ORLocate™

RFID-BASED SYSTEM TO COUNT, DETECT, AND RECORD
SURGICAL INSTRUMENTS AND SPONGES

USER MANUAL

REVISION 1

Haldor
advanced technologies ltd.

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1. INTRODUCTION

1.1. THE HALDOR ORLOCATE™ SYSTEM

Haldor ORLocate™ system is an RFID system providing a solution that enables the enumeration of RFID tagged sponges and surgical instruments for keeping track of the items during surgery, utilizing passive RFID tags (battery-less transponder which does 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 supplies also a semi-automatic application to help in counting untagged items, the count information is first entered manually and the calculations are automatic.

1.2. ABOUT THIS MANUAL

This manual provides the information necessary to operate the Haldor ORLocate™ system in a safe and efficient manner. **Please read and understand 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 other 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 seven antennas in the ORLocate™ system.

AUTOMATIC COUNT:

The count that is performed automatically by the system once every five minutes.

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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:

Sponges, gauzes or pads that are sterile and ready for use.

COUNT UPON REQUEST:

The count that is performed after the user clicks the "Count" button during surgery.

ITEMS NOT LOCATED:

The difference between the number of items that were registered and the number of items that are detected. For example, if ten items are registered, but only seven items are detected, then ITEMS NOT LOCATED is equal to three.

This is also referred to as MISSING ITEMS and ITEMS IN USE.

INITIAL COUNT:

The number of items that are counted before the start of surgery, at the end of preparation. 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.

INSTRUMENT TROLLEY (BACK TABLE):

A table containing sterile instruments used during surgery. This table is located in the sterile area.

MISSING ITEMS:

The difference between the number of items that were registered and the number of items that are detected. For example, if ten items are registered, but only seven items are detected, then MISSING ITEMS is equal to three.

This is also referred to as ITEMS NOT LOCATED and ITEMS IN USE.

MAYO:

A table containing sterile instruments that are in immediate use during surgery. The Mayo is located in the sterile area, near the patient.

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™, do not contain a battery.

RFID TAG:

The small, self-powered, self-enclosed device that contains an RFID and is placed inside a surgical sponge or attached to a surgical instrument. Each RFID tag holds a unique identification that separates it from other tags.

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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 and understanding this manual.

Plug the System Cart into a properly installed power outlet of the appropriate voltage.

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

If the AC power is interrupted, the system will automatically use battery power. If the battery power is then exhausted, the system will shut down.

Caution: If the battery power is exhausted, do not use the system until normal AC power is available.

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.

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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.
	For the ORLocate system to operate use only Haldor's RFID tagged sponges and instruments.
	Do not use the system in the presence of flammable anesthetic mixture with air, or with oxygen or nitrus oxide.
	Keep the ORLocate system cart out of the sterile field.
	Place only Haldor's RFID tagged sponges in the Sponge Bucket and in the Sponge Container.
	Sponges are for single-use only. Do not reuse sponges.
	If the RFID tag is disconnected from a sponge or instrument, do not use the item.
	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, and with patients who have an implanted metal plate in the area of the operation.
	The Sponge Bucket should be used only for the disposal of sponges from the current surgery.
	To avoid contaminating the sterile field, always use a sterile cover with all antennas except the Cart Antenna.
	Do not remove sterile covers from the antennas during the procedure.
	To avoid contaminating the sterile field, always use a sterile cover with the Mobile Antenna, the Mounted Antenna, the Sponge Container, and the Sponge Bucket.
	Clean all instruments according to their standard protocol before use.
	Clean all antennas and the System Cart, before the procedure.
	Do not use sponges if the sponge package is open or otherwise compromised.
	Dispose RFID tags according to standard environmental regulations.

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	Do not cut or tear RFID tagged sponges.
	Do not retain RFID tagged items inside the patient for more than 24 hours.
	While using the Mobile antenna interference may appear on the Monitor display ECG graph. User must be aware to this momentarily influence on the graph.
	While using the Mobile Antenna interference may appear on the Ultrasound sound image. Do not use Mobile antenna while using this device.
	An MRI scan must not be performed on a patient who has a retained RFID-tagged item.
	When using a surgical laser, ensure that the laser is not used while an RFID tagged item is inside patient.
	Do not use the system in the presence of a flammable gas.
	While using Diathermia or Argon diathermia do not use the Mobile antenna due to possible interference with antenna detection.
	While using Diathermia or Argon diathermia cables of diathermia device should not cross less than 20 cm from the top of the ORLocate antenna surface.
	If the RFID tag separates from an instrument or sponge during use, the item will not be detected by the ORLocate™ system. Search for the item according to standard search protocols.
	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.
	If items are not detected with the Mobile Antenna, search for the items according to standard search protocols.
	It is possible that two RFID-tagged items may be placed in the patient in close proximity, in such a way that one of the instruments in not detected by the system. Search for the item according to standard search protocols.
	If one of the antennas appears not to be functioning, do not use the system.
	Lock the wheels on the System Cart before setting up the system.

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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 instructions, 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.

2.3. INDICATIONS

The ORLocate™ system is indicated for use in recording and counting the number of RFID-tagged surgical sponges, laparotomy sponges, towels 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 and other tagged items within a surgical site, as an adjunctive detection method to current surgical counting systems and methods.

2.4. CONTRAINDICATIONS

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, and with patients who have an implanted metal plate in the area of the operation.

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2.5. SYSTEM LABELS

Main Cart Label

Discard properly

Haldor Advanced Technologies, Ltd.

ORLocate™ Cart

Model No. ORL100.011 S/N CA-000-501

Haldor Advanced Technologies, Ltd.
2nd Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861, Email: support@haldor-tech.com
[Date of manufacture Mo-yr]

AC Rating information:
100-240VAC ; 50-60 Hz ; 300 VA

FCC ID: X4V-ORLOCATE
This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:
1. This device may not cause harmful interference and
2. This device must accept any interference received, including interference that may cause undesired operation.

Rx Only Caution: US Federal Law restricts this device to sale by or on the order of a physician

Read instructions prior to use

Instrument Trolley antenna Label

Haldor Advanced Technologies, Ltd.

ORLocate™ Instrument Trolley antenna

Model No. ORL100.012 S/N BT-000-501

Haldor Advanced Technologies, Ltd.
2nd Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com
[Date of manufacture Mo-yr]

Consult accompanying documents.

Not user-serviceable. Service by trained personnel only.

Note Sterile cover required before use.

Mayo antenna Label

Haldor Advanced Technologies, Ltd.

ORLocate™ Mayo antenna

Model No. ORL100.013 S/N MA-000-501

Haldor Advanced Technologies, Ltd.
2nd Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com
[Date of manufacture Mo-yr]

Consult accompanying documents.

