

- WARNING:** Remove batteries when the device is not to be used for an extended period.
- WARNING:** If the integrity of the earth ground is in doubt, operate the unit on battery power only.
- WARNING:** This device emits and detects 20MHz signals. External 20 MHz signals may also be detected.
- WARNING:** Electrostatic discharges may cause changes to monitor settings. Always verify proper monitor settings when checking for the audible presence of blood flow.
- WARNING:** The use of accessories, transducers, and cables other than those specified for use with the device as detailed in the technical specifications below may result in increased emissions or decreased immunity of the equipment or system.
- WARNING:** Portable and Mobile RF communications equipment can affect the device as detailed in table 1 below.
- WARNING:** The device should not be used adjacent to or stacked with other equipment. If the device must be used under such conditions please verify the system's normal operation in the configuration used.
- CAUTION:** Federal law restricts the sale, distribution, or use of this device without the order of a physician.
- CAUTION:** NOT INTENDED FOR FETAL USE.
- CAUTION:** Before use, ensure that the probe packaging has not been opened or perforated.
- CAUTION:** The COOK-Swartz Doppler Flow Probe is NOT FOR USE ON THE CENTRAL CIRCULATORY SYSTEM.
- CAUTION:** The COOK-Swartz Doppler Flow Probe is for one-time use. DO NOT RE-USE.
- CAUTION:** The COOK-Swartz Doppler Flow Probe should only be used with the COOK Doppler Blood Flow Monitor.
- CAUTION:** 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).

TRANSPORT and STORAGE

The unit has been tested under the standards stated in ISTA Procedure 1A as follows:
 Vibratory Test, Vertical: 50 minutes at 285 CPM/14,250 impacts
 Shock Test, Free Fall Drop: 10 drops (1 corner, 3 edge, 6 face)
 Recommended Storage, Shipping Temperature: -40 C - +60C
 Recommended Humidity: non-condensing

POTENTIAL COMPLICATIONS:

Use of the COOK-Swartz Doppler Flow 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.

INTENDED USE

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

DESCRIPTION

The COOK-Swartz Doppler Flow Probe and the COOK Vascular Blood Monitor are the two main components of the Monitor System. The system consists of a probe having an ultrasound transducer assembly within a silicone cuff and a flow monitor. The cuff of the COOK-Swartz Doppler Probe is placed around the targeted vessel. When the COOK-Swartz Doppler Flow Probe is connected to the flow monitor, an audio signal corresponding to blood flow within the vessel is generated. Blood flow can be monitored continuously or periodically as required.

HOW SUPPLIED

The Cook-Swartz Doppler Blood Flow monitoring probes are supplied sterile and intended for one-time use. In the event of damage to the sterile packaging, do not re-sterilize the product. The Cook Doppler Blood Flow Monitor, Channel Verifier and Extension Cable Verifier are supplied non-sterile.

SUGGESTED INSTRUCTIONS FOR USE FOR COOK-SWARTZ DOPPLER FLOW PROBE

- Confirm proper operation of the COOK Vascular Blood Flow Monitor System. (See Suggested Instructions for Flow Monitor and TROUBLESHOOTING: Extension Cable Verifier and Channel Verifier).
 - 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.
 - Secure the free ends of the silicone cuff together around the target vessel, using non-bioabsorbable sutures or clip to maintain cuff position.
 - 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.
 - 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 COOK-Swartz Doppler Flow Probe by turning on the flow monitor and adjusting the volume and range settings until an adequate audible signal is obtained. (See the following sections for more detailed instructions for operating the flow monitor.)
- Note: The proximal connector of the COOK-Swartz Doppler Flow Probe should not be attached to the flow monitor 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.
- 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.
 - For operation of the flow monitor, refer to the following SUGGESTED INSTRUCTIONS FOR USE FOR THE COOK VASCULAR BLOOD FLOW MONITOR.
 - Following verification of proper function of the COOK-Swartz Doppler Flow Probe, close the incision site using standard techniques.
 - To remove the COOK-Swartz Doppler Flow 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.)

CAUTION: 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.

- Upon removal of the COOK-Swartz Doppler Flow Probe, examine the distal lip 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.

SUGGESTED INSTRUCTIONS FOR USE FOR COOK VASCULAR BLOOD FLOW MONITOR

Operators of the COOK-Swartz Doppler Flow Probe and Monitor System should minimize patient exposure of ultrasound energy using the principles of ALARA (As Low As Reasonably Achievable). The acoustic output intensity and duty factor of the COOK-Swartz Doppler Flow Probe and Monitor System cannot be adjusted by the user. The user should minimize the time that the unit is turned on to minimize patient exposure according to ALARA principles. Therefore, when not monitoring for blood flow, the unit should be turned off.

