Swelab Alfa

User´s manual

Swelab
Still counting, since 1956

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Preface

Introduction

Instrument description

Swelab Alfa 3-part hematology analyzer produced by Boule Medical for human application.

Serial number

Serial number is located on the rear of the instrument.

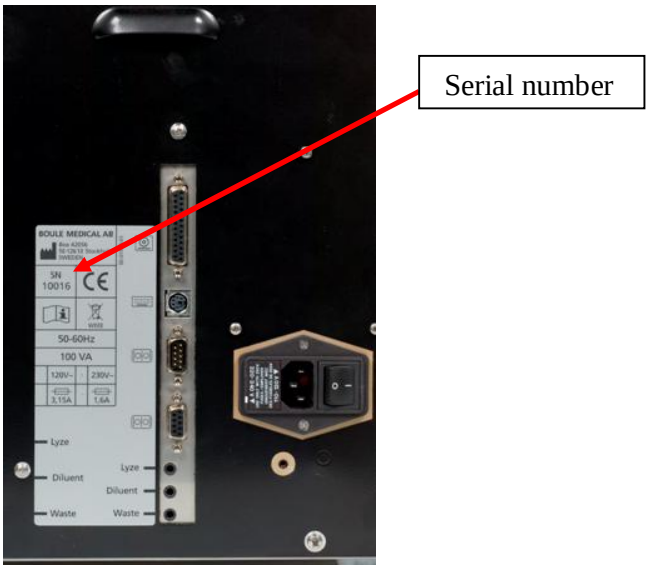

Figure 1.1

Software version

The software version is displayed when starting up the instrument.

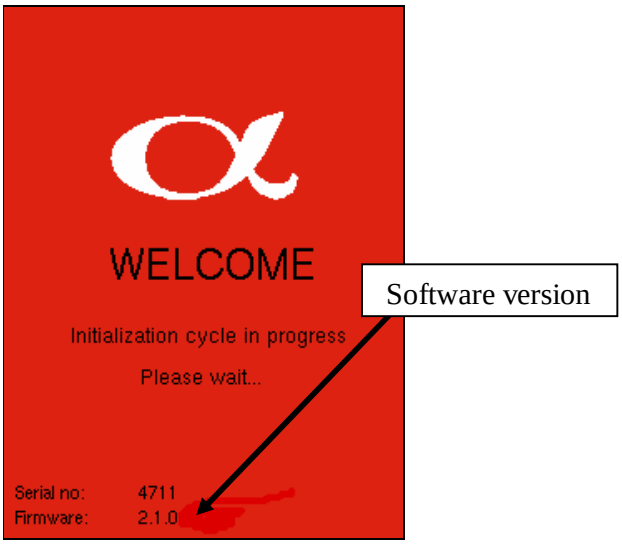

Figure 1.2

Additional Documentation

Additional documentation is available from your authorized distributor. Current additional documentation is listed below:

- Service Manual
- Basic Hematology
- Product data sheets

Operator requirements

The following operator requirements must be fulfilled before operating the Swelab Alfa 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 distributor.

Manufacturer's details

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P.O. Box 42056
SE-126 13 Stockholm
Sweden

Telephone number: +46 8 744 77 00
Fax number: +46 8 744 77 20
Email: info@bm.boule.se

Distributor details

Distributors are listed on http://www.boule.se

International standards

EN591:2001
IVD 98/79/EG
SSEN 61010-2-101 (Low Voltage 73/23/EEC)
EN 61326 (1997) with amendment EN 61326/A1 (1998) (EMC 89/336/EEC)
Standards harmonized with FDA

Date of Issue

April 2006 Article no: 1504154

Section 1: Safety Instructions

Section Overview

Introduction

This section describes the safety features and warnings associated with the Swelab Alfa.

Contents

This section contains the following topics:

Topic	See Page
Intended Use	5
Safety Instructions	6
Biohazards	6
Emergency Procedures	7
Warning Signs in Manual	7
Signs on Equipment	9

1.1 Intended Use

Description

The Swelab Alfa is a fully automatic hematology analyzer intended for in vitro diagnostic testing of blood specimens under laboratory conditions.

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, blood 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, blood 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 Instruction

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 insure 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)



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.

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, blood 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 National Committee for Clinical Lab Standards in the U.S.A. (NCCLS).
- Follow local regulatory documentation.

1.3 Biohazards (Continued)

Handling of biohazardous material

- Always wear protective gloves and goggles. Follow local regulations.
- Handle samples with great care. Report incident according to local regulations.
- Do not touch the waste liquid when discarding waste.



Mandatory Action

- If blood comes in contact with eyes or open cut, wash affected area with plenty of water.
- If the waste liquid is inadvertently touched, wash affected area with disinfectant solution first and follow with soap.

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 authorized distributor.

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 or loss of life 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.

1.6 Signs on Equipment

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

Signs on equipment

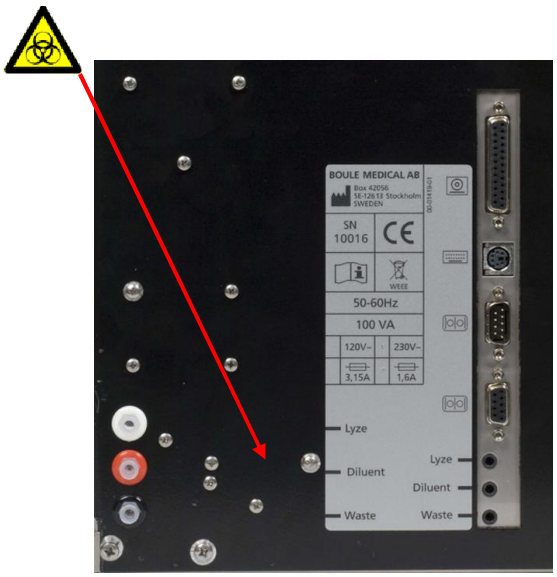


Figure 1.3

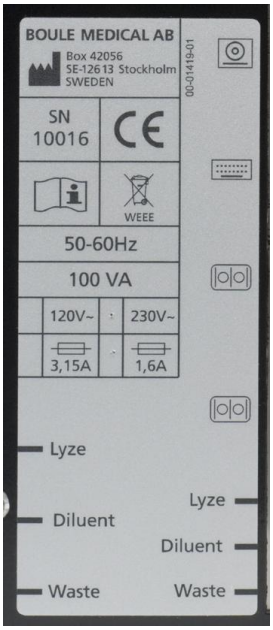


Figure 1.4

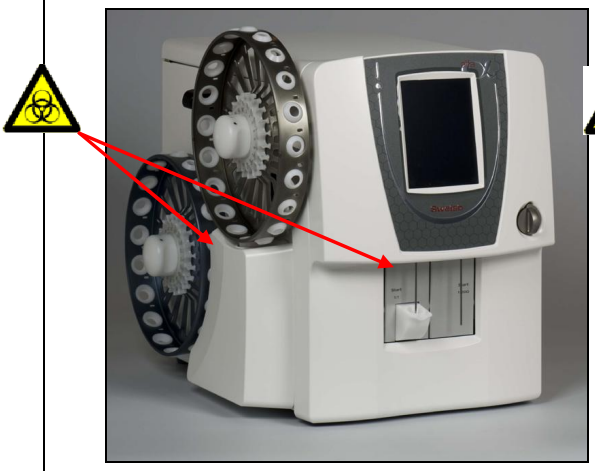


Figure 1.5



Figure 1.6

GB	**Symbols for IVD devices**
DE	**Symbole für IVD Produkte**
ES	**Símbolos de productos IVD**
IT	**Simboli per i prodotti IVD**
FR	**Symboles pour IVD produits**
DK	**Symboler for in vitro-diagnostisk udstyr**
GR	**Σύμβολα για Invitro Διαγνωστικά προϊόντα**
SE	**Symboler för IVD produkter**
PO	**Símbolos para dispositivos IVD**

Boule

art nr –utg okt-03

				Warnings/Warnungen/Advertencias/Avvertimenti/Avertissements/Advarsel/ προειδοποίηση/Varningar/Avisos				
				GB	Caution,consult instruction for use		GB	Biological risk
				DE	Achtung, Gebrauchsanweisung beachten		DE	Biologissche Risiken
				ES	Atención,ver instrucciones de uso		ES	Riesgo biológico
				IT	Attenzione, vedere le istruzioni per l'uso		IT	Rischio biologico
				FR	Attention voir notice d'instructions		FR	Risques biologiques
				DK	Forsigtig se brugsanvisning		DK	Biologisk fare
				GR	Προειδοποίηση, συμβουλευτείτε τα συνοδά έντυπα		GR	Βιολογικοί κίνδυνοι
				SE	Varsamhet, se bruksanvisning		SE	Biologisk risk
				PO	Atenção, ler as instruções de utilização		PO	Risco biológico
				Decree/Verordnung/Decreto/Decreto/Décret/Befaling/ διάταγμα/Påbud/Mandatório				
				GB	Consult Instructions for Use-		GB	Use by
				DE	Gebrauchsanweisung beachten		DE	Verwendbar bis
				ES	Consulte las instrucciones de uso		ES	Fecha de caducidad
				IT	Consultare le istruzioni per l'uso		IT	Utilizzare entro
				FR	Consulter les instructions d'utilisation		FR	Utiliser jusque
				DK	Se brugsanvisning		DK	Holdbar til
				GR	Συμβουλευτείτε τις οδηγίες χρήσης		GR	Ημερομηνία λήξης
				SE	Se bruksanvisning		SE	Använd före
				PO	Consultar as instruções de utilização		PO	Data de validade
				Information/Information/Información/Informazioni/Information/Informasjon/πληροφορία/Information/Informação				
			LOT	GB	Lot number	IVD	GB	In Vitro Diagnostic Medical Device
				DE	Chargenbezeichnung		DE	In Vitro Diagnostikum
				ES	Código de lote		ES	Producto sanitario para diagnóstico in vitro
				IT	Codice del lotto		IT	Dispositivo medico-diagnostico in vitro
				FR	Code du lot		FR	Dispositif médical de diagnostic in vitro
				DK	Lotnummer		DK	Medicinsk udstyr til in vitro-diagnostik
				GR	Αριθμός Παρτίδας		GR	In Vitro Διαγνωστικό Ιατροτεχνολογικό προϊόν
				SE	Lotnummer		SE	In vitro diagnostik
				PO	Número de lote		PO	Dispositivo médico para diagnóstico in vitro
CONT	GB	Content	REF	GB	Catalogue number	CONTROL	GB	Control
	DE	Inhalt		DE	Bestellnummer		DE	Kontrolle
	ES	Contenido		ES	Número de catálogo		ES	Control
	IT	Contenudo		IT	Numero di catalogo		IT	Controllo
	FR	Contenu		FR	Référence du catalogue		FR	Contrôle
	DK	Indhold		DK	Katalognummer		DK	Kontrol
	GR	Περιεχόμενο		GR	Αριθμός καταλόγου		GR	Πρότυπο ελέγχου
	SE	Innehåll		SE	Katalognummer		SE	Kontroll
	PO	Conteúdo		PO	Número de catálogo		PO	Controlo
			CONTROL N 16	GB	Normal control, 16 parameters	CONTROL H 16	GB	High control, 16 parameters
				DE	Normal Kontrolle, 16 Parameter		DE	Hoch Kontrolle, 16 Parameter
				ES	Control normal, 16 parámetros		ES	Control alto, 16 parámetros
				IT	Controllo normale, 16 parametri		IT	Controllo alto. 16 parametri
				FR	Contrôle normale, 16 paramètres		FR	Contrôle haut, 16 paramètres
				DK	Normal Kontrol, 16 parametrer		DK	Høj Kontrol, 16 parametrer
				GR	Πρότυπο ελέγχου Κανονικό, 16 Παράμετρος		GR	Πρότυπο ελέγχου Υψηλό, 16 Παράμετρος
				SE	Normal kontroll, 16 parametrar		SE	Hög kontroll, 16 parametrar
				PO	Controlo normal, 16 parâmetros		PO	Controlo alto, 16 parâmetros
			CONTROL L 16	GB	Low control, 16 parameters	CAL	GB	Calibrator
				DE	Nierig Kontrolle, 16 Parameter		DE	Kalibrator
				ES	Control bajo, 16 parámetros		ES	Calibrador
				IT	Controllo basso, 16 parametri		IT	Calibratore
				FR	Contrôle bas, 16 paramètres		FR	Calibrateur
				DK	Lav Kontrol, 16 parametrer		DK	Kalibrator
				GR	Πρότυπο ελέγχου Χαμηλό, 16 Παράμετρος		GR	Διάλυμα Βαθμονόμησης
				SE	Låg kontroll, 16 parametrar		SE	Kalibrator
				PO	Controlo baixo, 16 parâmetros		PO	Calibrador
				GB	Manufacturer		GB	Temperature limitation
				DE	Hersteller		DE	Zulässiger Temperaturbereich
				ES	Fabricante		ES	Limite de temperatura
				IT	Fabbricante		IT	Limiti di temperatura
				FR	Fabricant		FR	Limites de température
				DK	Producent		DK	Temperaturbegrænsning
				GR	Κατασκευαστής		GR	Περιορισμοί θερμοκρασίας
				SE	Tillverkare		SE	Temperaturbegränsning
				PO	Fabricante		PO	Limites de temperatura

Figure 1.7 IVD Symbol Table

Section 2: Installation

Section Overview

Introduction This section describes how to unpack and install the Swelab Alfa instrument.

Contents This section contains the following topics:

Subject	Topic
Unpacking	10
Installation Constraints	11
Electrical Connections	12
Power Supply	12
Printer Connection	13
Connection, Change and Priming Reagents	14

2.1 Unpacking

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's Manual
- Waste tube
- Reagent Level Sensor and reagent caps for isotonic diluent (Diluent)
- Reagent Level Sensor and reagent caps for hemolyzing reagent (Lyse)
- Power cord
- Installation form
- External Barcode reader

Optional Material

- Printer
- Printer paper
- MCI kit
- External Keyboard
- Reagents, blood controls, calibrators and cleaners

2.2 Installation Constraints

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 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.

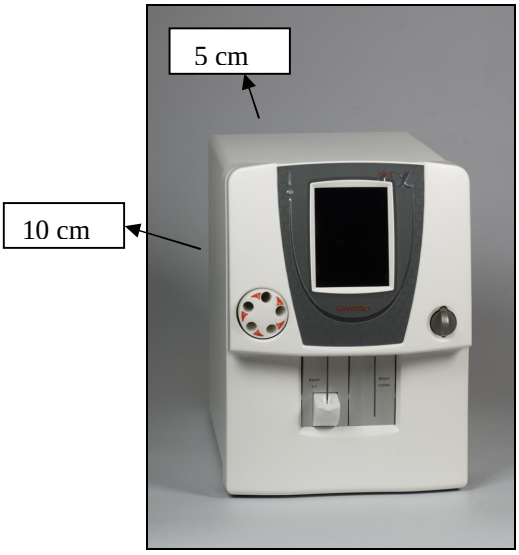


Figure 2.1

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.

2.3 Electrical Connections

Description

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



Figure 2.2

Number	Part	Function
1	Printer port	Connects Printer to analyzer
2	Keyboard port	Connects External Keyboard to analyzer.
3	Serial (male) port	Connects Computer to analyzer.
4	Serial (female) port	Connects Barcode Reader to analyzer.
5	Power Supply port	Connects Main power outlet to analyzer.
6	Ground Connector	Connects Ground connector to analyzer.
7	Electronic Sensors	Connects Reagent Level Sensors to analyzer.

2.4 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 loss of life and/or erroneous parameter results.

Continued on next page

2.4 Power Supply (Continued)

Handling high transient voltage

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



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 injuries and/or loss of life and/or erroneous parameter 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 authorized distributor 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 authorized distributor

Connecting Power Cable

Insert power cable 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.)

2.5 Printer Connection

Description

The printer is connected to the rear of the instrument with printer cable. (Printer is not manufactured by Boule.) See Figure 2.2 for further detail.

Continued on next page

2.5 Printer Connection (Continued)

Supported Printers

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

Compatible Printers

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

2.6 Connection, Change & Priming Reagents

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 Swelab Alfa system.)

Location of Reagent

This section describes placement of reagent containers.

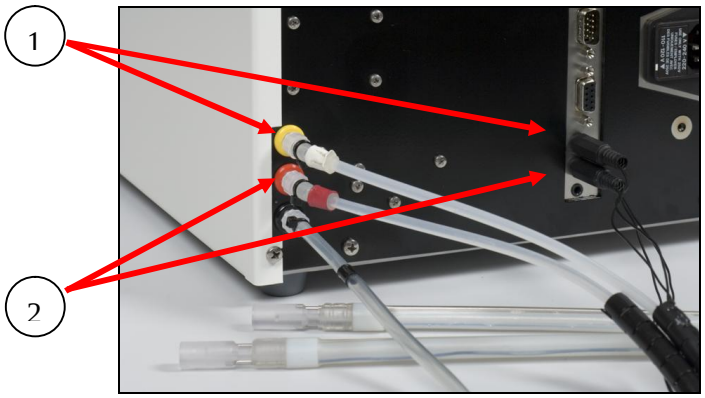
- It is recommended that both the Diluent and the Lyse reagents are placed at the instrument level or below.

Note

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

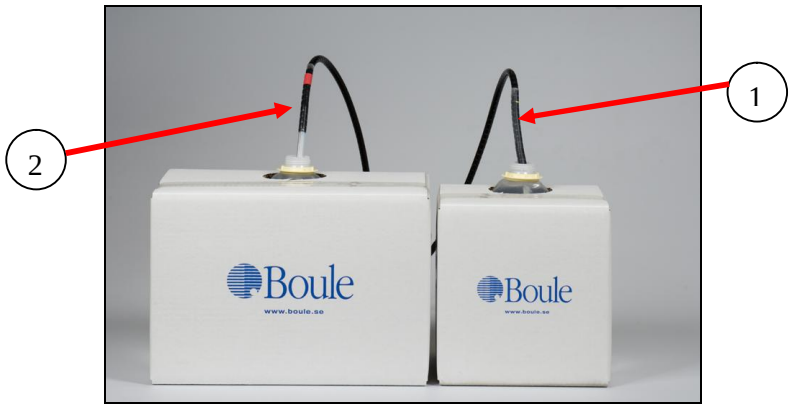
Connecting Reagent Containers

This section describes how to connect the reagent containers for use.

