Clinical Diagnostic Solutions, Inc.

a Boule Diagnostics, AB company

M-SERIES GUIDED CALIBRATION

The intent of this document is to supplement the information already contained in the Medonic M-Series User's Manual. Several important steps have been highlighted and further explained in this document. If calibrating using Advanced Calibration refer to Section 7.0 in User's Manual and/or the supplemental Advanced Calibration Quick Guide.

PRE-CALIBRATION

- Verify that required instrument maintenance and cleaning is current and completed.
- Remove calibrator and controls from refrigerator. Check calibrator expiration date. Allow calibrator to warm to room temperature for 30 minutes. Mix by hand only.
- Analyze control blood once in the Open Tube mode and compare results with the assigned values prior to calibration.

Print the calibration log:

- From the Main Menu tab press [ADVANCED]
- Press [GUIDED CALIBRATION] (instrument dependent)
- Select [CALIBRATION LOG]
- Press [PRINT] Label the printout "Pre-Calibration".

Calibration log can also be accessed by selecting [ADVANCED] from Main Menu, then [ADV CALIBRATION], then [CALIBRATION LOG], followed by [PRINT]

RUNNING THE CALIBRATOR

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.

Main Menu	
Guided Calibration Menu	
Whole Blood	
Pre-Dilute	
Capillary Device	
Exit	
Print New Sample	



- From Main Menu select [ADVANCED MENU]
- Select [GUIDED CALIBRATION]
- Choose [WHOLE BLOOD]
- Select [SCAN BAR CODE SHEET] to input calibrator values from calibrator assay sheet.
- Save all Product Inserts supplied with the Calibrator.
- Following prompts on Guided Calibration perform BACKGROUND ANALYSIS
- If the background count is acceptable, press [ACCEPT ANALYSIS] and proceed to Initial Run. If one or more background results are red or have parameter flags, press [RERUN] and repeat background.
- Proceed to side 2 of document.
- The same tube of Calibrator will be run in Open Tube Mode a total of 6 times: 1 Initial Run (prime) followed by 5 additional runs.

M-SERIES GUIDED CALIBRATION (continued)

Guided Calibration Initial Run Calibrator 0502912+ Results: RBC = 4.43 MCV = 79.6 PLT = 199 MPV = 11.5 WBC = 7.8 HGB = 12.5 - Press 'Continue' or 'Rerun' to Re-Analyze. Rerun	 After Initial Run is complete (result is not included in the final calibration) press [CONTINUE] Select [RERUN] only if a known calibrator issue is present (i.e. not mixed). Continue to Run 1 (1 of 5) of the Calibrator.
Guided Calibration 1 of 5 Calibrator 0502912+ Rocute: R8C - 1.49 MCV - 80.0 PLT = 199 MVV - 11.3 WBC - 8.1 HGE - 12.7 - Press 'Accept Analysis' or 'Berun' to Re-Analyse. Accept Analysis Exit	 After the calibrator analysis 1 of 5 is complete, the results will be displayed Select [ACCEPT ANALYSIS] (Select [RERUN] only if known calibrator issue) New dialog box will appear: Run 2 of 5, run calibrator, [ACCEPT ANALYSIS] Continue following prompts and accepting analysis until a total of 5 runs are complete Keep printouts of the calibrator results
Guided Calibration Whole Blood Calibrator 0502012+ Accuracy Results Mean CV Limit Status REC 4.47 0.8 2.2 Pass MCV 7.9.8 0.4 7.8 Pass PLT 22.0 6.4 5.0 FALL MPC 0.1 2.1 4.2 Pass HGB 1.2 1.0 1.8 Pass Press Print 1.4 Pass Press Print Colstance Support.	 After pressing [ACCEPT ANALYSIS] for run 5 of 5, the final Accuracy Results will be displayed in a status column either as PASS or FAIL. <u>PASS</u>: Accuracy and Precision are acceptable - proceed to Final Calibration. <u>FAIL</u>: Print the report and contact Technical Support for assistance.
Guided Calibration Whole Blood Calibrator D502912+ Final Calibrator D502912+ Old New Action RBC 40.7 +0.7 No Change MCV 40.1 +0.0 Calibrate PLT +2.1 +2.5 Calibrate MFV 40.9 +0.0 Calibrate WEC +2.5 +5.2 Calibrate HGB +1.5 +1.5 No Change Press Save' to save results indicated Calibrate	 FINAL CALIBRATION If all parameters passed, press [CONTINUE] to display Final Calibration Results. Results of each parameter are displayed as either NO CHANGE or CALIBRATE. Must select [SAVE] to save the calibration. Press [EXIT] to proceed to printing the final calibration report. Select [PRINT] and label "Post-Calibration". To verify calibration, run three levels of controls. Keep control printouts and label post-calibration.
Guided Calibration The Guided Calibration was successful. It is recommended to run control's to verify calibration. Do you want a calibration report? Print Exit	 <u>KEEP ALL PRINTED CALIBRATION DOCUMENTS</u> Calibrator assay insert/M-series barcode insert/product description insert (3 pages). Pre-Calibration log. Five Calibration Runs. Post-Calibration Report. Post-Calibration Control Results. If Calibrating the Micro Pipette Adapter (MPA), press [CAPILLARY DEVICE] instead of [Whole Blood] calibration and use MPA mode for calibrator analysis.