Doc. No. MK600

SUBJECT: *EarlySense User Guide – USA (FDA) version*

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7	Added the need that cable of sensor to be connected from back of the bed. – for safety purposes		Feb. 2, 2011 April 2011	Dalia Argaman
8	Changed pictured and changed labels, class A EMC	ECO-11-12		Dalia
9	Software ver. 3.0.13	ECO-11-21	June 2011	Shiraz
10	Clarifying "children" definition, updated cleaning and disinfection procedure and changing "EverOn" to "EarlySense System"	ECO-12-01	Dec 2011	Shiraz / Dalia / Aya
11	Change name of device to EarlySense (Labels with the new "EarlySense" logo)	ECO-12-13	April 2012	Shiraz

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EarlySense

Proactive Patient Care

The EarlySense System

(EarlySense Model 1.0 - Equivalent to model EverOn 1.0)

User Guide

EarlySense Ltd.

EarlySense 1.0
User Guide

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1 Introduction

The EarlySense System Bedside Monitor

The EarlySense System (also known as EverOn) is designed for continuous and contact-free measurement of respiration rate and heart rate when the patient is lying in bed. In addition the system tracks body motion and monitors patient movement and can notify users upon patient bed exit .The system displays numerical heart rate, respiration rate and movement level and graphical data of trends of these parameters.

The system's design allows the operator to adjust the settings of the threshold parameters and notifies the caregiver when heart or respiration rate averaged over time, passes above or below predefined limits. The system also allows the health practitioner to document the changes in the patient's position in bed by recording the event. The system then verifies the change in position and logs the information. The system also provides an option to notify the health care practitioner if a specific amount of time has passed since the nurse last changed the patient's position. The users can decide to activate or deactivate these notifications.

Providing contact-free, passive monitoring capabilities, with no need for patient activation or involvement, the EarlySense System enables continuous monitoring of patients in home, hospital or clinical settings. The data acquired by the System is continuously logged in a Bedside Unit, thus, when using the System at home, the data may be later presented, in a time stamped format, for off-line health care practitioner analysis.

The system includes a Sensing Unit that is placed beneath the bed mattress or between the mattress and a mattress pad or mattress cover, and a Bedside Unit which sets the system options and displays the collected data. Monitoring of the patient begins automatically as soon as the patient enters the bed. The data acquired by the system is continuously logged in the Bedside unit, thus allowing the data to 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 be interpreted by a health care practitioner only.

Note

The EarlySense System has not been studied on any specific patient group, neither has it been studied as a diagnostic tool of any specific disease or medical condition. It is meant as an adjunctive tool only for measuring respiratory rate, heart rate and movement rate.

About This Manual

This manual provides the information necessary to operate the EarlySense system in a safe and efficient manner. Please read the manual thoroughly and understand its contents before operating the system. If any part of this manual is not clear, contact EarlySense Customer Support for clarifications.

The manual is intended to serve as an accompanying document to the EarlySense system. It is not intended to replace the users training course.

This manual should always accompany the unit, and all personnel operating the unit must be aware of its location.

Manual Conventions

The following manual conventions are used throughout the manual.

Menus Screens and dialog boxes

The names of menus, screens and dialog boxes are presented in bold

Warnings, Cautions and Notes

Warnings, Cautions and Notes are used throughout this manual:

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 a damage to the equipment or to the quality of measurements

Note

Notes contain helpful information and tips

Terms

HR	Heart Rate
RR	Respiratory Rate

2 Safety

General Safety Guidelines

Warning

US Federal Law restricts this device to sale by or on the order of a physician.

The data acquired by the EarlySense System should be interpreted by a health care professional only.

- 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.
- 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 Unit should be used only with the EarlySense Bedside Unit, and the EarlySense Bedside Unit should be connected only to the EarlySense Sensing Unit.
- The EarlySense Bedside Unit is continuously operated equipment with water-proof splash sensor (IPX4).

General Hazards

- Do not use a damaged System. Use of damaged components might result in malfunctioning of the System.
- The EarlySense System should be installed and serviced only by qualified service personnel, authorized by EarlySense Ltd.

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 Defibrillation proof Type BF applied part.

Electric Magnetic Interference

This equipment complies with IEC EN 60601-1-2:2001 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 due to close proximity or strength of a source might disrupt the performance of this device. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed by qualified service personnel.

WiFi Communication

The system incorporates an off-the-shelf certified Wifi 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, which could result in an electrical fire. In such an event, only fire extinguishers approved for use on electrical fires should be used. The device 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 internally powered, continuously powered, ordinary portable equipment with applied part (IPX4).

Only equipment specified in this manual and complying with requirements of EN60601 should be connected to the system

The system complies with IEC 60601-1, IEC 60601-1-2 and IEC60601-1-4 EMC class A device.

Intended Use

The EarlySense 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 System has been studied in children (weight ≥ 10 Kg) and adults (weight ≤111 Kg) during sleep and resting condition.

Note

Definition of Age for Children: Children aged 2 and above

Contraindications for Use

The EarlySense System is contraindicated for use in:

- Patients in whom 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.
- An MR environment
- An explosive atmosphere or in the presence of flammable anesthetics or gases

Warnings and Cautions

- The EarlySense System should be installed and serviced only by qualified service personnel, authorized by EarlySense Ltd.
- Mounting bed-side unit to the wall should be performed while exercising out-most caution. DO NOT place the bed-side unit over patient's head, to avoid safety related conditions.

- Mounting of bed-side unit to the wall should be performed by mechanical experts of the institution (e.g., Biomed/ engineering), to make sure safe attachment. EarlySense is not responsible for any harm or damage related to wrongful placement of the bed-side unit
- Implementation of the nurse call connector option provided in The EarlySense Bedside Monitor requires coordination between the hospital 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 be interpreted only by a health care practitioner.
- In the event that the EarlySense System does not operate properly, contact EarlySense Ltd. customer support: (617) 800-6668 (for the east coast) or (818) 370-7748 (for the west coast).
- Never open the Bedside Unit housing as this may damage the System. Refer all servicing to an authorized technician.
- Only equipment specified in this manual and complying with requirements of EN60601 might be connected to the system.
- Measurements may be affected by cable lengths. Shorten or extend the lengths only according to the manual's direction.
- 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 10-35°C (50-95 °F) for the Bedside Unit, and 5-40°C (41-104 °F) for the Sensing Unit, and within a relative humidity of 30-80%, non condensing.
- Do not use a damaged System. Use of damaged components might 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 this event, only fire extinguishers approved for use on electrical fires should be used. Care should be taken for patients with poor bladder functioning or control, including small children, when an EarlySense sensor is placed under their mattress.

- Do not share the bed with another person or pet during 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 could 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 might result in malfunction of the Sensing Unit.
- The patient should not have a direct contact with the Sensing Unit. A mattress, mattress pad or mattress cover should be always placed as a barrier between the Sensing Unit of the EarlySense System and the patient. Patients should be frequently checked to insure direct contact does not occur.
- Careful oversight should be provided when the EarlySense System is used with children.
- 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.

