McKESSON

LUMEON® SERIES

DOPPLERS

USER'S MANUAL

Thank you for choosing McKesson LUMEON® SERIES Doppler Systems. Your total satisfaction is our highest priority as we strive to continually improve our products and services. Please contact us with any suggestions. We look forward to enjoying a long-term relationship with you!

TABLE OF CONTENTS:

Please read the manual carefully and become familiar with the operation, features and maintenance of your Doppler prior to using the device or accessories.

Manufactured for McKesson Medical-Surgical Inc.
By CooperSurgical, Inc.

Year of manufacture located on device.

INTENDED USE

Obstetric (2 and 3 MHz Probes)

This product will be used to detect fetal heart beats as an aid for determining fetal viability.

Vascular (4, 5 and 8 MHz Probes)

This product will be used to detect blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Contraindications

WARNING: The vascular probes (4, 5 and 8 MHz) are not for fetal use.

WARNING: The ultrasound probes are not to be used on or near the eyes.

WARNING: The device is for use only on intact skin.

WARNING: Do not plug any part of this device into a telephone or modem system.

WARNING: This device is not intended for use with HF surgical equipment.

If there are questions or concerns regarding these warnings or contraindications, please do not hesitate to contact Customer Service for further clarification.

CAUTION: Dropping the Doppler, probe or accessories may cause damage to the housing or electronics.

In order to preserve, protect and improve the quality of the environment, protect human health and utilize natural resources prudently and rationally – do not dispose of waste electrical or electronic equipment (WEEE) as unsorted municipal waster. Contact local WEEE disposal sites.

Safety of Ultrasound

McKesson LUMEON® SERIES Dopplers were designed with physician and patient safety in mind. In early design phases, all potential hazards were eliminated or reduced to As Low As Reasonably Achievable (ALARA) by adhering to good design practices and industry wide safety standards. Ultrasound procedures should be performed with the ALARA principle in mind when delivering ultrasound energy into the body.

DESCRIPTION OF PRODUCT

The McKesson LUMEON® SERIES Doppler is factory configurable to include many different features and product enhancements. Along with user interchangeable ultrasound transducers, the McKesson LUMEON® SERIES Doppler device is well suited to meet your specific needs.

Main Unit

The main handheld unit is ergonomically designed to fit the palm of your hand with comfort and allow easy access to each control feature. Each unit is individually tested and inspected to ensure the highest quality standards.

SSQ – Superior Sound Quality. Every McKesson LUMEON® SERIES Doppler is designed with a state of the art sound system that produces excellent sound quality and long-term reliability.

LCD Display – The LCD display (optional) allows you to view the fetal heart rate in larger easy to read digits, monitor battery life, and observe signal strength indicators, and features multiple diagnostic indicators that ensure your unit is functioning at peak performance levels.

Units without LCD display incorporate bright, easy to read LED indicators that also allow you to monitor battery life.

Main Unit	Features		Probe Type (see next page for details)				
Catalog #	Sound	Display	2 MHz	3 MHz	4 MHz	5 MHz	8 MHz
1154 (probe not included)	X	X					
1155 (no display or probe)	X						
1156	X	X	X				
1157	X	X		X			
1158	X				X		
1159	X					X	
1160	X						X

Probes

McKesson LUMEON® SERIES Doppler ultrasound transducers were designed to meet your specific applications needs. Each probe has been ergonomically designed for comfort while providing excellent maneuverability for locating the fetus or vascular target. Each probe is carefully measured and tested to ensure it meets exacting performance standards.

2 MHz – Late-term obstetrical examination. This probe frequency is typically used during the last trimester for deep fetal positions associated with larger women.

3 MHz - Early and general-purpose obstetrical examination. This probe frequency is a general-use model ideal for most stages of fetal examination. Fetal heart sounds can be heard as early as 12 weeks and sometimes sooner depending on the position and size of the fetus.

