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Millar Worldwide Distribution
Millar, LLC has a network of Authorized Distributors throughout the world. For information on country availability, please contact Millar Customer Service listed above.

M.I. P/N: 004-0930 Rev. H

Millar™

Making the improbable possible.

Millar Mikro-Tip™ Pulse Transducer

Instructions for Use

Model: SPT-301
Part Number: 808-1019

Non-Sterile Product

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MIKRO-TIP™ PULSE TRANSDUCER SPECIFICATIONS

Type of Sensor	Diffused Semiconductor
Pressure Range	0 to +300 mmHg (0 to 40 kPa)
Overpressure	+4000 mmHg (+530 kPa), -760 mmHg (100 kPa)
Rated Excitation	2.5 - 7.5 V_{dc} or V_{ac}, rms*
Sensitivity	5 µV/V/mmHg, nominal (37.6 µV/V/kPa)
Temperature Error Band at Zero Pressure	± 3 mmHg (± 0.4 kPa) BSL, 23 - 38 º C
Linearity and Hysteresis	± 1.5%, BSL of full scale
Natural Frequency	35 kHz, nominal
Bridge Resistance	1000 ohms, nominal
Reference Pressure	Atmosphere
Electrical Leakage	< 10 µA at 120V_{ac}
Zero Offset	< ± 50 mmHg (± 6.7 kPa)
Probe Length	13 cm
Length of Cable	1.5 m

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

Please Note: Specifications subject to change.

MILLAR LIMITED WARRANTY

Millar, LLC (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 (1-year) 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.

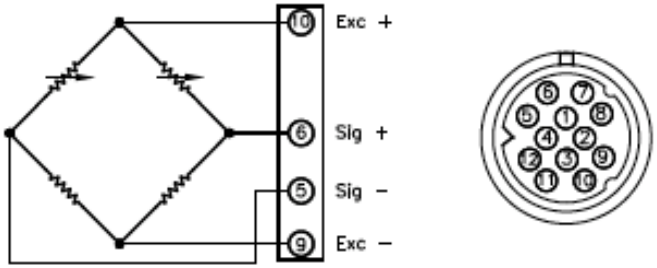
This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied warranties of merchantability or fitness of purpose. Since handling, storage, initial cleaning, and sterilization of the product, as well as factors relating to patient diagnosis, treatment, catheterization procedures, and other matters beyond the control of Millar, LLC directly affect the product and the results obtained from its use, Millar, LLC, shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the misuse of the 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 three (3) years from the date of manufacture.

CORRECTIVE MAINTENANCE AND TROUBLESHOOTING
Transducer Will Not Zero Balance
A Schematic diagram of the pressure sensor and electrical connector is shown in Figure 1. When a pressure cannot be electrically balanced (zeroed), or when the balance is extremely unstable, the cause may be moisture in the connector, damage to the wires within the transducer, or a fractured strain gauge within the pressure sensor. The following procedures should help identify the difficulty as being within the transducer.

1. Check the electrical continuity of the pressure sensor.
2. Substitute a transducer known to be operating properly into the recording system.
3. Measure the electrical resistance from pin 9 to pin 10 and pin 5 to pin 6 on the pressure sensor electrical connector (Figure 1). Both resistance values should be between 960 and 1040 ohms. If the resistance is not correct, the strain gauge element may be broken or damaged and the transducer should be returned for repair. Do not attempt to open the electrical connector or otherwise disassemble the transducer.

Figure 1: Sensor and Viking Connector



Accessories (sold separately)

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: 850-5089, Model PEC-10C Extension Cable to PCU-2000
Monitor input cables as appropriate for monitor.

SYMBOL DEFINITIONS

	Consult accompanying documents
	Catalog Number
	Serial Number
	Non-Sterile
	Manufacturer

DEVICE DESCRIPTION

NON-STERILE PRODUCT

The Millar Mikro-Tip™ Pulse Transducer consists of an ultra-miniature pressure sensor positioned at the tip of the distal end of the stainless steel tube with 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 tonometer is provided non-sterile and intended for external use only.

Flexible extension cables are available for connection between the pressure connector and the transducer control unit. This flexible cable facilities maneuvering the transducer during recording.

INDICATION FOR USE

The Mikro-Tip™ Pulse Transducer can be used when measuring non-invasive high-fidelity pressure waveforms from the carotid, femoral and radial artery.