Not user-serviceable. Service by trained personnel only.

Note Sterile cover required before use.

Sponge Bucket Label

Haldor Advanced Technologies, Ltd.

ORLocate™ Sponge Bucket

Model No. ORL100.014 S/N SB-000-501

Haldor Advanced Technologies, Ltd.
2nd Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com
[Date of manufacture Mo-yr]

Consult accompanying documents.

Always line the Sponge Bucket with biohazard bag

Not user-serviceable. Service by trained personnel only.

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Mobile Antenna

Haldor Advanced Technologies, Ltd.

ORLocate™ Mobile Antenna

Model No. ORL100.015 S/N MO-000-501

Haldor Advanced Technologies, Ltd.
2nd Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com
[Date of manufacture Mo-yr]

Consult accompanying documents.

Not user-serviceable. Service by trained personnel only.

Note Sterile cover required before use

Mounted Antenna

Haldor Advanced Technologies, Ltd.

ORLocate™ Mounted Antenna

Model No. ORL100.016 S/N MT-000-501

Haldor Advanced Technologies, Ltd.
2nd Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com
[Date of manufacture Mo-yr]

Consult accompanying documents.

Not user-serviceable. Service by trained personnel only.

Note Sterile cover required before use

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Sponge Container Label

Haldor Advanced Technologies, Ltd.

ORLocate™ Sponge Container

Model No. ORL100.017 S/N SC-000-501

Haldor Advanced Technologies, Ltd.
2nd Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com
[Date of manufacture Mo-yr]

Consult accompanying documents.

Not user-serviceable. Service by trained personnel only.

Note Sterile cover required before use

3. INTRODUCTION TO THE HALDOR ORLOCATE™ SYSTEM

3.1. DESCRIPTION OF SYSTEM COMPONENTS

SYSTEM CART

The System Cart contains the computer and touch screen monitor that the circulating nurse uses to control the system. It also houses the Cart Antenna.

The System Cart is placed outside of the sterile field.

CART ANTENNA

The Cart Antenna is located in the upper panel of the System Cart. 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 Container Antenna.

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

Note: sponges should be placed on top of the cart antenna in the marked area, as can be seen in the figure:

SPONGE CONTAINER

The Sponge Container is located near the Instrument Trolley (Back Table) on a **separate trolley**, near the scrub nurse. It is used to count and hold sterile sponges that are ready for use.

The Sponge Container is covered with a fresh sterile cover before each procedure.

Warning: Do not place the Sponge Container on top of the Instrument Trolley Antenna or Mayo Antenna.

Note: sponges should be placed in the sponge container bellow the blue line:

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.

The Sponge Bucket should be covered with a fresh cover before each procedure.

Note: When a sponge is deposited into the Sponge Bucket, the system records the sponge as Soiled and registers its location as the Sponge Bucket. This change in status is permanent. Later, when the sponge is physically moved from the Sponge Bucket, for the purpose of replacing the bucket liner, the sponge is still considered to be in the Sponge Bucket.
The sponge is *not* included in the count for the maximum number of sponges that can be in the Sponge Bucket (see next Note).

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Note: The Sponge Bucket can hold a maximum of 30 sponges. When the number of sponges actually in the Sponge Bucket reaches 20, the system displays a reminder message to empty the Sponge Bucket. If the number of sponges in the Sponge Bucket reaches 25, a second message displays.

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

INSTRUMENT TROLLEY ANTENNA

The Instrument Trolley Antenna is located on the instrument trolley (Back Table). It is used for counting instruments on the trolley.

MAYO ANTENNA

The Mayo Antenna is located on the mayo stand. It is used for counting instruments on the mayo.

Note: Although sponges are detected and counted if they are placed on the Mayo or the Trolley, these tables are not the preferred location for counting sponges.
This is because a tall pile of sponges may not be detected properly by the Mayo and Trolley Antenna. In order to ensure an accurate count, the nurse is required to place clean sponges in the Sponge Container and soiled sponges in the Sponge Bucket.

MOBILE ANTENNA

The Mobile Antenna is used to search for sponges or surgical instruments that may be in the OR.

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

Note: When not in use, the Mobile Antenna is placed on a hook on the System Cart, as shown below:

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Warning: The Mobile Antenna and cable must be covered with a fresh sterile cover before starting a search.

MOUNTED ANTENNA

The Mounted Antenna is used to detect surgical instruments that are added during surgery. To be scanned in the Mounted Antenna the nurse holds the instrument near the antenna, close to the side where the LED is located (see figure). There are three types of feedback:

1) LED is on, **2) Beep**, indicating that the instrument is detected by the Mounted Antenna.
3) A **pop up message** on the touch screen, specifying which instrument was detected.

Note: The Scrub nurse should move the instrument close to the Mounted Antenna and keep it steady for two seconds in front of the antenna.

Note: Instruments should be scanned one at a time with the Mounted Antenna.
steady for two seconds in front of the antenna.

Note: Instrument **tag** should be located near the marked area as shown in the figure bellow.

Warning: The Mounted Antenna must be covered with a fresh sterile cover before each procedure.

Warning: If no beep is heard and the LED is not lit, the instrument must be returned to the tray and should not be used during surgery.

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.

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4. STERILE CONSIDERATIONS

The following sterile procedures are required in order to use ORLocate™ in a safe manner.

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

4.1. MOUNTED ANTENNA, MOBILE ANTENNA AND SPONGE CONTAINER

These components must be covered with a sterile cover.

Place sponges in the Sponge Container after removing them from their original package.

Warning: If the Mobile Antenna is dropped to the floor **with** the sterile sleeve intact, place a new sterile sleeve on the antenna.

Warning: If the Mobile Antenna is dropped to the floor **without** the sterile sleeve, clean the Mobile Antenna with approved cleaning materials. Then place a new sterile sleeve on the antenna.

4.2. SPONGE BUCKET

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

4.3. MAYO TABLE AND MAYO ANTENNA

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

4.4. TROLLEY TABLE AND TROLLEY ANTENNA

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

4.5. SYSTEM CART

The system cart is not sterile. It should be maintained in a clean condition.

Place sponges on the Cart antenna while in their original package.

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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 corrected.

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

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

4.6. CLEANING SURGICAL INSTRUMENTS THAT HAVE RFID TAGS

Unless specially noted, surgical instruments and tools with RFID tags may be sterilized according to the standard protocol.

