Summit Doppler™ LifeDop® User Manual

L150 Series (Handheld Doppler without Display)

L250 Series (Handheld Doppler with Display)

CooperSurgical

CE 2797

Thank you for choosing LifeDop® Doppler products from CooperSurgical. We believe you have purchased the finest handheld 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!

CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611 USA

Year of manufacture
is located on the device.

Here's how you can reach us...
Phone: (800) 243-2974
Fax: (800) 262-0105

International
Phone: +1 (203) 601-9818
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Service and Repair
(800) 444-8456 or +1 (203) 601-9818 for international calls

www.coopersurgical.com

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

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
There are no known Contraindications associated with the use of this device.

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.

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

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

Caution
• Dropping the LifeDop 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 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.

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 Doppler is factory configurable to include many different features and product enhancements. Along with user interchangeable ultrasound transducers, the LifeDop 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 (available in all models) – Superior Sound Quality. Every LifeDop Doppler is designed with a state of the art sound system that produces excellent sound quality and long-term reliability.

Recharge (available in model numbers with "R") – We offer the ease of use of a rechargeable system or the attractive cost of a non-rechargeable unit. Either way, the LifeDop Doppler battery system has been designed with your long-term battery life needs in mind.

LCD Display (L250 Series models) – The LCD display (optional) allows you to view the fetal heart rate in larger easy to read digits, monitor battery life and battery recharging, observe signal strength indicators, Play/Record functions, and 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, battery recharging and Play/Record functions as appropriate to your unit.

Record (available in model numbers with "A") – This unique built-in enhancement allows you to record Doppler sounds during an examination and refer to these sounds for later evaluation, replay for parents or colleagues, or download the audio to a PC for permanent storage or e-mail.
NOTE: Downloading is "allowed" in those models with "AR".

Probes

LifeDop 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 and are carefully measured and tested to ensure they meet 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.

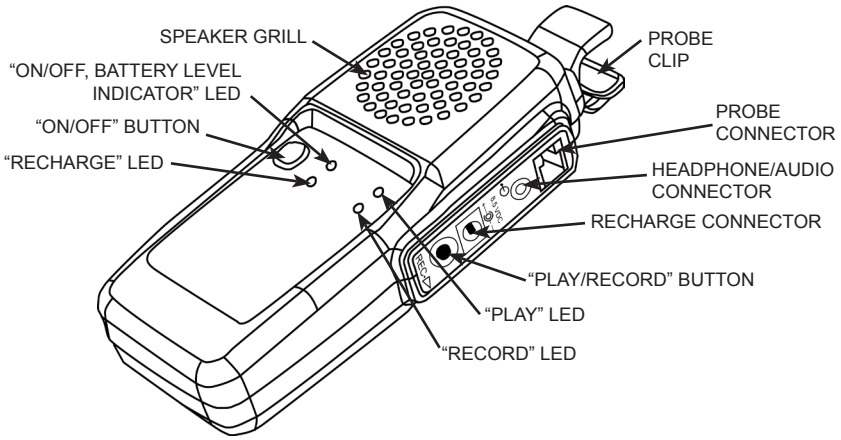
3 MHz – Early and general-purpose obstetrical examination. This probe frequency is a general use model ideal for most stages of fetal examination. Fetal heart sounds can be heard as early as 12 weeks and sometimes sooner depending on the position and size of the fetus.

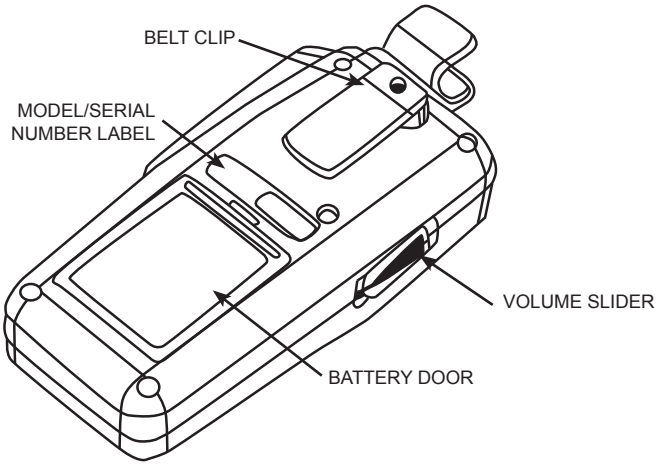
4 MHz Broad – This unique peripheral vascular probe is ideal for quickly locating brachial, radial and ankle arteries in the performance of Ankle/Brachial Index testing. The broad beam of the 4 MHz probe allows the user to place the probe over the general location of the artery and with very little movement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

