ORLocate™

Packing System

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

USER MANUAL

REVISION 0

Haldor advanced technologies ltd.

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2 Habanai Street, Hod Hasharon 45319, Israel

Tel: +972 9 7885858 , Fax: +972 9 7885861, Email: support@haldor-tech.com

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1. INTRODUCTION

1.1 THE HALDOR ORLOCATE™ PACKING SYSTEM

Haldor ORLocate™ **Packing** system is a supplementary system for the Operating Room ORLocate™ system and to the ORLocate™ Management system, which is described in a different User Manuals.

Generally, Haldor ORLocate™ system is an RFID system that provides a solution enabling the enumeration of RFID tagged sponges and surgical instruments to keep track of the items during surgery, by utilizing passive RFID tags (battery-less transponder that does not radiate any electromagnetic field when not activated).

Haldor ORLocate™ **Packing** system is an RFID system that provides a solution enabling the enumeration of RFID tagged surgical instruments to keep track of the items during their usage (OR-SPD cycle), by utilizing passive RFID tags (battery-less transponder that do not radiate any electromagnetic field when not activated).
The ORLocate **Packing** system provides a method for packing RFID-tagged surgical items within a surgical set, and is to be used during sterilization and while packing units in hospitals.

1.2 ABOUT THIS MANUAL

This manual provides the information necessary to operate the Haldor ORLocate™ Packing 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 an equipment malfunction.

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

1.3 GLOSSARY

ANTENNA:

A powered device that is capable of sending and receiving signals from the RFID tags. There is one antenna in the ORLocate™ Packing system called Tool Pack.

ITEMS MISSING:

Items that are listed in the inventory list but were not scanned in the *Tool Pack* antenna during assembly.

INVENTORY LIST:

The list of items that create a surgical set. This list is uploaded to the system by a system administrator at the ORLocate management system.

INSTRUMENT:

A specific tool that can be used on surgeries performed at a hospital. An instrument in the system will usually be part of a set and will be tracked and managed by ORLocate™ Management system.

INSTRUMENT TYPE:

a template of instrument that defines its expected use, the set in which it may belong to and its exact shape. Each instrument in the system is characterized by a single instrument type.

INSTRUMENT SET/ TRAY:

A box that contains a set of sterile surgical instruments. The Set includes a non-sterile external container, and a sterile inner "net" that contains the instruments. The instruments are arranged in a predefined layout within the set (in a Tray). A set in the system will be tracked and managed by ORLocate™ Management system.

SET TYPE:

A template of a set that defines its expected use, the procedures it might be used in, its specific packaging instructions, the type and quantity of required instruments and the layout of instruments in it.

SET TYPE CODE:

An alphanumeric code uniquely attached to a specific set type. The code serves as an internal convention in the hospital.

LAYER:

A segment within the set that refers to either a physical layer or to an area within the set layout. Each layer may include several instruments arranged in a specific layout. The layer may or may not include a physical container. The content of each layer is defined in the Set Type.

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:

A small, self-enclosed device that contains an RFID and is attached to a surgical instrument or is attached to an instrument set/tray.

PACKING PERSONNEL/TECHNICIAN:

A trained team member whose job is to assemble surgical sets at the packing unit

PACKING INSTRUCTIONS:

Instructions written by a system administrator that guides how to pack or place a certain item.

SET TAG

An RFID tag that is attached to a specific instrument set/tray. The tag is attached with a metal ring and is removable.

UNTAGGED ITEMS:

Instruments 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 Tool Pack Antenna 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

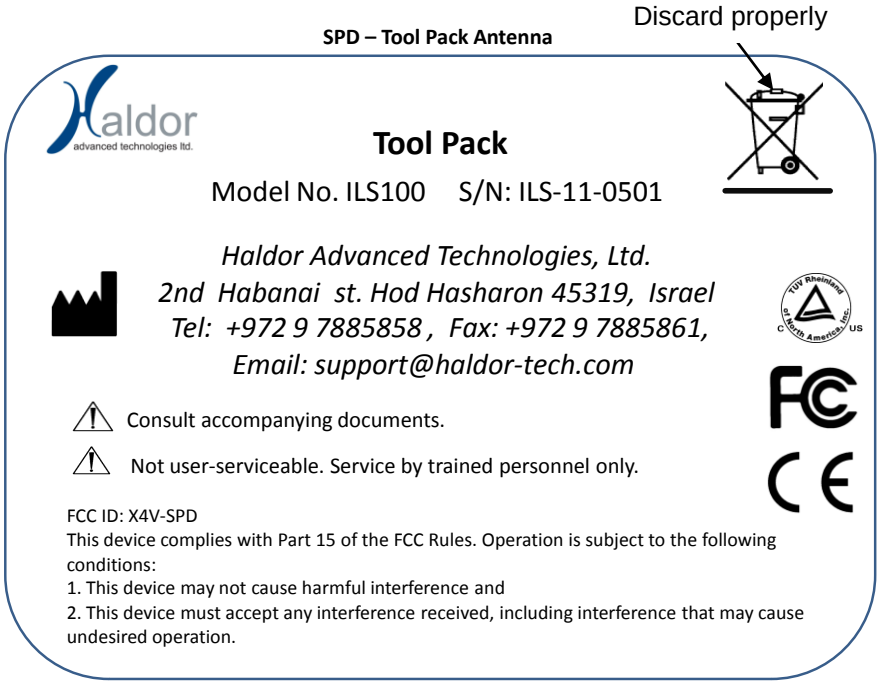
	FCC Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.	1
	For the ORLocate Packing system to operate use only Haldor's RFID tags.	2
	Dispose RFID tags according to standard environmental regulations.	3
	Do not use the system in the presence of a flammable gas.	4
	Continuous stay next to the Tool Pack Antenna should be limited for up to 3 minutes within a distance of 10 cm (4") or less.	5

	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.	6

2.3 INDICATIONS

The ORLocate™ Packing system is indicated for use in detecting RFID-tagged surgical instruments and set tags. The product is indicated for providing a method of packing surgical items to create surgical sets.

2.4 SYSTEM LABELS



Warning Label on Tool Pack Antenna:

Continuous stay next to the Tool Add should be limited for up to 3 minutes within a distance of 10 cm (4") or less.

Package Labeling for the ORLocate™ Packing System:

Outside Package Template

ORLocate™ Packing System:

Fragile: Handle with care

This Side Up

Keep Dry

70°C
-40°C
Transport & Storage

Model No. ___

S/N____

CE

Haldor Advanced Technologies, Ltd.
2 Habanai st, Hod Hasharon Israel 45319

Haldor advanced technologies ltd.

3. INTRODUCTION TO THE HALDOR ORLOCATE™ PACKING SYSTEM

For general introduction - see chapter 1.1. The Haldor ORLocate™ Packing System.

3.1 DESCRIPTION OF SYSTEM COMPONENTS

The system includes three main components:

(1) User interface component.
(2) Tool Pack Antenna.
(3) Tagged items.

3.1.1 USER INTERFACE COMPONENTS

- **The interface hardware consists of two modules:**

1. PC – Intel Core 2 Duo, 1.8MHz, 2G memory, 160G disk, Serial, USB and LAN ports.

2. Touch screen – 15” or 17” touch screen

The modules can be provided as one component combining both (Panel PC) or two separate components.

