ZOE Medica

Nightingale Monitoring System

PPM3 User's Guide

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Nightingale Monitoring System PPM3 User's Guide
Part Number 122-0062, Revision E

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Zoe Medical makes no warranty of any kind on this material, including but not limited to, the implied warranties of merchantability and fitness for a particular purpose. Zoe Medical shall not be liable for errors contained herein or for incidental or consequential damages concerning the furnishing, performance, or use of this material.

All Zoe Medical monitoring devices are intended for use only by qualified medical personnel.

Before using any Zoe Medical monitoring device, be sure to read carefully and understand all manuals provided with the device.

Caution: United States Federal law restricts this device to sale by or on the order of a physician.

User Assistance

If you have a question or need help operating the Nightingale PPM3, please contact Zoe Medical Technical Support:

Email: customersupport@zoemedical.com

Phone: (978) 887-4013

For the latest information about answers to frequently asked questions, please consult our web site:

www.zoemedical.com

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General Information

This User's Guide provides healthcare professionals the information required for the safe and effective use of the Nightingale PPM3 (Personal Patient Monitor, 3rd Generation). The Nightingale PPM3 is a small, lightweight patient monitor designed to acquire physiological waveforms and parameters, and to transmit this data to a Nightingale MPC (Multi-patient Console).

For the sake of brevity, the term PPM3 is sometimes used in this document to refer to the Nightingale PPM3.

The Nightingale MPC is the central monitoring station for the Nightingale Monitoring System. The Nightingale MPC connects to a network of Nightingale PPM3 bedside patient monitors, allowing you to view information from up to 64 patients at once.

For the sake of brevity, the term MPC is sometimes used in this document to refer to the Nightingale MPC.

Before using the PPM3, be sure to read carefully and understand all the chapters of this User's Guide. Failure to read and understand the instructions may lead to misuse of the PPM3, which could result in harm to the patients.

Typographical Conventions in this User's Guide

This guide contains warnings, cautions, and notes to help call your attention to the most important safety and operational aspects of the system. To help identify these items when they occur in the text, they are shown using the following typographical conventions:

WARNING – Statements that call attention to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION – Statements that call attention to the possibility of a problem with the device associated with its use or misuse. Such problems include device malfunction, device failure, damage to the device or damage to other property.

Note - Statements that provide supplemental information.

Indications for Use

The Zoe Medical Nightingale Monitoring System is indicated for use in adult & pediatric patient populations.

The Zoe Medical Nightingale Monitoring System facilitates the monitoring of:

- ECG
- Impedance respiration
- Non-Invasive blood pressure
- Invasive blood pressure
- Body temperature
- Functional arterial oxygen saturation (SpO_2)
- End-tidal & inspired CO_2

The Zoe Medical Nightingale Monitoring System is a prescription device intended to be used by healthcare professionals in all areas of a healthcare facility.

WARNING – The Nightingale PPM3 is not intended for use in the following cases:

- **Neonatal patients**
- **Apnea monitoring**
- **In an MRI environment**
- **Applications requiring automated arrhythmia detection**
- **Applications requiring diagnostic-quality ECG**

WARNING – DEFIBRILLATION. To avoid the possibility of serious injury or death during patient defibrillation, do not come into contact with patient monitor or patient cables. Additionally, proper placement of defibrillator paddles in relation to the ECG electrodes is required to minimize harm to the patient. Only use accessories approved by Zoe Medical for use with the Nightingale PPM3.

WARNING – PACEMAKER PATIENTS. Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon heart rate meter alarms. Keep pacemaker patients under close surveillance. See the Technical Data chapter for disclosure of the pacemaker pulse rejection capability of this instrument.

WARNING – ELECTROSURGERY. The Nightingale PPM3 is suitable for use in the presence of electrosurgical (ESU) equipment. The following precautions should be taken:

- **To minimize the risk of patient burns, only use ESU equipment that monitors the impedance of the ESU return wires.**
- **Users should be properly trained in the operation of the ESU equipment.**
- **Keep patient-applied cables (e.g., ECG lead wires) off of earth ground and away from the ESU knife and return wires to prevent burns to measurement sites.**
- **To prevent burns to the patient in the event of a defective neutral ECG electrode of the device, it is necessary to place ECG electrodes far from the neutral electrode, and as equidistant as possible from the blade-neutral axis of the surgical patient monitor.**
- **When activating the ESU device, the ECG signals may be distorted or may disappear, and Lead Fail or Noise alarms might be present. The signal should return once the ESU activation stops.**
- **When activating the device, using the SpO_2 parameter as the heart rate source rather than the ECG parameter to determine heart rate may be clinically preferred.**
- **Only use accessories approved by Zoe Medical for use with the Nightingale PPM3.**

WARNING – FLAMMABLE ANESTHETICS. An explosion hazard exists if the monitor is used in the presence of flammable anesthetics.

WARNING – ANESTHESIA PATIENTS. Constant attention by a qualified individual is needed whenever a patient is under anesthesia or connected to a ventilator.

WARNING – ALARM MONITORING. Alarm configuration settings can be individualized according to patient condition and demographics. The operator should check the appropriateness of the alarm settings with each patient admission. Inappropriate alarm configuration settings may render the alarm system useless. Always respond promptly to alarms.

WARNING – ARRHYTHMIA PATIENTS. The Nightingale PPM3 is designed to operate in the presence of cardiac arrhythmias. However, the heart rate meter may be adversely affected in some cases.

WARNING – DEVICE INTERCONNECTIONS. Through its OMD (Other Medical Device) port, the Nightingale PPM3 can be connected to external devices. The following precautions should be taken:

- **The OMD cable should not be applied to the patient.**
- **Connected devices should be located outside of the patient vicinity (greater than 1.5 meters) if they do not comply with IEC 60601-1.**
- **The PPM3 should not be connected to devices that are not described in this manual.**
- **The over-all system leakage current should be tested and should comply with IEC 60601-1-1.**
- **Nightingale MPC to PPM3 Network installation must be performed by service personnel that are authorized by Zoe Medical. Connection of the PPM3 to a network that includes other equipment could result in previously unidentified risks.**

WARNING – BATTERY HANDLING. The Nightingale PPM3 contains a lithium ion coin cell battery and transport battery pack. The following precautions should be taken regarding these batteries:

- **Do not immerse in water.**
- **Do not heat or throw in fire.**
- **Do not leave in conditions over 60 ºC or in a heated car.**
- **Do not attempt to crush or drop.**
- **Only use the battery pack with the Nightingale PPM3.**
- **Follow the instructions in the Disposal chapter of this manual when the PPM3 is taken out of service.**

WARNING – AUDIBLE TONES. The Nightingale PPM3 should sound audible startup tones whenever it is powered on (two tones followed by two higher beeps). If a unit does not sound the startup tones when it is powered on, remove the unit from service and contact Zoe Medical Technical Support.

WARNING - To avoid potential for spread of disease or infection, single-use disposable components (e.g., electrodes, IBP catheters, disposable SpO_2 sensors, disposable temperature probe covers, single-use blood pressure cuffs, etc.) must not be reused.

CAUTION – For continued operation, always connect the monitor to a wall outlet when a Low Battery alarm indication occurs. Failure to do this can lead to an interruption of monitoring.

CAUTION – Do not operate the Nightingale PPM3 near high frequency emissions (e.g. microwaves).

Note – The battery may need to be recharged if the Nightingale PPM3 has been powered off for an extended period of time. See the Battery Operation chapter of this manual for details regarding the battery.

Note – The Nightingale PPM3 NBP parameter is indicated for use pregnant patients, including those with pre-eclamptic or eclamptic conditions.

Note – Single Use devices should not be reused.

1. Overview

This chapter provides an overview of the PPM3, including a diagram showing how the PPM3 fits into the Nightingale Monitoring System, and a description of how this User's Guide relates to other Nightingale Monitoring System documents. This chapter also provides a basic overview of the PPM3 user interface and a list of the PPM3's main features.

1.1. System Diagram

The main components of the Nightingale Monitoring System are shown in the following diagram:

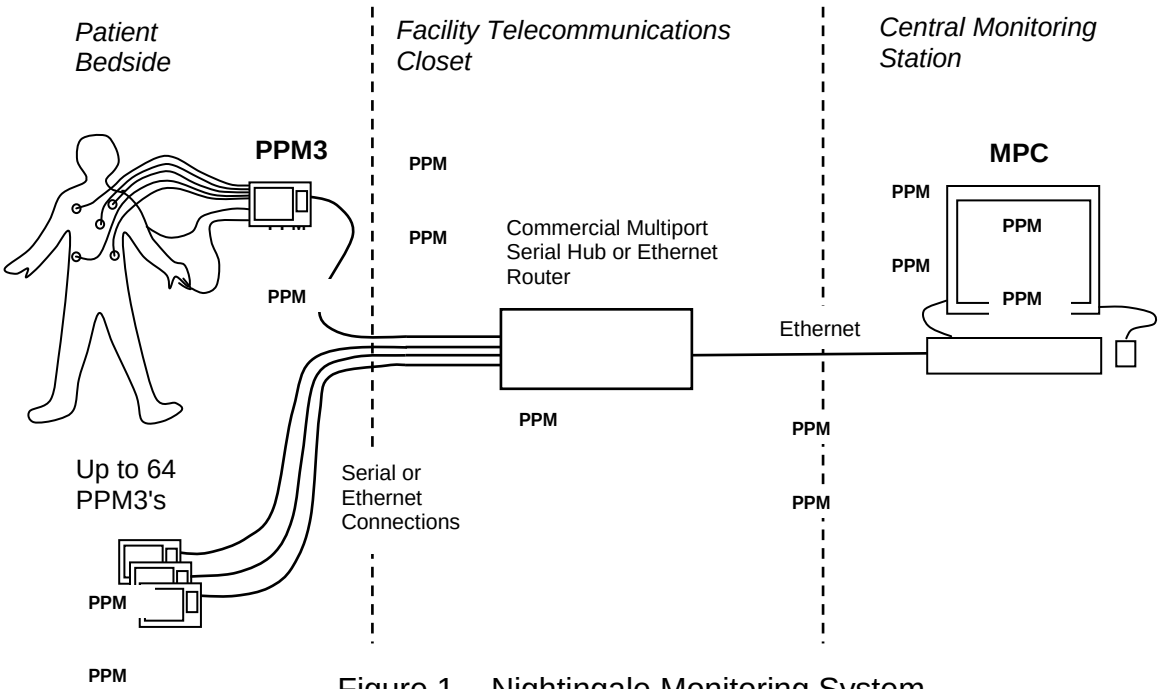


Figure 1. Nightingale Monitoring System

The PPM3 component serves as the bedside patient monitor. All the Nightingale PPM3 monitors are connected to the Nightingale MPC at the central station. The hub or router provides a connection between the Nightingale PPM3's and the MPC.

Note - The PPM3 is also designed to function in a stand-alone mode, independent of the MPC.

1.2. Scope of this User's Guide

This User's Guide provides healthcare professionals the information required for the safe and effective use of the Nightingale PPM3.

For information about how to use the MPC, please consult the Nightingale MPC User's Guide.

1.3. PPM3 Diagrams

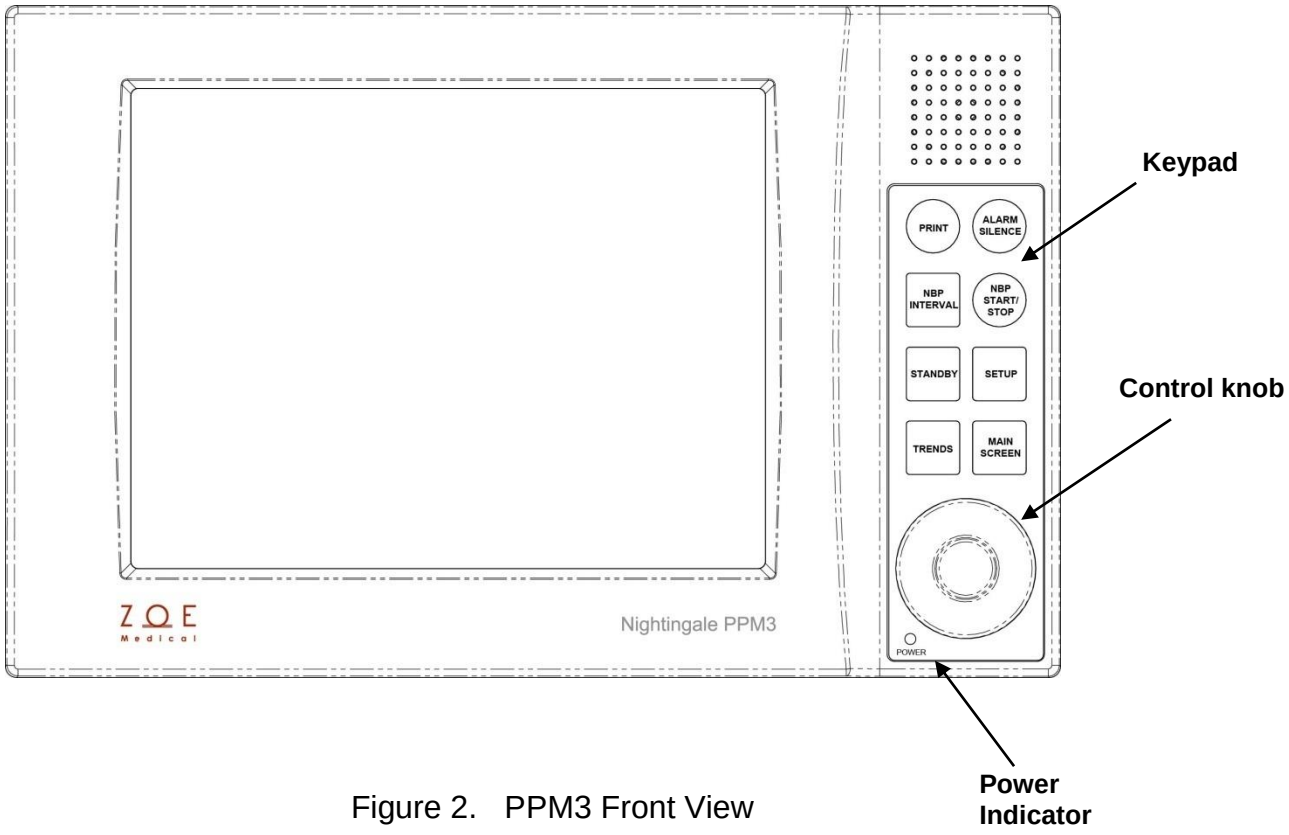


Figure 2. PPM3 Front View

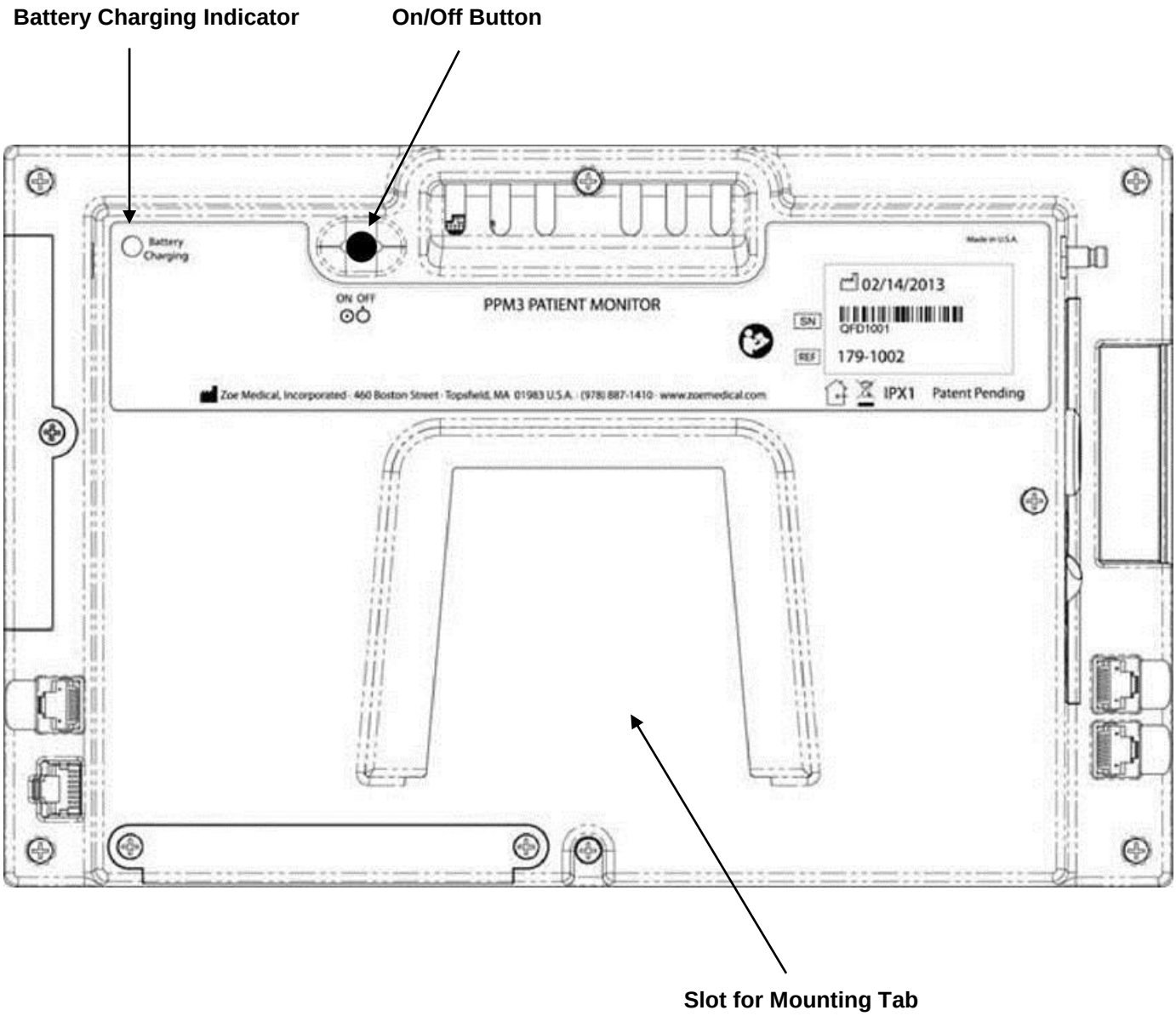


Figure 3. PPM3 Rear View

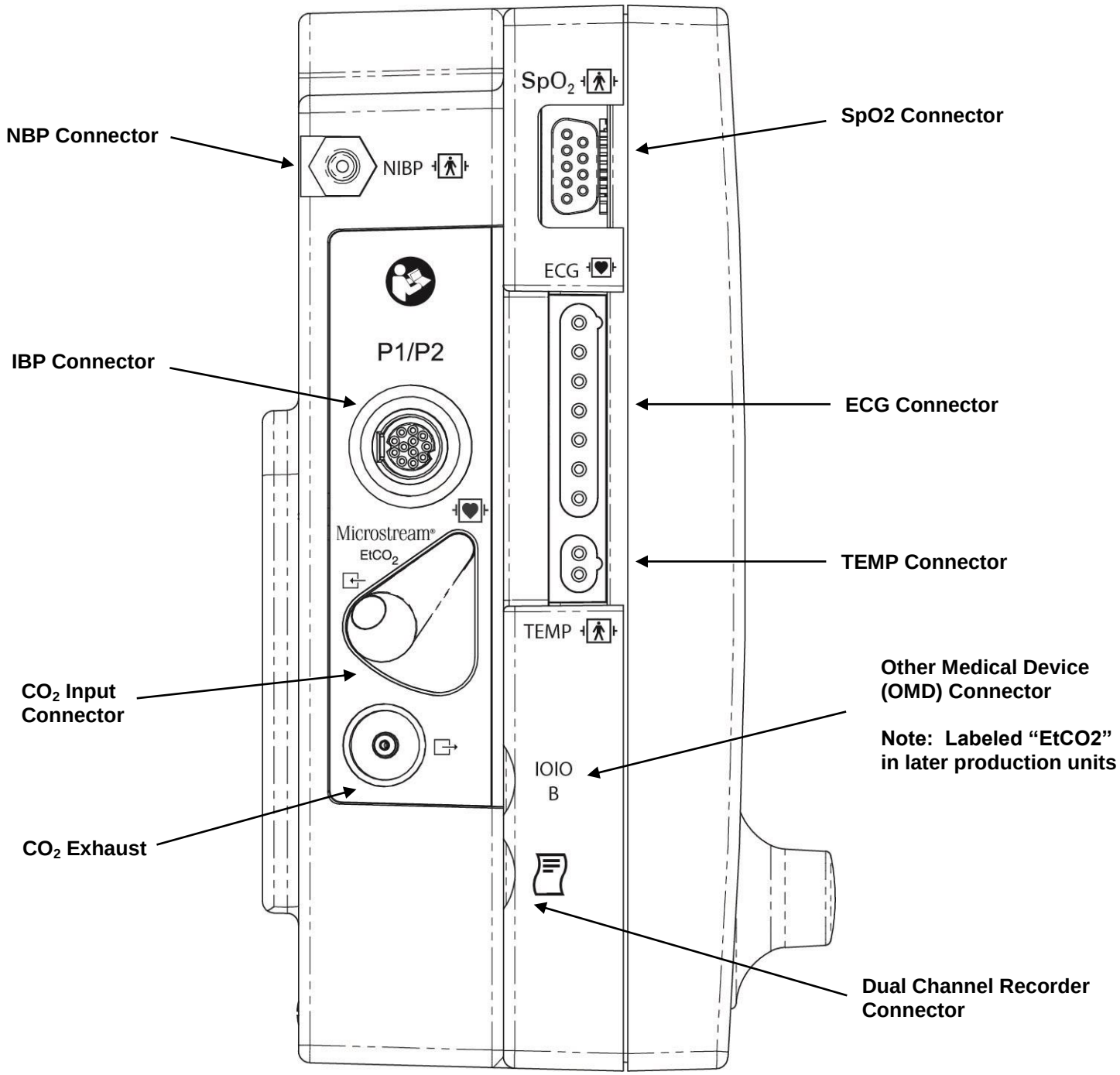


Figure 4. PPM3 Left View
(with Oridion Microstream® CO_2 and IBP)

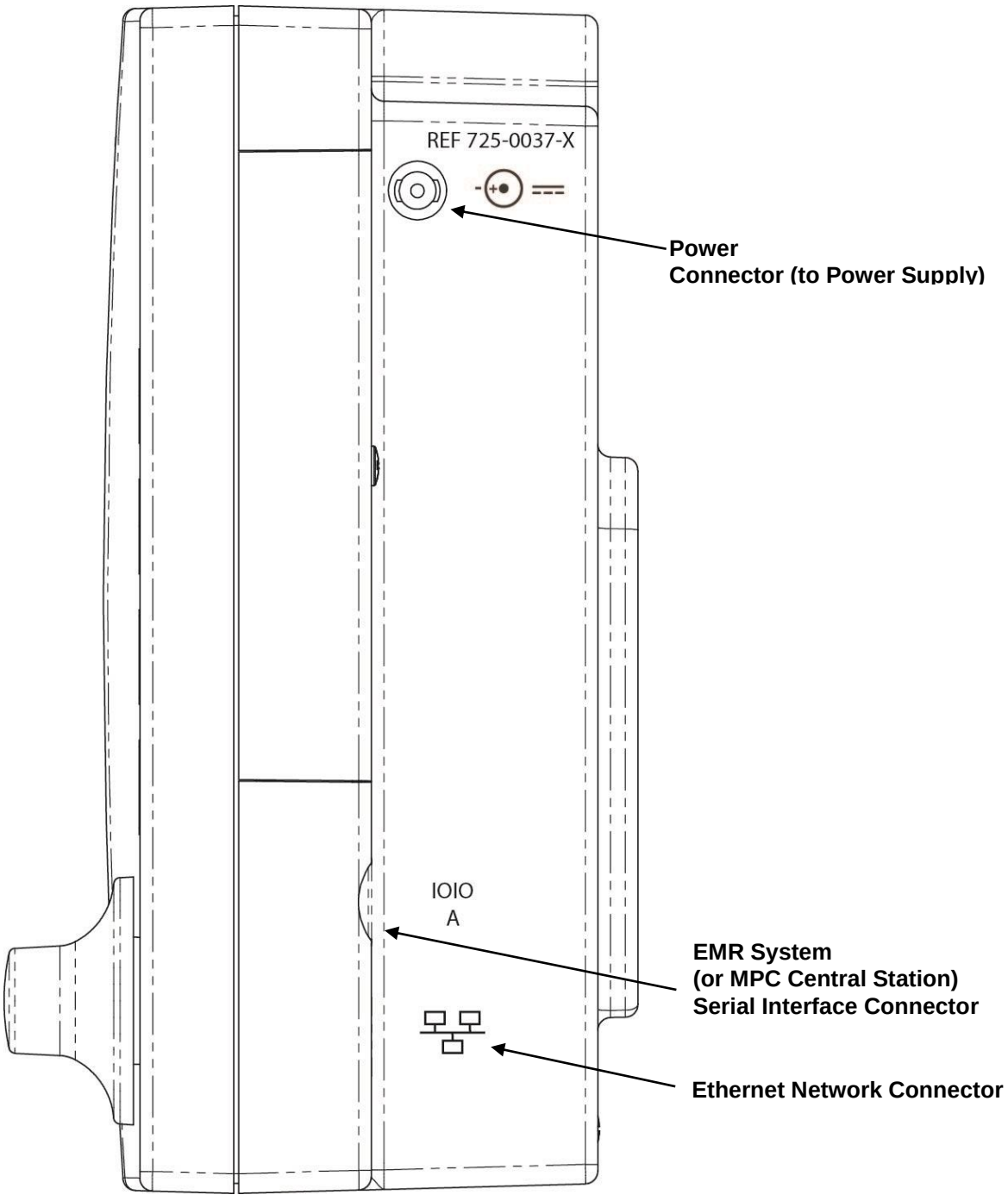


Figure 5. PPM3 Right View

To engage power connector, align with hole as shown holding connector body at 45° angle to the case and press into monitor.

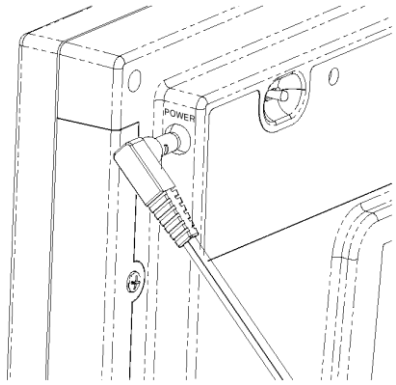


Figure 6. Partially Engaged Power Connector

When fully engaged rotate the connector body so that that it is parallel to the case.

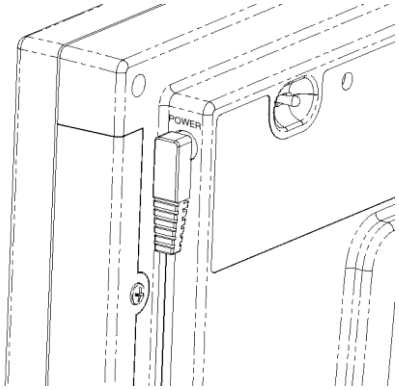


Figure 7. Fully Engaged Power Connector

Power connector is shown fully engaged in the locked position. To remove the power connector, reverse the above steps.

1.4. PPM3 User Interface

The PPM3 user interface makes use of a control knob and a set of keys on the front panel keypad (for input) and a display screen and speaker (for output). The front panel looks like the following diagram:

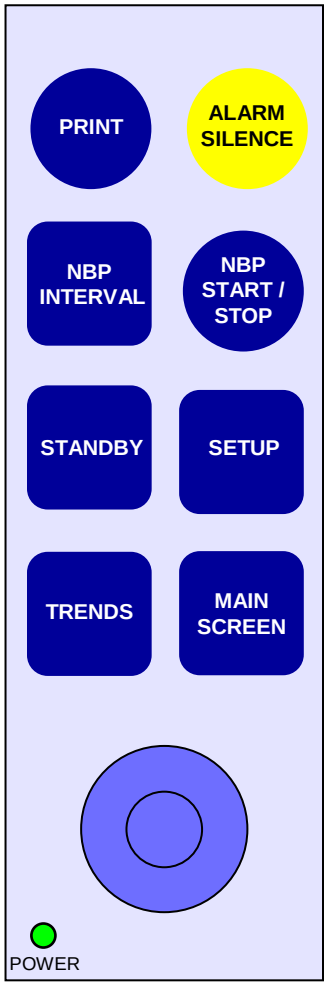


Figure 8. PPM3 Front Panel

You can use the PRINT key to generate a Vital Signs Report at the printer that is connected to the Nightingale MPC central monitoring station, or store a Vital Signs Report while the PPM3 is disconnected from the Nightingale MPC. When the Strip Chart Recorder Option is installed, pressing this key initiates a strip chart recording.

You can use the ALARM SILENCE key to silence alarm tones when they are annunciating, and also to remove messages that are being displayed after you have read them.

You can use the NBP INTERVAL key to change the interval between NBP measurements in Interval Mode (as well as to enable/disable NBP Interval Mode – see the NBP Monitoring chapter for more details).

You can use the NBP START / STOP key to start a NBP measurement, if one is not currently running, or to stop a NBP measurement, if one is currently running.

You can use the STANDBY key to place the monitor into Standby Mode, or when you are preparing to transport or discharge a patient.

You can use the SETUP key to bring up the menus used to change settings for the monitor.

You can use the TRENDS key to bring up the trend display.

You can use the MAIN SCREEN key to return to the normal Main Screen display.

You can use the control knob to navigate the PPM3 menus. Turn the knob to the left to navigate to the left or up. Turn the knob to the right to navigate right or down. Press the knob to select a highlighted menu item.

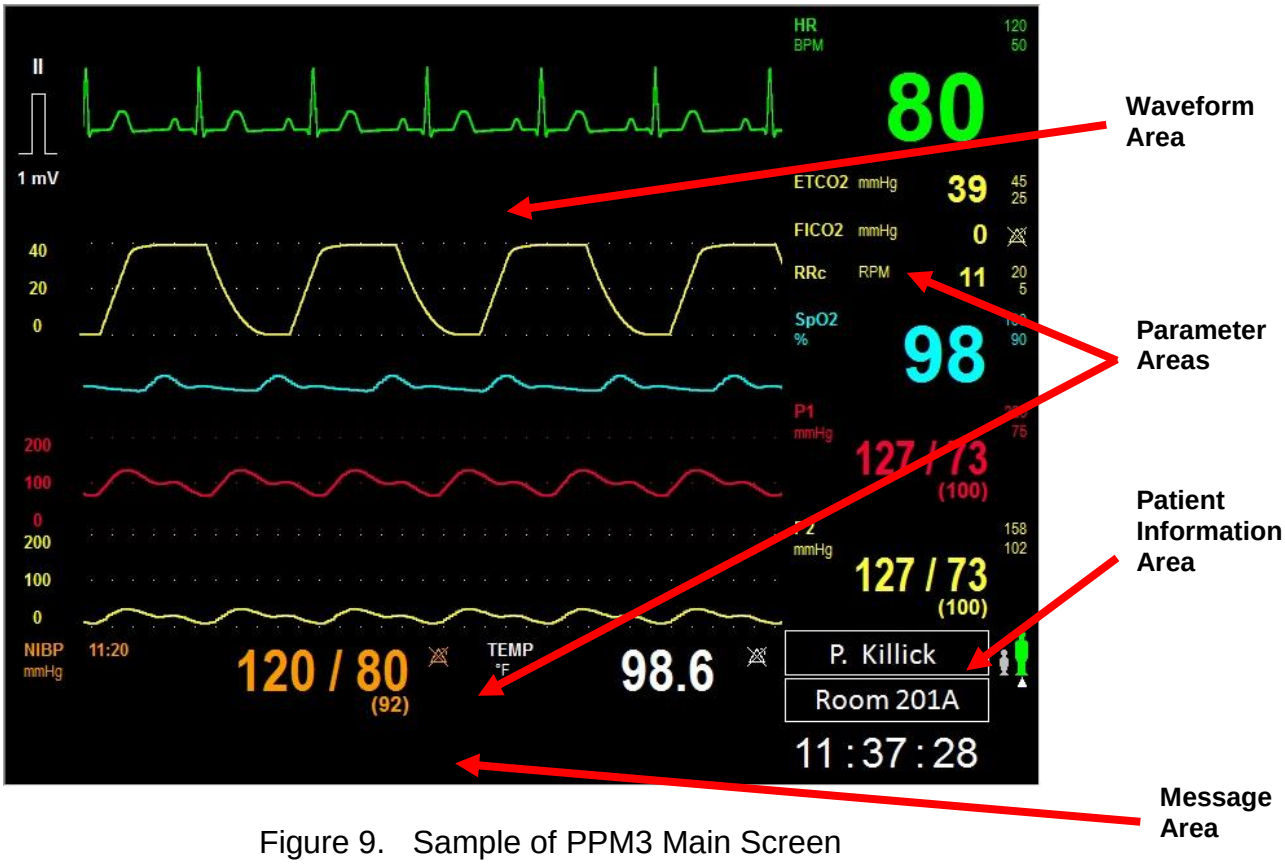


Figure 9. Sample of PPM3 Main Screen

The Main Screen of the PPM3 has four areas – one each for displaying waveforms, parameters, the patient information, and messages.

The Waveform Area has five channels. Menu selections allow you to choose which waveform to display in which channel.

The Parameter Area is actually in two parts, one to the right of the waveform area and one below it. The Parameter Area shows the current values of the monitored parameters.

The Patient Information Area is at the bottom right corner of the display.

The Message Area is at the bottom of the display. Alarm and technical condition messages are displayed here. One message is displayed at a time. If multiple messages are active, each message is displayed for approximately 3 seconds at a time.

1.5. Main Features of the PPM3

The Nightingale PPM3 connects to a patient and monitors the patient's vital signs. The PPM3 contains the hardware and software needed to perform complex data gathering and signal processing tasks that allow it to produce accurate and reliable measurements of physiological parameters. The patient's physiological signals and parameters are shown as waveforms and numbers on the PPM3 display. The PPM3 can be set up to generate an alarm when a physiological parameter goes beyond a preset limit.

The PPM3 can also connect to a Nightingale MPC central monitoring station and send the waveform and parameter information to the MPC. An operator at the MPC can then see the waveforms and parameters, and can respond in case there is an alarm (such as HR getting too high).

The chapters in this User's Guide explain the details of all the main features of the PPM3. These cover the basic monitoring tasks you may need to do when using the PPM3. The main features covered in this User's Guide are as follows:

- ECG and Heart Rate Monitoring (HR)
- Respiration Monitoring (RR)
- Pulse Oximetry Monitoring (SpO_2 and PR)
- Non-Invasive Blood Pressure Monitoring (NBP)
- CO_2/Capnography Monitoring ($ETCO_2$, $FICO_2$, RRc)
- Invasive Blood Pressure Monitoring (P1 and P2)
- Temperature Monitoring (TEMP)
- Connecting to the Nightingale MPC
- Managing Alarms
- Working With Menus
- Viewing Trends
- Standby Mode
- Battery Functions

In addition, a chapter at the end of this User's Guide includes information about troubleshooting (what to do if you have a problem with the PPM3). Other chapters at the end of this User's Guide discuss topics such as accessories for the PPM3, how to clean the PPM3, and maintenance, storage, and technical information for the PPM3.

2. Getting Started

This chapter explains how to get started using the Nightingale PPM3. It explains the parts you will need, how to make all the necessary connections, and how to check that everything has been set up and is working correctly.

2.1. Parts you should have

Note – Before proceeding, you should have a look at the PPM3 diagrams in the Overview Chapter, to make sure that you know what all the part names mean.

The first step in using the PPM3 is to make sure that you have all the parts you are going to need. Use the following list as a checklist:

1. Nightingale PPM3
2. PPM3 Power Supply with integral Power Cable
3. PPM3 Network Cable (if you will be connecting to the Nightingale MPC)
4. ECG Cables (if you will be monitoring ECG or Impedance Respiration)
5. ECG Electrodes (if you will be monitoring ECG or Impedance Respiration)
6. SpO_2 Sensor / Extender Cable (if you will be monitoring SpO_2)
7. CO_2 sampling lines or airway adapter (if your monitor is configured with a CO_2/Capnography monitoring module)
8. Invasive pressure Y-adapter (only needed if your monitor is configured for IBP monitoring, and you plan to use two IBP channels)
9. Temperature Cable (if you will be monitoring Temperature)
10. Temperature Probe (if you will be monitoring Temperature)
11. NBP Hose (if you will be monitoring NBP)
12. NBP Cuff (if you will be monitoring NBP)

If the PPM3 will be connected to a Nightingale MPC central monitoring station, you should also be close to a wall plate with a connector labeled "Nightingale Monitoring System." This wall plate is installed when the Nightingale Monitoring System network is installed.

2.2. Mounting solutions

The PPM3 can be mounted to a roll stand or wall bracket using a custom adapter bracket that is described in the accessories chapter. The maximum height of a roll stand mount is 100 cm.