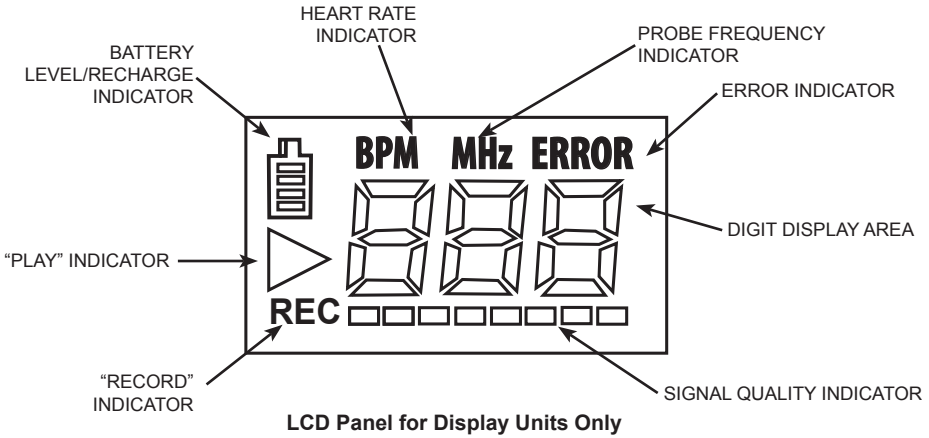
5 MHz – This standard "pencil" style probe is an excellent vascular tool for locating deep specific vessels in the peripheral vascular system. The narrow grip and small face of the probe make it ideal for maneuvering for maximizing the signal.

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.

Operation and Installation







LCD Panel for Display Units Only

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 LifeDop 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 LifeDop 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

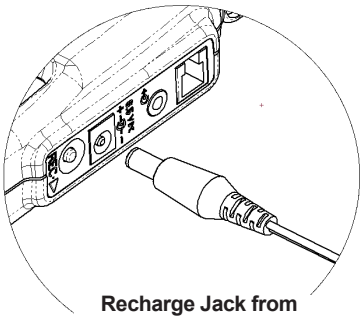
All LifeDop Doppler units perform continuous battery monitoring and give a visual indication of battery level. Display units use a multiple level battery shaped indicator that indicates the voltage level of the battery. The battery outline will flash when the battery level is very low indicating that the user should change or charge the batteries (depending on the model) soon after the current examination is complete. See Recharging Section to learn how to charge the batteries.

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 or charge the batteries (depending on the model) soon after the current exam is complete. See Recharging section to learn how to recharge the batteries. Remember, if your unit has alkaline batteries, do not recharge them.

Recharging (Rechargeable units only)

Warnings:

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



Recharge Jack from power supply plugs into connector

It is recommended that the LifeDop Doppler be recharged prior to first use. To recharge the unit, plug the recharge jack from the wall adaptor into the unit's recharge connector. For display units, the battery shaped indicator will cycle in a repeated rising pattern to indicate the unit is recharging. For non-display units, the Recharge LED will turn on.

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 or the Recharge LED 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.

Play and Record (Recorder units only)

Caution

- To distinguish between live audio and playback audio refer to the Play indicator or Play LED. If the indicator is on, the sound is coming from a recorded signal.

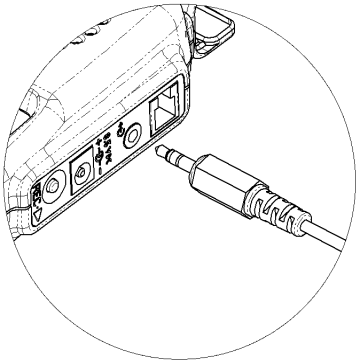
Play

To listen to a pre-recorded audio file on the LifeDop Doppler, press and release the Play/Record button on the side of the unit. For display units, the Play indicator is on during playback. For non-display units, the Play LED is on during playback. The recorded audio files are not re-processed for heart rate calculation - heart rates must be determined manually in the play mode.

The unit will continue to play the recorded audio until either the end of the stored data, or until the Play/Record button is pressed again. This will stop the playback audio and the unit switches back to real time audio when the indicators turn off. Volume control remains functional during playback.

Record

To record a new audio file on the LifeDop Doppler, obtain the desired Doppler signal and press and hold the Play/Record button until the Record LCD indicator or Record LED comes on (approximately 4 seconds). Once the indicator has turned on and the button is released, the Doppler signal will be stored for 32 seconds or until the Play/Record button is pressed again. Either of these events will stop the recording audio mode.



