GEM
Global Excellence in Microsurgery

FLOW COUPLER Monitor

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CE
2797

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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		Authorized Representative in the European Community	Authorized Representative in the European Community	5.1.2
ISO 15223-1		Catalogue number	Catalogue Number	5.1.6
ISO 15223-1		Serial number	Serial number	5.1.7
ISO 15223-1		Importer	Indicates the entity importing the medical device into the locale	5.1.8
ISO 15223-1		Keep away from sunlight	Indicates a medical device that needs protection from heat and radioactive sources.	5.3.3
ISO 15223-1		Country of Manufacture	Identify the country of manufacture of product. The date of manufacture will be adjacent to this symbol.	5.1.11
ISO 15223-1		Keep Dry	Indicates a medical device that needs to be protected from moisture.	5.3.4
ISO 15223-1		Temperature Limit	Indicates the temperature limits to which the medical device can be safely exposed.	5.3.7
ISO 15223-1		Medical Device Symbol	Indicates the item is a medical device	5.7.7
ISO 15223-1		Unique Device Identifier (UDI)	Indicates a carrier that contains Unique Device Identifier information	5.7.10
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
	Rx Only		Caution: Federal (USA) law restricts restricts this device to sale by or on the order of a physician	

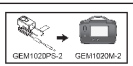
*ISO 15223-1 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements.

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

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

Standard	Symbol	Symbol Title	Symbol Meaning	Symbol No.
	SEE IFU FOR SYMBOL DEFINITIONS		See IFU for symbol definitions	
	CH REP		Indicates the authorized representative in Switzerland	

Additional symbols and graphics on the product labeling that are not derived from standards:

Symbol	Symbol Description
PN	Manufacturer part number
	Indicates a separate waste collection is required for Waste of Electrical and Electronic Equipment (WEEE)
	Power on/off
GTIN	GTIN number
CONTENT	Content
 GEM1020PS-2 GEM1020M-2	Indicates that the Power Supply can be used only with Flow Coupler Monitor (GEM1020M-2)

ETL CLASSIFIED

C ETL US LISTED

Intertek

5012669

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

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.

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 Monitor is a non-sterile, re-usable device with sequential multiple patient use.

CLINICAL BENEFITS AND PERFORMANCE OBJECTIVES

The FLOW COUPLER System reduces anastomotic and flap ischemic time, reduces rate of thrombosis, vessel size discrepancy apposition correction, patency rates for venous anastomoses comparable to hand suturing, reduces re-explorations, increases flap salvage rate, and minimizes flap loss.

PERFORMANCE CHARACTERISTICS

The FLOW COUPLER Monitor provides blood flow monitoring at the anastomotic site when used with the FLOW COUPLER Device. For more information about the FLOW COUPLER Device, refer to the FLOW COUPLER Device IFU.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE INFORMATION (SSCP)

The SSCP can be found at the following location after the launch of European Database on Medical Devices/Eudamed: https://ec.europa.eu/tools/eudamed

Basic UDI-DI:478180000000000000000337N

INTENDED USE / INTENDED PURPOSE

The FLOW COUPLER Monitor is intended to be used in conjunction with the FLOW COUPLER Device to detect blood flow and confirm vessel patency intra-operatively and post-operatively at the anastomotic site.

INTENDED PATIENT GROUP

The FLOW COUPLER Monitor provides blood flow monitoring at the anastomotic site when used with the FLOW COUPLER Device. For more information about the FLOW COUPLER Device, refer to the FLOW COUPLER Device IFU.

INDICATED USERS

The FLOW COUPLER Monitor during intraoperative use is intended to be used by surgeons but may be prepared by a nurse or a scrub technician.

The FLOW COUPLER Monitor during postoperative use is intended to be used by floor nurse, physician assistant or surgeon.

