7 CooperSurgical maintains a service facility which has the capability to promptly repair all products returned to the factory. Because special jigs, fixtures, and reference are required, repairs should not be attempted on the internal tuning adjustments and the piezoelectric transducer "crystal". Instruments requiring repair in these areas <u>must be returned to the factory</u> for service. Prepaid insured shipment for factory service should be made to:

Customer Service Manager CooperSurgical, 95 Corporate Drive, Trumbull, CT 06611

8 Certain replacement parts can be ordered by calling Customer Service at (800) 243-2974.

WARRANTY

It is important to return the warranty card supplied with your Doppler as soon as possible. Your MedaSonics Doppler is protected by a limited warranty. Specific warranty terms and conditions were included with your Doppler or may be obtained by calling Customer Service at **(800) 243-2974**.

SPECIFICATIONS

Ultrasonic frequency • 8 MHz
Outputs • Two 2.5mm jacks to drive one or two headsets, one headset and a speaker or a tape recorder
Controls • Volume control and push-button ON-OFF. Pressing the "ON" button turns the unit ON for approximately 3 minutes.
Power Source • One standard 9 volt alkaline battery.
Dimensions • 12.6cm x 6.4cm x 2.5cm (4.95" x 2.5" x 1.0")
Weight • 133gm (4.7 oz) with battery
Construction • Rugged ABS plastic case, integral transducers, solid state circuitry

SPARE PARTS LIST

 125-0001-010 • Battery
 103-0001-010 • Headset Transducer

 150-0144-010 • Battery Connector
 203-0764-010 • Knob

 203-0765-010 • Battery Cover
 203-0786-010 • Screw Cover

 101-0008-010 • Headset (SH3A)
 200-0104-050 • Speaker Cable

 200-0004-050 • Headset Cord
 243-0018-010 • Switch

 150-0033-010 • Headset Jacks
 218-0066-020 • Volume Control

OTHER PRODUCTS AVAILABLE

Pocket Speaker • Tapletop Speaker Models SA2, SA3 & SA6 FetalCalc[™] Speaker with Heart Rate Display Fetal Dopplers • First Beat[®] and FetalPulse Plus[™] Doppler Systems Blood Flow Dopplers • CardioBeat[®], Model FP3B, Model BF4B DoubleBeat[™] • Multi-Use Doppler Versatone[®] D8 • Multi-Use Doppler System

<u>CoperSurgical</u>

95 Corporate Dr., Trumbull, CT 06611 Phone: (203) 601-5200 Fax (800) 262-0105 Toll Free: (800) 243-2974

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MEDASONICS°

BLOOD FLOW ULTRASOUND STETHOSCOPE®

Model BF5A

Operating & Service Instructions



INTRODUCTION

The MedaSonics ULTRASOUND STETHOSCOPE® Doppler Blood Flow Detector Model BF5A is a pocket-sized instrument featuring a high ultrasonic frequency and one of the smallest probe tips commercially available. It has been designed specifically for detecting blood flow in small arteries such as those of the face and digits. Clinical experience has demonstrated that Doppler ultrasound is a simple, non-invasive aid to the assessment of arterial and venous blood flow.

The MedaSonics ULTRASOUND STETHOSCOPE is based on the Doppler shift principle. At the end of the instrument is a piezoelectric crystal of very low power ultrasonic waves. This crystal is located at the tip of the plastic cone. Ultrasonic waves are emitted at a frequency of approximately 8 MHz. Reflections occur at tissue interfaces and some of the backscattered ultrasound is returned to the recieving crystal. Reflections from moving blood will have their pitch shifted slightly. After arriving at the receiving crystal, these reflections are detected and greatly amplified. Further processing converts the Doppler-shifted ultrasound into audible sounds indicating blood flow.

INSTRUCTIONS FOR USE

- 1 Spread a generous amount of ultrasound coupling agent on the body surface to be examined. *A fluid coupling agent is essential for proper operation.* Commercial preparations provide good coupling, however, a soap solution or even water can be used. *Do not use alcohol* as a coupling agent. A tube of commercial coupling agent is supplied with each instrument.
- 2 Plug headset or speaker into either output jack. Set volume control midway. Place the plastic probe tip on the site to be examined. Press side-mounted ON button. Adjust volume control as desired. Unit will remain on as long as button is depressed and for about 3 minutes after it is released. The BF5A is designed for one-handed operation, with the middle finger controlling the ON button and the index finger controlling the volume.
- 3 Place the probe tip on the surface being examined. *Do not press hard or blood flow may be affected.* Use sufficient fluid coupling medium so it is not necessary to press

hard. The sensitivity pattern is analogous to a narrow beam of light, and some searching is necessary to locate the best flow signals. The frequency (pitch) of the audible flow sounds is related both to flow velocity and to the angle between the instrument and the axis of flow. *The instrument should therefore be tilted toward the axis of blood flow in order to produce the best signal.* Experiment with the pressure exerted and angle at which the instrument is held before initiating clinical use.

