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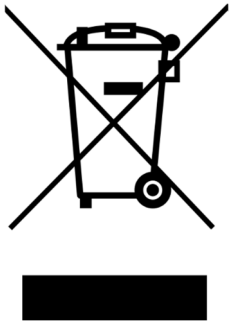
**Millar Worldwide Distribution**

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.

For your convenience, Millar provides translated IFUs in other languages. Please visit our website at eifu.millar.com (go to 'Manuals and Guides') to sign up for an account and follow the registration process to access the IFUs in additional languages. Documents are in PDF format and require free Adobe Acrobat Reader software to view. System requirements for Adobe Acrobat Reader software are Windows operating system (Windows 8 or later) or macOS (v10.14 or later).

OBSERVE PRECAUTIONS
FOR HANDLING
ELECTROSTATIC
SENSITIVE DEVICES





M.I. P/N: 004-2113 Rev. P

Millar®

Making the improbable possible.

# MODEL PCU-2000

# Pressure Control Unit with Patient Isolation

# Instructions for Use (IFU)

U.S.A. federal law restricts this device to sale by or on the order of a physician or other licensed practitioner, when used as a medical device

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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.



## Definition of Symbols

| | |
|---|---|
|  | Attention, consult accompanying documents |
|  | Date of Manufacture |
| REF | Catalog Number |
| SN | Serial Number |
|  | Batch Code |
|  | Type CF Applied Part |
|  | Double Insulated |
|  | Electrostatic Sensitive Device |
| MD | Medical device |
|  | Consult instructions for use or consult electronic instructions for use |
|  | Waste Electrical and Electronic Equipment |

## Definitions

| | |
|---|---|
| DC | Direct Current |
| IFU | Instructions for use |
| AC | Alternating Current |
| Transducer | Pressure tip catheter |
| AC Mains | Hospital Alternating Current Supply |
| RMA | Return Material Authorization |
| M.I. | Millar, Inc. |
| RF | Radio Frequency |
| EMC | Electromagnetic Compatibility |
| EMI | Electromagnetic Interference |

**READ ALL INSTRUCTIONS, WARNINGS AND PRECAUTIONS PRIOR TO USE**

## Device Description

The following information will provide data relating to the safe operation of the PCU-2000. The two-channel PCU-2000, M.I. P/N 880-0129, is an essential interface between one dual-pressure or two single-pressure Millar Mikro-Tip™ catheters and a CE-approved data acquisition system or patient monitor. The unit is powered by a Millar-supplied external AC/DC power supply.

The PCU-2000 pressure inputs (input channel 1 and input channel 2) are electrically isolated for patient safety. These inputs are also protected against the effects of a cardiac defibrillator discharge. The discharge of a cardiac defibrillator has no effect on the operation of the PCU-2000.

The pressure outputs have a sensitivity of 1V/100mmHg, which is ideally compatible with most monitors and computer data acquisition systems. The amplifier provides bridge excitation voltage, separate balance (zero) controls and lighted push buttons for electronic calibrations of 0, 25, 100 or 125 mmHg for both channels.

The PCU-2000 allows selection of standby mode to verify zero and calibration. The output connectors are standard ¼-inch phone jacks. Output cables are not provided. See Output Connector Wiring section in this IFU for additional information.



| | |
|---|---|
| Mechanical | |
| Size | 2.6 in. H x 6.1 in. W x 5.3 in. D |
| | 6.6 cm H x 15.5 cm W x 13.5 cm D |
| Weight | 1.1 lbs. (0.5kg) |
| Environmental | |
| 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 |
| Safety Protection | |
| Fuse | Re-settable, 0.4A |

Note: Specifications subject to change without notice.

## Factory Repair

If repair or return is needed, contact your distributor. If you purchased the PCU-2000 or accessory directly from Millar, Inc. contact Millar's Customer Service Department to obtain a Return Material Authorization (RMA) number and specific instructions regarding the return of the PCU-2000 or accessory. All returns must have a RMA number. Millar contact information may be found on the back cover of this IFU.

## Millar Limited Warranty

Millar, Inc. 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.

