Smith+Nephew

BRAND	LEAF		
SKU			
COMPONENT	Instructions for Use Manual		
PRODUCT			
THIS BSC/REF	28962		
PREV. BSC/REF	N/A		
DIMENSIONS	148 x 210mm (76pp)		
COLOURS *Match to coated stock PMS*	CMYK		
DATE	07.10.2021	**REVISION**	15

Strawberry

JOB NUMBER	S38053 - 6132		
ARTWORK	MP	**CHECKED**	SA

Smith+Nephew

LEAF◊ Patient Monitoring System Instructions for Use

Smith & Nephew Medical Limited
101 Hessle Road, Hull, HU3 2BN England
Telephone No.: 1-844-826-LEAF (5323)

Customer Support Email Addresses:
Leaf.ClinicalSupport@smith-nephew.com
Leaf.ITSupport@smith-nephew.com

CONTENTS

INTRODUCTION 5
DEVICE DESCRIPTION 6
HOW IT WORKS 6
DEVICE DIAGRAM 7
INDICATIONS FOR USE 10
CONTRAINDICATIONS 10
WARNINGS 10
PRECAUTIONS 13
RISKS 14
BENEFITS 14
HOW TO APPLY THE LEAF PATIENT SENSOR 15
REMOVING AND REPLACING THE LEAF PATIENT SENSOR 19
INTERPRETING THE LEAF PATIENT SENSOR 21
HOW TO USE THE LEAF USER INTERFACE 22
HOW TO USE THE LEAF REPORTING TOOL 49
DEVICE LABELS 58
TAKING CARE OF THE DEVICE 59
- Cleaning Instructions 59
- Washing and Bathing 59
- Storage of Sensors 59
- Maintenance 59
- Disposal 59
- Life of the Device 59

SUMMARY OF ALERTS 60
TROUBLESHOOTING 68
GLOSSARY 71
- Technical Specifications 72
- Electromagnetic Compatibility 73
- FCC Compliance Statements 73
- Guidance and Manufacturer's declaration – electromagnetic immunity 74
- Guidance and Manufacturer's declaration – electromagnetic emissions 75

INTRODUCTION

℞ only **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 LEAF Patient Sensor.

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 the LEAF Patient Monitoring System and provides information on the system operation once the LEAF Patient Monitoring System has been properly installed. Installation is required to be performed by qualified installation personnel from Smith+Nephew.

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

DEVICE DESCRIPTION

The LEAF Patient Monitoring System is a medical device designed for use in hospitals, nursing homes, or other patient care facilities to monitor and report patient body orientation, activity and mobility, as well as to provide visual alerts for orientations and activity levels that fall outside of thresholds set by healthcare providers.

By input of the institution's turning protocol criteria, the LEAF Patient Monitoring System allows caregivers to continuously monitor patient position and mobility, and to identify patients that are in need of caregiver-assisted turns. The use of the LEAF Patient Monitoring System can increase compliance with the care facility's prescribed patient turning protocols and facilitate early mobilization, in an effort to prevent pressure injuries.

The LEAF Patient Monitoring System is comprised of:

- LEAF Patient Sensors
- LEAF Relay Antennas
- LEAF USB Transceiver(s)
- LEAF Patient Monitoring Software and User Interface

Each LEAF 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 LEAF Patient Sensor is a small, disposable sensor that adheres to a patient's skin, much like a standard electrocardiogram (ECG) lead.

Once the LEAF Patient Sensor is applied to a patient, it continuously monitors the patient's orientation and movements, and communicates this data wirelessly (via the LEAF Relay Antennas) to a monitoring station running the LEAF Patient Monitoring Software and User Interface. Through the LEAF Patient Monitoring Software and User Interface, caregivers can associate Patient Sensors with specific patients, set individualized care parameters for each patient, and see the status of all monitored patients. Patient Sensors can also be directly interrogated by caregivers to see the status of the patients' positions.

Multiple LEAF Relay Antennas are installed throughout a monitoring environment to ensure adequate wireless coverage for a given area.

DEVICE DIAGRAM

LEAF Patient Monitoring System

LEAF Patient Monitoring System consists of:

- LEAF Patient Sensors
- LEAF Relay Antennas
- LEAF USB Transceiver(s)
- LEAF Patient Monitoring Software and User Interface

Figure 1 shows a high-level schematic representation of the communication flow for the LEAF Patient Monitoring System. The network needs to be installed and maintained by trained personnel. Please contact LEAF Technical Support staff for more information regarding network setup. The system's User Interface can be displayed on virtually any web-enabled computer.

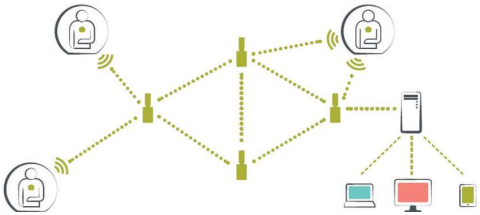

Figure 1: High-Level Schematic Representation of the System's Communication Flow

LEAF Patient Sensor (packaging)

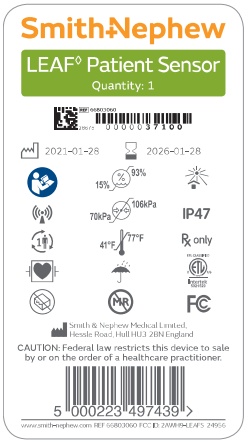

Figure 2: Packaging sleeve Label for Individual Patient Sensor

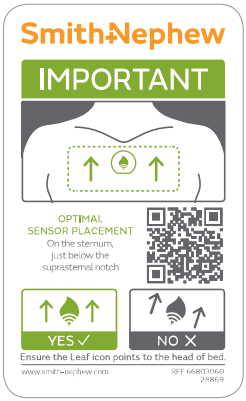

Figure 3: Packaging sleeve Label for Individual Patient Sensor

LEAF Patient Sensor

Figure 4: LEAF Patient Sensor

LEAF Relay Antenna and LEAF USB Transceiver

Figure 5: LEAF Relay Antenna (Left) and LEAF USB Transceiver (Right)

