



User Manual for LifeDop® L350R Series (Tabletop Doppler)



REF L350R, MC350R

WALACH[®]
SURGICAL DEVICES

CE0086

Thank you for choosing LifeDop® L350 products. We believe you have purchased the finest Doppler on the market today. 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!



Wallach Surgical Devices
 95 Corporate Drive
 Trumbull, CT 06611 USA



Year of manufacture
 located on the device.

Here’s how you can reach us...

Phone: 1-800-243-2463
 (203) 799-2000

Fax: (203) 799-2002

e-mail us at: customerservice@wallachsurgical.com
 visit our website at: www.wallachsurgical.com

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Please read the manual carefully and become familiar with the operation, features and maintenance of your LifeDop L350R prior to using the device or accessories.



(This mark excludes the
 Medichoic® model: MC350R)



EMERGO EUROPE
 Molenstraat 15
 2513 BH, The Hague
 The Netherlands

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

- U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner.

Contraindications

Warnings

- The vascular probes (4, 5 and 8 MHz) are not for fetal use.
- The ultrasound probes are not to be used on or near the eyes.
- The device is for use only on intact skin.
- Do not plug any part of this device into a telephone or modem system. Any line-connected accessory must meet applicable safety standards.
- 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 Wallach Surgical Devices for further clarification.

Caution

- Dropping the LifeDop 350, 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 waste. Contact local WEEE disposal sites.

Safety of Ultrasound

LifeDop 350s 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.

The following official statements from the American Institute of Ultrasound Medicine (AIUM) are provided for your general information regarding the safe use of ultrasound.

Clinical Safety

Approved March 1997, October 1982

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:

There are no confirmed biological effects on patients or instrument operators caused by exposures from present diagnostic ultrasound instruments. 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.

Prudent Use

Approved May 1999

The AIUM advocates the responsible use of diagnostic ultrasound. The AIUM strongly discourages the non-medical use of ultrasound for psychosocial or entertainment purposes. The use of either two-dimensional (2D) or three-dimensional (3D) ultrasound to only view the fetus, obtain a picture of the fetus or determine the fetal gender without a medical indication is inappropriate and contrary to responsible medical practice. Although there are no confirmed biological effects on patients caused by exposures from present diagnostic ultrasound instruments, the possibility exists that such biological effects may be identified in the future. Thus ultrasound should be used in a prudent manner to provide medical benefit to the patient.

Safety in Training and Research

Approved March 1997, March 1983

Diagnostic ultrasound has been in use since the late 1950s. There are no confirmed adverse biological effects on patients resulting from this usage. Although no hazard has been identified that would preclude the prudent and conservative use of diagnostic ultrasound in education and research, experience from normal diagnostic practice may or may not be relevant to extended exposure times and altered exposure conditions. It is therefore considered appropriate to make the following recommendation:

In those special situations in which examinations are to be carried out for purposes other than direct medical benefit to the individual being examined, the subject should be informed of the anticipated exposure conditions, and of how these compare with conditions for normal diagnostic practice.

Description of Product

The LifeDop 350 is factory configurable to include many different features and product enhancements. Along with user interchangeable ultrasound transducers, the LifeDop 350 device is well suited to meet your specific needs.

Main Unit

The tabletop style main unit is ergonomically designed to be comfortable to carry 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 LifeDop 350 is designed with a state of the art speaker sound system that produces excellent sound quality and long-term reliability.

Recharge – We offer the ease of use of a rechargeable system or in some limited areas a non-rechargeable unit. Either way, the LifeDop 350 battery system has been designed with your long-term battery life needs in mind.

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

Probes

LifeDop 350 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. Waterproof versions of the 2 MHz probe are available.

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.