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 2.3

Continued on next page

2.6 Connection, Change & Priming Reagents (Continued)

Step	Insert
3	The reagent level sensors into the corresponding reagent containers.
	 Figure 2.4

Waste

Connect the waste tube (black) to the analyzer. Place the other end of the waste tube 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 tubing 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

2.6 Connection, Change & Priming Reagents (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.
4	Return to MAIN Menu and press [ADVANCED].
5	Press [MAINTENANCE] and then [FILL SYSTEM].
6	The system is now filling up with reagents. This cycle will last for approximately 3 minutes.

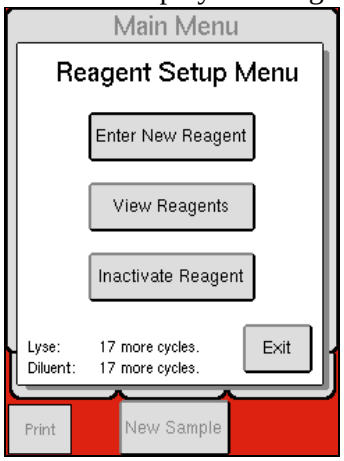


Figure 2.5

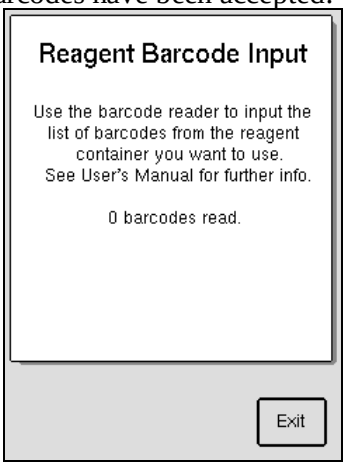


Figure 2.6

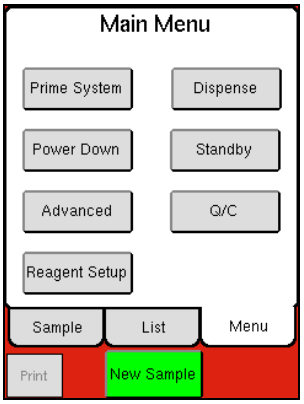


Figure 2.7



Figure 2.8

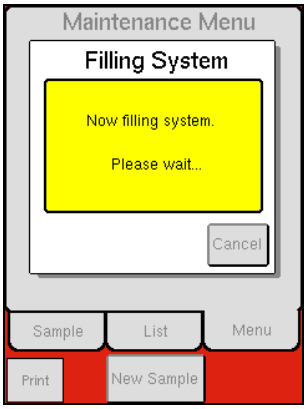


Figure 2.9

Priming

After running a fill cycle it is recommended to run a prime cycle.

Running a Prime cycle

To run a prime cycle select MENU tab and then press [PRIME SYSTEM].

Section 3: General Overview

Section Overview

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

Contents This section contains the following topics:

Topic	See Page
General Instrument Overview	17
System Menu	18
System Flow	20
Sample Volume, Throughput, and Parameters	21

3.1 General Instrument Overview

Instrument Overview

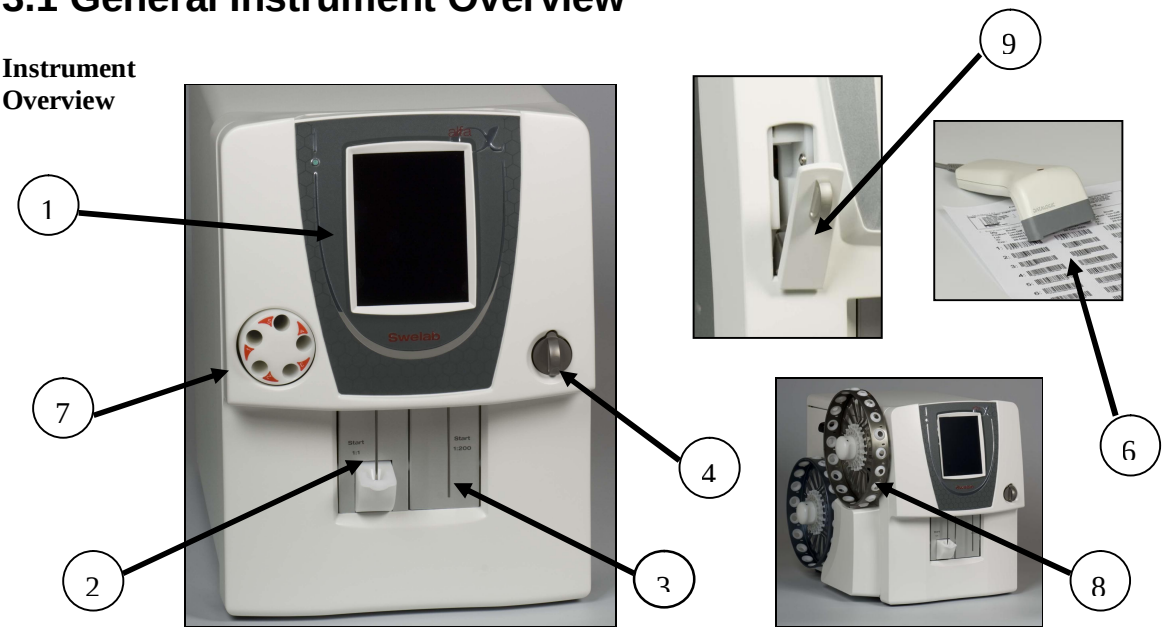
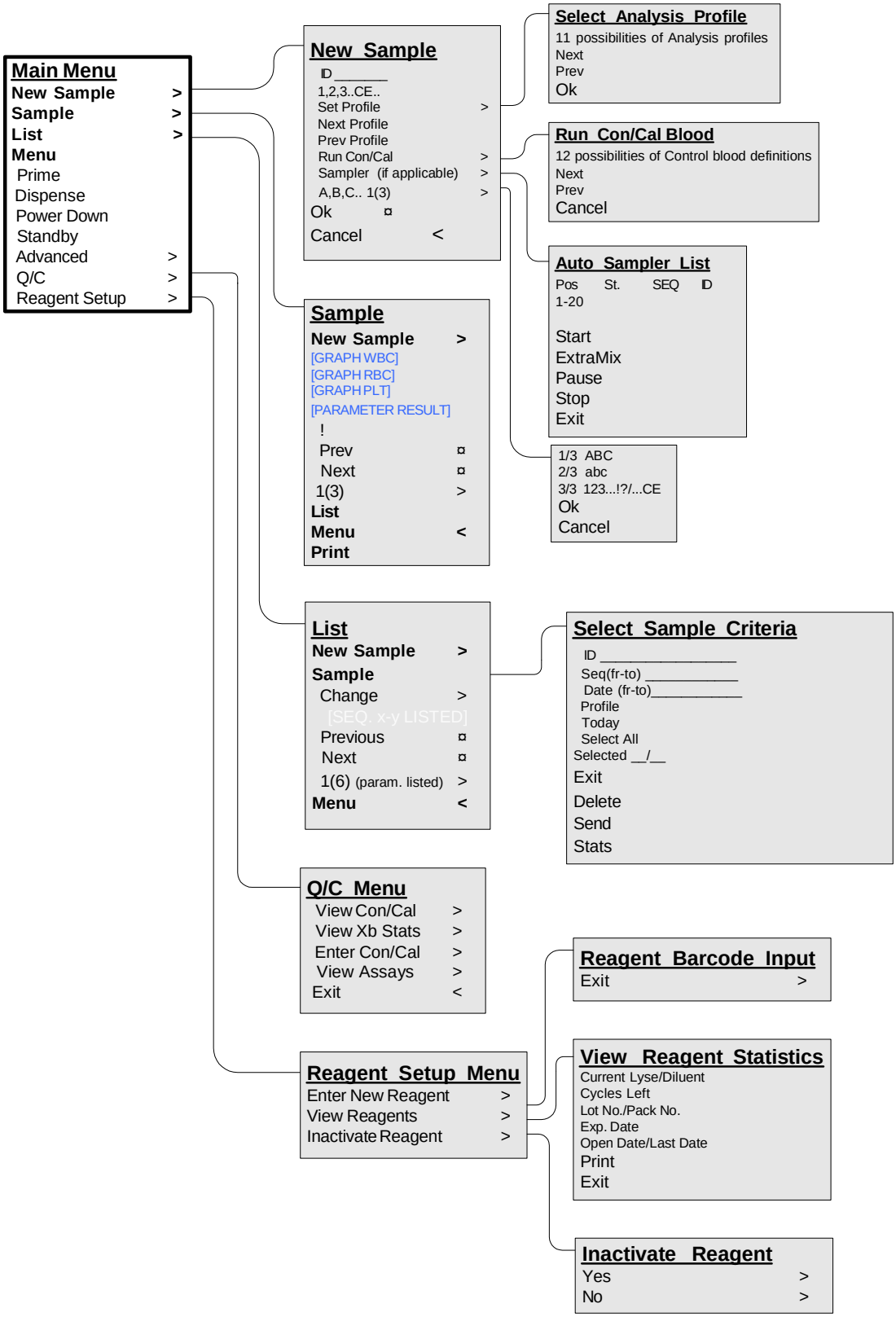


Figure 3.1

Part	Function
1. Display	LCD Touch screen, monochrome or 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. MCI (optional)	Micro Capillary Inlet enables the user to analyze 20 µl of blood.
5. Printer (optional)	Prints sample results. (Not shown, model is user dependent)
6. Barcode	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. Sampler (optional)	Enables consecutive samples to be analyzed automatically.
9. Cap Piercer (optional)	Analyzes samples with decreased risk of blood contact.

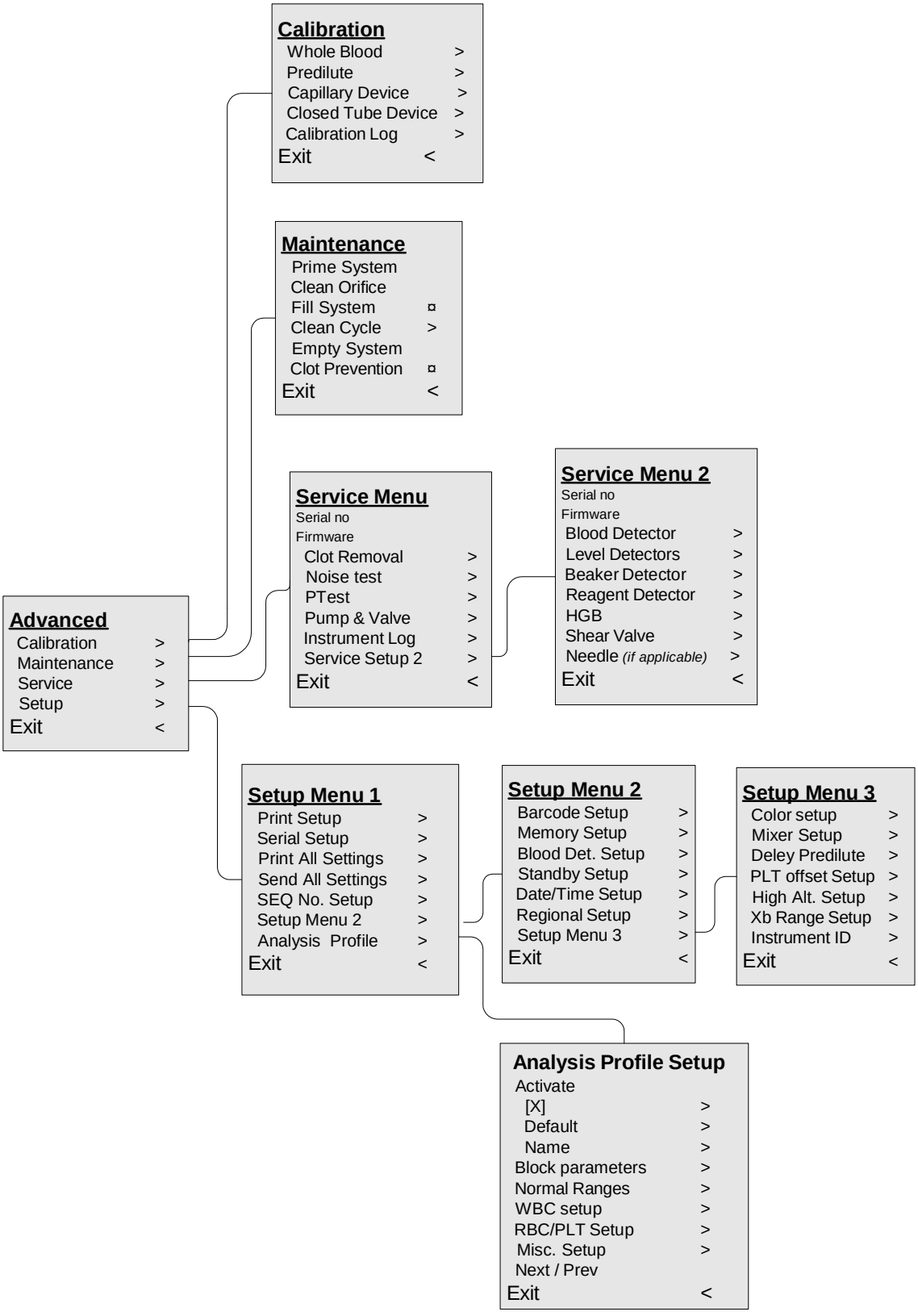
3.2 Menu Structure

Flowchart 3.1 Main Menu Structure



3.2 Menu System (Continued)

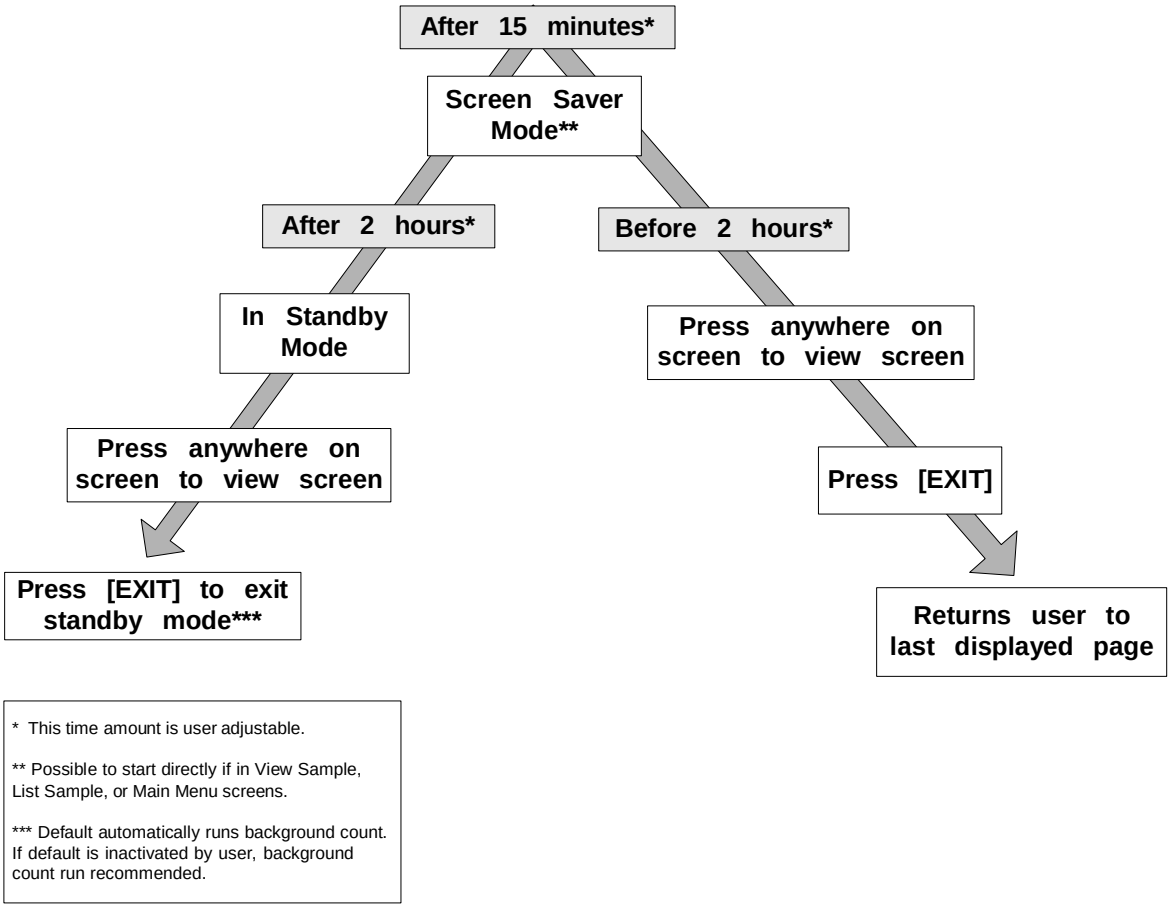
Flowchart 3.2 Advanced Menu Structure



3.3 System Flow

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

Flowchart 3.3 System Flow



3.4 Sample Volume, Throughput, and Parameters

Description The Swelab Alfa is a fully automated cell counter reporting up to 20 parameters.

Sample volume < 90 µl

Throughput > 67 (open tube, whole blood) samples per hour.

