Certification Exhibit

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Manufacturer: UltraClenz, LLC
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User Manual
(Part 1 of 2)

PSS Door Monitor User Guide

(FAS1521)

DOC1059 Revision 2

UltraClenz™

UltraClenz, LLC

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Abstract

This document provides a description of the features of the PSS Door Monitor unit in order to familiarize the user with the unit. Also, a brief description of the PSS Door Monitor functions are given, followed by instructions on how to install the unit.

Revision History

Revision	Date	By	Description
0	01/12/14	TRS	Initial Release
1	05/14/14	AJS/JH/TRS	Updated Pictures and Text to Reflect the New Trade Name, Changed to New Format
2	12/03/14	DLS	Added Appendix A-C, updated configuration software, made corrections to text and format

Terms, Acronyms and Abbreviations

GUI	Graphical User Interface
HCW	Health Care Worker
PIR	Passive Infrared
POST	Power On Self-Test

1. PSS Door Monitor Features

The PSS Door Monitor is designed to track healthcare worker hand hygiene compliance with respect to a specific hospital room, by recording whether or not a soap or sanitizer dispenser was used during patient room entries and exits.

6) Bypass Button

5) Audible Alert

4) Green & Red LEDs

3) RS485 Data Port

2) Battery Compartment

1) Removable Side Cover

7) Adjustable Sensor

8) Removable Front Cover
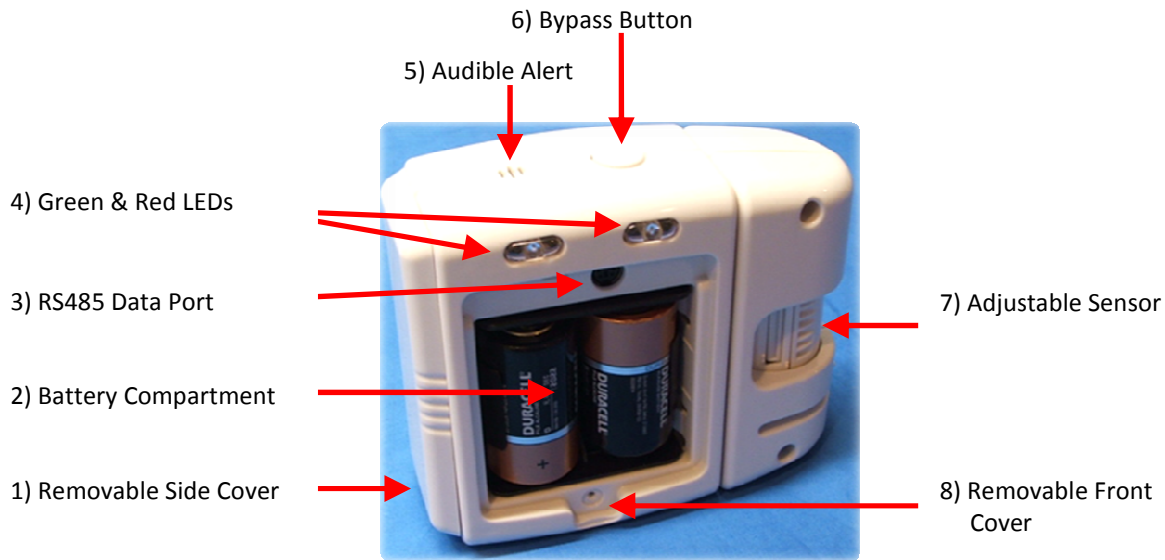
Figure 1. PSS Door Monitor Front View

