The SmartSponge® System Operator's Manual

clearcount
MEDICAL SOLUTIONS

100276 Rev. A User Manual, SmartSponge System

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, laparatomy 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 SmartBucket.
- 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 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 non-sterile contamination of the items being scanned in.
- Using the scanning wand without a sterile wand cover could contaminate the sterile field.
- Holding items close to the SmartBucket may result in items being added to the Count Out column prior to disposal. Dispose of any items into the SmartBucket without using them if the Count Out Bucket has detected them 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 the patient.
- 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 packed sponges from a previous surgical case into the SmartBucket. 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.

 **Note**

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

SECTION **PAGE**

Preface ..... i-ii

Chapter 1: System Description 1-1
Count In Scanner 1-1
Count Out Bucket & Wand Components 1-2
Display & Function Control Buttons 1-4
SmartSponge Disposables 1-6
SmartTags 1-8
SmartWand 1-9
Wand Cover 1-10
Override Card 1-10

Chapter 2: Initial Setup & Operation 2-1
Powering on the SmartSponge System 2-2
Placing the SmartTag 2-3
Boot-up Screens 2-4
Standby Mode 2-6
Setting Up for Surgery 2-7
Count Mode Operation 2-8
Scanning Items Into and Out of Surgery 2-10
Requesting Final Item Count Reports 2-11
Wand Mode Operation 2-14
Restoring Power 2-18

Chapter 3: Cleaning and Maintenance 3-1
Cleaning Instructions 3-2
Maintenance 3-3

Chapter 4: Troubleshooting 4-1
General Troubleshooting 4-2
System Alerts 4-4
System Warnings 4-6
System Failure 4-7

Appendix: Technical Specifications 5-1
SmartSponge System Dimensions 5-1
Power Requirements 5-2
Environmental Conditions 5-2
EMC Considerations 5-3
Device Label 5-8

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. 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. 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 Count In Scanner is located below the area marked **Touch Here to Scan.** The proximity sensor activates the Count In Scanner when sponges are present. As surgical sponges and towels are placed on the Count In Scanner, 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 scanner components.

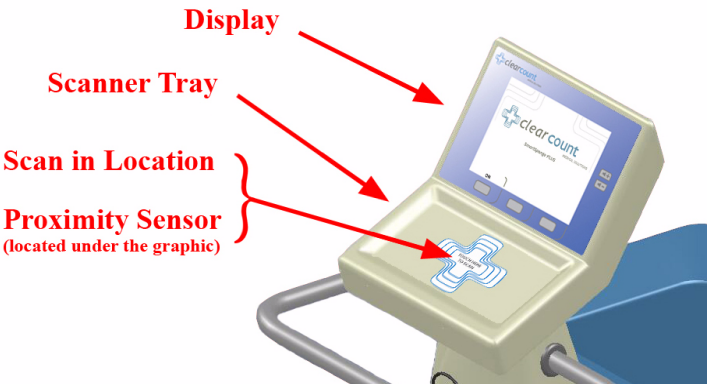


Figure 1-1 Count In Scanner Components

Table 1-1 Count In Scanner Components	
Component	**Description**
Scanner Tray	The area on which sponges and towels are to be placed when scanning them into a surgical case.
Proximity Sensor	This sensor detects the presence of items introduced to the Scan In Location automatically activating the Scanner Tray.
Display	Displays updated information for the user to track sponge counts throughout the surgical procedure. Also displays various modes of operation.
Scan In Location	The location on the Scanner Tray to scan sponges and towels into the surgical case. The Proximity Sensor is also located here under the **Touch Here to Scan** label.

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 comfortalbe means of manuvering 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. The power cord will be inserted into the Power Entry and then switched to On to begin. 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 postion 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
- Final Report: Counts Equal, or Final Report: Counts Not Equal
- Wand Mode

