RJC ENTERPRISES, LLC©
YOUR OEM SUPPLIER OF FIBER OPTIC SENSORS FOR MEDICINE

OEM Instruction Manual For

Fiber Optic Measurement System

Model 650-03

For use with EC Optical Connectors and the Arrow Slider Assembly

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I. INTRODUCTION

The RJC Model 650 Fiber Optic Measurement System (FOMS) is a microcontroller based Instrument designed to support biological measurements made using RJC pressure sensor assemblies. The Model 650 is **NOT** designed or certified for making measurements in humans.

The Fiber Optic Measurement System and related sensor assemblies are manufactured by RJC Enterprises, L.L.C., 11711 N Creek Parkway South, Suite D-103, Bothell WA 98011, USA.

II. THEORY OF OPERATION

The pressure sensor design is based on the Fabry-Perot interferometer, in which two parallel, minimally separated, partially reflecting surfaces form an optical reflecting cavity. If one of these parallel surfaces is a pressure sensitive diaphragm, changes in external pressure cause a change in depth of the optical reflecting cavity, which in turn alters optical cavity reflectance spectra.

The Instrument contains an 850nm LED whose emissions reach the sensor via an optical fiber. In the sensor's optical reflecting cavity, the spectral distribution of LED light is modified as a function of cavity depth, and this spectrally altered light is reflected back down the fiber to the Instrument. Light returning to the Instrument is optically split into two spectral components; the photocurrents from these two components form a ratiometric signal which in turn correlates with changes in the measured parameter

Pressure sensors based on this technology have been manufactured and sold for industrial applications since 1988 (MetriCor/Photonetics), and for selected medical applications since 1993 (Integra NeuroSciences). The combination of small size, high performance, and immunity to electromagnetic noise make this pressure sensor an obvious choice for modern medical product applications.

For additional information, see Wolthuis et al. "Development of Medical Pressure and Temperature Sensors Employing Optical Spectrum Modulation" in *IEEE Transactions on Biomedical Engineering*, vol. 38, no. 10, pp 974-981, October 1991, and Reesink et. al. "Feasibility Study of a Fiber Optic System for Invasive Blood Pressure Measurements" in *Catheterization and Cardiovascular Interventions*, vol. 57, pp 272-276, 2002.

SPECIAL NOTICE

THE MODEL 650-03 FIBER OPTIC MEASUREMENT SYSTEM (FOMS) IS DESIGNED FOR USE WITH EC OPTICAL CONNECTORS (WITH OR WITHOUT THE ARROW CLAMSHELL ASSEMBLY). OPTICAL CONNECTORS MUST BE CLEAN TO ENSURE EFFICIENT TRANSMISSION OF LIGHT BETWEEN INSTRUMENT AND SENSOR.

The FOMS EC optical connector is composed of two parts:

- The male Connector, on the Fiber Optic Pressure Sensor assembly, and
- The female Adapter, located within the instrument front panel.

The FOMS EC optical connector is highly efficient, and, susceptible to contamination. To ensure proper operation of the complete sensor system, *the following rules must be observed at all times*:

- The male Connector must be covered with a cap when not in use. The cap prevents the tip from being scratched and/or contaminated.
- The female Adapter is located within the front panel slider assembly and must be covered with a cap when not in use. The Adapter contains a special index-matching membrane.

CLEANING: The male connector and the female adapter are user cleanable. See the Cleaning section (Section 12).

