

Medicine Devices



USER MANUAL ***MDC 2000***

MDC 2000

Semi-automated hematology analyzer for blood count

Operator manual 1.0
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1. INTRODUCTION

1.1 APPLICATION

Haematology deals with the study of blood diseases and diseases of the blood-building organs. Because of the sensitivity of blood, a fairly exact diagnosis of different pathological conditions is possible.

Blood is the most important transporting organ of the body. Components carried by the blood, are either dissolved in the blood plasma (the serum), or are carried by the blood corpuscles.

Electrolytes and hormones belong to the first, an example for the latter is oxygen, which is carried by the erythrocytes. Certain pathological conditions are reflected in the change of the amount or quality of the blood corpuscles, for example: volume or content.

The cell counter serves to establish what is called the small blood picture. In addition to this, information on distribution as well as measuring and calculated parameters are given.

As a result of automation the processing of samples is made very easy. With the built-in analyzer the size of the particles can be measured and platelets can be determined simultaneously with the RBC measurement.

Please note however that blood cells are particles of the same size as for example dust and other pollution. Blood cells react with great sensitivity to changes in their physical surroundings.

The exactness of the measuring results depends not only on the system itself, but also to a large extent

- on how the system is handled,
- on how the blood is processed and
- on the quality of the solutions that are used.

Of course, the handling of the system will affect the total result most, while good results will in turn affect your satisfaction with the instrument. The following chapters want to help you with the proper handling of the instrument.

Before starting work with the instrument please read the manual carefully. Operation is allowed only to medically skilled staff with a special training for this cell counter!

1.2 PRINCIPLE OF OPERATION

The first step in cell counting is diluting the blood, which is performed by means of the built-in diluter semi-automatically. The blood is sampled and diluted with an isotonic particle-free solution. The first dilution is divided into two samples. A lysing reagent is added to one sample to remove RBCs before performing the WBC count. The second sample undergoes a second dilution with the isotonic particle-free solution before obtaining RBC and platelet results. An aliquot of the first dilution is used for the HGB determination. The two samples are then placed in the instrument.

After dilution the RBC, WBC and platelet counts are obtained using the volumetric impedance technique. The dilution of cells enters the counting chamber which has a small circular aperture showing an electrode on either side. The vacuum draws blood cells and diluent through the aperture. A flow of cell-free diluent through the aperture establishes a constant current between the electrodes. When a blood cell from the sample dilution enters the aperture, it momentarily interrupts the constant current, creating an impedance pulse. The pulses are amplified, and those whose impedance is above a particular threshold setting are counted. The magnitude of the pulse is directly proportional to the volume of the cell.

The cell counter is capable of performing a three-part differential. A special reagent is added to the WBC dilution to lyse RBCs and remove intercellular fluid from all WBCs. Due to the differences in their volume these cells are then identified and classified as lymphocytes, granulocytes and a category called MID cells that includes monocytes, eosinophils, basophils, blasts, and other WBC precursors.

1.3 SYMBOLS USED IN THE MANUAL

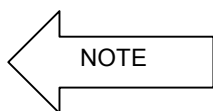
For better clarity the following symbols are used in this manual:



Danger!



Pay attention!



Important notice.



Useful hint.

1.4 ABBREVIATIONS

As the systems possibilities of data-display are limited, the customary international abbreviations of parameters are used.

RBC	-	Amount of Red Blood Cells (Erythrocytes)
HCT	-	Hematocrit (packed cell volume in %)
MCV	-	Mean Corpuscular Volume (average Cell Size, Erythrocytes)
WBC	-	Amount of White Blood Cells (Leukocytes)
LYM	-	Amount of White Blood Cells (Lymphocytes)
MID	-	Amount of White Blood Cells (Cells between LYM and GRAN)
GRAN	-	Amount of White Blood Cells (Granulocytes)
THR/PLT	-	Amount of Thrombocytes (Blood Platelets)
MPV	-	Mean Platelet Volume (average Platelet Size)
PCT	-	Platelet hematocrit (packed Cell Volume in %)
HGB	-	Hemoglobin Concentration
MCH	-	Mean Corpuscular Hemoglobin (average HGB weight/cell)
MCHC	-	Mean Corpuscular Hemoglobin Concentration (Average hemoglobin concentration in %)
RCDW	-	Distribution Control sector between RBC and THR-Population in %
LCDW	-	Distribution Control sector of THR towards Electronic Noise in %
RDW-SD	-	Red blood cell distribution width - Standard-Deviation
RDW-CV	-	Red blood cell distribution width - Coefficient of variation
PDW	-	Platelet distribution width (Standard-Deviation of the PLT graph)

1.5 NORMAL VALUES

Parameter	Unit	Normal Ranges
RBC	10^{12} blood c./l	4,5 - 5,5 male 4,0 - 5,0 female
HCT	%	42 - 50 male 37 - 43 female
MCV	fl (10^{-15} l)	76 - 96
THR / PLT	10^9 blood c./l	150 - 400
MPV	fl (10^{-15} l)	7.2 - 11.1
PCT	%	3 - 8
WBC	10^9 blood c./l	4,0 - 9,0
LYM	10^9 blood c./l	1,0 - 4,0
MID	10^9 blood c./l	0,1 - 0,8
GRAN	10^9 blood c./l	2,6 - 9,2
LYM	%	25 - 30
MID	%	2 - 8
GRAN	%	60 - 70
HGB	g/l	140 - 170 male 120 - 150 female
MCH	pg (10^{-12} g)	27 - 32
MCHC	g/l	320 - 360
LCDW	%	0 - 35
RCDW	%	0 - 15

