

ABBOTT ARCHITECT C-SERIES ANALYZER MAINTENANCE

BL.OP.CH.ARC.PR.003r00

Principle

The ARCHITECT c16000, c8000, and c4000 are high performance clinical chemistry diagnostic systems capable of quantifying selected analytes in biological fluids. The ARCHITECT c-series analyzers are composed of a System Control Center (SCC), Supply and Pump Center, a Processing Module, and a Robotic Sample Handler (RSH). Daily, weekly, monthly, quarterly, and as-needed maintenance are performed to assure that the instrument is functioning optimally.

Reagents

Bulk Solutions:

- a. Alkaline Wash 500mL (contains sodium hydroxide) - stored in the weight platform of the supply center of the instrument and used by the instrument to clean cuvettes after sample analysis. Stable on instrument until manufacturer's expiration.
- b. Acid Wash 500 mL (contains methanol and chloroacetic acid) – stored in the weight platform of the supply center and used by the instrument to clean cuvettes after sample analysis. A dilution of acid wash may also be used for probe washing during daily maintenance (6070 procedure). Stable on instrument until manufacturer's expiration date on bottle.
- c. ICT Reference Solution 2000 mL - stored in the supply center of the instrument on weight platform and contains a mid-concentration solution that is aspirated and analyzed by the ICT before and after each sample. The solution provides a reference potential to calculate results. It is also used by the ARCHITECT c-series analyzers for daily maintenance (procedure 6070). ICT reference solution is stable onboard until the manufacturer's expiration on the bottle.

Reagent Supply Center Solutions:

- d. ICT Sample Diluent (ICTD5) – located in Reagent Supply Center 1 (outer carousel only, any position). Used in ICT analysis. ICT diluent has a 30 day on-board stability.

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- e. Detergent A Solution- onboard solution used as part of the smart wash procedure to wash probes. Placed on Reagent Supply Centers 1 & 2 as configured on the Supply Status Screen. Detergent A is stable on board until the manufacturer's expiration date on the bottle.
- f. 10% dilution of Detergent B- onboard solution used as part of the smart wash procedure to wash reagent probes. Placed on Reagent Supply Centers 1 & 2 as configured on the Supply Status Screen. To make 10% dilution of detergent B, mix together:

- a. 50 mL of Detergent B
- b. 450 mL of purified water.
- c. Pour into appropriate container

Stability of 10 % Detergent B is 14 days after preparation.

- g. 0.5% Acid Wash solution- onboard solution used as part of the smart wash procedure to wash reagent probes. Placed on Reagent Supply Centers 1 & 2 as configured on the Supply Status Screen. To make 0.5% acid wash mix together:
 - a. 5 mL of acid wash.
 - b. 995 mL of purified water.
 - c. Pour into appropriate container

Onboard Stability is 30 days after preparation.

- h. Water Bath additive- Antimicrobial solution used to reduce microbial contamination in the water bath. A supply of water bath additive is placed in the Reagent Supply Centers as indicated in the onboard instructions for the daily automated cleaning (procedure 6070). Water bath additive is stable onboard until manufacturer's expiration date on the bottle.
- i. Saline- assigned as a diluent when running patient sample. Placed on reagent supply Center 1 as configured on reagent status screen. Saline is stable onboard until the manufacturer's expiration date on the bottle.

Sample Carousel Solutions:

- j. ICT Cleaning Fluid- Conditions and cleans ICT module. Added daily to empty sample cup placed in sample carousel position 1 or the first position of the Sample Wash Solution Carrier (As directed in 6070 Daily maintenance procedure).

To make ICT cleaning fluid:

- a. Add 12mL of ICT cleaning fluid to the lyophilized cleaning solution bottle.
- b. Mix gently by inversion.

Offline: Stable for 14 days at 2-8°C after preparation.