Press Button to play, hold 4 seconds to record

REC

Audio Jack from cable plugs into output connector (L250AR Only)

Recording a new audio file automatically overwrites any previous recording.

Download to Personal Computer (L150A and L250AR only – PC Sound Card Required)

Warnings

- The audio/headphone output should only be connected to external line powered accessories that comply with recognized safety standards such as IEC 60601-1, IEC 60065, UL2601-1 or UL544.

- The LifeDop Doppler is not specified for connection to any line powered accessories while it is being used on a patient.

For use with IBM style PCs (using Microsoft® Windows® Operating System)

1. To download the audio to a PC for permanent storage, connect one end of the provided 3.5 mm audio cable into the Audio Out jack on the side of the LifeDop. Connect the other end of the cable into your PC sound card “Audio In” port - typically the blue connector on the sound card.
2. Using operating system Windows 98 or higher, on your PC select the Sound Recorder Application by selecting: START MENU, PROGRAMS, ACCESSORIES, ENTERTAINMENT, SOUND RECORDER.
3. Click on the highlighted RECORD icon in the Sound Recorder Application to start recording.
4. Press the Play button on the side of the LifeDop Doppler. The audio should now be playing and the PC downloading the audio information as indicated by the graphical sound waveform.
5. If the sound waveform is a flat line while you are hearing the audio from the LifeDop, then the recorder input is not selected properly. To choose the proper input, open the Volume Control Application by selecting: START MENU, PROGRAMS, ACCESSORIES, ENTERTAINMENT, VOLUME CONTROL.
6. Click on Options and then Properties. Click on Recording and ensure that the LINE IN box is checked, then click OK. In the Recording Control Screen, ensure the Select Box for LINE IN is selected and then exit. The recorder is now set up to use the audio as an input. Restart the Sound Recorder Application and record as directed above.
7. When the audio playback is finished, click on the STOP icon in the Sound Recorder. The file can be played back on the PC by clicking the PLAY icon in the Sound Recorder or the file can be stored by selecting FILE, SAVE AS to locate and name the file.

Refer to your PC User’s Manual for problems associated with the sound card or Sound Recorder Application.

For use with Apple® computers

(Please note: SimpleSound is a program associated with OS 9 or earlier operating systems. For OS X or later operating systems SimpleSound may not be included)

1. To download the audio to a PC for permanent storage, connect one end of the provided 3.5 mm audio cable into the Audio Out jack on the side of the LifeDop. Connect the other end of the cable into your Mac sound card “Audio In” (microphone) port.
2. On your Macintosh, open the SimpleSound Application that is usually found in the Apple Menu. If you are unable to locate the application in the Apple Menu, do a FIND for ‘SIMPLESOUND’.
3. Once you open SimpleSound, an AlertSounds box may be shown. Select File and then New to open a new audio file.
4. Click on the highlighted RECORD icon in SimpleSound to start recording.
5. Press the ‘PLAY’ button on the LifeDop. The audio should now be playing and the Macintosh downloading the audio information as indicated by the graphical waveform from the Speaker icon.
6. If there is no graphical waveform from the Speaker icon while you are hearing the audio from the LifeDop, then the computer’s input is not selected properly. To choose the proper input, return to the Apple Menu and open the Control Panel. Open the Sound Application and select Input. Select ‘External Mic’ as the built-in sound source.
7. The computer is now set up to use the LifeDop as an input. Restart the SimpleSound Application and record as directed above.
8. When the audio playback is finished, click on the STOP icon in SimpleSound. The file can be played back by clicking the PLAY icon in SimpleSound or the file can be stored by selecting SAVE to locate and name the file.

Refer to your computer’s User Manual for problems associated with the sound card or SimpleSound Application.

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 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 heart beat 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 heart beat 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 sound depending on the position of the baby and probe.

Obstetrical (continued)

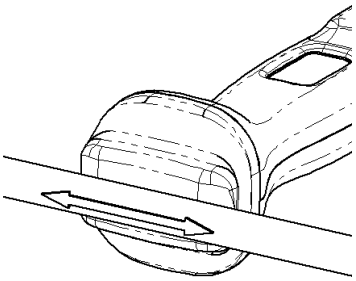
Many times when attempting to detect the fetal heart, the maternal vascular sounds are heard instead of (or in some cases, in addition to) the fetal sounds. These maternal sounds can come from one of the major arteries, the placenta or the umbilical cord. The maternal vascular sounds are typically higher 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 affect 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 is not designed for liquid immersion. Do not soak the Doppler main unit or probes in liquids. **Do not use products containing bleach.**
- The LifeDop is not designed for sterilization processes such as autoclaving, gamma radiation or hydrogen gas.
- **Do not allow water or spray to enter through the connectors or speaker grill.**
- The LifeDop 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.
- Examiners should wash hands and change gloves after every exam.
- Follow temperature and humidity guidelines as specified in the **Specifications** section.