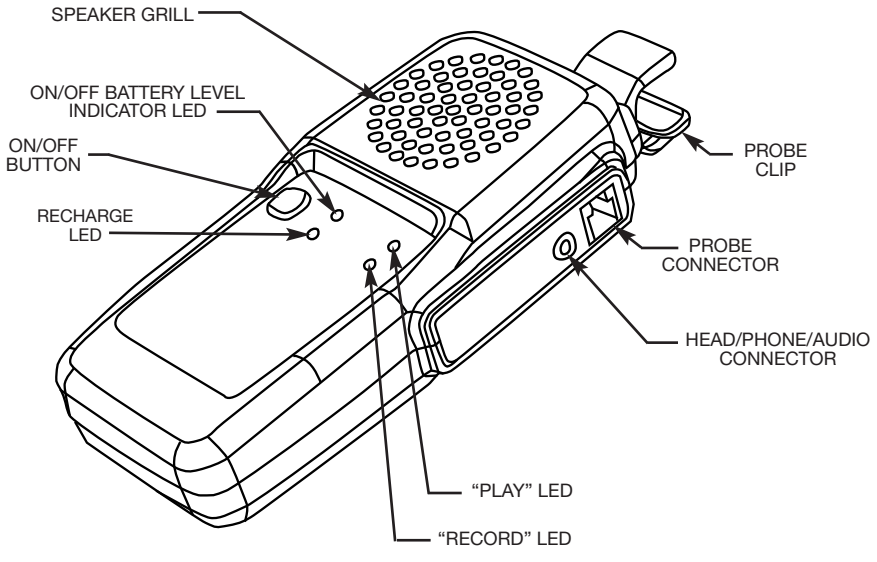
4 MHz Broad - This unique peripheral vascular probe is ideal for quickly locating brachial, radial and ankle arteries in the performance of Ankle/Brachial Index testing. The broad beam of the 4 MHz probe allows the user to place the probe over the general location of the artery and with very little movement find the vessel for fast blood pressure measurements.

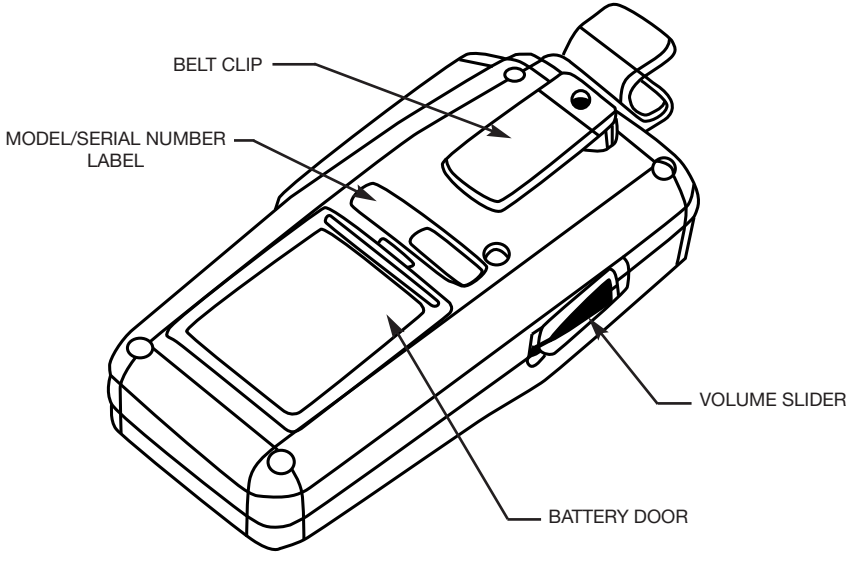
5 MHz Tip - This standard “pencil” style probe is an excellent vascular tool for locating deep specific vessels in the peripheral vascular system. The narrow grip and small face of the probe make it ideal for maneuvering for maximizing the signal. 8 MHz Tip - This standard “pencil” style probe is an excellent vascular tool for locating shallow specific vessels in the peripheral vascular system. The narrow grip and small face of the probe make it ideal for maneuvering for maximizing the signal.

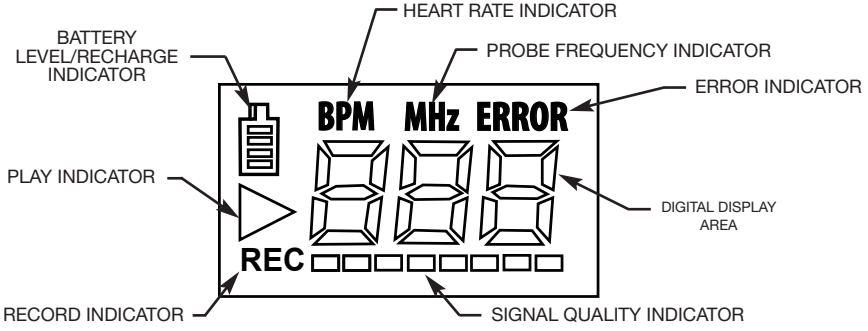
Probe		Application			
MFR#	Type	Late OB	General OB	PV ABI	PV General
1156	2 MHz	X			
1157	3 MHz		X		
1158	4 MHz			X	
1159	5 MHz				X
1160	8 MHz				X

OPERATION AND INSTALLATION

(Some features are optional)







Turning Unit On/Off

Turn the unit on by pressing the On/Off button. LED or LCD indicators (depending on the model) indicate power status.

