IVY BIOMEDICAL

Innovation in Cardiac Monitoring

PAM-200

TECHNICAL GUIDE

Patient Acquisition Module

Designed exclusively to operate with Hitachi MRI Devices

Part No. 3258-00-16 REV01

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1.0 User Responsibility

This product will perform in conformity with the description thereof contained in this Operation Manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, IVY Biomedical Systems, Inc. recommends that a telephone call or written request for service advice be made to IVY Biomedical Systems, Inc. Service Department. This product or any of its parts should not be repaired other than in accordance with instructions provided by IVY Biomedical Systems, Inc. trained personnel. The product must not be altered without the prior written approval of IVY Biomedical Systems, Inc. Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction, which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than IVY Biomedical Systems, Inc.

Ivy Biomedical Systems, Inc.
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Branford, Connecticut 06405 USA
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2.0 Manual Revision History

Revision	Date	Description
00	February 6, 2011	Initial Release of PAM-200 Operation Manual
01	May 24, 2016	Updated manual to comply with IEC 60601-1 3rd edition

3.0 WARRANTY

All products manufactured by Ivy Biomedical Systems, Inc. under normal use, are warranted to be free from defects in material and workmanship and to operate within published specifications, for a period of one year from date of original shipment.

All accessories such as patient cables and lead wires, supplied by Ivy Biomedical Systems, Inc. under normal use, are warranted to be free from defects in material and workmanship and to operate within published specifications, for a period of 90 days from date of original shipment.

If an examination by Ivy Biomedical Systems, Inc. discloses such product(s) or component part(s) to have been defective, then our obligation is limited to repair or replacement (at our option).

When a product or products need to be returned to the manufacturer for repair or examination, contact customer service personnel at Ivy Biomedical Systems, to obtain a Return Material Authorization number (RMA #) and the correct packing instructions:

Customer Service Telephone:
(203) 481-4183 or (800) 247-4614
Fax: (203) 481-8734
E-mail: sales@ivybiomedical.com
Website: www.ivybiomedical.com

All products being returned for warranty repair shall be shipped prepaid to:

Service Department
Ivy Biomedical Systems, Inc.
11Business Park Drive
Branford, CT. 06405 USA
Toll-Free (800) 247-4614
(203) 481-4183
Fax: (203) 481-8734
Email: service@ivybiomedical.com

Ivy will prepay the shipment of the repaired or replacement product to customer.

4.0 INTRODUCTION

This manual is to provide information on the correct use of the Patient Acquisition Module (PAM-200). It is up to the user to ensure that any applicable regulations regarding the installation and operation of the module are observed.

The PAM-200 is a Medical Electrical device intended for use on patients requiring R-wave synchronization. The PAM-200 must be operated by trained and qualified medical personnel only.

Manufacturer's Responsibility
The manufacturer of this equipment is responsible for the effects on safety, reliability, and performance of the equipment only if:

• Assembly operations, extensions, re-adjustments, or repairs are carried out by persons authorized by the manufacturer
• The electrical installation complies with all applicable regulations
• The equipment is used in accordance with the instructions in this manual. Incorrect operation or failure of the user to maintain the module in accordance with proper maintenance procedures relieves the manufacturer or his agent from all responsibility for consequent non-compliance, damage, or injury.

This manual explains how to use the PAM-200. Important safety information is located throughout the manual where appropriate. READ THE ENTIRE SAFETY INFORMATION SECTION BEFORE OPERATING THE MODULE.

5.0 SAFETY

5.1 Electrical

WARNING: Do not place the module in a position that may cause it to fall on the patient. Do not lift the module by the external cables.

WARNING: Electric shock hazard! Do not remove covers or panels. Refer service to qualified service personnel.

WARNING: Do not clean module while it is on and/or connected to a power source.

WARNING: If unit is accidentally wet, discontinue use until dry and then test unit for proper operation before reuse on a patient.

WARNING: This unit uses a common isolation path for the ECG leads. Do not connect any non-isolated accessories to the ECG input when connected to a patient, as this may compromise the safety of the unit. When attached to other devices, insure that the total chassis leakage currents of all units do not exceed 300 µA.

