CENTAURI MEDICAL, INC.

DynaSense

Instructions for Use

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INTRODUCTION

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

For important information about safety and how to use the device, read all the instructions in this booklet before you apply the Patient Sensor.

⚠ This Warning Symbol appears next to information about possible safety risks. Be sure to read and follow all the warnings and safety information.

We recommend that you save these instructions for future reference.

This Instructions For Use booklet describes the components of DynaSense and provides information on the system operation once DynaSense has been properly installed. Installation is required to be performed by qualified installation personnel from Centauri Medical.

If you have any questions, want more information, or to contact the qualified installation personnel, please call Customer Service at 510-574-0060.

CONTENTS

DEVICE DESCRIPTION

DynaSense is a medical device designed for use in hospitals, nursing homes, or other patient care facilities to monitor and report body orientation and activity as well as to provide visual alerts for orientations and activity levels that fall outside of thresholds set by healthcare providers. DynaSense is comprised of Patient Sensors, Relay Antennas, and USB RF Transceivers, Mesh Network Server Software, and a User Interface that can be installed on a monitoring station.

The Patient Sensor is associated with a single patient, such that the patient's orientation, movements, and other care parameters can be monitored.

HOW IT WORKS

The Patient Sensor is a small, disposable sensor that adheres to patients' skin, much like a standard EKG lead.

Once the Patient Sensor is applied to a particular patient, it continuously monitors the patient's orientation and movements and communicates this data wirelessly via the Relay Antennas to a remote station, equipped with a USB RF Transceiver and Mesh Network Server Software, which collects and stores the data. Data for all monitored patients is displayed through the User Interface. Through the User Interface, caregivers can enter patient data to associate individual Patient Sensors with specific patients.

Multiple Relay Antennas are installed to ensure adequate wireless coverage for a given area such as a hospital ward or nursing unit.

DEVICE DIAGRAM

DynaSense

DynaSense consists of:

- Patient Sensors
- Relay Antennas
- USB RF Transceiver(s)
- Mesh Network Server Software
- User Interface

Figure 1 below shows a high-level system communication flow of DynaSense.

Figure 1: High Level System Communication Flow

Note that the USB RF Transceiver can be plugged in the same computer on which the Mesh Network Server Software and User Interface software are installed, as is shown in Figure 1. However, the User Interface software can also be installed on a separate computer and the User Interface can be displayed on more than one computer.

Patient Sensor (inside packaging)

Figure 2: Patient Sensor inside packaging

Patient Sensor (removed from packaging)

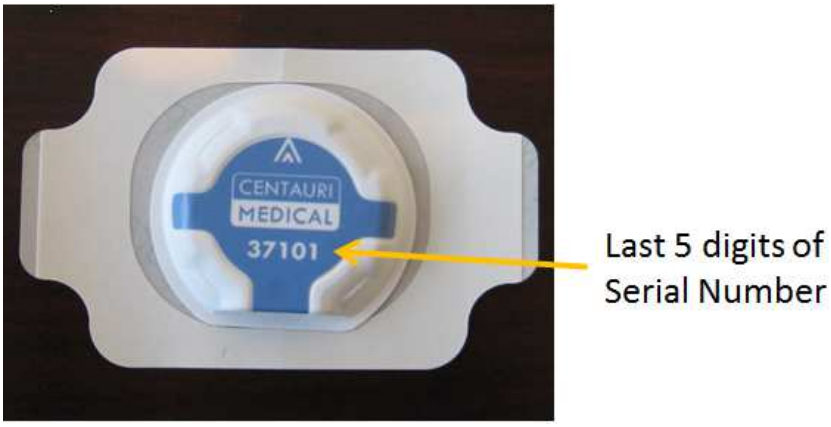

Figure 3: Patient Sensor outside of packaging

Relay Antenna and USB RF Transceiver

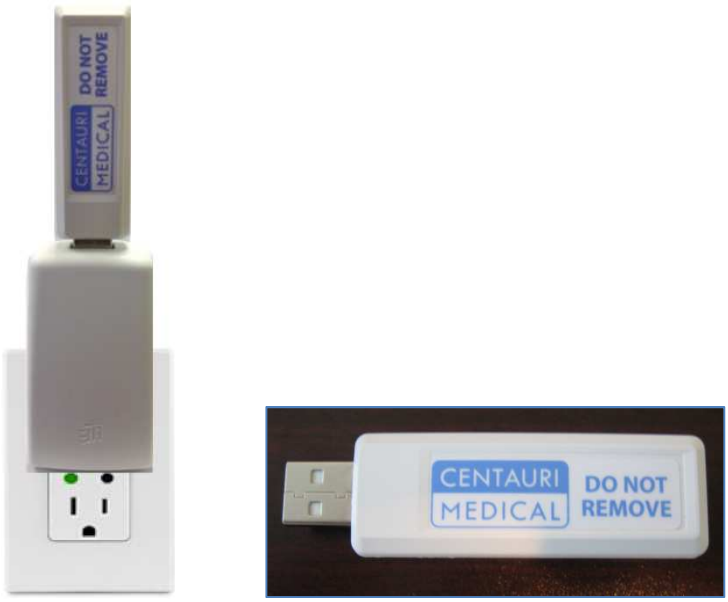

Figure 4: Relay Antenna (Left) and USB RF Transceiver (Right)

User Interface

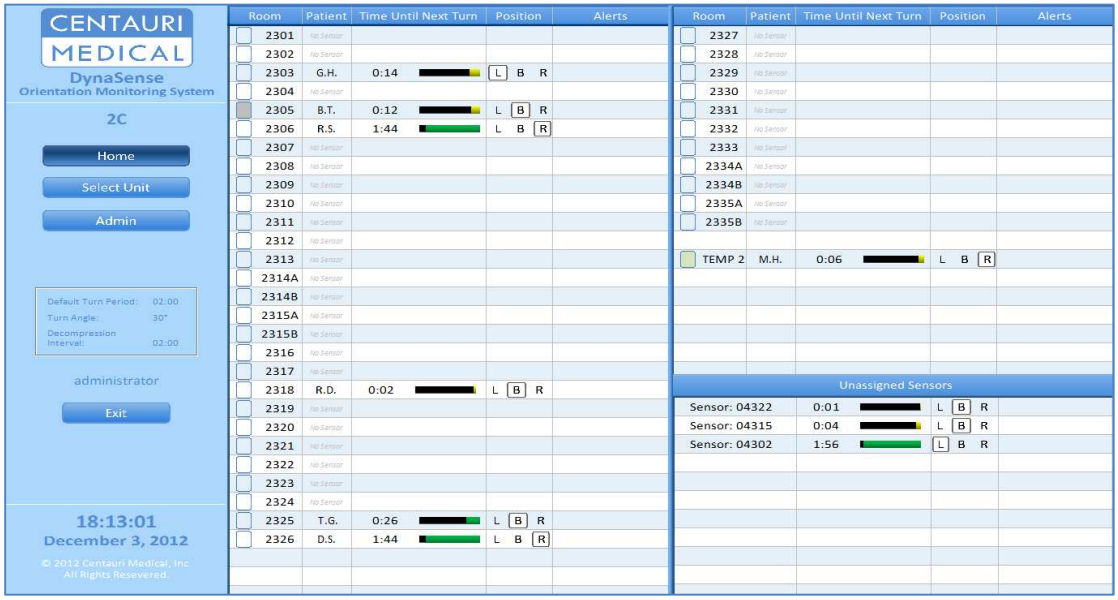

Figure 5: User Interface

INDICATIONS FOR USE

DynaSense monitors orientation and activity of patients susceptible to pressure ulcers. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. DynaSense provides alerts when patient orientation or activity deviates from parameters set by healthcare providers. The device is intended for use in medical, nursing and long-term care facilities including independent living, assisted living and rehabilitation facilities.

DynaSense is not intended as a substitute for vital signs monitoring or alerting equipment, or for professional judgment, and is not intended to provide automated treatment decisions.

CONTRAINDICATIONS

- DynaSense is contraindicated for patients who have a pacemaker or an implantable cardioverter-defibrillator (ICD).
- Wearing the Patient Sensor is contraindicated for patients undergoing X-ray, CT, MRI, and the use of any technology exposing the Patient Sensor to high levels of ionizing radiation. The Patient Sensor should be removed before these types of procedures are performed.
- DynaSense is contraindicated for patients with a known tape allergy or sensitivity to EKG leads or similar types of adhesives used in common medical products.
- DynaSense has not been tested on women who are pregnant or breastfeeding, so the risks to unborn fetuses and nursing children are unknown. As such, all women who are pregnant, planning on becoming pregnant, or are currently breastfeeding should not receive the DynaSense Patient Sensor.

WARNINGS

⚠ Do **NOT** apply the DynaSense Patient Sensor to broken, irritated, or infected areas of skin. Applying the Patient Sensor to broken or irritated areas of skin can lead to infection and other damage.

⚠ Do **NOT** re-use the DynaSense Patient Sensor. The DynaSense Patient Sensor is for ONE-TIME use on a SINGLE patient. Infection or cross-contamination can occur if the DynaSense Patient Sensor is re-used.

⚠ Do **NOT** re-apply the DynaSense Patient Sensor if it falls off or is removed. If a DynaSense Patient Sensor falls off or is removed, apply a new Patient Sensor.

⚠ If signs of skin irritation or hygiene issues are caused or aggravated by the Patient Sensor, **REMOVE** the Patient Sensor and evaluate the patient's skin. A new Patient Sensor may be used and placed on a non-irritated skin area.

⚠ The Patient Sensor should be left in place for no more than 7 days. REMOVE the Patient Sensor after 7 days. A new Patient Sensor may be used and placed on a new area of skin after the old Patient Sensor is removed.

⚠ Do **NOT** use a Patient Sensor if its packaging is damaged.

⚠ Do **NOT** use a Patient Sensor if the it is past the Use By date listed on its packaging.

