

# Leaf Patient Monitor: Technical Description

A technical description of an orientation and activity monitor and alerting system for patients susceptible to pressure injuries.

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## Introduction

In US hospitals alone, more than 1 million patients develop pressure injuries each year. Pressure injuries cost US Hospitals approximately \$10B annually.<sup>1</sup> Since 2008, the Centers for Medicare and Medicaid Services (CMS) classified pressure injuries as a preventable Hospital-Acquired Condition (HAC) that will no longer be reimbursed by current insurance guidelines.<sup>2,3</sup> As such, hospitals now bear the burden of costs associated with hospital acquired pressure injuries and are motivated to find solutions for the prevention of pressure injuries.

## Objective

This paper describes a unique, wireless, distributed system for monitoring the orientation and activity of patients susceptible to pressure injuries. This system will alert caregivers when extended periods of time have passed while the patient remains in the same orientation.

## Summary

The Leaf Patient Monitor has been designed in such a way as to provide a cost effective, convenient and easy way for hospitals to supplement their manual systems for managing turn protocols used for the prevention of pressure injuries.

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### About This White Paper

This paper summarizes the technical attributes of the Leaf Patient Monitoring System. The Leaf Patient Monitor is a system that enables hospitals, long term care facilities (LTC), and nursing homes to wirelessly monitor the real-time orientation and activity of patients susceptible to pressure injuries; and to provide alerts when patient orientation or activity deviates from individualized turn management protocols set by the healthcare provider. This document is not intended to be a substitute for the Instructions for Use. Instead, it is a technical supplement that includes a detailed description of the system architecture and how the system works with the hope that it gives insight into how the system can be configured to accommodate various IT infrastructures and caregiver workflows. This paper is written for information technology (IT) specialists, biomedical engineers, administrators, and nursing supervisors who want a better understanding of the technical attributes of the system beyond what the Instructions for Use provides.

### Background

Pressure injuries, also known as decubitus ulcers or bedsores, are localized injuries to the skin and/or underlying tissue that usually occur over a bony prominence as a result of pressure, or pressure in combination with shear and/or friction.<sup>4</sup> They are surprisingly common; of the 37 million admissions to US hospitals each year, about 3.5% (about 1.3 million) will develop a pressure injury. Pressure injuries are also common in nursing and long term care (LTC) facilities and in the home setting.

In total, pressure injuries cost US hospitals about \$10B, annually. For a typical 500 bed hospital, the cost is over \$4M, annually.<sup>5</sup>

The degree of injury associated with a pressure injury varies from a non-blanchable red region of the skin that may or may not be painful, to full thickness tissue loss with exposed bone, tendon or muscle. The cost to treat these injuries also varies; however, the average cost of a pressure injury is more than \$5,000. In total, pressure injuries cost US hospitals about \$10B, annually. For a typical 500 bed hospital, the cost is over \$4M, annually.<sup>5</sup> This is largely due to the cost of extended hospital stays necessary to treat the condition, but other costs include the direct cost of treatment (healthcare provided procedures and necessary supplies), fines, and legal expenses. Since 2008, the Centers for Medicare and Medicaid Services (CMS) have classified pressure injuries as a preventable hospital-acquired condition (HAC) that is not reimbursed by current insurance guidelines.<sup>2,3</sup> As such, hospitals now bear the burden of costs associated with hospital acquired pressure injuries and so hospitals are now especially motivated to find solutions for the prevention of pressure injuries.

Between 30% and 50% of all hospital patients (about 11 million to 18 million) are placed on pressure injury prevention protocols annually. Pressure injuries primarily develop because caregivers fail to turn patients.

The cause of pressure injuries is the compression of tissue that occurs when pressure is applied to a body region for an extended period of time. This can happen if the mobility of patients is compromised due to sickness or injury. To avoid tissue damage, it is important that patients be turned onto different body regions at regular intervals. Most hospitals have manual turning protocols that require caregivers to assist in turning patients that do not turn on their own. Caregivers typically ensure patients placed on pressure injury prevention protocols are alternately turned between their left side, back, and right side approximately every two hours. Between 30% and 50% of all hospital patients (about 11 million to 18 million) are placed on pressure injury prevention protocols annually. Pressure injuries primarily develop because caregivers fail to turn patients. It is well accepted that hospital staff adherence with existing (manual) turn protocols is low.<sup>6</sup> Further, because of the caregiver time required to document and assist patients needing a turn, it is not cost-effective for hospitals to place all at risk patients on pressure injury prevention protocols. Campaigns to improve caregiver adherence with established turn protocols require continued attention or else improvements in adherence are only temporary.