## PCU-2000 Specifications

| | |
|---|---|
| Equipment Classifications | |
| Class | II (USA), |
| Ingress Protection | IP20 |
| Type | CF |
| Pressure Transducer Characteristics | |
| Transducer Sensitivity | 5 µV/V/mmHg, nominal |
| Bridge Excitation Load Resistance | 1000 ohms, nominal |
| | 350 ohms, minimum |
| Transducer Bridge Excitation | 5.0 $V_{DC}$, nominal |
| Signal Input Resistance | 50 megohm, nominal |
| Pressure Outputs | |
| Sensitivity | 1 V/100 mmHg, nominal. |
| Accuracy Error Band | <± 1 mmHg or 1 % of reading, whichever is greater |
| Frequency Response | DC to1000 Hz (-3 Db), minimum |
| Output Resistance | 1000 ohms, nominal |
| Noise | <0.3 mmHg peak-to-peak |
| Zero-Offset Temperature Coefficient | <0.15 mmHg/°C |
| Gain Temperature Coefficient | <0.1 %/°C |
| Balance Adjustment Range | ± 140 mmHg, nominal |
| Standby-Calibration Mode | |
| Zero Offset | <±1 mmHg |
| Calibration Steps | 0, 25, 100 and 125 mmHg |
| Calibration Accuracy | <± 0.5 mmHg |
| LED Bar Graphs | |
| Range | -25 to 200 mmHg in 10 steps |
| Resolution | 25 mmHg |
| Out of Range | Top light stays on at high pressures |
| | Bottom light turns off at low pressures |
| Power Supply | External AC/DC desktop style |
| Input (Universal) | 100 to 240 $V_{AC}$, 0.3A, 50/60 Hz |
| Output | 5 $V_{DC}$/2.0 A, regulated (±5%) |
| Safety Approvals | EN 60601-1 |



## Intended Use/Indications

The PCU-2000 Pressure Control Unit is intended for use with Millar Mikro-Tip pressure catheters that have the standard medical sensitivity of 5 µV/V/mmHg. It is intended for use in monitoring diagnostic pressures, such as noninvasive or invasive blood pressures, intracranial pressures, gastrointestinal pressures, esophageal pressures, urinary tract pressures, intrauterine pressures, intraocular pressures and other physiological pressures with similar ranges. It is intended for use in critical care areas in a hospital and in diagnostic centers in hospitals or medical clinics. It is intended for use by trained clinicians or research personnel.

## Warnings

EXPLOSION HAZARD! Do not operate this unit in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

ELECTRIC SHOCK HAZARD! Use only those power supplies and power cables recommended and approved by Millar, Inc. In addition, use only Millar catheters. See the RECOMMENDED ACCESSORIES section for replacement parts.

ELECTRIC SHOCK HAZARD! The PCU-2000 is not to be used in wet environments. Discontinue use of the PCU-2000 if it is suspected that liquid has entered the case. Contact Millar customer service immediately.

No modification of this equipment is allowed.

## Precautions

DO NOT remove the cover. Refer servicing to qualified personnel.

DO NOT use the PCU-2000 and transducers with or near high-frequency surgical equipment.

DO NOT use the PCU-2000 in close proximity to high electrical noise-generating equipment, as this may cause interference with the signal. If interference occurs, move the PCU-2000 system away from the noise-generating device. Medical electrical equipment such as the PCU-2000 needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment such as the PCU-2000.

DO refer to the respective cardiac defibrillator manual prior to performing defibrillation if applicable.

## Contraindications

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

## Environmental protection

Disposal of this ME Equipment (PCU-2000 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.

## Normal Use Operating Instructions

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

Connect the PCU-2000 Control Unit to the monitor and insert the DC power plug into the DC IN jack on the rear panel. Plug the other end of the power cord into the AC mains connection. Refer to Fig. 2. Connect the power cord to the external power supply

Set the PCU-2000 mode switch to STANDBY and the power switch to ON. Ensure power switch LED is illuminated on the back panel. If power LED does not illuminate, see troubleshooting section for additional help.

Adjust the monitor for a zero baseline. Ensure the 25 and 100 mmHg calibration buttons are in the off position.