Several types of table stand are also available for the PPM3, as described in the accessories chapter.

WARNING – Please follow installation instructions provided with mounting hardware to avoid possible hazard of device falling.

2.3. How to Connect the PPM3 to Power and Communications

CAUTION – Before making any connections, you need to figure out a good place to put the PPM3 in relation to the patient. This is important in order to avoid creating a situation where cables are hanging in places where they could get tangled up or trip someone.

To connect the PPM3 to power use the following procedure:

1. Plug the PPM3 Power Supply into a live outlet.
2. Plug the Power Cable Plug into the Power Connector on the back of the PPM3 (right hand side). The green Battery Charging LED on the back of the PPM3 should now be illuminated.
3. Press the On/Off Button on the back of the PPM3. After pressing the On/Off Button you should hear a chirp accompanied by a flash of the screen. The Power Indicator LED on the front of the PPM3 should be illuminated.
4. The screen should then go black for a few seconds until the startup screen shown in the following figure appears. Then as the main screen appears, you will hear two startup tones followed by two higher-pitched beeps

Figure 10. PPM3 Startup Screen

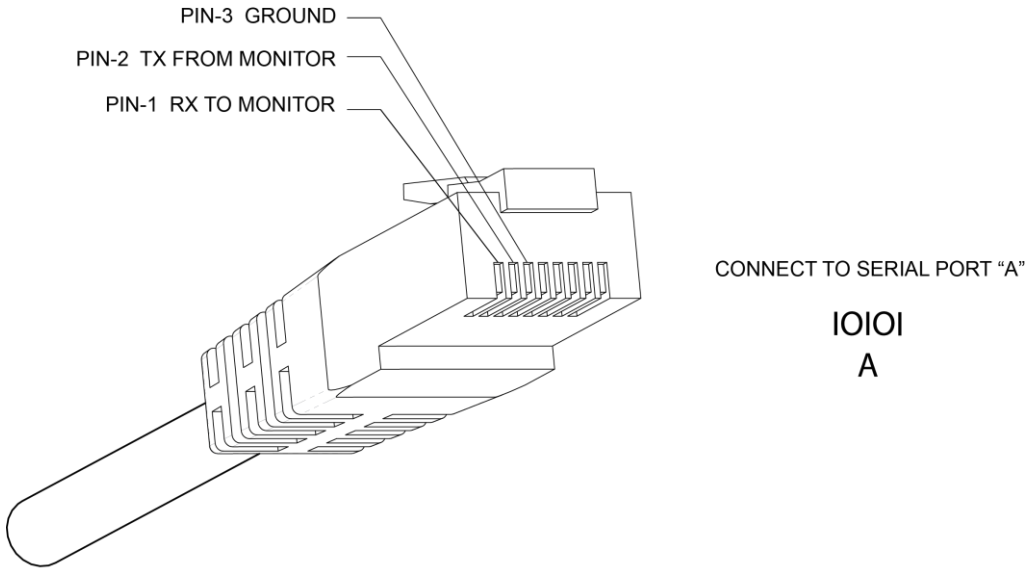
To power-down the PPM3, press the On/Off Button until the following screen appears. The rest of the power-down process will be completed automatically. The power supply should remain connected for the battery to be recharged.

Figure 11. PPM3 Shutdown Screen

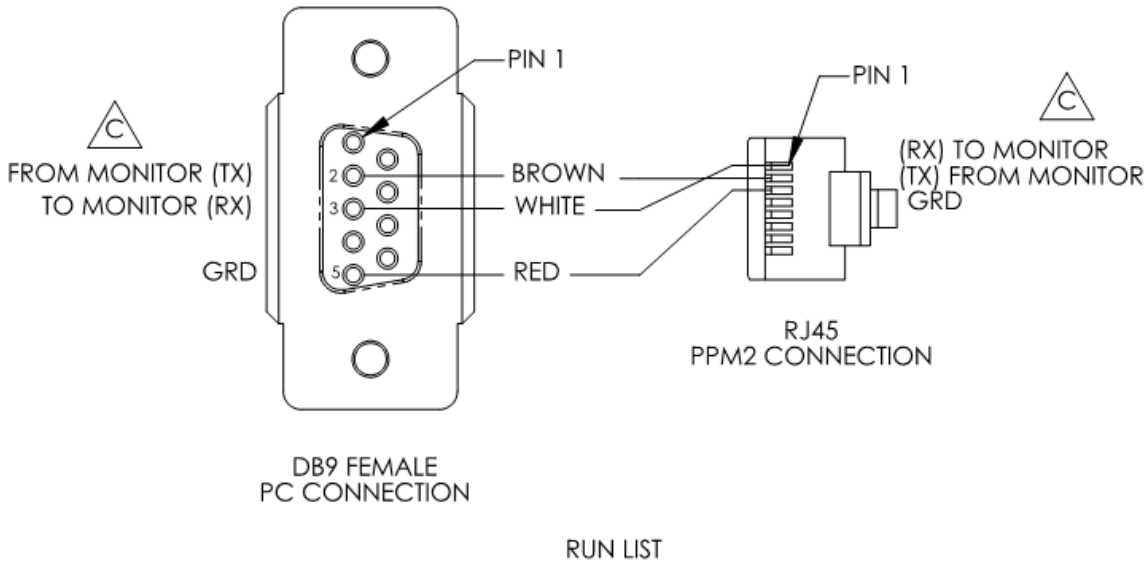
Connecting to an Electronic Medical Record (EMR) System

Connection to an EMR system requires a custom Network Cable from Zoe Medical (Part Number 421-0052) or an equivalent cable configured as shown below. One end of the cable has a DB-9 connector that interfaces to a standard PC serial port. The other end of the cable connects to an RJ45 port on the right side of the PPM3.

Note: To connect to PC's that do not have built-in DB9 connectors, a third party USB-to-serial cable of the type recommended by the EMR vendor may be used.



RJ45 SERIAL CONNECTION TO PPM3 MONITOR



RJ45 Pin	Signal	DB9 Pin
1	RX to monitor	2
2	TX from monitor	3
3	Ground	5
4	NC	1
5	NC	4
6	NC	6
7	NC	7
8	NC	8

The serial port is configured as follows:

Baud rate	38400
Data bits	8
Stop bits	1
Parity	None
Flow Control	None

To connect the PPM3 to an Electronic Medical Record (EMR) system:

1. Connect the Network Cable to the connector labeled IOIO A on the right side of the PPM3. Then plug the other end of the Network Cable into PC that is hosting the EMR software.

Note: For complete details of the communications protocol the PPM3 uses for interfacing with EMR systems, please refer to the document “PPM3 Data Transfer Interface” (Part Number 122-0064).

Connecting to the Nightingale MPC Central Station

Connection to the Nightingale MPC Central Station requires a custom Network Cable from Zoe Medical (Part Number 421-0053).

To connect the PPM3 to a Nightingale MPC:

2. Connect the Network Cable to the connector labeled IOIO A on the right side of the PPM3. Then plug the other end of the Network Cable into the wall plate connector marked "Nightingale Monitoring System."

Startup – New Patient Screen

The New Patient Screen follows the Startup Screen. If a patient has previously been admitted, their information will still be shown in the Patient Information Area as shown below. To continue with this patient, select "No," and the PPM3 will display the Main Screen with the same Patient Information displayed as before.

Figure 12. New Patient Screen With Previous Patient

Alternatively, if you will be monitoring a different patient as compared to when the PPM3 was last powered-down, select "Yes" to discharge the old patient from the PPM3. This will clear the Patient Information Area and bring up the Main Screen as shown in Figure 12.

Note – See the Working With Menus chapter for details on how to use the control knob to select the Yes/No menu items.
Note – If you are using the Nightingale MPC for centralized monitoring, the PPM3 will not establish a connection until the New Patient question is answered.

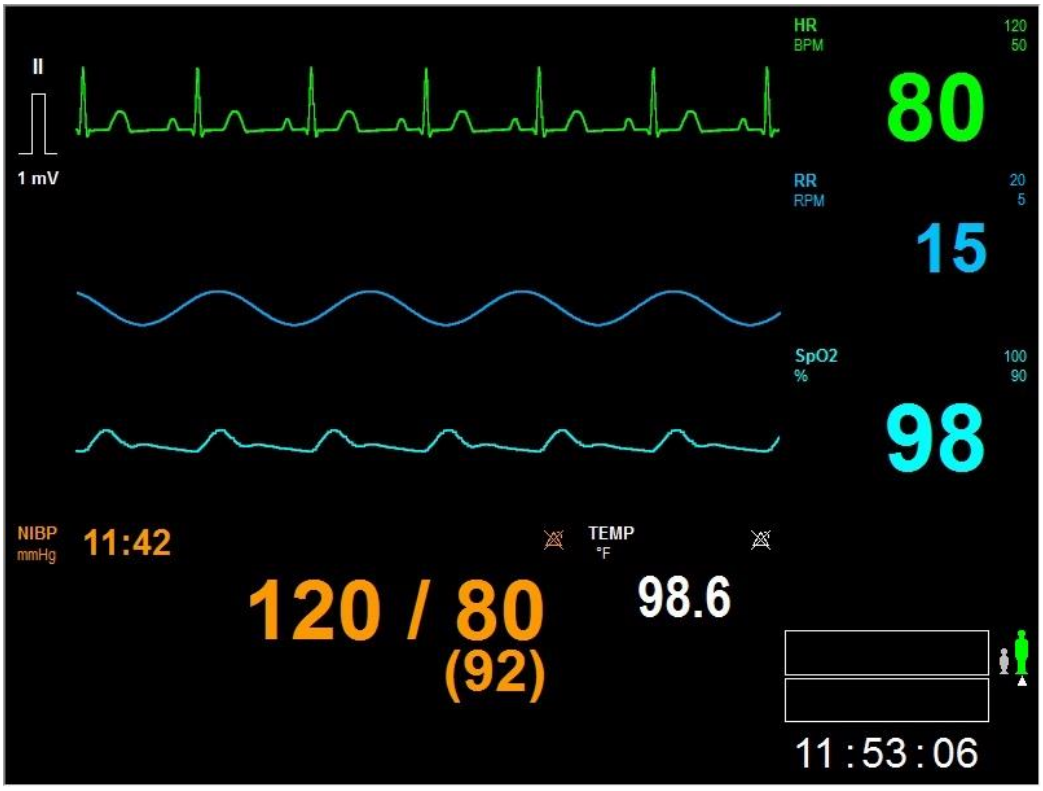


Figure 13. Main Screen With No Patient Admitted

The patient information area will not be filled in until the new patient is admitted via the Patient Information Menu (see the Working With Menus chapter) or the MPC.

The waveforms and parameter values will not be displayed until you connect the PPM3 to the patient.

2.3.1. Checklist before Connecting to Patient

Before connecting the PPM3 to a patient:

1. If connecting the PPM3 to a new patient, clean the unit according to the instructions in the Cleaning chapter.
2. Power up the unit, confirm that the startup tones sound (two tones followed by two higher-pitched beeps).
3. Confirm that the power-on LED is lit on the front panel.
4. Confirm that the display comes up, showing the home screen.
5. If monitoring SpO_2, connect sensor, confirm that LED is lit on sensor.
6. Press NBP Start Stop key, confirm that pump starts.
7. Press NBP Start Stop key again, confirm that pump stops.

If you notice any problem in going through the checklist, take the monitor out of service and contact Zoe Medical Technical Support.

2.4. How to Connect the PPM3 to the Patient

To connect the PPM3 to the patient requires special instructions depending on which signals and parameters you are monitoring. Please refer to the chapter for each signal for instructions about how to make the connection to monitor that signal.

WARNING – Check the PPM3 and its accessories for cracks, abrasive edges and other signs of damage before applying sensors to the patient.

2.5. How to Check the PPM3 Setup

For any patient connections you made, you should have already verified that the waveform displayed on the PPM3 shows that the connection was good. When connected to the MPC, you should verify that the patient name is displayed in the name area of the PPM3 Main Screen. If the patient's name is too long to fit in this area, you should verify that the patient's initials are displayed.

Before leaving the patient, make sure that the PPM3, the PPM3 Power Supply, and all the cables are secure and not hanging in a way that would be hazardous to the patient or to someone caring for the patient.

WARNING – Always make sure that the correct patient name is displayed in the PPM3 name area when connected to the MPC. This is to avoid any chance of mistaking the signals and parameters from one patient with the signals and parameters from another patient at the central monitoring station.

3. ECG and Heart Rate Monitoring

3.1. Overview of ECG and Heart Rate Monitoring

ECG Monitoring works through the sensing the electrical signals generated by the electrical activity of the heart as it beats. These signals are acquired from chest electrodes, and the PPM3 amplifies the signals so they can be displayed on the screen. The patient's heart rate (HR) is calculated and continuously updated based on running average of the R to R intervals between each QRS complex.

The ECG and HR monitoring capabilities of the Nightingale PPM3 include:

- Displaying up to three leads of ECG continuously
- 3-wire cable with lead II monitoring
- 5-wire cable with leads I, II, III, V, AVL, AVR, and AVF.
- Calculating the average heart rate (HR) in beats per minute (based the top displayed ECG lead, or Lead II if no ECG lead is displayed)
- Detecting asystole and ventricular fibrillation (based on heart rate lead)
- Pacer pulse detection (performed on Lead II)
- Generating an audible pulse tone for each detected beat

The Nightingale PPM3 is suitable for use in the presence of electrosurgical (ESU) equipment.

WARNING – ELECTROSURGERY. Consult the safety instructions at the front of this manual before using electrosurgical equipment.

3.2. Getting Started with ECG on the PPM3

To begin monitoring ECG, use the following procedure:

1. Select and prepare the electrodes.

   We recommend using pregelled, Ag/AgCl disposable electrodes. Depending on the situation, you may want to use either the short-term (foam-backed) or

long-term (cloth-backed) electrodes. Do not use electrodes after their expiration date, or if the gel has dried out.

2. Prepare the patient's skin for applying the electrodes.

   Getting a good quality ECG signal depends largely on how good the contact is between the electrodes and the patient's skin. To help assure this, you should first clip or shave any excess hair and remove any skin residue or oils using an alcohol pad. To reduce skin impedance, mildly abrade only the electrode contact site using ultrafine sandpaper (220-400 grit). For diaphoretic patients, use a benzoin prep to assure tighter adherence of the electrode.

3. Apply the electrodes to the patient.

   Apply the pad by using a circular motion on the adhesive area first, then pressing on the gel area gently, to avoid squeezing out the gel. Please refer to the diagrams on the following pages for guidance on proper electrode placement. You should change the electrodes every 24-48 hours to maintain a good quality ECG signal.

4. Connect the ECG cable lead set to the electrodes and to the PPM3.

3.3. Checking the ECG Signal

When you have connected the patient following the steps listed above, you should be able to see a clean ECG signal similar to the figure below on the PPM3 display. If the ECG contains artifact or noise, review the steps for proper electrode site preparation and placement. The PPM3 should also display a number for the patient's heart rate (HR) and the alarm limit settings.

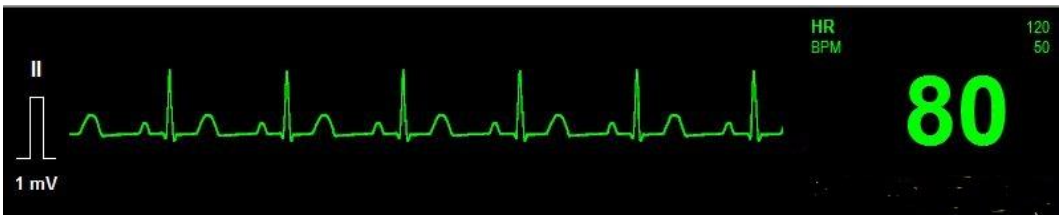


Figure 14. ECG Waveform and HR Value

To manually test ECG and HR alarm functionality on a daily basis, you may choose from two approaches. First, if a patient is currently being monitored with

ECG, make certain that the alarms are enabled, and then lower the HR upper alarm limit setting below its current value. Verify that "HR < [upper limit]" annunciates as a medium grade alarm. Press the ALARM SILENCE key, and then return the HR upper alarm limit to its previous value. Verify that the alarm is no longer active, and that ECG monitoring continues normally. Alternatively, disconnect the RA or LL electrode. Verify that "HR lead off" annunciates as a low grade alarm. Press ALARM SILENCE and reconnect the electrode. Verify that the alarm ceases and that the ECG waveform and HR parameter return.

The ECG and Heart Rate Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing configuration settings, such as sourcing pulse rate (PR) from SpO_2 while still displaying an ECG waveform, enabling a HR/PR tone, displaying multiple ECG waveforms, or adjusting alarm limits, may be found in the Working With Menus chapter.

WARNING – Conductive parts of the ECG patient cables, electrodes, and associated connections of type CF applied parts, including the neutral conductor of the patient cable and electrode should not come into contact with other conductive parts including earth ground.

WARNING – Read safety instructions provided with a defibrillator. The PPM3 is designed to withstand defibrillation and will recover within 5 seconds, per IEC 60601-1. Only use accessories approved by Zoe Medical for use with the Nightingale PPM3.

WARNING – Operating the Nightingale PPM3 with HR/PR limit alarms disabled means that no low or high HR/PR alarm conditions will produce alarm notifications. Use this feature with extreme caution. Patients must be closely observed if HR/PR limit alarms are disabled.

WARNING – Care should be taken to ensure that the total patient-applied current across all patient-connected equipment is less than 10 microamperes (uA). The PPM3 applies approximately 2½ uA.

CAUTION – Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. To avoid the risk of this happening, follow the directions for proper electrode placement, and keep the ECG lead wires away from sources of line noise.

CAUTION – To avoid large offset potentials due to polarization of electrodes, be sure to use pregelled, Ag/AgCl disposable electrodes, and be sure that all electrodes used on a patient are of the same type.

Note – The HR/PR numeric is displayed in green when sourced from ECG (default). The color changes to cyan or green respectively when sourced from SpO2 or an ART-labeled IBP.

Note – If an ECG waveform is not displaying on the PPM3, follow the instructions in the chapter Working With Menus to select one or more ECG waveforms for display.

Note – Visually inspect the ECG cables on a daily basis and follow the instructions in the Cleaning and Maintenance chapters as needed. Also, check for an inoperable ECG circuit which would manifest itself as a blank ECG waveform and a "HR lead off" message.

3.4. Standard Electrode Placement (AHA)

For ECG cable lead sets with AHA (USA) lead designations, position the electrodes as shown in the following diagram:

Note – If using a three-wire ECG cable lead set, you only need to apply the RA, LA, and LL electrodes, and only Lead II will be available.

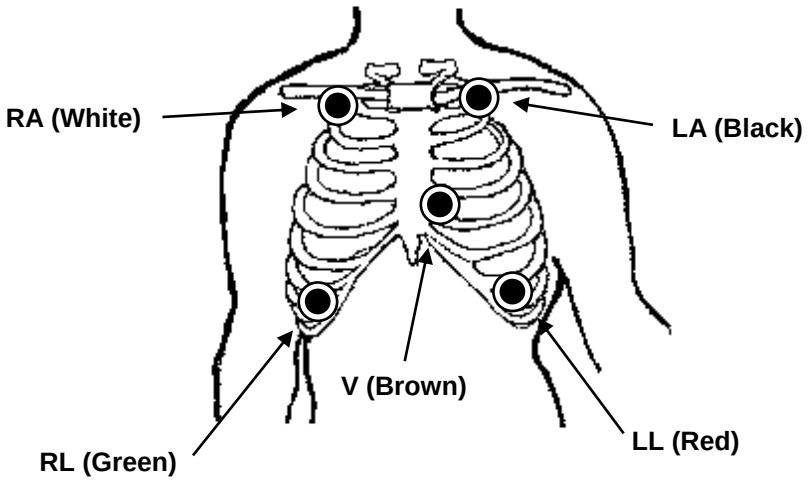


Figure 15. Standard AHA Electrode Placement

1. Position the right arm (RA) electrode on the right mid-clavicular line, directly below the clavicle.
2. Position the left arm (LA) electrode on the left mid-clavicular line, directly below the clavicle.
3. Position the right leg (RL) electrode on the right mid-clavicular line, 6th and 7th intercostal space (5-lead cable only).
4. Position the left leg (LL) electrode on the left mid-clavicular line, 6th and 7th intercostal space.
5. Position the chest (V) electrode on the 4th intercostal space, left sternal border (5-lead cable only).

3.5. Standard Electrode Placement (IEC)

For ECG cable lead sets with IEC (Europe) lead designations, position the electrodes as shown in the following diagram:

Note – If using a three-wire ECG cable lead set, you only need to apply the R, L and F electrodes, and only Lead II will be available.

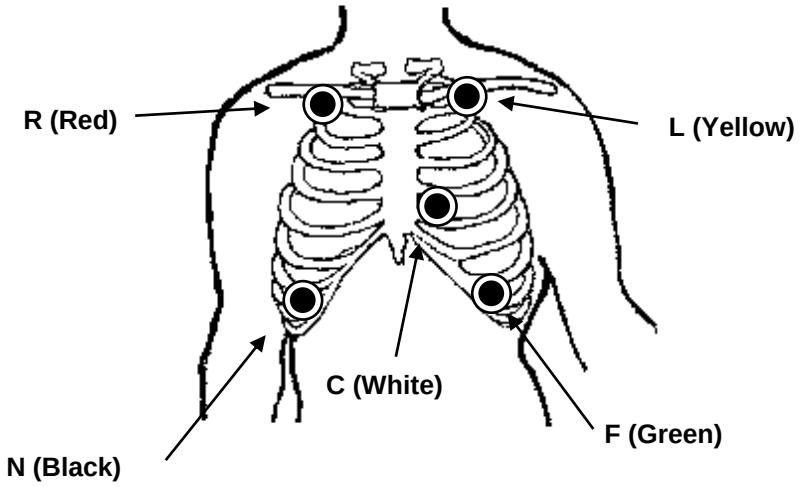


Figure 16. Standard IEC Electrode Placement

1. Position the right arm (R) electrode on the right mid-clavicular line, directly below the clavicle.
2. Position the left arm (L) electrode on the left mid-clavicular line, directly below the clavicle.
3. Position the neutral (N) electrode on the right mid-clavicular line, 6th and 7th intercostal space (5-lead cable only).
4. Position the left leg (F) electrode on the left mid-clavicular line, 6th and 7th intercostal space.
5. Position the chest (C) electrode on the 4th intercostal space, left sternal border (5-lead cable only).

3.6. Electrode Placement for Paced Patients (AHA)

For ECG cable lead sets with AHA (USA) lead designations, the optimal electrode placement for patients with pacemakers may be as illustrated in the following diagram:

Note – If using a three-wire ECG cable lead set, you only need to apply the RA, LA, and LL electrodes, and only Lead II will be available.

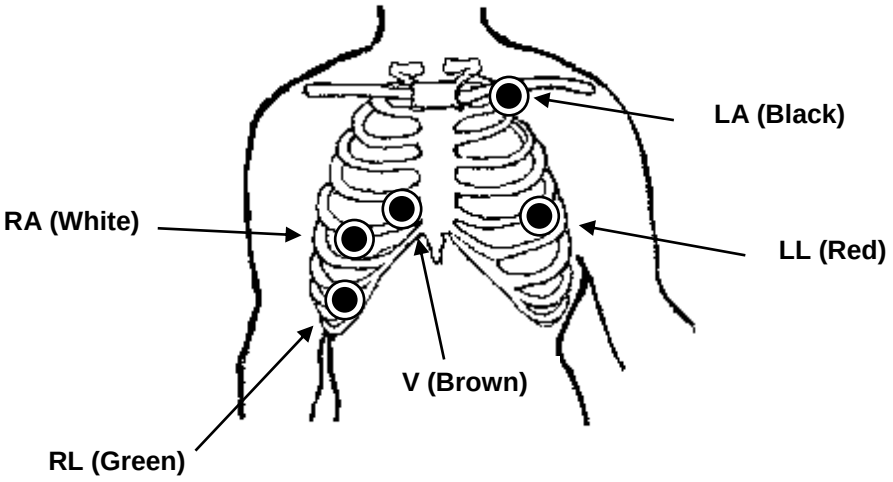


Figure 17. Paced AHA Electrode Placement

1. Position the right arm (RA) electrode on the right mid-clavicular line, 5th intercostal space.
2. Position the left arm (LA) electrode on the left mid-clavicular line, directly below the clavicle.
3. Position the right leg (RL) electrode on the right mid-clavicular line, 6th and 7th intercostal space (5-lead cable only).
4. Position the left leg (LL) electrode on the left mid-clavicular line, 6th and 5th intercostal space.
5. Position the chest (V) electrode on the 4th intercostal space, right sternal border (5-lead cable only).

3.7. Electrode Placement for Paced Patients (IEC)

For ECG cable lead sets with IEC (Europe) lead designations, the optimal electrode placement for patients with pacemakers may be as illustrated in the following diagram:

Note – If using a three-wire ECG cable lead set, you only need to apply the R, L, and F electrodes, and only Lead II will be available.

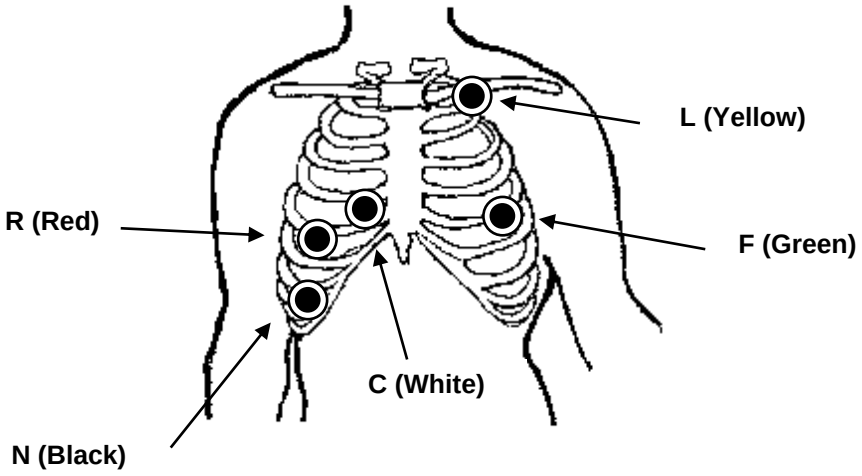


Figure 18. Paced IEC Electrode Placement

1. Position the right arm (R) electrode on the right mid-clavicular line, 5th intercostal space.
2. Position the left arm (L) electrode on the left mid-clavicular line, directly below the clavicle.
3. Position the neutral (N) electrode on the right mid-clavicular line, 6th and 7th intercostal space (5-lead cable only).
4. Position the left leg (F) electrode on the left mid-clavicular line, 6th and 5th intercostal space.
5. Position the chest (C) electrode on the 4th intercostal space, right sternal border (5-lead cable only).

3.8. Verifying Proper Pacemaker Handling

For paced patients, proper electrode placement results in pacer tick marks along the top of each ECG waveform channel on the Nightingale PPM3 and the MPC. These tick marks occur at the point where the PPM3 detects a pacer pulse.

The PPM3 rejects pacer pulses rather than calling them QRS's (per IEC 60601-2-27). However, it is important to keep paced patients under close surveillance and not to entirely rely on rate meters for these patients (as indicated in the warning at the start of this manual).

3.9. ECG and Heart Rate Monitoring Messages

Note – Factory default HR alarm and limit settings may be found in the PPM3 Monitor Settings chapter.

Message	Parameter Value	Possible Cause	Suggested Action
HR < [lower limit]	[number]	The patient's heart rate has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
HR > [upper limit]	[number]	The patient's heart rate has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
HR asystole	ASY	No QRS detected for last 4 seconds	Check the patient and provide any necessary clinical care. Check the ECG lead being used to calculate the heart rate (the top displayed lead) – make sure that the QRS amplitude on this lead is at least 0.5 mV. Change to another ECG lead to get adequate QRS amplitude. Reposition or change electrodes if no lead gives adequate QRS amplitudes. Remember the importance of good skin preparation techniques.
HR ventricular fibrillation	VF	No organized ventricular rhythm detected	Check the patient and provide any necessary clinical care. Check the ECG lead being used to calculate the heart rate (the top displayed lead) – make sure that the QRS amplitude on this lead is at least 0.5 mV. Change to another ECG lead to get adequate QRS amplitude. Reposition or change electrodes if no lead gives adequate QRS amplitudes. Remember the importance of good skin preparation techniques.

Message	Parameter Value	Possible Cause	Suggested Action
HR lead off	[blank]	Unplugged cable Broken cable Loose lead wire Faulty lead wire Dried out electrode Inoperable ECG circuit Intentional removal by clinician	Check to make sure electrodes are still securely attached to the patient, and reattach if necessary. Remember the importance of good skin preparation techniques. Check to make sure all the lead wires are still connected to the electrodes. Check to make sure the lead wires are securely connected to the PPM3. Check to make sure there are no broken lead wires. Turn monitor off, then back on If message persists, contact Zoe technical support. Press ALARM SILENCE in the event of intentional removal by clinician.
HR artifact	---	Patient movement Electrical noise from auxiliary equipment Bad electrode contact	Calm the patient. Isolate the patient from auxiliary equipment, if possible. Check to make sure electrodes are still securely attached to the patient, and reattach if necessary. Remember the importance of good skin preparation techniques.

4. Respiration Monitoring

4.1. Overview of Respiration Monitoring

Respiration monitoring works by measuring the impedance between the LL and RA electrodes (or the R and F electrodes for IEC lead designations). The impedance changes as the patient's chest expands and contracts during the breath cycle. To measure the changes in impedance, the PPM3 passes a very small, high-frequency current between the electrodes. This current is too small to cause any harm to the patient or any interference with ECG monitoring.

The Respiration monitoring capabilities of the Nightingale PPM3 include:

- Calculating the average respiration rate (RR) in respirations per minute
- Displaying the respiration waveform continuously

The same electrodes are used for both ECG and Respiration monitoring.

Note – PPM3 models configured with capnography modules are also able to calculate RR from the CO_2 waveform. See the CO_2 monitoring chapter in this user's guide for more information.

4.2. Getting Started with Respiration on the PPM3

To begin monitoring Respiration, follow the patient preparation and electrode placement procedures that are described at the start of the ECG monitoring chapter of this manual.

4.3. Checking the Respiration Signal

When you have connected the patient to the monitor, you should be able to see a clean, slowly oscillating Respiration signal on the PPM3 display. This may take up to 30 seconds after the patient has been connected. The PPM3 should also display the patient's respiration rate (RR) and alarm limit settings.

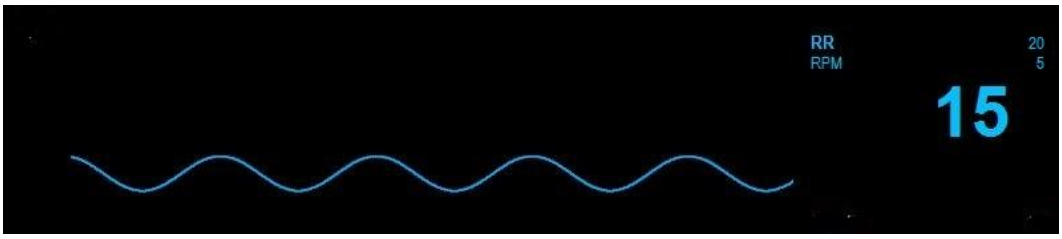


Figure 19. RR Waveform and Value

To manually test RR alarm functionality on a daily basis, you may choose from two approaches. First, if a patient's respiration is currently being monitored, make certain that the alarms are enabled, and then lower the RR upper alarm limit setting below its current value. Verify that "RR < [upper limit]" annunciates as a medium grade alarm. Press the ALARM SILENCE key, and then return the RR upper alarm limit to its previous value. Verify that the alarm is no longer active, and that RR monitoring continues normally. Alternatively, disconnect the RA or LL electrode. Verify that "RR lead off" (interleaved with "HR lead off") annunciates as a low grade alarm. Press ALARM SILENCE and reconnect the electrode. Verify that the alarm ceases and that the RR waveform and parameter return.

The Respiration Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing configuration settings, such as enabling alarms, or adjusting alarm limits, may be found in the Working With Menus chapter.

WARNING – Operating the Nightingale PPM3 with RR limit alarms disabled means that no low or high RR alarm conditions will produce alarm notifications. Use this feature with extreme caution. Patients must be closely observed if RR limit alarms are disabled.

WARNING – When using an ECG electrode to calculate respiration rate via the thorax impedance method, movement artifacts may create inaccurate results. Respiration rates derived from CO_2 parameter is not subject to such movement artifacts.

Note – If the Respiration waveform is not currently selected for display on the PPM3, follow the instructions in the chapter on Working With Menus to select this waveform for display.

4.4. Pediatric Considerations

Cardiogenic artifact (heart rate pulsations that appear as "breaths" in the respiration signal) can be quite pronounced in pediatric patients. This can cause the respiration rate to be artificially high (approaching the heart rate). To reduce cardiogenic artifact, move the White RA electrode (AHA lead designation) or the Red R electrode (IEC lead designation) from the right clavicle down to the right mid-clavical line, 4th intercostal space.

4.5. Respiration Monitoring Messages

Note – Factory default RR alarm and limit settings may be found in the PPM3 Monitor Settings chapter.

Message	Parameter Value	Possible Cause	Suggested Action
RR < [lower limit]	[number]	The patient's respiration rate has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR > [upper limit]	[number]	The patient's respiration rate has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR out of range (too high)	---	The patient's respiration rate has risen above the maximum value the monitor can accurately detect. Electrical noise from auxiliary equipment Monitor confused by signal artifact	Check the patient and provide any necessary clinical care. Isolate the patient from auxiliary equipment, if possible. Check to make sure electrodes are still securely attached to the patient, and reattach if necessary. Remember the importance of good skin preparation techniques.
RR lead off	[blank]	Unplugged cable Broken cable Loose lead wire Faulty lead wire Dried out electrode Inoperable respiration detection circuit Intentional removal by clinician	Check to make sure electrodes are still securely attached to the patient, and reattach if necessary. Remember the importance of good skin preparation techniques. Check to make sure all the lead wires are still connected to the electrodes. Check to make sure the lead wires are securely connected to the PPM3. Check to make sure there are no broken lead wires. Press ALARM SILENCE in the event of intentional removal by clinician. Turn monitor off, then back on If message persists, contact Zoe technical support.
RR artifact	---	Patient movement Electrical noise from auxiliary equipment Bad electrode contact	Calm the patient. Isolate the patient from auxiliary equipment, if possible. Check to make sure electrodes are still securely attached to the patient, and reattach if necessary. Remember the importance of good skin preparation techniques.

5. Pulse Oximetry Monitoring

5.1. Overview of Pulse Oximetry Monitoring

Pulse oximetry monitoring works by shining light of two different wavelengths through the patient's tissues (such as a fingertip) and measuring the absorption of the light by the hemoglobin in the patient's arterial blood. The way the blood absorbs the different wavelengths indicates the amount of oxygen in the blood. Since this amount is constantly changing during each beat of pulse as new blood comes in and old blood returns to the heart, it is also possible to detect a pulse rate from this signal. The Nightingale PPM3 SpO_2 algorithm uses the qualified pulsatile data averaged over a 60 second period to report the SpO_2 value.

The pulse oximetry monitoring capabilities of the Nightingale PPM3 include:

- Measuring the functional oxygen saturation of the patient's arterial hemoglobin (SpO_2)
- Calculating the patient's pulse rate (PR)
- Displaying the pulse oximetry waveform (plethysmograph) continuously
- Generating an audible pulse tone for each detected pulse, with the pulse tone pitch being tied to the SpO_2 value (higher pitch used for higher SpO_2)

5.2. Getting Started with Pulse Oximetry on the PPM3

To begin pulse oximetry monitoring, use the following procedure:

1. Select a sensor that is appropriate for the patient’s weight.
2. Attach the sensor to the patient per the instructions that come with the sensor. Please refer to the Accessories chapter for a list of approved SpO_2 sensors. Clean reusable sensors before and after each use.
3. Connect the sensor cable to the SpO_2 cable on the PPM3.

Note – See the Section 12.1.1 "ECG and Heart Rate" in the Working With Menus chapter for information on how to display pulse rate (PR) from the SpO_2 source.

5.3. Checking the Pulse Oximetry Signal

When you have connected the patient following the steps listed above, you should be able to see a clean pulse oximetry waveform on the PPM3 display as shown below. The PPM3 label for this waveform is SpO_2. The PPM3 should also display values for the patient's oxygen saturation (SpO_2) and alarm limit settings.