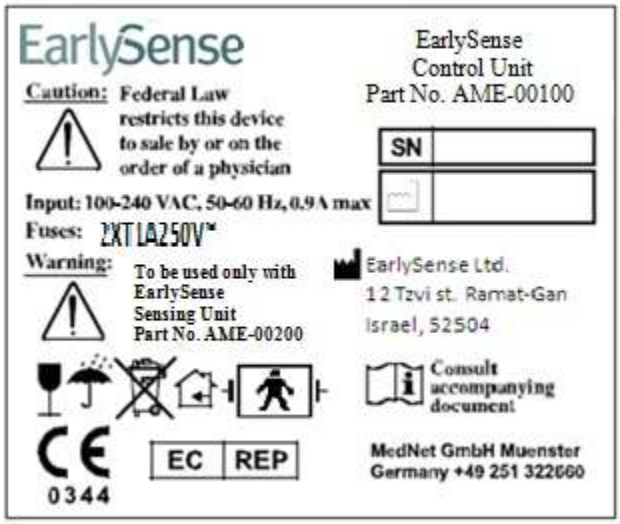
Warning

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 device to sale by or on the order of a physician.

System Labels

Bedside Unit Label



Incorporates WiFi module
FCC ID: PD9WM3B2200BG

Figure 1: Bedside Unit Label

Sensing Unit Label

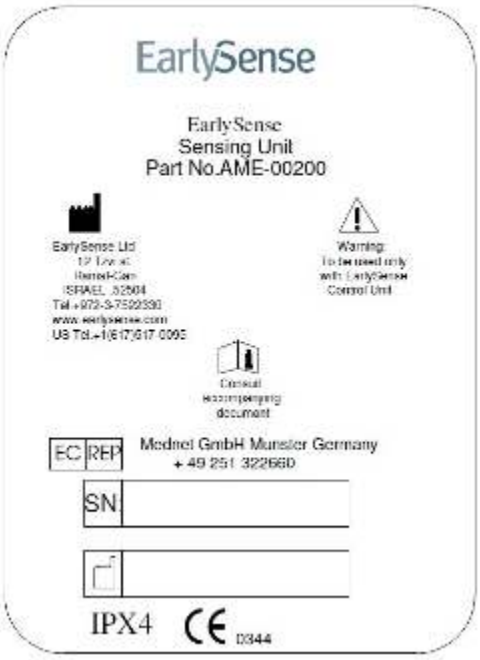


Figure 2: Sensing Unit Label

System Packaging Label

Figure 3: Packaging Label

Explanation of System Labels

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

	Caution/Warning
	Consult Accompanying documents
	Defibrillation proof, type BF, IPX4 applied part
	Fragile, handle with care
	Keep dry
	Indoor operation only
	Sorted disposal

Compliance with Standards

The EarlySense System was tested and found to be in compliance with the following standards:

	STANDARD	#
1.	Medical electrical equipment- general requirements for safety. Part 1: General Requirements for Safety	IEC 60601-8 (2006)
2.	Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests	EN/IEC 60601-1-2 (2005)

How the Bedside Unit is supplied

The EarlySense System is shipped in a protective package containing the following components:

- 1 Control Unit (Bedside unit)
- 1 Sensor

The System should be unpacked and installed only by an authorized EarlySense technician.

3 System Description

System Components

The system consists of a Sensing Unit and a Bedside Unit connected by a cable.

1.Bedside Unit

2. Sensor

Figure 4: The EarlySense System Components

Sensor

The Sensor is placed under the mattress (See Positioning the Bedside and Sensing Unit, page 23) and detects a signal generated by the patient's breathing, heartbeat and motion. The sensor's cable, which should be connected to the bedside unit, is three-meter long.

Sensor Extension Cable

Only if required, an optional two-meter extension cable for the sensor is available.

Note

Use only one extension cable per sensor.

Bedside Unit

The Bedside Unit shows system status, displays the heart rate, respiration rate, movement level, patient turns and bed exit data, and allows system configuration.

1. Alert indicator key that can be pressed as a response to an active alert
2. On/Off
3. Suspend alerts for 15 minutes
4. Download reports
5. Speaker/ buzzer

Figure 5: Bedside Unit Indicators and Keys

Bedside Unit Controls and Indicators

The Bedside Unit contains the following controls and indicators:

1. Alert indicator key - the light will flash red in case of red alerts (e.g. heart rate, respiration rate and bed exit), yellow in case of yellow alerts (movement and patient turn reminder) and blue in case of technical alerts. While an alert is active, alert light key can be pressed to respond to the alert.

2. ON-OFF button. Use the button to switch the bedside unit ON or OFF.

3. 15 min Suspend Key – Pressing it will disable the red and yellow alerts for 15 minutes. **No red or yellow alert will be given by the EarlySense System during the next 15**

minutes after this action! Alert symbols on the screen will turn into a Timer (see Figure 6) to notify of this temporary suspension mode. Pressing the Suspend key button again turns the alerts back on. Blue alerts cannot be suspended under any circumstances.

Figure 6: Suspension Timer

4. Download Reports Key – password will be required

1. USB Connector
2. Nurse Call Connector
3. Sensor Connector
4. Network Connector

Other connectors (for future use) are clearly labeled as not in use.

Figure 7: Bedside Unit - Side View

Note

The nurse call in the EarlySense System is a UL1069 compliant nurse call relay closure connector – Supplementary Device

The EarlySense bedside unit can interface with the existing nurse call systems found in the hospital., though the actual connection to the nurse call system requires the support of the Hospital Biomedical Engineering department

Battery

The system is internally powered by a lithium polymer rechargeable battery that provides power in case of a power failure (See Electrical Failure, page 24). The battery is not intended to be replaced by the operator. In standard operating mode, the battery is designed to allow approximately 30 minutes of operation while the unit is unplugged from the Electrical Outlet, or in case of power failure.

The battery is automatically recharged by the system. In case the battery no longer maintains the necessary charge, it must be replaced by an EarlySense authorized technician. Contact EarlySense technical support.

Note

The system batteries will function when the system is unplugged. In order to maintain the batteries adequately charged, make sure that the system is always plugged in to the Electrical outlet during routine operation.

Sorted Disposal

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

The EarlySense System's User Interface and Screens

User Interface

Interaction with the user interface is via touch screen. Touching some functions (Such as the **Discharge** and **Trends buttons)** will open additional screens, while other buttons **will** open additional adjustment functions in the **Home** screen (Such as **Patient Turn q** and **Bed Exit sensitivity level**). For any interaction, the screen must be unlocked by touching the lock image in the upper left corner of the **Home** screen. If the user attempts to press the touch screen while the system is locked, the lock in the upper left corner will show a red flash.

System Messages and Alerts

There are four types of system messages and alerts:

List of messages/alerts in this category	Example
High/Low HR High/Low RR Patient Signal Lost Bed Exit Patient Out of Bed	
Extremely High Motion Patient Turn is OFF – Low Patient Movement Patient Turn is OFF – Air Mattress Motion Detected Turn Counter Exceeded	
Technical Alert – indicates that there is a technical problem with the system: Check Sensor No AC Power Very Low Battery System Malfunction	
Functional Message - Informative message.	

Screens

The Home Screen displays the monitoring data and provides access to additional menus.

Choices are selected by touching the screen.

1. Lock/Unlock status
2. Nurses details (Name, Ext. Number and assigned color
3. Patient details (ID, Room and Bed numbers)
4. Date/Time
5. Battery status/AC indicator
6. Pause
7. Admit /Discharge patient
8. Enable/Disable heart rate alerts
9. Settable "High" HR threshold
10. Current heart rate
11. Settable "Low" HR threshold
12. Enable/Disable RR alerts
13. Settable "High" RR threshold
14. Current respiratory rate
15. Settable "Low" RR threshold
16. Enable/Disable movement alerts
17. Current movement level (0, Low, Medium, High, Extremely High)
18. Enable/Disable out of bed alert
19. Bed Exit Settings
20. Enable/Disable Patient Turns Counter
21. Patient Turn Counter: Time passed since last turn documented by nurse
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.

