EarlySense Modular Bedside Unit

User Guide

ALL-IN-ONE • SAFETY • VITALS

EarlySense
Proactive Patient Care

Important Notice

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EarlySense Ltd. assumes no responsibility for errors that may appear in this user guide. EarlySense Ltd. reserves the right to make changes without notice to this user guide and the products described herein.

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Intended Use

The EarlySense 2.0 System is intended for continuous measurement of respiration rate, heart rate and movement, in an automatic contact-less manner, at home, hospital or clinic setting. The system is indicated for use in children, adolescents and adults. The operation of the EarlySense has been studied in children (weight ≥ 10 Kg) and adults (weight < 111 Kg) during sleep and resting condition. In addition, the EarlySense 2.0 System can continuously monitor oxygen saturation of arterial hemoglobin (SpO_2) using pulse oximetry in pediatric (ages 2 years and older), adolescents, and adults at home, hospital, or clinical setting.

NOTE Definition of Age for Children: Children age 2 and above.

Contraindications for Use

The EarlySense System is contraindicated for use in:

- Patients whose proper positioning cannot be achieved or maintained.
- Patients who do not meet the weight limits tested or specified.
- Situations where a dry environment cannot be ensured.
- A Magnetic Resonance (MR) environment.
- An explosive atmosphere or in the presence of flammable anesthetics or gases.

About This User Guide

This user guide describes how to operate the EarlySense Bedside Unit (Bedside Unit):

- Please read this user guide thoroughly before operating the system. If any part of this user guide is not clear, contact EarlySense Customer Support for clarification.
- This user guide does not replace the Bedside Unit training course.
- This user guide only describes the Bedside Unit. Operation of the Central Display Station (CDS) is described in the *EarlySense Central Display Station (CDS) User Guide*.
- This user guide must always be located near the EarlySense System so that all personnel operating the EarlySense System are aware of its location and can locate it easily.

This user guide contains the following chapters:

- **Chapter 1, Introduction,** page 22, introduces the EarlySense System and its components.
- **Chapter 2, Set Up,** page 31, describes the initial set up and configuration of the Bedside Unit and Sensor.
- **Chapter 3, All-in-One Module,** page 39, describes the All-in-One module, its user interface and operation.
- **Chapter 4, Safety Module,** page 94, describes the Safety module, its user interface and operation.
- **Chapter 5, Vitals Module,** page 134, describes the Vitals module, its user interface and operation.

- **Appendix A, Electronic Patient Admission,** page 168, describes how to admit a patient by receiving electronic identification information for the patient from an EMR.
- **Appendix B, Troubleshooting,** page 172, describes various problems, possible causes and their solutions.
- **Appendix C, Nonin XPod® OEM Compatible SpO_2 Sensors,** page 176, provides a list of the Nonin XPod OEM-compatible Sp02 Sensors.
- **Appendix D, Manufacturer's Declaration,** page 178, describes the system's compliance with applicable IEC and RF standards.

Conventions

The following conventions are used throughout this user guide:

WARNING

A warning indicates precautions and instructions which, if not followed, may result in serious bodily injury or death.

CAUTION

A caution indicates instructions or cautionary notes which, if not followed, may result in damage to the equipment or to the quality of measurements.

NOTE Notes contain helpful information and tips.

Features and functionality that pertain to a specific module are marked throughout this guide, as follows:

All-in-One Module

Vitals Module

Safety Module

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Safety

General Safety Guidelines

WARNING!

US Federal Law restricts this system for sale by or on the order of a physician.

The data acquired by the EarlySense System should be interpreted by a healthcare practitioner only.

WARNING

All changes made on a Bedside Unit via remote control should only be performed by a healthcare professional.

WARNING

The installation of the remote view software on the portable device (tablet or PC) should be performed only by qualified service personnel authorized by EarlySense Ltd. in cooperation with the Enterprise IT department.

- This user guide, directions for use and all precautionary information and specifications should be read before use.
- Handle the Bedside Unit with care. Do not drop, knock or shake the Bedside Unit. Rough handling can damage the internal circuit boards.
- The system is intended for indoor operation only.
- To avoid the risk of electric shock, the Bedside Unit must only be connected to supply mains with protective earth.
- A damaged system should not be disposed of as unsorted municipal waste. Contact your local distributor for unit disposal.
- Changes or modifications not expressly approved by EarlySense Ltd. could affect the safety or effectiveness of the EarlySense System and void the system's warranty.
- The EarlySense Sensing Units (the under-the-mattress Sensor, the Chair Sensor and the Oximeter Module accessories) should be used only with the EarlySense Bedside Unit (Bedside Unit). The Bedside Unit should only be connected to the EarlySense Sensing Unit.
- The Contactless Sensor is a continuously operated, Solid object protected and splash-proof accessory (IP24).
- Optional Oximeter Module:
  - Use only with compatible Sensors. A list of compatible Sensors is provided in *Appendix C, Nonin XPod® OEM compatible SpO_2 Sensors* on page 176). Using other Sensors may result in inaccurate pulse oximeter performance and/or may result in increased emission and/or decreased immunity of this device.
  - Before using the Oximeter module, refer to the instructions for Sensor usage.

For additional warnings and cautions, refer to the Sensor's instructions for Sensor use.

General Hazards

- Do not use a damaged system. Use of damaged components may result in malfunctioning of the system.
- The EarlySense System should be installed and serviced only by qualified service personnel authorized by EarlySense Ltd. Technical diagrams and descriptions are available to authorized and qualified personnel.

Electrical Shock

The system contains no user-serviceable parts. Do not open the system covers. The Bedside Unit is not waterproof. Keep the Bedside Unit dry to avoid electrical shock or malfunction.

Defibrillation

The system is a Defibrillation-proof – Type BF applied part. The EarlySense System may optionally be used with an Oximeter module. You may refer to the sensor's instructions for a description of Sensor usage, as specific oximeter Sensors may not be defibrillation-proof.

Electromagnetic Compatibility

This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference may disrupt the performance of this system, due to close proximity or strength of a source. Medical electrical equipment needs special precautions regarding EMC and all equipment must be installed by qualified service personnel.

EarlySense 2.0 is intended to be used in the professional healthcare facility environment and in the home healthcare environment. The electromagnetic compatibility testing was performed according to the worst case scenario, which is the home healthcare environment. The detailed explanation of the performed tests and the recommended precautions as for the electromagnetic interference between the EarlySense System and other RF equipment can be found in Appendix D page 178, Manufacturer's Declaration.

Battery Storage

In case of long-term storage (over two years), remove the battery from the equipment and store it in a dry and cool place. This should be performed by an authorized technician.

Wi-Fi Communication

The system incorporates an off-the-shelf certified Wi-Fi communication card (complies with FCC part 15).

Electrical Fire

Avoid placing liquids or food on any part of the system. Do not allow conductive fluids to leak into the active circuit components of the system, as this may cause a short circuit that could result in an electrical fire. In the event of fire, only fire extinguishers approved for use on electrical fires should be used. The system is not intended for use in the presence of flammable mixtures.

Classification

Mode 1: The unit is classified as Class I.

Mode 2: The unit is an internally, continuously powered ordinary portable equipment with an applied part. The Contactless Sensor is a continuously operated, item of equipment, solid object protected and splash-proof accessory (IP24). Only equipment specified in this guide that complies with the requirements of IEC 60601 should be connected to the system.

The system complies with IEC 60601-1 and IEC 60601-1-2. The system has successfully passed emission tests (conducted and radiated).

Warnings and Cautions

- The EarlySense System should only be installed and serviced by qualified service personnel authorized by EarlySense.
- Mounting the Bedside Unit to the wall should be performed while exercising utmost caution. Do not place the Bedside Unit over the patient's head to avoid safety-related conditions.
- Mounting the Bedside Unit to the wall should be performed by mechanical experts of the institution (for example, Biomed/Engineering) to ensure that they are safely attached. EarlySense Ltd. is not responsible for any harm or damage related to the wrongful placement of the Bedside Unit.
- Implementation of the healthcare practitioner call connector option provided in the EarlySense System requires coordination between the institution and EarlySense. Do not implement this option without consulting with and receiving approval from the hospital administration.
- The data acquired by the EarlySense System should only be interpreted by a healthcare practitioner.
- In the event that the EarlySense System does not operate properly, contact EarlySense Support Services at (781) 373-3228.
- Never open the Bedside Unit housing as this may damage the system. Refer all servicing to an authorized technician.
- Clean the air vents every 6 months or as needed in case the air vents are clogged.
- Only equipment specified in this user guide that complies with the requirements of IEC 60601 should be connected to the system.
- The EarlySense Chair Sensing Unit should not be used adjacent to or stacked with other equipment. If adjacent or stacked, the EarlySense Chair Sensing Unit should be observed to verify normal operation in the configuration in which it is used.
- Measurements may be affected by cable lengths. Do not shorten or extend their lengths.
- The use of accessories, transducers and cables other than those specified by the system's specifications could result in increased emissions or decreased immunity.
- Changes or modifications not expressly approved by EarlySense Ltd. could affect the safety or effectiveness of the EarlySense System and void the system's warranty.
- The system should be operated within a temperature range of 5−40°C (41−104°F) for the Bedside Unit and for the Under-the-mattress and Chair Sensing Unit within a non-condensing relative humidity of 10%−90%. For an SpO_2 Sensor, you may refer to the package inserts for the specific Sensors.
- Do not use a damaged system. Use of damaged components may result in malfunctioning of the system.
- Avoid placing liquids or food on any part of the system. Do not allow conductive fluids to leak into the active circuit components of the system, as this may cause a short circuit, which could result in an electrical fire. In case of fire, only fire extinguishers approved for use on electrical fires should be used. Take caution when an EarlySense Sensor is placed under the mattress for patients with poor bladder function or control, including small children.
- Do not share the bed with another person or pet during the EarlySense System recording session. Sharing the bed could affect the effectiveness of the system and the accuracy of the measurements.
- Avoid using heating blankets. Use of heating blankets may affect the safety or effectiveness of the EarlySense System and void the system's warranty.
- Do not use the EarlySense System for patients who weigh more than 200 kg (440 pounds). Usage of the system for such patients may result in malfunction of the Sensing Unit.

- The patient should not have direct contact with the Sensing Unit. A mattress, mattress pad or mattress cover should always be placed as a barrier between the Sensing Unit of the EarlySense System and the patient. Patients should be frequently checked to ensure direct contact does not occur.
- If used by multiple patients, the Chair Sensing Unit should be covered by a clean bed sheet to prevent cross-contamination of the users.
- Make sure to carefully oversee the usage of the EarlySense System with children.
- False alerts may occur in some situations. The alert must be identified and understood. The cause(s) of the false alerts must be addressed whenever possible to eliminate the possibility of repeated false alerts and alert fatigue, which may result in a failure to respond to an actual alert situation.
- All wireless systems are prone to intermittent signal dropout. Make sure that the patient only has conditions that can tolerate intermittent monitoring interruptions. The EarlySense bedside monitor is the alerting monitor. Alert delays were measured between the bedside monitor and CDS and the same alert from the CDS to the bedside. Delays are less than 10 total seconds, not including any hold-off settings set by the clinical facility. However, network speeds vary and the system's performance may vary, depending on the speed of clinical facility network.
- External wireless alerting devices as used by the hospital or clinic setting should be used as secondary to the alerts as provided by the EarlySense systems.
- The system does not support life & nurses/healthcare providers are required to continue their standard practice. The EarlySense System is not intended for monitoring high risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.
- Alert limit settings are patient- or facility-specific. The clinician must set and verify alert limits appropriate for each patient. Each time the Bedside Unit is powered on, you must check that the alert settings are appropriate for your patient before you start monitoring. Failure to set alert limits properly can lead to false alerts or the failure to alert. Alerting only works properly if set up properly.
- It is strongly recommended that the Bedside Unit be installed with redundant power supplies.
- The usage of EarlySense 2.0 System on the bed or chair, close to any adjacent source of vibration, may influence the accuracy of the system's measurements or create periodic interference with the measurements.
- EarlySense 2.0 System should not be used adjacent to or stacked with other equipment and if adjacent or stacked use is necessary, the EarlySense 2.0 System should be observed to verify normal operation.
- Portable RF communications equipment, including antennas, such as mobile phones, Walkie-Talkie, mobile radios, etc. should not be used closer than 30 cm (12 inches) to any part of EarlySense System, including its cables, as it can negatively affect its performance.

WARNING

Configuring the possibility to remotely access the bedside via tablets, computers or other portable devices should be performed by EarlySense authorized technicians, and requires authorization from the hospital IT/Biomedical department for network setup.

WARNING

All wireless systems are prone to intermittent signal dropout due to communication lost. Make sure that the patient only has conditions that can tolerate intermittent monitoring interruptions. Do not pause or turn off an alert remotely if patient safety might be compromised.

WARNINGS

Patient harm risk. Do not pause or turn off an audible alert remotely if patient safety may be compromised. Do not adjust a patient's alert limits as a way to silence an alarm.

Remote monitoring is not a substitution for frequent patient assessment by attending clinicians, or a substitute for the alerting that occurs at the patient monitor.

Alerts and other events can go unnoticed if clinical personnel are not present at the bedside or if interruptions occur in power, network connections or Monitoring Units operation.

Using the Oximetry Module

- Use the Oximetry Module only with compatible Sensors. A list of compatible Sensors is provided in *Appendix C Nonin XPod® OEM-compatible SpO_2 Sensors* on page 176. Using other Sensors may result in inaccurate pulse oximeter performance and/or may result in increased emission and/or decreased immunity of this device.
- Before using the Oximeter Module, refer to the Sensor's instructions for proper Sensor usage.
- For additional warnings and cautions, you may refer to the Sensor's instructions for information about its usage.
- Single-patient-use Sensors are intended for single-patient use only. Refer to the IFU of Oximeter Sensors for additional warnings.
- The oximetry data is only intended as an adjunct in patient assessment. It must be used in conjunction with other methods of assessing clinical signs and symptoms. If any measurement seems questionable, first check the patient's vital signs by alternate means.
- For factors that may degrade pulse oximeter performance, see the cautions and warnings included in the inserts provided in the packaging of compatible Sensors.
- Supplemental oxygen attenuates patterns of desaturation. A patient's respiratory compromise can be proportionally more severe before patterns appear in the saturation trend. Remain vigilant when monitoring a patient on supplemental oxygen.
- In case of discrepancy between the oximeter-based heart rate and the contactless Sensor heart rate, check the position of the Pulse Oximetry Sensor on the finger, and use additional methods for measuring heart rate. Exercise clinical judgment at all times.
- As with all medical equipment, carefully route cables and connections to reduce the possibility of tripping, entanglement or strangulation.
- Do not create sharp bends in the cable, as this may tear or break the shielding.

WARNING

The EarlySense System is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

CAUTION

US Federal Law restricts this system for sale by or on the order of a physician.

Explanation of System Labels

The following provides a description of the graphical symbols that appear on the EarlySense System components and package.

Table 1: Explanation of System Labels

Explanation of System Labels	
	Caution/Warning
	Consult accompanying documents
	Defibrillation-proof, type BF, applied part
	Fragile; handle with care
	Keep dry
	Indoor operation only
	Non-ionizing Electromagnetic Radiation
IP24	Solid object protected and splash-proof accessory
	Sorted disposal
	Manufactured by
	Date of manufacture
	MR Unsafe: Keep away from magnetic resonance imaging (MRI) equipment

Compliance with Standards

The EarlySense System was tested and found to be in compliance with the standards described in Table 2.

Table 2: Standards Compliance

Standard	#
Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	IEC 60601-1
Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; Electromagnetic Compatibility − Requirements and Tests	IEC 60601-1-2
Medical Electrical Equipment – Part 1: General Requirements for Safety-Collateral Standard: Usability	IEC 60601-1-6
Medical devices – Application of usability engineering to medical devices	IEC 62366

This equipment complies with IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipment and/or systems, ESD Air Discharge was tested to ± 2kV, ± 4kV, ± 8kV only.

You may refer to *Appendix D, Manufacturer's Declaration* on page 178 for tables and specific information regarding compliance with IEC 60601-1-2.

Supplying Bedside Unit

The Bedside Unit is shipped in a protective package. In addition, the EarlySense System may be provided with an optional Oximetry Module and accessories. The system should be unpacked and installed only by an authorized EarlySense technician.

Supplying Sensors

The EarlySense Sensing Units are supplied in a separate package. Each Sensing Unit is isolated to ensure safe transport. In addition, the EarlySense System may be provided with optional Chair Sensing Unit(s) and/or with an Oximetry Module and accessories. The system should be unpacked and installed only by an authorized EarlySense technician.

Terms, Abbreviations and Definitions

Table 3: Terms, Abbreviations and Definitions

Term/Abbreviation	Definitions
°C	Degrees Centigrade
°F	Degrees Fahrenheit
AC	Alternating Current
ADT	Admission, Discharge and Transfer System
AM	Ante Meridiem (L) – Before Noon
BF	Type BF applied part – medical device classification
BPAP	Bi-level Positive Airway Pressure
BPM	The number of heartbeats per unit of time (beats per minute)
Br./min	Breaths per minute
Braden Score	A scale for predicting pressure sore risk
CDS	Central Display Station
CM	Centimeters
CPAP	Continuous Positive Airway Pressure
CSV	Comma Separated Values (text file format)
ECG	Electrocardiography
EMC	ElectroMagnetic Compatibility
EMR	Electronic Medical Record System
EN	European Norm (standard)
ESD	ElectroStatic Discharge
F	Female
FCC	Federal Communications Commission
FDA	US Food and Drug Administration
HIS	Hospital Information System
HR	Heart Rate
ID	Identification number
IEC	International Electrotechnical Commission
IFU	Instructions For Use
IP24	Protected against splashing water and solid object protected
IT	Information Technology
Kg	Kilogram = 2.2 pounds weight
kHz	Kilohertz
LAN	Local Area Network
LED	Light Emitting Diode
M	Male
MHz	Megahertz
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
MRN	Medical Record Number
O_2	Oxygen
OEM	Original Equipment Manufacturer
PDF	Portable Document Format
PIN	Personal Identification Number

Term/Abbreviation	Definitions
PM	Post Meridiem (L) – After Noon
q	Turn Interval
RR	Respiratory Rate
RF	Radio Frequency
SpO_2	Oxygen Saturation
VAC	Voltage Alternating Current
WiFi	Local area wireless technology

1 Introduction

This chapter introduces the EarlySense System and its components.

1.1 What Is the EarlySense System?

The EarlySense System manufactured by EarlySense Ltd. is designed for continuous, contact-free measurement of the heart rate and respiratory rate. In addition, the system tracks body motion, monitors patient movement and can notify users when the patient exits the bed. The system can numerically display the heart rate, respiratory rate and movement, as well as graphical trend data for these parameters. The system can notify the caregiver when heart rate or respiratory rates, averaged over time, exceed or fall below predefined limits. The system also enables a healthcare practitioner to document changes in a patient's position while in bed, by recording this information in the EarlySense System. In addition, an optional standard Pulse Oximetry Module is available. The standard Pulse Oximetry Module accessories include a Pulse Oximetry Measurement Module that is incorporated into the system. Compatible Sensors that can be attached to a patient's fingertip are provided.

The EarlySense System is a modular platform. The parameters displayed on the Bedside Unit are determined by the module that is chosen by the user. Three modules are available:

- **Safety Module**: When this module is chosen by the user, the system only displays information regarding the patient's motion, bed/chair occupancy, bed/chair exiting and patient turning information.
- **Vitals Module:** When this module is chosen by the user, the system displays the heart rate, respiratory rate and motion information.
- **All-in-One Module:** When this module is chosen by the user, the system displays all available parameters on one screen, including heart rate, respiratory rate, motion, bed/chair occupancy and bed/chair exiting. In addition, this module can display pulse oximetry monitoring information.

This guide contains a dedicated chapter for each module. Basic operational information as well as safety, contraindications, electrical safety and compatibility, and warning and caution information for the system are identical for all three modules. You should review this information at the beginning of this user guide.

Providing contact-free, passive monitoring capabilities, with no need for patient activation, the EarlySense System enables continuous monitoring of patients in homes, hospitals or clinical settings. The data acquired by the system is continuously logged at a Bedside Unit. When using the system at home, the data can be presented in a time-stamped format that is easily accessed offline by a healthcare practitioner for further analysis.

The basic system includes a Bed Sensing Unit that is placed beneath the bed mattress or between the mattress and a mattress pad/cover and a Bedside Unit, which sets the system options and displays the collected data. An optional Chair Sensing Unit that can be placed on a chair is also available to monitor the patient while resting in a chair. Monitoring of the patient automatically begins as soon as the patient enters the bed/chair. The data acquired by the system is continuously logged into the Bedside Unit, and can be presented in a time-stamped format. The data provided by the system is intended to aid in the evaluation process of a patient's clinical status and should only be interpreted by a healthcare practitioner.

The EarlySense System enables the operator to adjust the settings of the threshold parameters or other parameters, based on the chosen module. For example, in the Vitals module or in the All-in-One module, you can adjust the alert thresholds for heart rate and respiratory rate and notify the caregiver when these rates, averaged over time, exceed or fall below predefined limits. In the Safety module, you can adjust the settings of the Bed-Exit Alert and the Patient Turn Reminder.

When oxygen saturation monitoring is applicable (for example, in the All-in-One module), the SpO_2 Sensor should be attached to the patient's fingertip in accordance with the specific compatible Sensor's usage instructions. These instructions are provided in the inserts that are included in the packaging of the compatible Sensors.

NOTE	The EarlySense System has not been studied on any specific patient group, nor has it been studied as a diagnostic tool for any specific disease or medical condition. It is intended as an adjunct tool only for measuring respiratory rate, heart rate and movement. In addition, when the optional Oximeter module is used, oximetry data is available.

1.2 Multiple Modules Solution (Optional)

If the EarlySense system is preset to enable multiple modules, then the user is prompted to select the required module during the patient admission stage.

After the patient's details are confirmed, a multiple-choice window is displayed, as shown below:

NOTE	Only the enabled modules are available for the user to select.

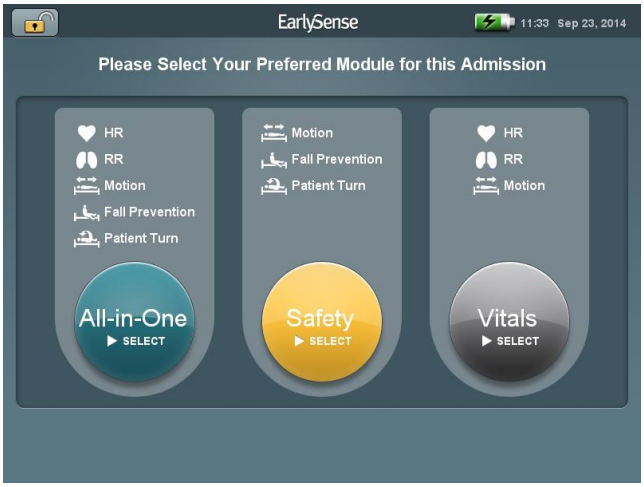

Figure 1: Modular Solution – Multiple Choices

1.3 System Components

The system consists of a Sensing Unit and a Bedside Unit, connected by a cable. An Oximeter module with appropriate Sensors may be provided (optional).

Figure 2: EarlySense Components

1.3.1 Bed Sensing Unit – The Sensor

The Bed Sensing Unit (also called the *Sensor*) is shown above. It is intended to be placed under the mattress, as described in the *Positioning the Bedside and Sensing Units* section on page 31, and detects physiological and motion signals generated by the patient. A solid base plate is designed to be fixed to the bed's frame for convenience during placement.

1.3.2 Chair Sensor (Optional)

The optional Chair Sensor is a contact-free Sensor inserted into a cushion, so that it is not in contact with the patient. The cushion can be placed on a chair and can detect a signal generated by the patient's breathing, heartbeat and motion while the patient rests in a chair.

The Chair Sensor can only be used if the Chair Sensor is connected and manually identified in the Bedside Unit. Two cushions are available with different softness levels.

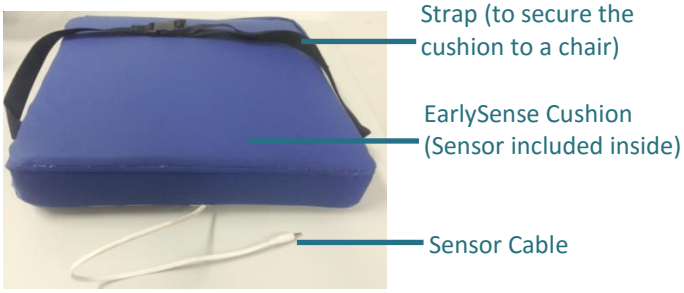

Figure 3: Chair Sensor – A Cushion with a Sensor Inside

An optional extension cable for the Sensor is available, if required.

NOTE The total length of the extension cable for each Sensor should not exceed 12 meters (39.4 feet).

1.3.3 Bedside Unit

The Bedside Unit displays the parameters for a specific EarlySense module and is used to configure the system, as follows:

Figure 4: Bedside Unit Indicators

WARNING	Active RED indicator light, requires an immediate response to understand the nature of the Alert. Active YELLOW indicator light, requires prompt response to understand the nature of the Alert.

S

Safety Module: When this mode is chosen or installed, the system only displays the following information:

- Patient's motion
- Bed/Chair occupancy
- Bed/Chair exit
- Patient turning information

You can configure the sensitivity of the Bed Exit alert and specify the time intervals for receiving Patient Turn reminders. All alerts can be enabled/disabled at any given time.

V

Vitals Module: When this mode is chosen or installed, the system monitors and displays the following information:

- Heart Rate
- Respiratory Rate
- Motion information

You can adjust the thresholds for these alerts and enable/disable alerts at any given time.

A

All-in-One Module: When installed in this mode, the system monitors and displays the following information:

- Heart rate
- Respiratory rate
- Patient motion information
- Bed/chair occupancy
- Bed/chair exiting
- Patient turning information
- Pulse oximetry monitoring information

All alerts and settings can be enabled/disabled at any given time.

1.3.4 Central Display Station (CDS)

Each EarlySense Bedside unit provides an option of communication with the EarlySense Central Display Station (CDS). The optional CDS system consists of a display, computer and mouse. The CDS comprises standard hardware (PC, communication and IT hardware). EarlySense developed the software running on the system's PC.

Figure 5: System Components

You may refer to the *EarlySense Central Display Station (CDS) User Guide* for a description of the CDS.

1.4 Main Bedside Unit Window

The main Bedside Unit *Home* window may appear differently according to the module that is installed and according to whether the system is operating in bed mode or chair mode.

Interaction with the user interface is via touch screen. Clicking some functions (such as the **Discharge** or **Trends** buttons) opens additional windows, while other buttons access additional adjustment functions in the *Home* window. For more details about the *Home* window, you may refer to the *Home Window* section on page 40.

1.5 Bedside Unit Specifications

Physical Characteristics

Table 4: Physical Characteristics

Characteristic	Bed Sensing Unit	Chair Sensing Unit	Bedside Unit
Dimensions	Sensor: 300 X 210 X 6.45 mm With handles: 420.7 X 210 X 13.8 mm	300 X 210 X 6.45 mm	230 X 270 X 70 mm
Weight	730 gr	482 gr	2.1 Kg
Materials	ABS + Polycarbonate	ABS + Polycarbonate Inserted into cushion: **Cushion:** Visco elastic (dimension: 400 X 450 X 60 mm)	ABS + Polycarbonate

Electrical

Table 5: Electrical

Voltage Input Range	100–240 VAC, 50–60 Hz, 0.9A maximum
Battery	Rechargeable battery
Fuses	2 x 1 Amp
Isolation	Medical grade isolation between the Bedside Unit and the power supply

Operating Conditions

Table 6: Operating Conditions

Relative Humidity	30%–95% Non-condensing
Ambient Operating Temperature	Bedside Unit: 5–40°C (41–104°F) Sensing Units: 5–40°C (41–104°F)
Atmospheric Pressure	700–1,060 hPa

Storage and Transportation Conditions

Table 7: Storage and Transportation Conditions

Temperature Range	-20–50°C (-4–122°F)
Relative Humidity	10%–95% Non-condensing
Atmospheric Pressure	500–1,060 hPa

Cables Used with the Chair Sensing Unit and EarlySense System

Table 8: Cables

Connector Name	Connector Type	Type of Cable	Length (m)	# of Identical Connectors
Power Inlet 100–240 VAC	Standard	Unshielded	>3	1
Sensor Extension Cable	Sensor Extension Cable	Unshielded	≤ 12	2
SpO_2	G51MA3-PO3LPH9-0020	Unshielded	3	1
Nurse Call	TINI Q-G SwitchCraft	Unshielded	2.5	1
LAN	RJ45	Shielded	>3	1

WARNING

The use of accessories, transducers and cables other than those specified by the systems' specifications and supplied by the manufacturer can result in increased emissions or decreased immunity.

Measurements may be affected by cable lengths. Do not shorten or extend the lengths.

1.6 Additional Specifications

1.6.1 System Performance – Contact-free Sensor

Table 9: Performance Specifications

Respiratory Rate	Heart Rate	Movement
Range		
6–45 Br./min.	30–170 BPM	0, L, M, H, EH
Averaging Period		
1 Min	1 Min	15 Sec
Accuracy		
±4% or ±1.5 Br/min., whichever is greater	±4% or ±5 BPM, whichever is greater	
The system detects HR that is > 1.8 times the RR. Total system accuracy, including undetected signals is 90% for RR and for HR. Total system accuracy was measured as +/- 10% of the predicate device.		

Respiratory Rate	Heart Rate	Movement
Alert Thresholds		
Default: Low=8 Br./min. High=32 Br./min.	Default Alert: Low=40 BPM; High=130 BPM	Default: Low = 0% High = Extremely High movement > 1 minute
Min. – Max. Settable Alert Thresholds		
Low: 8 Br./min. High: 44 Br./min.	Low: 35 BPM High: 150 BPM	

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2 Set Up

This chapter describes the initial setup and configuration of the Bedside Unit and Sensor.

2.1 Positioning the System Components

2.1.1 Positioning the Bedside and Sensing Units

Bedside Unit

The Bedside Unit must be positioned close to the patient's bed. When a Bedside Unit is mounted on a wall or fixed to the rail, ensure that the wall mount is not placed directly above the patient's bed.

The Bedside Unit power cable must be able to reach a power outlet.

The Sensing Unit cable must be connected to the sensing unit on one side and be able to reach the side of the Sensor Connector on the Bedside Unit. Make sure that the Sensor cable is not trailing on the floor.

Sensing Unit

Place the Bed Sensing Unit horizontally under the patient's mattress and locate it underneath the chest area. The mattress should be at least 7 cm / 3 inch thick. Position the Sensor so that the top surface, which says *THIS SIDE UP* on its sticker, faces upwards, as shown below. The cord from the Sensor is not detachable, and should not lie on top or under the Sensor.

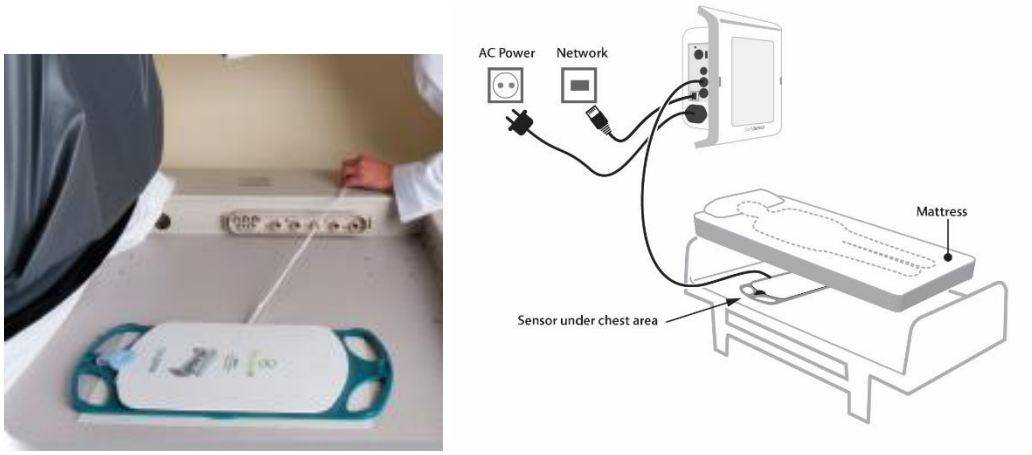

Figure 6: Positioning the Sensor and Bedside Units

Position the cord that connects the Sensor and the Bedside Unit so that it comes out from under the mattress at the head of the bed. Make sure that it does not interfere with the patient getting in and out of bed. If the Sensor is placed on framework that does not allow solid support for the Sensor, consult your authorized EarlySense representative.

