OBSERVE PRECAUTIONS FOR HANDLING ELECTROSTATIC SENSITIVE DEVICES

Mikro-Tip® Implantable Catheter Pressure Transducer

Animal Use Only

Instructions for Use
Service Provision
Consult web site below for service information:

www.millarimeters.com

Millar Limited Warranty

Millar Instruments, Inc. warrants that at the time of sale to the original purchaser, the device was free from defects in both materials and workmanship. For a period of 182 days (6) months from the date of original shipment to the original purchaser, Millar will, at no charge and at its option, either repair or replace any Mikro-Tip transducer found to have been shipped with defects in either materials or workmanship. Our warranty does not cover damage to the product from alterations, misuse, abuse, negligence, or accident.

Millar hereby excludes all warranties not herein stated, whether expressed or implied by operation of law or course of dealing or trade usage or otherwise, including but not limited to any implied warranties of fitness or merchantability.

Since handling, storage, cleaning and sterilization of the product, as well as factors relating to patient diagnosis, treatment, catheterization procedures, and other matters beyond Millar’s control, directly affect the product and the results obtained from its use, Millar shall not be liable for any incidental or consequential loss, damage, or expense arising directly or indirectly from the use of this product.

The user shall determine suitability for use of these medical devices for any surgical or clinical procedure. Therefore, the user accepts these devices subject to all the terms hereof. Further, Millar makes no warranty regarding device efficacy after one (1) year from the date of manufacture.
Recommended Accessories

M.I. P/N: 851-5918, Model TC-510 Control Unit, No patient isolation
M.I. P/N: 880-0129, Model PCU-2000 Control Unit with Patient Isolation
M.I. P/N: 850-1118, Model TEC-5C Extension Cable
M.I. P/N: 850-1108, Model TEC-10C Extension Cable
M.I. P/N: 850-1308, Model TEC-10D Extension Cable
M.I. P/N: 850-5088, Model PEC-1.5C Extension Cable to PCU-2000
M.I. P/N: 850-5089, Model PEC-10C Extension Cable to PCU-2000
M.I. P/N: 850-5103, PEC-4D Extension Cable to PCU-2000
M.I. P/N: 850-5090, PEC-10D Extension Cable to PCU-2000
Monitor Input Cables as appropriate for monitor.
All accessories sold separately.

Definition of Symbols

- **Attention, consult accompanying documents**
- **Date of Manufacture**
- **Catalog Number**
- **Serial Number**
- **Batch Code**
- **Use By Date**
- **Electrostatic Sensitive Device**
- **EU Declaration of Conformity**

Device Description

Mikro-Tip catheters consist of an ultra-miniature pressure sensor at the distal end of a catheter. The implantable part of the catheter terminates in an implantable skin button female connector. The catheter is supplied with an extension cable with a male connector that mates with the skin button connector, and has an electrical connector at the proximal end. The pressure sensor produces an electrical output signal, which varies in direct proportion to the magnitude of sensed pressure or sound. The implantable catheter connector is labeled with model & serial numbers that match the model & serial numbers on the electrical connector of the extension cable.

Mikro-Tip catheters are intended for multiple use. An implantation of no more than 14 days is recommended. Experience has proven that the instruments are safe and effective for extended service if proper handling, cleaning, disinfection and sterilization procedures are followed.

Immediately upon receipt of the transducer, and prior to its initial cleaning, disinfection, and use, the customer should verify that the transducer is operational.

Flexible extension cables are available for connection between the pressure connector and the pressure control unit. These flexible cables facilitate maneuvering the catheter during recording. They may be sterilized to permit connection of the transducer to a Millar control unit outside the sterile field.

Figures

- **Figure 1**
- **Figure 2**
**Intended Use/Indications**

The use of a Mikro-Tip catheter is indicated when physiological pressures are to be measured for diagnostic or other purposes in the cardiovascular system.