20 Parameters See list of parameters below:

Leukocyte parameters		20	16	10
WBC	Total White Blood Cell Count	Yes	Yes	Yes
LYM%	Lymphocytes percentage	Yes	Yes	No
LYM#	Lymphocytes (absolute)	Yes	Yes	No
MID%	Mid Cell Population percentage	Yes	Yes	No
MID#	Mid Cell Population (absolute)	Yes	Yes	No
GRAN%	Granulocytes percentage	Yes	Yes	No
GRAN#	Granulocytes (absolute)	Yes	Yes	No

Erythrocyte parameters		20	16	10
RBC	Total Red Blood Cell Count	Yes	Yes	Yes
HGB	Hemoglobin Concentration	Yes	Yes	Yes
HCT	Hematocrit	Yes	Yes	Yes
MCV	Mean Cell Volume of RBCs	Yes	Yes	Yes
MCH	Mean Cell Hemoglobin	Yes	Yes	Yes
MCHC	Mean Cell Hemoglobin Concentration	Yes	Yes	Yes
RDW%	Red Blood Cells distribution width percentage	Yes	Yes	Yes
RDWa	Red Blood Cells distribution width (absolute)	Yes	No	No

Thrombocyte parameters		20	16	10
PLT	Total Platelet Count	Yes	Yes	Yes
MPV	Mean Platelet Volume	Yes	Yes	Yes
PDW	Platelet Distribution Width	Yes	No	No
PCT	Platelet Crit	Yes	No	No
LPCR	Large Platelet Concentration Ratio	Yes	No	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:

Topic	See Page
Menu Selection	22
Initial Setup	23
Advanced Setup	24
Reagent Setup	27
User Interface	28

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

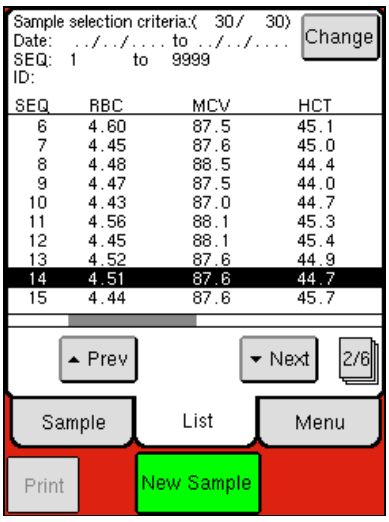


Figure 4.1

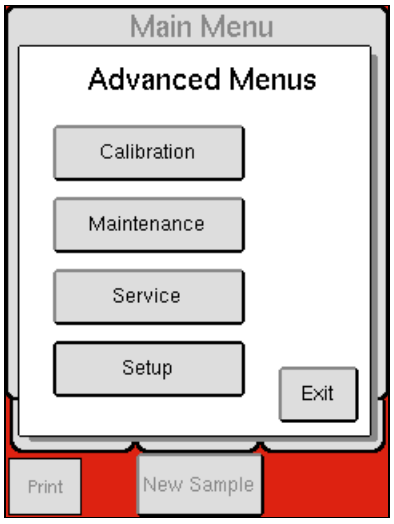
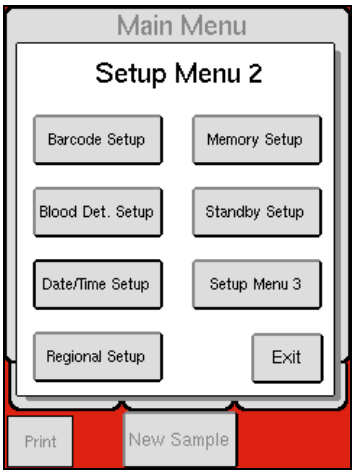
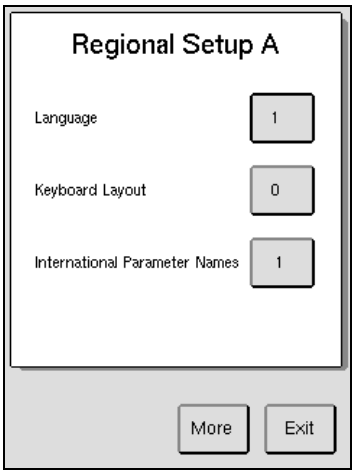


Figure 4.2

4.2 Initial Setup

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.
Menu	 Figure 4.3  Figure 4.4

Activate Mixer (optional)

To activate mixer follow the instruction below:

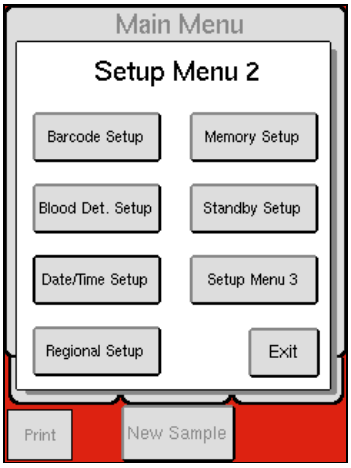
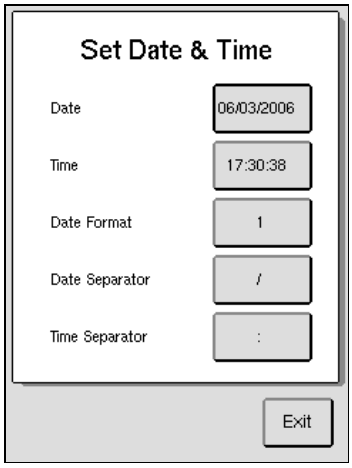
Step	Action
1	Start by pressing [ADVANCED] from the MENU tab.
2	Press [SETUP] and then [SETUP MENU 2].
3	Press [SETUP MENU 3].
4	Press [MIXER].
5	If the mixer is not activated the button will have empty brackets ([ ]). To activate press button and select [X].
Note	Upon sample aspiration mixer will discontinue 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 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 4.5  Figure 4.6

4.3 Advanced Setup

Description

This section describes how to install and configure external components such as barcode readers, printers, data communication, etc.

Select Printer Type

Follow the instruction below for interfacing analyzer to printer.
(To connect printer see Section 2.5)

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: 1 = Seiko DPU 411/12 and 414 2 = IBM proprinter / Epson compatible 3 = HP PCL 3 and 5 protocol compatible
4	To change printer type press [PRINTER TYPE], enter the correct number and press [OK] to save.

4.3 Advanced Setup (Continued)

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 refer to Document 02012. (www.Swelab.se/support/html/whatsnew.htm), for detailed information on how to set up a user definable format. Requirements: English language only. Requires basic understanding of printer protocol, formats and font definitions.

Barcode Setup

To setup the barcode reader follow the instructions below. (Note that the default barcode setting is 9600N81).

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.
5	Choose the format that is appropriate for the barcode reader being installed. (The generic driver is most common and is Compatible with most readers). 0 — No barcode reader 1 — Generic barcode reader (9600N81) 2 — Panasonic ZE-84RMSM (9600O72)
Note	An Internal barcode reader is also available on some models. To activate follow Steps 1-4 and select [X] button.

Keyboard Setup (optional)

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

Continued on next page

4.3 Advanced Setup (Continued)

Data Communication

The instrument is equipped with an output for connection to a computer (network). The serial output has a male 9 pin DSUB. It fulfills the RS232 specification.

The pinning of the male 9-PIN-DSUB is as follows: (instrument end)	
1	Not used
2	TX-OUTPUT
3	RX-INPUT
4	Not used
5	GND
6	Not used
7	CTS-INPUT
8	RTS-OUTPUT
9	Not Used

To connect to a PC computer that uses a 25 pin RS232 (Female -> Female) see instructions below:

Cable end instrument (9 pin)	**Cable end PC (25 pin)**
2 →	3
3 ←	2
5 —	7
7 ←	4
8 →	5

Connections to a pc using a 9pin RS232

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

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

4.4 Reagent Setup

Description

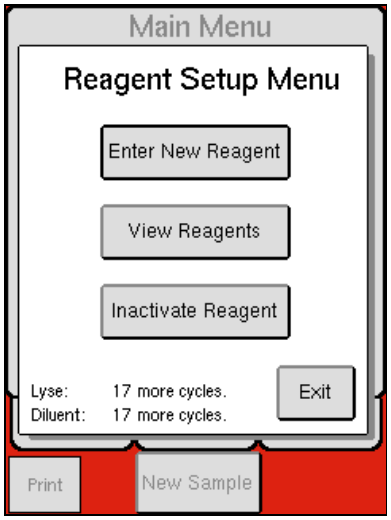
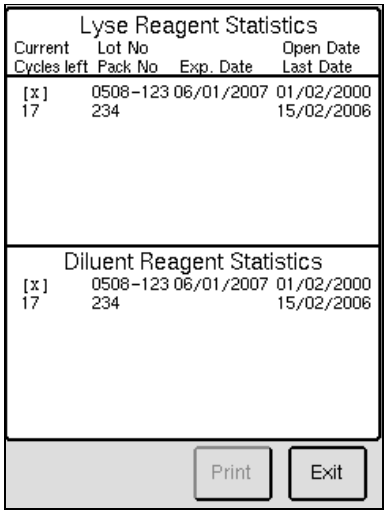
This section describes the functions of the reagent setup menu and how to access reagent statistics.

Reagent Input (Enter New Reagents)

The Swelab Alfa 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 2.6.

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 4.7  Figure 4.8
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.

Continued on next page

4.4 Reagent Setup (Continued)

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.

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.

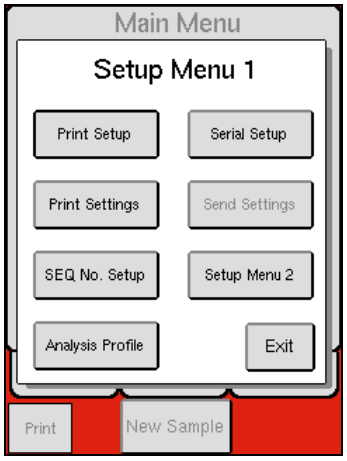
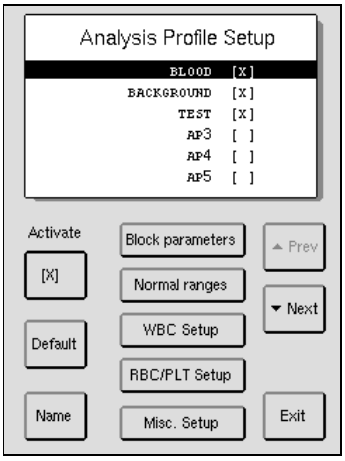
4.5 User Interface

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

It shall be possible for operators to customize analysis profiles. See following menu options:

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 4.9  Figure 4.10
4	To set profile name press [NAME]. • Press [PREV] or [NEXT] to choose an open profile on list. • 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.
5	To set new profile as default press [DEFAULT] and select [X].

Continued on next page

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.
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.

Sample Memory The following procedures explain how to search for previous sample analyses and statistics, and 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 [CHANGE] in List Menu. In this menu samples can be selected by Sample ID, SEQ, Date, and Sample profile. Press corresponding button to select.
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].

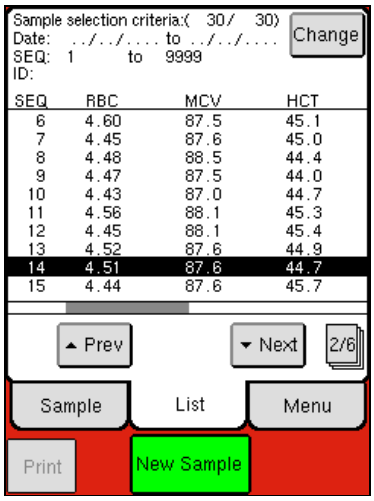


Figure 4.11

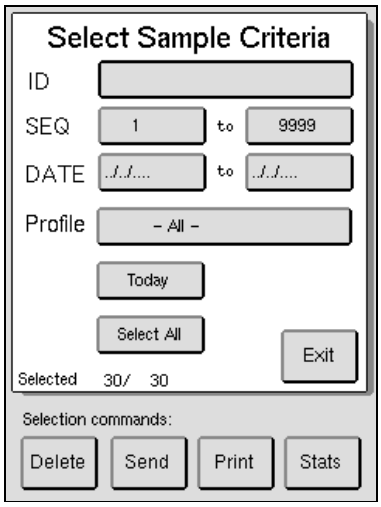


Figure 4.12

4.5 User Interface (Continued)

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 local distributor for more information on Platelet Concentrate Mode activation.

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 Swelab Alfa.

Contents

This section contains the following topics:

Topic	See Page
Preparations before Analysis	31
Background Count	32
Sample Identification	33
Analyzing the Sample (Open Tube)	34
Analyzing the Sample (Pre-dilution procedure)	35
Analyzing the Sample (Micro Capillary Inlet, MCI)	37
Analyzing the Sample (Cap Piercing Device)	39
Analyzing the Sample (Auto Sampler)	40
Results	42

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.

Limitations

Samples drawn in an open tube or vacuum tube should be analyzed between 15 minutes and 6 hours 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 of samples

- The blood should be allowed to adapt 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)

Important

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

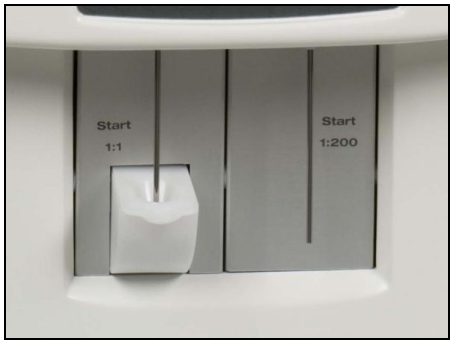
Warning

- As there are no assurances of the absence of HIV, Hepatitis B or C viruses or other infectious agents in blood samples, blood controls, calibrators and waste these products should be handled as potentially biohazardous.
- Always wear protective gloves and goggles. Follow local regulations.

5.2 Background Count

Background Check

The following sequence is performed to check that the background count is low enough to run a sample.

Step	Action
1	From the main screen press [NEW SAMPLE].
2	Press [NEXT PROFILE] or [PREV PROFILE] to scroll to Background and press OK to save.
3	Press the whole blood start plate, which is located behind whole blood aspiration needle. (See Figure 5.1 below)
	 Figure 5.1 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)

5.3 Sample Identification

Description

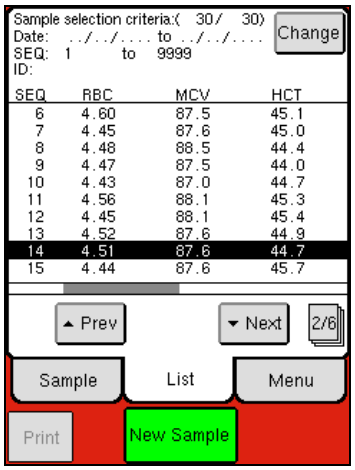
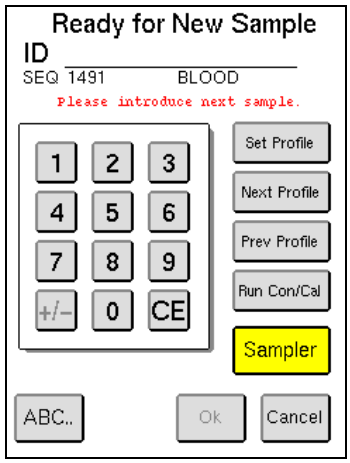
This section describes the different methods of inputting Sample IDs (Identification).

ID Input Methods

The ID can be entered with the following methods:
- Manually (touch screen or external keyboard)
- Barcode

Character Input Limitations

- 15 Characters

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.
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 5.2  Figure 5.3
5	Aspirate sample following selected procedures in sections 5.4 – 5.8.
Note	Sample ID entry and profile selection can be preformed up to 30 seconds after sample aspiration.

5.4 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:

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, press the whole blood start plate behind the left aspiration needle. (See Figure 5.4)
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



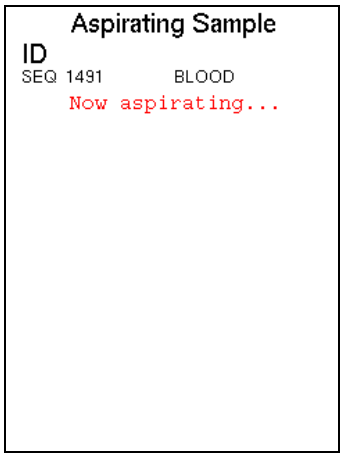
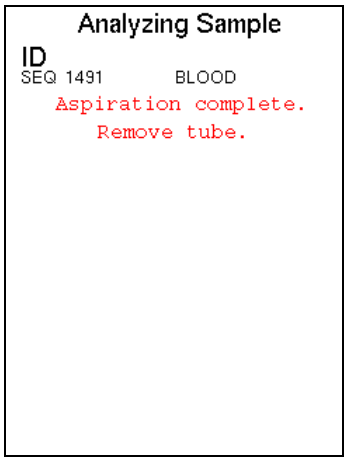
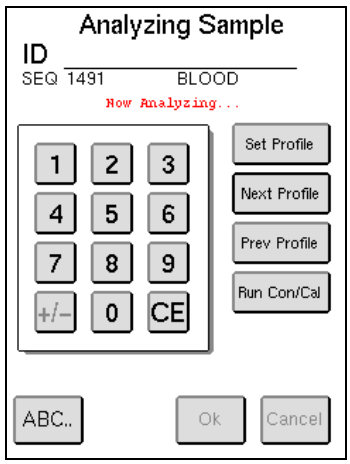
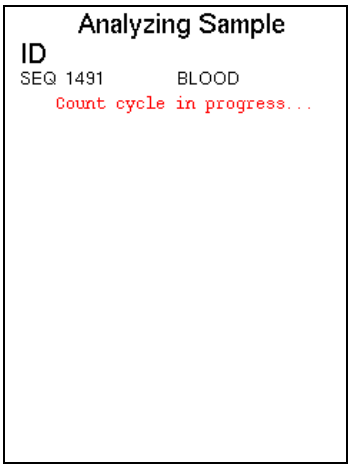
Figure 5.4

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.
- Always wear protective gloves and goggles. Follow local regulations.

Continued on next page

5.4 Analyzing the Sample (Open Tube) (Continued)

	Sample Aspiration Display
5	 Figure 5.5  Figure 5.6
	The instrument now switches to the Sample analysis screen.
6	 Figure 5.7  Figure 5.8
7	In first screen displayed above Sample ID and profile can still be added. If any buttons are pressed in this screen, [OK] must be pressed before sample analysis result screens can be viewed.
8	If no buttons are pressed in this screen then the display switches to that in Figure 5.8 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 5.9.
10	When NEW SAMPLE button returns to green, operator can begin analysis of next sample.

5.5 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 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 in 4.5 ml diluent)

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.

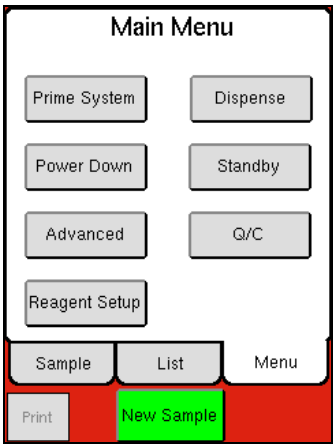
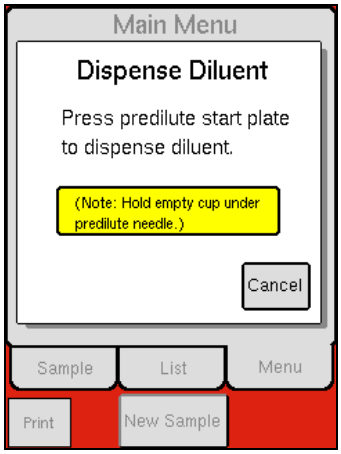
Externally Pre-diluted volumes and preparation

- 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 result; 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.

