

Patient SafetyNet™ Supplemental Alarm System Series 5.0.0.0



Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.


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

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.


For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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About this Manual

This manual explains how to configure and use the Patient SafetyNet™. Important safety information relating to general use of the Patient SafetyNet appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user. The following is an example of a warning:

Warning: This is a sample of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property. The following is an example of a caution:

Caution: This is a sample of a caution statement.

A *note* is given when additional general information is applicable. The following is an example of a note:

Note: This is a sample of a note.

Product Description, Features, and Intended Use

Product Description

Patient SafetyNet™ is a supplemental remote monitoring and clinician notification system. It provides a secondary display of Masimo SET® pulse oximetry, rainbow® SET pulse CO-Oximetry and acoustic respiration rate monitors. Patient SafetyNet enables clinicians to view and monitor patient physiological conditions when used in hospitals or hospital-type environments.

Patient SafetyNet may consist of the following components and/or features:

- Support for up to 200 devices per appliance.
- Bedside wireless radio(s) or serial-to-ethernet converter(s).
- Ability to communicate over a 802.11 (2.4 & 5 GHz) wireless or hard wired network.
- Patient SafetyNet Appliance/Switch/UPS
- Patient SafetyNet View Station
- Support for up to 80 pagers per appliance.
- Support for up to 10 Patient SafetyNet View Stations per appliance.
- Internet Protocol (IP) device notification support.
- Iris Connectivity
- Multiple User Interface (UI) Options:
 - Patient Centric
 - Device Centric
- MyView feature support.
- Connectivity gateway options.

Regulatory Notice

The following features are NOT AVAILABLE.

| Feature | NOT AVAILABLE in U.S.A. and territories relying on FDA market clearance |
|------------------|---|
| SpO ₂ | |
| PR | |
| Pi | |
| PVi | |
| SpHb | |
| SpCO | |
| SpOC | |
| SpMet | |
| RRa | |
| RRp | X |
| ORi | X |

Intended Use

The Patient SafetyNet (PSN) is intended to be used as a supplemental alarm system communicating with multiple patient monitoring devices. The PSN provides secondary display of physiological monitoring parameters. It enables the viewing and monitoring of patient physiological conditions. The PSN is used in hospitals or hospital-type environments.

Safety Information, Warnings and Cautions

CAUTION: Patient SafetyNet is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use. Refer to the separate Operator's Manuals for connected devices and instruments for additional safety information, warnings, and cautions.

Safety Warnings and Cautions

WARNING: Do not place the Patient SafetyNet View Station where it may be accessible by patients.

WARNING: Do not use Patient SafetyNet if it appears or is suspected to be damaged.

WARNING: Do not place accessories in any position that might cause it to fall on the patient.

WARNING: Explosion hazard: Do not use Patient SafetyNet or accessories in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING: To protect against injury, follow the directions below:

- Avoid placing the device or accessories on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Use cleaning solutions only as instructed in this operator's manual

WARNING: Do not use the Patient SafetyNet System during or near magnetic resonance imaging (MRI).

Performance Warnings and Cautions

WARNING: The Patient SafetyNet System is a supplemental alarm notification system and should not be used as the primary source for patient and system alarms. The standalone device's audible and visual alarms, used in conjunction with clinical signs and symptoms, are the primary sources for determining that an alarm condition exists.

WARNING: Do not place containers with liquids on or near the Patient SafetyNet System. Liquids spilled on the Patient SafetyNet System may cause it to perform inaccurately or fail.

WARNING: To indicate proper system operation, keep the Patient SafetyNet user interface open at all times.

CAUTION: The Patient SafetyNet System is intended to operate across the facility's network. Unanticipated failure or alteration of network components (including but not limited to: disconnection or malfunctioning of a networking device/switch/router/ethernet cable) may result in loss of supplemental notification by the Patient SafetyNet System. Altering or making changes to the Hospital Network should be done with proper knowledge.

CAUTION: The Quality of Service (QoS) of connectivity to the Point of Care (POC) Devices may be affected by:

- Network Failure
- Increased number of connected devices on the Network
- Modifications to the Network
- Presence of devices provided with radio transmitters
- Improper network configuration on POC
- Signal Priorities of the Network
- Latency

CAUTION: Network performance may be affected by changes in the network including the addition of additional network devices.

CAUTION: Use redundant network connections to ensure reliable network connectivity to the Patient SafetyNet Appliance.

CAUTION: Utilize a back-up AC power source to minimize the interruption of service due to the loss of power.

CAUTION: To prevent tampering with the Patient SafetyNet Appliance it should be located in a secure location.

CAUTION: Carefully route power supply cord to minimize the accidental disconnection.

CAUTION: Patient SafetyNet requires a dedicated Personal Computer (PC). This is necessary so that other applications do not interfere with the Patient SafetyNet View Station.

CAUTION: Do not place Patient SafetyNet on electrical equipment that may affect the device, preventing it from working properly.

CAUTION: Do not leave headphones, or any other apparatus plugged into the Patient SafetyNet Central View Station unattended, as they may affect the ability to detect audible notifications.

CAUTION: To ensure proper system operation, always verify successful connection between Point of Care devices and the Patient SafetyNet System.

Note: Successful connection between Patient SafetyNet and a standalone device via Root's Iris port requires:

- The standalone device is correctly configured to output data.
- The standalone device is connected to Root via an authorized and approved Iris Adapter
- The standalone device is the correct make, model, and software version for the attached Iris Adapter.
- Root is connected to Patient SafetyNet and displays successful Iris connection to the standalone device.

Note: Verify that at least one Patient SafetyNet View Station user interface is displaying the correct time to indicate Patient SafetyNet Appliance is functioning properly.

Performance Warnings and Cautions for Notification Modes

Clinician Paging/Notification Mode

WARNING: The Patient SafetyNet Clinician Paging System is a supplemental alarm notification system. Due to the potential issues with RF transmission and reception, there is no guarantee that each page will be received at the pager. Use the Point of Care (POC) device as the primary alarm system.

WARNING: The effective range (distance between the bedside radio and the pager or the paging transmitter and the pager) is affected by interfering objects such as walls, floors and other devices that emit radio frequency waves.

CAUTION: When using the Patient SafetyNet Clinician Notification System carefully plan the notification protocol to maximize the utility of the system.

Note: All Point of Care devices are automatically assigned to the default supervisory pager until they are admitted to the system.

Note: Users must login to the Patient SafetyNet System in order to change any of the device settings or to make any assignment changes.

Note: Verify that at least one user interface is visible to indicate server is functioning properly.

Connection to External Notification Systems Mode

WARNING: When using an external notification system, Patient SafetyNet is only responsible for the sending of notifications to the external notification system. Once a notification has been sent to the external notification system by Patient SafetyNet, per Masimo's network specifications, any failure to receive and transmit that notification will be a result of an error caused by the external notification system.

CAUTION: When using an external notification system it is strongly recommended that a test notification may be sent before actively monitoring patients to verify the external notification system is working properly.

CAUTION: Additional test notifications should be performed when any changes or modifications have been made to the external notification system.

Note: The use of HL7 external notification requires that Patient SafetyNet must be in Central Surveillance Mode.

Note: When using HL7 external notification, Patient SafetyNet sends all Point of Care device alarms to the external notification system without applying any alarm filters and/or delays previously configured on Patient SafetyNet.

Note: When using HL7 external notification, Patient SafetyNet may not operate in any manner indicated in the Clinician Notification sections of this manual. For information on notifications please consult your system administrator.

Central Surveillance Mode

WARNING: When in Central Surveillance Mode, Patient SafetyNet will no longer provide supplemental alarms to notification devices.

WARNING: To indicate proper system operation, the Patient SafetyNet user interface should be open at all times and not closed.

WARNING: In Central Surveillance Mode, alarms are only communicated through the Patient SafetyNet user interface and therefore it requires at all times that at least two user interfaces are actively being used or that a trained clinician is monitoring the Patient SafetyNet View. If one of the user interfaces is disconnected from the server, the other user interface will show audible and visual alarm status on the screen.

Cleaning and Service Warnings and Cautions

WARNING: Do not adjust, repair, open, disassemble, or physically modify the Patient SafetyNet System. Injury to personnel or equipment damage could occur. Return Patient SafetyNet for servicing.

WARNING: If the Patient SafetyNet System fails any part of the setup procedures or leakage spot check, remove the device from operation until qualified service personnel have corrected the situation.

WARNING: Do not autoclave, pressure sterilize, or gas sterilize Patient SafetyNet.

WARNING: Use cleaning solutions only as instructed in the operator's manual.

Note: Modifications to the Patient SafetyNet System's settings, and those of any components connected thereto, should be made by qualified personnel only.

Note: Patient SafetyNet installation must be completed by Masimo or an authorized service department.

Compliance Warnings and Cautions

WARNING: Do not attempt to repair or modify any part of the Patient SafetyNet system doing so may void the warranty or the authorization to use the device or devices.

WARNING: Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.

WARNING: When using devices with wireless features outside the United States, consideration should be taken to local government frequency allocations and technical parameters to minimize the possibility of interference to/from other wireless devices.

WARNING: In accordance with international telecommunication requirements, the frequency band of 2.4 GHz and 5.15 to 5.25 GHz is only for indoor usage to reduce potential for harmful interference to co-channel mobile satellite systems.

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

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

Chapter 1: Technology Overview

The Patient SafetyNet operating instructions are intended to provide the necessary information for proper operation of the Patient SafetyNet Supplemental Alarm Notification System.

General knowledge and an understanding of the features and functions of the Patient SafetyNet Supplemental Alarm Notification System are a prerequisite for proper use.

Do not operate the Patient SafetyNet Supplemental Alarm Notification System without completely reading and understanding these instructions.

The Patient SafetyNet System is a supplemental alarm notification system and should not be used as the primary source for patient and system alarms. The standalone device's audible and visual alarms, used in conjunction with clinical signs and symptoms, are the primary sources for determining that an alarm condition exists.

The following instructions assume that the Patient SafetyNet System is installed and ready for use.



SafetyNet Modes of Operation

Patient SafetyNet can function in two distinct modes of operation, either Clinician Paging/Notification Mode or Central Surveillance Mode.

The following table shows a feature comparison for each mode of operation.

| Feature | Clinician Paging/Notification Mode | Central Surveillance Mode | Section |
|----------------------------------|------------------------------------|---------------------------|--|
| Add/Remove/Modify Alarm Profiles | ✓ | ✓ | Alarm Profile Configuration on page 76 |
| Add/Remove/Modify Domain | ✓ | ✓ | Domains on page 69 |
| Add/Remove/Modify Device | ✓ | ✓ | Instruments on page 74 |
| Assign Instruments | ✓ | ✓ | Assign Instruments on page 45 |
| Audio Acoustic Playback | ✓ | ✓ | Acoustic Audio Playback on page 45 |
| Change Alarm Limits | ✓ | ✓ | Adjusting Alarm Limits on page 44 |
| Change Patient/Device View | ✓ | ✓ | About the Patient/Device Button on page 26 |
| Detail View Information | ✓ | ✓ | SafetyNet Modes of Operation on page 13 |
| Edit Patient Information | ✓ | ✓ | Edit Patient Information on page 43 |
| Icon View | ✓ | ✓ | Main Screen Information - Device Icon View on page 31 |

| Feature | Clinician Paging/Notification Mode | Central Surveillance Mode | Section |
|--------------------------------|------------------------------------|---------------------------|---|
| Iris | ✓ | ✓ | <i>Chapter 6: Iris</i> on page 63 |
| MyView Instrument | ✓ | ✓ | <i>Chapter 7: MyView</i> on page 65 |
| Numeric View | ✓ | ✓ | <i>Patient Window - Numeric View</i> on page 29 |
| Patient Admission | ✓ | ✓ | <i>Admit</i> on page 38 |
| Patient Discharge | ✓ | ✓ | <i>Discharge</i> on page 43 |
| Suspend Alarms | ✓ | ✓ | <i>Suspending Alarms</i> on page 43 |
| User Management | ✓ | ✓ | <i>User</i> on page 89 |
| View Trend | ✓ | ✓ | <i>Patient Trend Information</i> on page 36 |
| View Waveform | ✓ | ✓ | <i>Live Waveforms and Historical Waveform Review</i> on page 37 |
| Add/Remove/Modify Pager | ✓ | ✗ | <i>Pager Setup and Operation</i> on page 96 |
| Change Domain | ✓ | ✗ | <i>Domains</i> on page 69 |
| Escalation Policy | ✓ | ✗ | <i>Notification and Escalation Protocol</i> on page 20 |
| Login | ✓ | ✗ | <i>Login</i> on page 23 |
| MyView UI | ✓ | ✗ | <i>Chapter 7: MyView</i> on page 65 |
| Notification Device Assignment | ✓ | ✗ | <i>Assign Respondents</i> on page 42 |

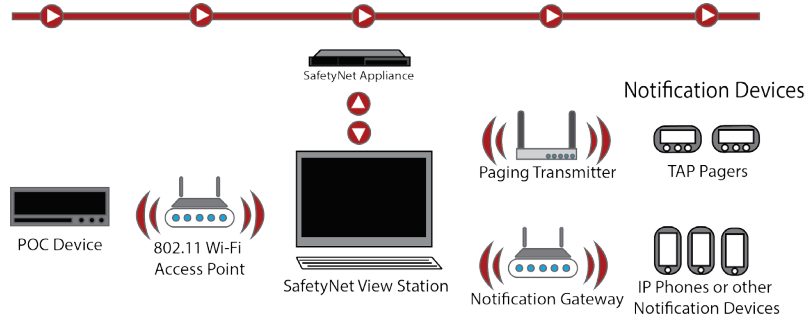
| Feature | Clinician Paging/Notification Mode | Central Surveillance Mode | Section |
|---------------|---|---|--|
| Reverse Video |  |  | <i>Re-Escalation and Audible Alarms</i> on page 21 |

Compatible Masimo Bedside Point of Care Devices

- Radical® Pulse Oximeter®
- Radical-7® Pulse CO-Oximeter®
- Rad-87® Pulse CO-Oximeter®
- Rad-8® Pulse Oximeter®
- Rad-97™ Pulse CO-Oximeter®
- Root®
- Radius-7® Pulse CO-Oximeter®

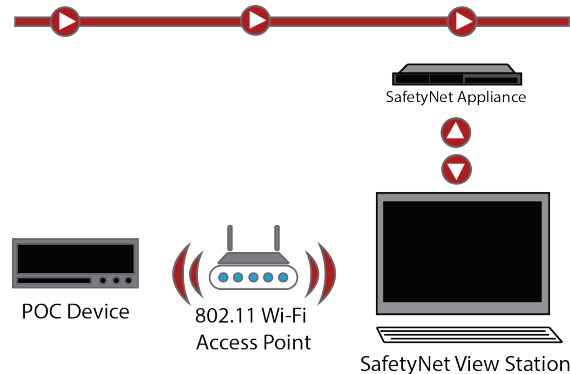
Chapter 2: System Components

For Clinician Paging/Notification Mode



1. The device is connected to the Point-of-Care (POC) Device via a DB9 serial (male-male) Null Modem Cable. In some cases, devices may have built-in communication technologies.
2. Depending on the network configuration, the POC Device communicates through a wireless access point(s), or hard wired to a switch.
3. The Wireless Access Point(s) transmit data through a network switch to the Patient SafetyNet Appliance. The Access Point(s) connect to the network switch via standard network cable.
4. The Patient SafetyNet Appliance is capable of communicating with the Wireless Access Points across the network.
5. The Patient SafetyNet View Station is capable of communicating with the Patient SafetyNet Appliance across the network. The Patient SafetyNet View Station allows clinicians access to the Patient SafetyNet Appliance for Admission, Discharge, and Notification Device assignments.
6. The Paging Transmitter is capable of communicating with the Patient SafetyNet Appliance across the network.
7. IP phones or other notification devices can communicate through a wireless access point(s) with the Patient SafetyNet Appliance across the network.

For Central Surveillance Mode



1. The device is connected to the POC Device via a DB9 serial (male-male) Null Modem Cable. In some cases, devices may have built-in communication technologies.
2. Depending on the network configuration, the POC Device communicates through a wireless access point(s), or hard wired to a switch.
3. The Wireless Access Point(s) transmit data through a network switch to the Patient SafetyNet Appliance. The Access Point(s) connect to the network switch via standard network cable.
4. The Patient SafetyNet Appliance is capable of communicating with the Wireless Access Points across the network.
5. The Patient SafetyNet View Station is capable of communicating with the Patient SafetyNet Appliance across the network. The Patient SafetyNet View Station allows clinicians access to the Patient SafetyNet Appliance for Admission, Discharge, and Notification Device assignments.

Chapter 3: SafetyNet Operation Mode

Clinician Paging/Notification Mode

The Patient SafetyNet Clinician Paging/Notification Mode may consist of the following components and/or features:

- Paging Transmitter
- Support for up to 80 Pagers per Patient SafetyNet Appliance
- Support for IP Notification Devices
- Support for up to 200 Point of Care devices per Patient SafetyNet Appliance
- Bedside wireless radio(s), Serial-to-Ethernet converter(s), or RJ45
- 802.11 (2.4 & 5 GHz) wireless or hard wired network
- Patient SafetyNet Appliance/Switch/UPS
- Patient SafetyNet View; up to 10 Patient SafetyNet View Stations may be connected to a Patient SafetyNet Appliance.

The image below is an example of the Patient SafetyNet Device Centric Clinician Paging/Notification Mode user interface. For information about the details of the Main Screen, see *Understanding the System Main Screen* on page 23.



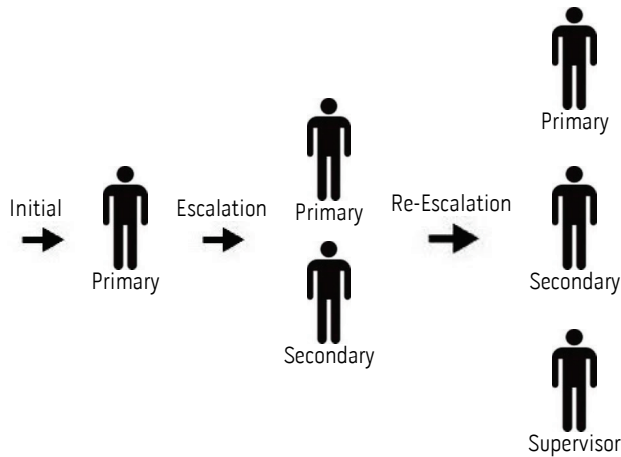
By using the Patient SafetyNet Clinician Paging/Notification Mode, users can define clinical assignments to notification devices. The system is designed to deliver the Alarm/Alert information from the device to the clinician worn Pager, IP devices, or mobile devices in approximately ten (10) seconds under normal load conditions. All alarms are set at the Point of Care Device. Be sure to verify the correct settings for alarms prior to using the device. Consult the Point of Care device operator's manual for setting alarms.

The Patient SafetyNet Clinician Paging/Notification Mode allows for up to 80 Pagers to be configured per Patient SafetyNet Appliance. Configuration of the Pagers is done at the time of installation by Masimo or a qualified service department. Do not exceed 80 Pagers per system; consult the Patient SafetyNet Installation Guide for information regarding the placement of the Paging Transmitter and range of the Pagers.

The Masimo Patient SafetyNet System can be connected to an external notification system. See the **Appendix** on page 109.

Notification and Escalation Protocol

Patient SafetyNet Clinician Paging/Notification Mode contains a Notification Escalation protocol which allows for configurable time intervals for *Initial*, *Escalation*, and *Re-Escalation* notifications on a device-by-device basis. All notifications display the escalation level when communicated to the respondent device. Primary and secondary respondents are assigned to respondent devices during the Patient Admit process. When a patient is not admitted to the system, all notifications go to the configured Supervisor respondent device, configured at the time of installation.



Level 1: Initial

When an Alarm/Alert condition is met, an *Initial* notification is sent to the Primary Respondent device(s) assigned to the Point of Care device at the time of patient admission to the Patient SafetyNet system. The notification displays the user configured patient label, the reason for the notification (example: SpO₂ Low), and the applicable clinical values. Additionally, the status *Initial* is displayed.

Level 2: Escalation

When the configured Escalation time interval has elapsed, notifications are sent to the Primary and Secondary respondent device(s) assigned to the Point of Care device. The notification displays the user configured patient label, the reason for the notification (example: SpO₂ Low) and updated clinical values. Additionally, the status *Escalation* is displayed.

Level 3: Re-Escalation

When the configured Re-Escalation time interval has elapsed, notifications are sent to the Primary, Secondary and Supervisory respondent device(s) assigned to the Point of Care device. The notification displays the user configured patient label, the reason for the notification (example: SpO₂ Low) and updated clinical values. Additionally, the status *Re-Escalation* is displayed.

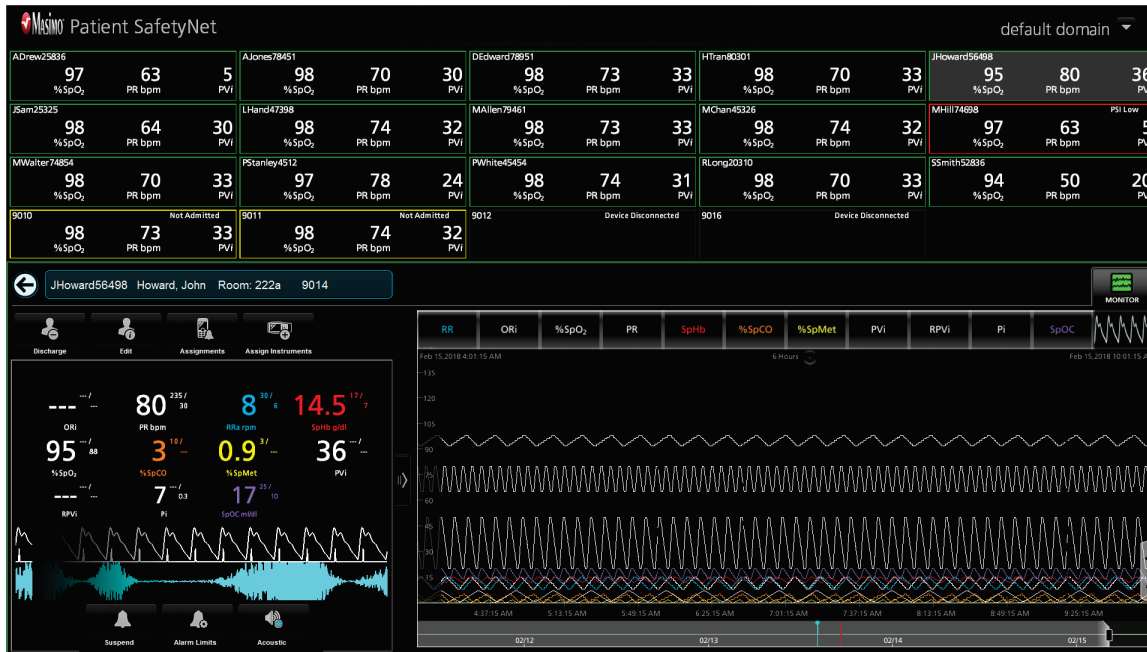
Note: All Point of Care devices are automatically assigned to the default supervisory respondent device until they are admitted to the system.

Central Surveillance Mode

The Patient SafetyNet Central Surveillance Mode may consist of the following components and/or features:

- Support for up to 200 Point of Care devices per Patient SafetyNet Appliance
- Bedside wireless radio(s), Serial-to-Ethernet converter(s), or wired RJ45
- 802.11 (2.4 & 5 GHz) wireless or hard wired network
- Patient SafetyNet Appliance/Switch/UPS
- Patient SafetyNet View; a minimum of two (2) and up to ten (10) Patient SafetyNet View Stations may be connected to a Patient SafetyNet Appliance.

The image below is an example of the Patient SafetyNet Patient Centric Central Surveillance Mode user interface. For information about the details of the Main Screen, see *Understanding the System Main Screen* on page 23.



The Patient SafetyNet View Station is capable of communicating with the Patient SafetyNet Appliance across the network; this Patient SafetyNet View Station allows access to the Patient SafetyNet Appliance by skilled clinicians for Admission, Discharge and Audible Alarms Notification.

The Patient SafetyNet Central Surveillance System is designed for medical facilities that operate using a central "war room" where someone is physically stationed at a Patient SafetyNet View at all times to manually alert the appropriate clinical staff for medical response when the system alarms.

The system can accommodate up to 10 Patient SafetyNet Views (each station can display up to 40 point of care (POC) devices).

When a point of care device is connected, but not entered into the user interface and an Alarm/Alert condition persists through the user defined re-escalation period, the point of care device Serial Number and Alarm/Alert condition will be present in the System Status bar.

Re-Escalation and Audible Alarms

The following is the Escalation protocol for Patient SafetyNet while in Central Surveillance mode.

Re-Escalation

When the configured *Re-Escalation* time interval has elapsed, the *Patient Window* border will remain red, and the background of the *Patient Window* will change to white, this is known as reverse video.

| | | | | | | | | | | | | | | | | | | | | |
|------------------------|-----------|-----------|--------------|-----------------------------|-----------|-----------|--------------|------------------------|-----------|-----------|--------------|------------------------|-----------|-----------|------------|-------------------|------------------------|-----------|------------|--------------|
| ALARMED 95 %SpO2 | 92 BPM | 16 Rta | 12.8 SpHb | ALARMED 95 %SpO2 | 80 BPM | 8 Rta | 13.2 SpHb | ALARMED 94 %SpO2 | 50 BPM | 19 Rta | 11.5 SpHb | ALARMED 97 %SpO2 | 50 BPM | 14 Rta | --- | SpHb | ALARMED 92 %SpO2 | 67 BPM | 11 Rta | 12.3 SpHb |
| OK 94 %SpO2 | 50 BPM | 21 Rta | 12.4 SpHb | OK 92 %SpO2 | 79 BPM | 10 Rta | 13.5 SpHb | OK 97 %SpO2 | 50 BPM | 14 Rta | 14 SpHb | OK 93 %SpO2 | 50 BPM | 25 Rta | 14 SpHb | OK 96 %SpO2 | 77 BPM | 11 Rta | 12 SpHb | |
| OK 97 %SpO2 | 50 BPM | 14 Rta | 14 SpHb | NOT ADMITTED 94 %SpO2 | 97 BPM | 18 Rta | 13.5 SpHb | | | | | | | | | | | | | |


Device Disconnection

In the event that the Point of Care device becomes disconnected from Patient SafetyNet Supplemental Alarm System while in Central Surveillance mode, an alarm will sound at the Central Station. The parameter values for the Point of Care device will appear as dashes. In order to silence the alarm, press the icon.

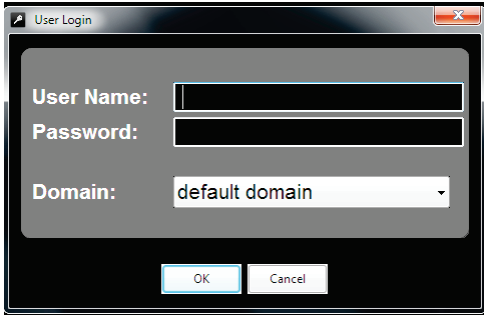
Chapter 4: SafetyNet User Operation

Login

To log into the system

1. On the *Navigation* bar, select the Login icon .
2. Enter the user name and password.

Note: If LDAP is enabled on the system, login using your network login credentials and select a domain. Domains are assigned to the credentials by the network administrator. Contact your network administrator for any domain or network credential support.