The Leaf Patient Monitor is a wireless system for monitoring the orientation and activity of patients susceptible to pressure injuries. It enables caregivers to define customized turn protocols for each patient and notifies the caregiver when an assisted turn is required. The system received FDA clearance in August, 2013, with the following indications for use<sup>7</sup>:

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

There are many advantages in using the Leaf Patient Monitor as compared with traditional manual systems for managing turn protocols to prevent pressure injuries. The following sections describe in detail the design and technical specifications of the Leaf Patient Monitor so that these advantages become evident.

### Basic System Architecture and Use

The Leaf Patient Monitor is a distributed, wireless system comprised of four main components:

1. Leaf Patient Sensors
2. Mesh Network of Leaf Relay Antennas
3. Leaf Network Bridges, Mesh Network Software, and SQL Database
4. Leaf Turn Management Software

In typical use, the caregiver defines an individualized turn protocol for a patient that requires monitoring. A disposable, wireless, Leaf Patient Sensor is affixed adhesively to the patient's upper torso. The sensor makes measurements of the patient's orientation and communicates data in messages that it transmits to the wireless mesh network of Leaf Relay Antennas that has previously been setup in the facility. The mesh network relays the messages from the Patient Sensors to a Network Bridge having an RF to USB transceiver. Leaf Mesh Network Software, running on the Network Bridge, collects the patient data from the transceiver and sends the data to a SQL database for subsequent analysis. The patient's orientation and other patient related metrics can be determined from analysis of the data stored in the SQL database. Leaf Turn Management Software displays patient history and current patient status through a thick or thin client, depending on the desired implementation. The Turn Management Software also alerts staff if the patient requires a caregiver assisted turn and automatically documents the patient's turn history.

The sensor makes measurements of the patient's orientation and communicates data in messages that it transmits to the wireless, mesh network of Leaf Relay Antennas that has previously been setup in the facility.

A more complete description of each of the components is given below:

### Leaf Patient Sensor

The Leaf Patient Sensor is a single-use, disposable, wireless device that may be adhesively affixed to a patient's skin. The sensor itself is comprised of several key components: a 3-axis accelerometer to measure patient orientation and activity; a phototransistor that measures ambient light levels and turns on the device when the packaging and/or adhesive liner is removed; a capacitive contact sensor that enables the device to sense when it is attached to skin and sense when it is removed from skin; LED indicators to visually communicate information to the caregiver; a microcontroller for automated data collection, analysis, and storage; an RF radio for transmitting and receiving messages; and a coin-cell battery for providing electrical power. The skin contacting portion of the Patient Sensor is a polyurethane and polyethylene dressing having an acrylic adhesive.<sup>8</sup>

The Leaf Patient Sensor is a single-use, disposable, wireless device that may be adhesively affixed to a patient's skin.

The Patient Sensor is shipped in a heat-sealed, optically opaque pouch that is easily opened by the caregiver at the time of use. While in the packaging, the Sensor is not powered, and so the shelf life of the non-rechargeable battery within the device is expected to be several years. After removing the device from the packaging, the caregiver needs only to remove the adhesive liner from the back of the device, exposing the adhesive surface, and apply the device to the patient. Indicia on the Patient Sensor indicate the proper orientation of the device with respect to the patient. The device contains a photo-sensitive electronic circuit that detects ambient light when the device is removed from the packaging and when the adhesive liner is removed. The photo-sensitive circuit turns on the device when ambient light is detected. The device indicates that the Sensor has been powered up by illuminating three LEDs on the front side of the device for a brief period. Next the device will automatically attempt to join the wireless Leaf Mesh Network. The Patient Sensor will communicate with a nearby Relay Antenna having the strongest RF signal. The device indicates that the sensor has successfully joined the mesh network by scrolling the LEDs (repeatedly turning each LED on and then off in sequence). After successfully joining the RF network, the Patient Sensor spends most of its time in a very low power “sleep” mode. Every ten to thirty seconds, the Sensor briefly “awakens” to make measurements and transmit the measured data to a nearby Relay Antenna. Once affixed to a patient, the Sensor continues to make measurements every ten to thirty seconds until the battery is depleted over a period greater than about three weeks.

In addition to the phototransistor, two additional sensors reside within the Leaf Patient Sensor: a three-axis accelerometer and a capacitive contact sensor. The three axis accelerometer is a semiconductor device that is sensitive to accelerative forces, including gravitational forces, applied to the device. By sensing the direction in which gravity pulls on the device, the orientation of the device and thus the position of the patient can be determined. The capacitance sensor is located just inside the bottom surface of the device and is used to sense the change in capacitance that occurs when the device is affixed to a patient’s skin. The capacitance data may be used to determine if the device is attached to (or has become unattached from) the patient. If the device is not attached to the patient, then orientation measurements made by the Sensor cannot be trusted to correspond to the present orientation of the patient. The orientation and contact status of the Sensor are displayed by the User Interface of the Turn Management Software used by the caregivers.