WARNING: Equipment not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.

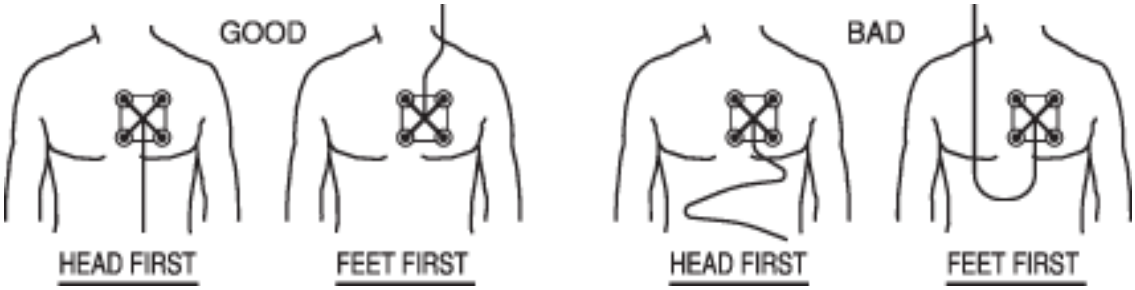
WARNING: Equipment not for use with oxygen or oxygen enriched atmospheres.

5.2 Patient Connections

Patient connections are electrically isolated. For all connections use isolated probes. Do not let patient connections contact other conductive parts, including ground. See instructions for patient connections in this manual. Carefully route patient cables to reduce the possibility of patient entanglement or strangulation. Leakage current is limited internally by this monitor to less than 50 µA. However, always consider cumulative leakage current that can be caused by other equipment used on the patient at the same time as this monitor.

To ensure that the leakage current protection remains within the specifications, use only the patient cables specified in this manual. This monitor is supplied with protected lead wires. Do not use cables and leads with unprotected lead wires having exposed conductors at the cable end. Unprotected lead wires and cables may pose an unreasonable risk of adverse health consequences or death.

⚠ **WARNING**: Hazard of RF energy burns from improperly placed cables. Avoid direct contact of cable with patient skin. Loops of cable must not be permitted! Such loops tend to collect burning levels of RF energy. Use extreme caution and check with patient frequently, especially when average S.A.R exceeds 1.0 W/Kg.



⚠ **WARNING**: Do not use four-lead MRI cable in magnet.

5.3 EMC (Electromagnetic Compatibility IEC 60601-1-2:2001)

This equipment has been certified to be protected to emissions and immunity according to IEC-60601-1-2.

⚠ **CAUTION**: Medical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following section.

⚠ **CAUTION**: Portable and mobile RF communications equipment can affect medical electrical equipment.

Please refer to the following table for detailed emissions information.

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

The PAM-200 is intended for use in the electromagnetic environment specified below. The customer or the user of the PAM-200 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The PAM-200 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS

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Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8kV air	±6 kV contact ±8kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±1.5 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on	< 5% U_T (> 95% dip in U_T) for 0.5 cycle	<5% U_T (>95% dip in U_T) for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the

power supply input lines IEC61000-4-11	40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (> 95% dip in U_T) for 5 sec cycle	40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles	user of the MDC-1 requires continued operation during power mains interruptions, it is recommended that the MDC-1 be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	Not applicable	Not applicable

GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS The PAM-200 is intended for use in the electromagnetic environment specified below. The customer or the user of the PAM-200 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment –guidance

Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communication equipment should be used no closer to any part of the MDC-1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2 p d = 1.2 p 80 MHz to 800 MHz d = 2.3 p 800 MHz to 2.5 GHz where p is the maximum output power rating of the transmitter in watts (W), according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of the equipment marked with the following symbol: 

5.4 Description of Warning Labels

 Consult Instructions For Use

 Warning

 Caution

RoHS RoHS Compliant

 Date of Manufacture

 WEEE Compliance

 Type BF Applied Part

 Manufacturer

 Earth (Ground)

6.0 Installation

Host MRI system shall provide a suitable enclosure sufficient not to allow the patient or operator access to the PAM-200 during normal use. The PAM-200 shall be protectively earthed by the host MRI system. Input fuse for MRI system to be determined by host installation instructions.

