TRAINING UPDATE

Lab Location:	FWMC and GEC	**Date Distributed:**	1/17/23
Department:	Core Lab	**Due Date:**	2/17/23

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:
Title: Maintenance, Siemens Dimension® EXL (GEC.C 251)
Description of change(s):
Added: Addendum A Enhanced Conditioning Procedure Section 5 E Non-Scheduled or As Needed Maintenance: • Enhanced Conditioning procedure after IMT tube change or whenever experiencing IMT errors (see addendum A) • Check and adjust IMT pump rates as necessary (See Operator's Guide) This revised SOP will be implemented February of, 2023

Document your compliance with this training update by taking the quiz in the MTS system.

GEC.C 251 Maintenance, Siemens Dimension® EXL

Copy of version 4.0 (approved, not yet effective)

Last Approval or Periodic Review Completed	1/9/2023
Next Periodic Review Needed On or Before	1/9/2025
Effective Date	2/1/2023

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Printed By Demetra Collier (110199)

Organization Adventist HealthCare

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	1/9/2023	4.0	Nicolas Cacciabeve MD Nicolas Cacciabeve	
Approval	Core lab approvals	1/9/2023	4.0	Robert SanLuis Robert SanLuis	
Approval	Lab Director	7/12/2021	3.0	Nicolas Cacciabeve	
Approval	Core lab approvals	7/9/2021	3.0	Robert SanLuis Robert SanLuis	
Approval	QA approval	7/9/2021	3.0	Leslie Barrett	
Approval	Lab Director	10/21/2020	2.0	Nicolas Cacciabeve	
Approval	Core lab approvals	10/20/2020	2.0	Robert SanLuis Robert SanLuis	
Approval	QA approval	10/14/2020	2.0	Leslie Barrett	
Approval	Lab Director	9/22/2020	1.0	Nicolas Cacciabeve	
Approval	Core lab approvals	9/22/2020	1.0	Robert SanLuis Robert SanLuis	
Approval	QA approval	9/21/2020	1.0	Leslie Barrett	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
4.0	Approved, Not Yet Effective	Major revision	12/30/2022	2/1/2023	Indefinite
3.0	Approved and Current	Major revision	7/9/2021	7/12/2021	2/1/2023
2.0	Retired	Major revision	10/13/2020	10/21/2020	7/12/2021
1.0	Retired	Initial version	9/21/2020	9/29/2020	10/21/2020

Linked Documents

- AG.F 541 Dimension EXL Daily System Check

• AG.F 542 Dimension EXL QuikLYTE Results
• AG.F 546 Dimension EXL Maintenance Log

Non-Technical SOP

Title	**Maintenance, Siemens Dimension® EXL**	
Prepared by	Demetra Collier	Date: 9/21/2020
Owner	Robert SanLuis	Date: 9/21/2020

Laboratory Approval		
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		
Local Issue Date:	Local Effective Date:	

TABLE OF CONTENTS

1. PURPOSE

To outline the maintenance procedure for the Siemens Dimension EXL instruments and describe all other maintenance that must be performed as scheduled.

2. SCOPE

This procedure applies to all Core Laboratory personnel working with the Siemens Dimension EXL instruments.

3. RESPONSIBILITY

Core Laboratory personnel are responsible for performing and complying with this procedure.
The Technical Supervisor is responsible for content and review of this procedure.

4. DEFINITIONS

None

5. PROCEDURE

A. General Information and Schedule

1. Maintenance schedule:

Instrument	EXL LM	EXL 200
Daily maintenance	Night shift	Day shift
Weekly maintenance	Night shift	Night shift
Monthly maintenance	Night shift	Night shift

2. The daily monitoring of the instrument waste will be performed on all three shifts.
3. The Core Laboratory Group Leads are responsible for the weekly review of maintenance logs.
4. The Core Laboratory Supervisor, Lab Services Director or designee is responsible for the monthly review of maintenance.
5. A check off log is provided on each instrument for the technologist to sign. The required checkpoints must be completed as scheduled. A technologist on each shift must initial that they have completed the required checkpoints.
6. Documentation - After **any** maintenance is completed the following must be performed.
   a. Run QC.
   b. Do not release any patient result until the QC successfully passes.
   c. Document function check on the maintenance Log Sheet.

