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Abbott Architect I-Series Analyzer Maintenance

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

To describe how to provide maintenance to the Architect I-Series Analyzers

II. 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.

III. 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.

IV. EQUIPMENT:

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

V. SUPPLIES

A. Cotton swabs

B. Gauze pads

C. Gloves

D. DI water

E. Maintenance Cleaning Bottle for daily maintenance (use the supplied maintenance cleaning bottle. It has no barcode and does not use a septum)

F. Probe Conditioning Solution Bottle for daily maintenance (use with new septum each time)

VI. QUALITY CONTROL

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

VII. DAILY MAINTENANCE PROCEDURE: i2000sr

A. **Daily Maintenance of the i2000sr consists of:**

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

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

1. Cleans and conditions sample pipettor probe
2. Cleans wash zone 1 and 2 (probes, tubing, sensors and vacuum vessels)
3. Mixes the micro particles on the reagent carousel
4. 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.

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

1. Select **Daily Maintenance Tab**.
2. Select **Daily maintenance (6041)**
3. Select **F5- Perform**.
4. Select **Proceed**, and then follow the instructions in the instruction box.
5. Add 25- 30 mL of Sodium Hypochlorite to the empty Maintenance cleaning bottle.
6. When instructed, place the Maintenance Cleaning bottle in the inner (yellow) ring of position 1 of the reagent Carousel
7. 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.
8. Click OK to perform procedure.
9. When instructed, remove the maintenance bottles
10. Select **Done** on the SCC display to complete the procedure.
    ** See Below for Visual on how to place maintenance bottles

D. **How to prepare sodium hypochlorite solution for daily maintenance**

1. To calculate the parts of tap water required to mix with one part of manufacturer-supplied sodium hypochlorite solution, use the following formula.
    a. A = % of sodium hypochlorite solution desired
    b. B = % of sodium hypochlorite (active or available chlorine) in manufacturer-supplied solution from bottle label).
    c. X = number of parts of water required to mix with one part of manufacturer-supplied sodium hypochlorite (active or available chlorine) solution.

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

    d. Solution is good for 30 days.
2. OR perform as-needed Maintenance Procedure 6100 for Module 5.

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

1. Select **Daily Maintenance Tab**.
2. Select **check iARM Wash Concentrate (9102)**
3. Select **F5- Perform**.
4. Select **Proceed**, and then follow the instructions in the instruction box.
5. 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.

F. **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.
   Note: 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.
7. The Load Cubitainer icon will be yellow when it needs to be replaced. Once the cubitainer has been replaced, select the yellow icon. The icon will return to the original status.

VIII. DAILY MAINTENANCE PROCEDURE: i1000sr

A. Daily Maintenance for the i1000sr consists of:
   1. A procedure that takes about 21 minutes to complete

B. During the first daily maintenance procedure (6040) the system automatically:
   1. Cleans and conditions sample pipettor probe
   2. Dry vacuum pump filter
   3. Mixes the micro particles on the reagent carousel
   4. 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.

C. From the System menu, select **Maintenance**. From the **Maintenance** screen, select the desired module then do the following:
   1. Select **Daily Maintenance Tab**.
   2. Select **Daily maintenance (6040)**
   3. Select **F5- Perform**.
   4. Select **Proceed**, and then follow the instructions in the instruction box.
   5. Add 25- 30 mL of Tap Water to the empty WZ Probe maintenance water bottle.
   6. Place the bottle in the reagent carrier in the yellow ring and place the carrier in the Maintenance Bay.
   7. Select **Proceed** to perform procedure.
   8. When instructed, remove the carrier.
   9. Select **Done** on the SCC display to complete the procedure.