LEAF Patient Monitoring Software and User Interface

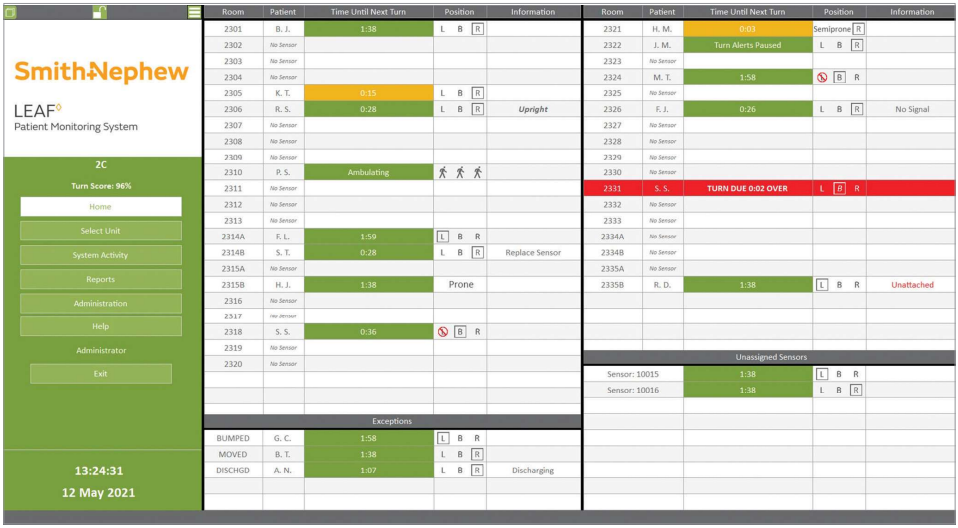

Figure 6: LEAF Patient Monitoring Software and User Interface

INDICATIONS FOR USE

The LEAF Patient Monitoring System monitors the orientation, activity and mobility of patients susceptible to pressure injuries. It allows healthcare providers to implement individualized turn management plans and continuously monitor each patient. The LEAF Patient Monitoring System 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.

CONTRAINDICATIONS

The LEAF Patient Monitoring System has no known contraindications for use.

WARNINGS

EXPLOSIVE ENVIRONMENTS

WARNING: LEAF Patient Sensors are unsuitable for areas where there is danger of explosion (e.g. hyperbaric oxygen unit, flammable anesthetics or other flammable substances in combination with air, oxygen-enriched environments or nitrous oxide).

MRI, Ionizing Radiation and Strong Magnetic Fields

WARNING: REMOVE the LEAF Patient Sensor prior to performing an MRI study. Strong magnetic fields can induce current within the device that could cause burns to the patient.

WARNING: Strong magnetic fields may cause the sensor to become a projectile hazard or may cause the patient to experience tugging or skin heating where the sensor has been applied. The LEAF Patient Sensor should be removed before these types of procedures are performed.

WARNING: High levels of ionizing radiation, strong magnetic fields and high frequency RF may cause the LEAF Patient Sensor to malfunction. The LEAF Patient Sensor should be removed before these types of procedures are performed.

X-Ray and CT Imaging Procedures

WARNING: Similar to ECG leads, the LEAF Patient Sensor is radio-opaque and therefore may block complete radiographic imaging of a body area located directly underneath the LEAF Patient Sensor. If it is anticipated that the LEAF Patient Sensor is going to block a critical part of the radiologic image (such as a chest X-ray or CT scan), then REMOVE the LEAF Patient Sensor prior to performing the radiologic exam.

Electrocautery and External Defibrillation

WARNING: REMOVE the LEAF Patient Sensor if an electric 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 patient has a medical emergency that requires external cardiac defibrillation or exposure to high frequency surgical equipment, the patient may experience a skin burn where the sensor has been applied.

Skin Sensitivity

WARNING: Do NOT apply the LEAF Patient Sensor to broken, irritated, or infected areas of skin. Applying the LEAF Patient Sensor to broken or irritated areas of skin can potentially lead to infection or tissue damage. Inspect the condition of the skin around the sensor application area periodically, or as indicated by clinical judgment, to look for signs of skin irritation or signs of infection.

WARNING: Though the silicone adhesive material used in the LEAF Patient Sensor is commonly used in other healthcare products and has a well-established safety profile, an allergic reaction to the adhesive is possible. If a patient experiences a rash, skin redness, itching, or swelling in the area where the LEAF Patient Sensor was applied, this may be a sign of an allergic reaction and should be evaluated immediately by the patient's doctor or other member of their care team. The LEAF Patient Sensor should not be used on patients who have a known tape allergy or sensitivity to commonly used medical-grade silicone adhesives and IV film dressings.

WARNING: If signs of skin irritation or hygiene issues are caused or aggravated by the LEAF Patient Sensor, REMOVE the LEAF Patient Sensor and evaluate the patient's skin. LEAF Patient Sensor may be reapplied on a non-irritated area. If the patient appears to have had an allergic reaction to the silicone adhesive, do NOT reapply another sensor. Notify the patient's doctor or other appropriate member of the patient's care team.

Cleaning

WARNING: Do NOT sterilize the LEAF Patient Sensor. It may cause the Sensor to not function properly.

WARNING: Do NOT use acetone to clean LEAF Patient Sensor. It may cause the Sensor to not function properly.

General

WARNING: Do NOT re-use the LEAF Patient Sensor on multiple patients. The LEAF Patient Sensor is for SINGLE patient use only. Infection or cross-contamination may occur if the LEAF Patient Sensor is re-used on multiple patients.

WARNING: Do NOT use a LEAF Patient Sensor if the sensor or its packaging is damaged, or previously opened, because the device may not function properly.

WARNING: Do NOT use a LEAF Patient Sensor past its expiry date.

WARNING: Keep unused Patient Sensors away from water or moisture that could get inside the Patient Sensor or its packaging.

WARNING: The LEAF System is not to be used to alert staff of situations that would require immediate action in order to maintain patient safety. Be aware that there is a possibility of ambulation/step detection inaccuracy. Some patient steps may not produce enough movement to be detected by the system. Conversely, some patient movement may resemble the movement associated with taking a step and therefore be recognized by the system as such.

WARNING: Do NOT modify the LEAF Patient Monitoring System (or any of its Components, including the port/network configuration between its components) without authorization from the manufacturer or the equipment may fail to operate properly. Inappropriate product modification or adulteration may void the user's authority to operate this equipment, and lead to the system failing to function. If this equipment is modified, appropriate analysis must be conducted by Smith & Nephew to ensure continued safe use of the equipment. Changes include;

- Changes in network configuration
- Connection of additional items
- Disconnection of items
- Update of equipment
- Upgrade of equipment

The scope of the changes listed above is within the LEAF patient monitoring system only, not the wider Medical IT Network.

WARNING: Do NOT cut the LEAF Patient Sensor as this may lead to device failure.

