Swelab AC970^{EO+}/AC920^{EO+}



User's Manual

SWELAB

Swelab AC920 $^{\rm EO+}$ Swelab AC920 $^{\rm EO+}$ with cap piercer Swelab AC970 $^{\rm EO+}$



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Preface

Name of product, serial number and software version

This manual describes:

This manual describes Swelab's fully automatic AutoCounters, AC970EO+ and AC920EO+. Read the user's manual carefully to obtain correct information about using the instrument.

The [7 Service menu] is not described in the user's manual, refer to the Service manual for the whole description.

The serial number is found on the serial plate on the rear panel of the instrument. Software version is displayed on the Service menu in the upper left corner of the display, see picture below marked "A".



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Other documentation related to this manual

Additional applications and notes, as well as service manual, product data sheets on reagents, controls and calibrators are available from your local distributor and listed on the <u>www.boule.se</u> support server <u>www.swelab.com/extranet</u>, which is exclusively available to your authorized distributor.

Operator training

Additional operator training is not required under the following conditions:

- 1. The operator must have basic skills in working under laboratory conditions.
- 2. The operator must have basic skills in hematology.
- 3. The operator must read and understand this manual.

Component lists, tools and other consumables

These are listed, including their special functions, in the Service Manual.



Name and address of manufacturer

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http://www.boule.se

http://www.swelab.com

Name and address of distributor

All Boule Medical's distributors will be referred to Boule's web site:

http://www.boule.se/medical/distributors_swelab.shtml If anything is unclear, please contact Boule for further information.

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)

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1 Safety Instruction

1.1 Intended Use

The Swelab AutoCounters are fully automated hematology cell counters used for human in vitro diagnostic testing of EDTA-whole blood samples. The Auto-Counters are designed to measure up to 19 parameters using whole blood dispensed into diluent.

1.2 Intended user

Boule sells the Swelab AutoCounters for professional use via distributors. All distributors are being authorized by Boule Medical in form of education about sales, service and operation of the Swelab AutoCounter program.

The distributors have the responsibility to install the Swelab AutoCounters properly and to educate the final customer in using the instrument in accordance to the User's Manual.

1.3 Counter Indications

- Do not use the instrument outdoors. Usage outside the specified temperature and humidity range might result in instrument malfunction or short circuit.
 Turn off the power immediately and contact your Service Department.
- Do not modify the instrument. Modification without written instructions from the manufacturer might cause erroneous results or risk for electrical shock.
- Do not remove the cover. Handling inside the instrument can result in electrical shock. Only authorized service personnel are allowed to open the instrument.
- Do not use the instrument for other purposes than indicated in this manual. Use for other purposes might impair the safety of the instrument.
- Do not operate the AutoCounter with the instrument door open.

1.4 Warranty Limitations

The AutoCounters are guaranteed to be free of defects in workmanship and materials under normal use for a period of one year from date of delivery to the distributor in the country.

The liability of Boule is limited to repair or replacement of parts and in no event shall Boule be liable for any collateral or consequential damages or loss. Instruments subjected to misuse, abuse, neglect, unauthorized repair or modifications are excluded from this warranty.

All warranty claims must be directed to the distributor responsible for the sale and service of the instrument on the local market. Boule will accept no responsibility for injury to person caused by misuse, abuse, neglect, unauthorized repair and modifications and negligence to read the manuals.

Only personnel educated and authorized by Boule are permitted to give service to Swelab AutoCounters.

• Service and extensive instrument maintenance, not described in this manual, must be performed by Boule or authorized service personnel.

• Use only original spare parts and by Boule authorized reagents, control blood, calibrators and cleaners.

Boule has designed the Swelab instruments as systems for optimal performance. Substituting reagents, calibrators, controls, and components not recommended by Boule may adversely affect the performance of the instrument. If the substituted products are defective or adversely affect the performance of the instrument it may void your warranty. Each Swelab system is tested at the factory using our recommended reagents, calibrators and controls, all performance claims are generated as part of this complete system.

• System operators and laboratory supervisors are responsible that Boule products are operated and maintained in accordance to the procedures described in the Product Labelling (manuals, package inserts and bulletins of any kind). They are also responsible for determining that product performance conforms to the applicable claims.

If, under these prescribed conditions of operation and maintenance, an aberrant or abnormal result occurs, as defined by the laboratory protocol, laboratory personnel should first make certain that the system is performing and is being operated in accordance with the Product Labelling. The laboratory protocol should then be followed to advise the clinician in case a result appears to have deviated from the norms established by the laboratory.

Boule products do not make diagnosis on patients. Boule intends its diagnostic products (systems, software and hardware) to be used to collect data reflecting the patient's hematological status at a certain point of time. Such data may be used in conjunction with other diagnostic information and with the attending physicians evaluation of the patients condition to arrive at a diagnosis and a clinical course of treatment.

1.5 General Warnings

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.

- Follow the procedures described in the User's Manual.
- Observe all warnings and notes.

Electrical hazard

- Do not spill blood, reagent, drop metal objects such as wire staples or paper clips into the instrument. This might cause a short circuit. If this should occur, turn off the power immediately and contact your service department.
 Note: The cover should only be opened/removed by authorised service personnel.
- Do not touch the electrical circuits inside the cover. There is a hazard of electrical shock.
 Note: The cover should only be opened/removed by authorised service personnel.

Piercing Hazard

Always excercise caution when handling and servicing the Cap Piercer. Handling and operation by unauthorised personell may result in injury.

The Cap Piercer houses a needle which is pushed upwards during use.

- Keep hands away from the needle while operating the Cap Piercer.

Potentially biohazardous material

Because no test method can offer complete assurance that HIV, Hepatitis B or C viruses, or other infectious agents are absent, these products should be handled at the Biosafety Level 2 as recommended for any infectious human blood specimens in Protection of Laboratory Workers From Infectious Disease Transmitted by Blood, Body Fluids and Tissues- 2nd Edition, Tentative Guidelines(1991) Document M29-T2 promulgated by the National Committee for Clinical Lab. Standards in the U.S.A. (NCCLS).

Contamination hazard

Always wear protective gloves when operating, handling and servicing the Swelab AutoCounter.

- Handle samples with great care.
 There is a risk of infection if contaminated blood splashes.
 If blood splashes, enter your eye or a cut, wash it off with plenty of water.
- Do not touch the waste liquid when discarding waste or disassembling/assembling the related parts outside the instrument. Risk of infection from contaminated blood.
 If you should touch the waste liquid inadvertently, wash off with disinfectant first, then wash it off with soap.
- When handling reagents.

- If a reagent happens to enter your eye, wash it off immediately using plenty of water and take action to seek medical treatment at once.

- If it happens to adhere to the hand or skin of other body parts, wash it off using plenty of water.

- If you should swallow it inadvertently, take action to seek medical treatment at once.

1.6 Emergency Procedure

In case of emergency due to an obvious malfunction of the instrument e.g. smoke or liquid coming out from the inside, proceed as follows:

1. Switch off the instrument immediately by: Turning the ON/OFF-Switch to OFF.



2. Disconnect the instrument immediately by:

Pulling out the mains cord from the power supply.

3. Contact your authorized distributor's service department immediately.



1.7 Warning Signs in Manual

These warning signs in the manual are used to identify possible hazards and to call the operators attention to the existence of this condition.

These warning signs in the manual are used to identify the possible hazards and to call the operators attention to the existence of this condition. If the warning signs are not observed it could result in personal injury, instrument damage and/ or test results for inaccuracies. The **Note!** symbol is used to increase the work efficiency.



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- 1. This label indicates that the safety instructions in the manual must be read before operating the instrument. See **Piercing Hazard** on page 9.
- 2. This label indicates potential bio hazard due to blood exposure or possible contaminated waste.
- 3. Serial Number, Voltage/Fuse specifications and CE markings

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			8 I	Low control, 16 parameters		GB	Calibrator
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2 Specifications

2.1 Short-List of Specifications

Number of	10	RBC, HCT, MCV, HGB, PLT, MPV, WBC, RDW%, MCH, MCHC, MCH			MCHC,MCHC		
parameters:	neters: Incl. KbC- PLI- and WBC-histograms $18 = 10 + PCT PDWI VM\# I VM% MID# MID% CPA# C$			$C \mathbf{P} \mathbf{A}^{0}$			
	10	18 + EO# incl. histogram			UNA /0		
	AC970EO+	AC920EO + -	AC920EO+ -				
	no,, olo	0, -1	2, -3				
Aspiration volume:	20 µl	20 µl	20 µl	Prediluted blo	ood volume		
	200 µl	200 µl	160 µl	Open tube vo	lume		
	400 µl	350 µl		Closed tube v	olume		
Sample volume:	20 µl	20 µl	20 µl				
Cycle time:	89s/analysis	89 s/analysis	89 s/analysis	Prediluted cyc	cle		
	85s/analysis	85 s/analysis	85 s/analysis	Open tube cy	cle		
	100s/analysis	90 s/analysis		Closed tube c	ycle		
Reagent volume/sample:	25 ml	25 ml	25 ml	Diluent reagent			
	3 ml	3 ml	3 ml	Hemolysing r	eagent		
	1.5 ml	1.5 ml	1.5 ml	Detergent	Detergent		
	4.5ml	4.5ml	4.5ml	EO reagent			
Dimensions:	40/45/34 cm	33/43/34cm	33/43/34cm	W/D/H			
Weight:	19 kg	16 kg	16 kg				
Discriminator:	Floating discri	minator RBC/1	PLT				
	RBC x $10^{12}/1$	HGB g/l	PLT x10 ⁹ /1	WBC x10 ⁹ /1	EO x10 ⁹ /1		
Linearity range:	1.00-9.90	25-400	50-999	0.5-99.0			
Measure range:	0-12.0	0-999	0-2000	0-99.9	0-9,99		
Background:	≤0.02	=0.0	≤10	≤0.2	≤0.10		
Precision at normal levels	RBC ≤2%		HGB≤2%	WBC ≤ 3%			
(CV):	$PLT \leq 5\%$		$MCV \leq 2\%$	$EO \le 5\%$ at 0.4 x $10^9/l$			
Dilution ratios:	WBC/HGB	1/400					
	RBC/PLT	1/40 000					
	EO	1/225					
Principles:	Dilution and c etry at 555 nm	ell counting by : 	aperture imped	pedance method.HGB determination by photom-			
Orifice:	70 µm						
Carry-over:	< 2%						
Voltage:	$230 V \pm 10\%$	or $120V \pm 10\%$ Frequency: 50/60 Hz					
Power:	150 VA						
Operation condition:	Temperature:	18°C to 32 °C		Rel. Humidity	r: <80%		
Storage temp.:	5 °C to 40 °C						
Noise level:	<65 dBA (measured from the front of the instrument, a height of 1.6 m and a distance of 1.0 m)						
QC-program:	Yes						
QC-memory:	800 controls w	vithout histogra	ms				
Sample memory:	600 samples w	rith histograms					
Printer:	External IBM,	DPU411-2/D	PU414 (The pr	inter must con	nply with stand	ard: EN 60950)	
Barcode/keyboard:	Option		_				
Interfaces:	Parallel centro	nics, serial RS2	32C				
Language:	In compliance with IVD-directives						



Reagent consumption/year

Samples/ day	Samples/ year	AC- type	Diluent	Lyse	Detergent	Cleaner
10	2.200	AC970EO+/AC920EO+	4 x 20 l	2 x 5 l	1 x 5 l	4 ml/day
20	4.400	AC970EO+/AC920EO+	7 x 20 l	4 x 5 l	2 x 5 l	9 x 100 ml/
30	6.600	AC970EO+/AC920EO+	10 x 20 l	6 x 5 l	2 x 5 l	year
40	8.800	AC970EO+/AC920EO+	13 x 20 l	6 x 5 l	3 x 5 l	
50	11.000	AC970EO+/AC920EO+	15 x 20 l	7 x 5 l	3 x 5 l	
100	22.000	AC970EO+/AC920EO+	29 x 20 l	14 x 51	6 x 5 l	



Installation

Manufacturers recommendation

Installation of the instrument should be carried out by the authorized distributor.



Important

The following procedures must be followed exactly. Boule has no responsibility in case of faulty or erroneous installation. Possible errors that may occur are:

- Indication numbers •
- **Erroneous** parameter results
- Excessive service needs

3.1 Unpacking the instrument

The AutoCounter is packed as standard in a box.

Before the box is opened check for any physical damages on the outside and notify your carrier immediately in such case.

3.2 **Delivered** accessories

Unpack the instrument and check that the accessories listed below are included.

Lift the instrument from the box using the straps included.



Check that the AutoCounter and the accessories are not physically damaged. If there is any damage or accessories are missing, contact distributor and carrier immediately.

To move the AutoCounter:

Lift the instrument by holding onto the bottom plate on both sides.



AC970EO+.

The instrument front door might be damaged.



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List of included accessories

1. One power cable	1217.gif
2. Two main fuses T630 mA at 230V or T2A at 120 V	1221.gif
3. One Case Book, one User's Manual	1222.gif
4. One tubing for waste	1210.gif
5. Three lid covers with a hole	0 1212.gif
6.Three reagent sensors and tubing	1209.gif
7. One box with 100 beakers	1220.gif
8. Pump tubing (only for 970/920)	1243.jpg
9. Installation checklist	

Optional accessories (delivered only on request)



3.3 Working Conditions

Mains Supply Environment

The instrument should be operated at an indoor location only. The instrument is designed to be safe for transient voltage as defined in IEC 801-4.

In case higher transient voltage, or mains voltage that exceed + 10% of the marking at the serial number plate are expected (e.g. within tropical areas), a CVT (Constant Voltage Transformer, also called "Magnetic Stabilizer" or "Ferro-Resonant Transformer") must be installed to protect the instrument against damage.

