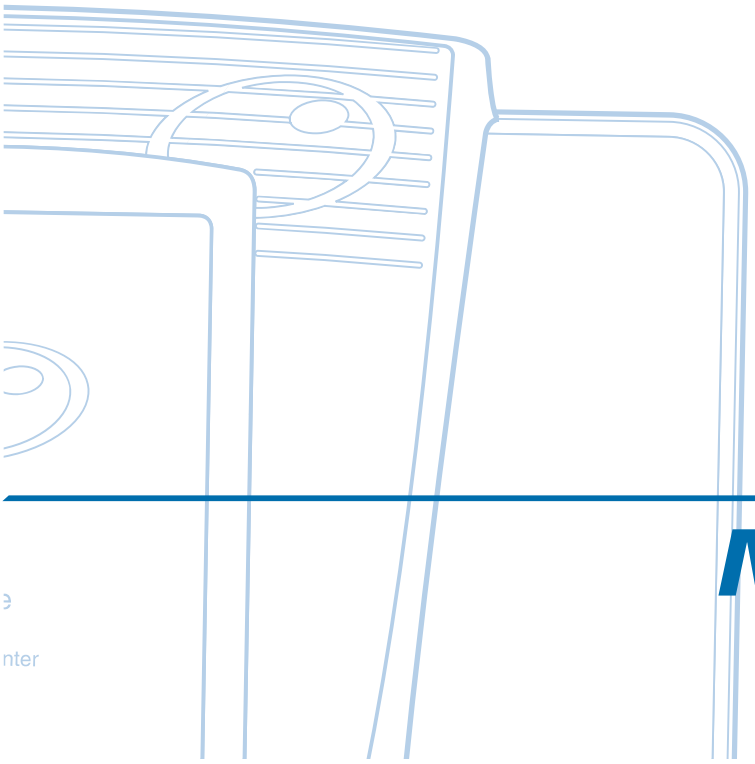
Medonic M-series

User Manual



Medonic

REVISION HISTORY

Previous Revisions

Date of issue	Software versions
2022-05	3.2.2
2021-01	3.2.2
2020-05	3.2.1
2016-02	2.9.4

Latest Revision

Date of issue: June 2022
Software version: 3.2.2 or later

Changes listed below:

Section revised	Page(s)	Changes	Updated	Added	Removed
1.6 Signs on Equipment	9	Explanation of CE mark	✓		
1.7 Hazard Information on Consumables	11	More detailed hazard information for reagents	✓		
8.9 Disposal Information	73	How to recycle reagent packaging		✓	

Contents

Preface

Introduction

Instrument description

Medonic M-Series 3-part hematology analyzer is produced by Boule Medical for human application.

Serial number

Serial number is located on the rear of the instrument.

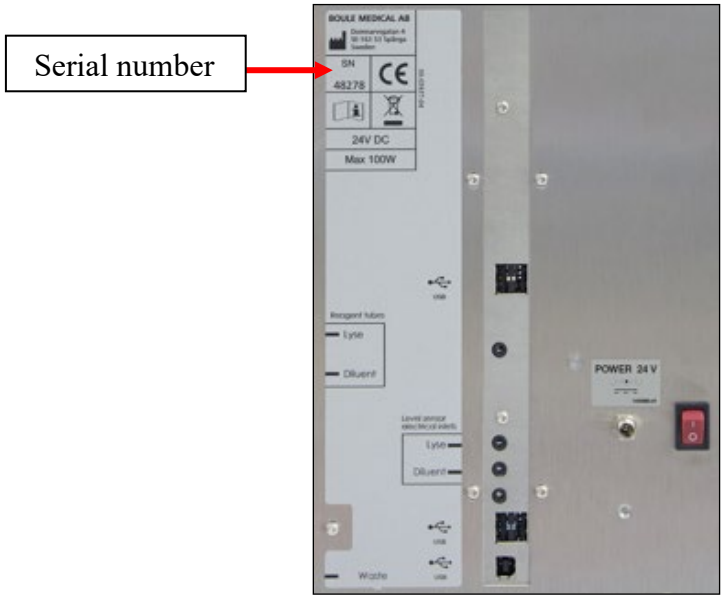


Figure 1.1

Figure 1.2

Software version

The software version is displayed when starting up the instrument.

Instrument

List of models

Product code	Product name
1400002	Medonic M-series M16
1400003	Medonic M-series M16M-GP
1400004	Medonic M-series M20M-GP
1400005	Medonic M-series M16C
1400006	Medonic M-series M20C
1400007	Medonic M-series M16C+ABR
1400008	Medonic M-series M20C+ABR
1400009	M-series M16S BD
1400010	M-series M20S BD
1400011	M-series M16S BD ABR
1400012	M-series M20S BD ABR
1400062	Medonic M-series M20
1400065	Medonic M-series M16S Sarstedt
1400066	Medonic M-series M20S Sarstedt
1400067	M-series M16S Sarstedt ABR
1400068	M-series M20S Sarstedt ABR

Additional Documentation	Additional documentation is available from your local Boule representative. Current additional documentation is listed below: • Service Manual • Medonic Case Book • User Definable Settings
Operator requirements	The following operator requirements must be fulfilled before operating the Medonic M-Series hematology system. • Basic skills in a laboratory environment. • Basic skills in hematology. • Awareness of IVD (EU)/FDA (US) requirements regarding laboratory equipment. • The operator must read and understand this manual.
Optional accessories and consumables	Accessories and consumable lists are available from your local Boule representative.
Manufacturer's details	Boule Medical AB Domnarvsgatan 4 SE-163 53 Spånga, Sweden Telephone number: +46 8 744 77 00 Email: info@boule.com Website: www.boule.com
Distributor details	Please contact Boule for information.
International standards and regulations	SS-EN ISO 18113-3:2011 IVD 98/79/EG IVDR (EU) 2017/746 (only applicable for Diluent, Lyse and Micropipette) SSEN 61010-2-101 (Low Voltage Directive 2006/95/EC) EN 61326 (2006) (EMC 2004/108/EC) 2012/19/EU WEEE Standards harmonized with FDA
Third-party Software	For information see Appendix C.

Section 1: Safety Instructions

Section Overview

Introduction

This section describes the safety features and warnings associated with the Medonic M-Series.

Contents

This section contains the following topics:

1.1 Intended Use

Description

Intended use, analyzer
The Medonic M-Series is a fully automatic hematology analyzer intended for in vitro diagnostic testing of human blood samples under laboratory conditions.

Intended purpose, reagents
Medonic M-series Diluent and Medonic M-series Lyse are accessories intended to be used in combination with Medonic M-series 3-part hematology analyzers to dilute and lyse blood cells and thereby enable the analyzer to count and classify platelets, red and white blood cells and measure the hemoglobin concentration.
The reagents do not provide any results on their own and can only be used as consumables in combination with Medonic M-series analyzers.

Intended purpose, micropipettes
The specimen receptacle Boule MPA Micro Pipettes, Plastic, is a K2EDTA-coated capillary tube intended for In Vitro Diagnostic use for blood collection from a finger stick or a venous blood sample for direct insertion into the Micro Pipette Adapter (MPA) inlet of Medonic M-series automated hematology analyzer series.

Operator Requirements

Operator must have basic laboratory skills and be aware of good laboratory practice.

Warranty limitations

- Service must be performed by Boule Medical AB (hereafter referred to as Boule) or by service personnel authorized by Boule.

- Use only original spare parts and Boule authorized reagents, controls, calibrators and cleaners. (If these products are substituted it may void your warranty)
- Operators and laboratory supervisors are responsible that Boule products are operated and maintained according to the procedures described in manuals, control inserts and technical bulletins.

Warranty limitations in depth

- Each Boule system is tested using recommended reagents, controls, calibrators and cleaners. All performance claims are generated as part of this complete system.
- Boule products do NOT make diagnoses on patients. Boule intends its diagnostic products (systems, software and hardware) to be used to collect data reflecting the patient's hematological status. This data, in conjunction with other diagnostic information and the evaluation of the patient's condition, can be used by a trained clinician to establish a patient's diagnosis and to define clinical treatment.

1.2 Safety Instructions

Description

Boule incorporates safety features within the instrument in order to protect the operator from injury, the instrument from damage and the test results from inaccuracies.

Restrictions

In order to ensure the safety of the operator and instrument follow the instruction below:

- Do not use the instrument outdoors.
- Do no modify the instrument.
- Do not remove the cover. (Authorized personnel only).
- Do not use the instrument for other purposes than described in this manual.
- Do not spill blood or other fluids on the instrument in such a way that it can leak through the instrument casing. (This might result in electrical malfunction or personal injury).
- Do not drop or place objects on the analyzer.
- Do not use this device in close proximity to source of strong electromagnetic radiation (e.g. unshielded international RF sources), as these can interfere with the proper operation.
- Do not use power supply other than supplied by your local Boule representative.

Important

- Unauthorized modification of the instrument might result in erroneous results or risk for electrical shock.
- Spilling fluids into the instrument might cause electrical malfunction and/or personal injury.

Handling of reagents

- If a reagent comes in contact with eyes, rinse with running water for several minutes. If symptoms occur seek medical attention.
- If the reagent comes into contact with skin, wash affected area with water.

- If swallowed, rinse out mouth. If persistent symptoms occur seek medical attention.
- Safety Data Sheets are available for all reagents.

Serious Incident

If a serious incident occurs in relation with Boule Medical´s product, a notice shall be reported to the distributor, the manufacturer Boule and the competent authority of the Member State in which the user and /or the patient is established.

1.3 Biohazards

Description

As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, calibrators and waste these products should be handled as potentially biohazardous.

Support documentation

- Protection of Laboratory Workers From Infectious Disease Transmitted by occupationally acquired infections – 2nd Edition, Approved Guidelines (2001) Document M29-T2 promulgated by the Clinical and Laboratory Standards Institute, CLSI (NCCLS).
- Follow local regulatory documentation.

Handling of biohazardous material

- Use universal precautions when handling samples and discarding waste.
- Handle any exposure according to established laboratory protocol regulations.
- The instructions for analyzer decontamination and disposal can be found at www.boule.com.

1.4 Emergency Procedure

In case of emergency

If there are any obvious signs of malfunction such as smoke or liquid leaking out of the instrument proceed as follows:

Step	Action
1	Disconnect the main power supply immediately by pulling out the cord from the main supply.
2	Contact your local Boule representative.

1.5 Warning Signs in Manual

Warning Signs

The following warning signs in the manual are used to identify possible hazards and to call on the operator’s attention to this condition.

Sign	Function
 **Warning**	Indicates operation procedures that could result in personal injury if not correctly followed.
 **Caution**	Indicates operation procedures that could result in damage or destruction of equipment if not strictly observed.
 **Important**	Emphasizes operating procedures that must be followed to avoid erroneous results.
 **Mandatory Action**	Indicates that protective clothing, gloves or goggles must be used when performing described procedures.

Section 1 continues on the next page

1.6 Signs on Equipment

Description Signs placed on the instrument define areas that need special attention or areas that contain danger. See Symbols Table on page 9.

Signs on equipment

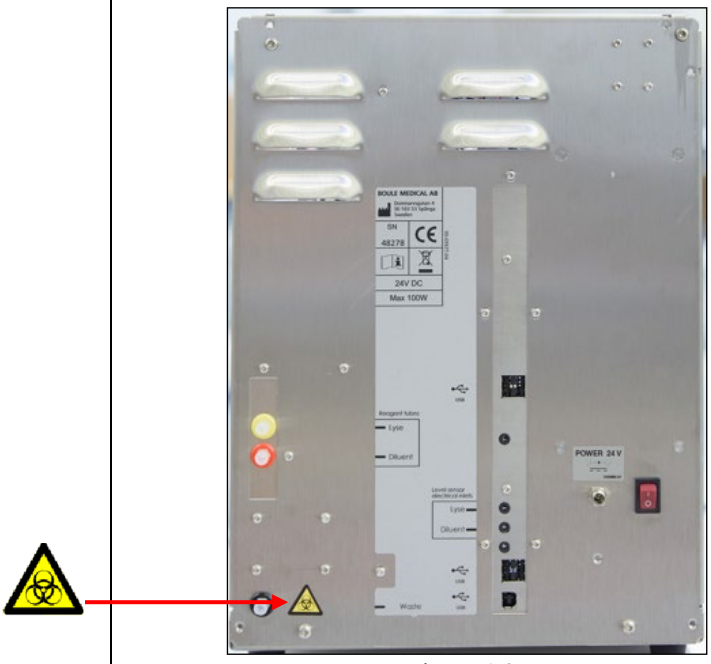


Figure 1.3

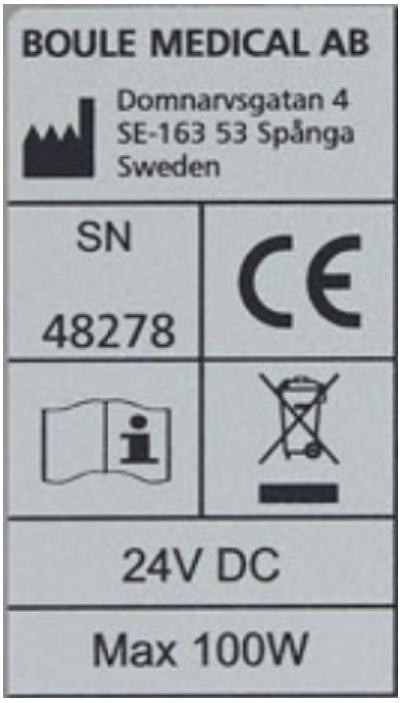


Figure 1.4

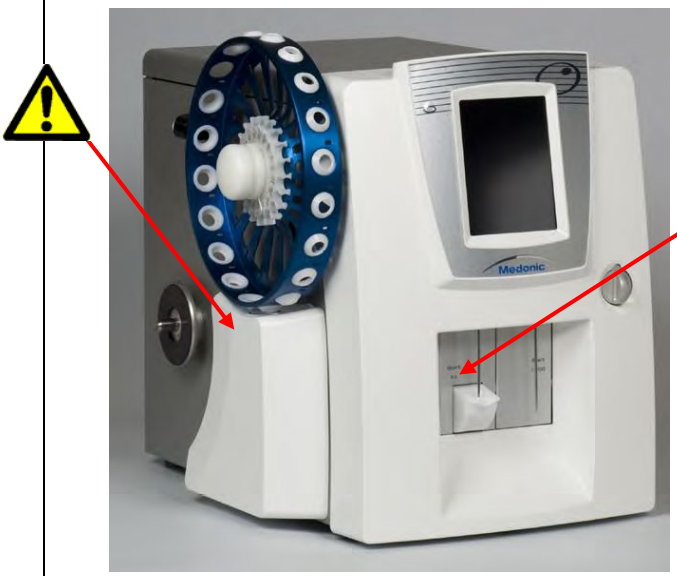


Figure 1.5

Figure 1.6

LOT	SN	REF	
Batch code	Serial number	Catalogue number	Manufacturer
EC REP			
Authorized* Representative in the European Community	Biological Risks	Fragile, handle with care	Use by
IVD			
In vitro diagnostic medical device	Lower limit of temperature	Upper limit of temperature	Temperature limitation
	www.boule.com	CONTROL L 16	CONTROL N 16
Consult instructions for use	Electronic instructions for use	Low control, 16 parameters	Normal control, 16 parameters
CONTROL H 16	CAL	CONT	CONTROL
High control, 16 parameters	Calibrator	Content	Control
	RFID	- +	
WEEE	Radio-frequency identification	Center pin positive polarity	Direct current
	CE		
Health hazard	CE mark of conformity	Single use	Warning
Recycling			

Figure 1.7 Symbols Table

1.7 Hazard Information on Consumables

Description

In compliance with the CLP regulation ((EC) No 1272/2008), any hazard related to the content of a Medonic reagent is identified on the product label by a hazard code and, if applicable, a pictogram. See the hazard identification below for codes, pictograms, and related precautionary statements. For detailed information, refer to the relevant Safety Data Sheet (SDS) at www.boule.com.
For hazard information for Boule Cleaning Kit, Boule Enzymatic Cleaner and Boule Hypochlorite (2%) Cleaner, see IFU Boule Cleaners, available at www.boule.com.

Hazard Identification

Hazard Identification, Medonic M-series Lyse	
Hazard pictogram	Not applicable
Signal word	Not applicable
Hazard code and statement	**H412** Harmful to aquatic life with long lasting effects.
Precautionary statements	**P273** Avoid release to the environment. **P501** Dispose of contents and container to authorized waste disposal facility.
Supplemental information	**EUH208** Contains REACTION MASS OF 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2HISOTHIAZOL-3-ONE (3:1). May produce an allergic reaction.

Hazard Identification, Medonic M-series Diluent	
Hazard pictogram	Not applicable
Signal word	Not applicable
Hazard code and statement	Not applicable
Precautionary statements	Not applicable
Supplemental information	**EUH208** Contains REACTION MASS OF 5-CHLORO-2-METHYL-2H-ISOTHIAZOL-3-ONE AND 2-METHYL-2HISOTHIAZOL-3-ONE (3:1). May produce an allergic reaction. **EUH210** Safety data sheet available on request.

Section 2: Installation

Section Overview

Introduction

This section describes how to unpack and install the Medonic M-Series instrument.

Contents

This section contains the following topics:

2.1 Unpacking / Operating Placement & Environment

Description

The instrument is packed in a specifically designed protective box.

Visual Checking

Check the box for physical damage. If damaged notify your carrier immediately.

Included Material

- Instrument
- User Manual
- Quick Reference Guide
- Waste tubing
- Reagent Level Sensor and reagent caps for isotonic diluent (Diluent)
- Reagent Level Sensor and reagent caps for hemolyzing reagent (Lyse)
- Power adapter and cord
- Installation form
- Declaration of Conformity
- Barcode reader

Optional Material

- Printer
- Printer paper
- MPA kit
- Sample wheels and control tube adapter (Autoloader model only)
- External Keyboard
- Boule reagents, controls, calibrators and cleaning kit

2.1 Unpacking / Operating Placement & Environment (continued)

Important

The following procedures must be followed exactly. Boule has no responsibility in case of faulty or erroneous installation.

Installation/ Operating Placement

The instrument should be placed in a laboratory environment according to the guidelines below:

- Place the instrument on a clean horizontal surface.
- Avoid lifting the analyzer by the front cover.
- Avoid exposure to sunlight.
- Make sure the instrument has access to proper ventilation. The instrument should have at least 5 cm (2 inches) of air above it.
- Place the rear of the instrument so it has at least 10 cm (4 inches) of free space behind it.

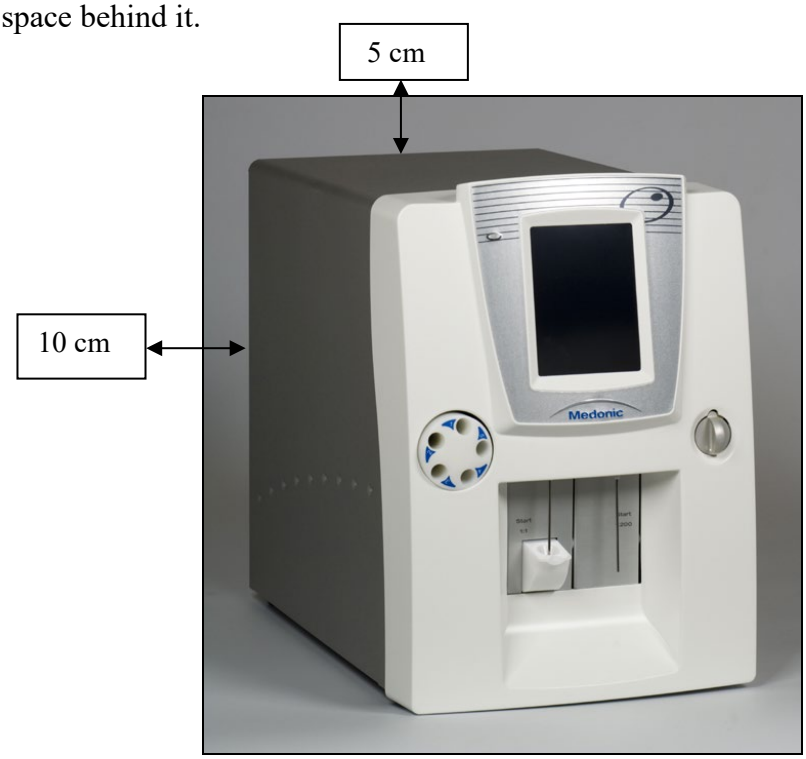


Figure 2.1

Installation/ Operating Environment

- Indoor Use
- Temperature +18 to +32 ºC (64 to 90 ºF)
- Humidity < 80% Relative
- Grounded main supply

Important

Operating the instrument in an environment over +32 °C (90°F) increases service needs, as well as degradation of sample specimen.

2.2 Installation Checklist and Menu

Description

Follow the quick Installation Checklist and Installation Menu step by step for best installation results. For more detail on each step refer to Sections 2.3 – 2.6.

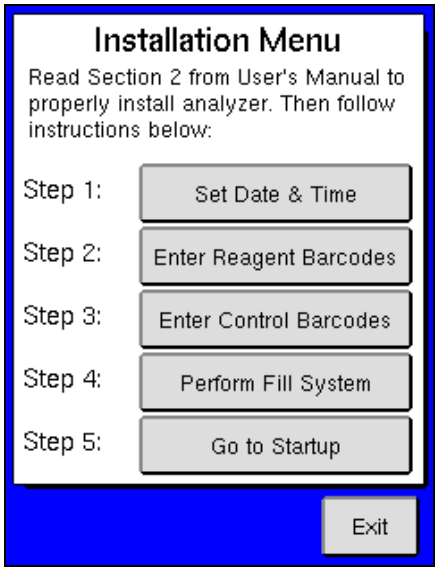
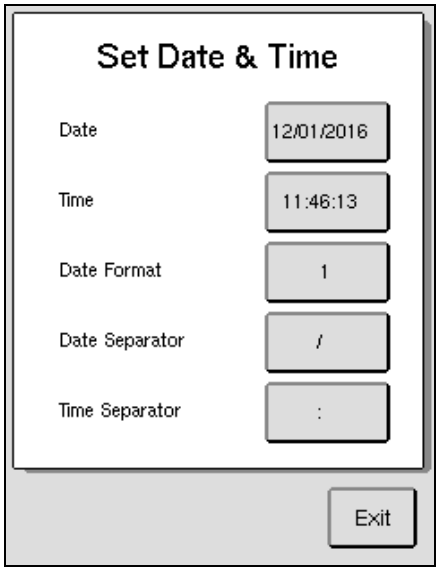
Installation Checklist	
☐	Complete Unpacking / Operating Placement and Environment instructions in Section 2.1.
☐	Connect the power adapter to the back of the analyzer, but do not plug it into an electrical socket.
☐	Connect the printer. (If not using Distributor provided printer see Section 4.3.)
☐	Connect the barcode reader to the back of the analyzer.
☐	Connect the waste line to the analyzer and plumb to waste container or drain.
☐	Connect the Diluent level sensor (red) and the electronic sensor to the analyzer.
☐	Connect the Lyse reagent level sensor (yellow) and the electronic sensor to the analyzer.
☐	Plug the power cord into the power adapter and the electrical socket to power up the analyzer.
☐	After system initialization follow Installation Menu instructions below.

Installation Menu

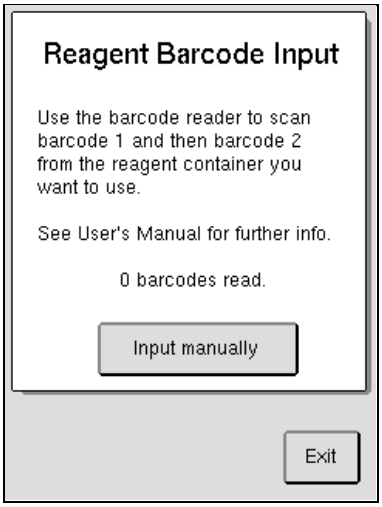
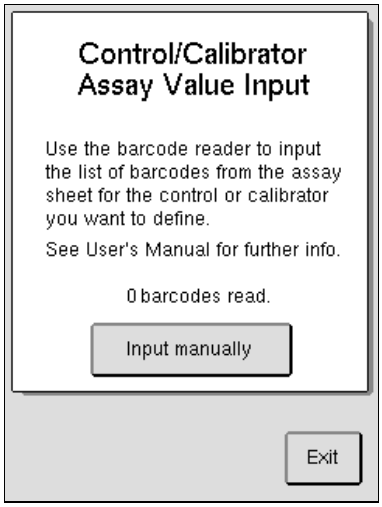
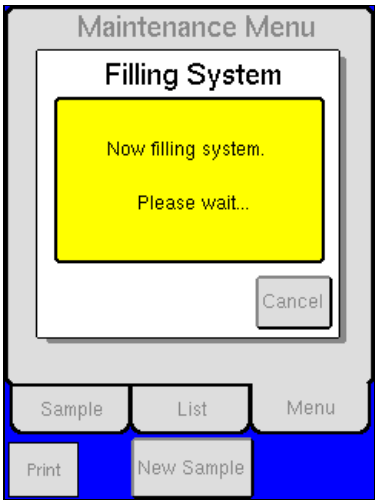
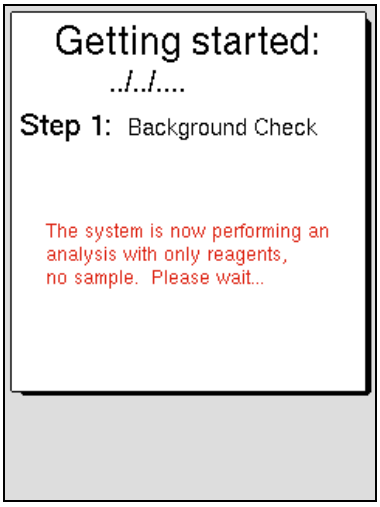
The following Installation Menu instructions were created to make installation as quick and easy as possible. After completing the following five steps (Step 5 is optional) on the Installation Menu, the system will be ready for the first sample analysis.

Important

The following Installation Menu Steps must be followed in sequential order.

Step	Action
1	Press Step 1 [SET DATE & TIME], set date and time, and press [EXIT] to return to Installation Menu.
	 Figure 2.2  Figure 2.3

Continued on next page

Step	Action
2	Press Step 2 [ENTER REAGENT BARCODES]. • Scan barcode 1 and then barcode 2 on the Diluent container. (Press and hold the ACTIVE or ON button each time a barcode is scanned.) ○ If using a Combination pack, following instruction for scanning in Diluent container. • If using single containers of Diluent and Lyse press [ENTER ANOTHER BARCODE] and scan barcode 1 and then barcode 2 on the Lyse container. • Press [EXIT] to return to Reagent Barcode Input screen and then press [EXIT] again to return to the Installation Menu.
Note	After reagents are scanned, then loosen reagent container caps, remove factory seals, and place reagent level sensors in respective containers.
	 Figure 2.4  Figure 2.5
3	Press Step 3 [ENTER CONTROL BARCODES] to enter assay value ranges into the system for the lot of Control being used. • Scan barcodes 1-9, in that order, for each control level. • Once accepted press [EXIT] to return to Installation Menu.
4	Press Step 4 [PERFORM FILL SYSTEM] to fill system with reagents. This cycle will last for approximately 3 minutes.
	 Figure 2.6  Figure 2.7
Optional	Press Step 5 [GO TO STARTUP]. See Section 5.2 for details on guided startup sequence.

2.3 Analyzer Cable, Interface, and Printer Connections

Description

All connections are located on the rear panel of the instrument. The connections available are as stated below:

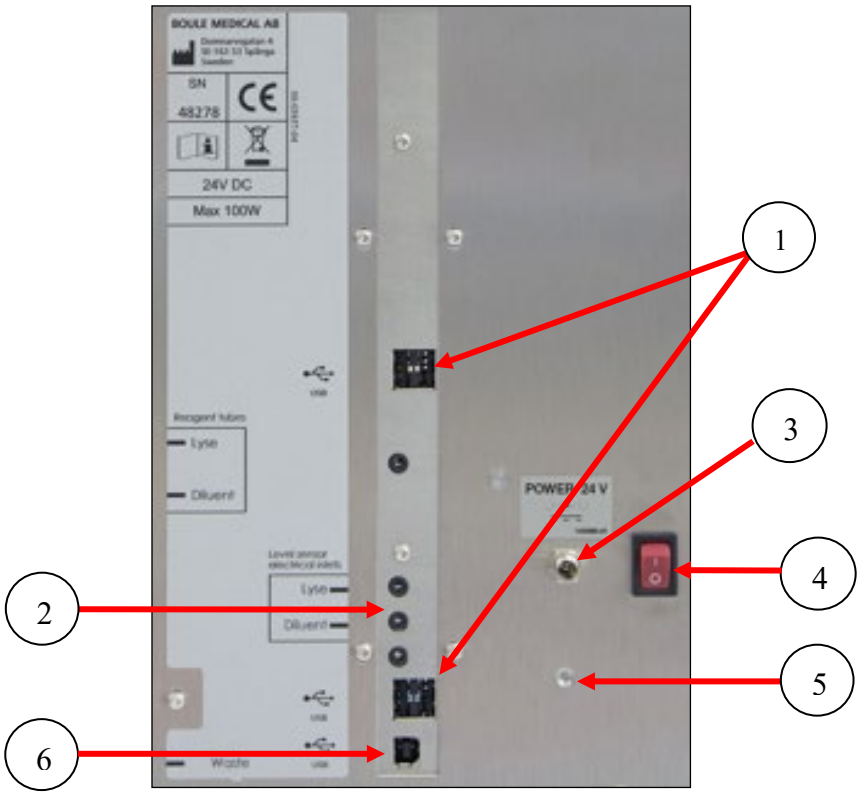


Figure 2.8

Number	Part	Function
1	USB host ports	Connects analyzer to USB devices
2	Electronic Sensors	Connects Reagent level sensors to analyzer.
3	Power Supply port	Connects Main power outlet to analyzer.
4	Power switch	Switches power On and Off.
5	Ground connector	Connects electrical ground to analyzer if alternative ground connection is required
6	USB Device Port	Connects analyzer to USB host

Printer Connection

The printer is connected to the rear of the instrument with USB printer cable. (Printer is not manufactured by Boule.) See Figure 2.8.

Supported Printers

DPU 411/2 and DPU 414 (Supplied by Boule as an optional accessory). Follow the instructions in the printer user manual to install.

Compatible Printers

HP-PCL compatible, IBM Proprinter compatible, or supported USB printers. If using one of these printers see Section 4.3 for setup instructions.

2.4 Reagent Installation

Description

The reagents for the instrument are delivered in cube formed boxes with plastic caps.

Supported Reagents

Hemolyzing reagent and Isotonic Diluent, hereafter referred to as Lyse and Diluent. (Specifically designed by Boule for the Medonic M-Series system.)

Location of Reagent

This section describes placement of reagent containers.

- It is recommended that both the Diluent and the Lyse reagents are placed at the instrument level or below.

Caution

Placing the reagent containers above the instrument level could cause system flow issue and is not recommended.

Connecting Reagent Containers

This section describes how to connect the reagent containers.

Step	Connect
1	The Lyse reagent level sensor (yellow) and the electronic sensor to the analyzer.
2	The Diluent level sensor (red) and the electronic sensor to the analyzer.

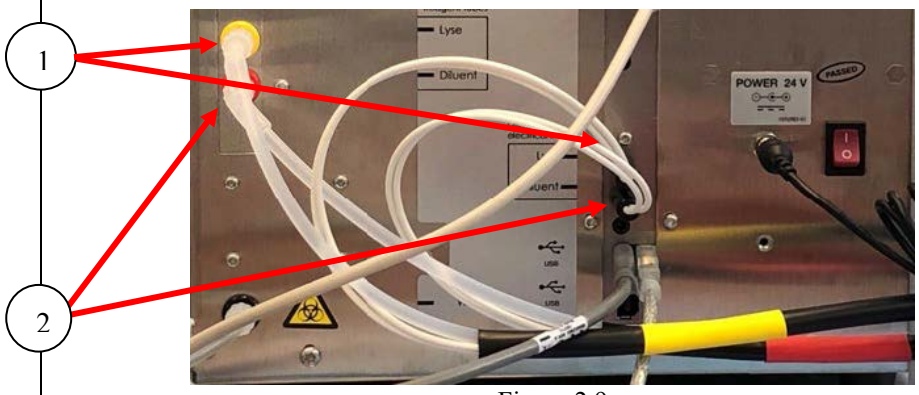


Figure 2.9

Continued on next page

2.4 Reagent Installation (continued)

Step	Insert
3	The reagent level sensors into the corresponding reagent containers.
	 Figure 2.10

Waste

Connect the waste tubing to the analyzer. Place the other end of the waste line directly into the drainage system or into a waste container, following local regulations. See Section 8.9 for Disposal information.

Caution

The end of the waste line must be at a lower level than the instrument itself. Not following this may lead to improper instrument functions and/or waste liquid flowing backwards into the instrument.

Mandatory Action

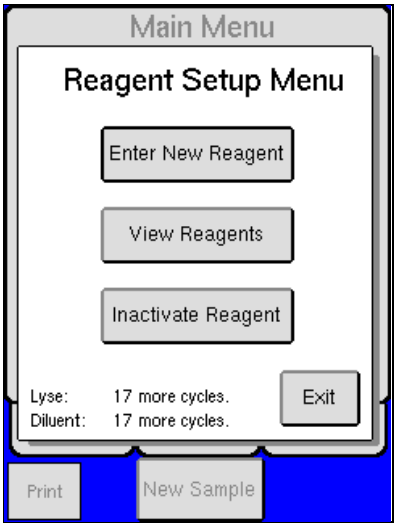
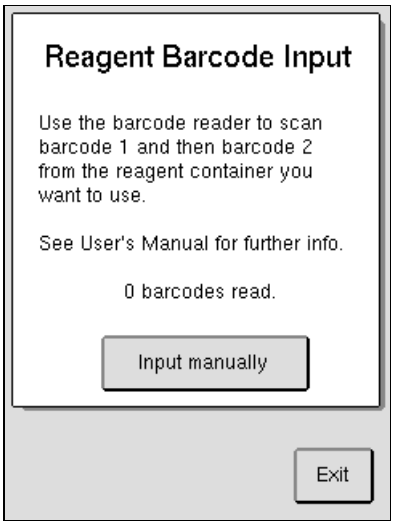
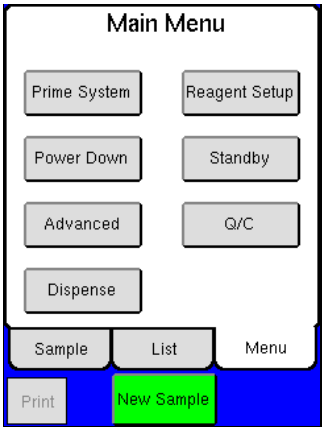
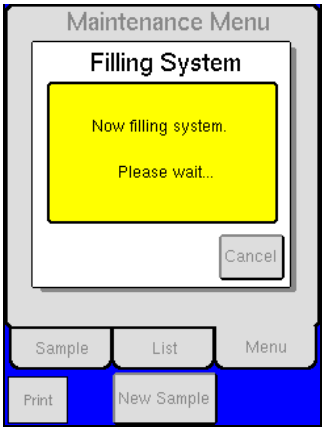
Always use protective gloves when working with the waste container and the waste tubing.