WARNING: Do NOT dismantle the LEAF Patient Sensor. The sensor contains small parts that may present a choking hazard.

PRECAUTIONS

General

CAUTION: The LEAF Patient Monitoring System is a support tool intended to support the monitoring of patient position and identification of patients that need to be turned as per the institution's turning guidelines or protocols. The System is for cuing of turns and alerting when a turn is due, however it does not replace clinical judgement or good clinical practice of monitoring patients in a hospital setting. The LEAF Patient Monitoring System does not treat the patient, determine a patient's treatment or provide a diagnosis of a patient's disease or condition.

CAUTION: The LEAF Patient Monitoring System has not been tested on women who are pregnant or breastfeeding, so the risks to unborn fetuses and nursing children are unknown. Safety and effectiveness for use by pregnant women and children (under the age of 18) has not been established.

CAUTION: Clip the patient's hair in the application area prior to applying the LEAF Patient Sensor to ensure good adhesion. Failure to adequately clip hair in the application area may result in sensor attachment errors or pain on removal.

CAUTION: Any initial settings present in the LEAF Patient Monitoring Software and User Interface at the time of installation must be reviewed by the user or facility for appropriateness based on their facility's procedures and protocols and updated accordingly.

CAUTION: The correct placement and orientation of the LEAF Patient Sensor is important to ensure that the correct orientation of the patient is being reported to the LEAF Patient Monitoring Software and User Interface. Carefully read and review the instructions for sensor application contained in this document.

CAUTION: Remove sensor before chest percussion therapy. Artifacts from chest percussion therapy may result in inaccurate operation of the sensor.

CAUTION: When the LEAF Patient Monitoring System is used alongside other medical devices consult the Instructions for Use for both devices to ensure compatibility.

Electrical and RF Communications

CAUTION: The LEAF Relay Antenna should only be powered by the Power Adapter that is provided with the LEAF Relay Antenna and should not be replaced by an alternative Power Adapter or the Relay antenna may not operate correctly.

CAUTION: The Leaf Patient Monitoring System may be affected by portable and mobile RF communications.

RISKS

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

These side effects are expected to spontaneously resolve within a few minutes to hours of sensor removal without medical intervention or treatment. If side effects do not spontaneously resolve within a few hours of sensor removal, the patient's skin should be further assessed and treated accordingly.

As with other medical adhesives, skin irritation or slight skin damage, including tearing of the skin, bleeding, or bruising may be experienced when the sensor is removed. These effects may be more pronounced in patients with fragile or sensitive skin.

For patients with extremely fragile or sensitive skin, an adhesive removal product may be used to assist the caregiver in removing the LEAF Patient Sensor to reduce the risk of these possible side effects.

Other wireless communication systems may interfere with the proper functioning of the LEAF Patient Monitoring System, or conversely the LEAF Patient Monitoring System may interfere with the proper functioning of other wireless communication systems. However, various measures have been taken to mitigate the risk of interference. The LEAF Patient Monitoring System is designed such that incidental interference will not put the patient at significant risk. The system's wireless network is also set up in a manner that further minimizes any interference with IEEE 802.11 (or WiFi) networks. Installation needs to be completed by qualified personnel. 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 LEAF Patient Sensor monitors a patient's orientation and movements and communicates this data wirelessly to the LEAF Patient Monitoring Software and User Interface. From the LEAF Patient Monitoring Software and User Interface, caregivers can monitor one or more patients. Care providers can help ensure that patients are turned according to their prescribed turning schedules by setting position/orientation and time thresholds. The system shows visual alerts via the LEAF Patient Monitoring Software and User Interface and on Patient Sensor, if applicable, when these predefined thresholds are passed.

HOW TO APPLY THE LEAF PATIENT SENSOR

A. Locate an area to apply the LEAF Patient Sensor.

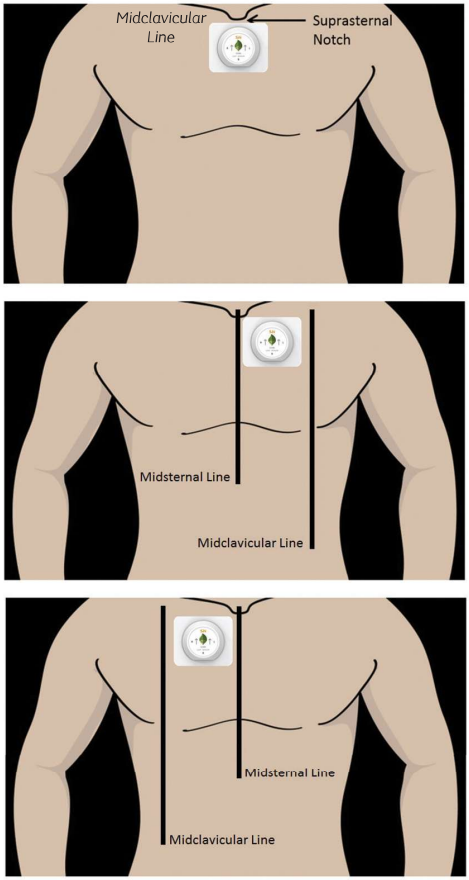

Figure 7: LEAF Patient Sensor placement location

The recommended location for placement of the LEAF Patient Sensor is on the midsternal line, just below the suprasternal notch. For patients who have a contraindication to sensor placement on the sternum (e.g. recent sternotomy), the sensor should be placed in an alternative location, as close to the midsternal line as possible, on either the right or left side, but not surpass the midclavicular line at either side. The sensor should be placed on a flat surface of healthy, intact skin.

Do not apply the sensor to broken skin.

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

If needed, clip the patient's hair in the area where you would like to apply the sensor. Hair may prevent good adhesion of the Patient Sensor and cause pain, discomfort and removal of hair upon sensor removal.

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

If needed, cleanse the application area with IPA wipes. The skin should be thoroughly dried to ensure good adhesion of the Patient Sensor.

