

Multi-Parameter Monitor Model MPM-1 Technical Manual

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1 Introduction

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1.1 Disclaimer and Warnings

PROPRIETARY INFORMATION

INFORMATION CONTAINED IN THIS TECHNICAL MANUAL IS PROPRIETARY TO INTEGRA NEUROSCIENCES AND MAY BE USED ONLY FOR THE PURPOSE OF PERFORMING OPERATIONAL CHECKS. THE PURCHASE OR POSSESSION OF THIS MANUAL DOES NOT CONFER, TRANSFER OR LICENSE ANY OTHER RIGHTS TO THIS INFORMATION. ANY OTHER USE OR DISCLOSURE AND/OR REPRODUCTION (BY ANY METHOD) OF THE INFORMATION CONTAINED HEREIN IS STRICTLY PROHIBITED UNLESS WRITTEN PERMISSION IS OBTAINED FROM INTEGRA NEUROSCIENCES.

AUTHORIZED SERVICE

This manual is intended for use by biomedical personnel to perform operational checks. Any adjustments or procedures that exceed the scope of this manual should be referred to Integra NeuroSciences.

Integra NeuroSciences does not condone or approve of service activity on its products by anyone other than Integra NeuroSciences personnel; and Integra NeuroSciences is not responsible for any unauthorized repairs.

DEFINITION OF DANGER, CAUTION AND NOTE

- Danger means there is the possibility of injury or death to you or others.
- Caution means there is the possibility of damage to the unit or other property.
- Note indicates points of particular interest for more efficient and convenient operation.

SAFETY CONSIDERATIONS

- Danger Risk of explosion if used in the presence of flammable anesthetics.
- Caution Do not autoclave or immerse the MPM-1 as damage may occur. If the MPM-1 is exposed to liquids, turn off the unit, remove the power cord and thoroughly dry the unit before reapplying power.
- Caution Do not use solvents or cleaning agents as they could damage the plastic exterior of the MPM-1.
- Caution To reduce the risk of electric shock do not remove the cover. Refer servicing to qualified personnel.
- Caution Read Directions for Use before connecting to bedside patient monitors.
- Caution Grounding reliability can only be achieved when connected to Hospital Grade Receptacle.
- Caution Where the integrity of the external PROTECTIVE EARTH CONDUCTOR arrangement is in doubt, the equipment shall be operated from its internal electrical power source (battery).

- Caution This equipment should not be used with high frequency surgical equipment.
- Caution Integra NeuroSciences Catheters are for single use only. Do not attempt to re-sterilize or reuse. Integra NeuroSciences cannot assume any responsibility for damage caused by re-sterilized Catheters. Used catheters should be considered as a potential biohazard. Follow all established laws and regulations pertaining to the handling and disposal of biohazardous materials.
- Caution The MPM-1 contains Static Sensitive Devices. Observe proper ESD precautions when working with Static Sensitive Devices.

SHIPPING INSTRUCTIONS

A shipping container is available. To insure proper preparation and shipping, contact Integra NeuroSciences for instructions.

APPLICABILITY

This Technical Manual is applicable to the Multi-Parameter Monitor with waveform display, Model MPM-1. Contact Integra NeuroSciences for information for equipment not covered in this manual.

Integra NeuroSciences reserves the right to change specifications and procedures without notice.

1.2 System Overview

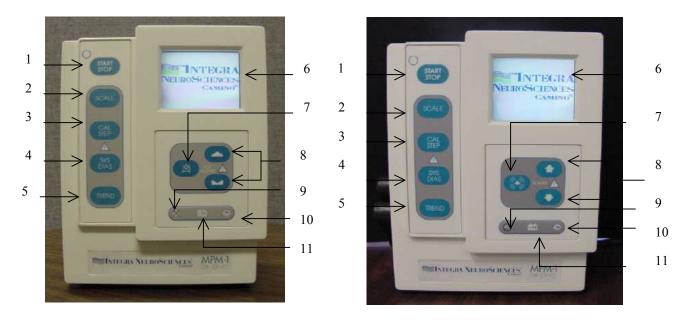


Figure 1-1 International Front Panel

Figure 1-2 Domestic Front Panel

- 1. **START/STOP** Press to turn MPM-1 on or off.
- 2. **SCALE** Press to change scale of pressure waveform on MPM-1 Display.
- 3. **CAL STEP** Used to calibrate or check correlation of external bedside monitor.
- 4. **SYS/DIAS** Press to toggle between the CPP-ICP-ICT display and the SYSTOLIC-ICP-DIASTOLIC display.
- 5. **TREND** Press to graphically display the last 12 or 24 hours of ICP and/or CPP values.
- 6. LCD DISPLAY Displays ICP waveform, numerical values and trend data.
- 7. **SILENCE ALARM** Press to silence the alarm for 3 minutes.
- 8. **UP and DOWN** Press the button(s) to set the desired alarm limit value.
- 9. **ALARM DISABLED INDICATOR** Illuminates whenever the ICP alarm limit is set to OFF. Flashes when alarm is temporarily silenced.
- 10. **AC POWER INDICATOR** Illuminates when MPM-1 is connected to ~AC power. The battery will charge whenever this indicator is illuminated.
- 11. **LOW BATTERY INDICATOR** Illuminates when MPM-1 is operating on Battery power and less than fifteen minutes battery life remains.



Figure 1-3 Rear Panel

- 12. COMBINATION CORD WRAP, HANDLE, and BED RAIL MOUNT
- 13. **DFU POCKET** Storage location for the Directions for Use booklet.
- 14. **BEDSIDE MONITOR CONNECTOR** Used for connection to the bedside monitor.
- 15. **EQUIPOTENTIAL CONNECTOR** Used as the connection point for equipotential systems.
- ICP ISOLATED ANALOG CONNECTOR Used for data acquisition needs. Provides 1V/100 mmHg output suitable for computer ADC's or a strip chart recorder.
- 17. **RS232 CONNECTOR** Used for data acquisition needs. Please contact Integra NeuroSciences for details on use of this digital data.
- 18. **AC CONNECTOR** Attachment point for the ~AC power cord. Automatically selects input ~AC voltage of 100, 115 or 230 Volts. Must be plugged into an AC source whenever it is desired to maintain a charge on the internal battery.
- 19. **POLE CLAMP** Used to secure the MPM-1 to an equipment pole.

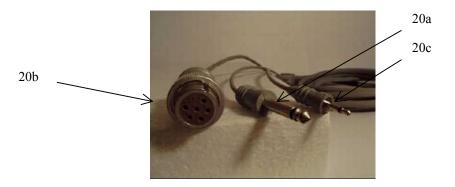


Figure 1-4 Bedside Monitor Cable

- 20. **BEDSIDE MONITOR CONNECTOR** Used for connection to the bedside monitor.
 - 20a. ICT data to Bedside Monitor (Standard Phone Plug)
 - 20b. ICP Waveform to Bedside Monitor (6-Pin Cannon Connector)
 - 20c. Arterial Pressure Data to MPM-1 (Miniature Phone Plug)

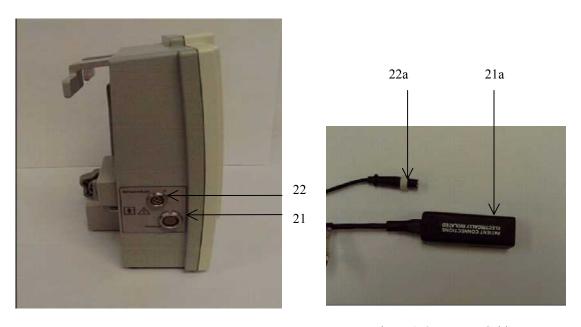


Figure 1-5 ICP & ICT Connectors

Figure 1-6 Preamp Cable

- 21. **ICP CONNECTION** Attachment point for the Preamp Cable Connector.
 - 21.a ICP Catheter to Preamp connection.
- 22. **TEMPERATURE CONNECTION** Attachment point for the Temperature Cable Connector.
 - 22.a ICT Catheter temperature connection.

1.3 Technical Specifications

INTRACRANIAL PRESSURE (ICP)

Sensor Type: Fiber-optic pressure transducer

Range: -10 to +250 mmHg

Resolution: 1mmHg for LCD display

0.125 mmHg for Patient Monitoring Systems

Linearity: See individual catheter specifications.

Hysteresis: See individual catheter specifications.

Freq. Response: 120 Hz nominal, 100 Hz minimum (3dB down)

1.32 mSec for analog output

Accuracy: $\pm 1 \text{ mmHg}$

Reference Pressure: Atmospheric

INTRACRANIAL TEMPERATURE (ICT)

Sensor Type: Thermistor transducer

Display Range: 16.7°C to 42.2°C (65°F to 108°F)

Accuracy: $\pm 0.3^{\circ}\text{C} (0.5^{\circ}\text{F}) [30^{\circ}\text{C} - 40^{\circ}\text{C}]$

MEAN CEREBRAL PERFUSION PRESSURE (CPP)

Type: Calculated

Range: 0 to 200 mmHg

Resolution: 1 mmHg

Accuracy: $\pm 1 \text{ mmHg}$

ALARMS

Audible: $2kHz \pm 1kHz$ signal, ON 0.5 seconds and OFF 0.5 seconds

at full amplitude

High ICP Alarm: 0 to 250 mmHg, 1 mmHg increments

Low CPP Alarm: 0 to 150 mmHg, 1 mmHg increments

Alarm Silence: 3 minutes

MONITOR INPUTS

"Trapezoidal" pre-amplifier input connection for Integra NeuroSciences ICP catheters

Isolated 3-wire thermistor based TDC input for Integra NeuroSciences ICP/ICT catheters.

