Excellence in Compliance Testing

Certification Exhibit

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IC: 10060A-FAS1510

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IC Radio Standards Specification: RSS-210

ACS Project: 11-2103

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User Manual

Patient Safeguard System (PSS)
Dispenser Beacon User's Guide

DOC1047 Revision 1

UltraClenz™

UltraClenz, LLC

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Revision History

Revision	Date	By	Description
0	3/14/12	MES	Initial Release
1	08/09/12	DLS	Corrected TOC and replaced FCC class A statement with class B statement

1.0 Introduction to the System

The Patient Safeguard System (PSS) was designed to help Healthcare Workers (HCW) protect their patients from the unintentional spread of pathogens. This is achieved by providing a tool to remind HCWs to perform hand hygiene when the opportunities are presented. Hand hygiene opportunities, in a patient care environment, are defined as instances when hand hygiene should be performed to reduce or eliminate a patient's exposure to harmful or even deadly pathogens carried on the HCW's hands. These patient care hand hygiene opportunities are described in detail by the World Health Organization's (WHO) **"Your 5 Moments for Hand Hygiene"**.

PSS software provides HCWs with real-time feedback when hand hygiene opportunities occur and will also provide a warning when hand hygiene opportunities are missed or ignored. The real-time data can be viewed at a designated computer terminal or a tablet running the PSS application software. PSS may also be configured to monitor and assess the hand hygiene performance of HCWs on either a group or individual basis. By assessing how well a HCW recognizes and engages in hand hygiene opportunities, the HCW will receive feedback that lets them know how well they're doing. This feedback can then be used to establish performance benchmarks and goals. HCW performance can then be tracked over time, measured against these benchmarks and goals to assess overall compliance to identify specific areas where improvement is needed. Ultimately, the purpose of PSS is to provide HCWs with a tool that allows them to improve upon, and then maintain, high levels of hand hygiene performance, thus providing a safer environment for their patients and themselves.

2.0 System Components

PSS consists of 4 basic components; a HCW badge, a soap/sanitizer dispenser beacon, a patient bed beacon and a patient bed antenna. These components work together to form a system that will allert HCWs when hand hygiene needs to occur or alarm them when hand hygiene failed to occur.

1.Healthcare Worker (HWC) Badge
FAS1509

2.Soap/Sanitizer Dispenser Beacon
FAS1510

3.Patient Bed Beacon
FAS1511

3.0 Soap/Sanitizer Dispenser Beacon

The soap/sanitizer dispenser beacon is installed next to a soap/sanitizer dispenser. In order for it to communicate with the dispenser, it is attached to the dispenser via a flat ribbon cable. The dispenser beacon will create an invisible "bubble" approximately 36 inches around the dispenser when the dispenser is activated. When a HCW activates the dispenser and the HCW's badge is within the bubble, the badge will communicate with the dispenser beacon. The dispenser beacon will then reply to the badge and the badge will immediately change its hand hygiene state to sanitary (green flashing LED). If the badge is already in the sanitary state, it will remain in the sanitary state.

The dispenser beacon provides both audio and visual alerts to indicate that it has successfully communicated with a HCW's badge. Upon successful communication, the status LED will flash green one time followed by a two tone chime (see *Figure 3*).

Figure 3. *Soap/Sanitizer Beacon Audible and Visual Alert Locations*

3.1 Adjusting the Soap/Sanitizer Dispenser Beacon Communication Range

The dispenser beacon range of communication is adjusted during installation to maximize communication with the Healthcare Worker (HCW) badge. To adjust the communication range, remove the battery cover located on the front of the beacon using a #2 Phillips screwdriver (see *Figure 3*). Note: the battery cover has a retaining ring to prevent the screw from being detached. After the cover has been removed, the beacon communication range is adjusted by repeatedly pushing either the "+" *increment* or the "–" *decrement* range buttons (see *Figure 4*) to achieve the desired range. The total adjustable range of each beacon is 1 to 32 increments between the lowest and the highest setting. Each push of either the "+" or "–" button will produce an audible beep indicating one increment up or down. When the lowest or the highest setting is reached, four audible beeps will be heard. To reset a beacon's range back to the factory default setting, push and hold both the "+" and the "–" buttons down, at the same time, until four audible beeps are heard. The factory default range setting for the dispenser beacon is 31. Replace the battery cover when the adjustment is complete.

