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.

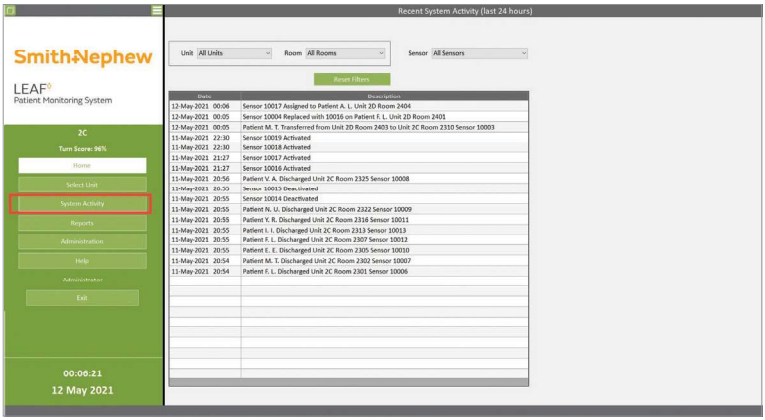

Figure 40: Recent System Activity

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.

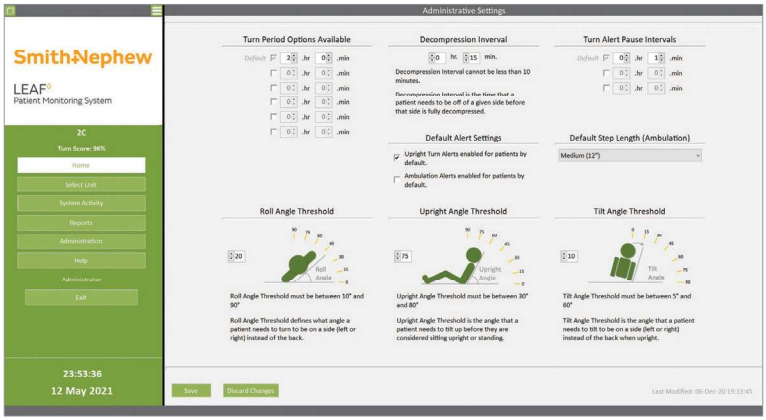

Figure 41: Administrative Settings Screen

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:

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

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.

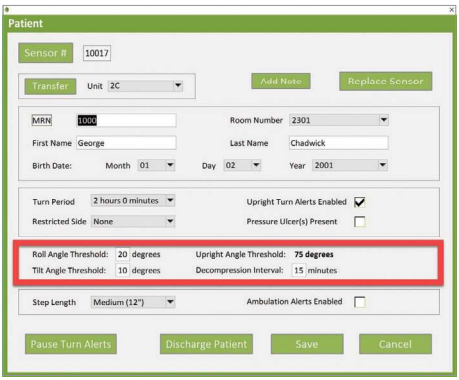

Figure 42: Patient Pop-Up Window

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.

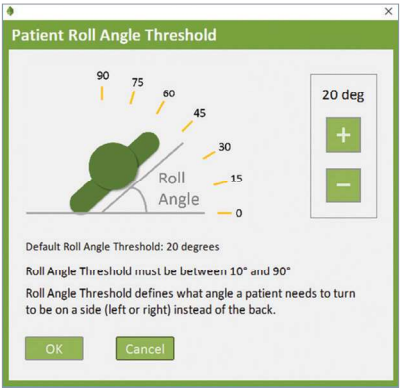

Figure 43: Patient Roll Angle Threshold Pop-Up Window

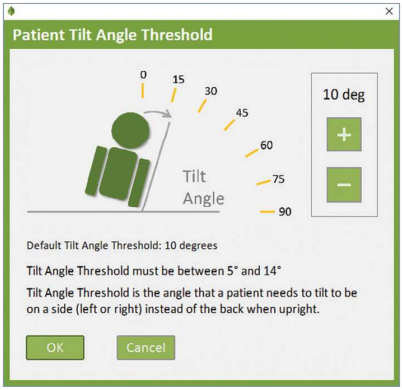

Figure 44: Patient Tilt Angle Threshold Pop-Up Window

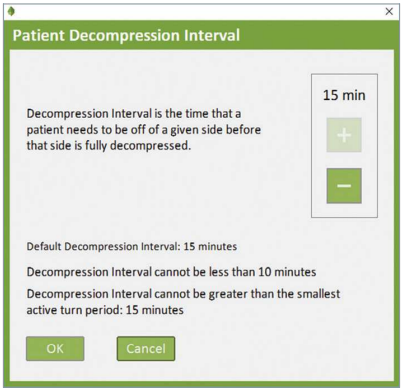

Figure 45: Patient Decompression Interval Pop-Up Window

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.

