

## EC Declaration of Conformity

### Classification

The MP150 System from BIOPAC Systems, Inc. is designed for use in life science research investigations. The MP150 System is a user-customized, physiological signal recording instrument. The MP150 System is intended for physiological research purposes and is designed to satisfy certain applicable test standards.

BIOPAC Systems, Inc. does not condone the use of its instruments for clinical medical applications. Instruments, components and accessories provided by BIOPAC Systems, Inc. are not intended for the cure, diagnosis, mitigation, treatment, or prevention of disease.

### Conformity


According to the original Low Voltage Directive 73/23/EEC and subsequent amendments which presently constitute Low Voltage Directive 2014/35/EU, the MP150 System conforms with the following standards as far as applicable:

EN 60950-1

According to the Electromagnetic Compatibility Directive 89/336/EEC and later replaced by EMC Directive 2014/30/EU, the MP150 System conforms with the following standards as far as applicable:

Emissions: EN 55011  
Immunity: EN 61000-4-2, EN 61000-4-3

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Alan J. Macy  
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## Self-Declaration of Conformity

### Classification

The MP150 System from BIOPAC Systems, Inc. is designed for use in life science research investigations. BIOPAC Systems, Inc. does not condone the use of its instruments for clinical medical applications. Instruments, components and accessories provided by BIOPAC Systems, Inc. are not intended for the cure, diagnosis, mitigation, treatment or prevention of disease.

The MP150 System is a user-customized, physiological signal recording instrument. The MP150 System is intended for physiological research purposes and is designed to satisfy certain applicable medical safety requirements.

The MP150 System is not, solely, designed for use in clinical medical applications. Individuals or businesses that employ the MP150 system, as a sub-assembly for these purposes, are subject to the local relevant standards for their complete system offering.

With respect to the criteria established by COUNCIL DIRECTIVE 93/42/EEC of June 14, 1993, the MP150 System is not considered a medical device. Accordingly, the MP150 System is subject to the Low Voltage (2014/35/EU) and Electromagnetic Compatibility (2014/30/EU) Directives.

However, the MP150 System can be used to collect physiological data from human subjects for educational and research purposes. Accordingly, BIOPAC Systems, Inc. has tested the MP150 System to certain applicable medical device standards, even though, strictly considered, the MP150 is not a medical device. The applicable standards for medical safety requirements are determined by IEC 60601-1 and the applicable standards for electromagnetic compatibility requirements are determined by IEC 60601-1-2.

BIOPAC Systems, Inc. has attempted to reconcile the classification and testing requirements for the MP150 System by performing a series of relevant tests. These test standards and methods have been guided by addressing the applicable parts of IEC 60601-1 and IEC60601-1-2.

The MP150 System and Accessories product line from BIOPAC Systems, Inc., as specified in the Research catalog, conform to the following standards as far as applicable:

### **Electromagnetic Compatibility Test Standards**

#### **Emissions**

|                      |          |
|----------------------|----------|
| Conducted Emissions: | EN 55011 |
| Radiated Emissions:  | EN 55011 |

#### **Immunity**

|                          |              |
|--------------------------|--------------|
| Electrostatic Discharge: | EN 61000-4-2 |
| Radiated RF:             | EN 61000-4-3 |

### **Medical Safety Test Standards**

|                               |             |
|-------------------------------|-------------|
| Earth Leakage Currents:       | IEC 60601-1 |
| Patient Leakage Currents:     | IEC 60601-1 |
| Insulations:                  | IEC 60601-1 |
| Dielectric Strengths:         | IEC 60601-1 |
| Creepages and Air Clearances: | IEC 60601-1 |

### **Electromagnetic Compatibility Testing Considerations**

The MP150 System is designed to be used in physiological research and teaching laboratories and accordingly is formally subject to EN 55011 Electromagnetic Compatibility Test Standards.

### **Electromagnetic Compatibility Testing Configuration**

The MP150 System was connected to a standard PC compatible computer, with all I/O ports properly terminated. The MP150 was initialized for standard operation prior to performing measurements.

### **Conducted Emissions**

The MP150 System met the level imposed by the average conducted emissions limit through the use of a quasi-peak detector, accordingly the MP150 System was deemed to meet both quasi-peak and average conducted emission limits. The data set was reduced to indicate worst case expected readings. The highest conducted emission values for a particular frequency, in any frequency band, were plotted (see Appendix) as representative of the entire band.

### **Radiated Emissions**

The MP150 System met the level imposed by the quasi-peak limit through the use of a quasi-peak detector. The readings at any particular frequency were observed for a 15 second period. The highest stable reading during this time period was recorded.

The data set was reduced to indicate worst case expected readings. The highest radiated emission values for a particular frequency, in any frequency band, were plotted (see Appendix) as representative of the entire band.

