COMPUTATION CONSTANTS for the use of BIOPTIMAL Thermodilution catheter

	COMPUTATION CONSTANTS								
Temperature (˚C)	Injectate Volume (CC)	TD 1504 5F	TD1604 6F	TD1704 7F	TD1755 7.5F	TD2504 5F	TD2604 6F	TD2704 7F	TD2755 7.5F
	10	-	0.555	0.542	0.564	-	0.555	0.542	0.564
0	5	0.274	0.265	0.247	0.257	0.274	0.265	0.247	0.257
To	3	0.154	0.152	0.132	0.143	0.154	0.152	0.132	0.143
+5	1	0.037	-	-	-	0.037	-	-	-
	10	-	0.572	0.595	0.607	-	0.572	0.595	0.607
+23	5	0.307	0.275	0.287	0.294	0.307	0.275	0.287	0.294
To	3	0.181	0.159	0.165	0.170	0.181	0.159	0.165	0.170
+25	1	0.055	-	-	-	0.055	-	-	-

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

WARRANTY

BIOPTIMAL warrants all its products free from defect in workmanship and materials under proper use and handling. This warranty is in lieu of all other warranties, whether expressed or implied, including any warranty of merchantability, suitability or fitness for a particular purpose since handling, storage as well as factors relating to the patient, his diagnosis, treatment, surgical procedures, and other matters beyond BIOPTIMAL'S control, directly affect BIOPTIMAL'S products and the results obtained from their use. BIOPTIMAL shall not be liable for any incidental or consequential loss, damage, or expense directly arising from the use of its products. BIOPTIMAL neither assumes, nor authorizes any other person to assume for it, any other additional liability or responsibility in connection with its products.

TECHNICAL ASSISTANCE

For further information or assistance relating to the BIOPTIMAL products, please contact:

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Bioptimal™

INSTRUCTIONS FOR USE OF THERMODILUTION CATHETER AND KITS

Read Instruction Manual Before Use

Do Not Use If Package Is Damaged

Sterile And Non-Pyrogenic

Keep From Direct Sunlight

For Single Use Only

Presence of Phthalates (DEHP)

Do Not Re-sterilize

Non-Pyrogenic

Keep Dry

READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS CAREFULLY PRIOR TO USE.

GENERIC MODELS

TD1504N TD1604N TD1704N TD1755N
TD2504N TD2604N TD2704N TD2755N

DEVICE DESCRIPTION

BIOPTIMAL Thermodilution catheters are extruded polyvinylchloride (PVC) or polyurethane (PU) tubing with a French Size of 5F, 6F, 7F or 7.5F, connected to a hub carrying 4 or 5 lumens with a total length of 90 or 110 cm. The extensions tubings comprise a proximal and distal extension of 5F or 7F, a thermistor extension of 5F or 7F and an inflation extension of 6F. Catheters can be supplied with or without built-in contamination shields and/or safetywedge as optional features.

Kits's alternate name is Biotray, Biotray is a more comprehensive procedure pack with an extended list of accessories and a catheter. This IFU only reflects the operation instructions related to Thermodilution catheter, and the operation instructions related to the accessory of Biotray can refer to IFU 51-000019-00.

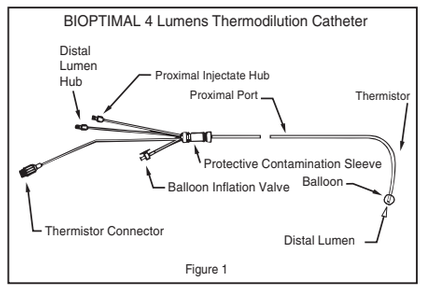

Figure 1

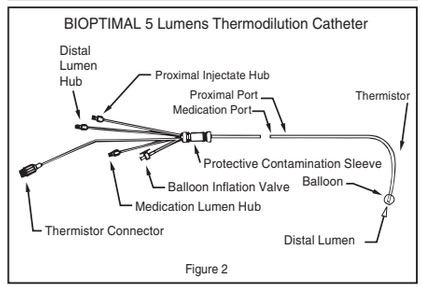

Figure 2

INDICATIONS AND INTENDED USE

BIOPTIMAL thermodilution catheters are designed for use in critical care patients to measure cardiac output, right atrium, pulmonary artery and pulmonary capillary wedge pressures; continuously monitor pulmonary artery temperature, sample blood and administer drugs and solutions intravenously and measure cardiac output via the computers which interface with 14k ohm catheters.

