

ECOLAB HAND HYGIENE PROGRAM COMPLIANCE MONITORING SYSTEM



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Healthcare Worker Badge User's Guide

Model HHCM915-BDG2450, (No. 53005389)

Ecolab Hand Hygiene Program Compliance Monitoring System

HEALTHCARE WORKER BADGE USER'S GUIDE

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COMPLIANCE MONITORING SYSTEM COMPONENTS



Figure 1. Ecolab Hand Hygiene Program Compliance Monitoring System Components

1. BADGE OVERVIEW

The Healthcare Worker (HCW) **Badge** is an integral component of the Ecolab Hand Hygiene Program Compliance Monitoring System (referred to as the **System** throughout the rest of this document). Each **Badge** has a unique identification address that is assigned to a specific HCW and **Badges** may not be exchanged between HCWs. Healthcare facilities may also assign **Badges** to therapists, visitors, students or any other persons who may have patient contact (having physical contact with a patient, their immediate surroundings or being in close proximity to a **System**-equipped patient bed).

The **Badge** provides a real-time hand hygiene status reminder through both visual and audible alerts. The **Badge's** visual alerts are provided by three LEDs (Light Emitting Diode) located just behind the **Badge's** clear LED window (see Figure 2). Only one visual alert will flash at a time, with a flash occurring once every 1.5 seconds. Each flash (green, yellow or red) represents the current status of the HCW's hand hygiene. The audible alerts produce beeps when the **Badge** status changes or when in the Non-Compliant Status level.



Figure 2. HCW Badge LED Window Location

2. BADGE SET UP

2.1 Powering the Badge on for the First Time

Each new **Badge** is supplied with a plastic pull-tab to prevent draining the internal battery during storage and shipment. Remove the pull-tab by firmly pulling it out of the **Badge** enclosure and discarding the tab. All three LEDs will flash in sequence as the **Badge** performs an internal power on self-test and the audible alert will beep for about 1 second. This is normal and provides feedback that all three LEDs and the audible alert are functioning properly. Please note that the **Badge** LEDs and audible alert will behave in the same manner when the battery is replaced.

2.2 How to Wear the Badge

It is recommended that the **Badge** either be worn on a lanyard around the neck, or clipped on a chest pocket, scrub collar, or on a jacket lapel. This allows the user (HCW), other healthcare staff members and patients a clear view of the current **Badge** status. The **Badge** has a loop located at the top of its enclosure so a lanyard or the supplied vinyl strap (with clip) can easily be attached. For convenience, hospital credentials may be attached directly to the loop at the base of the **Badge** with a vinyl strap, if desired.

3. HOW THE BADGE WORKS

The **System Badge** is a wireless device worn by a HCW that detects and communicates with **System** equipped **Dispensers** and patient beds, stretchers and cribs. The **Badge** communicates with other **System** devices (**Dispensers** or patient beds) based on its proximity to the device. A proximity bubble is created around a **Dispenser** or patient bed by an attached or embedded **Dispenser Beacon** or **Bed Beacon**. The **Badge** will only communicate with a **Beacon** when it is within the **Beacon's** proximity bubble.

The **Badge** is also responsible for maintaining the current hand hygiene status of the HCW. The **Badge** will automatically change or update the HCW's hand hygiene status based on internal timers and interactions with other **System** devices. The **Badge** will then use its visual and audible alerts to inform the HCW of their current hand hygiene status or of any changes to hand hygiene status.

3.1 Interaction with a Soap or Sanitizer Dispenser

When a **Monitored Dispenser** is activated, the internal **System Dispenser Beacon** will momentarily create a proximity bubble around the **Dispenser**. If the **Badge** worn by the HCW who activated the **Dispenser** is within the proximity bubble, the **Badge** will communicate with the **Dispenser Beacon** and then update its hand hygiene status level. If the **Badge** is not within the proximity bubble, it will not communicate with the **Dispenser Beacon** nor will its hand hygiene status level change. This will result in the HCW not receiving credit for using the **Dispenser**.

The default range of the **Dispenser Beacon's** proximity bubble is approximately arm's length in all directions but the range can be adjusted if necessary. It is important for HCWs to wear their **Badge** in a location that ensures it will be within the **Dispenser Beacon's** proximity bubble whenever a **Dispenser** is activated. It is also important that only one **Badge** is within the proximity bubble when a **Dispenser** is activated. If more than one **Badge** is within the proximity bubble, the **Dispenser Beacon** may communicate with the wrong **Badge**, *i.e.*, a **Badge** belonging to a HCW who did not activate the **Dispenser**. If this happens, the wrong **Badge** will change its hand hygiene status level and the wrong HCW will receive credit for using the **Dispenser**.

Every **Dispenser Beacon** is equipped with at least one user feedback LED. This LED will only flash when the **Beacon** has successfully communicated with a **Badge**. The LED flash will occur during or immediately after **Dispenser** activation. If the LED does not flash, the **Badge** may not have been within the proximity bubble or there was an error in communications. If this occurs, the HCW should move closer to the **Dispenser** and activate it again.

Please take the following steps to insure proper **Badge** communications and correct HCW credit when using a **Dispenser**.