3. Select a Domain from the drop-down menu.
4. Select **OK**.

After a successful Login, the icons on the *Navigation* bar will become active based upon the user's assigned privileges. The devices in the selected Domain will be displayed on the *Main Screen*.

Note: Users must login to the Patient SafetyNet System in order to change any of the device settings or to make any assignment changes.

To log out of the system

See *Logout* on page 46.

Understanding the System Main Screen

During initial configuration, the Patient SafetyNet System Main Screen may be configured to display up to 40 patients or Point of Care devices. Additionally, the Main Screen may be configured to display real-time *Device* numeric data or *Device* icons.

About the System Status Bar

System Status Bar

The System Status bar provides system status notifications and lists the current domain. Both *Numeric Views* and *Icon Views* display the *System Status Bar*.



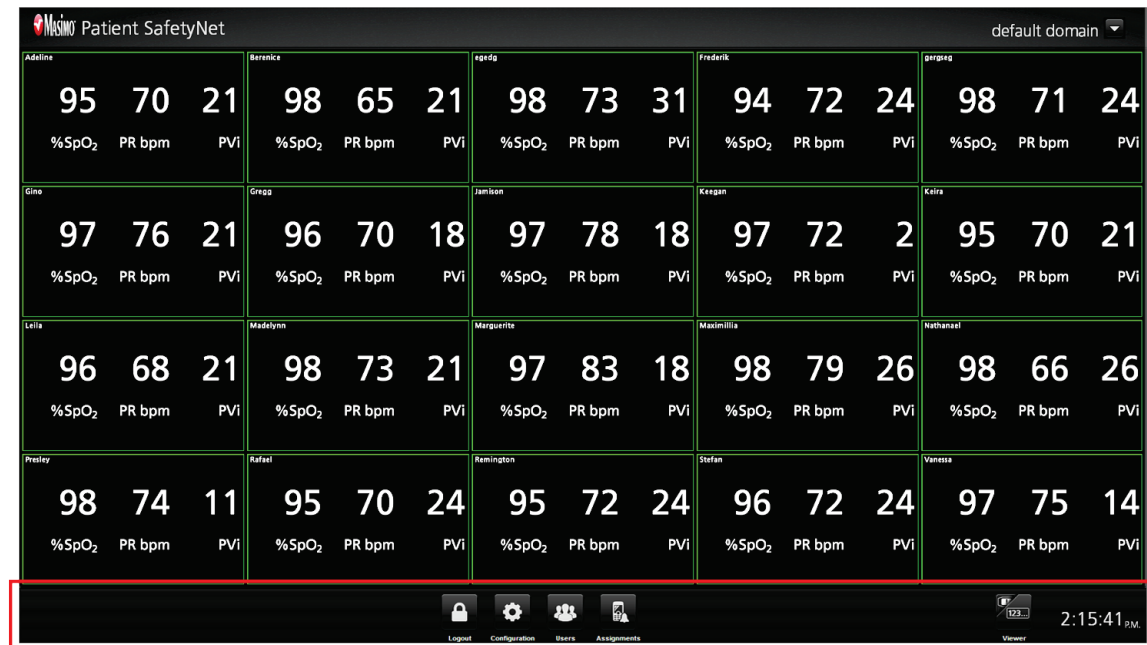
The table below describes the areas of the System Status Bar.

| Item | Description |
|------|--|
| 1 | Right click to see Software Version and Viewing Mode. |
| 2 | Displays system level warnings and generate audible tones. These include the following: <i>Key Lock Authentication Failure, System Down; Server Link Down; Paging Console Link Down; communication failed; Alert Reporter Link Down; and Link to All Devices/AP/Network Down</i> |
| 3 | Displays the loaded Domain when the application is opened. The devices and notification devices for the loaded Domain and sub-Domains will be shown in the user interface. |

About the Navigation Bar

The following are two primary types of viewing options through which the user can access additional screens and system options. The same *Navigation Bar* displays in both views.

Patient Numeric View











Patient Icon View



The Navigation bar contains various buttons that provide access to different functions in the system. Note that the buttons and their functions are determined by the viewing mode and user rights that are assigned at the time of setup.


The table below describes the buttons.

| Button | Description |
|---|--|
|  | Login - Login to the Patient SafetyNet System (displays when not logged in). See Login on page 23. |
|  | Logout - Logout of the Patient SafetyNet System (displays when logged in). See Logout on page 46. |
|  | Configuration - Access to the Configuration options. These include configuring domains, devices, Alarm Profiles, pagers, paging settings, Gateways Settings, location, system policy. See Configuration on page 69. |
|  | Users - Access to the User Management options. This includes the ability to add, modify and remove users and user roles. See User Management on page 89. |
|  | Assignments - Access to the Assignments options. This includes the ability to assign monitoring devices to respondents. See Modifying Assignments on page 44. |
|  | Viewer - The Viewer button toggles between the Patient Numeric and Patient Icon views of the Main Screen. See Switching Between Numeric View and Device Icon View on page 26. |

| Button | Description |
|---|--|
|  | Admit* - The Admit button starts the admit patient wizard. See Admit on page 38. |
|  | Patient/Device* - The Patient/Device button toggles between patient-centric and device-centric views of the Main Screen. See Switching Between Numeric View and Device Icon View on page 26. |

* Displays on the navigation bar only when Patient SafetyNet is in Patient Centric Mode.

About the Patient/Device Button

The *Patient/Device Button*  allows the user to switch between displaying patients who have been admitted to the system, or Patient Centric view, and devices on the system's domain, or Device Centric view.

Note: Devices on the system that do not have a patient admitted to them will still appear in Patient Centric view.

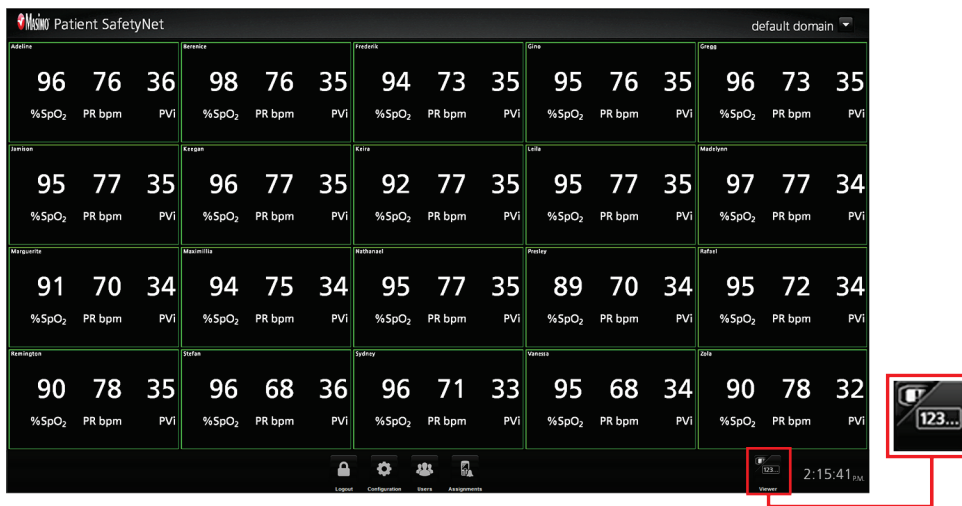
Switching Between Numeric View and Device Icon View

The following are the primary viewing options for the *Main Screen*.

Device Centric Mode

To toggle between the Numeric View and Icon View, select the **Viewer** button.

- Numeric View



- Icon View

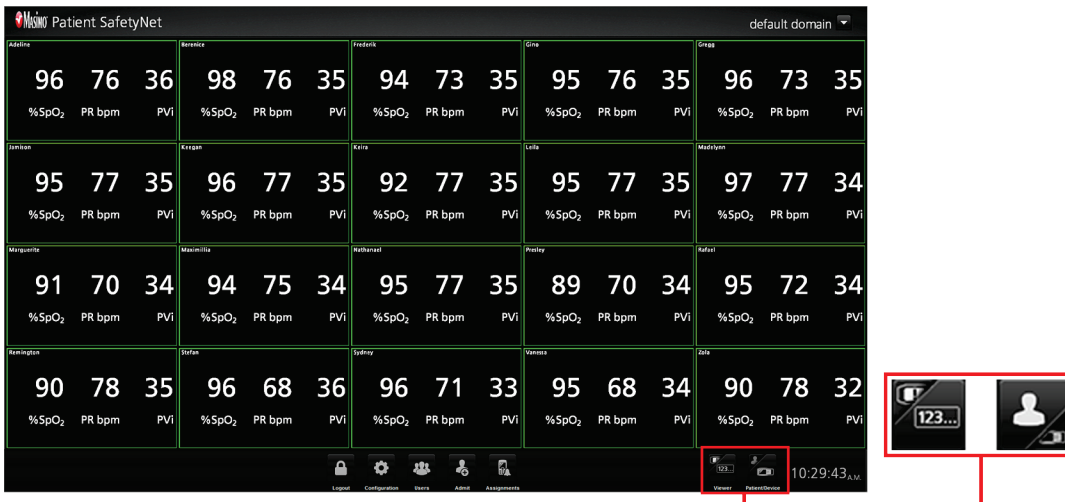


Patient Centric Mode

Patient Numeric/Icon View

To toggle between the Patient Numeric View and Patient Icon View, select the **Viewer** and **Patient/Device** buttons.

- Patient Numeric View



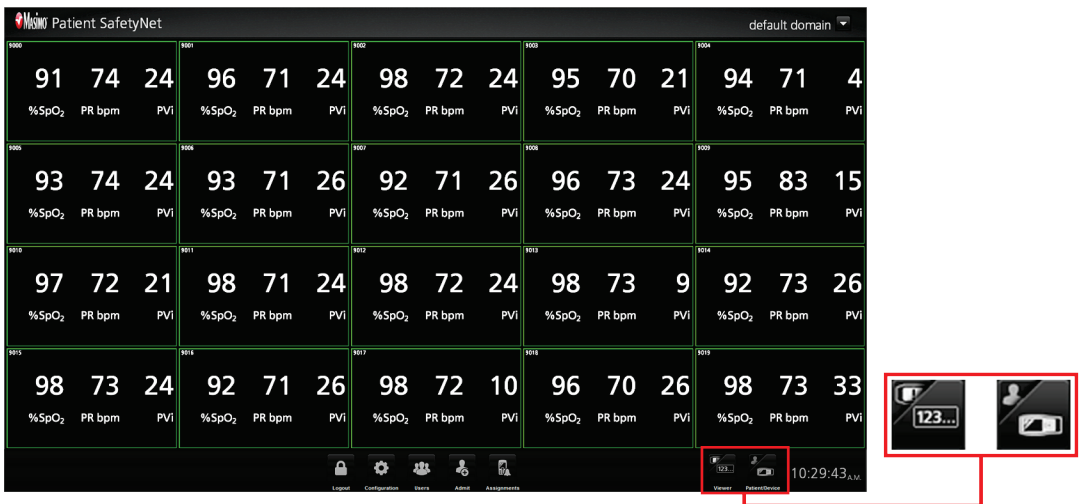
- Patient Icon View



Device Numeric/Device Icon View

To toggle between the Device Numeric View and Device Icon View, select the **Viewer** and **Patient/Device** buttons.

- Device Numeric View

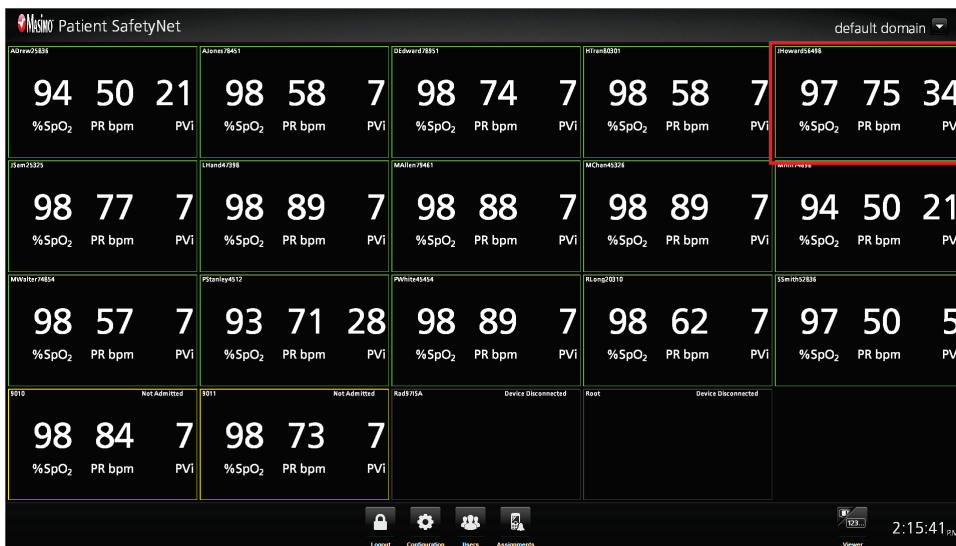


- Device Icon View

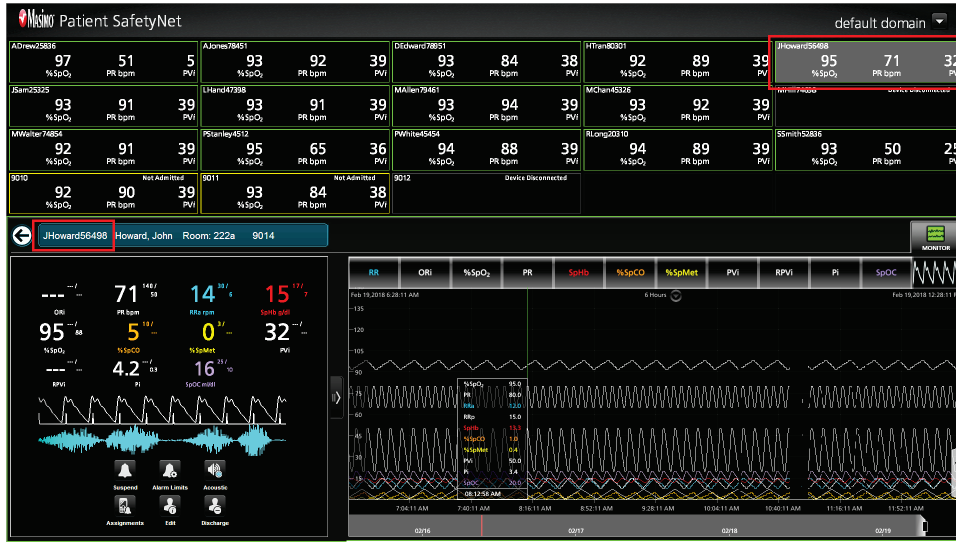


Patient Window - Numeric View

The user can view the details of a particular patient from the Numeric View or Detail View of the Main Screen. After successful admission to the system and sensor attachment to the patient, and there are no Alarm/Alert conditions, the cell's border color changes to green. In the example below, from the Numeric View of the Main Screen, one Patient Window is highlighted on the Numeric View screen.



When a user selects a Patient Window, the system displays the Patient Window in Detail View. More information about Detail View, see **Detail View Screens** on page 33.



Patient Numeric Window Details

The following lists the elements of a Point of Care (POC) device Patient Window in Patient Numeric View.

1 — JHoward56498

2 — **94 77 45**

3 — %SpO₂ PR bpm PVI

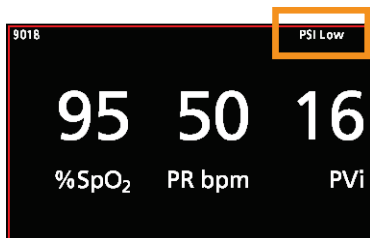
4 — [Red border]

1. Label
2. Numeric values
3. Parameters
4. Window border color

The border color of the Patient Window display one of several colors:

- Green: Successful admission and connection with device.
- Yellow: Successful connection to the device. This would include statuses, notifications, modifiers, notification devices not assigned to patient, or patients that have not been successfully admitted to the system
- Red: Device alarming.
- Gray: Disconnected device.

If the system triggers an alarm, the border of the Patient Window turns red (Device Numeric View is shown in the example). Also, the alarming parameter and numeric values turn red. A message appears on the top right corner of the window that conveys the nature of the alarm.



Main Screen Information - Device Icon View

The user can view the details of a particular patient. After successful admission to the system and sensor attachment to the patient, if there are no Alarm/Alert conditions, the display screen of the icon and cell's border changes to green. In the example below, from the Device View of the Main Screen, one Patient Window is highlighted

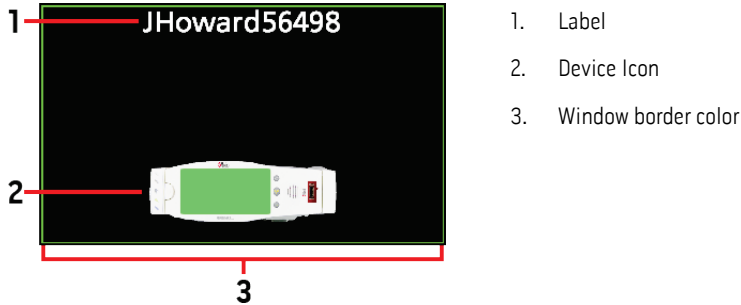


When a user selects a Patient Window, the system displays the Patient Window in Detail View. Note that the device icons do not display when in Detail View. More information about Detail View, see *Detail View Screens* on page 33.



Patient Device Window Details

The following lists the elements of a Point of Care device Patient Window in Device View. Device icons do not display when in Detail View.



The border color of the Patient Windows display one of several colors:

- Green: Successful admission and connection with device
- Yellow: Successful connection to the device. This would include statuses, notifications, modifiers, notification devices not assigned to patient, or patients that have not been successfully admitted to the system
- Red: Device alarming
- Gray: Disconnected device

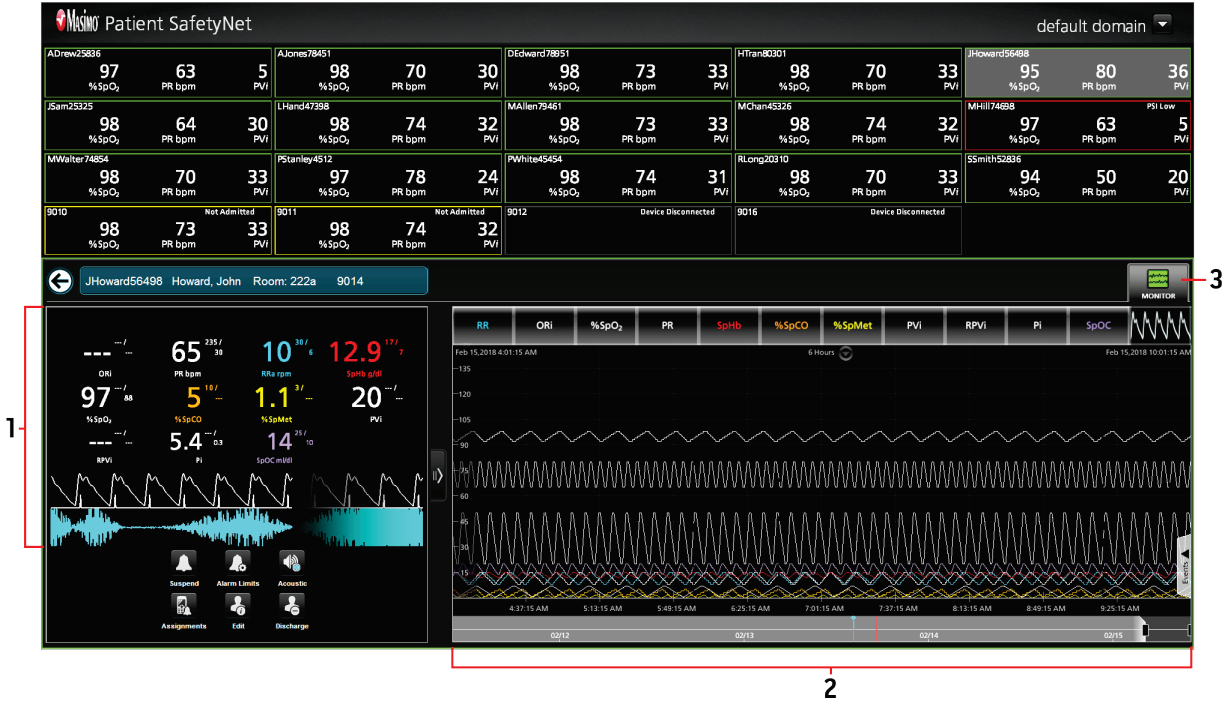
If the system triggers an alarm, the border of the Patient Window turns red. Also, the image of the device turns red. A message appears on the top of the window that conveys the nature of the alarm. Device icons do not display when in Detail View, only the label, window border and message.



Detail View Screens

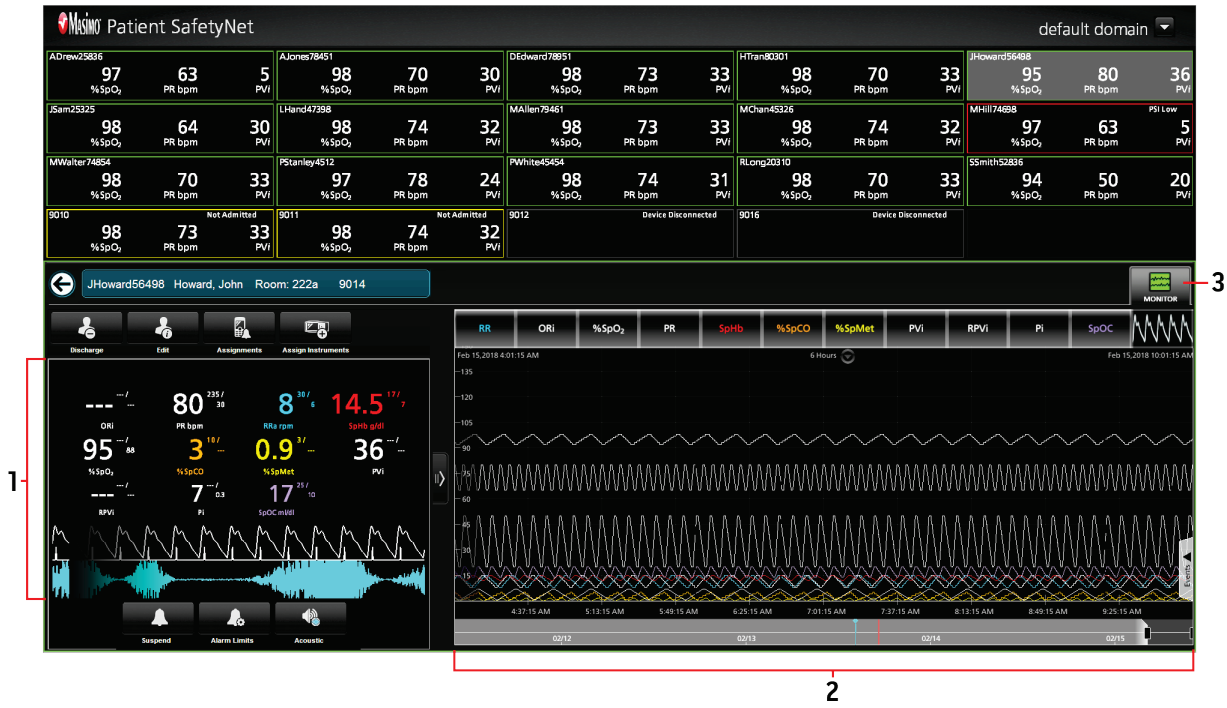
The *Detail View* screen is enabled after selecting a patient or device from the *Main Screen*. This view displays all of the installed parameters and up to two (2) waveforms from the bedside device, the *Trend Window* panel provides the ability to Suspend Alarms, Change Alarm Limits, Manage Assignments, and Discharge. Additional fields can be added to the detail screen as well. See *Modify System Settings* on page 86.

Device Centric Mode



| Item | Description |
|------|----------------|
| 1 | Parameter Well |
| 2 | Trend Window |
| 3 | Device Tab |

Patient Centric Mode











| Item | Description |
|------|-----------------|
| 1 | Parameter Well* |
| 2 | Trend Window |
| 3 | Device Tab |

* In Device Numeric and Icon View (Patient Centric Mode), the Discharge, Edit, Assignments and Assign Instruments options are disabled.

Detail View Screen Buttons

The buttons displayed on the Detail View screen allow functions to be access directly, while viewing patient data.

| Button | Description |
|---|---|
|  | Admit* , ** - The Admit button starts the admit patient wizard. See <i>Admit</i> on page 38. |
|  | Discharge* , ** - Discharge patient from system. See <i>Discharge</i> on page 43. |
|  | Edit* - Edit admitted patient's information. See <i>Edit Patient Information</i> on page 43. |
|  | Assignments* , ** - Manage the patients' notification Assignments. See <i>Modifying Assignments</i> on page 44. |
|  | Suspend - Suspend an active alarm on the PoC Device. See <i>Suspending Alarms</i> on page 43. |
|  | Alarm Limits - Change Alarm Limits. See <i>Adjusting Alarm Limits</i> on page 44. |
|  | Acoustic - Listen to patient's breath (RRa parameter is required on the Point of Care device). See <i>Acoustic Audio Playback</i> on page 45. |
|  | Assign Instruments* , *** - Add or Remove a point of care device to the admitted patient. See <i>Assign Instruments</i> on page 45. |

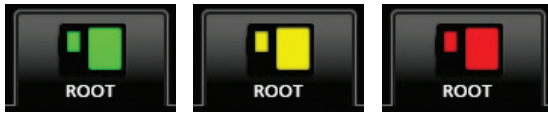
* Disabled when in Patient Centric Mode - Device View.

** Disabled when in Spot Check Mode.

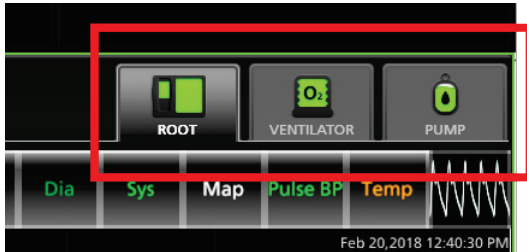
*** Displays in the Detail View only when Patient SafetyNet is in Patient Centric Mode.

Device Tab

The device tab icon corresponds to the device(s) currently assigned to the patient (assigned during the admit process). See **Admit** on page 38. The color of the device tab icon displays the device status and changes color with any active alarms (Root shown in the example below).



In Patient Centric Mode, multiple devices can be assigned to a single patient and are shown on separate tabs.



Patient Trend Information

Patient SafetyNet displays up to 96 hours of trended information for each monitored parameter. This information can be viewed at intervals of 10 or 30 minutes, 1, 6, 24 or 96 hours. The trends will provide live updates as the data is being collected when an interval is selected. By using the mouse, or touching the screen on a touch screen monitor, users can select specific areas of the trend to focus in on. To exit an area of focus, select a new time interval from drop down menu.

Note: The Trend Graph updates automatically every 2 minutes.

