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Certification Exhibit

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User Manual

Patient Safeguard System® (PSS) Healthcare Worker Badge User's Guide

FAS1527 DFU Revision 2



UltraClenz, LLC

Table of Contents

1.0 Healthcare Worker (HWC) Badge3

2.0 How the Badge works within PSS4

3.0 Installing the System6

 3.1 Healthcare Worker (HCW) Badge Installation6

Appendix A - System Component Care and Maintenance6

 Cleaning the Badge.....6

 Handling the Badge.....6

 Battery Replacement.....6

 Healthcare Worker (HCW) Badge.....6

Appendix B - FCC and Industry Canada Statements8

 Class B Devices:8

 RF Exposure8

 Industry Canada Statements:8

Warranty9

Revision History.....9

1.0 Healthcare Worker (HWC) Badge

The PSS badge is an integral component of the individual reminder system. Badges are assigned to specific healthcare workers (HCW) and may not be interchanged. It is worn by HCWs, such as doctors and nurses. Healthcare facilities may also choose to assign badges to therapists, visitors, students or any persons with patient contact. It is through the badge that the HCW is made aware, in real-time, of their hand hygiene status. The badge achieves this by providing both visual and audible status alerts. The badge’s visual alerts are provided by three visual indicator LEDs located just behind the badge’s clear window (see *Figure 1*). Only one visual indicator will flash at a time, with a flash occurring once every 1.5 seconds. Each indicator LED (green, yellow and red) represents the current level or state of the HCW’s hand hygiene compliance. Each badge has a unique programmed identification address.

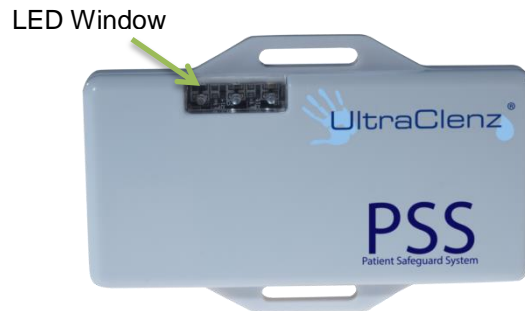


Figure 1. HCWs Badge -Visual Alert Location

The **GREEN** LED (see *Figure 2*) indicates a **SANITARY** state which occurs when a HCW has recently used a PSS enabled soap or sanitizer dispenser.

The **YELLOW** LED (see *Figure 2*) indicates a **REMINDER** state which occurs when a HCW is currently in a patient zone or has recently come in contact with a patient bed. It may also indicate that the HCW has not used a soap or sanitizer dispenser within the designated grace period. Please note that this is only a reminder state and it does not imply non-compliance. The HCW must use a soap or sanitizer dispenser before patient contact to remain compliant with the system’s hand hygiene requirements.

The **RED** LED (see *Figure 2*) indicates an **ALERT** state which occurs when a HCW comes in contact with more than one patient bed without using a soap or sanitizer dispenser between patient contacts. It may also indicate that the HCW has not used a soap or sanitizer dispenser within the designated grace period after leaving a patient zone. When a HCW’s badge is in the alert state (red flashing LED), it is possible that they may have already spread pathogens from one patient to another. They should use a soap or sanitizer dispenser immediately and avoid contact with everyone until proper hand hygiene has occurred.



Figure 2. HCWs Badge LEDs: Green (Sanitary State), Yellow (Reminder State) and Red (Alert State)

The audible alert is generated by a piezoelectric sounder. The piezoelectric sounder is basically a very small speaker that produces pleasant sounding beeps and chimes. These beeps and chimes occur when the badge’s state is changing or when the badge is in the alert state.

The badge can be worn at the waist, on a lanyard around the neck, on a chest pocket, inside a chest pocket or under a lab coat. However, the clear window is designed so HCWs and patients can view the current badge status.

2.0 How the Badge works within PSS

When a Healthcare Worker (HCW) begins their shift, they will attach their assigned badge to their clothing in a location above the waist that is clearly visible to themselves and 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 designated time period.

The first thing the HCW will do, after attaching their badge, is wash or sanitize their hands. The dispenser beacon attached to the soap or 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 three 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 the designated grace period, the badge will automatically change from the sanitary state to the reminder state. When this transition occurs, the badge will produce two 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 reminder 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 the designated grace period and that they may not approach a patient bed until doing so.

If the HCW does approach a patient bed while in the reminder state, this event will be considered a violation of hand hygiene protocol and the badge will change from the reminder state to the alert state. The badge will produce three 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 alert state, the badge will produce a rapid burst of four tones with each having a different pitch. This will be repeated four more times over the next twenty seconds and will indicate to the HCW that they must wash or sanitize their hands immediately.