1.6 INSTRUMENT DESCRIPTION

1.6.1 The Front side

Fig 1 shows the front side of the instrument with its functional units:

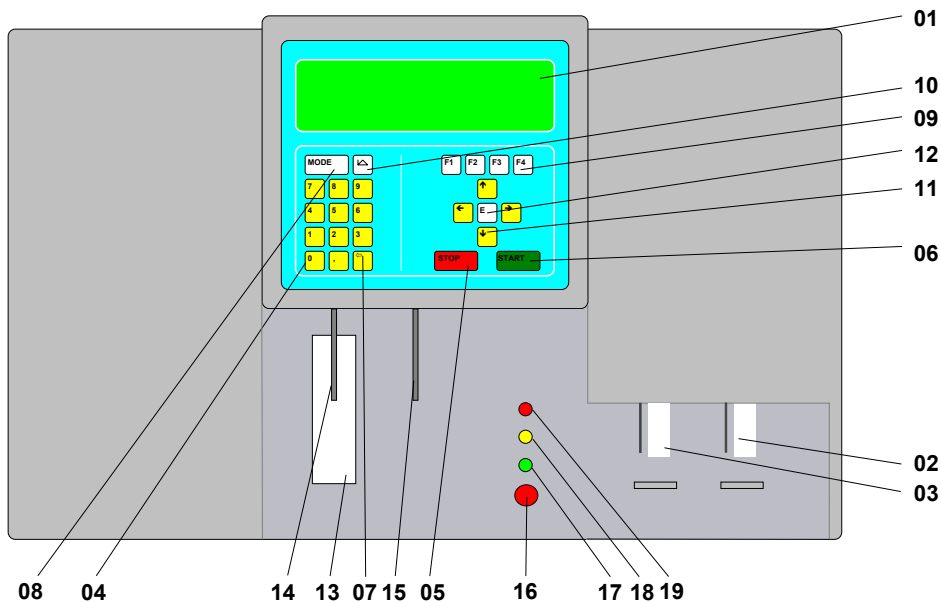


Fig 1: The Instrument and its functions (front side)

The functional units

01. LC-display	to display measuring results, user information
02. Aperture tube WBC-channel	capillary 100 μm
03. Aperture tube RBC-channel	capillary 80 μm
04. Number keys 0-9	to enter parameters or select options
05. Stop-key	to abort activated working cycle
06. Start-key	to start the measurement
07. Enter-key	to enter, confirm and select
08. Mode-key	to enter into main menu
09. Diluter reset-key	to reset diluter the function
10. Curve-key	to display the distribution histograms
11. Cursor-key	to move the cursor on the display
12. Print/Enter-key	for manual print confirmation
13. Touch plate	to release the built-in diluter
14. Sample tube	to suck in the blood sample/dispense the dilution
15. Lyse dispenser	to dispense lyser by the micro switch
16. Dilution switch	to dilute the first capillary blood dilution
17. Green light	signals: ready to suck in
18. Yellow light	signals: system in waiting position
19. Red light	signals: disturbance in the diluter

Removing the front-cover of the instrument, see Fig 2, the following function units are to be seen:

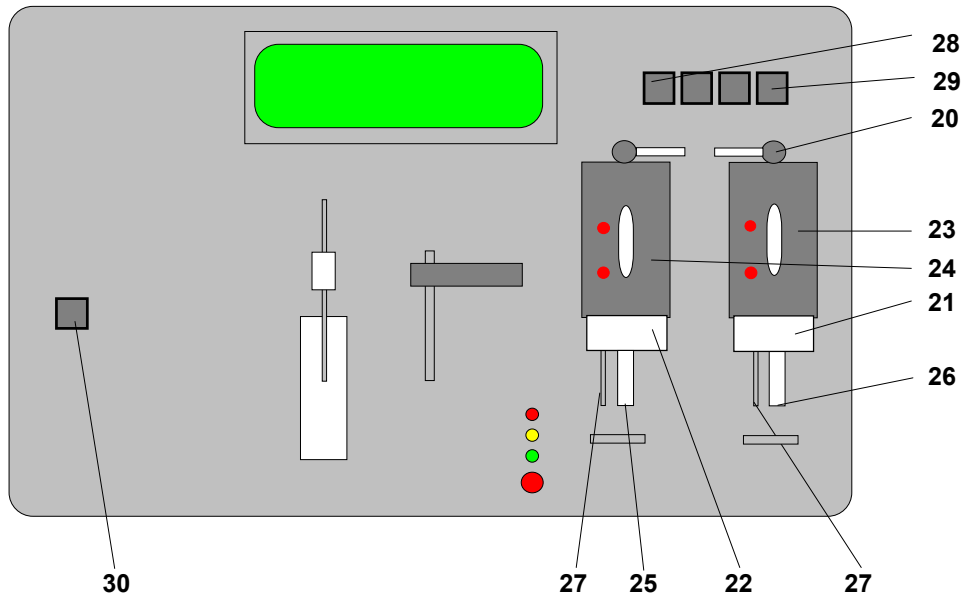


Fig 2: The Instrument and its functions (front side without front cover)