When wearing the wireless Patient Sensor, the patient is unencumbered by wires or any type of umbilical. The Sensor is sealed so that a patient wearing the device may shower or bathe as usual. The patient is free to move about, in-bed, or out-of-bed. The skin-contacting portion of the device is a polyurethane and polyethylene dressing having an acrylic adhesive very commonly used to secure IV lines.<sup>8</sup> The patient may wear the device continuously for many days. It is expected that for nearly all patients, a single Leaf device will provide monitoring for the patient’s entire hospital stay.

The Patient Sensor may communicate wirelessly up to 75 feet or more to an available Relay Antenna. However, many structures in the environment (walls, cabinets, carts, and even the patient's own body) may reflect and/or attenuate the RF transmissions. Practically, it is best to have antennas positioned about every 25 feet to ensure that at least one Relay Antenna is within range of any patients wearing Sensors. As the patient moves about, the Patient Sensor may not be able to communicate with the Relay Antenna with which it was initially communicating. If this occurs, the Sensor will automatically begin communicating with a different, nearby Relay Antenna having the strongest RF signal. In this way, the Sensor will always stay connected to the wireless mesh network of Relay Antennas, selecting a new Relay Antenna with which to communicate as necessary. The messages and the patient data they contain will automatically find their way to the server computer and be stored in the SQL database, no matter which Relay Antenna is communicating directly with the Patient Sensor.

Each Patient Sensor has a unique 64-bit serial number that is assigned to the device during manufacture. When the Sensor is turned on and joins the wireless mesh network, it is assigned a much shorter network address by the Mesh Network Server Software, by which it is subsequently addressed. Since the Sensor knows no patient identifying data such as patient name or patient electronic medical record number, the data transmitted by the Sensor is anonymous and obviates any concern about data security on the wireless network.

### Mesh Network of Relay Antennas

The Leaf Patient Monitoring System uses a proprietary wireless local area network (WLAN) to relay messages between the Patient Sensors and the Leaf Network Bridges running the Mesh Network Server Software. The proprietary WLAN is distinct from the facility's Wi-Fi network (discussed further below) and is comprised of many Relay Antennas that are plugged into available power outlets within the facility where patients are being monitored. The Relay Antennas are unobtrusive, being about the size of a deck of playing cards. The Relay Antennas communicate with each other via radio frequency (RF) transmissions. Each Relay Antenna communicates with multiple nearby Relay Antennas to form a mesh, or web-like, connection of antennas. Messages sent to or from Patient Sensors over the mesh network are relayed from the source to the destination by sequentially hopping from one Relay Antenna to the next.

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Typically, about 1.5 antennas are required for each bed being monitored, or about one antenna at least every 25 feet. A single mesh network can be composed of hundreds of relay antennas. Further, multiple mesh networks can be configured within a single facility. Physically separate mesh networks (different wings of the same facility or even mesh networks in different facilities) can be logically treated as a single network by the Leaf Patient Monitor System. In this way, nursing units, hospitals, and even hospital chains can be monitored as if they were a single network, if desired. The web-like architecture of the mesh network ensures there are redundant pathways between the sensor and server. If a Relay Antenna is

broken, removed, or obscured by equipment, cabinets, walls, or people, then messages will be automatically routed around the non-functioning antenna via one of the other redundant pathways. The route used to relay a message between the source and destination is determined cooperatively by the individual antennas that make up the mesh network, selecting a route having a combination of good RF signal strength and few hops. No intervention by the caregiver or IT staff of the facility is required when individual Relay Antennas are temporarily non-functional. When the Relay Antenna again becomes functional, it will automatically rejoin the mesh network and routes between the server and Patient Sensors will automatically be re-optimized. In this way, the mesh network is “self-assembled” and “self-healing”.

Even so, software tools to help administer the mesh network are provided to enable IT staff to have confidence the system is working properly and to diagnose problems if they arise. The Relay Antennas that make up the mesh network are designed to transmit status reports on regular intervals. Software monitoring the network can be configured to send email or text alerts to network administrators when Relay Antennas do not send status messages as expected on regular intervals (as would happen if a Relay Antenna was broken or removed). This makes maintenance of the network simple, requiring no manual monitoring—automatically identifying for the staff exactly where problems may exist.

The network over which the Patient Sensors and Relay Antennas communicate is conformant with the physical layer specifications proscribed by the 802.15.4 wireless standard.<sup>9</sup>

The network over which the Patient Sensors and Relay Antennas communicate is conformant with the physical layer specifications proscribed by the 802.15.4 wireless standard.<sup>9</sup> The 802.15.4 wireless standard defines a low-power wireless network architecture especially well-suited for battery powered devices and is the network on which the more commonly referenced Zigbee communication protocol is based. The Leaf Patient Monitoring System does not use the Zigbee communication protocol; however, conformance with the Physical Layer of 802.15.4 ensures that the Leaf Patient Monitor can coexist, without interference, with Zigbee Systems and any other 802.15.4 based systems that are conformant with the physical layer specifications of the 802.15.4 standard. This means that multiple 802.15.4 systems can be used simultaneously in the same physical location, even on the same 802.15.4 channel, without interfering with each other, as long as bandwidth (maximum data through-put) limitations are not reached. The maximum bandwidth of 802.15.4 systems, as established by the standard, is 250 kb/s, although the practical limit is below 200 kb/s.