If desired, a colleague may also listen through another headset plugged into the second output jack, or by means of the Model SA2, SA3, SA6 speaker. The extra headset and speakers are available as optional equipment. A tape recorder may also be connected to one of the outputs.

CLINICAL USAGE

The BF5A ULTRASOUND STETHOSCOPE may be used for—

- **1** Use before and after skin flap transfer to precisely locate small blood vessels.
- **2** Use after reconstructive surgery involving vascular repair to determine vessel patency.
- **3** Use during recovery from burns to check digital circulation.
- 4 Use to routinely study finger and toe arterial circulation.
- **5** Use prior to cannulation of radial artery to confirm presence of superficial palmar arch (supplements Allen test), even on unconscious patients.
- **6** Use to study arterial circulation in small facial arteries.
- 7 Use with appropriate cuff to take penile blood pressures.

CAUTIONS AND CONSIDERATIONS

- **1** Improper placement of the detector can result in an error of interpretation. While the Doppler signal itself may be objective, one should be certain that the signal heard is coming from a particular artery or vein, and not from a collateral vessel.
- 2 Sensitivity should be verified whenever expected Doppler signals cannot be found.
- **3** The Doppler instrument produces sounds in response to the velocity of flow in the blood stream, and depends on the angle between the transducer and the direction of blood flow. Holding the transducer at 90 degrees to the vessel will produce no sounds, while an angle of 0 degrees yields the best sounds. Although obtaining a 0 degree insonation of a vessel is usually impossible, the operator should attempt to make the angle between the transducer and the direction of flow as small as possible while still maintaining good skin contact.
- 4 Blood must be moving at a speed of approximately 4 cm per second before a Doppler signal can be heard. Operators should be aware that the Doppler signal does not indicate the volume of blood flow, only blood velocity. Presence of a Doppler signal is not a clinical indication that the volume of blood flow is adequate for nutritional tissue perfusion. Additionally, the Doppler does not produce a unique sound for every vessel configuration. Low volume flow through a narrow lumen (low flow, high velocity) may be indistinguishable from high volume flow in a large lumen (high flow, high velocity).

- **5 CAUTION** Do not use in the presence of explosive anesthetics.
- **6** According to the American Institute of Ultrasound in Medicine, no confirmed biological effects on patients or instrument operators caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported. 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.

CARE AND SERVICE

1 The probe tip area should be wiped clean with a tissue or soft cloth after each use. Do not immerse it in liquid. Do not autoclave.

CAUTION The piezoelectric crystal is located immediately underneath the plastic tip. This tip is necessarily very thin and provides only minimal structural protection. Do not drop instrument or subject the tip to physical stress or abuse. The crystal can break if the unit is dropped on the tip and repair is relatively expensive.

- **2** To Replace the 9 Volt Battery Slide the battery cover in the direction indicated by the arrow on the cover. Remove the battery from the chamber. Unplug the clip from the old battery and connect it to a fresh one. Observing proper polarity, carefully put the new battery into the chamber. Be sure the wire of the battery clip is not in the way of the cover. Slide the cover back in place. Replace the battery with a fresh one after six months.
- **3** Is it working? A quick check can be made by listening to one's own vascular sounds to verify sensitivity. In the event of any difficulty, make sure the battery is fresh, the volume control is up, the probe tip is clean, and that enough coupling agent is being used. If the coiled cord or the headset is damaged, please call CooperSurgical to order a replacement.
- **4** Transducer Inspection Carefully inspect the piezoelectric transducer crystal for cracks or chips. If the crystal is cracked, advise personnel to discontinue use of the instrument because ultrasound coupling agent will enter the front of the unit and internal damage may result.
- **5** Headset Test With the volume turned up, test the headset for intermittent connections by vigorously moving the cord at both ends. Be sure the plug fits snugly and that both headset jacks are making the connection. To test for lost sound or poor quality of sound, the headset must be compared with a Model SH3A headset known to be working well. Check that the sound pathway in the earpieces is not obstructed. Continued acoustic problems are indications that the headset transducer assembly should be replaced.
- **6** Volume Control / On/Off Switch Test While listening to the background noise, vary the volume from full to *OFF* and listen for excessive static caused by the potentiometer wiper.
- **WARNING** Do not spray clean the volume control as most control cleaners will harm the plastic case.