The functional units

- | | |
|----------------------|---|
| 20. Tube-cap | cover of the volume unit |
| 21. RBC-channel | RBC-measuring channel |
| 22. WBVC-channel | WBC-measuring channel |
| 23. RBC-volume unit | for control the RBC-channel |
| 24. WBC-volume unit | for control the WBC-channel |
| 25. Capillary 100 µl | instrument transformer inside the aperture-tube |
| 26. Capillary 80 µl | instrument transformer inside the aperture-tube |
| 27. Electrode | voltage feed |
| 28. WBC-valve | for measurement |
| 29. RBC-valve | for measurement |
| 30. HGB- Valve | for measurement |

1.6.2 The back side

Fig 3 shows the back side of the instrument with its functional units:

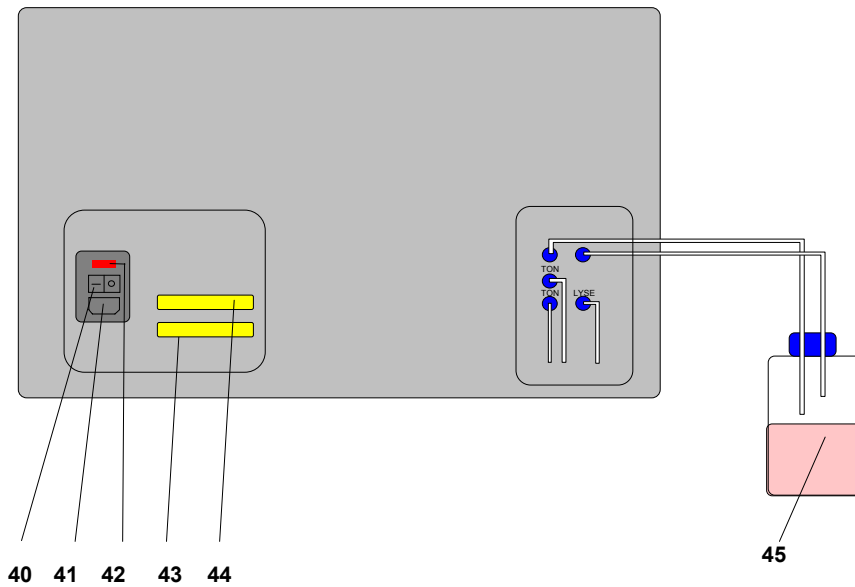


Fig 3: The Instrument and its functions (backside)

The functional units

- | | |
|-------------------|-------------------------------|
| 40. Power switch | main switch of the instrument |
| 41. Plug | for the mains cable |
| 42. Fuse | for mains connection |
| 43. Parallel port | for printer connection |
| 44. Serial port | for computer connection |
| 45. Waste bottle | for waste fluids |

1.6.3 The keyboard

Fig 4 shows the keyboard and its components:

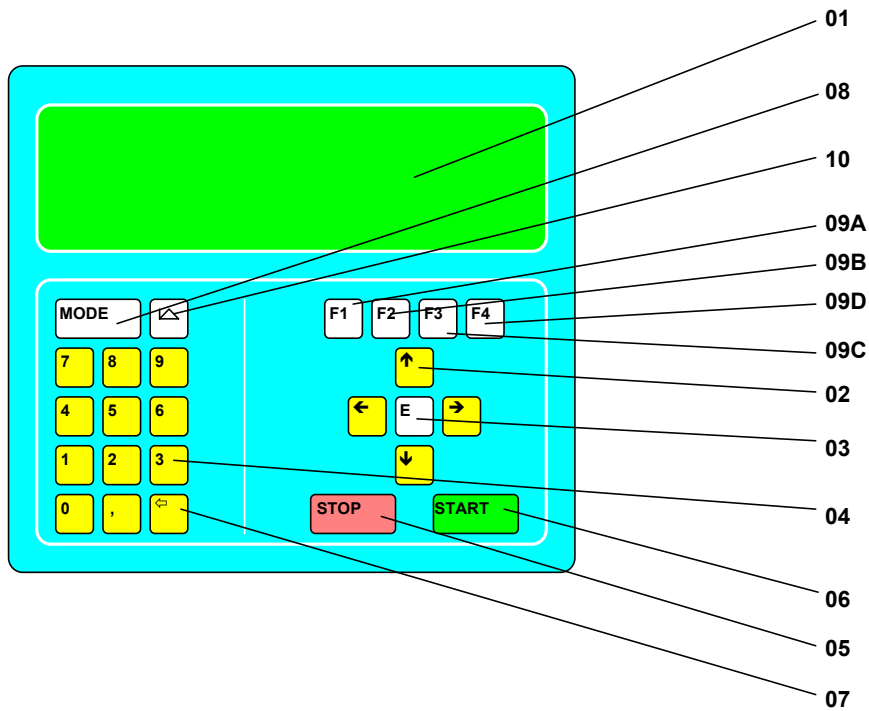


Fig 4: The keyboard

The functional units

01.	Liquid crystal display	to display measurement/ working instructions
02.	Cursor-keys	to move the cursor on display
03.	Print/Enter-key	for manual print confirmation
04.	Number keys 0-9	to enter parameters
05.	Stop-key	to abort activated working cycle
06.	Start-key	to start the measurement
07.	Enter-key	to enter, confirm, select
08.	Mode-key	to enter the system menu
09A	Capillary blood key	to select a dilution cycle for capillary blood
09B	Dispense key	to dispense isotonic solution for first capillary blood dilution
09C	Clean key	to clean both capillaries by inside pressure
09D	Diluter Reset key	to reset the diluter to the start position of dilution
10.	Curve-key	to display the distribution histograms

1.6.4 The display

The display is divided into two parts, separated by a horizontal line.

