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.

The product images shown are for illustration purposes only and may not be an exact representation of the product.

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.

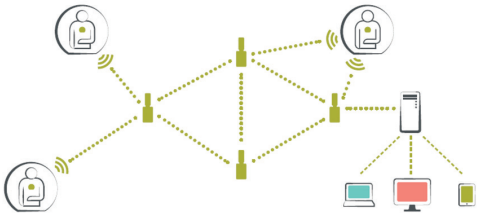


Figure 1: High-Level Schematic Representation of the System's Communication Flow

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

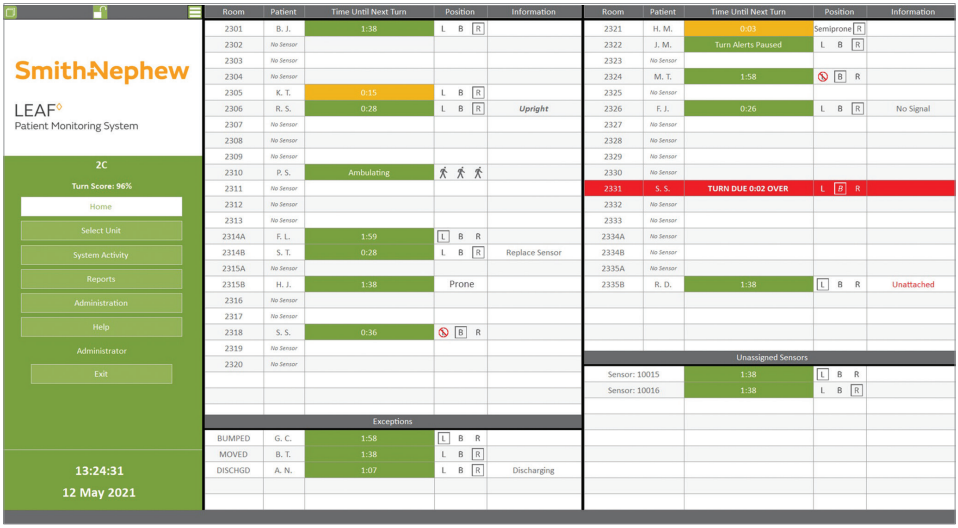


Figure 6: LEAF Patient Monitoring Software and User Interface

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

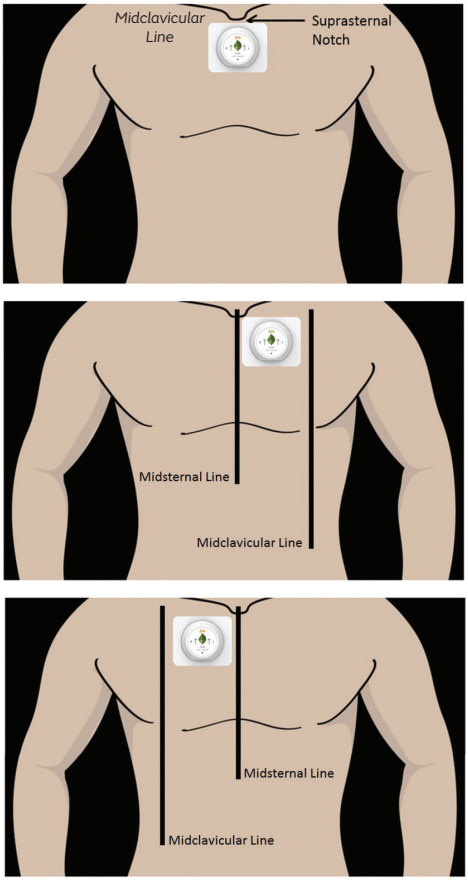


Figure 7: LEAF Patient Sensor placement location

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.

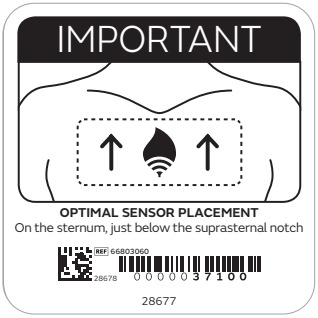


Figure 8: LEAF Patient Sensor placement label

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.

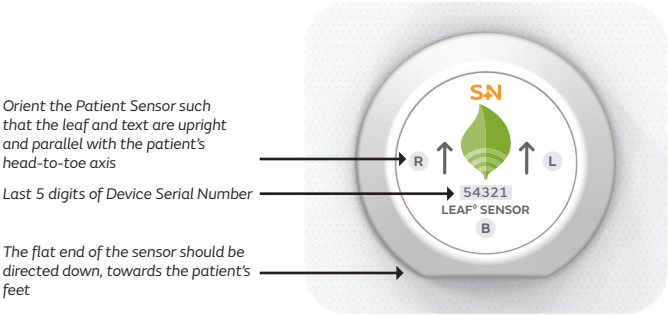


Figure 11: LEAF Patient orientation and serial number

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.

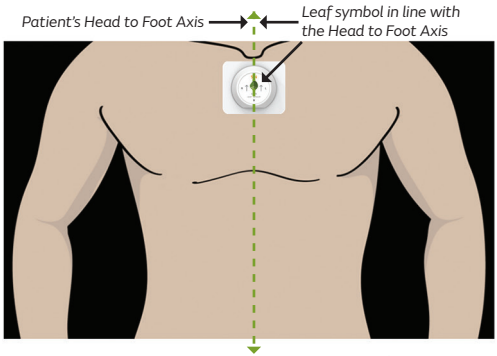


Figure 12: LEAF Patient Sensor orientation with respect to patient

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.

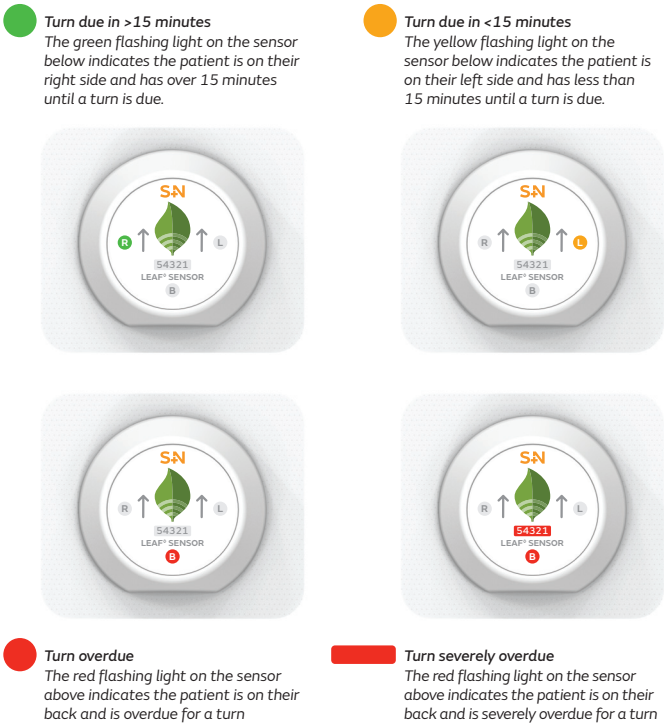


Figure 13: Interpreting the LEAF Patient Sensor

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.

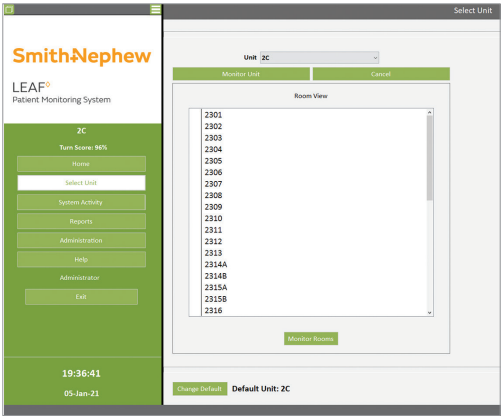


Figure 15: Select Unit Screen

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.

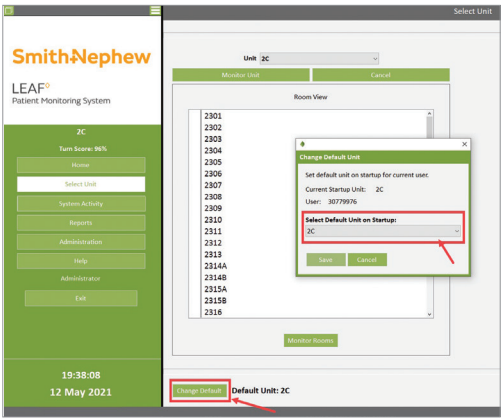


Figure 16: Change Default Unit Screen

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.