⚠ The DynaSense Relay Antenna should only be powered by the Power Adapter provided as part of the Relay Antenna, and should not be replaced by an alternative Power Adapter

⚠ DynaSense needs to be installed and put into service by trained personnel.

⚠ DynaSense may be affected by portable and mobile RF communciations.

⚠ Do not modify this equipment without authorization of the manufacturer. Inappropriate modification may void the user's authority to operate this equipment. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

⚠ This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

⚠ This device complies with the FCC RF exposure limits for a portable device operated within 5 mm of a person. The output power of this device is below the level for which the FCC requires Specific Absorption Rate measurements.

⚠ Any initial settings present in the DynaSense User Interface at the time of installation must be reviewed by the user or facility and changed accordingly.

⚠ **REMOVE** the Patient Sensor if current is going to be passed through the patient's skin or body, such as during external cardiac defibrillation or electrocautery. Failure to remove the Patient Sensor, may cause a skin burn where the sensor was been applied.

⚠ **REMOVE** the Patient Sensor prior to performing an MRI study. If the sensor is not removed, the patient may experience tugging from the MRI magnet or skin heating where the sensor has been applied.

⚠ The opacity of the Patient Sensor may block complete imaging of the body area located behind the Patient Sensor in a radiologic exam. If it is anticipated that the Patient Sensor is going to interfere with radiologic imaging, then **REMOVE** the Patient Sensor prior to performing the radiologic exam.

RISKS

A patient may experience skin irritation or redness where the Patient Sensor has been applied.

As with other adhesives, and especially on patients with delicate skin, skin irritation or slight skin damage, including tearing of the skin, bleeding, or bruising, may be experienced when the sensor is removed.

A patient may have an allergic reaction to the adhesive used to apply the Patient Sensor. If a subject experiences a rash, skin redness, itching, or swelling in the location where the Patient Sensor is applied, this may be a sign of an allergic reaction and should be evaluated immediately by the patient's doctor or other member of the care team. Though the adhesive material is commonly used in healthcare products and has a well-established safety profile, an allergic reaction to the adhesive is possible.

The Patient Sensor should be removed if current is going to be passed through the patient's skin or body, such as during external cardiac defibrillation or electrocautery. In the event that the sensor is not removed and the subject has a medical emergency that requires external cardiac defibrillation or exposure to high frequency surgical equipment, the subject may experience a skin burn where the sensor has been applied.

If a patient receives an MRI study, the Patient Sensor should be removed. If the sensor is not removed, the patient may experience tugging from the MRI magnet or skin heating where the sensor has been applied.

DynaSense has not been tested for compatibility on patients with pacemakers or internal cardiac defibrillators. As such, patients with pacemakers or internal cardiac defibrillators should not use the Patient Sensor. Electrical interference to a pacemaker or internal cardiac defibrillator from the Patient Sensor is unlikely, but has not been tested.

Other wireless communications may interfere with the proper functioning of DynaSense, or conversely DynaSense may interfere with the proper functioning of other wireless communication systems. However, the risk of interference has been mitigated. DynaSense is designed so that incidental interference will not put the patient at significant risk. Installation is required to be completed by qualified personnel, who can be contacted via Customer Service, to further minimize interference with 802.11 (or WiFi) networks. If the 802.11 networks undergo configuration changes or if new networks are being configured in the 2.4GHz spectrum, please contact Customer Service.

BENEFITS

The Patient Sensor monitors a patient's orientation and movements and communicates this data wirelessly to the User Interface. From the User

Interface, caregivers can monitor a group of patients. The facility using the system can set thresholds for activity or changes in orientation based on the clinical judgment of its clinicians and configure the system to show visual alerts on the User Interface when those thresholds are passed.

HOW TO USE AND APPLY THE PATIENT SENSOR

A. Locate the area for application of the Patient Sensor.

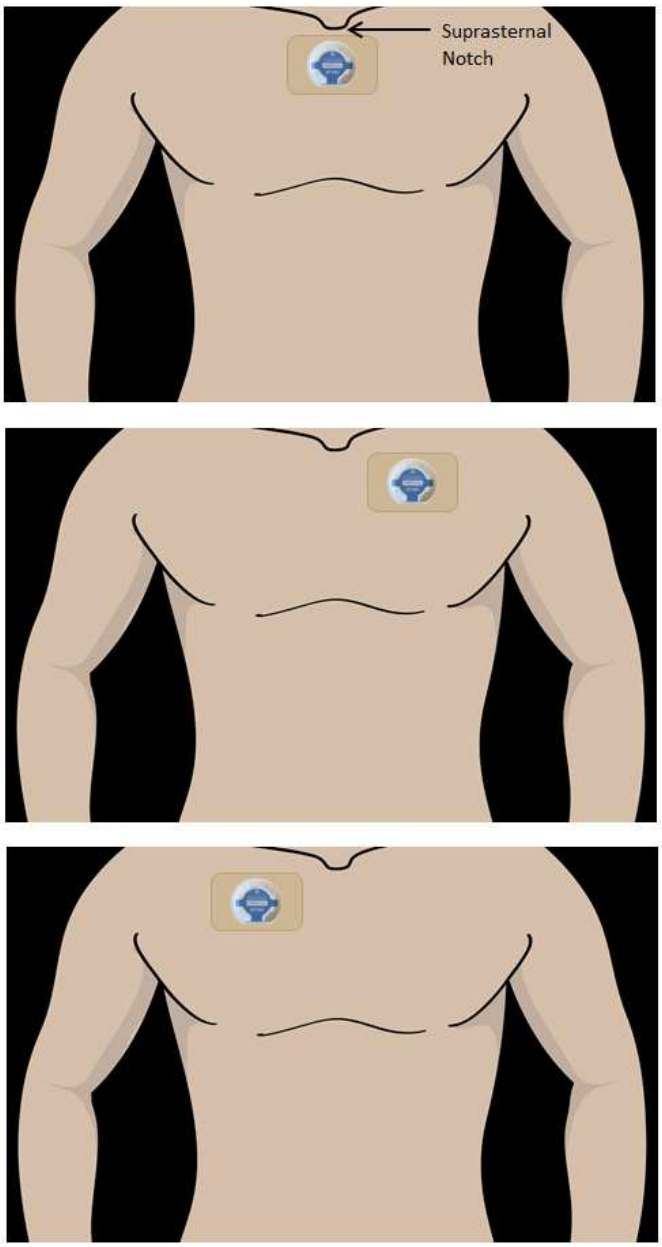

Figure 6: Patient Sensor placement location

The recommended location for placement of the Patient Sensor is on the sternum such that the sensor adhesive is just below the suprasternal notch. For patients who have a contraindication to sensor placement on the sternum (i.e. recent sternotomy), the Patient Sensor may also be placed on the upper chest on either the right or left side at approximately the midclavicular line.

B. If the patient has hair in the area where you wish to apply the Patient Sensor, clip or shave the patient's hair.

If needed, clip or shave the patient's hair in the area where you would like to apply the sensor. Long hair may prevent good adhesion of the Patient Sensor.

C. Examine the patient's skin in the area where you wish to apply the Patient Sensor and make sure it is clean and not broken, irritated, or infected.

If needed, cleanse and thoroughly dry the skin in the area where you would like to apply the Patient Sensor. The skin should be clean and dry to ensure good adhesion of the Patient Sensor.

D. Remove the Patient Sensor from the packaging.

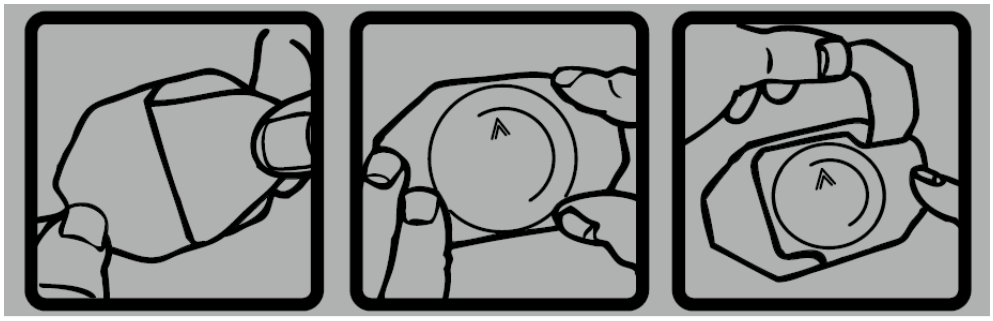

Figure 7: Patient Sensor placement

Peel back the opaque packaging from the back of the Patient Sensor. Then peel back the packaging around the perimeter of the Patient Sensor. Removing the opaque packaging exposes a light sensor, which *automatically* turns on and activates the Patient Sensor. There is no additional on/off switch on the Patient Sensor.

Keep the Patient Sensor packaging that you have just removed. The packaging, which contains the sensor's serial number, will help link your patient to the specific sensor that you just applied.

Note: Once a Patient Sensor has been removed from the packaging, it must be used immediately. Once the packaging has been opened and the Patient Sensor has been exposed to light, the device is activated and the battery has started.

E. Watch for the LED activation sequence.

Figure 8: Patient Sensor LED locations

Once the Patient Sensor has been removed from the packaging and exposed to light, it will immediately start searching for an available network. Initially, you may see the three LEDs turn to a solid green.

Figure 9: Patient Sensor LED scrolling pattern

Once an available DynaSense network is found within the range of the Patient Sensor, you will see three LED lights begin blinking in a scrolling pattern. This blinking light pattern indicates that the Patient Sensor has been turned on and communication with an available DynaSense network has been established. Once the blinking pattern of LEDs has been displayed, the Patient Sensor is ready to be applied to the patient.

