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Millar Worldwide Distribution
Millar, Inc. has a network of Authorized Distributors in most countries around the world. For information on the Millar distributor in your country, please contact the Millar Customer Service Department at our headquarters in Houston, Texas.

CE

M.I. P/N: 004-2186 Rev. C

Millar™

Making the improbable possible.

Ventri-Cath Pressure-Volume (PV) Combination Catheter Transducer

Intended for Non-Clinical Research Use Only

Instructions for Use

Nonsterile Product

Table of Contents

Millar Limited Warranty

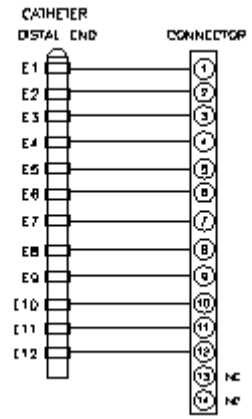
Millar, Inc. (Millar) warrants that at the time of sale to the original purchaser, the device was free from defects in both materials and workmanship. For a period of 365 days from the date of original shipment to the original purchaser, Millar will, at no charge and at its option, replace any Ventri-Cath catheter 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. This catheter is not repairable.

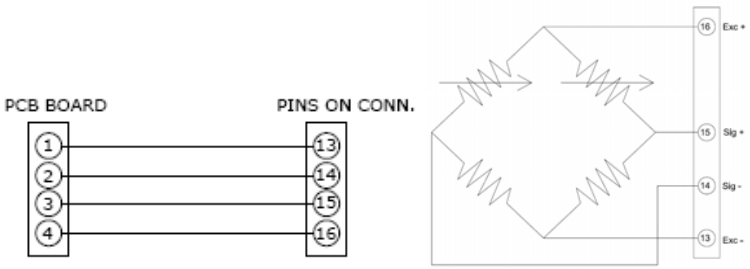
Millar hereby excludes all warranties not herein stated, whether express or implied by operation of law or course of dealing or trade usage or otherwise, including but not limited to any implied warranties of fitness or merchantability.

Since handling and storage of product, as well as factors relating to subject 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.

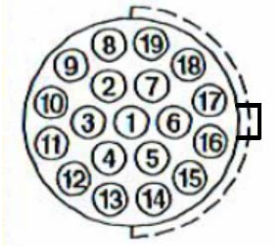
The user shall determine suitability for use of these medical devices for any surgical or clinical procedure. Therefore, the user accepts these devices subject to all the terms hereof.

Schematics





Connector Rear View



Recommended Accessories

M.I. P/N 880-0168 MPVS Ultra Pressure Volume Control Unit
M.I. P/N 850-5134 PV Cable 10Ft. CEC-10PV
M.I. P/N 880-0129 PCU-2000 Pressure Control Unit, Patient Isolated
Input Cables as appropriate for third party hardware.
All accessories sold separately.

Definition of Symbols

	Attention, consult accompanying documents
	Date of Manufacture
REF	Catalog Number
SN	Serial Number
LOT	Batch Code
	Use By Date
	Electrostatic Sensitive Device
	EU Distribution
	Single Use Only
	Manufacturer Information
	Temperature

Catheter Description

The Ventri-Cath catheter combines one pressure transducer and a series of electrodes mounted at various locations along the distal segment of the catheter body. It terminates in one electrical connection at the proximal end.

Intended Use / Indications

The Ventri-Cath catheter is indicated to be used when combined pressure and electrical impedance monitoring is required for non clinical research.

This product is designed for use by professionals with appropriate education and training in life science and medical research applications.

Warnings

- Ventri-Cath catheters are sold non-sterile for non clinical application.
- Ventri-Cath catheters are shipped with plastic tubing over the pressure sensor. The protective tubing should be in place during handling.
- Do not allow body fluids or any fluid to collect on catheter connector.

Precautions

- Inspect the Ventri-Cath catheter for damage (cracking, kinks, etc.) prior to use.
- Store the Ventri-Cath catheter in a dark, cool, dry place.
- Do not touch the sensor area with sharp objects. Do not make sharp bends in the catheter.
- Disconnect the Ventri-Cath catheter prior to defibrillation or electro surgery.
- Avoid electrostatic discharge to the Ventri-Cath catheter. Do not touch the pressure sensor element while the catheter is disconnected from monitoring equipment.

Insert and advance the Ventri-Cath catheter through a sheath introducer and/or guide catheter. Pigtail extensions may fold or buckle if the catheter is advanced without an introducer.

When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Maintaining Catheter Effectiveness

Storage

Store the catheter in the plastic tray provided by Millar. Make sure the catheter has a plastic tubing cover over the pressure sensor.