Isolated Arterial Pressure (AP) for bed side patient monitoring systems. (1V/100 mmHg)

MONITOR OUTPUTS

Analog ICP for patient monitoring systems. $(5\mu V/V/mmHg)$ (6-Pin CANNON WK-6 connector)

Analog ICT for patient monitoring systems. (Standard 3-wire YSI 400 interface) (SwitchcraftTM ¹/₄" Plug connector)

Analog ICP for data recording. (1V/100 mmHg) (Switchcraft™ Model 750 connector)

RS-232 Serial data port. Contact Integra NeuroSciences for details. (9 pin DB9 male connector)

DISPLAY

Type: Backlit TFT active matrix LCD panel

Parameters displayed: Pressure Waveform

CPP, ICP, ICT (Main Screen)

Systolic, ICP, Diastolic (Systolic/Diastolic Screen) 12 and 24 hour Trend Information (ICP and CPP)

BATTERY

Type: Rechargeable, sealed lead acid

Charge Time: 8-10 hours to full charge
Operation Time: 1-2 hour from full charge

POWER REQUIREMENTS

100-230 V, 50/60 Hz, 50 VA

MONITOR OPERATING LIMITS

Temperature: 15°C to 40°C (59°F to 104°F)

Pressure: 700 hPa to 1060 hPa (20.67 inHg to 31.30 inHg)

Humidity: 20% to 95% RH

SHIPPING/STORAGE LIMITS

Temperature: 0°C to 50°C (32°F to 122°F)

Pressure: 500 hPa to 1060 hPa (14.76 inHg to 31.30 inHg)

Humidity: 20% RH to 95% RH non-condensing

PHYSICAL DIMENSIONS

Size: 274 mm H x 216 mm W x 89 mm D

(10.8" x 8.5" x 3.5")

Weight: 4.4 kg (9.8 lbs.)

IEC-60601-1

Class of Equipment: Class 1

Protection Against Fluids: Ordinary

1.4 Limited Warranty

INTEGRA NEUROSCIENCES warrants that each new INTEGRA NEUROSCIENCES product is free from defects in material and workmanship under normal use and service for a period of two (2) years (except as otherwise expressly provided as to accessory items) from the date of delivery by INTEGRA NEUROSCIENCES to the first purchaser but not beyond the "Expiration" date stated on any product labeling. Surgical instruments are guaranteed to be free from defects in material and workmanship when used normally for their intended purpose. Any covered product which is placed by INTEGRA NEUROSCIENCES under a lease, rental or installment purchase agreement and which requires repair service during the term of such placement agreement shall be repaired in accordance with the terms of such agreement. If any such defect occurs during the warranty period or term of such placement agreement, the purchaser should communicate directly with the INTEGRA NEUROSCIENCES home office. If returned to INTEGRA NEUROSCIENCES at its home office, repair or replacement will be carried out at INTEGRA NEUROSCIENCES' sole discretion, at INTEGRA NEUROSCIENCES' expense, subject to the terms of this warranty and applicable agreements. The defective product should be returned promptly, properly packaged and postage prepaid. Loss or damage in return shipment to INTEGRA NEUROSCIENCES shall be at CUSTOMER's risk.

IN NO EVENT SHALL INTEGRA NEUROSCIENCES BE LIABLE FOR ANY INCIDENTAL, INDIRECT OR CONSEQUENTIAL DAMAGES IN CONNECTION WITH THE ACQUISITION OR USE OF ANY INTEGRA NEUROSCIENCES PRODUCT. Further, this warranty shall not apply to, and INTEGRA NEUROSCIENCES shall not be responsible for, any loss arising in connection with the purchase or use of any INTEGRA NEUROSCIENCES product which has be repaired by anyone other than an authorized INTEGRA NEUROSCIENCES service representative or altered in any way so as, in INTEGRA NEUROSCIENCES' judgment, to affect its stability or reliability, or which has been subject to misuse, negligence or accident, or which has been used otherwise than in accordance with the instructions furnished by INTEGRA NEUROSCIENCES. This limited warranty is exclusive and in lieu of all other warranties, express or implied, and of all other obligations or liabilities on INTEGRA NEUROSCIENCES' part and INTEGRA NEUROSCIENCES neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with INTEGRA NEUROSCIENCES products.

INTEGRA NEUROSCIENCES DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION OR WARRANTY OF QUALITY, OTHER THAN THOSE EXPRESSLY SET FORTH IN THE PRODUCT LABELING, INCLUDING THE APPLICABLE USER INFORMATION. The foregoing shall not relieve INTEGRA NEUROSCIENCES from strict tort liability, if otherwise applicable under governing law, for damages for personal injury caused by a product defect that made the product unreasonably dangerous at the time it was sold or placed.

1-10

1.5 Contact Information

Customer Service Department Integra NeuroSciences 105 Morgan Lane Plainsboro, New Jersey 08536 (800) 997-4868 (USA/Canada) (609) 275-0500 (International) (609) 275-5363 (FAX)



Authorized Representative:

MedPass International Limited Windsor House Barnett Way, Barnwood Gloucester GL4 3RT, United Kingdom

2 Operation

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2.1 General Operation

1. Turn on the MPM-1 by pressing the **START/STOP** button on the front panel. The MPM-1 will display the "Camino Logo" (Figure 2-1).



Figure 2-1 Camino Logo

2. Connect the Preamp Cable to the MPM-1 by inserting the two cable connectors in the appropriate receptacle (Figure 2-2). Note the red alignment marks on the cable connectors and the side panel.

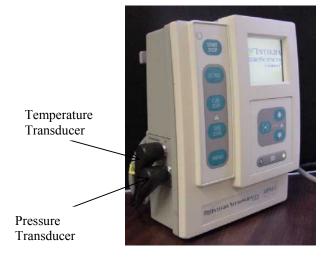


Figure 2-2 Preamp Cable to MPM-1

3. Select the desired Camino Pressure Monitoring kit. Specific Directions For Use may be found in the User information insert provided with each Pressure Monitoring Kit.



Figure 2-3 Catheter to Preamp Cable

- 4. Remove the Catheter from the kit tray, and firmly connect the Transducer Connector(s) into the Preamp Connector(s) (Figure 2-3). (If a pressure only catheter is used, then the temperature connector will remain unconnected). After a short system test, the MPM-1 Display will change to the ICP/ICT display (Figure 2-4).
- 5. Before inserting the Catheter into the patient, ensure that the MPM-1 Display indicates an ICP Pressure of "0 mmHg". If not, use the tool from the Catheter Kit to turn the zero adjustment (Figure 2-5) on the bottom side of the Transducer Connector until the ICP Pressure indicates "0 mmHg". Also, ensure that the temperature is a reasonable value, such as room temperature, before insertion of the Catheter into the patient.
- 6. After the Catheter has been inserted into the patient, (see the catheter Directions For Use for proper insertion technique) select the appropriate scale by repeatedly pressing the **SCALE** button on the MPM-1 front panel (Figure 2-6).



Figure 2-4 CPP/ICP/ICT Display

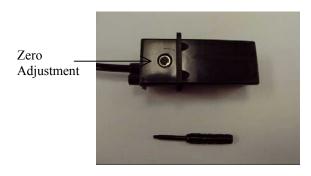


Figure 2-5 ICP Catheter Transducer

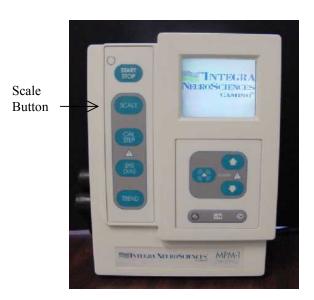
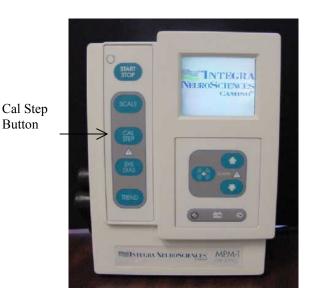


Figure 2-6 Scale Button

- 7. If the MPM-1 is connected to an external bedside monitor, the **CAL STEP** button (Figure 2-7) may be used to calibrate or balance the bedside monitor. Each press advances to the next mmHg value in the following series: 0, 20, 40, 100, 200 and back to 0. The CAL STEP momentarily interrupts normal pressure signal on both the MPM-1 and on the external bedside monitor. Press the CAL STEP button repeatedly until 0 mmHg is displayed on the MPM-1. While keeping the button depressed to maintain simultaneously zero the bedside monitor, then release the CAL STEP button. Within a few seconds, the MPM-1 will return to the pressure display. Note that the **CAL STEP** button may be used at any time, and does not affect the transducer calibration.
- 8. Press the SYS/DIAS button to toggle between CPP, ICP, ICT and SYS, ICP, DIAS displays (Figure 2-8).



Button

Figure 2-7 CAL STEP Button

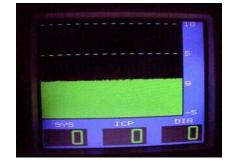


Figure 2-8 SYS/DIAS Display

9. Press the **TREND** button to display the mean ICP and CPP value recorded during the preceding 12 hours (Figure 2-9). With the next press of the trend button, the mean ICP and CPP for the preceding 24 hours will be displayed (Figure 2-10). Press again to return to the pressure display. To clear trend, turn MPM-1 off momentarily.

NOTE - The trend information will be lost if the MPM-1 is turned off or if the battery discharges completely and the MPM-1 turns itself off.

NOTE - ICT and CPP values will ONLY be displayed when using the appropriate Catheter and/or bedside monitor input connections.

NOTE - When not in use, the MPM-1 must be connected to ~AC power to maintain battery charge.

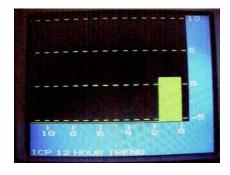


Figure 2-9 12 Hour Trend



Figure 2-10 24 Hour Trend

TO DISPLAY THE MPM-1 SOFTWARE VERSION

- Make sure that the MPM-1 is powered off.
- Connect the Pre-Amp cable.
- Insert a catheter to Pre-Amp cable.
- Press and hold the **DOWN** button.
- While keeping the DOWN button depressed, power on the MPM-1 by pressing the START/STOP button.
- Hold the **DOWN** button until the SOFTWARE VERSION appears on the screen (Figure 2-11).
- Wait approximately 5 seconds for the graph screen to appear.



Figure 2-11- Software Version Display

TO CHANGE THE GRAPH MODE

This feature is available on software version 1.29 and later.

- The graph mode can be either LINE or FILL (Figure 2-12).
- The initial default graph mode is FILL
- The graph mode is saved every time Directions:
- Make sure the MPM-1 is powered off.
- Press and hold the SYS/DIAS button depressed, power on the MPM-1 by pressing the START/STOP button.
- Hold the SYS/DIAS button until the graph screen appears.
- Repeat the above to revert to the FILL Graph Mode.

TO SET HIGH ICP ALARM

- The initial default ICP ALARM is set to OFF. After that, the level is saved every time it is set.
- Reminder: The alarm sounds and the ICP parameter blinks when ICP goes higher than the set point.