If the HCW approaches a patient bed while in the sanitary state, the badge will change to the reminder state. The badge will produce three 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 reminder 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 bed or has had contact with a patient bed within the designated grace period.

While the HCW is inside the patient zone, their badge will remain in the reminder 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 the designated grace period, the badge will automatically change from the reminder state to the alert state. When this transition occurs, the badge will produce two quick beep tones both having the same pitch. This indicates to the HCW that the badge has automatically changed state. Immediately after changing to the alert state, the badge will produce a rapid burst of four tones with each having a different pitch. This will be repeated four more times over the next twenty seconds and will indicate to the HCW that they must wash or sanitize their hands immediately. A HCW may contact a patient bed, leave the patient zone briefly and then re-contact the same patient bed without washing or sanitizing their hands. However, the HCW may not re-contact the patient bed without first using a soap or sanitizer dispenser if they are outside of the patient zone for more than the designated grace period. As long as

the HCW remains inside the patient zone, their badge will remain in the reminder 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 designated grace period, the badge will remain in the reminder state and the internal timer will be reset. If the HCW reenters the patient zone and the internal timer has reached or passed designated grace period, the badge will change to the alert state. The badge will produce three 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 alert state, the badge will produce a rapid burst of four tones with each having a different pitch. This will be repeated four more times over the next twenty seconds and will indicate to the HCW that they must wash or sanitize their hands immediately.

A HCW may not go from one patient zone to another without washing or sanitizing their hands in between. While a HCW is in a patient zone, their badge will be in the reminder state. When they leave the patient zone, their badge will remain in the reminder state for a designated grace period beyond which time their badge will automatically change to the alert state or until they wash or sanitize their hands, 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 or sanitizer dispenser, the badge will change from the reminder state to the alert state. The badge will produce three 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 alert state, the badge will produce a rapid burst of four tones with each having a different pitch. This will be repeated four more times over the next twenty seconds and will indicate to the HCW that they must wash or sanitize their hands immediately.

Below is a table that compares the various badge states.

State Index	Badge State	LED Color	Description	Next Action
0	SANITARY	GREEN	HCW has recently used a soap or sanitizer dispenser.	May freely enter a patient zone.
1	REMINDER	YELLOW	HCW is in sanitary contact with a patient bed or has recently had sanitary contact with a patient bed but not yet used a soap or sanitizer dispenser.	Wash or sanitize hands immediately after leaving patient zone. Do not enter a different patient zone.
2	ALERT	RED	HCW has had contact with more than one patient bed without using a soap or sanitizer dispenser between contacts.	Leave patient zone immediately and wash or sanitize hands.
3	ALERT	RED	HCW had contact with patient bed, left patient zone for more than the designated grace period and then reentered same patient zone without using a soap or sanitizer dispenser between contacts.	Leave patient zone immediately and wash or sanitize hands.
4	REMINDER	YELLOW	HCW was in the sanitary state for more than the designated grace period without using a soap or sanitizer dispenser.	Wash or sanitize hands before entering a patient zone.
5	ALERT	RED	HCW was in the reminder state for more than the designated grace period after leaving a patient zone without using a soap or sanitizer dispenser.	Wash or sanitize hands immediately. Do not enter a patient zone.

Table 1 - HCW Badge States

3.0 Installing the System

3.1 Healthcare Worker (HCW) Badge Installation

A new badge is supplied with a pull tab to protect battery life during shipment. Remove by firmly pulling this tab out and discarding before initial use. For best performance, the badge should be worn above the waist in a location that is clearly visible to the HCW as well as the patients and other healthcare staff. The badge was designed to easily attach to a lanyard or a vinyl strap and clip. Both attachment methods are commonly used by HCWs to carry credentials such as identification and RFID cards. For convenience, the badge was also designed so that a HCW’s credentials may be attached to the base of the badge with a vinyl strap (see *Figure 3*).