3.1.2 TOOL-PACK ANTENNA

The Tool Pack Antenna is used to scan RFID tagged surgical instruments and set tags before placing them inside the set. RFID tagged instruments and set tags should be held near the antenna as shown by the figure on the right. There are three types of feedback:

(1) **Beep**, indicating that the instrument is detected by the Tool Pack.
(2) **An indication** on the currently opened screen, specifying which instrument was detected.

Note: Move the RFID tagged item close to the Tool Pack Antenna and keep it steady for two seconds in front of the antenna until all RFID tagged items are registered in the system (i.e. information appears on screen).

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

Warning Label on Tool Pack Antenna:

Continuous stay next to the Tool Add should be limited for up to 3 minutes within a distance of 10 cm (4") or less.

3.1.3 TAGGED AND UNTAGGED ITEMS

Tagged items are RFID-tagged surgical instruments and trays. The system is designed to detect tagged items.

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

4. STERILE AND CLEANING CONSIDERATIONS

4.1 SURGICAL INSTRUMENTS THAT HAVE RFID TAGS

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

4.2 CLEANING TOOL PACK ANTENNA

The Tool Pack Antenna can be cleaned with any conventional material that is used to clean the packing station (see section 10.1 for detailed cleaning instructions).

5. SETTING ORLOCATE™ PACKING SYSTEM COMPONENTS

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

5.1 SETTING THE PANEL PC (TOUCH SCREEN)

The touch screen should be located close to where the packing personnel/technician is located during assembly to enable easy viewing of the screen, and close enough to the Tool Pack Antenna to enable an ergonomic operation, as shown in figure 1 below:

Figure 1

The panel pc should be connected to AC power and to the network as shown in figure 1 above.

5.2 SETTING THE TOOL PACK ANTENNA

The Tool Pack Antenna should be located on top of a table where the instrument sets/trays are located, and close to where the packing personnel/technician is located during assembly.

The Tool Pack Antenna should be connected to an AC power supply and to the panel PC/ touch screen, as shown in figure 2 below:

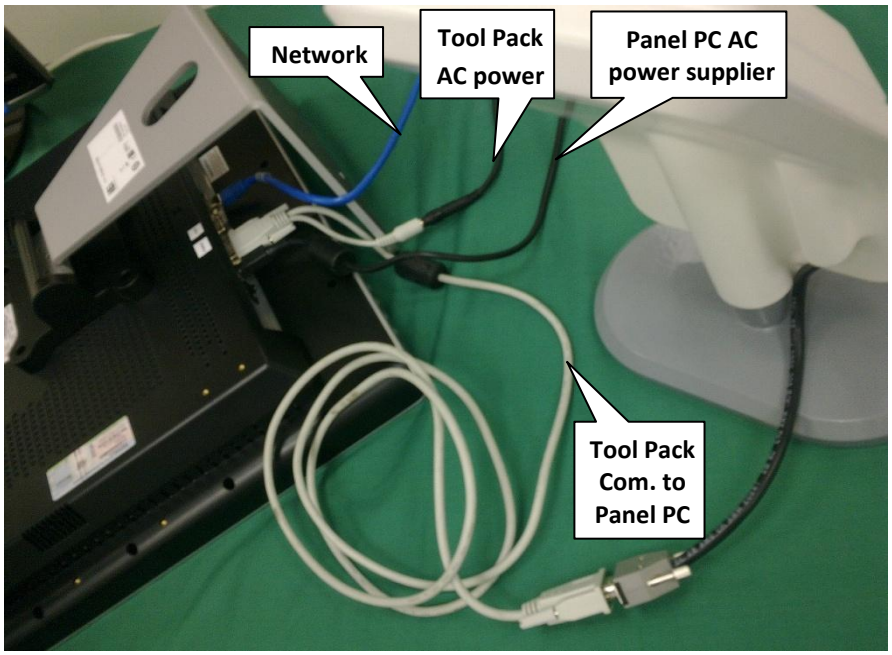


Figure 2

6. USING THE SYSTEM

6.1 GENERAL PRINCIPLES OF USE

(1) Each set tray has an RFID tag that indicates which type of set it is (e.g., "General Basic"). The tag is attached to the set tray with a metal ring and can easily be replaced with a different tag. The tag is able to withstand hundreds of sterilization cycles, after which the system notifies the user to replace the tag.

(2) Before the packing personnel/technician starts packing, the set tag should be scanned in the Tool Pack Antenna, to specify to the system which type of set is going to be assembled. Set inventory list will appear on the screen with two values for each item – 1) the quantity that is defined for that item (standard quantity), and 2) the actual number that was inserted into the set.

(3) Any RFID tagged item that is added to the set tray during packing must be scanned **before** inserting it into the set. The system will display the details of the scanned items on the screen. The inventory list will be updated automatically according to the progress of packing.

(4) Items that were already scanned (i.e., registered as part of the set) will not be displayed again on the screen when scanned again. The system ignores re-scanning.

(5) Untagged items should be registered manually.

(6) The system has two main views: the full inventory list or a list of only the missing items (items needed minus items scanned).

(7) Set may be sealed with missing items

6.2 SYSTEM WORKFLOW – USER INTERFACE

1. Welcome screen

Touch the “Start Packing” button on the welcome screen (Figure 3).

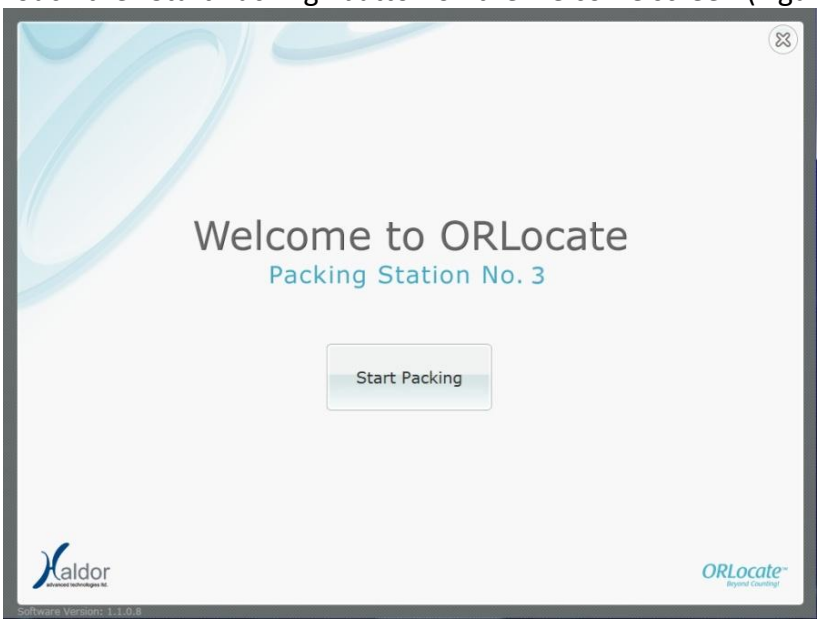


Figure 3

2. Set details screen

Scan the **Set Tag** in the Tool Pack Antenna Set type and set ID will appear on screen (Figure 4). Ensure set details are correct and select the “Start” button.