Installer information
Place PAM-200 in designated location indicated in the host installation instructions. Connect rear-panel cables as specified in host installation instructions. Make sure all cables are connected properly and securely.

Technician Information
Connect patient cables properly and securely to the front panel connectors.

7.0 Operation

7.1 Description

The PAM Module is an embedded instrumentation pack which provides an asynchronous gating trigger for use in an MRI environment. PAM MRI Gating Module can be supplied with three applied parts consisting of an ECG cable, an Optical Plethysmograph and a pneumatic respiration pad. There are no patient electrical connections on the Optical Plethysmograph or pneumatic respiration pad.

⚠ **CAUTION**: The PAM-200 is not intended for use with any other physiological monitoring unit.

⚠ **CAUTION**: The PAM-200 is restricted to use on one patient at a time.

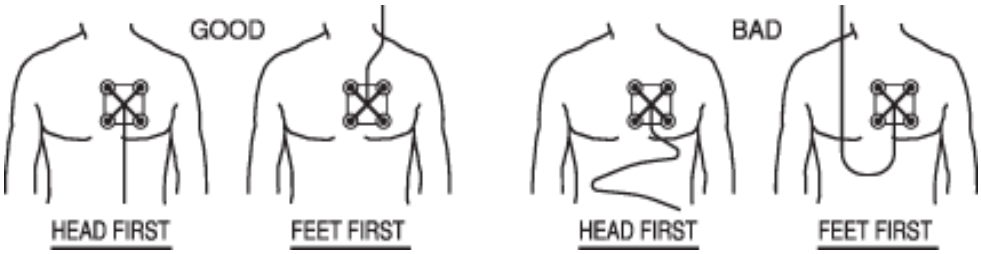
⚠ **CAUTION**: The PAM-200 is not intended for analysis of the ECG and QRS complexes.

7.2 Classification: Safety Approved (in accordance with UL-60601-1 Second Edition)

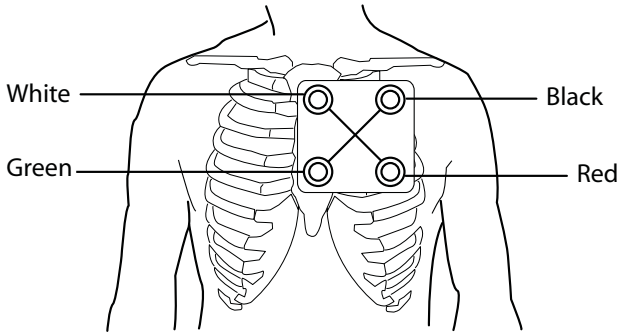
Classification:	Class I Equipment
Degree of protection against electric shock:	Type BF Applied Part
Degree of protection against ingress of water:	IPXO
Methods of Maintenance and Cleaning:	No sterilization or disinfecting required. See **Maintenance and Cleaning** section of this manual.
Degree of safety of application:	Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.
Mode of operation:	Continuous

7.3 ECG Patient Acquisition

Good placement has no loops and runs straight out from center of bore. Cables should make no unnecessary skin contact. Bad Placements run with slack and looping paths on way out of bore, or electrodes spread apart. Proper time and attention must be given to the routing of patient monitoring cables. There exists a great hazard of RF energy burns from improperly placed cables. Avoid direct contact of cable with patient skin. Loops of cable must not be permitted! Such loops tend to collect burning levels of RF energy. Use extreme caution and check with patient frequently, especially when average S.A.R exceeds 1.0 W/kg.



The PAM utilizes a 4 lead configuration in a Right Arm, Left Arm, Right Leg and Left leg setup. The Green is the reference lead with White, Black and Red as the active leads. The PAM provides for two simultaneous vectors. The first vector is White and Red. The second vector is White and Black. The two vectors are 45 degrees to each other and will result in one vector less affected by magnetic gradients.



