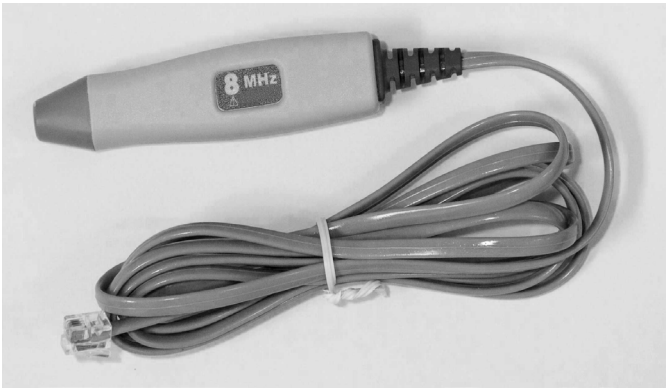
User Manual for Sterilizable Doppler Probes
(Supplement to TRIA®II System User Manual)



Non-Sterile: Sterilize before use

CE 0086

Thank you for choosing TRIA® II from CooperSurgical, Inc. MedaSonics® handheld Dopplers have been a standard of care for 30 years. 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!

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Please read the manuals for your probe and main unit carefully and become familiar with the operation, features and maintenance of your Doppler system prior to using the **sterilizable** probes or accessories.

This supplemental manual is intended for the care and use of the **sterilizable** doppler probes. For care and use of the TRIA®II main unit, please refer to the TRIA® II Manual provided with your system. Please contact CooperSurgical if additional copies of either manual are required.

Intended Use

This product is intended for detection of blood flow in veins and arteries.

Caution

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

Contraindications

The sterilizable probes are compatible only with TRIA® II Model TR150 and TR250 handheld Doppler main units. Do not attempt to use the device with other ultrasound systems**.**

Warnings

- The ultrasound probes are not to be used on or near the eyes.
- The device is for use only on intact skin.
- This probe is not for fetal use.
- Do not plug any part of this device into a telephone jack or modem system.
- This device is not intended for use simultaneously with HF surgical equipment.
- **Product is not delivered sterile. Sterilize before use.**

Caution

- Do not drop or mishandle the TRIA main unit, probes or accessories. Damage to sensitive electrical components, speaker, cables, transducers or plastic may occur

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

Medasonics 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 sterilizable probes are an 8 MHz non-directional vascular Doppler transducer. When properly sterilized per the processing instructions, this device is suitable for use in the sterile field.

This probe can be sterilized using an H_2O_2 gas process for use in a sterile environment. The 8 MHz probe is useful for checking pulses pre- and post-surgery. With a blood pressure cuff the Doppler system can be used to determine systolic blood pressure.

Processing Instructions

Warnings

- Use only the specified cleaning and sterilization process. This device is not suitable for steam sterilization. Damage will occur.
- Use gloves and protective eyewear during any manual cleaning.

Devices: TRIA® II 8 MHz Non-Directional Sterilizable Doppler probes

Method: H_2O_2 Gas

CAUTION	
Limitations on reprocessing:	Repeated processing causes gradual degradation of materials. See processing instructions for required inspection and test. No significant degradation was observed after 15 cycles using the STERRAD® 100NX or Steris V-PRO™ (Lumen cycle).

PROCESSING INSTRUCTIONS	
Point of Use:	Remove excess soil with a disposable wipe.
Containment and transportation:	It is recommended that probes are reprocessed as soon as is reasonably practical following use.
Preparation for cleaning:	Inspect probe surface for signs of degradation or damage including cracks or crazing. Discontinue use if damage is detected.