1. Verify that the **Badge** is being worn in a location that will be within a **Dispenser Beacon's** 36" proximity bubble.
2. Before activating a **Dispenser**, verify that other HCWs are not within the **Dispenser Beacon's** 36" proximity bubble. If there are other HCWs near the **Dispenser**, kindly ask them to move away before activating.
3. Verify that the **Dispenser** LED flashed when dispensing. If the LED did not flash, move closer to the **Dispenser** and activate it again.

3.2 Interaction with a Patient Bed (Patient Zone)

All **System**-equipped patient beds will either have a **Bed Beacon** mounted to them, or during trial periods, a **Bed Beacon** mounted to the wall in combination with a **Mat Antenna** under the bed. The **Bed Beacon** creates a proximity “bubble” around the patient bed once a second. When a **Badge** worn by the HCW enters the proximity bubble, it will communicate with the **Bed Beacon** and update its hand hygiene status appropriately, dependent upon its previous hand hygiene status.

The proximity bubble’s default range is approximately 18” from each side of the patient bed. The range can be adjusted to be either larger or smaller, to accommodate workflow or for areas where patient beds may be in close proximity with one another.

The **Bed Beacon**’s proximity bubble is designed to emulate the World Health Organization’s (WHO’s) **Patient Zone**, so from here on, the **Bed Beacon**’s proximity bubble will be referred to as the “**Patient Zone**.” The **Patient Zone** is defined by the World Health Organization as follows:

*“The **Patient Zone** contains the patient and his/her immediate surroundings. This typically includes the intact skin of the patient and all inanimate surfaces that are touched by or in direct physical contact with the patient such as the bed rails, bedside table, bed linen and infusion tubing and other medical equipment. It further contains surfaces frequently touched by HCWs while caring for the patient such as monitors, knobs and buttons, and other high frequency touch surfaces within the **Patient Zone**. It has been assumed that the patient flora rapidly contaminates the **Patient Zone**, but that it is being cleaned between patient admissions.”*

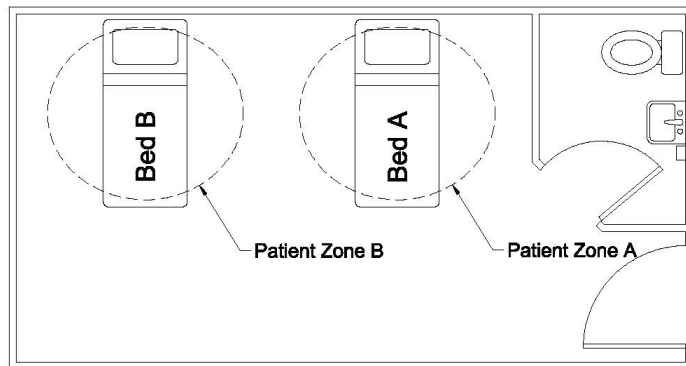


Figure 3. Patient Zones in Typical Bed Patient Room

By creating a **Patient Zone** around the patient, the patient's bed and the patient's immediate surroundings, the **Bed Beacon** can accurately monitor moments 1, 4 and 5 of the WHO's "Your 5 Moments for Hand Hygiene" (see Figure 4).

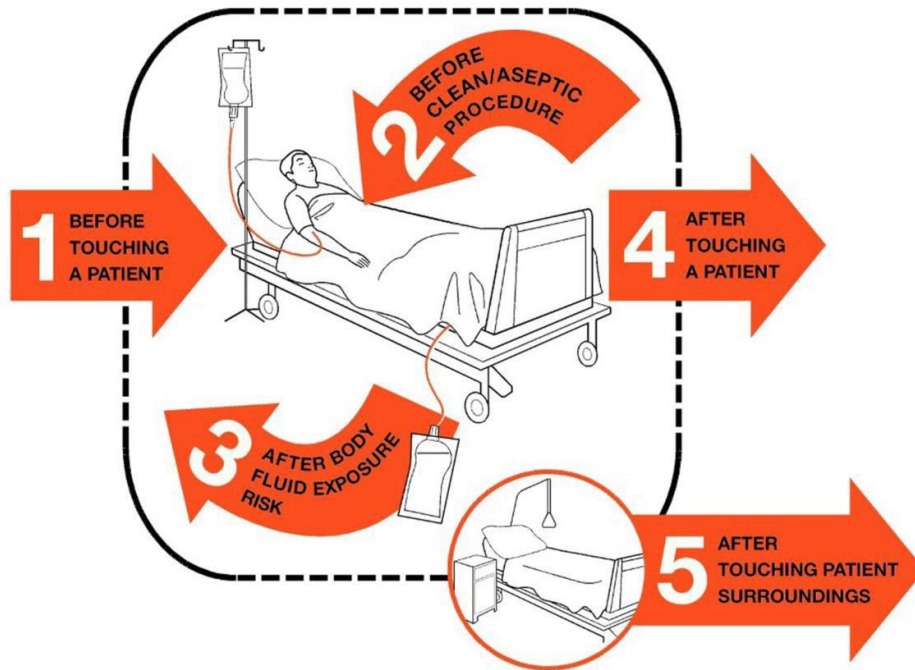


Figure 4. World Health Organization's "Your 5 Moments for Hand Hygiene"

Please take the following steps to ensure proper **Badge** interaction with the **Patient Zone**:

1. Avoid passing close to patient beds where **Patient Zone** entry is not intended.
2. Avoid standing directly in the middle between two patient beds. Instead, stand closer to the bed of the patient you intend to work with.
3. Verify that the **Badge** is at the green, "Clean" Status level before entering a **Patient Zone**. If it is not, perform hand hygiene and then enter the **Patient Zone**.