F. Apply the Patient Sensor to the patient.

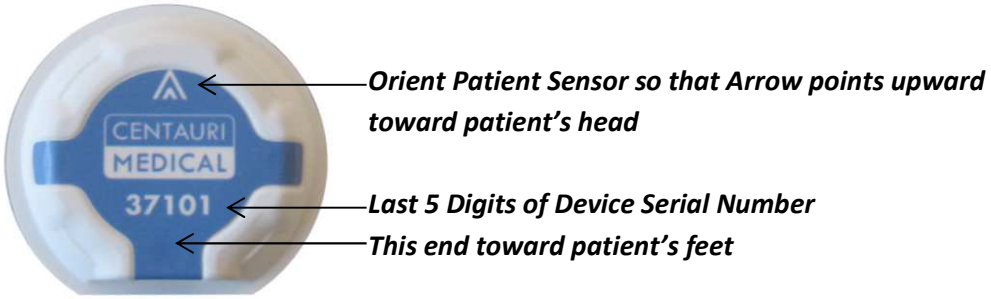

Figure 10: Patient Sensor orientation and serial number

Apply the Patient Sensor to the patient in the desired location by pressing it firmly against the patient's skin with the Arrow pointing toward the patient's head. The sensor should be positioned upright in line with the patient's head to foot axis.

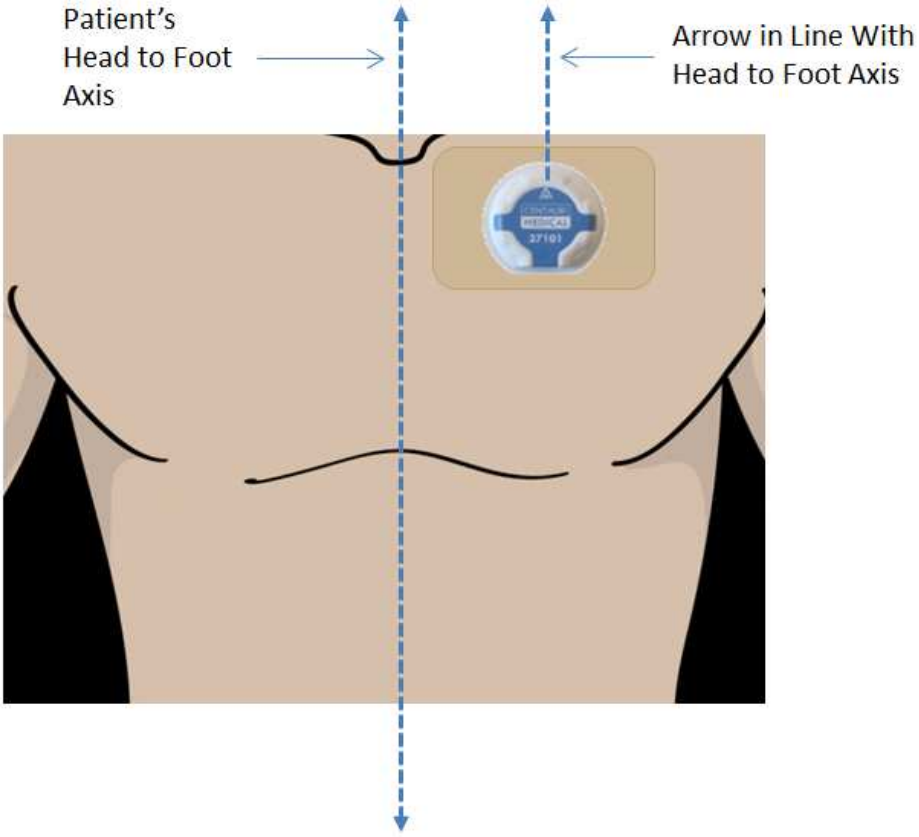

Figure 11: Patient Sensor orientation with respect to patient

The correct placement and orientation of the Patient Sensor is extremely important to ensure that the correct orientation of the patient is being reported to the User Interface.

G. Assign the Patient Sensor to the Patient in the User Interface

Once the Patient Sensor has been applied, access the User Interface to assign the sensor to the patient using the Patient Sensor's unique serial number. Refer to the sensor packaging that you removed to determine the sensor's serial number or locate the last 5 digits of the serial number on the face of the Patient Sensor.

H. Log into the DynaSense User Interface

Enter your user name and password, provided during installation or training, to log into the User Interface software. Some users will be set up with administrative privileges that allow them to change certain settings within the User Interface. Once successfully logged in, start the user interface application if it does not automatically start, and you will see the splash screen.

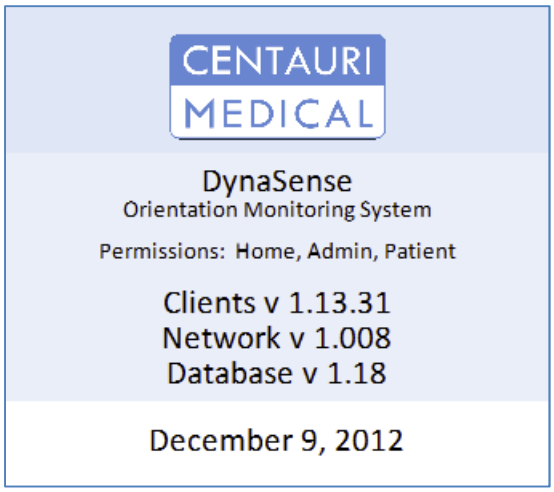

Figure 12: User Interface splash screen

I. Select the Unit from the Drop Down Menu (Note: if there is only one unit monitored at the hospital, that unit will be automatically selected)

Select the Unit (if needed) from the drop down menu and click "Monitor". To access the "Select Unit" screen at any time, click on the "Select Unit" button on the left panel of the screen.

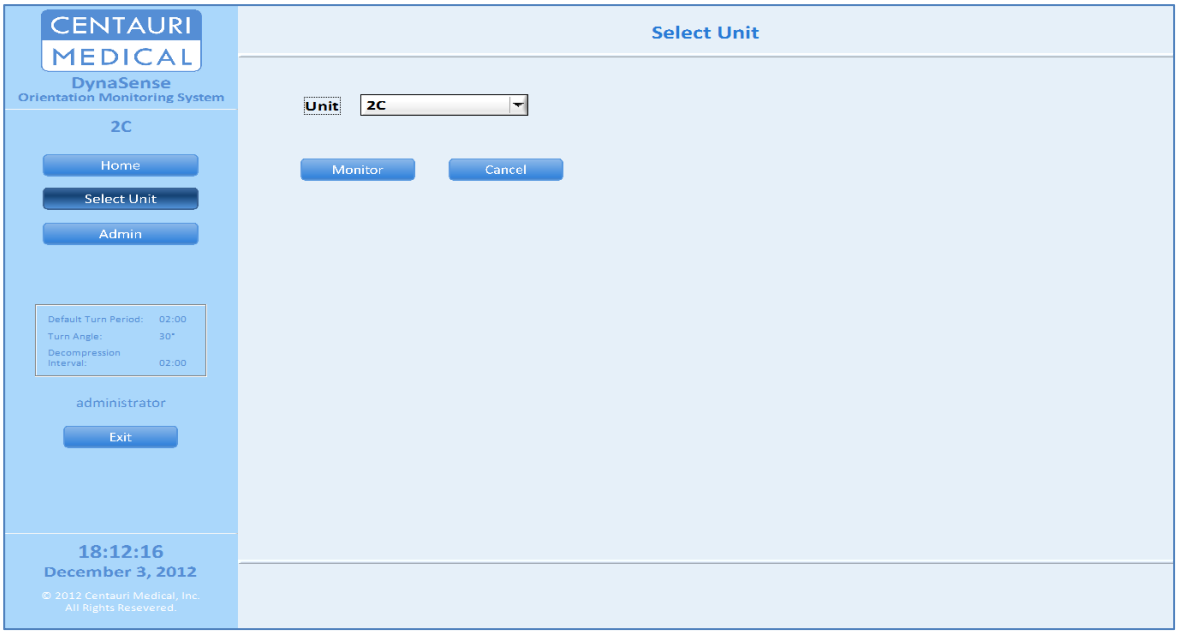

Figure 13: User Interface, Select Unit screen

J. Home Screen

The Home screen will now be displayed. To access the "Home" screen at any time, click on the "Home" button on the left panel of the screen. Here you will see a table of beds and monitored sensors sorted by Room. This table of monitored rooms may span one or both columns of the Home screen, depending on how many rooms are being monitored. In the example in Figure 14, 7 patients are monitored and the table of monitored rooms spans two columns (e.g.,

rooms 2301-TEMP 2 in Figure 14). The monitored rooms and units/wards of your facility will be entered at the time of installation. An Unassigned Sensors Table in the lower right corner displays the sensors that have been activated but have not yet been associated with patients.

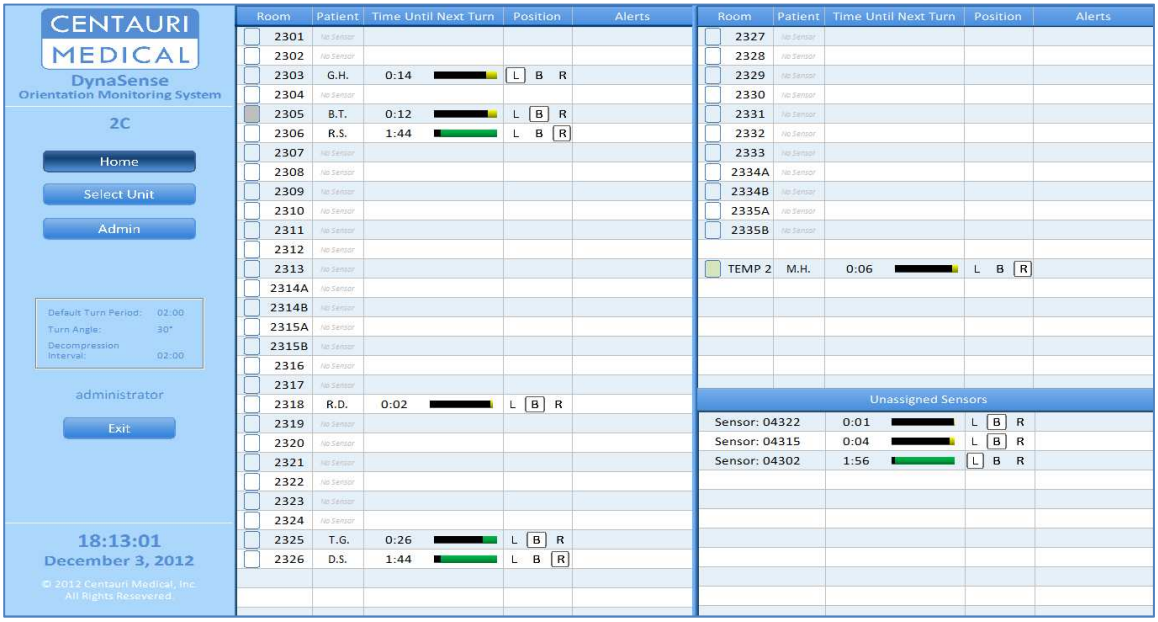

Figure 14: User Interface, Home screen

K. Assign the Patient Sensor to the Patient

Look at the Unassigned Sensor Table in the Lower Right of the Home screen.