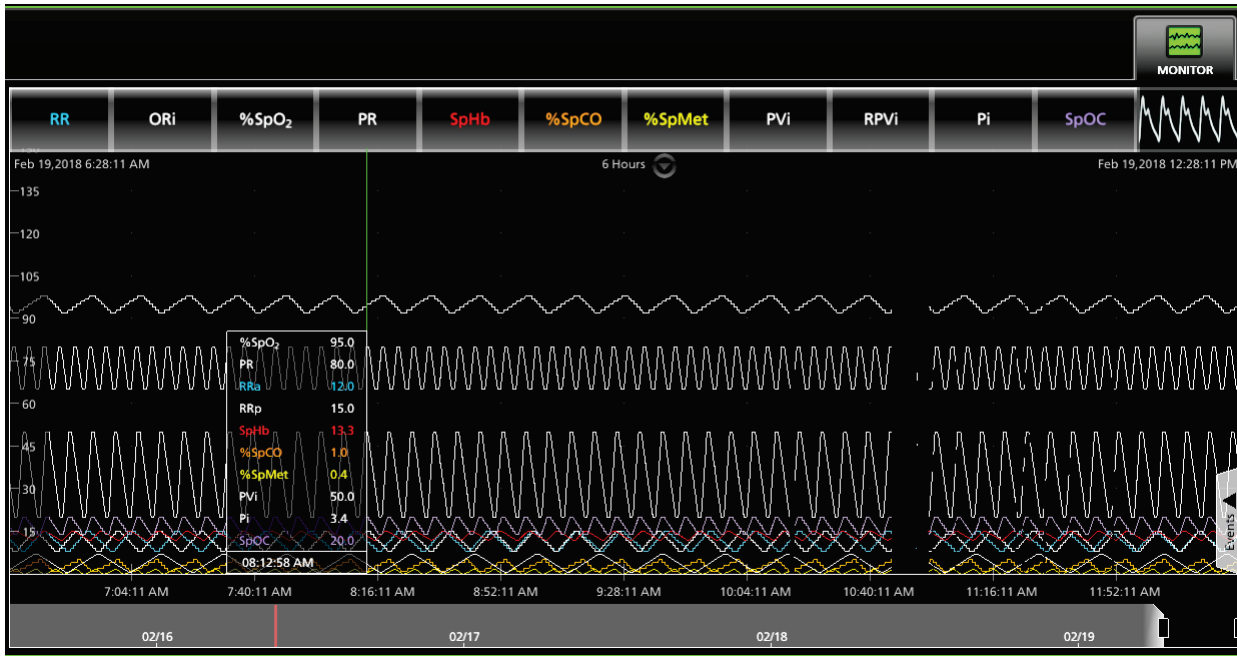
To view the Trend

1. Select the desired patient or point of care device from the *Main Screen*.

Note: By default, all trend information will be displayed.

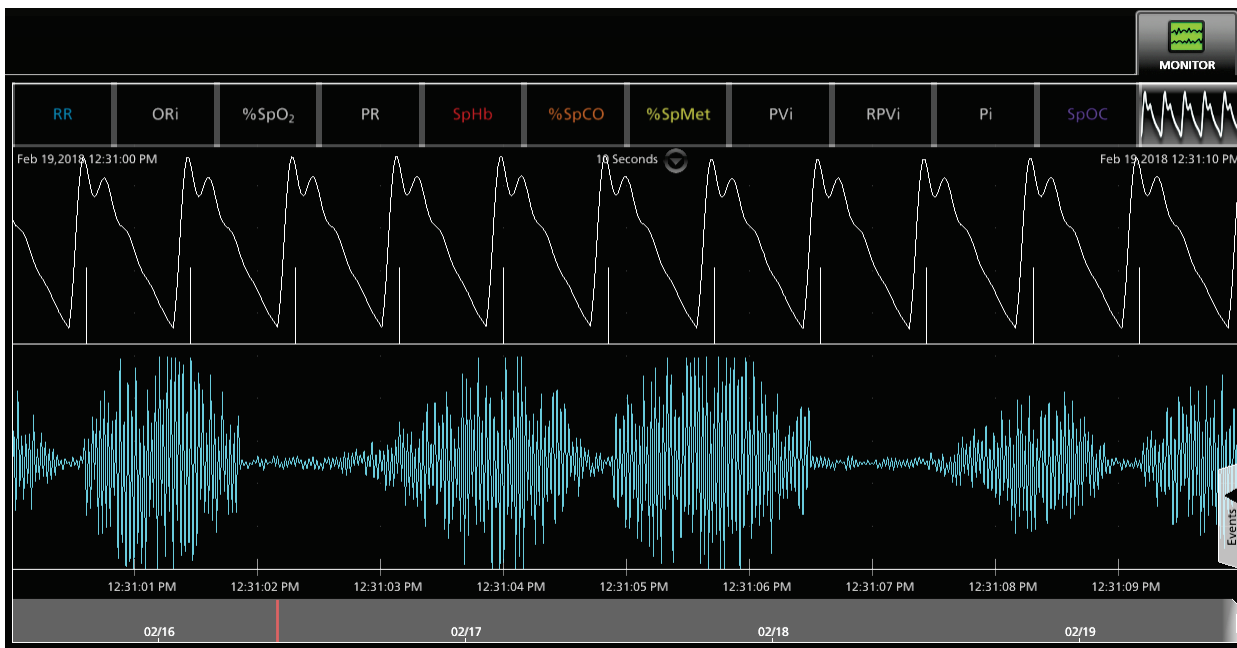
2. Click on the desired parameter in the *Parameter Options* area above the *Trend Window*.
3. The parameter trend will appear in the *Trend Window* of the *Detail View*.

By placing the mouse, or touching when using a touch screen monitor, over the trend line, the information will appear in a pop-up box in the *Trend Window*.



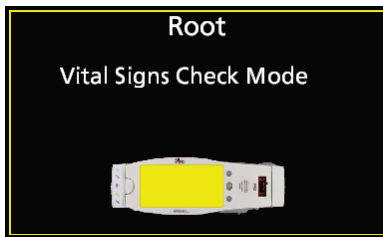
Live Waveforms and Historical Waveform Review

View live waveforms in Detail View. Live waveforms available include Pleth, SIQ and RRa (when option is installed on device). View up to 96 hours of collected waveforms.

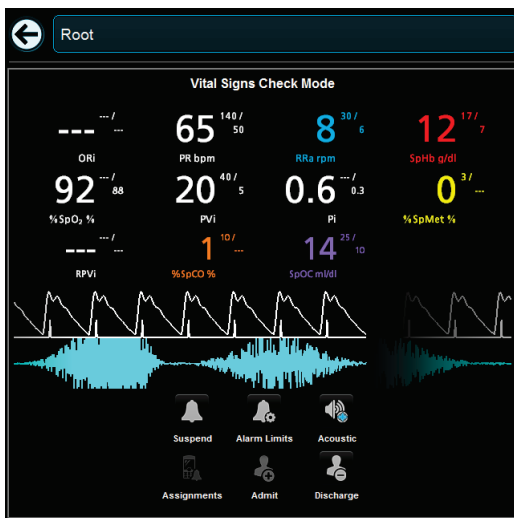


Vital Signs Check Mode

When a device is in Vital Signs Check mode, the *Main Screen* indicates that the device is currently in Vital Signs Check Mode. Refer to the Operator's Manual for the Masimo device for information on Vital Signs Check mode.



When in Vital Signs Check mode, Patient SafetyNet does not allow admitting of patients or assignments to be added (the *Admit* and *Assignment* options are grayed out).



Monitor Patient



Admit

When admitting patients to the Patient SafetyNet System, users enter patient information, as well as set, and approve alarms, assign instrument(s) and assign respondent devices to provide notifications to clinicians.

Note: The Patient SafetyNet System supports patient admission from other Masimo devices connected to the system, such as the Root device (please see the *Operator's Manual for Root* for more information). Patient admission from devices is a configurable feature and the system administrator can enable this feature from the Patient SafetyNet View Station.

Patient information may be entered manually or imported from a connected Electronic Medical Record (EMR) System (when this feature is available).


Import Patient Information from an EMR

1. Select  on the bottom of the *Main View* screen.
2. Select .
3. Select name of patient from the imported list or begin typing the name of the patient in the *Search* field. A list of patients with that name will appear.
4. Select the patient, and then select *Apply*.

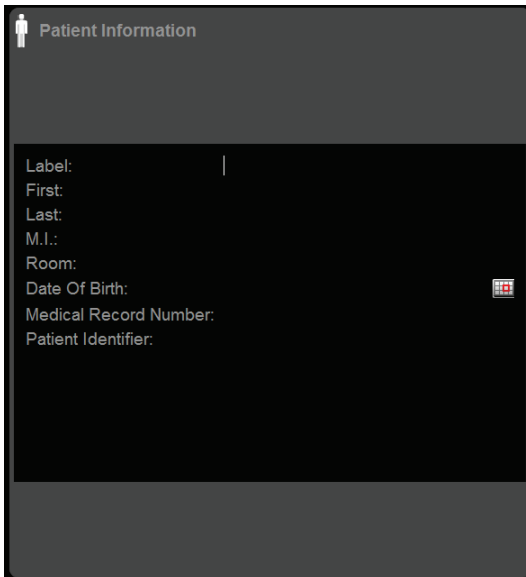
5. The label will be automatically created. If necessary the user can modify the label.
6. Click the *Next* button and go to **Assign Instrument(s) to a Patient**.

Note: For more information refer to *HL7 Interface (Inbound)* on page 67.

Enter Patient Information Manually

1. Select the Admit icon 
 - In Device Centric Mode, the Admit icon is at the bottom of the device *Detail View* screen.
 - In Patient Centric Mode, the Admit icon is at the bottom of the *Main View* screen.
2. Select the *Label* field and enter a label.

Note: The label is a required field to admit a patient.



3. Press the *Tab* key or select in the *First* field and enter the first name.
4. Press the *Tab* key or select in the *Last* field and enter the last name.
5. Press the *Tab* key or select in the *M.I.* field and enter the middle initial.
6. Press the *Tab* key or select in the *Room Number* field and enter the room number.
7. Press the *Tab* key or select in the *Date of Birth* field and select the date of birth.
8. Press the *Tab* key or select in the *Medical Record Number* field and enter the medical record number.
9. Press the *Tab* key or select in the *Patient Identifier* field and enter the patient identifier.
10. If in Patient Centric Mode, click the "Next" button.

Assign Instrument(s) to a Patient (Patient Centric Mode ONLY)

Note: In Device Centric Mode, the patient is admitted to the device and this option is not available.

In Patient Centric Mode, up to 6 devices can be assigned to a single patient.

1. Once the Patient Information has been entered (or imported from EMR), click *Next* to proceed to the *Instrument Selection* screen.

2. Select from the list of available instruments (devices) by clicking the device image.

Note: When selected, the device displays a green border around the image.

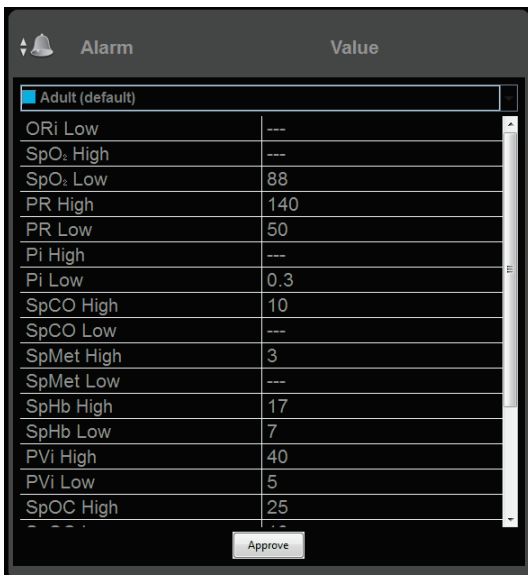
Note: Additional devices (up to 6 total) can be assigned after admitting the patient. See **Assign Instruments** on page 45.



3. Click the "Next" button.

Assign Alarm Profile/Limits to a Patient

1. Adjust the high and low limits as needed by manually entering the desired values, or select a pre-configured alarm profile. See **Alarm Profiles** on page 41.

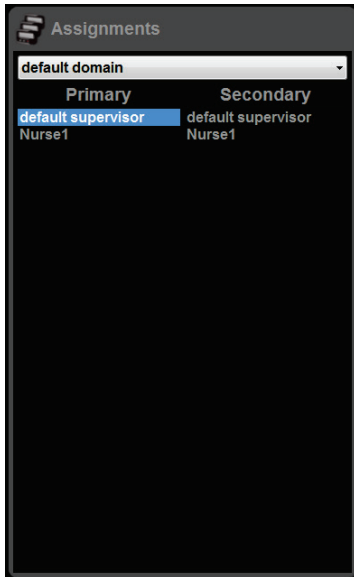


2. Click the "Approve" button when finished.
3. If in Patient Centric Mode, click the "Next" button.

Assign a Respondent to a Patient

From list of available respondents, select and assign at least 1 primary respondent to the patient.

Note: A secondary respondent can be set as a mandatory requirement when admitting. See **Assignments** on page 41.



Finalizing the Admit Procedure

Upon completion of the previous steps, click the *Admit* button to admit the patient, and complete the Admit process.

After successful admission to <prod-name_short> and sensor attachment to the patient:

- In the Numeric View, the cell's border color will change to green, if there are no Alarm/Alert conditions. See **Patient Window - Numeric View** on page 29.
- In the Device Icon View, the display screen of the icon and cell's border will change to green, if there are no Alarm/Alert conditions. See **Main Screen Information - Device Icon View** on page 31.

Alarm Profiles

An alarm profile is a pre-configured set of alarm limits for all parameters that can be applied to a point of care device in lieu of manually setting limits for each individual parameter. An alarm profile can be used to ensure that a pre-determined set of alarm limits are applied to the device. Up to eleven (11) profiles can be configured for each domain - three (3) default and eight (8) custom. Alarm profiles are identified by both a name and a color. An alarm profile can either be applied to the device during the process of admitting a patient, or any other time a device is connected to Patient SafetyNet.

Set and Approve Alarms

1. Alarm values appear from the settings in the device. To adjust Alarm Limits, select in the value column for the desired parameter and type a new value.
2. If Alarm profiles are pre-configured, then select the desired alarm profile using the pull-down selector at the top of the alarm panel.
3. Select the *Approve* button to confirm the existing alarm settings or any changes that have been made. Once the *Approve* button is selected, it will become deactivated. If alarm settings are changed after the *Approve* button has been selected, the button will again become active and you will be required to approve the new alarm settings before completing the Admit process.

Note: For additional information about alarms, see **Alarm Profile Configuration** on page 76.

Assignments

Note: The *Assignments* section can only be used in Clinician Paging/Notification Mode.



Changing Assignments

The Patient SafetyNet System is able to assign Primary and Secondary Respondent devices to patients. For information regarding the Alarm Escalation Protocol, see **Notification and Escalation Protocol** on page 20. A respondent is a user that is notified of alarms or alerts through one of the following methods:

- Pager
- IP phone
- Mobile device


Upon initial connection to the Patient SafetyNet System, patients are automatically assigned a Supervisory Respondent. The Supervisory Respondents devices are configured at the time of installation. Primary and Secondary Respondent assignments are made during the patient Admit process. Changes to Assignments may be made to a specific patient or by accessing the list of patients assigned to a specific respondent.

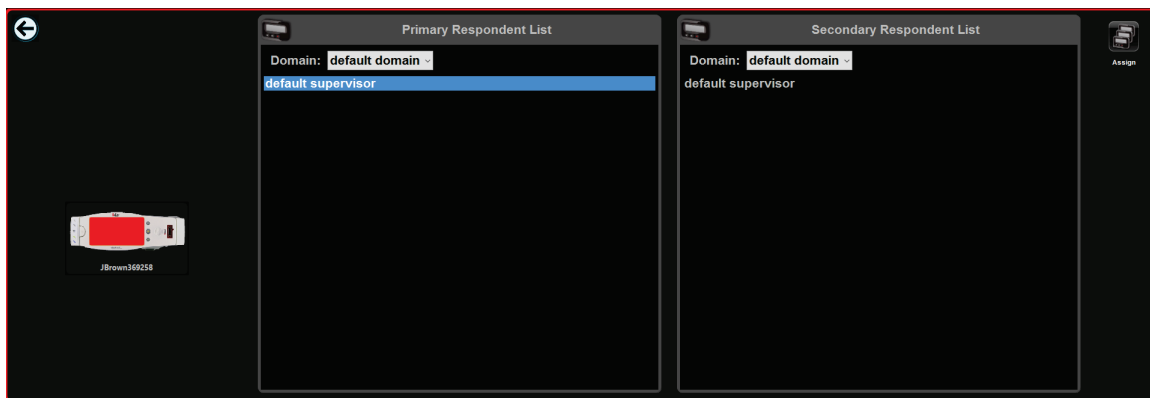
For a specific patient, to make changes to Respondent Device Assignments:


1. Go to the *Detail View* screen for a patient.
2. Select the *Assignments* icon  to see the assigned respondents. The Primary respondent assigned to a patient are highlighted in the *Primary Respondent* list. The Secondary respondent assigned to a patient are highlighted in the *Secondary Respondent* list.
3. Highlight or remove the highlight for the desired Primary and Secondary Respondent and click the *Assign* icon  to apply the changes.

Assign Respondents

Primary and Secondary Respondent assignments are made during the patient Admit process. See **Admit** on page 38. To assign additional respondent devices to a patient, not assigned during the Admit process, perform the following:

1. From the patient *Detail View*, select the *Assignments* icon .
2. Select a and highlight notification device(s) within the Primary and Secondary Respondent lists to assign a Primary and Secondary Respondent device.



3. Click the *Assign* icon  to apply the respondents.
4. Click the back arrow to exit.


Note: The respondent list may be further filtered by selecting a Domain in the drop-down list.

Note: To remove an assignment, select the highlighted respondent a second time to de-select (un-highlight) and unassign.


Remove Assignments


To remove an assignment from a Respondent from either list, click the highlighted Respondent to de-select

Note: To further filter the respondent device list:


1. Click on a lower level domain in the list located above the primary or secondary list.
2. Remove the highlight (de-select) the desired Primary or Secondary Respondent.
3. Click the *Assign* icon  to apply the changes.
4. Click the back arrow.

Suspending Alarms

When an Alarm Limit is exceeded, or a non-clinical alarm triggers on the point of care device, the border status for the patient or device turns red and when in patient detail view, the Alarm icon displays .

When the alarm is suspended on either the point of care device or Patient SafetyNet,  icon displays on the detail view to indicate the alarm is temporarily silenced. The suspend time is based upon the Alarm Silence setting on the device. Refer to the Operator's Manual for the device to set the Alarm Silence duration. Notifications to Pagers will not be sent while an alarm is suspended, the notification will stop and the alarm state will reset.


To suspend an alarm condition:

1. Click the alarming patient or device from any of the Main Screens.
2. Click the *Suspend* icon  to temporarily silence active patient alarms.

Discharge


When it is no longer necessary to monitor the patient, a discharge procedure must be performed to remove the patient from the Respondent Assignment and the instrument (device). The device Detail View of the Patient Name and Room Number is cleared, and the default Alarm Profile assigned to the domain the device is in, is sent to the device.

To discharge a patient

1. Select a patient from the *Main Screen*.
2. Select the *Discharge* icon .
3. Select **Yes** to confirm the discharge of the patient from the Instrument.


Edit Patient Information

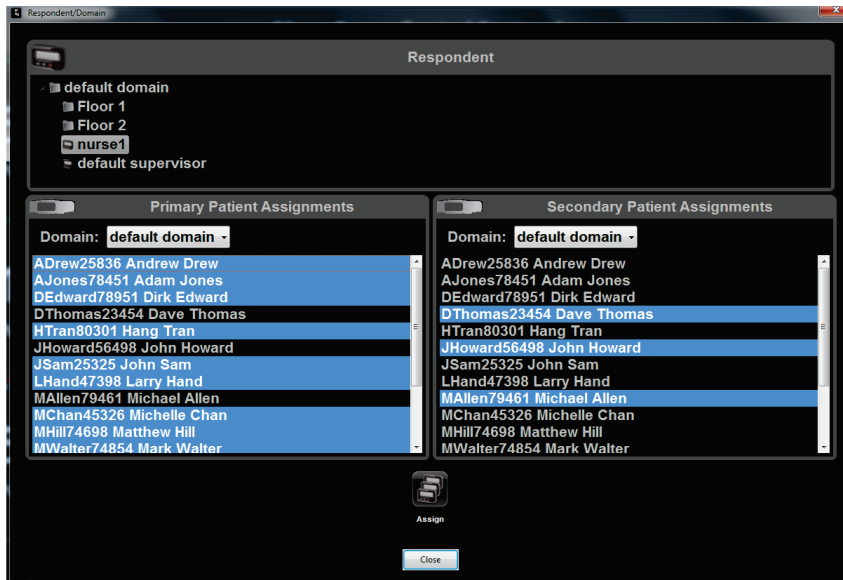
All information for an admitted patient, with the exception of the patient label, can be modified.


1. To edit the patients information, select the desired patient from the Main Screen.
2. From the patient *Detail View*, select the *Edit* icon .
3. Make the desired changes.
4. Select OK to save changes and close the window.

Modifying Assignments

Make changes to Assignments by accessing the list of patients assigned to a Device

1. From the *Navigation* bar, select the *Assignments* icon .
2. Select the respondent device from the *Respondent* list. The Primary patients assigned to the Respondent are highlighted in the *Primary Patient Assignments* list. Secondary patients assigned are highlighted in the *Secondary Patient Assignments* list.




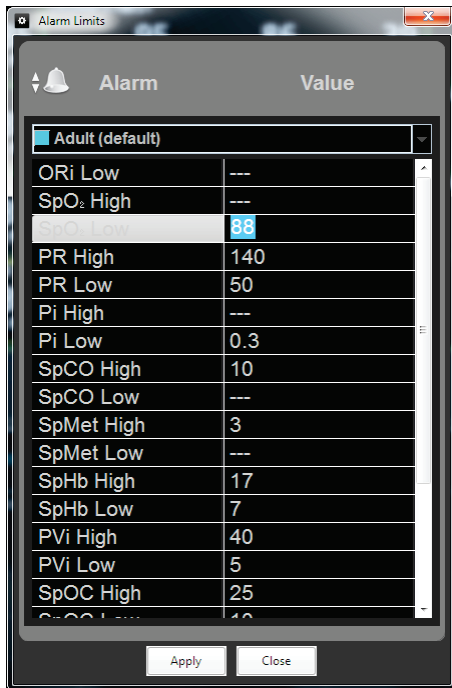
3. To assign a patient to the Respondent as a Primary, select to highlight the patient(s) from the *Primary Patient Assignments* list.
4. To assign a patient to the Respondent as a Secondary, select to highlight the patient(s) from the *Secondary Patient Assignments* list.
5. To remove an Assignment from either list, select the highlighted Respondent(s) to de-select.
6. Click the *Assign* icon  to apply the changes.
7. Select **Close**.

Adjusting Alarm Limits

Set or confirm the Alarm Limits each time the device is used. The Alarm Limits can be set on either the device or the Patient SafetyNet System. To adjust the Alarm Limits in the device, refer to the Operator's Manual for the device.

To adjust the Alarm Limits in the Patient SafetyNet System



1. Select the desired device or patient from any of the Main Screens.
2. From the patient *Detail View*, select the *Alarm Limits* icon .
3. To adjust the Alarm Limits, click in the value column for the desired parameter and type in a new value.
4. If Alarm profiles are pre-configured, then select the desired alarm profile using the pull-down selector at the top of the alarm panel. See **Alarm Profiles** on page 41.



5. Click *Apply* to set the new Alarm Limits/Alarm Profile.

Acoustic Audio Playback

Acoustic Audio Playback allows the user, from the Patient SafetyNet View Station, to listen to the breath sounds of a patients being monitored with Masimo Acoustic Respiratory Rate (RRa) sensors.


To suspend the Acoustic Audio Playback playback, select the Acoustic icon . When Acoustic Audio Playback is suspended, the Acoustic icon changes to Red .

Assign Instruments

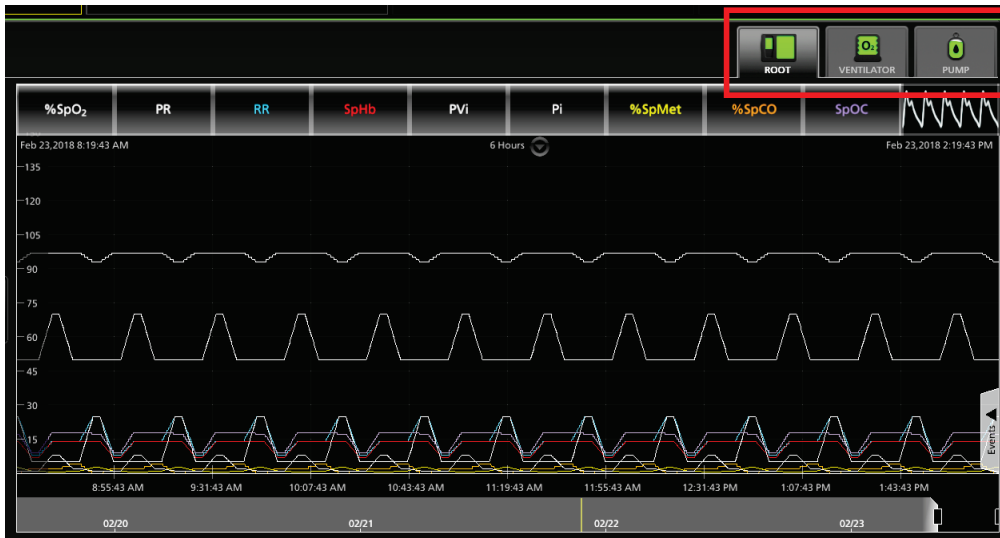
*** This options only applies when in Patient Centric Mode.**

When in Patient Centric Mode, after admitting a patient, additional instruments can be assigned to or removed from the patient.

Note: When in Device Centric Mode, only one device can be assigned to the patient.

1. Select the desired patient from the Main Screen.
2. From the patient *Detail View*, select the *Assign Instruments* icon .
3. From the *Instrument Selection* screen:
 - Select the instrument(s) to assign to the patient.
 - Deselect the instrument(s) to remove from the patient.
4. Select *Next*.
5. Select the Alarm Profile and adjust the alarm limits as needed.
6. When complete, select *Approve* to approve the *Alarm Limits*.

7. Select *Apply* to save the changes.
8. If instruments such as a pump or ventilator are added, new tabs appear in the patient *Detail View*. Select the tab to view information for that instrument.



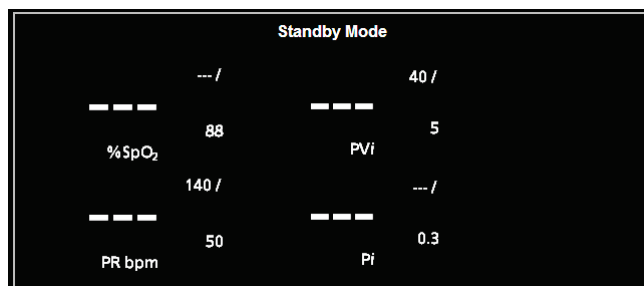
Device Standby

The Patient SafetyNet System supports the Standby feature for the Masimo point of care (PoC) device. When Root is in Standby mode, Patient SafetyNet will display Standby as a status message located near the top of the Patient Window in Main View and in the Parameter Well in Detail View. In Standby mode, the Masimo point of care device will stop transmitting parameter data, waveform data, clinical alarms, and non-clinical alarms to the Patient SafetyNet System. The only alarm that will be passed is the Low Battery alarm from Root.

