ORLocate®
Beyond Counting!

SPD
(Sterile Processing Department)
Work Stations

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

USER MANUAL
REVISION 3.0

Haldor
advanced technologies ltd.

Text revised January 2014.

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1.   INTRODUCTION

1.1 THE HALDOR ORLOCATE[R] SPD WORK STATIONS

Haldor ORLocate[R] **SPD** Work Stations system is a supplementary system for the Operating Room ORLocate[R] system and to the ORLocate[R] Management system, which is described in a different User Manuals.

Generally, Haldor ORLocate[R] 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[R] **SPD** Work Stations 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[R] **SPD** Work Stations provides a method for packing RFID-tagged surgical items within a surgical set, and is to be used during washing, sterilization and while packing units in hospitals.

1.2 ABOUT THIS MANUAL

This manual provides the information necessary to operate the Haldor ORLocate[R] SPD Work Stations 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[R] SPD Work Stations 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^R 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^R 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^R 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.

RFID:

Radio Frequency Identification – a technology that enables communication with items that have RFID-tags attached to them.
An RFID system includes a small radio transmitter that is activated by an antenna and in response sends its ID back to the antenna. Passive RFID tags, like those used in ORLocate^R, do not contain a battery.

RFID TAG:

A small, self-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^R 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

Flat Antenna (new revision name of the Mayo Antenna):

Discard properly

Flat Antenna Label

ORLocate® Flat Antenna

Model No. ORL100.013

S/N: MY-YY-0501

Haldor Advanced Technologies, Ltd.
2 Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com

EC | REP
Obelis s.a. Bd. Général Wahis 53
1030 Brussels, Belgium
Tel: +32 2 7325954

⚠ Consult accompanying documents.

⚠ Not user-serviceable. Service by trained personnel only.

Note Sterile cover required before use.

Tool Add Label

ORLocate® Tool Add

Model No. ORL100.016

S/N: TA-YY-0501

Haldor Advanced Technologies, Ltd.
2 Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com

EC | REP
Obelis s.a. Bd. Général Wahis 53
1030 Brussels, Belgium
Tel. +32 2 7325954

⚠ Consult accompanying documents.

⚠ Not user-serviceable. Service by trained personnel only.

Note Sterile cover required before use.

Tool Pack Label

ORLocate® Tool Pack

Model No. SPD-100

S/N: TP-YY-0501

Haldor Advanced Technologies, Ltd.
2 Habanai st. Hod Hasharon 45319, Israel
Tel: +972 9 7885858 , Fax: +972 9 7885861,
Email: support@haldor-tech.com

⚠ Consult accompanying documents.

⚠ Not user-serviceable. Service by trained personnel only.

FCC ID: X4V-SPD
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.

Package Labeling for the ORLocate^R Packing System:

ORLocate® Packing System:

Fragile: Handle with care

This Side Up

Keep Dry

Transport & Storage (-40°C / 70°C)

Model No. ___

S/N____

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

3.   INTRODUCTION TO THE HALDOR ORLOCATE^R SPD WORK STATIONS SYSTEM

For general introduction - see chapter 1.1. The Haldor ORLocate^R SPD Work Stations System.

The functionality of the SPD System and its stations in the complete solution workflow is presented in the following diagram:
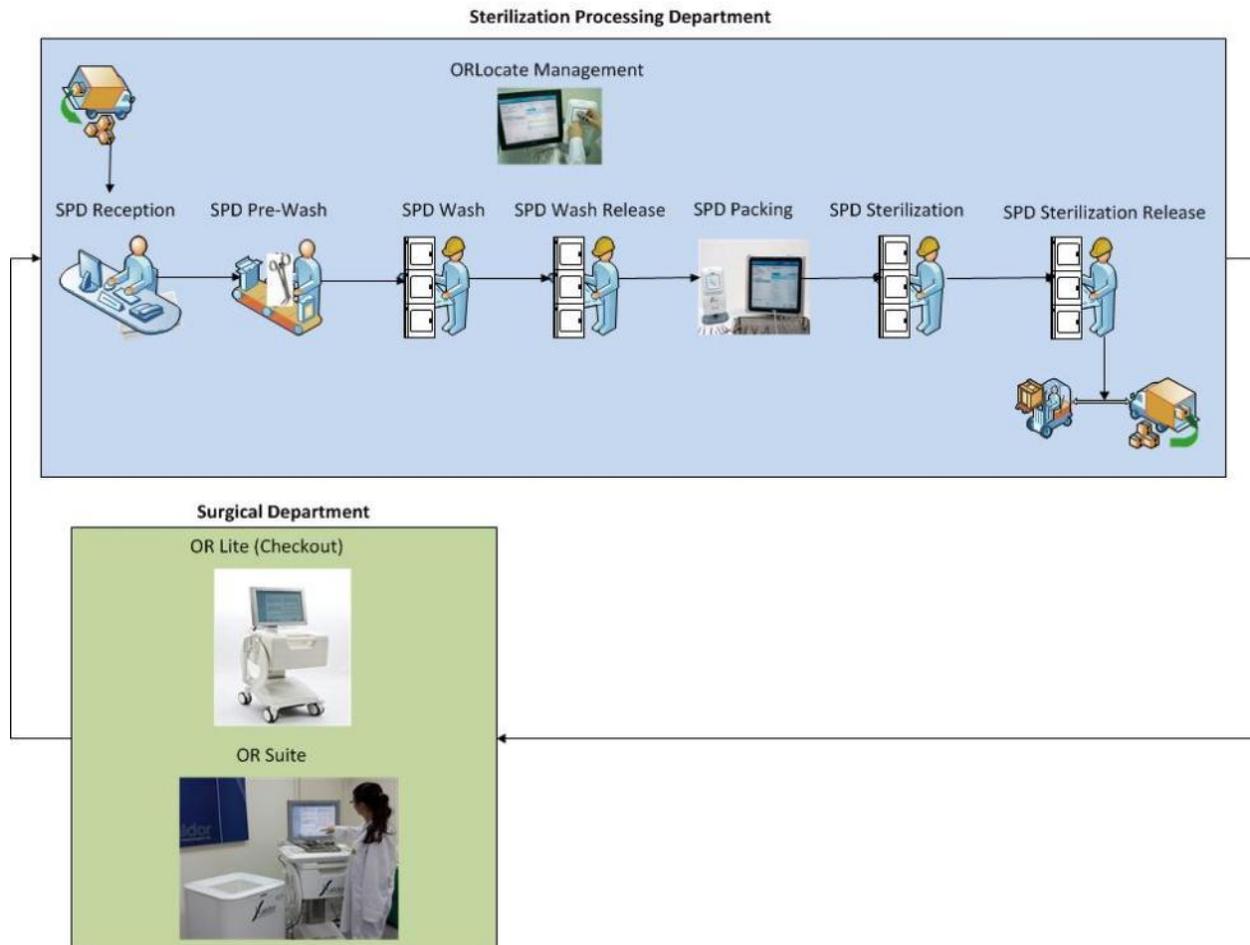
3.1 DESCRIPTION OF SYSTEM COMPONENTS

The system includes the following main components:

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.

Figure 1

3.1.2 FLAT ANTENNA

The Flat Antenna is used for counting RFID tagged surgical instruments, in the SPD Reception station.

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

3.1.3 TOOL-PACK ANTENNA

The Tool Pack Antenna is used to scan RFID tagged surgical instruments before placing them inside the set. RFID tagged instruments should be held near the antenna as shown in the figure on the right.

The feedback for reading the instrument is 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 hold it steady / rotate it 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:

> ⚠ **Continuous stay next to the Tool Pack should be limited for up to 3 minutes within a distance of 10 cm (4") or less.**
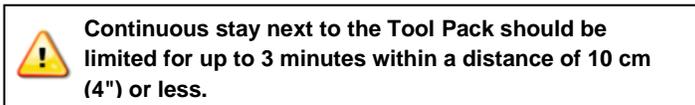
3.1.4 TOOL-ADD ANTENNA

The Tool Add Antenna is used to scan RFID tagged surgical instruments before placing them inside the set. RFID tagged instruments should be held near the antenna as shown in the figure on the right.

The feedback for reading the instrument is an indication on the currently opened screen, specifying which instrument was detected.

Note: Move the RFID tagged item close to the Tool Add Antenna and hold it steady / rotate it 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 Add:

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

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

3.1.5 HAND HELD READER (SCANNER)

The Hand-Held Reader is used to scan ID card, set, net, rack or trolley ID, in the Packing stations.

> **Note**: Only Single tag\barcode should be scanned at one time.

3.1.6 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 with RFID tags shall be sterilized according to the standard protocol.

4.2 CLEANING ANTENNAS

The Flat Antenna and Tool Pack Antenna can be cleaned with any conventional material that is used to clean the packing station (see section 9.2 for detailed cleaning instructions).

5. SETTING ORLOCATE^R PACKING SYSTEM COMPONENTS

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

5.1 SETTING THE PANEL PC (TOUCH SCREEN)

The Panel PC should be located close to where the processing personnel/technician is located during assembly to enable easy viewing of the screen, and close enough to the Hand Held reader or the Flat or Tool Pack/Add Antenna to enable an ergonomic operation, as shown in the following picture of each SPD station.

The components (Panel PC, Hand Held Reader and/or antenna) shall be connected to AC power and to the network as detailed in the specific following table in each SPD station.

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 the following figure:
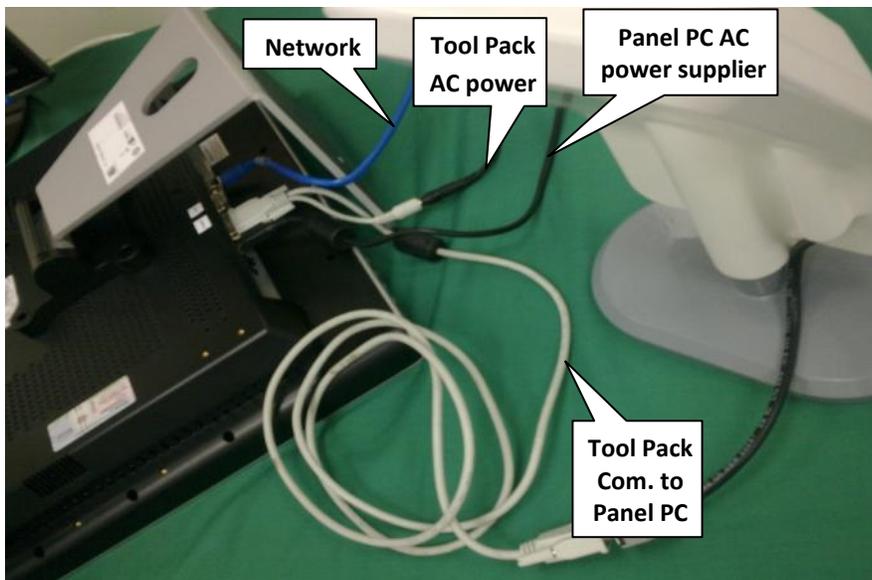
6.   USING THE SYSTEM

6.1 GENERAL PRINCIPLES OF USE

(1) Each set tray has a unique barcode label and/or an RFID tag that indicates which type of set it is (e.g., "General Basic").
(2) Before the packing personnel/technician starts packing, the set barcode or tag should be scanned via the Hand held reader (Scandy), 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 (required quantity), and 2) the actual number that was inserted into the set.
(3) Any RFID tagged instrument that is added to the set tray during packing must be scanned **via "tool pack" antenna 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

