Leaf Healthcare, Inc.

Leaf Patient Monitoring System

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 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 Leaf Healthcare.

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

CONTENTS

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 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.

The Leaf Patient Monitoring System allows caregivers to continuously monitor patient position and identify patients that are in need of caregiver-assisted turns, as per the institution's turning guidelines or protocols. The use of the Leaf Patient Monitoring System can increase compliance with the care facility's prescribed patient turning protocols in an effort to prevent pressure ulcers.

The Leaf Patient Monitoring System is comprised of Patient Sensors, Leaf Antennas, USB RF Transceivers, Turn Management Software, a User Interface that can be viewed on a monitoring station, and a Reporting Tool.

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 Antennas) to a monitoring station running the Leaf User Interface. Through the Leaf 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 with point-of-care (POC) features, may also be directly interrogated by caregivers to see the status of the patients' positions. Multiple Leaf 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 Antennas
- USB RF Transceiver(s)
- Leaf Turn Management Software
- Leaf 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 or mobile device.
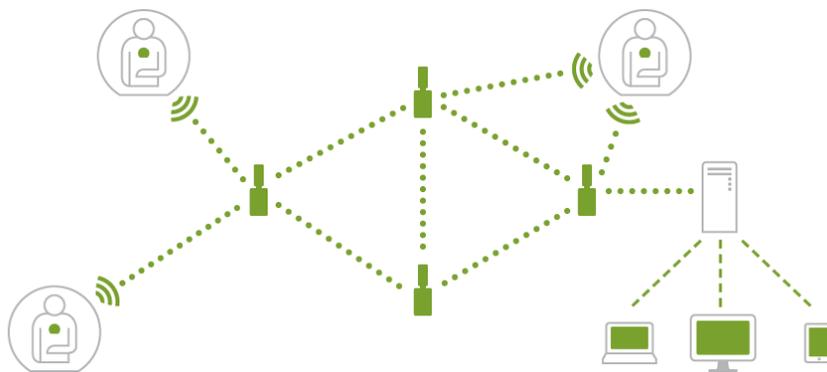

Figure 1: High-Level Schematic Representation of the System's Communication Flow

Leaf Patient Sensor (packaging)
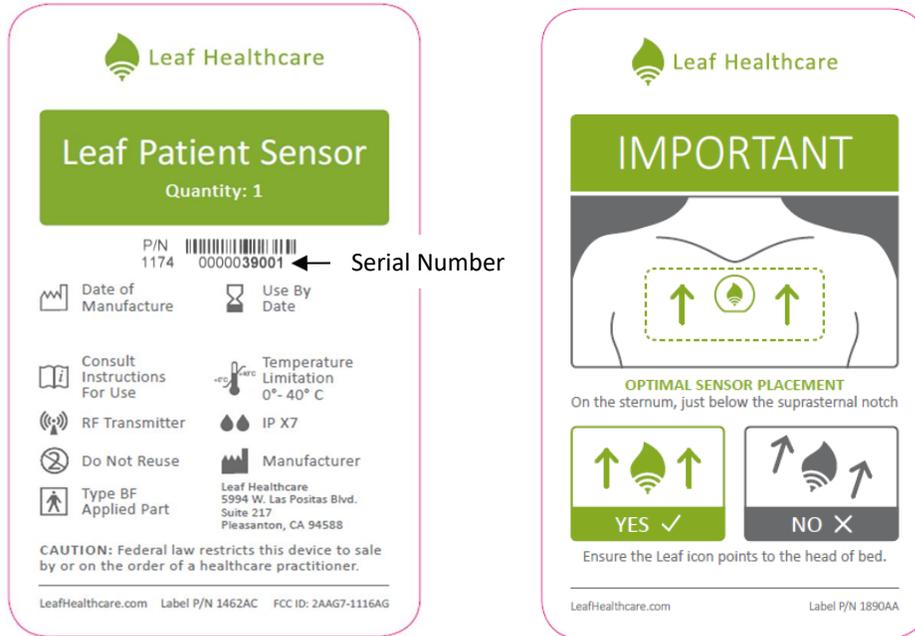
Figure 2: Packaging Sleeve Labels for Individual Patient Sensor

Leaf Patient Sensor

Figure 3: Leaf Patient Sensor

Figure 4: Leaf Point-of-Care Patient Sensor

Leaf Antenna and USB RF Transceiver

Figure 5: Leaf Antenna (Left) and USB RF Transceiver (Right)

Leaf User Interface

Figure 6: Leaf User Interface

INDICATIONS FOR USE

The Leaf Patient Monitoring System monitors the orientation and activity of patients susceptible to pressure ulcers. 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

General

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 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 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 adhesive, do NOT re-apply another sensor. Notify the patient's doctor or other appropriate member of the patient's care team.

WARNING: Do **NOT** re-use the Leaf Patient Sensor on multiple patients. The Leaf Patient Sensor is for SINGLE patient use. Infection or cross-contamination may occur if the Leaf Patient Sensor is re-used on multiple patients. If the Leaf Patient Sensor is re-applied, its adhesion performance may deteriorate and it may not function properly. Cover Patient Sensor with a new film dressing when re-applying sensor to the same patient to ensure good adherence.

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.

WARNING: Do **NOT** use a Leaf Patient Sensor if its packaging is damaged because the device may not function properly.

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.

Pacemakers and Implantable Cardioverter-Defibrillators

WARNING: The Leaf Patient Sensor must not be placed closer than 10 cm to a pacemaker or Implantable Cardioverter-Defibrillator (ICD) or other wearable cardioverter-defibrillator devices. If a patient has a pacemaker, an external

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defibrillator or ICD, the Leaf Patient Sensor should be placed on the contralateral side of the body. If it is not possible to place the sensor greater than 10 cm from the device, the Leaf Patient Sensor should not be applied. If a pacemaker, ICD or external defibrillator needs to undergo reprogramming, the Leaf Patient Sensor should be removed to eliminate any chance of interference during programming. Failure to follow these instructions could result in electromagnetic interference and lead to patient death.

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: The Leaf Patient Sensor must be removed 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.

Installation

WARNING: The Leaf Patient Monitoring System needs to be installed and put into service by trained personnel in order to ensure that it functions properly.

WARNING: Do not modify the Leaf Patient Monitoring System (or any of 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. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

PRECAUTIONS

General

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 (persons 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.

CAUTION: Any initial settings present in the Leaf 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 User Interface. Carefully read and review the instructions for sensor application contained in this document.

CAUTION : Do **NOT** use a Leaf Patient Sensor past the "Use By Date" listed on its packaging or the sensor may not operate properly or adhere to the patient.

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

Electrical and RF Communications

CAUTION: The Leaf Patient Monitoring System complies with Part 15 of FCC Rules and Regulations. 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.

CAUTION: This device complies with the FCC's 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.

CAUTION: The Leaf Antenna should only be powered by the Power Adapter that is provided with the Leaf Antenna and should not be replaced by an alternative Power Adapter or the 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 thin, delicate, or sensitive skin.

For patients with extremely thin, delicate 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 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 User Interface. From the Leaf 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 User Interface and on Point-of-Care 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.
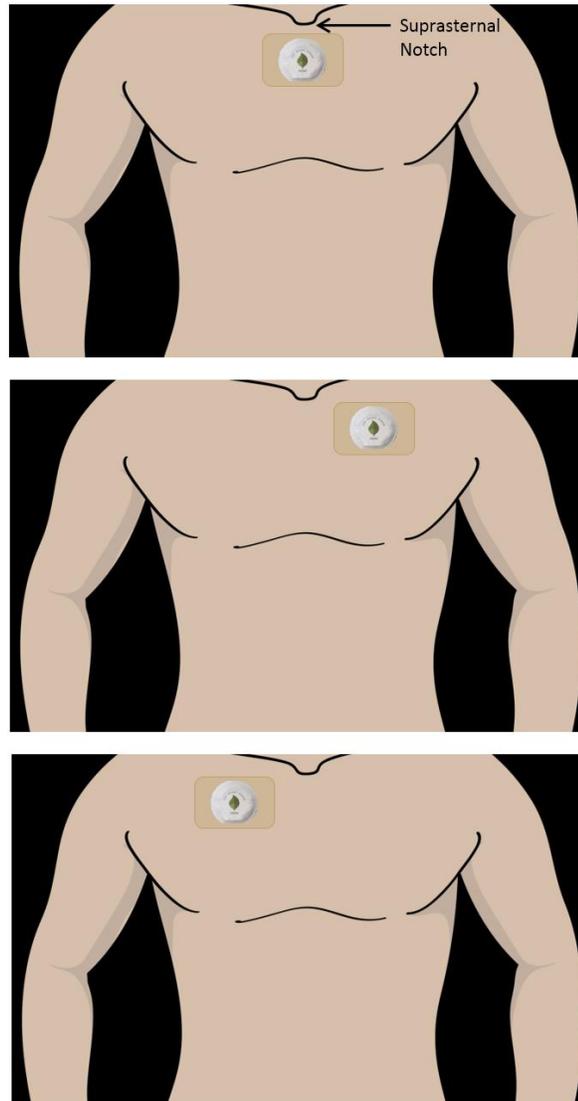
Figure 7: Leaf Patient Sensor placement location

The recommended location for placement of the Leaf Patient Sensor is on the sternum, 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, either the right or left side, at approximately the midclavicular line. The sensor should be placed on a flat surface.

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 discomfort upon 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 and thoroughly dry the skin in the area where you wish to apply the Patient Sensor. The skin should be clean and dry to ensure good adhesion of the Patient Sensor.

D. **Remove the Leaf Patient Sensor from the packaging.**

Figure 8: Leaf Patient Point-of-Care Sensor placement label

Peel off the opaque adhesive backing from the Patient Sensor. Removing the opaque backing exposes a light sensor, which *automatically* turns on and activates 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 section below (Applying Leaf Patient Sensor) 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 a Leaf Patient Sensor has been removed from the packaging, it must be used immediately. Once the packaging has been opened and the Leaf Patient Sensor has been exposed to light, the device is activated and the battery has been started.

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 within range of the Patient Sensor, you will see the sensor's three LED lights begin to blink in a scrolling pattern. This blinking light pattern indicates that the Patient Sensor has been 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.

F. Apply the Patient Sensor.

Orient the Patient Sensor such that the Leaf logo or Arrows are upright and directed towards the head of bed aligned with the patient's head-to-toe axis.

Last 5 Digits of Device Serial Number

The flat end of the sensor should be directed down, towards the patient's feet
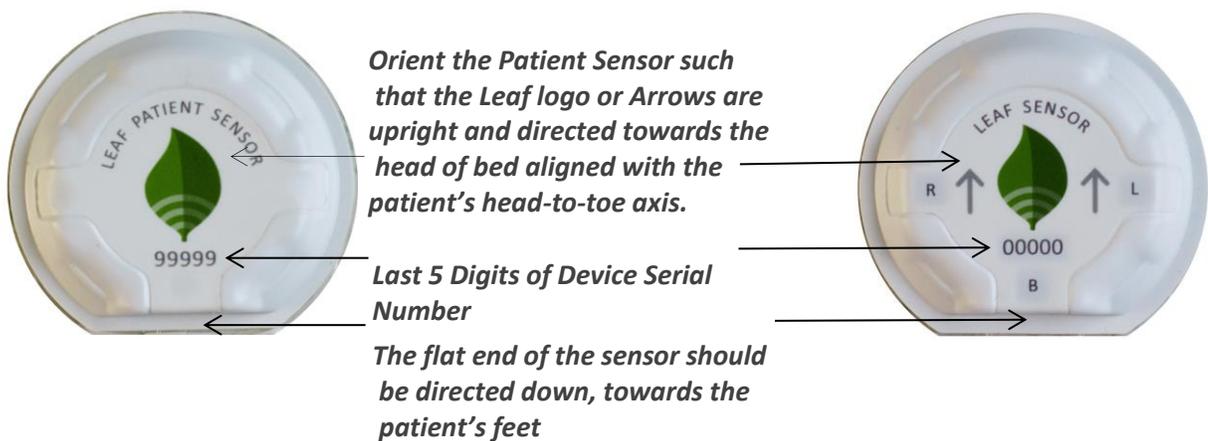
Figure 11: Leaf Patient Sensor orientation and serial number

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.
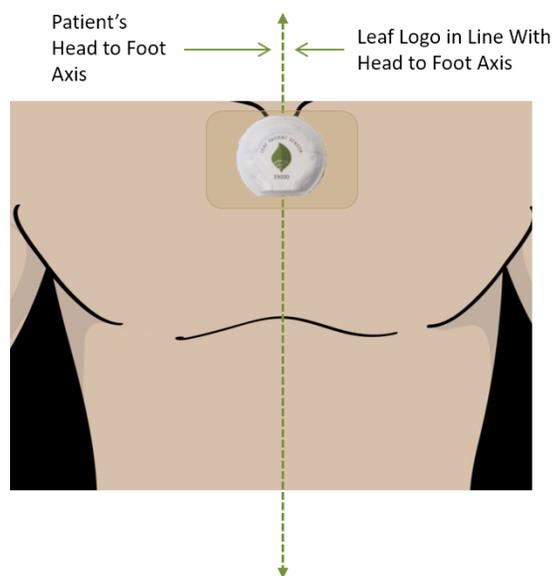
Figure 12: Leaf Patient Sensor orientation with respect to patient

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 User Interface.