7.4 Respiratory Acquisition

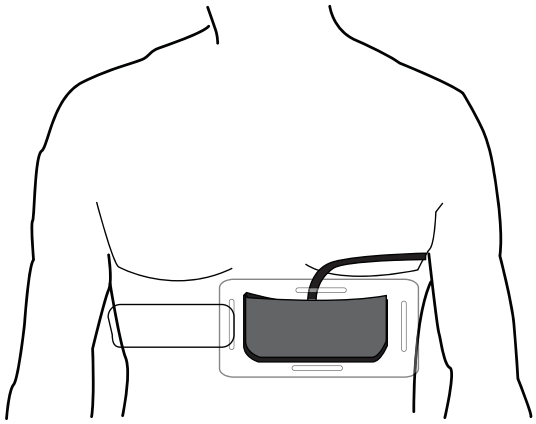
The PAM utilizes a pneumatic technique which responds to the expansion of the chest during respiration. A foam filled pillow is attached to the patient with a strap, and the air pressure in the pillow changes as the chest moves and compresses the pillow. The internal foam provides the spring action to return the pillow to the pre-compressed state. The pillow is attached to the PAM System Module by a flexible plastic tube, there is no electrical connection. The pillow has a stiff backing which aids in the compression action of the chest movement. Positive pressure (exhalation) will result in a positive going signal. The respiratory signal is transmitted in the digital stream to the console computer.

WARNING: Do not position the respiratory bellows or Velcro strap directly on the patient's skin. Position the respiratory bellows and Velcro Strap on the patient's clothes.

CAUTION: Overtightening the Velcro strap may cause patient discomfort and poor respiratory monitoring performance.

CAUTION: A loose or undertightened Velcro strap may cause a weak respiratory signal.

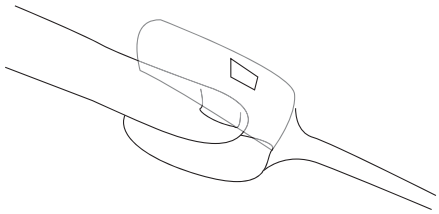
CAUTION: Carefully route the respiratory hose to avoid potential kinking. Do not place the respiratory hose underneath the patient.



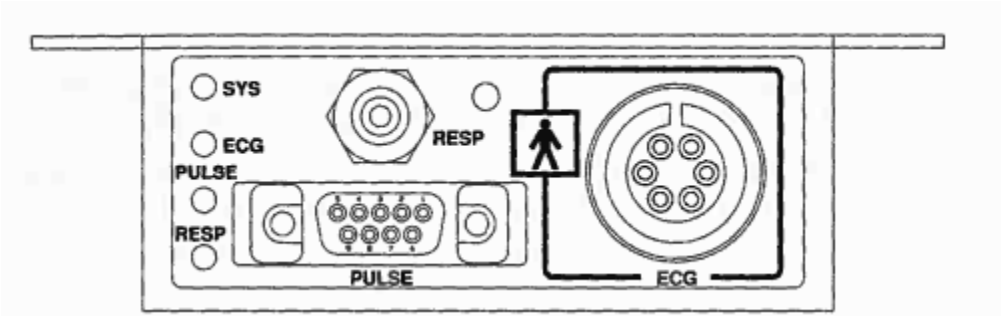
WARNING: Anatomical placement only. Do not position the respiratory bellows or Velcro strap directly on the patient's skin.

7.5 Peripheral Pulse Acquisition (Pleth)

The PAM has provision to perform cardiac gating by way of an optical based peripheral pulse, which is acquired on the patient finger. The optical emitter and detector are located within the PAM housing and the light energy is coupled to the patient through fiber optic cable. The patient connection is through a finger clip similar to a pulse oximetry sensor. The peripheral pulse signal is transmitted in the digital stream to the console computer, which could be located on the gantry or magnet housing.