6.2.1 SPD RECEPTION
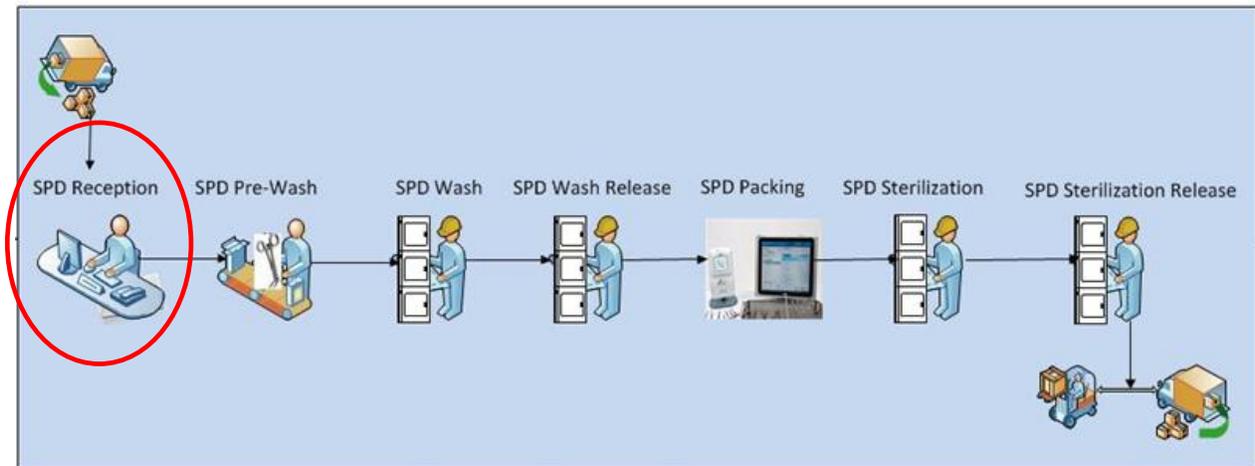
Reception Station Picture:

Station to be located on a table as shown:

Reception Station Components:

Tool Add Antenna	Flat Antenna	Hanfheld Scanner*	Reader Controler	Pannel PC*
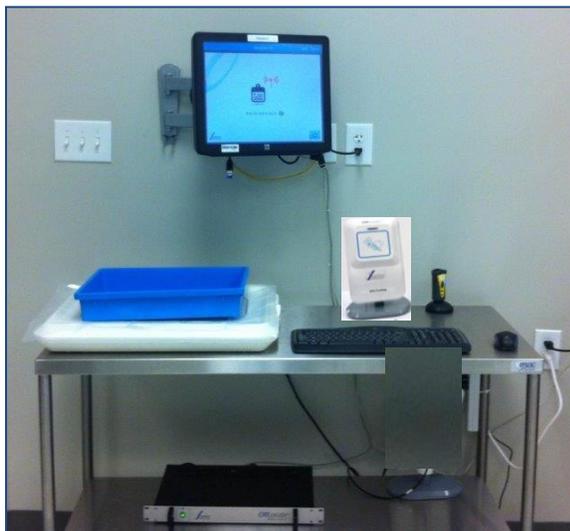
Required Infrastructure:

- 5 x power sockets.
- 1 x network socket.

Reception Station User Interface:

To login scan ID card of authorized technician using the handheld reader or manually enter ID # of the authorized technician by pressing on the **Keyboard icon** and then typing the name and password and touching the "Login" button as shown in the following figure.
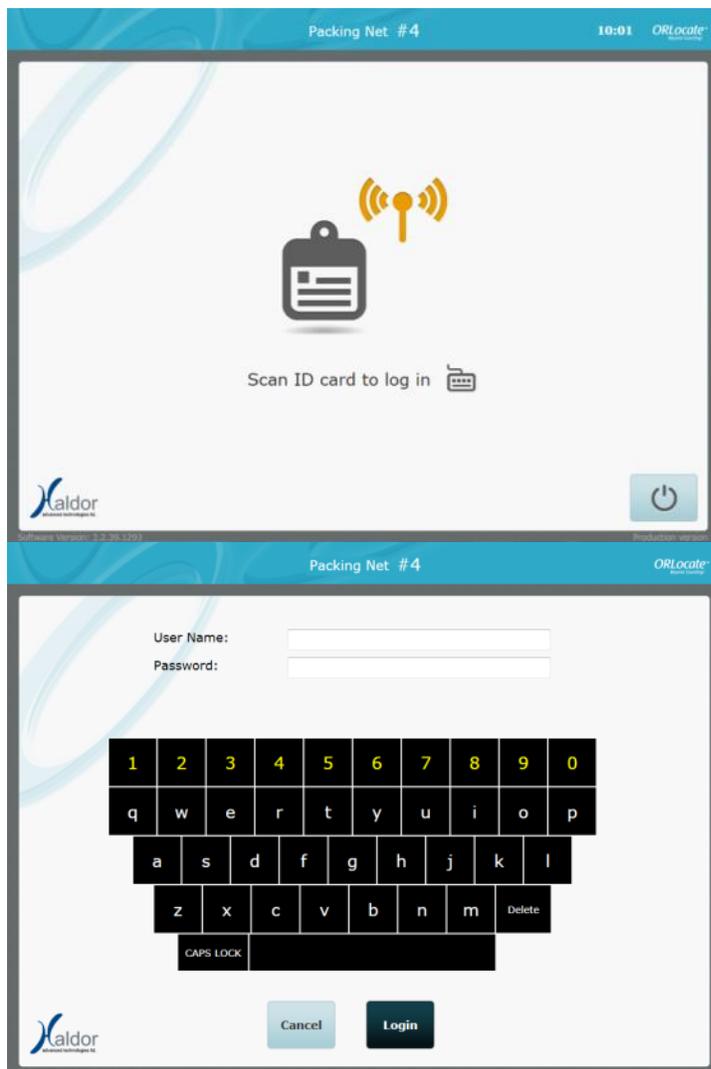
Scan Trolley ID by the handheld reader:
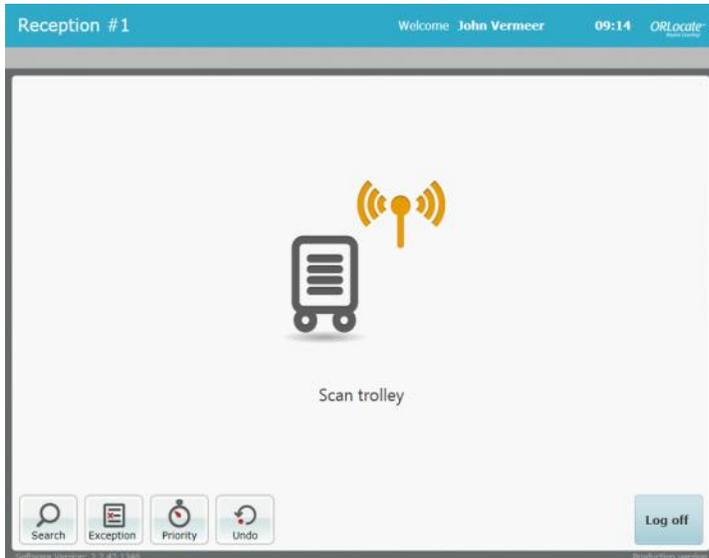
Scan Wash Net, Plastic Bin or Peel-Pack by the handheld reader:

The system will automatically move to the next screen, reception main screen as shown in the following figure.

The main screen includes 5 areas:

1. On the top of the screen is the main title displaying the set details: ID, Name, customer, priority.
2. Beneath this area is the secondary title displaying related Wash nets.
3. The table displaying the inventory list in the center of the screen. The inventory list includes all items that comprise the set divided to different areas or levels of packing.
4. In the forth area of the screen (bottom left and center) the function buttons are located.
5. In the fifth area (bottom right) the navigation button is located.

Activate Flat Antenna to count by clicking on the "Scan All" button.
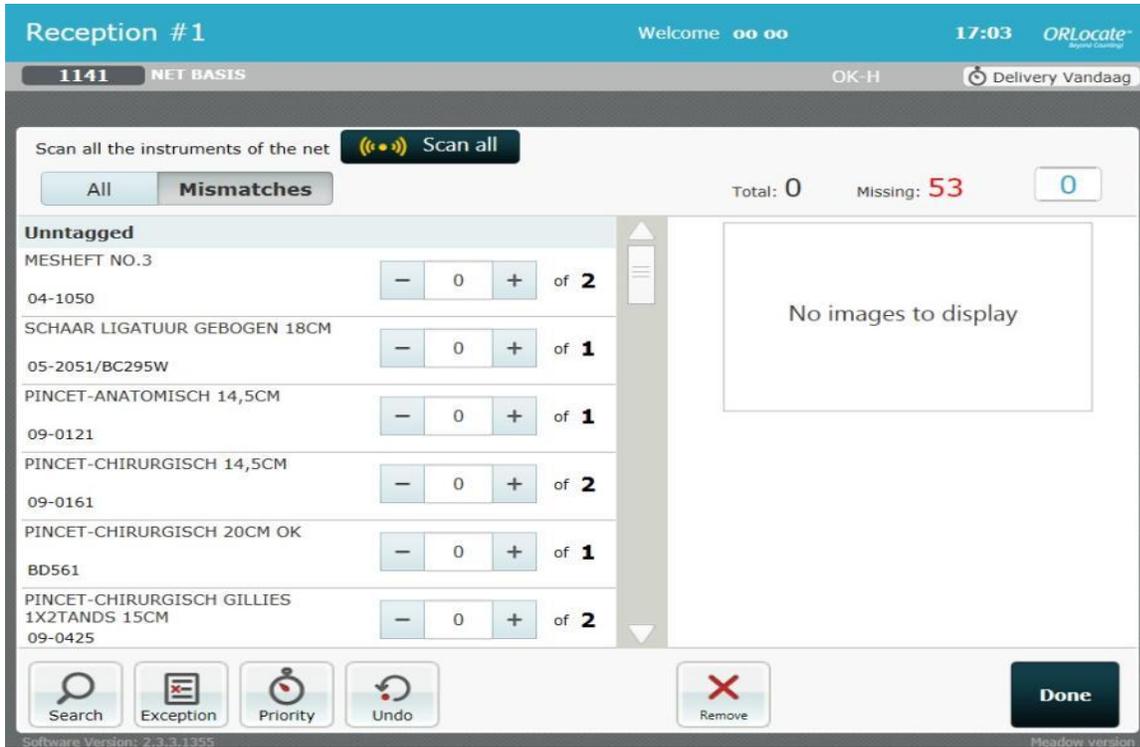
## 6.2.2   SPD PRE-WASH
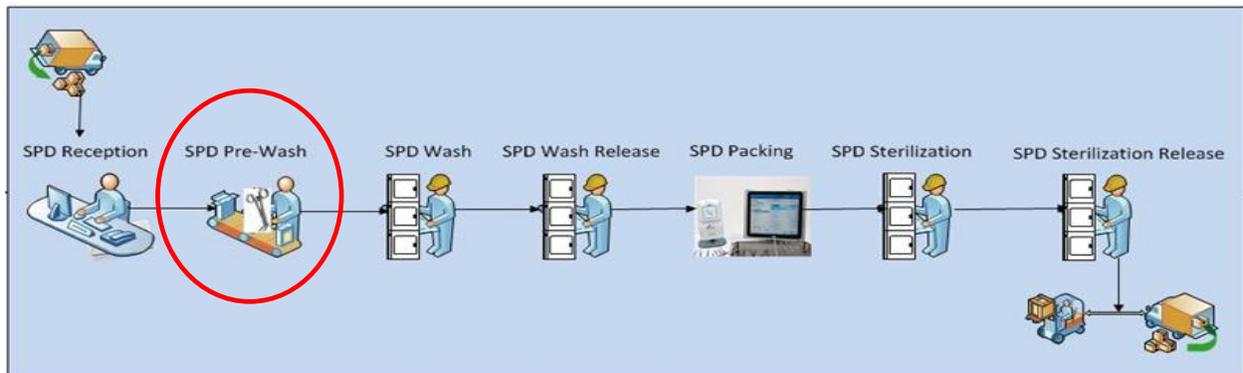
Pre-Wash Station Picture:
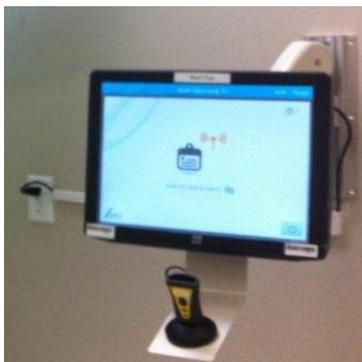
Station to be located on a table or mount on the wall with arm as shown.

