Edwards Lifesciences

Swan-Ganz Continuous Cardiac Output Thermodilution Catheters:
CCO Catheters: 139F75
CCO/SvO_2 Catheters: 744F75
CCO/SvO_2/VIP Catheters: 746F8
CCO V CCO/CEDV Catheters: 177F75N
CCOmbo V CCO/SvO_2/CEDV Catheters: 774F75
CCOmbo V CCO/SvO_2/CEDV/VIP Catheters: 777F8
For use with a compatible cardiac output computer†

Carefully read these instructions for use and all contained warnings and precautions before using this product.

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

For Single Use Only

For figures 1 and 2 please refer to page 4.

Description

The Swan-Ganz Continuous Cardiac Output thermodilution catheters are flow-directed pulmonary artery catheters designed to enable the monitoring of hemodynamic pressures and to provide continuous cardiac output. 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 monitoring, blood sampling, or infusion of solutions.

When used with a compatible cardiac output computer, the Swan-Ganz Continous Cardiac Output (CCO) thermodilution catheter (Models 139F75, and 177F75N) allows for continuous calculation and display of cardiac output. To measure cardiac output continuously, a compatible cardiac output computer uses thermal energy emitted by the thermal filament located on the catheter to calculate cardiac output using thermodilution principles. Alternatively, cardiac output can be measured by the traditional bolus thermodilution method.

When used with a compatible cardiac output computer, the Swan-Ganz CCO/SvO_2 catheter (Models 744F75, 774F75) allows for continuous 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.

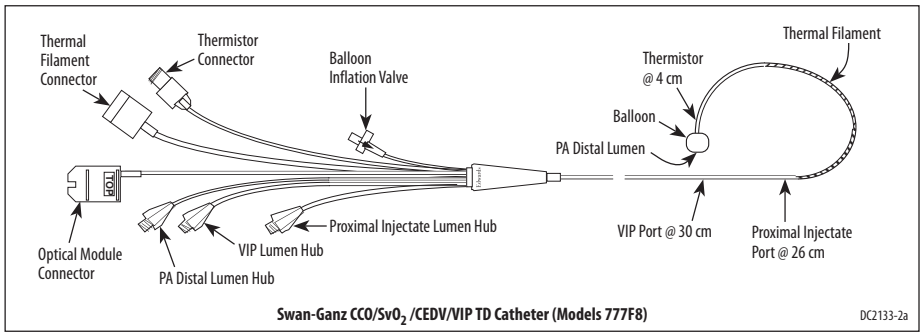
The CCO/SvO_2/VIP catheter (Models 139F75, 746F8, 777F8) provides an additional (VIP) lumen that allows for continuous infusion. The VIP lumen (proximal infusion lumen) terminates at a port located 30 cm from the distal tip. This port allows for infusion of solutions, pressure monitoring or blood sampling.

In addition to the capabilities listed above, models 177F75N, 774F75, 777F8 are designed to enable continuous end diastolic volume (CEDV) when used with the compatible cardiac output computer. To measure end diastolic volume continuously, the compatible cardiac output computer uses thermal energy emitted by the thermal filament located on the catheter, and an ECG monitor signal (preferably in lead II configuration) "slaved" into the compatible cardiac output computer (refer to the appropriate operator's manual for information regarding "slaving" techniques) to calculate ejection fraction using thermodilution principles. CEDV is then derived from the ejection fraction and cardiac output measurements.

Intended Use

The CCO/CEDV thermodilution catheter series is for use in patients who require hemodynamic monitoring. They are 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 continuously measure cardiac output. Models 744F75, 746F8, 774F75, and 777F8 also measure mixed venous oxygen saturation.

When used with the compatible cardiac output computer, models 177F75N, 774F75, and 777F8 also measure volumetric parameters, including right ventricular ejection fraction and end diastolic volume.



Swan-Ganz CCO/SvO_2/CEDV/VIP TD Catheter (Models 777F8) DC2133-2a

Indications

The primary indications for the Swan-Ganz CCO thermodilution 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

Models with CEDV capabilities are also indicated for volumetric determinations

Secondary indications include the following:

- Blood Sampling
- Infusion of saline and dextrose solutions

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.

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

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.

CCO monitoring should always be discontinued when blood flow around the thermal filament is stopped to avoid thermal tissue injury. Clinical situations where CCO monitoring should be discontinued include, but are not limited to:

- **Time periods when a patient is on cardiopulmonary bypass,**
- **Partial withdrawal of the catheter so that the thermistor is not in the pulmonary artery, or**
- **Removal of the catheter from the patient.**

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All other trademarks are the property of their respective owners.

