Endophys® BPM Model 651

Patient Blood Pressure Monitor

Operator's Manual

Endophys Inc.
494 Wilemon Road Maypearl,
TX 76064
www.endophys.com

NOTE

Due to continuing product innovation, specifications in this manual are subject to change without notice. Endophys Inc. shall not be liable for technical or editorial omissions made herein, nor for incidental or consequential damages resulting from the furnishing, performance, or use of this guide.

The information in this manual supports software versions **40-0018 Vers. 1.00** or later.

This manual is an integral part of the product and describes its intended use. It should always be kept close to the equipment. Observance of the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

Information that refers only to certain versions of the product is accompanied by the model number(s) of the product(s) concerned. The model number is given on the nameplate of the product or on labeling for disposable products.

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers**.** Endophys is responsible for the effects on safety, reliability, and performance of the product, only if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by Endophys;
- the electrical installation of the relevant room complies with the requirements of the appropriate regulations; and,
- the device is used in accordance with this Operator's Manual.

Contents

1. Introduction

CAUTION:
Federal (U.S.) law restricts this device to sale by or on the order of a physician.

1.1 Overview

The Endophys Blood Pressure Monitor (BPM) is an electronic and optical instrument designed to provide continuous patient blood pressure data when used in conjunction with the Endophys Pressure Sensing Sheath (PSS). The BPM produces an optical signal which passes through a fiberoptic channel in the PSS to a miniature high-precision sensor located at the tip of the PSS within the patient's vessel. The BPM measures and provides a read-out of blood pressure data based on the optical signal returned from the PSS sensor.

When used together, the Endophys Blood Pressure Monitoring System is designed to provide continuous and accurate systolic, diastolic and mean blood pressure data with no other arterial catheter, pressure transducer or fluid line required.

1.2 Equipment Information

- **Intended Use:** The Endophys Blood Pressure Monitor is intended to continuously provide systolic, diastolic, and mean blood pressure based on the output of the Endophys Pressure Sensing Sheath in patients undergoing therapeutic and/or diagnostic procedures involving percutaneous vascular access.

- **Contraindications:** There are no known contraindications for the use of this device.

- **Safety Statements:** The safety-related statements (Warnings and Cautions) presented in this section refer to the equipment in general and, in most cases, apply to aspects of the BPM monitor. The order in which safety-related statements are presented in no way implies order of importance.

Warnings

Warning statements identify a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

The following warning statements apply to this monitoring system:

WARNING

FLAMMABLE ANESTHETICS — An explosion hazard exists if the monitor is used in the presence of flammable anesthetics. Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

WARNING

ACCIDENTAL SPILLS — To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered a device, take it out of service and contact Endophys before it is used again.

WARNING

ACCURACY — If the accuracy of any value viewed on the monitor is questionable, determine the patient's vital signs by alternative means.

WARNING

ALARMS — Do not rely exclusively on the audible alarm system for patient monitoring. Muting of alarm tone during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment.

WARNING

BEFORE USE — Before putting the system into operation visually inspect all connecting cables for signs of damage. Damaged cables must be replaced immediately.

WARNING

CABLES — Route all cables away from patient's throat to avoid possible strangulation. Also route all cables safely away from floor areas to avoid risk of tripping/stumbling on them and away from the sterile/operative field.

WARNING

DISCONNECTION FROM MAINS — When disconnecting the system from the power line, remove the power plug from the wall outlet first. Then you may disconnect the power cord from the device. If you do not observe this sequence, there is a risk of coming into contact with line voltage by inserting metal objects, such as the pins of lead wires, into the sockets of the power cord by mistake.

WARNING

INTERFACING OTHER EQUIPMENT — The BPM has only been verified to be compatible with the General Electric Dash 3000 and Philips Health Care Systems model M1204A patient monitors.

WARNING

LEAKAGE CURRENT TEST — When interfacing with other equipment, a test for leakage current must be performed by qualified personnel before using with patients.

WARNING

POWER ADAPTER — The BPM power adapter must be connected to a properly installed power outlet with protective earth (ground) contacts only. If the installation does not provide for a protective earth (ground) conductor, disconnect the BPM until an appropriate power outlet can be found.

Precautions

Precaution or Caution statements identify a potential hazard or unsafe practice which, if not avoided, could result in minor or moderate personal injury or product/property damage.

The following caution statements apply to the Endophys Blood Pressure Monitor (BPM) system:

CAUTION

Familiarize yourself thoroughly with the operational procedures of the device prior to use.

CAUTION

INSTRUCTIONS FOR USE — For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

CAUTION

STABLE LOCATION — The BPM must be placed in a stable location that is within reach of the Pressure Sensing Sheath (PSS) optic cable that will be inserted into the patient. It is best to stabilize the BPM during use on an IV pole or procedure-bed railing. Attach the pole-mount adapter and IV pole clamp to the back of the BPM unit.

CAUTION

TRANSPORT — This system is not designed for use during patient transport.

CAUTION

DISPOSABLE PATIENT DEVICE REQUIRED — The BPM is designed to operate with the Endophys Pressure Sensing Sheath disposable device. To

ensure patient safety, use only with devices manufactured or recommended by **Endophys**.

CAUTION

DISPOSAL — At the end of its service life, the Endophys BPM, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, please contact **Endophys** or its authorized representatives.

