside of any equipment where a protective cover of any kind is removed. This includes the protective covers for the probe holders containing the ultrasound probe and power modules located at the patient table.

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The patient environment is defined as shown in the following figure.



#### Patient Environment

Portable and mobile RF communications equipment can affect medical electrical equipment such as the Terason Ultrasound System and should not be used in the patient environment.



**Caution:** The Terason Ultrasound System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the system should be observed to verify normal operation in the configuration in which it will be used.

#### Electromagnetic Interference (EMI)



**Note:** The Terason Ultrasound System is suitable for use in hospital environments. If it is used in a residential environment, the system may not provide adequate protection of radio-frequency communications, and may require mitigation measures such as relocating or reorienting the equipment.

Medical electrical equipment such as the Terason Ultrasound System requires special precautions regarding electromagnetic compatibility, and must be installed and put into service according to the tables in Chapter 6, [Electromagnetic Tables](#), on page 195.

To limit exposure to electromagnetic interference from nearby equipment that can degrade image quality, you should operate the Terason Ultrasound System under EMI conditions that minimize power supply transients, mechanical interactions, vibration, and thermal, optical, and ionizing radiation.

### **Isolating From Power Mains**

To isolate the ultrasound system from AC mains, disconnect either end of the AC power cord. Make sure one end of the power cord is always easily accessible.

### **Electrostatic Discharge (ESD)**

ESD, or static shock, is caused by rapid discharge of electrical energy from one body to another. ESD is common in conditions of low humidity, such as those resulting from heating or air conditioning. To avoid damage to probes, electronics, or system, use anti-static spray on carpets and linoleum, and anti-static mats.

The Terason Ultrasound System complies to a level of  $\pm 15$  kV ESD. When ESD shock discharges to a sensitive point on the system, the computer program may freeze, or windows may not respond. If this happens, the Terason software may require restarting. In extreme cases, the computer system may require restarting (reboot). These events are not dangerous to the patient or to the operator. There is no added risk of electric shock.

### **Liquids**

The Terason probe, electronics envelope, and computer are not protected from spilled liquids. The probe array is watertight up to the strain relief, as specified in [Cleaning and Disinfecting Terason Probes](#) on page 13. If the computer is exposed to liquids or moisture, purchase a keyboard drape. In addition, the Terason Ultrasound System electronics must be draped if exposed to liquids or moisture.

### **Couplants**

Use only couplants specifically designed for ultrasound examinations. Do not use mineral-oil or vegetable-based couplants, which can damage probes.

The following ultrasound gels are approved for use with Terason probes:

- Aquagel
- Aquasonic 100
- Aquasonic Clear
- Clear Image
- Clear Wave
- Scan
- Ultraphonic

### **Heat**

Do not expose probes to direct heat such as strong sunlight or local heat sources. Heat ages the crystal and causes loss of sensitivity.

### **Latex**

Terason strongly recommends that health-care professionals identify their latex-sensitive patients, and refer to the FDA's March 29, 1991 Medical Alert on Latex products. Be prepared to treat allergic reactions promptly.

### Care

Ultrasound probes and your Terason Ultrasound System are fragile. Handle with care. If the probe appears damaged, or misuse of the electronics envelope causes a malfunction, please return the equipment to Terason for service or replacement.



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**Warning:** Do not drop the ultrasound probe! If you accidentally drop the probe, check it carefully for damage. Perform a sample scan to make sure it operates correctly. If not, contact Terason for service or replacement.

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### Immersion

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

### HF (High Frequency) Surgical Equipment



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**Warning:** The Terason Ultrasound System is not approved for use with HF surgical equipment. Use of the Terason Ultrasound System in HF surgical procedures could result in failure of the electrical isolation, resulting in injury or death.

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### Ophthalmic Use



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**Warning:** To avoid injury, make sure the Ocular preset is selected before beginning any scan of the eye. The FDA has established lower acoustic energy limits for ophthalmic use, and if the Ocular preset is selected, the system will not exceed those limits.

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## Labels

Several labels are attached to the Terason system. The following sections describe what each label means.

## System Label Icons

### Manufacturer Mark



Manufacturer -- Terason manufactures the Terason Ultrasound System.

### Type BF Equipment Applied Part



The Terason Ultrasound System provides protection against electric shock. It is a Type BF applied part that has a lower leakage current than for non-BF applied parts.

### Double Insulated



This device is Class II (double insulated).

### Indoor Use Only



This device is intended for indoor use only.

### CE Mark



The Terason Ultrasound System conforms to all applicable European Directives - specifically, the Council Directive Concerning Medical Devices 93/42/EEC. The number adjacent to the CE marking (0413) is the number of the EU-notified body that certified meeting the requirements of Annex II of the Directive.

### U.S. and Canada Safety Standards



This certification mark indicates that the Terason Ultrasound System has been tested to and meets the minimum requirements of widely recognized U.S. and Canadian product safety standards. It also means that the manufacturing site has been audited, and that Terason has agreed to a program of periodic factory follow-up inspections to verify continued conformance.

### See User Guide



This label indicates that the user should refer to the User Guide for information on using this equipment.

## Dispose of Properly



Do not dispose of by dumping in garbage. Use a separate collection for electrical and electronic equipment.

Products bearing this symbol are subject to the European Community directive 2002/96/EC on waste electrical and electronic equipment (WEEE), amended by directive 2003/108/EC.

## EC Representative



Wellkang Tech Consulting  
Suite B 29 Harley Street  
London W1G9QR  
England, United Kingdom

## Alternating Current



This symbol indicates that the associated value is alternating current.

## Direct Current



This symbol indicates that the associated value is direct current.

## Radiation



This symbol indicates that the device emits non-ionizing radiation..

## Electrostatic Discharge

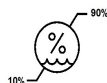


This symbol indicates that ESD-prevention procedures should be implemented. Pins of connectors marked with the symbol must not be touched, and connections require special precautions.

## Shipping Label Icons

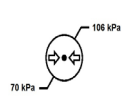
The following symbols appear on the shipping label.

### Environmental



The Terason Ultrasound System must be stored in the original shipping container in environments with 10% to 90% relative humidity non-condensing.

## Air Pressure



The Terason Ultrasound System must be stored in the original shipping container in environments between 70 kPa and 106 kPa (525 and 795 mm/Hg) air pressure.

## Temperature



The Terason Ultrasound System must be stored in the original shipping container in environments between  $-10^{\circ}$  and  $60^{\circ}$  C ( $14^{\circ}$  and  $140^{\circ}$ F).

## Terason Probes

Each Terason probe has a label that indicates its model and serial numbers: The following figure is an example of a probe label.



Example Probe Label

## Safety Standards

According to the American Institute of Ultrasound in Medicine (AIUM) *Official Statement of the Clinical Safety of Diagnostic Ultrasound* (March 1993):

Diagnostic ultrasound has been in use since the late 1950s. Given its known benefits and recognized efficacy for medical diagnosis, including use during human pregnancy, the American Institute of Ultrasound in Medicine herein addresses the clinical safety of such use: No confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. Although the possibility exists that such biological effects may be identified in the future, current data indicate that the benefits to patients of the prudent use of diagnostic ultrasound outweigh the risks, if any, that may be present.

This section addresses the following topics:

- [Ultrasound Safety](#), see page 149
- [Electrical Safety](#), see page 150
- [Surface Heating of Invasive Probes](#), see page 150

## Ultrasound Safety

The following is a Prudent Use Statement regarding the use of ultrasound:

Use diagnostic ultrasound only when there is a good medical reason. Also, the Terason Ultrasound System does not provide explicit control of acoustic power output. Therefore, to minimize the exposure to ultrasound energy, limit the duration of ultrasound examinations.

## Electrical Safety

The Terason Ultrasound System conforms to the UL 60601-1 electrical safety standard.

Each probe is insulated from the patient to minimize patient exposure in the presence of a system fault or a fault in other patient-connected equipment. The type of protection against electric shock is Class I. The degree of protection is Type BF, per safety standard IEC 60601-1.

To maintain compliance with electrical safety and emissions standards, the Terason Ultrasound System must be used *only* with the supplied Medical Grade Power Adapters.

## Surface Heating of Invasive Probes

The average and peak radiated acoustic powers of all Terason probes are limited by detection circuitry, to insure that the surface heating of the probe array is less than 43°C.

To limit the average acoustic power output, the maximum pulse repetition frequency (PRF) is tested in hardware by comparing a PRF counter to a preset value. Exceeding the maximum allowable PRF triggers an error message that displays on the host computer, and the Terason Ultrasound System acoustic output is disabled. The preset maximum PRF is chosen to limit the probe case temperature to less than 43°C when the probe is touching a patient.

The peak acoustic power is constrained by the maximum voltage applied to the probe-array elements. In hardware, peak power is monitored by a watchdog device that measures instantaneous power and compares it to two thresholds. The first threshold is a non-programmable four-watt limit. The second threshold is a programmable limit that Terason has set in accordance with IEC 60601-2-37.

## Surface Heating and the 8TE3 TEE probe

The 8TE3 TEE probe has a thermocouple inside it, attached to the back of the element array. The thermocouple monitors the temperature of the lens. The temperature measured by the thermocouple displays continuously on the right side of the imaging window. Accuracy of the temperature display is within  $\pm 10\%$  of the actual lens temperature.

If the temperature of the lens exceeds 41°C, a flashing yellow box surrounds the displayed temperature, warning the operator that the temperature of the probe lens is approaching the maximum temperature of 43°C. This gives the operator an opportunity to adjust the ultrasound system to a cooler setting (refer to Chapter 5 - [Working With Scan Modes](#)), or to freeze the image for a time, to allow the lens to cool.

If the displayed temperature exceeds 43°C, the ultrasound system automatically stops transmitting, resulting in a blank image. A flashing red box surrounds the displayed temperature, to indicate that the probe is no longer imaging. This allows the lens to cool and prevents burning the patient. To prevent the probe from turning on and immediately turning off again, the ultrasound system stops ultrasound transmission until the displayed

temperature falls below 41.5 °C. During this period, a flashing red box surrounds the displayed temperature, to indicate that the probe is not imaging. When the ultrasound system resumes imaging, a flashing yellow box surrounds the displayed temperature until the temperature either falls below 41°C or exceeds 43°C.

## Indications For Use

This section provides Diagnostic Ultrasound Indications for Use forms for the probes offered with the Terason ultrasound system.

The Terason Ultrasound System is a general-purpose imaging system intended for use by qualified physicians for analysis by ultrasound imaging or fluid-flow of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Intra-Operative (abdominal, organs and vascular), Pediatrics, Small Organ (Thyroid, Breast, Testes); Neonatal and Adult Cephalic; Trans-rectal, Trans-vaginal, Musculo-skeletal (Conventional and Superficial); Cardiac (Adult & Pediatric); Peripheral Vascular, and Ophthalmic.

## Essential Performance

The essential performance of the Terason system is to produce ultrasound energy, capture and interpret reflections of that energy, and display the results on a screen. The system operates in several modes, and has safety systems that prevent excessive levels of energy emission.



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**Caution:** The Terason Ultrasound System is for prescription use only.

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**Caution:** Federal law restricts this device to sale by or on the order of a physician. The Terason system should only be used in a medical facility under the supervision of a trained physician.

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**Caution:** Do not use the Terason Ultrasound System during an MRI exam, when using a defibrillator, or near other strong sources of EMI.

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**Warning:** To avoid injury, make sure the Ocular preset is selected before beginning any scan of the eye. The FDA has established lower acoustic energy limits for ophthalmic use, and if the Ocular preset is selected, the system will not exceed those limits.