### **Immunity Testing**

When exposed to Air (8 kV) and Contact (6 kV) Discharge, the MP150 System continued to operate in a normal fashion. When exposed to Radiated RF of 3 V/m (80 MHz to 2.5 GHz), the MP150 System continued to operate in a normal fashion.

### **Medical Safety Testing Considerations**

The MP150 System is a user-customized, physiological signal recording instrument. The MP150 System is intended for physiological research purposes and is designed to satisfy certain applicable medical safety requirements.

The MP150 System is not, by itself, designed for use in clinical medical applications. Individuals or businesses who employ the MP150 system, as a sub-assembly, for these purposes are subject to the local relevant standards for the complete clinical system offering.

For the relevant medical safety tests, the MP150 System was evaluated in accordance to the applicable standards associated with IEC60601-1.

## Medical Safety Testing Configuration

The MP150 System was connected to a standard PC compatible computer, with all I/O ports properly terminated. The MP150 System was initialized for standard operation prior to performing measurements.

## Leakage Current Testing

For the MP150 system, the applicable measurements concern Earth Leakage currents, Enclosure Leakage current and Patient Leakage currents. See the Appendix for test procedures.

IEC60601-1 Earth Leakage Current limits  
500 $\mu$ A (Normal) and 1000 $\mu$ A (Single Fault Condition)

In Normal Conditions, the MP150 leakage current is: < 8  $\mu$ A  
In S.F.C. Conditions, the MP150 leakage current is: < 200  $\mu$ A

IEC60601-1 Enclosure Leakage Current limits  
100 $\mu$ A (Normal) and 500 $\mu$ A (Single Fault Condition)

In Normal Conditions, the MP150 leakage current is: < 8  $\mu$ A  
In S.F.C. Conditions, the MP150 leakage current is: < 200  $\mu$ A

IEC60601-1 Patient Leakage Current limits (Floating Applied part to Earth)  
100 $\mu$ A (Normal) and 500 $\mu$ A (Single Fault Condition)

In Normal Conditions, the MP150 leakage current is: < 8  $\mu$ A  
In S.F.C. Conditions, the MP150 leakage current is: < 200  $\mu$ A

IEC60601-1 Patient Leakage Current limits (Mains Voltage on the Floating Applied part)  
5000 $\mu$ A (Single Fault Condition) – 240 VAC + 10% @ 60 Hz

In S.F.C. Conditions, the MP150 leakage current is:  
< 100 $\mu$ A 120 VAC + 10% @ 60 Hz  
< 200 $\mu$ A 240 VAC + 10% @ 60 Hz

## Dielectric Strength Testing

In reference to the MP150 System, the following definitions apply:

|                           |   |
|---------------------------|---|
| Mains or Live part:       | Subject to Wall Transformer (adapter)       |
| Signal Input/Output part: | Subject to Serial (USB) Computer Connection |
| Floating Applied part:    | Subject to Analog/Digital Connections       |

At least Double or Reinforced Insulation is required between the Mains (Live) part and Floating Applied part. This insulation was tested at 4000 V. No flashover or breakdown was observed.

At least Basic Insulation is required between a Floating Applied part and Signal Input/Output part. The Basic Insulated portions (DC/DC converters, optocouplers, and Ethernet transformer) of the MP150 System were tested to 1500 V. No flashover or breakdown was observed.

## Creepage Distance and Air Clearance Testing

At least Basic Insulation is required between a Floating Applied part and a Signal Input/Output part. The MP150 unit has internal Creepage Distance and Air Clearance spacing designed to meet Basic or Supplementary Insulation requirements. These requirements are:

### Basic Insulation

|                   |        |
|-------------------|--------|
| Creepage Distance | 3.0 mm |
| Air Clearance     | 1.6 mm |

### Double or Supplementary Insulation

|                   |        |
|-------------------|--------|
| Creepage Distance | 4.0 mm |
| Air Clearance     | 2.5 mm |

### MP150 Internal Construction (Spacing between Floating Applied part and Signal Input/Output part)

|                   |        |
|-------------------|--------|
| Creepage Distance | 4.0 mm |
| Air Clearance     | 3.0 mm |

# Technical Documentation

## Introduction

A representative sample of the MP150 System was examined and is described in the body of this report. Unless specifically stated otherwise, the following general definitions, terminology, and construction details apply:

### Agency Approvals:

An asterisk (\*) denotes that the agency logo appears on the component.

C or CSA = CSA Certified

UL = UL Listed

UR = UL Recognized

CUL = UL Listed to Canadian Standards

### SELV:

All references to “SELV” denote Safety Extra-Low Voltage (less than 25 VAC or 60 VDC) non-hazardous secondary circuits.

### Metal:

All references to “metal” denote painted or plated steel (minimum No 20 MSG) or aluminum (minimum No 16 AWG).

### Dimensions:

(Dim) All dimensions specified are approximations only.