See the "How to Use the Leaf User Interface" section below for setup instructions.

REMOVING AND REPLACING THE LEAF PATIENT SENSOR

A. Removing the Leaf Patient Sensor

Patient Sensors should 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 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 or around the Leaf Patient Sensor.

To remove the Leaf Patient Sensor, lift gently and slowly, but with continuous force, on the edge of the sensor adhesive. Forcefully ripping, tearing, or tugging the Leaf Patient Sensor may cause skin injury or skin irritation.

For patients with extremely thin, delicate, 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.
To deactivate the sensor, refer to the Leaf User Interface section below.

B. Replacing the Patient Sensor

If the Leaf Patient Sensor needs to be replaced, repeat the previous instructions to apply a new Leaf Patient Sensor in a new location. A 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 Leaf User Interface section below.

C. Re-Applying the Patient Sensor

The Sensor can be reused **on the same patient** as long as it is adhered to the patient with additional film dressing.

First, carefully remove the old adhesive material around the sensor without removing the polyurethane material underneath the sensor.

Then reapply the Sensor by covering it with additional film dressing.

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

Do **NOT** re-use the Leaf Patient Sensor on multiple patients. The Leaf Patient Sensor is for SINGLE patient use.

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.

HOW TO USE THE LEAF USER INTERFACE

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

To log in to the Leaf User Interface software, enter the username and password that was provided to you during installation or training. Some users will be provided with administrative privileges that allow them to change certain settings within the Leaf User Interface. Once you have successfully entered your username/password, the Leaf User Interface application should start automatically. If the application does not automatically start, click on the Leaf application icon. Once logged in, the application's splash screen will appear and the program will launch.

Figure 43: 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.
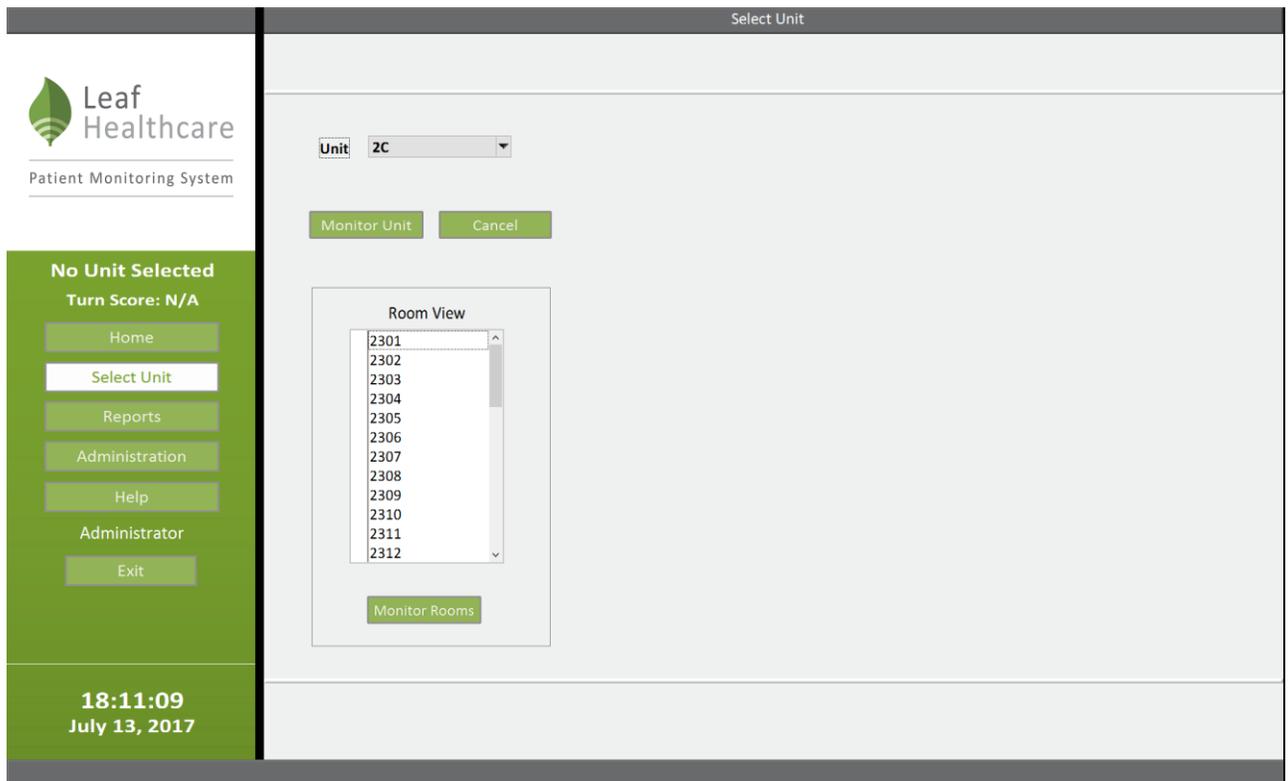
Figure 14: Select Unit Screen

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 15, eight patients are

monitored and the list of beds spans two columns (e.g., rooms 2301-TEMP 2 in Figure 15). The list of beds for each unit at your facility will be configured at the time of installation.

If HL7/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 have been activated anywhere in the facility but have not yet been associated with a specific patient.

Room	Patient	Time Until Next Turn	Position	Information	Room	Patient	Time Until Next Turn	Position	Information
2301	B. J.	1:38	L B R		2321	No Sensor			
2302	No Sensor				2322	No Sensor			
2303	No Sensor				2323	No Sensor			
2304	No Sensor				2324	M. T.	1:58	⊘ B R	
2305	K. T.	0:15	L B R		2325	No Sensor			
2306	R. S.	0:28	L B R		2326	F. J.	0:26	L B R	
2307	No Sensor				2327	No Sensor			
2308	No Sensor				2328	No Sensor			
2309	No Sensor				2329	No Sensor			
2310	P. S.	Ambulating	🚶 🚶 🚶		2330	No Sensor			
2311	No Sensor				2331	No Sensor			
2312	No Sensor				2332	No Sensor			
2313	No Sensor				2333	No Sensor			
2314A	No Sensor				2334A	No Sensor			
2314B	No Sensor				2334B	No Sensor			
2315A	No Sensor				2335A	No Sensor			
2315B	No Sensor				2335B	No Sensor			
2316	No Sensor								
2317	No Sensor				TEMP 2	R. D.	1:38	L B R	
2318	S. S.	0:36	⊘ B R						
2319	No Sensor								
2320	No Sensor								
		Exceptions					**Unassigned Sensors - Entire Facility**		
BUMPED	G. C.	1:58	L B R		Sensor: 10015		1:38	L B R	
MOVED	B. T.	1:38	L B R		Sensor: 10016		1:38	L B R	
DISCHGD	A. N.	1:07	L B R						

Sidebar: Leaf Healthcare Patient Monitoring System

2C
Turn Score: 96%
Home
Select Unit
Reports
Administration
Help
Administrator
Exit
18:08:08
July 13, 2017

Figure 15: 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 yet been assigned to a specific patient.

Figure 16: 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 5: Unassigned Sensor Pop-Up Window

Figure 18: Unassigned Sensor Pop-Up Window if HL7/ADT interface is activated

If the HL7/ADT interface has been enabled, select the patient from a drop-down menu. 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.

E. Monitoring Patient Movement

The Leaf User Interface is used to track 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). If the patient is upright or prone, then the message "Upright" or "Prone" will appear in the Information Column. Patients who exceed facility-set thresholds for inactivity or orientation (See "Section O: Administrative Settings" in this document) 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 19: Home Screen – Monitoring Turn Alerts

The Position Column displays the last reported orientation of the monitored patient. The sensor needs to be correctly applied to the patient in order for the correct orientation to be reported. After applying the Patient Sensor, check the patient to confirm that the patient's orientation matches the orientation reported in the Leaf User Interface. If the orientations do not match, a new Patient Sensor may need to be used. Please note that it may take up to a minute or longer for patient orientation information to update in the Leaf User Interface after a patient turn. An alert will be displayed on the Leaf User Interface if a significant period of time has elapsed without receiving a position update from a Patient Sensor.

F. Viewing or Updating Patient Information

For a sensor that has already been assigned to a patient, look on the Home Screen to identify the patient whose information you wish to view or update. Click on the patient 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 20: Patient Pop-Up Window

G. Unassign a Leaf Patient Sensor

For a sensor that has been assigned to the wrong patient, it can be unassigned by clicking on the "Sensor #" button in the Patient Pop-up Window, and selecting the "Unassign Sensor" button. A confirmation is required to complete the Unassign step by clicking the "Unassign" button.
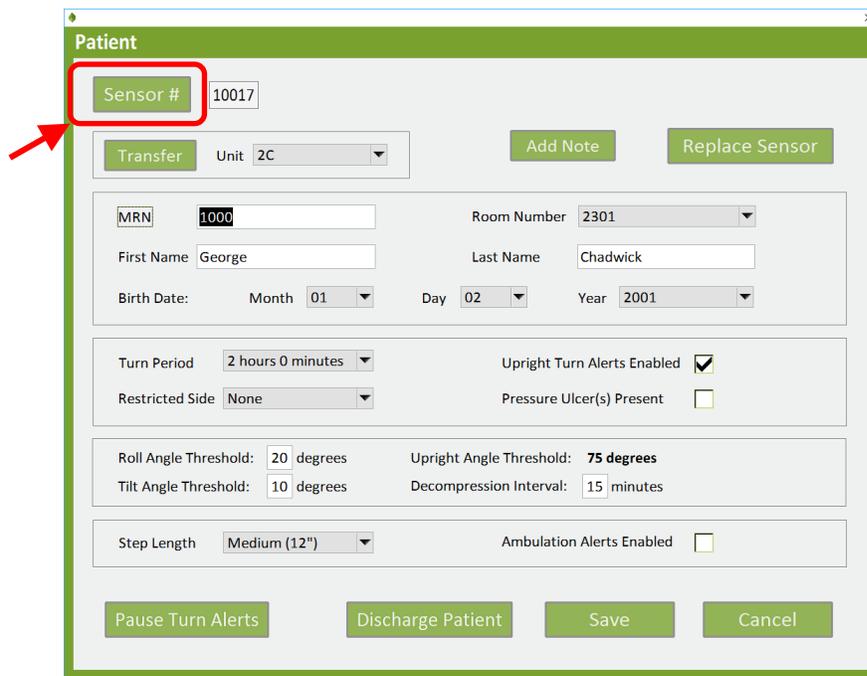
Figure 21: Sensor button on Patient Pop-Up Window
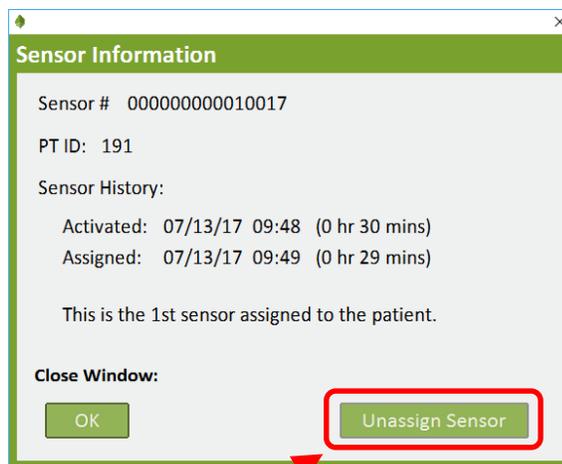
Figure 22: Sensor Information Pop-Up Window

H. 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 a patient's movement, click on the "Discharge Patient" button to discontinue monitoring of the patient in the Leaf Patient Monitoring System.

