

The SmartSponge® System Operating Procedures Manual



MEDICAL SOLUTIONS



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Preface

Indications for Use

The ClearCount Medical Solutions SmartSponge® System is indicated for use in counting and recording the number of RFID-tagged surgical sponges, laparotomy sponges, and towels used during surgical procedures. It also provides a non-invasive means of locating retained radio-frequency identification (RFID)-tagged surgical sponges, towels, and other tagged items within a surgical site.

Warnings

The following list of warnings applies to the SmartSponge System:

- Use only one SmartSponge System during a surgical procedure.
- Do not use the system in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.
- For the system to function, use only ClearCount disposables.
- Keep the SmartSponge System outside of the sterile field, unless it is properly covered.
- Place only ClearCount disposables in the Count Out Bucket.
- The sterility of disposables is guaranteed only for unopened, undamaged packages. Disposables are for single use only; do not re-use or re-sterilize disposables.
- Do not cut or tear SmartSponge disposables, as the RFID tags might become separated.
- When scanning items contained in a sterile surgical kit (bundles of items not in their own sterile packages) into the SmartSponge System, cover the head of the system with the sterilized bucket liner from the surgical kit. This prevents contamination of the items being scanned.
- Using the scanning wand without a sterile wand cover could contaminate the sterile field.
- Holding items that have been scanned in too close to the Count Out Bucket may result in these items being added to the Out column of the inventory (detected) prior to use and disposal. Dispose of any items into the Count Out Bucket without using them if they have been scanned out prior to use.
- Disposables should not be left inside the patient's body for more than 24 hours.
- Do not subject patients to an MRI with SmartSponge disposables still inside their body.

- Tags may become damaged by surgical lasers. Do not apply a surgical laser directly to a tag. The loss of tag function may result.
- Due to possible interference, the system should be separated by at least 1 meter from an active Electrosurgical Unit (ESU). The system should be checked for normal operation to ensure there is no interference present.
- Do not dispose of sponges from a previous surgical case into the Count Out Bucket. Sponge counts may not reconcile properly.
- No part of the ClearCount SmartSponge System is user serviceable. The system contains no user replaceable fuses. All Service is to be performed by trained personnel.

Conventions Used



Warning!

A warning is a statement that identifies conditions or actions that could result in personal injury or loss of life.



Caution!

A caution is a statement that identifies conditions or actions that could result in damage to the system.



Notes

A note is an advisory comment or recommendation regarding practices or procedures.

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Chapter 1: System Description

The SmartSponge® System is used in an operating room to detect and identify tagged surgical items for the purpose of reconciling surgical counts. It is intended to be used as an adjunct to count policy and procedure based on AORN Recommended Practices. The system employs radio-frequency identification (RFID) technology to detect ClearCount SmartSponge surgical sponges and towels. The system combines the benefits of counting and detection of surgical items (sponges, gauze, and towels) used during a surgical case. It has a user-friendly color display that provides detailed item counts along with audible notification. The counts are automatically updated as SmartSponge RFID-tagged sponges and towels are scanned “in” and “out” of the surgical procedure.

This chapter includes a brief overview of the system and a detailed description of its components.

System Components

Count In Scanner

The Count In Scanner, shown in **Figure 1-1**, is used to count items into the surgical case prior to using the items. The In-Scan Tray is located below the area marked “Touch Here to Scan”. The SCAN IN button is used to activate the In-Scan Tray. As surgical sponges and towels are placed on the In-Scan Tray, it adds the tagged items to the In-Scan Inventory. This inventory or quantity of scanned-in items appears in the IN column of the Count Mode screen on the display. **Table 1-1** lists the Count In Scanner components.

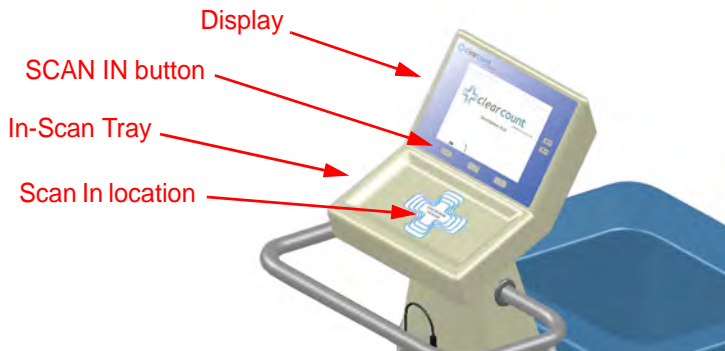


Figure 1-1 Count In Scanner Components

Table 1-1 Count In Scanner Components	
Component	Description
In-Scan Tray	The area on which sponge and towel packs are to be placed when scanning them into a surgical case.
SCAN IN button	This button activates the In-Scan Tray to detect items introduced to the Scan In Location.
Display	Displays information for the user to track sponge counts throughout the surgical procedure. Also displays various modes of operation.
Scan In Location	The surface of the In-Scan Tray where sponge and towel packs are scanned into the surgical case.



Notes

- The Count Out Bucket will not count items when the system is in SCANNING IN mode.

Count Out Bucket and Wand Components

The Count Out Bucket detects the RFID-tagged sponges and towels discarded into it during a surgical case. The Handle and Casters contribute to the mobility of the SmartSponge System. The Handle is strategically located to protect the Count In Scanner from forcefully hitting a wall, while also providing the user with a comfortable means of maneuvering the system. The two rear casters are able to be locked in place to keep the system stable during use. The Power Entry and On/Off Switch are located at the back of the system near the floor. Insert the power cord into the Power Entry and then switch to On to power up the system. When not in use, the SmartWand is mounted to the rear of the system by means of the Wand Holder; and the wand's cord is retained on the SmartWand Cord Wrap. See **Figure 1-2**.

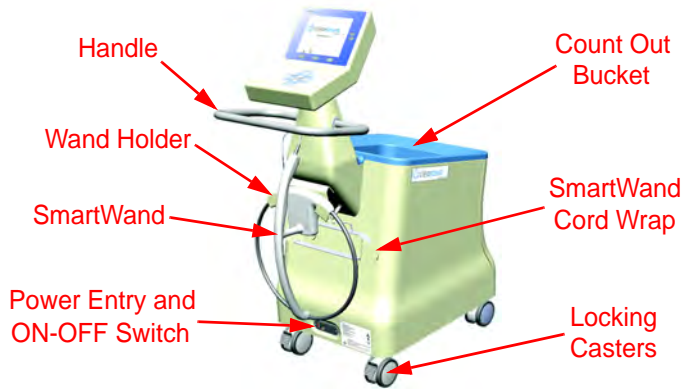


Figure 1-2 Count Out Bucket Components

Table 1-2 Count Out Bucket Components	
Component	Description
Handle	Used to move the SmartSponge System. Also positioned to protect the Count In Scanner and display from damage.
Count Out Bucket	Scans out and contains the discarded sponges and towels after their use in surgery.
Wand Holder	Used to mount the SmartWand to the SmartSponge System when not in use.
SmartWand Cord Wrap	Keeps the SmartWand's cord retained while the wand is mounted to the SmartSponge System.
SmartWand	Used to detect sponges. This is done by scanning the patient with the SmartWand.
Power Entry and On/Off Switch	The Power Entry connects the SmartSponge System to a 120 VAC power source via the power cable. The On/Off switch toggles the power to the system.
Locking Casters	Secures the position of the SmartSponge System.

Display and Function Control Buttons

The display, function control buttons, and volume buttons are the user's interface to the SmartSponge System. This backlit display shows the following types of screens at various points, depending on the mode of SmartSponge System operation:

- Starting, Boot, and Power & Diagnostic screens (during system boot-up)
- Standby, Ready to Count or Continuing case, and Count Mode (Scanning In/Counting Out)
- Final Report: Counts Equal, or Final Report: Counts Not Equal
- Wanding Mode

The Volume Control buttons allow for the adjustment of the SmartSponge System's internal buzzers. These may be set to four preset levels; off, low, medium, and high. The system will beep when booting up, when it is ready to count, when sponges are scanned in, detected with the SmartWand, or scanned out, and any system alert.

Each screen defines the operation of the control buttons for the associated mode of operation. There are three function control buttons along the bottom of the display and two volume control buttons to the right of the display. **Figure 1-3** shows the location of the control buttons in relation to the example screen.