9) Dispenser Connector
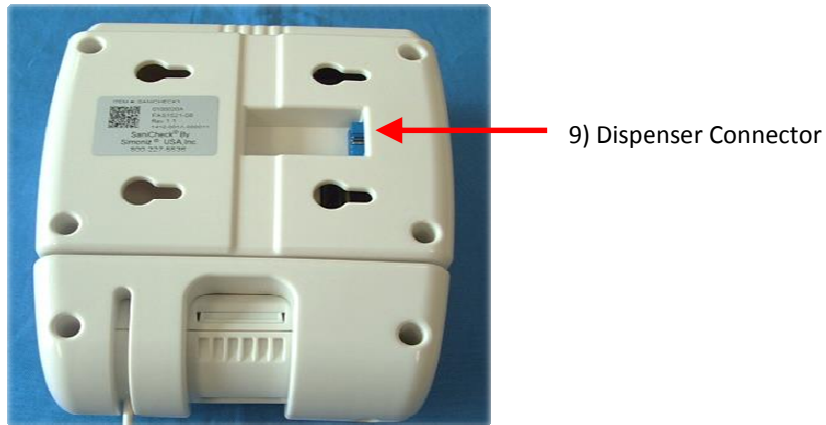
Figure 2.   PSS Door Monitor Back View

1.1 Component Descriptions - Front View (See Figure 1)

Removable Side Cover

This allows the user to change the PSS Door Monitor configuration from right side to left side room entry (See Figure 1 item 1).

Battery Compartment

Remove front cover to allow access to the battery compartment. Insert 2 quality D cell alkaline batteries. Note the battery polarity is shown in the battery box (See Figure.1 item 2).

RS485 Data Port

The RS485 Communications Port din connector is used to connect the PSS Door Monitor to a Host computer. The Communications port is used to configure the PSS Door Monitor, Upload and Download data (See Figure 1 item 3).

Green & Red LEDs

The green and red LEDs provide visual feedback to the healthcare worker (See Figure.1 item 4).

GREEN: The single green led flash indicates a door entry or exit with compliance.
RED: Indicates a wash compliance warning.

Audible Alert

The audible alert makes a beeping sound that is used to give feedback to the healthcare worker (See Figure.1 item 5).

Bypass Button

The bypass mode must be enabled in the PSS Door Monitor configuration software, see section 3.0 PSS Door Monitor Configuration (Figure 4) for this function to work. The override button is used to stop the PSS Door Monitor from sensing for a programmed time period (See Figure 1 item 6). The override mode can be used by housekeeping staff to prevent multiple non-compliance events while performing routine room maintenance.

The Override Time can be set as follows:
Momentarily depress the override button once for a 30-second default countdown. The override button grace period can be changed from the PSS Door Monitor configuration software (See Figure 4).

Adjustable Sensor

The Sensor can be adjusted to select the correct PIR angle. The sensor adjustment is done at the time of installation to optimize door entry and exit sensing (See Figure 1 item 7).

Front Cover

Removable front cover and screw assembly (See Figure. 1 item 8).

1.2 Component Descriptions - Back View (See Figure. 2)

Dispenser Connector

The dispenser plugs into this connector of the PSS Door Monitor (See Figure. 2 item 9). The PSS Door Monitor is attached to a dispenser via an interface connector and counts all patient room entries and exits with dispense (compliant event), without dispense (non-compliant event) and total room entries and exits.

2. PSS Door Monitor Led Functionality

2.1 Hand Hygiene Compliance Warning (Red LED)

The hand hygiene compliance LED warning will flash and the audible alarm will beep to alert the HCW entering or exiting the patient room. The alert will continue until the HCW has sanitized or the preset pass-through timer has timed out (see PSS Door Monitor Configuration Software). If the pass-through timer reaches the set terminal count, the event will be recorded and the red indicator LED will stop flashing.

2.2 Hand Hygiene Compliant - Enter or Exit Area (Green LED)

When a HCW activates the dispenser, the hand hygiene compliant LED will flash and the audible alarm will beep once. The event will be counted only if the HCW enters or exits the patient room. The PSS Door Monitor will not record an event if dispense activation occurs without a door entry, however the beeps will still occur.

2.3 Low Battery Indicator (Red LED)

The PSS Door Monitor will produce a single red LED flash every 3 seconds indicating a low battery condition.

2.4 Dead battery Indicator (Red LED)

The PSS Door Monitor will produce a double red LED flash every 3 seconds indicating a dead battery condition.

3. PSS Door Monitor Configuration Software

The PSS Door Monitor Configuration Software is a graphical user interface (GUI), which allows the installer to set-up the hardware and software parameters for desired operation. The PSS Door Monitor can be configured for a variety of room layouts.

