GEM
Global Excellence in Microsurgery

IntraOp Doppler™

Symbol Definitions:

Do not re-use

Consult instructions for use

Do not use if package is damaged

Does not contain natural rubber latex

Keep dry

Use by date

Manufacturer

Date of Manufacture

Refer to instruction booklet (symbol white on blue)

STERILE EO — Sterilized using ethylene oxide

Rx Only — CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

REF — Catalog number

LOT — Lot number

PN — Part number

MADE IN THE U.S.A. — Made in the USA

EC REP — Authorized representative in the European Community

Indications

The GEM IntraOp Doppler Probe is intended for the intraoperative and transcutaneous evaluation of blood flow.

Contraindications

- The Doppler probes are not intended specifically for use in the 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

- 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. Do not autoclave the probes.
- Use the probe only with compatible 20 MHz Doppler monitors. The recommended Doppler monitors is the GEM FlowCOUPLER Monitor (GEM1020M).
- 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

Instructions for Use

1. Using sterile technique, remove the sterile Doppler probe from its packaging.
2. Maintaining sterility, inspect the probe for damage or sharp edges. If damage or sharp edges are apparent, discard the probe.
3. Hand-off the probe's connector to someone outside the sterile field.
4. Attach the probe's connector to the coaxial receptacle on the monitor front panel.
5. Turn on the Doppler monitor and adjust the volume.
6. 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.
7. Place the tip of the probe directly on the vessel or other site to be evaluated. Turn the monitor 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 Used in Acoustic Output Reporting Table

$I_{SPTA.3}$ the derated spatial-peak temporal-average intensity (milliwatts per square centimeter).

$I_{SPPA.3}$ the derated spatial-peak pulse-average intensity (watts per square centimeter). The value of $I_{PA.3}$ at the position of global maximum MI ($I_{PA.3}$@MI) may be reported instead of $IS_{PPA.3}$ if the global maximum MI is reported.

MI the Mechanical Index. The value of MI at the position of $I_{SPPA.3}$, (MI@$I_{SPPA.3}$) may be reported instead of MI (global maximum value) if $I_{SPPA.3}$ is ≤ 190W/cm^2.

$p_{r.3}$ the derated peak rarefactional pressure (megapascals) associated with the transmit pattern giving rise to the value reported under MI.

W_o the ultrasonic power (milliwatts). For the operating condition giving rise to $I_{SPTA.3}$, W_o is the total time-average power; for the operating condition subject to reporting under $I_{SPPA.3}$, W_o is the ultrasonic power associated with the transmit pattern giving rise to the value reported under $I_{SPPA.3}$.

f_c the center frequency (MHz). For MI and $I_{SPPA.3}$, f_c is the center frequency associated with the transmit pattern giving rise to the global maximum value of the respective parameter. For $I_{SPTA.3}$, for combined modes involving beam types of unequal center frequency, f_c is defined as the overall range of center frequencies the respective transmit patterns.

z_{sp} the axial distance at which the reported parameter is measured (centimeters).

x_{-6}, y_{-6} tare respectively the in-plane (azimuthal) and out-of-plane (elevational) -6 dB dimensions in the x-y plane where z_{sp} 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 (centimters).

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, cm) using the derating factor $e^{-0.069\ fz}$.

Specifications

Acoustic Output Level: Less than 94 mW/cm^2

Track 1 Summary Table

Operating Mode(s)

Clinical Application	PWD
Fetal Imaging & Other*	___X___

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

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

Transducer Model: 20 MHz 1.0mm
Fetal Imaging & Others
Operating Mode: Pulse Doppler (PD)

Acoustic Output				MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value				0.0170	44.2	0.180
Associated Acoustic Parameter	$p_{r.3}$		(MPa)	0.0740		
	W_o		(mW)		0.206	0.206
	f_c		(MHz)	20.0	20.0	20.0
	z_{sp}		(cm)	0.200	0.200	0.200
	Beam dimension	x-6	(cm)		0.0688	0.0688
		y-6	(cm)		0.0840	0.0840
	PD (usec)		(µsec)	1.6		1.6
	PRF (kHz)		(kHz)	156.25		156.25
	EBD	Az.	(cm)		0.1	
		Ele.	(cm)		0.1	
Operating Control Conditions						

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MS-0725720B

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 TEMPORTALAVERAGE INTENSITY	IEC 62359, 3.38
$I_{ta,\alpha}(z)$	ATTENUATED TEMPORALAVERAGE 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 PEAKRAREFACTIONAL 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: 20 MHz 1.0 mm
Operating Mode: Pulse Doppler (PD)

Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					$A_{aprt} \leq 1cm^2$	$A_{aprt} \geq 1cm^2$		
Maximum Index Value			0.0163	#	0.0200	-	0.0362	(a)
Associated Acoustic Parameter	$P_{r,a}$	(Mpa)	0.0725					
	P	(mW)		#	0.210		0.210	#
	min of [$P_\alpha(z_s)$, $I_{ta}{}^*(z_s)$]	(mW)				-		
	z_s	(cm)				-		
	z_{bp}	(cm)				-		
	z_b	(cm)					-	
	z at max $I_{pi\,\alpha}$	(cm)	0.200					
	$d_{eq}(z_b)$	(cm)					-	
	f_{awf}	(MHz)	20.0	#	20.0	-	20.0	#
	Dim of A_{aprt}	X (cm)		#	0.10	-	0.10	#
		Y (cm)		#	0.10	-	0.10	#
Other Information	t_d	(µsec)	1.60					
	prr	(kHz)	156.25					
	p_r at max I_{pi}	(MPa)	0.0832					
	d_{eq} at max I_{pi}	(cm)					0.0695	
	$I_{pa.3}$ at max MI	(W/cm^2)	0.170					
Operating Control Conditions								

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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