ORLocate®
Beyond Counting!

OR Lite

RFID-BASED SYSTEM TO HELP ASSEMBLE SURGICAL SETS ACCURATELY AND EASILY

USER MANUAL

REVISION 0

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1. INTRODUCTION

1.1 THE HALDOR ORLOCATE[R] ORLITE SYSTEM

Haldor ORLocate[R] ORLite system is an RFID system that provide a solution enabling the enumeration of RFID tagged sponges and surgical instruments in order to keep track of the items during surgery, by utilizing passive RFID tags (battery-less transponder that not radiate any electromagnetic field when not activated). In addition, the system provides a non-invasive means of locating retained RFID-tagged surgical items within a surgical site. The system also supplies a semi-automatic application to help counting untagged items: the count information is first entered manually and the calculations are done automatically.

1.2 ABOUT THIS MANUAL

This manual provides the necessary information to operate the Haldor ORLocate[R] ORLite system in a safe and efficient manner. **Please read this manual before operating the system.** If any part of this manual is not clear, contact Haldor Customer Support for clarification.

1.2.1 WARNINGS, CAUTIONS AND NOTES

Three types of special messages appear in this User Guide:

- A **warning** indicates the possibility of injury to the patient or operator.

- A **caution** indicates a condition that may lead to equipment malfunction.

- A **note** provides additional important information.

1.3 GLOSSARY

ADDITIONS:

Items that are not part of the inventory before the start of surgery and that are added during surgery.

ANTENNA:

A powered device that is capable of sending and receiving signals from the RFID tags. There are 5 antennas in the ORLocate[R] ORLite system.

AUTOMATIC COUNT:

Count performed automatically by the system every 5 minutes (can be configured to any other counting interval depending on the O.R users' needs).

CIRCULATING NURSE:

The nurse who works in the non-sterile areas. The Circulating Nurse is responsible for the counts, and for the addition of new items to the sterile field.

CLEAN SPONGES:

Sterile and ready for use Sponges, gauzes or pads.

ADD SPONGES:

Functionality to add sponges at the beginning or during surgery.

IN OR:

The difference between the numbers of items that were registered initially plus number of items added and the number of items that were removed. For example, if ten items are registered, and only seven items were removed, then "In OR" is equal to three.

INITIAL COUNT:

The number of items that were registered in the preparation stage. This count is confirmed by the user.

INSTRUMENT SET/ TRAY:

A box that contains a pre-packaged set of sterile surgical instruments. The Instrument Set includes a non-sterile external container, and a sterile inner "net" that contains the instruments.

FLAT ANTENNA:

Antenna installed on the OR console to allow user to add tagged sponges and remove tagged instruments.

RFID:

Radio Frequency Identification – a technology that enables communication with items that have RFID-tags attached to them.

An RFID system includes a small radio transmitter that is activated by an antenna and in response sends its ID back to the antenna. Passive RFID tags, like those used in ORLocate^{R}, do not contain a battery.

RFID TAG:

A small, self-powered, self-enclosed device that contains an RFID and is placed inside a surgical sponge or is attached to a surgical instrument.

SCRUB NURSE:

The nurse who works in the sterile area assisting the surgeon.

SOILED SPONGES:

Sponges, gauzes or pads that are contaminated and cannot be further used.

UNTAGGED ITEMS:

Instruments or sponges that do not have an RFID tag attached, for example due to the small size of the instrument.

2. SAFETY

2.1 GENERAL SAFETY INSTRUCTIONS.

Do not use before reading this manual.

Plug the System ORLocate[R] Console into a properly installed power outlet of the appropriate voltage.

Caution: Do not use the system if the power supply is faulty or unreliable.

Changes or modifications not expressly approved by Haldor Advanced Technologies Ltd. can affect the safety and effectiveness of the system and will void the system's warranty.

Do not operate with damaged cords or plugs. If damaged, have the cord or plug replaced immediately by a qualified service technician.

The system contains no user-serviceable components. Do not open the system covers.

2.2 WARNINGS

	FCC Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.	1
	For the ORLocate[R] system to operate use only Haldor's RFID tagged instruments and RFID tagged sponges obtained from Haldor or any sponge supplier as long as they conforming Haldor standards.	2
	Do not use the system in the presence of flammable anesthetic mixture with air, or with oxygen or nitrous oxide.	3
	Keep the ORLocate[R] Console out of the sterile field.	4
	Sponges are for single-use only. Do not reuse sponges.	5
	If the RFID tag is disconnected from a sponge or instrument, do not use the item.	6
	The ORLocate[R] system is not indicated for use in emergency surgeries, in surgeries which involve the use of an MRI machine, with patients who have a pacemaker, cardioverter defibrillators and implantable neurostimulators and with patients who have an implanted metal plate in the area of the operation.	7
	The Sponge Bucket should be used only for the disposal of sponges from the current surgery.	8
	The Locator must not be used near metal objects.	9

	To avoid contaminating the sterile field, always use a sterile cover with the Locator, the Tool Add, and the Sponge Bucket.	10
	Do not remove sterile covers from the antennas during the procedure.	11
	Clean all instruments according to their standard protocol before use.	12
	Clean all antennas and the System ORLocate^{R} Console, before the procedure.	13
	Do not use sponges if the sponge package is open or otherwise compromise.	14
	Dispose RFID tags according to standard environmental regulations.	15
	Do not cut or tear RFID tagged sponges.	16
	Do not retain RFID tagged items inside the patient for more than 24 hours.	17
	While using the Locator interference may appear on the Ultrasound image. Do not use Locator while using this device.	18
	An MRI scan must not be performed on a patient who has a retained RFID-tagged item.	19
	When using a surgical laser, ensure that the laser is not used while an RFID tagged item is inside patient.	20
	Do not use the system in the presence of a flammable gas.	21
	While using Diathermia or Argon Diathermia do not use the Locator due to possible interference with antenna detection.	22
	Locator will shut down after 72 Seconds of continuous operation. Locator search will be available for use after 5 minutes timeout.	23
	Continuous stay next to the Tool Add Antenna once it is activated should be limited for up to 3 minutes within a distance of 10 cm (4") or less.	24
	While using Diathermia or Argon diathermia, cables of diathermia device should not cross less than 20 cm (8“) from the top of the Sponge Add and Flat antenna surface due to possible interference with proper antenna function.	25
	If the RFID tag separates from an instrument or sponge during use, the item will not be detected by the ORLocate^{R} system. Search for the item according to standard search protocols.	26
	If the patient has metallic implants or other objects in his body, the system may not correctly detect RFID-tagged instruments or sponges. Search for the items according to standard search protocols.	27

	If items are not detected with the Locator, search for the items according to standard search protocols.	28
	It is possible that two RFID-tagged items may be placed proximately in the patient in such a way that one of the instruments is not detected by the system. Search for the item according to standard search protocols.	29
	If one of the antennas appears to be not functioning, do not use the system.	30
	Lock the wheels on the System ORLocate^{R} Console before setting up the system.	31
	**The FCC Wants You to Know** 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.	32

2.3 INDICATIONS

The ORLocate^{R} system is indicated for use in recording, tracking and counting the number of RFID-tagged surgical sponges, laparotomy sponges, towels, surgical instruments and other tagged items used during surgical procedures in which counting is required.

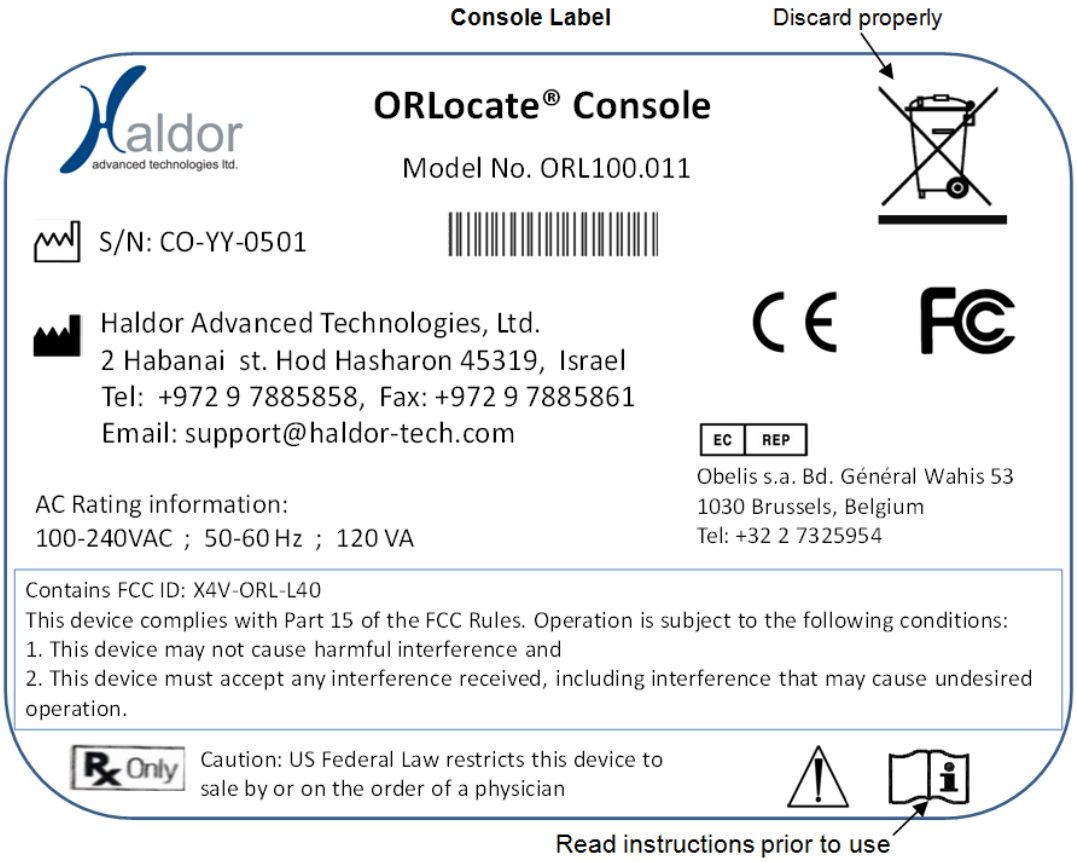
In addition, the product is indicated for providing a non-invasive means of detecting retained RFID-tagged surgical sponges, towels, surgical instruments and other tagged items within a surgical site

2.4 CONTRAINDICATIONS

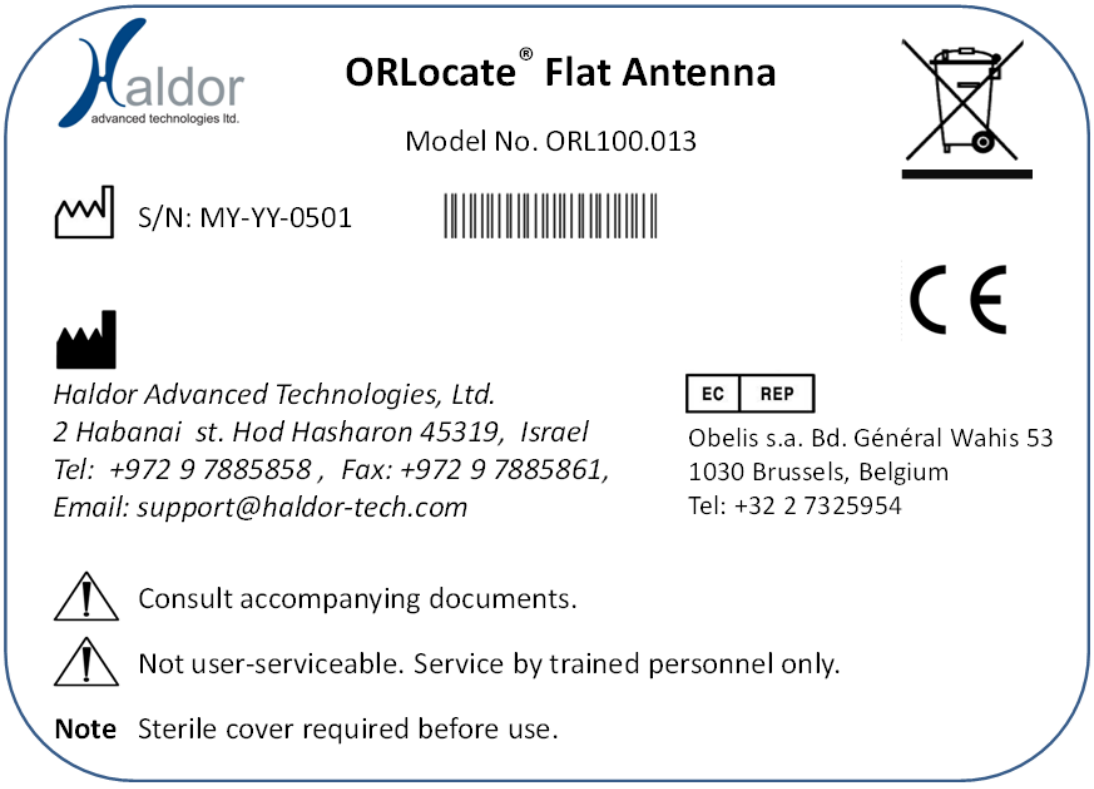
The ORLocate^{R} system is not indicated for use in emergency surgeries, in surgeries which involve the use of an MRI machine, with patients who have a pacemaker, cardiac defibrillators, or neurostimulators and with patients who have an implanted metal plate in the area of the operation.