Plastic Tubing Cover

All catheters are shipped with protective tubing over the pigtail and pressure sensor to protect the pressure sensor and catheter tip from damage.

Catheter

Inspect each catheter thoroughly before use. Carefully examine the catheter for defects.

If damage is found during inspection, DO NOT use the catheter. Contact Millar, Inc. or authorized distributor.

Connector(s) and Cable(s)

The connector(s) should be routinely inspected for corrosion or bad contacts. Liquid entering the connector(s) can cause electrical hazard, erratic operation and components corrosion.

The Ventri-Cath catheter should not be used earlier than 5 days after sterilization.

Catheter Model and Part Numbers

Model Number	Part Number
Ventri-Cath 507	840-8221-07
Ventri-Cath 507S	840-8221-07S
Ventri-Cath 510	840-8221-10
Ventri-Cath 510S	840-8221-10S
Ventri-Cath 512	840-8221-12
Ventri-Cath 512S	840-8221-12S
Ventri-Cath 515	840-8221-15
Ventri-Cath 515S	840-8221-15S

Environmental Specifications

Operating	59° to 104°F (15° to 40°C), 30% to 75% RH
Transport and Storage	-13° to 158°F (-25° to 70°C), 30% to 75% RH

Sensor Specifications

Type of Sensor	Diffused Semiconductor, piezoresistive
Pressure Range	-50 to + 300 mmHg (-6.7 to 40 kPa)
Overpressure	+4000 mmHg (+530 kPa), -760 mmHg (100 kPa)
Excitation*	DC Only
Rated Excitation*	5.0 V_{DC}
Excitation Impedance	1000 ohms nominal
Signal (output) Impedance	1000 ohms ± 5%
Sensitivity	5 µV/V/mmHg, nominal (37.6 µV/V/kPa)
Temperature Error Band at Zero Pressure	±3.5 mmHg (±0.13 kPa), BSL, 25-15 ºC ±3.5 mmHg (±0.27 kPa), BSL, 25-40 ºC
Sensitivity Error Band	< 3.5% referenced to 25 ºC , BSL 25-15 ºC < 3.5 % referenced to 25 ºC , BSL 25-40 ºC
Accuracy (nonlinearity,hysteresis, sensitivity and repeatability combined)	± 1 mmHg (0.13 kPa) ±1% of reading from -50 to 50 mmHg (-6.7 to 6.7 kPa) ±3% of reading from 50 to 300 mmHg (6.7 to 40 kPa)
Zero Drift	< 6 mmHg (0.8 kPa) in 4 hours at 25 ºC
Frequency Response	Flat to ≥10 kHz
Bridge Resistance	1000 ohms, nominal
Reference Pressure	Atmospheric
Electrical Leakage	< 10 µA at 120 V_{AC}
Zero Offset	<±50 mmHg (± 6.7 kPa)
Shock	500 G 3ms duration
Light Sensitivity	< 1mmHg darkness to 3000fc 3400ºK light source

* Performance specifications are for 5 VDC. Transient voltages up to 20 volts will not damage the transducer.

NOTE: Specifications subject to change without notice.

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

Catheter should be completely dry before sterilization.

Ethylene Oxide Sterilization Cycle Parameters

Preheat phase:	Starting Temperature 110 ºF (43ºC) min.
	Duration 30 minutes
Initial Vacuum:	6.0 inHgA (20.3 kPa)
	Rate: 3 minutes
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)
Rate:	1.0 ± 0.5 inHgA/min. (3.4 ± 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)
Relative Humidity:	15-70%
Ethylene Oxide Concentration:	500 ± 50 mg/L
Dwell Pressure:	16.5 ± 1.0 inHgA (55.8 ± 3.4 kPa)
Dwell Time:	2 hours
Temperature:	110-130 ºF (43-54 ºC)
Relative Humidity:	30-70% (35-44% nominal)
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)
Vacuum Hold:	10 min.
Gas Wash A:	4 cycles (minimum)
Release:	30.0 inHgA/min. (94.8 ± 1.7 kPa)
Rate:	1.4 ± 0.5 inHgA/min. (4.7 ± 1.7 kPa)
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 ºF (43 ºC)

Operating Instructions When Using a MPVS Ultra Control Unit (see Control Unit's IFU)

1. Soak the sensor in body-temperature sterile saline or deionized water for 30 minutes prior to use to minimize drift.
2. Connect the MPVS Ultra to a PC, turn it on and open the MPVS Control Interface Software and the data acquisition software.
3. Connect the Ventri-Cath to the MPVS Ultra control unit.
4. Use the MPVS Ultra control interface software to balance the pressure transducer and calibrate the data acquisition software channels.
5. Insert the Ventri-Cath into the subject and advance to the desired location, using the pressure and volume signals and preferably fluoroscopy to guide placement.
6. Once the catheter is optimally placed, use the MPVS Ultra control software to remove any volume segments located outside the ventricle.
7. Use the MPVS Ultra control software to calibrate the volume units in the data acquisition software.
8. The catheter and system are now ready to acquire data.

