

FLOW COUPLER Monitor



Symbols referenced on labeling

Symbol Glossary per US FD&C Act:

Standard	Symbol	Symbol Title	Symbol Meaning	Symbol No.
ISO 15223-1*		Manufacturer	Manufacturer	5.1.1
ISO 15223-1		Date of manufacture	Date of manufacture	5.1.3
ISO 15223-1		Catalog number	Catalog Number	5.1.6
ISO 15223-1		Serial number	Serial number	5.1.7
ISO 15223-1		Temperature Limit	Store at controlled room temperature	5.3.7
ISO 15223-1		Caution	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.	5.4.4
ISO 7010**		Refer to instruction booklet (symbol white on blue)	Refer to instruction booklet	M002
IEC 60417***		Direct Current	Direct Current	5031
IEC 60417		Non-ionizing electromagnetic radiation	RF Transmitter	5140
IEC 60417		Type CF Applied Part	Type CF applied part	5335
			Content	
			Caution: Federal (USA) law restricts this device to sale by or on the order of a physician	

*ISO 15223-1:2016 Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements

**ISO 7010:2019 Graphical symbols – Safety colours and safety signs – Registered safety signs

***IEC 60417:2002 Graphical symbols for use on equipment

Additional symbols and graphics on the product labeling that are not required by the US FD&C Act:

Symbol	Symbol Description
	Manufacturer internal code
	Manufacturer part number
	Manufacturer tracking number
	Separate collection
	Power on/off
	GTIN number
	Made in USA

ETL CLASSIFIED



Conforms to AAMI STD ES60601-1,
IEC STDS 60601-2-37 & 60601-1-6
Certified to CSA STD C22.2#60601-1

Intertek

5012669

Contains Transmitter Module
FCC ID: VRA-SG9011203
IC: 7420A-SG9011203

Description

The FLOW COUPLER System consists of a FLOW COUPLER Device and a FLOW COUPLER Monitor. The FLOW COUPLER Monitor is a pulsed Doppler ultrasound system designed for the detection of blood flow in vessels. The FLOW COUPLER Device includes a 20MHz ultrasonic Doppler transducer (probe) attached to one of the FLOW COUPLER rings, and an external lead. The probe connects to the monitor via the external lead and emits a pulsed ultrasonic signal. An audible signal of varying volume strength is produced when the probe detects flow.

Indications For Use:

The FLOW COUPLER Device is a single use, implantable device that is intended to be used in the end-to-end anastomosis of vein and arteries normally encountered in microsurgical and vascular reconstructive procedures. The FLOW COUPLER Device includes a pair of permanently implanted rings which secure the anastomosis and a removable Doppler probe that is press-fit onto one of the rings. When the FLOW COUPLER Device is used in conjunction with the FLOW COUPLER Monitor, the FLOW COUPLER System is intended to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site. Post-operatively, blood flow can be detected on an as-needed basis for up to 7 days. The FLOW COUPLER Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days post-operatively.

Contraindications:

The FLOW COUPLER Monitor is not intended specifically to diagnose, monitor or correct a defect of the heart or the central circulatory system.

Warnings:

- If procedures are not followed, injury may occur.
- Do not perform servicing and maintenance while the monitor is in use.
- Never sterilize the FLOW COUPLER Monitor with autoclave, ultraviolet, gamma radiation, gas, steam, or heat sterilization techniques. Severe device damage and/or injury may occur.
- The Monitor should not contact mucus membranes, blood, or compromised tissue, and is not used in sterile fields.
- Not for use in OXYGEN ENRICHED atmospheres.
- Do not remove internal rechargeable lithium ion battery pack. If required, return the monitor to the manufacturer for the battery replacement.
- Monitor not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

CAUTIONS:

- If procedures are not followed, possible equipment or software damage may occur.
- The FLOW COUPLER System may be susceptible to picking up interference through the coaxial cable that connects the probe to the Monitor. Do not use in the presence of any high frequency equipment, including high frequency surgical generators.
- The FLOW COUPLER Monitor may turn off or lose LCD touch screen function due to electrostatic discharge interference. Turn on the monitor and monitor's function to generate audible sounds and hardware control using buttons should not be impacted.
- Only use Monitor with FLOW COUPLER devices.
- Only use FLOW COUPLER AC Power Supply included with the COUPLER Monitor (GEM1020M-2) or Power Supply sold separately (GEM1020PS-2).
- Monitor and power supply may be returned to manufacturer for proper disposal.
- During the 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).
- No modification of this equipment is allowed.
- The FLOW COUPLER Monitor is intended for use by healthcare professionals only.
- The FLOW COUPLER Monitor and System may cause radio interference or may disrupt the operation of nearby equipment.
- Protected Health Information (PHI) or Personally Identifiable Information (PII) shall not be used as File ID or Facility ID.