INDICATIONS FOR USE

The FLOW COUPLER System is indicated for use with veins and arteries having an outside diameter no smaller than 1.8 mm and no larger than 4.3 mm and a wall thickness of 0.5 mm or less, normally encountered in microsurgical procedures which require vascular reconstruction only in the peripheral vascular system.

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. Severe device damage may occur.
- FLOW COUPLER Monitor is not sterilizable. 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. Severe device damage may occur.
- Not for use in OXYGEN ENRICHED atmospheres to reduce fire and explosion risk.
- Do not use the FLOW COUPLER Monitor if there is visible physical damage on the device as the performance of the FLOW COUPLER Monitor can be compromised.
- Do not remove internal rechargeable lithium-ion battery pack. Severe device damage may occur. 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. Fire or explosion may occur.
- Avoid usage of the FLOW COUPLER Monitor adjacent to or stacked with other equipment because it may result in inoperable Monitor. If such use is necessary observe to verify FLOW COUPLER Monitor and the other equipment are operating normally.
- Only use accessories (FLOW COUPLER Device and FLOW COUPLER Monitor Power Supply) as specified in this Instruction For Use with the FLOW COUPLER Monitor because usage with unspecified accessories may lead to increased electromagnetic emissions or decreased electromagnetic immunity of the Monitor.
- Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) no closer than 30cm (12 inches) to any part of the FLOW COUPLER Monitor and accessories (FLOW COUPLER Device and FLOW COUPLER Monitor Power Supply). Otherwise, degradation of the performance of the Monitor may occur.

PRECAUTIONS / 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. Monitor may not function properly and device damage may occur.
- Only use FLOW COUPLER AC Power Supply included with the FLOW COUPLER Monitor (GEM1020M-2) or Power Supply sold separately (GEM1020PS-2). Severe device damage may occur.
- 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. Severe device damage may occur.
- 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.
- Avoid obstructing with the audio output from the speakers located on sides of the FLOW COUPLER Monitor. Audio volume and quality may be negatively affected.
- Do not use any chemicals other than those listed within the cleaning instruction of this IFU for cleaning of the Monitor. Do not immerse the Monitor in the cleaning solution. Severe device damage may occur.
- If packaging is damaged, unintentionally opened before use, or is exposed to environmental conditions outside of those specified, the FLOW COUPLER Monitor may be damaged. Check to ensure the monitor powers on, hardware buttons and LCD screen operate, and audible signal is generated when connected to the FLOW COUPLER probe prior to use.

ADVERSE EVENTS / UNDESIRABLE EFFECTS

None Known

ADVERSE EVENTS REPORTING

If during the use of this device, or as a result of its use, a serious incident has occurred, please report this incident to the manufacturer, and/or its authorized representative, and/or the competent authority of the Member State and/or relevant regulatory bodies in which the user and/or patient is established. For reporting a device malfunction or adverse event, or for product inquiries, contact: Synovis MCA sales representative, or email SMCA_Quality@baxter.com.

PRODUCT SPECIFICATIONS

Figure 1: FLOW COUPLER Monitor Description

Hardware Controls (see Figure 1):

(1) Power Button: Turns the unit ON. Power ON is indicated by illumination of buttons and the LCD screen. When the push-button is depressed (and momentarily held) a second time the unit is turned OFF.

(2) Audio Volume Increase Button: Increase the volume of the audible Doppler signal. Output from the speakers located on sides of the Monitor

(3) Audio Volume Decrease Button: Decrease the volume of the audible Doppler signal. Output from the speakers located on sides of the Monitor

(4) Mute Button: Mutes the sound.

(5) Channel Selection Buttons: Sets the Doppler to a channel. The selected channel button will be illuminated.

LCD Controls (See Figure 1):

(6) Volume Indicator: 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.

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

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

(9) Battery Indicator: Displays the battery charge level.

