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Related Documents: N/A

ARCHITECT I-SERIES ANALYZER MAINTENANCE

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Principle

The ARCHITECT i1000SR and i2000SR are a high performance immunoassay diagnostic systems capable of quantifying selected analytes in biological fluids. Daily, weekly, monthly, quarterly, and as-needed maintenance are performed to assure that the instrument is functioning optimally. The system stores 12 months of maintenance logs.

Reagents

a. Wash buffer: The wash buffer is phosphate-buffered saline with an antimicrobial ingredient. Concentrated wash buffer is supplied in a 1 L bottle that must be manually diluted prior to use or prepared in a 10 L cubitainer for use with the ARCHITECT ARM (Automated Reconstitution Module) accessory. You can add wash buffer while the system is in Ready or Running mode
b. Trigger: Made of sodium hydroxide. Has 28 day stability on the instrument.
c. Pre-trigger solution: Made of hydrogen peroxide and kept refrigerated. It is sensitive to light. Has a 10 day stability on the analyzer.

Equipment

This maintenance procedure is intended for the Architect i1000sr and i2000sr.

Supplies

1. Cotton swabs (for weekly maintenance)
2. Gauze pads
3. Gloves
4. DI water
5. Maintenance Cleaning Bottle for daily maintenance (use the supplied maintenance cleaning bottle. It has no barcode and does not use a septum)
6. Probe Conditioning Solution Bottle for daily maintenance (use with new septum each time)

ARCHITECT I-SERIES ANALYZER MAINTENANCE
Quality Control

The ARCHITECT i1000sr and i2000sr use various quality control materials. Refer to the ARCHITECT Quality Control Procedure for details on quality control types, frequency, and acceptability criteria.

Procedure

A. Daily Maintenance: i2000sr

Daily Maintenance for the i2000sr consists of:

- A procedure that takes about 21 minutes to complete
- A manual user-defined procedure that takes 1 minute to complete.

During the first daily maintenance procedure (6041) the system automatically:

- Cleans and conditions sample pipettor probe
- Cleans wash zone 1 and 2 (probes, tubing, sensors and vacuum vessels)
- Mixes the micro particles on the reagent carousel
- Flushes and primes Pre-Trigger and Trigger manifolds

Note: The ARCHITECT i2000sr must be in **Warming or Ready status in order to complete daily maintenance.

1. From the System menu, select **Maintenance**. From the **Maintenance** screen, select the desired module then do the following:
    a. Select **Daily Maintenance Tab**.
    b. Select **Daily maintenance (6041)**
    c. Select **F5- Perform**.
    d. Select **Proceed**, and then follow the instructions in the instruction box.
    e. Add 25- 30 mL of Sodium Hypochlorite to the empty Maintenance cleaning bottle.
    f. When instructed, place the Maintenance Cleaning bottle in the inner (yellow) ring of position 1 of the reagent Carousel
    g. When instructed, place the septum on the Probe Conditioning Solution bottle and place it in the outer (pink) ring of position 1 of the reagent Carousel. The probe Conditioning Solution bottle is stored in the fridge.
    h. Click OK to perform procedure.
    i. When instructed, remove the maintenance bottles
    j. Select **Done** on the SCC display to complete the procedure.

** See Below for Visual on how to place maintenance bottles

ARCHITECT I-SERIES ANALYZER MAINTENANCE

ARCHITECT I-SERIES ANALYZER MAINTENANCE
HOW TO PREPARE SODIUM HYPOCHLORITE FOR DAILY MAINTENANCE:

PREPARATION OF SODIUM HYPOCHLORITE SOLUTION

TO CALCULATE THE PARTS OF **TAP WATER** REQUIRED TO MIX WITH ONE PART OF MANUFACTURER-SUPPLIED SODIUM HYPOCHLORITE SOLUTION, USE THE FOLLOWING FORMULA

