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Millar Worldwide Distribution

Millar, LLC. 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.



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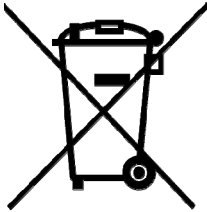
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M.I. P/N: 004-0590 Rev. W
2025-02



Making the
improbable possible.

Model TC-510 Control Unit

Instructions for Use

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 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.

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.

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.

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Recommended Accessories

Monitor Input Cable as appropriate for monitor, with EMC Ferrite (Fair-Rite P/N 2631540002 or Würth Electronics P/N 74271221S) attached to 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
	UK Conformity Assessed
	Waste Electrical and Electronic Equipment

Device Description

The TC-510 Pressure Control Unit is a passive interface between the pressure sensor of Mikro-Cath™ 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 µV/V/mmHg. The transducer is operational in the TRANSDUCER position and the TRANSDUCER BALANCE control allows balancing of the transducer.

^aField 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 TC-510 is used exceeds the applicable RF compliance level above, the TC-510 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the TC-510.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the TC-510			
The TC-510 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TC-510 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TC-510 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.			

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					

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 TC-510, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$, 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: 
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	

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.

Intended Use/Indications

The TC-510 Pressure Control Unit is intended for use with Millar Mikro-Cath 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	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.

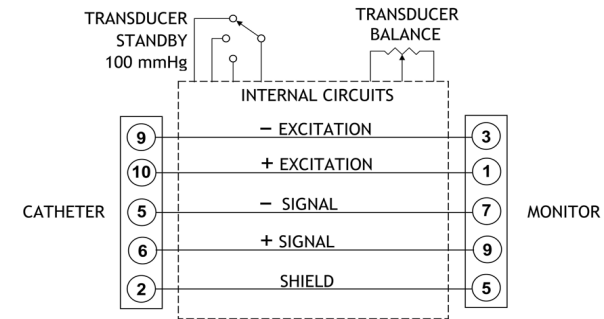
Operating Instructions

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 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, ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV Air	± 8 kV Contact, ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV 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.