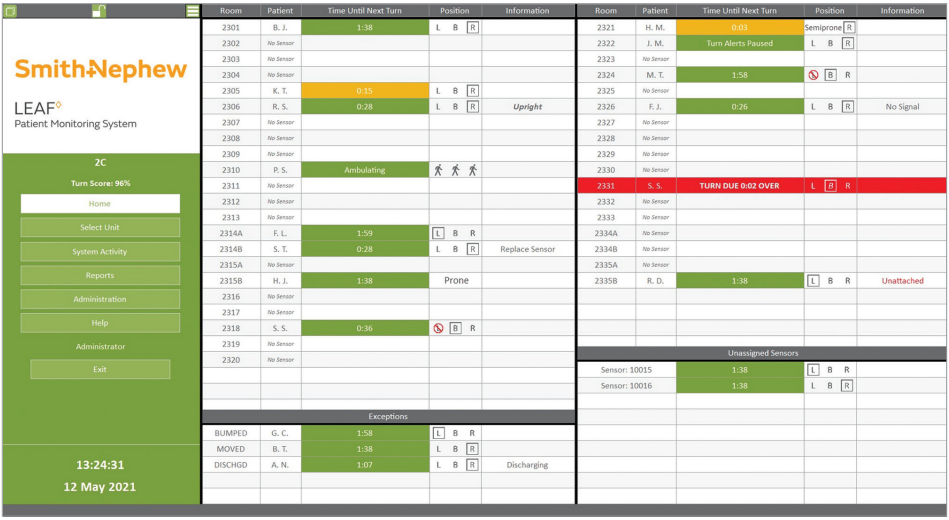


Figure 17: Home Screen

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.

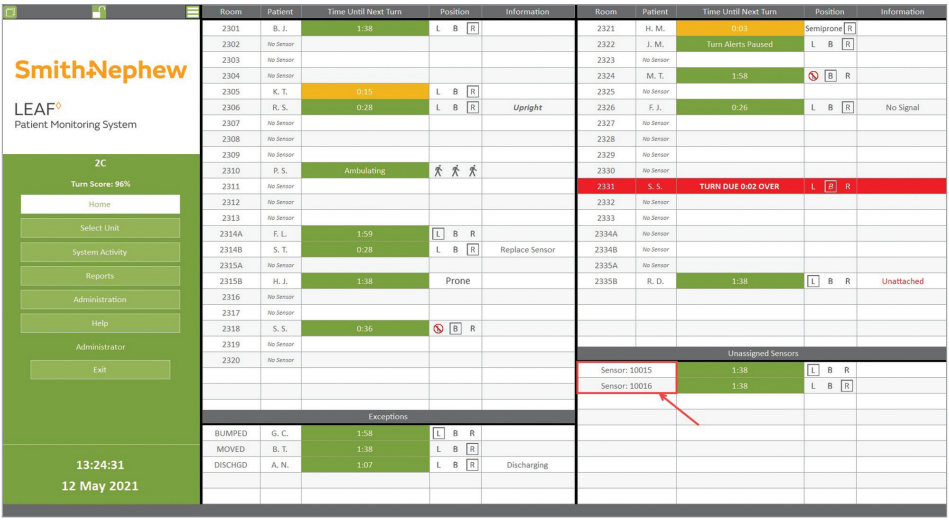


Figure 18: Home Screen – Unassigned Sensor List

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.

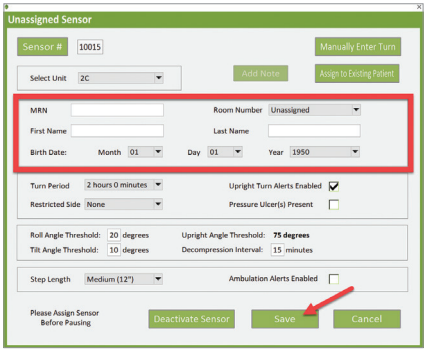


Figure 19: Unassigned Sensor Pop-Up Window

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.

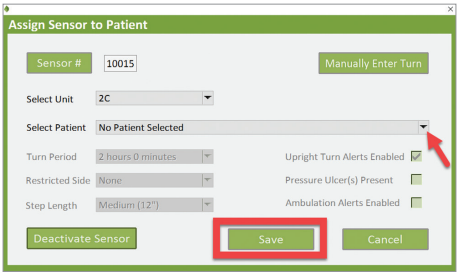


Figure 20: Unassigned Sensor Pop-Up Window if HL7/ADT interface is activated

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.

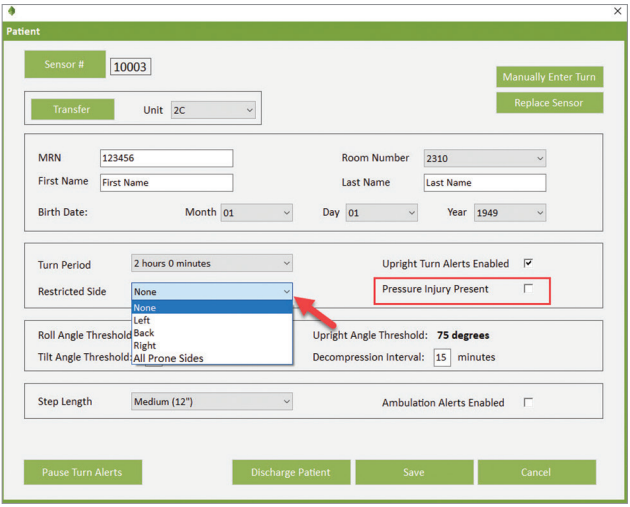
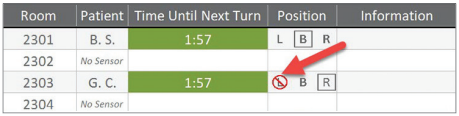


Figure 21: Restricted Side Drop-Down Menu

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.

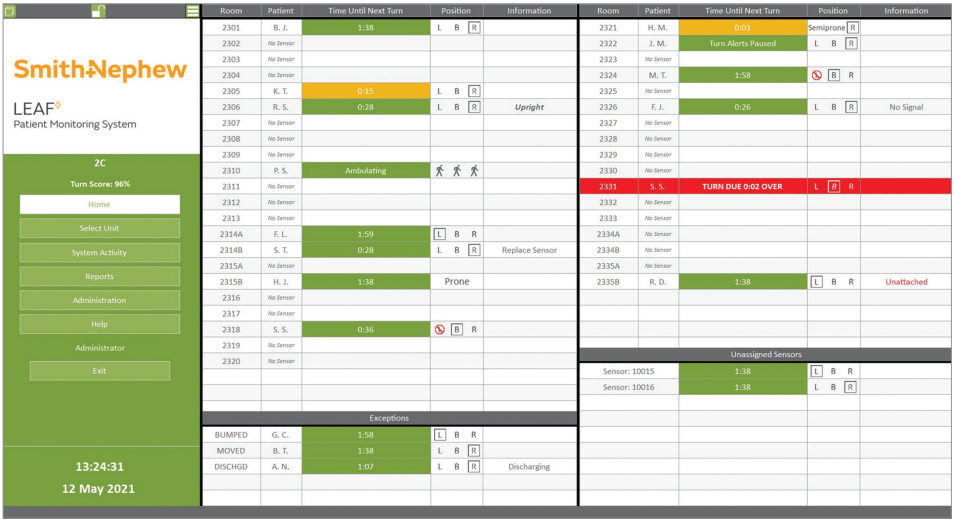


Room	Patient	Time Until Next Turn	Position	Information
2301	B. S.	1:57	L [B] R	
2302	No Sensor			
2303	G. C.	1:57	⊘ B [R]	
2304	No Sensor			

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.



