



# Doppler Blood Flow Monitor

## DP-M350

### 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 Doppler Blood Flow Monitor (DP-M350) is designed to provide audible (primary) and visual (secondary) feedback of blood flow when connected to Swartz Doppler Flow Probes and extension cables. Blood flow can be monitored continuously or periodically as required.

System: The Doppler Battery Charger (DP-M350-CHG 1) is to be used with the Doppler Blood Flow Monitor (DP-M350).

Accessory items:

Product	Catalog Number
Swartz Doppler Probe	DP-SDP001
Swartz Doppler Long Cuff Probe	DP-SDP002
Doppler Extension Cable	DP-CAB01
Doppler Battery Charger	DP-M350-CHG1
Doppler Monitor Cable-Verifier	DP-MCV01

#### 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

- No modification of the Doppler Blood Flow Monitor System is allowed.
- The Doppler Blood Flow Monitor System is not for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.
- Portable and Mobile RF communications equipment can affect the Doppler Blood Flow Monitor System as detailed in table 1 below.
- The Doppler Blood Flow Monitor System should not be used adjacent to or stacked with other equipment. If the Doppler Blood Flow Monitor System must be used under such conditions please verify the system operates normally.
- The Doppler Blood Flow Monitor System is not to be used with High Frequency surgical equipment.
- To isolate equipment from mains remove the battery charger from the AC mains socket.
- If the integrity of the earth ground is in doubt, operate the unit on internal battery power only.
- The Doppler Blood Flow Monitor System emits and detects 20MHz signals. External 20 MHz signals may also be detected.
- Electrostatic discharges may cause changes to monitor settings. Always verify proper monitor settings when checking for the audible presence of blood flow.
- The use of accessories, transducers, and cables other than those specified for use with the Doppler Blood Flow Monitor System as detailed in the technical specifications below may result in increased emissions or decreased immunity of the equipment or system.
- The Doppler Blood Flow Monitor System must not be exposed to temperatures in excess of 65°C (149°F).
- The Doppler Blood Flow Monitor System contains no user serviceable components and requires no maintenance or calibration.

- The Doppler Blood Flow Monitor contains a lithium ion battery pack. As long as this device is only used with the Doppler Battery Charger (Model: DP-M350-CHG1) no other special precautions are necessary to assure safe operation.

## PRECAUTIONS

- The Doppler Blood Flow Monitor System emits ultrasound energy. As with any ultrasound device, the operator should minimize the exposure of ultrasound energy to the patient using the principle of ALARA (As Low As Reasonably Achievable).
- The Doppler Blood Flow Monitor System is intended to be splash/spill resistant, however care should be taken to prevent the ingress of liquids.
- Exerting force on cables attached to the probe may cause the transducer assembly to separate and detach from the vessel being monitored. Therefore, the Doppler Blood Flow Monitor System should not be placed in a location that produces tension on the cables.
- Changes in audio signals produced by the Doppler Blood Flow Monitor System should be immediately documented and reported to the responsible healthcare provider.
- If monitoring the presence of blood flow using the monitor's lighted LED display, confirm a corresponding audio signal from the unit no less than every two (2) hours.
- Avoid the application of electrosurgical energy on or near a connected Swartz Doppler Flow Probe or extension cable as damage to the monitor may occur.
- Not intended for fetal use.

## INSTRUCTIONS FOR USE

Operators of the 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 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.

**WARNING:** To isolate equipment from mains, remove the battery charger from the AC mains socket.

Before using the Doppler Blood Flow Monitor, make sure the unit is fully charged. Attach the supplied charger to the rear of the unit, plug the AC line cord into a 110 to 220 volt AC wall receptacle and charge the internal batteries until the indicator on the top of the charger illuminates green.