Table 1: Recommended dimensions for sterile covers

Image	Element	Size recommended
	Sponge Bucket	100X120 cm
	Sponge Container	Radius 65 cm
	Mobile Antenna	Radius 65 cm
	Mounted Antenna	Radius 36 cm
	Cable from Cart to Antenna	15X250 cm

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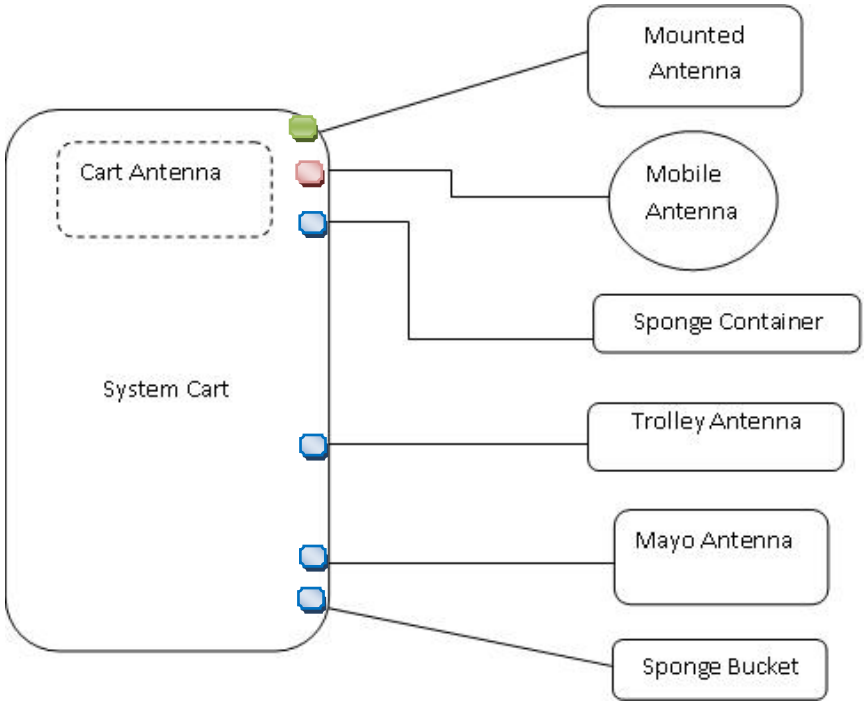
5. SETTING ORLOCATE™ COMPONENTS

5.1. SYSTEM DIAGRAM

The System Cart is the central connection point for the system. The following diagram illustrates the system connections.



5.2. SETTING THE ORLOCATE™ COMPONENTS

This section describes the setup procedures required, prior to using the ORLocate™ System.

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

5.2.1.SETTING THE MAYO, SPONGE CONTAINER AND INSTRUMENT TROLLEY ANTENNAS TO THEIR SUPPORTING TROLLEY

The Mayo Antenna, Sponge Container Antenna and Instrument Trolley Antenna must be secured to a regular supporting trolley. This is done via an elastic connecting cable, as follows:

1) Place the antenna on the top shelf of the regular supporting table.

2) Thread the plastic cover of the cable on both ends.

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3) Tie the two ends of the cable, forming a closed loop, and cover the tie with the plastic cover (if needed, cut the surpluses edges).

4) Grasp the first hook that attached to the lower side of the antenna, with the loop.

5) Firmly pull the cable under the supporting top shelf and grasp the second end of the loop with the second first hook that attached to the lower side of the antenna.

6) Repeat the process with a second cable to attach the second end of the antenna.

5.2.2.SETTING THE MOUNTED ANTENNA

The Mounted Antenna should be located on top of a trolley where the instrument sets (trays) are located, and close to where the scrub nurse is located during surgery.

5.2.3.SETTING THE MOBILE ANTENNA

Note: The Mobile Antenna can be located during surgery in the designated location on the System Cart.

5.2.4.SETTING THE SPONGE BUCKET

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

5.2.5.SETTING THE SPONGE CONTAINER

The Sponge Container should be located on top of a separate trolley, close to the scrub nurse location. The Sponge Container should NOT be located on top of any other antenna.

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6. USING THE SYSTEM

After the Operating Room has been configured for the ORLocate™ System, as detailed in the previous section, use of ORLocate™ can begin. System is turned on by pressing the black button on the right panel of the system cart , see Figure 1

Figure 1

6.1. GENERAL PRINCIPLES – HOW THE ORLOCATE COUNTS

1) Each RFID tag that is attached to a surgical item holds information on the type of item (e.g., forceps 100mm, Lap sponge 30X30, needle holder 130mm) and in addition has unique identification that separates it from other items, even items that are identical in their type. When a tag is physically close to an antenna, the antenna detects the tag and includes the tag information in the inventory. if the antenna detects the tag again, it will not recount it, but rather "know" that this specific tag was already detected and counted.
2) The initial count includes all items that are located either on the Trolley Antenna, Mayo Antenna, or Sponge Container. The system does not detect items that are left inside the set tray or instruments that fall on the floor before the initial count.
3) Any new instrument or sponge that is added during surgery, after the initial count, must be scanned **before** use. Instruments must be scanned by the Mounted Antenna (by the scrub nurse) and sponges must be scanned by the Cart Antenna (by the circulating nurse). 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.
4) The system performs a count every five minutes, and the user may also initiate a count upon request.
5) The system displays the number of Items "Not Located" = (Items that were registered in the system) minus (Items that are currently detected).
6) 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.
7) If in the final count the Circulating Nurse sees that there are items missing ("Not Located"), he can scan the contaminated items using the Mounted Antenna to reconcile the count.
8) Nurses may End Surgery with missing items and write down the reason why these items are missing.
9) Do not place instruments into the Sponge Bucket.

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10) Do not place instruments on the Cart Antenna.
11) Untagged items are registered manually using the touch screen.

Warning: Do not place metal devices on the Instrument Trolley Antenna. If a metal basket is used, place it on a separate trolley.

Warning: During the initial registration, the system counts the number of sponges in the Sponge Container. If the system count for a particular type of sponge does not match your manual count, discard all sponges of that type.

Warning: During surgery, the user enters additional packages of sponges into the system via the Cart Antenna. 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 corrected.

Warning: The system beeper and LEDs should be operated during system initialization. If no beep is heard and no LED lit, stop using the system until the problem is corrected.

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.

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The circulating nurse touch the "Start" on the welcome screen (Figure 2) .

