GEM2770-FN

FLOW NOW

Doppler Blood Flow Monitoring Device

GEM
Global Excellence in Microsurgery

Instructions for Use

SYMBOL GLOSSARY PER US FD&C ACT

STANDARD	SYMBOL	SYMBOL TITLE	SYMBOL MEANING	SYMBOL NUMBER
ISO 15223-1*		Manufacturer	Indicates the medical device manufacturer	5.1.1
ISO 15223-1		Use-by date	Indicates the date after which the medical device is not to be used	5.1.4
ISO 15223-1		Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	5.1.5
ISO 15223-1		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	5.1.6
ISO 15223-1		Country of manufacture	To identify the country of manufacture of products. The date of manufacture is adjacent to this symbol	5.1.11
ISO 15223-1		Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide	5.2.3
ISO 15223-1		Do not resterilize	Indicates a medical device that is not to be resterilized	5.2.6
ISO 15223-1		Medical device	Indicates the item is a medical device	5.7.7
ISO 15223-1		Do not use if package is damaged and consult instructions for use.	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information	5.2.8
ISO 15223-1		Single sterile barrier system	Indicates a single sterile barrier system	5.2.11

STANDARD	SYMBOL	SYMBOL TITLE	SYMBOL MEANING	SYMBOL NUMBER
ISO 15223-1		Double sterile barrier system	Indicates two sterile barrier systems	5.2.12
ISO 15223-1		Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed	5.3.7
ISO 15223-1		Do not reuse	Indicates a medical device that is intended for one single use only	5.4.2
ISO 15223-1		Consult instructions for use	Indicates the need for the user to consult the instructions for use	5.4.3
ISO 15223-1		Unique device identifier (UDI)	Indicates a carrier that contains unique device identifier information	5.7.10

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

STANDARD	SYMBOL	SYMBOL TITLE	SYMBOL MEANING	SYMBOL NUMBER
ASTM F2503-20		Magnetic Resonance (MR) Conditional (Symbol black on yellow)	A medical device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields.	
ISO 7010		Refer to instruction manual/booklet (symbol white on blue)	To signify that the instruction manual/ booklet must be read	M002
IEC 60417		Direct current	Indicates that the equipment is suitable for direct current only	50301
IEC 60417		RF Transmitter	Indicates generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems	5140
IEC 60417		Type CF applied part	Indicates a type CF applied part complying with IEC 60601-1	5335
	Rx Only		CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician	

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

SYMBOL	SYMBOL DESCRIPTION
SEE IFU FOR SYMBOL DEFINITIONS	See IFU for symbol definitions
	Outer diameter of vessel
PN	Manufacturer part number
TN	Internal tracking number
	Indicates this product and package are not made with natural rubber latex
CONTENT	Content

DEVICE DESCRIPTION

The FLOW NOW Device is a single-use Doppler-based monitoring device designed to be used with the FLOW COUPLER Monitor.

It is comprised of an active 20 MHz ultrasonic Doppler transducer (probe), attached to a non-active silicone strap. The probe ultimately connects to the FLOW COUPLER Monitor by means of an external lead. The FLOW NOW System consists of a FLOW NOW Device and a FLOW COUPLER Monitor.

Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The probe is removed from the patient 3 to 14 days after implantation. The silicone strap remains with the patient as a permanent implant.

The FLOW NOW Device can be used to monitor blood flow through veins and arteries ranging from 2.0 to 4.0 mm in outside diameter.

A single FLOW NOW Device contains 0.04 grams of permanently implanted silicone material.

INTENDED PURPOSE

FLOW NOW is intended for monitoring blood flow in vessels.

INTENDED PATIENT GROUP

The FLOW NOW Device is intended for patients who need to undergo anastomosis of veins or arteries for vascular reconstructive procedures.

Safe use of the FLOW NOW Device on growing vessels in children and adolescents has not been established. Not intended for fetal use.

INTENDED USERS

The FLOW NOW Device is intended to be used by surgeons intraoperatively but may be prepared by nurses or scrub technicians.

The FLOW NOW Device is intended to be used postoperatively by floor nurses, physician assistants or surgeons.