### Internal Wiring:

All primary, secondary and grounding circuit conductors are certified, Type TEW, TR-64, TR-32, AWG SR-PVC or AWM XL-PVC, rated minimum 80°C, 300 VAC. All wiring is suitably routed and secured away from sharp edges and moving parts to prevent chafing of the insulation.

Alternatively, additional insulation is provided where the wiring passes over sharp edges and through holes.

### SELV Wiring:

All non-certified conductors and connectors in SELV secondary circuits have insulation materials with a flammability rating of 94V-1 or better.

### Sleeving:

All thermoplastic and other insulating tubing used in primary and secondary circuits are certified, rated minimum 105°C, 300 VAC; or Teflon, rated minimum 200°C, 300 VAC.

### Crimp Connectors:

All crimp-type connectors used in primary, secondary and grounding circuits are certified and appropriately sized for the gauge of conductors used, vinyl insulated (optional for grounding), rated minimum 90°C, 250 VAC.

### Connectors:

All connectors used in primary and secondary circuits are certified, appropriately sized for the number and gauge of conductors used, rated minimum 250 VAC.

### Printed Wiring Boards (PWB):

All PWBs are made of paper phenolic, paper epoxy or glass epoxy, minimum 1.6 mm thick, flammability rated 94V-1 or better.

### Spacings:

All spacings in primary, secondary, and subject circuits between PWB conductive traces, and between other bare live parts and ground, conform to conform to Table XVI of IEC 60601-1.

### Bonding:

All accessible metal parts liable to become energized are acceptably connected together, and to the grounding means, by straps and/or conductors, bolts, screws, and washers (to ensure surface coating penetration), in conformance to Clause 3.4 of CSA Standard C22.2 No 0.4.

## System Description

### General:

The MP150 System is a stackable, modular system intended for the monitoring, recording, and analyzing of physiological data in the life science research environment. The system is not intended for clinical medical applications and is not for the diagnosis, mitigation, treatment or prevention of disease.

The MP150 System is a data acquisition hardware platform upon which various life science research and development systems can be implemented. The MP150 unit is an electrical system which contains high isolation DC-DC converters, optical isolators, amplifiers, analog to digital converters, microprocessor, and support components.

The MP150 unit resides in a durable ABS plastic (UL type 94HB) enclosure and connects to the computer (either PC compatible or Macintosh) via an Ethernet or serial (USB) extension cable. Modules for measuring a variety of physiological signals are plugged into the MP150 unit. Up to 16 modules can be used simultaneously with a single MP150 unit. Subject connected modules are isolated from Mains via a Safety Extra-Low Voltage (SELV) wall transformer and subsequently, a DC/DC converter, optocouplers, and Ethernet communications transformer within the MP150 unit.

The MP150 unit incorporates two sections, an unisolated part and an isolated part. The unisolated part receives power via a 12 VDC @ 2.5 amp TUV, UL and CSA approved wall transformer (adapter). This adapter also internally connects Mains Earth to the negative terminal of the 12VDC supply. The MP150 unisolated part is also connected to the computer Mains Earth via the serial (USB) cable. The unisolated part contains a high isolation (4000 V peak) DC-DC converter which provides power to the isolated part. The isolated part transmits its data to the unisolated part via high isolation optocouplers and Ethernet transformer. See Appendix for the isolation description block diagram.

### 1. Power Supply:

For 120 V or 240 V operation, CUL\* and UL\* and TÜV approvals, embedded IEC socket, BIOPAC P/N: AC150A, rated 120 - 240 VAC, 50 - 60Hz, 0.4 A (surge), output 12 V, 25 W.

For Rechargeable Battery option, use BIOPAC part number BAT100A.

### 2. Main Unit Enclosure:

Molded plastic, made of 'Polystyrene', Type BOPLA, color gray, minimum 3.0 mm thick, flammability rated CSA 0.6HB (for gray colors and minimum 1.6 mm thick) and UL 94HB (for gray colors and minimum 1.6 mm thick); shaped as shown. Consists of plastic shells, secured together by screws and integral channels.

### 3. Main PWB:

UR construction and (subject circuit) spacings are as described in Appendix, three printed wire boards and one metal shield, each measures 10.1 cm by 17.9 cm, secured to the rear panels by standoffs, screws, nuts and washers. Provided with the following components:

#### (a) Fuseholder and Fuse:

Fuseholder is C\*, UR\*, SEMKO, VDE, 'Littelfuse', P/N 345, rated 15 A, 250 VAC, shock safe type, PWB mount type. Fuse is C\*, UL\*, '3AG', P/N: AGC-2, rated 250 VAC, 2 Amp, fast blow. Note: Fuse rating and type is marked in a permanent manner adjacent to the fuse.