PRODUCT SPECIFICATIONS

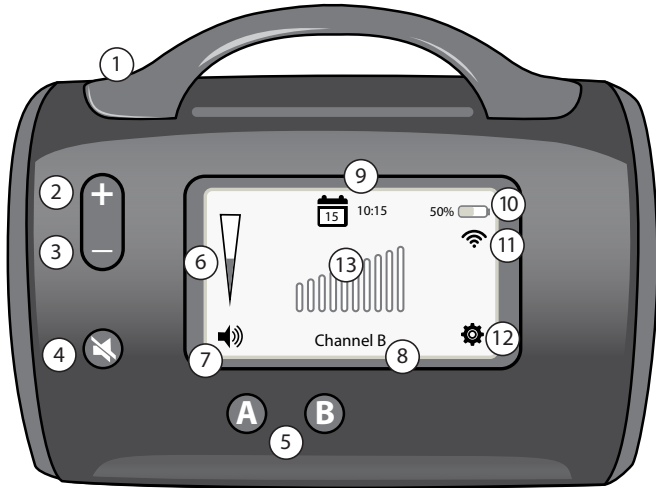


Figure 1: FLOW COUPLER Monitor Description

1. Power Button
2. Volume Toggle Button (increase)
3. Volume Toggle Button (decrease)
4. Mute Button
5. Channel Selection Buttons
6. Volume Indicator
7. Mute Indicator
8. Channel Selection
9. Date/Time
10. Battery Indicator
11. WiFi Indicator
12. Settings
13. Visual Indicator Audible Sound

Hardware Controls (see Figure 1):

- **Power Button (1):** A push-button switch turns the unit ON. Power ON is indicated by illumination of toggle buttons and the LCD screen. When the push-button is depressed (and momentarily held) a second time the unit is turned OFF.
- **Volume Increase Button (2):** A button that will increase the volume of the audible Doppler signal
- **Volume Decrease Button (3):** A button that will decrease the volume of the audible Doppler signal.
- **Mute Button (4):** A button that mutes the sound.
- **Channel Selection Buttons (5):** A button that sets the Doppler to a channel. The selected channel button will be illuminated.

LCD Controls (See Figure 1):

Volume Indicator (6): A graduated scale in the LCD screen indicates the volume of the audible Doppler signal. Volume can be changed by touch-and-drag the scale on the touchscreen.

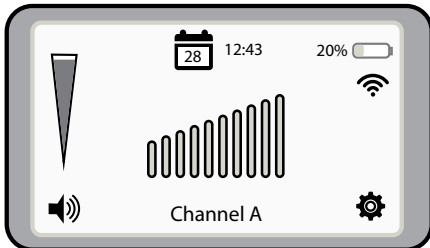
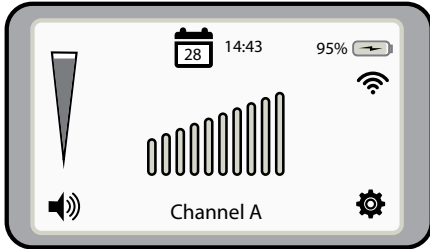
Mute Indicator(7): The icon indicates the mute status. Touch the icon to change the mute status.

Channel Selection Indicator (8): Confirms the channel selected. Touch the icon to change the channel.

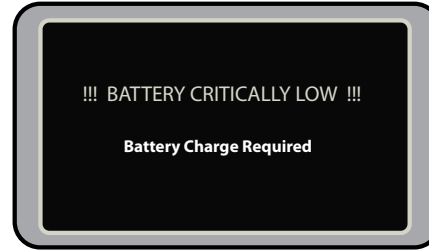
Date/Time (9): Displays the date and time. Touch the icon to correct Date/Time.