Figure 2

Circulating nurse enter the circulating nurse and scrub nurse names, and number of operating room (Figure 3)

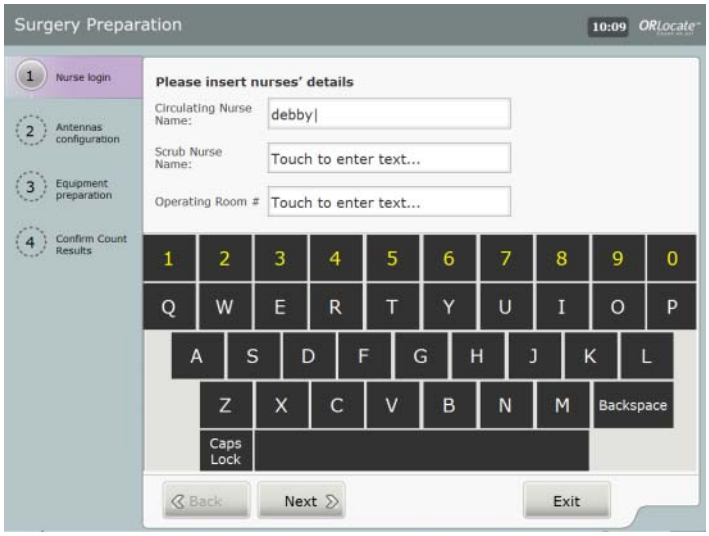

Figure 3

The system conducts a test and indicates to the nurse the antenna status (connected, not connected, problem detected). At this point the nurse must also verify that the LEDs on the mobile and Mounted Antennas are functioning and run a test sound. This can be seen below in figure 4.

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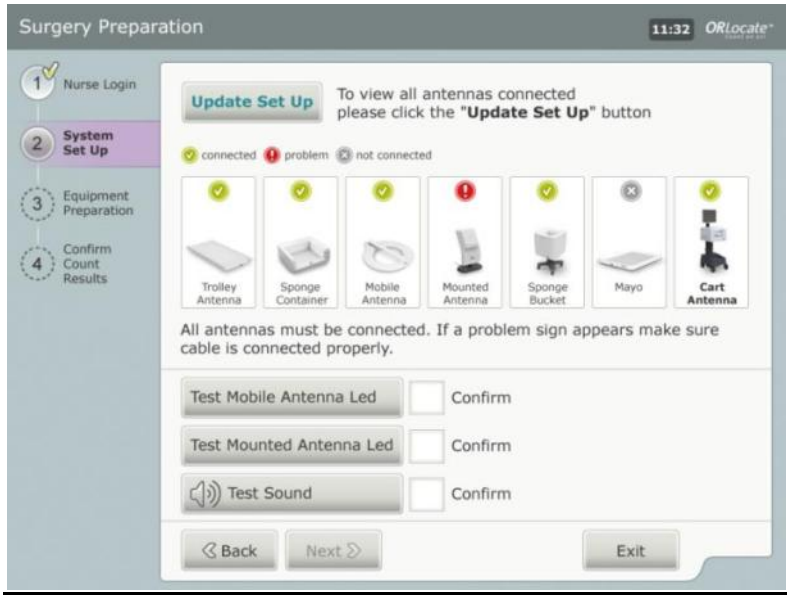
Surgery Preparation
11:32
ORLocate
1 Nurse Login
2 System Set Up
3 Equipment Preparation
4 Confirm Count Results
Update Set Up
To view all antennas connected please click the "Update Set Up" button
connected
problem
not connected
Trolley Antenna
Sponge Container
Mobile Antenna
Mounted Antenna
Sponge Bucket
Mayo
Cart Antenna
All antennas must be connected. If a problem sign appears make sure cable is connected properly.
Test Mobile Antenna Led
Confirm
Test Mounted Antenna Led
Confirm
Test Sound
Confirm
Back
Next
Exit

Figure 4

After the system functionality is confirmed, the nurse places the required surgical instruments on the Mayo antenna and the Instrument Trolley antenna.
An initial supply of sponges is opened and placed inside the Sponge Container to be registered into the system.
The nurse may include in the Initial Count items that are not tagged with RFID tags. This is done using the interface as shown in figure 5.

Registering Untagged Items:

The nurse selects a group (needles, blades, etc.) and type (if applicable). Then the nurse inserts the amount by pressing the # button or using the arrows.

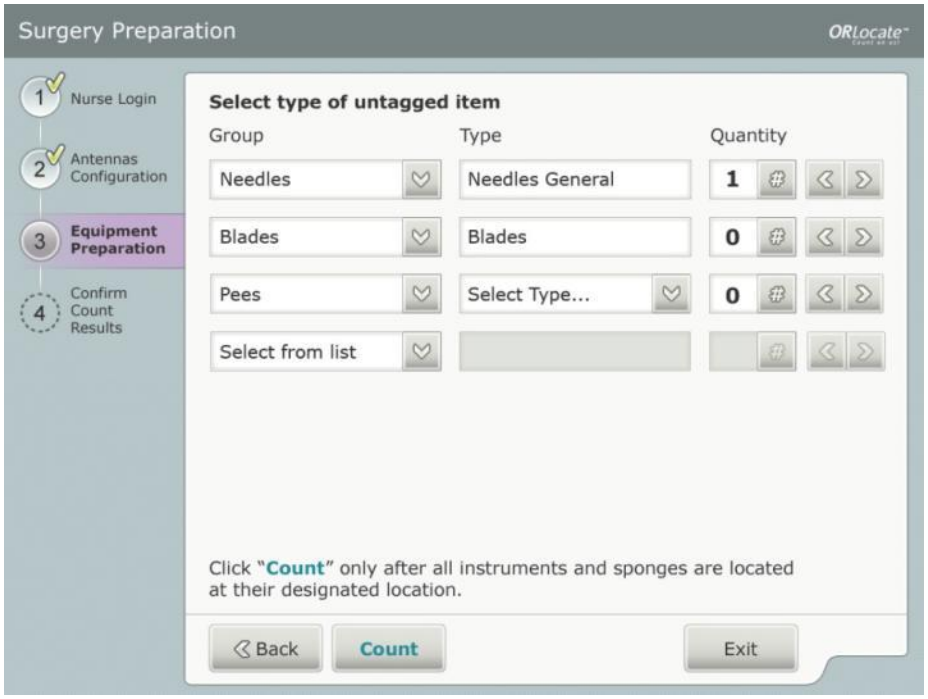

Figure 5

The circulating nurse instructs the system to perform a count after all consumables and instruments are spread out. The system counts the instruments that are spread on the tables and the clean sponges that are placed in the Sponge Container. This is called the Initial Count. In this stage there should be no items in the Sponge Bucket or on the Cart Antenna. System will display a warning if items are located not in the designated locations.

After the initial count is performed, the nurse can see a detailed view of count results where the type and amount of each item is specified. The nurse must then confirm this count. This can be seen below in figure 6.

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Figure 6

In case of a mismatch:

Instruments Mismatch:

A mismatch is a case when the number of items that the nurse placed does not match the amount that the system displays. In that case the nurse should select the item (touch the item name). A pop up will appear (figure 7) and the nurse will be guided to scan the instruments of that type using the Mounted Antenna.