The LifeDop Doppler requires very little maintenance. However, it is important to the continuing function of the unit and the health of the patients that the unit is cleaned and examined regularly per the following guideline:

Cleaning and Disinfection Process for Probes and Remotes

1. Devices should be cleaned as soon as possible. Do not allow soil to dry on the device. If cleaning cannot be performed immediately, keep device moist.
2. Moisten a disposable wipe with water. Remove excess gel and other visible soil from probe and remote. In particular, pay close attention to the seams along plastic lines. Do not allow water or spray to enter the connectors or other electrical components.
3. Prepare an enzymatic, neutral pH cleaner solution: dilute chemistry in accordance with Manufacturer's instructions.
4. Immerse a clean, lint-free wipe into cleaning solution and wring excess moisture. Thoroughly wipe the probe only for a minimum of 30 seconds, paying particular attention to seams. Discard the wipe.
5. Repeat step 4 with a new, clean wipe a minimum of one time or until all visible soil has been removed. Discard the wipe between successive repeats. (Do not place soiled wipe into cleaning solution.)
6. Immerse a new, clean, lint-free wipe into the cleaning solution and wring excess moisture. Wipe the remote and electrical cord for a minimum of 30 seconds. Discard the wipe.
7. Immerse a new, clean, lint-free wipe into warm (25-30 °C) utility water and wring excess water. Thoroughly wipe the remote and electrical cord first for a minimum of 30 seconds followed by the probe for an additional 30 seconds. Discard the wipe.
8. Repeat step 7 one time with a new, clean, lint-free wipe.
9. Use a sterile 70% IPA wipe, or a low-lint wipe, saturated with sterile 70% IPA, to thoroughly wipe the remote and electrical cord first, followed by the probe.
10. Wipe the remote, electrical cord, and probe dry with a new, clean, lint-free wipe.
11. Once dry, visually inspect the device for any residual soil. Repeat cleaning instructions if visible soil is present.

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 CooperSurgical for service at (800) 444-8456 or +1 (203) 601-9818 for international calls.

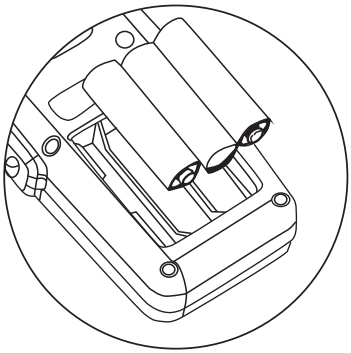
Replacing Batteries

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.

Caution

- If the unit is to be stored for longer than 90 days without use, remove the batteries prior to storage.
- It is recommended that rechargeable batteries be replaced annually.
- Replace batteries only with batteries supplied by CooperSurgical. 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.

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 will not be damaged.

Troubleshooting

Warning

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

Caution

- Do not drop or mishandle the LifeDop, probes or accessories. Damage to sensitive electrical components, speaker, 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 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 the correct probe is being used, contact the CooperSurgical Service Department at (800) 444-8456 or +1 (203) 601-9818 for international calls.

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 CooperSurgical products.
Batteries are old - Refer to Maintenance Section

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

Diagnostic Codes – Contact the CooperSurgical Service Department at (800) 444-8456 or +1 (203) 601-9818 for international calls.

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

Clinical 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, please contact CooperSurgical at (800) 243-2974 or +1 (203) 601-9818 for international calls.

Specifications

Degree of protection against electric shock:

 Type B Applied part

 Class II Equipment

Degree of protection against ingress of water:
2 MHz Waterproof: IPX7 – entire probe and cable excluding connector
All other probes: IPX4 – extending 2.5 cm from tip
IPX1 – entire probe 2.5 cm from tip, excluding connector

Designed and tested to meet:
IEC 60601-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, EN 55011

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 type and voltage	3 – AA Alkaline 1.5 volt (for non-rechargeable units) 3 – AA NiMH 1.5 volt (for rechargeable units)
Battery life:	Batteries provided with LifeDop Doppler: 1000, 1-minute exams (NiMH) 1250, 1-minute exams (Alkaline)
Audio bandwidth and power:	350 Hz – 2 KHz, 0.5 W
Record sampling rate, duration:	4 KHz, 32 seconds
Heart rate calculation accuracy:	± 3 BPM over range 50 to 220 BPM
Audio cable pin out: (L250AR version only)	3.5 mm stereo plug Tip – Audio out Ring – Audio out Shaft – Ground

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

EMC Compliance Information

Guidance and Manufacturer's Declaration – Electromagnetic emissions

The doppler system is intended for use in the electromagnetic environment specified below. The customer or the user of the doppler system should assure that it is used in such an environment.		
Professional Healthcare Facility Environment		
Emissions tests	**Compliance**	**Electromagnetic environment - guidance**
RF emissions Radiated & Conducted[1] EN 60601-1-2 IEC/EN 55011 (below 1 GHz)	Group 1 Class A	The Doppler 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.
[1] Measurement of Conducted Emissions do not apply if the EUT is powered by an external DC power source.		