B. Daily Maintenance

1. Run System Check:
   a. The instrument is preprogrammed at a specific time (EXL LM at 0300 and EXL 200 at 0700) to run a system check automatically on a daily basis.
      - Ensure there is a CHK Flex on the instrument prior to the system Check running.
      - The instrument will flag if there is not enough CHK Flex reagent in the inventory.

   b. At any time the operator has the ability to run the system check manually to verify instrument performance by accessing the Daily Maintenance Program. From the Operating Menu:
      - Press F4: System Prep
      - Press F8: Daily Maintenance
      - Enter your initial, then press F1: Start

   c. Record System Check results on the Dimension EXL Daily System Check log.
      Note: Unacceptable System Check results appear on the printout in white letters on a black background. An asterisk on the report indicates that the cuvette had a processing problem. If the System Check Printout

indicates that your results are not acceptable, then refer to System Check Trouble shooting in the Operators Guide.

2. Verify and record the cuvette, reagent and HM temperatures on the Maintenance Log. Acceptable temperature ranges are shown below:

Cuvette System	36.8 - 37.2C
Reagent System	2 - 8C
HM System	37.3 – 39.6C
Reagent (RMS)	2 - 8C

3. Clean the sample area, RMS, and empty cuvette waste
   a. With the instrument in Standby, press **Pause** to stop the sampler systems from moving.
   b. Raise the sample and reagent and RMS lids and remove all segments from the sample area.
   c. Clean the inside of the sample area and the inside of the bulk loader with a damp cloth.
   d. Close the sample, reagent and RMS lids.
   e. Press **Pause** to restart the sampler system.
   f. Open the right cabinet door of the EXL and cut the cuvette string about 12 inches down from the instrument. Be sure to cut the between two cuvettes to prevent spilling fluids from a sealed cuvette.
   g. Empty the accumulated cuvette waste.
   h. Empty the RMS Waste Container

   If any RMS maintenance is required, the function key F4:CHK RMS CNTS is displayed on the Daily Maintenance Screen. Check and update RMS counters as appropriate.

4. Check/replenish reagents, IMT, HM and RMS inventory.
   a. To access the System Counter screen, press:
      1) F4: System Prep
      2) F6: System Counters

      Items where the cycle field exceeds the *clean at* or *replace at* field appear in red. Those items should be cleaned or replaced now or at your earliest opportunity.

      Then press:
      3) F6: HM counters

   This shows the status of consumable items for the HM module. Any items appearing in red or whose fill level is <5% must be replaced before running any HM tests.
      4) F7: RMS counters

      Update RMS counters as appropriate.
   b. For reagent inventory, press Alt/I.
   c. For IMT, from the Operating Menu, press:
      1) F4: System Prep
      2) F3: IMT
      3) F1: Change Consumables

Every 5 days, replace IMT Sensor, Run Dilution Check and Condition Sensor. The instrument will give a reminder. Record results on the Dimension EXL Quiklyte Results log.
For step by step procedure see the IMT Info section in the EXL Quick Reference Guide or the Operator's Guide.

5. Process Quality Control according to Laboratory procedures.

C. Weekly Maintenance

1. Clean HM Wash Probes and the R2 reagents Probe
   a. With the system in Stand by, go to the HM Pump Prime screen
   b. Raise the sample and regent lids.
   c. Dip a clean cotton swab in water and, beginning at the top of the probe, wipe down the outside of both wash station probes.
   d. Turn the splined shaft on the R2 reagent arm until the R2 probe comes up out of the R2 reagent drain. Then move the arm until you can easily access the R2 probe.
   e. Dip a clean cotton swab in 0.1N sodium hydroxide (reagent probe cleaner) and scrub the nut at the top of the probe tube. Then, beginning at the top, wipe down the outside of the R2 reagent probe.
      Note: If a bottle of reagent probe cleaner is used as source of 0.1N sodium hydroxide, then only use that particular bottle for weekly R2 probe cleaning. Do NOT use that bottle on the instrument.
   f. Press F1: HM Wash Pump to prime the HM wash pump.
   g. Document the cleaning on the Weekly Log Sheet.

2. Clean Windows according to the Dimension EXL Maintenance Log.
   All the windows are cleaned the first week.
   Only the dirty windows are cleaned the rest of the month.