2.5 SYSTEM LABELS

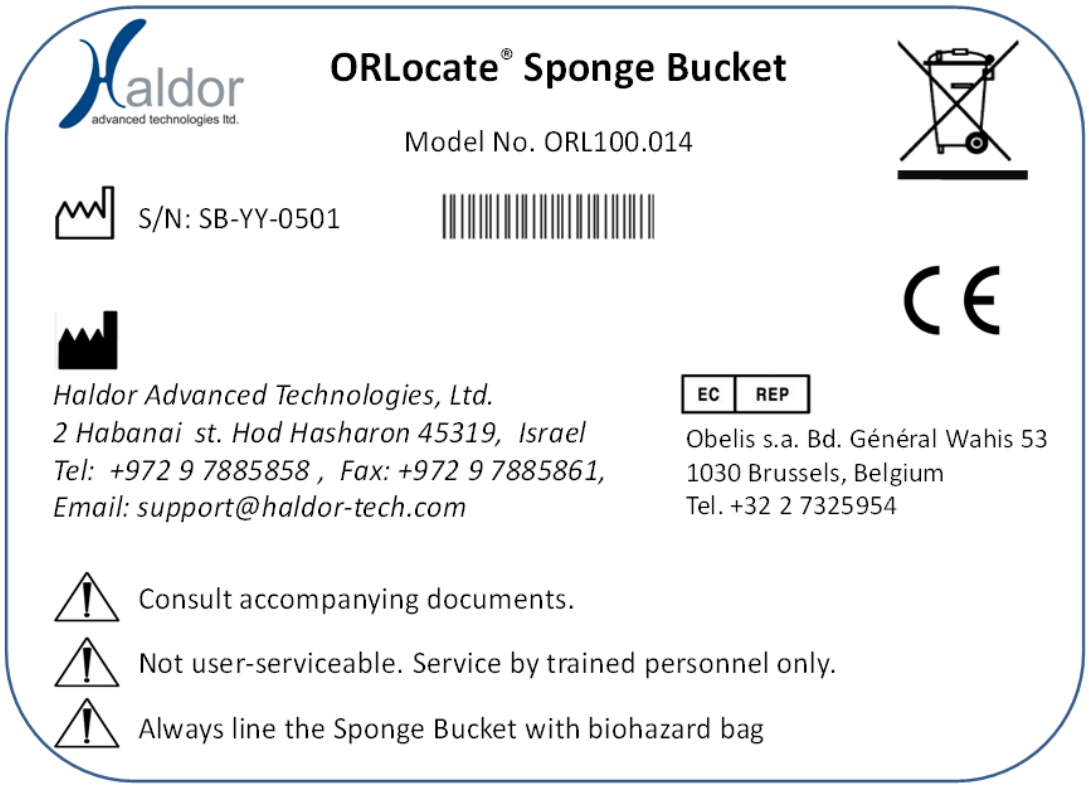
Console Label



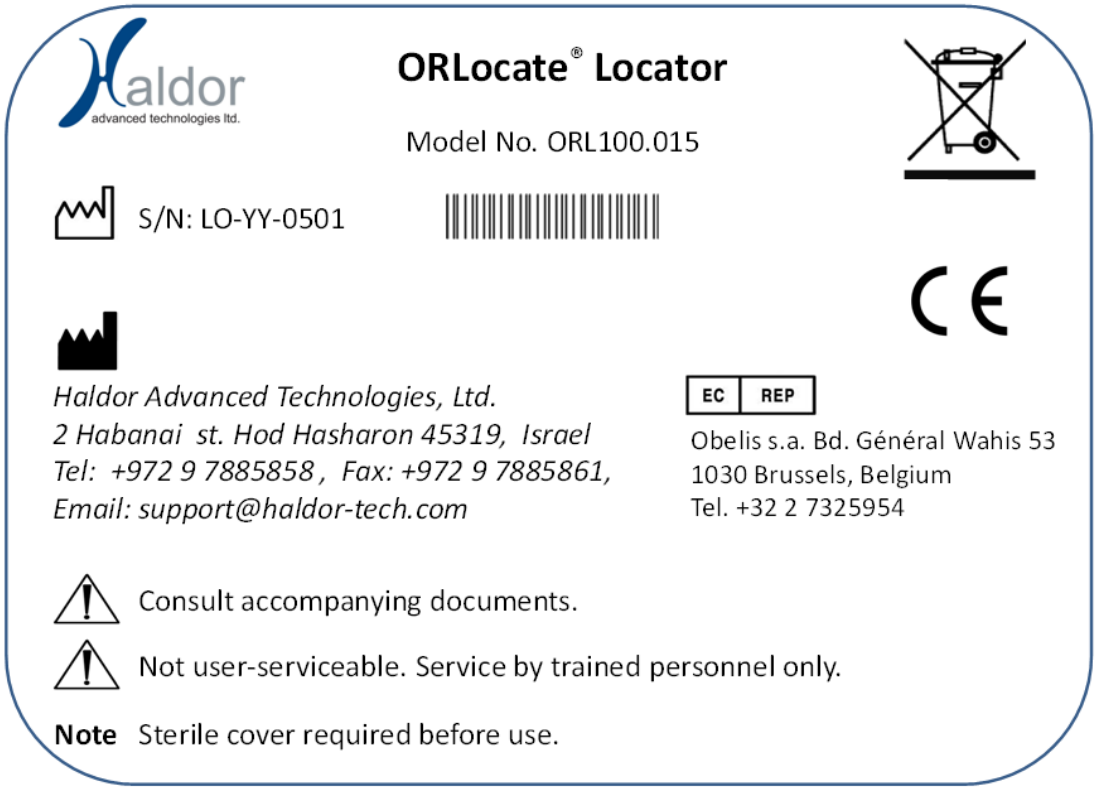
Flat Antenna Label



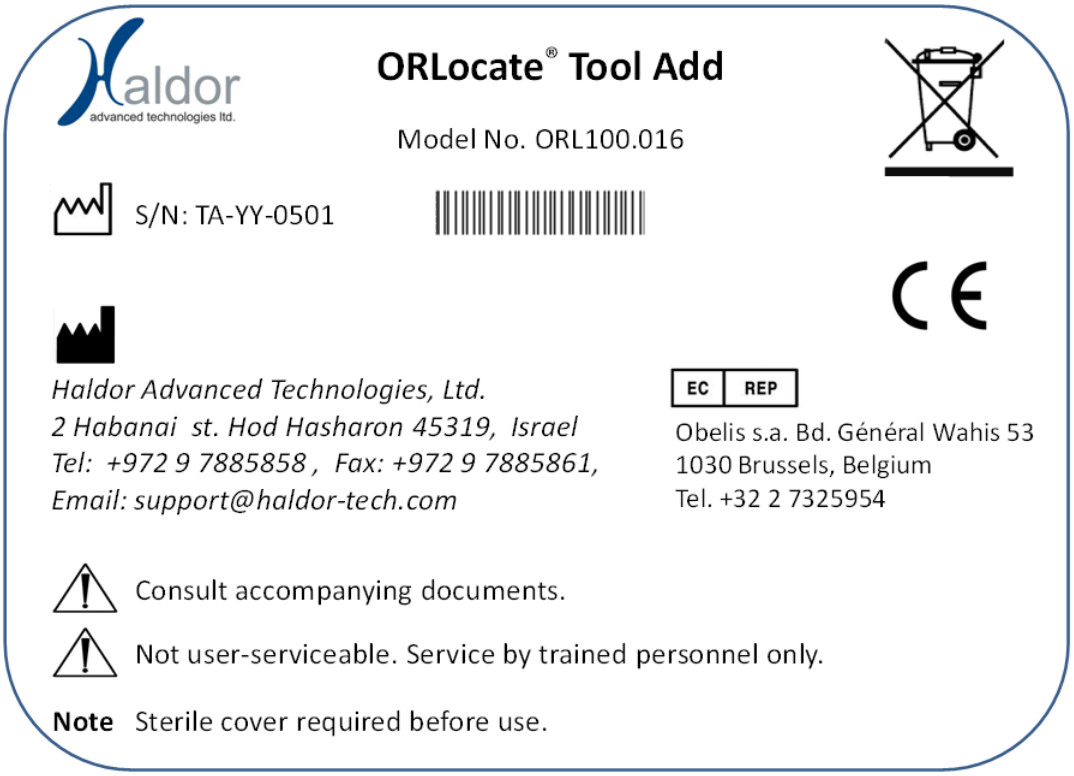
Sponge Bucket Label



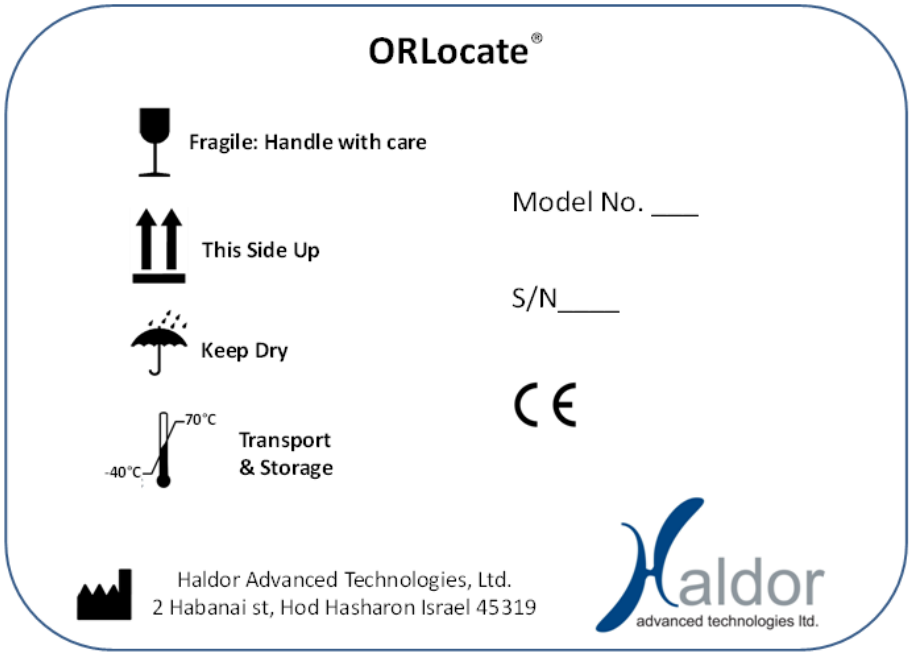
Locator Label



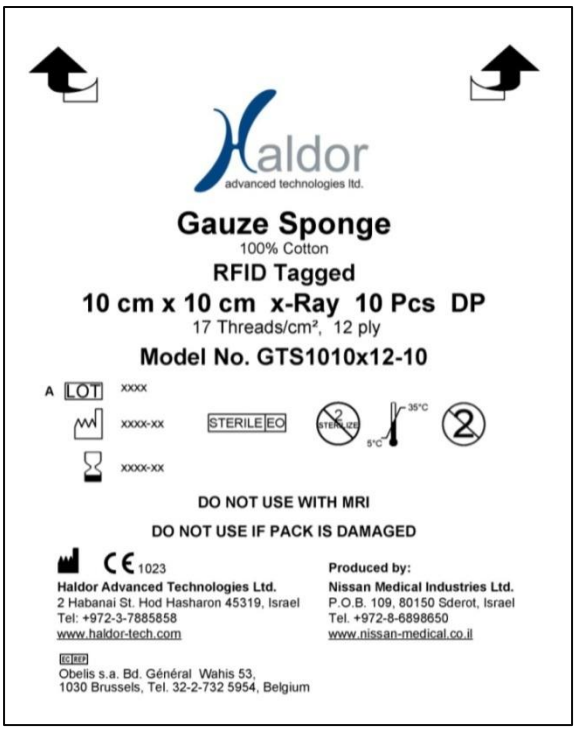
Tool Add Label



Package Label



In addition, specific Warning Labels are attached to the system components, as shown for each component below.


Haldor
advanced technologies ltd.
Gauze Sponge
100% Cotton
RFID Tagged
10 cm x 10 cm x-Ray 10 Pcs DP
17 Threads/cm², 12 ply
Model No. GTS1010x12-10
A LOT xxxx
xxxx-xx
xxxx-xx
STERILE EO
DO NOT USE WITH MRI
DO NOT USE IF PACK IS DAMAGED
CE 1023
Haldor Advanced Technologies Ltd.
2 Habanai St. Hod Hasharon 45319, Israel
Tel: +972-3-7885858
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Produced by:
Nissan Medical Industries Ltd.
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Tel. +972-8-6898650
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EC REP
Obelis s.a. Bd. Général Wahis 53,
1030 Brussels, Tel. 32-2-732 5954, Belgium


Haldor
advanced technologies ltd.
Gauze Sponge
100% Cotton
RFID Tagged
10 cm x 20 cm x-Ray 10 Pcs DP
17 Threads/cm², 16 ply
Model No. GTS1020x16-10
A LOT xxxx
xxxx-xx
xxxx-xx
STERILE EO
DO NOT USE WITH MRI
DO NOT USE IF PACK IS DAMAGED
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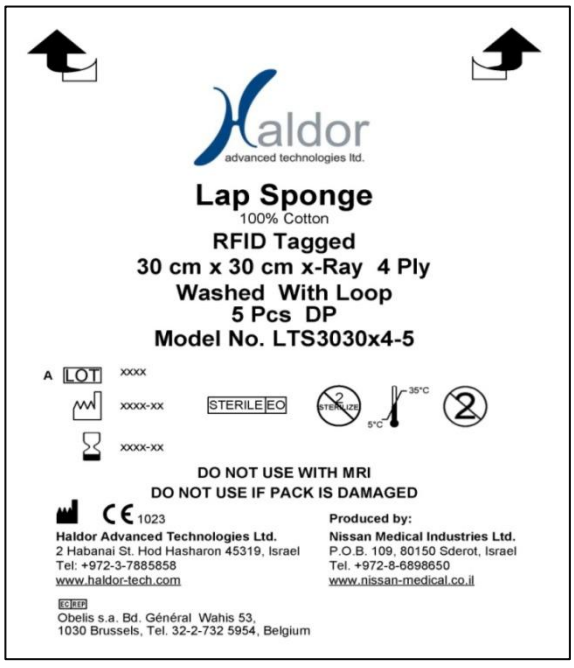
Haldor
advanced technologies ltd.
Lap Sponge
100% Cotton
RFID Tagged
30 cm x 30 cm x-Ray 4 Ply
Washed With Loop
5 Pcs DP
Model No. LTS3030x4-5
A LOT xxxx
xxxx-xx
xxxx-xx
STERILE EO
DO NOT USE WITH MRI
DO NOT USE IF PACK IS DAMAGED
CE 1023
Haldor Advanced Technologies Ltd.
2 Habanai St. Hod Hasharon 45319, Israel
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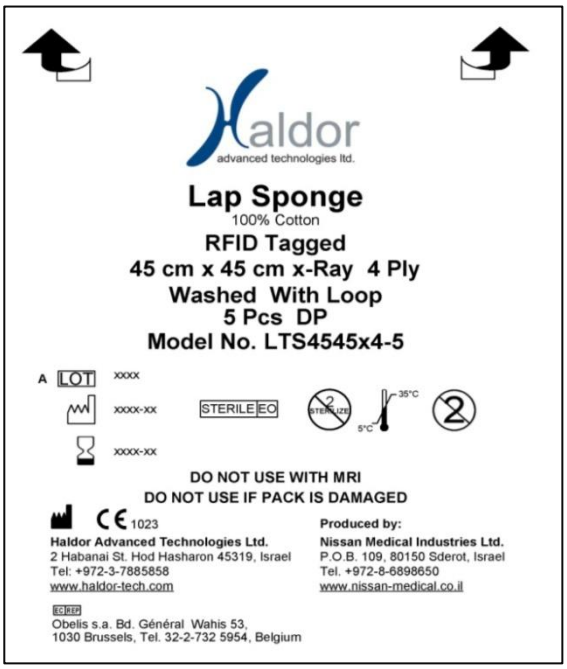
1030 Brussels, Tel. 32-2-732 5954, Belgium


Haldor
advanced technologies ltd.
Lap Sponge
100% Cotton
RFID Tagged
45 cm x 45 cm x-Ray 4 Ply
Washed With Loop
5 Pcs DP
Model No. LTS4545x4-5
A LOT xxxx
xxxx-xx
xxxx-xx
STERILE EO
DO NOT USE WITH MRI
DO NOT USE IF PACK IS DAMAGED
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1030 Brussels, Tel. 32-2-732 5954, Belgium

3. INTRODUCTION TO THE HALDOR ORLOCATE[R] ORLITE SYSTEM

3.1 SYSTEM ORLOCATE[R] CONSOLE

The System ORLocate[R] Console contains the computer and touch screen monitor that the circulating nurse uses to control the system. It also houses the Sponge Add.