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

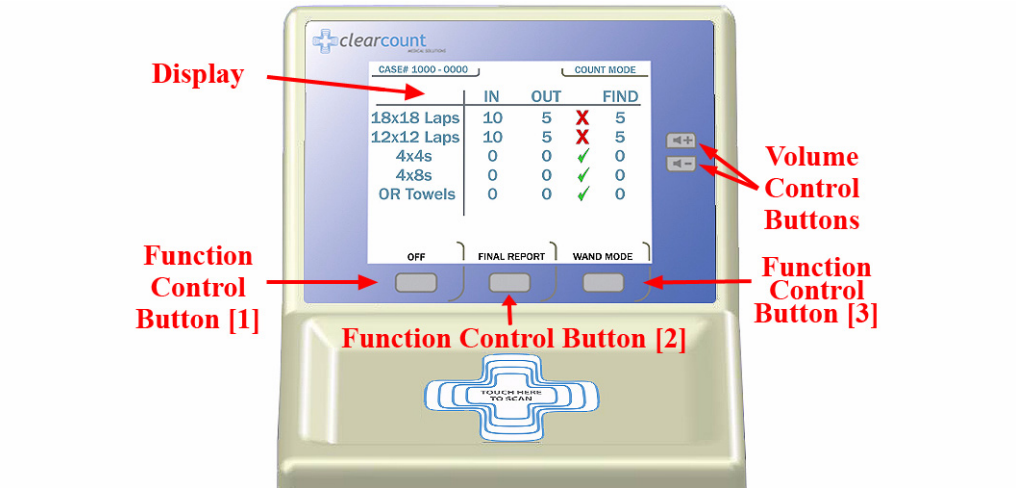


Figure 1-3 Display and Control Buttons

Table 1-3 Display/Controls	
Display / Controls	**Description**
Display	LCD that provides information to the user regarding operation of the system.
Volume Control Buttons	These up and down buttons control the volume of the audible alert. The Volume of the alert can be set to four different levels and off with each button.
Function Control Button [1]	Allows the following actions; **On** - Turns the system on from Standby Mode. **Off** - Returns the system to Standby Mode.
Function Control Button [2]	Allows; **Final Count** - Exits Count Mode and proceeds to a final count screen for verification before ending a case. **Back** - Lets the user exit the final count screen and return to Count Mode.
Function Control Button [3]	Allows; **Wand Mode** - Switches from Count Mode to Wand Mode. **Count Mode** - Switches Back from Wand Mode to Count Mode. **OverRide** - Allows the user an option to end a case without reconciling the sponge counts with an Admin Card. **End Case** - Ends case and returns to standby.

SmartSponge Disposables

The SmartSponge System utilizes surgical sponges and towels that have been “tagged” with an RFID identification device. This RFID tag is smaller than a dime 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 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 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.
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	
Accessory	**Description**
Override Card	A Smart Card used by the appropriate staff member to enable an unreconciled case to be closed.
SmartTag	A sticker applied between the sheets of the OR table prior to surgery, which allows the user to ensure that the SmartWand is operational.

Figure 1-4 Example of Surgical Kit

Figure 1-5 Example of Sterile Sponge Packages

Smart Tags

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 sheets on the OR table. Figure 1-7 shows a typical position of the SmartTag on the OR table.

This tag, working together with the SmartWand, provides feedback to the system that the SmartWand has scanned through the depth of the patient's body. The SmartTag provides notification that the scan is proceeding properly, reducing the possibility of user error. The user can thus quickly identify SmartSponges that remain in the patient.

Figure 1-6 SmartTag

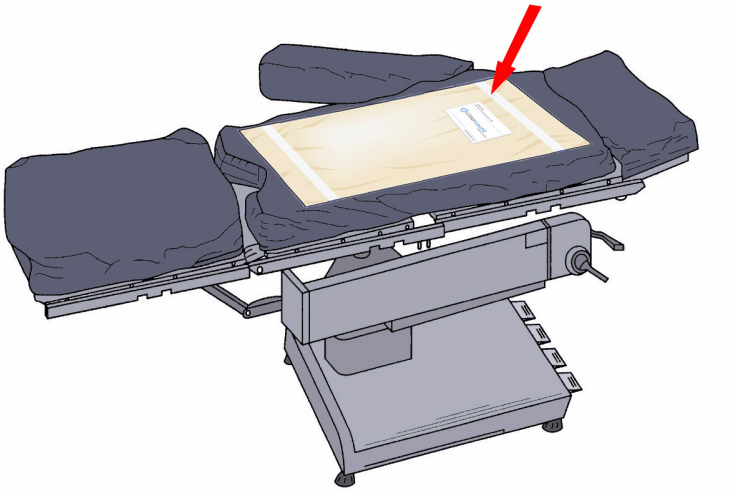


Figure 1-7 Location of SmartTag on OR Table

SmartWand

The SmartWand provides a fast and accurate patient scan for retained sponges. The handle of the circular shaped wand, shown in Figure 1-8, has two LEDs to give the operator feedback from the scan.

The Green LED will begin to blink when **WAND** Mode is entered. When the SmartWand detects the presence of a SmartTag the Green LED will stay illuminated; this also triggers a notification on the display. If the wand detects a sponge that is retained inside a patient, the Red LED on the wand flashes, and the Wand Mode screen displays the type and quantity of the item(s) found.

To use the wand, first remove it from the wand holder and pass it into the sterile field by means of the Sterile Wand Cover. Next place the system intoWand Mode. The user then holds the wand by its handle and passes it over the patient maintaining a distance of 1 to 3 inches above the body. As illustrated on the display, complete five sweeps over the patient at a rate of 0.2m/sec. This helps to ensure complete coverage is achieved.