WARNING

If you mount the Bedside Unit on a wall or fix it to a rail, ensure that the wall mount is not placed directly above the patient's bed.

CAUTION

The patient should not be in direct contact with the Sensing Unit. A mattress or mattress cover should always be placed as a barrier between the Sensing Unit of the EarlySense System and the patient.

CAUTION

Handle the Bedside Unit with care.

Do not drop, bang or shake the Bedside Unit. Rough handling can break the internal circuit boards.

NOTE Please ensure Sensor's correct positioning under the mattress. Misplacement of the Sensor might result in wrong readings and notifications.

2.1.2 Positioning the Chair Sensing Unit

Place the Chair Sensing Unit on a chair so that the top surface, which says *THIS SIDE UP* on its sticker, faces upwards. Secure the cushion to the chair's back using the strap. Position the cable so that it does not interfere with patient or staff movement in the room.

Figure 7: Example of Chair Sensing Unit Strapped to a Chair

2.2 Connecting the Bedside Unit

Connect the cables to the Bedside Unit connectors, shown below:

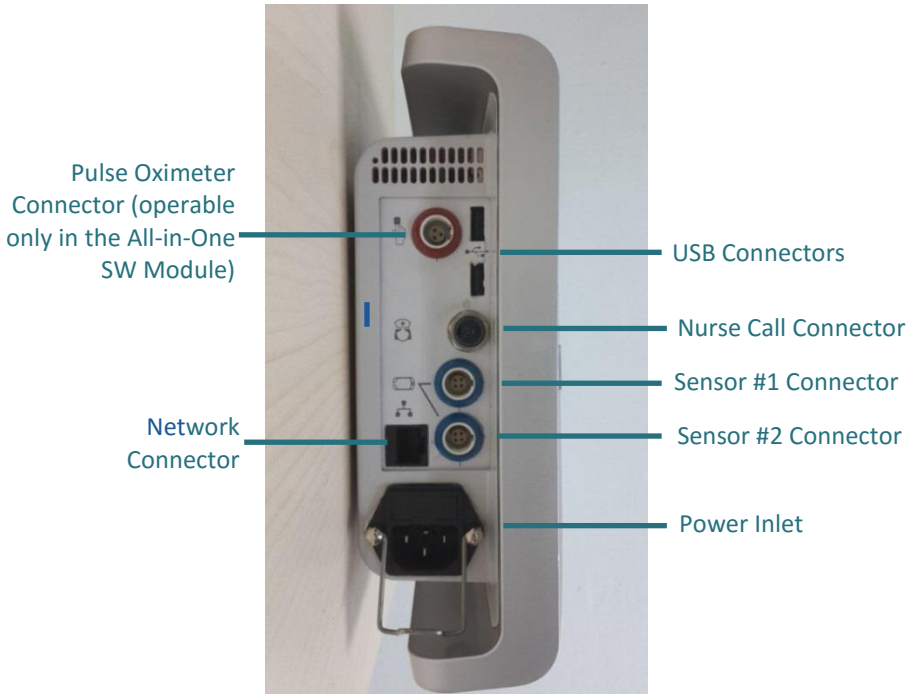

Figure 8: Bedside Unit – Side View

NOTE	The Bedside Unit can interface with existing nurse call systems in the institution. The actual connection to the nurse call system requires the support of the hospital's Biomedical Engineering department. The nurse call in the EarlySense System is a UL1069-compliant Nurse Call Relay Closure Connector – Supplementary Device.

2.3 Powering the Bedside Unit

Connect the Bedside Unit to a power outlet. The Bedside Unit power connector is shown above in Figure 8.

2.3.1 Battery

The system is internally powered by a battery that provides power in case of a power failure. During normal operation, the battery can operate for approximately three minutes if the Bedside Unit is unplugged from the electrical outlet or in case of a power failure.

The battery is automatically recharged by the system. You may refer to the *Battery Charge Indicator* section on page 45 for a description of the battery charge indicator at the top of the screen.

Do not attempt to replace the battery yourself. Should the battery lose its charge, it must only be replaced by an EarlySense authorized technician. Contact EarlySense Support Services for assistance.

NOTE	The system batteries function when the system is unplugged. In order to maintain the batteries with an adequate charge, make sure that the system is always plugged in to the electrical outlet during routine operation. During routine operation, the Bedside Unit should be always connected to AC Mains power.

NOTE	Do not discard this product. Contact your local authorized representative for additional information for collection and recovery programs available for this product and for appropriate facilities for recovery and recycling.

2.4 Turning the System On/Off

► **To turn the EarlySense System on:**

- Click the **On/Off** button on the side of the Bedside Unit (as shown in Figure 4). The *Admit* window is automatically displayed. After admitting the patient, the *Home* window is displayed.

► **To turn the system off:**

- Click the **On/Off** switch on the side of the Bedside Unit. The system asks you to confirm that it automatically discharges the patient. Confirm by clicking **Yes**.

2.4.1 Electrical Failure

In case of an electrical failure, the internal system battery can operate for approximately three minutes.

Check that the problem is not with the system itself by verifying that the power cable is not damaged and is connected both to the electrical outlet and to the Bedside Unit.

The battery icon displayed on the *Home* window indicates the status of the battery and whether the battery is being recharged.

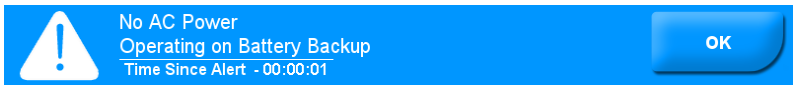

Figure 9: No AC Power Warning

2.5 Maintenance and Cleaning

The EarlySense System is designed to provide trouble-free, maintenance-free operation. The only maintenance required is to keep the system clean and dry and to verify that there is no physical damage to the Bedside Unit and to the Bed Sensing Unit.

- The Bed Sensing Unit should be replaced annually to ensure proper functionality of the system:
- For best Bedside Unit battery performance, it is recommended to replace the battery after two years of continuous use.
- In case of long-term storage (over two years), remove the battery from the equipment and store in a dry, cool place.
- Clean the air vents every 6 months or as needed in case the air vents are clogged.

2.5.1 Cleaning and Disinfection of the Bedside Unit

Please follow your institution guidance for bed cleaning, in order to clean the Bedside Unit. Cleaning detergents such as soft, wipes containing alcohol, Chlorhexidine, Peroxide and bleach material or slightly damp cloth/wipes containing anti-septic substances can be used. Avoid excessive liquids.

CAUTION

- Never open the Bedside Unit housing, as this may damage the system.
- Handle the Bedside Unit with care. Do not drop, knock, or shake the Bedside Unit. Rough handling can damage internal circuit boards.

2.5.2 Cleaning and Disinfection of the Sensing Unit

Please follow your institution guidance for bed mattress cleaning, in order to clean the contact-less Bed Sensing Unit. Cleaning detergents such as soft, wipes containing alcohol, Chlorhexidine,

Peroxide and bleach material or slightly damp cloth/wipes containing anti-septic substances can be used. Please ensure that the sensor is dry before re-use. Avoid excessive liquids.

CAUTION

Avoid placing liquids or food on any part of the system. Do not allow conductive fluids to leak into the active circuit components of the system, as this may cause a short circuit, which could result in an electrical fire. In case of fire, only fire extinguishers approved for use on electrical fires should be used.

ALL-IN-ONE MODULE

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3 All-in-One Module

This chapter describes the All-in-One module, its user interface and operation.

3.1 All-in-One Module Overview

The EarlySense System All-in-One module is designed to display and log Respiratory Rate (RR), Heart Rate (HR) and Movement parameters in an automatic, contact-free manner. The system is indicated for use in indoor environments. Monitoring of the patient begins automatically as soon as the patient gets into bed.

System design enables the user to set high and low threshold parameters that alert when the HR or RR cross predefined thresholds. The system can generate an alert if the patient leaves the bed (Bed Exit) or chair (Chair Exit), and enables the healthcare practitioner to document that he/she changed the patient's position in bed (bed only). The healthcare practitioner can document a patient's change of position on the Bedside Unit screen. The system then verifies the change in position and logs the information. The system can also notify healthcare providers when a certain amount of time (configurable) has passed since the last position change (timer expired). These notifications can be activated or deactivated based on the patient- or facility's policy .

Data is continuously displayed on the Bedside Unit *Home* window. The data obtained during the monitoring period is recorded by the system for offline presentation and printing. In addition, all of these functions are available when the patient is sitting in a chair, with the exception of Patient Turn.

The Bed Sensing Unit must be placed under the mattress, underneath the patient's chest area, and the system must be turned on. After the patient's ID and initials are entered into the system and the patient lies in bed or rests in a chair for approximately 60–120 seconds, the system begins to display the monitored values on the Bedside Unit *Home* window. The HR, RR and Patient Movement Level are continuously displayed on the screen. Heart and Lungs icons blink and their values display on the screen as long as their measurements are current.

3.2 Home Window

After the patient lies in bed or rests in a chair for approximately 60 – 120 seconds, the system begins to display the monitored values on the Bedside Unit *Home* window.

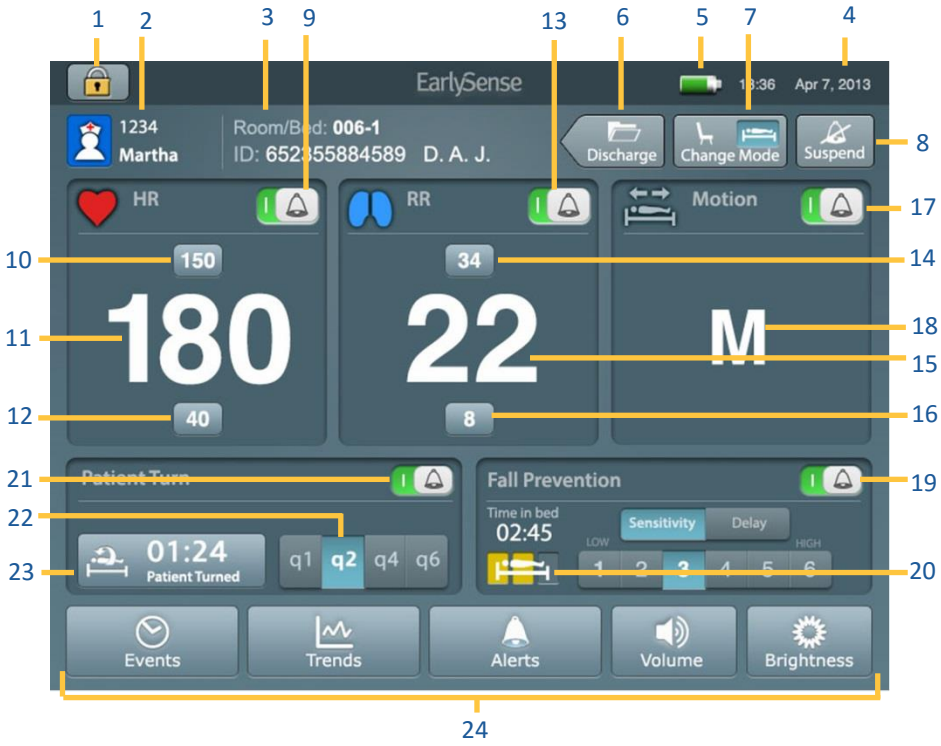


Figure 10: All-in-One Module Home Window

1 – Lock/Unlock status, page 44
2 – Nurse's details (Name, Ext. Number and assigned color), page 45
3 – Patient's details (Room and Bed numbers, ID, initials), page 45
4 – Date/Time
5 – Battery status/AC indicator, page 45
6 – Discharge Patient, page 46
7 – Change Mode between Bed and Chair, page 47
8 – Suspend Alerts button, page 61
9 – Enable/Disable HR Alerts, page 59
10 – Settable **High** HR Threshold
11 – Current Heart Rate
12 – Settable **Low** HR Threshold
13 – Enable/Disable RR Alerts
14 – Settable **High** RR Threshold
15 – Current Respiratory Rate
16 – Settable **Low** RR Threshold
17 – Enable/Disable Movement Alerts, page 70
18 – Current Movement Level (0, Low, Medium, High, Extremely High), page 70

19 – Enable/Disable Bed Exit Alert/Chair Exit Alert, page 65

20 – Bed/Chair Exit Settings, page 65

21 – Enable/Disable Patient Turns Counter, page 70

22 – Patient Turn Protocol Settings (q# - the counter time setting: 1 Hour, 2 Hours, 4 Hours, 6 Hours) indicating the number of hours between each reminder, page 70

23 – Patient Turn Counter: Time passed since last turn documented by healthcare practitioner, page 70

24 – Operational Buttons – To open additional screens for events (page 49), trends (page 50), alerts (page 61), brightness (page 55) and EarlySense settings (page 55)

3.3 Admitting a Patient

The *Admit Patient* window is automatically displayed on the screen when the system is turned on if no patient is currently admitted on this Bedside Unit, as shown below:

Figure 11: Admit Patient Window

NOTE	Upon installation, the room and the bed numbers in each individual Bedside Unit are configured by an EarlySense authorized technician. Relocation of the Bedside Unit to a different room or bed number should only be performed by an EarlySense authorized technician with the cooperation of the hospital's/clinic's Biomedical Engineering/IT personnel.

NOTE	After a patient has been admitted, patient identification details cannot be updated on the Bedside Unit.

► **To manually admit a patient:**

1. Enter the patient information in the *Admit Patient* window, as follows:

   - Enter the patient's name or initials (letters only) and ID (for example, Medical record number – MRN [alphanumeric only]) in the available fields.
   - The **ID**, **Room Number** and **Bed Number** must be entered for the patient to be admitted.
   - Mandatory fields are marked with an asterisk.
   - Select a nurse color in order to assign each patient to a nurse color. You may refer to the *EarlySense Central Display Station (CDS) User Guide* for more information about nurse colors.

   NOTE Only letters can be entered in the first, middle and last name fields and only alphanumeric characters can be entered in the ID field.

2. Click **Next** to open the *Patient Demographics* window, as shown below:

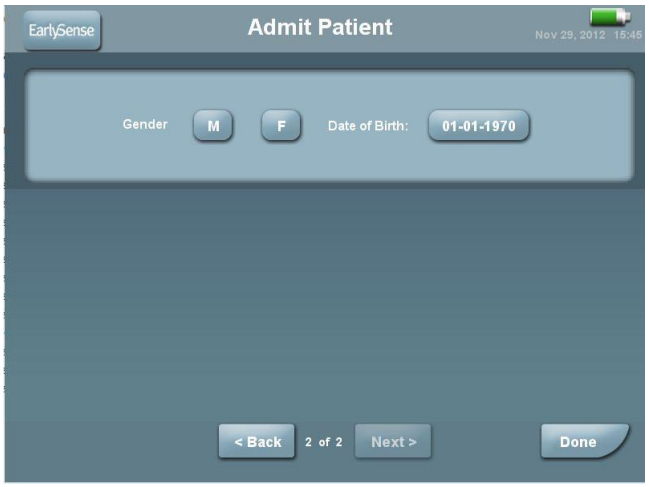


Figure 12: Admit Patient Window – Demographics

The following additional fields can also be entered, but are not mandatory:

- **Gender**: Select **M** or **F**.
- **Date of Birth**: Enter the patient's date of birth.

3. Click **Done**.

   NOTE The *Admit Patient – Demographics* window does not open unless a patient ID has been entered.

4. Click **Done** to complete admitting the patient.

5. The following windows are then displayed containing two settings-related questions:

   - **Question 1 – Do you want Bed Exit Alert for this patient?**:
     - Select **Yes** to enable the automatic Bed Exit alert with the default sensitivity level setting. This setting notifies the healthcare provider when the patient attempts to leave the bed.

- Select **No** to disable the Bed Exit alert.

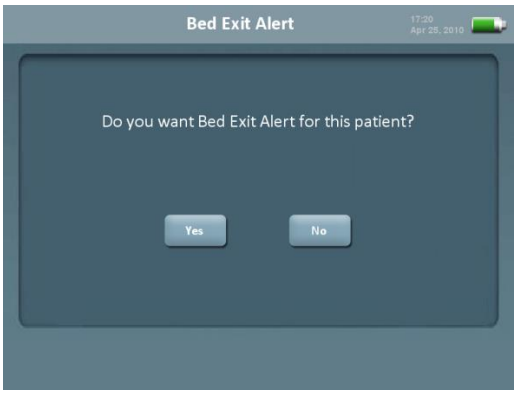


Figure 13: Bed Exit Alert Setting – Admission

- **Question 2 – Do you want a Patient Turn reminder for this patient?**
  - Select **Yes** to automatically enable the Patient Turn Counter with the default interval setting between patient turns.
  - Select **No** to disable the Patient Turn Counter.

If no response is given to these questions, after one minute the patient is admitted and the Bed Exit alert and the Patient Turn Reminder remain disabled.

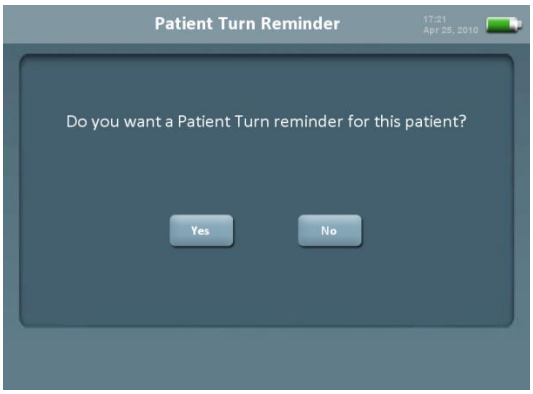


Figure 14: Patient Turn Setting – Admission

NOTE	The Admit process is not completed unless a healthcare practitioner actively verifies that the patient's information displayed on Bedside Unit's screen is correct and confirms the admission.

NOTE	Alerts are only generated after the patient lies still for one minute and either the heart rate or respiratory rate are displayed.

3.4 No Patient Admitted on the Bedside Unit

If a patient is detected in bed by the EarlySense System for 15 minutes or more, but no patient Admit process was completed (meaning that no name, initials or ID number were assigned to patient at the Bedside Unit) and if the EarlySense CDS is available and installed in your clinical setting, a message appears on the CDS, indicating that the patient has not been admitted.

NOTE	You may refer to EarlySense Central Display Station (CDS) User Guide for more information.

Measurements for HR, RR and movement are not displayed unless the patient identification parameters (ID/initials) are entered into the *Admit Patient* window and the admitting process is completed.

NOTE	Although no HR, RR or movement information is available on the display, the EarlySense System does detect bed entry and starts measuring movement. If the Bed Exit, Patient Turn or Movement parameter is enabled by default and system ready (3.26), alerts are generated and displayed and sounded. Monitored information of non-admitted patients is not saved and any information other than alerts is not communicated.

NOTE	The Admit process is not completed unless a healthcare practitioner actively verifies that the patient's information, as displayed on Bedside Unit's screen, is correct and confirms the Admit.

3.5 Unlocking the Bedside Unit Screen

The *Home* window is displayed showing the monitoring data and providing access to additional menus. Selections are made by clicking the screen.

For any interaction (except for responding to alerts), the window must be unlocked. The Bedside Unit automatically locks after a configured period of time.

► **To unlock the screen:**

- Click the  button in the top left of the window. If you click the touch screen while the system is locked, the lock icon flashes red.

Figure 15: Lock/Unlock

3.6 Nurse and Patient Details

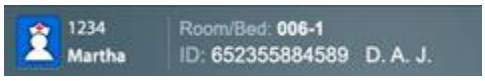


Figure 16: Patient Details

This area specifies the name, the extension number and the color coding of the nurse currently assigned to this patient. This indicates the nurse whose pager/phone is notified of this patient's alerts. The nurse responsible for a patient is determined during patient admission and can only be changed on the CDS.Refer to the *EarlySense Central Display Station (CDS) User Guide* for more information.

This area also specifies the patient details including the room/bed, patient ID and patient initials.

NOTE If you enter incorrect patient details by mistake, you can discharge the patient and then complete the admission process again for that patient.

3.7 Battery Charge Indicator

The following table shows the battery status indications.

Table 10: Battery Status Indication

Green (with lightning)		Battery is charging and is connected to a power outlet. The lightning symbol on the battery indicates that the battery is charging.
Green		Battery is charging, but is disconnected from a power outlet.
Orange		System is disconnected from a power outlet, and the battery is not charging.
Red		Battery is almost empty. The system is about to shut down.

After Electrical Power is Restored

1. Ensure that the system is plugged into the electrical outlet.
2. Turn the system on by clicking the **On/Off** switch on the side of the Bedside Unit (as shown in Figure 4).

   If a patient was already admitted, the *Home* window is automatically displayed and the system continues its monitoring session.

   The Internal battery automatically recharges when the electrical power is restored. If system operation is not restored, contact EarlySense Support Services.

3.8 Discharging a Patient

► **To manually discharge a patient and end the patient's monitoring session:**

1 Click **Discharge** in the *Home* window. The *Discharge Patient* window is displayed as shown below:

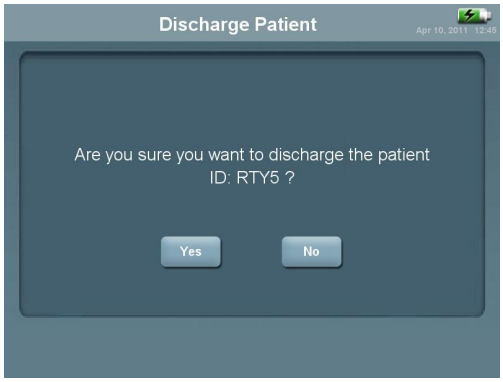


Figure 17: Discharge Patient Window

2 Click **Yes** to confirm discharging the patient from the EarlySense monitoring session.

You may refer to the *Electronically Discharging a Patient* section on page 171 for a description of how a patient can be automatically discharged on the Bedside Unit by the HIS system.

WARNING

To avoid recording patient data under erroneous identification, perform the discharge procedure before beginning the monitoring of a new patient.

3.9 Chair Mode Option

In addition to monitoring a patient in bed, the system allows monitoring of a patient while resting in a chair.

By default, the system is set to Bed Mode. The **Change Mode** button shows the mode that is currently active (Bed or Chair), as shown below:

Figure 18: Bed Mode

NOTES	Both a Chair Sensor and a Bed Sensor can be connected at the same time to the Bedside Unit, but only one sensor can provide monitoring. If an EarlySense technician configured the system to work only in Bed mode or Chair mode, then this button is not enabled.

► **To change to Chair Mode:**

1. Place the Chair Sensing Unit on a chair and secure the straps.
2. Connect the cable from the Chair Sensor to the Bedside Unit.
3. Click the **Change Mode** 

button to toggle the selection to the chair icon. The following displays:

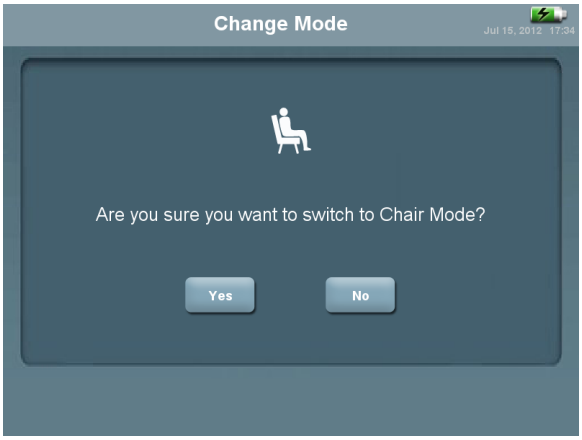


Figure 19: Confirming Chair Mode

If **Yes** is clicked, chair mode appears on the *Home* window.

NOTE	A Patient Turn reminder is not available when activating the Chair Mode monitoring option. The caregiver responsible for the patient should continue implementing their standard pressure ulcer prevention policy while the patient is in a chair.

The following shows the monitoring window in Chair Mode:

Figure 20: Chair Mode – All-in-One Module

NOTES

Both a Chair Sensor and a Bed Sensor can be connected at the same time to the Bedside Unit.

The **Change Mode** button shows the mode that is currently active (Bed or Chair).

If both Chair mode and Bed mode are enabled on the Bedside Unit, but the **Change Mode** button is set to Chair, then even if the patient is lying in bed, the icon shows that the patient is out of the chair. In this case, you might see a notification that patient signal is detected in bed.

If Chair mode is set to alert when the patient is out of the chair, the Bedside Unit generates an alert, even if the patient is in bed.

3.10 Events Button – Manually Recording an Event

This option is not available in the **Safety** module.

The following describes how to manually indicate that an event occurred. These events are recorded in the system with a timestamp and can be viewed in the *Trends* window.

► **To access the Events menu:**

1. Click the **Events** 

button at the bottom of the *Home* window. The **Events** menu displays, as shown below:

Figure 21: Events Window

2. Click one of the four primary events on the left or one of the secondary events on the right. The button changes color, showing that it was successfully selected. The following message appears: **Recording Event: <Event Name>**.
3. Click the **Home** button at the top of the window to confirm your selection and close the window, or **Cancel** to cancel your selection.

The following events are available:

- Primary Events:
  - Emerg. Med.: Emergency medication given when patient is in distress
  - CPAP/BPAP
  - Intubation
  - Patient Round
- Secondary Events:
  - Patient Fall
  - Continuous Med.: Routine medication
  - Pain Relief Med.: Pain relief medication
  - Patient Agitation
  - Skin Breakdown:
  - General Flag 1: Marks any event of type 1 that is not included in the list of events

3.11 Trends Button – Trends Graph

This option is not available in the **Safety** module.

The following describes how to display patient measurement trends in graphical form.

► **To display a trend graph:**

- Click the **Trends** 

button at the bottom of the *Home* window. The following displays:

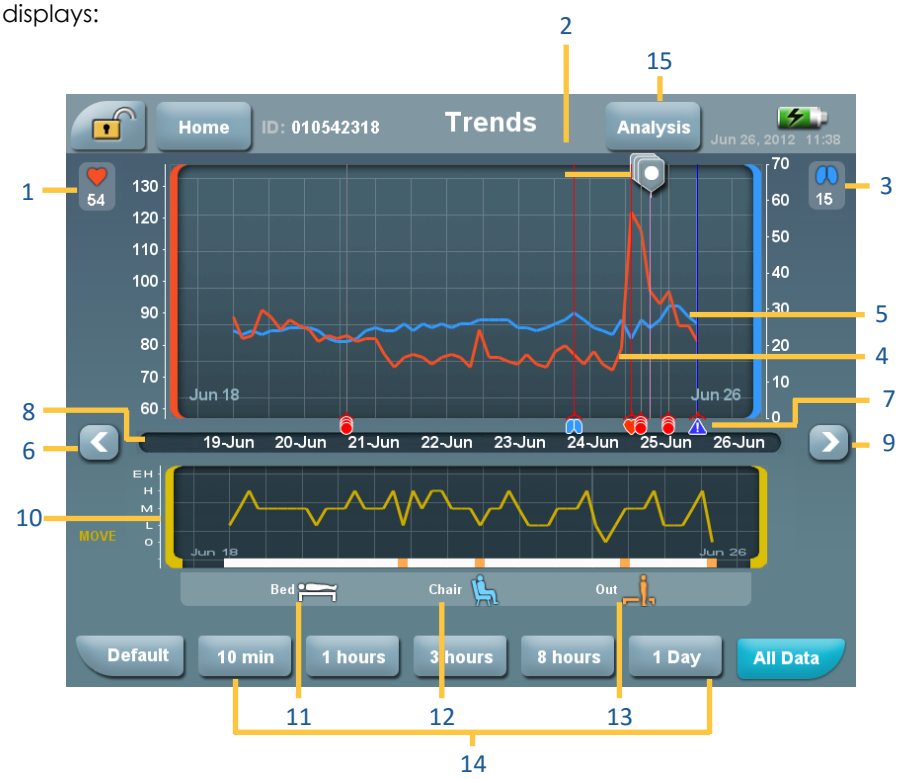


Figure 22: Viewing Patient Trends

1 – **Current Heart Rate –** Current Heart Rate in beats per minute.

2 – **Events –** Displays events that users have manually entered for documentation during the time displayed.

3 – **Current Respiratory Rate –** Current Respiratory Rate in breaths per minute.

4 – **Heart Rate Trend –** Displays Heart Rate in beats per minute (graph) during the time displayed.

5 – **Respiratory Rate Trend –** Displays Respiratory Rate in breaths per minute (graph) during the time displayed.

6 – **Scroll Back –** Click here to scroll back.

7 – **Alerts –** Displays alerts that occurred during the time displayed.

8 – **Time Scale –** Time scale for data presented.

9 – **Scroll Forward –** Click here to scroll forward.

10 – **Movement Trends –** Shows patient's movement level while in bed during the timescale presented (See page 73).

11 – **Bed –** Shows the time intervals patient spent in bed (in white)

12 – **Chair –** Shows the time intervals patient spent in chair (in blue).

13 – **Out –** Shows the time intervals when patient has been out of bed/chair (in orange).

14 – **Time Period Buttons (10 min, 1 hour, 3 hours, 8 hours, 1 day) –** Click one of these buttons to change the time period displayed in the graph.

15 – **Analysis Screen –** Opens the *Analysis* window (Figure 23).

► **To scroll forward or backwards within the time frame:**

- Click the forward (>) or back (<) arrows.

3.11.1 Alert Symbols

The following symbols may be displayed on the Trend graphs.

Table 11: Alert Symbols

Icon	Meaning
	Blue Alerts: Technical alerts, such as System Malfunction, Sensor Malfunction and Low Battery
	High/Low Heart Rate: Red Alert
	High/Low Respiratory Rate: Red Alert
	Movement Level High: Yellow Alert
	Lost Patient Signal: Red Alert
	Unstable Signal: Red Alert
	Patient Turn Counter: Yellow Alert
	HR and RR above thresholds: Red alert
	Out of Bed/Chair: Red Alert

3.11.2 Event Symbols

The following event symbols are used in Trend graphs.

Table 12: Event Symbols

Icon	Meaning
	Patient Round
	Intubation
	Patient Fall
	Emergency Medication.
	Continuous Medication – Routine Medication
	Patient Agitation
	Skin Breakdown.
	**General Flag 1:** Marks any event of type 1 that is not included in the list of events
	**Patient Turn:** Inserted automatically if a staff member clicked the **Reset** button on Patient Turn Counter.

3.11.3 Setting the Timescale

When entering the *Trends* window, the default timescale displayed is **All Data** (for up to seven days). You can return to this timescale at any time by clicking the **Default** button. Use the buttons under the graph to determine the timescale displayed. If you select a larger timescale, the current time that is in the center of the timescale remains the center point. If you select a shorter timescale, you are prompted to click the screen to determine where you would like the displayed timescale to appear on the screen.

NOTE The *Trends* window shows up to seven days of trend data.

3.11.4 Analysis

The **Analysis** button enables you to display the average respiratory rate, heart rate and movement time (%) for a specified interval each day. The following displays:

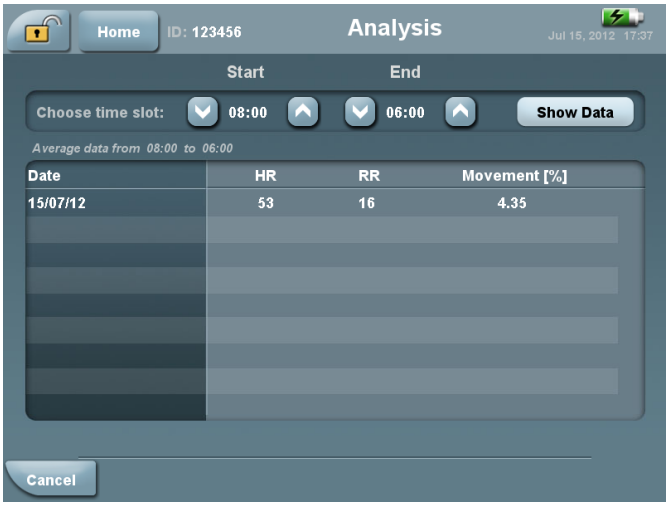


Figure 23: Analysis Window

Use the arrows to set the preferred time slot and then click the **Show Data button**. The data displays in the table.

3.11.5 Trend Indication

The **Trends** button turns red when the system detects a change in the trend of a patient's vital signs, including HR, RR or changes in the signals' patterns.

If the Bedside Unit is connected to an EarlySense CDS, the patient is also highlighted on the CDS screen.

Figure 24: Trend Indication

The **Trends** button remains red until the patient is discharged from the Bedside Unit.