The System ORLocate[R] Console is placed outside of the sterile field.

3.2 SPONGE ADD

If operated as part of the ORLite suite, the Sponge Add is located in the upper panel of the System ORLocate[R] Console, unless the Flat antenna (3.3) is located there instead of it. It is used to scan sponges added during surgery.
The sponges are scanned **while still in their packaging**. After they are scanned, the sponges can be used or be placed into the Sponge Tray.

Warning: Do not place any object on top of the Sponge Add (except for sponge packages).

Note: sponges should be placed on top of the Sponge Add in the marked area, as shown in the in the figure on the right:

Warning Label on System ORLocate[R] Console:

The ORLocate™ system is not indicated for use in emergency surgeries, in surgeries which involve the use of an MRI machine, with patients who have a pacemaker, cardiac defibrillators, or neurostimulators and with patients who have an implanted metal plate in the area of the operation.

3.3 FLAT ANTENNA

The Flat Antenna is located on the OR console. It is used for counting instruments and sponges.

Note: Maximum **60** instruments should be scanned at one time, according to the detailed instructions and obligations that shall be trained with the user.

Warning Labels on Flat Antenna:

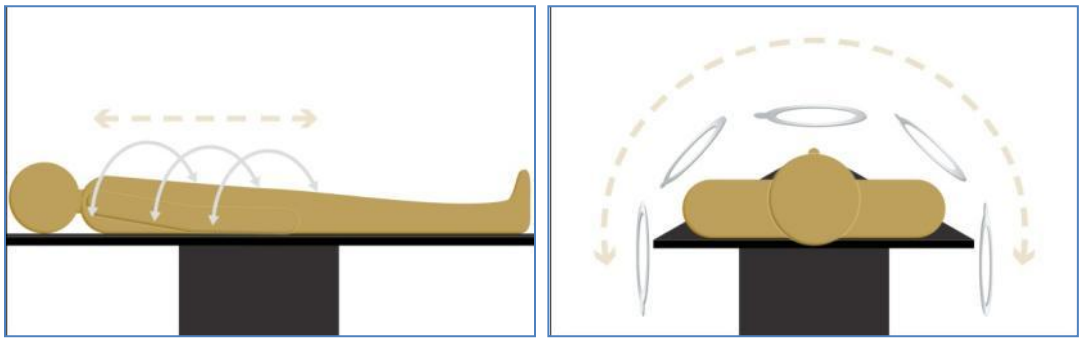
While using Diathermia or Argon diathermia, cables of diathermia device should not cross less than 20 cm (8") from the top of the ORLocate antenna surface due to possible interference with proper antenna function.

3.4 LOCATOR ANTENNA

The Locator is used to search for sponges or surgical instruments that may be in the Operating Room or in the surgical cavity.

To use the Locator, first remove it from the ORLocate^{R} Console hook. Holding the Locator by its handle, pass it over the patient. Scan the surgical cavity and its surrounding area in all directions.

Move the Locator at a maximum rate of 20 centimeters a second (7 inches/sec), maintaining a distance of 2.5 to 7.5 centimeters (1 to 3 inches) above the body, as illustrated in the figures below:

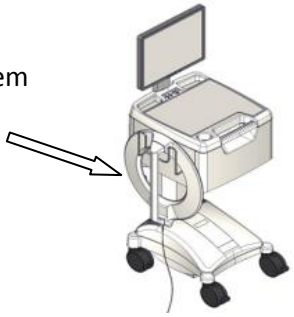


If the Locator detects an item, the screen will identify the instrument or sponge and a beep will be heard.

After the item was located it must be placed on the appropriate Antenna, i.e.: Instrument on flat antenna, sponge in the Sponge Bucket, in order to be included in next count.

Note: The detection of a tag by the Locator is affected by tag angle compared to antenna. Therefore, when used to scan the patient for retained items, the Locator should be held close to the operating site and be moved slowly in different angles.

Note: When not in use, the Locator is placed on a hook on the System ORLocate^{R} Console, as shown:



Warning: The Locator and the portion of its cable must be covered with a fresh sterile cover before starting a search.

Warning: The Locator must not be used near metal objects.

Warning Labels on Locator:

While using the Locator, interference may appear on ECG Graph Monitor display. User must be aware of this momentary influence on the graph.
While using the Locator interference may appear on the Ultrasound image. Do not use Locator while using this device.
While using Diathermia or Argon Diathermia do not use the Locator due to possible interference with antenna detection.
Locator will shut down after 72 Seconds of continuous operation. Locator search will be available for use after 5 minutes timeout.

3.5 HANDHELD RFID & BARCODE READER

Surgical set RFID tag or barcode can be scanned by the user utilizing a handheld reader during the surgery preparation stage. This device is also used to scan the user cards which are RFID as well.

The handheld device supported is PANMOBIL SmartScandy II.

3.6 TOOL ADD ANTENNA

The Tool Add is used to detect surgical instruments that are added or removed during surgery. The nurse holds the instrument near the Tool Add, close to the side where the LED is located (see figure). There are two types of feedback:

(1) **Beep**, indicating that the instrument is detected by the Tool Add.
(2) A **pop up message** on the touch screen, specifying which instrument was detected.

Note: The Scrub nurse should move the instrument close to the Tool Add and hold it steady / rotate it for two seconds in front of the Tool Add.

Note: Maximum **5** instruments should be scanned at one time.

Note: Instrument **tag** should be located near the marked area as shown:

Warning: The Tool Add and the portion of its cable that on the sterile surface must be covered with a fresh sterile cover before each procedure.

Warning Label on Tool Add:

Continuous stay next to the Tool Add should be limited for up to 3 minutes within a distance of 10 cm (4") or less.
While using Diathermia or Argon diathermia, cables of diathermia device should not cross less than 20 cm (8") from the top of the ORLocate antenna surface due to possible interference with proper antenna function.

3.7 SPONGE BUCKET

The Sponge Bucket is located near the surgical team, and is used for soiled sponges. The Sponge Bucket replaces the standard sponge bowl used for the disposal of used surgical sponges.

Warning: The Sponge Bucket must be covered with a fresh sterile cover before each procedure.

Note: When a sponge is deposited into the Sponge Bucket, and once a count is performed, the updated quantity will be presented. Later, when the sponge is physically removed from the Sponge Bucket, for the purpose of replacing the bucket liner, the sponge is still considered to be in the Sponge Bucket and is *not* included in the count for the maximum number of sponges that can be in the Sponge Bucket (see next Note).

Note: The Sponge Bucket can hold a maximum of 70 sponges. When the number of sponges in the Sponge Bucket is more than 30, the system will display a reminder message to empty the Sponge Bucket. If the number of sponges in the Sponge Bucket is more than 50, a second message will be displayed.

Note: The Sponge Bucket cable should be secured using T raps or strips as shown in the following figure, to prevent tiring-off of the cable from its connector.

When the user empties the Sponge Bucket, the total number of sponges in the Sponge Bucket is resets.

Warning Labels on Sponge Bucket:

While using Diathermia or Argon diathermia, cables of diathermia device should not cross less than 20 cm (8") from the top of the ORLocate antenna surface due to possible interference with proper antenna function.

3.8 TAGGED AND UNTAGGED ITEMS

Tagged items are RFID-tagged surgical instruments and sponges. The system is designed to track tagged items.

Untagged items do not have RFID tags. Examples of untagged items are blades and needles. The system allows for the optional manual recording of untagged items.

4. STERILE CONSIDERATIONS

The following sterile procedures are required in order to use ORLocate^{R} in a safe manner.

Warning: In order to avoid contamination, all sterile procedures described in this section must be followed.

4.1 TOOL ADD AND LOCATOR

These components must be covered with a sterile cover including the portion of the cable in the sterile zone (table surface) before each procedure.

4.2 LOCATOR

The Locator must be covered with a sterile cover before each use, including an appropriate portion of the cable that might have contact with the patient.

Warning: If the Locator is dropped on the floor **with** the sterile cover intact, or when placing back on the ORLocate^{R} Console (in the non-sterile zone) - a new sterile cover must be placed on the Locator.

Warning: If the Locator is dropped to the floor **without** the sterile cover, it must be cleaned with alcohol, as in the standard procedure before placing a new sterile cover on it.

4.3 SPONGE BUCKET

The Sponge Bucket must be covered with a sterile cover or a suitable liner. The cover must extend down the sides of the Sponge Bucket.

4.4 FLAT ANTENNA

The flat antenna is cleaned with alcohol, as in the standard procedure. The flat antenna is also cleaned with alcohol and placed on top of the system console. Both components are then covered with a single sterile hospital sheet.

4.5 SYSTEM ORLOCATE[R] CONSOLE

The system ORLocate[R] Console is not sterile. It should be maintained in a clean condition.

Place sponges on the Sponge Add while in their original package.

Warning: If the touch screen display is blank, or if the screen is not responsive to touch commands, do not use the system until the problem is solved.

Warning: If the touch screen is cracked, do not use the system until the problem is solved.

Warning: If you experience problems calibrating the touch screen, do not use the system until the problem is solved.

4.6 CLEANING SURGICAL INSTRUMENTS THAT HAVE RFID TAGS

Surgical instruments and tools with RFID tags shall be sterilized only using Steam Sterilization, according to the standard protocol.

4.7 RECOMMENDED DIMENSIONS FOR STERILE COVERS

Image	Element	Approximate Size Recommended
	**Sponge Bucket**	100 X 150 cm (40" x 60")
	**Tool Add**	50 X 100 cm (20" X 40")
	**Locator and Cable**	90 X 160 cm (36" X 64")

5. INSTALLATION OF ORLOCATE[R] ORLITE SYSTEM

This section describes the installation procedures required, prior to using the ORLocate[R] ORLite System.

Warning: The ORLocate[R] system must be connected to the main power supply and assembled by a technician authorized by Haldor, and not by the user.

	General cautions and instruction for Installation: • Install the system in a dry and clean environment. • Handle the LCD screen with care. • The system contains no user-serviceable components. Do not open the system covers. • If any component of the ORLocate^{R} system is cracked or damaged, do not use the system until the problem is corrected. • If the touch screen display is blank, the screen is not responsive to touch commands, or you experience problems calibrating the touch screen - do not use the system until the problem is corrected. See the Troubleshooting section of this document.

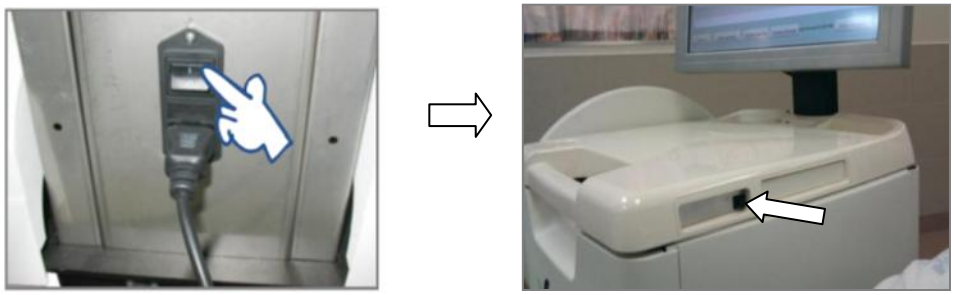
5.1 FIRST TIME INSTALLATION

Follow these steps only for first time installation.

(1) Unpack all system components at or near the designated working area, handle the LCD Screen with care.
(2) Ensure that all system components are present according to the following list (as relevant according to user requirements):
- Main ORLocate^{R} Console Unit
- Locator
- Tool Add
- Flat Antenna
- Sponge Bucket
- Power and GND Cables
- 2 Antenna Cables
- Locator Cable

(3) Lift the LCD Screen and mount it to its designated place with 4 screws supplied with the system.
(4) Connect the keyboard and the mouse to the dedicated USB port.
(5) Perform System power-up:

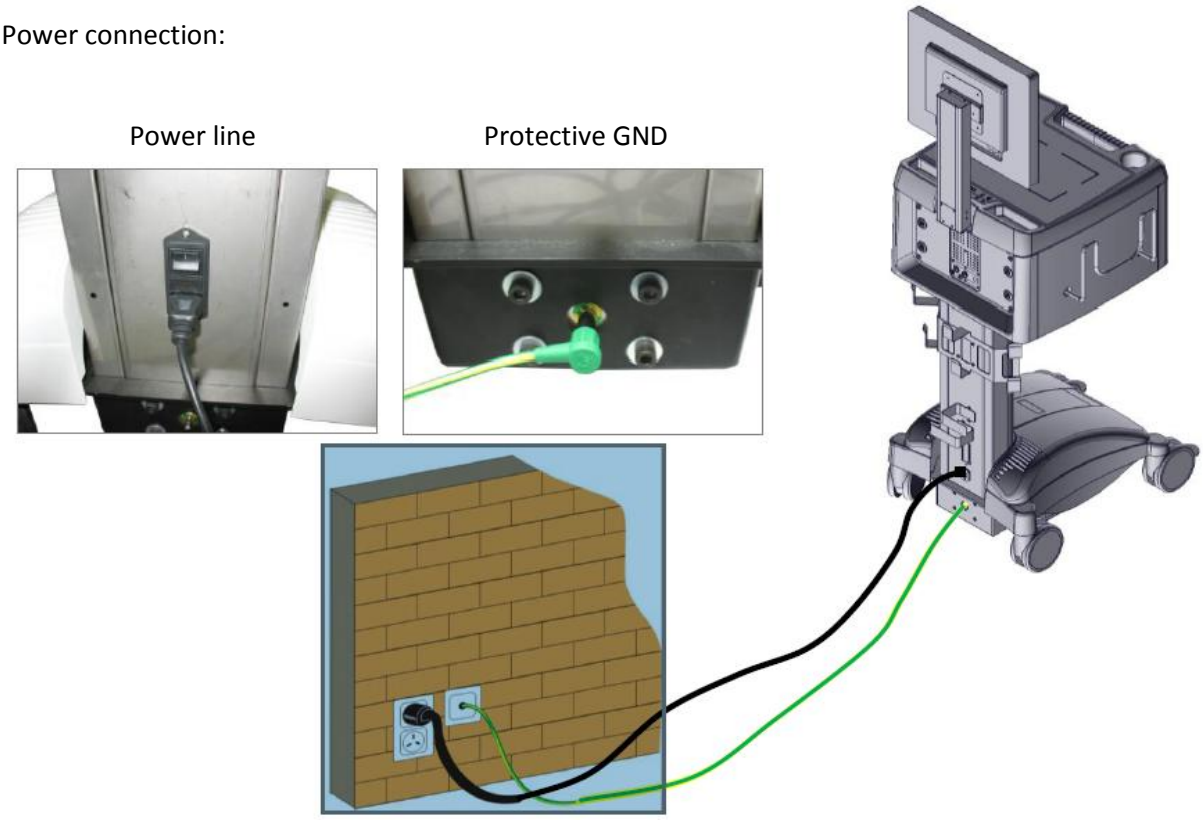
Switch main power switch to “I”: Press top tray pushbutton:



(6) First run set-up:
- Update Time.
- Update the ORLocate^{R} System Database to comply with the Hospital Database.