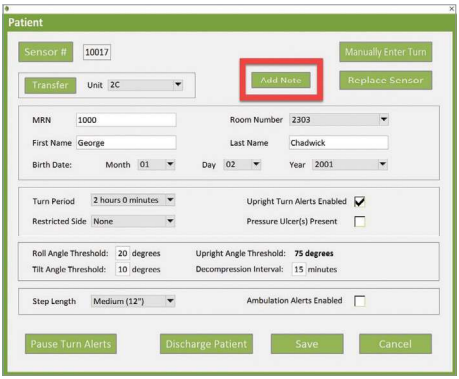

Figure 46: Patient Pop-Up Window

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.

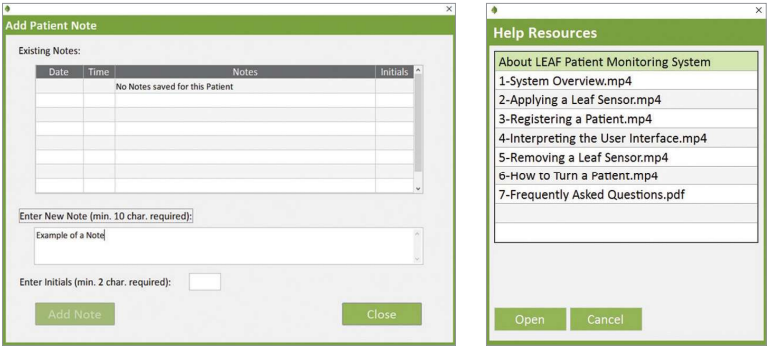

Figure 47: Add Patient Note Pop-Up Window and Help Resources Pop-Up Window

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.

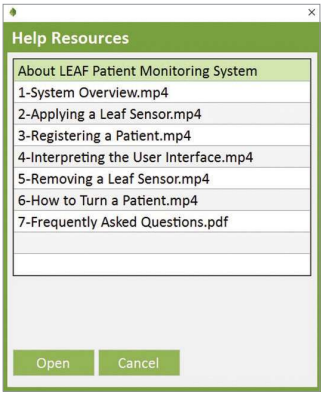

Figure 48: Help Resources Pop-Up Window

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.

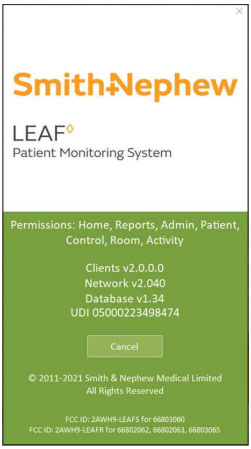

Figure 49: About LEAF Patient Monitoring System Pop-Up Window

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.

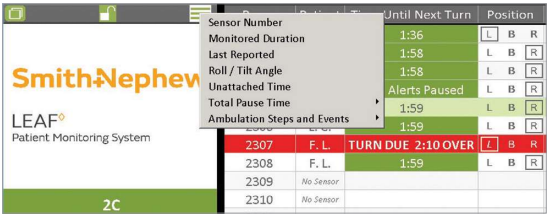

Figure 50: Side Menu Button

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.

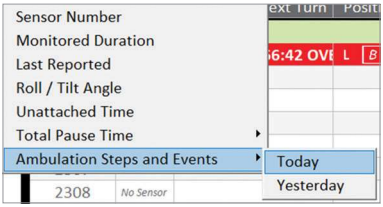

Figure 52: Ambulation Steps and Events Displayed using Side Menu Button

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.

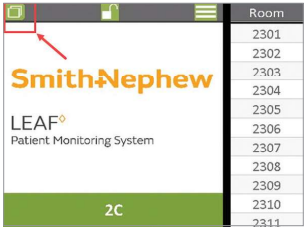

Figure 53: Minimize Button

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.