Directions:

- While the MPM-1 is on, press the UP or DOWN button, view the Alarm Select Screen.
- Press the UP button to select the High ICP ALARM (Figure 2-13).
- Press the UP or DOWN button to set the ICP ALARM to the desired level.
- Wait approximately 5 seconds for ICP ALARM to be set.
- Pressing the DOWN button until the word "OFF" appears disables this alarm (Figure 2-14).

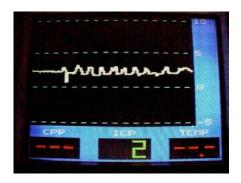


Figure 2-12 Line Graph Mode Display



Figure 2-13 High ICP Alarm

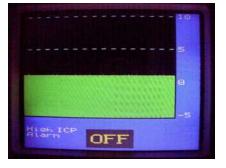


Figure 2-14 High ICP Alarm, OFF Mode

2-6

TO SET LOW CPP ALARM

This feature is available on software version 1.31 and later.

- The initial default CPP ALARM level is OFF. After that, the CPP ALARM level is saved every time it is set.
- Reminder: The alarm sounds and the CPP parameter blinks when CPP goes lower than the set point.

Directions:

- While the MPM-1 is on. Press the UP or DOWN button, view the Alarm Select Screen.
- Press the DOWN button to select the Low CPP ALARM (Figure 2-15).
- Press the UP or DOWN button to set the CPP ALARM to the desired level.
- Wait approximately 5 seconds for CPP ALARM to be set.
- Pressing the DOWN button until the word "OFF" appears disables this alarm (Figure 2-16).

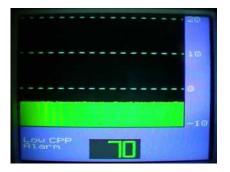


Figure 2-15 Low CPP Alarm



Figure 2-16 Low CPP Alarm, OFF Mode

TO SILENCE THE ALARM

 The initial default CPP ALARM and ICP ALARM levels are OFF. After that, the CPP ALARM and ICP ALARM levels are saved in memory every time they are set.

Directions:

 Press the SILENCE ALARM button. The ALARM DISABLED INDICATOR will flash and whichever parameter, ICP or CPP, was in alarm mode will now be silenced for 3 minutes and that parameter will flash on the screen (Figure 2-17).

NOTE: The parameter that is in alarm mode will blink (even if it has been silenced). If both alarms were in alarm mode when the SILENCE ALARM button was pressed, both alarms will be silenced. If one parameter (ICP or CPP) has been silenced and the other parameter goes into its alarm mode during the 3 minute silence period, the silence alarm mode is disabled (the alarm sounds).

BOTH ALARMS OFF

 As a warning, the ALARM DISABLED INDICATOR will be ON (and the alarms will be disabled) when both of the alarms have been set to OFF.

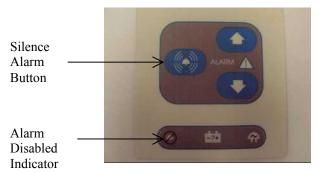


Figure 2-17 Alarm Button & Indicator

2.2 Principles of Operation

The Integra NeuroSciences Multi-Parameter Monitor with Waveform Display (MPM-1) is a compact, portable device for use with Integra NeuroSciences 110-4 series of Pressure/Temperature and Pressure Transducer-Tipped Catheters. Pressure and/or Temperature are measured at the Catheter tip, eliminating the need for external transducers, fluid, pressure tubing, and flush devices. The MPM-1 displays Intracranial Pressure (ICP), Intracranial Temperature (ICT), and calculates Cerebral Perfusion Pressure (CPP)

Note – CPP = MEAN ARTERIAL PRESSURE – MEAN INTRACRANIAL PRESSURE

The MPM-1 provides a continuous display of the ICP waveforms, as well as mean ICP, CPP and ICT, or mean ICP, systolic and diastolic values. A continuous record of ICP and CPP values over the most recent 24-hour period is stored in memory, and can be displayed on command as a TREND, either as the most recent 12 or 24-hour period.

Although the MPM-1 is intended to be a stand-alone system, it also conveniently connects to hospital bedside monitoring systems. Outputs for ICP and ICT are available for use with patient bedside monitors. An isolated analog output provides a continuous ICP waveform for hard copy documentation or data acquisition. An input to receive Mean Arterial Pressure from a compatible patient bedside monitor is available for use when it is desired to have a CPP reading.

A built-in rechargeable battery permits monitoring during patient transport.

Internally, the MPM-1 consists of four printed circuit board assemblies:

Board 1 – Digital Board

Board 2 – Analog Board

Board 3 – Power Supply, AC Input

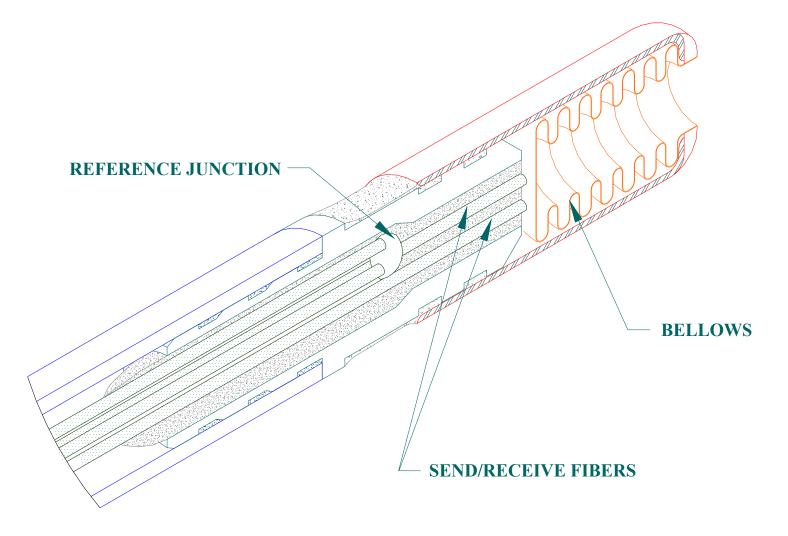
Board 4 – Power Supply, DC Output

2.2.1 The Camino Catheter

<u>Intracranial Pressure (ICP)</u>

A fiber optic device, that consists of four fibers, measures intracranial pressure. Light from an LED source is transmitted down one fiber, called the sender. The light is reflected off the polished surface of a mechanical bellows and is collected by another fiber, called the receiver. The reflected light, referred to as SIGNAL, is collected by a photo-detector.

The other pair of fibers have the same characteristics and length. They are mounted similarly and exposed to the same light source but the light is not reflected off the polished bellows surface. Instead, the light is looped around from the sender, back to the receiver. The light received from this dummy path, termed REFERENCE, is compared to the light received from the SIGNAL path, forming a ratio. If light from the LED is increased or decreased, both paths are affected, thus for a given pressure, the ratio of the two paths does not change.



The transducer has a close to linear response for the pressure range of -20 to 300 mmHg. However, the catheter response must be linearized in order to get the required resolution from the transducer. This is accomplished by applying a known pressure to the catheter during manufacture and recording the resultant output pressure. This pressure is used to construct a lookup table that the microprocessor in the MPM uses to correct the pressure. This process is called linearization correction.

Due to manufacturing variations, the ratio of the amount of reflected light from the bellows displacement to the reference is not the same for all transducers. In order to normalize the output of each transducer, the transducer response is rescaled so that the output to displacement ratio is the same for all transducers. This process is a slope correction.

When linearization and slope corrections are accomplished, CHARACTERIZATION of the transducer is complete. These corrections are encoded in resistor values that are measured by the instrument. These values are translated into correction factors that are then applied to the SIGNAL and REFERENCE outputs of the transducer.

<u>Intracranial Temperature (ICT)</u>

Intracranial temperature (ICT) is measured by an electrically isolated thermodilution style thermistor, placed directly behind the bellows region of the catheter. The thermodilution thermistor is a cardiac industry standard for temperature measurement, and the variation is quite linear over the region of 30 - 40 °C (normal body temperature is 37 °C).

2.2.2 Board 1 – Digital Board

Board 1 performs the Digital functions of the MPM-1.

The digital section of the MPM-1 consists of two Zilog Z180 processors with their PSD, SRAM and Flash RAM arranged in twin kernel configurations. The Programmable System Device (Wafer Scale Integration, PSD412) provides 64K EPROM and 2K SRAM, memory and I/O space decoding, as well as certain logic functions (glue logic). Also there is an external 32K SRAM for other temporary scratchpad and memory functions. These processor systems are linked together with a 12 bit parallel port to transfer data. The basic functions of these processor systems are as follows:

Pressure Processor System (consisting of Z180 U5, PSD U4 and SRAM U34):

- establishes communication with the catheter, reading the code resistors, then writes to the DACs on the Analog Board the corresponding values for that catheter.
- guards that the Reference Loop is maintained (catheter is not disconnected, nor inoperational).
- receives intracranial pressure, arterial pressure, intracranial temperature and membrane switch status data via its serial link from Board 2.
- transmits data via the same serial link to the ICT Output, PMIO and Isolated Analog port
- linearizes (straightens) intracranial pressure data received with an algorithm based on information received from the catheter Curve 1, 2 code resistors.
- communicates the received (modified) pressure data, with handshake, to the Video processor.

Video Processor System (consisting Z180 U24, PSD U25, Flash RAM U19, Dual Port RAM U21 and FPGA 8282 U26):

- interrogates most of the membrane switch inputs and takes appropriate action
- performs averaging of all data received and making it available for placement onto the LCD.
- computes CPP with Arterial Pressure data and ICP data.
- writes data to all stationary locations on the LCD screen such as mean ICP, CPP, etc.
- writes the first vertical line of pressure data received, then waits for a NTSC screen
 interrupt to write again, thus constantly refreshing the screen. As averaged data
 becomes available, this entire screen is written one vertical pixel line to the right and
 a new vertical line of pressure data is inserted to the left—this creates the animated
 display image.

Isolated Power Supply (consisting of U23, T2-T4, Q2):

• A current-mode, flyback topology switching regulator with isolation transformers provide isolated power for all electrical functions requiring low leakage and isolation from potential electrical faults.

2-12

2.2.3 Board 2 – Analog Board

Board 2 performs the Analog functions of the MPM-1.

