



Edwards

Swan-Ganz

Hi-Shore True Size Thermodilution Catheters: 131F7, 131F7P, 141F7

Thermodilution Catheter (S-Tip): 151F7

VIP Thermodilution Catheters: 831F75, 831F75P

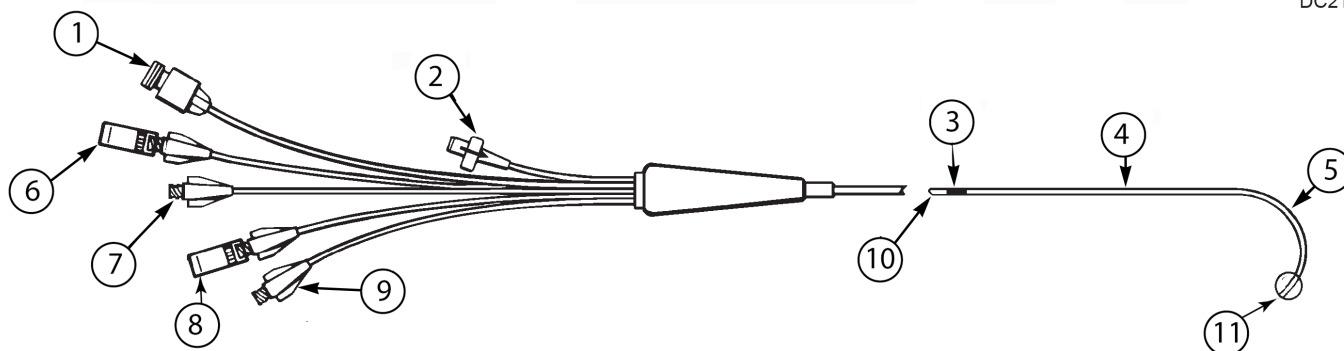
VIP+ Tri-Lumen Infusion Thermodilution Catheters: 834F75, 834F75P

True Size Thermodilution Catheters: TS105F5, 132F5

TS105F5 is not available in EU.

The devices described herein may not all be licensed in accordance with Canadian law or approved for sale in your specific country.

DC2141-1



Swan-Ganz VIP+ Tri-Lumen Infusion Thermodilution Catheter (Model 834F75)

1. Thermistor Connector
2. Balloon inflation Valve (Gate Valve)
3. RA Infusion Port @ 31 cm
4. RV Infusion Port @ 19 cm
5. Thermistor
6. RV Infusion Lumen Hub with heparin lock cap
7. PA Distal Lumen Hub
8. RA Infusion Lumen with heparin lock cap
9. Proximal Injectate Lumen Hub
10. Proximal Injectate Port @ 30 cm
11. PA Distal Lumen

Model 834F75 is illustrated. The models listed above contain some but not all of the features shown.

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

For Single Use Only

Please refer to Figure 1 on page 6 thru Figure 2 on page 6.

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 catheters are flow-directed pulmonary artery catheters used to monitor hemodynamic pressures. The distal (pulmonary artery) port on Swan-Ganz catheters allow sampling of mixed venous blood for the assessment of oxygen transport balance and the calculation of derived parameters such as oxygen consumption, oxygen utilization coefficient, and intrapulmonary shunt fraction when used with compatible hemodynamic monitor and accessories.

The Swan-Ganz Hi-Shore, CardioCath, and "S-Tip" thermodilution catheters (Models 141F7 and 151F7 respectively) have the same functions as the standard Swan-Ganz thermodilution catheter (Model 131F7). The "S-Tip" catheter (Model 151F7) is designed for

femoral vein insertion. The Swan-Ganz Hi-Shore thermodilution catheter (Model 141F7), is slightly stiffer than the standard Swan-Ganz catheter, and may be used when more torque control and maneuverability is needed (i.e., from the femoral approach). In addition to the standard distal (pulmonary artery) and injectate lumens, the Swan-Ganz VIP thermodilution catheter (Models 831F75, 831F75P) has an additional lumen that provides direct access to the right atrium. The Swan-Ganz VIP+ tri-lumen infusion thermodilution catheter (Models 834F75 and 834F75P) is equipped with a right atrium lumen and an additional lumen. The catheter's right ventricular (RV) lumen terminates 19 cm from the catheter tip and the right atrial (RA) lumen terminates at 31 cm. The VIP lumen allows for continuous infusion, even during cardiac output determinations.

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 the pediatric population or in pregnant or lactating women.

2.0 Intended Use / Purpose

Swan-Ganz catheters are pulmonary artery catheters intended for short-term use in the central circulatory system for patients who require intracardiac hemodynamic monitoring, blood sampling and infusing solutions. When used with a compatible monitoring platform and accessories, Swan-Ganz catheters offer a comprehensive hemodynamic profile to help clinicians assess cardiovascular function and guide treatment decisions.