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

Specifications

	Models 139F75, 177F75N	Models 744F75, 774F75	Models 746F8, 777F8
Body Color	yellow	yellow	yellow
Usable Length (cm)	110	110	110
Catheter Body	7.5F (2.5 mm)	7.5F (2.5 mm)	8F (2.7 mm)
Diameter of Inflated Balloon (mm)	13	13	13
Required Introducer Size	8.5F (2.8 mm)	8.5F (2.8 mm) or 9F (3.0 mm)	9F (3.0 mm)
Balloon Inflation Capacity (ml)	1.5	1.5	1.5
Distance from Distal Tip (cm)			
Thermistor	4	4	4
Thermal Filament	14-25	14-25	14-25
Injectate Port	26	26	26
VIP Port	30	-	30
Distance Between Markings (cm)	10	10	10
Lumen Volumes (ml)			
Distal Lumen	0.96	0.96	0.90
Injectate Lumen	0.8	0.95	0.85
Infusion Lumen	0.95	-	1.10
Infusion Rate* (ml/min)			
Distal Lumen	6	6	4
Injectate Lumen	9	14	9
VIP Lumen	16	-	16
Compatible Guidewire Diameter	0.025 in (0.64 mm)	0.018 in (0.46 mm)	0.018 in (0.46 mm)
Frequency Response Distortion at 10 Hz			
Distal Lumen	< 3 dB	< 3 dB	< 3 dB
Balloon Inflation Syringe	3 ml, limited to 1.5 ml	3 ml, limited to 1.5 ml	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.

This device is designed, intended, and distributed for single use only. Do not re-sterilize or reuse this device. There are no data to support the sterility, nonpyrogenicity, 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.

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.

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.

1. Swan-Ganz catheter
2. Percutaneous sheath introducer and contamination shield
3. Vigilance monitor for continuous cardiac output, mixed venous oxygen saturation and continuous end diastolic volume measurement (or other compatible cardiac output computer for measuring cardiac output by the bolus thermodilution method)
4. Injectate temperature sensing probe (if performing bolus thermodilution measurements)
5. Connecting cables
6. Model OM2 or OM2E Optical Module (Models 744F75, 746F8, 774F75, and 777F8)
7. Sterile flush system and pressure transducers
8. Bedside ECG and pressure monitor system
9. Appropriate ECG "slave" cables for CEDV models (177F75N, 774F75, and 777F8)

Catheter Models and Functions

	139F75	177F75N	744F75	774F75	746F8	777F8
ICO	X	X	X	X	X	X
CCO	X	X	X	X	X	X
SvO_2			X	X	X	X
VIP	X	X			X	X
CEDV		X		X		X

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.

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

This section only applies to the following models which have SvO_2 capability: 744F75, 746F8, 774F75, and 777F8.

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.

Catheter Preparation

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 or detach thermal filament leads from other circuit components if present.

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

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 page 4, Fig. 1, 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 page 4, Fig. 1, 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.
8. If using a compatible cardiac output computer for continuous cardiac output measurement, connect the thermistor and thermal filament to the monitor and observe the following message: "Press START to begin CCO monitoring."
9. If using a compatible cardiac output computer for CEDV measurement, connect the thermistor and thermal filament to the monitor and observe the following message: "Press START to begin CCO monitoring."

   Note: If proper ECG "slave" is implemented, CEDV measurement will begin.

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.

Computation Constants

For use with bath temperature probes

Models		139F75, 177F75N 744F75, 774F75	746F8, 777F8
Injectate Temp (°C)	Injectate Volume (ml)	Computation Constants (CC)***	
0 - 5	10	0.564	0.550
	5	0.257	0.256
	3	0.143	—
19 - 22	10	0.582	0.585
	5	0.277	0.282
	3	0.156	—
23 - 25	10	0.594	0.600
	5	0.283	0.292

Computation Constants for CO-Set+ Delivery System

6 °C - 12 °C	10	0.574	0.559
8 °C - 16 °C	5	0.287	0.263
18 °C - 25 °C	10	0.595	0.602
	5	0.298	0.295

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

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

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 4) 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.

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.

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.

Insertion of the thermal filament beyond the pulmonic valve may result in erroneous continuous cardiac output measurements.

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.

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.

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.

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.

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.

Cardiac Output Measurement

Continuous

Continuous cardiac output measurement is made by periodically warming the blood in the right atrium or ventricle with a known quantity of heat. The catheter thermistor detects the small change in blood temperature downstream, and the compatible cardiac output computer computes a dilution curve via a modified Stewart-Hamilton indicator dilution equation. This measurement technique is conducted without additional instrument calibration, material preparation, or operator intervention. If confirmation of the displayed continuous cardiac output value is deemed necessary, performing a bolus TD cardiac output measurement is recommended. Refer to the compatible cardiac output computer operator's manual for more information.

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*.

