Intended Use

The Doppler probe is intended for the intraoperative and transcutaneous evaluation of blood flow.

Indications for Use filed with the FDA for the Doppler probes lists the clinical applications as: Intraoperative (micro vascular and vascular), Intraoperative Neurological, Transesophageal, Transrectal, Laparoscopic and Peripheral Vascular.

European Union Notice:

The Doppler probes are intended for general use and each probe is intended to be used in multiple surgical specialties. The Doppler probes are not intended specifically for use in direct contact with the central nervous system (brain, meninges and spinal cord). The Doppler probes are not intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body. The Doppler probes are not intended to be dedicated disposable cardiovascular surgical instruments. The user must follow all Warnings, Cautions and Contraindications associated with this device.

Cautions

- Read Instruction for Use provided with compatible Doppler transceiver for additional information.
- Do not use if sterile barrier is opened or damaged.
- Prior to use, inspect probe for damage and/or sharp edges.
- The Doppler probe is delicate. Do not drop or strike against hard surfaces.
- Avoid excessive mechanical pressure on the probe or excessive tension on the probe cable.
- Do not re-use single-use disposable probes. Reuse may lead to cross contamination and mechanical damage.
- Do not autoclave the probes.
- Use the probe only with compatible 8 MHz Doppler transceivers.
- This Doppler probe is not intended for fetal use.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Do not immerse connector or handle in fluid.
- The Doppler probes are not to be used on or near the eyes.

WARNING: Never reuse single-use disposable probes. Reuse may lead to cross contamination and mechanical damage. No proven method exists which can eliminate the possibility of transmitting prion-based brain wasting disease such as variant Creutzfeldt-Jakob Disease (vCJD). Probes which come in contact with brain tissue must be disposed of by incineration.

Instructions for Use

1. Inspect sterile barrier, and do not use product if it has been opened or damaged.
2. Using sterile technique, remove the sterile Doppler probe from its packaging.
3. Maintaining sterility, inspect the probe for damage or sharp edges. If damage or sharp edges are apparent, discard the probe.
4. Hand-off the probe's connector to someone outside the sterile field.
5. Attach the probe's connector to the coaxial receptacle on the transceiver front panel.
6. Turn on the Doppler transceiver and adjust the volume.
7. To verify that the system is operational, gently draw the tip of the Doppler probe, using sterile technique, along any convenient sterile surface. This will produce a fairly loud rasping noise, confirming that the system is operational. If there is no signal or a weak signal is present, make sure the connector is securely connected, adjust the volume and test the probe again. If there is still no signal, discard the probe.
8. Place the tip of the probe directly on the vessel or other site to be evaluated.
9. Turn the transceiver on, adjust the volume. Adjust the angle between the probe and the tissue until the maximum audible signal is obtained. A lack of signal can indicate a lack of blood flow at the sensor or that additional repositioning is required.

Explanation of Symbols

Do not use if package is damaged

Indicates a medical device that is not to be resterilized

Explanation of Derivation of Derating Factor

The following is an explanation of how derated intensities were derived from intensities measured in water. The derated intensity calculations are based on the measured center frequency of the acoustical signal (f, MHz) and the distance from the transducer under test to the hydrophone (z, em) using the derating factor e -o.o69 fz.

Specifications - Acoustic Output Level: < 94.0 mW/cm²

Track 1 Summary Table

Clinical Application	Operating Mode(s) PWD
& Other*	_X_

*Abdominal, Intraoperative, Pediatric, Small Organ (breast, thyroid, testes, etc.), Neonatal Cephalic, Adult Cephalic, Musculo-Skeletal (conventional), Musculo-Skeletal (superficial)

Explanation of Symbols Used in Acoustic Output Reporting Table

IsPTA.3 — the derated spatial-peak temporal-average intensity (milliwatts per square centimeter).

IsPPA.3 — the derated spatial-peak pulse-average intensity (watts per square centimeter). The value of lrA.3 at the position of global maximum MI (IPA.3@MI) may be reported instead of IsPPA.3 if the global maximum MI is reported.

MI — the Mechanical Index. The value of MI at the position of IsPPA.3, (MI@IsPPA.3) may be reported instead of MI (global maximum value) if IsPPA.3 is s; 190Wjcm².

Pr.3 — the derated peak rarefactional pressure (megapascals) associated with the transmit pattern giving rise to the value reported under MI.

Wo — the ultrasonic power (milliwatts). For the operating condition giving rise to IsPTA.3, Wo is the total time-average power; for the operating condition subject to reporting under IsPPA.3, Wo is the ultrasonic power associated with the transmit pattern giving rise to the value reported under IsPPA.3·

fc — the center frequency (MHz). For MI and IsPPA.3, fc is the center frequency associated with the transmit pattern giving rise to the global maximum value of the respective parameter. For IsPTA.3, for combined modes involving beam types of unequal center frequency, fc is defined as the overall range of center frequencies the respective transmit patterns.

Zsp — the axial distance at which the reported parameter is measured (centimeters). x-6, Y-6 are respectively the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where Zsp is found (centimeters).

PD — the pulse duration (microseconds) associated with the transmit pattern giving rise to the reported value of the respective parameter.