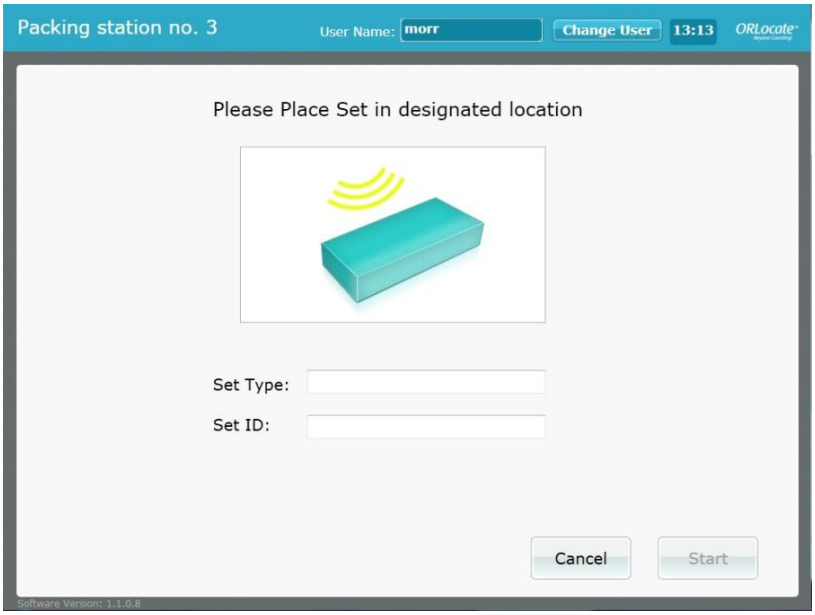


Figure 4

3. Packing main screen

Once the main screen appears (Figure 5) start packing by scanning items according to the inventory list. The main screen includes 4 areas: On the right side of the screen is the *set inventory list*. The inventory list includes all items that comprise the set divided to different areas or levels of packing (as seen in figure 5 “left side, right side”).
The second area of the main screen is the *Set Details area* (top left) in which the set type is indicated and there is a bar that represents graphically the progress of the assembly.
In the third area of the main screen (middle left) appears the *most recently scanned items*, and in the forth area of the screen (bottom left) the function buttons are located.

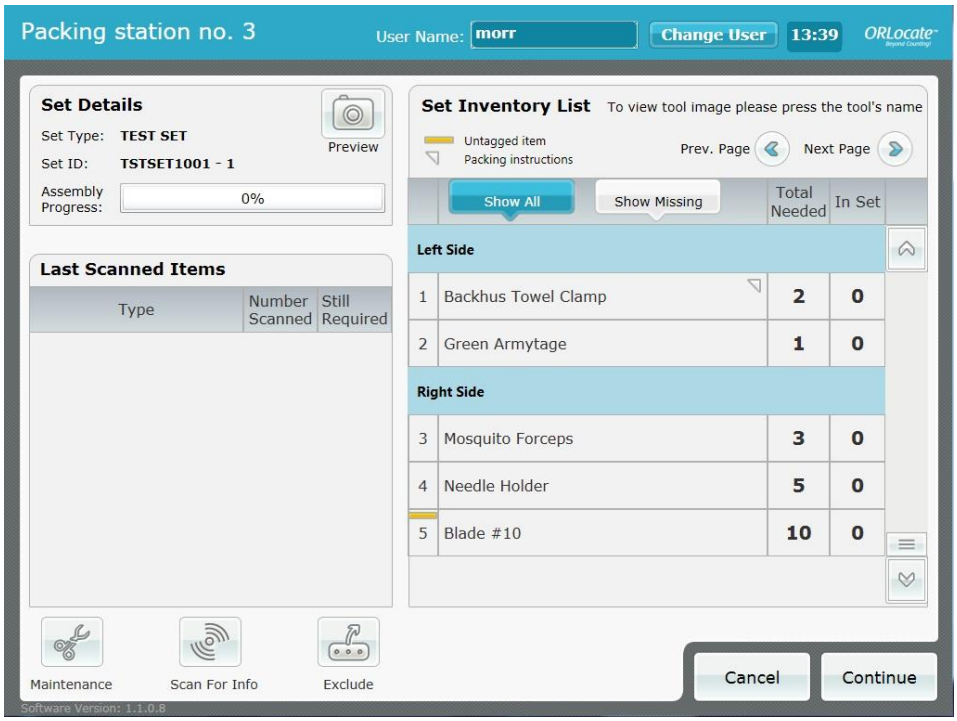


Figure 5

The four areas of the main screen will now be described in detail.

3.1. **Main screen : Set Inventory list**

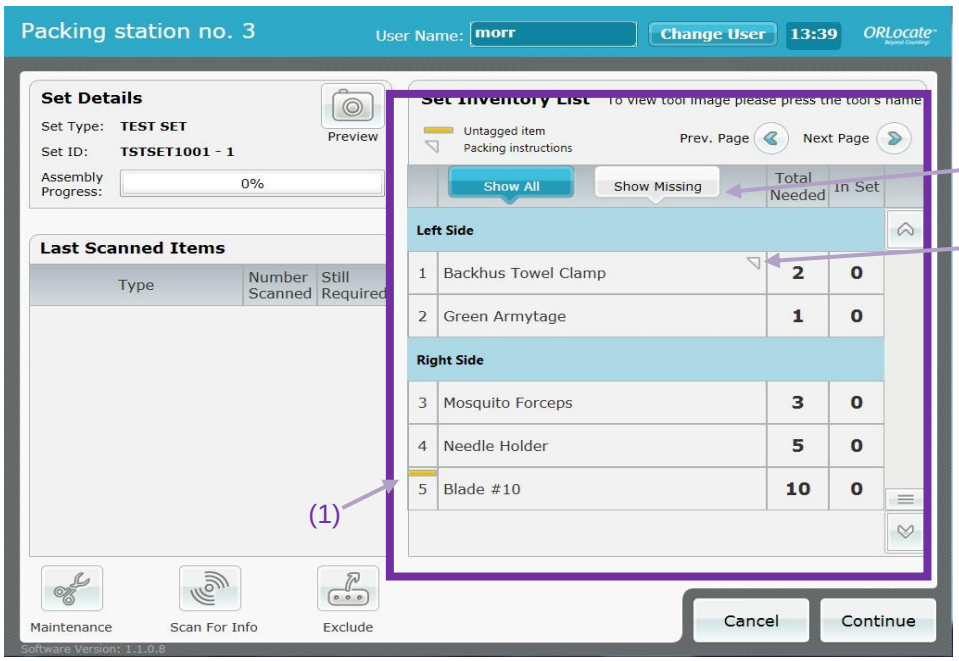


Figure 6

The inventory list displays a table listing all items that need to be packed in the set. Touching any row of the list will display details of the item in that row: a photo of that item and its packing instructions, if specified.

