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Certification Exhibit

FCC ID: Z90-FAS1541

IC: 10060A-FAS1541

FCC Rule Part: 15.209, 15.231, 15.249
IC Radio Standards Specification: RSS-210

ACS Project: 15-2042

Manufacturer: UltraClenz, LLC
Model: FAS1541-00

User Manual

Patient Safeguard System® Patient Bed Installation

Revision 0.0



UltraClenz, LLC

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Abstract

This document covers the basic operation of the Bed Installation and its components. Also covered is the installation of the various components used in a Bed Installation.

Revision History

Revision	Date	By	Description
0	08/12/15	AP	Initial Release

Reference Documents

Patient Safeguard System™ Healthcare Worker Badge User's Guide, DOC1046.

Terms, Acronyms and Abbreviations

Bentley	UltraClenz' Proprietary Wireless Network
HCW	Healthcare Worker
LED	Light Emitting Diode
POST	Power On Self-Test
PSS	Patient Safeguard System
ALPS	AC Line Power Sensor
AC	Alternating Current (Bed 120 volt power from wall socket)

1. Introduction to the Patient Safeguard System (PSS)

The Patient Safeguard System is a state of the art wireless hand hygiene reminder system designed to enable best practices for proper hand hygiene in a healthcare facility. Multiple studies from organizations like the World Health Organization (WHO) and the Centers for Disease Control (CDC) have repeatedly demonstrated that proper hand hygiene leads directly to improved infection control and a reduction in Healthcare Associated Infections (HAI). The PSS is a cost-effective, energy efficient, robust and easily installed system for coaching healthcare workers (HCWs) to always wash or sanitize their hands before and after patient contact. The system can be divided into three parts, hardware components, the Bentley Wireless Network and the Dashboard web-based application.

1.1 Hardware Components

The PSS is built on individual components or devices that work in concert to deliver real-time individual hand hygiene status to HCWs and near real-time statistics for both onsite and offsite monitoring of current and historical hand hygiene compliance data. Currently, the components of PSS are the HCW Badge, the Dispenser Beacon and the Bed Beacon.

1.1.1 Healthcare Worker Badge

The Badge is a wireless device worn by the HCW to provide real-time notification of the HCW's current hand hygiene status. Notification is provided by both visual and audible alerts. The Badge is responsible for determining, maintaining and transmitting the current hand hygiene status of the HCW to other PSS components.

1.1.2 Dispenser Beacon

The Dispenser Beacon is attached to or embedded within a soap or sanitizer dispenser. Its function is to communicate with the Badge worn by the HCW when the dispenser is activated (dispense event), collect dispense event data from that Badge and then transmit the collected data to a network where it will ultimately be sent to an offsite server for processing and archiving.

1.1.3 Bed Beacon

The Bed Beacon, along with its internal low frequency antenna, is mounted to a patient bed. Its function is to communicate with the Badge worn by the HCW when the HCW comes in close proximity with the patient bed (bed event), collect bed event data from that Badge and then transmit the collected data to a network where it will ultimately be sent to an offsite server for processing and archiving.

1.2 Bentley Wireless Network

Bentley is a wireless mesh network used to transport event data collected by Dispenser Beacons and Bed Beacons to the offsite server for processing and archiving. Bentley is composed of two types of devices, Hubs and a Gateway.

1.2.1 Hubs

Hubs are installed throughout a healthcare facility and communicate with nearby Bed Beacons and Dispenser Beacons. When an event is generated by a Beacon, it broadcasts the event data to the nearest Hub. The Hub then receives the event data and rebroadcasts it to the Gateway (if it is in range) or the next nearest Hub where the data is passed from Hub to Hub until it reaches the Gateway.

1.2.2 Gateway

The Gateway receives event data generated by Dispenser Beacons or Bed Beacons directly, if they are in range, or from Hubs which act as repeaters. The Gateway then transmits the event data to an offsite server via cellular modem for processing and archiving.

1.3 Dashboard and Offsite Server

The Dashboard is a web-based application running on a designated offsite server. It is responsible for collecting, processing and archiving onsite Dispenser Beacon and Bed Beacon event data sent by the onsite Gateway. The Dashboard provides a user interface which allows access to hand hygiene data, statistics and reports compiled from event data originating at the healthcare facility.



2. Required Materials



The materials needed for this install:

- (A) Small Phillips screwdriver
- (B) D cell alkaline batteries (2 ea.)
- (C) Wire cutters
- (D) Cable Ties 14in long (4ea.)
- (E) Alcohol Wipe
- (F) Test Badge (FAS1527)
- (G) HCW Badge (FAS1527)
- (H) Double sided tape
- (I) Tape Measuring device
- (J) Cable Tie Holder (10ea.)
- (K) Cable Tie 4in long (10ea.)

The Patient Bed installation is comprised of three main components. The first component is the Bed beacon which is used to create a zone around the patient bed and controls the zone around a patient bed. The second component is the AC Line Power Sensor that senses when bed is connected or disconnected from AC power. The third component is the Bed Mount which the Bed Beacon clips onto.



Figure 1. Bed Installation Components

3. PSS Patient Bed Installation Functions

The Bed Beacon works with the internal antenna to create a zone around a patient bed, referred to as the patient zone. When a healthcare worker (HCW) wearing a Badge enters the zone, the Bed Beacon wirelessly communicates with the Badge and lets the Badge know that it has entered the zone around a specific patient bed. The Bed Beacon will emit an audible beep and flash a green LED when it has successfully communicated with the Badge. If communications with the Badge are successful the Bed Beacon then sends information about its interaction with the Badge to the server via the Bentley wireless network. For more information about how the Badge will react to being in the patient zone, please read the document Patient Safeguard System® Healthcare Worker Badge User’s Guide (DOC1046).