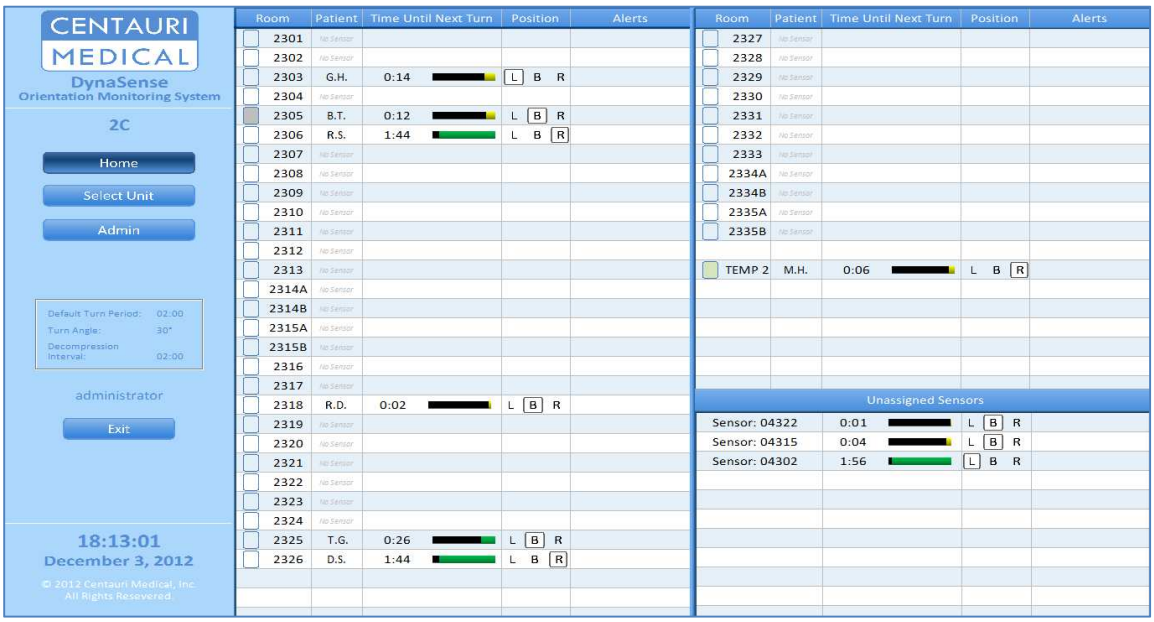

Figure 15: User Interface, Home screen Unassigned Sensors Table

Identify the Patient Sensor you wish to assign to the patient by looking for the matching sensor serial number, the last 5 digits of which are displayed. Click on the row of the unassigned sensor serial number to open the Unassigned Sensor pop-up window.

Once the pop-up window has displayed showing the sensor information, enter the patient information including at least the room number, the patient's first and last name, and medical record number (MRN). Optionally, you may also assign a tag color to patients to identify groups of patients by a common color. To save the information you have entered, click the "Save" button. Clicking the "Cancel" button will discard any changes entered.

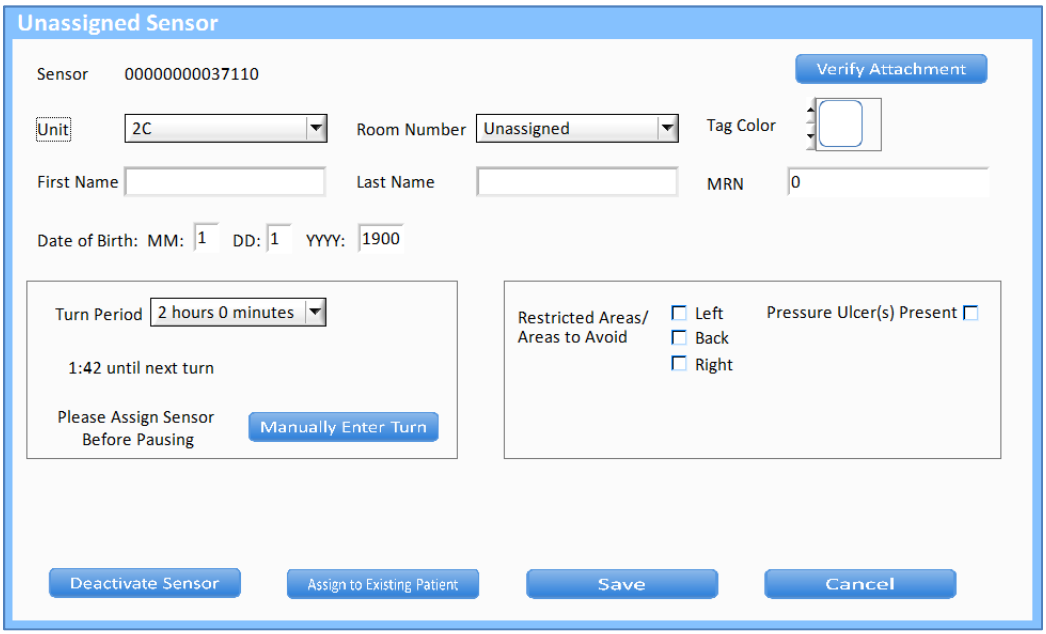

Figure 16: User Interface, Unassigned Sensor pop-up window

L. Monitoring Patient Movement

Use the User Interface to track and report patient orientation and activity. The Home screen displays patient position, either L, R, or B (Left, Right or Back), in the Position column. If the patient is upright or prone, then "upright" or "prone" will appear in the Alerts column. Patients who pass facility-set thresholds for inactivity or orientation (See Section S: Administrative Settings in this document) are indicated by red text as an alert. The count down time for the alert is displayed graphically next to each patient's information with the

colored bar. The amount of time remaining before the patient orientation or activity threshold is reached is displayed by the bar, which starts green and turns yellow when the next time threshold is less than 15 minutes away.

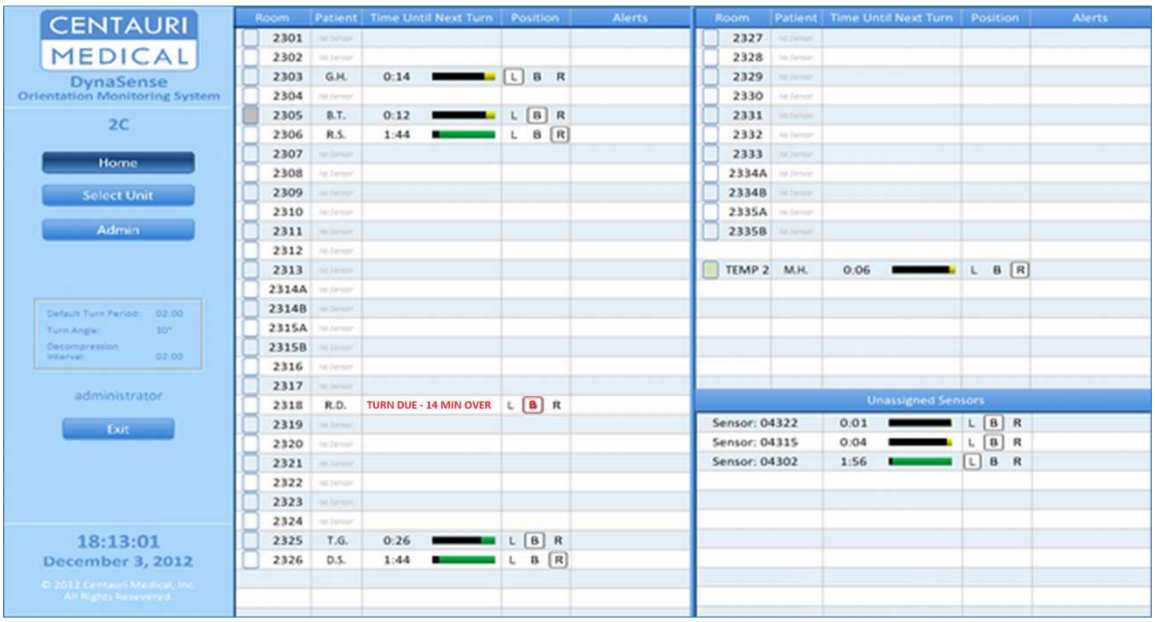

Figure 17: User Interface, Home screen

The Position column displays the orientation of the patient being monitored when the sensor is correctly applied to the patient. After applying the Patient Sensor, check the patient to confirm that the orientation of patient reported in the User Interface matches the patient's actual orientation. If it does not match a new Patient Sensor may be used. The patient data may take a few minutes to update. An alert will be displayed on the User Interface when the system detects a significant period of time without updates.

M. Viewing or Updating Patient Information

For a sensor that has already been assigned to a patient, look on the Home screen for the patient whose information you wish to view or

update. Click on the patient's row to open the Patient Information pop-up window. Once the pop-up window has displayed showing the patient information, you can edit and save that information. To save the information you have entered, click the "Save" button. Clicking the "Cancel" button will discard any changes entered.