INDICATIONS FOR USE

FLOW NOW is indicated for monitoring blood flow in peripheral vessels during and following reconstructive microvascular procedures, re-implantation, and free flap transfers. Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The FLOW NOW Doppler probe is not intended to be a permanent implant and should be removed 3 to 14 days postoperatively.

CONTRAINDICATIONS

- Not indicated for use in the central circulatory system
- Not indicated for patients with a known allergy to silicone
- Not indicated for use on patients presenting conditions that would normally preclude microvascular repair with suture technique

UNDESIRABLE SIDE-EFFECTS/POTENTIAL ADVERSE EVENTS

Use of the FLOW NOW Device involves potential risks normally associated with any implanted device as well as: allergic reaction, granuloma, erosion, thrombosis, venous insufficiency, ischemia, necrosis, fever, chills, infection, vasculitis, septic shock, tissue damage, surgical intervention for device removal, device migration, and foreign body reaction.

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.

WARNINGS

- Inspect packaging for damage prior to use. Do not use if the packaging is damaged, the seals of the sterile tray assembly are not intact, or the device is expired, as sterility may be compromised. Failure to observe this warning may result in surgical infection.
- The FLOW NOW Device is supplied sterile and is single use only. Do not resterilize or reuse the FLOW NOW Device. Resterilization may compromise the structural integrity of the product, which may lead to signal loss. Reuse or reprocessing of this single-use device may increase the risk of unintended trauma or infection.
- Do not cut the probe wire. A cut or fragmented probe wire may result in increased risk of unintended trauma or infection, as well as increased heating during MRI. See MRI Safety Information page.
- Ensure that the suture sleeve and connectors are not implanted. Failure to observe this warning may result in increased risk of unintended trauma or infection.
- **The FLOW NOW System may be susceptible to picking up interference through the wiring that connects the probe to the FLOW COUPLER Monitor in the presence of high frequency surgical equipment** (e.g., electrocautery or other high frequency surgical generators).
- Safe use of the FLOW NOW Device on tubular structures other than veins and arteries has not been established. Failure to observe this warning may result in signal loss or unintended trauma.

CAUTIONS

- Do not attempt to adjust the position of the probe within the probe-holder. The probe has been positioned within the probe-holder in a specific position during manufacturing. Adjustment may lead to vessel damage, vessel impingement, and loss of signal.
- If the probe is prematurely removed from the silicone strap, do not attempt to re-insert it, as this may lead to vessel damage, vessel impingement, and loss of signal. Instead, acquire a new device.
- Do not use the FLOW NOW Device if damaged. Instead, acquire a new FLOW NOW Device. Use of a damaged device may lead to vessel damage, vessel impingement, and loss of signal.
- To avoid unwanted kinking or twisting of the vessel during positioning of the flap, which may result in poor flap perfusion, care should be taken to establish the desired angle of the probe wire relative to the vessel.
- The probe wire and external lead are delicate. The use of crushing forceps or clamps may damage these wires.
- Use caution when manipulating the probe wire. Sharp bends may cause damage to the probe wire.

- Use of the following clips is recommended. Note: use of other clips or sutures to secure the strap has not been established.
    - Microclips: Synovis MCA GEM2431 Micro, Weck 005200 Micro, Vitalitec W6060/1 Micro
    - Small clips: Weck 001200 Small, Weck 001201 Small-Wide, Ethicon LT100 Small, Ethicon Ligaclip Small, Vitalitec J1180/1 Small, Covidien Premium Surgiclip Small
- When securing the strap with a manual clip applier, compress the handles using only the amount of pressure considered appropriate for applying a clip to a vessel. Excessive force with a manual clip applier can tear the strap and lead to signal loss.
- Gaps between the strap and the vessel can cause signal interruptions.
- Securing the strap too tightly around the vessel may cause vessel impingement.
- Use caution when routing the probe wire within the wound. Force or tension on the implanted device may lead to vessel damage, vessel impingement, and loss of signal.
- Avoid tugging on the probe wire or silicone strap. Tugging may lead to vessel damage, vessel impingement, and loss of signal.
- Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The probe is not intended to be a permanent implant and should be removed 3 to 14 days postoperatively.
- Avoid excessive force to remove the probe from the patient, which may cause injury to the vessel. If the probe cannot be removed using gentle traction, the probe should be surgically removed. Do not cut the probe wire.
- Ensure that the probe is attached to the probe wire and fully intact upon removal of the probe. If not, then surgical removal of the probe is required. The probe is not intended to be a permanent implant. See Warnings section for risks associated with permanent implantation of the probe and wire.
- The FLOW NOW Device should only be used with a FLOW COUPLER Monitor (GEM1020M or GEM1020M-2). The FLOW NOW Device is not compatible with other monitor devices.
- During the use of all ultrasound devices, minimize the exposure of ultrasound energy to the patient using the principle of ALARA (As Low As Reasonably Achievable).
- **Information for patient (clinician responsibility):**
    - Place information regarding the implant in the patient's medical record.
    - Inform patient they are receiving a permanent implant, which is comprised of an implantable grade silicone strap.
    - Inform patient that the probe wire will be left in place for up to 14 days after implantation.
    - Advise patient against engaging in physical activity that could result in tugging or tension on the wire during this time. Tugging or tension on the wire may lead to vessel damage, blood flow impingement, and loss of signal.
    - Advise patient against undergoing MRI imaging without consulting the IFU.