D. Remove the LEAF Patient Sensor from the packaging.

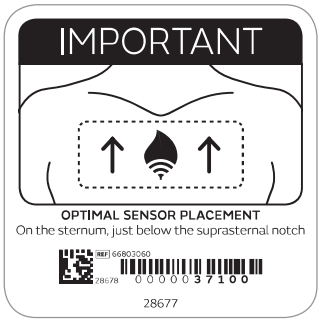

Figure 8: LEAF Patient Sensor placement label

Remove the sensor from the sensor pouch, exposing the sensor to light. Next, peel off the adhesive backing from the Patient Sensor. Exposing the sensor to light and then removing the backing will automatically turn on and activate the Patient Sensor. Ensure the sensor backing is removed in a well lit room to activate the Patient Sensor. There is no additional on/off switch on the Patient Sensor. After the LED activation sequence has occurred (see section below regarding LED activation sequence) apply the sensor to the patient. The sensor needs to be placed in the proper orientation with respect to the patient. Please refer to the How to Apply the LEAF Patient Sensor section for more information regarding proper sensor placement. After the sensor has been applied to the patient, peel off the paper frame from the dressing while smoothing down the edges.

Keep the adhesive backing that you have just removed. The adhesive backing contains the sensor's serial number, which is needed to link your patient to the specific sensor that you just applied.

Note: Once the LEAF Patient Sensor has been exposed to light and the adhesive backing has been removed, the device is activated and must be used immediately.

E. Watch for the LED activation sequence.

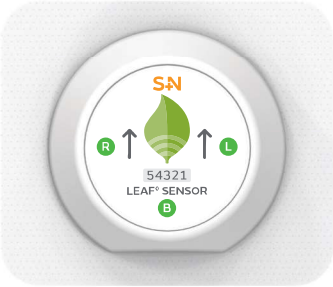

Figure 9: LEAF Patient Sensor LED locations

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

Figure 10: LEAF Patient Sensor LED scrolling pattern

Once an available LEAF wireless network is found the sensor's three LED lights will begin to blink in a scrolling pattern. This blinking light pattern indicates that the Patient Sensor has turned on and communication with the wireless network has been established. Once the blinking pattern of LEDs has been displayed, the Patient Sensor is ready to be applied to the patient.

If the activation sequence does not occur when the backing is removed, consult the troubleshooting section.

F. Apply the Patient Sensor.

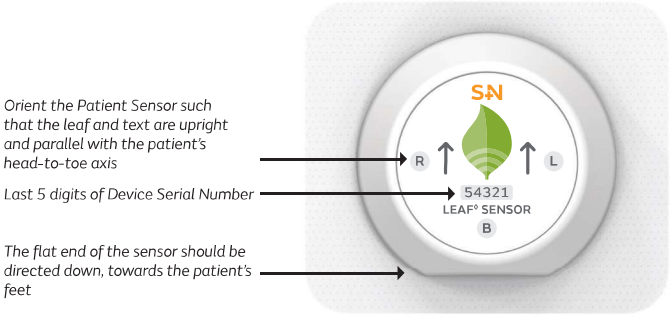

Figure 11: LEAF Patient orientation and serial number

Apply the LEAF Patient Sensor to the patient in the desired location by pressing the dressing around the sensor gently against the patient's skin with the LEAF Logo oriented towards the patient's head. The flat end of the sensor should be directed towards the patient's feet. In order to get accurate position data, it is critical that the sensor is properly oriented on the patient. Regardless of where on the body the sensor is located, the leaf logo should always be in-line with the patient's head-to-foot axis.

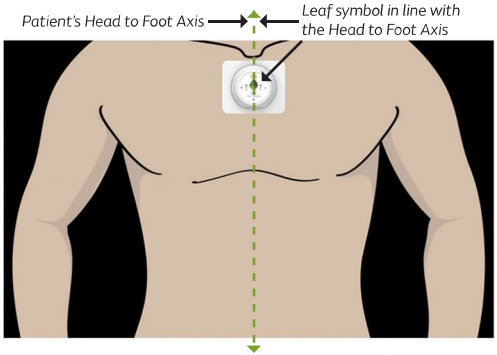

Figure 12: LEAF Patient Sensor orientation with respect to patient

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 LEAF Patient Monitoring Software and User Interface. After applying the Patient Sensor, check the patient to confirm that the patient's orientation matches the orientation reported in the LEAF Patient Monitoring Software and User Interface. If the orientations do not match, a new Patient Sensor may need to be used.

See the "How to Use the LEAF Patient Monitoring Software and User Interface" section below for setup instructions.

REMOVING AND REPLACING THE LEAF PATIENT SENSOR

A. Removing the LEAF Patient Sensor

Patient Sensors must be removed prior to MRI studies, or if electric current is going to be passed through the patient's body, such as during external cardiac defibrillation or electrocautery.

The LEAF Patient Sensor should also be removed if:

- the battery is depleted
- the adhesive is no longer firmly attached to the patient
- the patient is experiencing a skin reaction, such as an allergic reaction, rash, or any compromise to the integrity of the skin under or around the LEAF Patient Sensor.
- The patient no longer requires monitoring with the LEAF system.

To remove the LEAF Patient Sensor, slowly and gently, lift the edge of the sensor adhesive.

DO NOT forcefully rip, tear, or tug the LEAF Patient Sensor as it may cause skin injury or skin irritation.

For patients with extremely fragile or sensitive skin, an adhesive removal product may be used to assist the caregiver in removing the patient sensor to reduce the risk of these possible side effects. If the Patient Sensor will be reapplied later, keep it somewhere it will not become contaminated, lost or mixed with unused sensors.

If the sensor is no longer required, it can be deactivated, refer to the 'How to use the LEAF Patient Monitoring Software and User Interface' section.

B. Re-Applying the Patient Sensor

Patient sensors can be reused on the same patient.

If the original adhesive is no longer sticking to the patient, carefully remove the old adhesive from the sensor. Reapply the sensor to the patient by securing it with a suitable medical grade film.

The Patient Sensor should not be re-applied in the exact same location as where previously applied, as skin irritation may result. Only use suitable medical grade film to secure the sensor in place.

Follow recommendations in this Instructions For Use for proper sensor placement and orientation.

DO NOT re-use the LEAF Patient Sensor if the sensor or adhesive has become contaminated. DO NOT re-use the LEAF Patient Sensor on multiple patients. The LEAF Patient Sensor is for SINGLE patient use only.

C. Replacing the Patient Sensor

If the LEAF Patient Sensor needs to be replaced with a new sensor, remove the old sensor and follow the application instructions in the How to Apply the LEAF Patient Sensor section. The new Patient Sensor should not be applied in the exact same location as a previous Patient Sensor, as skin irritation may result.

Once a new Patient Sensor has been applied, the new sensor must be assigned to the patient as described in the How to Use the LEAF Patient Monitoring Software and User Interface Section.

D. Cleaning the Sensor

If the Sensor is visibly soiled it can be wiped clean with commonly used facility approved disinfectant wipes using the label's safety precautions and directions for use.