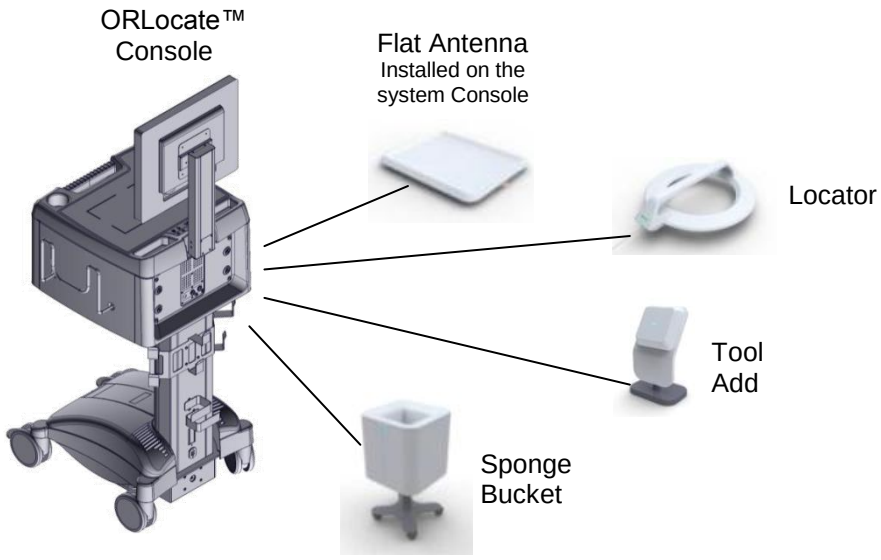
5.2 POWER AND GND INSTALLATION

Power connection:



5.3 CONECTING THE ANTENNAS TO THE ORLOCATE^{R} CONSOLE

The System ORLocate^{R} Console is the central connection point for the system. Connect all antennas to the ORLocate^{R} Console according to the following diagram:



5.4 LOCATION OF THE SPONGE BUCKET, TOOL ADD AND LOCATOR ANTENNAS

The Sponge Bucket should be located close to the surgeons and scrub nurse and should be covered with a sterile cover.

The Tool Add is located on top of system consol attached on the arm.

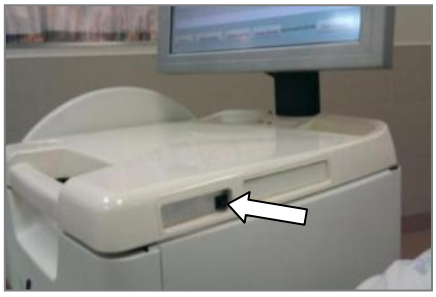
The Locator should be located during surgery in the designated location on the System ORLocate[R] Console.

5.5 SYSTEM CONFIGURATION

Perform System power-up:

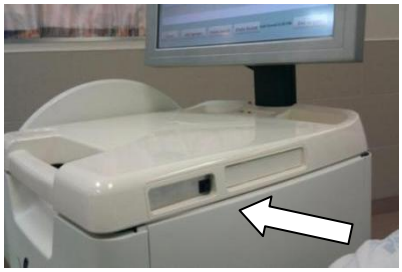
Switch main power switch to "I":

Press top tray pushbutton:



6. USING THE SYSTEM

After the Operating Room has been configured for the ORLocate[R] ORLite System, as detailed in the previous section, use of ORLocate[R] ORLite can begin. System is turned on by pressing the black push button on the right panel of the system ORLocate[R] Console, as shown in the following figure:



6.1 GENERAL PRINCIPLES – HOW THE ORLOCATE[R] COUNTS

(1) The initial count in surgery preparation includes all items that contained in the scanned surgical sets and sponges located on the flat antenna.

(2) Any new sponge that is added during surgery, after the initial count, must be scanned **before** use. Surgical instruments set tags must be scanned by the handheld or Tool Add and sponges must be scanned on the Sponge add or flat antenna. If the system detects items that were not registered in either of these two antennas, it alerts the user that items were improperly added to the inventory.

(3) The system displays the number of Items "In OR" = {Items that were registered in the system} minus {Items that were removed}.
(4) If an instrument falls on the floor or is otherwise contaminated, the instrument must be placed outside the sterile field, according to standard hospital procedure.
(5) If in the final count the Circulating Nurse sees that there are items missing ("In OR"), he / she can scan the contaminated items using the Tool Add or handheld antenna to reconcile the count.
(6) Use the Locator to search the surgical cavity for retained RFID tagged items before ending the surgery.
(7) Nurses may End Surgery with missing items and write down the reason why these items are missing.
(8) Do not place instruments into the Sponge Bucket.
(9) Do not place instruments on the Sponge Add.
(10) Untagged items are registered manually using the touch screen.

Warning: Do not place metal devices on the flat antenna or sponge add. If a metal basket is used, place it on a separate trolley.

Warning: During the initial registration, the system counts the number of sponges on the Flat Antenna. If the system count does not match your manual count, discard all sponges from the Flat Antenna.

Warning: During surgery, the user enters additional packages of sponges into the system via the Sponge Add. If the sponges fail to register, or if the system registers the sponges with an incorrect count, discard the sponge package.

Warning: If a package of sponges is opened **before** registration, this will compromise the sterility of the sponges. The package of sponges must be discarded, but NOT into the Sponge Bucket.

Warning: The system checks for available system resources (hard disk space and computer memory) during system initialization. If a message is displayed indicating insufficient resources, stop using the system until the problem is solved.

Warning: The system beeper should be operated during system initialization. If no beep is heard stop using the system until the problem is solved.

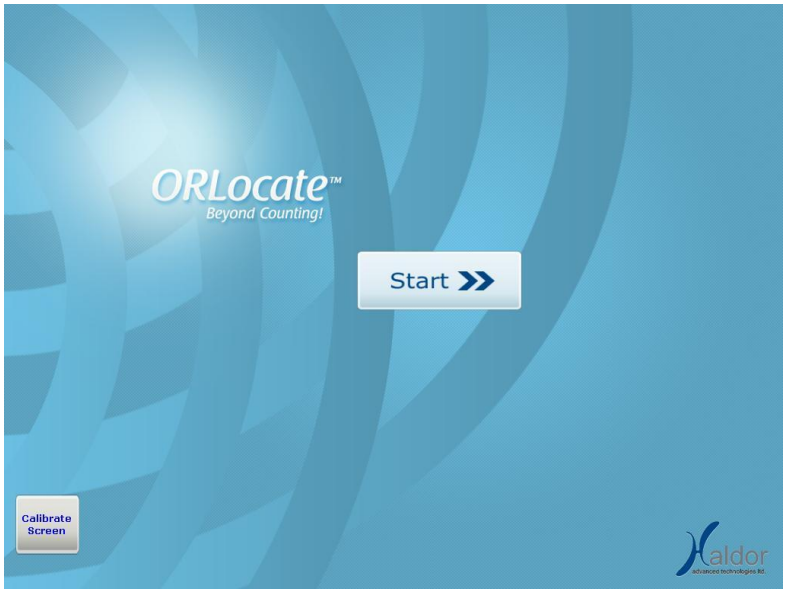
Note: Before each surgery, clean the system and visual inspect the cables according to paragraphs 9.2.1 and 9.2.2.

6.2 SYSTEM WORKFLOW – USER INTERFACE

6.2.1 PREPARATION MODE

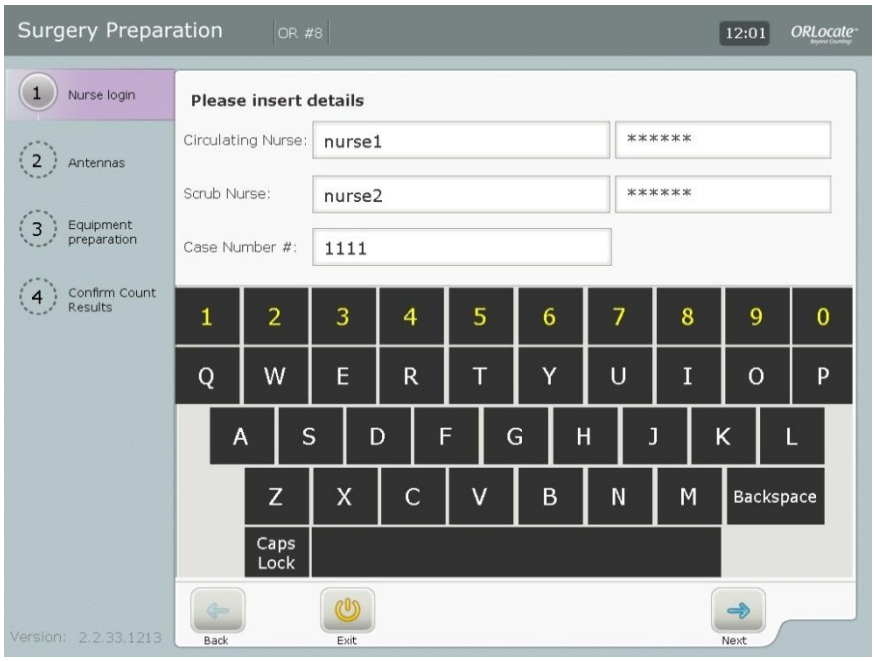
During the organization of the operating room, the required antennas are located in the room in the desired locations.

The circulating nurse touches the "Start" on the welcome view, as shown in the following figure**Error! Reference source not found.**:



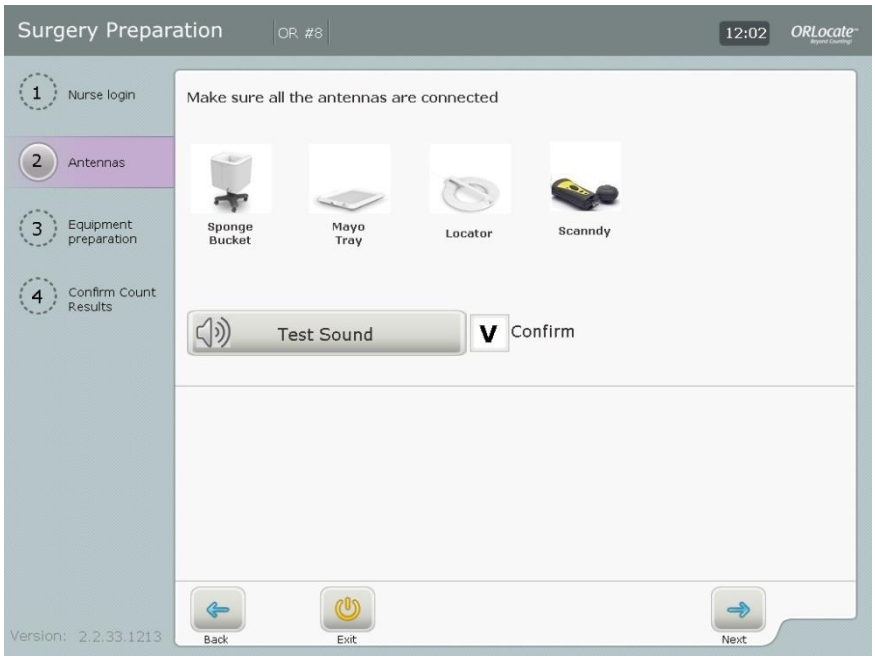
(1) Step 1 – Nurse Login:

To start the preparation mode it is required to enter the names and password of the authorized nurses, this can be done either manually by typing the nurse's details / name and password or by scanning the nurse's swipe card over using the handheld reader. The circulating nurse will also type the case # number, as shown in the following figure:



Step 2 – Antennas:

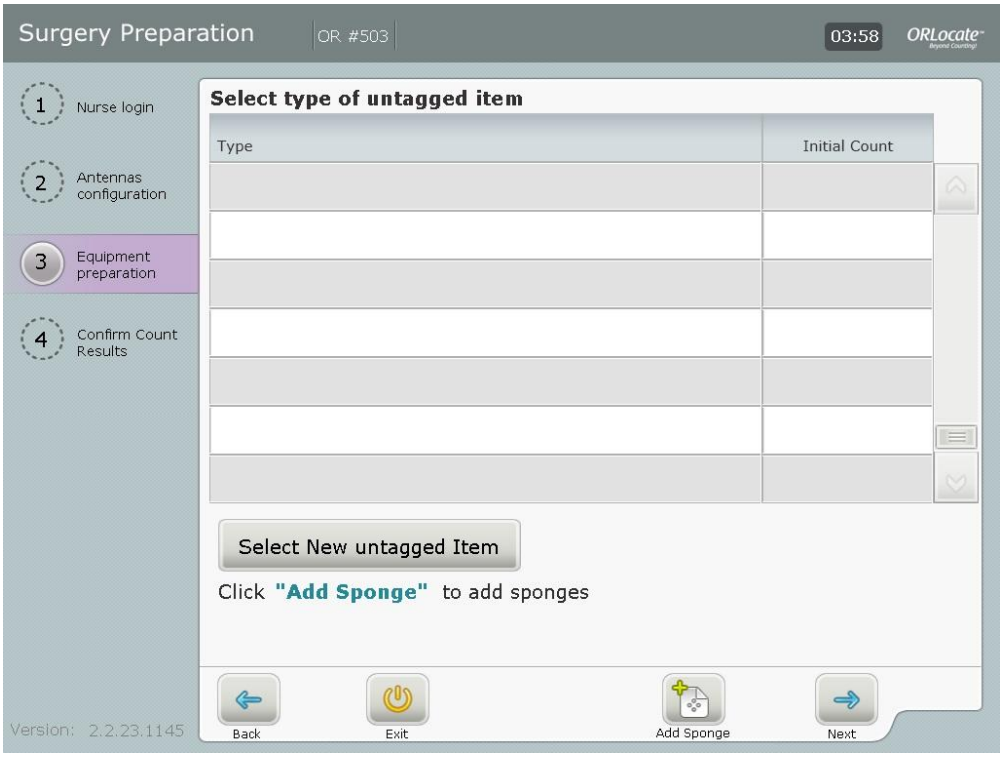
At this point the nurse is asked to make sure all the antennas are connected properly and system sound works as well. As shown in the following figure:



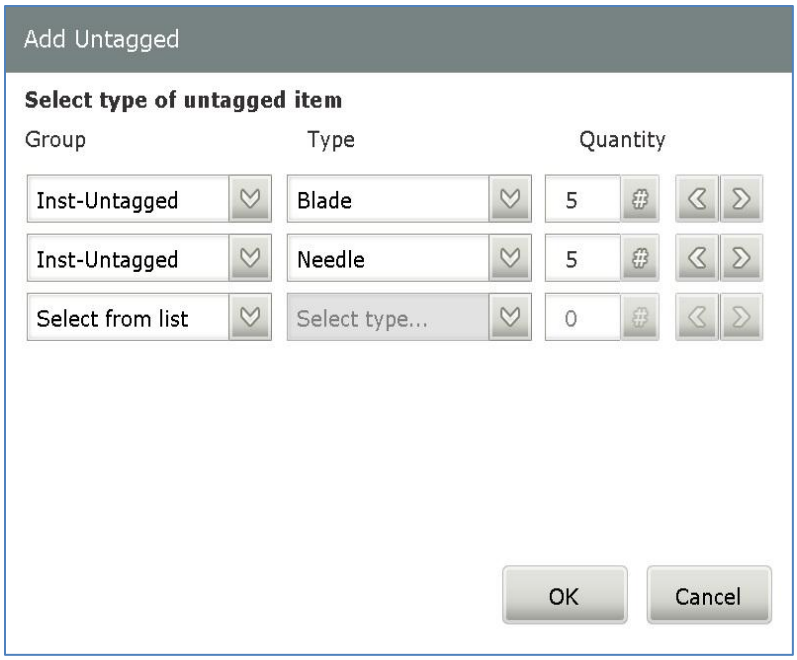
(2) Step 3 – Equipment Preparation:

<u>Adding untagged items</u>

The nurse may add items that are not tagged with RFID tags, by pressing the "Select New untagged Item" as shown in the following figure:

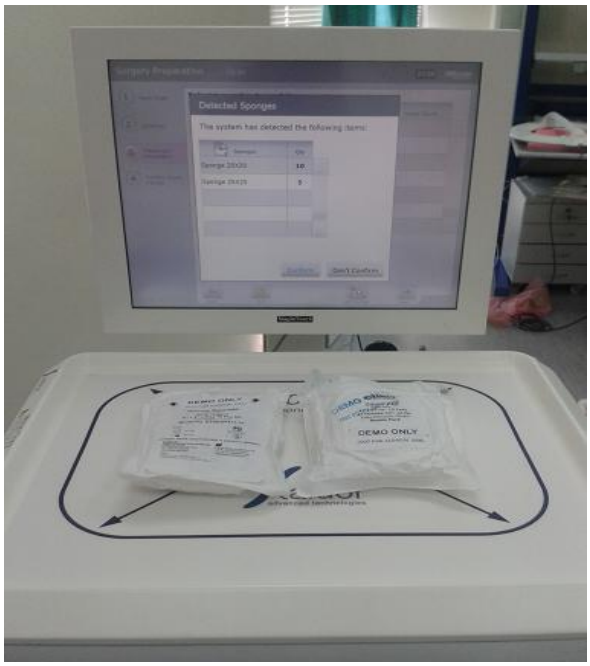


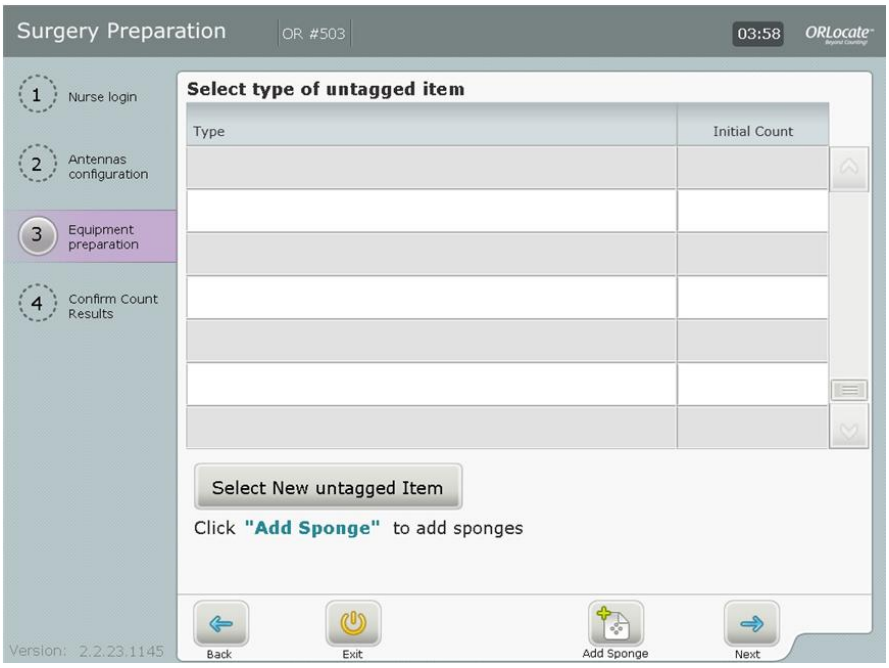
Then the nurse selects a group (needles, blades, etc.) and type (if applicable), and inserts the quantity by clicking the "#" button or using the arrows, as shown in the following figure**Error! Reference source not found.**:



Adding Sponges

For adding sponges the circulating nurse places the required clean sponges on the Flat Antenna and presses the "Add Sponge" button, as shown in the following figures:





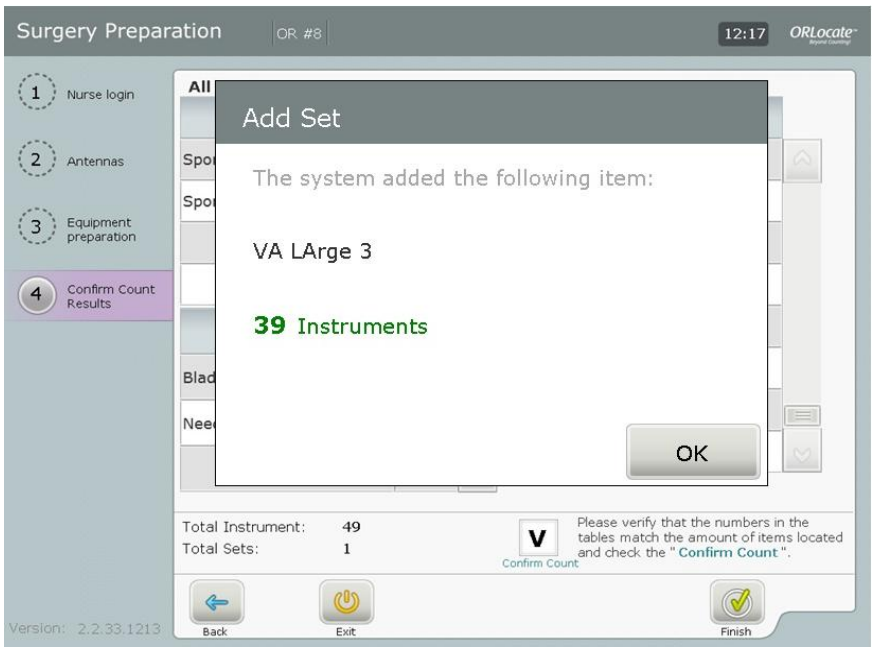
Sponges Mismatch:

If the system detects a quantity of sponges that cannot be divided by five or ten (depending on the type of sponge), the number of sponges is displayed in red. This indicates to the user that one or more sponges were not detected. In this case the user must discard the sponge packages that are on the Flat Antenna or Sponge Add, place new ones, and count again.

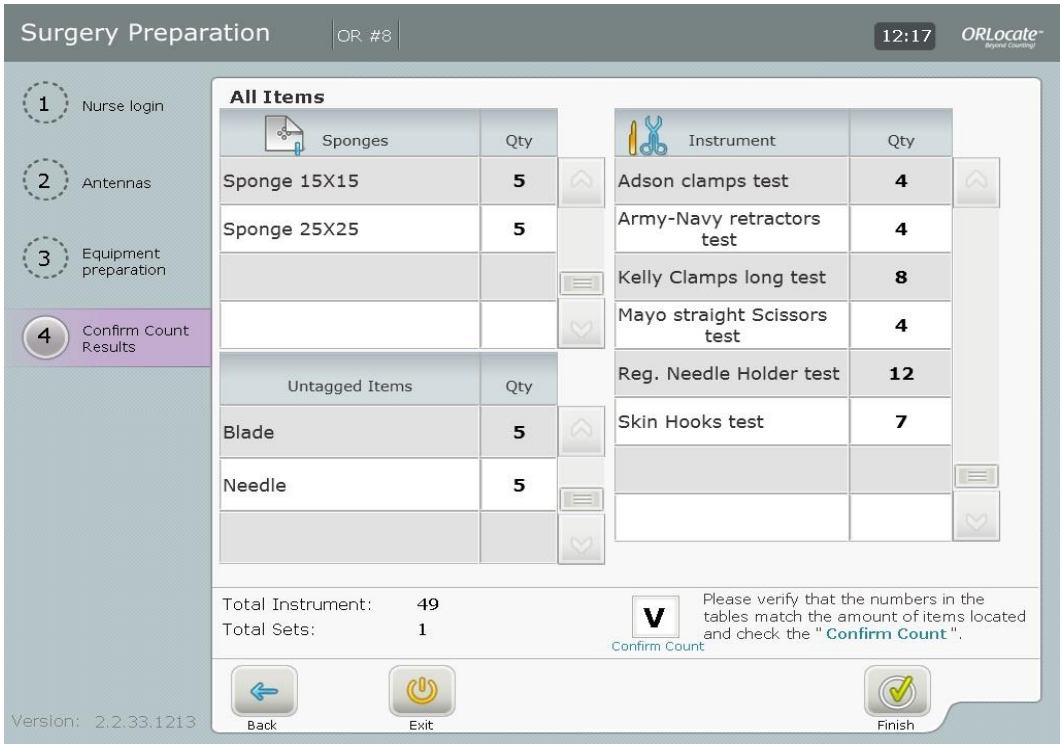
(3) Step 4 – Confirm Count Results:

<u>Adding instruments</u>

Scan the set RFID tag using the handheld reader in order to add all the instruments packed in the set, as shown in the following figure:



The nurse can see a detailed view of all added items the type and quantity of each item is specified, pressing on an item will display an image of the item. The nurse must then confirm these details, as shown in the following figure:***Error! Reference source not found.***



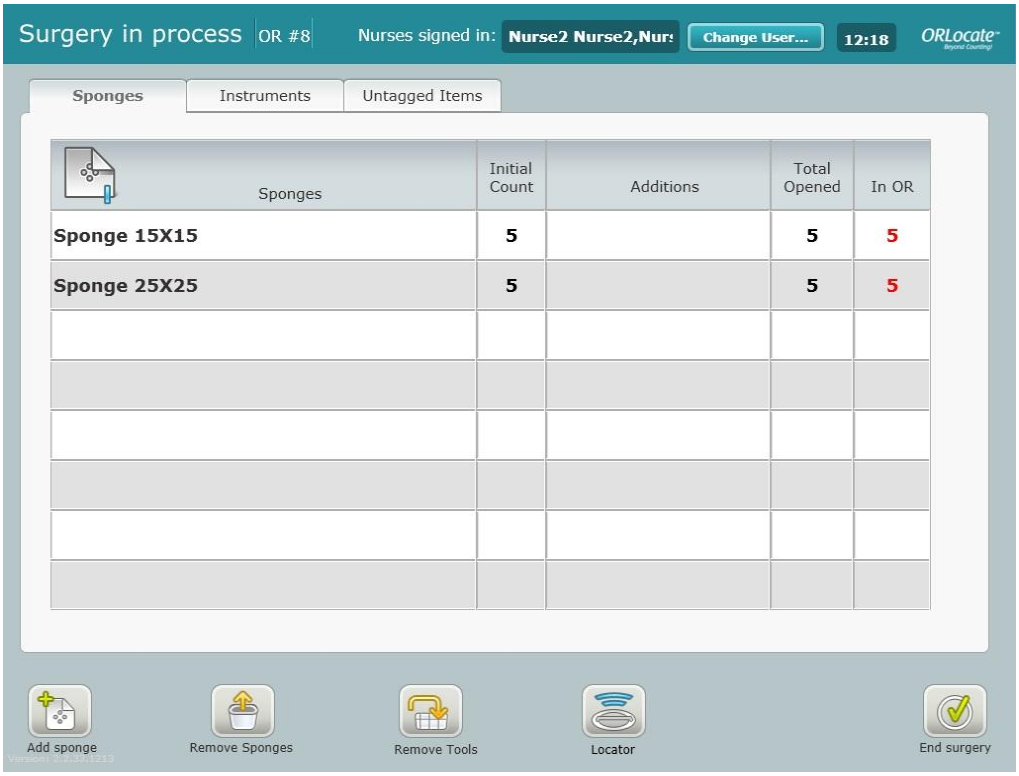
The nurse can now press the Finish button and the system will enter the Surgery in Process phase.