MRI SAFETY INFORMATION FOR CLINICIAN

DOPPLER PROBE SAFETY

The FLOW NOW Device probe and wire are MR-conditional based on non-clinical testing. To safely perform an MRI on a patient with a FLOW NOW Device probe present, the following conditions must be met:

- Disconnect Probe from external lead. Leave implanted probe intact.

  Warning: do not cut probe wire. MRI of cut probe wire can result in increased heat at the terminated end of the exposed wire which may be in contact with soft tissue.

- Tape connector down to skin; optional padding underneath connector may be added for patient comfort.
- Review proper placement within the MRI machine as stated in the Technical MRI Safety Information Table and Figure 1.
- It is the responsibility of the clinician to inform the patient that the probe wire will be left in place for up to 14 days after implantation, and to advise them against undergoing MR imaging without consulting the IFU.

SILICONE STRAP SAFETY

- The permanent silicone strap component is MR-safe.

  Caution: The vascular clips recommended for use to secure the silicone strap may cause the overall permanent implant to be MR-Conditional. Refer to vascular clip IFU for MRI safety information.

TECHNICAL MRI SAFETY INFORMATION

MRI SAFETY INFORMATION	
The following conditions are applicable to performing an MRI with the Doppler probe present. Failure to follow these conditions may result in injury. Note: The implanted Vessel Sleeve following Doppler probe removal has no special MRI conditions. Refer to vascular clip IFU for MRI safety information.	
Device Name	FLOW NOW
Static Magnetic Field Strength (Bo)	1.5 T or 3.0 T
Maximum Spatial Field Gradient	19 T/m (1,900 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode (subject to scan region limitations listed below)
Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	3.2 W/kg (Normal Operating Mode)

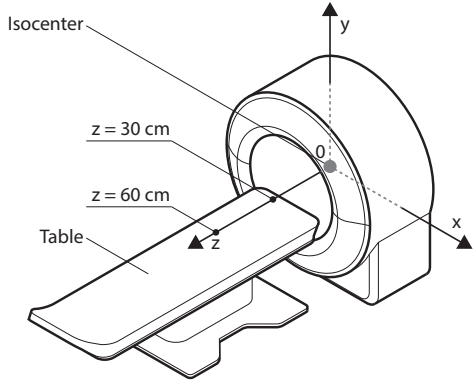
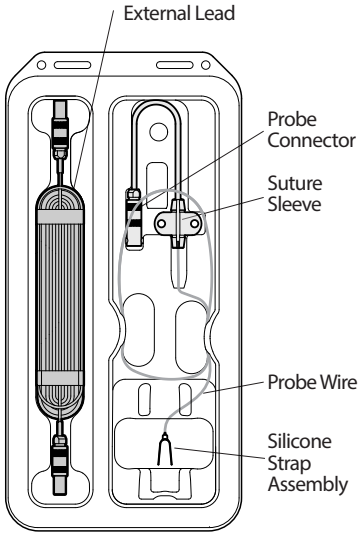