3.12 Setting Alert Volume and Tone

The following describes how to configure the alert settings (such as volume and tone) of specific types of alerts.

► **To configure specific types of alerts:**

1 Click the **Alerts** button at the bottom of the *Home* window (see Figure 10). The *Alerts Setup* window is displayed, as shown below, showing the current configuration of all types of alerts:

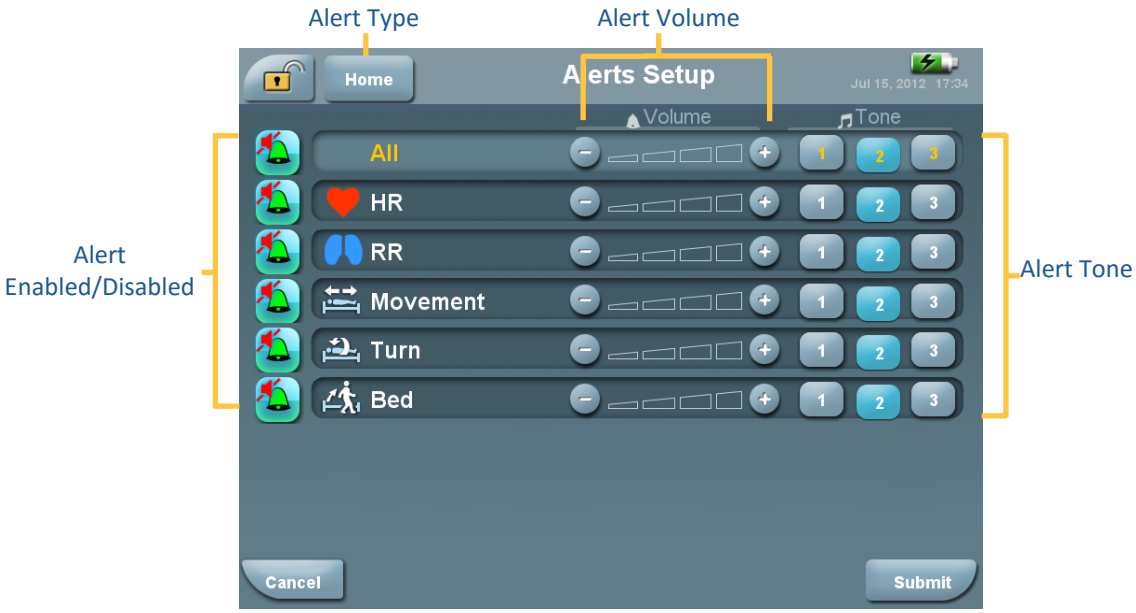


Figure 25: Alerts Setup Window

2 Click the **Plus** (**+**) or **Minus** (**-**) button to adjust the volume for each type of alert.

3 Click either the **1**, **2** or **3** button to select an alert tone.

4 Click the Bell icons to enable or disable specific alerts.

Table 13: Alerts Status Table

Enabled	Enabled and Silenced	Disabled
		

5 Click **Submit** to activate the settings or **Cancel** to preserve the existing settings.

NOTE In addition to changing the individual alert volumes, as described above, you can also change the general volume of all alerts on the Bedside Unit by setting the volume and tone of all alerts in the *Alerts Setup* window (page 55). Alert volumes are determined by whichever parameter (**General** or **Alert**) was set last.

NOTE When a patient is admitted or discharged, all alert settings return to their default settings.

WARNING An Audible Alert in the EarlySense System is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

3.13 Setting Bedside Unit Alert Volume

The following describes how to set the volume of all alert tones. The alert volumes are determined based on whichever of two parameters (**General** or **Alert**) was last set. The volume and tone for individual alerts can also be set, as described on page 54.

At startup and after admitting a new patient, the system returns to its default alert settings (silent alert). Alert settings automatically return to their default settings after discharging the patient.

▶ **To set the General Volume:**

1. Click the **Volume** button in the *Home* window. The **Volume** button then changes to appear as follows:

Figure 26: General Volume

2. Click the **Plus** (**+**) button to raise the volume or the **Minus** (**-**) button to lower the volume.

   When the volume is set to mute, the **Volume** icon is marked with an X and a mute sign appears on the alerts' **Bell** icons.

3.14 Setting Bedside Unit Alert Brightness

▶ **To adjust screen brightness:**

1. Click the **Brightness** button on the *Home* window.
2. Click the **Plus** (**+**) or **Minus** (**-**) button to adjust the brightness.

Figure 27: Brightness Adjustment

If the brightness level is set to the lowest level, the screen may appear black during daylight. Touch the screen and then continue to click the **Brightness** button to increase the screen's brightness.

3.15 Visual Alert Indications

The following figures show a visual alert, as it appears in the *Home* window. The area of the window indicating the measurement of concern is highlighted in red or yellow and a red or yellow message displayed at the bottom of the window, as shown below:

Figure 28: Home Window with Alert Indication – All-in-One Module

Click **OK** to acknowledge the alert or the **Suspend** button to suspend all alerts for 15 minutes.

3.15.1 Alert Indicators

Both sides of the Bedside Unit have an alert indicator that lights up according to the color of the alert, meaning blue, red or yellow. You can click either of them to acknowledge the alert.

Figure 29: Bedside Unit Alert Indicators

WARNING

Active RED indicator light, requires an immediate response to understand the nature of the Alert.

Active YELLOW indicator light, requires prompt response to understand the nature of the Alert.

3.16 Alert Sound Notification

The Bedside Unit sounds and alerts to notify personnel of situations that may require attention. The EarlySense System enables you to define and adjust alert configurations/settings. Audible and visual alert notifications are generated according to several settings.

When an alert is generated, an audible alert is sounded unless the volume is muted (lowest volume level), as described on page 55. By default, alerts at the Bedside Unit are silent, but may be audible on the CDS.

You may refer to the *Setting Bedside Unit Alert Volume* section on page 55 for a description of how to control the alert volume of all the alerts on the Bedside Unit.

You may refer to the *Setting Alert Volume and Tone* section on page 54 for a description of how to control the alert volume and tone of specific types of alerts on the Bedside Unit.

WARNING

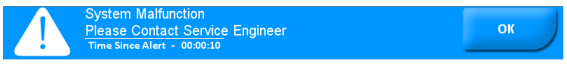
The Audible Alert in the EarlySense System is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

3.17 Alert Visual Notifications

When an alert is generated a visual notification displays on screen.

A message is displayed at the bottom of the window describing the nature of the alert and the elapsed time since the alert was activated, as shown below:

Table 14: Visual Alert Notifications

Key	Example
Blue Alerts	
Red Alerts	
Yellow Alerts	
Grey Notification Message	

3.17.1 Alert Colors

The background color of the alert corresponds to the alert priority in the following order: blue, red, yellow or gray. Blue alerts relate to a system problem and are not connected to a specific patient monitoring parameter.

3.17.2 Multiple Alerts

When more than one alert is generated for the same patient at the same time, only the highest-priority alert is active. Only one alert can be active at a time.

The following are a few examples:

- When a Yellow Alert (such as, low patient movement) is generated while a Red Alert is active (such as an HR), then only the Red Alert is shown.
- When a blue alert is generated while a red alert is in progress, then the blue alert is shown.
- When an HR or RR (red) alert is active (displayed on screen) and not acknowledged by the user, the Bed Exit alert is not generated when a patient exits the bed. This means that no other alert of the same priority or lower is generated.

A new alert becomes active only if the currently active alert has a lower priority.

NOTE Different types of alerts with the same priority cannot be generated when the same priority alert is still active. Make sure not to leave patients unattended who may be at risk of falling.

3.18 Alert Triggers

Table 15 describes alert triggers.

Table 15: All-in-One Module Alert Triggers

Default Status	Alerts
Heart Rate	ON
Respiratory Rate	ON
Heart Rate and Respiratory Rate (multiple parameters)	ON
Movement	OFF
Patient Turn Counter	OFF
Bed Exit	OFF
Chair Exit	OFF

3.19 Enabling/Disabling Alerts

An *Enabled Alert* means that the alert is displayed and will sound on the Bedside Unit.

An *Enabled and Silenced Alert* means that the alert is displayed, but will not sound on the Bedside Unit.

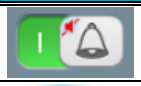
A *Disabled Alert* means that the alert is not displayed and will not sound on the Bedside Unit or the CDS.

If an alert is disabled while the alert is going off, the alert message remains active until it is acknowledged by a healthcare practitioner.

► **To disable/enable alerts for specific parameters:**

- Click the bell symbol next to the alert in either the *Home* window (described on page 40) or the *Alerts Setup* window (described on page 54).

Table 16: Alerts Status Table

Window	Enabled	Enabled and Silenced at Bedside	Disabled
Home Window			
Alerts Setup Window			

The following is displayed when the Bed Exit alert is being disabled. To disable the alert, click **Yes**.

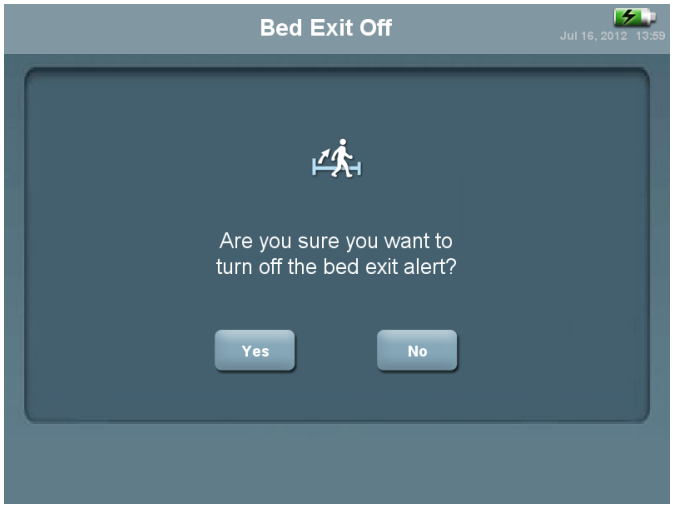


Figure 30: Bed Exit Off Window

The following is displayed when an HR alert is being disabled. To disable the alert, click **Yes**.

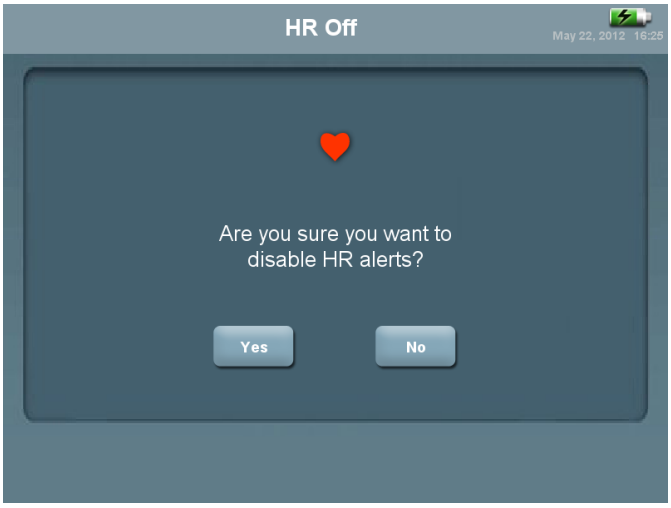


Figure 31: HR Off Window

The following is displayed when an RR alert is being disabled. To disable the alert, click **Yes**.

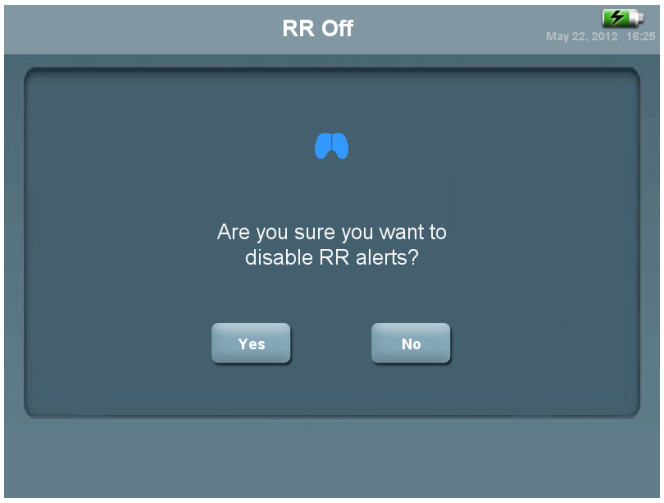


Figure 32: RR Off Window

The following is displayed when the Patient Turn Counter Alert is being disabled. To disable the alert, click **Yes**.

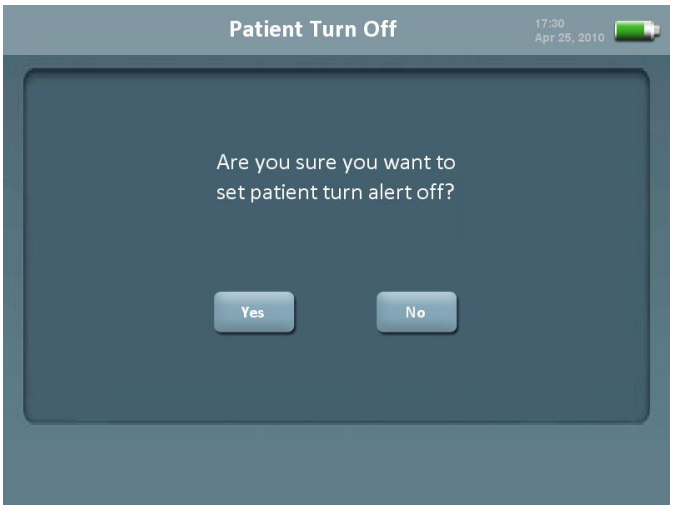


Figure 33: Patient Turn Off Window

► **To enable alerts:**

- Click the Bell symbol again.

3.20 Suspending Red and Yellow Alerts

The sounding and display of all Red and Yellow alerts can be suspended, meaning that the system does not generate any patient alerts, as follows:

- Click the **Suspend** button on the top right of the screen. An **Alert Suspension Timer** icon appears on the *Home* window and on the CDS screen, which suspends all Bedside Unit alerts for 15 minutes.

Figure 34: Alert Suspension Timer – All-in-One Module

- To stop the suspension of alerts, click the **Suspend** button again.
- After 15 minutes, if no one clicks the **Suspend** button again, the alert suspension is automatically terminated and new alerts are sounded and displayed again when the applicable alerting condition recurs or if it still exists.

NOTE Blue alerts cannot be suspended.

3.21 Handling Blue Alerts

Blue alerts represent a technical system problem, (not a patient problem), and are therefore handled differently than red and yellow alerts.

Blue alerts appear with an **OK** button or **Pause** button and remain active as long as the alert condition exists. Blue alerts disappear only after the technical issue is resolved and cannot be suspended.

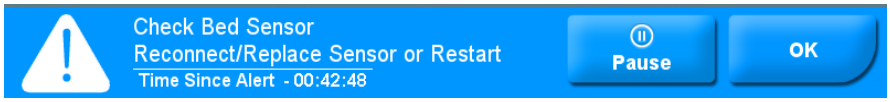


Figure 35: Blue Alert – Check Sensor (Bed Mode)

3.21.1 Blue Alerts – Pausing Patient Monitoring

The **Pause** button in the Blue Check Sensor Alert message temporarily stops patient monitoring. The **Pause** button can be used only when the Sensor is temporarily disconnected from the Bedside Unit in order to avoid a blue *Check Sensor* technical alert from going off. For example, this function should be used when the patient needs to be transported with his/her bed and therefore the Sensor must be disconnected from the Bedside Unit.

Monitoring of the patient can be resumed at any time, and all the previous trends are then displayed as usual.

► **To pause patient monitoring:**

- Click the **Pause** button when a blue alert appears. A *Pause* window displays, as shown below:

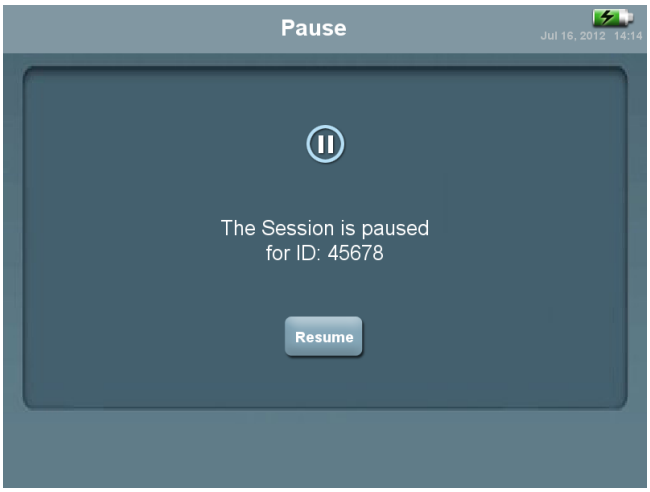


Figure 36: Pause Window

► **To continue patient monitoring:**

- Click the **Resume** button in the *Pause* window or connect a Sensor.

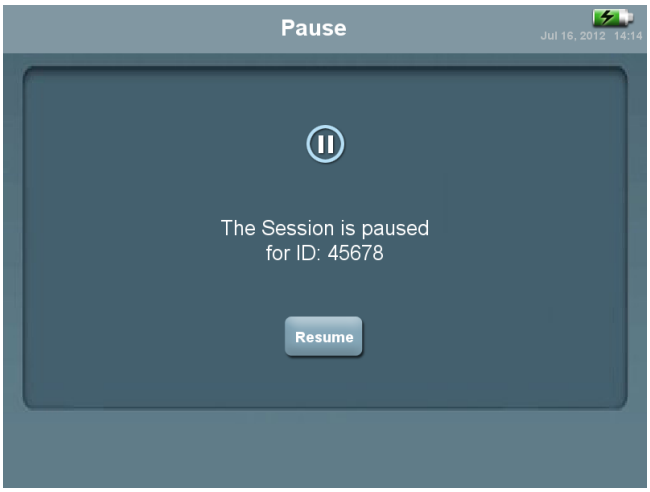


Figure 37: Pause Window

3.22 Modifying HR and RR Alert Thresholds

When beginning to monitor a new patient, it is advisable to set patient-specific alert thresholds.

► **To change the default HR and RR thresholds:**

1. Click the upper or lower thresholds in the HR and RR areas. Arrows appear, as shown below.

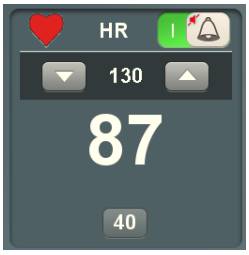


Figure 38: Adjusting the HR Upper Threshold

2. Click the  arrow to lower the threshold or the  arrow to raise the threshold.
3. When you reach the required threshold, click the displayed number or wait. If the new value is different from the default value, a red rim highlights the new threshold.

   The following are the lowest and highest threshold values that you can enter:

Table 17: Threshold Range Settings

	Lowest Settable Limit Threshold	Highest Settable Limit Threshold
Heart Rate	35 BPM	150 BPM
Respiratory Rate	8 Br/min	44 Br/min

3.23 Multiple Parameters Alert – HR and RR Above Thresholds

EarlySense can be configured to provide an alert if both HR and RR measurements exceed predefined thresholds for a specified amount of time. The thresholds and time periods should be configured by EarlySense Technician to suit specific patients' conditions, in accordance with hospital policy.

The alert notification text, as it appears on the Bedside screen, can also be modified to support hospital/clinic policy.

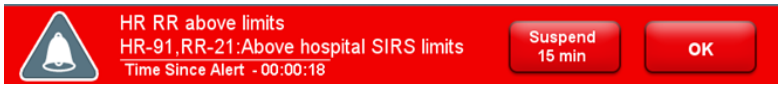


Figure 39: Multiple Parameters Alert

NOTE In order to adjust alerting thresholds and alert notification text, as they are to appear on screen, contact your authorized field service representative.

3.24 Motion Level and Bed Occupancy

When the patient is detected in bed, in addition to the HR and RR display, the Motion Level, In-Bed Occupancy and the **Time in bed** counter are displayed, as shown below:

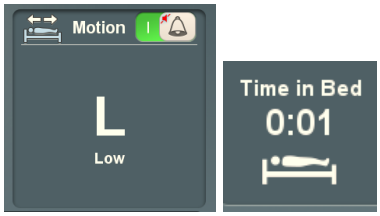


Figure 40: All-in-One Module – Bed Occupancy

When the patient is out of bed, no HR, RR or motion is displayed. An **Out of Bed** icon is shown and the **Out of Bed** counter is displayed, as shown below:

Figure 41: Bed Occupancy – Out-of-Bed Status

The **Time in Bed** counter starts as soon as a patient signal is detected. After the patient exits the bed, the **Out of Bed** counter starts automatically.

The **In/Out of Bed** icon appears when the system is set to Bed mode. The **In/Out of Chair** icon appears when the system is set to Chair mode.

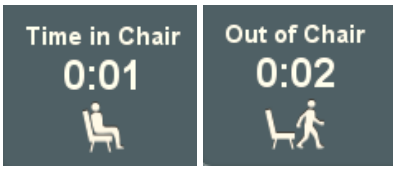


Figure 42: Chair Occupancy

3.24.1 Night Restlessness Indicator

During night hours (which are predefined), up to three yellow bars may be displayed in the background of the **In-Bed** icon. This icon visually indicates the patient's rest level. A fuller bar may indicate that the patient is more restless and more likely to exit the bed, thus serving as a pre-bed exit indication. No bar or one bar indicates a higher rest level and indicates that the patient is less likely to leave the bed.

Figure 43: All-in-One Module – Night Restlessness Indicator

3.25 Fall Prevention (Bed Exit)

The EarlySense System tracks whether there has been a Bed Exit. This alert is disabled by default.

► **To enable Bed Exit alerts:**

- Press the **Bell** icon to move it to the position shown below:

Figure 44: Fall Prevention Settings – Alert Enabled

NOTE If the patient is allowed to get out of bed without healthcare practitioner notification, you can disable the Bed Exit alert by clicking the bell in the Fall Prevention area.

► **To configure the Fall Prevention settings:**

1. Click **Sensitivity** or **Delay** 

to select the type of Fall Prevention alert. Clicking the **Sensitivity** button generates an alert as soon as the patient leaves the bed, based on the sensitivity that you select, as described below.

2. Select the sensitivity level by clicking one of the number buttons – **1** is the least sensitive and **6** is the most sensitive, as shown below:

Figure 45: Bed Exit Sensitivity

NOTES	Bed Exit levels can be set from level 1 (the least sensitive) to level 6 (the most sensitive), as described below. Use your clinical judgment and the patient's condition as governing criteria when setting the level between level 1 and level 6. Note that sensitivities 5 and 6 are highly sensitive and might be triggered due to excessive patient movements while in bed or in a chair.

3. Click the **Delay** button to generate an alert after a certain amount of time passes since the patient left the bed.

4. Select the time to alert by clicking one of the minute buttons. The default delay intervals are **5'**, **15'** or **30'**. The time intervals can be predefined in the *Technician* window by an EarlySense technician.

3.26 Bed Exit Not-Ready Indicator

When the Fall Prevention Alert is enabled, a short period of time is required by the system before a Bed Exit Alert can be generated. During this time, the **Fall Prevention Alert** icon status shows a Not-ready indication, as follows:  .

This icon also appears if the patient is out of bed.

NOTE	Even though alerts may sometimes be triggered when Bed Exit is still in a Not Ready status, Bed Exit alerts should NOT be expected before the Bed Exit turns Ready (meaning when the Not Ready indication disappears.

3.26.1 System-Wide Night Bed Exit Mode

The entire EarlySense System can be preconfigured for Night Bed Exit mode by an EarlySense technician. This feature automatically enables the Bed Exit alert for all patients (only for night hours) who currently have the Bed Exit alert disabled. The Nighttime period is preconfigured by a technician, based on user preferences.

NOTE During the night hours, you can see the patient status by observing the Night Restlessness Indicator.

The system exits the Night Bed Exit mode in the following cases:

- End of nighttime period (as preconfigured for a Bed Exit alert in the *Technician* window).
- A change in the Bed Exit setting (such as sensitivity) made by the user during night hours. For example, if the default sensitivity for a Night Bed Exit setting is 1, and this setting is changed by a healthcare practitioner during the night, then the regular Bed Exit setting with the newly set sensitivity applies instead of the Night Bed Exit setting.

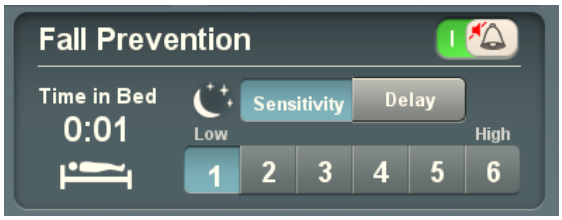


Figure 46: Night Bed Exit – All-in-One Module

You can disable the Night Bed Exit mode while it is active by touching the Bell icon on the Bedside Unit. This only disables the mode for that same patient during that same night. The mode is activated again the next night. Night Bed Exit mode is indicated by a dark background and a Moon icon.

3.26.2 Patient and Mattress Calibration Option

If the option is activated, calibration of the system to a specific patient and mattress can be performed using the procedure described below, which may enhance Bed Exit performance (for example, reduce nuisance bed exit alerts). The option can be inactivated at any given moment by pressing the "Clear calibration button."

► **To calibrate:**

1. Make sure that the patient is lying still in bed.
2. Click the **EarlySense** EarlySense button.
3. Click the **Calibrate** Calibrate button. The following displays during calibration:

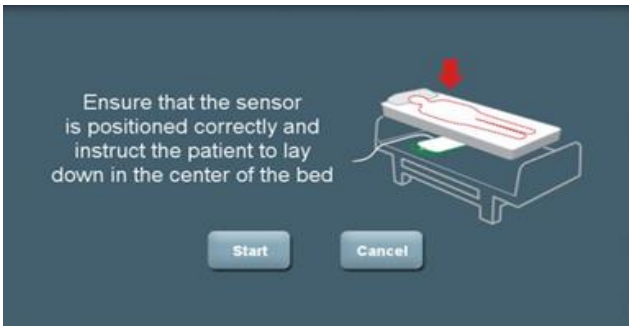


Figure 47: Patient and Mattress Calibration – 1

Figure 48: Patient and Mattress Calibration – 2

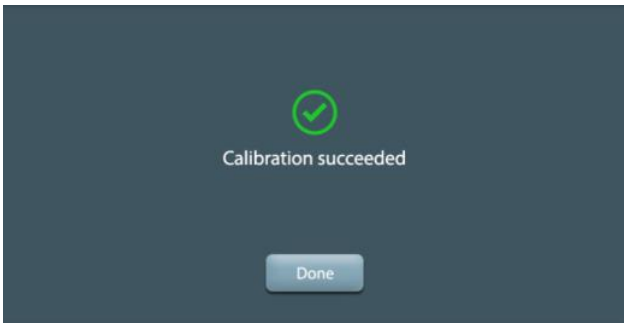


Figure 49: Patient and Mattress Calibration – 3

If the calibration was not performed successfully, the following displays:

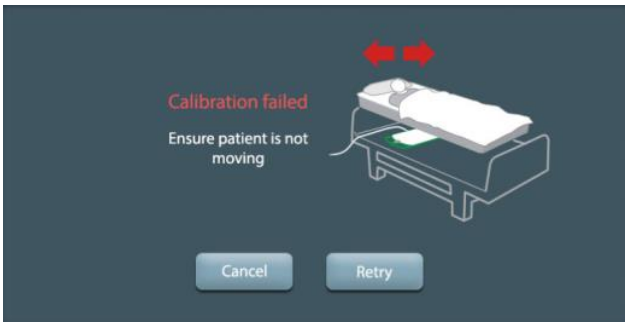


Figure 50: Patient and Mattress Calibration – 4

Figure 51: Patient and Mattress Calibration – 5

If calibration is performed while no sensor is connected, the following displays:

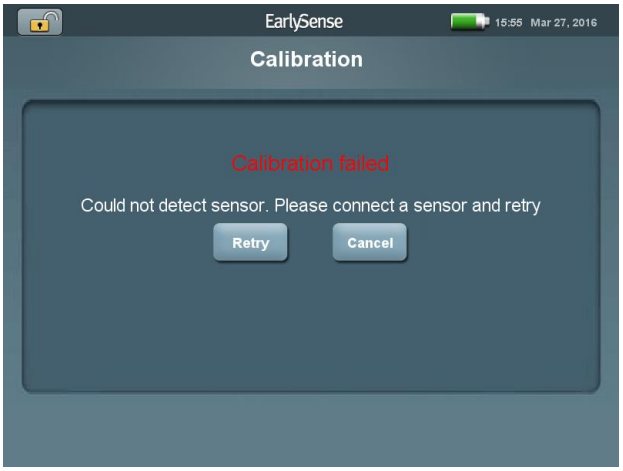


Figure 52: Patient and Mattress Calibration – 6

If calibration is performed while Chair mode is in use, the following displays:

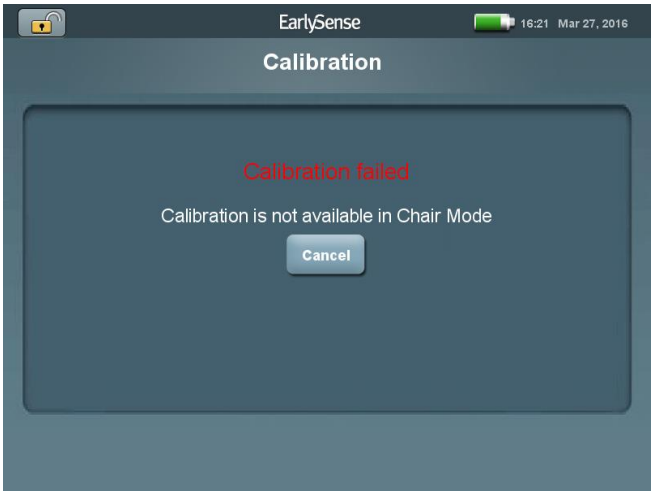


Figure 53: Patient and Mattress Calibration – 7

3.27 Patient Turn

Patient Turn is used to document the change of a patient's position in bed and to generate an alert if the interval set for changing the position has been exceeded (timer expired). The Patient Turn alert is disabled by default.

3.27.1 Configuring the Time Interval between the Turn Reminders

The Patient Turn Interval is referred to as **q**.

- **q1** means every hour.
- **q2** means every two hours.
- **q4** means every four hours.
- **q6** means every six hours.

For example, if you want the system to generate a reminder to turn the patient every two hours, click **q2**.

The turn interval buttons are predefined in the *Technician* window by an EarlySense technician.

► **To change the time interval between the turn reminders:**

- Click the applicable **q** button in the **Turn Period** field in the *Home* window.

Figure 54: Setting the Patient Turn Interval

3.27.2 Starting the Patient Turn Counter

- **To enable and disable the Patient Turn counter:**

  Touch the **Bell** icon in the Patient Turn section in the *Home* screen. The counter is then enabled (Figure 56).

- **To disable the counter:**

  Press the **Bell** icon again (Figure 55).

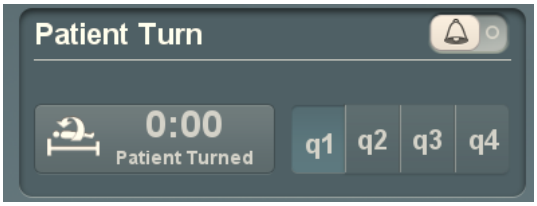


Figure 55: Patient Turn Field – Disabled Counter

Figure 56: Patient Turn Field – Enabled Counter

3.27.3 Documenting Patient Turn and Resetting the Counter

After turning the patient, press **Patient Turned** after the patient was turned. The system logs the event (Figure 57) and resets the time counter. In addition, the system detects the corresponding change in body movement and verifies the event. This verification appears in the printed report for the same day (see *Sample Reports*, page 81).

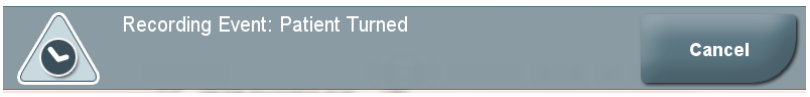


Figure 57: Recording Patient Turned Event

If the Patient Turn interval passes without the **Patient Turned** button being pressed, a Patient Turn alert occurs (Figure 60), indicating that the counter has exceeded its time threshold. The alert message disappears by pressing **OK** or by pressing **Patient Turned**. If **OK** was pressed, but the **Patient Turned** button is not pressed within 15 minutes, the alert is generated again. Counter will reset if patient exists bed before selected q expired.

Figure 58: Patient Turn Alert Screen

If the Patient Turn alert is turned off and an air mattress is being used, the following message displays (Figure 59).