- Set the Volume Control to minimum and turn the power switch to the ON position.
- Depress and hold the TEST button, adjusting the Volume control until a steady test tone is heard. If no tone is audible, the unit requires service.
- Position VOLUME control to the extreme counter-clockwise position. Also switch the RANGE LIMIT control to the third highest position and the CHANNEL SELECT control to the appropriate channel.
- Gradually increase VOLUME control toward the maximum setting until a blood flow sound is heard.
- Adjust the RANGE LIMIT control until the best audible signal is generated. Re-adjust the VOLUME, if necessary.

CAUTION: Adjusting the RANGE LIMIT control too high can result in the detection of flow in vessels adjacent to the vessel of interest.

- If no flow is heard, check the operation of the COOK-Swartz Doppler Flow Probe by tapping and/or pressing near the location of the probe, being careful not to put tension on the probe wire (to avoid potential dislodgment of the probe). This should generate signals that can be detected by the probe. Movements by the patient can also lead to some audible changes in flow.

- Always verify proper monitor settings when checking for audible presence of blood flow.

Precautio: Exerting force on cables attached to the probe may cause the transducer assembly to separate and detach from the vessel being monitored. Therefore, the flow monitor should not be placed in a location that produces tension on the cables.

STERILIZATION AND CLEANING

Cook-Swartz Blood Flow Monitoring Probes: Do not sterilize or reprocess. Cook Doppler Blood Flow Monitor, extension cable/channel verifier, pole mount, power supply and cart: Devices may be cleaned with a damp cloth. A mild detergent or alcohol may also be used. Prior to cleaning, make sure that the monitor is not connected to a wall charger. Do not immerse the unit in solution or allow solution to enter the connector inputs, outputs, or speaker grill. Be sure that the unit is completely dry before use. The unit cannot be sterilized.

DISPOSAL

To dispose of the monitor, please return to Cook Vascular Inc.

DESCRIPTION OF DOPPLER BLOOD FLOW MONITOR CONTROLS

Low Battery LED:

Located above the power switch. Illuminates red when the batteries should be replaced. Note: It is normal for the Low Battery LED to illuminate briefly when the unit is turned On or Off.

Channel Verifier:
Used to verify integrity of connection jack.

Extension Cable Verifier:
Used to verify integrity of cables and monitor output jacks.

Power Switch:
Turns the unit On and Off.

Volume Control:
Used to adjust the loudness of the audio output.

Test:
When depressed, a steady tone is produced indicating that the unit is functioning properly.

Range Limit Control:
Sets the range window within which flow is detected. When set to Minimum, a flow approximately 1 mm from the transducer assembly can be detected. When set to maximum setting, a flow approximately 8 mm from the transducer assembly can be detected.

CAUTION: The RANGE LIMIT should be set to obtain an adequate audible signal at the lowest range possible. Setting the RANGE LIMIT too high may detect flow in surrounding vessels.

Channel Select:
Used for selecting one of the two jacks into which the COOK-Swartz Doppler Flow Probe may be connected.

Connection Jacks:
Used for connecting one or two COOK-Swartz Doppler Flow Probes to the unit. The red marks on the proximal connector of probe and jack must be aligned. Only one connection jack is operable at one time.

MAINTENANCE AND FUNCTIONAL CHECKS

The device is to be serviced only by Cook Vascular Inc.

Test Mode

The Test button is to be depressed as stated in the SUGGESTED INSTRUCTIONS FOR USE prior to use of the unit. The Test mode verifies the proper operation of the unit excluding the channels used for connection of the probes.

Extension Cable Verifier (included)

The Cable Verifier connects to the distal end of the extension cable to verify function of the extension cable and monitor. Use is recommended if function problems have not been resolved at the probe site by maneuvering the patient and/or palpating near the probe.

PART I

- To use the Cable Verifier, disconnect the probe wire from the extension cable.
- The thinner red portion of the verifier slides into the red JST connector on the distal end of the extension cable. It should fit snugly, and not be easily removed. Turn the monitor on, and adjust the volume to the maximum point on the dial. Set the RANGE LIMIT control to the third highest level. By rubbing the exposed end of the verifier with your finger, you should be able to hear a corresponding sound from the speaker. (Wetting your finger prior to rubbing the verifier is recommended for enhanced signal coupling.)