Figure 3. HCWs Badge (ID Credentials can be attached at the bottom)

Appendix A - System Component Care and Maintenance

Cleaning the Badge

The badge should be cleaned by wiping with a soft cloth. The cloth should be damp but not wet. A pre-moistened alcohol swab may also be used. Only the exterior of each component may be cleaned. Do not attempt to clean any interior surface of a 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 Badge

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

Battery Replacement

Healthcare Worker (HCW) Badge

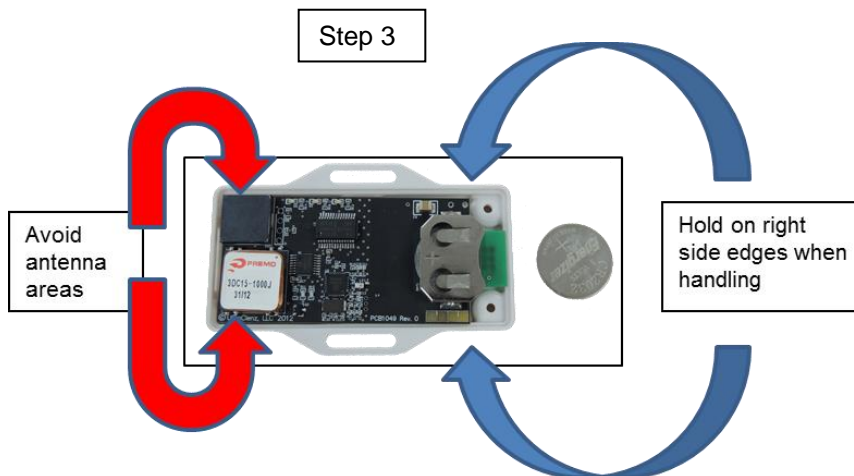
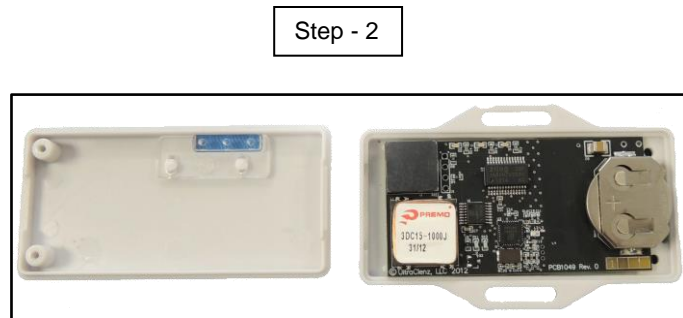
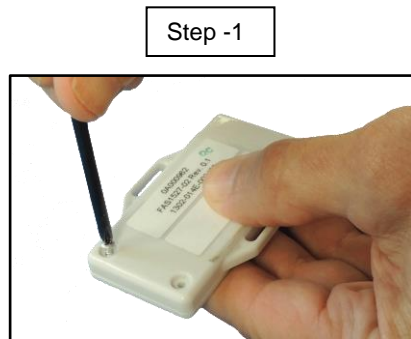
The badge is powered by a single 3 volt coin cell battery (CR2032). The PSS dashboard software monitors the badge battery good or low status flag to indicate when a replacement is required. The PSS dashboard software will send out a maintenance email to a designated administrator, alerting the email recipient of the low badge battery status along with any badge assignment information to locate and provide a replacement battery. It is recommended that only one badge battery is replaced at a time to avoid mixing up the identifier addresses that

are assigned to the HCWs. Take care to return the badge to the HCW in which it is assigned upon battery replacement.

Tools needed to replace the badge’s battery:

Quantity 1 - #2 Phillips head screwdriver

- Step 1 - Using the #2 Phillips head screwdriver, remove the two back cover screws. Save the screws.
- Step 2 - Flip the badge over and remove the front cover to expose the pc board and battery holder.
- Step 3 - Take care not to disturb or damage the antenna on the left hand side of the board, or any of the components while changing the battery. If you need to remove the board from the badge housing to replace the battery, hold the board securely from the right hand top and bottom edges only.
- Step 4 - Remove the battery from the battery holder and discard the old battery safely. Wait 30 seconds to allow all of the remaining energy to dissipate from the old battery.
- Step 5 - Install the new battery with the "+" side facing the installer and slide into the battery the holder.
- Step 6 - Once the battery is installed in the badge, it will perform a power on self-test by scrolling through the LED badge states and emitting an audio tone when complete to indicate it is functioning properly. If the audio tone is heard during the LED sequence instead of after, repeat the battery replacement process with a second replacement battery. If there is still no indication of proper function, request a replacement badge immediately.
- Step 7 - Replace the board assembly with the battery holder face down, then the back cover and tighten the screws into place.



Appendix B - FCC and Industry Canada Statements

Warning: Changes or modifications to this device not expressly approved by UltraClenz, LLC could void the user’s authority to operate the equipment.

Class B Devices:

“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 to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.*
- Increase the separation between the equipment and receiver.*
- 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.”*

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 Statements:

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 licence-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 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.

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
2	01/27/14	KAS	Updated to Directions for Use