The "zero" output produced by selecting the 0 mmHg button in the MPVS Ultra control software is an electrical zero, not an atmospheric zero.

Operational Notes

Use appropriate size introducer and/or guide catheter for catheter being used.

Consider use of systemic heparinization.

Handling Precautions for Ventri-Cath Disposable Pressure Volume Catheters

	DO:	DO NOT:
Pressure Sensor	Clean immediately after use	Clean with stiff-bristled brush
		Clean with high pressure water jet
	Protect with dome when not in use	Tap the sensor against a rigid surface
	Disconnect during electrical defibrillation or electrosurgery	Apply excessive force to the sensor surface
		Expose to excessive pressure
Catheter & Pigtail	Clean immediately after use	Cut, crease, knot, fold, kink, or crush with forceps or clamps of any kind
Connectors & Cables	Protect connectors from fluid	Immerse connectors in liquid
Cleaning	Keep catheter and sensor wet until cleaning	Expose to alcohol, cresols, phenols, mercury compounds, hypochlorites, acetone, peroxide, silicone chlorine, xylenes, trichloroethylene, or freon
	Clean thoroughly with approved enzymatic cleanser immediately after use	Use ultrasonic cleaner
		Immerse electrical connector

Disinfection or Sterilizing (Optional)	Dry catheter before sterilizing	Autoclave, irradiate (gamma/e-beam), plasma, peroxide or formaldehyde vapor solutions
	Remove plastic cover bag from catheter	Use Sporox or Cidex PA solutions

Troubleshooting and Corrective Maintenance

Problem	Probable Cause	Corrective Action
Excessive Drift	Deposit of foreign material on the diaphragm of the pressure sensor.	Carefully clean the catheter following the cleaning instructions provided in the IFU. If the problem persists, contact Millar, Inc.
Transducer will not balance (zero)	Moisture in the connector, damage to wires in the catheter, or fractured strain gauge within pressure sensor	Follow Operating Instructions or substitute a transducer known to be operating properly into the recording system.

Cleaning

Approved Cleaners and Disinfectants

Type	Trade Name	Manufacturer	Active Ingredient.	Soak Time/Temperature
Enzymatic Detergent	Enzol® (in UK: Cidezyme®)	Advanced Sterilization Products (J&J)	Propylene Glycol	15 minutes / room temperature
	Endozime®	Ruhoff Corporation	Propylene Glycol	15 minutes / room temperature
	Terg-A-Zyme®	Alconox	Sodium Dodecylbenzene	15 minutes / room temperature
High-level Disinfectant	Cidex Activated Dialdehyde Solution	Advanced Sterilization Products (J&J)	Glutaraldehyde	1-2 hours / 25 °C (77°F)
	Cidex® OPA	Advanced Sterilization Products (J&J)	Ortho-phthalaldehyde	16-30 minutes / 20 °C (68°F)
	MetriCide®	Metrex	Glutaraldehyde	1-2 hours / 25 °C (77°F)

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

Cleaning Procedure

DO NOT submerge the connectors. This will damage the catheter and void its warranty! Wipe with cleaner and gauze.

Use only the listed cleaners for the times/temperatures indicated.

Delays in rinsing greatly reduce cleaning effectiveness!

1. Wipe catheter with wetted gauze immediately after use to remove bulk contaminants.
2. Submerge only the distal contaminated portion of the catheter in room-temperature water (DO NOT use hot water).
3. Wipe the proximal outer surface of the catheter and connector with soft gauze.
4. Prepare cleaning solution. Place the distal portion of the catheter in the cleaning solution.
5. Wet soft surgical gauze with the cleaning solution. Wipe the outer surface of the catheter with gauze.
6. Soak distal portion of the catheter in a cleaning solution for the time specified, and then remove.
7. Gently wipe the catheter and sensor clean with a soft, wet gauze or tissue.
8. Immediately rinse the catheter and 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.
9. Dry the outside of the catheter with soft gauze.
10. Package for sterilization (optional).
11. Failure to clean and sterilize according to directions may void 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 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 only the distal end of the catheter into the disinfectant. Do not submerge the connector as it 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 exterior 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)

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 ºF, 63 ºC). Catheters may be sterilized in the white plastic shipping tray. The plastic cover bag must be removed and placed alongside the catheter inside pouch during sterilization.