



User Guide

Volume 2

Terason uSmart3200T and 3200T Plus Technical Manual

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Introduction

This manual includes safety information, technical data, and formulae required for safe and proper use of the Terason uSmart3200T 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 2, [Terason Probes](#), on page 10
- Chapter 3, [Maintenance](#), on page 103
- Chapter 4, [System Safety](#), on page 110
- Chapter 5, [System Specifications](#), on page 165
- Chapter 6, [Electromagnetic Tables](#), on page 168

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

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.

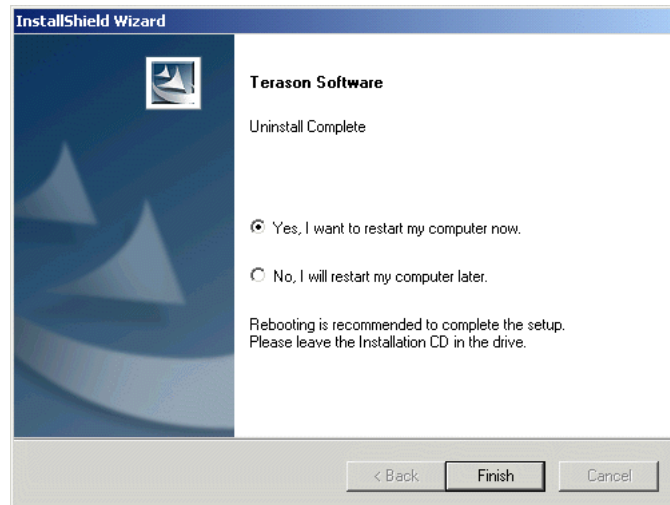
Upgrading Terason Software

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To upgrade to a newer version of the Terason software, complete these steps: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 USB drive** into a USB port on the tablet. The Uninstall dialog opens.
3. Tap **Next>**. The Confirm Uninstall dialog box opens.
4. Tap **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 tap **Yes**.

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

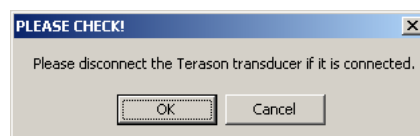
**Uninstall Complete Dialog Box**

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

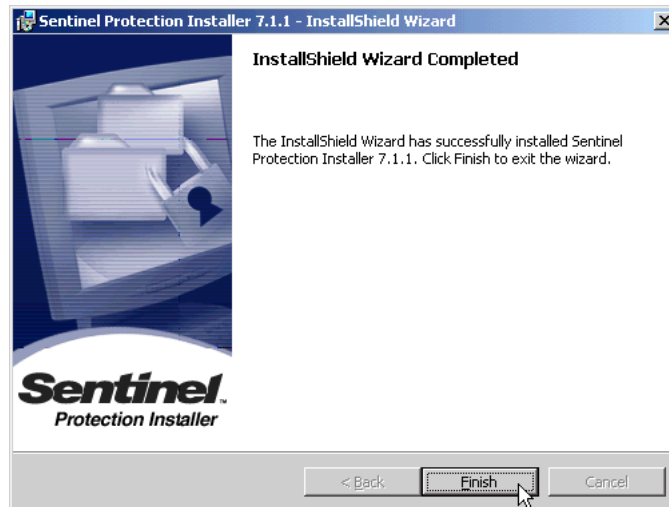
After the tablet finishes starting up, you may have to log on before proceeding.

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

6. Tap **Next>**. The License Agreement dialog appears. Read the License Information carefully.
7. Tap **Yes**. The Choose Destination Location dialog box opens.
8. Tap **Next>** to install the application in the default location. You can tap Browse to select a different location (not recommended). The wizard reminds you to unplug the Terason Probe.

**Reminder to Unplug the Probe**

9. Tap **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 tablet before you use the Terason software.

10. Tap Finish.

Remember to connect the probe.

2 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 110, [Cleaning the Ultrasound System](#) on page 103, and [Ultrasound System Specifications](#) on page 165.

Terason Probe Specifications

Probe	Elements	Description	Applications	
4V2A	64	Phased-array probe with a user-controllable field-of-view	Cardiac	Vascular FAST
5C2A	128	Curved linear array probe with a user-controllable field-of-view	Adult abdominal OB/GYN Fetal heart	Abdominal vascular Renal
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	Obstetric	Gynecological Prostate
8L2	128	Linear wideband array probe with a user-controllable field of view	Carotid Vascular access	Arterial Venous
8TE3	64	Transesophageal Phased-array transducer	Transesophageal cardiac	
8V3A	96	Phased-array-sector probe	Cardiac Vascular	
9MC3	80	Curved-linear probe	Small parts Cardiac Neonatal head	Abdominal Vascular access
10EC4	192	Convex-linear endocavity array probe with a 190° field-of-view	Obstetric	Gynecological Prostate

Terason Probe Specifications (Continued)

Probe	Elements	Description	Applications	
12L5A	128	Linear-array probe	Breast Dialysis access Musculoskeletal Vascular access Carotid Lung	Arterial Neonatal hip Nerve block Testes Thyroid Venous Ophthalmic
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	Abdomenal Pediatric Small organ	Musculoskeletal Peripheral vessel
16HL7	128	Angled-head linear wideband array probe	Venous	Musculoskeletal
16L5	192	Linear wideband array probe	Breast Musculoskeletal Vascular access	Lung Nerve block
PDOF	1	Single-element transducer with a single-point field-of-view	Cardiac	

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.



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.



Warning: To prevent patient injury, remove the 8TE3 probe from the patient before applying a defibrillator.

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.

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 mW/cm², and the global maximum MI must not exceed 0.23. For all other applications, the global maximum derated I_{SPTA} must not exceed 720 mW/cm² 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 14](#)
- 5C2A - see [page 19](#)
- 8BP4 (CLA) - [page 23](#)
- 8BP4 (Linear) - [page 27](#)
- 8EC4A - see [page 31](#)
- 8L2 - see [page 35](#)
- 8TE3 see [page 39](#)
- 8V3A - see [page 44](#)
- 9MC3 - see [page 49](#)
- 10EC4 - see [page 53](#)
- 12L5A - see [page 57](#)
- 12L5A - Ophthalmic - see [page 61](#)
- 14L3 - see [page 65](#)
- 14L3 - Ophthalmic - see [page 70](#)
- 15L4 - see [page 74](#)
- 15L4 - Ophthalmic - [page 78](#)
- 15L4A - [page 82](#)
- 15L4A - Ophthalmic - [page 86](#)
- 15WL4 - [page 90](#)
- 16HL7 - see [page 94](#)
- 16L5 - see [page 98](#)
- PDOF - see [page 102](#)

Acoustic Output Tables for Terason Probes

Acoustic Output Reporting Table for Track 3 for the 4V2A Probe
(Terason uSmart3200T 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	2.46			2.46			3.98	
Index Component Value				1.57	2.46	-	-	2.46	-	-	3.98	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.62								
	W_o	P	(mW)		156.6	-		156.6	-		198.4	-
	W_{o1}	P_{txt}	(mW)		156.6	-		156.6	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)									
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.9			-					
	Z_{sp}	Z_b	(cm)									
	$z@P_{II\max}$	Z_{pii}	(cm)	3.8								
	$z@P_{II3\max}$	Z_{MI}	(cm)	3.6								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)									
	D_{eq}	D_{eq}	(cm)								1.25	-
	f_c	f_{awf}	(MHz)	2.80	3.29	-		3.29	-		1.75	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm) Y (cm)		1.02 1.20	-		1.02 1.20	-		1.02 1.20	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.54								
	PRF	prf	(Hz)	77.5								
	SRF	srf	(Hz)	77.5								
		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 ²)	36.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	73.3								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	3.71								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	278.8								
	Focal Length	Focal Length	FL_x (cm) FL_y (cm)	4.0 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 uSmart3200T 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	2.44			2.54			3.98	
Index Component Value				1.57	2.30	0.14	0.09	2.30	0.14	0.24	3.75	0.23
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r.3}$	p_{ra} at Z_{MI}	(MPa)	2.62								
	W_o	P	(mW)		147.1	9.2		147.1	9.2		186.7	11.7
	W_{o1}	P_{bxt}	(mW)		147.1	9.2		147.1	9.2			
	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)				6.0					
	$I_{spta.3} @ Z_{sp}$	$I_{spta.a}$ at Z_b	(mW/cm ²)							35.0		
	Z_1	Z_s	(cm)				1.9					
	Z_{bp}	Z_{bp}	(cm)	1.9			1.9			1.9		
	Z_{sp}	Z_b	(cm)							3.5		
	$z@P_{II\max}$	Z_{pii}	(cm)	3.8			4.2			4.2		
	$z@P_{II3\max}$	Z_{MI}	(cm)	3.6								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.39		
	D_{eq}	D_{eq}	(cm)								1.25	1.25
	f_c	f_{awf}	(MHz)	2.80	3.29	3.29		3.29	3.29		1.75	1.75
	Dim of A_{aprt}	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
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.54								
	PRF	p_{rr}	(Hz)	570								
	SRF	s_{rr}	(Hz)	142.5								
		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 ²)	82.3								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	166.2								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	3.71								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.36		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	278.8								
	Focal Length	Focal Length	FL_x (cm)	4.0			4.0			4.0		
			FL_y (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 uSmart3200T 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	2.14			2.14			4.22	
Index Component Value				1.56	2.14	-	-	2.14	-	-	4.22	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.21								
	W_o	P	(mW)		168.8	-		168.8	-		266.2	-
	W_{o1}	P_{txt}	(mW)		168.8	-		168.8	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	2.4			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	4.8			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	4.6								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.58	-
	f_c	f_{awf}	(MHz)	1.99	2.65	-		2.65	-		1.99	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.02	-		1.02	-		1.63	-
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t_d	(μsec)	1.91								
	PRF	prf	(Hz)	7540								
	SRF	srf	(Hz)	45.4								
		n_{pps}		4								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	331.9								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	627.5								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	3.0								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	255.5								
	Focal Length	Focal Length	FLx (cm)	7.0			-			-		
Operating Control Conditions	Control 1			X								
	Control 2					X			X			
	Control 3										X	
	Control 4											

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 = 6.3 Hz, Color ROI = 5.47 cm, Packet size = 14, transmit pulses = 10, PRF = 13150 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 uSmart3200T 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	-	1.84	1.87	-	1.56	5.06	0.24	3.90
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.43								
	W_o	P	(mW)		-	241.8		-	246.3		10.6	237.9
	W_{o1}	P_{txt}	(mW)		-	161.2		-	164.2			
	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)				164.3					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							511.9		
	Z_1	Z_s	(cm)				2.3					
	Z_{bp}	Z_{bp}	(cm)	2.0			2.3			2.3		
	Z_{sp}	Z_b	(cm)							4.9		
	$z@P_{II,max}$	Z_{pii}	(cm)	3.9			5.6			5.8		
	$z@P_{II,3,max}$	Z_{MI}	(cm)	3.8								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.56		
	D_{eq}	D_{eq}	(cm)								1.08	1.53
	f_c	f_{awf}	(MHz)	2.40	-	2.39		-	1.99		2.43	1.99
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.52		-	1.52		0.76	1.52
			Y (cm)		-	1.20		-	1.20		1.20	1.20
Mode Components				D	-	D		-	D		B	D
Other Information	PD	t_d	(μsec)	3.18								
	PRF	prr	(Hz)	700								
	SRF	srr	(Hz)	-								
		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 ²)	576.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	973.1								
	$p_{r@P_{II,max}}$	p_r at Z_{pii}	(MPa)	3.31								
	$d_{eq@P_{II,max}}$	d_{eq} at Z_{pii}	(cm)							0.53		
	$I_{PA3} @ M_{I,max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	259.1								
	Focal Length	Focal Length	FL_x (cm)	5.5			13.0			16.5		
			FL_y (cm)	5.7			5.7			5.7		
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				
	Control 4										X	

NOTE 1: The non-scanned W_o was used to calculate the TIS since NEMA has not adopted the IEC calculation.

- 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 uSmart3200T 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	1.03			4.38			3.17	
Index Component Value				0.10	-	1.03	0.87	-	1.03	4.38	-	3.17
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.13								
	W_o	P	(mW)		-	129.7		-	129.7		-	129.7
	W_{o1}	P_{bxt}	(mW)		-	129.7		-	129.7			
	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)				109.2					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							501.2		
	z_1	z_s	(cm)				1.5					
	z_{bp}	z_{bp}	(cm)	1.5			1.5			1.5		
	z_{sp}	z_b	(cm)							2.7		
	$z@P_{II,max}$	Z_{pii}	(cm)	3.2			3.2			3.2		
	$z@P_{II,3,max}$	Z_{MI}	(cm)	2.8								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.50		
	D_{eq}	D_{eq}	(cm)								-	1.02
	f_c	f_{awf}	(MHz)	1.67	-	1.67		-	1.67		-	1.67
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	0.69		-	0.69		-	0.69
			Y (cm)		-	1.20		-	1.20		-	1.20
Mode Components				cwD	-	cwD		-	cwD		-	cwD
Other Information	PD	t_d	(μsec)	-								
	PRF	p_{rr}	(Hz)	-								
	SRF	s_{rr}	(Hz)	-								
		n_{pps}		-								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	514.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	709.6								
	$p_{r@P_{II,max}}$	p_r at z_{pii}	(MPa)	0.16								
	$d_{eq@P_{II,max}}$	d_{eq} at z_{pii}	(cm)							0.49		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	-								
	Focal Length	Focal Length	FL_x (cm)	4.0			16.0			16.0		
			FL_y (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 uSmart3200T 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	0.60			0.60			Note 1	
Index Component Value				1.48	0.60	-	-	0.60	-	-	-	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.22								
	W_o	P	(mW)		216.8	-		216.8	-		-	-
	W_{o1}	P_{txt}	(mW)		56.2	-		56.2	-			
	min of [$W_{s,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{s,3}(Z_s)$, $I_{ta,3}(Z_s)$ x 1cm ²]	(mW)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	2.2			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II,max}$	Z_{pii}	(cm)	4.4			-			-		
	$z@P_{II,3,max}$	Z_{MI}	(cm)	4.3								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	2.24	2.26	-		2.26	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		4.35	-		4.35	-		-	-
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t_d	(μsec)	0.94								
	PRF	prf	(Hz)	24.8								
	SRF	srf	(Hz)	24.8								
		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 ²)	49.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	96.9								
	$pr@P_{II,max}$	p_r at Z_{pii}	(MPa)	3.01								
	$d_{eq}@P_{II,max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	264.8								
	Focal Length	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 transducer 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 uSmart3200T 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	0.71			1.22			Note 1	
Index Component Value				1.48	0.40	0.16	0.30	0.42	0.18	0.80	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r.3}$	p_{ra} at Z_{MI}	(MPa)	2.22								
	W_o	P	(mW)		150.4	50.7		152.4	21.8		-	-
	W_{o1}	P_{txt}	(mW)		39.5	15.9		39.6	16.7			
	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)				29.3					
	$I_{spta.3} @ Z_{sp}$	$I_{spta.a}$ at Z_b	(mW/cm ²)							138.3		
	Z_1	Z_s	(cm)				3.6					
	Z_{bp}	Z_{bp}	(cm)	2.2			3.6			2.2		
	Z_{sp}	Z_b	(cm)							4.1		
	$z@P_{II\max}$	Z_{pii}	(cm)	4.4			15.2			4.4		
	$z@P_{II3\max}$	Z_{MI}	(cm)	4.3								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.32		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	2.24	2.15	2.15		2.26	2.24		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		6.40	3.60		4.35	1.30		-	-
					1.30	1.30		1.30	1.30		-	-
Mode Components				B+M	B	M		B	M		-	-
Other Information	PD	t_d	(μsec)	0.94								
	PRF	prr	(Hz)	570								
	SRF	srr	(Hz)	71.3								
		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 ²)	212.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	419.6								
	$pr@P_{II\max}$	p_r at Z_{pii}	(MPa)	3.01								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.31		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	264.8								
	Focal Length	Focal Length	FL_x (cm)	6.0			16.0			6.0		
							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 transducer 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 uSmart3200T 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	1.52			1.52			Note 1	
Index Component Value				1.53	1.52	-	-	1.52	-	-	-	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.30								
	W_o	P	(mW)		139.7	-		139.7	-		-	-
	W_{o1}	P_{txt}	(mW)		113.9	-		113.9	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	2.2			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	4.2			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	4.1								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	2.27	2.81	-		2.81	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.50	-		1.50	-		-	-
Mode Components				rD	B+rD	-		B+rD	-		-	-
Other Information	PD	t_d	(μsec)	1.23								
	PRF	prf	(Hz)	250								
	SRF	srr	(Hz)	14.2								
		n_{pps}		16								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	296.0								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	568.6								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	3.09								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	380.7								
	Focal Length	Focal Length	FLx (cm)	6.0			-			-		
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3											

