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Medonic

Medonic M-Series Hematology System

Quick Reference Guide

Read User Manual prior to using this guide

Medonic

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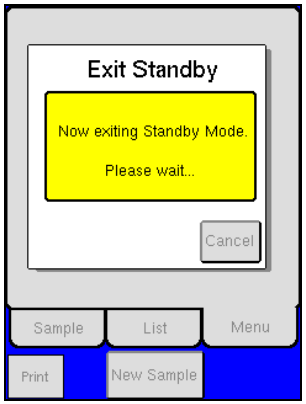
CE

Routine Procedures

A. Getting started each working day

1. If the system is in Standby

- Touch the screen to activate system.
- On the initial screen display, select [EXIT STANDBY]. The instrument is now preparing itself for the day.



Continue to Section B for automated daily startup menus (set as default) or Section C for manual daily performance verification.

Sample Collection and Handling

Correct sample processing is the most important step in obtaining accurate results on an automated hematology system. Most analytical errors are caused by improper sample collection and handling. The following protocol assists the user in minimizing microclot formation and obtaining the highest quality samples possible.

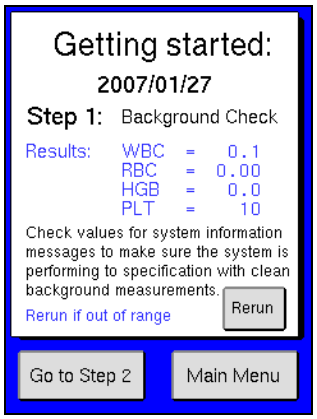
1. Swift, atraumatic venipuncture
2. Human venous blood samples should be collected in an EDTA K3 or EDTA K2 tube in sufficient quantity.
3. Immediately transfer blood into an EDTA collection tube, if not using a vacutainer, by one of two methods:
   A. Remove the needle from the syringe and remove the stopper from the tube. Hold the top of the syringe over the tube and gently dispense the blood into the tube. Fill the tube ½ - ¾ full then recap; **OR**
   B. Change needle on the syringe to 18-19G, push needle through the stopper and allow the vacuum to aspirate the blood into the tube. Do not press on the syringe plunger! This will cause hemolysis.
4. Immediately invert the tube 8 – 10 times to mix blood and anticoagulant.
5. The sample should be mixed for 10-15 minutes before analysis. It is recommended to use a mixer. A sample not correctly handled may give erroneous results.
6. Note: Samples should be analyzed between 15 minutes and 6 hours for most accurate results.

The Medonic M-Series analyzer has the option to analyze capillary whole blood samples with the use of the Micropipette Adapter (MPA). See Section 5.7 in the User Manual for complete instructions on MPA usage.

B. Daily Startup Sequence (Verifying Performance)

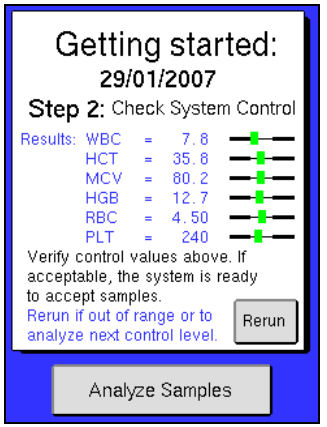
1. Perform a background check

- Press Start plate to automatically initiate background check.
- When background check passes, select [GO TO STEP 2].



2. Perform a quality control check

- Scan in control tube barcode.
- Follow the control preparation on the screen.
- Introduce control sample and press Start plate.
- Control results are displayed within one minute. Analyze next control level. When control results are acceptable, the daily startup sequence is complete.

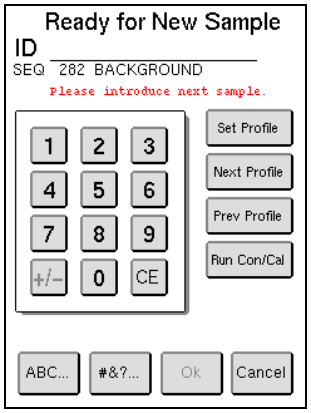


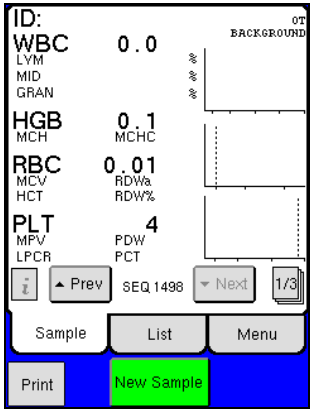
- Press [ANALYZE SAMPLES] to go to the main screen, and follow instructions in Section D to analyze samples.