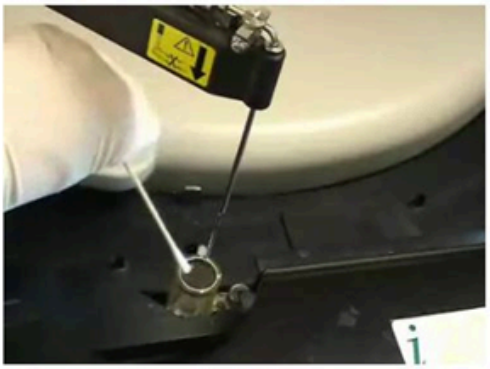
IX. WEEKLY MAINTENANCE PROCEDURE: i2000sr

A. The following are the required weekly maintenance procedures for the ARCHITECT i2000:
    1. Cleaning the air filters
    2. Cleaning the outside of the pipettor probes
    3. Cleaning the outside of the wash zone probes and wash manifold
    4. Cleaning the Routine and STAT Sample probe wash stations (User Defined)

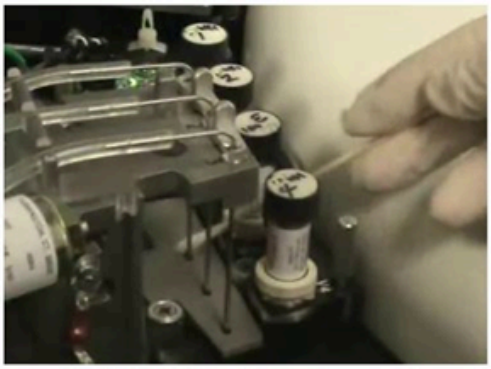
B. From the System menu, select **Maintenance**. From the **Maintenance** screen, select the desired module (instrument module in this case) then do the following:
    1. Select **Weekly Maintenance Tab**.
    2. Select the as weekly maintenance procedure that you wish to perform from the weekly Maintenance tab. The weekly maintenance procedures are listed above.
    3. Select **F5- Perform**.
    4. Click **OK** to perform procedure.
    5. Select **Proceed**, and then follow the instructions in the instruction box.
    6. If necessary, view the videos that are embedded in the individual maintenance procedures for instructions.
    7. 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:

i2000SR

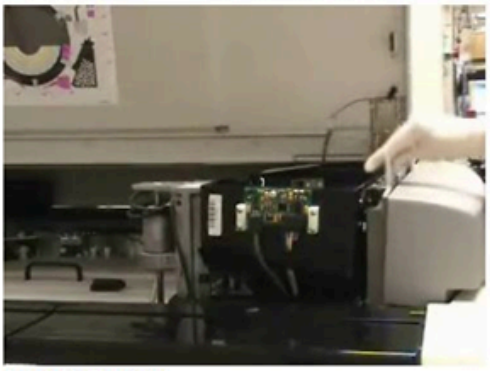
- **Cleaning the air filters**
- **Cleaning the outside of the pipettor probes**
- **Cleaning the outside of the wash zone probes and wash mainfold**



Outside Pipettor Probe Cleaning



Outside Wash Zone probe cleaning



Clean Air Filters #1

Clean Air Filter #2

X. WEEKLY MAINTENANCE PROCEDURE: i1000sr

A. The following are the required weekly maintenance procedures for the ARCHITECT i1000:
    1. Clean the wash Cup
    2. Cleaning the outside of the pipettor probes
    3. Cleaning the outside of the wash zone probes and wash manifold
    4. Cleaning the STAT Sample probe wash station (User Defined)

B. From the System menu, select **Maintenance**. From the **Maintenance** screen, select the desired module (instrument module in this case) then do the following:
    1. Select **Weekly Maintenance Tab**.
    2. Select the as weekly maintenance procedure that you wish to perform from the weekly Maintenance tab. The weekly maintenance procedures are listed above.
    3. Select **F5- Perform**.
    4. Click **OK** to perform procedure.

5. Select **Proceed**, and then follow the instructions in the instruction box.
6. If necessary, view the videos that are embedded in the individual maintenance procedures for instructions.
7. 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.