1. Depress the "ON/OFF" button to turn the monitor ON, then press the Volume Control ( - +) so that two or three lights are illuminated, while the volume control button is depressed.
2. Press the Test button. If no tone/beep is heard, the unit requires service. The device is to be serviced only by CooperSurgical, Inc (CSI) Contact your CSI Medical products distributor for information.
3. Select the desired channel by pressing channel button to ensure the LED corresponding to the desired channel is illuminated.
4. Adjust the volume control until an audible blood flow signal (sound) is heard. A correlating visual blood flow signal (LED display) will be observed.

**Caution:** Note that the Doppler Blood Flow Monitor Model audible signal is considered the primary response signal for the unit. If no audible signal (sound) is heard but a visual signal is present, confirm the presence of blood flow using alternate techniques and contact the responsible healthcare provider immediately.

**Caution:** Changes in audio signals produced by the Doppler Blood Flow Monitor system should be immediately documented and reported to the responsible healthcare provider.

**Caution:** If monitoring the presence of blood flow using the lighted LED display on the Doppler Blood Flow Monitor Model, always confirm a corresponding audio signal from the unit no less than every two (2) hours.

5. If no audio/ visual signals are identified, check the operation of the Swartz Doppler Flow Probe by tapping and/ or pressing near the location of the distal end of the probe, being careful not to put tension on the probe wire (to avoid potential dislodgement of the probe). A correctly operating probe should sense this tapping/pressing action and the monitor should deliver both an audio and a visual feedback signal correlating with the tapping/pressing action. Also, physical movement by the patient can also lead to audible and visual signal responses from the Doppler blood flow monitor.
6. Always verify proper monitor settings when assessing the presence of blood flow when using the Doppler Blood Flow Monitor system.

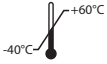
**NOTE:** The 10 blue flow indicators represent the relative velocity of the particles (blood cells) passing by and within range of the piezoelectric sensor at the distal end of the probe. The higher the velocity, the more of the indicators are illuminated.

## HOW SUPPLIED

The Doppler Blood Flow Monitor, Doppler Battery Charger and Doppler Monitor Cable-Verifier are supplied non-sterile.

## TRANSPORT AND STORAGE

This unit has been tested under the requirements of FedEx domestic standards for packaged products weighing up to 150 lbs.



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



Keep Dry

Recommended Humidity: Non-condensing



Keep away from sunlight

## MAINTENANCE AND CLEANING

### Cleaning and Disinfection Process - Monitor and Cable-Verifier

#### Manual Cleaning Instructions

1. Instruments should be cleaned as soon as possible. Do not allow gross soil to dry in the instrument. If cleaning cannot be performed immediately, keep the device moist.
2. Use a fresh Cavi wipe to clean surfaces for a minimum of 90 seconds. Pay particular attention to difficult to reach areas such as device seams and the area between buttons.
3. Repeat step 2. A minimum of 1 time or as needed until all device surfaces are visibly clean.
4. Allow the device to air dry. Once dry, visually inspect the device for any residual soil. Repeat cleaning/disinfection instructions if visible soil is present.
5. Place the cleaned device in an appropriate dry storage area.

#### Manual Disinfection Instructions

1. Use a 70% IPA wipe, or a low-lint wipe, saturated with 70% IPA, to wipe any gross visual soil from the device for a minimum of 15 seconds. Pay particular attention to difficult to reach areas such as seams and the areas between buttons.
2. After the device has been precleaned, use a fresh wipe saturated with 70% IPA to disinfect the device surfaces keeping the device surfaces wetted with the disinfection chemistry for a minimum of 90 seconds.
3. After a minimum of 90 seconds of active chemistry contact, repeat the disinfection process a second time with a fresh 70% IPA wipe, keeping the device surfaces wetted with the disinfection chemistry for a minimum of 90 seconds.
4. Allow the disinfection chemistry to evaporate from the device under ambient conditions.
5. When the device appears to be dry, wet a low-lint wipe with critical (purified) water and wipe the device surface to remove residual disinfection chemistry.
6. Allow the device to air dry.
7. Once dry, visually inspect the device for any residual soil.
8. Place the disinfected device in an appropriate dry storage area.