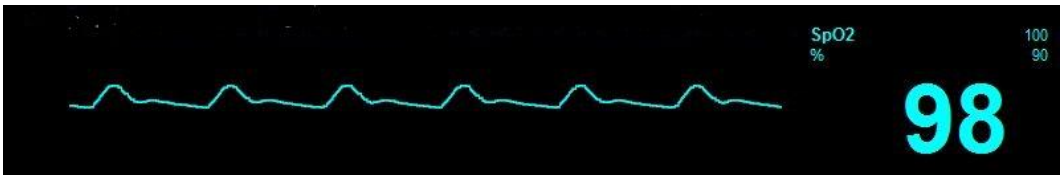


Figure 20. SpO_2 Waveform and Value

To manually test SpO_2 alarm functionality on a daily basis, apply a probe to a finger and wait for a SpO_2 value to appear. Then lower the upper alarm limit setting below the current value. Verify that "SpO_2 < [upper limit]" annunciates as a medium grade alarm. Press the ALARM SILENCE key, and return the upper alarm limit to its previous value. Verify that the alarm is no longer active and that SpO_2 monitoring continues normally.

The Pulse Oximetry Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing configuration settings, such as sourcing the pulse rate (PR) from SpO2, enabling a pulse tone, or adjusting alarm limits, may be found in the Working With Menus chapter.

WARNING – Only use pulse oximetry sensors and extender cables approved by Zoe Medical for use with the Nightingale PPM3. Unapproved components can result in degraded performance and/or device malfunction.

WARNING – Change the sensor at least every four hours (every 2 hours for poorly perfused patients). Move the sensor if you see any signs of skin irritation or impaired circulation. Reposition at least once every 24 hours to allow the patient's skin to breathe.

WARNING – Tissue damage or inaccurate measurements may be caused by incorrect SpO_2 sensor application or use, such as

wrapping too tightly, applying supplemental tape, failing to inspect periodically, or failing to position appropriately. Read the instructions provided with the SpO_2 sensor carefully prior to use.

WARNING – Elevated levels of carboxyhemoglobin or methemoglobin in monitored patients can result in inaccurate pulse oximetry readings.

WARNING – A pulse oximeter should be considered as an early warning device. As a trend towards patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter.

WARNING – Operating the PPM3 with SpO_2 limit alarms disabled means that no low or high SpO_2 alarm conditions will produce alarm notifications. Use this feature with extreme caution. Patients must be closely observed if SpO_2 limit alarms are disabled.

CAUTION – The Nightingale PPM3 does not produce a SpO_2 alarm until a valid SpO_2 signal is obtained. This is intended to reduce nuisance alarms during initial patient connection.

CAUTION – Read instructions provided with the sensor to understand the best application technique and all relevant safety information.

CAUTION – Do not apply the sensor on the same limb as the NBP cuff. During blood pressure measurements, the perfusion is temporarily reduced, which can result in inaccurate pulse oximetry readings.

CAUTION – Pulse oximetry sensors are susceptible to high ambient light interference including surgical lights, especially xenon light sources, ambient photodynamic therapy (e.g., Bilirubin lamps), fluorescent lights, infrared heating lamps, direct sunlight. Shield the sensor as necessary.

CAUTION – Pulse oximetry readings may be inaccurate in the presence of excessive motion artifact or tremors. If questionable readings are obtained, re-check the patient's vital signs by alternate means before administering medication.

Note – If the SpO_2 waveform is not currently selected for display on the PPM3, follow the instructions in the chapter on Working With Menus to select this waveform for display.

Note – The SpO_2 waveform is not proportional to pulse volume.

Note – The accuracy of a pulse oximeter probe or a pulse oximeter monitor cannot be assessed with a functional tester. The accuracy of the SpO_2 parameter in the Nightingale PPM3 has been validated with a co-oximeter per ISO 80601-2-61.

5.4. Pediatric Considerations

It is important to select a SpO_2 sensor that is appropriate for the weight of the patient. For example, a clean pulse oximetry waveform may not be obtainable when an adult sensor is used on a small child. Weight-range information can be found in the packaging that comes with the SpO_2 sensor.

5.5. Pulse Oximetry Monitoring Messages

Note – Factory default SpO_2 alarm and limit settings may be found in the PPM3 Monitor Settings chapter.

Message	Parameter Value	Possible Cause	Suggested Action
SpO_2 < [lower limit]	[number]	The patient's oxygen saturation has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
SpO_2 > [upper limit]	[number]	The patient's oxygen saturation has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
HR < [lower limit] Note – When PR is sourced from SpO_2 the Pulse Rate is labeled in cyan as "HR (SpO2)" in the HR parameter box. PR alarm conditions annunciate as HR alarms.	[number]	The patient's pulse rate has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate
HR > [upper limit] Note – When PR is sourced from SpO_2 the Pulse Rate is labeled in cyan as "HR (SpO2)" in the HR parameter box. PR alarms use the HR alarm limit settings. PR alarm conditions annunciate as HR alarms.	[number]	The patient's pulse rate has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care Change the alarm limit if it is no longer clinically appropriate

Message	Parameter Value	Possible Cause	Suggested Action
SpO_2 check sensor placement	---	Sensor has become detached from patient or is not fully inserted on patient's finger Sensor has been intentionally removed by the clinician Excessive ambient light Bad sensor (no red light coming from sensor)	Check to make sure the sensor is attached fully and securely to the patient Select "SpO_2 Alarm Pause" in the Setup SpO_2 menu Cover the sensor with opaque material, such as a towel, to reduce ambient light Reattach the sensor, possibly on a smaller or larger finger Replace sensor if there is no red light coming from it.
SpO_2 weak signal	---	Poor perfusion Large tissue mass Nail polish Bad SpO_2 sensor	Check the patient and provide any necessary clinical care Warm the patient's extremities if needed Reattach the sensor on a smaller finger Remove any nail polish that may be interfering with the red light Replace the SpO_2 sensor
HR weak signal Note – When PR is sourced from SpO_2 the Pulse Rate will be labeled in cyan as "HR (SpO2)" in the HR parameter box. A weak pulse rate signal will annunciate as "HR weak signal."	---	Poor perfusion Large tissue mass Nail polish Bad SpO_2 sensor	Check the patient and provide any necessary clinical care Warm the patient's extremities if needed Reattach the sensor on a smaller finger Remove any nail polish that may be interfering with the red light Replace the SpO_2 sensor
SpO_2 replace sensor	---	Bad SpO_2 sensor Incorrect set-up within the PPM3.	Replace the SpO_2 sensor. Contact Zoe technical support.
SpO_2 unplugged	[blank]	SpO_2 sensor not connected to SpO_2 cable	Check to make sure the SpO_2 sensor is securely connected to the SpO_2 cable on the monitor
SpO_2 artifact	---	Patient movement or coughing Hemodynamic interference Small tissue mass	Calm the patient Reattach the sensor on another finger with less movement Reattach the sensor on a larger finger

6. Non-Invasive Blood Pressure Monitoring

6.1. Overview of NBP Monitoring

The PPM3 uses an oscillometric method to measure the patient's blood pressure. In this method, a blood pressure cuff is quickly inflated above the patient's systolic pressure, and then the cuff pressure is slowly released in a series of steps. At each cuff pressure step, oscillations in the cuff pressure are measured. These oscillations are made by the underlying blood vessels which are pushing on the cuff during the cardiac cycle. From these oscillations, the patient's blood pressure can be derived.

The Non-Invasive Blood Pressure (NBP) monitoring capabilities of the Nightingale PPM3 include:

- Calculating the patient's systolic, mean, and diastolic blood pressures
- Spot check and automatic measurement intervals

6.2. Getting Started with NBP on the PPM3

To begin NBP monitoring, use the following procedure:

1. Attach the NBP cuff to the patient.

   Please refer to the Accessories chapter for a list of Zoe Medical approved NBP cuffs for use with the Nightingale PPM3. In order to get good quality NBP measurements, you need to use a cuff that is the appropriate size for the patient. Measure the circumference of the patient's limb and compare this to the size marked on the NBP cuff.

   The patient should be sitting or lying down, and the patient's arm or leg should be relaxed, extended, and resting on a stationary support.

   Wrap the deflated cuff snugly around the patient's arm or leg according to current AHA guidelines, taking care not to restrict blood circulation.

If wrapping around the arm, wrap the cuff at 2 to 5 cm above the elbow crease, and place the artery mark (↓) over the patient's brachial artery, pointing to the patient's hand.

If wrapping around the leg, wrap the cuff around the middle of the thigh, and place the artery mark (↓) over the patient's femoral artery, pointing to the patient's foot.

Instruct the patient to remain quiet and still during the measurement.

2. Connect the NBP cuff to the NBP hose, and connect the hose to the PPM3. Try to allow 5 min elapse before taking the first measurement in Step 3.

3. Start the NBP measurement by pressing the NBP START/STOP key on the PPM3 front panel.

4. After starting a measurement, if for any reason you want to stop it, simply press the NBP START/STOP key again.

5. To configure the PPM3 to take measurements automatically at a preset interval, press the NBP INTERVAL key on the front panel or select NBP Interval in the Setup NBP menu. Once changed from something other than Off, the PPM3 will display the message "NBP Interval – N minutes" in the message area, where N is the interval. See Section 10.2.3 NBP INTERVAL KEY for more information on NBP Interval Mode.

6.3. Checking the NBP Measurement

When you have connected the patient following the steps listed above, you should be able to take a blood pressure measurement. When the measurement completes, the PPM3 should display the blood pressure in the NBP parameter area as shown below along with alarm limit settings (shown as disabled below) and a time stamp. The patient's systolic and diastolic pressures are displayed in as SYS/DIA while the mean pressure is displayed in parentheses.

Figure 21. NBP Value with Interval

To manually test NBP alarm functionality on a daily basis, first apply the cuff to yourself or a patient according the instructions given above. Then enable NBP alarms and lower the systolic upper alarm limit setting to a value that is certain to generate an alarm when measured against you or the patient's pressure. Start the NBP measurement by pressing the NBP Start/Stop key. After the measurement completes, verify that "NBPs < [upper limit]" annunciates as a medium grade alarm. Press the ALARM SILENCE key, and return the systolic upper alarm limit to its previous value. Verify that the alarm is no longer active.

The NBP Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing configuration settings, such as enabling alarms, adjusting alarm limits, or setting up an automatic measurement interval, may be found in the Working With Menus chapter.

WARNING – Only use blood pressure (NBP) cuffs approved by Zoe Medical for use with the Nightingale PPM3. See the Accessories chapter.

WARNING – The cuff should fit snugly according to current AHA guidelines. Use the correct size cuff for the intended limb (see indication of cuff size in cm printed on the cuff) of the patient. The terminology printed on some BP cuffs like "child," "adult," "thigh," etc., is only an indication of the size of the cuff and should not be used to determine if the cuff is suitable for the limb. Make sure the index on the cuff is aligned with the brachial artery and that it falls within the range markers to determine whether the particular cuff fits the patient's limb or not.

WARNING – In some cases, frequent and prolonged measurements can result in petechia, ischemia, purpura or neuropathy. You should check the cuff site regularly when taking frequent measurements over an extended time period. You should also check the patient for any signs of restricted circulation in the extremities of the limb where the NBP cuff is wrapped. Switch the blood pressure cuff site as per hospital protocol or at least every four hours.

WARNING – Operating the PPM3 with NBP limit alarms disabled means that no low or high NBP alarm conditions will produce alarm

notifications. Use this feature with extreme caution. Patients must be closely observed if NBP limit alarms are disabled.

WARNING – Be sure that the NBP hose is not kinked during a measurement. Kinks in the hose could lead to sustained pressure in the blood pressure cuff, which could cause limb damage to the patient.

WARNING – Avoid applying the cuff to a wounded limb as this can cause further injury. Use with caution in patients with dermatological disease, subcutaneous laceration, or other integumentary compromise as there may exist a skin damage hazard during electronic NBP measurements. Follow prudent evidence-based clinical practice to determine if an electronic blood pressure is safe for these patients.

WARNING – There may be an increased risk of hematomas in patients with serious coagulation problems.

WARNING – Avoid applying the cuff to a limb with a catheter, arterio-venous shunt or infusion pump applied. The cuff pressure could produce damage to the tissues surrounding the catheter, shunt or the infusion needle, or compromise the infusion flow.

WARNING – Avoid placing the blood pressure cuff on the arm next to where a patient has had a mastectomy.

WARNING – To avoid the potential for spread of disease or infection, reusable blood pressure cuffs should be cleaned after each patient use. Disposable blood pressure cuffs should not be used with multiple patients.

CAUTION – Do not apply the NBP cuff on the same limb as the SpO_2 sensor. During blood pressure measurements, perfusion is temporarily reduced, which can result in inaccurate pulse oximetry readings.

CAUTION – Do not allow the NBP cuff or hose to come into contact with fluids. If this occurs, consult the Cleaning chapter of this manual for drying instructions. Check the hose and cuff frequently for signs of damage or debris. An obstruction in the hose may interfere with inflation and deflation, resulting in inaccurate NBP readings.

CAUTION – To obtain accurate blood pressure readings, keep the limb and the cuff motionless.

CAUTION – The NBP cuff should be at the same level as the patient's heart. If you cannot place the NBP cuff at this level, add to the measured pressure values 1.4 mmHg for each 2 cm above the heart level, or subtract 1.4 mmHg for each 2 cm below heart level.

CAUTION – NBP measurements may not be accurate if the patient is convulsive, experiencing tremors, or is defibrillated during the measurement.

CAUTION – NBP measurements may be affected by extremes of temperature, humidity, and altitude. Always ensure that the Nightingale PPM3 is operated and stored within its specified environmental conditions.

Note – Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or automated sphygmomanometers.

Note – The Auto Mode setting is remembered between power cycles. However, the PPM3 does not start Auto Mode NBP measurements after power up until the NBP Start/Stop key is pressed. This tells the PPM3 that the cuff has been applied to the patient and that NBP monitoring should commence.

Note – NBP readings are not continuous, but are updated each time a NBP measurement is taken. Use a shorter Auto Mode setting for more frequent updating of the patient’s blood pressure.

Note – During a measurement, a variety of safety checks are performed. These checks can cause the measurement to be cancelled and pressure to be released from the cuff. The safety checks include an overpressure check (to make sure the cuff pressure is not greater than 270 mmHg), a check to make sure the measurement does not take longer than 2¼ minutes, and other checks for technical problems such as a blocked line.

Note – This device functions according to specifications in the presence of common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation.

Note – This device can be used to determine blood pressure over a heart rate range of 30 bpm to 240 bpm.

6.4. Pediatric Considerations

The initial inflation pressure can be adjusted in the Set-up Parameter NBP menu. The default value is 160 mmHg. This can be lowered to 100 mmHg for pediatrics, thereby reducing measurement time and increasing patient comfort. If necessary after the initial measurement, the PPM will use the previous systolic pressure value to select the inflation cuff pressure.

The PPM3 automatically senses when an infant cuff is attached and limits the maximum cuff pressure to 180 mmHg, as opposed to 270 mmHg for larger cuffs.

6.5. Hypertensive Considerations

For hypertensive patients (e.g., systolic pressure greater than 220 mmHg), it may be necessary to repeat a NBP measurement if the first attempt is unsuccessful. The PPM3 will "learn" the patient's blood pressure profile from the first attempt, even if it is unsuccessful, and use a higher inflation pressure on a subsequent measurement attempt.

6.6. NBP Monitoring Messages

Note – Factory default NBP alarm and limit settings may be found in the PPM3 Monitor Settings chapter.

Message	Parameter Value	Possible Cause	Suggested Action
NBPs < [lower limit]	[number]	The patient's systolic pressure has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
NBPs > [upper limit]	[number]	The patient's systolic pressure has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
NBPd < [lower limit]	[number]	The patient's diastolic pressure has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
NBPd > [upper limit]	[number]	The patient's diastolic pressure has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
NBPm < [lower limit]	[number]	The patient's mean pressure has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
NBPm > [upper limit]	[number]	The patient's mean pressure has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
NBP Interval – N Minutes	NA	The PPM3 is in NBP Interval Mode with N being the time interval between automatic measurements.	None required.

Message	Parameter Value	Possible Cause	Suggested Action
NBP weak signal	---	Poor limb perfusion Improper cuff placement Cuff size too large for the patient	Check the patient and provide any necessary clinical care Check to make sure the cuff is wrapped properly, with the "artery" mark lined up over the brachial artery Check the limb circumference against the recommended range as printed on the cuff, to insure the cuff is not too big
NBP artifact	---	Persistent patient movement or coughing Hemodynamic interference (varying pulse amplitudes due to breathing or valvular problem) Hose is clogged or leaking	Check the patient and provide any necessary clinical care Calm the patient Move the cuff to another limb with less movement If no obvious patient motion, switching to the other limb may still help in the case of hemodynamic interference Check the cuff and hose for signs of damage
NBP cuff leak	---	Leaky cuff or hose Cuff not applied to patient	Check for leaks in the cuff or hose and replace if necessary Check that cuff and hose are connected to the monitor Check that cuff is applied to patient
NBP blocked hose – check patient	---	Pinched Hose	Check the patient and insure that the cuff is deflated Check for kinks or obstructions in the hose Replace hose if necessary
NBP measurement time exceeded	---	The measurement time limit (2¼ minutes) was exceeded, usually due to motion artifact	See suggestions for "NBP artifact" Repeat the measurement
NBP problem detected	---	Monitor has detected a hardware problem	Check the patient and insure that the cuff is deflated Turn the monitor off, then on. If message persists, contact Zoe technical support.
NBP cannot measure	---	Initial inflation pressure may not have been high enough (if patient's systolic pressure is above 200 mmHg) Patient movement	Repeat the measurement (monitor will automatically adjust to using a higher initial inflation pressure if needed)

7. Oridion CO_2 Monitoring

7.1. Overview of CO_2 Monitoring

CO_2 monitoring – also known as capnography – is a non-invasive method for monitoring the level of carbon dioxide in a patient's breath in order to help assess their ventilation status. The Oridion Microstream® modules used in the Nightingale PPM3 utilize a process known as sidestream capnography, whereby a portion of a patient's inhaled and exhaled gases are diverted and continuously passed through an infrared spectrometer. From the amount of infrared light absorbed, the amount of CO_2 present can be determined. In order to sample the patient's breath, a sampling line is typically placed in the nose and/or in the mouth for non-intubated patients and in-line with the airway tubing for intubated patients.

The CO_2 monitoring capabilities of the Nightingale PPM3 configured with Oridion Microstream® capnography include:

- Measuring the patient's end-tidal carbon dioxide ($ETCO_2$)
- Measuring the patient's fractional inspired carbon dioxide ($FICO_2$)
- Calculating the patient's respiration rate (RRc) from CO_2
- Calculating the patient's Integrated Pulmonary Index (IPI)
- Displaying CO_2 waveform (capnograph) continuously
- Detecting Apnea conditions with a configurable time setting

7.2. Getting Started with Oridion CO_2 on the PPM3

To begin CO_2 monitoring with Oridion Microstream® sidestream capnography, use the following procedure:

1. If CO_2 monitoring has *not* been enabled (indicated by the presence of impedance respiration box with *blue* labels underneath the green HR parameter box), press the SETUP key on the PPM3, scroll the control knob to Parameters, press the knob, press on the highlighted "$ETCO_2$ Enabled," scroll to "Yes," and press the knob. Press the Main Screen key to apply the changes. Now the CO_2 waveform area and parameter box

should appear in *yellow* beneath the top channel ECG lead – replacing the impedance respiration parameter box and waveform area.

2. Select the proper Oridion CapnoLine® or FilterLine® single-use sampling line based on clinical guidelines and hospital standard of care.
3. Open the cover labeled Microstream® $ETCO_2$ on the PPM3 left side.
4. Place the orange or yellow threaded connector of the sampling line into the CO_2 input port beneath the opened cover.
    a. Gently turn the connector clockwise into the CO_2 input port until a secure connection is achieved. DO NOT OVER TIGHTEN. Over tightening may warp the connector such that ventilation or the CO_2 measurement may be compromised. This assures that there is no leakage of gases during measurement at the connection point and that measurement accuracy is not compromised.
    b. When the connector is secure, the CO_2 pump should start and the "CO2 Warming Up" message will briefly appear.
5. Securely connect all components and check connections for leaks according to standard clinical procedures.
6. Connect the patient applied end of the sampling line to the patient as per instructions included with the CapnoLine ® or FilterLine® packaging.
7. The CO_2 waveform and numeric parameter values should appear within approximately 10 seconds.

7.3. Checking the CO_2 Signal

When you have connected the patient following the steps listed above, you should be able to see a CO_2 waveform on the PPM3 display as shown below. The PPM3 should also display values for the patient's end-tidal carbon dioxide ($ETCO_2$), fractional inspired carbon dioxide ($FICO_2$), respiration rate from CO_2 (RRc), Integrated Pulmonary Index (IPI), and alarm limit settings. The infrared light source used in the Microstream® module generates only the specific wavelengths characteristic of the CO_2 absorption spectrum. Therefore, no compensations are required when different concentrations of N_2O, O_2, anesthetic agents, and water vapor are present in the patient’s gases.

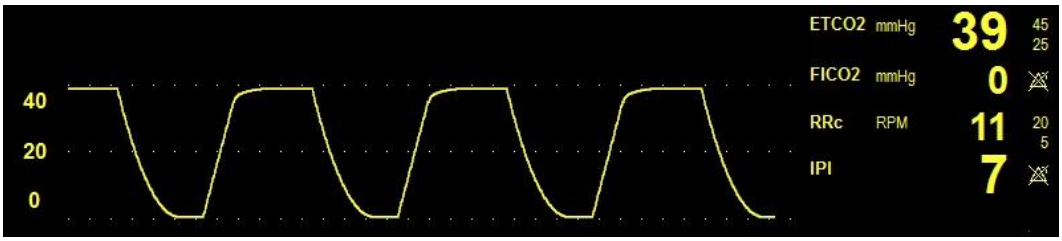


Figure 22. Oridion CO_2 Waveform and Values

To manually test CO_2 monitoring alarm functionality on a daily basis, you may use the following approach. First, either connect the patient to the Nightingale PPM3 using the above procedure or continue as follows with a patient who is already being monitored. Then, enable the alarms $ETCO_2$, RRc, $FICO_2$, and IPI. Next, lower the $ETCO_2$ upper alarm limit setting below its current value. Verify that "$ETCO_2$ < [upper limit]" annunciates as a medium grade alarm. Press the ALARM SILENCE key, and return the $ETCO_2$ upper alarm limit to its previous value. Verify that the alarm is no longer active, and that CO_2 monitoring continues normally. Repeat this process in turn for the RRc, $FICO_2$, and IPI parameters (lower limit).

The CO_2 Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing configuration settings, such as adjusting alarm limits, changing the waveform size (amplitude), setting the apnea time, or enabling or disabling IPI, etc. may be found in the Working With Menus chapter.

7.4. Integrated Pulmonary Index

The Integrated Pulmonary Index (IPI) is a parameter that uses capnography, respiration rate, pulse rate (from SpO_2), and pulse oximetry to articulate a single numeric value to describe a patient's overall ventilatory status. All four values are necessary to calculate the IPI parameter. The IPI may provide an early indication of ventilatory changes that may not be evident in any of the four parameters individually. Also, since IPI is based on physiological parameters that can change with age, the Nightingale PPM3 will prompt you to pick from one of three pediatric age changes (1-3 years, 3-6 years, and 6-12 years) when using IPI with a pediatric patient type selected.

The IPI is a numeric value ranging from 1 to 10, where 10 indicates optimal pulmonary status. According to Oridion Medical, the following table presents a guide for clinical intervention based on IPI numeric values. Contact Oridion Medical for further details on IPI clinical intervention. The Nightingale PPM3 supports an IPI low alarm limit such that an alarm is annunciated when the IPI value drops below a configured low alarm limit setting.

IPI	Patient Status
10	Normal
8-9	Within normal range
7	Close to normal range – requires attention
5-6	Requires attention and may require intervention
3-4	Requires intervention
1-2	Requires immediate intervention

Figure 23. Integrated Pulmonary Index

Oridion Medical (2009). *Integrated Pulmonary Index™*. Retrieved from http://www.oridion.com/Assets/Products/Technology/IPIChart.jpg.

WARNING – Operating the Nightingale PPM3 with CO_2x limit alarms disabled (where x = $ETCO_2$, RRc, $FICO_2$, and IPI) means that no low or high CO_2x alarm conditions will produce alarm notifications. Use this feature with extreme caution. Patients must be closely observed if CO_2x limit alarms are disabled.

WARNING – When monitoring an anesthetized patient in an operating room environment, it is recommended to connect the CO_2 exhaust port of the Nightingale PPM3 to the hospital's waste gas scavenging system so as to prevent exposure for other patients and hospital personnel to the patient's respiratory sample. Ensure that sampled gases are not returned from the exhaust port to a breathing system such as a ventilator. Use standard clinical guidelines and/or hospital

procedures. Scavenge vacuum greater than 1mmHg may result in damage to the Nightingale PPM3.

WARNING – Always inspect the airway for a tight connection before attaching it to the patient.

WARNING – Remove the airway sampling line from the patient's airway while nebulizing medications are being delivered.

WARNING – Route all tubing away from the patient's throat to avoid strangulation.

WARNING – Do not apply pressurized air to any outlet or tubing connected to the monitor. Pressure may destroy sensitive elements.

WARNING – When using a sampling line for intubated patients with a closed suction system, do not place the airway adapter between the suction catheter and endotracheal tube. This is to ensure that the airway adapter does not interfere with the functioning of the suction catheter.

WARNING – Do not cut or remove any part of the sampling line. Cutting the sampling line could lead to erroneous readings.

WARNING – If too much moisture enters the sampling line (i.e., from ambient humidity or breathing of unusually humid air), the message "Purging Line" will appear in the message area. If the sampling line cannot be cleared, the message "Occluded Line" will appear in the message area. Replace the sampling line once the "Occluded Line" message appears.

CAUTION – The Nightingale PPM3 does not produce a CO_2 alarms until a valid CO_2 signal is obtained. This is intended to reduce nuisance alarms during initial patient connection.

CAUTION – Microstream® $ETCO_2$ sampling lines are designed for single patient use, and are not to be reprocessed. Do not attempt to clean, disinfect, sterilize or flush any part of the sampling line as this can cause damage to the monitor.

CAUTION – Before use, carefully read the Microstream® $ETCO_2$ sampling lines Directions for Use.

CAUTION – Only use Microstream® $ETCO_2$ sampling lines to ensure the monitor functions properly.

Note – When the caution message "Occluded Line" appears on the screen, indicating that the sampling line which is attached to the monitor is blocked, the monitor's CO_2 pump will stop pumping the patient's breath into the monitor for testing. Follow the instructions that appear in the Troubleshooting chapter of this manual: First disconnect and reconnect the sampling line. If the message still appears, disconnect and replace the line. Once a working sampling lie is attached to the monitor, the pump will automatically resume operation.

Note – The IPI is not intended to replace accurate clinician assessment of the patient's ventilatory status. The IPI can be used as another data point in the overall assessment of the patient.

7.5. Oridion CO_2 Monitoring Messages

Note – Factory default CO_2 alarm and limit settings may be found in the PPM3 Monitor Settings chapter.

Message	Parameter Value	Possible Cause	Suggested Action
$ETCO_2$ < [lower limit]	[number]	The patient's $ETCO_2$ parameter value has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
$ETCO_2$ > [upper limit]	[number]	The patient's $ETCO_2$ parameter value has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
$FICO_2$ > [upper limit]	[number]	The patient's $FICO_2$ parameter value has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR < [lower limit]	[number] -or- [0]	[number]: The patient's respiration rate (RRc) has fallen below the current lower alarm limit. [0]: No breath has been detected for the user-configurable apnea time.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR > [upper limit]	[number]	The patient's respiration rate (RRc) has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR out of range (too high)	---	The patient's respiration rate (RRc) has risen above the maximum value the monitor can accurately detect. Monitor confused by signal artifact.	Check the patient and provide any necessary clinical care.
IPI < [lower limit]	[number]	The patient's IPI parameter value has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
CO_2 Warming Up	---	CO_2 module is preparing to acquire data.	Allow more time.

Message	Parameter Value	Possible Cause	Suggested Action
IPI age range not set	---	For pediatric patients, the age range must be set to correctly determine IPI.	Set the age range in the CO_2 setup screen.
CO_2 Unplugged	---	CO_2 sampling line is not connected.	Connect the CO_2 sampling line to the PPM3. Disable CO_2 monitoring in the PPM3 Parameters menu if these parameters are no longer clinically required.
CO_2 Occluded Line	---	CO_2 sampling line cannot be cleared due to moisture or other obstruction.	Replace the sampling line. If connected to scavenging system, disconnect to see if message disappears.
CO_2 Purging Line	---	Microstream module is trying to clear excess humidity	If the message disappears, resume usage. If the purging operation is unsuccessful or the Occluded Line message appears, disconnect the line and reattach. If the problem continues, replace the sampling line.
CO_2 problem detected	---	CO_2 interface has encountered a problem.	Check the CO_2 subsystem including sampling line and exhaust port. Verify that the exhaust port is not blocked.

8. Masimo CO_2 Monitoring

8.1. Overview of CO_2 Monitoring

CO_2 monitoring – also known as capnography – is a method for assessing a patient's ventilation status through the monitoring of carbon dioxide levels in their breath. Two different Masimo capnography modules – the ISA™ and the IRMA™ – are available for use with the Nightingale PPM3. The Masimo ISA™ utilizes a non-invasive approach known as sidestream capnography, whereby a portion of a patient's inhaled and exhaled gases are diverted into a disposable nasal cannula. The gases collected through the cannula are continuously passed through a moisture-eliminating wick/bacterial filter and then through an infrared spectrometer, which is housed within the small ISA module. Based on the amount of infrared light absorbed, the amount of CO_2 present and the respiration rate can be determined.

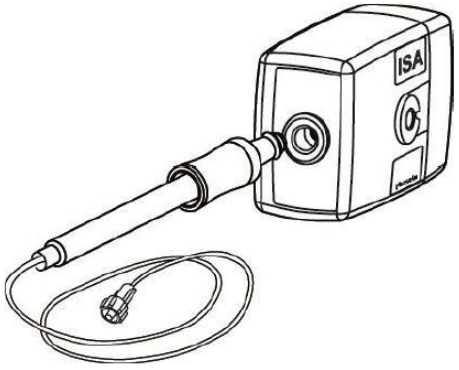


Figure 24. Masimo ISA Module With Nomoline

Figure 25. Masimo IRMA Module With Airway Adapter

The Masimo IRMA™ utilizes an approach known as mainstream capnography in which a disposable airway adapter is inserted directly in-line with the patient's breathing circuit, such that all of their inhaled and exhaled gases are analyzed. The IRMA module, which contains the infrared spectrometer, clips around the outside of the adapter. From the perspective of the clinician, the ISA and IRMA module uses the same user interface and connect through the same OMD port on the Nightingale PPM3.

The CO_2 monitoring capabilities of the Nightingale PPM3 configured with Masimo capnography include:

- Measuring the patient's end-tidal carbon dioxide ($ETCO_2$)
- Measuring the patient's fractional inspired carbon dioxide ($FICO_2$)
- Calculating the patient's respiration rate (RRc) from CO_2
- Displaying CO_2 waveform (capnograph) continuously
- Detecting Apnea conditions with a configurable time setting

8.2. Getting Started with Masimo CO_2 on the PPM3

To begin CO_2 monitoring with Masimo ISA or IRMA capnography, use the following procedure:

1. Connect the electrical/data cable which is part of the ISA module or IRMA adapter into the Other Medical Device (OMD) port labeled as "1010 B"or "EtCO2" on the left side of the PPM3.
2. If CO_2 monitoring has *not* been enabled (indicated by the presence of impedance respiration box with *blue* labels underneath the green HR parameter box), press the SETUP key on the PPM3, scroll the control knob to Parameters, press the knob, press on the highlighted "$ETCO_2$ Enabled," scroll to "Yes," and press the knob. Press the Main Screen key to apply the changes. Now the CO_2 waveform area and parameter box should appear in *yellow* beneath the top channel ECG lead – replacing the impedance respiration parameter box and waveform area.
3. Connect Masimo accessories:
   a. ISA (sidestream):

      Connect a Masimo Nomoline accessory to the Light Emitting Gas Inlet (LEGI) connector on the front of the ISA module (See Figure 24). The most commonly used accessory will be the Nomoline adapter with a female Luer Lock connector. Once the adapter is plugged in, the LEGI will begin flashing in green as the ISA self-zeroes, and the message area on the PPM3 will display "CO_2 Warming Up."

Figure 26. Nomoline Adpater – Female Luer Lock

This will only last a few seconds, and the LEGI will change to a steady green when the module is ready.

b. IRMA (mainstream):

Using the appropriate adult or pediatric IRMA airway adapter, snap the IRMA module in place onto the adapter. The LED on top of the module will begin flashing in green as the IRMA self-zeroes, and the message area on the PPM3 will display "CO_2 Warming Up." This will only last a few seconds, and the LED will change to a steady green when the module is ready.

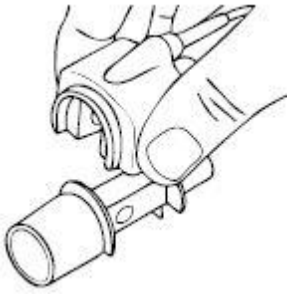


Figure 27. Snapping IRMA Onto Adapter

4. Apply to patient or breathing circuit:

   a. ISA (sidestream):

   Connect an appropriate nasal cannula or other sampling line with a male Luer Lock fitting to the Nomoline adapter. Apply the other end to the patient according to the instructions supplied.

   Note – Using sampling lines or cannulas with an inner diameter larger than 1 mm will increase the ISA's total response time.

   b. IRMA (mainstream):

   Connect the IRMA airway adapter between the breathing circuit Y-piece and the patient's endotracheal tube – or into any other suitable ventilation system. Perform a tightness check of the breathing circuit.

5. With either the ISA or IRMA module the CO_2 waveform and numeric parameter values should appear on the PPM3 main screen within a few seconds. Verify parameter values and waveforms for correctness.

8.3. Checking the CO_2 Signal

When you have connected the patient following the steps listed above, you should be able to see a CO_2 waveform on the PPM3 display as shown below. The PPM3 should also display values for the patient's end-tidal carbon dioxide ($ETCO_2$), fractional inspired carbon dioxide ($FICO_2$), respiration rate from CO_2 (RRc), and alarm limit settings. With either the ISA or IRMA modules there is negligible impact on CO_2 measurement accuracy in the presence of O_2 or N_2O as long as the correct O_2 and/or N_2O Compensation value has been selected. See Figure 37 as well as the PPM3 Monitor Settings chapter.

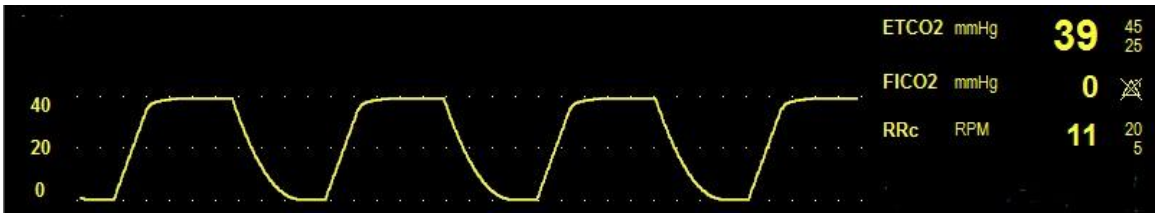


Figure 28. Masimo CO_2 Waveform and Values

To manually test CO_2 monitoring alarm functionality on a daily basis, you may use the following approach. First, either connect the patient to the Nightingale PPM3 using the above procedure or continue as follows with a patient who is already being monitored. Then, enable the alarms $ETCO_2$, RRc, and $FICO_2$. Next, lower the $ETCO_2$ upper alarm limit setting below its current value. Verify that "$ETCO_2$ < [upper limit]" annunciates as a medium grade alarm. Press the ALARM SILENCE key, and return the $ETCO_2$ upper alarm limit to its previous value. Verify that the alarm is no longer active, and that CO_2 monitoring continues normally. Repeat this process in turn for the RRc and $FICO_2$ parameters.

The CO_2 Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing configuration settings, such as adjusting alarm limits, changing the waveform size (amplitude), setting the apnea time, or selection O_2 and/or N_2O compensation values may be found in the Working With Menus chapter.

8.4. Masimo LED Indicator

The LEGI Status Indicator on the ISA module and the Status LED on the IRMA module may be interpreted according to the table presented below. Also consult any result messages the PPM3 may present as found in Section 8.6 – Masimo CO_2 Monitoring Messages.

Color and Pattern	Indication
Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check adapter

8.5. Zeroing Masimo CO_2 Modules

For the IRMA (mainstream) CO_2 module, zeroing is performed by snapping a new IRMA airway adapter onto the IRMA module, without connecting the airway adapter to the patient circuit, and then pressing the Zero Set menu button in the Setup CO_2 menu. An alert tone will sound when the zeroing procedure has started, along with a "CO_2 zeroing" message. The alert tone will resound when the zeroing procedure has completed.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter is of crucial importance for a successful zeroing.

Zeroing needs to be performed only when an offset in gas values is observed, or when the "CO_2 needs zeroing" message is displayed. When initially connecting the IRMA CO_2 probe to the PPM3 or when changing IRMA airway adapters, allow a 10-second warm-up period before initiating the zeroing procedure.

