

M-Series Calibration / Adv. Calibration Instructions

The intent of this document is to supplement the information already contained in Section 7 of the Medonic M-Series User's Manual. Several important steps have been highlighted and further explained in this document.

Prior to beginning calibration:

1. Verify that required instrument maintenance and cleaning is current and completed.
2. Ensure background check is within specifications.
3. Remove calibrator and controls from refrigerator. Check calibrator expiration date. Allow calibrator to warm to room temperature for 30 minutes.
4. Print the calibration log:
 - From the Main Menu tab press [Advanced].
 - Press [Calibration] or [Adv. Calibration]
 - Press [Calibration Log].
 - Press [Print]. Label the printout "Pre-Calibration" and save.
5. Input the parameter ranges for the calibrator into the M-Series:
 - From the Main Menu tab press [QC].
 - Press [Enter CON/CAL].
 - Locate the M-Series calibrator barcode sheet from the calibrator package.
 - Scan the 9 barcodes in order.

Calibration is to be run in the Open Tube mode (1:1 probe). The closed tube mode (Cap Pierce device) is calibrated with the calibration of the Open Tube mode.

6. Run a normal whole blood or control twice to prime the instrument. Disregard results.
7. Mix the calibrator tube thoroughly (Do NOT use a mechanical mixer).
8. Wipe the Open Tube aspiration probe using soft absorbent cloth.
9. Scan the calibrator tube barcode label. Ensure the analyzer screen displays "Calibrator" when scanned.
10. Aspirate calibrator material in Open Tube mode.
11. Repeat steps 7-10 until a total of five (5) calibrator samples have been run. Make sure the calibrator tube is mixed thoroughly between each analysis. Save all printed calibrator results.

When all 5 runs are completed:

12. From the Main Menu tab press [Advanced]
13. Press [Calibration] or [Adv. Calibration]
14. Press [Whole Blood]
15. Your display should resemble Figure 1.

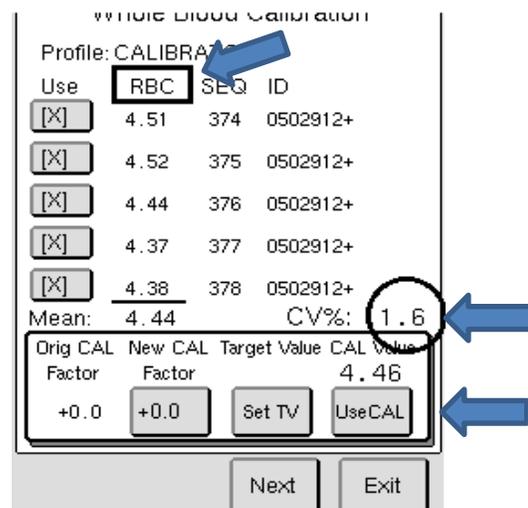


Figure 1

M-Series Calibration / Adv. Calibration Instructions *(continued)*

16. The CV% is indicated by the circle in Figure 1. The parameter you are verifying is indicated by the rectangle in Figure 1. Determine if the RBC CV% is less than the limit in the Open Tube column of Table 1 below.

Parameter	Open Tube	Capillary
RBC	< 2.2	< 3.2
MCV	< 1.8	< 1.8
PLT	< 5.8	< 6.2
MPV	< 4.0	< 4.0
HGB	< 1.8	< 2.9
WBC	< 4.2	< 4.8

Table 1

17. If CV% is within established limits, proceed to step 18. If not, one sample may be inactivated if it is determined to be a known sample handling error or erroneous result. To inactivate:
- Press button in the “use” column to the left of that particular sample and change to empty brackets [].
 - The sample will be removed from the calculation.
 - Check that the CV% is less than the limit in Table 1. If CV% is within established limits proceed to step 18. If not, call CDS Technical Support for assistance or refer to the User Manual.
18. Scroll through parameter screens by pressing the [NEXT] button and verify that the CV% for each parameter (RBC, MCV, PLT, MPV, HGB, and WBC) is within acceptable limits in Table 1.
19. If all CV% values are within the range for each parameter, press [NEXT] until you are back at the RBC calibration screen. (Note: there is no need to check the CV% for RDW%.)
20. Press [USE CAL] **IMPORTANT – to successfully calibrate the parameter displayed, the [USE CAL] button must be pressed.**
21. You will be prompted to enter your Operator ID and Authorization Code.
22. Enter your Operator ID or initials and enter 2576 as the Authorization Code. Press [OK].
23. Press [NEXT]
24. Perform steps 20 & 23 for RBC, MCV, PLT, MPV, HGB, and WBC.
25. There is no calibration needed for RDW%. When RDW% is displayed, simply press [Exit] until you reach the screen shown in Figure 2.
26. Press [PRINT]. Label the printout “Post Calibration” and save.
27. Press [Exit] until you return to Main Menu tab.
28. To verify calibration, run three levels of control. If controls are within range, the Open Tube calibration is complete.
29. To calibrate the Micro Capillary Adapter (MPA) follow steps 1-28 above except use MPA mode for analysis and press [Capillary Device] instead of [Whole Blood] calibration in step 14. Also use the limits in the Capillary column of Table 1 to determine if CV% is acceptable for steps 16-18.
30. Keep all important calibration documents together in a safe location:
- Five calibration runs
 - Pre Calibration Log
 - Calibrator assay insert/ M-Series barcode insert/ product description insert (3 inserts)
 - Post Calibration Report
 - Post Calibration Control Results

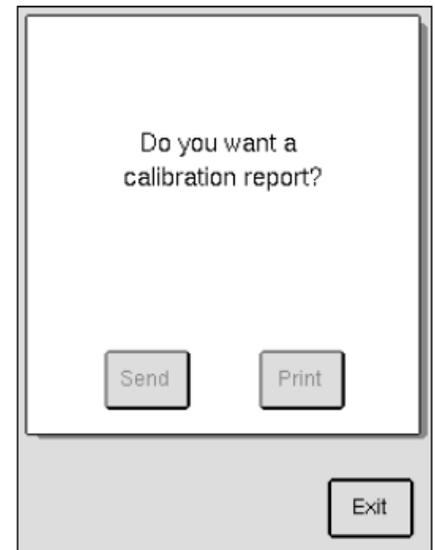


Figure 2