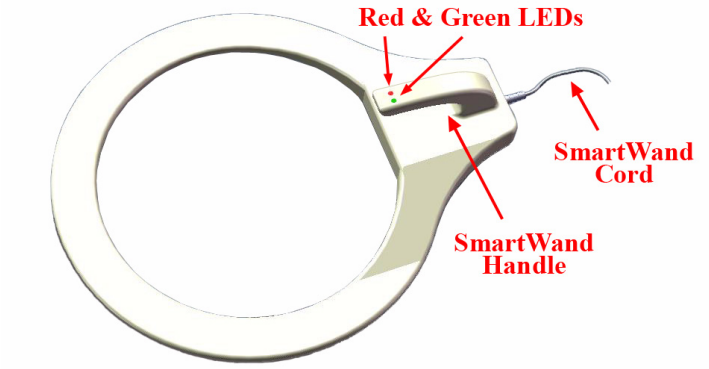


Figure 1-8 SmartWand

Table 1-5 SmartWand	
Component	**Description**
Red & Green LEDs	Illuminate when the SmartWand detects a SmartSponge (red) or a SmartTag (green).
SmartWand Cord	Provides power to the SmartWand while also allowing it to communicate with the SmartSponge System.
SmartWand Handle	Used to hold the SmartWand while performing the patient scan.

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 Smart Wand (outside of surgical kit)

Override Card

The SmartSponge System requires the user to acknowledge the closure of an unreconciled surgical case. The term "unreconciled" 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 touches the RFID-tagged Override Card on the Count In Scanner 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 surgical kits
  - Using individual sterile packages

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

- Using the 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

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 (|/O) switch shown in Figure 2-1 to the | (on) position, and observe that a series of power-up screens briefly appears on the display.

Figure 2-1 Location of On/Off Switch

Placing the SmartTag

Before the start of a surgery, a SmartTag must be placed under the patient. 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.

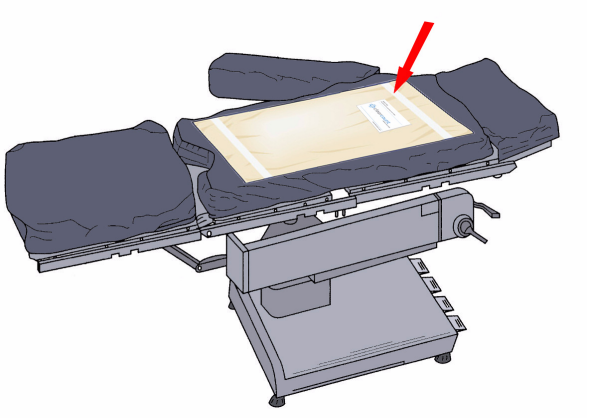


Figure 2-2 SmartTag Placement

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 OR table sheets.

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 (|), the Starting screens shown in Figure 2-3 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 version 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 displays the Standby (ON) 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.

Figure 2-3 Boot-up Screens

Standby Mode

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

The Standby Mode of operations 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, it automatically enters the Standby Mode.
- When you press the **OFF** button on the **Count Mode** screen during a surgical case. To resume normal system operation and return to the case, press the **ON** button shown in Figure 2-4.
- When a power failure occurs; upon restoration of power, the system will returned to the Standby Screen to allow restoration of the current case.

When you are ready to begin a new surgical case, press the ON button on the **Standby** screen.

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 uses both individually packaged sterile sponges, as well as sponges in pre-packaged surgical kits. The procedure for using one type versus the other is slightly different, as noted below.

Using Pre-Packaged Surgical Kits

Step 1 Locate and open the surgical kit. Within the kit, 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.

Notes

- If a package of sponges within the surgical kit is damaged or unable to be scanned into the surgical case, replace that package with an individual sterile package.
- After the sponges and towels have been scanned in, remove the bag liner from the Count In Scanner and install it into the Count Out Bucket.

Step 3 Using an Aseptic technique, cover the Count In Scanner and display with the Count Out Bucket liner. Make sure the scanner and display are completely covered. Proceed to scan sponges and towels into the surgical case.

Using Individual Sterile Packages

Step 1 Locate the following components:

- 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 CountOut Bucket. Proceed to scan sponges and towels into the surgical case.

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 the Count Mode until the surgery is complete and the sponge counts have been reconciled. While in the Count Mode, the display is continually updated on the number of sponges scanned into and out of the case. To enter the Count Mode, press the **ON** button while in the Standby Mode.

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

- Scan sponges and towels into and out of surgery.
- Press the **OFF** button to temporarily pause the surgical case; the system then enters the Standby Mode.
- Press the **FINAL REPORT** button to display a complete list of items used during surgery.
- Press the **WAND MODE** button to perform a patient scan using the SmartWand.