NOTE 1: Information need not be provided regarding TIC for any transducer 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 uSmart3200T 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	-	0.99	1.35	-	1.10	3.45	-	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.30								
	W_o	P	(mW)		-	188.4		-	90.8		-	-
	W_{o1}	P_{txt}	(mW)		-	74.1		-	90.8			
	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)				101.7					
	$I_{spta,3} @ Z_{sp}$	$I_{spta, a}$ at Z_b	(mW/cm ²)							419.9		
	z_1	z_s	(cm)				3.2					
	z_{bp}	z_{bp}	(cm)	2.2			3.2			1.4		
	z_{sp}	z_b	(cm)							1.4		
	$z@PII_{max}$	Z_{pii}	(cm)	4.2			12.0			4.1		
	$z@PII_{3max}$	Z_{MI}	(cm)	4.1								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.46		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	2.27	-	2.79		-	2.54		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	2.90		-	0.50		-	-
			Y (cm)		-	1.30		-	1.30		-	-
Mode Components				D	-	D		-	D		-	-
Other Information	PD	t_d	(μsec)	2.88								
	PRF	prr	(Hz)	350								
	SRF	srr	(Hz)	-								
		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 ²)	397.3								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	765.1								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	3.10								
	$d_{eq}@PII_{max}$	d_{eq} at z_{pii}	(cm)							0.40		
	$I_{PA3} @ MI_{max}$	$I_{pa, a}$ at $z_{pii, a}$	(W/cm ²)	394.3								
	Focal Length	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 transducer 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	1.46								
	W _o	P	(mW)		21.7	-		21.7	-		-	-
	W _{o1}	P _{txt}	(mW)		11.8	-		11.8	-			
	min of [W ₃ (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _o (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	1.1			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	2.6			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	2.4								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	5.85	5.78	-		5.78	-		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		2.52	-		2.52	-		-	-
Y (cm)				0.70	-		0.70	-		-	-	
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t _d	(μsec)	0.20								
	PRF	prr	(Hz)	150								
	SRF	srr	(Hz)	150								
		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 ²)	16.8								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	44.6								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.27								
	deq@PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	165.5								
	Focal Length	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 transducer 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 uSmart3200T 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	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	1.46								
	W_o	P	(mW)		18.0	0.8		18.0	0.8		-	-
	W_{o1}	P_{txt}	(mW)		9.8	0.8		9.8	0.8			
	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)				0.4					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							31.0		
	z_1	z_s	(cm)				1.2					
	z_{bp}	z_{bp}	(cm)	1.1			1.2			1.2		
	z_{sp}	z_b	(cm)							2.5		
	$z @ PII_{max}$	Z_{pii}	(cm)	2.6			2.9			2.9		
	$z @ PII_{3max}$	Z_{MI}	(cm)	2.4								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.16		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	5.85	5.78	5.78		5.78	5.78		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		2.52	0.68		2.52	0.68		-	-
			Y (cm)		0.70	0.70		0.70	0.70		-	-
Mode Components				B+M	B	M		B	M		-	-
Other Information	PD	t_d	(μsec)	0.20								
	PRF	prr	(Hz)	570								
	SRF	srr	(Hz)	142.5								
		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 ²)	25.7								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	69.7								
	$pr @ PII_{max}$	p_r at z_{pii}	(MPa)	2.00								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.15		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	121.0								
	Focal Length	Focal Length	FLx (cm)	2.5			3.5			3.5		
			FLy (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 transducer 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	1.11								
	W _o	P	(mW)		33.4	-		33.4	-		-	-
	W _{o1}	P _{txt}	(mW)		30.1	-		30.1	-			
	min of [W _{.3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta, α} (Z _s)x 1cm ²]	(mW)				-					
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	z _s	(cm)				-					
	Z _{bp}	z _{bp}	(cm)	1.1			-			-		
	Z _{sp}	z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	2.4			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	2.3								
	d _{eq} (Z _{sp})	d _{eq} (z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	4.77	4.77	-		4.77	-		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.41	-		1.41	-		-	-
Y (cm)				0.70	-		0.70	-		-	-	
Mode Components				rD	B+rD	-		B+rD	-		-	-
Other Information	PD	t _d	(μsec)	0.98								
	PRF	prr	(Hz)	13500								
	SRF	srr	(Hz)	82.5								
		n _{pps}		5								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta, a @ Z_{pii, a} or Z_{sii, a}}	(mW/cm ²)	199.2								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	425.4								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	1.58								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	75.1								
	Focal Length	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 T/C for any transducer 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 uSmart3200T 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	0.68			1.54			Note 1	
Index Component Value				0.91	-	0.68	0.41	-	0.60	1.54	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.00								
	W_o	P	(mW)		-	30.0		-	26.4		-	-
	W_{o1}	P_{txt}	(mW)		-	28.3		-	26.4			
	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)				18.4					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							495.7		
	z_1	z_s	(cm)				2.0					
	z_{bp}	z_{bp}	(cm)	1.1			1.5			1.2		
	z_{sp}	z_b	(cm)							2.4		
	$z @ PII_{max}$	z_{pii}	(cm)	2.4			3.8			2.6		
	$z @ PII_{3max}$	Z_{MI}	(cm)	2.3								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.18		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.77	-	4.73		-	4.77		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.07		-	0.68		-	-
			Y (cm)		-	0.70		-	0.70		-	-
Mode Components				D	-	D		-	D		-	-
Other Information	PD	t_d	(μsec)	1.77								
	PRF	prf	(Hz)	1250								
	SRF	srr	(Hz)	-								
		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 ²)	526.1								
	$I_{spta} @ Z_{pii}$ or z_{sii}	$I_{spta} @ z_{pii}$ or z_{sii}	(mW/cm ²)	1138.7								
	$p_r @ PII_{max}$	p_r at z_{pii}	(MPa)	2.85								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.17		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	238.3								
	Focal Length	Focal Length	FLx (cm)	2.5			8.0			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 T/C for any transducer 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 = 5.0 mm, SV Depth = 8.0 cm, PRF = 1750 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.06								
	W _o	P	(mW)		51.3	-		51.3	-		-	-
	W _{o1}	P _{txt}	(mW)		12.8	-		12.8	-			
	min of [W _{.3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	z _s	(cm)				-					
	Z _{bp}	z _{bp}	(cm)	0.9			-			-		
	Z _{sp}	z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.6			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	1.6								
	d _{eq} (z _{sp})	d _{eq} (z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	6.02	5.10	-		5.10	-		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		5.38	-		5.38	-		-	-
Y (cm)				0.50	-		0.50	-		-	-	
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t _d	(μsec)	0.14								
	PRF	prr	(Hz)	121.4								
	SRF	srr	(Hz)	121.4								
		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 ²)	28.8								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	57.7								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.81								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	417.2								
	Focal Length	Focal Length	FL _x (cm)	2.5			-			-		
			FL _y (cm)	1.5			-			-		
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3											

NOTE 1: Information need not be provided regarding T/C for any transducer 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 uSmart3200T 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	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.06								
	W_o	P	(mW)		41.9	3.5		41.9	3.5		-	-
	W_{o1}	P_{txt}	(mW)		10.5	0.9		10.5	0.9			
	min of [$W_{r,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{r,3}(Z_s)$, $I_{ta,3}(Z_s) \times 1 \text{ cm}^2$]	(mW)				1.5					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							5.1		
	Z_1	Z_s	(cm)				2.4					
	Z_{bp}	Z_{bp}	(cm)	0.9			2.4			2.4		
	Z_{sp}	Z_b	(cm)							2.4		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.6			8.1			8.1		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.6								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.63		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	6.02	5.10	5.10		5.10	5.10		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		5.38	4.03		5.38	4.03		-	-
						Y (cm)			Y (cm)		-	-
Mode Components				B+M	B	M		B	M		-	-
Other Information	PD	t_d	(μsec)	0.14								
	PRF	prf	(Hz)	570								
	SRF	srr	(Hz)	95.0								
		n_{pps}		1								
	$I_{spta,3} @ Z_{pii,3}$ or $I_{spt,3}$	$I_{spta,a} @ Z_{pii,a}$ or $I_{spt,a}$	(mW/cm ²)	57.2								
	$I_{spta} @ Z_{pii}$ or Z_{spt}	$I_{spta} @ Z_{pii}$ or Z_{spt}	(mW/cm ²)	114.6								
	$p_r@P_{II\max}$	p_r at Z_{pii}	(MPa)	2.81								
	$d_{eq}@P_{II\max}$	d_{eq} at Z_{pii}	(cm)							0.47		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	417.2								
	Focal Length	Focal Length	FLx (cm)	2.5			8.0			8.0		
							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 transducer 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	1.44								
	W_o	P	(mW)		35.7	-		35.7	-		-	-
	W_{o1}	P_{txt}	(mW)		25.9	-		25.9	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.9			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	1.55			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.50								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.78	4.78	-		4.78	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		5.38	-		5.38	-		-	-
Mode Components				rD	B+rD	-		B+rD	-		-	-
Other Information	PD	t_d	(μsec)	0.79								
	PRF	prf	(Hz)	20520								
	SRF	srf	(Hz)	100.1								
		n_{pps}		4								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	343.9								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	567.2								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	1.81								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	111.9								
	Focal Length	Focal Length	FLX (cm)	2.5			-			-		
			FLY (cm)	1.5			-			-		
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3											

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 uSmart3200T 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
Maximum Index Value				1.21	0.95 (Note 2)			1.81			Note 1	
Index Component Value				1.21	-	0.95	0.56	-	0.64	1.81	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.64								
	W _o	P	(mW)		-	41.9		-	32.8		-	-
	W _{o1}	P _{txt}	(mW)		-	24.0		-	28.1			
	min of [W _{.3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)				24.8					
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							384.4		
	Z ₁	Z _s	(cm)				1.60					
	Z _{bp}	Z _{bp}	(cm)	0.90			1.60			1.30		
	Z _{sp}	Z _b	(cm)							1.30		
	z@P _{II} _{max}	Z _{pii}	(cm)	1.55			4.30			3.05		
	z@P _{II} _{3max}	Z _{MI}	(cm)	1.50								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							0.26		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	4.78	-	4.76		-	4.77		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		-	1.76		-	1.18		-	-
			Y (cm)		-	0.50		-	0.50		-	-
Mode Components				D	-	D		-	D		-	-
Other Information	PD	t _d	(μsec)	1.77								
	PRF	p _{rr}	(Hz)	700								
	SRF	s _{rr}	(Hz)	-								
		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 ²)	426.9								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	709.3								
	pr@P _{II} _{max}	p _r at z _{pii}	(MPa)	3.31								
	deq@P _{II} _{max}	d _{eq} at z _{pii}	(cm)							0.20		
	I _{PA3 @M} _{max}	I _{pa, a} at z _{pii, a}	(W/cm ²)	344.2								
	Focal Length	Focal Length	FL _x (cm)	2.5			4.5			3.5		
			FL _y (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 transducer assembly not intended for transcranial or neonatal cephalic uses.