7.6 Hardware Interface

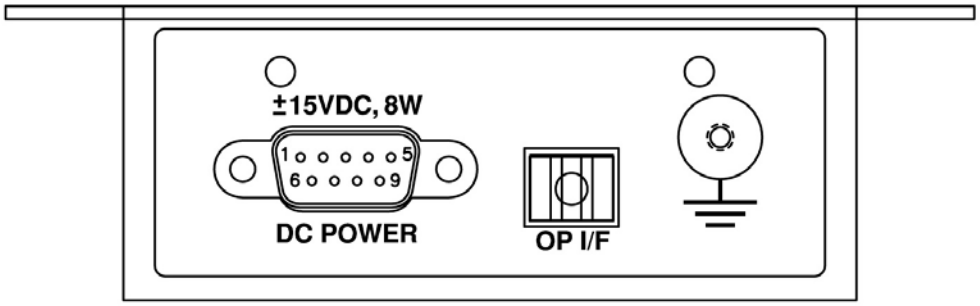


ECG Connector

Pin number	Function	Pin number	Function
A	Right Arm (RA)	D	N.C.
B	Left Arm (LA)	E	Right Leg (RL)
C	Left Leg (LL)	F	N.C.

Pulse Connector: 9 Pin Sub-D Female

Pin number	Function
1	Photo Diode Cathode
2, 4	LED Anode
6	Photo Diode Anode
3, 5	LED Cathode



DC Power Connector: 9 Pin Sub-D Male

Pin number	Function
2	+15V to ± 1V
3	-15V to ± 1V
6	PSGND

8.0 MAINTENANCE AND CLEANING

8.1 Cleaning and Disinfecting for Ivy Biomedical Reusable Respiration Bellows

If the respiration bellows or strap has been grossly contaminated with blood or other bodily fluids, it should be discarded.

Cleaning the Respiration Pillow

For normal cleaning with mild detergents / dilute bleach solution (1-2%), wipe the bellows and plastic with cleaning solution, rinse with water and dry. If the strap becomes soiled, it should be discarded and replaced. Reorder Ivy Biomedical p/n 2842-00-10.

Disinfecting Instructions

Using a disinfecting solution, such as Isopropyl alcohol (70%), Ethanol (70%), wipe or spray the respiration bellows and allow to stand approximately one minute, rinse well with water and dry.

8.2 Cleaning the Module

Although not exposed, when necessary, clean the exterior surfaces of the module with a cloth or swab dampened with a warm water and mild detergent solution. Do not allow liquids to enter the interior of the instrument.

⚠ **CAUTION**:

- Do not autoclave, pressure sterilize, or gas sterilize the module.
- Do not soak or immerse in any liquid.
- Use cleaning solution sparingly. Excessive solution can flow into the module housing and cause damage to internal components.
- Do not use petroleum based or acetones solutions, or other harsh solvents, to clean the module.

8.3 Cleaning Patient Cables

Wipe the cables using a mild detergent solution. Never submerge the cables in any liquid or allow liquids to enter the electrical connections.

8.4 Preventive Maintenance

Check before connecting the module to a new patient that cables and leads are clean and intact.

⚠ **CAUTION**: **There are no user serviceable items contained in the PAM-200.**

9.0 Accessories

ECG

Part No.	Description
5189-00-01	MRI Patient Cable
590384	Four Lead ECG Extension Cable 1 Meter (External Magnet Use only)
590425	Four Lead ECG Extension Cable 10 Ft. (External Magnet Use only)
590391	MRI Electrodes
590291	Nuprep Gel

Respiration

Part No.	Description
2802-00-01	Bellows
2842-00-10	42” Strap
2842-01-10	72” Strap
3215-00-01	Hose to Bellows

To order accessories, visit our website (www.ivybiomedical.com) or contact customer service:
• Toll Free (800) 247-4614 or (203) 481-4183
• Fax: (203) 481-8734
• E-mail: sales@ivybiomedical.com

9.1 Disposal

Disposal of devices or consumables must be done in accordance with local, state, and federal laws and regulations. WEEE Directive 2012/19/EU. Do not dispose of WEEE products in general waste. At the end of product life, contact IVY Biomedical Systems, Inc. customer service for return instructions.

10.0 Specifications

10.1 Communications

The PAM communicates to the console computer through a bi-directional fiber optic connection. In normal operation the PAM will be sending a packet every 1mS. The console computer can send a variety of opcodes to the PAM to force certain operations.