The McKesson LUMEON® SERIES Doppler automatically shuts itself off after 3 minutes if it is not being used. This complete power shutdown preserves the life of the batteries and ensures the unit will be ready for operation in case it was accidentally left on.

Diagnostic Monitoring (LCD Display units only)

Once the unit is on, the McKesson LUMEON® SERIES Doppler display units perform a series of diagnostic checks. The unit first checks and temporarily displays the frequency of the probe that is being used. This display will not reappear unless the probe is changed or the power is cycled, in which case the display will again temporarily confirm the frequency of probe that is connected.

The unit then checks for proper internal operating temperature, battery voltage, reference voltage and power supply voltage levels. If any of these characteristics are out of range, the display will show the ERROR indicator and a failure code associated with the diagnostic error. Diagnostic functions are periodically checked while the unit is on to ensure the Doppler is operating at peak performance. Refer to the Troubleshooting section for a listing of failure codes.

BATTERY MONITORING

All McKesson LUMEON® SERIES Doppler units perform continuous battery monitoring and give a visual indication of battery level. Display units use a multiple level battery-shaped icon that indicates the voltage level of the battery. The battery outline will flash when the battery level is very low, indicating that the user should change the batteries soon after the current examination is complete.

Non-display units use the On/Off LED as a battery indicator by flashing at a low rate (approximately once per second) when the battery level is low. Several exams can still be performed in this state of operation. The battery indicator will flash at a higher rate (approximately twice per second) when the battery level is very low. The user should change the batteries soon after the current exam is complete.

OBTAINING DOPPLER SIGNALS

Caution: Doppler examinations should be performed only by trained individuals.

For any Doppler examination, it is essential that an adequate supply of coupling gel is used to transmit the ultrasound energy from the probe to the surface of the skin. Reapply more gel if it starts to dry out or spread so thinly that an air gap occurs between the probe and the skin. It is not necessary to cover the entire surface of the probe, only the probe face. Applying too much gel makes the unit difficult to clean and does not aid in the performance of the probe.

Volume Slider

The audio level can be adjusted using the Volume Slider. Moving the slider up will increase the volume, while moving it down will decrease it.

Signal Quality Indicator (Display units only)

An inadequate signal can produce erroneous rates from the heart rate calculation. The signal level that is being obtained is shown on the Signal Quality Indicator bars. This indicator provides a visual aid in obtaining a strong audio signal by showing the pulsatile nature of the signal. A large difference between the highest and lowest signal bars that are lit confirms that the quality of the signal is good and thus ensures the heart rate calculation is operating at peak performance. The heart rate can be verified manually by counting the audible beats for 20 seconds and multiplying by 3, or for 15 seconds and then multiplying by 4. Counting for less than 15 seconds is not recommended due to a decrease in accuracy with the small sample size.

Obstetrical

Fetal heart sounds are quite different from peripheral vascular blood flow sounds. Fetal sounds are typically much lower in frequency and much higher in rate. For early term fetal detection, start the probe at the pubic bone and slowly move along the midline – rocking the probe slowly from side to side until a heartbeat is heard. For mid to late term fetal detection the best chance of finding the heart sounds are to start on the fundus and move toward the navel and from one side of the abdomen to the other, slowly rocking the probe until the heartbeat is heard. The fetal heart reminds many people of a galloping horse and can vary in tone from a distant swishing sound to a hard clopping.

Many times when attempting to detect the fetal heart, the maternal vascular sounds are heard instead of (or in some cases, in addition to) the fetal sounds. These maternal sounds can come from one of the major arteries, the placenta or the umbilical cord. The maternal vascular sounds are typically higher in frequency at a lower rate. The heart rate calculation will display either the maternal rate or the fetal rate, whichever portion of the signal is stronger.

If the fetal heart sounds cannot be located using the McKesson LUMEON® SERIES Doppler procedure as described above, a second exam should be performed using another commercially available fetal monitor as a repeated test.