Pressure

The pulsed output (representing raw Pressure) received from the PAC-1 preamplifier is conditioned by a scaling circuit with a ZERO DAC (digital-to-analog converter), then filtered to DC, and scaled with a SPAN DAC. This results in a 0 to 200mV output as pressure varies from 0 to 250 mmHg. Any catheter manufactured by Integra NeuroSciences is first characterized (the DAC levels are determined). When this particular catheter is used in any MPM-1 monitor, the DAC settings are reproduced by its analog pressure circuitry. Thus each catheter is "normalized," producing a consistent and accurate pressure output. This analog signal must now be routed to an ADC (analog-to-digital converter) which converts the analog level to a digital representation that can be used by the microprocessor. In order to adequately use the ADC with its 4 volts of input range, another scaling circuit follows this 0 to 200mV circuit to produce 1.172 to 3.125 volts, respectively. This optimally fits the ADC range allowing the ADC to output 1200 to 3200 counts, respectively. This 2000 count span from 0 to 250 mmHg is a sensitivity of 8 counts per mmHg (approximately 8 mV per mmHg).

Reference

The output of the Reference signal is essentially a mirror image of the Pressure signal discussed above. Its purpose is to faithfully produce an output that contains <u>no pressure signal</u> but otherwise emulates the Pressure signal path. The Reference signal is employed in a servo balancing scheme to carefully control the LED light output to minimize semiconductor temperature coefficients and other error producing variables.

LED Drive

The LED (located in the catheter) is pulsed by the LED Drive at an approximately 1.3 kHz rate, with an ON time that is 1/16 of the OFF time, i.e., it is ON for about 83 microseconds and OFF for 1.25 milliseconds. This allows for a chopper amplifier style sampling of signals at a higher frequency followed by low-pass filtering and the implementation of a unique method of subtracting dark currents and unwanted signals. The end result is a drift-free system that produces an output with a large signal-to-noise ratio.

Code Resistor Circuit

A 245 microampere current source is connected to each of 9 precision resistors one at a time, and the subsequent voltage (Ohms Law, Vout = Current x Resistance) is read by the ADC which enables the microprocessor to adjust DACs and certain parameters. As it was discussed in the <u>Pressure</u> description, the DACs are adjusted for any MPM-1 to duplicate the DACs of the manufacturing characterizing equipment. These code resistors contain the information needed to setup the DACs and the software curve-fitting algorithm coefficients.

ZAD Circuit

A 4 milliampere current source is connected to the ZERO potentiometer located in the catheter. Prior to placement of the catheter into the patient the nurse adjusts this potentiometer to achieve ZERO. This is a necessary system adjustment that allows catheters and monitors with normal variations to come together and operate correctly.

ICT Signal Connection

The analog signal from the IntraCranial Temperature measurement circuit is routed to the ADC for measurement and subsequent readout on the LCD display.

Arterial Pressure Signal Connection

The analog signal from the external Arterial Pressure circuit is routed to the ADC for calculation of CPP (CPP = AP, mean – ICP, mean).

Reference Voltages

The +7 volt supply from Board 1 is used to produce a precision +4 volt supply needed for the ADC reference and a –2 volt supply needed for Pressure offset bias and Reference servo command.

PMIO

The Patient Monitor Input/Output (PMIO) connects the MPM-1 to the bedside monitor. The bedside monitor "views" the MPM-1 as an external transducer. In the bedside monitor industry the typical input is from a transducer arranged as a Wheatstone Bridge which can be imagined as 4 resistors of equal value connected in a diamond shape. The top two resistors are connected to the excitation voltage provided by the bedside monitor and the lower two resistors are connected to the bedside monitor common. The center connections, by virtue of equal resistance value and by voltage dividing action produce an output of zero volts. By replacing one of the lower resistors with a strain gage of equal resistance, an output, linear to changes in the strain gage resistance with pressure, is obtained. By changing the excitation voltage higher or lower, a corresponding higher or lower gain of the signal is achieved. With this arrangement, the output is automatically positioned at the origin (no offset) and gain is a linear function of the excitation voltage. In the case of the MPM-1, the PMIO circuitry emulates an external transducer. Isooptical couplers enable the linearized pressure signal from the microprocessor to be output digitally, with isolation. This digital signal is converted by the DAC to an analog signal, then appropriately scaled by the excitation signal (with an offset that moves with gain), and is split from single-ended into a differential output. The desired result is to have proportionate gain by increasing the excitation signal without increasing the relative offset provided by the pressure. The output can be described as follows:

$$V_{out} := 5 \cdot 10^{-6} \cdot V_{exc} \cdot \left(512 \cdot \frac{counts}{4096} - 150 \right)$$

This equation implements the medical specification for transducers used with bedside monitors-- $5\mu V/V$ exc/mmHg, that is, $5\mu V$ output per 1 volt of excitation for 1 mmHg, except it additionally describes the pressure/ADC count scale used by the MPM-1.

Solving for 0 mmHg which would be Vout = 0 volts, the counts must be equal to 150*4096/512 = 1200 counts. Similarly, at the rate of 8 counts per mmHg, 2000 counts would be added to 1200 counts for a total of 3200 counts which reduces the amount in the parenthesis to 250, thus 250 would be taken times $5\mu V$ times the Vexc voltage used. As an example, for 5 volts excitation voltage and 200 mmHg of pressure, the differential output would be 5 mV. Note that at the special point of 1200 counts (0 mmHg), the output remains at zero regardless of excitation voltage therefore this circuit satisfies the above desired result of proportionate gain without undue influence from the normal offset.

Isolated Analog Output

The Isolated Analog Output provides an isolated, analog output to a printer, or to a computer ADC that is a function of linearized pressure from the microprocessor, centered at the origin (no offset), at 1V/100 mmHg. The purpose of isolation is to insure that a "dirty" printer or computer connection would not cause harm to the patient. The output is 0 volts for 0 mmHg and 2.5 volts for 250 mmHg. This pressure signal processor is output digitally to the Iso Analog ADC, which is followed by an offset and gain signal conditioning circuit. Finally, a special IC provides galvanic isolation, which performs the same function as in the PMIO above.

Arterial Pressure

The Arterial Pressure circuit interfaces the bedside monitor with the MPM-1 providing an arterial pressure value (in volts) needed for CPP calculations. The microprocessor computes:

$$CPP = AP$$
, mean – ICP , mean

This circuit provides high impedance buffering in order to not load the bedside monitor arterial pressure output. Additionally, it provides a low- pass filtered output to the MPM-1 ADC using a 2-pole active Butterworth filter with a cutoff frequency of 10 Hz. Since the bedside monitor is unknown and may be electrically "dirty", an IC that provides isolation is used to preclude any current carrying paths to the patient. A simple low-pass pole at 159 Hz follows this isolation circuit to eliminate bucket-charge noise spikes.

Additionally, this circuit provides voltage translation from the bedside monitor to the MPM-1. The electrical descriptions are:

Output of the Bedside Monitor:

1V/100 mmHg with its output centered at the origin for zero arterial pressure or,

$$y_1 = 0.01 x_1$$

where y_1 is the output in volts and x_1 is the arterial pressure in mmHg measured by the bedside monitor from an external source

Input of the MPM-1 Arterial Pressure Circuit:

$$x_2 = 128 y_1 - 150$$
 (or $y_1 = 0.007812 x_2 + 1.172$)

where y_1 is the input in volts and x_2 is AP in mmHg used by the microprocessor in CPP calculations

ICT Input

- The ICT Input circuit receives a voltage from a thermistor located in the tip of the temperature/pressure catheter and provides appropriate offset and gain for accurate temperature measurement.
- The thermistor is a custom device built/tested with a "pad" resistor enabling the thermistor manufacturer to state a narrow range of resistances over the range of 30° 40° C. The linear ICT input circuit is calibrated at these two points during Final Test of the monitor to minimize error, which, in turn, allows the MPM-1 specification to be $\pm 3.0^{\circ}$ C over this range.
- The thermistor has a characteristic that an <u>increasing</u> temperature causes its resistance to <u>decrease</u>. The thermistor (placed on top) and pad resistor (placed on bottom) are connected in series forming a voltage divider where the voltage at the center point with respect to common <u>increases</u> with an <u>increase</u> in temperature.
- When +1.0000 volt is applied as an excitation voltage, the above center point output varies from .3498 volts to .4376 volts for a temperature of 30° to 40° C, respectively. This excitation level, which would cause thermistor self-heating errors in air, was chosen because the application is, in fact, in fluid. Using this level produces a signal output much higher than noise or thermocouple errors.
- This thermistor output is defined as:

y (in volts) =
$$.0048779 \text{ x (in } ^{\circ}\text{F)} - 0.0696849 \quad \{^{\circ}\text{F} \}$$

y (in volts) =
$$.0087802 \text{ x (in } ^{\circ}\text{C}) + .0864079 \quad \{^{\circ}\text{C} \}$$

- In order to optimize the +4.0 volt ADC input range, the extreme displayed temperatures of 59 °F (15°C) to 113 °F (45°C) were chosen to have 0 to 3.78 volts, respectively. This essentially provides a 70 mV (126 mV) change for each degree °F (°C) displayed. This uses the entire ADC range and enables the use of a convenient software lookup constant.
- To provide an extremely stable and precise output with negligible input loading an instrumentation amplifier was used. Calibration during manufacturing is also easier with the unity/full gain feature of an instrumentation amplifier.
- Because the thermistor is patient connected, an IC that provides isolation is used to preclude any current carrying paths to the patient.
- This ICT Input circuit output is defined as:

y (in volts) =
$$.070 \text{ x (in °F)} - 4.13 \text{ {°F }}$$

y (in volts) = $.126 \text{ x (in °C)} - 1.89 \text{ {°C }}$

ICT Output

- The ICT Output circuit interfaces the MPM-1 to the bedside monitor providing a continuous set of resistance values for temperatures from 15° to 45° C. This emulates a standard 3-wire YSI 400 thermistor resistance. In essence, the bedside monitor is performing a thermistor meter function of type YSI 400 with digital readout on its screen and the MPM-1 is producing a varying resistance output as a function of patient temperature in similar fashion to a true YSI 400 thermistor. This approach was used because the YSI 400 series thermistor input plug-in module is a bedside monitor standard.
- This unusual configuration was necessary in order to maintain isolation between the MPM-1 and the bedside monitor, yet allow a temperature readout on the MPM-1 LCD display <u>and</u> the bedside monitor (in some cases the bedside monitor may be remotely located).
- Since this circuit connects an unknown bedside monitor that may be electrically "dirty" to the MPM-1, the ICT Output circuitry is isolated by virtue of ISO-optical couplers and an isolated power supply.
- The ICT Output circuitry consists of a processor controlled serial-to-parallel converter followed by latches that control eight solid-state switches, each connected to its precision resistor which is connected in parallel with a fixed 3500 ohm resistor. The switches are arranged in a kind of ladder form allowing binary closing. The switches are normally open, thus there is approximately 3500 ohms presented to the output terminals for the lowest temperature readout of 15° C. As the measured temperature increases, successive switches are closed in a binary fashion creating 256 unique states of resistance values. The resistance is thereby reduced for increasing temperatures. The selection of the precision resistance values is a one-time effort requiring the use of a curve-fitting computer program.
- Due to the inherent internal resistance of the solid-state switches, several gangs of switches are used in parallel (to reduce series switch resistance and minimize system error) for the last two rungs of the ladder where the output resistance is rapidly approaching that of the solid-state switch internal resistance.