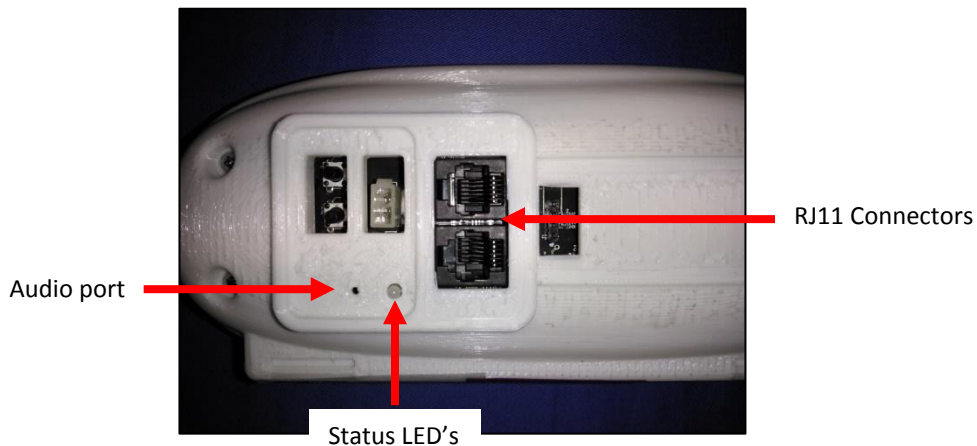


Figure 2. Bed Beacon Details

When the Bed Beacon is mounted on a bed and connected to the AC Line Power Sensor through the RJ11 jacks, it detects when the bed is connected to the wall outlet. This will cause the Bed Beacon to emit a beep and flash a green LED. Each time the state of the bed’s AC power changes state the Bed Beacon will send a message over the Bentley network. If the bed’s power cord is disconnected from AC wall power the patient zone will be turned off while the bed is in transit. When the ALP Sensor loses AC detection the Bed Beacon will emit 1 beep and flash 1 red LED. When the bed is brought back into the room and bed AC power is restored the Bed Beacon will emit 1 beep and flash 1 green LED. Each time any device is connected or disconnected from the Bed Beacon, the Bed Beacon will send a message over the Bentley network.

4. Installation

4.1 Bed Beacon Mount Installation

The Bed Beacon Mount can be mounted directly to the frame of the bed itself (see Figure 3).

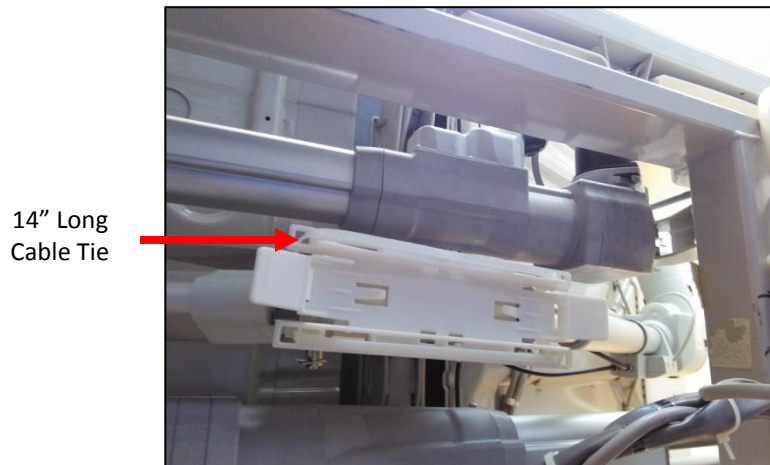


Figure 3. Bed Beacon Mounted on Patient Bed Model Hill-Rom Versa Care P3200

Tape mounting

Mount the Bed Beacon Mount onto the metal surface with the double-sided tape (supplied) and secure with the 14" long cable tie. Make sure the Bed Mount and the mounting surface are clean and free of dirt and oil. Spray a mixture of Dawn soap (1% of Dawn soap per a gallon of water) and scrub the mounting surface with a plain Scotch-Brite scouring pad. Wipe the surface with a lint free cloth to clean off any contaminants. Then use a soft cloth dampened with isopropyl alcohol to further clean the mounting surface. Repeat the process as necessary. Ensure the mounting surface is dry before attaching antenna and firmly push and hold in place for several minutes (see Figure 3).

4.2 Bed Beacon Installation

The Bed Beacon (see Figure 4) chips directly into the Bed Beacon Mount.

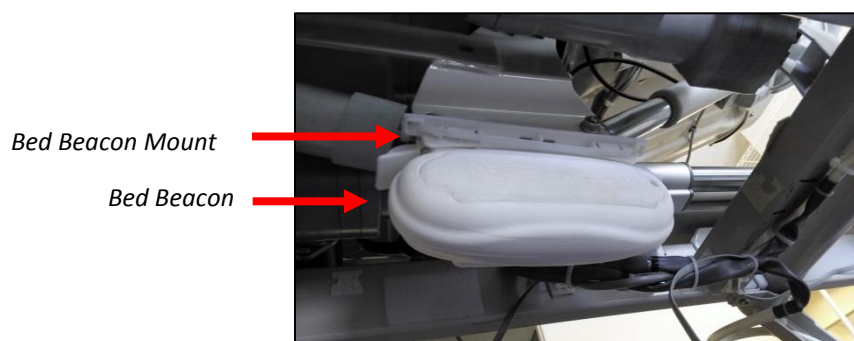


Figure 4. Bed Beacon Installation

4.3 AC Line Power Sensor (ALP)

The AC Line Power Sensor (*see Figure 6*) is mounted onto the bed's AC power cord (3" from cable gland). The ALP Sensor senses the AC power of the patient bed cord to activate or deactivate the Bed Beacon during the bed's connect or disconnect, for transit to another location. The ALP Sensor is attached directly to the Dock via a small cable. It mounts to bed's power cord with 2 cable ties. Make sure a service loop is left in the ALP Sensor's cable run, allowing for the bed to be raised and lowered.