6.2.2 SURGERY PHASE

During the surgery, the nurse may view the count in several ways, as shown in the following figures below (pressing on an item will display an image of the item)**:**

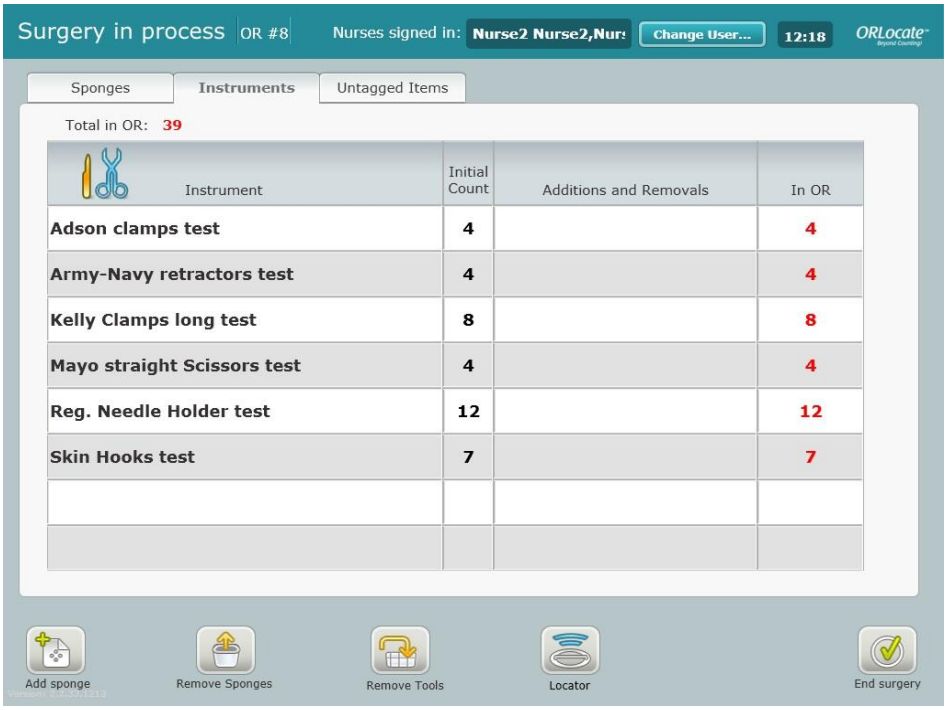
(4) Sponges view:

In this view the system displays information regarding the sponges count - Initial Count, Recent Additions, Total Opened sponge, and sponges that are currently still and the OR an were not removed yet (marked in red color), as shown in the following figure***Error! Reference source not found.***:



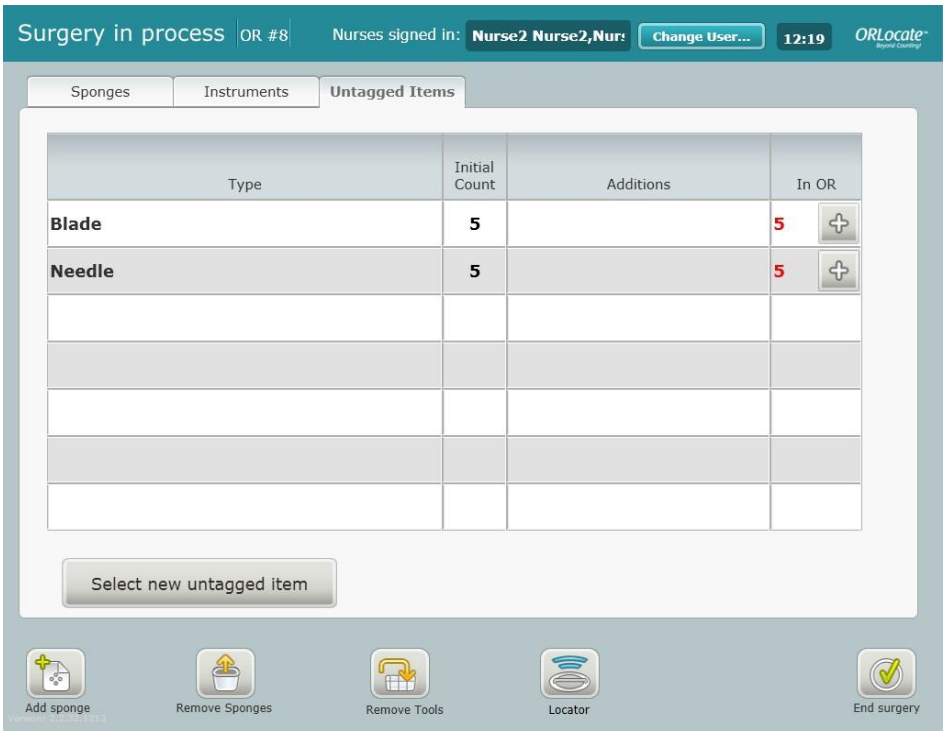
(5) Instruments view:

In this view the system displays information regarding the instruments count - initial count, additions and removals, and instruments that are currently still and the OR an were not removed yet (marked in red color). At the top of the screen the system displays the total number of instruments that are still in OR, As shown in the following figure:



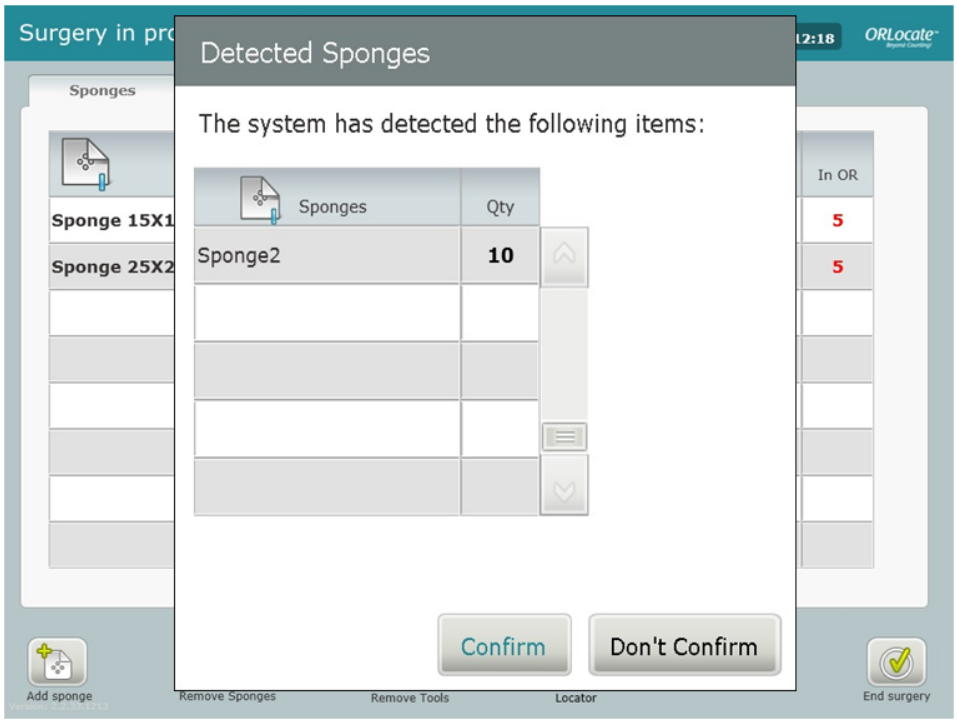
(6) Untagged Items view:

In this view the system displays information regarding the untagged items count - initial count, additions, and items that are currently still and the OR. The nurse can also register new untagged items by clicking the “Select new untagged item” button ,or add more unites to the untagged items types that are already registered by clicking the “+” button. The system also allows the nurse to register his / her count and get information on the items not located, as shown in the following figure***Error! Reference source not found.***:



In all views the nurse can perform the following functions using the buttons on the screens:

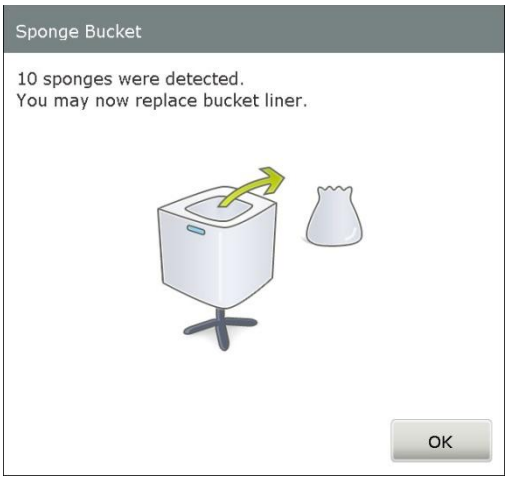
(7) Add sponges – When the nurse wishes to add new sponges to the inventory, the nurse should place a sponge package (closed package) on the Flat Antenna and click the "Add Sponges" button. The system will display the number of sponges that are detected in the package for user confirmation. If the system detects a number that cannot be divided by five or ten, it will notify the user and the user should discard the whole package. Only sponge packages that are confirmed are registered in the system, as shown in the following figure:



See also figure (11) - Display sponges' inventory.

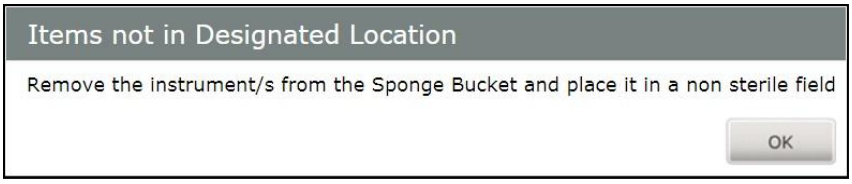
(8) Remove sponges – When the "Remove sponges" button is clicked, the system generates a count of the Sponges in the Bucket and display the quantity of the soiled sponges.

After counting, the nurse should replace the bucket liner, as shown in the following figure:

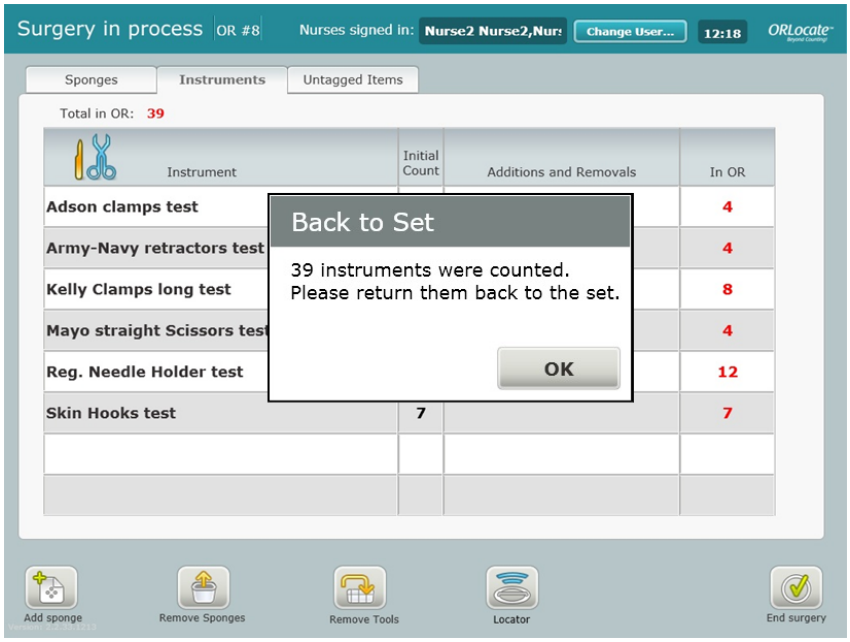


The user must not remove or add sponges to the Sponge Bucket while a count is being performed for the Empty bucket operation, as noted in the pop up during the count.

Unintended placement of instrument in Sponge Bucket – In case that instrument is identified by the system in the Sponge Bucket, the following message will appear, as shown in the following figure:



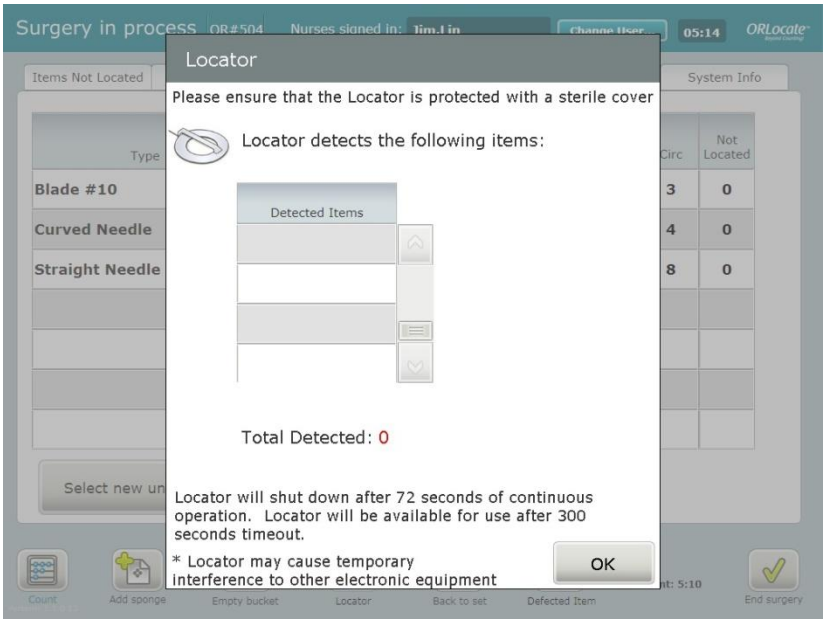
(9) Remove tools - The circulating nurse may scan instrument back into set, removing it from the inventory, by placing the instruments on the Flat Antenna and clicking on the "Remove Tool" button. A “Back to set” pop up will open displaying the quantity of instruments removed, as shown in the following figures:



Note: The user must not add, remove or move instruments while the Count is being performed.

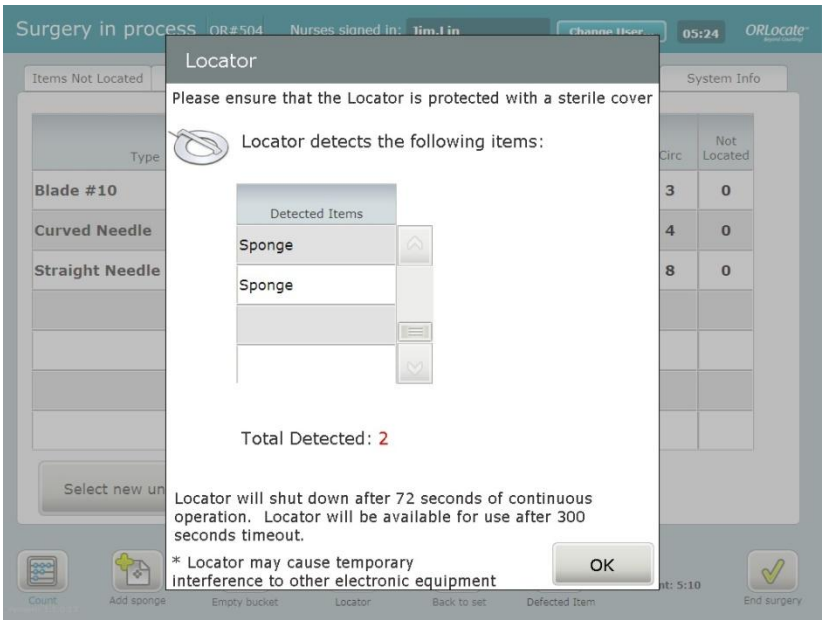
If one of the instruments removed was not previously added to the system. The instrument will now be removed; all the instruments packed in the same set will now be added to the inventory, a pop up will be displayed.

(10) Locator search – During surgery the nurse can activate the Locator in order to locate an item in the surgical site, as shown in the following figure:



Use the Locator as specified in paragraph 3.4 – Locator Antenna.

When the Locator detects an item, it will be displayed on the screen, as shown in the following figure:



To end the Locator search the nurse should press the “OK” button and the Locator will be deactivated.

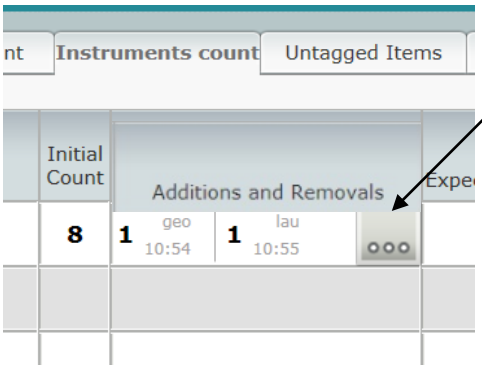
(11) Add Instrument using the handheld reader:

The circulating nurse may add a new set to the inventory by scanning the set/instrument (packed in the set) using the handheld reader. The system will display the all the instruments packed in the set (tagged and untagged) for user confirmation.