C. Manual Daily Performance Verification

1. Perform a background check

- It is recommended to run a background check at the beginning of each day on the different analysis modes that will be used.
- From the main screen press [NEW SAMPLE].
- Press [NEXT PROFILE] or [PREV PROFILE] to scroll to BACKGROUND.





- Press the Start plate. The aspiration time is approximately 10 seconds. After ~ 10 seconds the analyzer will time out due to no detection of blood, and continue its cycle.
- Check that the background is not higher than the figures shown below. Rerun sample if values are not acceptable.

Parameters	Values accepted
RBC	≤ 0.01 (10^{12}/ L)
WBC	≤ 0.2 (10^{9}/ L)
HGB	≤ 0.2 (g/ dL)
PLT	≤ 10 (10^{9}/ L)

2. Perform a quality control check

- Good laboratory practice indicates that the performance of the Medonic M-Series system is checked daily with certified blood controls authorized by Boule. Comparing the analyzer results to the known values on the Boule control assay sheet is a good assurance that the system is functioning properly.

D. Clot Prevention (cont'd)

- From Main Menu press [ADVANCED], then [MAINTENANCE] and then press [CLOT PREVENTION].
  - For Cap Piercer: Place filled cleaner tube into cap piercer, same as a normal sample analysis, close the door and continue to the next step.
  - For Sampling Device: Place filled cleaner tube into Position 1 on wheel, lock wheel into place, and continue to the next step.
- Hold the container (with cleaner) under the OT needle, submerged in cleaner, press [OK] to confirm. Do not remove container (with cleaner) for at least 5 seconds after aspiration has stopped. (This is important as Cap Piercer and Sampling Devices will take a few extra seconds to perform aspiration before the OT begins to aspirate.)
- The system will then perform the cleaning process for all analysis modes simultaneously, and upon completion instrument is ready for next analysis.
- Perform a background check to verify all values are within range. See Section C for more details.

E. Six (6) Month Cleaning Procedure

To increase the life of the analyzer's internal tubing, the following cleaning procedure is strongly recommended.

- Press [ADVANCED] from Main menu, then press [MAINTENANCE], and then press [CLEANING MENU] to enter the Cleaning Menu.
- Follow the instruction for the Boule Cleaning kit to clean the analyzer. (Instructions for use are supplied with the Boule Cleaning kit solutions).
- The Boule Cleaning kit contains: Hypochlorite (2%), Enzymatic Cleaner, and Detergent Cleaner
- The Annual Cleaning procedure takes approximately one hour and 15 minutes to complete.

F. LCD Display

When necessary, gently clean the display with a soft cloth, slightly moistened with water and a mild soap. Dry carefully.

G. Maintenance

The maintenance should be performed every year or 20,000 samples by local distributor or authorized service technician.

Maintenance Procedures

The majority of the analyzers cleaning procedures are automated to keep the user maintenance to an absolute minimum.

A. Daily Cleaning

Clean the sample probe and probe rinse cup using a paper tissue moistened with a 70% alcohol solution to remove any residual blood and salt crystals.

B. Automatic Cleaning Mode

The Medonic M-Series system has been designed to clean internal components on a daily basis. The system uses the diluent to flush and clean all components that come into contact with blood when in standby or power-off mode. This automatic daily cleaning increase the longevity of the analyzer and decreases maintenance procedures.

C. Monthly Cleaning Procedure

To insure the correct function of the instrument on a monthly basis, the following cleaning procedure is strongly recommended. (This procedure takes 10 minutes to complete.)

- Fill a cup with 10 ml 2% hypochlorite (bleach), certified by Boule, and one cup with 18 ml diluent. (Recommend use of dispense function for obtaining diluent, see Section 5.5 in user manual.)
- Aspirate the hypochlorite as a pre-diluted sample, and then repeat.
- Run 2 blank samples by aspirating diluent as a pre-diluted sample.
- Perform a background check, in pre-dilute mode, to verify all values are within range. See Section C for more details.