4. BADGE HAND HYGIENE STATUS LEVELS

By performing proper hand hygiene before and after each patient contact (*i.e.*, when entering and exiting a **Patient Zone**), a HCW is proactively reducing the potential for the spread of harmful or even deadly pathogens. This proactive behavior results in a higher level of protection for both the patient and the HCW. The purpose of the **Badge** is to assist in reaching this higher level of protection by reminding or alerting the HCW of their current hand hygiene status level at all times. This is done, in real-time, as the HCW interacts with both **System**-equipped patient beds and **Monitored** soap/sanitizer **Dispensers**. The combination of colored LED lights on the **Badge** can represent one of five hand hygiene status levels. By checking the **Badge's** current status level before entering a **Patient Zone** and after exiting a **Patient Zone**, the HCW will be reminded that it is necessary to perform hand hygiene, thus reinforcing good hand hygiene practices.

Sleep Mode: Please note that if the **Badge** does not interact with a **Bed** or **Dispenser Beacon** for a period of 30 minutes (default) or longer, it will go into a dormant or sleep mode, to conserve battery life. While in sleep mode, no lights are visible on the **Badge**. The **Badge** will “wake-up” in the same hand hygiene status level as when it entered sleep mode, and the LEDs will again be active once the HCW has interacted with a **System**-equipped **Dispenser** or patient bed.

4.1 Green LED – “Clean” Status (State 0)

A green LED light on the **Badge** indicates that the HCW is currently at a “Clean” Status, resulting from the recent use of a **System**-equipped soap or sanitizer **Dispenser**. When the green LED is on and the HCW enters a **Patient Zone**, this registers as a compliant patient interaction. The **Badge** will not remain in the “Clean” Status level indefinitely after performing hand hygiene. It has an internal timer that will eventually expire and change the **Badge** to the yellow or “Cue to Clean” Status level (State 4) unless the HCW performs hand hygiene. The internal timer, for the “Clean” Status level, has a factory default expiration time of 20 minutes, but this can be adjusted to accommodate a HCW’s workflow. Factory default is a **Badge** setting or parameter that is programmed with an initial default value by the manufacturer but may be modified by the healthcare facility.

4.2 Green LED – Compliant Patient Contact (State 1)

When a HCW enters a **Patient Zone** with a **Badge** at the “Clean” Status level (State 0), the **Badge's** LED will remain green while inside that **Patient Zone**. This informs both the HCW and the patient that the HCW has performed hand hygiene prior to contact with the patient.

4.3 Green and Yellow Alternating LEDs – Compliant Patient Re-Contact Status Level (State 1 Grace Period)

When the HCW leaves the **Patient Zone**, their **Badge** will flash the green LED and then the yellow LED in rapid succession. While the **Badge** is flashing alternating “green/yellow,” this indicates that the HCW may re-enter the **SAME Patient Zone** without the need to perform hand hygiene again. The **Badge** will only remain at the “Compliant Patient Re-Contact Status” level for a limited time. It has an internal timer that will eventually expire and change the **Badge** to the yellow “Cue to Clean Status” level unless the HCW performs hand hygiene. The internal timer for the “Compliant Patient Re-Contact Status” level has a factory default expiration time of 5 minutes, but this can be adjusted to accommodate a HCW’s workflow. Please see “State 3 Grace Period” later in this document for more details. It is recommended that the HCW check the status of their **Badge** before re-contacting a patient to determine if performing hand hygiene is necessary.

Please note that when the **Badge** shows alternating “green/yellow,” the HCW may NOT enter the **Patient Zone** of a *DIFFERENT* patient without first performing hand hygiene. Going from one **Patient Zone** to a different **Patient Zone** without performing hand hygiene would be recorded as a non-compliant event, and the **Badge** LED would immediately display a red LED. (See section 4.5 below).

4.4 Yellow LED – Cue to Clean Status Level (State 1 or State 4)

The yellow LED seen for the “Cue to Clean Status” level indicates that the HCW must perform hand hygiene before either entering or re-entering a **Patient Zone**. The “Cue to Clean Status” level occurs when the HCW has not recently performed routine hand hygiene (State 4) or when the HCW has recently exited a **Patient Zone** (State 1).

In the case of recent **Patient Zone** exit, the **Badge** has an internal timer that will eventually expire (6 minutes at default) and change the **Badge** to the “Non-Compliant Status” level (State 5), showing the red LED, unless the HCW performs hand hygiene.

The internal timer, for the “Cue to Clean Status” level (State 4), has a factory default expiration time of 20 minutes, but this can be adjusted to accommodate a HCW’s workflow. It is recommended that the HCW always perform hand hygiene immediately after leaving a **Patient Zone**.

