

LEAF Patient Sensor FCC E-Label Justification

Device Description

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

The LEAF Patient Monitoring System is comprised of:

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

Each LEAF Patient Sensor is associated with a single patient, such that the patient's orientation, movements, and other care parameters can be monitored.

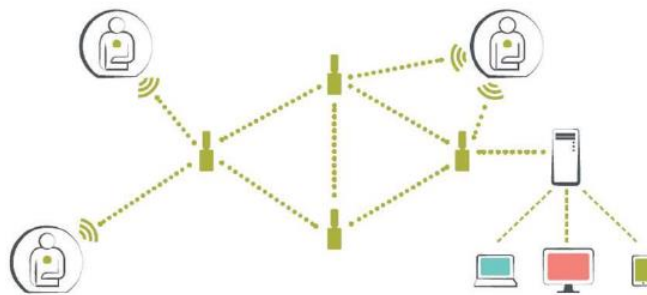


Figure 1: High level Schematic of LEAF Sensors, Distributed Meshnet and User Interface

When the LEAF Patient Sensor is taken out of its packaging and is powered ON, it will search for the LEAF Distributed Meshnet which is made up of LEAF Relay Antennas, LEAF USB Transceiver and LEAF Patient Monitoring Software and User interface. If the Distributed Meshnet is not present the Sensor cannot join the network and cannot operate normally (IFU Page 17 Section E – Watch for the LED activation sequence)

The LEAF Patient Sensor **does not have a digital display**; thus, the FCC ID is placed on the associated LEAF Patient Monitoring User Interface display which is needed for the normal operation of the Sensor. This use of e-label is consistent with the FCC guidance [784748 D01 General Labeling and Notification V09r01 Section 3](#) and [784748 D02 e-labeling v02r01 Section 2](#).

The LEAF Patient Monitoring Software and User Interface software run on a Windows computer with integrated display. When the software is started, the “Splash Screen” is shown which will have the FCC ID’s for the LEAF Patient Sensor and various SKU’s of LEAF Relay Antenna, USB Transceiver.

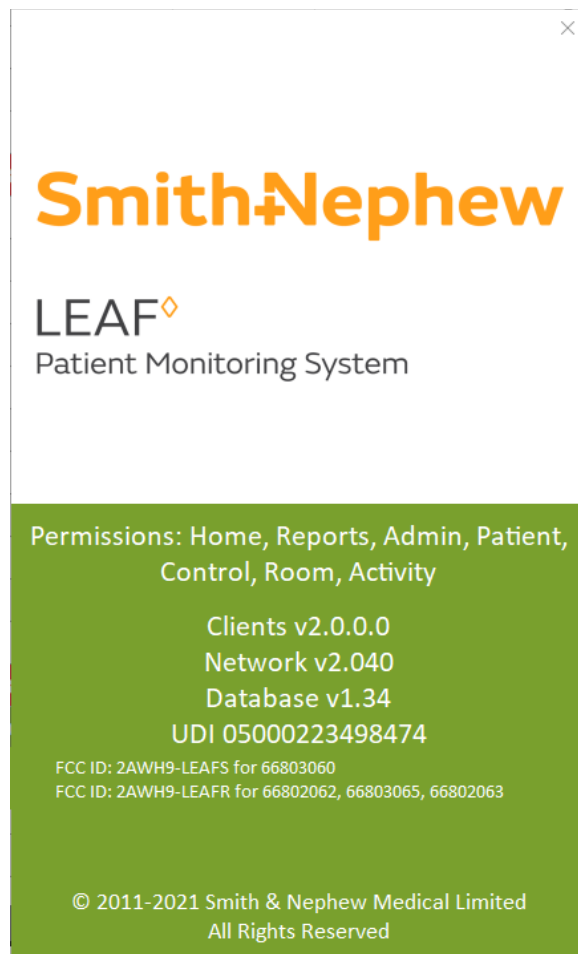


Figure 2: Start-up Splash Screen

The FCC ID information can also be accessed from the “Home screen” by accessing the Help -> About Menu. The About Menu will have the FCC ID’s for the LEAF Patient Sensor and various SKU’s of LEAF Relay Antenna, Transceiver.

The screenshot shows the LEAF Patient Monitoring System interface. On the left is a navigation menu with options: Home, Select Unit, System Activity, Reports, Administration, Help (highlighted with a red box), Administrator, and Exit. The main area displays a table of patient data with columns: Room, Patient, Time Until Next Turn, Position, and Information. A 'Help Resources' pop-up menu is open, listing various help topics like 'About LEAF Patient Monitoring System', '1-System Overview.mp4', '2-Applying a Leaf Sensor.mp4', etc. The table includes rows for patients like B. J., K. T., R. S., P. S., F. L., S. T., H. J., S. S., and G. C., with their respective turn times and positions.

The 'About' menu displays the following information:

- Smith+Nephew**
- LEAF** Patient Monitoring System
- Permissions: Home, Reports, Admin, Patient, Control, Room, Activity
- Clients v2.0.0.0
- Network v2.040
- Database v1.34
- UDI 05000223498474
- FCC ID: ZAWH9-LEAFS for 66803060
- FCC ID: ZAWH9-LEAFR for 66802062, 66803065, 66802063
- © 2011-2021 Smith & Nephew Medical Limited
All Rights Reserved

Figure 3: About Menu displaying software versions and FCC ID