Figure 1

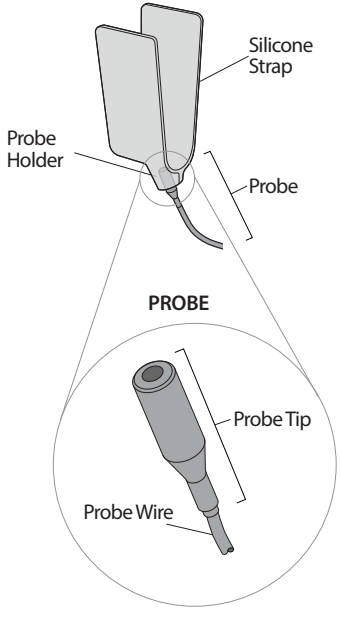
MRI SAFETY INFORMATION	
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)
Scan Regions	Patient landmark must assure the implanted device is at least 60 cm from isocenter for scanning at either 1.5 or 3.0 T.
MR Image Artifact	The presence of this implant may produce an image artifact of up to 39 mm from the construct.

GUIDE TO PARTS

FLOW NOW DEVICE IN TRAY



SILICONE STRAP ASSEMBLY



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 or to supersede institutional protocols or professional clinical judgment regarding patient care.

Read the Instructions for Use before use. No additional training is required beyond reading the Instructions for Use.

PREPARATION

1. Remove the packaged FLOW NOW Device and implant stickers from the carton. Note: Ensure implant stickers are applied to patient chart and implant records according to facility guidelines.
2. Inspect the outer tray.

   Warning: do not use if the outer tray is damaged, the seals are not intact, or the device is expired, as sterility may be compromised.
3. Peel off the Tyvek cover from the outer tray and aseptically transfer the inner tray to the sterile field.
4. Inspect the inner tray.

   Warning: do not use if the inner tray is damaged or if the seals are not intact, as sterility may be compromised

   NOTE: The inner tray may be saved for use as a sterile surface on which to set the device prior to implantation. Contact with other surfaces (e.g. sterile drape, sponge) may impart particulate onto the silicone strap.

5. Peel off the Tyvek cover from the inner tray. Remove the FLOW NOW Device from tray by gently lifting the wire, taking care not to tug on the wire (See Figure 2).
6. To verify probe function, first connect the probe to the FLOW COUPLER Monitor. To do so, join the probe connector to either end of the external lead and connect the other end of the external lead to the FLOW COUPLER Monitor.
7. Turn on the FLOW COUPLER Monitor.

   NOTE: For further instructions, refer to the FLOW COUPLER Monitor Instructions for Use.
8. Select the appropriate channel on the FLOW COUPLER Monitor.
9. Irrigate the probe by squirting sterile saline over the strap assembly until an audible signal is heard from the monitor (See Figure 3). Adjust monitor volume as needed.

   If no signal is identified, refer to the Troubleshooting section of these Instructions for Use.

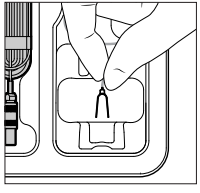


Figure 2

Figure 3

Handle the device with care to avoid accidental detachment of the probe wire from the silicone strap.

Caution: do not attempt to adjust the position of the probe within the probe-holder, as this may lead to vessel damage, vessel impingement, and loss of signal.

Caution: if the probe is prematurely removed from the silicone strap, do not attempt to reinsert it, as this may lead to vessel damage, vessel impingement, and loss of signal. Instead, acquire a new device.

FLOW NOW DEVICE PLACEMENT

Before placing the FLOW NOW Device on the target vessel, choose the probe wire's exit point (through the primary incision or through a counterincision) and arrange the device to allow slack and to avoid pulling on the wire.

1. Position the silicone strap around the target vessel, ensuring both ends of the strap are parallel to one another (See Figure 4). Note the probe is positioned at a 60° angle. For optimal wire removal, align the probe and wire with exit.

   Caution: the probe wire and external lead are delicate. The use of crushing forceps or clamps may damage the probe wire or external lead.

