



# IMMULITE® 2000 XPi System

Quick Reference Guide

**SIEMENS**  
Healthineers 

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# Daily Maintenance

## To Prepare the System for AutoStart

- Check the consumables: Water, Substrate, Probe Wash, Reaction Tubes
- Empty the Liquid and Solid Waste Containers
- Load a 12 x 75 mm sample tube with 1.5 mL of probe cleaning solution onto the Sample Carousel with a Probe Cleaning barcode.
- OPTIONAL: Load controls onto the Sample Carousel (if the system is configured to automatically run a QC Worklist with AutoStart).

## Manual AutoStart

- If AutoStart is not configured to run automatically, initiate AutoStart by selecting Run AutoStart from the Startup screen or from the Menu screen.

## Substrate Priming

- If the system is not configured to automatically dispense substrate, the substrate must be manually primed prior to running samples.



Initiate AutoStart Manually

# Scanning a Kit Lot

1. Open the kit and locate the kit barcode.
2. Kit barcodes can be scanned into the database from any screen. To scan the kit barcode, hold the scanner five to seven inches away from the kit barcode. Keep the angled face of the scanner parallel to the barcode.
3. Press and hold the trigger button on the scanner and point the scanner beam at the center of the barcode. Scan at the center of the barcode. Hold the scanner button until a tone sounds to indicate that the barcode was read successfully.
4. When the barcode is successfully scanned, the Kits screen appears, displaying the information about the kit lot.

The screenshot shows the 'IMMULITE 2000 XPi: Kits' software interface, Version 6.3. The top navigation bar includes buttons for HOME, WORKLIST, REVIEW, KITS (selected), LIS, QC, REPORTS, MENU, HELP, and LOG OFF. Below this, there are buttons for Allergens, Find, Kit Deactivation, Previous Kit, and Next Kit. The main display area shows the following information:

**IMMULITE 2000 Estradiol**

|                   |            |                   |            |
|-------------------|------------|-------------------|------------|
| Test Code         | E2         | Kit Lot           | 185        |
| Bead Lot          | 185        | Reagent Lot       | 185        |
| Low Adjustor Lot  | 115        | Low Adjustor CPS  | 13698300   |
| High Adjustor Lot | 115        | High Adjustor CPS | 1745571    |
| Adj Allergen Lot  |            | Ctrl Allergen Lot |            |
| Last Adjustment   | 06/21/2012 | Next Adjustment   | 07/05/2012 |
| Adjustment Status | Adjusted   | Kit Status        | Valid      |
| Diluent           | E2         | Kit Expiration    | 12/31/2012 |
| Slope             | 1.0209     | Intercept         | 46602.1085 |
| Slope Limits      | 0.5 - 1.8  | Sample Volume(µl) | 25         |
| Parameter 1       | 23906804   | Parameter 2       | -23252209  |
| Parameter 3       | -5.179302  | Parameter 4       | 1.0856042  |

On the right side of the interface, there is a vertical control panel with buttons for RUN, PAUSE, STOP, PRIME, COVER, Water, Wash, Substr, S Wste, L Wste, and Tubes.

# Loading a Reagent Pack

1. Prepare the reagent wedge by taking the clear tape off the glide at the top of the wedge, and removing the white foil from the wedge opening.
2. Check for bubbles inside the wedge, and use a lint free tissue to dry the glide and the areas surrounding it where the probe enters the wedge.
3. Snap the glide on the reagent wedge. Check to make sure the glide moves back and forth smoothly.
4. Open the reagent carousel door. If the system was in Run mode, wait for the system to enter Reagent Pause mode.
5. On the Reagent Status screen, select a gray position to rotate the reagent carousel to an empty position.
6. Tilt the side of the wedge with the barcode label down so the tab on the reagent carousel locks into the wedge slot under the barcode label.
7. Press down on the narrow side of the wedge to lock it into place.
8. Push the glide of the wedge toward the center of the carousel to ensure that it moves freely.
9. Close the reagent carousel cover and apply pressure until it clicks into place.
10. Select **RUN** to update the Reagent Status screen.



# Loading a Bead Pack

1. Open the bead carousel door. If the system was in Run mode, wait for the system to enter Bead Pause mode.
2. On the Bead Status screen, select a gray position to rotate the bead carousel to an empty position.
3. Place the bead pack between the carousel dividers with the barcode facing out.
4. Tilt the side of the bead pack opposite the barcode label down and insert the plunger into the opening at the center of the carousel.
5. Snap the barcoded side of the bead pack into position on the carousel. Be sure it is locked in place.
6. Close the bead carousel cover.
7. Select **RUN** to update the Bead Status screen.



# Loading a Sample Rack

1. If barcoded tubes are being run, make sure that the barcode is visible when the tubes are placed in the sample rack.
2. To determine if the system is ready for a new rack, view the lights to the left of the rack loader door.
  - Solid red light: the instrument is not ready to accept a rack. For example, if the rack loader is full, the light will remain red.
  - Solid green light: the instrument is ready to accept a rack.
3. If the light is green, lift the rack loader door and set the sample rack into the sample tray.
4. Close the rack loader door. The instrument automatically loads the rack onto the system when the sample carousel has an empty rack position.



# Ordering Adjustors

1. Select **WORKLIST**.
2. Select **Next** to view the low adjustor. The adjustor lot number, adjustor level, tube position and test ordered for the first adjustor sample appears.
3. Delete the 0 and type the kit lot number in the Kit Lot # field.
4. Select **ACCEPT ADJUSTOR**.
5. Follow the same steps for each adjustor level that needs to be ordered.
6. Select **Display/Edit** to view the worklist.

