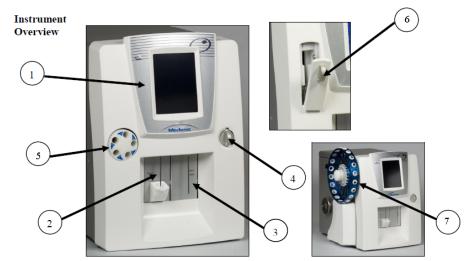
Clinical Diagnostic Solutions, Inc.

a Boule Diagnostics, AB company

Medonic M-Series Maintenance

The intent of this document is to supplement the information already contained in the Medonic M-Series User's Manual (Section 8) and the Boule Cleaning Kit package insert.



Part	Function
1. Display	LCD touch screen with incorporated keyboard and numerical pad.
2. Open Tube (OT) sample probe	Aspirates whole blood from open sample tube.
3. Pre-dilute (PD) probe/ Dispenser	Aspirates pre-diluted samples and dispenses diluent. Used in monthly cleaning procedure.
4. Micropipette Adapter (MPA/MC)	Micro Pipette Adapter enables users to analyze 20 μl of blood.
5. Mixer (optional)	Uniformly mixes samples.
6. Cap Pierce (CP) (optional)	Analyzes samples with decreased risk of blood contact.
7. Autoloader (AL) (optional)	Enables consecutive samples to be analyzed automatically.

Daily Maintenance

- 1. Clean the **Open Tube** sample probe and **Pre-dilute** probe using an alcohol wipe.
- 2. Remove possible traces of salt crystals or blood on the **Open Tube** probe, probe rinse cup, **Pre-dilute** probe, and around the top of the **Cap Pierce** or **Autoloader** using a paper tissue with a disinfecting solution.
- 3. Clean outside of the instrument with soft cloth and DI water if needed.

Monthly Cleaning Procedure (~10 minutes)

- 1. Fill a cup with 10 mL 2% hypochlorite from Boule Cleaning Kit (White Cap).
- 2. Fill another cup with 18 mL of diluent. The diluent can be obtained by using the dispense function on the M-Series. To dispense diluent:
 - a. Press [Dispense] from Main Menu.
 - b. Hold empty cup under **Pre-dilute** probe (1:200 probe on right side).
 - c. Press 1:200 Start plate behind probe
 - d. Discard first dispense.
 - e. Repeat steps b-c four times to achieve 18 mL of diluent.
 - f. Press [Cancel] to exit the dispense function.
- 3. Aspirate the hypochlorite (White Cap) as a Pre-dilute sample (1:200 probe) twice.
 - * Note: Pre-dilute mode has intentional delay. Press and hold start plate to start cycle (keep probe submerged in hypochlorite solution until the screen displays "Now Analyzing").

Medonic M-Series Maintenance (continued)

- 4. Aspirate the clean diluent obtained is step 2e as a Pre-dilute Sample. Repeat. Discard results.
- 5. Perform a background check in the Pre-dilute mode by aspirating the remaining clean diluent obtained in step 2e. Verify all values are within specifications.
- 6. Continue to the clot prevention procedure.

Clot Prevention Procedure (~15 minutes)

This procedure should be done at least once a month or every 1000 samples processed by the Medonic M-Series. You will not be able to run samples for approximately 15 minutes once the clot prevention cycle has started.

- 1. Fill a cup with 5 ml of Enzymatic Cleaner (Blue Cap) from the Boule Cleaning Kit.
- 2. If you have the **Cap Pierce** or **Autoloader** option, fill a clean standard 4.0-5.0 ml tube half full with the Enzymatic Cleaner (Blue Cap) as well.
- 3. From the Main Menu press [Advanced], then [Maintenance] and then [Clot Prevention]. (Do NOT press [OK] yet)
- 4. If you have the **Open Tube** configuration of the M-Series proceed to step 7. If you have the **Cap Pierce** proceed to step 5. If you have an **Autoloader** proceed to step 6.
- 5. If you have the optional **Cap Pierce** place the filled cleaner tube into **Cap Pierce** (Cap Down same as a normal sample analysis). Close the door and continue to step 7.
- 6. If you have the optional **Autoloader** configuration place the filled cleaner tube into position number one on the wheel, lock the wheel in place, and continue to step 7.
- 7. Hold the cup (with 5 ml cleaner) under the **Open Tube** probe, submerged in cleaner, press [OK] to begin clot prevention cycle. Do not remove container (with cleaner) for at least 5 seconds after aspiration has stopped.
- 8. The system will then perform the cleaning process for all analysis modes simultaneously. This will take 15 minutes.
- 9. Once the clot prevention cycle is completed, perform a background check. Verify all values are within specifications.

Six Month Cleaning Procedure (~1 hour and 15 minutes)

Cleaning Interval:

Less than 50 samples a day once every 6 months
More than 50 but less than 100 once every 3 months
100-200 samples a day once every 1 month

<u>Procedure Note</u>: It is very important that the cleaning procedure is performed in the correct order of the Boule Cleaning Kit to avoid elevated PLT background counts. The correct order is as follows:

- 1. Enzymatic cleaner (Blue Cap)
- 2. Hypochlorite cleaner (White Cap)
- 3. Detergent cleaner (Red Cap)

Procedure:

- 1. Remove the diluent (red) and lyse (yellow) level sensors from the reagent containers.
- 2. Press [Advanced] from the Main Menu, then [Maintenance] and then [Cleaning Menu] to enter the Cleaning menu.
- 3. Press [Clean Cycle Empty] and wait for the system to empty.
- 4. Wipe both level sensors clean on the outside. Then insert both level sensors directly into the Enzymatic Cleaner (Blue Cap).
- 5. Press [Clean Cycle Fill]. Allow the system to fill with the cleaning solution (the pump will stop). Ignore reagent alarms that may occur. Then set a timer for 15-30 minutes.
- 6. When the timer goes off remove both level sensors and press [Clean Cycle Empty]. Allow the system to empty completely.
- 7. Repeat steps 4-6 now using the Hypochlorite Cleaner (White Cap) followed by the Detergent Cleaner (Red Cap).
- 8. Take a soft tissue and wet it with diluent (**NOT** lyse) and wipe off any remaining cleaner from the level sensors. Dry the level sensors with a soft and dry tissue. When level sensors are clean insert them into the correct reagent containers. (DO NOT INTERCHANGE THE DILUENT AND LYSE LEVEL SENSORS).
- 9. Press [Clean Cycle Fill] and wait until the cycle is completed.
- 10. Go back to the Main Menu and perform a minimum of three passing background checks before analyzing the next sample.