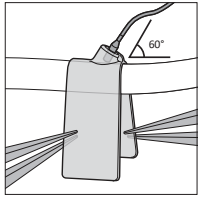


Figure 4

2. Hold the straps flat and against each other, leaving enough space to apply a vascular clip (See Figure 5).

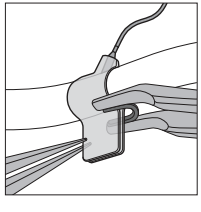


Figure 5

3. Use a vascular clip to secure the strap around the vessel, ensuring the device is snug enough around the vessel to produce a satisfactory Doppler signal (See Figure 6).

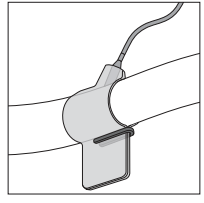


Figure 6

Please note the following when securing the strap:

- **Caution: use of the following clips is recommended. Note: use of other clips or sutures to secure the strap has not been established.**
  - **Microclips: Synovis MCA GEM2431 Micro, Weck 005200 Micro, Vitalitec W6060/1 Micro**
  - **Small clips: Weck 001200 Small, Weck 001201 Small-Wide, Ethicon LT100 Small, Ethicon Ligaclip Small, Vitalitec J1180/1 Small, Covidien Premium Surgiclip Small**
- **Caution: gaps between the strap and the vessel can cause signal interruptions.**
- **Caution: securing the strap too tightly around the vessel may cause vessel impingement.**

- **Caution: when securing the strap with a manual clip applier, compress the handles using only the amount of pressure considered appropriate for applying a clip to a vessel. Excessive force with a manual clip applier can tear the strap.**

- Ensure the clip is snug against the edge of the strap (See Figure 7). A clip extending off the strap can cause signal interruptions (See Figure 8).
- **Caution: if the device is damaged during placement, do not use. Instead, acquire a new FLOW NOW Device. Use of a damaged device may lead to vessel damage, vessel impingement, and loss of signal.**
- **Caution: avoid tugging on the probe wire or silicone strap. Tugging may lead to vessel damage, vessel impingement, and loss of signal.**

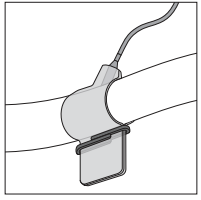


Figure 7 (Small clips shown, coverage of other clip sizes may vary)

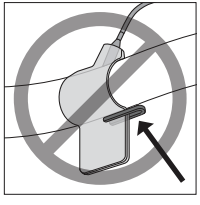


Figure 8

4. To ensure consistent contact between the probe and the vessel, a second clip may be applied distal to the first clip, on the opposing edge of the strap (See Figure 7).
5. If needed, trim excess strap material above applied clip(s) to minimize interference with surrounding tissue.

INTRAOPERATIVE FLOW DETECTION

Prior to closure of the surgical site verify detection of blood flow.

1. Temporarily secure the probe wire assembly to prevent the weight of the probe connector from pulling on the probe.
2. If not already connected, join the probe connector to either end of the external lead, and attach the other end of the external lead to the FLOW COUPLER Monitor (GEM1020M or GEM1020M-2).
3. If not already powered on, turn on the FLOW COUPLER Monitor.

   NOTE: For further instructions, refer to the FLOW COUPLER Monitor Instructions for Use.

   - The FLOW COUPLER Monitor (GEM1020M) can be powered by batteries (8 AA) or with the external power supply (GEM1020PS). If the low battery light illuminates, either replace all 8 batteries or use power supply.
   - The FLOW COUPLER Monitor (GEM1020M-2) can be powered by a rechargeable internal Lithium ion battery pack or with the external power supply (GEM1020PS-2). If the battery level is low or critically low, use power supply.
4. Select the appropriate channel on the FLOW COUPLER Monitor and listen for blood flow. Adjust volume as needed.

   If a strong audible signal is not identified, irrigate the site where the probe tip meets the vessel with saline to ensure there is fluid between the vessel and probe to conduct signal.

   During irrigation, an audible signal from the monitor verifies proper function of the device.

   Caution: do not attempt to adjust the position of the probe within the probe-holder, as this may lead to vessel damage, vessel impingement, and loss of signal.
5. When routing wire away from the vessel, a loose suture (See Figure 12) may be placed around the wire such that probe wire and tissue movement do not affect the orientation of the strap around the vessel but loose enough to allow for proper probe removal.