The screenshot shows the 'IMMULITE 2000 XPi: Worklist' software interface, Version 6.3. The interface is divided into several sections:

- Top Navigation Bar:** Contains icons for HOME, WORKLIST (highlighted with callout 1), REVIEW, KITS, LIS, QC, REPORTS, MENU, HELP, and LOG OFF.
- MANUAL ENTRY OPTIONS:** Includes tabs for PATIENT, ADJUSTOR (highlighted with callout 2), CONTROL, and CALIB. VER. Below these are checkboxes for 'Skip Name' and 'Skip Demographics'.
- Form Fields:** A central area with input fields for Kit Lot # (callout 3), Adjustor Lot #, Adjustor Level, and Adj Allergen Lot #. It also features buttons for STAT, Secondary Tube, Dilution, Manual Dilution, Batch Tests By Rack, and Assign Tube Position.
- Navigation and Action Buttons:** Includes 'Previous', 'Next', and 'New' buttons (callout 2), and 'ACCEPT ADJUSTOR' (callout 4) and 'DELETE ADJUSTOR' buttons.
- TESTS:** A field for entering test names, currently showing 'TT4'.
- WORKLIST FUNCTIONS:** A bottom bar with buttons for 'Display / Edit' (callout 5), 'Print All', 'Clear', 'Print Record', and 'Consumables'.
- Right Side Panel:** A vertical toolbar with buttons for RUN, PAUSE, STOP, PRIME, COVER, and a list of reagents: Water, Wash, Substr, S Wste, L Wste, and Tubes.

# Ordering Barcoded Controls

1. Select **WORKLIST**.
2. Select the **Next** button to view the first control sample accession number (which is read from the barcode label).
3. Select **TESTS** to view the Available Tests screen.
4. Select the test(s) to run and then OK. The test name is added to the Tests Ordered box.
5. Select **ACCEPT CONTROL**. The next barcoded sample is displayed.
6. Select **Display/Edit** when all control samples have been ordered to view the worklist.

The screenshot shows the 'IMMULITE 2000 XPi: Worklist' software interface, Version 6.3. The interface includes a top navigation bar with buttons for HOME, WORKLIST, REVIEW, KITS, LIS, QC, REPORTS, MENU, HELP, and LOG OFF. Below this is the 'MANUAL ENTRY OPTIONS' section with buttons for PATIENT, ADJUSTOR, CONTROL, and CALIB. VER., along with checkboxes for 'Skip Name' and 'Skip Demographics'. The main area contains a form for entering control sample details: Accession # (~CCON6 0212011034), Control Name (CON6), Control Lot # (021), and Control Level (4). There are also buttons for STAT, Secondary Tube, Dilution, Manual Dilution, Batch Tests By Rack, and Assign Tube Position. A 'Tests Ordered' box is visible on the right. At the bottom, there are 'WORKLIST FUNCTIONS' buttons: Display / Edit, Print All, Clear, Print Record, and Consumables. On the far right, there is a vertical toolbar with buttons for RUN, PAUSE, STOP, PRIME, COVER, and a list of test types: Water, Wash, Substr, S Waste, L Waste, and Tubes. Numbered callouts (1-6) point to the WORKLIST button, the Next button, the TESTS button, the ACCEPT CONTROL button, and the Display / Edit button, respectively.

# Manually Ordering Barcoded Patients

1. Select **WORKLIST**.
2. Select the **Next** button to view the first control sample accession number (which is read from the barcode label).
3. Select **TESTS** to view the Available Tests screen.
4. Select the test(s) to run and then the **OK** button. The test name is added to the Tests Ordered box.
5. Select **ACCEPT PATIENT**. The next barcoded sample is displayed.
6. Select the **Display/Edit** button when all patient samples have been ordered to view the worklist.

The screenshot shows the 'IMMULITE 2000 XPi: Worklist' software interface, Version 6.3. The interface is divided into several sections:

- Navigation Bar:** Contains buttons for HOME, WORKLIST (callout 1), REVIEW, KITS, LIS, QC, REPORTS, MENU, HELP, and LOG OFF.
- MANUAL ENTRY OPTIONS:** Includes buttons for PATIENT (callout 2), ADJUSTOR, CONTROL, and CALIB. VER. There are also checkboxes for 'Skip Name' and 'Skip Demographics'.
- Form Fields:** Includes fields for Accession # (77532177), Name, Patient ID, Birthdate, and Physician. There are also buttons for STAT, Secondary Tube, Dilution, Manual Dilution, Batch Tests By Rack, and Assign Tube Position.
- TESTS and PANELS:** Callout 3 points to the TESTS button, and callout 2 points to the PANELS button. Below these are Previous, Next, and New navigation buttons.
- ACCEPT PATIENT:** Callout 5 points to the ACCEPT PATIENT button (with a green checkmark icon). Next to it is a DELETE PATIENT button (with a red X icon) and fields for Kit Lot # and Agn Lot #.
- WORKLIST FUNCTIONS:** Callout 6 points to the Display / Edit button. Other buttons in this section include Print All, Clear, Print Record, and Consumables.
- Right Panel:** Contains a vertical stack of buttons: RUN, PAUSE, STOP, PRIME, COVER, Water, Wash, Substr, S Wste, Wste, and Tubes.

# Manually Ordering Barcoded Patients

1. Select **WORKLIST**.
2. Select **PATIENT** under Manual Entry Options.
3. Enter patient accession number in the Accession # field.
4. Select **Assign Tube Position**.
5. Under Select Rack To Use, select the letter of the Sample Rack where the sample was placed.
6. Under Select Position To Use, select the white position indicator for the sample. This position turns red.
7. Select **OK**. The tube position appears to the right of the **Assign Tube Position** button on the Worklist screen.
8. Order the appropriate tests using the **TESTS** button.
9. Select **ACCEPT PATIENT**.
10. Select the **Display/Edit** button when all patient samples have been ordered to view the worklist.

**IMMULITE 2000 XPi: Worklist** Version 6.3

1. HOME 2. **WORKLIST** 3. REVIEW 4. KITS 5. LIS 6. QC 7. REPORTS 8. MENU 9. HELP 10. LOG OFF

**MANUAL ENTRY OPTIONS**

2. **PATIENT** ADJUSTOR CONTROL CALIB. VER.