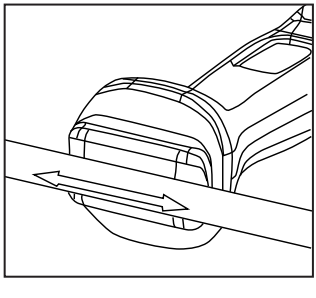
5 and 8 MHz Vascular

Peripheral arterial sounds are typically higher in frequency. For the best sounds, angle the probe approximately 45 degrees from the skin surface over the general location of the vessel. Slowly move the probe side to side and vary the angle of the probe until the vascular sounds are heard. Changing the angle of the probe has an effect on the frequency of the sound. The steeper the probe angle is, the higher the frequency of the sound.

Peripheral venous sounds are not typically periodic and vary greatly depending on patient movement and breathing. These sounds are more like the wind at the ocean and vary in pitch as the patient moves or breathes.

4 MHz Vascular

The use of the 4 MHz vascular probe is the same as the 8 MHz as described above, except tilting the probe 45 degrees is not necessary since the crystals are angled inside the probe cap. This allows the user to simply place the probe flat on the peripheral vascular surface to scan for the flow sounds by moving the flat probe face across the skin surface above the vessel.



Proper alignment of the 4 MHz vascular probe with respect to the vessel

MAINTENANCE AND CLEANING

WARNING: The McKesson LUMEON® SERIES Doppler is not designed for liquid immersion. Do not soak the Doppler main unit or probes in liquids. Use only spray or wipe cleaners and disinfectants. Do not use products containing bleach.

WARNING: The McKesson LUMEON® SERIES Doppler is not designed for sterilization processes such as autoclaving, gamma radiation or hydrogen gas.

WARNING: The McKesson LUMEON® SERIES Doppler is not intended to be used on open skin. If there is evidence of open wound contamination, disinfect the probe before using again as described below.

The McKesson LUMEON® SERIES Doppler requires very little maintenance. However, it is important to continuing function of the unit and the health of the patients that the unit is cleanedand examined regularly per the following guidelines:

After every examination:

Excess gel should be wiped off prior to docking the probe. Probes and main unit should be cleaned with a damp cloth using warm water or presaturated isopropyl alcohol wipes. In particular, pay close attention to clean the seams along the plastic lines at the probe face but **do not allow water to enter through the connectors or speaker grill.**

To disinfect unit, use commercially available spray or wipe disinfectants registered with the EPA. Clorox® Broad Spectrum Quaternary Disinfectant is the only disinfectant that is Wallach Surgical Devices approved for use on this McKesson LUMEON® SERIES product. Follow the manufacturer's instructions and wipe until it is dry of solutions. Examiners should wash hands and change gloves after every exam. Refer to local and hospital policies for cleaning and disinfection policies.

Store unit in a clean area free from dust and debris. Follow temperature and humidity guidelines as specified at the end of this manual.

WARNING: If the unit is to be stored for longer than 90 days without use, remove the batteries prior to storage.

Periodically (at least annually): Inspect the main unit and probes for signs of cracks or breaks in the mechanical housing. Inspect cables and connectors for signs of wear or failure. The user should discontinue use of the unit with any sign of loss of housing integrity. Contact a McKesson LUMEON® SERIES Doppler representative for service.

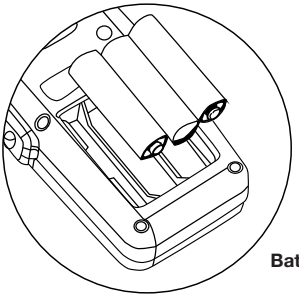
It is recommended that rechargeable batteries be replaced annually.

REPLACING BATTERIES

WARNING: Replace rechargeable batteries only with batteries supplied by McKesson Medical-Surgical Inc. See accessories list for part number and re-order information.

WARNING: The battery compartment only accepts AA size batteries. See accessories list for part number and re-order information.

Open the battery compartment by depressing the tab and pulling outward on the battery door. Remove the existing drained batteries by pushing on the end of the battery that compresses the battery contact spring and lift upwards. It is acceptable to carefully use a simple tool, such as a pen, to assist in lifting the batteries out.



Batteries slide into compartment

Replace the batteries by paying close attention to the polarity indicators on the battery and the polarity indicators on the battery holder in the compartment. Positive (+) aligns with positive (button) and negative (-) aligns with negative (spring). Insert the battery such that the spring contacts are loaded first and then press the battery firmly into place. After all three have been inserted, replace the battery door.

WARNING: If the batteries have been inserted incorrectly, the unit will not function but the McKesson LUMEON® SERIES Doppler will not be damaged.

TROUBLESHOOTING

WARNING: Use alternate equipment in case of unit failure. Call Service Department if the probe or main unit malfunctions.