Figure 23: Patient 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, click on the "OK" button to confirm deactivation.
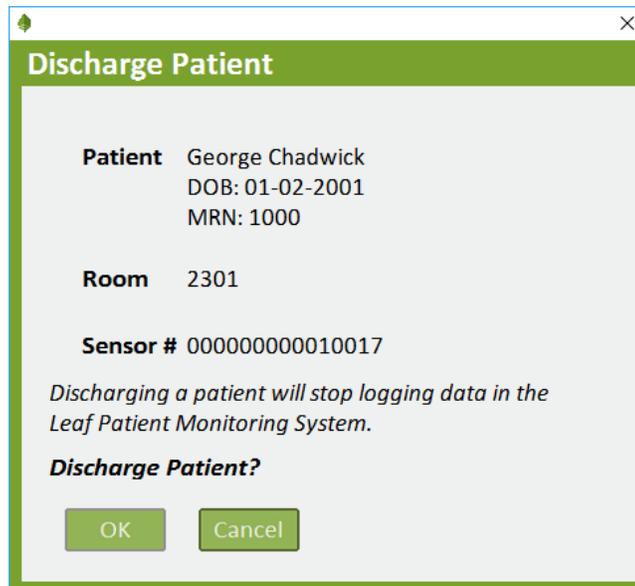
Figure 24: Discharge Patient Pop-Up Window

I. Replacing the Leaf Patient Sensor

To replace a sensor on an existing patient that is currently being monitored, you can either click the Assign to Existing Patient Button in the Unassigned Sensor pop-up window or the Replace Sensor Button on the Patient pop-up window. 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 25: Unassigned Sensor Pop-Up Window (top) and Assign Sensor to Existing Patient Popup-Up Window (bottom)

Figure 26: Patient Pop-up Window (top) and Replace Sensor Pop-Up Window (bottom)

J. 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.
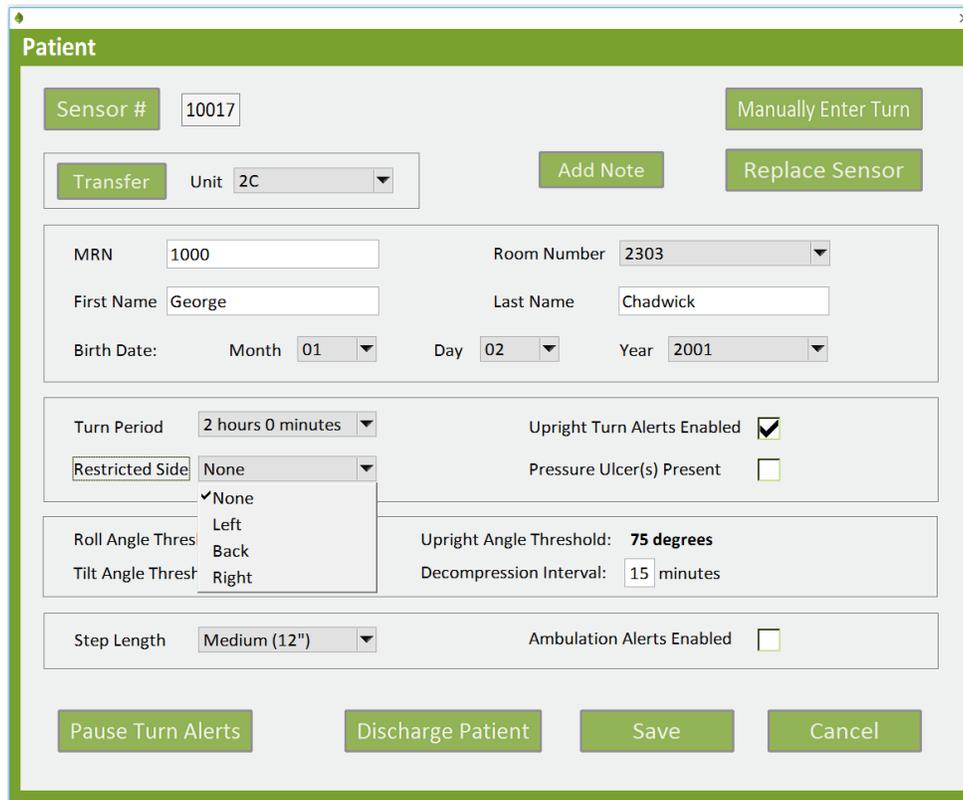
Figure 27: Restricted Side Pull-Down Menu

Patients may have a restricted side for a variety of reasons, such as if they have existing wounds (e.g. pressure ulcers) 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 Ulcer(s) 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.

Room	Patient	Time Until Next Turn	Position	Information
2301	B. S.	1:57	L B R	
2302	*No Sensor*			
2303	G. C.	1:57	🚫 B R	
2304	*No Sensor*			
2305	K. T.	**TURN DUE 0:03 OVER**	L 🚫 R	

Figure 28: Home Screen - Turn Alerts and Restricted Sides

K. 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 29: Pause Turn Alerts Pop-Up Window

L. 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 30: Manually Enter Turn Button

Figure 31: Manually Enter Turn Pop-Up Window

M. 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.

Room	Patient	Time Until Next Turn	Position	Information
2321	No Sensor			
2322	No Sensor			
2323	No Sensor			
2324	M. T.	1:34	🚫 B R	
2325	No Sensor			
2326	F. J.	0:23	L B R	Unattached

Figure 32: "Unattached" message after sensor has been removed or has come loose.

N. Viewing Patient History

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.
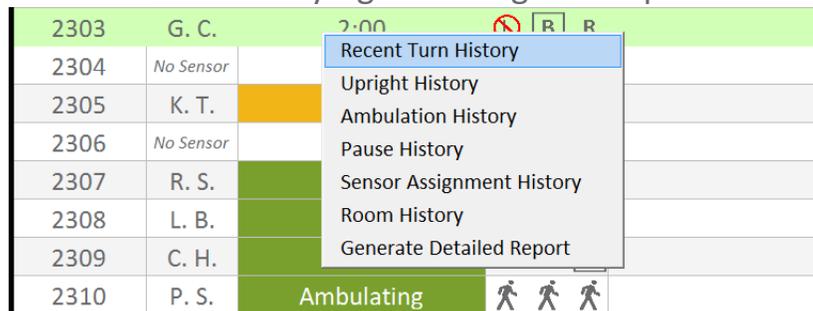
Figure 33: Patient history options menu accessed on home screen accessed via right-click
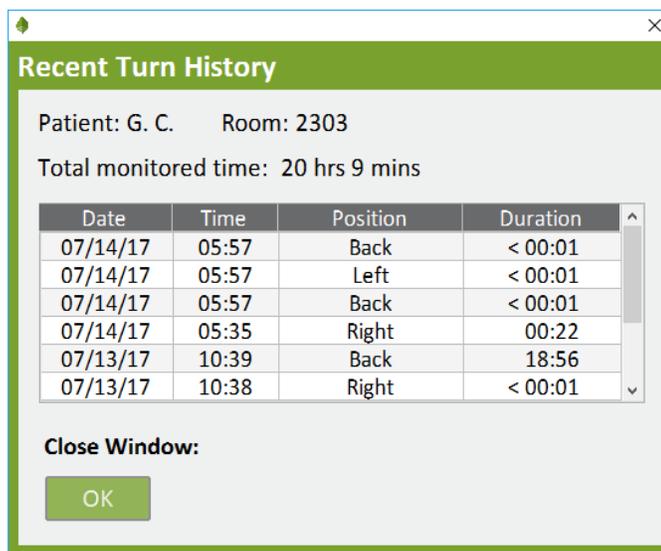
Figure 34: Recent Turn History Pop-Up Window

The Recent Turn History Pop-Up Window will display up to 20 of the most recent turns for the patient. Upright History Pop-Up Window will display daily summary of number of events and duration the patient was Upright, and the daily summary can be expanded to show every event. Ambulation History Pop-Up Window will display daily summary of number of events, steps, calculated distance, and duration the patient was Ambulating, and the daily

summary can be expanded to show every event. Pause History Pop-Up Window will display dates, times and duration of all pauses used on the patient. Sensor Assignment History will display all sensor serial numbers and dates and time of sensor application. Room History Pop-Up Window will display rooms the patient has been in and the date and time the patient was moved in the Leaf system. Generate Detailed Report Pop-Up Window will generate and display a full detailed PDF report of the patient.

O. Administrative Settings

If you are logged into the system as an Administrator, you can access the Administrative Settings Screen by clicking the Administration Button located on the left side panel.
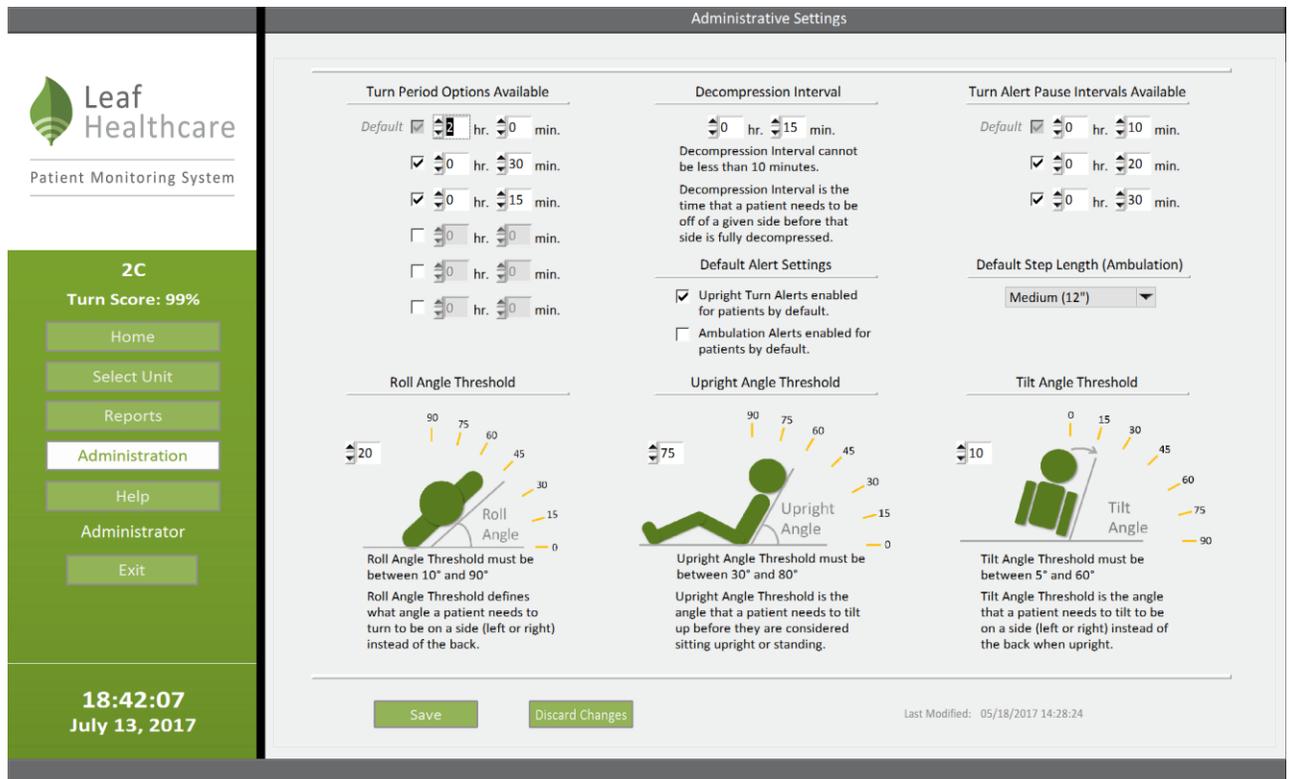
Figure 35: Administrative Settings Screen

On the Administrative Settings Screen you can set the following:

Available Turn Period(s) – The Turn Period defines the amount of time that a patient can be on a given side before a turn is due. As an administrator, you may define up to six possible turn periods, depending on your institution's turning protocol. General users of the system can select from any available turn period options that you have pre-defined (e.g. 1hr, 2hr, 4hr, etc.).

