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Knowledge for Health



UltraPlex™

SmartStation OPERATINGMANUAL

This manual describes the operation of the
Pronostics SmartStation liquid handling system
used to perform UltraPlex™ assays.

Pronostics Ltd. is an ISO 13485:2003 certified company

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UltraPlex™ SmartStation Operating Manual

1	Introduction	1	
2	Equipment	1	
3	Safety precautions	1	
4	Operation of the UltraPlex™ SmartStation	2	
	4.1	Switching on the SmartStation	2
	4.2	Preparation for running an assay	2
	4.3	Loading the SmartStation deck	3
	4.4	Running a SmartStation process	4
	4.5	Pausing the SmartStation	4
	4.6	Completion of the SmartStation process	4
	4.7	Switching off the SmartStation	5
	4.8	Fast stop button	5
5	Maintenance procedures	6	
	5.1	Daily maintenance	6
	5.2	Weekly maintenance	7
6	Cleaning agents and lubricants	8	
7	Troubleshooting guide	9	
	7.1	Barcode read errors	9
	7.2	Liquid level detection	9
	7.3	Tip errors	9
	7.4	Aborted run	10

1 Introduction

This is the operating manual for use of the UltraPlex™ SmartStation. It describes the instrumentation, procedures and software used to perform UltraPlex™ autoimmune assays. The walk-away robotic system is an automated liquid handling system that can aspirate and dispense liquids, with additional features to shake assay plates and vacuum aspirate liquids from filter plates. Following completion of a procedure, the filled read plate is then taken and analysed using the UltraPlex™ SmartReader.

2 Equipment

The UltraPlex™ SmartStation system is composed of the following components:

- Robotic workstation type X100-1-4
- Vacuum pump NSE 800
- Computer containing Lirix software version 2.2.22

3 Safety precautions

1. The instrument is designed for automatic 'hands-off' operation only. Never reach or lean into the working area when the SmartStation is in operation unless the system has paused and displays a dialogue box indicating that operator intervention is required. Reaching into the workspace at any other time exposes you to the mechanical hazard of the moving arm and sharp tip adapters and pipette tips, which may lead to injury of the operator, damage to the SmartStation and/or abortion of the run.
2. Appropriate local rules should be followed when using biological samples on the SmartStation, including but not limited to adherence to containment and disposal regulations.
3. The barcode CCD scanner uses LED lighting that can damage your eyes. To avoid damaging the retina, do not look into the light beam.
4. Operation of the UltraPlex™ SmartStation should be limited to those individuals who have been trained by Pronostics Ltd.

4 Operation of the UltraPlex™ SmartStation

4.1 Switching on the SmartStation

1. Switch on the UltraPlex™ SmartStation using the main switch located at the rear right-hand corner of the instrument (Figure 1).

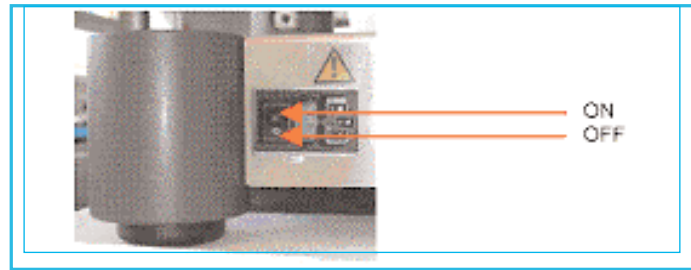


Figure 1. Main switch at the back of the UltraPlex™ SmartStation

2. Allow the UltraPlex™ SmartStation to fully boot up.
3. Turn on the vacuum pump (switch 1, Figure 2) and then the vacuum pump controller (switch 2, Figure 2).

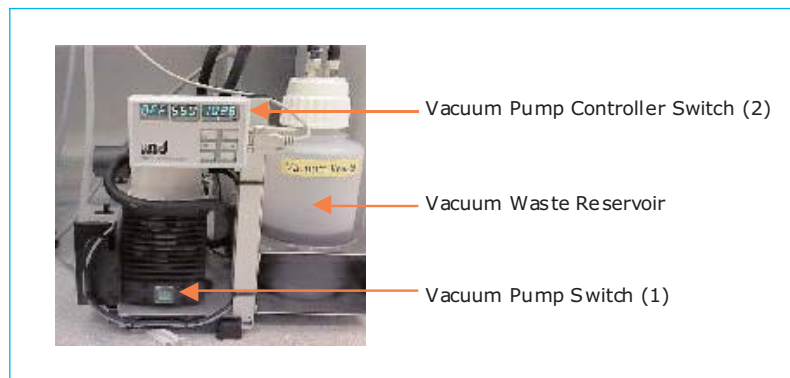


Figure 2. Location of vacuum pump switch, vacuum pump controller switch and waste reservoir

4. Double click on the Lirix shortcut icon on the Desktop.
5. To Log-on, enter username **Customer** and password **ultraplex**, then press ok.