Fill System

- For initial fill of analyzer, plug in analyzer and turn On/Off switch to ON.
- Press [EXIT] button upon display of Fill prompt, and follow the instructions below to fill analyzer.

Continued on next page

2.4 Reagent Installation (continued)

Step	Action
1	Select MENU tab.
2	Press [REAGENT SETUP] and then press [ENTER NEW REAGENTS].
3	Scan in barcodes on reagent containers, when all barcodes are entered a screen will display that reagent barcodes have been accepted.  Figure 2.11  Figure 2.12
4	Return to MAIN Menu and press [ADVANCED].
5	Press [MAINTENANCE] and then [FILL SYSTEM].  Figure 2.13  Figure 2.14  Figure 2.15
6	The system is now filling up with reagents. This cycle will last for approximately 3 minutes.

Print All Settings

After initial setup, it is recommended to print all analyzer settings and keep for personal records. Select [ADVANCED] from Main Menu, then [SETUP], and then [PRINT ALL SETTINGS].

Factory Calibration

All sample analysis modes (open tube, pre-dilute, MPA, cap piercer, sampling device) are factory calibrated. However, calibration should always be checked upon installation. See Section 7 for more details.

2.5 Changing Reagents

Description

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:

Step	Action
1	Select [MENU] to access the Main menu and then select [REAGENT SETUP].
2	Select [ENTER NEW REAGENT].
3	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.
4	When all barcodes are entered a screen will display that reagent barcodes have been accepted.
5	Select [EXIT] to return to the Main menu.
6	Remove the cap and seal on the new reagent container.
7	Transfer the reagent level sensor from the used container to the new reagent container.
8	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.

Important

A reagent alarm will display when at least one of the reagent containers is running low, empty, or expired. Once alarm is displayed it will continue to display after each sample run until the indicated container is changed.

2.6 Power Supply

Main supply environment

The main power supply is located internally and designed to be operated indoors. The power supply is safe for transient voltage as defined in IEC 801-4.

Warning

Electrical shock hazard.

- The instrument must only be connected to a grounded mains supply. Violating this might result in injuries and/or erroneous parameter results.

Handling high transient voltage

If high voltage transients are expected on the main supply, please follow the recommendations below.

Important

When cycling the power switch from power on – power off – power on, it is recommended to have a delay of 3 seconds after power off. If the power switch is cycled back to power on too quickly, sensitive components in the instrument electronics may get damaged.

Continued on next page

2.6 Power Supply (continued)

Warning

Electrical shock hazard.

- Installation of external electrical equipment such as CVT must only be carried out by authorized service engineers. Violating this might result in possible injury, shock and/or erroneous results.

In case of	Symptom	Solution
High transient voltage above 15%	-High background counts on RBC, PLT or WBC. -Defective instrument.	A CVT (magnetic stabilizer) should be implemented to keep the instrument from being damaged. (In general, avoid the use of an UPS.)

Guidelines

Guidelines are given in the Service Manual, "Installation auxiliary devices" section. Contact your local Boule representative in such a case.

Power interruptions

In case of an abrupt power loss there will be no damage done to the instrument. Calibration constants and other parameters necessary for operation are protected against main supply loss.

Before connecting

In order to run the instrument, the frequency and main voltage needs to correspond to user's power outlet.

- Locate the serial number plate on the rear of analyzer and check that the main voltage and frequency corresponds to local main outlet.
- If voltage and/or frequency does not correspond, then contact your local Boule representative.

Connecting Power Adapter

Insert power adapter into the instrument's main power inlet and connect it to the main power supply. (This should only be performed after connecting the reagent containers.)

Section 3: General Overview

Section Overview

Introduction

This section contains general information about the instrument, consumables, and optional accessories.

Contents

This section contains the following topics:

3.1 General Instrument Overview

Instrument Overview

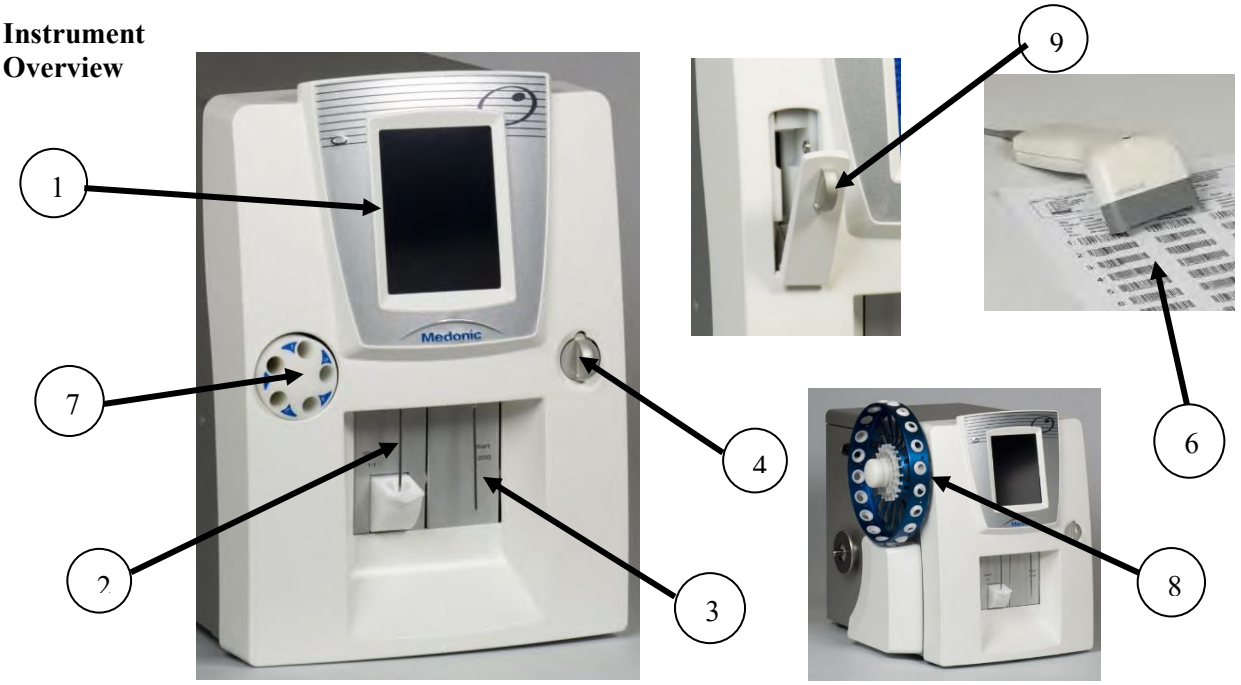


Figure 3.1

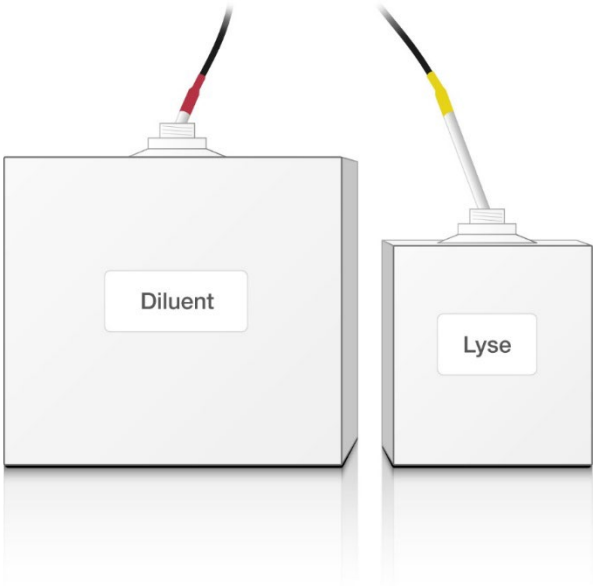
Part	Function
1. Display	TFT-LCD touch screen, color, with incorporated keyboard and numerical pad.
2. Whole Blood needle	Aspirates whole blood.
3. Pre-dilute needle/Dispenser	Aspirates pre-diluted samples and dispenses diluent.
4. MPA (optional)	Micro Pipette Adapter enables the user to analyze 20 µl of blood.
5. Printer (optional)	Prints sample results. (Not shown, model is user dependent)
6. Barcode Reader	Enables user to quickly enter patient, control, and reagent pack identifications and utilize the QC program.
7. Mixer (optional)	Uniformly mixes samples.
8. Sampling Device (optional)	Enables consecutive samples to be analyzed automatically.
9. Cap Piercer (optional)	Analyzes samples with decreased risk of blood contact.

3.2 Consumables Overview

Reagents

The reagents are accessories to be used in combination with the analyzer.

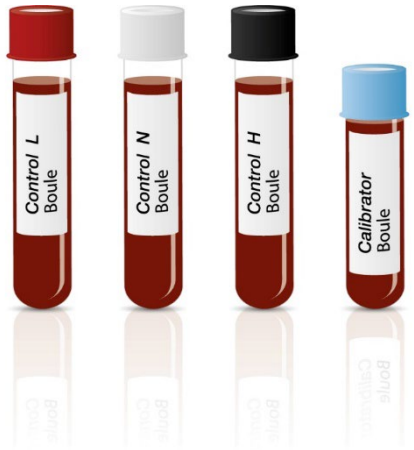
The diluent dilutes the blood sample to enable counting and sizing of red blood cells and platelets. The lyse lyses the red blood cells enabling sizing and counting of white blood cells and measurement of hemoglobin release from lysed red blood cells.



Part	Description / Function
Diluent	Isotonic diluting solution
Lyse	Lytic solution

QC Material

Boule Controls and Boule Calibrator are used to calibrate and monitor the performance of the analyzer.



Part	Description / Function
Boule Control	QC material to verify analyzer operation.
Boule Calibrator	QC material to calibrate analyzer.

Micropipette	The Boule MPA Micropipettes are used to collect a small amount of blood for immediate analysis via the MPA inlet of the analyzer. The micropipettes are for single use only.
Reagent Consumption Specifications	For information regarding consumption of diluent and lyse, see 11.4 Reagents and Reagent Consumption. For information regarding the consumption of cleaning solutions please refer to the Boule Cleaning Kit instruction. (Supplied with the Boule Cleaning Kit and on www.boule.com).

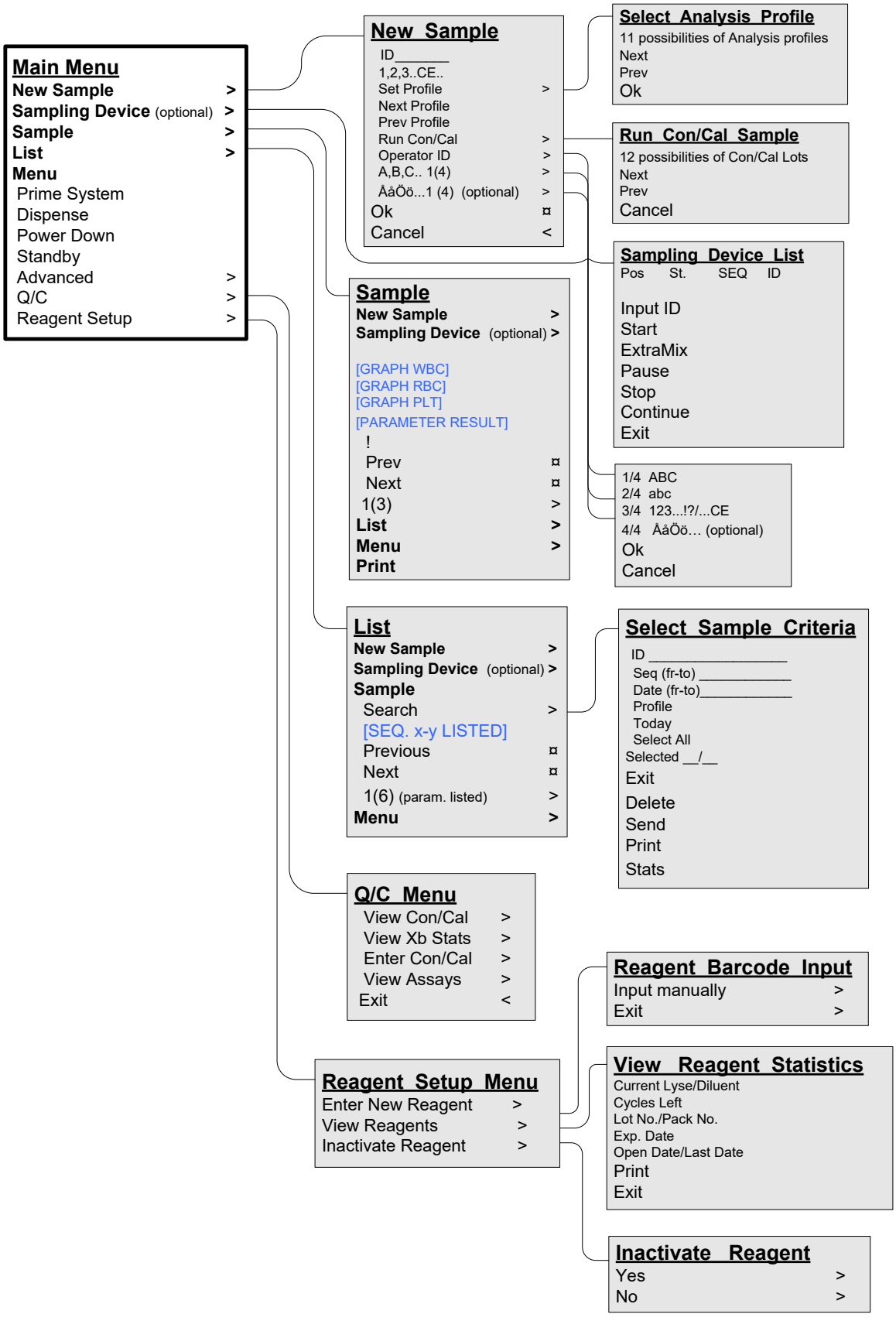
3.3 Consumables Details

Reagents	Storage and stability: The reagents are stable at least up until the expiration date as shown on labels when stored at a temperature between 4°C and 35°C. Open container stability is 3 months if storage recommendations are followed. Composition: o Lyse: quaternary ammonium compounds, antibacterial agents, buffering agents, water. o Diluent: protein complexing agents, antibacterial agents, buffering agents, water.
Micropipette	Storage and stability: The micropipettes provided by Boule are stable at least up until the expiration date as shown on labels, when stored at a temperature between 2°C and 30°C. Provided the container is resealed between uses, the open container stability is until the expiration date. Composition: Plastic capillary tube coated with K2EDTA.

Section 3 continues on the next page

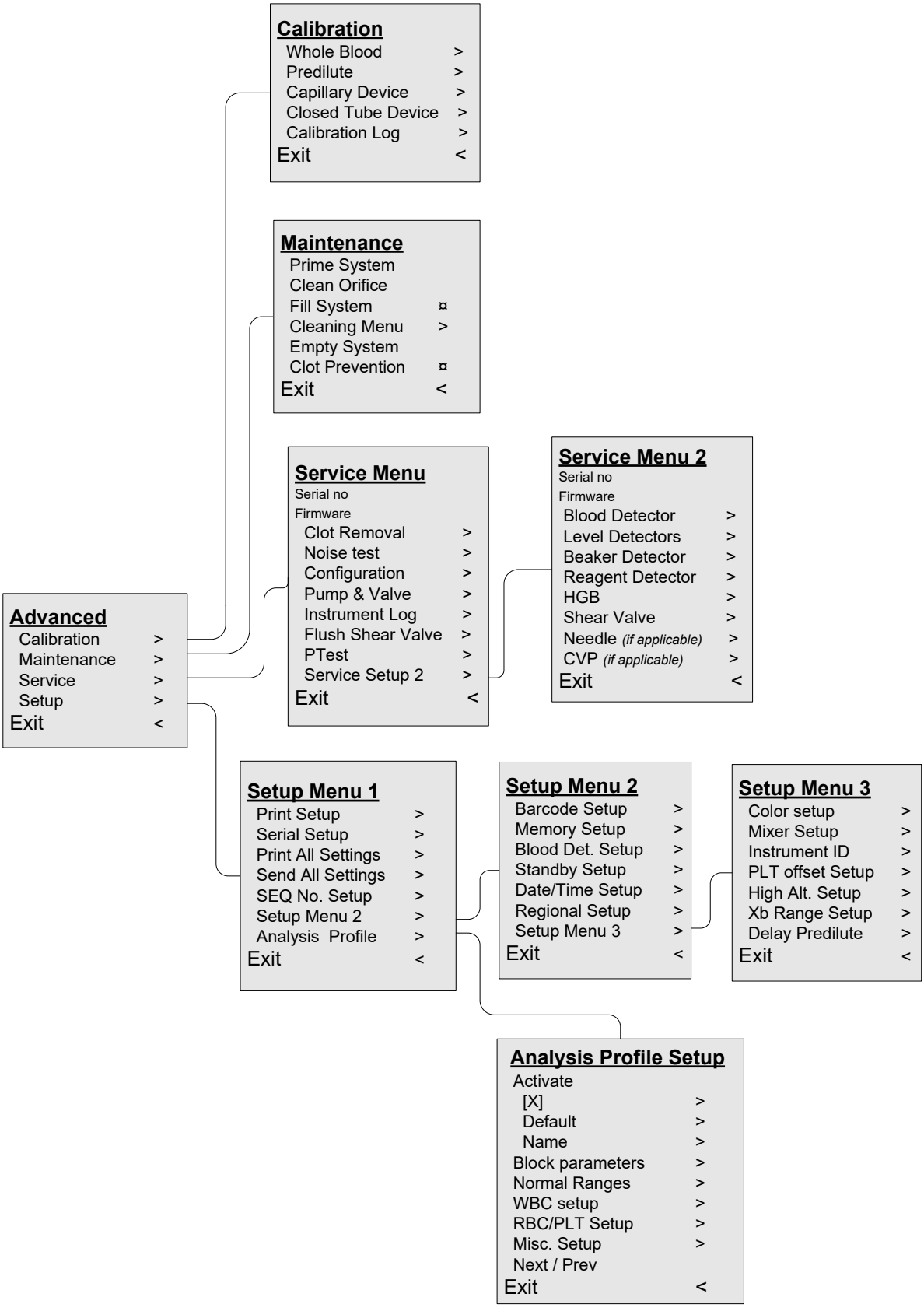
3.4 Menu Structure

Flowchart 3.1 Main Menu Structure



3.5 Menu Structure (continued)

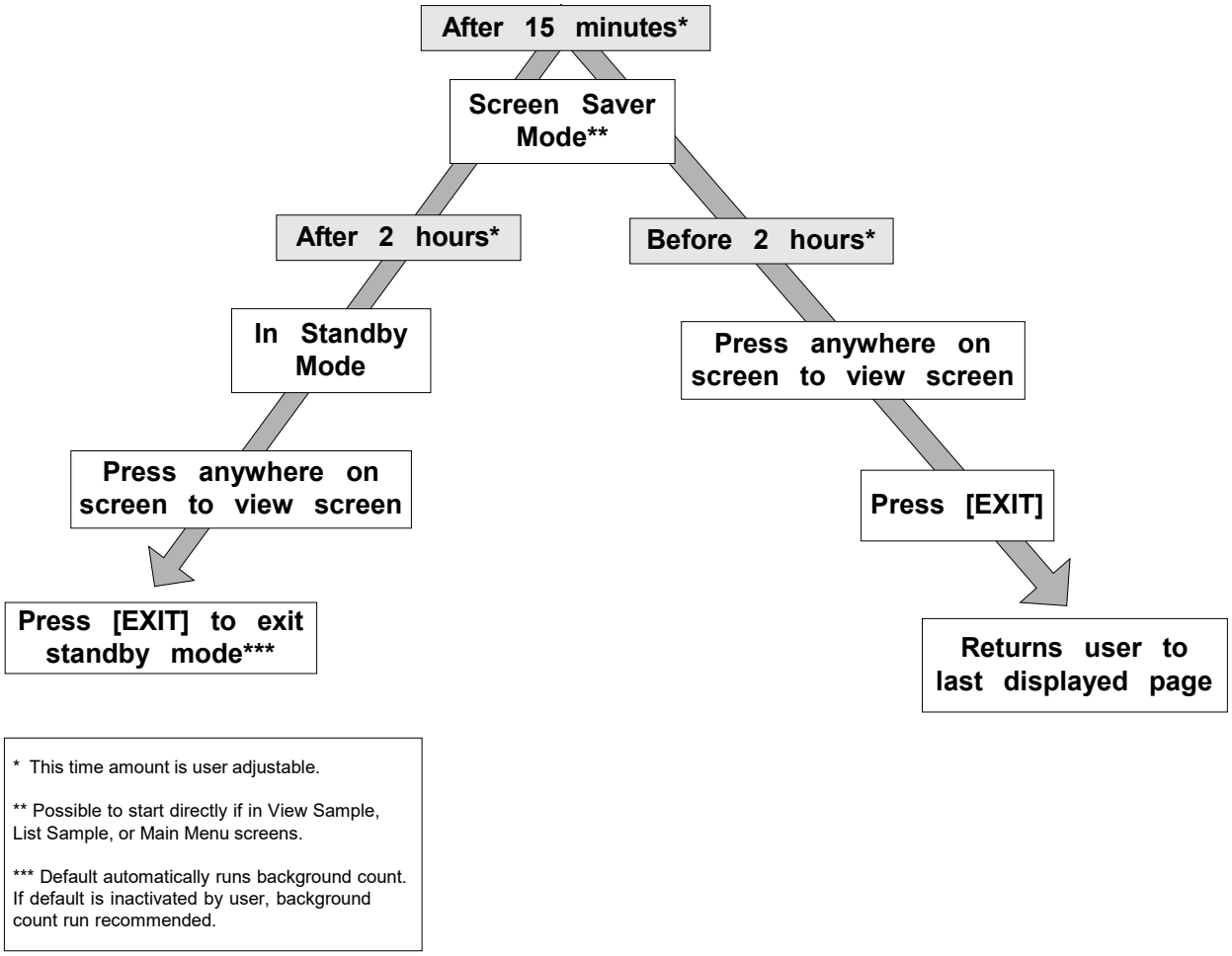
Flowchart 3.2 Advanced Menu Structure



3.6 System Flow

Description This section contains the system flow concerning standby and cleaning cycles.

Flowchart 3.3 System Flow



3.7 Sample Volume, Throughput, and Parameters

Description

The Medonic M-Series is a fully automated cell counter reporting up to 20 parameters.

Sample volume

- Autoloader: ≤ 300 µl
- Cap Piercer: ≤ 250 µl
- MPA: ≤ 20 µl
- Open Tube: ≤ 110 µl

Throughput

- Open Tube: ≥ 60 samples per hour.
- Cap Piercer: ≥ 45 samples per hour.
- Autoloader: ≥ 43 samples per hour.

Parameters

See list of parameters below:

Leukocyte parameters		20	16
WBC	Total White Blood Cell Count	Yes	Yes
LYM%	Lymphocytes percentage	Yes	Yes
LYM#	Lymphocytes (absolute)	Yes	Yes
MID%	Mid Cell Population percentage	Yes	Yes
MID#	Mid Cell Population (absolute)	Yes	Yes
GRAN%	Granulocytes percentage	Yes	Yes
GRAN#	Granulocytes (absolute)	Yes	Yes

Erythrocyte parameters		20	16
RBC	Total Red Blood Cell Count	Yes	Yes
HGB	Hemoglobin Concentration	Yes	Yes
HCT	Hematocrit	Yes	Yes
MCV	Mean Cell Volume of RBCs	Yes	Yes
MCH	Mean Cell Hemoglobin	Yes	Yes
MCHC	Mean Cell Hemoglobin Concentration	Yes	Yes
RDW%	Red Blood Cells distribution width percentage	Yes	Yes
RDWa	Red Blood Cells distribution width (absolute)	Yes	No

Thrombocyte parameters		20	16
PLT	Total Platelet Count	Yes	Yes
MPV	Mean Platelet Volume	Yes	Yes
PDW	Platelet Distribution Width	Yes	No
PCT	Platelet Crit	Yes	No
LPCR	Large Platelet Concentration Ratio	Yes	No

Section 4: Instrument Setup

Section Overview

Introduction

This section covers the initial configuration needed to customize the instrument settings.

Contents

This section contains the following topics:

4.1 Menu Selection

Main Menu upon initialization

- The List Menu will be displayed upon initialization.
- From this main screen all other menus can be accessed for setup.
- By selecting the MENU tab and then pressing [ADVANCED] the Advanced Menus will be displayed.

List and System Menu

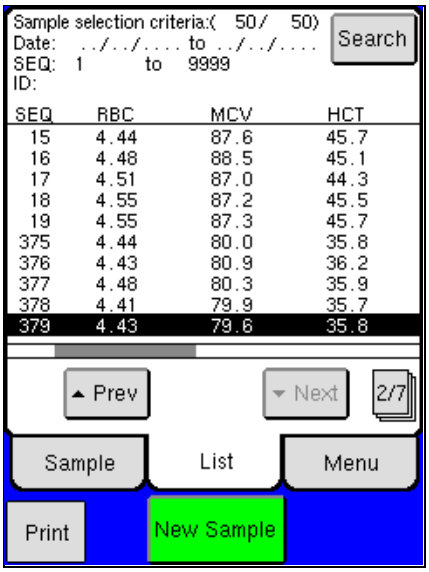


Figure 4.1

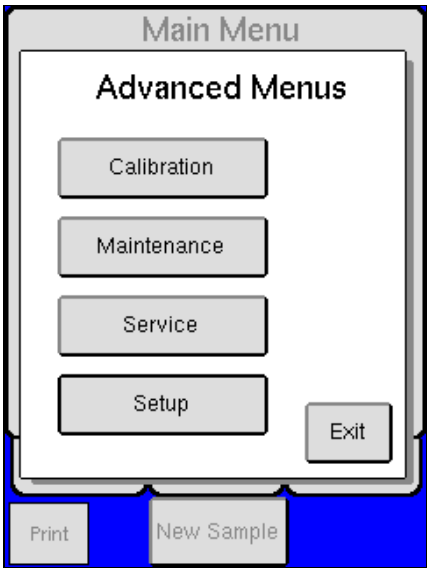


Figure 4.2

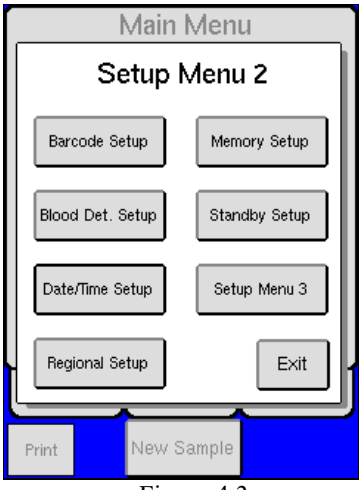
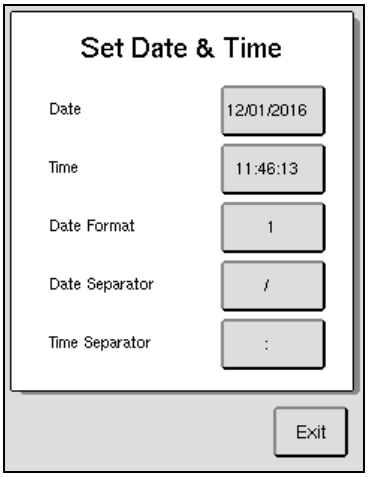
4.2 Initial Setup

Initial Setup

Initial setup of the instrument, except date and time, has been factory set to default values for the average Boule users. However, other user definable formats may be preferred, details are provided below.

Setting up date/time

The date/time function is shown on all samples and printouts and should always be setup correctly. To set date/time follow the instruction below:

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP], then press [SETUP MENU 2].
3	Press [DATE/TIME SETUP] to enter the set date/time menu.
4	Press [DATE FORMAT] to select date specific setting. 1 = DD/MM/YY; 2 = YY/MM/DD, 3 = YY/DD/MM, 4 = MM/DD/YY
5	Press on the item that you want to change and enter the changes on the numerical pad. See Menus below.
Menus	 Figure 4.3  Figure 4.4

Activate Mixer (optional)

To activate mixer follow the instruction below:

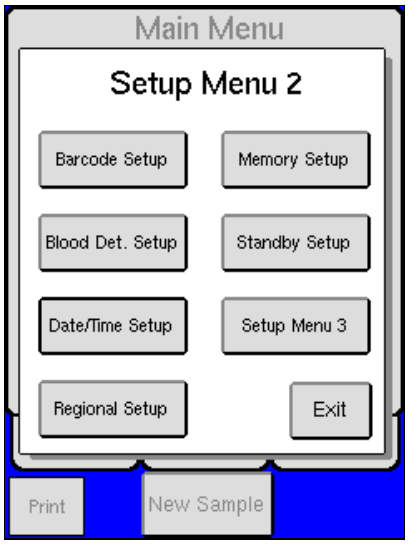
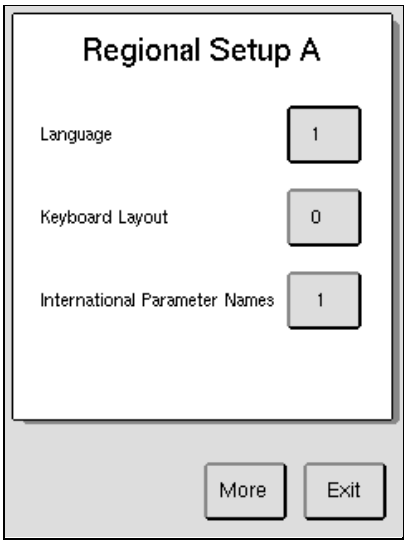
Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [SETUP MENU 2].
3	Press [SETUP MENU 3].
4	Press [MIXER].
5	If the mixer is not activated the button will have empty brackets ([ ]). To activate press button and select [X].
Note	Upon sample aspiration mixer will discontinue rotation until sample analysis is complete.
Important	It is recommended that whole blood samples are mixed for 10 – 15 minutes and then analyzed. Mixing for more than 4 hours may cause erroneous results.

Continued on next page

4.2 Initial Setup (continued)

Setting up language

Change of display language is performed by following the instructions below:

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP].
3	Press [SETUP MENU 2].
4	Press [REGIONAL SETUP], a list of local settings will be displayed.
5	Press [MORE] until language button is displayed.
6	Press [LANGUAGE] to enter language screen.
7	Choose the number that corresponds with the language desired and press [OK] to save.
Menus	 Figure 4.5  Figure 4.6
Note	If an option is not available, the number will not be accepted when operator presses [OK].

4.3 Advanced Setup

Description

Initial advanced setup of the analyzer, has been factory set to default values. However, other user definable formats may be preferred, details on how to install and configure external components such as barcode readers, printers, data communication, etc. are provided below.

Default Printer

The analyzer has been automatically set to USB printer provided by Boule. (Printer Type 4)

USB Printer

- Contact your local Boule representative for current list of available USB printers.
- If using USB printer other than that specified by distributor, the printer must be HP PCL 5 or IBM proprinter compatible.

Continued on next page

4.3 Advanced Setup (continued)

Select Printer Type

Follow the instruction below for interfacing analyzer to different printer types. (To connect printer see Section 2.3)

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [PRINT SETUP] to enter the Print Setup menu.
3	Press [MORE] to view Printer type. Printer types are as follows: 4 = USB printer 5 = Seiko DPU 411/12 and 414 6 = IBM proprinter / Epson compatible 7 = HP PCL 3 and 5 protocol compatible
4	To change printer type press [PRINTER TYPE], enter the correct number and press [OK] to save.

Print modes

To select options for printing results.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP].
3	Press [PRINT SETUP] to enter the printer setup menu.
4	To set Manual Print Mode function select from the following: 0 = None, 1 = Without Histograms, or 2 = With Histograms.
5	To select Auto Print Mode function select from the following: 0 = None, 1 = Without Histograms, or 2 = With Histograms.
Note	Extended printer format settings and user definable print layouts are also available. Please contact your local Boule representative for further detailed information on how to setup user definable formats.

Serial Setup

To select options for sending results and data follow instruction below:

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP].
3	Press [SERIAL SETUP] to enter the serial setup menu.
4	To set Manual Send Mode function select from the following: 0 = None, 1 = Without Histograms, or 2 = With Histograms.
5	To select Auto Send Mode function select from the following: 0 = None, 1 = Without Histograms, or 2 = With Histograms.
6	HW handshake is automatically activated to check serial port connection. To inactivate change [X] to ([ ]), and then [OK] to save.
7	Send with Ack. is automatically activated to send an acknowledgement message with each sample being transmitted to computer. To inactivate change [X] to ([ ]), and then [OK] to save.
8	Baud Rate sets the transfer speed on the serial port. The default is 1 (19200N81). To change to slower baud rate, select 2 (9600N81), and then [OK] to save.

Step	Action
9	Select Serial port sets the output port for sample data, select from the following: 2 = USB device port, 3 = USB memory stick, or 4 = USB RS232 serial port adapter
10	• Select USB vendor and product ID sets the USB identity for the analyzer. • Select 2 (Boule USB Vendor ID) if your PC application supports the Boule USB Vendor ID. • If not, select 1 (Gadget Serial USB Vendor ID). • If unsure, please check the documentation for your PC application, or contact the company that developed it.