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The first table provides indications for use for the system. The remaining tables list the indications for use for the following:

- Ultrasound system
- 4V2A probe
- 5C2A probe
- 8BP4 probe
- 8EC4A probe
- 8L2 probe
- 8TE3 probe
- 8V3A probe
- 9MC3 probe
- 10BP4 probe
- 10EC4 probe
- 12L5A probe
- 14L3 probe
- 15L4 probe
- 15L4A probe
- 15WL4 probe
- 16HL7 probe
- 16L5 probe
- 16SL5 probe
- PDOF probe
- XY probe

## Indications for use - Diagnostic Ultrasound System

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason uSmart3300 Ultrasound System								
Probe: See Comments								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	Ophthalmic	X	X	X		X	X	X
<b>Fetal Imaging and Other</b>	Fetal	X	X	X	X	X	X	X
	Abdominal	X	X	X	X	X	X	X
	Intra-operative (Spec.)	X	X	X		X	X	X
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric <sup>d</sup>	X	X	X	X	X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic	X	X	X	X	X	X	X
	Adult Cephalic	X	X	X	X	X	X	X
	Trans-rectal	X	X	X		X	X	X
	Trans-vaginal	X	X	X		X	X	X
	Trans-urethral							
	Trans-esoph. (non-Cardiac)	X	X	X	X	X	X	X
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult	X	X	X	X	X	X	X
	Cardiac Pediatric	X	X	X	X	X	X	X
	Trans-esoph. (Cardiac)	X	X	X	X	X	X	X
	Other (specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (specify)							

## Indications for Use - 4V2A probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 4V2A								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal	X	X	X	X	X	X	X
	Abdominal	X	X	X	X	X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X	X	X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	X	X	X	X	X	X	X
	Adult Cephalic	X	X	X	X	X	X	X
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other (Specify)								
Cardiac	Cardiac Adult	X	X	X	X	X	X	X
	Cardiac Pediatric	X	X	X	X	X	X	X
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

## Indications for Use - 5C2A Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 5C2A								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	Ophthalmic							
<b>Fetal Imaging and Other</b>	Fetal	X	X	X		X	X	X
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

Indications for Use - 8BP4 probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason 8BP4								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>							
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	X	X	X		X	X	X
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel							
	Other (Specify)							

## Indications for Use - 8EC4A Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM									
System: Terason Ultrasound System									
Probe: 8EC4A									
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other	
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	X	X	X		X	X	X	
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Thyroid, Breast, Testes, etc.)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		X	X	X		X	X	X
	Trans-vaginal		X	X	X		X	X	X
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Conventional)								
	Musculo-skel. (Superficial)								
Intra-luminal									
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esoph. (Cardiac)								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

## Indications for Use - 8L2 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM									
System: Terason Ultrasound System									
Probe: 8L2									
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other	
<b>Ophthalmic</b>	Ophthalmic								
<b>Fetal Imaging and Other</b>	Fetal								
	Abdominal	X	X	X		X	X	X	
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	X	X	X		X	X	X	
	Small Organ (Thyroid, Breast, Testes, etc.)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Conventional)		X	X	X		X	X	X
	Musculo-skel. (Superficial)		X	X	X		X	X	X
	Intra-luminal								
Other (Specify)									
<b>Cardiac</b>	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esoph. (Cardiac)								
	Other (Specify)								
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X	
	Other (Specify)								

## Indications for Use - 8TE3 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM									
System: Terason Ultrasound System									
Probe: 8TE3									
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp <sup>a</sup>	Comb. Modes <sup>b</sup>	Other <sup>c</sup>	
<b>Ophthalmic</b>	<b>Ophthalmic</b>								
<b>Fetal Imaging and Other</b>	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Thyroid, Breast, Testes, etc.)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Cardiac)		X	X	X	X	X	X	X
	Musculo-skel. (Conventional)								
	Musculo-skel. (Superficial)								
Intra-luminal									
Other (Specify)									
<b>Cardiac</b>	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esoph. (Cardiac)		X	X	X	X	X	X	
	Other (Specify)								
<b>Peripheral Vessel</b>	Peripheral vessel								
	Other (Specify)								

## Indications for Use - 8V3A probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
probe: 8V3A								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal	X	X	X	X	X	X	X
	Abdominal	X	X	X	X	X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X	X	X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	X	X	X	X	X	X	X
	Adult Cephalic	X	X	X	X	X	X	X
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other (Specify)								
Cardiac	Cardiac Adult	X	X	X	X	X	X	X
	Cardiac Pediatric	X	X	X	X	X	X	X
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

## Indications for Use - 9MC3 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason uSmart3300 Ultrasound System								
Probe: 9MC3								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>							
<b>Fetal Imaging and Other</b>	Fetal	X	X	X		X	X	X
	Abdominal							
	Intra-operative							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic	X	X	X		X	X	X
	Adult Cephalic	X	X	X		X	X	X
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other (specify)								
<b>Cardiac</b>	Cardiac Adult	X	X	X		X	X	X
	Cardiac Pediatric	X	X	X		X	X	X
	Trans-esoph. (Cardiac)							
	Other (specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (specify)							

Indications for Use-10BP4 Transducer

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason 10BP4								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>							
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	X	X			X		X
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel							
	Other (Specify)							

## Indications for Use - 10EC4 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM									
System: Terason Ultrasound System									
Probe: 10EC4									
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other	
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	X	X	X		X	X	X	
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Thyroid, Breast, Testes, etc.)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		X	X	X		X	X	X
	Trans-vaginal		X	X	X		X	X	X
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Conventional)								
	Musculo-skel. (Superficial)								
Intra-luminal									
Other (Specify)									
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esoph. (Cardiac)								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Specify)								

## Indications for Use - 12L5A Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason uSmart3300 Ultrasound System								
Probe: 12L5A								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
Ophthalmic	Ophthalmic	X	X	X		X	X	
Fetal Imaging and Other	Fetal							
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use - 14L3 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 14L3								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>	X	X	X		X	X	X
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use - 15L4 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 15L4								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>	X	X	X		X	X	X
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use - 15L4A Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 15L4A								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>	X	X	X		X	X	X
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use - 15WL4 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 15WL4								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal							
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use - 16HL7 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 16HL7								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>							
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal							
	Intra-operative (Specify)	X	X	X		X	X	X
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use -16SL5 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 16SL5								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
<b>Ophthalmic</b>	<b>Ophthalmic</b>	X	X	X		X	X	X
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use - 16L5 Probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: 16L5								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal							
	Abdominal	X	X	X		X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	X	X		X	X	X
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	X	X	X		X	X	X
	Musculo-skel. (Superficial)	X	X	X		X	X	X
Intra-luminal								
Other (Specify)								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	X	X	X		X	X	X
	Other (Specify)							

## Indications for Use - PDOF probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
probe: PDOF								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp <sup>a</sup>	Comb. Modes <sup>b</sup>	Other <sup>c</sup>
<b>Ophthalmic</b>	<b>Ophthalmic</b>							
<b>Fetal Imaging and Other</b>	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other (Specify)								
<b>Cardiac</b>	Cardiac Adult					X		
	Cardiac Pediatric					X		
	Trans-esoph. (Cardiac)							
	Other (Specify)							
<b>Peripheral Vessel</b>	Peripheral vessel							
	Other (Specify)							

## Indications for Use - XY probe

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Probe: XY								
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 and 3)	B	M	PWD	CWD	Color Dopp	Comb. Modes	Other
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal	X	X	X	X	X	X	X
	Abdominal	X	X	X	X	X	X	X
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	X	X	X	X	X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)							
	Neonatal Cephalic	X	X	X	X	X	X	X
	Adult Cephalic	X	X	X	X	X	X	X
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other (Specify)								
Cardiac	Cardiac Adult	X	X	X	X	X	X	X
	Cardiac Pediatric	X	X	X	X	X	X	X
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

## Acoustic Output Indices

The Terason Ultrasound System complies with particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007/AMD1:2015). When operating in any mode with the Freeze function disabled, the window displays the acoustic output indices relevant to the currently- active probe and operating mode. As described in this manual, minimizing the real-time displayed index values allows the practice of the ALARA principle (exposure of the patient to ultrasound energy at a level that is As Low As Reasonably Achievable).



**Warning:** Ultrasound procedures should be used for valid reasons, for the shortest period of time, and at the lowest mechanical/thermal index setting necessary to produce clinically acceptable images. The ultrasound system incorporates an output display of Mechanical and Thermal Indices to allow you to monitor, and to limit, the amount of ultrasound energy that is transferred to the patient.

**Note:** For systems distributed in the United States of America, refer to the Medical Ultrasound Safety ultrasound education program brochure produced by the AIUM.

### General Description of Indices

For a detailed explanation of the clinical significance and proper use of the real-time acoustic output indices displayed on the Terason image display, consult relevant literature and educational materials available from industry and professional organizations concerned with medical ultrasound. To help understand how adjustment of the controls may affect the display of indices during an exam, read the following overview.

In general, indexes are described in terms of the following factors.

- **Potential bioeffect of concern:** Mechanical (cavitation or other non-thermal mechanical effects), or thermal (heating of tissue through absorption of the ultrasound energy) -for all indices, an index value less than 1.0 indicates relatively low risk for harm to the patient when the index is applied properly.
- **Type of operating mode:** Generally, mechanical effects are a greater concern during 2D-only operation, while thermal effects are a greater concern during any non-2D operation. Thermal effects of non-scanned modes (M-Mode and Pulsed-Wave Doppler modes) are calculated separately from effects of scanned modes (Color Doppler and Power Doppler modes).
- **Type of and location of tissue of concern:** Bone or soft tissue, located either at the tissue surface nearest the probe, or at or near the beam focus.
- **Measured acoustic parameters:** Ultrasound power, time average intensity, or instantaneous peak pressure used in calculating the index value. All calculations assume an attenuation (or “derating”) rate of 0.3 dB/cm/MHz.

## MI: The Mechanical Index

MI is of possible clinical interest if the beam focus is close to the surface of lung tissue. MI has the following characteristics:

- **Potential bioeffect:** Any possible mechanical or non-thermal mechanisms - although the likelihood of adverse consequences from these causes is not well understood, such risk may be highest in the presence of gas-saturated structures such as lung tissue.
- **Mode type:** Calculated for all modes of operation.
- **Tissue type and location:** Soft tissue at all locations in the scan field.
- **Acoustic parameter:** Maximum negative (rarefactional) ultrasound pressure at focus.

## TIS: The Soft Tissue Thermal Index

TIS is of interest in the absence of bone, either at the tissue surface or near the beam focus. Applications of clinical interest include general abdominal examinations, first-trimester scanning before fetal bone has ossified, and cardiology. TIS has the following characteristics.

- **Potential bioeffect:** Thermal heating of soft tissue due to absorption of ultrasound. The TIS value is the ratio of the current probe power to the reference level that would cause a 1°C temperature rise in soft tissue.
- **Mode type:** Relevant for all modes, in both scanned and non-scanned modes.
- **Tissue type and location:** In scanned modes, soft tissue at the surface is of concern. In non-scanned modes, heating of soft tissue along the beam axis between the surface and focus is considered.
- **Acoustic parameters:** For scanned modes, the associated intensity at the surface is usually related to surface tissue heating. For unscanned modes, the maximum derated power through a 1-cm<sup>2</sup> area anywhere along the beam axis is the basis for estimating tissue heating: unscanned beams less than 1cm<sup>2</sup> in area at the surface are assumed to contribute only to surface heating, and the calculated effects are combined with those of scanned modes to estimate total soft-tissue heating at the surface. Unscanned beams larger than 1 cm<sup>2</sup> at the surface are assumed to heat tissue only near the focus. Total heating effects at the surface and focus are compiled separately, and the larger value is reported as TIS.