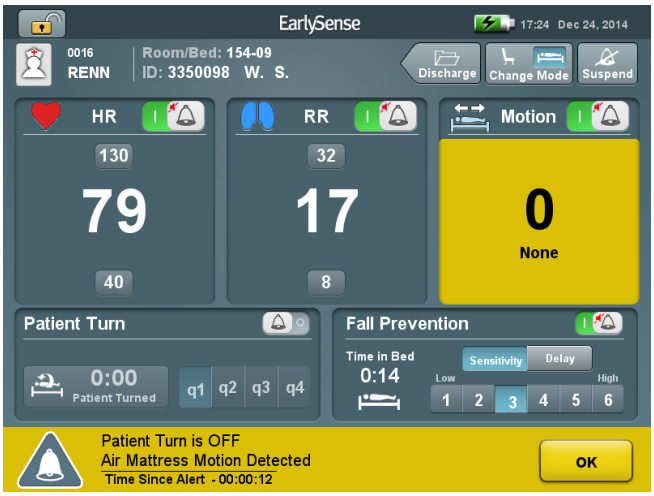


Figure 59: Air Mattress Motion Detected

After you press **OK**, you are asked if you want a Patient Turn reminder for the patient (Figure 60).

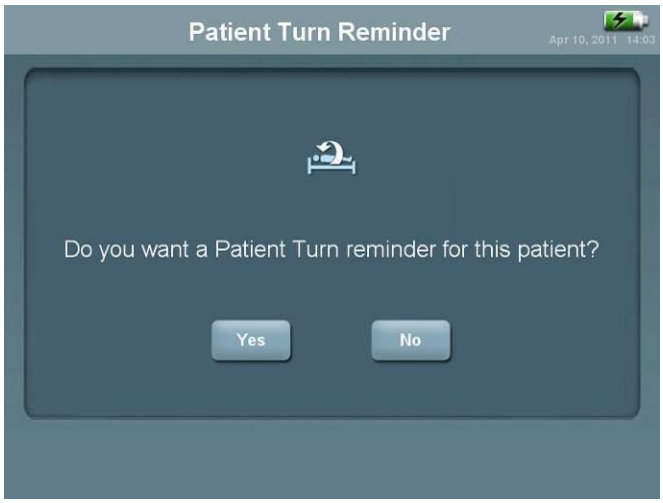


Figure 60: Patient Turn Reminder

In addition, if an air mattress is not being used and a Turn Counter Exceeded alert is generated, you may want to consider using an air mattress. This message may display once every 24 hours.

3.28 Patient Movement

Movement rates are determined based on the percentage of movement time within a defined period of time, as described in Table 18. The accuracy of the System in displaying different rates is also presented below.

Table 18: All-in-One Module Patient Movement Rates

Rate	Percentage of Movement During Defined Period	Accuracy of Rates Displayed for Adults	Accuracy of Rates Displayed for Children
0	0	100%	100%
L	Up to 40%	100%	100%
M	40–60%	81%	81%
H	60–80%	100%	86%
EH	80–100%	96%	94%

Trend data for patient movement over time can be viewed in trend graphs, as described in the *Trends Button – Trends Graph* section on page 50.

3.28.1 Low Patient Movement Alert

Movement alerts are displayed in cases of low and extremely high movement. An alert for low movement (Figure 61) may come up once a day at 6:00 AM (or as predefined by the user). If during the night (00:00−6:00), the amount of patient movement was below a certain threshold, it may imply that the patient is at risk for developing pressure ulcers. When dismissing a low-movement alert, you are asked whether you want a Patient Turn Reminder for this patient.

Figure 61: Low Patient Movement Alert

3.28.2 Patient Motion Detection

If while using the Patient Turn Reminder, the system detects additional patient movement during the night, the following recommendation is made following the first Turn Reminder in the morning (Figure 62).

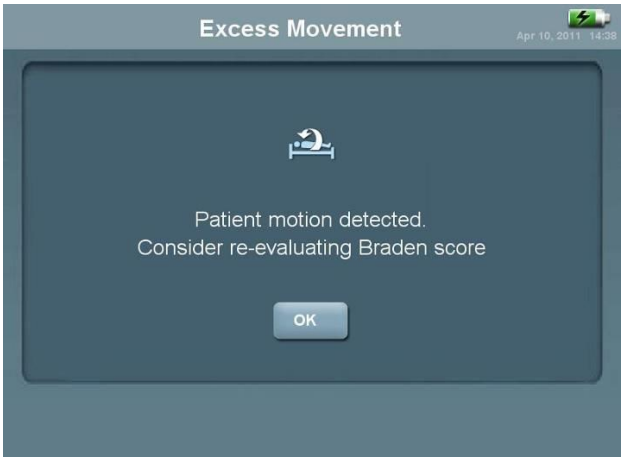


Figure 62: Patient Movement Detected

3.29 Gray Figures Display

If the system cannot detect or measure the current HR or RR for more than one minute, the last measured HR or RR is displayed on the window in gray with a measurement timestamp, and the blinking Heart or Lungs icon stops blinking, as shown below:

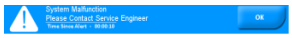
Figure 63: Gray Values of HR and RR

3.30 System Messages and Alerts

There are four types of System messages and alerts.

Table 19: All-in-One Module System Messages and Alerts

Example	List of Messages/Alerts in This Category	Description
	High/Low HR.	HR exceeds thresholds.
	High/Low RR.	RR exceeds thresholds.
	Multi-parameters Alert (HR and RR Above Thresholds)	System detected that both Heart Rate and Respiratory Rate exceeded predefined thresholds as set by the healthcare practitioners.
	High/Low SpO_2 (optional).	SpO_2 exceeds thresholds.
	Lost Patient Signal.	System cannot detect patient's signal. Check patient and sensor location.
	Unstable Signal.	The signal was not continually detected. Consider using alternative monitoring.
	Bed Exit/Chair Exit.	System detected that a patient is about to leave bed/chair. Available in six different sensitivities (1= Lowest and 6=Highest).
	Patient Out of Bed/Chair.	System detected that the patient is out of the bed/chair for a time interval exceeding a preset threshold.
	Extremely High Motion.	Patient Movement Rate has been extremely high during the last minute.
	Patient Turn is Off – Low Patient Movement at Night.	Patient Movement Level has been very low during night hours (00:00-6:00). Consider setting the Patient Turn reminder to on.
	Patient Turn is Off – Air Mattress Motion Detected.	Air Mattress operating on the bed. Consider setting the Patient Turn reminder to on.
	Turn Counter Exceeded.	Threshold time interval for turning the patient expired.
	Patient is in Chair More Than X Hours	Threshold time interval for turning the patient expired (in Chair Mode only).

Example	List of Messages/Alerts in This Category	Description
 Technical Alert: Indicates that there is a technical problem with the system.	Check Sensor (connection, position or location)	Indicates that the Sensor connection is malfunctioning or that the Sensor is disconnected. This may indicate that the location or the position of the Sensor is incorrect or upside down. (See Troubleshooting, page 173).
	No AC Power.	An alert indicating that the EarlySense 2.0 Bedside Unit is disconnected from the electrical power. Reconnect the EarlySense 2.0 Bedside Unit to the electrical power outlet. Otherwise, the Bedside Unit shuts down. (See *Troubleshooting*, page 172)
	Very Low Battery.	An alert indicating that the battery is low and that the system is about to shut down. Reconnect the Bedside Unit to the main electrical power. (See *Troubleshooting*, page 172)
	System Malfunction.	Technical alert indicating that the system is malfunctioning. Contact a Field Service Engineer. (See *Troubleshooting*, page 172)
	Sensor is about to expire within 30 days.	Technical alert indicating that this sensor will stop functioning within 30 days. Press **OK** to eliminate the message and to continue the monitoring session.
	Sensor Expired.	Technical alert indicating that this sensor has stopped functioning and should be replaced.
 Functional Message – Informative message	Patient not admitted.	The system detected a signal in bed, but no patient information was entered.
	No Patient Detected for X Hours.	The system did not detect a signal for X hours, although no patient discharge was performed.
	Signal is Detected in Bed.	The Bedside Unit is in Chair mode, but HR/RR or movement is detected in the bed.
	Recording Event.	The system is currently recording an event. A visual icon displays in the *Trends* screen.

3.30.1 Alerting Parameters (Contact-free Sensor)

Table 20: All-in-One Module Alerting Parameters

	Low Heart Rate	High Heart Rate
Time to alert for change in HR	90 seconds	90 seconds
	Low Respiratory Rate	**High Respiratory Rate**
Time to alert for change in RR	180 seconds	180 seconds

Alerts are generated by the system if heart rate or respiratory rate averages exceed predefined thresholds for above listed amount of time.

3.31 Generating Reports (Data Retrieval)

Reports can be downloaded at the Bedside Unit or printed at the Central Display Station (CDS), as described in the *EarlySense Central Display Station (CDS) User Guide*). To ensure the privacy of the patient's medical data, a PIN may be required before reports can be downloaded or printed.

The data can be downloaded either as a CSV file or as a complete report in Acrobat PDF format. For a CSV file, the data can be viewed by a clinician using standard software. For example, Microsoft Excel™. The data is presented numerically. The clinician can use the provided data and Excel to generate any other graph that is required.

Some of the reports generated by the system can be sent to users via email.

WARNING

The data acquired by the EarlySense System must only be interpreted by a healthcare practitioner.

3.31.1 Downloading Patient Data and Reports

► **To download patient data and reports:**

1. Insert a USB disk drive with at least 0.5 GB of free space into the USB slot. If the disk drive is already inserted, it must be removed and re-inserted before starting the data download procedure.
2. Click the **EarlySense** icon and then the **Maintenance** tab. The following is displayed:

Figure 64: Advanced Window – Maintenance Tab

3. Click the **Download Report** button. The following window is displayed:

Figure 65: Enter PIN Window

4 Enter a PIN (Personal Identification Number) and then click **Submit**. The following message is displayed at the bottom of the window indicating that downloading has started.

Figure 66: Downloading in Progress Message

The system automatically downloads the data (CSV file) and the report (PDF file) of the last two admitted patients.

A message displays when the download completes.

Sample reports are available on page 81.

3.31.2 Sample Reports

The following figures show a sample Patient Status report, which can be downloaded as described in the *Downloading Patient Data and Reports* section on page 79. This report can also be printed via the CDS. Refer to the *EarlySense Central Display Station (CDS) User Guide* for more details.

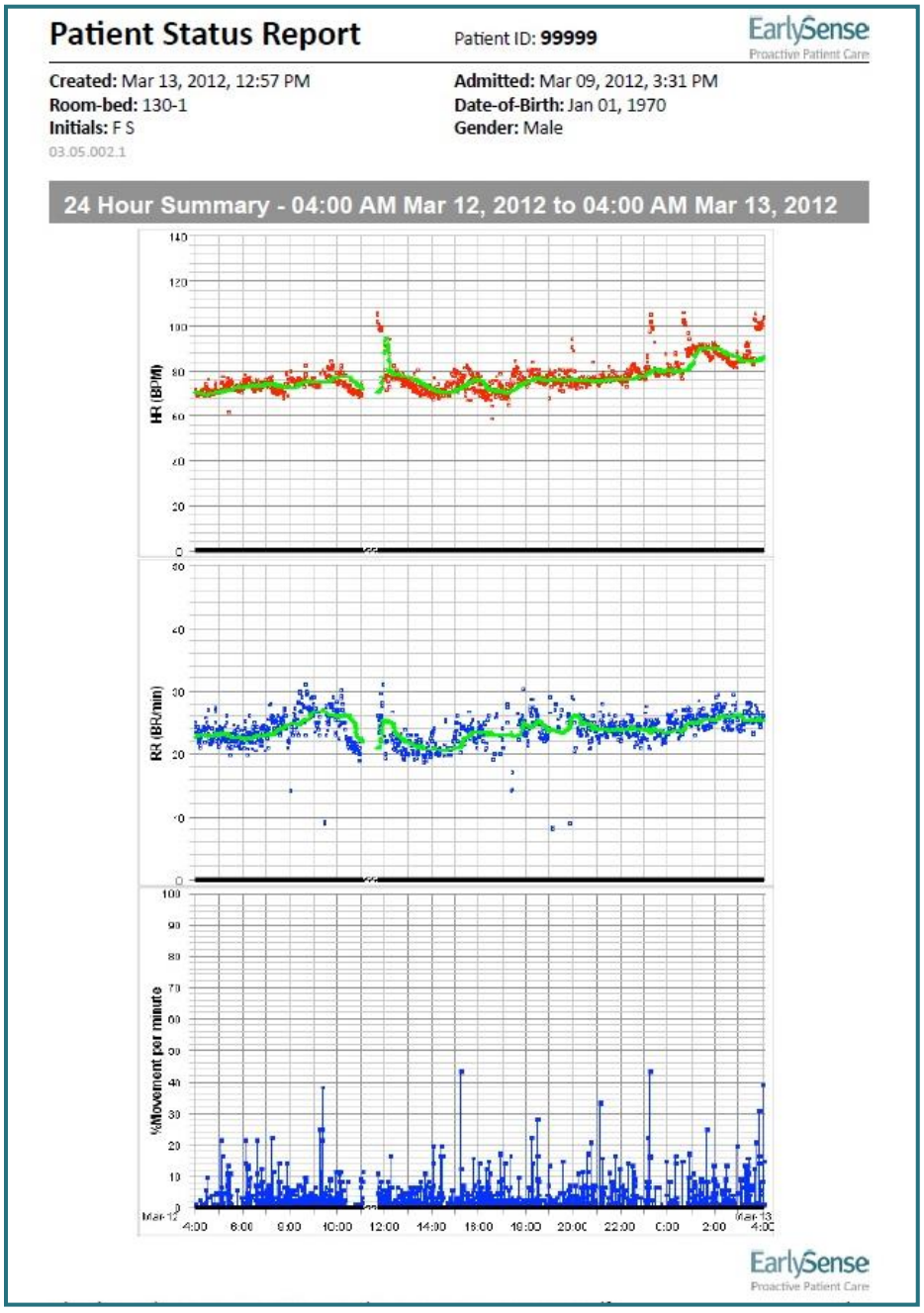


Figure 67: All-in-One Module – Patient Status Report – 1

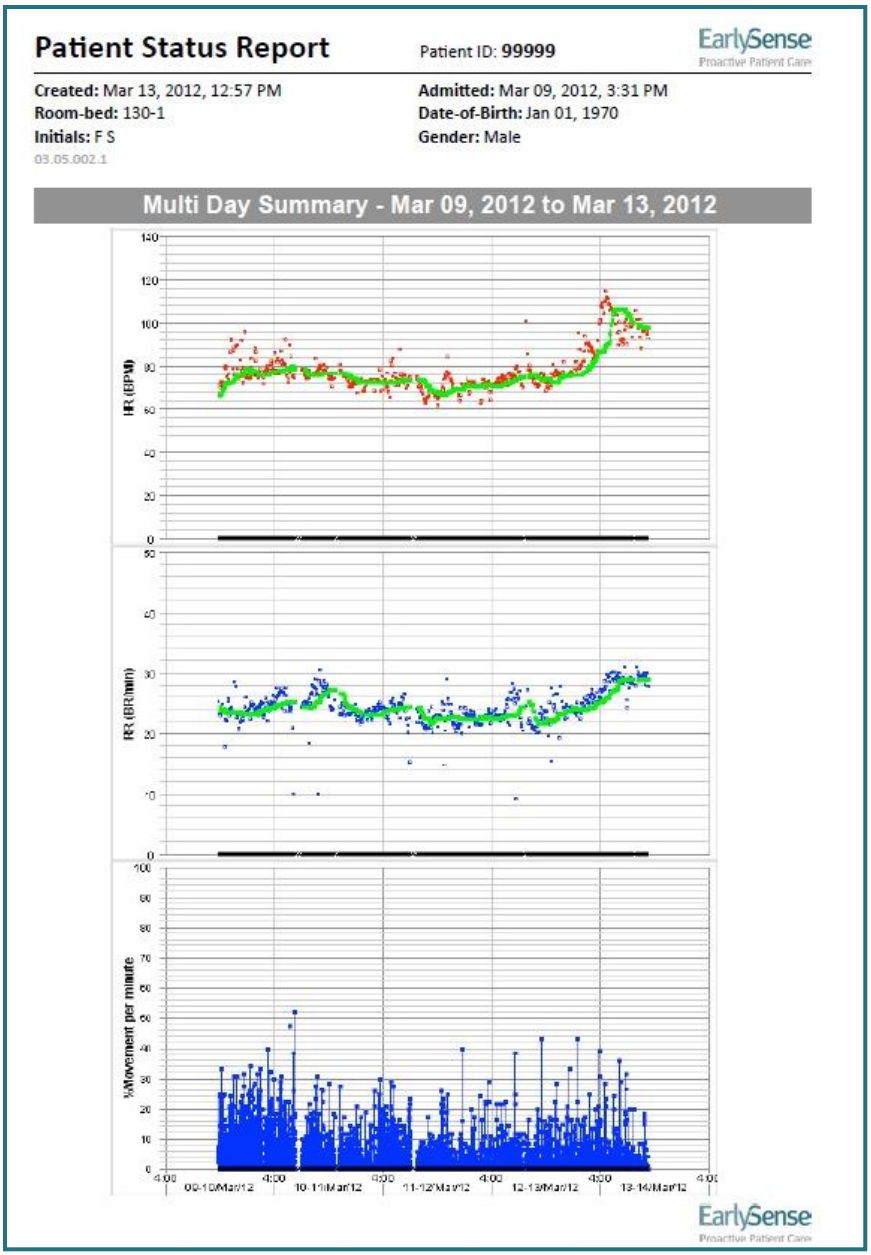
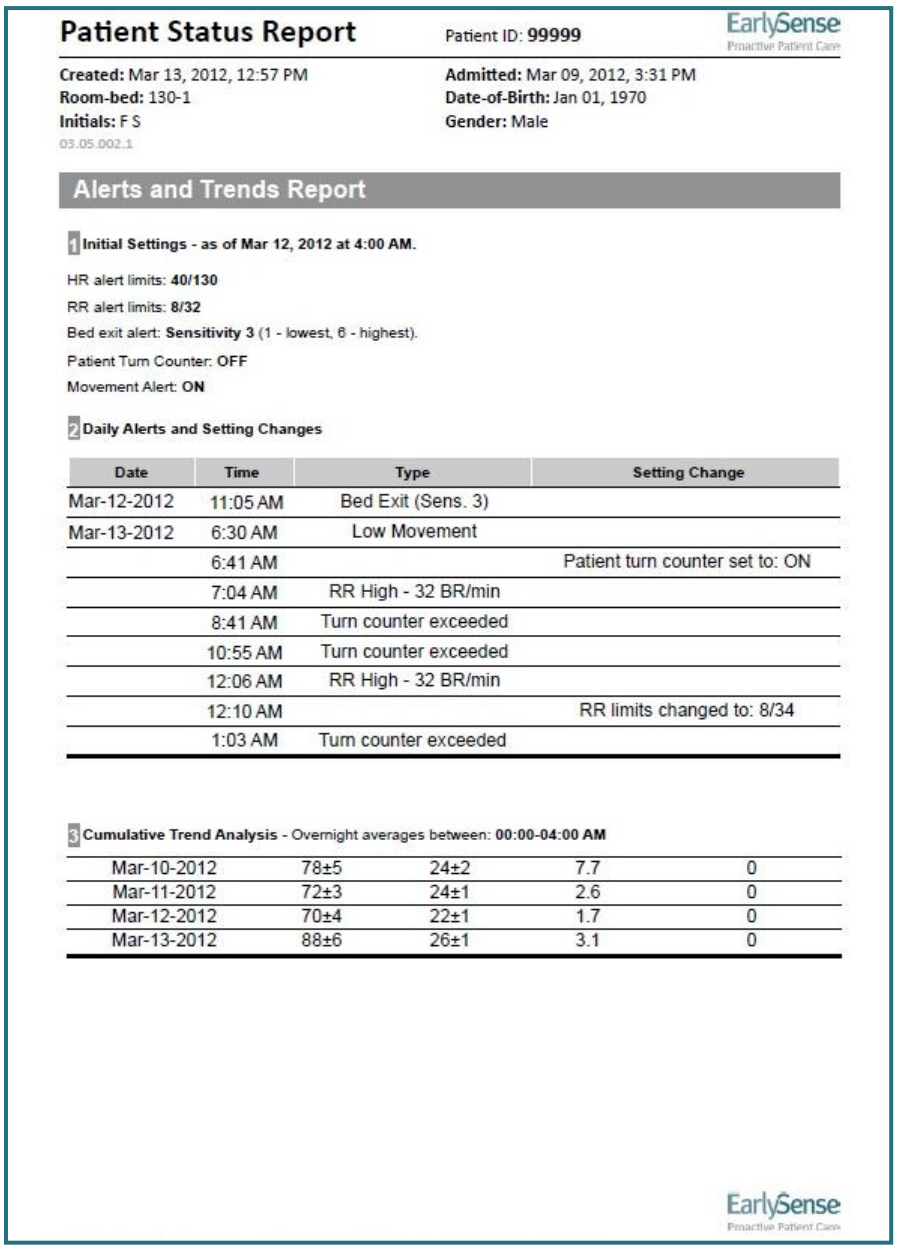


Figure 68: All-in-One Module – Patient Status Report – 2



Patient Status Report Patient ID: **99999**

EarlySense Proactive Patient Care

Created: Mar 13, 2012, 12:57 PM
Room-bed: 130-1
Initials: F S
03.05.002.1

Admitted: Mar 09, 2012, 3:31 PM
Date-of-Birth: Jan 01, 1970
Gender: Male

Alerts and Trends Report

1 Initial Settings - as of Mar 12, 2012 at 4:00 AM.

HR alert limits: **40/130**
RR alert limits: **8/32**
Bed exit alert: **Sensitivity 3** (1 - lowest, 6 - highest).
Patient Turn Counter: **OFF**
Movement Alert: **ON**

2 Daily Alerts and Setting Changes

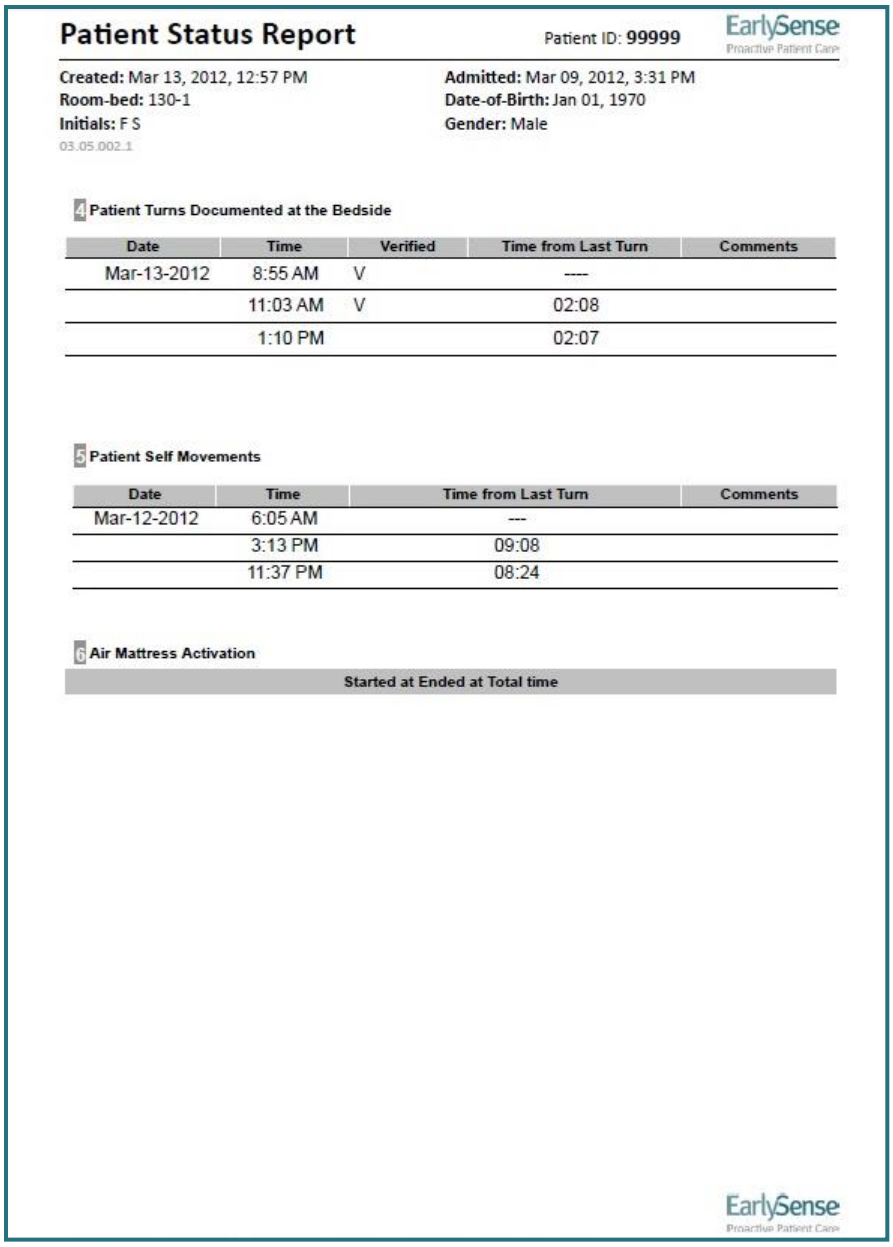
Date	Time	Type	Setting Change
Mar-12-2012	11:05 AM	Bed Exit (Sens. 3)	
Mar-13-2012	6:30 AM	Low Movement	
	6:41 AM		Patient turn counter set to: ON
	7:04 AM	RR High - 32 BR/min	
	8:41 AM	Turn counter exceeded	
	10:55 AM	Turn counter exceeded	
	12:06 AM	RR High - 32 BR/min	
	12:10 AM		RR limits changed to: 8/34
	1:03 AM	Turn counter exceeded	

3 Cumulative Trend Analysis - Overnight averages between: **00:00-04:00 AM**

Mar-10-2012	78±5	24±2	7.7	0
Mar-11-2012	72±3	24±1	2.6	0
Mar-12-2012	70±4	22±1	1.7	0
Mar-13-2012	88±6	26±1	3.1	0

EarlySense Proactive Patient Care

Figure 69: All-in-One Module – Patient Status Report – 3



Patient Status Report

Patient ID: **99999**

EarlySense
Proactive Patient Care

Created: Mar 13, 2012, 12:57 PM
Room-bed: 130-1
Initials: F S
03.05.002.1

Admitted: Mar 09, 2012, 3:31 PM
Date-of-Birth: Jan 01, 1970
Gender: Male

4 Patient Turns Documented at the Bedside

Date	Time	Verified	Time from Last Turn	Comments
Mar-13-2012	8:55 AM	V	----	
	11:03 AM	V	02:08	
	1:10 PM		02:07	

5 Patient Self Movements

Date	Time	Time from Last Turn	Comments
Mar-12-2012	6:05 AM	---	
	3:13 PM	09:08	
	11:37 PM	08:24	

6 Air Mattress Activation

Started at	Ended at	Total time

EarlySense
Proactive Patient Care

Figure 70: All-in-One Module – Example of Printed Report (PDF File)

3.32 Optional Oximeter Module

Pulse Oximetry is offered as an option. It can be used for continuous monitoring or for spot checks. An optional standard Oximeter module is only available if the All-in-One module is installed.

A standard OEM Pulse Oximeter module may be provided as an external accessory, which can be connected to the Bedside Unit In order to enable continuous oxygen saturation monitoring for patients. This option is available only if the Oximeter Sensor is connected to the Pulse Oximeter module and to the patient's finger, according to the Sensor's usage directions.

3.32.1 Standard OEM Pulse Oximeter Module

The following OEM Oximeter Module is the standard incorporated in the provided system: Nonin XPod® with compatible Sensors. You may refer to *Appendix C, Nonin XPod® OEM-compatible SpO_2 Sensors* on page 176 for a list of compatible Sensors.

Oximetry works by applying the Pulse Oximetry Sensor to a pulsating arteriolar vascular bed, such as a finger or a toe. The Sensors contain a dual light source and a photodetector. A list of Nonin Xpod-compatible Sensors is available in *Appendix C, Nonin XPod® OEM-compatible SpO_2 Sensors* on page 176.

The OEM Oximeter connector is connected to the Bedside Unit, as shown below:

Figure 71: Nonin Xpod Pulse Oximetry Module

Figure 72: Sample Pulse Oximeter Sensor to be Attached to the Fingertip

The components shown in Figure 71 and Figure 72 must be connected to each other. For directions about how to correctly attach the Oximeter Sensor to the finger, refer to the Sensor's usage instructions.

3.32.2 Oximetry Window

The Oximetry function is only enabled when the Sensor is connected to the Bedside Unit. In this case, the following window is displayed automatically showing the saturation level measured on the Bedside Unit screen.

Figure 73: Oximetry Window

1 – Enable/Disable Pulse Oximeter's Alerts.

2 – Settable High SpO_2 Alert Threshold (for oxygen saturation level).

3 – Current Oxygen Saturation Level (%SpO_2) Threshold (for oxygen saturation level).

4 – Settable Low SpO_2 Alert Threshold (for oxygen saturation level).

3.32.3 Oximetry Alert

When the SpO_2 level exceeds the upper or lower threshold, an Oximetry alert displays.

Figure 74: Oximetry Alert

Click **OK** to acknowledge the alert or the **Suspend** button to suspend the alerts for 15 minutes.

NOTE The HR displayed by the Oximetry module cannot be used for alert purposes.

3.32.4 Connecting the Pulse Oximeter

NOTE If the EarlySense Sensor that is placed under the bed/mattress is not connected to the Bedside Unit, the Pulse Oximeter cannot be used as a standalone unit.

► **To connecting the Pulse Oximeter:**

1. Attach the Pulse Oximeter module's connector to the Bedside Unit, as shown below:

Figure 75: Attaching the Pulse Oximeter's Connector to the Bedside Unit

2. Attach the Pulse Oximeter Sensor's connector to the Pulse Oximeter's module.
3. Place the Pulse Oximeter Sensor on the patient's finger. For correct placement of the Sensor on the finger, refer to the Sensor's usage instructions.

3.32.5 Common Default Settings for Alert Threshold Values for Pulse Oximetry Measurements

Table 21: Default Settings for Alert Threshold Values for Pulse Oximetry Measurements

	Low Limit Threshold	High limit Threshold
SpO_2	90%	100%

3.32.6 Alerting Parameters (Oximeter Module)

Table 22: Oximeter Module Alerting Parameters

	Low SpO_2	High SpO_2
Time to alert for change in SpO_2	60 seconds	60 seconds

SpO_2 alert is generated by the system if average SpO_2 exceed predefined threshold for above listed amount of time (Table 22)

3.32.7 Thresholds

Thresholds can be set in the ranges described in Table 23.

Table 23: Threshold Ranges

	Lowest Settable Limit Threshold	Highest Settable Limit Threshold
Heart Rate	35 BPM	150 BPM
Respiratory Rate	8 Br./min.	44 Br./min.
SpO_2 (if module connected)	70%	100%

WARNING

The use of accessories, transducers and cables other than those specified by the systems' specifications and supplied by the manufacturer can result in increased emissions or decreased immunity.

Measurements may be affected by cable lengths. Do not shorten or extend the lengths.

3.32.8 Performance – Nonin XPOD OEM Oximeter Module with Compatible Sensors

Table 24: Nonin XPOD OEM Oximeter Module with Compatible Sensors Performance

Displayed Oxygen Saturation Range	0–100%
Displayed Pulse Rate Range	18 to 250 BPM
Measurements, Wavelengths and Output Power	Red: 660 nanometers @ 0.8 mW maximum average Infrared: 910 nanometers @ 1.2 mW maximum average (using Nonin PureLight Sensor)
SpO_2 Accuracy (Arms*) 70–100%	
No Motion	
Reusable	Finger Clip
	Flex
	Soft Sensor
	8000R
	8000Q
Disposable	6000 Series
	7000 Series
Motion	
Reusable	Finger Clip
	Flex
	Soft Sensor
Low Perfusion	All Sensors
Pulse Rate Accuracy (*Arms)	
No Motion (18-250)	
Reusable	Finger Clip
	Flex
	Soft Sensor
	8000R
	8000Q
Disposable	6000 Series
	7000 Series
Motion (40-240)	
Reusable	Finger Clip
	Flex
	Soft Sensor
Low Perfusion (40-240)	All Sensors
Reusable Group	
Finger Clip Sensors	8000 AA-1, 8000AA-3, 8000AP-1, 8000AP-3
Flex Sensors	8000J-1, 8000J3, 8001J
Soft Sensors	8000SS, 8000SM, 8000SL

Disposable Group	
FlexiForm II (7000 series) Sensors	7000A, 7000P, 7000I, 7000N
6000 Series Sensors	6000A, 6000P, 6000I, 6000N
* ± 1 Arms	Represents approximately 68% of measurements

3.32.9 Cleaning the Oximeter Accessories

Refer to the Sensor's instructions for use (provided in the inserts that are included in the packaging of the compatible Sensors).