Do not use acetone on the Sensor or attempt to sterilize it. This may damage the Sensor and cause it to function improperly.

INTERPRETING THE LEAF PATIENT SENSOR

To check the patient's real-time turn status without using the LEAF Patient Monitoring Software home screen, gently tap the LEAF patient sensor twice. The appropriate light(s) will momentarily flash.

Figure 13: Interpreting the LEAF Patient Sensor

HOW TO USE THE LEAF PATIENT MONITORING SOFTWARE AND USER INTERFACE

A. Log in to the LEAF Patient Monitoring System's User Interface

After the initial installation, a connection to the database may need to be established when starting the LEAF Patient Monitoring Software and User Interface for the first time. After starting the LEAF Patient Monitoring Software and User Interface, if the Database Log In pop-up window is displayed enter the username and password provided during installation or training.

When starting the LEAF Patient Monitoring Software and User Interface, the program will automatically log in as the current computer user. Some users will be provided with administrative privileges that allow them to change certain settings within the LEAF Patient Monitoring Software and User Interface. The LEAF Patient Monitoring Software and User Interface application may start automatically after the computer is powered on. If the application does not automatically start, click on the LEAF application icon. Once started, the application's splash screen will appear and the program will launch

Figure 14: LEAF User Interface Splash Screen

B. 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 and displayed on Startup)

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

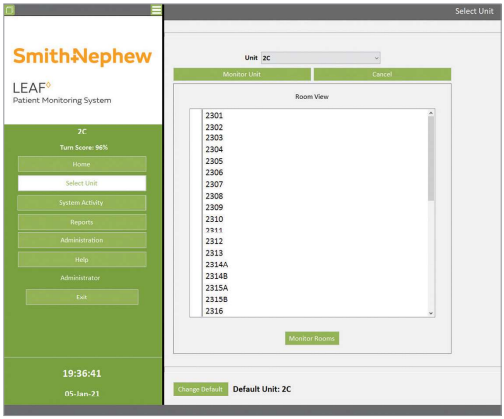

Figure 15: Select Unit Screen

To change the default unit associated with the current user, click on the “Change Default” button located in the lower left-hand corner, then select the desired unit from the pull-down menu that displays in the pop-up window.

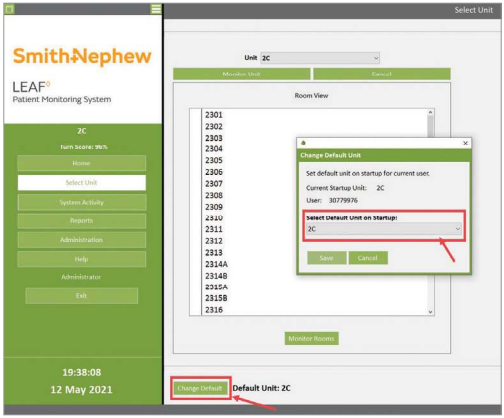

Figure 16: Change Default Unit Screen

C. Home Screen

The Home Screen will be displayed after a unit has been selected. To access the Home Screen at any time, click on the “Home” button on the left panel of the screen. From the Home Screen you will see a list of beds and active sensors, which are all sorted by room/bed number. The list of beds may span one or both columns of the Home Screen, depending on how many beds are present on the unit. In the example provided in Figure 17, eight patients are monitored and the list of beds spans two columns (e.g., rooms 2301-2335B in Figure 17). The list of beds for each unit at your facility will be configured at the time of installation.

If HL7 Admin Discharge Transfer (ADT) interface has been enabled, patients assigned to “Exceptions” rooms will be displayed in the lower left corner of the Home Screen.

A list of Unassigned Sensors will be displayed in the lower right corner of the Home Screen. Unassigned Sensors are sensors that may have been activated in the current unit being monitored or in other locations in the facility. Unassigned Sensors have not been associated with a specific patient and can be assigned to a patient.

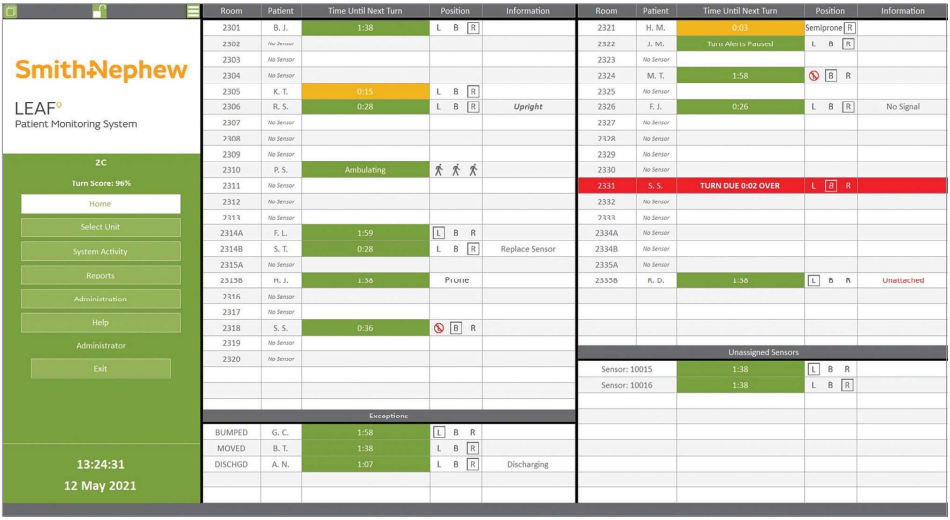

Figure 17: Home Screen

D. Assigning a Patient Sensor to a Patient

Look at the Unassigned Sensor List in the lower right corner of the Home Screen. The Unassigned Sensor List shows sensors that have been activated, but have not been assigned to a specific patient.