Battery Indicator (10): The system will automatically shut OFF when the battery voltage is too low to maintain proper operation of the Monitor. During the battery charge, a charging status icon is displayed.

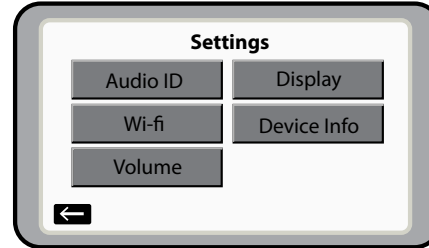
WiFi Indicator (11): Displays the WiFi status and signal strength.



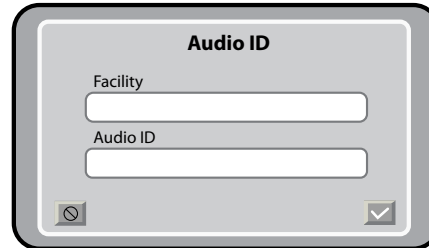
When the battery level falls below 20%, the icon turns orange.



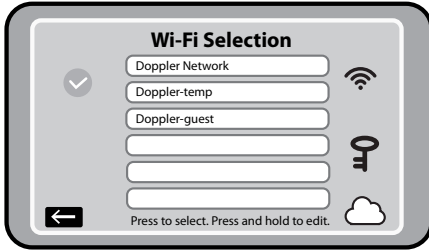
When the battery level is below 10%, critically low battery screen appears and monitor beeps.



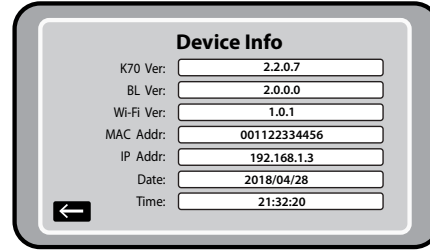
Settings (12): Touch the settings mode icon on the screen to display and/or change additional settings for: Audio ID, WiFi set up, Volume settings, Display and Device Information.



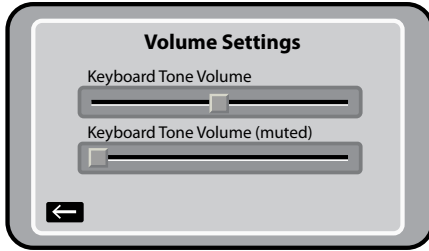
Audio ID Screen brings up two fields to enter in Facility information and Audio ID (Do not use PII and PHI). Once either is pressed a touchscreen with a QWERTY keyboard is displayed. Key in the information and press the green check bar to save it.



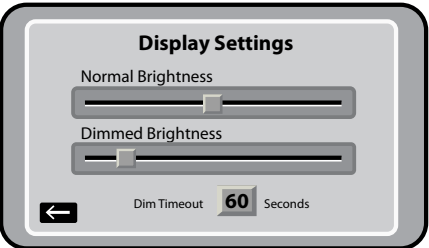
Wi-Fi Selection screen lets you store up to six wireless networks. Press and hold the fields to enter or edit network info. To connect to a stored network, briefly press the corresponding field.



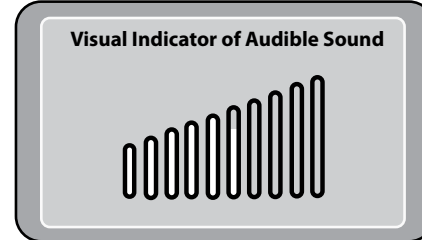
Device Info Screen contains technical specifications including versions of the hardware and software, MAC and IP addresses, and the date and time. Touch the Date/Time field to bring up a QWERTY keyboard to change the date and time. As shown in the figure below.



Volume Settings Screen contains two sliders where you can change the volume of the keyboard tone when the monitor volume is active (top bar) and when the monitor volume is muted (bottom bar).



Display Settings Screen contains two sliders where you can change the Normal Brightness or the Dimmed Brightness and the duration of the brightness (Dim Timeout Seconds) by toggling the Seconds Button (10, 15, 20, 30, 45, 60, 90, or 120).