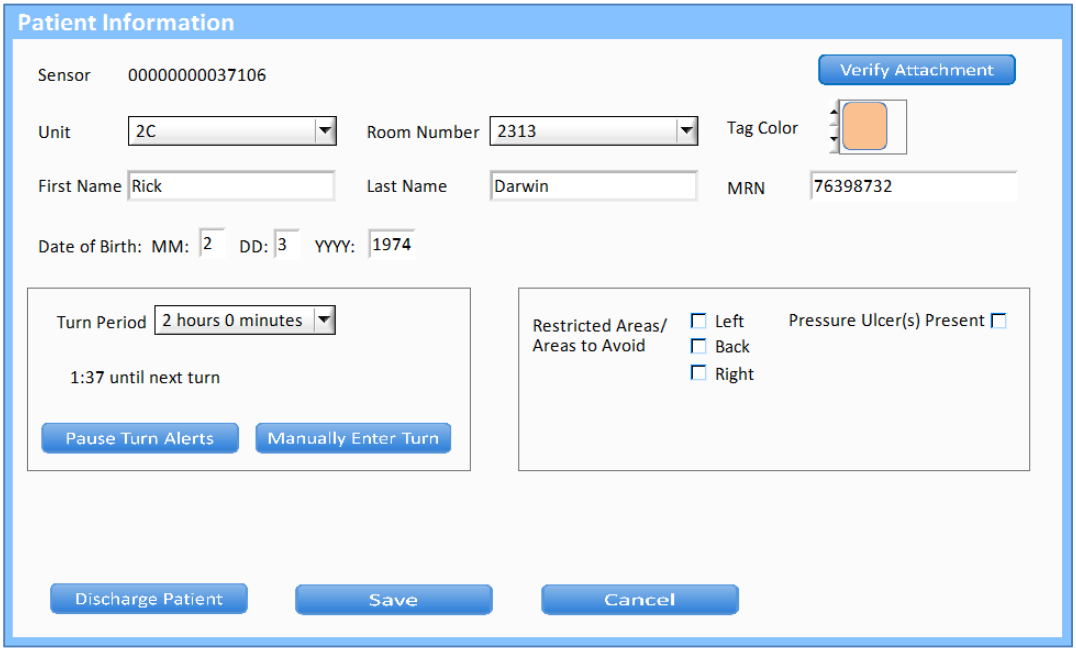

Figure 18: User Interface, Patient Information pop-up window

N. Removing the Patient Sensor

The Patient Sensor should be removed and replaced after it has been on the patient for up to 7 days. Patient Sensors should be removed during MRI studies, or if current is going to be passed through the patient's body, such as during external cardiac defibrillation or electrocautery. The Patient Sensor should also be removed if the adhesive is no longer firmly attached to the patient or if the patient is experiencing a skin reaction, such as an allergic reaction, rash, or any compromise to the integrity of the skin, under Patient Sensor.

To remove the Patient Sensor, lift gently and slowly, but with continuous force, on the edge of the sensor to peel it off the skin. Ripping, tearing, or tugging the Patient Sensor strongly from the patient's skin may cause skin injury or skin irritation.

Use the User Interface to stop tracking and reporting patient movement from the sensor that has been removed. Click on the patient's row in the Home screen to access the Patient Information pop-up window. Click on the "Discharge Patient" button to discharge the patient from DynaSense if the patient is ready to be discharged and/or you no longer wish to monitor patient movement using the sensor.

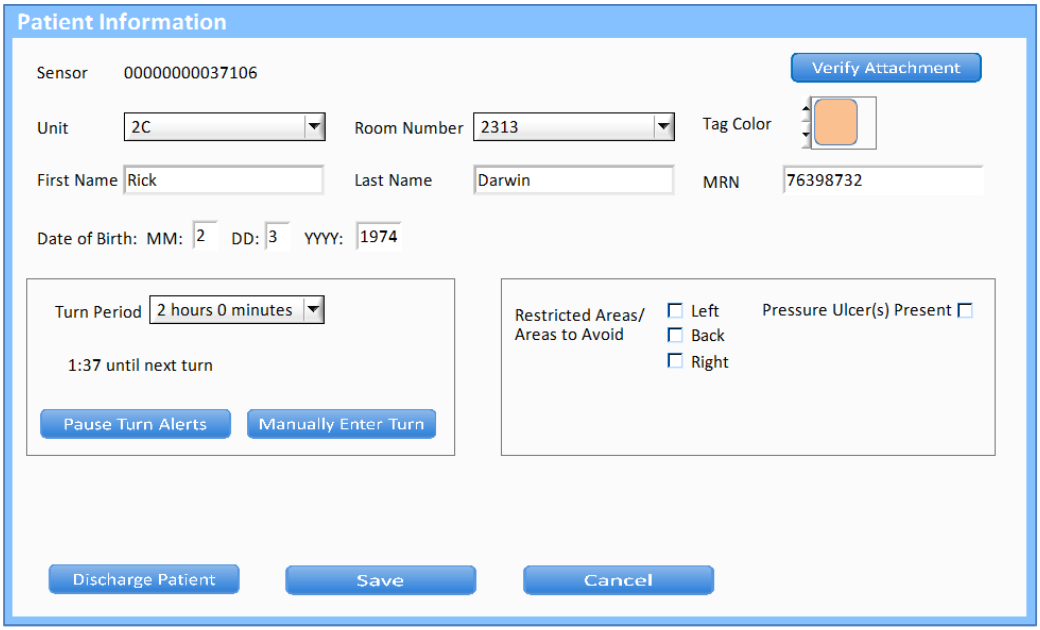

Figure 19: User Interface, Patient Information pop-up window

When the discharge pop-up window displays, click on the “OK” button to confirm discharge.

Figure 20: User Interface, Discharge Patient

O. Replacing the Patient Sensor

If the Patient Sensor has been removed or needs to be replaced, repeat the previous instructions to apply a new Patient Sensor in a new location. New Patient Sensors should not be applied in the exact same location as the previous Patient Sensor as skin irritation may result.

Once a new Patient Sensor has been applied, the new Patient Sensor must be assigned to the patient at the User Interface.

If you have put a new sensor onto a patient who is currently being monitored, you can click the “Assign to Existing Patient” button in the “Unassigned Sensor” pop-up window. This will allow you to assign

the sensor to an existing monitored patient. The already saved patient information will be associated with the new sensor and the original sensor will be deactivated. When assigning a new Patient Sensor to an existing patient, you do not need to discharge the patient to deactivate the old Patient Sensor. You can then remove the original sensor.

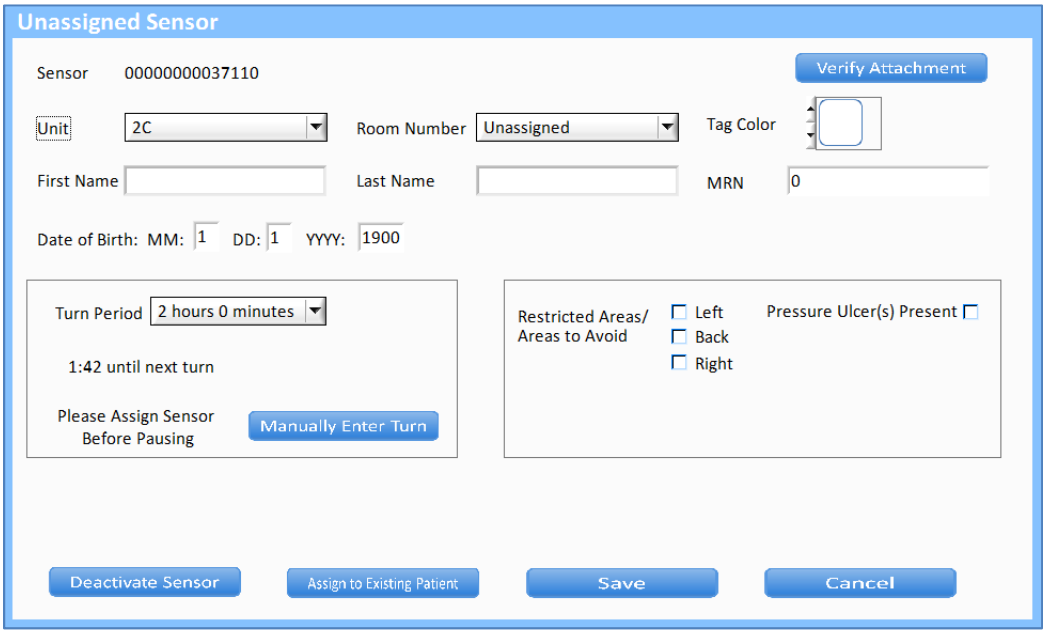

Figure 21: User Interface, Unassigned Sensor pop-up window

P. Adding Restricted Areas / Areas to Avoid

If the patient has areas that he / she should not lie on, these can be designated in the Patient Information / Unassigned Sensor pop-up window.