Figure 1 – Rear Panel

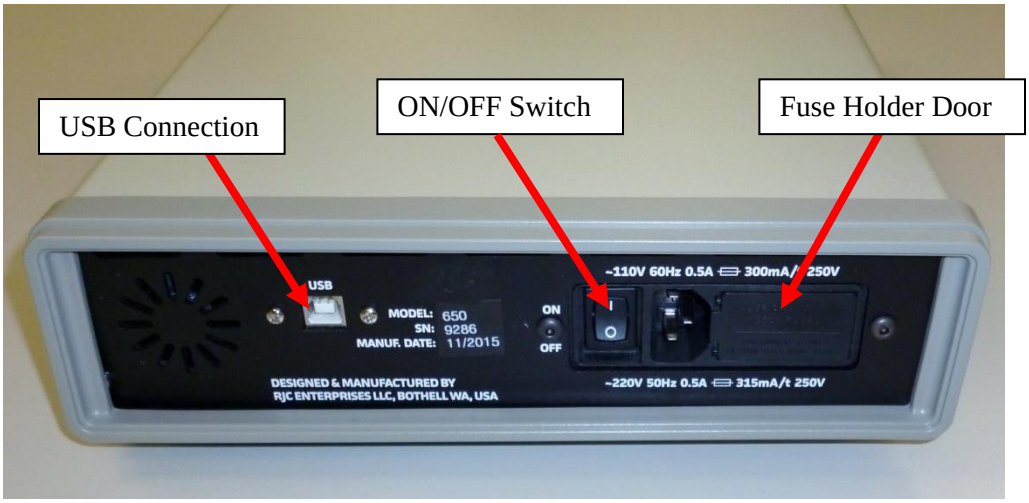


Figure 2 – Front Panel

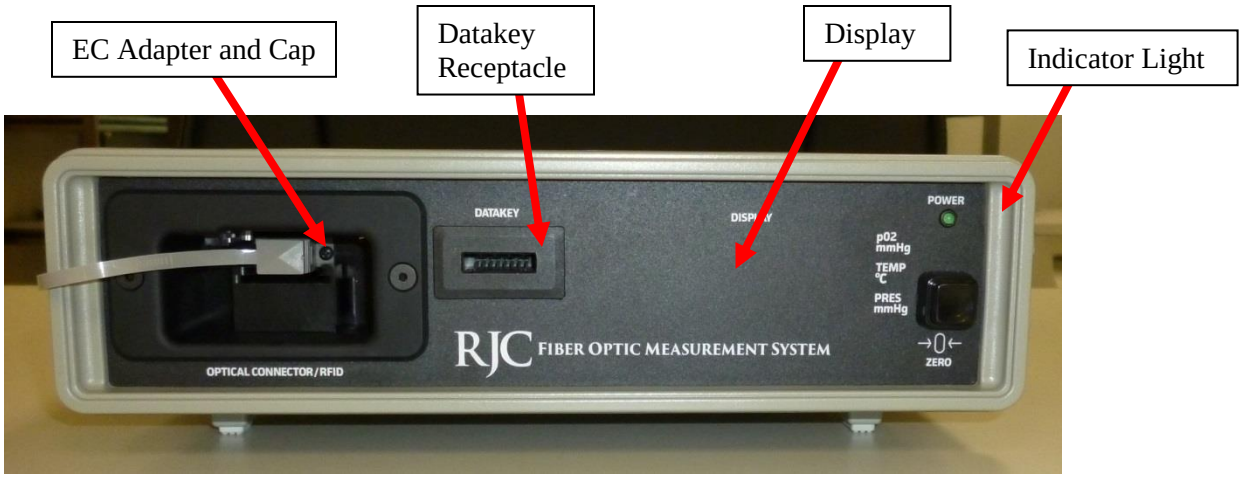
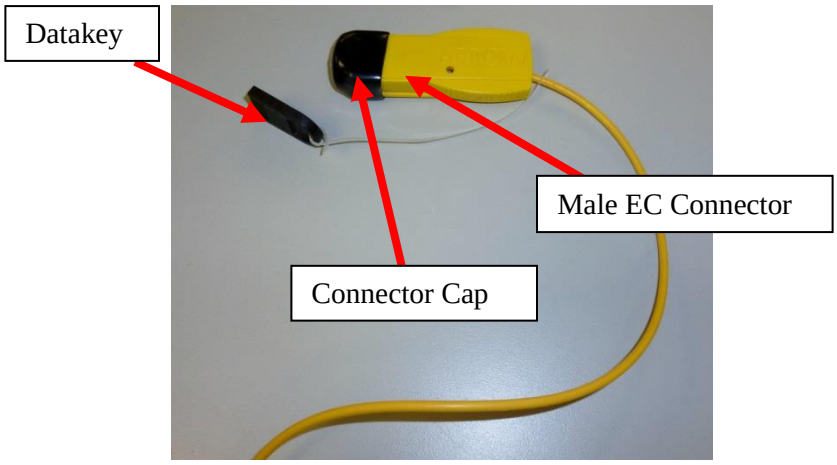


Figure 3 – Sensor Assembly (with clamshell)



III. OPERATING INSTRUCTIONS

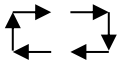
1. SETUP

   - Place Instrument in a well-ventilated location.
   - Attach line cord to an appropriate 110 VAC outlet (Note: See section 10 for 220 VAC operation).
   - If data logging is desired, connect an appropriate cable to the USB digital output (Figure 3).
   - Switch Instrument power to ON (Figure 1).
     - A green light (Figure 2) indicates Instrument is ON

2. INITIALIZATION AND WARM-UP

   The Instrument must initialize and warm to operating temperature before use, a process that takes about 5 minutes. [Optimal Instrument stability is achieved after 1-hour warm-up.]