4.2 Preparation for running an assay

1. Check that the vacuum waste reservoir (see Figure 2) is no more than $\frac{1}{2}$ full. To empty, remove the screw cap from the vacuum waste reservoir and empty any remaining liquid down a suitable sink according to local regulations. Re-attach to the vacuum pump and ensure that the cap is firmly screwed on.
2. Check that the tip waste bin and tip ejector mechanism (Figure 3) are empty.
3. Check that the waste trough (Figure 3) is empty.
4. Confirm that the barcode reader is in its 'home' position – that is as far right as it will go.

At least 20 minutes before use the following procedure should be carried out:

5. Confirm that the tip ejector mechanism is correctly located on the slider and pushed as far back as it will go.
4. Run the **UltraPlex maintenance** process (see "Maintenance procedures" under vacuum manifold (Section 5).

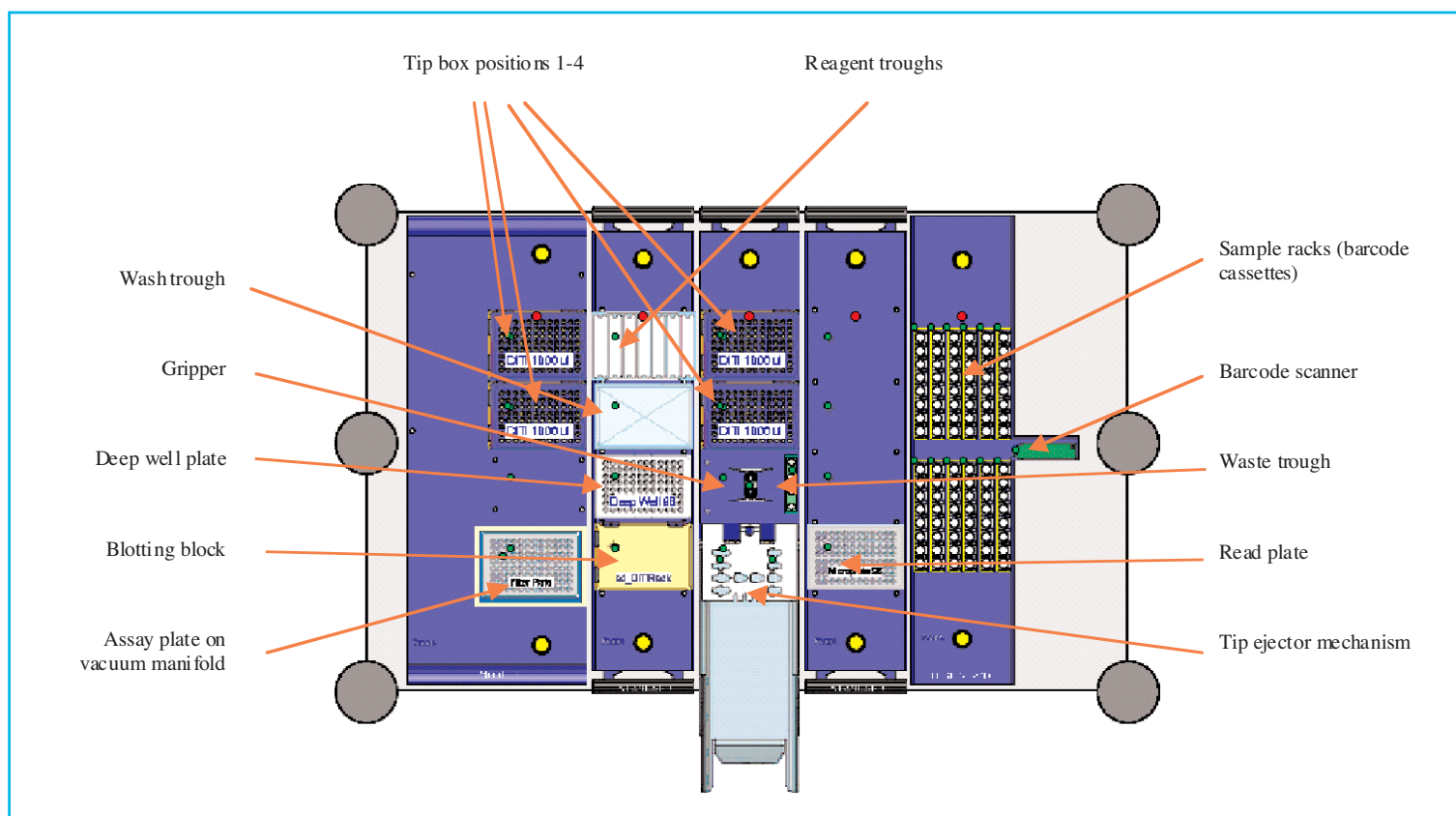


Figure 3. UltraPlex™ SmartStation hardware layout

4.3 Loading the SmartStation deck

Place the following items onto their respective positions on the deck:

1. Place diluted wash buffer in the wash trough.
2. Place four boxes of 96 Rainin 1000 µl tips onto the deck in positions 1, 2, 3 and 4, as indicated in Figure 3. Press tip boxes firmly down to ensure correct alignment on the holder.
3. Place a fresh piece of blotting paper on the blotting block and ensure that it is aligned with the edges of the blotting block.
4. Place the deep well dilution plate onto the deck, ensuring that well A1 is in the top left hand corner.
5. Place the UltraPlex™ read plate onto the deck, ensuring that well A1 is in the top left hand corner.
6. Place the UltraPlex™ assay plate containing the SmartBeads onto the deck, ensuring that well A1 is in the top left hand corner. Please take care when removing the plate sealer from the assay plate so as not to dislodge any of the SmartBeads.

Depending on the assay being run, other items will need to be loaded onto the SmartStation deck. For full details please refer to the relevant assay's user guide and/or the relevant assay's quick start guide. These are likely to include:

1. Controls and standards (provided)
2. Samples
3. Batch number tube
4. Sample dilution buffer (s)
5. Detection antibody (ies)