AC Line Power Sensor
attached to power cord

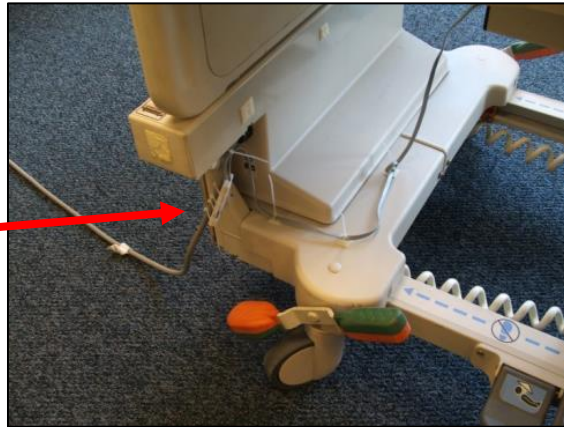


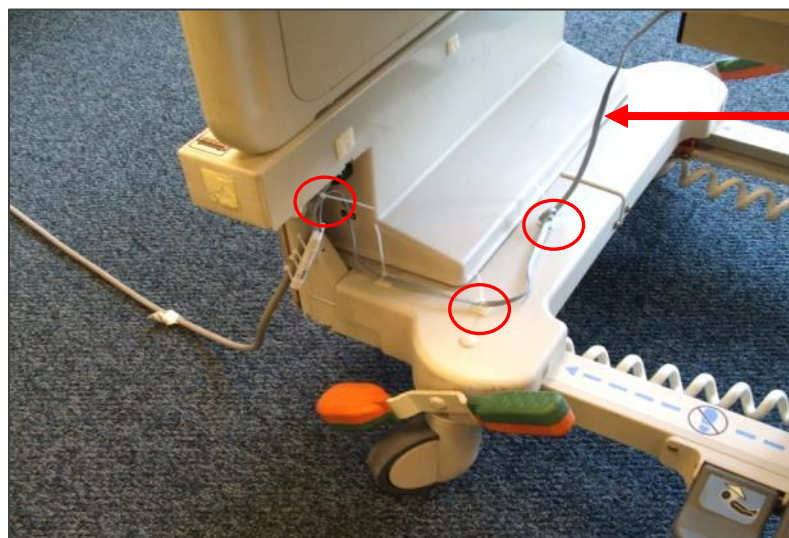
Figure 5. AC Line Power Sensor Attached to Power Cord

Cable Tie mounting

Mount the AC Line Power Sensor on the patient bed's AC power cord using 2 cable ties (*see Figure 5*). Use cable tie holders for routing the wire to the Dock, and make sure the mounting surface is clean and free of dirt and oil. A soft cloth dampened with isopropyl alcohol works well to clean both surfaces.

4.4 Cable Management

1. Place cable tie holders, cable ties and route cable to the Bed Beacon as shown (*see Figure 6, 7 & 8*). Make sure the mounting surfaces are clean and free of dirt and oil. A soft cloth dampened with isopropyl alcohol works well to clean the mounting surfaces.



Service Loop (17")

Figure 6. ALPS Cable Routing and Cable Tie Holder Placement

- Place cable tie holders and route the ALP Sensor cable along the inside rail and tie down any excess cable (Service Loop) as shown (see Figure 7).

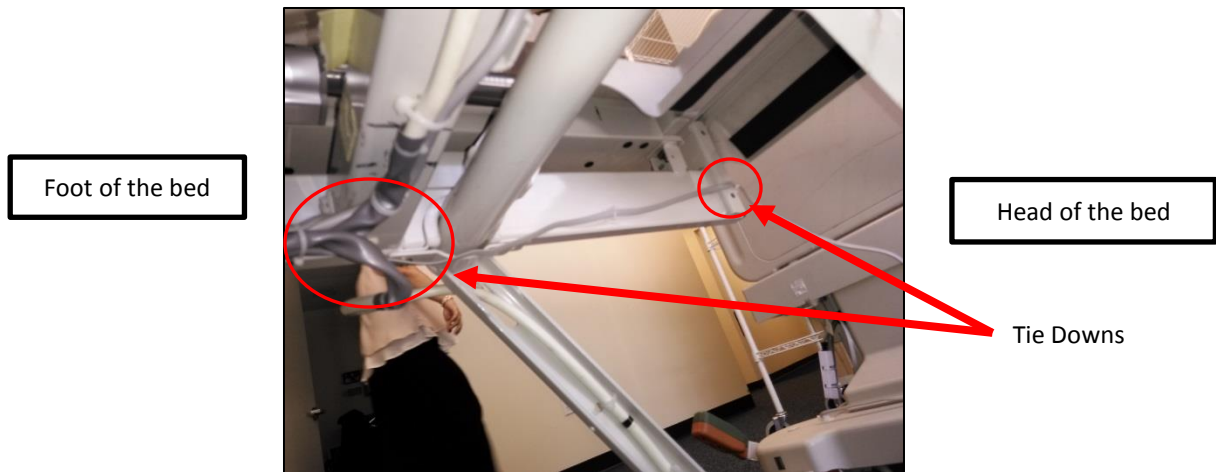


Figure 7. ALP Sensor Cable Routing and Cable Tie Holder Placement

- Place a cable tie holder and route the ALP Sensor cable as shown (see Figure 8).



Figure 8. ALP Sensor Cable Routing to Bed Beacon and Cable Tie Holder Placement

5. Adjusting the Communication Range

5.1 Range Adjustment on Bed Beacon

The Bed Beacon communication range is adjusted during installation to maximize communication with the healthcare worker Badge. To adjust the communication range, the range buttons are located on the back of the Bed Beacon. The Bed Beacon communication range is adjusted by repeatedly pushing either the “+” increment or the “-” decrement range buttons (see Figure 9) to achieve the desired range. The total adjustable range of the Bed Beacon is 1 to 15 increments between the lowest and the highest setting. Each push of the “+” button will produce an audible beep and the green LED will flash once indicating one (1) increment up. When the highest setting is reached, two (2) audible

beeps will be heard and two (2) green LED flashes will be visible. Each push of the “-” button will produce an audible beep and the red LED will flash once indicating one (1) increment down. When the lowest setting is reached, two (2) audible beeps will be heard and two (2) red LED flashes will be visible. To reset a Bed Beacon’s range back to the factory default setting, push and hold both of the “+” and “-” buttons at the same time. Four (4) audible beeps will be heard and the LEDs will flash in an alternating pattern between green and red. The factory default range setting for the Bed Beacon is position 9. Replace the battery cover when the adjustment is complete.

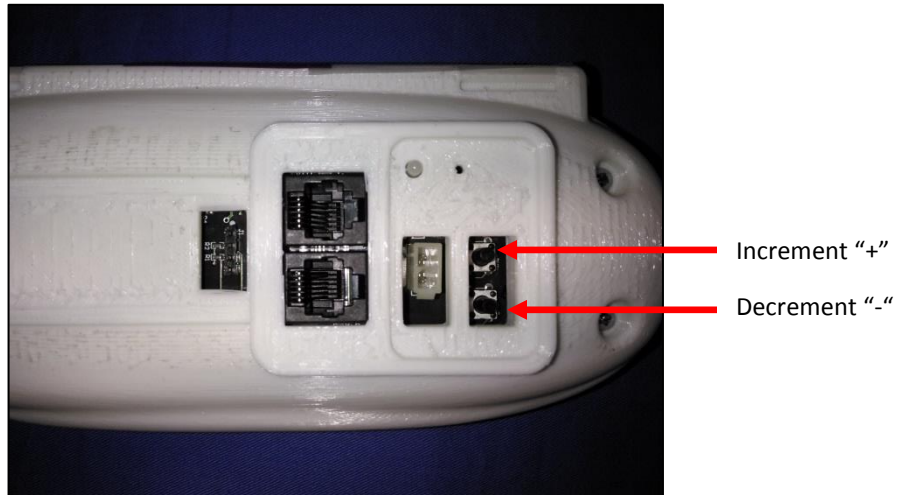


Figure 9. Bed Beacon Range Adjustments

5.2 Bed Beacon to Test Badge Range Adjustment

2. Set and adjust the bed and mattress height to the average height for beds in the facility.
3. While holding the Test Badge 50 inches from the floor and 24 inches from the bed’s handrail center location (side of bed) (see *Figures 10 & 11*), the Test Badge’s red and yellow LEDs should flash once a second, indicating that the proper activation range and communication have been successfully established. If range is not 24” adjust the Bed Beacon’s range buttons until the Badge activation range is 24 inches (see *Figure 9*).