Before installing the PSS Door Monitor Configuration Software on the Host computer, the user must first install the RS485 to USB serial Interface driver. The RS485 to USB Network Interface kit (part number FAS1502-00) includes the interface, driver CD, 2 communication cables and users guide. The first cable connects the serial Interface to the host computer's USB port. The second cable connects the serial Interface to the PSS Door Monitor's RS485 communications port DIN connector (See Figure 3 for the Communication Port locations).
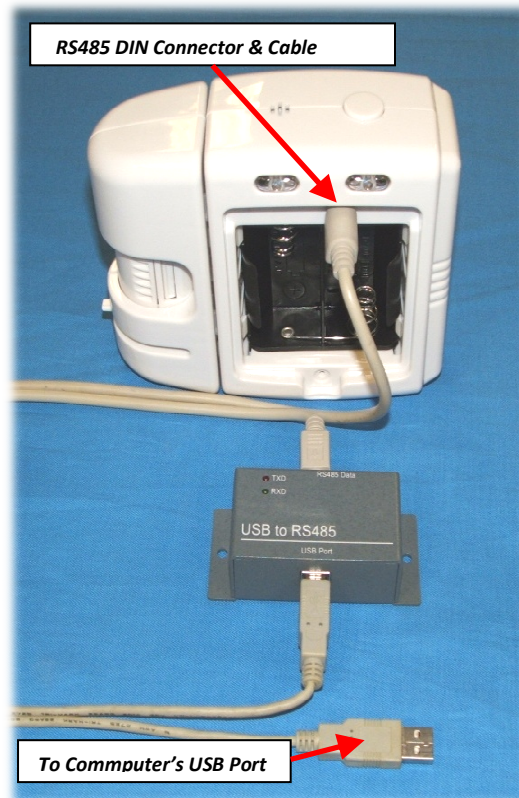
Figure 3. USB to RS485 Converter Cable Connection

3.1 PSS Door Monitor Configuration Software Menu (See Figure.4)

File
Exit - Closes the PSS Door Monitor Configuration Software

Setup
Scan for COM Port - Note, the PSS Door Monitor must be connected to the host PC. The software will scan each COM port until the PSS Door Monitor is found.

Tools
Reset Counts - Reset all counts to zero. A confirmation message "Do you really want to set the counts to zero" will appear, to prevent inadvertent resets.

3.2 Configuration Options

The following configurations setting are set during the installation process only. These settings can only be configured thru the RS485 to USB network Interface.

3.2.1 Operating Mode

• Normal PIR - Select when PSS Door Monitor is mounted near a patient room door.

• Counter Only - Select when PSS Door Monitor is mounted inside of a patient room but not near a door.

3.2.2 Mounting Location

• Outside of Room - Select when PSS Door Monitor is mounted on the outside of a patient room.

• Inside of Room - Select when PSS Door Monitor is mounted on the inside of a patient room.

NOTE: The User **must** select the correct mounting location of the PSS Door Monitor. The PSS Door Monitor will not function properly if the "Mounting Location" is incorrect.

3.2.3 Interface Options

• Bypass Mode Enabled - Checked enables, unchecked disables the override button

• LED(s) Enabled - Checked enables the red and green LEDs, unchecked disables red and green LEDs

• Entry Alarm Enabled - Checked enables, unchecked disables only the audible alarm on entry.

• Exit Alarm Enabled - Checked enables, unchecked disables only the audible alarm.

3.2.4 Bypass Mode

This enables and disables the Override Button which allows room entry without setting and alarm activation. Press the Bypass button once and the PSS Door Monitor will sound an audible alarm and the green LED will flash until the selected Bypass time is complete. When the Bypass time is complete, the audible alarm will sound once and the Red LED will flash once.

3.2.5 Alarm Timeout (Increment or Decrement)

The default is 5 seconds. The user may increment the alarm timeout as needed. The alarm timeout is the amount of time between exit or entry detection and a dispense activation. If the dispense activation occurs within the alarm timeout period, the event will be counted as a compliant event (entry or exit). If the dispense activation occurs after the alarm timeout period or there is no dispense activation, the event will be counted as a non-compliant event (entry or exit).