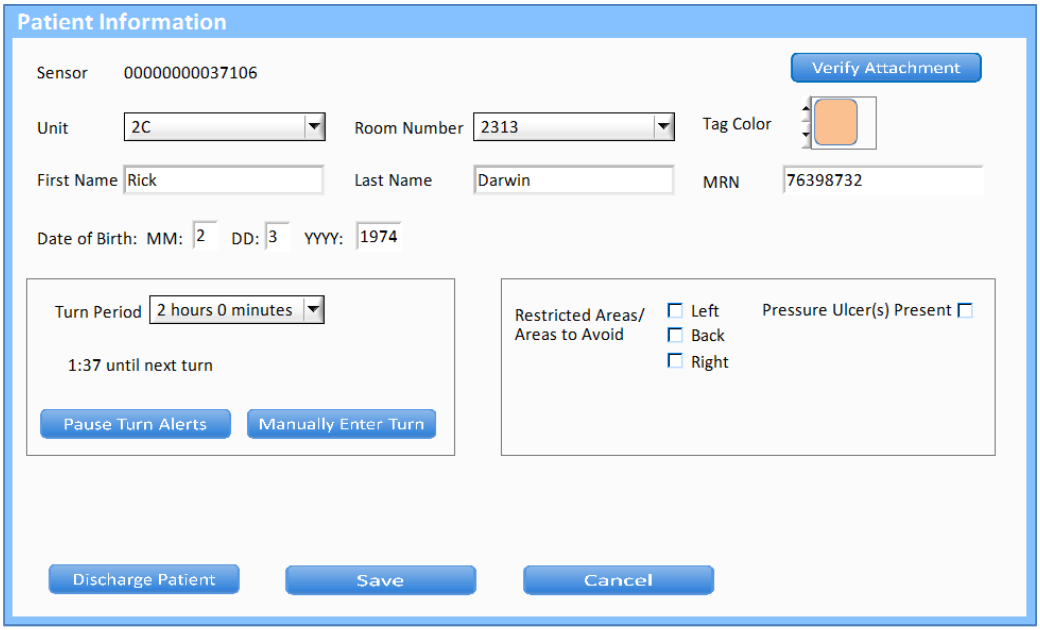

Figure 22: User Interface, Patient Information pop-up window

You may select one or more sides, Left, Back, or Right, to be Restricted Areas / Areas to Avoid. Patients may have areas to avoid if they have a wound or devices on one or more areas of their body. They may also have a pressure ulcer on an area of the body that they should not lie on. If a pressure ulcer is present, you can check the "Pressure Ulcer(s) Present" checkbox.

If one or more Restricted Areas are designated, the Restricted Area(s) will be designated in the Home screen in the "Position" column with a universal no symbol (red circle with a diagonal line through it) around the side(s) restricted. If the patient turns onto a restricted side, Home screen shows that the patient has a turn due in the "Time Until Next Turn" column and shows that the patient is positioned on the Restricted Area in the "Position" column.

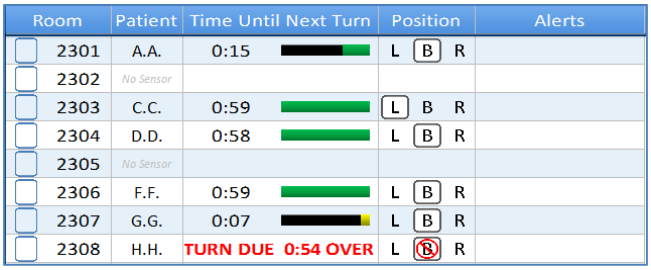

Figure 23: User Interface, Portion of Home screen showing Restricted Side

Q. Pause Turn Alerts

If the patient has a medical procedure scheduled, the patient has an exam in progress, the patient is out of the bed, or is otherwise unavailable to be re-oriented, you may pause the turn alerts and note the reason in the system. To pause turn alerts, select the patient by double-clicking on the appropriate row. The patient information screen will pop-up and display. Click on the “Pause Turn Alerts” button in the lower left-hand corner of the “Patient Information” pop-up window. The “Pause Turn Alerts” window will pop-up and display. Enter the desired time interval and reason, and click the “OK” button.

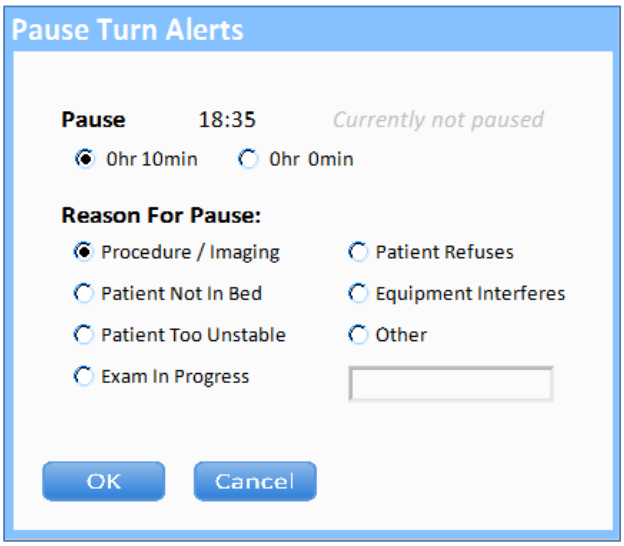

Figure 24: User Interface, Pause Turn Alerts pop-up window

R. Enter Manual Turns

If you detect that the system has not correctly recorded a patient re-orientation, you may force the system to record a patient re-orientation via manual entry of the orientation. To manually enter a patient re-orientation, select the specific patient by clicking on the row for that patient's room in the "Home" screen. The patient information screen will pop-up and display. Click on the "Manually Enter Turn" button in the lower left-hand corner of the pop-up window. The "Manually Enter Turn" window will pop-up and display. Select the side the patient was re-oriented to and click the "OK" button.

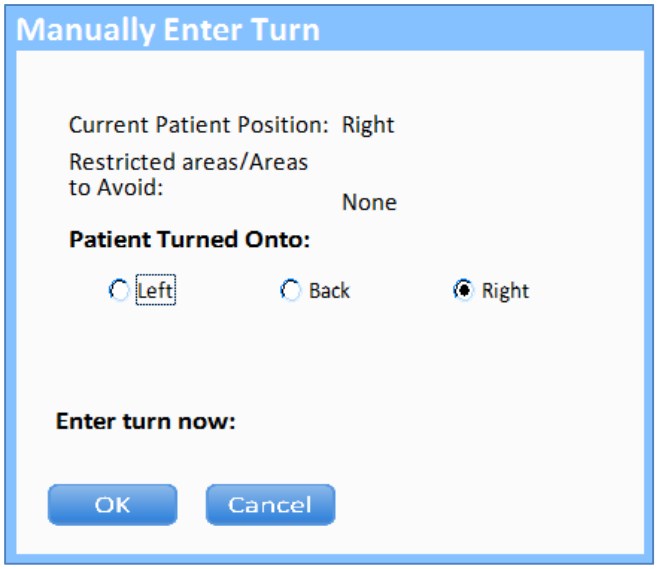

Figure 25: User Interface, Manually Enter Turns pop-up window

S. Verifying Sensor Attachment

The Patient Sensor checks to see if the sensor is attached to a patient. If the system detects that the Patient Sensor becomes unattached from the patient after being attached, it will label the sensor as “unattached” on the “Home” screen of the User Interface and it will stay that way even if the sensor becomes reattached again. This warns against potential shifting of the Patient Sensor that will take the sensor out of alignment with the head to foot axis of the patient. If you believe that the sensor marked “unattached” is actually correctly attached and aligned, you can remove the “unattached” designation by the sensor by clicking on the “Verify Attachment” button in the “Patient Information” pop-up window or the “Unassigned Sensor” pop-up window.

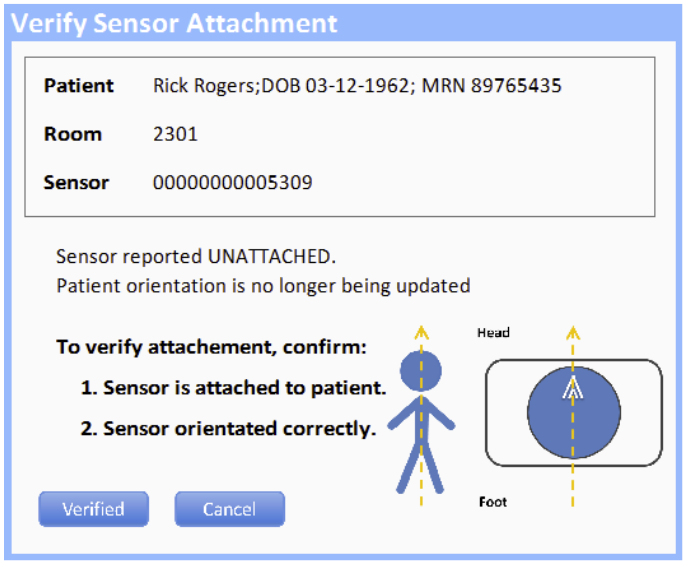

Figure 26: User Interface, Verify Sensor Attachment pop-up window

This opens a “Verify Sensor Attachment” pop-up window. If you have verified that the Patient Sensor is securely attached to the patient in the correct orientation, click “Verified” to verify.

T. Administrative Settings

If you are logged in as a user with Administrative privileges, you can access the Administrative Settings screen by clicking on the “Admin” button on the left.