Figure 10. Test Badge Height Is 50 Inches From the floor



Figure 11. Test Badge Activation Distance from Bed's Handrail Center is 24"

5.3 Dashboard Test with the PSS Badge and Bed Beacon

1. With the HWC Badge, verify that the Bed Beacon and Badge activates at 24 x 50 inches, and that Badge's device address is confirmed and verified on the dashboard.
2. Go to Google (Internet) and type your facility's Dashboard URL and you should see *Figure 12*.
3. Type in the correct email address, password, and answer the math question correctly to sign in.

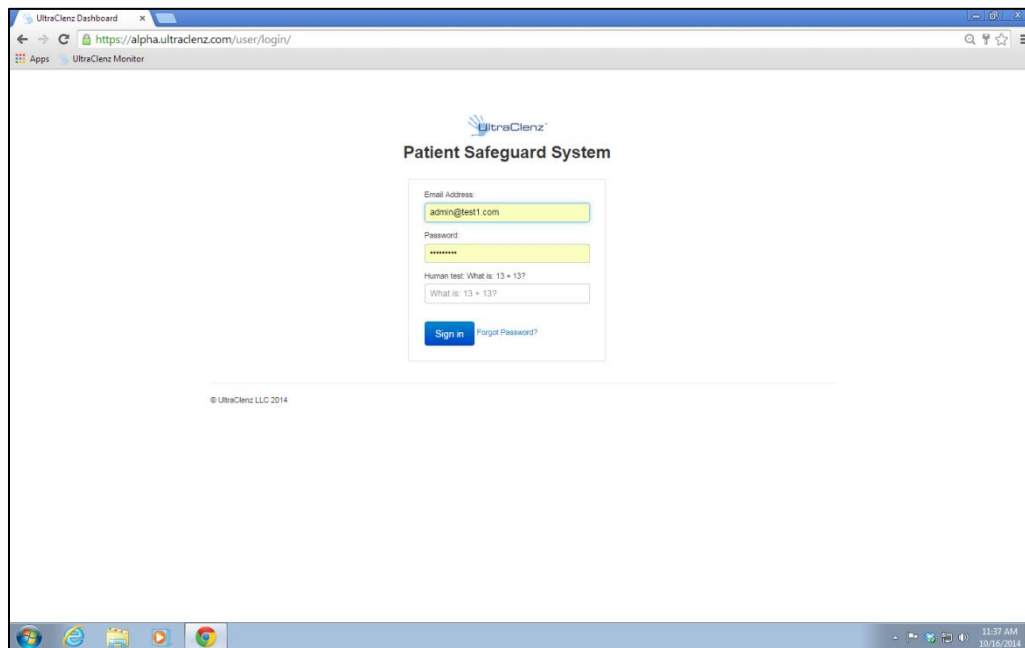


Figure 12. Dashboard Entry Screen

4. When access is granted you should see the screen shown in *Figure 13*.