Barcode Setup

To setup the barcode reader follow the instructions below. (Note that the default barcode setting is 9600N81). See barcode reader insert to determine types of barcodes that can be scanned, if using barcodes for patient IDs.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP].
3	Press [SETUP MENU 2].
4	Press [BARCODE SETUP] to enter the barcode setup menu.
External	For serial barcode readers, set Barcode Reader Type = 1. If not, set it = 0. To use another USB barcode reader, other than the one delivered by Boule, together with the instrument, perform the following: • Leave the barcode reader unconnected. • Press the button to the right of [Set USB barcode reader]. • The display shows [Connect a USB barcode reader to enable it]. • Connect the USB barcode reader to one of the USB host connectors. • The instrument returns to [Barcode Reader Setup]. • Check that you can input barcodes with the barcode reader. Note: If you want to go back to using the USB barcode reader delivered by Boule together with the instrument, follow the procedure above. The instrument can only handle one kind of USB barcode reader at a time.
Internal	An Internal barcode reader is also available on some models. To change the factory default setup follow Steps 1-4 and choose the format that is appropriate. (The Standard Setup is most common.) 0 — No internal barcode reader 1 — Standard Setup (I2of5 with checksum) 2 — I2of5 without checksum
Note	If Internal Barcode Reader setting is changed to Setting 1 or 2 press [INTERNAL BARCODE INITIALIZATION] to re-initialize the barcode reader.

Continued on next page

4.3 Advanced Setup (continued)

Keyboard Setup (optional)

To setup the keyboard follow manufacturer instruction for setup and plug into analyzer keyboard port. See Section 2.3 for details.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP], then [SETUP MENU 2].
3	Press [REGIONAL SETUP], and then [MORE].
4	Press [KEYBOARD LAYOUT], and select keyboard type.
5	Press [EXIT] until Main Menu is reached.
6	Turn analyzer OFF, and then turn ON again for changes to take effect.

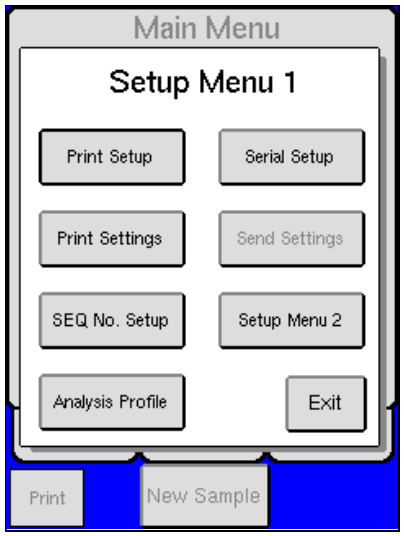
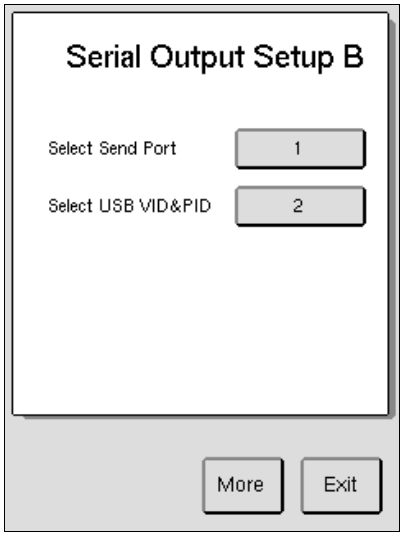
Data Communication

The analyzer is equipped with three different outputs for connection to a computer (network):

1. USB output with USB device port connector
2. USB memory stick
3. USB RS232 serial port adapter

USB connection

To connect to a PC computer using a USB connector, simply plug in USB connectors between analyzer and computer, and follow below instructions:

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP], then [SERIAL SETUP], and then [MORE].
Menus	 Figure 4.7  Figure 4.8
3	To activate the USB connection to a PC computer, press [SELECT SEND PORT] button, then type in [**2**], and then [OK] to save.
4	To activate the USB connection to a memory stick, press [SELECT SEND PORT] button, then type in [**3**], and then [OK] to save.
5	To activate the USB connection to the RS232 serial port adapter, press [SELECT SEND PORT] button, then type in [**4**], and then [OK] to save.

4.3 Advanced Setup (continued)

Menu

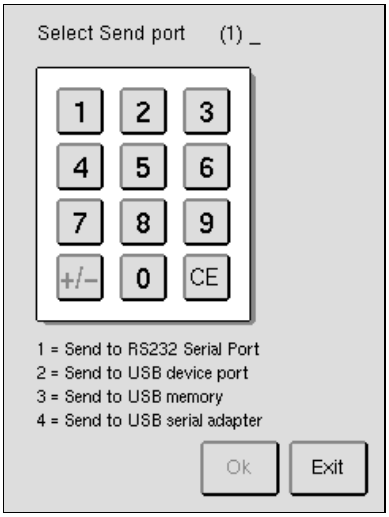


Figure 4.9

Note For Select Send Port activation to function correctly user must have a PC application that can receive and process reports.

To connect to a PC computer using a 9 pin RS232-USB converter see instructions below:

Cable end converter (9pin)		Cable end pc (9pin)
2	→	3
3	←	2
5	—	5
7	←	8
8	→	7

4.4 Reagent Setup

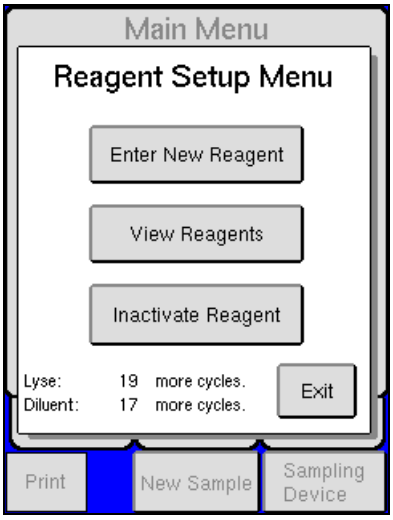
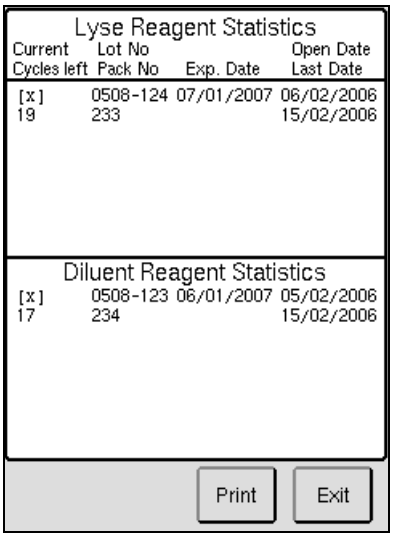
Description This section describes the functions of the reagent setup menu and how to access reagent statistics.

Reagent Input (Enter New Reagents) The Medonic M-Series System is interlocked with specified Boule reagents for optimal performance. The reagent containers must be identified by the instrument before analysis of samples can begin. To identify reagents, scan in or manually enter the barcodes on the reagent containers. See section 2.4.

Continued on next page

View Reagent

Reagent statistics can be viewed in two ways:

Step	Action
1	Start by pressing [REAGENT SETUP] from the MENU tab.
2	On the lower left-hand side of the Reagent Setup Menu, both the remaining cycles for Diluent and Lyse are displayed. (It is important to remember that cycles include analyses, wash cycles, background counts, primes, exit standbys, etc.)
3	 Figure 4.10  Figure 4.11
4	The second method of viewing reagent statistics is by pressing [VIEW REAGENTS] from the Reagent Setup Menu. This screen is divided into the last four Lyse Reagent Statistics and the last four Diluent Reagent Statistics. For each, the operator can view the following: • [X] indicates which reagent is currently activated. • The number of cycles left for specific reagent container. • The Lot and Pack Numbers • The expiration date of the specific reagent container. • The Open Date, when the reagent container was first used on the system. • The Last Date, when the last time that reagent container was used to run a cycle.

Inactivate Reagent

It is possible for the operator to inactivate the current reagent box by pressing the [INACTIVATE REAGENT] button and then [YES]. Once deactivated the operator must scan in or manually enter another reagent container before analysis of samples can begin. (If reagent level is adequate, an inactive reagent can be re-activated by simply scanning the barcode on the reagent bottle again.)

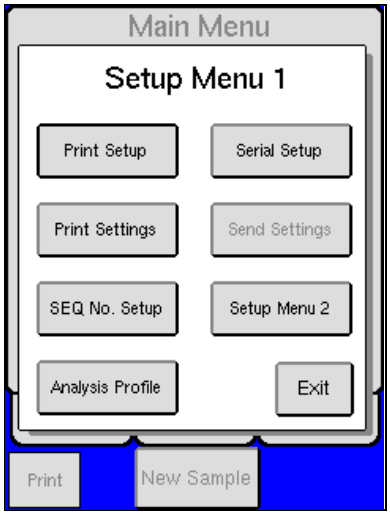
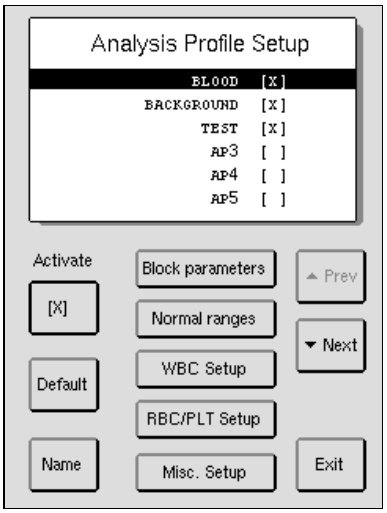
Reagent Indicators

The interlocked reagent system displays indicator and warning messages to alert the operator when reagents are running low and need to be changed. See Section 12.2 and 12.3.

4.5 User Interface

Description This section describes the functions of available menus in the instrument that have not been described in any other section of this manual.

Analysis Profile Authorized operators can customize analysis profiles. See the options below.

Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP], then [ANALYSIS PROFILE] to enter the Analysis Profile Setup menu.
3	 Figure 4.12  Figure 4.13
4	To set profile name press [NAME]. • Press [PREV] or [NEXT] to choose an open profile on list.(e.g. AP8, AP9, etc.) • Press [NAME ON DISPLAY] to enter new profile name and press [OK] when complete. • Press [NAME ON PRINTOUT] to enter new profile name to be displayed on printout and press [OK] when complete.
Note	Remember to [ACTIVATE] the new profile in order to view it as a selection for sample analysis.
5	To set new profile as default press [DEFAULT] and select [X].
6	To block certain parameters press [BLOCK PARAMETERS] to see list and then [MORE] to view specific parameters. Press any parameter and select [X] to block parameter.
7	To change RBC/PLT discriminators press [RBC/PLT SETUP] to see list and then [MORE] to view specific discriminators. Press specific discriminator button to change value and then [OK] to save.
8	To change WBC discriminators press [WBC SETUP] to see list and then [MORE] to view specific discriminators. Press specific discriminator button to change value and then [OK] to save.
9	To change normal ranges press [NORMAL RANGES] to see list and then [MORE] to view specific parameter range. Press specific parameter range button to change value and then [OK] to save.
Note	Indicative normal ranges are provided in this instrument. It is recommended to establish local reference ranges (normal ranges) for your laboratory. (See CLSI standard C28-A2 for guidance on how to establish these ranges and examples of normal ranges in the reference documents listed at the end of this section.)
10	New profiles are automatically included in Xb functions and Stats. To not include new profile in Xb functions or Stats press [MISC SETUP] and change [X] to ([ ]), respectively to inactivate default setting.

Continued on next page

11	To change background mode setting of the profile press [MISC. SETUP], choose [BACKGROUND MODE PROFILE] button, choose [X] or [ ] to activate or deactivate, and then [OK] to save. By enabling this setting, the current profile will behave like the factory default BACKGROUND profile (i.e. disable AF flagging, disable pathology messages, etc.).
12	To activate WBC Differential Fallback mode press [DIFFERENTIAL FALLBACK] and select [X]. This mode allows the user to view values for WBC Differential parameters when the WBC Differential Abnormalities flags are displayed. It is important that System Information Messages are still followed, see Section 9.2.
Note	The operator will be prompted to enter a 4-digit Operator ID (Operator ID is recommended for in-house records but not required) and Authorization Code (REQUIRED) before a change or update to an analysis profile can be made. To update or change analysis profiles input the Authorization Code [**2576**].

Sample Memory

The following procedures explain how to search for previous sample analyses and statistics, and how to print, send, and delete samples.

Step	Action
1	To view previous analyses at a quick glance press [PREV] or [NEXT] buttons to scroll through samples in either Sample or List menus.
2	To view a specific sample or a group of samples press [SEARCH] in List Menu. In this menu samples can be selected by Sample ID, SEQ, Date, and Sample profile. Press corresponding button to select, and then [EXIT] to return to List menu and view newly selected samples.
Note	To return to previous selection criteria either press [SEARCH], then [SELECT ALL], and then [EXIT] or analyze a new sample.
3	To view Sample Statistics, select sample or group of samples to view, and press [STATS] to enter the Statistical Results menu.
4	To print or send selected sample or sample statistics press [PRINT] or [SEND].
5	To delete selected sample or group of samples press [DELETE]. The instrument will display a prompt to verify deletions, press [YES].

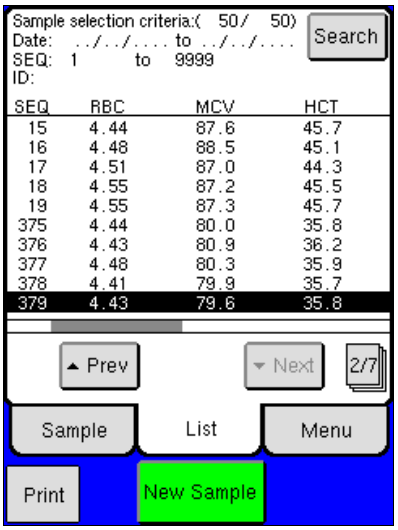


Figure 4.14

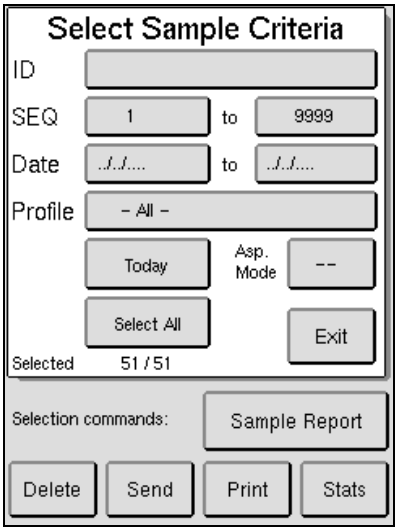
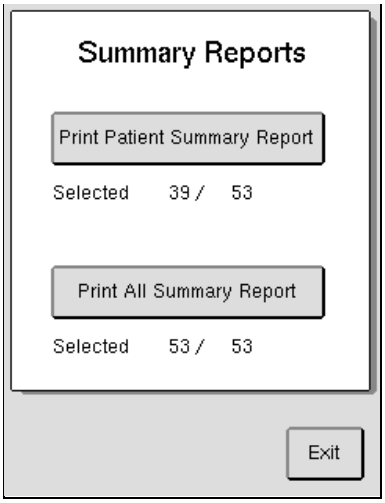


Figure 4.15

Continued on next page

6	To print a summary report of every sample run press [SAMPLE REPORT] and then [PRINT ALL SUMMARY REPORT].
7	To print a summary report of a selected group of samples, select desired criteria (See #2 above), then press [SAMPLE REPORT] and then [PRINT PATIENT SUMMARY REPORT].
Note	• These summary reports will print on a horizontal sheet of paper. • To print summary reports you can only use HP PCL 3 and 5 protocol compatible and USB printers.
Menu	 Figure 4.16

All Settings

From Menu tab press [ADVANCED] and then [SETUP] to enter Setup Menu.

- To print all instrument settings, verify instrument is connected to a printer and press [PRINT ALL SETTINGS].
- To send all instrument settings, verify instrument is connected to a computer and press [SEND ALL SETTINGS].

Change Sequence Number

From Menu tab press [ADVANCED] and then [SETUP] to enter Setup Menu. To change sequence number press [SEQ NUMBER SETUP], press [NEXT SEQ NUMBER], enter in new sequence number and press [OK] to save.

Platelet Concentrate Mode

Contact your local Boule representative for more information on Platelet Concentrate Mode activation.

User Definable Settings Document

More detailed Setup Menu descriptions can also be found in the User Definable Settings document. For further information, contact your local Boule representative.

Normal Range References

1. Cheng C, Chan J, Cembrowski G, van Assendelft O. Complete Blood Count Reference Interval Diagrams Derived from NHANES III: Stratification by Age, Sex, and Race *Laboratory Hematology* 10:42-53

2. Nordin G, et al. A multicentre study of reference intervals for haemoglobin, basic blood cell counts and erythrocyte indices in the adult population of the Nordic countries *Scand J Clin Lab Invest 2004*; 64: 385-398

3. How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition. CLSI C28-A2

Section 5: Sample Analysis

Section Overview

Introduction

This section covers the sample analysis routine, including how to analyze a sample in the five different modes offered in the Medonic M-Series.

Contents

This section contains the following topics:

5.1 Preparations before Analysis

Sample collection

- Human venous blood samples should be collected in an EDTA K3 or EDTA K2 tube in sufficient quantity and be gently mixed immediately after sampling in order to obtain accurate results. Please follow the recommendation of the EDTA tube supplier.
- Human capillary blood samples should be collected in either Boule supplied, plastic, high precision EDTA micropipettes or BD Microtainer® K_2EDTA tubes (or equivalent).

Limitations

- Samples drawn in an open tube or vacuum tube should be analyzed within 6 hours for most accurate results.
- Samples drawn into micropipettes should be analyzed within 10 minutes for most accurate results.

Anticoagulant recommendation

EDTA K3 (Ethylene Diamine Tetracetic Acid, Tri-potassium) liquid and EDTA K2 (Ethylene Diamine Tetracetic Acid, Di-potassium) spray-dried solution. Recommended by ICSH and NCCLS.

Handling venous blood samples

- The blood should be allowed to equilibrate to the EDTA for 10-15 minutes after sampling.
- The sample should be thoroughly and gently mixed before analysis. It is recommended to use a mixer.
- The sample should be mixed for 10-15 minutes. A sample not correctly handled may give erroneous results.

5.1 Preparations before Analysis (continued)

Handling of capillary blood samples

- The sample in the micropipette can be analyzed directly after collection and for optimal results not longer than 10 minutes from collection.
- For capillary samples collected in Microtainer tubes follow the "Handling of venous blood samples" section above.

Important

The sample should be kept at room temperature. Excessive cold or heat could cause erroneous results.

Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, calibrators and waste these products should be handled as potentially biohazardous.
- Refer to local regulations and established laboratory protocol for handling biohazardous materials.

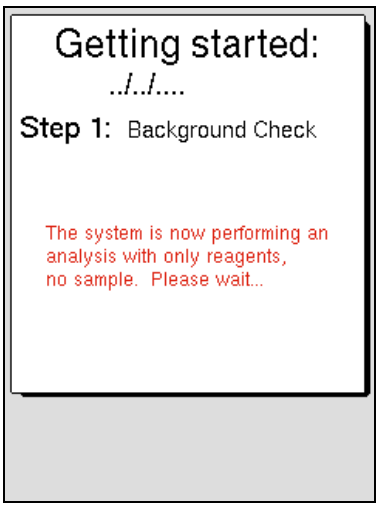
5.2 Startup Sequence

Startup Sequence

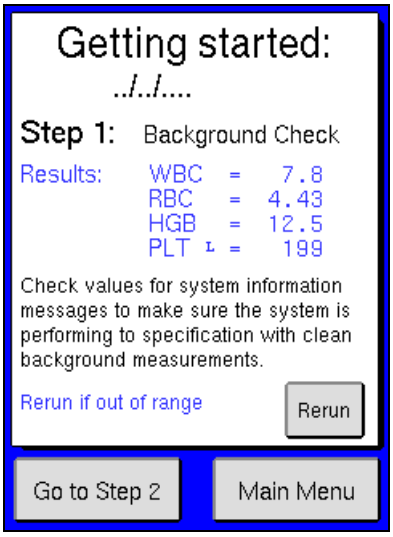
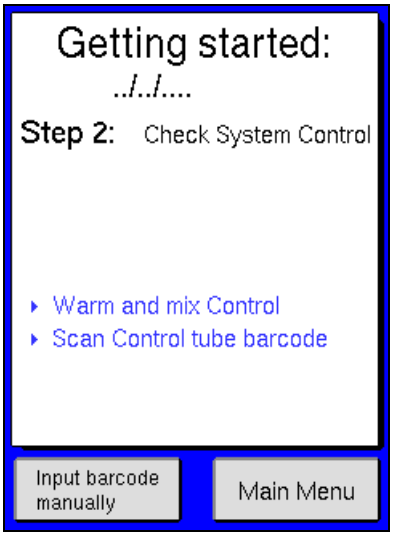
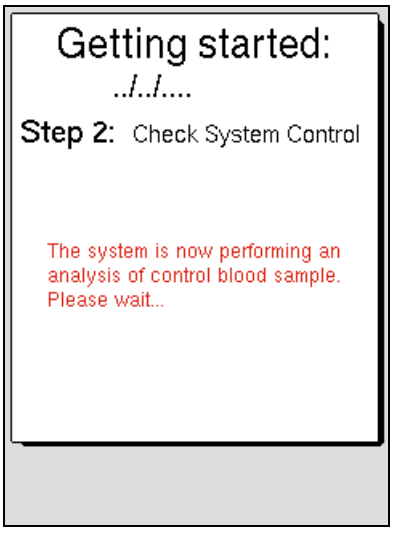
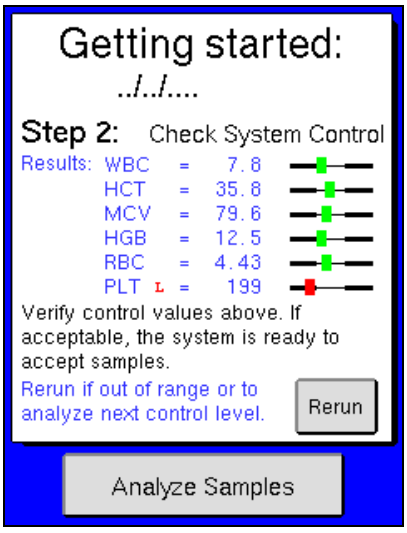
The following sequence guides the operator through the beginning of the day startup routine for the analyzer. There are 2 simple steps to follow which takes the user through a background and control analysis sequence with detailed guidance at each step. This startup sequence is optional and can be bypassed if a different startup routine is desired.

Note

The startup sequence must be activated to follow this procedure, alternatively follow the manual background and quality control checks, see 5.3 and 6.1.

Step	Action
1	Touch display or switch on power to the analyzer.
2	Press [EXIT STANDBY] or [PWRUP], depending on how the analyzer was shutdown previously.
3	Enter operator ID and press [OK] or press [CANCEL] to exit Standby. The analyzer will now run a "wake up" sequence.
4	When "wake up" cycle is complete, press start plate to begin the first step of the startup sequence.
	 Figure 5.1  Figure 5.2

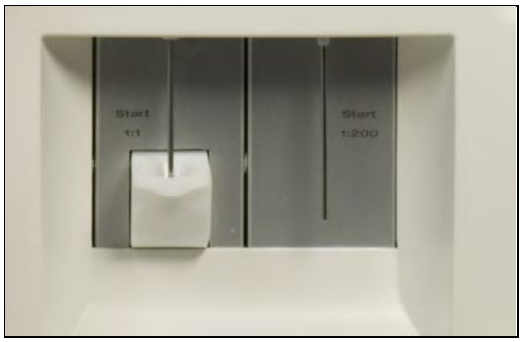
5.2 Startup Sequence (continued)

Step	Action
5	When complete the background count results are displayed. If the results are acceptable (see table for accepted background values according to section 5.3), scan in the barcode on control vial and follow directions on the display to begin the second step of the startup sequence.
Note	If the background count results have a H (high) indicator press [RERUN] and follow the screen instructions to analyze background count again.
	 Figure 5.3  Figure 5.4
6	When complete the control results are displayed. If control results are acceptable, press [RERUN] to run next level of control. The startup sequence is complete when all control results are acceptable. Press [ANALYZE SAMPLES] to go to the main screen, and follow instructions in the following sections to analyze samples.
Note	If control sample results have a H (high) or L (low) indicator press [RERUN] to analyze control sample again.
	 Figure 5.5  Figure 5.6

5.3 Background Count

Background Check

The following sequence is performed to check that the background count is low enough to run a sample. It is recommended to run a background check at the beginning of each shift.

Step	Action
1	From the main screen press [NEW SAMPLE].
2	Press [NEXT PROFILE] or [PREV PROFILE] to scroll to Background.
3	Press the whole blood start plate, which is located behind whole blood aspiration needle. (See Figure 5.7 below)
	 Figure 5.7 The aspiration time is approximately 10 seconds. After ~ 10 seconds the instrument will time out due to no detection of blood, and continue its cycle.

Accepted Background values

The background count should not be higher than the figures shown below, assuming that at least 2 “blanks” are run after a sample.

Parameters	Values accepted
RBC	≤ 0.01 (10^{12}/ L)
WBC*	≤ 0.1 (10^{9}/ L)
HGB	≤ 0.2 (g/ dL)
PLT	≤ 10 (10^{9}/ L)

*The micropipette inlets are acceptable at WBC ≤ 0.2 (10^{9}/ L) due to potential pre-analytical contributions.

5.4 Sample Identification

Description

This section describes the different methods of inputting Sample IDs (Identification). There are two (2) ID Fields available.

ID Input Methods

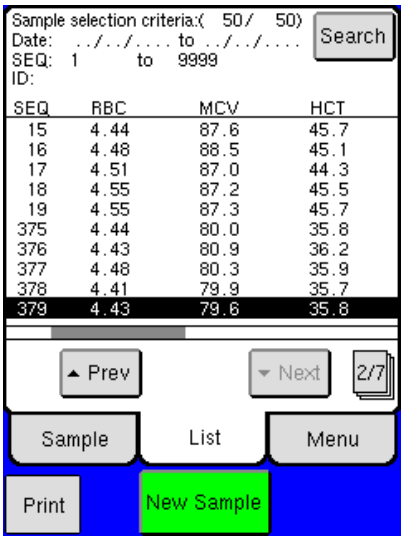
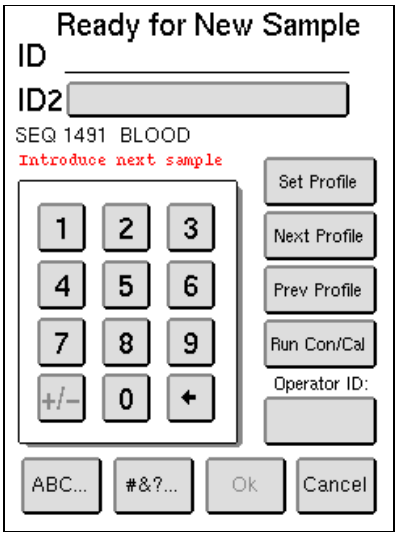
The ID can be entered with the following methods:
- Manually (touch screen or external keyboard)
- Barcode (Barcode entry is limited to ID 1 only)

Character Input Limitations

A maximum of 16 Characters (alpha and numeric) are allowed in both ID 1 and ID 2 fields.

Continued on next page

5.4 Sample Identification (continued)

Step	Action
1	From the main screen press [NEW SAMPLE] or begin sample aspiration, which automatically opens NEW SAMPLE menu.
2	Press numerical keys to enter sample ID or scan in the ID barcode from the sample tube. Press sample ID2 if a second ID is needed.
3	Press [NEXT PROFILE] or [PREV PROFILE] to scroll to desired profile.
4	Press [OK] to save profile and sample ID or begin sample aspiration.
Menu	 Figure 5.8  Figure 5.9
5	Aspirate sample following selected procedures in sections 5.5 – 5.9.
Note	Sample ID entry and profile selection can be performed up to 30 seconds after sample aspiration.

Operator ID

The Operator ID is an optional feature which can be entered prior to analyzing a sample or when exiting Standby Mode. To enter an Operator ID press the specified button and enter up to a 4-digit numerical or alphabetic ID. The Operator ID will stay the same until Operator ID button is pressed again and changed, or when the analyzer goes into Standby Mode.

5.5 Analyzing the Sample (Open Tube)

Description

This section describes how to aspirate and analyze a sample with the “Open Tube” procedure.

Starting procedure

Refer to Section 5.1 for blood sample preparation and then follow the procedure below:

Continued on next page

5.5 Analyzing the Sample (Open Tube) (continued)

Step	Action
1	Choose List, Sample, or Main menu to begin sample analysis. Analyzer must be in one of these operation modes to aspirate.
2	Aspirate the sample through the aspiration needle by gently inserting aspiration needle into the sample tube, and then press the whole blood start plate behind the left aspiration needle. (See Figure 5.10)
3	Follow the instruction on the menu when to remove the sample tube. A beep should be heard indicating sample removal.

Important

- Make sure that the blood sample tube is not touching the upper part of the aspiration needle.
- Not removing the sample tube could result in incorrect washing sequence of the aspiration needle.
- Do not remove sample prior to instruction, incomplete aspiration could occur, causing erroneous results.

Sample Aspiration

4

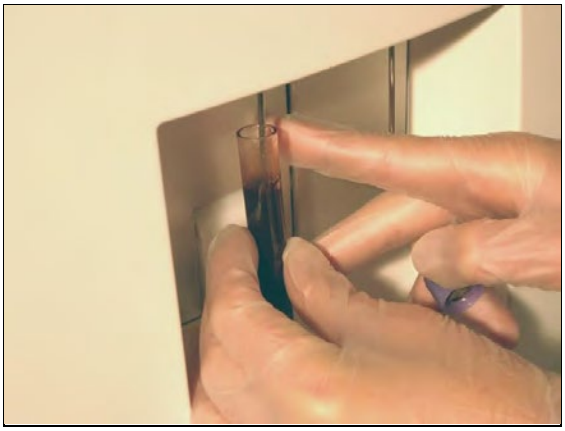


Figure 5.10

Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous.
- Refer to local regulations and established laboratory protocol for handling biohazardous materials.

Sample Aspiration Display

5

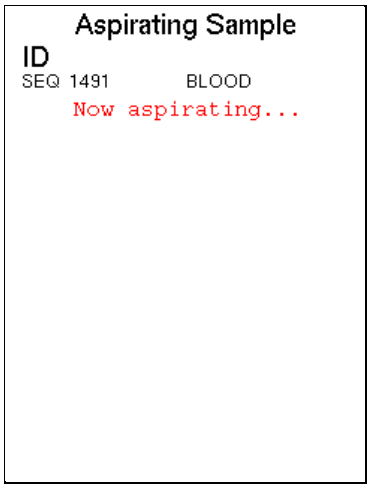


Figure 5.11

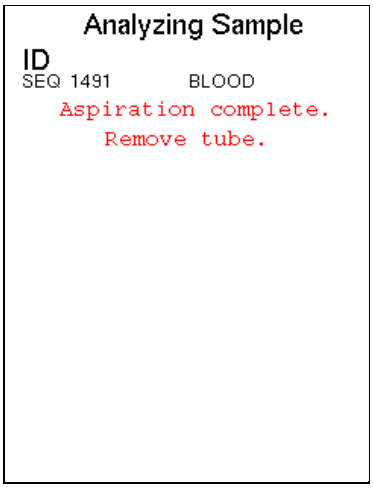
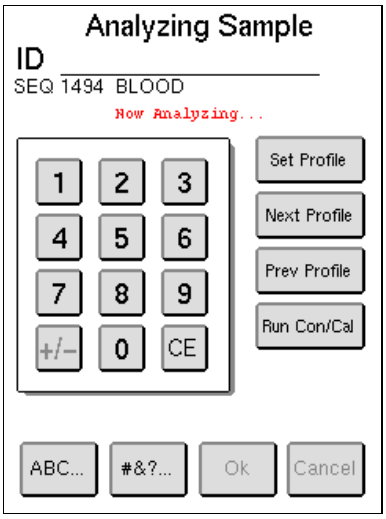
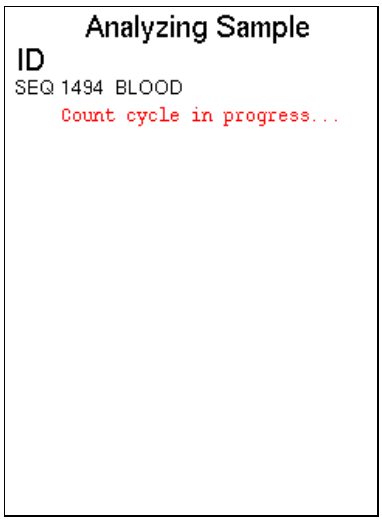


Figure 5.12

5.5 Analyzing the Sample (Open Tube) (continued)

The instrument now switches to the sample analysis screen.	
6	 Figure 5.13  Figure 5.14
7	In first screen displayed above Sample ID and profile can still be added.
8	Approximately 30 seconds after aspiration the display switches to that in Figure 5.14 and no further ID entry is possible.
9	After 45 seconds results will be displayed on List or Sample menu. For more information of results refer to Section 5.10.
10	When NEW SAMPLE button returns to green, operator can begin analysis of next sample.

5.6 Analyzing the Sample (Pre-dilution procedure)

Description

This section describes how to analyze a pre-diluted sample through the “pre-dilute” aspiration needle and how to use the dispense function. There are two ways of pre-diluting a sample. The recommended pre-dilute method is using the dispense function, which uses the factory calibrated dilution ratio of 1:225 (20 µl sample in 4.5 ml diluent). The second method is performing an external pre-dilution using in-house dilution procedures, dilution ratios between 1:200 – 1:300, and re-calibrating system using selected dilution ratio.

Dilution Rates and Ratios

Dilution Rates: 1:200 – 1:300
Recommended: 1:225 (20 µl sample in 4.5 ml diluent)

Continued on next page

Time limitations

Pre-dilute procedures are generally less precise than open and closed tube procedures and results may vary depending on local laboratory procedures and conditions. Blood cells may shrink and/or swell during the time between mixing in the beaker and the actual analysis, resulting in compromised values of MCV, MPV and the distribution between lymphocytes/mid-cells/ granulocytes (with indirect effect on calculated parameters, e.g. HCT). Thus, the time between mixing and analysis should be minimized and under no circumstances exceed 60 minutes, since RBC, PLT, HGB and WBC may also be affected.