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 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 start lever) 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 5.9  Figure 5.10
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.

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 for five seconds. (See Figure 5.11)
	 Figure 5.11
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 5.4 Steps 5 - 10 for remainder of analysis sequence.

5.6 Analyzing the Sample (Micro Capillary Inlet, MCI)

Description

This section describes how to analyze capillary whole blood samples with the use of the Micro Capillary Inlet (MCI).

Micropipettes

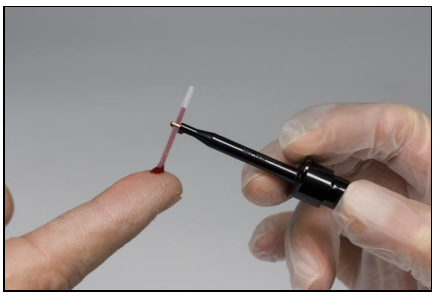
ONLY Boule supplied, plastic, high precision EDTA micropipettes should be used when running MCI. Glass micropipettes can cause damage to instrument if inserted incorrectly.

Starting procedure

Follow the procedure below to operate MCI:

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 MCI adapter. (The instrument will give an instruction to put back the MCI adapter to start).
3	Remove the previous sample micropipette. (If applicable)
4	Place the adapter on the table.

Drawing blood and sample preparation

Step	Action
1	Puncture, using the Micro Lancet.  Figure 5.12
	Always use gloves when in contact with potentially biohazardous materials.
2	Aspirate the sample as shown below.  Figure 5.13

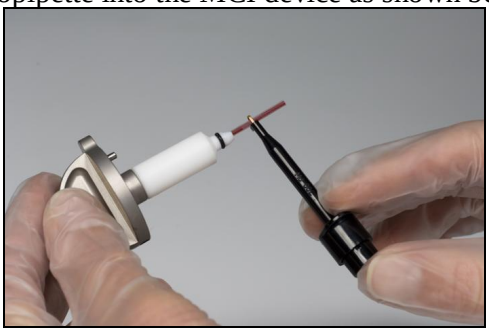
Warning

Continued on next page

5.6 Analyzing the Sample (Micro Capillary Inlet, MCI) (Continued)

Important

- 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.

3	Insert the micropipette into the MCI device as shown below:  Figure 5.14
4	Insert the MCI into its holder and the instrument will automatically start the analyzing sequence.  Figure 5.15

Important

Do not remove MCI during sample aspiration or analysis. Removal prior to completion of analysis may cause erroneous results.

5	Refer to Section 5.4 Steps 6 - 10 for remainder of analysis sequence.

Further information and demos

To find more information, visit www.boule.se The Boule website contains detailed video shots on how to use the MCI and cleaning procedures.

5.7 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 3.0 ml to 4.5 ml tubes, with a maximum length of 77 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.
3	 Figure 5.16  Figure 5.17
	• 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 5.4 Steps 6 - 10 for remainder of analysis sequence.

Warning

5.8 Analyzing the Sample (Auto Sampler)

Description

This section describes how to analyze whole blood samples using the Auto Sampler.

Sample tube description

Only standard 4.5 ml tubes can be used in the Auto Sampler. Do not use Sarstedt tubes. The minimum volume in the closed tube should be approximately 1 ml.

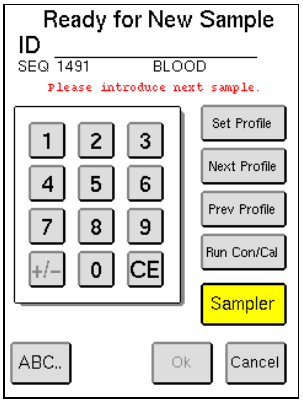
Selecting Sample ID

There are several ways to select the samples.

- If the Auto Sampler has a mounted barcode reader, the ID numbers will be read automatically. It is very important to line up barcode on tube with barcode reader.
- If no barcode reader is connected the operator can enter the ID numbers manually with the touch screen keyboard or barcode reader into a worklist.
- Samples can also be analyzed without identification, but then only the sequence numbers will be present.

Starting procedure

Follow the procedure below to operate the Auto Sampler:

Step	Action
1	Unlock the center piece by turning it counterclockwise.
2	Load the vacuum tube samples by placing the capped end towards outer edge of sample wheel and fitting it into designated slot.
3	Lock in samples by turning center piece clockwise.
4	Press [SAMPLER] button from the NEW SAMPLE Menu.
5	Press [START] to immediately begin analysis or press [EXTRA MIX] if extra mixing of samples is needed.
Warning	• Do not touch sample wheels or samples during operation. • Handling and operation by unauthorized personnel may result in injury.
6	Auto sampler begins analysis with the sample tube placed in the lowest position number.
	 Figure 5.18  Figure 5.19
7	List or Sample Menu will appear when analysis is complete.

5.9 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

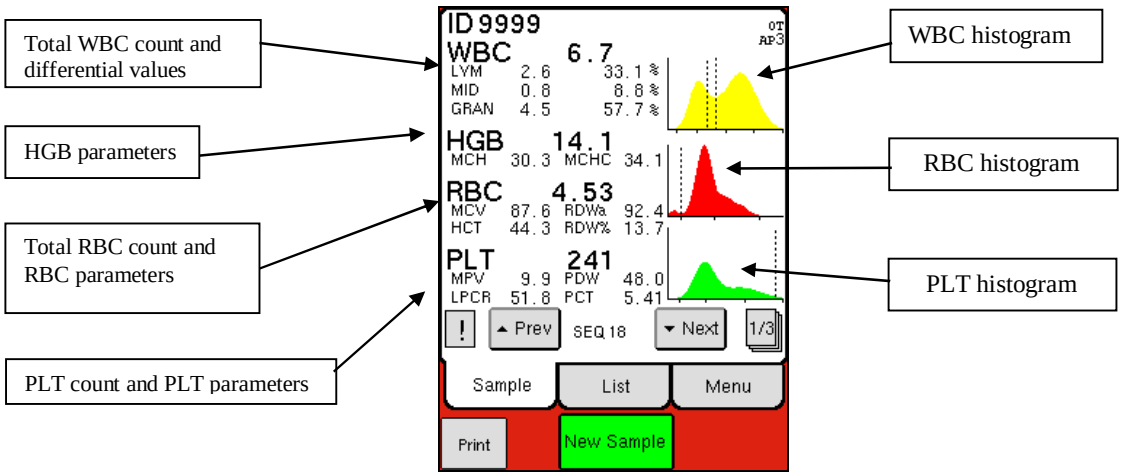


Figure 5.20

Sample View 2

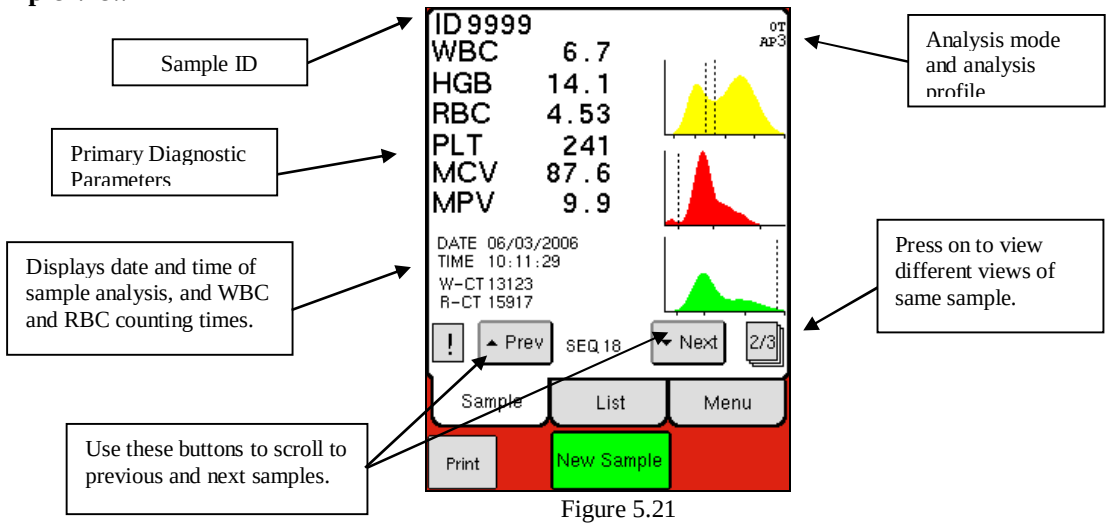


Figure 5.21

Continued on next page

5.9 Results (Continued)

Sample View 3

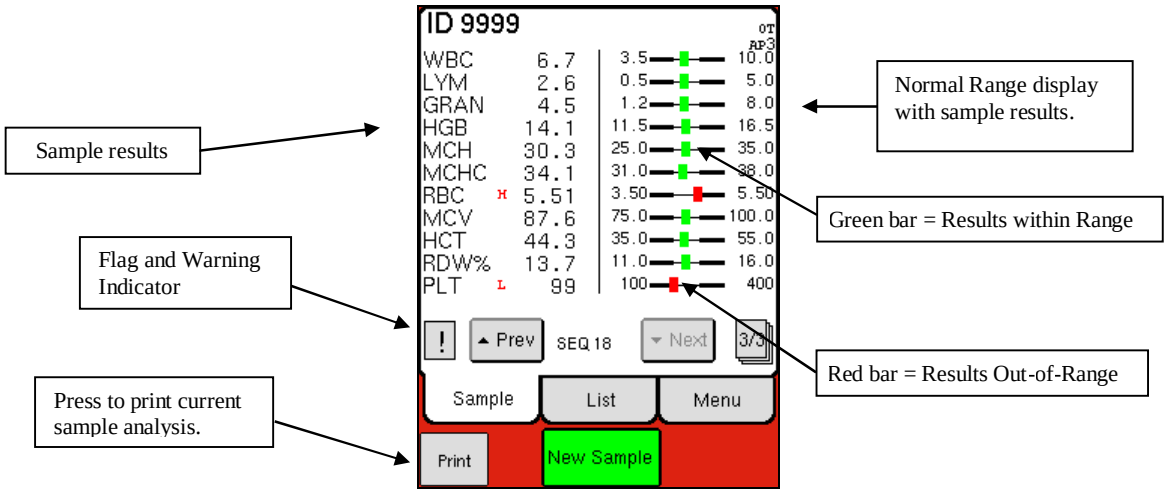


Figure 5.22

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

Section Overview

Introduction

The Swelab Alfa is equipped with a QC memory capable of displaying and printing X-B and Levey Jennings plots.

Contents

This section contains the following topics:

Topic	See Page
Quality Control (QC)	44
Levey-Jennings Plots	46
Initialization and Use of X-B Function	47

6.1 Quality Control (QC)

Introduction

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

QC Menu and CBD input

Follow the instruction below to access the QC menu and to input Control/Calibrator Blood Definitions (CBD) 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 control definitions. (These pages are delivered with authorized Boule controls).
Note	12 different CBD´s from Boule can be stored simultaneously. When renewing the definitions, the previously scanned CBD´s will be removed in a chronological order starting with the first entered CBD.

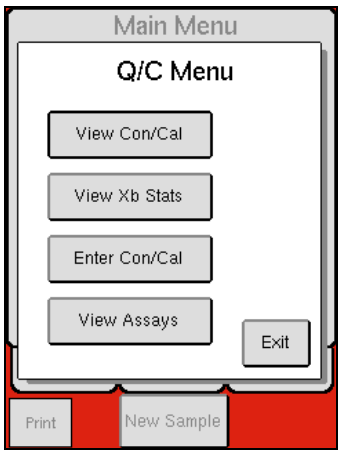


Figure 6.1

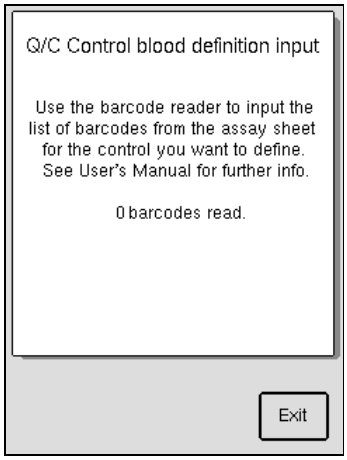


Figure 6.2

6.1 Quality Control (QC) (Continued)

Control Analysis

It is advisable that the performance of the Swelab Alfa system is checked daily with a certified blood control authorized by Boule. Comparing the analyzer results to the known values on the Boule control assay sheet is a good assurance that the system is functioning properly.



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 tissue before each control run. Not following this discipline might lead to decreasing parameter values.



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.
- Always wear protective gloves and goggles. Follow local regulations.

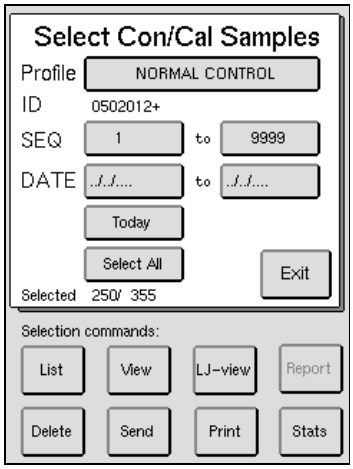
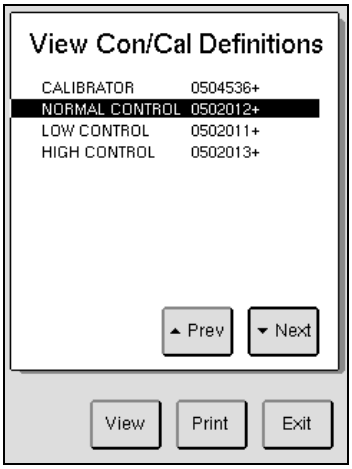
Step	Action
1	Follow directions on Assay Sheet to scan in values of CBDs.
2	Choose either List, Sample, or Main Menu to begin control analysis.
3	Using installed barcode reader, scan the Control ID from the blood control vial label.
4	Aspirate the blood control and wait for the results. The Swelab Alfa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

Search Function

Each blood control type can be found by control definition (Lot number and 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

	 Figure 6.3  Figure 6.4
4	Press the [SAMPLE] or [LIST] buttons to display the selected samples.

6.2 Levey-Jennings Plots

Procedure instruction

This section describes selecting and viewing Levey-Jennings Plots.

L-J Plots

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

Blood controls

To be able to use L-J plots, the Control/Calibrator Blood Definition for the blood controls, **must** be scanned with the installed barcode reader or manual entered in. Follow direction on Assay Sheet to scan in values of CBDs.

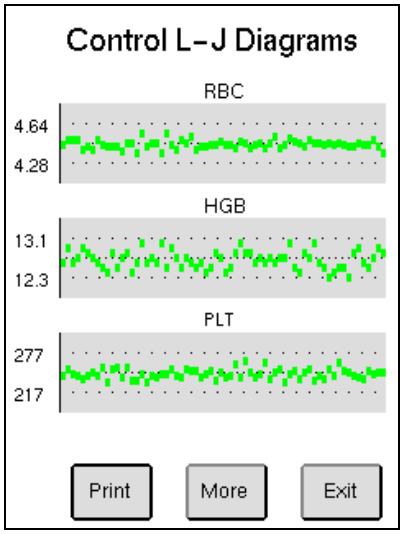
Displaying L-J Plots

To display 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.

Continued on next page

6.2 Levey-Jennings Plots (Continued)

L-J plot 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 6.5
4	Scroll through parameters by choosing [MORE].
5	Print diagrams by choosing [PRINT].

Parameters displayed on L-J Plots

The L-J plots are displayed for all parameters defined in the CBD page except the WBC differential parameter "MID".

Note

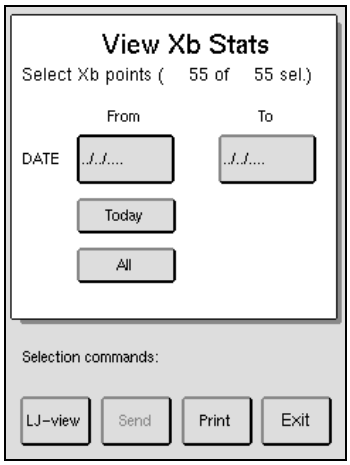
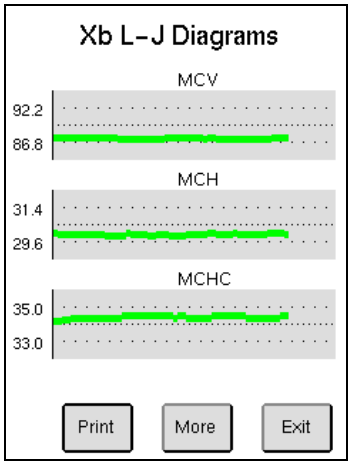
In case a control shows an error or warning flag SE, DE, FD, OF, LO, HI, NG, TU, TL or TB; the parameter values of such control will not be included in the L-J plots.

6.3 Initialization and Use of X-B Function

Description

The X-B function in the Swelab Alfa 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.

6.3 Initialization and Use of X-B Function (Continued)

Step	Action
1	Enter the QC menu and press [VIEW Xb STATS].
2	Select X-b 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 6.6  Figure 6.7
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.

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 Swelab Alfa. 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:

Topic	See Page
Preparations before calibration	49
Calibration	50

7.1 Preparations before calibration

Before Calibration

- It is advisable that the performance of the Swelab Alfa 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.
- Verify that nothing is erratic with the control blood, the reagents, or the instrument before calibrating instrument.
- Prior to calibration print Calibration Log. Select [ADVANCED] from Main Menu, then [CALIBRATION], then [CALIBRATION LOG], and then [PRINT].



Important

- Calibration operator must fulfill Operator Requirements in Preface Section.
- Handle and prepare controls in accordance to the 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 tissue before each calibrator run. Not following this discipline might lead to decreasing parameter values.



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.
- Always wear protective gloves and goggles. Follow local regulations.