SAFETY MODULE

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4 Safety Module

This chapter describes the Safety module, its user interface and operation.

4.1 Safety Module Overview

The EarlySense Safety module is designed to display and log movement parameters and bed occupancy status in an automatic, contact-free manner. The system is indicated for use in indoor environments. Patient monitoring begins automatically as soon as the patient gets into bed.

The system can alert the user if the patient leaves the bed (Bed Exit) or the chair (Chair Exit) and enables the healthcare practitioner to document that he/she changed the patient's position in bed. The healthcare practitioner can insert the event of having changed the patient's position by documenting the event in the Safety module on the Bedside Unit's screen. The system then verifies the change in position and logs the information. The system also provides an option to notify the user if a certain amount of time (configurable) has passed since the patient's position was last changed (Timer Expired). You can then decide to activate or deactivate these notifications.

Data is continuously displayed on the Bedside Unit's *Home* window. The data obtained during the monitoring period is recorded by the system in order to enable offline presentation and printing. In addition, all these functions are available when the patient is sitting in a chair (with the exception of Patient Turns).

The user of the Safety module can adjust the settings to suit the patient's condition. The system allows different settings for Fall Prevention sensitivities or delayed alerts when a patient fails to return to his/her bed/chair. In addition, the user can select the time intervals in which he/she would like to receive a reminder to turn a patient, in order to prevent pressure ulcers.

4.2 Safety Module Home Window

The Bed Sensing Unit should be placed under the mattress, underneath the patient's chest area, as described on page 31, and the system must be turned on.

After the patient's ID and initials are entered into the system and the patient lies in bed or rests in a chair for approximately 60−120 seconds, the system begins displaying the In Bed/Chair indicator and Timer on the EarlySense Safety module's Home window. Heart and Lung icons blink as soon as a patient is detected in the bed/chair by the system. If the system cannot detect the patient for more than one minute, the blinking Heart or Lung icons stop blinking

.

The Safety Module *Home* window displays monitoring data and provides access to additional menus. Available options are selected by clicking the screen.

Figure 76: Safety Module Home Window

1 – Current Movement Level (0, Low, Medium, High, Extremely High), page 112
2 – Immediate Bed/Chair Exit Sensitivities, page 113
3 – Switch between Sensitivity (immediate) Mode to Delay Mode of Bed/Chair Exit Alert, page 113
4 – Nurse's details (Name, Ext. Number and assigned color), page 99
5 – Lock/Unlock screen, page 99
6 – Patient's Details (Room and Bed numbers, ID, initials), page 99
7 – Enable/Disable Fall Prevention Alerts, page 113
8 – Discharge Patient, page 101
9 – Battery Status/AC indicator, page 100

10 – Date and Time
11 – Suspend Red and Yellow alerts for 15 minutes, page 106
12 – Switch between Bed and Chair modes (if available), page 102
13 – Enable/Disable Patient Turn Counter, page 120
14 – Patient Turn Intervals Settings, page 118
15 – Patient Turn Counter: Time passed since last turn documented by Caregiver, page 120
16 – Brightness Setting Button, page 105
17 – Volume Setting Button, page 105
18 – Alerts Setting Button, page 104
19 – Time In Bed/Chair Counter, page 121
20 – Bed Occupancy/Restlessness Indicator, page 112

4.3 Admitting a Patient – Manually

The *Admit Patient* window is automatically displayed on the screen when the system is turned on if no patient is currently admitted on this Bedside Unit, as shown below:

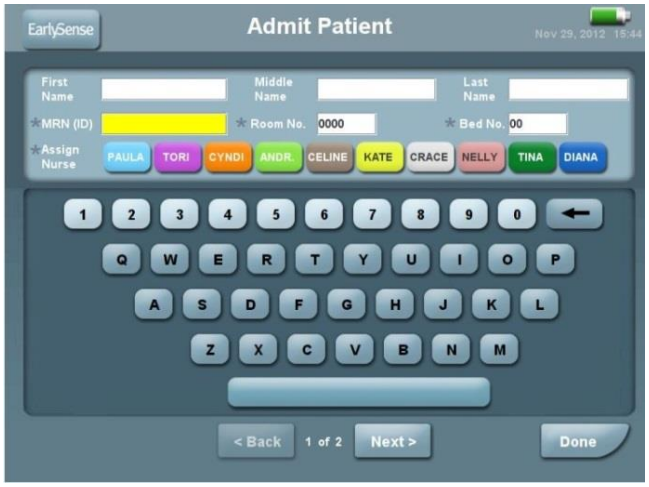


Figure 77: Admit Patient Window

NOTE	Upon installation, the room and the bed numbers in each individual Bedside Unit are configured by an EarlySense authorized technician. Relocation of the Bedside Unit to a different room or bed number should only be performed by an EarlySense authorized technician with the cooperation of the hospital's/clinic's Biomedical Engineering/IT personnel.

► **To manually admit a patient:**

1. Enter the patient information in the *Admit Patient* window, as follows:
   - Enter the patient's name or initials (letters only) and ID (for example, Medical record number – MRN [alphanumeric only]) in the available fields.
   - The **ID**, **Room Number** and **Bed Number** must be entered for the patient to be admitted.
   - Mandatory fields are marked with an asterisk.
   - Select a nurse color in order to assign each patient to a nurse color. You may refer to the *EarlySense Central Display Station (CDS) User Guide* for more information about nurse colors.

   NOTE Only letters can be entered in the first, middle and last name fields and only alphanumeric characters can be entered in the ID field.

2. Click **Next** to open the *Patient Demographics* window, as shown below:

Figure 78: Admit Patient Window – Demographics

The following additional fields can also be entered, but are not mandatory:

- **Gender**: Select **M** or **F**.
- **Date of Birth**: Enter the patient's date of birth.

3. Click **Done**.

   NOTE The *Admit Patient – Demographics* window does not open unless a patient ID has been entered.

4. Click **Done** to complete admitting the patient.

5 The following windows are then displayed containing two settings-related questions:

- **Question 1 – Do you want Bed Exit Alert for this patient?**:
  - Select **Yes** to enable the automatic Bed Exit alert with the default sensitivity level setting. For more details about a Bed Exit Alert, you may refer to the *Fall Prevention (Bed Exit)* section on page 113.
  - Select **No** to disable the Bed Exit alert.

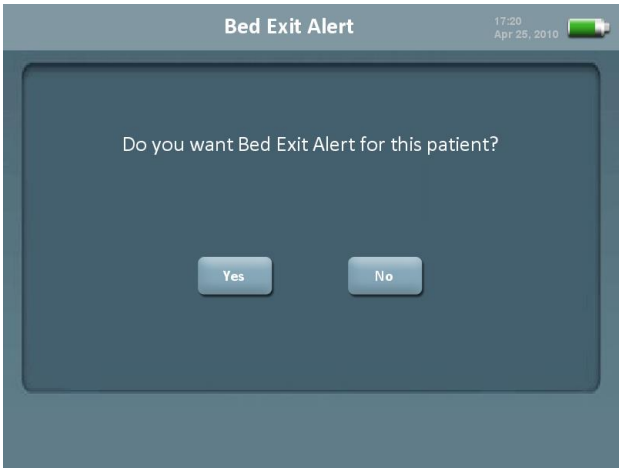


Figure 79: Bed Exit Alert Setting – Admission

- **Question 2 – Do want a Patient Turn reminder for this patient?**
  - Select **Yes** to automatically enable the Patient Turn Counter with the default interval setting between patient turns.
  - Select **No** to disable the Patient Turn Counter.

If no response is given to these questions, after one minute the patient is admitted and the Bed Exit alert and the Patient Turn Reminder remain disabled.

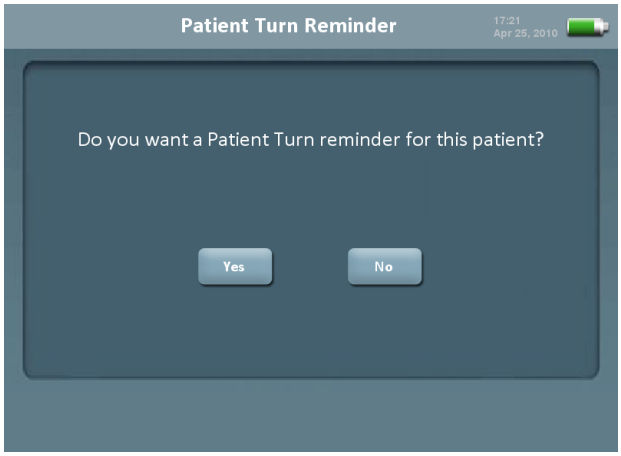


Figure 80: Patient Turn Setting – Admission

NOTE The Admit process is not completed unless a healthcare practitioner actively verifies that the patient's information displayed on Bedside Unit's screen is correct and confirms the admission.

NOTE Alerts are only generated after the patient lies still for one minute and either the heart rate or respiratory rate are displayed.

4.4 Unlocking the Bedside Unit Screen

The *Home* window is displayed showing the monitoring data and providing access to additional menus. Selections are made by clicking the screen.

For any interaction (except for responding to alerts), the window must be unlocked. The Bedside Unit automatically locks after a configured period of time.

► **To unlock the screen:**

- Click the  button in the top left of the window. If you click the touch screen while the system is locked, the lock icon flashes red.

Figure 81: Lock/Unlock

4.5 Nurse and Patient Details

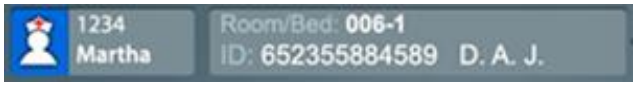


Figure 82: Patient Details

This area specifies the name and extension number of the nurse color responsible for this patient. This indicates the nurse whose pager/phone is notified of this patient's alerts. The nurse responsible for a patient is determined during patient admission and can only be changed on the CDS. You may refer to the *EarlySense Central Display Station (CDS) User Guide* for more information.

This area also specifies the details of the patients including the room/bed, patient ID and patient initials.

NOTE If you enter incorrect patient details by mistake, you can discharge the patient and then complete the admission process again for that patient.

4.6 Battery Charge Indicator

The following table shows the battery status indications.

Table 25: Battery Status Indication

Green (with lightning)		Battery is charging and is connected to a power outlet. The lightning symbol on the battery indicates that the battery is charging.
Green		Battery is charging, but is disconnected from a power outlet.
Orange		System is disconnected from a power outlet, and the battery is not charging.
Red		Battery is almost empty. The system is about to shut down.

After Electrical Power is Restored

1. Ensure that the system is plugged into the electrical outlet.
2. Turn the system on by clicking the **On/Off** switch on the front of the Bedside Unit (as shown in Figure 4).

   If a patient was already admitted, the *Home* window is automatically displayed and the system continues its monitoring session.

   The Internal battery automatically recharges when the electrical power is restored. If system operation is not restored, contact EarlySense Support Services.

4.7 Discharging a Patient

► **To manually discharge a patient and end the patient's monitoring session:**

1 Click **Discharge** in the *Home* window. The *Discharge Patient* window is displayed as shown below:

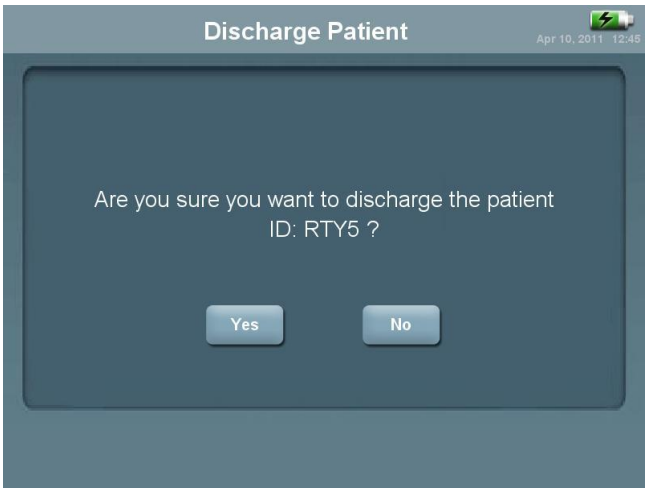


Figure 83: Discharge Patient Window

2 Click **Yes** to confirm discharging the patient from the EarlySense monitoring session.

You may refer to the *Electronically Discharging a Patient* section on page 171 for a description of how a patient can be automatically discharged on the Bedside Unit by the HIS system.

WARNING

To avoid recording patient data under an erroneous identification, perform the discharge procedure before beginning the monitoring of a new patient.

4.8 Chair Mode

In addition to monitoring a patient in bed, the system allows monitoring of a patient while resting in a chair.

NOTES Both a Chair Sensor and a Bed Sensor can be connected at the same time to the Bedside Unit. If an EarlySense technician configured the system to work only in either Bed mode or Chair mode, then this button is not enabled.

By default the system is set to Bed Mode as shown below:

Figure 84: Bed Mode

► **To change to Chair Mode:**

1. Place the Chair Sensing Unit on a chair and secure the straps.
2. Connect the cable from the Chair Sensor to the Bedside Unit.
3. Click the **Change Mode** 

button to toggle the selection to the chair icon. The following displays:

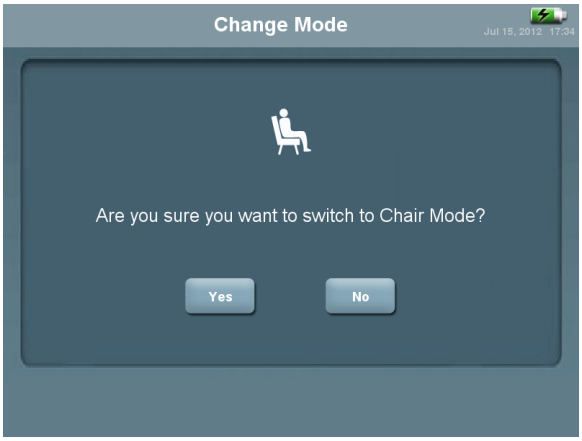


Figure 85: Confirming Chair Mode

If **Yes** is clicked, chair mode appears on the *Home* window.

NOTE A Patient Turn reminder is not available when activating the Chair Mode monitoring option. The caregiver responsible for the patient should continue implementing their standard pressure ulcer prevention policy while the patient is in a chair.

The following shows the monitoring window in Chair Mode:

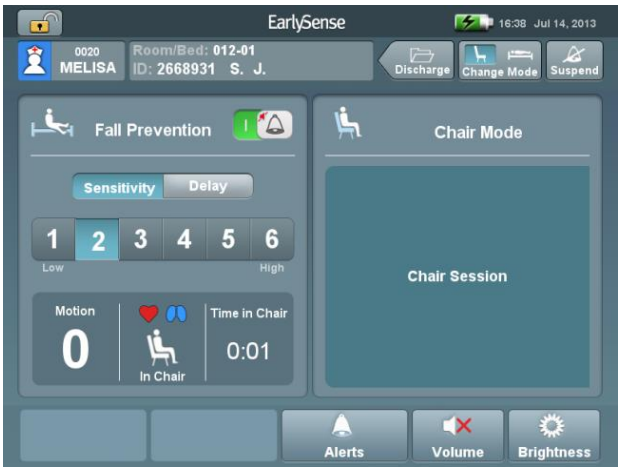


Figure 86: Chair Mode – Safety Module

4.9 Setting Alert Volume and Tone

The following describes how to configure the alert settings (such as volume and tone) of specific types of alerts.

► **To configure specific types of alerts:**

1 Click the **Alerts** button at the bottom of the *Home* window (see Figure 76). The *Alerts Setup* window is displayed, as shown below, showing the current configuration of all types of alerts:

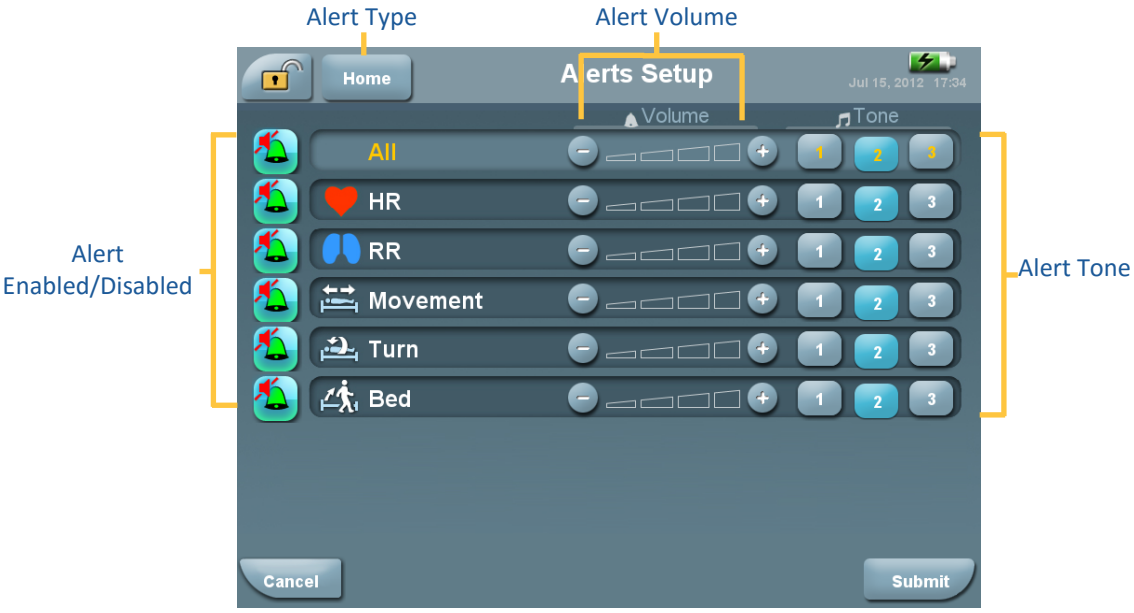


Figure 87: Alerts Setup Window

2 Click the **Plus** (**+**) or **Minus** (**-**) button to adjust the volume for each type of alert.

3 Click either the **1**, **2** or **3** button to select an alert tone.

4 Click the **Bell** icons to enable or disable specific alerts.

Table 26: Alerts Status Table

Enabled	Enabled and Silenced	Disabled
		

5 Click **Submit** to activate the settings or **Cancel** to preserve the existing settings.

NOTE In addition to changing the individual alert volumes, as described above, you can also change the general volume of all alerts it on the Bedside Unit (page 105) by setting the volume and tone of all alerts in the *Alerts Setup* window. Alert volumes are determined by whichever parameter (**General** or **Alert**) was set last.

NOTE When a patient is admitted or discharged, all alert settings return to their default settings.

WARNING An Audible Alert in the EarlySense System is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

4.10 Setting Bedside Unit Alert Volume

The following describes how to set the volume of all alert tones. The alert volumes are determined based on whichever of two parameters (**General** or **Alert**) was last set. The volume and tone for individual alerts can also be set, as described on page 104.

At startup and after admitting a new patient, the system returns to its default alert settings.

▶ **To set the General Volume:**

1. Click the **Volume** button in the *Home* window. The **Volume** button then changes to appear as follows:

Figure 88: General Volume

2. Click the **Plus** (**+**) button to raise the volume or the **Minus** (**-**) button to lower the volume.
3. Click **OK** to confirm.

   When the volume is set to mute, the **Volume** icon is marked with an X and a mute sign appears on the alerts' **Bell** icons.

4.11 Setting Bedside Unit Alert Brightness

▶ **To adjust screen brightness:**

1. Click the **Brightness** button on the *Home* window.
2. Click the **Plus** (**+**) or **Minus** (**-**) button to adjust the brightness.

Figure 89: Brightness Adjustment

If the brightness level is set to the lowest level, the screen may appear black during daylight. Clicking the screen when brightness is set to the lowest level increases the screen's brightness.

4.12 Suspending Red and Yellow Alerts

The sounding and display of all Red and Yellow alerts can be suspended, meaning that the system does not generate any patient alerts, as follows:

- Click the **Suspend** button on the top right of the screen. An **Alert Suspension Timer** icon appears on the *Home* window and on the CDS screen, which suspends all Bedside Unit alerts for 15 minutes.

Figure 90: Alert Suspension Timer – Safety Module

- To stop the suspension of alerts, click the **Suspend** button again.
- After 15 minutes, if no one clicks the **Suspend** button again, the alert suspension is automatically terminated and new alerts are sounded and displayed again when the applicable alerting condition recurs or if it still exists.

NOTE Blue alerts cannot be suspended.

4.13 Visual Alert Indications

The following figure shows a visual alert, as it appears in the Safety Module's *Home* window. The area of the window indicating the problematic measurement is highlighted in red or yellow and a red or yellow message displayed at the bottom of the window, as shown below:

Figure 91: Alert Window – Safety Module

Click **OK** to acknowledge the alert or the **Suspend** button to suspend all alerts for 15 minutes.

4.13.1 Alert Indicators

Both sides of the bedside unit have an alert indicator that lights up according to the color of the alert, meaning blue, red or yellow. You can click either of them to acknowledge the alert.

Figure 92: Bedside Unit Alert Indicators

WARNING

Active RED indicator light, requires an immediate response to understand the nature of the Alert.

Active YELLOW indicator light, requires prompt response to understand the nature of the Alert.

4.14 Alert Sound Notification

The Bedside Unit sounds and alerts to notify personnel of situations that may require attention. The EarlySense System enables you to define and adjust alert configurations/settings. Audible and visual alert notifications are generated according to several settings.

When an alert is generated, an audible alert is sounded unless the volume is muted, as described on page 105.

You may refer to the *Setting Bedside Unit Alert Volume* section on page 105 for a description of how to control the alert volume of all the alerts on the Bedside Unit.

You may refer to the *Setting Alert Volume and Tone* section on page 104 for a description of how to control the alert volume and tone of specific types of alerts on the Bedside Unit.

WARNING

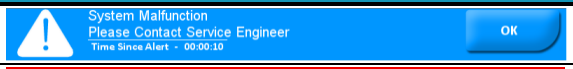
The Audible Alert in the EarlySense System is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

4.15 Alert Visual Notifications

When an alert is generated a visual notification displays on screen.

A message is displayed at the bottom of the window describing the nature of the alert and the elapsed time since the alert was activated, as shown below:

Table 27: Visual Alert Notifications

Key	Example
Blue Alerts	
Red Alerts	
Yellow Alerts	
Grey Notification Message	

4.15.1 Alert Colors

The background color of the alert corresponds to the alert priority in the following order: blue, red, yellow or gray. Blue alerts relate to a system problem and are not connected to a specific patient monitoring parameter.

4.15.2 Multiple Alerts

When more than one alert is generated for the same patient at the same time, only the most severe alert is active. Only one alert can be active at a time.

The following are a few examples:

- When a Yellow Alert (such as, low patient movement) is generated while a Red Alert is active (such as a Bed Exit), then only the Red Alert is shown.
- When a blue alert is generated while a red alert is in progress, then the blue alert is shown.
- When a Bed Exit (red) alert is active (displayed on screen) and not acknowledged by the user, another Bed Exit alert is not generated when a patient exits the bed.

A new alert becomes active only if the currently active alert has a lower priority.

NOTE Different types of alerts with the same priority cannot be generated when the same priority alert is still active. Make sure not to leave patients unattended who may be at risk of falling.

4.16 Enabling/Disabling Alerts

An *Enabled Alert* means that the alert is displayed and will sound on the Bedside Unit.

An *Enabled and Silenced Alert* means that the alert is displayed, but will not sound on the Bedside Unit.

A *Disabled Alert* means that the alert is not displayed and will not sound on the Bedside Unit or the CDS.

If an alert is disabled while the alert is going off, the alert message remains active until it is acknowledged by a healthcare practitioner.

► **To disable/enable alerts for specific parameters:**

- Click the bell symbol next to the alert in either the *Home* window (described on page x) or the *Alerts Setup* window (described on page X).

Table 28: Alerts Status Table

Window	Enabled	Enabled and Silenced at Bedside	Disabled
Home Window			
Alerts Setup Window			

- The following is displayed when the Bed Exit alert is being disabled. To disable the alert, click **Yes**.

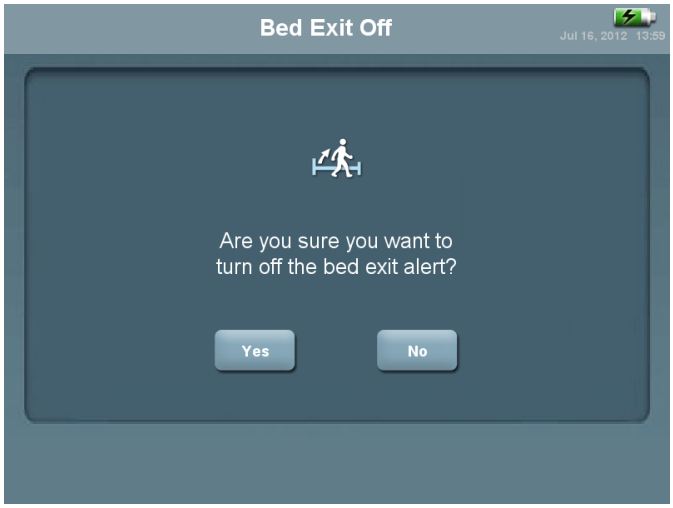


Figure 93: Bed Exit Off Window

- The following is displayed when the Patient Turn Counter Alert is being disabled. To disable the alert, click **Yes**.

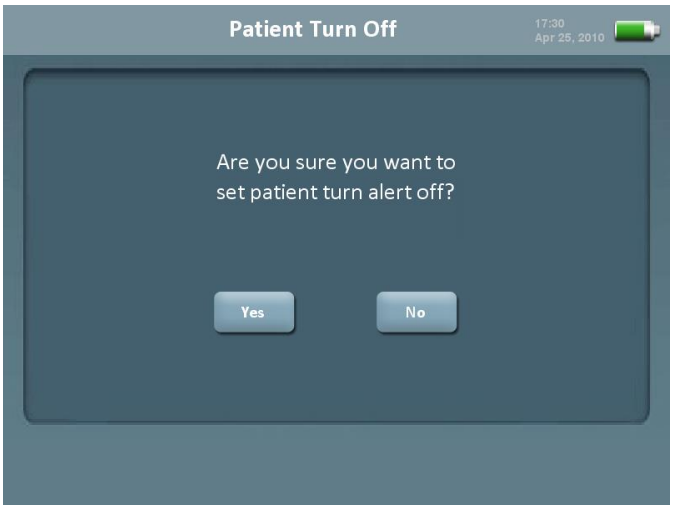


Figure 94: Patient Turn Off Window

► **To enable alerts:**

Click the Bell symbol again.

4.17 Handling Blue Alerts

Blue alerts represent a technical system problem, (not a patient problem), and are therefore handled differently than red and yellow alerts.

Blue alerts appear with an **OK** button or **Pause** button and remain active as long as the alert condition exists. Blue alerts disappear only after the technical issue is resolved and cannot be suspended.

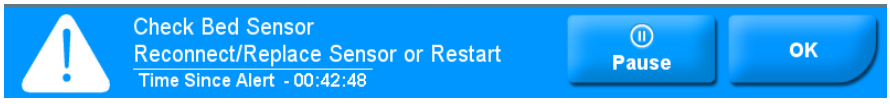


Figure 95: Blue Alert – Check Sensor (Bed Mode)

4.17.1 Blue Alerts – Pausing Patient Monitoring

The **Pause** button in the Blue Check Sensor Alert message temporarily stops patient monitoring. The **Pause** button can be used only when the Sensor is temporarily disconnected from the Bedside Unit in order to avoid a blue *Check Sensor* technical alert from going off. For example, this function should be used when the patient needs to be transported with his/her bed and therefore the Sensor must be disconnected from the Bedside Unit.

Monitoring of the patient can be resumed at any time, and all the previous trends are then displayed as usual.

▶ **To pause patient monitoring:**

- Click the **Pause** button when a blue alert appears. A *Pause* window displays, as shown below:

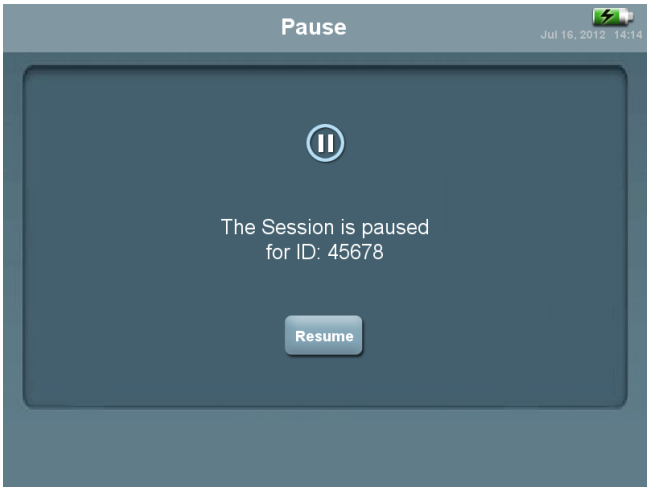


Figure 96: Pause Window

▶ **To continue patient monitoring:**

- Click the **Resume** button in the *Pause* window or connect a Sensor.

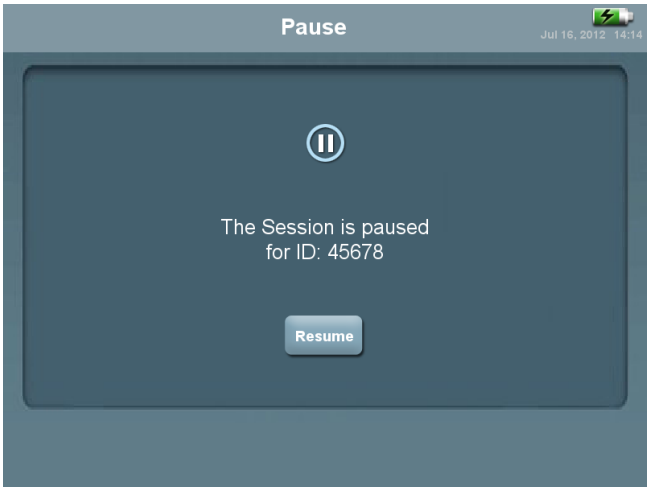


Figure 97: Pause Window

4.18 Motion Level and Bed Occupancy

When the patient is detected in bed, the Motion Level, In-Bed Occupancy, Heart and Lungs icons and the **Time in Bed** counter are displayed, as shown below:

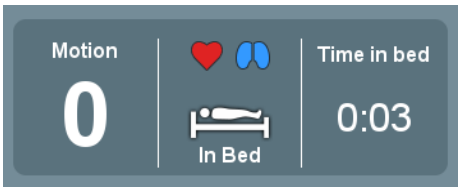


Figure 98: Safety Module – Bed Occupancy

When the patient is out of bed, no motion is displayed. An Out of Bed icon is shown, and the **Out of Bed** counter is displayed.

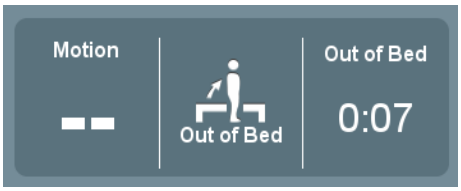


Figure 99: Bed Occupancy – Out of Bed Status

The Heart and Lungs icons blink continuously when a signal is detected by the EarlySense Sensing Unit.

The **Time in Bed** counter starts as soon as a patient signal is detected. After the patient exits the bed, the **Out of Bed** counter starts automatically.

The **In/Out of Bed** icon appears when the system is set to Bed mode. The **In/Out of Chair** icon appears when the system is set to Chair mode.

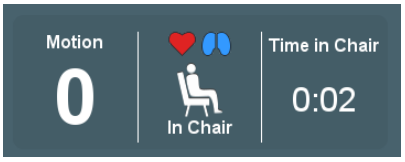


Figure 100: Chair Occupancy

4.18.1 Night Restlessness Indicator

During night hours (which are predefined), up to three yellow bars may be displayed in the background of the **In-Bed** icon. This Icon visually indicates the patient's rest level. A fuller bar may indicate that the patient is more restless and more likely to exit the bed, thus serving as a pre-bed exit indication. No bar or one bar indicates a higher rest level and indicates that the patient is less likely to leave the bed.