Room	Patient	Time Until Next Turn	Position	Information
2301	B. J.	1:38	L B [R]	
2302	No Sensor			
2303	No Sensor			
2304	No Sensor			
2305	K. T.	0:15	L B [R]	
2306	R. S.	0:28	L B [R]	*Upright*
2307	No Sensor			
2308	No Sensor			
2309	No Sensor			
2310	P. S.	Ambulating		
2311	No Sensor			
2312	No Sensor			
2313	No Sensor			
2314A	F. L.	1:59	[L] B R	
2314B	S. T.	0:28	L B [R]	Replace Sensor
2315A	No Sensor			
2315B	H. J.	1:38	Prone	
2316	No Sensor			
2317	No Sensor			
2318	S. S.	0:36	⊘ [B] R	
2319	No Sensor			
2320	No Sensor			
BUMPED	G. C.	1:58	[L] B R	
MOVED	B. T.	1:38	L B [R]	
DISCHGD	A. N.	1:07	L B [R]	Discharging

Room	Patient	Time Until Next Turn	Position	Information
2321	H. M.	0:03	Semiprone [R]	
2322	J. M.	Turn Alerts Paused	L B [R]	
2323	No Sensor			
2324	M. T.	1:58	⊘ [B] R	
2325	No Sensor			
2326	F. J.	0:26	L B [R]	No Signal
2327	No Sensor			
2328	No Sensor			
2329	No Sensor			
2330	No Sensor			
2331	S. S.	TURN DUE 0:02 OVER	L [B] R	
2332	No Sensor			
2333	No Sensor			
2334A	No Sensor			
2334B	No Sensor			
2335A	No Sensor			
2335B	R. D.	1:38	[L] B R	Unattached
Sensor: 10015		1:38	[L] B R	
Sensor: 10016		1:38	L B [R]	

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.

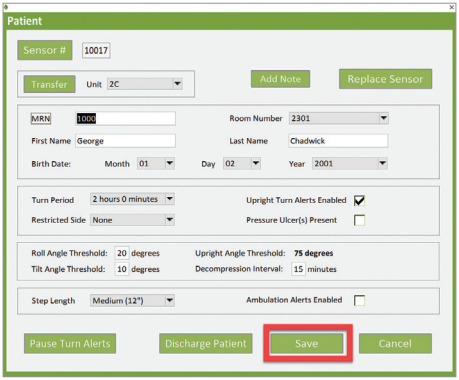


Figure 24: Patient Pop-Up Window

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.

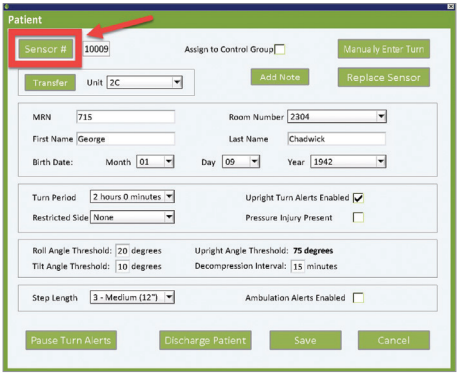


Figure 25: Sensor button on Patient Pop-Up Window

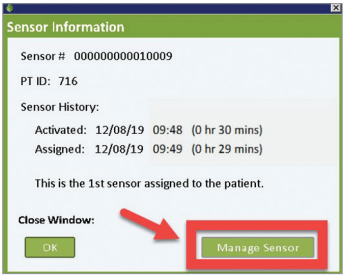


Figure 26: Sensor Information Pop-Up Window

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

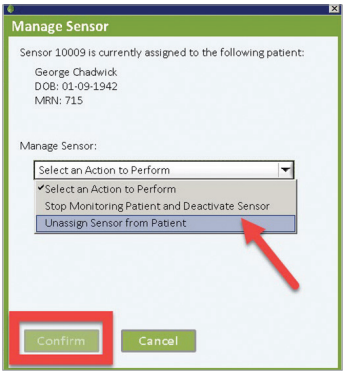


Figure 27: Sensor Information Pop-Up Window

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.

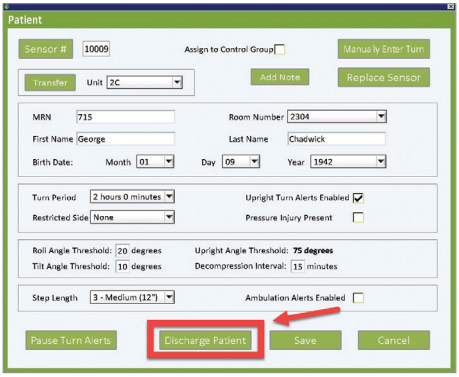


Figure 28: Sensor Information Pop-Up Window

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.

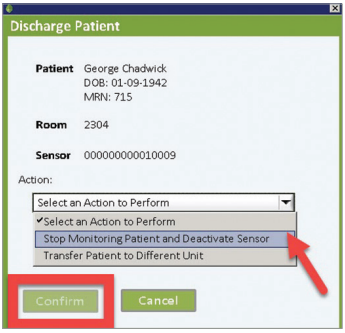


Figure 29: Discharge Patient Pop-Up Window

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.

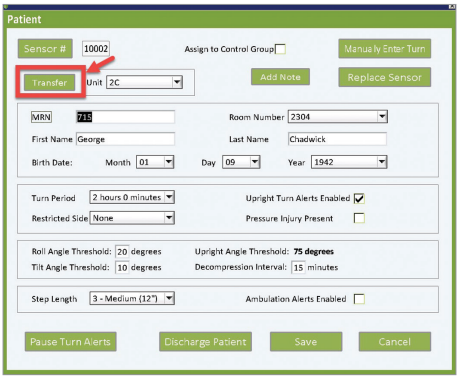


Figure 30: Sensor Information Pop-Up Window

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.

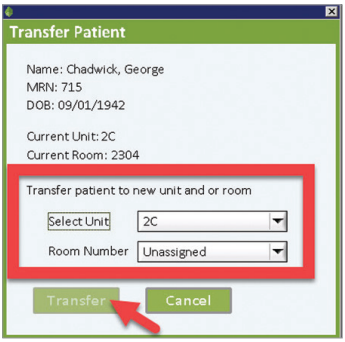


Figure 31: Transfer Patient Pop-Up Window

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.

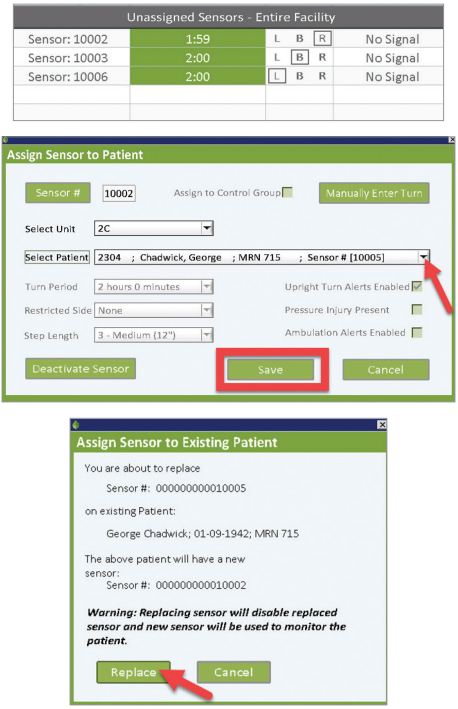


Figure 32: Unassigned Sensor Display from Home Menu (top), Assign Sensor Pop-Up Window (middle) and Assign Sensor to Existing Patient Pop-Up Window (bottom)

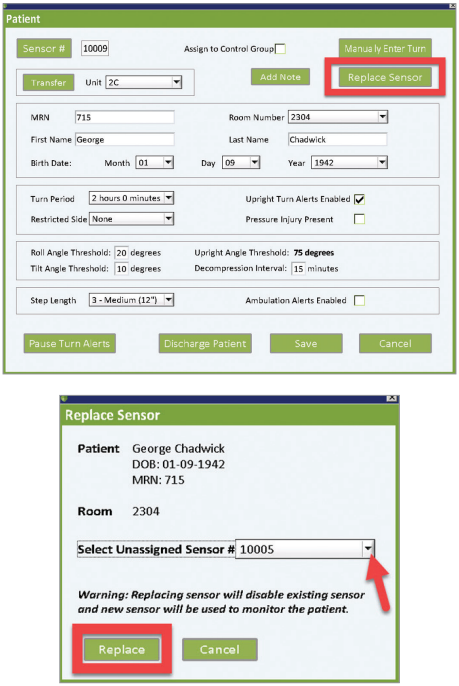


Figure 33: Patient Pop-up Window (top) and Replace Sensor Pop-Up Window (bottom)

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.