CAUTION

ELECTROMAGNETIC INTEREFERENCE — Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the BPM monitor comply with the relevant Electromagnetic Compatibility requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

CAUTION

POWER REQUIREMENTS — Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are within the limits indicated in this manual and on the label of the supplied AC adapter unit. If this is not the case, do not connect the system to the power line until an appropriate power source is available.

CAUTION

The Endophys BPM is intended for indoor use only.

CAUTION

The device and its accessories are not intended to be sterilized by any method. Attempting to do so may permanently damage the equipment.

CAUTION

OPTICAL CABLE INTEGRITY — Check that the optical cable leading from the hub of the Pressure Sensing Sheath is not kinked or damaged. This can result in inaccurate readings. Further, confirm the presence of the green RFID tag on the connector of the PSS that plugs into the BPM.

CAUTION

In case of malfunction, discontinue the use of the device and call Endophys Support Services at (972) 435-1984.

CAUTION

Do not open the BPM instrument case or attempt to make any modifications to the device. Any modifications made will void the warranty and possibly create a risk to the patient or user.

CAUTION

Do not use the device if it has failed its diagnostic self-test or pressure data is displayed with no sensor attached.

CAUTION

Prevent water or other fluids from entering any connectors or vents on the device. Should this happen, all connectors should be dried. Then, verify appropriate operating functions and absence of instrument alarms before use.

CAUTION

Endophys does not assume responsibility for damage to the equipment caused by improper or faulty power, improper mounting or excessive exposure to blood, water or other liquids. Use only the original power adapter and connecting power cord.

CAUTION

DISPOSAL — Dispose of packaging material and used devices appropriately, observing the applicable waste control and safety regulations.

Notes

Note statements provide application tips or other useful information.

The following note statements apply to this monitoring system:

- **The BPM must be turned on and connected to the patient disposable Pressure Sensing Sheath (PSS) <u>BEFORE</u> the PSS is inserted into the patient.**

- Place the BPM in a dry, stable location near the sterile field where you can easily see the screen and access the operating controls.

1.3 Compliance Information

The BPM has been verified to be in compliance with the following standards:

- IEC 60601-1 3rd Edition
- IEC 60601-1-2:2007
- IEC 60601-1-8:2012
- IEC 60601-2-34:2011
- IEC 62366:2011 (Direct Blood Pressure Monitoring)
- ANSI/AAMI BP22:1994/(R) 2011
- ASTM D4169-09: 2009Distribution Simulation
- ISTA 2A: 2012 Environmental Conditioning

Underwriters Laboratories, Inc. Classification Medical Equipment with respect to electric shock, fire and mechanical hazards only in accordance with IEC 60601 standards.

1.4 Radio and Telecommunications Information

The Endophys Model 651 Blood Pressure Monitor contains a radio-frequency (RF) transmitter. Users should be aware of known RF sources, such as radio or TV stations and handheld or mobile two-way radios, and consider them when using or installing a medical device or system.

FCC Compliance Information

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at his own expense.

Subject to Part 15 of the FCC Rules, operation of this device is subject to the following conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

EMI Environment Recommendations

Review the AAMI EMC Committee technical information report (TIR-18) titles Guidance of electromagnetic compatibility of medical devices for clinical/biomedical engineers – Part 1: Radiated radio-frequency electromagnetic energy. This TIR provides a means to evaluate and manage the EMI environment in the hospital. The following actions can be taken:

- Managing (increasing) distance between source of EMI and susceptible devices.
- Managing (removing) devices that are highly susceptible to EMI.
- Lower power from internal EMI sources under hospital control (such as paging systems).
- Labeling devices susceptible to EMI.
- Educating staff (nurses and doctors) to be aware of, and to recognize, potential EMI related problems.

WARNING: Changes/Modifications to the System

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

2. Operator's Manual Information

Purpose

This manual contains instructions necessary to operate the Endophys BPM Model 651 safely and in accordance with its functions and intended use.

Intended Audience

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology, as required for monitoring patients.

This manual must be used in conjunction with the Instructions for Use for the Endophys Pressure Sensing Sheath (PSS), which is to be used during the patient procedure.