   - The display shows a "racetrack" pattern while the Instrument is initializing and warming to operating temperature.



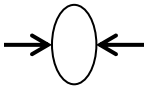
3. SENSOR ATTACHMENT

   To connect a sensor assembly to the Instrument:

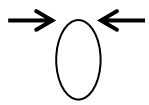
   - Remove protective cap from sensor assembly male Connector
   - Clean the male Connector tip with a soft alcohol saturated swab; use clean air to gently dry the tip. Cleaning the male Connector tip on every use ensures that contamination is not transferred to the female Adapter.
   - Remove protective cap from the Instrument female Adapter
   - *Carefully* insert the male Connector into the female adapter in the front panel; observe that this is keyed to accept the male Connector in only one orientation.
   - Check to make sure the male Connector is fully inserted.
   - If the sensor assembly has a Datakey attached (Figure 3), insert the Datakey into the Datakey receptacle (Figure 2). The Instrument will then load the sensor calibration data.
   - If there is no Datakey attached, the male connector contains an RFID tag (hidden) with calibration information, and this will be loaded automatically.

4. FOR PRESSURE SENSORS

   - When the Instrument reaches operating temperature, the LED display will prompt the operator as follows:
     - The green LED adjacent to "PRES, mmHg" will light, indicating a pressure sensor is connected.
     - The main LED display will show an alternating pattern "CAL–0 – CAL-0" etc., indicating the Instrument is ready for sensor zeroing.
   - With the Sensor at ambient pressure, press the Zero button once. (This sets the zero offset between the pressure Sensor and the reference barometric internal pressure transducer.)



- When the LED display shows "0", the Sensor is ready for use and may be placed at the desired measurement location. The Instrument is now in measurement mode.
- To re-zero a sensor that has already been zeroed, press the Zero button 3 times in less than 2 seconds.



Notice: The FOMS Display is for use with static pressure measurements only. For dynamic pressure measurements, the USB output must be used.

5. DEALING WITH THE TEMPERATURE SENSITIVITY OF PRESSURE SENSORS

Almost all pressure sensors have some sensitivity to temperature change, e.g., as the pressure sensor is moved from one temperature to another, the change in temperature is registered as a change in pressure.

RJC pressure sensors typically have a temperature sensitivity of -0.05 to -0.20 mmHg/°C. The temperature sensitivity is a function of the applied absolute pressure. All sensors are evaluated, for temperature sensitivity, at an absolute pressure of approximately 760 mmHg, and this data is written to the Datakey or RFID calibration Tag. Any sensors with temperature sensitivities exceeding ±0.25 mmHg/°C at 760 mmHg are considered to have failed calibration, and are not sold.

6. CHANGING A PRESSURE SENSOR

If the Instrument is running and it is necessary to change sensors, proceed as follows:

- Remove the currently installed male connector and Datakey (if present).
- Install a new Sensor Assembly male connector (per #3 "Sensor Attachment" above).
- The Instrument will ask for a new zero ("CAL-0 – CAL-0").

7. REMOVING & RE-INSTALLING THE SAME PRESSURE SENSOR

If a Sensor Assembly, which has been zeroed, is removed from an Instrument and then re-installed on the same Instrument, the Instrument will 'recognize' the sensor and its previous zero, and will immediately go to measurement mode.

8. OUTPUT TO USB PORT

- When the Instrument is connected to a PC running Windows 7, the computer will automatically install drivers and assign a COM port to the Instrument. It will be visible in the "Ports and LPT" section of the Device Manager as "USB Serial Port (COMXX)" where XX is the COM port to which the Instrument has been assigned. (Note: If drivers do not install automatically, they can be found here - http://www.ftdichip.com/Drivers/VCP.htm)
- A terminal application, such as HyperTerminal, or custom software capable of using a COM port, is needed to view or log information from the Instrument through the USB port. Notice: for sending commands to the instrument to work, HyperTerminal must be configured to not append line feeds to the end of lines sent.
- Data can be read from the COM port using the following communications parameters: 115,200 Bits Per Second, 8 data bits, no parity, 1 stop bit, and no flow control
- To show scrolling data, go to File and select Properties. On the Settings tab, click the ASCII Setup button. Check the box for Append line feeds to incoming line ends. Exit Properties.
- Stream mode
    - The instrument will start in stream mode. (Note: A sensor must be attached

to for data to show)