XI. MONTHLY MAINTENANCE SYSTEM BACKUP PROCEDURE: i2000sr AND i1000sr

A. As Monthly maintenance for the i2000sr and i1000sr, users will perform a System Backup. To perform a system back-up the system must be in Ready status
   1. From the System menu, select **Utilities.**
   2. Select **Create Back-up (F4)**, enter the date in the comment field and select **Done.**
   3. From the System menu, select **Diagnostics**.
   4. Choose the option for **Module 5 (the SCC)** at the top of the screen.
   5. Page down and select the **Utilities** tab.
   6. **Select procedure 6004 Copy Back-up Software.**
   7. Perform Select **F5- Perform**.
   8. Click **OK** to perform procedure.
   9. Select **Proceed**, and then follow the instructions in the instruction box.
   10. 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.

XII. REQUIRED MONTHLY MAINTENANCE PROCEDURE: ARCHITECT i1000sr - CLEANING AIR FILTERS

A. From the System menu, select **Maintenance**. From the **Maintenance** screen, select the desired module (instrument module in this case) then do the following:
   1. Select **Monthly Maintenance Tab**.
   2. Select the as monthly maintenance procedure that you wish to perform from the monthly Maintenance tab.
   3. Select **F5- Perform**.
   4. Click **OK** to perform procedure.
   5. Select **Proceed**, and then follow the instructions in the instruction box.
   6. If necessary, view the videos that are embedded in the individual maintenance

procedures for instructions.

7. 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.

XIII. QUARTERLY MAINTENANCE PROCEDURES: i2000sr AND i1000sr

****Note:** There are **NO** required quarterly maintenance procedures for the i2000sr or i1000sr.

XIV. AS NEEDED MAINTENANCE

A. 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:

1. **Sample Pipettor Calibrtion (111)**
2. **R1 Pipettor Calibration (1112)**
3. **R2 Pipettor Calibration (1113)**
4. **STAT Pipettor Calibration (117)**
5. **Flush Fluids (2130)**
6. **Air flush (2133)**
7. **Prime wash Zones (2151)**
8. **Prime Pre-Trigger and Trigger (2152)**
9. **Wash Buffer Unload (2185)**
10. **RV Loader Sensor Calibration (3131)**
11. **Temperature Status (3520)**
12. **Temperature Check- Manual (3530)**
13. **Buffer Run (4050)**
14. **WZ Probe Cleaning-Bleach (6043)**
15. **Calibrator Back-up (User Defined)**
16. **Check Routine and STAT pipettors (User Defined) – replace if in use > 3 months (Royal Oak and Dearborn)**
    a. **All others replace pipettors as needed**

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

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

C. Select **As Needed maintenance Tab**.

D. 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.

E. Select **F5- Perform**.

F. Click **OK** to perform procedure.

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

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

I. 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.

XV. REFERENCES

A. Architect ci16200 System Quick Reference Guide

B. AlinIQ Mobile Library

C. Architect System Operations Manual

Approval Signatures

Step Description	Approver	Date
CLIA Medical Directors	Jeremy Powers: Chief, Pathology	11/15/2021
CLIA Medical Directors	Muhammad Arshad: Chief, Pathology	11/10/2021
CLIA Medical Directors	Vaishali Pansare: Chief, Pathology	11/3/2021
CLIA Medical Directors	John Pui: Chief, Pathology	11/2/2021
Policy and Forms Steering Committee Approval (if needed)	Colette Kessler: Mgr Laboratory	11/2/2021
Policy and Forms Steering Committee Approval (if needed)	Gail Juleff: Project Mgr Policy	11/2/2021
	Ann Marie Blenc: System Med Dir, Hematopath	11/2/2021
	Elizabeth Sykes: System Med Dir, Chemistry	11/1/2021

Qian Sun: Tech Dir, Clin Chemistry, Path	11/1/2021
Colette Kessler: Mgr Laboratory	11/1/2021
Colette Kessler: Mgr Laboratory	11/1/2021

Applicability

Dearborn, Farmington Hills, Grosse Pointe, Royal Oak, Taylor, Trenton, Troy, Wayne