3. BPM Overview

3.1 Instrument Tour

Fig 3.1.a Left side

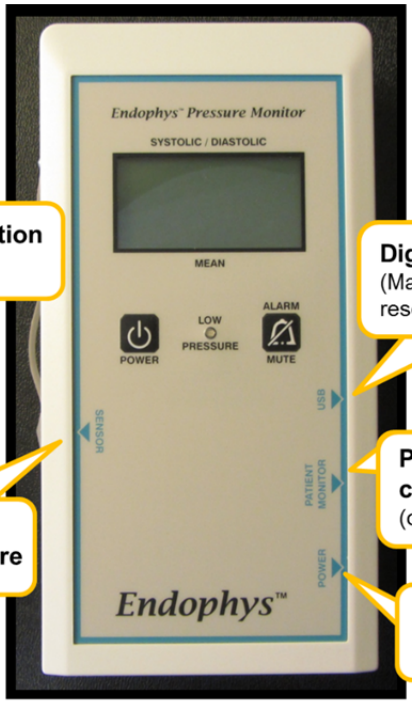


Fig 3.1.b Front view

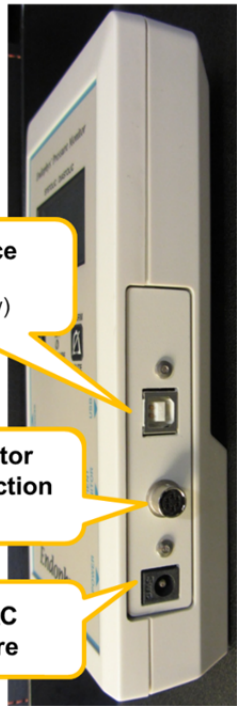


Fig 3.1.c Right side

Fig 3.1.d Left Side

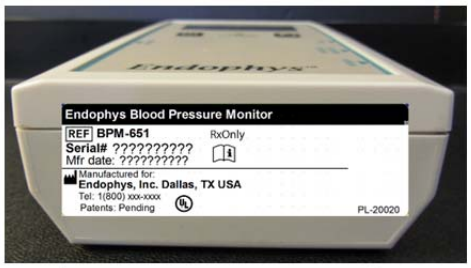


Fig 3.1.e Bottom view

Fig 3.1.f Rear view

3.2 Indicators

The BPM front panel provides visual indicators as illustrated below. The **LCD** displays the patient systolic, diastolic and mean blood pressure. The LCD also displays operator messages inlcuding a **Data Alert Icon** and an **Alarm Mute Indicator**. A **red LED** visually alerts the operator if patient mean blood pressure falls below 60mm Hg, as shown in Fig 3.2.

NOTE: The value of the Low Pressure Alert (60mm Hg) is not user-adjustable.

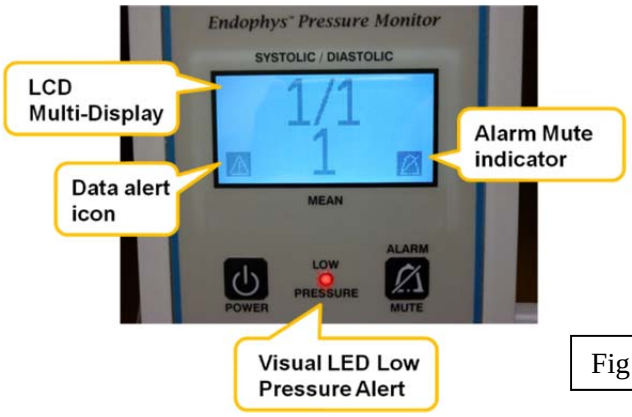


Fig 3.2

The Low Pressure red indicator accompanies some audible alerts, illuminating when the system has been “zeroed” but the PSS has not been inserted into the patient, when the BPM has been muted, or when the system has failed.

3.3 User interface overview

The BPM user interface consists of an LCD display, Low Pressure red indicator, and buttons (Power On/Off and Alarm Mute switch), as illustrated in Fig 3.3. The LCD display provides pressure measurements (systolic/diastolic and mean) and displays alerts.

The Power On/Off Button toggles the LCD Display ON or OFF and the Alarm Mute Switch mutes the audible alarm with a single depression. After muting the audible alarm, the alarm can be restored by pressing the same button a second time.

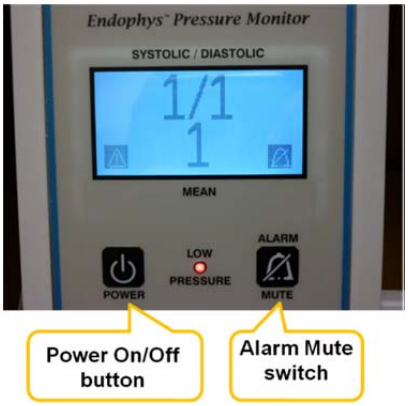


Fig 3.3

3.4 Operating modes

The Endophys BPM system may be operated in the following modes and configurations:

1) Simple digital pressure read-out on the BPM LCD

The simplest way to use the Endophys PSS/BPM system requires only the following connections:

- The Endophys Pressure Sensing Sheath (PSS)
- The Endophys Blood Pressure Monitor (BPM) connected to its inline AC power adapter, connected to wall (AC) power.
- A connection between the PSS and BPM.

This mode will provide continuous blood pressure read-out on the LCD screen of the BPM, including systolic, diastolic, and mean blood pressure.

2) Connection to multi-function patient monitor display

If desired, the patient pressure information can also be displayed on a multi-function display/ patient monitor. In addition to the set-up discribed above (1), the following is required:

- Supported patient monitor (GE Dash 3000 or Philips Health Care Systems model M1204A)
- A cable approved by Endophys (PMIO cable) to connect the BPM to the supported patient monitor unit.

3.5 System Specifications

General performance specifications

Category	Specification
Product name	Endophys Blood Pressure Monitor, Model 651
Product type	Electro-optical blood pressure monitor
Mechanical	
Product weightas shipped	3.6lbs
Product dimensions: H x W x D	7.7” x 4” x 2.3” (195mm x 101mm x 58mm)
Display size	2.2” x 1.1” (56mm x 28mm)
Mounting/stability in use	Includes mounting for IV or other pole location
Environmental	
Type of electrical protection	Class II
Degree of electrical protection	Liquids must not be allowed to enter the device
Disinfecting method	Superficial cleaning with common surface