NOTE 2: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 4.5 cm, PRF = 13600 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	3.86								
	W _o	P	(mW)		25.1	-		25.1	-		-	-
	W _{o1}	P _{txt}	(mW)		22.8	-		22.8	-			
	min of [W _{.3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)				-					
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	z _s	(cm)				-					
	Z _{bp}	z _{bp}	(cm)	0.9			-			-		
	Z _{sp}	z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.6			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	1.5								
	d _{eq} (z _{sp})	d _{eq} (z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	6.93	4.94	-		4.94	-		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.33	-		1.33	-		-	-
Y (cm)				0.50	-		0.50	-		-	-	
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t _d	(μsec)	0.21								
	PRF	prr	(Hz)	150.0								
	SRF	srr	(Hz)	150.0								
		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 ²)	55.4								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	116.2								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	5.19								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	590.9								
	Focal Length	Focal Length	FL _x (cm)	1.5			-			-		
FL _y (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 transducer 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 uSmart3200T 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	-	-	
	USFDA Track 3	IEC											
Associated Acoustic Parameter	P _{r.3}	p _{ra} at Z _{MI}	(MPa)	3.86									
	W _o	P	(mW)		22.6	2.8		22.6	2.8		-	-	
	W _{o1}	P _{txt}	(mW)		19.2	2.8		19.2	2.8				
	min of [W _{.3} (Z ₁), I _{TA.3} (Z ₁)]	Min of [P _α (Z _s), I _{ta, α} (Z _s)x 1cm ²]	(mW)			1.9							
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)						31.4				
	Z ₁	Z _s	(cm)				1.2						
	Z _{bp}	Z _{bp}	(cm)	0.9			1.2		1.2				
	Z _{sp}	Z _b	(cm)						2.3				
	z@PII _{max}	Z _{pii}	(cm)	1.6			2.6		2.6				
	z@PII _{3max}	Z _{MI}	(cm)	1.5									
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)						0.23				
	D _{eq}	D _{eq}	(cm)								-	-	
	f _c	f _{awf}	(MHz)	6.93	4.92	4.92		4.92	4.92		-	-	
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.62	0.96		1.62	0.96		-	-	
			Y (cm)		0.50	0.50		0.50	0.50		-	-	
Mode Components				B+M	B	M		B	M		-	-	
Other Information	PD	t _d	(μsec)	0.21									
	PRF	prr	(Hz)	570									
	SRF	srr	(Hz)	142.5									
		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 ²)	72.1									
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	153.0									
	pr@PII _{max}	p _r at z _{pii}	(MPa)	5.19									
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)						0.22				
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	590.9									
	Focal Length	Focal Length	FL _x (cm)	1.5			3.5			3.5			
		FL _y (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 transducer 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r.3}$	p_{ra} at Z_{MI}	(MPa)	2.89								
	W_o	P	(mW)		30.5	-		30.5	-		-	-
	W_{o1}	P_{txt}	(mW)		29.7	-		29.7	-			
	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)				-					
	$I_{spta.3} @ Z_{sp}$	$I_{spta.a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.9			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	1.5			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.4								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	5.93	4.97	-		4.97	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.19	-		1.19	-		-	-
			Y (cm)		0.50	-		0.50	-		-	-
Mode Components				rD	B+rD	-		B+rD	-		-	-
Other Information	PD	t_d	(μsec)	0.64								
	PRF	prf	(Hz)	1250								
	SRF	srr	(Hz)	8.6								
		n_{pps}		7								
	$I_{spta.3} @ Z_{pii.3}$ or $Z_{sii.3}$	$I_{spta.a} @ Z_{pii.a}$ or $Z_{sii.a}$	(mW/cm ²)	42.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	75.0								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	3.74								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	330.5								
	Focal Length	Focal Length	FL_x (cm)	1.5			-			-		
			FL_y (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 transducer 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 uSmart3200T 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	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.56								
	W_o	P	(mW)		-	27.3		-	22.5		-	-
	W_{o1}	P_{txt}	(mW)		-	27.3		-	22.5			
	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)				18.4					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							431.7		
	z_1	z_s	(cm)				1.55					
	z_{bp}	z_{bp}	(cm)	0.9			1.15			.60		
	z_{sp}	z_b	(cm)							.60		
	$z@P_{II\max}$	z_{pii}	(cm)	1.7			1.65			1.45		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.6								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.24		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	5.93	-	4.99		-	4.00		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	0.90		-	0.27		-	-
			Y (cm)		-	0.50		-	0.50		-	-
Mode Components				D	-	D		-	D		-	-
Other Information	PD	t_d	(μsec)	1.14								
	PRF	p_{rr}	(Hz)	800								
	SRF	s_{rr}	(Hz)	-								
		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 ²)	425.4								
	$I_{spta} @ Z_{pii}$ or z_{sii}	$I_{spta} @ z_{pii}$ or z_{sii}	(mW/cm ²)	820.4								
	$p_{r@P_{II\max}}$	p_r at z_{pii}	(MPa)	4.80								
	$d_{eq@P_{II\max}}$	d_{eq} at z_{pii}	(cm)							0.21		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	468.2								
	Focal Length	Focal Length	FL_x (cm)	2.5			4.5			0.8		
			FL_y (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 transducer 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 uSmart3200T 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	-	
	USFDA Track 3	IEC											
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.13									
	W _o	P	(mW)		79.6	-		79.6	-		101.1	-	
	W _{o1}	P _{txt}	(mW)		32.5	-		32.5	-				
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-							
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-			
	Z ₁	Z _s	(cm)				-						
	Z _{bp}	Z _{bp}	(cm)	1.2			-			-			
	Z _{sp}	Z _b	(cm)							-			
	z@PII _{max}	Z _{pii}	(cm)	2.4			-			-			
	z@PII _{3max}	Z _{MI}	(cm)	2.2									
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-			
	D _{eq}	D _{eq}	(cm)								1.71	-	
	f _c	f _{awf}	(MHz)	5.36	5.32	-		5.32	-		5.07	-	
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		3.84	-		3.84	-		3.84	-	
		Y (cm)		0.60	-		0.60	-		0.60	-		
Mode Components				B	B	-		B	-		B	-	
Other Information	PD	t _d	(μsec)	0.20									
	PRF	prr	(Hz)	47.3									
	SRF	srr	(Hz)	47.3									
		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 ²)	27.3									
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	61.7									
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.98									
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-			
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	378.1									
	Focal Length	Focal Length	FL _x (cm)	2.4			-			-			
		FL _y (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 uSmart3200T 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
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r.3}$	p_{ra} at Z_{MI}	(MPa)	2.13								
	W_o	P	(mW)		76.4		1.9	76.4		1.9	92.9	2.9
	W_{o1}	P_{txt}	(mW)		31.2		0.8	31.2		0.8		
	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)				0.9					
	$I_{spta.3} @ Z_{sp}$	$I_{spta.a}$ at Z_b	(mW/cm ²)							2.9		
	z_1	z_s	(cm)				2.0					
	z_{bp}	z_{bp}	(cm)	1.2			2.0			2.0		
	z_{sp}	z_b	(cm)							2.1		
	$z@PII_{max}$	Z_{pii}	(cm)	2.4			6.4			6.4		
	$z@PII_{3max}$	Z_{MI}	(cm)	2.2								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.63		
	D_{eq}	D_{eq}	(cm)								1.71	1.64
	f_c	f_{awf}	(MHz)	5.36	5.32		5.32	5.32		5.32	5.13	5.13
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm) Y (cm)		3.84 0.60	2.31 0.60		3.84 0.60	2.31 0.60		3.84 0.60	3.51 0.60
Mode Components				B+M	B		M	B		M	B	M
Other Information	PD	t_d	(μsec)	0.20								
	PRF	prr	(Hz)	280								
	SRF	srr	(Hz)	70.0								
		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 ²)	48.9								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	110.9								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	2.98								
	$d_{eq@PII_{max}}$	d_{eq} at z_{pii}	(cm)							0.32		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	378.1								
	Focal Length	Focal Length	FL_x (cm) FL_y (cm)	2.4 4.0			6.5 4.0			6.5 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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	1.63								
	W_o	P	(mW)		110.9	-		110.9	-		126.7	-
	W_{o1}	P_{txt}	(mW)		45.3	-		45.3	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.2			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	2.2			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	2.2								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.71	-
	f_c	f_{awf}	(MHz)	4.28	4.28	-		4.28	-		3.78	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
					Y (cm)	-		0.60	-		0.60	-
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t_d	(μsec)	2.34								
	PRF	prf	(Hz)	250								
	SRF	srr	(Hz)	14.5								
		n_{pps}		14								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	365.5								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	689.1								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	2.13								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	150.8								
	Focal Length	Focal Length	FLx (cm)	2.4			-			-		
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 = 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 uSmart3200T 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
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.50								
	W_o	P	(mW)		-	129.1		-	81.9		-	129.1
	W_{o1}	P_{txt}	(mW)		-	34.3		-	43.5			
	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)				59.9					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							225.9		
	z_1	z_s	(cm)				2.6					
	z_{bp}	z_{bp}	(cm)	1.2			2.6			1.8		
	z_{sp}	z_b	(cm)							2.15		
	$z @ PII_{max}$	z_{pii}	(cm)	2.1			10.2			5.4		
	$z @ PII_{3max}$	Z_{MI}	(cm)	2.1								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.50		
	D_{eq}	D_{eq}	(cm)								-	1.71
	f_c	f_{awf}	(MHz)	3.19	-	4.27		-	4.28		-	4.27
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	3.84		-	1.92		-	3.84
			Y (cm)		-	0.60		-	0.60		-	0.60
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	2.37								
	PRF	prr	(Hz)	400								
	SRF	srr	(Hz)	-								
		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 ²)	364.0								
	$I_{spta} @ z_{pii}$ or z_{sii}	$I_{spta} @ z_{pii}$ or z_{sii}	(mW/cm ²)	593.5								
	$pr @ PII_{max}$	p_r at z_{pii}	(MPa)	3.15								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.30		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	409.0								
	Focal Length	Focal Length	FL_x (cm)	2.4			10.0			5.6		
			FL_y (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 Transducer
(Terason uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r.3}$	p_{ra} at Z_{MI}	(MPa)	1.31								
	W_o	P	(mW)		9.1	-		9.1	-		-	-
	W_{o1}	P_{txt}	(mW)		9.0	-		9.0	-			
	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)				-					
	$I_{spta.3} @ Z_{sp}$	$I_{spta.a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.4			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	2.8			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	2.4								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.41	4.78	-		4.78	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.02	-		1.02	-		-	-
			Y (cm)		0.91	-		0.91	-		-	-
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t_d	(μsec)	0.15								
	PRF	prr	(Hz)	150								
	SRF	srr	(Hz)	150								
		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 ²)	14.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	29.8								
	$pr@P_{II\max}$	p_r at Z_{pii}	(MPa)	1.79								
	$d_{eq}@P_{II\max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	126.9								
	Focal Length	Focal Length	FL_x (cm)	3.0			-			-		
			FL_y (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 transducer 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 Transducer
(Terason uSmart3200T 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	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	1.31								
	W_o	P	(mW)		9.0	0.3		9.0	0.3		-	-
	W_{o1}	P_{txt}	(mW)		8.9	0.3		8.9	0.3			
	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)				0.2					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							1.0		
	z_1	z_s	(cm)				1.6					
	z_{bp}	z_{bp}	(cm)	1.4			1.6			1.6		
	z_{sp}	z_b	(cm)							4.0		
	$z@PII_{max}$	Z_{pii}	(cm)	2.8			4.6			4.6		
	$z@PII_{3max}$	Z_{MI}	(cm)	2.4								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.31		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.41	4.75	4.75		4.75	4.75		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.02	1.02		1.02	1.02		-	-
			Y (cm)		0.91	0.91		0.91	0.91		-	-
Mode Components				B+M	B	M		B	M		-	-
Other Information	PD	t_d	(μsec)	0.15								
	PRF	prr	(Hz)	210								
	SRF	srr	(Hz)	52.5								
		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 ²)	9.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	19.2								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	1.79								
	$d_{eq@PII_{max}}$	d_{eq} at z_{pii}	(cm)							0.27		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	126.9								
	Focal Length	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 transducer 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 Transducer
(Terason uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r.3}$	p_{ra} at Z_{MI}	(MPa)	1.04								
	W_o	P	(mW)		13.8	-		13.8	-		-	-
	W_{o1}	P_{txt}	(mW)		13.5	-		13.5	-			
	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)				-					
	$I_{spta.3} @ Z_{sp}$	$I_{spta.a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.6			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	2.9			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	2.6								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	3.33	3.33	-		3.33	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.02	-		1.02	-		-	-
			Y (cm)		0.91	-		0.91	-		-	-
Mode Components				rD	B+rD	-		B+rD	-		-	-
Other Information	PD	t_d	(μsec)	1.43								
	PRF	prf	(Hz)	2780								
	SRF	srr	(Hz)	14.7								
		n_{pps}		6								
	$I_{spta.3} @ Z_{pii.3}$ or $Z_{sii.3}$	$I_{spta.a} @ Z_{pii.a}$ or $Z_{sii.a}$	(mW/cm ²)	20.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	36.2								
	$pr@P_{II\max}$	p_r at Z_{pii}	(MPa)	1.37								
	$d_{eq}@P_{II\max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa.a}$ at $Z_{pii.a}$	(W/cm ²)	43.4								
	Focal Length	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 transducer 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 Transducer
(Terason uSmart3200T 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	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	1.85								
	W_o	P	(mW)		-	14.4		-	14.4		-	-
	W_{o1}	P_{txt}	(mW)		-	14.2		-	14.2			
	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)				10.0					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							175.2		
	Z_1	Z_s	(cm)				1.6					
	Z_{bp}	Z_{bp}	(cm)	1.6			1.6			1.6		
	Z_{sp}	Z_b	(cm)							2.6		
	$z@P_{II\max}$	Z_{pii}	(cm)	2.9			2.9			2.9		
	$z@P_{II3\max}$	Z_{MI}	(cm)	2.6								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.24		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	3.33	-	3.33		-	3.33		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.02		-	1.02		-	-
			Y (cm)		-	0.91		-	0.91		-	-
Mode Components				D	-	D		-	D		-	-
Other Information	PD	t_d	(μsec)	2.29								
	PRF	prr	(Hz)	500								
	SRF	srr	(Hz)	-								
		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 ²)	167.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	313.9								
	$pr@P_{II\max}$	p_r at Z_{pii}	(MPa)	2.44								
	$d_{eq}@P_{II\max}$	d_{eq} at Z_{pii}	(cm)							0.24		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	145.7								
	Focal Length	Focal Length	FL_x (cm)	4.0			4.0			4.0		
			FL_y (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 transducer 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 Transducer
(Terason uSmart3200T 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	-	-	
	USFDA Track 3	IEC											
Associated Acoustic Parameter	P _{r.3}	p _{ra} at Z _{MI}	(MPa)	0.07									
	W _o	P	(mW)		-	16.7		-	16.7		-	-	
	W _{o1}	P _{txt}	(mW)		-	16.7		-	16.7				
	min of [W _{.3} (Z ₁), I _{TA.3} (Z ₁)]	Min of [P _α (Z _s), I _{ta, α} (Z _s)x 1cm ²]	(mW)				13.4						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							153.1			
	Z ₁	Z _s	(cm)				1.05						
	Z _{bp}	Z _{bp}	(cm)	1.05			1.05			1.05			
	Z _{sp}	Z _b	(cm)							1.05			
	z@PII _{max}	Z _{pii}	(cm)	1.05			1.05			1.05			
	z@PII _{3max}	Z _{MI}	(cm)	1.05									
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							0.34			
	D _{eq}	D _{eq}	(cm)								-	-	
	f _c	f _{awf}	(MHz)	3.00	-	3.00		-	3.00		-	-	
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		-	0.43		-	0.43		-	-	
			Y (cm)		-	0.91		-	0.91		-	-	
Mode Components				cwD	-	cwD		-	cwD		-	-	
Other Information	PD	t _d	(μsec)	-									
	PRF	prr	(Hz)	-									
	SRF	srr	(Hz)	-									
		n _{pps}		-									
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta, a @ Z_{pii, a} or Z_{sii, a}}	(mW/cm ²)	153.1									
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	190.3									
	pr@PII _{max}	p _r at z _{pii}	(MPa)	0.07									
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							0.34			
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	-									
	Focal Length	Focal Length	FL _x (cm)	4.0			4.0			4.0			
FL _y (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 transducer 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 uSmart3200T 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			
Maximum Index Value				1.57	1.68			1.68			2.71	
Index Component Value				1.57	1.68	-	-	1.68	-	-	2.71	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.88								
	W _o	P	(mW)		107.1	-		107.1	-		82.0	-
	W _{o1}	P _{txt}	(mW)		105.5	-		105.5	-			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta, α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	1.4			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	2.6			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	2.6								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								0.76	-
	f _c	f _{awf}	(MHz)	3.27	3.34	-		3.34	-		3.36	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.02	-		1.02	-		0.56	-
			Y (cm)		0.80	-		0.80	-		0.80	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t _d	(μsec)	0.43								
	PRF	prr	(Hz)	150								
	SRF	srr	(Hz)	150								
		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 ²)	356.5								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	653.5								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	3.86								
	deq@PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	653.5								
	Focal Length	Focal Length	FL _x (cm)	4.0			-			-		
		FL _y (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 uSmart3200T 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
	USFDA Track 3	IEC										
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 ²)							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	(μsec)	0.43								
	PRF	prr	(Hz)	210								
	SRF	srr	(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 ²)	130.2								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	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		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	653.5								
	Focal Length	Focal Length	FL_x (cm)	4.0			5.5			5.5		
			FL_y (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

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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	1.84								
	W _o	P	(mW)		106.8	-		106.8	-		139.3	-
	W _{o1}	P _{txt}	(mW)		105.1	-		105.1	-			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	1.4			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	2.7			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	2.6								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.25	-
	f _c	f _{awf}	(MHz)	2.99	3.31	-		3.31	-		3.31	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.02	-		1.02	-		1.54	-
		Y (cm)		0.80	-		0.80	-		0.80	-	
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t _d	(μsec)	1.55								
	PRF	prr	(Hz)	2000								
	SRF	srr	(Hz)	30.6								
		n _{pps}		6								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta,a @ Z_{pii,a} or Z_{sii,a}}	(mW/cm ²)	349.0								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	599.0								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.38								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	218.7								
	Focal Length	Focal Length	FL _x (cm)	4.0			-			-		
		FL _y (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 uSmart3200T 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
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.12								
	W_o	P	(mW)		-	52.7		-	52.7		-	52.7
	W_{o1}	P_{txt}	(mW)		-	52.7		-	52.7			
	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)				44.6					
	$I_{spta,3} @ Z_{sp}$	$I_{spta, a}$ at Z_b	(mW/cm ²)							436.3		
	z_1	z_s	(cm)				0.8					
	z_{bp}	z_{bp}	(cm)	0.8			0.8			0.8		
	z_{sp}	z_b	(cm)							0.8		
	$z @ PII_{max}$	z_{pii}	(cm)	0.8			0.8			0.8		
	$z @ PII_{3max}$	Z_{MI}	(cm)	0.8								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.36		
	D_{eq}	D_{eq}	(cm)								-	0.79
	f_c	f_{awf}	(MHz)	3.00	-	3.00		-	3.00		-	3.00
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	0.27		-	0.27		-	0.27
			Y (cm)		-	0.80		-	0.80		-	0.80
Mode Components				cwD	-	cwD		-	cwD		-	cwD
Other Information	PD	t_d	(μsec)	-								
	PRF	prr	(Hz)	-								
	SRF	srr	(Hz)	-								
		n_{pps}		-								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	436.3								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	514.9								
	$pr @ PII_{max}$	p_r at z_{pii}	(MPa)	0.13								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.36		
	$I_{PA3} @ MI_{max}$	$I_{pa, a}$ at $z_{pii, a}$	(W/cm ²)	-								
	Focal Length	Focal Length	FL_x (cm)	4.0			4.0			4.0		
			FL_y (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 uSmart3200T 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
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.49								
	W_o	P	(mW)		-	121.6		-	141.9		-	146.7
	W_{o1}	P_{txt}	(mW)		-	95.8		-	93.1			
	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)				82.5					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							460.2		
	Z_1	Z_s	(cm)				1.7					
	Z_{bp}	Z_{bp}	(cm)	1.1			1.7			1.9		
	Z_{sp}	Z_b	(cm)							2.7		
	$z@P_{II,max}$	Z_{pii}	(cm)	2.4			4.3			5.3		
	$z@P_{II,3,max}$	Z_{MI}	(cm)	2.2								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.47		
	D_{eq}	D_{eq}	(cm)								-	1.25
	f_c	f_{awf}	(MHz)	3.32	-	3.31		-	2.98		-	2.99
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.28		-	1.54		-	1.54
			Y (cm)		-	0.80		-	0.80		-	0.80
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	2.28								
	PRF	prf	(Hz)	600								
	SRF	srr	(Hz)	-								
		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 ²)	457.0								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	776.9								
	$p_{r@P_{II,max}}$	p_r at Z_{pii}	(MPa)	2.96								
	$d_{eq@P_{II,max}}$	d_{eq} at Z_{pii}	(cm)							0.43		
	$I_{PA3} @ M_{I,max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	334.7								
	Focal Length	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 uSmart3200T 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			
Maximum Index Value				1.57	0.92			0.92			1.22	
Index Component Value				1.57	0.92	-	-	0.92	-	-	1.22	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	3.28								
	W _o	P	(mW)		47.2	-		47.2	-		68.2	-
	W _{o1}	P _{txt}	(mW)		44.4	-		44.4	-			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _o (Z _s), I _{ta} , _o (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	1.1			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	2.1			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	2.0								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.40	-
	f _c	f _{awf}	(MHz)	4.34	4.37	-		4.37	-		4.37	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.28	-		1.28	-		2.57	-
		Y (cm)		0.60	-		0.60	-		0.60	-	
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t _d	(μsec)	0.44								
	PRF	prr	(Hz)	150								
	SRF	srr	(Hz)	150								
		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 ²)	299.3								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	549.9								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	4.31								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	621.0								
	Focal Length	Focal Length	FL _x (cm)	2.5			-			-		
		FL _y (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 uSmart3200T 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	0.05	0.04	0.85	0.05	0.15	1.12	0.11
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.28								
	W_o	P	(mW)		43.5	2.3		43.5	2.3		63.0	2.0
	W_{o1}	P_{txt}	(mW)		40.8	2.3		40.8	2.3			
	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)				2.3					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							32.6		
	z_1	z_s	(cm)				0.7					
	z_{bp}	z_{bp}	(cm)	1.1			0.7			0.7		
	z_{sp}	z_b	(cm)							0.7		
	$z @ PII_{max}$	Z_{pii}	(cm)	2.1			1.8			1.8		
	$z @ PII_{3max}$	Z_{MI}	(cm)	2.0								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.26		
	D_{eq}	D_{eq}	(cm)								1.40	0.44
	f_c	f_{awf}	(MHz)	4.34	4.37	4.37		4.37	4.37		4.37	4.37
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm) Y (cm)		1.28 0.60	0.26 0.60		1.28 0.60	0.26 0.60		2.57 0.60	0.26 0.60
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.44								
	PRF	prf	(Hz)	210								
	SRF	srr	(Hz)	52.5								
		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 ²)	128.8								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	185.2								
	$pr @ PII_{max}$	p_r at z_{pii}	(MPa)	4.31								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.25		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	621.0								
	Focal Length	Focal Length	FL_x (cm) FL_y (cm)	2.5 2.2			0.8 2.2			0.8 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 uSmart3200T Ultrasound System in Color Mode)

Index Label				MI	TIS			TIB			TIC	
					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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	1.99								
	W_o	P	(mW)		51.2	-	-	51.2	-	-	29.6	-
	W_{o1}	P_{txt}	(mW)		47.1	-	-	47.1	-	-		
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.1			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	1.9			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.8								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								0.54	-
	f_c	f_{awf}	(MHz)	4.46	4.29	-	-	4.29	-	-	4.29	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.32	-	-	1.32	-	-	0.26	-
Mode Components				rD	B+rD	-	-	B+rD	-	-	B+rD	-
Other Information	PD	t_d	(μsec)	0.85								
	PRF	prf	(Hz)	3000								
	SRF	srr	(Hz)	33.7								
		n_{pps}		5								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	101.9								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	181.0								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	2.64								
	$d_{eq@PII_{max}}$	d_{eq} at z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	251.0								
	Focal Length	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 Hz