The Leaf Relay Antennas and Leaf Patient Sensors have undergone extensive testing and are certified by the Federal Communication Commission (FCC).<sup>10</sup> The RF transmissions made by the Relay Antennas and Patient Sensors of the Leaf Patient Monitor are at a frequency of about 2.4 GHz and are within the industrial, scientific and medical (ISM) radio bands reserved internationally for the use of radio frequency (RF) energy for industrial, scientific and medical purposes other than telecommunications.<sup>11</sup> US regulations require that low power communication devices operating within the ISM bands must accept interference from users of that frequency band, and the device must not cause harmful interference to

other users.<sup>12</sup> The ISM band is employed by other RF systems, including 802.11 (Wi-Fi) systems, Bluetooth (formerly 802.15.1), some cordless phones, and other equipment like microwave ovens and RF heaters. However, since the 802.15.4 standard was developed more recently, it addressed interference concerns with existing RF systems operating in the ISM band, and 802.15.4 systems have proven themselves to work very reliably in the presence of other 2.4 GHz systems, including Wi-Fi systems.

There are many features of 802.15.4 systems and more specifically, the Leaf Patient Monitor, that enable it to work without causing interference with and avoiding interference from other 2.4 GHz systems. Two collision avoidance (CA) techniques are employed. The first, direct-sequence spread spectrum (DSSS) modulation is used to minimize unintentional interference and to permit the sharing of a single channel among multiple users. The second, a clear channel assessment (CCA), is performed prior to any RF transmission, in which the transmission is delayed until any other device's transmissions that may have previously started are completed. In the case that multiple devices attempt to talk at the same time, random, logarithmic hold-offs (random time delays that increase in duration) are employed prior to attempts at re-transmission to avoid transmitting at the same time, again.

Data integrity is maintained over the wireless network by using hardware and software computed, 32-bit cyclical redundancy checks (CRCs). Use of CRCs enables the system to detect errors that occur during transmissions. Transmissions with detected errors are discarded and the transmission is automatically re-attempted.

The Leaf RF network protocol prevents the loss of data by acknowledging each message that is transmitted between a Sensor and Antenna or messages relayed between two antennas. When an acknowledgement is not received, the message is automatically re-transmitted, including a message ID to ensure that it is not duplicated. Even so, the system has been designed to be very tolerant of data loss so that no hazards are presented when individual messages do not reach their destination. Oversampling of data is employed so that occasional interruptions of data transmissions do not affect system performance. If, in rare circumstances, data transmission is lost for an extended period, the caregiver is notified via the User Interface of the Turn Management Software that the signal from the sensor(s) has been lost. Even so, the Turn Management Software continues to alert caregivers when turns must be performed.

The most significant and ubiquitous use of the 2.4 GHz frequency band in a typical healthcare facility is the use of 802.11 systems (Wi-Fi) to enable general purpose wireless local area networks for use by desktop and mobile computing devices. Special consideration of Wi-Fi networks was made during the design of the Leaf Patient Monitor to ensure that the Leaf Patient Monitor and Wi-Fi systems could coexist without interference. Both 802.11 and 802.15.4 define multiple physical channels near 2.4 GHz. Figure 1 shows the use of the 2.4 GHz band by 802.11 and 802.15.4 systems.

Special consideration of Wi-Fi networks was made during the design of the Leaf Patient Monitor to ensure that the Leaf Patient Monitor and Wi-Fi systems could coexist without interference.

In the case of Wi-Fi, there are 14 overlapping physical channels, each about 22 MHz wide and spaced only 5 MHz apart from each other (except channel 14 which is spaced 12 MHz from channel 13). In the US, only channels 1 through 11 are permitted. Therefore, in the US, channels 1, 6, and 11 are the only group of three non-overlapping channels. It is these three channels, 1, 6, and 11, that are exclusively used in nearly every large enterprise-scale Wi-Fi installation, such as in hospitals and LTC facilities. However, it’s interesting to note that Wi-Fi networks set up in this way not only ensure that channels 1, 6, and 11 are non-overlapping, but this configuration also leaves 3 MHz “gaps” between each of the Wi-Fi channels.