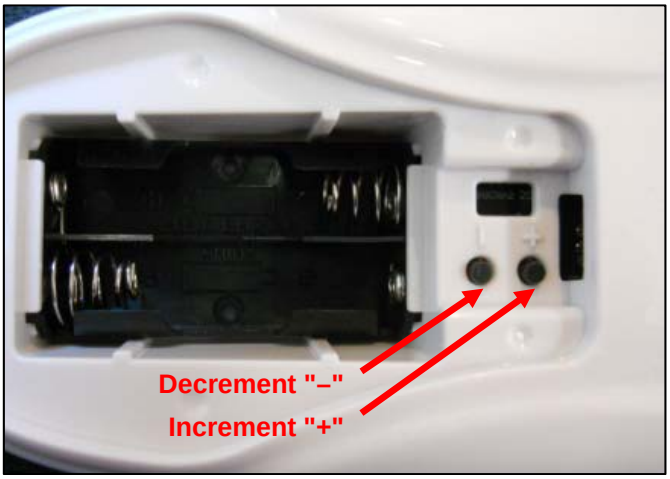


Figure 4 - *Dispenser Beacon Increment* "+" and *Decrement* "-" Communication Range Buttons

There may be circumstances which require a beacon's range to be adjusted, after the initial installation, to properly communicate with a badge. Examples of why dispenser beacon's range may need to be adjusted are explained below.

<u>Case for Dispenser Beacon Range Adjustment</u>

In tight quarters, there may be two or more HCWs standing in close proximity to a dispenser. If one of the HCWs activate the dispenser, the dispenser beacon may communicate with the incorrect HCW badge. Thus, when the intended HCW approaches a patient bed, the system will record that the intended HCW did not sanitize/wash their hands. The badge status LED will then be set to the red warning state even though the intended HCW did actually sanitize/wash. The dispenser beacon can be adjusted to reduced the communication range between the dispenser beacon and the HCW's badge. This is accomplished by removing the beacon's battery cover and pressing the "–" button to shorten the range. Continue pressing the "-" button until the desired range and thus proper communication is achieved.

4.0 How the System Works

When a Healthcare Worker (HCW) begins their shift, they will attach an assigned badge to their clothing in a location above the waist that is clearly visible to HCW as well as others. The badge will be dormant with no blinking LED visible. This is normal because the badge will go into a "sleep" state to conserve battery power when not in use for a period of 30 minutes or more.

The first thing the HCW will do, after attaching their badge, is wash or sanitize their hands. The dispenser beacon attached to the soap/sanitizer dispenser will communicate with the badge when the dispenser is activated. Even though the badge is in a sleep state, it is always listening and the dispenser beacon's communication will wake it up. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the dispenser beacon. The badge will then be set to the sanitary or clean state with the green LED blinking about once every 1.5 seconds. The HCW is now ready to begin their normal work routine.

When the badge is set to the sanitary state, the badge starts an internal timer. If there is no interaction between the HCW and a dispenser or patient bed, the timer will continue to increment. If the timer reaches 20 minutes, the badge will automatically change from the sanitary state to the cautionary state. When this transition occurs, the badge will produce 2 quick beep tones with both having the same pitch. This indicates to the HCW that the badge has automatically changed state. The badge's yellow LED will then blink about once every 1.5 seconds. The cautionary state does not imply a violation of hand hygiene protocol. In this case, it is indicating to the HCW and anyone else able to see the badge's yellow LED that the HCW has not washed or sanitized their hands for at least 20 minutes and that they may not approach a patient until doing so.

If the HCW does approach a patient while in the cautionary state, this event will be considered a violation of hand hygiene protocol and the badge will change from the cautionary state to the warning state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge's red LED will then blink about once every 1.5 seconds. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

If the HCW approaches a patient while in the sanitary state, the badge will change to the cautionary state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge's yellow LED will then blink about once every 1.5 seconds. The cautionary state does not imply a violation of hand hygiene protocol. In this case, it is indicating to the HCW and anyone else able to see the badge's yellow LED that the HCW is currently in contact with a patient or has had contact with a patient within the last 5 minutes.

