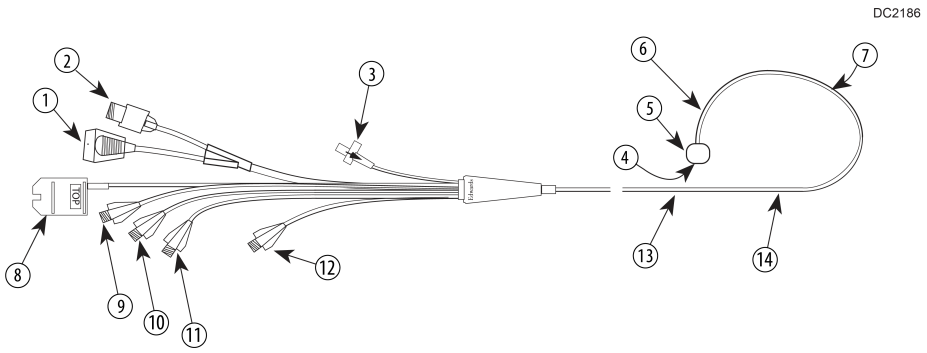
Edwards

Swan-Ganz IQ Pulmonary Arterial Catheter
SvO_2/VIP Catheter: AIQSGF8



Swan-Ganz IQ Pulmonary Arterial Catheter (Model AIQSGF8)

1. EEPROM Connector
2. Thermistor Connector
3. Balloon Inflation Valve
4. PA Distal Lumen
5. Balloon
6. Thermistor @ 4 cm
7. RV Port @ 12.7 cm
8. Optical Module Connector
9. RV Port Hub
10. PA Distal Lumen Hub
11. VIP catheter Lumen Hub
12. Proximal Injectate Lumen Hub
13. VIP catheter Port @ 30 cm
14. Proximal Injectate Port @ 26 cm

For use with a compatible cardiac output computer†

Carefully read these instructions for use, which address the warnings, precautions, and residual risks for this medical device.

CAUTION: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

For Single Use Only

For figures, see Figure 1 on page 8 and Figure 2 on page 8.

1.0 Description

The device is used by medical professionals who have been trained in safe use of invasive hemodynamic technologies and clinical usage of pulmonary artery catheters as part of their respective institutional guidelines.

The Swan-Ganz IQ pulmonary arterial catheter is a flow-directed pulmonary artery catheter designed to enable the monitoring of hemodynamic pressures. The pulmonary artery (PA) distal lumen terminates at the distal tip. The proximal injectate lumen terminates at a port located 26 cm from the distal tip. When the distal tip is located in the pulmonary artery, the proximal injectate port will reside in the right atrium or vena cava, allowing for bolus cardiac output injections, right atrial pressure and right ventricular pressure monitoring, blood sampling, or infusion of solutions.

When used with a compatible cardiac output computer, the Swan-Ganz IQ SvO_2/VIP catheter allows for intermittent calculation and display of cardiac output and mixed venous oxygen saturation. The oximetry lumen (optical module connector) terminates at the distal tip. This lumen contains the fibers that transmit the light to the pulmonary artery for measurement of mixed venous oxygen saturation. Mixed venous oxygen saturation is monitored by fiberoptic reflectance spectrophotometry. The amount of light absorbed, refracted, and reflected depends on the relative amounts of oxygenated and deoxygenated hemoglobin in the blood.

The SvO_2/VIP catheter provides an additional (VIP catheter) lumen that allows for continuous infusion. The VIP catheter lumen (proximal infusion lumen) terminates at a port located 30 cm from the distal tip. This port allows for infusion of solutions, pressure monitoring or blood sampling.

† Measurement capabilities (i.e. CCO, CCO/SvO_2) of the compatible cardiac output computer vary by model number. Ensure that the monitor being used is able to measure the desired parameters.

The intravascular catheter is inserted through the central vein into the right side of the heart and is advanced towards the pulmonary artery. Route of insertion can be internal jugular, femoral, antecubital and brachial veins. The body parts in contact are the atrium, ventricles, pulmonary artery and circulatory system.

Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.

The device is intended for use in adult critically ill or surgical patient populations. The device has not yet been tested in pediatric population or in pregnant or lactating women.