In addition, patients may be assigned "No Turn Protocol". Setting "No Turn Protocol" as a patient's Turn Period will prevent Turn Alerts from appearing in the system. The "No Turn Protocol" setting is intended to be used when monitoring patient ambulation events is the only interest.

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

Roll Angle Threshold – Set the minimum angle that a patient needs to turn to be considered on a given side (left or right) instead of on their back.

Upright Angle Threshold – Set the head-of-bed angle that defines when a patient is considered "upright". This is the angle that a patient needs to be upright before they are considered sitting upright or standing.

Tilt Angle Threshold – Set the angle that a patient needs to tilt to be on a side (left or right) instead of the back when "upright"

Decompression Interval – Set the interval of time that a patient needs to remain off a given side before that side is considered fully decompressed / re-perfused and can therefore accommodate pressure again. Note that if a patient returns to a recently compressed side before the decompression interval has elapsed, you may see the turn

time suddenly decrease. This occurs because the turn time increases by an amount of time equal to:

$$\frac{(\text{Turn Period}) \times (\text{Time Off Recently Compressed Side})}{(\text{Decompression Interval})}$$

Default Step Length – Set the default step length in inches that will be assigned to a patient when a sensor is assigned. Note that the default value can be changed during sensor assignment or afterward by editing the patient information.

For details on the Leaf Patient Monitoring System alerts, please refer to "Summary of Alerts" section of this document.

Note that for the "Available Turn Period(s)" and "Available Pause Interval(s)", you can choose to have one or more Turn Periods or Pause Intervals available. To do so, check the checkbox next to the Turn Period or 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 and Pause Interval are available.

P. Individualized Patient Settings

The default settings for Roll Angle Threshold, Tilt Angle Threshold, and Decompression Interval are assigned in the Administrative Settings window as described above. These default values can be edited for an individual patient using the Patient / Unassigned Sensor pop-up windows.
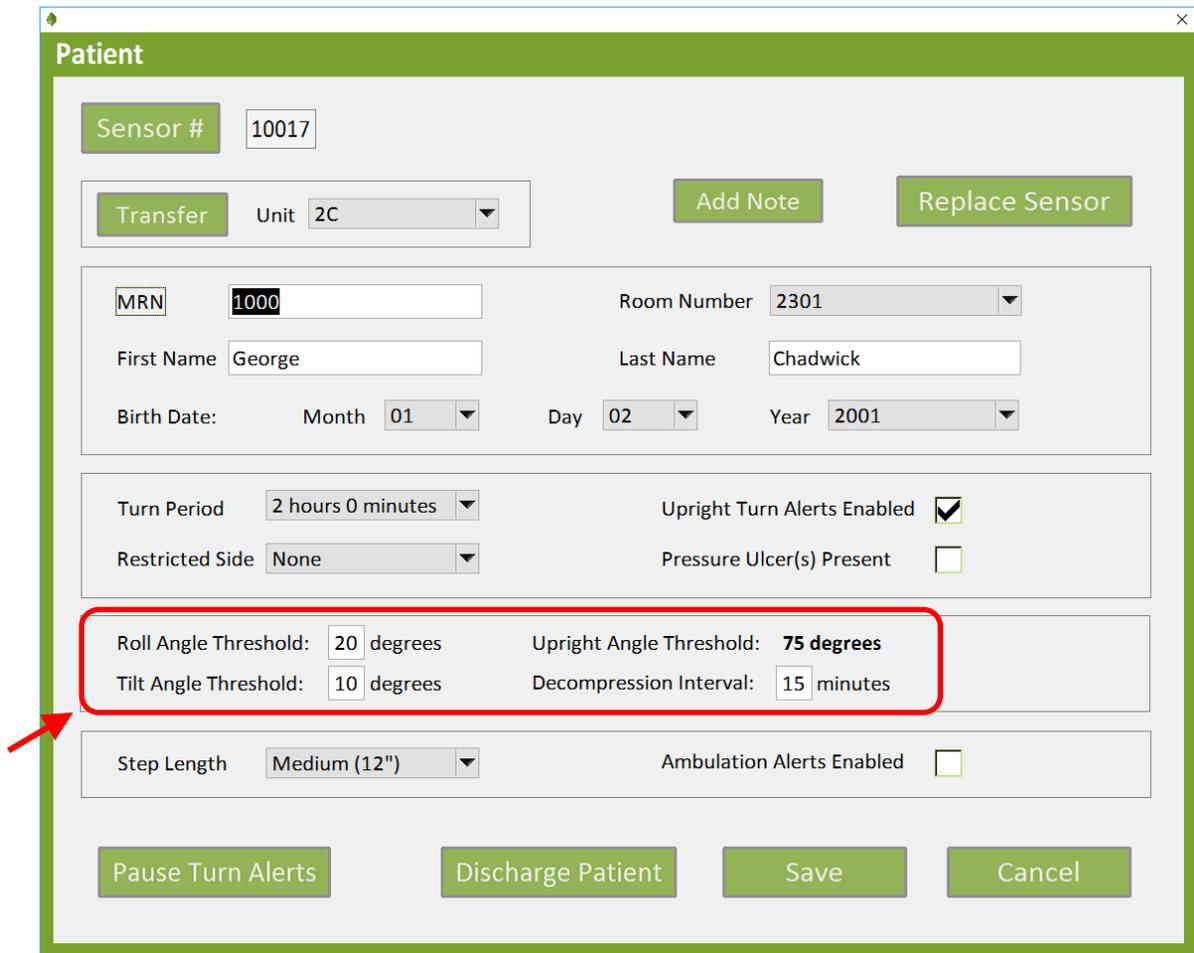
Figure 36: Patient Pop-Up Window

By clicking on the values for Roll Angle Threshold, Tilt Angle Threshold, and Decompression Interval, pop-ups will display and the settings can be edited. The settings are defined in the previous "Administrative Settings" section.
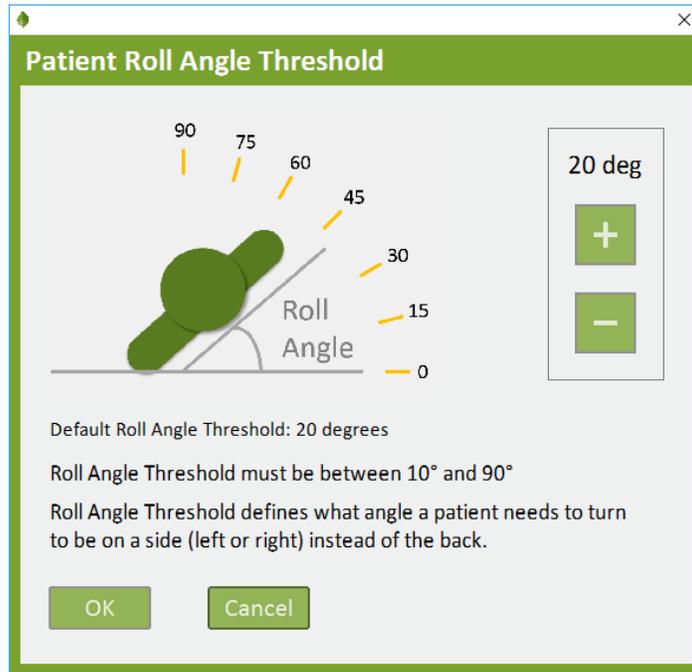
Figure 37: Patient Roll Angle Threshold Pop-Up Window
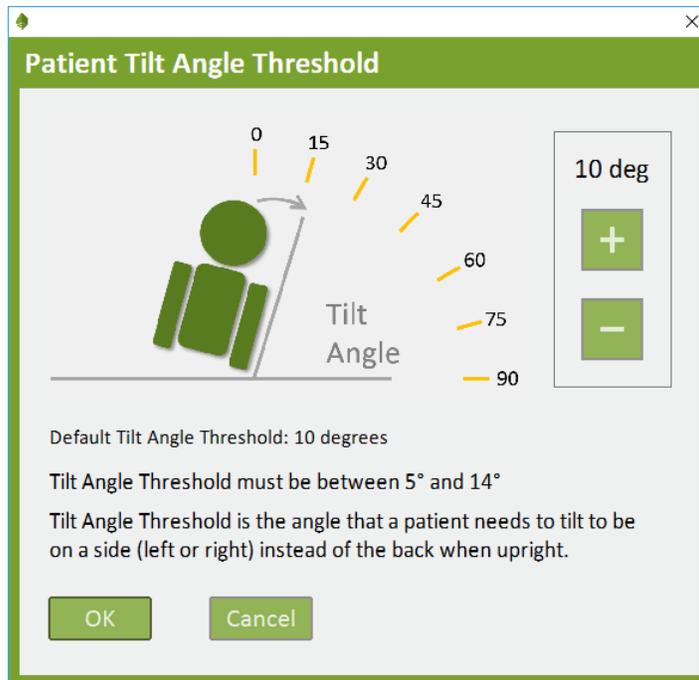
Figure 38: Patient Tilt Angle Threshold Pop-Up Window
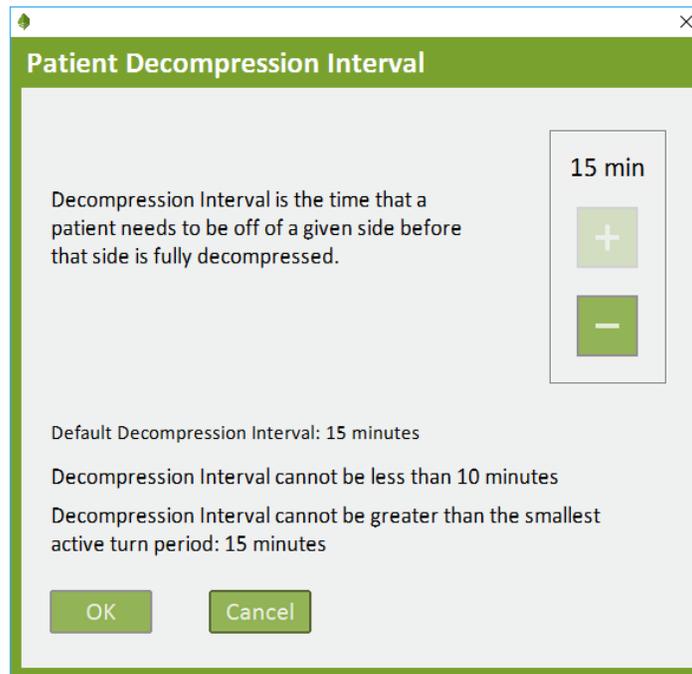
Figure 39: Patient Decompression Interval Pop-Up Window

Q. Patient Notes (Optional)

The Leaf Patient Monitoring System may be configured to allow patient notes to be entered into the system using the Add Patient Note Popup Window. To add a patient note, select the patient by clicking on the appropriate row on the Home Screen. The corresponding pop-up window will open. Click on the Add Patient Note Button in the upper right-hand corner of the pop-up window. The Add Patient Note pop-up window will open.

Figure 40: Patient Pop-Up Window

Enter the desired text into the note textbox. Then enter your initials and click the Add Note Button. This will save the patient note to the system. The note can be then be viewed at a later time by returning to the Add Patient Note pop-up window.