While the HCW is inside the patient zone, their badge will remain in the cautionary state. When the HCW leaves the patient zone, the badge starts an internal timer. If there is no interaction between the HCW and a dispenser, after leaving the patient zone, the timer will continue to increment. If the timer reaches 5 minutes, the badge will automatically change from the cautionary state to the warning state. When this transition occurs, the badge will produce 2 quick beep tones with both having the same pitch. This indicates to the HCW that the badge has automatically changed state. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

A HCW may contact a patient, leave the patient zone briefly and then re-contact the same patient without washing/sanitizing their hands. However, the HCW may not re-contact the patient without first using a soap/sanitizer dispenser if they are outside of the patient zone for more than 1 minute. As long as the HCW remains inside the patient zone, their badge will remain in the cautionary state. When the HCW leaves the patient zone, the badge starts an internal timer. If there is no interaction between the HCW and a dispenser, after leaving the patient zone, the timer will continue to increment. If the HCW then reenters the patient zone and the internal timer has not reached 1 minute, the badge will remain in the cautionary state and the internal timer will be reset. However, if the HCW reenters the patient zone and the internal timer has reached or passed 1 minute, the badge

will change to the warning state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge's red LED will then blink about once every 1.5 seconds. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

A HCW may not go from one patient zone to another without washing/sanitizing in-between. While a HCW is in a patient zone, their badge will be in the cautionary state. When they leave the patient zone, their badge will remain in the cautionary state for up to 5 minutes beyond which time their badge will automatically change to the warning state or until they wash/sanitize at which time their badge will then change to the sanitary state. If the HCW leaves a patient zone and then enters a different patient zone without first interacting with a soap/sanitizer dispenser, the badge will change from the cautionary state to the warning state. The badge will produce 3 quick beep tones with the second tone being lower in pitch than the first or third tones. This indicates successful communications between the badge and the bed beacon located within the patient zone. The badge's red LED will then blink about once every 1.5 seconds. Immediately after changing to the warning state, the badge will produce a rapid burst of 4 tones with each having a different pitch. This will be repeated 4 more times over the next 20 seconds and will indicate to the HCW that they must wash/sanitize their hands immediately.

5.0 Installing the System

5.1 Soap/Sanitizer Dispenser Beacon Installation

The soap/sanitizer dispenser beacon will be mounted on the wall next to the soap/sanitizer dispenser. It may be mounted on the left or right side of the dispenser but never below the dispenser. The dispenser beacon must know when the dispenser has been activated by the HCWs. For this reason, the dispenser beacon is physically connected to the dispenser via a 6 wire ribbon cable. This needs to be taken into consideration when selecting a mounting location for the dispenser beacon.

The dispenser beacon is to be powered by two alkaline AA-cell batteries or optionally by an UltraClenz DSP2000 ProClenz series touch-free dispenser if available at the installation site.

Mount Using Tape

Double sided tape may be used to mount the dispenser beacon to a wall. A minimum of a single strip, at least 3 inches long, should be used.

To insure the best adhesion of the tape, make sure that the mounting surface of both the dispenser beacon and the wall are clean and free of dirt and oil. A soft cloth dampened with isopropyl alcohol will work well to clean both surfaces. Most tape adhesives require about 24 hours of curing. Avoid installing batteries into the dispenser beacon until the tape's adhesive has had a chance to cure. Otherwise, the extra weight may cause the dispenser beacon to detach from the surface of the wall.