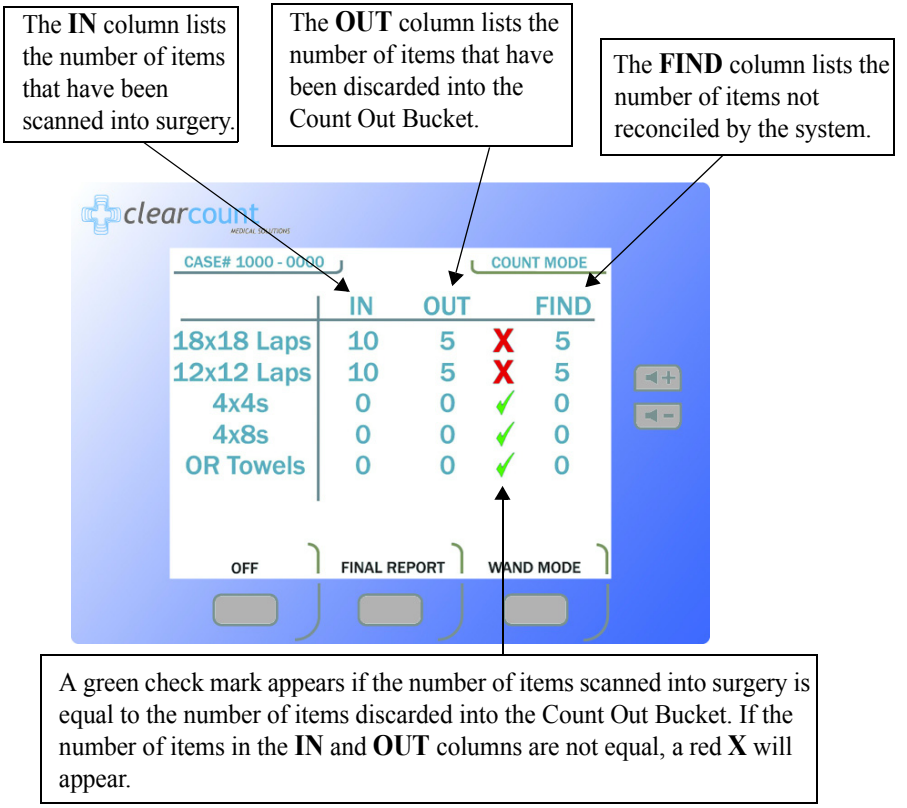


Figure 2-5 Count Mode Screen

Scanning Items Into and Out of Surgery

Warning!

- Holding items too close to the Count Out Bucket may result in items being added to the Count Out column prior to disposal. Dispose of any items into the SmartBucket without using them if the Count Out Bucket has detected them prior to use.
- For the system to function, use only ClearCount disposables.
- Do not place packed sponges from a previous surgical case into the Count Out Bucket. This will cause the sponge counts to not reconcile properly.
- Do not cut or tear SmartSponge disposables, as their RFID tags may become separated.
- Do not fill the SmartBucket beyond its top edge. Items above the top edge may not be counted.

Step 1 Scan packages of SmartSponge surgical sponges and towels into the surgical case by holding them flat on the Scanner Tray over the area marked **Touch Here to Scan**. A message Scanning In appears on the screen when items are placed on the Scanner Tray. Hold the item until the system adds them to the **IN** (inventory) column. If the package fails to scan, turn it over and try again. Figure 2-5 shows the **IN** column. Packages of sponges and towels must be scanned one package at a time. Immediately remove scanned packages. Do not rest sponge packages or any other items on the Count In Scanner.

Step 2 After sponges are scanned in, they may be passed into surgery using standard sterile technique. ClearCount SmartSponges are to be used in the same manner as generic surgical sponges.

Sponges may be discarded into the Count Out Bucket at any time during the surgical case.

If more than 50 SmartSponges are left in the Count Out Bucket together, the alert “Change Bag Do Not Scan” appears. If the alert occurs, remove the sponges or bag liner from the Count Out bucket and if desired replace it with a new liner. Sponge counts are not affected.

Notes

- It is recommended to have the Count In Scanner turned away from the Count Out Bucket when scanning items into the system. This helps to prevent items from being too close to the Count Out Bucket and having them falsely scanned and counted prior to use.
- The Count Out Bucket will not count items while the Scanning In message appears on the screen.

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.

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 **FINAL REPORT** button on the **Count Mode** screen.

If the counts are reconciled, the final report indicates that all counts are correct. See Figure 2-6.

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** screen appears. When the case has been closed, the system returns to the 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.

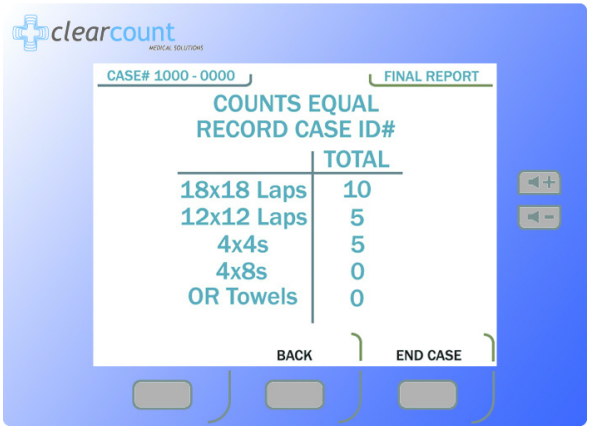


Figure 2-6 Final Report Screen: Counts Equal

Obtaining the Final Report: Counts Not Equal

If counts are not reconciled when you press the **FINAL REPORT** button, the **Counts Not Equal** screen appears. If items are intentionally withheld from the Count Out Bucket for procedural or clinical reasons, alert a nursing manager or an OR manager, and note this discrepancy on the patient's record.

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 manual at the time of shipment. The override card is used by placing it on the Count In Scanner until an audible alert is heard, while the system is in the Override Mode.

