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CE 2797

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OBSERVE PRECAUTIONS
FOR HANDLING
ELECTROSTATIC
SENSITIVE DEVICES

M.I. P/N: 004-2174 Rev. N
2023-04

Millar®

Making the
improbable possible.

Mikro-Cath™ Pressure Catheter

Instructions for Use

Model: Mikro-Cath

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

STERILE EO

-25°C 70°C

2 STERILIZE

Millar Limited Warranty

Millar, Inc. warrants all products of its manufacture to be free of defects in workmanship and material at the time of shipment.
This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied warranties of merchantability or fitness of purpose. Since handling, storage, initial cleaning, and sterilization of the product, as well as factors relating to patient diagnosis, treatment, catheterization procedures, and other matters beyond the control of Millar, Inc. directly effect the product and the results obtained from its use, Millar, Inc., shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the misuse of the product.

Table of Contents

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 (not available in the EU)M.I. P/N: 850-1308, Model TEC-10D Extension Cable to TC-510
M.I. P/N: 850-5090, Model PEC-10D Extension Cable to PCU-2000
M.I. P/N: 850-5148, Mikro-Cath to EP-Tracer Monitor Input Cable
Monitor Input Cables as appropriate for monitor, with EMC ferrite (Fair-Rite P/N 2631540002 or Wurth Electronics P/N 74271221S) attached to monitor cable close to control unit.
All accessories sold separately.

Definition of Symbols


Follow instructions for use


Date of Manufacture

Catalog Number

Serial Number

Batch Code


Use-by date


Electrostatic Sensitive Device


EU Declaration of Conformity

UK Conformity Assessed


Do not re-use


Temperature Limits


Relative Humidity Limits


Keep Dry


Do not resterilize


Do not use if package is damaged


Manufacturer

Sterilized using ethylene oxide

Compliance Test Levels to RF Wireless Communications Equipment					
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Immunity Test Level (V/m)**	**Compliance Test Level (V/m)**
385	380 - 390	TETRA 400	Pulse Modulation 18 Hz	27	27
450	430 - 470	GMRS 460, FRS 460	Pulse Modulation 18 Hz[(c)]	28	28
710	704 - 787	LTE Band 13, 17	Pulse Modulation 217 Hz	9	9
745					
780					
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	28	28
870					
930					
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, iDECT, LTE Band 1,3,4,25,UMTS	Pulse Modulation 217 Hz	28	28
1845					
1970					
2450	2400 - 2570	Bluetooth WLAN, 802.11b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	28	28
5240	5100 - 5800	WLAN 802.11, a/n	Pulse Modulation 217 Hz	9	9
5500					
5785					

(c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Serious Incident Reporting

For a patient and/or user of the device: if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorized representative and your national authority.

Recommended separation distances between portable and mobile RF communications equipment and the Mikro-Cath			
The Mikro-Cath is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Mikro-Cath can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Mikro-Cath as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

EC REP	Authorized representative in the European Community
MR	MR Unsafe
MD	Medical device
	Single sterile barrier system
UDI	Unique device identifier
	Consult instructions for use or consult electronic instructions for use

Device Description

The Millar Mikro-Cath Pressure Catheter is fitted with an ultra-miniature pressure sensor near the distal end. The sensor is side mounted at the catheter tip. There is a radiopaque marker located at the catheter tip proximal to the sensor. The proximal end terminates in a connector. The pressure sensor produces an electrical output signal which varies in direct proportion to the magnitude of sensed pressure or sound.

Extension cables are available for connection between the pressure connector and the pressure control unit. Cables may be sterilized.

Intended Use / Indications

The Mikro-Cath Pressure Catheter is a single-use catheter intended to be used for medical research and diagnostic purposes. The catheter is indicated to measure cardiovascular, intra-compartmental, and airway pressures in the human body. The catheter is used as a minimally invasive device under short term limited body contact (<24 hours).
The typical cardiovascular application will be through the femoral artery with the use of an additional guiding catheter.

Mikro-Cath Pressure Catheter may be introduced into the targeted muscle compartment through an introducer. The Mikro-Cath may be introduced into the respiratory system through an existing orifice.