Warning: DO NOT STERILIZE

## DISPOSAL



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.

## MAINTENANCE AND FUNCTIONAL CHECKS

**NOTE:** The Doppler Blood Flow Monitor System must only be returned to and repaired by CooperSurgical, Inc. (CSI) personnel at an authorized CSI facility. Should the Doppler Blood Flow Monitor System require repair, contact CSI or your CSI Medical Distributor for information on returning the device for repair.

**NOTE:** If required, the Doppler Blood Flow Monitor System lithium-ion battery pack replacement must be performed only by trained CSI personnel at an authorized CSI repair facility, as incorrect replacement could result in an unacceptable risk to untrained personnel, the monitor or the surrounding environment.

**WARNING:** The Doppler Blood Flow Monitor System contains no user serviceable components and requires no maintenance or calibration.

**WARNING:** To isolate equipment from mains remove the battery charger from the AC mains socket.

## TEST MODE (TEST BUTTON)

The Test Button is to be depressed (as stated in the suggested INSTRUCTIONS FOR USE), prior to use of the unit to verify its proper operation. If, while the Test Button is depressed, no sound /tone is produced and the monitor is properly powered, replace the monitor as it may require repair at CSI. Contact CSI or your CSI Medical distributor for information on returning the device for repair.

### Doppler Monitor Cable-Verifier

The Cable-Verifier (DP-MCV01), is provided to allow for real-time bedside testing of the Doppler Blood Flow Monitor individually or while the monitor is connected to a Extension Cable. Use is recommended if function problems have not been resolved at the probe site by maneuvering the patient and/or palpating near the probe. It is suggested that the system be tested using the following two-step approach.

#### Step 1 Monitor Only Test

The Cable-Verifier may be used to verify function of the flow monitor, and is to be used after testing via the TEST MODE.

- A. Align the red dot on the metal connector of the Cable-Verifier with the red dot on the connection jack of the monitor, and insert until a click is heard. You should not be able to remove the verifier with a slight pull. Turn the monitor on and set the volume to the maximum setting.
- B. Rub the exposed end of the verifier with your finger and listen for a corresponding sound from the speaker.
- C. If an audible signal is heard as a result of rubbing the Cable-Verifier, you have confirmed that the flow monitor is receiving the signal correctly through the selected channel connector. Proceed to Step 2 Monitor and Extension Cable Test to test the Doppler extension cable while it is connected to the Doppler Blood Flow Monitor. If no sound is heard, replace the monitor and follow the instructions provided in the TEST MODE (TEST BUTTON) section of this insert.

#### Step 2 Monitor and Extension Cable Test

- A. In this step the Cable-Verifier may be used to assess the function of the Doppler Blood Flow Monitor while it is connected to the Doppler extension cable. Be sure that the desired channel button has been depressed and its corresponding LED illuminated.
- B. Insert the thinner red connector located on the verifier into the red JST connector located on the distal end of the extension cable (black dots should be aligned). The two should fit snugly, and not be easily removed. Turn the monitor on, and adjust the volume to its maximum level. Rub the exposed end of the verifier with your finger and listen for corresponding sound from the speaker.
- C. 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. Proceed to D.
- D. If no sound is heard after rubbing the Cable-Verifier but sound was heard in Step 1, replace the extension cable and repeat Step 2.
- E. If the probe still does not produce an audible signal, either the probe is: not functional as desired, has been dislodged, flow has been disrupted from patient re-positioning, or flow restriction has occurred. The responsible physician should be consulted immediately 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.)

## Probe Distal End Temperature Rise

TEST CONDITION: Probe attached to Doppler Blood Flow Monitor. Probe distal end placed in still air test chamber@ 23.4°C.