3.0 Indications for Use

Swan-Ganz catheters are diagnostic and monitoring tools used for hemodynamic monitoring of adult critically ill patients including but not limited to post major surgical recovery, trauma, sepsis, burns, pulmonary disease, pulmonary failure, cardiac disease including heart failure.

4.0 Contraindications

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

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.

5.0 Warnings

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.

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.

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 intrapulmonary 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.

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, non-pyrogenicity and functionality of the device after reprocessing. Such action could lead to illness or an adverse event as the device may not function as originally intended.

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. Use of a Swan-Ganz Hi-Shore thermodilution catheter (Model 141F7) may be helpful in these patients. 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 (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; thermodilution catheter.
- Percutaneous sheath introducer and contamination shield.
- Compatible cardiac output computer, compatible injectate probe, and connecting cable or compatible computer.
- 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 Catheter Preparation

Use aseptic technique.

Visually inspect for breaches of packaging integrity prior to use.

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 if present.

Step	Procedure
1	Flush catheter lumens with a sterile solution to ensure patency and to remove air.
2	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.
3	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.
4	Test the thermistor's electrical continuity before insertion (refer to computer operations manual for detailed information).

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

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.

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	<p>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 6 shows the characteristic intracardiac and pulmonary pressure waveforms.</p> <p>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.</p>
3	<p>Using the syringe provided, inflate the balloon with CO₂ or air to the maximum recommended volume. Do not use liquid. Note that an offset arrow on the gate valve indicates the "closed" position.</p> <p>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.</p> <p>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.</p>
4	<p>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.</p> <p>Note: Avoid prolonged maneuvers to obtain wedge pressure. If difficulties are encountered, give up the "wedge".</p> <p>Note: Before re-inflation with CO₂ or air, completely deflate the balloon by removing the syringe and opening the gate valve.</p> <p>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.</p> <p>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.</p> <p>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.</p>
5	<p>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.</p> <p>Precaution: Do not pull the catheter across the pulmonic valve while the balloon is inflated to avoid damage to the valve.</p>
6	<p>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.</p> <p>Precaution: Overtightening the proximal Tuohy-Borst adaptor of the contamination shield may impair catheter function by potentially compressing and occluding the lumens.</p>
7	<p>Confirm final catheter tip position with chest X-ray.</p> <p>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.</p>

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.

10.0 Guidelines for Femoral Insertion

Fluoroscopy is recommended for femoral vein insertion.

Note: The "S-Tip" catheter is designed for femoral vein insertion only.

Precaution: Femoral insertion may lead to a redundancy of the catheter length in the right atrium and difficulties in obtaining a pulmonary artery wedge (occlusion) position.

Precaution: With femoral insertion, it is possible to transfix the femoral artery in some situations during percutaneous entry into the vein. Proper femoral vein puncture technique should be followed, including removal of the innermost occluding stylet when the insertion set needle is advanced toward the vein.

- When advancing the catheter into the inferior vena cava, the catheter may slip into the opposite iliac vein. Pull the catheter back into the ipsilateral iliac vein, inflate the balloon, and let the bloodstream carry the balloon into the inferior vena cava.
- If the catheter does not pass from the right atrium into the right ventricle, it may be necessary to change the orientation of the tip. Gently rotate the catheter and simultaneously withdraw it several centimeters. Care must be exercised so that the catheter is not kinked as it is rotated.
- If difficulty is encountered in positioning the catheter, a suitable sized guidewire may be inserted to stiffen the catheter.

Precaution: To avoid damage to intracardiac structures, do not advance the guidewire beyond the catheter tip. The tendency for thrombus formation will increase with the duration of guidewire use. Keep the period of time that the guidewire is used to a minimum; aspirate 2 to 3 ml from the catheter lumen and flush twice after guidewire removal.

11.0 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.

11.1 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.

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

11.2 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.

11.3 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.

11.4 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.

11.5 Catheter Contamination Shield

Secure distal Tuohy-Borst adapter to the catheter.

Extend the proximal end of the catheter contamination shield to desired length, and secure proximal Tuohy-Borst adapter to the catheter.

11.6 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.

11.7 General

Keep pressure monitoring lumens patent by intermittent flush or continuous slow infusion with heparinized saline solution or use of a heparin lock using the provided injection caps 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.

To use injection caps:

Step	Procedure
1	Disinfect injection caps before entry with syringe needle (see Complications).
2	Use a small bore needle (22 gauge (0.7 mm) or smaller) to puncture and inject through the injection caps.