The **status-line** informs about

- the actual working cycles,
- the system-status and
- the possibilities of entering commands or data.

The **menu-sector** shows

- the parameter to be measured,
- the measuring results,
- the system features and
- explanations.

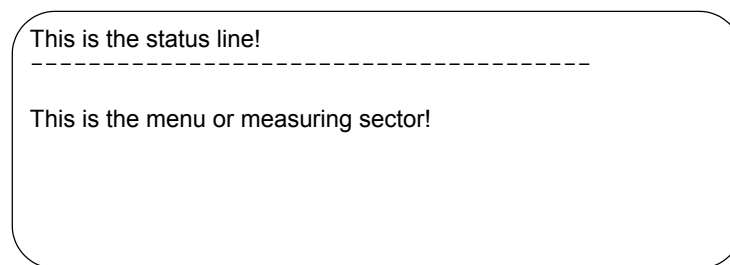


Fig 5: The Display

1.6.4.1 The standard or measuring display

Fig 6 shows the standard or measuring display during normal operating mode. It shows all important system information needed for the normal working routine.

CH2:	0.0	NO:	00000	[00:00]	
CH1:	0.0	ID:	00000		

RBC:	0.0	HCT:	0.0	MCV:	0.0
WBC:	0.0	LYM:	0.0	MPV:	0.0
THR:	0.0	MID:	0.0	MCHC:	0.0
HGB:	0.0	GRA:	0.0	MCH:	0.0
READY FOR WBC-SAMPLE!					

Fig 6: The standard or measuring display

The status line	shows the present system status or working step
The patient-identification number (patient ID)	can be entered for each sample separately. If the patient ID is different from zero, the printer waits for confirmation or change of the ID-number entered before out printing.
The sample number	is increasing with each new measuring cycle, and it also identifies each sample. Samples that are not documented by print-out will not affect the sample count. The count starts with the entered number.
The date display	A real-time clock controls the date, so you have to enter the date only ones (System menu → Date / Time).
The measuring duration	The values for the channels (CH1 - RBC and CH2 - WBC) show their measuring duration. These values also give information about the capillary condition and the vacuum system.
The measuring sector	displays the measured results of the activated parameters.

1.6.4.2 The graphic display

Fig 7 shows the graphic display after pressing the **Curve-key**. By using the up and down keys you can scroll through displays of the single curves or have a look to the overall graphic display.

The histograms will give you all information needed to check the measurements.

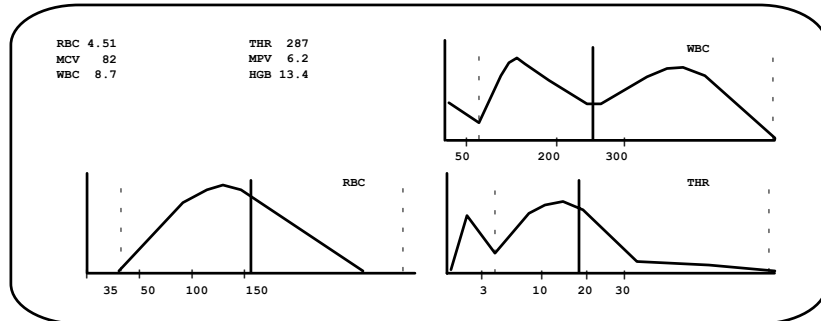


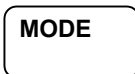
Fig 7: The graphic display

By pressing any key you go back to the measuring menu, while your last view in the graphic menu is saved.

1.6.5 The function keys

The system is equipped with function keys that execute a command directly. This way no selection by submenus is necessary.

1.6.5.1 The MODE-key



By pressing the MODE-key you reach the system menu. As well the MODE-key is used to go back to the previous display, no matter in which submenu you are actually.

1.6.5.2 The CURVE-key



By pressing the CURVE-key the distributions histograms are displayed. These histograms will help you to recognize different particle populations on the display. In case of an abnormal distribution the histograms will be automatically displayed so that a judgement on pathological results is possible.

1.6.5.3 The ENTER-key



By pressing the ENTER-key all inputs and selected options are confirmed.

1.6.5.4 The START-key



By pressing the START-key a measurement is started. It can be used for a multiple determination of a sample.

1.6.5.5 The STOP-key



By pressing the STOP-key the measuring cycle is aborted, while the diluter cycles are not interrupted. The Diluter functions can only be aborted in the service menu by selecting a >diluter reset<. This prevents losing a sample that has already been sucked in.

1.6.5.6 The E-PRINT-key



By pressing the E-PRINT-key the printout is started. This key serves to get printouts of results with error marks or of results that were already printed out.

1.6.5.7 F1-Key



The F1-key is used to select a dilution cycle for capillary blood after having done the first dilution for RBC measurement.

1.6.5.8 F2- Key



The F2-key is used to prepare the diluter to dispense the amount of diluent for the first dilution for capillary blood. By pressing the F2-key you switch this mode ON or OFF, how you can see in the status line. For dispensing use the touch plate.

1.6.5.9 F3-Key



The F3-key is used to clean both capillaries by pressure, which is made inside the system. Please note that the sample underneath the aperture tube is soiled afterwards!