Probe distal end temperature rise during operation: 0.2°C. +/- 0.5°C

## Uncertainty

Probe Model-Mode	MI Mean	MI StdDev %	Type B Uncertainty	Combined Uncertainty%	Combined Uncertainty	K for 4 Samples	MI Upper Bound
20 MHz 1 mm PW Doppler	0.058	12.9%	12.3%	17.9%	0.010	3.188	0.091
Probe Model	TIS Mean	TIS StdDev%	Type B Uncertainty	Combined Uncertainty %	Combined Uncertainty	K for 4 Samples	TIS Upper Bound
20 MHz 1 mm PW Doppler	0.018	23.3%	24.5%	33.8%	0.0060900	3.188	0.037

## SPECIFICATIONS

Signal:	20 MHz having a nominal output of 15 volts peak to peak into 50 ohms
Transmitter pulse repetition frequency:	78.1 kHz
Transmitter pulse width:	0.4 microseconds
Duty Cycle:	3.125%
Average output power to the probe:	17.6mW
Battery:	3 Lithium batteries in cells, chargeable
Battery Life:	Approximately 10 Hours (continuous operation) 12 Volts
DC Operating Voltage:	12 Volts
Dimensions:	W 21.6 cm, H 8.9 cm, L 16.5 cm
Weight:	980 grams

The Doppler Blood Flow Monitor is powered by a Lithium Battery pack, nominal rating: 10.8 Vdc, 2.6 Ah. The battery pack is charged by the Power Supply, Input rated 100-240 Vac, 50-60 Hz, 0.35 A; output rated 12.6 V, 1.2 A.

**TABLE 1: 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 $\leq 1 \text{ cm}^2$	Aaprt $> 1 \text{ cm}^2$		
Maximum index value		0.0575	#	0.0175	-	0.0338	(a)
Associated acoustic parameter	$P_{fa}$ (MPa)	0.258					
	P (mW)		#	0.183		0.183	#
	min of $[Pa(z_s), I_{ta,a}(z_s)]$ (mW)				-		
	$Z_s$ (cm)				-		
	$Z_{dp}$ (cm)				-		
	$Z_b$ (cm)					-	
	z at max. $I_{pi,a}$ (cm)	0.150					
	Deq( $Z_b$ ) (cm)					-	
	Fawf (MHz)	20.1	#	20.1	-	20.1	#
	Dim of Aaprt	X (cm)		#	0.100	-	0.100
Y (cm)			#	0.100	-	0.100	#
Other Information	$t_d$ ( $\mu\text{sec}$ )	0.345					
	$p_{rr}$ (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 ( $\text{W}/\text{cm}^2$ )	1.63					
<p><b><math>I_{spta} = 54.416 \text{ mW}/\text{cm}^2</math> -Average of 4 tested probes</b></p> <p><b>Note 1:</b> Information need not be provided for any formulation of TIS not yielding the maximum value of TIS for that mode.</p> <p><b>Note 2:</b> Information need not be provided regarding TIC for any TRANSDUCER ASSEMBLY not intended for transcranial or neonatal cephalic uses.</p> <p><b>Note 3:</b> MI and TI are less than 1.0 for all device settings.</p> <p>(a) Intended use does not include cephalic so TIC is not computed</p> <p># No data reported.</p>							

