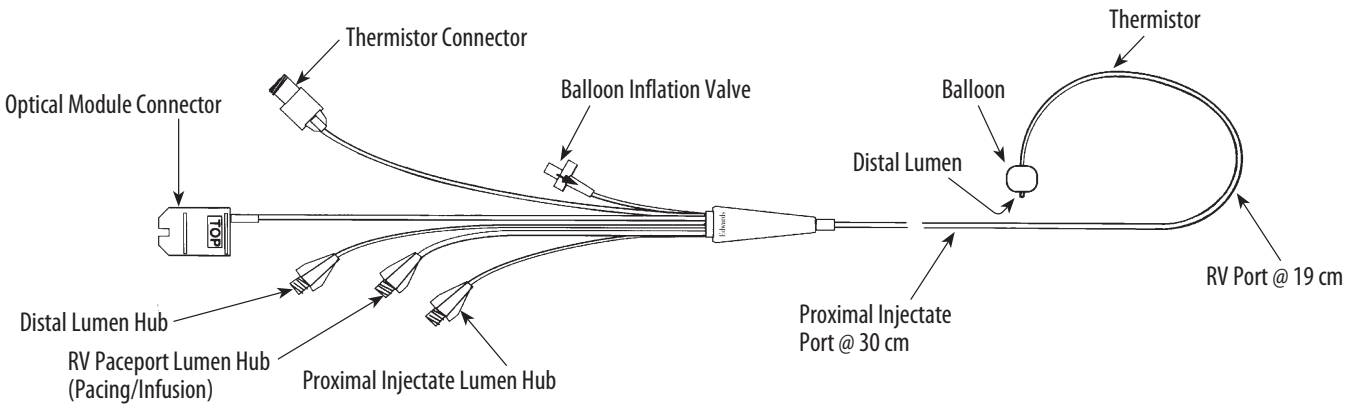
Edwards

Swan-Ganz Oximetry TD Catheters

Oximetry Catheter: 631F55N
Oximetry Paceport Catheter: 780F75M
VIP Oximetry Catheter: 782F75M



Swan-Ganz Oximetry Paceport TD Catheter Model 780F75M

Model 780F75M is illustrated. The models listed above contain some but not all of the features shown.

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 figure 1 please refer to page 7.

Description

The family of Swan-Ganz oximetry TD (thermodilution) catheters serves as diagnostic tools for the physician to continuously monitor mixed venous oxygen saturation. When used with an Edwards Lifesciences oximetry monitor or compatible bedside module system, or a compatible cardiac output computer it also monitors cardiac output.

Model 631F55N Swan-Ganz oximetry TD catheters enable monitoring of hemodynamic pressures, cardiac output, and continuous mixed venous oxygen.

Model 782F75M Swan-Ganz VIP oximetry TD catheters enable monitoring of hemodynamic pressures, cardiac output, and provide an additional (VIP) lumen that allows for continuous infusion. The VIP lumen terminates at a port located 31 cm from the distal tip. The VIP lumen provides direct access to the right atrium or vena cava and allows for continuous infusion of solutions, pressure monitoring or blood sampling.

Model 780F75M Swan-Ganz oximetry Paceport TD catheter is intended for use in patients who require hemodynamic monitoring when temporary transvenous pacing is anticipated. The oximetry Paceport catheter's right ventricular (RV) lumen terminates 19 cm from the tip and is used for the insertion of a model D98100 Chandler transluminal V-pacing probe into the right ventricle when the tip of the catheter is in the pulmonary artery. When the pacing probe is not inserted, the right ventricular lumen may be used for right ventricular pressure monitoring or infusing solutions.

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 oximetry lumen 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.

The proximal injectate lumen terminates at a port located 30 cm from the distal tip for models 780F75M and 782F75M; it terminates at 15 cm for model 631F55N. 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.

Indications

Swan-Ganz oximetry TD catheters are indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring, cardiac output determination, continuous mixed venous oxygen saturation monitoring, and for infusing solutions.

The oximetry Paceport catheters (model 780F75M) are also indicated for standby

temporary ventricular pacing using the model D98100 Chandler transluminal V-pacing probe.

For all models, the distal (pulmonary artery) port also allows 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.

Contraindications

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.

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.

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.

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 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, 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 oximetry TD catheter or oximetry Paceport TD catheter or VIP oximetry catheter
2. Percutaneous sheath introducer and contamination shield
3. An Edwards Lifesciences oximetry monitor or compatible bedside module system (or any compatible cardiac output computer for measuring cardiac output by the bolus thermodilution method)
4. Injectate temperature sensing probe
5. Connecting cables
6. Model OM-2 optical module
7. Chandler transluminal V-pacing probe (model D98100) (for use with oximetry Paceport catheters model 780F75M only)
8. Ventricular demand external pacemaker (for use with oximetry Paceport catheter model 780F75M and Chandler probe model D98100)
9. Sterile flush system and pressure transducers
10. 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.