#### (b) DC-DC Converter:

(U206), Accepted, 'Power-One, Inc.', P/N: DGP20S218, input: 9-18 VDC, 2160 mA, output: 5 VDC, 2500 mA,  $\pm$ 12 VDC, 310 mA. Rated for continuous 1500 VDC (4000 V pk) isolation input to output. Undergoes testing performed per methods set forth by VDE750, CSA 22.2 and IEC601-1.

(c) Optocouplers:

(U201, U203) Accepted, 'Hewlett-Packard', P/N HCPL 2630, rated 2500 VAC (rms) isolation input to output. Recognized under the component program of U.L. (File # E55361) for dielectric proof test.

4. Conditioning (Subject) Modules:

Conditioning Modules operate at Safety Extra-Low Voltage. Subject isolation from Mains is provided by the Wall Transformer (adapter) and subsequently by the MP150 unit internal DC/DC converter, optocouplers and Ethernet transformer.

Up to 16 modules may be provided. Power is provided to the modules through the DC-DC converter described above which limits the power output to maximum 25 W.

Molded plastic, made of 'Polystyrene', type BOPLA, color gray, minimum 3.0 mm thick, flammability rated CSA 0.6HB (for gray colors and minimum 1.6 mm thick) and UL 94HB (for gray colors and minimum 1.6 mm thick); shaped as shown. Consists of plastic shells, secured together by screws and integral channels.

5. Subject Leads and Transducers:

Typically ECG type, actual may vary. Subject leads are constructed to prevent engagement with any part on the equipment that could be a risk of electric shock, fire, or injury to persons. Also, the equipment is only intended for use with professional supervision.

# APPENDIX

## Important Measurement Considerations

As a general laboratory instrument, the MP150 System can be used to monitor signals from various laboratory equipment or, alternatively, live subjects. Because of the MP150 construction, it is possible to inadvertently ground the subject when connecting other laboratory equipment to the MP150 System during subject monitoring.

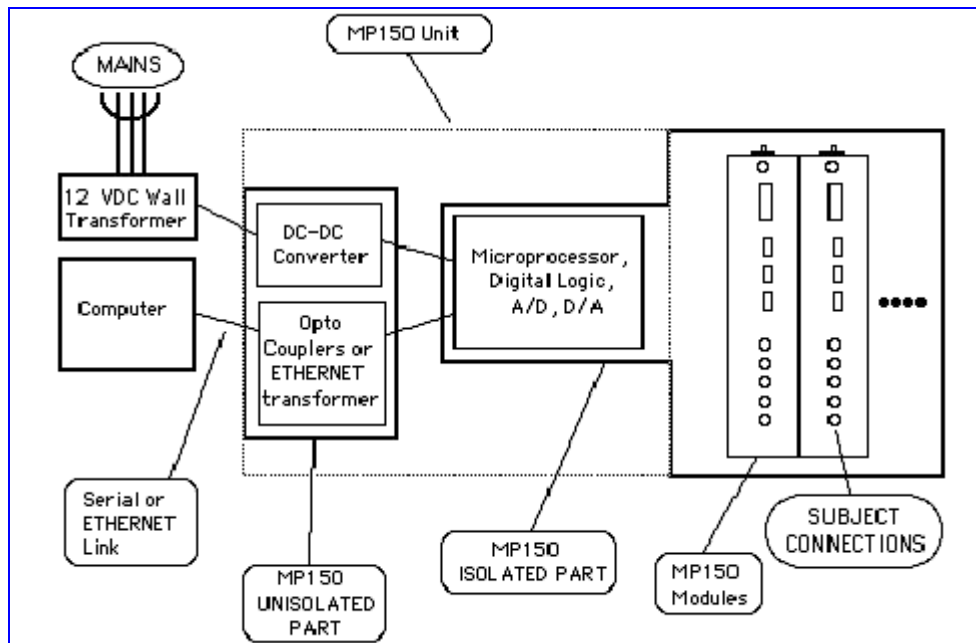
### **WHEN MEASURING FROM SUBJECTS, DO NOT HAVE ANY OTHER LABORATORY EQUIPMENT CONNECTED TO THE MP150 ANALOG OR DIGITAL INPUT PORTS.**

The MP150 System Analog/Digital ports (and UIM100) are part of the subject isolation circuit and thus can become accessible metal parts that may be incidentally grounded which would defeat the isolation provided by the internal DC to DC converter, optocouplers, and Ethernet transformer.

When connecting the MP150 system, via Conditioning Modules, to a subject, safety concerns often dictate the removal of all connections from mains powered or earthed equipment from the UIM100 module or other Conditioning Module.

If connections to other mains powered or earthed equipment are required while recording from subjects using the MP150 system, then those connections should be made via the INISO or OUTISO signal isolators, used in conjunction with the HLT100 module.