Pre-Wash Station Components:

Required Infrastructure:

- 2 x power sockets.
- 1 x network socket.

**Pre-Wash Station User Interface:**

Scan ID card or enter ID # :
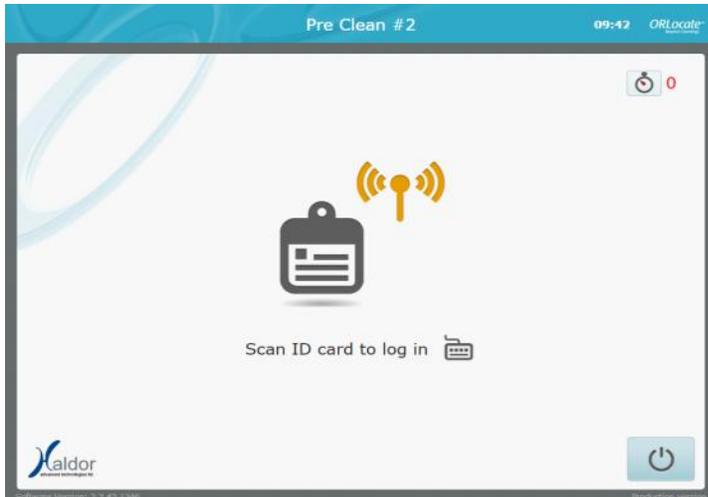
Review & Execute washing instructions per item:
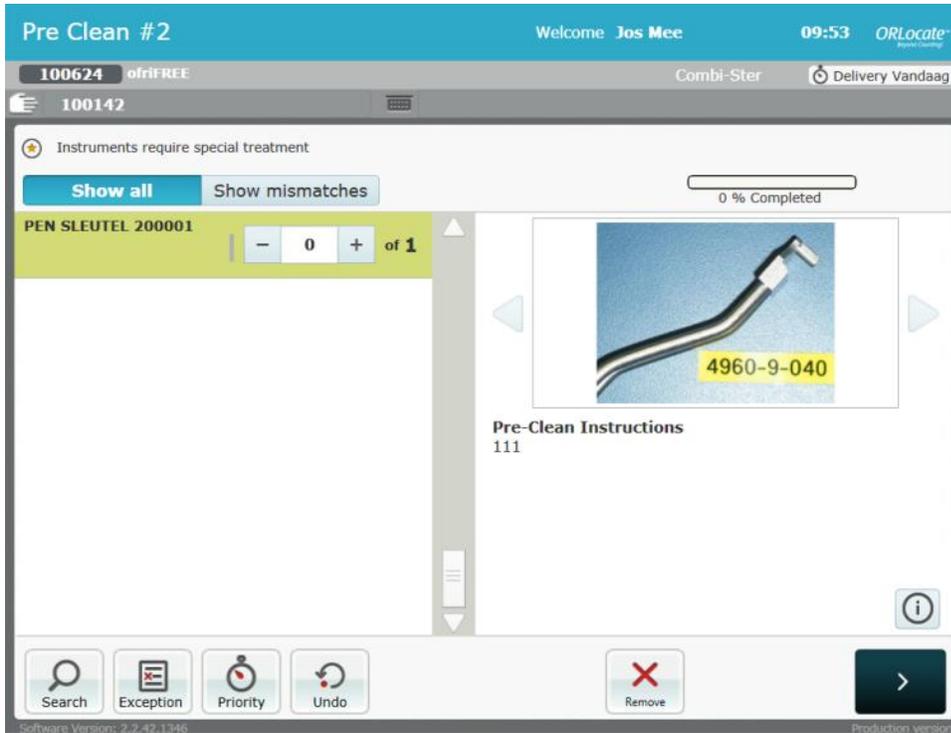
Separate to sub-net per instructions.

6.2.3   SPD WASH
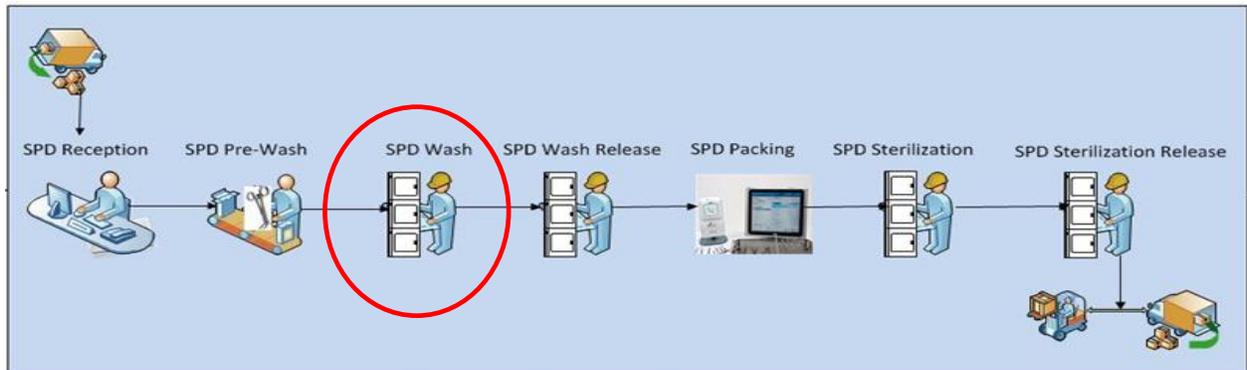
Wash Station Picture:

Station to be located on a table or mount on the wall with arm as shown:

Pre-Wash Station Components:


**Required Infrastructure:**

- 2 x power sockets.
- 1 x network socket.

Wash Station User Interface:

Scan ID card or enter ID # :
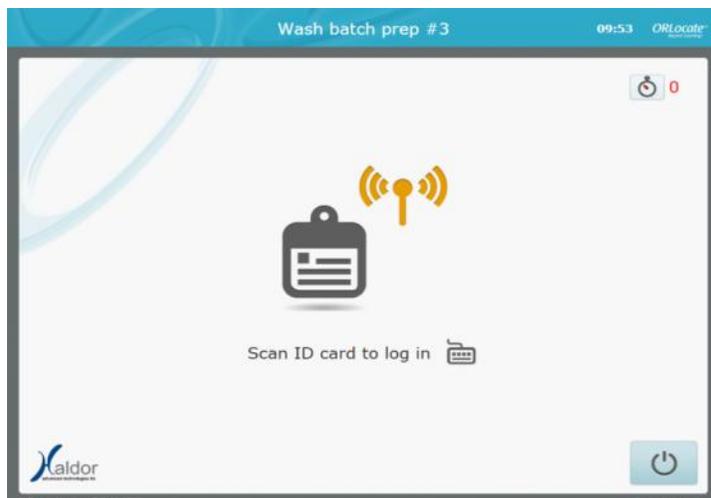
Select Washer:
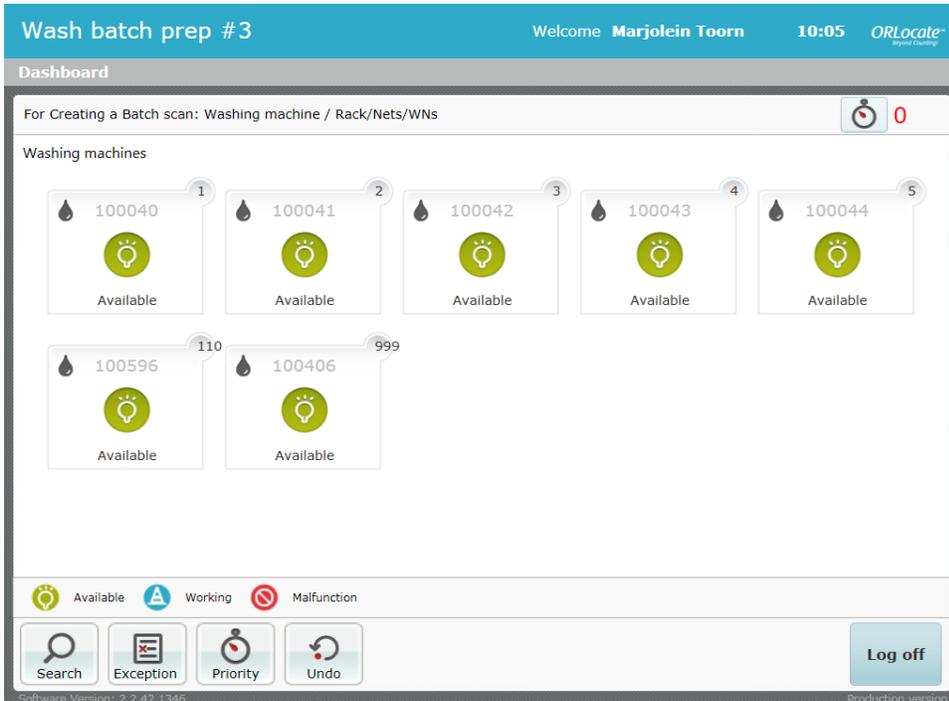
Load Wash Rack with items, and scan Wash Rack & items (create batch):
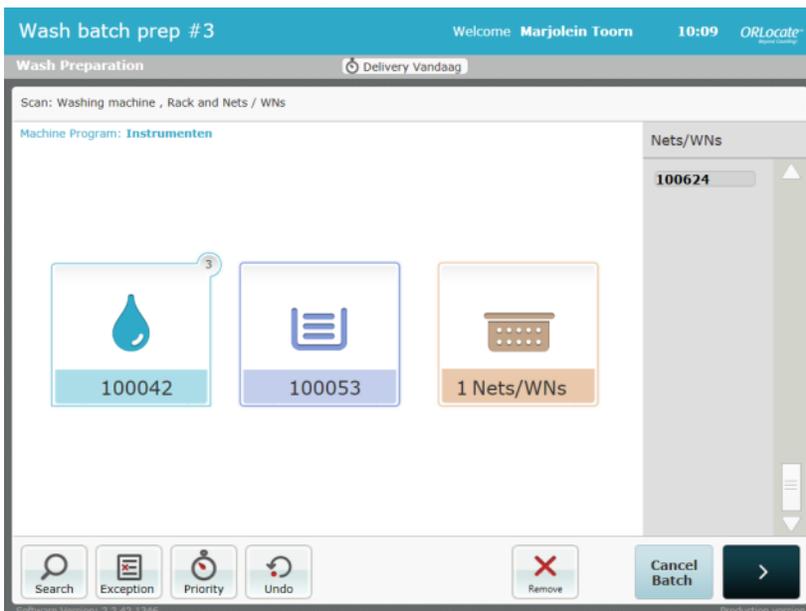
6.2.4 SPD WASH RELEASE
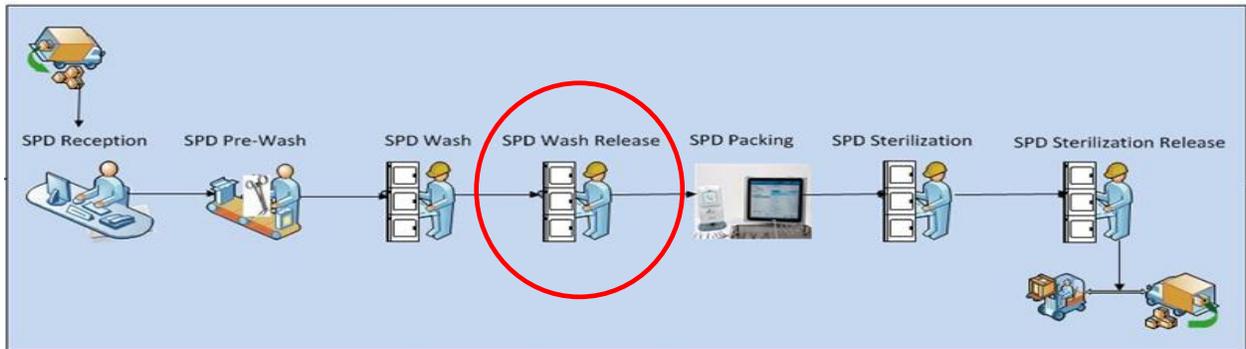
Wash Release Station Picture:

 Station to be located on a table or mount on the wall with arm as shown.