All Edwards oximetry catheters, except those with black oximetry connectors, are compatible with Edwards optical modules. Models ending with the letter 'P' are also compatible with Philips optical modules. The Catheter Factor required for *in vivo* calibration with Philips monitors is located on the top of the optical connector.

Monitor Set Up and Calibration for Mixed Venous Oxygen Saturation Monitoring

Precaution: *In vitro* calibration cannot be performed with catheter model 631F55N. For proper calibration, the catheter must be inserted into the patient and an *in vivo* calibration performed (see appropriate operations manual for *in vivo* calibration procedures).

The compatible cardiac output computers 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.

Note: To avoid damaging the balloon, do not pull the balloon through the silicone gripper.

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 optical fibers and/or thermistor wire circuitry, if present.

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).

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.

For ease of insertion when temporary transvenous pacing is anticipated, the model D98100 Chandler transluminal V-pacing probe should be placed prophylactically into the RV lumen immediately after placement of the oximetry Paceport catheter (Model 780F75M). Difficulty in probe passage may be encountered if probe insertion is attempted more than 24 hours after catheter placement.

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:

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 1 (on page 7) 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 re-inflation 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.

   Precaution: Do not pull the catheter across the pulmonic valve while the balloon is inflated.

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.

   Warning: Do not advance the catheter beyond the wedge position to avoid pulmonary artery rupture.

7. Confirm final catheter tip position with chest X-ray.

   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.

   Precaution: Overtightening the proximal Tuohy-Borst adapter of the contamination shield may impair catheter function.

8. To properly place the oximetry Paceport catheter model 780F75M for the insertion of the Chandler probe, consult the instructions for use included with each probe. The ideal placement of the RV port of the oximetry Paceport catheter is 1 to 2 cm distal to the tricuspid valve. Therefore, it is recommended that distal and RV lumen pressures be simultaneously monitored during insertion of the catheter. For proper placement of the RV port of the oximetry Paceport catheter, pull the RV port back into the right atrium and then advance the port 1 to 2 cm distal to the tricuspid valve.

   Note: A radiopaque marker is provided at the RV port to aid in port placement and identification by chest X-ray film or fluoroscopy.

   Advance the catheter into the pulmonary artery wedge position while simultaneously monitoring the distal and RV lumen pressures. Deflate the balloon.

   For precautions and a detailed description of the insertion procedure for the pacing probe, consult the package insert provided with each probe.

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.

Guidelines for Femoral Insertion

Fluoroscopy is recommended for femoral vein insertion.

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.

It is recommended that femoral insertion of the oximetry Paceport catheter model 780F75M and Chandler probe model D98100 be done under fluoroscopy.

Femoral insertion should be used only when short-term pacing is required (e.g., cath lab procedures) because of the possible placement of the Chandler probe in the RV outflow tract. Because of the characteristic shorter loop in the right ventricle as a result of the femoral insertion, the Chandler probe D98100 may become oriented towards the RV outflow tract, rather than the apex. This orientation may adversely affect stability of long-term pacing. In addition, the shorter catheter loop may require advancing the catheter tip into the peripheral pulmonary artery to position the RV port just distal to the tricuspid valve, possibly resulting in permanent wedge or difficulties in measuring wedge pressure.

- 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.

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.

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 re-inflation 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 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*.

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.

Computation Constants

Model		780F75M, 782F75M	631F55N
Injectate Temp (°C)	Injectate Volume (ml)	Computation Constants (CC)*	
0 - 5	10	0.564	—
	5	0.257	0.265
	3	0.143	0.148
	1	—	0.032
19 - 22	10	0.582	—
	5	0.277	0.294
	3	0.156	0.172
	1	—	0.049
23 - 25	10	0.607	—
	5	0.294	0.308
	3	0.170	0.183
	1	—	0.057

Computation Constants for CO-Set+

Cold Injectate			
6 °C - 12 °C	10	0.574	—
8 °C - 16 °C	5	0.287	0.284
	3	—	0.169
Room Temperature			
18 °C - 25 °C	10	0.595	—
	5	0.298	0.306
	3	—	0.182

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

Note: Computation constants for oximetry catheters are the same as for the Swan-Ganz VIP Catheter.

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 which are associated with fatal pulmonary artery rupture include pulmonary hypertension, advanced age, cardiac surgery with hypothermia and anticoagulation, distal catheter 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. EKG monitoring and immediate availability of antiarrhythmic drugs and defibrillator equipment is recommended.