2.2.4 Board 3 – Power Supply, AC Input

The AC Input Board of the Power Supply provides "Off-line" conversion from the MAINS (AC Line) to +16.5 volts of isolated, regulated power for Board 4.

Input requirements:

• 90 VAC (low-line Japan) to 264 VAC (high-line Europe).

Output drives 3 separate loads:

- The monitor circuitry (when the monitor when ON).
- A dummy load which minimally loads this supply (when the monitor is OFF).
- The battery charging circuit.

Features:

- Power is taken directly from the LINE, hence the term "Off-line" converter.
- Fixed frequency, current mode pulse width modulator topology.
- Isolation from the LINE exceeds 4500 VAC for safety.
- Output noise is in 'sync' with the master clock to minimize beat frequency noise.
- Output level is controlled by an isolated optocoupler with bandgap reference.

2.2.5 Board 4 – Power Supply, DC Output

The DC Output Board of the Power Supply provides DC-DC conversion from the source to +5V for Logic and LCD, +15V for LED Drive, +9V and -8V for OpAmps. This power is extracted from either of two sources, the 16.5 volts from Board 3 or the nominal 12 volts from the lead acid battery.

Input requirements:

- 16.5 volts from Board 3 (if AC power is available and connected).
- 12 volts, nominal, from the battery (10.8 volts, minimum).

Outputs:

- +5 volts for Logic and LCD.
- +15 volts for LED drive.
- +9 volts for Operational Amplifiers.
- -8 volts for Operational Amplifiers.

Features:

- AC LED is illuminated when AC power is connected.
- BATTERY LOW lamp is illuminated (whenever the unit is ON and using battery power) and the battery is discharged to less than 11.8 volts, warning that the battery charge is depleted.
- Long shelf life for fully charged battery (less than 10 uA leakage current).
- 5 volt output controlled by bandgap reference; other outputs track this output given nominal loading.
- Output noise is in 'sync' with master clock to minimize beat frequency noise
- Shutdown of Board 4 supply automatically occurs when the battery is discharged to less than 10.8 volts.
- Battery charging is current limited to about 330mA protecting both the battery and preventing overheating of the voltage regulator.
- Battery charging is maintained at two different, constant-voltage levels, nominally 14.4 volts and 13.8 volts, depending on the use and condition of the battery.
- Battery charging is temperature compensated, -4mV/degree C/cell.

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3 Testing and Preventive Maintenance

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3.1 Operational Testing - Introduction

Operational testing procedures verify that the MPM-1 is in good operating condition and accurate to significant levels. It can be a first step in locating a problem.

These tests can be performed in any order and individual tests may be selected for performance from the entire series of tests. None of these operational testing procedures require disassembly of the MPM-1.

If any performance parameter is not met, or an obvious malfunction occurs, the MPM-1 should be returned to Integra NeuroSciences for service.

Table 3-1 Recommended Tools and Test Equipment

]	Equipment Description	Characteristics
DC Power	supply	0-9VDC
Multimete	er, Digital	1 mV minimum reading
Safety Tester		BioTek Model 170 or equivalent
Cables	Power Cord	Integra Part Number 60-006 or 60-007
	Pre-Amp	Integra Part Number PAC-1
	PMIO	Integra Part Number PMIO-MPM
	Isolated Analog Output	A 3.5mm phone plug at one end; the other end to connect to a voltmeter (i.e., Fluke 79 using a double banana plug - See Figure 3-26).
Pressure Source	3.2.4. 5, 4.1. 5,	
	Pressure Gauge, Syringe, Tubing, Male Luer, 4-way stopcock with Luer Lock	Gauge 0 – 250 mmHg (minimum)
	Electronic Pressure Simulator	0 – 250 mm Hg (minimum)
Catheter		Integra Part Number 110-4BT
1 - 620Ω	Resistor	
2 - 10ΚΩ	Resistors	
1 - 10ΚΩ,	10 turn potentiometer	

3.1.1 AC and Low Battery Indicator



Figure 3-1 Front Panel Power Indicators

- 1. Connect one end of the AC power cord to the back of the MPM-1. Connect the other end of the AC power cord to a wall receptacle.
 - Note The MPM-1 should have normal connections to its battery.
- 2. Check that the ~AC indicator is illuminated (Figure 3-1).
- 3. Disconnect power cord. Check that the ~AC indicator turns off.
- 4. Let the MPM-1 run on battery power until the **LOW BATTERY INDICATOR** illuminates.
 - Note Discharging a fully charged battery takes approximately 1-2 hours.
- 5. Connect the power cord to the MPM-1 and wall receptacle. Let the monitor charge the battery for 8-10 hours to full charge.
- 6. Disconnect Power Cord.
- 7. Let the MPM-1 run briefly on battery power. Check that the **LOW BATTERY INDICATOR** does not illuminate.

3.1.2 Battery Charger, Condition of Battery

1. Disconnect power cord from MPM-1 and remove battery (follow Section 3.2 MPM-1 Battery Replacement).

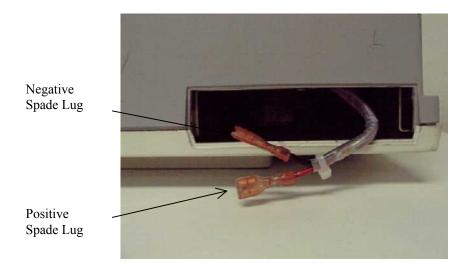


Figure 3-2 Battery Spade Lug Connectors

- 2. Connect power cord to MPM-1. Connect power cord to wall receptacle. Measure the voltage across the spade lug connectors that connect to the battery. At room temperature (20°C, 68°F), voltage will read approximately 13.8 volts.
 - Note If room temperature is warmer, the voltage will be lower. If room temperature is cooler, the voltage will be higher.

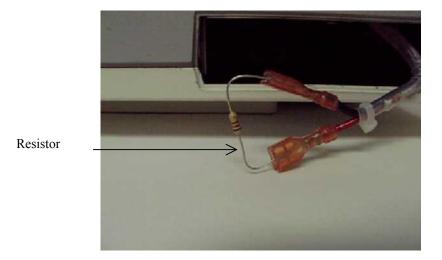


Figure 3-3 Spade Lugs with 620Ω Resistor

- 3. Disconnect the power cord from the wall receptacle. Connect a 620Ω resistor to the spade lug connectors. Reconnect the power cord to the wall receptacle. Measure the voltage across the resistor. At room temperature (20°C, 68°F), voltage will read approximately 14.4 volts.
 - Note If room temperature is warmer, the voltage will be lower. If room temperature is cooler, the voltage will be higher.
- 4. If 13.8V and 14.4V are found, the charger is working properly.
- 5. With a properly working battery charger, reinstall battery and recharge the battery for more than 12 hours, preferably 24 hours.
- 6. Operate the MPM-1 from battery power only. Operation should last 1 hour and 30 minutes (nominal) ± 20 minutes. If less, charge an additional day. If performance improves so that operation time is greater than 1 hour and 10 minutes, battery is acceptable. Repeat charge/discharge cycle a total of two more times if necessary to improve operation time to acceptable levels.
- 7. Replace battery if operation is less than 1 hour and 10 minutes, and three charge/discharge cycles does not improve operation time.

3.1.3 Front Panel Checks

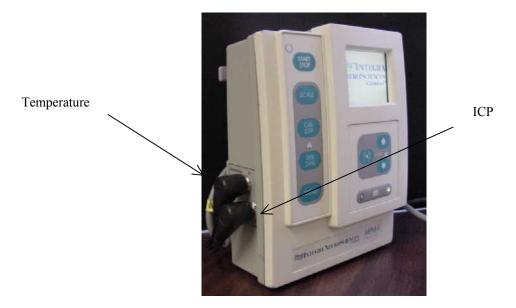


Figure 3-4 Pre-Amp Cable to MPM-1

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a good catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1). Do not connect the temperature transducer connector if you are using a 110-4BT or 110-4HMT model catheter.

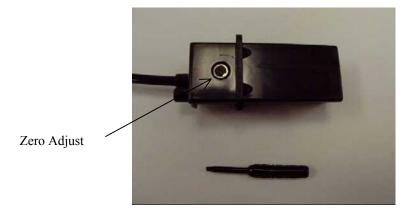


Figure 3-5 ICP Catheter Transducer

3. Turn on the MPM-1 by pressing the **START/STOP** button on the front panel. After a short system test, the MPM-1 will display the "Integra Neurosciences Camino" logo, then change to the CPP-ICP-ICT display. Ensure that the MPM-1 display indicates an ICP Pressure of "0 mmHg". If not, use the tool from the Catheter Kit to turn the zero adjustment on the bottom side of the Transducer Connector until the ICP Pressure indicates "0 mmHg".

Note – At this point, the MPM-1 should <u>not</u> be displaying a numerical value for CPP and ICT. Both should read "---" in red.