Figure 41: Add Patient Note Pop-Up Window

R. Help Resources

The Help Resources pop-up window can be accessed by clicking on the Help Button on the left side panel. The Help Resources pop-up window will contain a scrollable list of help files. The first item listed will be "About Leaf Patient Monitoring System". Clicking on an entry in this list will cause that item to be selected. The selected item can then be opened by clicking the Open Button. Alternatively, double-clicking an entry in the list will select and open the entry. Clicking the Cancel Button will close the Help Resources pop-up window.
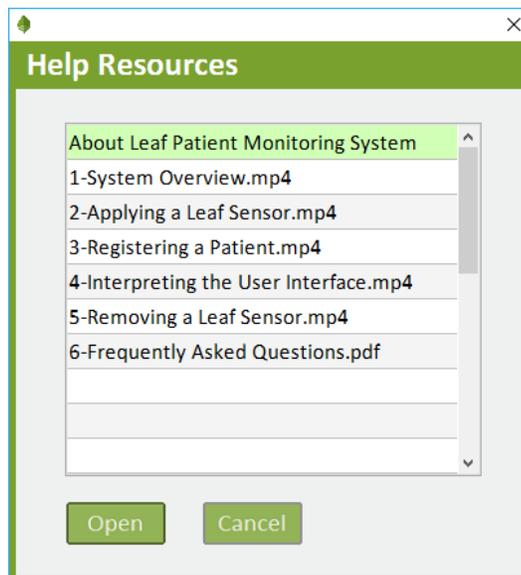
Figure 42: Help Resources Pop-Up Window

S. Reports

If the Reporting Tool has been installed and the user has permissions, the Reporting Tool may be accessed by clicking on the Reports Button on the left side panel.

T. About Leaf Patient Monitoring System

The About Leaf Patient Monitoring System pop-up window can be opened by selecting the "About Leaf Patient Monitoring System" item from the Help Resources pop-up window. This pop-up window will display the user's permissions, the client version, the network version and the database version being used. The About Leaf Patient Monitoring System pop-up window can be closed by clicking the "Cancel" button.
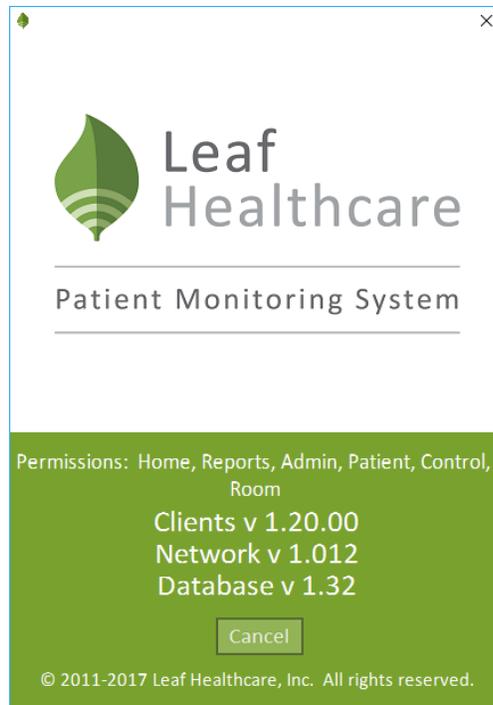
Figure 43: About Leaf Patient Monitoring System Pop-Up Window

U. Side Panel Buttons

The Side Menu Button and the Minimize / Maximize Button are located in the upper left hand corner of the application and are only visible when moused over.

The Side Menu Button can be used to temporarily display additional information on the Home Screen. If clicked the corresponding Side Menu selection will be displayed in the Information Column.
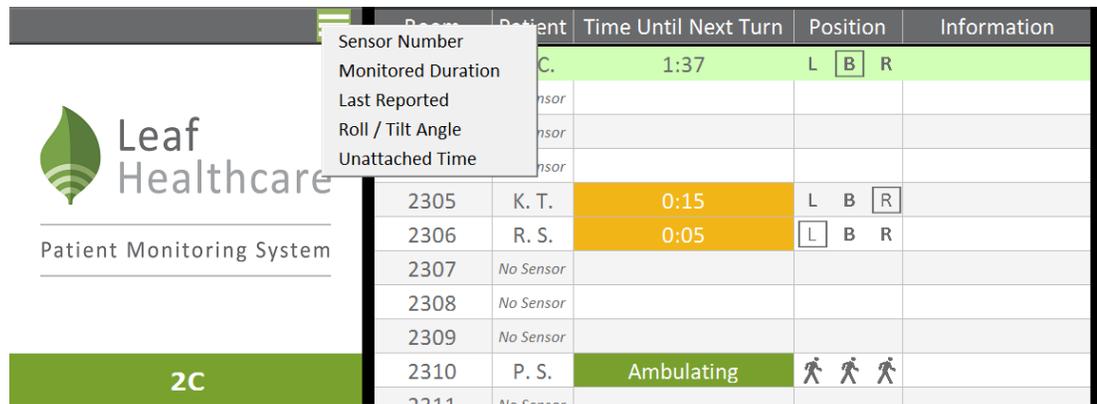
Figure 44: Side Menu Button
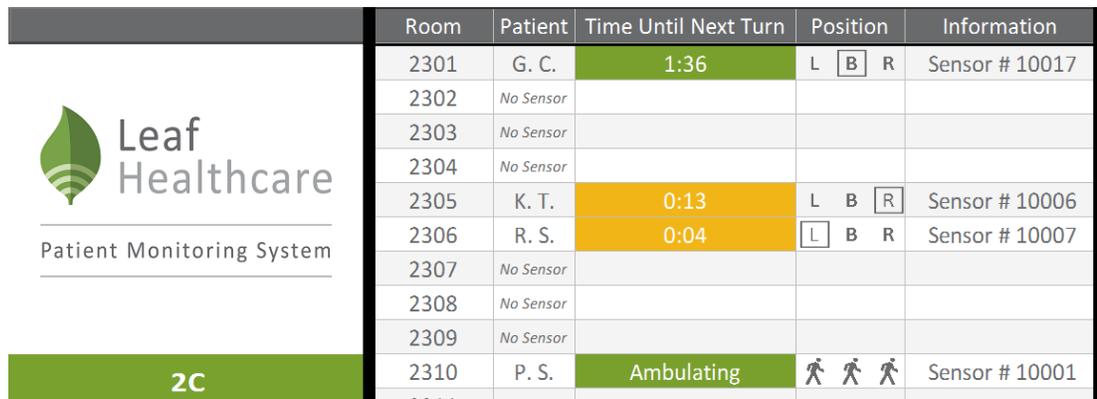
Figure 45: Sensor Serial Number Displayed using Side Menu Button

When the application is in full screen mode the Minimize Button is displayed. If clicked the application will cease to be displayed in the full screen mode and will be displayed in window mode.
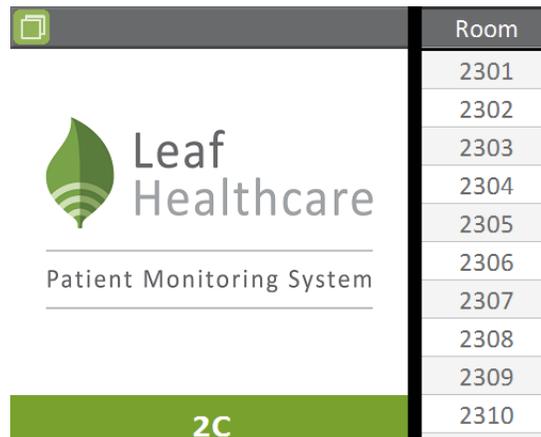
Figure 46: Minimize Button

When the application is in window mode the Maximize Button is displayed. If clicked the application will cease to be displayed in window mode and will be displayed in full screen mode.
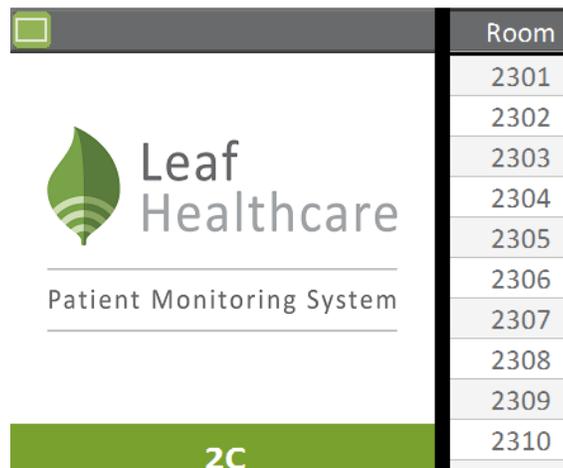
Figure 47: Maximize Button

V. Exiting the Leaf User Interface

To exit the Leaf User Interface, click the Exit Button on the side panel.

W. HL7 Interface (Optional)

The Leaf Patient Monitoring System may be configured to receive and process HL7 messages during the system installation process. When HL7 has been activated, patient location and demographic information will automatically be updated on the Leaf Patient Monitoring System on monitored patients. HL7 messages will be used to populate the Select Patient drop-down menu of the Assign Sensor to Patient Pop-Up Window.
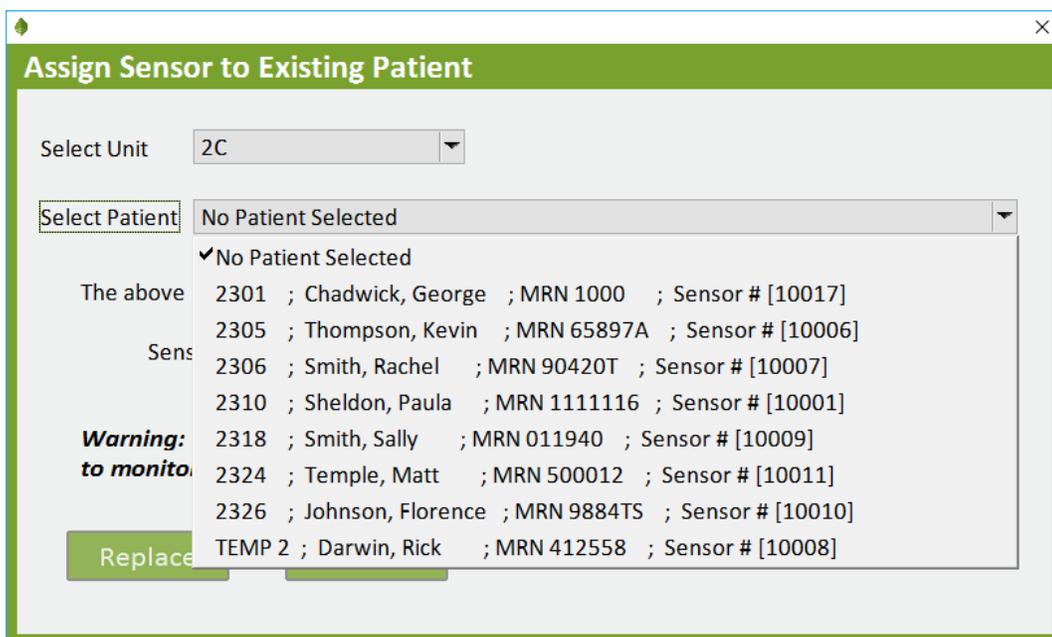
Figure 48: Select Patient Drop-down Menu

If the Leaf system receives an HL7 message changing the location of a monitored patient in the system, the system will automatically move the patient to the new location. If the location (room and unit) is outside the list of rooms and units monitored by the system, or the patient is moved to an occupied room, or the patient is discharged (all of these via HL7), the patient will be moved to the Exceptions Table at the bottom of the Home screen.

Figure 49: Home Screen – Exceptions Table.

Three possible exceptions exist:

> **"BUMPED"** – Another patient has been moved into the monitored patient's room.

> **"MOVED"** – The monitored patient has been moved into a non-monitored room or ward.

> **"DISCHGD"** – The monitored patient has been discharged.

The Leaf Patient Monitoring System may also be configured during installation to Auto-discharge patients on the Exceptions Table. After a set period, the system may be configured to discharge patients on the exception list that have sensors detected as Unattached or sensors that are detected as either Unattached and have No Signal. These sensors will be deactivated and patients will be removed from the Exceptions Table automatically.