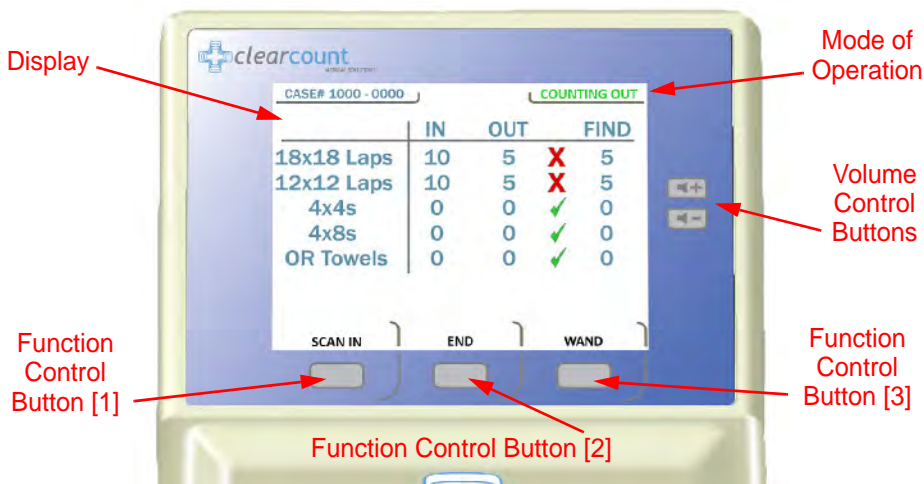


Figure 1-3 Display and Control Buttons

Table 1-3 Display/Controls	
Display / Controls	Description
Display	An LCD that displays information for the user to track sponge counts throughout the surgical procedure. Also displays various modes of operation.
Mode of Operation	Located in the upper right-hand corner of the Display, this indicates the current status of the system.
Volume Control Buttons	These up and down buttons control the volume of the audible tones. The Volume of the tones can be set to four different levels; off, low, medium, and high.
Function Control Button [1]	Allows the following actions; ON - Turns the system on from Standby Mode. SCAN IN - Activates the In-Scan Tray. BACK - Returns to the previous screen and mode. STANDBY - Returns the system to Standby Mode.
Function Control Button [2]	Allows; END - Exits Count Mode and proceeds to the Final Report screen for verification before ending a case. RESET - Clears the detection status for a rescan in Wanding Mode. Also BACK in Final Report Mode.
Function Control Button [3]	Allows; WAND - Switches from Counting Out Mode to Wanding Mode. OVERRIDE - Allows the user to end a case without reconciling the sponge counts by using an Override Card. END CASE - Saves case data and returns system to Standby Mode. BACK - Returns to the previous screen and mode.

SmartSponge Disposables

The SmartSponge System utilizes surgical sponges and towels that have been “tagged” with an RFID identification device. This RFID tag is about the size of a typical medicine capsule and does not contain a battery. Because each sponge contains a tag with unique identification, the SmartSponge system can quickly and accurately count and identify each sponge.

Surgical sponges are provided for surgery in two forms: pre-packaged sterile surgical kits (**Figure 1-4**) and individual sterile packages (**Figure 1-5**). There are different procedures involved when using one presentation versus the other. Refer to Chapter 2 of this manual for further details.

Additionally, the SmartSponge System relies on several accessories for proper use and patient care. These accessories are described briefly in **Table 1-4**.

Table 1-4 SmartSponge Disposables and Accessories	
Accessory	Description
Surgical Kits	A pre-packaged sterile kit of materials and equipment assembled for a specific surgery. Included are various banded packs of SmartSponges for use with the SmartSponge System.
Sterile Packages	SmartSponges packaged by type for use with the SmartSponge System that are not pre-packaged in Surgical Kits.
Bucket Liner	A large drawstring plastic bag used to protect the Count Out Bucket from contamination as soiled sponges are discarded. Sterile when provided in surgical kits.
Wand Cover	A large, sterile, clear plastic sheath used to protect the sterile field when using the SmartWand. The sheath covers the wand and a portion of the wand cord.

Table 1-4 SmartSponge Disposables and Accessories (Continued)	
Accessory	Description
Override Card	A Smart Card used by the authorized staff member to enable an un-reconciled case to be closed.
SmartTag / SmartTag Special	A sticker applied between the sheets of the OR table prior to surgery, which allows the user to ensure that the SmartWand is operational. (SmartTag Special is only for use with carbon fiber top OR tables)



Figure 1-4 Example of Sterile Surgical Kit



Figure 1-5 Example of Sterile Sponge Packages

SmartTags

SmartTags are passive RFID labels that have an adhesive backing (see **Figure 1-6**). Prior to surgery, a SmartTag is positioned under the surgical site between the bottom sheet and the draw sheet on the OR table. **Figure 1-7** shows a typical position of the SmartTag on the OR table.

The purpose of the SmartTag is to provide confidence to the user that the SmartWand is scanning the entire depth of the surgical site. Using a SmartTag is a direct indication of effective scan depth and thereby better than proxy methods such as BMI. Detection of the SmartTag assures the user that the wand is functioning and being used properly such that any SmartSponges remaining inside the patient can be identified quickly.

There are two types of SmartTags.

- The standard SmartTag is for use with OR tables with phenolic tops. These are the most common OR tables.
- SmartTag Special is for use on OR tables with carbon-fiber tops. These are less common.

It is important to use the correct SmartTag so that indication of scan depth by the wand is dependable. If you are uncertain, ClearCount can provide assistance at the time of installation to help determine which SmartTag type should be used with your OR tables.



Figure 1-6 SmartTag / SmartTag Special

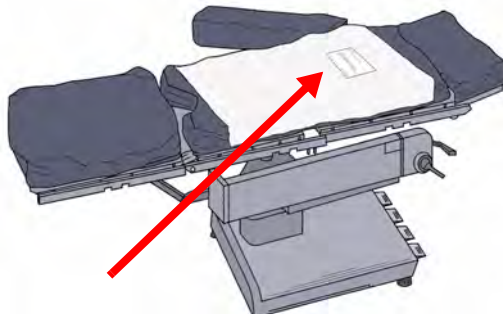


Figure 1-7 Location of SmartTag on OR Table

SmartWand

The SmartWand, shown in **Figure 1-8** is a patient scanning wand that houses an antenna for detecting ClearCount SmartSponges.

The Handle of the wand is designed to ease the process of sterile sheathing while handing it into the sterile field by giving each person a place to grip. The Wand Cord exits the back end of the handle and connects to the Wand Connection on the back of the SmartSponge System. Two LEDs mounted on the wand provide visual cues about the system's operation. The Bi-Color LED displays detection status while the Single Color LED displays the wand's power status. To scan the patient; Press the WAND button after the wand has entered the sterile field, hold the wand by its handle, pass it over the body maintaining a distance of 2 to 3 inches above, while completing five head to toe sweeps shown on the display at a rate of 7 inches a second. Refer to Chapter 2 for the complete patient scanning procedure.

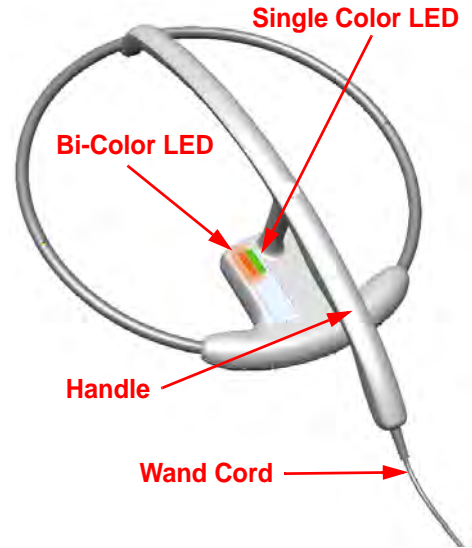


Figure 1-8 SmartWand

Table 1-5 SmartWand	
Component	Description
Bi-Color LED	Changes with the wand's detection status. Solid Blue - SmartTag detected Off - SmartTag not yet detected Solid Amber - SmartSponge detected
Single-Color LED	Changes with the wand's status. Solid Green - Wand attached Off - Wand not attached or system error
SmartWand Handle	Used to hold the SmartWand while performing the patient scan.
SmartWand Cord	Provides power and communications to the SmartWand from the SmartSponge System.

Wand Cover

A sterile wand cover is used when the patient needs to be scanned with the SmartWand. The cover is passed into the sterile field and then applied to the SmartWand as it is handed in. **Figure 1-9** shows the wand cover package.