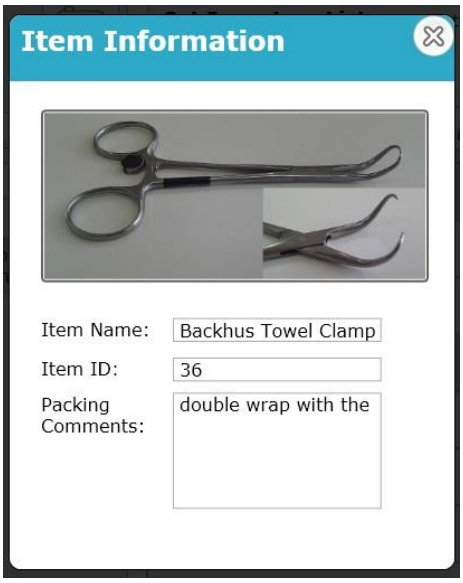


Figure 7

A yellow bar **(1)** next to the serial number represents an item that has no RFID tag attached, i.e.: **untagged item**. These items should be manually registered into the system. Touch the row of that item to open a pop-up in which the number of items can be specified, as shown in figure 8 below:

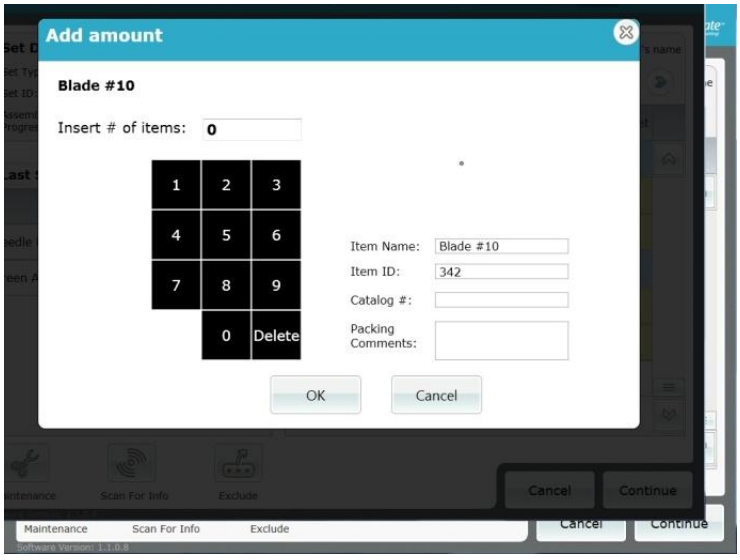


Figure 8

Items that have a triangle on the upper right corner of their row **(2)** are items for which packing instruction exist. Touching the row will open a pop-up with packing instructions for that item (as can be seen in Figure 7).

The inventory list has two different views that are controlled by two buttons titled “Show all” and “Show missing”**(3)**. The default view is “show all” in which all items are listed. The “Show Missing” view will filter the list so that only types of items that are still not packed (either not packed at all or have not been fully packed) will appear on the list.

Once all items of a certain type are packed the row changes the color to green, as shown in figure 9 below:

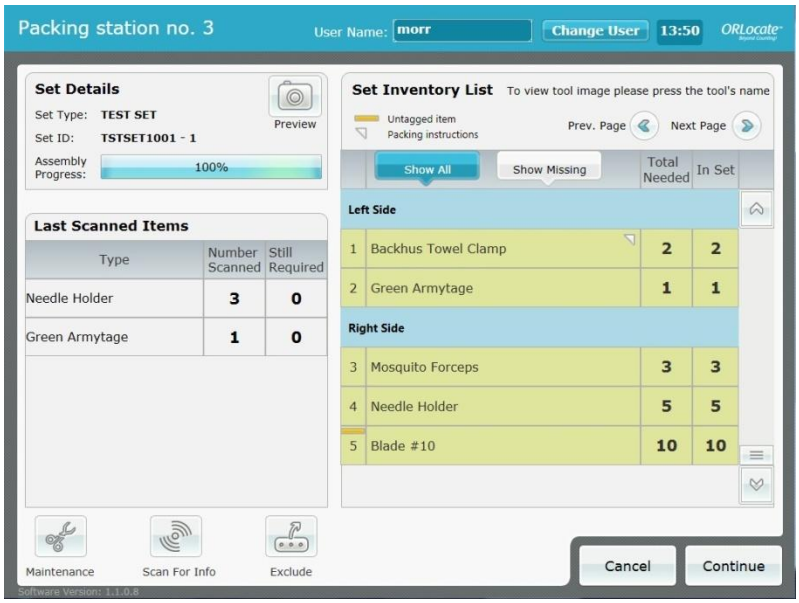


Figure 9

3.2. Main screen : Set details area

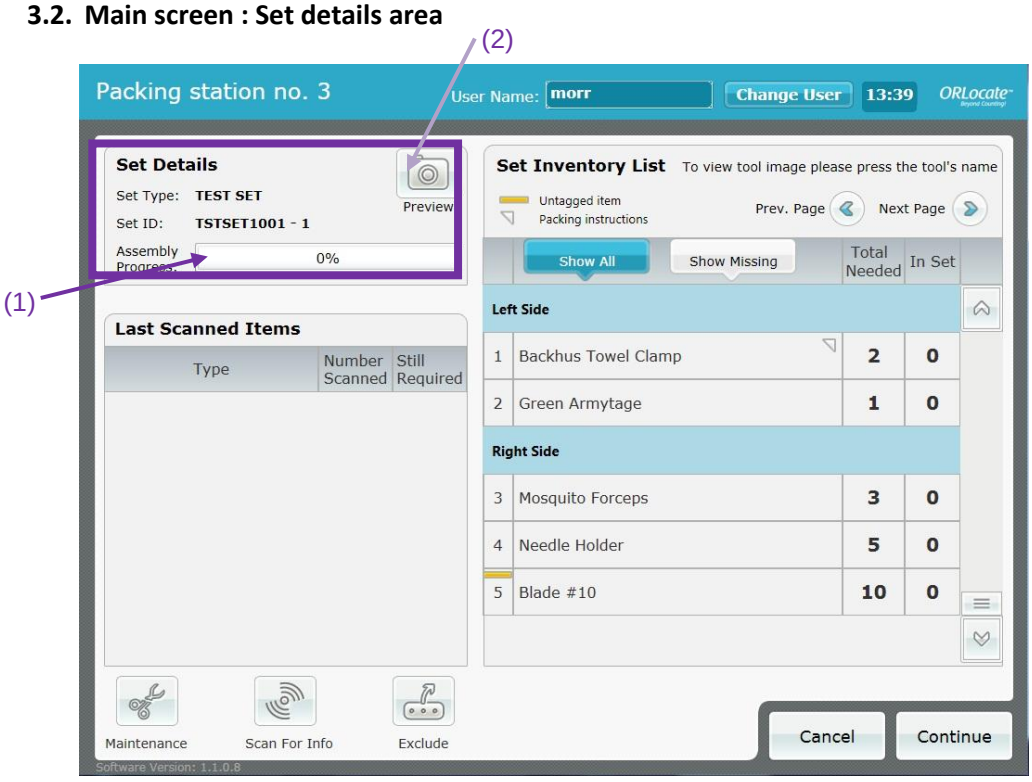


Figure 10

In the set details area appears the set type and ID and a progress bar that represents the progress of the set assembly (approximation) **(1)**. Also in this area is a "Preview" button **(2)** – pressing the button will display a photo of a packed set, as shown in figure 11 below:

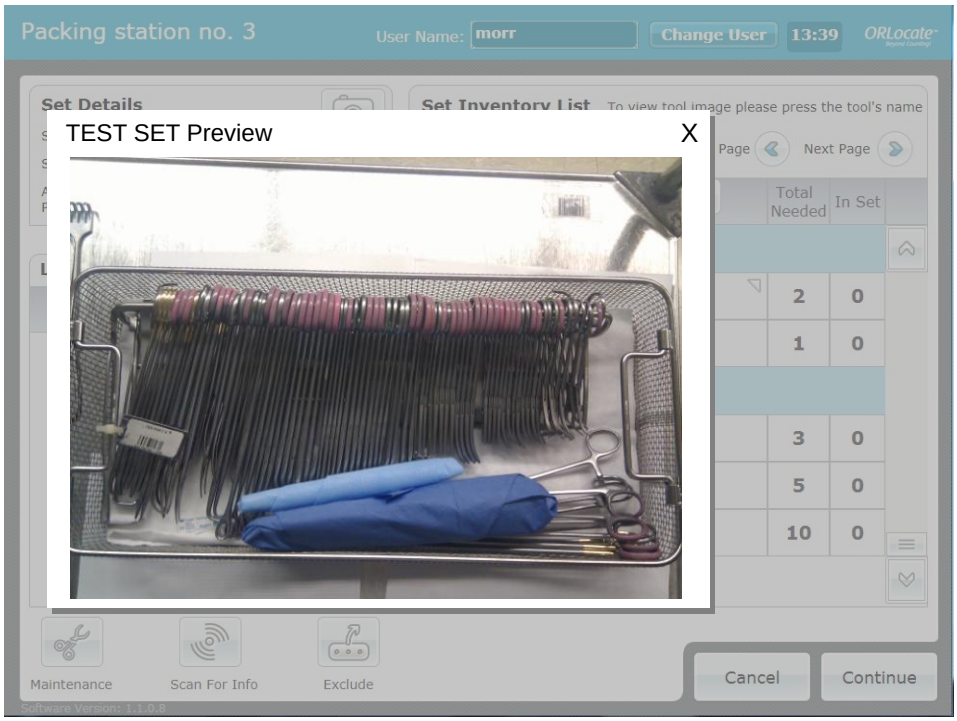


Figure 11

3.3. Main screen: last scanned items

In this area all items that are scanned at a given time (maximum 5 items at once) will appear. Each item type appears in a separate row with two values: the quantity of the items that were scanned **(1)**, and the still required number of items **(2)**.

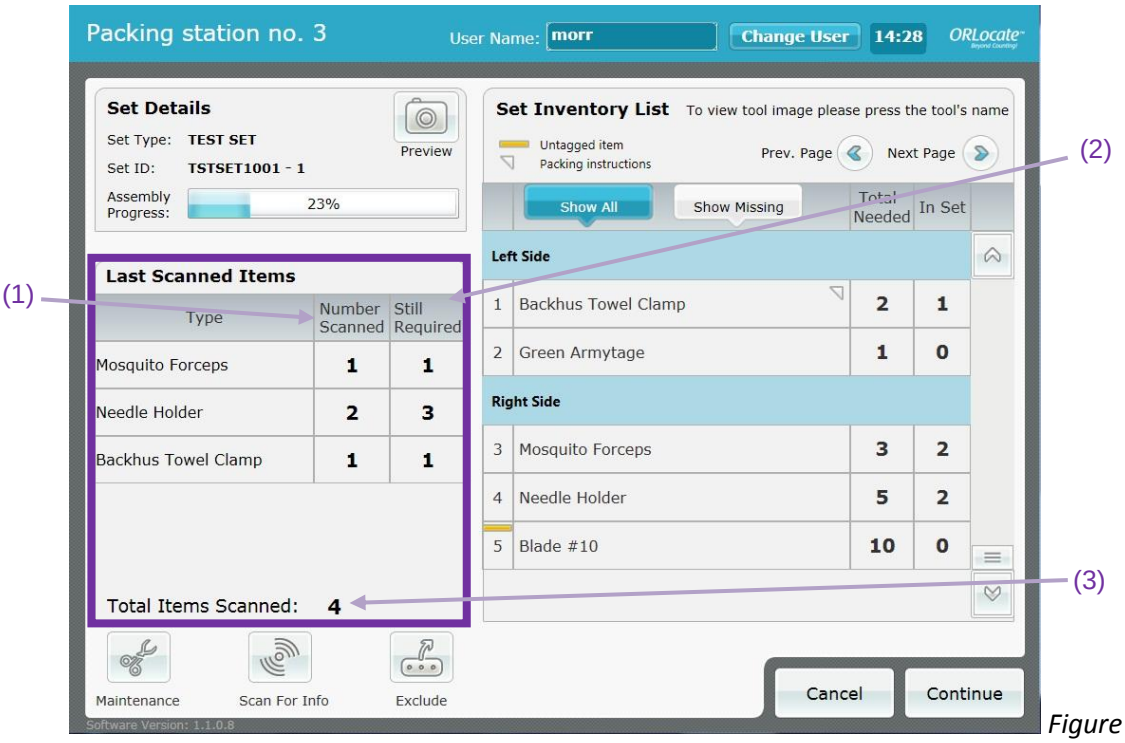


Figure 12

After scanning items ensure that the information that appears is correct and that every item that is scanned actually appears on the screen. Match between the number of items that are scanned to the value that appears at the bottom of this area **(3)**

3.4. Main screen: Function buttons

Three function buttons exist on the main screen (figure 13):

3.4.1. Maintenance button: if a defected tool is detected before inserting into the set during the routine examination of items, then the item should be registered as defected. This is done by touching the "maintenance button" and scanning the item again in the Tool Pack Antenna. See figure 14 to view the maintenance pop up.