Wash Release Station Components:

Required Infrastructure:

* 2 x power sockets.
* 1 x network socket.

Wash Release Station User Interface:

Select Washer and Manage Dryer Cycles:
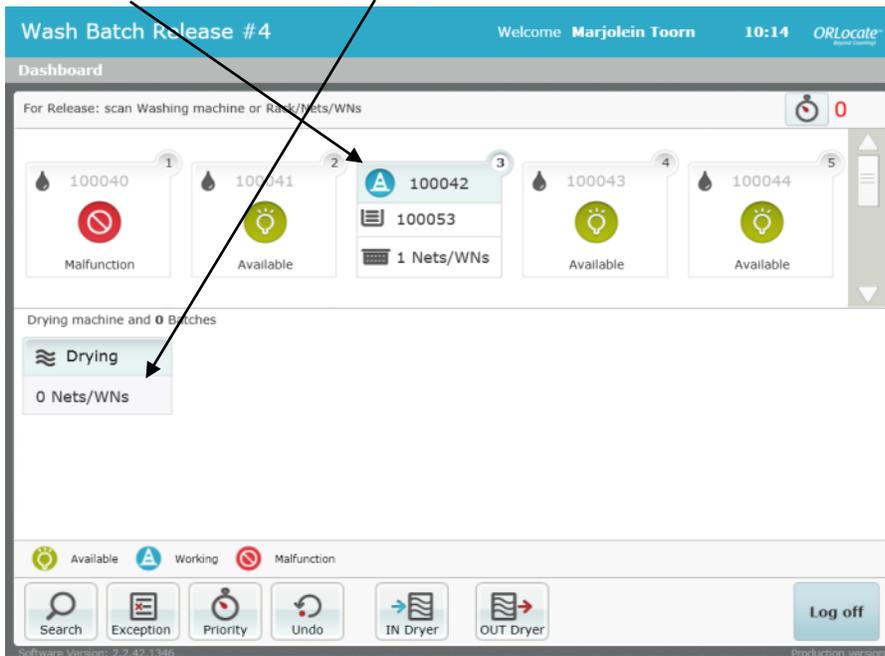
Release from Dryer:
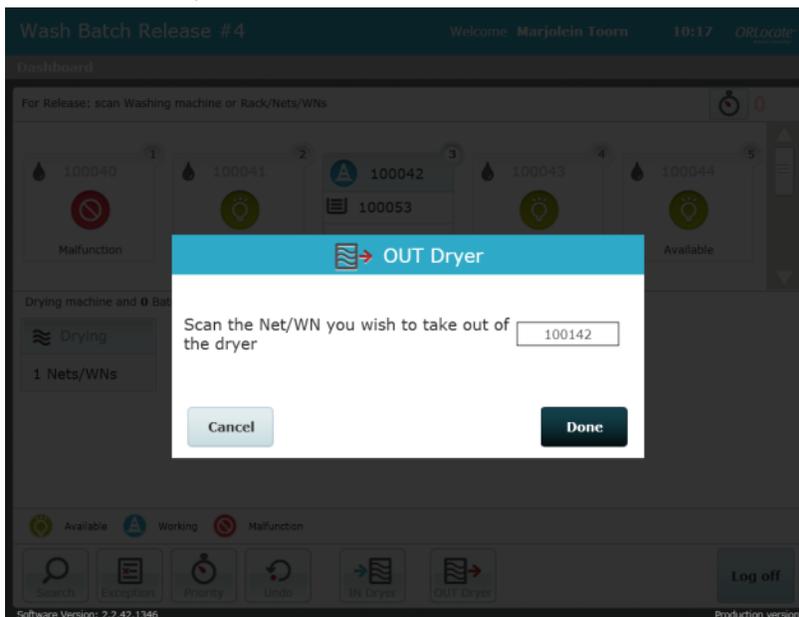
6.2.5   SPD PACKING
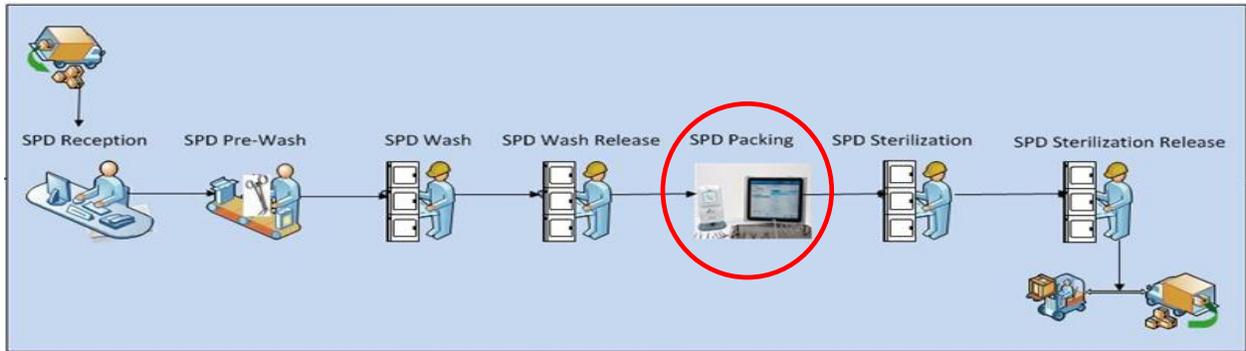
Packing Station Picture:

Station to be located on a table as shown.

Packing Station Components:


Required Infrastructure:

- 4 x power sockets.
- 2 x network sockets.
- A4 laser printer.

Packing Station User Interface:

Scan Set/Net ID:
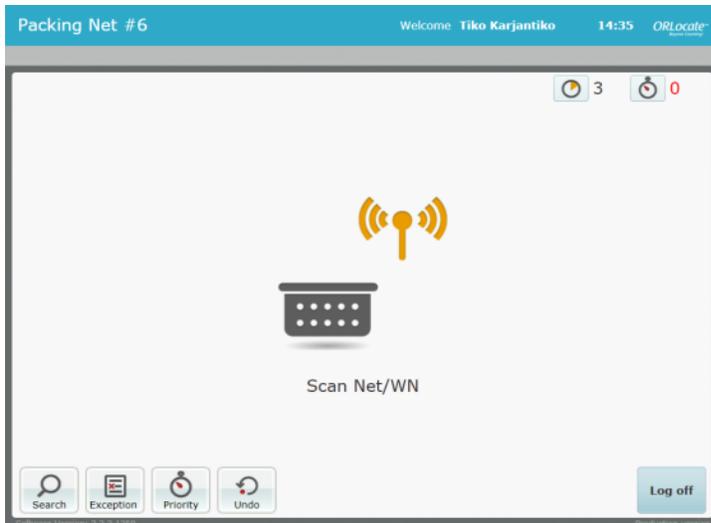
The next screen is the packing main screen shown in the following figure.
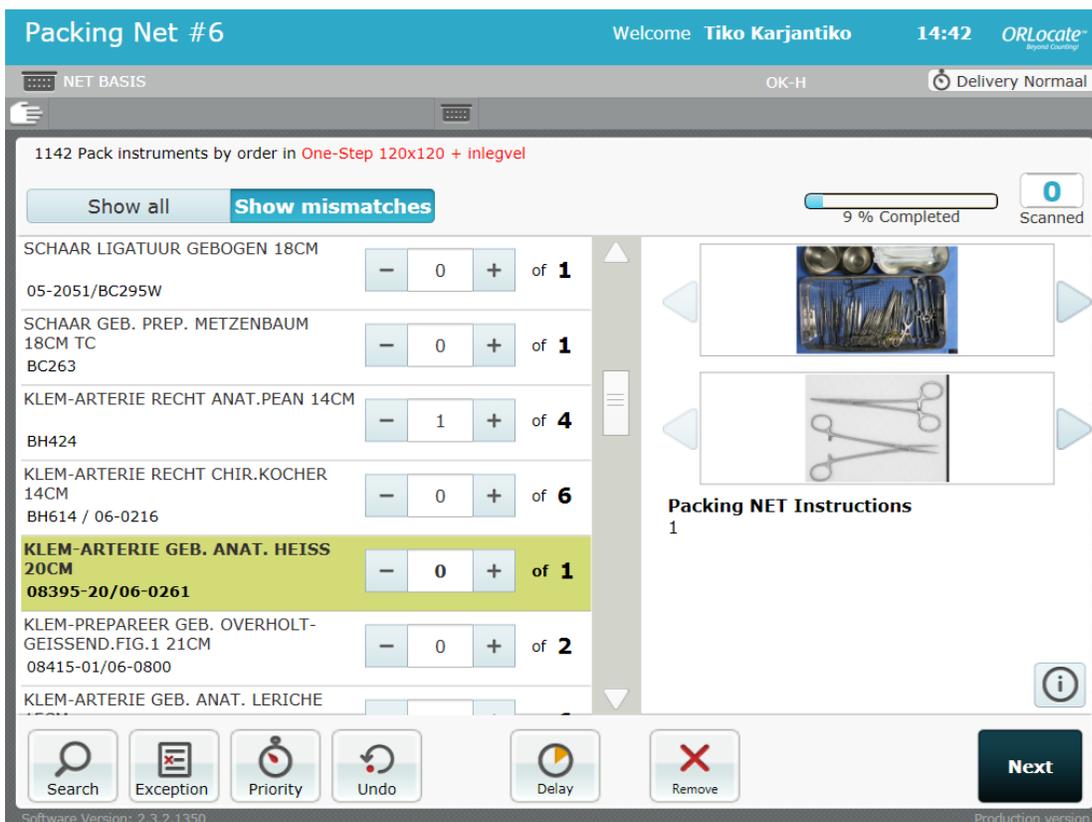
Once the main screen appears, start packing by scanning items according to the inventory list or enter manually if the instrument is not tagged.

In this screen you can also view the list of sets with high priority that are pending for packing and sets that are in delay by touching the relevant icon.

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

(1) The top part of the screen displays:

- The packaging type required for the set.
- Show all / Show mismatches - Toggle buttons that displaying two different views of the table:
  a. Show all - for a view in which all items are listed.
  b. Show mismatches - the default view that 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) or packed with more than required will appear on the list.
- Progress bar that represents graphically the progress of the assembly.
- Scanned box- displaying the number of instruments that are now being scanned.