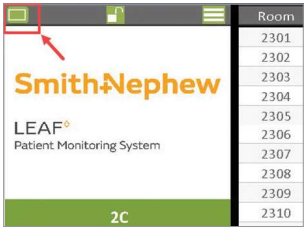

Figure 54: Maximize Button

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.

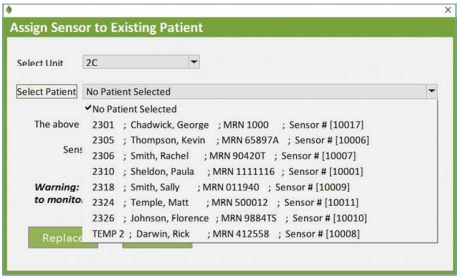

Figure 58: Select Patient Drop-down Menu

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.

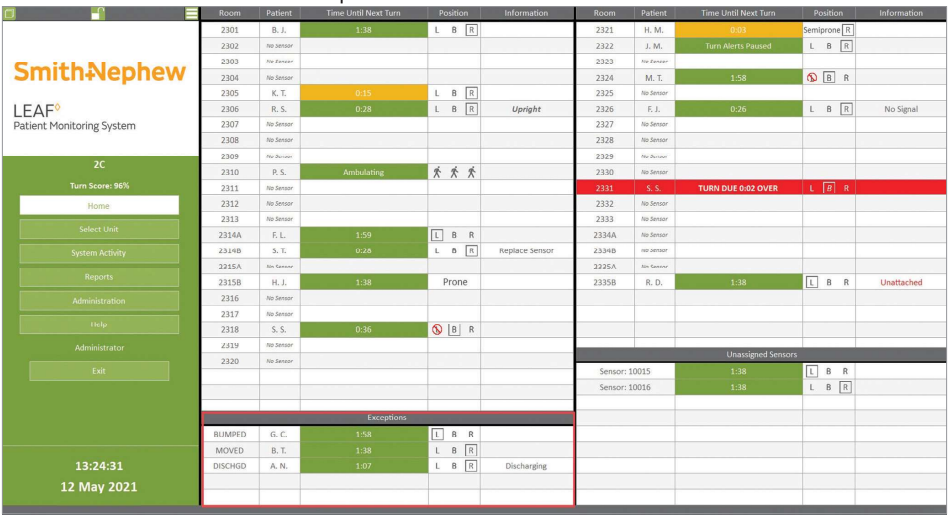

Figure 59: Home Screen – Exceptions Table

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.

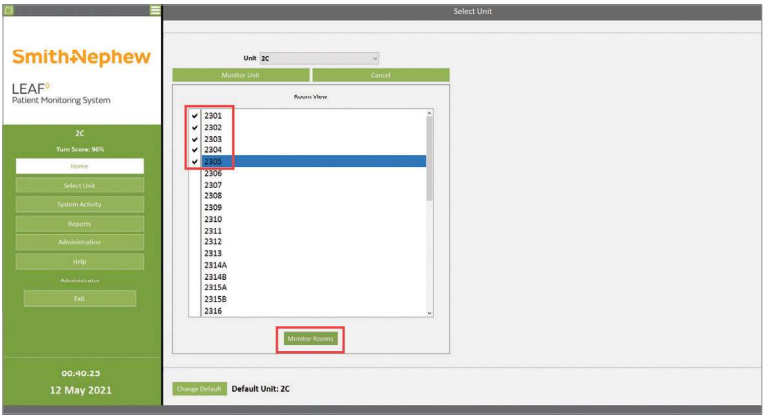

Figure 60: Select Unit Screen with Room View Selection Box

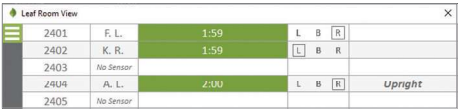

Figure 61: Room View Pop-up Window

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.