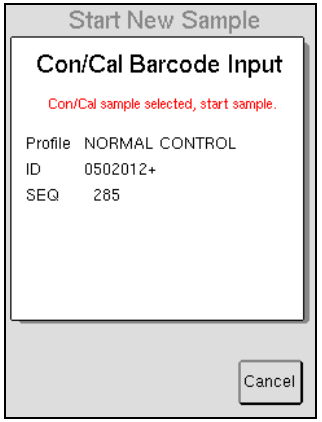
D. Clot Prevention

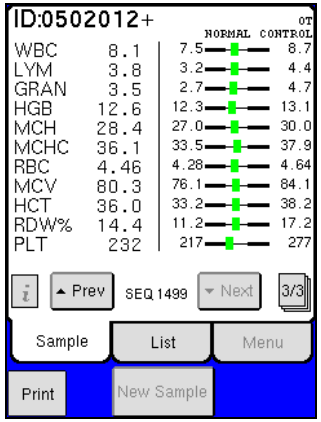
This process will decrease the risk of debris material building up in the instrument system. This should be performed at least once a month or every 1000 samples. (This procedure will take 15 minutes to complete.)

- Fill a small container with 5 ml of Enzymatic Cleaner. (Enzymatic Cleaner from the cleaning kit can be used.)
- **Note:** If system has the optional Cap Piercer or Sampling Device, fill a CLEAN standard 4.0 – 5.0 ml tube half full with Enzymatic Cleaner.

C. Manual Daily Performance Verification (cont'd)

- Refer to the Blood Control Product Insert for complete instructions for handling and use of blood control materials.
- Never use an open vial longer than recommended by the manufacturer or subject any vial to excessive heat or agitation.
- Wipe the sample probe with a clean, dry tissue before each control run. Not following this discipline might lead to decreasing parameter values.
- Choose either List, Sample, or Main Menu to begin control analysis.
- Using installed barcode reader, scan the Control ID from the blood control vial label.



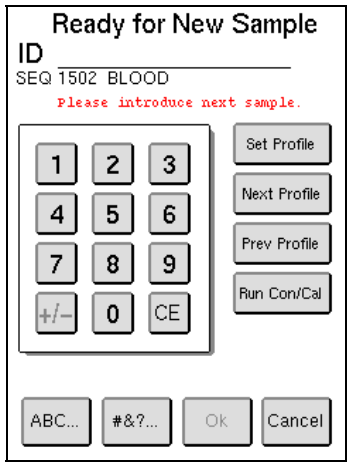


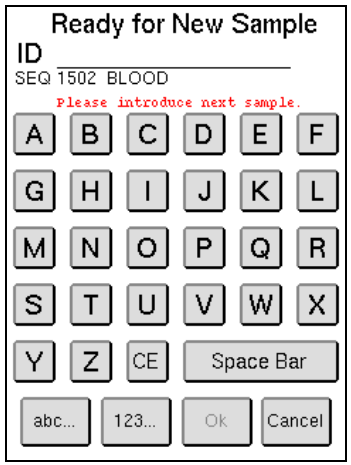
- Aspirate the blood control and wait for the results. The Medonic M-Series analyzer will identify this ID and match the results with the previously defined assay values.
- Compare Control results to assay values on results screen.
- If control results are acceptable, the daily performance verification is complete and system is now ready to accept patient samples.

D. Patient Sample Analysis

1. Sample analysis

- Choose List, Sample, or Main menu to begin sample analysis. Analyzer must be in one of these operation modes to aspirate.
- From one of these screens press [NEW SAMPLE] or begin sample aspiration, which automatically opens NEW SAMPLE menu.
- Press [NEXT PROFILE] or [PREV PROFILE] to scroll to desired profile.





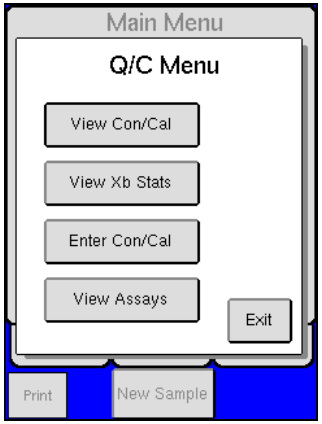
- Press numerical keys to enter sample ID or scan in the ID barcode from the sample tube. Touch the text key to move between alpha and numeric ID screens.
- Introduce the sample to the sample probe and press the Start plate to analyze the sample.
- Follow the instruction on the menu when to remove the sample tube. The analyzer also gives an audible indication, a beep, when the sample should be removed from the sample probe.
- After 45 seconds results will be displayed on List or Sample menu. For more information of results screens see next page.
- When NEW SAMPLE button returns to green, operator can begin analysis of next sample.