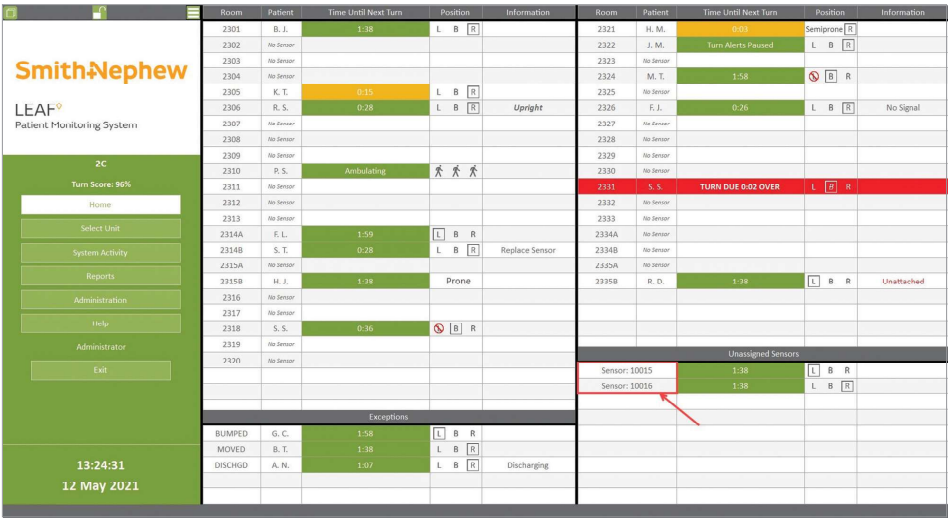

Figure 18: Home Screen – Unassigned Sensor List

Identify the Patient Sensor that you wish to assign by finding the correct sensor serial number. (Note: only the last 5 digits of the serial number are displayed in the Unassigned Sensor list). Click on the desired Unassigned Sensor to open the Unassigned Sensor pop-up window.

Once the pop-up window opens, double check that it is the correct sensor for your patient and then enter the patient's information, including at least the room number, the patient's first and last name, and their medical record number (MRN). To save the information you have entered, click the "Save" button. Clicking the "Cancel" button will discard any changes entered.

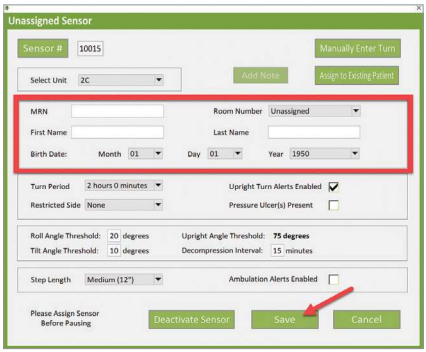

Figure 19: Unassigned Sensor Pop-Up Window

If the HL7/ADT interface has been enabled, select the patient from the drop-down menu. Once the patient has been selected, click the *Save* button. The HL7/ADT interface provides the LEAF Patient Monitoring System with patient names, room-numbers, and other information. Some institutions may not have provided an HL7/ADT interface to the LEAF Patient Monitoring System, so patient information and room assignments need to be entered manually.

Figure 20: Unassigned Sensor Pop-Up Window if HL7/ADT interface is activated

E. Adding a Restricted Side

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

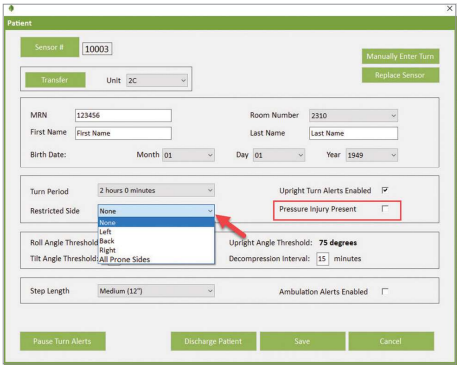

Figure 21: Restricted Side Drop-Down Menu

Patients may have a restricted side for a variety of reasons, such as if they have existing wounds (e.g. pressure injuries) or have sustained prolonged pressure on a given side (e.g. post-surgery). If a pressure ulcer is present, you can also check the “Pressure Injury Present” checkbox.

The restricted side will be designated in the Home screen in the “Position” column with a “restriction symbol”, which appears as a red circle with a diagonal line through it. If the patient turns onto a restricted side, the

user interface will indicate that a turn is due and show that the patient is positioned on a Restricted Side in the “Position” column.

Figure 22: Home Screen - Turn Alerts and Restricted Sides

F. Monitoring Patient Movement

The LEAF Patient Monitoring Software and User Interface is used to monitor and report patient orientation and activity. The Home Screen displays patient position. The patient’s current position is displayed in the Position column and is indicated as either L, B, or R (Left, Back, or Right), Prone, L Semiprone, Semiprone R. If the patient is upright , then the message “Upright” will appear in the Information column. Patients who exceed facility-set thresholds for inactivity or orientation (See “Section O: Administrative Settings”) are issued alerts (indicated by red highlighting). The countdown timer for a turn alert is displayed in the Time Until Next Turn column. The highlighting changes color based on how much time remains until a turn alert is issued. Green indicates that a turn alert is greater than 15 minutes away. Yellow indicates that a turn is less than 15 minutes away. Red indicates that a turn is past due.

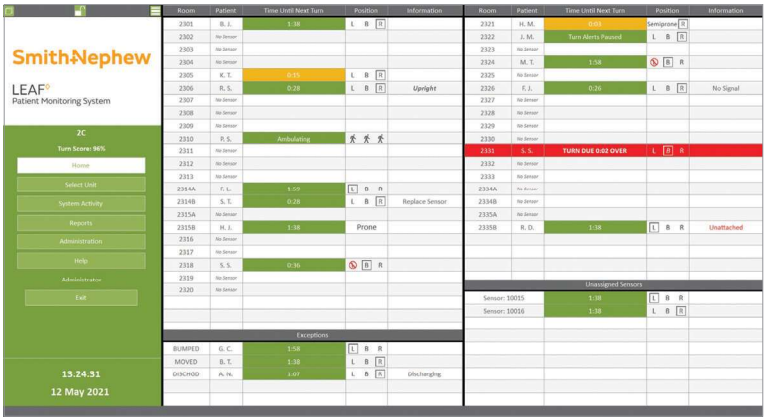

Figure 23: Home Screen – Monitoring Turn Alerts

The Position column displays the last reported orientation of the monitored patient. Please note that it may take up to a minute or longer for patient orientation information to update in the LEAF Patient Monitoring Software and User Interface after a patient turn. An alert will be displayed on the LEAF Patient Monitoring Software and User Interface if a significant period of time has elapsed without receiving a position update from a Patient Sensor.

G. Viewing or Updating Patient Information

Locate the patient on the Home Screen. Click on the patient details to open the Patient pop-up window. Once the pop-up window has opened, you can view, edit and save patient information. To save the information you have entered, click the “Save” button. Clicking the “Cancel” button will discard any changes entered.