Onboard Stability: change daily

- k. 0.5% Acid Wash solution- Added daily to fresh sample cup and placed on Position 31 on the sample carousel or the 2nd position of the Sample Wash Solution Carrier. Used to wash sample probe as part of the daily maintenance (6070 procedure). Onboard stability

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is 1 day. To make 0.5% Acid wash solution, refer to Acid wash solution preparation in the section above titled "Reagent supply center Solutions".

- I. Detergent A- Added daily to fresh sample cup and placed on Position 32 on the sample carousel, or 3rd position of the Sample Wash Solution Carrier. Used to wash sample probe as part of the daily maintenance (6070 procedure). Onboard stability is 1 day. Stability of original bottle of detergent A is the manufacturer's expiration date

Supplies

1. Architect Sample cups
2. Cotton swabs (For weekly maintenance)
3. Gauze pads
4. Detergent A (weekly maintenance)
5. Gloves
6. DI water.
7. Sample Probes (quarterly maintenance)
8. 1 mL syringes (quarterly maintenance)
9. Source Lamp (quarterly maintenance)
10. ICT Reference Solution Check Valve (Quarterly maintenance)
11. Wash Solution Check Valve (Quarterly Maintenance)
12. ICT Module (Quarterly Maintenance)
13. CD (Monthly Maintenance for system back up)

Quality Control

The ARCHITECT c16000, c8000, and c4000 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:

Daily maintenance on the c-series analyzers consists of **four** procedures that should take approximately 20 minutes to complete.

During the maintenance procedure (6070), the system automatically:

- Flushes sample and reagent probe lines.
- Changes the water bath.
- Cleans the ICT module and checks database integrity.

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You will manually check the syringes (6024), as well as the purity of the water supply (6028), and visually check the mixers (user-defined).

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

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 **Daily Maintenance Tab**.
 - b. Select **Check 1mL syringes (6024)**.
 - c. Select **F5- Perform**.
 - d. Click **OK** to perform procedure.
 - e. Manually check the syringes for any leaks.
 - f. Select **Proceed**, and then follow the instructions in the instruction box.
 - g. Select **Done** to return to maintenance screen.
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 **Daily Maintenance Tab**.
 - b. Select **Check DI water Purity (6028)**.
 - c. Select **F5- Perform**.
 - d. Click **OK** to perform procedure.
 - e. Manually check purity of DI water.
 - f. Select **Proceed**, and then follow the instructions in the instruction box.
 - g. Select **Done** to return to maintenance screen.
3. 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 (6070)**.
 - c. Select **F5- Perform**.
 - d. Click **OK** to perform procedure.
 - e. Select **Proceed**, and then follow the instructions in the instruction box.
 - f. You may also view the videos that are embedded in the individual maintenance procedures for instructions.
 - g. Click the scroll down arrows to view more instructions if necessary.
 - h. Enter the required information in the **User Input** data entry box.
 - i. You will be prompted to load the following three solutions onto the ARCHITECT C16000 sample carousel during the daily maintenance procedure. All three solutions are required in order to complete the daily maintenance:
 - 0.5% Acid Wash
 - Detergent A
 - ICT Cleaning Solution

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* * Replace the solutions daily or when the sample cup or tube is empty.

- j. Select **Continue**.
 - k. Continue to follow the instructions in the INSTRUCTIONS box.
 - l. When maintenance procedures are complete, select **Done** to return to the Maintenance screen.
4. 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 **Daily Maintenance Tab**.
 - b. Select **Check Mixers (User Defined)**.
 - c. Select **F5- Perform**.
 - d. Click **OK** to perform procedure.
 - e. Manually check for the mixers and mixer screws.
 - f. Select **Proceed**, and then follow the instructions in the instruction box.
 - g. 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.

B. Weekly Maintenance:

The following are the required weekly maintenance procedures for the ARCHITECT c16000:

- **Check ICT Components (6019).**
- **Clean mixers (6021).**
- **Clean sample/reagent probes (6023).**
- **Clean cuvettes with detergent (6056)** - This is an automated procedure that takes 25 minutes and requires a full cartridge of detergent A to be in the Reagent Carousel.
- **Check high concentration waste pump tubing (6308).**
- **Empty and Refill bottles (User Defined)**
- **Wash Station Flush (User Defined)**
- **Calibration Back-Up (User Defined)**
- **Check Sample Probe for last date changed (User Defined)**

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

1. From the System menu, select Maintenance. From the Maintenance screen, select the desired module then do the following:
 - a. Select **Weekly Maintenance Tab**.