23. Clock time of last self movement

24.Operational buttons - to open additional screens

Figure 8: Home Screen

The following menus are accessed from the bottom of the Home Screen.

Menu	Use For
	Adding an event (See Recording and Viewing Events, page 50).

	Viewing trends (See Trends, page 51)
	Setting or deactivating Alerts (See Alerts, page 34).
	Setting the volume level of the bedside unit (page 32)
	Access advanced functions

4 System Operation

Overview

The EarlySense System is designed to display and log respiration rate, heart rate and movement parameters in an automatic contact-free manner when the patient is lying in bed. 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 design allows the user to set high and low threshold parameters that will alert the user if either heart or respiration rate have crossed predefined thresholds. The system can alert the user if patient leaves the bed (bed-exit) and allows the healthcare practitioner to document that s/he changed patients' position in bed. The health-care practitioner can insert the event of patient's change of position by documenting the event on the EarlySense bedside 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 (as set by the user) has passed since last position changing (timer expired). The users can decide to activate or deactivate these notifications

Data is continuously presented on the Bedside Unit main screen. The data obtained during the monitoring period is recorded by the system in order to enable off-line presentation and data printing.

The Sensing Unit should be placed under the mattress, underneath the patient's chest area and the system should be turned on. After approximately 60-120 sec of the patient lying in bed in resting position, the system will begin displaying the monitored values on the bedside Unit Home screen.

By entering the patient's basic information (MRN, Initials) into the system the data will be transferred to the Central Display Station (if being used). Heart and respiration rates and patient movement level will be continuously displayed on screen. Heart and lung icons will blink and the values will appear in white on the screen as long as measurements of HR and RR are current.

If the system cannot detect (or measure) the momentary heart or respiration rate for more than 1 minute, the last measured result of HR or RR will be displayed on screen in grey and the blinking heart or lung icon will stop blinking.

Positioning the Bedside and Sensing Units

The Bedside Unit should be mounted to the wall beside the patient's bed. The power cable should be connected to the power outlet and the short "telephone" cable should be connected to the monitor from one side and to the sensor cable on the other side. Please make sure the cable is not trailing on the floor.

Place the Sensing Unit under the patient's mattress, and locate it underneath the chest area, horizontally. Position the sensor so the top surface is facing upwards (as marked) (See Figure 9). Position the cord that connects between the Sensor and the Bedside Unit so that it comes out from under the mattress from the head of the bed, in order to not interfere with the movement of the patient in and out of bed. If the sensor is placed on a metal framework that does not allow solid support for the sensor, please consult your authorized EarlySense representative.

Warning

If you mount the Monitor to the wall, 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, mattress pad 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.

Figure 9: Positioning the Sensor and Bedside Units

Turning the System On/Off

Turn the EarlySense System "ON" by pressing the On/Off button on the front of the Bedside Unit (See Figure 5). The **Admit** Window will automatically appear. After admitting the patient, the Home Screen will be displayed.

To turn the system off, press the On/Off switch on the front of the Bedside Unit. You will be asked if you are sure you want to turn the system off. Confirm turning off by hitting Yes on the touch screen.

Electrical Failure

In case of electrical failure, the internal system battery allows the system to function for approximately 30 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 main screen indicates the status of the battery and if the battery is being recharged.

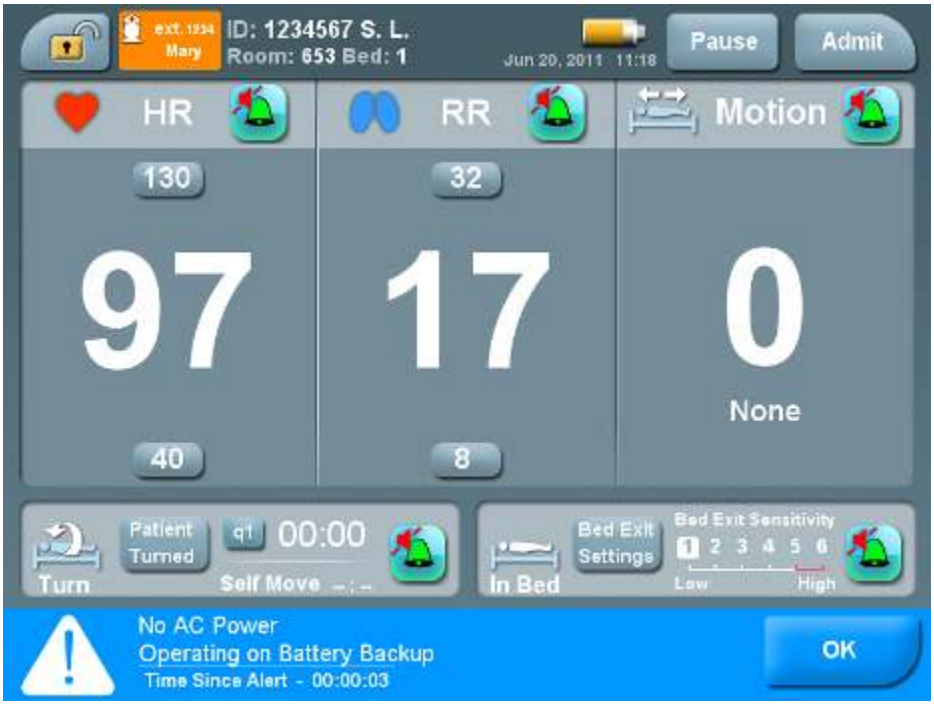


Figure 10: No AC Power Warning

The battery icon displayed on the main screen indicates the status of the battery as follows:

Green with a lightning		Battery is charged and connected to a power outlet
Green		Battery is charged but disconnected from a power outlet
Orange		System is disconnected from power outlet, battery is not charged.

Red		Battery is almost empty. System is about to shut down.

The lightning symbol on the battery indicates that the battery is charging.

After Electrical Power is Restored

1. Make sure that the system is plugged into the Electrical Outlet.
2. Turn the System On by pressing the On/Off switch on the front of the Bedside Unit (See Figure 5). The System automatically starts operating, as detailed above (see Turning the System On/Off – page 24).

The internal battery automatically recharges when the electrical power is restored.

If System operation is not restored, contact EarlySense Ltd. customer support.

Patient Information (Admit/Discharge)

Admitting a Patient

The **Admit Patient** screen appears every time the system is switched on automatically and can also be found by touching the **Admit** button in the upper right corner of the **Home** screen.

Monitoring can take place without entering a patient ID / MRN; however it is advisable to enter a new patient ID before starting the monitoring, otherwise the monitored information will not be saved and the information will not be transferred to the main nurses' station.

1. Choose Admit in the Home Screen. The first **Admit Patient** screen will open (Figure 11).

Note

Only letters can be entered in the first and last name boxes and only alphanumeric characters can be entered in the ID box.

Figure 11: Patient Admit Screen

2. Insert the patient's name (Letters only), MRN (ID) (Alphanumeric only), room number (digits only) and bed number (Alphanumeric only). The MRN (medical record number), Room No. and Bed No. must be entered for the patient to be admitted. Choose a color to assign the patient to a nurse, in case you are using the EarlySense Central Display Station (also referred to as "Patient Care Manager")
3. To advance to the **Patient Demographics** screen (Figure 12) press **Next**.
4. To return to the **Home** screen without admitting the patient press **Cancel** or **Home**. To admit the patient and return to the **Home** screen press **Done**. After pressing **Done**, two questions regarding the required settings will show (Figure 14: Bed Exit Alert).

Note

The **Patient Demographics** screen will not open unless a patient ID / MRN has been entered.