Contraindications

The device should not be used if:

- in the opinion of the physician, the risk of use clearly outweighs the benefits.
- there is substantial risk of patient harm because of patient characteristics (e.g., accompanying therapy, disease state, or health status).
- there is a probability of tissue or organ damage.
- there is vascular obstruction
- there is undiagnosed vasospasm
- Mikro-Cath has passed expiration date.
- Mikro-Cath is not sealed in its original sterile package
- Avoid areas of cellulitis, infections or burns

Complications

Possible complications include the following:

- Air embolism
- Hematoma at the puncture site
- Infection
- Cardiac perforation
- Thrombus formation
- Vasospasm
- Myocardial infarction
- Serious arrhythmia
- Vascular injury
- Protamine reaction
- Congestive heart failure
- Death

Warnings

- Use only one time for a single patient.
- Use only with CE-approved monitoring equipment that has patient isolated input circuitry, type CF patient applied part per EN 60601-1. The monitoring equipment used should be compliant to relevant harmonized standards.
- Patient isolated input is not required if used with Millar PCU-2000.
- Discard catheters after one procedure. Risk of infection may result if device is not discarded using proper regional disposal guidelines for procedures relating to Biological Hazards.
- Do not expose to organic solvents.
- This pressure transducer is not protected against defibrillation discharges. It must be used only with monitors labeled as having an isolated defibrillator-protected patient connection or shall be disconnected.
- Disconnect the transducer from the Millar Control Unit prior to defibrillation or electrosurgery.
- EXPLOSION HAZARD! Do not operate this catheter in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- Do not use Mikro-Cath in MRI environment. The Mikro-Cath has not been tested for MRI compatibility.
- Appropriate anticoagulation procedures must be observed to prevent thrombus formation, and the duration of each diagnostic procedure should be kept to a minimum.
- No modification of this equipment is allowed.
- DO NOT use the Mikro-Cath in close proximity to high electrical noise-generating equipment, as this may cause interference with the signal.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories and cables other than those specified could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Mikro-Cath, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Conducted Immunity IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz, 6 Vrms ISM Band	3 Vrms 150 kHz to 80 MHz, 6 Vrms ISM Band	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$, 80 MHz to 800 MHz $d = 2.3\sqrt{P}$, 800 MHz to 2.7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Mikro-Cath is used exceeds the applicable RF compliance level above, the Mikro-Cath should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Mikro-Cath. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Electromagnetic Compatibility

Electromagnetic Emissions		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Mikro-Cath uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Mikro-Cath is suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes.

Electromagnetic Immunity			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic environment - guidance**
Electrostatic Discharge IEC 61000-4-2	±8 kV Contact, ± 2kV,± 4kV,± 8kV,± 15kV Air	±8 kV Contact, ± 2kV,± 4kV,± 8kV,± 15kV Air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±1 kV for input/output Lines	±1 kV for input/output Lines	Mains power quality should be that of a typical commercial or hospital environment.
Magnetic Immunity IEC 61000-4-8	30 A/m, 50 Hz or 60 Hz	30 A/m, 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated Immunity, Immunity to RF portable Transmitters IEC 61000-4-3	3 V/m, 80 MHz to 2.7 GHz Wireless frequencies 385MHz (27V/m); 450MHz (28V/m); 710,745,780MHz (9V/m); 810,870,930MHz (28V/m); 1720,1845,1970MHz (28V/m); 2450MHz (28V/m); 5240,5500,5785MHz (9V/m)	3 V/m, 80 MHz to 2.7 GHz Wireless frequencies 385MHz (27V/m); 450MHz (28V/m); 710,745,780MHz (9V/m); 810,870,930MHz (28V/m); 1720,1845,1970MHz (28V/m); 2450MHz (28V/m); 5240,5500,5785MHz (9V/m)	Portable and mobile RF communications equipment should be used no closer to any part of the Mikro-Cath, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**

- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Precautions

- Use of Mikro-Cath should be restricted to specialists who are familiar with, and have been trained to perform, the catheterization procedures for which the device is intended.
- Exercise care to prevent perforating or traumatizing the linings and associated tissue of the cardiovascular system.
- Avoid electrostatic discharge to the Mikro-Cath sensor. Do not touch the sensor element while the catheter is disconnected from monitoring equipment.
- Insert and advance the Mikro-Cath through an appropriately sized introducer or guiding catheter.
- When the Mikro-Cath 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.
- Excessive handling, such as forcibly pulling or twisting the Mikro-Cath may cause breakage to the catheter or sensor tip.
- Observe recommended storage and operating conditions listed in “Environmental Specifications”
- Avoid impact to the Mikro-Cath greater than the shock specified in “Sensor Specifications."
- Reuse of this single use device (Mikro-Cath) is prohibited. Reuse may cause infection and/or impact performance.
- See package labeling information for expiration date allowing for safe use of Mikro-Cath.
- Ensure any casting or bandaging is removed prior to performing intra-compartmental pressure measurements.
- Completely inspect package prior to use. Do not use if the sterile packaging has been opened or damaged.