2.0 Intended Use

The Swan-Ganz IQ catheter (model AIQSGF8) is for use in patients who require hemodynamic monitoring. It is intended to be used in combination with clinical pressure monitoring equipment to measure right heart and pulmonary artery pressures, and with a compatible cardiac output computer to measure intermittent cardiac output. Model AIQSGF8 also measures mixed venous oxygen saturation.

3.0 Indications

The primary indications for the Swan-Ganz IQ pulmonary arterial catheters include:

- Acute heart failure
- Severe hypovolemia
- Complex circulatory situations
- Medical emergencies
- Adult respiratory distress syndrome
- Gram negative sepsis
- Drug intoxication
- Acute renal failure
- Hemorrhagic pancreatitis
- Intra and post-operative management of high risk patients
- History of pulmonary or cardiac disease
- Fluid shifts (e.g., extensive intra-abdominal operations)
- Management of high-risk obstetrical patients
- Diagnosed cardiac disease
- Toxemia
- Premature separation of placenta
- Cardiac output determinations
- Differential diagnosis of mitral regurgitation and ventricular septal rupture
- Diagnosis of cardiac tamponade

Secondary indications include the following:

- Blood Sampling
- Infusion of saline and dextrose solutions

4.0 Contraindications

Patients with either recurrent sepsis, or with hypercoagulopathy, in which the catheter could serve as a focal point for septic or bland thrombus formation, should not be considered candidates for a balloon flotation catheter.

These products contain metallic components. Do NOT use in a Magnetic Resonance (MR) environment.

Electrocardiographic monitoring during catheter passage is encouraged and is particularly important in the presence of either of the following conditions:

- Complete left bundle branch block, in which the risk of complete heart block is somewhat increased.
- Wolff-Parkinson-White syndrome and Ebstein's malformation, in which the risk of tachyarrhythmias is present.

No absolute contraindications to the use of flow-directed pulmonary artery catheters exist. However, a patient with a left bundle branch block may develop a right bundle branch block during catheter insertion, resulting in complete heart block. In such patients, temporary pacing modes should be immediately available.

5.0 Warnings

Do not modify or alter the product in any way. Alteration or modification may affect product performance.

Air should never be used for balloon inflation in any situation where it may enter the arterial circulation, e.g., in all pediatric patients and in adults with suspected right to left intracardiac or intra-pulmonary shunts. Bacteria-filtered carbon dioxide is the recommended inflation medium because of its rapid absorption into the blood in the event of balloon rupture within the circulation. Carbon dioxide diffuses through the latex balloon, diminishing the balloon's flow-directed capability after 2 to 3 minutes of inflation.

Do not leave the catheter in a permanent wedge position. Furthermore, avoid lengthy balloon inflation while the catheter is in a wedge position; this occlusive maneuver may result in pulmonary infarction.

While the RV Port can be used for infusion of solutions such as normal saline or Ringer's lactate, infusion of medication may lead to complications including Cardiac Arrhythmias.

This device is designed, intended, and distributed for SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE this device. There are no data to support the sterility, non-pyrogenicity, and functionality of the device after reprocessing.

Cleaning and resterilization will damage the integrity of the latex balloon. Damage may not be obvious during routine inspection.

6.0 Precautions

Failure of a balloon flotation catheter to enter the right ventricle or pulmonary artery is rare, but may occur in patients with an enlarged right atrium or ventricle particularly if the cardiac output is low or in the presence of tricuspid or pulmonic incompetence or pulmonary hypertension. Deep inspiration by the patient during advancement may also facilitate passage.

Clinicians using the device should be familiar with the device and understand its applications prior to use.

7.0 Recommended Equipment

WARNING: Compliance to IEC 60601-1 is only maintained when the catheter or probe (Type CF applied part, defibrillation proof) is connected to a patient monitor or equipment that has a Type CF defibrillation proof rated input connector. If attempting to use a third party monitor or equipment, check with the monitor or equipment manufacturer to ensure IEC 60601-1 compliance and compatibility with the catheter or probe. Failure to ensure monitor or equipment compliance to IEC 60601-1 and catheter or probe compatibility may increase the risk of electrical shock to the patient/operator.

- Swan-Ganz catheter
- Percutaneous sheath introducer and contamination shield
- Compatible cardiac output platform for intermittent cardiac output and mixed venous oxygen saturation
- Connecting cables
- Model OM2 or OM2E Optical Module (Model AIQSGF8)
- Sterile flush system and pressure transducers
- Bedside ECG and pressure monitor system

In addition, the following items should be immediately available if complications arise during catheter insertion: antiarrhythmic drugs, defibrillator, respiratory assist equipment, and a means for temporary pacing.