Figure 12: Patient Demographics Screen

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

Gender: Choose M or F.

Date of Birth: Enter the patient's date of birth (Figure 13).

Figure 13: Date of Birth

Choose **Done** to finish admitting the patient, or **Cancel** to return to the Home screen without admitting the patient. If after 10 minutes you have not pressed a button the screen will close automatically without admitting the patient.

5. After pressing **Done**, you will be asked two setting questions. The first is whether you want to set a Bed Exit alert for this patient (Figure 14). If you choose **Yes**, the Bed Exit alert will be enabled automatically with the default setting of sensitivity level. If you choose **No**, the Bed Exit alert will be disabled. After answering the first question, you will be asked whether you want a Patient Turn reminder for this patient (Figure 15). If you choose **Yes**, the Patient Turn Counter will be enabled automatically with the default setting of a reminder every 2 hours, and if you choose **No**, the Patient Turn Counter will be disabled. If after 1 minute you have not pressed a button the screen will close automatically, the patient will be admitted and the Bed Exit alert and the Patient Turn Reminder will remain disabled.

Figure 14: Bed Exit Alert

Figure 15: Patient Turn Reminder

Discharging a Patient / Ending a Patient Monitoring Session ("Discharge")

Warning

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

When the recording session is completed perform the "Discharge" procedure:

1. In the **Home** screen choose **Discharge**. The Confirm Discharge screen will open (Figure 16)
2. Choose **Yes**.

Figure 16: Confirm Discharge Screen

3. You will be asked if you want to admit a new patient (Figure 17)

Figure 17: Admit Confirmation Screen

4. Touch **Yes** to admit a new patient and **No** to return to the **Home** screen without any patient being admitted.

Pausing a Patient Monitoring Session

The Pause button stops the recording session temporarily, while the patient's identification and trends are saved. At any time the patient's recording can be resumed, and all the previous trends will be displayed as usual. Pause should be used when the sensor is temporarily disconnected from the bedside unit to avoid a blue 'Check Sensor' technical alert from sounding, this function should be used for example when the patient needs to be transported with his/her bed and the sensor needs to be disconnected from the Bedside unit.

To pause the recording session:

1. Press the Pause button at the Home screen (See Figure 8). A Pause screen will be displayed (Figure 18).

Figure 18: Pause Screen

2. To continue the recording session, press Resume at the Pause Screen (Figure 18).

Setting the General Volume

The General Volume sets the volume of all alert tones. In addition volumes and tones for individual alerts can also be set (See Alerts Setup

Setting Individual Alert Volume and Tone, page 42). Note that the alert volumes are determined by which of the two parameters (General or Alert) was set last and that the default setting for the alerts in the bedside unit is mute. At startup and when admitting a new patient following discharge, the system returns to default alert settings.

To set the General Volume:

1. Choose the **Volume** button from the **Home** screen. The **General Volume** box opens (Figure 19)

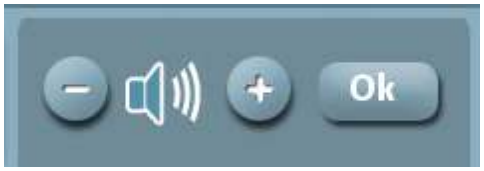


Figure 19: General Volume Box

2. Push the **Plus** button to raise the volume or the **Minus** button to lower the volume.
3. Click **OK** to confirm

The Volume icon is marked with an X if the volume is set to zero.

Figure 20: Alerts Volume Off Status

Alerts

Alerts are used to notify personnel of situations that may require attention. The EarlySense System enables the user to define upper and lower thresholds for the heart rate, respiration rate, time out of bed and patient turn. If any of the parameters, as set by the user, cross these specified thresholds, an audible and visual alert notification is triggered.

Alerts Table

The system uses the following alerts:

Message	Color	Description
High/Low Heart Rate:___	Red	Heart Rate exceeds thresholds.
High/Low Resp. Rate:___	Red	Respiration Rate exceeds thresholds.
Bed Exit Sensitivity Settings: 1 (Low) – 6 (High)	Red	Bed Exit
Patient Out of Bed For ____ Min	Red	System detected that patient is out of bed for a time interval exceeding a preset threshold.
Patient Signal Lost	Red	System cannot detect patient's signal. Check patient and sensor location.
Extremely High Motion	Yellow	Patient Movement Level has been extremely high during the last minute.
Patient Turn is OFF Low Patient Movement	Yellow	Patient Movement Level has been very low during nighttime (00:00-6:00). Consider setting Patient Turn reminder ON.
Patient Turn is OFF Air Mattress Motion Detected	Yellow	Air Mattress was detected on the bed. Consider setting Patient Turn reminder ON.

Turn Counter Exceeded ____ Hours	Yellow	Threshold time interval for turning the patient expired.
Check Sensor Reconnect/Replace Sensor or Restart	Blue	Technical alert indicating that the sensor connection is malfunctioning. Try to reconnect the sensor and if problem persists replace the sensor (See Troubleshooting page 66).
No AC Power Operating on Battery Backup	Blue	An alert indicating that the EarlySense Bedside unit is disconnected from the electrical power outlet. Reconnect the EarlySense bedside unit to the electricity Mains – otherwise the bed-side will shutdown (See Troubleshooting page 66).
Very Low Battery System Shutting Down	Blue	An alert indicating that the battery is low, and system is about to shut down. Reconnect the control unit to the electricity Mains (See Troubleshooting page 66).
System Malfunction Please Contact Service Engineer	Blue	Technical alert indicating that the system is malfunctioning. User should contact a service engineer (See Troubleshooting page 66).

Multiple Alerts

Multiple alerts occur when more than one alert is triggered at the same time. For instance if a blue system malfunction occurs while an elevated HR is in progress, this situation is defined as a multiple alert.

There can only be one active alert at a time. If an additional alert occurs while an alert is already active, the system will then determine which alert will be active according to the following priority:

- Blue
- Red

- Yellow

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

Alert Triggers

Default alert status is:

	Alert Status
Heart Rate	ON
Respiratory Rate	ON
Movement	ON
Patient Turn counter	OFF
Bed Exit	OFF

Default alert threshold values are:

	Low limit threshold	High limit threshold
Heart Rate	40 BPM	130 BPM
Respiratory Rate	8 Br/min	32 Br/min
Patient Turn counter (default)	2 hours	
Bed Exit (default)	Immediate – sensitivity 3	

Alerting Parameters

	Low Heart Rate	High Heart Rate
Time to alert for change in HR	Max. 60 seconds	Max 60 seconds

	Low Respiration Rate	High Respiration Rate
Time to alert for change in RR	Max. 150 seconds	Max. 120 seconds

Modifying Alert Thresholds

When beginning to monitor a new patient, it is advisable to set patient specific alert thresholds. If relevant for a specific patient, Bed Exit alert sensitivity or duration and Patient Turn interval should be set from the relevant section in the home screen next to each function setting (see pages. 44 and 45). To change the default HR and RR thresholds:

1. Touch the upper or lower thresholds in the HR or RR boxes in the **Home** screen
2. Touch the down-pointing arrow to lower the threshold or the up-pointing arrow to raise the threshold (Figure 21)
3. When you reach the desired threshold touch the number displayed, or wait.