Acoustic Output Reporting Table for Track 3 for the 9MC3 Probe
(Terason uSmart3200T 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	0.82			1.77			1.61	
Index Component Value				1.53	-	0.82	0.53	-	0.52	1.77	-	1.61
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.97								
	W_0	P	(mW)		-	38.8		-	25.5		-	28.5
	W_{01}	P_{txt}	(mW)		-	32.7		-	25.5			
	min of [$W_{3,3}(z_1)$, $I_{TA,3}(z_1)$]	Min of [$P_{\alpha}(z_s)$, $I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$]	(mW)				22.4					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							378.9		
	Z_1	Z_s	(cm)				1.4					
	Z_{bp}	Z_{bp}	(cm)	1.1			1.4			0.7		
	Z_{sp}	Z_b	(cm)							0.7		
	$z@P_{II,max}$	Z_{pii}	(cm)	2.0			3.6			1.7		
	$z@P_{II,3,max}$	Z_{MI}	(cm)	2.0								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.26		
	D_{eq}	D_{eq}	(cm)								-	0.44
	f_c	f_{awf}	(MHz)	3.77	-	4.45		-	4.29		-	3.77
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.22		-	0.26		-	0.26
			Y (cm)		-	0.60		-	0.60		-	0.60
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.75								
	PRF	p_{rr}	(Hz)	400								
	SRF	s_{rr}	(Hz)	-								
		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 ²)	407.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	693.5								
	$p_{r@P_{II,max}}$	p_r at Z_{pii}	(MPa)	3.75								
	$d_{eq@P_{II,max}}$	d_{eq} at Z_{pii}	(cm)							0.25		
	$I_{PA3} @ M_{I,max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	582.1								
	Focal Length	Focal Length	FL_x (cm)	2.5			4.5			0.8		
			FL_y (cm)	2.2			2.2			2.2		
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				
	Control 4										X	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 9.0 MHz, PWD Frequency = 4.5 MHz, SV Size = 2.5 mm, SV Depth = 4.5 cm, PRF = 5000 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 10EC4 Probe
(Terason uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.72								
	W_o	P	(mW)		58.2	-		58.2	-		-	-
	W_{o1}	P_{txt}	(mW)		48.9	-		48.9	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.9			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.9			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.8								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.23	5.90	-		5.90	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.58	-		1.58	-		-	-
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t_d	(μsec)	0.45								
	PRF	p_{rr}	(Hz)	150								
	SRF	s_{rr}	(Hz)	150								
		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 ²)	149.5								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	251.7								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	3.54								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	323.3								
	Focal Length	Focal Length	FL_x (cm)	3.5			-			-		
							-			-		
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3											

NOTE 1: Information need not be provided regarding *TIC* for any transducer 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 uSmart3200T 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	-	-	
	USFDA Track 3	IEC											
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.72									
	W _o	P	(mW)		50.9	3.1		50.9	3.1		-	-	
	W _{o1}	P _{txt}	(mW)		35.0	3.1		35.0	3.1				
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			2.0							
	I _{spta 3} @ Z _{sp}	I _{spta a} at Z _b	(mW/cm ²)						19.8				
	Z ₁	Z _s	(cm)				1.1						
	Z _{bp}	z _{bp}	(cm)	0.9			1.1		1.1				
	Z _{sp}	z _b	(cm)						2.1				
	z@PII _{max}	Z _{pii}	(cm)	1.9			2.6		2.6				
	z@PII _{3max}	Z _{MI}	(cm)	1.8									
	d _{eq} (Z _{sp})	d _{eq} (z _b)	(cm)						0.29				
	D _{eq}	D _{eq}	(cm)								-	-	
	f _c	f _{awf}	(MHz)	4.23	5.73	5.73		5.73	5.73		-	-	
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		2.12	0.69		2.12	0.69		-	-	
		Y (cm)		0.60	0.60		0.60	0.60		-	-		
Mode Components				B+M	B	M		B	M		-	-	
Other Information	PD	t _d	(μsec)	0.45									
	PRF	prr	(Hz)	570									
	SRF	srr	(Hz)	142.5									
		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 ²)	164.4									
	I _{spta} @ Z _{pii} or Z _{sii}	I _{spta} @ Z _{pii} or Z _{sii}	(mW/cm ²)	279.7									
	pr@PII _{max}	p _r at z _{pii}	(MPa)	3.54									
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)						0.26				
	I _{PA3} @MI _{max}	I _{pa, a} at z _{pii, a}	(W/cm ²)	323.3									
	Focal Length	Focal Length	FL _x (cm)	3.5			5.0		5.0				
		FL _y (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 transducer 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	1.69								
	W _o	P	(mW)		71.0	-		71.0	-		-	-
	W _{o1}	P _{txt}	(mW)		67.2	-		67.2	-			
	min of [W _{.3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta, α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	z _s	(cm)				-					
	Z _{bp}	z _{bp}	(cm)	0.9			-			-		
	Z _{sp}	z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.8			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	1.7								
	d _{eq} (z _{sp})	d _{eq} (z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	4.76	4.77	-		4.77	-		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.22	-		1.22	-		-	-
Y (cm)				0.60	-		0.60	-		-	-	
Mode Components				rD	B+rD	-		B+rD	-		-	-
Other Information	PD	t _d	(μsec)	0.79								
	PRF	prr	(Hz)	1500								
	SRF	srr	(Hz)	22.9								
		n _{pps}		7								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta, a @ Z_{pii, a} or Z_{sii, a}}	(mW/cm ²)	67.3								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	117.6								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.16								
	deq@PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	180.3								
	Focal Length	Focal Length	FL _x (cm)	3.5			-			-		
FL _y (cm)			2.2			-			-			
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3											

NOTE 1: Information need not be provided regarding T/C for any transducer 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 uSmart3200T 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	1.19			2.17			Note 1	
Index Component Value				1.41	-	1.19	0.78	0.04	0.64	2.13	-	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.09								
	W_o	P	(mW)		-	52.4		1.7	28.0		-	-
	W_{o1}	P_{txt}	(mW)		-	50.9		1.3	28.0			
	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)				34.1					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							496.0		
	Z_1	Z_s	(cm)				1.7					
	Z_{bp}	Z_{bp}	(cm)	0.9			1.3			0.6		
	Z_{sp}	Z_b	(cm)							0.6		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.8			2.1			1.7		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.7								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.25		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.76	-	4.76		6.05	4.77		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.04		1.99	0.23		-	-
			Y (cm)		-	0.60		0.60	0.60		-	-
Mode Components				D	-	D		B	D		-	-
Other Information	PD	t_d	(μsec)	1.79								
	PRF	prf	(Hz)	500								
	SRF	srr	(Hz)	-								
		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 ²)	489.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	879.2								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	3.95								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.23		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	548.7								
	Focal Length	Focal Length	FL_x (cm)	3.5			8.5			1.5		
			FL_y (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 transducer 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 = 1.5 mm, SV Depth = 8.5 cm, PRF = 1000 Hz, Update = off

Control 3: Sector depth = 9.0 cm, Focus = 8.5 cm, B-Mode Frequency = 6.0 MHz, B-Mode lines = 22, 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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.68								
	W_o	P	(mW)		44.8	-		44.8	-		61.1	-
	W_{o1}	P_{txt}	(mW)		18.3	-		18.3	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.85			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.50			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.50								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.40	-
	f_c	f_{awf}	(MHz)	6.67	6.07	-		6.07	-		5.88	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
			Y (cm)		0.40	-		0.40	-		0.40	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.19								
	PRF	prr	(Hz)	31.0								
	SRF	srr	(Hz)	31.0								
		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 ²)	23.9								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	47.8								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	3.73								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	657.8								
	Focal Length	Focal Length	FL_x (cm)	1.8			-			-		
			FL_y (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 uSmart3200T 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	0.57			0.55			1.05	
Index Component Value				1.04	0.47	0.10	0.05	0.47	0.04	0.08	0.99	0.06
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.68								
	W_0	P	(mW)		39.6	3.4		39.6	3.4		55.3	3.5
	W_{01}	P_{txt}	(mW)		16.2	1.5		16.2	1.5			
	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)				1.7					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							79.2		
	Z_1	Z_s	(cm)				1.60					
	Z_{bp}	Z_{bp}	(cm)	0.85			1.60			1.60		
	Z_{sp}	Z_b	(cm)							1.60		
	$z@PII_{max}$	Z_{pii}	(cm)	1.50			6.30			6.30		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.50								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.48		
	D_{eq}	D_{eq}	(cm)								1.40	1.35
	f_c	f_{awf}	(MHz)	6.67	6.07	6.07		6.07	6.07		5.88	5.88
	Dim of A_{aprt}	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
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.19								
	PRF	prr	(Hz)	570								
	SRF	srr	(Hz)	71.3								
		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 ²)	104.5								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	208.6								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	3.73								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							0.38		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	657.8								
	Focal Length	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	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.42								
	W _o	P	(mW)		99.5	-		99.5	-		118.7	-
	W _{o1}	P _{txt}	(mW)		40.7	-		40.7	-			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta, α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	0.85			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.45			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	1.35								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.40	-
	f _c	f _{awf}	(MHz)	5.12	5.10	-		5.10	-		5.09	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
		Y (cm)		0.40	-		0.40	-		0.40	-	
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t _d	(μsec)	0.75								
	PRF	prr	(Hz)	3000								
	SRF	srr	(Hz)	9.7								
		n _{pps}		10								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta, a @ Z_{pii, a} or Z_{sii, a}}	(mW/cm ²)	108.7								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	173.6								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.86								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	341.3								
	Focal Length	Focal Length	FL _x (cm)	1.8			-			-		
		FL _y (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 uSmart3200T 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	1.94			2.20			2.15	
Index Component Value				1.42	-	1.94	1.11	-	1.00	2.20	-	2.15
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.18								
	W_o	P	(mW)		-	80.1		-	46.1		-	116.6
	W_{o1}	P_{txt}	(mW)		-	35.4		-	41.3			
	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)				45.6					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							401.6		
	z_1	z_s	(cm)				1.60					
	z_{bp}	z_{bp}	(cm)	0.85			1.60			1.15		
	z_{sp}	z_b	(cm)							1.20		
	$z@P_{II\max}$	z_{pii}	(cm)	1.65			6.40			2.80		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.60								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.31		
	D_{eq}	D_{eq}	(cm)								-	1.35
	f_c	f_{awf}	(MHz)	5.01	-	5.10		-	5.11		-	5.09
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	2.31		-	1.14		-	3.60
			Y (cm)		-	0.40		-	0.40		-	0.40
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.13								
	PRF	p_{rr}	(Hz)	600								
	SRF	s_{rr}	(Hz)	-								
		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 ²)	482.7								
	$I_{spta} @ Z_{pii}$ or z_{sii}	$I_{spta} @ z_{pii}$ or z_{sii}	(mW/cm ²)	858.5								
	$p_{r@P_{II\max}}$	p_r at z_{pii}	(MPa)	4.14								
	$d_{eq@P_{II\max}}$	d_{eq} at z_{pii}	(cm)							0.21		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	718.8								
	Focal Length	Focal Length	FL_x (cm)	2.4			6.5			3.2		
			FL_y (cm)	1.4			1.4			1.4		
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				
	Control 4										X	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 4.5 mm, SV Depth = 6.5 cm, PRF = 400 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

Control 4: 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

Acoustic Output Reporting Table for Track 3 for the 12L5A (Ophthalmic) Probe
(Terason uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.49								
	W_o	P	(mW)		2.5	-		2.5	-		2.5	-
	W_{o1}	P_{txt}	(mW)		0.7	-		0.7	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.90			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	3.40			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.60								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.40	-
	f_c	f_{awf}	(MHz)	7.75	7.75	-		7.75	-		7.75	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
			Y (cm)		0.40	-		0.40	-		0.40	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.16								
	PRF	prr	(Hz)	64.2								
	SRF	srr	(Hz)	64.2								
		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 ²)	4.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	10.6								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	0.72								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	12.7								
	Focal Length	Focal Length	FL_x (cm)	5.0			-			-		
			FL_y (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 uSmart3200T 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
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.49								
	W_o	P	(mW)		2.2	0.08		2.2	0.08		2.2	0.08
	W_{o1}	P_{txt}	(mW)		0.6	0.08		0.6	0.08			
	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)				0.05					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							1.0		
	z_1	z_s	(cm)				0.90					
	z_{bp}	z_{bp}	(cm)	0.90			0.90			0.90		
	z_{sp}	z_b	(cm)							1.30		
	$z @ PII_{max}$	Z_{pii}	(cm)	3.40			3.40			3.40		
	$z @ PII_{3max}$	Z_{MI}	(cm)	1.60								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.24		
	D_{eq}	D_{eq}	(cm)								1.40	0.62
	f_c	f_{awf}	(MHz)	7.75	7.75	7.75		7.75	7.75		7.75	7.75
	Dim of A_{aprt}	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
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.16								
	PRF	prf	(Hz)	570								
	SRF	srf	(Hz)	114								
		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 ²)	5.2								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	13.5								
	$p_r @ PII_{max}$	p_r at z_{pii}	(MPa)	0.72								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.18		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	12.7								
	Focal Length	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											

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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			
Maximum Index Value				0.17	0.16			0.16			0.35	
Index Component Value				0.17	0.16	-	-	0.16	-	-	0.35	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	0.38								
	W _o	P	(mW)		19.5	-		19.5	-		19.5	-
	W _{o1}	P _{txt}	(mW)		6.4	-		6.4	-			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	1.40			--			-		
	Z _{sp}	Z _b	(cm)							-		
	z@P _{II} _{max}	Z _{pii}	(cm)	4.80			-			-		
	z@P _{II} _{3max}	Z _{MI}	(cm)	4.65								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.40	-
	f _c	f _{awf}	(MHz)	5.12	5.12	-		5.12	-		5.12	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
			Y (cm)		0.40	-		0.40	-		0.40	-
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t _d	(μsec)	0.74								
	PRF	prr	(Hz)	22220								
	SRF	srr	(Hz)	10.8								
		n _{pps}		10								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta,a @ Z_{pii,a} or Z_{sii,a}}	(mW/cm ²)	28.7								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	47.1								
	pr@P _{II} _{max}	p _r at z _{pii}	(MPa)	0.85								
	d _{eq} @P _{II} _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI} _{max}	I _{pa, a} at z _{pii, a}	(W/cm ²)	10.1								
	Focal Length	Focal Length	FL _x (cm)	5.0			-			-		
		FL _y (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 uSmart3200T 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	0.11			0.15			0.12	
Index Component Value				0.17	-	0.11	0.07	-	0.07	0.15	-	0.12
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.38								
	W_0	P	(mW)		-	4.5		-	4.5		-	4.5
	W_{01}	P_{txt}	(mW)		-	2.7		-	2.7			
	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)				2.8					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							19.4		
	Z_1	Z_s	(cm)				1.40					
	Z_{bp}	Z_{bp}	(cm)	1.40			1.40			1.40		
	Z_{sp}	Z_b	(cm)							1.40		
	$z@P_{II\max}$	Z_{pii}	(cm)	4.80			4.80			4.80		
	$z@P_{II3\max}$	Z_{MI}	(cm)	4.65								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.42		
	D_{eq}	D_{eq}	(cm)								-	0.93
	f_c	f_{awf}	(MHz)	5.12	-	5.12		-	5.12		-	5.12
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.71		-	1.71		-	1.71
			Y (cm)		-	0.40		-	0.40		-	0.40
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.84								
	PRF	prf	(Hz)	1500								
	SRF	srr	(Hz)	1								
		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 ²)	28.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	149.8								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	0.85								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.19		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	10.2								
	Focal Length	Focal Length	FL_x (cm)	5.0			5.0			5.0		
			FL_y (cm)	1.4			1.4			1.4		
Operating Control Conditions	Control 1			X								
	Control 2				X			X			X	
	Control 3											