Mount Using Screws

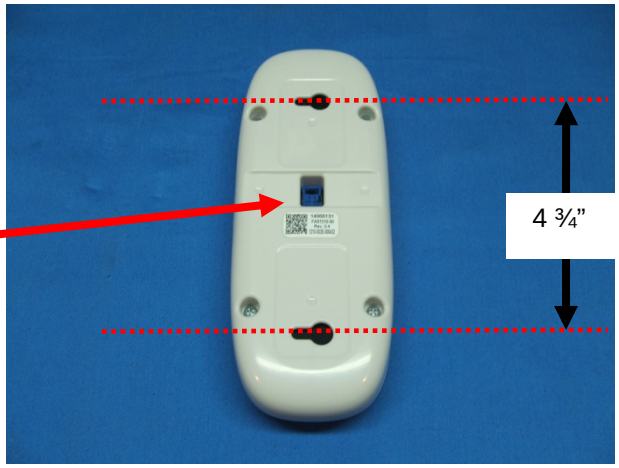
The rear surface of the dispenser beacon has two keyhole shaped openings that are $4\,3/4$ inches on center. Locate the position and height on the wall where the dispenser beacon will be mounted. Mark the location for the first mounting screw. Then, measure up or down $4\,3/4$ inches and mark the location of the second mounting screw. Use a level to verify that the screw locations are plumb.

The keyhole openings will accept #6 or #8 screws and it is advisable to use properly sized wall anchors. Using a correctly sized drill bit, drill a hole in the wall for each mounting screw at the locations marked. Insert the wall anchors into the wall and then install the screws. Both screws will need a gap between the base of the screw's head and the surface of the wall. Start with about 1/8 of an inch.

Attach the dispenser beacon to the wall by lining up the large portion of the keyhole openings with the mounting screw heads and push the bed beacon flush against the wall. Then, gently slide the bed beacon left until the smaller portion of the keyhole openings make contact with the shaft of both mounting screws. The dispenser beacon may slide to the left as much as ½ inch so take this into consideration when selecting a mounting location especially if mounting on the right side of the dispenser.

If the dispenser beacon is not in tight contact with the wall, remove the dispenser beacon and tighten both mounting screws a little more to reduce the gap between the screw's head and the surface of the wall.

The Soap / Sanitizer Dispensers are connected to the Dispenser Beacon by connecting the appropriate "Activation Interface" ribbon cable to this port.



Appendix A - System Component Care and Maintenance

Cleaning the Components

The dispenser beacon should be cleaned by wiping with a soft cloth. A mixture of 90% water and 10% chlorine (bleach) or water and mild detergent (dish soap) may be used. The cloth should be damp but not wet. Only the exterior of the component may be cleaned. Do not attempt to clean any interior surface of the component 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.

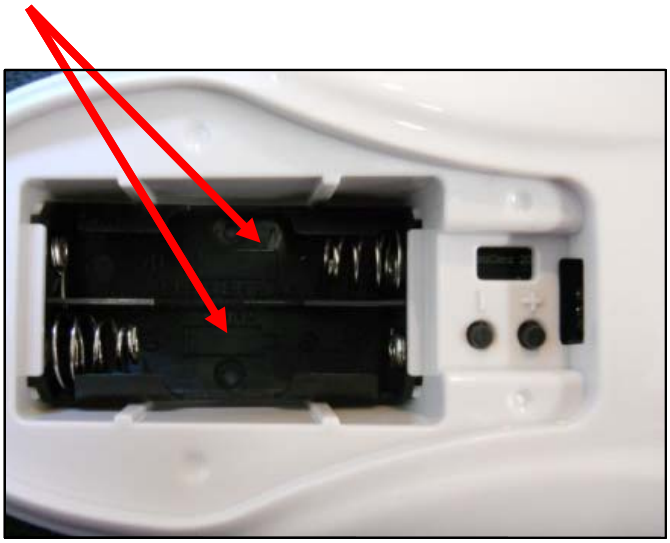
Handling the Dispenser Beacon

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

Battery Replacement:

Soap/Sanitizer Dispenser Beacon

The dispenser beacon is powered by 2 AA alkaline batteries. These batteries are accessed by removing the battery cover using a #1 Phillips screwdriver.



Appendix B - Certification and Safety Approvals

FCC

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 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 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.

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.

Warranty

This device is warranted against defective materials and workmanship for one year from the date of delivery.

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, also the shipping charges must be pre-paid and a copy of your receipt must be enclosed.

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 mounting 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 PUCHASER 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.

Patent Pending