Note: If an audible signal is heard from rubbing the end of the verifier, you have confirmed that the monitoring system is functioning from the extension cable back to, and including, the monitor. At this point, there is no need to use the channel verifier.

PART II

If no sound is heard after rubbing the Cable Verifier at the maximum volume control setting, disconnect the extension cable from the monitor, and follow the instructions for the Channel Verifier.

Channel Verifier (included)

The Channel Verifier is used to verify function of the flow monitor, and is to be used after testing with the Cable Verifier if no signal is heard.

- Align the red dot on the metal connector of the Channel Verifier with the red dot on the connection jack of the monitor, and insert until a click is heard. At this point you should not be able to remove the verifier with a slight pull. Turn the monitor on and the volume to the maximum setting. Switch the range limit control to the third highest position.
- By rubbing the exposed end of the verifier with your finger, you should be able to hear a corresponding sound from the speaker. (Wetting your finger prior to rubbing the verifier is recommended for enhanced signal coupling.)
Note: If an audible signal is heard from rubbing the Channel Verifier, you have confirmed that the flow monitor is functioning properly. If there is still no signal produced, either the extension cable is malfunctioning, the probe is malfunctioning, the probe has been dislodged, flow has been disrupted from patient re-positioning, or flow restriction has occurred.
- If the probe still does not produce an audible signal, either the probe is malfunctioning, it has been dislodged, flow has been disrupted from patient re-positioning, or flow restriction has occurred. The physician should be consulted to determine the plan of action, unless he/she has already established a protocol. (Repositioning the patient or palpating close to the probe site may be all that is needed to re-establish the signal and continue monitoring.)

Battery Operation:


The Flow Monitor requires eight (8) 1.5V AA, NEDA 15A, IEC LR6 alkaline batteries. When the red LOW BATTERY LED illuminates, replace all batteries with fresh "AA" alkaline batteries. To replace batteries, open the battery compartment located on underside of case.


Power Supply (12 volts):


When Batteries are not available or AC power usage is desired, the following power adaptors available exclusively from Cook Vascular Inc. may be used as applicable for your power source when attached to the connector labeled "external supply" on the case exterior: DP-PS DP-PS2 DP-PS3.


Acoustic Output:

The maximum derated spatial-peak, temporal average output intensity ($I_{SP,TA,3}$) of the COOK-Swartz Doppler Flow Probe and Monitor System was measured to be 59.6 mW/cm² with a calculated statistical upper limit value of 80.8 mW/cm². Derated intensity calculations are based on measurements in water and using the relationship $e^{f \cdot d}$ where f (MHz) is the center frequency of the acoustic signal measured in water and d (cm) is the distance between the transducer under test and hydrophone. (See accompanying Acoustic Output Tables)

 Low Battery Power - Located above the power switch, illuminates red when the batteries should be replaced.

 Attention: Consult accompanying documents and instructions.

 Test - Located below switch. When depressed indicates proper functioning of unit.

 Range Limit - Located above switch. When depressed sets the range window within which flow is detected. When set to Minimum, flow approximately 1 mm from transducer assembly can be detected. When Set to Maximum, flow approximately 8 mm from the transducer assembly can be detected.

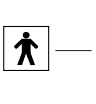
 Minimum

 Maximum

 Volume Control - Used to adjust loudness of the audio output.

 Denotes power ON.

 Denotes power OFF.

 Class II, Type BF equipment. The device provides a high degree of protection against electrical shock including an output that is floating (isolated) with respect to ground.

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COOK

EC REP

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ACOUSTIC OUTPUT TABLES FOR TRACK 1

Cook-Doppler Flow Probe and Monitor System

Clinical Application	OPERATING MODE(S)						
	B	CD	M	PWD	CWD	A	Combined (specify)
Ophthalmic							
Other (Intraoperative)				X			
Cardiac							
Clinical Application							

OUTPUT DATA

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

DP-M100

	Max. Value	P _{r3} (MPa)	W ₀ (mW)	F _c (MHz)	Z _{sp} (cm)	X ₋₆ Y ₋₆ (cm)	PD (μs)	PRF (Hz)	EBD (cm ²)
I _{SP,TA,3} [†] (mW/cm ²)	75.7 (±25%)		.362	21.4	0.20	0.064			0.008
I _{SP,PA,3} [†] (W/cm ²)	3.06 (±25%)		.362	21.4	0.20	0.064	0.36	78000	

DP-M250

	Max. Value	P _{r3} (MPa)	W ₀ (mW)	F _c (MHz)	Z _{sp} (cm)	X ₋₆ Y ₋₆ (cm)	PD (μs)	PRF (Hz)	EBD (cm ²)
I _{SP,TA,3} [†] (mW/cm ²)	59.6 (±25%)		.293	19.9	.15	.076			.01
I _{SP,PA,3} [†] (W/cm ²)	2.03 (±25%)		.293	19.9	.15	.076	.378	78125	

†NOTE: Auto-Scanning Mode is not available on the COOK-Swartz Doppler Flow Probe and Monitor System.