Figure 21: Adjusting the HR Upper Threshold

Thresholds can be set in the following ranges:

	Lowest settable limit threshold	Highest settable limit threshold
Heart Rate	35 BPM	150 BPM
Respiratory Rate	8 Br/min	44 Br/min

Audible and Visual Alert Notification

When an alert is triggered an audible alert sounds and the corresponding alert parameter on the monitor main screen will be shown with its background color corresponding to the alert color, either red or yellow (Blue alerts are not connected to a specific monitoring parameter). A message will appear on the bottom of the window detailing the nature of the Alert (Figure 22) and the time passed since alert was raised

Figure 22: Alert Screen

Blue Alerts

Blue alerts are managed differently than yellow or red alerts. Blue alerts cannot be suspended; their volume is set at maximum and is non-adjustable. Blue alerts appear only

with an “OK” button and remain active as long as the alert condition exists. They disappear only after the technical issue is resolved. The rest of the information in this section relates to red and yellow alerts only.

Suspending Red and Yellow Alerts

Press the “**OK”** button to close an active alert (Figure 22). Notice that as long as the alert condition exists, the alert will show up again. To close an active alert and temporarily disable for 15 minutes - all red and yellow alerts, press the **15 min Suspend Alert** button (Figure 22). To cancel the 15 min suspension, press twice on the external “Suspend alerts for 15 min” button (See Figure 5).

Disabling and Enabling Alerts

When beginning to monitor a new patient, it is advisable to set the specific alerts that should be enabled for this specific patient. By default all alerts apart from the Bed Exit and Patient Turn alerts are enabled. Per each patient’s condition, the user is advised to enable Bed Exit or Patient Turn alert as required.

To disable alerts for specific parameters touch the bell symbol next to the alert in either the **Home** screen or the **Alerts Setup** screen. To enable alerts touch the bell symbol again.

If an alert is disabled while the alert is active, the alert will remain active until it is suspended by the user.

When the Bed Exit alert is being disabled, the question “Are you sure you want to set bed exit alert off?”(Figure 23) To disable the alert, choose Yes.

Figure 23: Bed Exit Off

When the Patient Turn Counter alert is being disabled, the question "Are you sure you want to set patient turn alert off?" (Figure 24) To disable the alert, choose Yes.

Figure 24: Patient Turn Off

In case the alerts are disabled for a specific parameter the bell icon for the corresponding parameter in the main and alerts setup screens will be marked with an X as follows:

To suspend all red and yellow alerts for 15 minutes, press the hardware Suspend alerts for 15 min button (Figure 5). Press again the same button to enable alerts.

Alerts Setup

Setting Individual Alert Volume and Tone

Press the **Alerts** button on the bottom of the **Home** screen. The **Alerts Setup** screen will open (Figure 25). When entering the **Alerts Setup** screen the current status of all alerts, as shown in the following list, is displayed:

- Alert volume
- Tone
- Enabled/disabled

Figure 25: Alerts Setup Screen

- Click the plus or minus button to raise each alert volume
- Press buttons 1, 2 or 3 to choose a Tone.

- After setting up the alerts, touch **Submit** to activate these 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 (See page 32) or by setting volume and tone of all in the alerts setup screen. The alert volumes are determined by which of the two parameters (General or Alert) was set last.

Note

When a patient is admitted or discharged all alert settings will return to default.

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

Silencing Alerts

A green bell icon indicates that the alert is active.

Silence alerts volume by setting the alerts volume to zero in either the general alerts volume icon in the **Home** screen or in the **Alerts Setup** screen.

In case the alerts are silenced for a specific parameter the bell icon for the corresponding parameter in the main screen will be displayed with a mute sign as follows:

Bed Exit

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

Note

If the patient is allowed to get out of bed without the nurse being notified, you can disable the Bed Exit alert by touching the bell in the In Bed section of the **Home** Screen.

Configuring the Bed Exit Alert

Bed Exit alert can be configured in terms of alert volume and tone (See Setting Individual Alert Volume and Tone, page 42) and sensitivity.

Setting Bed Exit Sensitivity

Press the Bed Exit Settings button on the lower right of the Home screen. The Bed Exit Settings Area will open (Figure 26).

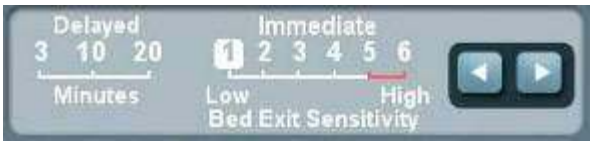


Figure 26: the Bed Exit Settings Area

The Bed Exit Alert can be set either to provide an immediate alert when the patient exits the bed (varying in 6 levels of bed exit sensitivity levels) or to provide an alert when the patient has been out of bed for a period ranging from 3-20 minutes.

Use the arrows to choose the desired delay or sensitivity setting. After 3 sec the arrows will disappear and the change will be applied.

- If you want an immediate alert when a patient exits the bed, click the arrows to choose a sensitivity ranging from 1-6, with 1 being the least sensitive and 6 being the most sensitive. Note that sensitivities 5 and 6 are highly sensitive and might be triggered due to excessive movements of a patient while in bed.
- If you want the system to alert after a period of time that the patient is out of bed, choose the time duration you would like between when the patient leaves the bed, and when the alert sounds. Use the same set of arrows that you use to set the sensitivity to select the number of minutes for the delayed Bed Exit alert.

The Bed Exit alert is disabled by default. Enable the Bed Exit alert by pressing the bell icon.

The active mode of the Bed Exit alert is indicated by the bell icon at the Bed Exit section of the **Home** screen (Figure 27).

Figure 27: Bed Exit Box

Patient Turn

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

Setting the Patient Turn Interval

The turn interval is referred to as "q". For instance if you would like the system to generate an alert as a reminder to turn the patient every 2 hours, set q to q2.

To change the time interval between the turn reminders touch the q button in the Patient Turn box (Figure 28) in the **Home** screen (Figure 8). Using the arrows, choose the relevant q number (number of hours). After 3 sec the arrows will disappear and the change will be applied.

Figure 28: Setting Patient Turn Interval

Starting the Patient Turn Counter

To enable and disable **Patient Turn** counter touch **the Bell Icon** in the **Patient Turn** section that is in the **Home** screen. The counter will become enabled (Figure 30). To disable the counter press the Bell icon again (Figure 29).

Figure 29: Patient Turn Box – Disabled Counter

Figure 30: Patient Turn Box – Enabled Counter

Documenting Patient Turn and Resetting Counter

After turning the patient, press **Patient Turned** within 1 minute from the time that the patient turn was performed. The system logs the event (Figure 31). In addition, the system detects the corresponding change in body movement and verifies the event. The verification will appear in the printed report of the same day (See Reports, page 59)

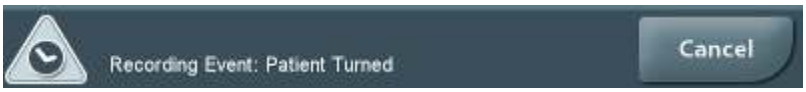


Figure 31: Recording Patient Turned Event

If the patient turn interval passes without the **Patient Turned** button being pressed by the user, a **Patient Turn** alert will occur (Figure 32) indicating that the counter has exceeded its time threshold. The alert message will disappear by pressing **Ok** or by documenting a patient turn by pressing **Patient Turned**. If **Ok** was pressed, but the **Patient Turned** button was not pressed within 15 minutes, the alert will go off again.

Figure 32: Patient Turn Alert Screen

Air Mattress

If the Patient Turn alert is turned off and the system detects an air mattress in operating condition, the following alert will appear (Figure 33).

Figure 33: Air Mattress Alert

After you press "**OK"** you will be asked if you would like a patient turn reminder for the patient (Figure 34**Error! Reference source not found.**).