X. Room View (Optional)

The Leaf Patient Monitoring System may be configured to have a Room View option during installation. The Room View allows for monitoring of selected rooms. If configured, the Room View selection box will be displayed in the Select Unit Screen. After selecting the rooms to monitor and clicking Monitor Rooms the Room View Pop-Up Window will appear. By closing the Room View the Select Unit window will be displayed again.
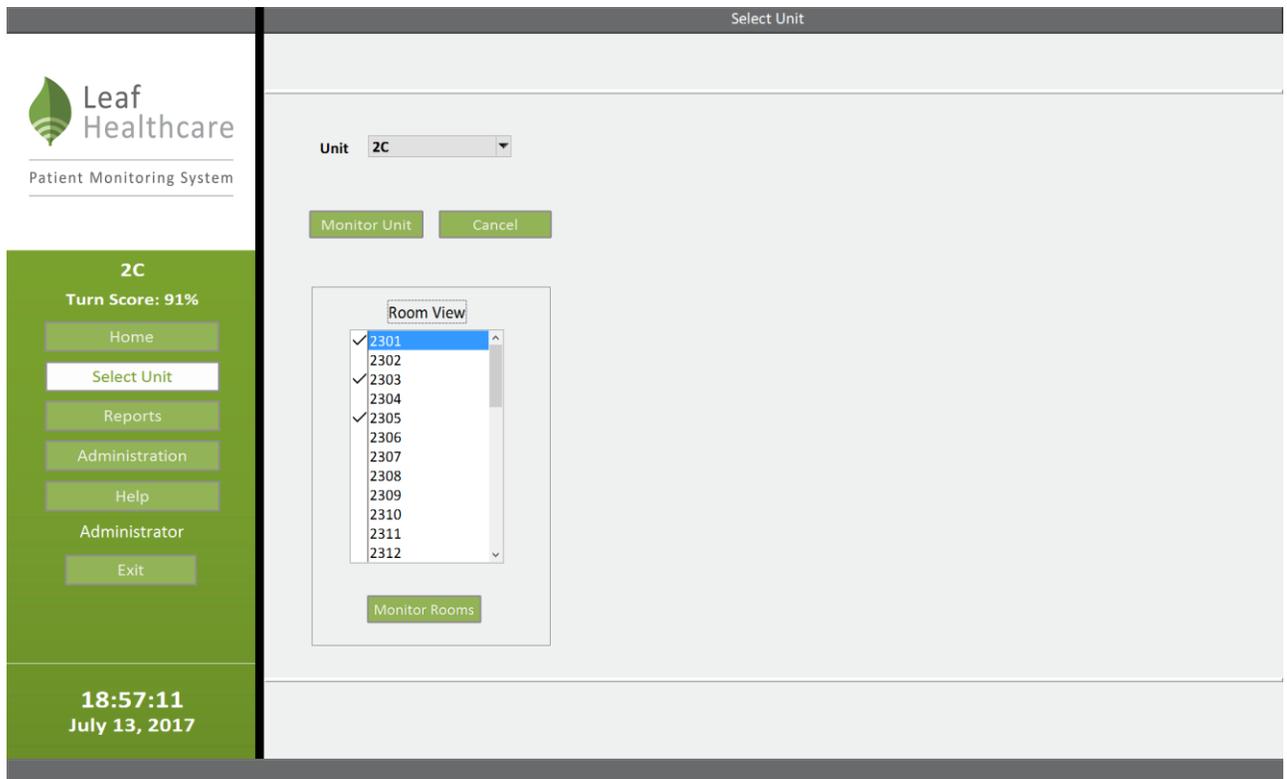
Figure 50: Select Unit Screen with Room View Selection Box

Figure 51: Room View Pop-up Window

HOW TO USE THE LEAF REPORTING TOOL

The Leaf Reporting Tool allows users to generate a detailed report that documents all repositioning events for a patient. The report is provided in a PDF format, which can be saved locally, printed, or uploaded to an EMR or other documentation system.

A. Open the Leaf Reporting Tool

To open the Leaf Reporting Tool, select the Reports Button located on the left side panel.

Figure 52: Reports Button

After clicking the Reports Button on the left side panel, the Leaf Reporting Tool will launch and the Patient Lookup Screen will be displayed. It is from this screen that users can search for patients.

Figure 53: Reporting Tool and the Patient Lookup Screen

B. Searching For a Patient Record

To search for a patient record, enter only as much identifying information as is necessary to locate the patient in the Patient Lookup Screen. Uniquely identifiable information such as a patient MRN or Sensor ID will return only records associated with a single patient or sensor. More generalized search criteria, such as Patient First Name and Last Name may return multiple records that are associated with multiple different patients. General searches that use only the Start Date or End Date can return many records associated

with many patients. Searches can be refined based on a number of different criteria:

Last Name: Users can enter the patient's full last name, or just the first initial of the last name, or as many letters as is desired of the patient's last name. If left blank, the patient report search will not be filtered based on last name.

First Name: Users can enter the patient's full first name, or just the first initial of the first name, or as many letters as desired of the patient's first name. If left blank, the patient report search will not be filtered based on first name.

MRN: Users can enter the patient's full Medical Record Number (MRN) or as many characters as are known for the MRN. If left blank, the patient report search will not be filtered based on MRN.

Sensor ID: Users can enter the patient's entire Sensor ID number, or as many numbers as are known for the Sensor ID. The unique Sensor ID is printed on the front of the sensor, on the sensor packaging, and also on the adhesive backing for the sensor. If left blank, the patient report search will not be restricted based on Sensor ID.

Start Date: Users can refine the search by only returning reports from patients that were monitored during a defined window of time. Only patients monitored on or after the Start Date will be displayed in the search results. If left blank, the patient report search will not be restricted based on Start Date.

Stop Date: Users can refine the search by only returning reports from patients that were monitored during a defined window of time. Only

patients monitored before or on the End Date will be displayed in the search results. If left blank, the default End Date is the current date.

Patient Status: Select either All Patients, Active Patients Only, or Discharged Patients Only. All Patients will include both active and discharged patients. Active Patients Only will include only patients currently active in the system. Discharged Patients Only will include only patients who have been discharged from the system.

Unit: Users can restrict the search to include only patients that are currently admitted or were discharged from a particular unit. Using the drop down menu, select the unit that the patient is currently admitted to, or was discharged from. If the patient was admitted to multiple units during a particular monitoring period, only the current unit or most recent unit can be used. By default, All Units are searched.

Once the search criteria have been entered, click the Search Button and all results that match the search criteria will be displayed. To clear the search fields, users can click the Clear Button at any point.

C. Search Results Warnings

There are two possible search result warnings that can be displayed.

No Data Found: If the search criteria does not return any matches, a popup window will be displayed that says, "No data was found for the

specified search criteria". Click the OK Button to close the popup window.
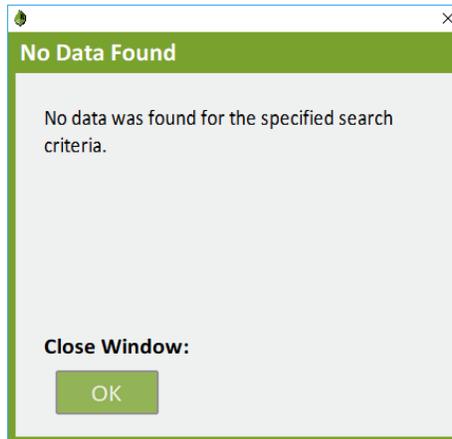
Figure 54: No Data Found Popup Window

Max Search Results Exceeded: If the entered search criteria returns more than 50 search results, a popup window will be displayed that says "Max Search Results Exceeded".
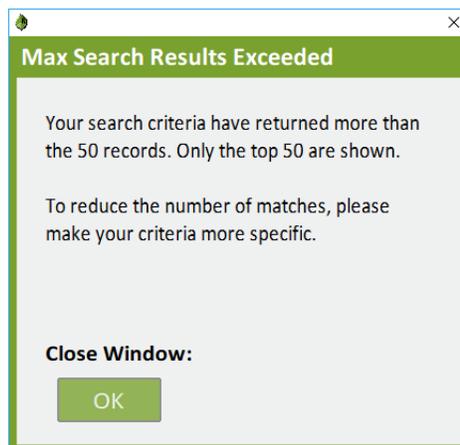
Figure 55: Max Search Results Exceeded Popup Window

Click the OK Button to close the popup window. Refine your search criteria to limit the number of results provided.

D. Selecting a Patient Record

Search results will be displayed on the Search Results Screen. Users can double click on the desired patient or highlight the patient and click the Select Button.

To navigate back to the Select Patient Screen, click the Cancel Button.
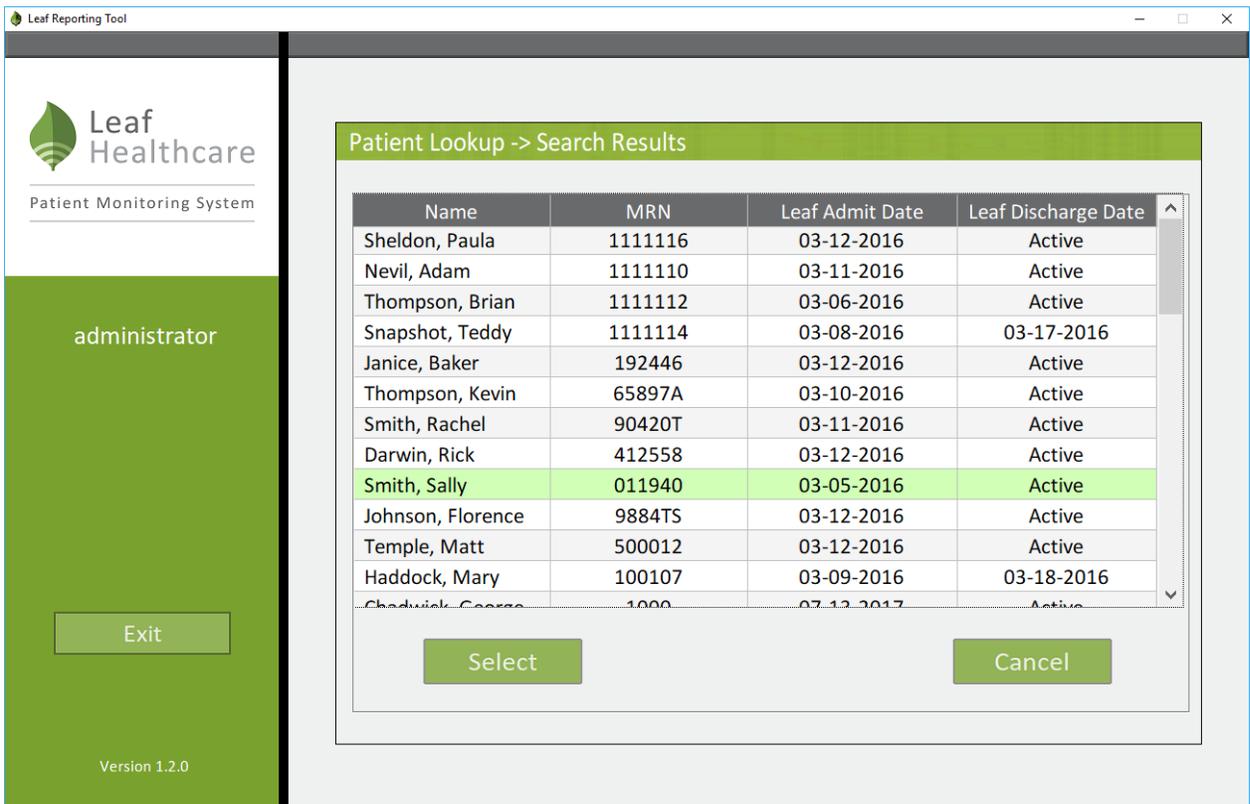
Figure 56: Search Results Screen