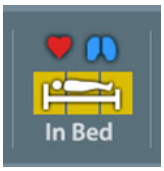


Figure 101: Safety Module – Night Restlessness Indicator

4.19 Fall Prevention (Bed Exit)

The EarlySense System tracks if there is a Bed Exit. This alert is disabled by default.

► **To enable Bed Exit alerts:**

- Press the Bell icon to move it to the position shown below:

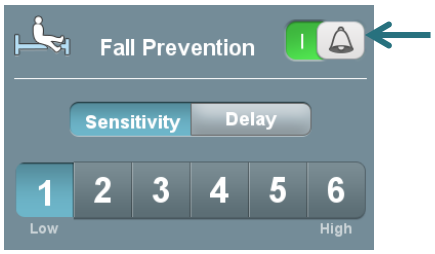


Figure 102: Fall Prevention Settings – Alert Enabled

NOTE	If the patient is allowed to get out of bed without healthcare practitioner notification, you can disable the Bed Exit alert by clicking the bell in the Fall Prevention area.

► **To configure the Fall Prevention settings:**

1. Click **Sensitivity** or **Delay** 

to select the type of Fall Prevention alert. Clicking the **Sensitivity** button generates an alert as soon as the patient leaves the bed, based on the specified sensitivity that you select, as described below.

2. Select the sensitivity level by clicking one of the number buttons – **1** is the least sensitive and **6** is the most sensitive, as shown below:

Figure 103: Bed Exit Sensitivity

NOTES

Bed Exit levels can be set from level 1 (the least sensitive) to level 6 (the most sensitive), as described below. Use your clinical judgment and the patient's condition as governing criteria when setting the level between level 1 and level 6.

Note that sensitivities 5 and 6 are highly sensitive and might be triggered due to excessive patient movements while in bed or in a chair.

3. Click the **Delay** button to generate an alert after a certain amount of time passes since the patient left the bed.

4. Select the time to alert by clicking one of the minute buttons. The default delay intervals are **5'**, **15'** or **30'**. The time intervals can be predefined in the *Technician* window by an EarlySense technician.

4.20 Bed Exit Not-Ready Indicator

When the Fall Prevention Alert is enabled, a short period of time is required by the system before a Bed Exit Alert can be generated. During this time, the **Fall Prevention Alert** icon status shows the Not-Ready indication  .

This icon also appears if the patient is out of bed.

CAUTION

Even though in some situations alerts may go off when Bed Exit is still in a Not Ready status, Bed Exit alerts must **not** be expected before the Bed Exit turns to Ready mode (when the Not Ready indication disappears).

4.20.1 System-wide Night Bed Exit Mode

The entire EarlySense System can be preconfigured for Night Bed Exit mode in the *Technician* window by an EarlySense technician. This feature automatically enables the Bed Exit alert for all

patients (only for night hours) who currently have the Bed Exit alert disabled. The Nighttime period is preconfigured by a technician, based on user preferences.

NOTE During the night hours you can see if the patient is rest peacefully by observing the Night Restlessness Indicator described on page 113.

The system exits the Night Bed Exit mode in the following cases:

- End of nighttime period (as preconfigured in the *Technician* window by an EarlySense technician.
- A change in the Bed Exit setting (such as sensitivity) made by the user during night hours. For example, if the default sensitivity for a Night Bed Exit setting is 1, and this setting is changed by a healthcare practitioner during the night, then the regular Bed Exit setting applies instead of the Night Bed Exit setting.

Figure 104: Night Bed Exit – Safety Module

You can disable the Night Bed Exit mode while it is active by touching the Bell icon on the Bedside Unit. This only disables the mode for that same patient during that same night. The mode is activated again the next night. Night Bed Exit mode is indicated by a dark background and a Moon icon.

4.20.2 Patient and Mattress Calibration

If the option is activated, calibration of the system to a specific patient and mattress can be performed by performing the procedure described below which might enhance Bed Exit performance (i.e., reduce nuisance bed exit alerts(.

► **To calibrate:**

1. Make sure that the patient is lying still in bed.
2. Click the **EarlySense** EarlySense button.
3. Click the **Calibrate** Calibrate button. The following displays during calibration:

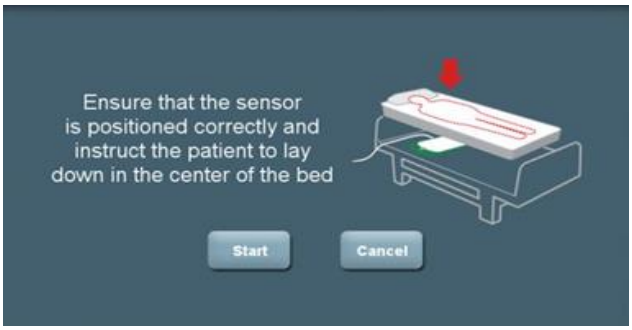


Figure 105: Patient and Mattress Calibration – 1

Figure 106: Patient and Mattress Calibration – 2

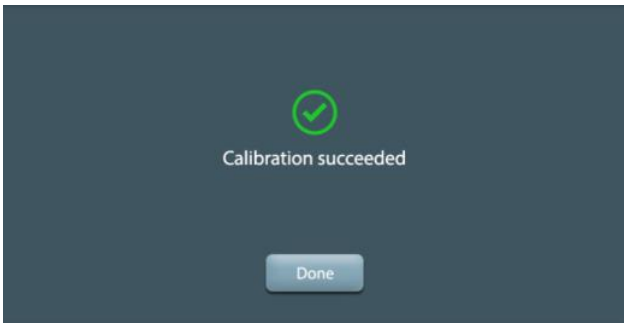


Figure 107: Patient and Mattress Calibration – 3

If the calibration was not performed successfully, the following displays:

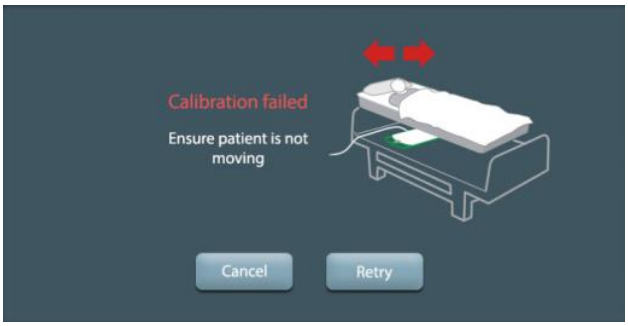


Figure 108: Patient and Mattress Calibration – 4

Figure 109: Patient and Mattress Calibration – 5

If calibration is performed while no sensor is connected, the following displays:

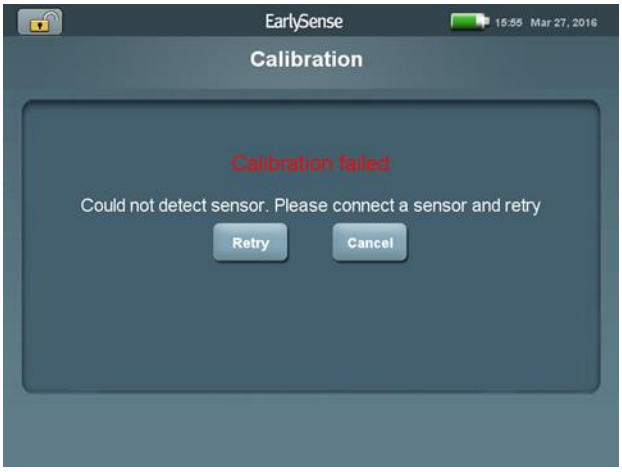


Figure 110: Patient and Mattress Calibration – 6

If calibration is performed while Chair mode is in use, the following displays:

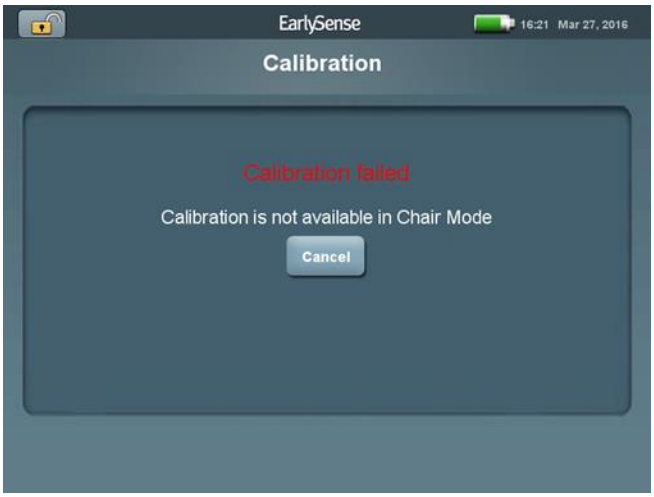


Figure 111: Patient and Mattress Calibration – 7

4.21 Patient Turn

Patient Turn is used to document the change of a patient's position in bed and to generate an alert if the interval set for changing the position has been exceeded (timer expired). The Patient Turn alert is disabled by default.

► **To enable Patient Turn alerts:**

- Press the Bell icon to move it to the position shown below:

Figure 112: Patient Turn – Alert Enabled

4.21.1 Configuring the Time Interval Between the Turn Reminders

The Patient Turn Interval is referred to as **q**.

- **q1** means every hour
- **q2** means every two hours

- **q4** means every four hours
- **q6** means every six hours

For example, if you want the system to generate a reminder to turn the patient every two hours, click **q2**.

The turn interval buttons are predefined in the *Technician* window by an EarlySense technician.

► **To change the time interval between the turn reminders:**

- Click the applicable **q** button in the **Turn Period** field in the *Home* window.

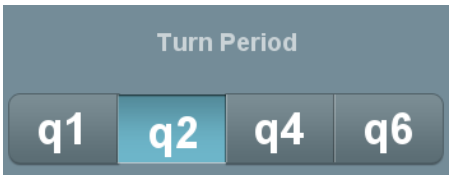


Figure 113: Setting the Patient Turn Interval – Safety Module

4.21.2 Handling a Patient Turn Alert

If the patient turn interval passes without the **Patient Turned** button being clicked, a yellow Turn Counter Exceeded alert is generated. This alert indicates that the counter exceeded its time threshold.
Counter will reset if patient exists bed before selected q expired

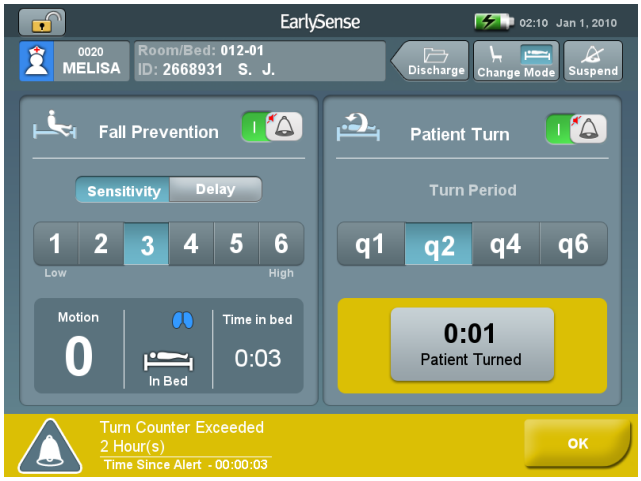


Figure 114: Turn Counter Exceeded Alert

To acknowledge the alert, click the **OK** button.

To document that you have turned the patient, click the **Patient Turned** button.

The alert message disappears either when you click the **OK** button or when you click **Patient Turned**.

If **OK** was clicked, but the **Patient Turned** button is not clicked within 15 minutes, the alert is generated again.

Documenting Patient Turn and Resetting the Counter

After turning the patient, click the **Patient Turned** button. The system logs the event and resets the time counter.

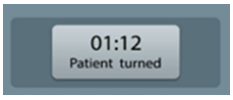


Figure 115: Patient Turned Counter – Safety Module

If an alert was acknowledged, but the **Patient Turned** button was not yet pressed, the **Patient Turned** button appears as shown below:

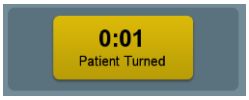


Figure 116: Patient Turned Counter – Acknowledged Alert – Safety Module

In addition, the system detects the corresponding change in body movement and verifies the event. Verification appears in the printed report for the same day. You may refer to the *Sample Reports* section on page 129 for more information.

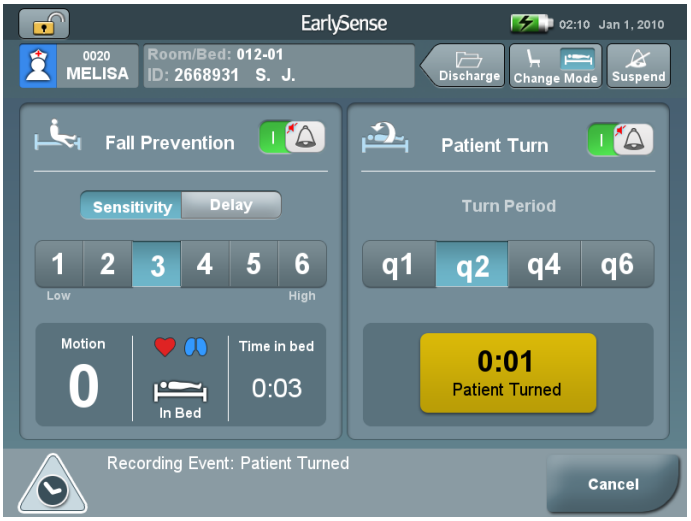


Figure 117: Recording Patient Turned Event – Safety Module

Using an Air Mattress – Disabled Patient Turn Counter

If the Patient Turn counter is disabled (off) and an air mattress is in use, the following message displays.

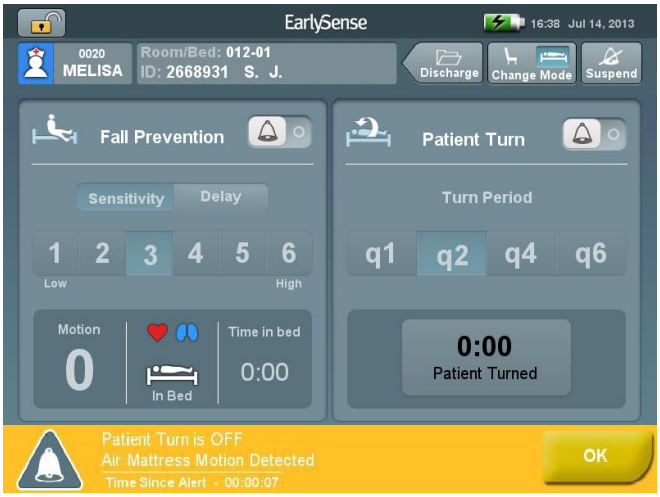


Figure 118: Turn Alert On Reminder – Safety Module

After you click **OK**, you are asked whether to receive Patient Turn reminders for this patient.

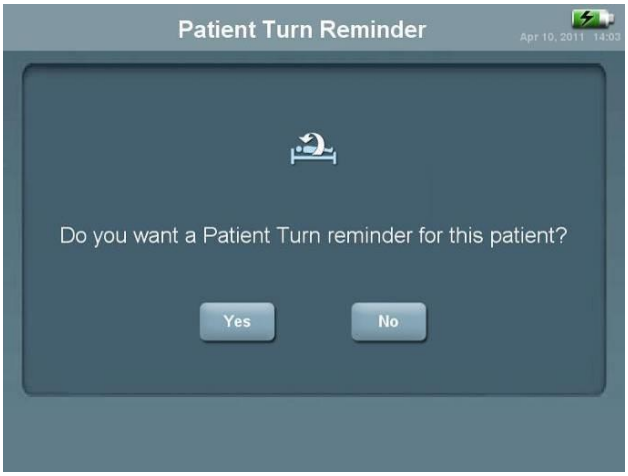


Figure 119: Safety Module – Patient Turn Reminder

In addition, if the Patient Turn counter is enabled and an air mattress is not detected, a message displays, suggesting that an air mattress be used. This message may display once every 24 hours.

NOTE This alert is configurable by an EarlySense technician, based on user preferences.

4.22 Patient Movement

Movement rates are calculated, based on the percentage of movement time within a defined period of time, as described in the following table. This table also describes the accuracy of the system while displaying different rates.

NOTE This alert is configurable by an EarlySense technician, based on user preferences.

Table 29: Patient Movement

Rate	Percentage of Movement During Defined Period	Accuracy of Rates Displayed for Adults	Accuracy of Rates Displayed for Children
0	0	100%	100%
L	Up to 40%	100%	100%
M	40–60%	81%	81%
H	60–80%	100%	86%
EH	80–100%	96%	94%

When a patient has an extremely high motion level in a period of one minute, an Extremely High Movement alert is generated.

4.22.1 Low Patient Movement Alert

Movement alerts are displayed in cases of low and extremely high movement. An alert for low movement may come up once a day at 6:00 AM (or as predefined in the *Technician* window). If during the night (00:00–6:00), the amount of patient movement was below a certain threshold, it may suggest that the patient is at risk for developing pressure ulcers. When dismissing a Low Patient Movement alert, you are asked whether you want a Patient Turn Reminder for this patient.

NOTE This alert is configurable by an EarlySense technician, based on user preferences.

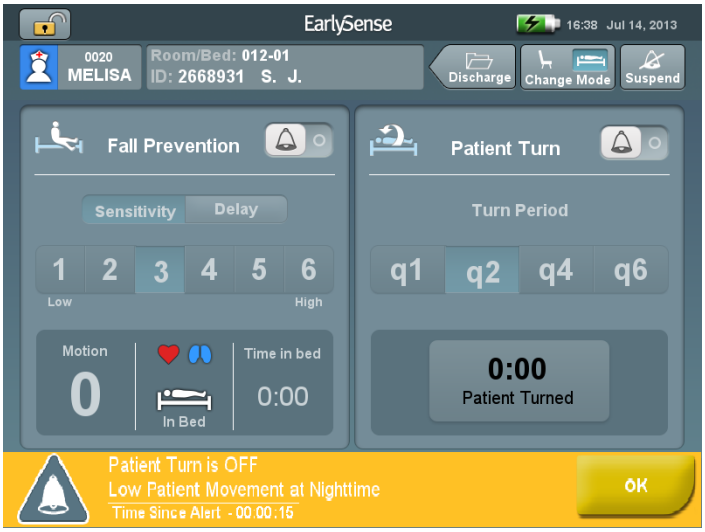


Figure 120: Low Patient Movement Alert – Safety Module

4.22.2 Patient Motion Detection

If when using the Patient Turn Reminder, the system detects additional patient movement during the night, the following recommendation is made following the first Turn Reminder in the morning.

NOTE This alert is configurable by an EarlySense technician, based on user preferences.

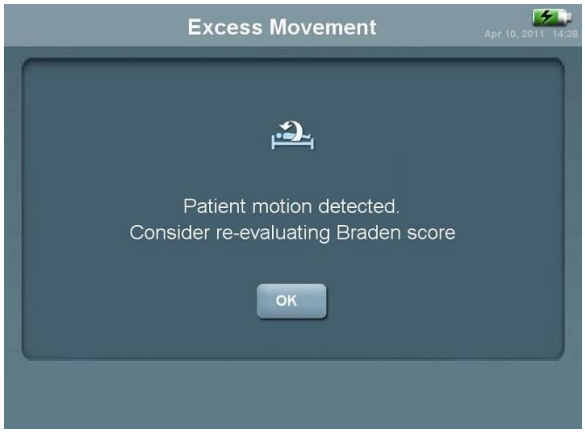


Figure 121: Patient Movement Detected

4.23 Settings – Advanced Functions and Technician Mode

► **To access the settings:**

- Click the **EarlySense**  button in the *Home* window. The *Settings* window has two tabs: **Setup** and **Maintenance**, as described below.

4.23.1 Setup – Languages

The **Setup** tab specifies the language of the user interface and reports. Setting a language can only be performed by an authorized EarlySense technician.

Figure 122: Advanced Window – Setup Tab

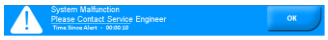
4.23.2 Maintenance

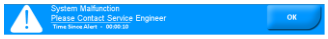
This mode should only be used by a technician authorized by EarlySense. It requires a PIN code.

4.24 Safety Module – Messages and Alerts

There are four types of system messages and alerts: **Red**, **Yellow** and **Blue** alerts, and **Gray** notifications.

Table 30: Safety Module System Messages and Alerts

Alert Display Color	Messages/Alerts in This Category	Description
	Bed/Chair Exit	System detected that a patient is about to leave the bed/chair; available in six different sensitivities (1 – Lowest, 6 – Highest).
	Patient Out of Bed/Chair	System detected that patient is out of bed/chair for period of time exceeding a preset threshold.
	Extremely High Motion	Patient Movement Rate has been extremely high during the last minute.
	Patient Turn is Off – Low Patient Movement at Night	Patient Movement Level has been very low during the night (00:00–6:00). Consider setting Patient Turn Reminder on.
	Patient Turn is Off – Air Mattress Motion Detected	Air mattress operating on the bed. Consider setting Patient Turn Reminder on.
	Turn Counter Exceeded	Threshold time interval for turning the patient expired.
	Patient in Chair More Than X Hours	Threshold time interval for turning the patient expired (in Chair Mode only).
 Technical Alert – Indicates a technical problem with the system	Check Sensor (connection, position or location)	Indicates that the Sensor connection is malfunctioning or that the Sensor is disconnected. This may indicate that the location or the position of the Sensor is incorrect or upside down. (See *Troubleshooting*, page 172).
	No AC Power	Indicates that the Bedside Unit is disconnected from the electrical power. Reconnect the Bedside Unit to the electrical power outlet. Otherwise, the Bedside Unit shuts down. (See *Troubleshooting*, page 172).
	Very Low Battery	Indicates that the battery is low and that the system is about to shut down. Reconnect the Bedside Unit to an electric outlet. (See *Troubleshooting*, page 172).
	System Malfunction	Indicates that the system is malfunctioning. Contact a Field

Alert Display Color	Messages/Alerts in This Category	Description
		Service Engineer (See *Troubleshooting*, page 172).
 Technical Alert – Indicates a technical problem with the system	Sensor is about to expire within 30 days	Indicates that this Sensor stops functioning within 30 days. Click **OK** to eliminate the message and to continue the monitoring session.
	Sensor Expired	Indicates that this Sensor has stopped functioning and must be replaced.
 Functional Message – Informative message	Patient not admitted	The system detected a signal in bed, but no patient information was entered.
	No Patient Detected for X hours	The system has not detected a signal for X hours (configurable in the *Technician* window), although a patient was not discharged.
	Signal Detected in Bed	The Bedside Unit is in Chair mode, but a patient's signal is being detected in the bed.
	Recording Event: Patient Turned	**Patient Turn** button was clicked to document that a turn was performed.

4.25 Generating Reports (Data Retrieval)

Reports can be downloaded at the Bedside Unit or printed at the Central Display Station (CDS), as described in the *EarlySense Central Display Station (CDS) User Guide*). To ensure the privacy of the patient's medical data, a PIN must be entered before reports can be downloaded or printed.

The data can be downloaded either as a CSV file or as a complete report in Acrobat PDF format. For a CSV file, the data can be viewed by a clinician using standard software. For example, Microsoft Excel™. The data is presented numerically. The clinician can use the provided data and Excel to generate any other graph that is required.

Reports are sent via email.

WARNING

The data acquired by the EarlySense System must only be interpreted by a healthcare practitioner.

4.25.1 Downloading Patient Data and Reports

► **To download patient data and reports:**

1. Insert a USB disk drive with at least 0.5 GB of free space into the USB slot. If the disk drive is already inserted, it must be removed and re-inserted before starting the data download procedure.
2. Click the **EarlySense** icon and then the **Maintenance** tab. The following displays:

Figure 123: Advanced Window – Maintenance Tab

3. Click the **Download Report** button. The following window displays:

Figure 124: Enter PIN Window

4 Enter a PIN (Personal Identification Number) and then click **Submit**. The following message is displayed at the bottom of the window indicating that downloading has started.

Figure 125: Downloading in Progress Message

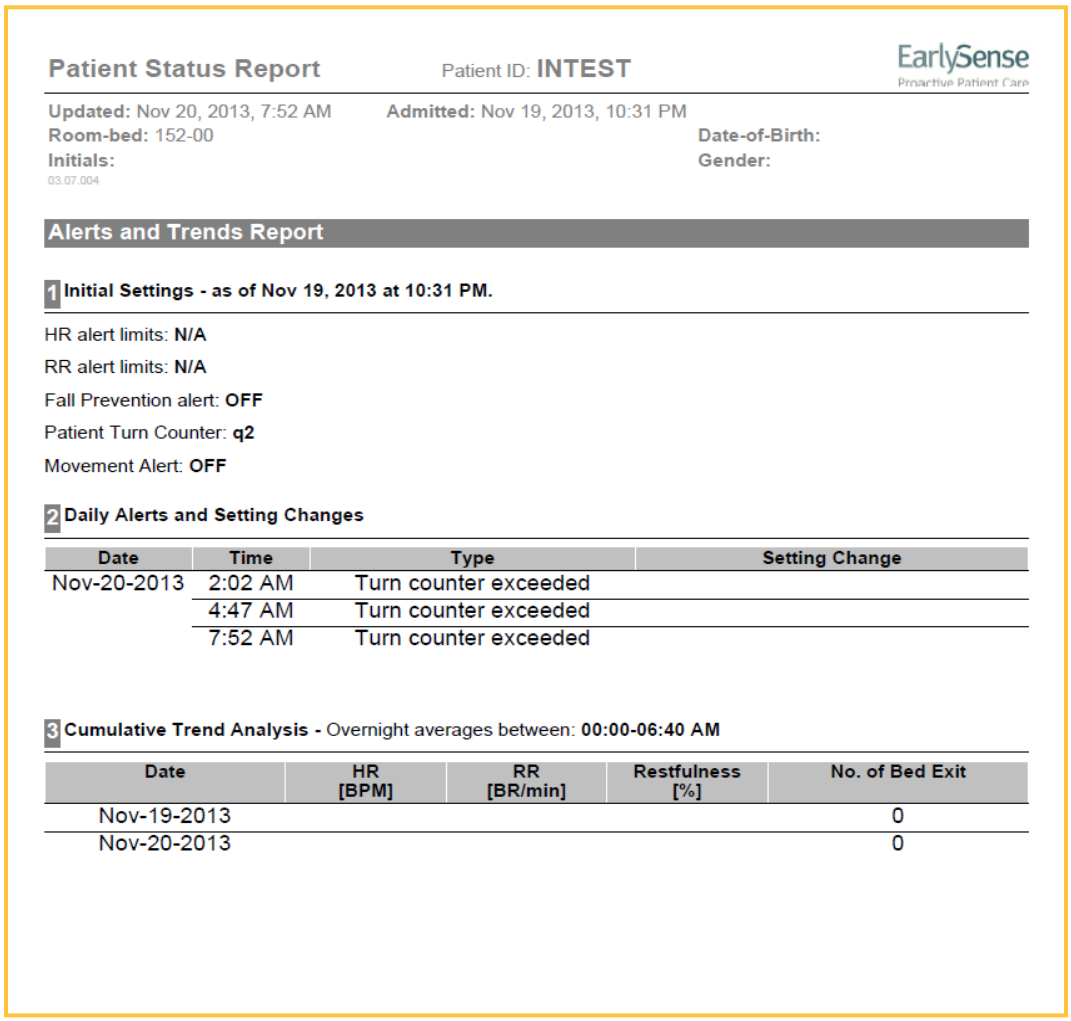
The system automatically downloads the data (CSV file) and the report (PDF file) of the last two admitted patients.

A message displays when the download completes.

Sample reports are available on page 129.

4.25.2 Sample Reports

The following figures show a Patient Status report. Reports can be downloaded, as described in the *Downloading Patient Data and Reports* section on page 127. This report can also be printed using the CDS. Refer to the *EarlySense Central Display Station (CDS) User Guide* for more details.



Patient Status Report Patient ID: **INTEST**

EarlySense
Proactive Patient Care

Updated: Nov 20, 2013, 7:52 AM **Admitted:** Nov 19, 2013, 10:31 PM
Room-bed: 152-00 **Date-of-Birth:**
Initials: **Gender:**
03.07.004

Alerts and Trends Report

1 Initial Settings - as of Nov 19, 2013 at 10:31 PM.

HR alert limits: **N/A**
RR alert limits: **N/A**
Fall Prevention alert: **OFF**
Patient Turn Counter: **q2**
Movement Alert: **OFF**

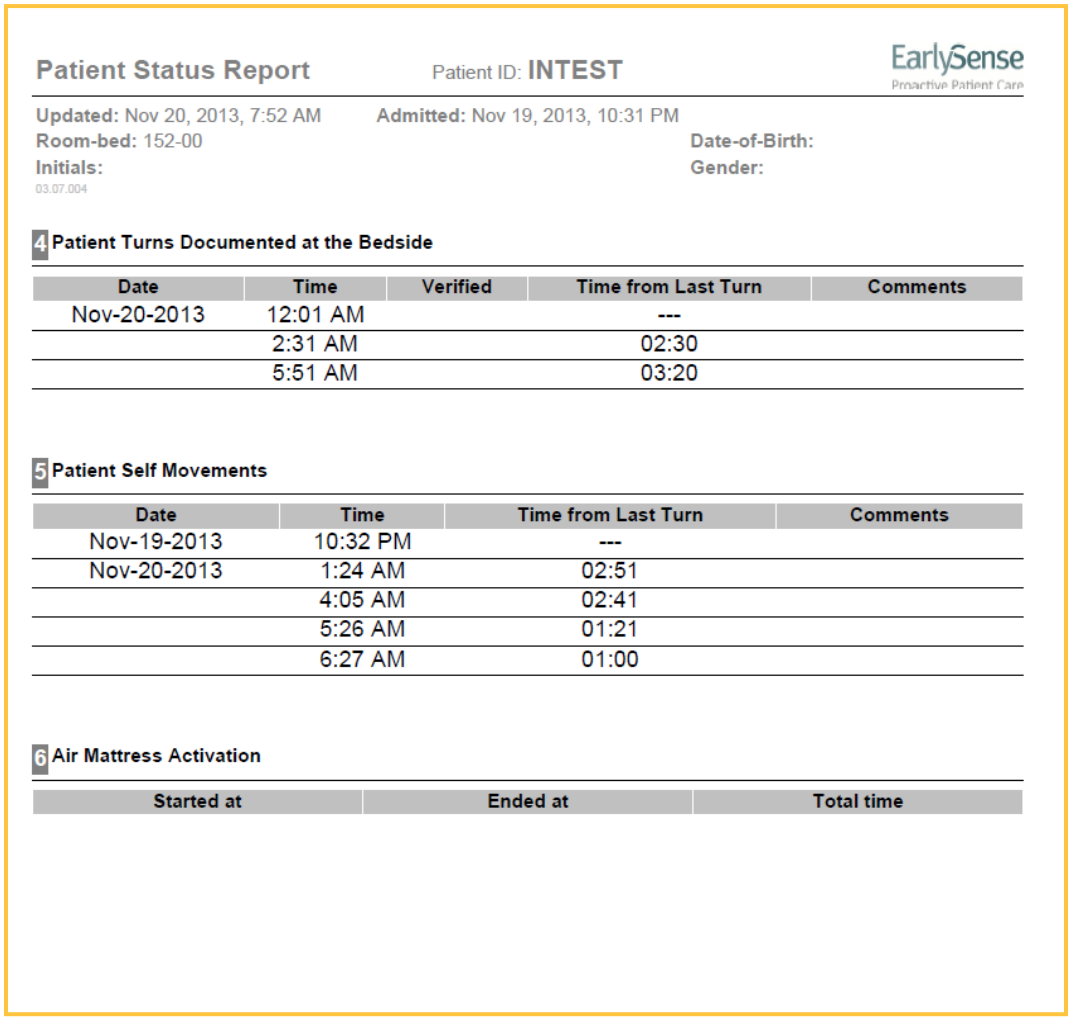
2 Daily Alerts and Setting Changes

Date	Time	Type	Setting Change
Nov-20-2013	2:02 AM	Turn counter exceeded	
	4:47 AM	Turn counter exceeded	
	7:52 AM	Turn counter exceeded	

3 Cumulative Trend Analysis - Overnight averages between: **00:00-06:40 AM**

Date	HR [BPM]	RR [BR/min]	Restfulness [%]	No. of Bed Exit
Nov-19-2013				0
Nov-20-2013				0

Figure 126: Safety Module – Patient Status Report – 1



Patient Status Report Patient ID: INTEST

EarlySense
Proactive Patient Care

Updated: Nov 20, 2013, 7:52 AM **Admitted:** Nov 19, 2013, 10:31 PM
Room-bed: 152-00 **Date-of-Birth:**
Initials: **Gender:**
03.07.004

4 Patient Turns Documented at the Bedside

Date	Time	Verified	Time from Last Turn	Comments
Nov-20-2013	12:01 AM		---	
	2:31 AM		02:30	
	5:51 AM		03:20	

5 Patient Self Movements

Date	Time	Time from Last Turn	Comments
Nov-19-2013	10:32 PM	---	
Nov-20-2013	1:24 AM	02:51	
	4:05 AM	02:41	
	5:26 AM	01:21	
	6:27 AM	01:00	

6 Air Mattress Activation

Started at	Ended at	Total time

Figure 127: Safety Module – Patient Status Report – 2

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VITALS MODULE

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5 Vitals Module

This chapter describes the Vitals module, its user interface and operation.