An abrupt interruption of the power supply might damage the instrument. It may also cause loss of all calibration constants and other parameters necessary even if the instrument is protected against power supply loss.



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.



Warning Electrical shock hazard

The instrument must only be connected to a grounded power supply. Violating this, might result in injuries and/or loss of life and/or erroneous parameter results.



3.4 First Start-Up



The rear panel

- 1. Keyboard
- Barcode reader
- Transport fixing 5.
 Ground connection 8.
- Printer parallel port 6.

Waste

2.

11.

Detergent 9.

3.

- Computer serial port Power cable
- Lyse
- 12. Power switch

13. Fuse box

10. Diluid

Checklist

- □ Check that the voltage and the frequency on the instrument's data plate corresponds to the voltage of the electrical supply and that ground connection is available.
- □ The detergent should always be placed at the same level as the AutoCounter.
- □ The isotonic diluent and hemolysing reagent should always be placed below the AutoCounter.
- **□** Remove the transport fixing (no. 4 see picture above) for the air pump.

Follow the instructions below.

- Remove the reagent tubing plugs on the rear panel (no. 8-11).
- Connect:

-the isotonic detergent tubing and the electric plug, marked green, to the position marked DETERGENT (no. 8)

-the hemolysing reagent tubing and the electric plug, marked white, to the position marked LYSE (no. 9).

-the isotonic diluent tubing and the electric plug, marked red, to the position marked DILUID (no. 10).

-the waste tubing, marked black to position marked WASTE (no. 11).



Always keep the liquid containers well protected from dirt and dust. Use the supplied covers. Whenever possible, supply the Auto-Counter directly from the original containers. Transfer into secondary bottles always contaminates the solution resulting in increased background counts.

Never add remaining reagent from one container to a new container. Never refill a used container with fresh reagent.



Mandatory action Always use protective gloves whenever working with the waste container and the waste tubing.

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Warning Contamination hazard

Because no test method can offer complete assurance that HIV, Hepatitis B or C viruses, or other infectious agents are absent, the waste should be handled at the Biosafety Level 2 as recommended for any infectious human blood specimens in Protection of Laboratory Workers From Infectious Disease Transmitted by Blood, Body Fluids and Tissues- 2nd Edition, Tentative Guidelines (1991) Document M29-T2 promulgated by the National Committee for Clinical Lab. Standards in the U.S.A. (NCCLS)

Waste connection

The instrument has an open waste outlet and can be connected to a central waste system within the laboratory. The waste outlet, or container, must always be at a lower level than the instrument. National and/or local regulations must be followed in all cases.

- Place the reagent sensors in their respective reagent containers. The reagent tubing is interconnected with the reagent level detector.
- Place the waste tubing in a waste container placed on the floor or directly to the sink according to local regulations.
 See **Disposal information** on page 68.
- Check that the tubing is not squeezed.
- Connect the power cable to the AutoCounter (no. 6) and switch it ON.

The internal power up program brings the instrument to home position.

The display shows that the instrument has no reagent.

-Return to the [Main menu] with the "MENU" key.

The "REAG LOW" lamp may flash until the system is completely filled with reagent.

When ready, the display shows the [Main Menu] and the "READY" lamp shows a green light.

When delivered, The Auto Counter is filled with a transport liquid. To make sure that the transport liquid is rinsed out, an [8.3 Start filling system] is needed.

□ In the [Main Menu] move to [8 Maintenance] with down-arrow key and press "ENTER". Move to [8.3 Start Filling system] and press "ENTER".

The AutoCounter fills the syringes and tubing automatically with the new reagents and rinses out the transport liquid.

□ Move to [8.1 Start a Prime cycle] and press "ENTER".

The AutoCounter carries out a prime cycle.

- □ Return to [Main Menu] with the "MENU" key and move to [6 Setup menu] to check that all pre-settings are OK.
- □ After a printer has been installed move to [6.12 Print all settings] and press "ENTER". Save the printout for later reference.

If Barcode, Keyboard, Computer and Printer will be connected (1-3 and 5) in the figure on page 18 see further information in the chapter: **Optional Accessories** on page 75.

When the pre-settings are OK the instrument is ready to analyse blood samples, see further information in chapter: **Routine Operation** on page 55.



4 Description of the AutoCounter

4.1 The probe and the AutoSampler panel



The probe panel AC920EO+ -0/-1

- 1. Adjustment knob for different tube lengths.
- 2. Cap piercer for whole blood in closed tubes.
- 3. **Pipette** for whole blood in open tubes.
- 4. Beaker holder of pre-diluted position.



The probe panel AC920EO+ -2 /-3

- 1. **Beaker holder** of pre-diluted position.
- 2. **Start plate** for whole blood measurement
- 3. **Pipette** for whole blood in open tubes.





The AutoSampler side of AC970EO+

- 1. The **White knobs** are used to release the sample plates from the driving units.
- 2. The **Driving units** are moving the plates round by friction force and according to instruction from the keyboard of the side panel.
- 3. The **AutoSampler** can handle 2 x 20 samples placed in the front and back sample plate.
- 4. The **Plate position detector** is used to detect and determine the plate position by reading the position chart on the back of the sample plate.
- 5. The **Tube detector** is used to detect sample tubes in the sample plate through the windows of the plate.
- 6. The AutoSampler is operated by the **AutoSampler keyboard** situated on the side panel.
- 7. The **AutoSampler cap piercer** in AC970EO+ is situated in a cover below the tube detector.



4.2 The front panel



The left side of the front panel

- 1. The **Air valve** is used to regulate the air pressure.
- 2. In Mixing beaker I (right) the primary dilution is prepared.
- 3. The remaining primary dilution in mixing beaker I, is transferred into **Mixing beaker II** (left) where it is mixed with hemolysing reagent.
- 4. The sample dilution is pulled into the **Measuring tube** by the vacuum pump and the cells are counted when they pass the orifice in the
- 5. Transducer.
- 6. The **Counting beaker** has nozzles for delivery of the secondary RBC/ PLT dilution and the hemolyzed WBC/HGB dilution. The same nozzles deliver the isotonic diluent used for rinsing the counting beaker between samples. The air used for mixing the secondary RBC/PLT dilution in the counting beaker enters via the bottom nozzle which is also the drain.
- 7. The lower part of the counting beaker is the HGB cuvette, fitted into the **HGB photometer**.





The right side of the front panel

- 8. The **Peristaltic pump** (left) delivers detergent for cleaning the cap piercer and the whole blood pipette and for lubricating the rotary valve.
- 9. The aspiration of blood and detergent through the cap piercer and the whole blood pipette is carried out by the **Peristaltic pump** (right).
- 10. The blood volume is determined by the **Blood sensor**. The whole blood volume required by the AutoCounter is approximate 200 µl using the whole blood pipette, approx. 350 µl using the cap piercer and approx. 400 µl using the AutoSampler.
- 11. The **Rotary valve** determines the blood volume, 20 µl, of the primary and secondary dilution.
- 12. Isotonic diluent syringe (left). The syringe is set to approx. 4 ml.
- 13. Hemolysing reagent syringe (right). The syringe is set to approx. 1.5 ml.

4.3 The rear panel



Rating plate

1. The power inlet i equipped with a filter and two fuses T630 mA at 230V or two fuses at T2A at 120V.

4.4 Keyboard

The keyboard is used to change or enter into the different programs and files.



Keyboard AC970EO+

Keyboard functions

The **"ENTER"** key is used to:

- Enter into a selected menu.
- Enter options within a file.

The left-, up-, down-, right-arrow keys are used to:

- Move forwards, backwards or sideways within a menu.
- Change digital position.

The + (plus) and - (minus) keys are used to:

- Switch a function on or off.
- Increase (+) or decrease (-) a numerical value.

The "START PreDilute" key is used in the [1 Measurement] to:

• Start the aspiration of a prediluted sample, a prediluted EO sample and a cleaning solution through the prediluted pipette.

The **"MENU"** key is used to:

- Return to the previous menu.
- Restore alarm indication.

The "START Whole Blood" key is used in the [1 Measurement] to:

• • Start the aspiration of a whole blood sample in an open tube using the pipette.

READY lamp:

- Green light=home position, ready to start next analysis.
- Red light=sample aspiration.
- No light=the time between aspiration and home position.

REAG LOW lamp:

• flashes red when the reagent level is low in any of the reagent containers. The reagent which is too low is indicated on the display all the time except during measurement.



AC970EO+, The Auto- Sampler

The AutoSampler functions

The"AUTO SAMPLE" key is used in the [3 Auto sampling] to:

• Start sampling from the tubes placed in the sample plate.

The "SINGLE SAMPLE" key is used to:

• Start aspiration of a single sample stepped into sampling position.

The **"STEP"** key is used to:

• Step to a sample tube, one position at a time.

The **"MIX"** key is used to:

• Mix the samples in the front and back plate.

5 Process Description

5.1 Aspiration process

The aspiration procedure of whole blood and prediluted blood is described in the **Blood count, closed tube (CT) AC920EO+** on page 57, **Blood count open tube (OT)** on page 57 and **Blood count, prediluted blood (PD)** on page 58.

5.2 Whole blood process

- 1. After the aspiration process, 20 µl blood is present in the sample channel of the rotary valve.
- 2. The rotary value is turned and the $20 \,\mu$ l blood is flushed into the mixing beaker no.1 together with 4 ml isotonic diluent (primary dilution 1/200).

At the same time the first portion, 1.5 ml of hemolysing reagent, is added to mixing beaker no. 2.

3. The primary dilution in mixing beaker no. 1 is mixed using air and thereafter a portion is aspirated into the rotary valve.

The rotary value is turned and $20 \,\mu$ l of the primary dilution is delivered together with 4 ml isotonic diluent into the counting beaker.

The RBC/PLT dilution (1/40 000) is mixed using air in the counting beaker. The dilution is pulled into the measuring tube by the vacuum pump and the RBC/PLT counting starts.

The cleaning cup below the pipette or the cap piercer, the cannula and the rotary valve are cleaned with isotonic detergent.

When the RBC/ PLT counting is ready the HGB blank is measured and the dilution is drained from the counting beaker.

- 4. The remaining dilution in mixing beaker no.1 is transferred into mixing beaker no. 2 with a second portion of hemolysing reagent and mixed using air. While the RBC and PLT are counted the hemolysed WBC/HGB dilution stays in mixing beaker no. 2.
- 5. The WBC/HGB dilution is transferred to the counting beaker and the WBC counting starts. When the WBC counting is ready the HGB is measured and the orifice is cleaned. The dilution is drained and the counting beaker is rinsed once with isotonic diluent. During WBC counting mixing beaker no.1 and beaker no. 2 are rinsed with isotonic diluent. The pipette and rotary valve, or cap piercer and rotary valve, are once again cleaned with isotonic detergent. The "READY" lamp shows a green light showing that the analysis process is ready and a new sample may be aspirated while the results of the previous

sample are printed.





Flow diagram of the analysis process



6 Measuring principles

6.1 Introduction

This chapter describes the available parameters for different models of the instrument and the different methods and principles of measurement and calculations.

6.2 Available parameters

The available parameters are:

The number of Red Blood Cells	(RBC)
The number of White Blood Cells	(WBC)
The number of Platelets	(PLT)
The Mean Cell Volume of red cells	(MCV)
The Mean Platelet Volume	(MPV)
The Hemoglobin Concentration	(HGB)
Hematocrit	(HCT)
The Mean Cell Hemoglobin	(MCH)
The Mean Cell Hemoglobin Concentration	(MCHC)
The Red Cell distribution Width	(RDW)
The Lymph. concentration in absolute number and percentage	(LYMF #) (LYMF%)
The Mid-sized cells (e.g. Monocytes) in absolute number and percentage	(MID #) (MID%)
The Gran. concentration in absolute number and percentage	(GRAN#) (GRAN%
The Platelet distribution Width (Absolute)	(PDW)
The Plateletcrit	(PCT)
The number of Eosinophil Granulocytes	(EO#)

The available models are:

Available models of AutoCounter	Parameters
AC920EO+ -0 (cap piercer) AC920EO+ -2 (without a cap piercer) AC970EO+ -0	18 parameters: RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV, PCT, PDW, WBC, LYM #, LYM%, MID #, MID%, GRA # and GRA%. Histograms for PLT, RBC and WBC-differential. Eosinophil analysis option (19th parameter, EO # and hist.)
AC920EO+ -1 (cap piercer) AC920EO+ -3 (without a cap piercer) AC970EO+ -1	10 parameters: RBC, HCT, MCV, RDW, HGB, MCH, MCHC, PLT, MPV and WBC. Histograms for PLT, RBC and WBC

6.3 Aperture impedance method

Detection of RBC, PLT and WBC is accomplished by measuring the impedance in the orifice of the transducer. The transducer is mounted in a conductive solution. Electrodes with opposite charges establish a weak current. As blood cells pass through the orifice, they block the current, causing voltage pulses. The amplitude of the pulse is directly related to the size of the represented cell. The number of pulses is equivalent to the number of cells passing through the orifice during the counting period.



Aperture impedance method

With this technique, thousands of particles can be counted in a few seconds. To be able to count blood cells they must be diluted in an isotonic solution. Thereby the RBC/PLT can be counted and the volume determined. In order to count WBC, the red blood cells must first be destroyed i.e. hemolysed. Otherwise the red blood cells interfere with the white cell counting, both due to their size and the fact that the number of the red blood cells are approximately 10³ more per liter blood, compared to the white blood cells. The amplitude of each pulse, that directly corresponds to the cell volume, is measured and accumulated. The Auto-Counter has LOW and HIGH discriminators to filter any amplitudes not within the required range.