Once zeroing has completed, reconnect the airway adapter into the breathing circuit, using the Getting Started instructions that are described earlier in this section.

For the ISA (sidestream) CO2 module, zeroing is performed automatically by the module by switching the gas sampling from the breathing circuit to ambient air. This auto-zeroing is performed 1 to 3 times per 24 hours, and takes less than 3 seconds to complete. The zeroing procedure can also be initiated via the Zero Set menu button in the Setup CO_2 menu, though this is not usually needed.
.

WARNING (ISA) – The ISA sidestream gas analyzer is intended for use by authorized healthcare professional only.

WARNING (ISA) – Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.

WARNING (ISA) – Do not lift the ISA or the PPM3 monitor by the sampling line as it could disconnect from the ISA or PPM3, causing the ISA or PPM3 to fall on the patient.

WARNING (ISA) – Dispose Nomoline Family sampling lines in accordance with local regulations for biohazardous waste.

WARNING (ISA) – Use only airway T-adapters with the sampling point in the center of the adapter.

WARNING (ISA) – Do only use sample lines intended for anesthetic agents if N_2O or anesthetic agents are being used.

WARNING (ISA) – Do not use T-adapter with infants, as this adds 7 ml dead space to the patient circuit.

WARNING (ISA) – Do not use the ISA analyzer with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.

WARNING (ISA) – Since a successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2), ensure that the ISA is placed in a well ventilated place. Avoid breathing near the ISA sidestream gas analyzer before or during the zeroing procedure.

WARNING (ISA) – Never sterilize or immerse the ISA sidestream gas analyzer in liquid.

WARNING (ISA) – ISA sidestream gas analyzer is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

WARNING (ISA) – Measurements can be affected by mobile and portable RF communications equipment. Make sure that the ISA sidestream analyzer is used in the electromagnetic environment specified in this manual.

WARNING (ISA) – Replace the sampling line if the sampling line input connector starts flashing red, or a "CO_2 Occluded Line" message appears on the PPM3.

WARNING (ISA) – No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.

WARNING (ISA) – ISA sidestream gas analyzers are not appropriate for MRI environments.

WARNING (ISA) – During MRI scanning, the ISA must be placed outside the MRI suite.

WARNING (ISA) – Use of high frequency electrosurgical equipment in the vicinity of the ISA analyzer may product interference and cause incorrect measurements.

WARNING (ISA) – Do not apply negative pressure to remove condensed water from the Nomoline family sampling line.

WARNING (ISA) – Too strong positive or negative pressure in the patient circuit might affect the sample flow.

WARNING (ISA) – Strong scavenging suction pressure might affect the sample flow.

WARNING (ISA) – Exhaust gases should be returned to the patient circuit or to a scavenging system.

WARNING (ISA) – Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.

WARNING (ISA) – Do not place the ISA gas analyzer in any position that might cause it to fall on the patient.

WARNING (ISA) – Do not re-use disposable single-patient use Nomoline Family sampling lines due to the risk of cross contamination.

WARNING (ISA) – Do not sterilize or immerse Nomoline Family sampling lines in liquid.

WARNING (ISA) – Do not operate the ISA sidestream gas analyzer if the enclosure is damaged.

WARNINGS (IRMA) – The IRMA probe is intended for use by authorized and trained medical personnel only.

WARNINGS (IRMA) – The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.

WARNINGS (IRMA) – The IRMA probe must not be used with flammable anesthetic agents.

WARNINGS (IRMA) – Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.

WARNINGS (IRMA) – Used airway adapters shall be disposed of in accordance with local regulations for medical waste.

WARNINGS (IRMA) – Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.

WARNINGS (IRMA) – Do not use the IRMA infant airway adapter with adults as this may cause excessive flow resistance.

WARNINGS (IRMA) – Measurements can be affected by mobile and RF communications equipment. It should be assumed that the IRMA probe is used in the electromagnetic environment specified in this manual.

WARNINGS (IRMA) – Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.

WARNINGS (IRMA) – To keep secretions and moisture from pooling on the windows or oxygen sensor port, always position the IRMA probe in a vertical position with the LED pointing upwards.

WARNINGS (IRMA) – Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.

WARNINGS (IRMA) – Incorrect probe zeroing will result in false gas readings.

WARNINGS (IRMA) – Incorrect agent selection by the user for IRMA OR (no automatic agent identification) will result in false agent readings.

WARNINGS (IRMA) – Replace the airway adapter if rainout or condensation occurs inside the airway adapter.

WARNINGS (IRMA) – Use only PHASEIN manufactured IRMA airway adapters.

WARNINGS (IRMA) – The IRMA probe is not intended to be in patient contact.

CAUTION (ISA) – The ISA analyzer should be securely mounted in order to avoid the risk of damage to the ISA.

CAUTION (ISA) – Do not operate the ISA sidestream gas analyzer outside the specified operating environment.

CAUTION (ISA) – (U.S. only) Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

CAUTION (IRMA) – Never sterilize or immerse the IRMA probe in liquid.

CAUTION (IRMA) – IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.

CAUTION (IRMA) – Do not apply tension to the probe cable.

CAUTION (IRMA) – Do not operate the IRMA probe outside the specified operating environment.

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

8.6. Masimo CO_2 Monitoring Messages

Note – Factory default CO_2 alarm and limit settings may be found in the PPM3 Monitor Settings chapter.

Message	Parameter Value	Possible Cause	Suggested Action
$ETCO_2$ < [lower limit]	[number]	The patient's $ETCO_2$ parameter value has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
$ETCO_2$ > [upper limit]	[number]	The patient's $ETCO_2$ parameter value has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
$FICO_2$ > [upper limit]	[number]	The patient's $FICO_2$ parameter value has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR < [lower limit]	[number] -or- [0]	[number]: The patient's respiration rate (RRc) has fallen below the current lower alarm limit. [0]: No breath has been detected for the user-configurable apnea time.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR > [upper limit]	[number]	The patient's respiration rate (RRc) has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
RR out of range (too high)	---	The patient's respiration rate (RRc) has risen above the maximum value the monitor can accurately detect. Monitor confused by signal artifact.	Check the patient and provide any necessary clinical care.
CO_2 Warming Up	---	CO_2 module is preparing to acquire data.	Allow more time.
CO_2 Unplugged	---	ISA module or IRMA sensor have become unplugged from PPM3.	Reconnect the electrical/data cable to OMD port labeled "1010 B" or "EtCO2".

Message	Parameter Value	Possible Cause	Suggested Action
CO_2 Occluded Line	---	ISA CO_2 sampling line cannot be cleared due to moisture or other obstruction.	Replace the sampling line. If connected to scavenging system, disconnect to see if message disappears.
CO_2 No Sampling Line	---	ISA CO_2 sampling line has become unplugged from the LEGI connector on the front of the module.	Reconnect the sampling line.
CO_2 Check Adapter	---	1) The lens within IRMA airway adapter has become fogged or blocked. 2) IRMA airway adapter has become unplugged from the sensor.	Replace or reconnect the airway adapter.
CO_2 Needs Zeroing	---	CO_2 zero offset needs to be removed.	Follow the zeroing procedure provided in this chapter.
CO_2 Check Sensor	---	ISA module or IRMA sensor have reported an internal error.	Disconnect the module or adapter from the PPM3 and then reconnect. Contact technical support if the problem continues.
CO_2 problem detected	---	CO_2 interface has encountered a problem.	Check the CO_2 subsystem including sampling line and exhaust port. Verify that the exhaust port is not blocked. Power-cycle the PPM3. Contact technical support if the problem continues.

9. Invasive Blood Pressure Monitoring

9.1. Overview of IBP Monitoring

Invasive blood pressure monitoring (P1 and P2) is a direct measurement of the patient's arterial or venous pressure. The invasive pressure setup, consisting of connecting tubing, a pressure transducer, and a fluid source to maintain pressure (all connected together by stopcocks) is attached to the catheter. The transducer is placed at the same level with the heart, and is electrically zeroed. The transducer is a piezo-resistive device that converts the pressure signal to a voltage. The monitor interprets the voltage signal so that pressure data and pressure waveforms can be displayed.

The IBP monitoring capabilities of the Nightingale PPM3 include:

- Measuring the patient's pressures across two IBP channels (P1 and P2)
- Calculating the P1 and P2 values in mmHg using either Sys/Dia (Mean) or (Mean) Sys/Dia formats
- Calculating pulse rate from an IBP labeled as ART
- Displaying P1and P2 values with a choice of P1 and P2 (default) or ART, PA, and CVP labels
- Displaying P1 and P2 waveforms continuously

To connect pressure transducers made by various manufacturers to the PPM3, Zoe provides a connector adapter kit (Part Number 350-0280).

To begin IBP monitoring, use the following procedure:

1. If IBP monitoring has not been enabled (indicated by the absence of P1 or P2 parameter boxes and waveform areas below SpO_2), press the Setup key on the PPM3, scroll the control knob to Parameters and press, scroll to "IBP Channels," press the knob, and scroll from "None" to "1" or "2" pressing the knob to select your choice. Press the Main Screen key to apply the changes. Now the P1 and P2 waveform areas and parameter boxes (or just P1 if "1" was selected) should appear beneath the SpO_2 area. "P1 needs zeroing" and "P2 needs zeroing" messages should also appear in the message area.
2. If "1" was selected, connect a pressure transducer cable to the invasive pressure port on the left side of the Nightingale PPM3 labeled P1/P2. If "2" was selected, connect a PPM3 IBP Y-cable, (Zoe Medical accessory, Part Number 421-6102). Then connect the invasive pressure cable(s) to the Y-cable, while keeping track of the P1 and P2 labels on Y-cable connectors to make sure you have the correct IBP cable connected to the correct port on the Y-cable.

Note – From this point, complete steps 3 through 9 first for P1. Repeat, substituting P2 for P1 as required.

3. Connect each transducer manifold to the correct invasive pressure cable.
4. Scroll the control knob to the P1 parameter box and press the knob.
5. Select the invasive pressure label for this channel if the P1 default is not appropriate.
6. Verify format (Sys/Dia or Mean) and waveform size are appropriate.
7. Zero the pressure by opening the transducer vent, and then scrolling the PPM3 control knob to "Zero Set" and pressing. This should cause the "P1 needs zeroing message" to transition to "P1 zeroing" and then "P1 zero okay." The numeric values for P1 should also display as zeroes.
8. Close the transducer vent.
9. Connect the transducer to the patient per clinical guidelines. Follow standard hospital procedures for zeroing and flushing the pressure line.

9.2. Checking the IBP Signal(s)

When you have connected the patient following the steps listed above, you should be able to see IBP waveform(s) on the PPM3 display as shown below. The PPM3 should also display values for the patient's P1 and P2 pressures (with correct formats and labels) as well as the alarm limit settings (shown as disabled for systolic, mean, and diastolic below).

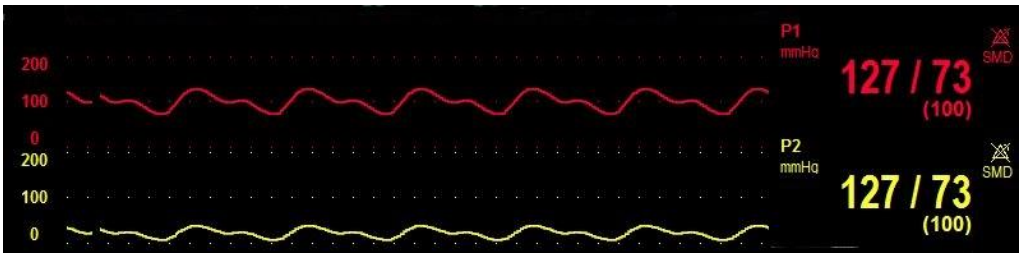


Figure 29. IBP Waveforms and Values

To manually test IBP alarm functionality on a daily basis, you may choose from two approaches. First, if a patient is currently being monitored with IBP, make certain the alarms are enabled, and then lower the P1 (or P2) systolic upper alarm limit setting below its current value. Verify that "P1s < [upper limit]" (or P2s) annunciates as a medium grade alarm. Press the ALARM SILENCE key, and return the upper alarm limit to its previous value. Verify that the alarm is no longer active. Alternatively, when first connecting an IBP, unplug the IBP cable from the Y-cable after completing step 7 above. Verify that "P1 unplugged" (or P2) alarm annunciates as a low grade alarm. Plug the cable back in. Verify that the alarm ceases. Then re-zero the pressure and continue with steps 8 and 9.

The IBP Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing configuration settings, such as adjusting waveform sizes, alarm limits, etc. may be found in the Working With Menus chapter.

WARNING – All invasive procedures involve risks to the patient. Use aseptic technique. Follow catheter manufacturer's instructions and established hospital guidelines.

WARNING – Always follow the hospital standard of care and prudent clinical discretion for connecting, zeroing, and monitoring IBP lines.

WARNING – Operating the Nightingale PPM3 with P1 and/or P2 alarm limits disabled means that no low or high P1 and/or P2 alarm conditions will product alarm notifications. Use this feature with extreme caution. Patients must be closely observed if P1 and/or P2 limit alarms are disabled.

WARNING – Ensure that no part of the patient connections touches any electrically conductive material including earth.

WARNING – Only use invasive pressures transducers that can withstand defibrillation as required by ANSI/AAMI BP22 standard.

WARNING – Mechanical shock to the invasive blood pressure transducer may cause severe shifts in zero balance and calibration, and cause erroneous readings.

Note – To reduce nuisance alarms, the invasive pressure alarms are inactivated for a few seconds during the zeroing process. Invasive pressure alarms are reactivated shortly after the zeroing process has been completed.

9.3. IBP Monitoring Messages

Note – Factory default IBP alarm and limit settings may be found in the PPM3 Monitor Settings chapter.

Note – Substitute P2 for P1 as required in the following table.

Message	Parameter Value	Possible Cause	Suggested Action
P1s < [lower limit] P1m < [lower limit] P1d < [lower limit]	[number]	The patient's invasive systolic/diastolic/mean pressure has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Verify that the values are not due to artifact by checking the position of the patient, cables and transducer. Zero set the pressure if necessary. Change the alarm limit if it is no longer clinically appropriate.
P1s > [upper limit] P1m > [upper limit] P1d > [upper limit]	[number]	The patient's invasive systolic/diastolic/mean pressure has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Verify that the values are not due to artifact by checking the position of the patient, cables and transducer. Zero set the pressure if necessary. Change the alarm limit if it is no longer clinically appropriate.
P1 signal out of range [low] P1 signal out of range [high]	--	The invasive signal is out of range.	Verify the position of the patient, cables and transducer. Zero set the pressure if necessary
P1 unplugged	--	IBP cable or transducer not plugged	Verify that the cable and transducer are properly connected. Press ALARM SILENCE if intentionally unplugged by clinician.
Unable to zero	--	Stopcock is not open	Open the stopcock and check tubing and cables
Zero required	--	IBP channel not zeroed	Zero the IBP channel
Zero required and 60 seconds has expired	--	IBP channel not zeroed	Zero the IBP channel
Calibration required	--	IBP channel requires calibration	Arrange for calibration service of the IBP channel
Calibration in progress	--	IBP channel calibration is in progress	Wait until the calibration process is completed
Cannot calibrate	--	Calibration failed	Contact Zoe Medical technical support
ART: Check Transducer	--	ART IBP pressure below 10mmHg	Check ART catheter to ensure that it is properly positioned and connected

10. Temperature Monitoring

The temperature monitoring capabilities of the Nightingale PPM3 include:

- Measuring the patient's temperature using a core temperature probe
- Displaying the TEMP parameter in degrees Celsius or degrees Fahrenheit

To begin temperature monitoring, use the following procedure:

1. Fully insert the probe into a probe cover.
2. Apply the probe to the patient

   Please refer to the Accessories chapter for a list of Zoe Medical approved temperature probes for use with the Nightingale PPM3.

   For oral application: Insert the probe as indicated in the Zoe Medical "Oral Temperature Probe Instructions," P/N 122-0030.

   For surface application: Apply the probe to a location on the patient that stays fairly dry (the abdomen is recommended). To ensure good adhesion, clean the skin with alcohol before-hand. Tape the probe and cable to the patient's skin.
3. Connect the temperature probe cable to the PPM3.

Note – Probe performance is unaffected when used without a probe cover.
Note – Follow the instructions for use provided with the probe packaging.
Note – Place the probe according to the clinical techniques of your hospital.
Note – Skin surface temperature is typically 2 to 3 °F below core temperature.

10.1. Checking the Temperature

When you have connected the patient following the steps listed above, you should be able to see a temperature value on the PPM3 display as well as the alarm limit settings (shown as disabled below).

Figure 30. TEMP Value

To manually test TEMP alarm functionality on a daily basis, you may choose from two approaches. First, if a patient's temperature is currently being monitored, make certain the alarms are enabled, and then lower the TEMP upper alarm limit setting below its current value. Verify that "TEMP < [upper limit]" annunciates as a medium grade alarm. Press the ALARM SILENCE key, and return the upper alarm limit to its previous value. Verify that the alarm is no longer active, and that temperature monitoring continues normally. Alternatively, before initiating temperature monitoring with a patient, you can verify TEMP alarm functionality by rubbing a probe (with cover applied) between your hands until an upper limit alarm is generated.

The Temperature Monitoring settings and specifications for the Nightingale PPM3 may be found in the PPM3 Monitor Settings and Technical Data chapters. Procedures for changing the units or adjusting alarm limits may be found in the Working With Menus chapter.

WARNING – Disabling the Temperature alarm limits means that no low or high TEMP alarm conditions will produce alarm notifications.

10.2. Temperature Monitoring Messages

Note – Factory default Temperature alarm and limit settings may be found in the Menu Settings table in the PPM3 Monitor Settings chapter.

Message	Parameter Value	Possible Cause	Suggested Action
TEMP < [lower limit]	[number]	The patient's temperature has fallen below the current lower alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
TEMP > [upper limit]	[number]	The patient's temperature has risen above the current upper alarm limit.	Check the patient and provide any necessary clinical care. Change the alarm limit if it is no longer clinically appropriate.
TEMP unplugged	[blank]	Temperature probe disconnected	Check to make sure the temperature probe is connected to the temperature cable. Check to make sure the temperature cable is connected to the PPM3.
TEMP out of range	---	The patient's temperature has risen above the maximum value the monitor can accurately detect. There is a problem with the connections or with the hardware.	Check the patient and provide any necessary clinical care. Check the temperature cable connections. Turn the monitor off, then on. If message persists, contact Zoe technical support.
TEMP problem detected	---	Monitor has detected a hardware problem.	Turn the monitor off, then on. If message persists, contact Zoe technical support.

11. Working With Menus

The PPM3 menus allow you to view the configuration settings for each of the vital sign parameters and make changes to the settings as necessary. This is accomplished by navigating the different menus via the control knob. Turning the knob clockwise or counterclockwise allows you to scroll through menu items. Pressing the knob selects the currently highlighted menu item.

When the PPM3 is displaying the Main Screen, turning the knob highlights the various parameter boxes in turn. Selecting a given parameter box brings up a menu that allows you to change settings related to that parameter. When you have entered the change you wanted to make, select OK. If you select Cancel, the menu will disappear, and the setting will keep the value it had when you first brought up the menu.

This chapter instructs you in how to use these parameter setup menus as well as the menus behind keys on the PPM3 front panel.

Note – The complete list of factory default settings for the Nightingale PPM3 may be found in the PPM3 Monitor Settings chapter.

11.1. Parameter Menus

11.1.1. ECG and Heart Rate

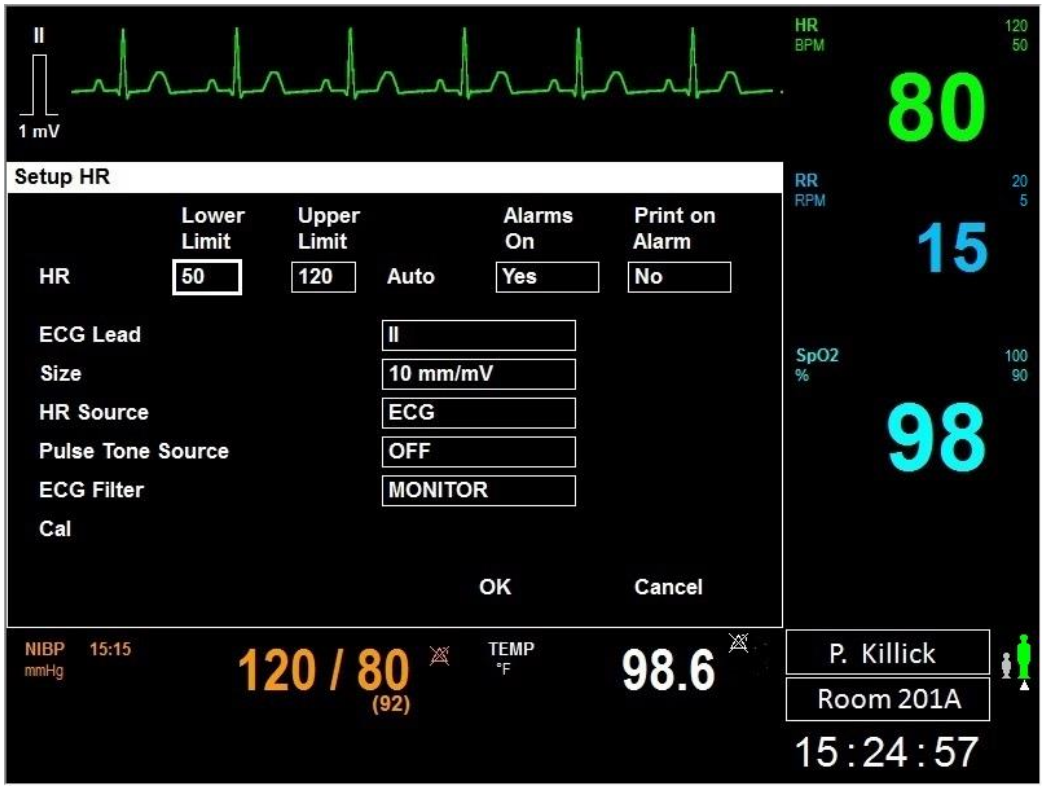


Figure 31. Setup HR Menu

Setting	Description
Lower Limit	HR/PR alarm lower limit
Upper Limit	HR/PR alarm upper limit
Auto	Auto-adjust lower limit to 80% of current value and upper limit to 125% of current value (or the nearest allowable values given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm condition
ECG Lead	Select lead used for HR processing

Size	Changes display amplitude of ECG waveform
HR Source	Calculate HR/PR from ECG (default – green), SpO_2 (cyan), or ART-labeled IBP (red). See Figure 28 for HR/PR parameter box appearance when HR Source is SpO_2 or ART.
Pulse Tone Source	Enables audible tones for each detected beat. When source is SpO_2, the tone pitch varies (higher SpO_2 % = higher pitch).
ECG Filter	Set to either Monitor (0.67 – 40 Hz) or Diagnostic (0.05 – 40 Hz)
Cal	Injects a simulated 1 mv calibration pulse into the ECG waveform

Figure 32. HR/PR Values Sourced From SpO2 or ART

11.1.2. Respiration

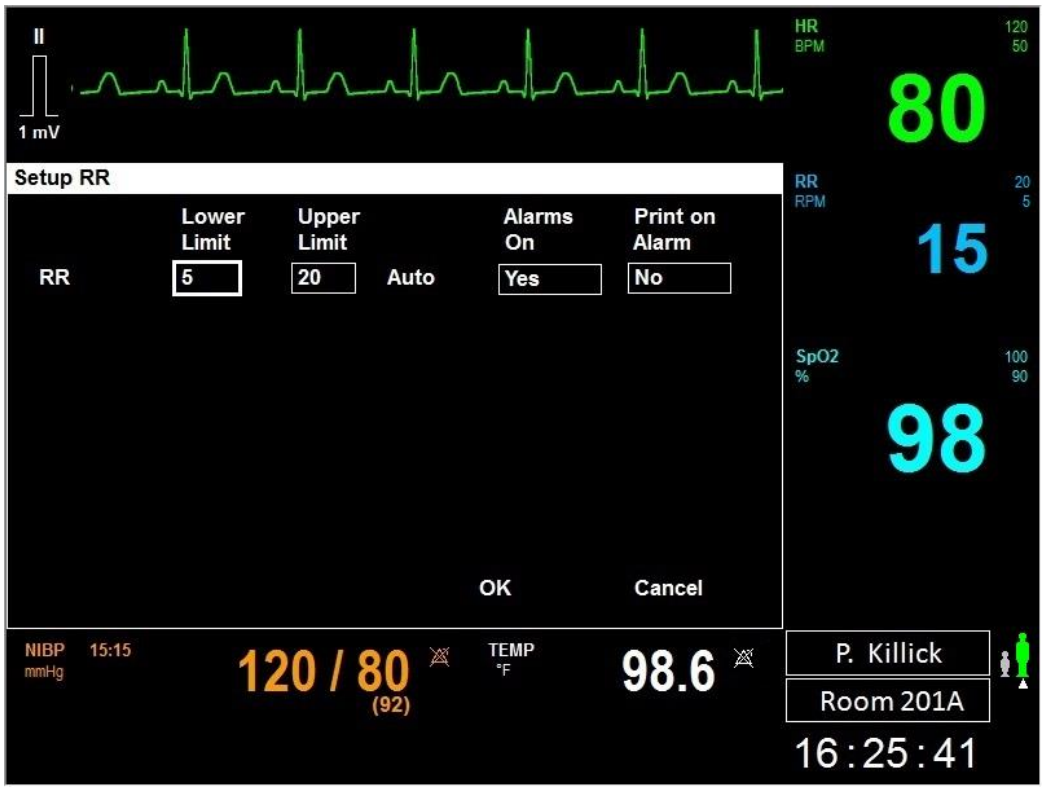


Figure 33. Setup RR Menu

Setting	Description
Lower Limit	RR alarm lower limit
Upper Limit	RR alarm upper limit
Auto	Auto-adjust lower limit to 80% of current value and upper limit to 125% of current value (or the nearest allowable values given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm condition

11.1.3. Pulse Oximetry

Figure 34. Setup SpO_2 Menu

Setting	Description
Lower Limit	SpO_2 alarm lower limit
Upper Limit	SpO_2 alarm lower limit
Auto	Auto-adjust lower limit to 95% of current value and upper limit to 105% of current value (or the nearest allowable values given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm condition
HR Source	Calculate HR/PR from ECG (default), SpO_2, or ART-labeled IBP. See Figure 28 for HR/PR parameter box appearance when HR Source is SpO_2 or ART.

Pulse Tone Source	Enables audible tones for each detected beat. When source is SpO_2, the tone pitch varies (higher SpO2 % = higher pitch)
SpO2 Alarm Acknowledge	Clears SpO_2 alarms until a patient is once again detected at the SpO_2 sensor

11.1.4. Non-Invasive Blood Pressure

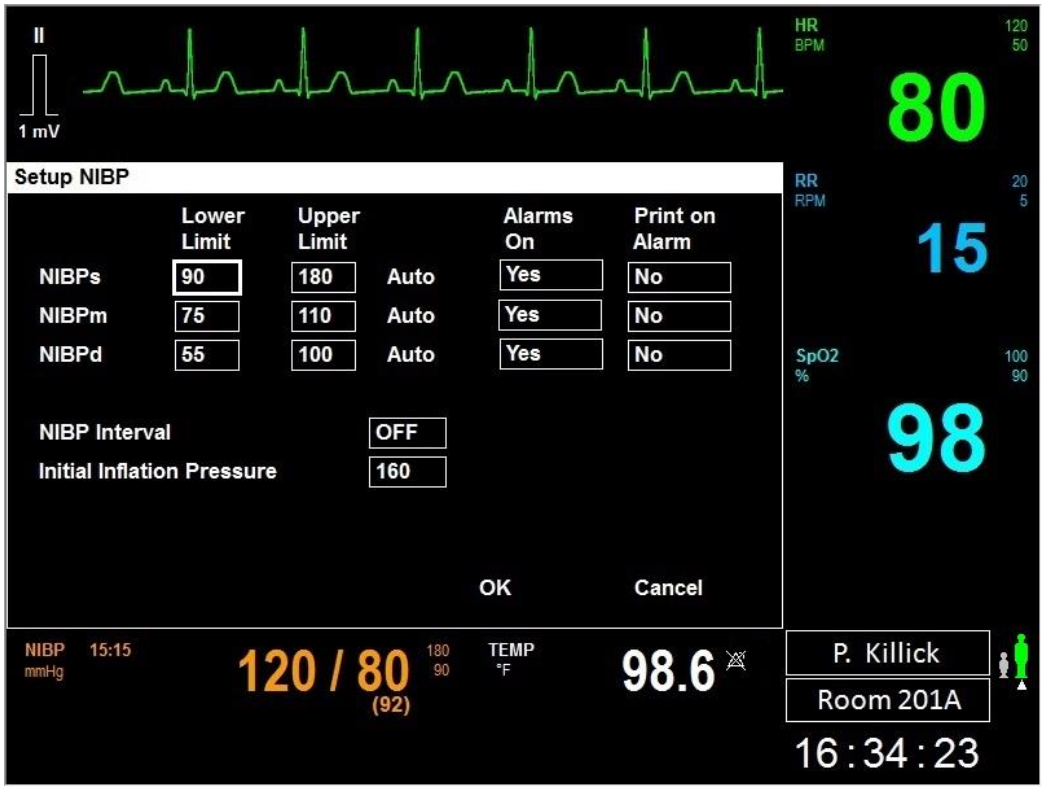


Figure 35. Setup NBP Menu

Setting	Description
Lower Limit	NBP systolic/mean/ diastolic alarm lower limits
Upper Limit	NBP systolic/mean/ diastolic alarm upper limits
Auto	Auto-adjust lower limit to 80% of current value and upper limit to 125% of current value (or the nearest allowable values given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm conditions

NBP Interval	Take NBP measurements automatically at periodic intervals. The NBP Interval setting is remembered between power cycles. However, the PPM3 does not start Interval Mode NBP measurements after power up until the NBP Start/Stop key is pressed. This tells the PPM3 that the cuff has been applied to the patient and that NBP monitoring should commence.
Initial Inflation Pressure	The NBP cuff is inflated to this pressure if a systolic pressure from previous measurement is not displayed. Otherwise, 40 mmHg is added to the previous systolic pressure for the next inflation pressure.

11.1.5. Oridion CO_2 / Capnography

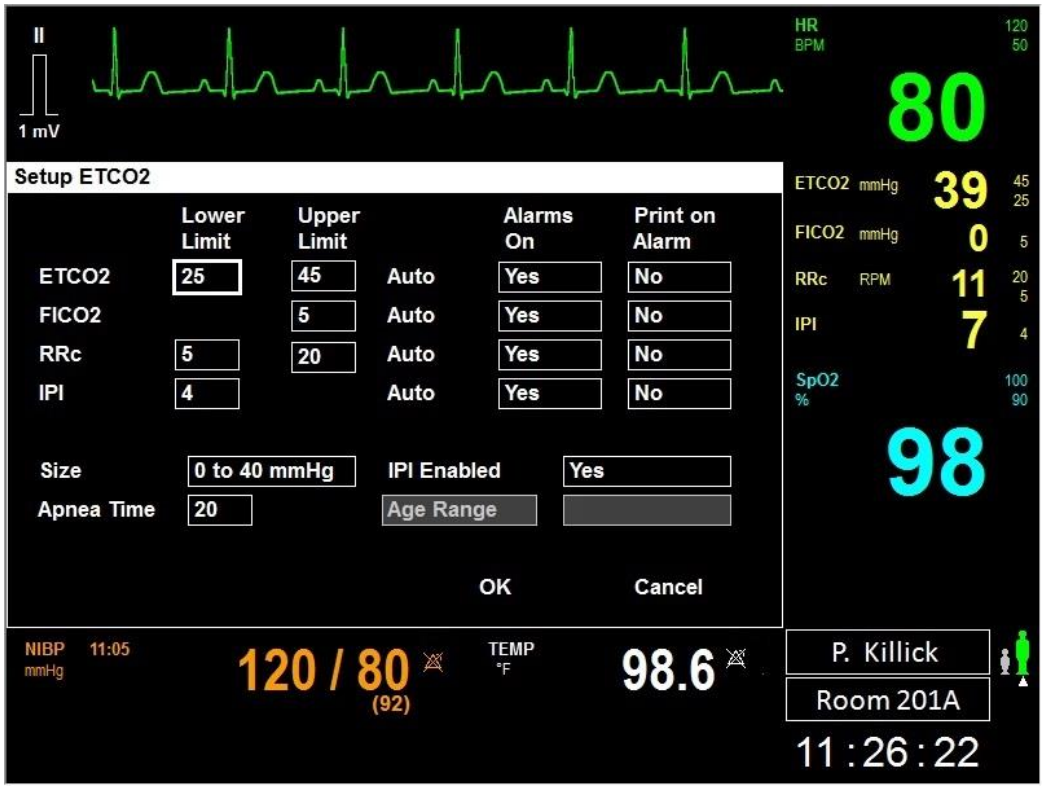


Figure 36. Setup CO_2 Menu With Oridion Capnography

Setting	Description
Lower Limit	$ETCO_2$, RRc, IPI alarm lower limits
Upper Limit	$ETCO_2$, $FICO_2$, RRc alarm upper limits
Auto	For $ETCO_2$ and RRc, auto-adjust lower limit to 80% of current value and upper limit to 125% of current value (or the nearest allowable values given alarm limit rules) For $FICO_2$, auto-adjust upper alarm limit to 125% of current value (or the nearest allowable value given alarm limit rules) For IPI, auto-adjust lower alarm limit to 75% of current value (or the nearest allowable value given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm conditions

Size	Changes display amplitude of CO_2 waveform
Apnea Time	Time since last breath before RRc alarm annunciates
IPI Enabled	Enables (Yes) or disables (No) Integrated Pulmonary Index
Age Range	Required age range for IPI use with pediatric patient

11.1.6. Masimo CO_2 / Capnography

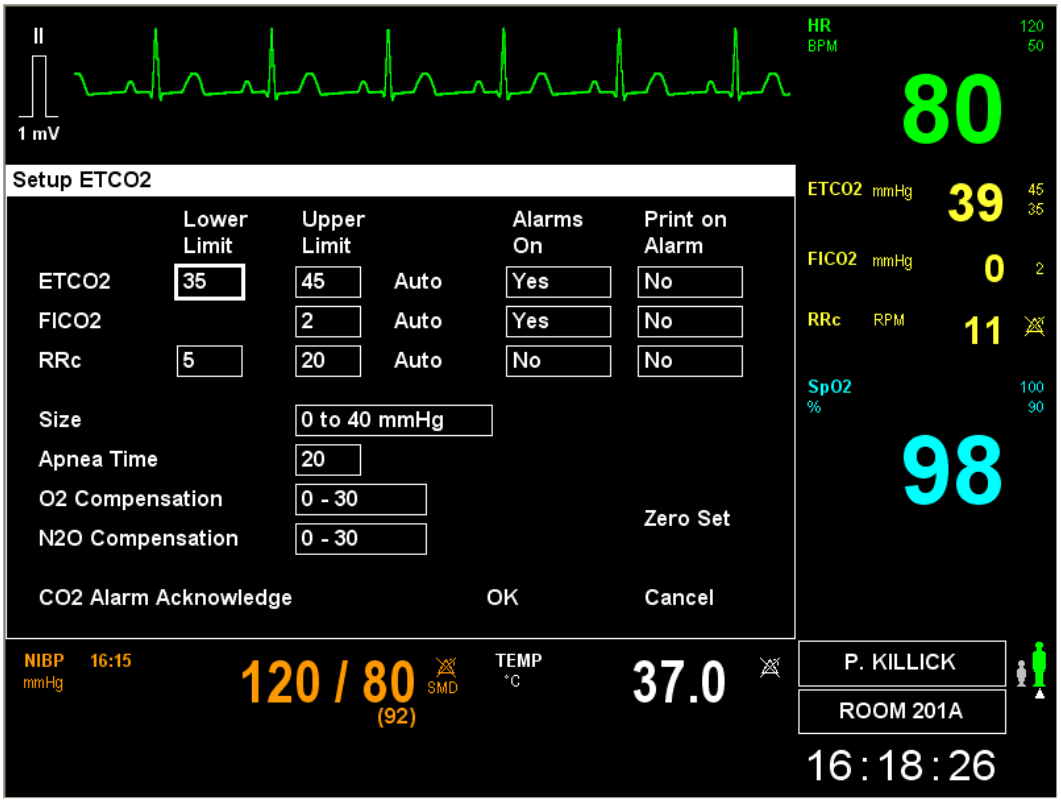


Figure 37. Setup CO_2 Menu With Masimo Capnography

Setting	Description
Lower Limit	$ETCO_2$, RRc alarm lower limits
Upper Limit	$ETCO_2$, $FICO_2$, RRc alarm upper limits
Auto	For $ETCO_2$ and RRc, auto-adjust lower limit to 80% of current value and upper limit to 125% of current value (or the nearest allowable values given alarm limit rules) For $FICO_2$, auto-adjust upper alarm limit to 125% of current value (or the nearest allowable value given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm conditions
Size	Changes display amplitude of CO_2 waveform
Apnea Time	Time since last breath before RRc alarm annunciates