8.0 Monitor Set-Up and Calibration for Mixed Venous Oxygen Saturation Monitoring

This section only applies to the AIQSGF8 model with SvO_2 capability.

The compatible cardiac output computer can be calibrated prior to catheter insertion by performing an *in vitro* calibration. When performing an *in vitro* calibration, do so before preparing the catheter (i.e. flushing the lumens). **The catheter tip must not get wet before an *in vitro* calibration is performed.** An *in vivo* calibration is required if an *in vitro* calibration is not done. *In vivo* calibration may be used to periodically recalibrate the monitor. Refer to the monitor operator's manual for detailed calibration instructions.

9.0 Catheter Preparation

Visually inspect for breaches of packaging integrity prior to use.

Use aseptic technique.

Note: Use of a protective catheter sheath is recommended.

Precaution: Avoid forceful wiping or stretching of the catheter during testing and cleaning as not to break the thermistor wire circuitry.

Before the catheter is inserted, the following preparation procedure should be followed:

Step	Procedure
1	Perform *in vitro* calibration (when measuring mixed venous oxygen saturation).
2	To open the catheter for calibration, peel back the top left perforated portion of the lid and fold diagonally according to the dotted fold line. In order to gain access to the catheter lumens for flushing, peel lid from the top right corner and fold according to the dotted fold line; otherwise peel off the entire tray lid by peeling back the lid from the bottom right corner. Flush lumens with sterile saline or dextrose solution to ensure patency and to remove air.
3	Gently lift the catheter up and remove it from the silicone gripper (see Figure 1 on page 8, Step 1).
4	Once the catheter has cleared the silicone gripper, pull the balloon out of the calibrator cup and remove the catheter from the tray (see Figure 1 on page 8, Step 2). **Note: To avoid damaging the balloon, do not pull the balloon through the silicone gripper.**
5	Check balloon integrity by inflating it to the recommended volume. Check for major asymmetry and for leaks by submerging in sterile saline or water. Deflate balloon before insertion.
6	Connect the catheter's injectate and pressure monitoring lumens to the flush system and pressure transducers. Ensure that the lines and transducers are free of air.
7	Test the thermistor's electrical continuity before insertion. Connect the thermistor to the monitor and confirm that no fault messages appear. **Note: The AIQSGF8 catheter is not capable of CCO monitoring. The EEPROM connector is not required for intermittent cardiac monitoring. The AIQSGF8 catheter contains no thermal filament. On some monitors when the thermistor and EEPROM connector are connected together, the message "Connect thermal filament for CO monitoring" or "Fault: CO - Check Thermal Filament Connection" or "Fault: CCO - Check Thermal Filament Connection" will display and an alarm may sound. As such, leave unconnected and intermittent cardiac monitoring may proceed.**
8	If using a compatible cardiac output computer for intermittent cardiac output measurement, connect the thermistor to the monitor.

10.0 Insertion Procedure

Swan-Ganz catheters can be inserted at the patient's bedside without the aid of fluoroscopy, guided by continuous pressure monitoring.

Simultaneous pressure monitoring from the distal lumen is recommended. Fluoroscopy is recommended for femoral vein insertion.

Note: Should the catheter require stiffening during insertion, slowly perfuse the catheter with 5 ml to 10 ml of cold sterile saline or 5% dextrose as the catheter is advanced through a peripheral vessel.

Note: The catheter should pass easily through the right ventricle and pulmonary artery and into a wedge position in less than a minute.

Although a variety of techniques can be used for insertion, the following guidelines are provided as an aid to the physician:

Step	Procedure
1	Introduce the catheter into the vein through a sheath introducer using percutaneous insertion using modified Seldinger technique.
2	Under continuous pressure monitoring, with or without the aid of fluoroscopy, gently advance the catheter into the right atrium. Entry of the catheter tip into the thorax is signaled by an increased respiratory fluctuation in pressure. Figure 2 on page 8 shows the characteristic intracardiac and pulmonary pressure waveforms. **Note: When the catheter is near the junction of the right atrium and the superior or inferior vena cava of the typical adult patient, the tip has been advanced approximately 40 cm from the right or 50 cm from the left antecubital fossa, 15 to 20 cm from the jugular vein, 10 to 15 cm from the subclavian vein, or about 30 cm from the femoral vein.**
3	Using the syringe provided, inflate the balloon with CO_2 or air to the maximum recommended volume. **Do not use liquid.** Note that an offset arrow on the gate valve indicates the "closed" position. **Note: Inflation is usually associated with a feeling of resistance. On release, the syringe plunger should usually spring back. If no resistance to inflation is encountered, it should be assumed that the balloon has ruptured. Discontinue inflation at once. The catheter may continue to be used for hemodynamic monitoring. However, be sure to take precautions to prevent infusion of air or liquid into the balloon lumen.** **WARNING: Pulmonary complications may result from improper inflation technique. To avoid damage to the pulmonary artery and possible balloon rupture, do not inflate above the recommended volume.**
4	Advance the catheter until pulmonary artery occlusion pressure (PAOP) is obtained, then passively deflate the balloon by removing the syringe from the gate valve. Do not forcefully aspirate as this may damage the balloon. After deflation, re-attach the syringe. **Note: Avoid prolonged maneuvers to obtain wedge pressure. If difficulties are encountered, give up the "wedge".** **Note: Before reinflation with CO_2 or air, completely deflate the balloon by removing the syringe and opening the gate valve.** **Precaution: It is recommended that the provided syringe be re-attached to the gate valve after balloon deflation to prevent inadvertent injection of liquids into the balloon lumen.** **Precaution: If a right ventricular pressure tracing is still observed after advancing the catheter several centimeters beyond the point where the initial right ventricular pressure tracing was observed, the catheter may be looping in the right ventricle which can result in kinking or knotting of the catheter (see Complications). Deflate the balloon and withdraw the catheter into the right atrium. Reinflate the balloon and readvance the catheter to a pulmonary artery wedge position, then deflate the balloon.** **Precaution: Catheter looping may occur when excessive length has been inserted, which could result in kinking or knotting (see Complications). If the right ventricle is not entered after advancing the catheter 15 cm beyond entry into the right atrium, the catheter may be looping, or the tip may be engaged in a neck vein with only the proximal shaft advancing into the heart. Deflate the balloon and withdraw the catheter until the 20 cm mark is visible. Reinflate the balloon and advance the catheter.**
5	Reduce or remove any excessive length or loop in the right atrium or ventricle by slowly pulling the catheter back approximately 2 to 3 cm. **Precaution: Do not pull the catheter across the pulmonic valve while the balloon is inflated to avoid damage to the valve.**
6	Reinflate the balloon to determine the minimum inflation volume necessary to obtain a wedge tracing. If a wedge is obtained with less than the maximum recommended volume (see specifications table for balloon inflation capacity), the catheter must be withdrawn to a position where full inflation volume produces a wedge tracing. **Precaution: Overtightening the proximal Tuohy-Borst adapter of the contamination shield may impair catheter function.**
7	Confirm final catheter tip position with chest X-ray.

Note: After deflation, the catheter tip may tend to recoil towards the pulmonic valve and slip back into the right ventricle, requiring that the catheter be repositioned.

Note: If using a contamination shield, extend the distal end towards the introducer valve. Extend the proximal end of the catheter contamination shield to desired length, and secure.

11.0 Bolus Thermodilution Method

Bolus TD cardiac output measurement is made by injecting an exact amount of physiological solution (saline or dextrose) of known temperature into the right atrium or superior vena cava and by using the thermistor in the pulmonary artery to detect the resultant change in blood temperature. Cardiac output is inversely proportional to the area under the temperature-versus-time curve. The accuracy of this method depends on the accuracy with which the quantity and temperature of the injectate are known. The accuracy of the thermodilution method correlates well with the dye dilution technique and with the direct Fick method.

Edwards Lifesciences cardiac output computers require that a computation constant be used to correct for injectate temperature rise as it passes through the catheter. The computation constant is a function of injectate volume, temperature, and catheter dimensions. The computation constants listed in the specifications have been determined *in vitro*.

12.0 Maintenance and Use *in situ*

The catheter should remain indwelling only as long as is required by the patient's condition.

Precaution: The incidence of complications increases significantly with indwelling periods longer than 72 hours.

12.1 Catheter Tip Position

Keep catheter tip centrally located in a main branch of the pulmonary artery near the hilum of the lungs. Do not advance tip too far peripherally. Tip should be kept where full or near full inflation volume is required to produce a wedge tracing. The tip migrates toward periphery during balloon inflation.