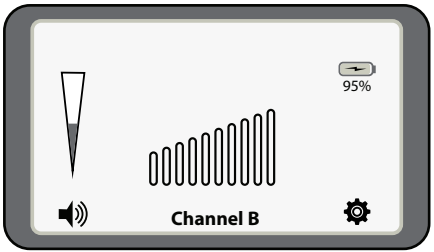
(10) Settings Menu: Touch the icon to access the Settings menu.

(11) Visual Indicator of Audible Sound

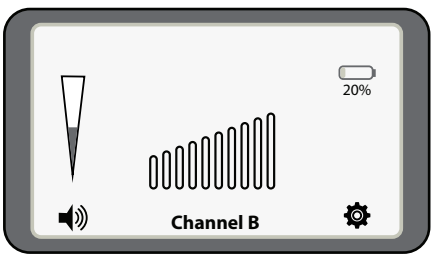
Component Interfaces (See Figure 1):

(12) Power Supply connector: Connect Power Supply to the monitor.

(13) External lead connector: Connect external lead(s) to the Monitor. Up to 2 external leads can be connected to the Monitor.

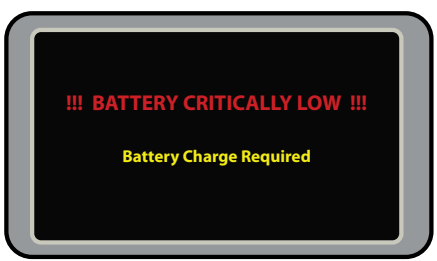


During the battery charge, a charging status icon is displayed.



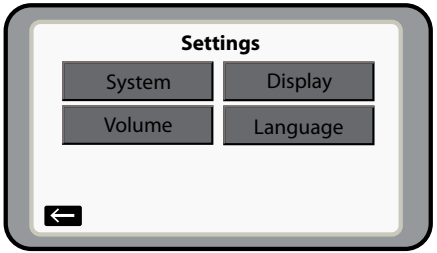
When the battery level falls below 20%, the icon turns orange.

NOTE: Immediately plug monitor into power supply and wall outlet to charge the battery.

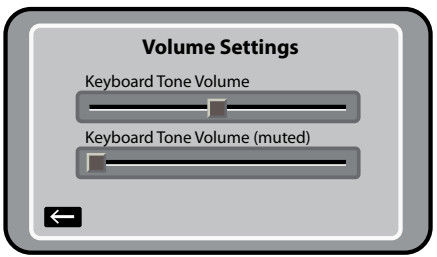


When the battery level is below 10%, critically low battery screen appears and monitor beeps. Monitor will automatically shut OFF shortly after reaching the battery charge level of 10%.

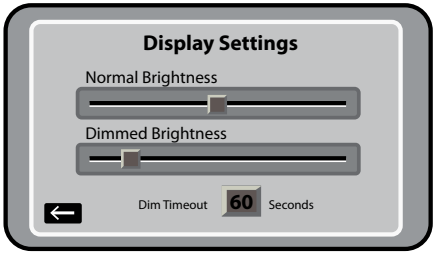
NOTE: Immediately plug monitor into power supply and wall outlet to charge the battery.



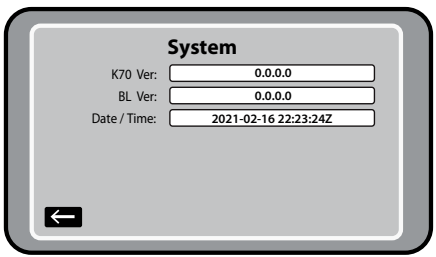
Settings: Touch the settings mode icon on the screen to display and/or change additional settings for: Volume settings, Display settings, System information and Language section.



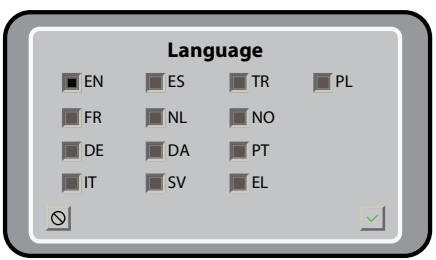
Selecting Volume button in the settings screen opens Volume Settings screen. Volume Settings Screen contains two sliders where you can change the volume of the keyboard tone when the monitor volume is active (top bar) and when the monitor volume is muted (bottom bar).