Hemorrhage

The use of heparin infusions to maintain the patency of vascular catheters has been associated with germinal matrix-intraventricular hemorrhage in infants with birth weights under 2000 grams.

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.

Specifications

Functions Model Number	Oximetry 631F55N**	Oximetry Paceport 780F75M	VIP Oximetry 782F75M
Usable Length (cm)	75	110	110
Catheter Body French Size	5.5F (1.8 mm)	7.5F (2.5 mm)	7.5F (2.5 mm)
Body Color	White	Yellow	Yellow
Required Introducer Size	6.5F (2.2 mm)	8.5F (2.8 mm)	8.5F (2.8 mm)
Diameter of Inflated Balloon (mm)	8	13	13
Balloon Inflation Capacity (ml - CO_2)	0.7	1.5	1.5
Thermistor (cm from tip)	1.5	4	4
Injectate Port (cm from tip)	15	30	30
RV Port (cm from tip)	—	19	—
VIP Infusion Port (cm from tip)	—	—	31
Infusion Rates* (ml/min)			
RV (without probe)	—	13	—
Distal Lumen	3	6	6
Injectate Lumen	4	9	8
VIP Lumen	—	—	14
Lumen Volume (ml)			
Distal Lumen	0.49	—	—
Injectate Lumen	0.51	—	—
Compatible Guidewire Diameter			
Distal Lumen	0.012 in. (0.30 mm)	0.025 in. (0.64 mm)	0.025 in. (0.64 mm)
Frequency Response			
Distortion at 10 Hz			
Distal Lumen	< 3 dB	< 3 dB	< 3 dB
Total Catheter Sensing Function			
Accuracy, Normalized @ 37 °C	—	0.5%	0.5%

All specifications given are nominal values.

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

All Edwards oximetry catheters, except those with black oximetry connectors, are compatible with Edwards optical modules. Models ending with the letter "P" are also compatible with Philips optical modules. The Catheter Factor required for *in vivo* calibration with Philips monitors is located on the top of the optical connector.

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

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, thrombosis, and heparin-induced thrombocytopenia. 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 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.

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

Sterilized Using Ethylene Oxide

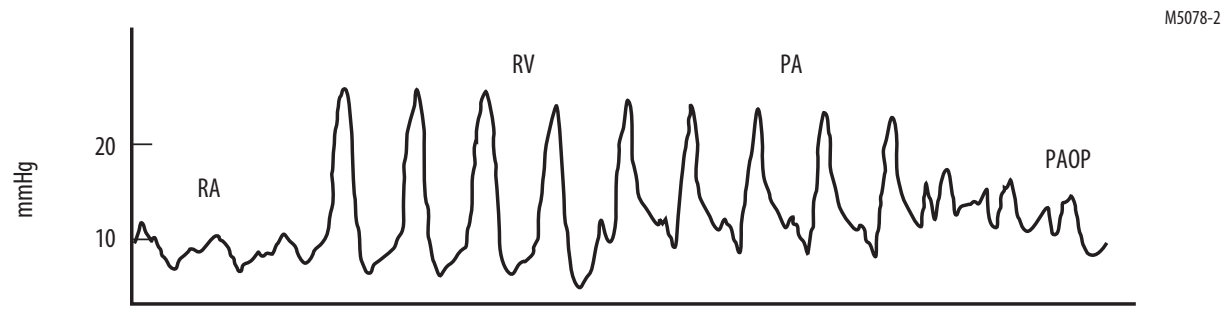


Figure 1. Standard Pressure Waveform showing RA-RV-PA-PAOP progression

Symbol Legend

	English		English		English
	Number of Lumens		Sterile		MR Unsafe
	Exterior Diameter		Sterilized Using Ethylene Oxide		MR Safe
	Usable Length		Sterilized Using Irradiation		MR Conditional
	Recommended Guidewire Size		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
	Catalogue Number		Manufacturer		Do not resterilize
	Minimum Introducer Size		Date of Manufacture		Non-pyrogenic
	Caution		Contains or presence of natural rubber latex		Type B Applied Part
	Single use		Contains phthalates		Type CF Applied Part
	Quantity		Size		Do not use if package is opened or damaged.
	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		Temperature Limitation		Aspirate Balloon -0.5 cc Before Introduction or Withdrawal.
	Inner Diameter		Humidity Limitation	EC REP	Authorized Representative in the European Community
	Balloon Capacity		Consult Instructions for use on the website eifu.edwards.com		CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
	Keep dry		Follow Instructions for use on the website eifu.edwards.com		

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

SGNHEMSL8x11.3

Edwards

EC REP

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WEB IFU
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DOC-0059536 B