(2) The table:

- Each row displays the item details:
  a. Item name
  b. Article # (if there are several article numbers the system will display the first)
  c. Inventory required of the item
  d. Number of packed (scanned or manually registered).
  e. If a test is required for this item it will an icon will be displayed on the row 👁 .
  f. Once all items of a certain type are packed the row changes the color to green in the Show all view. In the Show mismatches view the row disappears.
  g. Options for registering manually into the system the quantity of untagged items:
    - Pressing on the "+" or "-" icons.
    - Pressing on the number field will open a pop up for entering the number of items, as shown in the following figure.
    - If the item was taken from the storage also press on the number field for opening the pop up and then press on the plus button next to the storage icon, as shown in the following figure:
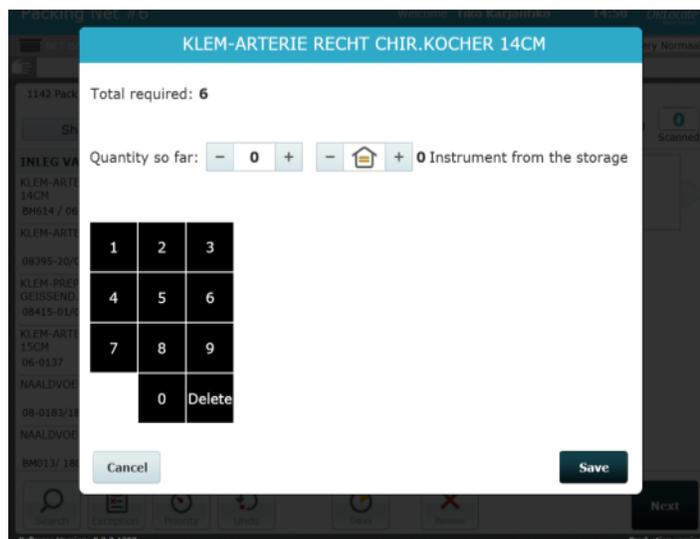
- Touching any row of the list will display details of the item on the right side: a photo of the set and of the item and its packing instructions, if specified.

a. Pressing on a photo will display the image enlarged. Pressing on the arrows next to the photo will move between the different images of the item, as shown in the following figure:

b. If a test is required for this item on the right side user will be required to mark that test was completed .

c. If in the last time the set was packed it was without the required inventory of the item, an icon of the approval will be displayed and the quantity that was missing ![icon] .

d. Touching the info button will display general information about the item, as shown in the following figure:
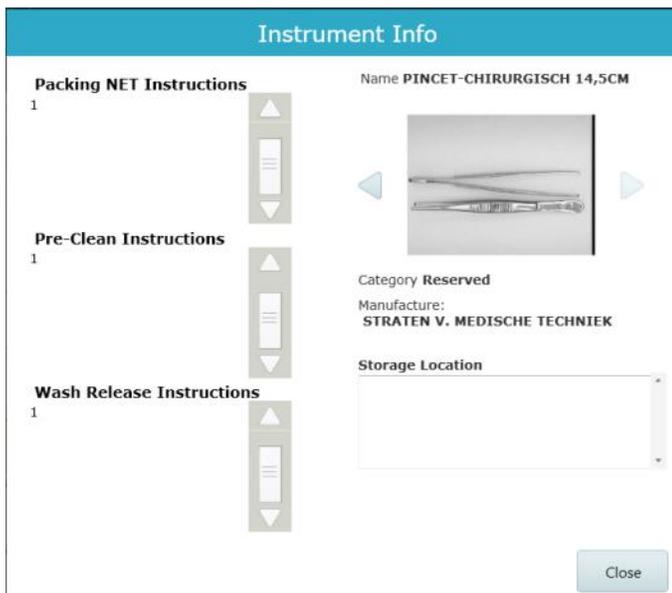
Three function buttons exist on the bottom part of the main screen, as shown in following figure:
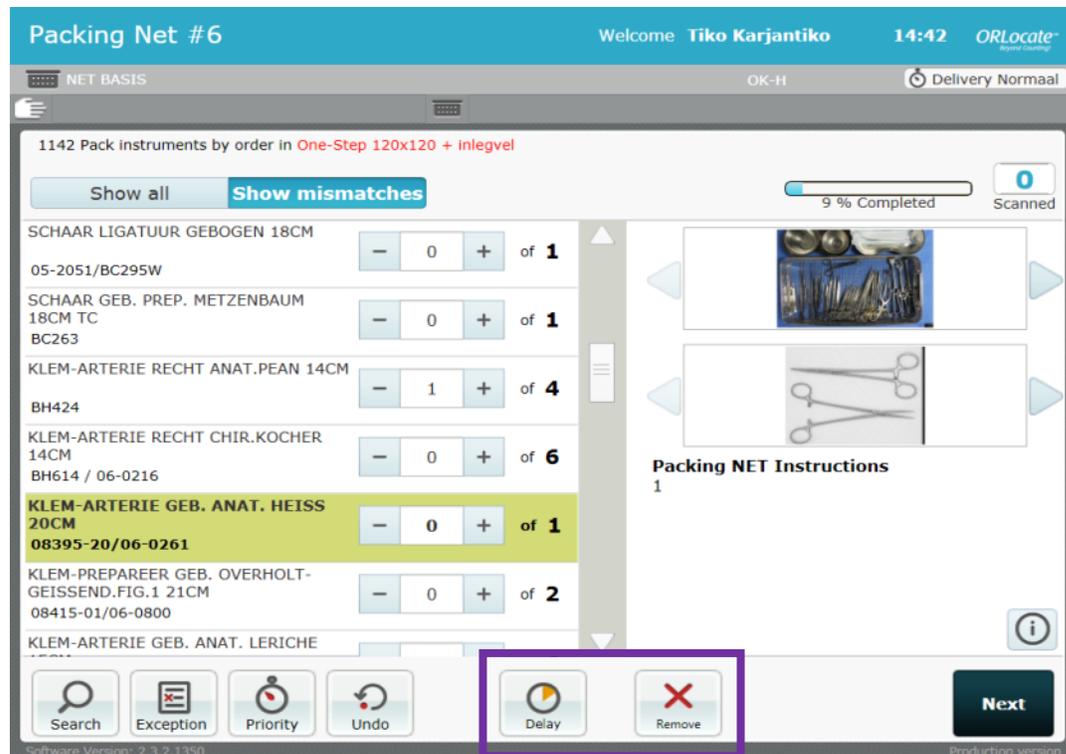
(3) Remove button:

If items were scanned by mistake or for any other reason, they can be removed from the set inventory by touching the "Remove" button. The Remove Item pop will be opened, as shown in following figure:
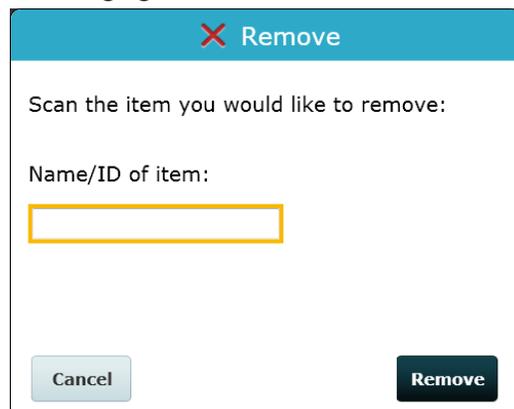
(4) Delay button

If for any reason you wish to stop packing the packing process, at any time you can press the delay button and later start the packing process from begging.

After delaying the set the number of sets in delay status will increase by one and you can view the list in the Scan set screen.

For delaying the set touch the delay button and a pop up will open for selecting the delay reason, as shown in following figure:
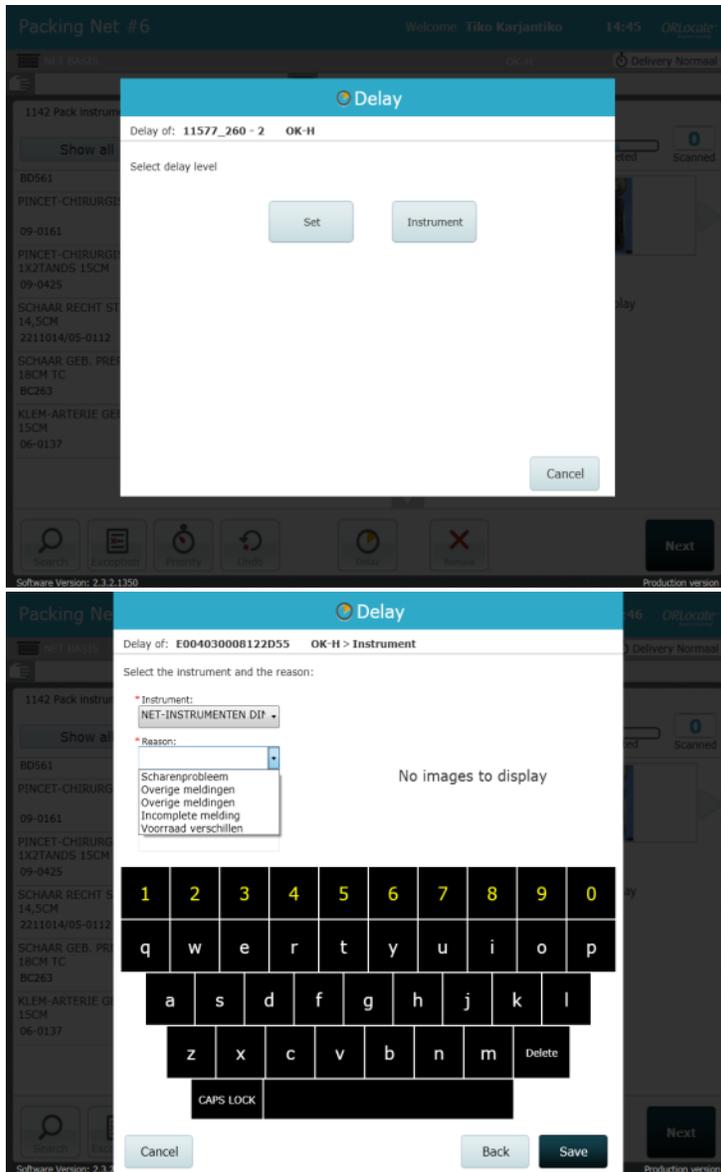
(5) Finish packing + print Count Sheet.