12.2 Catheter Tip Migration

Anticipate spontaneous catheter tip migration towards periphery of pulmonary bed. Continuously monitor distal lumen pressure to verify tip position. If wedge tracing is observed when balloon is deflated, pull catheter back. Damage may be caused by prolonged occlusion or over-distension of vessel upon re-inflation of the balloon.

Spontaneous catheter tip migration towards the periphery of the lung occurs during cardiopulmonary bypass. Partial catheter withdrawal (3 to 5 cm) just before bypass should be considered, as it may help reduce distal migration and prevent permanent catheter wedging postbypass. After termination of bypass, the catheter may require repositioning. Check the distal pulmonary artery tracing before inflating the balloon.

Precaution: Over a period of time, the catheter tip may migrate towards the periphery of the pulmonary bed and lodge in a small vessel. Damage may occur either by prolonged occlusion or by over-distension of the vessel upon reinflation of the balloon (see Complications).

PA pressures should be continuously monitored with the alarm parameter set to detect physiologic changes as well as spontaneous wedge.

12.3 Balloon Inflation and Wedge Pressure Measurement

Re-inflation of the balloon should be performed gradually while monitoring pressures. Inflation is usually associated with a feeling of resistance. If no resistance is encountered, it should be assumed that the balloon has ruptured. Discontinue inflation at once. The catheter may still be used for hemodynamic monitoring, however, take precautions against infusion of air or liquids into the balloon lumen. During normal catheter use, keep inflation syringe attached to gate valve to prevent inadvertent injection of liquid into the balloon inflation lumen.

Measure wedge pressure only when necessary and only when tip is properly positioned (see above). Avoid prolonged maneuvers to obtain wedge pressure and keep wedge time to a minimum (two respiratory cycles or 10 - 15 seconds), especially in patients with pulmonary hypertension. If difficulties are encountered, discontinue wedge measurements. In some patients, pulmonary arterial end-diastolic pressure can often be substituted for pulmonary artery wedge pressure if the pressures are nearly identical, obviating the need for repeated balloon inflation.

12.4 Spontaneous Tip Wedging

The catheter may migrate into the distal pulmonary artery and spontaneous tip wedging may occur. To avoid this complication, pulmonary artery pressure should be monitored continuously with a pressure transducer and display monitor.

Forward advancement should never be forced if resistance is encountered.

12.5 Patency

All pressure monitoring lumens should be filled with a sterile, heparinized saline solution (e.g., 500 I.U. heparin in 500 ml saline) and flushed at least once each half hour or by continuous slow infusion. If loss of patency occurs and cannot be corrected by flushing, the catheter should be removed.

12.6 General

Keep pressure monitoring lumens patent by intermittent flush or continuous slow infusion with heparinized saline solution. Infusion of viscous solutions (e.g., whole blood or albumin) is not recommended, as they flow too slowly and may occlude the catheter lumen.

WARNING: To avoid pulmonary artery rupture, never flush the catheter when the balloon is wedged in the pulmonary artery.

Periodically check IV lines, pressure lines, and transducers to keep them free of air. Also ensure that connecting lines and stopcocks remain tightly fitted.

13.0 MRI Information

MR Unsafe

The Swan-Ganz device is MR unsafe as the result of the device containing metallic components, which experience RF-induced heating in the MRI environment; therefore the device poses hazards in all MRI environments.

14.0 Complications

Invasive procedures involve some patient risks. Although serious complications are relatively uncommon, the physician is advised, before deciding to insert or use the catheter, to consider the potential benefits in relation to the possible complications. The techniques for insertion, methods of using the catheter to obtain patient data information, and the occurrence of complications is well described in the literature.

Strict adherence to these instructions and awareness of risks reduces the incidence of complications. Several known complications include:

14.1 Perforation of the Pulmonary Artery

Factors associated with fatal pulmonary artery rupture include pulmonary hypertension, advanced age, cardiac surgery with hypothermia and anticoagulation, distal catheter tip migration, arteriovenous fistula formation and other vascular traumas.

Extreme care should be used during the measurement of pulmonary artery wedge pressure in patients with pulmonary artery hypertension. In all patients, balloon inflation should be limited to two respiratory cycles, or 10 to 15 seconds.

A central location of the catheter tip near the hilum of the lung may prevent pulmonary artery perforation.