The size distribution graphs show the size of the counted cells in femtolitres along the x-axis and the relative number of cells along the y-axis. The x-axis is divided into 80 different channels in varying size depending on the cell type. The AutoCounter reports the number of cells which have been registered in the respective channels. The findings are then presented in a histogram in relation to the number of cells in each channel.

Each RBC, PLT and WBC count is measured on a precise volume of the dilution. The amount measured is determined by the distance between two optical sensors, which are mounted on a precision column called the measuring tube.



Size distribution graphs

During each measurement cycle of RBC/PLT and WBC a vacuum pump pulls the dilution through the measuring tube. When the liquid meniscus passes the optical path of the start sensor, the counting is activated. Detected pulses within the discriminators are accepted and accumulated only when the cycle is in counting mode.

When the liquid meniscus reaches the optical path of the stop sensor, the counting stops. During each measurement, two or more cells can enter the orifice simultaneously. The corresponding change in impedance is detected as a single pulse with a high amplitude, resulting in the loss of one or more pulses (counts). The reduction, referred to as coincidence passage loss, is statistically predictable and is related to the effective volume of the orifice and to the concentration of the dilution. The AutoCounter automatically corrects each RBC, PLT and WBC count for coincidence passage loss.

In order for the method to work properly the following is required:

- a correct cell dilution.
- a sufficient and repeated mixing of the cell dilution.
- a constant flow rate through the orifice.
- a constant radius of the orifice.
- a constant measuring volume

(The orifice radius is influenced by proteins which are concentrated in the transducer, thereby reducing the radius. This results in an imprecise determination of the cell size. Frequent cleaning of the transducer and its orifice is thus important in order to eliminate the proteins.)

RBC - Red Blood Cell Count

RBC is presented in the number of cells per liter or cubic millimeter. For human blood the minimum RBC discriminator is floating between 15- 30 fl and maximum discriminator is set to 250 femtolitres.

MCV - Mean Cell Volume

MCV is presented in femtolitres or cubic micrometer. Determination is based on statistical methods from size distribution span of counted red blood cells.

PLT - Platelet Cell Count

PLT is presented in the number of cells per liter or cubic millimeter. The Auto-Counter uses floating discriminators for PLT counting. Within the defined limits the software automatically finds the minimum concentration of cells and sets the discriminator to this point. The range for human samples is from 2 and the upper limit is floating between 15 and 30 fl. This means that the AutoCounter will search for a distinct discrimination point between 15 and 30 fl.

MPV - Mean Platelet Volume

MPV is presented in femtolitres or cubic micrometer determined on the total number of PLT counted. The histogram describes the size distribution span of the counted cells. When the PLT count is less than $40 \ge 10^9/1$ MPV it is not reported.

WBC - White Blood Cell Count

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 per-centage of total number of WBC cells. The MID discriminator of WBC is set to 95 and 120 fl. The WBC histogram is automatically adjusted depending on the number of cells, i.e. expanded for low values and compressed for high values.

The size distribution of non-differential WBC should be seen as a check of the hemolysing process only. A too low concentration of hemolyzer gives a too high number of cells due to presence of only partially hemolyzed red blood cells at 30 femtolitres or just above. A too high concentration of hemolyzer gives a too low number of WBC. The cells will decrease in size to below 30 femtolitres.

The WBC differentiation as in the AutoCounter, is a screening method. Less common normal and abnormal cells and cell distribution must be visually investigated under a microscope.



Normal distribution curve

LYM region (small size cells): Ranges from 30 to 95 femtolitres. 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 95 to 120 femtolitres. 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 120 to 400 femtolitres. 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.

EO - Eosinophils

In the models AC920EO+-2, AC920EO+-0 and AC970EO-0 it is possible to determine the eosinophils using the Swelab EO-kit. EO is presented in the number of cells per liter.

The eosinophils belong to the granulocytes and in normal samples the total amount is low and cannot be detected in a 3-part differential.

The semi automatic EO measurement is a quantitative method that is performed when a significant high MID cell count is obtained or when a high EO content can be suspected.

Detection of EO is accomplished by lysing all cells except the eosinophils using an alkaline non-ionic based surfactant. The remains, activated and non-activated eosinophils, are counted in the AutoCounter.



WBC histogram with a MID cell fraction



The size distribution of the cell fraction eosinophils

The EO appear in an intermediate position overlapping the MID and GRA areas in the WBC histogram. After treatment with the lyse reagent the eosinophil nuclei is similar in size to nuclei of monocytes, some abnormal cells and occasionally granulocytes. The presence of elevated MID cells can therefore be an indication of high eosinophil levels.

The discriminators set in the [6 Set up menu], determine the minimum and maximum size of the eosinophils. The EO discriminators are set to 70 and 200 femtolitres.

6.4 Photometric method

HGB - Hemoglobin

The quantitative determination of the prepared sample is obtained by measuring the light absorption. Light from a diode is passed through the cuvette. First only with the reagents as a zero reference, known as a blank value. The zero reference value for each sample is obtained from the RBC/PLT dilution immediately before this dilution is drained from the counting beaker. The light transmission is measured by a photocell. The light transmission is measured once again in the WBC/HGB dilution to absorb light at 555 nm and is converted to a digital value. HGB - the hemoglobin concentration in blood is measured by the photometer and is presented in grams per liter, grams per deciliter or millimol per liter.

The hemolysing reagent is lysing the RBC-membranes and the hemoglobin molecules are released. The Fe2+is oxidated to Fe3+and a stable hemoglobin complex is formed. The photometer measures the absorption and calculates the concentration of hemoglobin.



Photometric principle

6.5 Calculated parameters

HCT - Hematocrit

The HCT is presented as a percentage or as liter per liter. The HCT is the volume of packed erythrocytes in relation to the total blood volume.

RDW - Red Cell Distribution Width

The RDW is the relative distribution of the red cell volume and is presented as a percentage. The RDW is an index of the relative variation in red cell size (aniso-cytosis). The RDW is calculated directly from the RBC histogram. Not all cells are included in the RDW calculation thus RDW is only measured on a portion of the RBC histogram.

HCT=RBCxMCV



MCH=HGB/RBC

MCHC=HGB/HCT

PCT=PLT x MPV

MCH and MCHC, indices calculation

MCH - Mean Cell Hemoglobin - is presented in picogram or femtomol per liter.

MCHC - Mean Cell Hemoglobin Concentration - is presented in grams per liter, grams per deciliter or millimol per liter.

The red cell indices provide an indication of red cell morphology and can also be used to indicate instrument calibration and stability. The indices are very stable parameters. They do not significantly change from day to day or year to year even though the parameters which are used to calculate them dramatically increase or decrease. The indices are calculated automatically.

PCT - Plateletcrit

The PCT is presented as a percentage. The PCT is the volume of packed platelets in relation to the total blood volume.

PDW - Platelet Distribution Width

The PDW is an index of the absolute variation in platelet cell size and is presented in femtolitres. The PDW is calculated directly from the histogram. Not all cells are included in the PDW calculation thus PDW is only measured on a portion of the PLT histogram.

Note!

PCT and PDW are for laboratory use only.




7 User Interface

7.1 Selection of Menus

This section describes the function of each available menu in the instrument that is not described in any other section of this manual.

The service menu is described in the service manual and is available in English only at your authorized distributor.

The Main Menu is used to directly select menus in the instrument.

7.2 Main Menu



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1 Measurement

2 EO Menu

2.1 Measurement EO 2.2 EO Memory

3 Auto sampling menu (AC970EO+)

3.1 Work list 3.2 Print list 3.3 Clear work list

4 Sample memory menu

5 Calibration /QC menu

- 5.1 Quality Control
 - 5.1.1 Control memory
 - 5.1.2 Setup controls
 - 5.1.3 Control L-J plots
 - 5.1.4 X-bar L-J plots

6 Set up menu

- 6.1 Printer setup
- 6.2 Computer communication setup
- 6.3 Set next sequence number 6.4 Set date and time
- 6.5 Set reference ranges
- 6.6 Set floating discr. RBC/PLT
- 6.7 Set discr. WBC & EO

7 Service menu

- 7.1 WBC transfer time setup
- 7.2 Flush pump time setup
- 7.3 Sample pump time setup
- 7.4 Pump and valve test 7.5 HGB LED adjustment
- 7.6 Volume detector test 7.7 Reagent detector test
- 7.8 Noise test
- 7.9 Diluent syringe motor test

5.2 Calibration

5.2.1 Whole blood 5.2.2 Predilute

6.8 Set units

- 6.9 Select barcode reader
- 6.10 Select external keyboard
- 6.11 Select language
- 6.12 Set instrument ID 6.13 Set X-bar values
- 6.14 Print all settings
- 7.10 Lyser syringe motor test
- 7.11 Asp. pipette motor test
- 7.12 Vacuum pump motor test
- 7.14 High altitude comp. setup
- 7.15 Blood detector setup
- 7.16 Set power line freq.
- 7.17 Printer port status
- 7.18 Set new volume detector 7.19 Print machine statistics



8 Maintenance menu

- 8.1 Start a Prime cycle
- 8.2 Cleaning cycle
- 8.3 Start Filling system
- 8.4 Start Emptying system 8.5 Start Capillary cleaning
- 8.6 Single count test

7.3 Set next sequence number

The menu is used when the next sequence number will be changed. Avoid using two or more equal sequence numbers at the same day.

- 1. From the [Main Menu] move to the [6 Set up menu] with the down-arrow key and press "ENTER".
- 2. Move to [6.3 Set next sequence number] and press "ENTER".
- 3. In AC920eo+

Press "ENTER" to change the seq. no. with the + (plus) and - (minus) and the left/right-arrow keys and press "ENTER".

Alternatively:

In AC970eo+

Select with the up/down-arrow keys if [normal] or [autosampler] seq. no. will be changed. Press "ENTER" to change the seq. number with the + (plus) and/or - (minus) and the left/right-arrow keys and press "ENTER" to confirm. Only the two first figures in the seq. no. can be changed in the [autosampler seq. no.] The last two figures are the fixed position numbers in the plate.

4. Exit by pressing the "MENU" key.

7.4 Set date and time

There are four different date formats available:

- (0) = DD/MM/YY
- (1) = YY/MM/DD
- (2) = MM/DD/YY
- (3) = YY/DD/MM
- 1. From the [Main Menu] move to the [6 Set up menu] with the down-arrow key and press "ENTER". Move to [6.4 Set date and time] and press "ENTER".
- 2. Move to [Date format] and press "ENTER". Select the requested format number; (0), (1), (2) or (3) and press "ENTER".
- 3. Move to [Date] and press "ENTER". Enter the correct date with the + (plus) and (minus) and the left/right-arrow keys and press "ENTER".
- 4. Select character of date separator by moving to [Date separator] and press "ENTER". Select character with the + (plus) and (minus) and the left/right-arrow keys and press "ENTER".
- 5. Move to [Time] with the down-arrow key and press "ENTER". Enter the correct time with the + (plus) and (minus) keys and press "ENTER".
- 6. Exit by pressing the "MENU" key.

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7.5 Set reference ranges

The reference ranges are factory preset but can be adjusted for the local reference ranges. In the [1 Measurement] or in the [4 Sample memory menu] a star "*" will be shown in front of the result which is out of range.

- 1. From the [Main Menu] move to the [6 Set up menu] with the down-arrow key and press "ENTER".
- 2. Move to [6.5 Set reference ranges] and press "ENTER". The first parameter is selected.
- 3. Press "ENTER" to set/change the reference ranges with the + (plus) and (minus) and the left/right-arrow keys and press "ENTER" to confirm. To continue with the other parameters use the up/down-arrow or the left/right-arrow keys.
- 4. Exit by pressing the "MENU" key.

7.6 Set floating discr. RBC/PLT

The AutoCounter can use floating or fixed discriminators according to the operators request. With floating discriminators PLT is separated from RBC by the software. Within the defined limits the software automatically finds the minimum concentration of cells and sets the discriminator to this point.

The range for human samples is between 15 and 30 fl. This means that the Autocounter will search for a distinct discrimination point between 15 and 30 fl. It is not recommended to change this range.

With fixed discriminators a certain point is set to the low limit, equal to the upper limit. Slightly better reproduction on extreme low PLT counts could be e.g. setting the limits to 25 and 25 which means that a fixed discriminator is introduced at 25 fl. Do not use this setting unless there is a very specific reason.

7.7 Set discr. WBC & EO

The AutoCounter uses fixed discriminators for WBC differential which should not be changed. The low WBC discriminator is 95 and the high is120.

The low EO discriminator is 70 and the high is 200.

7.8 Set units

The AutoCounter has four different parameter unit modes.

- 1. In the [Main Menu] move to the [6 Set up menu] and press "ENTER".
- 2. Move to [6.8 Set units] and press "ENTER".
- 3. Press "ENTER" to select one of the four alternatives 1-4 (see the list below) with the + (plus) and (minus) keys and press "ENTER".
- 4. Exit by pressing the "MENU" key.

Systems	1	2	3	4
RBC	$10^{6}/mm^{3}$	1 0 ^{1 2} /l	10 ¹² /1	1 0 ^{1 2} /l
НСТ	%	1/1	%	1/1
MCV	μm ³	fl	fl	fl
RDW	%	%	%	%
HGB	g /d l	m m o l/l	g /l	g /l
MCH	рg	fm o l	pg	рg
MCHC	g /d l	m m o l/l	g /l	g /l
PLT	$10^{3}/mm3$	1 0 9/1	1 0 ⁹ / 1	1 0 ⁹ /l
MPV	μm ³	fl	fl	fl
PDW	fl	fl	fl	fl
РСТ	%	%	%	%
WBC	$10^{3}/mm^{3}$	1 0 9/1	10 ⁹ /1	1 0 ⁹ /l
LYM	$10^{3}/mm^{3}$	1 0 9/1	1 0 ⁹ / 1	1 0 ⁹ /l
MID	$1 0^{3}/m m^{3}$	1 0 9/1	10 ⁹ /1	1 0 ⁹ /l
GRA	$10^{3}/mm^{3}$	1 0 9/1	10 ⁹ /1	1 0 ⁹ /l
LYM	%	%	%	%
MID	%	%	%	%
GRA	%	%	%	%
EO	1 0 ⁹ /l	1 0 9/1	1 0 9/1	1 0 9/1







7.9 Select language

The software of the AutoCounter presents different language options for the

display and the printouts.