Adverse Events

None known

Special Flushing Instructions

To prevent thrombus formation:

1. Use these catheters only for short term pressure measurements.
2. If a guide catheter is used, forcibly aspirate, then flush the guide catheter with heparinized saline every two minutes, or more frequently.
3. Consider use of systemic heparinization (see Bibliography references 1. and 2.).
4. Prefill the guide catheter lumen(s) with saline before introducing the guide catheter

   OR
   Follow guide catheter IFU to ensure that proper flushing and heparinization procedures are followed per the guide catheter manufacturer’s recommendation.
5. The guide catheter lumen(s) should always be filled with either flushing solution or saline while the Mikro-Cath catheter is in the vascular system (3).

Operating Instructions

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

Note: Millar Mikro-Cath is a sterile single use catheter. It does not require a 30-minute presoak prior to balancing.

1. Connect the Millar pressure control unit to the monitor.
2. Turn the pressure control unit function switch to STANDBY 0 and adjust the monitor to zero baseline.
3. Turn the pressure control unit function switch to 100 mmHg and adjust the monitor sensitivity.
4. Connect the extension cable to the pressure control unit.
5. Connect Mikro-Cath to the extension cable.
6. Turn the pressure control unit function switch to TRANSDUCER. Shield the sensor from light. Adjust the TRANSDUCER BALANCE CONTROL to zero baseline. LOCK Mikro-Cath balance.
7. The Mikro-Cath system is now ready for use.

Monitor ZERO-REFERENCE can be verified by turning 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 turning 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!

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Judkins, M. "Percutaneous Transfemoral Selective Coronary Arteriography." Radio Clin N Amer 6: 467-492, 1968

David Roscoe,*yz§ MRCGP, MFSEM(UK), MSc(SEM), DipIMC RCSEd, MPA, Andrew J. Roberts,y|| MSc, and David Hulse,y MB ChB, MSc, FFSEM(UK) Investigation performed at the Defence Medical Rehabilitation Centre (Headley Court), Epsom, UK, 2014

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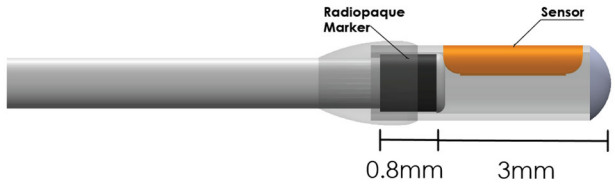
Catheter Specifications

Mikro-Cath	
Tip Size	3.5F (1.2mm)
Body Size	2.3F (0.8mm)
Length	120 cm
Tip Characteristics	Straight

Sensor Tip View



The Sensor Tip contains a 0.8mm radiopaque marker located approximately 3mm from the distal end of the catheter. (Dimensions are approximate)

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	-30 to + 300 mmHg (-4 to 40 kPa)
Overpressure	+4000 mmHg (+530 kPa), -400 mmHg (-53 kPa)
Rated Excitation	5 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	±1.0 mmHg (±0.13 kPa), BSL, 25-15°C ±2.0 mmHg (±0.27 kPa), BSL, 25-40°C
Sensitivity Error Band	< 2.3% referenced to 25 °C, BSL 25-15°C < 3.5 % referenced to 25 °C, BSL 25-40°C
Accuracy (nonlinearity, hysteresis, sensitivity and repeatability combined)	± 1 mmHg (0.13 kPa) plus ±1% of reading from -30 to 50 mmHg (-4 to 6.7 kPa) ±3% of reading from 50 to 300 mmHg (6.7 to 40 kPa)
Zero Drift	< 3 mmHg (0.4 kPa) in 4 hours at 25°C
Frequency Response	≥ 200 Hz
Bridge Resistance	1000 ohms, nominal
Reference Pressure	Atmospheric
Electrical Leakage	< 10 µA at 120 V_{AC}
Zero Offset	< ±75 mmHg (±10 kPa)
Shock	500 G 3ms duration
Light Sensitivity	< 1mmHg darkness to 3000fc 3400°K light source