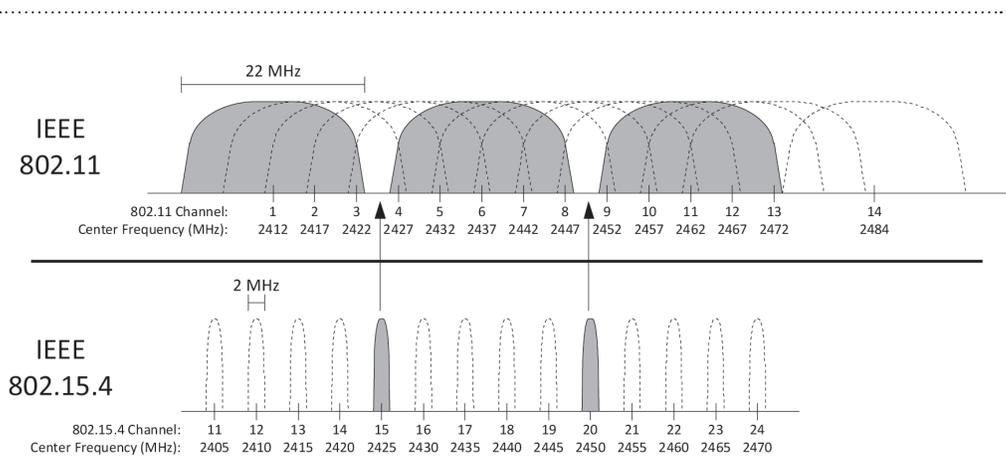


Figure 1: Use of the 2.4 GHz band by 802.11 and 802.15.4 systems

In the case of 802.15.4, there are 16 non-overlapping physical channels in the 2.4 GHz band identified as channel 11 through channel 26. Each of the 802.15.4 physical channels is about 2 MHz wide and spaced about 5 MHz apart from each other. In general, the 14 Wi-Fi channels overlap with the 16 channels defined by 802.15.4 at 2.4 GHz. However, two of the 802.15.4 channels (channel 15 and channel 20 at 2.425 GHz and 2.450 GHz, respectively) fit nicely into the frequency “gaps” left by typical Wi-Fi configurations between Wi-Fi channels 1 and 6 and between Wi-Fi channels 6 and 11. In the U.S., 802.15.4 channels 25 and 26 also do not overlap with Wi-Fi channels 1, 6, and 11, being situated at frequencies beyond that of Wi-Fi channel 11. Previously, it was claimed that Wi-Fi and 802.15.4 could coexist by relying on modulation and collision avoidance techniques. Even better, by using 802.15.4 physical channels 15 and/or 20, it can be ensured that the frequency bands used by the 802.15.4 and Wi-Fi systems do not overlap, and therefore do not interfere. Further, when Wi-Fi and 802.15.4 systems are configured in this way, they don’t even need to share the bandwidth available in their respective channels so that maximum data transmission rates are not affected in either system.

Figure 2 shows a spectrum taken of the 2.4 GHz band at a hospital using a Wi-Fi system. The three large top-hat like lobes are RF transmissions on Wi-Fi channels

1, 6, and 11. The gaps at 802.15.4 channels 15 and 20, between the three Wi-Fi channels, can easily be distinguished. Figure 3 shows the same spectral range when 802.15.4 channel 15 is being used by the Leaf Patient Monitoring System.

The Leaf Patient Monitor System further divides each of the 802.15.4 physical channels into 16 software channels. Mesh networks can be configured to operate on any of the available 16 software channels. By using different software channels, separate, independently operating mesh-networks can be defined that coexist in the same physical location but are “blind” to each other. Data collected by these two independent mesh networks would be isolated from each other and operate as if the other system did not exist. This enables the operation of two, independent Leaf Patient Monitoring Systems within the same facility, even if they operate on the same physical channel, if desired.

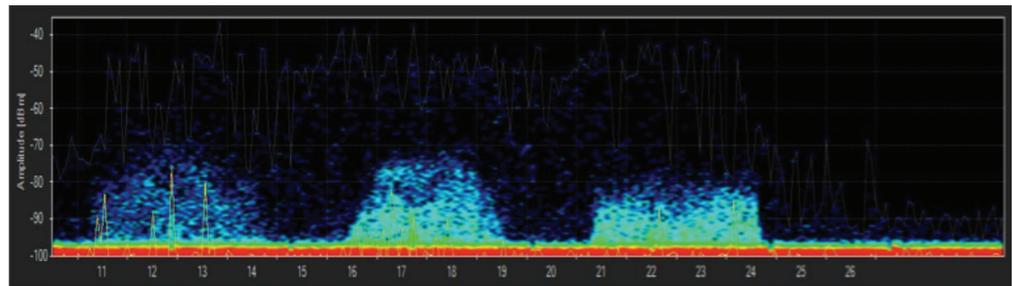


Figure 2: Hospital WiFi use of 2.4 GHz spectrum showing “gaps” at 802.15.4 channels 15 and 20