	disinfectants. DO NOT STERILIZE
Anesthetic safety	NOT suitable for use in the presence of flammable anesthetic agents
EMC/EMI, RFID Standards	IEC 60601-1-2; FCC part 15
Patient Monitor Compatibility	• General Electric Dash 3000 o Use Endophys PMI-1010 connector cable • Philips Health Care Systems model M1204A o Use Endophys PMI-1020 connector cable
Operating Conditions	
Operating temperature range	15ºC (59º F) to 35ºC (95º F)
Operating altitude range	0 to 10,000 feet MSL (3,048m)
Operating humidity	5% to 95% relative humidity, non-condensing
Operating ambient pressure range	500-800mm Hg
Supply current at 12V	At start-up: Max 2600mA (4A fast-blow fuse) Typical operating: <290mA
Storage conditions	-40º C (-40º F) to +65º C (149º F)
Performance	
Required patient disposable	Endophys Pressure Sensing Sheath (PSS)
Warm-up time	Up to 5min after plug-in or up to10sec after power-on, if already plugged in
System pressure accuracy	±2mm Hg or ±5% of reading, whichever is greater
Data acquisition rate	1000 measurements/second
Operating pressure range	Pressures measured and displayed between 0mm Hg and 300mm Hg
Audible alarms - low pressure	Low BP <60mm Hg mean pressure
Effect of fiber bend (>4mm/0.16” radius)	< ±0.5mm Hg
Instrument temp coefficient	< ±0.1mm Hg/ºC

System specifications per ANSI/AAMI BP-22:

Category: **ANSI/AAMI BP-22: 1994/ (R) 2011 Transducer requirements (a) through (r):**	**Specification:** **Endophys BPM/System Compliance**
a) the excitation voltage (or voltage range)	0 to 8 Vrms
b) the excitation frequency (or frequency range)	0 to 5kHz
c) the excitation impedance or component characteristics for the excitation voltage and frequency specified in (a) and (b)	350Ω
d) the transducer signal impedance, with a specified tolerance	350Ω ±5%
e) the maximum phase shift or phase characteristic over the excitation frequency range specified in (b), where applicable	5°
f) the nominal transducer sensitivity for the ideal transducer output	5uV/V/mmHg
m) the names and addresses of acceptable customer service facilities	See Endophys contact information in this Operator's Manual.
n) the magnitude of half-sine shock acceleration that the transducer can be subjected to on each axis and still meet the requirements of section 4.2, given that the unbalance limits of 4.2.3.7 may increase to 150 mmHg	>100g
o) the maximum deviation from the initial transducer zero at 25 ± 1°C over 4 hours in mmHg after the recommended warm-up time	±2mm Hg
p) the error band of zero shift in mmHg for a temperature change of 25°C to 15°C and 25°C to 40°C in mmHg after the recommended warm-up time	Error band 25°C to 15°C: ± 2mm Hg Error band 25°C to 35°C*: ± 2mm Hg
q) the error band of sensitivity from 25°C to 15°C and from 25°C to 40°C expressed as a percentage change from 25°C	Error band 25°C to 15°C: ± 3% Error band 25°C to 35°C*: ± 5%
r) the light sensitivity of the transducer at 3,000 foot-candles from a 3,400° Kelvin (K) tungsten light source at zero pressure in mmHg. The maximum error should be stated over the stated excitation voltage range.	±2mm Hg over 0 to 8 Vrms

*Note: Maximum operating temperature range for the BPM is 35°C. Performance above this range has not been evaluated.

4. BPM Set-up

4.1 Initial receipt, uppacking and set-up of the BPM.

Please refer to Section 10 of this Manual for instructions on initial unpacking and set-up of the BPM.

4.2 Physical location

The BPM must be placed in a stable location that is within reach of the Pressure Sensing Sheath (PSS) optical cable that will be inserted into the patient. Review the Instructions for Use of the PSS for the specific length of this cable.

It is best to secure the BPM during use to an IV pole or procedure-bed railing. Attach the pole-mount adapter and IV pole clamp to the back of the BPM unit. The BPM can then be firmly clamped onto the rail, pole or other appropriate mounting location.

4.3 Power adapter

The BPM requires connection to the AC power adapter to operate. If the BPM is not already plugged into wall power, first plug the AC adapter into the receptacle on the right side of the BPM unit. The AC adapter may then be plugged into the wall socket.

4.4 Connection to multi-function monitor/display units.

If desired, the BPM may be connected to a supported multi-function monitor or display unit. This must be done during the Start-up procedure (See Section 5.1, below) **PRIOR TO CONNECTION OF THE PSS TO THE BPM**.

- Use the patient monitor interface cable supplied by Endophys to attach to the "**Patient Monitor**" receptacle on the right side of the BPM unit. The other end of the cable is used to connect to the patient monitor/display unit.

5. BPM Start-up

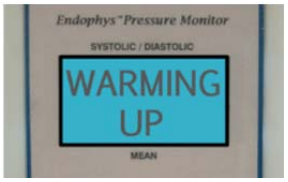
5.1 Start-up procedure when using a patient monitor/display.

When the BPM data will be displayed on a patient monitor/display unit, the monitor muct be zeroed with the signal originating from the BPM PRIOR to connecting the PSS to the BPM. To do so, perform the following checks upon connection of the BPM to the patient monitor:

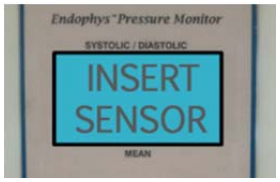
1. With the BPM connected to power, but turned OFF, the patient monitor should be zeroed (adjusted) to read "0mmHg", following the pressure-zerioing or initialization instructions of the monitor unit manufacturer.
2. By pressing the **Alarm Mute** button of the BPM, the patient monitor response can be verified to read "100mmHg".
3. Repeated toggling of the Alarm Mute botton of the BPM will toggle the pressure signal sent by the BPM to the patient monitor between "0" and "100".