Optical Transmitter: Avago HFBR-1522
Maximum Distance: 45M
Transmission Rate: 115.2KBaud
Optical Frequency: 660nM
Serial Configuration: 8bit, 1 start bit, 1 stop bit, no parity

Communication Protocol

The PAM-200 protocol is comprised of a fixed length of 6 bytes of data transmitted once every 4.166mS (240Hz) and are asynchronous. The bytes are at 19.2K baud, 1 stop bit, no parity. The PAM-200, with this protocol, is a talker only and at power up will start transmission as soon as the module is fully initialized.

There will be 4 packets, or groups, which will be sent round robin, repeating every 16.66mS. Each packet will contain two sample points of ECG data and trigger information, and either a pulse plethysmographic sample point, respiration sample point or status information. All physiological data will be 12 bit unsigned. The ECG data is sent at an equivalent sample rate of 480 Hz and pulse plethysmographic and respiration data is at 60 Hz sample rate.

10.2 Electrical and Optical Interfaces

This section describes the various electrical and optical connections to the PAM along with the connector and pinout for each.

ECG Performance

Detection Amplitude Range:	0.3mV to 4.5mV
ECG Bandwidth:	1Hz to 20Hz
Digitization Rate:	10 kHz
Digitization Resolution:	16 bits
Delay:	< 30 mS
ECG Scaling at electrode:	7313 counts / mV or 136.7nV / count

ECG Electrical

Patient Leakage:< 50uA @264Vac 60Hz
Patient Isolation: 4000V @60Hz for 1 minute

Patient Connector Pinout Amphenol 97-3106A14S-6P

Pin	Signal Name	Description
C	LL	Left Leg (RED) ECG Lead
D	NC	Key plug location (pin removed)
A	RA	Right Arm (WHITE) ECG Lead
B	LA	Left Arm (BLACK) ECG Lead
E	RL	Right Leg (GREEN) ECG Lead

Respiratory Performance
Pressure Range: 0 to 1psi (760 mm Hg)
Digitization Rate: 1 kHz
Waveform transmission rate: 200Hz
Digitization Resolution: 16 bit
Bandwidth: 3Hz
Baseline restoration: 20 seconds
AGC Range: 40dB
ACG lock: 60 seconds
AGC lock amplitude: 70% of full scale amplitude

Respiratory Patient Connection
Pneumatic connection: Rectus 20KFTF05MPN
Hose to pillow connection: Lure Lock
Pillow strap: 2” wide Velcro Strap

Peripheral Pulse Performance
Peripheral Pulse Bandwidth: 10Hz
Peripheral Pulse Digitization Rate: 1kHz
Waveform transmission rate: 200Hz
Digitization Resolution: 16 bit
Baseline restoration: 10 sec
AGC Range: 30dB
ACG lock: 20 seconds
ACG lock amplitude: 70% of full scale amplitude

10.3 Power Connector
Power is applied to the PAM through a 9 pin male sub D connector. The connector is filtered with a 5000pF cap integral to the connector. The supply ripple not to exceed 50mV RMS and each voltage must have a tolerance of ± 5%. There is also provision in the connector and the PAM circuitry for a single wire diagnostic system, which could provide the console computer with basic information about the operation of the PAM, irrespective of the ability of the PAM to communicate to the console computer optical interface.

10.4 Physical Specifications

The PAM is housed in a RF tight Cast Aluminum hosing with a removable Aluminum top cover.

Length:	9.3 inches	236.2 mm
Width:	10.4 inches	264.2 mm
Height:	2.75 inches	69.85 mm
Weight:	5.5 lbs.	2.5 Kg
Length:	9.3 inches	236.2 mm

10.5 Power Requirements

+15V ±1V of negative supply @1A; Ripple < 50mV, 8W
-15V ±1V @500mA; Ripple < 50mV, 8W

10.6 System Environmental Performance

The PAM can operate in close proximity of up to a 3 Tesla magnet, with a maximum continuous filed strength of up to 0.6 Tesla. The attraction in such a field is less then 5lbs.