4.5 Red LED – Non-Compliant Status Level (State 2, State 3 or State 5)

When the red LED is visible, the **Badge** is at the “Non-Compliant Status” level. This indicates that the HCW has broken the proper hand hygiene protocol of performing hand hygiene before entering a **Patient Zone** (State 2 – Non-Compliant Patient Contact), before re-entering a **Patient Zone** (State 3 – Non-Compliant Patient Re-contact) or after exiting a **Patient Zone** (State 5 – Non-Compliant after Patient Contact). At this status level, the HCW has the potential to spread pathogens from one patient to another. Both the HCW and the patients they are in contact with are now at risk. As soon as the HCW recognizes that they are at a “Non-Compliant Status” level, they should immediately perform hand hygiene, unless a critical patient need takes priority.

There are only four ways that a HCW can reach the “Non-Compliant (red LED) Status” level:

1. Failing to perform hand hygiene before entering a **Patient Zone**.
2. Failing to perform hand hygiene when going directly from one **Patient Zone** to another **Patient Zone**.
3. Failing to perform hand hygiene before re-entering a **Patient Zone** after being away from that same **Patient Zone** for more than 5 minutes (default); i.e., exiting and re-entering the same Patient Zone after being away for an extended time period.
4. Failing to perform hand hygiene after exiting a **Patient Zone**.

The simple steps below can be followed to prevent reaching the “Non-Compliant (red LED) Status” level:

1. If the **Badge** is asleep, i.e., there is no flashing LED visible, perform hand hygiene at a **System Monitored Dispenser** to wake it up, and reset hand hygiene status to “Clean.”
2. Check the **Badge’s** status level before entering a **Patient Zone**.
 - a. If the **Badge** is at the green or “Clean” Status level, **Patient Zone** entry will be compliant.
 - b. If the **Badge** is at the “Cue to Clean Status” level (yellow LED), avoid **Patient Zone** entry until hand hygiene has been performed, assuming that there is no overriding patient safety concern.
3. Before re-entering the same **Patient Zone**, verify that the **Badge** is at the “Compliant Patient Re-Contact Status” level (green/yellow LEDs). Otherwise, perform hand hygiene before re-entering the **Patient Zone**.
4. Always perform hand hygiene immediately after leaving a **Patient Zone**.

4.6 Badge Status Level Summary

The following table (Table 1) provides a quick reference summary of the Badge Status levels.






| LED Color | Status Level | State | Action |
|--|------------------------------|---------|---|
|  Green | Clean | 0 | HCW has recently used an Ecolab Hand Hygiene Program. Compliance Monitoring System soap or sanitizer dispenser and may enter a Patient Zone . |
|  Green | Compliant Patient Contact | 1 | HCW has recently used an Ecolab Hand Hygiene Program. Compliance Monitoring System soap or sanitizer dispenser and is currently inside a Patient Zone . |
|  Green and Yellow | Compliant Patient Re-contact | 1 | HCW has recently exited a Patient Zone . The HCW may re-enter the same Patient Zone without performing hand hygiene. |
|  Yellow | Cue to Clean | 1, 4 | HCW must perform hand hygiene before entering a Patient Zone . If HCW has recently exited a Patient Zone , perform hand hygiene immediately. |
|  Red | Non-Compliant | 2, 3, 5 | HCW has not performed hand hygiene either after exiting a Patient Zone or when moving between different Patient Zone entries. Hand hygiene should be performed immediately. |

Table 1. System Badge Status Levels

5. BADGE PATIENT ZONE DETECTION TIME

Badge Patient Zone Detection Time (or “bed attach time”) is the length of time a **Badge** must be inside a **Patient Zone** before changing from the “Clean” Status level (green LED, State 0) to the “Patient Contact Status” level (State 1). The **Patient Zone** Detection Time is programmable from 0 seconds to 30 seconds with a default time of 3 seconds.

NOTE: **Patient Zone** Detection Time only applies if the HCW’s **Badge** is at the “Clean” Status level (State 0) when entering the **Patient Zone**.

This feature is designed to allow the **Badge** to determine if **Patient Zone** entry is intentional or unintentional and thus prevent a brief, unintentional **Patient Zone** entry from changing the **Badge’s** status level (state).

6. BADGE GRACE PERIOD

The **System Badge** is equipped with three programmable grace period that assist in maintaining a normal workflow. Each grace period is designed to make the **System** fit smoothly into a HCW’s daily tasks. Adjustable grace period also provide flexibility to HCWs with specialized workflows that may otherwise not be compatible with the **System**.

6.1 State 0 Grace Period (Clean – After Washing or Sanitizing Hands)

The purpose of the State 0 Grace Period is to allow time after a HCW uses a **System-equipped Dispenser**, during which their **Badge** will ignore **Patient Zones**.

6.1.1 Description

Immediately after using a **System-equipped Dispenser**, the **Badge** will ignore **Patient Zone** entry and maintain the “Clean” Status level (State 0) for the duration of the grace period. After the grace period expires, the **Badge** will behave normally and change to the “Clean” Patient Contact Status level (State 1) when **Patient Zone** entry occurs.

The State 0 Grace Period can be adjusted between 0 and 60 seconds. The factory default is 15 seconds.