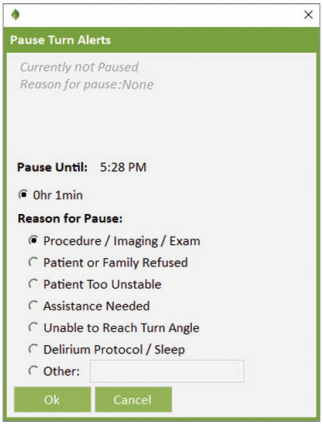


Figure 34: Pause Turn Alerts Pop-Up Window

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.

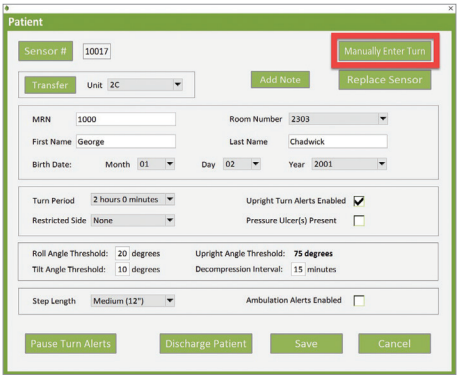


Figure 35: Manually Enter Turn Button

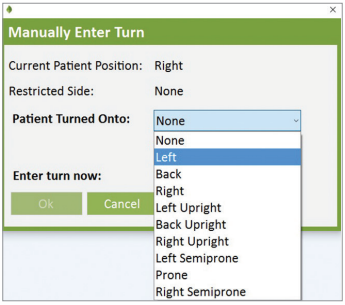


Figure 36: Manually Enter Turn Pop-Up Window

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.

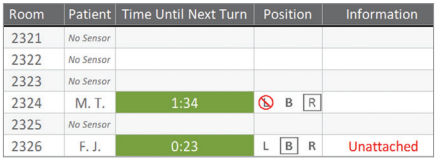


Figure 37: "Unattached" message after sensor has been removed or has come loose.

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.

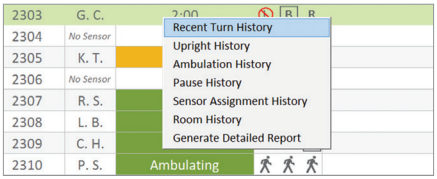


Figure 38: Patient history options menu accessed on home screen accessed via right-click.

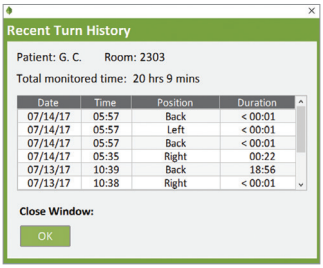


Figure 39: Recent Turn History Pop-Up Window

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. The Generate Detailed Report Pop-Up Window will generate and display a full detailed PDF report of the patient.

P. Viewing Recent System Activity

Recent System Activity like Sensor Activation, Sensor Assignment, Sensor Unassigned, Sensor Replaced on Patient, Patient Transfer and, Patient Discharge can be viewed by clicking the “Recent Activity” button located on the left side panel.

System Activity for the past 24 hours will be shown in this panel.

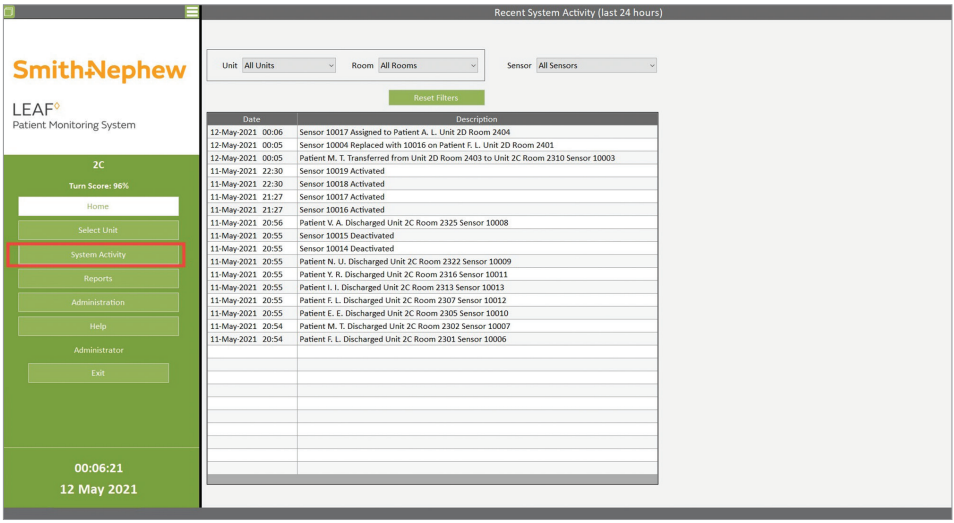


Figure 40: Recent System Activity

Q. 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.

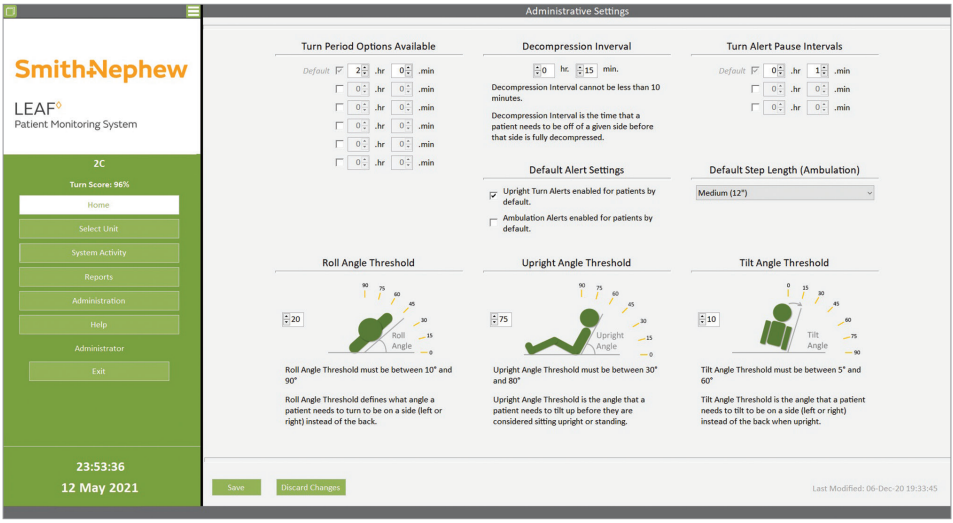


Figure 41: Administrative Settings Screen

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: 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.

R. 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.

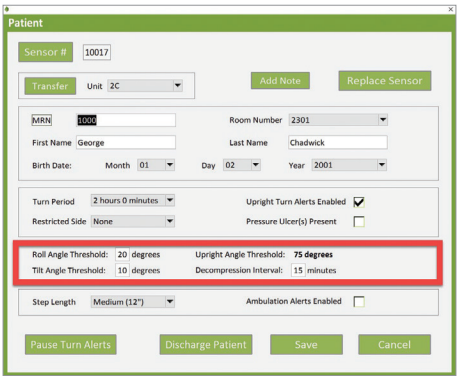


Figure 42: Patient Pop-Up Window

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.

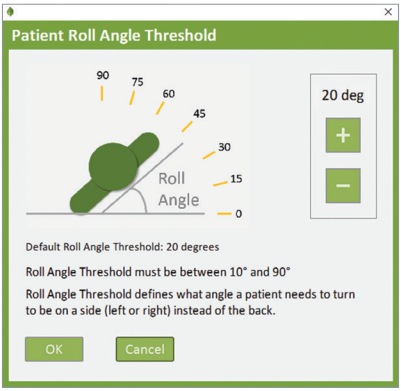


Figure 43: Patient Roll Angle Threshold Pop-Up Window

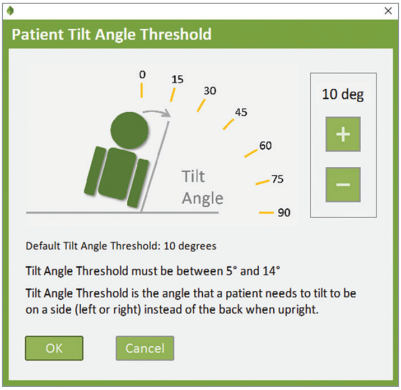


Figure 44: Patient Tilt Angle Threshold Pop-Up Window

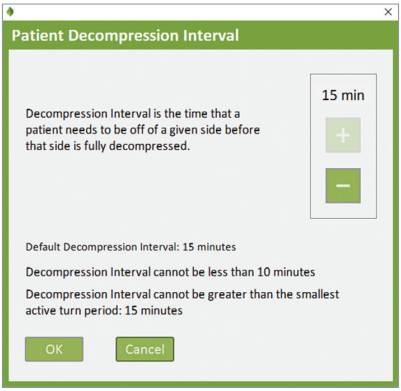


Figure 45: Patient Decompression Interval Pop-Up Window

S. Patient Notes (Optional)

According to institution preferences, 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.