Visual Indicator of Audible Sound (13): Displays the level of the audible sound. The visual indicator is a secondary feedback of blood flow. The primary indicator of the blood flow is the audible sound.

Operation:

Transmission Frequency: 20 MHz

Transmission Characteristic: Pulsed transmission, continuous reception

Sensitivity: See FLOW COUPLER Device and System IFU

Environment:

Recommended shipping and storage temperature: 5°C to 40°C, non-condensing

IPX 0 (Monitor): No special protection

Power:

Class II External Power Supply shipped with the monitor or sold separately (GEM1020PS-2), A/C to D/C Power Supply Internally rechargeable Lithium Ion Battery, Power Requirements: 12 VDC

Physical:

Dimensions: 8.2in L x 5.7in W x 2.8in H. (216 mm x 127 mm x 99 mm)

Weight: 1.84 lb, (0.835 kg)

Instructions for use:

1. Carefully unpack your FLOW COUPLER Monitor. Inspect the monitor for damage. If the monitor is damaged, contact the manufacturer for further instructions.
 2. Place the Monitor on a suitable stand, cart or table outside the sterile field, near the physician who will be using the FLOW COUPLER System. Avoid using the Monitor in the presence of any high frequency equipment, including high frequency surgical generators. The Monitor has a rating of IPX-0. Keep the Monitor away from all open liquids.
NOTE: *If the external lead is near electrically active conductors, such as electro-surgery cables or an electronic equipment chassis, signals from the cables or chassis may be picked up by the Monitor and produce undesired audible signals. This interference is easily distinguished from blood flow and is remedied by moving the external lead away from the source of the interference.*
 3. Connect the Power Supply provided with the monitor or sold separately (GEM1020PS-2) to the Monitor, if desired. Connect the Power Supply to the appropriate adaptor plugs supplied with the Power Supply. Connect the adaptor plug to a grounded hospital grade outlet. The monitor contains internally rechargeable batteries. If charged, the Power Supply is not required for the operation of the monitor.
NOTE: *Patient isolation from the AC power is accomplished in the following ways: The DC power output lines from the power supply are isolated from the mains in the DC power supply. There is no connection between the "green" safety ground and the Monitor. The final isolation mechanism is the cable insulation and potting of the probe that provides an additional insulation layer between the isolated electrical signals and the patient.*
4. Turn the Monitor on by depressing the Power Button located on the back of the monitor.
 5. Enter Audio ID and Facility ID. Do not use PII or PHI for IDs.
NOTE: *Use instructions for the remote monitoring via APP are included in the User Manual supplied with the Monitor.*
 6. Check for the battery level shown in upper right portion of the LCD screen. Connect the Power Supply to the monitor as instructed in Step 3, if desired.
 7. Refer to FLOW COUPLER Device and System Instructions for Use for handling of the FLOW COUPLER Device. **NOTE:** *Probe leads may be labeled with the Channel A or B for identification.*
 8. Transfer the free connector of the external lead (supplied with the FLOW COUPLER device) outside the sterile field. Insert this free connector into either Channel receptacle A or Channel receptacle B on the front side of the Monitor.
 9. Ensure that correct Channel Selection Button is illuminated and Channel Selection Indicator on the LCD screen is displayed.
 10. Listen for blood flow. Some background noise may be audible.
NOTE: *If blood flow is not detected with the Monitor post-operatively, rely on clinical indications for patient status.*
 11. Adjust the volume by depressing and holding the Volume Increase Button or Volume Decrease Button to the desired level. If a strong audible signal is not identified, irrigate the anastomotic site with saline and inspect the probe is in contact with the vessel. During irrigation, an audible signal from the Monitor verifies proper function of the device.
 12. Turn off the Monitor after use by depressing the Power Button.

Special instructions:

Maintenance and Cleaning:

The Monitor requires minimal maintenance. Keep it clean and free of dust.

The exterior may be cleaned using the following steps:

1. After every use, check the Monitor for any sign of damage or wear.
2. Wipe the Monitor with a dry or water-moistened soft cloth. Ensure any residual organic material is removed. Do not pour or spray liquid directly on the Monitor. Allow to air dry before use.
3. Do not put liquid near the speaker.