6. Decoding buffer

4.4 Running a SmartStation process

When the Xiril software is started by double-clicking on the Xiril icon on the desktop (Section 4.1), the following procedure can be started immediately. If the vertical panel on the left hand side does not show the "Start process" icon at the top left then select "Lirix shortcuts" button above that panel.

1. Select the **Start process** icon at the top of the grey panel to the left of the screen.
2. Double-click on the process that you would like to run (select from list in upper part of the screen).
3. The next window that opens up will be entitled "Start run". Where tips are going to be used, the tip boxes should all be filled, and the tick box next to "Start with refilled DiTi tip boxes" checked. This is unnecessary when tips are not going to be used (e.g. during UltraPlex™ maintenance procedure). Click on **Next**.
4. The next window (entitled "Verify rack placement") is for information only and is to prompt the user to confirm that the SmartStation deck has been correctly loaded for the process being run. Click on **Start run**.

4.5 Pausing the SmartStation

This procedure can be used if reagents or deck components need to be added or removed from the UltraPlex™ SmartStation.

1. Press the **Pause/Break** key on the keyboard.
2. This will bring up a dialogue box on the screen.
3. To continue the process, click Continue.

4.6 Completion of the SmartStation process

When the SmartStation process has completed a message will inform you that the process has finished. On completion, a ".dat" file (stamped with time and date) is generated which must be transferred to the SmartReader system together with the read plate. To do so, open the "Shortcut to output" folder on the desktop and copy the appropriately date and time-stamped .dat file to the USB flash drive.

4.7 Switching off the SmartStation

1. Turn off the vacuum pump. First switch off the vacuum pump controller (switch 2, Figure 2) and then turn off the pump using the vacuum pump switch (switch 1, Figure 2).
2. Close all applications and shut down Windows operating system.
3. Once the software has closed down, switch the main switch to the off position (see Figure 1). The UltraPlex™ SmartStation will shut down.