Display of added and removed items:

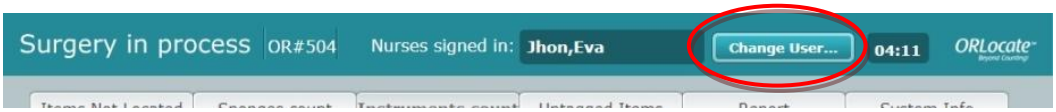
When nurse adds new items, these additional items will be displayed as Items In OR.

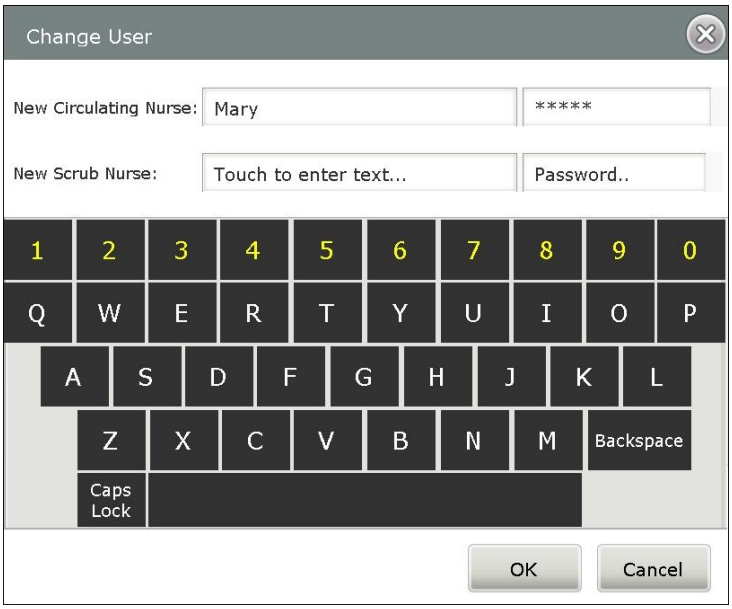
Each addition or removal of item will be recorded and displayed with the time it was added or removed (with "-" mark) and name of the nurse who was logged-in at that time, as shown in the following figure:



If more than 3 additions occur, this button appears. Upon clicking this button the nurse will get a full list of additions during surgery.

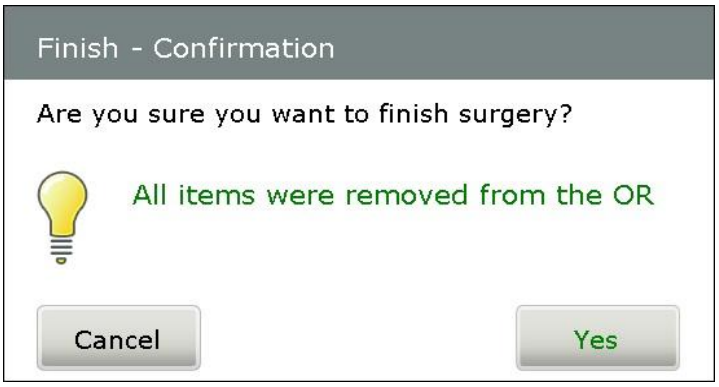
(12) Change user – if a nurse is being replaced (due to shift change or breaks) the circulating nurse should clicking the "Change user" button (top of main view) and enter his/her name and password in the open pop up as shown in the following figure, either manually or by scanning the user card with the handheld device or with Tool Add antenna.





(13) End Surgery – When this button is clicked, the system will display a pop up as shown in the following figure, indicating whether there are still item in OR and ask for confirmation to finish surgery. After

confirmation the system will enter the "End Surgery" phase - as specified in paragraph 6.2.3 - End Surgery phase.

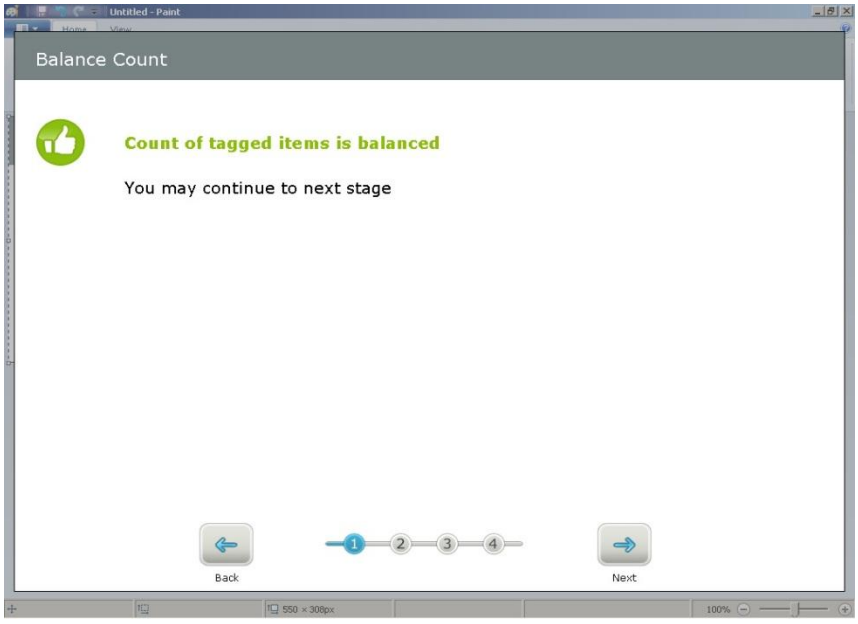


If the count is not balanced the team must find the items, first visually and if not found, by using the Locator to search the surgical cavity for retained RFID tagged items, as specified in paragraph 3.4 - Locator Antenna, before ending the surgery.

6.2.3 END SURGERY PHASE

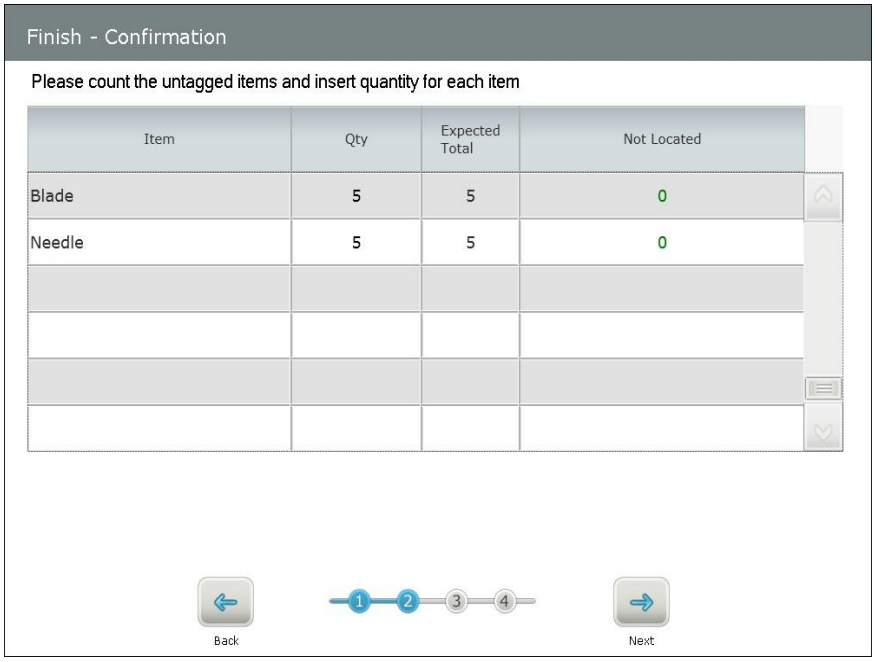
At the end of surgery the Circulating Nurse clicks on the “End Surgery” button the system enters the End Surgery phase.

If the count of all the tagged items (Instruments and Sponges) is balanced the system will inform that the count is balanced, as shown in the following figure:

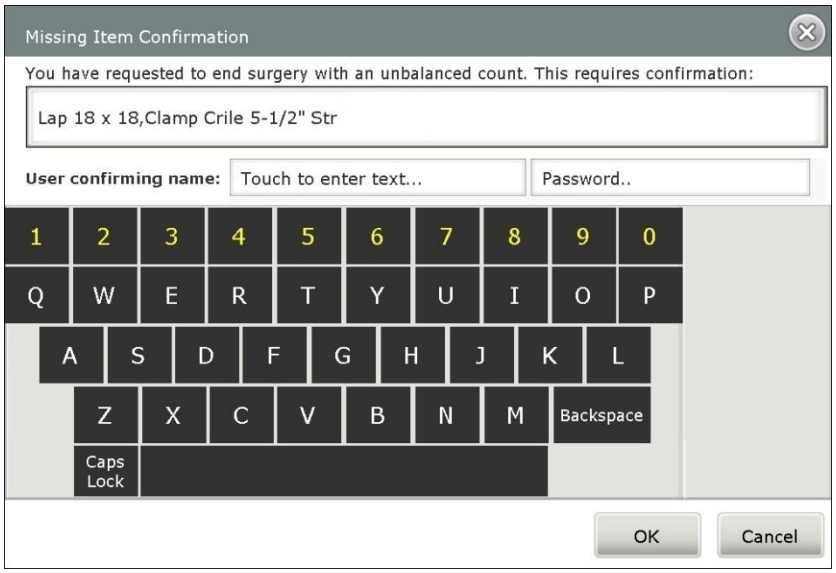


If the count in not balanced the system will ask the nurse to go back to the Surgery in Process module or to approve the unbalanced count.

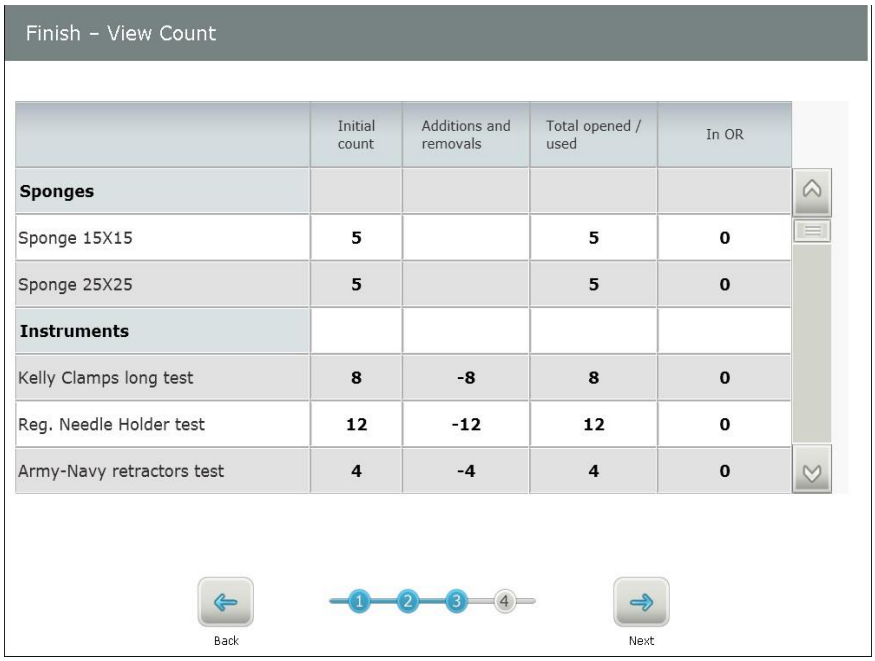
After clicking the “Next” button, the system will request the nurses to count all untagged items, as shown in the following figure:



The system will indicate whether the count entered matches the registered untagged item count by displaying any mismatch in red color. The system will require a confirmation by an authorized user to end the surgery without balanced count, as shown in the following figure:



The system displays a full count report, as shown in the following figure, and the surgery may be closed by pressing the "Next" button:



7. THE ORLOCATE^{R} ORLITE FUNCTIONALITY

7.1 INFORMATION THAT IS AVAILABLE IN THE SYSTEM

The user interface displays the following information:

- Items In OR - Number and type of items that were registered but were not removed.
- Initial count – numbers of items opened/placed on tables before start of surgery (by item type).
- Additions – number and type of items added to sterile field during surgery, and the team member responsible for the addition.
- Expected total – total number of items and type that were included in the inventory.
- Number of sponges (Initial Count and Total Opened).
- Last time the count was performed (either automatically or upon nurse request).

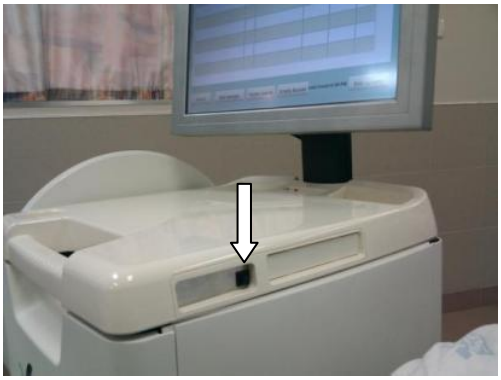
7.2 PRODUCT FUNCTIONS

- Antenna set-up check
- Add sponges during surgery
- Add untagged items during surgery
- Add instruments during surgery
- Status report
- Detection warnings
- End Surgery
- Locator search
- Change user
- Remove instruments

- Remove Untagged items
- Remove sponges

8. SHUTTING DOWN THE SYSTEM

In order to shut down the system user should press the black push-button on the right panel of the system console top panel, as shown in the following figure:



9. MAINTENANCE AND SERVICE

9.1 PERIODIC MAINTENANCE SCHEDULE

Routine maintenance should be performed on the system as follows:

Action	When is Action Performed	Action is Performed by…
Clean System (see below)	Before and after each surgery	Operating Room personnel
Visual Inspection - Check cords and cables for signs of wear (see below)	Before each surgery	Operating Room or Maintenance personnel
Visual Inspection - Check components for signs of damage (see below)	Monthly	Maintenance personnel.
Yearly system check	Once each year	Haldor authorized Technician

In case of damage, wear or any other problem, contact service.

9.2 MAINTENANCE PROCEDURE

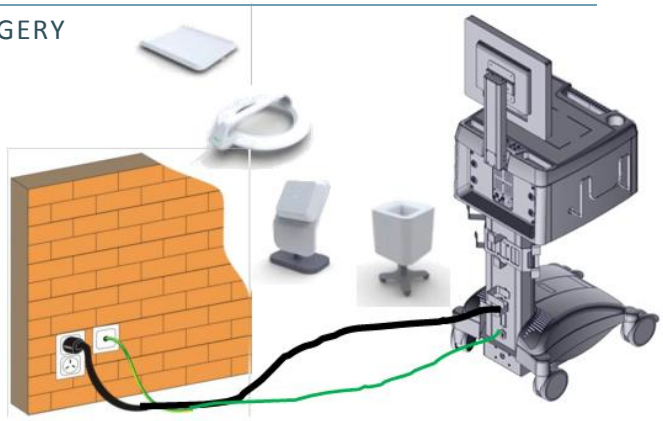
9.2.1 CLEANING – BEFORE EACH SURGERY

Caution: Power Off and Unplug the AC power cord before cleaning the system.