The Following Sections apply to the FLOW COUPLER 20 MHz Doppler Probe

Acoustic Output:

There are no user controls meant to affect acoustic outputs. All acoustic outputs are below the application specific pre-amendments acoustical output limit of an Ispta of 94 mW/cm² and a MI of 1.9.

Explanation of Derivation of Derating Factor:

The derated intensity calculations are based on measured center frequency of the acoustical signal (f , MHz) and the distance from the transducer under test to the hydrophone (z , cm) using the derating factor $e^{-0.069 fz}$

Track 1 summary

System: 20 MHz FLOW COUPLER Monitor and Probe System

Monitor: 20 MHz FLOW COUPLER Monitor

Mode of Operation							
Clinical Application	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic							
Other (intra-operative and post-operative)			X				
Cardiac							
Clinical Application							

Symbol Index	
PWD:	Pulsed Wave Doppler
MI	Mechanical Index
TIS	Soft Tissue Thermal Index
TIB	Bone Thermal Index
TIC	Cranial Bone Thermal Index
$P_{r,a}$	Attenuated Peak-Rarefractional Acoustic Pressure
P	Power Output
P_{1x1}	Power Output through 1 cm ² of area
z_s	Depth for TIS
z_b	Depth for TIB
Z_{MI}	Depth for Mechanical Index
$Z_{pii,a}$	Depth for Peak Attenuated Pulse Intensity Integral
f_{awf}	Acoustic Working Frequency
prf	Pulse Repetition Rate
srr	Scan Repetition Rate
n_{pps}	Number of Pulses per Ultrasonic Scan Line
$I_{pa,a}$	Attenuated Pulse-Average Intensity
$I_{spta,\alpha}$	Attenuated Spatial-Peak Temporal Average Intensity
$Z_{sii,a}$	Depth for Peak Sum of Attenuated Pulse
I_{spta}	Spatial-Peak, Temporal-Average Intensity
Z_{pii}	Depth for Peak Pulse-Intensity Integral
Z_{sii}	Depth for Peak Sum of Pulse-Intensity Integral
P_r	Peak-Rarefractional Acoustic Pressure

Acoustic output format for track 1:

Non-Autoscanning Mode

System: 20 MHz FLOW COUPLER Monitor and Probe System

Operating Mode: PW Doppler

Transducer Model: 20 MHz Doppler Probe

Application(s): Other (intra-operative and post-operative)

Index Label			MI	TIS		TIB		TIC
				At Surface	Below Surface	At Surface	Below Surface	
Maximum index value			0.0105	9.80E-4		5.14E-3		
Index component value				9.80E-4	7.98E-4	5.14E-3	1.90E-3	-
Associated acoustic parameter	P_{ra} at Z_{MI}	(MPa)	0.0470					
	P	(mW)		1.03E-2		1.03E-2		-
	P_{1x1}	(mW)		1.03E-2		1.03E-2		-
	z_s	(cm)			0.15			
	z_b	(cm)					0.15	
	Z_{MI}	(cm)	0.15					
	$Z_{ppi,a}$	(cm)	0.15					
	f_{awf}	(MHz)	20.0	20.0		20.0		-
Other Information	prr	(Hz)	78000					
	srr	(Hz)	78000					
	n_{pps}		1					
	$I_{pa,a}$ at $Z_{pii,a}$	(W/cm ²)	3.44					
	$I_{spta,a}$ at $Z_{ppi,a}$ OR $Z_{sii,a}$	(mW/cm ²)	4.24					
	I_{spta} at Z_{pii} OR Z_{sii}	(mW/cm ²)	4.24					
	P_r at Z_{pii}	(MPa)	0.0470					
Operating Control Conditions	Single mode		X	X	X	X	X	

Performance Criteria


Failures include any time the unit does not produce an audible signal when detectable flow is present. In addition to component malfunction, failures also include units that produce a false audible that is indistinguishable from a signal produced by flow. Non-intentional audible signal tones are allowed to be produced by the unit, so long as they cannot be easily mistaken for flow.

The equipment or system may exhibit performance degradation (e.g., deviation from specifications) that does not affect essential performance or safety.