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- 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 applicable, view the videos that are embedded in the individual maintenance procedures for instructions.
- g. 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.

C. Monthly Maintenance:

The following are the required monthly maintenance procedures for the ARCHITECT c-series analyzers:

- **Check dispense components (for bubbles, tight screws and non-discolored tubing 6016).**
- **Clean cuvette washer nozzles (6018).**
- **Check syringes and valves for leaks (6026).**
- **Clean ICT drain tip (6300)** - This is a manual procedure that involves wiping the drain tip with gauze moistened with DI water.
- **Perform Monthly System Backup (9100)** - This is a manual procedure that creates a backup of the instrument system software and then writes the backup to a cd.
- **Replace Bottles (User Defined)**
- **Clean R2 Probe (User Defined)**

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 **Monthly Maintenance Tab**.
 - b. Select monthly maintenance procedure that you wish to perform from the monthly maintenance tab. The monthly 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 applicable, view the videos that are embedded in the individual maintenance procedures for instructions.
 - g. 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.

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D. Quarterly Maintenance:

The following are the required quarterly maintenance procedures for the ARCHITECT c16000:

- **Change lamp (1003)**
- **Sample Syringe Maintenance (6301)**
- **Wash syringe Maintenance (6302)**
- **Reagent Syringe Maintenance (6303)**
- **Change 1mL Syringe (6304)**
- **Change ICT Asp Check valve (6305)**
- **Check ICT Ref check valves (6306)**

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

1. From the System menu, select Maintenance. From the Maintenance screen, select the desired module then do the following:
 - a. Select **Quarterly Maintenance Tab**.
 - b. Select the as quarterly procedure that you wish to perform from the quarterly maintenance tab. The as needed 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 applicable, view the videos that are embedded in the individual maintenance procedures for instructions.
 - g. 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.

E. As Needed 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:

- **Detergent B Probe wash (6055)**
- **Detergent A Probe wash (6057)**
- **Clean R2 Probe (6058)**
- **Wash ICT with Cleaning Fluid (6062)**

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- Flush ICT Module (6063)
- Clean Reaction Carousel (6064)
- Clean Cuvettes manually (6310)
- Sample Pipettor Calibration (1120)
- R1 Pipettor Calibration (1121)
- R2 Pipettor Calibration (1122)
- Add Water Bath additive (2129)
- Flush ICT Cup (2131)
- Flush Water lines (2132)
- Change water Bath (2134)
- Change ICT Module (

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

1. From the **System menu**, select **Maintenance**. From the Maintenance screen, select the desired module then do the following:
 - a. Select **As Needed maintenance Tab**.
 - b. 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.
 - c. Select **F5- Perform**.
 - d. Click **OK** to perform procedure.
 - e. Select **Proceed**, and then follow the instructions in the instruction box.
 - f. If applicable, view the videos that are embedded in the individual maintenance procedures for instructions.
 - g. 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

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ARCHITECT C-SERIES ANALYZER Maintenance Attachments

Authorized Reviewers

Section Medical Director or Technical Director.

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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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Location of circulating Controlled Copies: Chemistry Labs- Dearborn, Farmington Hills, Grosse Pointe, Taylor, Trenton, Troy, Wayne, Royal Oak Automated Chemistry Stat Lab

Document History

Signature	Date	Revision #		Related Documents Reviewed/
Prepared by: Kimberly Geck, MT (ASCP) and Kelly Walewski, C (ASCP)cm	2/28/19			
Reviewed by:				
Approved by:				
Reviewed by: (Signature)	Date	Revision #	Modification	Related Documents Reviewed/

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