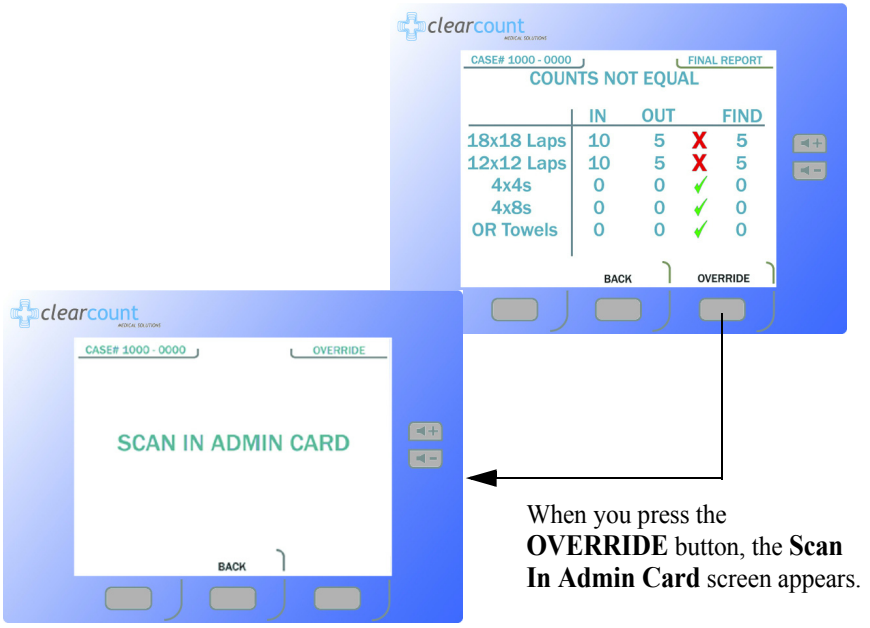


Figure 2-7 Final Reports Screen: Counts Not Equal

Step 1 Press the **OVERRIDE** button at the bottom of the display.

Step 2 The responsible party for the Admin card will need to be sent for or on hand. Then scan the Admin card by placing it onto the Count In Scanner and holding it there until you hear an audible alert. The Verified by Admin screen shown in Figure 2-8 will then appear.

Step 3 Enter the case number in the patient's record.

Step 4 By pressing the **OVERRIDE** 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.

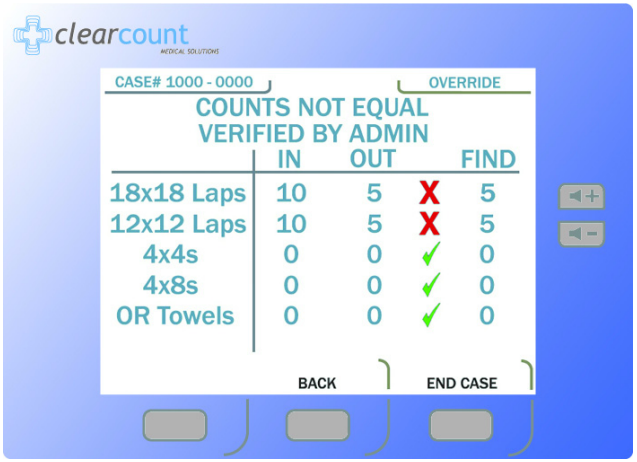


Figure 2-8 Counts not Equal Verified By Override Screen

Step 5 Remove the bag 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 6 Clean the SmartSponge System according to the procedure in Chapter 3 before entering it into the next surgical case.

Wand Mode Operation

The SmartWand may be used to scan patients for retained SmartSponge System 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, the red indicator on the wand flashes and the screen displays the type and quantity as shown in Figure 2-10.

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 1 to 3 inches above the patient. On a typical patient, each scan pass should take approximately 5 seconds to complete.