6.1.2 Example 1

A HCW uses a **System-equipped sanitizer Dispenser** next to a patient room door. The HCW’s **Badge** is now at the “Clean” Status level (green LED, State 0). The HCW then enters the patient room, which happens to have two beds (Figure 5 step 1). The HCW needs to attend to the patient in the bed furthest from the door (Bed B). The HCW must walk past the bed of the patient closest to the door (Bed A) (Figure 5 step 2). Without the State 0 Grace Period, it is possible that the HCW’s **Badge** could detect the **Patient Zone** of Bed A as the HCW passes, turn to the “Compliant Patient Contact” Status level (State 1) and then turn to the “Non-Compliant” Status level (State 2) when the HCW approaches Bed B (Figure 5 step 3). With the State 0 Grace Period set to 15 seconds, the HCW has 15 seconds, from the time the **Dispenser** was activated (Figure 5 step 1), to walk past Bed A (Figure 5 step 2) without worry that the **Badge** will detect Bed A’s **Patient Zone**. When the HCW enters the **Patient Zone** of Bed B (Figure 5 step 3), their **Badge** will correctly turn to the “Compliant Patient Contact” Status level (State 1) when the **Badge’s** State 0 Grace Period expires.

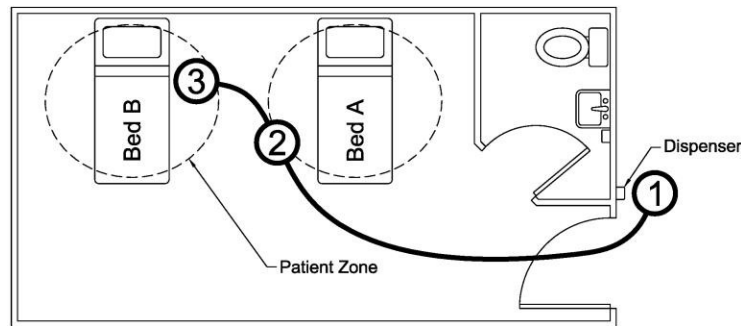


Figure 5. State 0 Grace Period Example 1

6.1.3 Example 2

A HCW uses a **System**-equipped sanitizer **Dispenser** next to a patient room door and then enters the patient room (Figure 6 step 1). The HCW's **Badge** is now at the "Clean" Status level (State 0). The HCW enters the **Patient Zone**, their **Badge** changes to the "Compliant Patient Contact" Status level (State 1) and they attend to the patient (Figure 6 step 2). The HCW then approaches the hand-washing sink next to the patient bed, activates the **Dispenser** and washes their hands (Figure 6 step 3). In this example, the soap **Dispenser** location is within the **Patient Zone**. Without the State 0 Grace Period, the HCW's **Badge** would change to the "Clean" Status level (State 0) after **Dispenser** activation and then immediately change back to the "Compliant Patient Contact" Status level (State 1). This would require the HCW to activate the **Dispenser** outside the patient room door to get the **Badge** back to the "Clean" Status level (State 0) after exiting the **Patient Zone**.

With the State 0 Grace Period set to 15 seconds, the HCW activates the **Dispenser** (Figure 6 step 3) causing the **Badge** to change to the "Clean" Status level. After activating the **Dispenser**, the HCW has 15 seconds to complete their hand-wash and exit the **Patient Zone** (Figure 6 step 4). All the while, the **Badge** is ignoring the **Patient Zone** allowing the **Badge** to remain at the "Clean" Status level.

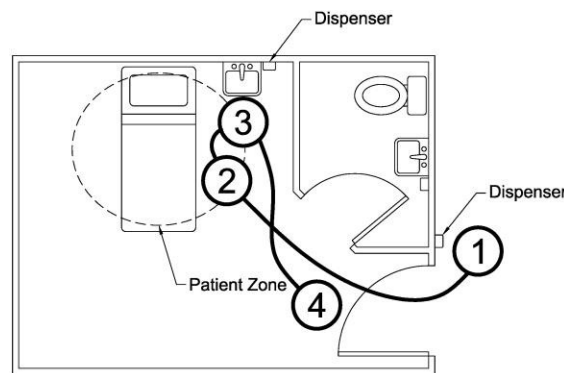


Figure 6. State 0 Grace Period Example 2

6.2 State 2 Grace Period (Non-Compliant Patient Contact)

The purpose of the State 2 Grace Period is to prevent the HCW's **Badge** from entering the "Non-Compliant" Status level if the HCW briefly and unintentionally moves from one **Patient Zone** to another.

6.2.1 Description

When a **Badge** with a "Clean" Status level (State 0) enters a **Patient Zone**, it will change to the "Compliant Patient Contact" Status level (State 1). If the HCW wearing the **Badge** exits the **Patient Zone** and enters a different **Patient Zone**, the **Badge** should immediately change to the "Non-Compliant" Status level (State 2). However, in areas where patient beds are particularly close to one another, it may be unreasonable to enforce Non-Compliant bed-to-bed contact so strictly. To this end, the State 2 Grace Period allows a HCW to briefly enter a second **Patient Zone** without penalty.

The **Badge's** internal State 2 Grace Period timer starts the moment a HCW exits the **Patient Zone** of initial contact. During this time, the HCW's **Badge** will ignore other **Patient Zones** until the grace period expires (30 seconds for default setting). If the HCW enters a second **Patient Zone** within 7 seconds after leaving the first **Patient Zone**, the **Badge** will produce three warning beeps indicating the HCW has entered the second **Patient Zone**. Once the grace period expires, the **Badge** will change to the "Non-Compliant" (red LED) Status level (State 2) if the HCW is currently inside a second **Patient Zone** or enters a second **Patient Zone**. If the HCW re-enters the **Patient Zone** of initial contact prior to grace period expiration, the internal timer will reset and the **Badge** will remain at the "Compliant Patient Contact" Status level (State 1).