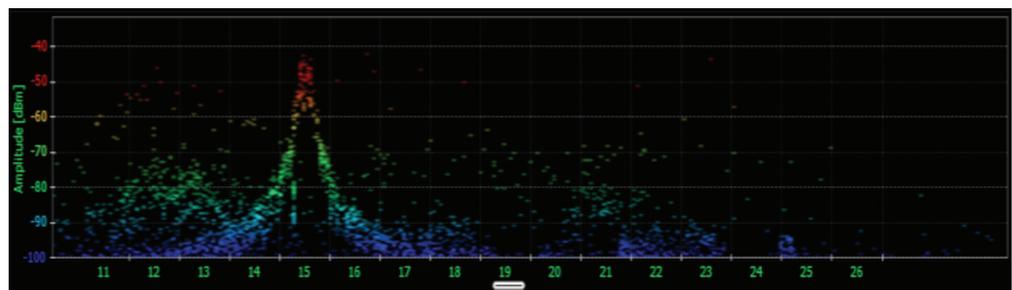


Figure 3: Leaf Patient Monitor use of 2.4 GHz on Channel 15

### Leaf Network Bridges, MeshNet Software, and SQL Database

Messages sent by the Leaf Patient Sensors are relayed by the Leaf Mesh Network to a server computer running the Leaf Mesh Network Server Software.

Messages sent by the Leaf Patient Sensors are relayed by the Leaf Mesh Network to one of multiple Leaf Network Bridges running MeshNet Software. The Leaf Network Bridge is a small form factor Windows PC with a Leaf USB RF Transceiver attached. The Leaf Network Bridge serves as the bridge between the Leaf RF mesh network and the Leaf SQL database running on a server computer, which may or may not be co-located within the healthcare facility depending upon customer requirements. In addition to relaying Patient Sensor data from the RF mesh network to the central database, the Leaf Network bridge collects and generates

status messages and network information that can be used to monitor the uptime and stability of the overall Leaf Patient Monitoring System, allowing potential network problems to be addressed before they can impact patient care and clinical workflows.

The MeshNet Software is a Microsoft Windows compatible application that has been tested to work on computers and servers running Windows Server 2012/2016, and Windows 10 operating systems. The server software runs equally well on dedicated server computer hardware or on hardware more typical of desktop systems or even laptop computers. Multiple instances of the MeshNet Software can be run on multiple computers, ensuring data relayed from Patient Sensors have multiple, redundant means of being collected and entered into the SQL database.

Software tools to help administer the mesh network are provided to enable IT staff to have confidence the system is working properly and to diagnose problems if they arise. Software monitoring the MeshNet Software can be configured to send email or text alerts to network administrators if the MeshNet Software stops working.

Software tools to help administer the mesh network are provided to enable IT staff to have confidence the system is working properly and to diagnose problems if they arise. Software monitoring the MeshNet Software can be configured to send email or text alerts to network administrators if the MeshNet Software stops working. In addition, the monitoring software can be configured to automatically restart the Leaf Network Bridge to resolve such issues. This makes maintenance of the network simple, requiring no manual monitoring, and automatically identifies for the staff when problems with the MeshNet Software or Leaf Network Bridge arise.

Connection to the SQL database is made through Windows ODBC (Open Database Connectivity) drivers. ODBC drivers provide a means for accessing the database independently of the actual database system and operating system.<sup>13</sup> Presently, the Leaf Patient Monitor has been shown to be compatible with Microsoft SQL Server 2012/2016. The SQL database may reside on the same computer on which the MeshNet Software is running, though is more typically running on a dedicated virtualized server located onsite at the healthcare facility or offsite at the customer's datacenter.

Since the database may be located on any network accessible drive, redundancy of data storage may be achieved by any common technique used to administer any server data storage including: RAID 5 disk arrays which spread data across multiple disk drives in real-time, iSCSI network attached drives that additionally provide a means for redundant NICs, and the use of regular, automated back-ups.

Multiple instances of the MeshNet Software/Leaf Network Bridges may access the SQL database simultaneously. In this way, data may be aggregated from a single nursing unit, hospital, or enterprise system as if a single Mesh Network was collecting all of the data, if desired.

Data exchanged between the MeshNet Software and the SQL database contain no patient identifying data such as patient name or patient electronic medical record number and so obviates any concern about data security on any network links between the MeshNet Software/Leaf Network Bridge and SQL database.

## Leaf Turn Management Software

A user interface to the system is provided by the Leaf Turn Management Software. The Turn Management Software accesses the SQL database, analyzes the data, and displays in near real-time the relevant information.

A user interface to the system is provided by the Leaf Turn Management Software. The Turn Management Software accesses the SQL database, analyzes the data, and displays in near real-time the relevant information. Caregivers using the system can customize a turn protocol for each patient being monitored. The software alerts caregivers when a patient has been in an orientation for a duration longer than was specified by the individualized turn protocol.