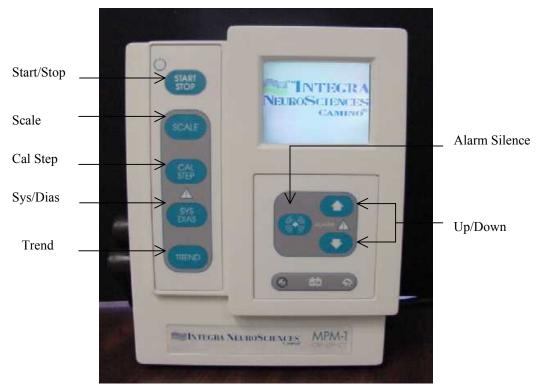


Figure 3-6 Front Panel Controls

4. Make sure that the buttons function properly. The following table summarizes the function of each button.

Table 3-2 Membrane Switch Functions

BUTTON	MPM	
	FUNCTION	
START/STOP	Turns off and on	
SCALE	Changes Scale	
CAL STEP	Changes Bedside	
	Monitor Calibration	
	Pressure	
SYS/DIAS	Changes Display	
TREND	Displays last 12	
	hours / 24 hours of	
	ICP and CPP values	
UP/DOWN	Sets or disables the	
	ICP and/or CPP	
	alarm	
SILENCE	Silences alarms for	
ALARM	three minutes	

3.1.4 Software Version



Figure 3-7 Typical Software Version Display

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a good catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1). Do not connect the temperature transducer connector if you are using a 110-4BT or 110-4HMT model catheter.
- 3. Depress **DOWN ARROW** button and hold while powering the MPM-1. Wait until the current software version appears. System should display the most current software version (call Integra NeuroSciences for current software version). If earlier software version is displayed, the monitor should be returned to Integra NeuroSciences for upgrade.
- 4. Release the **DOWN ARROW** button, and the MPM-1 should change to the CPP-ICP-ICT display.
- 5. Turn off monitor.

3.1.5 ICP Input Checkout (Graduated Drainage Bag)

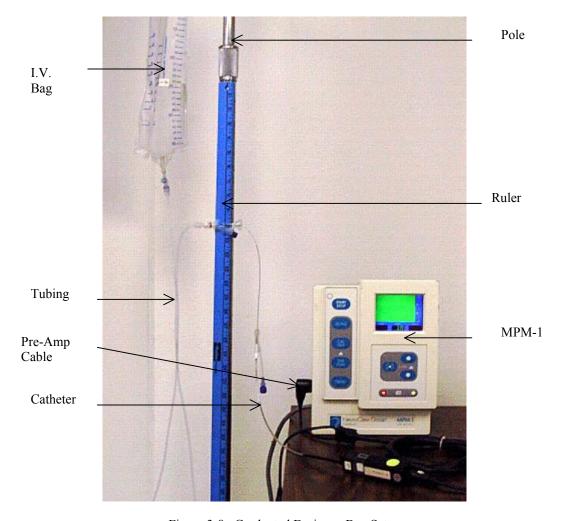


Figure 3-8 Graduated Drainage Bag Setup

Note: Before beginning this test, assure that MPM-1 is off, and it is not connected to any cables.

- 1. Connect one end of AC cord to the wall and other end into MPM-1 on the back.
- 2. Connect Pre-Amp cable and a functional Camino catheter.
- 3. Fill half of the I.V. bag with water.

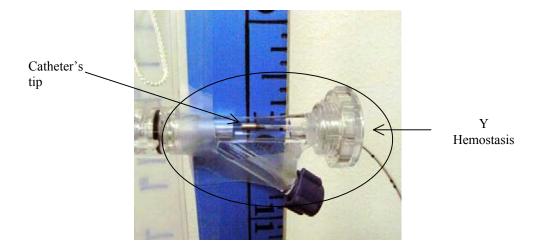


Figure 3-9 Y Hemostasis

- 4. Connect one end of tubing to the I.V. bag and other end to a Y hemostasis valve.
- 5. Insert the tip of the catheter into the Y Hemostasis valve through the duckbill valve.

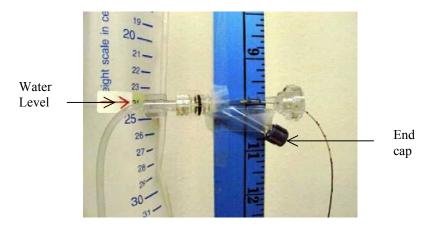
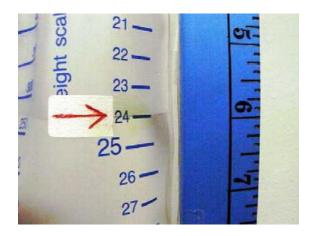


Figure 3-10 0 mmHg Position

- 6. Open the valve from the I.V. bag and remove the end cap from the Y Hemostasis valve. Let water flow until tubing and Y Hemostasis valve fill with water.
- 7. Make sure that air bubbles are not present, then replace end cap.
- 8. Make sure that the water level (see red arrow) from the I.V. bag and the tip of the catheter are at the same level. The MPM-1 should display 0 mmHg. In this example, the catheter's tip and the water are leveled with the 10-inch mark of the ruler.

9. Turn on MPM-1 and make sure that it reads 0 mmHg. If not, zero adjust catheter.



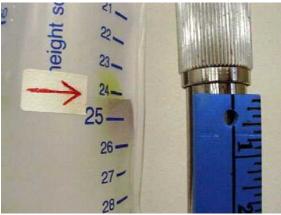


Figure 3-11 7 mmHg position

Figure 3-12 18 mmHg position

10. Raise the I.V. bag 4 inches. The water level should be leveled with the 6-inch mark of ruler.

Note: 1 inch $H_2O = 1.8683$ mmHg.

- 11. The MPM-1 should read 7 ± 1 mmHg.
- 12. Raise I.V. bag for another 6 inches, and the MPM-1 should read 18 ± 1 mmHg.
- 13. End of test.

3.1.6 ICP Input Checkout (Pressure Gauge)



Figure 3-13 Pressure Gauge Setup

Note: Before beginning this test, assure that MPM-1 is off, and it is not connected to any cables.

- 1. Connect one end of AC cord to the wall and other end into MPM-1 on the back.
- 2. Connect Preamp cable and a functional Camino catheter.
- 3. Turn on MPM-1 and make sure that it reads 0 mmHg. If not, zero adjust catheter.

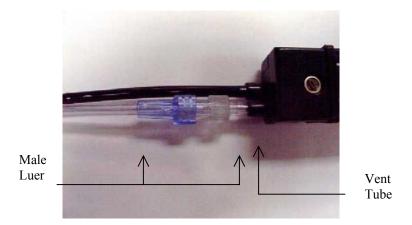


Figure 3-14 Catheter Vent Tube

4. Insert the male luer into the vent tube of catheter.

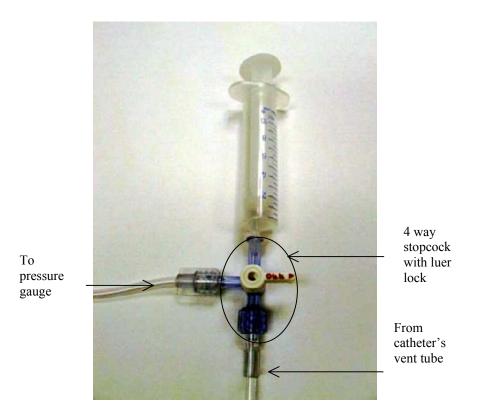


Figure 3-15 Syringe Connection

- 5. Connect the other end, coming from the catheter's vent tube, to the 4 way stopcock with luer lock.
- 6. Ensure the syringe's plunger is firmly seated.
- 7. Connect the 4 way stopcock to the pressure gauge and syringe.
- 8. Confirm that the pressure gauge and MPM-1 read 0 mmHg.



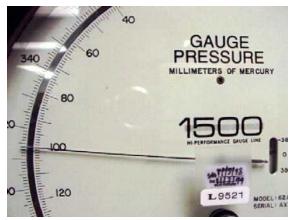


Figure 3-16 20 mmHg

Figure 3-17 100 mmHg

- 9. Once the pressure gauge and MPM-1 are zero adjusted, pull on the syringe's plunger until the pressure gauge reads 20 mmHg. The MPM-1 will settle and should display the same simulated pressure value within \pm 2 mmHg.
- 10. Repeat the same test for the following pressures: 40, 60, 100, 250 and back to 0 mmHg.

Table 3-3 Acceptable Range of Pressure

Applied Pressure	MPM-1 Reading
0 mmHg	0 mmHg
20 mmHg	18 to 22 mmHg
40 mmHg	38 to 42 mmHg
60 mmHg	57 to 63 mmHg
100 mmHg	94 to 106 mmHg
250 mmHg	233 to 267 mmHg

3.1.7 ICP Input Checkout (Pressure Simulator)

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1). Do not connect the temperature transducer connector if you are using a 110-4BT or 110-4HMT model catheter.

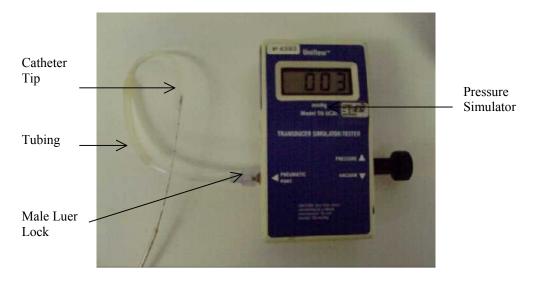


Figure 3-18 Pressure Simulator

- 3. Connect tip of catheter to pressure simulator using silicon tubing. Make sure that the catheter tip fits firmly in the silicon tubing.
- 4. Turn the MPM-1 and the pressure simulator on and set the MPM-1 at the highest sensitivity scale of -5 to +10 mmHg.
- 5. Adjust the Pressure Simulator to 0 mmHg, and zero adjust the catheter.
- 6. Set pressure simulator to 20 mmHg. Wait 15 seconds. The MPM-1 system will settle and should display the same simulated pressure value within \pm 2 mmHg. Check for leaks in the set-up if the readings do not agree.
- 7. Repeat the same test for the following pressures: 40, 60, 100, 250 and back to 0 mmHg.

Applied Pressure	MPM-1 Reading
0 mmHg	0 mmHg
20 mmHg	18 to 22 mmHg
40 mmHg	38 to 42 mmHg
60 mmHg	57 to 63 mmHg
100 mmHg	94 to 106 mmHg
250 mmHg	233 to 267 mmHg

3-15

Table 3-4 Acceptable Range of Pressure

3.1.8 High ICP Alarm Checkout

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1). Do not connect the temperature transducer connector if you are using a 110-4BT or 110-4HMT model catheter.
- 3. Provide pressure to the catheter using any of the methods discussed in sections 3.1.5, 3.1.6 or 3.1.7.