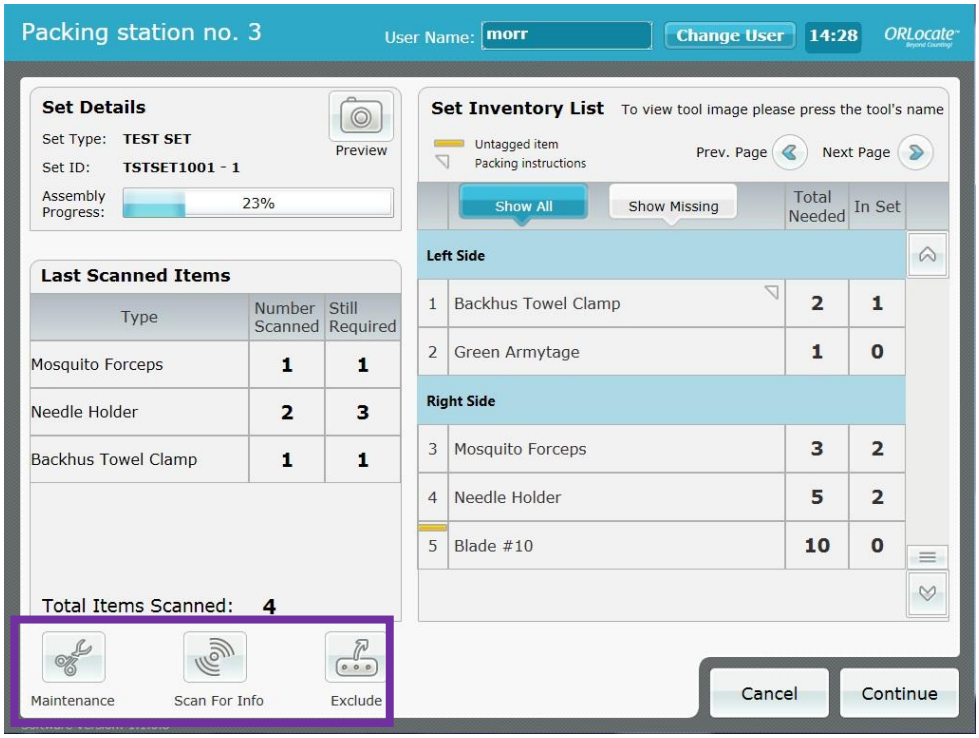


Figure 13

Screen 3.4.1: maintenance pop up

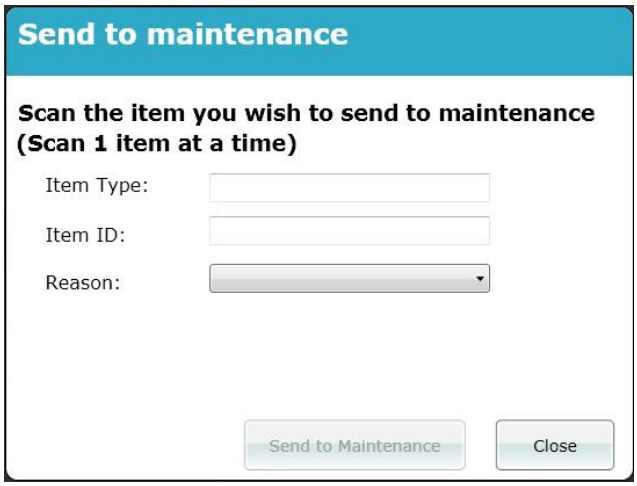


Figure 14

After scanning the item, the item's details appear on screen and the nature of the malfunction should be specified by selecting a reason in the dropdown list (figure 15).

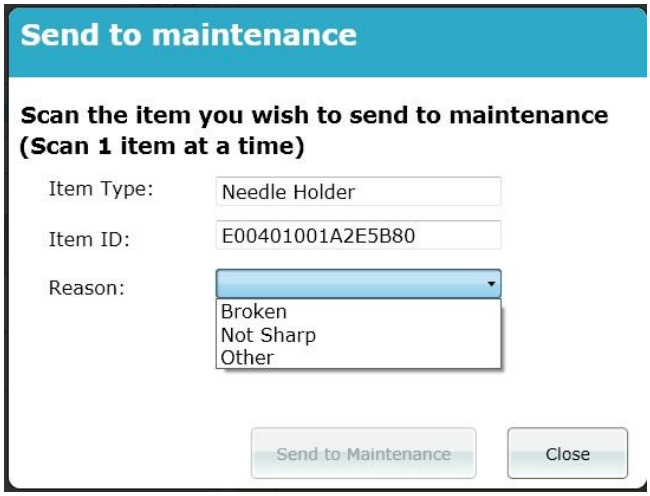


Figure 15

3.4.2. "Scan for info" button

This button enables the scanning of items for the purpose of viewing their information (figure 16). The items scanned will not be registered as packed in the set.

Screen 3.4.2 : scan for information pop up

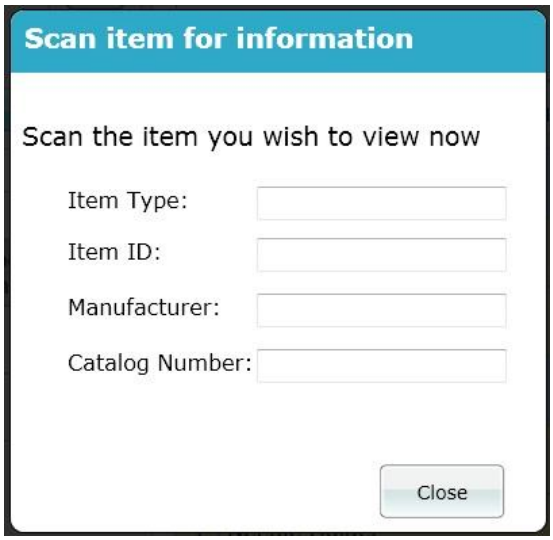


Figure 16

3.4.3. Exclude button

If items were scanned by mistake or for any other reason, they can be removed from the set inventory by touching the "Exclude" button (figure 17 shows the exclude pop-up).

Screen 3.4.3: exclude

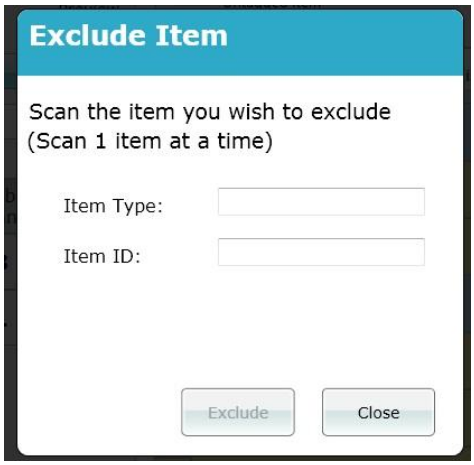


Figure 17

4. System alerts

4.1. If an RFID tagged item was registered in the ORLocate **operating room** system as defected, it will appear as defected in the ORLocate Packing system once it is scanned (figure 18). This item can't be packed and should be sent to maintenance using the "maintenance" button as described in section 3.4.1.

If there were several items scanned and only few of them are registered as defected, all items should be scanned again one by one. When the item/s that is defected is scanned, the message will appear again.

System message: Defected item scanned

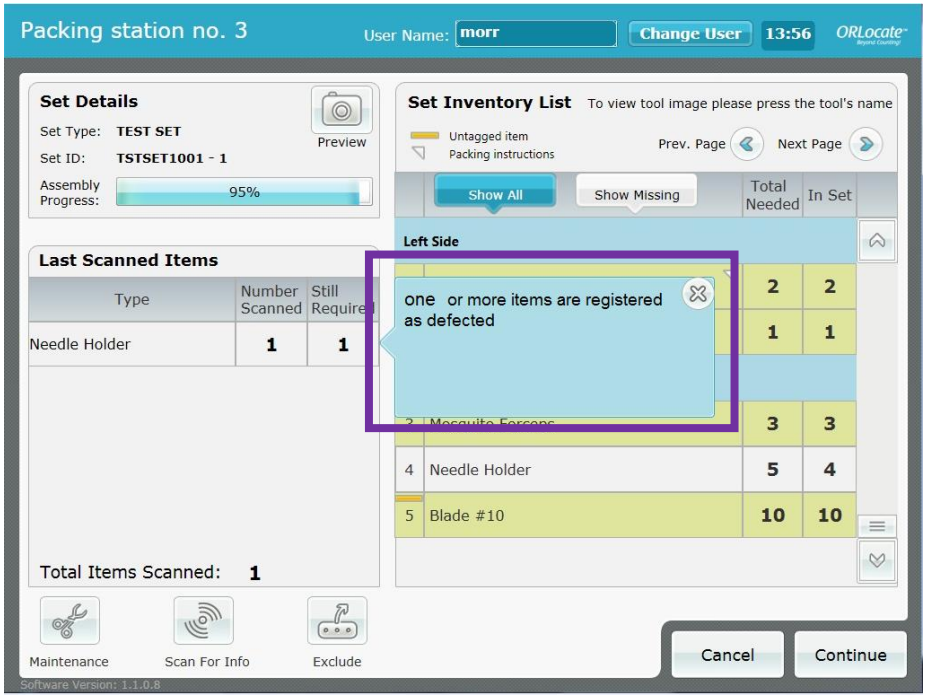


Figure 18

4.2. If items that were previously registered as going to maintenance are scanned again in the system, the system will show the following alert:

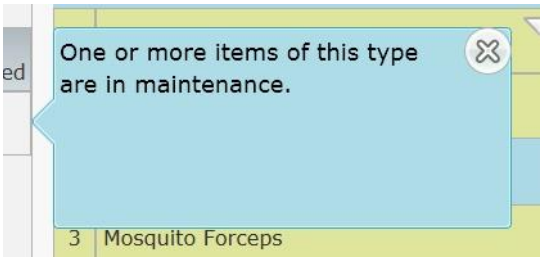


Figure 19

Items that were registered as defected (i.e. were scanned in the maintenance pop-up) cannot be packed until a system administrator scans the item as repaired in the **ORLocate Management system.**

4.3. **Replace set tag**: when the set tag has exceeded its usage period (defined by the number of times the set was packed with that tag), the tag should be replaced. The system will show an alert (see figure 20 below) right after the set tag is scanned.
Take the current set tag and discard. Take a new set tag and attach to the metal ring and to the set tray. Scan it in the Tool Pack Antenna and continue packing.

Figure 20

5. Register <u>untagged item</u>

Items that have no RFID tag should be registered manually in the system. These items are marked with a yellow line in the inventory list as shown in figure 21 below:

Figure 21

To register these items, touch the name of the item (anywhere on that row) and a pop-up will appear as shown in figure 22 below.

Insert the number of items that are being packed into the set by using the numeric keypad

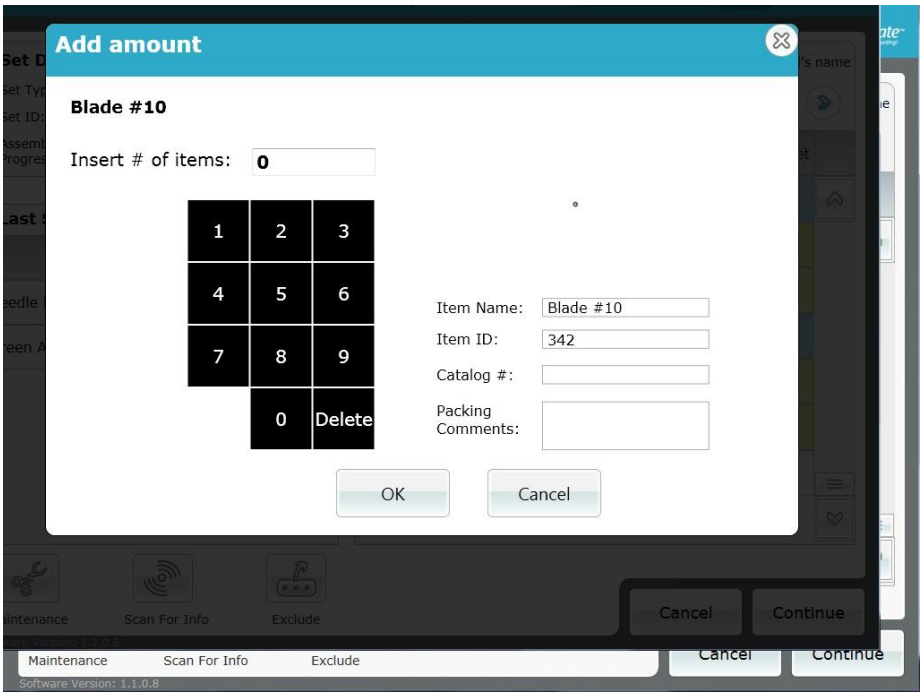


Figure 22

6. Finish packing

Once packing is finished touch the "Continue" button as shown in figure 23 below:

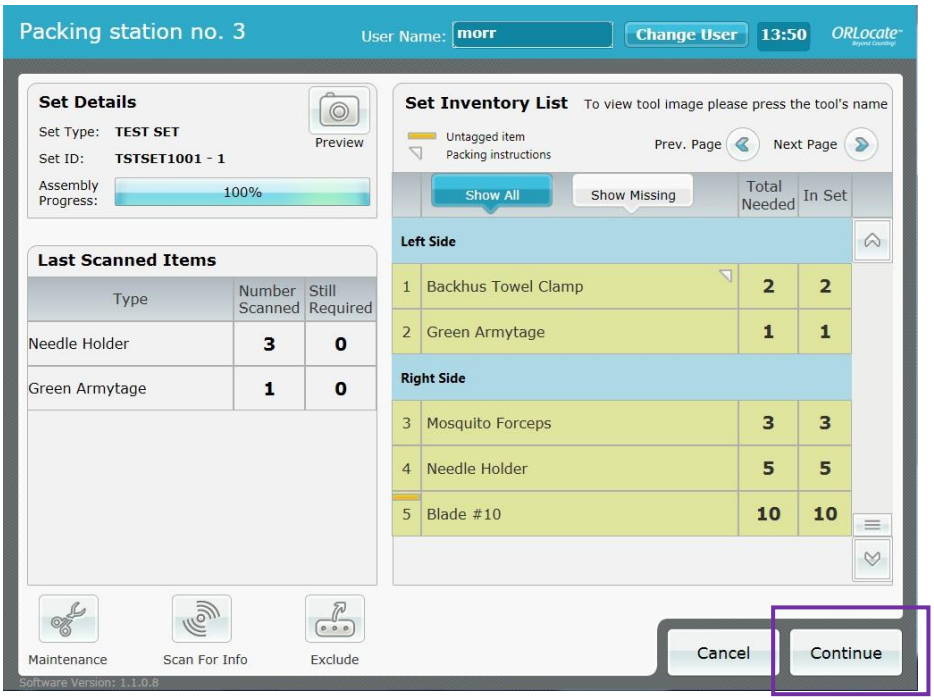


Figure 23

If there are items not packed, the system will show on the left side of the screen the missing items, as shown in figure 24 **(1).** To continue packing the missing items, touch the "Back" button **(2).** To finish the packing procedure for this set, touch the "Done" button **(3).**

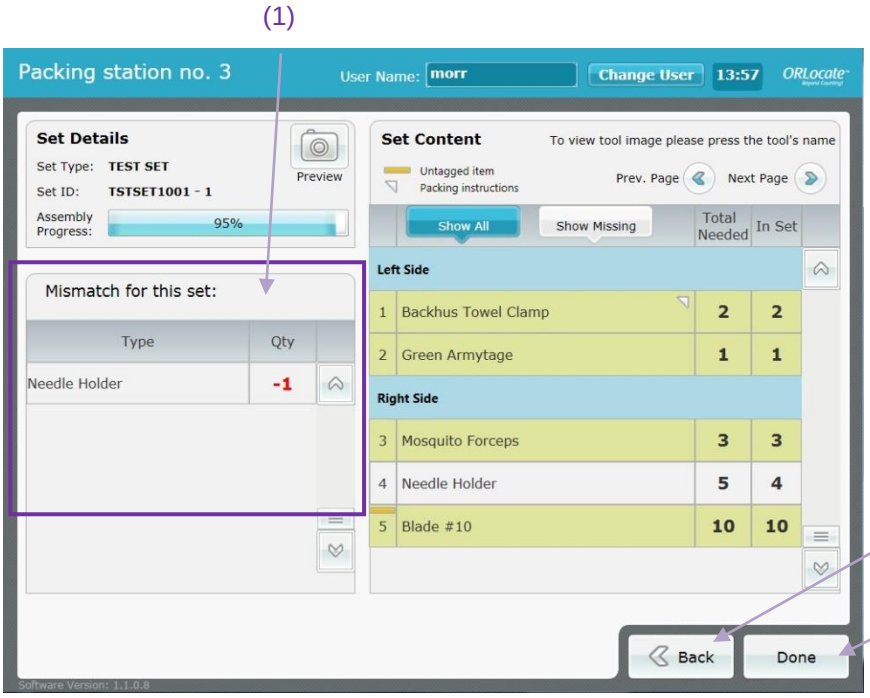


Figure 24

7. THE ORLOCATE™ FUNCTIONALITY

7.1 INFORMATION THAT IS ALWAYS AVAILABLE IN THE SYSTEM

The user interface continuously displays the following information (main screen):