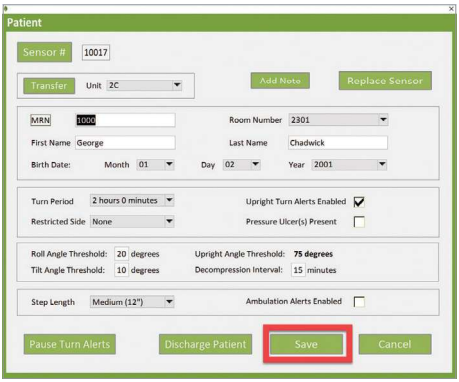

Figure 24: Patient Pop-Up Window

H. Unassign a LEAF Patient Sensor

If a sensor has been assigned to the wrong patient, it can be unassigned by clicking on the “Sensor #” button in the Patient Pop-Up Window, and then clicking on the “Manage Sensor” button.

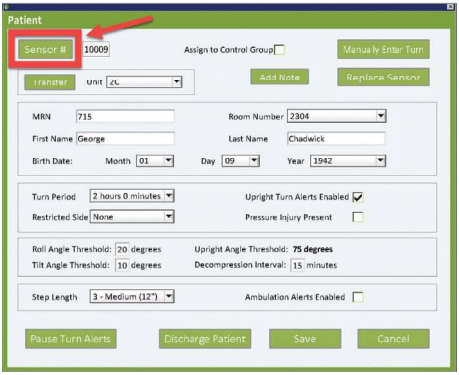

Figure 25: Sensor button on Patient Pop-Up Window

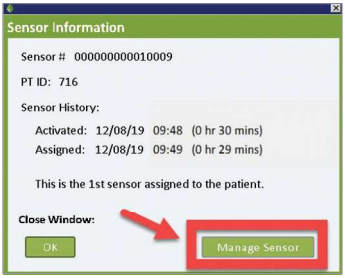

Figure 26: Sensor Information Pop-Up Window

Select "Unassign Sensor from Patient" from the Manage Sensor Drop-Down Menu, then click on the Confirm button.

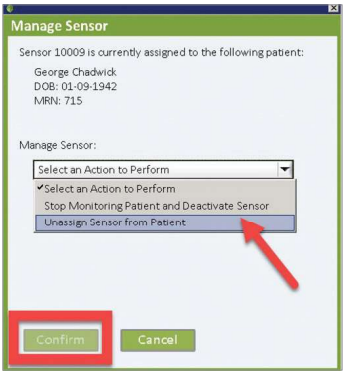

Figure 27: Sensor Information Pop-Up Window

I. Deactivating the LEAF Patient Sensor

To discontinue tracking and reporting of patient movement after the sensor has been removed, click on the patient's row in the Home Screen to access the Patient pop-up window. If the patient is ready to be discharged and/or you no longer wish to monitor the patient's movement, click on the "Discharge Patient" button to discontinue monitoring of the patient in the LEAF Patient Monitoring System.

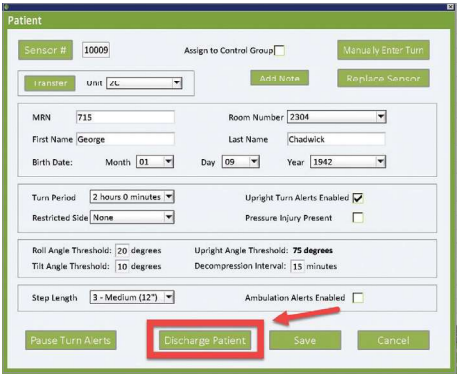

Figure 28: Sensor Information Pop-Up Window

When the Discharge Patient Pop-Up Window opens, review the information displayed and confirm that this is the correct sensor to deactivate. If correct, select "Stop Monitoring Patient and Deactivate Sensor" from the drop-down menus. Click on the "Confirm" button to deactivate the sensor.

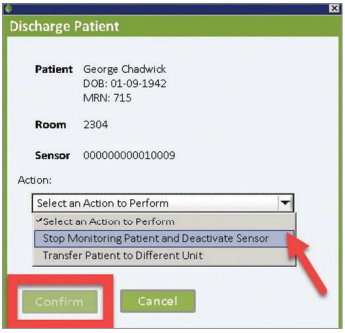

Figure 29: Discharge Patient Pop-Up Window

Note: Once a sensor has been deactivated, there is no way to reactivate it. If a sensor has been deactivated in error, then a new sensor will need to be applied and assigned to the patient.

J. Transferring the Patient to Different Hospital Unit or Ward

To transfer a patient to different unit or ward within the same hospital, click on the patient's row in the Home Screen to access the Patient pop-up window. If the patient is ready to be transferred, click on the "Transfer" button.

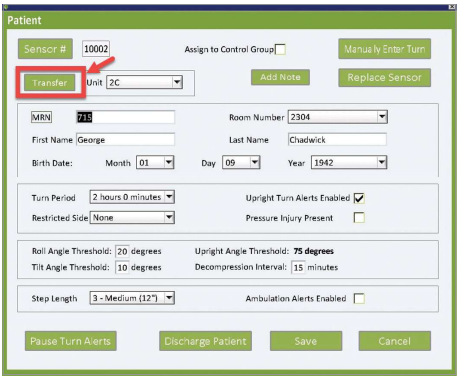

Figure 30: Sensor Information Pop-Up Window

When the Transfer Patient Pop-Up Window opens, review the information displayed and select the patient's new Unit and Room Number from the drop-down menus. Click on the "Transfer" button to transfer the patient.

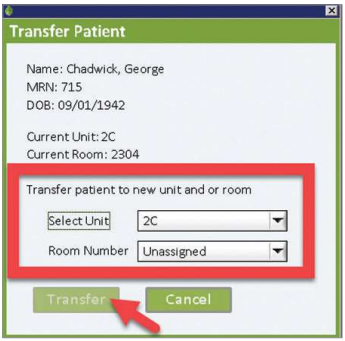

Figure 31: Transfer Patient Pop-Up Window

Note: A patient can also be transferred from the Discharge menu, by selecting "Transfer Patient to Different Unit" from the Discharge Patient drop-down menu.

K. Assigning a new LEAF Patient Sensor to an existing patient

To assign a new sensor to an existing patient that is currently being monitored, you can either click on an Unassigned Sensor (in the lower right hand corner of the Home Screen) to open the pop-up window or open the Patient pop-up window and select “Replace Sensor”. This will allow you to assign the sensor to an existing monitored patient. The existing 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. After you assign the new Patient Sensor, the original Patient Sensor automatically deactivates and you can then remove the original sensor from the patient.