**Warnings**

- The Mikro-Tip catheter is shipped with the pressure sensor in a foam holder.
- The plastic pressure dome (see figure 1) is for use for calibration only.

**Precautions**

Use of Mikro-Tip catheters should be restricted to specialists who are familiar with, and have been trained to perform, the catheterization procedures for which the device is intended.

- Inspect the Mikro-Tip catheter for damage (cracking, kinks, etc.) prior to each use.
- Clean the Mikro-Tip catheter immediately after each use (see Cleaning).
- Store Mikro-Tip catheters in a dark, cool, dry place.
- Do not touch the sensor area with sharp objects. Do not make sharp bends in the catheter.
- Refrain from applying direct pressure to the sensor area with instruments such as forceps or tweezers.
- When handling the catheter with either fingertips or surgical instruments, always grip several millimeters (5-10 mm) proximal to the sensor area. The sensor area contains very fragile wires which may be damaged or broken if the catheter is gripped too close to the sensor.
- Avoid electrostatic discharge to the Mikro-Tip sensor. Do not touch the sensor element while the catheter is disconnected from monitoring equipment.

**Adverse Events**

None known at this time

**Maintaining Device Effectiveness**

**Storage**

The catheter and cable should be stored in a sterilizing bag or the original plastic tray. The foam shields the sensor from breakage caused by the direct application of excessive force to the sensing surface.

Recommended storage temperature: 19° to 27° C (67° to 80° F) @ 15% to 95% relative humidity.

**Foam Holders & Plastic Dome Fittings**

All catheters are shipped from the factory with the catheter tip in a protective foam holder. The foam shields the sensor from breakage caused by the direct application of excessive force to the sensing surface. The plastic dome fitting is for pressurizing the sensor for calibration only (figure 1).
Transducer Verification and Setup

CAUTION: DO NOT handle or squeeze the pressure sensor during catheter manipulation!

Each transducer is calibrated for a standardized sensitivity of 5μV/V/mmHg (37.6 μV/V/kPa). Each transducer is made up of an implantable (distal) section and an external (proximal) section. Note that each section has a serial number; during installation, be sure that both of the sections used on a given animal have the same serial number. The parts of individual transducers may not be interchanged. Interchanging these parts will change the calibration of the transducer.

To verify system outputs, apply a reference pressure signal to adjust sensitivity or to specific monitor requirement. Use a mercury manometer or electronic manometer as shown in Figure 2 or Figure 3. Apply a known pressure to the Millar catheter and verify the signal at the monitor.

Follow the instructions for the Millar pressure control unit being used. Set up the manometer as shown in Figures 2 or 3 and compare the 100 mmHg (13.3 kPa) output produced using the manometer with the electrical 100 mmHg (13.3 kPa) produced by the control unit.

Reading errors at or near the 0 mmHg (0kPa) manometer indication can be minimized by offsetting the manometer zero indication to 20 mmHg (26.6 kPa) or 25 mmHg pressure indication rather than the 0-100 mmHg (0-133 kPa) pressure indication.

Errors due to inconsistent meniscus shape between consecutive readings can be minimized by adjusting the pressure at each reading to maintain a consistent curve at the top of the meniscus. These errors may be avoided by using an electronic manometer as shown in Figure 3.

Operating Instructions

When Using a Millar Pressure Control Unit (see Control Unit’s IFU)

1. Soak the sensor in room-temperature sterile water or sterile saline for 30 minutes prior to use to minimize drift. Do not submerge the connector. It is preferable for the transducer sections to be connected at this point.
2. Connect the Millar pressure control unit to the monitor.
3. Set the pressure control unit function switch to STANDBY 0 and adjust the monitor to zero baseline.
4. Set the pressure control unit function switch to 100 mmHg and adjust the monitor sensitivity.
5. Connect the extension cable to the pressure control unit.
6. Connect the catheter to the extension cable.
7. Set the pressure control unit function switch to TRANSDUCER. Shield the sensor from light. Adjust the TRANSDUCER BALANCE CONTROL to zero baseline. LOCK the TRANSDUCER BALANCE CONTROL.
8. The catheter system is now ready for use. The sections of the transducer may now be separated for implanting the device. Do not allow blood to reach the sockets and the vent hole on the implantable connector. Take special care to observe ESD precautions when the transducer is separated because the sensor is especially vulnerable in this condition.