**Figure 1. MP150 System Isolation Construction**



### MP150 System Isolation Construction Notes (see Figure 1):

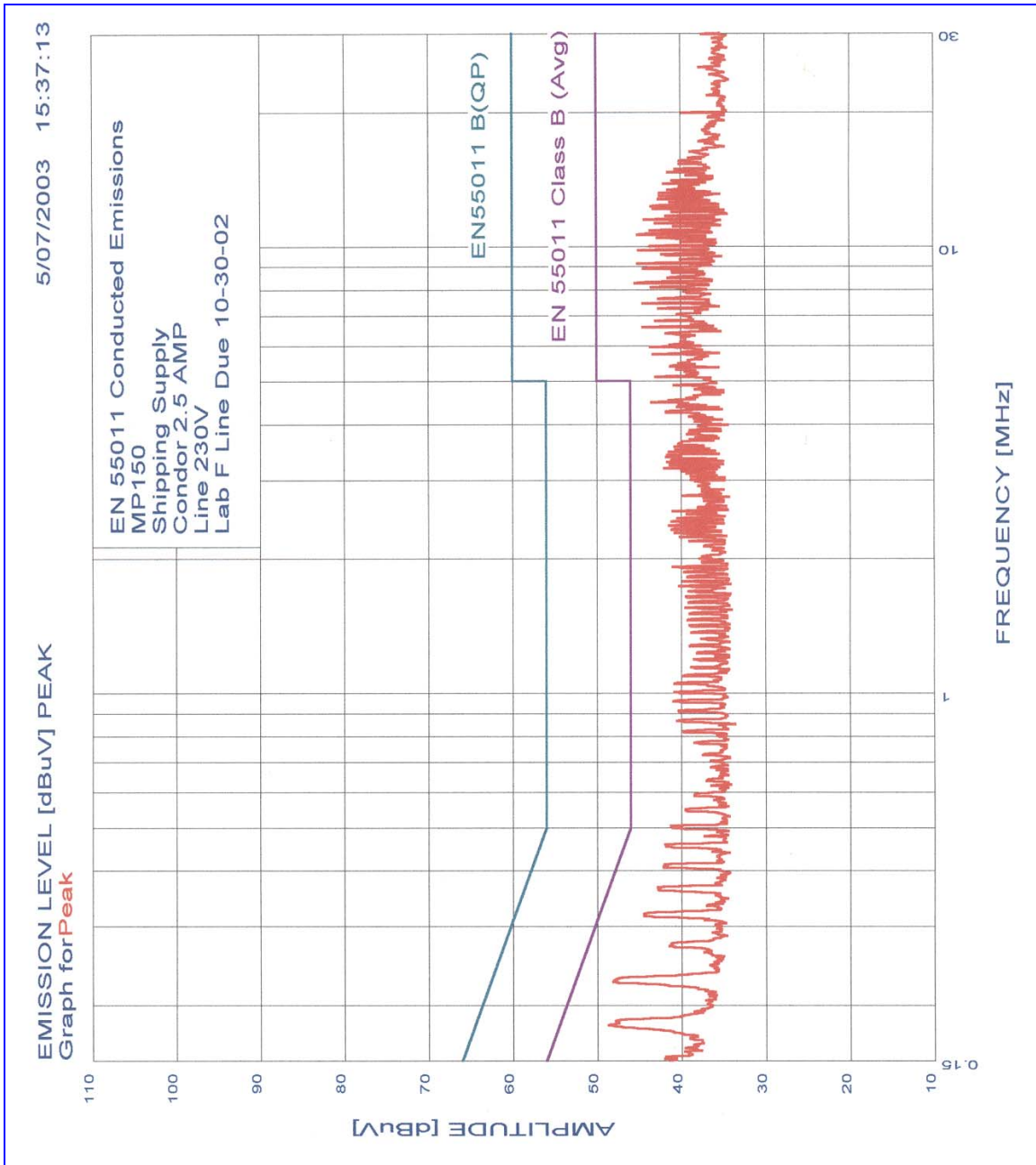
1. The SELV (TUV, CSA, UL) 12 VDC wall transformer adapter powers the DC-DC converters and the Unisolated Part of the optocoupler digital communications circuitry and Ethernet transformer. The DC-DC converter output powers the MP150 Isolated Part – including the MP150 Conditioning Modules, where Subject Connections are made.
2. The Computer Serial (ETHERNET or USB) Link ground is connected to the MP150 Unisolated ground, which is connected to Mains Earth. Mains Earth is connected to the MP150 Unisolated ground via the 12 VDC wall transformer to provide an Earth connection (for Leakage Current Safety) when the MP150 is connected to either portable or non-portable computers.
3. The MP150 Unisolated Part and Isolated Part are linked by a high isolation DC-DC converter, two optocouplers, and one Ethernet transformer. All MP150 (Conditioning) Modules connect to the MP150 Isolated Part. The MP150 Isolated Part appears as an 1800pF capacitor to Mains Earth.