The tips of the catheters are mounted with a latex balloon which, when inflated, protects the heart tissues from the product's tips during insertion; utilizes blood flow to direct the catheter tip through the right ventricle into the pulmonary artery. Different models are available for use in pediatric and adult patients.

Device is intended to be used by trained clinicians who are aware of the benefits and risks of the catheter usage.

CVP Proximal Lumen:

At full insertion, this port will reside in the right atrium, allowing for injection of the thermal bolus during cardiac output determination, blood sampling or drug administration, and central venous pressure monitoring.

Thermistor Lumen:

The lumen provides the electrical connection for cardiac output computations and measurement of pulmonary artery blood temperature.

PA Distal Lumen:

This lumen terminates into a port at the catheter tip and is used to monitor the catheter location during insertion. At full insertion, this port will reside in the pulmonary artery allowing the pulmonary artery and pulmonary capillary wedge pressure measurements, and mixed venous blood sampling.

Balloon Lumen:

This lumen terminates in a latex balloon near the catheter tip and is used to inflate and deflate the balloon to facilitate advancement of the catheter and provides measurement of pulmonary capillary wedge pressure.

Medication Lumen (for TD1755 and TD2755 model only):

This Lumen may be used for infusion of solutions, pressure monitoring, cardiac output injections, and blood withdrawal.

Note: Administration of blood through the 5-lumen catheter is not recommended.

CONTRAINDICATIONS

1. Catheter with natural latex balloon is contraindicated for patient with known or suspected allergy to natural rubber latex.
2. Absolute contraindications to cardiac catheterization include tricuspid or pulmonary valvular Stenosis, right atrial or right ventricular masses (tumor or thrombus) and Tetralogy of fallot.
3. Relative contraindications to cardiac catheterization include unstable ventricular rhythm, heart block and temporary transvenous pacemaker (wire dislodgement).

PRECAUTIONS

1. This product is designed for single use only. Do not reuse or resterilize the catheter.
2. Do not use catheter after indicated expiration date printed on the tyvek lid of the package.
3. Do not use catheter or components if package is opened or damaged as contents may lose sterility.
4. To avoid damage to the catheter or balloon when a cut-down is used, it is recommended that a vessel dilator or disposable vein guide be used. NEVER use forceps on the catheter.
5. Always deflate the balloon by removing the syringe, and always deflate the balloon prior to withdrawing the catheter.

6. Never use liquid for balloon inflation. Liquid within the balloon inflation lumen may cause the balloon to stay inflated even after removal of the inflation syringe.
7. To minimize infection, it is generally recommended that the catheter should not be left in the patient for longer than three days.
8. Do not advance the catheter after it has been set in place; the portion of the catheter left outside the body may not be sterile. If a catheter sterility sheath is used, the catheter may be repositioned as needed.
9. To determine wedge pressure, inflate balloon slowly, stopping when PA waveform changes to wedge pressure waveform. Deflate balloon after completing measurement.
10. Use filtered CO_2 for balloon inflation in any situation where balloon rupture may result in air embolus entering the arterial circulation, as in a right-to-left shunt.
11. To minimize ventricular irritation, always inflate the balloon before the catheter reaches the right ventricle.
12. To avoid balloon rupture during inflation, do not exceed the recommended balloon inflation volume (1.5cc for 7F and 7.5F, 1.00cc for 6F and 0.75cc for 5F).
13. Initial placement of the catheter in the pulmonary artery should always be made with the maximum recommended balloon inflation volume. An under-deflated balloon will be smaller, allowing the catheter to be positioned in a narrower portion of the pulmonary artery. This may increase the likelihood of spontaneous wedging.
14. A flow directed catheter may migrate into the distal pulmonary artery, and spontaneous wedging may occur. To detect the occurrence of spontaneous wedging, the PA pressure waveform should be monitored continuously or at short intervals.
15. The biological activity of the thrombo-resistant coating used on the latex balloon is initiated by blood contact, therefore the efficiency of the coating is guaranteed for one patient use only.
16. Used catheter must be properly disposed as biohazard material and processed according to facility protocol.
17. The package is designed to prevent kinking to the catheter. A damaged catheter cannot be repaired. The catheter balloon is fragile; therefore, reasonable care should be employed when removing the catheter from the package.
18. Ensure that sampling/distribution devices are connected to the right extension of the catheter.