Monitor ZERO-REFERENCE can be verified by setting the Millar pressure control unit selector switch to STANDBY 0 to reproduce the original zero baseline. Monitor zero baseline adjustment can be performed at this time if required. Monitor GAIN can then be verified by switching the selector switch to the 100 mmHg (13.3 kPa) position on the control unit. Monitor GAIN adjustments can be made at this time if required.

CAUTION: The “zero” output produced by placing the control unit function switch in the STANDBY 0 position is an electrical zero, not an atmospheric zero!

<table>
<thead>
<tr>
<th>Sensor Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2F Catheter</strong></td>
</tr>
<tr>
<td><strong>≥3F Catheter</strong></td>
</tr>
<tr>
<td>Type of Sensor</td>
</tr>
<tr>
<td>Pressure Range</td>
</tr>
<tr>
<td>Overpressure</td>
</tr>
<tr>
<td>Rated Excitation*</td>
</tr>
<tr>
<td>Sensitivity</td>
</tr>
<tr>
<td>Temperature Error Band at Zero Pressure</td>
</tr>
<tr>
<td>Linearity and Hysteresis</td>
</tr>
<tr>
<td>Drift**</td>
</tr>
<tr>
<td>Natural Frequency</td>
</tr>
<tr>
<td>Bridge Resistance</td>
</tr>
<tr>
<td>Reference Pressure</td>
</tr>
<tr>
<td>Electrical Leakage</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Zero Offset</td>
</tr>
</tbody>
</table>

* Performance specifications are for 5 V_{dc}. Transient voltages up to 20 volts will not damage the transducer.

** Based on 30 minute presoak.

Packaging Contents

- Catheter proximal section with vinyl cap on pressure connector
- Catheter distal (implantable) section with vinyl cap on button connector
- Pressurizing dome with red cap for side port
- Female-Female Luer fitting
- Extra vinyl caps in zip-loc bag
- Instructions for Use booklet
- Plastic tray (sterilizable)
Ethylene Oxide Sterilization Cycle Parameters

- **Preheat phase:**
  - Starting Temperature 110 °F (43 ºC) min.
  - Duration 30 minutes
- **Initial Vacuum:**
  - 6.0 inHgA (20.3 kPa)
- **Nitrogen Flush:** 2 cycles
  - Nitrogen Addition to: 28.0 ± 0.5 inHgA (94.8 ± 1.7 kPa)
  - Rate: 1.4 ± 0.5 inHgA/min. (4.7 ± 1.7 kPa/min.)
- **Evacuation:** 6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
- **Conditioning**
  - Humidification: 1.5 ± 0.5 inHgA (5.1 ± 1.7 kPa)
  - Steam Conditioning: 10 min.
  - Humidity Dwell: 30 ± 5 min. at 7.5 ± 0.5 inHgA (25.4 ± 1.7 kPa)
- **After Vacuum**
  - Vacuum: 6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
  - Rate: 1.0 ± 0.5 inHgA/min. (3.4 ± 1.7 kPa)
- **Gas Wash A:**
  - Release: 30.0 inHgA/min. (94.8 ± 1.7 kPa)
  - Rate: 1.4 ± 0.5 inHgA/min. (4.7 ± 1.7 kPa/min.)
- **Vacuum:**
  - 6.0 ± 0.5 inHgA (20.3 ± 1.7 kPa)
  - Rate: 1.0 ± 0.5 inHgA/min. (3.4 ± 1.7 kPa)
- **Release (Filtered Air):**
  - 28.0 ± 0.5 inHgA (94.8 ± 1.7 kPa)
  - Rate: 2.0 ± 0.5 inHgA/min. (6.6 ± 1.7 kPa)
- **Aeration (Hot Cell):**
  - Duration: At least 8 hours
  - Temperature: 110 ± 10 °F (43 °C)

