English	en

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CooperSurgical®

Swartz Doppler Probe and Doppler Extension Cable DP-SDP001, DP-SDP002 and DP-CAB01

Instructions for Use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

DEVICE DESCRIPTION

The Swartz Doppler Probe contains at its distal end an ultrasound transducer (20 MHz) assembly that is attached to a silicone cuff which is designed to be secured around a blood vessel. Proximal to the cuff, a flexible wire connects the transducer to stress retention tabs and finally to a terminal connector. The Doppler Extension Cable connects the proximal connector of the Probe to either of the Doppler Blood Flow Monitor's output channels.

INTENDED USE

For monitoring blood flow in vessels intraoperatively, and following reconstructive micro-vascular procedures, re-implantation, and free-flap transfers.

CONTRAINDICATIONS

None Known.

WARNINGS

The Swartz Doppler Probe emits and detects 20 MHz signals. External 20 MHz signals may also be detected.

MR Unsafe – Do Not expose patient to an MRI procedure while Swartz Doppler Probe is implanted. Substantial MRI-related heating of the Doppler Probe may occur. Doppler Probe must be removed prior to any MRI procedure.

The Swartz Doppler Probe is not to be used with High Frequency surgical equipment.

PRECAUTIONS

- Not intended for fetal use.
- The Swartz Doppler Probe is NOT FOR USE ON THE CENTRAL CIRCULATORY SYSTEM.
- The Swartz Doppler Probe should only be used with the Doppler Blood Flow Monitor.
- During use of all ultrasound devices, the operator should minimize the exposure of ultrasound energy to the patient using the principle of ALARA (As Low As Reasonably Achievable).
- Avoid use of excessive force to remove the transducer assembly from the patient, which may cause injury to the blood vessel. If the transducer assembly can not be removed using gentle traction, the transducer assembly should be removed surgically.
- Changes in audio signals produced by the Doppler Blood Flow Monitor system should be immediately documented and reported to the responsible healthcare provider.
- **Caution**: Do Not remove the probe conductor wire and crystal assembly (leaving only the cuff in situ on the vessel), until vessel monitoring is completed (commonly 3-5 days). Probe conductor wire and crystal assembly placement must not exceed 29 days. Cuff alone may remain within the patient indefinitely.
- Avoid the application of electrosurgical energy on or near a connected Swartz Doppler Probe or Extension Cable as damage to the monitor may occur.

POTENTIAL ADVERSE EVENTS

Use of the Swartz Doppler Probe involves potential risks normally associated with any implanted device, e.g., infection, perforation or laceration of vessels, erosion, implant rejection, or device dislodgement/migration.

Device specific risks include separation of the doppler crystal from the cuff, inability to percutaneously remove the crystal after monitoring is complete, loss of reception or transmission of ultrasound monitoring signal.

INSTRUCTIONS FOR USE

IPX7 - Ingress Protection Rating. The distal 28cm of the Doppler Probe which contains the crystal transducer is rated IPX7 - Water Immersible.

1. Confirm proper operation of the Doppler Blood Flow Monitor system. (See Suggested Instructions for the Doppler Blood Flow Monitor.)
2. Trim curved silicone cuff to accommodate vessel size. The cuff length should allow close approximation of the crystal to the vascular adventitia. Position the silicone cuff around the targeted blood vessel, ensuring that the transducer assembly is directed towards the targeted vessel.
3. Secure the free ends of the silicone cuff together around the target vessel, using appropriate sutures or clip to maintain cuff position.

4. Stabilize the location of the probe by suturing the braided wire adjacent to the skin incision site, leaving some slack to alleviate tension on the cuff transducer assembly. Enough wire length should be provided so that there is no tension on the vascular anastomosis. Loop any remaining braided wire, and suture or tape to the skin. The retention tab may be placed over the braided wire and sutured or taped to the skin providing additional strain relief.
5. Attach the metal connector end of the Extension Cable (DP-CAB01) into either of the two channels by pushing it firmly into place. Attach the proximal (red plastic) connector of the probe to the distal (red plastic) connector of the extension cable, aligning the black dots. Verify appropriate position of the Swartz Doppler Probe by turning on the flow monitor and adjusting the volume until an adequate audible signal is obtained.

   Note: The proximal connector of the Swartz Doppler Probe should not be attached to the flow monitor/extension cable until the retention tabs are secured to the skin. This helps ensure that accidental tugging of the wires does not disrupt the attachment of the probe to the vessel.
6. If a strong audible signal is not identified, irrigate the crystal with saline at its interface with the blood vessel adventitia. During irrigation of the crystal, an audible signal from the monitor verifies proper function of the device.
7. For operation of the blood flow monitor, refer to the following suggested INSTRUCTIONS FOR USE for the Doppler Blood Flow Monitor.
8. Following verification of proper function of the Swartz Doppler Probe, close the incision site using standard techniques.
9. To remove the Swartz Doppler Probe, first free the retention tab and braided wires to the skin by cutting the sutures (and/or removing the tape). Remove the probe by applying gentle traction to the braided wires at the skin entry site until the transducer assembly is withdrawn. (The silicone cuff remains in situ.)
10. Upon removal of the Swartz Doppler Probe, examine the distal tip of the probe to ensure that the transducer assembly is present. In the unlikely event that the transducer assembly has become detached and remains in the cuff in the patient, the transducer assembly should be removed surgically.