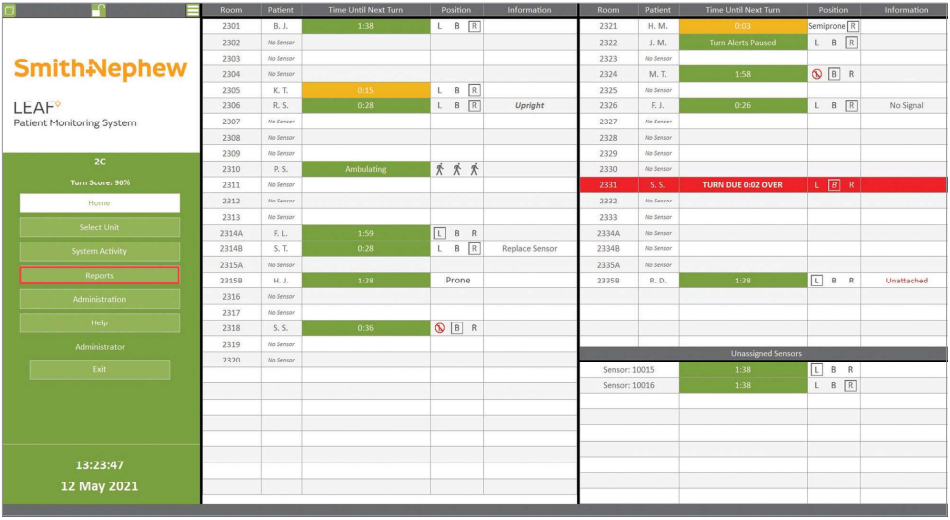

Figure 62: Reports Button

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.

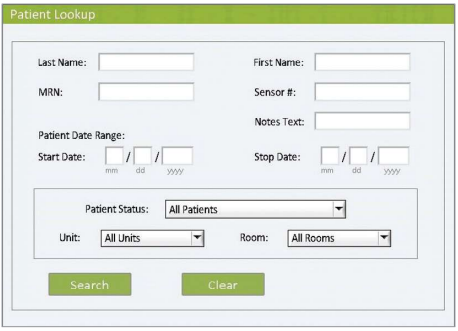

Figure 63: Reporting Tool and the Patient Lookup Screen

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.

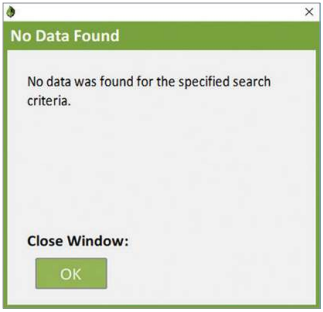

Figure 64: No Data Found Popup Window

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".

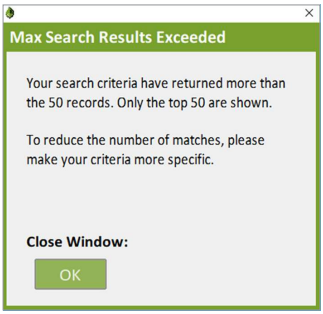

Figure 65: Max Search Results Exceeded Popup Window

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.

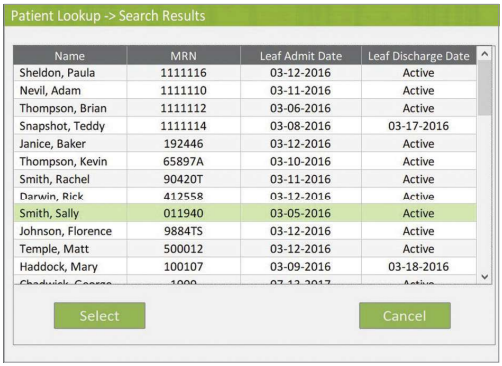

Figure 66: Search Results Screen

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	

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

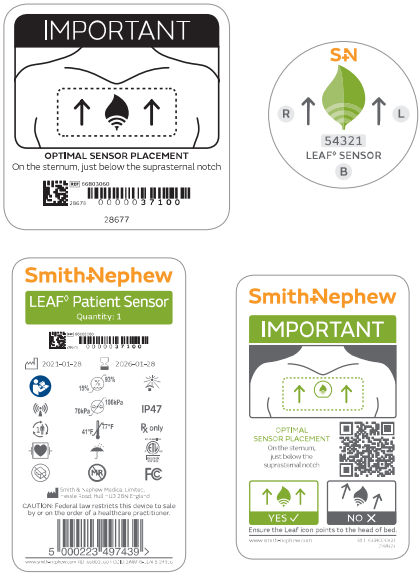

Figure 72: LEAF Sensor Labels

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
	Safety Agency Mark	MR	MR Unsafe
	Use-By-Date		RF Transmitter
	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 700 to 1060 mbar atmospheric pressure

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 (ESD) 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

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

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