Skip Name  Skip Demographics

3. Accession # 77532177 STAT Secondary Tube

Name Dilution Manual Dilution

Patient ID

Birthdate

Physician

4. **Assign Tube Position** C-2

8. **TESTS**

PANELS

9. **ACCEPT PATIENT** **DELETE PATIENT** Kit Lot # Agn Lot #

**WORKLIST FUNCTIONS**

10. **Display / Edit** Print All Clear Print Record Consumables

Tests Ordered Dilution Factor

FT4

TSH

TT4

FT3

UP

DOWN

RUN PAUSE STOP PRIME COVER Water Wash Substr S Wste Wste Tubes

**Note:**

Before ordering unbarcoded samples, the tubes must be on the system and the system must be in Run mode.

# Ordering Dilutions and STATs

## Manual Dilution

- Locate the accession number of the manually diluted sample from the Worklist screen.
- Order the appropriate test(s).
- Select **Manual Dilution**.
- Enter the appropriate dilution factor.
- Select **OK**.
- Select **ACCEPT PATIENT**.

**Note:**

The manual dilution factor is applied to all tests ordered on the sample.

## Onboard Dilution

- Locate the accession number of the sample to be diluted from the Worklist screen.
- Order the appropriate test(s).
- Select **Dilution** and then select the test to dilute.
- Select **X3, X5, X10, X20, X40, or X100** for a 1:3, 1:5, 1:10, 1:20, 1:40, or 1:100 dilution, respectively. The dilution factor will now appear next to the test in the Tests Ordered box.
- Select **ACCEPT PATIENT**.

## STAT

- Select the STAT button on the Worklist screen and then the test name in the Tests Ordered window. The test name selected turns red.

# Microsample Tubes and Tube Top Cups

On the IMMULITE 2000 XPi system, the dead volume of secondary and primary tubes is 250 $\mu$ L. There are two options for running tests using samples whose volumes are less than 250  $\mu$ L:

## 1. Micro sample Tubes

- The dead volume of microsample tubes is 50 $\mu$ L.
- Microsample tubes are identified on the system by a permanent barcode label attached to a reusable microsample tube holder. A disposable 10 x 50 mm polystyrene sample tube is inserted into the holder.
- Microsample tubes are placed in the same standard sample racks that are used to run secondary and primary tubes.

## 2. Tube Top Cups

- The dead volume of tube top cups is 100 $\mu$ L.
- Tube top cups must be placed in a dedicated tube top sample rack. The tube top racks are identified with a lower case letter on the rack barcode. The tube top rack has a capacity of 15 tubes. However, you can only load 8 shorter tubes (75 mm) in the front row and 7 taller tubes (100 mm) in the back row.



# Entering a New Control

1. From the Control Entry screen, select **New Control** to clear the screen of existing control information.
2. From the Control Identification Window enter the control:
  - Name (maximum 6 characters)
  - Source (optional)
  - Lot # (up to 3 characters)
  - Expiration Date
3. Select **Add New Tests**.
  - Select the appropriate test and select **OK**.
  - Type in the control level and select **OK**.
4. Type in the Mean and SD values for the appropriate level. The SD Multiplier reflects the range for the standard deviation. The default is 2.
5. Select **Calculate Range** to calculate the Low and High Limits.
6. From the Acceptance Criteria Options area of the screen, select one of the QC acceptance criteria options. The default is Control Not For OnLine QC.
7. Select **Save**.
8. Select **OK** once the message "Record Saved Successfully" appears.

IMMULITE 2000 XPI: QC Data Entry Version 6.1

HOME WORKLIST REVIEW KITS LIS QC REPORTS MENU HELP LOG OFF

**Control Identification**

Name:

Source:

Lot #:

Expiration Date:

**Add New Tests** **Add New Level** **Change Level**

Accession Num:

Tests Selected Level Test Type

**Control Entry** pg/mL

**Target Values**

Mean:

SD:

SD Multiplier: 2

Low Limit:

High Limit:

**Calculate Range**

Control Not For OnLine QC

Use Single Rule

Use Multi Rule

1 (2S) Rule

1 (3S) Rule

2 (2S) Rule

R (4S) Rule

4 (1S) Rule

**Use Control for QC**

Result #1:

Result #2:

Result #3:

Result #4:

**Save** **New Control** **Delete Control**

**UP** **DOWN** **Previous Control** **Next Control**

**RUN** **PAUSE** **PRIME** **COVER**

Water Wash Substirt S Waste L Waste Tubes

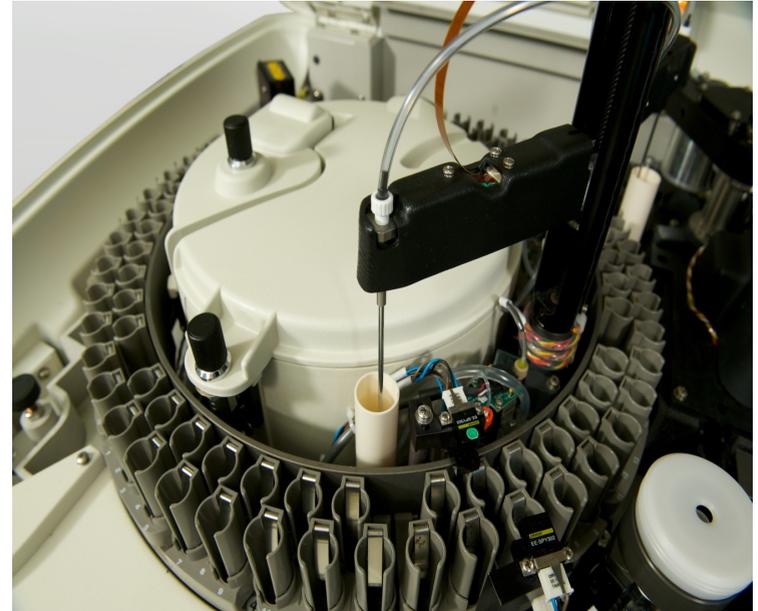
# Weekly Maintenance – Cleaning the Waste Tube

1. If necessary, initialize diagnostics.
2. Select **Waste Tube Cleaning**.
3. Select **Run** at the top of the window.
4. When the program is finished initializing, follow the prompt on the screen to place a sample tube with 3 mL Probe Cleaning Solution into position 1 of the Sample Rack.
5. Follow the prompt on the screen to add 3 mL of Probe Cleaning Solution to compartment A of the Probe Cleaning Wedge and place the wedge into position 1 of the Reagent Carousel.
6. Select the button labeled **Press When Sample Tube and Reagent Wedge are Loaded**.
7. Allow the program to complete its running cycle. When complete, "Program Complete" appears on the screen.
8. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic. Otherwise, select **EXIT**, followed by **QUIT**.