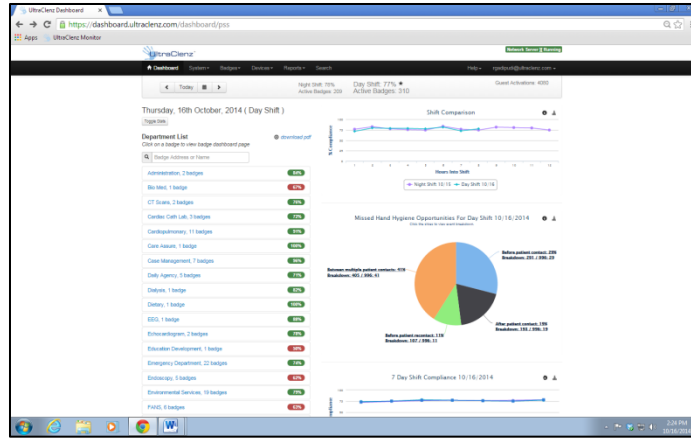


Figure 13. First Screen of Dashboard

5. Click on **Device** and **Bed Beacon** as shown in Figure 14.

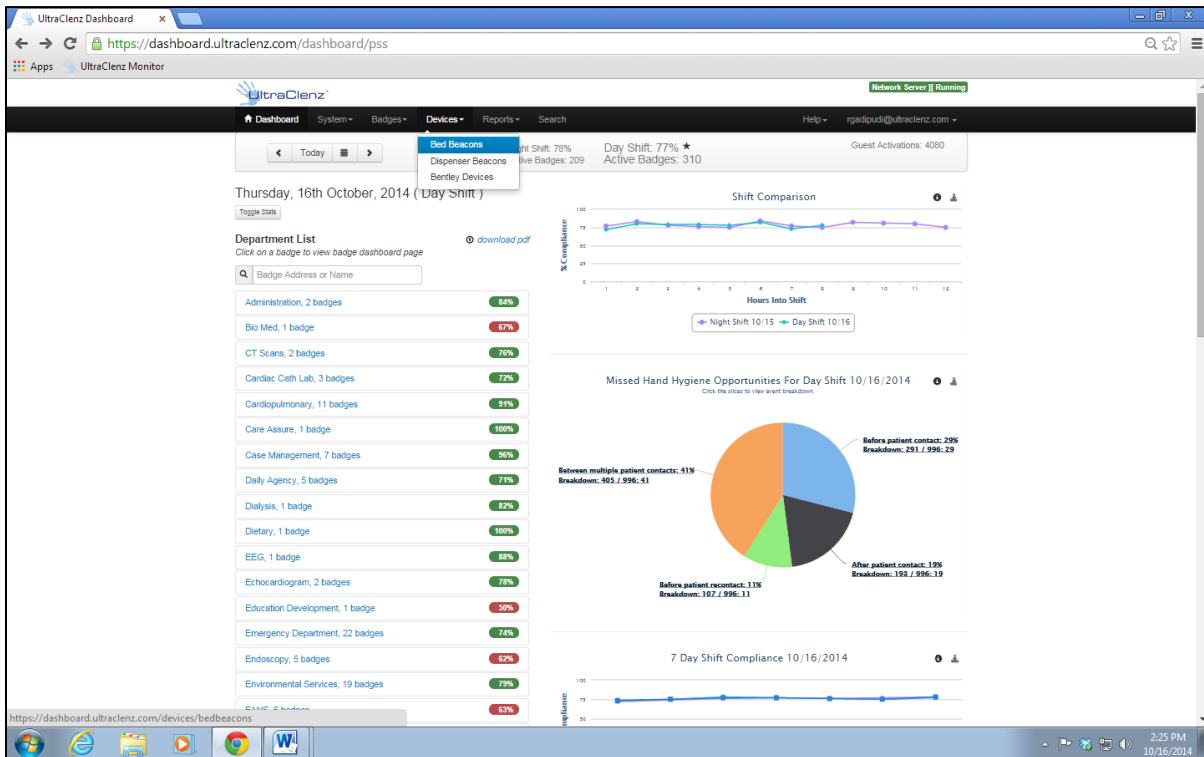


Figure 14. Choose Device Screen

6. Click on **Column** and you should see the choose selection block as shown in Figure 15.

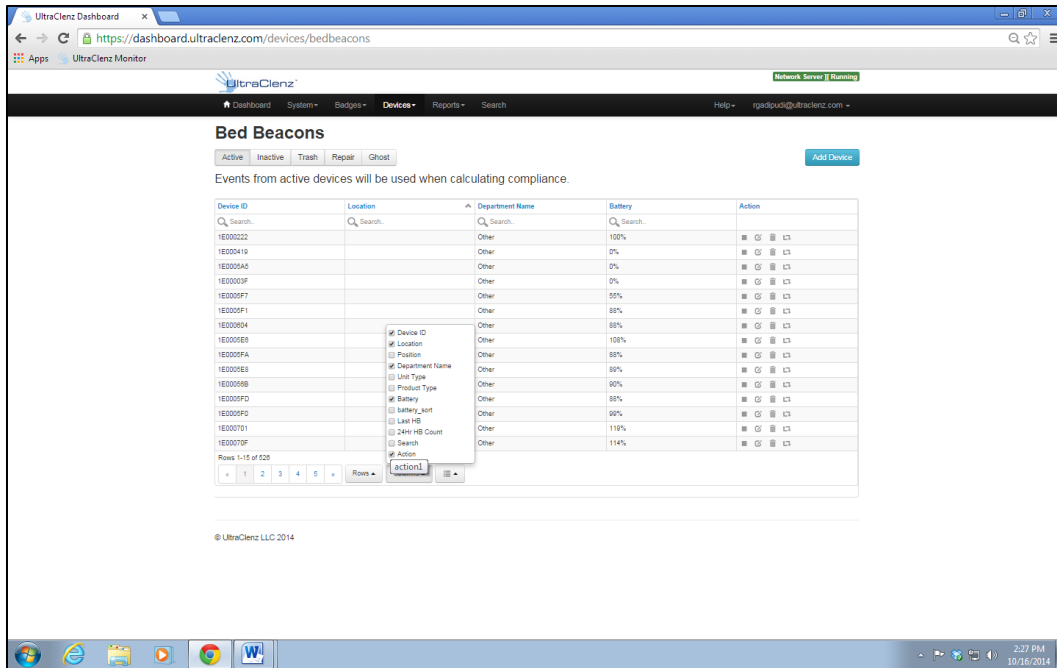


Figure 15. Device Bed Beacon Screen

7. Check the box Search choice as shown in Figure 16.

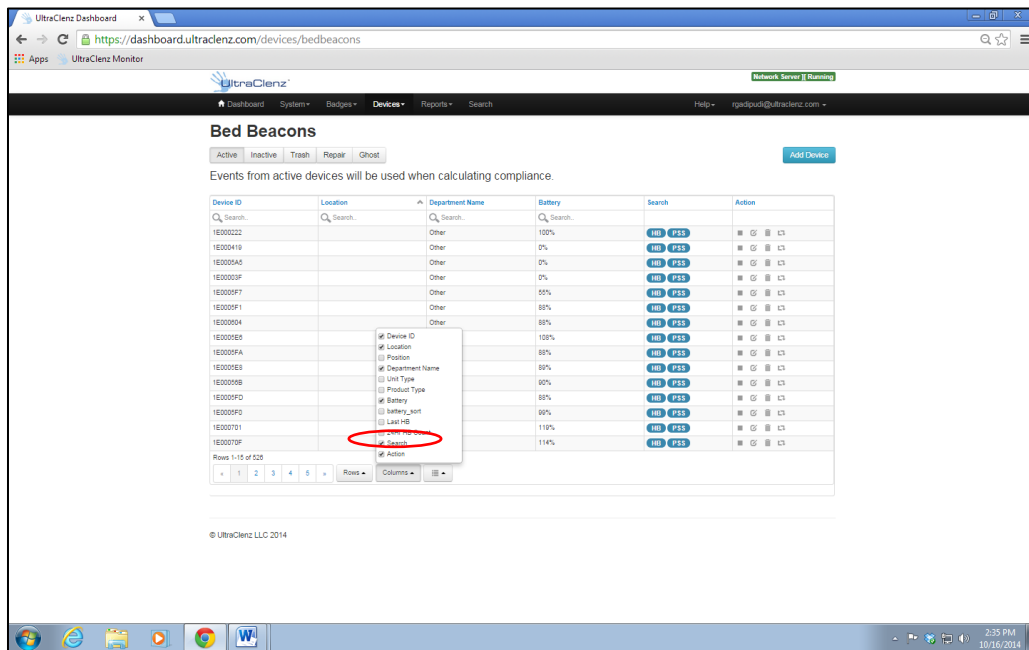


Figure 16. Choose the Search for Bed Beacon

8. Enter the Bed Beacon’s device address number as shown in Figure 17 and the device should be found as shown. Click on the PSS button shown.