CONTRAINDICATIONS

None known

WARNINGS/PRECAUTIONS

None

INSTRUCTIONS

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

2. Connect the Pulse Transducer, through the control unit, to the pressure monitor being used.

3. Calibrate the monitor according to the control unit instructions.

4. Place the tip of the Pulse Transducer on the skin of the subject, over a pulsating blood vessel. The probe should be perpendicular to the surface of the skin.

5. Gently press the Pulse Transducer onto the vessel until a satisfactory pulse wave contour is obtained.

6. Clean immediately after use and handle with care.

Note: The Pulse Transducer provides a good reproduction of the pulse wave contour. Because the pressure sensed by the probe is a composite of the forces compressing intervening tissue, as well as the blood vessel, the signal output is not a measure of absolute intravessel pressure.

STORAGE

When the transducer is not in use, protect the transducer pencil end by storing in the protection cover that was originally shipped with the unit.

ROUTINE INSPECTION AND TESTING

If damage is detected during the following inspection, the transducer should not be used and Millar, LLC or authorized distributor should be notified. Store the transducer in a cool, dark, dry place.

PRESSURE SENSOR

The active surfaces (diaphragm) of the pressure sensor should be examined for any film of body fluids, or other materials that may not have been properly removed by cleaning. Any such film should be removed. Cleaning may require a thorough soaking in dilute Alconox detergent followed by a gentle, persistent wiping action along the sensor surface with a moist tissue.

CONNECTOR

Conductive liquid entering the connector can cause erratic operation and possible corrosion of wires and components within the connector. The connector should be routinely inspected for corrosion or bad contacts.

CABLE

Both connectors on the cable should be routinely inspected for corrosion or bad contacts.

HANDLING PRECAUTIONS FOR MILLAR MIKRO-TIP PULSE TRANSDUCERS

CLEANING

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

Routine cleaning:
Gently wipe the sensor surface with an alcohol moistened tissue.

Cleaning for use in a sterile field:
If the transducer is to be used in a sterile field, soak the transducer in a diluted solution of Alconox (see manufacturer's directions). Do not immerse the connector. Gently wipe the sensor clean with a soft, wet gauze or tissue. Immediately rinse the sensor (do not allow to dry). Wipe the transducer and sensor dry.

Note: The transducer should be completely dry before sterilization
Note: Sterilization only needs to be performed if the transducer is to be used in a sterile field.

Recommended Method for Sterilization for Transducers and Extension Cables

Ethylene Oxide Gas (85º – 145 º F, 28 º – 63 ºC): Follow the recommendations furnished by the manufacturer of the gas sterilization equipment for proper sterilization and aeration times. The ethylene oxide sterilizer should be thoroughly cleaned before each sterilization cycle. Transducers should be completely dry before sterilization as water on the units may react with ethylene oxide and reduce its effectiveness. Aeration may be performed at room temperature or in a heated aeration (max 145 º F, 63 º C) cabinet. The transducer should be sterilized in a breathable polyethylene bag (e.g. 3M™ Steri-Lok™). Do not sterilize in the shipping container.

Alternative Method of Sterilization
Glutaraldehyde Solution (e.g. Cidex): Cidex may be used when the transducer connector and proximal end of the transducer will not be in the sterile field. Follow the manufacturer's sterilization recommendations for proper dilution, sterilization time and rinsing. Do not immerse the electrical connector.

Consult Millar, LLC before attempting sterilization by any other means. Sterilization by autoclaving, ionizing (gamma) radiation and exposure to formaldehyde vapor solution are known to be incompatible with the Mikro-Tip™ Transducers or cables and must not be used.

HANDLING PRECAUTIONS

	DO	DO NOT
Pressure Sensor	Protect with protective cover when not in use	Tap the sensor against a rigid surface
	Handle with care	Apply excessive force to the active surface
	Clean immediately after use	Squeeze the sensor
		Clean with stiff-bristled brush or high pressure water jet
		Expose to excessive pressure
		Use ultrasonic cleaner
Connector	Protect from fluid	Immerse in liquid
Cables	Protect connectors from fluid	Sterilize by autoclave or radiation
Cleaning	Clean immediately after use	Expose to cresols, phenols, acetone, peroxide, mercury compounds, chlorine, hypo-chlorites, xylene, Freon, tri-chloroethylene, silicone
		Use ultrasonic cleaner
		Immerse electrical connector