Figure 1-9 Sterile Cover for SmartWand (outside of surgical kit)

Override Card

The SmartSponge System requires the user to acknowledge the closure of an un-reconciled surgical case. The term “un-reconciled” indicates that the number of sponges scanned in and counted out is not the same. The user acknowledges this condition by placing the system into Override Mode. This is done by pressing the OVERRIDE button on the Final Reports: Counts Not Equal screen to enter the Override Mode and end the case with unequal counts. The user then places the RFID-tagged Override Card on the In-Scan tray until an audible alert is heard and the display confirms. **Figure 1-10** shows the Override Card. Each use of the Override Card is logged into the system’s database. A notation of this discrepancy should also be recorded on the patient record.



Figure 1-10 Override Card



Chapter 2: Initial Setup and Operation

Chapter 2 describes the initial setup of the SmartSponge® System. The setup includes the following topics:

- Powering on the SmartSponge System
- Placing the SmartTag
- Boot-up screens
- Standby mode
- Setting up for surgery
 - Using pre-packaged sterile surgical kits
 - Using individual sterile packages

The chapter also covers operating the SmartSponge System to perform the following surgery-related functions:

- Using the System in Count Mode
 - Scanning items into and out of surgery
- Requesting final item count reports
 - Obtaining the final report: counts equal
 - Obtaining the final report: counts not equal
- Scanning a Patient for Retained Items
 - Using the SmartWand
- Restoring Power

Initial Setup

Powering on the SmartSponge System

The following procedure describes how to set up the SmartSponge System before each surgical case. Before its initial use, a technician will unpack, set up, and check the system to ensure it is functioning properly. If problems with the system occur later during its use, call ClearCount Medical Solutions.

After the SmartSponge System has been set up, place it in the desired position in the Operating Room (OR) and lock the rear casters.



Warning!

Inspect the power cord prior to each use, and replace it if damaged. A frayed or worn cord presents an electrical shock hazard that may result in personal injury or death.

- Step 1 Connect the system to a grounded, 120 VAC power outlet using the power cord supplied.
- Step 2 Check that the other end of the power cord is securely plugged into the power entry module of the system.
- Step 3 Set the power (I/O) switch shown in **Figure 2-1** to the | (on) position. There will be an audible tone and a series of power-up screens that briefly appear on the display.



Figure 2-1 Location of On/Off Switch

Placing the SmartTag

Before the start of a surgery, place a SmartTag between the surgical sheets under the patient. The standard SmartTag is to be used on phenolic top OR tables while the SmartTag Special is for use with carbon fiber top OR tables. **Figure 2-2** shows a SmartTag and its placement. The SmartTag is an adhesive sticker that contains a radio-frequency identification (RFID) tag. This tag provides feedback to the SmartSponge System that the SmartWand is reading through the depth of the patient when a scan is performed.



Notes

- If the wrong SmartTag is used on the wrong type of table, it will perform improperly.
-

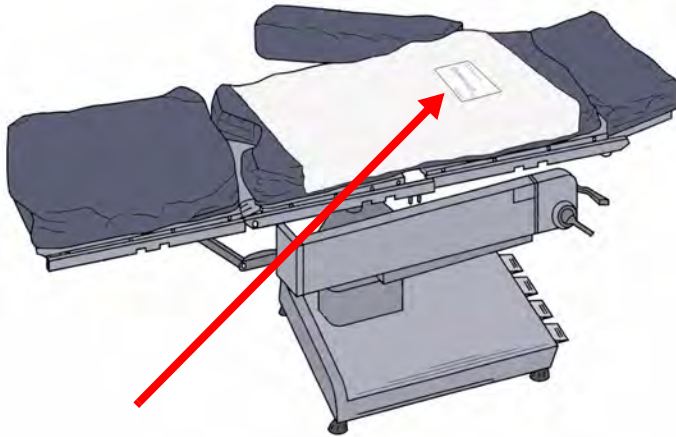


Figure 2-2 SmartTag Placement

During pre-surgery setup, proceed as follows:

- Step 1 Peel the backing from the SmartTag.
- Step 2 Position the SmartTag below the surgical site and apply between the bottom sheet and the draw sheet.
- Step 3 Place the tag adhesive-side down.



Warning!

The SmartTag is not approved for application to the patient's skin.

Boot-up Screens

After the on/off switch is set to on (I), the system will produce an audible tone, and the Starting screens shown in **Figure 2-3** will appear.

Starting Screen

The Starting Screen, shown at the top of **Figure 2-3**, appears on the display first for 10 seconds after the on/off switch is set to on.

Boot Screen

The Boot Screen, which follows the Starting Screen appears for 3 seconds. Shown in the center of **Figure 2-3**, this screen shows the versions of system firmware and the device (SmartSponge System) identification (ID).

Diagnostic Screen

The Diagnostic Screen, shown at the bottom of **Figure 2-3**, appears for 9 seconds. This screen has a Progress Bar that fills in from left to right in segments. When the bar completely fills in, the system produces an audible tone, and displays the Standby Screen. See **Figure 2-4**. The Standby Screen remains on the display until the user presses the ON button to start or continue a surgical case.



Notes

- If the device is powered on without the SmartWand connected, the device will display a “Please Connect the Wand” screen. To advance to Count Mode, plug in the wand and a green check-mark will appear in the check-box next to connect the wand. The system will then advance to Count Mode.
-

Starting Screen



Boot Screen



Diagnostic Screen

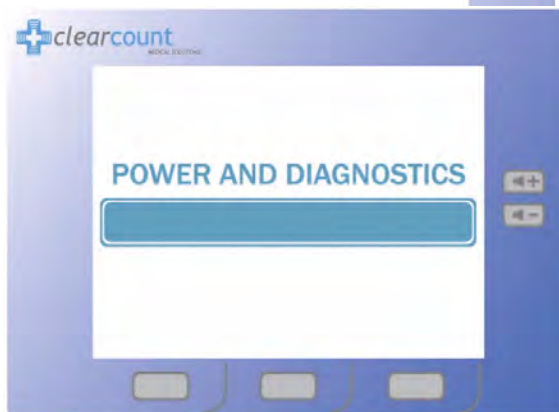


Figure 2-3 Boot-up Screens

Standby Mode

Following the startup screens, the Standby screen appears, and the system enters Standby Mode. The system should be left in this state when not in use.

The Standby Mode of operation is the starting point for operating the SmartSponge System. The system can remain in this mode for as long as necessary while you prepare for surgery. The SmartSponge System enters the standby mode under the following conditions:

- When the system powers up.
- When you press the **STANDBY** button on the Final Report screen during a surgical case.
- After the **END CASE** button is pressed to save the case data and power down the device.
- Upon restoration of power following a power failure.

When you are ready to begin a new surgical case, press the ON button on the Standby screen. If the Standby Mode has been entered during a case (either by pressing **STANDBY** or due to power failure), pressing **ON** will resume the case in progress.



Figure 2-4 Standby Screen

Setting Up for Surgery

With the system in position, and the SmartTag placed between the sheets on the OR table, you are ready to prepare the sponges and other supplies necessary for surgery. The SmartSponge System must be used with ClearCount sponges. These may either be packages of sterile sponges, or sponges in sterile surgical kits. The procedure for using one type versus the other is slightly different, as noted below.

Using Sterile Surgical Kits

- Step 1 Locate and open the surgical kit. Using sterile technique, locate the following components:
- Bucket Liner
 - Wand Cover - this should be set aside within the sterile field in case the patient must be scanned for sponges.
 - Surgical sponges and towels - these will be contained within a paper band with the ClearCount logo. Banded sponges should be scanned in one bundle at a time. Do not remove the band until the bundle has been scanned in.
- Step 2 Move the system as close as possible to the sterile field.
- Step 3 Using aseptic technique, cover the Count In Scanner and display with the Bucket Liner. Make sure the In-Scan Tray and display are completely covered. Proceed to scan sponges and towels into the surgical case.
- Step 4 After the sponges and towels have been scanned in, remove the Bucket Liner from the Count In Scanner and install it into the Count Out Bucket.



Notes

- If a bundle of sponges within the surgical kit is damaged or unable to be scanned into the surgical case, replace that bundle with a package of sterile ClearCount sponges.
-

Using Packaged Sponges

- Step 1 Locate the following items:
- All of the sponges and towels that will be used in the surgical case
 - Bucket Liner
 - Pre-packaged sterile wand cover - this will be used if the patient needs to be scanned with the SmartWand.
- Step 2 Install the liner into the Count Out Bucket.
- Step 3 Scan in sponges and towels while still in the sterile packaging.