*Derated intensity calculations were determined from output values measured in water using the factor $e^{-0.069 \cdot f \cdot d}$, where f (MHz) is the center frequency of the acoustic signal measured in water and d (cm) is the distance between the transducer under test and hydrophone.

SYMBOL INDEX

PWD:	Pulsed Wave Doppler
I_{SP,TA,3}[†]:	Derated spatial-peak, temporal-average intensity (milliwatts per square cm)
I_{SP,PA,3}[†]:	Derated spatial-peak, pulse-average intensity (watts per square cm)
W₀[†]:	Ultrasound power (milliwatts)
F_c[†]:	Center frequency (megahertz)
Z_{sp}[†]:	Axial distance at which the reported parameter is measured (centimeters)
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 (centimeters).
PD:	Pulse duration (microseconds)
PRF:	Pulse repetition frequency (hertz)
EBD:	Entrance beam dimensions for the azimuthal and elevational planes (square cm)

Specifications:

Output Signal:	Approx. 12 V _{pp} @ 20 MHz into 50 ohms
Range:	Approx. 1 to 8 mm from probe
Audio Output Freq. Range:	Approx. 80 to 3000 Hz
Flow Velocity Detection Range:	Approx. 0.5 to 15 cm/sec
Voltage Requirements:	12 Volts: 8 1.5V AA NEDA 15A, IEC LR6 Alkaline Batteries or power supply
Power Consumption:	150 mA nominal, 250 mA max.
Battery Life:	Approximately 10 hours (continuous operation)
Dimensions:	4.3" W x 5.75" H x 7.2" L
Cable Lengths	DP-PS, DP-PS2, DP-PS3 Power Supplies - 72.0 ± 2.0 in or 182.9 ± 5.1 cm DP-CAB01 Extension Cable for SDPO01 - 60.0 ± 1.0 in or 152.4 ± 2.5 cm DP-SDPO01 Doppler Flow Probe - Cable length (from the winged tie down to the connector) 42.5 ± 0.6 in or 107.9 ± 1.5 cm

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TABLE 1 Guidance and manufacturer's declaration - electromagnetic emissions


The DP-M250 Doppler Blood Flow Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the DP-M250 Doppler Blood Flow Monitor should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The DP-M250 Doppler Blood Flow Monitor 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	The DP-M250 Doppler Blood Flow Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Not Applicable	

TABLE 2 Guidance and manufacturer's declaration - electromagnetic immunity

The DP-M250 Doppler Blood Flow Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the DP-M250 Doppler Blood Flow Monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	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 IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U _r (>95% dip in U _r) for 0.5 cycles 40% U _r (60% dip in U _r) for 5 cycles 70% U _r (30% dip in U _r) for 25 cycles	<5% U _r (>95% dip in U _r) for 0.5 cycles 40% U _r (60% dip in U _r) for 5 cycles 70% U _r (30% dip in U _r) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the DP-M250 Doppler Blood Flow Monitor requires continued operation during power mains interruptions, it is recommended that the DP-M250 Doppler Blood Flow Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz magnetic field) IEC 61000-4-8	3 A/m	10 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_r is the a.c. mains voltage prior to application of the test level.

TABLE 3 Guidance and manufacturer's declaration - electromagnetic immunity

The DP-M250 Doppler Blood Flow Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the DP-M250 Doppler Blood Flow Monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the DP-M250 Doppler Blood Flow Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1,2√P
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	d = 1,2√P 80 MHz to 800 MHz d = 2,3√P 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range. (b) Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the DP-M250 Doppler Blood Flow Monitor is used exceeds the applicable RF compliance level above, the DP-M250 Doppler Blood Flow Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the DP-M250 Doppler Blood Flow Monitor.

b) Over the frequency range 150kHz to 80MHz, field strengths should be less than [V] V/m.

TABLE 4 Recommended separation distances between portable/mobile RF communications equipment and the DP-M250 Doppler Blood Flow Monitor.

The DP-M250 Doppler Blood Flow Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the DP-M250 Doppler Blood Flow Monitor can help prevent electromagnetic