In order to maintain the system in optimum condition, clean the system before each surgery:
(1) Wipe down **all system components** with a damp cloth and then dry thoroughly.
(2) Wipe the entire length of all **cables and power cords** with a cloth soaked with 70% alcohol.

(3) Wipe down the **entire system** with a cloth soaked with 70% alcohol. This includes all Antennas, and the inside and outside of the Sponge Bucket.
(4) Wipe the Touch Screen panel with a damp cloth.
(5) In case of dirt that is not removed using a damp cloth, such as blood stains, use a spray cleaner for LCD panels or a cloth soaked with 70% alcohol.

9.2.2 VISUAL INSPECTION – BEFORE EACH SURGERY



Check the following cables and cords for signs of wear:

(1) Antenna cables:
- Sponge Bucket
- Tool Add
- Locator

(2) Power Cables:
- Power Line cable
- Protective GND cable

9.2.3 VISUAL INSPECTION – MONTHLY CHECK

Check the following system components for signs of damage:

(1) System ORLocate^{R} Console:
- LCD Touchscreen
- Top Tray Plastics.
- Wheels are not jammed.

(2) Antennas:
- Verify that antennas are not damaged, cracks.

9.3 OBTAINING SERVICE:

Contact the Haldor ORLocate^{R} representative:

USA Support	**ROW (Rest Of the World) Support**
Haldor USA Inc. **E-mail:** support@haldor-tech.com	Advanced Technologies Ltd. **Tel:** +972 9 7885858 **Fax:** +972 9 7885861 **Address:** 2 Habanai Street Hod Hasharon 45319, Israel **E-mail:** support@haldor-tech.com

9.4 STORAGE

Between operations the system may be stored in the OR room, or, if needed by the user, in a dedicated dry and reasonably clean storage area, as specified below.

The system should be cleaned as described in paragraph 9.2.1 – Cleaning, prior to storing in storage area.

While system is stored, it should be plugged to the AC power and LAN, and its components shall be placed on appropriate surfaces in such a manner that prevents mechanical or other damages to its components, including cables and screen.

9.5 SYSTEM OR COMPONENTS END-OF-LIFE:

Note: Do not discard. At end of life or end of use of the system or one of its components, please inform your Haldor representative, for disposal arrangement.

10. TROUBLE SHOOTING

The following chart lists some typical conditions or problems that may occur with the Haldor ORLocate^{R} ORLite System.

Condition	Possible Cause	Recommended Action
System Will Not Turn On	Power cord is not plugged into the System or wall outlet.	Ensure that both ends of the power cord are plugged in.
	Power cord is damaged.	Contact service for replacement cord.
	Power is not available at power outlet.	Check that the power source is working properly.
	Main Power Switch is at On position and Top Tray LED is lit.	Press 10 Sec at On/Off Push button wait 2 Sec and press again shortly at the On/Off push button.
	ORLocate^{R} System failure.	Contact service.
Sponge or Instrument registered into System, but Subsequent Counts No Longer Indicate Item as Present	Antennas have been affected by surrounding electro-surgical equipment.	Remove electro-surgical equipment from the vicinity of the system, or wait until ES equipment is no longer in use.
	Item's tag is not located properly on top of the antenna.	Locate item close to its designated antenna.
	RFID tag is faulty.	Remove the item that is faulty and contact Haldor Advanced Technologies Ltd. for a replacement.
Antenna Housing is Cracked or Broken	Antenna has been dropped or misused.	Contact service for an antenna replacement.
System does not update any data received, leading to wrong instrument and sponge counts	Hard disk is full.	Stop using the system until the problem is corrected.
	RAM memory is full.	Stop using the system until the problem is corrected.

Condition	Possible Cause	Recommended Action
Screen freezes – system crash loses all data	Faulty computer CPU.	Stop using the system until the problem is corrected.
	Faulty power supply.	Stop using the system until the problem is corrected.
	Faulty/crashed Windows operating system.	Stop using the system until the problem is corrected.
No indication if Tag is read and is correct, leading to Instrument not monitored and a wrong instrument count	Faulty beeper mechanism on Tool Add or Locator.	Stop using the system until the problem is corrected.
	Faulty LEDs on Tool Add or Locator.	Stop using the system until the problem is corrected.
Antenna is not functional	Faulty digital input/output mechanism Module (internal component of System ORLocate^{R} Console).	Stop using the system until the problem is corrected.
	Faulty RF Multiplexor unit Module (internal component of System ORLocate^{R} Console).	Stop using the system until the problem is corrected.
	Faulty RF Module (internal component of System ORLocate^{R} Console).	Stop using the system until the problem is corrected.
	Faulty RF Multiplexor Module (internal component of System ORLocate^{R} Console).	Stop using the system until the problem is corrected.
System not functional -- counting is discontinued, and current count is lost	Power supply failure. DC Converter is not working properly.	Stop using the system until the problem is corrected. Stop using the system until the problem is corrected.
Display on screen is faulty or incorrect position, causing errors in Touchscreen use	Touchscreen is cracked.	Stop using the system until the problem is corrected.
	Touchscreen is not calibrated.	Stop using the system until the problem is corrected.
	Touchscreen is dirty.	Clean the screen.
Touchscreen detects touch in wrong position	Touchscreen is not calibrated.	Stop using the system until the problem is corrected.
Instrument not detected, leading to a wrong instrument count	Not receiving any electrical signals because connector to Flat Antenna or Tool Add or Locator is faulty.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because cable to Flat Antenna or Tool Add or Locator is damaged.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because antenna of Flat Antenna or Tool Add or Locator is not tuned.	Stop using the system until the problem is corrected.

Condition	Possible Cause	Recommended Action
	RFID tag is disconnected from the instrument.	Stop using the instrument if the RFID tag is disconnected.
	RFID tag damaged during production, transportation or storage.	Stop using the item and contact Haldor Advanced Technologies Ltd. for a replacement.
	Sterilization process damaged the RFID tag and it is not functional.	Register all instruments prior to use, and take appropriate action for a bad instrument.
	Temperature or humidity in the operating room is too high or low, causing the RFID tag to not function.	Observe the temperature and humidity ranges for operating the system.
	Instrument placed in Sponge Bucket and discarded in external bio-hazardous bags.	Extract the instrument and set it aside until the final count.
	Instrument is added without prior registration.	Each instrument must be scanned under the Tool Add before being placed into the sterile field.
Sponge not monitored, leading to a wrong sponge count	Not receiving any electrical signals because connector to Sponge Bucket or Sponge Add is disconnected or faulty.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because cable of Sponge Bucket or Sponge Add is damaged.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because antenna of Sponge Bucket or Sponge Add is damaged.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because antenna of Sponge Bucket or Sponge Add is not tuned.	Stop using the system until the problem is corrected.
	The RFID tag damaged during production, transportation or storage.	Register sponges prior to use, and take appropriate action for a bad sponge.
	The RFID tag is disconnected from the sponge when the sponge is first opened.	Do not use the sponge.
	Sterilization process damaged the RFID tag and it is not functional.	Register all sponges prior to use, and take appropriate action for a bad sponge.
	Temperature or humidity in the operating room is too high or low, interfere the RFID function.	Observe the temperature and humidity ranges for operating the system.

Condition	Possible Cause	Recommended Action
	Sponge discarded straight into external bio-hazardous bags, bypassing the Sponge Bucket	Discard used sponges into Sponge Bucket, and from the Sponge Bucket to the external bio-hazardous bags.
	Sponge is added without prior registration.	Scan each sponge package under the Sponge Add
Sponge becomes non-sterile, leading to patient contamination	Sterile sponge placed on Sponge Add.	Place sponges on the Sponge Add only while in original package.
Locator is not sterile	Locator was dropped to the floor while enclosed in sterile cover.	Replace sterile cover
Locator is not sterile and may be contaminated with blood	Locator was dropped to the floor while not enclosed in sterile cover.	Clean the Locator.
Misuse of instrument causes patient injury	Instrument tag location interferes with the intended use of the instrument.	Discard the instrument until the final count.
	Instrument tag location changes instrument balance, causing incorrect use of the instrument.	Discard the instrument until the final count.
Misuse of sponge causes patient injury	Sponge tag location changes sponge balance causing incorrect use of the instrument.	Discard the sponge.
RFID tag is in the operational site	RFID tag disconnects from the instrument or sponge during use.	Item will be missing in final count. Refer to paragraph 3.4 for instructions on how to perform a Locator Search to locate the missing RFID tag.
Instrument or sponge is in the operational site and cannot be located or cannot be removed	RFID tag disconnects from the item during use.	Find the item according to existing protocols.
Instrument becomes non-sterile, leading to patient contamination	Instrument is placed on Sponge Add antenna	Set aside the instrument until the final count.
Instrument or sponge not found and may lead to incorrect count	RFID tag inside patient is blocked by metallic objects in the patient, is out of range, or is interfered with by another tag, and is not detected	Change the position and angle of the Locator, in order to get more complete coverage. If item remains missing, search for item according to hospital procedures.
Sponge package fails to register	Defective RFID tag	Discard the package of sponges
Sponges not registered and therefore are not monitored, leading to a wrong sponge count	Sponges are still in their non-sterile packaging and their tags interfere with each other	Discard the package of sponges
Wrong sponge registration, leading to an incorrect sponge count	Sponge package not full	Discard the package of sponges when the number of sponges is less than a full package

Condition	Possible Cause	Recommended Action
Bio-contamination leading to patient infection	Sponge package opened before registration	Discard the package of sponges
	Sterile covering is removed from Flat Antenna during procedure	Do not remove the sterile covering on the antenna during the procedure.
	Sterile covering is removed from Locator during procedure	Do not remove the sterile covering on the antenna during the procedure.
	ORLocate^{R} Console/Sponge Add biocontaminated	Clean the ORLocate^{R} Console after every use.
	Tools not cleaned and sterilized well enough	Clean the tools after every use.
	Sponges not sterile due to compromised packaging	Do not use products with open or damaged packaging.

11. OPERATING SPECIFICATIONS

Note: Unless otherwise indicated, all specifications are subject to change without notice. Specifications and test methods will be made available upon request.

11.1 OPERATING, STORAGE AND TRANSPORTATION ENVIRONMENT

	Operating Environment	Storage and Transportation Environment
Temperature:	10°C to 40°C (50° F to 104° F)	-40°C to 70°C (-40°F to 158°F)
Relative Humidity:	30% to 75%	10% to 100%
Pressure:	700 hPa to 1060 hPa	500 hPa to 1060 hPa

11.2 ELECTRICAL POWER

Consumption (max): Up to 120 Watt

Input Voltage Range: 100 to 240 VAC at 50 to 60 Hz

12. SYSTEM SPECIFICATIONS

In addition to the specified in paragraph 3 - Introduction to the Haldor ORLocateR ORLite System - Description of System Components, for each Component, the following specification shall be applied:

Note: The System and its components can hold a maximum quantity of RFID- tagged items (instruments and sponges).
Do not exceed the quantities detailed in the table below:

	 **Flat Antenna**	 **Sponge Bucket**	 **Tool Add**	 **Sponge Add**	 **Locator**
Max. quantity of items	70 instruments	70 sponges	7 instrument	10 Sponges (1 package)	4 items (instruments and sponges)
Max detection distance / limitation	Up to 5 cm (2”). No stacked items on top of the other. Tags horizontal	Items should be inside bucket	Up to 5 cm (2”)	Up to 6 cm (2.5”). Inside the lines	up to 38 cm (15”) for tagged sponges and up to 28 cm (11”) for tagged instrument
Weight (Kg)	10	36	5 (2 w/o the base)	NA	2.3
Dimensions (cm / inches)	60.5x47x6.5 cm	55x55x88 cm	22x13x33 cm	NA	57x51x9.5 cm
	24x18.5x2.5 inches	22x22x35 inches	9x5x13 inches	NA	22.5x20x4 inches

- System ORLocate^{R} Console dimensions: 50x58x130cm (20x23x51”), weight: 63 Kg.
- Maximum quantity of sponges that can be detected in one cycle of count: 120 sponges.
- Maximum quantity of instruments that can be detected in one cycle of count: 75.

13. FCC ID CROSS REFERENCE TABLE

ORLocate^{R} OR-Lite System	 **Flat Antenna**	 **Sponge Bucket**	 **Tool Add**	 **Locator**
Channel Setting	Single Channel	Single Channel	Single Channel	Single Channel
Max. Output Power	4W	4W	2W	4W
Power Supply	RPS-60-24 (Meanwell)	RPS-60-24 (Meanwell)	RPS-60-24 (Meanwell)	RPS-60-24 (Meanwell)
FCC ID	X4V-ORL-L40	X4V-ORL-L40	X4V-ORL-L40	X4V-ORL-L40

14. EMC CONSIDERATIONS

The ORLocate[R] 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 Locator RF equipment can affect the ORLocate[R] System. Compatibility of cables, transducers, and other accessories: Not applicable

Table 1 - According to Table 204 from IEC 60601-1-2
Guidance and Manufacturer's Declaration – Emissions

Equipment and Systems that is NOT Life-supporting

The ORLocate[R] System is intended for use in the electromagnetic environment specified below. The customer or user of the ORLocate[R] System 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 Locator communications equipment should be separated from the ORLocate[R] System by no less than the distances calculated/listed below: D = (3.5/3)(√P)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	D = (3.5/3)(√P) - 80 to 800 MHz D = (7/3)(√P) - 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. 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 ORLocate[R] System is used exceeds the applicable RF compliance level above, the ORLocate[R] System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ORLocate[R] System.

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 2 - According to Table 206 from IEC 60601-1-2
Recommended Separation Distances between portable and
Mobile RF Communications equipment and the ORLocate^{R} System

Equipment and Systems that is NOT Life-supporting

The ORLocate^{R} system is intended for use in the electromagnetic environment in which radiated disturbances are controlled. The customer or user of the ORLocate^{R} System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications Equipment and the ORLocate^{R} System 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)(√P)	Separation (m) 80 to 800MHz D = (3.5/3)(√P)	Separation (m) 800MHz to 2.5GHz D = (7/3)(√P)
0.01	0.1166	0.1166	0.2333
0.1	0.3689	0.3689	0.7378
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 ORLocate^{R} System contains a receiver operating at a frequency of 13.56 MHz +/- 7 kHz.

The ORLocate^{R} System may be affected 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 ORLocate^{R} 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 130.7 mW.