- The instrument can change to stream mode from monitor mode by typing ‘stream??’
- When a sensor is attached to the Instrument and has been zeroed, the Instrument will output differential pressure readings to the USB port at a rate of 1000 samples per second.
- Each line of streaming data will contain: a sign for negative values, differential pressure in 1 count per 0.1 mmHg, a comma separator, a sequence decimal digit, and two hexadecimal digits that encode a CRC8 value for the previous characters on the line. Each line is terminated with a carriage return without a line feed. Some examples are:
  - “-1,44a” is -0.1 mmHg with a sequence digit of 4 and CRC8 value of 0x4a.
  - “2301,2b8” is 230.1 mmHg with a sequence digit of 2 and a CRC8 value of 0xb8.
- When no sensor is attached, or the sensor has not been zeroed, the Instrument will not output to the USB port.

- Monitor mode
  - The instrument can be changed to monitor mode by typing ‘monitor??’
  - The first line of output will be the headings for each column
  - Each subsequent line will contain the values, comma separated
  - Lines will be output once per second

9. FUSE REPLACEMENT

Note: Use the same type and rating of fuses supplied by RJC:

- North America and supplies ~110V 60Hz, use a fuse rated [300mA/t 250V].
- Central Europe and supplies ~220V 50Hz, use the fuses (2 required) rated[315mA/t 250V].
- Japan and suppies ~100V 50/60Hz, use a fuse rated [375mA/t 250V].

- If connected, disconnect power cord-set from AC power module.
- Use a small flat head screwdriver to open fuse holder door on the AC power module (Figure 1).
- Loosen fuse holder block by rocking back and forth; remove block when loose.
- Remove existing fuse(s) from the block and replace with new one(s). Always replace fuse(s) with recommended type.
- Reinstall fuse holder block. Note – the fuse(s) that goes into the power module first is the active fuse(s).
- Close the fuse holder door.

10. CHANGING POWER CONFIGURATION

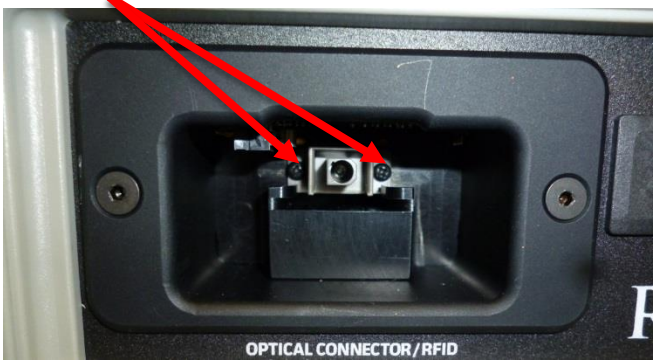
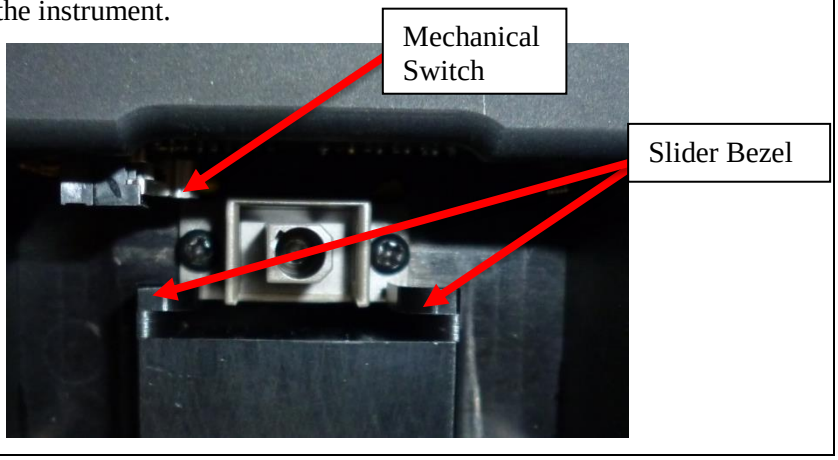
To change from North American (110 VAC) to European (220 VAC) fusing:

- Use a small flat head screwdriver to open fuse holder door on the AC power module (Figure 1).
- Loosen fuse holder block by rocking back and forth; remove block when loose.
- If not already present, install fuses into block (note - two European fuses are required).
- Reinstall fuse holder block. Note – the European fuses go into the power module first.
- Close the fuse holder door.