1.6.5.10 F4-Key



The F4-key is used to reset the diluter to its start position for the standard dilution cycle.

1.6.6 The CURSOR-Keys



By moving the cursor by the CURSER-keys a choice is made. The selection will be marked.



The cursor normally moves vertically and automatically jumps from the deepest point back to the start line when moved further in that direction. The cursor moves horizontally in the patient's identification number line, the sample number line and the date line.



- **To adjust the contrast of the LCD use cursor up and down.**



- **To move the WBC-discriminators left or right use cursor left and right.**

1.6.7 The NUMBER-keys



The NUMBER-keys are needed to do numerical inputs and modifications. Please note that the system can only accept inputs within the range displayed in the status line.



1.7 INSTALLATION

Please note that this automatic cell counter has to be installed by qualified and trained technicians. The system is menu driven. For right operation please follow all displayed instructions!

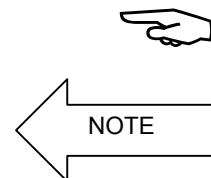
Proceed as follows to install the cell counter:

1. Check if there are damages on the packing, the instrument or the accessories and verify completeness of the equipment and accessories.
2. Remove the front-cover (it is stuck - not fixed by screws).
Check if all components are fixed correctly.
Remove the cover, and check tubes, plugs, PC-Boards etc. inside the instrument.
Check the correct fixation of the vacuum pump (fixed with rubber) and remove the transport screw.
3. Check if the HGB - chamber is fixed correctly.
4. Connect the waste-bottle, the supply-canisters and the printer. The tubes and connectors at the backside of the instrument are marked accordingly.
5. Connect the instrument and printer with mains and switch on the instrument (backside).
6. Read the manual carefully before you start working.
7. Switch on the instrument. A self-test is started automatically.
If the instrument works properly, close main cover.
8. Fill the instrument with **MEDILUID III DIFF** by selecting the command FILL in the system menu for at least 2-3 times.
9. Fill the counter with **CELLOLYSE** by pushing the **micro switch** at the **lyse dispenser** for at least 2 times. Afterwards the **red LED** has to be off and the **green LED** has to light up.
10. Close the front-cover (it is to stuck - not fixed by screws).
11. Carry out some blank measurements.
12. Check correct setting of the **HGB measuring chamber** with a zero **HGB-measurement**.
13. Check all menu options and settings. **Auto diff** and the right **Printer Emulation** should be **chosen**.
14. If the instrument works properly, you can start measuring and calibration.

Adjust blood- and lyser needle if necessary.
For special blood needle ask your distributor.

Important Notice:
When the cover is removed you cannot measure HGB.

The HGB-measuring chamber has to be completely dark for an exact result.



1.7.1 Self test

After the instrument is switched on a self-test is performed automatically.

The system is capable to detect defects/errors and reports them on the display.

Of course, an automatic system can only offer standardized proposals for problem solutions.

However, after some experience with the instrument, you will be able to interpret the error indications correctly.

Fig 8 shows the display after the self-test is completed.

```
.MDC 2000 .....SELFTEST ..... FINISHED...  
-----  
RBC      V 1.01  
WBC      V 1.02  
DILUTER  V 5.00  
SPOOLER  V 3.32  
MEMORY  O.K.                PUSH ANY BUTTON
```

Fig 8: Display after the self-test

2 THE MENU FUNCTIONS

The instrument has a menu-based user interface. As not all functions and parameters are always needed, it is possible to change them or switch them off / on in a certain submenu. The selection of system features is called up by pressing the **MODE-key**. Then the **system menu** is displayed, see Fig 9.

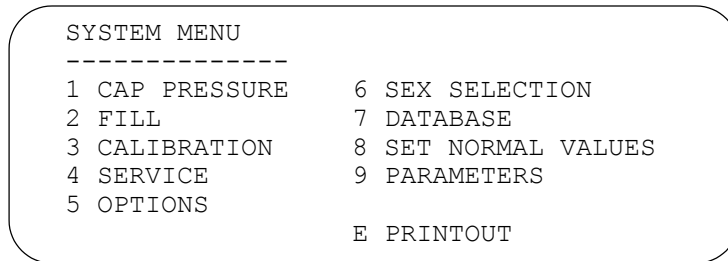


Fig 9: The system menu

Each menu point can be reached by using the corresponding **Number-keys**. Afterwards either a submenu opens or an action starts directly.

2.1 CAP PRESSURE

From this menu point the program does not switch into a submenu. By pressing **Number-key 1** in the system menu the capillaries are reopened by pressure cleaning. This is necessary when a capillary is blocked.

F3

The same you can reach by pressing **F3-Key**, without going through several menus.

However, please note that the solution standing underneath the capillaries is soiled afterwards.

NOTE

2.2 FILL

From this menu point the program does not switch into a submenu. When **Number-key 2** is pressed in the system menu the measuring channels and all the system are filled.

Make sure there is enough liquid in the measuring cups to cover the capillary apertures when activating this menu.