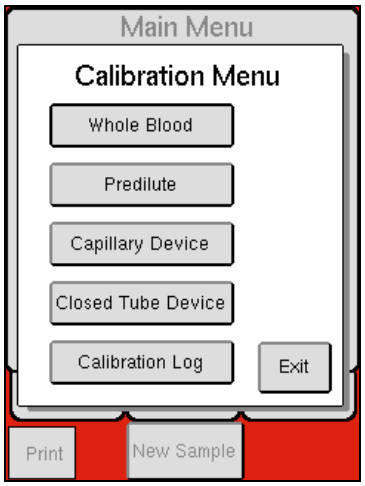
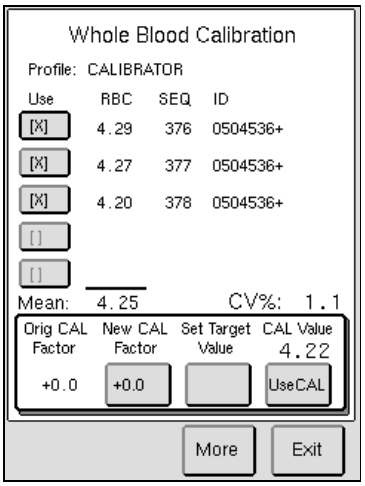
7.2 Calibration

Input calibrator definitions

Follow the instruction in Section 6.1 Quality Control to access the QC menu and to input Control/Calibrator Blood Definitions (CBD) from the Assay sheet.

Whole Blood Calibration

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

Step	Action
1	Follow directions on Assay Sheet to scan in calibrator definitions.
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.
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 [MORE] button and verify that the CVs for the following parameters:

RBC	< 2.2
MCV	< 1.8
PLT	< 5.8
HGB	< 1.8
WBC	< 4.2

Important

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 flags will automatically inactivate that analysis from the CV calculation and depending on flag may not be stored on list at all.) If a know 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 CBD. • The second method, if no calibrator is available, is to perform Steps 4-9 using a sample with target values from a CBD 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 local distributor 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 Calibration Code (REQUIRED) before the new value can be changed or updated.
NOTE	Calibration 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 Calibration Code [**2576**].

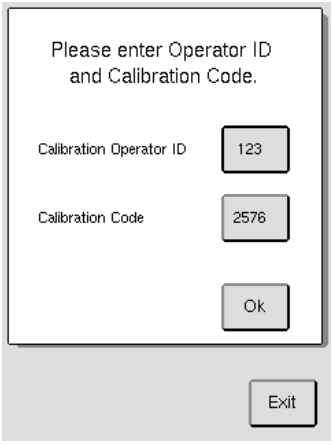


Figure 7.3

Continued on next page

14	Perform steps 9-12 for RBC, MCV, PLT, MPV, HGB, and WBC parameters. To move to the next parameter press [MORE].
15	It is recommended to not change preset calibration factors for RDW%, RDWa, and PDW. If necessary, please contact local distributor or Boule service technician for procedure.
16	Once parameters are calibrated, a screen will be displayed asking operator if a calibration report is wanted, [SEND], [PRINT], or [EXIT] can be selected.  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 MCI follow Steps 1-16 above except select [CALIBRATION] and then choose [CAPILLARY DEVICE] instead of Whole Blood calibration in Step 6 and use MCI mode for analysis.

Pre-dilute Calibration

To calibrate pre-dilute follow Steps 1-16 above except select [CALIBRATION] and then choose [PREDILUTE] instead of Whole Blood calibration in Step 6 and use pre-dilute mode for analysis.

Section 8: Cleaning, Maintenance & Transport

Section Overview

Introduction

This section contains information that is crucial for maintaining, transporting and storing the Swelab Alfa.

Contents

This section contains the following topics.

Topic	See Page
Daily Cleaning	53
Monthly Cleaning	54
Six (6) Month Cleaning	55
Instrument Maintenance	56
Re-location of instrument (within the laboratory)	56
Short Term Transport (<12h)	57
Re-packaging and Long Term Transport	57
Permanent Shut-Down and Storage	58
Disposal Information	59

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 needles using a paper tissue with a 70% alcohol solution.
2	Remove possible traces of salt crystals or blood 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.
3	Aspirate the hypochlorite as a whole blood sample.
4	Repeat step 2 but aspirate the hypochlorite as a pre-diluted sample.
5	Run 2 blank samples by aspirating 10 ml diluent as a whole blood sample.
6	Repeat step 5, but aspirate diluent as a pre-diluted sample.

Clot Prevention

This process will decrease the risk of system to build up debris material in the instrument system. This should be preformed 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.)
2	From Main Menu press [ADVANCED] and then press [MAINTENANCE].
3	Hold the container under the OT needle, submerged in cleaner, press [CLOT PREVENTION] and then [OK] to confirm. Do not remove container with cleaner for at least 5 seconds after aspiration has stopped.
4	The system will then perform the cleaning process, and upon completion instrument is ready for next sample analysis.

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 [CLEAN CYCLE] 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.

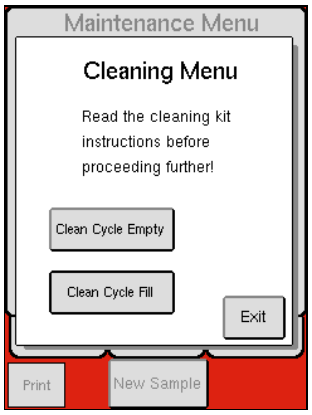


Figure 8.1



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 local distributor for warranty requirements.

Maintenance

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

- 1 year or 20,000 samples
- 2 years or 40,000 samples
- Auto Sampler only (every 5,000 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.

1. **Do not** detach the reagent level sensors or waste tube, place the sensors on top of the instrument when moving. (Avoid reagent level sensor contact.)
2. Remove the waste tube from waste container or drain.
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

1. Place the waste tube in waste container or drain.
2. Reconnect the electrical connections.
3. Insert the level sensors back into the reagent containers.

8.6 Short Term Transport (<12h)

Description

This section describes the procedure performed before transporting the instrument over short distances. This procedure **only** describes the preparations performed before transporting the instrument for less than 12 hours.

Empty System

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 tubing, and all electrical connections. Package all components carefully for transport.

Guidelines for transport

- The instrument should be transported in temperature conditions between 5 to 30 ºC (41 to 86 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.

Continued on next page

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

Long term Shut-Down

Step	Action
1	Select [EMPTY SYSTEM] from MAINTENANCE Menu. See Section 7.5 “Short term transport” 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 [FILL SYSTEM] from MAINTENANCE Menu.
4	When the instrument has been filled with distilled water select [EMPTY SYSTEM] from MAINTENANCE Menu.
5	When system is emptied, disconnect the main supply cable and other connections such as reagent sensors and waste tubing.
6	Pack the instrument 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.

Manufacturer Guidelines

- 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 tubing is securely fastened in the drain.



Mandatory Action

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

Disposal Materials

- Used reagents
- Reagents mixed with potentially biohazardous material
- Instrument and instrument components
- Controls and calibration material



Warning

Always use gloves when in contact with potentially biohazardous materials.

Section 9: Parameter Flags

Section Overview

Introduction

The Swelab Alfa has several error and warning flags related to the measured parameters. These flags alert the operator of possible pathologic samples and parameter value errors.

Contents

This section contains the following topics:

Topic	See Page
Short Description of Flags and Troubleshooting	60
Detailed Description of Flags	62
Flagging Capabilities	65

9.1 Short Description of Flags and Troubleshooting

Description

The instrument has several parameter error flags related to the measured parameters. The flags are shown on the display and printouts.

Resolving Error Flags

The sample should be re-analyzed. If the problem persists see list below to identify the issue and/or refer to Section 12 Troubleshooting.

Note

Note that a parameter that is outside the “Normal Range”, refer to Section 9.4 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.

Continued on next page

9.1 Short Description of Flags and Troubleshooting (Continued)

Parameter Flags

Flag	Cause	Action
TU	Blockage in aperture	Run a "Prime cycle", before re-analyzing the sample.
TL	Blockage in aperture	Run a "Prime cycle", before re-analyzing the sample.
ST	Counting time too short	Run a "Prime cycle", before re-analyzing the sample.
TB	Air bubbles present in system	Run a "Prime cycle", before re-analyzing the sample.
OR	• Air bubbles • Electrical disturbances • Incomplete lysing	Re-analyze sample
SE	• Clogging • Air bubbles • Electrical disturbances • Incomplete lysing	Re-analyze sample
DE	• Air bubbles • Electrical disturbances • Incomplete lysing • Incorrect gain settings • Pathological blood sample	Re-analyze sample
FD	Insufficient cell separation between RBC and PLT ranges	Re-analyze sample
HS	HGB readings vary too much	Re-analyze sample
HH	HGB light levels too high	Run a "Prime cycle", before re-analyzing the sample.
HL	HGB light levels too low	Run a "Prime cycle", before re-analyzing the sample.
HO	HGB offset level error	Switch off the instrument and switch it back on after 3 seconds, and then re-analyze sample
HN	HGB reading has a higher light level than a "blank"	Re-analyze sample
NM OM TM BD	WBC differential abnormality	Blood sample too old or pathological sample
AF	Aspiration failure	Re-analyze sample
DF	Diluent pipette fill error	Re-analyze sample (Verify instrument is filled)
DP	Diluent pipette emptying error	Re-analyze sample
LF	Lyse pipette fill error	Re-analyze sample
LP	Lyse pipette emptying error	Re-analyze sample
TE	Liquid transfer error	Re-analyze sample
EC	Expired control blood	Use a fresh blood control
NR	No Reagent	Check reagent levels
ER	Expired Reagent	Use a new lot of reagents

9.2 Detailed Description of Flags

Description	This section covers the full description of the parameter warning and error flags that might occur. The list below is in order of the severity of the flag.
TU	"Timeout upper detector" (RBC, PLT, WBC) The liquid meniscus in the measuring tube passed the lower detector but never passed the upper one.
TL	"Timeout lower detector" (RBC, PLT, WBC) The liquid meniscus in the measuring tube never passed the lower detector.
ST	"Short counting time error" (RBC, PLT, WBC) The time for the liquid meniscus to pass from the lower to the upper detector is unreasonably short.
TB	"Tube bubbles error" (RBC, PLT, WBC) Air bubbles were detected by the start detector in the diluent column.
OR	"Cell counting overrun error" (RBC, PLT, WBC) The cell pulses arrived faster than the instrument 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.
SE	"Statistical error/flow rate variation error" (RBC, PLT, WBC) 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.
DE	"Distribution error" (RBC, PLT, WBC) The size distribution of the cell pulses departs from the expected one. Possible reasons might be air bubbles, electrical disturbances, difficult to lyse cells or an incorrect gain setting.
FD	"Floating discriminator error" (PLT) 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.

Continued on next page

9.2 Detailed Description of Flags (Continued)

HS	"HGB statistical error" (HGB) Individual HGB readings vary too much.
HH	"HGB high level error" (HGB) The HGB blank or sample readings reported a too high light level.
HL	"HGB low level error" (HGB) The HGB blank or sample readings reported a light level that was too low.
HO	"HGB offset error" (HGB) The HGB dark (offset) reading reported a light level that was too high or too low.
HN	"HGB negative value error" (HGB) The HGB sample reading reported more light than the blank reading. This gives a negative HGB value.
NM	"No WBC mode error" (LYM, MID, GRAN) There was no mode in the WBC distribution between the LYM-L and GRAN-H settings.
OM	"One WBC mode error" (LYM, MID, GRAN) 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	"Triple WBC mode error" (LYM, MID, GRAN) There were more than two modes in the WBC distribution between the LYM-L and GRAN-H settings.
BD	"WBC bad distribution error" (LYM, MID, GRAN) The calculated populations for LYM, MID, GRAN overlap too much. Often in pathological samples with granulocytosis or lymphocytosis a blood smear is recommended.
AF	"Aspiration failure" (Whole blood, Pre-dilute) 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.

Continued on next page

9.2 Detailed Description of Flags (Continued)

DF	"Diluent pipette fill error" (RBC, PLT, WBC) 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.
DP	"Diluent pipette emptying error" (RBC, PLT, WBC) 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 pipette fill error" (WBC) 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 pipette emptying error" (WBC) 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.
TE	"Liquid transfer error" (RBC, PLT, WBC) The instrument 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.
EC	"Expired control" (RBC, PLT, WBC, LYM/MID/GRAN) A control blood was used past its expiry date.
NR	"No Reagent" (RBC, PLT, HGB,WBC) The instrument'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.
ER	"Expired Reagent" (RBC, PLT, HGB,WBC) The reagent was used past its expiry date. Change to a non-expired lot of reagent.

9.3 Flagging Capabilities

Description	This section describes the limitations of the flagging capabilities of the Swelab Alfa series.
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.

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:

Topic	See Page
Measuring Principles	66
Counting Time RBC & WBC	67
WBC Differentials	68

10.1 Measuring Principles

Description

This section describes the measuring principles of the Swelab Alfa.

General Measuring Principles

The measuring principles of the Swelab Alfa 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. The analyzer uses a fixed division factor of 67.5 calculated as 33,750 / 67.5 = 500 which is the correct value. (Based upon this calculation the instrument would show RBC = $5.0x10^6$ cells/µl).

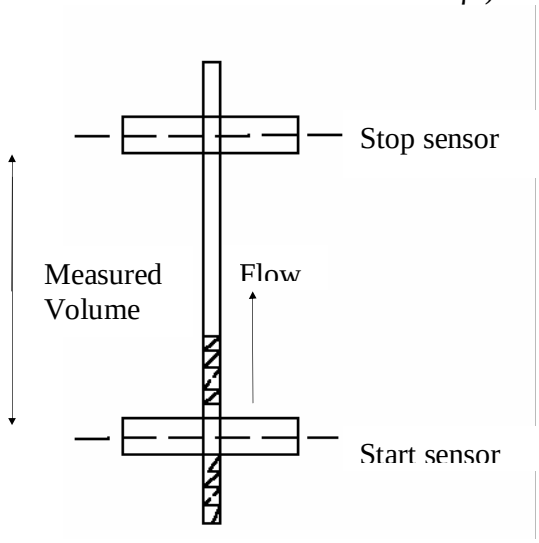


Figure 10.1

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 “LO” or “HI” 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 Swelab Alfa uses a fixed discriminator technology.

Fixed Discriminators

The differentiation of the WBC cells into lymphocytes, mid-cells and granulocytes is presented in the number of cells per liter or cubic millimeter and in the percentage of the total number of WBC cells. The MID discriminator of WBC is set to 140 and 180 fl. The WBC histogram is automatically adjusted depending on the number of cells, i.e. expanded for low values and compressed for high values.

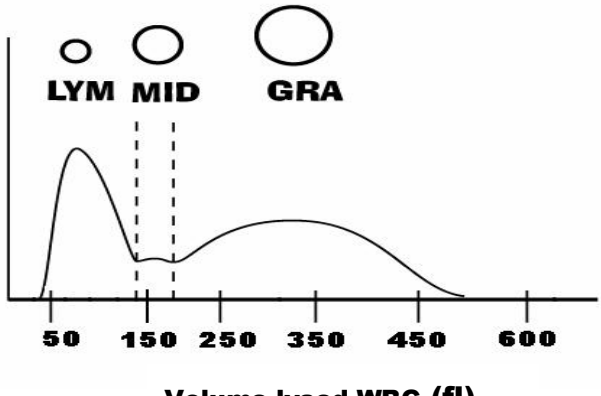


Figure 10.2 (Normal distribution curve)

Differential parameters

- LYM region (small size cells): Ranges from 30 to 150 fl. Cells in this area typically correlate to lymphocytes. Other cell types that could locate in this region are nucleated red blood cells, clumped platelets, macrocyte platelets, variant (atypical) lymphocytes or blasts.

- MID region (mid size cells): Ranges from 140 to 180 fl. Cells in this area typically correlate to monocytes, eosinophils and basophils and also degranulated neutrophils, precursor cells, blasts and plasmacytes.

- GRA region (large size cells): Ranges from 210 to 600 fl. Cells in this area typically correlate to neutrophils. In approximately 20% of the samples eosinophils can also locate in this region. Precursor granulocytic cells, especially bands, have a tendency to locate close to the mid cell region.

Section 11: Specifications

Section Overview

Introduction This section describes the specifications for the Swelab Alfa and its parameters.

Contents This section contains the following topics:

Topic	See Page
General	69
Short List of Specifications	70
Parameter Ranges	71
Reagent and Reagent Consumption	71

11.1 General

Description This section describes the Swelab Alfa 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
- Hemolyzing reagent

Technology The Swelab Alfa is a fully automatic hematology analyzer designed to measure up to 20 parameters using whole blood from an open inlet, closed tubes, 20µl micro pipettes 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 tubes)	≤ 90 µl
Blood volume using the Micro Capillary Inlet (MCI)	20 µl
Pre-diluted mode	1:200 to 1:250 using min. 20 µl e.g. 20 µl to 5 ml diluent (1:225)
LCD	Graphical color touch screen, 240 columns x 320 rows
Keyboard	Virtual incorporated keyboard (External keyboard possible)
Number of Samples per hour	67 samples
QC capabilities	Mean, SD, CV, Levey-Jennings plots and X-B with >10,000 samples history
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	RBC, HGB, WBC ≤ 1%, PLT ≤ 2%
Bar-code reader input	Yes
Serial output	Yes (Must conform to standard EN 60950)
Main Voltage / Fuses	230V Fuse 5x20mm T1,6 A, 250V 120V Fuse 5x20mm T3,15A, 250V
Power consumption	Max 100VA
Power consumption (stand-by)	Max 20VA
Frequency	50 / 60 HZ
Built-in test / adjustment programs	Yes
Temperature	18 - 32°C (64 - 90°F)
Humidity (none condensing)	Up to 80%
Dimensions	HxWxD 410x290x460 mm
Weight	≤ 18 kg (Standard Version)

Continued on next page

11.3 Parameter Ranges

Linearity

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

Parameter	Maximum Non-Linearity	Within the following range:
WBC	3%	0 – 80.0 x 10^9/l
RBC	2%	0 – 7.00 x 10^{12}/l
PLT	Not Detected	0 – 1800 x 10^9/l
HGB	3%	0 - 25.0 g/dl

Measuring Range and Correlation

The correlation is performed using a Bayer/Advia 120 as reference.

Parameter	Measuring range	Correlation
WBC	0 - 99.9 x10^9/l	R > 0.97
RBC	0 – 14 x10^{12}/l	R > 0.98
MCV	15 – 250 fl	R > 0.98
PLT	0 - 1999 x10^9/l	R > 0.95
HGB	0 – 99.9 g/dl	R > 0.98

Reproducibility

Measured according to Boule I-1040 Section 7, based on Standard EP6-A.