After completing the packing process touch the "Next" button.
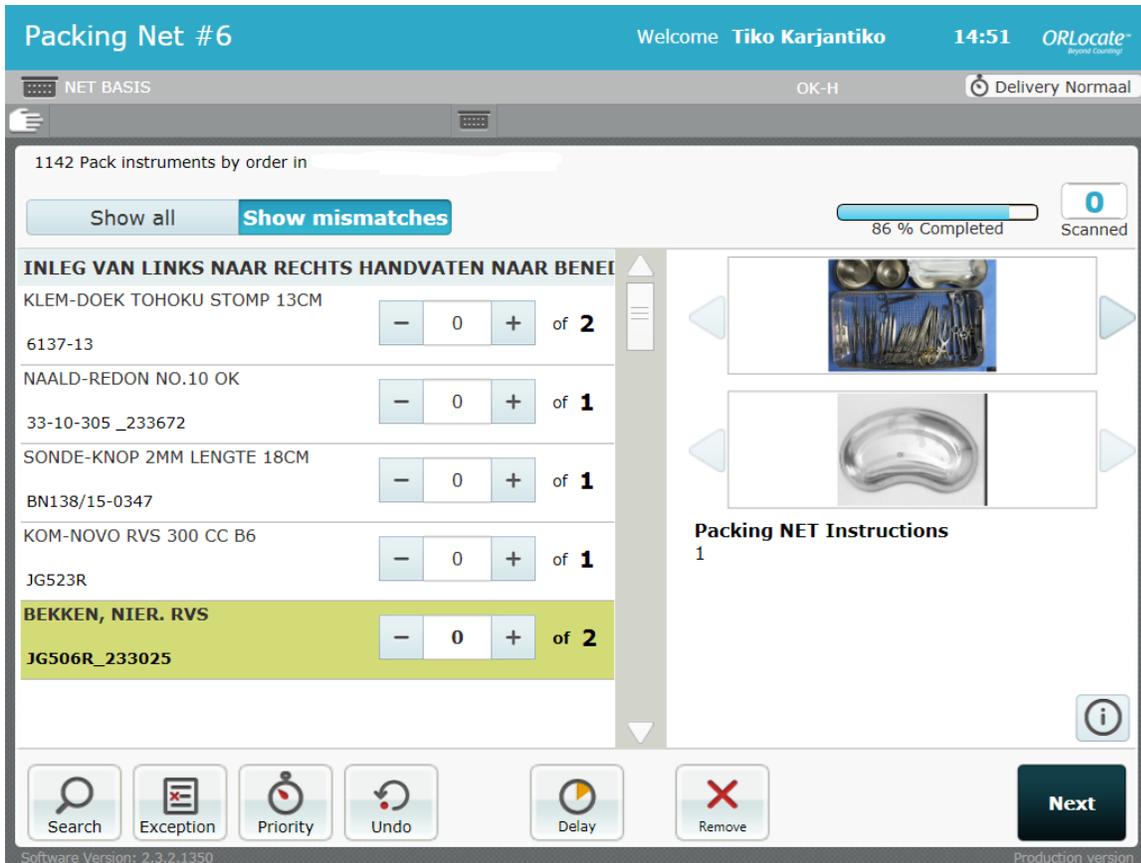
If all the items were indeed packed the system will automatically open the Packing completed pop up and the content report will be printed, as shown in following figure:
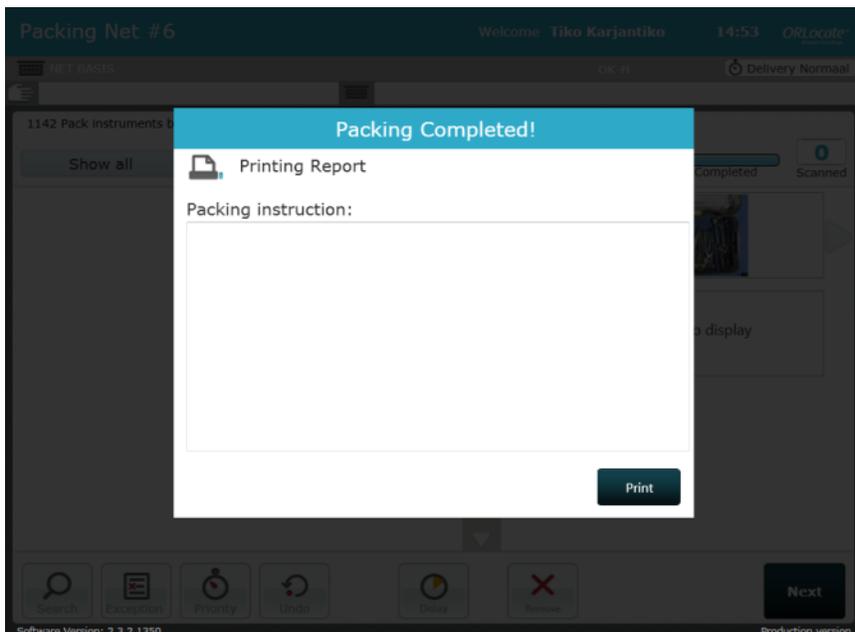
If not all the items were packed a pop will open indicating that not all the items were packed and ask you to confirm that you wish to continue to the next screen.

Since not all the items were packed the next screen will be Instrument Count Mismatches screen, supervisor approval will be required for completing the packing process with missing items (two types of approvals can be given regular approval and approval for critical items), as shown in following figure:
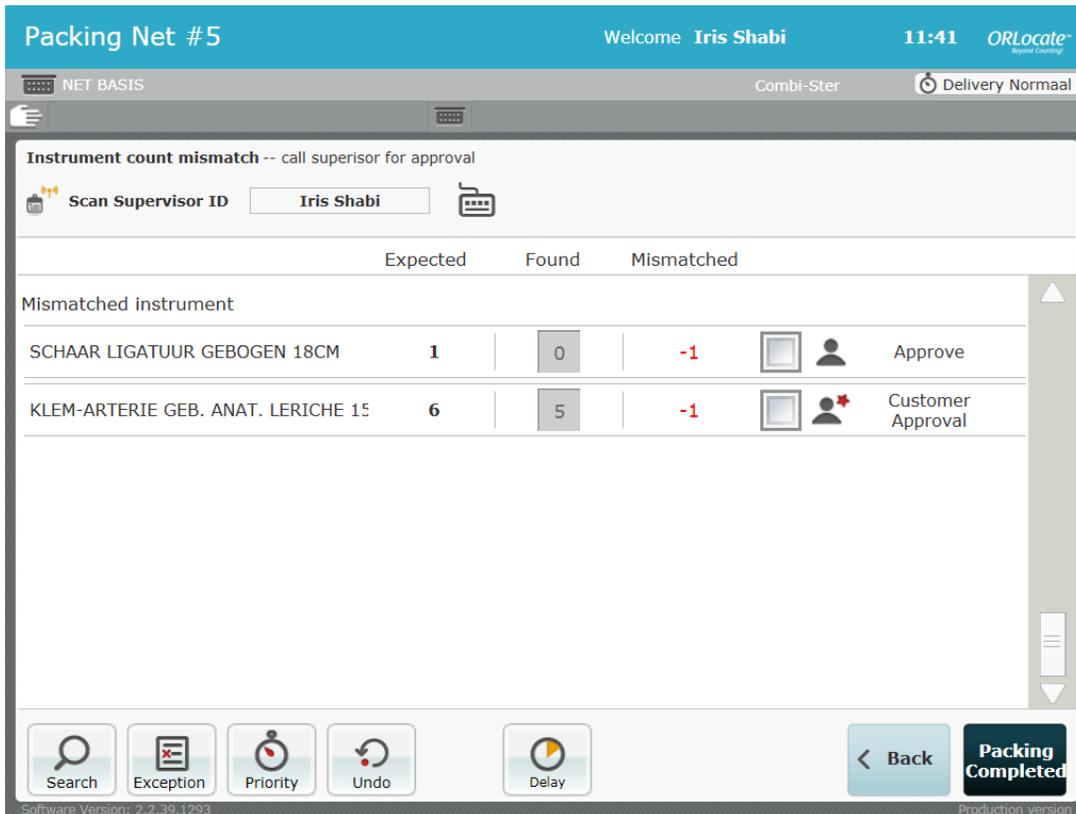
(6) System alert - Flow process - Cannot treat the scanned item:

If according to the flow process as defined by your organization the set cannot be proceed in the current station an alert will be displayed, as shown in following figure:
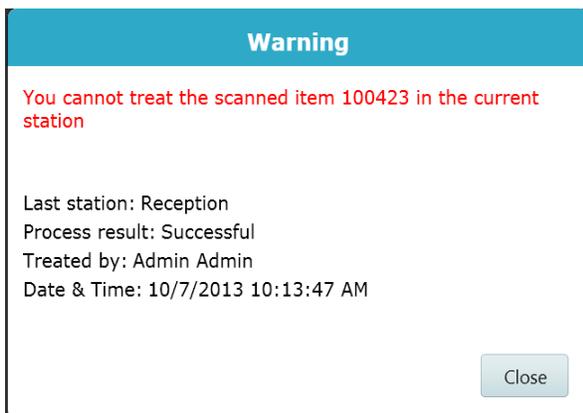
**(7) System alert - Related Wash Nets*:**

System requires the set and all the related Wash nets arrived to the Packing station before starting the packing process, as shown in following figure:
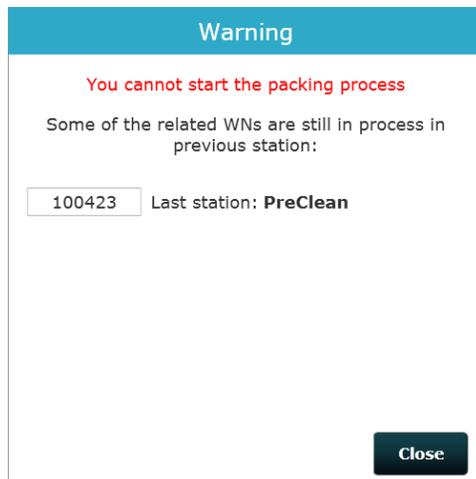
System requires the user to scan all related Wash nets for starting the packing process, as shown in following figure:
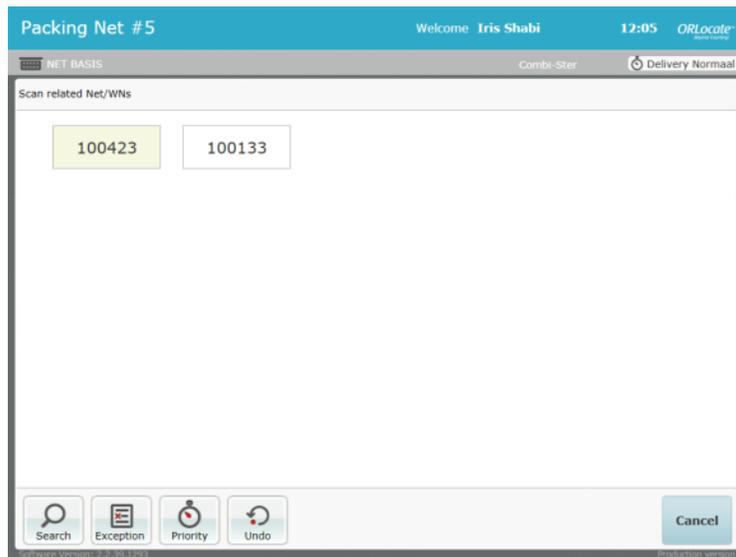
* Related wash nets- if the instruments of a set were distributed to different Wash nets (either because the set is big or some of the instruments requires different cleaning procedure such as hand washing). The set and wash nets are called Related.

(8) System alert - Set was delayed/ exception attached:

If the set was delayed or an exception was assigned to it or to one of the instruments in the set, in the first screen in the Packing station the user will be required to treat the delay/exception reasons, as shown in following figure:
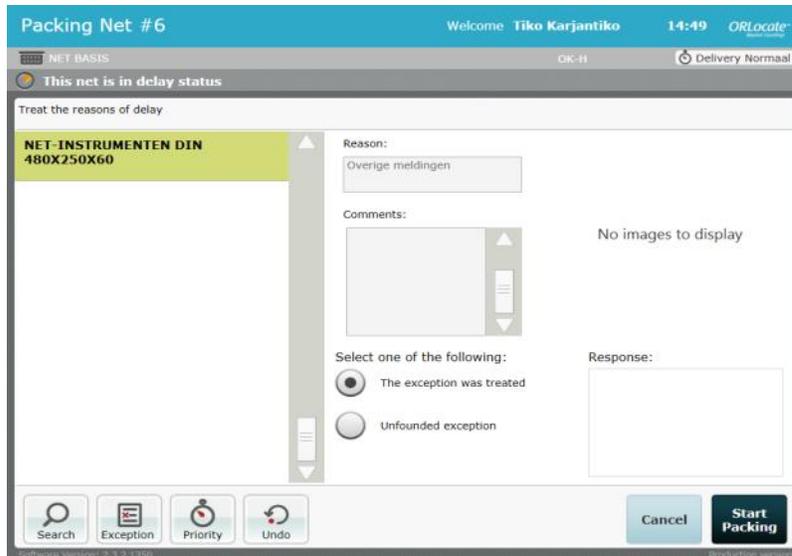
(9) System alert – as defined in Management at the set type or in the set instance level.