5.1 Vitals Module Operation Overview

The EarlySense Vitals module is designed to display and log Respiratory Rate, Heart Rate and Movement parameters in an automatic, contact-free manner. The system is indicated for use in indoor environments. Monitoring of the patient begins automatically, as soon as the patient gets into bed.

The system's design enables you to set high and low threshold parameters that alert you if either heart or respiratory rates cross predefined thresholds. Data is continuously displayed on the Bedside Unit's *Home* window. The data obtained during the monitoring period is recorded by the system for offline presentation and printing. All these functions are also available when the patient sits in a chair.

The Bed Sensing Unit should be placed under the mattress, underneath the patient's chest area, and the system should be turned on. After the patient's ID and initials are entered into the system and the patient lies in bed or rests in a chair for approximately 60−120 seconds, the system begins to display the monitored values on the Bedside Unit *Home* window. The HR, RR and Patient Movement Level are continuously displayed on the screen. Heart and Lungs icons blink and their values display on the screen as long as their measurements are current

Settings for the Vitals module can be adjusted to suit the patient's condition. You can set different settings for high and low HR and RR thresholds. The specified settings generate an alert, when the patient's HR and/or RR cross the defined threshold.

5.2 Vitals Module Main Window

Monitoring of the patient begins automatically, as soon as the patient gets into bed.

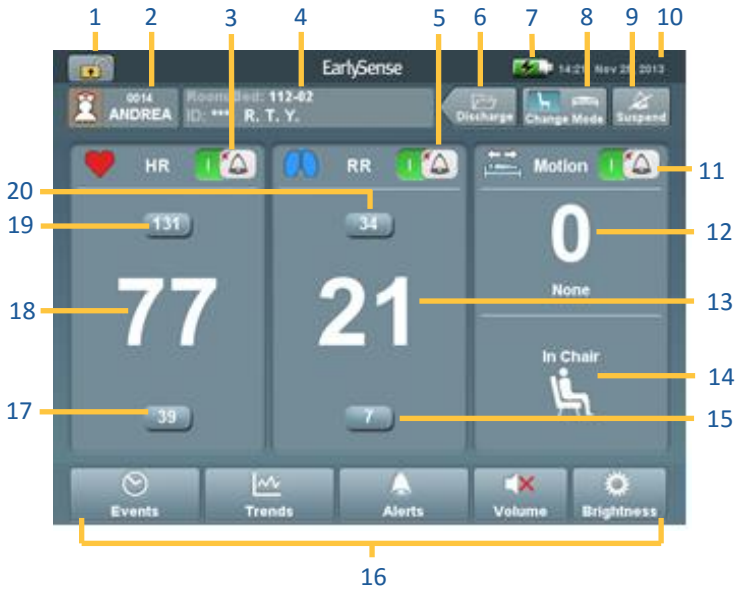


Figure 128: Vitals Module Main Window

1 – Lock/Unlock screen, page 137

2 – Nurse' details (Name, Ext. Number and assigned color), page 138

3 – Enable/Disable HR Alerts, page 155

4 – Patient's details (Room and Bed numbers, ID, initials), page 138

5 – Enable/Disable RR Alerts, page 155

6 – Discharge Patient, page 139

7 – Battery status/AC Indicator, page 138

8 – Switch between Bed and Chair modes (if available), page 140

9 – Suspend Red and Yellow Alerts for 15 minutes, page 154

10 – Date and Time

11 – Enable/Disable Movement Alerts, page 155

12 – Current movement level (0, Low, Medium, High, Extremely High), page 155

13 – Current Respiratory Rate

14 – Bed/Chair Occupancy Icon

15 – Settable **Low** RR Threshold, page 154

16 – Operational Buttons – To open additional screens for events (page 141), trends (page 143), alerts (page 147), brightness (page 148) and volume (page 148)

17 – Settable **Low** HR Threshold, page 154

18 – Current Heart Rate

19 – Settable **High** HR Threshold, page 154

20 – Settable **High** RR Threshold, page 154

5.3 Admitting a Patient – Manually

The *Admit Patient* window is automatically displayed on the screen when the system is turned on if no patient is currently admitted on this Bedside Unit, as shown below:

Figure 129: Admit Patient Window

> **NOTE** Upon installation, the room and the bed numbers in each individual Bedside Unit are configured by an EarlySense authorized technician. Relocation of the Bedside Unit to a different room or bed number should only be performed by an EarlySense authorized technician with the cooperation of the hospital's/clinic's Biomedical Engineering/IT personnel.

► **To manually admit a patient:**

1. Enter the patient information in the *Admit Patient* window, as follows:
   - Enter the patient's name or initials (letters only) and ID (for example, Medical record number – MRN [alphanumeric only]) in the available fields.
   - The **ID**, **Room Number** and **Bed Number** must be entered for the patient to be admitted.
   - Mandatory fields are marked with an asterisk.
   - Select a nurse color in order to assign each patient to a nurse color. You may refer to the *EarlySense Central Display Station (CDS) User Guide* for more information about nurse colors.

> **NOTE** Only letters can be entered in the first, middle and last name fields and only alphanumeric characters can be entered in the ID field.

2 Click **Next** to open the *Patient Demographics* window, as shown below:

Figure 130: Admit Patient Window – Demographics

The following additional fields can also be entered, but are not mandatory:

- **Gender**: Select **M** or **F**.
- **Date of Birth**: Enter the patient's date of birth.

3 Click **Done**.

NOTE The *Admit Patient – Demographics* window does not open unless a patient ID has been entered.

4 Click **Done** to complete admitting the patient.

NOTE The Admit process is not completed unless a healthcare practitioner actively verifies that the patient's information displayed on Bedside Unit's screen is correct and confirms the admission.

NOTE Alerts are only generated after the patient lies still for one minute and either the heart rate or respiratory rate are displayed.

5.4 Unlocking the Bedside Unit Screen

The *Home* window is displayed showing the monitoring data and providing access to additional menus. Selections are made by clicking the screen.

For any interaction (except for responding to alerts), the window must be unlocked. The Bedside Unit automatically locks after a configured period of time.

► **To unlock the screen:**

- Click the  button in the top left of the window. If you click the touch screen while the system is locked, the lock icon flashes red.

Figure 131: Lock/Unlock

5.5 Nurse and Patient Details

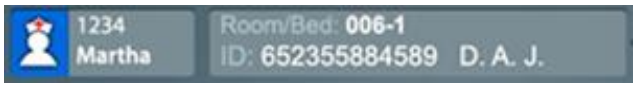


Figure 132: Patient Details

This area specifies the name and extension number of the nurse color responsible for this patient. This indicates the nurse whose pager/phone is notified of this patient's alerts. The nurse responsible for a patient is determined during patient admission and can only be changed on the CDS. Refer to the *EarlySense Central Display Station (CDS) User Guide* for more information.

This area also specifies the details of the patients including the room/bed, patient ID and patient initials.

NOTE If you enter incorrect patient details by mistake, you can discharge the patient and then complete the admission process again for that patient.

5.6 Battery Charge Indicator

The following table shows the battery status indications.

Table 31: Battery Status Indication

Green (with lightning)		Battery is charging and is connected to a power outlet. The lightning symbol on the battery indicates that the battery is charging.
Green		Battery is charging, but is disconnected from a power outlet.
Orange		System is disconnected from a power outlet, and the battery is not charging.
Red		Battery is almost empty. The system is about to shut down.

After Electrical Power is Restored

1. Ensure that the system is plugged into the electrical outlet.
2. Turn the system on by clicking the **On/Off** switch on the front of the Bedside Unit (as shown in Figure 4).

   If a patient was already admitted, the *Home* window is automatically displayed and the system continues its monitoring session.

   The Internal battery automatically recharges when the electrical power is restored. If system operation is not restored, contact EarlySense Support Services.

5.7 Discharging a Patient

► **To manually discharge a patient and end the patient's monitoring session:**

1 Click **Discharge** in the *Home* window. The *Discharge Patient* window is displayed as shown below:

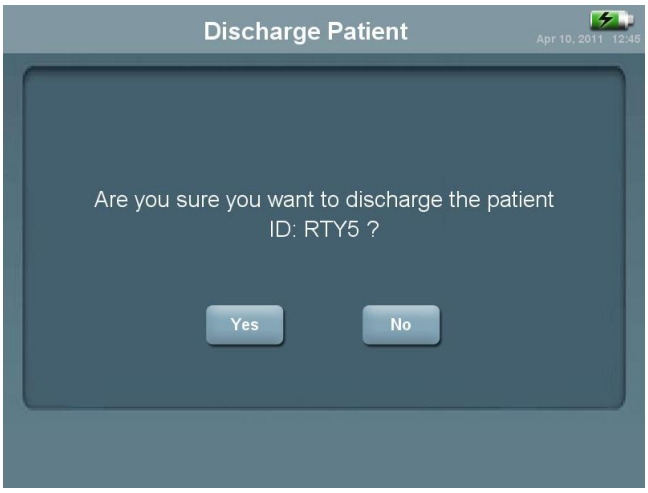


Figure 133: Discharge Patient Window

2 Click **Yes** to confirm discharging the patient from the EarlySense monitoring session.

You may refer to the *Electronically Discharging a Patient* on page 171 for a description of how a patient can be automatically discharged on the Bedside Unit by the HIS system.

WARNING

To avoid recording patient data under an erroneous name, perform the discharge procedure before beginning the monitoring of a new patient.

5.8 Chair Mode

In addition to monitoring a patient in bed, the system allows monitoring of a patient while resting in a chair.

NOTES Both a Chair Sensor and a Bed Sensor can be connected at the same time to the Bedside Unit. If an EarlySense technician configured the system to work only in either Bed mode or Chair mode, then this button is not enabled.

By default the system is set to Bed Mode as shown below:

Figure 134: Bed Mode

► **To change to Chair Mode:**

1. Place the Chair Sensor, which is inserted into a cushion, on a chair.
2. Connect the cable from the Chair Sensor to the Bedside Unit.
3. Click the **Change Mode** 

button to toggle the selection to the chair icon. The following displays:

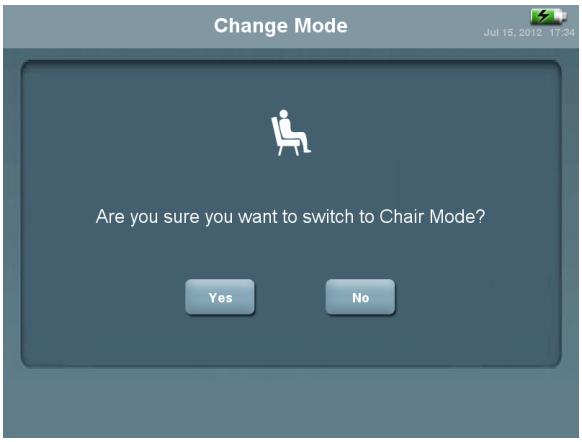


Figure 135: Confirming Chair Mode

If **Yes** is clicked, chair mode appears on the *Home* window.

The following shows the monitoring window in Chair Mode for each of the EarlySense Modules:

Figure 136: Chair Mode – Vitals Module

5.9 Events Button – Manually Recording an Event

The following describes how to manually indicate that an event occurred. These events are recorded in the system with a timestamp and can be viewed in the *Trends* window.

► **To access the Events menu:**

1 Click the **Events** 

button at the bottom of the *Home* window (see Figure 128). The **Events** menu displays, as shown below:

Figure 137: Events Window

2 Click one of the four primary events on the left or one of the secondary events on the right. The button changes color, showing that it was successfully selected. The following message appears: **Recording Event: <Event Name>**.

3 Click the **Home** button at the top of the window to confirm your selection and close the window, or **Cancel** to cancel your selection.

The following events are available:

- Primary Events:
  - Emerg. Med.: Emergency medication given when patient is in distress
  - CPAP/BPAP
  - Intubation
  - Patient Round
- Secondary Events:
  - Patient Fall
  - Continuous Med.: Routine medication
  - Pain Relief Med.: Pain relief medication
  - Patient Agitation
  - Skin Breakdown:
  - General Flag 1: Marks any event of type 1 that is not included in the list of events

5.10 Trends Button – Trends Graph

The following describes how to display patient measurement trends in graphical form.

NOTES Trend graphs may contain up to seven days of data.

► **To display a trend graph:**

- Click the **Trends** 

button at the bottom of the *Home* window (see Figure 128). The following displays:

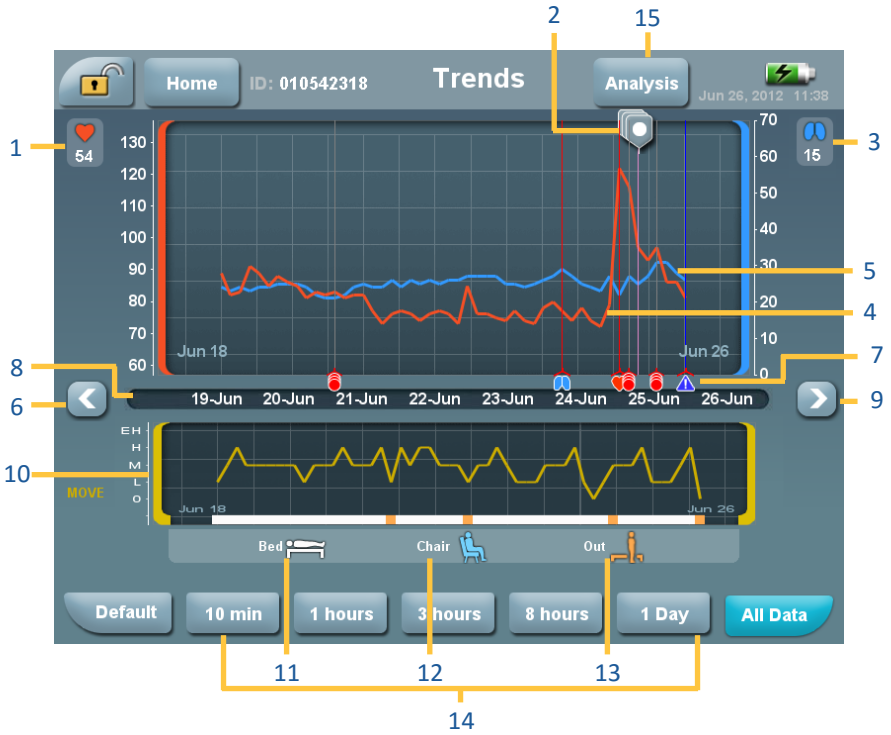


Figure 138: Viewing Patient Trends

1 – **Current Heart Rate –** Current Heart Rate in beats per minute.

2 – **Events –** Displays events that users have manually entered for documentation during the time displayed.

3 – **Current Respiratory Rate –** Current Respiratory Rate in breaths per minute.

4 – **Heart Rate Trend –** Displays Heart Rate in beats per minute (graph) during the time displayed.

5 – **Respiratory Rate Trend –** Displays Respiratory Rate in breaths per minute (graph) during the time displayed.

6 – **Scroll Back Alerts –** Click here to scroll back.

7– **Alerts –** Displays alerts that occurred during the time displayed.

8 – **Time Scale –** Time scale for data presented.

9 – **Scroll Forward –** Click here to scroll forward.

10 – **Movement Trends –** Shows patient's movement level while in bed during the timescale presented (See page 146).

11 – **Bed –** Shows the time intervals patient spent in bed. (White)

12 – **Chair –** Shows the time intervals patient spent in chair. (Blue)

13 – **Out –** Shows the time intervals when patient has been out of bed/chair. (Orange)

14 – **Time Period Buttons (10 min, 1 hour, 3 hours, 8 hours, 1 day) –** Click one of these buttons to change the time period displayed in the graph.

15 – **Analysis Screen –** Opens the *Analysis* window (Figure 139).

▶ **To scroll forward or backwards within the time frame:**

- Click the forward (>) or back (<) arrows.

5.10.1 Alert Symbols

The following symbols may be displayed on the Trend graphs.

Table 32: Alert Symbols

Icon	Meaning
	Blue Alerts: Technical alerts, such as System Malfunction, Sensor Malfunction and Low Battery
	High/Low Heart Rate: Red Alert
	High/Low Respiratory Rate: Red Alert
	Movement Level High: Yellow Alert
	Lost Patient Signal: Red Alert
	Unstable Signal: Red Alert
	HR and RR above thresholds

5.10.2 Event Symbols

The following event symbols are used in Trend graphs.

Table 33: Event Symbols

Icon	Meaning
	Patient Round
	Intubation
	Patient Fall
	Emergency Medication.
	Continuous Medication – Routine Medication
	Patient Agitation
	Skin Breakdown.
	General Flag 1: Marks any event of type 1 that is not included in the list of events
	General Flag 2: Marks any event of type 2 that is not included in the list of events
	Patient Turn: Inserted automatically if a staff member clicked the **Reset** button on Patient Turn Counter and the system detected that a patient-turn occurred

5.10.3 Setting the Timescale

When entering the *Trends* window, the default timescale displayed is **All Data**. You can return to this timescale at any time by clicking the **Default** button. Use the buttons under the graph to determine the timescale displayed. If you select a larger timescale, the current time that is in the center of the timescale remains the center point. If you select a shorter timescale, you are prompted to click the screen to determine where you would like the displayed timescale to appear on the screen.

5.10.4 Analysis

The **Analysis** button enables you to display the average respiratory rate, heart rate and movement time (%) for a specified interval each day. The following displays:

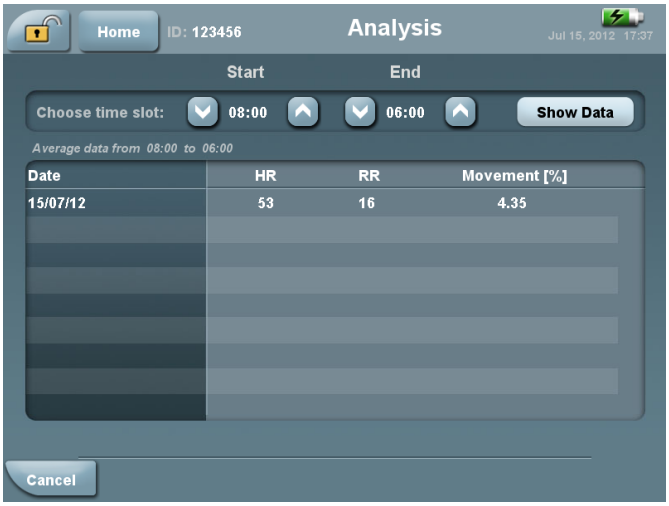


Figure 139: Analysis Window

Use the arrows to set the preferred time slot and then click the **Show Data button**. The data displays in the table.

5.10.5 Trend Indication

The **Trends** button turns red when the system detects a change in the trend of a patient's HR and/or RR vital signs

If the Bedside Unit is connected to an EarlySense CDS, the patient is also highlighted on the CDS screen.

Figure 140: Trend Indication

The **Trends** button remains red until the patient is discharged from the Bedside Unit.

5.11 Setting Alert Volume and Tone

The following describes how to configure the alert settings (such as volume and tone) of specific types of alerts.

► **To configure specific types of alerts:**

1. Click the **Alerts** 

button at the bottom of the *Home* window (see Figure 128). The *Alerts Setup* window is displayed, as shown below, showing the current configuration of all types of alerts:

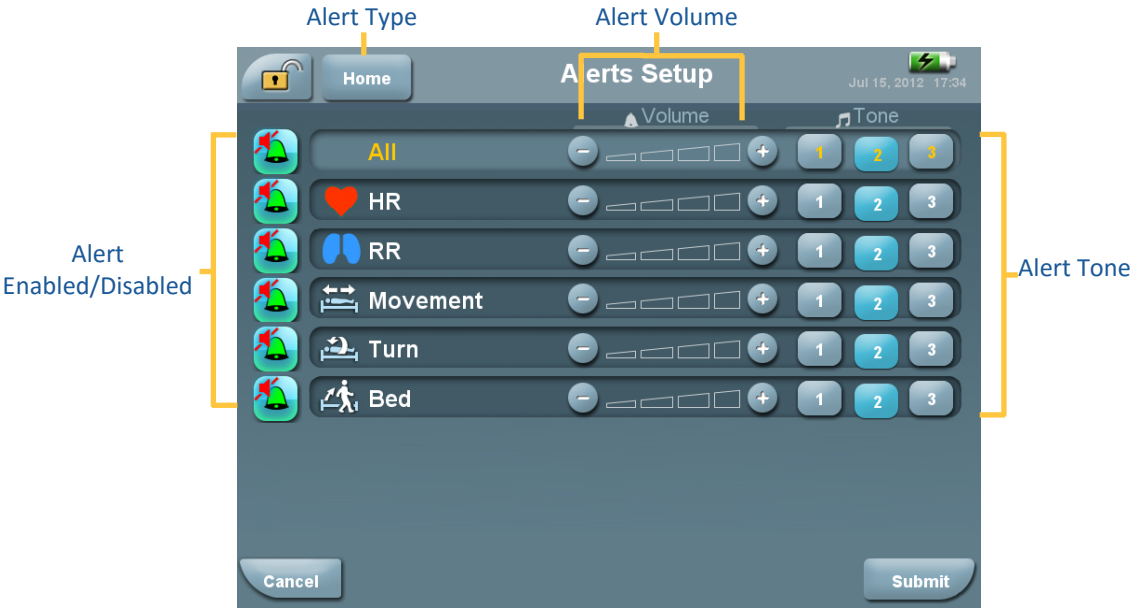


Figure 141: Alerts Setup Window

2. Click the **Plus** (**+**) or **Minus** (**-**) button to adjust the volume for each type of alert.
3. Click either the **1**, **2** or **3** button to select an alert tone.
4. Click the **Bell** icons to enable or disable specific alerts.

Table 34: Alerts Status Table

Enabled	Enabled and Silenced	Disabled
		

5. Click **Submit** to activate the settings or **Cancel** to preserve the existing settings.

NOTE In addition to changing the individual alert volumes, as described above, you can also change the general volume of all alerts it on the Bedside Unit (page 148) by setting the volume and tone of all alerts in the *Alerts Setup* window. Alert volumes are determined by whichever parameter (**General** or **Alert**) was set last.

NOTE When a patient is admitted or discharged, all alert settings return to their default settings.

WARNING An Audible Alert in the EarlySense System is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

5.12 Setting Bedside Unit Alert Volume

The following describes how to set the volume of all alert tones. The alert volumes are determined based on whichever of two parameters (**General** or **Alert**) was last set. The volume and tone for individual alerts can also be set, as described on page 147.

At startup and after admitting a new patient, the system returns to its default alert settings (silent alert). Alert settings automatically return to their default settings after discharging the patient.

▶ **To set the General Volume:**

1. Click the **Volume** button in the *Home* window (see Figure 128). The **Volume** button then changes to appear as follows:

Figure 142: General Volume

2. Click the **Plus** (**+**) button to raise the volume or the **Minus** (**-**) button to lower the volume.

   When the volume is set to mute, the **Volume** icon is marked with an X and a mute sign appears on the alerts' **Bell** icons. To mute the volume, press the  button until the volume reaches its lowest setting.

5.13 Setting Bedside Unit Alert Brightness

▶ **To adjust screen brightness:**

1. Click the **Brightness** button on the *Home* window.
2. Click the **Plus** (**+**) or **Minus** (**-**) button to adjust the brightness.

Figure 143: Brightness Adjustment

If the brightness level is set to the lowest level, the screen may appear black during daylight. Clicking the screen when brightness is set to the lowest level increases the screen's brightness.

5.14 Visual Alert Indications

The following figures show a visual alert, as it appears in each Module's *Home* window. The area of the window indicating the measurement of concern is highlighted in red or yellow and a red or yellow message displayed at the bottom of the window, as shown below:

Figure 144: Alert Window – Vitals Module

Click **OK** to acknowledge the alert or the **Suspend** button to suspend all alerts for 15 minutes.

5.14.1 Alert Indicators

Both sides of the bedside unit have an alert indicator that lights up according to the color of the alert, meaning blue, red or yellow. You can click either of them to acknowledge the alert.

Figure 145: Bedside Unit Alert Indicators

WARNING

Active RED indicator light, requires an immediate response to understand the nature of the Alert.

Active YELLOW indicator light, requires prompt response to understand the nature of the Alert.

5.15 Alert Sound Notification

The Bedside Unit sounds and alerts to notify personnel of situations that may require attention. The EarlySense System enables you to define and adjust alert configurations/settings. Audible and visual alert notifications are generated according to several settings.

When an alert is generated, an audible alert is sounded unless the volume is muted, as described on page 148.

You may refer to the *Setting Bedside Unit Alert Volume* section on page 148 for a description of how to control the alert volume of all the alerts on the Bedside Unit.

You may refer to the *Setting Alert Volume and Tone* section on page 147 for a description of how to control the alert volume and tone of specific types of alerts on the Bedside Unit.

WARNING

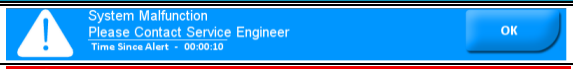
The Audible Alert in the EarlySense System is not intended for monitoring high-risk situations where ECG monitoring is required. The most reliable method of patient monitoring combines close personal surveillance with correct operation of the monitoring equipment.

5.16 Alert Visual Notifications

When an alert is generated a visual notification displays on screen.

A message is displayed at the bottom of the window describing the nature of the alert and the elapsed time since the alert was activated, as shown below:

Table 35: Visual Alert Notifications

Key	Example
Blue Alerts	
Red Alerts	
Yellow Alerts	
Grey Notification Message	

5.16.1 Alert Colors

The background color of the alert corresponds to the alert priority in the following order: blue, red, yellow or gray. Blue alerts relate to a system problem and are not connected to a specific patient monitoring parameter.

5.16.2 Multiple Alerts

When more than one alert is generated for the same patient at the same time, only the most severe alert is active. Only one alert can be active at a time.

The following are a few examples:

- When a Yellow Alert (such as, Extremely High movement) is generated while a Red Alert is in active (such as an HR), then only the Red Alert is shown.
- When a blue alert is generated while a red alert is in progress, then the blue alert is shown.
- When an HR or RR (red) alert is active (displayed on screen) and not acknowledged by the user, a second HR or RR alert is not generated when conditions for another HR/RR Alert occur again.

A new alert becomes active only if the currently active alert has a lower priority.

NOTE Different types of alerts with the same priority cannot be generated when the same priority alert is still active. Make sure not to leave patients unattended who may be at risk of falling.

5.17 Enabling/Disabling Alerts

An *Enabled Alert* means that the alert is displayed and will sound on the Bedside Unit.

An *Enabled and Silenced Alert* means that the alert is displayed, but will not sound on the Bedside Unit.

A *Disabled Alert* means that the alert is not displayed and will not sound on the Bedside Unit or the CDS.

If an alert is disabled while the alert is going off, the alert message remains active until it is acknowledged by a healthcare practitioner.

▶ **To disable/enable alerts for specific parameters:**

- Click the bell symbol next to the alert in either the *Home* window (described on page 135) or the *Alerts Setup* window (described on page 147).

Table 36: Alerts Status Table

Window	Enabled	Enabled and Silenced at Bedside	Disabled
Home Window			
Alerts Setup Window			

The following is displayed when an HR alert is being disabled. To disable the alert, click **Yes**.

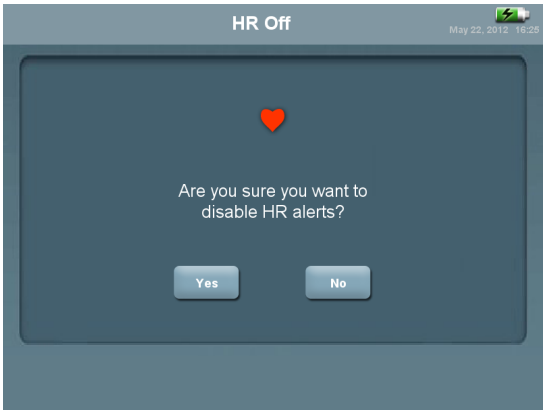


Figure 146: HR Off Window

The following is displayed when an RR alert is being disabled. To disable the alert, click **Yes**.

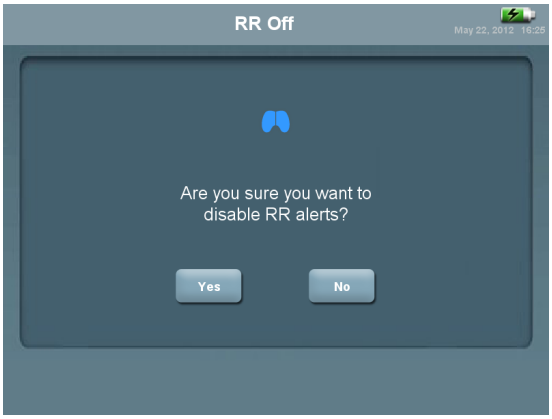


Figure 147: RR Off Window

► **To enable alerts:**

- Click the Bell symbol again.

5.18 Handling Blue Alerts

Blue alerts represent a technical system problem, (not a patient problem), and are therefore handled differently than red and yellow alerts.

Blue alerts appear with an **OK** button or **Pause** button and remain active as long as the alert condition exists. Blue alerts disappear only after the technical issue is resolved and cannot be suspended.

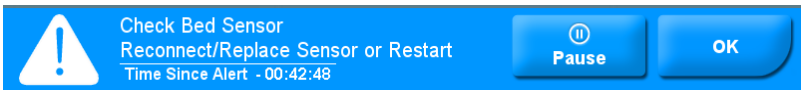


Figure 148: Blue Alert – Check Sensor (Bed Mode)

5.18.1 Blue Alerts – Pausing Patient Monitoring

The **Pause** button in the Blue Check Sensor Alert message temporarily stops patient monitoring. The **Pause** button can be used only when the Sensor is temporarily disconnected from the Bedside Unit in order to avoid a blue *Check Sensor* technical alert from going off. For example, this function should be used when the patient needs to be transported with his/her bed and therefore the Sensor must be disconnected from the Bedside Unit.

Monitoring of the patient can be resumed at any time, and all the previous trends are then displayed as usual.

▶ **To pause patient monitoring:**

- Click the **Pause** button when a blue alert appears. A *Pause* window displays, as shown below:

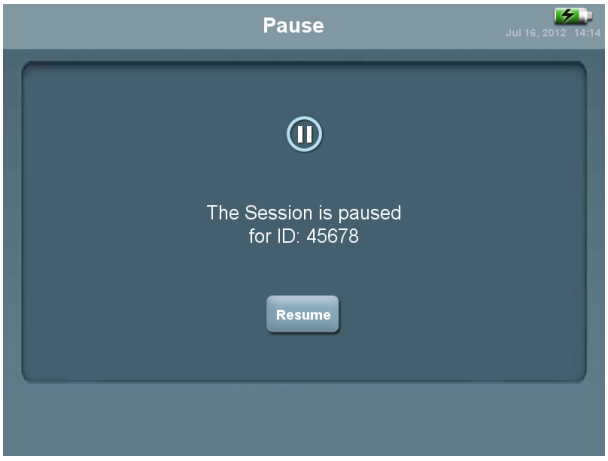


Figure 149: Pause Window

▶ **To continue patient monitoring:**

- Click the **Resume** button in the *Pause* window or connect a Sensor.