## Electromagnetic Compatibility Test Results

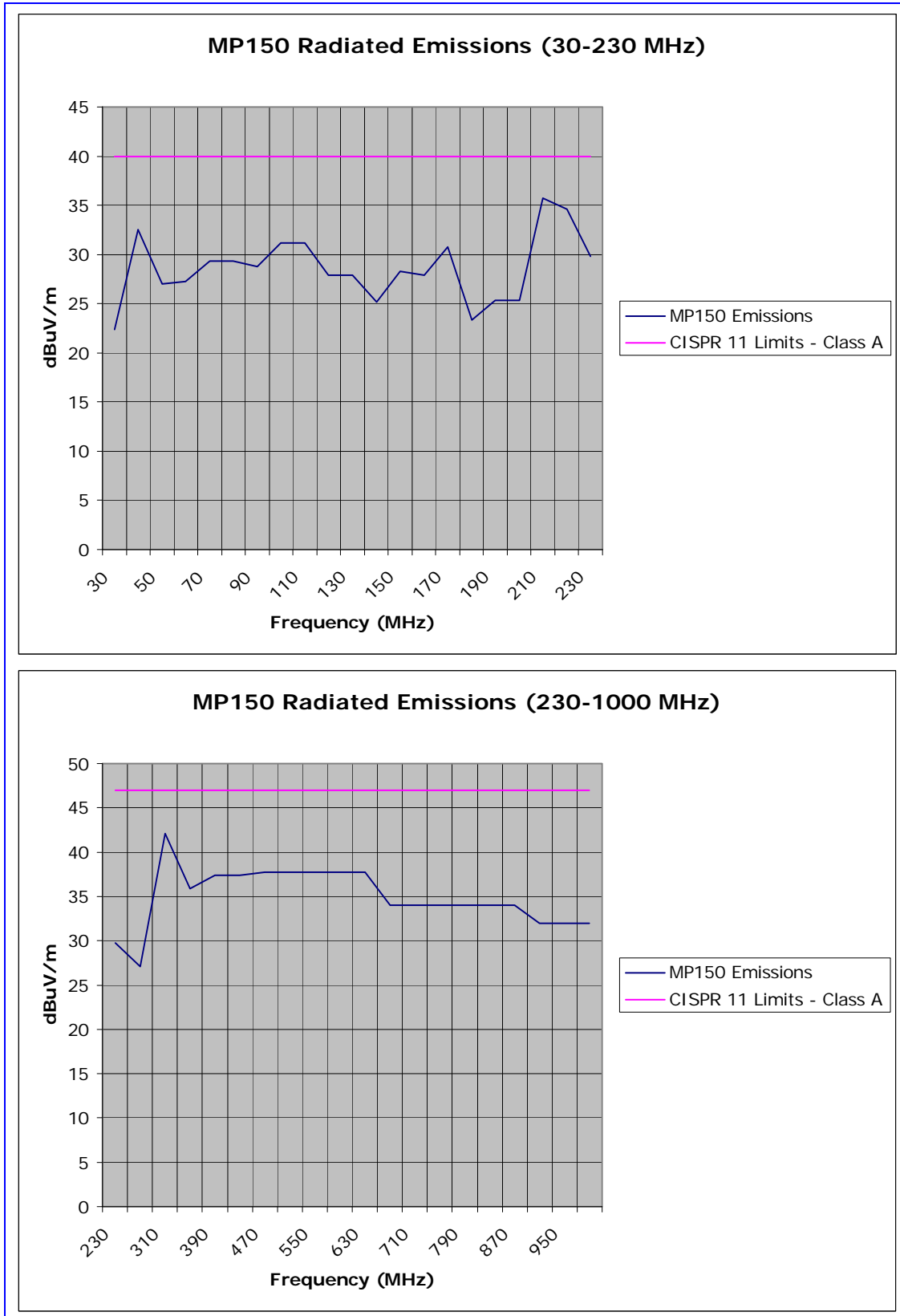
The following graph (Figure 2) illustrates the performance of the MP150 System for Conducted Emissions. The Limit lines indicate the not-to-exceed emission levels associated with EN55011 Class A and Class B.

Figure 2. MP150 Conducted Emissions



The following graphs (Figure 3) illustrate the performance of the MP150 System for Radiated Emissions. The Limit lines indicate the not-to-exceed emission levels associated with EN55011 Class A.

**Figure 3. MP150 Radiated Emissions**



## Factory Testing Procedures for Medical Safety

### Dielectric Testing

The equipment at the conclusion of manufacture, before shipment, shall withstand for one second, without breakdown, the application of 2000 VDC between Live parts and Signal Input/Output parts. The same test is performed between Signal Input/Output parts and Floating Applied parts. The factory test is made at existing room temperature.