PRF — the pulse repetition frequency (Hz) associated with the transmit pattern giving rise to the reported value of the respective parameter.

EBD — the entrance beam dimensions for the azimuthal and elevational planes (centimeters).

EDS — the entrance dimensions of the scan for the azimuthal and elevational planes (centimeters).

Acoustic Output Reporting Table for Track 1. Non-Autoscanning Mode

Transducer Model: 8 MHz 3.5mm
Fetal Imaging & Others
Operating Mode: Pulse Doppler (PD)

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value				0.0220	30.2	0.121
Associated Acoustic Parameter	$P_{r.3}$		(MPa)	0.0610		
	W_0		(mW)		0.823	0.823
	f_c		(MHz)	7.90	7.90	7.90
	z_{sp}		(cm)	0.976	0.976	0.976
	Beam dimensions	x_{-6}	(cm)		0.135	0.135
		y_{-6}	(cm)		0.145	0.145
	PD		(µsec)	4.00		4.00
	PRF		(KHz)	62.5		62.5
	EBD	Az.	(cm)		0.350	
		Ele.	(cm)		0.350	
Operating Control Conditions	The system has no adjustments					
	that impact acoustic output					

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Table 201.101- List of Symbols

Symbol	Term	Reference
A_{aprt}	-12dB OUTPUT BEAN AREA	IEC 62359, 3.25
D_{eq}	EQUIVALENT BEAM DIAMETER	IEC 62359, 3.22
f_{awf}	ACOUSTIC WORKING FREQUENCY	IEC 62359, 3.2
$I_{pa,\alpha}$	ATTENUATED PULSE-AVERAGE INTENSITY	IEC 62359, 3.5
I_{pi}	PULSE-INTENSITY INTEGRAL	IEC 62359, 3.32
$I_{pai,\alpha}$	ATTENUATED PULSE-INTENSITY INTEGRAL	IEC 62359, 3.6
I_{spta}	SPATIAL PEAK TEMPORTAL-AVERAGE INTENSITY	IEC 62359, 3.38
$I_{ta,\alpha}(z)$	ATTENUATED TEMPORAL-AVERAGE INTENSITY	IEC 62359, 3.8
MI	MECHANICAL INDEX	IEC 62359, 3.23
P	OUTPUT POWER	IEC 62359, 3.27
P_a	ATTENUATED OUTPUT POWER	IEC 62359, 3.3
$Pr_{,\alpha}$	ATTENUATED PEAK-RAREFACTIONAL ACOUSTIC	IEC 62359, 3.4
P_r	PEAK-RARE-FACTIONAL ACOUSTIC PRESSURE	IEC 62359, 3.28
prr	PULSE REPETITION RATE	IEC 62359, 3.34
TI	THERMAL INDEX	IEC 62359, 3.41
TIB	BONE THERMAL INDEX	IEC 62359, 3.11
TIC	CRANIAL-BONE THERMAL INDEX	IEC 62359, 3.15
TIS	SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.37
t_d	PULSE DURATION	IEC 62359
X, Y	-12dB OUTPUT BEAM DIMENSIONS	IEC 62359, 3.26
z_b	DEPTH FOR BONE THERMAL INDEX	IEC 62359, 3.17
z_{bp}	BREAK-POINT DEPTH	IEC 62359, 3.13
z_s	DEPTH FOR SOFT-TISSUE THERMAL INDEX	IEC 62359, 3.18

Table 201.103 – Acoustic Output Reporting Table

Transducer Model: 8 MHz 3.5 mm
Operating Mode: Pulse Doppler (PD)

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt}\leq 1$ cm^2	$A_{aprt}>1$ cm^2		
Maximum index value			0.0210	#	0.0405	-	0.0827	(a)
Associated acoustic parameter	$p_{r.a}$	(MPa)	0.0587					
	P	(mW)		#	1.08		1.08	#
	min of $[P_a(z_s), I_{ta,\alpha}(z_b)]$	(mW)				-		
	z_s	(cm)				-		
	z_{bp}	(cm)				-		
	z_b	(cm)					1.08	
	z at max. $I_{pi,\alpha}$	(cm)	1.02					
	$d_{eq}(z_b)$	(cm)					0.169	
	f_{awf}	(MHz)	7.90	#	7.90	-	7.90	#
	Dim of A_{aprt}	X (cm)		#	0.350	-	0.350	#
		Y (cm)		#	0.350	-	0.350	#
Other Information	t_d	(µsec)	4.00					
	prr	(KHz)	62.5					
	p_r at max. I_{pi}	(MPa)	0.0774					
	d_{eq} at max. I_{pi}	(cm)					0.169	
	$I_{pa.3}$ at max. MI	(W/cm^2)	0.110					
Operating Control Conditions	No operating controls change the acoustic output							

Note 1: Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.
Note 2: Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.
Note 3: Information on MI and TI need not be provided if the equipment meets both the exemption clauses given in 51.2 aa) and 51.2 dd).
(a) Intended use does not include cephalic so TIC is not computed
No data reported.

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(a) Intended use does not include cephalic so TIC is not computed

No data reported.

The 8 MHz, 3.5mm Doppler Probe

INSTRUCTIONS FOR USE

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