Press the 25 mmHg CALIBRATION button, the 100 mmHg CALIBRATION button, or both buttons to get a 125 mmHg calibration signal, according to the desired range, and then adjust the monitor sensitivity.

Connect the catheter and extension cable to the PCU-2000 pressure input(s) on back of unit; channel 1 or 2 or both (Fig. 2). Turn the PCU-2000 function switch located on the front panel (Fig. 1) to TRANSDUCER and, with the pressure sensor just below the surface of water or saline and shielded from ambient light, adjust the TRANSDUCER BALANCE control to the same zero baseline as in step 3. Place the catheter balance locking mechanism in the LOCK position.

The catheter is now ready for use. Refer to the catheter IFU for additional information.

During sustained use, calibration can be checked without removal of the catheter from the subject by switching the PCU-2000 function switch to STANDBY, reproducing the original zero baseline. Subsequently, calibration signals equivalent to 25 mmHg, 100 mmHg, or 125 mmHg (using both switches) can be obtained by selecting the corresponding buttons.

To remove the transducer connections after use, simply hold the outside collar of the connector and pull out. The Power Input Connection and the Output Monitor Connection can be removed by holding the connector body and pulling out. Do not pull the cable of any connection to remove it from the back panel. Always use the connector body.



**Recommended separation distances between portable and mobile RF communications equipment and the PCU-2000**

The PCU-2000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PCU-2000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PCU-2000 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 in ISM bands $d = 1.17\sqrt{P}$ | 80 MHz to 800 MHz in ISM bands $d = 1.17\sqrt{P}$ | 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.117 | 0.117 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.73 |
| 1 | 1.17 | 1.17 | 2.3 |
| 10 | 3.7 | 3.7 | 7.3 |
| 100 | 11.7 | 11.7 | 2.3 |

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.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Medical electrical equipment such as the PCU-2000 needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document.

Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment such as the PCU-2000.

The PCU-2000 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the PCU-2000 should be observed to verify normal operation in the configuration in which it will be used.

| Guidance and manufacturer's declaration – electromagnetic immunity | | | |
|---|---|---|---|
| The PCU-2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the PCU-2000 should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Conducted RF<br>IEC 61000-4-6<br><br>Radiated RF<br>IEC 61000-4-3 | 3 Vrms<br>150 kHz to 80 MHz<br><br>3 V/m<br>80 MHz to 2.5 GHz | 3 V<br><br>3 V/m | Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>**Recommended separation distance**<br>$d = 1.17\sqrt{P}$<br>$d = 1.17\sqrt{P}$ , 80 MHz to 800 MHz<br>$d = 2.3\sqrt{P}$ , 800 MHz to 2.5 GHz<br>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).<br>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]<br>Interference may occur in the vicinity of equipment marked with the following symbol: |
| NOTE 1 At 80 MHz and 8000 MHz, the higher frequency range applies.<br>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 PCU-2000 is used exceeds the applicable RF compliance level above, the PCU-2000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the PCU-2000.<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [$V_1$] V/m. | | | |



## Figures

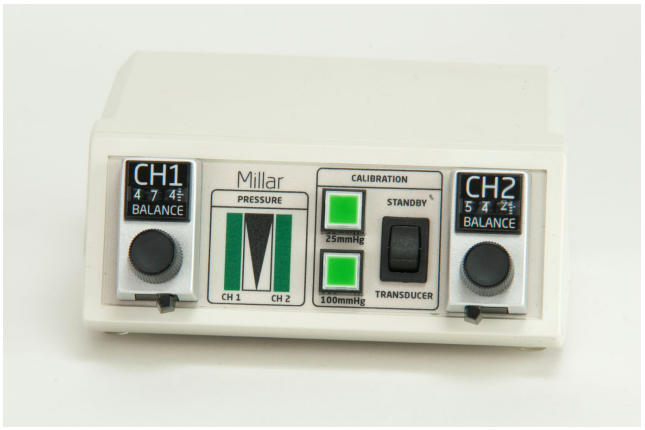



**Fig. 1. PCU-2000 Front Panel Controls**


**Fig. 2. PCU-2000 Rear Panel**

Since monitors have different input wiring requirements, a control unit with a specified monitor input cable should be used only with same make and model of monitor for which it is supplied, even if the connector fits another monitor.