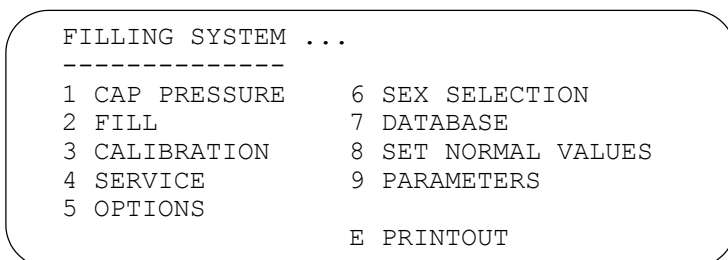


Fig 10: Display during filling

During operation, bubbles in the volume unit cannot always be avoided. The consequence would be a wrong measuring result. This problem is recognized by the system and an automatic removal of the bubbles is performed.

In case the system does not succeed an error report is displayed and the system switches into an error menu. This way the user does not have to go through the system menu for refilling the system.

The whole measuring channel can be emptied and refilled completely by activating menu point 2 in the system menu.



2.3 CALIBRATION

2.3.1 Control blood

At first a few words about control blood. For calibration of the instrument so called control blood is used. Please note that not all control blood samples are suitable for calibration as some are extremely viscous. We recommend using control bloods already tested by us.

Attention!

Along with each control blood sample you will receive an extra paper showing the chart of expected results for different cell counters. For calibration always use the values for your cell counter!



Attention!

In case different control substances are used, it has to be taken into consideration that not every control blood is suitable to be analysed by the analyzer, because the analysing criteria are adjusted for human-blood. This particularly applies to abnormal blood.



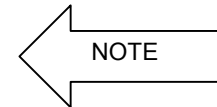
For this reason, it has to be guaranteed that the control-blood does not contain any latex particles and corresponds to human blood. It is important that the measured values are correct for human-blood rather than for control-blood that has non-human particles.

2.3.2 Calibrate

By pressing **number-key 3** in the system menu the program branches to the calibration submenu. After a measurement the standard values can be calibrated by adjusting the results for all activated parameters.

Notice:

The calibration can be carried out in this calibration for normal level blood only! Do not use low-level or high-level blood for calibration!



First of all the calibration mode has to be switched ON by pushing the **ENTER-key**. By pushing the **ENTER-key** once again the calibration mode is switched OFF.

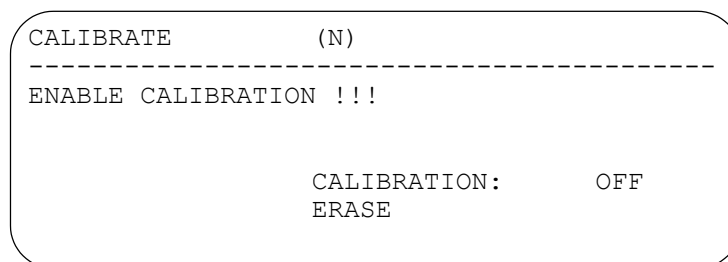


Fig 11: Display in Calibration of standard values

Now you can start a measurement with **control blood of normal-blood level**. Afterwards the program branches into the menu shown in Fig 12.

In this menu the measured values can be calibrated or adjusted. To do so, you have to place the cursor on the required value and to push the **ENTER-key**. The value is now in modification mode and can be adjusted. The acceptable range of adjustment will be displayed in the status line.

CALIBRATE			

N	RBC:	4.56	LYM: 25.9
N	WBC:	8.0	MID: 5.6
N	THR:	225	MCV: 90.0
N	HGB:	14.5	MPV: 8.2
N	HCT:	38.0	CALIBRATION: ON
			ERASE

Fig 12: Calibration display

In order to finish the calibration switch OFF the calibration mode. In order to return to the measuring menu push the **MODE-key**.

2.3.3 Erase

When you've carried out a wrong calibration, there is the possibility to erase the calibrated setting and to recover the factory settings. For this in calibration mode the ERASE option can be selected at the calibration display. Place the cursor on the menu point **ERASE** and press the **ENTER-key**.

RESET ALL SETTINGS !!!			

N	RBC:	4.56	LYM: 25.9
N	WBC:	8.0	MID: 5.6
N	THR:	225	MCV: 90.0
N	HGB:	14.5	MPV: 8.2
N	HCT:	38.0	CALIBRATION: ON
			ERASE

Fig 13: Calibration display for erasing settings

Afterwards in the status line is displayed "Reset all setting" and "Erase? -> Enter!", see Fig 13. Now you have to use the real ENTER-key (see chapter 1.6.5.3) to confirm the reset. After that you have to switch off and on the instrument. From now on the factory setting for all parameters will be used.

Return to the system menu by pushing the **MODE-key**.

2.4 SERVICE

By pushing the **Number-key 5** in the system menu the system switches into the service submenu. Here a technician can make system-checks and adjustments.

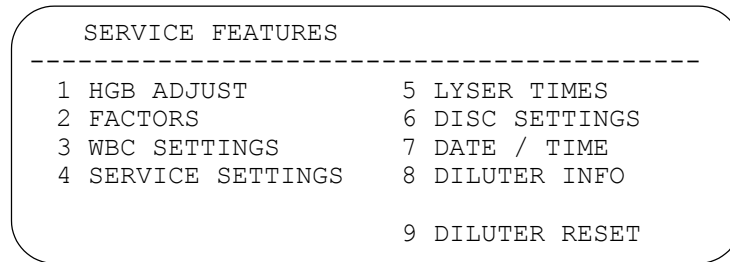
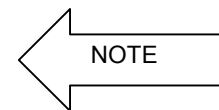


Fig 14: Display Service Menu

Notice!

