



BIOGENIX

CELL DYN EMERALD AL MAINTENANCE POLICY

NAME		DESIGNATION	SIGNATURE	DATE
Prepared by	Ms Preety Raheja	Quality Manager		30/06/2020
Reviewed by	Dr Bhagyashree	Deputy Lab Director		01/07/2020
Approved by	Dr Sally Abdulla	Lab Director		01/07/2020



CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 2 of 9

REVIEW DATE: 30/06/2022

1. Table of Content

1. TABLE OF CONTENT.....	2
2. REVISION REVIEW.....	3
3. REVIEW HISTORY	4
4. POLICY STATEMENT.....	5
5. PURPOSE	5
6. SCOPE.....	5
7. DEFINITIONS.....	5
8. ACRONYMS.....	5
9. RESPONSIBILITIES.....	5
10. PROCEDURE	6
11. CROSS REFERENCE.....	9
12. RELEVANT DOCUMENTS & RECORDS	9





CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 3 of 9

REVIEW DATE: 30/06/2022

2. REVISION REVIEW

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				





CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 4 of 9

REVIEW DATE: 30/06/2022

3. REVIEW HISTORY

#	Version	Date	Changes Made by	Reason for Changes	Clause Changed
1	1.0				





CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 5 of 9

REVIEW DATE: 30/06/2022

4. POLICY STATEMENT

4.1. This policy elaborates the details of Maintenance process of Cell Dyn Emerald 22 AL CBC analyzer.

5. PURPOSE

5.1. The Purpose of this document is to establish procedures for the Maintenance of Cell Dyn Emerald 22 AL which is a CBC analyzer.

5.2. This Policy explains routine maintenance and cleaning. Also included are detailed instructions for removing and cleaning certain components to ensure proper system performance

6. SCOPE

6.1. This Procedure applies to Biogenix Lab, in Hematology section.

7. DEFINITIONS

7.1. The CELL-DYN Emerald 22 System has been designed to require minimal routine maintenance. To ensure optimum performance, the operator is encouraged to routinely perform the scheduled maintenance procedures. Failure to perform recommended maintenance can result in inaccurate or imprecise results.

8. ACRONYMS

8.1. N/A

9. RESPONSIBILITIES

9.1. The medical lab technologist, trained, authorized in the Hematology section are responsible for Maintenance of the instrument





CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 6 of 9

REVIEW DATE: 30/06/2022

10. PROCEDURE

10.1. Daily Shut Down

- 10.1.1. The CELL-DYN Emerald 22 must be put through a Shut Down cycle once during every 24 hours of operation
- 10.1.2. The system must remain in the shutdown mode at least 3 hours every 24 hours.
- 10.1.3. From the **MAIN** menu, touch **[SHUT DOWN]** to initiate the Shut Down Cycle.
- 10.1.4. All of the fluidics are rinsed and cleaned with CELL-DYN Emerald 22 Easy cleaner Reagent.
- 10.1.5. The cycle stops automatically when it is complete.

10.2. Cleaning the cover:

- 10.2.1. Wipe the outside surfaces with a non-abrasive detergent cleaning solution to remove any soil. Then, wipe the surfaces with a tuberculocidal disinfectant, such as a 0.5% sodium hypochlorite solution.

10.3. Weekly Maintenance:

10.3.1. Bleach Cleaning:

- 10.3.1.1. Cleaning the system with a 3.6% sodium hypochlorite (bleach) solution is performed weekly or as needed when a parameter is repeatedly rejected.
- 10.3.1.2. Access the bleaching function as follows: From the **MAIN** menu, touch **[MAINTENANCE]** and Touch **[BLEACH]** to start the bleaching
- 10.3.1.3. Open the instrument's right side door using the flat screwdriver. Measure 4mL of the prepared bleach solution into each counting chamber as shown, touch **[OK]**.





CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 7 of 9

REVIEW DATE: 30/06/2022

10.3.1.4. When the information box indicates **PLEASE CLOSE FLUIDS DOOR**, close the right side door using the flat screwdriver/key, and touch **[OK]**.

10.3.1.5. The instrument automatically draws the bleach through the apertures and then goes into a Stand-By mode for two minutes.

10.3.1.6. When the status LED turns green the cycle is complete. Perform a Start Up and verify that all parameters are within specifications before running patient or other samples.

10.3.1.7. This maintenance will be automatically recorded on the event log

10.4. Quarterly Maintenance

10.4.1. Lubricating the Pistons

10.4.1.1. From the **MAIN** menu, touch **[MAINTENANCE]** and then touch **[LUBRICATION POS.]**

10.4.1.2. When the information window displays, **[CONTINUE]**, proceed as follows

10.4.1.3. Open the instrument's right side door using the flat screwdriver / key.

10.4.1.4. Put a small amount of lubricant on your fingertip (Silicone Grease supplied in the Installation Kit).

10.4.1.5. Apply a thin film of lubricant around the white Teflon pistons as shown. Small pistons can be turned with your fingertips. The large pistons can be turned with the Short Arm Torx T20 Tool provided in the Service Kit. Insert the Torx Tool into the socket at the bottom of





CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 8 of 9

REVIEW DATE: 30/06/2022

the syringes to turn the Waste syringes.



10.4.1.6. When all pistons are lubricated, close the right side door using the key.

10.4.1.7. Touch **[OK]** on warning window to return the pistons to their operational position.

10.5. As Needed Maintenance

10.5.1. **Emergency Stop:** If there is a mechanical or fluidic problem, press and release the **ON/OFF** button to immediately stop the instrument

10.5.2. To initialize the system after an Emergency Stop, From the **MAIN** menu touch **[MAINTENANCE]**, Touch **[SYSTEM CHECKS]** and then touch **[INITIALIZE SYSTEM]**

10.6. Event Log:

10.6.1. The instrument provides an Event Log. This log maintains a record of certain activities by date and holds 365 records. Access the log from the **MAIN** menu by touching **[EVENT LOG]**.

10.6.2. To print the **EVENT LOG**: Select the range of records by touching either **[ALL]** radio button or the **[DAY]** radio button. If using the **DAY** method, enter the number(s) representing the desired day(s) to print in the fields to the right and Touch **[PRINT]** to print

10.6.3. To save the **EVENT LOG**: Select the range of records by touching either the **[ALL]** radio button or the **[DAY]** radio button. using





CELL DYN EMERALD AL MAINTENANCE POLICY

CODE: BG/PP/HEM/001

BIOGENIX

VERSION: 1.0

DATE OF EFFECTIVITY: 30/06/2020

PAGE: 9 of 9

REVIEW DATE: 30/06/2022

the DAY method, enter the number(s) representing the desired day(s) to print in the fields to the right and Touch **[SAVE]**.

11. CROSS REFERENCE

- 11.1. CELL – DYN Emerald 22 (Operator's Manual)

12. RELEVANT DOCUMENTS & RECORDS

- 12.1. BG/REC/HEM/001 Maintenance record for Cell Dyn Emerald 22 AL