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.17								
	W_o	P	(mW)		113.4	-		113.4	-		145.8	-
	W_{o1}	P_{txt}	(mW)		40.6	-		40.6	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.85			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	1.50			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.35								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.48	-
	f_c	f_{awf}	(MHz)	4.76	4.33	-		4.33	-		4.09	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.27								
	PRF	prr	(Hz)	150								
	SRF	srr	(Hz)	150								
		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 ²)	71.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	112.0								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	3.77								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	478.8								
	Focal Length	Focal Length	FL_x (cm)	1.8			-			-		
			FL_y (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 uSmart3200T 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
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.17								
	W_o	P	(mW)		104.5	8.9		104.5	8.9		135.0	4.8
	W_{o1}	P_{bxt}	(mW)		37.4	3.2		37.4	3.2			
	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)				5.0					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							15.0		
	z_1	z_s	(cm)				1.90					
	z_{bp}	z_{bp}	(cm)	0.85			1.90			1.90		
	z_{sp}	z_b	(cm)							1.90		
	$z@PII_{max}$	Z_{pii}	(cm)	1.50			8.10			8.10		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.35								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.64		
	D_{eq}	D_{eq}	(cm)								1.48	1.48
	f_c	f_{awf}	(MHz)	4.76	4.33	4.33		4.33	4.33		4.12	4.12
	Dim of A_{aprt}	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
Mode Components				B	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.27								
	PRF	prf	(Hz)	570								
	SRF	srf	(Hz)	142.5								
		n_{pps}		2								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	178.0								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	283.5								
	$p_{r@PII_{max}}$	p_r at z_{pii}	(MPa)	3.77								
	$d_{eq@PII_{max}}$	d_{eq} at z_{pii}	(cm)							0.48		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	478.8								
	Focal Length	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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.60								
	W _o	P	(mW)		73.3	-		73.3	-		184.6	-
	W _{o1}	P _{txt}	(mW)		66.1	-		66.1	-			
	min of [W _{s,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _o (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)									
	I _{spta 3} @ Z _{sp}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)									
	Z _{bp}	Z _{bp}	(cm)	0.85						-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.35						-		
	z@PII _{3max}	Z _{MI}	(cm)	1.30								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.48	-
	f _c	f _{awf}	(MHz)	5.09	4.97	-		4.97	-		4.25	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.32	-		1.32	-		3.84	-
Y (cm)				0.45	-		0.45	-		0.45	-	
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t _d	(μsec)	0.74								
	PRF	prr	(Hz)	600								
	SRF	srr	(Hz)	34.4								
		n _{pps}		14								
	I _{spta 3} @ Z _{pii 3} or Z _{sii 3}	I _{spta, a} @ Z _{pii, a} or Z _{sii, a}	(mW/cm ²)	425.7								
	I _{spta} @ Z _{pii} or Z _{sii}	I _{spta} @ Z _{pii} or Z _{sii}	(mW/cm ²)	674.8								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	3.26								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3} @MI _{max}	I _{pa, a} at z _{pii, a}	(W/cm ²)	454.4								
	Focal Length	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 = 2220 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 uSmart3200T 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	2.59			2.96			3.39	
Index Component Value				1.54	-	2.59	1.47	-	1.31	2.96	-	3.39
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.47								
	W_0	P	(mW)		-	106.4		-	85.2		-	201.2
	W_{01}	P_{txt}	(mW)		-	52.4		-	64.4			
	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)				60.5					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							406.8		
	z_1	z_s	(cm)				1.60					
	z_{bp}	z_{bp}	(cm)	0.85			1.60			1.30		
	z_{sp}	z_b	(cm)							1.55		
	$z@PII_{max}$	z_{pii}	(cm)	1.35			1.60			3.65		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.30								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.41		
	D_{eq}	D_{eq}	(cm)								-	1.48
	f_c	f_{awf}	(MHz)	5.09	-	5.10		-	4.27		-	4.25
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	2.07		-	1.35		-	3.84
			Y (cm)		-	0.45		-	0.45		-	0.45
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.48								
	PRF	prr	(Hz)	450								
	SRF	srr	(Hz)	-								
		n_{pps}		1								
	$I_{spta,3} @ Z_{pii,3}$ or $z_{sij,3}$	$I_{spta,a} @ z_{pii,a}$ or $z_{sij,a}$	(mW/cm ²)	515.4								
	$I_{spta} @ Z_{pii}$ or z_{sij}	$I_{spta} @ z_{pii}$ or z_{sij}	(mW/cm ²)	826.9								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	4.35								
	$d_{eq@PII_{max}}$	d_{eq} at z_{pii}	(cm)							0.30		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	775.5								
	Focal Length	Focal Length	FL_x (cm)	1.8			6.5			4.0		
			FL_y (cm)	1.5			1.5			1.5		
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				
	Control 4										X	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 12 MHz, PWD Frequency = 5.1 MHz, SV Size = 0.5 mm, SV Depth = 5.6 cm, PRF = 11500 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

Control 4: 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

**.Acoustic Output Reporting Table for Track 3 for the 14L3 (Ophthalmic) Probe
(Terason uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.52								
	W_o	P	(mW)		3.4	-		3.4	-		3.4	-
	W_{o1}	P_{txt}	(mW)		0.9	-		0.9	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.0			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	3.55			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.55								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.48	-
	f_c	f_{awf}	(MHz)	7.51	7.51	-		7.51	-		7.51	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.19								
	PRF	prr	(Hz)	86.8								
	SRF	srr	(Hz)	86.8								
		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 ²)	4.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	10.4								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	0.95								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	8.0								
	Focal Length	Focal Length	FL_x (cm)	4.5			-			-		
			FL_y (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 uSmart3200T 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
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.52								
	W_o	P	(mW)		2.8	0.09		2.8	0.09		2.8	0.09
	W_{o1}	P_{txt}	(mW)		0.7	0.09		0.7	0.09			
	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)				0.05					
	$I_{spta,3} @ Z_{sp}$	$I_{spta, a}$ at Z_b	(mW/cm ²)							0.77		
	z_1	z_s	(cm)				1.0					
	z_{bp}	z_{bp}	(cm)	1.0			1.0			1.0		
	z_{sp}	z_b	(cm)							1.4		
	$z @ PII_{max}$	z_{pii}	(cm)	3.55			3.55			3.55		
	$z @ PII_{3max}$	Z_{MI}	(cm)	1.55								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.25		
	D_{eq}	D_{eq}	(cm)								1.48	0.66
	f_c	f_{awf}	(MHz)	7.51	7.51	7.51		7.51	7.51		7.51	7.51
	Dim of A_{aprt}	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
Mode Components				B	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.19								
	PRF	prr	(Hz)	142.5								
	SRF	srr	(Hz)	570								
		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 ²)	4.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	13.5								
	$pr @ PII_{max}$	p_r at z_{pii}	(MPa)	0.95								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.16		
	$I_{PA3} @ MI_{max}$	$I_{pa, a}$ at $z_{pii, a}$	(W/cm ²)	8.0								
	Focal Length	Focal Length	FL_x (cm)	4.5			4.5			4.5		
			FL_y (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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	0.48								
	W _o	P	(mW)		33.1	-		33.1	-		51.4	-
	W _{o1}	P _{txt}	(mW)		23.9	-		23.9	-			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	1.3			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@P _{II} _{max}	Z _{pii}	(cm)	4.30			-			-		
	z@P _{II} _{3max}	Z _{MI}	(cm)	4.15								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.48	-
	f _c	f _{awf}	(MHz)	7.02	7.02	-		7.02	-		7.02	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.92	-		1.92	-		3.81	-
		Y (cm)		0.45	-		0.45	-		0.45	-	
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t _d	(μsec)	0.56								
	PRF	prr	(Hz)	35.2								
	SRF	srr	(Hz)	35.2								
		n _{pps}		14								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta,a @ Z_{pii,a} or Z_{sii,a}}	(mW/cm ²)	29.8								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	221.9								
	pr@P _{II} _{max}	p _r at z _{pii}	(MPa)	1.30								
	d _{eq} @P _{II} _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @M} _{max}	I _{pa, a} at z _{pii, a}	(W/cm ²)	14.7								
	Focal Length	Focal Length	FL _x (cm)	4.5			-			-		
		FL _y (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 uSmart3200T 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			
Maximum Index Value				0.19	0.23			0.19			0.19	
Index Component Value				0.19	-	0.23	0.12	-	0.17	0.19	-	0.19
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	0.51								
	W _o	P	(mW)		-	6.9		-	6.9		-	6.9
	W _{o1}	P _{txt}	(mW)		-	5.1		-	5.1			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta, α} (Z _s)x 1cm ²]	(mW)			3.6						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							26.4		
	Z ₁	Z _s	(cm)				1.35					
	Z _{bp}	Z _{bp}	(cm)	1.30			1.30			1.30		
	Z _{sp}	Z _b	(cm)							1.35		
	z@PII _{max}	Z _{pii}	(cm)	4.30			4.30			4.30		
	z@PII _{3max}	Z _{MI}	(cm)	4.15								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							0.39		
	D _{eq}	D _{eq}	(cm)								-	0.89
	f _c	f _{awf}	(MHz)	7.02	-	7.02		-	7.02		-	7.02
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		-	1.38		-	1.38		-	1.38
			Y (cm)		-	0.45		-	0.45		-	0.45
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t _d	(μsec)	1.26								
	PRF	prr	(Hz)	1750								
	SRF	srr	(Hz)	-								
		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 ²)	34.3								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	262.2								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	1.38								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							0.18		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	15.6								
	Focal Length	Focal Length	FL _x (cm)	4.5			4.5			4.5		
		FL _y (cm)	1.5			1.5			1.5			
Operating Control Conditions	Control 1			X								
	Control 2				X			X			X	
	Control 3											

NOTE 2: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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
Maximum Index Value				1.34	1.01			1.01			1.87	
Index Component Value				1.34	1.01	-	-	1.01	-	-	1.87	
	USFDA Track 3	IEC										
Associated Acoustic Parameter	Pr,3	p_{ra} at Z_{MI}	(MPa)	3.54								
	W _o	P	(mW)		44.4	-		44.4	-		104.8	
	W _{o1}	P _{txt}	(mW)		30.9	-		30.9	-			
	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)				-					
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	0.70			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.25			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	1.15								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.40	
	f _c	f _{awf}	(MHz)	7.03	6.86	-		6.86	-		4.85	
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		2.07	-		2.07	-		3.84	
		Y (cm)		0.40	-		0.40	-		0.40		
Mode Components				B	B	-		B	-		B	
Other Information	PD	t _d	(usec)	0.16								
	PRF	prr	(Hz)	103.4								
	SRF	srr	(Hz)	103.4								
		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 ²)	27.1								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	47.2								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	4.35								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	690.5								
	Focal Length	Focal Length	FL _x (cm)	1.3			-			-		
		FL _y (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 uSmart3200T 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	0.95			0.95			1.88	
Index Component Value				1.34	0.82	0.13	0.07	0.82	0.09	0.13	1.76	0.11
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.54								
	W_o	P	(mW)		40.4	4.0		40.4	4.0		98.6	6.2
	W_{o1}	P_{bxt}	(mW)		25.1	2.9		25.1	2.9			
	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)				2.2					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							18.1		
	z_1	z_s	(cm)				1.25					
	z_{bp}	z_{bp}	(cm)	0.70			1.25			1.25		
	z_{sp}	z_b	(cm)							1.25		
	$z@PII_{max}$	Z_{pii}	(cm)	1.25			3.95			3.95		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.15								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.41		
	D_{eq}	D_{eq}	(cm)								1.40	1.35
	f_c	f_{awf}	(MHz)	7.03	6.86	6.86		6.86	6.86		4.85	4.85
	Dim of A_{aprt}	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
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.16								
	PRF	prf	(Hz)	570								
	SRF	srr	(Hz)	142.5								
		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 ²)	65.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	114.5								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	4.35								
	$d_{eq@PII_{max}}$	d_{eq} at z_{pii}	(cm)							0.34		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	690.5								
	Focal Length	Focal Length	FL_x (cm)	1.3			4.0			4.0		
			FL_y (cm)	1.4			1.4			1.4		
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3										X	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.40								
	W_o	P	(mW)		99.4	-		99.4	-		116.1	-
	W_{o1}	P_{txt}	(mW)		40.6	-		40.6	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.85			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	1.50			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.50								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.40	-
	f_c	f_{awf}	(MHz)	5.00	4.99	-		4.99	-		5.07	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t_d	(μsec)	0.78								
	PRF	prf	(Hz)	350								
	SRF	srf	(Hz)	30.7								
		n_{pps}		10								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	324.7								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	544.6								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	3.07								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	307.3								
	Focal Length	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 uSmart3200T 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	1.96			2.15			2.16	
Index Component Value				1.36	-	1.96	1.12	-	0.93	2.15	-	2.16
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.82								
	W_0	P	(mW)		-	81.1		-	65.2		-	117.1
	W_{01}	P_{txt}	(mW)		-	35.8		-	38.2			
	min of [$W_{03}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{\alpha}(Z_s)$, $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$]	(mW)				46.3					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							149.2		
	Z_1	Z_s	(cm)				1.60					
	Z_{bp}	Z_{bp}	(cm)	0.70			1.60			1.40		
	Z_{sp}	Z_b	(cm)							1.40		
	$z@PII_{max}$	Z_{pii}	(cm)	1.15			6.50			4.65		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.05								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.42		
	D_{eq}	D_{eq}	(cm)								-	1.35
	f_c	f_{awf}	(MHz)	4.29	-	5.08		-	5.09		-	5.07
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	2.31		-	1.74		-	3.60
			Y (cm)		-	0.40		-	0.40		-	0.40
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.77								
	PRF	prr	(Hz)	500								
	SRF	srr	(Hz)	-								
		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 ²)	280.7								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	395.4								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	3.39								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							0.34		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	337.8								
	Focal Length	Focal Length	FLx (cm)	1.8			6.5			4.8		
			FLy (cm)	1.4			1.4			1.4		
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				
	Control 4										X	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 6.0 mm, SV Depth = 6.5 cm, PRF = 1500 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

Control 4: 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

Acoustic Output Reporting Table for Track 3 for the 15L4 (Ophthalmic) Probe
(Terason uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.52								
	W_o	P	(mW)		4.6	-		4.6	-		4.6	-
	W_{o1}	P_{txt}	(mW)		1.2	-		1.2	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.90			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	3.50			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.70								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.40	-
	f_c	f_{awf}	(MHz)	8.64	8.64	-		8.64	-		8.64	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
			Y (cm)		0.40	-		0.40	-		0.40	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.15								
	PRF	prr	(Hz)	86.8								
	SRF	srr	(Hz)	86.8								
		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 ²)	5.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	15.0								
	$pr@P_{II\max}$	p_r at Z_{pii}	(MPa)	0.84								
	$d_{eq}@P_{II\max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	12.7								
	Focal Length	Focal Length	FL_x (cm)	5.0			-			-		
			FL_y (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 uSmart3200T 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
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.52								
	W_o	P	(mW)		3.8	0.1		3.8	0.1		3.8	0.1
	W_{o1}	P_{bxt}	(mW)		1.0	0.1		1.0	0.1			
	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)				0.1					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							2.3		
	z_1	z_s	(cm)				0.90					
	z_{bp}	z_{bp}	(cm)	0.90			0.90			0.90		
	z_{sp}	z_b	(cm)							1.40		
	$z @ PII_{max}$	Z_{pii}	(cm)	3.50			3.50			3.50		
	$z @ PII_{3max}$	Z_{MI}	(cm)	1.70								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.27		
	D_{eq}	D_{eq}	(cm)								1.40	0.62
	f_c	f_{awf}	(MHz)	8.64	8.64	8.64		8.64	8.64		8.64	8.64
	Dim of A_{aprt}	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
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.15								
	PRF	prf	(Hz)	570								
	SRF	srf	(Hz)	142.5								
		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 ²)	5.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	16.6								
	$p_r @ PII_{max}$	p_r at z_{pii}	(MPa)	0.84								
	$d_{eq} @ PII_{max}$	d_{eq} at z_{pii}	(cm)							0.20		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	12.7								
	Focal Length	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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.33								
	W_o	P	(mW)		25.5	-		25.5	-		25.5	-
	W_{o1}	P_{bxt}	(mW)		8.4	-		8.4	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.40			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II,max}$	Z_{pii}	(cm)	4.95			-			-		
	$z@P_{II,3,max}$	Z_{MI}	(cm)	4.80								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.40	-
	f_c	f_{awf}	(MHz)	5.12	5.12	-		5.12	-		5.12	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
					0.40	-		0.40	-		0.40	-
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t_d	(μsec)	0.77								
	PRF	prf	(Hz)	22220								
	SRF	srr	(Hz)	8.4								
		n_{pps}		14								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	32.8								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	53.8								
	$p_{r@P_{II,max}}$	p_r at Z_{pii}	(MPa)	0.75								
	$d_{eq@P_{II,max}}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ M_{I,max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	8.1								
	Focal Length	Focal Length	FLx (cm)	5.0			-			-		
							-			-		
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 uSmart3200T 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	0.14			0.18			0.16	
Index Component Value				0.17	-	0.14	0.09	-	0.09	0.18	-	0.16
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.40								
	W_0	P	(mW)		-	5.9		-	5.9		-	5.9
	W_{01}	P_{txt}	(mW)		-	3.5		-	3.5			
	min of [$W_{0.3}(z_1)$, $I_{TA,3}(z_1)$]	Min of [$P_{\alpha}(z_s)$, $I_{ta, \alpha}(z_s) \times 1 \text{ cm}^2$]	(mW)				3.6					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							22.9		
	Z_1	Z_s	(cm)				1.40					
	Z_{bp}	Z_{bp}	(cm)	1.40			1.40			1.40		
	Z_{sp}	Z_b	(cm)							1.40		
	$z@P_{II\max}$	Z_{pii}	(cm)	4.95			4.95			4.95		
	$z@P_{II3\max}$	Z_{MI}	(cm)	4.80								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.44		
	D_{eq}	D_{eq}	(cm)								-	0.93
	f_c	f_{awf}	(MHz)	5.12	-	5.12		-	5.12		-	5.12
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.71		-	1.71		-	1.71
			Y (cm)		-	0.40		-	0.40		-	0.40
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.92								
	PRF	prr	(Hz)	1500								
	SRF	srr	(Hz)	-								
		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 ²)	33.8								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	187.9								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	0.89								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.20		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	11.7								
	Focal Length	Focal Length	FL_x (cm)	5.0			5.0			5.0		
			FL_y (cm)	1.4			1.4			1.4		
Operating Control Conditions	Control 1			X								
	Control 2				X			X			X	
	Control 3											