# SYMBOL INDEX

PWD:	Pulsed Wave Doppler
$I_{\text{SPTA},3}$ :	Derated spatial-peak, temporal-average intensity (milliwatts per square cm)
$I_{\text{SPPA},3}$ :	Derated spatial-peak, pulse-average intensity (watts per square cm)
$W_0$ :	Ultrasound power (mW)
$F_c$ :	Center frequency (MHz)
$Z_{\text{sp}}$ :	Axial distance at which the reported parameter is measured (cm)
$X_{-6}$ & $Y_{-6}$ :	Respectively the in-plane (azimuthal) and out of plane (elevational) -6 dB dimensions in the x-y plane where $Z_{\text{sp}}$ is found (cm)
PD:	Pulse duration ( $\mu\text{S}$ )
PRF:	Pulse repetition frequency (Hz)
EBD:	Entrance beam dimensions for the azimuthal and elevational planes ( $\text{cm}^2$ )
$\alpha$	Acoustic Attenuation Coefficient
$A_{\text{aprt}}$	-12dB Output Beam Area
$Deq$	Equivalent Aperture Diameter
$Deq$	Equivalent Beam Diameter
$F_{\text{awf}}$	Acoustic Working Frequency
$/pa$	Pulse-Average Intensity
$/pi$	Pulse-Intensity Intergral
$/pi, a$	Attenuated Pulse-Intensity Intergral
$/ta, a(z)$	Attenuated Temporal-Average Intensity
$MI$	Mechanical Index
$P$	Output Power
$Pa$	Attenuated Output Power
$P_r$	Peak-Rarefactional Acoustic Pressure
$Pr_a$	Attenuated Peak-Rarefactional Acoustic Pressure
$pr_r$	Pulse Repetition Rate
$TIS$	Soft-Tissue Thermal Index
$t_d$	Pulse Duration
$z$	Distance from the source to a specified point
$z_b$	Depth for TIB
$Z_{\text{bp}}$	Break-Point Depth
$Z_s$	Depth for TIS

**TABLE 2: Guidance and Manufacturer's declaration - electromagnetic emissions**

The Doppler Blood Flow Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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 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.  The 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.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000_3_2	Class A	
Voltage Fluctuations/ Flicker Complies emissions IEC 61000-3-3	Complies	

**TABLE 3: Guidance and Manufacturer's declaration - electromagnetic immunity**

The Doppler Blood Flow Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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	±6kV contact ±8kVair	±6kV contact ±8kVair	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Test transient/ burst IEC 61000-4-4	±2kV for power supply lines ± 1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV differential mode ±2kV common mode	±1kV differential mode ±2kV 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 <sub>1</sub> (>95% dip in U <sub>1</sub> ) for 0.5 cycles 40% U <sub>1</sub> (60% dip in U <sub>1</sub> ) for 5 cycles 70% U <sub>1</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>1</sub> (>95% dip in U <sub>1</sub> ) for 5 sec	<5% U <sub>1</sub> (>95% dip in U <sub>1</sub> ) for 0.5 cycles 40% U <sub>1</sub> (60% dip in U <sub>1</sub> ) for 5 cycles 70% U <sub>1</sub> (30% dip in U <sub>T</sub> ) for 25 cycles <5% U <sub>1</sub> (>95% dip in U <sub>1</sub> ) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Doppler Blood Flow Monitor requires continued operation during power mains interruptions, it is recommended that the Doppler Blood Flow Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz magnetic field) 1IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U<sub>1</sub> is the a.c. mains voltage prior to application of the test level.

**TABLE 4: Guidance and Manufacturer's declaration - electromagnetic immunity - for the Doppler Blood Flow Monitor that are not Life Supporting**

**Guidance and Manufacturer's declaration - electromagnetic immunity**

The Doppler Blood Flow Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the 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
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3Vrms 150 kHz to 80 MHz</p> <p>3V/m 80 MHz to 2.5 GHz</p>	<p>3Vrms</p> <p>3V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Doppler Blood Flow Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.2 P^{0.2}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 P^{0.2}</math> 800 MHz to 2.3 GHz</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

**NOTE 1:** At 80 MHz and 800 MHz, the higher the 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 Doppler Blood Flow Monitor is used exceeds the applicable RF compliance level above, the Doppler Blood Flow Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Doppler Blood Flow Monitor.
- b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

**TABLE 5: Recommended separation distances between portable and mobile RF communications equipment and the Doppler Blood Flow Monitor for the Doppler Blood Flow Monitors that are not Life Supporting**

Recommended separation distances between portable and mobile RF Communications equipment and the Doppler Blood Flow Monitor at 3Vrms			
The 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 Doppler Blood Flow Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Doppler Blood Flow Monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter  W	Separation distance according to frequency of transmitter  m		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.34	0.34	0.74
1	1.7	1.7	2.3
10	3.7	3.7	7.4
100	11.7	11.7	23.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**NOTE 1:** At 80 MHz and 800 MHz, the separation distance for 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.