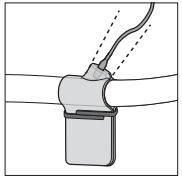


Figure 9

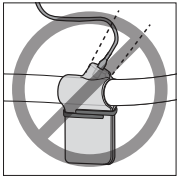


Figure 10

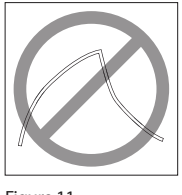


Figure 11

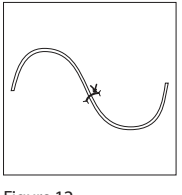


Figure 12

Optimal wire position would be aligned with probe tip (See Figure 9 and 10). Do not bend probe wire at a sharp angle (See Figure 11). See Figure 12 for an example of proper probe wire (curved angle). **Caution: to avoid unwanted kinking or twisting of the vessel during positioning of the flap which may result in poor flap perfusion, care should be taken to establish the desired angle of the probe wire relative to the vessel.**

6. Carefully position the probe wire, leaving enough redundant wire length in the wound to ensure there is neither force nor tension on the device.

   Caution: take care when routing the probe wire within the wound. Force or tension on the implanted device may lead to vessel damage, vessel impingement, and loss of signal.

7. Secure the suture sleeve to the skin (suture, tape or staple). Ensure adequate slack in the wire and do not bend probe wire at a sharp angle at the suture sleeve (See Figure 13 and 14).

   Warning: ensure that the suture sleeve and connectors are not implanted (See Figure 14 and 15). Failure to observe this warning may result in increased risk of unintended trauma or infection.

8. Listen for Doppler signal to confirm proper contact between probe and vessel and blood flow. If a strong signal is not heard, check installation of the FLOW NOW Device. For additional help, refer to probe and monitor troubleshooting guides.

9. Following verification of probe function and wire placement, close the incision using standard techniques. Cover the exposed probe wire with medical dressing.

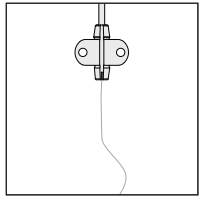


Figure 13

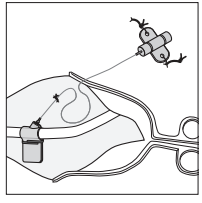


Figure 14

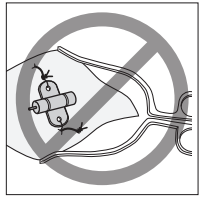


Figure 15

PROBE TROUBLESHOOTING GUIDE

SYMPTOMS	POSSIBLE PROBLEMS	SOLUTION
No sound output intra-operatively	No moisture contact	Site irrigation
		Verify no vessel stricture
		Check blood flow (vein and artery)
		Massage blood vessel to increase blood pressure
		Wait until blood flow can be seen and heard
		Ischemia or reperfusion rate may delay or affect the initial Doppler signal. Check with handheld probe
		Confirm strap is appropriately snug to ensure probe is in continuous contact with vessel
	No power	Check all connections: • Probe Connector to External Lead • External Lead to Monitor
	External Lead is not functioning	Replace External Lead
	Probe is not functioning	Rely on clinical indications for patient status
		Confirm strap is appropriately snug to ensure probe is in continuous contact with vessel
		Remove the FLOW NOW Device and start with a new device
	Probe is dislodged from silicone strap	Remove the FLOW NOW Device and start with a new device. **Do not attempt to reinsert probe into silicone strap**
No sound output post-operatively	No power	Check all connections: • Probe Connector to External Lead • External Lead to Monitor
	External Lead is not functioning	Replace External Lead
	Probe may have lost contact with vessel	Rely on clinical indications for patient status
	Probe is not functioning	Rely on clinical indications for patient status.

POSTOPERATIVE FLOW DETECTION

1. On an as needed basis, blood flow can be detected for up to 7 days. The probe and probe wire are not intended to be permanent implants and should be removed 3 to 14 days postoperatively.

NOTE:

- When the monitor is not being used to detect flow, the external lead may be disconnected from the probe connector.
- Ischemia or reperfusion rate may delay or affect the initial Doppler signal.
- If blood flow is not detected with the monitor postoperatively, rely on clinical indications for patient status.
- Doppler signal may vary during monitoring period.