Reproducibility (typical)		
Measured as an average of 10 measurements each on 3 different vein K2-EDTA collected normal samples, on three instruments. Values shown have been corrected to show 95% confidence limits.		
Parameter X-mean (CGS units)		CV (%)
WBC	8.4	< 3.5
RBC	4.34	< 1.8
MCV	94.4	< 1.5
PLT	313	< 4.8
HGB	13.7	< 1.5

11.4 Reagents and Reagent Consumption

Description

This section describes the reagent consumption for the Swelab Alfa 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

11.4 Reagents and Reagent Consumption (Continued)

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

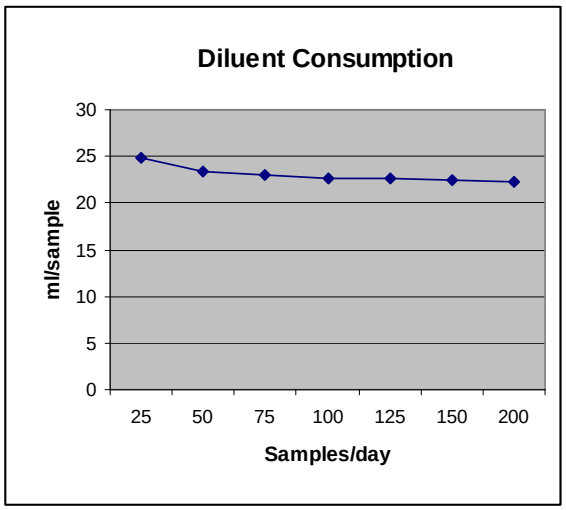


Figure 11.1

Lyse Consumption

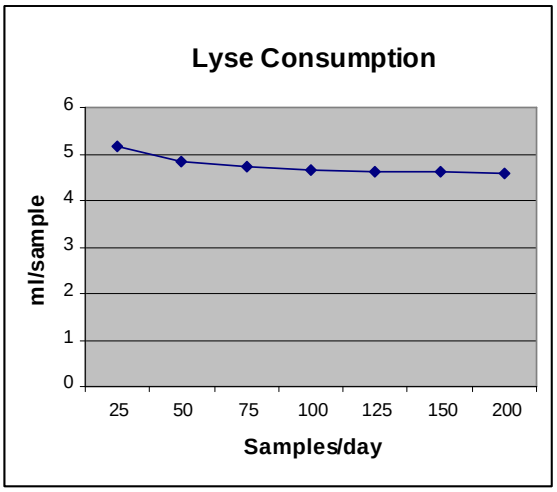


Figure 11.2

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 Swelab Alfa instrument.

Contents This Section contains the following topics:

Topic	See Page
Communication Issues	73
General Information Displays	74
Warning Displays	78
Aspiration Issues	83
Troubleshooting Other Issues	85

12.1 Communication Issues

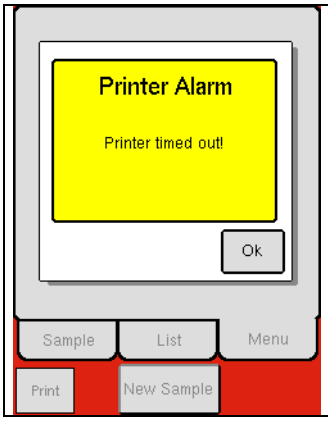
Description This section contains information regarding errors associated with printers, barcode readers and serial data communication.

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

12.1 Communication Issues (Continued)

	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 Print Mode is NOT set to '0'.	1. Auto Print Mode was turned off and not reset.

Barcode Issues See Section 4.3 Barcode Setup for further detail.

If	Then	Possible cause
Error message when trying to read ID on control vial.	1. Check control lot number is in system. 2. Verify that lot of control being used has been entered in correctly from supplied CBD.	1. CBD from new lot of controls has not been scanned in. 2. Control has expired. 3. CBD scanned in incorrectly.
Error message when trying to read ID on sample vial.	1. Verify that correct barcode format has been selected.	1. New barcode was connected but did not match instrument setup.

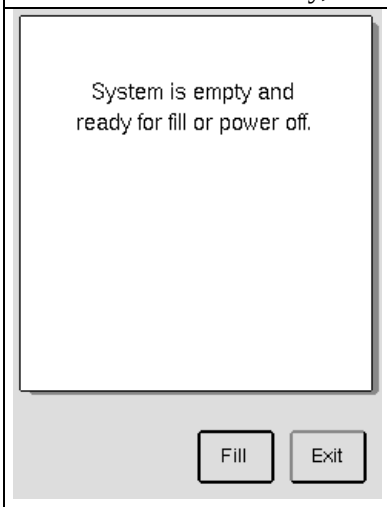
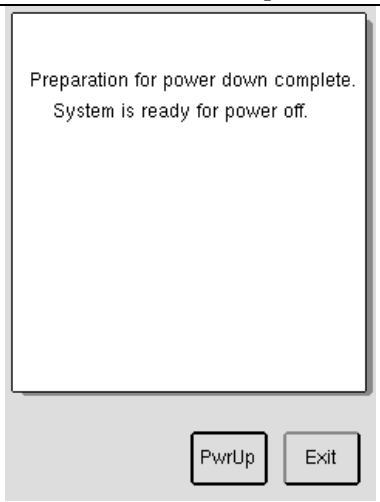
12.2 General Information Displays

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.

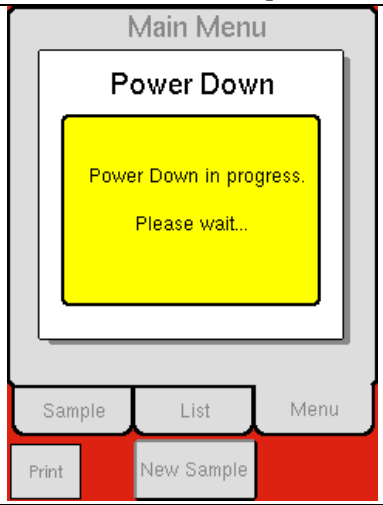
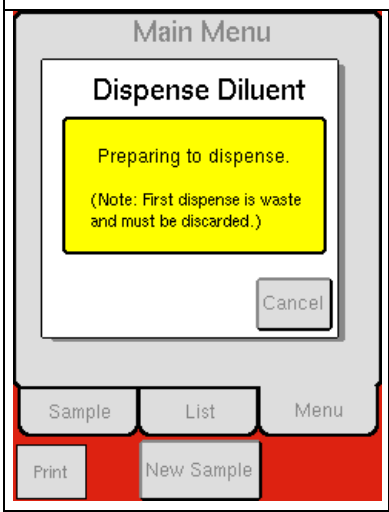
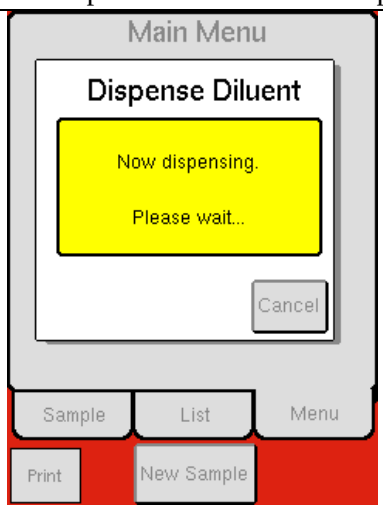
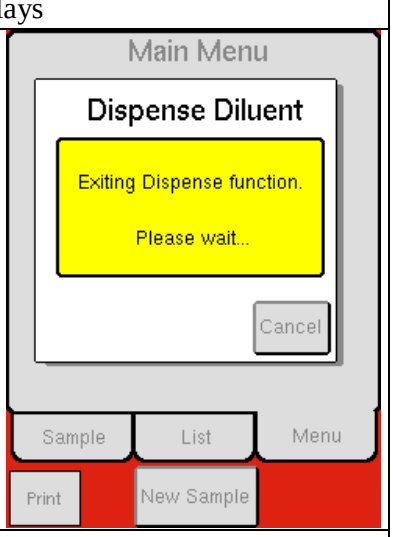
Continued on next page

12.2 General Information Displays (Continued)

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.
		
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.

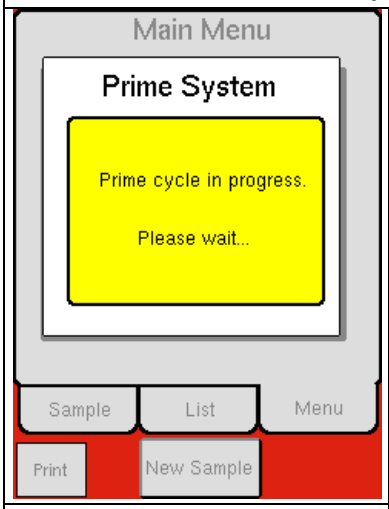
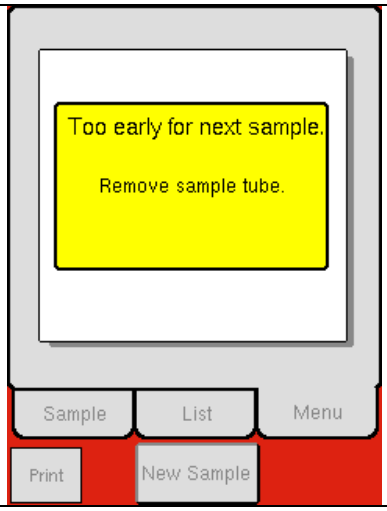
Continued on next page

12.2 General Information Displays (Continued)

<table>
<tr><td colspan="3">Standby, Power Down, and Power Up Informational Displays</td></tr>
<tr>
<td>
</td>
<td>
</td>
<td>
</td>
</tr>
<tr>
<td>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.</td>
<td>The instrument is in process of powering down. Please wait.</td>
<td>The instrument is in process of powering up. Please wait.</td>
</tr>
<tr><td colspan="3">Diluent Dispense Informational Displays</td></tr>
<tr>
<td>
</td>
<td>
</td>
<td>
</td>
</tr>
<tr>
<td>The instrument is preparing to dispense diluent. Dispose of first dispense for best results.</td>
<td>The instrument is now dispensing 4.5 ml of diluent. Please wait.</td>
<td>The instrument is exiting dispense function. Please wait.</td>
</tr>
</table>

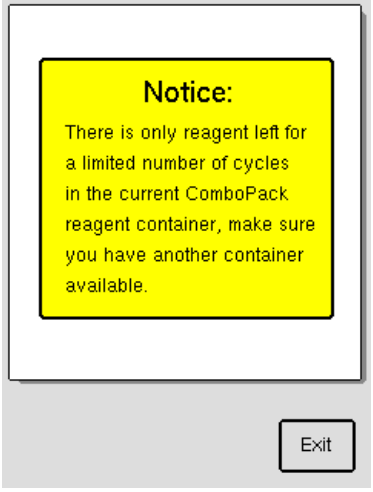
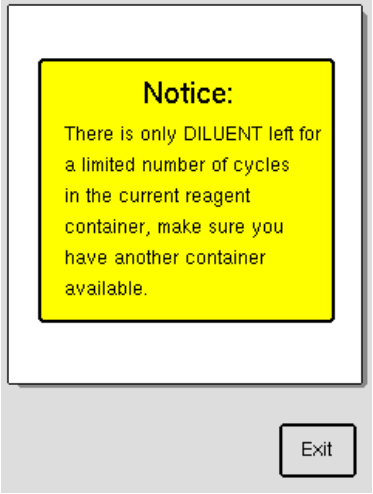
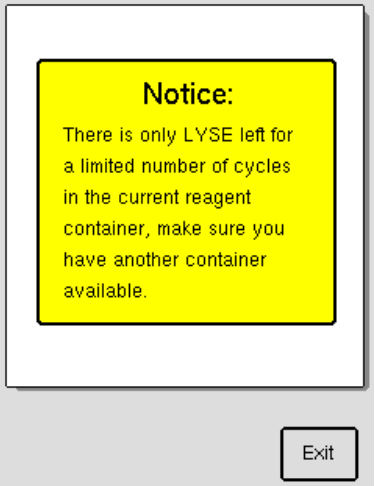
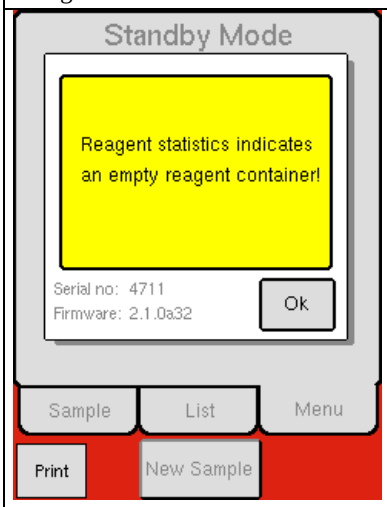
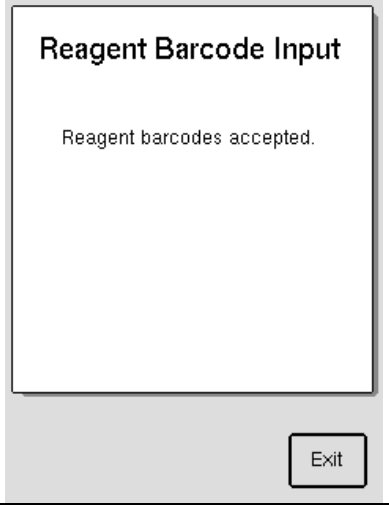
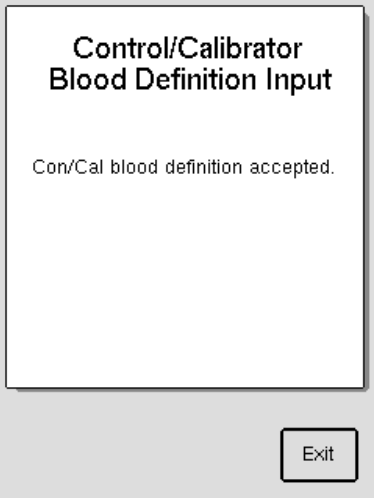
Continued on next page

12.2 General Information Displays (Continued)

Cycle In Progress Informational Display		
		
The instrument is priming the system. Please wait.	The instrument is filling the system. Please wait.	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.

Continued on next page

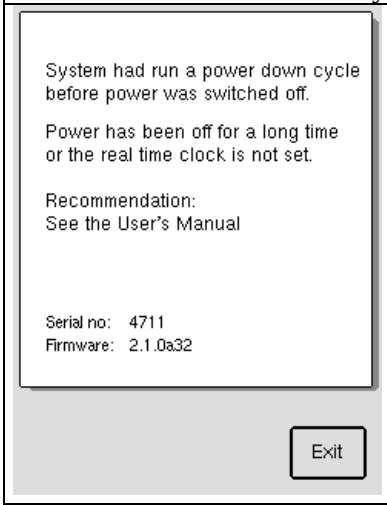
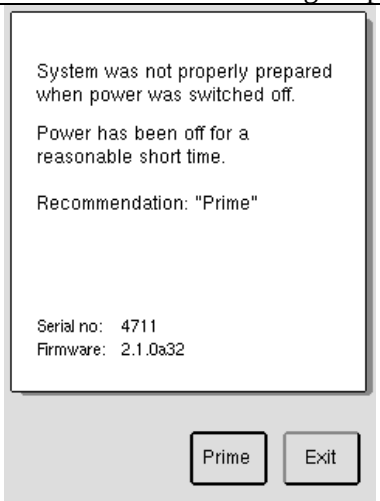
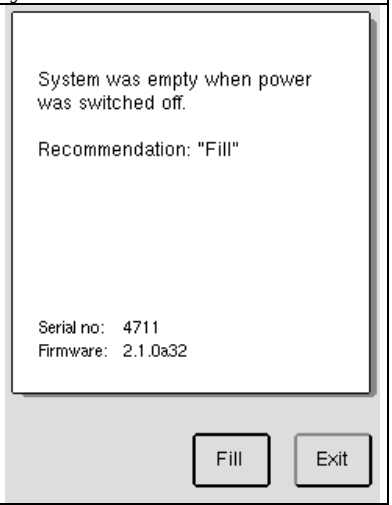
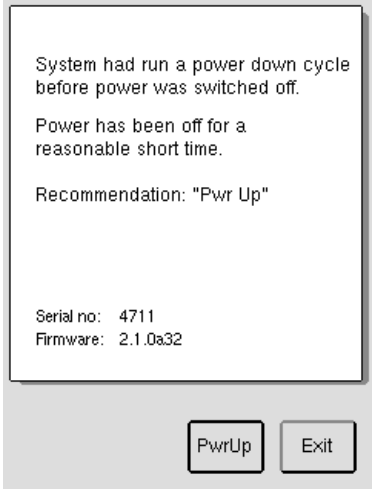
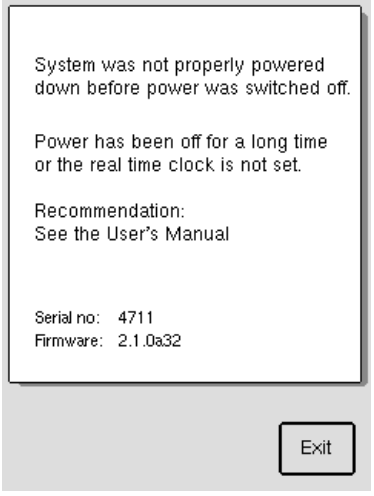
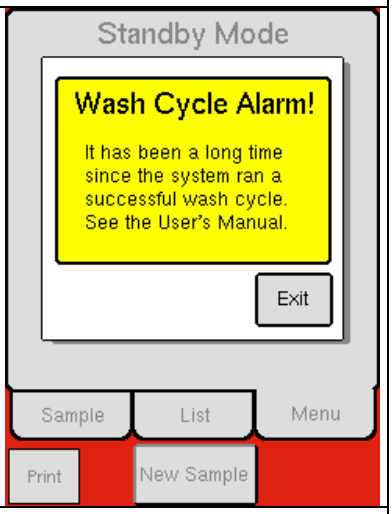
12.2 General Information Displays (Continued)

Reagent and Control Informational Displays		
		
Instrument displays this notice to inform operator that ComboPack reagents will soon need to be changed.	Instrument displays this notice to inform operator that Diluent reagent will soon need to be changed.	Instrument displays this notice to inform operator that Lyse reagent will soon need to be changed.
		
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.	The reagent barcodes were scanned in correctly using the barcode reader and the instrument has accepted the values.	The CBDs were scanned in correctly using the barcode reader and the instrument has accepted the values.