OR

PERFORM AS-NEEDED MAINTENANCE PROCEDURE 6100 FOR MODULE 5

- A = % OF SODIUM HYPOCHLORITE SOLUTION DESIRED
- B = % OF SODIUM HYPOCHLORITE (ACTIVE OR AVAILABLE CHLORINE) IN MANUFACTURER-SUPPLIED SOLUTION FROM BOTTLE LABEL.)
- X = NUMBER OF PARTS OF WATER REQUIRED TO MIX WITH ONE PART OF MANUFACTURER-SUPPLIED SODIUM HYPOCHLORITE (ACTIVE OR AVAILABLE CHLORINE) SOLUTION.

$$X = \frac{B - A}{A}$$

SOLUTION IS GOOD FOR 30 DAYS.

2. From the System menu, select **Maintenance**. From the **Maintenance** screen, select the desired module then do the following:
    a. Select **Daily Maintenance Tab**.
    b. Select **check iARM Wash Concentrate (9102)**
    c. Select **F5- Perform**.
    d. Select **Proceed**, and then follow the instructions in the instruction box.

How to Replace Concentrated Wash Buffer on the iARM:
Note: Do not replace a cubitainer until the Load cubitainer icon displays. The cubitainer is supplying concentrated wash buffer until the icon displays.

Note: The iARM does not have to be stopped when a cubitainer is replaced.

1. Remove the concentrated wash buffer straw assembly from the cubitainer.
2. Store the concentrated wash buffer straw in the straw holder.
3. Remove the empty cubitainer from the iARM.
4. Lift the new cubitainer into position on the iARM. The cardboard cutout handle can be used to lift the cubitainer but should never be used to support the full weight of the cubitainer.
5. Remove the cardboard cutout on top of the cubitainer and cubitainer cap and insert the concentrated wash buffer straw into the full cubitainer. Twist the fitting to tighten.

   On the iARM Home screen, the cubitainer percentage of remaining concentrated wash buffer is updated.
6. Discard the empty cubitainer according to applicable local regulations.

Select **Done** on the SCC display to complete the procedure.

Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead. The System Status returns to ready when a maintenance procedure is complete

ARCHITECT I-SERIES ANALYZER MAINTENANCE

B. Daily Maintenance: i1000sr

Daily Maintenance for the i1000sr consists of:

- A procedure that takes about 21 minutes to complete

During the first daily maintenance procedure (6040) the system automatically:

- Cleans and conditions sample pipettor probe
- Dry vacuum pump filter
- Mixes the micro particles on the reagent carousel
- Flushes and primes Wash Zone, Pre-Trigger, and Trigger manifolds

Note: The ARCHITECT i1000sr must be in **Warming or Ready status in order to complete daily maintenance.

1. From the System menu, select **Maintenance**. From the **Maintenance** screen, select the desired module then do the following:
    a. Select **Daily Maintenance Tab**.
    b. Select **Daily maintenance (6040)**
    c. Select **F5- Perform**.
    d. Select **Proceed**, and then follow the instructions in the instruction box.
    e. Add 25- 30 mL of Tap Water to the empty WZ Probe maintenance water bottle.
    f. Place the bottle in the reagent carrier in the yellow ring and place the carrier in the Maintenance Bay.
    g. Select **Proceed** to perform procedure.
    h. When instructed, remove the carrier.
    i. Select **Done** on the SCC display to complete the procedure.

C. Weekly Maintenance: i2000sr

The following are the required weekly maintenance procedures for the ARCHITECT i2000:

- Cleaning the air filters
- Cleaning the outside of the pipettor probes
- Cleaning the outside of the wash zone probes and wash manifold

1. From the System menu, select Maintenance. From the Maintenance screen, select the desired module (instrument module in this case) then do the following:
    a. Select **Weekly Maintenance Tab**.
    b. Select the as weekly maintenance procedure that you wish to perform from the weekly Maintenance tab. The weekly maintenance procedures are listed above.
    c. Select **F5- Perform**.
    d. Click **OK** to perform procedure.
    e. Select Proceed, and then follow the instructions in the instruction box.
    f. If necessary, view the videos that are embedded in the individual maintenance procedures for instructions.
    g. Select **Done** on the SCC display to complete the procedure.