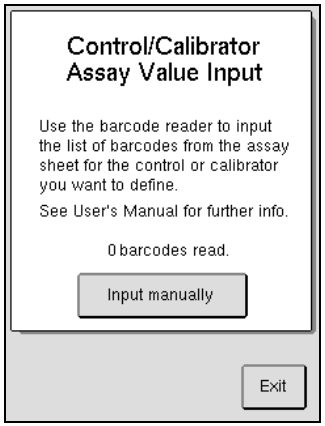
See Section 5 of User Manual for more details on pre-dilute, Micro Pipette Adapter, Cap Piercing Device, and Sampling device analysis modes.

H. Activation of New lot of Blood Control

When a current lot of blood control is replaced by a new lot, follow the instruction below to input Control Assay Values from the Assay sheet.

- Select [QC] from Main menu.
- Select [ENTER CON/CAL].





- Sequentially scan all the barcodes on the Control Assay Sheet. Press and hold the ON button on the barcode reader each time a barcode is scanned. More detailed instructions are present on the assay sheet.
- When all barcodes are entered a screen will display that the control barcodes have been entered correctly and accepted.
- Select [EXIT] to return to the Main menu.

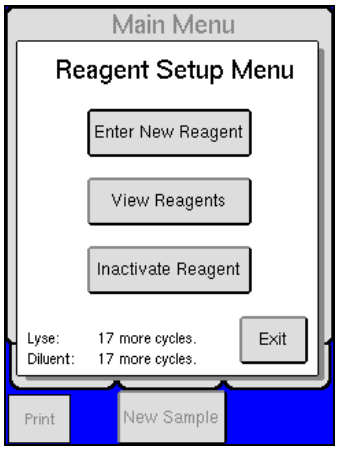
This procedure enters all Control assay value ranges for the new lot of control, which means the systems automatically recognizes the control tube when it is scanned in and analyzed each day.

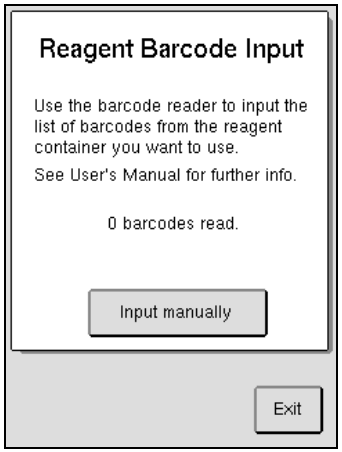
Note: Assay values for 12 different lots can be stored simultaneously. When renewing the assay values, the previously scanned CON/CAL assay values will be removed in a chronological order starting with the assay values that were entered first.

G. Changing Reagents

The interlocked reagent system displays indicator and warning messages to alert the operator when reagents are running low and need to be changed. When this occurs perform the following:

- Select [MENU] to access the Main menu and then select [REAGENT SETUP].
- Select [ENTER NEW REAGENT].



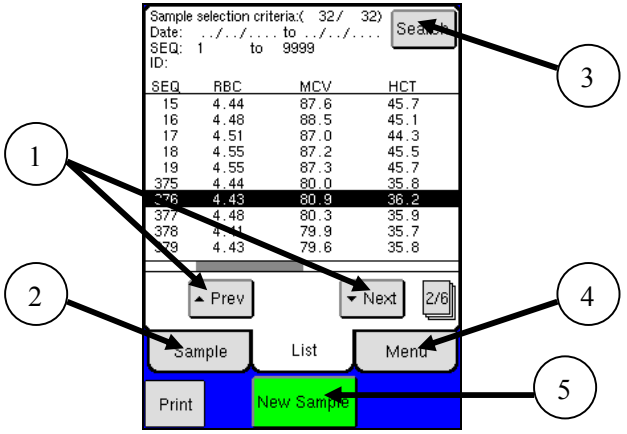


- Scan Barcode 1 and then Barcode 2 on the reagent container. Press and hold the ON button on the barcode reader each time a barcode is scanned.
- When all barcodes are entered a screen will display that reagent barcodes have been accepted.
- Select [EXIT] to return to the Main menu.
- Remove the cap and seal on the new reagent container.
- Transfer the reagent level sensor from the used container to the new reagent container.
- The analyzer is now ready to resume operation or analyze samples. No priming or fill cycle is necessary when putting on a new reagent container, if indicator and warning messages are followed.