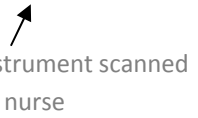

Figure 7

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When the nurse scans the instruments with the Mounted Antenna the system will display each item. The nurse can determine which item of that type is not tagged or has a faulty RFID tag.

Sponges Mismatch:

If the system detects an amount 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 in the Sponge Container (of that type only), place new ones, and count again.

Once the initial count is ready and confirmed the procedure may begin and the system enters Surgery Mode. The system performs another count before entering Surgery Mode.

Note: The user must not add, remove or move instruments or sponges while a count is being performed. If the system detects a change in the count the system will not enter the surgery mode. The system will enter surgery mode only after the amount that the user confirm is equal to the amount that the system detects in the initial count.

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6.2.2. SURGERY MODE

During the surgery the nurse may view the count in several ways, as shown in the figures below**.**

Figure 8: Items Not Located view:

In this view the system display only the items that are not located by the system:

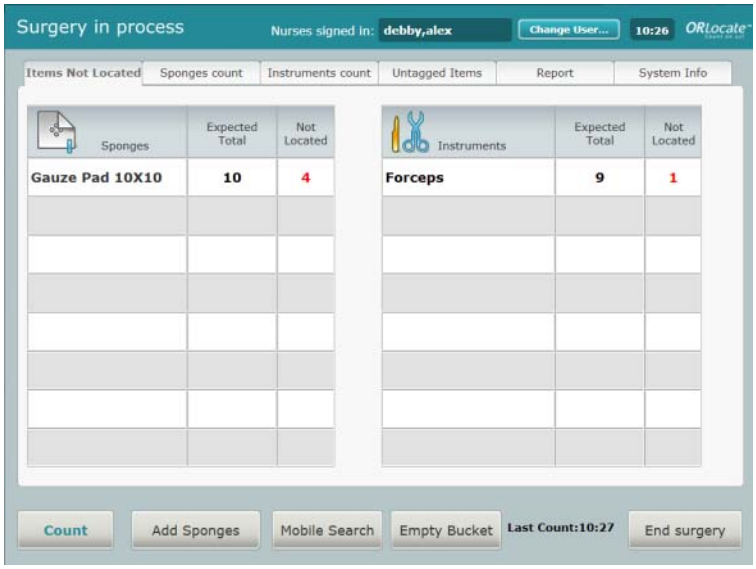

Figure 8

Figure 9: Sponges Count view:

In this view the system displays information regarding the sponges – initial count, additions, expected total, number of sponges in Sponge Container (i.e., clean), number of sponges in Sponge Bucket (i.e., soiled), and not located items (marked in red color):

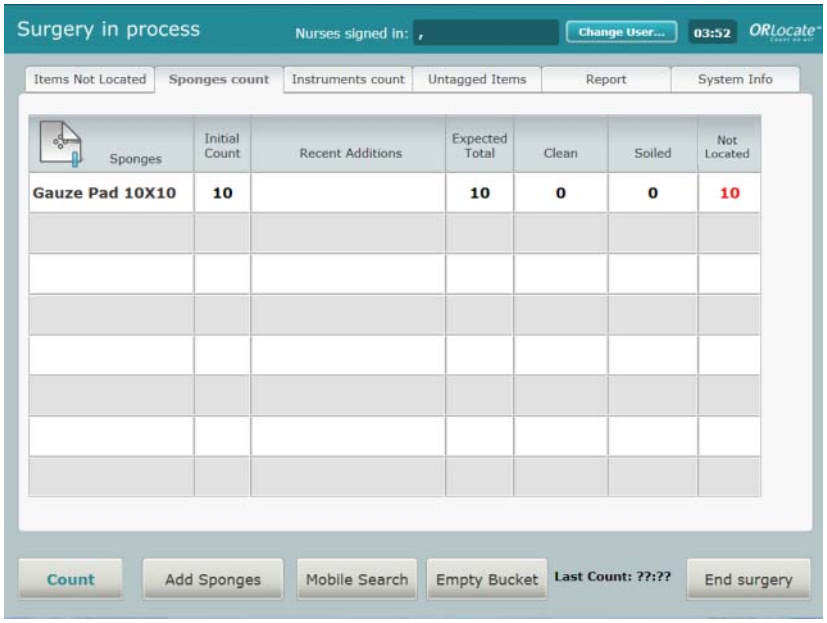

Figure 9

Figure 10: Instruments Count view:

In this view the system displays information regarding the instruments – initial count, additions, expected total, number of detected items, and not located items:

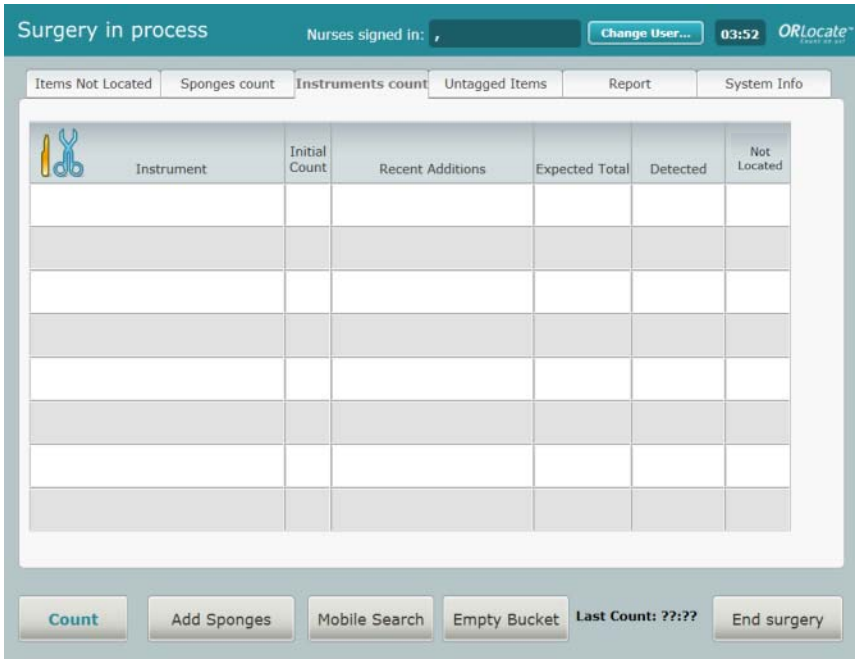

Figure 10

Figure 11: Untagged Items view:

In this screen the nurse can register new untagged items and add items of types that are already registered. The system also allows the nurse to register his count and get information on the items not located:

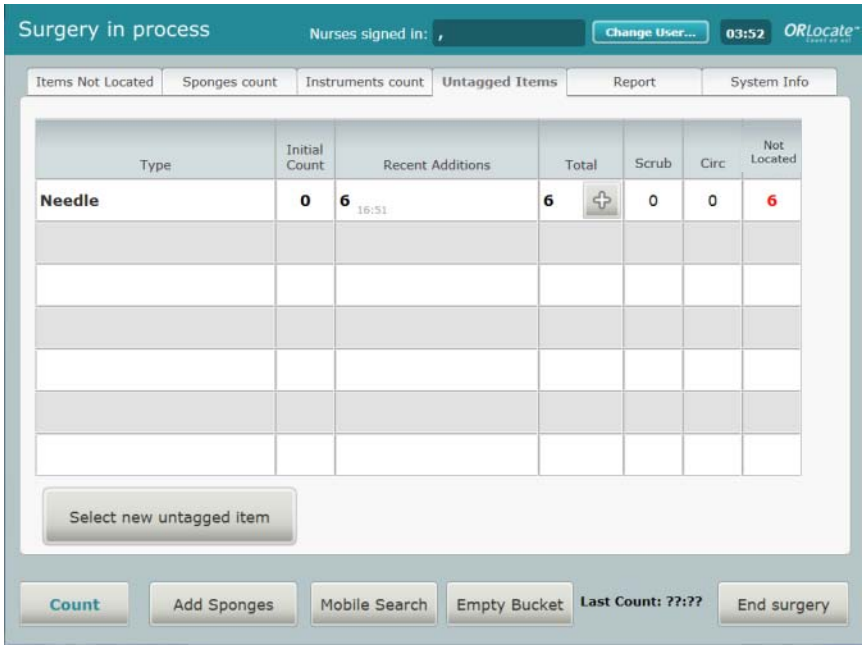

Figure 11

Figure 12: Report view:

This view displays the count for all types of items:

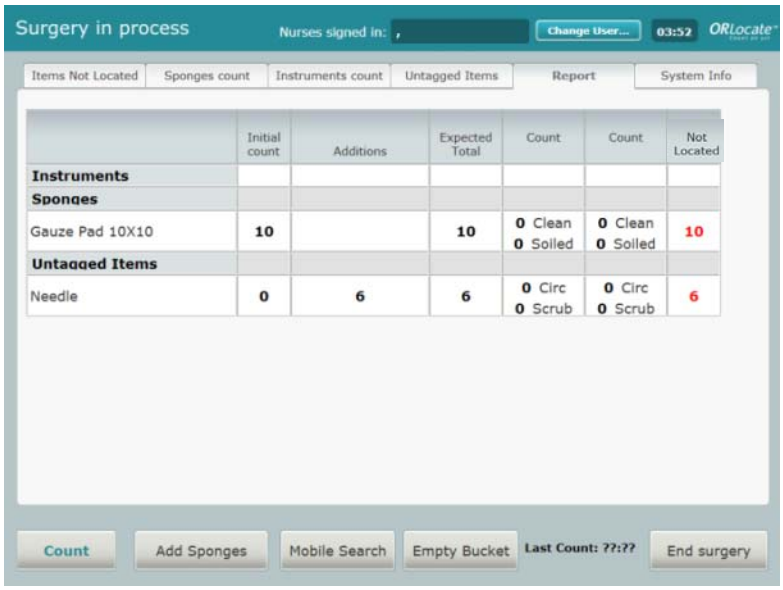

Figure 12

Figure 13: System Information view (antenna configuration view):

In this view the system displays the status of the antennas. This screen pops up automatically if there is a problem that cause antenna to be not functional. The antenna that is not functional will be marked in red or gray (depending on the problem). The nurse cannot exit this tab until all antennas are connected and functioning. If a change in set up has occurred (for example, reconnection of cables by a technician) the nurse can update the system by clicking the "update set up" button, as can be seen in figure 13 bellow:

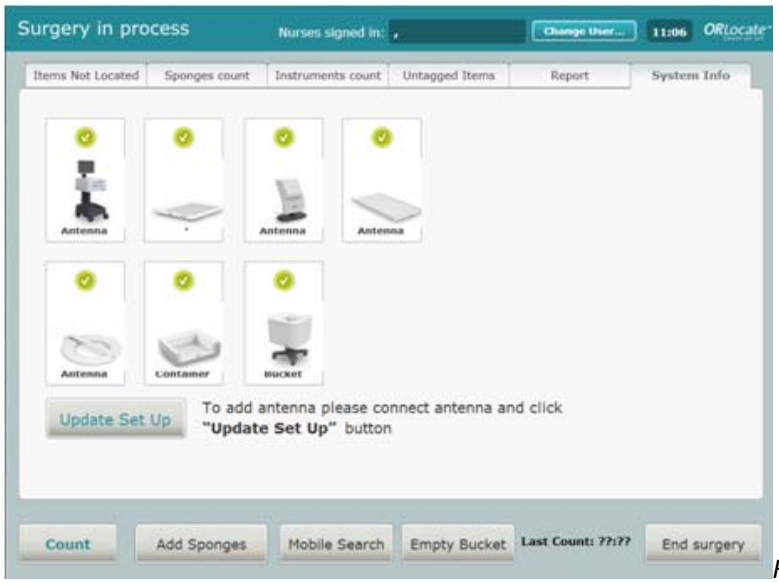

Figure 13

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

1) **Count** – When the nurse clicks the "Count" button the system operates all antennas and performs a full count. During the count the nurse sees a system message that the count is taking place and can optionally enter the numbers of untagged items.

2) **Add sponge** – When the nurse wishes to add new sponges to the inventory the nurse should place a sponge package (closed package) on top of the Cart Antenna surface 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.

3) **Mobile search** – During surgery the nurse can activate the Mobile Antenna in order to locate an item in the surgical site. The mobile antenna should be covered with a sterile cover, including a cover for the cable.

   In order to cover the cable the nurse should disconnect the Mobile Antenna from the System Cart, place the sterile cover and reconnect the cable.

   The Mobile Antenna should be held close to the surgical site and moved slowly just above the patient body. When the antenna detects an item it will be displayed in the screen, as shown in figure 14 below.

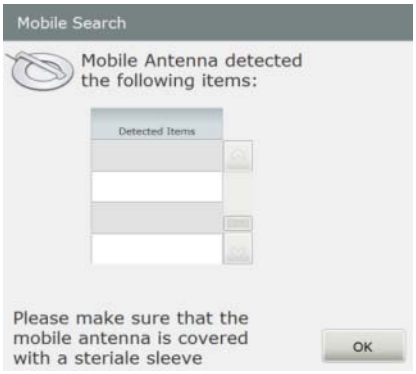

Figure 14

4) **Empty bucket** – When "Empty Bucket" button is clicked a count begins of the Sponge Bucket. At that time sponges should not be removed or added to the Sponge Bucket. After the count is complete the nurse may change the bucket liner and continue. The system will save the number of sponges that were removed and will display these sponges as part of the inventory.