D. Monthly Maintenance

1. Siemens Dimension
   a. Replace IMT Pump Tubing (including enhanced conditioning See Addendum A)
   b. Replace / Clean Air Filters (including RMS filters)
   c. Replace HM Pump Heads
      For step by step procedure see the EXL Quick Reference Guide
   d. Stylette the HM Wash Probes
   e. IMT System Clean (The instrument will give a reminder)
      For step by step procedure see the IMT Info section in the EXL Quick Reference Guide
   f. Clean the Clot Check Drain on the IMT Port
      For Step by Step instructions, see the EXL Quick Reference Guide

2. Millipore (performed by Night Shift)
   a. Culture Millipore Water. Clean tip with alcohol pads first. Let water flow into the basin until half full and then culture the water.

b. Replace Chlorine Tablet as needed by the indicator light on the Millipore. Refer to Millipore (AFS – Analyzer Feed System) procedure for step-by-step instructions.

E. Non-scheduled or 'As Needed' Maintenance (performed by any shift)
Note: not limited to those listed below

1. Sample probe change before or at 48,000 cycles.
2. Reagent probes (R1, R2 and RMS)
   - R1 change at 48,000 cycles
   - R2 change at 36,000 cycles
   - RMS change at 48,000 cycles
3. Source lamp changed (3-130)
4. Cuvette Cartridge and Diaphragm change 12,000 cycles
5. Sample probe and Drain cleaning 20,000 cycles
6. Clean the R1, R2 and R3 drains (See Chapter 5 of the EXL Operator's Guide).
7. Enhanced Conditioning Procedure (See Addendum A) After tube X0, X1 or X2 tube change and when experiencing IMT errors.
8. Check and Adjust IMT pump rates as necessary (See Operator's Guide)
9. Any scheduled maintenance that is performed off-cycle

6. RELATED DOCUMENTS

Millipore (AFS – Analyzer Feed System), Siemens Dimension® EXL Chemistry procedure
The Dimension EXL Quick Reference Guide
Dimension EXL Maintenance Log (AG.F546)
Dimension EXL Daily System Check (AG.F541)
Dimension EXL QuikLYTE Results (AG.F542)

7. REFERENCES

Dimension EXL 200 and EXL with LM Operators' Guide, 10/2019
Dimension RMS Operators Guide, 3/2019

8. REVISION HISTORY

Version	Date	Reason for Revision	Revised By	Approved By
1	10/12/20	Section 5: Updated shift time for daily maintenance and system check times; corrected HM system temp. range	L Barrett	R SanLuis
2	7/9/21	Header: Added FWMC	L Barrett	R SanLuis
3	12/30/22	Section 5: Added enhanced conditioning reference. Added check IMT pump rates. Section 9: Added Addendum: Enhanced Conditioning procedure.	D Collier	R SanLuis

9. ADDENDA AND APPENDICES

A. Enhanced Conditioning Procedure

Enhanced Conditioning Procedure for X0, X1, and X2 Tubing and the IMT Sensor

This procedure must be performed every time the X0, X1, and X2 tubing is replaced. The procedure can also be performed when experiencing IMT errors that are not resolved using the standard troubleshooting steps listed in the Operator's Guide.

NOTE: These steps can be completed in approximately 40 minutes. The instrument is not available to run patient samples during this time.

NOTE: Complete this procedure using paper towels, fresh serum or plasma free of hemolysis, icterus, or lipemia (HIL), disposable pipettes, water, and the QuikLYTE Integrated multisensor.

To condition the X0, X1, and X2 tubing or the IMT Sensor, perform the following steps:

1. From the Operating Menu, and with the instrument in standby, select **F7: DIAGNOSTICS > F1: ELECTRO/MECH > F3: IMT > F8: ADVANCED DIAG.**
2. In the IMT Rotary Valve area, select **<ENTER>** to change the field from NONE to SAMPLE.
3. Manually fill the IMT port with serum or plasma free of HIL.
4. Select **F3: PUMP JOG** 10 times, with 1 second in between, to fill the X0, X1, and X2 tubing.

   NOTE: Ensure that the fluid is flowing up to the X tubing. The pump can be heard, and the fluid level in the IMT port will drop.
5. Fill the IMT port again with serum or plasma free of HIL. Select **F3: PUMP JOG** 10 times, with 1 second in between, to fill the X0, X1, and X2 tubing, ensuring the entire tubings are filled with serum or plasma.
6. Leave the serum or plasma sitting inside the tubing for 30 minutes of conditioning. The system does not display a countdown.

   NOTE: Wait for 30 minutes before proceeding to Step 7. Do not exit the IMT Advanced Diagnostics screen during the 30-minute conditioning period.
7. From the home screen, select **F4: SYSTEM PREP > F3: IMT > F2: CALIBRATION > F1: CALIBRATE**. The system primes and calibrates.