4.8 Fast stop button

The “fast stop” button is located at the front right corner of the UltraPlex™ SmartStation (Figure 4). This is for emergency stops only and will result in an aborted run. It must not be used as a regular stop button.



Figure 4. Location of fast stop button

If the fast stop button is pressed the following procedure must be followed to restart a robotic programme.

1. Press the fast stop button once more
2. Follow the procedure detailed in Section 4.7 above to switch the SmartStation off.
3. Follow the procedure detailed in Section 4.1 above to turn the SmartStation back on again. From here on, the normal procedures apply to running a SmartStation process.

5 Maintenance procedures

The UltraPlex™ SmartStation must only be operated under normal laboratory conditions. To ensure optimum performance and reliability, preventive and corrective maintenance procedures must be performed as described.

5.1 Daily maintenance

These procedures should be performed prior to operating the instrument or after 8 operating hours.

Module	Maintenance Steps
Tip adapters	Clean with lint-free tissue and 70% ethanol. Visually inspect for scratches. Replace the MPP if tip adapters are scratched*.
Vacuum waste reservoir	Check that the vacuum waste reservoir is empty. If not remove the screw cap from the vacuum waste reservoir and empty any remaining liquid down a suitable sink according to local regulations. Re-attach to the vacuum pump and ensure that the cap is firmly screwed on. Note: failure to empty the vacuum waste reservoir may cause the deck to flood resulting in contamination of the instrument. This is a serious hazard to the operating personnel and may affect test results.
Waste trough	Empty.
Tip waste bin	Empty.
Deck & labware	Clean with lint-free tissue.
Vacuum manifold	Place absorbent tissue below the front vent hole. Pour 200 ml of dH2O into manifold and wait until water starts seeping through the hole. Run UltraPlex_Maintenance process (See Section 4.4). Ensure that all liquid has been removed. Note: when using unscreened sera that may pose a biological hazard, we recommend this procedure is carried out twice, first with a suitable detergent (e.g. 4% Decon) and finally with dH2O.

* These steps must only be carried out by Pronostics technical support.

5.2 Weekly maintenance

These procedures should be performed at the end of every week or after 40 operating hours.

Module	Maintenance Steps
Micro pipetting pump	Inspect for leaks. Replace leaking MPPs*.
Vacuum Manifold	Place absorbent tissue below the front vent hole. Pour 200 ml of dH2O into manifold and wait until water starts seeping through the hole. Run UltraPlex_Maintenance process (See Section 4.4). Ensure that all liquid has been removed. Note: when using unscreened sera that may pose a biological hazard, we recommend this procedure is carried out twice, first with a suitable detergent (e.g. 4% Decon) and finally with dH2O.
Barcode scanner	Visually inspect and clean the beam output window on the scanner head using lint-free tissue and 70% ethanol. Avoid using abrasive substances. WARNING! The CCD scanner uses LED lighting that can damage your eyes. To avoid damaging the retina, do not look into the light beam.

* These steps must only be carried out by Pronostics technical support.

6 Cleaning agents and lubricants

WARNING

- Unless otherwise instructed, never use ethanol as the first cleaning agent. Ethanol precipitates both nucleic acids and proteins and renders them insoluble to most cleaning agents.
- Wipe up spillages using mild detergent solution before using 70% ethanol.
- Do not use strong detergents - these may dissolve racks and instrument surface coatings.
- Wipe all surfaces thoroughly with distilled/de-ionised water after cleaning.

UltraPlex™ SmartStation parts	Cleaning agent/ lubricant
Stainless steel and aluminium parts	<ul style="list-style-type: none"> • Distilled / de-ionised water • Bleach (2-4%) • Weak detergent • Low concentrated salt solution • Ethanol (70%)
Thermoplastic parts	<ul style="list-style-type: none"> • Distilled / de-ionised water • Bleach (2-4%) • Weak detergent • Ethanol (70%)
Painted parts <ul style="list-style-type: none"> • Support stands • Instrument feet • Arm cover • Deck tray handles 	<ul style="list-style-type: none"> • Distilled / de-ionised water • Ethanol (70%)
Pipetting channel	<ul style="list-style-type: none"> • Ethanol (70%)
Tube-ScanX beamer window	<ul style="list-style-type: none"> • Ethanol (70%) • Ethanol (70%)
Arm bearings, linear guide and pulleys	Lubricants: <ul style="list-style-type: none"> • KLÜBER Paraliq GA 351 • Shell Retinax A • Mobil Savavex Grease L2

7 Troubleshooting guide

7.1 Barcode read errors

In the event of a barcode failing to be read, a message box will be displayed on screen. When this occurs the following steps should be taken:

1. Check the label of the tube concerned (its position will be shown in the Message box).
2. Reposition the tube, if appropriate, and select **Retry**.
3. If the Barcode reader is unable to read the label, the barcode number can be entered by the user.