## TIB: The Bone Tissue Thermal Index

TIB is of concern when bone is near the beam focus. Applications of clinical interest include second- and third-trimester Doppler (when the beam focus is near fetal bone), and Neonatal Cephalic Doppler (when the beam focus is near cranial bone). TIB has the following characteristics.

- **Potential bioeffect:** Thermal heating of bone (and indirect heating of adjacent soft tissue) due to absorption of ultrasound at the bone surface. The TIB value indicates the

ratio of the current power level from the probe to the reference power level that would cause a 1°C steady-state temperature rise in bone located at the beam focus.

- **Mode type:** Calculated for all operations, in both scanned and non-scanned modes.
- **Tissue type and location:** In scanned modes, the model for soft tissue at the surface is also used to calculate the maximum possible heating of bone at the beam focus. For non-scanned modes, possible heating of bone near the beam focus is considered directly.
- **Acoustic parameters:** For scanned modes, the time-average intensity at the probe surface is closely related to estimated heating effects. For unscanned modes, the maximum product along the beam axis of both derated power and intensity is the basis for calculating possible bone heating. Total heating effects for scanned and unscanned modes are compiled separately, and the larger value is reported as TIB.

## TIC: The Cranial (Bone) Thermal Index

TIC is of concern when bone is near the tissue surface and in close proximity to the probe aperture. Clinical applications of interest are specific to those involving transcranial scanning. General information about the Cranial Thermal Index follows.

- **Potential bioeffect:** Thermal heating of cranial bone (with indirect heating of adjacent brain tissue) due to absorption of ultrasound by the cranial bone. TIC is defined as the ratio of the current probe power level to the reference power level that would cause a 1°C steady-state temperature rise in cranial bone located at the probe surface.
- **Mode type:** Calculated for all operations, in both scanned and non-scanned modes.
- **Tissue type and location:** Cranial bone, located near the tissue surface and near the probe aperture.
- **Acoustic parameter:** For each active mode, the product of estimated power and intensity at the probe surface is the basis for calculating cranial bone heating. Heating effects of all modes are combined to calculate the TIC.

## Relevant Acoustic Output Indices

When live imaging in any mode, the window displays the indices relevant to the active probe and operating mode. The definition of relevant indices is as follows:

### Acoustic Output Indices for Modes and Probes

Mode Type Currently Active	Allowed Probe Applications	Relevant Indices <sup>1</sup>
All modes	Include <i>neither</i> Adult Cephalic <i>nor</i> Neonatal Cephalic	MI, TIS, TIB
All modes	Include <i>either</i> Adult Cephalic <i>or</i> Neonatal Cephalic	MI, TIS, TIB, TIC

1. The TIC index can be chosen and displayed even when the connected probe is not intended for cephalic applications.

## Acoustic Output Index Displays

This section describes the acoustic output display in various modes.

Only certain probes used with the Terason Ultrasound System are intended for transcranial examinations (Neo-natal Cephalic uses). If the probe used does not support transcranial exams, the index display does not include TIC.



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**Warning:** For neonatal head imaging, Terason recommends that you exercise special care during neonatal cephalic scanning to avoid possible damage to the posterior region of the eye. The ultrasound energy emitted by the probe easily penetrates the fontanels of the infant.

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### Index Display

When any mode is active, a display shows the mechanical index and one thermal index relevant to the probe in use. The index information appears at the top of the column of text to the right of the scan image. The indices are TIS (soft tissue), TIB (bone), and TIC (cranial).

The probe in use may display either the TIS, the TIB, or the TIC.

You can select a different thermal index to display.

#### To select a thermal index:

1. Click **Setup**.
2. Click the **Display** tab.
3. In the TI Selection section, click the **desired thermal index**.
4. Click **OK**.

If the value of the selected index is greater than 0.4, the value displays. If the value is less than 0.4, “<0.4” displays.

### Control of Acoustic Index Parameters

For any probe used in the intended clinical applications with the Terason Ultrasound System in which all relevant acoustic indices are displayed in standard video (without an associated real-time value), operation is normally without significant risk due to mechanical effects or heating of tissues by ultrasound energy. No real-time MI or TI values need be monitored, and the probe may be used without concern for minimizing the displayed value of any index. However, in keeping with ALARA, the system should generally be operated in the shallowest depth control setting that yields the desired image quality (to minimize the MI value).

For all probes, real-time values are displayed to allow monitoring and control. The displayed indexes may show the following values (shown along with the corresponding labels, where x indicates the actual calculated index value):

#### Acoustic Index Parameters

Display of TI Values		Display of MI Values	
Range of calculated value $x_{\text{Calc.}}$	Displayed value $x_{\text{Display}}$	Range of calculated value $x_{\text{Calc.}}$	Displayed value $x_{\text{Display}}$
$x < 0.4$	< 0.4	$0 \leq x < 0.05$	0.0
$0.4 \leq x < 0.5$	0.4	$0.05 \leq x < 0.15$	0.1
$0.5 \leq x < 0.7$	0.6	$0.15 \leq x < 0.25$	0.2
$0.7 \leq x < 0.9$	0.8	$0.25 \leq x < 0.35$	0.3
$0.9 \leq x < 1.1$	1.0	$0.35 \leq x < 0.45$	0.4
$1.1 \leq x < 1.3$	1.2	$0.45 \leq x < 0.55$	0.5
$1.3 \leq x < 1.5$	1.4	$0.55 \leq x < 0.65$	0.6
$1.5 \leq x < 1.7$	1.6	$0.65 \leq x < 0.75$	0.7
$1.7 \leq x < 1.9$	1.8	$0.75 \leq x < 0.85$	0.8
Etc.	Etc.	Etc.	Etc.

In all operating modes with the Terason Ultrasound System, control of acoustic exposure is available indirectly. For a description of the indirect effects that certain control adjustments may have on displayed index values, consult the “Working With Scan Modes” chapter in Volume 1 of the *User Guide*.

#### Accuracy of Acoustic Output Display

The acoustic output display indices are calculated on the basis of measured values of acoustic parameters (acoustic power, intensity, pressure, etc.). The accuracy of the indices (discussed in the Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, IEC 60601-2-37:2007/AMD1:2015 clause 201.12) described below refers to accuracy of the measurement of the acoustic parameters and the effect of these errors on the estimated index values. (For a discussion of statistical considerations in acoustic measurement, refer to “Measurement Uncertainty in Ultrasonic Exposimetry”, in *Ultrasonic Exposimetry*, M. C. Ziskin and P. A. Lewin, eds., CRC Press).

The remainder of this section lists the relative errors for the following items:

- Intensity measurements
- Spatial-peak derated pulse-intensity integral, defined as  $\epsilon_{\text{SPPA.3}}$
- Spatial-peak derated temporal average intensity for unscanned modes
- Spatial-peak derated temporal average intensity for scanned modes
- Peak derated rarefactional pressure
- Mechanical Index
- Soft-Tissue Thermal Index for scanned modes, total acoustic power at the scan/beam entrance to the body
- Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is less than 1 cm<sup>2</sup> in area
- Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is greater than 1 cm<sup>2</sup> in area
- Bone Thermal Index for unscanned modes
- Cranial Thermal Index

The **relative error in intensity measurements due to uncertainty in the hydrophone calibration**, defined as  $\epsilon_k$ , is approximately:

$$\epsilon_k = (\epsilon_{\text{Cal}}^2 + \epsilon_A^2 + \epsilon_{\sqrt{2}}^2)^{\frac{1}{2}} = 22\%$$

where the following are defined:

- $\epsilon_{\text{Cal}}$  Calibration error, as supplied by Sonic Consulting, Inc.; 21% at the frequency range of the probes tested.
- $\epsilon_A$  Relative error in the reproducibility of positioning the hydrophone at the point of the spatial peak of the pulse intensity integral, estimated as 5%
- $\epsilon_{\sqrt{2}}$  Relative error resulting from errors in reading peak squared voltage in the recorded waveform, estimated as 4%

The **relative error in the spatial-peak derated pulse-intensity integral, defined as  $\epsilon_{\text{SPPA.3}}$** , is approximately:

$$\epsilon_{\text{SPPA.3}} = (\epsilon_k^2 + \epsilon_{\text{TI}}^2 + \epsilon_{\text{stab}}^2 + \epsilon_{.3}^2 + \epsilon_{\text{lin}}^2 + \epsilon_v^2 + \epsilon_{\text{PD}}^2)^{1/2} = 23\%$$

where the following is defined:

- $\epsilon_{\text{TI}}$  Relative error due to hydrophone positioning and temporal integration of the waveform, estimated as 4%
- $\epsilon_{\text{stab}}$  Relative error due to temporal instability of the hydrophone, estimated as 1%
- $\epsilon_{.3}$  Relative error in estimating derating factor, due to uncertainties in estimating frequency and reproducibility in determining derating location, estimated as 4%
- $\epsilon_{\text{lin}}$  Relative error due to the effects of non-linearities in the pressure waveform upon the hydrophone and integral amplifier, estimated as 0% for this probe set

$\epsilon_{PD}$  Relative error in estimate of pulse duration, estimated as 5%

The **relative error in the spatial-peak derated temporal average intensity for unscanned modes**, defined as  $\epsilon_{SPTA.3-unc.}$ , is approximately:

$$\epsilon_{SPTA.3-unc.} = (\epsilon_{SPPII.3}^2 + \epsilon_{prf}^2)^{1/2} = 23\%$$

where the following is defined:

$\epsilon_{prf}$  Relative error in prf estimation for operating condition giving actual peak ISPTA.3-unc., estimated as 1%

The **relative error in estimating spatial-peak derated temporal average intensity for scanned modes**, defined as  $\epsilon_{SPTA.3-scan.}$ , is approximately:

$$\epsilon_{SPTA.3-scan.} = (\epsilon_{SPII.3}^2 + \epsilon_{srf}^2 + \epsilon_{BOF}^2)^{1/2} = 23\%$$

where the following are defined:

$\epsilon_{srf}$  Relative error in estimating srf (scan repetition frequency) for operating condition giving actual peak ISPTA.3-scan., estimated as 1%

$\epsilon_{BOF}$  Relative error in estimating BOF (beam-overlap factor) for operating conditions giving actual peak ISPTA.3-scan., estimated as 5%

The **relative error in the peak derated rarefactional pressure**, defined as  $\epsilon_{pr.3}$ , is approximately:

$$\epsilon_{pr.3} = \left(\frac{1}{2}\right) \epsilon_{SPPII.3} = 11\%$$

The **relative error in the Mechanical Index**, defined as  $\epsilon_{MI}$ , is approximately:

$$\epsilon_{MI} = \left( \epsilon_{pr.3}^2 + \left(\frac{\epsilon_{fc}}{2}\right)^2 + \epsilon_{DAMI}^2 + \epsilon_{TVMI}^2 + \epsilon_{SVMI}^2 \right)^{1/2} = 31\%$$

where the following is defined:

$\epsilon_{fc}$  Relative error in estimating center frequency, estimated as 8%.

$\epsilon_{DAMI}$  Relative error in displaying the Mechanical Index, estimated as 20%.

$\epsilon_{TVMI}$  Relative error in the Mechanical Index due to probe variability, estimated as 20%.

$\epsilon_{SVMI}$  Relative error in the Mechanical Index due to ultrasound system variability, estimated as 2%.

The **relative error in the Soft-Tissue Thermal Index for scanned modes**, defined as  $\epsilon_{TISscan.}$ , is approximately:

$$\varepsilon_{\text{TISscan}} = \left( \varepsilon_{\text{W01}}^2 + \varepsilon_{\text{fc}}^2 + \varepsilon_{\text{DATISscan}}^2 + \varepsilon_{\text{TVW0}}^2 + \varepsilon_{\text{SVW0}}^2 \right)^{1/2} = 35\%$$

where the following is defined:

$\varepsilon_{\text{W01}}$	Relative measurement error in estimating the peak acoustic power from 1cm width of the active scanned aperture, estimated as 10%.
$\varepsilon_{\text{DATISscan}}$	Relative error in displaying the Soft-Tissue Thermal Index for scanned modes, estimated as 20%.
$\varepsilon_{\text{TVW0}}$	Relative error in peak acoustic power due to probe variability, estimated as 25%.
$\varepsilon_{\text{SVW0}}$	Relative error in peak acoustic power due to ultrasound system variability, estimated as 2%.