Externally Pre-diluted volumes and preparation

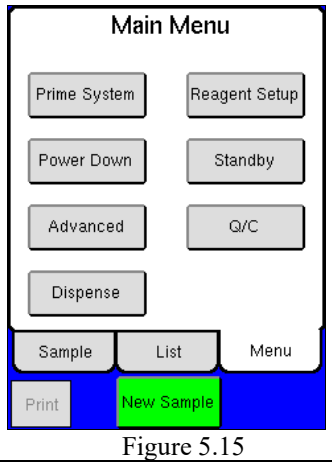
- Pre-dilute volumes 4.5ml – 5.0ml. The dilution ratio must always be the same as the dilution it is calibrated to in order to avoid erroneous results; any dilution variation in an externally diluted sample will affect the parameter test results.
- Prepare pre-dilute sample according to internal documentation and time limitations section above.

Note

In order to get accurate results always use the same dispenser for calibration and sample analysis.

Dispense Function

- This feature is to be used as a precision dispenser for dilution of blood samples.
- Dispense amount: 4.5 ml.
- Dilution: 20 µl sample in 4.5 ml diluent (1:225)
- Follow the instruction below:

Step	Action
1	Press the [DISPENSE] button from the MENU tab.
2	Before pressing the pre-dilute start plate make sure that a waste beaker is placed under the pre-dilute aspiration needle.
3	Press the pre-dilute start plate (right-side start plate), to enable dispense mode. (The instrument will fill the waste beaker with a small amount of diluent, this is to be discarded)
4	Fill the pre-dilute beaker by pressing the start plate again. If more than one beaker is to be filled repeat this step.
Menus	 Figure 5.15  Figure 5.16
5	Prepare pre-dilute sample according to internal documentation and time limitations section above.
6	To re-enter analyze mode press [CANCEL] and follow instructions below to analyze pre-dilute samples.

Continued on next page

5.6 Analyzing the Sample (Pre-dilute procedure) (continued)

Pre-dilute procedure

Start by selecting pre-diluted sample beaker and follow the procedure below:

Step	Action
1	Choose List, Sample, or Main menu to begin sample analysis. Analyzer must be in one of these operation modes to aspirate.
2	Aspirate the pre-diluted sample through the pre-dilute aspiration needle by pressing and holding the pre-dilute start plate behind the right-side aspiration needle until aspiration starts. (See Figure 5.11)
	 Figure 5.17
3	Follow the instruction on the menu when to remove the sample tube. A beep should be heard indicating sample removal.
4	Refer to Section 5.5 Steps 5 - 10 for remainder of analysis sequence.

Important

Do not analyze a whole blood sample in the pre-dilute mode, this will cause erroneous results. If this happens following the instructions below, as soon as possible, to return analyzer to normal operation status:
1. Use dispense mode to dispense diluent into waste beaker until diluent has no traces of blood left. Then dispense two more times and discard waste.
2. Next, dispense clean diluent into beaker and run diluent in pre-dilute mode.
3. Check background results. If results pass, instrument is now ready to use. If results do not pass, repeat step 2 until background results pass.

5.7 Analyzing the Sample (Micro Pipette Adapter, MPA)

Description

This section describes how to analyze capillary whole blood samples with the use of the Micro Pipette Adapter (MPA).

Micropipettes

ONLY Boule supplied, plastic, high precision EDTA micropipettes should be used when running MPA. Glass micropipettes can cause damage to instrument if inserted incorrectly.

Lancets Recommendation

Recommended to use BD Microtainer® Contact-Activated Lancet, Blue, High flow, 2.0 mm x 1.5 mm (e.g. Article number 366594).

Continued on next page

5.7 Analyzing the Sample (Micro Pipette Adapter, MPA) (continued)

Collection methodology

Samples can be analyzed using the MPA from both venous and capillary blood specimens.

- For venous collection, see Section 5.1 and steps at the end of this section for details of sample handling and preparation.
- For capillary collection, follow steps below and the procedure for optimal collection of capillary blood specimens given in the CSLI standard H04-A6 "Procedures and devices for the collection of diagnostic capillary blood specimens". (For latest edition of this standard go to www.clsi.org.)

Starting procedure

Follow the procedure below to operate MPA:

Step	Action
1	Choose List, Sample, or Main menu to begin sample analysis. Analyzer must be in one of these operation modes to aspirate.
2	Pull out the MPA adapter. (The instrument will give an instruction to put back the MPA adapter to start).
3	Remove the previous sample micropipette. (If applicable)
4	Place the adapter on the table.

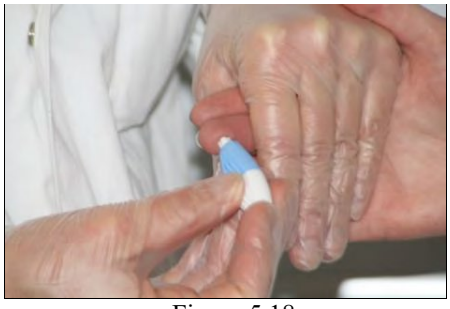
Puncture site preparation for capillary blood collection

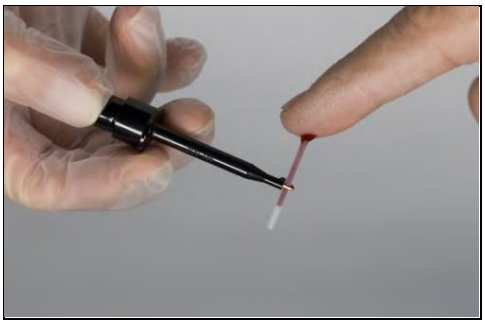
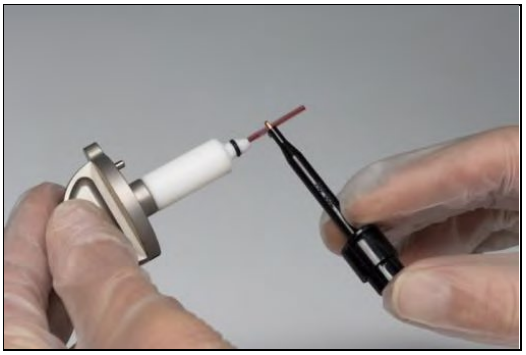
Step	Action
5	Choose site for skin puncture. (See CLSI standard for details on recommended site for finger and heel punctures.)
6	Warm the skin site for 3 -5 minutes before puncture to increase blood flow to the site (arterialization). This can be done using a warm, moist towel or other warming device.
7	Cleanse site with 70% aqueous solution of isopropanol or appropriate disinfectant. Allow the skin to dry before puncture.

Important

- Due to PLT adhesion to tissue and capillary walls and imprecision in preparation and blood draw procedures, discrepancies between capillary and venous blood values may occur on the following parameters:
  - PLT may be lower in capillary blood by 5-10%
  - WBC may be slightly elevated if PLT clumping occurs

Drawing blood and sample preparation:

Step	Action
8	Follow lancet packaging insert for instructions on proper use. Puncture middle or ring finger, using the lancet.  Figure 5.18

Step	Action
Always use gloves when in contact with potentially biohazardous materials.	
9	After puncture, wipe away the first drop of blood with a clean tissue or gauze pad. (First drop of blood often contains excess tissue fluid.)
10	When second drop forms, aspirate the sample as shown below, being careful to only allow the tip of the micropipette to touch the drop of blood (not the finger directly).  Figure 5.19
Note	By holding puncture site downwards and applying gentle, intermittent pressure above the site, the blood flow will be enhanced. **Do not** use scooping motion or strong repetitive pressure, "milking", to the site. (This can cause hemolysis or contaminate sample with excess tissue fluid.)
• Fill the micropipette completely with fresh whole blood and wipe off excessive blood on the outside surface. • Be careful not to wick blood from open ends of the micropipette. • Ignoring these instructions might cause incorrect and non-reproducible results.	
11	Insert the micropipette into the MPA device as shown below:  Figure 5.20
12	Insert the MPA into its holder and the instrument will automatically start the analyzing sequence.  Figure 5.21
Do not remove MPA during sample aspiration or analysis. Removal prior to completion of analysis may cause erroneous results.	
13	Refer to Section 5.5 Steps 6 - 10 for remainder of analysis sequence.

Warning

Important

Important

5.7 Analyzing the Sample (Micro Pipette Adapter, MPA) (continued)

Venous collection sample preparation

Step	Action
1	Follow sample preparation in Section 5.1.
2	Use the micropipette holder to grasp a micropipette. (Holding the micropipette towards one end or the other, instead of in the middle, is best for filling and insertion.)
3	Tilt sample vial at a 45 degree angle until blood is near the lip of the vial, but does not overflow.
4	Place one end of micropipette in blood column and aspirate blood until entire micropipette if filled. (This filling process uses capillary action.)
5	Remove micropipette from vial and wipe off excessive blood on the outside surface being careful not to wick blood from open ends of the micropipette.
6	Follow steps 11 – 13 above to analyze sample.

5.8 Analyzing the Sample (Cap Piercing Device)

Description

This section describes how to analyze whole blood samples using the Cap Piercing Device.

Sample tube description

Most standard 5.0 ml tubes, with a maximum length of 82 mm, can be used in the cap piercing device. The minimum volume in the closed tube should be approximately 1 ml.

Caution

The Cap Piercer can be damaged if incorrect sized tube is used.

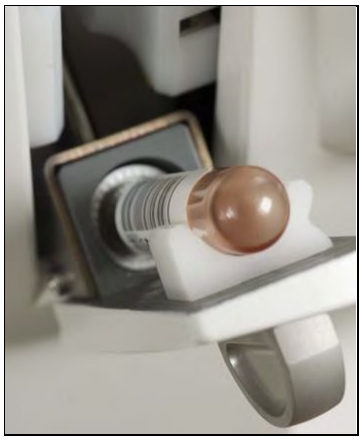
Starting procedure

Follow the procedure below to operate the Cap Piercing Device.

Step	Action
1	Choose List, Sample, or Main menu to begin sample analysis. Analyzer must be in one of these operation modes to aspirate.
2	Open door to cap piercer and insert vacuum tube upside down, pressing the tube in place, aligning with lower support.

Continued on next page

5.8 Analyzing the Sample (Cap Piercing Device) (continued)

Step	Action
3	 Figure 5.22  Figure 5.23
	• Always use gloves when in contact with potentially biohazardous materials. • Caution should be applied when handling the cap piercer. Handling and operation by unauthorized personnel may result in injury. • Insert the sample tube with lid facing downwards. Ignoring this instruction may damage the aspiration needle.
4	Close the door to the cap piercer to begin sample analysis.
5	Refer to Section 5.5 Steps 6 - 10 for remainder of analysis sequence.

Warning

5.9 Analyzing the Sample (Autoloader)

Description

This section describes how to analyze whole blood samples using the Autoloader (Sampling Device).

Sample tube description

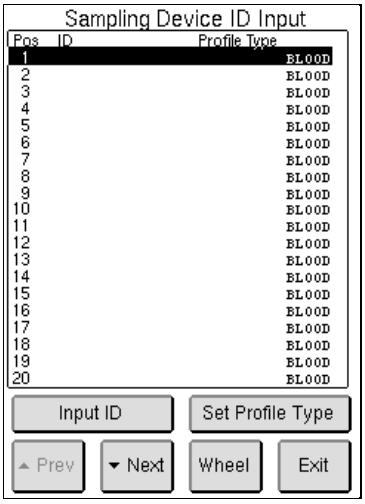
Only standard 4.0 to 5.0 ml tubes can be used in the Sampling Device. A sample wheel adapted for Sarstedt tubes is available as an option. The minimum volume in the closed tube should be approximately 1 ml.

Selecting Sample ID

There are several ways to select the samples.

Method	Action
1	The Sampling Device has a mounted internal barcode reader. If a barcode is used for the ID number, the operator can simply place the tube in sample wheel and the ID number will be read automatically. It is very important to line up barcode on tube with barcode reader.
2	Another option is to manually enter in ID numbers, using the external barcode reader or the touch screen keyboard. • To manually enter ID number press [SAMPLING DEVICE] and then [INPUT ID]. • Then either scan in ID number with external barcode reader or press [INPUT ID], type in desired ID number, and then press [OK] to accept. • After ID number is entered the next position for entry will automatically be highlighted.

Continued on next page

Step	Action
Menu	 Figure 5.24
3	Samples can also be analyzed without identification, but then only the sequence numbers will be present on the worklist.

Selecting Profile Type

To select a different profile type for a sample press [SET PROFILE TYPE] in Sampling Device ID Input display, select desired profile, and then press [OK].

Editing Sample ID Number

Changing a sample ID number or position must be performed prior to pressing [START] on Sampling Device List display.

Step	Action
1	Press [SAMPLING DEVICE] and then [INPUT ID].
2	Press [NEXT] or [PREVIOUS] to scroll to corresponding ID number.
3	Manually enter in new ID number, using the external barcode reader or the touch screen keyboard.

Wheel Selection

When numerous samples are being analyzed an additional wheel may be needed. Additional wheel entry can begin before or after previous wheel has begun analysis.

Step	Action
1	Press [WHEEL], on Sampling Device ID Input display, until position numbers on display match the position numbers on the wheel the operator is currently loading with new samples.
2	Follow steps 1-3 on Selecting Sample ID.
3	Wait for previous wheel to finish before placing new wheel on front position of analyzer. Previous wheel is finished when [SAMPLING DEVICE] button is highlighted green.

Continued on next page

5.9 Analyzing the Sample (Autoloader) (continued)

Emergency Sample Analysis

Emergency (STAT) samples can be analyzed after the Sampling Device has been started or during Sampling Device ID entry. There are several ways to analyze an emergency sample.

Step	Action
1	Emergency sample can be analyzed through OT, pre-dilute, or MPA mode. • Press [PAUSE], wait for [NEW SAMPLE] button to highlight green, and then analyze sample in preferred mode. • There may be a slight delay after pressing [PAUSE] button before emergency sample can be analyzed. This is because analyzer will complete the counting cycle of the last sample run on sample wheel before continuing with emergency sample analysis. • When emergency sample is complete, press [CONTINUE] to restart sampling in next position on the wheel.
2	Emergency sample can also be analyzed using the sample wheel. • Press [STOP], unlock sample wheel and place emergency sample in Position 1 or 21. • If a sample is already occupying Position 1 or 21 and has already been analyzed, remove sample and place emergency sample in its place. • If emergency sample has a barcode for ID number, align barcode correctly, lock sample wheel and press [CONTINUE]. • See Editing Sample ID number is manual entry of sample is desired, and lock sample wheel and press [CONTINUE]. • Analyzer will automatically analyze emergency sample and then continue sampling where it left off prior to pressing [STOP] button.
Note	DO NOT press [START] after sampling device has been paused or stopped unless operator wants to rerun all samples on wheel.

Control Sample Analysis

If analyzing samples using the Autoloader mode it is recommended to also run daily control samples using the sample wheel.

Step	Action
1	Follow instruction in Section 6 for control handling and assay sheet input.
2	Firmly press capped end of control sample into control tube adapter.
3	Load the control sample by placing the adapter towards the outer edge of the sample wheel and fitting it into Position 1 for all tubes except Sarstedt. Place Sarstedt control sample in Position 40. • Position control tube barcode facing TOWARDS analyzer and centered in slot. • If using all three levels of control, add adapters to all levels of controls and fit them into Positions 1, 2, and 3.
4	Following instruction below for Starting Sampling Device.

Continued on next page

5.9 Analyzing the Sample (Autoloader) (continued)

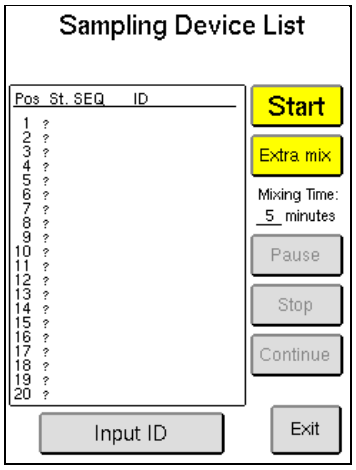
Starting Sampling Device

Follow the procedure below to operate the Sampling Device.

Step	Action
1	Unlock the center piece by turning it counterclockwise and lightly pulling it away from analyzer.
2	Load the vacuum tube samples by placing the capped end towards outer edge of sample wheel and fitting it into designated slot. (The first positions of sample wheel (example: Position 1 and 21) are recommended to be left open for emergency samples.)
Note	It is important that tubes are positioned correctly. • Position tubes with barcodes facing TOWARDS analyzer and centered in slot. • Position tubes without barcodes so that label on tube is facing AWAY from analyzer.
3	Lock in samples by turning center piece clockwise.
4	Press [SAMPLING DEVICE] button from the List, Sample, or Main menu.
5	Press [START] to immediately begin analysis or press [EXTRA MIX] if extra mixing of samples is needed. Default mix setting = 10 minutes. (Extra mixing can be set from 1 to 15 minutes in Setup Menu 3 by choosing [MIXER SETUP] and then [SET MIXING TIME (SAMPLER)].

Warning

- Do not touch sample wheels or samples during operation.
- Handling and operation by unauthorized personnel may result in injury.

6	Sampling Device begins analysis with the sample tube placed in the lowest position number.
	 Figure 5.25  Figure 5.26
7	Sample Status (St.), SEQ, and ID number will appear in Sampling Device List as they are analyzed.

Continued on next page

5.9 Analyzing the Sample (Autoloader) (continued)

Step	Action
8	Sample Status has three columns: • Column 1 is sample tube detection: (+) = Detected, (-) = Not detected, (?) = Not yet determined. • Column 2 is first analysis: (+) = Complete, (-) = Aspiration Failure, (!) = System Information Message, (0) = No Sample in tube. Column 3 is Re-analysis: same as Column 2 except re-analysis is not repeated.
9	Press [EXIT] to view sample results. [NEXT] button will highlight when the next sample being run is complete. For more information of results refer to Section 5.10.

5.10 Results

Description

This section describes the information that can be obtained from the sample analysis results.

After sample analyze

After a sample has been analyzed the result information can be viewed in the following three screen displays:

Sample View 1

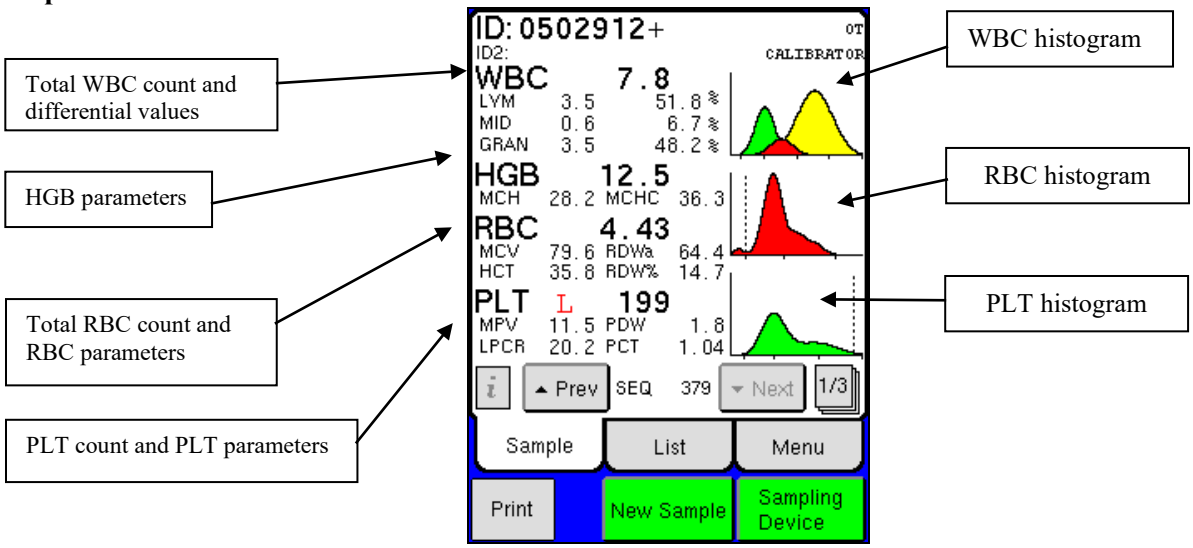


Figure 5.27

Sample View 2

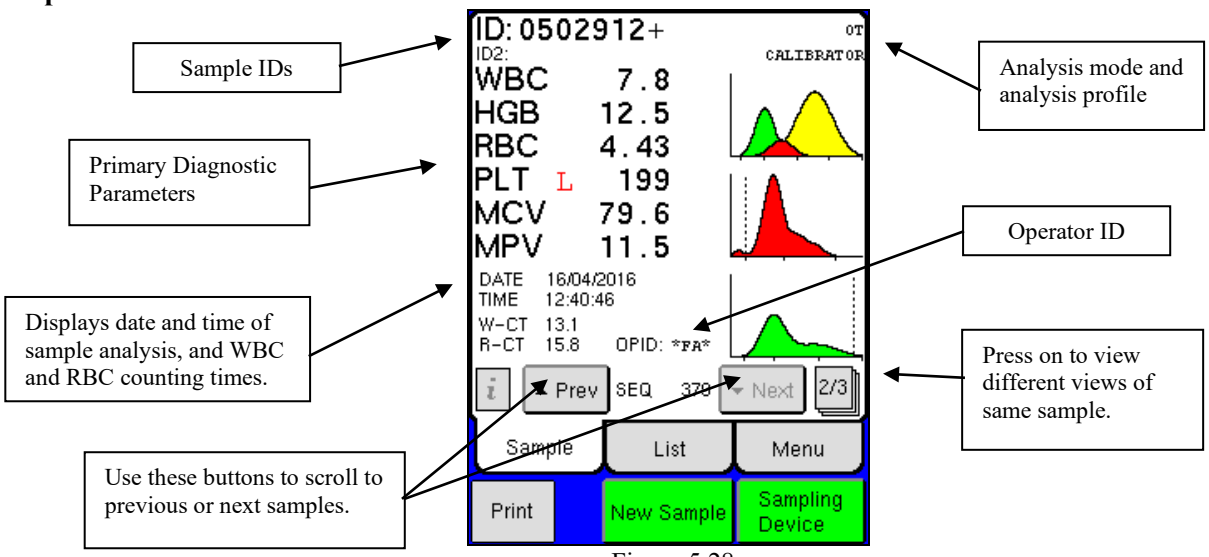


Figure 5.28

Sample View 3

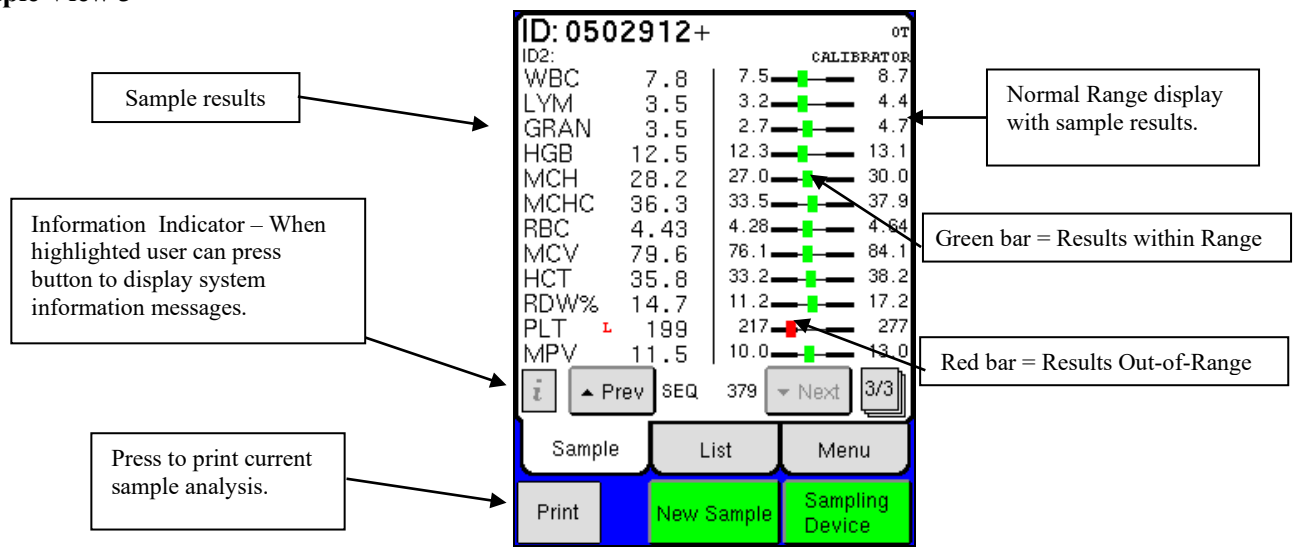


Figure 5.29

Section 6: Quality Control (QC) and Blood Control Memory

Section Overview

Introduction

The Medonic M-Series is equipped with a QC memory capable of displaying and printing Xb and Levey Jennings plots.

Contents

This section contains the following topics:

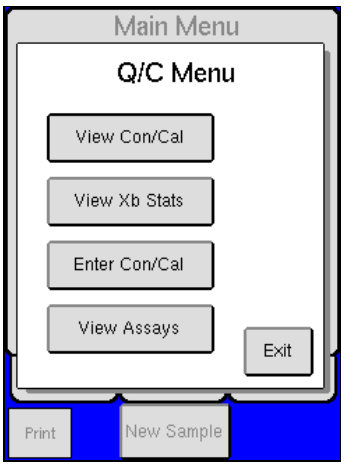
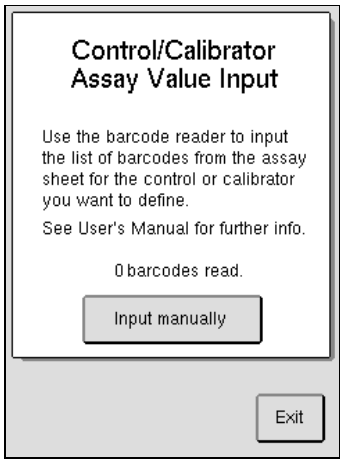
6.1 Quality Control (QC)

Introduction

This section describes the procedures to be performed for running control samples.

QC Menu and Assay Value Input

Follow the instruction below to access the QC menu and to input Control/Calibrator Assay Values from the Assay sheet.

Step	Action
1	Enter the QC menu by pressing [QC] from the menu tab.
2	Press [ENTER CON/CAL].
3	Refer to the Assay sheet for instructions on how to input Assay Values. (These pages are delivered with authorized Boule controls).  Figure 6.1  Figure 6.2
Note	12 different Assay Lots from Boule can be stored simultaneously. When entering a new Assay Lot, the previously scanned Assay Lot will be removed in a chronological order starting with the first entered Lot.

Continued on next page

Control Analysis

It is advisable that the performance of the Medonic M-Series system is checked daily with a certified blood control authorized by Boule. For good laboratory practice controls may also be used for troubleshooting purposes and when changing to a new lot of reagents, to check for damage during transport or storage. Comparing the analyzer results to the known values on the Boule control assay sheet is a good assurance that the system is functioning properly.

Important

- Handle and prepare controls in accordance to control package insert.
- Never use an open vial longer than recommended by the manufacturer or subject any vial to excessive heat or agitation.
- Wipe the aspiration needle with a clean, dry lint free absorbent cloth before each control run. Not following this technique will impact control accuracy.

Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous.
- Refer to local regulations and established laboratory protocol for handling biohazardous materials.

Step	Action
1	Follow directions on Assay Sheet to scan in assay values.
2	Choose either List, Sample, or Main Menu to begin control analysis.
3	Using installed barcode reader, scan the Control ID from the blood control vial label or manually enter in barcode.
4	Aspirate the blood control and wait for the results. The Medonic M-Series will identify this ID and match the results with the previously defined control assay values.

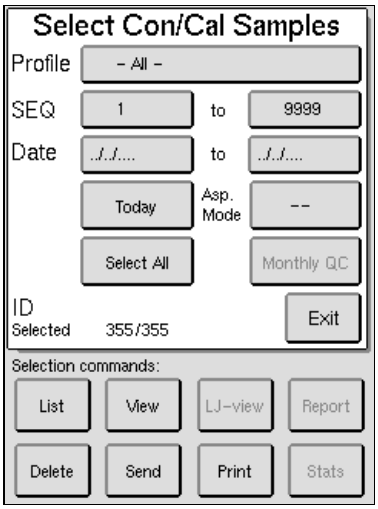
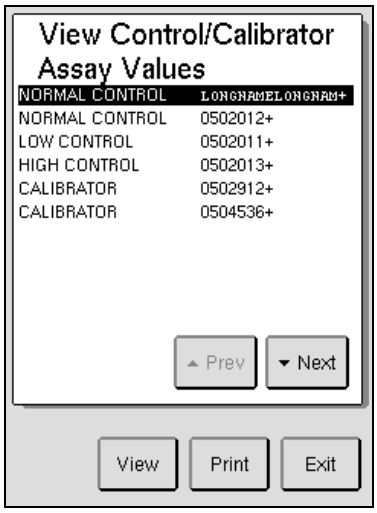
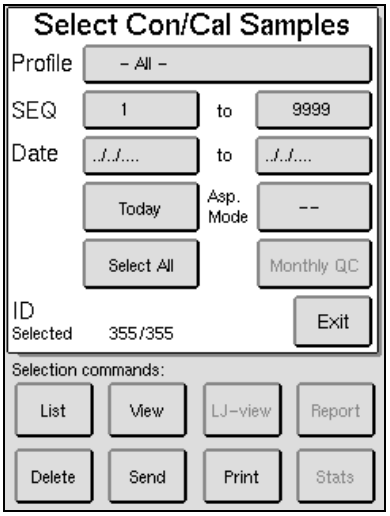
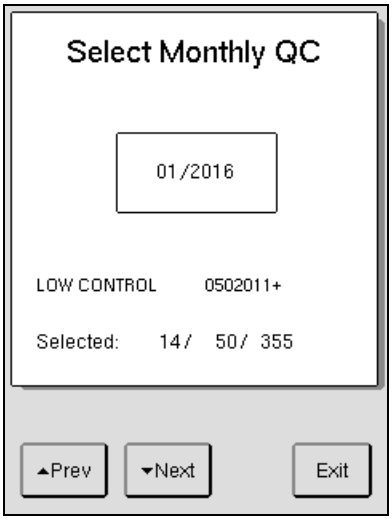
Search Function

Each blood control type can be found by control lot number, level, date or sequence number.

Step	Action
1	Enter the QC menu and press [VIEW CON/CAL].
2	Input the search criteria to be used.
3	Pressing on the SEQ bar will display Figure 6.4, in which one particular lot or level can be selected.

Continued on next page

6.1 Quality Control (QC) (continued)

Menus	 Figure 6.3  Figure 6.4
4	Press the [SAMPLE] or [LIST] buttons to display the selected samples.
5	Once samples are displayed they can also be printed out in a Monthly QC summary report. • After the control lot (profile) has been selected the Monthly QC button will become active. • Press [MONTHLY QC] button, use the [PREV] and [NEXT] buttons to scroll to desired month, and press [EXIT]. • The Monthly QC button will turn green when lot and month have been chosen. Press [REPORT] button to print out report.
Menus	 Figure 6.5  Figure 6.6
6	To exclude a sample from the Monthly QC or LJ Diagram summary reports perform the following steps prior to Step 5 above: • Scroll to the control sample to be excluded using the [PREV] and [NEXT] buttons in the Con/Cal Sample or List tabs. • Then press [EXCLUDE/INCLUDE] button. An “X” will be placed next to excluded sample. • To include the sample press the [EXCLUDE/INCLUDE] button again.

6.2 Levey-Jennings Plots

Procedure instruction

This section describes selecting, viewing, and printing Levey-Jennings Plots.

L-J Plots

Levey-Jennings (L-J) plots are used to monitor the long term stability of the instrument using Boule controls.

Controls

To be able to use L-J plots, the Control/Calibrator Assay Values for the controls, **must** be scanned with the installed barcode reader or manually entered in. Follow direction on Assay Sheet to scan in assay values.

Displaying and printing L-J Plots

To display and print the L-J plots, follow the instructions below:

Step	Action
1	Enter the QC menu and press [VIEW CON/CAL].
2	Scan the barcode label on the blood control tube, with the barcode reader, select control from Select Con/Cal Sample Menu, or manually enter in value.
3	Press [L-J VIEW] to display the Levey - Jennings plots.
4	Scroll through parameters by choosing [MORE].
5	Print diagrams by choosing [PRINT].
L-J plot Diagrams	Image 6.7 below is constructed from several samples and will not be shown as below until a sufficient amount of samples have been analyzed.
6	A Monthly QC L-J Diagram report can also be viewed and printed: • Follow Steps 5 -6 in Section 6.1 to select control lot and month. • Press [L-J VIEW] to view the monthly diagrams. The Monthly L-J diagrams will differ from the normal L-J plots as the x-axis uses the expected range for its out-of-bounds criteria and on the y-axis the points can be visibly traced to which day of the month it was analyzed on. • To print the diagrams on the displayed page, press [PRINT] or to print all diagrams, scroll to the last display page without plots and press [PRINT].

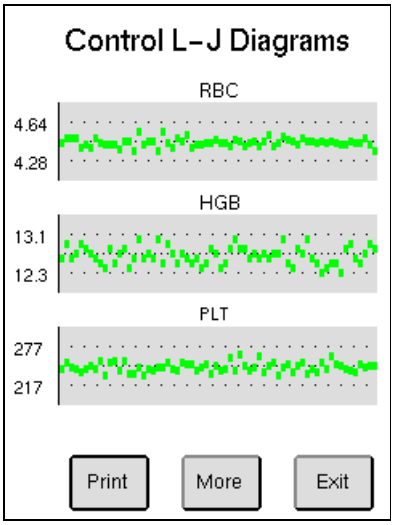


Figure 6.7

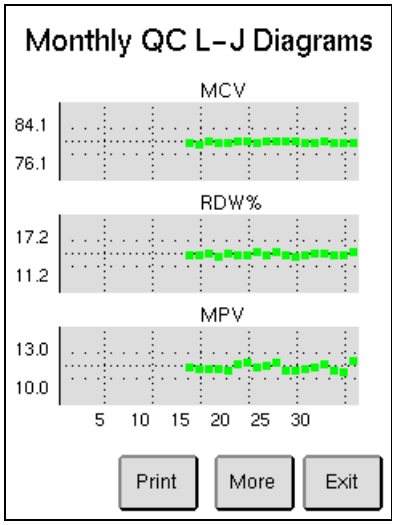


Figure 6.8

Continued on next page

6.2 Levey-Jennings Plots (continued)

Parameters displayed on L-J Plots

The L-J plots are displayed for all parameters defined in the Assay Sheet except the WBC differential parameter “MID”.