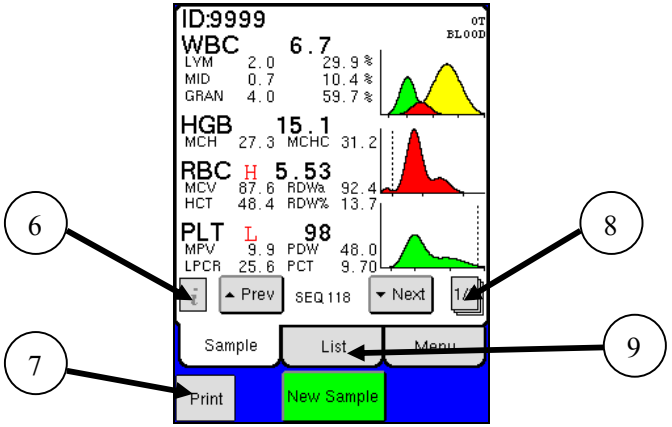
D. Patient Sample Analysis (cont'd)

2. Sample Result Screens

1. Select [PREVIOUS] or [NEXT] to navigate samples in list.
2. Select [SAMPLE] to display results of the sample highlighted in the list below.
3. Select [SEARCH] to recall a list of results in memory based on search criteria.
4. Select [MENU] to move the Main menu.
5. Select [NEW SAMPLE] to analyze more samples.

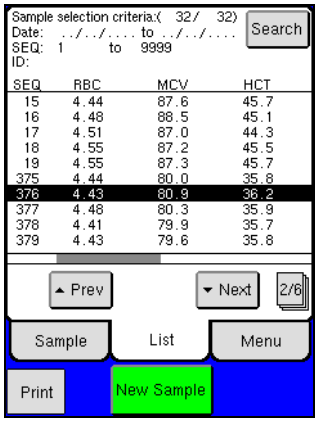


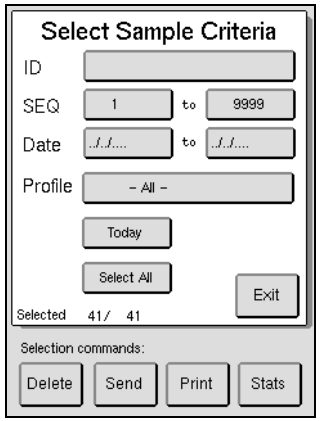
6. Select [***i***] to view system information messages.
7. Select [PRINT] to print sample results.
8. Select to see different views of the same sample.
9. Select [LIST] to move to the List menu.



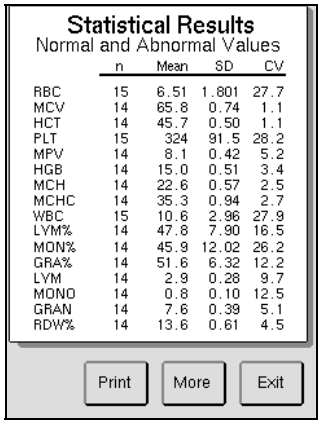
E. Locating Sample Records

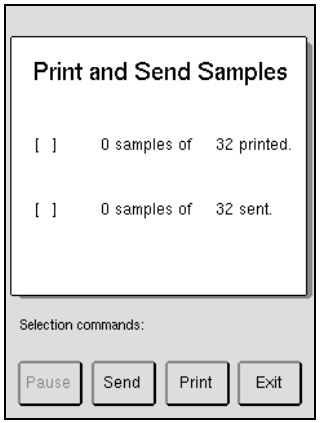
- To recall a sample or set of sample records, select [LIST] and then [SEARCH] to go to search criteria.
- A search may be performed using the following criteria: Sample ID, Analysis sequence, Date range, and Profile type.





- Select the criteria desired for the search and enter the criteria.
- Select [EXIT] to return to the List menu and view the results of the search.
- From the List menu, it is possible to view results in Sample menu, view statistics, print and/or send results.





- To erase the results of a search and restore all samples to the List and Sample menus, press [SELECT ALL] in the Select Sample Criteria screen or analyze a new sample.

F. End of workday system care

- Clean the sample probe and probe rinse cup using a paper tissue moistened with a 70% alcohol solution to remove any residual blood and salt crystals.

- The Medonic M-Series system has been designed to clean internal components on a daily basis. After 12 hours of inactivity, the system will initiate a self cleaning cycle using diluent to flush and clean all components that come into contact with blood. (The analyzer remains filled with the diluent until it is powered back on or taken out of standby.) The analyzer can be manually put into Standby by selecting [STANDBY] in the Main menu.