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.

12.0 Cardiac Output Determination

To determine cardiac output by thermodilution, a known amount of sterile solution of known temperature is injected into the right atrium or vena cava, and the resultant change in blood temperature is measured in the pulmonary artery by the catheter thermistor. Cardiac output is inversely proportional to the integrated area under the resulting curve. This method has been shown to provide good correlation with the direct Fick method and dye dilution technique for cardiac output determination.

Consult the references on the use of iced versus room temperature injectate or open versus closed injectate delivery systems.

Refer to the appropriate cardiac output computer manual for specific instructions in the use of thermodilution catheters for cardiac output determination. Correction factors or computation constants needed to correct for indicator heat transfer are given in the specifications.

Edwards 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*.

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.

The general risks and complications associated with indwelling catheters are 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 which are associated with the development of fatal pulmonary artery rupture include pulmonary hypertension, advanced age, cardiac surgery with hypothermia and anticoagulation, distal catheter tip migration, and arteriovenous fistula formation and other vascular traumas.

Extreme care should therefore be exercised during the measurement of pulmonary artery wedge pressure in patients with pulmonary 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

Although usually transient and self-limited, arrhythmias may occur during insertion, withdrawal, and repositioning of the tip from the pulmonary artery into the right ventricle. Whereas premature ventricular contractions are the most commonly encountered arrhythmias, ventricular tachycardia and atrial and ventricular fibrillation have also been reported. ECG monitoring and the immediate availability of antiarrhythmic drugs and defibrillating equipment are recommended. Use of prophylactic lidocaine should be considered to decrease the incidence of ventricular arrhythmias during catheterization.

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 and complete heart block, tricuspid and pulmonic valve damage, pneumothorax, thrombosis, blood loss, cardiac structure/wall injury or damage, hematoma, embolism, anaphylaxis, and cardiac tissue/artery burn.

In addition, allergic reactions to latex have been reported. Physicians should identify latex sensitive patients and be prepared to treat allergic reactions promptly.

Refer to <https://meddeviceinfo.edwards.com/> for a Summary of Safety and Clinical Performance for this medical device. After the launch of the European Database on Medical Devices/Eudamed, refer to <https://ec.europa.eu/tools/eudamed> for a SSCP for this medical device.

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

14.7 Long Term Monitoring

The duration of catheterization should be the minimum required by the patient's clinical state since the risk of thromboembolic and infection 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.

15.0 How Supplied

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

The packaging 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.

16.0 Storage

Store in a cool, dry place.

17.0 Operating Conditions/Use Environment

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

18.0 Shelf Life

The shelf life is marked on each package. Storage or usage beyond the expiration date may result in product deterioration and could lead to illness or an adverse event as the device may not function as originally intended.

19.0 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: 01 821 1012 - Option 4

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

20.0 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.



Computation Constants						
Model	131F7, 131F7P, 141F7, 151F7		831F75, 831F75P	834F75 and 834F75P	132F5	TS105F5
Injectate Temp (°C)	Injectate Volume (ml)	Computation Constants (CC)***				
0-5	10	0.542	0.564	0.564	--	0.542
	5	0.247	0.262	0.257	0.270	0.255
	3	0.132	0.139	0.143	0.154	0.143
	1	--	--	--	0.037	--
19-22	10	0.578	0.588	0.582	--	--
	5	0.274	0.283	0.277	0.292	--
	3	0.154	0.158	0.156	0.170	--
	1	--	--	--	0.048	--
23-25	10	0.595	0.612	0.607	--	0.605
	5	0.287	0.301	0.294	0.307	0.297
	3	0.165	0.177	0.170	0.181	0.175
	1	--	--	--	0.055	--
Computation Constants for CO-Set+ closed injectate delivery system						
Cold Injectate						
6 °C - 12 °C	10	0.561	0.578	0.574	--	0.552
8 °C - 12 °C	5	0.259	0.272	0.287	0.285	0.265
Room Temperature						
18 °C - 25 °C	10	0.608	0.592	0.595	--	0.589
8 °C - 25 °C	5	0.301	0.290	0.298	0.307	0.289
***CC = (1.08)C _T (60)(V _I)						

