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improbable possible.

Model TC-510 Control Unit

Instructions for Use

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Recommended Accessories

Monitor Input Cables as appropriate for monitor, with Ferrite bead (Würth Electronics P/N 74270062) attached to monitor cable or Ferrite clamp (Würth Electronics P/N 74271221S) on monitor cable close to TC-510 Control Unit. **All accessories sold separately**

Definition of Symbols	
	Operating instructions
	Catalog Number
	Serial Number
	Batch Code
	Temperature Limits
	Relative Humidity Limits
	Manufacturer
	Authorized representative in the European Community
	Electrostatic Sensitive Device
	EU Declaration of Conformity
	Waste Electrical and Electronic Equipment

Device Description

The TC-510 Pressure Control Unit is a passive interface between the pressure sensor of any standardized sensitivity Mikro-Tip® catheter and strain gauge pressure monitors or recording systems which supply bridge excitation voltage and have balance and calibration controls for full-bridge strain gauge pressure transducers.

The TC-510 contains circuitry which facilitates monitor setup. In the STANDBY (0) position the TC-510 provides an electrical zero. In the 100 mmHg (13.3 kPa) position the TC-510 provides a signal equal to 100 mmHg (13.3 kPa) at a sensitivity of 5 $\mu\text{V/V/mmHg}$. The transducer is operational in the TRANSDUCER position and the TRANSDUCER BALANCE control allows balancing of the transducer.

Intended Use/Indications

The TC-510 Pressure Control Unit is intended for use with Millar Mikro-Tip pressure catheters that have the standard medical sensitivity of 5 $\mu\text{V/V/mmHg}$. It is intended for use in

monitoring diagnostic pressures, and when used in a clinical setting, must be used with CE monitors equipped with patient isolated circuitry.

Warnings

- 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.
- **EXPLOSION HAZARD!** Do not operate this unit in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.
- Ensure the Balance knob is locked after adjustment.
- Recording system input impedance < 500k Ohm can affect output of unit.
- This pressure control unit 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.
- Do not use TC-510 in MRI environment. The TC-510 has not been tested for MRI compatibility.
- The TC-510 is not to be used in wet environments. Discontinue use of the TC-510 if it is suspected that liquid has entered the case. Contact Millar customer service immediately.
- No modification of this equipment is allowed.
- 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 TC-510, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 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

- The TC-510 control unit should be used with Millar catheters and cables only.
- **DO NOT** use the TC-510 and transducers with or near high-frequency surgical equipment.

Environmental protection

Disposal of this ME Equipment (TC-510 and all accessories) is to be performed following all Governmental standards that may be applicable to your country and / or origin of use. There are no inherent risks to the user with the disposal of this ME Equipment.

Contraindications

Results obtained by using non-Millar catheters have not been validated.

Adverse Events

None Known.

Specifications

Power Source	Monitor must supply bridge excitation voltage
Excitation Load Resistance	325 Ω , nominal
Signal Output Load Resistance	1000 Ω , nominal
Operating	50° to 104°F (10 to 40°C), 30 to 75 % RH
Transport and Storage	-4° to 149°F (-20 to 65°C), 30 to 75% RH

Recording System Specifications

Recording System Input Impedance	500 k Ω *
Bridge Excitation Voltage	4 to 7.5 V _{DC}
Bridge Balance Control	The recording system should have a bridge balance control which does not load the transducer bridge.

* If the recording system input impedance is less than 500 k Ω , the output voltage of the transducer will be lowered proportionally due to loading (e.g., 10 k Ω input impedance reduces the output by 10%) thereby requiring a higher gain setting on the amplifier.

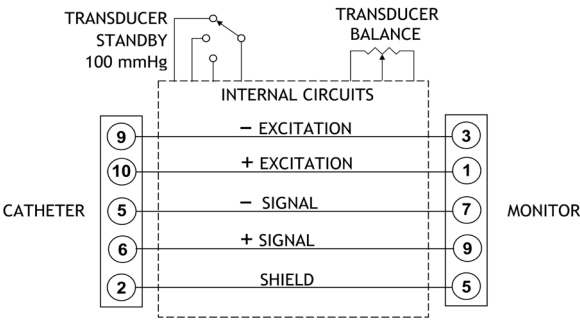
Operating Instructions

Note: Refer to pressure sensor “Instructions for Use” for presoak instructions.

1. Connect the TC-510 Monitor Input Cable to the TC-510. Tighten the screws on the connector.
2. Connect the TC-510 Monitor Input Cable to the monitor.
3. Turn the TC-510 switch to STANDBY and adjust the monitor for a zero baseline.
4. Turn the TC-510 switch to 100 mmHg (13.3 kPa) and adjust the monitor output to indicate 100 mmHg (13.3 kPa) **.
5. Connect the transducer catheter and extension cable, turn the TC-510 switch to TRANSDUCER and follow transducer catheter “Instructions for Use” for transducer zeroing and, adjust the TRANSDUCER BALANCE control to the same zero baseline as in step 4. Lock the TRANSDUCER BALANCE control.
6. The transducer is now zeroed and ready for use.

** To calibrate in cmH₂O, substitute “136 cmH₂O” for “100 mmHg.”

Schematic



Electromagnetic Compatibility

Electromagnetic Emissions		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The TC-510 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 TC-510 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)	
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	

Factory Repair

If repair or return is needed, contact your distributor. If you purchased the TC-510 or accessory directly from Millar, contact Millar's Customer Service Department to obtain a Return Material Authorization (RMA) number and specific instructions regarding the return of the TC-510 or accessory. All returns must have an RMA number. Millar contact information may be found on the back cover of this IFU.

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 (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 this product if 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 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, 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, may 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 research or clinical procedure. Therefore, the user accepts these devices subject to all the terms hereof

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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.



Authorized Representative

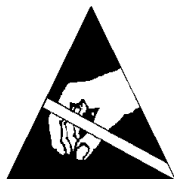
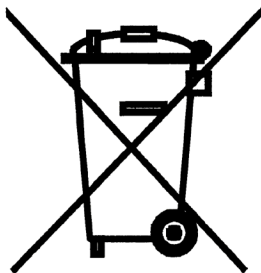
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OBSERVE PRECAUTIONS
FOR HANDLING
ELECTROSTATIC
SENSITIVE DEVICES

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