- 1. In the [Main Menu] move to the [6 Set up menu] with the down-arrow key and press "ENTER".
- 2. Move to [6.11 Select language] and press "ENTER".
- 3. To see all the available languages move to [Print a list of all available languages] and press "ENTER". Select required language number from the list and enter the number with the + (plus) and - (minus) keys and press "ENTER".
- 4. Exit by pressing the "MENU" key.

7.10 Set instrument ID

By default the AutoCounter ID is equal to the serial number on the plate of the rear panel. The ID number is shown in the [6.14 Print all settings] or when sending from a computer. This number can be changed by the operator.

- 1. In the [Main Menu] move to the [6 Set up menu] with the down-arrow key and press "ENTER".
- 2. Move to [6.12 Set instrument ID] and press "ENTER".
- 3. Change the serial number to the required number with the + (plus) and (minus) and the left/right-arrow keys and press "ENTER".
- 4. Exit by pressing the "MENU" key.

7.11 Set X-bar values

The X-bar target values are factory preset according to reference values from literature and should not be changed. See **X-bar L-J plots** on page 47.

The target values can however be adjusted by the operator. The limits of 3% are a fixed value and cannot be changed.

- 1. In the [Main Menu] move to the [6 Set up menu] and press "ENTER" and move to [6.13 Set X-bar values] and press "ENTER".
- 2. Press "ENTER" to enter the new values with the + (plus) and (minus) and the left/right-arrow keys and press "ENTER" to confirm .
- 3. Exit by pressing the "MENU" key.

7.12 Print all settings

[6.14 Print all settings] is usually used after a completed installation procedure.

All user definable settings are printed to the connected printer for later reference.

- 1. In the [Main Menu] move to the [6 Set up menu] with the down-arrow key and press "ENTER".
- 2. Move to [6.14 Print all setting] and press "ENTER". All settings are printed.
- 3. Exit by pressing the "MENU" key.



8 Quality Control

8.1 Setup controls

In this menu controls/calibrators can be specified. Please note that a new control ID needs to be unique and must not be equal to an existing routine sample-ID or to an existing control-ID. The controls are stored both in the [4 Sample memory menu] and in the [5.1.1 Control memory]. To save the control in the control file the ID-number has to be identified, the other parameters in the setup do not need to be identified. Twelve controls can be specified and when all twelve fields are occupied, the oldest control setup can be replaced by a new unique control-ID. If the specific control is marked there is a possibility with the +/- key to put the control in a specific place in the list.



Display view of Setup controls

- 1. In the [Main Menu] move to [5 Calibration/QC] menu with the down-arrow key and press "ENTER".
- 2. In the [5.1 Quality control] move to [5.1.2 Setup controls] and press "EN-TER".
- 3. Move to a new empty control field and press "ENTER".
- 4. Press "ENTER" to name the control with an unique ID-number. Move with the + (plus) and/or (minus) keys to the requested character (press the up-arrow key and it shows the character in this order: 0-9abcdef etc.) and press the right-arrow key to continue with the second character etc. Press "ENTER" to confirm.
- 5. Press "ENTER" to enter the manufacturer (Mfg) with the +(plus) and/or -(minus) keys. Press "ENTER" to confirm. Continue with all the other fields as above:

Itm = Item, as article number

Lot = Lot/batch number

Level = as High, Low or Normal control

Exp.date = Expiry date

Control blood type = is set to 0, (not in use)

- 6. Continue with the right-arrow key to enter the reference ranges of the red cell parameters of the control.
- 7. Continue with the right-arrow key to enter the reference ranges of the platelet parameters of the control.

- 8. Continue with the right-arrow key to enter the reference ranges of the white cell parameters.
- 9. Finally continue with the right-arrow key and answer the question for a printout or if the control should be deleted. The specified control can only be deleted if there are no results of the control in the [5 Control memory] and in [4 Sample memory menu].
- 10. Exit with the "MENU" key.

8.2 **Control memory**

The AutoCounter control memory can store 800 samples without histograms. The control results can also be viewed in the [4 Sample memory menu] with histograms. To show results on the display, one of the search condition fields has to be entered, ID-number, DATE and/or SEQ-number. Every control which has been specified in [5.1.2 Set up controls] is easy to enter in the control memory. Below the ID number field, is the number of selected controls of the total control memory.



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Display view of Control memory

The above figure shows there are 45 normal controls of total 100, with an IDnumber or lot-number: n 1661, in a period of one month. The sequence numbers are not selected.

There are three different memories: Control memory, Sample memory and EO memory.

To distinguish which memory is entered open the [5.1.1.1 View selected controls] and the letter "C" in the upper right corner of the display appears to show that the current memory is the Control memory.

Using the control memory

- In the [Main Menu] move to [5 Calibration/QC] menu with the up/down-1. arrow key and press "ENTER".
- 2. Move to [5.1 Quality control]/[5.1.1 Control memory] and press "EN-TER".
- 3. Select the different options of the search conditions with the up-arrow/ down-arrow, right-arrow/left-arrow keys: Move to the ID-field and press "ENTER". Move with the up-arrow/down-arrow keys to the requested control-ID, provided that a control has been specified in [5.1.2 Setup controls] or enter the ID-number with the + (plus) and/or - (minus) keys or with an external keyboard and press "ENTER".

Enter the DATE and/or SEQ number with the + (plus) and/or - (minus) keys or with an external keyboard and press "ENTER". See further information in Sample memory menu on page 62.

- After the above selection it is possible to view results, view statistics, print, 4. send or delete results, see further information on the next page.
- Exit the [5.1.1 Control memory] with the "MENU" key. 5.

View selected controls

Enter [5.1.1.1 View selected controls] and press "ENTER" to view the results of the selected control/controls on the display. If more than one control is selected press the up-arrow/down-arrow keys to view the next or previous control. If "ENTER" is pressed the results are printed.

Control/QC

Statistical calculation is either on Normal or Normal + Abnormal parameter values. Normal control values are values within the control range as set in the [5.1.2] Setup controls]. Abnormal control values are values outside the range.

The statistical calculations are displayed for each parameter.

Sd = Standard deviation	x = mean value
CV = coefficient of variation	n = number of samples

When the requested control-ID is selected, move to [5.1.1.2 Control/QC] and press "ENTER" to view the statistical calculations. To view the Normal or Normal + Abnormal values, press the up-arrow/down-arrow key. To print all available data press "ENTER". Abort printing with "MENU" key.

Print selected controls

When the requested ID, DATE or SEQ is set, move to 5.1.1.3 Print selected controls] and press "ENTER" to print the result of the selected sample/samples. Abort printing with "MENU" key.

Send selected controls

If a computer is connected to the AutoCounter this option can be selected. See further information in chapter: **Computer communication setup** on page 82.

When the requested ID, DATE or SEQ is set, move to [5.1.1.4 Send selected controls] and press "ENTER" to send the results to the computer. Abort sending with "MENU" key.

Delete selected controls

Use this option to delete a control. When the requested ID, DATE or SEQ is set:

- 1. Move to [5.1.1.5 Delete selected controls] and press "ENTER".
- Confirm the command to delete the results by pressing the + (plus) key. 2.

To delete the total control batch, all control values of the specific batch have to be deleted both in the control memory and in the Sample memory.

When all the values in the Control memory and in the Sample memory are deleted move to [5.1.2 Setup controls] and press the right-arrow key to page 5/5 and move to Delete this control Press the + key to confirm.

Then a new batch can be specified in the [5.1.2 Setup controls].



Important

Note that a selection of ID, DATE or SEQ numbers can show more than one sample and it is important to know which sample is to be deleted.

Note that! several samples can be deleted by mistake!

8.3 Control L-J plots

The Levey-Jennings plots are used to discover any shift or trends of the controls. The assigned value of the control is represented by a dotted line in the center and the acceptable limits by the two lines either side. The vertically dotted line is a guide to compare the parameters with each other. Shifts in results occur after an abrupt change, either high or low, of control values. Trends are a slowly developing alteration of control values, either increasing or decreasing. Shifts or trends usually occur after a change of reagents or control blood.

It is possible to plot and overview approx. 800 control values. Parameters included in the control Levey-Jennings plot are RBC, HGB, HCT, RDW, MCV, MCHC, MCH, PLT, MPV, WBC, LYM, MID and GRAN. Every single control value is plotted as a single point.

- 1. In the [Main Menu] move to [5 QC/Calibration] menu with the down-arrow key and press "ENTER".
- 2. Move to [5.1.3 Control L-J plots] and press "ENTER".
- 3. Press "ENTER" to select the ID of the control with the up-arrow/downarrow keys, provided that a control has been specified in the [5.1.2 Set up controls]. Control blood values within a specific time period or between specific sequence numbers can also be selected.
- 4. Move to [5.1.3.1 View selected controls] with the down-arrow key and press "ENTER". Press the right-arrow/left-arrow keys to view the remaining selected control parameters.
- 5. Move to [5.1.3.2 Print selected controls] with the down-arrow key and press "ENTER" to print the selected control plots.
- 6. Exit with the "MENU" key.



Display view example of L-J plots

8.4 X-bar L-J plots¹

The X-bar calculation and plot give information on the day to day stability of the total analysis system from blood collection through to reporting of results. The X-bar method is recommended for laboratories which have a general patient population and a work load of minimum 60 samples/24 hours. The X-bar Levey Jennings plot is calculated on MCV, MCH and MCHC. The calculation is carried out on groups of 20 samples and the previous mean value of 20 samples is compared with each value of 20 new samples to create a new mean value.

All samples, except for those runned in the control memory, are included in the L-J plot. In order to stop the inclusion of a sample result in the L-J plot the sample has to be deleted immediately after measurement.

Results already included in the L-J plot cannot be deleted. Thus when results are deleted in the Sample Memory the same results are not removed from the L-J plot.

The X-bar plot can store 200 points which corresponds to 4000 samples. When the limit is reached the first point in the plot is skipped. The target values and the limits set in the AutoCounter are derived from the reference below. The values can however be adjusted by the operator in the [6 Set up menu]/[6.13 Set X-bar values].

The target values and limits set in the AutoCounter program are:

 $MCV = 89.5 \pm 3.0\%$ $MCH = 30.5 \pm 3.0\%$ $MCHC = 340 \pm 3.0\%$

- 1. In the [Main Menu] move to [5 Calibration/QC] menu with the down-arrow key and press "ENTER".
- 2. Move to [5.1.4 X-bar L-J plots] and press "ENTER".
- 3. Move to [5.1.4.1 View] with the down-arrow key and press "ENTER" to view the X-bar.
- 4. Move to [5.1.4.2 Print] with the down-arrow key and press "ENTER" to print the X-bar.

1. Reference to X-bar calculation.

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:



5. Exit with the "MENU" key.

First X-bar Last X-bar	point: Date	te 2000/1/1 2000/3/10
MCV 89.5 ± 3 %	MCH 30.5 ± 3 %	s: 14 MCHC 340 ±3%
	\mathbf{T}	\mathbf{T}

Example of a print out of an X-bar plots



9 Calibration and QC Menu



Calibrate only when necessary. Make sure that there is nothing wrong with the control-, calibrator- material or the instrument before calibration It may lead to incorrect calibration on the instrument.



Important

In AC920EO+ -2 and -3, with a pipette cleaning device:

Repeated precision measurement for example of control/calibrator material, wipe off the pipette carefully otherwise it might be diluted with remains of diluent from the pipette and cause bad precision.



Important

Do not calibrate the MCV parameter using commercial controls with values given for other analyzers, unless approved by Boule.

Not following this might lead to incorrect MCV values on processed samples

9.1 Calibration

General

To facilitate calibration enter the unique batch ID no. from the calibrator into the [Setup controls] menu. See **Control memory** on page 44.

The AutoCounter is factory calibrated only in whole blood mode and should be *verified* once a year with a calibrator or according to national/laboratory regulation. The AutoCounter should be *recalibrated* when:

- a new brand of reagent is introduced.
- the mean value of any parameter of the control, analysed three times from two tubes/bottles consecutively is out of range.

All parameters are factory calibrated and can be recalibrated except for MPV, RDW and PDW since there are no assay values for these parameters.

Before calibration

- Verify the calibration every day by analysing a control blood from each level (low, normal and high).
- Analyse control blood once in the open tube and once in the prediluted position. Compare the results with the assigned values.
- If a single value is out of range, analyse the control blood again twice. Calculate the mean value of the three analysis. The easiest way to see the mean value is to enter the [4.2 Statistical calculations] menu. If the mean value is out of range, take a new bottle/tube of control blood and analyse three times. Calculate the mean value. If the mean value is still out of range the instrument might need a new calibration. Verify that nothing is erratic with the control blood, the reagents or the instrument before calibrating.

Note

Check that the control blood has been stored, mixed etc. in the correct way before calibration.

9.2 Use of Calibrators and Controls

The calibration of the instrument can be verified by counting pre-assayed commercial reference calibrator samples or by counting retained patient samples with known reference values from another reference instrument.

To ensure the accuracy of the values obtained whenever commercial controls are used:

- 1. Always re-suspend according to the manufacturer's recommendations.
- 2. Never use an open vial longer than recommended by the manufacturer or subject any vial to excessive heat or agitation.
- 3. Verify the condition of controls when received. Make sure that they are cold and not leaking.
- 4. Do not use a commercial control for calibrating the instrument, use only "Calibrators".