After selecting a patient from the Search Results Screen, the Patient Report
Screen will be displayed. The Patient Report Screen displays the patient's
name, MRN, and the date range for the monitoring period.
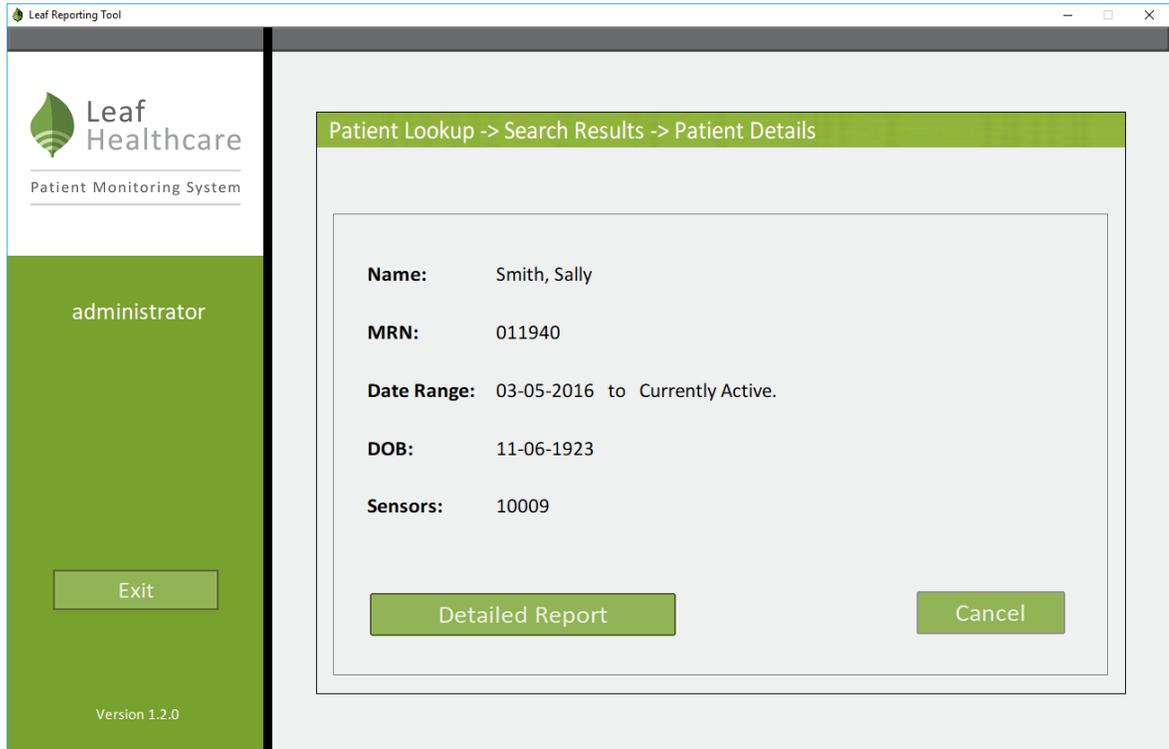
Figure 57: Patient Report Screen

If you wish to view a detailed turn history for a patient, click the Detailed
Report button at the bottom of the window. After clicking Detailed Report,
the Please Wait Popup Window will open and then close once a PDF report
has been generated for the patient. If your system has a PDF viewer, the
report will then open automatically. Please note that depending on the length
of the monitoring period, the detailed patient report may require some time
to generate and load.

E. Interpreting a Patient Report

The reporting tool will generate a detailed turn history report for a given patient. The report is generated in PDF format and can be saved locally, printed, or uploaded to an EMR or other documentation system. The detailed patient report has several key components:

Patient Information: This section of the report contains identifying information for the patient and indicates the monitoring period that the report covers. This section also indicates the last location for the patient (Unit and Room Number).

Turn Protocol Settings Used for Calculations: This section of the report lists the settings that are used for calculating turns.

Summary: This section of the report provides a summary of the turn history for a patient. This section includes information regarding the total monitoring time, total number of turns, distribution of positions, patient movement time (an assessment of quick micro-movement turns), and total time spent upright.

Patient Data: This section of the report contains a chronological turn history for a patient. Every patient repositioning event is recorded and time stamped. Furthermore, any changes to the patient's information, turn protocol settings, or turn alert pauses are documented in this section.

Leaf Patient Monitoring System Instructions For Use

Generated by: Leaf Reporting Tool v 1.2.0

Report Generated: 08-23-2017
                                         16:09

Patient Information:

Name:	Smith, Sally
MRN:	011940
Start Date:	08-20-2017 07:07
End Date:	Patient is currently active.
Patient Status:	Active
Unit:	2C
Room:	2331

Turn Protocol Settings Used For Calculations:

Tilt Angle Threshold:	10
Roll Angle Threshold:	20
Upright Angle Threshold:	74
Decompression Interval:	00:15
Turn Period:	02:00

Summary:

Total Turns:	38	
Total Monitored Time:	73:32	
Total Time Upright:	08:25	
Total Time Patient Movement:	00:00	
Total Time on Left:	17:57	(24.4 %)
Total Time on Back:	28:07	(38.2 %)
Total Time on Right:	19:03	(25.9 %)
Total Time on Left Upright:	03:00	(04.0 %)
Total Time on Back Upright:	05:16	(07.1 %)
Total Time on Right Upright:	00:09	(00.2 %)
Total Time Ambulating:	< 00:01 (00.0 %)	

Page 1 of 3

Figure 58: Page 1 of an example Detailed Patient Report PDF

Generated by: Leaf Reporting Tool v 1.2.0

Patient Data:

Date	Time	Orientation	Duration	Notes
		Default Settings at Time of Sensor Activation		
			Turn Period: 02:00	
			Decompression Interval: 00:15	
			Roll Angle Threshold: 20°	
			Tilt Angle Threshold: 10°	
			Upright Angle Threshold: 74°	
			Upright Alerts: On	
			Ambulation Alerts: Off	
			Step Length: 12"	
08-20-2017	07:07	Back	02:04	
	07:18	Patient Registered	Name: Smith, Sally	
			DOB: 11-06-1953	
			MRN: 011940	
			Room: 2331	
			Unit: 2C	
			Restricted Side: None	
			Turn Period: 02:00	
			Decompression Interval: 00:15	
			Roll Angle Threshold: 20°	
			Tilt Angle Threshold: 10°	
			Upright Angle Threshold: 74°	
			Pressure Ulcer: NOT Present.	
			Upright Alerts: On	
			Ambulation Alerts: Off	
			Step Length: 12"	
	07:20	Modified Setting	Step Length: 9"	
	09:12	Left	01:30	
	10:42	Right	02:30	
	13:12	Back	00:30	
	13:43	Back – Upright	01:12	
	14:55	Left – Upright	03:00	
	17:55	Back – Upright	01:06	
	19:01	Right – Upright	00:09	
	19:10	Back	02:09	
	21:19	Left	00:27	

Page 2 of 3

Figure 59: Page 2 of an example Detailed Patient Report PDF

Leaf Patient Monitoring System Instructions For Use

Generated by: Leaf Reporting Tool v 1.2.0

Date	Time	Orientation	Duration	Notes
	21:46	Left - Prone	02:09	
	23:56	Back	00:31	
08-21-2017	00:27	Ambulating	< 00:01	
		Back	00:49	
	01:16	Right	01:12	
	02:29	Left	02:00	
	04:30	Ambulating	< 00:01	
		Back - Upright	01:28	
	05:58	Back	04:24	
	06:11	Modified Setting	Room: 2318 Unit: 2C	
			Step Length: 12"	
	10:23	Right	00:33	
	10:56	Left	01:34	
	12:31	Back	07:00	
	19:31	Right	01:30	
	21:01	Left	03:06	
08-22-2017	00:07	Left	01:48	
	01:55	Back	02:24	
	04:19	Right	04:06	
	08:25	Back	01:06	
	09:31	Right	04:40	
	14:12	Left	00:26	
	14:38	Back	04:13	
	18:51	Left	03:06	
	21:57	Right	02:06	
08-23-2017	00:03	Back	01:54	
	00:18	Pause 20 Minutes	Procedure / Imaging / Exam	
	01:57	Right	02:24	
	04:21	Left	01:48	
	06:09	Back	01:00	
	07:09	Back - Upright	01:30	
	08:39	Patient Movement	< 00:01	

Figure 60: Page 3 of an example Detailed Patient Report PDF

DEVICE LABELS

The following labels appear on the Leaf Patient Sensor and the Leaf Antenna, or their respective packaging:

Leaf Patient Sensor Labels

Figure 61: Leaf Patient Sensor Labels

Figure 62: Leaf Point-of-Care Sensor Labels

Leaf Antenna Labels

Figure 63: Leaf Antenna Labels

TAKING CARE OF THE DEVICE

Cleaning Instructions

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

Storage

Always store unused Patient Sensors in a dry, temperature-controlled location, 0°C-40°C. Keep unused Patient Sensors away from water or moisture that could get inside the Patient Sensor or its 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 and replace it with a new Patient Sensor. Be sure to apply the new Patient Sensor in a different location from prior sensors. Call Customer Service if assistance is needed.

Disposal

A battery is included in the Patient Sensor. Used Patient Sensors should be disposed of in the manner required by local regulations regarding battery disposal. The Patient Sensor contains perchlorate material and special handling may apply. See www.dtsc.ca.gov/hazardouswaste/perchlorate.

Life of the Device

The Leaf Patient Sensor is designed to work until the battery is depleted or the adhesive is worn out, which is typically 7-16 days. The device is designed for one-time use (on a single patient). There are no parts that need to be replaced. The Patient Sensor is working properly if it functions as described in this booklet.

Leaf Patient Monitoring System Instructions For Use

SUMMARY OF ALERTS

The alerts displayed by the system and the actions that will resolve the alerts are listed below. This device is not a substitute for sound medical judgment and individualized patient management. Please 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. The alert appears in white bold text with red highlighting: "TURN DUE *hh:mm* OVER". This alert is triggered if the amount time that a patient has been in a given position exceeds the threshold set by the user or facility. The amount of time that the turn is overdue is also displayed.
  - Action That Will Resolve Alert: Repositioning of the patient can lead to automatic resolution of this alert trigger once the Leaf Patient Sensor updates its status. When repositioning the patient, be sure that they are turned adequately (e.g. pass the defined angle threshold) and that they remain in the new position for a period of time greater than the decompression interval.

- **Upright Alert**
  - Displayed in gray italic text in the Information Column of the Home Screen: "*Upright*". Alert is triggered if the angle that the Patient Sensor is tilted is greater than the pre-set Upright Angle threshold (what is defined through Administrative Settings).
  - Action That Will Resolve Alert: This is not an alert that inherently requires action. However, repositioning the patient or decreasing the head-of-bed angle can lead to resolution of this alert.

- **Prone Alert**
  - Displayed in gray italic text in the Information Column of the Home Screen: "*Prone*". Alert is triggered if the orientation of the patient

detected by the Patient Sensor indicates that the patient's upper body is facing downwards (i.e. prone positioning).

- o 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.

- **No Signal Alert**
  - o Displayed in gray text in the Information Column of the Home Screen: "No Signal". Alert triggered if data from the Patient Sensor has not been received for at least 5 minutes.
  - o Action That Will Resolve Alert: The user may determine if the Patient Sensor is too far from an available Leaf Antenna, or if something is preventing the Patient Sensor from communicating with a Leaf Antenna. Alternatively, the sensor battery may be depleted in which case the user needs to replace the sensor.
  - o 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 Leaf 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.
  - o 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 Leaf Antenna.

- **Replace Sensor Alert**
  - o Sensor battery is depleted and must be replaced. Apply a new sensor to the patient. Under "Unassigned Sensors" area of the Home Screen, click on the serial number of the new sensor and select "Assign to Existing Patient". Select the appropriate patient from the drop down menu.

- **Unattached Alert**

- o Displayed in red text in the Information Column of the Home Screen: "Unattached". Alert triggered if the Patient Sensor does not detect that it is properly attached to the patient's skin.
  Action That Will Resolve Alert: If the sensor is not attached to the patient, reapply the sensor while ensuring proper orientation of the sensor with respect to the patient. As soon as the system determines that the sensor is attached to a patient, the "Unattached" alert will automatically disappear.

- **Pause Alert**
  - o Displayed in white text with green highlighting in the Time Until Next Turn Column of the Home Screen: "Turn Alerts Paused". Alert triggered when a user pauses a turn alert for a patient. The pause lasts for the duration specified by the user.
  - o Action That Will Resolve Alert: This is not an Alert that inherently requires action. It will disappear when the pause has expired. To remove a Pause, open the Pause Turn Alert pop-up window for the patient and select "Resume Turn Alerts".

- **Ambulation Alert**
  - o Displayed in white text with red highlighting in the Time Until Next Turn Column of the Home Screen: "Ambulating". Alert triggered when the patient has the "Ambulation Alerts Enabled" checkbox checked and the patient is determined to be ambulating.
  - o Action That Will Resolve Alert: When the system determines the patient is no longer ambulating the alert will expire and disappear.