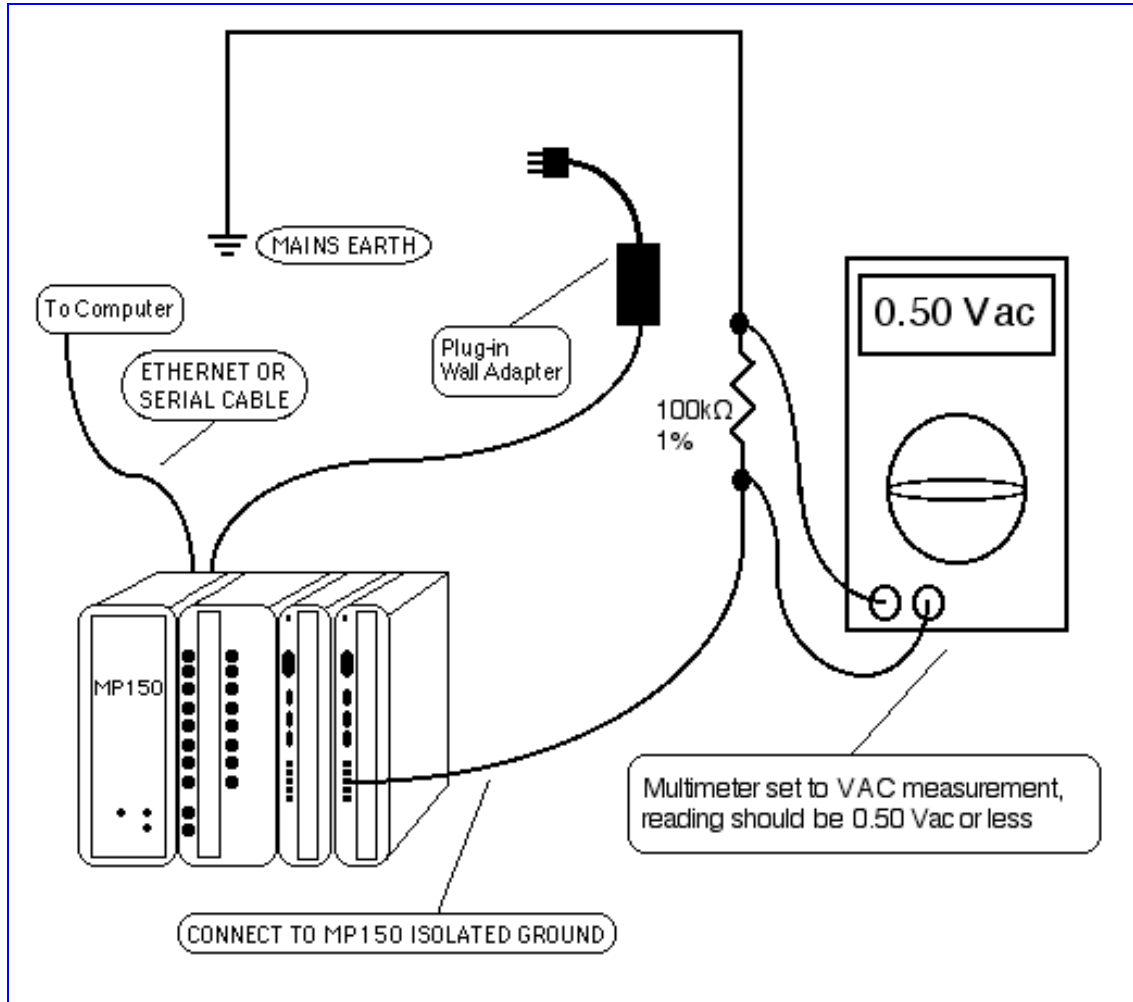
### Leakage Current Testing

- 1) The equipment at the conclusion of manufacture, before shipment, shall permit a leakage current of no more than  $8\mu\text{A}$  from the Floating Applied (Subject Connected) parts to Earth, during normal system operation. The factory test may be made at existing room temperature. The test procedure is illustrated in Figure 4.
- 2) The equipment at the conclusion of manufacture, before shipment, shall permit a leakage current of no more than  $100\mu\text{A}$ , resulting from the application of 120 VAC between Floating Applied (Subject Connected) parts and Signal Input/Output parts. Note that Signal Input/Output parts ground is connected to Mains Earth. The factory test may be made at existing room temperature. The test procedure is illustrated in Figure 5.

### **WARNING**

The factory test(s) specified may present a hazard of injury to personnel and/or property and should only be performed by persons knowledgeable of such hazards and under conditions designed to minimize the possibility of injury.