This sector is only needed for the service. However some functions can be used or looked up to get more information on system errors.



Attention!

Do not make any changes! Even a small change can seriously affect the functioning of the system!



Normally only a service engineer uses this service submenu. However, there are some points that can be interesting for the user in order to check the system.

2.4.1 HGB Adjustment

When this menu is activated the automatic zero adjustment is switched off and the entered standard factors for the adjustment are put back on factory calibration. The calibration can now be checked and if necessary the service engineer can undertake basic adjustments: a measurement is carried out.

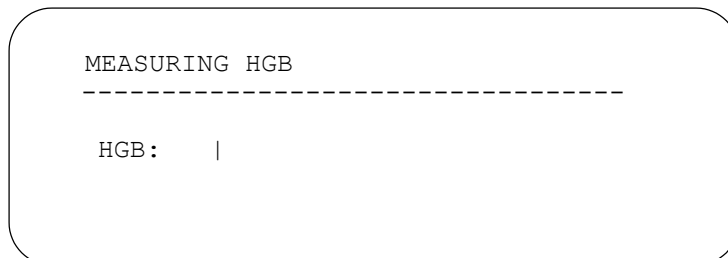


Fig 15: HGB adjustment

Attention!

By using this menu a zero adjustment as well as a standard adjustment becomes necessary!



2.4.2 Calibration factors

In this menu the intern used calculation factors can be checked, changed or entered. The factors to be changed can be selected by the **Cursor-keys** and activated by the **Enter-key**. The number will be underlay and using the **Number-keys** the required values can be entered. Press the **Enter-key** to confirm the change.

The values given in brackets are the standard factory calibrations. By activating the menu point **ERASE CALIBRATIONS** all entered calibrations are set back to the standard factory calibration.

```
FACTORS
-----
DRBC: 2.0 (2.0)      RDW-CV: 1.000 (1.000)
DWBC: 3.0 (3.0)      RDW-SD: 1.000 (1.000)
DPLT: 3.0 (3.0)
DHGB: 3.0 (3.0)
ERASE CALIBRATIONS
```

Fig 16: Calibration of calculation factors

Attention!

An improper usage will render the system unusable!
Only a service engineer should enter this menu.



2.4.3 WBC-differentiation settings

```
DIFFERENTIATION SETTINGS
-----
G          2 ( 2)      LMID      6 ( 6)
DELTA      5 ( 5)      RMID      6 ( 6)
LYMF 1.000 (1.000)    LOWER    30 (30)
MIDF 1.000 (1.000)    ERASE    SETTINGS
```

Fig 17: WBC-Differentiation settings

In this sub-menu the WBC-differentiation settings can be adjusted. Use the up and down **Cursor-keys** to reach the parameter, the **Enter-key** to activate the modification mode and type in the new value. Press the **Enter-key** to confirm the change. The values given in brackets are the standard factory calibrations. By activating the menu point **ERASE SETTINGS** all entered settings of this submenu are set back to the standard factory calibration.

2.4.4 Service Settings

SERVICE SETTINGS					

LYSING	:	20.0	PLT-CHECK :	20.0	
TRANSFER	:	20	PLT-CURVE :	ORIG	
RBC-TMIN	:	10.0	BEEP	:	10
RBC-TMAX	:	15.0	PASSWORD	:	000000
WBC-TMIN	:	6.0			
WBC-TMAX	:	14.0	INIT SETTINGS		

Fig 18: Menu for service settings

The instrument has an integrated time monitoring for measuring times of the RBC- and WBC-channel and for the transfer time. This is used e.g. for internal detecting of blockages in the system and if necessary to give an advice for cleaning. Adjusting the factory values could be necessary when changes on the vacuum system were made.

In this sub-menu for service settings, see Fig 18, the acceptable measuring times for the RBC- and WBC-channel can be adjusted as well as times or intervals for further system actions that depend on exact time.

Use the **Cursor-keys** to reach the parameter, the **Enter-key** to activate the modification mode and type in the new value or scroll through the given values. In case you have to type in the value, the possible range is displayed in the status-line. Press the **Enter-key** to confirm the change.

2.4.5 Lyser Times

SERVICE SETTINGS			

V-TIME 01:	0	V-TIME 07:	0
V-TIME 02:	0	V-TIME 08:	0
V-TIME 03:	0	V-TIME 09:	0
V-TIME 04:	0	V-TIME 10:	0
V-TIME 05:	0		
V-TIME 06:	0	INIT SETTINGS	

Fig 19: Menu for lyser times settings

This sub menu is without function on this instrument version.

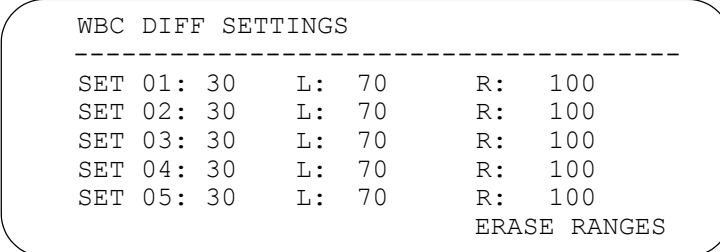
2.4.6 Disk settings

The instrument uses for WBC differentiation fix differentiation settings (discriminators) for the sizes of lymphocytes and granulocytes. In this sub menu it is possible to adapt these settings if necessary, see Fig 20. When you press the Curve-key in the measuring display you reach the graphic display (see chapter 1.6.4.2). Here you can control the actual location of the three single discriminators in the distribution curve.

