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Millar Worldwide Distribution

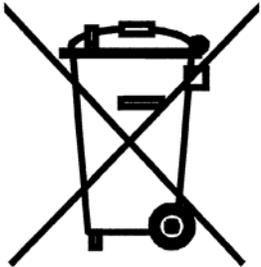
Millar, Inc. has a network of Authorized Distributors in most countries around the world. For information on the Millar distributor in your country, please contact the Millar Customer Service Department at our headquarters in Houston, Texas.



Authorized Representative

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For your convenience, Millar provides translated IFUs in the following languages: Dutch, French, German, Spanish and Swedish. Please visit our website at millar.com to access the additional languages



Making the
improbable possible.

Model TC-510 Control Unit

Instructions for Use

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Products and company names used are the trademarks or trade names of their respective companies.
Models referred to herein are protected by USA and International patents.

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

Operating Instructions

To minimize drift, presoak the pressure sensor in sterile water or sterile saline for 30 minutes prior to use.

Connect the TC-510 Monitor Input Cable to the TC-510. Tighten the screws on the connector.

Connect the TC-510 Monitor Input Cable to the monitor.

Turn the TC-510 switch to STANDBY and adjust the monitor for a zero baseline.

Turn the TC-510 switch to 100 mmHg (13.3 kPa) and adjust the monitor output to indicate 100 mmHg (13.3 kPa)**.

Connect the transducer catheter and extension cable, turn the TC-510 switch to TRANSDUCER and with the pressure sensor just below the surface of sterile water or saline and shielded from ambient light, adjust the TRANSDUCER BALANCE control to the same zero baseline as in step 4. Lock the TRANSDUCER BALANCE control.

The transducer is now zeroed and ready for use.

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

Schematic

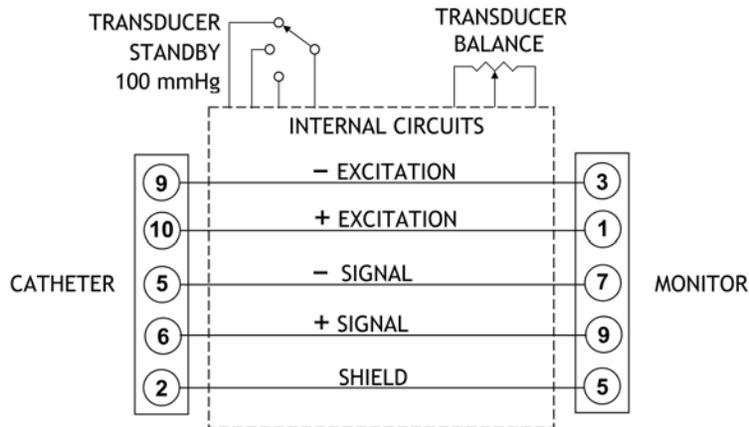


Table of Contents

RECOMMENDED ACCESSORIES	1
DEFINITION OF SYMBOLS	1
DEVICE DESCRIPTION.....	1
INTENDED USE/INDICATIONS	1
WARNINGS.....	1
PRECAUTIONS	2
CONTRAINDICATIONS.....	2
ADVERSE EVENTS.....	2
SPECIFICATIONS	2
RECORDING SYSTEM SPECIFICATIONS	2
OPERATING INSTRUCTIONS	3
SCHEMATIC	3
FACTORY REPAIR	4
MILLAR LIMITED WARRANTY	4

Recommended Accessories

M.I. P/N: 850-3008 TC-510 Output Monitor Cable 6.5 ft. (198 cm)

All accessories sold separately

Definition of Symbols	
	Attention, consult accompanying documents
	Date of Manufacture
REF	Catalog Number
SN	Serial Number
	Batch Code
	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 $\mu\text{V}/\text{V}/\text{mmHg}$. 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 $\mu\text{V}/\text{V}$ 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.
- 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.

Precautions

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	2.5 to 7.5 V_{DC} or V_{AC} rms
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.