PROBE REMOVAL

Postoperatively, blood flow can be detected on an as needed basis for up to 7 days. The probe and probe wire are not intended to be permanent implants and should be removed 3 to 14 days postoperatively.

1. Disconnect the external lead from the FLOW COUPLER Monitor.
2. Detach the suture sleeve and wire from the skin (remove suture, tape or staple).

   Warning: Do not cut probe wire. A cut or fragmented probe wire may result in increased risk of unintended trauma or infection, as well as increased heating during MRI. See MRI Safety Information Page.
3. Remove the probe and probe wire by applying gentle traction to the wire while applying counter pressure externally at the site of incision until the probe is extracted.

   Caution: Avoid excessive force to remove the probe from the patient, which may cause injury to the vessel. If the probe cannot be removed using gentle traction, the probe should be surgically removed.
4. Inspect the probe tip to ensure that it is fully intact. (See Figure 16)

   Caution: if, upon removal, the probe tip is not attached to the probe wire or fully intact, surgical removal is required. The probe is not intended to be a permanent implant.
5. Dispose of the probe, probe wire, and external lead in accordance with the biohazard disposal requirements of your facility or local regulations.

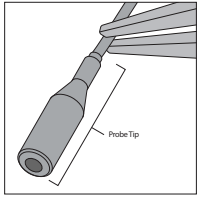


Figure 16

STORAGE CONDITIONS

Recommended storage conditions are between 15°C and 25°C (59°F and 77°F).

DISPOSAL METHOD

Any open, used or unused, FLOW NOW Device components (i.e., probe, probe wire and external lead) except the FLOW COUPLER Monitor should be discarded due to compromised sterility. Any packaging or components exposed to human tissue/ fluids should be disposed of per hospital protocols.

MONITOR TROUBLESHOOTING GUIDE

SYMPTOMS	POSSIBLE PROBLEMS	SOLUTION
No sound output	Monitor power is off	• Turn on Monitor.
	Power Supply disconnected and the battery level critically low	If the Monitor does not power on, connect the Power Supply to the monitor. Check connections: • Monitor to Power Supply • Power Supply to Power Cord/Adapter Plug* • Power Cord/Adapter Plug* to outlet *Power Cord is a component of GEM1020M. Adapter plug is a component of GEM1020M-2 Replace Batteries (GEM1020M only)
	Probe disconnected	Check connections: • Probe Connector to External Lead • External Lead to Monitor
	Volume muted	GEM1020M: Adjust volume using Volume Increase switch GEM1020M-2: 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	GEM1020M: Verify the correct channel is illuminated GEM1020M-2: Verify the correct channel button is illuminated and the correct channel is displayed 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).
Weak sound output	(GEM1020M only): Weak batteries (low battery indicator is illuminated)	Replace batteries or use external power supply
	Volume is too low	GEM1020M: Adjust volume using Volume Increase switch GEM1020M-2: Increase volume by pressing Volume Increase Button or touch-and-drag Volume Indicator on the LCD screen
Weak Sound output	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.
(GEM1020M-2 only): LCD touch screen malfunction	(GEM1020M-2 only): 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).

ACCESSORIES & PARTS

ITEM	REF
FLOW NOW Device	GEM2770-FN
FLOW COUPLER Monitor	GEM1020M , GEM1020M-2
Power Supply	GEM1020PS, GEM1020PS-2
External Lead, 4 pack	GEM1003EXT-FC

DISCLAIMER OF WARRANTY

Synovis Micro Companies Alliance, Inc., (SMCA), a subsidiary of Baxter International Inc., warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties whether expressed, implied, written or oral, including, but not limited to, any implied warranties of merchantability or fitness. Since SMCA has no control over the conditions under which the device is used, diagnosis of the patient, methods of administration or its handling after it leaves its possession, SMCA does not warrant either a good effect or against an ill effect following its use. The manufacturer shall not be liable for any incidental or consequential loss, damage or expense arising directly or indirectly from the use of this device. SMCA will replace any device which is defective at the time of shipment. No representative of SMCA may change any of the foregoing or assume any additional liability or responsibility in connection with this device.

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