The patient monitor unit must be zeroed again after the PSS is connected and zeroed (See Section 5.4, below).

5.2 Turn BPM power on



If not already done, connect the AC power adapter to the BPM **"Power"** receptacle on the right side of the instrument. The system requires up to 5 minutes to warm up. Press the **"Power"** switch to turn the BPM on.



When the warm-up process is complete, BPM displays "**Insert Sensor**".

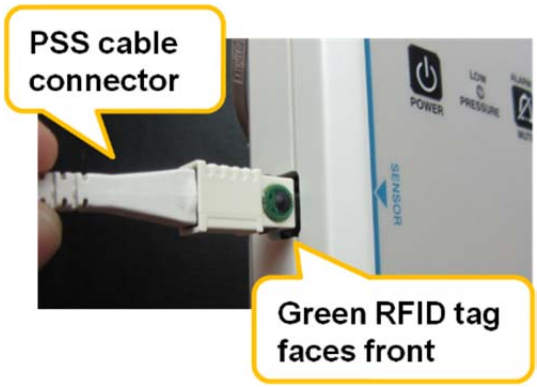
5.3 Connection to the Pressure Sensing Sheath

NOTE: The BPM must be turned on and connected to the Pressure Sensing Sheath (PSS) BEFORE the PSS is inserted into the patient.

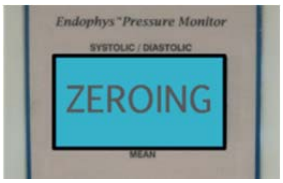
5.3.1 Place the PSS in the sterile field and pass the optical connection cable to the non-sterile area for connection to the BPM per the PSS Instructions for Use.

5.3.2 Detach the BPM Sensor Connection Protector and connect the PSS optical cable to the **"Sensor"** port of the BPM to initiate the Zeroing process, which allows the BMP to display the blood pressure reading relative to the atmosphere in the room.

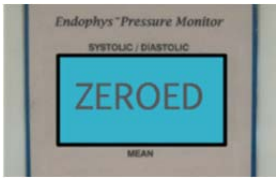
NOTE: The PSS cable connector is keyed (will fit in one direction only). In order to ensure proper insertion, be sure that the green RFID tag mounted on the surface of the PSS cable connector is facing the front panel of the BPM (facing the operator).



5.3.3 BPM self-zeroes to PSS

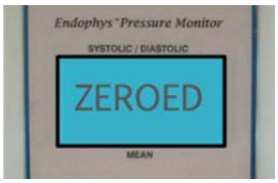


Once connected to the PSS, the BPM will automatically Zero the system to the current ambient pressure conditions. This process takes only a few seconds.



When properly set-up and Zeroed, the BPM displays "**ZEROED**".

5.4 Re-zero patient monitor



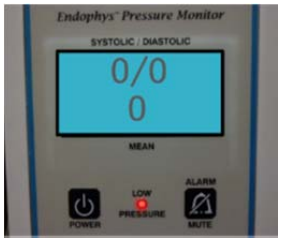
After the BPM/PSS system is zeroed (**"ZEROED"** message on LCD display of the BPM) - and PRIOR to insertion of the PSS into the patient, follow the pressure-zeroing or initialization instructions of the monitor unit manufacturer.

5.5 Insert the PSS into the patient

Insertion of the PSS into the patient may proceed at this point.

6. Monitoring mode

6.1 BPM status prior to PSS insertion



Seconds after the "ZEROED" notification, the system begins measuring and displaying actual pressures. If the PSS has not been inserted into the patient, relative ambient pressure (usually the zeroed value, "0") is displayed, and this triggers both the "Low Pressure" red LED visual alert and the audible alarm. This condition will remain until the PSS is inserted into the patient.

The **Alarm Mute** switch can be pressed to silence the audible alarm until patient insertion is performed. All alarms will be re-enabled when the BPM detects mean pressure above 60.

6.2 Standard monitoring mode

Seconds after patient insertion of the PSS, the system will begin displaying systolic, diastolic and mean blood pressure, updated every 4 seconds. The “Low Pressure” LED and audible alarm indicators will be turned off when the system detects the patient’s BP.

6.3 Patient monitor/display status

The BPM LCD will continue to display the digital pressure data while connected to a patient monitor. The patient monitor will display pressure based on the PSS data, using the chosen parameters of the patient monitor manufacturer. Due to algorithm differences, pressure data displayed by the patient monitor may differ from that displayed by the BPM by up to 2mm Hg or ±5% of reading, whichever is greater.