After a Patient Sensor has been applied to a patient for whom monitoring is desired, the Turn Management Software can be used to easily assign the sensor to the patient. During the assignment process, the patient's name, electronic medical record number, and bed can be entered. Optionally, an HL7 ADT feed can be provided to the system to significantly streamline the Patient Sensor assignment process, eliminating the need for the caregiver to manually enter patient information.

Since both patient self-turns and staff assisted turns are logged by the system, there is no need to provide assistance to a patient that has recently self-turned, and so no alert is issued. This saves the caregiver of having to perform a turn that is unnecessary, reducing the overall number of staff-assisted turns. Further, the system enables the facility to monitor patients that would otherwise be too expensive to place on turn protocols. Since patients that have moderate to good levels of mobility will likely frequently perform turns unassisted, placing them on turn protocol does not burden the nurse with frequent unnecessary turns.

The user interface is designed to show status for any patient in the facility. The Turn Management Software allows the caregiver to select and change the unit of interest. This makes the system appropriate for single units, complete hospitals, or even hospital chains.

Reports may be generated showing the turn history of patients throughout the facility that is being monitored by the system. These reports are capable of documenting every one of the patient's changes in position, based on the configured thresholds. Beyond these detailed, individualized patient reports, Leaf can also provide customized reports that summarize turn compliance across the facility and across shifts, at daily and monthly intervals.

Different permission levels may be assigned to various users by IT staff to give nursing administrators the ability to change the default turn periods provided to caregivers.

Different permission levels may be assigned to various users by IT staff to give nursing administrators the ability to change the default turn periods provided to caregivers. Administrators may also change the default decompression time—the time duration any side should be “off loaded” in order to achieve desired decompression and clinical outcomes. The threshold angle through which a patient must be turned for the system to recognize the change in orientation as a turn, and the threshold angle that defines if a patient is upright may also be configured by a user with administrator privileges. The ability to generate and view reports is also controlled by user permissions.

One installation methodology of the Leaf Patient Monitoring System is to use Citrix XenApp to serve the Turn Management Software to virtually all common desktop or mobile computing devices, including Microsoft Windows and Apple desktop systems, iPads, and Android tablets. Citrix XenApp must be used to push the LPMS software to iPads or Android tablets.

The high degree of configurability of the Leaf Patient Monitoring System gives the IT and nursing staff of the facility in which it is used the flexibility to decide how best to implement the system.

The implementation details of the Leaf Patient Monitoring system are highly configurable. In a “thick client” configuration, the Leaf Turn Management Software may be installed on Windows-based computers as needed throughout a monitored unit, either on dedicated Leaf All-in-One computers, the facility’s existing “workstations on wheels”, or both. Alternatively, in a “thin client” configuration, an application delivery service such as Citrix XenApp or an alternative Virtual Desktop Infrastructure (VDI) can be used to deliver a server-hosted instance of the Turn Management Software to client devices. By leveraging a facility’s existing deployment system, the Turn Management Software can be centrally managed and maintained just like any other server-hosted Windows application the facility currently supports. In either thick or thin client configurations, user permissions can be administered and maintained through Active Directory Domain Services to ensure compliance with a facility’s security policies.

The high degree of configurability of the Leaf Patient Monitoring System gives the IT and nursing staff of the facility in which it is used the flexibility to decide how best to implement the system. A status board and/or computing device may be positioned at the central station to give caregivers access to the Leaf User Interface. Additionally, a display device providing care giver access to the Leaf User Interface can be positioned in each patient’s room. The use of mobile computing devices such as laptops or tablet computers enable dedicated turning teams to easily check which patients are due or soon due for an assisted turn.

### Typical Installation Requirements

The following sections detail the requirements for a typical installation of the Leaf Patient Monitoring System. In addition to the components required for basic functionality of the Leaf Patient Monitoring System, additional optional features that improve the overall usability and effectiveness of the system are detailed as well.

**Relay Antenna Installation:** Throughout each monitored unit, a Relay Antenna should be plugged into every patient room, as well as in hallways and near nursing stations as power outlet availability allows. Relay Antennas can often be plugged into outlets that are high and out-of-place and thus less often used than more conveniently placed outlets. Installation is as simple as plugging the Relay Antenna into an outlet. No individual registration or pairing step is needed. If desired, the Relay Antenna can be installed with a strong adhesive tape that deters tampering by staff or guests, while still allowing removal without causing damage to the outlet. Relay Antennas are typically installed by Leaf Field Support personnel, with their general locations recorded to aid troubleshooting in case a Relay Antenna is lost, stolen, damaged or malfunctions.