The State 2 Grace Period can be adjusted between 0 and 60 seconds. The factory default is 30 seconds.

6.2.2 Example

A HCW uses a **System**-equipped sanitizer **Dispenser** next to a patient room door and then enters the patient room (Figure 7 step 1). The HCW's **Badge** is now at the "Clean" Status level (State 0). The HCW enters the Bed A **Patient Zone**, their **Badge** changes to the "Compliant Patient Contact" Status level (State 1) and they attend to the patient (Figure 7 step 2). The HCW unintentionally steps out of the Bed A **Patient Zone** and into the Bed B **Patient Zone** (Figure 7 step 3). Without the State 2 Grace Period, the HCW's **Badge** would change to the "Non-Compliant" (red LED) Status level (State 2) and a non-compliant event would be logged by the system. With the State 2 Grace Period, the HCW's **Badge** will ignore the Bed B **Patient Zone** until the grace period expires. If the HCW moves back into Bed A's **Patient Zone** before the grace period expires (Figure 7 step 4), the **Badge** will remain at the "Compliant Patient Contact" Status level (State 1) and no event is reported to the **System**. By re-entering the Bed A **Patient Zone** before the grace period expired, the **Badge's** internal State 2 Grace Period timer was reset. This means that the HCW could repeat Figure 7 steps 3 and 4 indefinitely, as long as the grace period does not expire during step 3.

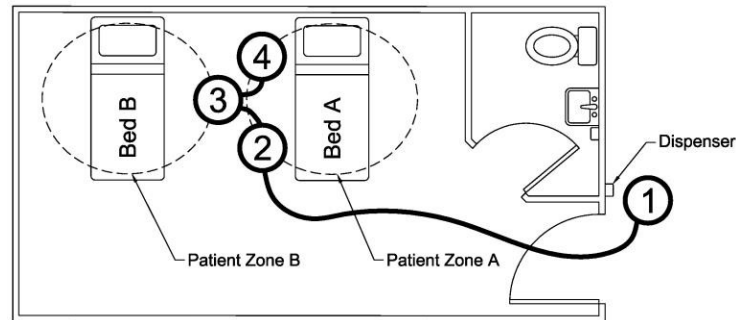


Figure 7. State 2 Grace Period Example

6.3 State 3 Grace Period (Compliant Patient Re-contact)

The purpose of the State 3 Grace Period is to provide a HCW with flexibility while working around a patient bed by giving them the ability to enter, exit and re-enter the **Patient Zone** as many times as necessary without having to perform hand hygiene before each re-entry.

6.3.1 Description

When a **Badge** having a “Clean” Status level (State 0) enters a **Patient Zone**, it will change to the “Compliant Patient Contact” Status level (State 1). When the **Badge** leaves the **Patient Zone**, it will change to the “Compliant Patient Re-Contact Status” level (State 1) with green and yellow flashing LEDs (see table 1).

The State 3 Grace Period begins at the moment the **Badge** leaves the **Patient Zone** and will reset when the **Badge** re-enters the **Patient Zone**, unless the State 3 Grace Period has expired before re-entry. If the State 3 Grace Period has expired, the **Badge** will beep three times and change to the “Cue to Clean” Status level with only the yellow LED flashing. Now, the **Badge** will change to the “NON-Compliant” (red LED) Status level (State 3) if it re-enters the **Patient Zone** unless the HCW performs hand hygiene prior to entry.

The State 3 Grace Period can be adjusted between 5 seconds and 6 minutes. The factory default is 5 minutes.

6.3.2 Example

A HCW uses a **System**-equipped sanitizer **Dispenser** next to a patient room door and then enters the patient room (Figure 8 step 1). The HCW’s **Badge** is now at the “Clean” Status level (State 0). The HCW enters the **Patient Zone**, their **Badge** changes to the “Compliant Patient Contact” Status level (State 1) and they attend to the patient (Figure 8 step 2). The HCW then exits the **Patient Zone** (Figure 8 step 3), the **Badge** changes to the “Compliant Patient Re-contact” Status level (State 1), the green and yellow LEDs flash and the State 3 Grace Period internal timer starts. If the HCW re-enters the **Patient Zone** before the State 3 Grace Period has expired (Figure 8 step 4), the **Badge** will return to the “Compliant Patient Contact” Status level (State 1), only the green LED will flash and the State 3 Grace Period internal timer will be reset.

If the State 3 Grace Period expires, the **Badge** will beep three times and change to the “Cue to Clean” Status level (State 1) with only the yellow LED flashing. If the HCW re-enters the **Patient Zone** while at the “Cue to Clean” Status level (Figure 4 step 4), the **Badge** will change to the “Non-Compliant” Status level (red LED). When the State 3 Grace Period expires, the HCW must perform hand hygiene before re-entering the **Patient Zone**.