5) **End Surgery** – When this button is clicked the system enters the "End Surgery" mode – a final count is performed.

6) **Change user –** if a nurse is being replaced (due to shift change or breaks) the replacing nurse should enter his name in the pop up, as shown in figure 15 that is opened upon clicking the "Change user" button (top of main view)

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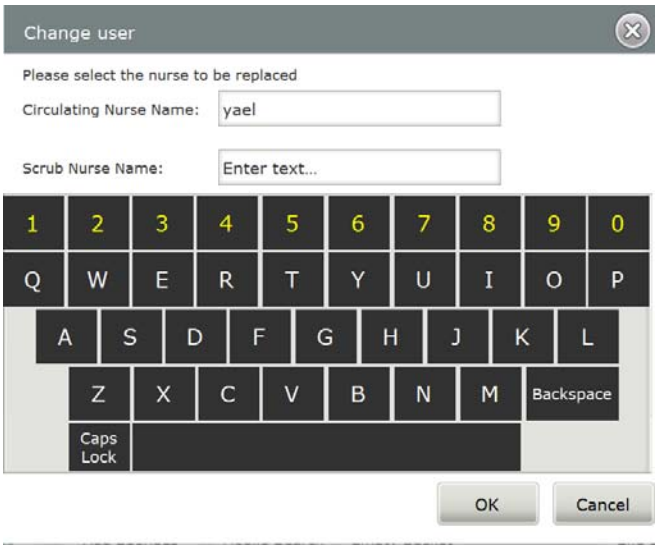
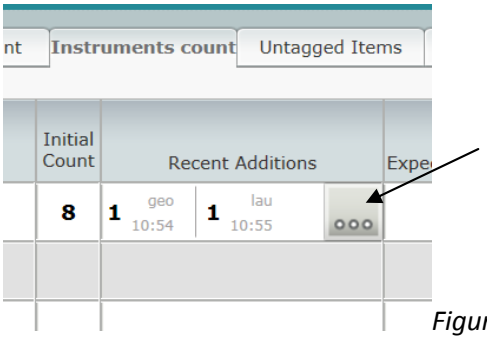


Figure 15

Display of added items

When nurses add new items (sponges or instruments) they are added to count and being displayed on the relevant screen (sponges will be displayed in the sponges view, figure 9, and instruments displayed in the instruments view, figure 10) under the column "Recent Addition". This can be viewed in figure 16 bellow. Each addition will be recorded and displayed with the time of addition and name of circulating nurse who was logged in at that time.



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

Figure 16

6.2.3. END SURGERY MODE

At the end of surgery the Circulating Nurse clicks on the End Surgery button and the system enters End Surgery mode. The system performs a final count and displays whether all items are accounted for or not. If not all items are accounted for, the team must find the items and may use the Mobile Antenna to search. Items that are recovered during the search may be placed on an antenna (for example sponges

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should be placed in sponge bucket) or may be scanned with the Mounted Antenna and a recount performed.

Figure 17

After the system displays the count results for the tagged items (auto count confirmation), the nurses are instructed to count all untagged items. The system will indicate whether the count entered matches the registered untagged item count by displaying any mismatch in red color, as can be shown in figure 18.

Figure 18

After the counts are all balanced the system displays a full count report and the surgery may be closed.

7. THE ORLOCATE™ FUNCTIONALITY

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7.1. INFORMATION THAT IS ALWAYS AVAILABLE IN THE SYSTEM

The user interface continuously displays the following information:

- Not Located items - Number and type of items that were registered but are currently not detected
- 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 soiled sponges and number of clean sponges
- Last time the count was performed (either automatically or upon nurse request).

7.2. PRODUCT FUNCTIONS

- Antenna set-up check
- Auto count (tagged items)
- Count upon request (tagged items)
- View of not located items (tagged items)
- Untagged items count during surgery
- Add sponges during surgery
- Add untagged items during surgery
- Add instruments during surgery
- Status report
- System information (antenna set up check during surgery)
- Detection warnings
- End Surgery – final automatic count
- End Surgery – final count of untagged items
- Mobile search
- Change user
- Empty Sponge Bucket (count of items in Sponge Bucket).

8. SHUTTING DOWN THE SYSTEM

In order to shut down the system user should press the black button on the right panel of the cart antenna (next to the cart antenna surface) as can be seen in the figure 19 bellow:

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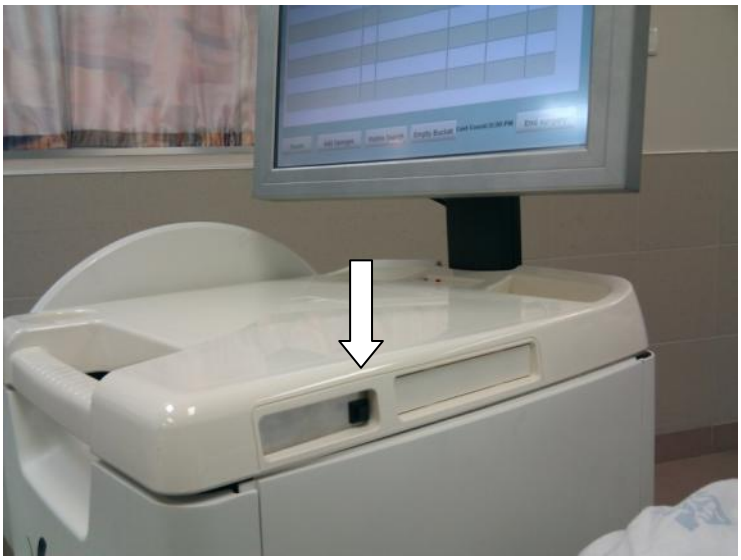
figure 19: on/off button

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9. TROUBLE SHOOTING

The following chart lists some typical conditions or problems that may occur with the Haldor ORLocate™ 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.
	ORLocate™ System failure.	Contact service.
Sponge or Instrument registered into System, but Subsequent Counts No Longer Indicate Item is 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 service. For a replacement for a replacement.
System Indicates Antenna Failure	An Antenna has been placed on or near a metal surface.	Move Antenna away from metal.
	An Antenna is experiencing interference from other surgical equipment.	Move the Antenna away from the interfering equipment, or wait until the equipment is no longer in use.
	An Antenna cable has become detached.	Connect cable.
	An Antenna cable is damaged or kinked.	Contact service for a replacement.