Main Screen




Detail View Screen



Logout

When assignments, adjustments or changes to the Patient SafetyNet System are complete, users are required to Logout. The user must Logout of the Patient SafetyNet System to prevent unauthorized access to the system. When logged out of the system, the user interface is not active. All notifications continue to be sent to the assigned respondent devices.

To Logout

1. Select the Logout icon  on the *Navigation* bar.
2. Select **Yes** to confirm.

Chapter 5: Reports

The following chapter describes the various types of reports that are available in Patient SafetyNet. This chapter also provides use cases for each report. The following are the top-level reports and descriptions of individual sections contained within those reports.

- System Report
- Patient Report.
- Patient Trend Analysis Report.
- **Data Export Report** on page 58
- **Notification Summary Report** on page 59
- **Patient Summary Report** on page 60

The Patient SafetyNet System provides the ability to generate reports from any computer that has access to the same network as the Patient SafetyNet Appliance with a user account that has privileges to generate the reports using a web browser.

Note: The URL used to access Patient SafetyNet Reports is system specific and configured upon installation. Please contact your local system administrator for more information.

Events versus Notifications

Event: The Patient SafetyNet System records an event when a physiological parameter exceeds the configured alarm threshold or a non-physiological alarm is triggered on the device.

Notification: The Patient SafetyNet System records a notification when an event exceeds the configured device alarm delay in addition to the Patient SafetyNet System initial alarm delay.

Note: Patient SafetyNet System can record events without audible alarms ever being generated. This would be caused by a parameter exceeding the alarm threshold for a time shorter than the configured device alarm delay. An example would be an SpO₂ low or sensor off alarm delay.

System Report

The *System Report* encapsulates system data for up to 30 days for a specified time range within the previous year.

Use Cases

- Provides the user the ability to understand alarm distribution across the care area
- Provides the user the ability to compare different alarm protocols
- Provides the user the ability to understand clinician response to alarms by looking at the percentage of non-clinical alarms escalating through the Patient SafetyNet Escalation Protocol
- Provides the user the ability to compare various clinical units to each other when multiple domains are configured

Generate Report

1. From the Report Type drop-down list, select system report.
2. From the Domain drop-down list, select the desired domain.
3. Select **Start Date** and **End Date**.
4. Click the boxes for desired report types.
5. Click the boxes for desired report categories.
6. Select **Generate Report**.

Header Information

The following is an example of the *Header Information* section.

Hospital Title

Hospital Address

| | |
|-------------------------------|-------------------------|
| Top Level Domain | Report Date |
| Parent Domain | Report Start Date |
| Domain | Report End Date |
| Number of Instruments (Avg) | Report First Event Time |
| Utilization | Report Last Event Time |
| # of Active Instruments | Total Monitoring Time |
| Active Instrument Utilization | |

The following table defines the terms used in the *Header Information* section.

| Terms | Description |
|-------------------------------|---|
| Top Level Domain | Name of facility where the Patient SafetyNet System is located (configured during installation) |
| Parent Domain | The highest level domain of the Patient SafetyNet System (configured during installation) |
| Domain | A subset of the parent domain (configured during installation) |
| Number of Instruments (Avg) | The average number of instruments connected to the Patient SafetyNet System for the selected time frame |
| Report First Event Time | The date and time of the first event for the selected time frame |
| Report Last Event Time | The date and time of the last event for the selected time frame |
| Total Monitoring Time | The total time monitored during the selected time frame |
| Report Date | The date and time that the report was generated |
| Report Start Date | The start of the time frame selected before the report was generated |
| Report End Date | The end of the time frame selected before the report was generated |
| Monitoring Time | The summation of all of the active instrument monitoring time since system installation |
| Utilization | Monitoring Time divided by the number of connected instruments divided by the selected time frame |
| # of Active Instruments | The number of instruments connected to the Patient SafetyNet System |
| Active Instrument Utilization | Monitoring Time divided by the number of connected instruments actively monitoring divided by the selected time frame |

Event Reports

The following is an example of the *Clinical Events Report*.

1.1 Event Report: Clinical Event

| Type [of Clinical Event] | Count | % [Count] | Total Duration (sec) | % [Duration] | Max Duration (sec) |
|--------------------------|-------|-----------|----------------------|--------------|--------------------|
|--------------------------|-------|-----------|----------------------|--------------|--------------------|

The following is an example of the *Non-Clinical Events Report*.

1.2 Event Report: Non-Clinical Event

| Type [of Non-Clinical Event] | Count | % [Count] | Total Duration (sec) | % [Duration] | Max Duration (sec) |
|------------------------------|-------|-----------|----------------------|--------------|--------------------|
|------------------------------|-------|-----------|----------------------|--------------|--------------------|

The following is an example of the *Modifiers Event Report*.

1.3 Event Report: Modifiers Event

| Type [of Modifiers Event] | Count | % [Count] | Total Duration (sec) | % [Duration] | Max Duration (sec) |
|---------------------------|-------|-----------|----------------------|--------------|--------------------|
|---------------------------|-------|-----------|----------------------|--------------|--------------------|

The following table defines the terms used in the *Clinical Events*, the *Non-Clinical Events*, and the *Modifiers Event* reports.

| Terms | Description |
|------------------------------|---|
| Type [of Clinical Event] | An event is recorded when a physiological parameter exceeds the configured alarm threshold. See Clinical Events on page 110. |
| Type [of Non-Clinical Event] | An event that triggers an audible alarm but is not related to physiological parameters. See Non-Clinical Events on page 114. |
| Type [of Modifiers Event] | Environmental states that affect monitored parameters, but do not generate alarms by themselves. See Modifiers on page 115. |
| Count | The number of times that one of the above events or modifiers occurred for the selected time frame |
| % [Count] | The percentage of occurrence of a type of event or modifier for the selected time frame |
| Total Duration (sec) | The total number of seconds for all events or modifiers of a particular type for a selected time frame |
| % [Time Duration] | The percentage of one type of an event or modifier compared to the combined total duration of all other events or modifiers within the same report category of the <i>System Report</i> |
| Max Duration (sec) | The duration of the longest event or modifier of a particular type |

Event Duration Report

The following is an example of the *Clinical Event Duration Report*.

2.1 Event Duration Report: Clinical Event

| Type [of Clinical Event] | 2 - 15 (sec) | 16 - 30 (sec) | 31 -60 (sec) | 61 - 180 (sec) | 3 - 4 (min) | 4 - 5 (min) | >5 min |
|--------------------------|--------------|---------------|--------------|----------------|-------------|-------------|--------|
|--------------------------|--------------|---------------|--------------|----------------|-------------|-------------|--------|

The following is an example of the *Non-Clinical Event Duration Report*.

2.2 Event Duration Report: Non-Clinical Event

| Type [of Non-Clinical Event] | 2 - 15 (sec) | 16 - 30 (sec) | 31 -60 (sec) | 61 - 180 (sec) | 3 - 4 (min) | 4 - 5 (min) | >5 min |
|------------------------------|--------------|---------------|--------------|----------------|-------------|-------------|--------|
|------------------------------|--------------|---------------|--------------|----------------|-------------|-------------|--------|

The following is an example of the *Modifiers Event Duration Report*.

2.3 Event Duration Report: Modifiers Event

| | | | | | | | |
|------------------------------|--------------|---------------|--------------|----------------|-------------|-------------|--------|
| Type [of Modifiers Event] | 2 - 15 (sec) | 16 - 30 (sec) | 31 -60 (sec) | 61 - 180 (sec) | 3 - 4 (min) | 4 - 5 (min) | >5 min |
|------------------------------|--------------|---------------|--------------|----------------|-------------|-------------|--------|

The following table defines the terms used in the *Clinical Events*, the *Non-Clinical Events*, and the *Modifiers Event* reports.

| Terms | Description |
|------------------------------|---|
| Type [of Clinical Event] | An event is recorded when a physiological parameter exceeds the configured alarm threshold. See Clinical Events on page 110. |
| Type [of Non-Clinical Event] | An event that triggers an audible alarm but is not related to physiological parameters. See Non-Clinical Events on page 114. |
| Type [of Modifiers Event] | Environmental states that affect monitored parameters, but do not generate alarms by themselves. See Modifiers on page 115. |

Notification Report

Note that only events that become notifications appear in this section.

The following is an example of the *Clinical Notification Report*.

3.1 Notification Report: Clinical Event

| | | | | | | |
|------------------------------------|-------------|-------------|----------------|----------------|------------------|------------------|
| Type [of Clinical Notification] | Initial (#) | Initial (%) | Escalation (#) | Escalation (%) | Reescalation (#) | Reescalation (%) |
|------------------------------------|-------------|-------------|----------------|----------------|------------------|------------------|

The following is an example of the *Non-Clinical Notification Report*.

3.2 Notification Report: Non-Clinical Event

| | | | | | | |
|---|-------------|-------------|----------------|----------------|------------------|------------------|
| Type [of Non- Clinical Notification] | Initial (#) | Initial (%) | Escalation (#) | Escalation (%) | Reescalation (#) | Reescalation (%) |
|---|-------------|-------------|----------------|----------------|------------------|------------------|

The following table defines the terms used in the *Clinical Notification* and *Non-Clinical Notification* reports.

| Terms | Description |
|-------------------------------------|--|
| Type [of Clinical Notification] | A notification is recorded when a physiological parameter exceeds the configured alarm threshold for a time frame longer than the configured instrument alarm delay in addition to the configured Patient SafetyNet System initial alarm delay |
| Type [of Non-Clinical Notification] | A notification that triggers an audible alarm but is not related to physiological parameters |
| Initial (#) | The total number of one type of notification that occurred in a selected time frame |
| Initial (%) | The percentage of one type of notification that occurred in a selected time frame |
| Escalation (#) | The total number of one type of notification that escalated in a selected time frame |
| Escalation (%) | The percentage of one type of notification that escalated in a selected time frame |
| Reescalation (#) | The total number of one type of notification that reescalated in a selected time frame |
| Reescalation (%) | The percentage of one type of notification that reescalated in a selected time frame |

Patient Report

The *Patient Report* encapsulates patient data for up to 30 days for a specified time range within the previous year.

Use Cases

- Provides the user detailed event and notification information
- Provides the user the ability to determine how patient events turned into notifications
- Provides the user the ability to see which notification devices were alerted

Generate Report

1. From the Report Type drop-down list, select patient report.
2. From the Domain drop-down list, select the desired domain.
3. Select **Start Date** and **End Date**.
4. Select desired patient in the **Patient List**.
5. Click the boxes for desired report types.
6. Click the boxes for desired report categories.
7. Select organize report by event type or time.
8. Select **Generate Report**.

Note: See *Reports Glossary* on page 110 for detailed information and terminology.

Header Information

The following is an example of the *Header Information* section.

Hospital Title

Hospital Address

| | |
|---|-------------------------|
| Top Level Domain | Report Date |
| Parent Domain | Report Start Date |
| Domain | Report End Date |
| Patient Name | Report First Event Time |
| Instrument Label - Serial Number - Type | Report Last Event Time |
| Room Number | Total Monitoring Time |
| Admit Time | |

The following table defines the terms used in the *Header Information* section.

| Terms | Description |
|------------------|---|
| Top Level Domain | Name of facility where the Patient SafetyNet System is located (configured during installation) |
| Domain | A subset of the parent domain (configured during installation) |

| Terms | Description |
|---|--|
| Patient Name | Name given to the patient during the admission process |
| Instrument Label - Serial Number - Type | The instrument's label, serial number, and type of instrument |
| Room Number | Room number assigned to patient |
| Admit Time | The time that patient was admitted |
| Report First Event Time | The date and time of the first event for the selected time frame |
| Report Last Event Time | The date and time of the last event for the selected time frame |
| Total Monitoring Time | The total time monitored during the selected time frame |
| Report Date | The date and time that the report was generated |
| Report Start Date | The start of the time frame selected before the report was generated |
| Report End Date | The end of the time frame selected before the report was generated |

Patient Information Report

The following is an example of the *Patient Information Report*.

Patient Information Report:

| |
|---|
| Patient Name |
| Instrument Label - Serial Number - Type |
| Room Number |
| Admit Time |
| Discharge Time |
| Admit Duration |
| Total Number of Events |

The following table defines the terms used in the *Patient Information Report*.

| Terms | Description |
|--------------------------|--|
| Patient Name | Name given to the patient during the admission process |
| Instrument Label | Name given to the instrument (configured during installation) |
| Instrument Serial Number | The serial number of the instrument that is connected to the patient |
| Type | The instrument type associated with the patient |
| Room Number | Room number given to the patient during the admission process |

| Terms | Description |
|------------------------|---|
| Admit Time | The date and time that the patient was admitted to the system |
| Admit Duration | The elapsed time between Admit Date and Discharge Date |
| Total Number of Events | The total number of events. |

Events Report

The following is an example of the *Clinical Events Report*.

1.1 Events Report: Clinical Event

| Event | Start Value | Stop Value | Duration (sec) | Start Time | Stop Time | Instrument Label |
|-------|-------------|------------|----------------|------------|-----------|------------------|
|-------|-------------|------------|----------------|------------|-----------|------------------|

The following is an example of the *Non-Clinical Events Report*.

1.2 Events Report: Non-Clinical Event

| Event | Duration (sec) | Start Time | Stop Time | Instrument Label |
|-------|----------------|------------|-----------|------------------|
|-------|----------------|------------|-----------|------------------|

The following is an example of the *Modifier Events Report*.

1.3 Events Report: Modifiers Event

| Event | Duration (sec) | Start Time | Stop Time | Instrument Label |
|-------|----------------|------------|-----------|------------------|
|-------|----------------|------------|-----------|------------------|

The following table defines the terms used in the *Clinical Events*, the *Non-Clinical Events*, and the *Modifiers Event* reports.

| Terms | Description |
|----------------------|---|
| Event | See Reports Glossary on page 110. |
| Start Value | The value of the parameter at the start of an event |
| Stop Value | The value of the parameter at the end of the event |
| Event Duration (sec) | The time in seconds between the Start Value and the Stop Value |
| Start Time | The time and date that the conditions for a type of event were met |
| Stop Time | The time and date that the conditions for a type of event were no longer met |
| Instrument Label | The Instrument ID that was entered when the instrument was first added to the SafetyNet System. |

Notification Report

Note that only events that become notifications appear in this section. See **Events versus Notifications** on page 47.

The following is an example of the *Clinical Notification Report*.

2.1 Notification Report: Clinical Event

| Type of Event | Notified Value | Time | Notification ID | Instrument Label |
|---------------|----------------|------|-----------------|------------------|
|---------------|----------------|------|-----------------|------------------|

The following is an example of the *Non-Clinical Notification Report*.

2.2 Notification Report: Non-Clinical Event

| Type of Event | Time | Notification ID | Instrument Label |
|---------------|------|-----------------|------------------|
|---------------|------|-----------------|------------------|

The following is an example of the *Modifiers Notification Report*.

2.3 Notification Report: Modifiers Event

| Type of Event | Time | Notification ID | Instrument Label |
|---------------|------|-----------------|------------------|
|---------------|------|-----------------|------------------|

The following table defines the terms used in the *Clinical Notification*, the *Non-Clinical Notification*, and the *Modifiers Notification* reports.

| Terms | Description |
|------------------------------|--|
| Type of Event [Clinical] | A notification is recorded when a physiological parameter exceeds the configured alarm threshold for a time frame longer than the configured instrument alarm delay in addition to the configured Patient SafetyNet notification delay |
| Type of Event [Non-Clinical] | A notification that triggers an audible alarm but is not related to physiological parameters |
| Type of Event [Modifiers] | See Modifiers on page 115. |
| Notified Value | The value of the triggering parameter when the notification was sent |
| Time | The date and time that the notification was sent |
| Notification ID | The Cap Code of the pager, badge, or phone to which the notification was sent |
| Instrument Label | The Instrument ID that was entered when the instrument was first added to the SafetyNet system. |

User Interaction Report

The following is an example of the *Alarm Silence User Interaction Report*.

1. User Interaction Report: Alarm Silence

| Event | Duration (sec) | Start Time | Stop Time | Instrument Label |
|-------|----------------|------------|-----------|------------------|
|-------|----------------|------------|-----------|------------------|

The following is an example of the *Respond Instrument User Interaction Report*.

2. User Interaction Report: Respondent Instrument Assignment

| Start Time | Stop Time | Notification ID | Respondent Name | Role |
|------------|-----------|-----------------|-----------------|------|
|------------|-----------|-----------------|-----------------|------|

The following table defines the terms used in the *Alarm Silence User Interaction* and *Respondent Instrument User Interaction* reports.

| Terms | Description |
|---|---|
| Event | The instances when the alarm was silenced at the bedside instrument or using the Patient SafetyNet user interface |
| Duration (sec) | The duration in seconds that the alarm was silenced |
| Start Time [Alarm Silence] | The time and date that the alarm silence began |
| Stop Time [Alarm Silence] | The time and date that the alarm silence ended |
| Start Time [Respondent Instrument Assignment] | The time and date that the Respondent Instrument was assigned to the patient |
| Stop Time [Respondent Instrument Assignment] | The time and date that the Respondent Instrument was unassigned to the patient |
| Instrument Label | The Instrument ID that was entered when the instrument was first added to the SafetyNet system |
| Notification ID | The Cap Code of the pager, badge, or phone to which the notification was sent |
| Respondent Name | The name given to pager, badge, or phone when it was added to the system (configured during installation) |
| Role | Whether the recipient of the notification was the primary, secondary, or supervisory |

Patient Trend Analysis Report

The *Patient Trend Analysis Report* encapsulates patient data for up to five days for a specified time range within the previous 30 days.

Use Cases

- Provides the user the ability to view patient clinical trends over a selected time frame
- Provides the user the ability to view overnight clinical information for patients who may be at risk of excessive oxygen desaturations

Generate Report

1. From the Report Type drop-down list, select patient trend analysis report.
2. From the Domain drop-down list, select the desired domain.
3. Select desired patient in the **Patient List**.
4. Select **Start Date** and **End Date**.
5. Click the boxes for desired parameters and desired trend characteristics.
6. Select a device from the device list.
7. Select **Generate Report**.

Header Information

The following is an example of the *Header Information* section.

Hospital Title

Hospital Address

| | |
|------------------|-------------------|
| Top Level Domain | Report Date |
| Parent Domain | Report Start Date |
| Domain | Report End Date |
| Patient Name | Admit Date |
| Instrument Name | Discharge Date |
| Report ID | Admit Duration |

The following table defines the terms used in the *Header Information* section.

| Terms | Description |
|-------------------|---|
| Top Level Domain | The name of facility where the Patient SafetyNet System is located (configured during installation) |
| Domain | The domain where the patient is located in the system |
| Patient Name | The name given to the patient during the admission process |
| Instrument Name | The name given to the instrument (configured during installation) |
| Report ID | The sequential number of times for which the report was generated |
| Admit Date | The date and time that the patient was admitted to the system |
| Discharge Date | The date and time that the patient was discharged from the system |
| Admit Duration | The elapsed time between the Admit Date and the Discharge Date |
| Report Date | The date and time that the report was generated |
| Report Start Date | The start of the time frame selected before the report was generated |
| Report End Date | The end of the time frame selected before the report was generated |

Histograms

High and Low thresholds for SpO₂, Respiratory Rate, and Pulse Rate can be adjusted in the Patient Trend Analysis Report.

Select a date range from the last 30 days of the admit/discharge cycle of the selected patient. A max of 5 days is allowed.

Start Date: End Date:

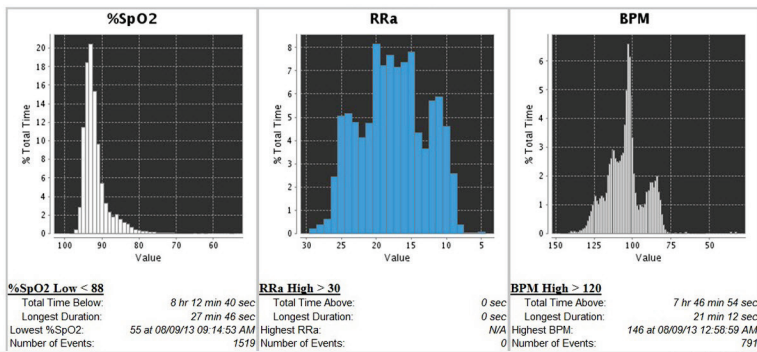
Parameter List

| SpO ₂ | Resp Rate | Pulse Rate |
|---|---|--|
| <input checked="" type="checkbox"/> Trend Graph | <input checked="" type="checkbox"/> Trend Graph | <input checked="" type="checkbox"/> Trend Graph |
| <input checked="" type="checkbox"/> Heuristic Graph | <input checked="" type="checkbox"/> Heuristic Graph | <input checked="" type="checkbox"/> Heuristic Graph |
| <input checked="" type="checkbox"/> Low | <input checked="" type="checkbox"/> Low | <input checked="" type="checkbox"/> Low |
| <input checked="" type="checkbox"/> Total Time Below | <input checked="" type="checkbox"/> Total Time Below | <input checked="" type="checkbox"/> Total Time Below |
| <input checked="" type="checkbox"/> Longest Duration | <input checked="" type="checkbox"/> Longest Duration | <input checked="" type="checkbox"/> Longest Duration |
| <input checked="" type="checkbox"/> Lowest SpO ₂ | <input checked="" type="checkbox"/> Lowest Resp Rate | <input checked="" type="checkbox"/> Lowest Pulse Rate |
| <input checked="" type="checkbox"/> Number of Events | <input checked="" type="checkbox"/> Number of Events | <input checked="" type="checkbox"/> Number of Events |
| <input type="checkbox"/> High | <input checked="" type="checkbox"/> High | <input checked="" type="checkbox"/> High |
| <input type="checkbox"/> Total Time Above | <input checked="" type="checkbox"/> Total Time Above | <input checked="" type="checkbox"/> Total Time Above |
| <input type="checkbox"/> Longest Duration | <input checked="" type="checkbox"/> Longest Duration | <input checked="" type="checkbox"/> Longest Duration |
| <input type="checkbox"/> Highest SpO ₂ | <input checked="" type="checkbox"/> Highest Resp Rate | <input checked="" type="checkbox"/> Highest Pulse Rate |
| <input type="checkbox"/> Number of Events | <input checked="" type="checkbox"/> Number of Events | <input checked="" type="checkbox"/> Number of Events |

Generate Report

Total time, longest duration, and number of events below or above a threshold can be set as an output for the report.

Histogram Images provide the duration the patient was monitored at a certain value as a percentage of total time monitored.

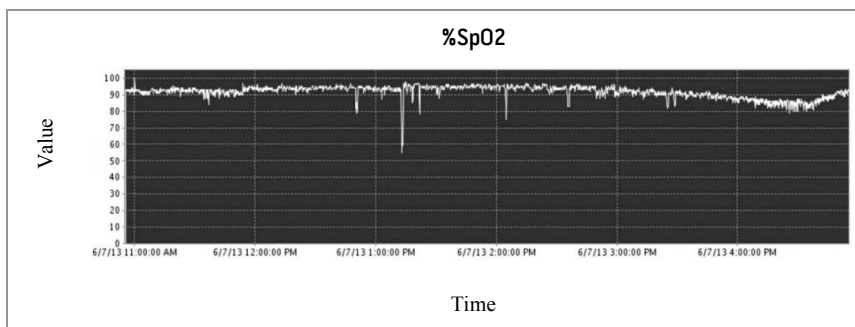


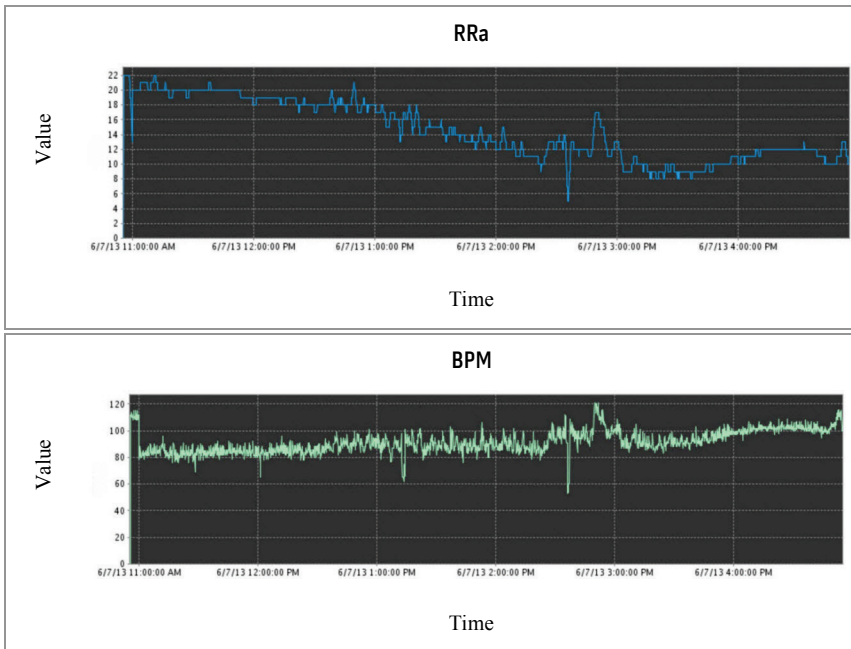
The Histogram section can display a five-day window of SpO₂, RRa, and BPM data for up to the previous 30 days.

Trends

The Trends section can display a five-day window of SpO₂, RRa, and BPM data for up to the previous 30 days.

The following is an example of the Trends section.





Data Export Report

The *Data Export Report* encapsulates system data for up to the previous 30 days.

Use Cases

- Provides the user the ability to extract the raw second by second data for each parameter and instrument for a patient
- Provides the user the ability to create unique trends from raw data

Generate Report

1. From the Report Type drop-down list, select data export report.
2. From the Domain drop-down list, select the desired domain.
3. Select **Start Date** and **End Date**.
4. Select **Apply**
5. Select desired patient in the **Patient List**.
6. Select desired instrument in the **Instrument List**.
7. Select **Generate Report**.
8. Save .csv file in the desired location.

Notification Summary Report

The *Notification Summary Report* encapsulates system data for up to 30 days for a specified time range within the previous year.

Use Cases

- Provides the user detailed notification information
- Provides the user the ability to determine how many notifications were sent to specific instruments

Generate Report

1. From the Report Type drop-down list, select notification summary report.
2. From the Domain drop-down list, select the desired domain.
3. Select **Start Date** and **End Date**.
4. Select **Generate Report**.

Header Information: Notification Summary Report

The following is an example of the *Header Information* section.

Hospital Title

Hospital Address

| | |
|------------------|-------------------|
| Top Level Domain | Report Start Date |
| Parent Domain | Report End Date |
| Domain | Report Date |

The following table defines the terms used in the *Header Information* section.

| Terms | Description |
|-------------------|---|
| Top Level Domain | The name of facility where the Patient SafetyNet System is located (configured during installation) |
| Domain | The domain where the patient is located in the system |
| Parent Domain | The parent domain where the patient is located in the system |
| Admit Date | The date and time that the patient was admitted to the system |
| Report Start Date | Start date and time selected for the report |
| Report End Date | End date and time selected for the report |
| Report Date | The date and time that the report was generated |

Respondent Instrument List

The following is an example of the *Clinical Events Report*.