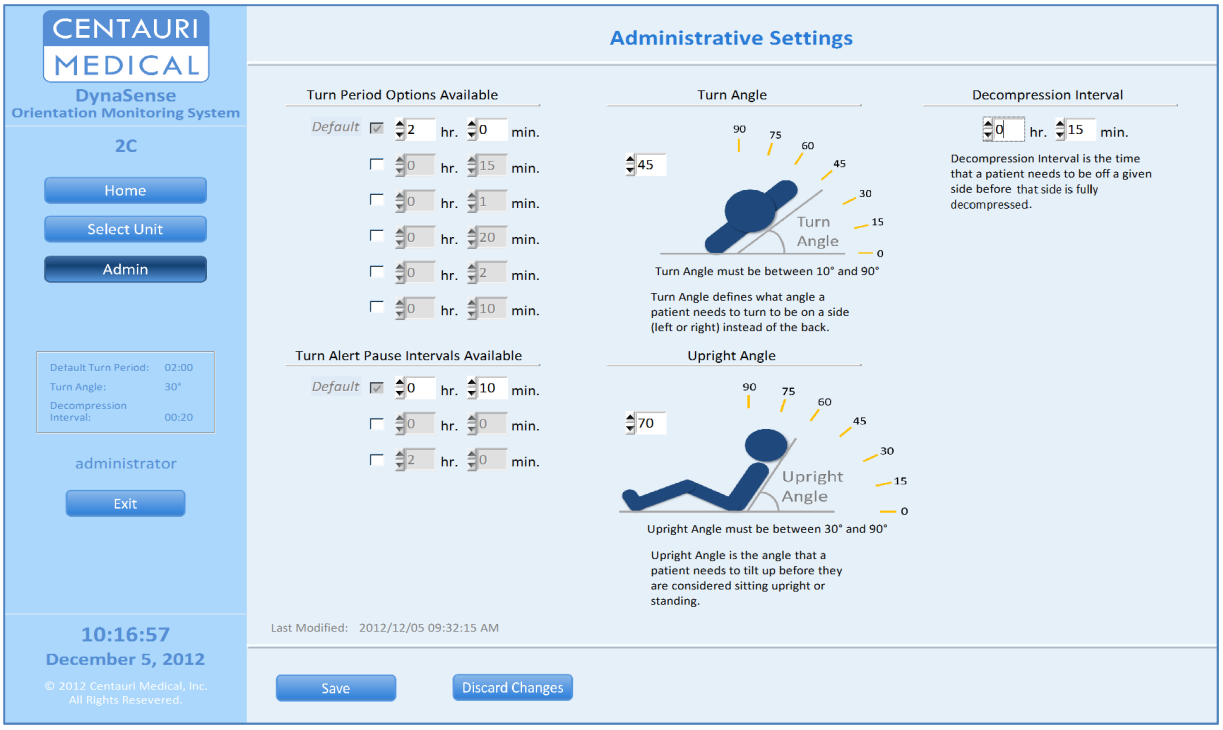

Figure 27: User Interface, Administrative Settings

On this page you can set the following:

Turn Period Options – Set the Turn Period, which defines the amount of time a patient can be on a given side before a visual alert is shown on the Home screen. More than one option can be set here allowing users of the User Interface to select different Turn Periods for a given patient.

Turn Alert Pause Intervals Available – Set which pause interval(s) can be selected in the Pause Turn Alerts pop-up window.

Turn Angle – Set the angle that a patient needs to turn to be on a side (left or right) instead of the back

Upright Angle – Set the angle that a patient needs to tilt up before they are considered sitting upright or standing.

Decompression Interval – Set the interval of time that a patient needs to be off a given side before that side is fully decompressed and can take a full turn period again. Note that if a patient is off a given side for less than the turn interval and then turns back on that given side, the time until next turn for that given side is incremented by a period of time equal to: (turn period)*(time off side)/(decompression interval)

For details on the DynaSense alerts, please refer to “Summary of Alerts” section of this document.

Note that for the “Turn Period Options” and “Turn Alert Pause Intervals Available”, you can choose to have one or more Turn Periods or Turn Alert Pause Intervals available. To do so, check the checkbox next to the Turn Period or Turn Alert Pause Interval and then enter a time period next to the checked box. One checkbox is checked by default to ensure that at least one Turn Period or Turn Alert Pause Interval is available.

U. Exiting the User Interface

To exit the User Interface, click the “Exit” button on the side panel.

DEVICE LABELS

The following labels appear on the Patient Sensor and the Relay Antenna or their packaging:

Patient Sensor Labels

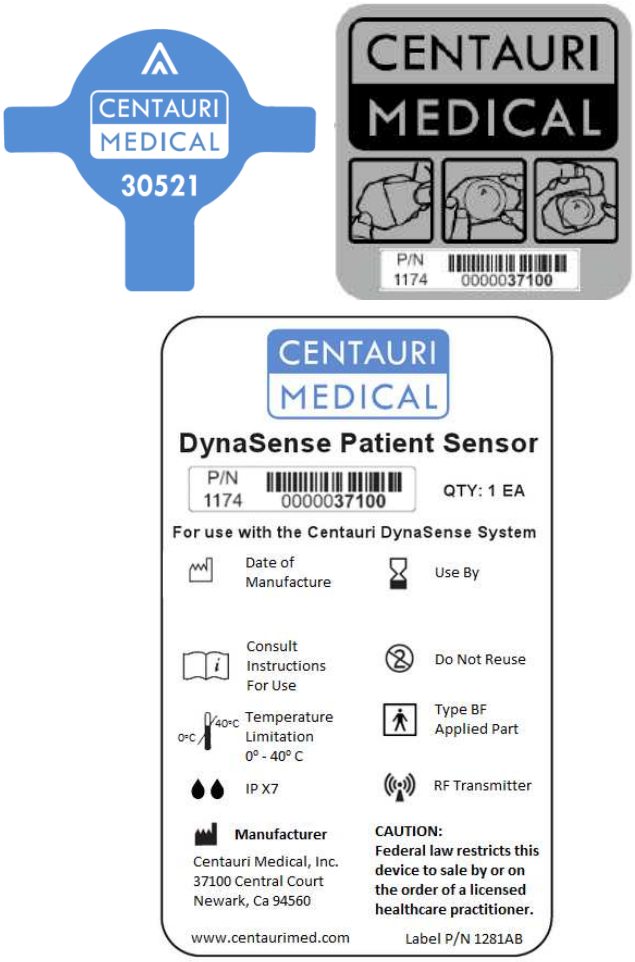

Figure 28: Patient Sensor Labels

Relay Antenna Labels

Figure 29: Relay Antenna Labels

TAKING CARE OF THE DEVICE

Cleaning Instructions

The Patient Sensor does not require cleaning. Patients may bathe and engage in other daily activities while the Patient Sensor is still applied.

If the Patient Sensor is removed, becomes loose, is dislodged, malfunctions, or stops working, DO NOT re-apply the Patient Sensor. Apply a new Patient Sensor in a different skin location.

Storage

Always store unused Patient Sensors in a dry, temperature-controlled location, 0^{o}C-40^{o}C. Keep unused Patient Sensors away from water or moisture that could get inside the Patient Sensor or the packaging.

Maintenance

The Patient Sensor does not require any maintenance. If you think the Patient Sensor is not working properly or is damaged in any way, **DO NOT** apply or use the Patient Sensor.

Replace the Patient Sensor with a new Patient Sensor and apply the new Patient Sensor in a new location. Call Customer Service at 510-574-0060 for assistance if needed.

Disposal

A battery is included in the Patient Sensor. Used Patient Sensors should be disposed of in the manner as required by local regulations for the disposal of used batteries.

Life of the Device

The Patient Sensor is designed to work properly for up to 7 days of normal use when applied once on a single patient. The device is designed for one-time use on a single patient and should not be re-used. There are no parts that need to be replaced. The Patient Sensor is working properly if it functions as described in this booklet.

SUMMARY OF ALERTS

The alerts displayed by the system and the Actions That Will Resolve the Alerts listed below are not a substitute for sound medical judgment and individualized patient management. Also note that the terms 'Customer Service' and 'Technical Support' are used interchangeably throughout this section.

- **Turn Due Alert**
  - Displayed in the Time Until Next Turn Column of the Home screen in red bold text: "TURN DUE *hh:mm* OVER". Triggered if the time that the patient has been in a given position exceeds the threshold set by the user or facility. The time that the patient has been overdue for a repositioning is also displayed.
  - Action That Will Resolve Alert: Repositioning of the patient can lead to automatic resolution of this alert trigger once the Patient Sensor updates its status.
- **Upright Alert**
  - Displayed in grey italic text in the Alerts Column of the Home screen: "*Upright*". Triggered if the angle at which the Patient Sensor on the patient's torso is tilted is greater than the threshold Upright Angle set on the Administrative Settings in the User Interface.
  - Action That Will Resolve Alert: This is not an alert that inherently requires action. However, repositioning the patient can lead to resolution of this alert trigger.
- **Prone Alert**
  - Displayed in grey italic text in the Alerts Column of the Home screen: "*Prone*". Triggered if the orientation of the patient detected by the Patient Sensor indicates that the patient's upper body is facing downwards.

  - Action That Will Resolve Alert: This is not an Alert that inherently requires action. However, repositioning the patient can lead to resolution of this alert trigger.
- **No Signal Alert**
  - Displayed in black text in the Alerts Column of the Home screen: “No Signal”. Triggered if data from the Patient Sensor has not been detected by the User Interface to have been updated in 5 minutes or more.
  - Action That Will Resolve Alert: The user may determine if the Patient Sensor is too far from any Relay Antennas or if something may be blocking the signal. Alternatively, the user may replace the sensor or contact Centauri Medical Customer Service.
- **Unattached Alert**
  - Displayed in red text in the Alerts Column of the Home screen: “Unattached”. Triggered if the Patient Sensor does not detect that it is attached to the patient’s skin.
  - Action That Will Resolve Alert: If the user believes the sensor marked “unattached” is firmly attached and properly aligned (arrow pointing to patient’s head) on the patient’s torso, the user can click the “Verify Attachment” button in the “Patient Information” pop-up window (if this alert is triggered for an assigned sensor) or in the “Unassigned Sensor” pop-up window (if this alert is triggered for an unassigned sensor). Otherwise, the user should replace the Patient Sensor.
- **Pause Alert**
  - Displayed in grey italic or black text in the Alerts Column of the Home screen: “Pause”. Triggered when the user sets a Pause Turn Alert for a patient. The Pause alert lasts for the duration of the pause selected by the user

- Action That Will Resolve Alert: This is not an Alert that inherently requires action. It will disappear when the pause has expired.