Operations

Count Mode Operation

Count Mode is the primary mode of operation for the SmartSponge System. It is used for scanning sponges into and out of the case during surgery. The SmartSponge System remains in Count Mode for the majority of the surgery (unless switched by the user), until it is complete and the sponge count has been reconciled. This mode consists of two available functions; Scanning In and Counting Out (appears on the mode of operation line of the display in the top right). These functions of Count Mode are cycled by the first Function Control button which changes from **SCAN IN** to **BACK**. While in the Count Mode, the display is continually updating the number of sponges scanned into and out of the case by either the In-Scan Tray or Count Out Bucket, depending on the mode selected. To enter Count Mode, press the ON button while in the Standby Mode.

From the Count Mode screen, shown in **Figure 2-5**, you can:

- Press **SCAN IN** to scan sponges and towels into the surgery. (In-Scan Tray active)
- Press **BACK** to return to Counting Out Mode to discard used items. (Count Out Bucket active)
- Press **END** to display the Final Report Screen.
- Press **WAND** to activate the SmartWand and perform a patient scan.

The **IN** column lists the number of items that have been scanned into surgery.

The **OUT** column lists the number of items that have been discarded into the Count Out Bucket.

The **FIND** column lists the number of items not reconciled by the system.

A green check mark appears if the number of items scanned into surgery is equal to the number of items discarded into the Count Out Bucket. If the number of items in the **IN** and **OUT** columns are not equal, a red **X** will appear.

Scanning In appears on the screen when the **SCAN IN** button is pressed to activate the In-Scan Tray.

	IN	OUT	FIND	
18x18 Laps	10	5	X	5
12x12 Laps	10	5	X	5
4x4s	0	0	✓	0
4x8s	0	0	✓	0
OR Towels	0	0	✓	0

Figure 2-5 Count Mode Screen

Scanning Items Into and Out of Surgery



Warning!

- Holding items that **have not been** scanned in too close to the Count Out Bucket may result in the items unintentionally being detected prior to use. Follow the on screen prompts to remove the sponges from the scanned out inventory or accept them into the case.
 - Holding items that **have been** scanned in too close to the Count Out Bucket may result in the items unintentionally being detected prior to use. Dispose of any items into the Bucket that have been scanned in and then scanned out (detected) by the Count Out Bucket prior to use.
 - For the system to function, use only ClearCount disposables.
 - Do not place sponges from a previous surgical case into the Count Out Bucket. This will cause the sponge counts not to reconcile properly.
 - Do not cut or tear SmartSponge disposables, as their RFID tags may separate.
 - Do not fill the Count out Bucket beyond its top edge. Items above the top edge may not be counted.
-

- Step 1 Press the **SCAN IN** button to activate the In-Scan Tray; “**Scanning In**” will appear on the screen as notification. Scan packages of SmartSponge surgical sponges and towels into the surgical case by holding them flat on the In-Scan Tray over the area marked “**Touch Here to Scan**”. Hold the item until an audible tone is heard, and the system adds the pack contents to the **IN** (inventory) column. See **Figure 2-5**. If the system displays the alert “**Pack Not Verified - Retry Pack**” attempt to re-orient the package and scan again. If the alert “**Discard Pack**” is displayed, throw out the defective package and start again with a new one. Packages of sponges and towels must be scanned one package at a time. If two or more packages are detected by the In-Scan Tray at once the system will display the “**Multiple Packs Detected**” alert. Remove the scanned packages and re-scan one at a time. Do not rest sponge packages or any other items on the In-Scan Tray.
- Step 2 After sponges are scanned in, they may be opened to the sterile field using standard sterile technique. ClearCount SmartSponges are to be used in the same manner as generic surgical sponges.
- Step 3 Sponges may be discarded into the Count Out Bucket at any time during the surgical case. If a sponge(s) that has not been scanned in is detected by the Count Out Bucket, the system will prompt the user on what action to take with the detected sponge(s). There is an option to **Accept** the detected sponge(s) into the case or **Decline** them. See **Figure 2-6**. Accepting infers that a sponge(s)

that was not scanned in was intentionally discarded into the bucket. Declining infers that a sponge(s) was held too close to the Count Out Bucket prior to being scanned in (in this case move the sponges away from the bucket and select **Decline**).

If declined, the system will go back to the previous counts and continue. Before pressing **Decline**, be sure to remove the detected sponge(s) from the vicinity of the Count Out Bucket or the system will continue to prompt for Accept/Decline of the detected sponge(s). If the sponge(s) is accepted into the case, the user must re-confirm their selection and the sponge(s) will be added to the current counts. All absent sponges from the same package as the accepted sponge(s) automatically become accepted into the case. The package contents will be added to the **IN** column, with the detected sponge(s) entered into the **OUT** column. The subsequent sponges from the package will not need to be accepted; they will already exist in the **FIND** column. A note will then be displayed stating that protocol has been broken (this will not affect system performance or function). See **Figure 2-7**. This function will accommodate accidental or intentional scenarios.

If more than **50** SmartSponges are in the Count Out Bucket, the alert “**Change Bag - Bucket Limit Has Been Exceeded**” appears. When this alert occurs, remove the sponges from the Count Out bucket and replace the bucket liner (if necessary). Sponge counts are not affected by removing sponges from the Count Out Bucket.

If the “**Change Bag**” message is ignored and the sponge counts reach **70**, the system alert “**Bag Overflow Warning - Bucket Limit Has Been Exceeded**” is displayed. This message will persist until sponges are removed from the bucket. The system will give a system warning and require the system to be restarted if the sponge count reaches **80**. These measures are taken to assure accurate sponges counts. See Chapter 4 for explanations of System Alerts and Warnings.



Notes

- When using the In-Scan Tray, it is best to keep it turned away from the Count Out Bucket. This prevents items from being prematurely scanned out due to being too close to the Count Out Bucket.
 - The Count Out Bucket will not count items while the system is in **Scanning In** mode. Likewise, the In-Scan Tray will not scan items in while the system is in **Counting Out** mode.
 - Scanning In mode will revert back to Counting Out mode after **60** seconds of inactivity.
 - Sponges contained within count bags or pocket-type devices may be discarded directly into the Count Out Bucket.
-

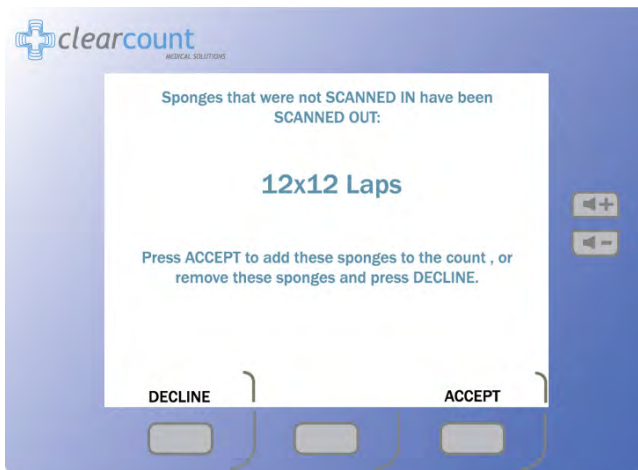


Figure 2-6 Example of Decline or Accept Screen

Protocol Broken note shows up after the user accepts sponges into the Count Out Bucket inventory without first scanning them into the case via the In-Scan Tray.



Figure 2-7 Example of Protocol Broken Note

Requesting Final Item Count Reports

When placed in the **Final Report** Mode, the system provides final sponge counts for the surgery. Before ending the case, verify that the quantities displayed in the **IN** and **OUT** columns on the **Count Mode** screen are equal, and a green check mark appears next to them. See **Figure 2-5**. The green check mark indicates that the count is reconciled. If the user has accepted sponges into the case that hadn't been pre-scanned in using the In-Scan Tray, the “**Protocol Broken**” note will show up on the **Final Report** screen. This will not affect the final counts but it will be saved with the rest of the case data.

Obtaining the Final Report: Counts Equal

Step 1 When all items used in the surgery have been discarded into the Count Out Bucket, press the **END** button on the **Count Mode** screen.

If the counts are reconciled, the final report indicates that all counts are correct. See **Figure 2-8**.

Step 2 Enter the case number in the patient's record.

Step 3 Press the **END CASE** button to close the surgical case and the **Ending Case** progress bar will appear. Once the case has been closed, the system returns to Standby Mode.