Respondent Instrument List

| Label | Cap Code | Number of Clinical Notifications | Number of Non Clinical Notifications |
|-------|----------|----------------------------------|--------------------------------------|
|-------|----------|----------------------------------|--------------------------------------|

The following table defines the terms used in the *Respondent Instrument List*.

| Terms | Description |
|--------------------------------------|---|
| Label | Label given to notification device |
| Cap Code | Cap Code for the notification device |
| Number of Clinical Notifications | Number of Clinical Notifications in selected time frame |
| Number of Non Clinical Notifications | Number of Non Clinical Notifications in selected time frame |

Patient Summary Report

The *System Report* encapsulates system data for up to 30 days for a specified time range within the previous year.

Use Cases

- Provides the user detailed event and notification information
- Provides the user the ability to determine how patient events turned into notifications
- Provides the user the ability to see which notification devices were alerted
- Provides the user with specific patient monitoring statistics
- Provides the user the ability to determine what percentage of time the patient was being monitored
- Provides the user the ability to determine how many events led to notifications

Generate Report

1. From the Report Type drop-down list, select patient summary report.
2. From the Domain drop-down list, select the desired domain.
3. Select **Start Date** and **End Date**.
4. Select desired parameters from the **Parameter List**.
5. Select **Generate Report**.
6. Select the desired patient from the **Patient List**.
7. Select **Generate Report**.

Header Information: Patient Summary Report

The following is an example of the *Header Information* section.

Hospital Title

Hospital Address

| | |
|------------------|-------------------|
| Top Level Domain | Report Start Date |
| Parent Domain | Report End Date |
| Domain | Report Date |

The following table defines the terms used in the *Header Information* section.

| Terms | Description |
|-------------------|---|
| Top Level Domain | The name of facility where the Patient SafetyNet System is located (configured during installation) |
| Domain | The domain where the patient is located in the system |
| Parent Domain | The parent domain where the patient is located in the system |
| Admit Date | The date and time that the patient was admitted to the system |
| Report Start Date | Start date and time selected for the report |
| Report End Date | End date and time selected for the report |
| Report Date | The date and time that the report was generated |

Patient Information Report

The following is an example of the *Patient Information Report*.

Patient Information Report:

| |
|-----------------|
| Patient Name |
| Instrument Name |
| Admit Date |
| Discharge Date |
| Admit Duration |

The following table defines the terms used in the *Patient Information Report*.

| Terms | Description |
|-----------------|---|
| Patient Name | Name given to the patient during the admission process |
| Instrument Name | The name of the instrument that is connected to the patient |

| Terms | Description |
|----------------|---|
| Admit Date | The date and time that the patient was admitted to the system |
| Discharge Date | The date and time that the patient was discharged to the system |
| Admit Duration | The elapsed time between Admit Date and Discharge Date |

Patient Event List

The following is an example of the *Clinical Events Report*.

Patient Notification List

| Label | Cap Code | Start Time | Stop Time | Role | Number of Clinical Notifications | Number of Non Clinical Notifications |
|-------|----------|------------|-----------|------|----------------------------------|--------------------------------------|
|-------|----------|------------|-----------|------|----------------------------------|--------------------------------------|

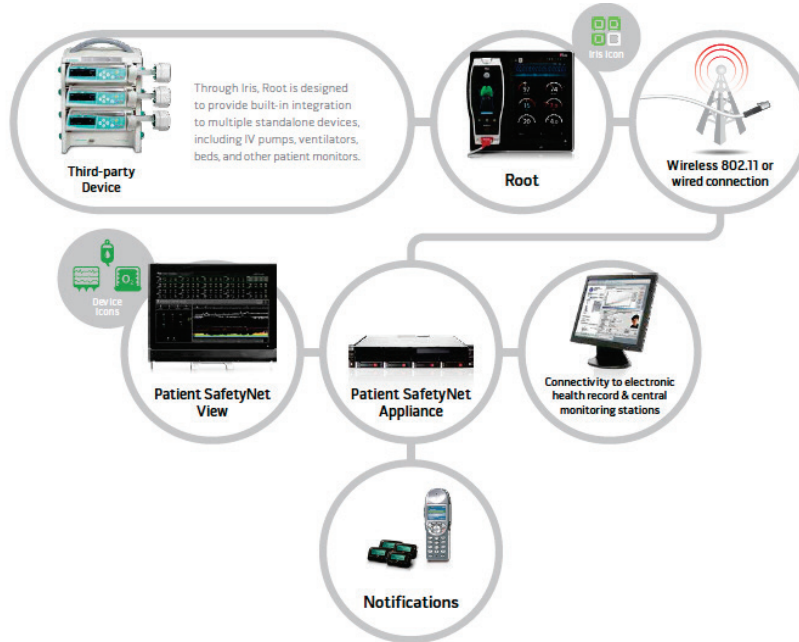
The following table defines the terms used in the *Patient Notification List*.

| Terms | Description |
|--------------------------------------|--|
| Label | Label given to notification device |
| Cap Code | Cap Code for the notification device |
| Start Time | The time and date that the conditions for a type of event were met |
| Stop Time | The time and date that the conditions for a type of event were no longer met |
| Role | Whether the recipient of the notification was the primary, secondary, or supervisory |
| Number of Clinical Notifications | Number of Clinical Notifications in selected time frame |
| Number of Non Clinical Notifications | Number of Non Clinical Notifications in selected time frame |

Chapter 6: Iris

Iris allows a variety of standalone devices to connect to the Patient SafetyNet System. When standalone devices are connected to the Patient SafetyNet System via the Iris port of Root, patient data and alarms can be passed through Root to Patient SafetyNet which can send the data to the patient's electronic health records.

Below is an example of one scenario in which standalone device can be connected to Root.



Connecting a Standalone Device

In order to connect a standalone device to Patient SafetyNet via Root and Iris please ensure you have the correct *Iris Adapter* for the make and model of the standalone device you wish to connect.

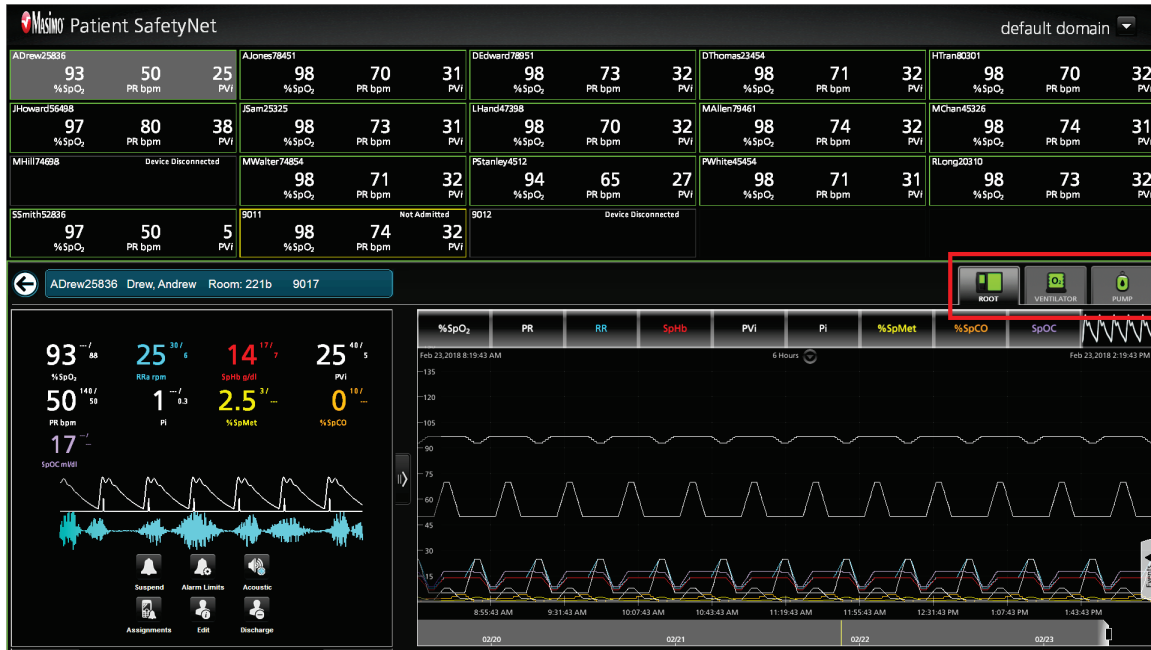
1. Ensure the standalone device is configured to output data. For more information on how to configure the standalone device to output data consult that standalone device's manual(s).
2. Connect the proprietary end of the *Iris Adapter* to the standalone device.
3. Connect the RJ-45 end of the *Iris Adapter* to any of the 4 compatible Iris Connectivity Ports on Root using an Ethernet cable.

For more information on ensuring proper connection of standalone device to Root consult the Root Operator's Manual and the Iris Adapter Directions For Use.

Viewing Standalone Device Information

To view data from a standalone device on Patient SafetyNet select the appropriate *Patient Window* from the *Main View* screen. In *Detail View* you will see multiple tabs corresponding to the various devices associated with the patient. Select the tab of the appropriate standalone device and that device's data will populate the *Trend Window*. Available parameters from the standalone device will populate the *Parameter Options* bar above the trend window, as well as, the *Parameter Well* to the left of the trend window. The standalone devices trend information in the *Trend Window* can be adjusted and viewed in a similar fashion to that of a connected Masimo pulse oximeter, for more information on the *Trend Window* see **Patient Trend Information** on page 36.

Successful connection between Patient SafetyNet and a standalone device will be indicated when the standalone device tab turns Green, Yellow or Red and trended information from the standalone device can be seen in the *Trend Window* in *Detail View*. Gray tab color indicates improper connection to standalone devices and will display a status message that indicates improper connection.




Chapter 7: MyView

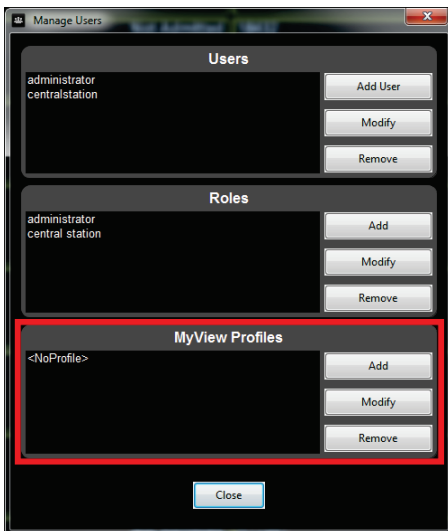
MyView allows clinicians to configure a preferred viewing profile in the Patient SafetyNet system. This MyView profile is then associated with a Masimo MyView Presence Tag, or other eligible Bluetooth device. When a device with MyView that is connected to Patient SafetyNet senses the presence of the Bluetooth enabled device, the device will then alter its display to conform to the MyView profile associated with the Bluetooth device. Devices with MyView can display any available parameters and up to 1 trend or waveform.

Compatible MyView devices:

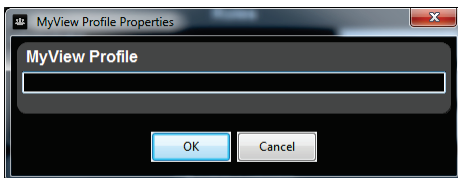
1. Radical-7 Touchscreen
2. Root
3. Patient SafetyNet View Station.

Add MyView Profiles


1. Select the *Users* icon  on the *Navigation* bar.
2. Select **Add** from the MyView Profiles section.

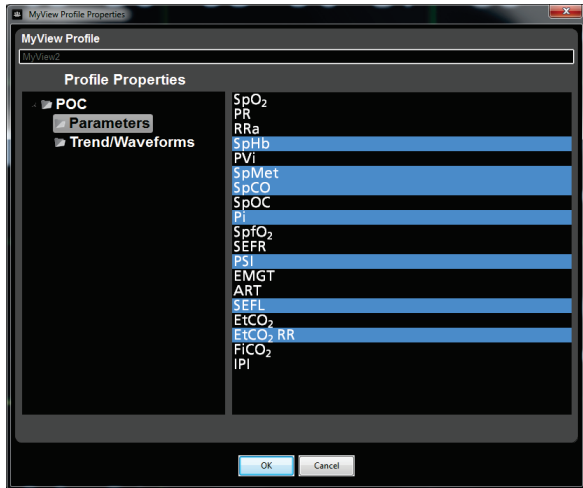


3. Enter the name of the MyView profile and select *OK* to create the new profile.




Modify MyView Profiles

1. Select the *Users* icon  on the *Navigation* bar.
2. Select the MyView profile you wish to edit from the list of the available profiles in the MyView Profiles section of the Manage Users window.
3. Select **Modify**.
4. To add parameters to the MyView profiles select the Parameters folder from the Profile Properties section in the MyView Profile Properties window.
5. Select the parameters to be associated with the MyView profile. Selecting a parameter highlights the parameter name, to de-select a parameter select the highlighted area a second time.



6. To add a trend or waveform to the MyView profile, select the Trend/Waveforms folder from the Profile Properties section.
7. Select 1 trend to be associated with the MyView profile. Selecting a trend highlights the trend name. To de-select a trend select the highlighted area a second time, or select another trend option.
8. When finished editing the MyView profile select *OK* to save the changes.

Remove My View Profiles

1. Select the *Users* icon  on the *Navigation* bar.
2. From the *MyView Profiles* list, highlight the desired MyView Profile and select the *Remove* button.
3. Confirm you wish to remove the MyView Profile by selecting *Yes* in the pop-up window.

Chapter 8: Interfaces

Masimo offers a variety of connectivity options enabling the transmission of patient data to and from hospital systems, devices and notification gateways. By implementing one of the connectivity options, a device can transmit patient vital signs to these systems and devices at defined time intervals. For example, the system can be an electronic medical record (EMR), and a device can be an Anesthesia machine.

HL7 Interface (Inbound)

The Patient SafetyNet HL7 Interface supports inbound communication of patient ADT using HL7 messaging on a configured socket. The HL7 ADT message allows Patient SafetyNet to receive patient ADT information and make the information available to clinicians in order to admit a patient to the Patient SafetyNet system. The Patient SafetyNet admission process is an internal process to associate a connected Instrument to a patient.

Deploying Patient SafetyNet HL7 ADT interface will facilitate the following:

- Facilitate Patient Admission: Clinicians can use the patient information provided by the interface to admit patient to Patient SafetyNet system see **ADT Patient Information Import** on page 67.
- Facilitate Vital Signs Reporting: Using patient information provided by the interface will facilitate vital signs reporting (outbound messages) to the EMR. Patient SafetyNet system will use patient information (e.g. Master Record Number) to report patient vital signs to the EMR and send alarms to the hospital alarm management system.

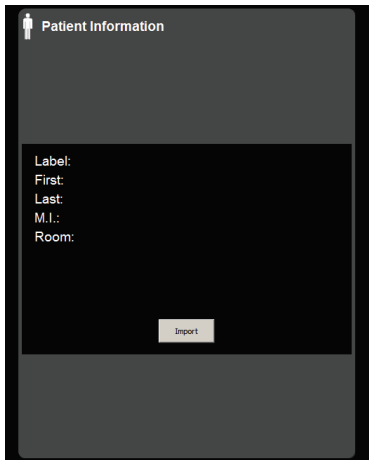
ADT Patient Information Import

To provide more insight into the Patient SafetyNet admission process and how Patient ADT information will be used, a step-by-step outline of the Patient SafetyNet admission process is shown below.

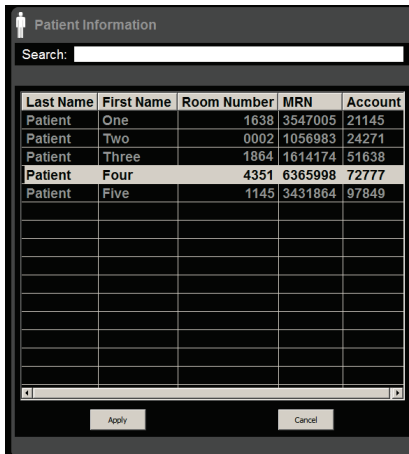
Select *Admit Patient* from the Main View

Next, the user presses the Patient Admit Button  to access the admission interface as shown below:

The user can access the list of patients in the appropriate units as received from the HL7 ADT message feed by pressing the Import button.



Select a patient and press Apply.



The screenshot shows a software window titled "Patient Information". At the top is a search bar labeled "Search:". Below it is a table with the following columns: Last Name, First Name, Room Number, MRN, and Account. The table contains five rows of patient data. At the bottom of the window are two buttons: "Apply" and "Cancel".

| Last Name | First Name | Room Number | MRN | Account |
|-----------|------------|-------------|---------|---------|
| Patient | One | 1638 | 3547005 | 21145 |
| Patient | Two | 0002 | 1056983 | 24271 |
| Patient | Three | 1864 | 1614174 | 51638 |
| Patient | Four | 4351 | 6365998 | 72777 |
| Patient | Five | 1145 | 3431864 | 97849 |

Patient information will be automatically populated.

Note: Fields are configurable and will vary. Optional fields include but are not limited to First Name, Last Name, Master Record Number (MRN), Room Number, Account, etc.

HL7 Interface (Outbound)

The Patient SafetyNet HL7 Interface supports outbound communication of patient vitals using HL7 messaging on a configured socket. Once the patient is associated to a point of care device, the Patient SafetyNet HL7 interface will start sending the patient vitals to the hospital EMR system.

Notification Interface

An advantage of Masimo connectivity options is the remote delivery and receipt of clinical and non-clinical alarm events that may occur during patient monitoring that is communicated through a notification gateway. Notification gateways can then deliver the alarm data to clinician notification devices such as pagers, IP Notification devices, or mobile devices. TAP, Cisco, and HL7 are examples of notification gateways.

TAP

Patient SafetyNet supports the transmission of notification messages in TAP version 1.6 or 1.8.

Cisco

Patient SafetyNet supports the transmission of notification messages to Cisco Call Manager version 7 or later.


Note: Cisco Notification is not supported for Patient SafetyNet software revision V55xx.

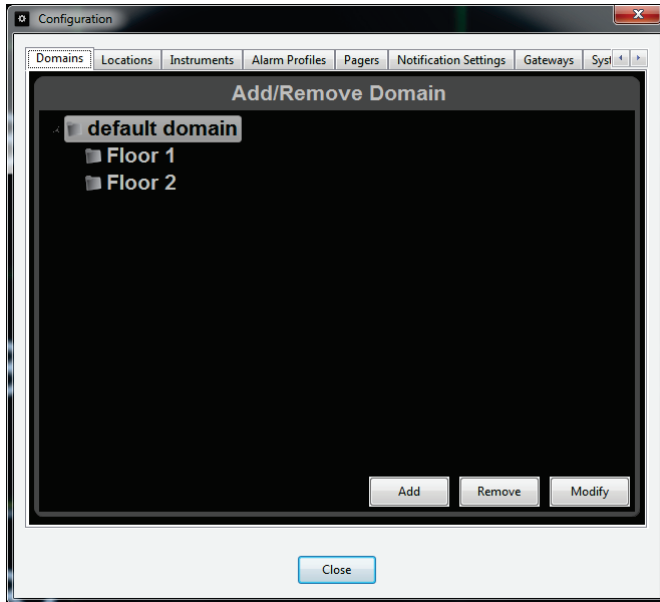
HL7

Patient SafetyNet supports the transmission of alarm messages in HL7 version 2.X. When this option is configured, Patient SafetyNet will send all alarms to the hospital alarm management system.

Chapter 9: System Administration

Configuration

Use the Configuration function to manage the Domains and Devices for the system. Select the *Configuration* icon  on the *Navigation* bar to open the *Configuration Window*. Select the different tabs at the top of the *Configuration Window* to access settings. The Domains tab is displayed by default when the *Configuration Window* is opened.




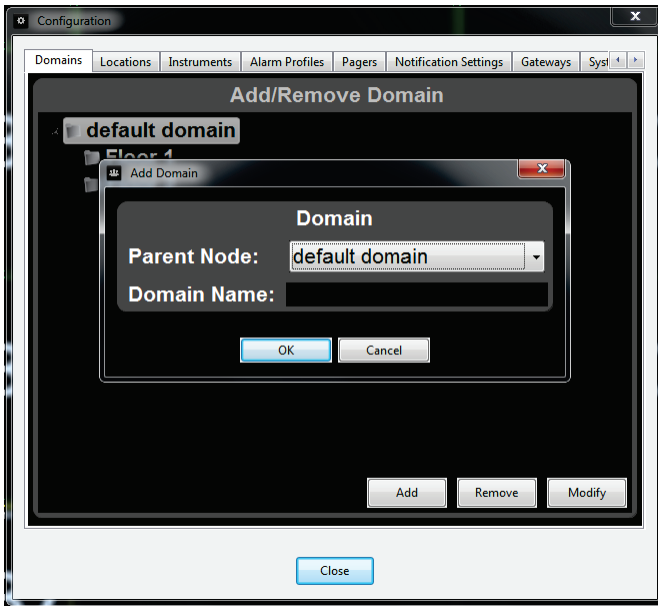
Domains

Domains provide the functionality to organize devices into groups. Once Domains are created, devices are then assigned to a Domain. Based on the Domain selection, Patient SafetyNet will display specific devices assigned to that Domain. This is useful when Clinicians wish to focus specifically on the devices in their care area.

When new Users are created, the System Administrator determines which Domains the User has the ability to view in working with the Patient SafetyNet System.


Add Domain

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Domain* tab.
3. Under Add/Remove Domain, select on an existing Domain that you wish to have the new Domain fall under.
4. Select *Add*.



5. The Parent Node automatically displays the selection from Step #3. To change, make a selection from the drop down list.
6. In the text field, enter the *Domain Name*.
7. Select *OK* and the new domain is added.


Modify Domain

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Domain* tab.
3. From within the Domain tree, select an existing Domain and Select *Modify*.
4. Edit the Parent Node and/or Domain Name.
5. Select *OK* to save the changes.

Remove Domain

Note: When a domain has additional domains listed below it, those will be removed also.


Note: Domains cannot be removed if devices are assigned. All devices must be removed before a domain can be removed.

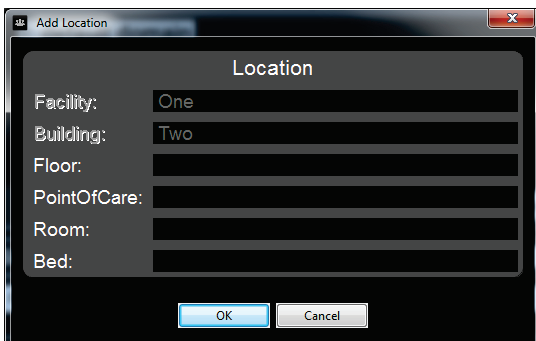
1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Domain* tab.
3. Under *Add/Remove Domain*, highlight the desired domain and select *Remove*.
4. Confirm the domain removal by selecting *Yes* in the pop-up window.

Locations

Location can be used to define a point of care device physical location. The device and its physical location can be used by the HL7 interface when the device is without an actual patient association. See *HL7 Interface (Inbound)* on page 67.

Add Location

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Locations* tab.
3. Select a domain and select the *Add*.
4. Enter desired fields and select *OK*.



The screenshot shows a dialog box titled "Add Location". Inside the dialog, there is a section titled "Location" with five text input fields. The first field, labeled "Facility:", contains the text "One". The second field, labeled "Building:", contains the text "Two". The other three fields, labeled "Floor:", "PointOfCare:", and "Room:", are empty. Below the input fields, there is a "Bed:" label followed by an empty input field. At the bottom of the dialog, there are two buttons: "OK" and "Cancel".

Note: Creating a location is optional.

Note: Only *PointOfCare* and *Room* fields are required if a location is created.

Note: Locations cannot have the same *PointOfCare*, *Room*, or *Bed*, the location needs to have a unique identifier(s).

| Field | Definition |
|-------------|--|
| Facility* | Highest level physical designation of an institution, medical center or enterprise. |
| Building* | Building where the person is located. |
| Floor | Floor where the patient is located. |
| PointOfCare | Where patient care is administered. It is related Person Location Type (e.g., nursing unit or department or clinic). |
| Room | The patient's room. |
| Bed | Patient's bed. |

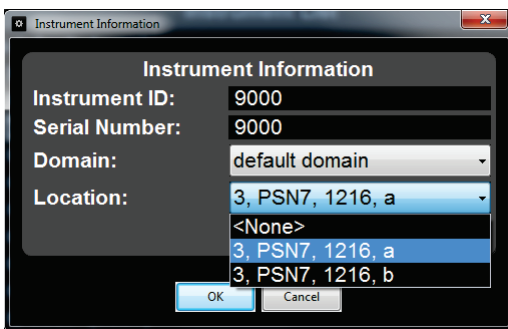
* This field is determined during Patient SafetyNet installation and is not user configurable.

To Add Location to an Instrument.

Note: Assigning a location to an instrument is optional.


Note: To assign a location to an instrument a location must be added from the *Locations* tab.

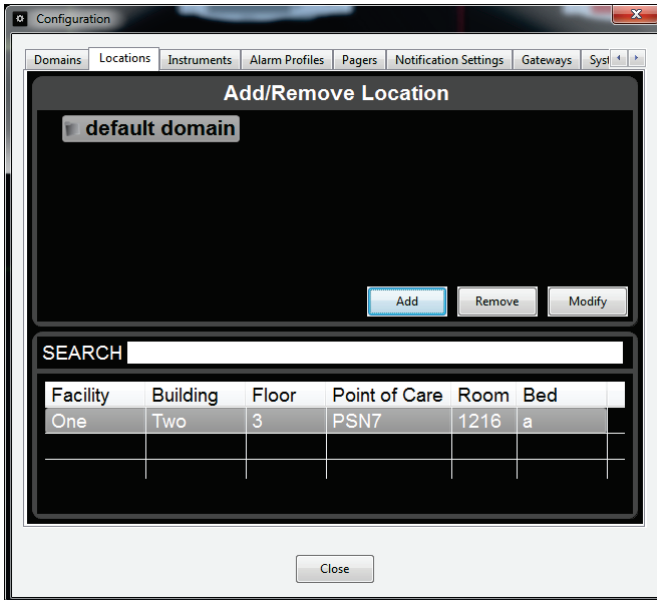
1. Select the *Instruments* tab.
2. Select a domain then select the *Add*.
3. Enter the *Instrument ID* and *Serial Number*.
4. Select a location from the Location drop down menu.
5. Select *OK* to add the instrument with a location.



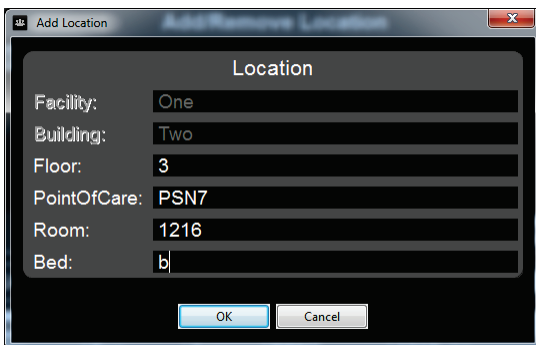
Modify Location

To Modify Location from *Locations Tab*

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Locations* tab.
3. Select an existing location from the list at the bottom of the window and select *Modify*.



4. Enter desired fields.




5. Select *OK* to save the modified location.

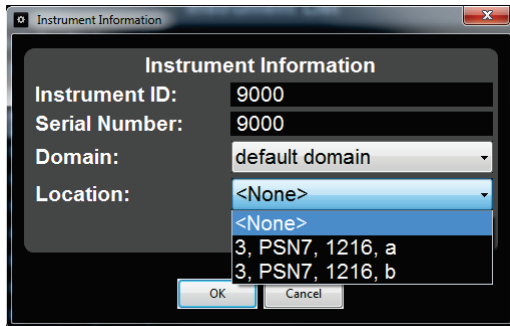
Note: Only *PointOfCare* and *Room* fields are required.