Figure 34: Patient Turn Reminder

In addition, if an air mattress is not detected and a Turn Counter Exceeded alert is generated, you will be suggested to consider using an air mattress.

Patient Movement

Movement rates are determined in terms of percentage of movement time within a defined period of time as described in the following table. The accuracy of the system in displaying different rates is also presented below.

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%

Patient movement over time can be viewed in **Trends** (See Trends, page 51).

Low Patient Movement Alert

Alerts for movement are displayed in cases of low and extremely high movement. An alert for Low movement (Figure 35) may come up once a day at 6:00 AM if during the night (00:00-6:00) the amount of patient movement or activity level was below a certain threshold, which might imply the patient is in risk for developing pressure ulcers. Following dismissing the alert of low movement, you will be asked if you want a Patient Turn reminder for this patient (Figure 34).

Figure 35: Low Patient Movement Alert

Patient Motion Detection

In case that the Patient Turn Reminder is being used, and the system detects additional patient movement during the night – following the first Turn Reminder in the morning you will be suggested to consider re-evaluating Braden score (Figure 36).

Figure 36: Excess Patient Movement Detected

Recording and Viewing Events

Occurring events can be noted by the user and entered into the system for documentation purposes. These events will then appear in the Trends display.

Manually Recording an Event

1. To access the Events menu click Events in the Home Screen. The Events menu appears (
2. Figure 37).

Figure 37: Events Menu

3. Touch one of the four primary events on the left or secondary events on the right. The button changes color showing that it has been successfully chosen. The following message appears: **Recording Event: <Event Name>**
4. Touch the **Home** button to confirm your choice and close the screen or **Cancel** to cancel your choice.

The following Events are available:

Primary:

- Emerg. Med. – Emergency medication given when patient is in distress
- CPAP/BPAP
- Intubation
- Patient Fall

Secondary:

- Continuous Med. – routine medication
- Pain Relief Med. – pain relief medication
- Patient Agitation
- Skin Breakdown – a situation that may lead to pressure ulcer development
- General Flag 1 – can be used in order to mark any desired event of type 1 which is not included in the list of events
- General Flag 2 – can be used in order to mark any desired event of type 2 which is not included in the list of events

Trends

Trends are displayed in a graph format.

Trends Graph

To view the **Trends Data** click **the "Trends" button** in the lower section of the **Home Screen**.

To advance or go back in the time frame press the forward or back arrows.

Figure 38: Trends Data Screen

Number	Name	Description
1	Current heart rate	Current heart rate in beats per minute
2	Events	Displays events that users have manually entered (for documented) during the time displayed
3	Respiratory rate	Current respiratory rate in breaths per minute
4	Heart rate trends	Displays heart rate in beats (graphs) per minute during the time displayed.
5	Respiration rate trends	Displays respiration rate (graphs) in breaths per minute during the time displayed.

6	Scroll back	Touch here to scroll back.
7	Alerts	Displays alerts that occurred during the time displayed (See Alerts, page 34).
8	Time scale	Time scale for data presented
9	Scroll forward	Touch here to scroll forward.
10	Movement trends	Shows patients movement level while in bed during the timescale presented (See Patient Movement, page 48).
11	Out of bed	Shows the time intervals when patient has been out of bed (Bed Exit, page 43)
12	In bed	Shows the time intervals patient spent in bed
13	Time period buttons (10 min, 1 hour, 3 hours, 8 hours, 1 day)	Touch one of these buttons to change the time period displayed in the graph.
14	Analysis screen	Open the Analysis screen (Figure 39).

Alert Symbols

The following symbols are used in the Trends graph:

Icon	Meaning
	Blue Alerts —Technical Alerts: System Malfunction, Sensor Malfunction, Low Battery.
	High/Low Heart Rate – Red Alert
	High/Low Respiration Rate – Red Alert
	Movement Level High/Low – Yellow Alert
	Patient Turn Counter – Yellow Alert
	Out of Bed – Red Alert
	Signal Lost – Red Alert

Event Symbols

When entered by the user, the following Event symbols are used in the Trends Graph:

	Intubation
	Patient Fall
	Emergency Medication
	Continuous Medication – Routine Medication
	Pain Relief Medication
	Patient Agitation
	Skin Breakdown
	General Flag 1 - Can be used in order to mark any desired event of type 1 which is not included in the list of events
	General Flag 2 - Can be used in order to mark any desired event of type 2 which is not included in the list of events
	Patient Turn – Inserted automatically if a staff member pressed the RESET on patient turn counter and the system detected that patient turn occurred.

Setting the Time Scale

Upon entering the **Trends** screen, the default time scale displayed is 3 hours. You can return to this time scale at any time by touching the **Default** button. Use the buttons under the graph to determine the time scale displayed. If you choose a larger time scale the current time that is in the center of the time scale will remain the center. If you choose a shorter time scale you will be prompted to touch the screen to determine where you would like to center the displayed timescale.

Analysis

The Analysis function allows you to see the average respiration, heart rate and movement time percentage for a specified interval each day. Touch the **Analysis** in the trends screen to open the **Analysis** screen (Figure 39).

Figure 39: Analysis Screen

Use the arrows to set the time slot you want, and then click Show Data. The data will appear in the table.

Settings

To access the settings click Settings in the Home Screen. The Settings screen has three tabs: Brightness, Setup and Maintenance.

Brightness

In the Brightness tab (Figure 40) Press the "-" to darken the screen, and press the "+" to brighten it.

Please note that if the brightness level is set to the lowest level, the screen might be seen as black in daylight. Touching the screen while brightness is set to the lowest level will change the brightness to a higher level, in order to be able seeing buttons and labels and enabling adjustment of brightness to higher level manually.

Figure 40: Brightness

Choosing a Language

In the **Setup** tab (Figure 41) choose the desired language to be used in the system interface and click **Done**.

Figure 41: Setup Tab

Maintenance

This mode should be used only by a technician authorized by EarlySense Ltd.

Entering the technician mode requires a password. To access the **Technician** mode, press the **Maintenance** tab (Figure 42).

Figure 42: Maintenance Tab

Reports

Generating Reports (Data Retrieval)

Data analysis may be performed on-line during the monitoring session based on the bedside unit display or reports.

Reports to be printed may be downloaded at the bedside unit or at the Central Display Station (See EarlySense Central Display Station manual). To ensure the privacy of the patient's medical data a PIN must be entered before reports can be downloaded.

The data can be downloaded as CSV file and as a complete report in Acrobat PDF format. In case of CSV file the data can be viewed by the physician using standard available software e.g., Microsoft Excel™. The data is presented numerically; any other desired graph can be generated by the physician, based on the data. The PDF report includes both numerical and trend vs. time graph that can also be printed and includes information about Heart and Respiratory rates as well as patient's movement, in/out of bed status, alerts history and patient turns (See Figure 45 for an example).

Warning

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

Downloading Patient Data and Reports

1. Insert a flash drive with at least 0.5 GB of free space into the USB slot. (If the flash drive is already inserted it must be removed and re-inserted before commencing the data download procedure).
2. Press the **Download Report** button (See Figure 5) on the front panel.
3. You will be prompted to insert a PIN (Figure 43) and click **Submit**. A message will appear on the bottom of the screen informing you that downloading has commenced (Figure 44)

Figure 43: PIN Window

Figure 44: Downloading Message

4. The system will automatically download the data (CSV file) and the report for (.PDF) file of the last 2 admitted patients.
5. A message is displayed when the download is completed.