The **relative error in total acoustic power at the scan/beam entrance to the body**, defined as  $\varepsilon_{\text{W0}}$ , is approximately:

$$\varepsilon_{\text{W0}} = \varepsilon_{\text{FB}} = 10\%$$

The **relative error in the Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is less than 1 cm<sup>2</sup> in area**, defined as  $\varepsilon_{\text{TISunsc-A} \leq 1}$ , is approximately:

$$\varepsilon_{\text{TISunsc-A} \leq 1} = \left( \varepsilon_{\text{W0}}^2 + \varepsilon_{\text{fc}}^2 + \varepsilon_{\text{DA TISunsc-} \leq 1}^2 + \varepsilon_{\text{TVW0}}^2 + \varepsilon_{\text{SVW0}}^2 \right)^{1/2} = 35\%$$

where the following is defined:

$\varepsilon_{\text{DA TISunsc} \leq 1}$	Relative error in displaying the Soft-Tissue Thermal Index display for unscanned modes, when the beam-entrance dimension is less than 1 cm <sup>2</sup> in area, estimated as 20%.
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The **relative error in the Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is greater than 1 cm<sup>2</sup> in area**, defined as  $\varepsilon_{\text{TISunsc-A} > 1}$ , is approximately:

$$\varepsilon_{\text{TISunsc-A} > 1} = \left( \varepsilon_{\text{W0}}^2 + \varepsilon_{\text{fc}}^2 + \varepsilon_{\text{ITA.6}}^2 + \varepsilon_{\text{DA TISunsc-} \leq 1}^2 + \varepsilon_{\text{TVITA.6}}^2 + \varepsilon_{\text{SVITA.6}}^2 \right)^{1/2} = 47\%$$

where the following is defined:

$\varepsilon_{\text{ITA.6}}$	Relative error in estimating the spatial peak intensity, when derated at 0.6 dB/cm/MHz, estimated as 23%.
$\varepsilon_{\text{DA TISunsc} > 1}$	Relative error in displaying the Soft-Tissue Thermal Index display for unscanned modes, when the beam-entrance dimension is greater than 1 cm <sup>2</sup> in area, estimated as 20%.

$\varepsilon_{TV\ ITA.6}$  Relative error in the spatial peak intensity, when derated at 0.6 dB/cm/MHz, due to probe variability, estimated as 34%.

$\varepsilon_{SV\ ITA.6}$  Relative error in the spatial peak intensity, when derated at 0.6 dB/cm/MHz, due to ultrasound system variability, estimated as 2%.

The **relative error in the Bone Thermal Index for unscanned modes**, defined as  $\varepsilon_{TIBunsc.}$ , is approximately:

$$\varepsilon_{TIBunsc.} = \left(\frac{1}{2}\right)(\varepsilon_{W0}^2 + \varepsilon_{ITA.6}^2 + \varepsilon_{DATIBunsc}^2 + \varepsilon_{TVW0}^2 + \varepsilon_{TVITA.6}^2 + \varepsilon_{SVW0}^2 + \varepsilon_{SVITA.6}^2)^{1/2} = 27\%$$

where the following is defined:

$\varepsilon_{DATIBunsc}$  Relative error in displaying the Bone Thermal Index for unscanned modes, estimated as 20%.

The **relative error in estimating the Cranial Thermal Index**, defined as  $\varepsilon_{TIC}$ , is approximately:

$$\varepsilon_{TIC} = (\varepsilon_{W0}^2 + \varepsilon_{Deq}^2 + \varepsilon_{DATIC}^2 + \varepsilon_{TVW0}^2 + \varepsilon_{SVW0}^2)^{1/2} = 34\%$$

where the following is defined:

$\varepsilon_{Deq}$  Relative error in estimating the equivalent diameter of the active aperture, estimated as 2%.

$\varepsilon_{DATIC}$  Relative error in displaying the Cranial Thermal Index, estimated as 20%.

The **estimated relative errors of the calculated indices** are as follows.

$$\varepsilon_{MI} = 31\%$$

$$\varepsilon_{TISscan} = 35\%$$

$$\varepsilon_{TISunsc-A<1} = 35\%$$

$$\varepsilon_{TISunsc-A>1} = 47\%$$

$$\varepsilon_{TIBunsc} = 27\%$$

$$\varepsilon_{TIC} = 34\%$$

## Relationship of Index to Display Accuracy

The discussion above concerns the relationship between the calculated index value ( $x_{Calc.}$ ), and the “true” value ( $x_{Actual}$ ), which would be obtained under conditions without measurement uncertainty. Display precision is the relationship between the displayed index value ( $x_{Display}$ ) and ( $x_{Calc.}$ ). The displayed values (shown in reverse video along with the corresponding labels) may take on the following values (where  $x$  indicates the actual calculated index value ( $x_{Calc.}$ ))

## Display Precision of TI Values

The following table indicates the precision of the display for TI values.

**TI Value Precision**

Range of calculated value $x_{Calc.}$	Displayed value $x_{Display}$
$x < 0.4$	<0.4
$0.4 \leq x < 0.5$	0.4
$0.5 \leq x < 0.7$	0.6
$0.7 \leq x < 0.9$	0.8
$0.9 \leq x < 1.1$	1.0
$1.1 \leq x < 1.3$	1.2
$1.3 \leq x < 1.5$	1.4
$1.5 \leq x < 1.7$	1.6
$1.7 \leq x < 1.9$	1.8
$1.9 \leq x < 2.1$	2.0
Etc.	Etc.

## Display Precision of MI Values

See the table [Acoustic Index Parameters](#) on page 178 for a listing of the precision of the display for MI values.

When the effects of calculation errors are combined with the effects of display precision, overall Display Accuracy can be defined as follows:

$$\text{DisplayAccuracy} = \frac{x_{Display} - x_{Actual}}{x_{Actual}}$$

The following table lists the values of Display Accuracy that are estimated to occur with the Terason Ultrasound System. These values of Display Accuracy are given in conjunction with the values of relevant indices that may be displayed with probes available with the system.

Items in the following table correspond to index values actually displayed with the Terason Ultrasound System. For those indices for which no values are displayed, all calculated values of the index are less than 1.0 when the given index is considered relevant to the operating mode and possible intended use of the probe.

**Estimated Display Accuracy Values**

Display Value	MI	TI
0	(1) (2)	(a) (b)
0.1	100% to -33%	(a) (b)
0.2	33% to -20%	(a) (b)

Estimated Display Accuracy Values (Continued)

Display Value	MI	TI
0.3	20% to -14%	(a) (b)
0.4	14% to -11%	0% to -20%
0.5	11% to -9%	
0.6	9% to -8%	20% to -14%
0.7	8% to -7%	
0.8	7% to -6%	14% to -11%
0.9	6% to -5%	
1	5% to -5%	11% to -9%
1.1	5% to -4%	
1.2	4% to -4%	9% to -8%
1.3	4% to -4%	
1.4	4% to -3%	8% to -7%
1.5	3% to -3%	
1.6	3% to -3%	7% to -6%
1.7	3% to -3%	
1.8	3% to -3%	6% to -5%
1.9	3% to -3%	
2	(3)	5% to -5%
2.2		5% to -4%
2.4		4% to -4%
2.6		4% to -4%
2.8		4% to -3%
3		3% to -3%
3.2		3% to -3%
3.4		3% to -3%
3.6		3% to -3%
3.8		3% to -3%
4		3% to -2%
4.2		2% to -2%
4.4		2% to -2%
4.6		2% to -2%
4.8		2% to -2%
5		2% to -2%
5.2		2% to -2%
5.4		2% to -2%

## Estimated Display Accuracy Values (Continued)

Display Value	MI	TI
5.6		2% to -2%
5.8		2% to -2%
6		2% to -2%

1. Display Accuracy is not defined for actual index values ( $x_{Actual}$ ) of zero.
2.  $x_{Display} - x_{Actual}$  is always greater than zero.
3. Mechanical Index (MI) values greater than 1.9 exceed FDA Guideline levels.

## Acoustic Output Tables

Terason tests all probes it sells for use on humans, to determine their maximum acoustic outputs in the scanning modes supported by the probes. When the results of those tests require reporting, a table is generated and included in Chapter 3, [Terason Probes](#), on page 20. The following table lists which combinations of probe and mode can produce acoustic outputs that exceed the reporting thresholds. There are also tables for some combinations that do not produce outputs exceeding the thresholds

## Track 3 Probe/Mode Combination Summary

Probe Model	Mode						
	2D	M	PWD	CWD	Color Doppler <sup>1</sup>	Combined <sup>2</sup>	ENV <sup>3</sup>
4V2A	X	X	X	X	X	X	
5C2A	X	X	X		X	X	
8BP4	X	X	X		X	X	
8EC4A	X	X	X		X	X	
8L2	X	X	X		X	X	
8TE3	X	X	X	X	X	X	
8V3A	X	X	X	X	X	X	
9MC3	X	X	X		X	X	
10BP4	X	X			X		
10EC4	X	X	X		X	X	
12L5A	X	X	X		X	X	X
14L3	X	X	X		X	X	X
15L4	X	X	X		X	X	X
15L4A	X	X	X		X	X	X
15WL4	X	X	X		X	X	X

Track 3 Probe/Mode Combination Summary (Continued)

Probe Model	Mode						
	2D	M	PWD	CWD	Color Doppler <sup>1</sup>	Combined <sup>2</sup>	ENV <sup>3</sup>
16HL7	X	X	X		X	X	X
16L5	X	X	X		X	X	X
16SL5	X	X	X		X	X	X
PDOF				X			
XY	X	X	X	X	X	X	

1. Includes Directional Power Doppler (DPD), Non-Directional Power Doppler (PD), and Color Doppler (CD).
2. 2D+PWD: refer to acoustic output tables for PWD in Chapter 3 - [Terason Probes](#).
3. See "Using Needle Image Enhancement" in Volume 1 of the User Guide.

## Accuracy Measures

The following general assumptions can be made about the accuracy of any ultrasound system:

- Velocity of sound uncertainty = 5%
- Tissue shape is modeled as an ellipse or an ellipsoid
- Caliper placement accuracy is one pixel (operator dependent)
- Measurement accuracy is based on the root-mean-square combination of all independent sources of error
- RMS errors are due to velocity of sound uncertainty, pixel error, and typical probe geometry

## Distance Accuracy

Distance accuracy measures are as follows:

**Formula:**

$$D = \sqrt{(x_1 + x_2)^2 + (y_1 + y_2)^2}$$

where  $(x_1, y_1)$  and  $(x_2, y_2)$  are the coordinates of the end points.

**Range:** 0-20 cm

**Accuracy:** For a 20 cm measurement, a 1 pixel error is 0.2 mm.

**RMS errors:**

- For  $D = 10\text{mm}$ , accuracy = 9%
- For  $D = 20\text{mm}$ , accuracy = 6%
- For  $D > 50\text{mm}$ , accuracy = 5%

## Area

Area accuracy measures are as follows:

**Assumptions:** Circular cross section, length of axes: 2a, 2b

**Formula:**  $K = \pi ab$

**Range:** 0-300 cm<sup>2</sup>

**Accuracy:** Determined by two independent distance measurements. The derivation of a particular tissue shape from the circular model cannot be quantified.