Step 4 Remove the bag liner that contains the discarded sponges from the Count Out Bucket. Dispose of the bagged items according to the standard protocol for your hospital.

Step 5 Clean the entire SmartSponge System according to the procedure in Chapter 3 before entering it into the next surgical case.



Figure 2-8 Final Report Screen: Counts Equal

Obtaining the Final Report: Counts Not Equal

If counts are not reconciled when you press the **END** button, the **Counts Not Equal** screen appears. **Figure 2-9** shows the screen progression to scan the Override card. The **OVERRIDE** button allows the case to be closed if the counts are not reconciled. Sponges may be intentionally withheld from the Count Out Bucket for procedural or clinical reasons. Alert the OR manager, and note this on the patient's record along with the Case Number. See the upper left corner of the screen in **Figure 2-5** for the Case Number location.

The SmartSponge System requires that the user acknowledge the closure of an unreconciled case. This is accomplished by using the Override Card. This card is an RFID-tagged card included with the system at the time of shipment. The Override Card is used by placing it on the In-Scan Tray until an audible alert is heard, while the system is in the **OVERRIDE Mode**.

- Step 1 Press the **END** button at the bottom of the display.
- Step 2 With the COUNTS NOT EQUAL press the **OVERRIDE** button.
- Step 3 The person responsible for the Override card will need to present the card. Scan the Override card by placing it onto the In-Scan Tray and holding it there until an audible alert is heard. The **VERIFIED BY ADMIN** screen shown in **Figure 2-10** will then appear.
- Step 4 Enter the case number in the patient's record.
- Step 5 By pressing the **END CASE** button again, the Ending Case and the Powering Down screens will appear. The system then displays the **Standby** screen and waits to start a new case.
- Step 6 Remove the bucket liner that contains the discarded sponges from the Count Out Bucket. Dispose of the bagged sponges according to the standard protocol for your hospital.
- Step 7 Clean the SmartSponge System according to the procedure in Chapter 3 before entering it into the next surgical case.

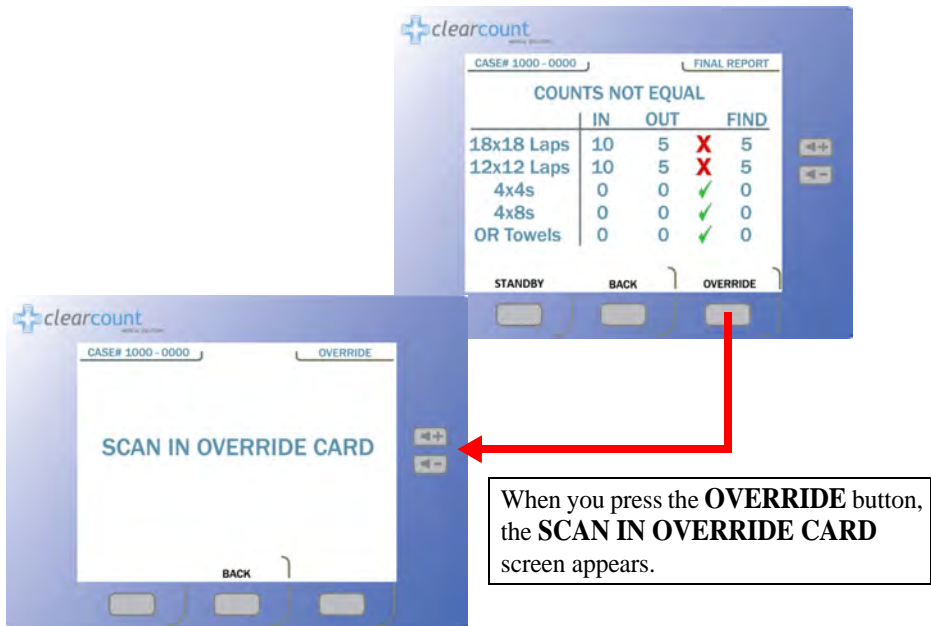


Figure 2-9 Final Reports Screen: Counts Not Equal



Figure 2-10 Counts not Equal Verified By Override Screen

Wand Mode Operation

The SmartWand may be used to scan patients for retained ClearCount sponges and towels at any point during the surgery. Onscreen instructions guide the user on performing a patient scan. If the SmartWand detects a retained item(s) in a patient, an audible alert is produced while the amber indicator on the wand flashes and the screen displays the type and quantity found, as shown in **Figure 2-11**.

The SmartWand performs best when passed over the patient in a slow, steady fashion, no faster than 0.2 m/second (approximately 7 inches/second). Maintain a distance of 2 to 3 inches above the patient. On a typical patient, each scan pass should take approximately 5 seconds to complete.

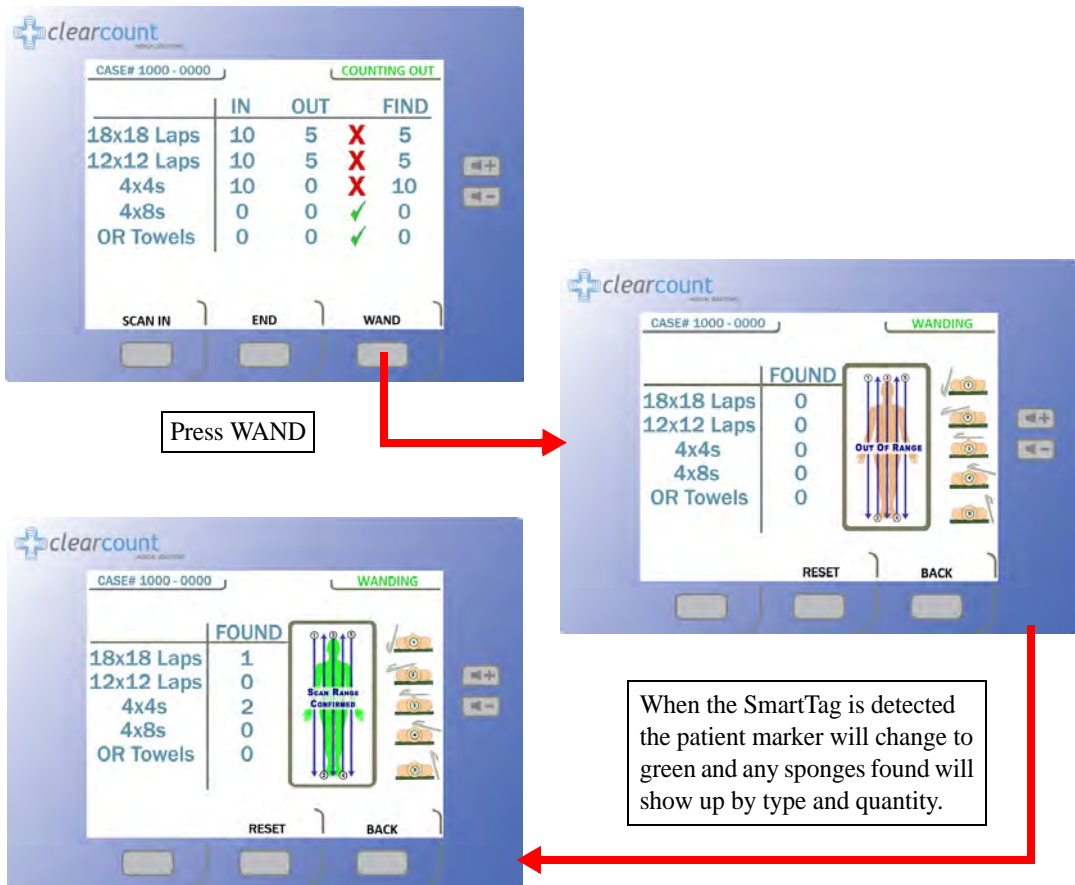


Figure 2-11 Wand Mode Screen



Warning!

- Using the SmartWand without a sterile wand cover may contaminate the sterile field.

Scanning Procedure

- Step 1 Remove the SmartWand from its holder below the Count In Scanner and free its cable.
- Step 2 Cover the SmartWand with a sterile cover using sterile technique while passing the wand into the sterile field.
- Step 3 Press the **WAND** button on the **Count Mode** screen to activate the wand. The green LED on the handle will start to flash when the wand is activated. The **Wand Mode** screen shown in **Figure 2-12** will then appear.