Note: Locations cannot have the same *PointOfCare*, *Room*, or *Bed*.

To Modify Location of an Instrument.

Note: Assigning a location to an instrument is optional.


1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Instruments* tab.
3. Select an instrument and select *Modify*.
4. Select a location from the Location drop down menu. *None* can be selected to remove location from instrument.



5. Select *OK* to save the changes.

Remove Location


Note: A location cannot be removed if it is assigned to an instrument.

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Locations* tab.
3. Under *Locations*, highlight the desired location and select *Remove*.
4. Confirm the location removal by selecting *Yes* in the pop-up window.

Instruments

Add Instrument


Note: The instrument ID only allows the entry of English characters and numbers.

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Instruments* tab.
3. Under *Instruments*, select the Domain for the instrument. A Domain supports a maximum of 40 instruments.
4. Select the *Add* button.

5. Enter the Instrument ID and Serial Number.

6. Confirm the Domain selection. To change, make a selection from the drop down list.
7. Select a location from the Location drop down menu.
Note: Assigning a location to an instrument is optional.
Note: To assign a location to an instrument a location must be added from the *Locations* tab.
8. Select *OK* and the instrument is added.


Modify Instrument

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Instruments* tab.
3. Select an existing instrument to modify from the *Instrument* list.
4. Select the *Modify* button.

5. Edit the instrument ID or serial number.
6. Confirm the *Domain* and *Location* selections. To change, make a selection from the drop down list.
7. Select *OK* to save the changes.

Remove Instrument

Note: Instruments cannot be removed if a patient is assigned to it.

1. Select  on the *Navigation* bar.
2. Select the *Instruments* tab.
3. Under *Instruments*, highlight the desired profile and select *Remove*.
4. Confirm the instrument removal by selecting *Yes* in the pop-up window.

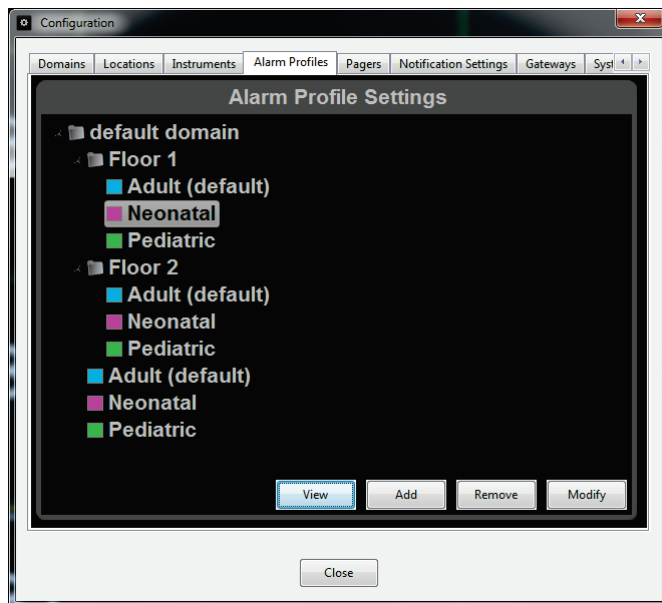
Alarm Profile Configuration

Profiles Overview

An alarm profile is a pre-configured set of alarm limits for all parameters that can be applied to a device in lieu of manually setting limits for each individual parameter. An Alarm Profile can be used to ensure that a pre-determined set of alarm limits are applied to the device. Multiple profiles can be configured for each domain. Alarm Profiles are identified by both a name and a color. An Alarm Profile can either be applied to the device during the process of admitting a patient, or any other time a device is connected to Patient SafetyNet.

The Patient SafetyNet contains three pre-determined alarm profiles located within **each** domain, which lets the user customize different settings for different patient populations.

- **Adult (default)**
- **Pediatric**
- **Neonatal**




These alarm profiles are shipped with the Patient SafetyNet system. These alarm profiles match the default profiles shipped with the Masimo point of care device. For complete information pertaining to these alarm profiles, including limits and settings, refer to the Operator's Manual for the device.

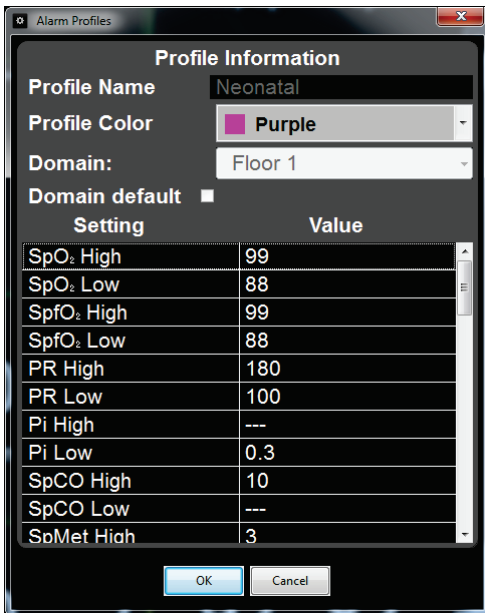
When a new domain is created, the three (3) pre-determined alarm profiles automatically appear. The parameter settings for these pre-determined profiles are copied from the pre-determined profiles in the root domain. *Adult* is the default profile for all domains.

Up to eight (8) additional custom alarm profiles can be created. See **Creating an Alarm Profile** on page 78.

Note: The three (3) pre-determined alarm profiles cannot be removed, only the custom profiles can be removed.


View Profile

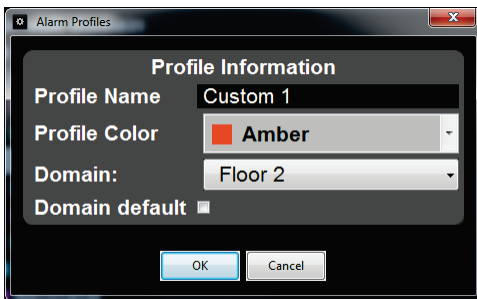
1. To view an existing profile, select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Alarm Profiles* tab.
3. Select the desired profile and select *View*.
4. The selected profile values will be displayed, but cannot be modified.



Creating an Alarm Profile

When creating a new profile, the settings from that domain's default profile are used by default, and can be modified as needed.

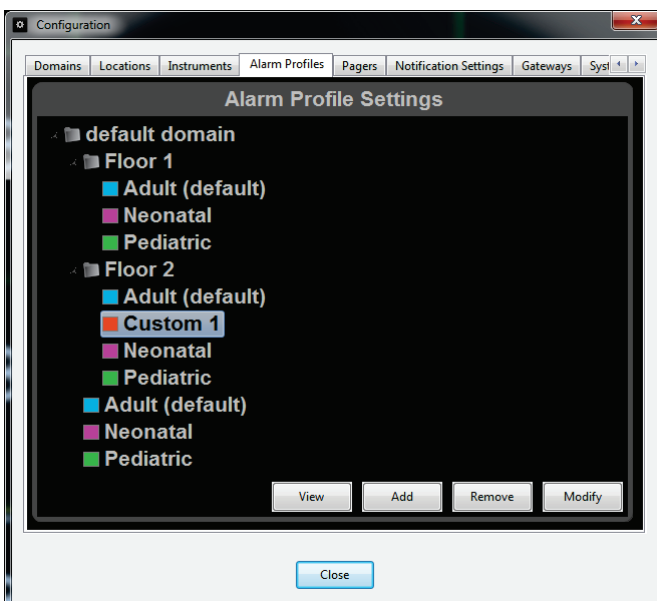
1. Select the *Configuration* icon  on the *Navigation* bar.
2. On the Configuration screen, select on the *Alarm Profiles* tab. *Adult* is the default profile for all domains.
3. To create a new profile for the top level domain:
 - Select the domain to place the new profile within.
 - Select the *Add* button.
4. Select *Yes* to create the default alarm profile. Enter the following:
 - Enter a Profile Name.
 - Select a Profile color.
 - Select a Domain.
 - If this is to be the default domain, select the Domain Default box.
 - Select *OK*.



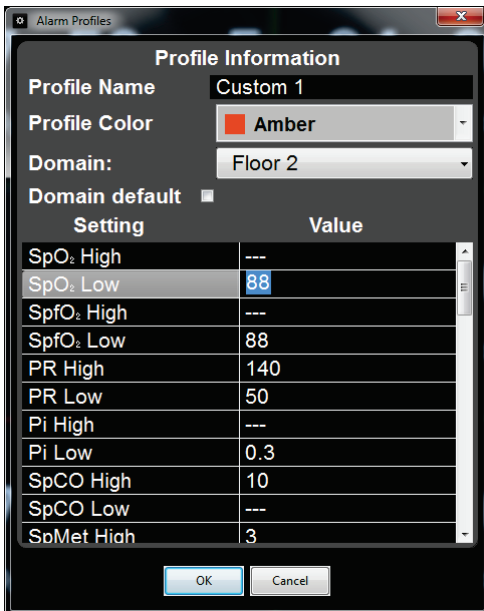
Note: The profile name must be unique.

Note: Each profile color can only be assigned to one profile.

5. The new profile will be displayed under the domain.



6. To set the alarm setting values for the new profile, select the profile and click the *Modify* button.
7. Enter the Alarm Setting Values for every field.




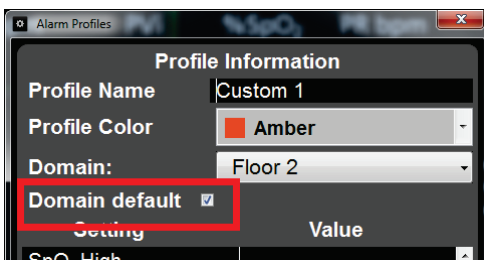
8. If this is to be the default profile for this domain, insure the *Domain default* box is checked. Every field under *Value* must be entered, even if it is not applicable to the monitor being used.
9. Once all values are entered, select *OK* and the new profile is added.

Change Default Profile

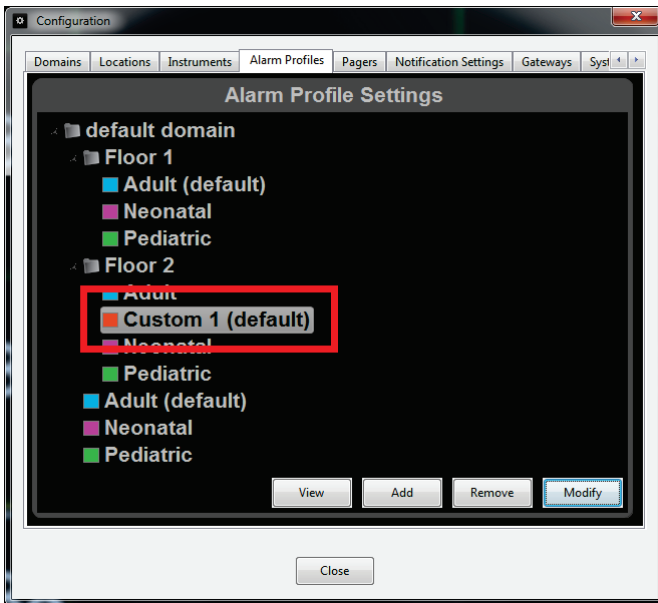
Note: *Adult* is the default profile for all domains.

Note: When a patient is discharged, the profile defaults back to *Adult* for the next patient.


1. Select the *Configuration* icon  on the *Navigation* bar.
2. On the Configuration screen, select on the *Alarm Profiles* tab.
3. Highlight the desired profile and select *Modify*.
4. If this is to be the default profile, insure the *Domain default* box is checked.

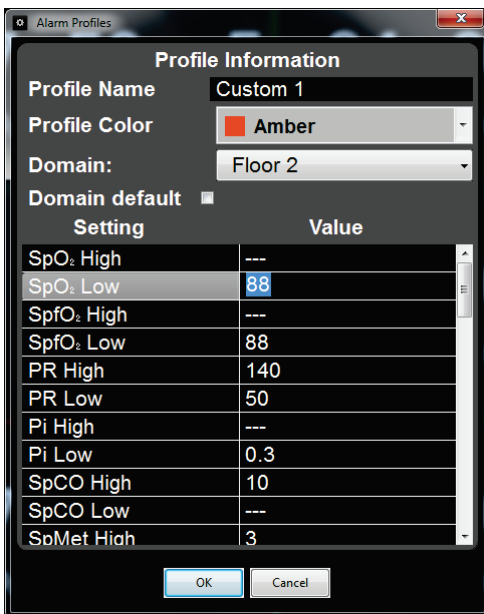


5. Select *OK* to change the default profile.
6. The new default profile will be indicated on the *Alarm Profiles* screen.



Modify Profile


1. Select the *Configuration* icon  on the *Navigation* bar.
2. On the Configuration screen, select on the *Alarm Profiles* tab.
3. Highlight the desired profile and select *Modify*.



4. From this screen, change the *Alarm Setting Values* as necessary.
5. If this is to be the default profile for this domain, insure the *Domain default* box is checked. Note that every field under *Value* must be entered, even if it is not applicable to the monitor being used.
6. Select *OK* to save the changes.


Remove Profile

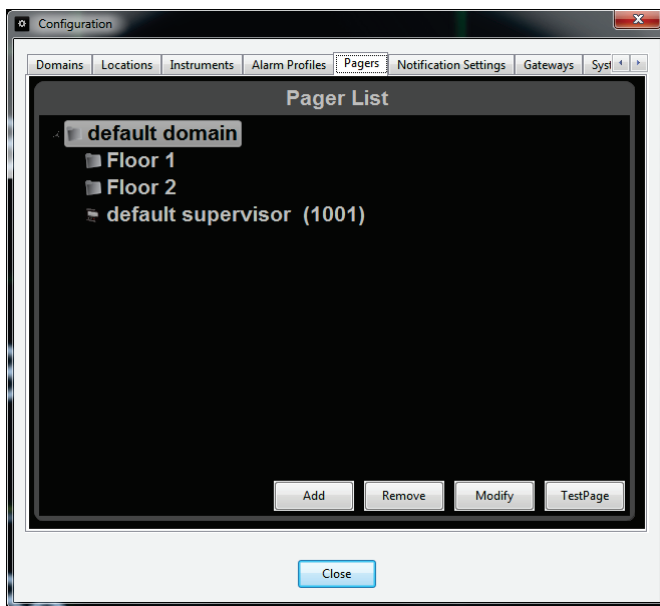
Note: The three (3) pre-determined alarm profiles cannot be removed.

1. To delete a custom profile, select the *Configuration* icon  on the *Navigation* bar.
2. On the Configuration screen, select on the *Alarm Profiles* tab.
3. Under *Alarm Profiles*, highlight the desired profile and select *Remove*.
4. Confirm you wish to remove the profile by selecting *Yes* in the pop-up window.

Pagers

Add Pagers

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Pagers* tab.
3. Under *Pager list*, select the *Domain* for the *Pager*.




4. Select the *Add* button.

5. Insert the Pager Name and Cap Code.


6. Confirm the Domain selection. To change, make a selection from the drop down list.
7. If this is a supervisor pager, select the *Supervisory* box.
8. Confirm the Gateway selection. To change, make a selection from the drop down list.
9. Enter the *Pager Username*, *Password* and *Password* again to confirm.
10. Select *OK* and the pager is added.

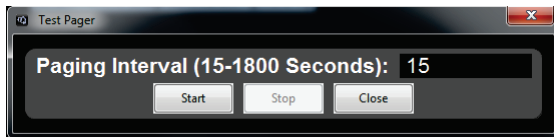
Modify Pagers

1. Select the *Configuration* icon  on the Navigation bar.
2. Select the *Pagers* tab.
3. Under *Pager* list, select the *Pager*.
4. Select the *Modify* button.

5. Edit the *Pager Name* or *Cap Code*.
6. Confirm the *Domain* selection. To change, make a selection from the drop down list.
7. Change any other information as required.
8. Select *OK* to save the changes.

Test Pagers


1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Pagers* tab.
3. Under *Pager List*, select the *Pager*.
4. Select the **Test Page** button.
5. Enter a *Paging Interval*.



6. Select **Start**. A test page will be sent to the *Pager*.
7. Once the test is complete, select **Stop** to end the test.
8. Select **Close** to return to the *Pager Configuration Window*.


Remove Pagers

A pager can **ONLY** be removed if it is not assigned to a patient or a device.

1. Select the *Configuration* icon  on the *Navigation* bar.
2. Select the *Pagers* tab.
3. Under *Pager list*, highlight the desired *Pager* and select *Remove*.
4. Confirm the pager removal by selecting *Yes* in the pop-up window.
5. If there no more *Pagers* to remove, select *Close* to return to *Detail View*.

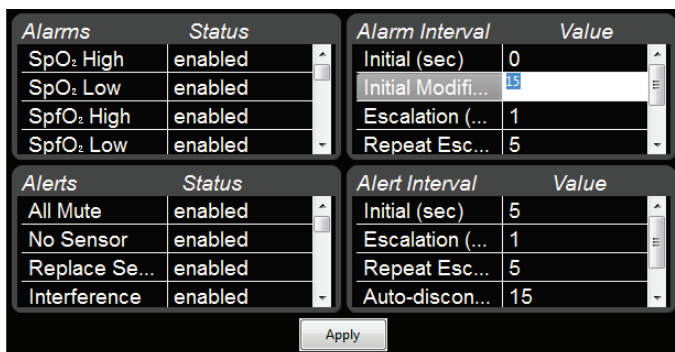
Notification Settings

Modify Notification Settings

1. Select the *Configuration* icon  on the Navigation bar.
2. Select the *Notification Settings* tab.
3. Under *Instrument*, select an instrument.



4. Click in the *Status* column and Enable or Disable the Alarm parameters and Alert messages.
5. Click in the *Alarm/Alert Interval Value* column and set the Escalation Intervals for the Alarms and Alerts based on hospital protocols.



6. Select *Apply* to save the changes.

Testing the Clinician Paging/Notification System


Note: It is critical to test the Clinician Notification System after any modifications to configuration, or software upgrades have occurred.

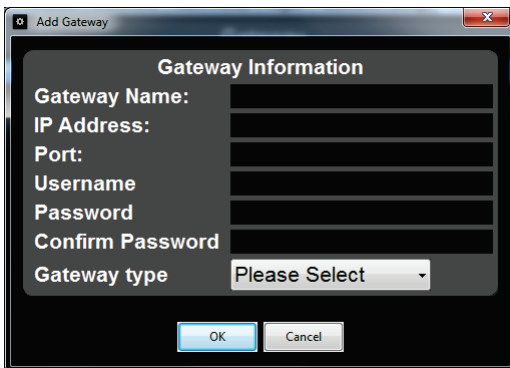
To verify the system is operating properly

1. Assign a Primary Respondent device to an installed instrument with connection to the Patient SafetyNet System.
2. Generate an alarm condition on the instrument.
3. Confirm that a notification is received on the Respondent device.

Gateways


Add Gateway

1. Select the *Configuration* icon  on the Navigation bar.
2. Select the Gateways tab.
3. Select the Add button.
4. Insert the Gateway Name, IP Address, Port, Username, Password, and the Password again to confirm.




5. Confirm the current Gateway Type or select a Gateway Type from the drop-down list.
6. Select OK. and the gateway is added.

Modify Gateway


1. Select the *Configuration* icon  on the Navigation bar.
2. Select the *Gateways* tab, highlight a desired gateway and select the *Modify* button.
3. Change the Gateway Name, IP Address, Port, Username, or Password.
4. Select a different Gateway Type from the drop down list.
5. Select *OK* to save the changes.

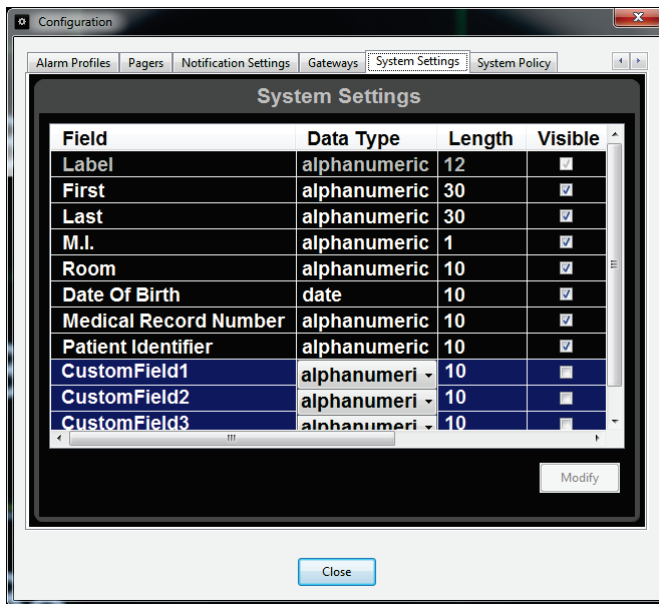
Remove Gateway

1. Select the *Configuration* icon  on the Navigation bar.
2. Select the *Gateway* tab.
3. Under the Gateway list, highlight the desired Gateway and select *Remove*.
4. Confirm you wish to remove the Gateway by selecting *Yes* in the pop-up window.

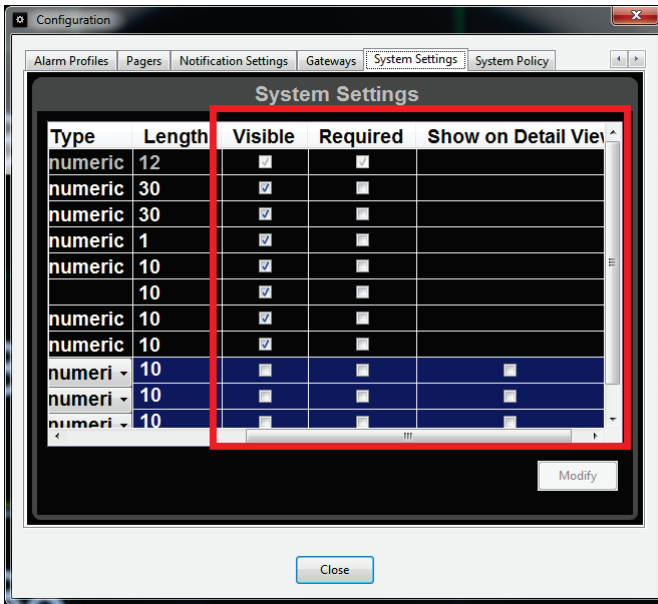
System Settings

Modify System Settings

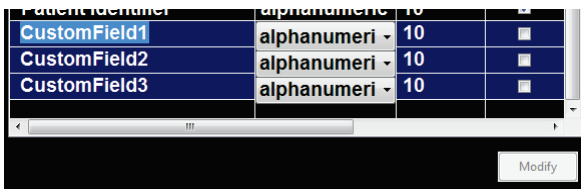
1. Select the *Configuration* icon  on the Navigation bar.
2. Select the *System Settings* tab.
3. The information fields displayed and/or required for patient admission can be customized. Scroll left or right to view all available settings.



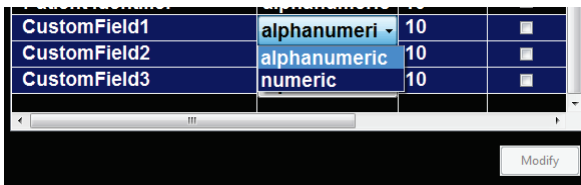
4. Check and uncheck the desired fields to be visible, present during patient admission, and/or required (mandatory) for patient admission.



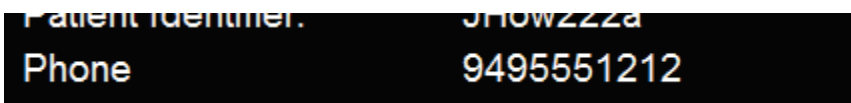
5. Patient SafetyNet provides three (3) custom fields that can be modified by the user. The *CustomField* label itself can be changed by selecting the text and typing in a new field label.



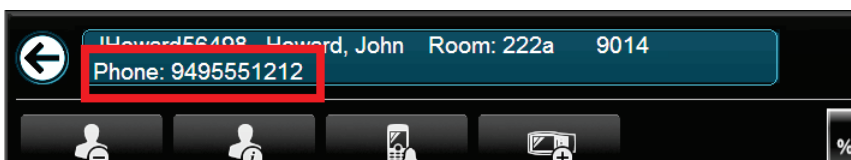
6. The *Data Type* can be selected as either alphanumeric or numeric. *Length* can be used to define how many characters the *Field* is limited to between 1 and 30 characters.



Note: For example, this field could be used to add a telephone number (Phone). This adds a field for the telephone number at the bottom of the patient admit screen.




7. By selecting the *Show on Detail View* checkbox, this information will display in the detail view on the main screen.

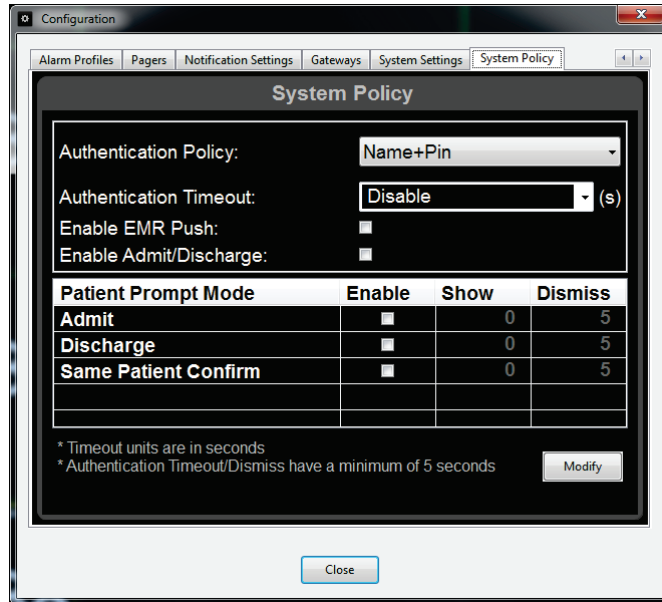


- When done, select *Modify* to save the changes.

System Policy

User Authentication Policy

- Select the *Configuration* icon  on the Navigation bar.
- Select the *System Policy* tab.