Guidance and Manufacturer's Declaration – Electromagnetic immunity

The doppler system is intended for use in the electromagnetic environment specified below. The customer or the user of the doppler system should assure that it is used in such an environment.		
Professional Healthcare Facility Environment		
Immunity tests	**IEC 60601 Test and Compliance (Specifications/Units)**	**Electromagnetic environment – guidance**
Electrostatic Discharge EN 61000-4-2	±2,4,8 kV Air ±2,4,6 kV Contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst EN 61000-4-4	±2 CM (AC & DC) Direct ±1 CM (Signal) Capacitative clamp	Mains power quality should be that of a typical commercial or hospital environment.
Surge EN 61000-4-5	±2 kV CM, ± 1 kV DM (AC)	
Voltage Dips, Short Interruptions and Voltage Variations EN 61000-4-11	>95% reduction/10 msec (AC) 30% reduction/500 msec (AC) 60% reduction/100 msec (AC) >95% reduction/5 sec (AC)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Doppler System requires continued operation during power mains interruptions, it is recommended that the Doppler System be powered from an uninterruptible power supply or a battery.

continued

Guidance and Manufacturer's Declaration – Electromagnetic immunity

The doppler system is intended for use in the electromagnetic environment specified below. The customer or the user of the doppler system should assure that it is used in such an environment.		
Professional Healthcare Facility Environment		
Immunity tests	**IEC 60601 Test and Compliance (Specifications/Units)**	**Electromagnetic environment – guidance**
Power Frequency Magnetic Field EN 61000-4-8	50/60 Hz, 3.0 A_{RMS}/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted Disturbances, Induced by Radio - Frequency Fields EN 61000-4-6	3 V_{RMS} (unmodulated, RMS) 80% 2 kHz AM 150 kHz - 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the Doppler System, including cables, than the recommended separation distance calculated from the equation applicable to 3 V/m the frequency of the transmitter. **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the doppler system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated, RF Electromagnetic Field - Amplitude Modulated - Proximity fields from RF wireless communications equipment EN 61000-4-3	3 V/m (unmodulated, RMS) 80%, 2 Hz AM 80 MHz - 2.5 GHz	
Radiated, RF Electromagnetic Field - Pulse Modulated ENV 50204	3 V/m (unmodulated, RMS) 50% duty cycle 200 Hz repition frequency 900 ±5 MHz	–

Transducer Model: LifeDop 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**	**0.278**
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 **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**	**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 **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			**0.03**	**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	
	2MHz	3MHz
ISATA (max) (mW/cm²)	19.6	17.0
Po (mW)	48.0	24.4
Effective Radiating Area (cm²)	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 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/cm²

5 MHz: $I_{ob} < 51$ mW/cm²

8 MHz: $I_{ob} < 47$ mW/cm²

The 2 MHz, 2 MHz WP and 3 MHz obstetrical probes are exempt from the declaration requirements of IEC 61157. These probes meet the conditions: $I_{ob} < 20$ mW/cm², $I_{spta} < 100$ mW/cm², and $P_r < 1$ 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.

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 CooperSurgical. Products shall be repaired or replaced in a reasonable amount of time.

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

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

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

Service Returns – To return products:

1) Call CooperSurgical for any final instructions prior to shipping.
2) Clean the product before shipping.
3) Ensure the product is well packaged and suitable for shipment.

Send the product to: Repair Department
CooperSurgical, Inc.
95 Corporate Drive
Trumbull, CT 06611 USA

For Service and Repair, please call: (800) 444-8456 or +1 (203) 601-9818 for international calls.

Explanation of Symbols

REF Reorder Number

SN Serial Number

 Date of Manufacture (located on device)

 Consult instructions for use

 Caution

 Not made with natural rubber latex

 Class II Equipment

 Type B Applied Part

 Keep Dry

 Manufacturer

R_xOnly **Caution**: U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner

EC REP Authorized Representative in the European Community

 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.

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