WARNINGS

1. Please use product with contamination shield.
2. This device is intended for single patient use only.
3. **DO NOT** resterilize and/ or reuse this device, as this can compromise its performance and can lead to device failure and procedure complications with severe injury or patient death. Reuse and resterilisation bear the risk of cross contamination and patient infection and may also cause transmission of infectious diseases from patient to patient..

INSTRUCTIONS FOR USE

Read carefully your hospital's policies, rules and procedures relating to the use of thermodilution catheters, if any.

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.

Preparation and Use of Catheter:

1. Inspect the catheter package to ensure that it has not already been opened or damaged. The catheter will lose its sterility and become pyrogenic if the package is opened or damaged.
2. Flush the catheter lumens with sterile solution to ensure patency and air-free.
3. Test the latex balloon for leakage by inflating it with 1.5cc of either bacteria-filtered CO_2 or air under sterile solution for 7F and 7.5F catheters (1.0cc for 6F and 0.75cc for 5F).

CAUTION: REMOVE THE BALLOON COVER BEFORE CONDUCTING THE BALLOON INFLATION TEST.

4. Check thermistor integrity by connecting the catheter electrical connector to the cardiac output computer according to the computer manufacturer's instruction, and observe that there is no sign of fault.
5. Read carefully the instruction manual of your instruments for additional information.

Catheter Insertion:

1. Insert the catheter into the vein by either the percutaneous or cutdown technique. However, as the cutdown technique will prolong the closure of surgical wound, percutaneous insertion is preferred.
2. Under continuous pressure monitoring, with or without fluoroscopy gently advance the catheter into the superior or inferior vena cava and right atrium.
3. Should the catheter require stiffening during insertion, slowly inject 5 to 10 cc of cold sterile solution (0.9% Saline or 5% Dextrose) via the Distal lumen as the catheter is advanced.
4. Entry of the catheter tip into the thorax is indicated by an increased respiratory fluctuation in pressure.
5. At this point inflate the balloon with either bacteria-filtered CO_2 or air to the recommended volume printed on the inflation catheter body.
6. Advance the catheter until pulmonary capillary wedge pressure is obtained, and then deflate the balloon. The catheter should pass easily through the right ventricle and pulmonary artery and into a wedge position.
7. Reinflate the balloon to determine the inflation volume necessary to obtain wedge tracing. Deflate the balloon. If a wedge is obtained with volume substantially less than the recommended volume printed on the catheter, then the catheter must be withdrawn slightly.
8. Figure 3 shows the standard pressure waveform of the heart and pulmonary circulation during catheter insertion.

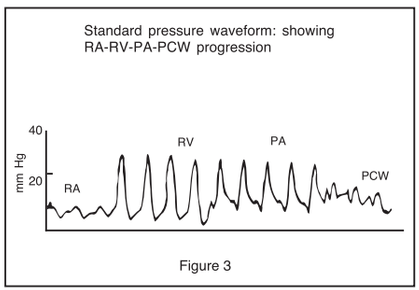

Figure 3

Maintenance and Use in situ

The Catheter should remain indwelling only as long as is required by the patient's condition. However, physician should note that the incidences of complications increase significantly with indwelling periods longer than 72 hours (Ref 12).

Cardiac Output Computation:

Device is to be used with a compatible monitor that shall be approved accordance to IEC60601-1 and must be a CE or FDA approved monitor. Refer to the operating instruction manual provided with your cardiac output computer for specific instructions in the use of thermodilution catheters for cardiac output computation.

A Correction Factor or Computation Constant is required to account for the mixture of cold indicator with the warm residue fluid in the catheter injection lumen and the heat transfer from the catheter walls to the cold indicator. These factors are provided below.