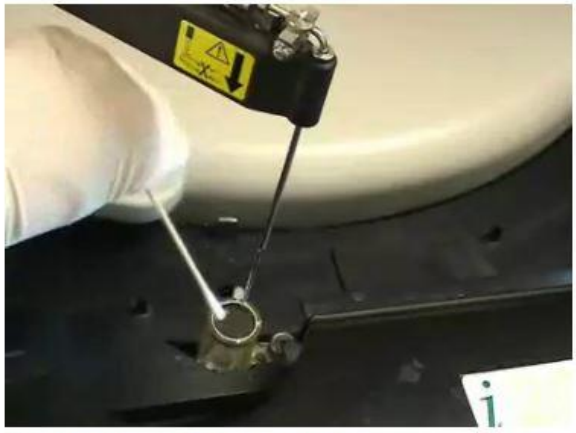
Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead. The System Status returns to ready when a maintenance procedure is complete

** See Below for i2000sr weekly maintenance visual:

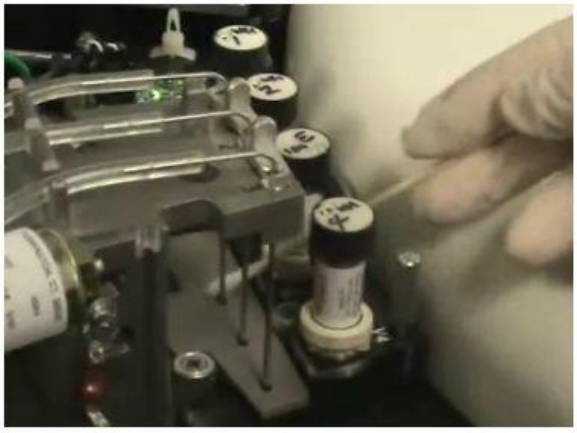
ARCHITECT I-SERIES ANALYZER MAINTENANCE

i2000SR

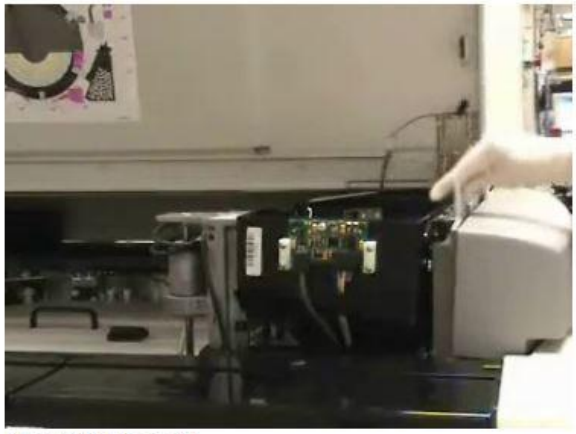
- **Cleaning the air filters**
- **Cleaning the outside of the pipettor probes**
- **Cleaning the outside of the wash zone probes and wash mainfold**



Outside Pipettor Probe Cleaning



Outside Wash Zone probe cleaning



Clean Air Filters #1

Clean Air Filter #2

ARCHITECT I-SERIES ANALYZER MAINTENANCE

D. Weekly Maintenance: i1000sr

The following are the required weekly maintenance procedures for the ARCHITECT i1000:

- Clean the wash Cup
- Cleaning the outside of the pipettor probes
- Cleaning the outside of the wash zone probes and wash manifold

2. From the System menu, select Maintenance. From the Maintenance screen, select the desired module (instrument module in this case) then do the following:
    a. Select **Weekly Maintenance Tab**.
    b. Select the as weekly maintenance procedure that you wish to perform from the weekly Maintenance tab. The weekly maintenance procedures are listed above.
    c. Select **F5- Perform**.
    d. Click **OK** to perform procedure.
    e. Select Proceed, and then follow the instructions in the instruction box.
    f. If necessary, view the videos that are embedded in the individual maintenance procedures for instructions.
    g. Select **Done** on the SCC display to complete the procedure.

Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead. The System Status returns to ready when a maintenance procedure is complete.

E. Monthly Maintenance: i1000sr

**Note: There is no monthly maintenance for the i2000sr.

The following is the required monthly maintenance procedure for the ARCHITECT i1000:

- Cleaning the air filters

3. From the System menu, select Maintenance. From the Maintenance screen, select the desired module (instrument module in this case) then do the following:
    a. Select **Monthly Maintenance Tab**.
    b. Select the as monthly maintenance procedure that you wish to perform from the monthly Maintenance tab.
    c. Select **F5- Perform**.
    d. Click **OK** to perform procedure.
    e. Select Proceed, and then follow the instructions in the instruction box.
    f. If necessary, view the videos that are embedded in the individual maintenance procedures for instructions.
    g. Select **Done** on the SCC display to complete the procedure.

Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead. The System Status returns to ready when a maintenance procedure is complete.

****Note:** There are NO required monthly or quarterly maintenance procedures for the i2000sr.

F. As Needed Maintenance:

ARCHITECT I-SERIES ANALYZER MAINTENANCE

As needed maintenance is usually performed as part of troubleshooting and should only be performed when the need arises. Abbott technical support personnel or the Online System Operations Manual may instruct medical technologists and technicians to perform as needed maintenance as part of troubleshooting. The following procedures are found under as needed maintenance:

- **Sample Pipettor Calibrtion (111)**
- **R1 Pipettor Calibration (1112)**
- **R2 Pipettor Calibration (1113)**
- **STAT Pipettor Calibration (117)**
- **Flush Fluids (2130)**
- **Air flush (2133)**
- **Prime wash Zones (2151)**
- **Prime Pre-Trigger and Trigger (2152)**
- **Wash Buffer Unload (2185)**
- **RV Loader Sensor Calibration (3131)**
- **Temperature Status (3520)**
- **Temperature Check- Manual (3530)**
- **Buffer Run (4050)**
- **WZ Probe Cleaning-Bleach (6043)**

Note: The ARCHITECT i-series analyzer must be in **Ready status in order to complete any of the maintenance.

1. From the **System menu**, select **Maintenanc**e. From the Maintenance screen, select the desired module then do the following:

h. Select **As Needed maintenance Tab**.

i. Select the as needed maintenance procedure that you wish to perform from the as needed maintenance tab. The as needed maintenance procedures are listed above.

j. Select **F5- Perform**.

k. Click **OK** to perform procedure.

l. Select **Proceed**, and then follow the instructions in the instruction box.

m. If applicable, view the videos that are embedded in the individual maintenance procedures for instructions.

n. Select **Done** to return to maintenance screen.

Do **NOT select Quit, as this will not show the maintenance procedure as complete. Select **Done** instead at the end of each procedure. The System Status returns to ready when a maintenance procedure is complete.

References

Architect ci16200 System Quick Reference Guide
AlinIQ Mobile Library
Architect System Operations Manual

Attachments

Authorized Reviewers

Section Medical Director or Technical Director.

ARCHITECT I-SERIES ANALYZER MAINTENANCE

Document Control

Location of Master: Master electronic file stored on the Beaumont Laboratory server under S:/ClinPathChem/Automated Chemistry/Document Control Library/NEW INDEX AND TEMPLATE/CSL/ARC/BL ARCHITECT

Master printed document stored in the Automated Chemistry CORE Lab, Royal Oak.
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Number of circulating Controlled Copies: 8
Location of circulating Controlled Copies: Chemistry Labs- Dearborn, Farmington Hills, Grosse Pointe, Taylor, Trenton, Troy, Wayne, Royal Oak Automated Chemistry Stat Lab

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Document History

Signature	Date	Revision #		Related Documents Reviewed/
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Approved by:				
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