Millar does not assume responsibility for calibration of external monitors.

**CAUTION:** The bar graph pressure displays in Fig. 1 are intended for use in set-up and operation of the unit. The displays are intended to show a presence of signal. They are NOT intended to supply quantitative or qualitative signal information for use in diagnosis of patient condition.

## Repair, Cleaning, Preventative Maintenance and Inspection

There are no user-serviceable parts inside the PCU-2000 or its accessories. If the unit or accessory is found to be defective, it MUST be returned to Millar for repair or replacement. The user must call Millar Customer Service to obtain a Return Material Authorization (RMA) number and specific instructions regarding the return of the PCU-2000 or accessory. All returns must have a RMA number.

The PCU-2000 should be cleaned periodically with a damp cloth and mild detergent, if needed. Disconnect the power connection from the unit before cleaning. Care should be taken to prevent excessive water from entering the case during cleaning. A 70/30 alcohol wipe may be used to disinfect the case; however, repeated use of alcohol may damage the case or labels. A diluted solution of bleach in water (<5 % bleach) may be used to disinfect the case exterior by wiping with a dampened cloth.

The following items should be periodically checked as part of a yearly preventative inspection program.

Check the plastic nuts on the PRESSURE INPUT connectors to ensure that they are secure. Hand-tighten, if needed.

Check all switches to ensure that they are fully seated into the case.

Verify that the plastic feet are securely attached to the bottom of the case. Replace any missing feet.

Check the enclosure to ensure that the cover is securely installed on the base. Inspect the horizontal seam to verify that it does not have a visible clearance that can be pulled apart. To secure the top to the bottom, place the unit on a flat surface and press firmly down on each side to snap the top to the bottom.

The PCU-2000 should be tested yearly by the user for electrical safety per the ANSI/AAMI (ES1) standard for Safe Current Limits for Electromedical Apparatus.



| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The PCU-2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the PCU-2000 should assure that it is used in such an environment. | | | |
| **Immunity test** | **IEC 60601 test level** | **Compliance level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge (ESD) IEC 61000-4-2 | ±6 kV contact<br>±8 kV air | ±6 kV contact<br>±8 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<br>IEC 61000-4-4 | ±2 kV for power supply lines<br>±1 kV for input/output Lines | ±2 kV for power supply lines<br>±1 kV for input/output Lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br>IEC 61000-4-5 | ±1 kV differential mode<br>±2 kV common mode | ±1 kV differential mode<br>±2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | <5 % *U*T<br>(>95 % dip in *U*T)<br>for 0.5 cycle<br>40 % *U*T<br>(60 % dip in *U*T)<br>for 5 cycles<br>70 % *U*T<br>(30 % dip in *U*T)<br>for 25 cycles<br><5 % *U*T<br>(>95 % dip in *U*T)<br>for 5 sec | 100%-0.5cycle and 250 cycles (Performance Criteria A & B),<br>60%-5 cycles (Performance Criteria A),<br>30%-25c (Performance Criteria A) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the PCU-2000 requires continued operation during power mains interruptions, it is recommended that the PCU-2000 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz)<br>magnetic field<br>IEC 61000-4-8 | 3 A/m | Not applicable | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE *U*T is the a.c. mains voltage prior to application of the test level. | | | |

# Safety and EMC Testing Standards

## Electrical Safety

This device was tested for electrical safety and approved under the general standard EN 60601-1.

## Electromagnetic Compatibility (EMC)

This device was tested for electromagnetic compatibility (EMC) under the EN 60601-1-2 standard.