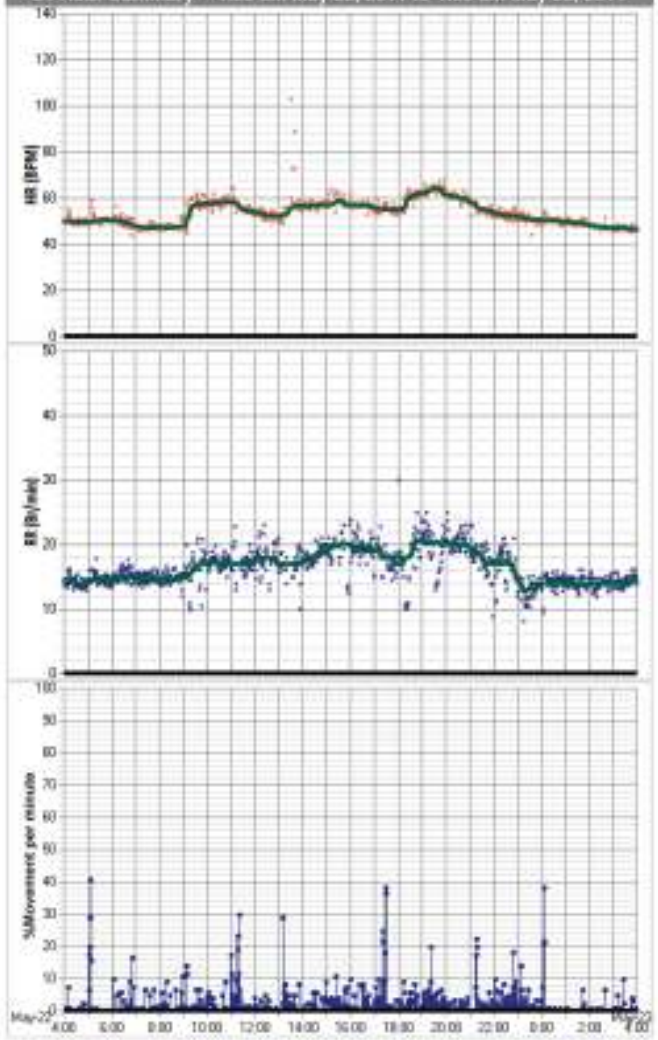
EarlySense
Proactive Patient Care

Patient Statua Report

Patient ID: 999999

Updated: May 23, 2011 11:49 PM
Admitted: May 19,2011, 7:41 PM
Room-bed: 305-2
Initials: C H
Date-of-Birth:
Gender:

24 Hour Summary - 4:00 am May 22, 2011 to 4:00 am May 23, 2011



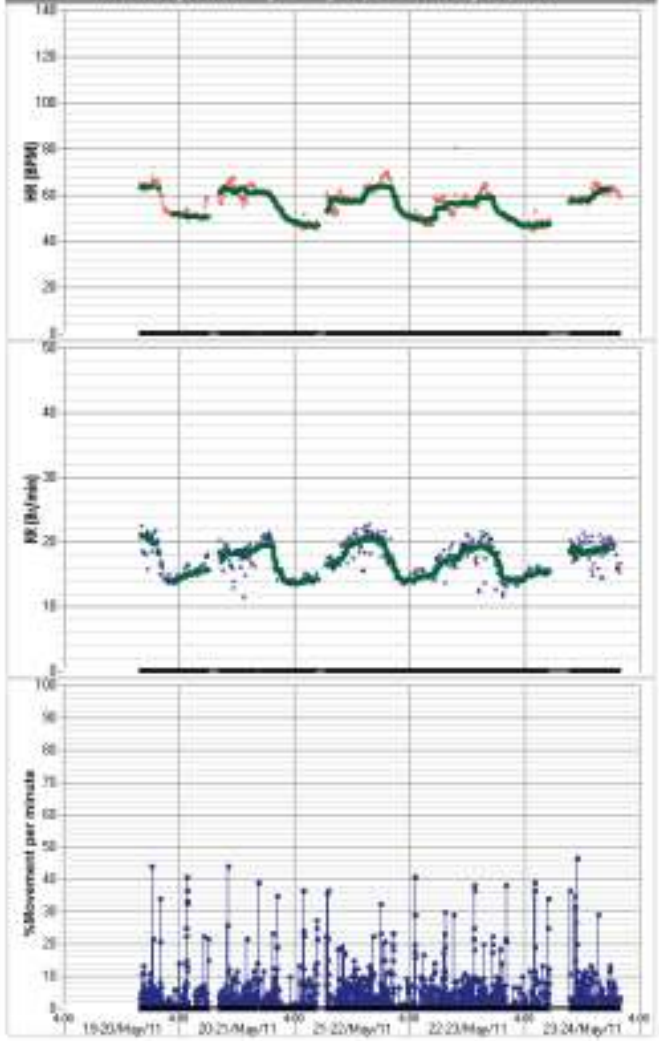
EarlySense
Proactive Patient Care

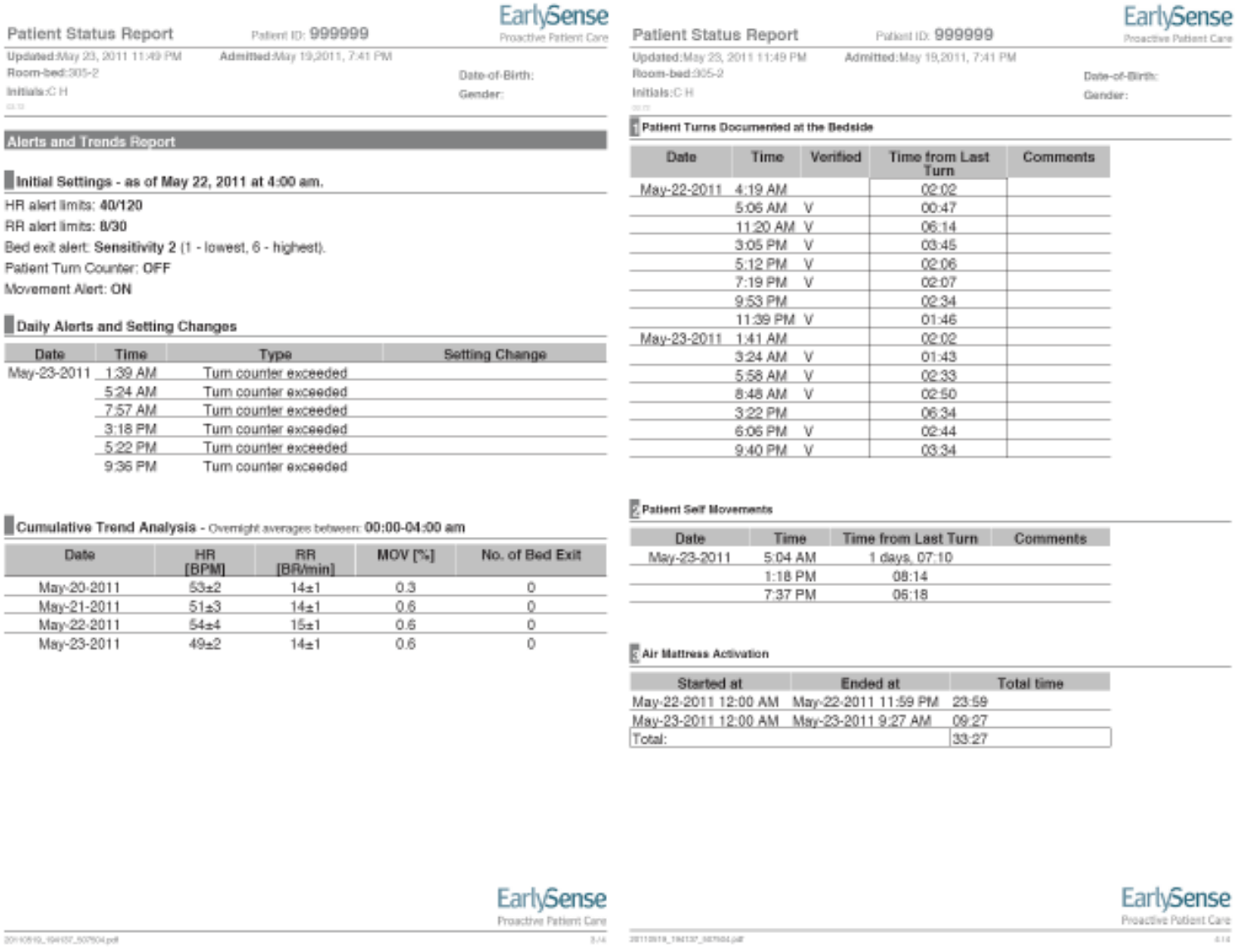
Patient Status Report

Patient ID: 999999

Updated: May 23, 2011 11:49 PM
Admitted: May 19,2011, 7:41 PM
Room-bed: 305-2
Initials: C H
Date-of-Birth:
Gender:

Multi Day Summary - May 19, 2011 to May 23, 2011





Patient Status Report Patient ID: 999999

EarlySense Proactive Patient Care

Updated:May 23, 2011 11:49 PM Admitted:May 19,2011, 7:41 PM

Room-bed:305-2

Initials:C H

Date-of-Birth:

Gender:

Alerts and Trends Report

Initial Settings - as of May 22, 2011 at 4:00 am.

HR alert limits: 40/120

RR alert limits: 8/30

Bed exit alert: Sensitivity 2 (1 - lowest, 6 - highest).

Patient Turn Counter: OFF

Movement Alert: ON

Daily Alerts and Setting Changes

Date	Time	Type	Setting Change
May-23-2011	1:39 AM	Turn counter exceeded	
	5:24 AM	Turn counter exceeded	
	7:57 AM	Turn counter exceeded	
	3:18 PM	Turn counter exceeded	
	5:22 PM	Turn counter exceeded	
	9:36 PM	Turn counter exceeded	

Cumulative Trend Analysis - Overnight averages between: 00:00-04:00 am

Date	HR [BPM]	RR [BR/min]	MOV [%]	No. of Bed Exit
May-20-2011	53±2	14±1	0.3	0
May-21-2011	51±3	14±1	0.6	0
May-22-2011	54±4	15±1	0.6	0
May-23-2011	49±2	14±1	0.6	0

EarlySense Proactive Patient Care

Patient Status Report Patient ID: 999999

EarlySense Proactive Patient Care

Updated:May 23, 2011 11:49 PM Admitted:May 19,2011, 7:41 PM

Room-bed:305-2

Initials:C H

Date-of-Birth:

Gender:

1 Patient Turns Documented at the Bedside

Date	Time	Verified	Time from Last Turn	Comments
May-22-2011	4:19 AM		02:02	
	5:06 AM	V	00:47	
	11:20 AM	V	06:14	
	3:05 PM	V	03:45	
	5:12 PM	V	02:06	
	7:19 PM	V	02:07	
	9:53 PM		02:34	
	11:39 PM	V	01:46	
May-23-2011	1:41 AM		02:02	
	3:24 AM	V	01:43	
	5:58 AM	V	02:33	
	8:48 AM	V	02:50	
	3:22 PM		06:34	
	6:06 PM	V	02:44	
	9:40 PM	V	03:34	

2 Patient Self Movements

Date	Time	Time from Last Turn	Comments
May-23-2011	5:04 AM	1 days, 07:10	
	1:18 PM	08:14	
	7:37 PM	06:18	

3 Air Mattress Activation

Started at	Ended at	Total time
May-22-2011 12:00 AM	May-22-2011 11:59 PM	23:59
May-23-2011 12:00 AM	May-23-2011 9:27 AM	09:27
Total:		33:27

EarlySense Proactive Patient Care

EarlySense Proactive Patient Care

Figure 45: Example of Printed Report (PDF File)

5 Specifications, Maintenance and Troubleshooting

Specifications

Physical Characteristics

Sensing Unit	**Bedside Unit**
Dimensions	
300 x 210 x 2.5 mm	250 x 260 x 110 mm
Weight	
160 g	3.0 kg
Materials	
ABS + Poly carbonate	ABS + Poly carbonate

Performance

Respiration Rate	**Heart Rate**	**Movement**
	Range	
6 – 45 Br./min	30 - 170 BPM*	0, L, M, H, EH
Averaging Period		
1 Min.	1 Min.	15 seconds
Accuracy		
±4% or ±1.5 Br/min, whichever is greater	±4% or ±5 BPM, whichever is greater	
• The System detects heart rate that is > 1.8 times the respiration rate • Total system accuracy including undetected signals 90% for RR and for HR. The total system accuracy was measured as +/- 10% of the predicate device		
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: 35BPM High: 150 BPM	

Electrical

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

Operating Conditions

Relative Humidity	30% - 80% non condensing
Ambient Operating Temperature	Bedside Unit: 10- 35 °C (50-95 °F) Sensing Unit: 5- 40°C (41-104 °F)

Storage and Transportation Conditions

Temperature Range	0-50 °C (32-122 °F)
Relative Humidity	10%-90% non condensing

Maintenance and Cleaning

The EarlySense System is designed to provide a trouble-free and 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 Sensing Unit.

The sensing unit should be replaced on an annual basis to ensure proper functionality of the system.

Cleaning and Disinfection of the Bedside Unit

Gently wipe the exterior of the Bedside Unit using soft, slightly damp cloth / wipes containing anti-septic substances. Wipes containing alcohols, Chlorohexidine, and bleach material with concentration up to 5% 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.

Cleaning and Disinfection of the Sensing Unit

Gently wipe the Sensing Unit using a soft, slightly damp cloth / wipes containing anti-septic substances. Wipes containing alcohols, Chlorohexidine, and bleach material with concentration up to 5% 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 such an event, only fire extinguishers approved for use on electrical fires should be used.

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 Technical problem	Touch the screen once, it will become brighter. To changes the brightness press the button Settings (see page no. 57). Turn off the system by pressing the On/Off switch for 10 seconds, and then turn the system back ON by briefly pressing the On/Off switch. If problem is not resolved call your service engineer
Blue Alert is On "System Malfunction" Message	System Malfunction	Contact a service engineer.
Blue Alert is On "Check Sensor" Message	Bedside Unit has detected that the sensor is not connected	• Check if the sensor is connected to bedside Unit. Reconnect if necessary. • If problem persists, replace sensor • If problem persists, restart system • If problem persists, call your service engineer
Blue Alert is On "Low Battery" Message	System is unplugged and battery is discharging	• Reconnect Bedside Unit to the Electrical Outlet.
Bedside Unit is not responding (ON /OFF is not possible)	No electrical power as system is unplugged and battery is discharged or, System error.	• Check connection to the electrical Power • Reconnect if necessary. • If problem persists, call the service engineer.
The Bedside Unit is operating but no HR or RR is displayed.	Difficulty in detecting a signal	• Check sensor location. The sensor should be placed under the mattress below the patient's chest area, horizontally. • Reposition the sensor if it moved from the specified location. If the problem persists, replace the sensor.

6 European Representative and Contact Information

Contact EarlySense at:

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West Coast - (818) 370-7748