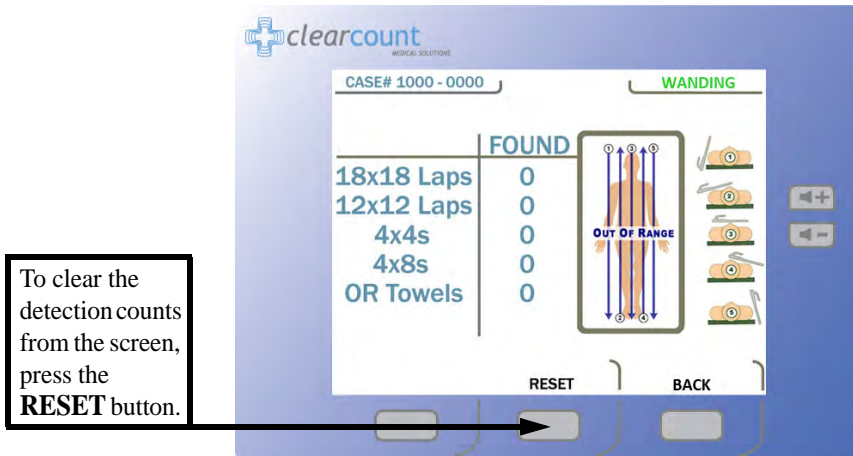


Figure 2-12 Wand Mode Screen

- Step 4 Using the handle, hold the SmartWand over the site where the SmartTag has been placed. When detected, the green LED on the wand will stay illuminated and the screen displays the message “**Scan Range Confirmed**”. This message confirms that the wand is reading completely through the patient.

Without a SmartTag under the patient, the user is unable to verify they are scanning completely through the patient. However the scanning operation may still be successful.

Step 5 Slowly scan the patient from head to toe moving at a rate of 0.2 meters a second (7 inches/sec), holding the SmartWand 2 to 3 inches above the patient. Follow the onscreen instructions shown in **Figure 2-12**. It is important to do all the scans(1-5) in order to most accurately identify potential retained sponges. (**Figure 2-13**)

If the wand detects an item retained in a patient, the system produces an audible alert while the amber light on the wand flashes, and the Wand Mode screen displays the type and quantity of the item(s). Search the patient for the retained item(s).

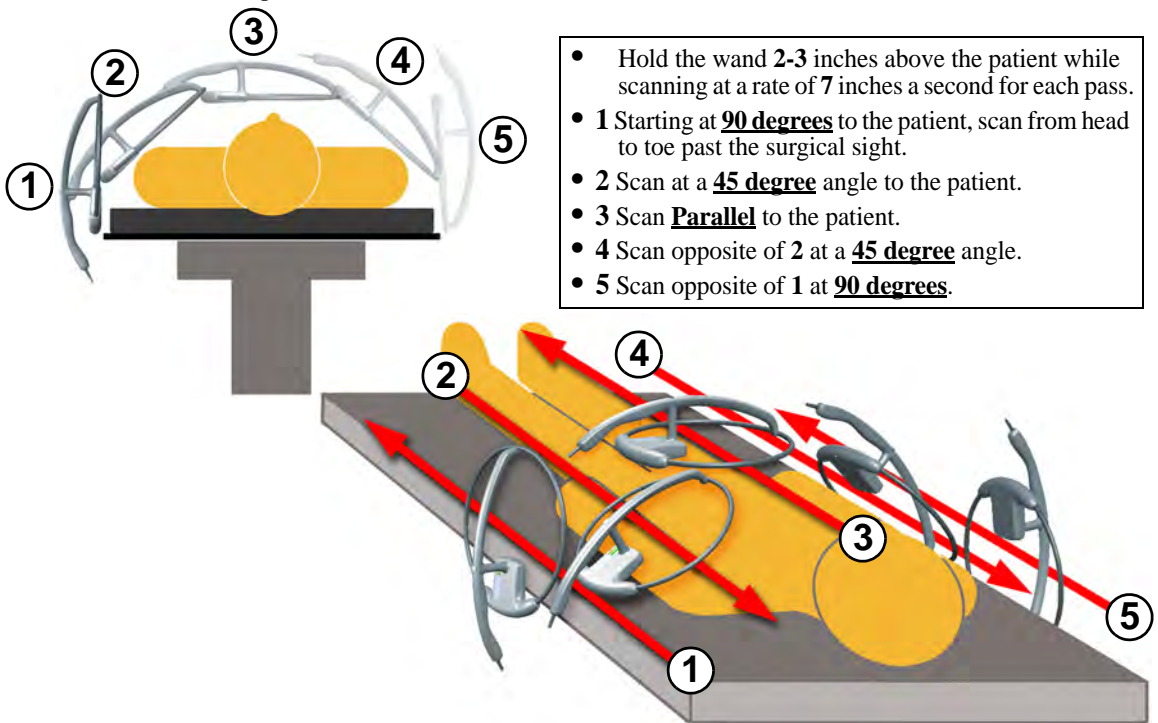


Figure 2-13 Patient Scan Procedure

Step 6 When the patient scan is complete, press the **BACK** button to return to the **Count Mode** screen. If a retained item was found, place the item into the Count Out Bucket.

Step 7 Remove the SmartWand from the sterile field. Remove the sterile cover and discard it according to the standard protocol.

Step 8 Return the SmartWand to its holder and the cable to the cord wrap.



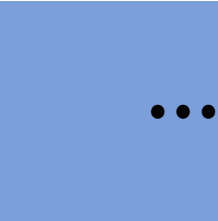
Notes

- Remove instruments from the surgical site prior to scanning with the SmartWand.
 - Before removing the SmartWand from the sterile field, the user should return the system to Count Mode to reduce the chance of inadvertently detecting items in the path of the wand.
 - While in Wand Mode do not set the wand on large metal surfaces. If this occurs, remove the wand from the surface and give the system 20 seconds to readjust.
 - Do not attempt to scan trash cans or other metal receptacles for disposable items, as the wand may not be able to detect them.
 - While in Wand mode do not place the SmartWand on the Count Out Bucket or on the Count In Scanner: the wand will fail to operate. Removing the wand from these locations will restore normal functionality.
 - Do not use the wand in conjunction with any large reusable, capacitive-coupled return electrode systems that are placed under the patient for electrosurgical devices, as the read range of the wand will be drastically reduced.
 - When scanning a patient, hold the SmartWand only by its handle.
-

Restoring Power

In the event of a power failure, move the power cord from a standard wall outlet to a red battery backed outlet. Restart the SmartSponge System with the On/Off switch in the up (ON) position. When the **StandBy** screen appears press the **ON** button to continue the current case. The screen will prompt the user that it is continuing from the current case. Sponge counts are resumed upon the return of power.

If the power cord is accidentally unplugged during use, replace it into the power entry module or the wall outlet. With the On/Off switch in the ON position the **StandBy** screen will appear. Press the **ON** button to resume the current case. All sponge counts are stored in the SmartSponge System's database whenever there is a loss of power. Sponge counts are resumed upon the return of power.



Chapter 3: Cleaning and Maintenance

This chapter includes a post-surgery cleaning procedure for the SmartSponge System. Also included is information regarding routine maintenance of the system.

Before cleaning the system or performing maintenance on it, check that:

- The SmartSponge System is off
- The system is unplugged from its 120 VAC power source



Notes

- No disassembly is required prior to cleaning.
-

Cleaning Instructions

Collect the following supplies for cleaning the SmartSponge System:

- Disposable cloths
- Rubber gloves
- Hospital grade disinfectant solution. (Follow the disinfectant manufacturer's instructions regarding the duration of contact time for specific biological contaminants.)



Warning!

The System needs to be unplugged from its power source before cleaning of the wand, box, and cords can take place.

Cleaning the System

- Step 1 Unplug the power cord from the power entry module.
- Step 2 Pre-clean surfaces by removing any contaminants with a damp cloth and wiping them dry.
- Step 3 Wipe the entire length of the cord with disinfectant.
- Step 4 Wipe down the entire system; including the display, the Count In Scanner, all four sides of the Count Out Bucket (inside and outside), the SmartWand, its cable and holder, and all four casters with disinfectant.
- Step 5 After disinfectants dry on the surface or according to manufacturer's instructions, rinse it with a water-dampened cloth.



Caution!

Do not immerse the wand or apply cleaning fluids directly to the wand, but apply the solution with a dampened cloth; otherwise damage to the electronics could occur.