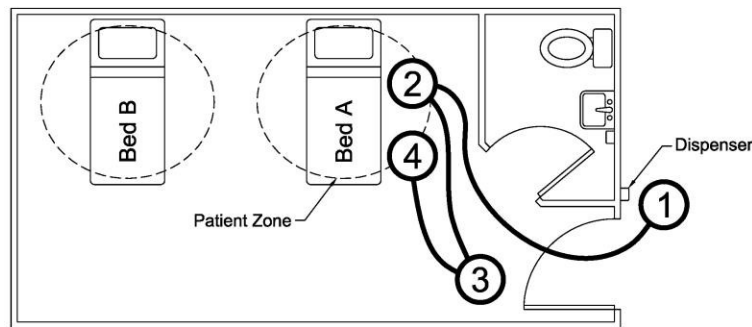


Figure 8. State 3 Grace Period Example

6.4 Grace Period Summary

The following table (Table 2) provides a quick reference summary of the System Badge grace period.




| LED Color | Grace Period | State | Default Timeout mm:ss | Description |
|--|-------------------------------|-------|-----------------------|---|
|  Green | Clean | 0 | 00:15 | Prevents change of Badge from Clean Status level (State 0) to Compliant Patient Contact Status level (State 1) for duration of timeout. |
|  Green and Yellow | Compliant Patient Re-contact | 1 | 05:00 | Prevents change of Badge from Compliant Patient Contact Status level (State 1) to Non-Compliant Status level (State 3 – non-compliant Patient Re-contact) for duration of timeout. |
|  Green | Non-Compliant Patient Contact | 2 | 00:30 | Prevents change of Badge from Compliant Patient Contact Status level (State 1) to Non-Compliant Status level (State 2 – Non-Compliant Patient Contact) for duration of timeout. |

Table 2. System Badge Grace Period

7. BADGE CARE AND MAINTENANCE

The **System Badge** is equipped with three programmable grace period that assist in maintaining a normal workflow. Each grace period is designed to make the **System** fit smoothly into a HCW's daily tasks. Adjustable grace period also provide flexibility to HCWs with specialized workflows that may otherwise not be compatible with the **System**.

7.1 Handling

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. Dropping or tossing the **Badge** can result in damage to the internal electronics.

7.2 Cleaning

The **Badge** should be cleaned by wiping with a soft cloth. The cloth should be damp but not wet. A pre-moistened alcohol swab or any common hospital cleaner may also be used. Only the exterior of the **Badge** may be cleaned. Do not attempt to clean any interior surface of the **Badge** as this can damage the circuitry. Do not use abrasive cleaners or cleaning products in aerosol cans as they will damage the **Badge's** finish.

7.3 Battery Replacement

Typical **Badge** battery life is about 2 years but this may vary depending on use. When a **Badge's** battery is dead, it will no longer communicate with other **System** devices and the red LED will flash two times in rapid succession about once every 1.5 seconds. The **System Dashboard** software also monitors the battery level of each **Badge**. It will send an email alert to a designated administrator assigned by the healthcare facility when a **Badge** battery is low. The administrator should contact the owner of the **Badge** (the HCW) to provide a new battery and assist with battery replacement.

7.3.1 Tools and Supplies

The following tools and supplies are required to replace the **Badge's** battery:

1. The Ecolab Badge Opener Toolkit (Part Number 53005669)
2. Panasonic CR2450 3.0V Lithium Coin Cell Battery

7.3.2 Battery Replacement Steps

The following steps describe how to replace the **Badge's** battery:

1. Using the Badge Opener Tool (Part Number 53005456), slowly rotate the opener inside the removal enclosure slot until both enclosures separate. (See Figure 9)



Figure 9. Badge Opening

2. Lay the Badge face up on a solid working surface and remove the front half of the Badge enclosure. This will expose the Badge printed circuit board (see Figure 10).
3. Use Spudger Tool (Part Number 50002274) to carefully push the battery up and towards positive side of battery holder until it can be grasped and removed from the battery holder (see Figure 10).
4. Install the new battery by sliding it into the battery holder with the “+” side facing up.
5. All three LEDs will flash in sequence as the Badge performs an internal power on self-test and the audible alert will beep for about 1 second. This is normal and provides feedback that all three LEDs and the audible alert are functioning properly.
6. Carefully place the front half of the enclosure to the bottom half.
7. Firmly place both enclosures together until a notable popping sound is heard.
8. Verify that both enclosure halves are securely attached. No visible gaps should be seen between both enclosure halves.
9. Dispose of the old battery. Check with the healthcare facility for the proper disposal procedure.

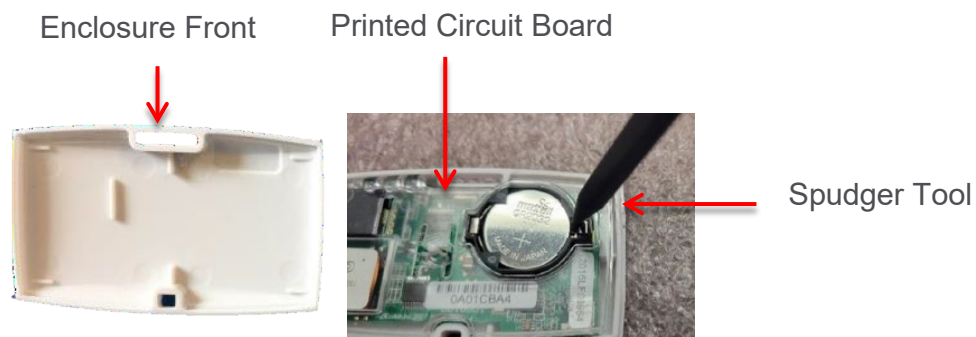


Figure 10. Badge Battery Replacement

APPENDIX A – SYSTEM BADGE STATES

The following is a brief description of **Badge** states. **Badge** states are useful for analyzing and understanding **Badge** interactions with other **System** devices. However, it is not necessary for a HCW to be intuitively familiar with them.