- The system administrator can configure the authentication level required for users to admit patients from applicable bedside devices (for more information see the Root Operator's Manual). The following settings can be modified:
 - Authentication Policy determines the level of credentials required for a user to access action on the device such as the patient admit and discharge feature from applicable bedside devices:
 - None: The device will not ask the user to authenticate.
 - Pin: The device will prompt the user to enter a PIN number to authenticate.
 - Name+Pin: The device will prompt the user to enter a username and PIN number to authenticate.
 - Name+Password: The device will prompt the user to enter a username and password to authenticate.
 - Authentication Timeout is a configured time that the system administrator can set to allow a user's authentication to remain valid, without interaction, before requiring the user to input their credentials again.:
 - Disable: The user will only need to authenticate (enter their credentials) once and the admit and discharge menu on the applicable device will remain open.
 - n** seconds: The length of time a user's authentication remains valid, where **n** is the number of seconds. After the specified number of seconds has elapsed the admit and discharge menu will close requiring the user to input their credentials again.
 - Enable EMR Push, if checked, allows for the EMR Push feature to be enabled and the icon to be displayed on the bottom of the applicable bedside devices Main screen.
 - Enable Admit/Discharge, if checked, allows for the Admit/Discharge feature to be enabled and the icon to be displayed on the bottom of the applicable bedside devices Main screen.
 - Patient Prompt Mode allows the administrator to configure messages which will display on applicable devices. All three messages can be enabled by checking the applicable check box or disabled by not checking. The Show input field specifies the number of seconds a device

will wait before displaying a particular prompt message. The Dismiss input field specifies the number of seconds a device will display a particular prompt message before removing the prompt. The prompt messages are as follows:

- Admit Message: This message will display when the device enters an active monitoring state and there is no patient admitted to the device currently. The message will display after the configured time specified in the Show input field, it will disappear after the configured time specified in the Dismiss input field.
- Discharge Message: This message will display when the device exits an active monitoring state and there is a patient admitted to the device currently. The message will display after the configured time specified in the Show input field, it will disappear after the configured time specified in the Dismiss input field.
- Same Patient Confirm Message: This message will display when the device exits an active monitoring state and there is a patient admitted to the device currently and the device then enters an active monitoring state. The message will display after the configured time specified in the Show input field, it will disappear after the configured time specified in the Dismiss input field.


4. When done, select *Modify* to save the changes.

User Management

User

Add User

Note: On systems with LDAP enabled, the on-site network administrator creates users and assigns domains the user can access. The user is also added to a group and is given a Group ID by the network administrator, that is used when adding or modifying roles for the user. Only the *Remove* function of the *Users* menu is available for LDAP enabled systems.

1. Select the *Users* icon  on the *Navigation* bar.
2. Select the *Add User* button.




3. Input the User Name, Password, and Pin (optional) into the text field. Confirm the Password and Pin (optional).

The 'Add User' dialog box is a vertical window with a dark background. It features several sections of controls. At the top, there are five text input fields labeled 'User Name', 'Password', 'Password Confirm', 'Pin', and 'Pin Confirm'. Below these is a 'User Role' dropdown menu. The 'Respondent Information' section includes a 'Respondent Label' text field and a 'Primary Domain' dropdown menu. The 'User Profile' section has a dropdown menu. The 'Badge' section contains a 'Hardware Address' text field. The 'Domain Allowed' section is a list box with 'default domain' selected. At the bottom, there are 'OK' and 'Cancel' buttons.

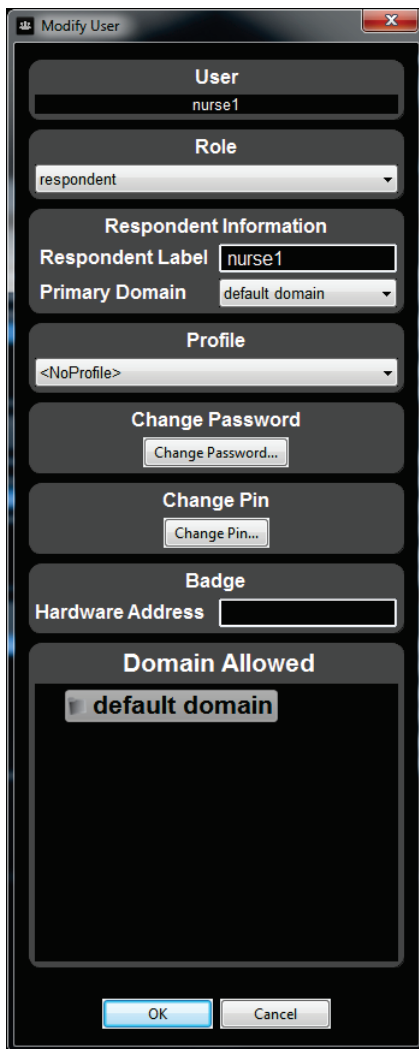
4. Assign a User Role if applicable from the drop down box.
5. Assign a Respondent Information if applicable.
Note: Respondent information can only be added to a user if the users role has respondent privileges.
6. Assign a User Profile if applicable from the drop down box.
7. Assign a Badge Hardware Address if applicable.
8. Select the domains the user can have access to.
9. Select *OK* and the new user is added.

The 'Manage Users' dialog box displays a list of users under the heading 'Users'. The list contains the following entries: 'administrator', 'centralstation', 'default administrator', and 'nurse1'. The 'nurse1' entry is highlighted with a red rectangular box. To the right of the list are three buttons: 'Add User', 'Modify', and 'Remove'.

Modify User

1. Select the *Users* icon  on the *Navigation* bar.
2. Select the *User* from the Users list.
Note: When a user is selected, the defined role for the user is highlighted in the *Role* section.
3. Select the *Modify* button.
4. Make changes to the Role, Profile, Respondent Information, Password, Pin, Badge Hardware Address, and/or assigned Domains.
Note: On LDAP enabled systems, neither the *Role* nor *Password* cannot be changed, as they are assigned by the on-site network administrator.
5. Select *OK* to save the changes.

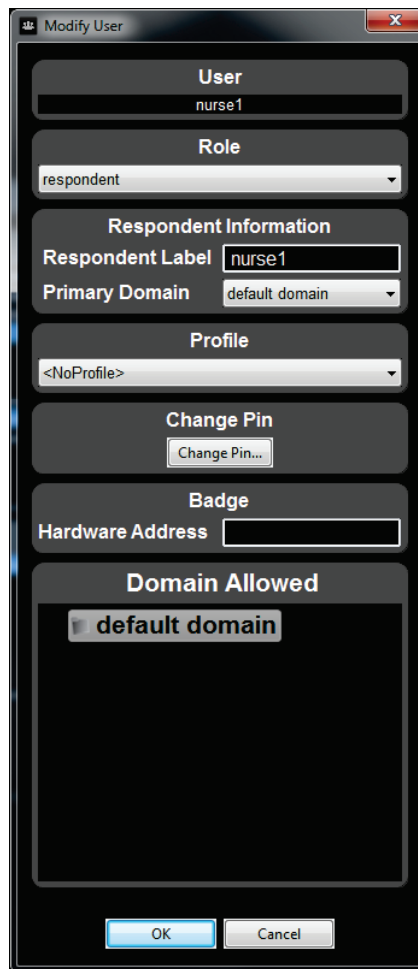
LDAP Disabled



The 'Modify User' dialog box for LDAP Disabled shows the following fields and options:

- User:** nurse1
- Role:** respondent
- Respondent Information:** Respondent Label: nurse1, Primary Domain: default domain
- Profile:** <NoProfile>
- Change Password:** Change Password...
- Change Pin:** Change Pin...
- Badge:** Hardware Address
- Domain Allowed:** default domain
- Buttons:** OK, Cancel


LDAP Enabled



The 'Modify User' dialog box for LDAP Enabled shows the following fields and options:

- User:** nurse1
- Role:** respondent
- Respondent Information:** Respondent Label: nurse1, Primary Domain: default domain
- Profile:** <NoProfile>
- Change Pin:** Change Pin...
- Badge:** Hardware Address
- Domain Allowed:** default domain
- Buttons:** OK, Cancel


Remove User

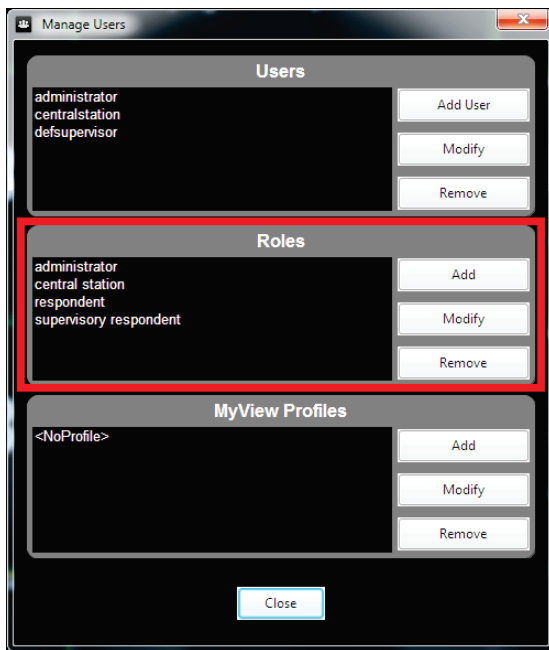
1. Select the *Users* icon  on the *Navigation* bar.
2. From the *Users* list, highlight the desired user and select the *Remove* button.
3. Confirm you wish to remove the User by selecting *Yes* in the pop-up window.

Role

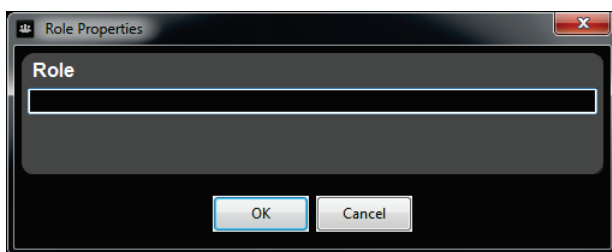
Add Role

The Patient SafetyNet System allows for the configuration of User Roles. Each Role created is assigned User *Privileges* that determine what functions the user may perform within the Patient SafetyNet System. Defining a Role is only required if the Role does not exist in the list.

1. Select the *Users* icon  on the *Navigation* bar.
2. Under Roles, select *Add* to access the Role Properties window.




3. Input the Role name.
Note: The roll name must be less than 12 characters and only letters can be used.

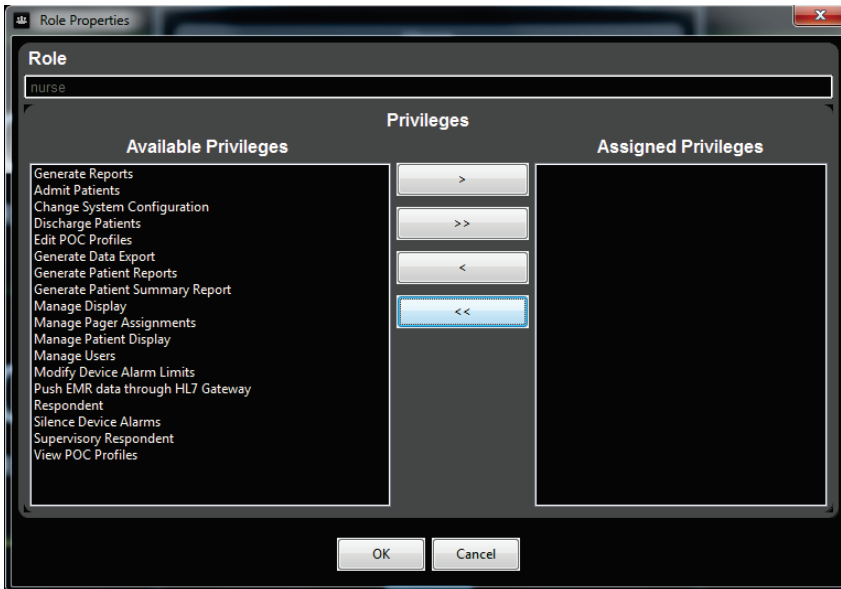


4. Select *OK*.
5. Once a new Role has been created, the *Privileges* must be added under *Modify Role*.

Modify Role

CAUTION: If a role is modified, it affects all users associated with that modified role. A new role may be considered depending on the desired purpose of the role modifications.

1. Select the *Users* icon  on the *Navigation* bar.
2. Select the *Role* from the Role list.
3. Select the *Modify* button.



Note: On systems with LDAP enabled, the LDAP Group Identifier is displayed below the *Role* field.

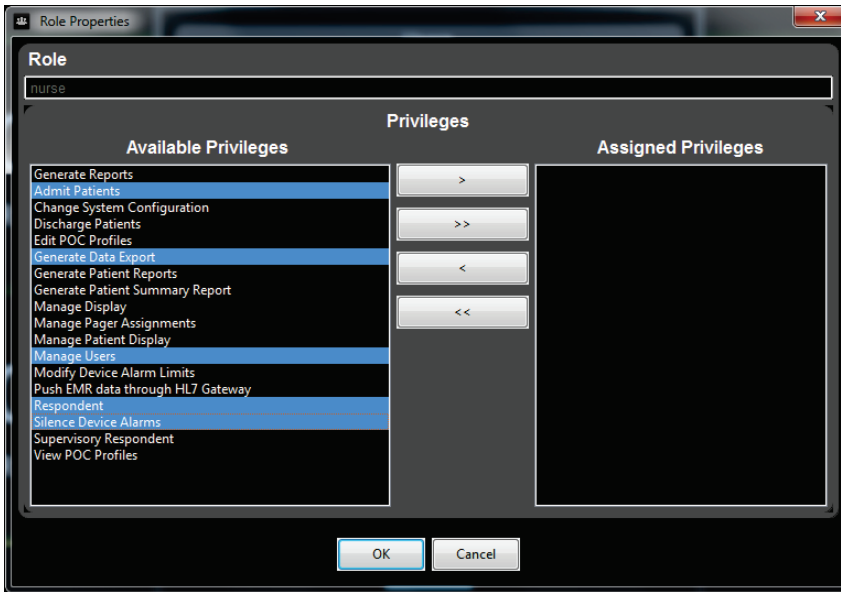



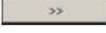
4. Privileges can be assigned or removed for the role. See **Assign Privileges** on page 94 or **Remove Privileges** on page 95.

Assign Privileges

1. Select the Role from the Roles list.
2. Select the *Modify* button.
3. Highlight the desired Privilege within the *Available Privileges* list.

Note: To select multiple items, hold the Ctrl key while selecting the items.

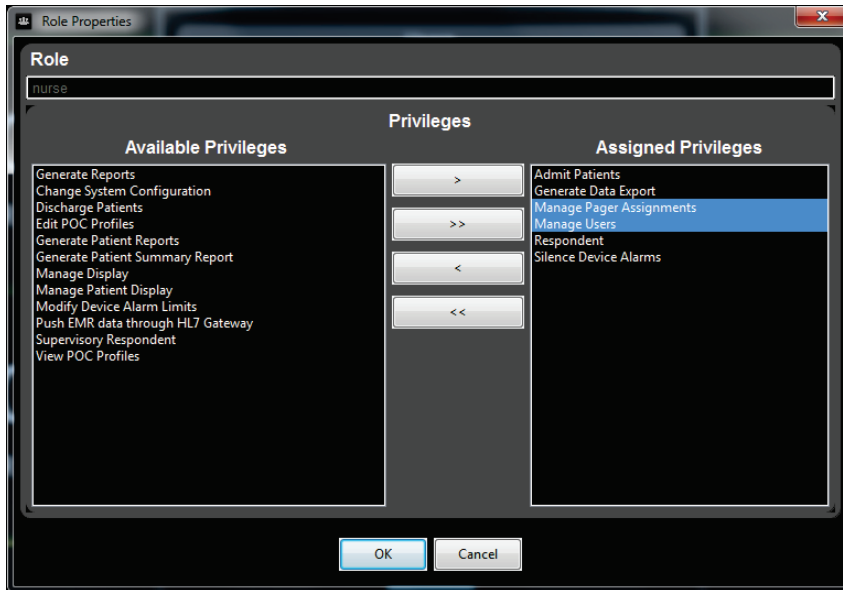


4. Select the single right arrow button  to assign the selected Privileges to the Role. To assign all available Privileges, select the double right arrow button .
5. Select OK to close the Role Properties.

Remove Privileges


1. Select the Role from the Roles list.
2. Select the *Modify* button
3. Highlight the desired Privilege within the *Assigned Privileges* list.

Note: To select multiple items, hold the Ctrl key while selecting the items.



4. Select the single left arrow button  to remove the Privilege from the Role. To remove all the Assigned Privileges, select the double left arrow button .
5. Select OK to set and close the Role Properties.

Remove Role

1. Select the *Users* icon  on the *Navigation* bar.
2. Verify that no current Users are assigned to this Role.
3. From the *Roles* list, highlight the desired role and select the *Remove* button.
4. Confirm you wish to remove the Role by selecting Yes in the pop-up window.

Pager Setup and Operation

The Pager is worn by the clinician to provide notification of Alarm or Alert events from the device connected to the Patient SafetyNet System. Users must be fully trained on the features and operation of the Pager to ensure they can receive, read and properly respond to Alarm and Alert pages. For functions not listed in this manual, please refer to the pager manufacturer's manual.

Pager Setup

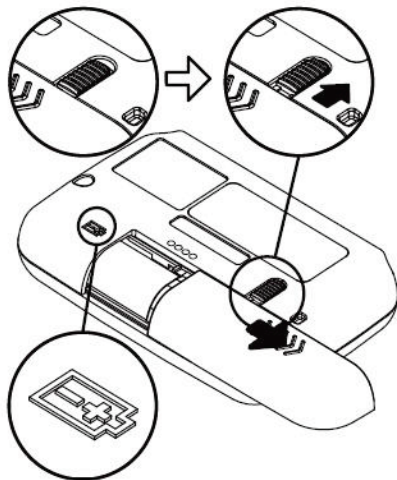
The Pager is configured to work on the same frequency with the Paging Transmitter. These settings are configured by Masimo personnel at the factory prior to shipment.

Battery Information

This Pager is designed to operate on one AA size alkaline battery (Do not use any other battery type other than AA alkaline). If the Pager main menu screen displays, "The Battery Level is low," replace the battery as described below. The correct time and any stored Messages will remain intact for up to one minute after removing the battery.

Note: Be sure to follow local regulations in regards to battery disposal.

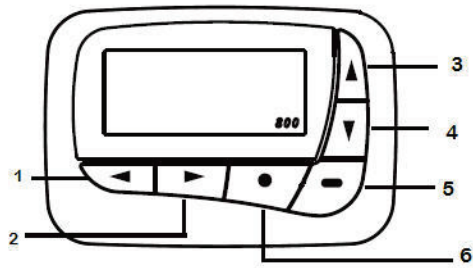
Battery Installation and Removal



- Place the Pager face down or in the palm of your hand.
- Unlock the battery door lock by sliding it to the unlocked position.
- Push the battery door and slide it out as shown.
- Place a new battery into the battery compartment.
- Ensure that the battery polarity is correct as indicated by the housing.


To close, slide the battery door back into position and lock it.

Button Definition








| | | |
|---|-----------------|---|
| 1 | Backward Button | navigate back |
| 2 | Forward Button | navigate forward |
| 3 | Up Button | navigate up |
| 4 | Down Button | navigate down/hold to quick access vibrate mode |
| 5 | Read/On Button | read messages/ hold to turn Pager on |
| 6 | Function Button | access the function menus |



Pager On

Press and hold  for 2 seconds to turn on the Pager.

Pager Off

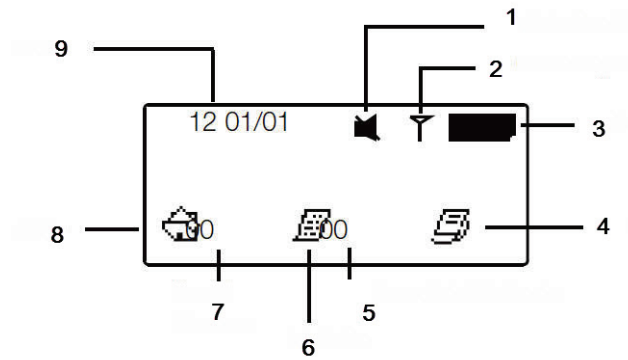
- Press  button once from the Main Menu screen to go to the Function Menu screen, then
- Press  button 5 times to select TURN OFF function.
- Press  button, *TURN OFF* is displayed.
- Press  button again to confirm turning your Pager off, or  button to cancel.

Backlight

- Press and hold  for 2 seconds to turn ON the backlight manually.
- Press and hold  for 2 seconds to turn OFF the backlight manually

Note: The pager should not be turned off while assigned to a device. Turning the pager off will result in missed pages to that pager.

Main Pager Menu Screen



| | |
|---|--------------------------|
| 1 | Status Icon Display |
| 2 | Out of Range Indicator |
| 3 | Battery Level Indicator |
| 4 | Saved Folder |
| 5 | Unread Info Slot Counter |
| 6 | Info Folder |
| 7 | Unread Messages |
| 8 | Inbox Folder |
| 9 | Time and Date |

The Pager returns to the Standby screen after the time-out period. Time, date and battery level indicators are displayed in the Standby screen. Press any button to return to the Main Menu Screen.





Receiving a Page

- When a page is received, it will be accompanied by a beep tone (and/or vibration) from the Pager. Press the button to acknowledge the page.
- The Pager has the ability to keep 40 pages on the Pager. When the number of pages has exceeded 40, the oldest read pages will be overwritten followed by the oldest unread pages.
- The information on the Pager will display the Patient Label, Alarm/Alert with Alarm Modifier (if present), applicable clinical value and Alarm Level.

Note: The pager supports English characters only. IF non-English characters were entered for the Patient Label when the patient was admitted, the device ID will be displayed on the pager.

Deleting a Page

From the main menu, with the *Inbox* selected, do the following

1. Press .
2. Press .
3. Press  twice.
4. Press  twice.

Low Battery Alert

When the battery is on low power, the Pager will emit an Alert every hour during the day (8 am to 8 pm).

Out of Range Alert

The Out of Range indicates that the Pager is not communicating with the Paging Transmitter. When this occurs, the  symbol appears on the Pager screen.

Patient SafetyNet Pages

The table below is an example of possible messages that may be displayed on the respondents pager.

| Alarm Parameter | Alert Parameter | Parameter Modifiers |
|---|--|---|
| Rainbow Channel <ul style="list-style-type: none"> • SpO₂ High • SpO₂ Low • SpfO₂ High • SpfO₂ Low • PR High • PR Low • SpHb High • SpHb Low • SpCO High • SpCO Low • SpMet High • SpMet Low • PVi High • PVi Low • Pi High • Pi Low • RRa High • RRa Low • RRp High* • RRp Low* • SpOC High • SpOC Low • ORI Low** • Desat Index | Rainbow Channel <ul style="list-style-type: none"> • No Sensor • Defective Sensor / Replace Sensor • Interference • Sensor Off • Ambient Light • Unrecognized Sensor • Check Sensor • Incompatible Sensor • No Cable Connected • Incompatible Cable • Unrecognized Cable • Replace Cable / Defective Cable • Emitter Temp Out of Range • Sensor Current Limit Exceeded • No Adhesive • Invalid Adhesive • Defective Adhesive • All Mute • Replace Reusable • No Acoustic Sensor Connected • Defective Acoustic Sensor • Acoustic Sensor Off Patient • Bad Acoustic Sensor Placement | <ul style="list-style-type: none"> • Low Signal IQ • Low Perfusion • Low PR SIQ • SpHb Low Confidence • SpCO Low Confidence • SpMet Low Confidence • Low Pi SIQ • Low PVi SIQ • Low SpOC SIQ • Low RR Confidence • Low RR Signal Strength • Patient Interference • Background Interference |

| Alarm Parameter | Alert Parameter | Parameter Modifiers |
|--|---|---------------------|
| <ul style="list-style-type: none"> • Pi Delta • Respiratory Pause • Low Battery | <ul style="list-style-type: none"> • Unrecognized Acoustic Sensor • Incompatible Acoustic Sensor • No Acoustic Cable Connected • Incompatible Acoustic Cable • Unrecognized Acoustic Cable • Defective Acoustic Cable • No Resp Detected | |
| <p>Capnography Channel</p> <ul style="list-style-type: none"> • EtCO₂ High • EtCO₂ Low • FiCO₂ High • FiCO₂ Low • EtCO₂ RR High • EtCO₂ RR Low • SedLine Channel • PSI High • PSI Low | <p>Capnography Channel</p> <ul style="list-style-type: none"> • Sensor Error • Sampling Line Clogged • No Breath Detected • No Sampling Line • Replace O₂ Sensor • O₂ Port Failure • EtCO₂ Accuracy Error • FiCO₂ Accuracy Error • O₂ Calibration Required • Temperature Out of Range • Ambient Pressure Out of Range • Zeroing Required • Capnography Disconnected | |
| <p>System</p> <ul style="list-style-type: none"> • System Down • Key Lock Auth Failure | <p>SedLine Channel</p> <ul style="list-style-type: none"> • Impedance Value Indeterminate • High Impedance Detected • Gel Bridging Detected • Improper Sensor Connection Patient Wait • Replace Sensor – 24 Hr • SedLine Disconnected | |

* RRp is currently not available in the U.S.A. and territories relying on FDA market clearance.

** ORi is currently not available in the U.S.A. and territories relying on FDA market clearance.

Mobile Device Setup and Operation

The mobile device with the Masimo Replica application installed is worn by the clinician to provide parameter viewing and notification of Alarm or Alert events from the connected Patient SafetyNet System. Users must be fully trained on the features and operation of the Masimo Replica application to ensure they can receive, read and properly respond to Alarm and Alert pages. Please refer to **Operator's Manual for Replica** for complete operating instructions.

Chapter 10: Specifications

Note: Use only components and accessories approved by Masimo. The use of non-approved parts may produce unreliable system operation.