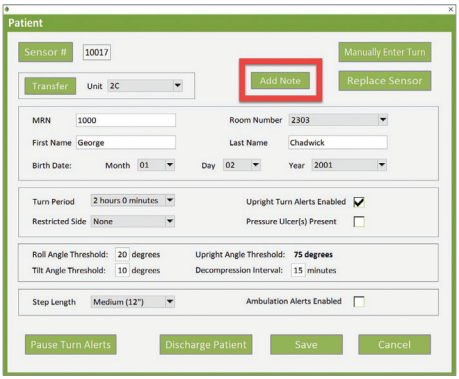


Figure 46: Patient Pop-Up Window

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.

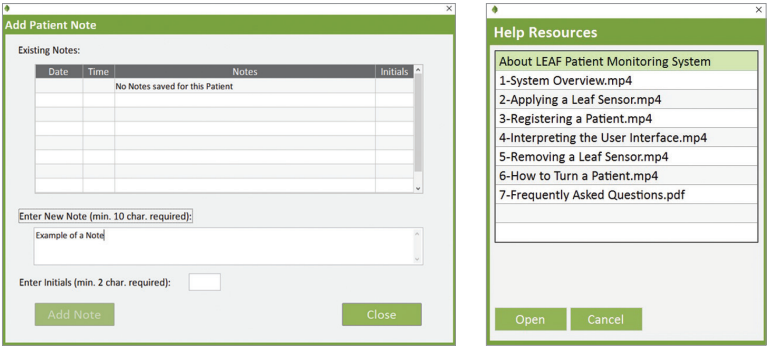


Figure 47: Add Patient Note Pop-Up Window and Help Resources Pop-Up Window

Where the LEAF Patient Monitoring System is configured not to allow patient notes, the Add Patient Note option will not be present.

T. 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.

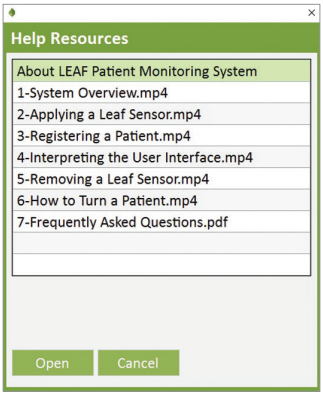


Figure 48: Help Resources Pop-Up Window

U. Reports

If the LEAF 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.

V. 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.

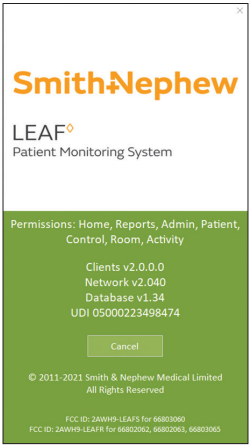


Figure 49: About LEAF Patient Monitoring System Pop-Up Window

W. Side Panel Buttons

The Side Menu Button and the Minimize / Maximize Button are located in the upper left hand corner of the application.

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.

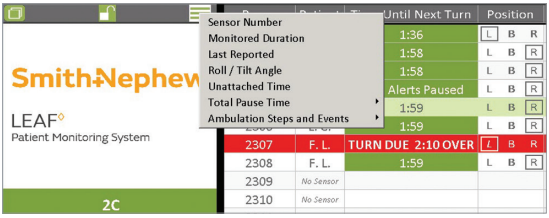


Figure 50: Side Menu Button

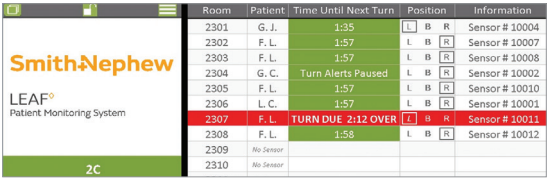


Figure 51: Sensor Serial Number Displayed using Side Menu Button

For example, to view Ambulation Steps and Events, click on the Side Menu and select Ambulation Steps and Events from the pop-up menu and select “Today” or “Yesterday” to view the results.

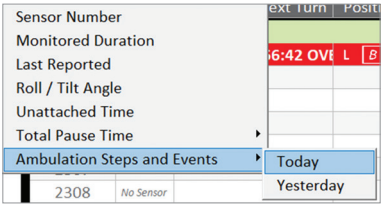


Figure 52: Ambulation Steps and Events Displayed using Side Menu Button

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.

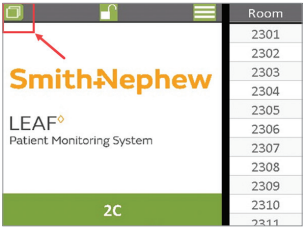


Figure 53: Minimize Button

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.

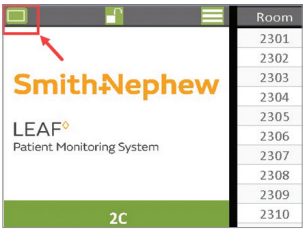


Figure 54: Maximize Button

X. User Authentication Mode (Optional)

User Authentication Mode is an optional feature which may be enabled by the customer's Information Technology team. When the application has User Authentication Mode enabled, the lock icon will be displayed.

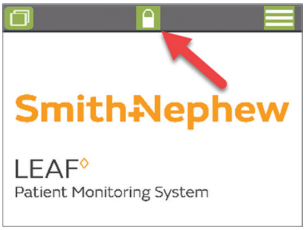


Figure 55: Lock Icon Closed

Once a user has authenticated, the Lock Icon will be displayed as open. If the Lock Icon is displayed as closed, click on the Lock Icon to access additional features. When the Authentication Required window opens, enter the username and password and click on the Authenticate button.

Figure 56: Authentication Window

When a user has entered their username and password and has been authenticated to access the detailed screens showing patient turn records, the Lock Icon will be displayed as open.

Figure 57: Lock Icon Open

Y. Exiting the LEAF Patient Monitoring Software and User Interface

To exit the LEAF Patient Monitoring Software and User Interface, click the Exit Button on the side panel.

Z. 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 Existing Patient Pop-Up Window.

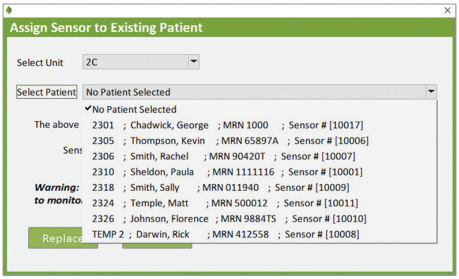


Figure 58: Select Patient Drop-down Menu

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.

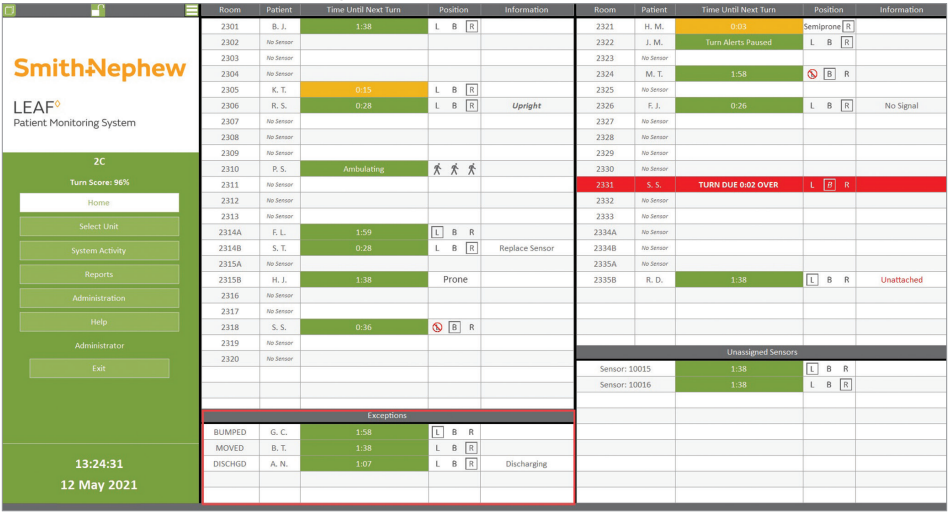


Figure 59: Home Screen – Exceptions Table

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.