- **Database Inaccessible Alert**
  - Displays as a pop-up window when the database is not accessible by the User Interface.
    - If the User Interface is in the process of starting up and the database is inaccessible the following message will be displayed in a pop-up window: “Database currently inaccessible and program will be shutdown. If the problem persists please contact technical support.”
    - If the User Interface has successfully started and the database is inaccessible, when the user attempts to perform an action which requires database interaction, the following message will be displayed in a pop-up window: “Database currently inaccessible and program is unable to perform desired action. If the problem persists, please contact technical support.”
  - Action That Will Resolve Alert: The user should try to perform the desired action again. If the problem persists, the user can restart the User Interface. If the problem still persists, Centauri Medical Customer Service can be contacted.
- **Home Screen Warning Alert**
  - If all the patient and Patient Sensor information displayed on the Home screen has not been updated over a period equal to a preset threshold (initially set to 10 minutes and configurable during installation) the following red text alert in the Side Panel of the Home screen will appear: “Elapsed time since last update: *hh:mm.ss*”.
  - A pop-up window will also open:

        - If the database is accessible, the following message will be displayed in the Home Screen Warning pop-up window: “System Warning: Patient information not updating. Please shutdown and restart software. If problem persists please contact technical support.”
        - If the database is inaccessible the following message will be displayed: “Database Warning: Patient information not updating. Last patient position recorded by system is displayed. Please contact technical support.”
    - Action That Will Resolve Alert: The user should be aware that for both warnings the data displayed may be out of date by the amount of time elapsed since last update as displayed in the Side Panel. The User Interface can be restarted. If the problem persists, Centauri Medical Customer Service can be contacted.
- **Patient Information Warning Alert**
    - If a user tries to perform an action on a patient that has been discharged, a pop-up window with the following Alert message appears: “Selected Patient is no longer available. Patient has been discharged.”
    - Action That Will Resolve Alert: No action is required by the user.
- **Unassigned Sensor Warning Alert**
    - If a user tries to perform an action on a Patient Sensor in the unassigned sensor column when that Patient Sensor has been assigned or deactivated (but the User Interface has yet to update) one of the following two pop-up windows will open:
        - If the unassigned sensor has been assigned, the following message is displayed: "Sensor ##### is no longer available. Sensor has been assigned to Patient.” The First and Last Name, MRN, Unit, Room, and Patient Sensor

Serial Number of the patient to which the sensor has been assigned will be displayed.
    - If the unassigned sensor has been deactivated the following message is displayed: " Sensor ##### is no longer available. Sensor has been deactivated."
  - Action That Will Resolve Alert: No action is required by the user.
- **Unable to Save Changes Alert**
  - If a user attempts to assign a Medical Record Number (MRN) that is currently assigned to another patient or attempts to assign a room that is currently assigned to another patient, a pop-up window is opened alerting the user. For a duplicate MRN entry, a pop-up window with the following message is displayed:
    - "Duplicate MRN assigned to patient. MRN ## has been assigned to Patient:" The First and Last Name, MRN, Unit, Room, and Patient Sensor Serial Number of the patient with that MRN will be displayed.
  - For a duplicate room selection, a pop-up window with the following message is displayed:
    - "Room not available. Room ## has been assigned to Patient:" The First and Last Name, MRN, Unit, Room, and Patient Sensor Serial Number of the patient with the occupied room number will be displayed.
  - Action That Will Resolve Alert: No action is required by the user.
- **Administrative Settings Out of Range Alert**
  - If a user sets an Administrative Setting that is outside of the restricted range and attempts to save these changes a pop-up window will be opened alerting the user. This only applies to the Decompression Interval. The user cannot set a Decompression

Interval that is greater than the shortest Turn Period option entered.

- The following message will be displayed: “Warning the following items must be entered correctly before a save can be performed: Decompression Interval: Decompression time must be smaller than the smallest active turn period.” The smallest active turn period refers to the shortest “Turn Period Options Available” option set in the Administrative Settings screen
- Action That Will Resolve Alert: The user can select a setting for the Decompression Interval that is within acceptable range, thus, smaller than the smallest active Turn Period.

- **Administrative Settings Save Changes Alert**
  - If a user modifies the administrative settings and tries to navigate away, a pop-up window will be opened alerting the user and prompting them to save or discard changes. The following alert will be displayed: “Save changes made to Administrative Settings before proceeding? *Warning: These changes will affect all monitored units.*”
  - Action That Will Resolve Alert: The user can select to save or discard changes.
- **Additional Alert Details**
  - The Alerts in DynaSense are low priority alerts and should be regarded with the caregivers’ discretion
  - The delay time from the onset of the Alert condition to the display of the Alert on the User Interface will be less than or equal to 10 minutes. In a situation in which an Alert would be generated by DynaSense, the appropriate Alert will be displayed within 10 minutes or an Alert specifying a malfunction in the system will be displayed.

- Alerts and data display that involve information from the Patient Sensor may not be accurate within 10 minutes if the Patient Sensor is not in communication range of or is otherwise blocked from communicating with a Relay Antenna or USB RF Transceiver. In such a case, the User Interface will show the 'No Signal' Alert after 5 minutes without communication with the Patient Sensor as described above.
- **Warning**: Be aware that confusion amongst users may occur if different alert settings are used for one or more DynaSense systems or other similar systems in any single area.
- Users with Administrative Privileges are able to set Alert presets and options in the Admin Settings page of the User Interface for the 'Turn Due', 'Upright', and 'Pause' alerts
- Users should check that the current Alert preset is appropriate prior to use on each patient
- Alert presets are stored in non-volatile storage that can be recovered after a power interruption.

TROUBLESHOOTING

Use this chart to help solve any problems that may occur. If you still have problems, please call Customer Service at 510-574-0060.

Problem	Cause	What you should do
I opened the packaging and removed the adhesive backing from the sensor, but no LED lights are blinking.	You may be too far away from a Relay Antenna.	Check to be sure that you are within 10 feet of a Relay Antenna. When DynaSense was installed, Relay Antennas should have been placed within 10 feet of each patient room on the unit.

Problem	Cause	What you should do
	The packaging adhesive may not be entirely removed.	Check to make sure that the opaque backing has been entirely removed.
	You may not have enough light in the room to activate the Patient Sensor.	If the patient's room is dark, temporarily move the sensor to a well-lit location (such as a hallway) within 10 feet of the Relay Antenna and check to see if this causes the LED lights to start blinking.
	The Patient Sensor may have a dead battery.	Open a new Patient Sensor and see if the problem is resolved. Return the first Patient Sensor to Centauri Medical for evaluation.
	Unknown	If you have tried all of the above and continue to have problems, call Customer Service.
The Patient Sensor has been applied to the patient, the LED lights are displayed, but the Patient Sensor is not shown in the User Interface.	The Relay Antenna has not been found by the Patient Sensor.	If three solid green lights are displayed on the Patient Sensor, then the Patient Sensor has been turned on, but a Relay Antenna has NOT been found. Make sure that the Patient Sensor is within 10 feet of a Relay Antenna.

Problem	Cause	What you should do
	Unknown	If you have tried all of the above and continue to have problems, call Customer Service.
Correct patient movement data is not being monitored or reported.	The Patient Sensor has fallen off or has been removed or was not oriented correctly with respect to the patient.	Replace the Patient Sensor. Be sure to assign the new Patient Sensor in the User Interface once the new sensor has been applied. Be sure that the arrow on the sensor is pointing towards the patient's head and aligned with the patient's head-to-foot axis.
	Unknown	If you have tried all of the above and continue to have problems, call Customer Service.
Patient Sensor data was being displayed previously by the User Interface, but is no longer being displayed.	The patient has been temporarily moved off the unit or is out of range of a Relay Antenna.	Verify that the patient is still physically located on the unit. If the patient has been taken off the unit for an exam or other procedure, monitoring will automatically resume when the patient returns to the unit and the sensor is within range of a Relay Antenna.

Problem	Cause	What you should do
	The patient has been discharged from the unit.	Verify that the patient is still physically located on the unit. If the patient has been discharged from the unit, then use the discharge feature in the User Interface to remove the patient from the list of monitored patients. Discharging the patient from the system will discontinue the recording of all movement data for this patient.
	The Patient Sensor has fallen off or has stopped working.	Replace the Patient Sensor. Be sure to assign the new Patient Sensor in the User Interface once the new sensor has been applied.

Problem	Cause	What you should do
I don't know which sensor serial number to assign to the patient.	Patient Sensor serial number is not known to caregiver.	Look at the serial number located on the packaging that was removed. If you have already discarded the sensor packaging, then you can determine the sensor's serial number by looking on the sensor that was applied to the patient. The last 5 digits of the serial number are located on the front of the Patient Sensor. (See Figure 3). Once you know the sensor's serial number, you can assign it to the correct patient using the User Interface.

EXPLANATION OF SAFETY SIGNS AND SYMBOLS

The following signs and symbols are present on the immediate packaging of the Patient Sensor, as shown in Figure 26.

	Manufacturer
	Date of Manufacture
	Consult Instructions for Use
	Use By Date
	Do Not Reuse
	Temperature Limitations, 0^{o} to 40^{o}C
	Type BF Applied Part
	IPX7 Rating
	RF Transmitter

TECHNICAL SPECIFICATIONS

Electrical Voltage (USB RF Transceiver)	5 VDC
Electrical Voltage (Relay Antenna)	120 VAC
Electrical Voltage (Relay Antenna Power Adapter)	100-240V ~ 50/60Hz, .18A, Output: 5.0V DC 1.0 A
Electrical Voltage (Patient Sensor)	3 VDC
Patient Sensor Power Source	Internally Powered
Patient Sensor Size	1.8” x 2.0”, adhesive extends to 2.4” x 2.8”
Patient Sensor Weight (max)	20 g
Patient Sensor Skin Adhesive Material	Acrylic adhesive on polyurethane carrier
Patient Sensor Applied Part Type	Type BF Applied Part 
Patient Sensor Cover Material	Polystyrene
Optimal Distance between Patient Sensor and Relay Antenna	15 feet
Wireless Transmission Protocol	IEEE 802.15.4 Compliant
Wireless Transmission Frequency	2.4 GHz
Relay Antenna Classification	Class II Medical Electrical Equipment, IEC 60601
Ingress Protection (IP) Rating	IPX7 for Patient Sensor, IP2X for Relay Antenna and USB RF Transceiver
Intended System Operation	Continuous Operation

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
DynaSense is intended for use in the electromagnetic environment specified below. The customer or the user of DynaSense should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	DynaSense 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	DynaSense is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating DynaSense or shielding the location.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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