Continuous Volumetric Measurement

Continuous volumetric measurements are made by periodically warming the blood in the right atrium or ventricle with a known quantity of heat, and by sensing heart rate from a "slaved" ECG signal (refer to the appropriate operator's manual for information regarding "slaving" techniques). The catheter thermistor detects the small change in blood temperature downstream, and the compatible cardiac output computer computes an ejection fraction based on thermodilution principles. Subsequently, continuous stroke, end systolic and end diastolic volume measurements are derived from the ejection fraction and cardiac output measurements as follows:

CSV = CCO/HR
CEDV = CSV/CEF
CESV = CEDV - CSV
Where:
CSV = Continuous Stroke Volume
CCO = Continuous Cardiac Output
HR = Heart Rate
CEF = Continuous Ejection Fraction
CEDV = Continuous End Diastolic Volume
CESV = Continuous End Systolic Volume

This measurement technique is conducted without additional instrument calibration, material preparation or operator intervention. Refer to the compatible cardiac output computer operator's manual for more information.

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.

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:

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.

Pulmonary Infarction

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

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.

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.

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.

Other Complications

Other complications include right bundle branch block, complete heart block, tricuspid and pulmonic valve damage, thrombocytopenia, pneumothorax, thrombophlebitis, nitroglycerin absorption, 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.

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.

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.

Storage

Store in a cool, dry place.

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

Operating Conditions

Intended to operate under physiological conditions of the human body.

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.

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.

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.

These products are manufactured and sold under one or more of the following US patent(s): US patent No. 6,036,654; 6,045,512; and corresponding foreign patents.

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

Sterilized Using Ethylene Oxide

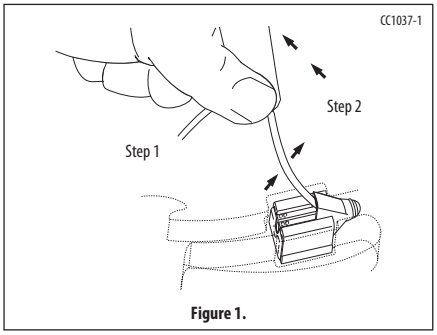

Figure 1.

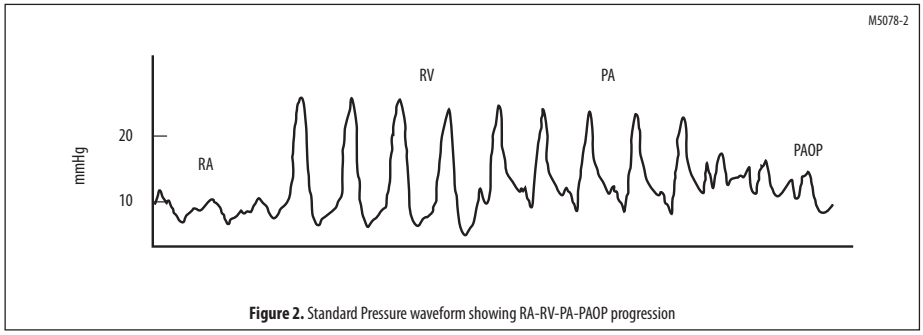

Figure 2. Standard Pressure waveform showing RA-RV-PA-PAOP progression

Symbol Legend

	English		English		English
	Number of Lumens	STERILE	Sterile	MR	MR Unsafe
	Exterior Diameter	STERILE EO	Sterilized Using Ethylene Oxide	MR	MR Safe
cm	Usable Length	STERILE R	Sterilized Using Irradiation	MR	MR Conditional
GW	Recommended Guidewire Size	STERILE	Sterile Using Steam or Dry Heat		Consult instructions for use
	Lumen Size	Rx only	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician.		Consult instructions for use
REF	Catalogue Number		Manufacturer		Do not resterilize
I	Minimum Introducer Size		Date of Manufacture		Non-pyrogenic
	Caution	LATEX	Contains or presence of natural rubber latex		Type B Applied Part
	Single use	PHT	Contains phthalates		Type CF Applied Part
#	Quantity	SZ	Size		Do not use if package is opened or damaged.
LOT	Lot Number		No components of this package or the products it contains are made from natural rubber latex or dry natural rubber.		Open
	Use By	40 °C 0 °C	Temperature Limitation		Aspirate Balloon -0.5 cc Before Introduction or Withdrawal.
	Inner Diameter	90% 5%	Humidity Limitation	EC REP	Authorized Representative in the European Community
BC	Balloon Capacity	eifu.edwards.com + 1 888 570 4016	Consult Instructions for use on the website	CE 0123	CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
		eifu.edwards.com + 1 888 570 4016	Follow Instructions for use on the website		

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

SGNHEMSL8x11.2

Edwards

EC REP

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CE 0123

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