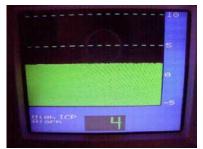


Figure 3-19 High ICP Alarm

- 4. Turn on the MPM-1 and set the High ICP Alarm to 4 mmHg by pressing the **UP-ARROW**.
- 5. Set the pressure source to 10 mmHg. The MPM-1 should display approximately 10 ± 2 mmHg. After approximately 5 seconds, the alarm speaker should beep.
- 6. Silence the alarm by pressing the **SILENCE ALARM** button. The **ALARM DISABLED INDICATOR** and ICP parameter should flash.
- 7. Wait approximately 3 minutes, and the alarm should resume beeping.
- 8. Decrease simulated pressure to 0 mmHg, and the alarm should silence.
- 9. Set High ICP Alarm to "OFF".

3.1.9 Arterial Pressure Test

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1). Zero adjust the catheter. Do not connect the temperature transducer connector if you are using a 110-4BT or 110-4HMT model catheter.
- 3. Connect a PMIO cable to the rear connector of MPM-1, but do not connect to an external bedside monitor.

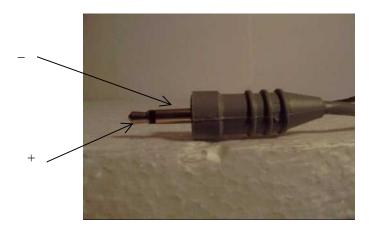


Figure 3-20 Arterial Pressure Connector

4. Using a power supply, provide 1.000 ± 0.001 volts to the Arterial Pressure connector (see Figure 3-20).

Note: AP = 1V/100 mmHg.

5. Turn on MPM-1. Wait until the CPP-ICP-ICT display appears. CPP parameter should read 100 mmHg \pm 1 mmHg since AP = 100 mmHg and ICP = 0 mmHg.

Note: CPP = AP-ICP.

3.1.10 Low CPP Alarm

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1). Zero adjust the catheter. Do not connect the temperature transducer connector if you are using a 110-4BT or 110-4HMT model catheter.
- 3. Connect tip of catheter to a pressure source. Make sure that tip of catheter fits firmly to the pressure source with no leaks.
- 4. Connect a PMIO cable to rear connector of MPM-1, but do not connect to an external bedside monitor.
- 6. Using a power supply, provide 1.000 ± 0.001 volts to the Arterial Pressure Connector (see Figure 3-20).
- 5. Turn on MPM-1.



Figure 3-21 Low CPP Alarm

- 7. Set the **LOW CPP ALARM** to 4 mmHg by pressing the **DOWN-ARROW**. Set pressure source to 98 mmHg. The CPP parameter should display 2 mmHg since CPP = (100-98) mmHg. This value is lower than the value set in the alarm mode. After approximately 5 seconds, the alarm speaker should beep.
- 8. Silence the alarm by pressing the **SILENCE ALARM** button. The **ALARM DISABLED INDICATOR** and the CPP parameter should flash. Wait approximately 3 minutes, and the alarm should resume beeping.
- 9. Decrease the value from pressure source to 92 mmHg. The alarm should silence since now CPP = 8 mmHg which is greater than the value set in the alarm mode.
- 10. Increase simulated pressure to 98 mmHg (CPP = 2 mmHg), and the alarm should resume beeping.

- 11. Set LOW CPP ALARM to "OFF" by pressing the DOWN-ARROW. The alarm should silence, and at this point the SILENCE ALARM INDICATOR will illuminate since both alarm parameters, HIGH ICP ALARM and LOW CPP ALARM, are set to "OFF".
- 12. Set pressure source to 0 mmHg. Turn off MPM-1.
- 13. Disconnect power supply from AP connector.

3.1.11 ICP Output Test

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1).
- 3. Connect a PMIO cable to the rear connector of MPM-1, but do not connect to an external bedside monitor.



Figure 3-22 PMIO Connector

- 4. Set power supply to 5 ± 0.001 volts and connect "+" and "-" leads to pins "1" and "4" of the six pin cannon connector, respectively.
- 5. Connect the "+" and "-" leads of the Digital Multimeter (DMM) to pins "2" and "3" of the six pin cannon connector, respectively.
- 6. Turn on monitor, and wait until the CPP-ICP-ICT display appears.
- 7. Press and hold the **CAL STEP** to produce 0 mmHg on the display. The DMM should read less than .010 mVDC offset from 0 volts. The following table shows simulated pressures by pressing and holding the **CAL STEP** button, and expected voltages at pins "2" and "3".
- 8. Turn off MPM-1. Remove power supply and DMM leads from PMIO cable connector.

Simulated Pressure (mmHg)	Simulated Voltage (mVDC)
0	$0.000 \pm .001 \text{ mVDC}$
20	$0.500 \pm .001 \text{ mVDC}$
40	1.000 ± .001 mVDC
100	2.500 ± .001 mVDC
200	5 000 ± 001 mVDC

Table 3-5 Simulated Pressure & Voltage

3.1.12 ICT Input Test

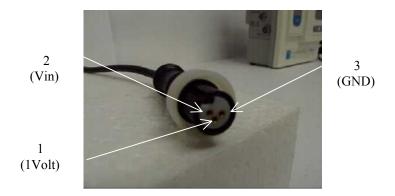
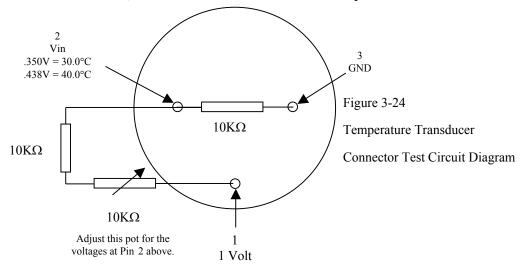


Figure 3-23 Temperature Transducer Connector

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1).
- 3. Connect the leads of the Digital Multimeter (DMM) to pins 1 (1 Volt) and 3 (GND) of Pre-Amp cable (PAC-1) temperature connector (Figure 3-23). **Note:** The ICT parameter should be reading "---" up to this point.
- 4. Turn on the monitor, and the DMM should read 1.0000 ± 0.0001 VDC.
- 5. Turn off MPM-1, and remove DMM leads from temperature connector.



- 6. Connect two $10K\Omega$ resistors and a $10K\Omega$ potentiometer to the temperature transducer connector as shown in Figure 3-24. Connect the leads of the Digital Multimeter (DMM) to pins 2 (Vin) and 3 (GND).
- 7. Turn on MPM-1, and adjust the $10K\Omega$ potentiometer to produce a reading on the DMM of 0.350 VDC. The monitor should display 30.0 ± 0.3 °C.
- 8. Adjust the $10\text{K}\Omega$ potentiometer to produce a reading on the DMM of 0.438 VDC. The monitor should display 40.0 ± 0.3 °C.
- 9. Turn off MPM, and remove all components from the temperature connector.

3.1.13 ICT Output Test

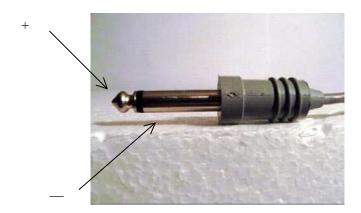


Figure 3-25 ICT Output Connector

- 1. Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.
- 2. Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1).
- 3. Connect a PMIO cable to the rear connector of MPM-1, but do not connect to an external bedside monitor.
- 4. Connect the Digital Multimeter (DMM) leads to Switchcraft ¼" connector and set DMM to ohms.
- 5. Press and hold the **UP** arrow, then press and release the **START/STOP** button. Do not release the **UP** arrow until the MPM-1 displays "STUCK KEYBOARD" in red color. The DMM should read a resistance value between 3465.9 Ω and 3608.1 Ω . The nominal value is 3537.0 Ω .
- 6. Press and release the **UP** arrow, and the resistance value will change to the next value shown in **Table 3-6**. Repeat this step until all resistance values are verified.

LOW Ω	NOMINAL Ω	HIGH Ω
3465.9	3537.0	3608.1
3431.7	3501.4	3571.1
3398.1	3466.5	3534.8
3332.6	3398.2	3463.8
3208.5	3269.3	3330.1
2984.7	3037.3	3089.8
2635.7	2676.4	2717.1
2121.7	2141.8	2161.9
1525 1	1535.4	1545 7

Table 3-6 Output Temperature Resistances

4. Disconnect DMM, and turn off monitor.

3.1.14 Isolated Analog Output Test

Connect a Pre-Amp cable to the ICP and Temperature connections of MPM-1.

Using a functional Camino catheter, firmly connect the pressure transducer connector to the Pre-Amp cable (PAC-1).



Figure 3-26 Isolated Analog Connector

- 1. Connect one end of cable to the isolated analog output of the MPM-1, and the other end to a Digital Multi Meter (DMM).
- 2. Turn ON the MPM-1, and wait until the CPP-ICP-ICT display appears.
- 3. Press and hold **CAL STEP.** Verify that the MPM-1 and DMM display "0 mmHg" and " $0.000 \pm .001$ mV" respectively. The following table shows simulated pressures and voltages by pressing and holding the **CAL STEP** button.

Table 3-7 Isolated Analog Voltage Output

MPM-1 DISPLAY (mmHg)	Multi-Meter Display (VDC)
0	0.0
20	0.2
40	0.4
100	1.0
200	2.0

6. Turn off MPM-1 once pressures and voltages are verified. Remove analog cable and DMM.

3.1.15 Ground Continuity Test

Note – This procedure assumes use of a Bio-Tek Model 170 safety tester. If a different safety tester is used, check safety tester's instructions for proper operation.

- 1. Plug the Bio-Tek Model 170 safety tester into an A.C. outlet.
- 2. Ensure that only the two "OK" neon lamps on the Bio-tek front panel illuminate.
- 3. Turn the Model 170 on using the On/Off switch.
- 4. The Model 170 display should indicate LINE VOLTAGE of 120 ± 10 volts for domestic units and 220 ± 10 volts for international units.
- 5. Connect one end of the AC power cord to the back of the MPM-1. Connect the other end of the AC power cord to the Model 170.
- 6. Turn the GROUND switch on the Model 170 to the NORMAL position.
- 7. Turn the Model 170 function selector to GROUND WIRE RESISTANCE position.
- 8. Set the Model 170 POLARITY switch to OFF.
- 9. Connect the Model 170 ground probe to the equipotential plug on the back panel of the MPM instrument.
- 10. Check that the Model 170 display indicates less than 0.10 ohms.
- 11. If resistance read is higher than 0.10 ohm, check for damaged power cord or bad power cord connections. If the problem cannot be solved, return unit to Integra NeuroSciences for service.