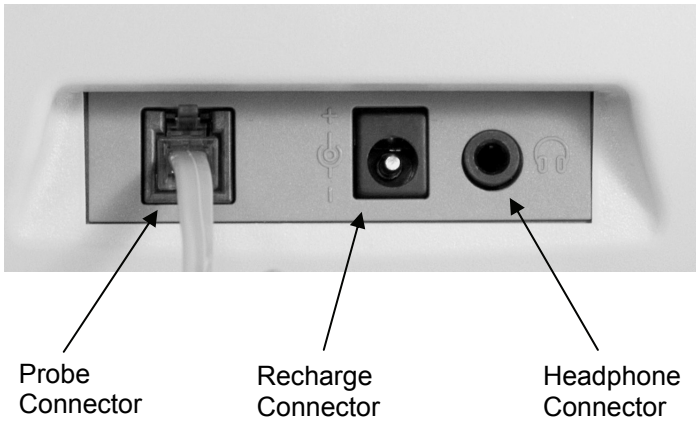
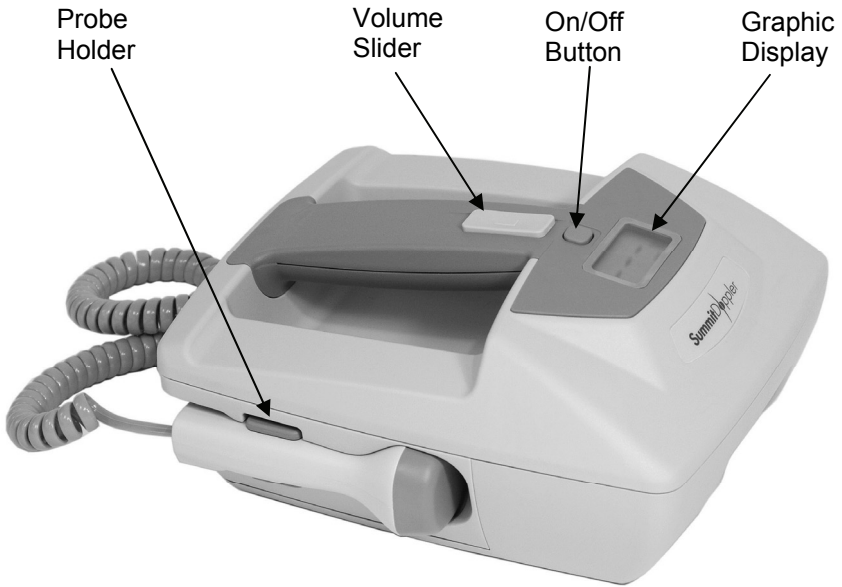
4 MHz Broad – This unique peripheral vascular probe is ideal for quickly locating brachial, radial and ankle arteries in the performance of Ankle/Brachial Index testing. The broad beam of the 4 MHz probe allows the user to place the probe over the general location of the artery and with very little movement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

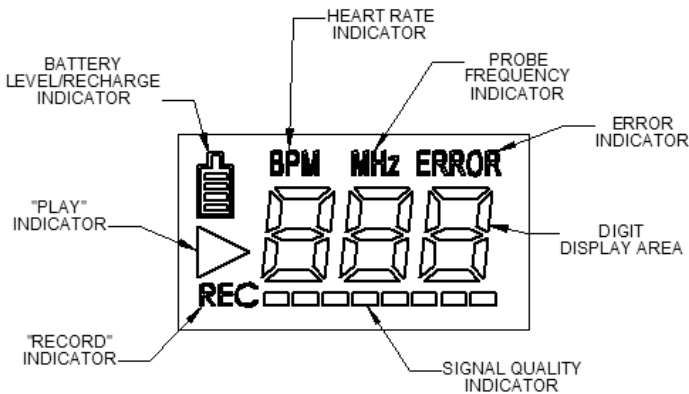
5 MHz – This standard “pencil” style probe is an excellent vascular tool for locating deep specific vessels in the peripheral vascular system. The narrow grip and small face of the probe make it ideal for maneuvering for maximizing the signal.

8 MHz – 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.

8 MHz Sterilizable – This vascular probe has a narrow beam for detection of blood flow in both veins and arteries. It is validated for use in sterile fields.

Operation and Installation





LCD Panel

Turning Unit On/Off

Turn the unit on by pressing the On/Off button. LCD indicators indicate power status.

The LifeDop 350 automatically shuts 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

Once the unit is on, the LifeDop 350 performs 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 LifeDop 350 is operating at peak performance. Refer to the Troubleshooting section for a listing of failure codes.

Battery Monitoring

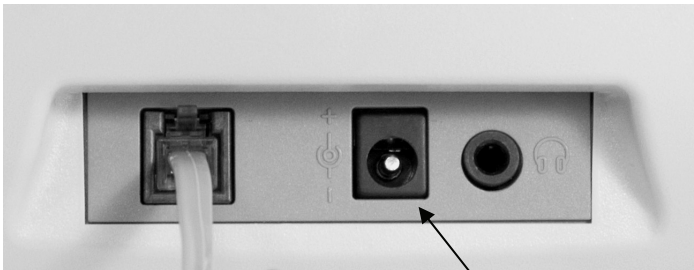
All LifeDop 350 units perform continuous battery monitoring and give a visual indication of battery level. The display shows a multiple level battery-shaped indicator that indicates the voltage level of the battery. The battery outline will flash when the battery level is very low, indicating that the user should change the batteries soon after the current examination is complete.

Recharging


Warnings

- Do not use any other wall adaptor unit other than that supplied with the LifeDop 350. Otherwise, major electrical damage is likely to occur. See the Accessories section for reordering of parts information.
- Do not attempt to recharge alkaline batteries. Otherwise, major electrical damage is likely to occur.