3.2.6 Pass-through Timeout (Increment or Decrement)

The default is 30 seconds. The user may increment the pass-through timeout as needed. The pass-through timeout is the amount of time a HCW has between a dispense activation and a room Entry or Exit. After a HCW has entered or exited a room, the timer will reset. If a HCW enters or exits after the pass-through timeout period, then the HCW must activate the dispenser again or an alarm timeout will occur which will cause a non-compliant event to be counted.

3.2.7 Room Entry Counts (Uploaded from the PSS Door Monitor)

• With Dispense

• Without Dispense

• Total Room Entries

NOTE: It is up to the user to keep track of the date and unit address when counts are uploaded from the PSS Door Monitor, because the events are not time stamped. The counts will be uploaded and saved as a CSV file that may be imported into spreadsheet software for data analysis.

3.2.8 Room Exit Counts (Uploaded from the PSS Door Monitor)

• With Dispense

• Without Dispense

• Total Room Exits

NOTE: It is the user's responsibility to keep track of the date and unit address when counts are uploaded from the PSS Door Monitor, because the events are not time stamped. The counts will be uploaded and saved as a CSV file that may be imported into spreadsheet software for data analysis.

3.3 Firmware Version (Uploaded from the PSS Door Monitor)

When the PSS Door Monitor is connected, the firmware version will be displayed.

3.4 Device Address (Uploaded from the PSS Door Monitor)

When the PSS Door Monitor is connected, the device address will be displayed. The device address is unique for each PSS Door Monitor.

3.5 Upload Configuration

This will upload all of the configuration selections to the PSS Door Monitor unit. Menu selections that are available for reconfiguration are Interface Options, Mounting Location, Alarm Time, Room Entry/Exit Time and Bypass Timeout (See Figure 4).

3.6 Download Configuration

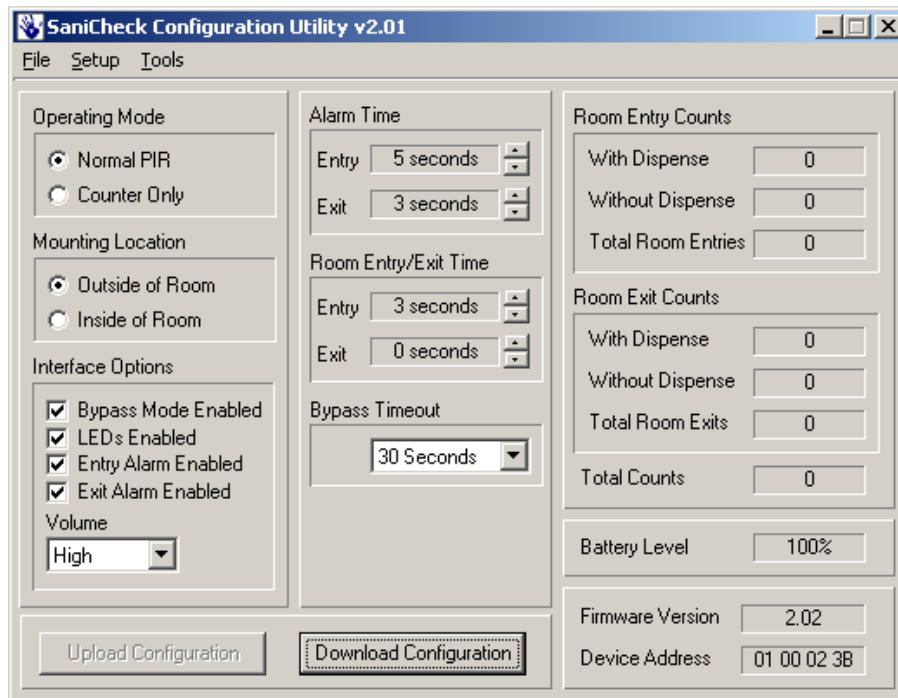This will download the room counts, configuration selections, firmware version and device address from the PSS Door Monitor unit.

Figure 4. Configuration Settings Screen