14.2 Pulmonary Infarction

Tip migration with spontaneous wedging, air embolism, and thromboembolism can lead to pulmonary artery infarction.

14.3 Cardiac Arrhythmias

Cardiac arrhythmias may occur during insertion, withdrawal, and repositioning, but are usually transient and self-limited. Premature ventricular contractions are the most commonly observed arrhythmia. Ventricular tachycardia and atrial tachycardia have been reported. Use of prophylactic lidocaine should be considered to decrease the incidence of ventricular arrhythmias during catheterization. ECG monitoring and immediate availability of antiarrhythmic drugs and defibrillator equipment is recommended.

14.4 Knotting

Flexible catheters have been reported to form knots, most often as a result of looping in the right ventricle. Sometimes the knot can be resolved by insertion of a suitable guidewire and manipulation of the catheter under fluoroscopy. If the knot does not include any intracardiac structures, the knot may be gently tightened and the catheter withdrawn through the site of entry.

14.5 Sepsis/Infection

Positive catheter-tip cultures resulting from contamination and colonization have been reported, as well as incidences of septic and aseptic vegetation in the right heart. Increased risks of septicemia and bacteremia have been associated with blood sampling, the infusing of fluids, and catheter-related thrombosis. Preventive measures should be taken to guard against infection.

14.6 Other Complications

Other complications include right bundle branch block, complete heart block, tricuspid and pulmonic valve damage, blood loss, cardiac structure/wall injury or damage, hematoma, embolism, anaphylaxis, pneumothorax, and thrombosis. In addition, allergic reactions to latex have been reported. Physicians should identify latex sensitive patients and be prepared to treat allergic reactions promptly.

15.0 Long-Term Monitoring

The duration of catheterization should be the minimum required by the patient's clinical state since the risk of thromboembolic and infectious complications increases with time. The incidence of complications increases significantly with indwelling periods longer than 72 hours. Prophylactic systemic anticoagulation and antibiotic protection should be considered when long-term catheterization (i.e., over 48 hours) is required, as well as in cases involving increased risk of clotting or infection.

16.0 How Supplied

Contents sterile and nonpyrogenic if package is unopened and undamaged. Do not use if package is opened or damaged. Do not resterilize.

The packaging within is designed to avoid crushing of the catheter and to protect the balloon from exposure to the atmosphere. It is therefore recommended that the catheter remain inside the package until use.

17.0 Storage

Store in a cool, dry place.

Temperature/Humidity Limitations:
0° - 40 °C, 5% - 90% RH

18.0 Operating Conditions/Use Environment

Intended to operate under physiological conditions of the human body in a controlled clinical environment.

19.0 Shelf Life

The recommended shelf life is marked on each package. Storage beyond the recommended time may result in balloon deterioration, since the natural latex rubber in the balloon is acted upon and deteriorated by the atmosphere.

Note: Resterilization will not extend the shelf life.

20.0 Technical Assistance

For technical assistance, please call Edwards Technical Support at the following telephone numbers:

Inside the U.S. and Canada
(24 hours): 800.822.9837
Outside the U.S. and Canada
(24 hours): 949.250.2222
In the UK: . . . . . 0870 606 2040 - Option 4
In Ireland: . . . . . 01 8211012 - Option 4

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

21.0 Disposal

After patient contact, treat the device as biohazardous waste. Dispose of in accordance with hospital policy and local regulations.

Prices, specifications, and model availability are subject to change without notice.

Refer to the symbol legend at the end of this document.

STERILE EO

Specifications:

	Model AIQSGF8
Body Color	yellow
Usable Length (cm)	110
Catheter Body	8F (2.7 mm)
Diameter of Inflated Balloon (mm)	13
Required Introducer Size	9F (3.0 mm)
Balloon Inflation Capacity (ml)	1.5
Distance from Distal Tip (cm)	
Thermistor	4
RV Port	12.7
Injectate Port	26
VIP catheter Port	30
Distance Between Markings (cm)	10
Lumen Volumes (ml)	
Distal Lumen	0.90
RV Lumen	0.78

	Model AIQSGF8
Injectate Lumen	0.85
Infusion Lumen	1.10
Infusion Rate* (ml/min)	
Distal Lumen	4
RV Lumen	5
Injectate Lumen	9
VIP catheter Lumen	16
Compatible Guidewire Diameter	0.018 in (0.46 mm)
Frequency Response	
Distortion at 10 Hz	
Distal Lumen	< 3 dB
RV Lumen	< 3 dB
Balloon Inflation Syringe	3 ml, limited to 1.5 ml

All specifications given are nominal values.

