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## **Certification Exhibit**

**FCC ID: Z90-FAS1509  
IC: 10060A-FAS1509**

**FCC Rule Part: 15.249  
IC Radio Standards Specification: RSS-210**

**ACS Project: 11-2105**

Manufacturer: UltraClenz, LLC  
Models: FAS1509-00, FAS1509-01, FAS1509-02,  
FAS1509-03, FAS1509-04

## **User Manual**

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

DOC1046 Revision 1



**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 alert 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

### 2.1 Healthcare Worker (HWC) Badge

The badge is worn by HCWs, such as doctors and nurses, however, healthcare facilities may 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 LED’s 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. For group monitoring, badges are not assigned to a particular HCW. For individual monitoring, badges are assigned to a designated HCW.



**Figure 1.** HCWs Badge - Audible and Visual Alert Locations

The **GREEN** LED (see *Figure 2*) indicates a **SANITARY** state which occurs when a HCW has recently used a soap/sanitizer dispenser. The soap/sanitizer dispenser must have a beacon attached to achieve a sanitary state.

The **YELLOW** LED (see *Figure 2*) indicates a **CAUTIONARY** state which occurs when a HCW is currently in a patient zone or has recently come in contact with a patient. It may also indicate that the HCW has not used a soap/sanitizer dispenser within the last 20 minutes. Please note that this is only a cautionary state and it does not imply noncompliance. The HCW must use a soap/sanitizer dispenser before patient contact to remain compliant with the system’s hand hygiene requirements.

The **RED** LED (see *Figure 2*) indicates a **WARNING** state which occurs when a HCW comes in contact with more than one patient without using a soap/sanitizer dispenser between patient contacts. It may also indicate that the HCW has not used a soap/sanitizer dispenser within 5 minutes after leaving a patient zone. When a HCW’s badge is in the warning state (red flashing LED), it is possible that they may have already spread pathogens from one patient to another. They should use a soap/sanitizer dispenser immediately and avoid contact with everyone until proper hand hygiene has occurred.



**Figure 2.** HCWs Badge LEDs: Green (Sanitary State), Yellow (Cautionary State) and Red (Warning State)

The audible alert is generated by a piezoelectric sounder located behind the badge’s audio port opening (see *Figure 1*). 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 warning state.

The badge placement is not critical with respect to system detection, however the clear window is designed so the HCW and patient can view the current badge status.

### 3.0 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.

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/sanitizer dispenser.	May freely enter a patient zone.
1	CAUTIONARY	YELLOW	HCW is in sanitary contact with a patient or has recently had sanitary contact with a patient but not yet used a soap/sanitizer dispenser.	Wash/Sanitize hands immediately after leaving patient zone. Do not enter a different patient zone.
2	WARNING	RED	HCW has had contact with more than one patient without using a soap/sanitizer dispenser between contacts.	Leave patient zone immediately and wash/sanitize hands.
3	WARNING	RED	HCW had contact with patient, left patient zone for more than 1 minute and then reentered same patient zone without using a soap/sanitizer dispenser between contacts.	Leave patient zone immediately and wash/sanitize hands.
4	CAUTIONARY	YELLOW	HCW was in the sanitary state for more than 20 minutes without using a soap/sanitizer dispenser.	Wash/sanitize hands before entering a patient zone.
5	WARNING	RED	HCW was in the cautionary state for more than 5 minutes after leaving a patient zone without using a soap/sanitizer dispenser.	Wash/Sanitize hands immediately. Do not enter a patient zone.

*Table 1 - HCW Badge States*



## 4.0 Installing the System

### 4.1 Healthcare Worker (HCW) Badge Installation

This is to be worn by the HCW. 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 5*).



*Figure 5. HCWs Badge ( ID Credentials can be attached at bottom )*

## **Appendix A - System Component Care and Maintenance**

### **Cleaning the Components**

The badge, bed beacon and 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 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 software monitors the badge battery good/low status flag to indicate when a replacement is required. The PSS software will send out a maintenance email to a designated administrator(s), alerting the email recipient of the low badge battery status along with any badge assignment information to locate and rectify the problem.

Tools needed to replace the badge battery:

Quantity 1 - #2 Phillips head screwdriver

Quantity 1 - Small slotted head screwdriver

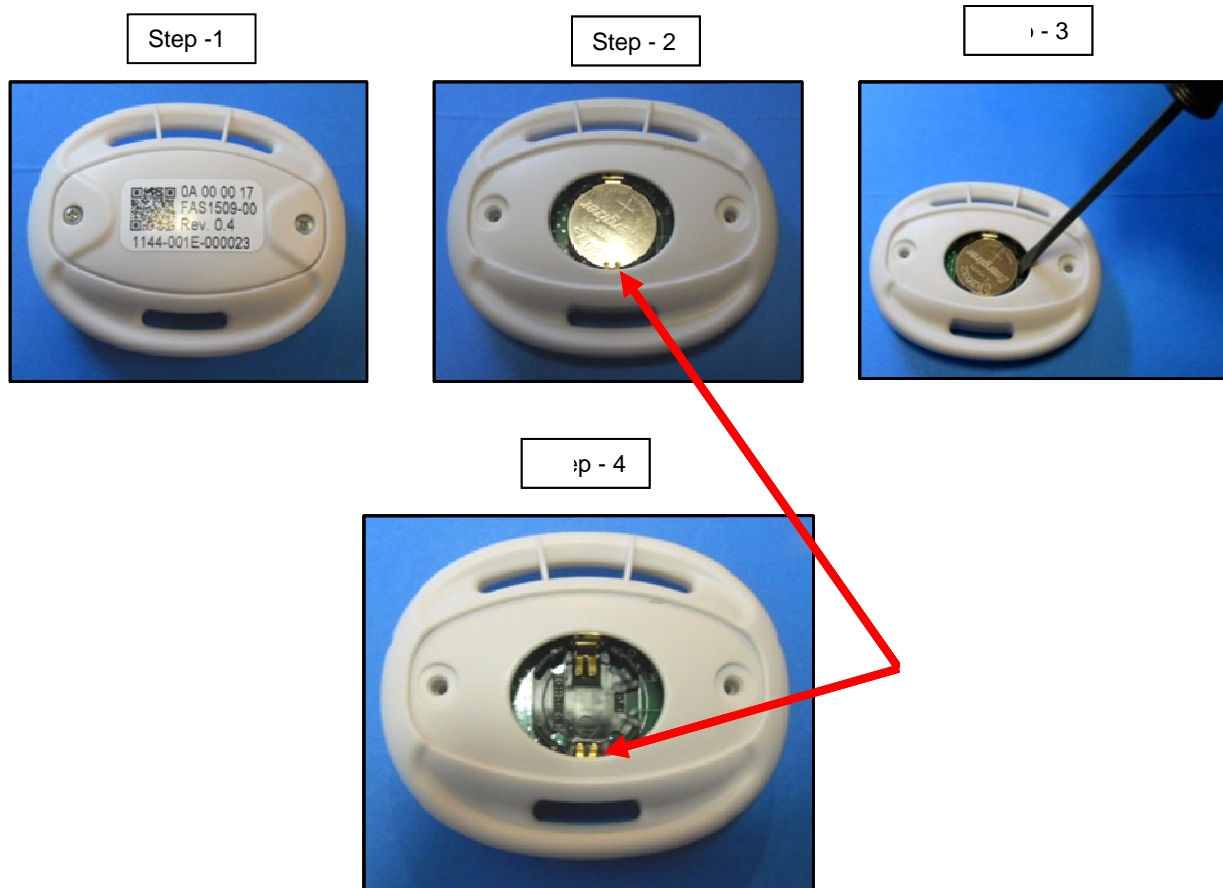
Step 1 - Using the #2 Phillips head screwdriver, remove the 2 back cover screws. Save the screws.

Step 2 - Remove the back cover

Step 3 - Using the small slotted screwdriver, gently lift the battery up and out of the holder. Discard the old battery.

Step 4 - Install the new battery, "+" side facing the installer and slide the corner edge under the connector bottom fingers first.

Step 5 - Once the battery is installed the badge with perform a "Power On Self Test"



### Healthcare Worker Badge Power On Self Test (POST)

Insert the new 3VDC coin cell battery into the battery holder on the PCB1034. Observe and verify the sequential LED functions below. If the PCB fails any of the steps below, set it aside for inspection and rework.

1. As the PCB powers up, it performs a power on self test (POST). The red, yellow and green LED will flash once each in consecutive order. This test will verify that the LEDs are working. See Figure 12 for LED locations.
2. The PCB will then tune the X, Y and Z antennas (L1). The green LED will flash several times as the X antenna is tuned. Then the yellow LED will flash several times as the Y antenna is tuned. Finally, the red LED will flash several times as the Z antenna is tuned.

*NOTE: During the antenna tuning process, if a short beep is heard after any one of the X, Y or Z antenna tuning cycles (green, yellow or red LED flash), the corresponding antenna did not tune properly. Typical reasons for failure include incorrect capacitor values for any of C1 to C5 or an unconnected lead on L1.*

3. After the antennas have tuned, the green and yellow LEDs will alternately flash back and forth while tuning U1’s internal RC oscillator.

*NOTE: If a failure occurs, the red LED will flash twice along with 2 short beeps from the piezo. This rarely happens and the cause is usually poor soldering of U1.*

4. A long **chime** will then be heard to conclude the POST. This chime will verify the operation of the piezo.
5. Once the POST has completed, the green LED will blink once every 1.5 seconds to indicate normal operation.

## Appendix B - Certification and Safety Approvals

### FCC

THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES. OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS.

- (1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE, AND
- (2) THIS DEVICE MUST ACCEPT ANY INTERFERENCE RECEIVED, INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRE OPERATION.

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**