## PRODUCT SYMBOLS



Low Battery Power – Located beside the power button, illuminates red when the internal battery pack needs to be recharged.



Attention: Consult accompanying documents and instructions.



Test- Located beside test button. When depressed indicates proper functioning of unit.



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



“ON” for part of equipment



“OFF” for part of equipment



Class II Equipment



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



BLOOD FLOW MONITOR; WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, IEC60601-2-37 CAN/CSA C22.2 No. 601.1

# DOPPLER BATTERY CHARGER FOR BLOOD FLOW MONITOR (DP-M350)

## INSTRUCTIONS FOR USE

### PRODUCT COMPONENTS



1. Charger
2. Cable Manager
3. Adapter plugs

### Read these instructions before using the charger



This product is designed for indoor use only and should not come into contact with water or dust. To prevent overheating the product should not be covered during use.



The mains socket should be easily accessible. In the event of operational error, the plug should be immediately removed from the socket.



The product contains dangerous voltages and the cover should not be removed. All service or maintenance work should be carried out by qualified personnel who can get assistance by contacting the manufacturer's agent.



The unit is double insulated (in insulation class II).

System: The Battery Charger (DP-M350-CHG1) is to be used with the Doppler Blood Flow Monitor (DP-M350).

### Technical specification: See product labeling.

### CHARGING INSTRUCTIONS

1. Do not connect the charger to the mains before it is connected to the monitor.
2. Connect the charger to the mains.
3. When charging is complete, disconnect from the mains before removing monitor connections.

### CHARGE INDICATOR (LED)

**RED** - Indicates battery pack is being charged.

**GREEN** - Indicates battery pack is fully charged

### USE OF ALTERNATE (SUPPLIED) PLUG ADAPTERS

1. The Battery Charger for the Doppler Blood Flow Monitor is supplied with various plug adapters that are configured to connect to regional mains input connections. The charger is designed to operate at input voltages of 100-240VAC 50-60Hz max 0.35A without any action on the part of the user.
2. Prior to using the charger, confirm that the voltage at the mains is compatible with the unit.
3. Select the appropriate plug adapter for the local mains.
4. If the appropriate plug adapter is not connected to the primary charger unit, remove the existing plug adapter by pressing on the grated area directly beneath its output plugs while pushing in the direction of arrow (Figure 1a) or by placing fingers directly below the elevated plug adapter and pushing upward and away from the cable (Figure 1b). The attached plug adapter will detach and slide upward and off the primary charger unit.
5. Orient the appropriate plug adapter so that it is appropriately in-line with the receiving channel of the primary charger unit (Figure 2).
6. Slide the plug adapter fully onto the primary charger unit (Figure 3).
7. Plug into mains as required.

## Cable/ Cord Manager

The Cable/ Cord Manager (as supplied) can be used to organize the charger's cable when the unit is not in use (Figure 4).



Figure 1a



Figure 1b



Figure 2



Figure 3



Figure 4

## MAINTENANCE AND CLEANING

### Cleaning and Disinfection Process - Battery Charger

#### Manual Cleaning Instructions

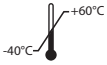
1. Instruments should be cleaned as soon as possible. Do not allow gross soil to dry in the instrument. If cleaning cannot be performed immediately, keep the device moist.
2. Use a fresh Cavi wipe to clean surfaces for a minimum of 90 seconds. Pay particular attention to difficult to reach areas such as device seams and the area between buttons.
3. Repeat step 2. A minimum of 1 time or as needed until all device surfaces are visibly clean.
4. Allow the device to air dry. Once dry, visually inspect the device for any residual soil. Repeat cleaning/disinfection instructions if visible soil is present.
5. Place the cleaned device in an appropriate dry storage area.