# Weekly Maintenance – Checking the Sample Probe Dispense Angle

1. If necessary, initialize diagnostics.
2. Select Home All Motors.
3. Select Run at the top of the window.
4. When “Program Complete” appears on the screen, select Load Program.
5. Select Cover Unlock.
6. Select Run at the top of the window.
7. Open the top cover.
8. Select Load Program.
9. Select Sample Probe Dispense Angle.
10. Select Run at the top of the window.
11. When the program is finished initializing, select the button labeled Probe must be centered in the blind hole. Press to continue.
12. Select Press to Dispense Water.
13. Visualize the dispense of fluid from the sample probe to the blind hole. It should be a straight solid stream.
14. To end the sample probe dispense test, select the button labeled Confirm that Probe Angle Passed. Press to end Program. “Program Complete” appears on the screen.
15. To continue running diagnostics, select Load Program and load the appropriate diagnostic. Otherwise, select EXIT, followed by QUIT



# Monthly Maintenance – Decontaminating the System Bottles

1. Disconnect the water and probe wash bottles from the system.
2. Empty the bottles and thoroughly wash the inside of the bottles with 70% isopropyl alcohol.
3. Empty the fluid bottles of the 70% isopropyl alcohol and then rinse the fluid bottles well with distilled or de-ionized water to completely remove any residue of isopropyl alcohol in the bottles.
4. Allow the bottles to air dry.
5. Fill the clean water bottle with fresh distilled or de-ionized water, and the clean probe wash bottle with freshly prepared probe wash.
6. Reinstall the fluid bottles on the system



# Monthly Maintenance – Decontaminating the System Bottles

1. Disconnect the water and probe wash bottles from the system.
2. Empty the bottles and thoroughly wash the inside of the bottles with 70% isopropyl alcohol.
3. Empty the fluid bottles of the 70% isopropyl alcohol and then rinse the fluid bottles well with distilled or de-ionized water to completely remove any residue of isopropyl alcohol in the bottles.
4. Allow the bottles to air dry.
5. Fill the clean water bottle with fresh distilled or de-ionized water, and the clean probe wash bottle with freshly prepared probe wash.
6. Reinstall the fluid bottles on the system



# Monthly Maintenance – Decontaminating the Lines

1. If necessary, initialize diagnostics.
2. Select **Decontamination**.
3. Select **Run** at the top of the window.
4. When the program is finished initializing, follow the prompts by placing the water probe into the reagent pipettor wash station.
5. Continue to follow the prompts by disconnecting the water and probe wash lines from the water and probe wash bottles. Place the water and probe wash lines into an empty beaker.
6. Select **Press to continue**.
7. Allow the diagnostic to continue. When the next prompt appears, connect the fluid lines to the decontamination bottle containing 350mL of prepared probe wash.
8. Select **Press to continue**.
9. Allow the diagnostic to continue. When the next prompt appears, disconnect the water and probe wash lines and place them into the empty beaker.
10. Select **Press to continue**.
11. Allow the diagnostic to continue. When the next prompt appears, connect the water line into the water bottle and the probe wash line into the probe bottle.
12. Select **Press to continue**.
13. Allow the diagnostic to continue. When the next prompt appears, take the water probe from the reagent pipettor wash station and place it back into the water probe station. After replacing the water probe, the system will indicate that the program is complete.
14. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic. Otherwise, select **EXIT**, followed by **QUIT**.



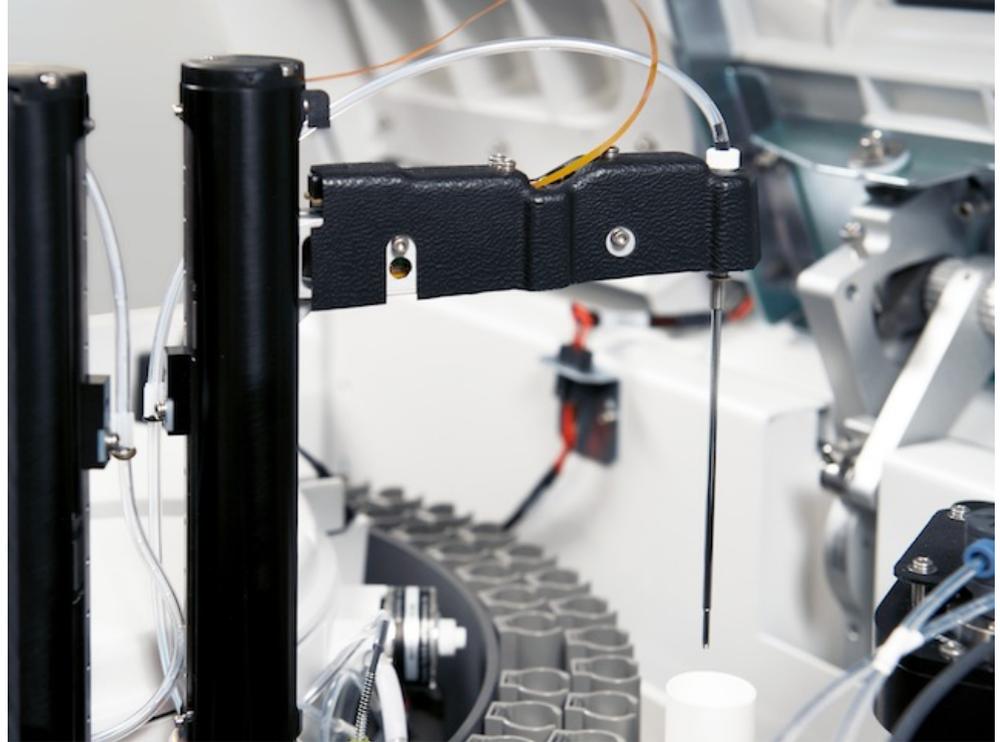
# Monthly Maintenance – Decontaminating the Clot Transducer