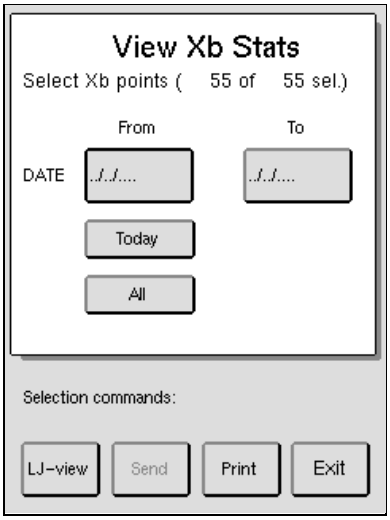
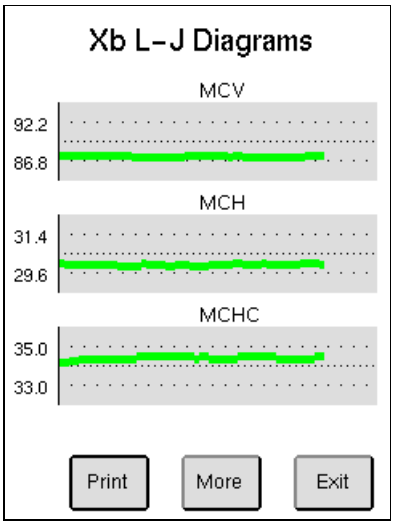
Note

If a control shows a system information indicator, the parameter values of such a control will not be included in the L-J plots.

6.3 Initialization and Use of Xb Function

Description

The Xb function in the Medonic M-Series follows strictly the Bull algorithm for the parameters MCV, MCH and MCHC. These parameters should not drift as a function of time within a large patient population. The recommended range setting is ± 3% from the expected mean value of these parameters.

Step	Action
1	Enter the QC menu and press [VIEW Xb STATS].
2	Select Xb points by Date or by default all sample data is selected.
3	Press [LJ VIEW] to display Xb L – J diagrams.
Xb L-J Diagrams	The image below is constructed from several samples and will not be shown as below until a sufficient amount of samples have been analyzed.  Figure 6.9  Figure 6.10
4	Select [MORE] to view selected conditions and matched ranges.
5	Print diagrams by choosing [PRINT].
6	To change ranges on Xb Diagrams go to Setup Menu 3 and press [XB RANGE SETUP]. Here operator can change low and high ranges on the three parameters. To update or change Xb range setup input the Authorization Code [**2576**].

Reference

Bull BS, Hay KL. The blood count, its quality control and related methods: X-bar calibration and control of the multichannel hematology analysers. In: Clangoring I. editor. Laboratory Hematology: An account of Laboratory Techniques. Edinburgh.

Section 7: Calibration

Section Overview

Introduction

This section describes the step-by-step procedure for calibration of the Medonic M-Series. The instrument has been calibrated by Boule prior to shipment. Good laboratory practice, however, requires regular checks and calibration of the measured parameters.

Contents

This section contains the following topics:

7.1 Preparations before calibration

Before Calibration

- It is advisable that the performance of the Medonic M-Series system is checked daily with a certified blood control authorized by Boule.
- Analyze control blood once in the open tube mode and compare results with the assigned values prior to calibration.
- Before recalibration of the instrument check that calibrator and reagents are not outdated and exclude instrument failure.
- Verify that instrument maintenance/cleaning is current. (See Sections 8.1 – 8.3)
- Prior to calibration print Calibration Log. Select [ADVANCED] from Main Menu, then [CALIBRATION], then [CALIBRATION LOG], and then [PRINT].

Important

- The user should be thoroughly familiar with the analyzer system and the calibration procedure before performing calibration.
- Refer to the Calibrator Product Insert for complete instructions for handling and use of blood calibration materials.
- Never use an open vial longer than recommended by the manufacturer or subject any vial to excessive heat or agitation.
- Wipe the aspiration needle with a clean, dry lint free absorbent cloth before each calibrator run. Not following this technique will impact control accuracy.

Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, controls, and calibrators these products should be handled as potentially biohazardous.
- Refer to local regulations and established laboratory protocol for handling biohazardous materials.

7.2 Calibration

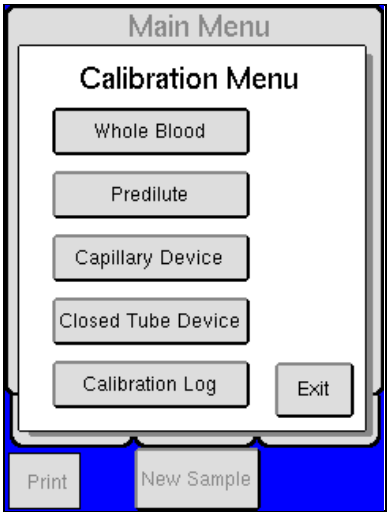
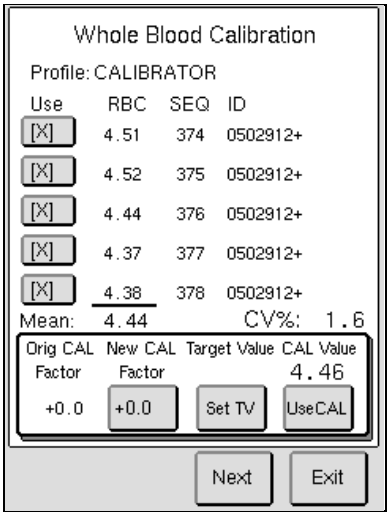
Input Calibrator Assay Values

Follow the instruction in Section 6.1 Quality Control to access the QC menu and to input Control/Calibrator Assay Values from the Assay sheet.

Whole Blood Calibration

The following instructions calibrate Open Tube, Cap Piercer, and Sampling Device modes. Follow the instructions below to calibrate:

Important

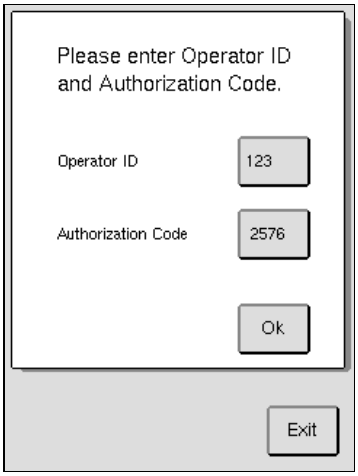
Step	Action
1	Follow directions on Assay Sheet to scan in calibrator assay values.
2	Choose either List, Sample, or Main menu to begin calibrator analysis.
3	Using installed barcode reader, scan the Calibrator ID from the calibrator vial label.
4	To perform calibration, it is recommended that five calibration analyses be performed in consecutive order through the open tube mode.
Note	**DO NOT** use Cap Piercer or Autoloader mode to aspirate calibrator.
5	When analyses are complete press [ADVANCED] from the MENU tab.
6	Press [CALIBRATION] and then choose [WHOLE BLOOD].  Figure 7.1  Figure 7.2
Note	Calibration analysis must be last analysis performed on instrument for parameter values to be shown in calibration menus. (e.g. no values will show if in the middle of calibration a patient sample analysis was performed)
7	Scroll through parameter screens by using the [NEXT] button and verify that the CVs for the following parameters are within the stated limits:

Parameter	OT/CT CV%	MPA/PD CV%
RBC	< 2.2	< 3.2
MCV	< 1.8	< 1.8
PLT	< 5.8	< 6.2
HGB	< 1.8	< 2.9
WBC	< 4.2	< 4.8
MPV	< 4.0	< 4.0

*CV limits are wider on the MPA/Pre-dilute calibration due to differences in pipetting and blood collection techniques at the operator level.

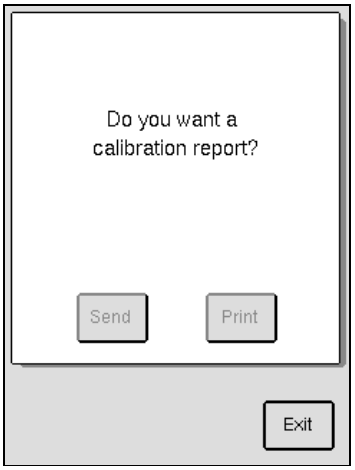
Continued on next page

7.2 Calibration (continued)

8	If CV values are not within range operator will be unable to perform calibration. (Analyses with system information indicators will automatically inactivate that analysis from the CV calculation and depending on flag may not be stored on list at all.) If a known sample handling error or erroneous result is present, then sample can be inactivated by pressing button to the left of that particular analysis and changing to empty brackets [ ].
9	If all parameters have acceptable CVs proceed to next step, if not rerun calibration following steps above.
10	The new calibration factor can be entered in three ways. • The recommended method is to select the [USE CAL] button which will automatically calculated the new calibration factor using target range from assay values. • The second method, if no calibrator is available, is to perform Steps 4-9 using a sample with target values from an assay sheet or determining target values using a reference analyzer or a microscope method with an in-house sample. The target values can be entered selecting the [SET TARGET VALUE] button and manually entering in the values. • The third method is to manually calculate and enter in calibration factor. This method should only be used with instruction from your local Boule representative or authorized service technician.
11	In the first and second methods the calibration factor is automatically calculated once either the [USE CAL] button is pressed or target value is entered.
12	Once calibration factor has been entered using one of the methods above, operator will be prompted to enter a 4-digit Operator ID (Operator ID is recommended for in-house records of calibration operator but not required) and an Authorization Code (REQUIRED) before the new value can be changed or updated.
Note	Authorization Code prompt is displayed only once per calibration sequence when [USE CAL], [TARGET VALUE], or [NEW CAL FACTOR] buttons are pressed.
13	Authorized operator can update or change calibration factor by inputting the Authorization Code [2576].  Figure 7.3

Continued on next page

7.2 Calibration (continued)

14	Perform steps 9-12 for RBC, MCV, PLT, HGB, MPV and WBC parameters. To move to the next parameter press [NEXT].
15	It is recommended to not change preset calibration factors for RDW%, RDWa, and PDW. If necessary, please contact your local Boule representative or Boule service technician for procedure.
16	Once parameters are calibrated, press [EXIT] and a screen will be displayed asking operator if a calibration report is wanted, [SEND], [PRINT], or [EXIT] can be selected. It is recommended that calibration reports be printed and archived in case it may be needed for future reference.  Figure 7.4
17	It is recommended to run controls after calibration to verify that all parameters have been calibrated correctly. See section 6.1 to perform QC.

Capillary Device Calibration

To calibrate MPA follow Steps 1-17 above except select [CALIBRATION] and then choose [CAPILLARY DEVICE] instead of Whole Blood calibration in Step 6 and use MPA mode for analysis. (See Section 5.7 for details on capillary device sample analysis.)

Pre-dilute Calibration

To calibrate pre-dilute follow Steps 1-17 above except select [CALIBRATION] and then choose [PREDILUTE] instead of Whole Blood calibration in Step 6 and use pre-dilute mode for analysis. (See Section 5.6 for details on pre-dilute sample analysis.)

Closed tube Device Calibration

The closed tube device is calibrated with the calibration of the Open Tube inlet. However, if the same systematic differences are seen on RBC, HGB, WBC, and PLT when analyzing blood in the closed tube device compared to the open tube, a calibration factor can be calculated. This method should only be used with instruction from your local Boule representative or authorized service technician.

Note

DO NOT use Cap Piercer mode to aspirate calibrator.

Section 8: Cleaning, Maintenance & Transport

Section Overview

Introduction

This section contains information that is crucial for maintaining, transporting and storing the Medonic M-Series.

Contents

This section contains the following topics.

8.1 Daily Cleaning

Description

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

Warning

Always use gloves when in contact with potentially biohazardous materials or parts of the instrument that might be contaminated with blood.

Cleaning Procedure

The Daily Cleaning takes only a few minutes, the instructions are as follows:

Step	Action
1	Clean the aspiration and pre-dilute needles using a paper tissue with a 70% alcohol solution.
2	Remove possible traces of salt crystals or blood at the top of the aspiration and pre-dilute needles, probe rinse cup, and around top of sampling device needle inlet (if applicable) using a paper tissue with a disinfecting solution.

8.2 Monthly Cleaning

Description

This section describes the cleaning procedure to be used to secure the correct function of the instrument on a monthly basis.

Cleaning procedure

The Monthly Cleaning procedure takes approximately 10 minutes, instructions are as follows:

Step	Action
1	Clean the aspiration needles using a paper tissue with a 70% alcohol solution.
2	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: Dispense Function.)
3	Aspirate the hypochlorite as a pre-dilute sample.
4	Run 2 blank samples by aspirating diluent as a pre-diluted sample.
5	Perform a background check, in pre-dilute mode, to verify all values are within range. See Section 5.3 for more details.

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.

Important

- Once this procedure is started the operator will be unable to abort the cycle until it is completed.
- Prematurely aborted the cycle could cause erroneous patient results if system is not cleaned properly.

Step	Action
1	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.
2	From Main Menu press [ADVANCED], then [MAINTENANCE] and then press [CLOT PREVENTION].
3	• For Cap Piercer: Place filled cleaner tube into cap piercer, same as a normal sample analysis, close the door, and go to Step 4. • For Sampling Device: Place filled cleaner tube into Position 1 on wheel, lock wheel into place, and go to Step 4.
4	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.)
5	The system will then perform the cleaning process for all analysis modes simultaneously, and upon completion instrument is ready for next analysis.
6	Perform a background check to verify all values are within range. See Section 5.3 for more details.

LCD Display

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

8.3 Six (6) Month Cleaning

Description

To increase the life of internal tubing in the instrument, the following cleaning procedure is strongly recommended.

Cleaning Procedure

- 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 instrument. (Instructions for use are supplied with the Boule Cleaning kit solutions).
- The Six Month Cleaning procedure takes approximately one hour and 15 minutes to complete.

Figure 8.1

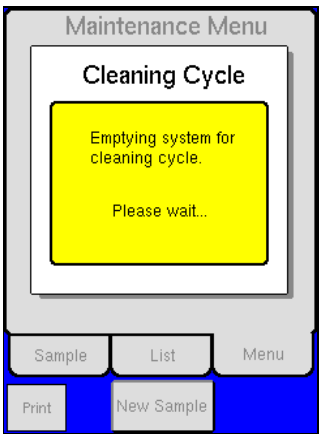


Figure 8.2

Figure 8.3

Boule Cleaning Kit

The Boule Cleaning Kit contains the following items:

- Hypochlorite (2%)
- Enzymatic cleaner
- Detergent cleaner

Cleaning Interval

Depending on daily sample analyses, it is recommended that the following cleaning intervals be followed:
Less than 50 samples/day = every six months
More than 50 samples/day = every three months
100 – 200 samples/day = every month

8.4 Instrument Maintenance

Description

This section describes the maintenance that is required to maintain and increase the life of the instrument. Refer to your local Boule representative for warranty requirements.

Maintenance

The maintenance should be performed at the following intervals by your local Boule representative or authorized service technician:

- 1 year or 20,000 samples

8.5 Re-location of instrument (within the laboratory)

Description

This section describes the procedure performed to move the instrument over **very short** distances. (From table to table).

Before the re-location

If the instrument is in "standby" mode **do not** unplug instrument. Make sure that the instrument is in Sample or List menu before turning off.

Step	Action
1	**Do not** detach the reagent level sensors or waste line, place the sensors on top of the instrument when moving. (Avoid reagent level sensor contact.)
2	Remove the waste line from waste container or drain, but do not detach tube from analyzer.
3	Disconnect all electrical connections.

Re-location

Make sure that the instrument is lifted from beneath to avoid unnecessary stress on the front cover.

After re-location

Step	Action
1	Place the waste line in waste container or drain.
2	Reconnect the electrical connections.
3	Insert the level sensors back into the reagent containers.
4	Power on unit.
5	Perform Prime.
6	Verify Background.
7	It is recommended that the performance of the Medonic M-series system is checked with certified blood controls authorized by Boule.

8.6 Short Term Shutdown (<12h)

Description

This section describes the procedure when transporting or shutting down the instrument for a shorter period of time (< 12 hours).

Empty System

Step	Action
1	Remove the reagent level sensors from the reagent containers.
2	Press [ADVANCED] button on MENU tab.
3	Press [MAINTENANCE] and then [EMPTY SYSTEM].
4	When empty procedure is complete, the following statement will appear on screen: 'System is empty and ready for fill or power off.'
5	Switch off power and then unplug analyzer.

Before the re-location

After instrument is powered off, detach reagent level sensors, waste line, all electrical connections, and sample wheels (if applicable). Package all components carefully for transport.

8.6 Short Term Shutdown (<12h) (continued)

Guidelines for transport

- The instrument should be transported in temperature conditions between 5 to 32 ºC (41 to 90 ºF)
- Humidity should be less than 80%.

8.7 Re-packaging and Long Term Transport (>12h)

Description

This section describes the procedure when transporting or shutting down the instrument for a longer period of time (>12 hours).

Important

- It is very important to follow the below instructions for preparing the analyzer for long term transport or re-packaging, to avoid erroneous results upon re-installation.
- The main difference between Section 8.6 and 8.7 is the importance of cleaning the instrument with the Boule cleaning kit and distilled water, prior to re-packaging to avoid contaminates.

Long term Shut-Down

Step	Action
1	Select [EMPTY SYSTEM] from MAINTENANCE Menu. See Section 8.6 “Short Term Shutdown” for emptying instructions.
2	Remove the reagent sensors from the reagent containers and follow the instructions for the Boule cleaning kit. (Instruction is supplied with the Boule cleaning kit solutions).
3	After completing the cleaning of the instrument, insert the reagent sensors into distilled water. Select [CLEAN CYCLE FILL] from CLEANING Menu.
4	When the instrument has been filled with distilled water select [CLEAN CYCLE EMPTY] from CLEANING Menu.
5	When system is emptied, disconnect the main supply cable and other connections such as reagent sensors and waste line.
6	If transporting instrument, pack securely using the original shipping container.
7	Mark the container with DELICATE INSTRUMENT, FRAGILE and THIS SIDE UP.
8	Follow Guidelines for transport below.

Guidelines for transport

The instrument in its export package should fulfill the following transport/storage conditions:

- Does not exceed - 40°C for ≥ 24 hours.
- Does not exceed a Dry heat of + 70°C for ≥ 24 hours.
- Dramatic change of temperature between - 40°C and + 30°C.
- Does not exceed a Damp heat steady state of 90% RH and + 40°C during 48 hours.
- Does not exceed a Damp heat cyclic of 90-100% RH and + 25°/+40°C 12+12 hours.

8.8 Permanent Shut-Down and Storage

Permanent Shut-Down and Storing

See Section 8.7 Long Term Transportation.

8.9 Disposal Information

Description	Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the content of effluent streams, before disposing of waste in public sewer systems or recycling decontaminated equipment.
Disposal Materials	• Used reagents • Reagent containers • Reagents mixed with potentially biohazardous material • Instrument and instrument components • Control and calibration material
Manufacturer Guidelines for waste products	• Place the instrument close to a waste container or drain suitable for disposal of used reagents. • Check that the drainage is suitable for disposal of chemical and biological waste. • Check that the waste line is securely fastened in the drain.
Recycling reagent packaging and container	The cardboard box can be recycled after removal of the LPDE cubitainers. The LPDE container can be recycled after removal of any remaining reagent and a rinse with water.
 **Mandatory Action**	Always use protective gloves when working with the waste container, waste line and when in contact with potentially biohazardous materials.

Instrument decontamination and disposal

The European Directive 2012/19/EU on Waste Electric and Electronic Equipment (WEEE) aims to minimize the impact on the environment by prevention of waste. The Medonic M-Series hematology analyzer has been labeled with the WEEE symbol (as given in the margin) and there is a procedure to allow waste collection and recycling of the equipment at the end of its life cycle.

Important

- The instructions for decontamination can be found at www.boule.com.
- If there are any question on how to follow this procedure, contact your local Boule representative for more information.

Warning

The analyzer should be considered as infected, and the end user must follow a decontamination procedure before it is safe to hand over to a recycler.

Section 9: Parameter and System Information Messages

Section Overview

Introduction

The Medonic M-Series has several parameter and system information messages related to the measured parameters and the instrument. These messages alert the operator of possible pathologic samples and parameter value and instrument errors.

Contents

This section contains the following topics:

9.1 Out-of-Range and Information Message Indicators

Description

The instrument has several out-of-range, parameter, system information messages related to the measured parameters and the instrument. The messages are shown on the display and printouts.

Out-of-Range Indicators

- A parameter that is outside the "Normal Range", refer to Section 4.5 for User Interface setup, is either marked with "H" or "L" on the printout and display to indicate if the value is higher or lower than the pre-set "Normal Range" values.
- #### indicates an out of displayed range parameter, the count is too high or too low to measure. If it is expected that the parameter is too high, the sample can be diluted and rerun, and then the dilution factor can be multiplied with the result to calculate the correct value.

Description of System Information Indicators

For System Information Messages, the touch screen's ***i*-button** becomes active when a message is present. The user has the preference to access this information detail by either touching the ***i*-button** on the touch screen or reviewing the printout. System Information Messages are outlined in detail below.

Abnormalities

All samples with anomalies and /or abnormal distributions signaled by the instrument should be analyzed manually by a blood smear. Pathological cells may vary in their stability towards lysing of their cytoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments.

9.2 System Information Messages

Description The system software monitors a number of analytical and system functions and will display information that indicates the possible attention of the operator. This information will alert the operator to check the system or sample or institute selected troubleshooting procedures. This information is presented on the touch screen as a code next to one or more parameters. Additional detail and recommendations may be accessed by either pressing the ***i*-button** on the touch screen or reviewing the printed report.

System Information Messages

Aspiration Indicators (Sample Probe)			
Indicator	**Message**	**Description**	**Action**
AF	Aspiration failed, check sample	Possible reasons for AF flag include a short sample, clogging or air bubbles in sample tube. **Note:** This flag is also displayed when running a background count (blank) without selecting the background analysis profile.	Check profile type is correct and then re-analyze sample.
Distribution Indicators (RBC, PLT, WBC)			
Indicator	**Message**	**Description**	**Action**
DE	Small particle interference; re-analyze	The size distribution of the cell pulses departs from the expected one. Possible reasons might be pathological blood sample (e.g. nRBCs), PLT clumps, air bubbles, electrical disturbances, incomplete lysing or incorrect gain setting.	Re-analyze sample.
FD	RBC/PLT: Irregular Distribution, re-analyze	It was not possible to find the correct position for the floating RBC/PLT distribution curve. This flag often occurs on low PLT counts. The FD flag should only be reported if the corresponding parameter (PLT) value is high enough.	Re-analyze sample.
HGB Indicators (HGB)			
Indicator	**Message**	**Description**	**Action**
HF	HGB Measuring Problem – run prime cycle	The instrument detected a problem during the filling of liquid in WBC counting chamber during HGB blank.	Run a "Prime cycle", before re-analyzing the sample.
HH	HGB Measuring Problem – run prime cycle	The HGB blank or sample readings reported a too high light level.	
HL	HGB Measuring Problem – run prime cycle	The HGB blank or sample readings reported a light level that was too low.	
HN	HGB Measuring Problem – wait one minute then re-analyze	The HGB sample reading reported more light than the blank reading. This gives a negative HGB value.	Wait one minute, and then re-analyze sample.
HO	HGB Measuring Problem – restart system	The HGB dark (offset) reading reported a light level that was too high or too low.	Switch off the analyzer and switch it back on after 3 seconds, and then re-analyze sample.
HS	HGB Measuring Problem – run prime cycle	Individual HGB readings vary too much.	Run a "Prime cycle", before re-analyzing the sample.
Note: If various HF, HH, HL, or HN Indicators repeatedly appear check High Altitude Compensation, mode may need to be changed to Moderate or Maximum compensation in higher elevations. A more detailed description can also be found in the User Definable Settings document. For further information, contact your local Boule representative.			

Continued on next page

Measuring Chamber Indicators (RBC, PLT, WBC)			
Indicator	**Message**	**Description**	**Action**
OR	Measurement warning – re-analyze	The cell pulses arrived faster than the analyzer could process them. Possible reasons might be air bubbles, electrical disturbances or incomplete lysing. **Note:** Filtered away cell pulses might raise the OR flag, so it might not be possible to see them in the histograms or the result parameters. This is a hard limit determined by the software.	Re-analyze sample
SE	Measurement Statistics Warning; re-analyze	The rate of cell pulses per time unit varies too much. Possible reasons might be clogging, air bubbles, electrical disturbances or difficult to lyse cells. **Note:** Filtered away cells might raise the SE flag, so it might not be possible to see them in the histograms or the result parameters.	Re-analyze sample
Mixing Beaker Indicators (RBC, PLT, WBC)			
Indicator	**Message**	**Description**	**Action**
TE	Liquid System Problem – run prime cycle	The analyzer detected an abnormality during the emptying of the first dilution from the mixing beaker. Reasons for flagging might be timeout, or too short of a transfer time.	Run a "Prime cycle", before re-analyzing the sample.
Reagent and Control Indicators (RBC, PLT, WBC, LYM/MID/GRAN)			
Indicator	**Message**	**Description**	**Action**
EC	Expired control	A control blood was used past its expiry date.	Use a fresh blood control
ER	Expired Reagent	The reagent was used past its expiry date. Change to a non-expired lot of reagent.	Use a new lot of reagents
NR	Not enough reagent left, check reagent levels	The analyzer's capacity counter has gone below zero and no reagent is detected. Reason for no reagent may include empty reagent container or reagent level sensor not inserted correctly into reagent container.	Check reagent levels
Reagent Pipette Indicators (RBC, PLT, WBC)			
Indicator	**Message**	**Description**	**Action**
DF	Diluent system problem – run prime cycle	The instrument detected an abnormality during one of the fill cycles of the diluent pipette. Reasons for flagging might be timeout, short time or bubbles at the upper detector.	Verify instrument is filled, run a "Prime cycle" and then re-analyze sample.
DP	Diluent system problem – run prime cycle	The instrument detected an abnormality during one of the empty cycles of the diluent pipette. Reasons for flagging might be timeout, short time or liquid not detected at the lower detector.	
LF	Lyse system problem – run prime cycle	The instrument detected an abnormality during the fill cycle of the lyse pipette. Reasons for flagging might be timeout, short time or bubbles at the upper detector.	
LP	Lyse system problem – run prime cycle	The instrument detected an abnormality during the empty cycle of the lyse pipette. Reasons for flagging might be timeout, short time or liquid not detected at the lower detector.	

Continued on next page

9.2 System Information Messages (continued)

Reagent Pipette Indicators (RBC, PLT, WBC)			
Indicator	**Message**	**Description**	**Action**
ST	Air bubbles – run prime cycle	The time for the liquid meniscus to pass from the lower to the upper detector is unreasonably short.	Run a "Prime cycle", before re-analyzing the sample.
TB	Air bubbles – run prime cycle	Air bubbles were detected by the start detector in the measuring tubes.	
TL	Possible orifice blockage: Run prime cycle and then re-analyze	The liquid meniscus in the measuring tube never passed the lower detector.	
TU	Possible orifice blockage: Run prime cycle and then re-analyze	The liquid meniscus in the measuring tube passed the lower detector but never passed the upper one.	
WBC Differential Abnormalities (LYM, MID, GRAN)			
Indicator	**Message**	**Description**	**Action**
BD	WBC DIFF: High interference between populations.	The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended.	Blood sample too old or pathological sample. Slide review advised.
NM	WBC DIFF: No WBC population found; slide review advised.	There was no mode in the WBC distribution between the LYM-L and GRAN-H settings.	
OM	WBC DIFF: Only one WBC population found; slide review advised.	There was only one mode in the WBC distribution between the LYM-L and GRAN-H settings. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended.	
TM	WBC DIFF: Too many WBC population found; slide review advised.	There were more than two modes in the WBC distribution between the LYM-L and GRAN-H settings.	

9.3 Parameter Limitations of Automated Blood Cell Counters

Description This section describes the different factors that may interfere with HCT, HGB, MCV, MPV, PLT, RBC, RDW, WBC and WBC differential determination.

HGB Limitations	
Turbidity, in the blood sample, due to any number of physiological and/or therapeutic factors may produce falsely elevated HGB results. The instrument however, is compensated throughout the linear range of the instrument.	
Limitation	**Description**
Unlysed Red Blood Cells	Increased turbidity may be seen in cases where the red blood cells are resistant to lysing. This condition will cause a falsely elevated HGB result but can be detected by monitoring the MCHC.
Leukocytosis	Extremely elevated WBC may produce falsely elevated HGB results due to turbidity. In case of extreme WBC counts, the following is recommended: The diluted sample should be centrifuged and the supernatant fluid checked on a spectrophotometer for turbidity.
Lipemia, hyperproteinemia and hyperbilirubinemia	Elevated lipids in the blood sample will give the plasma a "milky" appearance which may disturb the spectrophotometric measurement of HGB. Similar problems may occur with hyperproteinemia (high protein concentration) and hyperbilirubinemia (high bilirubin concentration). Accurate HGB determination can be achieved by using reference methods and a plasma blank.
Fetal blood	The mixing of fetal and maternal bloods may produce a falsely elevated HGB value.

Continued on next page

9.3 Parameter Limitations (continued)

MCV / HCT Limitations	
As HCT is the product of MCV x RBC, any erroneous result in MCV and/or RBC will produce an equal error in the HCT parameter.	
Limitation	**Description**
Red Blood Cell Agglutination	Agglutination of RBC may produce an erroneous MCV value and therefore a false HCT.
WBC	An excessive number of WBCs might cause interference within the RBC population and therefore a false MCV value.
Thrombocytosis (elevated PLT)	Excessive numbers of PLT, in most cases, do not interfere with the MCV parameter due to the use of the floating discriminator technology in the instrument.
PLT / MPV Limitations	
Measurement of low PLT levels may influenced by circulating RBCs, which may cause falsely high results. Measurement of high PLT levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The instrument is compensated for these effects by separate algorithms to produce linearity ranges according to the specifications.	
Limitation	**Description**
Microcytosis (small RBC, low MCV)	Very small RBCs might falsely elevate a PLT count and affect the MPV. This effect is minimized in the instrument due to the use of a floating threshold (discriminator). By observing the PLT and RBC histograms, this effect is seen as an overlapping PLT/RBC area.
Agglutinated RBCs	Agglutinated RBCs might trap platelets and may give an erroneous low PLT count and affect the MPV. The presence of agglutinated RBCs is detected by monitoring the MCHC parameter and by careful examination of the stained blood film.
Giant platelets in excessive numbers	This may cause a low PLT count since they might fall within the RBC threshold range.
Chemotherapy	Cytotoxic and immunosuppressive drugs may increase the fragility of these cells, which may cause low PLT counts. Reference (manual) methods may be necessary to obtain an accurate platelet count.
Hemolysis	Hemolyzed specimens contain red cell stroma, which may elevate platelet counts.
A.C.D. blood	Blood anti coagulated with Acid Citrate Dextrose may contain platelet aggre-gates, which could depress the platelet count.
RBC inclusions	Erythrocyte inclusions may also produce a spuriously increased platelet count. (e.g. Howell-Jolly bodies, siderotic and basophilic granules)
Platelet agglutination	Clumped platelets due to poor collection techniques or platelet satellitosis caused by EDTA activation of immunoglobulins may cause a decreased platelet count and/or an elevated WBC count. The specimen should be recollected in sodium citrate anticoagulant and re analyzed for only the platelet count. The final PLT result must be corrected for the sodium citrate dilution effect.
MPV Limitations	
Giant platelets	Large platelets counted as RBCs will fall outside the PLT range and therefore lower the MPV.
Small erythrocytes	Very small RBCs might fall into the PLT region and might be counted as PLTs and therefore influence the MPV parameter.
Agglutinated erythrocytes	This may trap platelets and therefore affect the MPV parameter. Note that agglu-tinated erythrocytes may be detected by carefully examine the MCHC parameter and/or the stained blood film.
Chemotherapy	May also effect the size of the PLTs.
EDTA	Note that all samples collected in EDTA will not maintain a stable MPV. The PLTs will swell as a function of time and temperature.

Continued on next page

9.3 Parameter Limitations (continued)

RBC Limitations	
The red blood cell dilution contains all the cellular elements of the blood: RBC, WBC, and PLT. Platelets are not counted since the size falls below the discriminator threshold. Leukocytes are included in the RBC count, but since the ratio of RBCs to WBCs is approximately 1000:1, the introduced WBC count is almost negligible. Exceptions are noted below. Measurement of high RBC levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The instrument is compensated for this effect by an algorithm to produce a linearity range according to the specifications	
Limitation	**Description**
Leukocytosis with concurrent anemia	In samples where the WBC is very high and at the same time the RBC is low, the WBC may cause a false increase in the RBC count. The WBC is always included in the RBC count, but the contribution is not significant under normal circumstances. The RBC count may be corrected by simply subtracting the WBC from RBC.
Agglutinated Red Blood Cells	This might cause a falsely decreased RBC count. Blood samples containing the agglutinated red blood cells may be identified by observing abnormal MCH and MCHC values, as well as by examination of the stained blood film.
Cold Agglutinins	IgM immunoglobulins which are elevated in cold agglutinin disease may lower RBC and PLT counts and increase the MCV.
RDW Limitations	
The red cell distribution width is a function of the RBC count and derived from the RBC histogram. In most cases, any error introduced in the MCV may also cause the RDW to be erroneous.	
Limitation	**Description**
Blood transfusions	Blood transfusions may raise the RDW significantly due to the presence of bi-modal populations.
WBC Limitations	
Measurement of high WBC levels is influenced by coincidence factors (e.g. counting of two cells as one) which may produce falsely low results. The instrument is compensated for this effect by an algorithm to produce a linearity range according to the specifications.	
Limitation	**Description**
Leukocytosis	WBC in concentrations that exceeds the linearity limits of the system will require dilution of the blood sample. Re-assaying the diluted sample will help to obtain the correct assay value.
Nucleated Red Blood Cells, NRBC	Immature, nucleated red blood cells are large and not lysed like mature RBCs, thus they will be classified as a WBC and may cause falsely elevated WBC and lymphocyte results. If the number of the NRBC is sufficient to activate the DE alarm, such interference will be detected. An overview of a stained blood film can reveal the presence of NRBCs.
Unlysed Red Blood Cells	In particularly rare instances, the RBC in the blood sample may not completely lyse like expected. These non-lysed cells may be detected on the WBC histogram with a DE alarm, or as an elevated baseline on the side of the lymphocyte population. Non-lysed RBCs will cause a falsely elevated WBC and lymphocyte count. (See also NRBC above)
Hemolysis	Hemolyzed specimen contains red cell debris, which may falsely elevate the WBC and/or PLT count. Hemolysis can be detected by looking at the color of the plasma in an EDTA-sample that has been allowed to sediment.
Leukemias	This disease state may result in a spurious low WBC count, if the leukocytes are more fragile than normal and becomes destroyed in the sample. The cell fragments will also interfere with the WBC differential parameters (LYM, GRAN and MID). A falsely low WBC count may also be seen in patients with lymphocytic leukemias due to the presence of abnormally small lymphocytes, which may not be counted by the instrument.