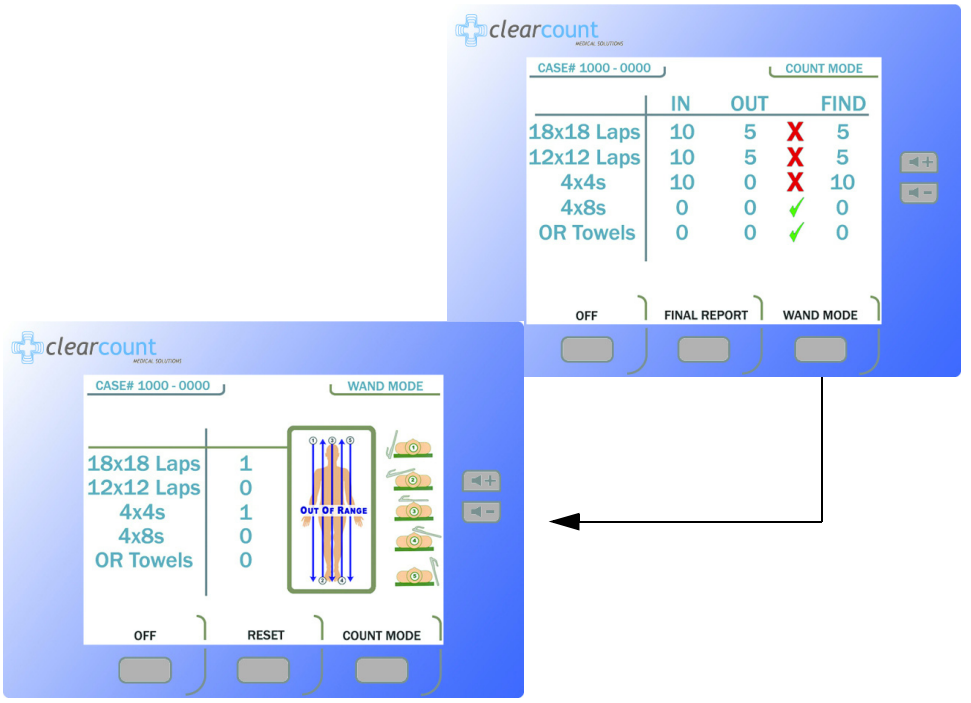


Figure 2-9 Wand Mode Screen

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 a standard sterile technique while passing the wand into the sterile field.

Step 3 Press the **WAND MODE** button on the **Count** Mode screen to activate the wand. The **Wand** Mode screen shown in Figure 2-10 will then appear.

To clear the detection counts from the screen, press the **RESET** button.

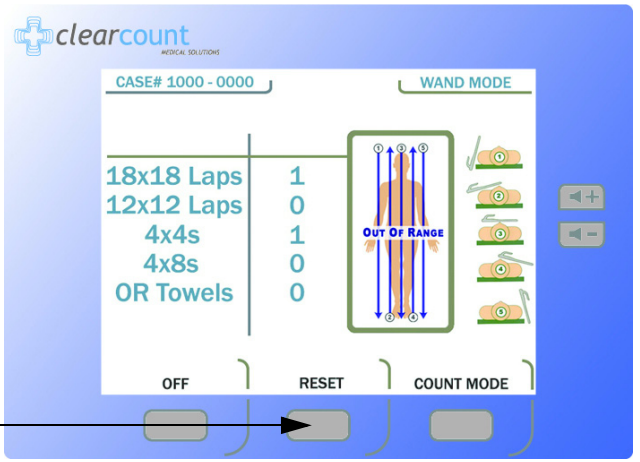


Figure 2-10 Wand Mode Screen

Step 4 Using the handle, hold the SmartWand over the site where the SmartTag has been placed. A green indicator on the wand flashes 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 1 to 3 inches above the patient. Follow the onscreen instructions shown in figure 2-10. It is important to do all the scans(1-5) in order to most accurately identify potential retained sponges.(Figure 2-11)

If the wand detects an item retained in a patient, the red 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).

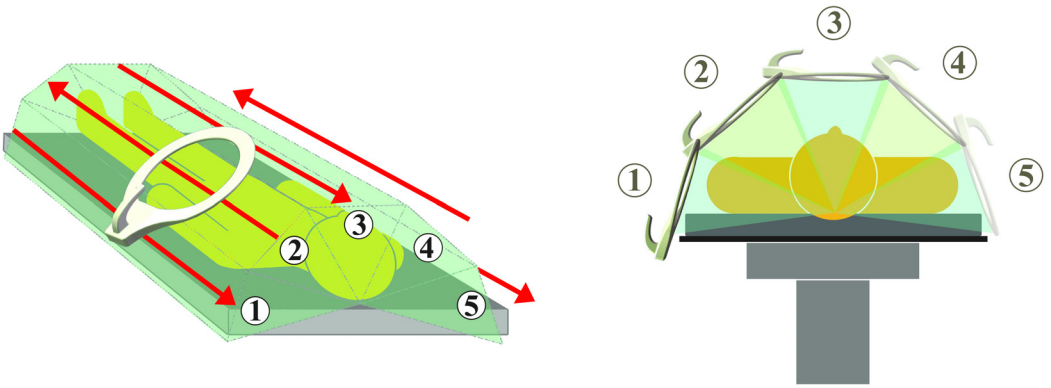


Figure 2-11 Patient Scan Procedure

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

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 grounding pads from electo-surgical 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. All sponge counts will be correct.

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. The 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
- Sporicidin brand disinfectant or equivalent hospital-grade disinfectant. (Follow the manufacturer's instructions regarding the duration of contact time for specific biological contaminants.)

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 Sporicidin 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 Sporicidin disinfectant.

Step 5 After wiping down the system, rinse it with a water-dampened cloth.

Maintenance

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

Frequency	Required Action	Responsible Party
After each surgical case	Follow the cleaning procedure.	User
Prior to each use	Visually inspect the SmartWand's cord and power cord for fraying and signs of wear. Also check for cracks or other damage to system components.	User or maintenance personnel
Monthly	Check for any damage to the display, user controls, the Count In Scanner, the Count Out Bucket, and the power switch.	Maintenance personnel
Annually	Contact ClearCount Medical Solutions to schedule annual maintenance.	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.
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 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 1 inch to the body of the patient.	Hold the wand at least 1 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 or Broken

CAUSE:	ACTION:
Wand has been dropped 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.