- Number and type of items that need to be in the set.
- Number and type of items that were already scanned for this set.
- Set name and ID number.
- Assembly progress status (% of set already packed).
- Number and type of items recently scanned.
- Upon user request the system will show a photo of the item chosen along with packing instructions, if they exist for that item.
- System shows an indication for an untagged item.

7.2 PRODUCT FUNCTIONS

- Scan RFID tagged items.
- Update inventory according to scan.

- View only missing items (items not yet packed).
- Untagged items registration.
- Item information – photo and packing instructions for items.
- Warnings - item that was registered as defected at a different station cannot be packed.
- Registering items as defected (during the quality check of an item, before scanning into the set).
- Change user – in the middle of packing.

8. SHUTTING DOWN THE SYSTEM

In order to shut down the system the user should turn off the on/off switch on the back of the Panel PC as seen in the figure 25 bellow:

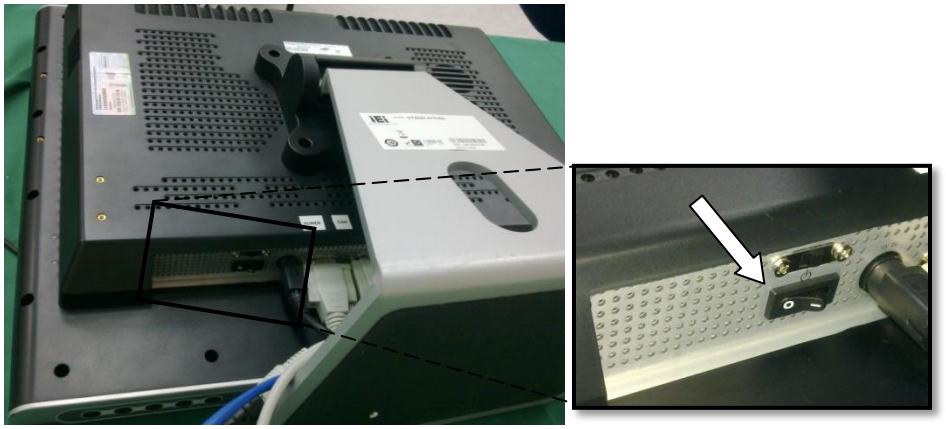


Figure 25: on/off switch

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 the System (see below)	From time to time, as needed	User / cleaning personnel
Check components and cables for signs of damage or wear.	Monthly	Maintenance personnel.

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

9.2 CLEANING PROCEDURE

In order to maintain the system in optimum condition, clean the system periodically.

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

To clean the system:

(1) Wipe down **the Tool Pack Antenna** 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 the Touch Screen panel with a damp cloth.
(4) In case of dirt that is not removed using a damp cloth, use a spray cleaner for LCD panels or a cloth soaked with 70% alcohol.

9.3 OBTAINING SERVICE:

Contact the Haldor ORLocate™ representative:

USA Support	Outside of USA Support
Haldor USA Inc. **Tel:** 314-963-3223 **Address:** 1401 S. Brentwood Blvd. STE # 585, St Louis, MO 63144 **E-mail:** support@haldor-tech.com	Haldor 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 SYSTEM 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 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™ Packing System failure.	Contact service.

Condition	Possible Cause	Recommended Action
Item scanned but does not appear on screen	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 closer to the antenna
	RFID tag is faulty.	Remove the item that is faulty and contact Haldor Advanced Technologies Ltd. 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 cable has become detached.	Connect cable.
	An Antenna cable is damaged	Contact service for a replacement.
	An Antenna is disconnected from the Panel PC	Connect cable
	An Antenna is disconnected from power supply	Connect cable to power supply
System Indicates Antenna Failure	Antenna electronics have failed.	Contact service for an antenna replacement.
Antenna Housing is Cracked or Broken	Antenna has been dropped or misused.	Contact service for an antenna replacement.
Screen freezes – system crash loses all data	Faulty computer CPU.	Stop using the system and contact service for support.
	Faulty power supply.	Stop using the system and contact service for support.
	Faulty/crashed Windows operating system.	Stop using the system and contact service for support.
Antenna is not functional	Faulty digital input/output mechanism Module (internal component of Tool Pack).	Stop using the system and contact service for support.
System not functional	Power supply failure.	Stop using the system and contact service for support.

Condition	Possible Cause	Recommended Action
Display on screen is faulty or incorrect position, causing errors in touchscreen use	Touchscreen is cracked.	Stop using the system and contact service for support.
	Touchscreen is not calibrated.	Stop using the system and contact service for support.
	Touchscreen is dirty.	Clean the screen.
Touchscreen detects touch in wrong position	Touchscreen is not calibrated.	Stop using the system and contact service for support.

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):	300 Watt
Input Voltage Range:	100 to 240 VAC at 50 to 60 Hz
Current (max):	3 A

12. SYSTEM SPECIFICATIONS

In addition to the specified in paragraph 3.1 - Description of System Components, the following specifications shall apply to each component:

Note: The Tool Add antenna can hold a maximum amount of RFID- tagged items (instruments). Do not exceed the quantities detailed in the table below:

	Tool Pack Antenna 	**Panel PC** 
Max. amount of items	5 instruments	NA
Max detection distance	Up to 6 cm	NA
Weight (Kg)	4.8	**According to the PC model**
Dimensions WxHxD (cm)	22x33x13	**According to the PC model**

13. EMC CONSIDERATIONS

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

Table 2 - 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 System is intended for use in the electromagnetic environment specified below. The customer or user of the ORLocate 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 mobile communications equipment should be separated from the ORLocate 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 System is used exceeds the applicable RF compliance level above, the ORLocate 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 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 3 - According to Table 206 from IEC 60601-1-2
Recommended Separation Distances between portable and
Mobile RF Communications equipment and the ORLocate System

Equipment and Systems that is NOT Life-supporting

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

Max Output Power (Watts)	Separation (m) 150 kHz to 80MHz $D = (3.5/3)(\sqrt{P})$	Separation (m) 80 to 800MHz $D = (3.5/3)(\sqrt{P})$	Separation (m) 800MHz to 2.5GHz $D = (7/3)(\sqrt{P})$
0.01	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 Packing System contains a receiver operating at a frequency of 13.56 MHz +/- 7 kHz.

The ORLocate Packing 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 Packing 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.