9.3 Parameter Limitations (continued)

Chemotherapy	Cytotoxic and immunosuppressive drugs may increase the fragility of the leukocytes, which may cause falsely low WBC counts.
Cryoglobulins	Increased levels of cryoglobin may cause elevated levels of WBC, RBC or PLT counts as well as HGB. Cryoglobulins may be associated with myeloma, carcinoma, leukemias, macroglobulinemia, lymphoproliferative disorders, metastatic tumors, autoimmune disorders, infections, idiopathic disease, aneurism, pregnancy, thromboembolic phenomena, diabetes, etc. The specimen can be warmed up to 37°C and re-analyzed immediately or a manual WBC, RBC or PLT count can be performed.
Multiple myeloma	The precipitation of proteins in multiple myeloma patients may give falsely elevated WBC counts.
Large lymphocytes, atypical lymphocytes, blasts, and basophils in excessive numbers	The presence of large or atypical lymphocytes, blasts, or an excessive number of basophils may interfere with the MID cell area which otherwise consists mainly of monocytes.
Metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells in excessive numbers	The presence of excessive numbers of metamyelocytes, myelocytes, promyelocytes, blasts and plasma cells may interfere with an accurate granulocyte count.

Section 10: Technology

Section Overview

Introduction

This section describes the different methods and principles of measurement and calculations.

Contents

This section contains the following topics:

10.1 Measuring Principles

Description

This section describes the measuring principles of the Medonic M-Series.

General Measuring Principles

The measuring principles of the Medonic M-Series are based on impedance and spectrophotometry principles.

Whole Blood Dilution

The number of cells for determining RBC and WBC values are counted from a suspension of 1:40,000 for the RBC and 1:400 for the WBC dilution ratio of whole blood.

Theoretical Principles (RBC Example)

If a sample contains 5 million red blood cells per µl, a dilution of 1:40 000 will give a final concentration of 5 million divided by 40,000 = 125 cells per µl. Each µl containing 125 cells, drawn through the aperture, will generate 125 pulses.

Continued on next page

10.1 Measuring Principles (continued)

Measured Volumes (Example)

The measured volume drawn through the aperture is 270 µl (Manufacturer calibrated). Based on the assumption made above, the system will count 270*125 = 33,750 pulses, which is equivalent to $5.0x10^6$ cells/µl in the concentrated blood.

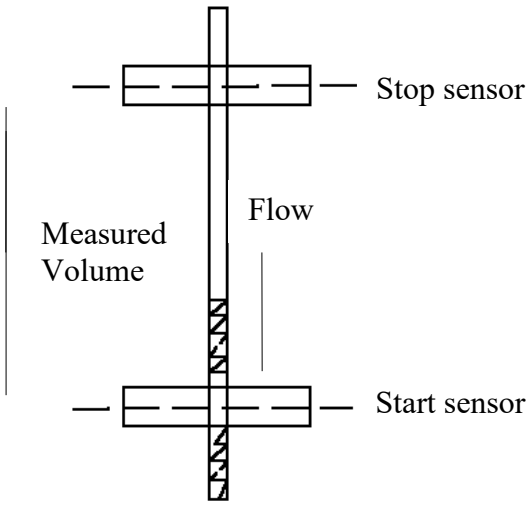


Figure 10.1

Theoretical Principles (WBC Example)

The calculation principle for white blood cells is the same but with a difference in dilution ratio and cell quantity. An example of this could be as follows: 5,000 cells/ µl diluted 1:400 =12.5.

10.2 Counting Time RBC & WBC

Description

The counting time is defined as being the time needed for the sample to fill the metering unit from the start to the stop detector.

Counting Time Limits

The normal counting time limits for the RBC and WBC metering units are between 13 – 18 seconds and 10 – 13 seconds respectively. If the counting time is below or exceeds the above mentioned limits, the flag ST, TL or TU will be displayed.

Note

The ´counting time´ is not related to the actual result. Atmospheric pressure variations, protein built up within the orifice (aperture) and other secondary effects that might cause pressure changes will NOT affect the counted parameters RBC, PLT and WBC.

10.3 WBC Differentials

Description

The Medonic M-Series uses a floating discriminator technology which performs a mathematical calculation to estimate the best separation between 3 populations of white blood cells (lymphocytes, granulocytes and mid cell fractions).

Floating Discriminator technology in general

After the analyzing process, the instrument finds two main modes (Granulocyte Peak and Lymphocyte Peak) within the total distribution. By extrapolating the two main population peaks value a third population can be mathematically calculated. This third population is classified as MID cell area, which mainly consists of monocytes. See Figure 10.2 below:

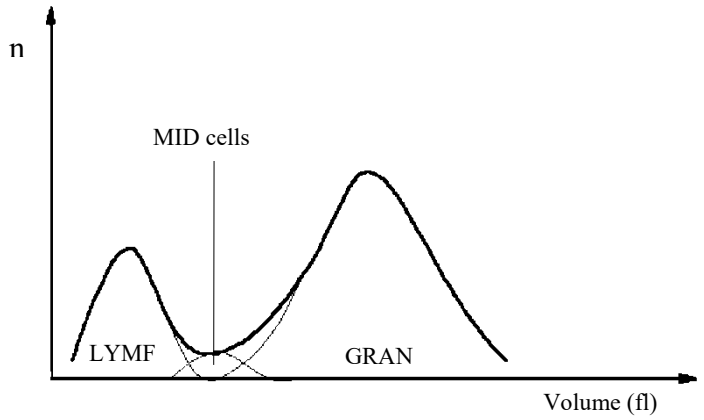


Figure 10.2

Differences in technologies

Some 3-part diff. technologies use a fixed discriminator analogue to separate the 3 populations. However, as shown in the figure below, as a sample begins to age, it can clearly be seen that the Granulocyte population is shifting towards the Lymphocyte population. As the Granulocyte curve moves, the accuracy of the results will decrease. Whereas, the floating discriminator system is not dependent on the actual position of the two main populations and thus overcomes this problem, and provides more accurate results.

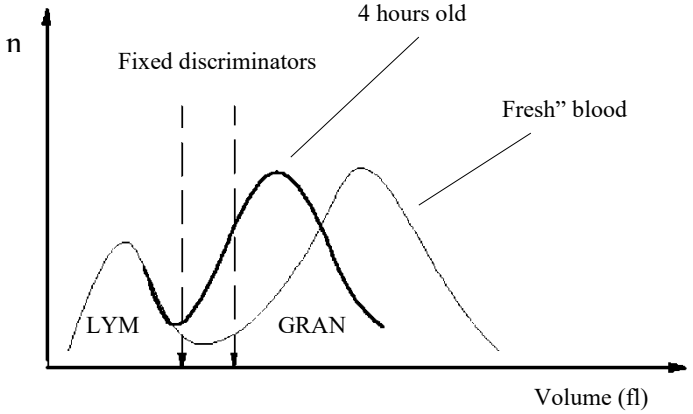


Figure 10.3

10.4 Photometric Method – HGB Hemoglobin

HGB (Hemoglobin Concentration)

The hemoglobin is determined from the same dilution as the WBC. For each sample a blank is measured as a reference, this means that any drift in reagent-, cuvette-absorption, or diode is eliminated. The photometer system consists of a photodiode, a cuvette with a length of 15 mm and a filter at a wavelength of 535 nm (bandwidth 20 nm). The HGB readings are slightly corrected for turbidity in case of extreme WBC counts. The diode is switched off if the instrument is in standby mode, giving it an extended lifetime.

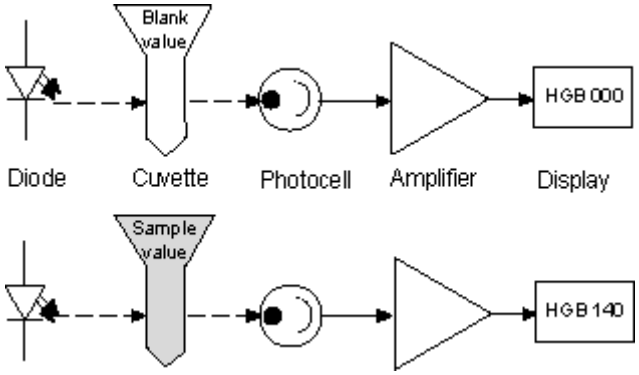


Figure 10.4

10.5 Parameter Definitions

Description

This section describes the parameter definitions that have not been defined yet in other sections.

MCV (Mean Cell Volume RBCs)

- The MCV parameter is derived from the RBC distribution curve. As the distribution curve has a maximum volume range of 250fl, the maximum channel also contains clumps of cells that are larger than this volume. Therefore this channel is excluded from the MCV calculation. The MCV is calculated from the volume position of the discriminator to 249 fl. Be aware that the discriminator might be 'floating' or fixed by the user in the 'Discriminator set-up program'
- In general, RBC counts that are lower than 0.60 (displayed value) do not give a MCV/HCT value due to low statistical significance.
- If the MCV is calibrated by using the 'calibration' procedure, in the user manual, the whole curve is recalculated and moved in a correct way that reflects the new calibration setting. The printed curve will therefore always be correct in respect to the actual MCV value.

RDW (Red Cell Distribution Width)

The RDW parameter is calculated from the RBC distribution curve. The CV of the curve is calculated. However, the CV is only calculated on a portion of the curve. This avoids that other populations might interfere. The RDW value is therefore only measured on a portion of the RBC size distribution curve. I.e. not all particles are included in the RDW calculation. The RDW parameter is only valid if the MCV value is not zero.

HCT (Hematocrit)

The HCT is defined as being the packed volume of red cells in whole blood and is calculated through MCV * RBC. If no MCV is derived from a sample due to too low a number of RBC cells, no HCT is calculated.

10.5 Parameter Definitions (continued)

PLT (Platelets)

- Platelets are defined (for the purpose of discrimination) as cells in a range from 2.5fl to the discriminator level that is either set on a fixed volume or 'floating' and determined by the software on each sample. The setting of the upper discriminator is done in the setup menu.
- The platelets are determined from the same dilution as the RBC, in fact, the system is counting just 'cells' during the RBC/PLT counting process. The determination of which cell is a PLT or RBC is done at the end of the counting procedure and fully determined by the setting of the user defined discriminator behavior (‘floating’ or fixed)
- Example: Let us suppose that a sample contains 200,000 platelets/µl in whole blood. After a dilution of 1:40,000 the sample contains 200,000 divided by 40,000 = 5 cells/µl. So, each µl drawn through the aperture gives 5 pulses. As the counting volume (the volume of the metering glass tube) is 270 µl, the total number of cells that are analyzed will be 5*270=1350 cells.
- In other words, the total number passing through the orifice when determining the PLT is the value shown on the display screen without decimals multiplied by the division factor 6.75.
- The reproducibility is directly dependent on the total number of cells entering the orifice.
- Measuring PLT from the same dilution as RBC, the CV will be less than 3.5% for most of the samples within normal range. A 'mean' CV of about 3.2 % is expected for well-treated fresh EDTA whole blood samples within the range of 250-350 10e3/uL.
- As the system uses an orifice size of 80 µm diameter, coincidence losses will take place with extreme sample RBC/PLT counts. The system has a well-balanced mathematical correction algorithm for these effects within the software.
- Please note that if a floating discriminator is used and no well-defined minimum is found between the RBC and PLTs the reproducibility of mainly the PLT is affected. To check the reproducibility of the low PLTs, it might be wise to put the analyzer in a fixed discriminator mode to exclude any error introduced by a not well-defined RBC-PLT population.

MPV (Mean Platelet Volume)

- The mean cell volume of the platelets is determined from the PLT size distribution curve.
- The MPV is defined as being the mean value of the PLT size distribution curve from the lower discriminator (2.5 fl) to the position of the upper discriminator which can be programmed as 'floating' or fixed.
- MPV is not displayed in case of extreme low PLT counts due to high statistical inaccuracy of such a population.

MCH (Mean Cell Hemoglobin)

The MCH is a calculated value and is defined as HGB/RBC giving the mean HGB concentration in the red cells.

MCHC (Mean Cell Hemoglobin Concentration)

- The MCHC is a calculated value and is defined as HGB/HCT.
- The MCHC is calculated from 3 measured parameters and therefore an excellent instrument stability check. MCHC=HGB/HCT=HGB/(MCVxRBC).
- In general it could be stated that if a daily mean value is found outside the range 32-36 g/dl, the instrument has been incorrectly calibrated. The daily mean value of the MCHC parameter should always be 34.5 +/- 1.5 g/dl.

Section 11: Specifications

Section Overview

Introduction

This section describes the specifications for the Medonic M-Series and its parameters.

Contents

This section contains the following topics:

11.1 General

Description

This section describes the Medonic M-Series and its parts in general.

User Environment

The operator works with a menu from which the desired program is chosen, e.g. discriminator settings.

Reagents

Two external reagent reservoirs are used:

- Isotonic diluent (Diluent)
- Hemolyzing reagent (Lyse)

Technology

The Medonic M-Series is a fully automatic hematology analyzer designed to measure up to 20 parameters using whole blood from an open inlet, closed tubes, 20µl micropipettes or pre-diluted blood.

3-Part WBC

The instrument performs a 3-part WBC differential by means of a cyanide free hemolyzing reagent.

Protected Sample Memory

A sample memory is available and protected against main power failures. The sample memory also contains a search function with selective printing and QC Options.

11.2 Short List of Specifications

Specifications (Short)

Measuring principle RBC, WBC, PLT	Impedance
Measuring principle HGB	Photometer, Cyanide free method 535nm ±5nm
Programmable WBC Discriminator	Yes
Sampling system	Closed shear valve
Parameters reported	RBC, MCV, HCT, PLT, MPV, HGB, MCH, MCHC, WBC, RDW%, LYMF abs, MID abs, GRAN abs, LYMPH%, MID%, GRAN%, RDW abs, PDW abs, LPCR, PCT
Size distributions printed for	RBC, PLT and WBC diff.
Aspirated blood volume (Open Tube)	< 110 µl
Aspirated blood volume (Cap Piercer)	< 250 µl
Aspirated blood volume (Autoloader)	< 300 µl
Sample display time (Open Tube)	≤ 50 seconds
Blood volume, Micro Pipette Adapter (MPA)	20 µl
Pre-diluted mode	1:200 to 1:300 using min. 20 µl e.g. 20 µl to 4.5 ml diluent (1:225)
TFT-LCD display	Graphical color touch screen, 240 columns x 320 rows
Keyboard	Virtual incorporated keyboard (External keyboard option)
Number of Samples per hour (Open Tube)	> 60 samples
Number of Samples per hour (Cap Piercer)	> 45 samples
Number of Samples per hour (Autoloader)	> 43 samples
QC capabilities	Mean, SD, CV, Levey-Jennings plots and X-B with up to 10,000 samples history
Control sample memory capacity	At least 1000 control samples
Sample memory capacity	At least 1000 samples
HGB correction on high WBC counts	Yes
Warning flags on parameter abnormalities	Yes
Floating discriminator RBC/PLT	Yes (position printed)
Automatic HGB blank on each sample	Yes
Carry over	HGB, PLT, RBC, WBC ≤ 1%
Barcode reader input	Yes
Serial output	Yes (Conformed to standard EN 60950)
Main Voltage	100 – 240 V AC External Power Adapter 24 V DC
Power consumption	Max 100VA
Power consumption (stand-by)	Max 20VA
Frequency	50 / 60 HZ
Noise level	< 65 dB(A)
Built-in test / adjustment programs	Yes
Temperature	18 - 32°C (64 - 90°F)
Humidity (noncondensing)	Up to 80%
Dimensions (Basic/Standard/Closed Tube)	HxWxD = 410 x 290 x 460 mm
Dimensions (Autoloader)	HxWxD = 430 x 330 x 460 mm
Instrument weight (Basic/Standard/Closed Tube)	≤ 18 kg
Instrument weight (Autoloader)	≤ 22 kg
Diluent Consumption	Approximately 22 ml per analysis cycle.
Lyse Consumption	Approximately 4.5 ml per analysis cycle.

11.3 Parameter Ranges

Linearity-Regression and Linear Range

Linearity measured according to Boule I-1040 Section 8, based on Standard EP6-A.

Parameter	Difference (whichever is greater)	Linearity Range
WBC	± 0.4 x 10^9/L or 3%	0.5 – 99.9 x 10^9/L
RBC	± 0.05 x 10^{12}/L or 2%	0.30 – 7.00 x 10^{12}/L
PLT	± 10 x 10^9/L or 3%	20 – 1800 x 10^9/L
HGB	± 0.2 g/dL or 2%	2.0 – 24.0 g/dL

Displayed Range

Total range where results are reported, also outside of linearity range.

Parameter	Displayed range
WBC	0 - 119.9 x 10^9/L
RBC	0.00 – 14.00 x 10^{12}/L
MCV	15.0 – 250.0 fL
PLT	0 - 1999 x 10^9/L
HGB	0.0 – 35.0 g/dL

Correlation

Correlation was performed, using an Advia 120 and Medonic CA620 as references. Data derived from 965 normal and abnormal fresh blood samples.

Parameter	Correlation Coefficients (R^2), Advia/Medonic
WBC	≥ 0.98/ 0.98
RBC	≥ 0.97/ 0.98
MCV	≥ 0.98/ 0.99
PLT	≥ 0.98/ 0.99
HGB	≥ 1.00/ 1.00

Reproducibility

Measured as an average of 10 measurements each on 9 different vein K2-EDTA collected normal samples, on 3 instruments, in OT, MPA, Cap Piercer, and Autoloader modes.

Parameter		OT CV (%)	MPA CV (%)
WBC	7.0 x10^9/L	≤1.8	≤2.5
RBC	4.59 x10^{12}/L	≤0.9	≤1.5
MCV	86.8 fL	≤0.5	≤0.5
PLT	239 x10^9/L	≤3.0	≤3.0
HGB	14.3 g/dL	≤0.8	≤1.3

Total System Precision

Typical value from QC testing (n=10), using Boule Con. Calculations are based on 380 instruments, using the highest moving average value of 50 instruments as a **typical value** for each parameter.

Parameter	CV (%)
WBC	≤ 1.8
RBC	≤ 1.1
MCV	≤ 0.3
PLT	≤ 3.3
HGB	≤ 1.0

11.4 Reagents and Reagent Consumption

Description	This section describes the reagent consumption for the Medonic M-Series depending on a sample per day calculation.
Supported Reagents	Use **only** Boule authorized reagents. Erroneous results and damage may occur if other reagents are used.
Diluent Consumption	Approximately 22 ml per analysis cycle
Lyse Consumption	Approximately 4.5 ml per analysis cycle.
Consumption Calculation	The consumption can be approximately calculated depending on the number of samples per day as shown on the graphs below. The figures, presented in the graphs, assume one exit standby and one wash per day. The consumption relation between the Isotonic diluent and the hemolyzing reagent is 5:1, based on 50 samples per day.

Diluent Consumption

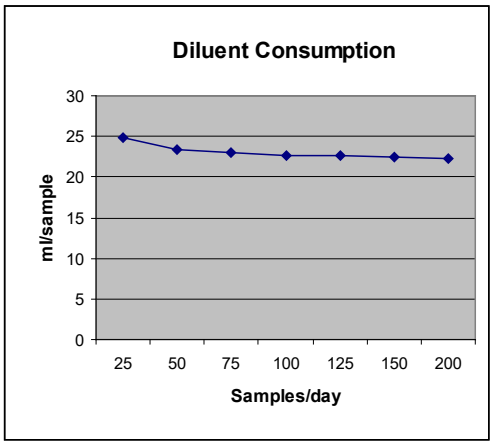


Figure 11.1

Lyse Consumption

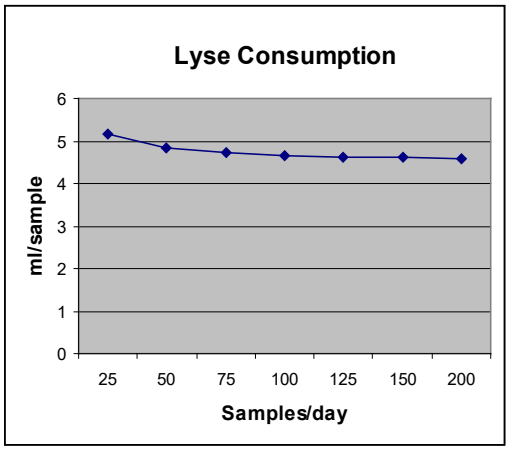


Figure 11.2

Additional Information	For additional information regarding the consumption of cleaning solutions please refer to the Boule Cleaning Kit instruction. (Supplied with the Boule Cleaning Kit).

Section 12: Troubleshooting

Section Overview

Introduction

This section contains information needed to troubleshoot the Medonic M-Series instrument.

Contents

This Section contains the following topics:

12.1 Communication Issues

Description

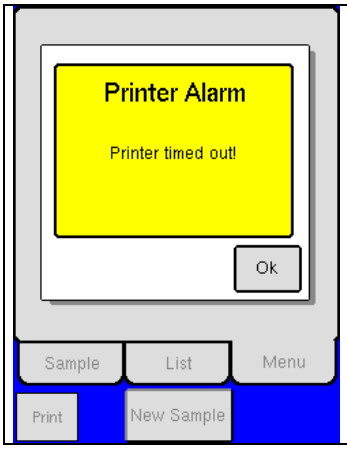
This section contains information regarding errors associated with printers, barcode readers and serial data communication.

Printer Issues

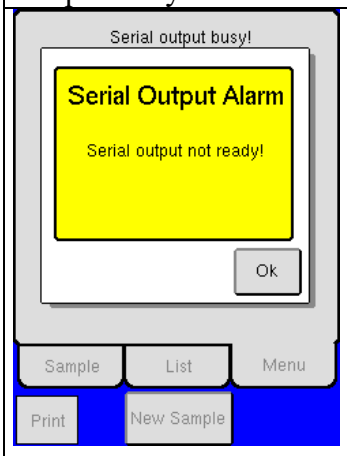
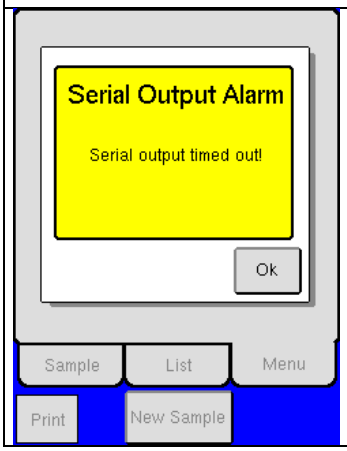
See Section 4.3 Printer Modes for further detail.

If	Then	Possible cause
The printout has unusual layout or strange characters.	1. Verify that printer type matches the printer being used. 2. Verify that the correct paper format has been selected for the printer paper.	1. New printer was connected but not matched with analyzer setup. 2. Printer may need maintenance or to be reset.
Results are not printing out after sample or control analysis.	1. Verify that Auto Print Mode is NOT set to '0'.	1. Auto Print Mode was turned off and not reset.
	1. Printer Alarm message is displayed. 2. Printer is not ready to print, wait unit printer has finished with previous printout. 3. Verify that printer is connected the instrument. 4. Verify that the setup of the instrument is correct for the printer in use.	1. The printer is not connected to the instrument or the printer setup is incorrect. 2. The printer has not completed last printout.

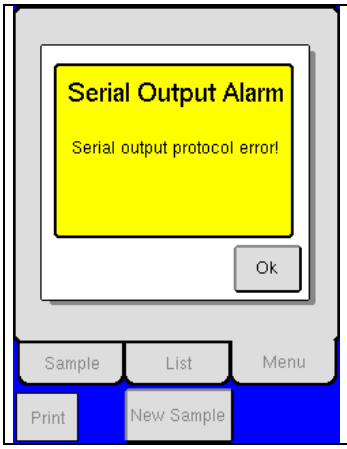
Continued on next page

	1. The Printer is connected to the instrument and on, but not activated. 2. Verify that printer is not in standby or offline. 3. Verify that printer is set to print and not serial port only setup.	1. The printer has timed out. 2. Printer paper may need to be refilled. 3. Incorrect setup for information transmission.

Serial Data Issues See Section 4.3 Data Communication for further detail.

If	Then	Possible cause
The data sent does not seem correct	1. Make sure that the correct HW handshake and Auto Send Mode has been selected.	1. Serial setup in analyzer is incorrect.
Results are not being sent to computer after sample analysis	1. Verify that Auto Send Mode is NOT set to '0'.	1. Auto Print Mode was turned off and not reset.
	1. Serial Output in not ready to transmit. 2. Wait until previous sample has finished transmitting. 3. Then resend selected sample.	1. The analyzer has not completed transmission of last sample.
	1. Make sure that the HW handshake has been selected. 2. Verify that analyzer is connected to computer. 3. Verify that computer is turned on. 4. Verify that analyzer is set to serial output and not print mode only.	1. The serial output has timed out. 2. The computer is not connected to the instrument or the serial output setup is incorrect.

Continued on next page

	1. Make sure that the Send with Ack. has been selected. 2. Verify that computer is turned on and connected to the analyzer. 3. Verify that computer's receiving program is active.	1. Serial output Ack. problem.

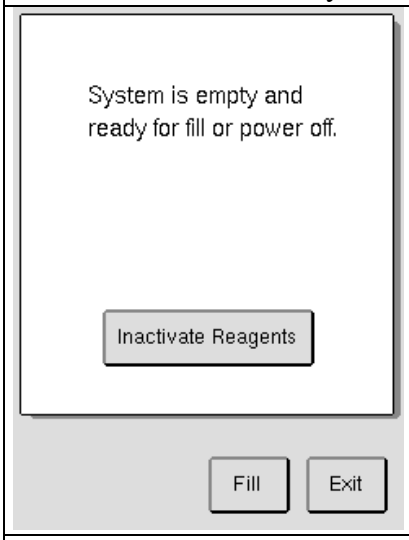
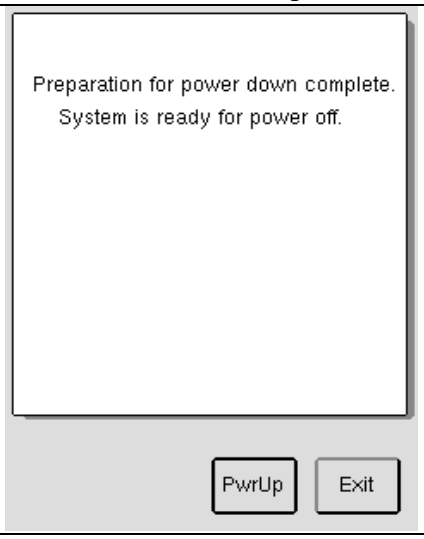
12.2 General Information Displays

Description

This section contains information regarding general information displays.

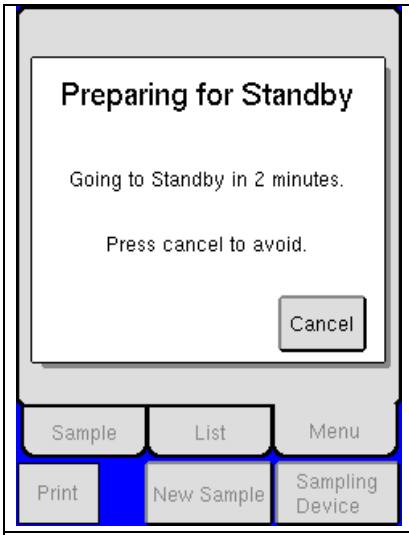
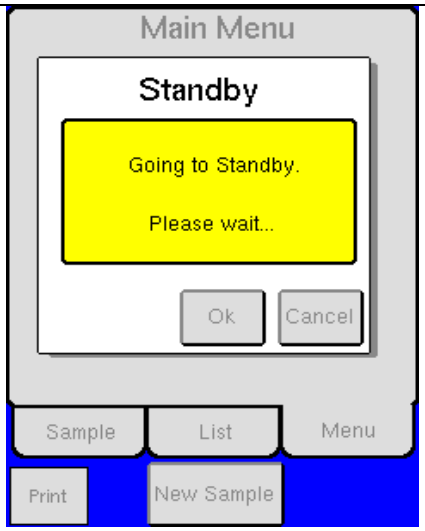
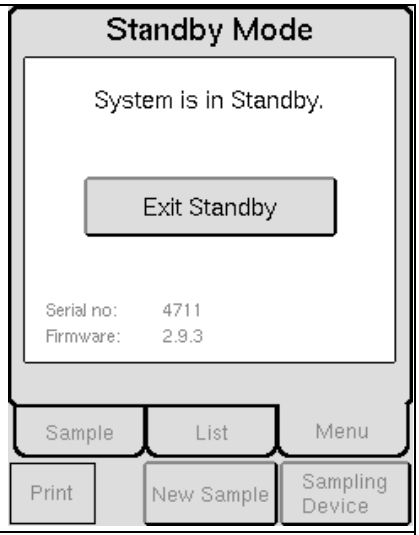
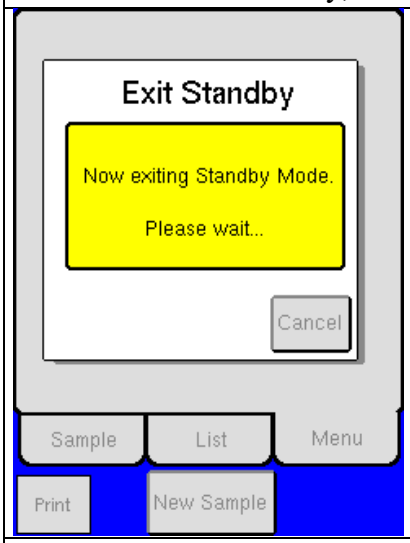
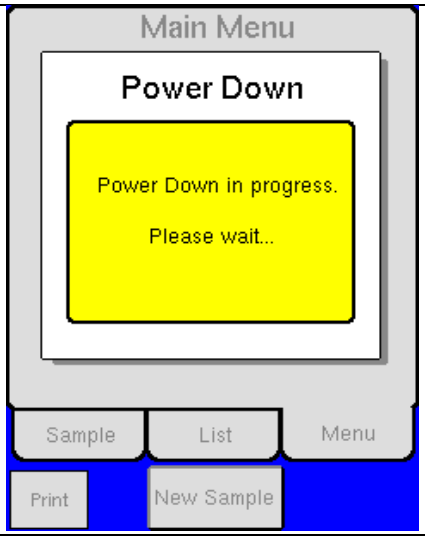
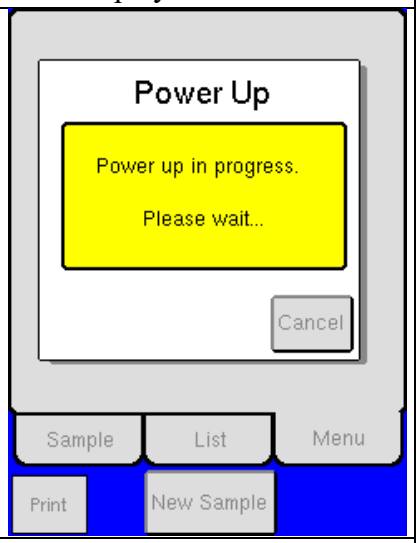
General Information Displays

General information displays are informative screen displays that appear after a function has been completed. Instruction is then displayed for the operator on next step or function to be performed.

Standby, Power Down, and Power Up Informational Displays		
		
The system is empty from all liquid and prepared to be filled with other liquid or be stored away. Press [FILL] if you want to refill system or [EXIT] if you want to return to instrument menu. No analyze can be performed before the instrument is refilled with reagents.	The system is filled with liquid and is prepared for power off. Press [PWR UP] if you want to return the system to active status or [EXIT] if you want to return to instrument menu. It is recommended to use [ENTER STANDBY] and that power is left on, instead of using this feature.	The system has not been used during the preset display saver time. Press [RESUME] to activate the instrument. Once activated, the instrument is ready to perform an analysis.