7.2 Liquid level detection

Steps involving aspiration of reagents or serum employ liquid level detection. When the volume of liquid in the vessel is calculated to be less than that required, a message box will be displayed listing the required and detected volumes. When this occurs the following steps should be taken:

1. Check that the correct volume has been added to the reservoir in question, and add more reagent if applicable.
2. Sample, control or standard tubes should be checked carefully – the presence of air bubbles can cause liquid level detection errors. If air bubbles are present, spin down tubes or tap sides to disperse air bubbles.

7.3 Tip errors

There are two error messages that may be generated in the event of tip-associated problems:

- “Unable to get tips with motor(s) 1 (2, 3 or 4)”
- “No tips found with motor(s) 1 (2, 3 or 4)”

In both cases the number of the motor(s) listed corresponds to the number of the tip adapter concerned. Note that the tip adapters are numbered 1 to 4 from the back (furthest from the user) of the robotic system.

Before performing any of the steps below, ensure that the tip boxes are correctly located, securely positioned and sitting flat on the deck.

Error Message	Action
“Unable to get tips with motor(s) 1 (2, 3 or 4)”	<p>Tip is present on the motor</p> <ul style="list-style-type: none">• If the tip is secure, select Ignore and observe next “Get tips” step before leaving the unit to continue.• If the tip is loose, carefully remove by gently twisting. Place a new tip in the rack below, select Retry. If this is unsuccessful, repeat Retry. If a tip fails to load, note any visible reason (e.g. adapter is out of alignment) and contact Pronostics technical support.

Error Message	Action
	<p data-bbox="810 154 1246 185">Tip is not present on the motor</p> <ul data-bbox="810 219 1437 315" style="list-style-type: none"> <li data-bbox="810 219 1437 315">• Select Retry provided that a tip is present in the rack below the adapter and access to the tip is unimpeded. <p data-bbox="810 338 1410 434">The last tip used was not removed, causing the adapter to “crash” when attempting to load the next tip.</p> <ul data-bbox="810 468 1430 685" style="list-style-type: none"> <li data-bbox="810 468 1430 591">• If it is possible to do so, carefully remove the tip from the adapter. Discard both this tip and that in the rack below, and put a new tip in the rack. Select Retry. <li data-bbox="810 591 1430 685">• If the tip cannot be removed, or repeated Retry attempts are unsuccessful, select Abort run (see section 7.4).
<p data-bbox="201 719 596 786">“No tips found with motor(s) 1 (2, 3 or 4)”</p>	<p data-bbox="810 719 1190 750">Tip is present on the motor</p> <ul data-bbox="810 750 1430 945" style="list-style-type: none"> <li data-bbox="810 750 1430 846">• If the tip is secure, select Ignore and observe next “Get tips” step before leaving the unit to continue. <li data-bbox="810 846 1430 945">• If the tip is loose, carefully remove by gently twisting. Discard tip and place a new tip in the rack below. Select Retry. <p data-bbox="810 974 1246 1005">Tip is not present on the motor</p> <ul data-bbox="810 1039 1430 1135" style="list-style-type: none"> <li data-bbox="810 1039 1430 1135">• Select Retry if tips are present in the next rack position. If necessary, refill or replace rack with new tips.

7.4 Aborted run

When it is necessary to abort a run carry out the following steps:

1. Press the **Pause/Break** key on the keyboard and/or select **Abort** in the User Interrupt window.
2. Select **Continue** in each message box as it is displayed.
3. Run the **Reset Arm** process in the main Lirix window (see Section 4.4).

When the run is aborted before any reagents (including wash buffer) have been added to the assay plate, it is possible to start the process again, provided that any reagents and tips used are replaced first (note that the sample dilution plate will need to be discarded if any reagents have been added to it). In all other instances, the assay plate and sample dilution plate will need to be discarded.

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