Operational Environmental Conditions:

Category	Units Celcius	Units Farenheit
Ambient Temperature	5 to 40 °C	41 to 104 °F
Ambient Temperature Change	< 3 °C/hr	< 37 °F/hr
Humidity(non-condensing)	30 to 75 %RH	
Humidity Change (non-condensing)	< 5 %/hr	
Altitude (feet above sea level)	-1300 to 10000 Ft (-396 to 3048 meters)	
Atmospheric Pressure	1060 to 700 Hpa	
Shock	Maximum 20G @ less than 3 rms half sine-	
Maximum Continuous Magnetic Filed	0.6 Tesla (6000 Gauss)-	
Vibration	Maximum random 0.21G RMS	

Storage and Transportation Environmental Conditions:

Category	Units Celcius	Units Farenheit
Ambient Temperature	- 40 to +70 °C	-40 to 158 °F
Humidity(non-condensing)	5 to 95 %RH	

10.7 Peripheral Pulse Connector

The Peripheral Pulse input connector supplies power for the remote optical Plethysmograph electronics and accepts the photodiode return signal from the sensor device. This is a male 15 pin sub D connector.

Peripheral Pulse Connector

Pin	Description
1	LED supply current
2	
3	Photodiode input
4	+5 Volt probe power
5	Analog Ground
6	
7	Continuity Loop (PPG probe selection control)
8	-5- Volt probe power
9	Continuity Loop (PPG probe selection control)
10	Analog ground

10.8 System Noise Performance

The PAM is adequately shielded from the ambient RF noise and will not cause any coherent noise of more than –180 DBM with a bandwidth of +/- 1 MHz. The PAM does not emit any radiation which will interfere with the image quality of the MR scans and/or cause image artifacts. The PAM has been designed to operate in the following radio frequency environments.

PAM Frequencies of Operation

System	Center Frequency (MHZ)
0.2T	8.518
0.35T	14.906
0.7T	29.811
1.5T	63.881
3T	127.763

10.9 Patient Isolation Scheme

To ensure patient isolation, the PAM uses an isolation circuit consisting of an isolated power supply and 2-vector ECG front end. The barrier between the isolation circuit and the non-isolation circuit has a creepage distance of no less than 5mm on the PCB and no less than 8mm through the air.

10.10 Dielectric Withstand Test

To ensure patient isolation and safety, the PAM is subjected to a hipot test of 4kVac, 60Hz for 60 seconds. The voltage is applied between shorted patient leads of the patient cable and the chassis of the PAM.

10.11 Defibrillation Statement

The PAM does not offer defibrillation protection. The PAM is a complete system for providing reliable cardiac gating in the demanding MR environment and is not intended for diagnostic waveform analysis.

10.12 Pacemaker Statement

The PAM does not offer pacemaker detection or rejection.

10.13 Regulatory

The PAM-200 device shall comply with both domestic and international regulatory standards and guidelines relevant to medical devices including, but not limited to:

- UL60601-1: 2nd Ed. Medical Electrical Equipment, part 1: General Requirement for Safety and Essential Performance
- UL60601-1: 3rd Ed. Medical Electrical Equipment, part 1: General Requirement for Safety and Essential Performance
- UL60601-1-2: 2001 Rev 2.1 Electric Magnetic Compatibility, Requirements and Tests – (Plus Amendment 1)
- UL60601-1-4: 2004 Programmable Electrical Medical Systems
- ISO 14971: 2007 Medical Device Risk Analysis
- ISO 60529 Enclosure Protection
- ISO 62304 Software Life Cycle
- IVY 207-5EN Design Controls
- IVY 207-6EN Risk Management Process
- IVY 207-8EN CAD System Function and Backup
- IVY 207-9EN Engineering Revision Control
- IVY 9940-00-18 ECG Performance Tests

Conforms to UL STD 60601-1. Certified to CAN/CSA STD C22.2 No. 601.1

Ivy Biomedical Systems, Inc. has declared that this product conforms with the Eurpean Council Directive 93/42/EEC Medical Device Directive when its used in accordance with the instructions provided in the Operation and Maintenace Manual.