Cleaning—Automated:	Automated cleaning has not been validated by the manufacturer.
Cleaning – Manual:	Equipment: brush, enzymatic detergent (Enzol®) prepared per manufacturer's recommendations (1 oz./gal lukewarm tap water). Method: 1. Rinse the probe in lukewarm tap water until all visible soil is removed. 2. Immerse the probe in the prepared detergent and allow to soak for a minimum of 1 minute. 3. After soaking, brush the probe and cable using a soft bristle brush to remove any soil. A syringe or pipe cleaner may be used to assist in the cleaning. 4. Be sure to clean the cable strain relief and labels using an appropriate brush. 5. Rinse under clean water for a minimum of 1 minute. Ensure that both probe and cable are rinsed. 6. Visually inspect the device.
Disinfection:	Not applicable. These instructions are for H_2O_2 gas sterile processing.
Drying:	Do not exceed 120° C.
Maintenance:	Not applicable.
Inspection and functional testing:	Inspection: Visually inspect for damage. Labels should be intact; the plastic on the probe face should be smooth and free of crazing. Cable should be pliable and free of cracks. Functional Test: Plug the probe cable into the appropriate TRIA main unit. Rub the probe tip with your finger and verify there is audible output.
Packaging:	Standard packaging material may be used such as single ply polypropylene wrap. Cable may be secured with appropriate tie.
Sterilization:	Equipment: Steris Amsco® V-PRO 1 Steris Amsco V-PRO 1 Plus Steris Amsco V-PRO Max STERRAD Model 100s STERRAD Model NX STERRAD Model 100NX
Storage:	No particular requirements

The instructions above have been validated by the manufacturer as being CAPABLE of preparing a TRIA® II sterilizable probe for reuse. It remains the responsibility of the processor to ensure that the processing as actually performed, using the equipment, materials, and personnel in the processing facility, achieves the desired result. This requires validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

Additional Information:
Mark the below Processing Tracking Table after each use.

Probe Serial Number:_____

Processing Tracking Table

Instructions: Mark Each Processing Cycle							
1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	

Warning
- Discard the probe if degradation is observed during inspection or functional test.

Use and Care

Warnings
- Do not continue to use the probe if cracks or other signs of damage to the housing are discovered.
- Arrange to use alternate equipment in the event of probe failure and call CooperSurgical to seek service if a malfunction is suspected.
- Any connected equipment that is line powered must meet appropriate standards.
- Dropping or otherwise mishandling the probe may result in damage and loss of use.

Caution
- The TRIA® II Main Unit is not suitable for sterilization or immersion in liquids. Only the probe is intended to be reprocessed. Damage may occur if the main unit is improperly cleaned.

Maintenance:
Inspect the probe after each use for mechanical and housing integrity. If the probe is not in use, inspect the probe at least annually. Refer to Processing instructions for additional probe maintenance instructions.

Preparation for use:

1. Inspect the probe for signs of damage. Discontinue use if any damage is detected.
2. Clean and sterilize the probe per the Processing Instructions.
3. Use of a sterile probe sheath is recommended in addition to sterilization. If the sterile sheath does not have pre-applied ultrasound gel, it will be necessary to place a small amount of sterile gel on the tip of the probe prior to covering.
4. Using proper aseptic techniques, present the probe cable for connection to the TRIA main unit.
5. Plug the probe cable into the main unit.
6. For operation of the main Doppler unit, refer to the system's User Manual.

Examination Technique

1. Apply sterile ultrasound gel to the exam site as needed.
2. Place the tip of the probe on the skin over the approximate location of the artery or vein. Slowly move the probe side to side to find the location with the maximum signal.
3. Changing the angle of the probe with respect to the artery will change the Doppler frequency of the audible signal. Steeper angles offer higher frequency signals, but when the probe is angled too much it may be more difficult to detect weak flow. Normally the optimal combination of sensitivity and Doppler shift occurs with probe angles of 45 to 60 degrees from the vessel.

After the Examination

1. Remove the probe sheath (if applicable).
2. Wipe off any remaining gel and soil with a disposable wipe.
3. Reprocess the probe prior to next use per the Processing Instructions.
4. Discard probe if degradation is apparent.