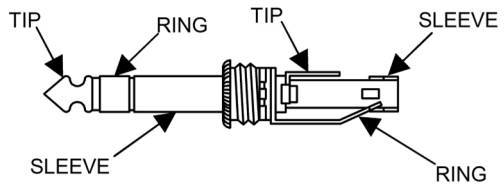
| **Guidance and manufacturer's declaration – electromagnetic emissions** | | |
|---|---|---|
| The PCU-2000 is intended for use in the electromagnetic environment specified below. The customer or the user of the PCU-2000 should assure that it is used in such an environment. | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF emissions<br>CISPR 11 | Group 1 | The PCU-2000 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<br>CISPR 11 | Class B | The PCU-2000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Class A | |
| Voltage fluctuations/ flicker emissions<br>IEC 61000-3-3 | Complies | |



# Output Connector Wiring

**Pressure Output Connection**

The customer is to supply a ¼" phone plug which mates with the model PCU-2000 PRESSURE OUTPUT connector. An example plug is the Switchcraft® #267, which is a ¼" 3-conductor phone plug or equivalent. The input and output are isolated from ground but they are connected to each other. See accessories section.




**DC Amplifier with Differential Input Circuitry**

| | |
|---|---|
| Tip | + Signal |
| Ring | - Signal |
| Sleeve | Cable Shield |

**DC Amplifier with Single-ended Input Circuitry**

| | |
|---|---|
| Tip | Signal Input Lead |
| Ring and Sleeve | Cable Shield |

**Reverse Polarity**

| | |
|---|---|
| Ring | Signal Input Lead |
| Tip and Sleeve | Cable Shield |

**CAUTION:** Millar, Inc. cannot assume responsibility for the performance of the PCU-2000 if the plug is incorrectly wired.

Use shielded wire ≤ 3 feet in length for the output cable. Using longer cable could result in noise pickup to your monitor.

## Troubleshooting

| Effect | Cause | Solution |
|---|---|---|
| No power light illuminated on power switch | No AC mains power to external power supply | Check to be sure that the AC power cord is securely plugged into power supply |
| | | Ensure that the DC input power cable is securely attached to back of PCU-2000 unit |
| | | Ensure that the circuit breaker supplying AC mains power to the system has not been tripped |
| No light(s) illuminated on LED bar graph | No AC Mains power to external power supply | Check to be sure that the AC power cord is securely plugged into power supply |
| | No transducer is plugged into PCU-2000 | Plug transducer into PCU-2000 |
| | Faulty Transducer | Replace with known good transducer |
| | PCU-2000 is defective | Contact Millar Customer Service for RMA to return unit |



## Recommended Accessories

Only Millar accessories are to be used with the PCU-2000. All accessories are sold separately.

The use of accessories, transducers, and cables other than those specified or supplied by Millar, Inc. may result in increased EMI emissions or decreased immunity to EMC.

### PCU-2000 Interface Cables

| Cable Model | M. I. Part Number | Cable Length | Catheter End Connector Type |
|---|---|---|---|
| | | | |
| | | | |
| PEC-4D | 850-5103 | 4 ft. (122 cm) | Low Profile |
| PEC-10D | 850-5090 | 10 ft. (305 cm) | Low Profile |

Note: Viking connectors are round with 4 pins. Low Profile connectors are flat with 4 pins.

Note: The maximum length of interface cables is 10ft. EMC testing has not been performed with longer cables.

### Power Supply Information

| Item | M.I. Part Number | Description | Connectors |
|---|---|---|---|
| Power Supply | 249-2365 * GlobTek GTM21089-1305-T3 | Power Supply | C14 |
| North American Power Cord | 850-5117 | Power Cord | Hospital Grade NEMA 5/15 and C13 |
| European Power Cord | 850-5118 | Power Cord | Type CEE 7/7 and C13 |

* This unit must be purchased from Millar, Inc. The separate power supply is considered part of this ME Equipment.

Cords used in other regions will require a C13 connector for the power supply connection and the appropriate regional plug for connection to the power source. The cord must be SJT, 18AWG, and rated for at least 10 amperes at the appropriate regional voltage. The maximum power cord length is 8.2 feet or 2.5m.

You may contact Feller directly at the numbers listed below.

### Interface and Adapter Cables

To purchase interface and adapter cables to connect pressure transducers and monitors, please contact Fogg System Company, Inc.

Fogg System Company, Inc
15592 East Batavia Drive
Aurora, CO 80011 USA

Phone: 303-344-1883
Fax: 303-344-1780
Email: sales@foggsystem.com
Web site: www.foggsystem.com