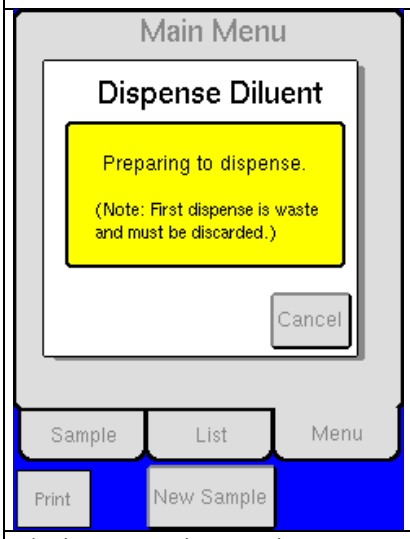
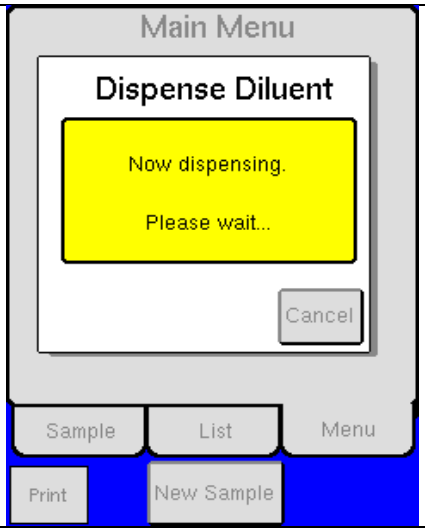
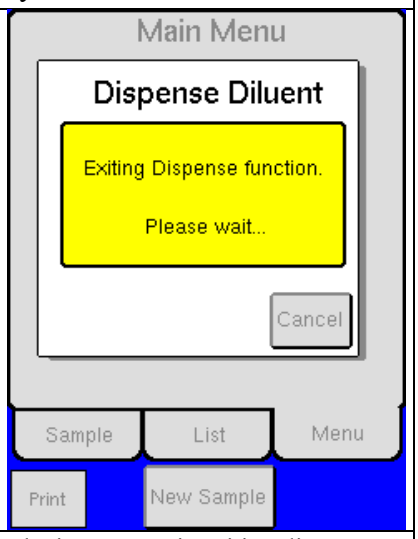
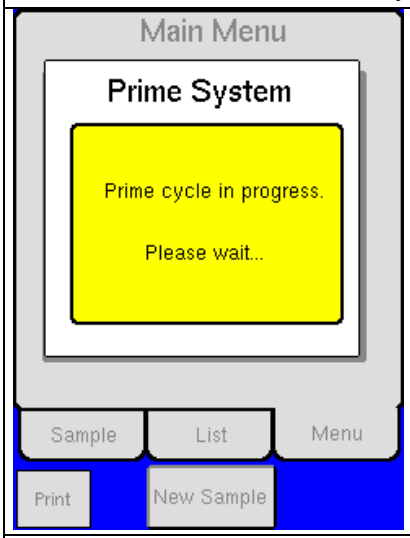
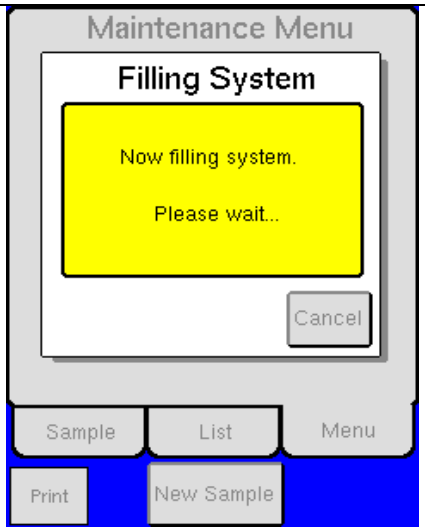
Continued on next page

12.2 General Information Displays (continued)

		
Instrument will enter Standby mode in 2 minutes. Press [CANCEL] to return to instrument menu.	The instrument is in the process of going into Standby. Please wait.	The system is in Standby. Press [EXIT STANDBY] to activate the instrument. Once activated, the instrument is ready to perform an analysis.
Standby, Power Down, and Power Up Informational Displays		
		
The system is preparing the instrument for analysis mode. If the background check is activated, background result will be displayed. Once activated, the instrument is ready to perform an analysis.	The instrument is in process of powering down. Please wait.	The instrument is in process of powering up. Please wait.

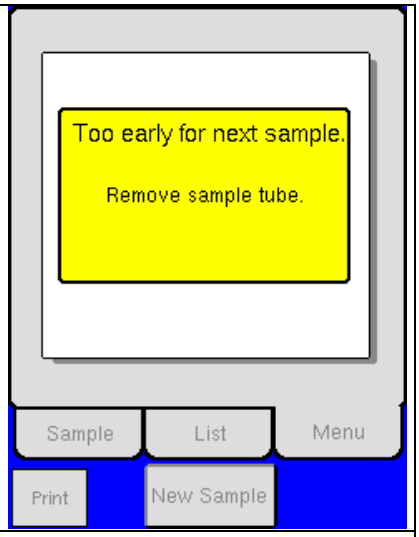
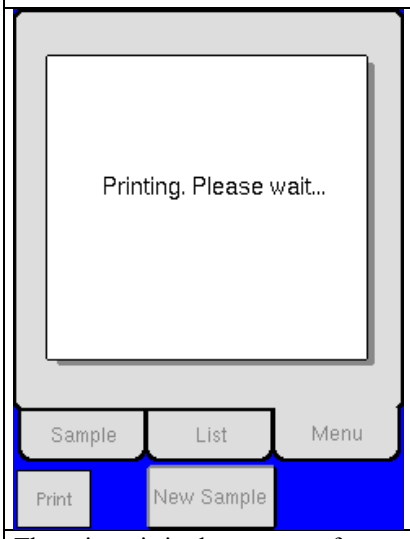
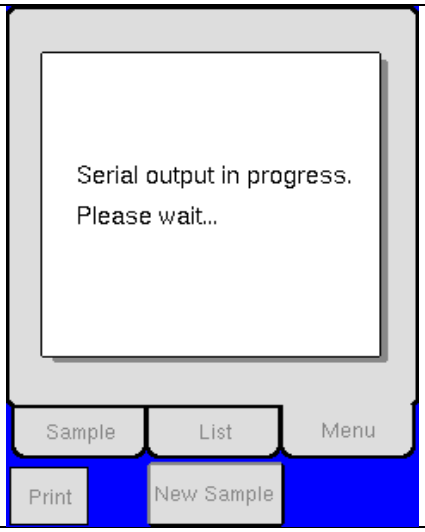
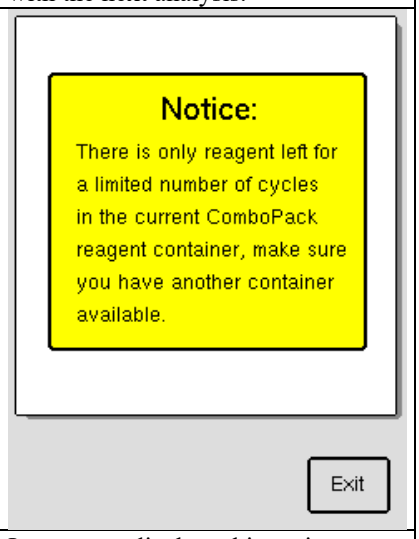
Continued on next page

12.2 General Information Displays (continued)

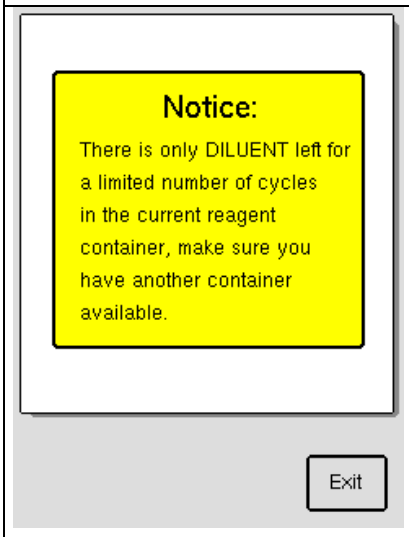
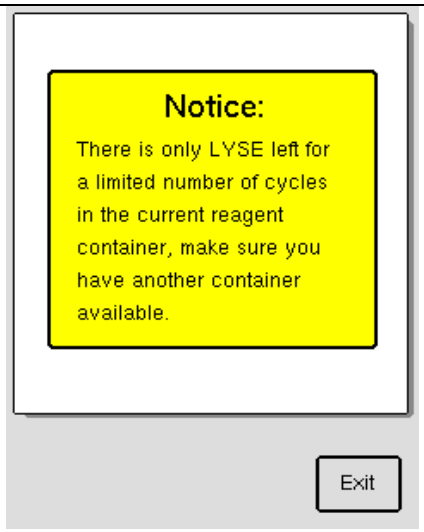
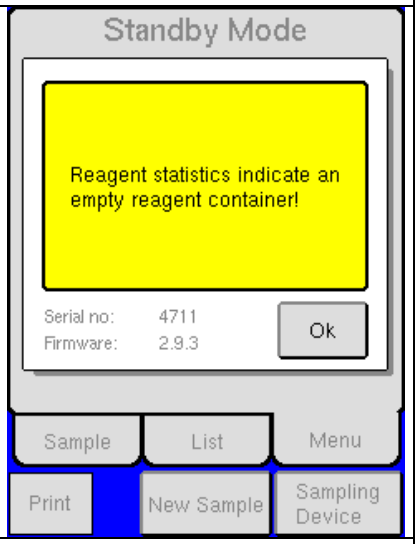
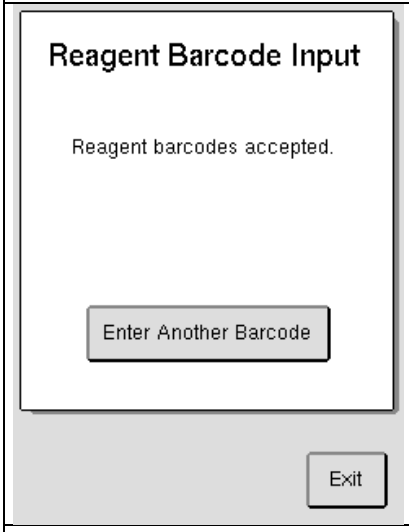
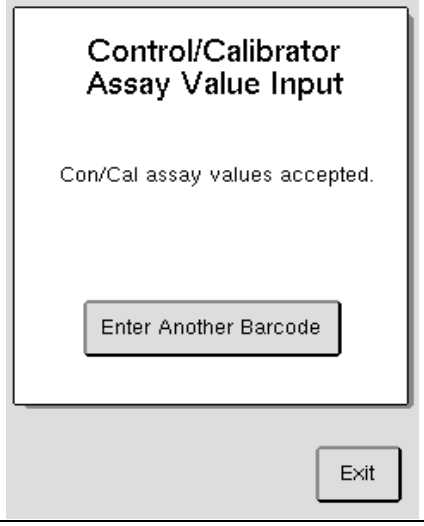
Diluent Dispense Informational Displays		
		
The instrument is preparing to dispense diluent. Dispose of first dispense for best results.	The instrument is now dispensing 4.5 ml of diluent. Please wait.	The instrument is exiting dispense function. Please wait.
Cycle In Progress Informational Display		
		
The instrument is priming the system. Please wait.	The instrument is filling the system. Please wait.	The instrument is emptying the system. Please wait.

Continued on next page

12.2 General Information Displays (continued)

		
The instrument is cleaning the Open Tube needle. Please wait.	Every twelve hour the instrument performs a wash of the system. During wash cycle the instrument can not be used for performing an analysis.	The system has finished the count of cells and displays the results. The analysis cycle in not yet completed, as the system still needs to perform wash cycle for an accurate next sample result. Please wait until the [NEW SAMPLE] button is activated. If needle was submerged in next sample by mistake, perform a background count before continuing with the next analysis.
		
The printer is in the process of printing. Please wait.	The analyzer is in the process of transmitting serial output data. Please wait.	Instrument displays this notice to inform operator that ComboPack reagents will soon need to be changed. (See Section 2.5 for more detail.)

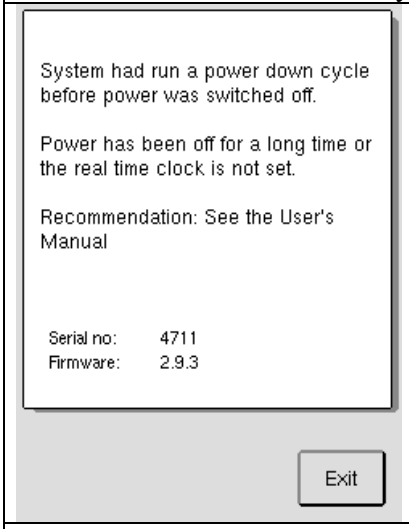
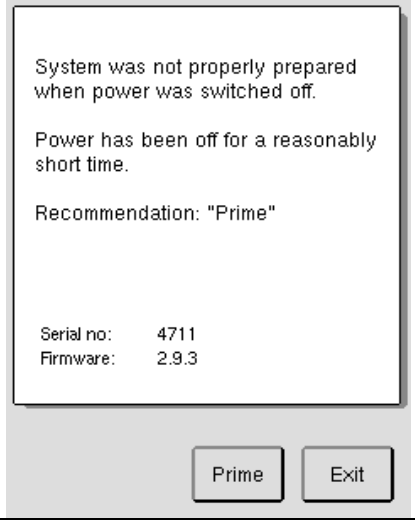
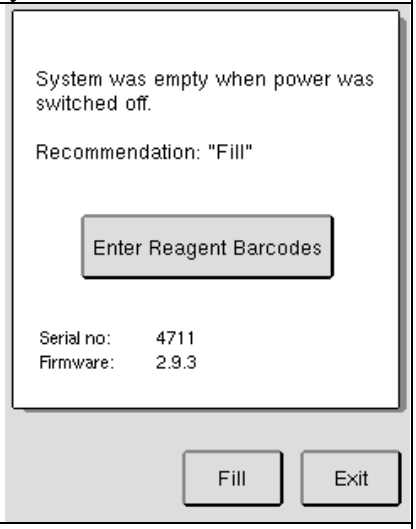
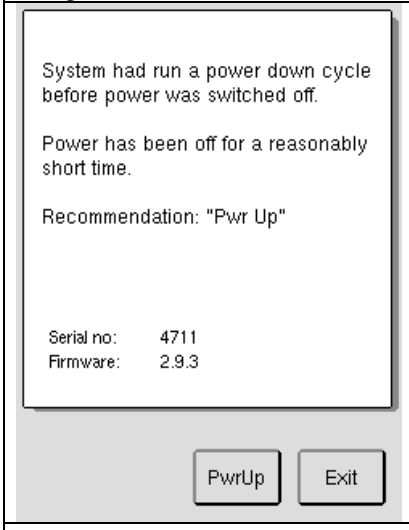
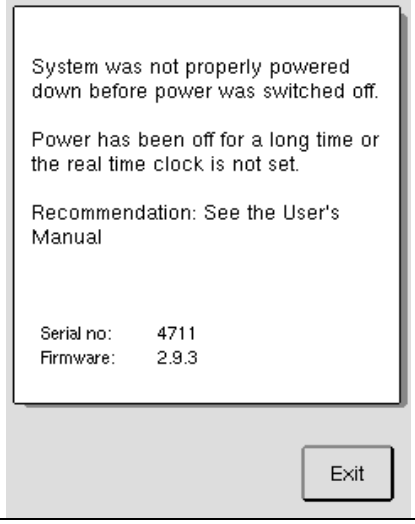
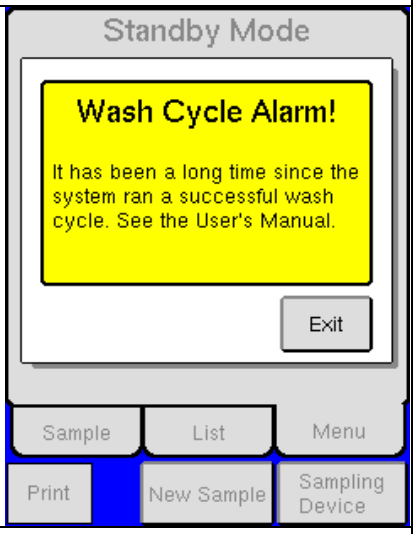
Continued on next page

<table>
<tr><th colspan="3">Reagent and Control Informational Displays</th></tr>
<tr>
<td> 
</td>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>Instrument displays this notice to inform operator that Diluent reagent will soon need to be changed. (See Section 2.5 for more detail.)</td>
<td>Instrument displays this notice to inform operator that Lyse reagent will soon need to be changed. (See Section 2.5 for more detail.)</td>
<td>Instrument displays this notice when reagent container or containers need to be changed. Not changing reagents at this time could cause erroneous results or possible damage the instrument.</td>
</tr>
<tr>
<td> 
</td>
<td> 
</td>
<td></td>
</tr>
<tr>
<td>The reagent barcodes were scanned in correctly using the barcode reader and the instrument has accepted the values.</td>
<td>The Assay Values were scanned in correctly using the barcode reader and the instrument has accepted the values.</td>
<td></td>
</tr>
</table>

12.3 Warning Displays

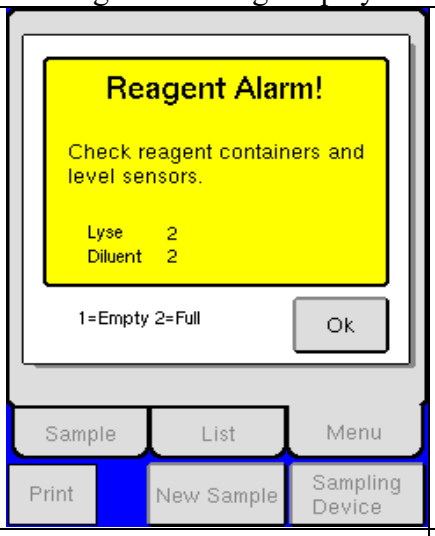
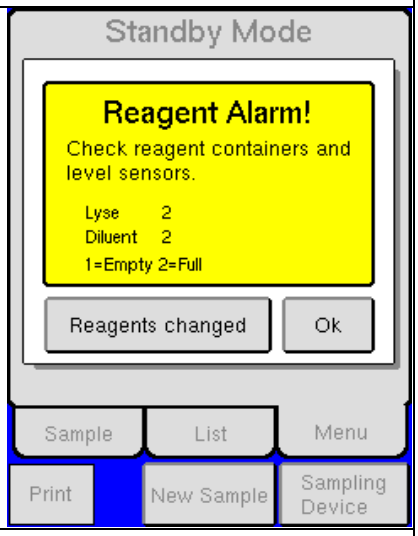
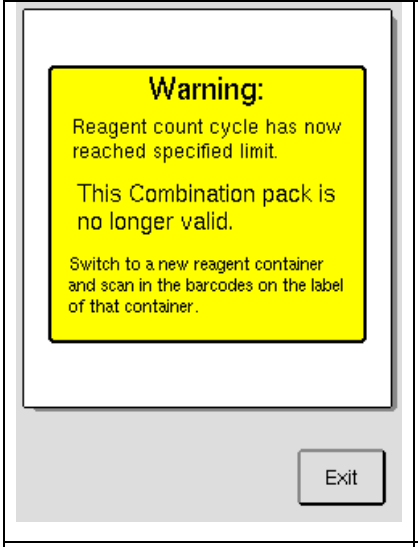
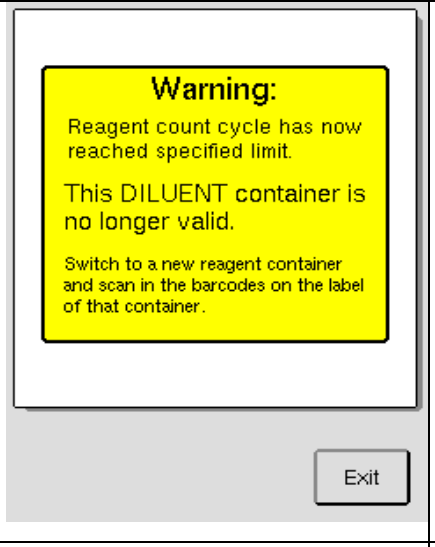
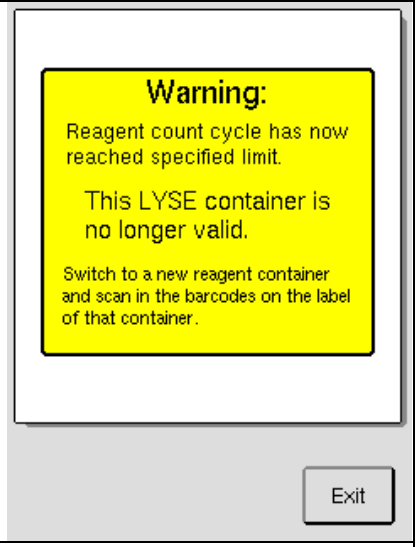
Warning Displays

Warning displays appear after a function has been performed incorrectly or to inform the operator that further action is needed to complete the desired task. The warning display describes the situation and instructs the operator on next step or function to resolve issue.

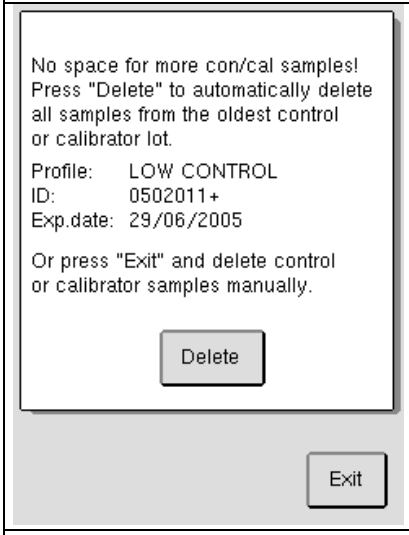
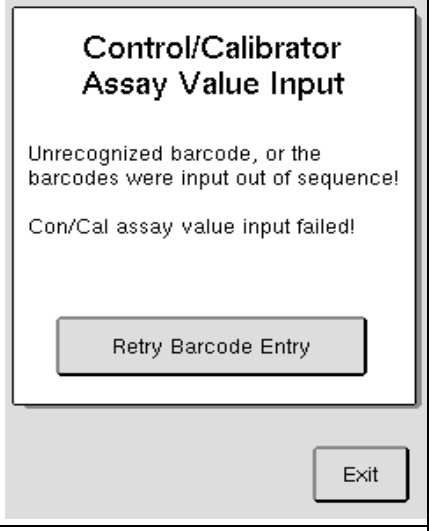
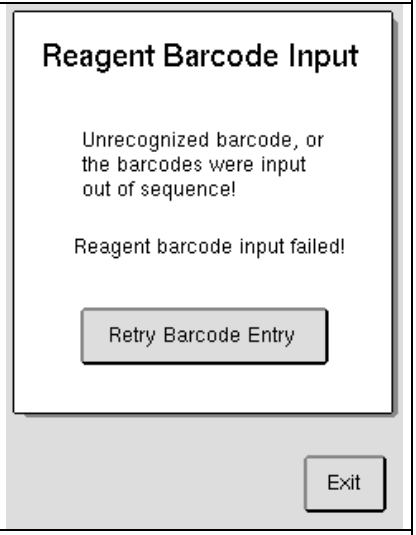
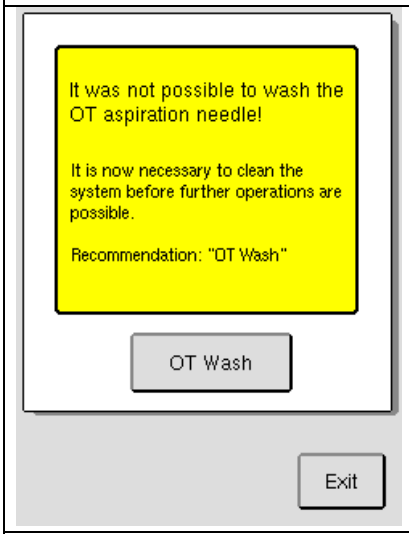
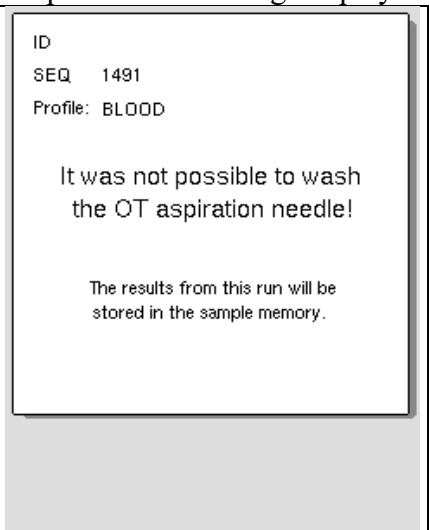
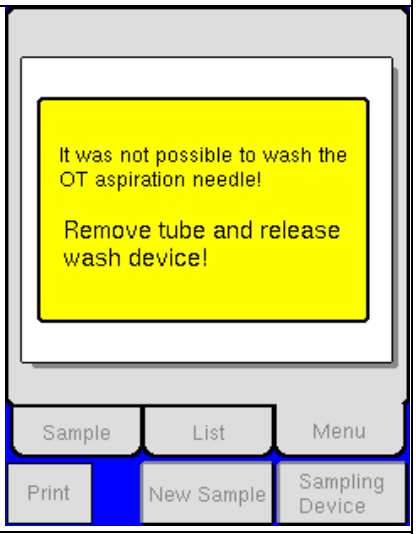
<table>
<tr><th colspan="3">System Power Down Warning Displays</th></tr>
<tr>
<td> 
</td>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>The system has been switched off for a long time period. The instrument has been powered down with all valves open and filled with liquid. Empty and refill the system with reagents, and perform a background count.</td>
<td>The system was switched off incorrectly. Perform a prime to prepare the system for analysis. Check method for correct instrument power down procedure.</td>
<td>The system was manually switched off with system emptied of reagents. Fill the instrument with reagents to prepare for analysis or exit if only a search of instrument menus is needed.</td>
</tr>
<tr>
<td> 
</td>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>The instrument has been switched off with power down function before power was switched off. Perform a power up to prepare the reagent system for analysis.</td>
<td>The system was powered down with liquid in system and has been unused for long period of time. Perform the cleaning procedure according to cleaning kit instruction. Perform a background check.</td>
<td>The regular 12 hour wash has failed. Make sure that reagent containers are filled and the detectors are inserted correctly.</td>
</tr>
</table>

Continued on next page

12.3 Warning Displays (continued)

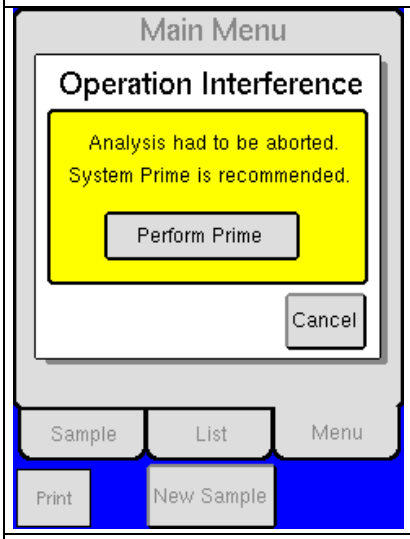
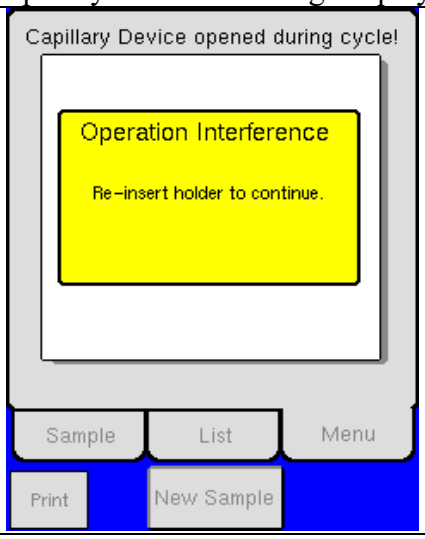
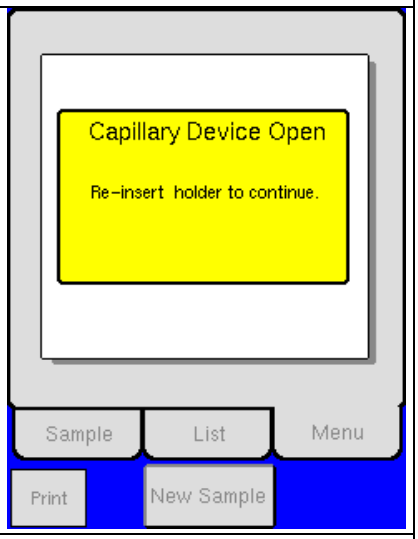
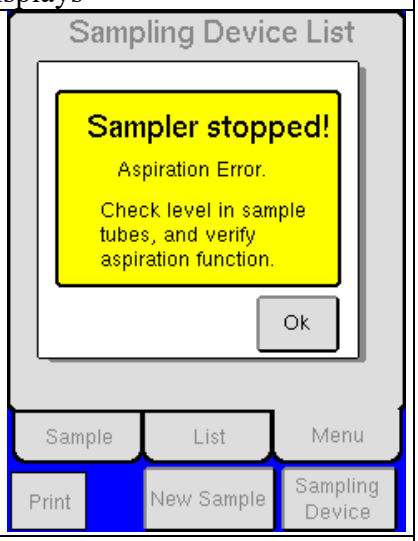
<table>
<tr><th colspan="3">Reagent Warning Displays</th></tr>
<tr>
<td> 
</td>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>The regular 12 hour wash has not been performed. Check if reagent containers are empty and if the reagent detectors are in contact with reagent.</td>
<td>The reagent container or containers are empty. Check if the containers are empty and if level sensors and reagent contact plugs are inserted correctly.</td>
<td>This message is displayed if reagent container or containers are empty when coming out of Standby. Check if the containers are empty and if level sensors and reagent contact plugs are inserted correctly.</td>
</tr>
<tr>
<td> 
</td>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>ComboPack container needs to be changed. Not changing reagents at this time could cause erroneous results or possible damage the instrument. Connect new reagent container and scan in barcode on container. (See Section 2.5 for more detail.)</td>
<td>Diluent container need to be changed. Not changing reagents at this time could cause erroneous results or possible damage the instrument. Connect new reagent container and scan in barcode on container. (See Section 2.5 for more detail.)</td>
<td>Lyse container needs to be changed. Not changing reagents at this time could cause erroneous results or possible damage the instrument. Connect new reagent container and scan in barcode on container. (See Section 2.5 for more detail.)</td>
</tr>
</table>

Continued on next page

Barcode Warning Displays		
		
No more space is available to scan in new assay values. Follow the recommendation or manually delete all the controls with same ID, to free space for scanning the new Control lot. (See Section 6.1 for more detail.)	Assay Value Input failed. The Assay sheet or order of scanning in the barcodes may have been incorrect. Verify that setups on the instrument match the required setup for the barcode reader. (See Section 4.3 and 6.1 for more detail.)	Reagent barcode scanning failed. Barcode printing or order of scanning in the barcodes may have been incorrect. Verify that setups on the instrument match the required setup for the barcode reader. (See Section 4.3 and 4.4 for more detail.)
Open Tube Warning Displays		
		
The instrument was unable to wash the Open Tube aspiration needle. Verify that tube is removed and wash device is in correct position, then perform OT Wash.	The instrument was unable to wash the Open Tube aspiration needle. Verify that tube is removed and wash device is in correct position. It is recommended that background count is performed before next sample analysis.	The instrument is unable to wash the Open Tube aspiration needle. Verify that tube is removed and wash device is in correct position. It is recommended that background count is performed before next sample analysis.

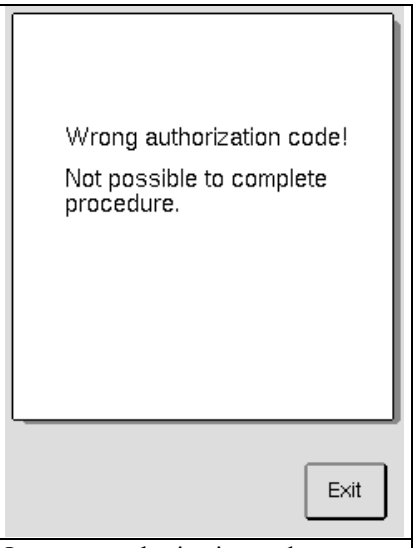
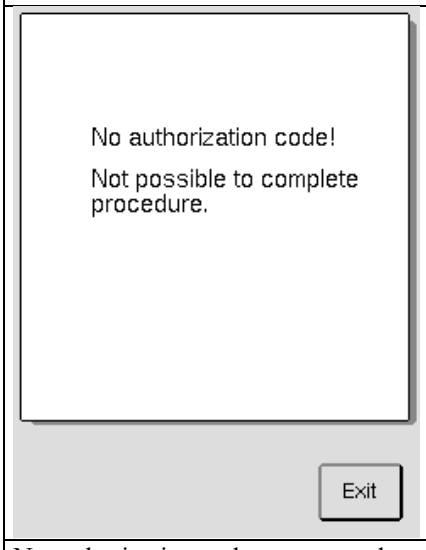
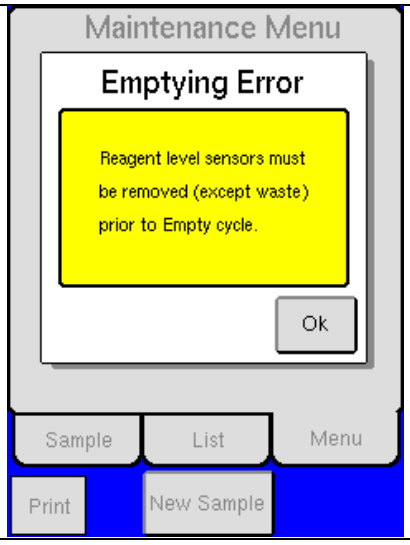
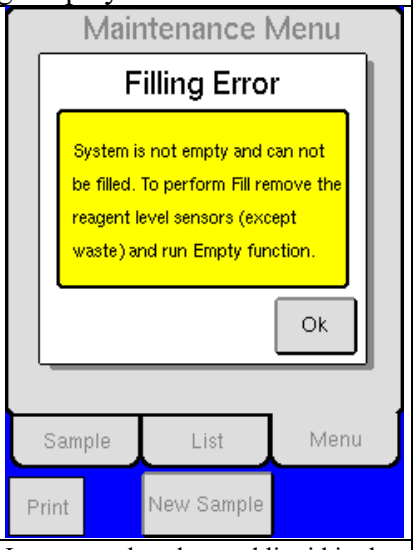
Continued on next page

12.3 Warning Displays (continued)

<table>
<tr><th colspan="3">Capillary Device Warning Displays</th></tr>
<tr>
<td> 
</td>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>The MPA was opened during an inappropriate time. It is recommended to perform a prime cycle before next analysis.</td>
<td>The MPA was opened during a cycle or analysis. Re-insert holder, and follow suggested recommendation.</td>
<td>The MPA holder was opened during an inappropriate menu. The MPA holder should only be opened in List, Sample or Main menu.</td>
</tr>
<tr><th colspan="3">Cap Piercer and Autoloader Warning Displays</th></tr>
<tr>
<td> 
</td>
<td> 
</td>
<td> 
</td>
</tr>
<tr>
<td>The Cap Piercer door was opened before the CAP door lock had been activated. Close the Cap Piercer door to continue with the analysis.</td>
<td>The aspiration wheel has been interfered with during mixing. Press [OK] to return to the Sample menu. To proceed with the analyses press [CONTINUE] in Sampling Device List Menu.</td>
<td>Three aspirations have been attempted. All have failed. Verify that sample tubes contain at least 1 ml of blood. (See Section 5.9 for more detail.)</td>
</tr>
</table>

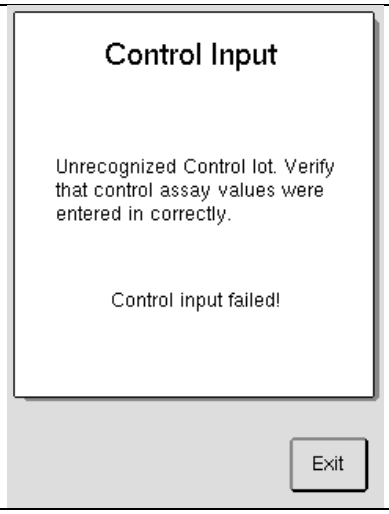
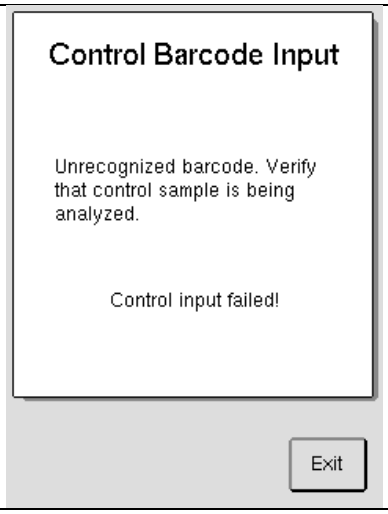
Continued on next page

12.3 Warning Displays (continued)

		
A counting error has been detected in Sampling Device mode. Verify that tubes are in correct position and order. (See Section 5.9 for more detail.)	OT wash device was touched while sampling device was running. See Section 5.9 if emergency sample analysis is needed.	Incorrect authorization code was entered. See calibration section in User Manual for entry of correct authorization code for calibration, or contact your local Boule representative or authorized service technician for service related authorization codes.
Authorization Code and Installation Warning Displays		
		
No authorization code was entered. See calibration section in User Manual for entry of correct authorization code for calibration, or contact your local Boule representative or authorized service technician for service related authorization codes.	Reagent level sensors must be removed from the reagent containers when emptying the system. Verify that both level sensors have been removed.	Instrument has detected liquid in the system. The empty cycle must be run prior to a fill cycle. Run the Empty function to remove any extra liquid remaining in the system then fill the instrument with reagents.