The system will alert the users in of different alerts: Sterilization cycles until maintenances, Sterilization cycles until discard, set has a hold request.

6.2.6   SPD STERILIZATION
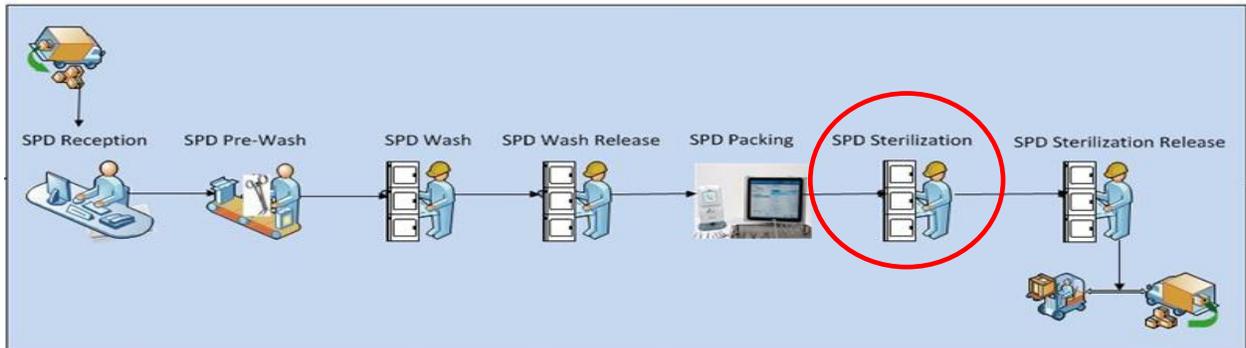
Sterilization Station Picture:

Station to be located on a table or mount on the wall with arm as shown.

Sterilization Station Components:

Required Infrastructure:

- 4 x power sockets.
- 2 x network sockets.

Sterilization Station User Interface:
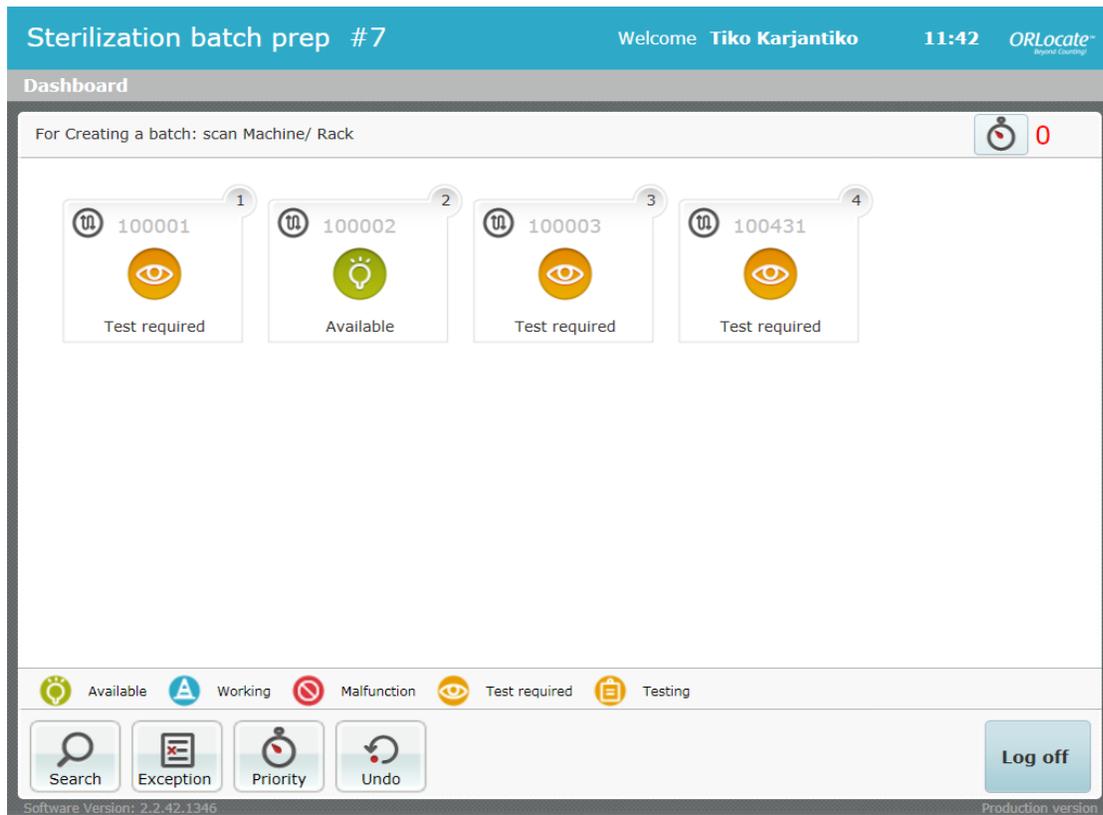
Select Machine:

Define Machine status (Malfunction):
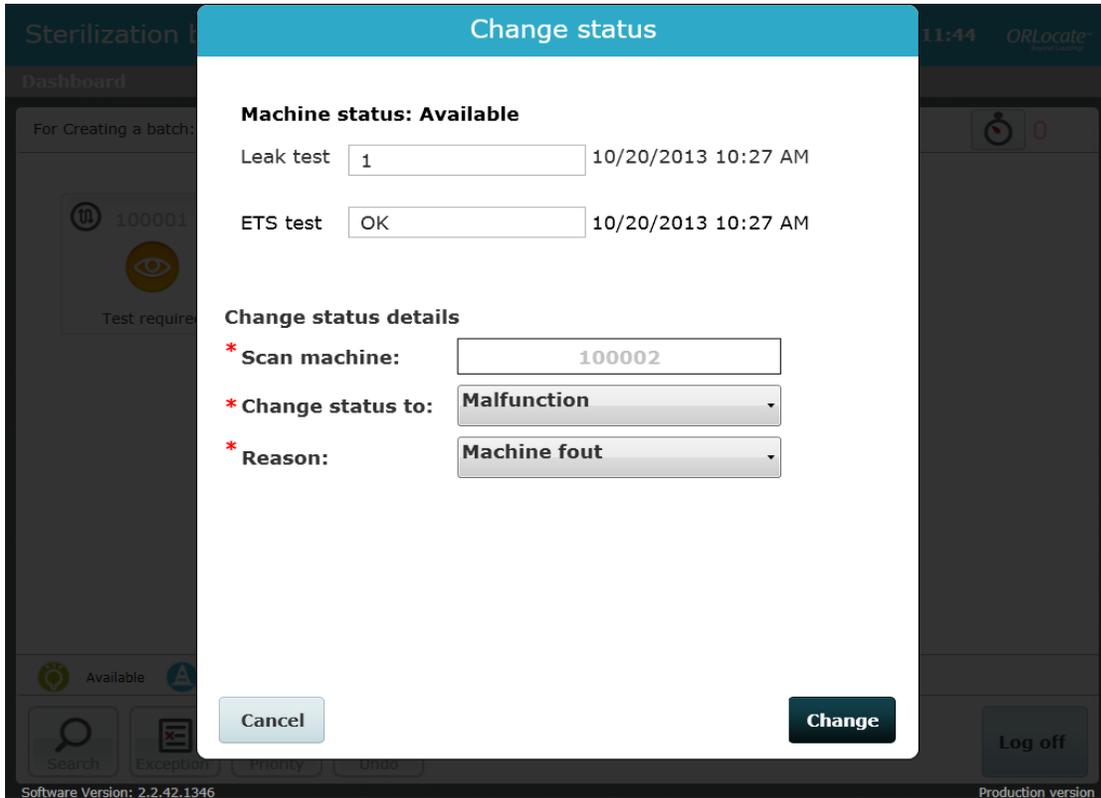
Machine status Malfunction:
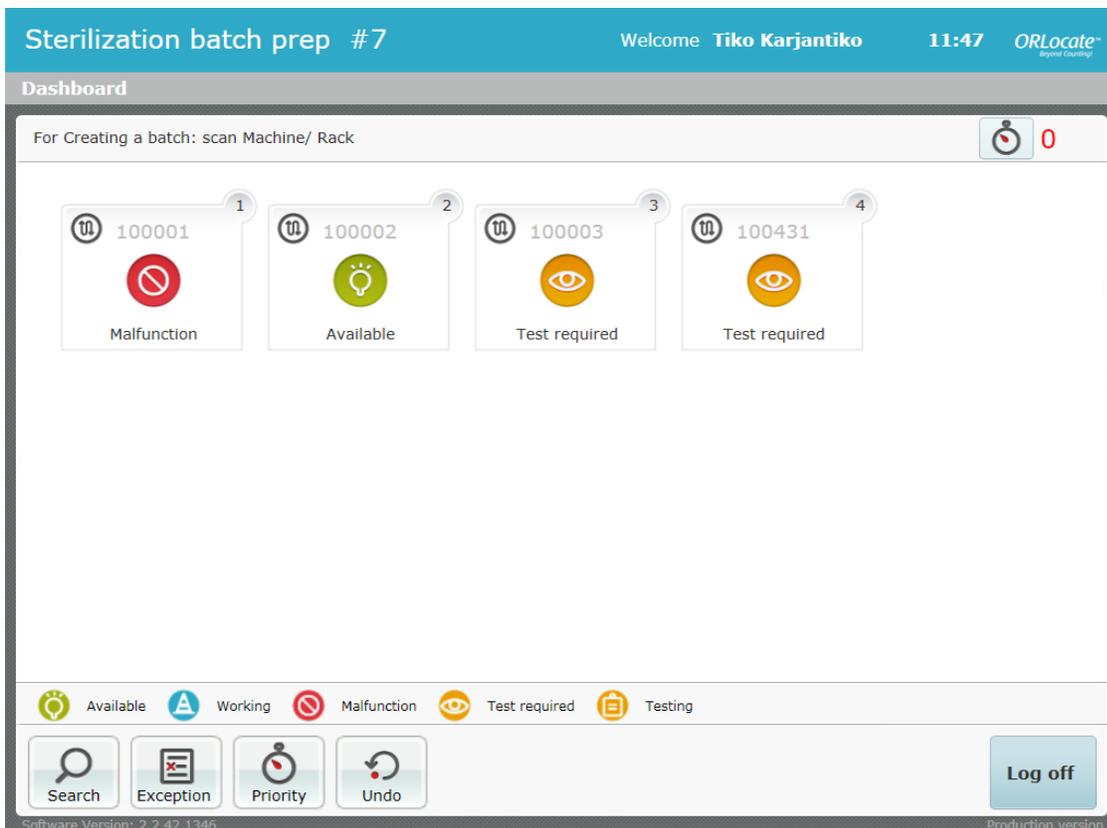
Create Batch:
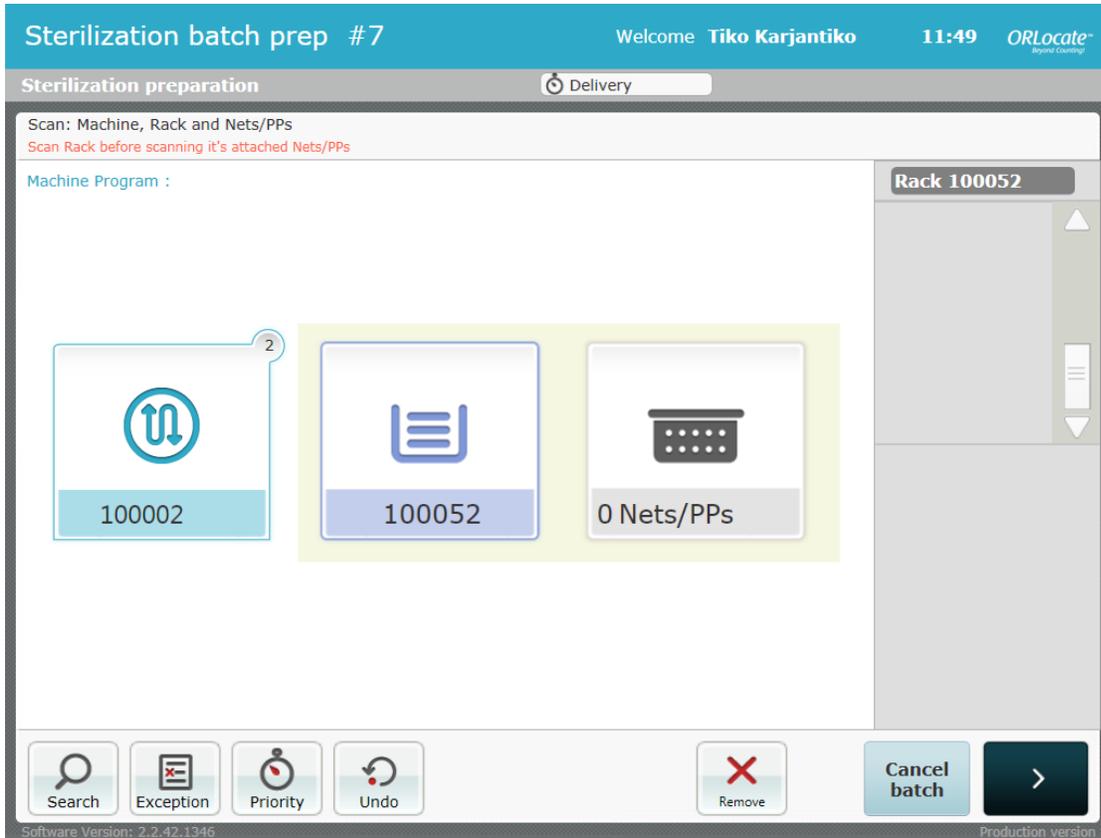
Select Machine:
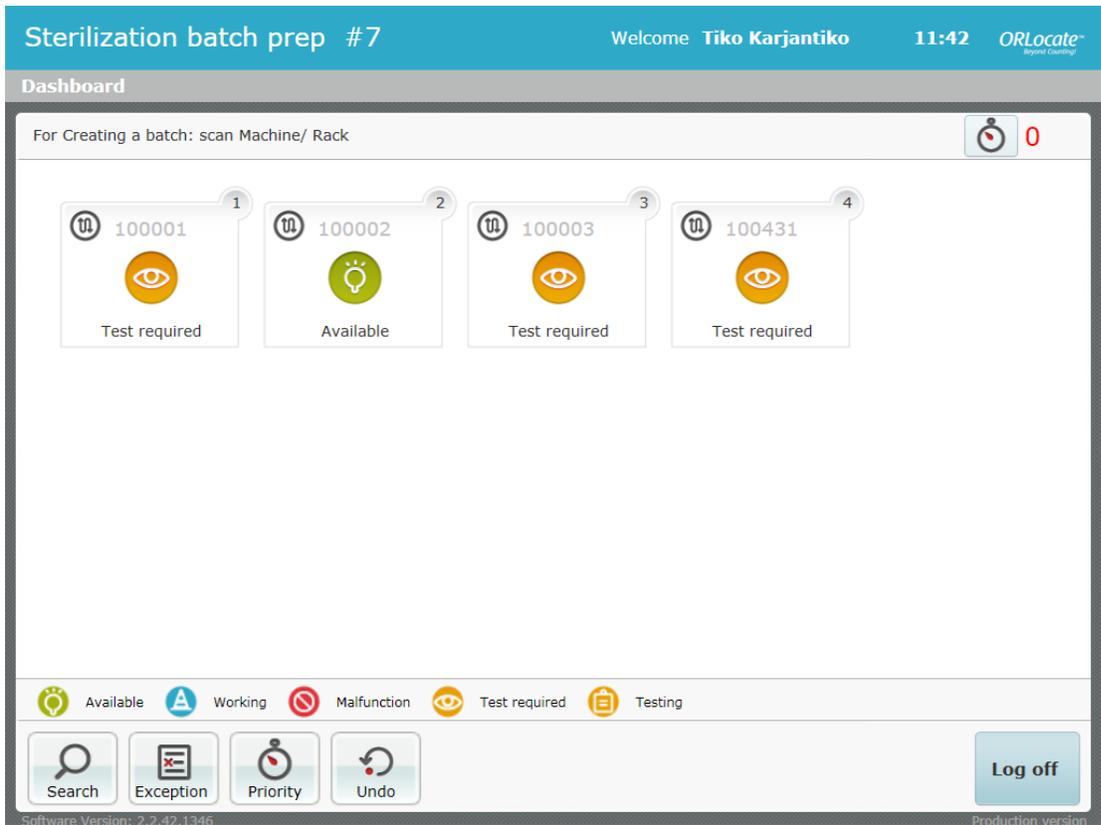
6.2.7 SPD STERILIZATION RELEASE
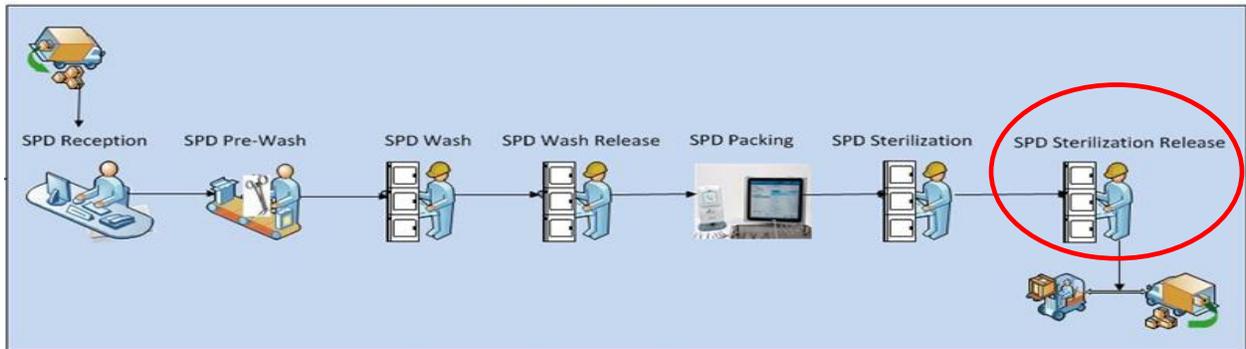
Sterilization Release Station Picture:
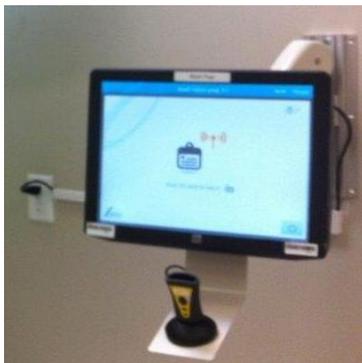
Station to be located on a table or mount on the wall with arm as shown.

Sterilization Release Station Components:

Required Infrastructure:

- 2 x power sockets.
- 1 x network sockets.

Sterilization Release Station User Interface:

Select Machine:

Release Batch:

7.   THE ORLOCATE^R 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 shown in the following figure:
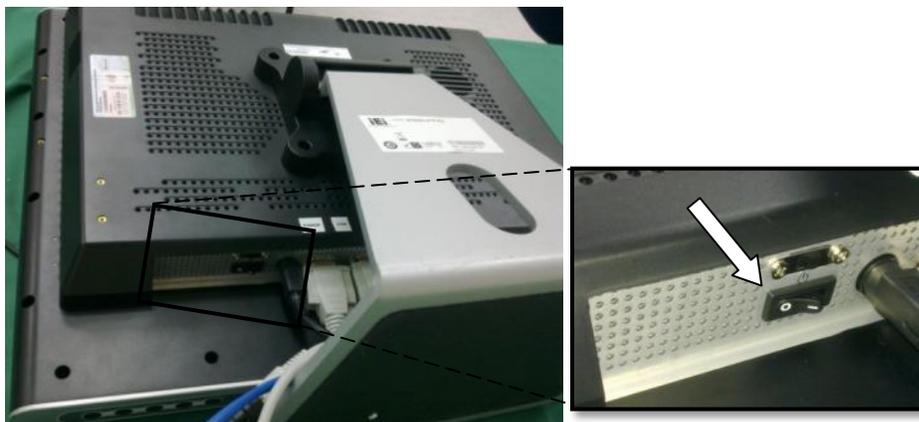
9. MAINTENANCE AND SERVICE

9.1 PERIODIC MAINTENANCE SCHEDULE

Routine maintenance should be performed on the system as follows:

Action	When is Action Performed	Action is Performed by…
Clean 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 Antennas** 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^R representative:

USA Support	Outside of USA Support
Haldor USA Inc. **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^R 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^R 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 touch screen use	Touch screen is cracked.	Stop using the system and contact service for support.
	Touch screen is not calibrated.	Stop using the system and contact service for support.
	Touch screen is dirty.	Clean the screen.
Touch screen detects touch in wrong position	Touch screen 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 OPERATING, STORAGE AND TRANSPORTATION ENVIRONMENT

	Operating Environment	Storage and Transportation Environment
Temperature:	10°C to 40°C (50° F to 104° F)	-20°C to 60°C (-4°F to 140°F)
Relative Humidity:	30% to 75%	10% to 100%
Pressure:	700 hPa to 1060 hPa	500 hPa to 1060 hPa

11.2 ELECTRICAL POWER

Consumption (max):   Tool Pack - Up to 12 Watt

Reader Controller, Tool Add, Flat Antenna, Locator - Up to 60 Watt

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

12. SYSTEM SPECIFICATION

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:

	Flat Antenna	Tool Add/Pack Antenna	Handheld Scanner	Reader Controller	Panel PC
Max. quantity of items	60 instrument	5 instrument	1 instrument	NA	NA
Max detection distance	Up to 5 cm (2")	Up to 5 cm (2")	Up to 5 cm (2")	NA	NA
Weight (Kg)	10	5	0.1	3	According to the PC model
Dimensions (cm / inches)	60.5x47x6.5 cm	22x33x13 cm	11.5x5x3 cm	50x30x5 cm	According to the PC model
	24x18.5x2.5 inches	9x13x5 inches	4.5x2x1.2 inches	20x12x2 Inches	

13. FCC ID CROSS REFERENCE TABLE

	ORLocate SPD Reception		ORLocate SPD Packing
	Flat Antenna	Tool Add Antenna	Tool Pack Antenna
Channel Setting	Single Channel	Single Channel	Single Channel
Max. Output RF Power	4W	2W	1W
Power Supply	RPS-60-24 (Meanwell)	RPS-60-24 (Meanwell)	1829584 (Friwo)
FCC ID	X4V-ORL-L40	X4V-ORL-L40	X4V-SPD

14. 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 1 - According to Table 204 from IEC 60601-1-2
Guidance and Manufacturer's Declaration – Emissions
Equipment and Systems that is NOT Life-supporting

The ORLocate 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: $D = (3.5/3)(\sqrt{P})$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$D = (3.5/3)(\sqrt{P})$ - 80 to 800 MHz $D = (7/3)(\sqrt{P})$ - 800 MHz to 2.5 GHz Where P is the max power in watts and D is the recommended separation distance in meters. 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 2 - 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 <u>NOT</u> 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.