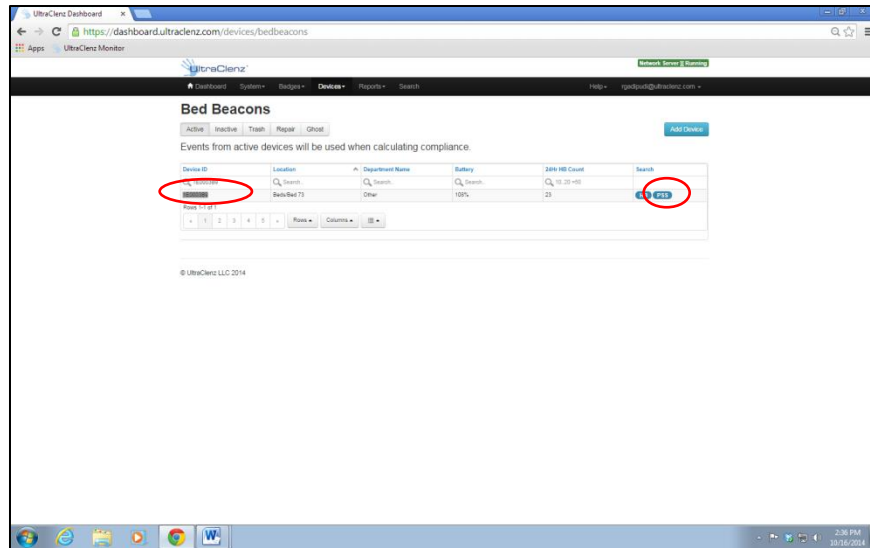


Figure 17. Search for and See Device Screen

9. You should now see the Bed Beacon and HCW Badge device addresses as shown in Figure 18.

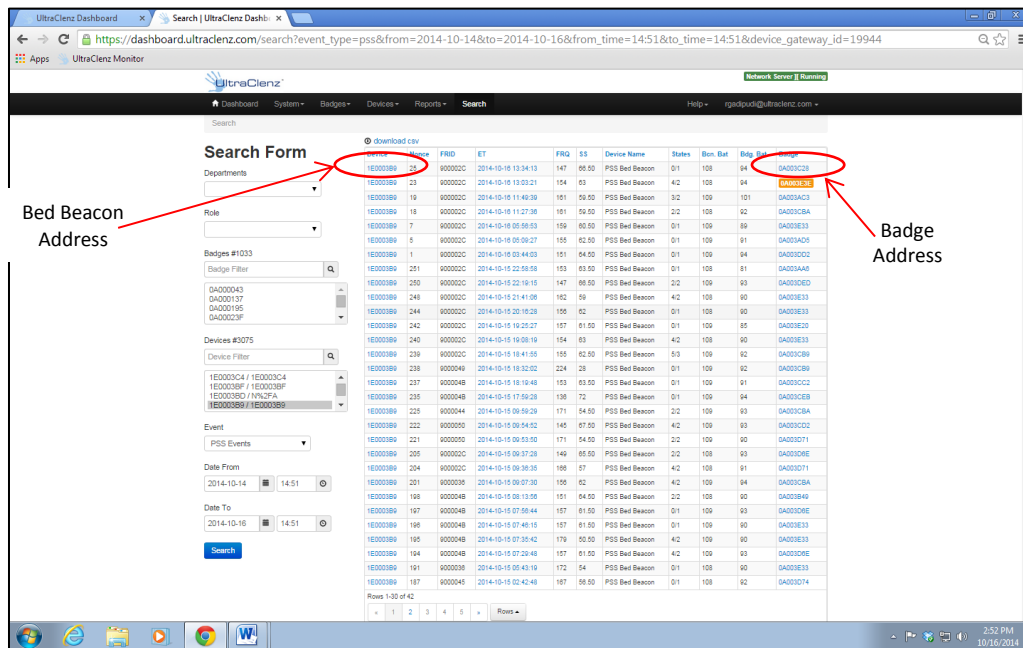


Figure 18. PSS Event Screen

There may be circumstances which require a Bed Beacon’s range to be adjusted, after the initial installation, to properly communicate with a Badge. Examples of why a Bed Beacon’s range may need to be adjusted are explained below.

Cases for Bed Beacon Range Adjustment

1. Two beds with Bed Beacons in one room.

- Two beds with Bed Beacons in separate but adjacent rooms separated by a wall.

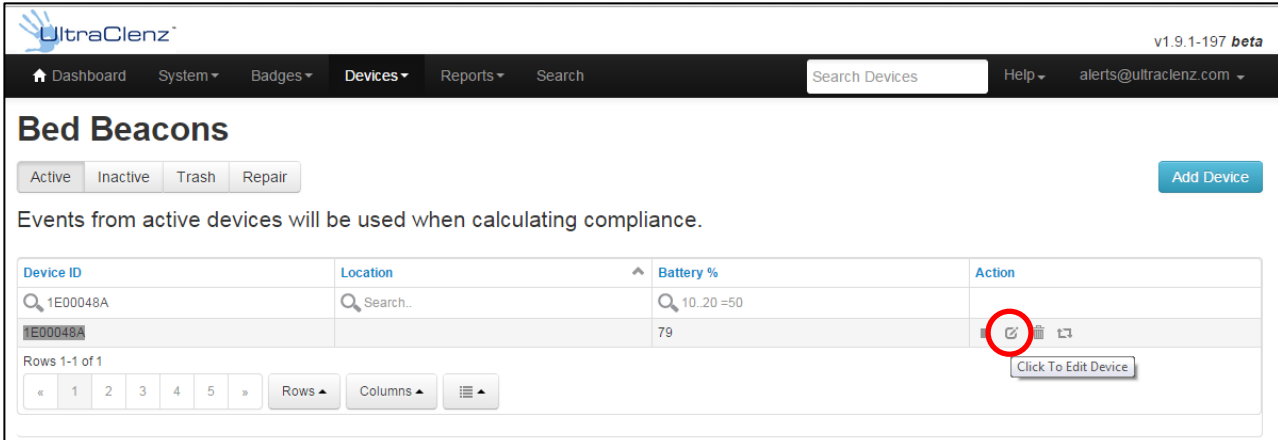
In both cases, the range of communication of a given Bed Beacon may overlap or interfere with a nearby Bed Beacon. If this occurs, the HCW's Badge may communicate with a nearby Bed Beacon instead of the intended Bed Beacon. This miscommunication can result in the system reporting contact with the wrong patient. To eliminate the possibility of miscommunication, the range of Bed Beacons in close proximity may be decreased, at any time, to insure that a HCW's Badge will communicate with the intended Bed Beacon.