COMPLICATIONS

All invasive procedures inherently involve some patient risks. Although serious complications associated with Thermodilution catheters are relatively uncommon, the physician is advised to weigh the potential benefits and risks associated with the use of the catheter against alternative procedures before deciding to use the catheter.

Strict adherence to the given instructions and awareness of the possible risks reduces the incidences of the complications. Several known complications described in literatures are as follows:

Perforation of the Pulmonary Artery

Causes of pulmonary artery rupture during the use of the flow-directed balloon-tipped catheters are pulmonary hypertension, advance age and distal tip migration (Ref 7 and 14). Factors that predispose to ventricular perforation during catheterization include small chamber size, stiff catheter, outflow tract obstruction, and myocardial infarction (Ref 6).

Pulmonary Infarction

Over-inflation of balloon and tip migration with spontaneous wedging, air embolism, and thromboembolism are factors of this complication (Ref 4, 9 and 13).

Cardiac Arrhythmias

Cardiac arrhythmias may occur during catheter insertion and removal but are usually associated with transient hypotension (Ref 1). Ventricular arrhythmias are the most commonly observed. Predisposing factors of ventricular arrhythmias are myocardial infarction or ischemia, shock, acidosis, hypoxia and electrolyte disturbances (Ref 3 and 10). Use of prophylactic lidocain should be considered to reduce the incidence of ventricular arrhythmias during catheter catheterization (Ref 11).

Kinking, Looping and Knotting

Soft flexible and excessive length catheters are often reported to have looped or knotted. Loose knot can be untied by a radiologist using guide wires under fluoroscopy control. Alternatively, knot can be gently tightened and withdraw the catheter percutaneously together with the introducer sheath through the entry site (Ref 2 and 5).

Sepsis/Infection

Catheter infections have been reported due to poor aseptic technique at the time of insertion or during subsequent use, contamination infusion fluids and devices used in the cardiac surgery, ingrown of organisms from the skin along the catheter as well as hematogenous spread from remote foci (Ref 7 and 9). Preventive measures are recommended to guard against all possible infections, including the practice of aseptic technique, application of topical antibiotics ointment, and frequent sterile dressing changes.

Air Embolism

Air embolism is an uncommon but potentially catastrophic event which occurs as a consequence of the entry of air into the vasculature. Efforts should be made to reduce the risk of air embolism during mechanical ventilation and central line placement.

Other Complications

Other complications include right bundle branch block, complete heart block, pneumothorax, venous thrombosis thrombophebitis and triscupid valve injury (7.5 In addition, allergic reactions to latex have been reported. Before using catheter, physicians should identify latex sensitive patients and prepare to treat the allergic reactions promptly.

PACKAGING AND STERILITY

Product is supplied sterile and non-pyrogenic if package is undamaged or unopened. Do not use if package is opened or damaged. Catheters are for single use only. Do not clean or resterilized a used catheter.

STORAGE

BIOPTIMAL Thermodilution Catheter and Kits should be stored unopened in its original packaging in dark, cool dry places.

SHELF-LIFE

The recommended shelf-life is indicated on each package. Storage beyond the stated time may result in balloon deterioration, since the balloon is acted upon and deteriorated by the atmosphere.

SPECIFICATIONS of BIOPTIMAL Thermodilution Catheter

MODEL	TD1504	TD1604	TD1704	TD1755	TD2504	TD2604	TD2704	TD2755
Usable Length (cm)	90 /110	110	110	110	90 /110	110	110	110
Catheter Body French Size	5F	6F	7F	7.5F	5F	6F	7F	7.5F
Body Color	White	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow
Required Introducer Size	6F	7F	8F	8.5F	6F	7F	8F	8.5F
Balloon Inflation Capacity (cc)	0.75	1.0	1.5	1.5	0.75	1.0	1.5	1.5
Number of Lumen	4	4	4	5	4	4	4	5
Proximal Port Location (cm from tip)	15	29	29	29	15	29	29	29
Thermistor Location (cm from tip)	1.5	3.5	3.5	3.5	1.5	3.5	3.5	3.5
Medication Port (cm from tip)	N.A	N.A	N.A	3	N.A	N.A	N.A	31
Distance Between Length Marking	10	10	10	10	10	10	10	10
External Catheter Body	Polyvinylchloride Material				Polyurethane Material			