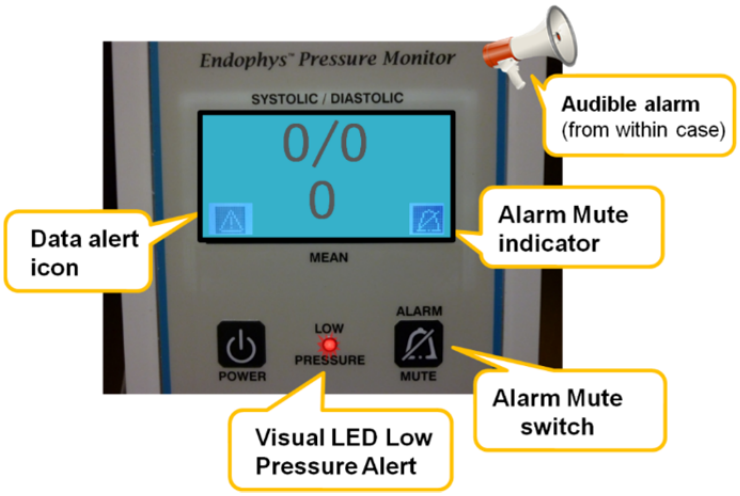
6.4 Disconnecting the system

When there is no further clinical need for blood pressure monitoring, the PSS optical cable connector can be detached from the BPM. Check the Sensor Connection Protector for contamination, clean as necessary, then use it to cover the Sensor port on the left side of the BPM. The BPM may be switched off and returned to a holding or storage position.

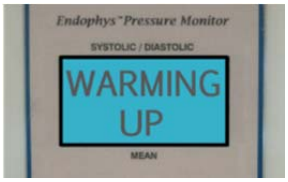
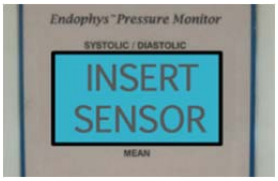
Follow the Instructions for Use of the PSS patient device for removal of the PSS from the patient.

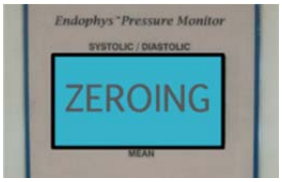
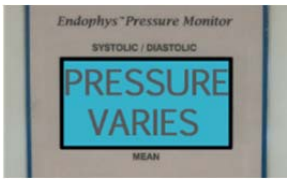
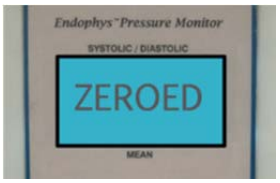
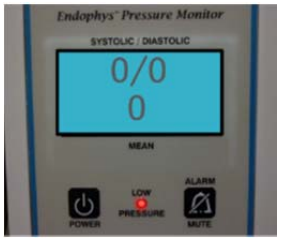
7. BPM Display Messages, Alarms & Alerts

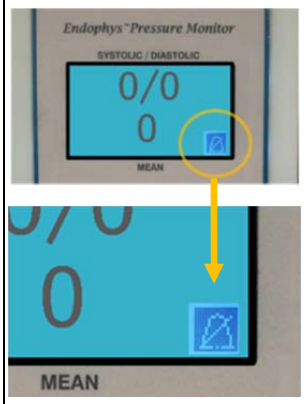
The BPM is designed to alert clinicians to its operating status to guide the set-up process - and also to indicate an alert or alarm status for specific operating conditions that may be important indicators of patient or device safety.



7.1 Table of Display Messages, Alarms & Alerts

BPM Display	Audible alarm*	LED "Low Pressure"	LCD Data-Alert icon	> What it means >> What to do
	High tone Alarm*	**ON**	Off	> The BPM system has failed a self-check during start-up. >> See Troubleshooting 8.1.
	None	Off	May be on temporarily	> The BPM is warming up. >> BPM should be ready in 5min or less.
	Medium tone Alarm*	Off	Off	> BPM warm-up is complete, and ready for connection to the PSS sensor. **NOTE:** Initial attachment of PSS must be **BEFORE** PSS is inserted into the patient. >> When the sensor cable is passed out of the sterile field, connect the PSS cable connector to the BPM.
	Medium tone Alarm*	Off	Off	> An error has occurred in the recognition of the PSS sensor or in the pressure zeroing process. >> See Troubleshooting 8.2.

BPM Display	Audible alarm*	LED "Low Pressure"	LCD Data alert icon	**> What it means** **>> What to do**
	None	Off	Off	> The BPM has recognized the PSS sensor, and is in the process of zeroing the system to ambient pressure. >> System should be ready in less than 10 seconds.
	Medium tone Alarm*	Off	Off	> BPM is detecting a fluctuating pressure from the PSS during the Zeroing process. **NOTE:** A stable (ambient) pressure is needed for zeroing the system prior to monitoring. >> See Troubleshooting 8.3.
	None	Off	Off	> The BPM monitor/PSS sensor system has been successfully zeroed. >> The system is ready for the PSS sheath to be inserted into the patient.
	High tone Alarm*	**ON**	Off	> The BPM monitor/PSS sensor system is reading ("0") pressure outside the patient. The system is alerting you that it is ready. >> The Alarm Mute button can be pressed to mute the audible alarm while the system awaits insertion. >> When appropriate, insert the PSS sheath into the patient. The alarm/alert conditions will be reset as the system detects the patients actual BP. >> See Troubleshooting 8.4.
	Medium tone Alarm*- approx 8 sec	Off	**ON**	> BPM has been re-connected to a PSS sensor which had been zeroed and then subsequently became disconnected. > Monitoring values will be accurate, using the previous zero value. See Troubleshooting 8.5.