AA. 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.

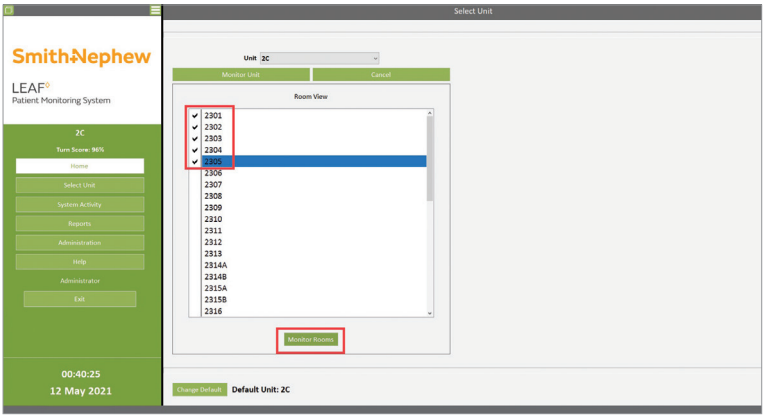


Figure 60: Select Unit Screen with Room View Selection Box

Figure 61: 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.

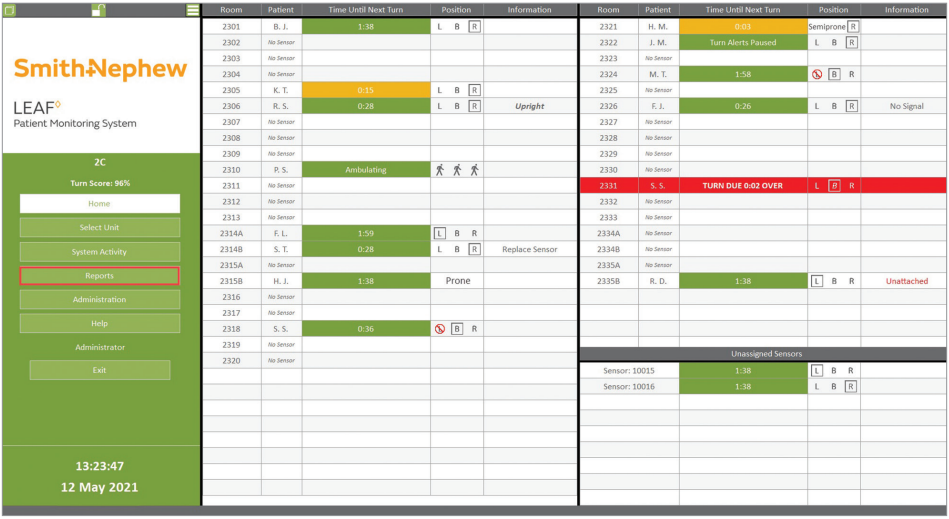


Figure 62: Reports Button

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.

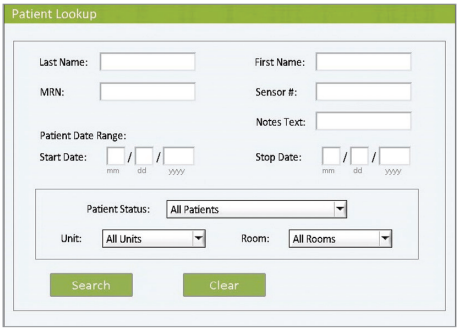


Figure 63: Reporting Tool and the Patient Lookup Screen

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. If a search field is left blank, the patient report search will not be filtered by that search criteria . 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.

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.

MRN: Users can enter the patient's full Medical Record Number (MRN) or as many characters as are known for the 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. .

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.

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

There are two possible search result exceptions 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.

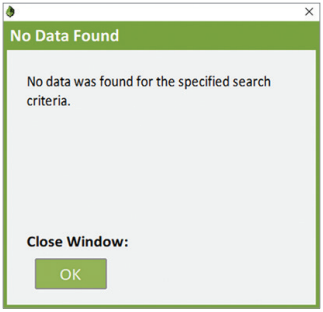


Figure 64: No Data Found Popup Window

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".

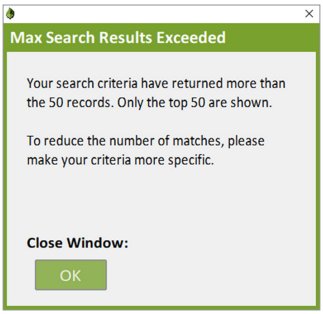


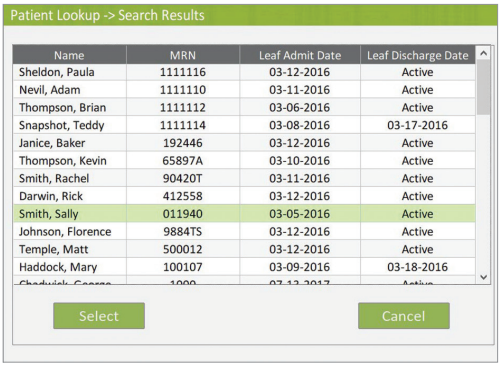
Figure 65: Max Search Results Exceeded Popup Window

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.



Name	MRN	Leaf Admit Date	Leaf Discharge Date
Sheldon, Paula	1111116	03-12-2016	Active
Nevil, Adam	1111110	03-11-2016	Active
Thompson, Brian	1111112	03-06-2016	Active
Snapshot, Teddy	1111114	03-08-2016	03-17-2016
Janice, Baker	192446	03-12-2016	Active
Thompson, Kevin	65897A	03-10-2016	Active
Smith, Rachel	90420T	03-11-2016	Active
Darwin, Rick	412558	03-12-2016	Active
Smith, Sally	011940	03-05-2016	Active
Johnson, Florence	9884TS	03-12-2016	Active
Temple, Matt	500012	03-12-2016	Active
Haddock, Mary	100107	03-09-2016	03-18-2016

Figure 66: 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.

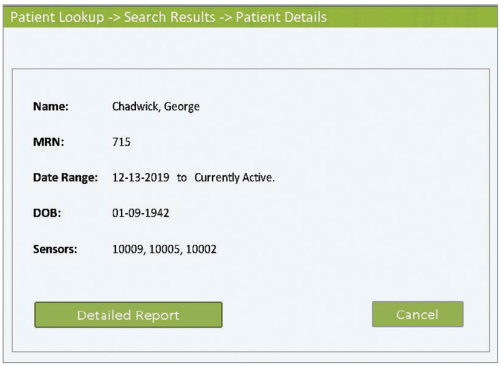


Figure 67: Patient Report Screen

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.

Generated by: Leaf Reporting Tool v 1.4.0

Smith+Nephew

LEAF◊
Patient Monitoring System

Report Generated: 08-13-2021 01:16

Patient Information:

Name:	LAST_NAME, FIRST_NAME
MRN:	123456
Start Date:	08-10-2021 00:04
End Date:	Patient is currently active.
Patient Status:	Active
Unit:	2C
Room:	2310

Turn Protocol Settings Used For Calculations:

Tilt Angle Threshold:	10	**Decompression Interval:**	00:15
Roll Angle Threshold:	20	**Turn Period:**	02:00
Upright Angle Threshold:	50		
Prone Roll Angle Threshold:	30		
Prone Threshold Angle:	120		

Summary:

Total Turns:	50
Total Monitored Time:	73:12
Total Time Upright:	31:44
Total Time Prone:	14:01
Total Time Patient Movement:	00:00

Total Time on:

Left:	10:00	(13.6 %)	**Left Upright:**	09:00	(12.2 %)
Back:	08:10	(11.1 %)	**Back Upright:**	09:09	(12.5 %)
Right:	09:17	(12.6 %)	**Right Upright:**	13:35	(18.5 %)

Left Semiprone:	03:00	(04.0 %)
Prone:	09:01	(12.3 %)
Right Semiprone:	02:00	(02.7 %)
Total Time Ambulating:	00:00	(00.0 %)

MRN: 123456

Page 1 of 4

Figure 68: Page 1 of an example Detailed Patient Report PDF

Generated by: Leaf Reporting Tool v 1.4.0

Patient Data:

Date	Time	Orientation	Duration	Notes
		Default Settings at Time of Sensor Activation		
			Turn Period: 00:15	
			Decompression Interval: 00:15	
			Roll Angle Threshold: 20°	
			Tilt Angle Threshold: 10°	
			Upright Angle Threshold: 75°	
			Prone Roll Angle Threshold: 30°	
			Prone Threshold Angle: 120°	
			Upright Alerts: On	
			Ambulation Alerts: On	
			Step Length: 18"	
08-10-2021	00:04	Back	00:10	
	00:10	Patient Registered	Name: LAST_NAME, FIRST_NAME	
			DOB: 03-14-1975	
			MRN: 123456	
			Room: 2310 Unit: 2C	
			Restricted Side: None	
			Turn Period: 02:00	
			Decompression Interval: 00:15	
			Roll Angle Threshold: 20°	
			Tilt Angle Threshold: 10°	
			Upright Angle Threshold: 75°	
			Prone Roll Angle Threshold: 30°	
			Prone Threshold Angle: 120°	
			Pressure Ulcer: NOT Present.	
			Upright Alerts: On	
			Ambulation Alerts: On	
			Step Length: 18"	
	00:14	Right	01:00	
	01:14	Left	01:00	
	02:14	Back - Upright	01:08	
	03:23	Left - Upright	01:00	
	04:23	Right - Upright	02:01	
	06:24	Left	01:00	

MRN: 123456

Page 2 of 4

Figure 69: Page 2 of an example Detailed Patient Report PDF

Generated by: Leaf Reporting Tool v 1.4.0

Date	Time	Orientation	Duration	Notes
	07:24	Right - Upright	01:03	
	08:27	Prone	01:00	
	09:28	Left	01:00	
	10:28	Left Semiprone	01:00	
	11:28	Prone	01:00	
	12:28	Right Semiprone	01:00	
	13:28	Left	01:00	
	14:28	Back	01:00	
	15:28	Right	01:16	
	16:45	Left	01:00	
	17:45	Back	01:00	
	18:45	Right	01:00	
	19:45	Left - Upright	01:00	
	20:45	Back - Upright	01:00	
	21:45	Right - Upright	01:00	
	22:45	Left	01:00	
	23:45	Back	01:00	
08-11-2021	00:45	Right	01:00	
	01:45	Left - Upright	01:00	
	02:45	Back - Upright	02:00	
	04:45	Right - Upright	01:00	
	05:45	Left	01:00	
	06:45	Back	01:00	
	07:45	Right	01:00	
	08:45	Left - Upright	02:00	
	10:45	Back - Upright	01:00	
	11:45	Right - Upright	01:07	
	12:53	Left Semiprone	02:00	
	14:53	Prone	01:00	
	15:53	Right Semiprone	01:00	
	16:53	Left	01:00	
	17:53	Back	02:00	
	19:53	Right	02:00	
	21:53	Left - Upright	02:00	
	22:28	Modified Setting	Upright Angle Threshold: 50°	
	23:53	Back - Upright	02:00	
08-12-2021	01:53	Right - Upright	01:00	
	02:53	Left	02:00	
	04:53	Back	02:00	
	06:53	Right	02:00	

MRN: 123456

Page 3 of 4

Figure 70: Page 3 of an example Detailed Patient Report PDF

Generated by: Leaf Reporting Tool v 1.4.0

Date	Time	Orientation	Duration	Notes
	08:53	Prone	06:00	
	14:53	Left - Upright	02:00	
	16:53	Back - Upright	02:00	
	18:53	Right - Upright	06:23	
End of Report				

MRN: 123456

Page 4 of 4

Figure 71: Page 4 of an example Detailed Patient Report PDF

DEVICE LABELS

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

LEAF Patient Sensor Labels

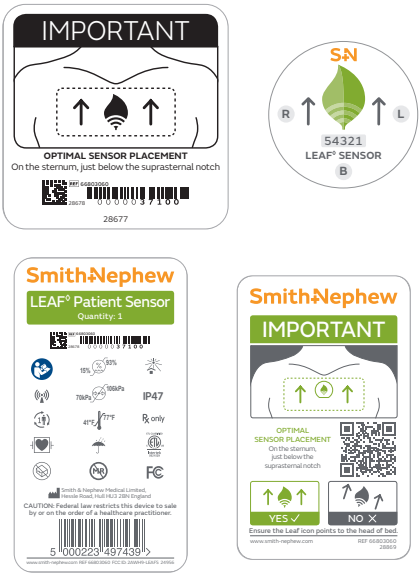


Figure 72: LEAF Sensor Labels

LEAF Relay Antenna Labels

Figure 73: LEAF Relay Antenna Labels

For the full list of LEAF S+N SKU numbers see page 75.

TAKING CARE OF THE DEVICE

Cleaning Instructions

The LEAF Patient Sensor may be subject to basic cleaning according to institutional protocol. DO NOT clean the LEAF Patient Sensor with acetone.

Washing and Bathing

Patients may shower and engage in other daily activities while the Patient Sensor is attached. The sensor should not be submerged under water.

Storage of Sensors

Unused Patient Sensors should be stored in accordance with the storage information stated on the sensor packaging.

Sensors temporarily removed from patients should be kept where they will not become contaminated or mixed with unused sensors.

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 Lithium coin cell non-rechargeable 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, which is typically up to 21 days. The device is designed for single patient multiple use. If the sensor needs to be removed from a patient temporarily follow instructions on “Removing the LEAF Patient Sensor”, to reapply the sensor follow instructions for “Re-Applying the Patient Sensor. There are no parts that need to be replaced. The Patient Sensor is working properly if it functions as described in this booklet.

SUMMARY OF ALERTS

The alerts displayed by the system and the actions that will resolve the alerts 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.
- **No Signal Alert**
  - 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.
  - Action That Will Resolve Alert: 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.

- 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 Relay Antenna.
- If the patient is still physically located on the unit, add a LEAF Relay Antenna closer to the patient. If this resolves the alert, the original distance to the patient was too far or something was preventing the Patient Sensor from communicating with a LEAF Relay Antenna. If the alert is not resolved, the sensor battery may be depleted in which case the user needs to replace the sensor.

▪ **Replace Sensor Alert**

- 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**

- 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**

- 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.
- 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**

- 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.

- Action That Will Resolve Alert: When the system determines the patient is no longer ambulating the alert will expire and disappear.

- **Turn Score**
  - 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, Smith+Nephew Customer Service should be contacted.

- **Home Screen Warning**
  - 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 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.”

- Action That Will Resolve Warning: The LEAF User Interface can be restarted. If the problem persists, Smith+Nephew 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**
  - 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**
  - If a user tries to perform an action on a discharged patient, a pop-up window with the following message appears: “Selected Patient is no longer available. Patient has been discharged.”
  - 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.”
  - Action That Will Resolve Warning : Warning will be resolved when Warning Window is closed by the user.
- **Unassigned Sensor Warning**
  - 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: Warning will be resolved when Warning Window is closed 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.
  - Action That Will Resolve Alert: Assign patient a unique MRN or to an available room.
- **Administrative Settings Out of Range Alert**
  - If a user sets an Administrative Setting that is outside of the restricted range and attempts to save these changes a pop-up window will be opened alerting the user. This 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).
  - 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.
  - 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."

- 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."

- 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**

- 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."

- Action That Will Resolve Alert: The user can choose to save or discard changes.

- 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."

- Action That Will Resolve Alert: Alert will be resolved when Alert Window is closed by the user.

▪ **HL7 Associated Alerts**

- 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.

- 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 Smith+Nephew Customer Service.