Whole blood

1. In the [Main Menu] move to [1 Measurement] with the up/down-arrow keys and press "ENTER".

Press "START Whole Blood" and analyse a background count until the values do not exceed the recommended level.
See Background count of whole blood on page 56.

RBC	$\leq 0.02 \ge 10^{12}/l$	PLT	$\leq 10 \ge 10^9/l$
HGB	0 g/l	WBC	$\le 0.2 \ge 10^9/l$

- 3. Make sure that the calibration material is well mixed.
- 4. In the [1.Measurement] menu move with the up-arrow/down-arrow keys to the requested ID, providing that the calibration material has been specified in [5.1.2 Setup controls] or enter the ID number with the + (plus) and/or (minus) keys and press "ENTER".
- Analyse the calibration material five times as in a normal routine sample. See Blood count open tube (OT) on page 57. Return to the [Main Menu] by the "MENU"-key.
- 6. From the [Main Menu] move to the [5 Calibration/QC] menu using the down-arrow key and press "ENTER".
- 7. Move to [5.2 Calibration]/[5.2.1 Whole blood] and press "ENTER". A picture as below is shown on the display with the five last measurements.





Display picture of the calibration

The number in front of each analyses relates to whether the results are included in the mean value calculation.

1 = Included in the mean value. 0 = Not included in the mean value.

A marked analysis can be manually deleted from the mean value calculation with the - (minus) key.

Next to the mean values (MV) are the number of analysis (n) used for the mean value calculation.

The target values (TV) are entered by the operator if a calibration is needed.

Percentage (%) is the difference between the raw data and the mean value. The raw data is the value before calibration and cannot be shown.

The adjustment possibility of the calibration is listed below. A warning signal is heard when the calibration is out of range and the value will not be accepted.

The calibration low limits		Adjustment possibility in% from raw data	
RBC	1.0	RBC	± 50
MCV	50	MCV	± 25
HGB	50	HGB	± 50
PLT	100	PLT	-50 to + 80
MPV	3.0	MPV	± 25
WBC	2.0	WBC	± 50

- 8. Move to requested parameter, that needs calibration, with the down-arrow and right-arrow keys and press "ENTER".
- 9. Insert the target value (TV) of RBC, MCV and HGB according to the calibrator document or to the known values of the human blood, using the + (plus) or (minus) keys. Press "ENTER".
- 10. Continue to page 2/4 on the display using the right-arrow key and insert the remaining parameters (PLT and WBC) in the same way, except for MPV which should not be calibrated.
- 11. In pages 3/4-4/4 on the display a calibration of RDW and PDW can be performed but not at the same time as for the other parameters.

5.2.1 Whole Blood Calibration	1	5.2.1 Whole Blood Calibration
New RDW value = 0.0		New PDW value = 0.0
An initial value of 0.0 indicates that calibration isn't possible. See User's Manual for further info.		An initial value of 0.0 indicates that calibration isn't possible. See User's Manual for further info.
1198en.gif		1218en.gif

Display views of RDW and PDW calibration

An initial value of 0,0 indicates that a calibration is not possible. A human blood sample with known value has to bee analysed before calibration.

Note:

The MPV, RDW and PDW are factory calibrated and should not be recalibrated. If a calibration is needed of RDW/PDW, make sure that the MCV is correctly calibrated.

- Use a fresh human blood with known RDW/PDW-values. Analyse the sample twice.
- Enter [5.2 Calibration] / [5.2.1 Whole blood]. Move to page 3/4 and/or 4/4 with the right-arrow key, enter the known value and press "ENTER".



- 12. When all the parameters are calibrated, exit the [5.2.1 Whole blood] with the "MENU" key.
- 13. The display shows:



Display view of the question of calibration report

Always print and save the calibration data after a calibration.

14. Verify the calibration by analysing a control blood and compare the results with the assigned values.

Prediluted blood

Prepare the predilutions using the same devices as used in preparation of the routine samples.

- 1. In the [Main Menu] move to [1 Measurement] with the up/down-arrow keys and press "ENTER".
- 2. Start with a background count. Add 4 ml isotonic diluent to an unused sample beaker.
- 3. Place it in the prediluted position and press "START PreDilute". Repeat the background count until the values do not exceed the recommended level.

RBC	$\leq 0.02 \ge 10^{12}/l$	PLT	$\le 10 \ge 10^9/l$
HGB	0 g/l	WBC	$\le 0.2 \ge 10^9/l$

- 4. Make sure that the calibration material is well mixed. Prepare the predilutions of the calibration material.
 - a) Dispense 4 ml isotonic diluent into five unused sample beakers.

b) Collect 20 µl calibration blood using a micro capillary tube and immediately transfer the blood into one of the sample beakers with diluent.

- c) Rinse the capillary tube carefully with the isotonic diluent.
- d) Seal the sample beaker and mix gently.
- e) Do the same with the rest of the sample beakers.
- 5. Mix the dilution gently and analyse the calibrator in same way in the Auto-Counter as for routine prediluted samples. Do the same with all five prediluted calibrators.
- 6. Return to the [Main Menu] by the "MENU"-key.
- 7. From the [Main Menu] move to the [5 Calibration/QC] menu using the down-arrow key and press "ENTER".



- 8. Move to [5.2 Calibration/5.2.2 Prediluted blood] and press "ENTER".
- 9. Follow the calibration procedure as for [5.2.1 Whole blood] above from item 8.





10 Routine Operation



Mandatory action

Always wear protective gloves when handling infectious or potentially infectious materials.



Important

For good quality results on venous blood it is recommended that hematology samples are analysed as quickly as possible after 15 minutes' rest.

10.1 Sample collection

Venous blood

Collect the blood by venipuncture in a tube containing tripotassium ethylenediaminetetra-acetic acid (K3EDTA) as anticoagulant (0.07 mol/ml blood).

After blood collection the test tubes should immediately be gently mixed by reversing them approx. 10 times and thereafter left to rest for 15 minutes prior to analysis in order for the cells to stabilise. If the sample is analysed immediately, the MVC and WBC differential can be affected.

Stability

For whole blood cell counts which include WBC differential, the best results are obtained when the samples are analysed within 8 hours after drawing. These samples should be kept at room temperature.

Total blood count, except WBC differential can be analysed up to 24 hours after drawing if the specimens are stored in refrigerator. Make sure that the samples are brought to room temperature and well mixed before analysing.

Capillary blood

- 1. Dispense 4 ml isotonic diluent into a sample beaker.
- 2. Collect 20 µl capillary blood using a micro capillary tube and immediately transfer the blood into the sample beaker with 4 ml diluent.
- 3. Rinse the capillary tube carefully with the isotonic diluent. Seal the sample beaker and mix gently.

Stability

The analysis of the prediluted sample should be performed as soon as possible but no later than within 60 minutes after collection and the sample dilution should be kept at room temperature.

10.2 General and start-up

The RBC, PLT, MCV, MPV, WBC and EO are detected by using the impedance method. HGB is detected by using the photometric method and the rest of the parameters are calculated, se further information in chapter **Measuring principles** on page 29.

• Start-up the instrument from stand-by mode by pressing the "MENU" key.



10.3 Background count of whole blood

In the [Main Menu]

- 1. Move to [1 Measurement] with the up/down arrow keys and press "EN-TER".
- 2. Press "START Whole Blood". The AutoCounter measures the background count and presents the results on the display.

When measurement is completed the "READY" lamp shows a green light. The results remain on the display until the start of the next analysis.

3. Repeat the background count until the values do not exceed the recommended level.

RBC	$\leq 0.02 \ge 10^{12}/l$	PLT	$\le 10 \ge 10^9/l$
HGB	0 g/l	WBC	$\le 0.2 \ge 10^9/l$



Example of print-outs of a background count and results of a normal sample with histograms

Note:

The first background count after a blood measurement could be higher than after repeated background counts. This is due to a carry-over effect from the previous measured blood sample. The result of the first background count, after a blood sample, should not exceed 2%.

10.4 Background count of prediluted samples

Add 4 ml isotonic diluent to an unused sample beaker.

- 1. In the [Main Menu] step to [1 Measurement] with the, up-arrow/down-arrow keys and press "ENTER".
- 2. Place the sample beaker in the prediluted position and press "START Pre-Dilute". The AutoCounter dilutes and measures the background and presents the values on the display. When the analysis is completed the "READY" lamp shows a green light.
- 3. Repeat the background count until the values do not exceed the recommended level, see page 56.





Caution must be applied when handling the cap piercer. Handling and operation by unauthorised personnel may result in injury.

10.5 Blood count, closed tube (CT) AC920EO+

- 1. Make a background count. See **Background count of whole blood** on page 56.
- 2. Mix the blood samples for at least 10 minutes before measurement.
- 3. In the [Main Menu] step to [1 Measurement] with the, up-arrow/down-arrow keys and press "ENTER".
- 4. Place the vacuum tube upside down in the cap piercer and press the tube in place into the upper support. It is possible to adjust the length of the tube holder, see figure on page 23. The AutoCounter immediately starts the analysis.

When the red light has gone off the tube can be removed or left in the cap piercer until the next analysis.

- 5. Press "ENTER" to enter the ID-number with the + (plus) or -(minus) keys or with an external keyboard and press "ENTER" to confirm. If a control ID has been specified in the [5.1.2 Set up controls] it can appear on the ID field when the up-arrow/down-arrow keys are pressed. It is possible to enter the ID number during the total counting time. When the measurement is completed the "READY" lamp shows a green light. The results remain on the display until the start of the next analysis. To view the date and time, the RBC/PLT/WBC counting time and the histograms press the right-arrow key. Press the left-arrow key to return to the results.
- 6. Remove the tube and continue with the next blood sample. Repeat from step 3 for all blood samples.

Extra print-out

When the display shows the results of a blood sample, an extra print-out of the last measurement is obtained by pressing the "ENTER" key.

Set next Seq. no.

If the sequence number has to be changed see [6.3 Set next sequence number].

10.6 Blood count open tube (OT)

- 1. Make a background count. See **Background count of whole blood** on page 56.
- 2. Mix the blood samples for at least 10 minutes before measurement.
- 3. In the [Main Menu] step to [1 Measurement] with the up-arrow/down-arrow keys and press "ENTER".

4. AC920EO+ -0/-1:

Immerse the open whole blood pipette into the blood sample and press "START Whole Blood". Wipe the outside of the pipette carefully.

Alternative:

AC920EO+ -2/-3:

Immerse the open whole blood pipette into the blood sample and press the plate behind the pipette.



Important

In AC920EO+ -2 and -3, with a pipette cleaning device:

Repeated precision measurement for example of control/calibrator material, wipe off the pipette carefully otherwise it might be diluted with remains of diluent from the pipette and cause bad precision. The "READY" lamp switches from the green to the red light and at the same time the blood is aspirated via the pipette. Do not remove the tube until the red "READY" lamp has gone off.

- 5. Press "ENTER" to enter the ID-number with the + (plus) or -(minus) keys or with an external keyboard and press "ENTER" to confirm. If a control ID has been specified in the [5.1.2 Set up controls] it can appear on the ID field when the up-arrow/down-arrow keys are pressed. It is possible to enter the ID-number during the total counting time. When the measurement is completed the "READY" lamp shows a green light. The results remain on the display until the start of the next analysis. To view the date and time, the RBC/PLT/WBC counting time and the histograms press the right-arrow key. Press the left-arrow key to return to the results.
- 6. Repeat from step 3 for all blood samples.

Extra print-out

When the display shows the results of a blood sample, an extra print-out of the last measurement is obtained by pressing the "ENTER" key.

Set next Seq. no.

If the sequence number has to be changed see [6.3 Set next sequence number].

10.7 Blood count, prediluted blood (PD)

See Sample collection on page 55.

- 1. Make a background count. See **Background count of prediluted samples** on page 56.
- 2. In the [Main Menu] step to [1 Measurement] and press "ENTER".
- 3. Mix the predilution, see Sample collection **Capillary blood** on page 55, carefully and place the sample beaker into the prediluted position.
- 4. Press "START PreDilute". The "READY" lamp switches from green to a red light and at the same time the dilution is aspirated.
- 5. Press "ENTER" to enter the ID-number with the + (plus) or -(minus) keys or with an external keyboard and press "ENTER" to confirm. If a control ID has been specified in the [5.1.2 Set up controls] it can appear on the ID field when the up-arrow/down-arrow keys are pressed. It is possible to enter the ID number during the total counting time. The AutoCounter performs the second dilution and measures the blood sample. When the measurement is completed the "READY" lamp shows a green light. The results remain on the display until the start of the next analysis. To view the date and time, the RBC/PLT/WBC counting time and the histograms press the right-arrow key. Press the left-arrow key to return to the results.
- 6. Remove the beaker and continue with the next blood sample. Repeat from step 2 for all samples.

Extra print-out

When the display shows the results of a blood sample, an extra print-out of the last measurement is obtained by pressing the "ENTER" key.

Set next Seq. no.

If the sequence number has to be changed see [6.3 Set next sequence number].





Caution must be applied when handling the cap piercer. Handling and operation by unauthorised personnel may result in injury.

10.8 Autosampling Menu (in AC970EO+)

This menu is used when several blood samples are to be analysed in the autosampler of the AC970EO+. The autosampling can only be run if [3 Auto sampling] is selected.

There are different ways to select the samples:

- 1. If the AutoCounter has a fixed mounted barcode reader, the ID numbers will be read automatically.
- 2. If no fixed barcode reader is connected the operator can, before analysis, enter the ID-numbers in the worklist with the internal or external keyboard.
- 3. Samples can be analysed without identification, but then only the sequence numbers are presented. The sequence numbers which are used in [3 Auto sampling] are 1001 to 9940.