**Leaf Network Bridge Installation:** Leaf Network Bridges are typically installed in pairs to provide redundancy in case a Bridge is accidentally unplugged or otherwise malfunctions. Depending on the size of a facility’s unit/floor, a single pair of bridges may provide sufficient coverage. If a unit is large, or physically divided into separate areas that would prevent communication across all Relay Antennas, additional Bridges

may be required. Leaf Network Bridges are typically installed at nursing stations. The exact location of the placement of a Bridge is not important as long as the Bridge has an Ethernet connection, access to an electrical outlet, and is within range of a Relay Antenna that is part of the mesh network. An Ethernet connection and static IP address are required for each Leaf Network Bridge. Leaf Network Bridges are pre-configured with all appropriate Leaf software including the Leaf MeshNet software and are installed within the facility by Leaf Field Support personnel.

**Leaf SQL Server Installation:** Leaf can provide server hardware pre-configured with SQL Server and additional Leaf support software, or can work with the customer's IT team to configure the Leaf SQL database as part of the facility's existing IT infrastructure. This typically takes the form of a Leaf-provided 1U rackmount server in the facility's data center, a virtual machine provisioned on the facility's existing hardware, or a shared SQL Cluster instance shared with other databases. Proper configuration of local firewalls and VLANs may be required of the facility's IT staff to ensure proper communication between the Leaf Network Bridges, SQL server, and Leaf Turn Management Software devices, as well as the assignment of static IP addresses.

**Leaf Turn Management Software Device Installation:** A Leaf-provided All-in-One computer workstation dedicated to displaying the Leaf Turn Management Software is typically placed at each nursing station (or comparable centralized area depending on the facility). The facility's existing application deployment system/ VDI infrastructure can be leveraged. In this case, the Leaf Turn Management Software can be installed and delivered just as any native Windows application would be. Each All-in-One computer requires a static IP address, and an Ethernet connection is strongly recommended.

**SMTP E-mail Support:** Leaf support software can be run on the Leaf SQL Server, a separate application server, or one of the Leaf Network Bridges that can be used to monitor Relay Antennas and send an e-mail alert to Leaf Support Personnel when any of the Relay Antennas fail to send in their periodic status messages. This can be used to preemptively investigate the cause and solve the problem before the overall Patient Monitoring System is affected. To achieve this, a facility's existing SMTP server can be used, or Leaf can provide one as long as outgoing messages are not blocked by the firewall.

**Remote Access for Reporting, Support, and Maintenance:** In order to provide remote maintenance and support, as well as up-to-date Patient Reports, remote access to the Leaf systems will need to be provided by the facility. This typically takes the form of the facility's existing VPN or some other remote access portal.

Before installing the Leaf Patient Monitoring System, Leaf Field Support personnel carry out a walkthrough of the facility, plan the locations of the required devices, and make sure all installation requirements can be met. The Leaf IT team can work with the customer's IT team to enable remote access and ensure proper connectivity. Once an installation and "go-live" date are set, Leaf can configure the required equipment off-site to simplify the on-site installation process. A typical

multiple-unit installation of the physical hardware across multiple floors of a hospital or long-term care facility is often completed in only a few days.

### Requirements for Additional Recommended Features

**ADT Integration:** The Leaf Patient Monitoring System is compatible with HL7 ADT feeds which can be used to streamline the patient assignment and discharge procedures within the Leaf Turn Management Software. While not a requirement to use the Leaf System, this increases the usability of the software and places less burden on the caregiver. Configuration typically involves the facility providing a sample HL7 feed prior to installation and directing the HL7 feed to the Leaf SQL or Application Server so it can be interpreted and interfaced with the Turn Management Software.

**Active Directory Domain Services:** User permissions can be configured within the Leaf System by username used to log into the computer running the Leaf Turn Management Software, but managing user permissions can often be streamlined by leveraging a facility's existing Active Directory. The facility can assign Active Directory security groups to the Leaf Turn Management Software to determine user permissions.

**Additional Displays for Turn Management Software:** Though the minimum number of displays for the Turn Management Software typically means a display at each nursing station or analogous centralized location, the caregiver's user experience can be improved by providing additional displays throughout the unit. One example would be a wall-mounted display run by a small form factor PC installed in a highly trafficked area. Additionally, the Turn Management Software could be installed on "workstations on wheels" or other computers within patient rooms. This provides the caregiver with immediate positioning feedback when turning a patient, increasing usability and potentially improving the quality of caregiver-assisted patient turns.

### Conclusion

The Leaf Patient Monitoring System is a valuable tool to enable hospitals, long term care facilities (LTC), and nursing homes to wirelessly monitor the real-time orientation and activity of patients susceptible to pressure injuries; and to provide alerts when patient orientation or activity deviates from individualized turn management protocols set by the healthcare provider. The system helps to address a problem that is costing a typical hospital over \$4M annually. The system architecture is flexible, allowing the healthcare facility to configure the system to best accommodate existing nursing workflow and IT infrastructure.

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**Leaf Healthcare****About Leaf Healthcare, Inc.**

Leaf Healthcare creates wireless patient mobility monitoring solutions for health care providers who are seeking more efficient and cost effective ways to improve patient safety and clinical outcomes.

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