#### Manual Disinfection Instructions

1. Use a 70% IPA wipe, or a low-lint wipe, saturated with 70% IPA, to wipe any gross visual soil from the device for a minimum of 15 seconds. Pay particular attention to difficult to reach areas such as seams and the areas between buttons.
2. After the device has been precleaned, use a fresh wipe saturated with 70% IPA to disinfect the device surfaces keeping the device surfaces wetted with the disinfection chemistry for a minimum of 90 seconds.
3. After a minimum of 90 seconds of active chemistry contact, repeat the disinfection process a second time with a fresh 70% IPA wipe, keeping the device surfaces wetted with the disinfection chemistry for a minimum of 90 seconds.
4. Allow the disinfection chemistry to evaporate from the device under ambient conditions.
5. When the device appears to be dry, wet a low-lint wipe with critical (purified) water and wipe the device surface to remove residual disinfection chemistry.
6. Allow the device to air dry.
7. Once dry, visually inspect the device for any residual soil.
8. Place the disinfected device in an appropriate dry storage area.

Warning: Make sure the battery charger plug is completely dry before using.

## TRANSPORT AND STORAGE



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



Keep Dry

Recommended Humidity: Non-condensing



Keep away from sunlight

## DISPOSAL



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.

## LIMITED WARRANTY - DOPPLER BLOOD FLOW MONITOR

CooperSurgical, Inc. (CSI), the manufacturer of the device, warrants to the purchaser only that the device and its components shall be free from defects in material and workmanship for a period of one year commencing on the date of purchase by the initial purchaser of the device.



CSI shall cause the replacement or repair of any device or component that shall prove, upon CSI's inspection, to be defective in material or workmanship provided that purchaser shall have notified CSI of the defect during the one year warranty period. The warranty period on any replacement device or component will be limited to the unexpired term of the original one (1) year warranty.

The foregoing shall be purchaser's sole and exclusive remedy for any claim arising in connection with the sale, purchase, delivery or use of its device or component, thereof. CSI shall not be liable for loss of use, lost profits or any other collateral, or any incidental or consequential damages incurred or suffered by the purchaser or any other person as a result of a defect in any CSI device or component thereof. This limited warranty shall not apply to any device or component thereof that has been repaired or altered outside CSI's factory or service facility. This limited warranty also shall not apply to any device or component thereof that has been subject to misuse, negligence or accident.

THE LIMITED WARRANTY CONTAINED HEREIN IS THE ONLY WARRANTY MADE BY CSI AND NO OTHER WARRANTIES, EXPRESS OR IMPLIED, ORAL OR WRITTEN, ARE GIVEN ON ANY DEVICE OR COMPONENT THEREOF. THERE ARE NO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR OF INFRINGEMENT.

# GLOSSARY OF SYMBOLS

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

Symbol	Title	Symbol	Title
	Packaging unit		Type BF applied part.
	Catalogue number		Class II equipment
	Serial number		Temperature Limit
	Country of manufacture ("CC" shall be replaced by either the two letter or the three letter country code)		Warning; Electricity
	Date of manufacture		WEEE (Waste Electrical and Electronic Equipment)
<b>R<sub>x</sub>Only</b>	Caution: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner		BLOOD FLOW MONITOR; WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL60601-1, IEC60601-1, IEC60601-2-37 CAN/ CSA C22.2 No. 601.1
	Medical Device		Manufacturer
	Caution		Keep dry
	Consult instructions for use or consult electronic instructions for use		Keep away from sunlight

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**Notes:**

CooperSurgical®

Made in the USA

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