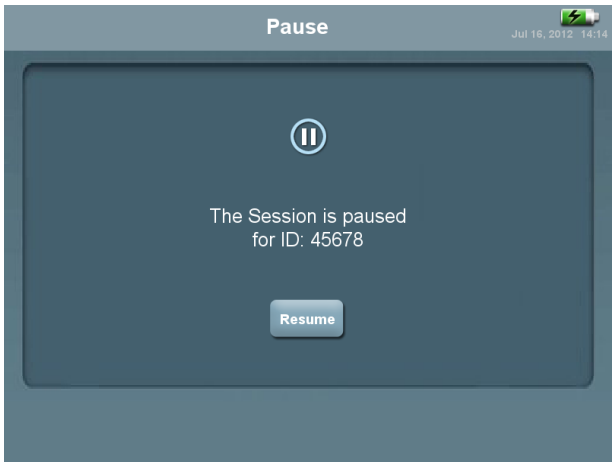


Figure 150: Pause Window

5.19 Suspending Red and Yellow Alerts

The sounding and display of all Red and Yellow alerts can be suspended, meaning that the system does not generate any patient alerts, as follows:

- Click the **Suspend** button on the top right of the screen. An **Alert Suspension Timer** icon appears on the *Home* window and on the CDS screen, which suspends all Bedside Unit alerts for 15 minutes.

Figure 151: Alert Suspension Timer – Vitals Module

- To stop the suspension of alerts, click the **Suspend** button again.
- After 15 minutes, if no one clicks the **Suspend** button again, the alert suspension is automatically terminated and new alerts are sounded and displayed again when the applicable alerting condition recurs or if it still exists.

NOTE Blue alerts cannot be suspended.

5.20 Modifying HR and RR Alert Thresholds

When beginning to monitor a new patient, it is advisable to set patient-specific alert thresholds.

► **To change the default HR and RR thresholds:**

1. Click the upper or lower thresholds in the HR and RR areas. Arrows appear, as shown below.

Figure 152: Adjusting the HR Upper Threshold

2. Click the  arrow to lower the threshold or the  arrow to raise the threshold.
3. When you reach the required threshold, click the displayed number or wait. If the new value is different from the default value, a red rim highlights the new threshold.

The following are the lowest and highest threshold values that you can enter:

Table 37: Threshold Range Settings

	Lowest Settable Limit Threshold	Highest Settable Limit Threshold
Heart Rate	35 BPM	150 BPM
Respiratory Rate	8 Br/min	44 Br/min

5.21 Disabling and Enabling Vitals and Movement Alerts

Alerts can be enabled or disabled, as defined by the user.

► **To disable alerts for specific parameters:**

Click the bell symbol next to the alert in either the *Home* window or the *Alerts Setup* window.

To enable alerts, click the Bell symbol again.

5.22 Patient Movement

Movement rates are determined based on the percentage of movement time within a defined period of time, as described in Table 18. The accuracy of the System in displaying different rates is also presented below.

Table 38: Patient Movement Rates

Rate	Percentage of Movement During Defined Period	Accuracy of Rates Displayed for Adults	Accuracy of Rates Displayed for Children
0	0	100%	100%
L	Up to 40%	100%	100%
M	40–60%	81%	81%
H	60–80%	100%	86%
EH	80–100%	96%	94%

Trend data for patient movement over time can be viewed in trend graphs, as described in the *Trends Button – Trends Graph* section on page 143.

5.23 Gray Figures Display

If the system cannot detect or measure the current HR or RR for more than one minute, the last measured HR or RR is displayed on the window in gray with a measurement timestamp, and the blinking Heart or Lungs icon stops blinking, as shown below:

Figure 153: Gray Values of HR and RR

5.24 Settings – Advanced Functions and Technician Mode

► **To access the settings:**

- Click the **EarlySense** EarlySense button in the top row of the *Home* window. The *Settings* window has two tabs: **Setup** and **Maintenance**, as described below.

5.24.1 Setup – Languages

The **Setup** tab specifies the language of the user interface and reports. Setting a language can only be performed by an authorized EarlySense technician.

Figure 154: Advanced Window – Setup Tab

5.24.2 Maintenance

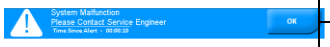
This mode should only be used by a technician authorized by EarlySense. It requires a PIN code.

5.25 Vitals Module – Messages and Alerts

The following describes the four types of system messages and alerts provided by them vitals Module: **Red**, **Yellow** and **Blue** alerts, and **Gray** notifications.

Table 39: Vitals Module System Messages and Alerts

Alert Display Color	List of Messages/Alerts in This Category	Description
	High/Low HR.	Heart Rate exceeds thresholds.
	High/Low RR.	Respiratory Rate exceeds thresholds.
	Multi-parameters Alert (HR and RR Above Thresholds)	System detected that both Heart Rate and Respiratory Rate exceeded predefined thresholds as set by the healthcare practitioners.
	Lost Patient Signal.	System cannot detect patient's signal. Check the patient and the Sensor location.
	Unstable Signal.	The signal was not continually detected. Consider using alternative monitoring.
	HR RR Above Limit.	An indication that a patient may be at risk of developing Sepsis, because the detected HR and RR measurements are above the limit defined by the hospital's SIRS protocol.
	Extremely High Motion.	Patient Movement Rate was extremely high during the last minute.

Alert Display Color	List of Messages/Alerts in This Category	Description
 Technical Alert – Indicates that there is a technical problem with the system.	Check Sensor (connection, position or location)	Indicates that the Sensor connection is malfunctioning or that the Sensor is disconnected. This may indicate that the location or the position of the Sensor is incorrect or upside down. (See *Troubleshooting*, page172)
	No AC Power.	Indicates that the Bedside Unit is disconnected from the electrical power. Reconnect the Bedside Unit to the electrical power outlet. Otherwise, the Bedside Unit will shut down. (See *Troubleshooting*, page 172)
	Very Low Battery.	Indicates that the battery is low and that the system is about to shut down. Reconnect the Bedside Unit to the main electrical power. (See *Troubleshooting*, page 172)
	System Malfunction.	Indicates indicating that the System is malfunctioning. Contact the Field Service Engineer. (See *Troubleshooting*, page 172)
	Sensor is about to expire within 30 days.	Indicates that this Sensor stops functioning within 30 days. Click **OK** to eliminate the message and to continue the monitoring session.
	Sensor Expired.	Indicates that this Sensor has stopped functioning and should be replaced.
 Functional Message – Informative message	Patient Not Admitted.	The system detected a signal in bed, no patient information was entered.
	No Patient detected for X hours.	The system has not detected a signal for X hours, although a patient was not discharged.
	Signal is Detected in Bed.	The Bedside Unit is in Chair mode, but HR/RR or movement is detected in the bed.
	Recording Event.	The system is currently recording an event. A visual icon displays in the *Trends* window.

5.25.1 Alerting Parameters (Contact-free Sensor)

Table 40: Vitals Module Alerting Parameters

	Low Heart Rate	High Heart Rate
Time to alert for change in HR	90 seconds	90 seconds
	Low Respiratory Rate	**High Respiratory Rate**
Time to alert for change in RR	180 seconds	180 seconds

5.26 Generating Reports (Data Retrieval)

Data analysis may be performed online during the monitoring session, based on the Bedside Unit display or reports.

Reports can be downloaded at the Bedside Unit or printed at the Central Display Station (CDS), as described in the *EarlySense Central Display Station (CDS) User Guide*). To ensure the privacy of the patient's medical data, a PIN must be entered before reports can be downloaded or printed.

The data can be downloaded either as a CSV file or as a complete report in Acrobat PDF format. For a CSV file, the data can be viewed by a clinician using standard software. For example, Microsoft Excel™. The data is presented numerically. The clinician can use the provided data and Excel to generate any other graph that is required.

WARNING

The data acquired by the EarlySense System must only be interpreted by a healthcare practitioner.

5.26.1 Downloading Patient Data and Reports

► **To download patient data and reports:**

1 Insert a USB disk drive with at least 0.5 GB of free space into the USB slot. If the disk drive is already inserted, it must be removed and re-inserted before starting the data download procedure.**2** Click the **EarlySense** icon and then the **Maintenance** tab. The following displays:

Figure 155: Advanced Window – Maintenance Tab

3 Click the **Download Report** button. The following window displays:

Figure 156: Enter PIN Window

4 Enter a PIN (Personal Identification Number) and then click **Submit**. The following message is displayed at the bottom of the window indicating that downloading has started.

Figure 157: Downloading in Progress Message

The system automatically downloads the data (CSV file) and the report (PDF file) of the last two admitted patients.

A message displays when the download completes.

Sample reports are available on page 162.

5.26.2 Sample Reports

The following figures show a sample Patient Status report, which can be downloaded, as described in the *Downloading Patient Data and Reports* section on page 160. This report can also be printed via the CDS. You may refer to the *EarlySense Central Display Station (CDS) User Guide* for more information.

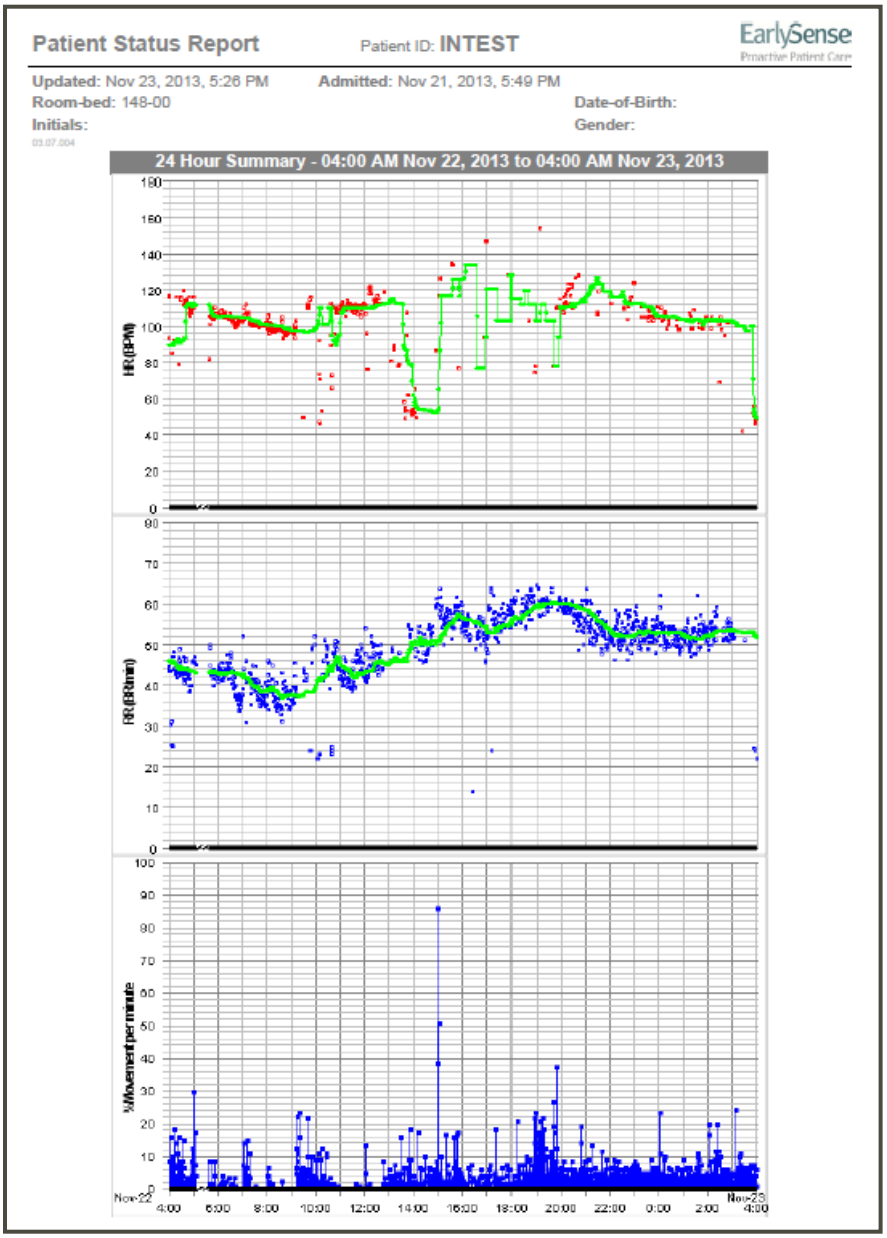


Figure 158: Vitals Module – Patient Status Report – 1

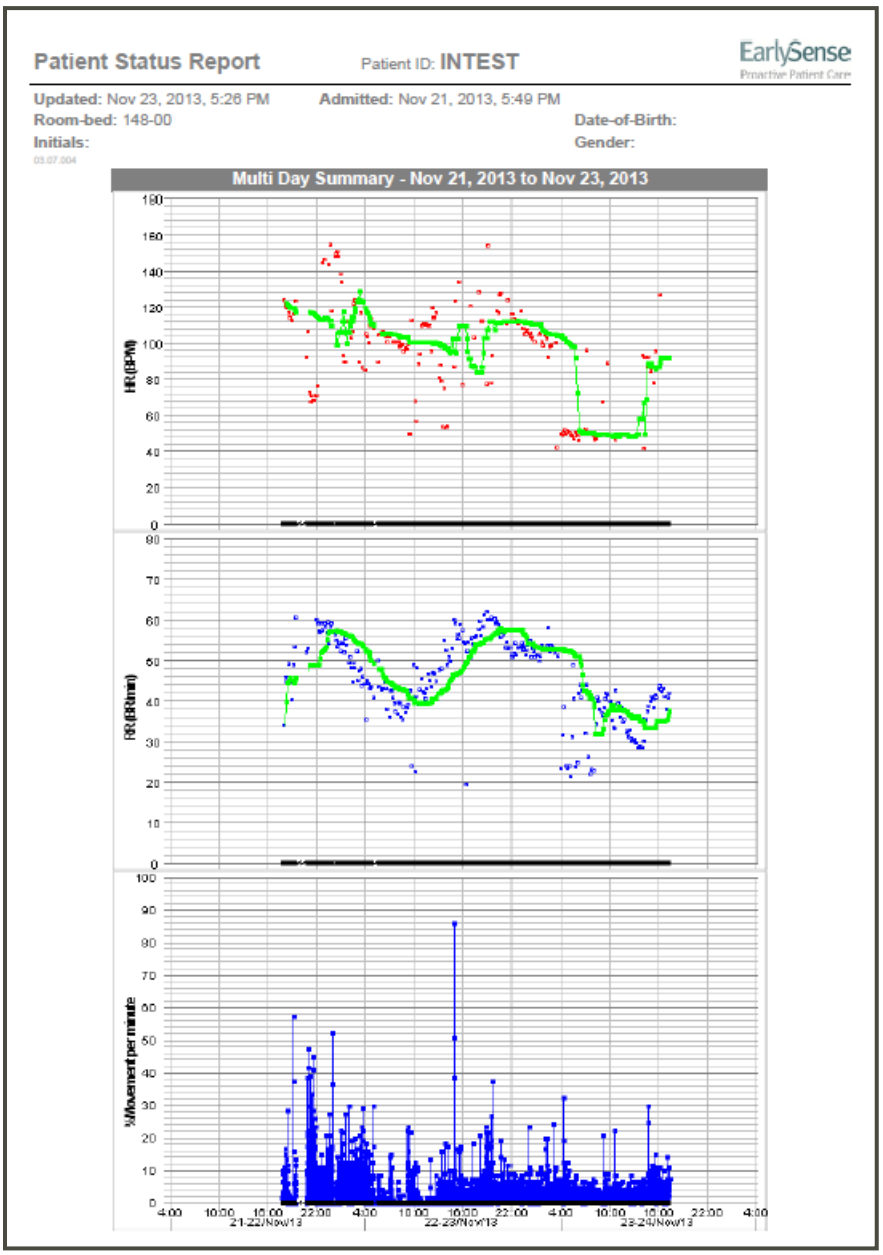
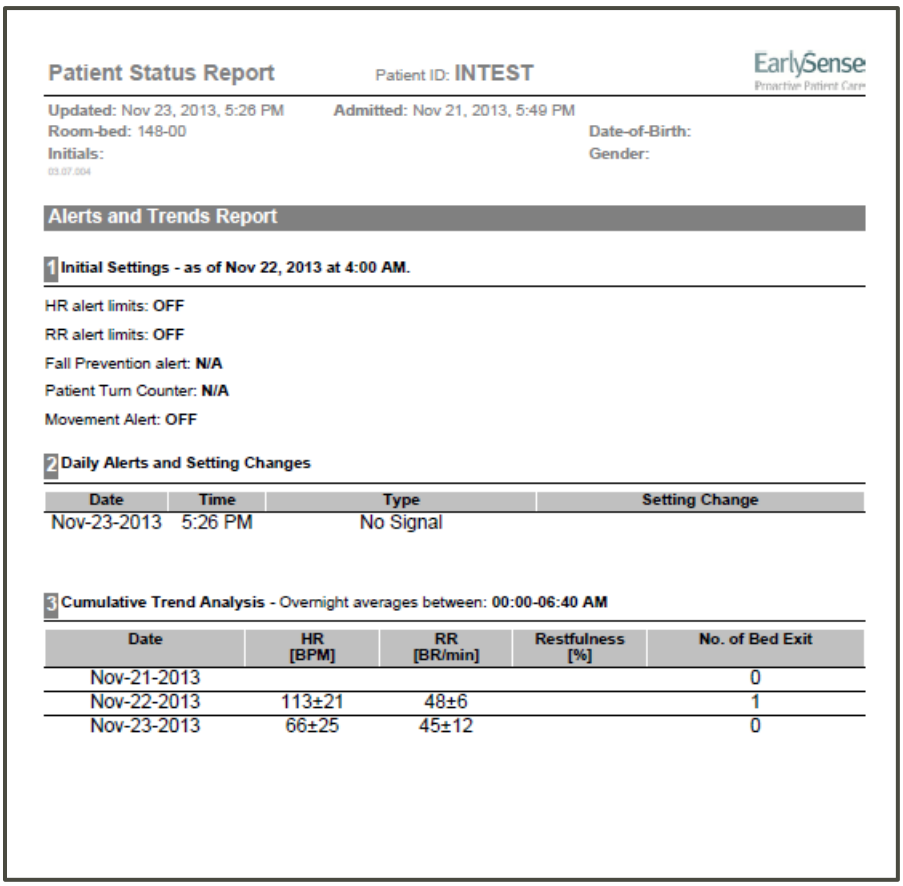


Figure 159: Vitals Module – Patient Status Report – 2



Patient Status Report Patient ID: INTEST

EarlySense
Proactive Patient Care

Updated: Nov 23, 2013, 5:26 PM **Admitted:** Nov 21, 2013, 5:49 PM
Room-bed: 148-00 **Date-of-Birth:**
Initials: **Gender:**
03.07.004

Alerts and Trends Report

1 Initial Settings - as of Nov 22, 2013 at 4:00 AM.

HR alert limits: **OFF**
RR alert limits: **OFF**
Fall Prevention alert: **N/A**
Patient Turn Counter: **N/A**
Movement Alert: **OFF**

2 Daily Alerts and Setting Changes

Date	Time	Type	Setting Change
Nov-23-2013	5:26 PM	No Signal	

3 Cumulative Trend Analysis - Overnight averages between: **00:00-06:40 AM**

Date	HR [BPM]	RR [BR/min]	Restfulness [%]	No. of Bed Exit
Nov-21-2013				0
Nov-22-2013	113±21	48±6		1
Nov-23-2013	66±25	45±12		0

Figure 160: Vitals Module – Patient Status Report – 3

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APPENDICES

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A Electronic Patient Admission

This appendix describes how to admit a patient by receiving electronic identification information for the patient from an EMR (HIS or ADT).

NOTE After a patient has been admitting, patient identification details cannot be updated on the Bedside Unit.

A.1 Admitting a Patient Electronically

A.1.1 Overview

If an EMR is available in the hospital/clinic setting, the EarlySense System can receive and log the basic admission information (ID, patient's initials/name or other demographic information) from the HIS, as available, into the EarlySense System, rather than requiring manual entry of these data.

The information from the EMR populates fields in the *Admit* window. After this information has been added from the EMR, the healthcare practitioner must confirm the information in the window, shown below.

NOTE The Admit process is not completed until a healthcare practitioner actively verifies that the identification information transferred from the EMR to the EarlySense System is correct for the patient and until he/she confirms the admission.

Figure 161: Admit Patient Window with Patient Information from EMR

► **To complete the process of patient admission to the EarlySense System:**

1. Select a nurse color to assign the patient to a nurse.
2. Click **Done** to confirm the patient admission to the system.

   To dismiss this admission or to manually admit a patient with different patient information, click **Cancel**.

Figure 162: Updated Admit Patient Window (Patient's Name Fields Highlighted)

All fields entered from the EMR are shown in blue.

To complete admission on the Bedside Unit, confirm the updated patient information by clicking **Done** as prompted by the system. This confirmation ends the current monitoring session and restarts a new session, with the updated patient information and with the default system settings.

Click **Yes** to confirm the patient with the updated information. Click **No** to return to the updated *Admit Patient* window (Figure 162).

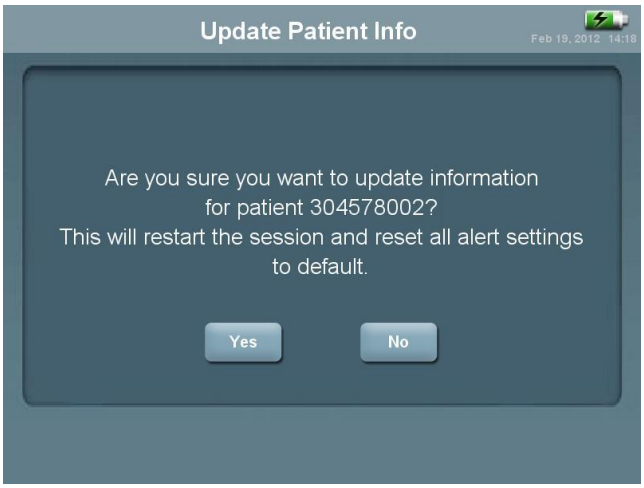

Figure 163: Confirming Readmitting Patient with Updated Information from EMR

To continue the current monitoring session without updating the patient information, click **Cancel** in the updated *Admit Patient* window (Figure 162). You must confirm the dismissal of the patient information (Figure 164).

Click **Yes** to confirm or click **No** to return to the updated *Admit Patient* window (Figure 162).

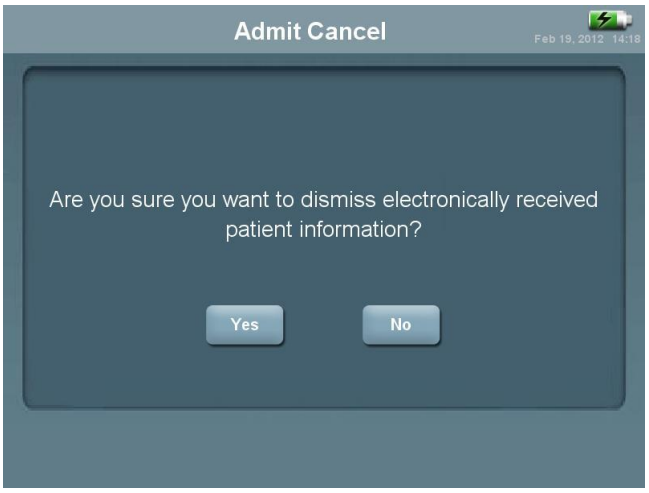

Figure 164: Confirming Dismissal of the Updated Patient Information

A.1.2 Electronically Discharging a Patient

When communication with the HIS (Admit/Transfer/Discharge mode) exists, upon receipt of information from the HIS that a patient is discharged from the department, the patient's EarlySense monitoring session is ended automatically and an *Admit Patient* window is displayed on the Bedside Unit.

A.1.3 Electronically Transferring a Patient to Another Room/Bed

If communication with the HIS (Admit/Transfer/Discharge mode) exists, upon indication from the HIS that a patient has been transferred from one room or bed to another, the patient is automatically discharged from the EarlySense System at the current bed and an *Admit Patient* window with the patient's information (Figure 161) is displayed on the EarlySense System at the new bed to which the patient is being transferred. In order to complete the new admission process in the new location (room/bed), you must confirm the admission on the Bedside Unit in the new room/bed, including assigning a new nurse (color) and selecting **Done**. During the new admission, the same questions regarding bed exit and patient turn display and must be addressed by you.

To dismiss the new admission of the transferred patient in the destination bed location, click **Cancel**. In this case, if there had been another patient admitted to this EarlySense System, the previous patient's *Home* window is displayed. If no patient has been admitted to this EarlySense System, an *Admit Patient* window with empty fields is displayed.

B Troubleshooting

This appendix describes various problems, possible causes and their solutions.

The following table describes the problems that may occur in all the EarlySense Modules.

Table 41: Troubleshooting

Problem	Possible Cause	Solution
The system is functioning, but the AC Icon is not displayed on the Battery icon.	System is unplugged from the electrical outlet.	Reconnect the unit to the electrical outlet.
Screen is dark, but LEDs are on.	The screen was set to be darkened or there is a technical problem.	• Click the screen once to make it brighter. To change the brightness, click the **Brightness** button. • Turn off the system by clicking the On/Off switch for 10 seconds and then turn the system back on by briefly clicking the On/Off switch. If problem is not resolved, contact the Field Service Engineer.
Blue Alert displays the System Malfunction message.	System malfunction.	Contact the Field Service Engineer.
Blue Alert displays Low Battery message.	System is unplugged and the battery is discharging.	Reconnect the Bedside Unit to the electrical outlet.
Screen displays Sensor is about to Expire within X Days message.	This Sensor stops functioning within X days.	Contact a Field Service Engineer.
Screen displays Sensor Expired message.	Sensor has stopped functioning.	Replace the sensor and contact the Field Service Engineer.

Problem	Possible Cause	Solution
Blue alert displays Check Sensor. Blue Alert displays SpO_2 check Sensor alert.	• Bedside Unit has detected that the Sensor is not connected, or that the position or the location of the Sensor is incorrect. • Technical malfunction of the SpO_2 Sensor.	• Check if the Sensor is connected to the Bedside Unit. Reconnect if necessary. • Check if the Sensor is located in the proper place and on the correct side. • If the problem persists, replace the sensor. • If the problem persists, restart the system. • If the problem persists, call the Field Service Engineer. • Replace the SpO_2 Sensor.
Bedside Unit is not responding (On/Off is not available).	No electrical power, as the system is unplugged and the battery is discharged, or there is a system error.	• Check the connection to the electrical power. • Reconnect if necessary. • If the problem persists, call the Field Service Engineer.
No alerts are being generated when a patient exits the bed.	Bed Exit alert is disabled. Too low bed-exit sensitivity selected (incorrect system setting) or, difficulty in detecting a signal.	• Confirm that the Bed Exit alert is enabled. • Select a higher Bed Exit sensitivity (level 6). • Verify that the HR or RR measurements are displayed for at least one minute, to ensure that the alert mode is re-charged in the system.
The Bedside Unit is operating, but no SpO_2 is displayed.	SpO_2 Sensor is disconnected.	Check that the SpO_2 Sensor is connected.

Problem	Possible Cause	Solution
The Bedside Unit is operating, but no HR or RR is displayed.	Difficulty in detecting a signal.	• Check the sensor location. The Sensor should be placed horizontally under the mattress below the patient's chest area. • Reposition the Sensor if it moved from the specified location. If the problem persists, replace the Sensor.
No alerts are being generated or alerts are delayed when a patient exits the bed.	• Bed Exit alert is disabled. • Difficulty in detecting a signal. • Sensor location is incorrect. • Too low bed-exit sensitivity selected (incorrect system setting by the caregiver).	• Confirm that Bed Exit alert is enabled. • Verify that the Sensor position is correct, meaning that the Sensor is not upside down and that it is positioned at the top 1/3 of the patients torso. • Verify that the EarlySense System is actually monitoring the patient (meaning that HR and/or RR measurements are displayed for at least one minute, to ensure that alert modes are active). • Select a higher Bed Exit sensitivity. Note: The least-sensitive level is 1 and the most-sensitive level is 6.
The Bedside Unit is operating, but no SpO_2 is displayed.	Oximeter module is unplugged.	• Check that the Oximeter module is connected to the Bedside Unit. • Check that the finger Sensor is placed correctly. • If the problem persists, call the Field Service Engineer.

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C Nonin XPod® OEM-compatible SpO_2 Sensors

This appendix provides a list of the Nonin XPod OEM-compatible $Sp0_2$ Sensors.

- 8000AA Adult Articulated Internal Spring Finger Clip, 3 Foot/1 Meter Cable
- 8000AP Pediatric External Spring Finger Clip, 3 Foot/1 Meter Cable
- 8000J Adult Flex, 3 Foot/1 Meter Cable
- 8000SS Sensor, Reusable, Soft, Small, 1 Meter
- 8000SM Sensor, Reusable, Soft, Medium, 1 Meter
- 8000R Reflectance, 3 Foot/1 Meter Cable
- 8000SL Sensor, Reusable, Soft, Large, 1 Meter
- 7000A Flexi-Form® II Adult, 3 Foot /1 Meter
- 7000P Flexi-Form® II Pediatric, 3 Foot/1 Meter Cable
- 7000N Flexi-Form® II Adult, 3 Foot/1 Meter
- 6000A Sensor, Disposable, Adult, 45cm Cable
- 6000P Sensor, Disposable, Pediatric, 45cm Cable
- UNI-RA-0 7.5" 90-degree Patient Cable
- UNI EXT-X Patient Extension Cable (select 1, 3, 6 or 9 Meters)

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D Manufacturer's Declaration

This appendix describes the system's compliance with applicable IEC and RF standards.

C.1 Overview

See the following tables for specific information regarding the system's compliance with the IEC 60601-1-2 standards.

The EarlySense system is intended for use in the electromagnetic environment specified below. The customer or the user of the EarlySense System should ensure that it is used in such an environment.

Table 42: System Compliance Information – Emissions

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The EarlySense System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EarlySense System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 43: System Compliance Information – Enclosure Port Immunity to RF Wireless communications equipment–

Test Frequency (MHz)	Band[a] (MHz)	Service[a]	Modulation[b]	Maximum power (W)	Distance(m)	Immunity Level (V/m)	Compliance Level (V/m)
385	380 –390	TETRA 400	Pulse Modulation[b] 18 Hz	1,8	0,3	27	27
450	430 – 470	GMRS 460, FRS 460	FM[c] □ 5 kHz deviation 1 kHz sine	2	0,3	28	28
710	704 – 787	LTE Band 13, 17	Pulse modulation[b] 217 Hz	0,2	0,3	9	9
745							
780							
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation[b] 18 Hz	2	0,3	28	28
870							
930							
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation[b] 217 Hz	2	0,3	28	28
1 845							
1 970							
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation[b] 217 Hz	2	0,3	28	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse Modulation[b] 217 Hz	0,2	0,3	9	9
5 500							
5 785							
NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.							

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Table 44: System Compliance Information − Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact discharge ± 2 kV, ± 4 kV, ± 8 kV air discharge	The relative humidity should be at least 5 %. The device intended to be used in professional and home healthcare environment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	± 2 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 Line-to-ground	± 0.5 kV ±1 kV ± 2 kV	± 0.5 kV ±1 kV ± 2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips IEC 61000-4-11	0 % U_T; 0.5 cycle At 0%, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase at 0°	0 % U_T; 0.5 cycle At 0%, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle and 70% U_T; 25/30 cycles Single phase at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continued operation during power mains interruptions, it is recommended that the EarlySense System be powered from an uninterruptible power supply.
Voltage interruptions IEC 61000-4-11	0% U_T; 250/300 cycle	0% U_T; 250/300 cycle	
Rated Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment and are not expected to affect the EarlySense System.

NOTE U_T is the AC Mains voltage prior to application of the test level.

The EarlySense system is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Table 45: Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	6.0 Vrms 150 kHz to 80 MHz outside ISM bands	Portable and mobile RF communications equipment should be used no closer to any part of the EarlySense 2.0 including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d=0.58\sqrt{P}$ $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 MHz Where **P** is the maximum output power rating of the transmitter, in watts (W), according to the transmitter manufacturer and **d** is the recommended separation distance, in meters (m)[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
	10 Vrms 150 kHz to 80 MHz in ISM bands [a]	10 Vrms 150 kHz to 80 MHz outside ISM bands	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m 80 MHz to 2,5 GHz	

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

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

NOTE	At 80 MHz and 800 MHz, the higher frequency range applies.

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

Table 46: Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the EarlySense System (Non-Life-Supporting)

Rated Maximum Output Power of Transmitter (W)	Separation Distance According to Frequency of Transmitter (M)			
	150 kHz to 80 MHz outside ISM bands $d=0.58\sqrt{P}$	150kHz to 80MHz in ISM bands $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0,01	0.06	0.12	0.12	0.2
0,1	0.2	0.3	0.3	0.7
1	0.6	1.2	1.2	2.3
10	1.8	3.7	3.7	7.2
100	5.8	12	12	23

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

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

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

NOTE	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

NOTE	An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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