It is recommended that the LifeDop 350 be recharged prior to first use. To recharge the unit, plug the recharge jack from the wall adaptor into the unit's recharge connector. The battery-shaped indicator will cycle in a repeated rising pattern to indicate the unit is recharging.



**Recharge jack from
power supply plugs
into connector**

8.5 VDC
+  -

The recharge cycle will be limited to 14 hours or until the maximum battery voltage level has been reached. Once the recharge cycle has been discontinued normally, the LCD indicator will flash at a low rate. The unit will not overcharge the batteries. If it determines that the batteries do not require charging, the charge cycle will be interrupted after 30 seconds.

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. Re-apply 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 Control

The audio level can be adjusted using the Volume Slider. Slide the control up toward the display to increase the volume. Slide the control back away from the display to decrease it.

Signal Quality Indicator

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 clapping sound depending on the position of the baby and probe.

Obstetrical (continued)

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 procedure as described above, a second exam should be performed using another commercially available fetal monitor as a repeated test.

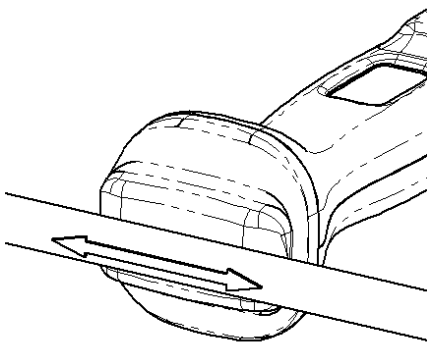
5 and 8 MHz Vascular

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

Warnings

- The LifeDop 350 is not designed for liquid immersion. Do not soak the main unit or probes in liquids. Use only spray or wipe cleaners and disinfectants. **Do not use products containing bleach.**
- The LifeDop 350 is not designed for sterilization processes such as autoclaving, gamma radiation or hydrogen gas.
- The LifeDop 350 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 LifeDop 350 requires very little maintenance. However, it is important to continuing function of the unit and the health of the patients that the unit is cleaned and 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 or spray 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 with the 350 Series Products. Follow the manufacturer's instructions and wipe unit 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 Wallach Surgical Devices for service.

It is recommended that rechargeable batteries be replaced annually.

Replacing Batteries

Warnings

- Replace batteries only with batteries supplied by Wallach Surgical Devices. See the Accessories section for reordering of parts information.
- The battery compartment only accepts AA size batteries. See the Accessories section for reordering of parts 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 out the batteries.



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 LifeDop 350 will not be damaged.

Troubleshooting

Warning

- Use alternate equipment in case of unit failure. Call Wallach Surgical Devices' Service Department if the probe or main unit malfunctions.

Caution

- Do not drop or mishandle the LifeDop 350, probes or accessories. Damage to sensitive electrical components, speakers, cables, transducers or plastic is likely to occur.

Poor sound quality

Inadequate gel use

Try to relocate the probe for a better signal – refer to Signal Strength Indicator

Improper choice of probe Frequency

Interference from other equipment

Probe coiled cable or battery contacts may be intermittent

Debris in the speaker may cause poor sound

Device damage from dropping the LifeDop 350, 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 220 BPM

Battery indicator flashing

Consult the Battery Monitoring section; replace batteries as described in the Replacing Batteries section.

Probe frequency does not match the connected probe

Check probe that is attached to ensure it is the correct one, or check to see if probe is attached. If correct probe is being used, contact Wallach Surgical Devices' Service Department.

Error 5 or 7

Batteries are low. They require replacement or recharging.

Recharge indicator flashing

Recharge cycle is complete or the batteries didn't require recharge.

Recharge indicator off after charging

Battery level error has occurred – refer to Diagnostic Codes and contact service.

Rechargeable unit does not hold a charge

Verify that the correct recharge adaptor is being used - Use only Wallach Surgical Devices products.

Batteries are old - Refer to Maintenance Section.

Radio Frequency Interference

The LifeDop 350 family was tested for immunity to electromagnetic interference at a level of 3 V/meter. Interference during normal operation may occur in the presence of fields stronger than 3 V/meter. If this occurs, try to increase the distance between the LifeDop 350 and the source of interference. Contact Wallach Surgical Devices for more information.

Diagnostic Codes – Contact Wallach Surgical Devices’ Service Dept.

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

To order accessories (gel, batteries, rechargers, stands, and probe cleaner), contact Wallach Surgical Devices at 1-800-243-2463 or (203) 799-2000 to order by phone.

Specifications

Degree of protection against electric shock:



Type B Applied part



Class II Equipment

Degree of protection against ingress of water:

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, IEC60601-2-37

Dimensions (h x w x l): 200 x 150 x 100 mm

Weight: 1000 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 life: Batteries provided with LifeDop 350:
5 hours continuous minimum
1000 1-minute exams typical

Battery type and voltage: 3 – AA NiMH 1.5 volt (rechargeable)

Audio bandwidth and power: 350 Hz – 2 kHz, 0.5 W

Heart rate calculation accuracy: ± 3 BPM over range 50 to 220 BPM

Operating Conditions: There are no user controls which affect the ultrasound output.