State 0  **Clean State**

- The HCW has recently used a **System**-equipped soap or sanitizer **Dispenser**.
- The **Badge's** green LED is flashing and the HCW is free to enter any **Patient Zone**.
- The State 4 timeout timer is reset and restarted.
- If the State 4 timeout expires, the **Badge's** yellow LED will flash and the **Badge** will change to State 4.

State 1 or or Compliant Patient Contact

- The HCW has had compliant patient contact, *i.e.*, the HCW was at State 0 when entering the **Patient Zone**.
- While inside the **Patient Zone**, the **Badge's green** LED will flash and both the State 3 Grace Period and Unsanitary After Patient Contact timeout are reset.
- If the HCW steps outside of the **Patient Zone**, the **Badge's green** and **yellow** LEDs flash in sequence and both the State 3 Grace Period and Non-Compliant After Patient Contact timer are started.
- If the State 3 Grace Period expires while outside of the **Patient Zone**, the **Badge's yellow** LED will flash and the HCW should not re-enter the **Patient Zone** without performing hand hygiene.
- If the HCW re-enters the **Patient Zone** after the State 3 Grace Period has expired, the **Badge's red** LED will flash and the **Badge** will change to State 3.
- If the HCW is outside of the **Patient Zone** and the Non-Compliant After Patient Contact timer expires, the **Badge's red** LED will flash and the **Badge** will change to State 5.

State 2 Non-Compliant Patient Contact

- The HCW's **Badge** was *NOT* at State 0 when the HCW entered a **Patient Zone**.
- The **Badge's red** LED will flash.

State 3 Non-Compliant Patient Re-contact

- The HCW's **Badge** was at State 1 and the HCW re-entered the **Patient Zone** after the State 3 Grace Period expired.
- The **Badge's red** LED will flash.

State 4 Unknown Hand Hygiene State After Timeout

- The HCW's **Badge** was at State 0 and the State 4 timer expired.
- The **Badge's yellow** LED will flash.

State 5 Non-Compliant State after Patient Contact

- The HCW's **Badge** was at State 1, the HCW left the **Patient Zone** and the Non-Compliant After Patient Contact timeout expired.
- The **Badge's red** LED will flash.

Ecolab Hand Hygiene Program Compliance Monitoring System

APPENDIX B – ECOLAB HAND HYGIENE PROGRAM COMPLIANCE MONITORING SYSTEM BADGE DEFAULT CONFIGURATION

| HHCM Badge Configuration Options | | |
|---|--|--|
| Configurable Setting | Configuration Options (mm:ss) | Default Setting |
| LED (lights) | 0- Always off, 1-Always on, 2- On for Noncompliant states only | 1-Always On |
| Sounds | 0-Always off, 1-Always on, 2-On for Noncompliant states only | 2-On for Noncompliant states only |
| Bed Attach Time | 0s, 4.5s± 1.5s, 7.5s± 1.5s, 10.5s± 1.5s, 13.5s± 1.5s | 4.5s± 1.5s |
| State 0 - "Clean" | | |
| | | Green LED |
| State 0 Grace Period | 00:00-01:00 | 00:15s |
| State 2 - Non-Compliant Patient Contact | | |
| | | Red LED |
| State 2 Grace Period | 00:00-02:00 | 00:30s |
| | | Alarm |
| State 3 - Non-Compliant Patient Re-Contact | | |
| | | Red LED |
| State 3 Grace Period | 01:00-45:00 | 05:00 min |
| | | Alarm |
| State 4 - Unknown Hand Hygiene Status | | |
| | | Yellow LED |
| State 4 Grace Period | 05:00-45:00 | 10:00 min |
| State 5 Non-Compliant After Patient Contact | | |
| | | Red LED |
| State 5 Grace Period | | 06:00 min |
| | | Alarm |
| Configuration Priority Rules (a) State 2 Grace Period < State 3 Grace Period (b) State 3 Grace Period < State 5 Grace Period | | Badge Sleep Timeout = 50 min (non-configurable) |

APPENDIX C – 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 Ecolab 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.

This radio transmitter (IC: 10060A-53005389) 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-53005389) 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.

RF Exposure:

This equipment complies with FCC and ISED radiation exposure limits set forth for an uncontrolled environment. End user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Cet appareil est conforme aux limites d'exposition au rayonnement RF stipulées par la FCC et ISED pour une utilisation dans un environnement non contrôlé. L'utilisateur final doit suivre les instructions de fonctionnement spécifiques pour le respect d'exposition aux RF. Les émetteurs ne doivent pas être placés près d'autres antennes ou émetteurs ou fonctionner avec ceux-ci.

FCC & IC Label Information

The FCC & IC label information that contains the FCC ID Number, IC ID Number, Device Model Number, and FCC Statement "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." is located on the back portion of the Badge.