**RMS errors:** For A = 3.1 cm<sup>2</sup>, accuracy = 7%

## Circumference

Circumference accuracy measures are as follows:

**Assumptions:** Elliptical cross section, length of axes: 2a, 2b

**Formula:**  $C = 2\pi \sqrt{\frac{a^2 + b^2}{2}}$

**Range:** 0-60 cm

**Accuracy:** Determined by two independent distance measurements

**RMS errors:** For C=6.3 cm, accuracy=6%

## Volume

Volume accuracy measures are as follows:

**Assumptions:** Cylinder, length of axes: 2a, 2b, 2c (height)

**Formula:**  $V = 4/3(\pi abc)$

**Range:** 0-3000 ml

**Accuracy:** Determined by three independent distance measurements. The deviation of a particular shape from the ellipsoid cannot be quantified.

**RMS errors:** For V=16 ml, accuracy = 9%

Reference information for the above accuracy measures was obtained from the following source:

*Standard Mathematical Tables*, 24th Edition, (Cleveland: CRC Press, 1976), 12, 17.

## Compliance and Approvals

The Terason Ultrasound System is in compliance with the following:

- CE Marking: Medical Device Directive, 93/42/EEC (Annex II)
- EN 60601-1 Medical Electrical Equipment – General Requirements for Safety
- IEC 60601-1 Medical Electrical Equipment – General Requirements for Safety
- IEC 60601-1-1 Collateral Standard: Safety Requirements for Medical Electrical Systems
- UL Std. 60601-1, “Medical Electrical Equipment General Requirements for Safety”;
- CAN/CSA C22.2 No. 601.1-M90 “Medical Electrical Equipment, General Requirements for Safety.”
- Electromagnetic Compatibility: EN60601-1-2, (CISPR11) Group 1, Class B
- Electric Shock: IEC 60601-1, Class I, Type BF

## Environmental Protection

### Product Recycling and Disposal

Terason has programs for return of used products. For more information, contact your local Terason representative.

Terason provides disassembly instructions to treatment facilities for the safe and proper removal and recycling of electronic components in this product. For more information, contact your local Terason representative.

## Caring for Batteries



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**Warning:** Do not strike or drop batteries, allow batteries to contact water or other fluids, disassemble batteries, allow conductive object to contact a battery's terminals, cause a battery to become short-circuited, heat batteries, or expose batteries to fire. Any of these actions can compromise the structural integrity of a battery. Compromising the structural integrity of a battery can result in battery leakage, heat generation, fire, or explosion, causing possible personal injury.

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**Warning:** Do not use a battery if it leaks fluid or has changed shape. If skin or clothing comes in contact with fluid from the battery, thoroughly wash the area immediately with clean water. If any fluid comes in contact with a user's eyes, immediately flush their eyes with water and seek medical attention.

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**Caution:** The battery only fits in the system in one orientation, and inserts easily when oriented properly. Do not try to force it into place in the wrong orientation.

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For maximum battery life, do the following:

- Use the system in an environment with a temperature range between 10°C and 35°C.
- Store the system in an environment with low humidity and a temperature range between -5° and 50° C.
- When the system is stored for extended periods, connect the power supply for several hours every few weeks to prevent the battery from draining completely.

## Recycling Batteries



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**Warning:** Never dispose of batteries by burning or by flushing into any waste water system, for example, a lavatory. Compromising the structural integrity of a battery can result in leakage or explosion and the potential for personal injury.

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**Warning:** Do not throw batteries into the trash. Collect and recycle used batteries separate from other waste.

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Item	Estimated Use Period	Handling Instructions
lithium manganese dioxide batteries and lithium-ion polymer batteries	300 full charge and discharge cycles	See also: <a href="#">Caring for Batteries</a> on page 189

Recycle batteries according to local, state, and regional regulations. Use a battery collection program available in your country to recycle batteries.

To the extent required by local laws and regulations, Terason will collect and recycle batteries for this product at no charge. Contact your local Terason representative for battery shipment instructions.

## Disposing of the Packaging Materials

To the extent required by local laws and regulations, Terason will collect and dispose of packaging materials for this product. For more information, contact your local Terason representative.

## Disposing of Components and Accessories



**Warning:** Observe local, state, and regional regulations for the disposal of the ultrasound system components and accessories.




**Warning:** To eliminate the possibility of exposing patients, operators, or third parties to hazardous or infectious materials, always dispose of the needle from the needle guide according to local, state, and regional regulations.

Component or Accessory	Estimated Use Period	Handling Instructions
5C2A, 14L3, 15L4, 16L5, and 16SL5 needle guide bracket assemblies	single use	The needle guide for use with the bracket assemblies is a single-use item. Refer to the in-box instructions for disposal procedures.

## Energy Conservation

For moderate energy conservation when the system is not in use, exit the ultrasound system software and place the system in standby status.

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To	Do This
Exit the ultrasound system software	Click the  at the top right of the menu bar Select File>Exit from the menu bar
Activate or exit standby status <sup>1</sup>	Refer to the Windows help menu for instructions to activate or exit standby status.

1. Standby status will end the imaging session. Exit the ultrasound system software before you place the system in standby status.
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For maximum energy conservation when the system is in storage, power off and unplug the system from the power outlet.

## 5 System Specifications

The following table lists the system specifications for the Terason Ultrasound System. Gray blocks signify that the category does not apply to that component.

### Ultrasound System Specifications

terason Ultrasound System Specifications

Category	Specification	Terason Ultrasound System	Power Adapter
Frequency	PDOF	2 MHz	
	4V2A, 5C2A, XY	1.7 – 4 MHz	
	8TE3	3 – 9 MHz	
	8EC4A	4 – 9 MHz	
	8V3A	3 – 9 MHz	
	9MC3	3 – 9 MHz	
	8L2	3 – 10 MHz	
	8BP4, 10BP4	4 - 8 MHz	
	10EC4	4 - 10 MHz	
	14L3	3.8 - 12 MHz	
	15L4, 15L4A, 12L5A, 15WL4	4.3 – 12 MHz	
16HL7, 16L5 16SL5	6 – 13 MHz		
Frame Rate	2D Imaging (based on input data rate)	124 Hz Maximum	
Ultrasound Lines/Frame		256	
Display		15.6" LED backlit wide-screen	
Size	Width	15.29" (38.8 cm)	3.63" (9.2 cm)
	Height	3.5" (8.9 cm)	2.25" (5.7 cm)
	Depth	15.58" (39.6 cm)	6.5" (16.5 cm)
Weight	Weight	14.6 lbs (6.62 kg)	1 lbs. (0.45 kg)

## Terason Ultrasound System Specifications (Continued)

Category	Specification	Terason Ultrasound System	Power Adapter
Power Adapter	Input		100V – /240 V~ 47 – 63 Hz @ 1.4 – 0.6 A
	Output		19 VDC @ 0–6 A
System Battery	Type	Lithium-Polymer battery	
	Voltage	10.8V	
	Capacity	6500 mAh, 70.2 Wh	
Safety Standards		IEC 60950-1:2001 IEC 60950:1999, Edition 3 IEC 60825-1:1993 +A2:2001 EN 60950-1:2000 EN 60825:1994 +A2:2001	UL60601-1 UL60950-1, C22.2 No. 601-1, C22.2 No. 60950.1 EN 60601-1 EN 60950-1
Operating Temperature		-10 to 40°C (14 to 140°F)	0 to 40°C (32 to 104°F)
Humidity		30 -75% RH, non-condensing	10-95% RH, non-condensing
Water Resistance		Probe array watertight to the strain relief	
Operating / Storage Altitude	Pressure	70 kPa to 106 kPa (525 to 795 mm/Hg)	70 kPa to 106 kPa (525 to 795 mm/Hg)
Storage	Temperature	-10 to 60°C (14 to 140°F)	-5° to 50° C (23° to 122° F)
	Humidity	10-90% RH, non-condensing	< 95% RH, non-condensing

## Optional Equipment Specifications

The following table lists the system specifications for optional equipment that may be shipped with the Terason Ultrasound System:

### Optional Equipment Specifications

Category	Specification	ECG	ECG Lead Set	Printer	Footswitch	Cart
Size	Width	1.5" (3.8 cm)		6" (15.2 cm)	6.25" (15.88 cm)	19.3" (49 cm)
	Height	1" (2.5 cm)		3.46" (8.79 cm)	1.2" (3.05 cm)	58" max.
	Depth	6" (15.2 cm)		9.45" (24 cm)	6.0"	23.54"
	Cable Length	10' (3 Meters)	29" (74 cm)	9' (2.74 m)	9.6' (2.93 m)	N/A
Weight	Weight	8 oz (0.2 kg)		5.75 lb (2.61 kg)	31 lb (14.1 kg)	45 lb (20 kg)
Power	Input	650 mW		1.0 W	1.0 W	N/A

## RF Communication Specifications

The Terason uSmart3300 system contains an IEEE 802.11 a/b/g/n/ac LAN plus Bluetooth 4.0 combination transmitter. The unit is capable of transmitting in the following bands:

- 2.400 to 2.484 GHz
- 5.150 to 5.850 GHz

The maximum effective radiated power is 18.0 dBm.

### WiFi Specifications

Characteristic	Specification
<b>Frequency Range</b>	2.400 GHz - 2.4835 GHz 5.1500 GHz - 5.3500 GHz 5.4700 GHz - 5.725 GHz 5.725 GHz - 5.8500 GHz
<b>Modulation Techniques</b>	802.11b: CCK, DQPSK, DBPSK 802.11a/g/n: 64QAM, 16QAM, QPSK, BPSK, OFDM 802.11ac: 256QAM, 64QAM, 16QAM, QPSK, BPSK, OFDM BT: GFSK, $\pi/4$ DQPSK, 8DPSK
<b>Data Rate</b>	802.11b: 11, 5.5, 2,1 Mbps 802.11g: 54, 48, 36, 24, 18, 12, 9, 6 Mbps 802.11n: MCS 0 to 15 for HT20 MHz MCS 0 to 15 for HT40 MHz 802.11ac: MCS 0 to 8 for HT20 MHz MCS 0 to 9 for HT40 MHz MCS 0 to 9 for HT80 MHz
<b>Output Power</b>	8802.11a: 13 dBm $\pm$ 2 dBm (54 Mbps) 8802.11b: 16 dBm $\pm$ 2 dBm (11 Mbps) 8802.11g: 14 dBm $\pm$ 2 dBm (54 Mbps) 8802.11n @2.4 GHz: 13 dBm $\pm$ 2 dBm (HT20 MCS7) 8802.11n @2.4 GHz: 13 dBm $\pm$ 2 dBm (HT40 MCS7) 8802.11n @5 GHz: 12 dBm $\pm$ 2 dBm (HT20 MCS7) 8802.11n @5 GHz: 12 dBm $\pm$ 2 dBm (HT40 MCS7) 8802.11ac @5 GHz: 12 dBm $\pm$ 2 dBm (HT80 MCS7) 8802.11ac @5 GHz: 10 dBm $\pm$ 2 dBm (HT80 MCS9)

## 6 Electromagnetic Tables

This chapter provides reference tables for emissions and immunity requirements.

The Terason Ultrasound System is intended for use in the electromagnetic environment specified in the following tables. The customer or user of the Terason system should ensure that it is used in such an environment.

### Electromagnetic Emissions

#### All Equipment

The uSmart3300 is intended for use in the electromagnetic environment specified below. The customer or user of the uSmart3300 should ensure that it is used in such an environment.