**Figure 4. Leakage Current Testing of MP150 System**  
– Floating Applied Part to Mains Earth –

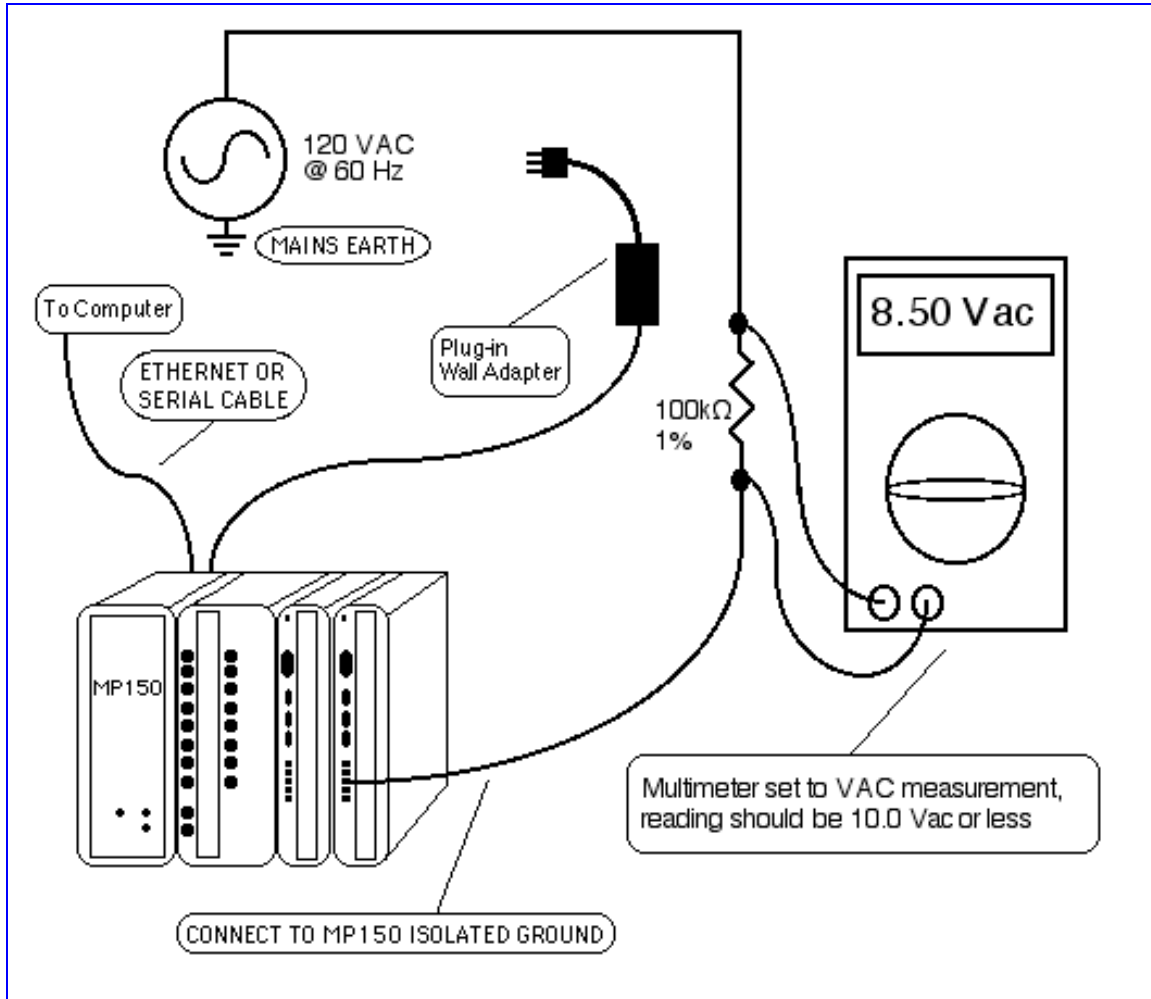


**Testing Notes:**

When testing for Leakage Currents the MP150 should be connected to the computer via the Ethernet or Serial (USB) Cable. Also, the wall transformer adapter must be connected to Mains power and the MP150 unit. Leakage current test should be performed at intervals coincident with general calibration procedures.

The MP150 Leakage Current (Floating Applied Part to Mains Earth) passes through the 100k Ohm resistor. The multimeter measures the voltage developed across the 100k Ohm resistor. Accordingly, the maximum measured voltage should be 0.80 VAC, which indicates a maximum leakage current of 8µA.

**Figure 5. Leakage Current Testing of MP150 System  
– Floating Applied Part to Mains Line –**



**Testing Notes:**

When testing for Leakage Currents the MP150 should be connected to the computer via the Ethernet or Serial (USB) Cable. Also, the wall transformer adapter must be connected to Mains power and the MP150 unit. Leakage current test should be performed at intervals coincident with general calibration procedures.

The MP150 Leakage Current (Floating Applied Part to Mains Line) passes through the 100k Ohm resistor. The multimeter measures the voltage developed across the 100k Ohm resistor. Accordingly, the maximum measured voltage should be 10.0 VAC, which indicates a maximum leakage current of 100 $\mu$ A.

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Contact BIOPAC Systems, Inc. if you need

- **MP150 Schematic**
- **MP150 PWB Layout**
- **MP150 Product Catalog**