The two first digits change when 40 samples have been analysed (see no 1 below). The two last digits in the numbers are the position of the plate (see no 2 below).

See further examples below.



els before running the autosampler. AutoSampler can run out of reagent and cause that air enters in the system.



Background count in the autosampler

Fill an empty vacuum tube with distilled water and place it in the sample plate in front of the series of blood samples. Repeat the background count until the values do not exceed the recommended level, see further information on page 56.

Autosampling with a fixed mounted barcode reader

- 1. Load the vacuum tube samples in the sample plates with the ID number towards the barcode reader and lock the sample tubes by turning the centre piece clockwise.
- 2. Install the plates on the shaft while pressing the white knobs downwards. Press "MIX" to start mixing.
- 3. In the [Main Menu] move to [3 Auto sampling menu] with down-arrow the key and press "ENTER".

When the samples are well mixed after approx. 10 minutes:

4. Press AUTOSAMPLE. The automatic autosampling starts.

When the operation sequence is from "MIX" to "AUTO SAMPLE" the autosampling will always start from the beginning i.e. with the sample tube placed at the lowest position number. The front plate will rotate between the analysis of samples and will continue to rotate at the end of the analysis. The back plate will continuously rotate and the samples will be well mixed by the time the analysis of the front plate is finished.

The AC970EO+ dilutes and measures the blood sample and presents the results on the display.

- 5. When all front plate samples have been measured a short signal is heard. Check the results to see if any of the samples need to be re-analysed. Press "MIX" to stop mixing.
- 6. Replace the front plate with the back plate and press "MIX".
- 7. After a few rotations press "AUTO SAMPLE".
- 8. After both sample plates have been analysed press "MIX" to stop mixing and remove the sample plates while pressing the white knobs.

Autosampling and preparation of worklist of internal/external keyboard

- 1. Install the empty plates on the shaft while pressing the white knobs downwards.
- 2. In the [Main Menu] step to [3 Auto sampling menu] with the down-arrow key and press "ENTER". Move to [3.1 Enter/view the work list] and press "ENTER".



Display view of "3.1 Enter/view worklist"

- 3. Enter the ID number of the sample tube with the internal keyboard, use the + (plus) and (minus) keys or enter the ID number with an external keyboard.
- 4. Load the sample tube in position number one in the sample plate. Continue in the same way with all sample tubes. Press the right-arrow key to enter the ID-numbers of the following next ten samples.
- 5. When the first plate is loaded, lock the sample tubes by turning the centre shaft clockwise. Press the right-arrow key to continue to enter the ID numbers for the second plate.
- 6. When all ID numbers are entered and the plates are loaded, exit with the "MENU" key. Move to [3.2 Print list] and press "ENTER". Save the printed list until all samples have been analysed.
- 7. Press "MIX" to start mixing.

When the samples are well mixed:

8. Press "AUTO SAMPLE". The autosampling starts.

When the operation sequence is from "MIX" to "AUTO SAMPLE" the autosampling will always start from the beginning i.e. with the sample tube placed at the lowest position.

The front plate will rotate between the analysis of samples and will continue to rotate at the end of the analysis.

The back plate will continue to rotate and will be well mixed by the time the analysis of the front plate is ready.

The AC970EO+ dilutes and measures the blood sample and presents the results on the display.

When all front plate samples have been measured a short signal is heard.

9. Press "MIX" to stop mixing.

Check the results to see if any of the samples need to be re-analysed.

- 10. Replace the front plate with the back plate while pressing the white knobs and press "MIX".
- 11. After a few rotations press "AUTO SAMPLE".
- 12. After both sample plates have been analysed press "MIX" to stop mixing and remove the sample plates while pressing the white knobs.

After verifying the results move to [3.3 Clear worklist] and press "ENTER". Move to [3.1 Enter/view work list] to enter new ID numbers of new samples.

Emergency sample during autosampling

Interruption of autosampling is used to start autosampling at a specific tube position e.g. after analysing an emergency blood sample. Autosampling will start with the selected sample tube position and continue with the following sample tubes.

- 1. To interrupt the autosampling press "AUTO SAMPLE" and wait for the stop signal and for the current analysis to finish. Let the "MIX" be on.
- 2. Press "MENU" twice and step to [1 Measurement] and run the emergency sample.
- 3. When the emergency blood sample has been analysed step back to [3 Auto sampling menu] and continue with the autosampling, making sure that the samples are well mixed. Press "MIX" to stop mixing. Press "STEP" until the sample where the autosampling was interrupted is in sampling position.
- 4. Press "AUTO SAMPLE" to start autosampling. When the operation sequence is from "STEP" to "AUTO SAMPLE" the autosampling will always make a complete turn of the sample plate. The sampling starts from the sample tube stepped into the sampling position and then continues with the following sample tubes.

Step and single sample

"STEP" and "SINGLE SAMPLE" are used to run or rerun a single sample in the sample plate.

- 1. Make sure that the samples are well mixed. Press "MIX" to stop mixing.
- 2. Press "STEP" until the required sample is in the sampling position.



- 3. Press "SINGLE SAMPLE" to start the measurement. The AutoCounter will make two turns of the sample plate before it starts sampling. The sample plates will not be mixed during a single sample operation.
- 4. After measurement of the sample, another single sample or autosampling can be selected.

10.9 Stand-by Mode

The AutoCounter can only go in stand-by mode when the display shows the [Main menu], the [1.Measurement menu] or the last sample. When the Auto-Counter is not used within 43 minutes it will give a warning signal before going into standby mode.

2 minutes after the warning signal the display is switched off.

The AutoCounter is now in standby mode and will make an automatic cleaning every 4 hours.

To light up the display press the "MENU" key.



1201en.gif

Display view before standby mode

10.10 Sample memory menu

The AutoCounter sample memory can store 600 samples including histograms. When the memory is "full" the oldest sample is automatically deleted. To show results on the display, one of the search condition fields has to be entered, ID-number, DATE and/or SEQ-number. Below the ID number field, the number of selected samples of the total sample memory is presented.

There are three different memories: Control memory, Sample memory and EO memory.

To distinguish which memory is entered open the [4.1.1 View selected samples] and the letter "M" in the upper right corner of the display appears to show that the current memory is the Sample memory.

Different search options are available:



1179en.gif

Display view of Sample memory

- 1. In the [Main Menu] move to [4 Sample memory] with the up-arrow/downarrow key and press "ENTER".
- 2. Select any of the search conditions (ID, DATE and/or SEQ) with the right-arrow/left-arrow, up-arrow/down-arrow keys and press "ENTER". Press "ENTER" to enter the ID-number with the + (plus) or -(minus) keys or with an external keyboard and press "ENTER". If a control ID has been specified in the [5.1.2 Set up controls] it can appear on the ID field when the up-arrow/down-arrow keys are pressed.
- 3. When entering [4 Sample memory] the current date is viewed on the display. Move to the date field and press "ENTER" and change the date with the + (plus) or -(minus) keys. To delete the date, move to the date field and press "ENTER" and press the up-arrow key. To set the current date in a blank field press "ENTER" and press the up-arrow key twice and then press "ENTER" again.
- 4. When entering [4 Sample memory] the sequence numbers 1-9999 are viewed. Move to the SEQ field and press "ENTER". Change the sequence number with the + (plus) and/or (minus) keys and press "ENTER".

View selected samples

- 1. To view the results of selected samples on the display, move to [4.1 View selected samples] and press "ENTER".
- 2. Press the right-arrow key to view the histogram. Press left-arrow to return to the results.
- 3. Press the up-arrow or down-arrow keys to view the previous or the next results. If "ENTER" is pressed the results are printed.
- 4. Exit with the "MENU" key.

Statistical calculations

Statistical calculation is used if the operator wants to perform a precision study of a single blood sample. Statistical calculation is either on Normal or Normal + Abnormal parameter values. Normal parameter values are values within the parameter normal range as set in the [6 Setup menu/6.5 Set reference ranges].

Abnormal parameter values are values outside the set normal range except background count values and over range values. The statistic calculation is displayed for each parameter.

Sd = Standard deviation	x = mean value
CV = coefficient of variation	n = number of samples

- 1. When the requested sample-ID is set, move to [4.2 Statistical calculation] and press "ENTER".
- 2. Press right-arrow key to view the remainder of the parameters.
- 3. Press up-arrow/down-arrow to view either Normal or Abnormal + Normal parameter values.
- 4. To print all available data, press "ENTER".
- 5. Exit with the "MENU"-key.



Print selected samples

This menu is used to print out the results and histograms for a specified sample.

- 1. When the requested ID, DATE or SEQ is set, move to [4.3 Print selected samples] and press "ENTER". All the results and histograms of the selected sample/samples are printed. Abort printing with "MENU"-key.
- 2. Exit with the "MENU"-key.

Send selected samples

If a computer is connected to the AutoCounter, this option can be selected. See further information in chapter **Computer communication setup** on page 82.

- 1. When the requested ID, DATE or SEQ is set, move to [4.4 Send selected samples] and press "ENTER" to send the results to the computer. Abort sending with "MENU"-key.
- 2. Exit with the "MENU"-key.

Delete selected samples

- 1. When the requested ID, DATE or SEQ is set, move to [4.5 Delete selected samples] and press "ENTER".
- 2. If the sample should be deleted, press the + (plus) key.
- 3. Exit with the "MENU"-key.



Note that a selection of ID, DATE or SEQ numbers can show more than one sample and it is important to know which sample is to be deleted.

Note that! several samples can be deleted by mistake!



1 Maintenance & Special Procedures



Contamination hazard if contaminated blood enters into open cut.

1.1 Daily check of the calibration

Always start a measurement series with a background count and a daily control from each level (low, normal and high).

Before any analysis of routine human blood samples it is important to be aware of the calibration of the instrument. Always verify the calibration with a daily control blood in the current position, Closed Tube (CT)/Open Tube (OT) or Pre-Diluted (PD).

1.2 Daily maintenance

Daily wiping of the pipette with protein cleaner is recommended.

• Pour protein cleaner on a tissue paper and wipe the pipette.

Cleaning cycle

At the end of the day run an [8.2 Cleaning cycle]: use enzymatic cleaner or 0.5% sodium hypochlorite.

- 1. In the [Main Menu] move to [8 Maintenance] and press "ENTER".
- 2. Move to [8.2 Cleaning cycle] and press "ENTER". Add 4 ml of the cleaning solution into an unused beaker and place it into the predilute position of the AutoCounter.
- 3. Press "START PreDilute" to start cleaning cycle.
- 4. Leave the AutoCounter for at least 4 hours.
- 5. Exit by pressing the "MENU" key.
- 6. Restart by making a background count in [1 Measurement] menu.

1.3 Yearly maintenance - servicing

All service for Swelab AutoCounters shall be serviced by the local service engineer. Boule strongly recommends at least one yearly maintenance performed by a local service engineer authorised by Boule.

1.4 Change to a new reagent container

When the REAG LOW lamp is flashing it is time to change to a new reagent container. The display shows which reagent is too low.

- 1. Remove the empty reagent container and put the reagent sensor into a new container.
- 2. In the [Main Menu] move to [8 Maintenance] and press "ENTER".
- 3. Move to [8.3 Start fill system] and press "ENTER". The system is now filled with the new reagent.
- 4. Check the new reagent with a control blood.



Mandatory action Always wear protective gloves when operating or servicing the AutoCounter



Important

The AutoCounter is factory calibrated but should be verified with a control blood sample when the instrument has been subjected to a service.

1.5 Decontamination

Use Sodium hypochlorite 4%

- 1. Remove all the three reagent detectors from their containers.
- 2. In the [Main Menu] move to [8 maintenance] and press "ENTER"
- 3. Move to [8.4 Start Emptying system] and press "ENTER".
- 4. Place the three detectors in a bottle containing at least 1liter sodium hypochlorite.
- 5. Move to [8.3 Start fill system] and press "ENTER".
- 6. Aspirate 4 ml sodium hypochlorite via the predilute pipette.
- 7. Leave the AutoCounter idle for at least 2 hours.
- 8. Remove the reagent detectors from the sodium hypochlorite bottle and run [8.4 Start emptying system].
- 9. Place the reagent detectors in a bottle containing 1liter isotonic diluent.
- 10. Run [8.3 Start fill system].
- 11. Remove the detectors and run [8.4 Start emptying system].
- 12. Place the three reagent detectors in their original containers and run [8.3 Start fill system].
- 13. The AutoCounter is now ready for measurement.

Cleaning of the exterior.

Use a mild detergent, distilled water or a mild alcohol solution to clean the exterior surfaces of the AutoCounter.

Clean the outside of the measuring head and counting beaker with distilled water and a soft tissue paper.

1.6 Start a Prime cycle

The [8.1 Start a Prime cycle] is used to flush the AutoCounter with reagent without counting.

- 1. In the [Main Menu] move to [8 Maintenance] and press "ENTER".
- 2. Move to [8.1 Start a prime cycle] and press "ENTER". The AutoCounter starts a priming cycle.
- 3. Exit by pressing the "MENU" key.

1.7 Start Filling system

The menu is used to fill up the AutoCounter system with reagents.

- 1. In the [Main Menu] move to [8 Maintenance] and press "ENTER".
- 2. Move to [8.3 Start Filling system] and press "ENTER". The system will be filled completely with all reagents. No air and bubbles should appear in the syringes. This will take a few minutes.
- 3. Exit by pressing the "MENU" key.



Make sure that there is no hypochlorite left on the detectors inside and outside surfaces before placing them in their original containers.

MCV, RBC and HGB can give false low values.

1.8 Start Emptying system

The menu is used to empty the AutoCounter system completely from reagents.

- 1. Remove the reagent tubing from the reagent container.
- 2. In the [Main Menu] move to [8 Maintenance] and press "ENTER".
- 3. Move to [8.4 Start Emptying system] and press "ENTER". This will take a few minutes.
- 4. Exit by pressing the "MENU" key.