#### Guidance and Manufacturer's Declaration - Electromagnetic Emissions - All Equipment

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF Emissions CISPR 11	Group 1	The Terason Ultrasound System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Group 2	
RF Emissions CISPR 11	Class A	NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment
Harmonics IEC 61000-3-2	Class A or B	
Flicker IEC 61000-3-3	Complies	
RF Emissions CISPR 14-1	Complies	The uSmart3300 is not suitable for interconnection with other equipment.
RF Emissions CISPR 15	Complies	The uSmart3300 is not suitable for interconnection with other equipment.

## Electromagnetic Immunity

### All Equipment

The uSmart3300 is intended for use in the electromagnetic environment specified below. The customer or user of the uSmart3300 should ensure that it is used in such an environment.

#### Guidance and Manufacturer's Declaration - Electromagnetic Immunity - All Equipment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
ESD IEC 61000-4-2	±8kV Contact ±15kV Air	±8kV Contact ±15kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains ±1kV I/Os	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	
Voltage Dips/ Dropout IEC 61000-4-11	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles 0 % UT; 250/300 cycles	0 % UT; 0,5 cycle g) At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles 0 % UT; 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the uSmart3300 requires continued operation during power mains interruptions, it is recommended that the 35700 be powered from an uninterruptible power supply or battery.
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power Frequency magnetic fields should be that of a typical commercial or hospital environment.
Immunity to Proximity Magnetic Fields in the Frequency Range of 9kHz to 13.56 MHz IEC61000-4-39 ed1.0	65 A/m at 134.2 kHz  7.5 A/m at 13.56 MHz	65 A/m at 134.2 kHz  7.5 A/m at 13.56 MHz	



**Warning:** To maintain compliance with IEC 60601-1, the system must connect only to network and data couplings that employ network electrical isolators that protect patients from harmful electrical leakage.

Test frequency (MHz)	Band <sup>a)</sup> (MHz)	Service <sup>a)</sup>	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation <sup>b)</sup> 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM <sup>c)</sup> ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation <sup>b)</sup> 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation <sup>b)</sup> 18 Hz	28
870				
930				
1 720	1 700 to 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation <sup>b)</sup> 217 Hz	28
1 845				
1 970				
2 450	2 400 to 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation <sup>b)</sup> 217 Hz	28
5 240	5 100 to 5 800	WLAN 802.11 a/n	Pulse modulation <sup>b)</sup> 217 Hz	9
5 500				
5 785				
If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT OF ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
<sup>a)</sup> For some services, only the uplink frequencies are included.				
<sup>b)</sup> The carrier shall be modulated using a 50 % duty cycle square wave signal.				
<sup>c)</sup> As an alternative to FM modulation, the carrier may be pulse modulated using a 50 % duty cycle square wave signal at 18 Hz. While it does not represent actual modulation, it would be worst case.				

## Non-Life-Supporting Equipment

The uSmart3300 is intended for use in the electromagnetic environment specified below. The customer or user of the uSmart3300 should ensure that it is used in such an environment.

### Guidance and Manufacturer's Declaration - Electromagnetic Immunity - Non-Life-Supporting Equipment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz to 80 MHz	$[V_1] = 3$ Vrms	Portable and mobile communications equipment should be separated from the Terason Ultrasound System by no less than the distances calculated/listed below $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	$[E_1] = 3$ V/m	$d = \left[ \frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ to } 800 \text{ MHz}$ $d = \left[ \frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.7 \text{ GHz}$ <p>where <math>P</math> is the max power in watts and <math>d</math> is the recommended separation distance in meters.</p> <p>Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (<math>V_1</math> and <math>E_1</math>).</p> <p>Interference may occur in the vicinity of equipment containing a transmitter.</p>

## Separation Distances

The uSmart3300 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the uSmart3300 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the uSmart3300 as recommended below, according to the maximum output power of the communications equipment.

Maximum Output Power of Transmitter Watts (W)	Separation Distance According to Frequency of Transmitter Meters (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$\frac{3.5\sqrt{P}}{V1} = D$	$\frac{3.5\sqrt{P}}{E1} = D$	$\frac{7\sqrt{P}}{E1} = D$
0.01	0.12 m	0.17 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69m	7.38 m
100	11.67 m	11.67 m	23.34 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rate of the transmitter in watts (W) according to the transmitter manufacturer.



**Note:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**Note:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



## 7 Gestational Tables

### Tables Used in Gestational Calculations

This chapter contains gestational tables for the measurements included with the Obstetrical exam type:

- AC Chart, Hadlock, 12-42 weeks
- BPD Chart, Hadlock, 12.1 - 41.6 weeks
- CRL Chart, Hadlock, 5.7 - 18 weeks
- FL Chart, Hadlock, 12.2 - 42 weeks
- GSD, Hansmann - 6.0 - 14.0 weeks
- HC Chart, Hadlock, 12.2-41.9 weeks
- HL Chart, Jeanty, 12.6 - 40.1 weeks

“Calculating Estimated Fetal Weight” in the Working With Measurements chapter of the *User Guide* for your system describes the procedure for measuring an obstetrical scan to estimate the fetal weight. The fetal weight calculation is based on the Hadlock tables in this chapter, and uses the following formula:

$$EFW[g] = 10^{\left(1.326 - (0.00326 * AC[cm] * FL[cm]) + (0.0107 * HC[cm]) + (0.0438 * AC[cm]) + (0.158 * FL[cm])\right)}$$

where:

<b>EFW</b>	Estimated Fetal Weight
<b>AC</b>	Abdominal Circumference
<b>HC</b>	Head Circumference
<b>FL</b>	Femur Length

**AC Chart, Hadlock, 12-42 weeks**

AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)
51	12.1	93	15.5	135	19.0	177	22.6	219	26.4	261	30.2	304	34.4	346	38.5
52	12.2	94	15.5	136	19.0	178	22.7	220	26.4	262	30.3	305	34.5	347	38.6
53	12.2	95	15.6	137	19.1	179	22.8	221	26.5	263	30.4	306	34.6	348	38.7
54	12.3	96	15.7	138	19.2	180	22.9	222	26.6	264	30.5	307	34.7	349	38.8
55	12.4	97	15.8	139	19.3	181	22.9	223	26.7	265	30.6	308	34.7	350	38.9
56	12.5	98	15.9	140	19.4	182	23.0	224	26.8	266	30.7	309	34.8	351	39.0
57	12.5	99	15.9	141	19.5	183	23.1	225	26.9	267	30.8	310	34.9	352	39.1
58	12.6	100	16.0	142	19.6	184	23.2	226	27.0	268	30.9	311	35.0	353	39.2
59	12.7	101	16.1	143	19.6	185	23.3	227	27.1	269	31.0	312	35.1	354	39.3
60	12.8	102	16.2	144	19.7	186	23.4	228	27.2	270	31.1	313	35.2	355	39.4

AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)	AC (mm)	MA (wks)
61	12.9	103	16.3	145	19.8	187	23.5	229	27.3	271	31.2	314	35.3	356	39.5
62	12.9	104	16.4	146	19.9	188	23.6	230	27.4	272	31.3	315	35.4	357	39.6
63	13.0	105	16.4	147	20.0	189	23.7	231	27.5	273	31.4	316	35.5	358	39.7
64	13.1	106	16.5	148	20.1	190	23.7	232	27.5	274	31.5	317	35.6	359	39.8
65	13.2	107	16.6	149	20.2	191	23.8	233	27.6	275	31.6	318	35.7	360	39.9
66	13.3	108	16.7	150	20.2	192	23.9	234	27.7	276	31.7	319	35.8	361	40.0
67	13.3	109	16.8	151	20.3	193	24.0	235	27.8	277	31.8	320	35.9	362	40.1
68	13.4	110	16.9	152	20.4	194	24.1	236	27.9	278	31.9	321	36.0	363	40.2
69	13.5	111	16.9	153	20.5	195	24.2	237	28.0	279	32.0	322	36.1	364	40.3
70	13.6	112	17.0	154	20.6	196	24.3	238	28.1	280	32.0	323	36.2	365	40.4
71	13.7	113	17.1	155	20.7	197	24.4	239	28.2	281	32.1	324	36.3	366	40.5
72	13.7	114	17.2	156	20.8	198	24.5	240	28.3	282	32.2	325	36.4	367	40.6
73	13.8	115	17.3	157	20.8	199	24.6	241	28.4	283	32.3	326	36.5	368	40.7
74	13.9	116	17.4	158	20.9	200	24.6	242	28.5	284	32.4	327	36.6	369	40.8
75	14.0	117	17.4	159	21.0	201	24.7	243	28.6	285	32.5	328	36.7	370	40.9
76	14.1	118	17.5	160	21.1	202	24.8	244	28.7	286	32.6	329	36.8	371	41.0
77	14.2	119	17.6	161	21.2	203	24.9	245	28.7	287	32.7	330	36.9	372	41.1
78	14.2	120	17.7	162	21.3	204	25.0	246	28.8	288	32.8	331	37.0	373	41.2
79	14.3	121	17.8	163	21.4	205	25.1	247	28.9	289	32.9	332	37.1	374	41.3
80	14.4	122	17.9	164	21.5	206	25.2	248	29.0	290	33.0	333	37.2	375	41.4
81	14.5	123	17.9	165	21.5	207	25.3	249	29.1	291	33.1	334	37.3	376	41.5
82	14.6	124	18.0	166	21.6	208	25.4	250	29.2	292	33.2	335	37.4	377	41.6
83	14.6	125	18.1	167	21.7	209	25.5	251	29.3	293	33.3	336	37.5	378	41.7
84	14.7	126	18.2	168	21.8	210	25.5	252	29.4	294	33.4	337	37.6	379	41.8
85	14.8	127	18.3	169	21.9	211	25.6	253	29.5	295	33.5	338	37.7	380	42.0
86	14.9	128	18.4	170	22.0	212	25.8	254	29.6	296	33.6	339	37.8		
87	15.0	129	18.5	171	22.1	213	25.8	255	29.7	297	33.7	340	37.9		
88	15.0	130	18.5	172	22.2	214	25.9	256	29.8	298	33.8	341	38		
89	15.1	131	18.6	173	22.2	215	26.0	257	29.9	300	34.0	342	38.1		
90	15.2	132	18.7	174	22.3	216	26.1	258	30.0	301	34.1	343	38.2		
91	15.3	133	18.8	175	22.4	217	26.2	259	30.1	302	34.2	344	38.3		
92	15.4	134	18.9	176	22.5	218	26.3	260	30.2	303	34.3	345	38.4		

BPD Chart, Hadlock, 12.1 - 41.6 weeks

BPD (mm)	MA (weeks)	BPD (mm)	MA (weeks)	BPD (mm)	MA (weeks)
15	12.1	44	19.3	73	29.3
16	12.3	45	19.6	74	29.7
17	12.5	46	19.9	75	30.1
18	12.8	47	20.2	76	30.5
19	13.0	48	20.5	77	30.9
20	13.2	49	20.8	78	31.3
21	13.4	50	21.1	79	31.7
22	13.6	51	21.5	80	32.1

BPD (mm)	MA (weeks)	BPD (mm)	MA (weeks)	BPD (mm)	MA (weeks)
23	13.8	52	21.8	81	32.5
24	14.1	53	22.1	82	33.0
25	14.3	54	22.4	83	33.4
26	14.5	55	22.8	84	33.8
27	14.8	56	23.1	85	34.2
28	15.0	57	23.4	86	34.7
29	15.2	58	23.8	87	35.1
30	15.5	59	24.1	88	35.6
31	15.7	60	24.5	89	36.0
32	16.0	61	24.8	90	36.5
33	16.3	62	25.2	91	36.9
34	16.5	63	25.5	92	37.4
35	16.8	64	25.9	93	37.8
36	17.0	65	26.3	94	38.3
37	17.3	66	26.6	95	38.7
38	17.6	67	27.0	96	39.2
39	17.9	68	27.4	97	39.7
40	18.1	69	27.7	98	40.2
41	18.4	70	28.1	99	40.6
42	18.7	71	28.5	100	41.1
43	19.0	72	28.9	101	41.6