BPM Display	Audible alarm*	LED "Low Pressure"	LCD Data alert icon	> What it means >> What to do
	Alarm **MUTED**	**ON**	Off	> The Alarm Mute button has been activated. > This silences the current alarm condition only. A subsequent alarm condition occurence will remove the "Mute" icon and produce an audible alarm.
	None	Off	**ON**	> An event or condition has occurred which has produced potentially inconsistent or questionable data within the current data on display. >> Be aware that currently displayed pressure data may be inaccurate - and should be verified via an independent source of patient blood pressure. >> This Data Alert Icon will be removed from the display if the data returns to a more stable, consistent range. >> See Troubleshooting 8.6.

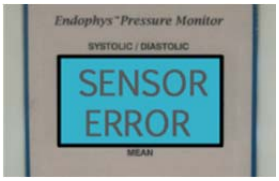
* **CAUTION**
The Audible Alarm may be muted by the user, possibly reducing the ability of the BPM to alert the user of a low pressure condition or of a device malfunction.

7.2 Silencing alarms

- To continue monitoring patient pressure with the audible alarm silenced, depress the **Alarm Mute** button on the front panel.
- To re-activate the audible alarm capability, press the **Alarm Mute** button a second time.

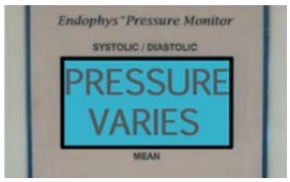
8. Troubleshooting

8.1 The **"Call for Service"** alert on the LCD display indicates that the system has failed an internal system check during initialization.
> You may attempt to resolve this by unplugging the system for 10 seconds, then plug back in and turn power on again. If "Call for Service" reappears, the BPM must be taken out of service. Contact Endophys for repair or replacement.



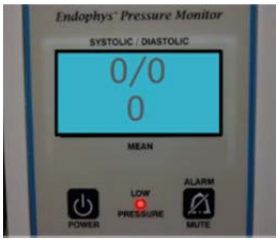
8.2 The **"Sensor Error"** alert on the LCD display indicates that the PSS sensor attached to the BPM has not been properly calibrated or zeroed.

> Detach the PSS sensor from the BPM. Reattached the PSS optical connector to the BPM.If the "Sensor Error" alert appears a second time, the current PSS patient device must be discarded and the patient montioring initialization begun with a new PSS unit.
> Should the "Sensor Error" alert appear with a second PSS unit, the BPM optical connector may be the cause of the error. Remove the current BPM unit from service and follow the initialization and zeroing procedure using a replacement BPM.



8.3 The **"Pressure Varies"** alert on the LCD display indicates that the BPM is not able to zero the sytem properly with the PSS. A stable, constant pressure is needed, whilethe BPM is measuring a varying pressure.

> Check that the PSS sheath assembly is NOT inserted into the patient. Check that the PSS is not moving or being disturbed by movement in the sterile field. The BPM will automatically return to the "Zeroing" display and attempt to zero the system.
> Once the zeroing process has properly completed, the "Zeroed" message will appear.



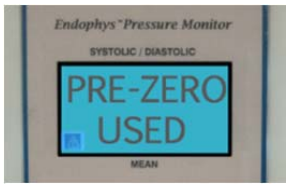
8.4 The "0/0" pressure reading generally indicates that the PSS has not yet been inserted into the patient. The red LED Low Pressure Alert is illuminated and the audible alram is sounding.

>> You may silence the alarm using the Alarm Mute switch.

>> Check that the PSS is not yet inserted in the patient.

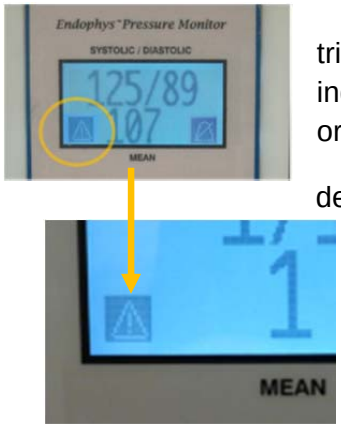
- When appropriate, insert the PSS into the patient.

> If the PSS already is inserted in the patient, check all connections and verify the patient's blood pressure through an independent means.



8.5 The **"PRE-ZERO USED"** alert on the LCD display indicates that the BPM is connected to a PSS that was previously properly zeroed and in service - but the PSS became disconnected or the BPM power was disconnected during monitoring.

> The PSS cannot be re-zeroed, since it is in position within the patient. The ongoing pressure data displayed by the BPM should be accurate - however, since the zero cannot be re-established, the **"Data Alert Icon"** will remain on display on the LCD. Any questionable readings by the BPM/PSS system should be verified using an independent method of blood pressure measurement.



8.6 The presence of the **"Data Alert Icon"** - an alert triangle displayed in the lower left corner of the LCD display - indicates that the pressure data of the BPM may be inconsistent or not completely reliable. Patient movement, PSS sensor deflection, inadvertant disconnection of the PSS from the BPM, or disconnection of the BPM from AC power, very high ambient temperature and other issues may cause spurious data.

> Most of these conditions are temporary and the alert icon will be taken off the LCD display automatically when appropriate.

> If room temperature conditions approach 35º C (95º F) or higher, the BPM system may not be able to measure accurately. If possible, re-establish an ambient temperature below 35º C (95º F).

9. Maintenance

The software maintenance and upgrades process is password-protected is intended be performed by an authorized representative of Endophys.

There are no user-serviceable components of the BPM, so no internal access is required. Opening the case of the BPM unit or making any modifications voids any warranty of the device or its performance. Any maintenance or serviceability issues should be brought to the attention of Endophys at (972) 435-1984.