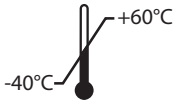
HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

DISPOSAL

Upon completion of procedure, dispose of the device per institutional guidelines for biohazardous medical waste.

TRANSPORT and STORAGE



Recommended Storage,
Shipping Temperature: -40°C - +60°C

Keep Dry

Recommended Humidity: Non-condensing

Keep away from sunlight

ACOUSTIC OUTPUT:

See following tables.

ACOUSTIC OUTPUT TABLES FOR TRACK 1

Doppler Probe and Monitor System

OPERATING MODE(S)

Clinical Application	B	CD	M	PWD	CWD	A	Combine (specify)
Ophthalmic							
Other (Intraoperative)				X			
Cardiac							
Clinical Application							

OUTPUT DATA

Transducer Model: **20 MHz Swartz Doppler Probe with Monitor System**
Operating Mode: **PWD-Mode**
Application(s): **Intraoperative**

DP-M350

Acoustic Output Reporting Table

Transducer Model: 20 MHz 1mm					**Operating Mode:** Pulse Doppler (PD)			
Index Label			MI	TIS			TIB	TIC
				Scan	Non-scan		Non-scan	
					Aaprt ≤1 cm^2	Aaprt >1 cm^2		
Maximum index value			0.0575	#	0.0175	-	0.0338	(a)
Associated acoustic parameter	$p_{r.a}$	(MPa)	0.258					
	P	(mW)		#	0.183		0.183	#
	min of [P*a*(z_s), *I*ta,*a*(z_s)]	(mW)				-		
	z_s	(cm)				-		
	z_{bp}	(cm)				-		
	z_b	(cm)					-	
	z at max. *I*pi,*a*	(cm)	0.150					
	Deq(z_b)	(cm)					-	
	*F*awf	(MHz)	20.1	#	20.1	-	20.1	#
	Dim of *A*aprt	X (cm)		#	0.100	-	0.100	#
		Y (cm)		#	0.100	-	0.100	#
Other Information	t_d	(µsec)	0.345					
	prr	(Hz)	7.81E+4					
	pr at max. *I*pi	(MPa)	0.286					
	deq at max. *I*pi	(cm)					0.0658	
	*I*pa.3 at max. *MI*	(W/cm^2)	1.63					

Note 1: Information need not be provided for any formulation of *TIS* not yielding the maximum value of *TIS* for that mode.

Note 2: Information need not be provided regarding *TIC* for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.

Note 3: *MI* and *TI* are less than 1.0 for all device settings.

(a) Intended use does not include cephalic so *TIC* is not computed.

\# No data reported.

SYMBOL INDEX

PWD:	Pulsed Wave Doppler	/pi	Pulse-Intensity Intergral
$I_{SPTA.3}$:	Derated spatial-peak, temporal-average intensity (milliwatts per square cm)	/pi, *a*	Attenuated Pulse-Intensity Intergral
$I_{SPPA.3}$:	Derated spatial-peak, pulse-average intensity (watts per square cm)	/ta, *a(z)*	Attenuated Temporal-Average Intensity
W_O:	Ultrasound power (mW)	*MI*	Mechanical Index
F_C:	Center frequency (MHz)	*P*	Output Power
Z_{sp}:	Axial distance at which the reported parameter is measured (cm)	*Pa*	Attenuated Output Power
X_{-6} & Y_{-6}:	Respectively the in-plane (azimuthal) and out of plane (elevational) -6 dB dimensions in the x-y plane where Z_{sp} is found (cm)	Pr	Peak-Rarefactional Acoustic Pressure
PD:	Pulse duration (µS)	*P*ra	Attenuated Peak-Rarefactional Acoustic Pressure
PRF:	Pulse repetition frequency (Hz)	*prr*	Pulse Repetition Rate
EBD:	Entrance beam dimensions for the azimuthal and elevational planes (cm^2)	*TIS*	Soft-Tissue Thermal Index
a	Acoustic Attenuation Coefficient	t_d	Pulse Duration
*A*aprt	-12dB Output Beam Area	*z*	Distance from the source to a specified point
*D*eq	Equivalent Aperture Diameter	z_b	Depth for TIB
*D*eq	Equivalent Beam Diameter	z_{bp}	Break-Point Depth
*F*awf	Acoustic Working Frequency	z_s	Depth for TIS
/pa	Pulse-Average Intensity		

Glossary of Symbols

Source: ISO 15223-1, ISO 7000 and IEC 60601-1

Symbol	Title
	Packaging unit
	Catalogue number
	Batch code
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)
	Date of manufacture
	Manufacturer
	Use-by date
	Medical Device
	Do not re-use
	Do not resterilize
	Sterilized using ethylene oxide

Symbol	Title
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
	Caution
	Consult instructions for use or consult electronic instructions for use
	Do not use if package is damaged and consult instructions for use
	MR Unsafe
	Temperature Limit
	Keep dry
	Keep away from sunlight
R_x Only	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner

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