

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.

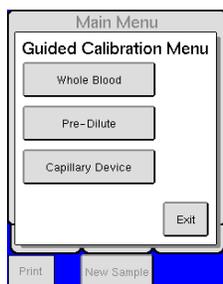
Print the calibration log:

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

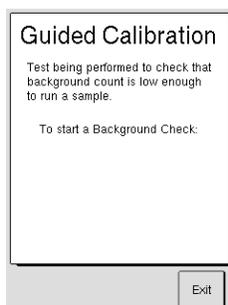
Calibration log can also be accessed by selecting [ADVANCED] from Main Menu, then [ADV CALIBRATION], then [CALIBRATION LOG], followed by [PRINT]

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.

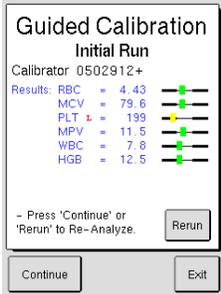
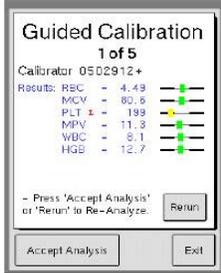
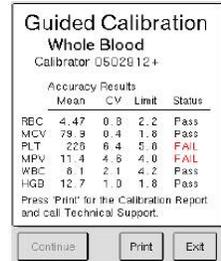
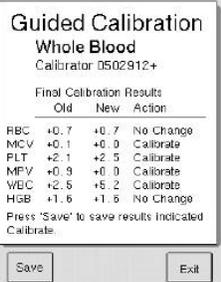


- From Main Menu select [ADVANCED MENU]
- Select [GUIDED CALIBRATION]
- Choose [WHOLE BLOOD]
- Select [SCAN BAR CODE SHEET] to input calibrator values from calibrator assay sheet.
- Save all Product Inserts supplied with the Calibrator.



- 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)*

	<ul style="list-style-type: none"> 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.
	<ul style="list-style-type: none"> 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
	<ul style="list-style-type: none"> 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. PASS: Accuracy and Precision are acceptable - proceed to Final Calibration. FAIL: Print the report and contact Technical Support for assistance.
	<p style="text-align: center;"><u>FINAL CALIBRATION</u></p> <ul style="list-style-type: none"> 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.
	<p><u>KEEP ALL PRINTED CALIBRATION DOCUMENTS</u></p> <ol style="list-style-type: none"> 1) Calibrator assay insert/M-series barcode insert/product description insert (3 pages). 2) Pre-Calibration log. 3) Five Calibration Runs. 4) Post-Calibration Report. 5) Post-Calibration Control Results. <p>If Calibrating the Micro Pipette Adapter (MPA), press [CAPILLARY DEVICE] instead of [Whole Blood] calibration and use MPA mode for calibrator analysis.</p>