9.1 Cleaning

Cleaning of the BPM must be done using only water, alcohol and/or mild liquid surface cleaning detergents applied with a damp cloth or equivalent. In all cases, protect the sensor cable connector, preventing any contact with cleaning solutions. The BPM is not intended to be submersed or subjected to excessive

moisture. The PSS connector is not serviceable by the operator. Cleaning could cause damage to the membrane within the adaptor. It should periodically be inspected by the maintenance group for cleanliness and debris. Replacement at this time is only done at the factory.

The BPM is not intended to be sterilized by any means.

9.2 Inspection and Safety tests

Performance properties of the BPM system are internally evaluated every time the device is powered on and connected to a PSS sensor. Performance issues are indicated by the BPM instrument itself in the various alerts and LCD display notifications listed in Section 7.1.

9.3 Disposal

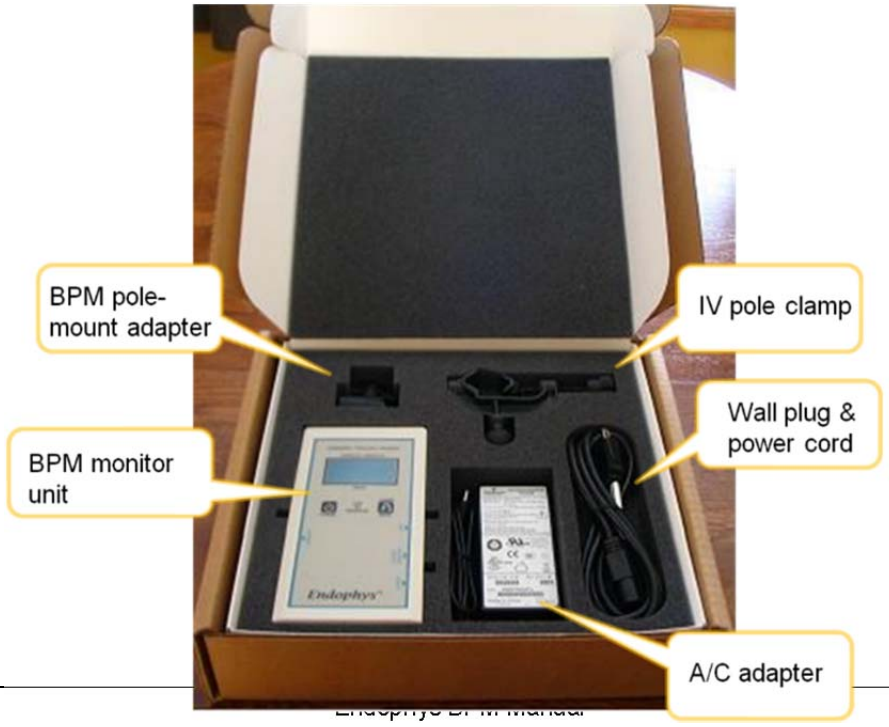
The BPM is composed of electronic components that may represent an environmental hazard if not properly handled during disposal. Please contact Endophys for information and appropriate techniques should disposal become necessary.

10. Initial receipt, unpack and set-up of BPM

All components of the BPM are received in a single shipping carton, as pictured below:

- BPM Monitor Unit
- AC adapter and the power cord with wall plug
- Pole-mount adapter
- IV pole clamp

Verify that all components have been received and are undamaged.



10.1 Set-up steps

10.1.1 Remove the BPM from the protective foam

10.1.2 Firmly attach the pole-mount adapter to the rear of the BPM

10.1.3 Firmly attach the IV pole clamp to the pole-mount adapter

10.1.4 Attach the IV pole clamp to an appropriate IV pole or other pole/rail to be used to hold the BPM.

10.1.5 Insert the power cord into the AC adapter.

10.1.6 Insert the 12V plug of the AC adapter into the BPM using the bottom receptacle on the right side of the BPM, marked “Power”.

WARNING

POWER ADAPTER — The device must be connected to a properly installed power outlet with protective earth (ground) contacts only. If the installation does not provide for a protective earth (ground) conductor, disconnect the monitor until an appropriate power outlet can be found.

1. Connect the wall plug to an appropriate power outlet with protective earth (ground) contact.

NOTE: The BPM may be left plugged in, providing power to allow the BPM to remain in “ready mode”, which provides the ability to connect to a PSS sensor and begin monitoring with no delay. Alternatively, the BPM may be stored without connection to power, requiring a brief (up to 5 minutes) warm-up time period before pressure sensing can commence.

11. Table of Symbols used and definitions

Symbol	Meaning/Definition
REF	Reference or catalog number
RxOnly	Federal (U.S.) law restricts this device to sale by or on the order of a physician.
UL	Registered with UL as conforming to IEC 60601

Manufacturing location

12. DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

Endophys warrants that reasonable care has been used in the design and manufacture of this instrument. Endophys, Inc. makes no other warranties expressed or implied, with regard to the device described in this document. Endophys, Inc. disclaims all representations or warranties, expressed or implied, including, but not limited to, the warranties of merchantability, fitness for a particular use, title or non-infringement, arising by statute or in law, or arising from a course of conduct, course of dealing or usage of trade.

Endophys, Inc.
494 Wilemon Road Maypearl,
TX 76064
www.endophys.com
(972) 435-1984