- **Turn Score**
  - o The Turn Score is displayed below the Unit Name and displays the average turn protocol compliance for patients on the currently selected

unit. The Turn Score is a moving-window calculation and has a configurable window duration with a default of 2 hours.

- **Database Inaccessible Alert**
  - Displays as a pop-up window when the Leaf User Interface cannot access the database.
    - If the Leaf 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 Leaf User Interface has successfully started, and the database is inaccessible, whenever a user attempts to perform an action that requires the database, 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 Leaf User Interface. If the problem still persists, Leaf Healthcare Customer Service should be contacted.

- **Home Screen Warning Alert**
  - If the information displayed on the Home Screen has not been updated for a period equal to a preset threshold (initially set to 10 minutes and configurable during installation) the following alert will appear in the Side Panel of the Home Screen: "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 as a pop-up over the Home Screen: "System Warning:

Patient information not updating. Please exit and restart
program. 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."

o Action That Will Resolve Alert: The Leaf User Interface can be restarted.
If the problem persists, Leaf Healthcare Customer Service can be
contacted. Note: During this alert state, all data displayed on the user-
interface is outdated by the amount of time displayed on the Side
Panel.

- **System Update Status Alert**
    o If system settings have changed that require a restart of the User
    Interface to take affect, the following alert will appear on the Side Panel
    of the Home Screen in yellow text: "System settings have changed,
    please exit and restart program"

- **Patient Information Warning Alert**
    o If a user tries to perform an action on a discharged patient, a pop-up
    window with the following Alert message appears: "Selected Patient is
    no longer available. Patient has been discharged."
    o If while a user is modifying a patient's information, another user
    modifies and saves changes to that patient, a pop-up window with the
    following Alert message will appear when the user attempts to save
    "Another user has made and saved modifications to the Patient's
    information since the Patient Popup Window was opened. Please re-
    open the Patient Popup Window and review any changes before
    saving."
    o 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 from the Unassigned Sensors Table, where this Patient Sensor has already been assigned or deactivated (but the Leaf User Interface has yet to update to reflect this change) 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 Leaf 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 to the conflict. 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 Leaf 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 Leaf Patient Sensor

    Serial Number of the patient with the occupied room number will be displayed.

- o Action That Will Resolve Alert: Assign patient a unique MRN or to an available room.

- **Administrative Settings Out of Range Alert**
  - o 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 applies to the Decompression Interval and to the Tilt Angle Threshold. The user cannot set a Decompression Interval that is greater than the shortest Turn Period option available. The user cannot set a Tilt Angle Threshold that is greater than or equal to the complement of the Upright Angle Threshold (i.e. 90 degrees minus the Upright Angle Threshold).
  - o The following message will be displayed for the Decompression Interval: "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.
  - o The following message will be displayed if the user attempts to set the Decompression Interval to 0 minutes: "Warning the following items must be entered correctly before a save can be performed:
    Decompression Interval: Decompression Interval cannot be set to 0 minutes."
  - o The following message will be displayed for the Tilt Angle Threshold: "Warning the following items must be entered correctly before a save can be performed:
    Tilt Angle Threshold: Tilt angle threshold must be less than 90° minus the Upright Angle Threshold."

- o Action That Will Resolve Alert: The user can select a setting for the Decompression Interval that is within the acceptable range, thus, shorter than the shortest available Turn Period. The user can select a setting for the Tilt Angle that is within the acceptable range, thus, less than 90 degrees minus the Upright Angle Threshold.

- **Administrative Settings Save Changes Alert**
  - o If a user modifies the administrative settings and tries to navigate away, a pop-up window will open and prompt the user 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.*"
  - o Action That Will Resolve Alert: The user can choose to save or discard changes.
  - o If while a user is modifying administrative settings, another user modifies and saves changes to administrative settings, a pop-up window with the following Alert message will appear when the user attempts to save "Another user has made and saved modifications to the Administrative Settings. Press the OK Button to refresh the Administrative Settings Screen."
  - o Action That Will Resolve Alert: No action is required by the user.

- **HL7 Associated Alerts**
  - o If the Leaf Patient Monitoring System has been installed in a configuration that uses HL7 messages, a few possible alerts may occur. These alerts are associated with merging patient data within HL7 that conflicts with patients being monitored by the Leaf Patient Monitoring System or HL7 messages leading to an excessive amount of exceptions as defined during initial configuration.

- o Action That Will Resolve Alert: The user can review the information provided in the alert and address appropriately. If the user is unable to resolve the alert or the alert persists, contact Leaf Customer Service.

- **HL7 Automatic Discharge Alert**
  - o If the Leaf Patient Monitoring System has been installed in a configuration that uses HL7 messages and an HL7 discharge message is received for an actively monitored patient and specific discharge criteria are met the following Alert message will temporarily be displayed in the Information Column of the Home Screen: "Discharging"
  - o Action That Will Resolve Alert: No action is required by the user, the alert will resolve itself.

- **Too many search results**
  - o If the Leaf Reporting Tool returns more than 50 search results, an error message will be displayed to indicate that too many records satisfy the search criteria.
  - o Action That Will Resolve Alert: The user can refine the search criteria to restrict the number of search results provided. If the user is unable to resolve the alert or the alert persists, contact Leaf Customer Service.

- **No Data Found**
  - o If the search doesn't return any matches, a popup window will be displayed that says "No data was found for the specified search criteria".
  - o Action That Will Resolve Alert: The user can un-restrict the search criteria to increase the number of search results provided. If the user is unable to resolve the alert or the alert persists, contact Leaf Customer Service.

- **Invalid Search Criteria**
    - If a user enters invalid search criteria, an "Invalid Search Criteria" alert will be displayed. Further details regarding the invalid search may also be provided.
    - Action That Will Resolve Alert: The user can re-enter valid search criteria. If the user is unable to resolve the alert or the alert persists, contact Leaf Customer Service.

- **Additional Alert Details**
    - The Alerts in the Leaf Patient Monitoring System are low priority alerts and should be considered within the context of the caregivers' medical judgment and discretion.
    - The delay time from the onset of an Alert condition to the display of the Alert on the Leaf User Interface will be less than or equal to 10 minutes. In a situation in which an Alert would be generated by the Leaf Patient Monitoring System, the appropriate Alert will be displayed within 10 minutes or an Alert specifying a malfunction in the system will be displayed.
    - Alerts and patient data originating from a given Patient Sensor may not be accurate within 5 minutes if the Patient Sensor is not communicating with a Leaf Antenna or a USB RF Transceiver. In such a case, the User Interface will show the "No Signal" Alert after 5 minutes without communication with the Leaf Patient Sensor as described above.
    - Users with Administrative Privileges are able to set Alert presets and options in the Administrative Settings page of the User Interface for the 'Turn Due', 'Upright', and 'Pause' alerts
    - Users should ensure that Alert presets are appropriate on a case-by-case basis. The Leaf Patient Monitoring System is not a substitute for sound medical judgment.
    - 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.

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 Leaf Antenna.	Check to be sure that you are within 10 feet of a Leaf Antenna. When the Leaf Patient Monitoring System was installed, Leaf Antennas should have been placed within 10 feet of each patient room on the unit.
	The packaging adhesive may not be entirely removed.	Ensure that the opaque adhesive backing has been completely 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 Leaf Antenna and check to see if this causes the LED lights to start blinking.

Leaf Patient Monitoring System Instructions For Use

Problem	Cause	What you should do
	The Leaf Patient Sensor may have a dead battery.	Open a new Leaf Patient Sensor and see if the problem is resolved. Return the first Leaf Patient Sensor to Leaf Healthcare for evaluation.
	The activation sequence may have occurred without you noticing the blinking LEDs	If the Leaf Patient Sensor has been activated and a connection to the network has been established, the Patient Sensor will appear in the Unassigned Sensor list.
	Unknown	If you have tried all of the above and continue to have problems, call Customer Service.
The Leaf Patient Sensor has been applied to the patient, the LED lights are displayed, but the Leaf Patient Sensor is not appearing in the Leaf User Interface.	A Leaf 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 Leaf Antenna has NOT been found. Make sure that the Patient Sensor is within 10 feet of a Leaf Antenna.
	Unknown	If you have tried all of the above and continue to have problems, call Customer Service.

Problem	Cause	What you should do
Correct patient orientation data is not being monitored or reported.	The Patient Sensor has fallen off, 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 leaf on the sensor is pointing towards the patient's head and aligned with the patient's head-to-foot axis.
	Administrative Settings may have changed.	Open the Patient pop-up window or the Unassigned Sensor pop-up window and verify that the correct Roll Angle Threshold, Tilt Angle Threshold, and Upright Angle Threshold is being referenced.
	Unknown	If you have tried all of the above and continue to have problems, call Customer Service.
Patient Sensor data was being displayed previously on the User Interface, but is no longer being updated.	The patient has temporarily moved off the unit or is out of range of a Leaf 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 Leaf 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 Leaf 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 Leaf 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.	The Patient Sensor serial number is not known to caregiver.	Look at the serial number located on the sensor's packaging or adhesive backing. If you have already discarded the sensor packaging/adhesive backing, 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 or Figure 4). Once you know the sensor's serial number, you can assign it to the correct patient using the User Interface.
I see Unattached message on the patient row. What do I do?	The sensor may have become dislodged.	Verify that the sensor is properly attached to the patient and the Leaf logo is pointing up. Reapply the sensor to the patient if necessary. The "Unattached" message will automatically disappear once sensor is reattached to patient.

Leaf Patient Monitoring System Instructions For Use

Problem	Cause	What you should do
I turned the patient but the system is not registering my turn.	Patient may not have been turned to sufficient angle that exceeds the minimum angle threshold set in the system for a side lying position.	Ensure that the patient is turned to sufficient angle to register a side-lying position.
		Use proper patient repositioning techniques and log roll the patient's torso and hips as one unit to maintain spinal alignment and to relieve pressure from the scapulae and occiput.
		Ensure that any repositioning devices such as pillows are not allowing patient to fall below the threshold for a side-lying position.
	Sensor placement may not properly reflect patient position.	Ensure the sensor position and alignment reflects the alignment of the patient's core. Placing the sensor on an angle or incline may cause the system to not record patient's positions properly. Relocate the sensor to a position that better reflects the patients core position if necessary.
I just turned the patient but the system didn't grant a full turn period. Why?	Patient turned back to previous side before the full decompression time was met.	No action needed until the Leaf system shows that a turn is due.

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 61 and Figure 62.

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

Electrical Voltage (USB RF Transceiver)	5 VDC
Electrical Voltage (Leaf Antenna)	120 VAC
Electrical Voltage (Leaf Antenna Power Adapter)	100-240V ~ 50/60Hz, .18A, Output: 5.0V DC 1.0 A
Electrical Voltage (Patient Sensor)	3 VDC
Leaf Patient Sensor Power Source	Internally Powered
Leaf Patient Sensor Size	1.8" x 2.0", adhesive extends to 2.4" x 2.8"
Leaf Patient Sensor Weight (max)	20 g
Leaf Patient Sensor Skin Adhesive Material	Acrylic adhesive on polyurethane carrier
Leaf Patient Sensor Applied Part Type	Type BF Applied Part
Leaf Patient Sensor Cover Material	Polystyrene
Optimal Distance between Leaf Patient Sensor and Leaf Antenna	15 feet
Wireless Transmission Protocol	IEEE 802.15.4 Compliant
Wireless Transmission Frequency	2.4 GHz
Leaf Antenna Classification	Class II Medical Electrical Equipment, IEC 60601
Ingress Protection (IP) Rating	IPX7 for Patient Sensor, IP2X for Leaf Antenna and USB RF Transceiver
Intended System Operation	Continuous Operation
Battery use life	7 to 16 days

TECHNICAL SPECIFICATIONS

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
Leaf Patient Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of Leaf Patient Monitoring System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic Environment-Guidance
RF emissions CISPR 11	Group 1	Leaf Patient Monitoring System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Leaf Patient Monitoring System 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 Leaf Patient Monitoring System 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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