1.9 Start Capillary cleaning

The orifice is automatically cleaned by an electric pulse after each WBC count. This cleaning minimises the risk of clogging. If several clogs appear in a row of analysis it is possible to perform a manual cleaning of the orifice with [8.5 Start Capillary cleaning].

- 1. In the [Main Menu] move to [8 Maintenance] with the down-arrow key and press "ENTER".
- 2. Move to [8.5 Start Capillary cleaning] with the down-arrow key and press "ENTER". A clicking sound is heard and the orifice is cleaned by an electric pulse.
- 3. Exit by pressing the "MENU" key.

1.10 Single count test

The menu is used to verify the cell counting time and also the background count of the diluent. The counts and time reported refer to the RBC/PLT and MCV/ MPV counts.

- 1. In the [Main Menu] move to [8 Maintenance] and press "ENTER".
- 2. Move to [8.6 Single count test] and press "ENTER".
- 3. Press "ENTER" to start the single count.

The dilution is pulled into the measuring tube by the vacuum pump and the counting starts. The time is presented on the display and should be in the range of 11.0-15.0 seconds.

The counts of the RBC/PLT and MCV/MPV will be presented on the display. Press "ENTER" to print.

4. Exit by pressing the "MENU" key.



Display view of Single count test

In the latest of the processor program a new parameter, CVP is shown in the picture but it is only a test function for service.



1.11 Transport procedure

Switching off the AutoCounter

Normally the AutoCounter should never be switched off.

Short Term Transport

The AutoCounter can be transported over short distances without performing any special procedure. Just follow the daily cleaning procedure before the instrument is switched off and transported. Take care that the instrument is lifted at the base chassis.

Long Term Transport

If the system has to be switched off over a period longer than three weeks it is necessary to follow the instructions below.

- 1. Remove the reagent aspiration tubes from the reagent containers.
- 2. In the [Main Menu] move to [8 Maintenance] and press "ENTER".
- 3. Move to [8.4 Start emptying system] and press "ENTER". The system is now emptied from reagents.
- 4. Put the reagent sensors in a container with distilled water and move to [8.3 Start filling system]. The system is now filled with distilled water, this procedure lasts for some minutes.
- 5. Switch off the instrument and remove the power supply cable.

Whenever the AutoCounter is transported over a longer distance: Do exactly as item 1-3 in the paragraph above and then follow the instructions below.

- 1. Switch off the instrument and remove the power supply cable.
- 2. Pack the instrument using the ORIGINAL shipping box.
- 3. Mark the box with DELICATE INSTRUMENT, FRAGILE and THIS SIDE UP.

1.12 Storage

Storage should take place by following the packing instructions above and storing under the following conditions:

Temperature between 5 and 40 °C.

Humidity should be less than 80%.

1.13 Disposal information

Manufacturers recommendation

- Place the instrument close to a waste container 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.



Do not fill the Auto-Counter with ethanol!

Can cause damage to tubing and beaker.



Caution not disconnect th

Do not disconnect the instrument from the mainssupply as the analyzer performs automatic selfcheck cycles every 4th hour to prevent clogging and bacterial growth in the system. Please call your authorised distributor in case the instrument has to be powered off during a period longer than 1 week.

Not doing so might lead to bacterial growth or block-ages in the system.



Mandatory action Always wear protective equipment when working with infectious or potentially infectious materials.



Note:

Customers are advised to be knowledgeable of applicable local, state and federal requirements, and the contents of effluent streams, before disposing of waste in public sewer systems.

The disposal material are:

- used reagents
- reagents mixed with infectious specimen
- instrument
- components of the instrument
- controls and calibration material

1.14 Consumables

Reagents

The reagents are intended for human in vitro diagnostic use only.

Boule recommends all our AutoCounter customers to use reagents approved by Boule. If there is any obscurities about which reagent to use, contact your local distributor or Boule for correct information.

Reagent		Description	Description	
Reagent Isotonic diluent		Buffering solution Boule	Buffering solution approved by Boule	
Hemolysing reagent WBC		Cyanide free reagent approved by Boule		
Isotonic detergent	Isotonic detergent		oule	
Cleaner		Enzymatic cleaner or hypoclorite approved by Boule		
Control blood		Low, normal and approved by Bo	Low, normal and high levels approved by Boule	
Calibrator		Approved by Boule		
Reagent	Active ingredients	Art. No.	Dim	
EO-reagent	Poly-ethylene based non-ionic surfactant. Approved by Boule	1503842	1liter	



Warning

The reagents can be harmful if swallowed. Avoid contact with eyes, skin and clothing.



Please note that the conductivity in the reagent changes with temperature. Try to maintain a fairly constant room temperature within this range: 18-32°C

MCV and the calculated parameters, where MCV is included, changes when temperatures fluctuate.



12 Warning flags & Trouble shooting

12.1 Warning flags

Warning flags	Description	Suggested solution
*	A * (star) will show when the result is out- side the specified refer- ence ranges.	
####	This will occur when the result is over the mea- surement range.	Add 10 µl blood to 4 ml diluent. Rerun the sam- ple and multiply the re- sults by 2.
	This will occur when the result is under the mea- surement range.	Take 40 µl blood in 4 ml diluent and rerun as a prediluted sample. Di- vide the result with 2
LT Long Time	This error flag might be displayed on RBC, PLT, and/or WBC. The error flag is shown when the counting time is too long and is probably caused by a clogged ori- fice.	Related parameters are not reliable. Perform a capillary cleaning in the [8.5 capillary cleaning] menu and press "EN- TER". Reanalyse the sample.
NC No Count	This error flag might be displayed on RBC, PLT, and/or WBC. The error flag is shown when the system is unable to move the liquid level in the measuring unit up to the lower detector and is probably caused by a clogged orifice.	Related parameters are not reliable. Perform a capillary cleaning in the [8.5 capillary cleaning] menu and press "EN- TER". Reanalyse the sample.
ST Short Time	This error flag might be displayed on RBC, PLT, and/or WBC. The error flag is shown when the counting time is too short. Problem with the measuring tube, measur- ing head and tubing.	Go to [8 Maintenance menu]/[8.6 Single count test] and try single count.
TB Tube Bubbles	Bubbles present in the measuring tube.	Go to [8 Maintenance menu]/[8.6 Single count test] and try single count. Repeat the test until no warning flags.



Warning flags	Description	Suggested solution
DE Distribution Error	This error flag might be displayed on RBC, PLT and WBC. Abnormal distribution histograms due to disturbances.	Reanalyse the sample. If it still occurs, contact your local service engi- neer. DE can also ap- pear in some diseases.
FD Floating Discriminator	No acceptable mini- mum found between the RBC and PLT popula- tion.	This warning occurs fre- quently on low PLT counts. FD can also ap- pear in some diseases.
LO Low blank level HGB	Warning flag only for HGB.	Contact your local ser- vice engineer.
HI High blank level HGB	Warning flag only for HGB.	Contact your local ser- vice engineer.
NG Negative HGB	Warning flag only for HGB. Occurs when the blank measuring is dark- er than the reagent in the counting beaker.	Contact your local ser- vice engineer.
SE Statistical Error HGB	Warning flags only for HGB. The measure- ments of HGB are vary- ing too much.	Contact your local ser- vice engineer.
12.2 Trouble shooting

Indication numbers

Indication numbers are displayed when a system failure occurs. The AutoCounter will stop immediately and will not continue with the process until the indication failure has been deleted.

Indication numbers in the AutoCounter can occur when there has been a main power failure, motor failure, electrical failure and/or memory failure.

The indication numbers can be deleted by the "MENU" key. Each number has a specific indication source. Refer to the service manual for detailed information.

Indication Numbers	Message	Suggested solutions
1	Date and time not set.	Set date and time in the [6 Setup menu][6.4 Set date and time].
101 121-122 141-142 151-152	Unspecified motor failure Dilutor motor failed Vacuum pump motor failed Cap piercer/needle motor failed	Press the "MENU" key until all error indication disappear. Then turn off and restart the Auto- Counter. If the indica- tion remains, contact your local service engi- neer.
200-209	Internal communication error be- tween the processor and the dilu- tor board.	Contact your local ser- vice engineer.
230-255	Internal failure in the software.	Contact your local ser- vice engineer.
351 352 353 354 355 356 357-358 359 360-365 366 367	The process cycle could not terminate. Power on cycle failed Prime cycle failed Cleaning cycle failed Fill cycle failed Empty cycle failed Capillary cleaning cycle failed Wash cycle failed Exit-standby cycle failed Measurement cycle failed Autosampler cycle failed Service cycle failed	If it occurs at power on; delete any indication numbers with the "MENU" key. Start a Prime cycle. If it occurs in a process; turn off and restart the AutoCounter. Delete any indication numbers with the "MENU" key. Start a Prime cycle.
901-905 911 921 931 941 951 961 999	Configuration failure Machine statistics lost Stored samples lost Normal ranges lost Calibration raw data lost Stored control samples lost X-bar lost Battery low	Contact your local ser- vice engineer.



Indication Numbers	Message	Suggested solutions
2000-2255	Hardware or software failure.	Contact your local ser- vice engineer.
2500	DSP failure.	Contact your local ser- vice engineer.
3000	Internal failure in the software.	Contact your local ser- vice engineer.



13 Optional Accessories

13.1 Printer setup

Printer standard formats are available for:

- Seiko DPU 411-2/ DPU 414 or an
- IBM-compatible printer.

For IBM compatible printers it is important that the printer is switched to a true IBM mode. Please refer to the printer manual and set the printer protocol to IBM format.

- 1. Connect the printer cable to the rear panel of the AutoCounter and to the printer input.
- 2. Make sure that the connectors are fastened properly.
- 3. Connect the power supply from the printer to the correct voltage and frequency.
- 4. Switch on the printer.

- Check that the printer paper is inserted according to the printer manual.

- 5. From the [Main Menu] in the AutoCounter move to the [6 Set up menu] and press "ENTER".
- 6. [6.1 Printer set up] is already marked, press "ENTER".

There are three different print modes and three different ways to present the results.

(0) = Off, (1) = Only text, (2) = Text + graphs

Manual print mode = (0), (1) or (2)

Automatic print mode = (0), (1) or (2)

Memory print mode = (0), (1) or (2)

There are different print formats available in the AutoCounter software. To see the different print formats, move to [Print a list of all print formats] and press "ENTER" or see below the most common print formats of DPU 411.



correct printing might fol-

low if an improper format

or printer is selected.

7. Exit by pressing the "MENU" key.



Print formats 91 and 93 of DPU printer



Print formats 94 and 99 of DPU printer

13.2 Serial computer data format

The data format is of such an extent that the connected computer system also can trace abnormalities in samples or in the instrument. Below an example is given of a typical sample. Note that the parameter transmission is independent of language settings. The data transmission is always in English. Use a computer in terminal mode to visualise the output as shown below.





	CRBC=
+++++	04:0B:14:1A:1B:18:13:0F
INSTR= AC920-1875	:0B:09:07:06:05:06:07:08
DATE= 2000/6/6-15:58	:09:0C:13:1E:32:4E:74:A0
MODE= OT-B0-A1-U2-P1-D002	:C9:E9:FA:FF:F6:E2:C8:AB
DISC= 15-30-30/095-120	:94:7E:6A:59:4F:49:47:46
ID= 1234567890	:46:47:49:4A:4A:48:46:43
SEQ= 44	:3E:37:2F:28:22:1D:18:12
RBC= 4.77 O-OK-O	:0E:0B:09:07:05:04:04:04
MCV= 102.3 O-OK-H	:03:02:02:02:01:01:01:02
НСТ= 48.8 О-ОК-Н	:02:01:01:01:01:01:02:04
PLT= 224 O-OK-O	CPLT=
MPV= 12.5 O-OK-H	:00:00:00:00:00:01:01:02
WBC= 4.3 O-OK-O	:03:03:04:05:06:06:07:07
HGB= 148 O-OK-O	:08:08:09:09:0A:0A:0B:0B
MCH= 31.0 O-OK-O	:0B:0C:0C:0C:0B:0B:0B:0A
MCHC= 303 O-OK-L	:0A:09:09:08:08:08:08:08
TRBC= 11.7 O-OK-O	:08:08:08:08:08:07:07:07
TWBC= 11.7 O-OK-O	:06:06:06:06:06:05:05:05
LYMF= 1.5 O-OK-O	:04:04:04:04:04:04:04:04
GRAN= 2.1 O-OK-O	:03:03:03:03:03:03:03:03:03
MID= 0.7 O-OK-O	:03:03:03:03:03:03:03:03:03
LPR= 34.4 O-OK-O	CWBC=
GPR= 49.9 O-OK-O	:00:00:00:00:00:00:04:0F
MPR= 15.7 O-OK-H	:19:1C:1C:1B:19:17:15:13
RDWR= 30.9 O-OK-H	:12:13:13:13:14:16:17:17
PDW= 17.8 O-OK-O	:17:17:15:14:15:15:14:13
PCT= 0.30 O-OK-O	:12:11:11:10:0E:0E:0E:0D
	:0B:08:07:07:07:07:06:05
	:06:05:04:04:03:02:02:02
	:02:02:01:01:01:01:00:00
	:00:00:00:00:00:00:00:00
	:00:00:00:00:00:00:00:00
	#####
	CRC-16

An explanation of the above transmission format follows below:

+++++

Five + signs are given to indicate a start of transmission

INSTR= AC920-1875

The instrument identification is transmitted. The first part is a string of characters indicating the type of instrument, followed by a dash and a user selectable 5-digit number.

The user selectable number is chosen in the [6.Setup Menu], and is only used in the serial output format. Study section **Set instrument ID** on page 41 in the user manual for further details.