**CRL Chart, Hadlock, 5.7 - 18 weeks**

CRL (mm)	Menstrual Age	CRL (mm)	Menstrual Age	CRL (mm)	Menstrual Age
2	5.7	42	11.1	82	14.2
3	5.9	43	11.2	83	14.2
4	6.1	44	11.2	84	14.3
5	6.2	45	11.3	85	14.4
6	6.4	46	11.4	86	14.5
7	6.6	47	11.5	87	14.6
8	6.7	48	11.6	88	14.7
9	6.9	49	11.7	89	14.8
10	7.1	50	11.7	90	14.9
11	7.2	51	11.8	91	15.0
12	7.4	52	11.9	92	15.1
13	7.5	53	12.0	93	15.2
14	7.7	54	12.0	94	15.3
15	7.9	55	12.1	95	15.3
16	8.0	56	12.2	96	15.4
17	8.1	57	12.3	97	15.5
18	8.3	58	12.3	98	15.6
19	8.4	59	12.4	99	15.7
20	8.6	60	12.5	100	15.9

CRL (mm)	Menstrual Age	CRL (mm)	Menstrual Age	CRL (mm)	Menstrual Age
21	8.7	61	12.6	101	16.0
22	8.9	62	12.6	102	16.1
23	9.9	63	12.7	103	16.2
24	9.1	64	12.8	104	16.3
25	9.2	65	12.8	105	16.4
26	9.4	66	12.9	106	16.5
27	9.5	67	13.0	107	16.6
28	9.6	68	13.1	108	16.7
29	9.7	69	13.1	109	16.8
30	9.9	70	13.2	110	16.9
31	10.0	71	13.3	111	17.0
32	10.1	72	13.4	112	17.1
33	10.2	73	13.4	113	17.2
34	10.3	74	13.5	114	17.3
35	10.4	75	13.6	115	17.4
36	10.5	76	13.7	116	17.5
37	10.6	77	13.8	117	17.6
38	10.7	78	13.8	118	17.7
39	10.8	79	13.9	119	17.8
40	10.9	80	14.0	120	17.9
41	11.0	81	14.1	121	18.0

FL Chart, Hadlock, 12.2 - 42 weeks

FL (mm)	MA (weeks)	FL (mm)	MA (weeks)	FL (mm)	MA (weeks)
7	12.2	33	20.3	58	30.3
8	12.4	34	20.7	59	30.8
9	12.7	35	21.0	60	31.2
10	13.0	36	21.4	61	31.7
11	13.3	37	21.8	62	32.1
12	13.5	38	22.2	63	32.6
13	13.8	39	22.5	64	33.1
14	14.1	40	22.9	65	33.5
16	14.4	41	23.3	66	34.0
17	14.7	42	23.7	67	34.5
18	15.3	43	24.1	68	34.9
19	15.6	44	24.5	69	35.4
20	16.0	45	24.9	70	35.9
21	16.3	46	25.3	71	36.4
22	16.6	47	25.7	72	36.9
23	16.9	48	26.1	73	37.4
24	17.2	49	26.5	74	37.9
25	17.6	50	26.9	75	38.4
26	17.9	51	27.3	76	38.9
27	18.2	52	27.7	77	39.4
28	18.6	53	28.2	78	39.9

FL (mm)	MA (weeks)	FL (mm)	MA (weeks)	FL (mm)	MA (weeks)
29	18.9	54	28.6	79	40.4
30	19.3	55	29.0	80	40.9
31	19.6	56	29.5	81	41.4
32	20.0	57	29.9	82	42.0

**GSD, Hansmann - 6.0 - 14.0 weeks**

Sac (mm)	Menstrual Age (weeks + days)	Sac (mm)	Menstrual Age (weeks + days)	Sac (mm)	Menstrual Age (weeks + days)
10	5 + 6	30	8 + 5	50	11 + 3
11	5 + 7	31	8 + 6	51	11 + 4
12	6 + 1	32	8 + 7	52	11 + 5
13	6 + 2	33	9 + 1	53	11 + 6
14	6 + 3	34	9 + 2	54	11 + 7
15	6 + 4	35	9 + 3	55	12 + 1
16	6 + 5	36	9 + 4	56	12 + 2
17	6 + 6	37	9 + 4	57	12 + 3
18	6 + 7	38	9 + 5	58	12 + 4
19	7 + 1	39	9 + 6	59	12 + 5
20	7 + 2	40	9 + 7	60	12 + 6
21	7 + 3	41	10 + 1	61	12 + 7
22	7 + 4	42	10 + 2	62	13 + 1
23	7 + 5	43	10 + 3	63	13 + 2
24	7 + 6	44	10 + 4	64	13 + 3
25	7 + 7	45	10 + 5	65	13 + 4
26	8 + 1	46	10 + 6	66	13 + 5
27	8 + 2	47	10 + 7	67	13 + 6
28	8 + 3	48	11 + 1	68	13 + 7
29	8 + 4	49	11 + 2		

**HC Chart, Hadlock, 12.2-41.9 weeks**

HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)
56	12.0	94	14.3	132	16.8	170	19.6	208	22.9	246	26.7	284	31.2	322	36.4
57	12.1	95	14.3	133	16.8	171	19.7	209	23.0	247	26.8	285	31.3	323	36.5
58	12.2	96	14.4	134	16.9	172	19.8	210	23.1	248	26.9	286	31.4	324	36.7
59	12.2	97	14.5	135	17.0	173	19.9	211	23.2	249	27.0	287	31.5	325	36.8
60	12.3	98	14.5	136	17.1	174	19.9	212	23.3	250	27.1	288	31.7	326	37.0
61	12.3	99	14.6	137	17.1	175	20.0	213	23.4	251	27.3	289	31.8	327	37.1
62	12.4	100	14.7	138	17.2	176	20.1	214	23.5	252	27.4	290	31.9	328	37.3
63	12.4	101	14.7	139	17.3	177	20.2	215	23.6	253	27.5	291	32.1	329	37.4
64	12.5	102	14.8	140	17.3	178	20.3	216	23.6	254	27.6	292	32.2	330	37.6
65	12.6	103	14.8	141	17.4	179	20.3	217	23.7	255	27.7	293	32.3	331	37.7
66	12.6	104	14.9	142	17.5	180	20.4	218	23.8	256	27.8	294	32.5	332	37.9

HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)	HC (mm)	MA (wks)
67	12.7	105	15.0	143	17.6	181	20.5	219	23.9	257	27.9	295	32.6	333	38.0
68	12.7	106	15.0	144	17.6	182	20.6	220	24.0	258	28.0	296	32.7	334	38.2
69	12.8	107	15.1	145	17.7	183	20.7	221	24.1	259	28.2	297	32.9	335	38.3
70	12.8	108	15.2	146	17.8	184	20.8	222	24.2	260	28.3	298	33.0	336	38.5
71	12.9	109	15.2	147	17.9	185	20.8	223	24.3	261	28.4	299	33.1	337	38.6
72	13.0	110	15.3	148	17.9	186	20.9	224	24.4	262	28.5	300	33.3	338	38.8
73	13.0	111	15.4	149	18.0	187	21.0	225	24.5	263	28.6	301	33.4	339	39.0
74	13.1	112	15.4	150	18.1	188	21.1	226	24.6	264	28.7	302	33.5	340	39.1
75	13.1	113	15.5	151	18.1	189	21.2	227	24.7	265	28.9	303	33.7	341	39.3
76	13.2	114	15.6	152	18.2	190	21.3	228	24.8	266	29.0	304	33.8	342	39.4
77	13.3	115	15.6	153	18.3	191	21.4	229	24.9	267	29.1	305	33.9	343	39.6
78	13.3	116	15.7	154	18.4	192	21.5	230	25.0	268	29.2	306	34.1	344	39.7
79	13.4	117	15.8	155	18.4	193	21.5	231	25.1	269	29.3	307	34.2	345	39.9
80	13.4	118	15.8	156	18.5	194	21.6	232	25.2	270	29.4	308	34.4	346	40.1
81	13.5	119	15.9	157	18.6	195	21.7	233	25.3	271	29.6	309	34.5	347	40.2
82	13.6	120	16.0	158	18.7	196	21.8	234	25.4	272	29.7	310	34.6	348	40.4
83	13.6	121	16.0	159	18.8	197	21.9	235	25.5	273	29.8	311	34.8	349	40.6
84	13.7	122	16.1	160	18.8	198	22.0	236	25.6	274	29.9	312	34.9	350	40.7
85	13.7	123	16.2	161	18.9	199	22.1	237	25.8	275	30.0	313	35.1	351	40.9
86	13.8	124	16.2	162	19.0	200	22.2	238	25.9	276	30.2	314	35.2	352	41.1
87	13.9	125	16.3	163	19.1	201	22.3	239	26.0	277	30.3	315	35.3	353	41.2
88	13.9	126	16.4	164	19.1	202	22.3	240	26.1	278	30.4	316	35.5	354	41.4
89	14.0	127	16.4	165	19.2	203	22.4	241	26.2	279	30.5	317	35.6	355	41.6
90	14.0	128	16.5	166	19.3	204	22.5	242	26.3	280	30.7	318	35.8	356	41.7
91	14.1	129	16.6	167	19.4	205	22.6	243	26.4	281	30.8	319	35.9	357	41.9
92	14.2	130	16.6	168	19.5	206	22.7	244	26.5	282	30.9	320	36.1		
93	14.2	131	16.7	169	19.5	207	22.8	245	26.6	283	31.0	321	36.2		

## HL Chart, Jeanty, 12.6 - 40.1 weeks

HL (mm)	MA (weeks)	HL (mm)	MA (weeks)	HL (mm)	MA (weeks)
10	12.57	30	19.86	50	29.29
11	12.86	31	20.29	51	29.86
12	13.14	32	20.71	52	30.29
13	13.57	33	21.14	53	30.86
14	13.86	34	21.57	54	31.43
15	14.14	35	22.00	55	32.00
16	14.57	36	22.57	56	32.57
17	14.86	37	22.86	57	33.14
18	15.14	38	23.43	58	33.57
19	15.57	39	23.86	59	34.14
20	15.86	40	24.29	60	34.86
21	16.29	41	24.86	61	35.29
22	16.71	42	25.29	62	35.86

HL (mm)	MA (weeks)	HL (mm)	MA (weeks)	HL (mm)	MA (weeks)
23	17.14	43	25.71	63	36.57
24	17.43	44	26.14	64	37.14
25	17.86	45	26.71	65	37.71
26	18.14	46	27.14	66	38.29
27	18.57	47	27.71	67	38.86
28	19.00	48	28.14	68	39.57
29	19.43	49	28.86	69	40.14

## 8 Formulas used for Values in the Cardiac Report

This chapter provides the formulas used to calculate values that display in the Cardiac Report.