O_2 Compensation	Adjust CO_2 value based on this range O_2% in fresh gas
N_2O Compensation	Adjust CO_2 value based on this range N_2O% in fresh gas
Zero Set	Initiate manual zeroing of CO_2 sensor (see Masimo CO_2 Monitoring chapter)
CO2 Alarm Acknowledge	Clears CO_2 alarms and parameter values until a patient is once again detected at the CO_2 sensor

11.1.7. Invasive Blood Pressure

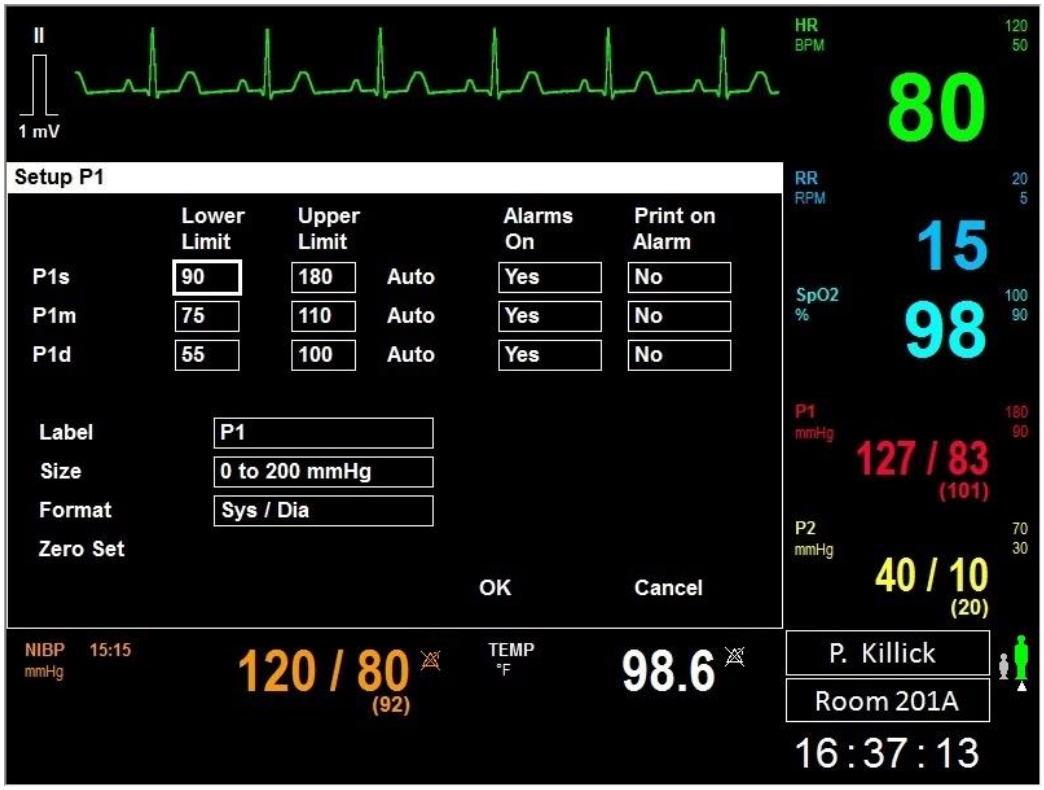


Figure 38. Setup IBP Menu

Setting	Description
Lower Limit	P1 systolic/mean/diastolic alarm lower limits
Upper Limit	P1 systolic/mean/diastolic alarm upper limits
Auto	Auto-adjust lower limit to 80% of current value and upper limit to 125% of current value (or the nearest allowable values given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm conditions
Label	Changes label from default to ART, PAP, or CVP.
Size	Changes display amplitude of P1 waveform
Format	Displays either Sys/Dia or Mean numeric value in larger font

Zero Set	Zeroes P1 when transducer vent has been opened

11.1.8. Temperature

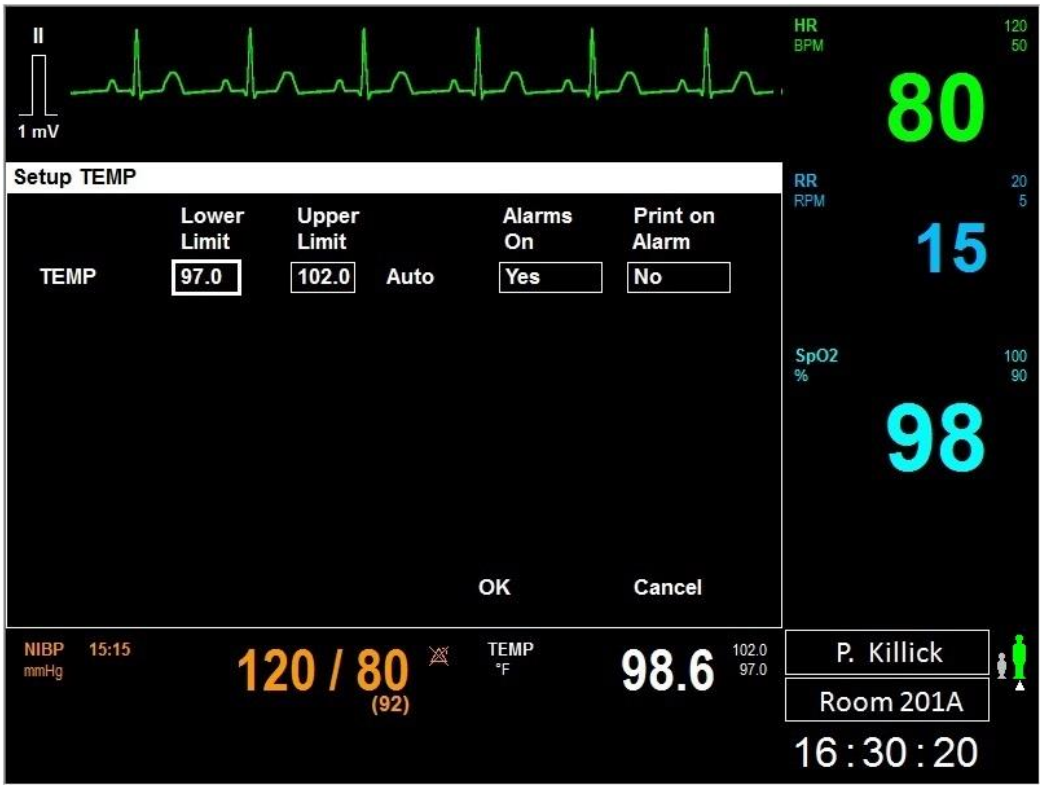


Figure 39. Setup TEMP Menu

Setting	Description
Lower Limit	TEMP alarm lower limit
Upper Limit	TEMP alarm upper limit
Auto	Auto-adjust lower limit to 98% of current value and upper limit to 101% of current value (or the nearest allowable values given alarm limit rules)
Alarms On	Enables (Yes) or disables (No) alarms
Print on Alarm	Print a strip chart summary upon alarm conditions

Note – When you change the TEMP Units setting (°F or °C) from the Setup System menu, recheck the TEMP alarm limit settings, as some round-off error may occur when the limit settings are switched to the new units of measure.

11.2. Front Panel Keypad Menus

11.2.1. SETUP Key and Submenus

When you press the SETUP key on the PPM3 front panel, the top-level Setup Menu appears.

Figure 40. SETUP Key Menu

This menu gives you access to a variety of functions and sub-menus.

If you select the "Alarm Pause" item, the PPM3 will temporarily disable all alarm monitoring. Selecting "Alarm Resume" from the same spot on the Setup Menu will resume alarm monitoring. An "Alarms Paused" condition is indicated in the message area with a timer indicating when alarm monitoring will resume. There is also an alarms paused symbol displayed to the left of the message area.

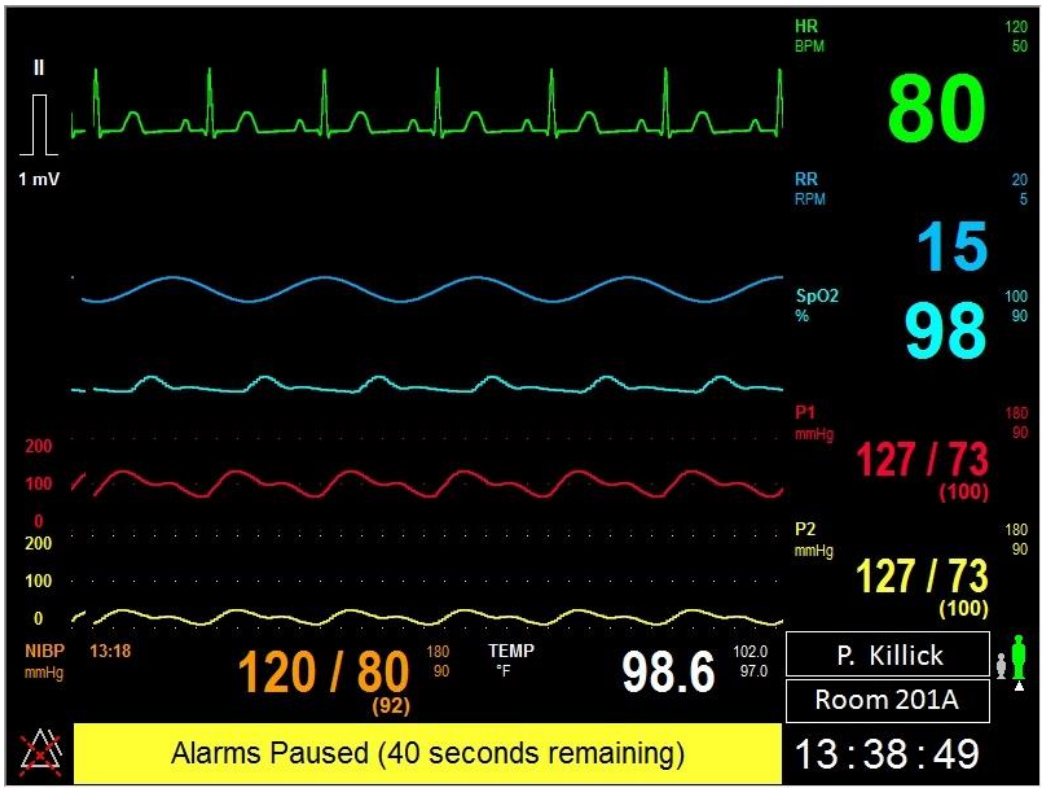


Figure 41. Main Screen With Alarms Paused Message & Timer

WARNING – Pausing all alarms pauses all alarm conditions including lethal arrhythmias (Asystole and VFib). Use this feature with extreme caution as alarm checking is suspended for all alarm conditions. Patients must be closely observed if all alarms are suspended.

If you select the "Parameters" item, the Setup Parameters Menu appears.

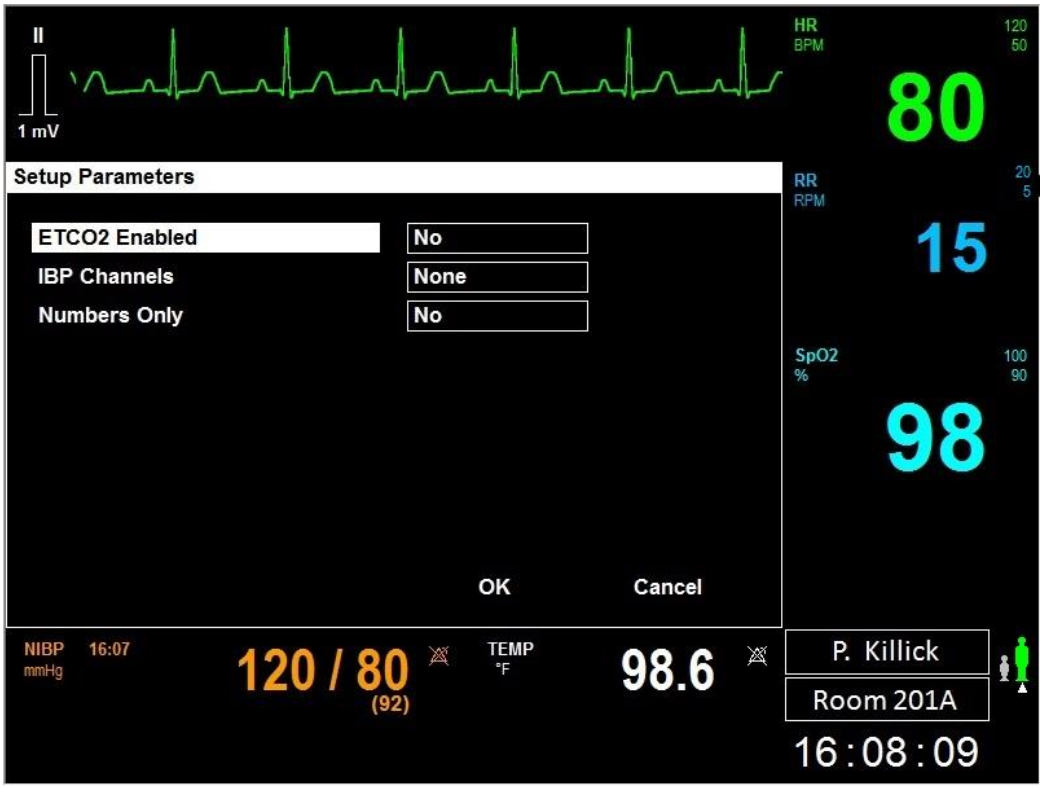


Figure 42. Setup Parameters Menu

The Setup Parameters menu allows you to enable $ETCO_2$ (CO_2 / Capnography) and IBP (Invasive Blood Pressure) Monitoring, if these components are present in your Nightingale PPM3 monitor, but have not been turned on from a software standpoint.

If you change "Numbers Only" to "Yes," the Main Screen will display all the monitored physiological parameters with large numbers instead of sharing some of the space with waveforms.

Figure 43. Numbers Only Main Screen

If you select the "Waveforms" item, the Setup Waveforms Menu is displayed. Figure 37 below shows the Setup Waveforms Menu as it is appears when IBP Monitoring is not enabled. Figure 38 shows the menu as it appears when two IBP channels have been enabled.

Figure 44. Setup Waveforms Menu

The Setup Waveforms Menu allows you to choose which physiological waveforms to display in each of the three possible waveform display channels (five with two IBP channels enabled). The range of possible choices for the waveform display channels may be found in the Waveform Settings table in the PPM3 Monitor Settings chapter. For ECG and CO_2 waveforms, you can also choose what size (amplitude) setting to use. For the CO_2 waveform, you can also choose whether the CO_2 waveform is filled in to make it more visible from a distance.

This menu is also used to set the sweep speed for the eraser bar, turn on or turn off the display of ECG labels on the main display, and to turn on or turn off the display of spikes that are drawn in the waveforms to show where the monitor detects beats.

Figure 45. Setup Waveform Menu with IBPs

You may also choose the size (amplitude) of the invasive pressure waveforms.

Note – When a communications link with the MPC is established, these settings will be overridden by those that are received from the MPC. In the case where the sweep speed is set to 50 mm/sec at the MPC, the PPM3 will use a 25 mm/sec sweep speed instead. This is the highest sweep speed that is supported by the PPM3.

If you select the "Audio" item, the Setup Audio Menu appears.

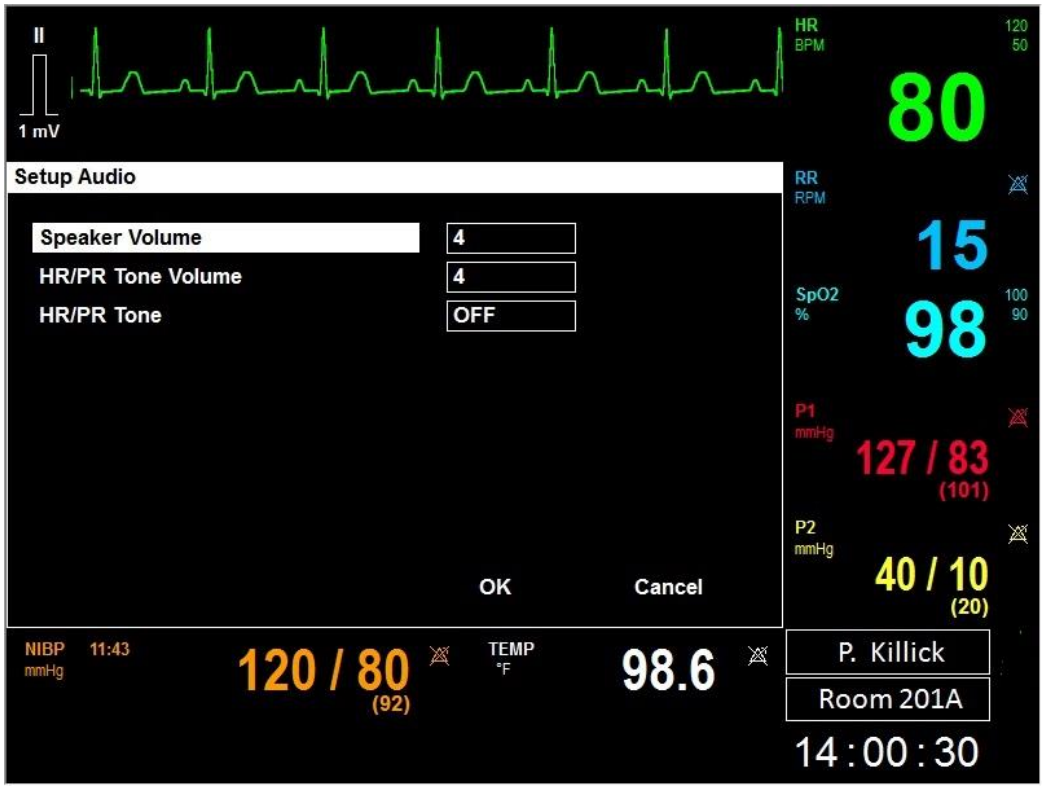


Figure 46. Setup Audio Menu

The Speaker Volume allows you to change the volume for alarm tones.

The HR/PR Tone Volume allows you to change the volume for pulse tones. You can also enable the HR/PR Tone and select the source from this menu, just as you can from the Setup HR and Setup SpO_2 menus.

If you select the "Alarms" item, the Setup Alarms Menu appears. The three screens associated with this menu are presented below and on the following two pages.

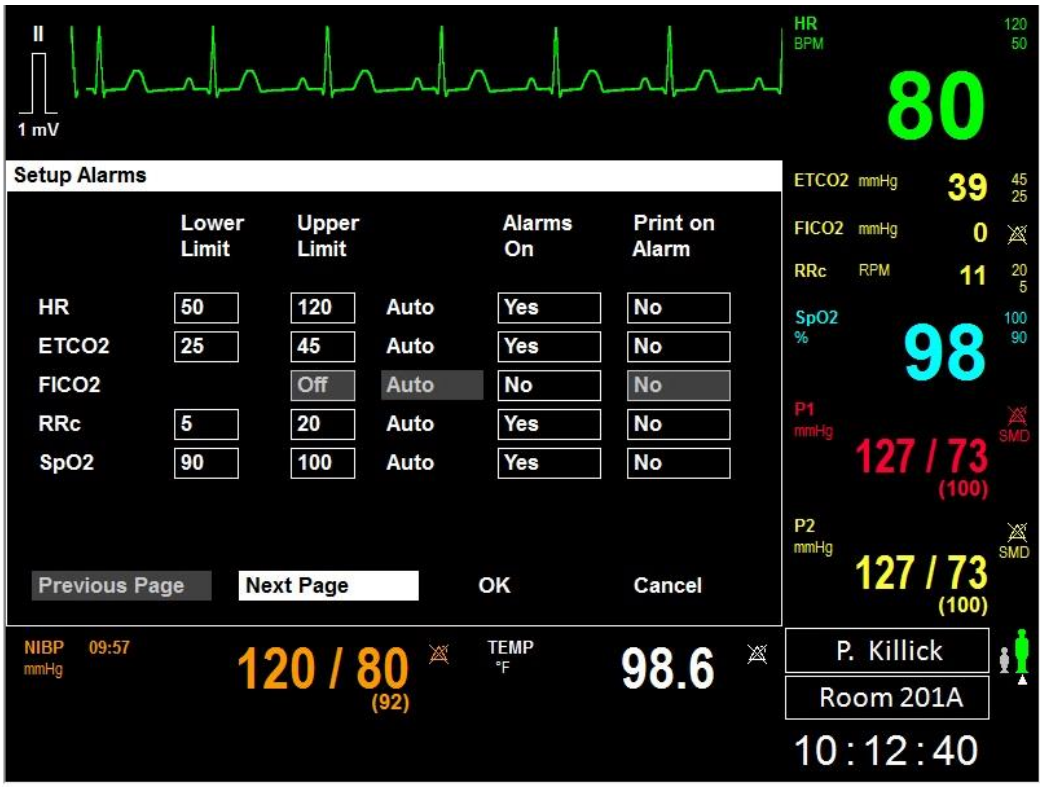


Figure 47. Setup Alarms Menu – Screen 1

This menu provides access to the alarm settings for all parameters at once for your convenience. Any changes made here are also reflected in the individual parameter box menus, and vice versa.

The factory default values and ranges of possible values for all alarm limits may be found in the Parameter Settings table of the PPM3 Monitor Settings chapter.

When you select the "Auto" feature for a parameter's alarms, the PPM3 automatically adjusts the upper and lower limits based on the current value of the parameter. The rules used for each of the parameters are provided in the table on the next page.

Parameter	Lower limit adjustment	Upper limit adjustment
HR/PR, RR, $ETCO_2$, RRc NBPs/m/d, P1s/m/d, P2s/m/d	Changed to 80% of the current parameter value (or the nearest allowable value given alarm limit rules)	Changed to 125% of the current parameter value (or the nearest allowable value given alarm limit rules)
$FICO_2$	N/R	Changed to 125% of the current parameter value (or the nearest allowable value given alarm limit rules)
IPI	Changed to 75% of the current parameter value (or the nearest allowable value given the alarm limit settings rules)	N/R
SpO_2	Changed to 95% of the current parameter value (or the nearest allowable value given alarm limit rules)	Set to 100%
Temp	Changed to 95% of the current parameter value (or the nearest allowable value given alarm limit rules)	Changed to 105% of the current parameter value (or the nearest allowable value given alarm limit rules)

Figure 48. Setup Alarms Menu – Screen 2

Figure 49. Setup Alarms Menu – Screen 3

If you select the "Patient Information" item, the Patient Information Menu appears.

Figure 50. Patient Information Menu

This menu provides a way of entering and examining patient information. Entries such as name, ID, or room will appear on the Main Screen and printed reports. If you are using the Nightingale MPC, entries made here when admitting a patient will be transmitted to the MPC. Also, if a patient is admitted at the MPC and assigned to a particular PPM3, the information will be transmitted to this menu.

The Patient Information Menu is also the place to change the patient type from Adult to Pediatric. As shown in the figure, a symbol indicating the current patient type is displayed in the lower right area of the Main Screen. Refer to the PPM3 Monitor Settings chapter to compare factory default adult and pediatric settings.

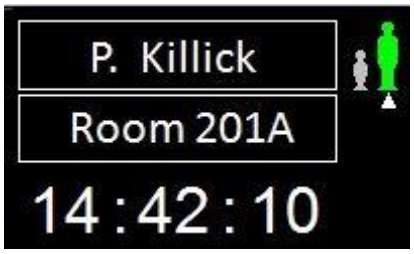


Figure 51. Adult Patient Type

If you select the "Restore Department Defaults" item, the Restore Department Defaults Menu appears.

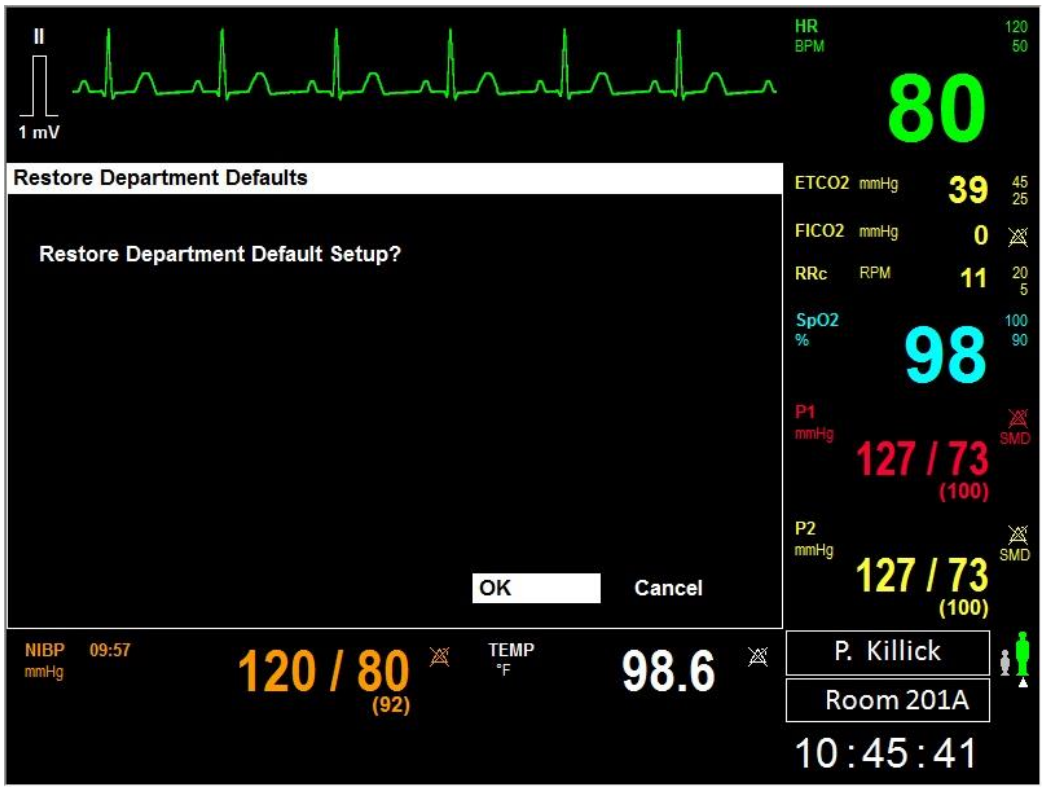


Figure 52. Restore Department Defaults Menu

When you choose to Restore Department Defaults, any changes made to the patient settings (parameter & waveform settings) for the current patient will be restored to the previously saved Department Default values. Or, if no Department Defaults have previously been created, the settings will be restored to the Factory Default values found in the PPM3 Monitor Settings chapter.

Department Defaults can only be saved from within the password protected Setup System Menu.

If you select the "Administration" item, the Setup Administration Menu appears.

Figure 53. Setup Administration Menu

Each of the selections on this menu leads to further submenus.

If you select the "Configuration" item, the Setup Configuration Menu appears.

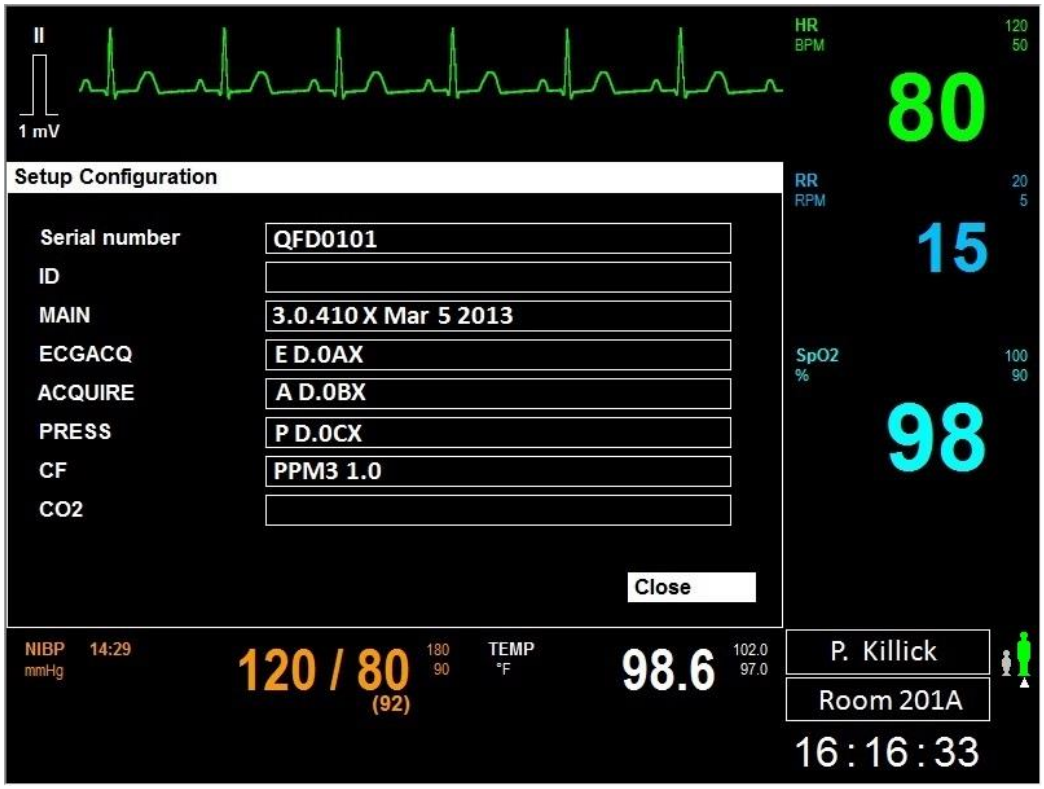


Figure 54. Setup Configuration Menu

The Setup Configuration menu provides a way of seeing what hardware and software versions are currently installed on the Nightingale PPM3.

11.2.2. Password Protected Menus

If you select "Alarms," "System," "Service," or "Factory" on the Setup Administration Menu, the PPM3 brings up the Enter Password Menu.

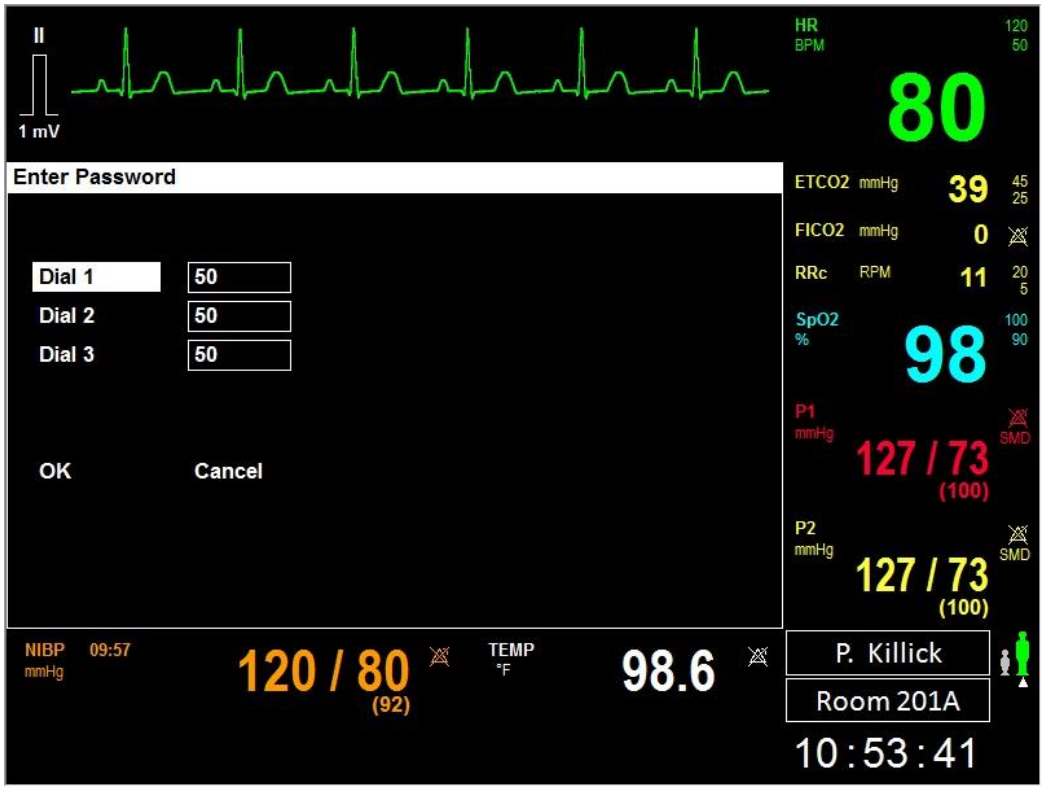


Figure 55. Enter Password Menu

This menu allows you to enter a password to proceed to the Setup Alarms or Setup System menu.

The password for these menus is located at the end of the Maintenance and Storage chapter of this document.

Note – The Service and Factory setup menus are intended to be used by trained service and production personnel.

The Setup Alarms Menu allows changes to certain aspects of alarm handling.

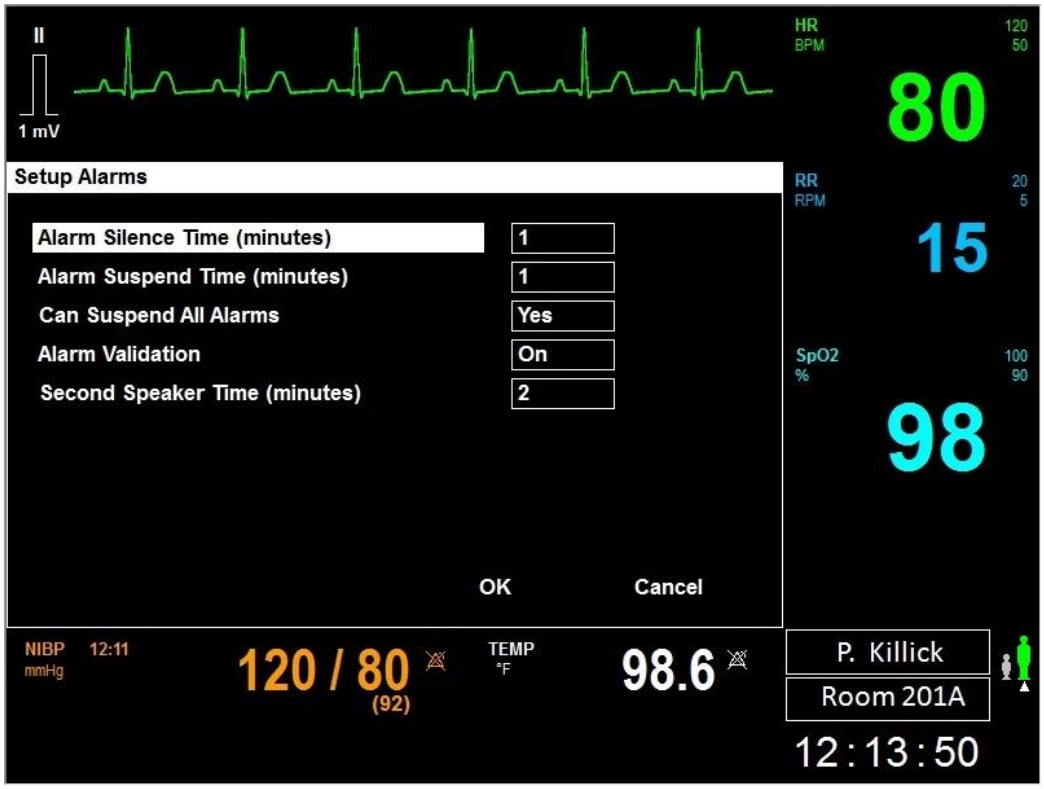


Figure 56. Setup Alarms Menu

The settings that can be changed via the Setup Alarms menu include:

Setting	Description
Alarm Silence Time	Time that alarm will be silenced after you press the ALARM SILENCE key (unless a new alarm comes in)
Alarm Suspend Time	Time that alarms will be suspended after you select the Alarm Suspend item in the top level Setup menu
Can Suspend All Alarms	This setting controls if the clinician is able to suspend all alarms including lethal arrhythmias (Asystole and VFib).
Alarm Validation	Enables/disables alarm validation (if enabled, limit alarms are not annunciated until values have been out of limits for a set period of time – see Managing Alarms chapter)
Second Speaker Time	Time that elapses while an alarm tone in sounding before the second speaker starts sounding

Note -- When a communications link with the MPC is established, these settings will be overridden by those that are received from the MPC.

The Setup System Menu allows changes to a few items that are rarely changed.