Attention: Consult Accompanying Documents

Transducer Model: LifeDop 4 MHz
 Application(s): Peripheral Vascular

Operating Mode: Continuous-Wave (cw)

<i>ACOUSTIC OUTPUT</i>		<i>MI</i>	<i>I_{SPTA.3}</i> <i>(mW/cm²)</i>	<i>I_{SPPA.3}</i> <i>(W/cm²)</i>	
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: LifeDop 5 MHz
 Application(s): Peripheral Vascular

Operating Mode: Continuous-Wave (cw)

<i>ACOUSTIC OUTPUT</i>		<i>MI</i>	<i>I_{SPTA.3}</i> <i>(mW/cm²)</i>	<i>I_{SPPA.3}</i> <i>(W/cm²)</i>	
Global Maximum Value		0.04	223	0.22	
Associated Acoustic Parameter	P _{r,3} (Mpa)	0.09			
	W _o (mW)		12.8	0.013	
	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: LifeDop 8 MHz
 Application(s): Peripheral Vascular

Operating Mode: Continuous-Wave (cw)

<i>ACOUSTIC OUTPUT</i>		<i>MI</i>	<i>I_{SPTA.3}</i> <i>(mW/cm²)</i>	<i>I_{SPPA.3}</i> <i>(W/cm²)</i>	
Global Maximum Value		0.03	229	0.23	
Associated Acoustic Parameter	P _{r,3} (Mpa)	0.09			
	W _o (mW)		13.9	0.014	
	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:

	Model Number	
	2 MHz	3 MHz
$I_{SATA (max)}$ (mW/cm ²)	19.6	17.0
P_o (mW)	48.0	24.5
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 cm²).
 $I_{SPTA.3}$ the **derated spatial-peak temporal-average intensity** (mwatts per cm²).
 $I_{SPPA.3}$ the **derated spatial-peak pulse-average intensity** (watts per cm²).
 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 z_{sp} 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 (p_r) 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: $I_{ob} < 91 \text{ mW/cm}^2$

5 MHz: $I_{ob} < 51 \text{ mW/cm}^2$

8 MHz: $I_{ob} < 47 \text{ mW/cm}^2$

The 2 MHz, 2 MHz WP and 3 MHz obstetrical probes are exempt from the declaration requirements of IEC61157. These probes meet the conditions: $I_{ob} < 20 \text{ mW/cm}^2$, $I_{spta} < 100 \text{ mW/cm}^2$, and $P_r < 1 \text{ MPa}$. 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.

Warranty and Servicing Policy

The warranty on this product is that it will be free from defects in material and workmanship for 24 months from the original sale of the device. Product life is specified to be 5 years from manufacture, though the device may be repairable beyond this timeframe. This includes all parts and labor required to repair or replace the unit to original specifications and shipping costs associated with sending the product back to the customer. Customer is responsible for providing adequate packaging materials and shipping costs to Wallach Surgical Devices. Products shall be repaired or replaced in a reasonable amount of time.

Wallach Surgical Devices' liability for any claim is limited to materials and labor associated with repair or replacement. In no event shall Wallach Surgical Devices be liable for incidental or consequential losses or damages in connection with the purchase of this product.

Wallach Surgical Devices disclaims all express or implied warranties, agreements or arrangements other than issued in this warranty.

Wallach Surgical Devices is not responsible for damages to the device that occur as a result of the inadequate packaging on return shipments to Wallach Surgical Devices, improper maintenance or cleaning as described in the user manual, misuse, abuse, alteration of the equipment from its original specifications, or dismantling of the unit (other than by Wallach Surgical Devices approved service technicians).

Service Returns – To return products:

1. Call Wallach Surgical Devices to obtain a Return Authorization and to receive any final instructions prior to shipping.
2. Clean the product prior to shipping.
3. Ensure the device is well-packaged and suitable for shipment.

Send the product to:

Repair Department
Wallach Surgical Devices
95 Corporate Drive
Trumbull, CT 06611 USA

For customer service, please call 1-800-243-2463 or (203) 799-2000.

Explanation of Symbols



Reorder Number



Serial Number



Latex Free



ATTENTION:
See instructions for use.



Manufacturer



Date of Manufacture



Symbol indicates that the device should be sent to the special agencies according to local regulations for separate collection after its useful life.



Product conforms to the Medical Device Directive 93/42/EEC



Authorized Representative in the European Community.



Keep Dry



Type B Applied Part



Class II Equipment

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Medichoice[®] is a registered trademark of Owens & Minor, Inc.

Clorox[®] is a registered trademark of The Clorox Company.

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