Poor sound quality

- Inadequate gel use
- Try to relocate the probe for a better signal
- Improper choice of probe frequency
- Interference from other equipment
- Probe coiled cable or battery contacts intermittent
- Debris in the speaker may cause poor sound
- Device damage from dropping the device, probes or accessories

Heart Rate inaccurate

- Try to relocate the probe for a better signal – refer to Signal Strength indicator
- For OB, ensure maternal sounds are not mixing with fetal sounds
- Ensure by manual counting that the rate is between 50 and 210 BPM

Battery indicator flashing

- Consult Battery Monitoring; replace batteries as described in Replacing Batteries
- Probe frequency does not match the connected probe
- Check probe that is attached to ensure it is the correct one: If correct probe, contact Customer Service

Probe frequency 0.0

- No probe is attached: If probe is attached, contact Customer Service
- Error 5 or 7
- Batteries are low. They require replacement or recharging.

RADIO FREQUENCY INTERFERENCE

The McKesson LUMEON® SERIES Doppler was tested for immunity to electromagnetic interference at a level of 3 V/meter. Interference during normal operation may occur in the presenceof fields stronger than 3 V/meter. If this occurs, try to increase the distance between the McKesson LUMEON® Doppler and the source of interference. Contact a McKesson LUMEON® representative for more information.

Diagnostic Codes – Contact Customer Service

1 – Temperature too low	5 – 5 Volt Supply too low
2 – Temperature too high	6 – 5 Volt Supply too high
3 – Reference Voltage too low	7 – Battery Voltage too low
4 – Reference Voltage too high	8 – Battery Voltage too high

Reference materials for Obstetrical and Peripheral Vascular testing:

Handbook of Fetal Heart Rate Monitoring; Julian T. Parer, 1997

Doppler Ultrasound and Its Use In Clinical Measurement; Peter Atkinson and John P. Woodcock, 1982

Noninvasive Diagnosis of Peripheral Vascular Disease; W. Robert Felix, Jr., 1988

Current Noninvasive Vascular Diagnosis; Ali F. Aburahma, Edward B. Diethrich,1988

Accessories

Contact a McKesson LUMEON® representative at 1-800-777-4908 for ordering and additional information.

Description	Part Number
Rechargeable Battery	B150
Alkaline Battery	B155
Recharge Adaptor	R150
Audio Cable	CBL0002
Audio Headphone	H150
Gel (60 gm)	G150
Gel (250 gm)	G155
Ultrasound Probe Cleaner	C150
Carry Case	K260

SPECIFICATIONS

Degree of protection against electric shock:

Type B Applied Part

Class II Equipment

Degree of protection against ingress of water:

All probes: IPX4 – extending 2.5 cm from tip
IPX1 – entire probe 2.5 cm from tip, excluding connector

Designed and tested to meet:

IEC601-1, IEC60601-1-2, IEC60601-1-4, IEC60601-2-37, EN5011-A

Dimensions (h x w x l):	140 x 70 x 35 mm
Weight:	320 grams
Operating temperature:	10 to 40 °C
Operating humidity:	30 to 75 %
Transport/Storage temperature:	–20 to 50 °C
Transport/Storage humidity:	5 to 90%, non-condensing (beyond 30 days, battery to be stored between –20 and 30 °C)
Battery voltage, type:	3 – AA Alkaline 1.5 volt (for non-rechargeable units) 3 – AA NiMH 1.5 volt (for rechargeable units) (as applicable)
Battery life:	Batteries provided by factory 1250, 1-minute exams (Alkaline)
Audio bandwidth and power:	350 Hz – 2 KHz, 0.5 W
Heart rate accuracy:	±3 BPM from 50 to 220 BPM
Audio cable pin out:	3.5 mm stereo plug
Operating Conditions:	**There are no user controls that affect the ultrasound output.**

Transducer Model: McKesson LUMEON® SERIES 4 MHz **Operating Mode:** Continuous-Wave (cw)
Application(s): Peripheral Vascular

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value			0.05	278	.278
Associated Acoustic Parameter	$P_{r.3}$ (Mpa)		0.07		
	w_o (mW)		47.2	0.047	
	f_c (MHz)		4.0	4.0	4.0
	z_{sp} (cm)		1.2	1.2	1.2
	Beam Dimensions	x_{-6} (cm)		0.5	0.5
		y_{-6} (cm)		1.0	1.0
	EBD	Az (cm)		0.45	
		Ele. (cm)		1.15	