1. If necessary, initialize diagnostics.
2. Select **Transducer Decon**.
3. Select **Run** at the top of the window.
4. When the program is finished initializing, follow the prompt on the screen by placing a 12x75 mm sample tube with 2.5 mL of 0.1M of sodium hydroxide in position 1 of a sample rack, and place the sample rack in position 1 of the sample carousel.
5. Select **Press to Start**.
6. Allow the program to complete its running cycle. When complete, "Program Complete" appears on the screen.
7. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic. Otherwise, select **EXIT**, followed by **QUIT**.



# Monthly Maintenance – Checking the Reagent Probe Dispense Angle

1. If necessary, initialize diagnostics.
2. Select **Cover Unlock**.
3. Select **Run** at the top of the window.
4. Open the top cover.
5. Select **Load Program**.
6. Select **Reagent Probe Dispense Angle**.
7. Select **Run** at the top of the window.
8. When the program is finished initializing, select the button labeled **Press to Dispense Water**.
9. Visualize the dispense of fluid from the reagent probe. It should be a straight solid stream.
10. To end the sample probe dispense test, select the button labeled **Press to End Program**. "Program Complete" appears on the screen.
11. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic. Otherwise, select **EXIT**, followed by **QUIT**.



# Monthly Maintenance – Cleaning the Fan Filter

1. On the side of the system with the monitor arm, pull open the side panel of the system.
2. Unscrew the top and bottom screws of the fan filter guard, and then remove the fan filter guard.
3. Remove the fan filter from the system.
4. Clean the fan filter by either holding it under running water and rubbing gently to remove the dust, or it can be vacuumed. If the fan filter is clean with water, blot the fan filter dry before placing it back into the system.
5. Place a clean fan filter on the system.
6. Replace the fan filter guard by screwing the top and bottom screws.
7. Close the side panel of the system.



# Monthly Maintenance – Running Water Test PM

1. If necessary, initialize diagnostics.
2. Select **WatertestPM**.
3. Select **Run** at the top of the window.
4. When the program is finished initializing, follow the prompt on the screen to place a clean empty 12x75 mm tube in position 1 of a sample rack, and place the sample rack in position 1 of the sample carousel.
5. Select **Load tube and press to continue**.
6. When prompted, remove the water probe from the wash station and place it inside the empty 12x75 mm tube in position 1 of the sample rack in position 1 of the sample carousel.
7. Select **Place water probe in tube 1-1**.
8. Select **Press to dispense from the Water Probe** to collect water from the water probe.
9. When prompted by the software, remove the water probe from the tube and return it to the wash station.
10. Select **replace** Water Probe.
11. Allow the program to complete its running cycle.  
When complete, "Program Complete" appears on the screen.
12. To continue running diagnostics, select **Load Program** and load the appropriate diagnostic. Otherwise, select **EXIT**, followed by **QUIT**



## Quarterly Maintenance – Replacing the CO2 Scrubber

1. Pull the old CO2 scrubber tube away from the holding clips
2. Pull off the white connector that attaches the CO2 scrubber tube to the black tubing.
3. Write the date on the new CO2 scrubber tube.
4. Remove the clear plastic end from the new CO2 scrubber tube.
5. Connect the new CO2 scrubber tube to the white connector attached to the black tubing.
6. Insert the new CO2 scrubber tube into the holding clips, with the red cap on top and the white connector on the bottom.

**Note:**

To maintain proper airflow and to reduce the chance of developing an obstruction, the bottom end of the CO2 Scrubber tube must not touch the load scale plate.



# Diagnostic Jams

## 1. Identify the slave and motor number.

If a jam occurs while a diagnostic program is running, the slave and motor number of the component that jammed will be shown on the top of the screen. Use the Slave Motor Chart to determine the part of the system associated with the jam.

If the part of the system that jams is accessible to the operator (for example, the sample carousel or tube indexer), then investigate and try to resolve the problem. After resolving the problem, continue with the following steps.

If the part is not accessible to the operator (for example, the PMT shuttle or luminometer chain), then contact technical support.

## 2. Run the Home All Motors

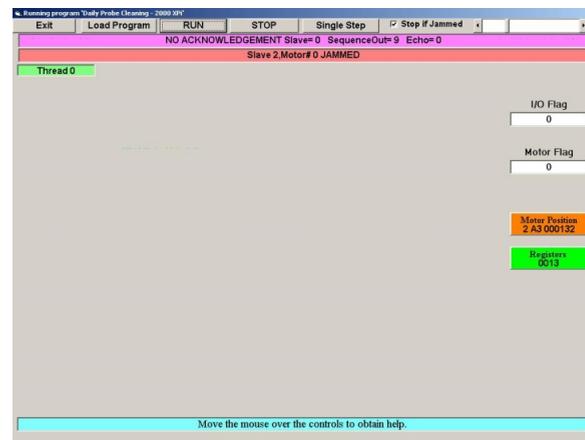
Run the Home All Motors diagnostic if the problem was resolved using the Slave Motor Chart:

- Select Load Program at the top of the screen to exit the current diagnostic and return to the list of diagnostic programs.
- Select Home All Motors from the list.
- Press Run in menu bar to start.

## 3. Determine if Home All Motors completes successfully.

If Program Complete displays at the top of the screen, then Home All Motors successfully completed. Rerun the diagnostic that had jammed by selecting Load Program and selecting the diagnostic from the list.

If the system jams while Home All Motors is running, contact technical support.