**CAUTION:** The Mikro-Tip transducer should not be used earlier than 5 days after sterilization.

## Handling Precautions for Mikro-Tip Transducers

<table>
<thead>
<tr>
<th>DO</th>
<th>DO NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure Sensor</td>
<td>Clean immediately after use</td>
</tr>
<tr>
<td>Catheter</td>
<td>Clean immediately after use</td>
</tr>
<tr>
<td>Connectors &amp; Cables</td>
<td>Protect from fluid</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Keep catheter and sensor wet until cleaning</td>
</tr>
<tr>
<td>Disinfection or Sterilization</td>
<td>Dry catheter before sterilizing</td>
</tr>
<tr>
<td>Troubleshooting and Corrective Maintenance</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Problem</th>
<th>Probable Cause</th>
<th>Corrective Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excessive Drift</td>
<td>Deposit of foreign material on the diaphragm of the pressure sensor.</td>
<td>Follow Cleaning Instructions. If problem persists, contact Millar.</td>
</tr>
<tr>
<td>Transducer will not balance (zero)</td>
<td>Moisture in the connector, damage to wires in the catheter, or fractured strain gauge within pressure sensor</td>
<td>Follow Operating Instructions or substitute a transducer known to be operating properly into the recording system.</td>
</tr>
</tbody>
</table>

## Cleaning

### Approved Cleaners and Disinfectants

<table>
<thead>
<tr>
<th>Type</th>
<th>Trade Name</th>
<th>Manufacturer</th>
<th>Active Ingredient</th>
<th>Soak Time/ Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Enzymatic Detergent</strong></td>
<td>Enzol® (in UK: Cidezyme®)</td>
<td>Advanced Sterilization Products (J&amp;J)</td>
<td>Propylene Glycol</td>
<td>15 minutes / room temperature</td>
</tr>
<tr>
<td><strong>Endozime®</strong></td>
<td>Ruhoff Corporation</td>
<td>Propylene Glycol</td>
<td>15 minutes / room temperature</td>
<td></td>
</tr>
<tr>
<td><strong>Terg-A-Zyme®</strong></td>
<td>Alconox</td>
<td>Sodium Dodecylbenzene</td>
<td>15 minutes / room temperature</td>
<td></td>
</tr>
<tr>
<td><strong>High-level Disinfectant</strong></td>
<td>Cidex Activated Dialdehyde Solution</td>
<td>Advanced Sterilization Products (J&amp;J)</td>
<td>Glutaraldehyde</td>
<td>1-2 hours / 77 °F (25 °C)</td>
</tr>
<tr>
<td><strong>Cidex® OPA</strong></td>
<td>Advanced Sterilization Products (J&amp;J)</td>
<td>Ortho-phthalaldehyde</td>
<td>16-30 minutes / 68 °F (20 °C)</td>
<td></td>
</tr>
<tr>
<td><strong>MetriCide®</strong></td>
<td>Metrex</td>
<td>Glutaraldehyde</td>
<td>1-2 hours / 77 °F (25 °C)</td>
<td></td>
</tr>
</tbody>
</table>
DO NOT USE:
- Glutaraldehyde solutions containing surfactants (e.g., Cidex 7 or Cidex Plus 28 Day)
- Solutions containing hydrogen peroxide (e.g. Sporox)
- Cidex PA solution

Water Resistant Connector Caps
Each catheter has water-resistant caps to protect electrical pins and circuitry. Place caps over the open end of the connectors before cleaning and disinfecting. Remove caps prior to sterilization. Save and reuse these caps each time the catheter is cleaned and disinfected.