Maintenance

ClearCount recommends that routine maintenance be performed on the SmartSponge System according to the following schedule:

Frequency	Required Action	Responsible Party
Per hospital protocol	Follow the cleaning procedure.	User
Prior to each use	Visually inspect the SmartWand's cord and power cord for fraying and signs of wear. Check for cracks or other damage to system components. Make sure the wand antenna is not bent and the wand housing is not damaged.	User or maintenance personnel
Monthly	Check for any damage to the wand housing, wand antenna, display, user controls, the Count In Scanner, the Count Out Bucket, and the power switch. Also check for correct operation of the LEDs on the wand housing by scanning a SmartTag and SmartSponge.	Maintenance personnel
Annually	Annual check per the service manual.	ClearCount Medical Solutions 101 Bellevue Road Pittsburgh, PA 15229 (888) 931-0787



Chapter 4: Troubleshooting

This chapter describes the alerts, warnings, and system failures that can occur while operating the SmartSponge System.

This chapter is divided into the following sections:

- General troubleshooting
- System Alerts
- System Warnings
- System Failures

Each section contains a list of the error conditions, possible causes for each condition, and suggested actions to help you resolve the situation.

General Troubleshooting

This section contains general troubleshooting information to help you resolve issues that may arise while operating the SmartSponge System.

SmartSponge System Will Not Turn On

CAUSE:	ACTION:
Power cord is not plugged into the SmartSponge System or wall outlet.	Ensure that both ends of the power cord are plugged in.
Power cord is damaged.	Call ClearCount Medical Solutions for replacement cord.
Power is not available at power outlet.	Check that the power source is working properly.
SmartSponge System failure.	Call ClearCount Medical Solutions.

Sponge Detected with Wand, but Subsequent Scans No Longer Indicate Sponge Present

CAUSE:	ACTION:
Operator is moving the wand over the patient too quickly.	Scan at a rate no faster than 0.2m/sec (7 inches/sec).
Operator has not completed all scan paths recommended.	Complete all recommended scan paths, per the onscreen instructions.
System has not been placed into wand mode.	Place the system into wand mode and scan the patient.
Wand has been effected by surrounding electro-surgical equipment.	Remove active electro-surgical equipment from the vicinity of the wand, or wait until ES equipment is no longer in use.
Wand has been placed closer than 2 inch to the body of the patient.	Hold the wand at least 2 inch away from the patient and re-scan.
Wand has been held too far from the patient.	Hold the wand within 3 inches of patient while performing a re-scan.

System Indicates Wand Failure

CAUSE:	ACTION:
Wand has been placed on or near a metal surface.	Move wand away from metal, and allow 20 seconds for the wand to adjust.
Wand is experiencing interference from other surgical equipment.	Move the wand away from the interfering equipment, or wait until the equipment is no longer in use.
Wand cable has become detached.	Connect wand cable.
Wand cable is damaged or kinked.	Call ClearCount Medical Solutions for a replacement.
Wand has been placed on the Count In Scanner of the device or over the Count Out Bucket.	Move wand away from the system.
Wand electronics have failed.	Call ClearCount Medical Solutions for a replacement wand.

Wand Housing is Cracked, Bent or Broken

CAUSE:	ACTION:
Wand has been physically damaged or misused.	Call ClearCount Medical Solutions for a replacement wand.

Wand LED Indicators Fail to Indicate that SmartTag is Present

CAUSE:	ACTION:
Wand has not be placed over the SmartTag.	Ensure a SmartTag is present and re-scan the patient.
SmartTag has been moved or was not placed prior to surgery.	Continue without the SmartTag. (unable to verify scan depth)
Wand cable is damaged.	Call ClearCount Medical Solutions for a replacement.
Wand cable is disconnected.	Connect cable.
Patient is too large to detect the SmartTag through the patient.	Scan the patient despite not being able to detect the SmartTag.
Wand electronics have failed.	Call ClearCount Medical Solutions for a replacement wand.

System Alerts

System Alerts are temporary warning messages of which you should be aware to ensure proper operation of the SmartSponge System. Once the condition causing the alert has been corrected, the case will continue.

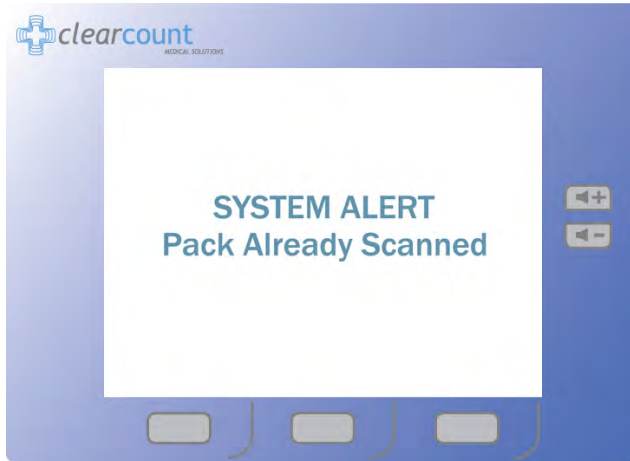


Figure 4-1 Example System Alert Message Screen

Pack Not Verified - Retry Pack

CAUSE:

The system is unable to scan the sponge pack.

ACTION:

Flip or rotate sponges and rescan the pack. If rescanning does not correct the condition, discard the pack and resume scanning a new pack.

Discard Pack

CAUSE:

The system has detected a problem with the sponge pack.

ACTION:

Discard the sponge pack and resume scanning with a new pack.

Multiple Packs Detected - Remove and Scan One Pack at a Time

CAUSE:

The system is unable to scan in multiple packs at the same time.

ACTION:

Ensure that only one pack of sponges is being placed on the In-Scan Tray at a time.

Pack Already Scanned

CAUSE:

The sponge pack has already been counted.

ACTION:

The sponge pack is ready for use - continue with system setup or operation.

Change Bag - Bucket Limit Has Been Exceeded - Remove Sponges to Continue

CAUSE:

There are over **50** sponges in the Count Out Bucket.

ACTION:

Remove sponges or discard the full bag and replace with a new liner - sponge counts will not change.

Bag Overflow Warning - Bucket Limit Has Been Exceeded - Remove Sponges to Continue

CAUSE:

There are over **70** sponges in the Count Out Bucket.

ACTION:

Remove sponges or discard the full bag and replace with a new liner - sponge counts will not change. Alert will remain until less than **70** sponges are present in the Count Out Bucket.

Wand Disconnected

CAUSE:

The SmartWand is not connected.

ACTION:

Ensure that the SmartWand is properly plugged into the system.

System Warnings

System Warnings are serious conditions that have been caused by misuse of the SmartSponge System. To correct a system warning condition, remove the full bag of sponges, place a new liner on the Count Out Bucket, and power cycle the system.

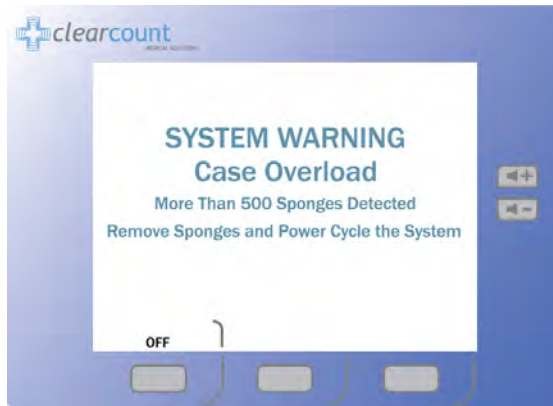


Figure 4-2 Example Warning Message Screen

System Reset - Bucket Limit Has Been Exceeded - Remove Sponges and Power Cycle the System

CAUSE:

There are **80** or more sponges in the Count Out Bucket.

ACTION:

Remove sponges and separate into groups of no more than **50** - Power cycle the system and then reinsert the groups into the Count Out Bucket one group at a time to assure all sponges have been accounted for. The system suspends counting while in this warning state. To assure accurate counting, there should never be more than **50** sponges in the Count Out Bucket at a time.

Case Overload - More Than 500 Sponges Detected - Remove Sponges and Power Cycle the System

CAUSE:

The overall sponge count limit for the surgery has been exceeded.

ACTION:

Manually count used sponges.

System Failure

A system failure is a serious condition that will cause the SmartSponge System to stop working.

If you receive a system failure message:

- Contact ClearCount Medical Solutions for service,
- Provide service with the numeric error code, and
- Power down the system.

The system should not be used again until it has been serviced.