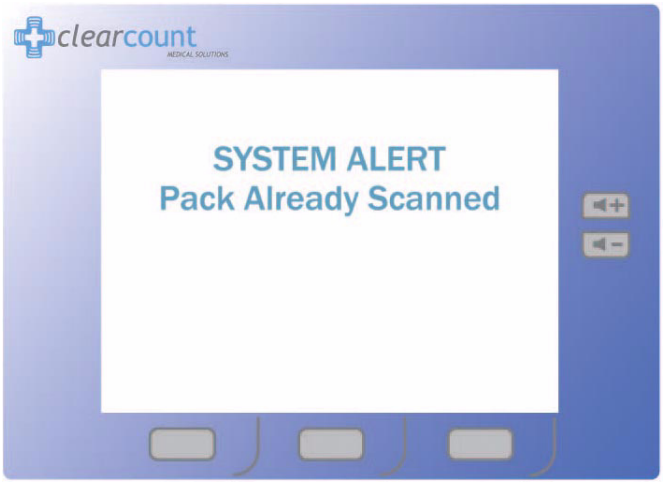


Figure 4-1 Example System Alert Message Screen

Bad Pack

CAUSE:	ACTION:
The system is unable to scan the sponge pack.	Flip or rotate sponges before rescanning the pack. If rescanning does not correct the condition, discard bad pack and resume use with a new one.

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

CAUSE:	ACTION:
There are over 50 sponges in Count Out Bucket.	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:	ACTION:
There are over 75 sponges in the Count Out Bucket.	Remove sponges or discard the full bag and replace with a new liner - sponge counts will not change.

Multiple Packs

CAUSE:	ACTION:
The system is unable to scan in multiple packs at the same time.	Ensure that only one pack of sponges is being scanned in at a time.

Pack Already Scanned

CAUSE:	ACTION:
The sponge pack has already been counted.	The sponge pack is ready for use - continue with system setup or operation.

Wand Disconnect

CAUSE:	ACTION:
The SmartWand is not connected.	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.

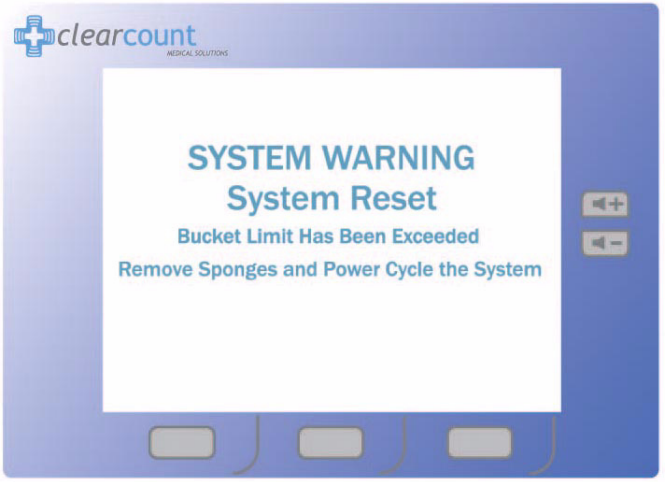


Figure 4-2 Example Warning Message Screen

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

CAUSE:	ACTION:
There are 100 or more sponges in the Count Out Bucket.	Remove sponges or discard the full bag and replace with a new liner - Power cycle the system.