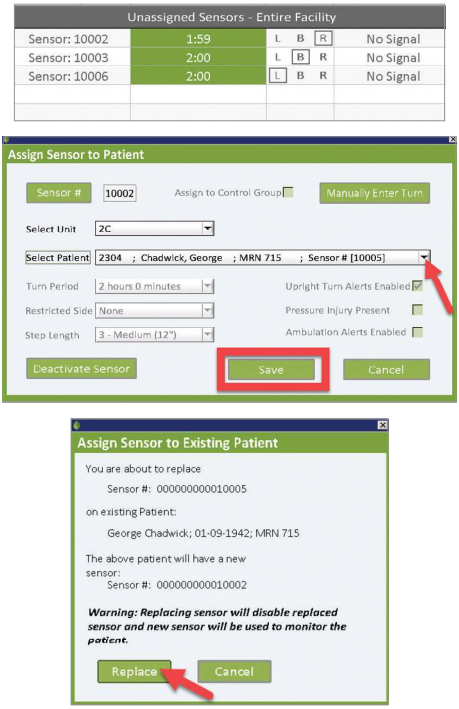

Figure 32: Unassigned Sensor Display from Home Menu (top), Assign Sensor Pop-Up Window (middle) and Assign Sensor to Existing Patient Pop-Up Window (bottom)

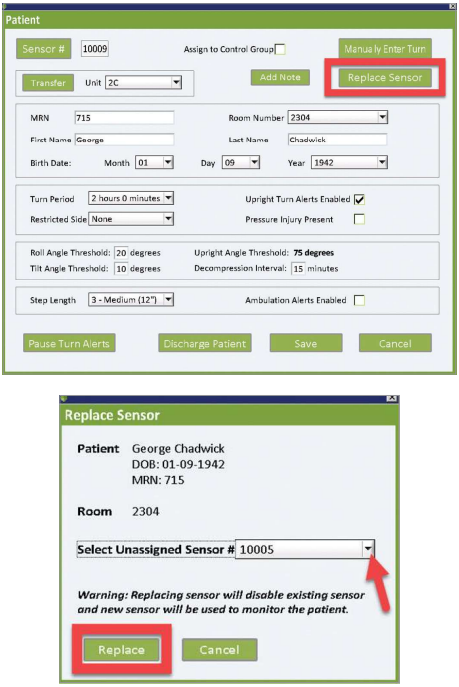

Figure 33: Patient Pop-up Window (top) and Replace Sensor Pop-Up Window (bottom)

L. Pause Turn Alerts

There are circumstances when required turns cannot be performed (e.g. clinical circumstances, patient refusal, patient off unit, procedure in progress, etc.). If a required turn cannot be performed, you may pause the turn alerts and note the reason for the pause.

To pause turn alerts, select the patient by clicking on the appropriate row. The Patient pop-up window will open. Click on the Pause Turn Alerts Button in the lower left-hand corner of the Patient pop-up window. The Pause Turn Alerts pop-up window will open. Select the desired time interval for the pause and document the reason for the pause. Click the OK Button to initiate and document the pause. Once a pause has been initiated it will naturally expire after the selected time interval has elapsed. If the pause is no longer warranted, the pause may be terminated by opening the Pause Turn Alerts pop-up window while a pause is active, selecting the Resume Turn Alerts option and clicking the OK Button.

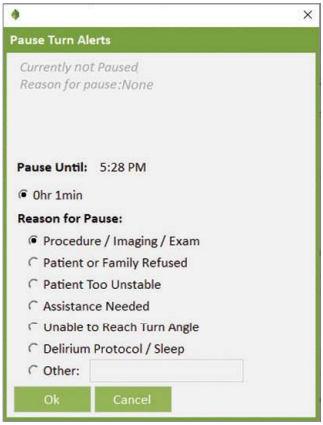

Figure 34: Pause Turn Alerts Pop-Up Window

M. Enter Manual Turns

During No Signal alert conditions, the Manually Enter Turn Button will become visible and allow you to record a patient turn by manually entering the patient's orientation. To manually enter a patient turn, select the patient or unassigned sensor by clicking on the appropriate row on the Home Screen. The corresponding pop-up window will open. Click on the *Manually Enter Turn Button* in the upper right-hand corner of the pop-up window. The Manually Enter Turn pop-up window will open. Select the side the patient was turned to and click the OK Button.

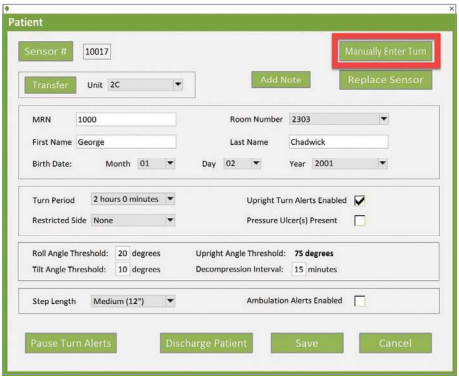

Figure 35: Manually Enter Turn Button

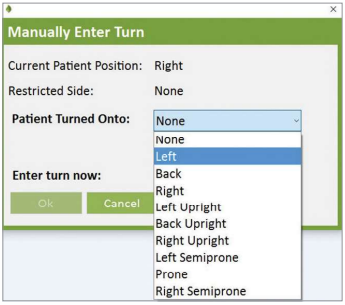

Figure 36: Manually Enter Turn Pop-Up Window

N. Ensuring Proper Sensor Attachment

The LEAF Patient Sensor continuously checks if the sensor is attached to a patient.

If the system detects that the LEAF Patient Sensor has become unattached from the patient, an Unattached warning will appear on the Home Screen.

This warning will remain until the sensor is properly reattached to the patient. Once the sensor is reattached to the patient the Unattached warning will disappear from the Home Screen.

Figure 37: "Unattached" message after sensor has been removed or has come loose.

O. Viewing Patient History

A patient's most recent turn history, upright history, ambulation history, pause history, sensor assignment history, room history and full detailed report can be viewed on the home screen by right-clicking on the patient's line.

Figure 38: Patient history options menu accessed on home screen accessed via right-click.

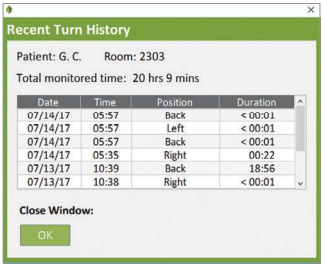

Figure 39: Recent Turn History Pop-Up Window