Continued on next page

12.3 Warning Displays (continued)

		
Assay Value Input failed. The Assay sheet or order of scanning in the barcodes may have been incorrect. Verify that setups on the instrument match the required setup for the barcode reader. (See Section 4.3 and 6.1 for more detail.)	The barcode scanned in is not recognized as a control sample in the system. Verify that control sample is being scanned in. (See Section 6.1 for more detail.)	

12.4 Aspiration Issues

Description This section contains information regarding errors associated with aspiration and the aspiration needle.

If	Then	Possible cause
No aspiration of sample is taking place.	1. Verify that there are no leaks and tubing is connected properly and not kinked. 2. Perform valve check in Service Menu. 3.Perform clot prevention. See Section 8.2. 4. If clot prevention cycle does not work perform clot removal procedure. See Appendix A.	1. Blockage of tubing or leak causes sample to not be pulled correctly through shear valve. 2. Valve malfunction. 3. Clot in sample caused by incorrect sample handling or pathologic sample.
No cleaning of aspiration probe	1. Suggest cleaning upper area of aspiration needle. 2. Verify that there are no leaks and tubing is connected properly and not kinked	1.Sample tube is touching the upper part of the aspiration needle when analyzing. 2.Diluent is not flowing correctly through tubing to aspiration needle.

12.5 Troubleshooting Other Issues

Description

See Troubleshooting Flowchart in Appendix B for other possible issues that may arise. Areas on Flowcharts highlighted in dark grey should only be performed by service technician or authorized personnel.

Indication Error Codes

Indications error codes are specific instrument situations that in most cases need the attention of the operator or might need service action.

- The three number indications usually occur after the two number indications. For example, an indication 302 will be displayed due to interference with an OT analysis. It states that the OT cycle was aborted.
- The first indication display is the most important as it describes the issue and how to solve the problem. The three digit indication after a two digit one is added information for the user.
- In most cases, the instrument is stopped and the operator has to confirm with [OK] to continue. Once [OK] is pressed and instrument returns to display menus, user should repeat previous actions again (e.g. re-analyze sample, printing results, etc.)
- If indication error appears again or a three digit indication was displayed as the first indication message, contact your local Boule representative or authorized service technician.

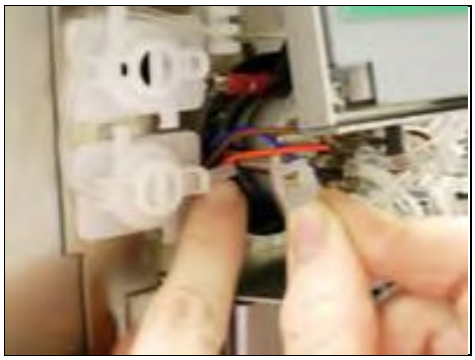
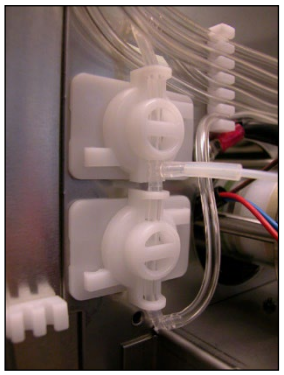
Indication Series	Description
1 - 19	Indication series for auxiliary errors like battery faults or similar.
20 - 29	Indication series for ‘Liquid’ errors.
30 - 39	Indication series for Communication errors between the PCBs (CAN bus).
40 - 49	Indication series for Printer and serial output errors.
50 - 59	Indication series for General Memory errors.
60 - 69	Indication series for EEPROM/HPC (High Performance Controller) errors.
70 - 79	Indication series for Shear Valve problems.
80 - 89	Indication series for Cap Piercer errors (Closed Tube Adaptor)
90 - 99	Indication series for Sampling device errors.
100-255	Indication series for internal hardware and software problems, and messages during subboard firmware upgrades.
300 -399	Indication series for cycle aborted indication numbers.

Appendix A: Clot Removal

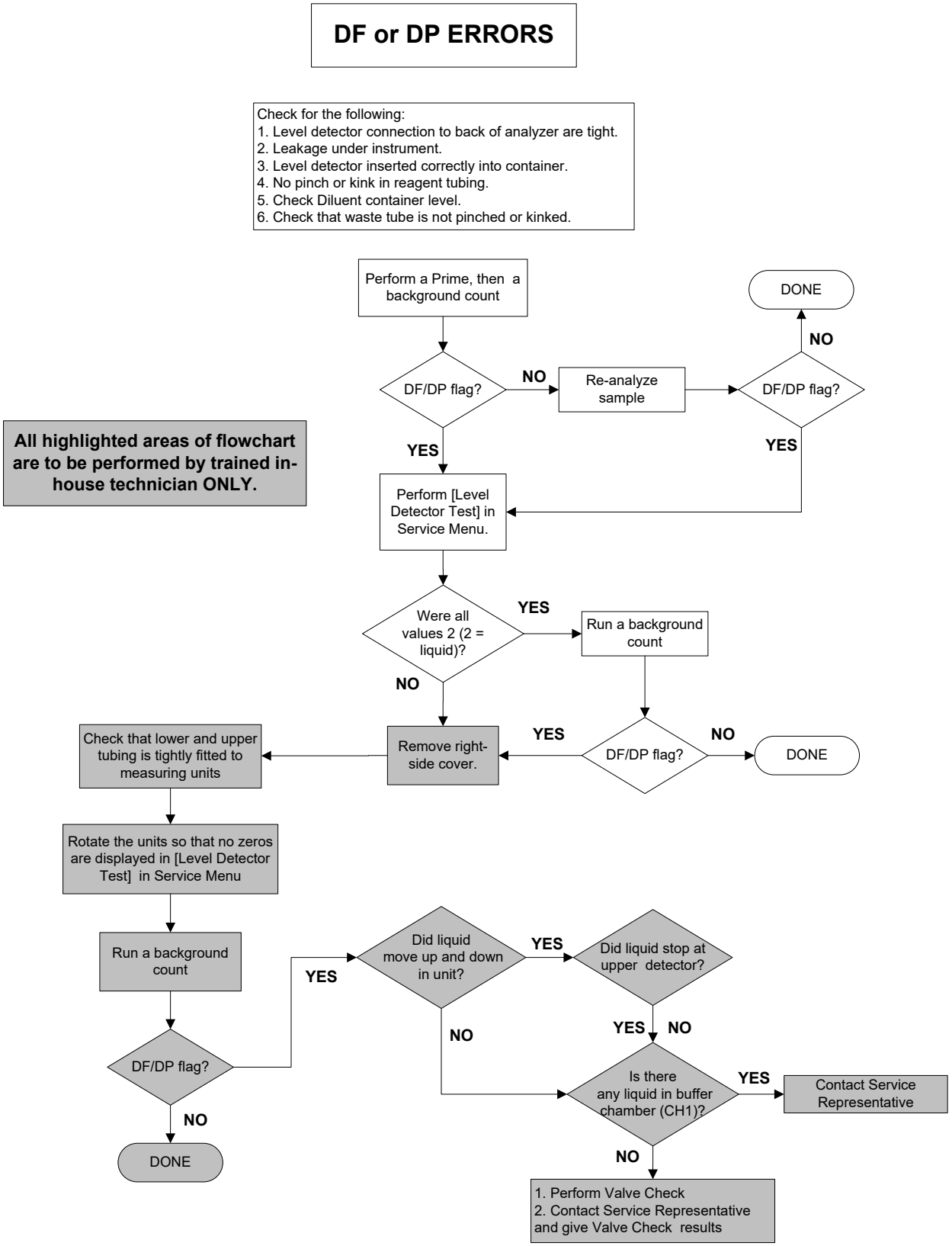
Clot Removal This process will help operator to remove a clot from the system. This should only be used when the OT aspiration needle is blocked and Clot Prevention procedure can not be performed. THIS SHOULD ONLY BE PERFORMED BY A SERVICE TECHNICIAN OR AUTHORIZED PERSONNEL.

Step	Action
1	Remove outer cover: • Press release lever on underside of cover.  Figure 13.1 • While pressing release lever, place one hand on top of analyzer to stabilize and then gently pull bottom of cover forward (only enough to slide pass release lever)  Figure 13.2  Figure 13.3 • Place both hands on upper sides of cover and carefully pull towards you.  Figure 13.4 • Place cover aside.
Important	• Be very careful when removing cover to not damage analyzer. • Follow directions and do not force. • Be aware of aspiration and pre-dilute needles. • Wear protective gloves and safety goggles for this procedure.

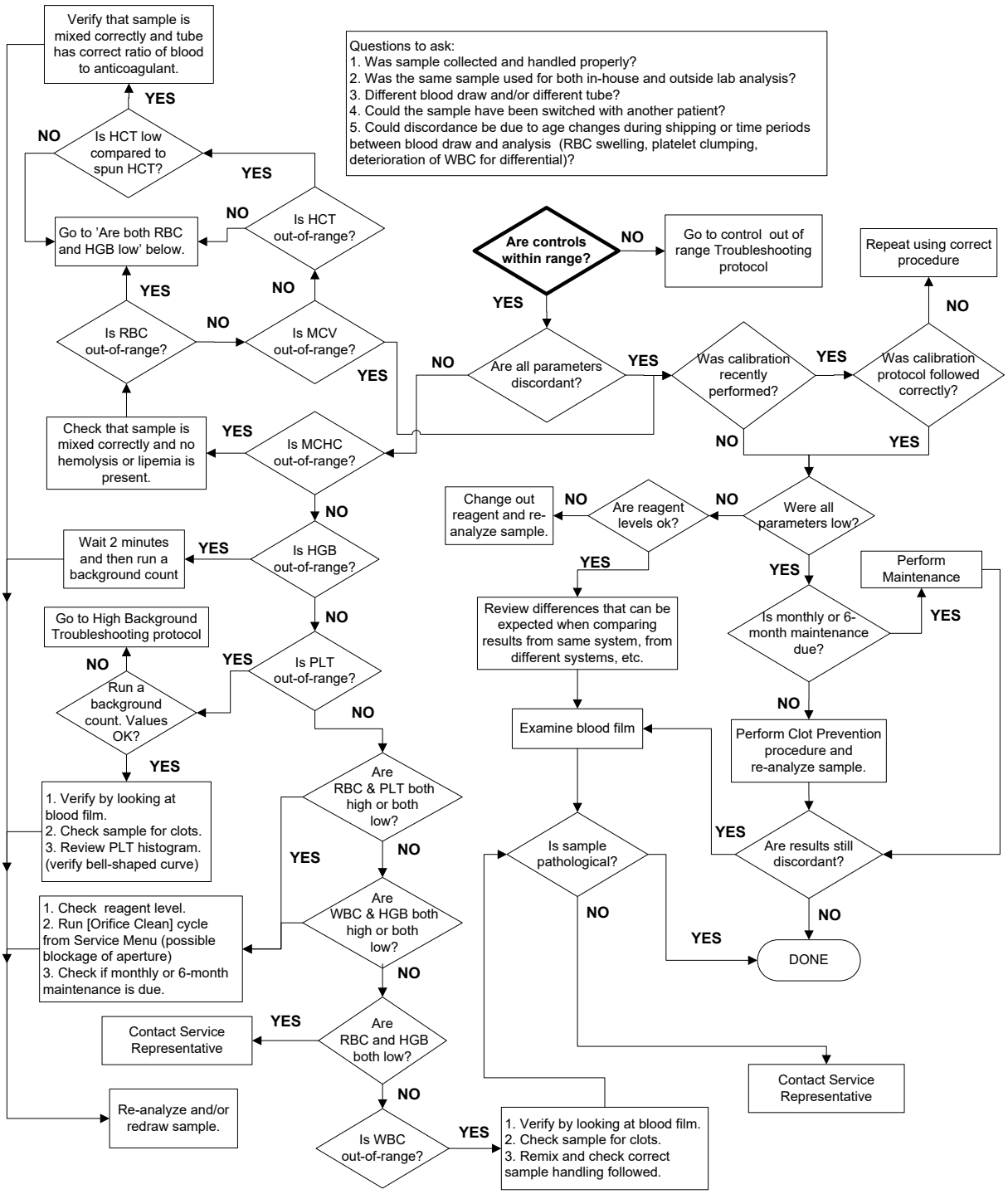
CLOT REMOVAL PROCEDURE (continued)

Step	Action
2	Disable blood mixer by selecting [ADVANCED] from Main menu, then [SETUP], then [SETUP 2], then [SETUP 3], and then [MIXER SETUP]. To inactivate select button and select ([ ]). Press [EXIT] four times to return to Advanced menu.
3	Prepare a syringe by attaching a piece of maintenance tubing to syringe tip and fill syringe with 2% Hypochlorite solution. (Hypochlorite from the cleaning kit can be used.)
4	Locate the Valve 27, the lower valve directly to the left of shear valve.
5	Locate the L (elbow) connector on the right-hand side of this valve and disconnect the L connector from ONLY the tubing that is threaded through valve. (For Cap Piercer and Sampling Device disconnect tube from T connector between Valves 27 and 30.)
6	From Main Menu press [ADVANCED] and then press [SERVICE].
7	 Figure 13.5  Figure 13.6
8	Attach prepared syringe tubing to L connector, press [CLOT REMOVAL], press [OK], and gently apply pressure back and forth to syringe until clot is loosened. If obstruction is not removed at this point, flush in 2% Hypochlorite solution and wait 15 minutes allowing the solution to dissolve the clot.  Figure 13.7  Figure 13.8
9	After 15 minutes, if screen has gone blank, touch screen and select [RESUME]. Press [OK] to run clot removal cycle and, using the syringe, flush again. Thoroughly flush tubing with 2% Hypochlorite solution until all obstructions are removed.
10	Disconnect syringe and reattach L connector to valve tubing.
11	Replace analyzer cover: • Carefully align top edge of analyzer and display with cover. • Gently, partial push on upper part of cover to fit over display. • Using both hands on sides of covers, slowly press on, fitting over aspiration plates. • If aligned properly release lever will automatically click into place, there will be no spacing between cover and display, and aspiration plates will move freely.
12	Once cover it replaced, press [EXIT] twice to exit out of Service menu. Select [MAINTENANCE] and then perform [CLOT PREVENTION]. See Section 8.2 for more detail.
13	Reactivate the blood mixer by following the steps in Step #2. At the mixer SETUP screen, press the button and select ([X]). Press [EXIT] five times to return to main menu.
14	Run a background count and check that it is within limits (See Section 5.2), and if necessary a control to verify that clot removal was successful.

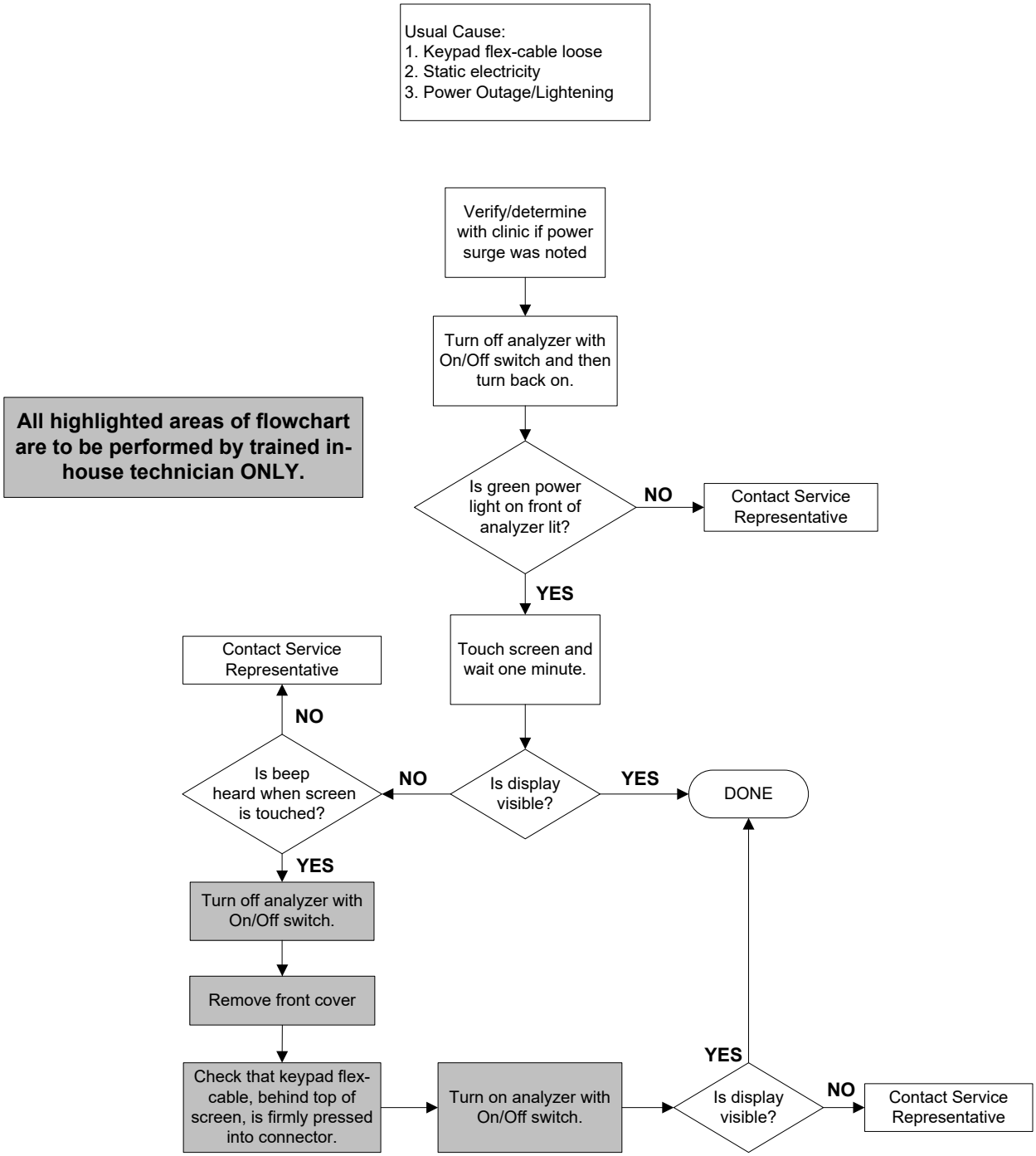
Appendix B: Troubleshooting



Discordant Results

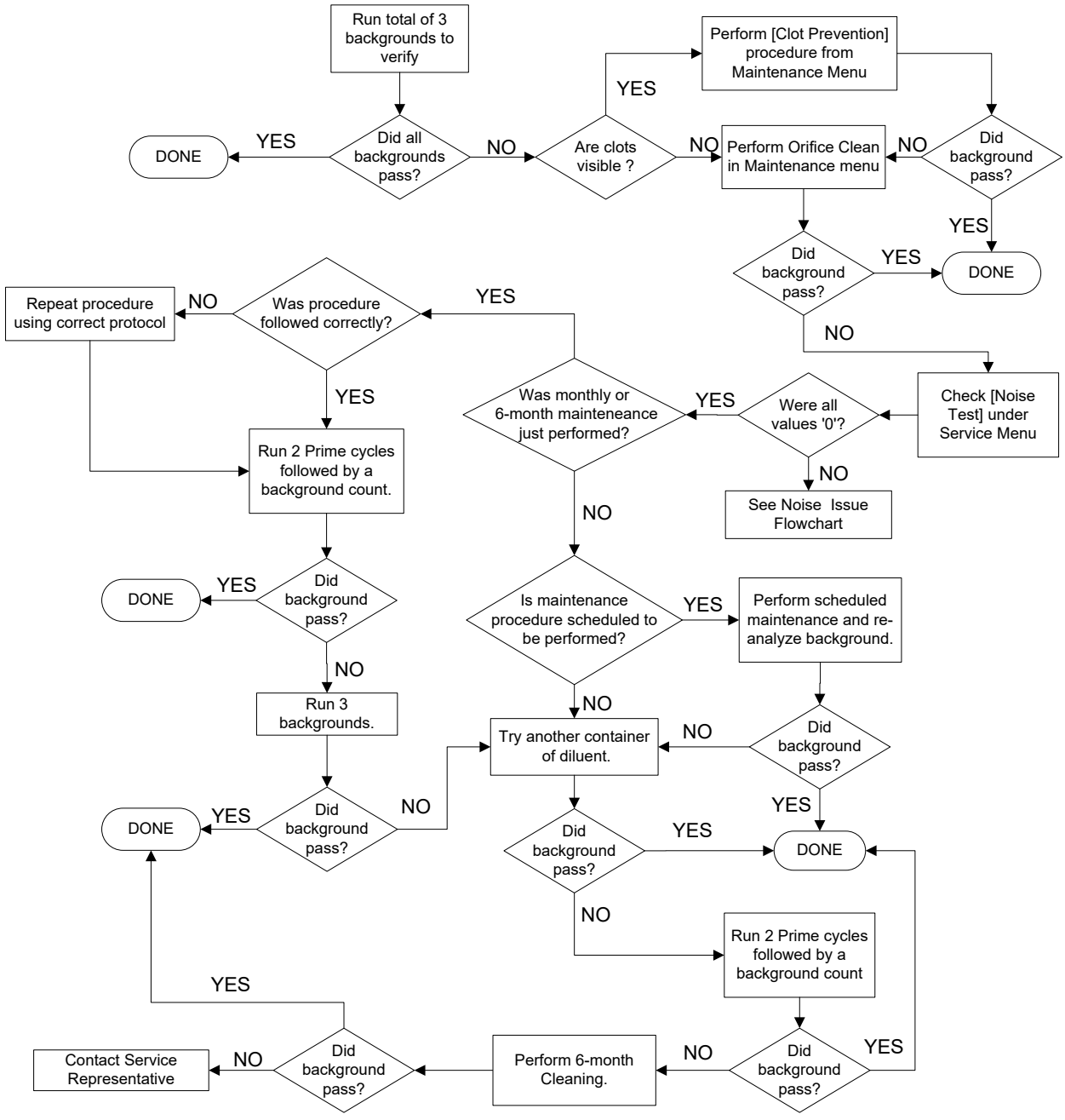


Display Issues

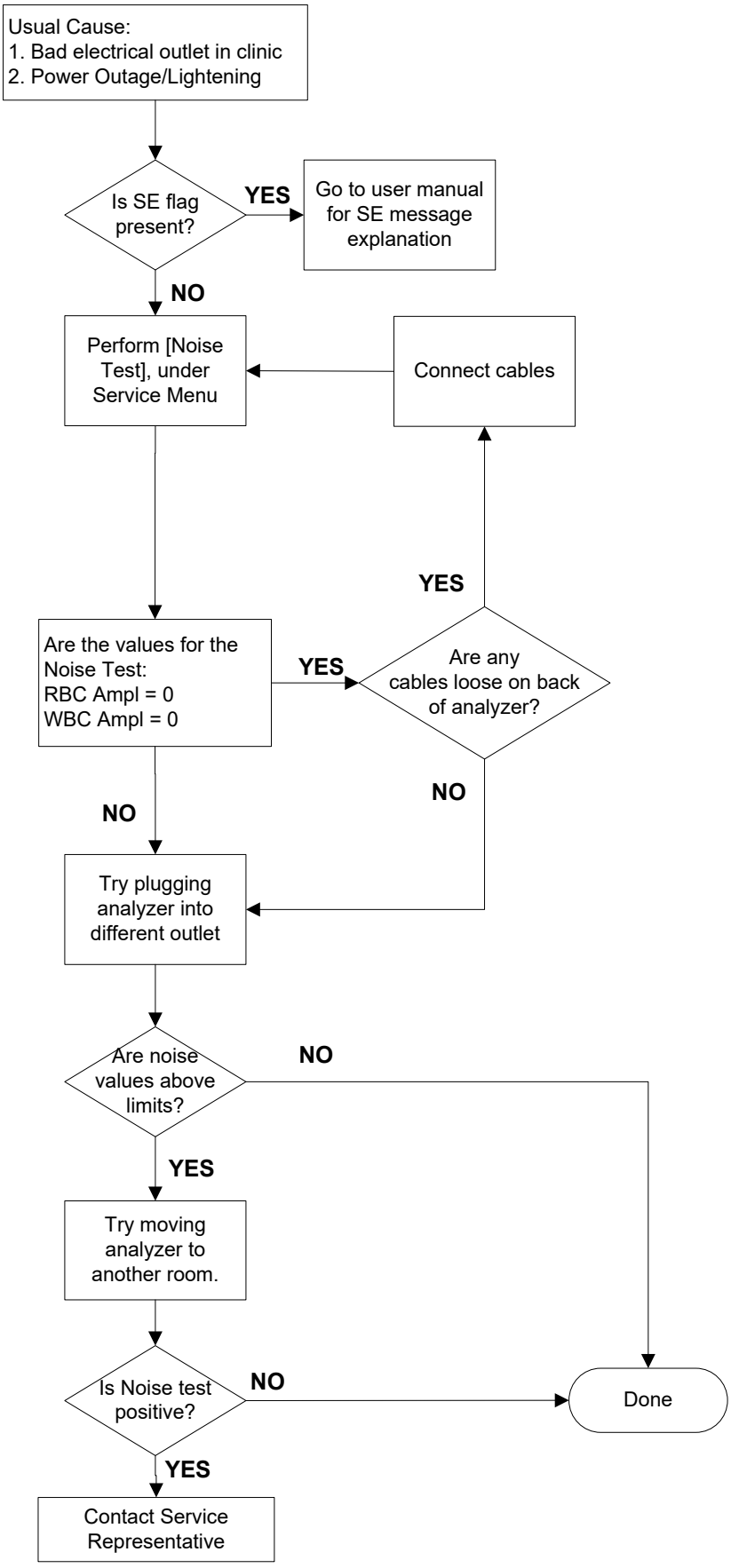


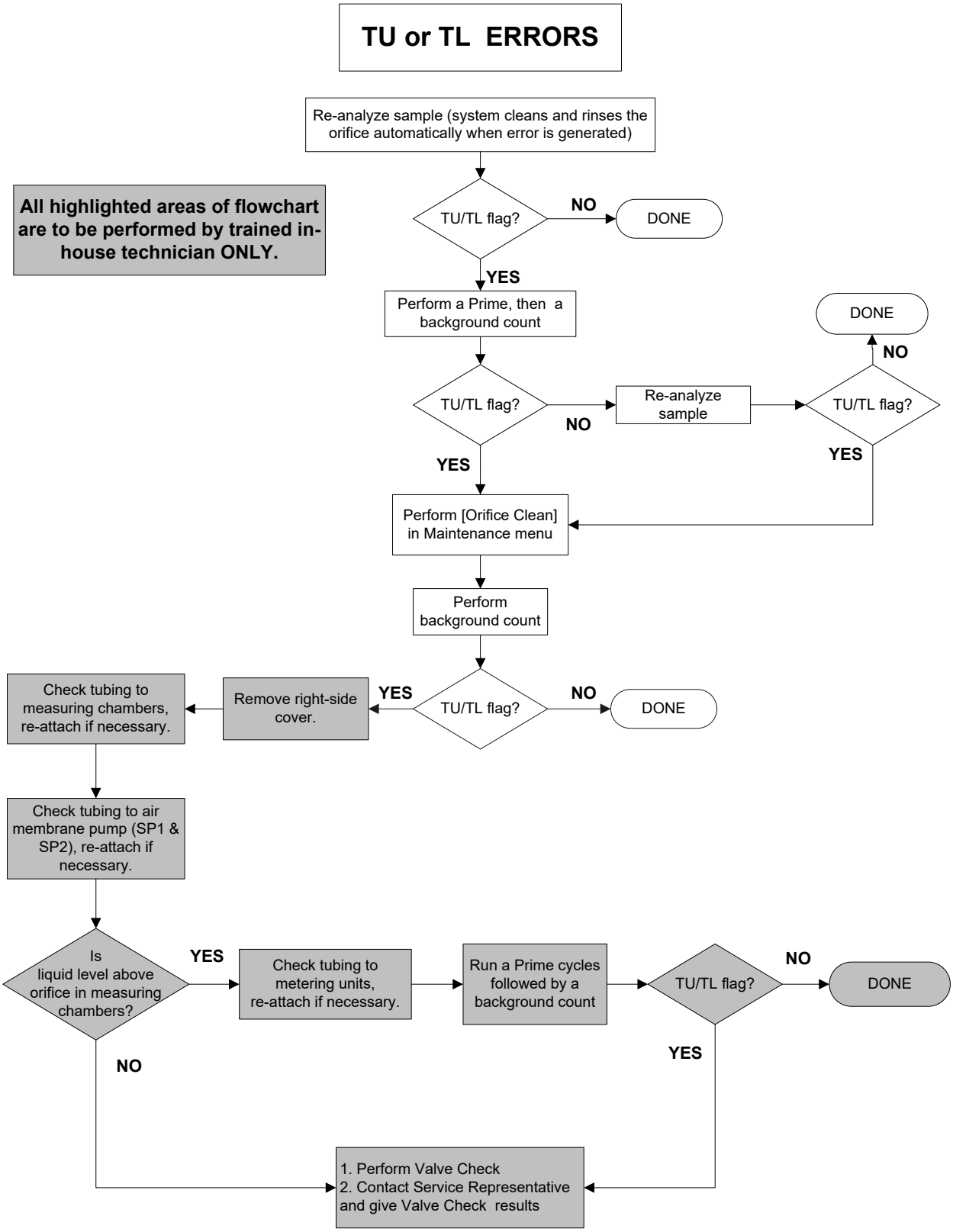
HIGH BACKGROUND COUNTS

Initial Procedure:
1. Check Diluent Lot Number and expiration date.
2. Check age of Diluent (i.e. when was it opened?)
3. Check that level detectors are placed correctly on the reagent containers and firmly tightened on back of analyzer.
4. Check that level detectors are in correct reagent containers (red=diluent, yellow = lyse)
5. Check reagent level.
6. Check environmental condition (i.e. extreme temperature fluctuations?)



Noise Issues




TU or TL ERRORS
Re-analyze sample (system cleans and rinses the orifice automatically when error is generated)
All highlighted areas of flowchart are to be performed by trained in-house technician ONLY.
TU/TL flag?
NO
DONE
YES
Perform a Prime, then a background count
DONE
NO
TU/TL flag?
Re-analyze sample
TU/TL flag?
NO
YES
YES
Perform [Orifice Clean] in Maintenance menu
Perform background count
Check tubing to measuring chambers, re-attach if necessary.
Remove right-side cover.
YES
TU/TL flag?
NO
DONE
Check tubing to air membrane pump (SP1 & SP2), re-attach if necessary.
Is liquid level above orifice in measuring chambers?
YES
Check tubing to metering units, re-attach if necessary.
Run a Prime cycles followed by a background count
TU/TL flag?
NO
DONE
YES
NO
1. Perform Valve Check
2. Contact Service Representative and give Valve Check results

Appendix C: Third Party Software

This page will not be translated from English.

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Appendix D: Consumables

This appendix provides additional information about Boule consumables.

For ordering information, contact your local Boule representative

Consumables

Article number	Article name	Quantity
1500002	Plastic Beaker	≥ 500
1070030	Plastic Micropipettes	10 x 100
1070039	Micropipette, plastic EDTA	1 x 100
1504122	Medonic M-series Diluent 20L*	1
1504123	Medonic M-series Lyse, 5L*	1
1504128	Medonic M-series Dual-pack	1
1504460	Medonic M-series Diluent, RFID	1
1504461	Medonic M-series Lyse, RFID	1
1504465	Medonic M-series DualPack, RFID	1
1504111	Boule Cleaning Kit 3 × 450 ml*	1
1504112	Boule Enzymatic Cleaner 100mL	1
1504113	Boule Hypochlorite Clean 500mL	1
1504019	Boule Con-Diff N 1×4.5 ml	1
1504020	Boule Con-Diff L 1×4.5 ml	1
1504021	Boule Con-Diff H 1×4.5 ml	1
1504022	Boule Con-Diff Tri-L 6×4.5 ml*	2
1504043	Boule Con-Diff N 6×4.5 ml	6
1504176	Boule Con-Diff L 6×4.5 ml	6
1504216	Boule Con-Diff H 6×4.5 ml	6
1504025	Boule Cal 1 × 3.0 ml*	1
1504045	Boule Cal 2 × 3.0 ml	2

*For Latin America, see the table below.

Consumables for Latin America

Article number	Article name	Quantity
501-212	M-series Diluent, 900 cycles	1
501-211	M-series Lyse, 900 cycles	1
501-036	Boule Cleaning Kit 3 × 450 ml	1
501-012	Boule Con-Diff Tri-L 6×4.5 ml	2
501-018	Boule Cal 1 × 3.0 ml	1

For further information on which consumables you require for your analyzer, contact your local Boule representative.

Medonic M-series

Art no 1504614. June 2022

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