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 • 5.3 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 BF5A

DoubleBeat™ • Multi-Use Doppler

Versatone® D8 • Multi-Use Doppler System



95 Corporate Dr., Trumbull, CT 06611

Phone: (203) 601-5200 Fax (800) 262-0105 Toll Free: (800) 243-2974



BLOOD FLOW ULTRASOUND STETHOSCOPE®

Model BF4B

Operating & Service Instructions



INTRODUCTION

The MedaSonics ULTRASOUND STETHOSCOPE® Doppler Blood Flow Detector Model BF4B has been designed specifically for detecting blood flow in the arterial and deep venous systems of the extremities. Clinical experience has demonstrated that doppler ultrasound is a simple, noninvasive aid to the assessment of venous and arterial flow in the extremities. This Doppler instrument is manufactured to give quality performance in a rugged, truly pocket size package.

The MedaSonics ULTRASOUND STETHOSCOPE is based on the Doppler shift principle. At the narrow end of the instrument is the faceplate, covering two piezoelectric crystals. One crystal is a transmitter of very low power ultrasonic waves at a frequency of approximately 5.3 MHz. The other crystal receives reflections of the transmitted signal which occur at various tissue interfaces. Reflections from moving blood cells will have their pitch shifted slightly. Arriving at the receiving crystals, these reflections are detected and greatly amplified. Further processing converts the Doppler-shifted ultrasound into audible sounds indicating blood flow.

INSTRUCTIONS FOR USE

- 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 faceplate-crystal end of the instrument 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 a few seconds after it is released. The BF4B is designed for one-handed operation, with the middle finger controlling the ON button and the index finger controlling the volume.
- **3** Move the instrument very slowly across the surface being examined. The sensitivity pattern is like a searchlight. The frequency (pitch) of the doppler-shifted sounds is relat-

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ed 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. Do not press hard or blood flow may be affected. Use sufficient fluid coupling medium so it is not necessary to press hard.

If desired, a colleague may also listen, through another headset plugged into the second output jack, or by means of the Model SA2, SA3 or 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 BF4B ULTRASOUND STETHOSCOPE may be used for—

- 1 Following the results of reconstructive vascular surgery in the recovery room, at bedside and later during office exams. The non-invasive clinical evaluation with this Doppler instrument can be directly related to arteriographic findings.
- 2 Taking systolic blood pressure using Doppler ultrasound. Leg and ankle pressures taken by Doppler can provide information as to the severity of arteriosclerotic involvement of the arteries of the leg and the location of the impaired segments.
- **3** Preoperative and postoperative evaluation of the femoral artery when this artery is used as the cannulation site in cardiopulmonary bypass procedures.
- **4** Screening for venous thrombosis. The pocket-sized, portable nature of the instrument makes it particularly appropriate for everyday usage at bedside.
- **5** Taking a pulse rate or Doppler systolic blood pressure on the hypotensive and hypovolemic patient.
- **6** Useful in checking any arterial injection or catheterization site before and after such procedures.
- **7** Useful in emergency medicine and in noisy environments to take blood pressure, pulse rate, and to evaluate suspected arterial injuries.
- 8 Urologic applications include evaluation of varioceles, testicular torsion diagnosis and impotence assessment.

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. Instrument sensitivity may easily be verified on the radial artery.
- 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 4cm 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 transducer crystal area should be wiped clean with a tissue after each use. *Do not clean with alcohol or other organic solvents*. Do not autoclave the unit, do not immerse it in liquid, and avoid dropping it.
- 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 transducer crystal area 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. Also, press the ON button several times to the ON/OFF momentary switch for intermittent operation. When the switch is released, the sound will decay in 2 or 3 seconds.

WARNING Do not spray clean the volume control as most control cleaners will harm the plastic case.