Specifications

Function	Thermodilution catheter			Thermodilution and Infusion catheter		True Size catheter	
Model Number	131F7, 131F7P (Standard)	141F7 (Hi-Shore catheter)	151F7 ("S" Tip)	831F75, 831F75P (VIP catheter)	834F75, 834F75P (VIP+ catheter)	132F5**	TS105F5
Usable Length (cm)	110	110	110	110	110	75	100
Catheter Body French Size	7F (2.3 mm)	7F (2.3 mm)	7F (2.3 mm)	7.5F (2.5 mm)	7.5F (2.5 mm)	5F (1.7 mm)	5F (1.7 mm)
Body Color	-	-	-	-	-	-	-
Minimum Recommended Introducer Size	8F (2.7 mm)	8F (2.7 mm)	8F (2.7 mm)	8.5F (2.8 mm)	8.5F (2.8 mm)	6F (2.0 mm)	6F (2.0 mm)
Diameter of Inflated Balloon (mm)	13	13	13	13	13	8	8
Balloon Inflation Capacity (ml)	1.5	1.5	1.5	1.5	1.5	0.7	0.8
Distance from Tip (cm)							
Injectate Port	30	30	30	30	30	15	24
Infusion VIP Port	-	-	-	31	31	-	-
RV Infusion VIP+ Port	-	-	-	-	19	-	-
Thermistor	4	4	4	4	4	1.5	-
Lumen Volume (ml)							
Distal Lumen	1.02	1.01	1.02	0.86	0.89	0.64	0.67
Injectate Lumen	0.81	0.81	0.81	0.86	0.75	0.57	0.58
VIP/RA Lumen	-	-	-	0.87	0.97	-	-
RV Lumen	-	-	-	-	0.93	-	-
Infusion Rate* (ml/min)							
Infusion VIP Lumen	-	-	-	13	14	-	-
RV Infusion VIP+ Lumen	-	-	-	-	7	-	-
Distal Lumen	-	-	-	-	5	-	1.7
Proximal Injectate Lumen	-	-	-	-	9	-	2.6
Maximum Guidewire Diameter							
Distal Lumen	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.025 in (0.64 mm)	0.020 in (0.51 mm)	0.018 in (0.46 mm)
Frequency Response Distortion at 10 Hz							
Distal Lumen	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB	< 3 dB

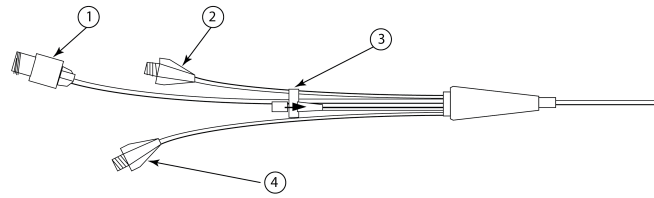
All specifications given are nominal values. A syringe is provided with each catheter.

* Using normal saline at room temperature, 1 m above insertion site, gravity drip; rates represent average values.

**In situations where the insertion site or patient physiology requires a larger insertion distance, a longer catheter model or larger introducer size should be selected.

Figures

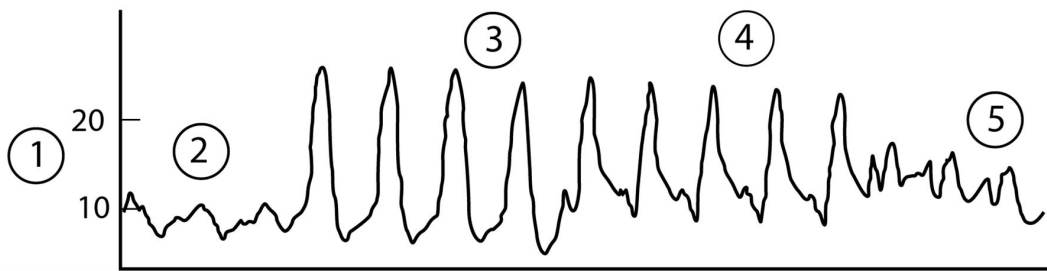
DC2146-1



1. Thermistor Connector
2. Injectate Lumen Hub
3. Balloon Inflation Valve
4. Distal Lumen Hub

Figure 1: Swan-Ganz ControlCath Thermodilution Catheter or Swan-Ganz Torque Support Thermodilution Catheter

M5078-12



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

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

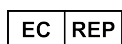
Symbol Legend

	English
	Number of lumens
	Exterior diameter
	Usable length
	Recommended guidewire size
	Lumen size
	Model Number
	Minimum introducer size
	Caution
	Do not re-use
	Quantity
	Lot Number
	Use-by date
	Inner diameter
	Balloon capacity
	Keep dry
	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
	Not made with natural rubber latex
	Size
	Consult instructions for use on the website
	Follow instructions for use on the website
	MR Unsafe
	MR Safe
	MR Conditional
	Consult instructions for use or consult electronic instructions for use
	Follow instructions for use

	English
	Do not re-sterilize
	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
	Importer
	Store in a cool, dry place
	Double sterile barrier system
	Fragile, handle with care
	This way up
	Unique device identifier

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



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