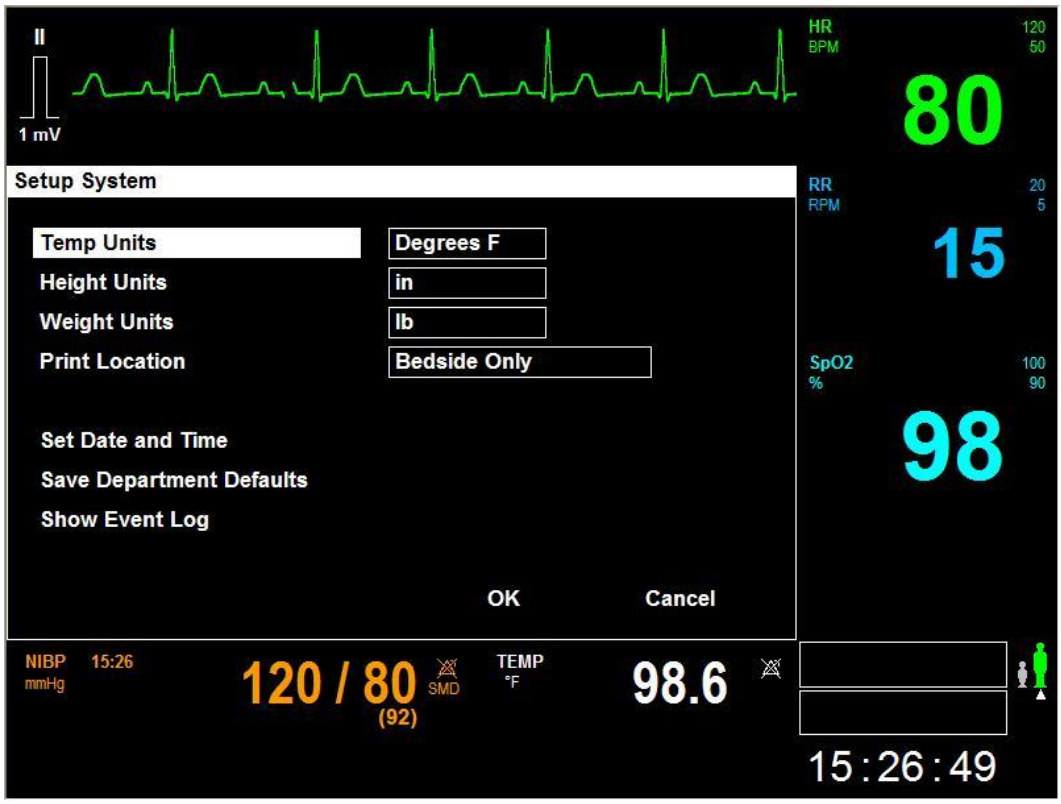


Figure 57. Setup System Menu

The settings that can be changed via the Setup System menu include:

Setting	Description
Temp Units	Allows you to choose °F or °C
Height Units	Allows you to choose inches (in) or centimeters (cm)
Weight Units	Allows you to choose pounds (lb) or kilograms (kg)
Print Location	When connecting to the MPC, allows you to specify where hard copy reports are printed (Bedside Only, Central Only, Bedside And Central)

NOTE – When a communications link with the MPC is established, these Units settings will be overridden by those received from the MPC.

If you select the "Select Date and Time" item, the Set Date and Time Menu appears.

Figure 58. Set Date and Time Menu

If you select the "Save Department Defaults" item, the Save Department Defaults Menu appears.

Figure 59. Save Department Defaults Menu

The Save Department Defaults menu allows you to configure the PPM3 for your particular application. Once the patient monitoring settings have been configured as desired, selecting this choice will allow you to save the current settings as the baseline for all new patients. The settings that are saved include all of those listed in the Parameter Settings and Waveform Settings tables found in the PPM3 Monitor Settings chapter.

WARNING – A potential hazard can exist if the department default alarm settings are not consistent among all the Nightingale PPM3 monitors deployed within the same clinical area.

The Show Event Log item brings up the system event log, which contains useful troubleshooting information.

11.2.3. NBP INTERVAL Key

If you press the NBP INTERVAL key, the PPM3 brings up the menu that allows you to change the automatic NBP Interval Mode settings.

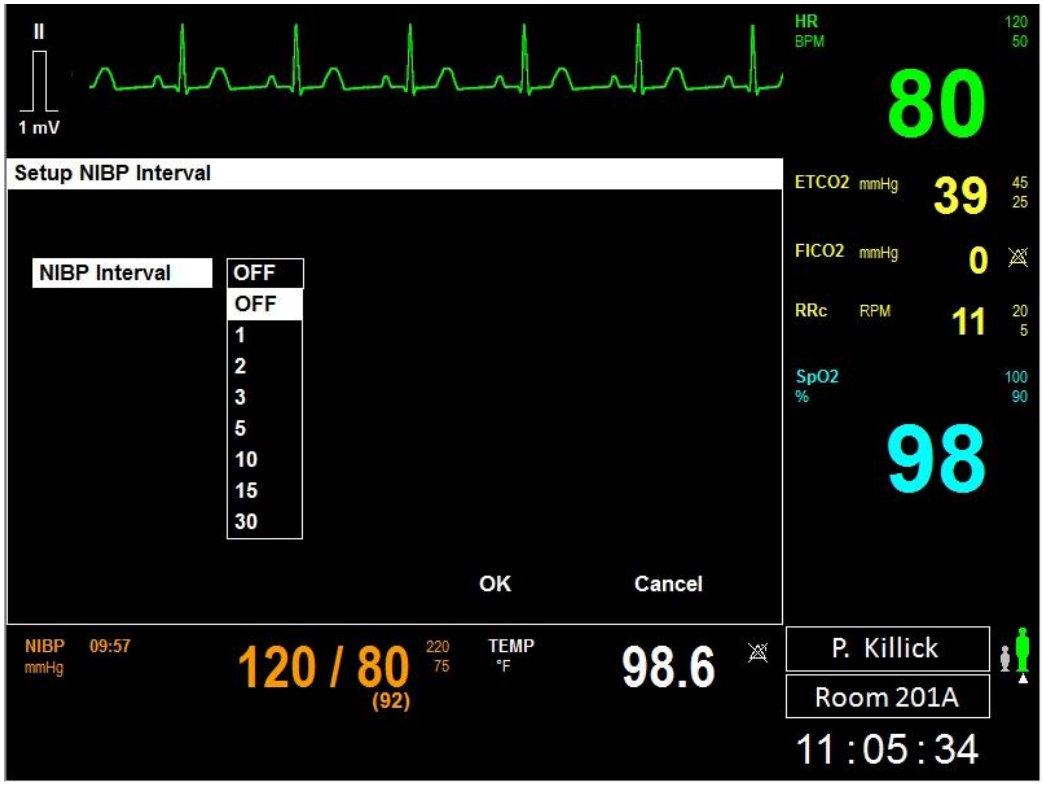


Figure 60. Setup NBP Interval Menu

To select an automatic NIBP interval:

1. Press the NBP INTERVAL key to display the Setup NBP Interval menu.
2. Select the NBP Interval item by pressing the control knob.
3. Scroll the control knob to the desired NIBP Interval (Off, 2m, 3m, 5m, 10m, 15m, 30m, and 60 minutes) and press to select it.
4. Press OK button or the MAIN SCREEN key to enter/apply that change or press Cancel to cancel the changes.
   - Selecting OK with an interval chosen prompts the monitor to begin that interval. You can manually initiate by pressing the NBP START/STOP

key, but the system will automatically take the first and subsequent measurements based on the o'clock as per the system time.

- The chosen interval is displayed as "NBP Interval – N Minutes" in the system message area, where N is the value selected.

To stop a particular measurement within NBP Interval Mode, simply press the NBP START/STOP key. However, "NBP Interval – N Minutes" will continue to be displayed in the message area, and another measurement will automatically be initiated at the next interval. To fully disable NBP Interval Mode, you must re-enter the Setup NBP Interval menu and change the Interval to Off.

The NBP Interval setting is remembered after a Standby or a power cycle with the same patient. However, the PPM3 does not automatically initiate NBP Interval Mode measurements after a Standby or a power cycle until the NBP START/STOP key is pressed. This tells the PPM3 that the cuff has been applied to the patient and that NBP monitoring should commence. Once the key has been pressed, the interval will display in the message area and the measurements will proceed thereafter based on the o'clock as per the system time.

11.2.4. STANDBY Key

If you press the STANDBY key, the Standby Menu appears, presenting you with the various Standby options. See the Entering Standby Mode chapter for details regarding Standby Mode.

11.2.5. TRENDS Key

If you press the TRENDS key, the Nightingale PPM3 brings up the Trends display. See the Viewing Trends chapter for details regarding trends.

11.2.6. MAIN SCREEN Key

If you press the MAIN SCREEN key, the Nightingale PPM3 goes back to the Main Screen.

Note – If a menu is on display when you press the MAIN SCREEN key, the PPM3 interprets this as if you had first selected the OK button on the menu. Any settings changes that would have been effected with the OK button are applied.

12. Managing Alarms

You can configure the PPM3 to audibly and visually report an alarm condition when a patient's physiological parameter goes beyond a predetermined limit. Some parameter alarms are enabled as a factory defaults. One example is the heart rate alarm, which sounds and flashes when the patient's heart rate rises above 120 bpm or drops below 50 bpm. Alarm monitoring can be individually configured for each physiological parameter.

Both the Nightingale PPM3 and the Nightingale MPC support alarm monitoring. When the PPM3 and MPC are connected, they use the same alarm monitoring settings. If a setting is changed at either the PPM3 or the MPC, then the setting is updated at both the PPM3 and the MPC. This is also true for alarm silencing. For example, if you silence an alarm at the PPM3 by pressing the ALARM SILENCE key on the front panel keypad, it is also silenced at the MPC.

When the PPM3 and MPC are initially connected, there is special handling to merge the alarm settings of the two devices. Please see the Centralized Monitoring chapter (Remote Control Settings) for more details.

In addition to the physiological parameter alarm monitoring, the PPM3 will report technical alarm conditions that prevent monitoring such as lead off, a low battery condition, or when the connection is lost between the PPM3 and the MPC for some reason.

12.1. Alarm Presentation Basics

There are three "grades" of alarms on the PPM3 – high, medium, and low – and they all present in different ways as described in the following two tables.

12.1.1. Audible Alarm Tones

If you hear a…	It represents…
Five higher-pitch tones (three quick, pause, two more) repeated every 8 seconds	A "high grade" alarm indicating an immediately life-threatening condition (e.g. asystole or ventricular fibrillation)
Three medium-pitch tones repeated every 15 seconds	A "medium grade" alarm indicating a physiological condition that may be serious (e.g. parameter limit violations)
A single lower-pitch tone repeated every 20 seconds	A "low grade" alarm indicating a technical condition (e.g. lead off)

12.1.2. Visual Alarm Colors

If you see a…	And …	It represents…
Red background parameter box and message area	Flashing color – twice per second	A "high grade" alarm is currently active and has not been acknowledged
	Solid color with alarm silence symbol to the left of the message area	A "high grade" alarm is currently active but has already been silenced
Yellow background parameter box and message area	Flashing color – once every 2 seconds	A "medium grade" alarm is currently active and has not been acknowledged
	Solid color with alarm silence symbol to the left of the message area	A "medium grade" alarm is currently active but has already been silenced
Cyan background parameter box and message area	Solid color	A "low grade" alarm is currently active and has not been acknowledged
	Solid color with alarm silence symbol to the left of the message area	A "low grade" alarm is currently active but has already been silenced

Since several parameters could be alarming at the same time, the alarm tone and color will reflect the highest grade alarm condition that is currently active on the PPM3. Refer to the tables in Section 11.2 Alarm Conditions to see how different alarm conditions are categorized by grade.

12.1.3. How to Silence Alarms

Action may be taken to “silence" alarms in one of the following two ways.

- Pressing the ALARM SILENCE key on the front panel
- Changing the parameter alarm limits such that the current value is no longer out of limits (if the alarm was a limit violation alarm)

If after pressing ALARM SILENCE, the alarm condition is still true, the tone will cease, the flashing backgrounds will change to a solid color, and the alarm silence symbol will appear to the left of the message area.

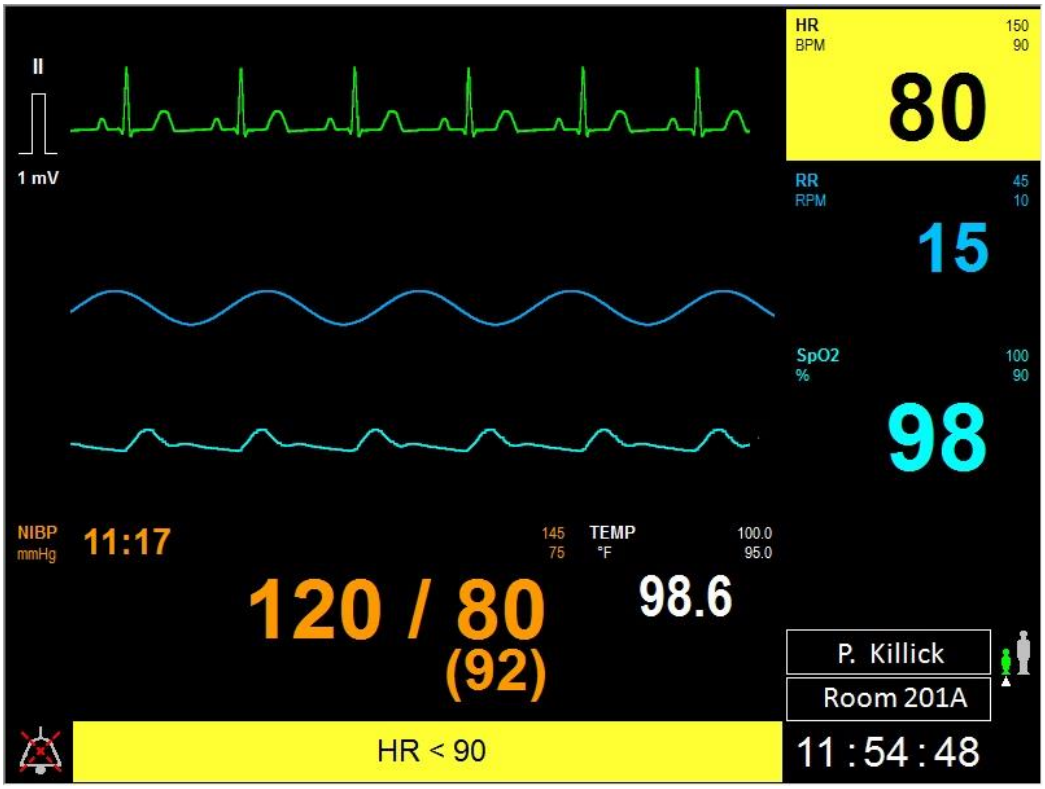


Figure 61. Silenced & Active HR Limit Alarm

If the alarm condition is still true when the "alarm silence time" expires (as configured in the Setup Alarms menu), then the backgrounds of the parameter box and message area will automatically resume flashing and the alarm tone resume as well. However, if the alarm condition goes away while the alarm is silenced, then the backgrounds will automatically switch to black and the tone will not resume.

Each alarm condition has an associated "annunciation type." The annunciation type is one of the following:

- "One-time" – the annunciation will be done only once (annunciation ends once you silence the condition, even if the condition is still true).
- "Persistent" – the annunciation will repeat after the "alarm silence time" expires, as long as the alarm condition is true.

Alarm conditions that are "one-time" include an unplugged probe, a lead-off and all NBP alarm conditions. The remaining alarm conditions are "persistent."

The lethal Asystole and Ventricular Fibrillation alarms are both "persistent" and "latching." What is meant by "latching" is that they require acknowledgment. So if a patient goes into an asystole or ventricular fibrillation condition and then returns to a normal sinus rhythm within the HR alarm limits, the "HR Asystole" or "HR Ventricular Fibrillation" alarms will continue to annunciate until they are acknowledged with the ALARM SILENCE key. If the patient is in a normal sinus rhythm at the time the key is pressed, they will not resume. On the other hand, if the ALARM SILENCE key is pressed when either of these two lethal alarms first annunciate, they will behave like other persistent alarms.

12.1.4. Alarm Messages

When an alarm condition is active, a text message is displayed in the message area at the bottom of the display (e.g. "HR lead off"). If there are multiple alarm conditions, then the messages are displayed in a "round-robin" manner. That is, one message is displayed at a time. If multiple messages are active, each message is displayed for approximately 3 seconds at a time. See the Alarm Conditions section of this chapter for a list of alarm messages.

12.1.5. How to Enable or Disable Alarms

Alarm conditions are not annunciated unless alarms are enabled for a given parameter. The enabling or disabling of alarms is done via the "Alarms On" selection item in the Setup Alarms menu or in the individual parameter setup menus. See Figures 47, 48, and 49 in the "Working With Menus" chapter, which present the Setup Alarms Menu.

Alarms may be temporarily disabled for all parameters by choosing the Alarm Pause item in the Setup menu. See Figure 34 in the "Working With Menus" chapter, which shows the main screen with the "Alarms Paused" message, timer, and symbol. When this menu item is selected, all alarms are disabled for the "Alarm Pause Time" (as configured in the Setup Alarms menu under the Setup Administration menu).

When the alarm pause time expires, alarm monitoring is restored for each parameter based on the "Alarms On" menu setting for the parameter. You can restore alarm monitoring before the alarm pause timer expires by selecting the Alarm Resume item – which takes the place of Alarm Pause on the Setup menu (the two items toggle).

Alarms can be indefinitely disabled for all parameters by entering Standby Mode. See the Entering Standby Mode chapter for details.

WARNING – Pausing all alarms pauses all alarm conditions including lethal arrhythmias (Asystole and VFib). Use this feature with extreme caution as alarm checking is suspended for all alarm conditions. Patients must be closely observed if all alarms are suspended.

12.1.6. Alarm Validation

Under the password-protected Setup Alarms menu (under the Setup Administration menu), there is a feature called Alarm Validation. When this feature is enabled, certain parameter limit violations are not considered to be in alarm until they have existed for a certain time period, as listed below:

Limit Violation	Alarm Validation Time
HR Upper Limit	5 seconds
HR Lower Limit	5 seconds
RR Upper Limit	5 seconds
SpO_2 Upper Limit	5 seconds
SpO_2 Lower Limit	5 seconds
IBP Upper Limit	5 seconds
IBP Lower Limit	5 seconds

The purpose of this feature is to reduce nuisance alarms in which parameter values may go out of limits for a very short time.

Note – Alarm Validation is enabled as a factory default.

12.1.7. Alarm Handling at Start-up

When the PPM3 is initially powered-up or brought out of standby, alarms will not be annunciated for a given parameter until the lead set or probe has been applied to the patient. This prevents nuisance alarms for parameters that are not being monitored on a given patient.

12.1.8. Alarm Reports

When the Nightingale PPM3 is connected to the MPC Central Station, an alarm report is stored at the MPC for each medium- and high-grade alarm that is annunciated for the HR parameter. This includes upper and lower limit

violations, Asystole, and Ventricular Fibrillation. These reports include a snapshot of the physiological parameters and an ECG waveform "strip" from the PPM3.

When the PPM3 is disconnected from the MPC (in Transport Mode), the 10 most recent alarm reports are stored within the PPM3. The reports will remain in the PPM3 memory even if power is turned off. When the PPM3 is reconnected to the MPC, the reports are transferred to the MPC. Manually-generated reports (via the PPM3's print key) are also stored while in Transport Mode, and are counted as part of the 10 reports.

See the MPC User's Guide discussion on the Alarm Log for more details on alarm reports.

12.1.9. Audible Alarm Tones While Connected to the MPC

When the PPM3 is connected to the MPC central station, it can be configured to sound an alarm tone for high-grade alarms only (e.g., Asystole). This may be especially helpful at night when the patient is sleeping. If the communications link between the PPM3 and MPC is broken, the monitor will once again generate an alarm tone for all alarms.

This feature is configured at the MPC. See the MPC User's Guide for more details.

12.1.10. Second Speaker Alarm Tones

The second speaker feature of the Nightingale PPM3 enhances the alarm tone functionality by providing a completely independent backup to the monitor's main speaker.

The way the second speaker works is very simple. Whenever the monitor starts sounding an audible tone for an alarm condition, it starts a timer. If the alarm tone is still sounding after a certain length of time (normally two minutes), the second speaker will also start sounding. When you silence the alarm, both the main speaker and the second speaker (if it was sounding) are silenced.

The amount of time delay between when the main speaker starts sounding and when the second speaker starts sounding can be set anywhere between 0 to 180 seconds via the Setup Alarms menu (under the Setup Administration menu).

Since the second speaker has a slightly different sound than the main speaker, it also serves to provide you with an indication of when a given alarm has been sounding for longer than the pre-set delay time.

Other than starting the second speaker after the pre-set delay time, there is no change to the way the monitor handles alarms, or to the way you need to respond in order to silence or suspend the alarm tones.

12.2. Alarm Conditions

The tables in this section contain lists of all the conditions the PPM3 can detect for each parameter, along with alarm characteristics of the condition. The first row in each table contains the "normal condition" for the parameter, and the other rows contain the "alarm conditions" for the parameter.

Columns in these tables have the following meaning:

- Condition – the name of the condition
- Display value – the value displayed for the parameter when the condition is true (applies only to physiological parameters)
- Alarm grade – as defined earlier in this chapter
- Message – the text of a message displayed in the message area when the condition is true
- Annunciation type – as defined earlier in this chapter

Note – The delay between alarm annunciation on the PPM3 and remote annunciation on the MPC central station should be no more than 1 sec.

General Monitor Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
Monitor okay	N/A	None	None	Persistent
Monitor problem detected	N/A	Low	Monitor need service	One-time

MPC Communication Link Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
MPC link okay	N/A	None	None	Persistent
MPC link lost	N/A	Low	MPC connection lost	Persistent

PPM3 Battery Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
Battery okay	N/A	None	None	Persistent
Battery low	N/A	Low	Battery low	One time

HR Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
HR within limits	<Number>	None	None	Persistent
HR < LL	<Number>	Medium	HR < LL	Persistent
HR > UL	<Number>	Medium	HR > UL	Persistent
HR Asystole	ASY	High	HR asystole	Persistent
HR Ventricular Fibrillation	VF	High	HR ventricular fibrillation	Persistent
HR Lead-off (after startup/standby)	<Blank>	None	None	Persistent
HR Lead-off (after leads applied)	<Blank>	Low	HR lead off	One Time
HR Artifact	---	Low	HR artifact	Persistent

RR Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
RR within limits	<NUM>	None	None	None
RR < LL	<NUM>	Medium	RR < LL	Persistent
RR > UL	<NUM>	Medium	RR > UL	Persistent
RR > 120 breaths/min	---	Low	RR out of range (too high)	Persistent
Lead-off (after start-up / standby)	<Blank>	None	None	Persistent
Lead-off (after leads applied)	<Blank>	Low	RR lead off	One Time
Resp Artifact	---	Low	RR artifact	Persistent

SpO_2 Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
SpO_2 within limits	<NUM>	None	None	None
SpO_2 < LL	<NUM>	Medium	SpO_2 < LL	Persistent
SpO_2 > UL	<NUM>	Medium	SpO_2 > UL	Persistent
SpO_2 Bad Probe	---	Low	SpO_2 replace sensor	One Time
SpO_2 Cannot regulate LED intensity (after start-up/standby)	<Blank>	None	None	Persistent
SpO_2 Cannot regulate LED intensity (after finger in probe)	---	Low	SpO_2 check sensor placement	Persistent
SpO_2 Pulsations Too Weak	---	Low	SpO_2 weak signal	Persistent
SpO_2 Probe is disconnected (after start-up/standby)	<Blank>	None	None	Persistent
SpO_2 Probe is disconnected (after finger in probe)	---	Low	SpO_2 unplugged	One Time
SpO_2 motion artifact	---	Low	SpO_2 artifact	Persistent

PR Conditions:

Note – When PR is sourced from SpO_2, the Pulse Rate is labeled in cyan as "HR (SpO2)" in the HR parameter box. When PR is sourced from an ART-labeled IBP, the PR is labeled in red as "HR (ART)." PR alarm conditions annunciate as HR alarms.

Condition	Display Value	Alarm Grade	Message	Annunciation Type
PR within limits	<NUM>	None	None	None
PR < LL	<NUM>	Medium	HR < LL	Persistent
PR > UL	<NUM>	Medium	HR > UL	Persistent
PR Bad Probe	---	Low	SpO_2 replace sensor	One Time
PR Cannot regulate LED intensity (after start-up/standby)	<Blank>	None	None	Persistent
PR Cannot regulate LED intensity (after finger in probe)	---	Low	SpO_2 / HR check sensor placement	Persistent
PR Pulsations Too Weak	---	Low	SpO_2 / HR weak signal	Persistent
PR Probe is disconnected (after start-up/standby)	<Blank>	None	None	Persistent
PR Probe is disconnected (after finger in probe)	---	Low	SpO_2 / HR unplugged	One Time
PR motion artifact	---	Low	SpO_2 artifact	Persistent

NBP Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
NBPs within limits	<NUM>	None	None	None
NBPs < LL	<NUM>	Medium	NBPs < LL	One Time
NBPs > UL	<NUM>	Medium	NBPs > UL	One Time
NBPm within limits	<NUM>	None	None	None
NBPm < LL	<NUM>	Medium	NBPm < LL	One Time
NBPm > UL	<NUM>	Medium	NBPm > UL	One Time
NBPd within limits	<NUM>	None	None	None
NBPd < LL	<NUM>	Medium	NBPd < LL	One Time
NBPd > UL	<NUM>	Medium	NBPd > UL	One Time
NBP Pulsations Too Small	---	Low	NBP weak signal	One Time
NBP Too Much Motion	---	Low	NBP artifact	One Time
NBP Leaky Cuff or Hose	---	Low	NBP cuff leak	One Time
NBP Pinched Hose	---	Medium	NBP blocked hose -- check patient	One Time
NBP Measurement Time-out (2¼ minutes)	---	Low	NBP measurement time exceeded	One Time
NBP Pump or Valve Failure or NBP Safety Timer Expired or Other H/W-related problem	---	Medium	NBP problem detected	One Time
NBP Bad Profile Shape	---	Low	NBP cannot measure	One Time

CO_2 Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
$ETCO_2$ within limits	<Number>	None	None	Persistent
$ETCO_2$ < [lower limit]	<Number >	Medium	$ETCO_2$ < LL	Persistent
$ETCO_2$ > [upper limit]	<Number >	Medium	$ETCO_2$ > UL	Persistent
$FICO_2$ within limits	<Number>	None	None	Persistent
$FICO_2$ > [upper limit]	<Number >	Medium	$FICO_2$ > UL	Persistent
RRc within limits	<Number>	None	None	Persistent
RRc < [lower limit]	<Number >	Medium	RR < LL	Persistent
RRc > [upper limit]	<Number >	Medium	RR > UL	Persistent
$ETCO_2$ out of range (high)	<Number >	Medium	CO_2 out of range (high)	Persistent

$FICO_2$ out of range (high)	<Number >	Medium	CO_2 out of range (high)	Persistent
CO2 Unplugged (after start-up/standby)	<Blank>	None	None	Persistent
CO2 Unplugged (after line connected)	<Blank>	Low	CO_2 unplugged	One Time
Power up (10 to 30 seconds)	<Blank>	None	CO_2 warming up	Persistent
In Self-Maintenance Mode (auto-zero)	<Blank>	None	CO_2 zeroing	Persistent
Module is purging the line	<Blank>	None	CO_2 purging line	Persistent
Line is occluded	---	Low	CO_2 occluded line	Persistent
H/W failure – module malfunction	---	Low	CO_2 problem detected	One Time
Calibration in progress	<Blank>	None	CO_2 calibrating	Persistent
Calibration completed – ok	N/A	Alert	CO_2 calibration ok	Alert
Calibration failed – supplied gas is not close to expected value	N/A	Alert	CO_2 cal failed – wrong gas	Alert
Calibration failed – occlusion during known gas sampling	N/A	Alert	CO_2 cal failed	Alert
Calibration failed – FilterLine unplugged during calibration	N/A	Alert	CO_2 cal failed	Alert

IBP (P1 and P2) Conditions:

Note – P2 has the same conditions as P1. Substitute P1 with P2 as required in the following table.

Condition	Display Value	Alarm Grade	Message	Annunciation Type
Systolic pressure within limits	<Number>	None	None	Persistent
Systolic pressure < LL	<Number >	Medium	P1s < LL	Persistent
Systolic pressure > UL	<Number >	Medium	P1s > UL	Persistent
Mean pressure within limits	<Number>	None	None	Persistent
Mean pressure < LL	<Number >	Medium	P1m < LL	Persistent
Mean pressure > UL	<Number >	Medium	P1m > UL	Persistent
Diastolic pressure within limits	<Number>	None	None	Persistent
Diastolic pressure < LL	<Number >	Medium	P1d < LL	Persistent
Diastolic pressure > UL	<Number >	Medium	P1d > UL	Persistent
HR (ART) within limits	<Number>	None	None	Persistent
HR (ART) < LL	<Number >	Medium	HR < LL	Persistent
HR (ART) > UL	<Number >	Medium	HR > UL	Persistent

Pressure signal out of range (low)	<Number >	Medium	P1 out of range (low)	Persistent
No pulse rate due to static pressure	---	Low	HR weak signal	Persistent
Unplugged (after start-up/standby)	<Blank>	None	None	Persistent
Unplugged (after line connected)	<Blank>	Low	P1 unplugged	One Time
Zero required (when transducer is initially connected)	<Blank>	None	P1 needs zeroing	Persistent
Zero required and 60 seconds has expired.	---	Low	P1 needs zeroing	Persistent
Zero in progress	<Blank>	None	P1 zeroing	Persistent
Zero failed – pulsatile waveform	N/A	Alert	P1 unable to zero - unstable	Alert
Zero failed – out of range	N/A	Alert	P1 unable to zero - out of range	Alert
Calibration required	<Blank>	None	P1 needs calibration	Persistent
Calibration required and 60 seconds has expired.	---	Low	P1 needs calibration	Persistent
Calibration in progress	<Blank>	None	P1 calibrating	Persistent
Calibration failed – pulsatile waveform	N/A	Alert	P1 unable to calibrate - unstable	Alert
Calibration failed – bad cal resistor	---	Low	P1 problem detected	Persistent

Temperature Conditions:

Condition	Display Value	Alarm Grade	Message	Annunciation Type
TEMP within limits	<NUM>	None	None	None
TEMP < LL	<NUM>	Medium	TEMP < LL	Persistent
TEMP > UL	<NUM>	Medium	TEMP > UL	Persistent
Temp > 50 degrees C	---	Low	TEMP out of range	Persistent
TEMP probe disconnected	---	Low	TEMP unplugged	One Time
TEMP bad calibration resistor	---	Low	TEMP problem detected	Persistent

12.3. What To Do When You Hear An Alarm Tone

When you hear an alarm tone, you should look at the message area of the PPM3 display screen to see why the tone is sounding. The action you should take depends on the message you see, as the following table shows:

Message displayed	**What to do**
Any physiological alarms	Check the patient. Consult the messages table in the appropriate physiological monitoring chapter (e.g., ECG Monitoring) for possible causes and suggested actions.
MPC connection lost	Check to make sure that the Network Cable is still securely connected to the PPM3 and to the wall plate marked "Nightingale Monitoring System." Talk to the MPC operator and check to make sure that the MPC is still operating normally. If none of these steps is successful, contact Zoe Medical Technical Support.
Monitor problem detected	Power-cycle the PPM3. If this message continues, contact Zoe Medical Technical Support.
Battery low	Plug the PPM3 Monitor into a wall outlet to recharge the internal battery.

12.4. Manual Self-test of the Alarm System

You can manually self-test test the alarm system by the following steps:

- Make certain that the SpO_2 alarms on (via the Setup SpO_2 parameter menu). Attach the SpO_2 sensor to your index finger and wait for the monitor to display a SpO_2 parameter value. Unplug the sensor from the PPM3. After 10 seconds, the PPM3 should sound a low grade alarm tone, flash the SpO_2 parameter box, and display the message "SpO_2 unplugged."

- If the PPM3 is being monitored at the MPC, then disconnect the PPM3 from the communications wall outlet. After 30 seconds, the PPM3 should sound a low grade alarm tone and display the message "MPC connection lost."

13. Centralized Monitoring

This chapter describes how to connect the Nightingale PPM3 to the Nightingale MPC central monitoring station. In such installations, communication lines will have been installed from the MPC to the various patient locations where monitoring will be performed. Near the patient location, these communication lines will be connected to a wall plate marked "Nightingale Monitoring System." The PPM3 is connected to this wall plate.

In the Nightingale Monitoring System, the MPC can automatically track the patient's movement when the PPM3 is moved from one patient location to another. It is not necessary to reassign the patient at the MPC.

For details on patient monitoring at the MPC, please see the Nightingale MPC User's Guide.

13.1. Connecting to the MPC

In order to connect the PPM3 to the MPC, connect the Network Cable to the Network Connector labeled as  on the right side of the PPM3. Then plug the other end of the Network Cable into the wall plate connector marked "Nightingale Monitoring System."

When this connection is made (and the PPM3 is powered-on), the MPC and PPM3 will start to communicate with each other. If a patient is already admitted at the PPM3, the MPC will start monitoring that patient (even if a different patient had been admitted at the MPC). However, if no patient had been admitted at the PPM3, then patient information is loaded into the PPM3 from the MPC.

In either case, you should see the patient name in the patient name area of the PPM3 main display screen. For new patients, it is a good idea to admit the patient at the MPC first, since you can then verify that the connection has been made correctly while you are at the patient's bedside.

WARNING – Always make sure that the correct patient name is displayed in the PPM3 name area when connected to the MPC. This is to avoid any chance of mistaking the signals and parameters from one patient with the signals and parameters from another patient at the central monitoring station.

13.2. Remote Control Settings

Most settings used to control the PPM3 can also be set by the MPC operator. These settings are described in the Working With Menus chapter and include:

- Patient information (name and initials)
- Alarm settings (limit settings, alarm on/off settings)
- Waveforms to display
- NBP initial inflation pressure and auto-mode setting
- Pulse tone source

If a setting is changed at either the PPM3 or the MPC, the new setting is used at both the PPM3 and MPC.

If a patient is already admitted at the PPM3 when a connection is initially made between the PPM3 and MPC, the PPM3 and MPC alarm settings are merged such that the more conservative settings are used. That is, the narrower alarm limit range is used and a parameter alarm remains enabled if it was enabled at either the PPM3 or MPC.

If no patient is admitted at the PPM3 when the connection is made, then the PPM3 will use the MPC's settings without modification.

Some settings are not controllable at the PPM3 when the PPM3 is connected to the MPC. These include settings that have a system-wide impact at the MPC (e.g., the temperature units of measure, alarm suspend time-out values). These settings are identified in the Working With Menus chapter.

13.3. Disconnecting from the MPC

The PPM3 can be disconnected from the MPC either by detaching the Network Cable from the wall box or from the connector on the right side of the monitor.

If this is done in order to transport the patient somewhere, then the "Transport Patient" menu item should be selected in the Standby menu before detaching the from the network. This will place the MPC in Transport Mode for this patient and will prevent a "connection lost" alarm from sounding at either the PPM3 or the MPC. See the Entering Standby Mode chapter for more details.

14. Viewing Trends

Each time the PPM3 takes a NBP blood pressure measurement or at user-selectable intervals, it stores the following physiological parameters (provided they are in use or are enabled) in the trends table along with the current time:

- Heart Rate or Pulse Rate
- Non-Invasive Blood Pressure (s/d/m)
- Respiration Rate
- Oxygen Saturation (SpO_2)
- End-tidal CO_2 ($ETCO_2$)
- Fractional inspired CO_2 ($FICO_2$)
- Integrated Pulmonary Index (IPI)
- Temperature (T1)
- Invasive Blood Pressure (P1 s/d/m and P2 s/d/m)

If a HR value is being sourced from ECG, the trends table will show a HR column labeled in green.

If PR is being sourced from SpO_2, there will be a PR column labeled in cyan.

If PR is being sourced from an ART-labeled IBP, there will be a PR column labeled in red.

Up to 72 hours of trends data may be stored on the PPM3. All trend samples can be manually deleted via the trends menu. They are also deleted when a patient is discharged at the MPC.

You can view the trends for a patient by pressing the TRENDS key.