Note: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.18								
	W_o	P	(mW)		38.4	-		38.4	-		55.4	-
	W_{o1}	P_{txt}	(mW)		15.7	-		15.7	-			
	min of [$W_{r,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{r,3}(Z_s)$, $I_{ta,3}(Z_s) \times 1 \text{ cm}^2$]	(mW)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.90			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.65			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.55								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.44	-
	f_c	f_{awf}	(MHz)	5.03	6.28	-		6.28	-		4.86	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.28								
	PRF	prf	(Hz)	79.2								
	SRF	srr	(Hz)	79.2								
		n_{pps}		2								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	47.8								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	81.8								
	$p_{r@P_{II\max}}$	p_r at z_{pii}	(MPa)	4.15								
	$d_{eq@P_{II\max}}$	d_{eq} at z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	280.3								
	Focal Length	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 uSmart3200T 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	0.54			0.51			0.96	
Index Component Value				1.42	0.42	0.12	0.06	0.42	0.05	0.9	0.86	0.10
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.18								
	W_o	P	(mW)		34.0	4.1		34.0	4.1		49.4	5.6
	W_{o1}	P_{txt}	(mW)		13.9	1.8		13.9	1.8			
	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)				2.0					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							10.3		
	Z_1	Z_s	(cm)				1.60					
	Z_{bp}	Z_{bp}	(cm)	0.90			1.60			1.60		
	Z_{sp}	Z_b	(cm)							1.60		
	$z@PII_{max}$	Z_{pii}	(cm)	1.65			6.50			6.50		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.55								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.52		
	D_{eq}	D_{eq}	(cm)								1.44	1.40
	f_c	f_{awf}	(MHz)	5.03	6.28	6.28		6.28	6.28		4.86	4.86
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	2.31		3.84	2.31		3.84	3.60
						Y (cm)			Y (cm)			
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.28								
	PRF	prr	(Hz)	570								
	SRF	srr	(Hz)	114								
		n_{pps}		2								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	92.8								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	161.1								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	4.15								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							0.43		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	280.3								
	Focal Length	Focal Length	FLx (cm)	1.8			6.5			6.5		
							FLy (cm)			FLy (cm)		
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3										X	

NOTE 1: The non-scanned W_o was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.45								
	W_o	P	(mW)		33.7	-		33.7	-		72.8	-
	W_{o1}	P_{txt}	(mW)		31.6	-		31.6	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.90			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	1.50			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.45								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.44	-
	f_c	f_{awf}	(MHz)	5.12	5.13	-		5.13	-		5.09	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.17	-		1.17	-		3.84	-
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t_d	(μsec)	0.74								
	PRF	prf	(Hz)	500								
	SRF	srf	(Hz)	38.6								
		n_{pps}		10								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	261.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	435.9								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	3.05								
	$d_{eq}@PII_{max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	345.5								
	Focal Length	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 uSmart3200T 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	1.31			1.59			1.39	
Index Component Value				1.55	-	1.31	0.75	-	0.71	1.59	-	1.39
USFDA Track 3 IEC												
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.52								
	W_o	P	(mW)		-	54.1		-	32.7		-	77.7
	W_{o1}	P_{txt}	(mW)		-	23.9		-	29.3			
	min of [$W_{r,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{r,3}(Z_s)$, $I_{ta,3}(Z_s) \times 1 \text{ cm}^2$]	(mW)				30.8					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							301.4		
	Z_1	Z_s	(cm)				1.60					
	Z_{bp}	Z_{bp}	(cm)	0.70			1.60			1.15		
	Z_{sp}	Z_b	(cm)							1.25		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.30			6.40			2.90		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.20								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.30		
	D_{eq}	D_{eq}	(cm)								-	1.40
	f_c	f_{awf}	(MHz)	5.13	-	5.10		-	5.11		-	5.09
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	2.31		-	1.14		-	3.60
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.83								
	PRF	prf	(Hz)	350								
	SRF	srr	(Hz)	-								
		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 ²)	450.5								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	702.8								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	4.18								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.20		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	705.4								
	Focal Length	Focal Length	FLx (cm)	1.8			6.5			3.2		
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				
	Control 4										X	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 2.0 mm, SV Depth = 6.5 cm, PRF = 500 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

Control 4: 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

Acoustic Output Reporting Table for Track 3 for the 15L4A Ophthalmic Probe
(Terason uSmart3200T 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	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.56								
	W_o	P	(mW)		6.0	-		6.0	-		6.0	-
	W_{o1}	P_{txt}	(mW)		1.6	-		1.6	-			
	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)				-					
	$I_{spta,3 @ Z_{sp}}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.95			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@PII_{max}$	Z_{pii}	(cm)	3.60			-			-		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.70								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.44	-
	f_c	f_{awf}	(MHz)	9.10	9.10	-		9.10	-		9.10	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
Mode Components				B	B	-		B	-		B	-
Other Information	PD	t_d	(μsec)	0.12								
	PRF	prf	(Hz)	86.8								
	SRF	srf	(Hz)	86.8								
		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 ²)	2.0								
	$I_{spta @ Z_{pii}}$ or Z_{sii}	$I_{spta @ Z_{pii}}$ or Z_{sii}	(mW/cm ²)	7.6								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	0.91								
	$d_{eq@PII_{max}}$	d_{eq} at z_{pii}	(cm)							-		
	$I_{PA3 @ MI_{max}}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	15.9								
	Focal Length	Focal Length	FL_x (cm)	5.0			-			-		
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 uSmart3200T 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
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.56								
	W_o	P	(mW)		5.0	0.2		5.0	0.2		5.0	0.2
	W_{o1}	P_{txt}	(mW)		1.3	0.2		1.6	0.2			
	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)				0.1					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							1.0		
	z_1	z_s	(cm)				0.95					
	z_{bp}	z_{bp}	(cm)	0.95			0.95			0.95		
	z_{sp}	z_b	(cm)							1.40		
	$z@PII_{max}$	Z_{pii}	(cm)	3.60			3.60			3.60		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.70								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.29		
	D_{eq}	D_{eq}	(cm)								1.44	0.64
	f_c	f_{awf}	(MHz)	9.10	9.10	9.10		9.10	9.10		9.10	9.10
	Dim of A_{aprt}	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
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.12								
	PRF	prf	(Hz)	570								
	SRF	srf	(Hz)	142.5								
		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 ²)	6.0								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	18.4								
	$p_r@PII_{max}$	p_r at z_{pii}	(MPa)	0.91								
	$d_{eq}@PII_{max}$	d_{eq} at z_{pii}	(cm)							0.22		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	15.9								
	Focal Length	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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.39								
	W_o	P	(mW)		27.5	-		27.5	-		27.5	-
	W_{o1}	P_{txt}	(mW)		9.1	-		9.1	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	1.45			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	5.00			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	4.80								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								1.44	-
	f_c	f_{awf}	(MHz)	5.13	5.13	-		5.13	-		5.13	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		3.84	-		3.84	-		3.84	-
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t_d	(μsec)	0.74								
	PRF	prf	(Hz)	300								
	SRF	srr	(Hz)	11.4								
		n_{pps}		10								
	$I_{spta,3} @ Z_{pii,3}$ or $I_{spt,a} @ Z_{spt,a}$	$I_{spta,a} @ Z_{pii,a}$ or $I_{spt,a} @ Z_{spt,a}$	(mW/cm ²)	31.5								
	$I_{spta} @ Z_{pii}$ or Z_{spt}	$I_{spta} @ Z_{pii}$ or Z_{spt}	(mW/cm ²)	56.5								
	$pr@P_{II\max}$	p_r at Z_{pii}	(MPa)	0.88								
	$d_{eq}@P_{II\max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	9.2								
	Focal Length	Focal Length	FLx (cm) FLy (cm)	5.0 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 uSmart3200T 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	0.15			0.20			0.16	
Index Component Value				0.19	-	0.15	0.09	-	0.09	0.20	-	0.16
USFDA Track 3 IEC												
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.44								
	W_o	P	(mW)		-	6.3		-	6.3		-	6.3
	W_{o1}	P_{txt}	(mW)		-	3.8		-	3.8			
	min of [$W_{r,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{r,3}(Z_s)$, $I_{ta,3}(Z_s) \times 1 \text{ cm}^2$]	(mW)				3.8					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							26.2		
	Z_1	Z_s	(cm)				1.45					
	Z_{bp}	Z_{bp}	(cm)	1.45			1.45			1.45		
	Z_{sp}	Z_b	(cm)							1.45		
	$z@P_{II\max}$	Z_{pii}	(cm)	5.00			5.00			5.00		
	$z@P_{II3\max}$	Z_{MI}	(cm)	4.80								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.43		
	D_{eq}	D_{eq}	(cm)								-	0.96
	f_c	f_{awf}	(MHz)	5.13	-	5.13		-	5.13		-	5.13
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.71		-	1.71		-	1.71
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.85								
	PRF	prf	(Hz)	1250								
	SRF	srr	(Hz)	-								
		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 ²)	29.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	165.3								
	$pr@P_{II\max}$	p_r at Z_{pii}	(MPa)	0.99								
	$d_{eq}@P_{II\max}$	d_{eq} at Z_{pii}	(cm)							0.21		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	12.8								
	Focal Length	Focal Length	FLx (cm)	5.0			5.0			5.0		
Operating Control Conditions	Control 1			X								
	Control 2				X			X			X	
	Control 3											

NOTE 1: The non-scanned W_o was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.89								
	W_o	P	(mW)		82.4	-		82.4	-		-	-
	W_{o1}	P_{txt}	(mW)		22.5	-		22.5	-			
	min of [$W_{r,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{r,3}(Z_s)$, $I_{ta,3}(Z_s) \times 1 \text{ cm}^2$]	(mW)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.85			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.45			-			-		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.40								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.68	6.15	-		6.15	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		5.49	-		5.49	-		-	-
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t_d	(μsec)	0.31								
	PRF	prf	(Hz)	86.8								
	SRF	srf	(Hz)	86.8								
		n_{pps}		2								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	38.2								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	59.9								
	$p_{r@PII\max}$	p_r at Z_{pii}	(MPa)	3.55								
	$d_{eq@PII\max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	242.9								
	Focal Length	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 transducer 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 uSmart3200T 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			0.67			Note 1	
Index Component Value				1.34	0.61	0.05	0.07	0.61	0.05	0.06	-	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	2.89								
	W_o	P	(mW)		75.8	5.9		75.8	5.9		-	-
	W_{o1}	P_{txt}	(mW)		20.7	1.6		20.7	1.6			
	min of [$W_{r,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{r,3}(Z_s)$, $I_{ta,3}(Z_s) \times 1 \text{ cm}^2$]	(mW)				2.6					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							4.1		
	Z_1	Z_s	(cm)				2.0					
	Z_{bp}	Z_{bp}	(cm)	0.85			2.0			2.0		
	Z_{sp}	Z_b	(cm)							2.0		
	$z@PII_{max}$	Z_{pii}	(cm)	1.45			8.1			8.1		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.40								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.91		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	4.68	6.15	6.15		6.15	6.15		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		5.49	3.66		5.49	3.66		-	-
						0.40		0.40	0.40		-	-
Y (cm)						0.40		0.40	0.40		-	-
Mode Components				B+M	B	M		B	M		-	-
Other Information	PD	t_d	(μsec)	0.31								
	PRF	prf	(Hz)	570								
	SRF	srr	(Hz)	71.3								
		n_{pps}		2								
	$I_{spta,3} @ Z_{pii,3}$ or $I_{spt,3}$	$I_{spta,a} @ Z_{pii,a}$ or $I_{spt,a}$	(mW/cm ²)	74.5								
	$I_{spta} @ Z_{pii}$ or Z_{spt}	$I_{spta} @ Z_{pii}$ or Z_{spt}	(mW/cm ²)	117.3								
	$p_{r@PII_{max}}$	p_r at Z_{pii}	(MPa)	3.55								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							0.63		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	242.9								
	Focal Length	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 transducer 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 = 8 cm, focus = 8.0 cm, PRF = 570 Hz

Acoustic Output Reporting Table for Track 3 for the 15WL4 Probe
(Terason uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.09								
	W _o	P	(mW)		47.4	-		47.4	-		-	-
	W _{o1}	P _{txt}	(mW)		40.2	-		40.2	-			
	min of [W _{.3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	z _s	(cm)				-					
	Z _{bp}	z _{bp}	(cm)	0.70			-			-		
	Z _{sp}	z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.05			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	0.95								
	d _{eq} (Z _{sp})	d _{eq} (z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	4.30	5.07	-		5.07	-		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.29	-		1.29	-		-	-
Y (cm)				0.40	-		0.40	-		-	-	
Mode Components				rD	B+rD	-		B+rD	-		-	-
Other Information	PD	t _d	(μsec)	0.89								
	PRF	prr	(Hz)	15800								
	SRF	srr	(Hz)	50.0								
		n _{pps}		14								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta,a @ Z_{pii,a} or Z_{sii,a}}	(mW/cm ²)	321.4								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	422.4								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.33								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	160.2								
	Focal Length	Focal Length	FL _x (cm)	1.3			-			-		
FL _y (cm)			1.5			-			-			
Operating Control Conditions	Control 1			X								
	Control 2				X			X				
	Control 3											

NOTE 1: Information need not be provided regarding T/C for any transducer 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 uSmart3200T 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	1.66 (Note 2)			1.86			Note 1	
Index Component Value				1.45	-	1.66	0.99	-	0.92	1.86	-	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.27								
	W_o	P	(mW)		-	70.0		-	59.6		-	-
	W_{o1}	P_{txt}	(mW)		-	37.1		-	38.6			
	min of [$W_{3,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{\alpha}(Z_s)$, $I_{ta, \alpha}(Z_s) \times 1 \text{ cm}^2$]	(mW)				41.8					
	$I_{spta,3} @ Z_{sp}$	$I_{spta, a}$ at Z_b	(mW/cm ²)							230.3		
	Z_1	Z_s	(cm)				1.50					
	Z_{bp}	Z_{bp}	(cm)	0.85			1.50			1.35		
	Z_{sp}	Z_b	(cm)							1.35		
	$z@PII_{max}$	Z_{pii}	(cm)	1.40			5.30			4.50		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.40								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.46		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	5.10	-	4.97		-	4.97		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.89		-	1.54		-	-
Mode Components				D	-	D		-	D		-	-
Other Information	PD	t_d	(μsec)	1.11								
	PRF	prf	(Hz)	600								
	SRF	srr	(Hz)	-								
		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 ²)	394.6								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	636.6								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	4.18								
	$d_{eq}@PII_{max}$	d_{eq} at z_{pii}	(cm)							0.43		
	$I_{PA3} @ MI_{max}$	$I_{pa, a}$ at $z_{pii, a}$	(W/cm ²)	593.3								
	Focal Length	Focal Length	FLx (cm)	1.8			5.6			4.8		
Operating Control Conditions	Control 1			X								
	Control 2				X							
	Control 3							X				

NOTE 1: Information need not be provided regarding *TIC* for any transducer assembly not intended for transcranial or neonatal cephalic uses.

NOTE 2: The non-scanned W_o was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 1.0 mm, SV Depth = 5.6 cm, PRF = 3500 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 uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	3.38								
	W _o	P	(mW)		21.2	-		21.2	-		-	-
	W _{o1}	P _{txt}	(mW)		8.3	-		8.3	-			
	min of [W _{.3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	z _s	(cm)				-					
	Z _{bp}	z _{bp}	(cm)	0.60			-			-		
	Z _{sp}	z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.05			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	1.00								
	d _{eq} (Z _{sp})	d _{eq} (z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								-	-
	f _c	f _{awf}	(MHz)	9.28	9.58	-		9.58	-		-	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		2.56	-		2.56	-		-	-
Y (cm)				0.35	-		0.35	-		-	-	
Mode Components				B	B	-		B	-		-	-
Other Information	PD	t _d	(μsec)	0.13								
	PRF	prr	(Hz)	76.9								
	SRF	srr	(Hz)	76.9								
		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 ²)	15.5								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	29.2								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	4.51								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	571.2								
	Focal Length	Focal Length	FL _x (cm)	1.2			-			-		
FL _y (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 transducer 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 uSmart3200T 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	0.43 (Note 2)			0.38			Note 1	
Index Component Value				1.11	0.34	0.09	0.03	0.34	0.04	0.03	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.38								
	W_0	P	(mW)		19.2	2.0		19.2	2.0		-	-
	W_{01}	P_{bxt}	(mW)		7.5	0.8		7.5	0.8			
	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)				0.7					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							2.4		
	Z_1	Z_s	(cm)				1.60					
	Z_{bp}	Z_{bp}	(cm)	0.60			1.60			1.60		
	Z_{sp}	Z_b	(cm)							1.60		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.05			1.60			1.60		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.00								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.60		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	9.28	9.58	9.58		9.58	9.58		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		2.56	2.56		2.56	2.56		-	-
			Y (cm)		0.35	0.35		0.35	0.35		-	-
Mode Components				B+M	B	M		B	M		-	-
Other Information	PD	t_d	(μsec)	0.13								
	PRF	prf	(Hz)	570								
	SRF	srf	(Hz)	81.4								
		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 ²)	44.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	83.9								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	4.51								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.60		
	$I_{PA3} @ M_{I\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	571.2								
	Focal Length	Focal Length	FL_x (cm)	1.2			5.8			5.8		
			FL_y (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 transducer assembly not intended for transcranial or neonatal cephalic uses.