## Slave Motor Chart

| Slave 0 Module     | Motor # | Slave 2 Module      | Motor # |
|--------------------|---------|---------------------|---------|
| Sample Arm X       | 0       | Bead Carousel       | 0       |
| Sample Arm Z       | 1       | Tube Indexer        | 1       |
| Sample Valve       | 2       | Tube Transporter    | 2       |
| Sample Dilutor     | 3       | Processor Shuttle   | 3       |
| Sample Carousel    | 4       | PMT Shuttle         | 4       |
| Slave 1 Module     | Motor # | Bead Dispenser      | 5       |
| Reagent Arm X      | 0       | Slave 3 Module      | Motor # |
| Reagent Arm Z      | 1       | Luminometer Chain   | 0       |
| Reagent Valve      | 2       | Luminometer Shuttle | 1       |
| Reagent Dilutor    | 3       | Tube Lifter         | 2       |
| Reagent Carousel   | 4       | Geneva Indexer      | 3       |
| Reagent Lid Opener | 5       | PMT Attenuator      | 4       |
|                    |         | Slave 4 Module      | Motor # |
|                    |         | Dilution Well       | 0       |
|                    |         | Wash Well           | 1       |

# Tube Indexer Jam

To resolve this error:

1. Ensure the instrument is in Pause mode.
2. Open the front panel doors and verify that the proper reaction tubes are in the tube hopper.
3. Pull out the pin that connects the orientation brush to the orientation chute.
4. Lift the orientation brush and place it behind the orientation chute. Be sure not to pull the orientation brush towards the front of the instrument to prevent the disconnecting of wires.
5. Take out and discard all reaction tubes in the orientation chute including any tubes that are in the tube indexer itself.
6. Place the orientation brush back in the orientation chute.
7. Put the pin back in place to secure the orientation brush.
8. Push the tube hopper back into place and place the instrument back into Run.



# Bulk Exit Chute Error

To resolve this error:

1. Ensure the instrument is in Stop mode and open the instrument top cover and the front panel doors.
2. Remove the Solid Waste Container and check to see if it's full.
3. Place a shallow container or an absorbent cloth over the Solid Waste Load Scale, toward the back wall.
4. Insert the Waste Chute Clean Out Tool into the Waste Chute opening from the bottom. The Waste Chute Clean Out Tool should never be inserted into the top opening of the Waste Chute.
5. Remove the tool. The jammed Reaction Tubes and beads will fall onto the shallow container or absorbent pad.
6. Locate the Waste Chute Cover on top of the instrument behind the Wash Spin Station. Using a flashlight, look into the opening for the presence of Reaction tubes.
7. If tubes are present, manually remove them.
8. To ensure the blockage was removed, drop an empty Reaction Tube marked with an "X" down the Solid Waste Chute. The marked Reaction Tube should travel freely down the chute to the tray or cloth in the Solid Waste Container area.
9. If the marked Reaction Tube does not drop through, repeat the above steps to dislodge the jam.



# Reagent Probe Errors

## Tip Jam Reagent Pipettor

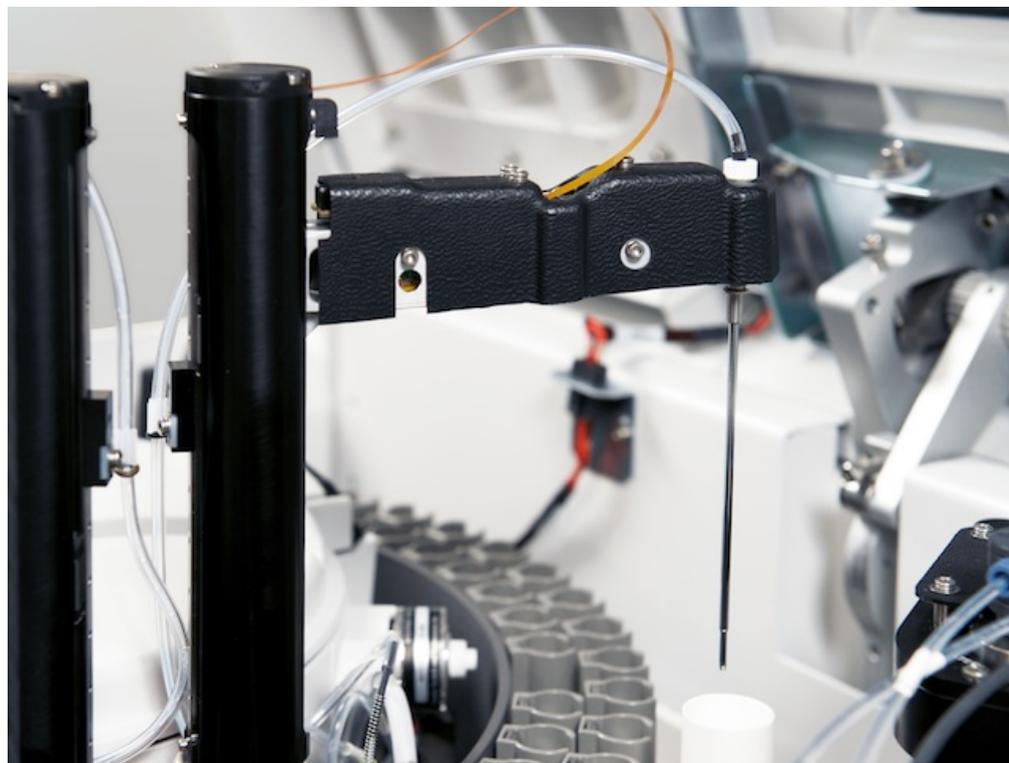
To resolve this error:

1. Identify the reagent position with the error.
2. Remove the reagent wedge from the system.
3. Check the glide.
4. Reload the reagent wedge.
5. Select **RUN**.