6. Metadata Entry

6.1 New Bed Beacon Metadata Entry

Activate the Bed Beacon with a Badge, twice, at the hospital. The events will be transmitted to the server to be viewed on the dashboard. To locate the active Bed Beacon, login to the dashboard and select the "Device" tab and select "Bed Beacons" from the drop down list as shown in Figure 14.

The metadata can only be accessed by restricted logins. Read the Bed Beacon address on the product label. The Bed Beacon hexadecimal address will start with a 1E. The 1E at the beginning of the address is the device type and tells the dashboard that this is a Bed Beacon. Enter the full address into the "Device ID" column search window. In the example below, the address is 1E00048A (see Figure 19). Click the "Click To Edit Device" icon under the "Action" column to open the device's metadata page.



The screenshot shows the UltraClenz dashboard interface. At the top, there is a navigation bar with tabs for Dashboard, System, Badges, Devices, Reports, and Search. A search bar for devices and a user profile for alerts@ultraclenz.com are also visible. The main content area is titled 'Bed Beacons' and includes filters for Active, Inactive, Trash, and Repair, along with an 'Add Device' button. A note states: 'Events from active devices will be used when calculating compliance.' Below this is a table with the following data:

Device ID	Location	Battery %	Action
1E00048A	Search..	10..20 =50	
1E00048A		79	Click To Edit Device

The 'Click To Edit Device' icon in the Action column is circled in red.

Figure 19. Active Bed Beacon List

- Device Information (see Figure 19)
The Bed Beacon device information is optional. The device information can be found on the product label.
- Facility (see Figure 14)
Select the facility location from the drop down list. The facility location is pre-populated in the "System" tab, "Facility Setup" before the installation.

The box below the facility setup is used to enter the building metadata for large hospitals with multiple buildings or wings. For single building hospitals this field can be left blank.

- Unit Type (see Figure 20)
Unit type: Bed Beacon (not optional metadata). The unit types are pre-populated in the "System" tab, "Unit Types Management".

- Bed Number: example – “001” (optional metadata). The installer can choose to place a numbered label at the bed’s footboard frame to easily identify beds because the Bed Beacon label may not be in a convenient location to easily view.
- Bed Make: example – “Hill Rom” (optional metadata). The bed manufacturer information can assist staff in identifying a bed.
- Bed Model: example – “Versacare” (optional metadata). The bed model information can assist staff in identifying a bed.
- Bed Serial Number: example – “123456” (optional metadata). The bed serial number information can assist staff in identifying a bed.

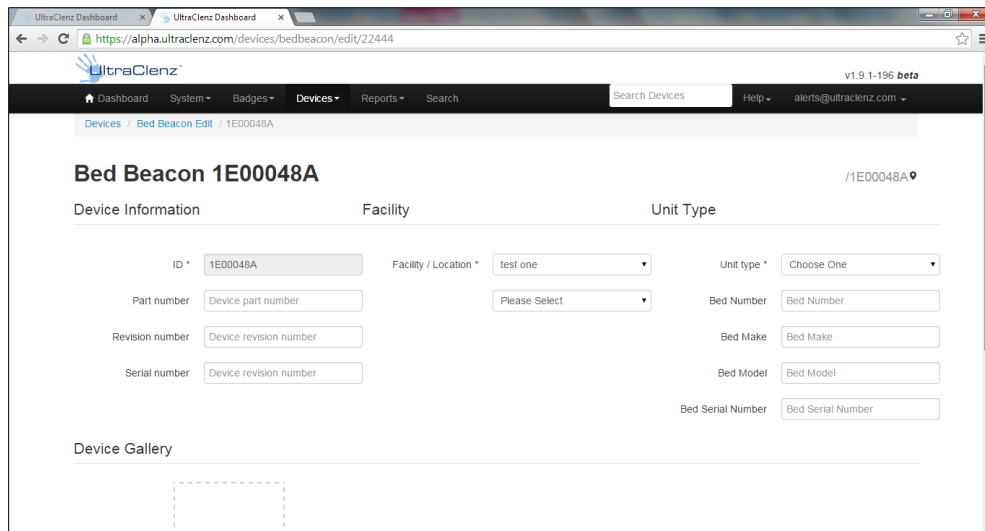


Figure 20. Bed Beacon Metadata

6.2 Replacing an Existing Bed Beacon – Swapping Metadata

Remove the Bed Beacon and read the address from the product label. Enter the Bed Beacon’s address in the active Bed Beacon device list (see Figure 19 above). Click the replace icon in the device list “Action” column (see Figure 19). The replacement tab will open. Enter the new Bed Beacon’s address into the blue box. Check the “I have verified the device ID” then click “Replace” to transfer the old Bed Beacon’s red box to the new Bed Beacon blue box (see Figure 22). The old Bed Beacon will be marked for repair and deleted from the active device list. Click “Replace Another Device?” to replace another Bed Beacon.



Figure 21. Replace Icon

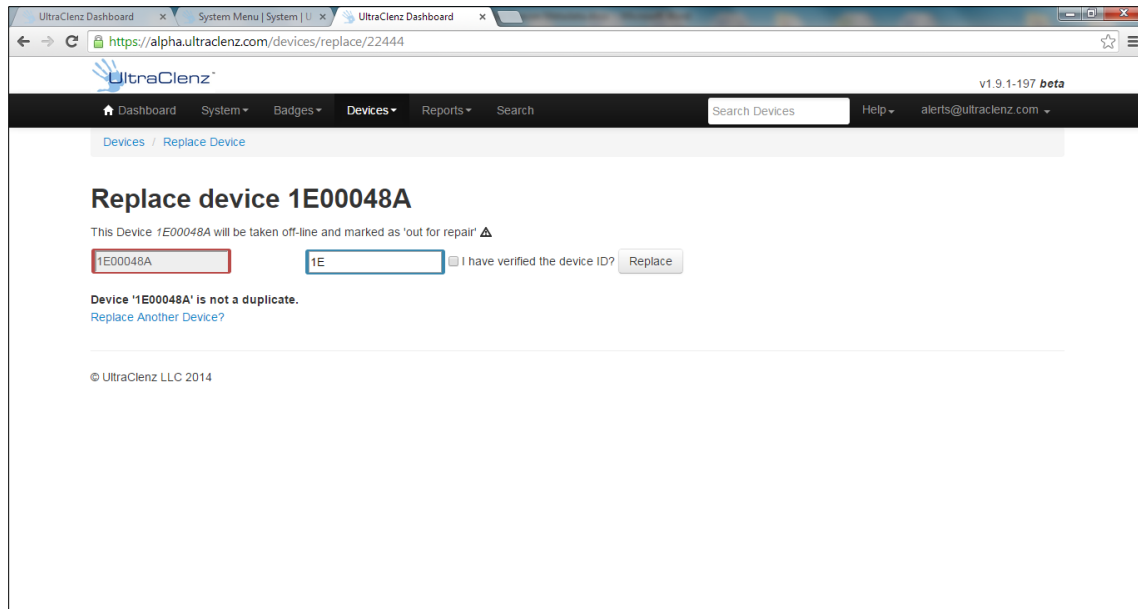


Figure 22. Replace Device Tab

7. Troubleshooting

7.1 No Bed Beacon Heartbeats on the Dashboard

If the Bed Beacon has stopped transmitting heartbeats to the Dashboard there is one of three possible solutions:

1. The batteries have died. Place a new set of batteries in the Bed Beacon and test the Bed Beacon's other function, communications with a Badge as described in section 5. If the unit tests well, then give the Bed Beacon a couple of hours to transmit a few heartbeats to the Dashboard.
2. If new batteries do not fix the problem, there is a problem with the wireless network hardware. Remove and replace the Bed Beacon. Refer to section 6.2 – **Replacing an Existing Bed Beacon – Swapping Metadata** for instructions on how to replace device information on the dashboard.
3. If replacing the Bed Beacon does not remedy the problem there, may be a problem with the Bentley network.

7.2 The Bed Installation Does Not Communicate with a Badge

If a Bed Installation is not communicating with Badges but is sending heartbeats to the dashboard, there are a number of possible causes. The following steps will help to find the cause of the problem.

7.3 Bed Beacon FAS1541

1. Verify that the bed's AC power cord is plugged into an active power source and the ALP Sensor is connected to the Bed Beacon. Verify that you get an alert and a red flash when disconnecting from the Bed Beacon.
2. Verify the batteries of the Bed Beacon are 2.20v or Higher.

Note: *If any of the components of the Bed Installation are replaced, the bed's range will have to be re-checked and readjusted as needed.*

8. System Component Care and Maintenance

8.1 Cleaning the Components

The components should be cleaned by wiping with a soft cloth. The cloth should be damp but not wet. A soft cloth dampened with isopropyl alcohol works well to clean the external surfaces. Only the exterior of the components may be cleaned. Do not attempt to clean any interior surface of these components as this will damage the component's circuitry. Do not use abrasive cleaners or cleaning products in aerosol cans as they will damage the component's finish.

8.2 Handling the Bed Beacon

The Bed Beacon is an electronic device and should be handled with care. Like other electronic devices such as cell phones, the Bed Beacon must be protected from extreme heat, cold and moisture. Avoid handling the Bed Beacon with wet hands or exposing it to rain. Avoid dropping or tossing the Bed Beacon. The shock can damage the Beacon's sensitive internal electronics.

8.3 Battery Replacement

Bed Beacon is powered by 2 "D" Cell Alkaline Batteries. Avoid reverse polarity by installing the batteries as indicated.



Figure 23. Battery Cover

Appendix A - Certification and Safety Approvals

FCC Statement

NOTE: This equipment has 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 causes harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try and 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.
- 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.

WARNING: Changes or modifications not expressly approved by UltraClenz, LLC could void the user's authority to operate the equipment.

RF EXPOSURE:

"This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter."

Industry Canada

Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada. Dans le but de réduire les risques de brouillage radioélectrique à l'intention des autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

This radio transmitter (IC:10060A-FAS1541) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

Le présent émetteur radio (IC:10060A-FAS1541) a été approuvé par Industrie Canada pour fonctionner avec les types d'antenne énumérés ci-dessous et ayant un gain admissible maximal et l'impédance requise pour chaque type d'antenne. Les types d'antenne non inclus dans cette liste, ou dont le gain est supérieur au gain maximal indiqué, sont strictement interdits pour l'exploitation de l'émetteur.

Appendix B - Warranty

This device is warranted against defective materials and workmanship for two years from the date of purchase.

Equipment covered by this warranty will be repaired or replaced in the United States and Canada, WITHOUT CHARGE, except for shipping and handling, by our Factory Service Center.

When returning equipment for warranty service, you must first call your distributor's **Warranty Service Department** for your Return Merchandise Authorization Number (RMA). The RMA must be on your return label and the shipping charges must be pre-paid and a copy of your receipt must be enclosed. Equipment should be returned to UltraClenz Customer Service, 1201 Jupiter Park Drive, Jupiter, FL 33458.

This warranty covers all defects incurred from normal use of the equipment and does not apply in the following cases:

- a. Loss or damage to the equipment due to abuse, mishandling, accident or failure to follow installation or use instructions.
- b. If the equipment is defective as a result of leaking batteries.
- c. If the equipment has been serviced or modified by someone other than our authorized agents.

THE AFOREMENTIONED IS IN LIEU OF ALL WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE. IN NO EVENT SHALL THE VENDOR BE LIABLE FOR CONSEQUENTIAL, INCIDENTAL, INDIRECT OR SPECIAL DAMAGES OR LIABILITY, TRANSPORTATION, INSTALLATION OR SUBSTITUTION COSTS, DELAYS, OR FOR ANY OTHER DAMAGES, COSTS, OR EXPENSES INCURRED, IRRESPECTIVE OF HOW THEY OCCUR. THIS WARRANTY SHALL NOT EXTEND TO ANY OTHER PERSON OTHER THAN THE ORIGINAL PURCHASER OF THIS EQUIPMENT OR THE PERSON FOR WHOM IT WAS PURCHASED AS A GIFT.

This warranty gives you specific legal rights, and you may also have other rights, which may vary from state to state. This warranty is given with respect to equipment purchased in the United States.

Appendix C – Bed Label

The bed label (Figure 1) is a unique bed number that will be linked to the PSS dashboard Bed Beacon Metadata. During installation, the bed labels are located on or near the foot-board frame of the patient bed (Figure 2). The bed number helps to quickly identify the PSS Bed Beacon address that's on the bed.

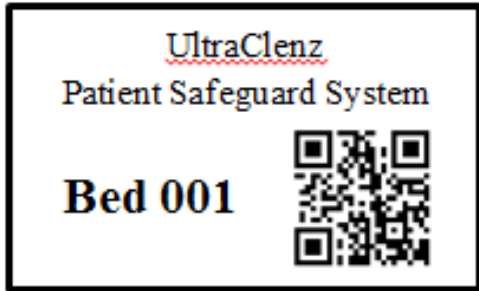


Figure 1. Bed Installation Label



Figure 2. Bed Label Location