3.1.16 Chassis Leakage Test

Note – This procedure assumes use of a Bio-Tek Model 170 safety tester. If a different safety tester is used, check safety tester's instructions for proper operation.

- 1. Plug the Bio-Tek Model 170 safety tester into an A.C. outlet.
- 2. Ensure that only the two "OK" neon lamps on the Bio-tek front panel illuminate.
- 3. Turn the Model 170 on using the On/Off switch.
- 4. The Model 170 display should indicate LINE VOLTAGE of 120 ± 10 volts for domestic units and 220 ± 10 volts for international units.
- 5. Connect one end of the AC power cord to the back of the MPM-1. Connect the other end of the AC power cord to the Model 170.
- 6. Turn the GROUND switch on the Model 170 to the NORMAL position.
- 7. Turn the Model 170 function selector to CHASSIS LEAKAGE position.
- 8. Touch the equipotential plug on the MPM back panel with the Model 170 probe.
- 9. <u>Check</u> that the Model 170 display indicates less than 12 micro amperes for the following POLARITY switch positions:

NORMAL REVERSE

10. Set the Model 170 GROUND switch to OPEN.

Ensure that the display reads less than or equal to 120 micro amperes for domestic units (MPM-1-6).

Ensure that the display reads less than or equal to 180 micro amperes for international units (MPM-1-7).

- 11. Set the Model 170 POLARITY switch to OFF. Disconnect the instrument.
- 12. If the chassis leakage is found higher than specified above, return unit to Integra NeuroSciences for service.

3.2 Battery Replacement

CAUTION – Ensure that the unit is turned off and the power cord has been removed from the unit before attempting this procedure.

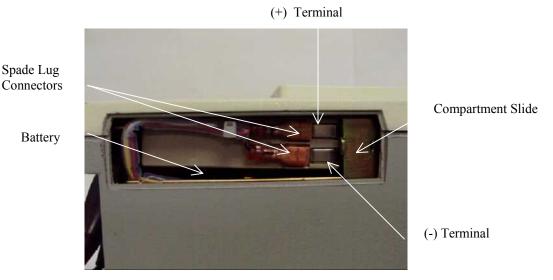


Figure 3-27 Battery Compartment

- 1. Using a flat bladed screwdriver, carefully lift off the battery compartment door, by inserting the screwdriver into the battery compartment notch and twisting.
- 2. Move the metal battery compartment slide in the direction indicated to open.
- 3. Remove the spade lug connectors from the positive and negative terminals.
- 4. Gently slide the battery out of the battery compartment.
- 5. Replace the battery in the battery compartment.
- 6. While observing polarity, reconnect the spade lug connectors to the battery terminals. The "+" wire to the positive terminal and the "-" wire to the negative terminal. Ensure that the black side of the battery is on the right side.
- 7. Move the metal battery compartment slide in the direction indicated until it is closed.
- 8. Replace the battery compartment door and snap into place.
- 9. Dispose of old battery properly, per applicable and local regulations.

3.3 Bedside Monitor Calibration

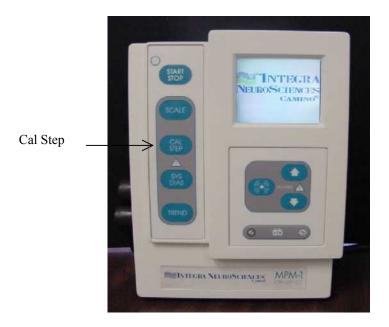


Figure 3-28 Cal Step Button

- 1. Connect the MPM-1 to an external bedside monitor.
- 2. With a catheter connected, energize the MPM-1.
- 3. Press the **CAL STEP** button repeatedly until 0 mmHg is displayed on the MPM-1.
 - Note The **CAL STEP** momentarily interrupts normal pressure signal on both the MPM-1 and on the external bedside monitor.
- 4. While keeping the button depressed to maintain 0, simultaneously zero the bedside monitor.
- 5. Press the **CAL STEP** button to advance to the next mmHg value in the following series: 0, 20, 40, 100, 200 and back to 0. Verify the bedside monitor reading at each step.
- 6. Release the **CAL STEP** button. Within a few seconds, the MPM-1 will return to the pressure display.
 - Note The **CAL STEP** button may be used at any time, and does not affect the transducer calibration.

4 Troubleshooting

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4.3	LCD Malfunctions	. 4-4
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4.1 Introduction

The troubleshooting guide is intended to resolve problems that may occur while using the MPM-1. This section contains troubleshooting isolation tables. If the difficulty persists after attempting to troubleshoot, or if a problem other than those described below occurs, routine technical assistance may be obtained by contacting Integra NeuroSciences.

Note: If it is necessary to return the MPM-1 monitor or catheter to Integra NeuroSciences, please provide a detailed description of the problem and any errors which were shown. This will assist in the proper servicing of your equipment. Please call Integra NeuroSciences for specific instructions on returned goods procedures.

4.2 Power Supply Malfunctions

Symptom	Possible Cause	Corrective Action
MPM-1 does not operate on AC power, but system works on battery.	AC power cord not connected.	Verify power cord is plugged into a live AC power source.
	Faulty AC power cord.	Replace power cord.
	Blown fuse.	Replace fuse.
	Power module malfunctioning.	Send unit in for service.
MPM-1 does not operate on battery, but system operates on AC power. Or Battery does not charge.	Faulty battery.	Connect to AC power for 24 hours to fully charge battery. The MPM-1 may be used on AC while charging. If battery does not charge, replace battery. Refer to section 3.2 in TESTING and PREVENTIVE MAINTENANCE.
	Battery terminal wires were reversed.	Send unit in for service.
ON and OFF button does not work properly.	Faulty membrane switch and/or power supply.	Send unit in for service.

4.3 LCD Malfunctions

Symptom	Possible Cause	Corrective Action
MPM-1 is operating, but a dark display is present.	Faulty LCD or connections.	Send unit in for service.
OR		
LCD displays white vertical lines or a certain color is dominant.		

4.4 Error Messages

Symptom	Possible Cause	Corrective Action
MPM-1 Display reads: "CHECK CATHETER CONNECTION"	Defective external connection.	Check connection between Catheter, Pre-Amp cable and MPM-1.
CONTIDENT	Damaged catheter.	Replace catheter.
	Faulty Pre-Amp cable.	Replace Pre-Amp cable.
	Faulty connection between Analog Board and Pre-Amp flex cable at J1.	Send unit in for service.
	Faulty Digital Board or Analog Board.	Send unit in for service.
ICP, Systolic or Diastolic reads: ""	Value outside operating range of MPM-1 (-50 mmHg to 300mmHG).	Check connection between catheter and Pre-Amp cable.
	Imperfect connection between Pre-Amp cable and MPM-1.	Check connection between Pre-Amp cable and MPM-1.
	Damaged Catheter.	Replace Catheter.
	Damaged Pre-Amp cable.	Replace Pre-Amp cable.
	Faulty connection between Analog Board and Pre-Amp flex cable.	Send unit in for service.
	Faulty Digital or Analog Board.	Send unit in for service.

Symptom	Possible Cause	Corrective Action
CPP reading "".	Value outside operating range of MPM-1 (0 mmHg to 210 mmHg).	Check connection between catheter, Pre-Amp cable and MPM-1.
	Faulty connection between bedside monitor and MPM-1.	Check connection between PMIO cable and Bedside Monitor.
	Defective Adapter Cable.	Replace adapter cable.
	Defective PMIO cable.	Replace PMIO cable.
	Damaged catheter.	Replace catheter.
	Faulty Pre-Amp cable.	Replace Pre-Amp cable.
	Faulty bedside monitor.	Replace bedside monitor.
	Faulty connection between PMIO flex cable and Analog Board.	Send unit in for service.
	Malfunction of Analog Board.	Send unit in for service.
ICT reads:""	Value outside operating range of MPM-1 (15°C to 45°C).	Check connection between catheter temperature connector, Pre-Amp cable and MPM-1.
	Faulty catheter.	Replace catheter.
	ICP only catheter in use.	Replace catheter.
	Damaged Pre-Amp cable.	Replace Pre-Amp cable.
	Faulty connection between Temperature cable and Analog Board.	Send unit in for service.
	Malfunction of Analog Board.	Send unit in for service.

4.5 Cabling and Interfacing Problems

Symptom	Possible Cause	Corrective Action
Discrepancy in pressure reading between the MPM-1 and the host monitor.	Host monitor out of calibration.	Re-calibrate or re-zero the Host monitor using the MPM-1 CAL STEP button. Refer to section 3.3 in TESTING AND PREVENTIVE MAINTENANCE.
	Incorrect host monitor adapter cable being used.	Verify correct host monitor cable is used.
	Faulty PMIO cable.	Replace PMIO cable.
Discrepancy in temperature reading between the MPM-	Incorrect host monitor adapter cable being used.	Verify correct host monitor cable is used.
1 and the host monitor.	Faulty PMIO cable.	Replace PMIO cable.
No pressure waveform or numerical display on host monitor, but MPM-1 displays mean pressure.	PMIO or host monitor adapter cable is loose.	Check cable connections between host monitor and MPM-1.
	PMIO cable or monitor adapter cable is faulty.	Replace cable.
	Host monitor malfunctioning.	Verify proper operation of host monitor.
	Faulty connection between PMIO flex cable and Analog Board.	Send unit in for service.
No temperature waveform or numerical display on host monitor, but MPM-1 displays mean temperature.	PMIO cable or monitor adapter cable is faulty.	Replace cable(s).
	Host monitor malfunctioning.	Verify proper operation of host monitor.
	Imperfect connection between PMIO flex cable and Analog Board.	Send unit in for service.

Symptom	Possible Cause	Corrective Action
Host monitor displays numerical or waveform Arterial Pressure. MPM-1 displays numerical ICP, but does not display CPP.	PMIO or host monitor adapter cable is loose.	Check cable connections between host monitor and MPM-1.
	PMIO cable or monitor adapter cable is faulty.	Replace cable(s).
	Faulty connection between PMIO flex cable and Analog Board.	Send unit in for service.
No Isolated Analog Output.	Loose cable.	Reconnect cable.
	Faulty Cable.	Replace cable.
	Faulty Connection between Analog Board and Isolated Analog Output Cable.	Send unit in for service.
No RS-232 communication.	Loose cable	Reconnect cable.
	Faulty Cable.	Replace cable.
	Faulty Connection between Digital Board and RS-232 cable.	Send unit in for service.