### Formulas Used for Measurements in the 2D Window

#### 2D Formulas

Name	Variables	Formula	Units
LV Volume: Method of Disks, Biplane	$a_{di}$ : $i^{\text{th}}$ disk diameter of LV apical 2-chamber (cm) $b_{di}$ : $i^{\text{th}}$ disk diameter of LV apical 4-chamber (cm) L: chamber length from the longer of A4c or A2c (cm) 20: number of disk segments in ventricle	$V = \frac{\pi}{4} \sum_{i=1}^{20} a_{di} b_{di} \cdot \frac{L}{20}$	ml
LV Volume: Method of Disks, Single Plane	$a_{di}$ : $i^{\text{th}}$ disk diameter of LV apical 2- or 4-chamber (cm) L: chamber length of cavity	$V = \frac{\pi}{4} \sum_{i=1}^{20} a_{di}^2 \cdot \frac{L}{20}$	ml
Ejection Fraction	$V_s$ : LV volume systolic (ml) $V_d$ : LV volume diastolic (ml)	$EF = \left( \frac{V_d - V_s}{V_d} \right) \cdot 100$	%
Stroke Volume	$V$ : LV volume (ml) s: systole d: diastole	$SV = V_d - V_s$	ml
Cardiac Output	$SV$ : stroke volume (ml) $HR$ : heart rate (bpm)	$CO = \frac{(SV \cdot HR)}{1000}$	l/min
Cardiac Index	$CO$ : Cardiac Output $BSA$ : body surface area ( $m^2$ )	$CI = \frac{CO}{BSA}$	l/min/ $m^2$

2D Formulas (Continued)

Name	Variables	Formula	Units
LV Mass	A <sub>1</sub> : SAX epicardial diastolic area (cm <sup>2</sup> ) A <sub>2</sub> : SAX endocardial diastolic area (cm <sup>2</sup> ) L: apical length in diastole (cm) t: mean myocardial thickness	$VMass = 1.05 \left( \frac{5}{6} (A_1(L+t)) - \frac{5}{6} (A_2 \cdot L) \right)$ $t = \left( \left( \sqrt{\frac{A_1}{\pi}} \right) - \left( \sqrt{\frac{A_2}{\pi}} \right) \right)$	g  cm
LV Mass Index	LV: (g) BSA: body surface area	$LVMI = \frac{LVMass}{BSA}$	m <sup>2</sup>
Body Surface Area	W: weight (range: 0.5–160 kg) H: height (range: 150–204 cm)	$BSA = 0.007184 (W_{kg}^{0.425} H_{cm}^{0.725})$	m <sup>2</sup>
Fractional Area Change%	LVd: LV diastolic area (cm <sup>2</sup> ) LVs: LV systolic area (cm <sup>2</sup> )	$FAC = \left( \frac{LVd - LVs}{LVd} \right) \cdot 100$	%
Flow Area	d: diameter (cm)	$FlowArea = \pi \cdot \left( \frac{d^2}{4} \right)$	cm <sup>2</sup>
Fractional Shortening%	LVd: diastolic dimension (cm) LVs: systolic dimension (cm)	$FS = \left( \frac{LVd - LVs}{LVd} \right) \cdot 100$	%
Fractional Thickening% - Interventricular Septum	IVSs: interventricular septum in systole IVSd: interventricular septum in diastole	$FT = \left( \frac{IVSs - IVSd}{IVSd} \right) \cdot 100$	%
Fractional Thickening% - Left Ventricular Posterior Wall	LVPWs: left ventricular posterior wall in systole LVPWd: left ventricular posterior wall in diastole	$FT = \left( \frac{LVPWs - LVPWd}{LVPWd} \right) \cdot 100$	%

## Formulas Used for Measurements in the M-Mode Window

### M-Mode Formulas

Name	Variables	Formula	Units
Fractional Shortening %	LVd: diastolic dimension (cm) LVs: systolic dimension (cm)	$FS = \left( \frac{LVd - LVs}{LVd} \right) \cdot 100$	%
Fractional Thickening % - Interventricular Septum	IVSs: interventricular septum in systole IVSd: interventricular septum in diastole	$FT = \left( \frac{IVSs - IVSd}{IVSd} \right) \cdot 100$	%
Fractional Thickening % - Left Ventricular Posterior Wall	LVPWs: left ventricular posterior wall in systole LVPWd: left ventricular posterior wall in diastole	$FT = \left( \frac{LVPWs - LVPWd}{LVPWd} \right) \cdot 100$	%
Volume Cubed	LVID: left ventricle inside diameter	$V = LVID^2$	ml
Volume Teichholz	LVID: left ventricle inside diameter	$V = \left( \frac{7}{2.4 + LVID} (LVID^3) \right)$	ml
Ejection Fraction Cubed	Vs: systolic volume cubed (ml) Vd: diastolic volume cubed (ml)	$EF = \left( \frac{Vd - Vs}{Vd} \right) \cdot 100$	%
Ejection Fraction Teichholz	Vs: systolic volume Teichholz (ml) Vd: diastolic volume Teichholz (ml)	$EF = \left( \frac{Vd - Vs}{Vd} \right) \cdot 100$	%
Stroke Volume Cubed	Vs: systolic volume cubed (ml) Vd: diastolic volume cubed (ml)	$SV = Vd - Vs$	ml
Stroke Volume Teichholz	Vs: systolic volume Teichholz (ml) Vd: diastolic volume Teichholz (ml)	$SV = Vd - Vs$	ml

**M-Mode Formulas (Continued)**

Name	Variables	Formula	Units
Cardiac Output Cubed	SV: stroke volume cubed (ml) HR: heart rate (bpm)	$CO = \frac{(SV \cdot HR)}{1000}$	l/min
Cardiac Output Teichholz	SV: stroke volume Teichholz (ml) HR: heart rate (bpm)	$CO = \frac{(SV \cdot HR)}{1000}$	l/min
Cardiac Index Cubed	CO: Cardiac Output cubed (l/min) BSA: body surface area (m <sup>2</sup> )	$CI = \frac{CO}{BSA}$	l/min/ m <sup>2</sup>
Cardiac Index Teichholz	CO: Cardiac Output Teichholz (l/min) BSA: body surface area (m <sup>2</sup> )	$CI = \frac{CO}{BSA}$	l/min/ m <sup>2</sup>
LV Mass	IVSd: interventricular septum diastole (cm) LVIDd: left ventricle inside diameter diastole LVPWd: left ventricle posterior wall diastole	$LVMass = 0.8(1.04) ((IVSd + LVIDd + LVPWd)^3 - LVIDd^3) + 0.6$	g
LV Mass Index	LV Mass: (g) BSA: body surface area	$LVMI = \frac{LVMass}{BSA}$	g/m <sup>2</sup>
Body Surface Area	W: weight (range: 0.5–160 kg) H: height (range: 150–204 cm)	$BSA = 0.007184(W_{kg}^{0.425} H_{cm}^{0.725})$	m <sup>2</sup>

## Formulas Used for Measurements in Doppler Windows

### Doppler Formulas

Name	Variables	Formula	Units
Pressure Gradient	V: velocity	$PG = 4V^2$	mmHg
Mean Velocity	V: average velocity between two successive velocity trace points (m/s) N: number of velocity trace points $\Delta_{ti}$ : time between two successive velocity trace points (sec)	$V_{mean} = \frac{\sum_{i=1}^{N-1} V_i \Delta_{ti}}{\sum_{i=1}^{N-1} \Delta_{ti}}$	m/s
Mean Pressure Gradient	V: average velocity between two successive velocity trace points (m/s) N: number of velocity trace points $\Delta_{ti}$ : time between two successive velocity trace points (sec)	$P_{mean} = \frac{\sum_{i=1}^{N-1} 4V_i^2 \Delta_{ti}}{\sum_{i=1}^{N-1} \Delta_{ti}}$	mmHg
Time Velocity Integral		$TVI = \text{area under curve}$	cm
Stroke Volume	TVI: time velocity integral (cm) Flow Area: derived from the flow diameter (cm <sup>2</sup> )	$SV = TVI \cdot \text{FlowArea}$  $\frac{TVI}{\text{Flow Area}}$ Aortic: AoV TVI LVOT FA Mitral: MV TVI Mitral FA Pulmonic: PV TVI Pulmonic FA Tricuspid: TV TVI Tricuspid FA	ml
Cardiac Output	SV: stroke volume (ml) HR: heart rate (bpm)	$CO = \frac{SV \cdot HR}{1000}$	l/min
Cardiac Index	CO: Cardiac Output BSA: body surface area (m <sup>2</sup> )	$CI = \frac{CO}{BSA}$	l/min/ m <sup>2</sup>
Pressure Half Time	Vmax: Maximum velocity (m/s) Deceleration Slope (ms <sup>2</sup> )	$PHT = \left( \frac{V_{max} \cdot \left(1 - \frac{1}{\sqrt{2}}\right)}{\text{DecelerationSlope}} \right) \cdot 1000$	ms

Doppler Formulas (Continued)

Name	Variables	Formula	Units
Valve Area by PHT	PHT: Pressure half time (msec)	$VA = \frac{220}{PHT}$	cm <sup>2</sup>
Aortic Valve Area by Continuity Equation Using Vmax	AVA: aortic valve area (cm <sup>2</sup> ) CSA <sub>LVOT</sub> : cross-section area of LVOT (cm <sup>2</sup> ) Vmax <sub>LVOT</sub> : maximum velocity in LVOT (m/s) Vmax <sub>AoV</sub> : maximum velocity across aortic valve (m/s) LVOT: left ventricular outflow tract	$AVA = CSA_{LVOT} \cdot \frac{Vmax_{LVOT}}{Vmax_{AoV}}$	cm <sup>2</sup>
Aortic Valve Area by Continuity Equation Using TVI	AVA: aortic valve area (cm <sup>2</sup> ) CSA <sub>LVOT</sub> : cross-section area of LVOT (cm <sup>2</sup> ) TVI <sub>LVOT</sub> : time velocity integral in LVOT (m) TVI <sub>AoV</sub> : time velocity integral across aortic valve (m) LVOT: left ventricular outflow tract	$AVA = CSA_{LVOT} \cdot \frac{TVI_{LVOT}}{TVI_{AoV}}$	cm <sup>2</sup>
Flow Area	d: diameter (cm)	$FlowArea = \pi \cdot \left(\frac{d^2}{4}\right)$	cm <sup>2</sup>
Mitral Valve Area by Continuity Equation Using Aorta	MVA: mitral valve area (cm <sup>2</sup> ) CSA <sub>LVOT</sub> : cross-section area of LVOT (cm <sup>2</sup> ) TVI <sub>LVOT</sub> : time velocity integral in LVOT (m) TVI <sub>MV</sub> : time velocity integral of mitral valve (m) LVOT: left ventricular outflow tract	$MVA = CSA_{LVOT} \cdot \frac{TVI_{LVOT}}{TVI_{MV}}$	cm <sup>2</sup>
Mitral Valve Area by Continuity Equation Using Pulmonary Artery	MVA: mitral valve area (cm <sup>2</sup> ) CSA <sub>PA</sub> : cross-section area of pulmonary artery (cm <sup>2</sup> ) TVI <sub>PA</sub> : time velocity integral of pulmonary artery (m) TVI <sub>MV</sub> : time velocity integral of mitral valve (m)	$MVA = CSA_{PA} \cdot \frac{TVI_{PA}}{TVI_{MV}}$	cm <sup>2</sup>

Doppler Formulas (Continued)

Name	Variables	Formula	Units
Right Ventricular Systolic Pressure from Tricuspid Regurgitation	$P_{RA}$ : estimated right arterial pressure (mmHg) $V_{max}$ : regurgitant velocity of tricuspid valve (m/s)	$RVSP = P_{RA} + 4V_{max}^2$	mmHg
Right Ventricular Systolic Pressure from Ventricular Septal Defect	$BP_{sys}$ : systolic blood pressure (mmHg) $V_{max}$ : maximum velocity of ventricular septal defect (m/s)	$RVSP = BP_{sys} - 4V_{max}^2$	mmHg
Shunt Ratio	$CO_{Qp}$ : pulmonic cardiac output (l/min) $CO_{Qs}$ : systemic cardiac output (l/min)	$\frac{Qp}{Qs} = \frac{CO_{Qp}}{CO_{Qs}}$	—
Shunt Difference	$CO_{Qp}$ : pulmonic cardiac output (l/min) $CO_{Qs}$ : systemic cardiac output (l/min)	$Qp - Qs = CO_{Qp} - CO_{Qs}$	l/min

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