* Using normal saline at room temperature, 1 m above insertion site, gravity drip.

Catheter Model and Functions:

	AIQSGF8
ICO	X
SvO_2	X
VIP catheter	X

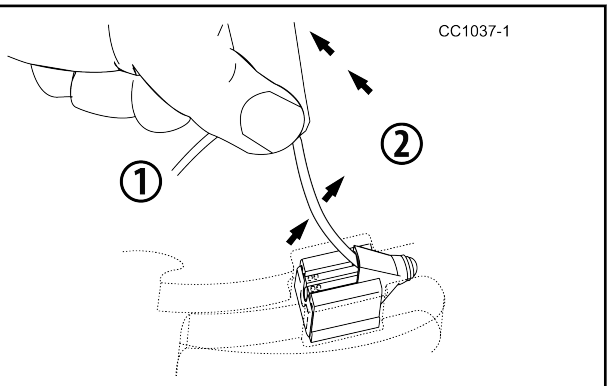
Computation Constants

For use with bath temperature probes

Model		**AIQSGF8**
Injectate Temp (°C)	**Injectate Volume (ml)**	**Computation Constants (CC)****
0 - 5	10	0.550
	5	0.256
	3	—
19 - 22	10	0.585
	5	0.282
	3	—
23 - 25	10	0.600
	5	0.292
Computation Constants for CO-Set+ Delivery System		
6 °C - 12 °C	10	0.559
8 °C - 16 °C	5	0.263
18 °C - 25 °C	10	0.602
	5	0.295

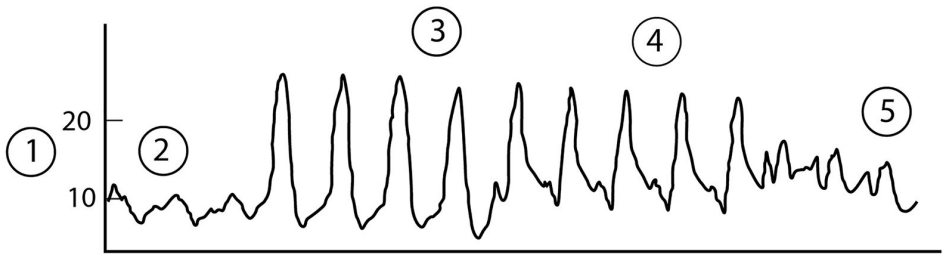
**$CC = (1.08)C_T(60)(V_I)$

Figure



1. Step 1
2. Step 2

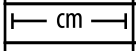
Figure 1

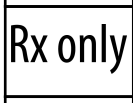
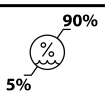


1. mmHg
2. RA
3. RV
4. PA
5. PAOP

Figure 2: Standard Pressure Waveform showing RA-RV-PA-PAOP progression

Symbol Legend

	English
	Number of lumens
	Exterior diameter
	Usable length
	Recommended guidewire size
	Lumen size
	Catalogue Number
	Minimum introducer size
	Caution
	Do not re-use
	Quantity
	Lot Number
	Use-by date
	Inner diameter
	Balloon capacity
	Sterile

	English
	Sterilized using ethylene oxide
	Sterilized using irradiation
	Sterilized using steam or dry heat
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
	Manufacturer
	Date of manufacture
	Contains or presence of natural rubber latex
	Contains or presence of Phthalates
	Size
	No components of this package or the products it contains are made from natural rubber latex or dry natural rubber.
	Temperature limit
	Humidity limitation
	Consult instructions for use on the website
	Follow instructions for use on the website
	MR Unsafe

	English
	MR Safe
	MR Conditional
	Consult instructions for use or consult electronic instructions for use
	Follow instructions for use
	Do not resterilize
	Non-pyrogenic
	Type B applied part
	Type CF applied part
	Do not use if package is damaged and consult instructions for use
	Open
	Aspirate balloon -0.5 cc before introduction or withdrawal
	Authorized representative in the European Community/European Union
	Conformité Européenne (CE Mark)
	Medical device

Note: Not all symbols may be included in the labeling of this product.

EC REP

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07/23
10048652003 A / DOC-0222632 A

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