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

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

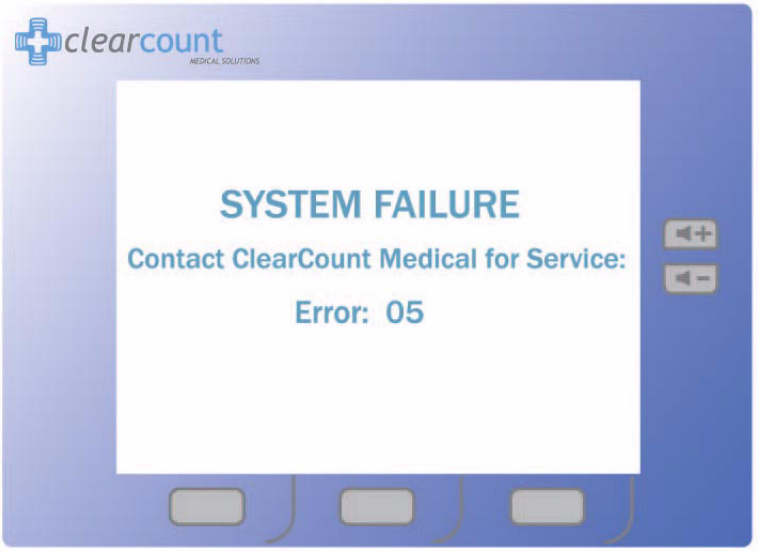


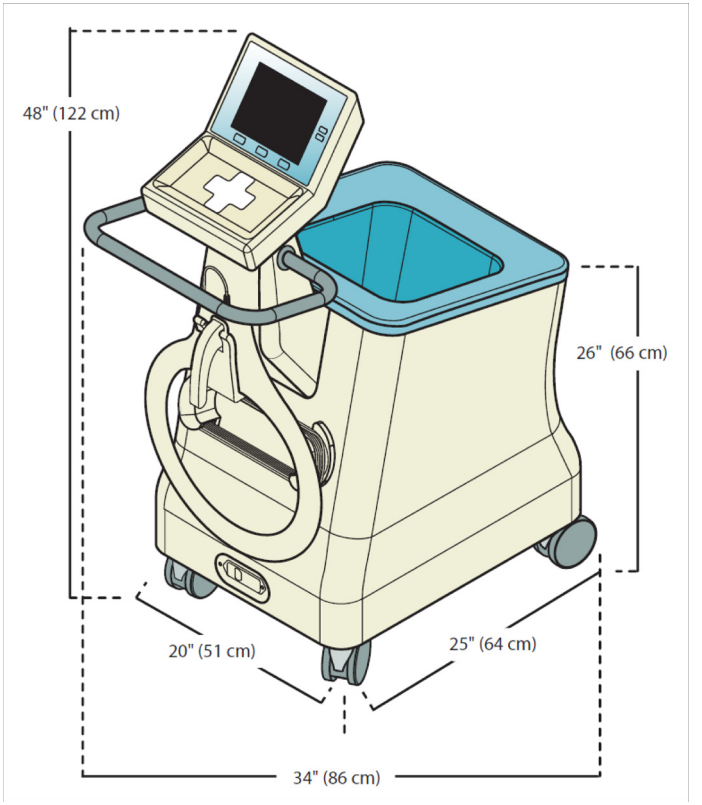
Figure 4-3 Example System Failure Screen

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

Appendix: 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 100%
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 plastic.

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.

Table 201 – 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 1	The ClearCount SmartSponge System Model A02 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	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.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Table 202 – 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	Mains 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	Mains 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	3A/m	30 A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Table 204 – 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**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	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)(Sqrt P) D=(3.5/3)(Sqrt P) 80 to 800 MHz D=(7/3)(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.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	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].  Interference may occur in the vicinity of equipment marked with the following symbol: .

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.

Table 206 – 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) 150 kHz to 80MHz D=(3.5/3)(Sqrt P)	Separation (m) 80 to 800MHz D=(3.5/3)(Sqrt P)	Separation (m) 800MHz to 2.5GHz D=(7/3)(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.

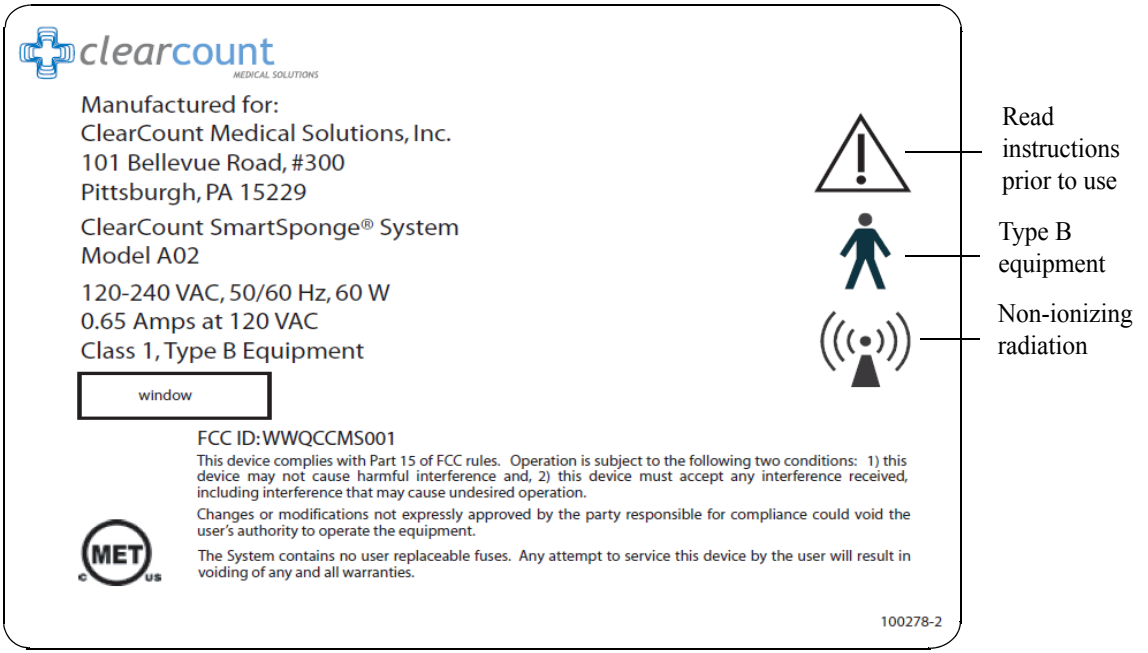
The SmartSponge System contains a receiver operating at a frequency of 13.56 MHz +/- 7 kHz.

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



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