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Condition	Possible Cause	Recommended Action
System Indicates Antenna Failure	Antenna electronics have failed.	Contact service for a replacement Antenna.
Antenna Housing is Cracked or Broken	Antenna has been dropped or misused.	Contact service for a replacement.
Antenna LED Indicators Fail to Indicate that Tag is Present	RFID tag too far from antenna.	Ensure the Tag is close and re-scan it.
	LED is faulty.	Contact service for a replacement.
	Antenna cable is damaged.	Contact service for a replacement.
	Antenna cable is disconnected.	Connect cable.
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.
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 Mounted Antenna or Mobile Antenna.	Stop using the system until the problem is corrected.
	Faulty LEDs on Mounted Antenna or Mobile Antenna.	Stop using the system until the problem is corrected.
Antenna is not functional	Faulty digital input/output mechanism Module (internal component of System Cart).	Stop using the system until the problem is corrected.
	Faulty RF Multiplexor unit Module (internal component of System Cart).	Stop using the system until the problem is corrected.

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Condition	Possible Cause	Recommended Action
	Faulty RF Module (internal component of System Cart).	Stop using the system until the problem is corrected.
	Faulty RF Multiplexor Module (internal component of System Cart).	Stop using the system until the problem is corrected.
System not functional -- counting is discontinued, and current count is lost	Power supply failure.	Stop using the system until the problem is corrected.
	DC Converter is not working properly.	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.
Battery status displayed on the screen indicates a low battery charge.	Charger is disconnected or faulty.	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 Trolley Antenna or Mayo Antenna or Mounted Antenna or Mobile Antenna is faulty.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because cable to Trolley Antenna or Mayo Antenna or Mounted Antenna or Mobile Antenna is damaged.	Stop using the system until the problem is corrected.

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Condition	Possible Cause	Recommended Action
	Not receiving any electrical signals because antenna of Trolley Antenna or Mayo Antenna or Mounted Antenna or Mobile Antenna is not tuned.	Stop using the system until the problem is corrected.
	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 Mounted Antenna 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 Container Antenna or Sponge Bucket Antenna or Cart Antenna is disconnected.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because connector to Sponge Container Antenna or Sponge Bucket Antenna or Cart Antenna is faulty.	Stop using the system until the problem is corrected.

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Condition	Possible Cause	Recommended Action
	Not receiving any electrical signals because cable of Sponge Container Antenna or Sponge Bucket Antenna or Cart Antenna is damaged.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because antenna of Sponge Container or Sponge Bucket or Cart Antenna is damaged.	Stop using the system until the problem is corrected.
	Not receiving any electrical signals because antenna of Sponge Container or Sponge Bucket or Cart Antenna is not tuned.	Stop using the system until the problem is corrected.
	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, causing the RFID tag to not function.	Observe the temperature and humidity ranges for operating the system.
	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 Cart Antenna before placing it into the Sponge Container.
Sponge becomes non-sterile, leading to patient contamination	Sterile sponge placed on Cart Antenna.	Place sponges on the Cart Antenna only while in original package.

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Condition	Possible Cause	Recommended Action
Mobile Antenna is not sterile	Mobile Antenna was dropped to the floor while enclosed in sterile sleeve.	Replace sterile sleeve
Mobile Antenna is not sterile and may be contaminated with blood	Mobile Antenna was dropped to the floor while not enclosed in sterile sleeve.	Clean the Mobile Antenna.
Misuse of instrument causes patient injury	Instrument tag location interferes with the correct 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 page 32 for instructions on how to perform a Mobile 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 Cart 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 Mobile Antenna, 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

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Condition	Possible Cause	Recommended Action
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
Bio-contamination leading to patient infection	Sponge package opened before registration	Discard the package of sponges
	Sterile covering is removed from Mayo Antenna during procedure	Do not remove the sterile covering on the antenna during the procedure.
	Sterile covering is removed from Mobile Antenna during procedure	Do not remove the sterile covering on the antenna during the procedure.
	Cart/Cart Antenna biocontaminated	Clean the Cart after every use.
	Tools not cleaned/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.

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10. MAINTENANCE AND SERVICE

10.1. CLEANING PROCEDURE

In order to maintain the system in optimum condition, clean the system periodically. This cleaning procedure should be used before each surgery using the system.

Caution: Unplug the AC power cord before cleaning the system.

To clean the system:

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 Container and the Sponge Bucket.

To clean the Touch Screen:

1) Wipe the Touch Screen panel with a damp cloth.
2) 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.

10.2. MAINTENANCE SCHEDULE

Routine maintenance should be performed on the system as follows:

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

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

10.3. OBTAINING SERVICE:

Contact the Haldor ORLocate™ representative:

Tel: +972 9 7885858

Fax: +972 9 7885861

Address: 2 Habanai Street
Hod Hasharon 45319, Israel

E-mail: support@haldor-tech.com

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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. ENVIRONMENTAL

11.1.1. OPERATING ENVIRONMENT

Temperature: 10°C to 40°C (50° F to 104° F)

Relative Humidity: 30% to 75%

Pressure: 700 hPa to 1060 hPa

11.1.2. STORAGE AND TRANSPORTATION ENVIRONMENT

Temperature: -40°C to 70°C (-40°F to 158°F)

Relative Humidity: 10% to 100%

Pressure: 500 hPa to 1060 hPa

11.2. ELECTRICAL POWER

- Consumption (max): 200 watts
- Input Voltage Range: 100 to 240 VAC at 50 to 60 Hz
- Current (max): 2 A

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12. SYSTEM SPECIFICATIONS

In addition to the specified in paragraph 3.1 - Description of System Components, for each Component, the following specification shall be applied:

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

	Trolley	Mayo	Sponge Container	Sponge Bucket	Mounted Antenna	Cart Antenna	Mobile Antenna
Max. amount of items	50 instruments	25 instruments	50 sponges	40 sponges	1 instrument	10 sponges	4 items (instruments and sponges)
Max detection distance	Up to 6 cm	Up to 6 cm	Items should be inside container	Items should be inside bucket	Up to 6 cm	Up to 6 cm	up to 38 cm for tagged sponges and up to 28 cm for tagged instrument
Weight (Kg)	7.5	4.5	5.8	35	4.8	NA	2.5
Dimensions (cm)	97x52x5	60.5x47x6.5	50x42x20	50x50x90	22x13x33	NA	57x50x9.5

- System Cart dimensions: 48x55x130cm, weight: 80 Kg.
- Maximum amount of RFID -tagged items that can be detected at one cycle of count – 165 items (sponges and instruments)
- Maximum amount of sponges that can be detected in one cycle of count: 90 sponges
- Maximum amount of instruments that can be detected in one cycle of count: 75

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