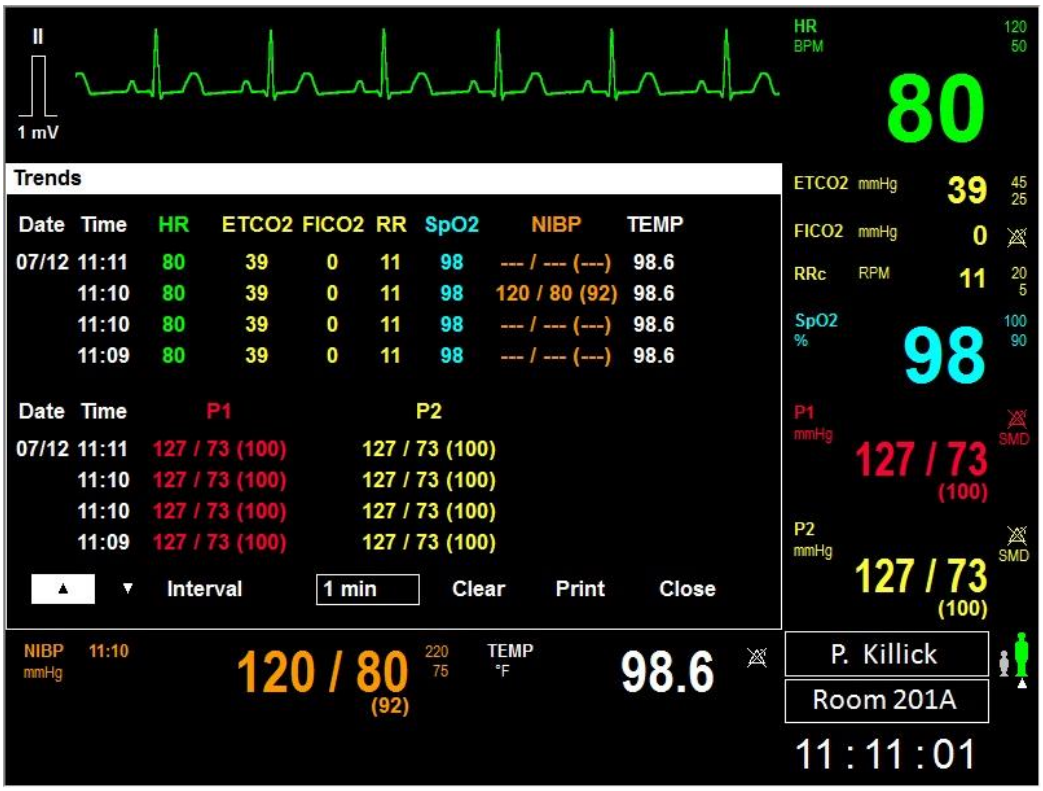


Figure 62. Trends Menu

By selecting the "Print" item, you can get a hard copy of the trends data if the optional Strip Chart Recorder is configured with your PPM3 (see the Strip Chart Recorder Option chapter).

If your PPM3 is connected to the MPC, this report will print out immediately on the printer configured with the MPC. Otherwise, the data will be stored internally, and will upload and print automatically the next time the PPM3 is connected to the MPC.

Using the up and down arrows on the Trends menu, you can scroll backward and forward in time through the trends data.

The "Clear" menu item will cause all the trends data to be deleted. Before this happens, you will be prompted with the following confirmation.

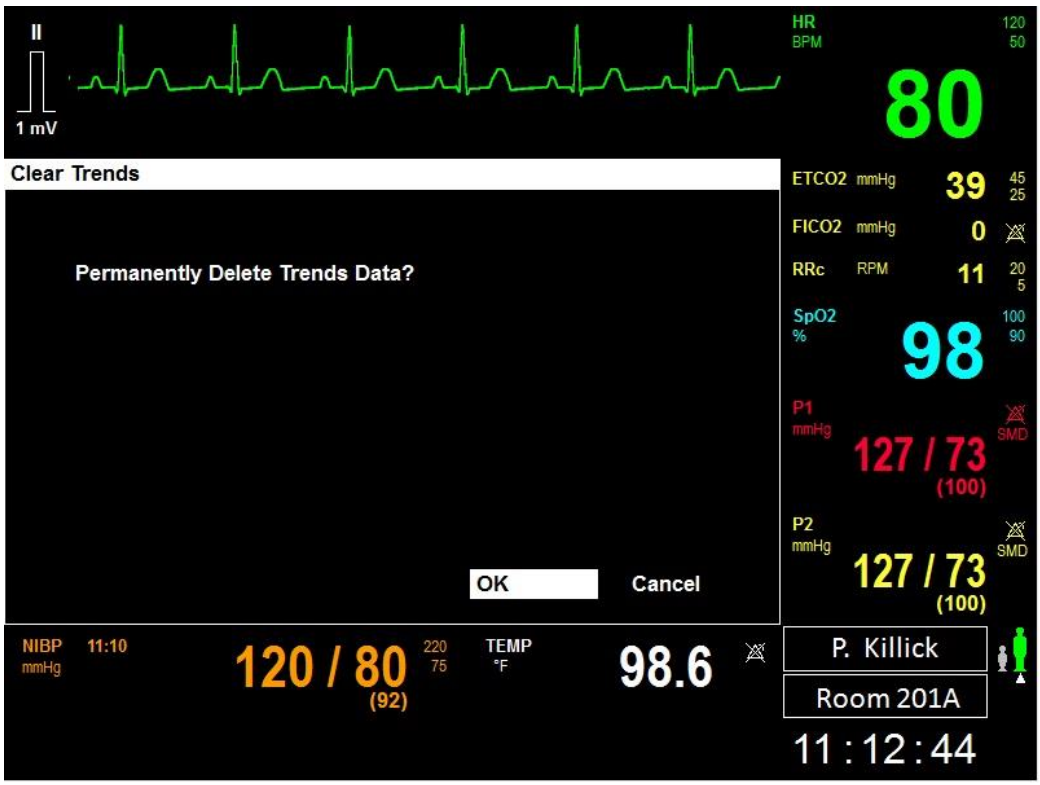


Figure 63. Clear Trends Menu

15. Entering Standby Mode

If you press the "Standby" key while a patient is admitted to the PPM3, the PPM3 will present you with the various Standby Mode options.

Figure 64. Standby Menu

Select the "Enter Standby Mode" menu item if you wish to temporarily suspend all monitoring for this patient (say, when the patient is being bathed). This will place both the PPM3 and the MPC in Standby Mode for this patient. In addition, the PPM3 will display the Standby Mode Display.

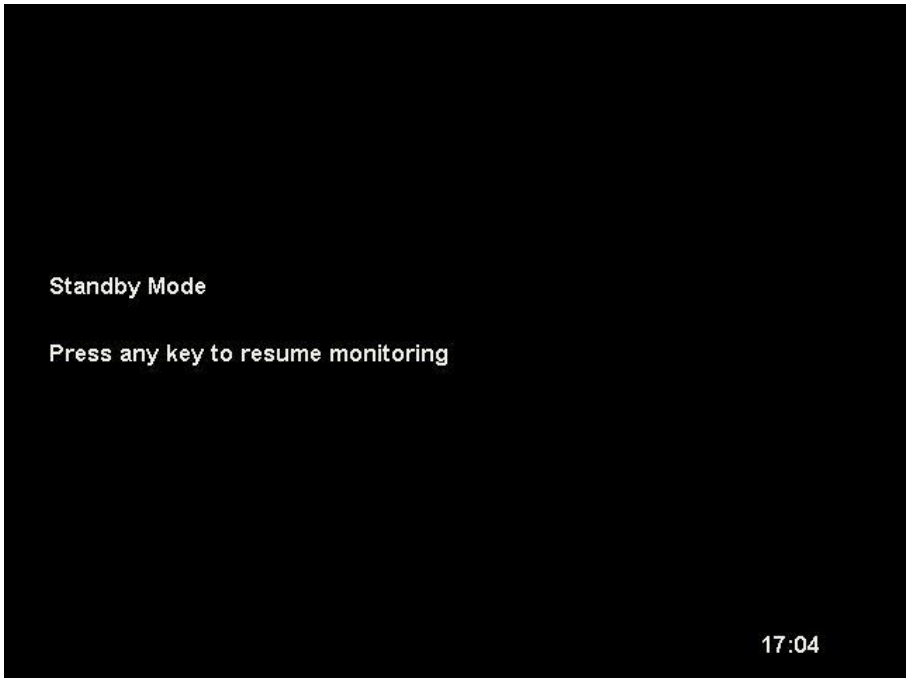


Figure 65. Standby Mode

When a key is pressed the previous patient must be confirmed. If you select "No," that patient will be discharged and a new patient will be admitted. Navigate to the Setup Patient Information Menu to enter information for the new patient.

Figure 66. Wakeup From Standby Mode

WARNING – Patient monitoring will be suspended at both the PPM3 and MPC for this patient when the Enter Standby Mode menu item is selected.

Select the "Transport Patient" menu item if you are about to disconnect the PPM3 from the MPC in order to move the patient. This will place the MPC in Transport Mode for this patient and will prevent Connection Lost alarms from being sounded at both the PPM3 and MPC.

WARNING – Patient monitoring will be suspended at the MPC for this patient when the Transport Patient menu item is selected.

When the PPM3 is reconnected to the MPC, the MPC will automatically exit Transport Mode and resume monitoring.

Select the "Discharge Patient" menu item if you are finished monitoring this patient. This will de-assign the patient from both the PPM3 and MPC (although the patient's trend data will still be archived at the MPC). In addition, the PPM3 will restore the monitor's parameter and waveform settings to the Department Defaults (last saved setup), and suspend monitoring (as described above).

WARNING – Patient monitoring will be suspended at the MPC for this patient when the Discharge Patient menu item is selected.

16. Battery Operation

The PPM3 contains a lithium-ion rechargeable battery that allows you to disconnect the PPM3 from the wall power and use it for applications where mobility is required.

When the PPM3 battery is fully charged, it provides for at least 4 hours of normal operation. When the PPM3 is operating on battery power, a battery icon appears on the PPM3 screen to the right of the time. The battery icon is designed to give an approximate sense of how much battery life is remaining.

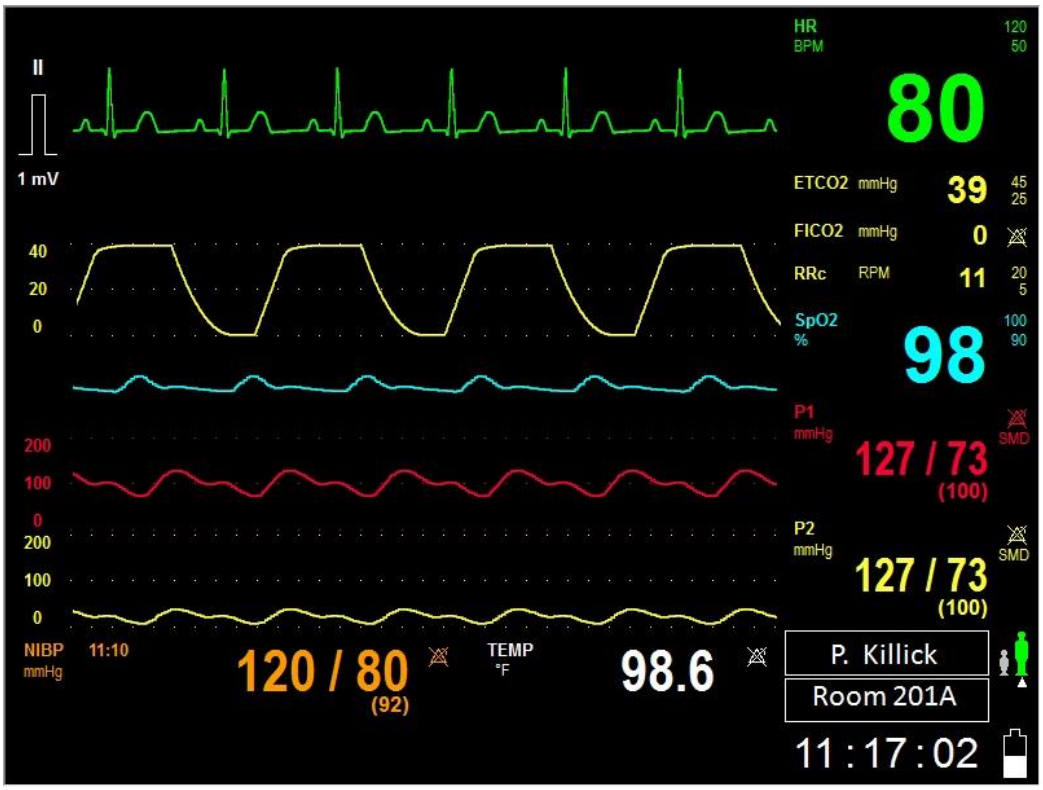


Figure 67. Main Screen With Battery Icon

When the battery is running out of charge, the battery icon starts to blink, a Low Battery alarm message is displayed, and an alarm tone is annunciated. When this happens, as little as 5 minutes of battery charge is remaining, and the PPM3

should be connected to a wall outlet in order to prevent a loss of patient monitoring.

When the battery power is too low to continue normal operation, the PPM3 display will go blank and a constant low-grade tone will be generated.

When the PPM3 is reconnected to the wall power it will begin recharging. Battery charging occurs regardless of whether the PPM3 is powered on. For every hour of battery use, it takes about one hour to recharge the battery. A fully depleted battery takes about 5 hours to fully recharge.

The green LED on the back of the PPM3 indicates that the battery is being charged. To determine when the battery is full charged, disconnect the battery from the wall power and check the battery icon on the PPM3 Main Screen (shown above).

The toggle switch on the back of the PPM3 allows you to turn the PPM3 on and off.

See the Maintenance chapter for details on how to have the battery replaced.

WARNING – Consult the safety instructions at the front of this manual regarding the proper use and disposal of the battery.

17. Strip Chart Recorder Option

17.1. Basic Operation

PPM3 monitors may be configured with an optional 50mm strip chart recorder available from Zoe Medical. To start a recording, press the Print key. When a recording is in progress, you can press the Print key to stop it.

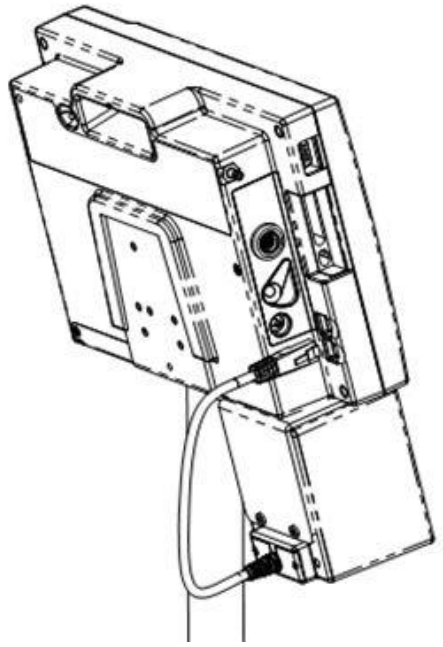


Figure 68. PPM3 Recorder Connection

Plug the recorder cable into the connector labeled as on the left side of the PPM3.

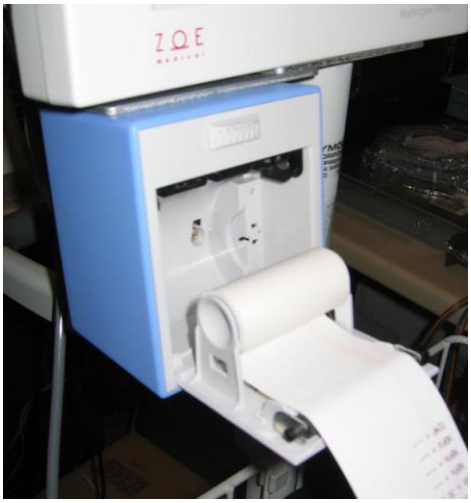


Figure 69. Replacing Recorder Paper

Press down on the recorder door latch to release the door. Remove the old spool, and replace with a new roll. The paper should come out from under the roll, as shown in the photo.

17.2. Recorder Settings

If after pressing the SETUP key, you select the "Recorder" item, the Setup Recorder menu will appear.

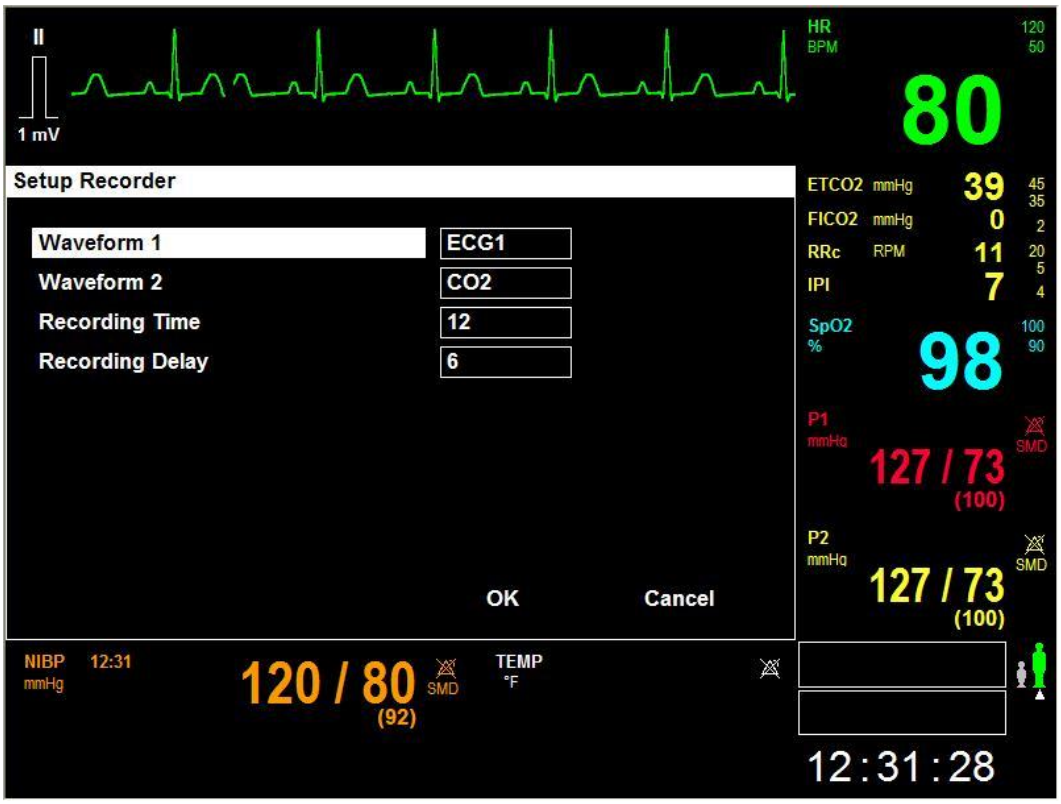


Figure 70. Setup Recorder Menu

The Waveform 1 setting controls which waveform is shown in the top channel of the strip chart recordings. The Waveform 2 setting controls which waveform is shown in the bottom channel of the strip chart recordings. If this setting value is Off, or if it is set to ECG2 but only one ECG waveform is selected for display, the strip chart recording will have only one waveform.

The Recording Time setting controls the amount of time represented on strip chart recordings. The Recording Delay setting controls how much of the printed strip represents time prior to the event that initiated the recording, whether a key press or an alarm.

17.3. Strip Chart Recordings

Strip chart recordings contain a waveform area that includes a 40 mm-wide grid with descriptive text above and below the grid. The waveform grid has major divisions at 5 mm intervals and minor divisions at 1 mm intervals, in both the x and y direction.

The waveform area contains one or two user-selected waveforms. If one waveform is selected, the waveform uses the entire grid. If two waveforms are selected, each waveform uses half of the grid, with no overlap. If the same waveform is selected for both waveform channels, it is treated as a single waveform selection (i.e., one waveform using the entire grid).

Any displayed waveform may be selected for printing. The printed waveform scaling and lead-off handling matches that of the displayed waveform. The descriptive text above the waveform area describes the top waveform. The text below the waveform area describes the bottom waveform (or is left blank if only 1 waveform is printed). The descriptive text includes the waveform label, the waveform scale and the associated parameter value. For ECG waveforms, the frequency response (fixed at monitor) is printed. Additionally, the descriptive text above the waveform area includes the current date/time, the waveform delay, and the sweep speed (fixed at 25 mm/sec).

Strip chart recordings contain a trailer with the current date/time and a list of all parameters (label, value, and units of measure) that are currently on display.

Alarm-generated strip chart recordings contain a header with an "Alarm Snapshot" banner and a list of the parameters (label, value, and units of measure) that are currently in alarm.

When a strip chart recording is in progress, you can cancel it by pressing the Print key.

17.4. Trend Recordings

When the recorder option is installed, the recorder can print out a Trend Report. This report contains the same information that is presented in the trends display, with the following additions:

- A header that includes a Trend Report title and the date/time of the trend report.
- The date is displayed along with the time of trend data entries.
- All trend data entries are printed (including those more than 24 hours old).
- Temperature is printed in the currently active units of measure along with the units of measure.
- A "Patient Demographic" trailer is printed. This provides a space for the user to write the patient's name and id, as well as comments. If patient has been admitted, the patient's name is printed.

17.5. Recorder Messages

If the recorder door is open, a technical alarm tone sounds and the message "Recorder door open" is displayed in the bottom display message area.

If the recorder is out of paper, a technical alarm tone sounds and the message "Recorder out of paper" is displayed in the bottom display message area.

When the recorder option is installed but the recorder is not physically connected, a technical alarm tone sounds and the message "Recorder problem detected" is displayed in the bottom display message area.

If the monitor senses a recorder error condition, a technical alarm tone sounds and the message "Recorder problem detected" is displayed in the bottom display message area.

When the "Recorder problem detected" message is displayed, the cause of the failure is logged in the event log for viewing by service personnel.

18. Troubleshooting

The following table is meant to help you solve problems that you may encounter while operating the PPM3. If you are still experiencing a problem and none of these steps seem to help, please contact Zoe Technical Support:

WARNING – With the exception of battery replacement, modifications or repairs of the PPM3 must be done by service personnel that are authorized by Zoe Medical. Unauthorized modification or repairs may void the warranty.

Email: customersupport@zoemedical.com

Phone: (978) 887-4013

Trouble Symptom	Possible Causes	Things to Try
The PPM3 is plugged in but it does not start up	No power to outlet	Verify that the power outlet is working. Verify that the green power LED on the PPM3 front panel is illuminated.
	The PPM3 Power Supply is not working	Verify that the green charging LED on the PPM3 rear panel is illuminated. If possible, try using a different PPM3 Power Supply to see if that is the problem.
	The PPM3 is powered off.	Set the power switch to the On position.
	Internal system error	Power cycle the PPM3 – if condition persists, stop using the PPM3, contact Zoe Medical Technical Support to request a repair or replacement
The PPM3 won't run on battery power.	Battery needs recharging.	Connect the PPM3 to wall power. Verify that the green charging LED on the PPM3 rear panel is illuminated.
	Battery will not hold a charge	Replace battery according to the instructions in the Maintenance and Storage chapter.

Trouble Symptom	Possible Causes	Things to Try
No patient name appears on the PPM3	Patient Information has not been entered into a standalone PPM3.	Supply the information in the Setup Patient Information menu.
	No connection to MPC	Verify the PPM3 is powered on, the Network Cable is securely connected to the PPM3 and the wall plate labeled "Nightingale Monitoring System"
	Patient has not been admitted at the MPC	Verify that the patient is admitted at the MPC
The patient name on the PPM3 does not match the name on the MPC	The patient was admitted to the wrong small view area on the MPC	Verify that the patient is admitted into the correct small view area for the PPM3
	The connection cabling to the PPM3 has been changed in the telecommunications closet	Stop using the PPM3, contact Zoe Medical Technical Support to re-check the system installation
The PPM3 front panel keypad is not working right	Keypad failure	Stop using the PPM3, contact Zoe Medical Technical Support to request a repair or replacement
The PPM3 knob is not working right	Knob failure	Stop using the PPM3, contact Zoe Medical Technical Support to request a repair or replacement
The PPM3 display is not working right	Display failure	Stop using the PPM3, contact Zoe Medical Technical Support to request a repair or replacement
The PPM3 is not working right and displays an error message	Operating system failure	Power cycle the PPM3 – if condition persists, stop using the PPM3, contact Zoe Medical Technical Support to request a repair or replacement
The PPM3 displays a message stating that the disk is too full.	The PPM3's disk is too full and needs to be cleaned up.	Stop using the PPM3, contact Zoe Medical Technical Support to request a repair or replacement
The PPM3 displays a message stating that the CPU is too busy.	Internal system failure	Stop using the PPM3, contact Zoe Medical Technical Support to request a repair or replacement
Recorder problem detected (Recorder option only)	Recorder is disconnected, or monitor has sensed an error condition in the recorder.	Check to be sure the recorder is still connected. If this does not help, stop using the recorder, and contact Zoe Medical Technical Support to request a repair or replacement

19. PPM3 Monitor Settings

The following tables show the factory default settings (Patient Data, Parameter, Waveform, and Device) for the Nightingale PPM3 monitor. Note the differences in certain parameter settings for Adult and Pediatric patient types. You may adjust the parameter and waveform settings for your particular application, and then save this configuration as a department default for all new patients. These department default settings can be adjusted as needed for specific patients, as shown in the Working With Menus chapter. System Settings are specific to a particular PPM3 device.

Patient Data Settings		
Setting name	**Default value**	**Possible values**
Patient Last Name	<BLANK>	any text string (39 characters maximum)
Patient Middle Initial	<BLANK>	any text string (1 characters maximum)
Patient First Name	<BLANK>	any text string (39 characters maximum)
Patient ID	<BLANK>	any text string (39 characters maximum) but may not include the following characters (since they are not legal Windows file names, and the Patient ID is used to create folder and file names): \ / : * ? " < > |
Patient Type	Adult	Adult, Pediatric
Patient Sex	<BLANK>	Unknown (BLANK), Male, Female
Patient Date Of Birth Year	<BLANK>	(Current Year – 150) up to Current Year
Patient Date Of Birth Month	<BLANK>	1 - 12
Patient Date Of Birth Day	<BLANK>	1 – maximum number of days in specified month and year
Patient Height	<BLANK>	0 – 157 inches 0 – 400 cm
Patient Weight	<BLANK>	0 – 1100 lbs 0 – 500 kg

Parameter Settings			
Setting name	**Default value Adult / Pediatric**		**Possible values**
$ETCO_2$ Enabled	No	No	Yes, No
IBP Channels	None	None	None, 1, 2
Numbers Only	No	No	Yes, No
HR Lower Alarm Limit	50 bpm	---	15 to 299 bpm
HR Upper Alarm Limit	120 bpm	150 bpm	16 to 300 bpm
HR Alarms On	Yes	Yes	Yes, No
HR Print on Alarm	No	No	Yes, No
ECG Lead	II	II	I, II, III, V, aVL, aVR, aVF
(ECG Lead) Size	10 mm/mV	10 mm/mV	2.5 mm/mV, 5 mm/mV, 10 mm/mV, 15 mm/mV, 20 mm/mV
HR Source	ECG	ECG	Auto, ECG, SpO2, NIBP, ART
Pulse Tones	Off	Off	Off, On
ECG Filter	Monitor (0.67 – 40 Hz)	Monitor (0.67 – 40 Hz)	Monitor (0.67 – 40 Hz), Diagnostic (0.05 – 40 Hz)
RR Lower Alarm Limit	5 bpm	10 bpm	5 to 149 bpm
RR Upper Alarm Limit	20 bpm	45 bpm	6 to 150 bpm
RR Alarms On	Yes	Yes	Yes, No
RR Print on Alarm	No	No	Yes, No
$ETCO_2$ Upper Alarm Limit(Note: Depends On User Setting For CO2 Units)	45 mmHg 6.0 kPa	45 mmHg 6.0 kPa	5 to 150 mmHg 0.7 to 20.0 kPa
$ETCO_2$ Lower Alarm LimitLimit(Note: Depends On User Setting For CO2 Units)	35 mmHg 4.7 kPa	35 mmHg 4.7 kPa	0 to 145 mmHg 0.0 to 19.3 kPA
$ETCO_2$ Alarms On	Yes	Yes	Yes, No
$ETCO_2$ Print on Alarm	No	No	Yes, No
$FICO_2$ Upper Alarm Limit Limit(Note: Depends On User Setting For CO2 Units)	5 mmHg 0.7 kPa	5 mmHg 0.7 kPa	0 to 25 mmHg 0.0 to 3.5 kPa
$FICO_2$ Alarms On	Yes	Yes	Yes, No
$FICO_2$ Print on Alarm	No	No	Yes, No
RRc Lower Alarm Limit	5 bpm	10 bpm	5 to 149 bpm
RRc Upper Alarm Limit	20 bpm	45 bpm	6 to 150 bpm
RRc Alarms On	Yes	Yes	Yes, No
RRc Print on Alarm	No	No	Yes, No

Parameter Settings			
Setting name	**Default value Adult / Pediatric**		**Possible values**
Apnea Time	20 seconds	20 seconds	10, 15, 20, 25, 30 seconds
O_2 Compensation (Masimo)	0 to 30	0 to 30	0 to 30, 31 to 70, 71 to 100
N_2O Compensation (Masimo)	0 to 30	0 to 30	0 to 30, 31 to 70
IPI Enabled (Oridion)	Yes	Yes	Yes, No
IPI Lower Limit	4	4	1 to 9
IPI Alarms On	No	No	Yes, No
IPI Print on Alarm	No	No	Yes, No
IPI Pediatric Age Range	N/A	<BLANK>	1 to 3 years, 3 to 6 years, 6 to 12 years
SpO_2 Lower Alarm Limit	90%	90%	50 to 99%
SpO_2 Upper Alarm Limit	100%	100%	51 to 100%
SpO_2 Alarms On	Yes	Yes	Yes, No
SpO_2 Print on Alarm	No	No	Yes, No
P1s Lower Alarm Limit	90 mmHg	90 mmHg	-10 to 249 mmHg
P1s Upper Alarm Limit	180 mmHg	145 mmHg	-9 to 250 mmHg
P1s Alarms On	No	No	Yes, No
P1s Print on Alarm	No	No	Yes, No
P1m Lower Alarm Limit	75 mmHg	75 mmHg	-10 to 229 mmHg
P1m Upper Alarm Limit	110 mmHg	110 mmHg	-9 to 230 mmHg
P1m Alarms On	No	No	Yes, No
P1m Print on Alarm	No	No	Yes, No
P1d Lower Alarm Limit	55 mmHg	55 mmHg	-10 to 209 mmHg
P1d Upper Alarm Limit	100 mmHg	100 mmHg	-9 to 210 mmHg
P1d Alarms On	No	No	Yes, No
P1d Print on Alarm	No	No	Yes, No
P1 Label	P1	P1	P1, ART, PA, CVP
P1 Format	SYS/DIA	SYS/DIA	SYS/DIA, MEAN
TEMP Lower Alarm Limit (Note: Depends On User Setting For TEMP Units)	36.0 °C 97.0 °F	36.0 °C 97.0 °F	15.0 to 44.9 °C 59.0 to 112.9 °F
TEMP Upper Alarm Limit (Note: Depends On User Setting For TEMP Units)	39.0 °C 102.0 °F	39.0 °C 102.0 °F	15.1 to 45.0 °C 59.1 to 113.0 °F
TEMP Alarms On	No	No	Yes, No
TEMP Print on Alarm	No	No	Yes, No

Parameter Settings			
Setting name	**Default value Adult / Pediatric**		**Possible values**
NBPs Lower Alarm Limit	90 mmHg	90 mmHg	30 to 249 mmHg
NBPs Upper Alarm Limit	180 mmHg	145 mmHg	31 to 250 mmHg
NBPs Alarms On	No	No	Yes, No
NBPs Print on Alarm	No	No	Yes, No
NBPm Lower Alarm Limit	75 mmHg	75 mmHg	20 to 229 mmHg
NBPm Upper Alarm Limit	110 mmHg	110 mmHg	21 to 230 mmHg
NBPm Alarms On	No	No	Yes, No
NBPm Print on Alarm	No	No	Yes, No
NBPd Lower Alarm Limit	55 mmHg	55 mmHg	10 to 209 mmHg
NBPd Upper Alarm Limit	100 mmHg	100 mmHg	11 to 210 mmHg
NBPd Alarms On	No	No	Yes, No
NBPd Print on Alarm	No	No	Yes, No
NBP Interval	Off	Off	Off, 1, 2, 3, 5, 10, 15, 30, 60, 120 minutes
NBP Initial Inflation Pressure	160 mmHg	120 mmHg	80 to 270 mmHg in steps of 10 mmHg
Trend Interval	15 min	15 min	1 min, 5 min, 15 min, 1 h, 4 h

Note -- Regarding limits settings, the upper limit must always be higher than the lower limit, in addition to the constraints implied by the ranges listed in the table above.

Waveform Settings		
Setting name	**Default value**	**Possible values**
Channel 1 Waveform	II	I, II, III, V, aVL, aVR, aVF
Channel 2 Waveform	RESP	I, II, III, V, aVL, aVR, aVF, RESP, CO2
Channel 3 Waveform	SpO2	I, II, III, V, aVL, aVR, aVF, SpO_2
Channel 4 Waveform	P1	I, II, III, V, aVL, aVR, aVF, P1
Channel 5 Waveform	P2	I, II, III, V, aVL, aVR, aVF, P2
ECG I Waveform Size	10 mm/mV	2.5, 5, 10, 15 mm/mv
ECG II Waveform Size	10 mm/mV	2.5, 5, 10, 15 mm/mv
ECG III Waveform Size	10 mm/mV	2.5, 5, 10, 15 mm/mv
ECG V Waveform Size	10 mm/mV	2.5, 5, 10, 15 mm/mv
ECG AVL Waveform Size	10 mm/mV	2.5, 5, 10, 15 mm/mv
ECG AVR Waveform Size	10 mm/mV	2.5, 5, 10, 15 mm/mv
ECG AVF Waveform Size	10 mm/mV	2.5, 5, 10, 15 mm/mv
CO_2 Waveform Size	0 to 40 mmHg	0 to 20, 0 to 40, 0 to 60, 0 to 80 mmHg
P1 Waveform Size	0 to 200 mmHg	-10 to 20, -10 to 60, 0 to 150, 0 to 200, 0 to 250, 0 to 300 mmHg
P2 Waveform Size	0 to 200 mmHg	-10 to 20, -10 to 60, 0 to 150, 0 to 200, 0 to 250, 0 to 300 mmHg
Sweep Speed	25 mm/sec	6.25, 12.5, 25 mm/sec
Show Beat Detect Spikes	No	No, Yes

Recorder Settings		
Setting name	**Default value**	**Possible values**
Waveform 1	ECG1	ECG1, ECG2, RESP, CO2, SpO2, P1, P2, NIBP
Waveform 2	RESP	ECG1, ECG2, RESP, CO2, SpO2, P1, P2, NIBP
Recording Time	12 seconds	8, 12, 20 seconds
Recording Delay	6 seconds	0, 6, 10 seconds

Device Settings		
Speaker Volume	6	1 to10
Pulse Tone Volume	4	1 to 10
Alarm Silence Time	1 minute	1, 2, or 3 minutes
Alarm Pause Time	1 minute	1, 2, or 3 minutes
Can Pause All Alarms	Yes	Yes, No
Alarm Validation	On	On, Off
Second Speaker Time	2 minutes	0, 1, 2, 3 minutes
Temp Units	Degrees F	Degrees F, Degrees C
CO2 Units	mmHg	mmHg, kPa
Height Units	in	in, cm
Weight Units	lbs	lbs, kg
Print Location	Bedside Only	Bedside Only, Central Only, Bedside and Central
Set Date / Time Year	--	1980 - 3000
Set Date / Time Month	--	1 - 12
Set Date / Time Day	--	1 – 31 (depending on month and leap year status)
Set Date / Time Hour	--	0 - 23
Set Date / Time Minute	--	0 -59
Simulated Data Mode	Off	On, Off
Language	English	English
Notch Filter	60 Hz	60 Hz, 50 Hz, Off
NIBP Cal. Mode	Off	On, Off
Monitor ID	<BLANK>	Any text string (23 characters maximum)
Serial Number	<BLANK>	Any text string (11 characters maximum, must obey serial number convention for product)
Show Diagnostic Messages	No	Yes, No
SpO2 Tracing	Off	On, Off
NIBP Tracing	Off	On, Off
IBP Installed	None	None, 2
$ETCO_2$ Installed	None	None, Oridion (Internal), PhaseIn (External)

20. Accessories

The following table shows the accessories approved by Zoe Medical for use with the Nightingale PPM3.

WARNING – Use only approved accessories with the PPM3. Using non-approved accessories may result in damage to the monitoring equipment, measurement error, or harm to the patient, and may void warranty coverage.