NOTE 2: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 5.8 cm, PRF = 570 Hz

**Acoustic Output Reporting Table for Track 3 for the 16HL7 Probe
(Terason uSmart3200T 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	-	-	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	1.88								
	W_o	P	(mW)		15.3	-		15.3	-		-	-
	W_{o1}	P_{bxt}	(mW)		12.9	-		12.9	-			
	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)				-					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							-		
	Z_1	Z_s	(cm)				-					
	Z_{bp}	Z_{bp}	(cm)	0.55			-			-		
	Z_{sp}	Z_b	(cm)							-		
	$z@P_{II,max}$	Z_{pii}	(cm)	0.80			-			-		
	$z@P_{II,3,max}$	Z_{MI}	(cm)	0.75								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							-		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	7.16	7.91	-		7.91	-		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		1.46	-		1.46	-		-	-
Mode Components				rD	B	-		B	-		-	-
Other Information	PD	t_d	(μsec)	0.52								
	PRF	prf	(Hz)	1000								
	SRF	srr	(Hz)	36.0								
		n_{pps}		10								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	187.8								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	273.4								
	$pr@P_{II,max}$	p_r at Z_{pii}	(MPa)	2.23								
	$d_{eq}@P_{II,max}$	d_{eq} at Z_{pii}	(cm)							-		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	190.3								
	Focal Length	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 transducer 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 uSmart3200T 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	1.11 (Note 2)			0.94			Note 1	
Index Component Value				1.29	-	1.11	0.47	-	0.47	0.94	-	-
USFDA Track 3 IEC												
Associated Acoustic Parameter	$P_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.44								
	W_o	P	(mW)		-	29.5		-	12.4		-	-
	W_{o1}	P_{txt}	(mW)		-	11.5		-	12.4			
	min of [$W_{r,3}(Z_1)$, $I_{TA,3}(Z_1)$]	Min of [$P_{r,3}(Z_s)$, $I_{ta,3}(Z_s) \times 1 \text{ cm}^2$]	(mW)				12.6					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							291.0		
	Z_1	Z_s	(cm)				1.60					
	Z_{bp}	Z_{bp}	(cm)	0.55			1.60			0.80		
	Z_{sp}	Z_b	(cm)							0.90		
	$z@P_{II\max}$	Z_{pii}	(cm)	0.80			5.80			1.65		
	$z@P_{II3\max}$	Z_{MI}	(cm)	0.75								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.19		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	7.16	-	7.87		-	7.93		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	2.56		-	0.66		-	-
Mode Components				D	-	D		-	D		-	-
Other Information	PD	t_d	(μsec)	1.17								
	PRF	prf	(Hz)	500								
	SRF	srr	(Hz)	-								
		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 ²)	380.1								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	566.8								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	4.08								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.14		
	$I_{PA3} @ MI_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	647.6								
	Focal Length	Focal Length	FL_x (cm) FL_y (cm)	0.90 1.0			5.8 1.0			2.0 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 transducer assembly not intended for transcranial or neonatal cephalic uses.

NOTE 2: The non-scanned W_o was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 4.5 mm, SV Depth = 5.8 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 uSmart3200T 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	-	
	USFDA Track 3	IEC											
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	3.26									
	W _o	P	(mW)		53.4	-		53.4	-		57.9	-	
	W _{o1}	P _{txt}	(mW)		15.4	-		15.4	-				
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _α (Z _s), I _{ta,α} (Z _s)x 1cm ²]	(mW)			-							
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-			
	Z ₁	Z _s	(cm)				-						
	Z _{bp}	Z _{bp}	(cm)	0.65			-			-			
	Z _{sp}	Z _b	(cm)							-			
	z@P _{II} _{max}	Z _{pii}	(cm)	1.20			-			-			
	z@P _{II} _{3max}	Z _{MI}	(cm)	1.20									
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-			
	D _{eq}	D _{eq}	(cm)								1.31	-	
	f _c	f _{awf}	(MHz)	5.94	9.55	-		9.55	-		7.76	-	
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		3.84	-		3.84	-		3.84	-	
			Y (cm)		0.35	-		0.35	-		0.35	-	
Mode Components				B	B	-		B	-		B	-	
Other Information	PD	t _d	(μsec)	0.22									
	PRF	prr	(Hz)	86.8									
	SRF	srr	(Hz)	86.8									
		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 ²)	35.7									
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	58.8									
	pr@P _{II} _{max}	p _r at z _{pii}	(MPa)	4.16									
	d _{eq} @P _{II} _{max}	d _{eq} at z _{pii}	(cm)							-			
	I _{PA3 @MI} _{max}	I _{pa, a} at z _{pii, a}	(W/cm ²)	275.5									
	Focal Length	Focal Length	FL _x (cm)	1.4			-			-			
		FL _y (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 uSmart3200T 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	0.71			0.68			1.09	
Index Component Value				1.34	0.60	0.12	0.05	0.60	0.08	0.06	1.02	0.07
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.26								
	W_0	P	(mW)		45.3	2.6		45.3	2.6		53.4	2.1
	W_{01}	P_{bxt}	(mW)		13.1	1.7		13.1	1.7			
	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)				1.2					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							7.3		
	Z_1	Z_s	(cm)				1.20					
	Z_{bp}	Z_{bp}	(cm)	0.65			1.20			1.20		
	Z_{sp}	Z_b	(cm)							1.20		
	$z@P_{II\max}$	Z_{pii}	(cm)	1.20			1.30			1.30		
	$z@P_{II3\max}$	Z_{MI}	(cm)	1.20								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.48		
	D_{eq}	D_{eq}	(cm)								1.31	0.72
	f_c	f_{awf}	(MHz)	5.94	9.55	9.55		9.55	9.55		7.76	7.76
	Dim of A_{aprt}	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
Mode Components				B+M	B	M		B	M		B	M
Other Information	PD	t_d	(μsec)	0.22								
	PRF	prf	(Hz)	570								
	SRF	srr	(Hz)	95.0								
		n_{pps}		2								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	65.7								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	108.2								
	$p_{r@P_{II\max}}$	p_r at Z_{pii}	(MPa)	4.16								
	$d_{eq@P_{II\max}}$	d_{eq} at Z_{pii}	(cm)							0.47		
	$I_{PA3} @ M_{\max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	275.5								
	Focal Length	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	

NOTE 1: The non-scanned W_0 was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 uSmart3200T 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	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	P _{r,3}	p _{ra} at Z _{MI}	(MPa)	2.00								
	W _o	P	(mW)		40.4	-		40.4	-		78.7	-
	W _{o1}	P _{txt}	(mW)		34.0	-		34.0	-			
	min of [W _{,3} (Z ₁), I _{TA,3} (Z ₁)]	Min of [P _o (Z _s), I _{ta, o} (Z _s)x 1cm ²]	(mW)			-						
	I _{spta 3 @ Z_{sp}}	I _{spta a} at Z _b	(mW/cm ²)							-		
	Z ₁	Z _s	(cm)				-					
	Z _{bp}	Z _{bp}	(cm)	0.70			-			-		
	Z _{sp}	Z _b	(cm)							-		
	z@PII _{max}	Z _{pii}	(cm)	1.10			-			-		
	z@PII _{3max}	Z _{MI}	(cm)	1.10								
	d _{eq} (Z _{sp})	d _{eq} (Z _b)	(cm)							-		
	D _{eq}	D _{eq}	(cm)								1.31	-
	f _c	f _{awf}	(MHz)	6.02	6.64	-		6.64	-		6.65	-
	Dim of A _{aprt}	Dim of A _{aprt}	X (cm)		1.36	-		1.36	-		3.84	-
		Y (cm)		0.35	-		0.35	-		0.35	-	
Mode Components				rD	B+rD	-		B+rD	-		B+rD	-
Other Information	PD	t _d	(μsec)	0.63								
	PRF	prr	(Hz)	13000								
	SRF	srr	(Hz)	63.1								
		n _{pps}		10								
	I _{spta 3 @ Z_{pii 3} or Z_{sii 3}}	I _{spta, a @ Z_{pii, a} or Z_{sii, a}}	(mW/cm ²)	369.6								
	I _{spta @ Z_{pii} or Z_{sii}}	I _{spta @ Z_{pii} or Z_{sii}}	(mW/cm ²)	582.6								
	pr@PII _{max}	p _r at z _{pii}	(MPa)	2.48								
	d _{eq} @PII _{max}	d _{eq} at z _{pii}	(cm)							-		
	I _{PA3 @MI_{max}}	I _{pa, a} at z _{pii, a}	(W/cm ²)	201.5								
	Focal Length	Focal Length	FL _x (cm)	1.4			-			-		
		FL _y (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 uSmart3200T 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	1.74			1.69			1.66	
Index Component Value				1.48	-	1.74	1.00	-	1.22	1.69	-	1.66
USFDA Track 3 IEC												
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	3.62								
	W_o	P	(mW)		-	55.0		-	44.8		-	55.0
	W_{o1}	P_{txt}	(mW)		-	35.7		-	38.6			
	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)				31.7					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							275.3		
	z_1	z_s	(cm)				1.20					
	z_{bp}	z_{bp}	(cm)	0.70			1.20			1.10		
	z_{sp}	z_b	(cm)							1.20		
	$z@PII_{max}$	Z_{pii}	(cm)	1.10			1.20			3.20		
	$z@PII_{3max}$	Z_{MI}	(cm)	1.10								
	$d_{eq}(z_{sp})$	$d_{eq}(z_b)$	(cm)							0.36		
	D_{eq}	D_{eq}	(cm)								-	0.83
	f_c	f_{awf}	(MHz)	6.02	-	6.65		-	6.63		-	6.65
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	1.54		-	1.16		-	1.54
			Y (cm)		-	0.35		-	0.35		-	0.35
Mode Components				D	-	D		-	D		-	D
Other Information	PD	t_d	(μsec)	1.26								
	PRF	prr	(Hz)	500								
	SRF	srr	(Hz)	-								
		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 ²)	417.4								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	658.0								
	$pr@PII_{max}$	p_r at z_{pii}	(MPa)	4.50								
	$d_{eq}@PII_{max}$	d_{eq} at z_{pii}	(cm)							0.28		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $z_{pii,a}$	(W/cm ²)	662.3								
	Focal Length	Focal Length	FLx (cm)	1.4			5.8			3.5		
			FLy (cm)	1.5			1.5			1.5		
Operating Control Conditions	Control 1			X								
	Control 2				X						X	
	Control 3							X				

NOTE 1: The non-scanned W_o was used to calculate the TIS since NEMA has not adopted the IEC calculation.

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 = 5.0 mm, SV Depth = 5.8 cm, PRF = 300 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 = 2.0 mm, SV Depth = 3.3 cm, PRF = 17600 Hz, Update = off

**Acoustic Output Reporting Table for Track 3 for the PDOF Probe
(Terason uSmart3200T 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	0.95			3.54			Note 1	
Index Component Value				0.08	-	0.95	0.78	-	0.95	3.54	-	-
	USFDA Track 3	IEC										
Associated Acoustic Parameter	$p_{r,3}$	p_{ra} at Z_{MI}	(MPa)	0.11								
	W_o	P	(mW)		-	100.0		-	100.0		-	-
	W_{o1}	P_{txt}	(mW)		-	100.0		-	100.0			
	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)				81.9					
	$I_{spta,3} @ Z_{sp}$	$I_{spta,a}$ at Z_b	(mW/cm ²)							417.7		
	Z_1	Z_s	(cm)				1.45					
	Z_{bp}	Z_{bp}	(cm)	1.45			1.45			1.45		
	Z_{sp}	Z_b	(cm)							2.10		
	$z@PII_{max}$	Z_{pii}	(cm)	2.75			2.75			2.75		
	$z@PII_{3max}$	Z_{MI}	(cm)	2.30								
	$d_{eq}(Z_{sp})$	$d_{eq}(Z_b)$	(cm)							0.47		
	D_{eq}	D_{eq}	(cm)								-	-
	f_c	f_{awf}	(MHz)	2.00	-	2.00		-	2.00		-	-
	Dim of A_{aprt}	Dim of A_{aprt}	X (cm)		-	0.69		-	0.69		-	-
			Y (cm)		-	1.38		-	1.38		-	-
Mode Components				cwD	-	cwD		-	cwD		-	-
Other Information	PD	t_d	(μsec)	-								
	PRF	prr	(Hz)	-								
	SRF	srr	(Hz)	-								
		n_{pps}		-								
	$I_{spta,3} @ Z_{pii,3}$ or $Z_{sii,3}$	$I_{spta,a} @ Z_{pii,a}$ or $Z_{sii,a}$	(mW/cm ²)	417.0								
	$I_{spta} @ Z_{pii}$ or Z_{sii}	$I_{spta} @ Z_{pii}$ or Z_{sii}	(mW/cm ²)	580.9								
	$pr@PII_{max}$	p_r at Z_{pii}	(MPa)	0.13								
	$d_{eq@PII_{max}}$	d_{eq} at Z_{pii}	(cm)							0.46		
	$I_{PA3} @ MI_{max}$	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	-								
	Focal Length	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 transducer not intended for transcranial or neonatal cephalic uses.

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

3 Maintenance

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

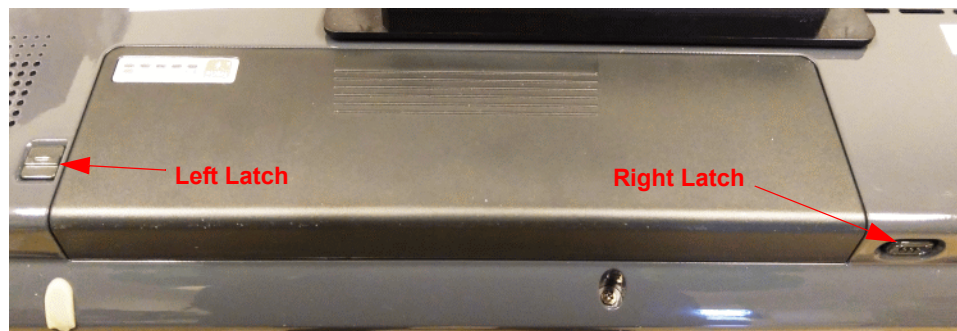
- [Cleaning the Ultrasound System](#), see page 103
- [Processing Terason Probes Between Uses](#), see page 104
- [Recommended Maintenance](#), see page 108

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. Push the **latch** on the bottom of the case (to the left of the battery) into the case.
- b. Slide the **latch** on the edge of the case (to the right of the battery) to the right and hold it.
- c. While holding the latch 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 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 and multiple-probe unit.

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.



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



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.



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

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 107.

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. See [Cleaners](#) on page 107 for a list of approved cleaners.
 - a. Follow the manufacturer's instructions for proper **dilution** of the selected detergent.



Note: Klenzyme detergent packaging may not include dilution instructions. If you find that to be the case, dilute Klenzyme at 1 ounce Klenzyme to 1 gallon of water (8 ml to 1 liter of water).

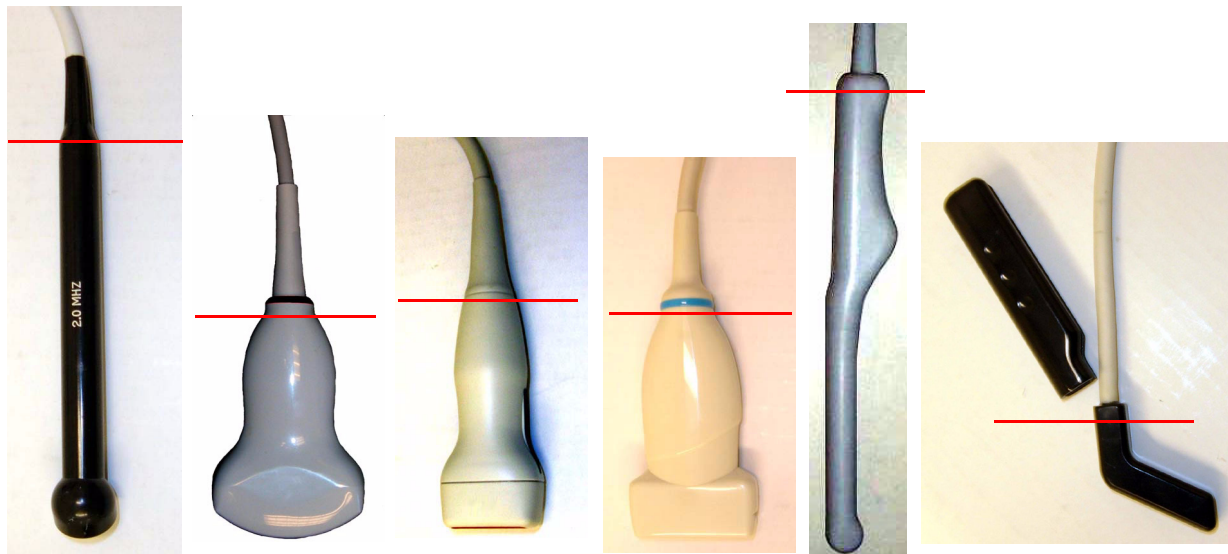
- b. Moisten a soft cloth with the detergent solution, and **wipe** the probe until all visible soil is removed.
 - c. Moisten a second cloth with **sterile water** and wipe all the probe surfaces to remove any detergent residue and prevent it from drying on the probe.