Guidance and manufacturer's declaration – electromagnetic emissions		
The 20 MHz FLOW COUPLER Monitor system is intended for use in the electromagnetic environment specified below. The user of the 20 MHz FLOW COUPLER Monitor should assure that it is used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment - guidance
RF Emissions, CISPR 11:2015 +A1:2016	Group 1	The 20 MHz FLOW COUPLER Monitor system 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 11:2015 +A1:2016 Harmonic Current Emissions IEC 61000-3-2:2014 Voltage Fluctuations and Flicker IEC 61000-3-3:2013	Class A Class A Complies	The 20 MHz FLOW COUPLER Monitor meets the conducted and radiated performance requirements for non-life supporting equipment and also meet the harmonic current emissions, and voltage fluctuations (flicker) requirements for non-life supporting equipment pursuant to IEC 60601-1-2:2014. The 20 MHz FLOW COUPLER Monitor is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Caution the FLOW COUPLER Monitor is intended for use by healthcare professionals only. The FLOW COUPLER Monitor and system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the 20 MHz FLOW COUPLER Monitor system or shielding the location.

Guidance and manufacturer's declaration – electromagnetic immunity

The 20 MHz FLOW COUPLER Monitor system is intended for use in the electromagnetic environment specified below. The user of the 20 MHz FLOW COUPLER Monitor should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge IEC 61000-4-2:2008	IEC 60601-1-2:2014 (± 8kV Contact Discharge ± 2, ± 4, ± 8, and ± 15kV Air Discharge)	± 8kV Contact Discharge ± 15kV Air Discharge	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. The monitor LCD screen may flicker or restart. The function of generating audible signal is not impacted. The monitor may turn off or lose LCD touch screen function due to electrostatic discharge interference. Turn on the monitor and monitor's function to generate audible sounds and hardware control using buttons should not be impacted.
Radiated Immunity IEC 61000-4-3:2010	EN 60601-1-2:2015 IEC 60601-1-2:2014	$E_1 = 3 \text{ V/m}$, 80 MHz – 2.7 GHz 27 V/m 28 V/m 9 V/m 28 V/m 28 V/m 9 V/m	$d = (3.5/E_1) = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = (7/E_1) = 2.3 \sqrt{P}$ 800 MHz to 2.7 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: 
Radiated Immunity – Proximity Fields from RF Wireless Communications Equipment	$E_1 = 3 \text{ V/m}$, 80 MHz – 2.7 GHz 385MHz; 18Hz Pulse Modulation (PM) 450MHz; FM ±5KHz deviation 1kHz sine 710, 745, 780MHz; 217Hz PM 810, 870, 930MHz; 18Hz PM 1720, 1845, 1970, 2450MHz; 217Hz PM 5240, 5500, 5785MHz; 217Hz PM		
Electrical Fast Transients and Bursts (EFT)	IEC 60601-1-2:2014 (± 1kV, 100 kHz repetition frequency)	± 1kV	Mains power quality should be that of a typical commercial or hospital environment. The FLOW COUPLER Monitor may go into the charging state due to transient disturbance. It will require manual reset of the monitor by pressing power ON button. It does not impact the monitor's function to generate audible signal when detecting the blood flow.
Surge	IEC 60601-1-2:2014 (± 0.5 kV, ± 1 kV for line-to-line, ± 0.5 kV, ± 1 kV, ± 2 kV for line-to-ground)	± 1 kV for line-to-line ± 2 kV for line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Immunity IEC 61000-4-6:2013	IEC 60601-1-2:2014 (3Vrms, 0.15 MHz – 80 MHz, 6V in ISM bands between 0.15 MHz and 80 MHz, 80% AM at 1 KHz)	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Doppler system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = (3.5/E_1) \sqrt{P} = 1.2 \sqrt{P}$
Magnetic Field Immunity	IEC 60601-1-2:2014 (50Hz or 60Hz)	30 A/m, 50Hz and 60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage Dips and Interruptions (VDI)	IEC 60601-1-2:2014 (Voltage dips: 0% U _r ; 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°. 0% U _r ; 1 cycle and 70% U _r ; 25 cycles. Single phase: at at 0° Voltage Interruptions: 0% UT; 250 cycle)	Voltage Dips: 0% U _r ; 0.5 cycle, 0% U _r ; 1 cycle, and 0% U _r ; 25 cycles Voltage Interruption 0% U _r ; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 20 MHz FLOW COUPLER Monitor requires continued operation during power mains interruptions, it is recommended that the FLOW COUPLER Monitor system be powered from an uninterruptible power supply or the built-in battery.
NOTE 1: UT is the a.c. mains voltage prior to application of the test level. NOTE 2: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 3: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
<p>^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 system is used exceeds the applicable RF compliance level above, the Doppler system 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 system.</p> <p>^bOver the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.</p>			