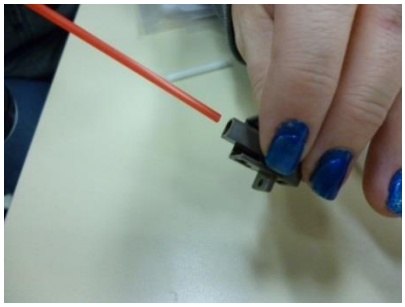
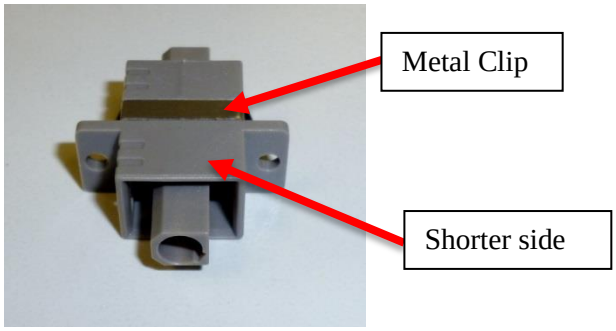
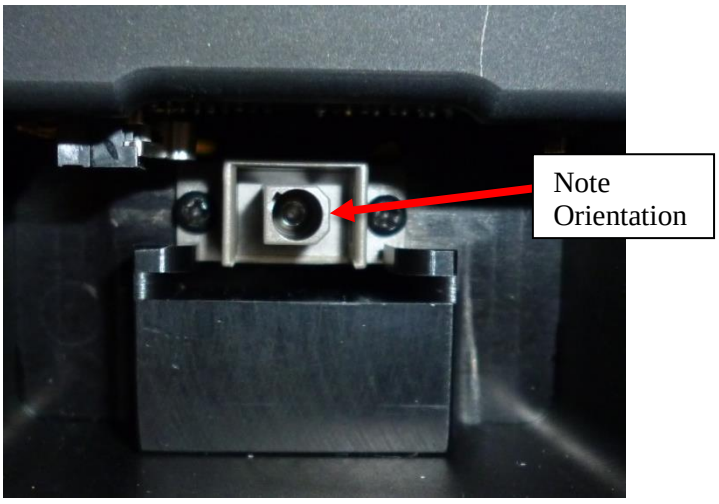
11. CALIBRATION

For optimal performance, the Model 650 FOMS should be returned to RJC for annual calibration.

12. CLEANING THE FEMALE OPTICAL ADAPTER

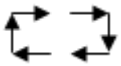
Step	Action
1	Make sure the instrument is unplugged. Using a small Philips head screwdriver, remove two small screws holding the Female optical Adapter in place. 
2	**Carefully** pull the optical Adapter forward. Note that the Adapter must be lifted up slightly to clear the slider bezel. It must also be gently pulled around the mechanical switch to clear the instrument. 

Step	Action
3	After pulling the adapter clear of the instrument, **gently** remove the internal male connector from the adapter, being careful not to touch or bump the end/tip of the connector. Set the fiber assembly/connector to the side where it will not be damaged. 
4	Inspect the adapter under a microscope for tears or debris. • If any tears or holes are noted, replace the adapter. If the adapter is dirty, proceed with steps 7-11 below.
5	Fill one side of the adapter with alcohol. 
6	Insert adapter cleaning tool (RJC Part 69-0015-01) into the side with alcohol … gently rotate the tool, being careful not to use pressure (this can tear the adapter membrane). 

Step	Action
7	Blow out the alcohol with compressed air. 
8	Repeat Steps 7-9 for opposite side of the adapter.
9	Inspect the adapter under microscope for debris. Re-clean as needed.
10	Remove the metal clip from the female optical adapter if present. Clean the tip of the internal male connector using a cotton swab and alcohol. Blow dry. Install the male connector in the **"shorter"** side of the adapter. 
11	Slide the connector/adapter gently back into the enclosure as shown. Note the orientation shown below. The female optical adapter placement is critical. 

IV. DIAGNOSTIC MESSAGES

The following messages will appear on the FOMS LED display.