- **HL7 Automatic Discharge Alert**
  - 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”
  - Action That Will Resolve Alert: No action is required by the user, the alert will resolve itself.
- **Too many search results**
  - 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.
  - 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 Smith+Nephew Customer Service.
- **No Data Found**
  - 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”.
  - 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 Smith+Nephew 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 Smith+Nephew 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 Relay Antenna or a LEAF USB 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 Relay Antenna.	Check to be sure that you are within 10 feet (3 meters) of a LEAF Relay Antenna. When the LEAF Patient Monitoring System was installed, LEAF Relay Antennas should have been placed within 10 feet (3 meters) 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 (3 meters) of the LEAF Relay Antenna and check to see if this causes the LED lights to start blinking.
	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 Smith+Nephew 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 Relay Antenna has not been found by the Patient Sensor.	If three solid green lights are displayed on the Patient Sensor, then the Patient Sensor has been turned on, but a LEAF Relay Antenna has NOT been found. Make sure that the Patient Sensor is within 10 feet (3 meters) of a LEAF Relay 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 or has been removed.	If the sensor has fallen off, it can be re-applied to the patient and secured with a suitable medical grade film.
	Patient sensor not oriented correctly on the patient.	Ensure sensor is aligned correctly on patient, with the leaf on the sensor pointing towards the patient's head and aligned with 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 Relay Antenna.	Verify that the patient is still physically located on the unit. If the patient has been taken off the unit for an exam or other procedure, monitoring will automatically resume when the patient returns to the unit and the sensor is within range of a LEAF Relay Antenna.
	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.	If the sensor has fallen off but is still working, it can be re-applied to the patient and secured with a suitable medical grade film.
	Sensor has stopped working.	Replace the patient sensor. Be sure to assign the new patient sensor to the patient in the LEAF User Interface.
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 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.

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.

GLOSSARY

The following signs and symbols are present on the immediate packaging of the Patient Sensor, as shown in Figure 74.

	Manufacturer		Defibrillation Proof Type CF Applied Part
	Date of Manufacture	Rx only	Prescription Only
	Consult Instructions for Use	IP47	Sensor protected against small objects, showering and temporary immersion
ETL CLASSIFIED Intertek 5021529	Safety Agency Mark	MR	MR Unsafe
	Use-By-Date		RF Transmitter
1	Single Patient Multiple Use		Do Not Use if Package is Damaged
41°F 77°F	Transport and Storage Temperature		Keep Dry
15% 93%	Relative Humidity Limits		Keep Away From Sunlight
70kPa 106kPa	Atmospheric Pressure Limits	FC	Federal Communications Commission identifier

Figure 74: Patient Sensor Packaging Symbols

TECHNICAL SPECIFICATIONS

Compliance	Certified to: CSA STD C22.2 No 60601-1. Conforms to: ANSI/AAMI STD ES60601-1, IEC STD 60601-1-6. Evaluated to IEC STD 60601-1 and IEC 60601-1-2
Essential Performance	The LEAF Patient Monitoring System does not have Essential Performance
Electrical Voltage (LEAF USB Transceiver)	5 VDC
Electrical Voltage (LEAF Relay Antenna)	5V DC
Electrical Voltage (LEAF Relay Antenna Power Adapter)	100-240V ~ 50/60Hz, .18A, Output: 5.0V DC 1.0 A
Electrical Voltage (LEAF Patient Sensor)	3 VDC
LEAF Patient Sensor Power Source	Internally Powered - 1 fixed non-replaceable 3V, 285mAh Lithium coin tabbed/surface mounting battery. IEC 60086-4.
LEAF Patient Sensor Size	1.8” x 2.0”, adhesive extends to 2.4” to 3.4”
LEAF Patient Sensor Weight (max)	0.7 oz (20 g)
LEAF Patient Sensor Skin Adhesive Material	Silicon Adhesive
LEAF Patient Sensor Applied Part Type	Defibrillation Proof Type CF Applied Part
LEAF Patient Sensor Cover Material	Thermoplastic vulcanizate
Optimal Distance between LEAF Patient Sensor and LEAF Relay Antenna	15 feet (4.5 meters)
Wireless Transmission Protocol	IEEE 802.15.4 Compliant
Wireless Transmission Frequency	2.4 GHz
Ingress Protection (IP) Rating	IP47 for Patient Sensor, IP2X for LEAF Relay Antenna and LEAF USB Transceiver
Battery Use Life	Up to 21 days
Storage/Transport	32 to 77°F 15 to 93% relative humidity 700 to 1060 mbar atmospheric pressure
Operating Environment	50 to 97°F 15 to 93% relative humidity

Electromagnetic Compatibility
The LEAF Patient Monitoring System has been tested and found to comply with the limits for medical devices to IEC 60601-1-2. These limits are intended to provide reasonable safety regarding electromagnetic disturbances when the system is used in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation.

FCC Compliance Statements
The LEAF Patient Monitoring System complies with Part 15 of FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

These devices comply with the FCC's RF exposure limits for portable devices operated within 5mm (Sensor) and 20mm (Relay Antenna/USB Transceiver) of a person. The output power of these devices is below the level for which the FCC requires Specific Absorption Rate measurements.

Changes or modifications made to this equipment not expressly approved by Smith and Nephew may void the FCC authorization to operate this equipment.

Note: This equipment has also been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- In case of the power supplier of the Relay Antenna, connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

The field strength of radiated emission is below 150 microvolts/meter from 88 MHz to 13 GHz.

Guidance and Manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidelines
Electrostatic discharge IESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±6 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2kv for power supply lines	The LEAF Sensor is a battery powered device - Test Not Applicable	Not applicable
Surge IEC 61000-4-5	±1kv lines(s) to lines(s) ±2kv lines(s) to earth	The LEAF Sensor is a battery powered device – Test Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° phases 0% UT (100% dip in UT) for 0.5 cycle At 0° single phase 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 250 cycles 0% UT (100% dip in UT) for 300 cycles	The LEAF Sensor is a battery powered device – Test Not applicable	Not applicable
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m 50 or 60Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz In ISM and amateur radio bands	The LEAF Sensor is a battery powered device	Portable and mobile communications equipment should be separated from the device by no less than distances calculated/listed below: **Recommended separation distance:** $d = 0.58 \sqrt{P}$
Radiated RF IEC 61000-4-3	10V/m 80MHz to 2.7GHz IEC 60601-1-2:2014 Table 9	10V/m 80MHz to 2.7GHz IEC 60601-1-2:2014 Table 9	$d = 0.175 \sqrt{P}$ (80 MHz to 800 MHz) $d = 0.35 \sqrt{P}$ (800 MHz to 2.7 GHz)

NOTE 1: At 80MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the LEAF System is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m. Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol:

Guidance and Manufacturer's declaration – electromagnetic emissions

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

Emissions test	Compliance	Electromagnetic environment – guidelines
RF emissions CISPR 11.	Group 1.	The 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 interference in nearby electronic equipment.
RF emissions CISPR 11.	Class B.	The LEAF Patient Monitoring System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2.	Not applicable.	
Voltage fluctuations/flicker emissions. IEC 61000-3-3.	Not applicable.	

WARNING: The system should not be used adjacent to or stacked with other electrical equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used. Do not use accessories other than those specified or sold by Smith & Nephew as it may result in increased electromagnetic emissions or decreased electromagnetic immunity of the LEAF Patient Monitoring System. Portable and mobile RF communication devices (mobile telephones) can affect the system.

Recommended separation distances between portable and mobile RF communications equipment and the LEAF Patient Monitoring System.

The LEAF Patient Monitoring System is intended for use in an electromagnetic environment in which radiated RF disturbances are uncontrolled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be no closer than 30cm (12 inches) to any part of the system. Otherwise, degradation of the performance of this equipment could result.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150kHz to 80MHz $d = 0.58\sqrt{P}$	80MHz to 800MHz $d = 0.175\sqrt{P}$	800MHz to 2.7GHz $d = 0.35\sqrt{P}$
0.01	N/A	0.02	0.03
0.1	N/A	0.05	0.1
1	N/A	0.2	0.3
10	N/A	0.5	1.1
100	N/A	1.7	3.5

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

NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

S+N SKU	Description	FCC ID
66803060	LEAF Patient Sensor, Box 10	2AWH9-LEAFS
66802062	Assy, Relay Antenna	2AWH9-LEAFR
66803065	Assy, Relay Antenna, Modular	2AWH9-LEAFR
66802063	Assy, USB Transceiver	2AWH9-LEAFR

Smith+Nephew

Smith & Nephew Medical Limited,
101 Hessle Road, Hull, HU3 2BN England

◊Trademarks of Smith+Nephew
©2021 Smith+Nephew
All rights reserved.

Customer Service

Toll Free: 1-844-826-LEAF (5323)

Clinical Support: Leaf.ClinicalSupport@smith-nephew.com
IT Support: Leaf.ITSupport@smith-nephew.com

(01)05000223498382(240)28962

This product may be covered by one or more US Patents.
See: www.smith-nephew.com/patents

28962 Revision: 12/2021