Cleaning Procedure

CAUTION: DO NOT submerge the wye junction or connectors. This will damage the catheter and void its warranty! Wipe with cleaner and gauze.

CAUTION: Use only the listed cleaners and disinfectants for the times/temperatures indicated.

CAUTION: Delays in rinsing greatly reduce cleaning effectiveness!

1. Wipe catheter with wetted gauze immediately after use to remove bulk contaminants.
2. Submerge the distal (implantable) section of the transducer in room-temperature water (DO NOT use hot water) up to the implantable connector. Wipe the surface of the catheter with a soft gauze. Take care not to get water on the connector’s sockets or the adjacent vent hole.
3. For initial cleaning of the clean the proximal (external) section of the transducer, hold the in-line connector and the main (pressure) connector in one hand and submerge only the catheter in room-temperature water. Wipe the surface of the catheter with a soft gauze. Take care not to get water on the connectors’ pins or vent holes.
4. Prepare the cleaning solution according to the manufacturer’s instructions. Place the implantable section of the catheter in the cleaning solution, but do not submerge the connector. Wet soft surgical gauze with the cleaning solution and wipe the catheter. Soak the implantable portion of the catheter in the cleaning solution for the time specified in this IFU.
5. Repeat the previous step with the catheter of the proximal section of the transducer. Do not submerge the connectors. In order to hold the implantable connector above the liquid, cover the jaws of a hemostat with soft tubing and use it to gently grasp the connector; lay the hemostat across the rim of the beaker. To hold the main (pressure) connector, use a second hemostat with soft tubing to grip the catheter near the connector.
6. Remove the catheter sections from the cleaning solution after soaking and wipe them with a clean wet gauze.
7. Immediately rinse the catheter sections and the sensor at least three times with sterile, pyrogen-free water. Do not reuse the water from each rinse, as it will contain residuals from the cleaner.
8. Dry the catheter with soft gauze.
9. Package the transducer for sterilization. Do not connect the two sections of the transducer.
10. Failure to clean and/or disinfect according to these directions may void the catheter warranty.

Disinfection

1. The catheter must be cleaned, rinsed and dried prior to disinfection. Soil, debris, proteins, and water can interfere with the effectiveness of the following procedure, posing a risk to the patient and the user. Note that some disinfectants have a limited usable life after activation or opening the container. Failure to heed such warnings can inhibit the effectiveness of the disinfection process.
2. Prepare the disinfectant according to the manufacturer’s instructions.
3. Submerge the catheter into the disinfectant using the same techniques described in the cleaning instructions above. Do not submerge the connectors as this will damage the transducer and void the warranty.
4. Soak the transducer in the disinfectant at the temperature and time intervals listed.

Rinsing after Disinfection

1. Rinse the device by submerging all disinfected surfaces in sterile pyrogen-free water. The volume of the water should be at least two gallons (7.6 liters) and the soak time should be at least one minute.
2. At least three separate rinses are required. Do not reuse any of the water used for rinsing since it will be contaminated with the disinfectant.

Method of Sterilization for Catheters and Extension Cables (Optional)

CAUTION: DO NOT sterilize by autoclaving, radiation (gamma or e-beam), plasma, peroxide or formaldehyde vapor solutions.

Catheters must be completely cleaned and dried before sterilization. Aerate at room temperature or in a heated aeration cabinet (max. 145 °F, 63 °C). Catheters may be sterilized in the white plastic shipping tray. The foam dome and connector caps must be removed and placed alongside the catheter inside the pouch during sterilization. The caps should be saved and reused each time the catheter is cleaned. Disconnect the two sections of the transducer. (The EtO may not reach all surfaces if the two sections are connected during sterilization.)

The tray, with lid, should be placed in a breathable polyethylene pouch (e.g., 3M™ Steri-Lok™).

CAUTION: The catheter should be completely dry before sterilization.