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



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



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



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

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.

To perform high-level disinfection of probes:

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. See [Cleaners](#) on page 107 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 108. Follow the disinfectant manufacturer's instructions for use of the product.



Caution: Do not submerge the probe beyond the line shown in the figure labeled [Do Not Submerge Probes Above Line](#) on page 106.

- a. Submerge the probe in the high-level disinfectant up to the line shown in the figure labeled [Do Not Submerge Probes Above Line](#) on page 106.
 - b. Follow the disinfectant manufacturer's instructions for duration, temperature, etc.
6. Moisten a cloth with **sterile water** and wipe all the probe surfaces to remove any disinfectant residue and prevent it from drying on the probe.
 7. Pat the probe dry, using a soft sponge, cloth, or gauze pad.

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



Note: These high-level disinfectants are for use only on endocavity and TEEprobes.



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

- Alkazyme
- Klenzyme
- Cidex 2%

Using other disinfectants can damage the 16HL7 probe.

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 monthly. 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

Refer to the tablet manual for information on tablet maintenance.



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.

4 System Safety

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

- [Infection Control](#) on page 110
- [Safety Cautions and Warnings](#) on page 112
- [Labels](#) on page 123
- [Safety Standards](#), see page 126
- [Indications For Use](#), see page 128
- [Acoustic Output Indices](#), see page 148
- [Relationship of Index to Display Accuracy](#), see page 156
- [Acoustic Output Tables](#), see page 159
- [Accuracy Measures](#), see page 160
- [Compliance and Approvals](#), see page 162
- [Environmental Protection](#), see page 162

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 110
- [Disinfection](#) on page 111

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
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
PDOF	Refer to the Civco Website



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 105 and [Semicritical Device Applications](#) on page 107 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 110 for recommended sterile covers for each type of probe. Follow the manufacturer's instructions for use of sheaths.



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.



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.

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.



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

Terason Probes

Each probe model has indications for use (see [Indications For Use](#) on page 128) concerning specific applications.

Ultrasound System

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



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.



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

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.



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.

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.



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



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.

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.



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.

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 tablet battery.



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.



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.



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.

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.



Caution: Use only Medical-Grade peripherals in the patient environment. See [Patient Environment](#) on page 119 for a diagram of the patient environment.



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



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.

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 168 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 170 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 168 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

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 ¹
Ultrasound system	Terason	10-3232	Ultrasound system	IPX-0 ³
4V2A probe	Terason	10-3216	Ultrasound probe	IPX-7 ² (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
5C2A probe	Terason	10-3278	Ultrasound probe	IPX-7 ³ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
8BP4 probe	Terason	10-3075	Ultrasound probe	IPX-7 ⁴ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
8EC4A probe	Terason	10-3374	Ultrasound probe	IPX-7 ⁵ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
8L2 probe	Terason	10-3593	Ultrasound probe	IPX-7 ⁶ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance

Spill Protection of Applied Parts (Continued)

Component	Manufacturer	Mfr. Part No.	Use	IPX Level ¹
8TE3 probe	Terason	10-3283	Ultrasound probe	IPX-7 ² (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
8V3A probe	Terason	10-3319	Ultrasound probe	IPX-7 ⁷ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
9MC3	Terason	10-3255	Ultrasound probe	IPX-7 ⁸ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
10EC4	Terason	10-3514	Ultrasound probe	IPX-7 ² (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
12L5A probe	Terason	10-3276	Ultrasound probe	IPX-7 ⁹ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
14L3	Terason	10-3397	Ultrasound probe	IPX-7 ² (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
15L4 probe	Terason	10-3512	Ultrasound probe	IPX-7 ¹⁰ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
15L4A probe	Terason	10-3512	Ultrasound probe	IPX-7 ¹¹ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
15WL4 probe	Terason	10-3390	Ultrasound probe	IPX-7 ² (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
16HL7 probe	Terason	10-3599	Ultrasound probe	IPX-7 ¹² (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
16L5 probe	Terason	10-3389	Ultrasound probe	IPX-7 ¹³ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
PDOF probe	Terason	10-3282	Ultrasound probe	IPX-7 ¹⁴ (at probe head); IPX-0 for connector. See Chapter 3 - Maintenance
DC power adapter	Sinpro	15-33101	Power source and battery charger for ultrasound system	IPX-0 ³
Power supply cord	Interpower	86610820	AC line cord	IPX-0
ECG module	Terason	10-3306	3-lead ECG module to connect to ultrasound system	IPX-0
Footswitch	Kinassis	FS20A-USB-UL	Footswitch programmed for image freeze and image save	IPX-1

Spill Protection of Applied Parts (Continued)

Component	Manufacturer	Mfr. Part No.	Use	IPX Level ¹
Cart	Terason	15-38000	Cart for ultrasound system	N/A
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 3 - [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 3 - [Maintenance](#) for detailed description of how much of the probe can be immersed during cleaning.
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4. Refer to Chapter 3 - [Maintenance](#) for detailed description of how much of the probe can be immersed during cleaning.
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5. Refer to Chapter 3 - [Maintenance](#) for detailed description of how much of the probe can be immersed during cleaning.
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6. Refer to Chapter 3 - [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.
7. Refer to Chapter 3 - [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.
8. Refer to Chapter 3 - [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.
9. Refer to Chapter 3 - [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.
10. Refer to Chapter 3 - [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.
11. Refer to Chapter 3 - [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.
12. Refer to Chapter 3 - [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.
13. Refer to Chapter 3 - [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.
14. Refer to Chapter 3 - [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.



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.

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.



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

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

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).

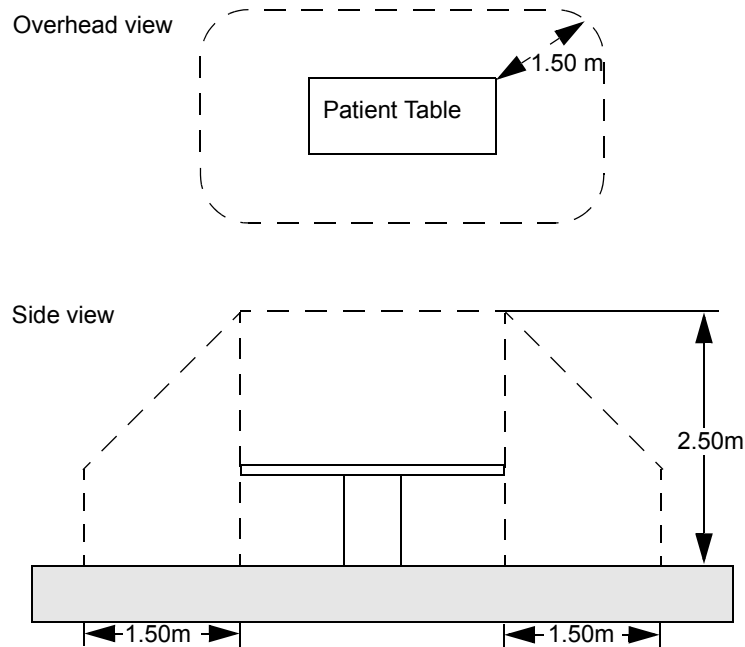
During scanning, the patient is typically lying on an exam table with the ultrasound technician sitting or standing to one side. There are usually no other persons in the exam room.

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



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.

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 168.

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 $\pm 2\text{kV}$ ESD. The latch for locking the ultrasound probe is sensitive to ESD and should not be touched when operating the system. In cases where an ESD shock discharges to one of these points, the computer program may freeze or windows may open unexpectedly. In these cases, the Terason software may require restarting, and you may have to close extra windows. In extreme cases, the computer may require restarting. These events are not dangerous to the patient or to the operator.

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 105. 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.



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.

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



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.

Ophthalmic Use



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.

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.

Terason Ultrasound System Emits Ultrasound Energy



This device complies with FDA Track 3 guidelines on acoustic output labeling for the intended uses of the probes.

Double Insulated



This device is Type 2 (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



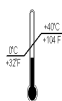
The Terason Ultrasound System must be stored in the original shipping container in environments with 10% to 90% relative humidity non-condensing.

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 -5°C and 50°C (23°F and 122°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 126
- [Electrical Safety](#), see page 126
- [Surface Heating of Invasive Probes](#), see page 127

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 Transducer

The 8TE3 TEE transducer 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 transducer 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 Volume 1 of this guide, Chapter 4 - 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 transducer is no longer imaging. This allows the lens to cool and prevents burning the patient. To prevent the transducer 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 transducer 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.



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



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.



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



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.

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
- 10EC4 probe
- 12L5A probe
- 14L3 probe
- 15L4 probe
- 15L4A probe
- 15WL4 probe
- 16HL7 probe
- 16L5 probe
- PDOF probe

Indications for use - Diagnostic Ultrasound System

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason uSmart3200T 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
Ophthalmic	Ophthalmic	X	X	X		X	X	X
Fetal Imaging and Other	Fetal	X	X	X	X	X	X	X
	Abdominal	X	X	X		X	X	X
	Intra-operative (Spec.)	X	X	X		X	X	X
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric ^d	X	X	X		X	X	X
	Small Organ (Thyroid, Breast, Testes, etc.)	X	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)								
Cardiac	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)							
Peripheral Vessel	Peripheral vessel	X	X	X		X	X	X
	Other (specify)							

Indications for Use - 5V1 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
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	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)								
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 -8BP4 Transducer

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
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	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)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	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)							
	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
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.)							
	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 - 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 ^a	Comb. Modes ^b	Other ^c
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	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)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)	X	X	X	X	X	X	X
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

Indications for Use - 8V3A Transducer

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Transducer: 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 uSmart3200T 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
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	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)							
	Cardiac	Cardiac Adult	X	X		X	X	X
Cardiac Pediatric		X	X		X	X	X	X
Trans-esoph. (Cardiac)								
Other (specify)								
Peripheral Vessel	Peripheral vessel	X	X	X	X	X	X	X
	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 uSmart3200T 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
Ophthalmic	Ophthalmic	X	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 - 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
Ophthalmic	Ophthalmic	X	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 - 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
Ophthalmic	Ophthalmic	X	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 - 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
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	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)							
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 - 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 Transducer

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM								
System: Terason Ultrasound System								
Transducer: 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 ^a	Comb. Modes ^b	Other ^c
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	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)							
	Cardiac	Cardiac Adult				X		
Cardiac Pediatric					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) and the *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment* (UD3-2004).

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-cm² area anywhere along the beam axis is the basis for estimating tissue heating: unscanned beams less than 1cm² 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 cm² 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 ¹
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.



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.

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. Tap **Setup**.
2. Tap the **Display** tab.
3. In the TI Selection section, tap the **desired thermal index**.
4. Tap **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_{Display}	Range of calculated value $x_{\text{Calc.}}$	Displayed value x_{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 cm² in area
- Soft-Tissue Thermal Index for unscanned modes, when the beam-entrance dimension is greater than 1 cm² 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 ϵ_k , is approximately:

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

where the following are defined:

- ϵ_{Cal} Calibration error, as supplied by Sonic Consulting, Inc.; 21% at the frequency range of the probes tested.
- ϵ_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%
- ϵ_{V^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:

- ϵ_{TI} Relative error due to hydrophone positioning and temporal integration of the waveform, estimated as 4%
- ϵ_{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%
- ϵ_{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

ε_{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 $\varepsilon_{SPTA.3-unc.}$, is approximately:

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

where the following is defined:

ε_{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 $\varepsilon_{SPTA.3-scan.}$, is approximately:

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

where the following are defined:

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

ε_{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 $\varepsilon_{pr.3}$, is approximately:

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

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

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

where the following is defined:

ε_{fc} Relative error in estimating center frequency, estimated as 8%.

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

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

ε_{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 $\varepsilon_{TISscan}$, is approximately:

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

where the following is defined:

ε_{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 ε_{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 cm² in area**, defined as $\varepsilon_{\text{TISunsc-A} \leq 1}$, is approximately:

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

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 ² 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 cm² in area**, defined as $\varepsilon_{\text{TISunsc-A} > 1}$, is approximately:

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

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 ² in area, estimated as 20%.

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

$\epsilon_{SV\ ITA.6}$ 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 $\epsilon_{TIBunsc.}$, is approximately:

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

where the following is defined:

$\epsilon_{DATIBunsc}$ 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 ϵ_{TIC} , is approximately:

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

where the following is defined:

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

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

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

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

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

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

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

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

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

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 $x_{\text{Calc.}}$	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 152 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:

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

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. $x_{\text{Display}} - x_{\text{Actual}}$ 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 2, [Terason Probes](#), on page 10. 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 ¹	Combined ²	ENV ³
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	
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
16HL7	X	X	X		X	X	

Track 3 Probe/Mode Combination Summary (Continued)

Probe Model	Mode						
	2D	M	PWD	CWD	Color Doppler ¹	Combined ²	ENV ³
16L5	X	X	X		X	X	X
PDOF				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 2 - [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 (x₁,y₁) and (x₂,y₂) 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 = 10mm, accuracy = 9%
- For D = 20mm, accuracy = 6%
- For D > 50mm, 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 cm²

Accuracy: Determined by two independent distance measurements. The derivation of a particular tissue shape from the circular model cannot be quantified.

RMS errors: For $A = 3.1 \text{ cm}^2$, 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 $C = 6.3 \text{ cm}$, accuracy = 6%

Volume

Volume accuracy measures are as follows:

Assumptions: Cylinder, length of axes: 2a, 2b, 2c (height)

Formula: $V = \frac{4}{3}(\pi abc)$

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 $V = 16 \text{ ml}$, 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



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.



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.

The system batteries are not accessible to users. If you suspect a problem with a system battery, contact your local Terason representative.

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 –25° and 45° 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



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.



Warning: Do not throw batteries into the trash. Collect and recycle used batteries separate from other waste.

Item	Estimated Use Period	Handling Instructions
lithium manganese dioxide batteries and lithium-ion polymer batteries	300 full charge and discharge cycles	See also: Caring for Batteries on page 162

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 and 16L5 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.

To	Do This
Exit the ultrasound system software	Tap the  at the top right of the menu bar Select File>Exit from the menu bar
Activate or exit standby status ¹	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.

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 uSmart3200T 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	
	4V2, 5C2A	1.7 - 4 MHz	
	8V3A	3 - 9 MHz	
	8TE3, 9MC3	3 - 9 MHz	
	8L2	3 - 10 MHz	
	8BP4	4 - 8 MHz	
	8EC4A	4 - 9 MHz	
	10EC4	4 - 10 MHz	
	14 L3	3.75 - 12 MHz	
	12L5A, 15L4, 15L4A, 15WL4	4.3 - 12 MHz	
	16HL7, 16L5	6 - 13 MHz	
Frame Rate	2D Imaging (based on input data rate)	150 Hz maximum	
Ultrasound Lines/Frame		512 maximum	
Display		11.5" LED backlit touch screen	
Size	Width	12.64" (321 mm)	5.63" (143 mm)
	Height	8.82" (224 mm)	1.63" (41.3 mm)
	Depth	1.25" (32 mm)	2.88" (73 mm)
Weight	Weight	4.9 lbs (2.21 kg)	1.6 lbs. (0.73 kg)
Power Adapter	Input		100V~/240 V~
	Output		19 VDC @ 5 A

Terason Ultrasound System Specifications (Continued)

Category	Specification	Terason Ultrasound System	Power Adapter
Tablet 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		10-35°C (50-95°F)	0-40°C (32-104°F)
Humidity		20-80% RH, non-condensing	10-95% RH, non-condensing
Water Resistance		Probe array watertight to the strain relief	
Operating Altitude	Pressure	63 kPa to 101.3 kPa (472.5 to 759.8 mmHg)	70 kPa to 106 kPa (525 to 795 mm/Hg)
Storage	Temperature	-24 to 45°C (-13 to 113°F)	-40 to 75°C (-40 to 167°F)
	Humidity	15-90% 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 uSmart3200T 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
Frequency Range	2.400 GHz - 2.4835 GHz 5.1500 GHz - 5.3500 GHz 5.4700 GHz - 5.725 GHz 5.725 GHz - 5.8500 GHz
Modulation Techniques	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
Data Rate	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
Output Power	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 uSmart3200T is intended for use in the electromagnetic environment specified below. The customer or user of the uSmart3200T 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	Class A	The Terason Ultrasound System is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Electromagnetic Immunity

All Equipment

The uSmart3200T is intended for use in the electromagnetic environment specified below. The customer or user of the uSmart3200T 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	±6kV Contact ±8kV Air	±6kV Contact ±8kV 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	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles > 95% Dip for 5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles > 95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the uSmart3200T 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.



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.

Non-Life-Supporting Equipment

The uSmart3200T is intended for use in the electromagnetic environment specified below. The customer or user of the uSmart3200T 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 2.5 GHz	$[E_1] = 3$ V/m	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ where P is the max power in watts and d is the recommended separation distance in meters. Field strengths from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V_1 and E_1). Interference may occur in the vicinity of equipment containing a transmitter.

Separation Distances

The uSmart3200T is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the uSmart3200T can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the uSmart3200T 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.

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