Clinician Assignment Station PC

| | |
|-------------------------|--------------------------------|
| CPU | minimum 500 MHz |
| Memory | minimum 512 MB RAM |
| Storage | minimum 5 GB HDD |
| Operating System | Windows 7 |
| External Drive | CD-ROM or DVD-ROM |
| Input/Output Connection | Ethernet 10/100 Base T |
| AC Power | 110 - 240 VAC 50/60 Hz |
| Accessories | Keyboard/Mouse |
| Monitor | 19" Flat Panel TFT LCD Monitor |
| Video card with OpenGL | minimum NVidia GeForce 210 |

Touchscreen Clinician Assignment Station

| | |
|------------------------------------|---|
| CPU | Intel Core 2 Duo Processor |
| Memory | 4 GB |
| Storage | 250 GB |
| Operating System | Windows 7 Professional Edition |
| Audio | High Definition Audio 2.0 |
| Speakers | Built-in |
| AC Power | 100 – 240 V, 50/60 Hz, 2.0A |
| Screen Size | 23" |
| Networking | 10/100/1000 BaseT network interface 802.11b/g Up to 300 mbps data rate Bluetooth v2.1 compliant (optional) Wireless LAN with built-in WLAN antenna |
| Physical Dimensions (H x W x D) | 17.6 x 22.8 x 2.8 in (44.7 x 57.9 x 7.2 cm) |
| Weight (approximate) | 25.4 lbs (11.5 kg) |
| Video card with OpenGL | minimum NVidia GeForce 210 |

Patient SafetyNet Appliance

| | |
|----------------------------------|---|
| CPU | minimum Quad-Core Intel Xeon 2.0 GHz |
| Memory | minimum 4 GB RAM |
| Storage | minimum 1 TB RAID 1 storage array |
| Management | Remote access capable |
| Operating System | Linux |
| Input/Output Connection | Redundant Gigabit 10/100/1000 BaseT Ethernet NICs |
| AC Power: | Redundant power supplies (110 - 240 VAC, 50/60 Hz) |
| Operating Temperature | 10°C to 35°C (50°F to 95°F) |
| Storage Temperature | -30°C to 60°C (-22°F to 140°F) |
| Operating Humidity | 10% to 90% Relative Humidity |
| Storage Humidity | 5% to 90% Relative Humidity |
| Physical Dimensions (H x W x D): | 3.44 x 17.64 x 27.50 in (8.75 x 44.80 x 69.88 cm) |
| Weight (approximate): | 51.5 lbs (23.36 kg) |

Bedside Radio

| | |
|---|--|
| Radio Standards | IEEE 802.11a/b/g TX Max Radiated EIRP FCC Part 15 |
| Frequency Characteristics of Modulation | DSSS, OFDM |
| Encryption | WEP, TKIP, and AES |
| Authentication | Pre-Shared Key (PSK), EAP (TTL, PEAP, and TLS); Mutual Authentication and Anonymous Outer Identity supported |
| Support Data Rates | 1, 2, 5.5, 6, 9, 11, 12, 18, 24, 36, 48, 54, and MCS Rates 0-7 |
| AC Power | 110 - 240 VAC, 50/60 Hz |
| Temperature, Operating | 32 - 104 degrees F (0 - 40 degrees C) |
| Dimensions (L x W x H) | 6.5 x 3.3 x 1.2 in (16.5 x 8.5 x 3.0 cm) |

Paging Transmitter

| | |
|---|--|
| Frequency | UHF 440 - 470 MHz |
| Radio Standards (RF Type) | POCSAG Protocol FCC Part 15 |
| Network Connection | Ethernet (RJ-45) |
| Frequency Characteristics of Modulation | FSK |
| Transmit Power | 0.5, 2, and 5W |
| Data Throughput | 512 to 1900 Baud |
| Data Integrity: | Messages digitally encoded with checksum |
| AC Power | 110 - 240 VAC, 50/60 Hz |
| Temperature, Operating | 32 - 122 degrees F (0 - 50 degrees C) |
| Dimensions (L x W x H) | 10 x 8 x 2.7 in (255 x 230 x 70 mm) |
| Weight: | 1.5 lbs (0.7 kg) |


Pager


| | |
|------------------------|---|
| Display Type | LCD |
| Display Information | Origin & type of alarm, SpO ₂ and Pulse Rate, Level of alarm |
| Battery Power | One AA Alkaline Battery |
| Alarm Feature: | Tone and vibrate |
| Maximum Pagers/System | 40 |
| Dimensions (L x W x H) | 3.2 x 2.1 x .75 in (80 x 54 x 19 mm) |
| Weight (with battery) | 2.3 oz (65 g) |

Mobile Device

| Item | Specification |
|------------------|---------------------------------|
| Operating System | Android 5.0 (Lollipop) or above |

Troubleshooting

| Issue | Resolution |
|--|--|
| Patient SafetyNet View: Hardware Authentication Failure | <p>The Patient SafetyNet USB Security Key is not inserted into the Patient SafetyNet Appliance</p> <ul style="list-style-type: none"> • Confirm the Patient SafetyNet USB Security Key is inserted into the Patient SafetyNet Appliance • Contact Masimo Technical Services |
| Patient SafetyNet View: System Down | <p>Time allowed for Patient SafetyNet to run <i>without</i> the Patient SafetyNet Security Key has expired</p> <ul style="list-style-type: none"> • Confirm the Patient SafetyNet USB Security Key is inserted into the Patient SafetyNet Appliance • Contact Masimo Technical Services |
| Patient SafetyNet View: Server Link Down | <p>Loss of communication to the Patient SafetyNet Appliance</p> <ul style="list-style-type: none"> • Confirm Appliance has power, booted up and is working properly • Confirm connection to the network switch • Confirm network switch has power and is working properly • Confirm Ethernet cables are connected and working properly • Contact BioMed • Contact Masimo Technical Services |
| Patient SafetyNet View: Paging Link Down (Clinician Paging System) | <p>Connection is lost to the Paging Transmitter</p> <ul style="list-style-type: none"> • Confirm the Paging Transmitter has power and is working properly • Ensure that the paging transmitter is connected to network switch • Confirm network switch has power and is working properly • Confirm Ethernet cables are connected and working properly • Contact BioMed • Contact Masimo Technical Services |
| Patient SafetyNet View: Link to All Devices / AP / Network Down | <p>No devices connected to system</p> <ul style="list-style-type: none"> • Confirm that there is at least one connected bedside device • Confirm the Access Point(s) have power and functioning properly • Confirm Access Point connection to the network switch • Confirm network switch has power and is working properly • Confirm Ethernet cables are connected and working properly • Confirm power connected to wireless radios • Contact BioMed |
| Patient SafetyNet Pager: <i>No Comm</i> message (Clinician Paging System) | <p>Bedside device has lost communication with the Patient SafetyNet System. The <i>No Comm</i> page will include a label to identify a bedside device.</p> <ul style="list-style-type: none"> • Confirm the bedside device has power and is functioning properly • Confirm Radical Handheld is properly connected to Docking Station (If applicable) • Confirm that there is power to the Bedside Radio and it is working properly • Confirm that the serial cable from the bedside device to the bedside radio is securely connected • Confirm Access Point(s) connection to the network switch • Confirm network switch has power and is working properly • Confirm Ethernet cables are connected and working properly • Contact BioMed • Contact Masimo Technical Services |
| Pager:  symbol displays (Clinician Paging System) | <p>Pager is out of range from the Paging Transmitter or loss of communication to Patient SafetyNet Appliance</p> <ul style="list-style-type: none"> • Move back into range of the Paging Transmitter • Confirm Appliance has power, booted up and is working properly • Confirm the Paging Transmitter has power and is working properly • Ensure that the paging transmitter is connected to network switch • Confirm network switch has power and is working properly • Confirm Ethernet cables are connected and working properly • Contact BioMed • Contact Masimo Technical Services |

| Issue | Resolution |
|--|--|
| Patient SafetyNet Pager -  symbol is displayed (Clinician Paging System) | The battery in the Patient SafetyNet Pager is low <ul style="list-style-type: none"> • Replace the battery Note: Battery must be replaced within a 60 seconds. After 60 seconds, all the information on the Patient SafetyNet Pager will be deleted. |
| MyView Presence Tag | For troubleshooting information, refer to the Masimo Presence Tag Directions For Use. |

For technical information and assistance, contact Masimo Technical Services at 800-326-4890.

Compliance

IEC 60601-1-2

All components within the patient realm, operating together as a system, comply with IEC 60601-1-2, with intentional radiation at 2.4 and 5 GHz

FCC Part 15

Applicable components of this system have been labeled to comply with FCC Part 15.

Chapter 11: Service and Maintenance

Routine Maintenance

For all Patient SafetyNet components, refer to the product manufacturer's instructions for cleaning.

Service and Repair

Repair Policy

Masimo or an authorized Service Department must perform warranty repair and service. Do not use malfunctioning equipment. Have the device repaired.

Clean contaminated and/or dirty equipment before returning, follow the procedure described in the product manufacturer's instructions for cleaning. Make sure the equipment is fully dry before packing.

To return the device for service, refer to **Return Procedure** on page 107.

Return Procedure

Clean contaminated/dirty equipment before returning, follow the product manufacturer's instructions for cleaning. Make sure the equipment is fully dry before packing. Call Masimo at 800-326-4890 and ask for Technical Support. Ask for an RMA number. Package the equipment securely, in the original shipping container if possible, and enclose or include the following information and items:

- A letter describing in detail any difficulties experienced with the Patient SafetyNet. Include the RMA number in the letter.
- Warranty information, a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the Patient SafetyNet is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the Patient SafetyNet has been decontaminated for bloodborne pathogens.
- Return the Patient SafetyNet to the shipping address listed in the Contacting Masimo section below.

Contacting Masimo

Masimo Corporation
52 Discovery
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product (Patient SafetyNet™) and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months and any batteries for six (6) months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

Limitation of Warranty

Except as otherwise required by law or altered by the purchase agreement, the above warranty is the exclusive warranty that applies to the Product and software media, and Masimo does not make any other promises, conditions, or warranties regarding the Product. No other warranty applies, express or implied, including without limitation, any implied warranty of merchantability, fitness for a particular purpose, satisfactory quality, or as to the use of reasonable skill and care. See the licensing terms for the terms and conditions that apply to and Software accompanying the Product. Additionally, Masimo will not be liable for any incidental, indirect, special, or consequential loss, damage, or expense arising from the use or loss of use of any Products or Software. In no event shall Masimo's liability arising from any Product or Software (under contract, warranty, tort, strict liability, or otherwise) exceed the amount paid by purchaser for the Product or Software. The above limitations do not preclude any liability that cannot legally be disclaimed by contract.

Sales & End-User License Agreement

This document is a legal agreement between you ("purchaser") and Masimo Corporation ("Masimo") for the purchase of this Product ("Product") and a license in the included or embedded Software ("Software") except as otherwise expressly agreed in a separate contract for the acquisition of this Product, the following terms are the entire agreement between the parties regarding your purchase of this Product. If you do not agree to the terms of this agreement, promptly return the entire Product, including all accessories, in their original packages, with your sales receipt to Masimo for a full refund.

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Appendix

Patient SafetyNet Connection to External Notification Systems

Customers may elect to deploy their own End-User Notification Solution in conjunction with Patient SafetyNet. In this configuration an End-User notification solution (*Notification System*) would include a Notification Gateway and a Notification device. The term *Notification Gateway* means a user-provided communication interface, such as a paging transmitter, that receives Patient SafetyNet alarms and alerts notification messages (collectively, *Notification[s]*) and delivers them to Notification devices; and *Notification device(s)* means an instrument, such as a pager, that delivers the Notification to the End-User clinician. *End-User* means the hospital or other facilities where Patient SafetyNet is installed.

Warning: Under these circumstances, Patient SafetyNet is responsible for sending Alarm/Notifications to the End-User Notification System. Once a Notification has been appropriately sent by Patient SafetyNet, per Masimo's network specifications, to the Customer's Notification System, the Customer is responsible for, and Masimo cannot be held liable for, any failure of Customer's Notification System to receive and transmit that Notification to the End-User.

In this configuration, Masimo recommends the following:

- The End-User should perform a risk analysis prior to installation, before actively monitoring patients. Additional risk analysis should be performed when any changes or modifications have been made to the End-User Notification System.
- Perform testing of the End-User Notification System. The following table lists the minimum recommended tests to be performed.

| | Tasks | Actions | Results |
|---|--|--|---|
| 1 | Verify communication between the Patient SafetyNet Appliance and Notification Gateway. | Ping the following instruments the Notification Gateway from the Appliance. | Ping Statistics Notification Gateway: |
| 2 | <ul style="list-style-type: none"> • Profile End-User Notification System traffic and identify peak notification times. • Assess performance and verify that Notifications are received by all Notification devices in all areas where clinicians will be within the patient care area during peak notification times. | Send a Test Page to all Notification devices in all Care Areas during peak notification times. | Notification device(s) Results <Location>: Peak Time: |
| 3 | Verify that all information from Masimo Notifications are received. | <ul style="list-style-type: none"> • Admit a test patient to a Masimo instrument in the Patient SafetyNet System. • In the label field, enter <i>Test</i>. • Approve the alarms. • Under Assignments select the applicable notification device to receive the test notifications and select <i>Admit</i>. • Generate alarms from the connected instrument. • Confirm Notification device received Label, Notification type, Notification value and Escalation in full. | Notification device(s) Results |
| 4 | Verify Notification messages from Masimo Patient SafetyNet are at a higher priority than general notifications. | Confirm configuration in Notification System | |
| 5 | Verify Notification device indicates when it is unable to receive notifications from the Notification System (i.e. Out of Range, Interference, Defective, etc.) | Provide documentation related to the Notification device | |
| 6 | Verify Notification System has the ability to store and retransmit Notifications that it was unable to send | Provide documentation related to Notification System | |
| 7 | Verify the Notification device has a battery indicator | Provide documentation related to Notification device | |
| 8 | Verify the Notification device has a low battery notification | Provide documentation related to Notification device | |
| 9 | Verify that the Notification device cannot be turned off with a single key press. | Provide documentation related to Notification device | |

Reports Glossary

Clinical Events

| Alarm Parameter | Notification | Definition |
|---------------------------|---------------------------|--|
| No Breath Detected | NO BREATH DETECTED | No breath detected. See capnography module Operator's Manual |
| SpO ₂ High | SpO ₂ HIGH | SpO ₂ parameter exceeds high threshold |
| SpO ₂ Low | SpO ₂ LOW | SpO ₂ parameter exceeds low threshold |
| SpfO ₂ High | SpfO ₂ HIGH | SpfO ₂ parameter exceeds high threshold |
| SpfO ₂ Low | SpfO ₂ LOW | SpfO ₂ parameter exceeds low threshold |
| PR High | PR HIGH | Pulse rate parameter exceeds high threshold |
| PR Low | PR LOW | Pulse rate parameter exceeds low threshold |
| RRa High | RRA HIGH | Acoustic respiration rate parameter exceeds high threshold |
| RRa Low | RRA LOW | Acoustic respiration rate parameter exceeds low threshold |
| RRp High* | RRP HIGH | RRp parameter exceeds high threshold |
| RRp Low* | RRP LOW | RRp parameter exceeds low threshold |
| EtCO ₂ RR High | EtCO ₂ RR HIGH | EtCO ₂ RR parameter exceeds high threshold |
| EtCO ₂ RR Low | EtCO ₂ RR LOW | EtCO ₂ RR parameter exceeds low threshold |
| EtCO ₂ High | EtCO ₂ HIGH | EtCO ₂ parameter exceeds high threshold |
| EtCO ₂ Low | EtCO ₂ LOW | EtCO ₂ parameter exceeds low threshold |
| SpHb High | SPHB HIGH | SpHb parameter exceeds high threshold |
| SpHb Low | SPHB LOW | SpHb parameter exceeds low threshold |
| SpCO High | SPCO HIGH | SpCO parameter exceeds high threshold |
| SpCO Low | SPCO LOW | SpCO parameter exceeds low threshold |
| SpMet High | SPMET HIGH | SpMet parameter exceeds high threshold |
| SpMet Low | SPMET LOW | SpMet parameter exceeds low threshold |
| FICO ₂ High | FICO ₂ HIGH | FICO ₂ parameter exceeds high threshold |
| FICO ₂ Low | FICO ₂ LOW | FICO ₂ parameter exceeds low threshold |
| PVi High | PVi HIGH | PVi parameter exceeds high threshold |
| PVi Low | PVi LOW | PVi parameter exceeds low threshold |
| Pi High | Pi HIGH | Pi parameter exceeds high threshold |

| Alarm Parameter | Notification | Definition |
|-------------------------------|-----------------------------------|--|
| Pi Low | Pi LOW | Pi parameter exceeds low threshold |
| SpOC High | SPOC HIGH | SpOC parameter exceeds high threshold |
| SpOC Low | SPOC LOW | SpOC parameter exceeds low threshold |
| PSI High | PSI HIGH | PSI parameter exceeds high threshold |
| PSI Low | PSI LOW | PSI parameter exceeds low threshold |
| ORi Low** | ORi LOW | ORi parameter exceeds low threshold |
| Desaturation Index | DESAT INDEX | When Desaturation Index alarm is triggered based on user defined values, see Radical-7 Operator's Manual for more information. |
| Pi Delta | Pi DELTA | When Pi Delta alarm is triggered based on user defined values, see Radical-7 Operator's Manual for more information. |
| All Mute | ALL MUTE | Device is in all mute state. See device Operator's Manual |
| No Sensor | NO SENSOR | A Sensor has not been detected |
| Defective Sensor | DEFECTIVE SENSOR / REPLACE SENSOR | Check/Replace Defective Sensor |
| Interference | INTERFERENCE | Light interference detected by pulse oximetry sensor. See sensor Directions For Use |
| Sensor Off | SENSOR OFF | Sensor is no longer on patient |
| Unrecognized Sensor | UNRECOGNIZED SENSOR | Unrecognized sensor has been detected |
| Incompatible Sensor | INCOMPATIBLE SENSOR | An Incompatible sensor has been detected |
| Check Sensor | CHECK SENSOR | Check connected sensor |
| No Cable Connected | NO CABLE CONNECTED | A cable has not been detected |
| Incompatible Cable | INCOMPATIBLE CABLE | Incompatible cable has been detected |
| Unrecognized Cable | UNRECOGNIZED CABLE | Unrecognized cable has been detected |
| Defective Cable | DEFECTIVE CABLE / REPLACE CABLE | Check/Replace Defective Cable |
| Emitter Temp Out of Range | EMITTER TEMP OUT OF RANGE | The sensor emitter temperature is out of range of operation. |
| Sensor Current Limit Exceeded | SENSOR CURRENT LIMIT EXCEEDED | Sensor monitoring limit has been reached. |
| No Adhesive | NO ADHESIVE | Adhesive on sensor has not been detected |
| Incompatible Adhesive | INCOMPATIBLE ADHESIVE | An incompatible adhesive on sensor has been detected |
| Defective Adhesive | DEFECTIVE ADHESIVE | A defective adhesive on sensor has been detected |
| No Acoustic Sensor Connected | NO AC SENSOR | Acoustic sensor has not been detected |

| Alarm Parameter | Notification | Definition |
|--|--|--|
| Defective Acoustic Sensor | DEFECTIVE AC SENSOR | A defective acoustic sensor has been detected |
| Respiratory Pause | RESP PAUSE | Acoustic sensor has detected a respiratory pause. See sensor Directions For Use |
| Acoustic Sensor Off Patient | AC SENSOR OFF | Acoustic sensor is no longer on patient |
| Bad Acoustic Sensor Placement | BAD AC SENSOR PLACEMENT | Check acoustic sensor placement. See sensor Directions For Use |
| Unrecognized Acoustic Sensor | UNRECOGNIZED AC SENSOR | Unrecognized acoustic sensor has been detected |
| Incompatible Acoustic Sensor | INCOMPATIBLE AC SENSOR | Incompatible acoustic sensor has been detected |
| No Acoustic Cable Connected | NO AC CABLE CONNECTED | Acoustic cable has not been detected |
| Incompatible Acoustic Cable | INCOMPATIBLE AC CABLE | Incompatible acoustic cable has been detected |
| Unrecognized Acoustic Cable | UNRECOGNIZED AC CABLE | Unrecognized acoustic cable has been detected |
| Defective Acoustic Cable | DEFECTIVE AC CABLE | A defective acoustic sensor cable has been detected |
| No AC Adhesive | NO AC ADHESIVE | Acoustic sensor adhesive has not been detected |
| Incompatible AC Adhesive | INCOMPATIBLE AC ADHESIVE | Incompatible acoustic sensor adhesive has been detected |
| Defective AC Adhesive | DEFECTIVE AC ADHESIVE | A defective acoustic sensor adhesive has been detected |
| (CO ₂) Sensor Error | SENSOR ERROR | Capnography module sensor error. See capnography module Operator's Manual |
| (CO ₂) Sampling Line Clogged | (CO ₂) SAMPLING LINE CLOGGED | Sampling line is clogged. See Nomoline Directions For Use |
| (CO ₂) Replace O ₂ Sensor | (CO ₂) REPLACE O ₂ SENSOR | Replace capnography module O ₂ sensor. See capnography module Operator's Manual |
| (CO ₂) Calibration Required | (CO ₂) CALIBRATION REQ | Capnography module requires calibration. See capnography module Operator's Manual |
| (CO ₂) Temp Out Of Range | (CO ₂) TEMP OUT OF RANGE | Capnography module temperature is out of range. See capnography module Operator's Manual |
| (CO ₂) Pressure Out Of Range | (CO ₂) PRESSURE OUT OF RANGE | Capnography module pressure is out of range. See Capnography module Operator's Manual |
| (CO ₂) Zeroing Required | (CO ₂) ZEROING REQUIRED | Capnography module requires zeroing. See capnography module Operator's Manual |
| (CO ₂) No Sampling Line | (CO ₂) NO SAMPLING LINE | No sampling line detected. See Nomoline Directions For Use |
| (CO ₂) O ₂ Port Failure | (CO ₂) O ₂ PORT FAILURE | Capnography module port has failed. See capnography module and Root Operator's manual |
| Capnography Disconnected | O ₂ MODULE DISCONN | Capnography module is disconnected. See capnography module Operator's Manual |
| EMG No Cable | (EMG) NO CABLE | No SedLine cable detected. See SedLine Operator's Manual |

| Alarm Parameter | Notification | Definition |
|----------------------------|----------------------------|---|
| EMG Incompatible Cable | (EMG) INCOMPATIBLE CABLE | Cable attached to SedLine module is incompatible. See SedLine Operator's Manual |
| EMG Cable Life Expired | (EMG) CABLE LIFE EXPIRED | SedLine cable has expired. See SedLine Operator's Manual |
| EMG Defective Cable | (EMG) DEFECTIVE CABLE | SedLine cable is defective. See SedLine Operator's Manual |
| EMG No Sensor | (EMG) NO SENSOR | No SedLine sensor detected. See SedLine Operator's Manual |
| EMG Incompatible Sensor | (EMG) INCOMPATIBLE SENSOR | Sensor attached to SedLine cable is incompatible. See SedLine Operator's Manual |
| EMG Sensor Life Expired | (EMG) SENSOR LIFE EXPIRED | SedLine sensor has expired. See SedLine Operator's Manual |
| EMG Defective Sensor | (EMG) DEFECTIVE SENSOR | Sedline sensor is defective. See SedLine Operator's Manual |
| EMG Sensor Off | (EMG) SENSOR OFF | SedLine sensor is off patient. See SedLine Operator's Manual |
| EMG No Tape | (EMG) NO TAPE | No SedLine sensor adhesive detected. See SedLine Operator's Manual |
| EMG Incompatible Tape | (EMG) INCOMPATIBLE TAPE | Sedline sensor adhesive is incompatible. See SedLine Operator's Manual |
| EMG Defective Tape | (EMG) DEFECTIVE TAPE | SedLine sensor adhesive is defective. See SedLine Operator's Manual |
| EMG Tape Life Expired | (EMG) TAPE LIFE EXPIRED | SedLine sensor adhesive has expired. See SedLine Operator's Manual |
| EMG High Impedance | (EMG) HIGH IMPEDANCE | High impedance detected. See SedLine Operator's Manual |
| EMG Gel Bridging | (EMG) GEL BRIDGING | Problem with Gel Bridging. See SedLine Operator's Manual |
| Improper Sensor Connection | (EMG) IMPROPER SENSOR CONN | Improper SedLine sensor connected. See SedLine Operator's Manual |
| Sedline Disconnected | SEDLINE DISCONNECTED | SedLine module disconnected. See SedLine and Root Operator's Manual |
| Low Battery | INST BATT LOW | Battery is low |

Note: Displayed alarm parameters may depend on the monitoring bedside device.

* RRp is currently not available in the U.S.A. and territories relying on FDA market clearance.

** ORi is currently not available in the U.S.A. and territories relying on FDA market clearance.

Non-Clinical Events

| Alert Parameter | Notification | Definition |
|-------------------------------|-----------------------------------|--|
| All Mute | ALL MUTE | Instrument is in an <i>All Mute</i> state. |
| No Sensor | NO SENSOR | No sensor detected as being attached to the patient cable. |
| Defective Sensor | DEFECTIVE SENSOR / REPLACE SENSOR | Sensor appears to be defective. |
| Interference | INTERFERENCE | Ambient light interference is detected by sensor. |
| Sensor Off | SENSOR OFF | The sensor is off the patient. |
| Unrecognized Sensor | UNRECOGNIZED SENSOR | Instrument does not recognize sensor. |
| Check Sensor | CHECK SENSOR | Check the sensor placement to ensure that emitter and detector are in alignment. |
| No Cable Connected | NO CABLE CONNECTED | Cable is disconnected from the instrument. |
| Incompatible Cable | INCOMPATIBLE CABLE | Instrument is incompatible with cable. |
| Unrecognized Cable | UNRECOGNIZED CABLE | Instrument does not recognize cable. |
| Defective Cable | DEFECTIVE CABLE / REPLACE CABLE | Cable is defective. |
| Emitter Temp Out of Range | EMITTER TEMP OUT OF RANGE | The temperature of the sensor emitter is out of range. |
| Sensor Current Limit Exceeded | SENSOR CURRENT LIMIT EXCEEDED | The sensor has exceeded the current limit. |
| No Adhesive | NO ADHESIVE | Instrument does not detect adhesive. |
| Invalid Adhesive | INVALID ADHESIVE | Instrument detects invalid adhesive. |
| Defective Adhesive | DEFECTIVE ADHESIVE | The adhesive is defective. |
| No Acoustic Sensor Connected | NO AC SENSOR | Instrument does not detect acoustic sensor connected. |
| Defective Acoustic Sensor | DEFECTIVE AC SENSOR | The acoustic sensor is defective. |
| Respiratory Pause | RESP PAUSE | Sensor detects a respiratory pause longer than the user defined time period. |
| Acoustic Sensor Off Patient | AC SENSOR OFF | The acoustic sensor is disconnected from the patient. |
| Bad Acoustic Sensor Placement | BAD AC SENSOR PLACEMENT | The acoustic sensor is incorrectly placed. |
| Unrecognized Acoustic Sensor | UNRECOGNIZED AC SENSOR | Instrument does not recognize the acoustic sensor. |
| Incompatible Acoustic Sensor | INCOMPATIBLE AC SENSOR | The acoustic sensor is incompatible with the instrument. |
| No Acoustic Cable Connected | NO AC CABLE CONNECTED | There is not acoustic cable connected. |
| Incompatible Acoustic Cable | INCOMPATIBLE AC CABLE | The acoustic cable is incompatible with the instrument. |
| Unrecognized Acoustic Cable | UNRECOGNIZED AC CABLE | Instrument does not recognize acoustic cable. |
| Defective Acoustic Cable | DEFECTIVE AC CABLE | The acoustic cable is defective. |

| Alert Parameter | Notification | Definition |
|-----------------|---------------|--------------------------------|
| Low Battery | INST BATT LOW | The instrument battery is low. |

Modifiers

| Modifier Parameter | Notification | Definition |
|---------------------------|---------------------------|---|
| Patient Interference | PAT INTERFERENCE | Acoustic sensor detects interference from the patient. |
| Background Interference | BACKGROUND INTERFERENCE | Acoustic sensor detects interference from the room. |
| Low SIQ | SIQ LOW | Instrument detects low SIQ at sensor site. |
| Low Perfusion | LOW PERF | Instrument detects low perfusion at sensor site. |
| Low PR SIQ | LOW PR SIQ | Instrument detects low pulse rate SIQ at sensor site. |
| Low EtCO ₂ SIQ | LOW EtCO ₂ SIQ | Instrument detects low EtCO ₂ SIQ at sensor site. |
| Low RR Confidence | LOW RR SIQ | Instrument detects low confidence of respiration rate at sensor site. |
| Low RR Signal Strength | LOW RR SIG STR | Instrument detects weak signal of respiration rate at sensor site. |
| SpHb Low Confidence | LOW SPHB SIQ | Instrument detects low confidence of SpHb at sensor site. |
| SpCO Low Confidence | LOW CO SIQ | Instrument detects low confidence of SpCO at sensor site. |
| SpMet Low Confidence | LOW MET SIQ | Instrument detects low confidence of SpMet at sensor site. |
| Low FiCO ₂ SIQ | LOW FiCO ₂ SIQ | Instrument detects low FiCO ₂ SIQ at sensor site. |
| Low PVi SIQ | LOW PVi SIQ | Instrument detects low Pleth Variability Index SIQ at sensor site. |
| Low Pi SIQ | LOW Pi SIQ | Instrument detects low Perfusion Index SIQ at sensor site. |
| Low SpOC SIQ | LOW SPOC SIQ | Instrument detects low SpOC SIQ at sensor site. |
| Low PSI SIQ | LOW PSI SIQ | Instrument detects low PSI SIQ at sensor site. |

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