Additional Information about Sterile Sheaths and Sterile Gel

1. Probe performance is improved when probe covers designed for ultrasound transmission are used, rather than using a condom or the end of rubber glove. Commercially available probe covers subject to the FDA 510(k) process are recommended.
2. Some probe covers have pre-applied sterile gel in the tip. When this is not the case, you must apply gel on the tip of the probe before applying the sheath.
3. When used in a sterile environment, use of sterile gel is required. Commercially available sterile gel subject to the FDA 510(k) is recommended.

Warning

- Some condoms and sheaths may contain natural rubber Latex and talc, which can cause allergic reactions in some individuals. For more information, reference the FDA's "Allergic Reactions to Latex Containing Medical Devices," FDA Medical Alert, Pub. No. MDA91-1 (March 29, 1991).

Specifications

Compatibility: This probe is compatible with the TRIA® II **TR150** and **TR250** handheld Doppler main units.

 Consult Accompanying Documents

Degree of protection against electric shock:

 Type B Applied part

 Class II Equipment

Degree of protection against ingress of water: IPX7

Designed and tested to meet:
IEC 60601-1 Safe Extra Low Voltage
IEC 60601-1-2, Class A
IEC 60601-2-37

Dimensions (L x Dia):	10 cm x 2 cm Tip = 1cm
Weight:	72 grams
Operating temperature:	10 to 28 °C
Operating humidity:	30 to 90 %, non-condensing
Transport/Storage temperature:	–20 to 50 °C
Transport/Storage humidity:	5 to 90%, non-condensing
Cable Length:	2.1 meters (7 feet)

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

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

Transducer Models: TRIA® II Sterilizable 8 MHz Vascular Probes
Operating Mode: Continuous-Wave
Application(s): Peripheral Vascular

ACOUSTIC OUTPUT			***MI***	$I_{SPTA.3}$ ***(mW/cm²)***	$I_{SPPA.3}$ ***(W/cm²)***
Global Maximum Value			**0.04**	**185**	**0.185**
Associated Acoustic Parameter	$P_{r.3}$ (Mpa)		0.08		
	W_o (mW)			9.1	0.009
	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	

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:	29%
Pressure:	13%
Intensity (Ispta):	27%
Frequency:	<1%

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

8 MHz: $I_{ob} < 45$ mW/cm²

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

Warranty and Servicing Policy

This warranty is in lieu of all other warranties, expressed or implied. CooperSurgical warrants this Doppler probe against defects in material or workmanship as follows: The sterilizable doppler probes are warranted to be free from defects in material and workmanship for 12 months from the original sale of the device or 10 sterilization cycles, whichever comes first.
Limitations - This product is to be used only for the intended purpose and labeled indications presented in the literature accompanying the product. This warranty shall not apply to any products repaired or altered by anyone not authorized in writing by CooperSurgical. CooperSurgical makes no warranty of the results to be obtained. CooperSurgical's sole responsibility shall be to replace or repair this product under the terms stated above and does not cover loss or damage from external causes such as, but not limited to, weather, theft or abuse. **This warranty does not apply to batteries, shipping case or other accessories, or to damage from shipping, tampering, misuse or negligence.** Preventive maintenance, the refinishing or replacement of any cosmetic defect or deterioration, or the replacement of batteries unless damaged by a component failure, is not covered by this warranty. CooperSurgical will not be responsible for any loss, damage or injury resulting from delay in rendering service under this warranty. COOPERSURGICAL SHALL NOT BE RESPONSIBLE FOR ANY SECONDARY CHARGES OR CONSEQUENTIAL DAMAGES FROM ANY BREACH OF ANY WARRANTY, EXPRESSED OR IMPLIED. Since some states do not allow the exclusion or limitation of consequential damages, some of this limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To return products to CooperSurgical:

1. Call CooperSurgical for any final instructions prior to shipping
2. Clean the product prior to shipping
3. Ensure the device is well-packaged and suitable for shipment
4. Send the product to:

    Service Center
    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

℞ Only U.S. Federal law restricts this device to sale by or on the order of a physician


Consult instructions for use

Not made with natural rubber latex


Class II Equipment


Type B Applied Part


Keep Dry


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.


Manufacturer

EC REP Authorized Representative in the European Community

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