12.3 Warning Displays

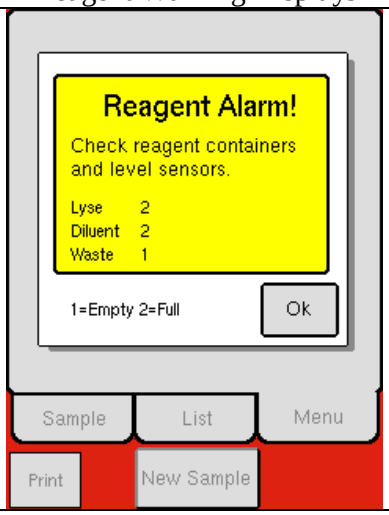
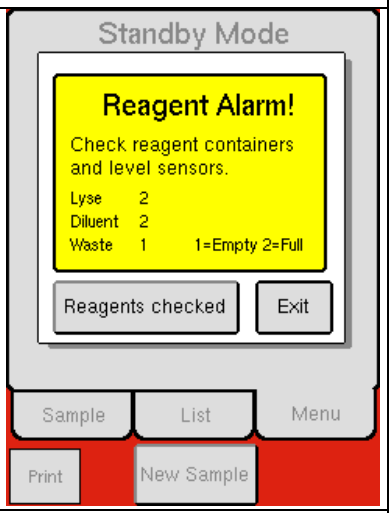
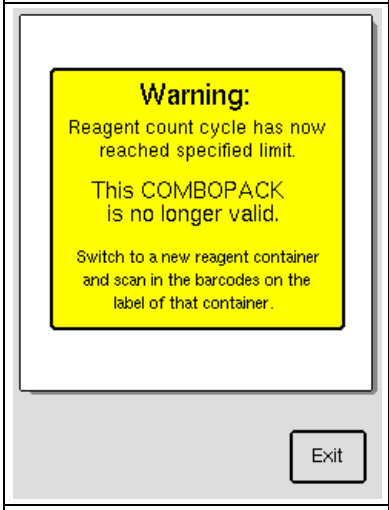
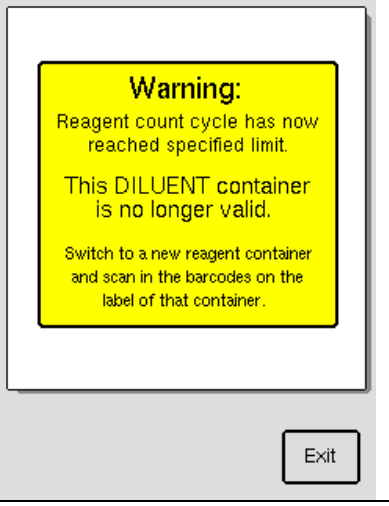
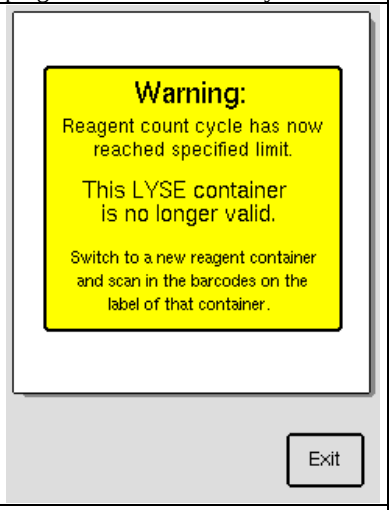
Warning Displays

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>

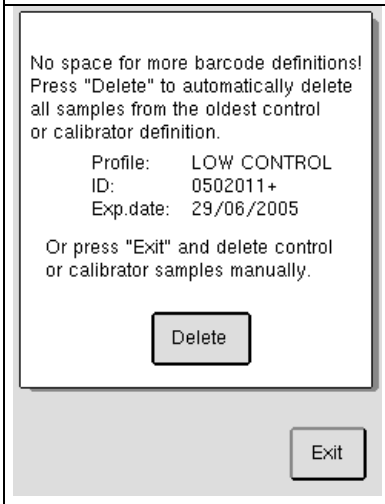
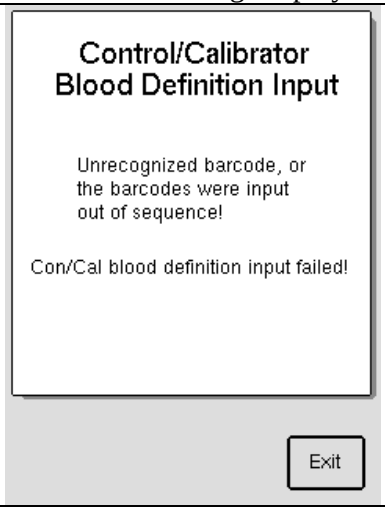
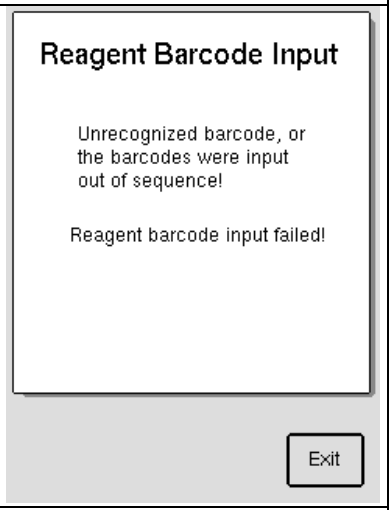
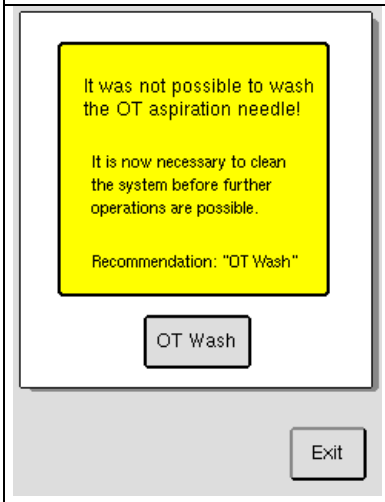
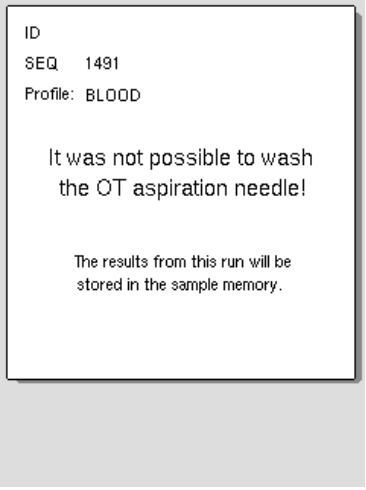
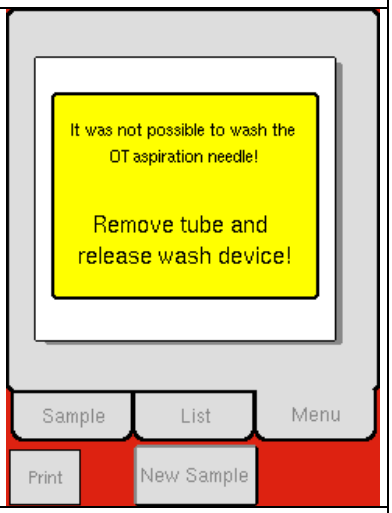
Continued on next page

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 preformed. 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.</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.</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.</td>
</tr>
</table>

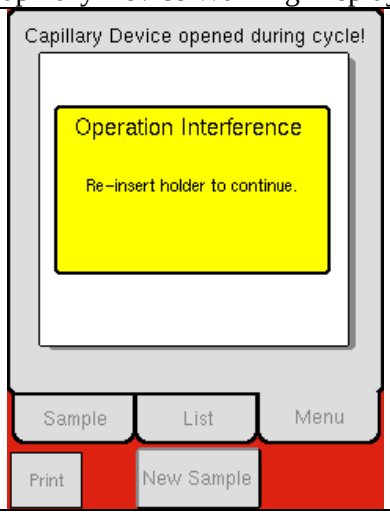
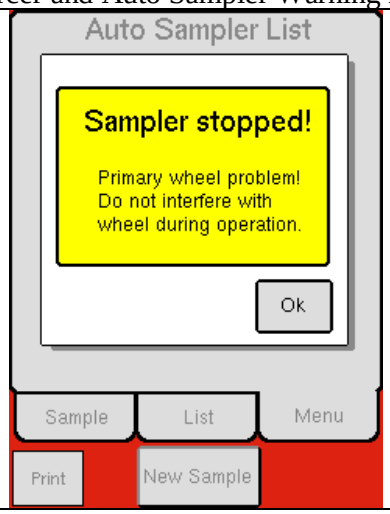
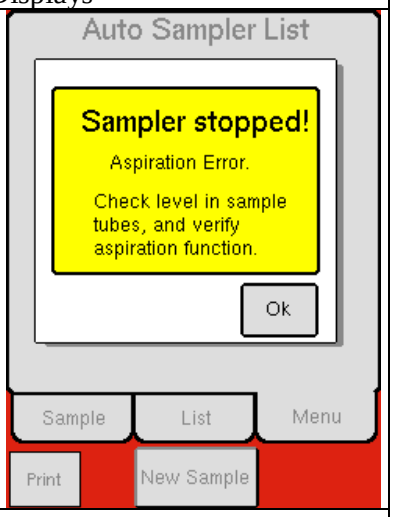
Continued on next page

12.3 Warning Displays (Continued)

<table>
<tr><th colspan="3">Barcode Warning Displays</th></tr>
<tr>
<td>
</td>
<td>
</td>
<td>
</td>
</tr>
<tr>
<td>No more space is available to scan in new CBD. Follow the recommendation or manually delete all the controls with same ID, to free space for scanning the new CBD.</td>
<td>CBD barcode scanning failed. The CBD 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.</td>
<td>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.</td>
</tr>
<tr><th colspan="3">Open Tube Warning Displays</th></tr>
<tr>
<td>
</td>
<td>
</td>
<td>
</td>
</tr>
<tr>
<td>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.</td>
<td>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.</td>
<td>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.</td>
</tr>
</table>

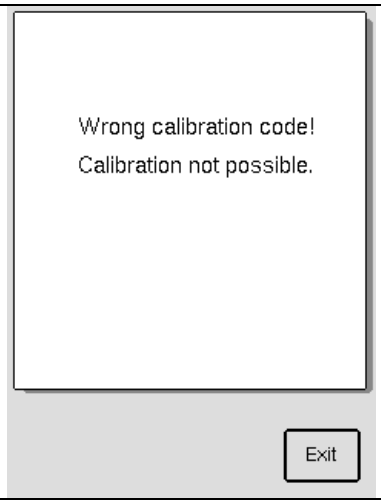
Continued on next page

12.3 Warning Displays (Continued)

Capillary Device Warning Displays		
		
The MCI was opened during an inappropriate time. It is recommended to perform a prime cycle before next analysis.	The MCI was opened during a cycle or analysis. Re-insert holder, and follow suggested recommendation.	The MCI holder was opened during an inappropriate menu. The MCI holder should only be opened in List, Sample or Main menu.
Cap Piercer and Auto Sampler Warning Displays		
		
The Cap Piercer door was opened before the CAP door lock had been activated. Close the Cap Piercer door to continue with the analysis.	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 Auto Sampler List Menu.	Three aspirations have been attempted. All have failed. Verify that sample tubes contain at least 1 ml of blood.

Continued on next page

12.3 Warning Displays (Continued)

		
A counting error has been detected in Auto Sampler mode. Verify that tubes are in correct position and order.	Incorrect calibration code was entered. See calibration section in User's Manual.	

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.Suggest performing 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 A for other possible issues that may arise. Areas on Flowcharts highlighted in dark grey should only be performed by service technician or authorized personnel.

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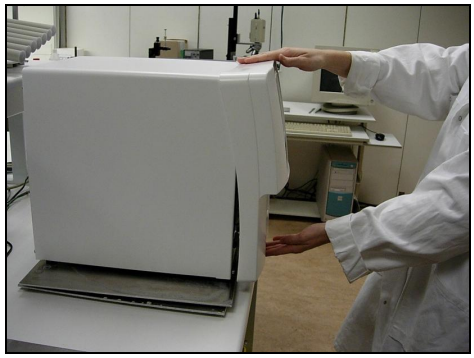
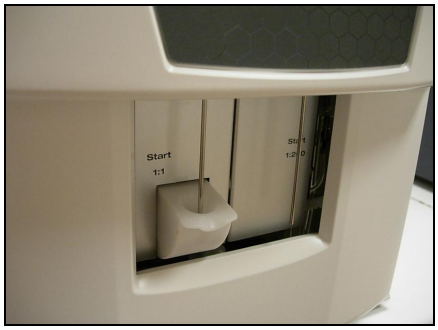
X

X-B function 47

Appendix A

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.

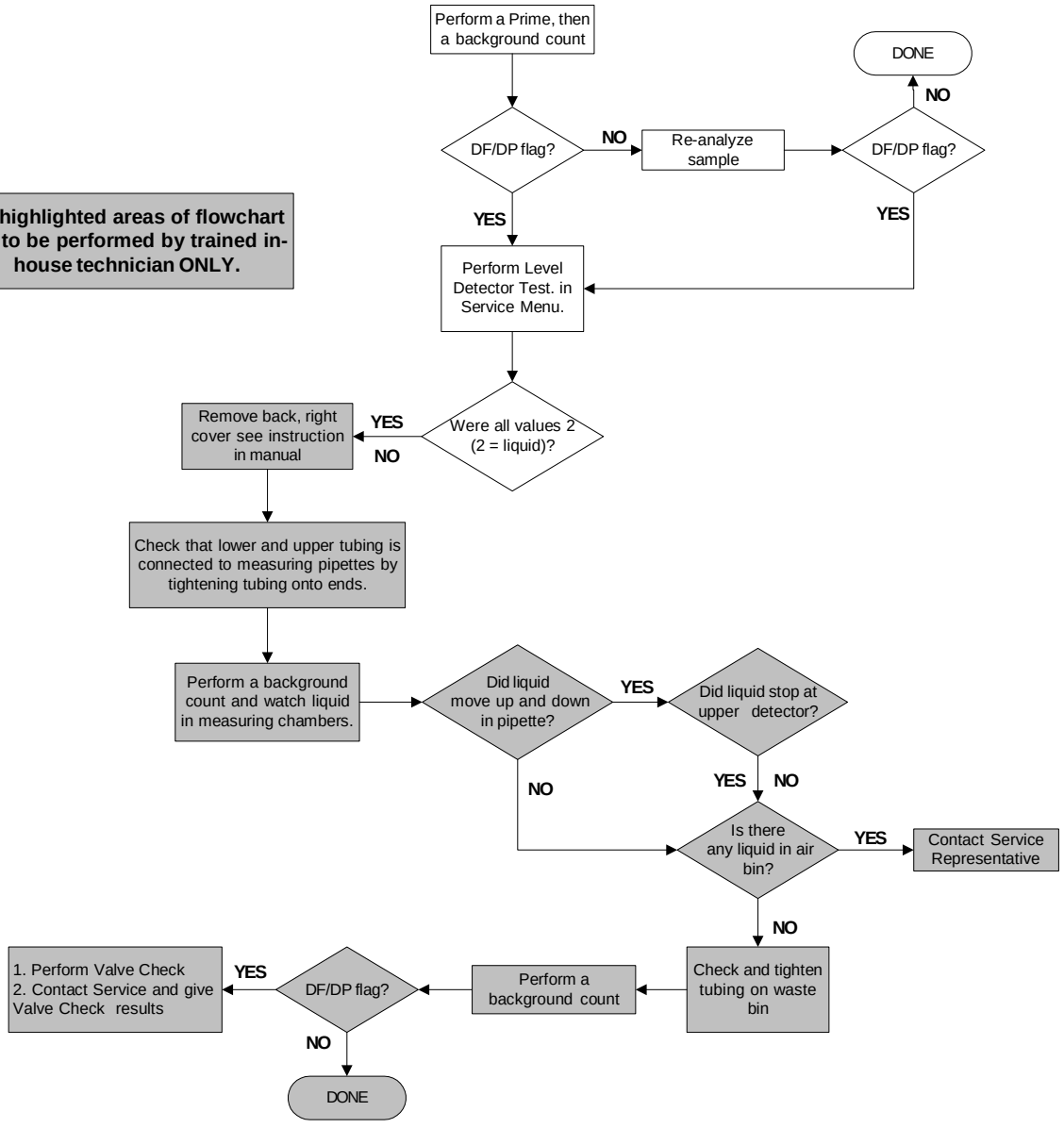
CLOT REMOVAL PROCEDURE (Continued)

Step	Action
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.
2	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.)
3	Locate the Valve 27, the lower valve directly to the left of shear valve.
4	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.
5	From Main Menu press [ADVANCED] and then press [SERVICE].
6	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.  Figure 13.5  Figure 13.6
7	Thoroughly flush tubing with Hypochlorite Solution until all obstructions are removed.  Figure 13.7
8	Disconnect syringe and reattach L connector to valve tubing.
9	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.
10	Once cover it replaced Exit out of Service menu. Press [MAINTENANCE] and then perform two Clot Prevention cycles following instructions above.
11	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.