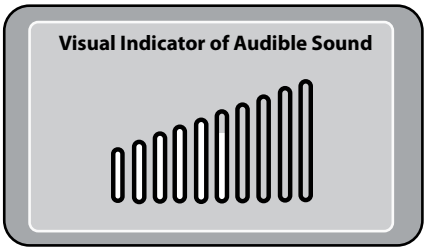
Selecting Display button in the settings screen opens Display Settings screen. Display Settings Screen contains two sliders where you can change the Normal Brightness or the Dimmed Brightness and the duration of the brightness (Dim Timeout Seconds) by toggling the Seconds Button (10, 15, 20, 30, 45,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



Selecting System button in the settings screen opens System screen. System Screen contains technical specifications including versions of the hardware and software, and the date and time.



Selecting Language button in the settings screen opens Language Screen. Language Screen allows user to select language for the device screen. (Currently only English is available.)



Visual Indicator of Audible Sound:
The visual indicator is a secondary feedback of the audible sound, which is the primary indicator of the blood flow.

Icons of states:

Battery	
100%	Charging
90%	Using battery
20%	Need charging

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, non-condensing
Avoid direct sunlight
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: 8.2 in L x 5.7 in W x 2.8 in H. (216 mm x 127 mm x 99 mm)
Weight: 1.84 lb (0.835 kg)

INSTRUCTIONS FOR USE

These Instructions for Use are designed for proper use of this device. They are not intended to serve as a reference to surgical technique, to supersede institutional protocols or professional clinical judgment regarding patient care. Read the Instructions for Use before use. No special training is required beyond reading the Instructions for Use.

NOTE: The electronic version of the Instructions for Use can be found at the following location: http://edocs.baxter.com.

Instructions for Use (Intraoperative Monitoring):

1. Carefully unpack your FLOW COUPLER Monitor. Inspect the monitor for damage. If the monitor is damaged, contact the manufacturer for further instructions.
2. Handle the Monitor with caution to prevent damages and the handle is provided for safe handling of the Monitor.
3. 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, and within 4 feet of the patient. Avoid using the Monitor in the presence of any high frequency equipment (e.g. High frequency surgical generator, cordless phone). 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 electronic equipment, signals from the cables or electronic equipment 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.*
4. Connect the Power Supply provided with the monitor or sold separately (GEM1020PS-2) to the Monitor. 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.*
5. Turn the Monitor on by depressing the Power Button located on the back of 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.
   NOTE: *If the battery level is below 20%, it is recommended to recharge the Monitor using the Power Supply.*
7. Refer to FLOW COUPLER Device and System Instructions for Use for handling of the FLOW COUPLER Device.
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.
   NOTE: *If more than one lead is to be used, it may be helpful to label the leads to facilitate identification (e.g. Lead A, Lead B)*
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, rely on clinical indications for patient status. Ischemia or reperfusion rate may delay or affect the initial Doppler signal.*
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 ensure the probe tip 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.

Instructions for Use (Postoperative Bedside Monitoring):

1. Disconnect the Power Supply from the electrical outlet.
2. Transport the patient with the Monitor and the Power Supply to postoperative care area: use the handle on the Monitor to prevent damages and for safe handling of the Monitor.
3. Repeat steps 3 to 6 outlined in Intraoperative Monitoring Instructions for use.
4. Ensure the external lead is connected to the probe and the Monitor and the Power Supply is connected to the Monitor or battery power is used during the transportation of the Monitor.
5. Ensure that correct Channel Selection Button is illuminated, and Channel Selection Indicator on the LCD screen is displayed.
6. When Monitor is not being used to detect flow, external lead may be disconnected from the probe by pulling probe connectors apart and external lead remain connected to the Monitor.
7. Listen for blood flow. Some background noise artifacts from the Monitor may be audible.
   NOTE: *If blood flow is not detected with the Monitor, rely on clinical indications for patient status.*
   NOTE: *Doppler signal may vary during monitoring period.*
8. Turn off the Monitor after use by depressing the Power Button.