Message	Reason for Message	Suggested Action	USB Output
	Instrument not warmed up.	• Allow Instrument to warm up for approximately 10 minutes.	• None
no SnSr	No Sensor	• Attach a sensor • Ensure connector is fully inserted	• None
CAL 0	Attached sensor is ready to zero	• Zero the sensor	• None
rEAd	Calibration data is being read	• Wait for the RFID tag to be read	• None
LoAd	The calibration is being loaded	• Wait for the calibration to finish loading	• None
ZEro	A zero is being performed.	• Wait for Instrument to complete zero	• None
OFSt Err	Sensor not zeroed AND the sensor pressure is more than 25mmHg from the ambient pressure.	• Ensure that pressure is not being applied to the sensor • Replace Sensor • Cycle power	• None
SYS Err	Instrument calibration data is corrupt	• Return Instrument to manufacturer for repair	• None
CAL Err	The calibration has failed to load.	• Ensure connector is fully inserted • Replace Sensor	• None
Err	The measured pressure values are outside the calibrated range for the sensor.	• Make sure Instrument is being operated between -183 m (-600 ft.) and 2,728 m (8,950 ft.).**	• Forced to “Error”

** Blood pressure measurements in the range -30 to +300 mmHg can be made between -600 to +8,950 feet.

If ‘suggested action’ does not resolve the problem(s), contact seller or manufacturer for instructions before returning Instrument for repair.

V. WARNINGS

The RJC Fiber Optic Measurement System (FOMS) will operate safely and accurately if instructions are followed.

- Use of Sensors other than those manufactured by RJC Enterprises can lead to erroneous measurements and/or Instrument malfunction.
- The pressure Sensor must be zeroed before use; follow operating instructions given above.
- The FOMS Instrument must be connected to a grounded, 110/220 VAC, 50/60 Hz power source. Verify correct fuses and power cord for line power used before operation.
- Accessory equipment connected to the FOMS Instrument Digital output must be certified according to IEC standards. Further, all configurations shall comply with established safety standards for medical electrical equipment (e.g., the international standard IEC 60601-1-1, or an equivalent national standard).
- The Instrument is not suitable for use in the presence of flammable gas mixtures.
- Do not sterilize or immerse the Instrument.
- The Instrument contains delicate optical components which cannot be repaired in the field. If the Instrument fails, it must be returned to RJC for servicing.

FCC Part 15

This device complies with FCC Rules Part 15 operation is subject to the following two conditions:

1. This device may not cause harmful interference.

2. This device must accept any interference, including interference that may cause undesired operation of the device.

Changes or modifications to this device, not expressly approved by RJC Enterprises could void the user's authority to operate the equipment.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

VI. TECHNICAL SPECIFICATIONS

Dimensions	26 cm wide, 27 cm deep, 7 cm tall
Operating Conditions	15-35 °C, 0-90% RH non-condensing, -183 m to +2,728 m (-600 to +8,950 ft.) **
Shipping/Storage Conditions	-30 to 50 °C, 0-90% RH non-condensing
Protection from Water Ingress	Ordinary
Protection from Flammable Gases	Not suitable for use in the presence of flammable gases
Power	110/220 VAC, 50/60 Hz
Self-Test Program	Automatic when power applied
Mode of Operation	Continuous
Display	4-digit LED
Pressure Sensor Display Resolution Display Accuracy	 1 mmHg $\pm$1 mmHg or $\pm$2 % of reading****
Digital output: USB	 115,200 Bits Per Second, 8 data bits, No parity, 1 stop bit, No flow control [1000 samples/s]

** Blood pressure measurements in the range -30 to +300mmHg can be made from -600 to +8,950 feet

**** AAMI standard for Intravascular Blood Pressure Transducers is $\pm$2 mmHg or $\pm$5 % of reading.

VII. LIMITED WARRANTY

RJC Enterprises, LLC, (RJC) warrants that each new Fiber Optic Measurement System Instrument is free from defects in material and workmanship under normal use and service for a period of one(1) year from date of delivery by RJC to first purchaser. If any such defect occurs during the warranty period, the purchaser must contact RJC directly for instructions regarding return of the Instrument. In returning the Instrument, the purchaser assumes responsibility for proper packaging and shipping costs; loss or damage during shipment is the purchasers' responsibility. If the Instrument is returned to RJC, and is under warranty, the Instrument will be repaired free of charge and then returned to the purchaser.

In no event shall RJC be liable for any incidental, indirect or consequential damages in connection with the acquisition or use of any RJC product. Further, this warranty shall not apply to any loss arising in connection with the purchase or use of any RJC product which has been repaired by anyone other than an authorized RJC service representative, or altered in any way so as 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 RJC. This limited warranty is exclusive and in lieu of all other obligations or liabilities on RJC's part, and RJC neither assumes nor authorizes any representative or other person to assume for it any other liability in connection with RJC products.

RJC 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.