DF or DP ERRORS

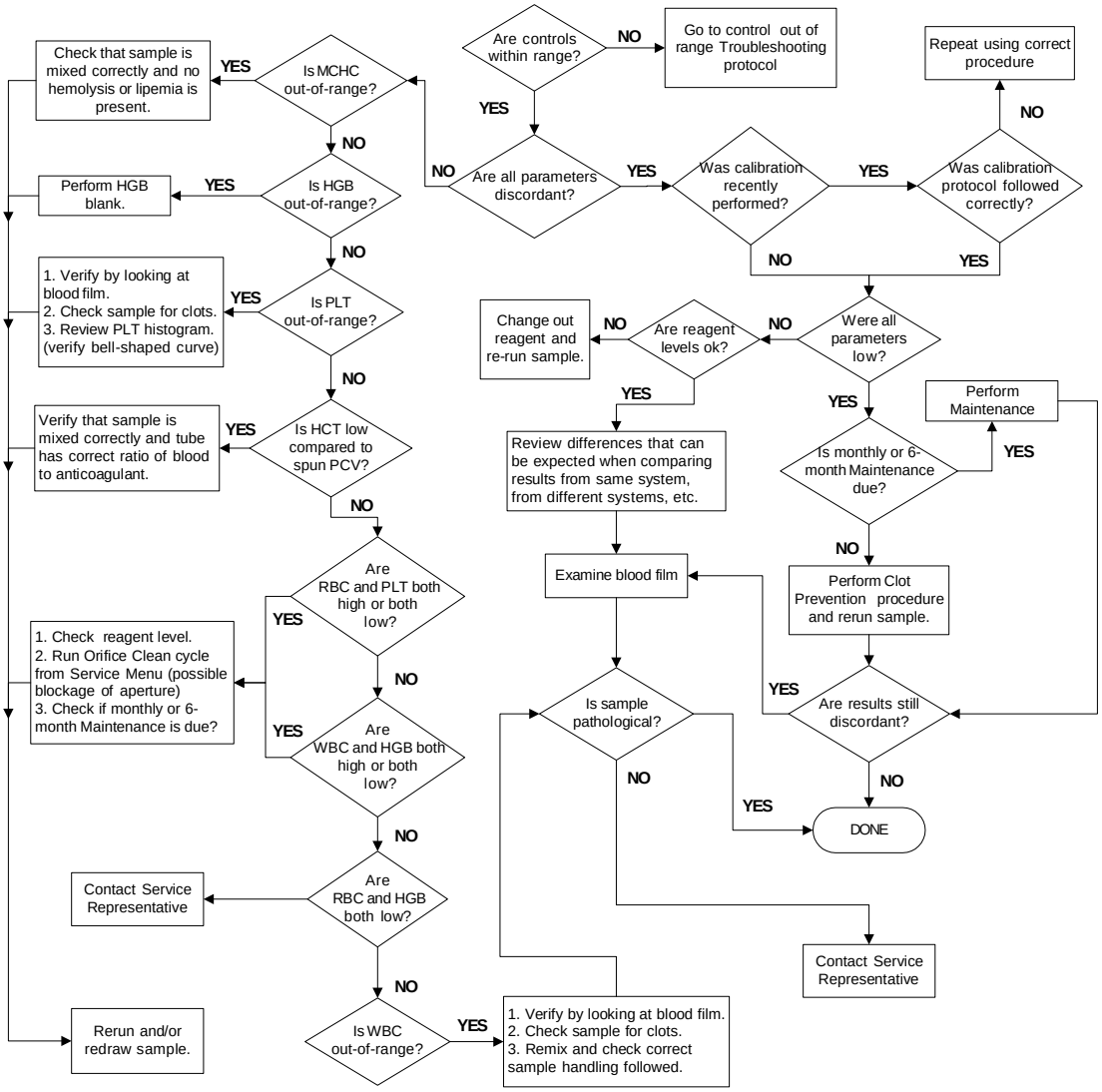
Check for the following:
1. Level detector connection to back of analyzer are tight.
2. Leakage under instrument.
3. Level detector inserted correctly into box.
4. No pinch or kink in level detector

All highlighted areas of flowchart are to be performed by trained in-house technician ONLY.



Discordant Results

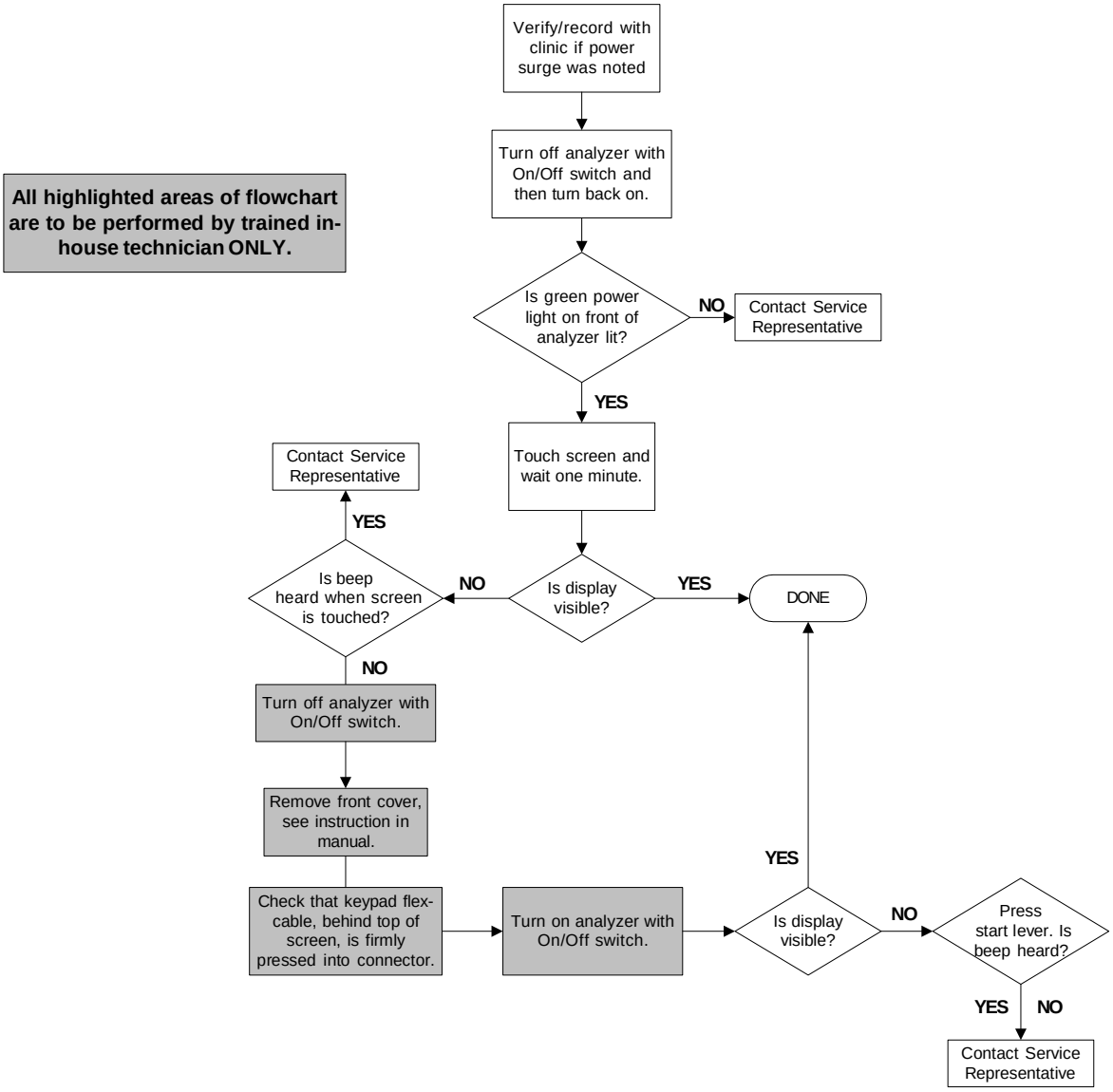
Questions to ask:
1. Was sample collected and handled properly?
2. Was the same sample used for both in-house and outside lab analysis?
3. Different blood draw and/or different tube?
4. Could the sample have been switched with another patient?
5. Could discordance be due to age changes during shipping or time periods between blood draw and analysis (RBC swelling, platelet clumping, deterioration of WBC for differential)?



Display Issues

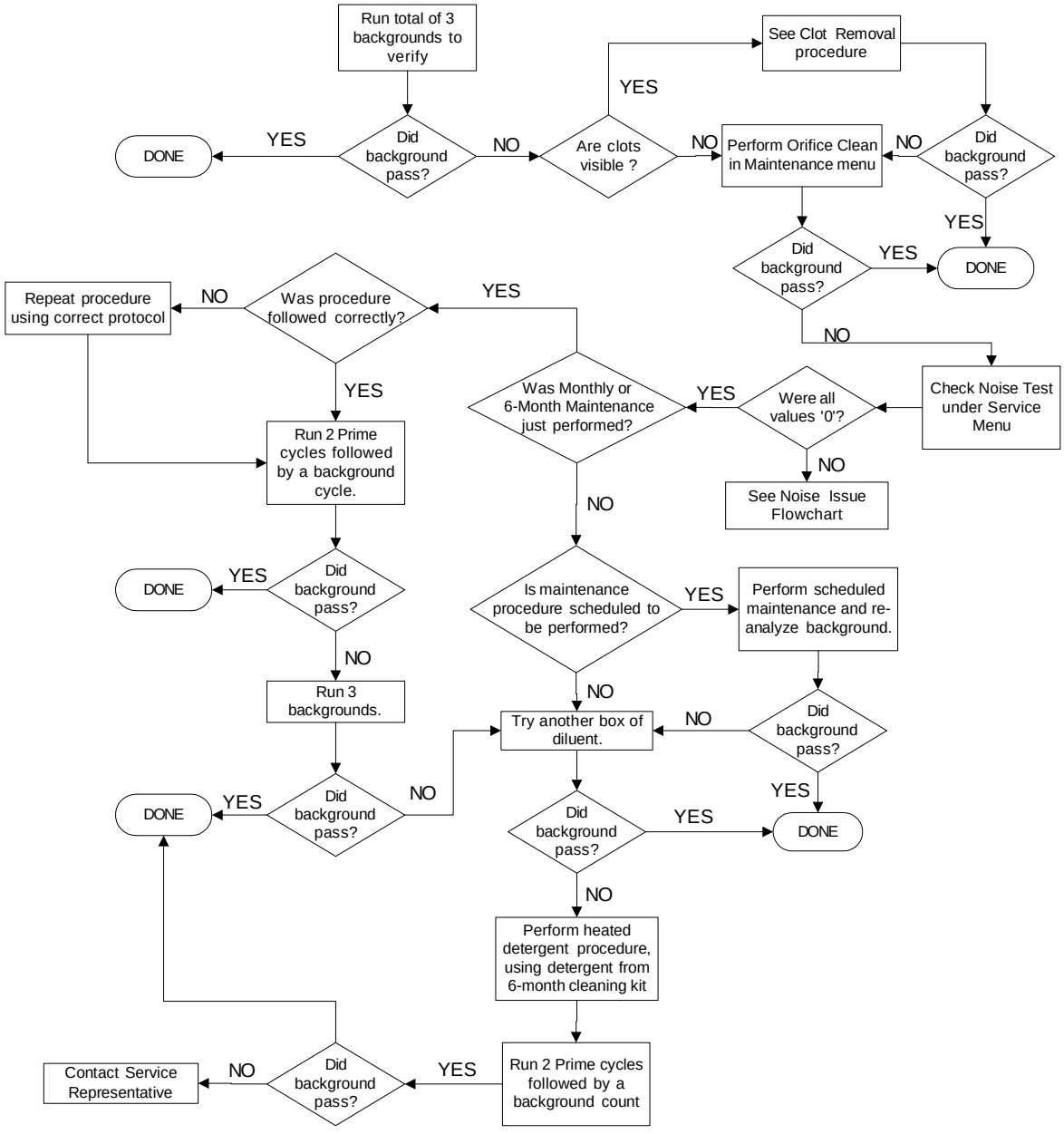
Usual Cause:
1. Keypad flex-cable loose
2. Static electricity
3. Power Outage/Lightening

All highlighted areas of flowchart are to be performed by trained in-house technician ONLY.

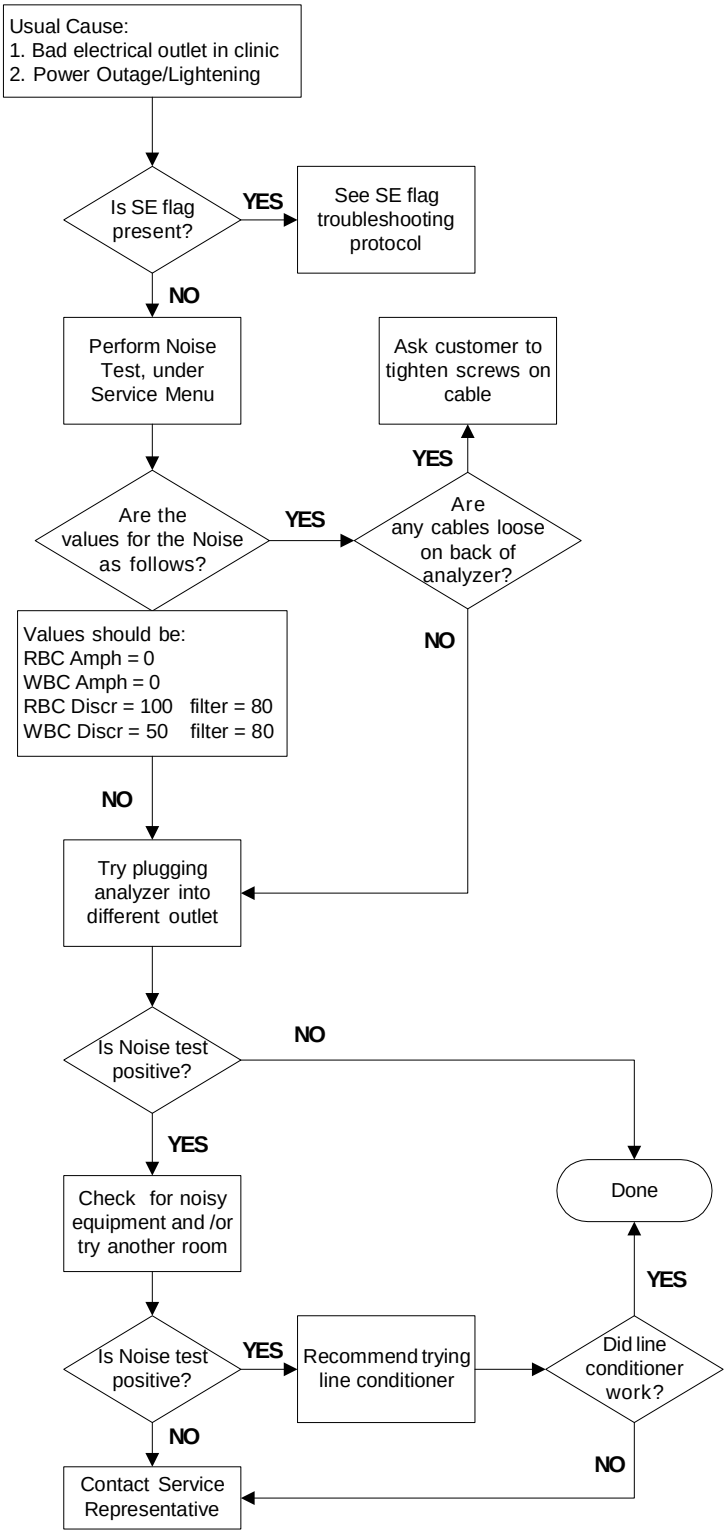


HIGH BACKGROUND COUNTS

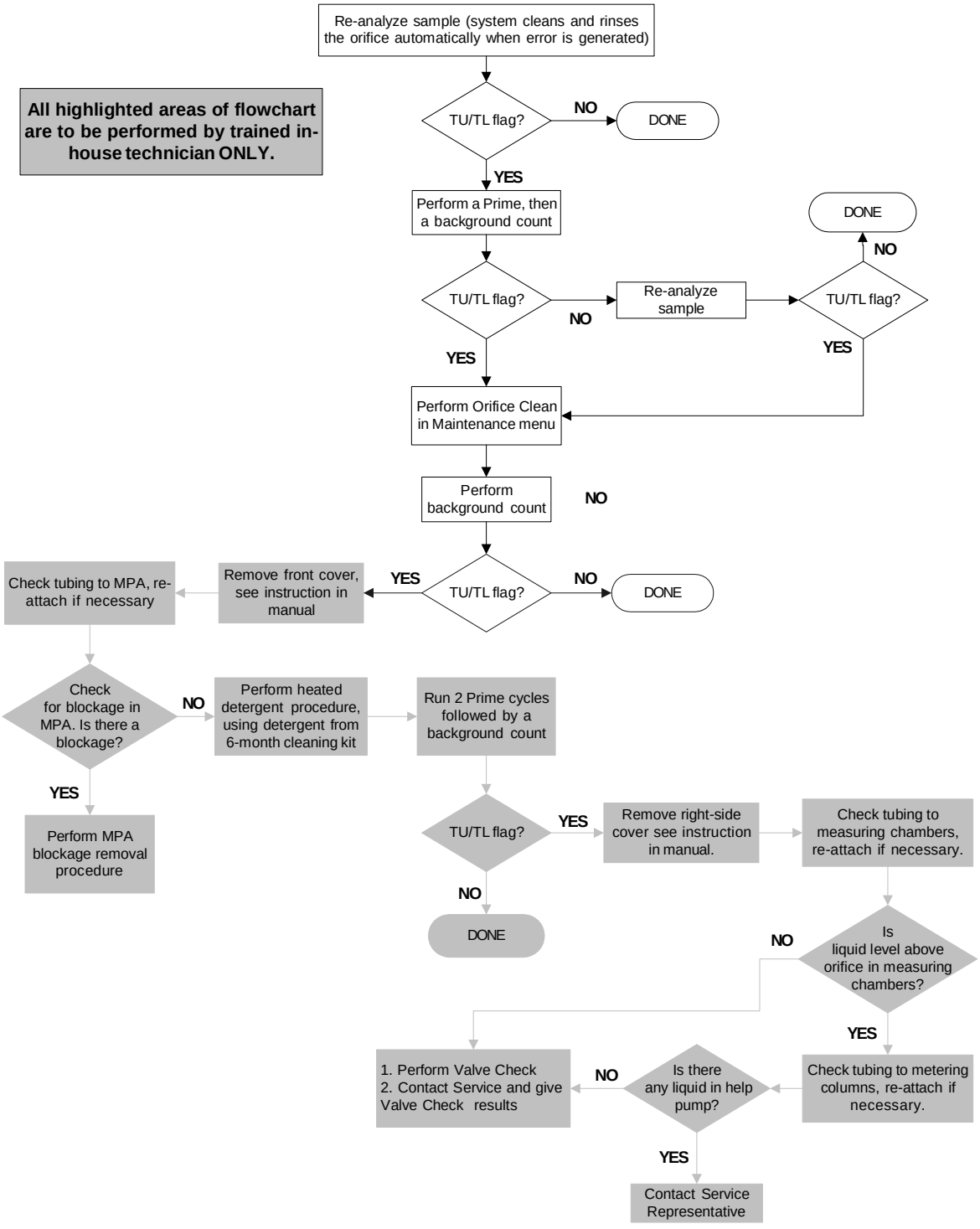
Initial Procedure:
1. Check Diluent Lot Number and expiration date.
2. Check age of Diluent (i.e. when was it opened?)
3. Check that level sensors are pushed all the way to the bottom of the reagent containers and firmly tightened on back of analyzer.
4. Check that level sensors are in correct reagent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



Noise Issues



TU or TL ERRORS





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