DATE= 2000/6/6-15:58

The date and time when the sample was analysed. Note that the date is always in the format YYYY/MM/DD (YEAR/MONTH/DAY) and the time in 00-24 hours

MODE= OT-B0-A1-U2-P1-D002

The MODE is expressed as AA-BB-CC-DD-EE-FFFF and represents the following:

AA= How the sample was measured

OT= open tube

PD= pre-diluted sample

CT= cap piercing device

BB= Bottle status

B0= All bottles (containers) OK

B4= Haemolyser container empty

B2= Diluent container empty

B1= Detergent container empty

B3= Diluent AND detergent container empty

B5= Detergent AND haemolyser container empty

B6= Diluent AND haemolyser container empty

B7= All bottles (containers) empty

CC=Aspiration status

A0= No blood detected

A1= Blood detected

DD= Used parameter units

U=0 Corresponds to the user manual section Set units on page 40; selection 1

U=1 Corresponds to the user manual section **Set units** on page 40; selection 2

U=2 Corresponds to the user manual section Set units on page 40; selection 3

U=3 Corresponds to the user manual section Set units on page 40; selection 4

EE= P1

For future expansion. Currently it is P1 when an ordinary sample is analysed, and PA when an EOS sample is analysed.

FFFF= D002

For future expansion.

DISC= 15-30-30/095-120

The discriminator settings. The first group of three numbers (to the left of the slash character) shows the discriminator settings between the platelets and the red blood cell's as follows: the first digits represent the MIN level, the second the AC-TUAL setting and the third the MAX setting.

In this case the minimum level of the RBC discriminator was at 15 fl, the actual setting of the floating discriminator was at 30 fl and the MAX discriminator level was at 30 fl. See chapter **Set floating discr. RBC/PLT** on page 39 and **WBC - White Blood Cell Count** on page 32.

The last group of two numbers (to the right of the slash-character) shows the discriminator settings for the white blood cell's. The first number is the discriminator level between the LYM region and the MID region, and the second number is the discriminator level between the MID region and the GRA region. Study section **Set discr. WBC & EO** on page 39.

ID= 1234567890

This is the sample identification string and it is entered by the user at the time of sample aspiration. It is a variable length string of 0-15 alphanumeric characters. Numeric characters are entered from the built-in or optional keyboard, but alphanumeric characters can only be entered by the use of a barcode reader.

SEQ= 44

The sequential number of the sample. It is automatically incremented for every sample.

RBC= 4.75 O-SE-O

The parameter values has a field width of 5 digits, right justified and a line has a total width of 40 characters

The flagging system is in the format X-YY-Z

X= Value status

O= OK digit value is available

N = N/A No value available, transmitted as zero (0.00 for RBC)

L= LOW under range

H= HIGH over range

YY= Sample flags (See Warning flags on page 71.)

OK= OK, no sample errors

LT= Long time

NC= No count

ST= Short time

TB= Tube bubbles

DE= Distribution error

FD= Floating discr. warning

LO= Blanking error HGB photometer

HI= Blanking error HGB photometer

NG= Negative HGB error

SE= Statistical error



Z= Sample abnormalities

O= OK, sample value within parameter limits

L= Sample value LOW

H= Sample value HIGH

TRBC and TWBC

These 2 'parameters' are the actual counting times for the RBC and the WBC process.

CRBC=:04:0B: etc..

Here the size distribution curves are transmitted. 80 numerical HEXADECI-MAL values are given. Note that the size distribution curve for the RBC values ALSO includes the PLT curve. As the total scale is 250 fl; each 'channel' represents a value of 250/80 = 3.1 fl.

CPLT=

See CRBC above. Note that 80 'channels' are transmitted and that the maximum channel represents 30fl. Each channel represents therefore 30/80 fl.

CWBC=

See CRBC above. For WBC the maximum scale is 400 fl. As 80 'channels' are transmit-ted, this corresponds to 400/80 = 5 fl / 'channel'. In case of a 2-part diff.; CWBCL and CWBCG are transmitted which are the LYMF and GRAN curves. In case of a 3-part differential, the CWBCM (MID) curve is also transmitted.

The cell differential curves, like the other curves, always have a max. channel value of 400fl. This means that each channel always represents 400/80 = 5 fl.

NOTE:

that in all cases, the first transmitted channel represents channel number 0! The channel values are always in HEXADECIMAL form proceeded with a '!' sign.

####

The end of a transmission is always marked with 5 '#' signs, followed by a CR and LF.

CRC-16

A CRC16 containing four hexadecimal digits. It is calculated on all data between the ++++ and ##### marks, excluding all CR and LF.

EO sample

For an EOS-sample data is transmitted in a similar way as described above. There are a few differences however which are listed below the sample printout.

+++++

INSTR= AC920-1875 DATE= 2000/6/6-16:42

MODE= PD-B0-A1-U2-PA-D002

DISC= 00-00-00/070-200

ID=

SEQ= 46

EOS= 0.02 O-OK-O

TEOS= 23.7 O-OK-O

CEOS=

:00:00:00:00:00:01:02:03

:02:01:00:01:01:01:01:02

:01:01:00:00:00:00:01:01

:01:00:00:00:00:00:00:00

:00:00:00:00:00:00:00:00

:00:00:00:00:00:00:00:00

:00:00:00:00:00:00:00:00

:00:00:00:00:00:00:00:00

:00:00:00:00:00:00:00:00

#####

CRC-16

MODE= PD-B0-A1-U2-PA-D002

The fifth element in the "mode"-string is set to PA when an EOS sample is analysed.

DISC= 00-00-00/070-200

The last group of two numbers (to the right of the slash-character) shows the discriminator settings for the eosinophil white blood cells. The EOS value presented is the counted number of cells between these two limits. Note that the figures DO NOT correspond to cell volume (due to several reasons).

EOS= 0.02 O-OK-O

This is the EOS-parameter and it is formatted as described above.

TEOS= 23.7 O-OK-O

This is the counting time in seconds for the eosinophil bloodcell's. It is about twice as long compared to the RBC and WBC counting time, because a larger volume of specimen is analyzed.



CEOS=

:00:00: etc...

See CRBC above. This is the eosinophil cell size distribution histogram. Note that the x-axis (or size) has no reference value (the eosinophil cell size is not related to any kind of reference).

13.3 Computer communication setup

If the AutoCounter is connected to a computer follow the procedure below, see also further information in **Serial computer data format** on page 76.

- 1. Connect the computer cable to the rear panel of the AutoCounter and to the computer input.
- 2. Make sure that the connectors are fastened properly.
- 3. In the [Main Menu] of the AutoCounter move to the [6 Setup menu] with the down-arrow key and press "ENTER".
- 4. Move to [6.2 Computer communication setup] and press "ENTER".

There are three different ways and send modes to present the results.

(0) = Off(1) = Only text(2) = Text + graphs

Manual send mode = (0), (1) or (2)

Automatic send mode = (0), (1) or (2)

Memory send mode = (0), (1) or (2)

Serial port set up

Baud = 300 / 600 / 1200 / 2400 / 4800 / 9600 / 19200

Parity = No / Odd / Even

Databits = 7 / 8

Stopbits = 1

HW - handshake = No / Yes

To confirm the set up change press "ENTER" and to skip press "MENU".

Exit by pressing the "MENU" key.



13.4 Select barcode reader

The AutoCounter can be used with a barcode reader.

- 1. Connect the barcode reader cable to the rear panel of the AutoCounter.
- 2. From the [Main Menu] move to the [6 Set up menu] with the key and press "ENTER". Move to [6.9 Select barcode reader] and press "ENTER".
- 3. Three different modes are available
- 0 = No barcode reader
- 1 = Standard barcode reader: 9600, 0, 7, 2
- 2 = Autosampler barcode reader: 9600, N, 8, 1

If a standard barcode reader is used, select (1) with the + (plus) and - (minus) keys and press "ENTER".

Select (2) if the fixed barcode reader of AC970EO+ is used.

4. Exit by pressing the "MENU" key.

Barcode reader functions

This menu is used when the operator wants to test the fixed barcode reader

in AC970EO+.

- Test barcode reader ID
- Init. autosampler barcode reader
- Set autosampler barcode reader to factory defaults

When an ID-marked blood sample is placed in the right position in front of the barcode reader move to [Test barcode reader ID] and press "ENTER", the ID number is showed. If the barcode reader cannot read, it shows NL = No Label.

If the barcode reader does not read move to [Init autosampler bacode reader] and press "ENTER". Move back to [Test barcode reader ID] and press "ENTER", the ID number is showed.

13.5 Select external keyboard

If the internal keyboard or an external keyboard are used, no setup is necessary in this menu. (0) is only for an internal keyboard and (1) is for both internal and external keyboards which is the default setup.

If an external keyboard with the Num-Lock function is used, it is possible to see in the upper right corner of the display, either number "1" = for figures or " \blacktriangle " = for the arrow keys.

13.6 EO Menu

This parameter is an option which only can be used when the Swelab EO-kit is available. The Swelab AutoHeater is intended for preheating of reagent used for determination of eosinophile granulocytes in Swelab's AutoCounters. Further information; see the user's manual of the AutoHeater.



Sample preparation

- 1. Switch on the AutoHeater. The red light diode marked with POWER is switched ON during warm up of the AutoHeater. When the AutoHeater has reached the right temperature, after approx. 10 minutes, the green light diode marked TEMP is switched ON.
- 2. Dispense 4.5 ml of the EO reagent with SWELAB's EO-dispenser into a sample beaker.
- 3. Preheat the EO reagent in the position 1-5, approx. 10 minutes. If more than 5 EO samples are to be analysed, load the AutoHeater during the measurement process.

Preparation of the AutoCounter

- 1. In the [Main Menu] step to [2 EO menu] and press "ENTER". Step to [2.1 Measurement EO] and press "ENTER".
- 2. Start to measure a background count with only pre-heated EO-reagent: Take one beaker of preheated EO reagent and place it in the prediluted position.
- 3. Press "START PreDilute". The "READY" lamp switches from the green to the red light and at the same time the dilution is aspirated.
- 4. Repeat the background count until the values do not exceed the recommended level $\leq 0.10 \ge 10^9/l$.

Measurement of EO dilution in the AutoCounter

(See an example of an EO sample print out figure on **WBC histogram with a MID cell fraction** on page 33.)

- 1. Remove the beaker from position 1 in the AutoHeater and turn the beaker wheel clockwise one step.
- 2. Add 20 µl of blood using the micro capillary tubes and mix the dilution gently by swirling the beaker. Put the beaker lid on.
- 3. Place the EO dilution in the position marked green and press the beaker to the bottom. An alarm sounds and the timer starts.
- 4. Fill position 5 in the beaker wheel with a new beaker with EO-reagent if necessary.
- 5. After 90 seconds the lysing of all cells, except EO, is completed and an alarm sounds. Once again press the beaker to the bottom to switch off the alarm. Measure the sample in the AutoCounter within 30 seconds.
- 6. Swirl the EO dilution carefully and place it in the prediluted position.
- 7. Press "START PreDilute". The "READY" lamp switches from the green to the red light and at the same time the sample is aspirated.
- 8. Press "ENTER" to enter the ID-number with the + (plus) or -(minus) and right-arrow/left-arrow keys or with an external keyboard and press "EN-TER" to confirm. It is possible to enter the ID-number during the total counting time. The AutoCounter measures the EO sample and presents the



Always start EO-measurement with a background count using pre-heated EO-reagent, otherwise contamination from lyse reagent will give erroneous results.



Do not turn the beaker upside down. The reagent can leak out due to the surface active ingredient in the EO reagent.



Mandatory action Always wear protective gloves when handling infectious or potentially infectious materials. results on the display. When measurement is completed the "READY" lamp shows the green light. The results and the histogram remain on the display until the start of the next analysis.

Note:

Results below 0.10 should be reported as $< 0.10 \times 10^9/l$.

- 9. Repeat from step 1 for all EO samples.
- 10. Clean and restore the system when all EO samples are measured. Run a background count in an unused beaker with 4 ml diluent.



1237en.gif

Display view of Cleaning procedure

11. After the background count the instrument is ready for measurement of routine blood samples.

EO Memory

The [2.2 EO Memory] is designed in the same way as for the [4 Sample memory] but the EO memory only contains the eosinophil results including the histograms.

There are three different memories: Control memory, Sample memory and EO memory.

To distinguish which memory is entered open the [2.2.1 View selected EO samples] and the letter "E" in the upper right corner of the display appears to show that the current memory is the EO memory.

When the memory is "full" the oldest sample is automatically deleted. To show results on the display, one of the search condition fields has to be entered, ID-number, DATE and/or SEQ-number.

- 1. Select the different ways of search conditions ID, DATE and/or SEQnumber.
- 2. Select one of the different options below, and press "ENTER"

[2.2.1 View selected EO samples]

[2.2.2 Statistical calculation]

[2.2.3 Print selected samples]

[2.2.4 Send selected samples]

[2.2.5 Delete selected samples]

3. Exit with the "MENU" key.



Accessories for the EO kit

To obtain a complete spare part list, contact your local distributor.

Description	Art No.	Dim
EO start-up kit for 200 samples Auto Heater EO reagent Dispenser 803-EO Beakers 100 pcs/bag Pipettes 100 pcs/package	1900020	1 pcs 1 liter 1 pcs 2 bags 2 pkgs
Consumables EO-kit for 200 samples EO reagent Beakers 100 pcs/bag Pipettes 100 pcs/package	1900021	1 liter 2 bags 2 pkgs
Separate order:		
Dispenser 803-EO EO reagent Beakers 500 pcs/bag Micro capillary pipettes 100 pcs/package	1900025 1503842 1500002 1500004	1 pcs 1 liter 1 bag 1 pkgs



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