Special instructions:

STORAGE CONDITIONS:

Recommended shipping and storage at 5°C - 40°C, non-condensing
Avoid direct sunlight.

Maintenance and Cleaning:

The Monitor has a useful life of 5 years. The Monitor contains no user serviceable components and requires no maintenance or calibration. 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. Remove any external lead still connected in the A or B ports and discard per local procedures.
2. Wipe the Monitor with a dry or water-moistened soft cloth, Isopropyl Alcohol, Ammonium Hydroxide based surface cleanser, Ammonium Chloride based surface cleanser or 2% bleach solution. 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.
4. The FLOW COUPLER Monitor is no longer usable when hardware buttons, LCD screens are inoperable, or audible signal is not generated when connected to the FLOW COUPLER probe.

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/cm^2 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: FLOW COUPLER Monitor and Probe System
Monitor: 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 $1cm^2$ 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
prr	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
$z_{sii,\alpha}$	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: 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	$P_{r,a}$ 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 FLOW COUPLER Monitor system is intended for use in the electromagnetic environment specified below. The user of the 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 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 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. NOTE: The EMISSIONS characteristics of the FLOW COUPLER Monitor make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

Guidance and manufacturer's declaration – electromagnetic immunity			
The FLOW COUPLER Monitor system is intended for use in the electromagnetic environment specified below. The user of the 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	± 8kV contact ± 2kV, ± 4kV, ± 8kV, and ± 15kV air	± 8kV contact ± 15kV air	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 functioning. Turn on the Monitor and Monitor's function to generate audible sounds and hardware control using buttons should not be impacted.
Radiated RF Immunity IEC 61000-4-3:2006/AMD2:2010	3V/m, 80-2700MHz, 80% 1kHz AM, 80-2700MHz, 80% 1kHz AM	3V/m, 80-2700MHz, 80% 1kHz AM, 80-2700MHz, 80% 1kHz AM	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30cm (12 inches) to any part of the FLOW COUPLER Monitor and accessories (FLOW COUPLER Device and FLOW COUPLER Monitor Power Supply). 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: 
Proximity fields from RF wireless equipment IEC 61000-4-3:2006/AMD2:2010	Section 8.10, Table 9 of the IEC 60601-1-2: Edition 4.1 standard	Section 8.10, Table 9 of the IEC 60601-1-2: Edition 4.1 standard	
Electrical Fast Transients and Bursts Immunity IEC 61000-4-4:2012	2kV, 100kHz repetition rate	2kV	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 Immunity IEC 61000-4-5:2014/AMD1:2017	± 0.5kV, ± 1kV for line-to-line ± 0.5kV,± 1kV, ± 2kV for line-to-ground	± 0.5kV, ± 1kV for line-to-line ± 0.5kV, ± 1kV, ± 2kV for line-to-ground	Mains power quality should be that of a typical commercial or hospital environment.
Conducted Disturbances, Induced by RF Fields Immunity IEC 61000-4-6:2013	3V, 0.15-80MHz, 80% 1kHz AM 6V in ISM Band within 0.15-80MHz, 80% 1kHz AM	3V	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30cm (12 inches) to any part of the FLOW COUPLER Monitor and accessories (FLOW COUPLER Device and FLOW COUPLER Monitor Power Supply).
Power Frequency Magnetic Field Immunity IEC 61000-4-8:2009	30A/m, 50Hz or 60Hz	30A/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 Immunity IEC 61000-4-11:2004 / AMD1:2017	0% (100% reduction), 0.5 cycle 0% (100% reduction), 1 cycle 70% (30% reduction) UT, 0.5 sec	0% (100% reduction), 0.5 cycle 0% (100% reduction), 1 cycle 70% (30% reduction) UT, 0.5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 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.
Voltage Interruptions Immunity IEC 61000-4-11:2004 / AMD1:2017	0% (100% reduction), 5 sec	0% (100% reduction), 5 sec	
Immunity to Proximity Magnetic Fields	Section 8.11, Table 11 of the IEC 60601-1-2: Edition 4.1 standard	Section 8.11, Table 11 of the IEC 60601-1-2: Edition 4.1 standard	Immunity to proximity magnetic fields in the frequency range 9kHz to 13.56MHz was evaluated.