Part Number	Description
ECG Monitoring Accessories	
421-0014	ECG 3 Lead Set, US, 1.5 meter, Snap-On
421-0038	ECG 3 Lead Set, US, 3.0 meter, Snap-On
421-0110	ECG 5 Lead Set, US, 1.5 meter, Snap-On
421-0032	ECG 5 Lead Set, US, 3.0 meter, Snap-On
SpO_2 Monitoring Accessories	
180-3014	SpO_2 Sensor, Reusable
180-3008	SpO_2 Extender Cable (4 foot)
180-3007	SpO_2 Extender Cable (8 foot)
NBP Monitoring Accessories	
180-1004	NBP Hose
180-1022	NBP Cuff, Adult (26-35 cm)
180-1023	NBP Cuff, Large Adult (32-42 cm)
180-1029	NBP Cuff, Infant (8-14 cm)
180-1030	NBP Cuff, Child (13-20 cm)
180-1031	NBP Cuff, Adult Long (29-38 cm)
180-1033	NBP Cuff, Thigh (42-50 cm)
CO_2 Monitoring Accessories	
010-427	Oridion Smart CapnoLine Plus and FilterLine Sample Pack

Part Number	Description
IBP Monitoring Accessories	
421-6102	PPM3 Invasive Pressure Y Cable
421-0047	Transducer Adapter Cable Utah to PPM3
421-0057	Transducer Adapter Cable Edwards to PPM3
421-0058	Transducer Adapter Cable BD to PPM3
Temperature Monitoring Accessories	
180-4009	Oral Temperature Probe Kit
180-4005	Probe Covers, 250 count
Mounting Brackets and Accessories	
180-8008	Table Stand (tilted)
180-8008-1	Table Stand for PPM3
180-8008-2	Table Stand for PPM2 & PPM3 w-Recorder
180-8016	Pole Mount (C Clamp Mount)
180-8017	Roll Stand Kit
180-8014	Wall Mount Channel and Arm Kit. Requires PPM3 Pole Mount
Power Supply	
725-0037	PPM3 Power Supply
180-6001	Power Cord US (10 ft)
180-1055	Lithium-Ion Battery
Strip Chart Recorder Option	
180-0100	50mm Strip Chart Recorder
180-8024	50mm Strip Chart Recorder Mounting Bracket
180-0102	Thermal Paper Roll, 50 mm wide 10 each
180-0101	Thermal Paper Roll, 50 mm wide 100 each
Communication Cables	
421-0052	PPM3 Serial Cable
421-0053	PPM3 Network Cable

21. Cleaning

This table provides cleaning instructions for the PPM3, which should be cleaned monthly or as warranted. Accessories should be cleaned before application to a patient. Before cleaning, refer to the cautions listed after the table.

Part	**Recommended cleaning method**
Nightingale PPM3 ECG Cables TEMP Cable SpO_2 Cable IBP Y-Cable NBP Cuff NBP Hose PPM3 Power Supply PPM3 Power Cord OMD Cable	<u>Materials</u> • Enzymatic detergent such as ENZOL (US) or CIDEZYME (outside the US) • Distilled water • Disinfectant solution (such as CIDEX OPA, or a 10% solution of household bleach (5.25% sodium hypochlorite) in distilled water) • Soft cloths and/or soft-bristled brushes • Protective gloves and eyewear <u>Procedure</u> 1. Disconnect the unit from the wall outlet. 2. Put on gloves and protective eyewear. 3. Prepare the enzymatic detergent according to the manufacturer's instructions, and also the disinfectant solution, in separate containers. 4. Apply detergent to product using a soft cloth. If material is dried on, allow to sit for 1 minute. 5. Wipe smooth surfaces with the cloth. 6. Use a soft-bristle brush on visibly soiled areas and irregular surfaces. 7. Remove detergent from product using cloth dampened in distilled water. 8. Repeat as necessary. 9. Apply disinfectant solution on affected area using a soft cloth. Allow product to sit for 5 minutes. 10. Wipe away excess solution and clean product again with cloth dampened in distilled water. 11. Allow 2 hours for drying.
Temperature Probe Covers	Temperature probes are one-time use only.

Part	Recommended cleaning method
Reusable SpO_2 Sensor	Materials • 70% isopropyl alcohol Procedure Remove sensor from patient and disconnect from sensor cable. Wipe off with alcohol pad. Allow sensor to dry before placing it on a patient.
Masimo IRMA (Mainstream) CO_2 Probe	Materials • Cloth moistened with 70% (max) ethanol or isopropyl alcohol Procedure Remove probe from patient and disconnect from airway adapter. Wipe off with cloth. Allow probe to dry before placing it on a patient.
Masimo ISA (Sidestream) CO_2 Analyzer	Materials • Cloth moistened with 70% (max) ethanol or isopropyl alcohol Procedure Remove probe from patient. Keep sampling line connected while cleaning to prevent liquids and dust from entering the analyzer via the LEGI connector. Wipe off with cloth. Allow analyzer to dry before placing it on a patient.

CAUTION – Always disconnect the PPM3 from AC mains before cleaning.

CAUTION – Do not use harsh chemicals for cleaning – in particular, do not use disinfectants that contain phenol as they can spot plastics. Do not steam autoclave, gas sterilize, irradiate, subject to intense vacuum, or immerse in water or cleaning solution. Be careful to avoid getting cleaning liquids into connectors or the unit. If this occurs, allow the unit to dry in

warm air for 2 hours, then check to make sure all monitoring functions are still working properly.

CAUTION – Take particular care when cleaning the NBP cuff, NBP hose, and NBP connector on the PPM to prevent fluid from entering the connectors. Fluid in the NBP airway may affect blood pressure determination accuracy and damage the monitor.

CAUTION – Microstream® $ETCO_2$ sampling lines are designed for single patient use, and are not to be reprocessed. Do not attempt to clean, disinfect, sterilize or flush any part of the sampling line as this can cause damage to the monitor.

CAUTION – Accessories that fall on the floor should be inspected for contamination and proper functionality. If contamination is observed, then this cleaning procedure should be followed.

CAUTION – The user has the responsibility to validate any deviations from the recommended method of cleaning and disinfection.

22. Maintenance and Storage

The following table shows the recommended maintenance procedures for the Nightingale PPM3 monitor and its accessories. The Nightingale PPM3 monitor does not require periodic recalibration – with the exception of the Oridion Microstream® CO_2 module (see the PPM3 Calibration Procedures after the Functional Tests). However, it is a good idea to check that the monitor is in good working order, as described in the following table. These functional tests should be done every 12 months, and they can be performed by clinicians or qualified service personnel. The following equipment is needed to perform these procedures:

- ECG/Respiration Simulator (e.g., Fluke Biomedical MPS-450)
- SpO_2 Simulator (e.g., Fluke Biomedical Index-2)
- Blood Pressure Simulator (e.g., Fluke Biomedical BP-Pump2)
- Safety Analyzer (e.g., Fluke Biomedical 505 Series)
- Oridion Microstream® calibration kit from Air Liquide (Scott Medical); Part Number T4653ORFCD – including a canister of 5% CO_2, 21% O_2, with the balance N_2 along with a T-piece connection and a calibration Filterline.

22.1. PPM3 Functional Tests

PPM3 Function	Procedure
Mechanical Integrity	Check for cracks, abrasive edges and other signs of damage.
Knob	Verify menu navigation functionality by turning and pressing.
Front Panel Keys	PRINT key: verify that a Vital Signs Report is generated at the MPC's printer. ALARM SILENCE key: verify that alarm tone can be silenced. NBP INTERVAL key: verify NBP Interval menu is displayed. NBP START / STOP key: verify NBP measurement starts and stops. STANDBY key: verify that unit enters Standby mode or displays Standby Menu SETUP key: verify that the top level Setup menu is displayed. TRENDS key: verify that the Trends menu is displayed MAIN SCREEN key: verify that the Main Screen is displayed
Power LED	Verify that the green power LED is illuminated on the front of the PPM3.
Battery Charging LED	Verify that the green charging LED is illuminated on the back of the PPM3

PPM3 Function	Procedure
	when plugged into mains power.
Speaker	Power-cycle the PPM3 and verify that the power-up speaker test tones are generated.
Second Speaker	Power-cycle the PPM3 and verify that the power-up second speaker test tones are generated.
ECG / Respiration	Connect ECG leads to Patient Simulator. • Verify proper heart rate at 30 and 300 bpm (+/- 2 bpm or +/- 1%). • Verify 1 mV test pulse (Lead II). • Verify proper respiration rate at 15 and 120 bpm (+/- 3 bpm).
SpO_2	Connect to Patient Simulator (select appropriate sensor type). • Verify proper SpO2 value at 84% and 96% (+/- 2%). • Verify proper PR value at 30 and 240 bpm (+/- 5%).
NBP	***NOTE:*** *Do not allow system to remain pressurized and stable below 20 mmHg. The monitor will remove this pressure as a zero offset and this will affect the validity of the calibration check.* ***NOTE:*** *The following are required to perform this test: NIBP simulator or sphygmomanometer along with a Y-adapter and a hand inflation bulb.* **Pressure Accuracy Test:** Via the Service settings, put the NIBP in to calibration mode. Set the pressure to 25 mmHg and 225 mmHg respectively and verify that the pressure values reported by the PPM3 patient monitor matches (±2 mmHg) of that reported on the simulator or sphygmomanometer. Release pressure. **Overpressure Test:** Inflate cuff to 300 mmHg. Verify that the pressure is automatically dumped at 300 +/- 30 mmHg. **Leak Test:** Inflate a cuff to 150 mmHg. Allow cuff pressure to settle (thermal effect). Verify that the pressure drops less than 4 mmHg in 1 minute. Verify that the pressure is automatically dumped after 180 seconds. Set the NIBP back to normal mode. Power cycle the monitor. **Measurement Accuracy Test:** Connect to Patient Simulator and take a NIBP measurement. Verify proper NIBP value at 120/80 (+/- 5 bpm).

<table>
<tr><th>PPM3 Function</th><th>Procedure</th></tr>
<tr><td>Oridion Microstream® CO_2</td><td>

***NOTE**: Use only certified calibration gas apparatus that has not reached its expiration date. This cal gas can be applied to the PPM3 patient monitor in pulses that simulate patient breaths.*

1. Connect the supplied CO_2 calibration FilterLine between the PPM3 and the cal gas canister.
2. Pulse the calibration gas actuator, holding it depressed for 10 seconds and released for 10 seconds (3 BPM). This will allow enough time for the $ETCO_2$ to stabilize in both inhaled and exhaled states.
3. Verify that the $ETCO_2$ value reads 38 ± 2 mmHg and the $FICO_2$ value reads 0 ± 2 mmHg.

***NOTE**: Factor a ±0.05 correction for every 100mmHg of ambient barometric pressure above or below sea level respectively.*

***NOTE**: The PPM3 should be returned to Zoe Medical for periodic servicing of the CO_2 system after 30,000 hours of CO_2 use.*

</td></tr>
<tr><td>Masimo IRMA and ISA CO_2</td><td>

***NOTE**: Use only certified calibration gas apparatus that has not reached its expiration date. This cal gas can be applied to the PPM3 patient monitor in pulses that simulate patient breaths.*

1. Connect the PPM3 to a calibration gas canister (5% CO_2, 21% 0_2, Balance N_2)
2. Pulse the calibration gas actuator, holding it depressed for 10 seconds and released for 10 seconds (3 BPM). This will allow enough time for the CO_2 values to stabilize.
3. Verify that the $FiCO_2$ value is 0-2 mmHg and that the $ETCO_2$ value is within the range that is defined in the following table:

Current Atmospheric Pressure		Expected etCO2
mmHg	mbar	mmHg
600 - 619	800 - 825	28 - 33
620 - 639	826 - 852	29 - 34
640 - 659	853 - 879	30 - 35
660 - 679	880 - 905	31 - 36
680 - 699	906 - 932	32 - 37
700 - 719	933 - 959	33 - 38
720 - 739	960 - 985	34 - 39
740 - 759	986 - 1012	35 - 40
760 - 779	1013 - 1039	36 - 41
780 - 799	1040 - 1065	37 - 42

</td></tr>
<tr><td>Masimo ISA (Sidestream) CO_2</td><td>

1. Connect a new Nomoline sampling line with male luer lock to the ISA LEGI and check that the LEGI shows a steady green light.
2. Connect a short silicon tubing with an inner diameter of 3/32” (2.4 mm) to the Nomoline male luer.
3. Exhale a long breath into the silicon tubing until the CO2 concentration is greater than 34 mmHg.
4. Quickly connect the silicon tubing tightly to the ISA exhaust port.
5. Wait 1 minute until the CO2 concentration has stabilized. Note the value.

</td></tr>
</table>

PPM3 Function	Procedure
	6. Wait 1 minute and check that the CO2 concentration has not decreased more than 3 mmHg. If it has decreased more there is a major leakage in the ISA unit or in the Nomoline. Do not operate the ISA if there is a major leakage in the unit.
IBP (P1 and P2)	• Connect static pressure sources at 20 and later at 100 mmHg to IBP sensors P1 and P2. Verify correct pressure is displayed for each (± 2 mmHg). • Connect a patient simulator with dynamic IBP waveform for radial artery of 120/80. Verify correct pressure waveform and values are displayed (± 2 mmHg).
Temperature	None (self-checking).
Leakage Current	Connect to Safety Analyzer. WARNING – FOLLOW SAFETY INSTRUCTIONS AS INDICATED IN THE MANUAL FOR THE ANALYZER. Verify Patient Lead Leakage (to ground): < 10 uA. Verify Patient Lead Leakage (inter-lead): < 10 uA. Verify Patient Lead Leakage (mains applied to leads): < 50 uA. Verify Leakage to ground (normal): < 500 uA. Verify Leakage to ground (reversed polarity): < 1000 uA. Verify Leakage to ground (neutral opened): < 1000 uA.

In order to prevent the Nightingale PPM3 monitor's risk current from increasing beyond safe limits, the ECG cable should be cleaned according to the instruction in the Cleaning chapter of this manual.

To place the PPM3 back in service after maintenance has been performed, connect the PPM3 to a wall outlet, insuring that cables do not present a tripping hazard.

22.2. PPM3 Calibration Procedures

Trained service technicians with the PPM3 Service password can perform the following procedures.

PPM3 Function	Procedure
Oridion Microstream® CO_2 module	The Oridion Microstream ® CO_2 module within the PPM3 does not require calibration during normal clinical operation. The PPM3 displays a "CO_2 Calibration Due" message when the manufacturer's suggested number of operating hours has been reached. Calibrate the CO_2 module when this message is displayed. It is recommended to calibrate the CO_2 module on an annual basis or after 4000 hours of use, whichever comes first. In the first year, the CO_2 module should be calibrated after 1200 hours of use. The number of hours until calibration is due may be found in the PPM3 event log, which is accessed by pressing the PPM3 SETUP Key, then selecting "Administration," then "System," and then "Show Event Log." ***NOTE**: Calibration should be performed by a trained technician.* ***NOTE**: Ensure that the calibration gas and regulator are functioning properly before calibration.* ***NOTE**: Calibration of the CO_2 module will require a calibrated gas mixture of 5% CO_2, 21% O_2, with the balance N_2. The calibration kit available from Air Liquide (Scott Medical); Part Number T4653ORFCD contains a canister of the above gas mixture, a T-piece connector and a Calibration Filterline.* To calibrate the CO_2 module: 1. Press the PPM3 SETUP Key, then select "Administration," followed by "Service," and "Calibration" (password required to access this screen) 2. Prior to calibration initiation, connect the CO_2 calibration line to the monitor. 3. Attach the calibrated CO_2 gas mixture to the CO_2 calibration line. 4. Select "Start CO_2 Calibration" on the screen. The PPM3 displays "CO_2 Calibrating" for up to 1 minute. 5. Once completed, the PPM3 displays "CO_2 Calibration Complete" or "CO_2 Calibration Failed." 6. If the calibration fails, determine the cause of failure appropriate to the displayed error message given then repeat the CO_2 calibration procedure. 7. Upon successful completion, remove the calibration gas from the monitor. Dispose of it according to the instructions supplied with the kit.

PPM3 Function	Procedure
IBP – Invasive Blood Pressure	The IBP (P1 and P2) interfaces do not require calibration during normal clinical operation. In order to calibrate the IBP interfaces, perform the following: 1. Connect a static pressure source, such as ambient air, to pressure transducer that is connected to the P1 invasive pressure interface. 2. Select "Start P1 Calibration," after first pressing the SETUP key, then "Administration," then "Service," then "Calibration" (password required to access this screen). 3. Await "P1 Calibration OK" message, or similar if the interface is labeled something other than P1. 4. Repeat for interface P2.
NBP – Non-Invasive Blood Pressure	The NIBP interface does not require calibration during normal clinical operation. The accuracy of the NIBP pressure sensor and overall functionality of the NIBP interface can be verified as detailed in the Nightingale PPM3 Functional Tests. If further calibration is required, contact Zoe Medical Technical Support.

If there is a failure in one of the above procedures, please contact Zoe Medical Technical Support. If a PPM3 unit needs to be returned to the factory for repair, Technical Support will provide a return authorization number.

Email: customersupport@zoemedical.com

Phone : (978) 887-4013

22.3. Battery Replacement

The internal Lithium-Ion battery does not require any special maintenance. If the battery is no longer holding a charge, it may need to be replaced. Under normal conditions of use, the battery lifetime is around three years.

The procedure for replacing the battery is as follows:

1. Power down the device.
2. Remove the battery access door on the bottom of the device.
3. Remove the old battery by pulling on the strap that is attached to the battery.
4. Insert the new battery, taking care to face the label-side of the battery towards the front of the device. (The battery will not fully insert, otherwise.)
5. Reattach the battery access door.

WARNING – APPROVED BATTERIES. Only use batteries that are listed in the Accessories chapter.

22.4. Storage

Storage Temperature	-4 to 140 °F (-20 to 60 °C)
Storage Humidity	15% to 95% non-condensing
Storage Altitude	0 to 40,000’ (0 to 12,192 m)

CAUTION – The monitor may not conform to all of its performance specifications if stored outside these environmental specifications or used outside of the environmental specifications in the Technical Data chapter of this manual.

22.5. Warranty

ZOE MEDICAL INCORPORATED warrants this product, other than its expendable parts, to be free from defects in materials and workmanship for a period of thirty-six (36) months from the date of original delivery to the buyer or to buyer's order, provided that same is properly operated under conditions of normal use, and that periodic maintenance and service is performed. This same warranty is made for a period of thirty (30) days on expendable parts. This warranty shall become null and void if product has been repaired other than by Zoe Medical, Inc. (Zoe), or if the product has been subject to misuse, accident, negligence or abuse.

Warranty Policy for Accessories and Certain Components:
In all cases, policy applies from date of purchase from Zoe Medical or its authorized distributors or agents.

Roll Stand:	Out-of-box failure only
Batteries:	1 year
CO_2 Modules:	1 year
SpO_2 Sensors & Cables:	90 days
ECG Cables:	90 days
Printers:	1 year
Other Accessories:	Out-of-box failure only

Zoe Medical's sole obligation under this warranty is limited to repairing a product which has been reported to Zoe's Technical Service Center during normal business hours and shipped transportation prepaid. Zoe Medical shall not be liable for any damages including but not limited to incidental damages, consequential damages or special damages.

This warranty is in lieu of any other warranties, guarantees or conditions, including merchantability or fitness for a particular purpose. The remedies under this warranty are exclusive and Zoe Medical neither assumes nor authorizes anyone to assume for it any other obligation in connection with the sale or repair of its products.

Non-Warranty (Billable) Service Returns Policy:
Customer must contact Zoe Medical for an RMA number to initiate a return. The customer will be required to provide a P.O. or Credit Card for the repair at a flat rate price. If an estimate is required, a P.O. or Credit Card will be required to initiate the process and a flat rate charge will be applied for the estimate. The

customer is responsible for shipping charges to send the monitor to Zoe Medical and for the return shipping back to the customer.
If an estimate is required and the estimate of repairs is declined after the monitor has been evaluated at Zoe Medical, the customer is responsible for the evaluation fee ** plus the shipping back to the customer.
Zoe Medical will honor rush repair requests. Please inform Customer Support at the time of the RMA request. A flat rate fee will be added to the cost of the repair / invoice.
** Contact Zoe Medical Customer Support for current flat rate and estimate fees.

22.6. Password Control

To access the Setup Alarms or Setup System menu, perform the following steps when presented with the Password menu:

- Set Dial 1 to 49
- Set Dial 2 to 48
- Set Dial 3 to 46
- Select OK

23. Disposal

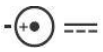
The disposal of accessories such as electrodes, blood pressure cuffs, temperature probes, SpO_2 sensors, and CO_2 sampling lines & calibration gases should be carried out according to the manufacturer's recommendations.

At the end of its useful life, the Nightingale PPM3 should be properly disposed of as well. In particular, the PPM3 contains a lithium coin battery, a lithium ion battery, and electronic circuit boards which should not be incinerated or exposed to extreme heat. See warnings at the start of this manual for further precautions.

Contact your local waste disposal agency for guidance on the proper recycling or disposal of these components.

24. Technical Data

General	
Dimensions	11.3”W x 7.2”H x 2.4”D (288 mm x 182 mm x 60 mm)
Weight	4.5 lb (2.0 g), 5.0 lb w/ Oridion Microstream® CO_2 (2.3 kg)
Finish	PC/ABS
Power Requirements	100 – 240 VAC, 1.2 A max
Mains Frequency Range	50 – 60 Hz
Power Consumption	12W nominal, 30W (when charging battery)
Standards Conformance	IEC 60601-1:2005 (General Safety) AAMI ES60601-1:2005 (General Safety) CSA C22.2#60601-1:2008 (General Safety) IEC 60601-1-2:2007 (Class B) (EMC) IEC 60601-1-4:2000 (General Safety) IEC 60601-1-8:2006 (Alarms) IEC 60601-2-27:2011 (ECG Monitoring) AAMI SP10:2002/A1:2003 (Non-Invasive Blood Pressure) ISO 80601-2-30:2009 (Non-Invasive Blood Pressure) IEC 60601-2-34:2011 (Invasive Blood Pressure) ISO 80601-2-55:2011 (CO_2 Respiratory Gas Monitoring) ISO 80601-2-56:2009 (Temperature) ISO 80601-2-61:2011 (SpO_2) IEC 62366:2007 (Usability) IEC 62304:2006 (Software)
Patient Risk Current (IEC 60601-1)	Electromedical Apparatus with Isolated Patient Connection. Meets the following limits: Enclosure Risk Current < 100 µA Patient-applied Risk Current < 10 µA Patient Isolation Risk Current < 50 µA Earth Risk Current < 500 µA
Type of Protection (Electrical)	Class I
Degree of Protection (Electrical)	Type CF, Defibrillation-proof
Degree of Protection (Water)	Ordinary Equipment (IPX1)
Disinfecting Method	Per the instructions in the Cleaning chapter
Degree of Safety (Flammable Anesthetic Mixture)	Not suitable for use in the presence of a Flammable Anesthetic Mixture
Mode of Operation	Continuous

PPM3 Device Markings	
	For indoor-use only
	Consult accompanying documents before using this device.
 06/2013	Manufacture date (month/year)
	Type CF Equipment (Defibrillation-proof)
REF	Zoe Medical Part Number
SN	Serial Number
	Do not dispose as unsorted municipal waste. European Union Directive 2002/96 on Waste Electrical and Electronic Equipment (WEEE) requires separate handling for waste disposal according to national requirements
IPX1	Indicates device has been tested for safety from vertically dripping water; specifically, it indicates DRIP PROOF, a higher than ordinary level of protection from drips, leaks, and spills.
REF 725-0037-X 	External AC/DC power supply; only use Zoe Medical P/N 725-0037-X
	Local Area Network interface
IOIO A	Interface for Nightingale MPC central station
IOIO B	Interface for Other Medical Devices – Reserved for future use
	Recorder interface
ECG	3 and 5 wire ECG connector
SpO_2	Pulse Oximetry connector

NBP	Non-Invasive Blood Pressure connector
P1/P2	Invasive Blood Pressure (dual) connector for P1 and P2
TEMP	Temperature connector
Microstream® $ETCO_2$ 	Oridion CO_2 input connector
	Oridion CO_2 exhaust connector
$ETCO_2$	Masimo CO_2 module connector
Battery	
Type	Lithium-Ion Rechargeable
Discharging Time	4 hours (minimum)
Charging Time	5 hours
Charging Method	Battery is charged while monitor is connected to AC main
Environmental	
Cooling	Convection (no fan)
Operating Temperature	32 to 104 °F (0 to 40 °C)
Storage Temperature	-4 to 140 °F (-20 to 60 °C)
Operating Humidity	15% to 90% non-condensing
Storage Humidity	15% to 95% non-condensing
Operating Altitude	0 to 15,000’ (0 to 4572 m)
Storage Altitude	0 to 40,000’ (0 to 12,192 m)
Alarm Signal Sound Pressure	45 to 80 dB(A)
Display	
Type	Active Matrix LCD
Size	8.4 inches (diagonal)
Matrix	800 x 600 pixels
Number of Waveform Channels	Up to 5
Sweep Speed	6.25, 12.5, 25 mm/s

Display Mode	Eraser Bar
ECG	
Accessories	3-lead cable, 5-lead cable
Input Connector	7-pin connector
Displayable Leads	3-lead cable: I, II, III, AVL, AVR, AVF 5-lead cable: I, II, III, AVL, AVR, AVF, V
HR Resolution	1 bpm (beats per minute)
Measurement Range	15 to 300 bpm
Measurement Accuracy	±2 bpm or ±1%, whichever is greater
Response Time	Per IEC 60601-2-27, change from 80 to 120 bpm: < 7 seconds Per IEC 60601-2-27, change from 80 to 40 bpm: < 11 seconds
Report Interval	1 second
HR Averaging Scheme	Average of the 10 most recent, valid R-R intervals, discarding the shortest and longest interval
Time To Alarm - Tachycardia	IEC 60601-2-27, ECG Complex B1: < 10 sec (5 sec typical) IEC 60601-2-27, ECG Complex B2: < 10 sec (9 sec typical)
Notch Filter Frequency	50Hz, 60 Hz, Off
Filter Bandwidth	Monitor Mode: 0.67 Hz to 40 Hz (-3 dB) Diagnostic Mode: 0.05 to 40 Hz (-3 dB)
Dynamic Range AC	±5 mV, per IEC 60601-2-27
Dynamic Range DC	±300 mV, per IEC 60601-2-27
Electrode Impedance	>2.5 MOhm , per IEC 60601-2-27
Defibrillation Protection	Complies with IEC 60601-2-27
Pacer Pulse Detection	Lead II, I and V
Pacer Pulse Rejection	Rejects all pulses of amplitude ±2mV to ±700mV and duration 0.1 to 2 ms, per IEC 60601-2-27, Clause 201.12.1.101.13
Tall T-Wave Rejection	Rejects T-Waves less than or equal to 120% of a 1mV QRS and a Q-T interval of 350 ms, per IEC 60601-2-27, Clause 201.12.1.101.17
HR Response to Irregular Rhythm	IEC 60601-2-27, ECG Complex A1: HR is 80 bpm IEC 60601-2-27, ECG Complex A2: HR is 65 bpm IEC 60601-2-27, ECG Complex A3: HR is 120 bpm IEC 60601-2-27, ECG Complex A4: HR is 91 bpm
Active Noise Suppression	RL drive (< 5 µA)

Pulse Tone	Yes
Respiration	
Method	Impedance Pneumography
Input Connector	Same as ECG
Sensing Lead	II
RR Resolution	1 bpm (breaths per minute)
Measurement Range	0 to 120 bpm
Measurement Accuracy	±3 bpm
Measurement Sensitivity	0.25 ohms (minimum)
Report Interval	1 second
Bandwidth	0.17 to 3.3 Hz (-3dB)
Impedance Measuring Current	40 µA @ 28 kHz square wave across Lead II
Pulse Oximetry	
Method	Absorption – Spectrophotometric (dual wavelength) (Functional oxygen saturation of arterial hemoglobin)
Input Connector	9-pin connector
SpO_2 / PR Resolution	SpO_2: 1 O_2% PR: 1 bpm (beat per minute)
Measurement Range	SpO_2: 20 to 100% PR: 30 to 240 bpm
Measurement Accuracy	SpO_2: from 70 to 100%: ±2% (O_2%), < 70%: unspecified PR: ± 3 bpm
Measurement Test Method	Comparison versus co-oximeter, per ISO 80601-2-61
Report Interval	1 second. Numeric values held < 30 seconds
Pulse Tone	Yes (pulse tone pitch tied to SpO_2 parameter value)
Alarm Signal Generation Delay	< 0.5 sec
Non-Invasive Blood Pressure	
Method	Oscillometric
Input Connector	Single Lumen Hose (Quick-Disconnect fitting)
Cuff	Infant, Child, Small Adult, Adult, Large Adult

Derived Parameters	Systolic, Mean, Diastolic
Resolution	1 mmHg
Measurement Range	Systolic: 30 to 250 mmHg Mean: 20 to 230 mmHg Diastolic: 10 to 210 mmHg
Measurement Accuracy	Complies with AAMI SP10
Transducer Accuracy	± 3 mmHg
Pulse Rate Range	30 to 240 bpm
Pulse Rate Accuracy	± 5% or ± 2 bpm, whichever is greater
Update Interval	Upon measurement completion
Measurement Time	30 seconds (typical) < 135 seconds (maximum)
Initial Cuff Pressure	160 mmHg (user-selectable)
Repeated Cuff Pressure	Previous systolic + 40 mmHg
Static Cuff Pressure Accuracy	± 3 mmHg
Overpressure Cutoff	290 ± 3 mmHg (normal means), 300 ± 10 mmHg (back-up)
Measurement Modes	Single Measurement or Auto (Interval) Measurement
Auto Measurement Settings	Off, 3, 5, 10, 15, 30, 60, 120 minutes
Oridion CO_2 / Capnography	
OEM Board	Oridion miniMediCO$_2$
Method	Sidestream (Non-dispersive IR)
Units	mmHg
Parameters	ETCO$_2$, FICO$_2$, RRc, IPI
CO_2 Measurement Range	ETCO$_2$ & FICO$_2$: 0 to 150 mmHg

CO_2 Measurement Accuracy	$ETCO_2$ & $FICO_2$: 0 to 38 mmHg: ± 2 mmHg > 38 to 150 mmHg: ± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg) Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12 % of reading whichever is greater, for $ETCO_2$ values exceeding 18 mmHg. This is tested according to and is compliant with ISO 21647. To achieve the specified accuracies for breath rates above 60 bpm, the Microstream FilterLine H Set for Infant/Neonatal (p/n 006324) must be used. Above 55°C module temperature, ±1mmHg or ± 2.5% (whichever is greater) has to be added to the tolerance of the accuracy specs.
CO_2 Resolution	$ETCO_2$ & $FICO_2$: 1 mmHg
RRc (Resp. Rate) Measurement Range	0 to 120 bpm
RRc Measurement Accuracy	0 to 70 bpm: ± 1 bpm 71 to 120 bpm: ± 2 bpm $ETCO_2$, $FICO_2$, and Respiration accuracy tested according to ISO21647 using a mixture of gases (5% CO_2, 21% O_2, N_2 balance) supplied via function generator and breath simulator application. Respiration rates from 10-60 bpm for adults/pediatrics as measured in 10 bpm discrete steps were tested for 1 minute before moving forward to the next value and at the end of this one minute period modules readings were taken.
RRc Resolution	1 bpm
IPI Range	0 to 10
Barometric Pressure Range	430 to 795 mmHg
Barometric Pressure Compensation	Automatic
Report Interval	1 second
Flow Rate	50 ml / min (-7.5 to +15 ml / min), flow measured by volume
Warm-up Time Required to Meet Accuracy Specifications	Typical: 30 seconds Max: 180 seconds (No readings until warm-up completed)
Total System Response Time	3.5 sec (typical) using standard Microstream FilterLine ®
Drift of Measurement Accuracy	Meets accuracy specifications when the calibration schedule is followed in the General Care & Maintenance section

Measurement Accuracy for Gas Mixture	Meets ISO 21647 Clause 51.101.3 (Tables 101 and 103): ± (volume fraction of 0.43% + 8% of gas level)
Measurement Accuracy in the Presence of Interfering Gases	Meets ISO 21647 Clause 101.1 (Tables 101 and 105): ± (volume fraction of 0.43% + 8% of gas level)
Masimo ISA™ CO_2 / Capnography	
Method	Sidestream (Non-dispersive IR)
Units	mmHg
Parameters	$ETCO_2$, $FICO_2$, RRc
CO_2 Measurement Range	$ETCO_2$ & $FICO_2$: 0 to 150 mmHg
CO_2 Measurement Accuracy	As measured with dry single gases: 0 to 15 vol%: ±(0.2 vol% + 2% of reading) 15 to 25 vol%: unspecified
CO_2 Resolution	1 mmHg
RRc (Resp. Rate) Measurement Range	0 to 150 ± 1 bpm
RRc Resolution	1 bpm
Barometric Pressure Range	525 to 1200 hPa
Barometric Pressure Compensation	Automatic
Report Interval	Per breath
Flow Rate	50 ± 10 sml/min
Warm-up Time Required to Meet Accuracy Specifications	< 10 seconds (concentrations reported and full accuracy)
Total System Response Time	< 3 seconds (with 2m Nomoline sampling line)
Drift of Measurement Accuracy	Complies with EN ISO 21647:2004 standard
Measurement Accuracy for Gas Mixture	Complies with EN ISO 21647:2004 standard
Measurement Accuracy in the Presence of Interfering Gases	Complies with EN ISO 21647:2004 standard
Masimo IRMA™ CO_2 / Capnography	
Method	Mainstream

Units	mmHg
Parameters	$ETCO_2$, $FICO_2$, RRc
CO_2 Measurement Range	$ETCO_2$ & $FICO_2$: 0 to 150 mmHg
CO_2 Measurement Accuracy	Dry single gases at 22 ± 5°C and 1013 ± 40 hPa 0 to 15 vol%: ±(0.2 vol% + 2% of reading) 15 to 25 vol%: unspecified All conditions ±(0.3 kPa + 4% of reading)
CO_2 Resolution	1 mmHg
RRc (Resp. Rate) Measurement Range	0 to 150 bpm. RRc is displayed after 3 breaths and the average value is updated every breath.
RRc Resolution	1 bpm
Barometric Pressure Range	525 to 1200 hPa
Barometric Pressure Compensation	Automatic
Report Interval	Per breath
Warm-up Time Required to Meet Accuracy Specifications	< 10 seconds (concentrations reported and full accuracy)
Total System Response Time	< 1 second
Drift of Measurement Accuracy	Complies with EN ISO 21647:2004 standard
Measurement Accuracy for Gas Mixture	Complies with EN ISO 21647:2004 standard
Measurement Accuracy in the Presence of Interfering Gases	Complies with EN ISO 21647:2004 standard
Invasive Blood Pressure	
Transducer Type	Strain gauge
Transducer Excitation Voltage	5.00 VDC ± 1 %
Frequency Response	0-12 Hz
Measurement Units	mmHg
Parameters	Diastolic, Systolic, Mean for all except Mean-only for CVP
Measurement Range	-50 to 300 mmHg
Measurement Accuracy	± 1 mmHg or ± 1 %, whichever greater

IBP Resolution	1 mmHg
Pulse Rate Measurement Range	30 - 250 bpm
Pulse Rate Accuracy	± 2 bpm or ±2 %, whichever greater
Numeric Update Rate	Every 3 seconds
Temperature	
Compatibility	YSI 400-series probes
Measurement Mode	Direct (as defined in ISO 80601-2-56)
Input Connector	2-pin connector
Display Units	°F and °C (user-selectable)
Measurement Resolution	0.1 °F (0.1 °C)
Measurement Range	41.0 to 122.0 °F (5.0 to 50.0 °C)
Measurement Accuracy	±0.2 °F (±0.1 °C) plus probe tolerance
Transient Response	Within 30 seconds from 25 to 27 °C

Electromagnetic Compatibility (EMC) Information

Medical electrical equipment requires special precautions regarding Electromagnetic Compatibility (EMC). Portable and mobile Radio Frequency (RF) communications equipment can affect devices like the Nightingale PPM3. As such, the Nightingale PPM3 should not be used adjacent to other equipment. If this is not practical, then observe the Nightingale PPM3 to make sure it is operating properly after installation.

Also, the use of accessories other than those recommended by Zoe Medical may result in increased EMC emissions or decreased EMC immunity of the Nightingale PPM3.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration: electromagnetic emissions</th></tr>
<tr><td colspan="3">The Nightingale PPM3 is intended for use in the electromagnetic environment specified below. The user of the Nightingale PPM3 should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment / guidance</th></tr>
<tr><td>RF emissions

CISPR 11</td><td>Group 1</td><td>The Nightingale PPM3 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions

CISPR 11</td><td>Class B</td><td rowspan="3">The Nightingale PPM3 is suitable for use in all establishments including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions

IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions

IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration: electromagnetic immunity			
The Nightingale PPM3 is intended for use in the electromagnetic environment specified below. The user of the Nightingale PPM3 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment / guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV 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	±2 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 power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T)	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Nightingale PPM3 requires continued operation during power mains interruptions, it is recommended that the Nightingale PPM3 be powered from an uninterruptible power supply or a fully charged battery.

	for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 5 s	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note – U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration: electromagnetic immunity			
The Nightingale PPM3 is intended for use in the electromagnetic environment specified below. The user of the Nightingale PPM3 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 communications equipment should be used no closer to any part of the Nightingale PPM3, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d = 1.2 $\sqrt{P}$ d = 1.2$\sqrt{P}$ 80 MHz to 800 MHz d = 2.3$\sqrt{P}$ 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 equipment marked with the following symbol: 
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless)			

telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Nightingale PPM3 is used exceeds the applicable RF compliance level above, the Nightingale PPM3 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PPM3 monitor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Nightingale PPM3

The Nightingale PPM3 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Nightingale PPM3 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Nightingale PPM3 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.