The technical WiFi specifications and maximum theoretical WiFi data rate (bandwidth) are listed below:	
A pre-approved WiFi module with an integrated antenna is utilized in this product, 1.5MB flash, 64KB RAM	
Protocol:	802.11b/g/n
Modulation:	DSSS, OFDM
Wireless band:	2.4GHz
Max data rate possible:	72.2Mbps
Max power output possible:	16dBm
Sensitivity:	-98dBm

Recommended separation distances between portable/mobile RF communications equipment and the 20 MHz FLOW COUPLER Monitor system.

The 20 MHz FLOW COUPLER Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FLOW COUPLER Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Doppler system 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 and power of transmitter (m)		
	150 kHz to 80 MHz $d=1.2 \sqrt{P}$	80 MHz to 800 MHz $d=1.2 \sqrt{P}$	800 kHz to 2.7 GHz $d=2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.4
100	12	12	23

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 power in watts (W) according to the transmitter manufacturer.

Troubleshooting:

There are no user serviceable components inside this device. Disassembly of the internal components of this unit may result in circuit damage.

Troubleshooting Guide

Standard	Possible Problem	Solution
No sound output	No power	Verify Monitor power is on
	No power	Check all connections: <ul style="list-style-type: none">• Probe Connector to External Lead• External Lead to Monitor• Monitor to Power Supply• Power Supply to Adaptor Plug• Adaptor Plug to outlet
	Volume is too low	Adjust volume using Volume Increase Button or LCD volume control
	Wrong channel is being used	Verify the correct channel button is illuminated and the correct channel is displayed on the LCD screen.
	Critically Low Battery screen displays on LCD screen	Connect the Power Supply to the monitor
	Monitor not functioning	Connect a different Monitor
	Monitor not functioning	Contact Synovis Micro Companies Alliance Customer Service
LCD touch screen malfunction	LCD touch screen unresponsive	Power off and on the monitor Contact Synovis Micro Companies Alliance Customer Service
Weak sound output	Volume is too low	Adjust volume using Volume Increase switch
	Monitor not functioning	Connect a different Monitor
	Monitor not functioning	Contact Synovis Micro Companies Alliance

SERVICE:

For Customer or Technical service, contact:

Phone: + 205.941.0111 or 1.800.510.3318 (U.S. only) • Fax: + 205.941.1522

Website: synovismicro.com

STORAGE CONDITIONS:

Recommended shipping and storage at 5°C - 40°C, non-condensing

Avoid direct sunlight


ACCESSORIES & PARTS

Item	REF
FLOW COUPLER Monitor	GEM1020M-2
Power Supply	GEM1020PS-2
FLOW COUPLER Device 2.0	GEM2752-FC
FLOW COUPLER Device 2.5	GEM2753-FC
FLOW COUPLER Device 3.0	GEM2754-FC
FLOW COUPLER Device 3.5	GEM2755-FC
FLOW COUPLER Device 4.0	GEM2756-FC
External Lead, 4-pack	GEM1003EXT-FC

LIMITED WARRANTY

The FLOW COUPLER Monitor is warranted for one year from the date of shipment from Synovis MCA against defects in materials and workmanship. Defective GEM FLOW COUPLER Monitors will be repaired or replaced, at Synovis MCA's option, when returned prepaid to Synovis MCA within this year. The customer assumes full responsibility that this equipment meets the specifications, capabilities and other requirements of the customer. Synovis MCA makes no warranty of fitness for a particular purpose except as provided herein. The customer assumes full responsibility for the proper installation, operation and maintenance of this equipment as described in this manual as well as other instructions that may be provided by Synovis MCA. This warranty is void if the equipment has been mishandled, operated outside of its specified operating or environmental limits or otherwise subjected to improper or abnormal use.



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