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.

[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, and 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.

[b] Over the frequency range 150kHz to 80MHz, field strength should be less than 3 V/m.

The technical WiFi specifications and maximum theoretical WiFi data rate (bandwidth) are listed below:	
A 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**

Troubleshooting Guide (Bedside Monitoring)

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

Symptom	Possible Problem	Solution
No sound output	Monitor power is off	Verify Monitor power is on.
	Power Supply disconnected and the Battery level critically low	If Monitor does not power on, connect the Power Supply to the Monitor. Check connections: • Monitor to Power Supply • Power Supply to Adaptor Plug • Adaptor Plug to outlet
	Volume is muted	Unmute the Monitor by pressing Mute button or Mute Indicator on the LCD screen. Increase volume by pressing Volume Increase Button or touch-and-drag Volume Indicator on the LCD screen.
	Wrong channel is being used	Verify the correct channel button is illuminated and the correct channel is displayed on the LCD screen.
	Probe Disconnected	Check connections: • Probe Connector to External Lead • External Lead to Monitor
	Monitor not functioning	Connect a different FLOW COUPLER Monitor. Contact Synovis Micro Companies Alliance Customer Service (Ph. *+1 205.941.0111* or *+1 800.510.3318* (U.S. only).
Weak sound output	Volume is too low	Increase volume by pressing Volume Increase Button or touch-and-drag Volume Indicator on the LCD screen.
	Monitor not functioning	Connect a different FLOW COUPLER Monitor. Contact Synovis Micro Companies Alliance Customer Service (Ph. *+1 205.941.0111* or *+1 800.510.3318* (U.S. only).
Signal Interference/ feedback	Monitor location is too close to electrosurgical generator Monitor speaker outputs noise from interfering equipment	Move monitor away from generator to location that does not result in interference. Move monitor to new location in room.
LCD touch screen malfunction	LCD touch screen unresponsive	Power off and on the monitor. Contact Synovis Micro Companies Alliance Customer Service (Ph. *+1 205.941.0111* or *+1 800.510.3318* (U.S. only).

SERVICE:

For Customer or Technical service, contact:

Phone: +1 205.941.0111 or 1.800.510.3318 (US Toll free) • Fax: + 205.941.1522

Website: synovismicro.com

ACCESSORIES & PARTS

Item	REF	Cable Length
FLOW COUPLER Monitor	GEM1020M-2	NA
Power Supply	GEM1020PS-2	245cm (96.5 inches)
FLOW COUPLER Device 2.0	GEM2752-FC	43cm (17 inches)
FLOW COUPLER Device 2.5	GEM2753-FC	43cm (17 inches)
FLOW COUPLER Device 3.0	GEM2754-FC	43cm (17 inches)
FLOW COUPLER Device 3.5	GEM2755-FC	43cm (17 inches)
FLOW COUPLER Device 4.0	GEM2756-FC	43cm (17 inches)
External Lead, 4-pack	GEM1003EXT-FC	198cm (78 inches)

LIMITED WARRANTY

The FLOW COUPLER Monitor is warrantied 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.

MONITOR AND POWER SUPPLY DISPOSAL:

Monitor and power supply may be returned to manufacturer for proper disposal or dispose of in accordance with local ordinance.

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GEM

Global Excellence in Microsurgery

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