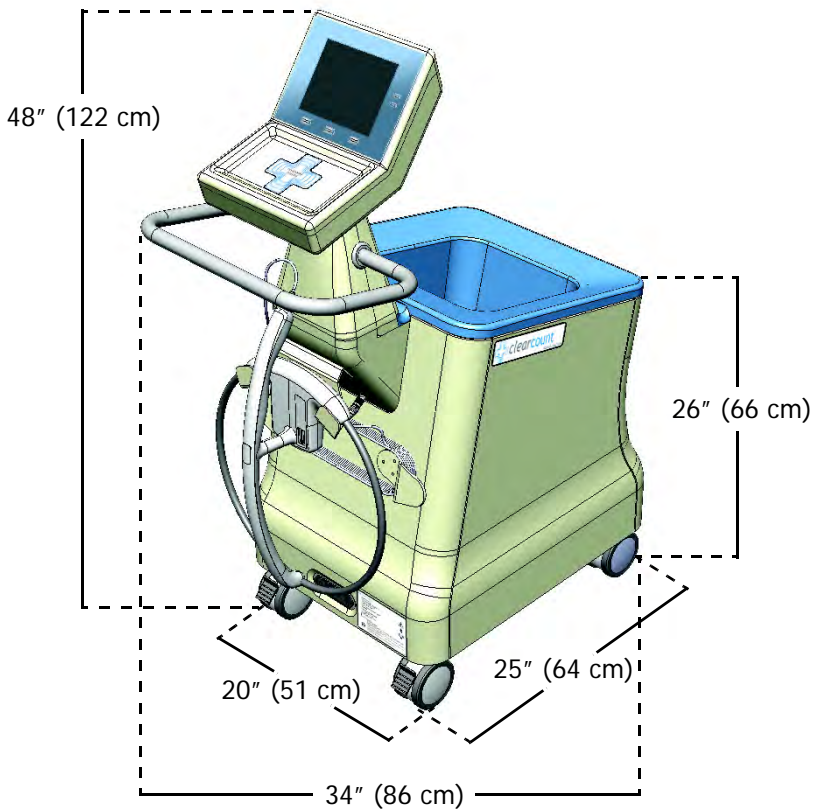
Figure 4-3 Example System Failure Screen

For additional information please call customer service at **(888) 931-0787**

Appendix A: Technical Specifications

SmartSponge® System Dimensions

Figure A-1 SmartSponge System - Model A02



Weight - 96 lbs (44 kg)

Power Requirements

Power supply:	120 - 240 VAC, 50/60 Hz, 60 W
Power consumption:	0.65 Amps at 120 VAC
Outlet requirement:	standard, single-phase, grounded three-prong outlet
Power cord length:	20 feet
Internal fuse rating:	3 Amp, fast acting on Neutral (N) and Line (L)

Environmental Conditions

Operating Temperatures:

Ambient temperature:	50°F to 104°F (+10°C to +40°C)
Relative humidity	30 to 75%
Atmospheric pressure	700 to 1060 hPa

Transport and Storage Temperatures:

Ambient temperature:	-40°F to 158°F (-40°C to +70°C)
Relative humidity:	10 to 95% noncondensing
Atmospheric pressure:	500 to 1060 hPa

SmartSponge System Sponges and Towels

- All SmartSponge Sponges and Towels are constructed of 100% cotton.
- ClearCount RFID tags are encapsulated in bio-compatible epoxy.

EMC Considerations

The ClearCount SmartSponge System needs special precautions regarding Electromagnetic Compatibility (EMC), and must be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF equipment can affect the ClearCount SmartSponge System.

Compatibility of cables, transducers, and other accessories: Not applicable.

Guidance and Manufacturer's Declaration – Emissions

All Equipment and Systems

Guidance and Manufacturer's Declaration - Emissions

The ClearCount SmartSponge System Model A02 is intended for use in the electromagnetic environment specified below. The customer or user of the ClearCount SmartSponge System Model A02 should ensure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 2	The ClearCount SmartSponge System Model A02 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. The ClearCount SmartSponge System Model A02 is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF Emissions CISPR 11	Class B	
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity

All Equipment and Systems

Guidance and Manufacturer's Declaration – Immunity

The ClearCount SmartSponge System Model A02 is intended for use in the electromagnetic environment specified below. The customer or user of the SmartSponge System Model A02 should ensure that it is used in such an environment.


Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	±2kV Mains No I/Os	Main power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Main power quality should be that of a typical commercial or hospital environment.
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle	>95% Dip for 0.5 Cycle	Main power quality should be that of a typical commercial or hospital environment. If the user of the ClearCount SmartSponge System Model A02 requires continued operation during power mains interruptions, it is recommended that the ClearCount SmartSponge System Model A02 be powered from a power source that has automatic emergency backup.
	60% Dip for 5 Cycles	60% Dip for 5 Cycles	
	30% Dip for 25 Cycles	30% Dip for 25 Cycles	
	>95% Dip for 5 Seconds	>95% Dip for 5 Seconds	
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer’s Declaration – Emissions

Equipment and Systems that are NOT Life-supporting

Guidance and Manufacturer’s Declaration – Emissions

The ClearCount SmartSponge System Model A02 is intended for use in the electromagnetic environment specified below. The customer or user of the ClearCount SmartSponge System Model A02 should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
<p>Conducted RF IEC 61000-4-6</p>	<p>3 Vrms 150 kHz to 80 MHz</p>	<p>3Vrms</p>	<p>Portable and mobile communications equipment should be separated from the ClearCount SmartSponge System Model A02 by no less than the distances calculated/listed below: $D=(3.5/3)(\text{Sqrt } P)$ $D=(3.5/3)(\text{Sqrt } P)$ 80 to 800 MHz $D=(7/3)(\text{Sqrt } P)$ 800 MHz to 2.5 GHz where P is the max power in watts and D is the recommended separation distance in meters.</p>
<p>Radiated RF IEC 61000-4-3</p>	<p>3 V/m 80 MHz to 2.5 GHz</p>	<p>3V/m</p>	<p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a, should be less than the compliance level in each frequency range^b.</p> <p> Interference may occur in the vicinity of equipment marked with the following symbol:</p>

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ClearCount SmartSponge System Model A02 is used exceeds the applicable RF compliance level above, the ClearCount SmartSponge System Model A02 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ClearCount SmartSponge System Model A02.

Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Recommended Separation Distances between portable and mobile RF Communications equipment and the ClearCount SmartSponge System Model A02

Equipment and Systems that are NOT Life-supporting

Recommended Separations Distances for the SmartSponge System Model A02

The ClearCount SmartSponge System Model A02 is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ClearCount SmartSponge System Model A02 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF Communications Equipment and the ClearCount SmartSponge System Model A02 as recommended below, according to the maximum output power of the communications equipment.

Max Output Power (Watts)	Separation (m)	Separation (m)	Separation (m)
	150 kHz to 80MHz $D=(3.5/3)(\text{Sqrt } P)$	80 to 800MHz $D=(3.5/3)(\text{Sqrt } P)$	800MHz to 2.5GHz $D=(7/3)(\text{Sqrt } P)$
0.01	.1166	.1166	.2333
0.1	.3689	.3689	.7378
1	1.1666	1.1666	2.3333
10	3.6893	3.6893	7.3786
100	11.6666	11.6666	23.3333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The SmartSponge System contains a receiver operating at a frequency of 13.56 MHz +/- 7 kHz.

The SmartSponge System may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements. If abnormal behavior is observed, please refer to the separation distance chart provided in this appendix.

The SmartSponge system contains a transmitter operating at a frequency of 13.56 MHz, using 10% amplitude shift keying at a modulation frequency of 423.75 kHz, and maximum effective radiated power of 200 mW.

Device Label

Figure A-2 Device Label

 **clearcount**
MEDICAL SOLUTIONS

Manufactured for:
ClearCount Medical Solutions, Inc.
101 Bellevue Road, #300
Pittsburgh, PA 15229

ClearCount SmartSponge® System
Model A02

120-240 VAC, 50/60 Hz, 60 W
0.65 Amps at 120 VAC
Class 1, Type B Equipment

window

FCC ID: WWQCCMS003
This device complies with Part 15 of 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 undesired operation.
Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
The System contains no user replaceable fuses. Any attempt to service this device by the user will result in voiding of any and all warranties.
U.S. Patent Nos. 5,650,596, 5,923,001, 6,998,541, D557421, other patents pending.

 Read instructions prior to use

 Type B equipment

 Non-ionizing radiation



100278-C