## Reagent Probe False Level Sense Error

To resolve this error:

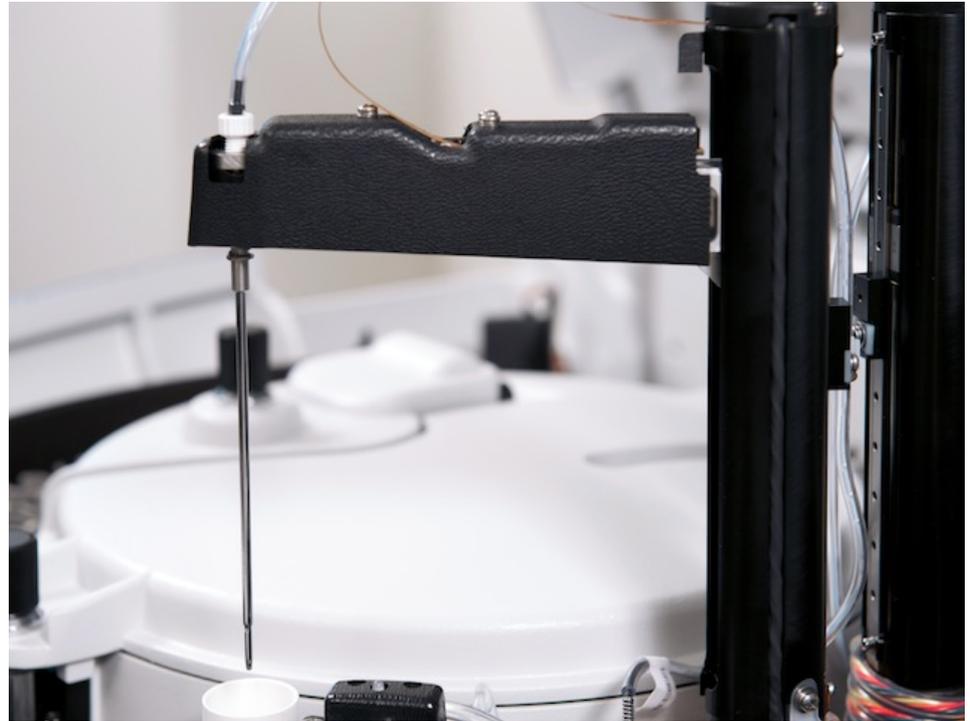
1. Identify the reagent position with the error.
2. Remove the reagent wedge from the system.
3. Check the top of the wedge.
4. Check for bubbles in the liquid.
5. Reload the reagent wedge.
6. Select **RUN**.



# Sample Pipettor Level Sense Error

To resolve this error:

- Identify the sample position with the error.
- Remove the sample from the system.
- Add more sample or transfer to another tube.
- Reload the sample on the system.



# Sample Pipettor Clot Detection Error

To resolve a clot detection error that places the system into sample pause:

1. Open the pipettor cover.
2. Visually inspect the probe – If necessary, clean or replace the probe.
3. Close the pipettor cover.
4. Prime the DRDs.
5. Locate and remove the sample.
6. Select **RUN** to resume system operation.

**Note:**

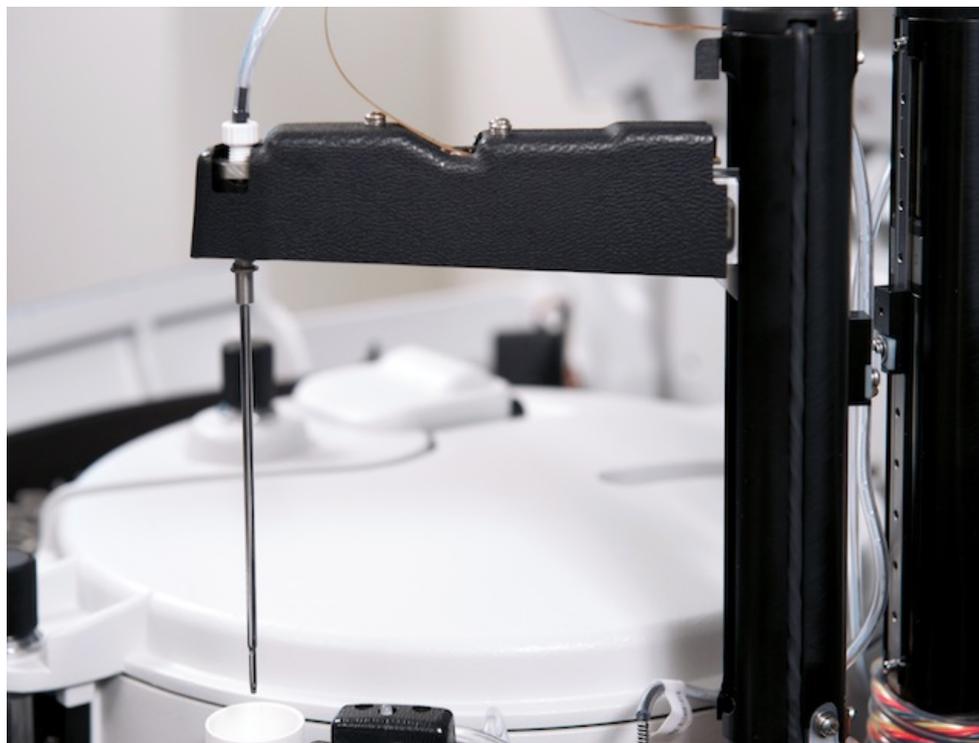
If the clot detection error is caused by air in the system, it is necessary to thoroughly prime the system



# Damaged Probe

To replace a damaged probe:

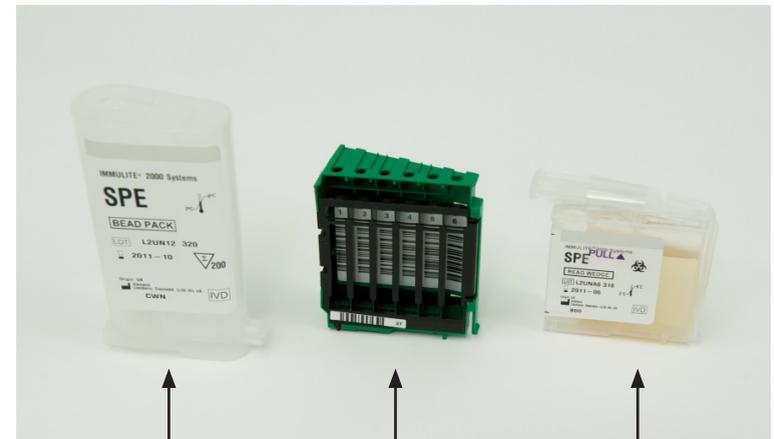
1. Remove the probe tube retaining clip from the reagent/sample arm column.
2. Unscrew the probe from the arm mount, and remove the probe from the arm.
3. Unscrew the black probe extension from the manifold block, turning both the entire probe and extension piece together.
4. Unscrew the probe extension from the probe. The extension piece will be reused to mount the new probe.
5. Attach the probe extension to the fitting of the new probe.
6. Attach the probe extension to the manifold block by turning both the entire probe and the extension piece together.
7. Insert the probe into the arm mount and tighten securely.
8. Verify the tubing is on the left side of the sample/reagent arm and secure the tubing into the probe tube retaining clip on the reagent/sample arm column.



# Loading

1. Scan the 2D barcode from the 3gAllergy Specific IgE Universal kit.
2. Prepare the following vials for processing:
  - Scan and remove the adjustor allergen vial 2D-barcode sleeve.
  - Scan and remove the control allergen vial 2D-barcode sleeve.
  - Scan and remove the 2D-barcode sleeves on each patient allergen vial to be tested.
  - Replace all allergen vial caps with septum caps.
  - Insert allergen vials into allergen wedges.
3. Scan the front of the loaded allergen wedge into the database.
4. Load the allergen wedge into the reagent Carousel.
5. Load the universal reagent wedge and bead Pack.
6. Prepare and load adjustors, controls and patient samples.
7. Select **Run** to start sample processing.

Allergen Vials



Universal  
Bead Pack

Allergen  
Wedge

Universal  
Reagent  
Wedge

# Ordering Allergy Adjustors

1. Select **WORKLIST**.
2. Select **Next** to view the low adjustor. The adjustor lot number, adjustor level, tube position and test ordered for the first adjustor sample appears.
3. Delete the 0 and type the kit lot number in the Kit Lot # field.
4. Enter the adjustor allergen lot number in the Adj Allergen Lot # field.
5. Select **ACCEPT ADJUSTOR**.
6. Follow the same steps for the high adjustor.
7. Select **Display/Edit** to view the worklist.

The screenshot shows the 'IMMULITE 2000 XPi: Worklist' software interface, Version 6.1. The interface includes a top navigation bar with icons for HOME, WORKLIST, REVIEW, KITS, LIS, QC, REPORTS, MENU, HELP, and LOG OFF. Below this is a 'MANUAL ENTRY OPTIONS' section with tabs for PATIENT, ADJUSTOR, CONTROL, and CALIB. VER., and checkboxes for 'Skip Name' and 'Skip Demographics'. The main area contains input fields for 'Kit Lot #', 'Adjustor Lot #', 'Adjustor Level', and 'Adj Allergen Lot #', along with buttons for 'STAT', 'Secondary Tube', 'Dilution', 'Manual Dilution', 'Batch Tests By Rack', and 'Assign Tube Position'. A 'TESTS' field is also present. Navigation buttons include 'Previous', 'Next', and 'New'. At the bottom, there are 'ACCEPT ADJUSTOR' and 'DELETE ADJUSTOR' buttons. A 'WORKLIST FUNCTIONS' section at the very bottom includes 'Display / Edit', 'Print All', 'Clear', 'Print Record', and 'Consumables' buttons. On the right side, there is a vertical toolbar with 'RUN', 'PAUSE', 'STOP', 'PRIME', 'COVER', and a list of reagents: Water, Wash, Substr, S Wste, L Wste, and Tubes. Numbered callouts 1 through 7 point to the WORKLIST button, the 'Next' button, the Kit Lot # field, the Adj Allergen Lot # field, the ACCEPT ADJUSTOR button, the 'Next' button, and the Display / Edit button, respectively.

# Ordering Universal Allergy Controls

1. Select **WORKLIST**.
2. Select the **Next** button to view the first control sample accession number (which is read from the barcode label).
3. Select **TESTS** to view the Available Tests screen.
4. Select **ON BOARD** under Allergen.
5. Select **CONIGE** and then **OK**. The test name is added to the Tests Ordered box.
6. Select **ACCEPT CONTROL**.
7. Follow the same steps for the next level of universal allergy control.
8. Select **Display/Edit** when all control samples have been ordered to view the worklist.

The screenshot shows the 'IMMULITE 2000 XPi: Worklist' software interface, Version 6.1. The interface is divided into several sections:

- Navigation Bar:** Contains buttons for HOME, WORKLIST (highlighted with callout 1), REVIEW, KITS, LIS, QC, REPORTS, MENU, HELP, and LOG OFF.
- MANUAL ENTRY OPTIONS:** Includes buttons for PATIENT, ADJUSTOR, CONTROL (highlighted with callout 2), and CALIB. VER. There are also checkboxes for 'Skip Name' and 'Skip Demographics'.
- Control Entry Form:** Contains fields for Accession # (~CSPE 1312011121), Control Name (SPE), Control Lot # (131), and Control Level (1). It also has buttons for STAT, Secondary Tube, Dilution, Manual Dilution, Batch Tests By Rack, and Assign Tube Position (D-1).
- TESTS PANELS:** A section with callout 3 pointing to the TESTS button and callout 2 pointing to the PANELS button. Below it are Previous, Next, and New navigation buttons.
- ACCEPT CONTROL:** A button with a green checkmark icon, highlighted with callout 6. Next to it is a DELETED CONTROL button with a red X icon.
- Kit Lot # and Agn Lot #:** Input fields for tracking kit and agent lots.
- WORKLIST FUNCTIONS:** A row of buttons at the bottom including Display / Edit (highlighted with callout 8), Print All, Clear, Print Record, and Consumables.
- Right Side Panel:** A vertical column of control buttons: RUN, PAUSE, STOP, PRIME, COVER, Water, Wash, Substrt, S Wstp, L Wstp, and Tubes.

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