Transducer Model: McKesson LUMEON® SERIES 5 MHz **Operating Mode:** Continuous-Wave (cw)
Application(s): Peripheral Vascular

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value			0.04	223	.22
Associated Acoustic Parameter	$P_{r.3}$ (Mpa)		0.09		
	w_o (mW)			12.8	0.13
	f_c (MHz)		5.3	5.3	5.3
	z_{sp} (cm)		0.85	0.85	0.85
	Beam Dimensions	x_{-6} (cm)		0.4	0.4
		y_{-6} (cm)		0.6	0.6
	EBD	Az (cm)		0.4	
		Ele. (cm)		0.8	

Transducer Model: McKesson LUMEON® SERIES 8 MHz **Operating Mode:** Continuous-Wave (cw)
Application(s): Peripheral Vascular

ACOUSTIC OUTPUT			MI	$I_{SPTA.3}$ (mW/cm²)	$I_{SPPA.3}$ (W/cm²)
Global Maximum Value			0.02	140	.14
Associated Acoustic Parameter	$P_{r.3}$ (Mpa)		0.07		
	w_o (mW)			5.5	0.006
	f_c (MHz)		8.0	8.0	8.0
	z_{sp} (cm)		0.66	0.66	0.66
	Beam Dimensions	x_{-6} (cm)		0.2	0.2
		y_{-6} (cm)		0.4	0.4
	EBD	Az (cm)		0.3	
		Ele. (cm)		0.6	

Obstetrical Probe Information:

VARIABLE DESCRIPTION	MODEL NUMBER	
	2 MHz	3 MHz
I_{SATA} (max) (mW/cm^2)	19.6	15.5
P_o (mW)	48.0	24.4
Effective Radiating Area (cm^2)	2.45	1.57
Ultrasound Frequency (MHz)	2.1 MHz	3.2 MHz
Pulse Duration	CW	CW
Repetition Freq.	CW	CW

I_{SATA}	the **spatial-average temporal-average intensity** (mwatts per cm^2).
$I_{SPTA.3}$	the **derated spatial-peak temporal-average intensity** (mwatts per cm^2).
$I_{SPPA.3}$	the **derated spatial-peak pulse-average intensity** (watts per cm^2).
MI	the **Mechanical Index**.
$P_{r.3}$	the **peak rarefactional pressure** (megapascals) associated with the transmit pattern giving rise to the value reported for MI.
W_o	the total time-average **ultrasonic power** (mwatts).
f_c	the probe **center frequency** (MHz).
z_{sp}	the axial distance at which the reported parameter is measured (cm).
x_{-6}, y_{-6}	are the –6dB beam dim. in the x-y plane where zsp is found (cm).
EBD	the **entrance beam dimensions** (cm). These dimensions are the same as the dimensions of the transmit crystal.

Measurement Uncertainties:

Power: +34, -42%
Pressure: +11, -16%
Intensity (Ispta): +23, -26%
Frequency: ± 5%

Acoustic Output Parameters are measured in water. Derated values, denoted by the subscript ".3", take into account a conservative level of attenuation that would be encountered in the human body. The derated intensity values ($I_{.3}$) are obtained from water values of intensity (I_w) at a depth of z calculated by:

$$I_{.3} = \exp(-0.23*0.3*f*z)*I_w$$

(where f is the probe frequency in MHz and z is the depth in centimeters)

The derated peak rarefactional pressure is calculated from the value of measure water (pr) by:

$$P_{r.3} = \exp(-0.115*0.3*f*z)*p_r$$

(where pressure is given in megapascals)

Additional Output Reporting Information for IEC 61157

4 MHz: $I_{ob} < 91$ mW/cm^2
5 MHz: $I_{ob} < 51$ mW/cm^2
8 MHz: $I_{ob} < 39$ mW/cm^2

The 2 MHz, 2 MHz WP and 3 MHz obstetrical probes are exempt from the declaration requirements of IEC61157. These probes meet the conditions: $I_{ob} < 20$ mW/cm^2, $I_{spta} < 100$mW/cm^2, and Pr < 1 MPa. I_{ob} is output power divided by beam area.

Note that parameter Z_{sp} in the probe reporting tables is the same parameter as I_p in IEC 61157.

NOTES:

NOTES:

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Questions? Call 1-800-777-4908

Satisfaction Guaranteed
If you are not completely satisfied with any McKesson Brands product, you may return it for a full refund or credit.

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Richmond, VA 23233
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MAN0025-IFU • Rev. A • 10/15