In this instrument version the settings number 01 to 04 are used as follows:

01	-	general,
02	-	male,
03	-	female,
04	-	child.

To enter a new value set the cursor to the corresponding position and press the **Enter-key**: Now the value is in modification mode and the possible range for the new value is displayed in status line. Type in the new value and confirm by pressing the **Enter-key**.



WBC DIFF SETTINGS		

SET 01:	30	L: 70 R: 100
SET 02:	30	L: 70 R: 100
SET 03:	30	L: 70 R: 100
SET 04:	30	L: 70 R: 100
SET 05:	30	L: 70 R: 100
ERASE RANGES		

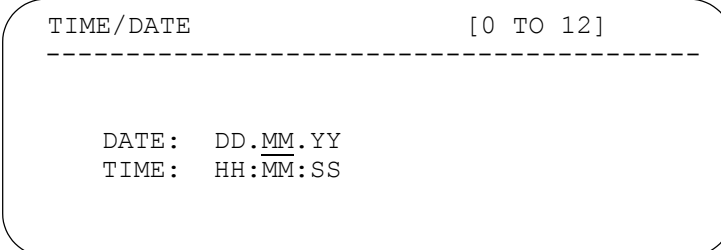
Fig 20: Menu for WBC differentiation settings

By the **Cursor-key** you can scroll to a second page of settings, which is not used in this instrument version. There you also find the menu point **ERASE** for resetting all values to standard factory settings.

2.4.7 Setting Time and Date

By pressing **Number-key 7** in the system menu you get into the time and date sub menu. In this sub menu time and date can be changed performing the following steps:

- (1) Enter the changing mode by pressing the **Enter-key**: in the status line the possible range of the changeable digit is displayed
- (2) Select the digit to be changed using the **Cursor-keys**
- (3) Type in the new number
- (4) Accept/confirm the changes by pressing the **Enter-key**



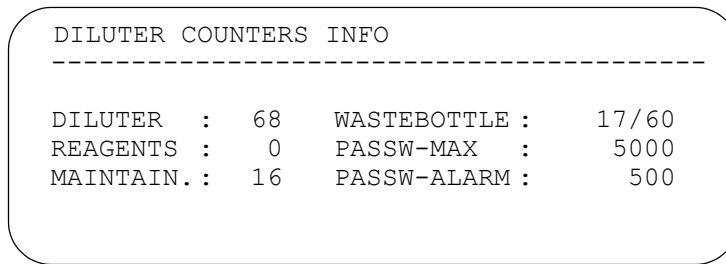
TIME/DATE	[0 TO 12]

DATE:	DD.MM.YY
TIME:	HH:MM:SS

Fig 21: Setting time and date

2.4.8 Diluter Infos

In this sub menu the diluter information can be checked.



```
DILUTER COUNTERS INFO
-----
DILUTER   :   68   WASTEBOTTLE :   17/60
REAGENTS  :    0   PASSW-MAX   :   5000
MAINTAIN. :   16   PASSW-ALARM :    500
```

Fig 22: Display for diluter counter infos

The meanings of the single terms are as follows:

- DILUTER: counter of diluter movements
- REAGENTS: counter of reagents consumption
- MAINTAIN.: counter of measurements
- WASTEBOTTLE: count/ number of measurements per waste bottle
- PW-MAX: number of maximum measurements per password
- PW-ALARM: number of measurement for giving alarm before the current password is out-of-date

2.4.9 Diluter Reset

Electronic disturbances can cause a malfunction in the built-in diluting station. By activating this menu point the diluter goes through some working steps and is thus brought back to the starting position. If the diluter has returned to its position the display signals "READY FOR WBC-SAMPLE" and the next sample can be diluted.

F4

The same you can reach by pressing **F4-Key**, without going through several menus.

2.5 OPTIONS

In this submenu several options such as print mode settings and communication options can be set. Selection is made by the **Cursor-keys**.

SYSTEM SETTINGS			

AUTO	:	ON	PAPER SIZE : 12''
PARALLEL	:	GRAPHIC	EMULATION : IBM
RS232	:	OFF	AUTO STANDBY : OFF
BAUD	:	9600	AUTO CLEAN : OFF
S.I.	:	OFF	AUTO START : OFF
HGB	:	GRAM	AUTO DIFF. : ON

Fig 23: The sub-menu Options

2.5.1 Auto

By pressing the **ENTER-key** the **automatic printout** can be switched **ON** or **OFF**. If it is switched **on**, the results will be printed automatically after the measurement. Otherwise you can print by selecting printout in the system menu.

2.5.2 Parallel

By pressing the **ENTER-key** the parallel port setting can be changed. You can scroll among **GRAPHIC**, **TICKET** and **OFF** by using the Cursor-keys.

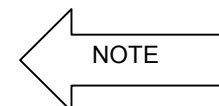
By choosing **GRAPHIC** the printout of the measuring results includes the distribution histograms. By choosing **TICKET** the printout of measuring results will not include the distribution histograms. The option **OFF** means that the parallel port at the instrument is not used for printing.

2.5.3 RS 232

By pressing the **ENTER-key** the RS232 port setting can be changed. You can scroll among **SETUP**, **COMPUTER** and **OFF** by the Cursor-keys.

By choosing **SETUP** you can connect a computer to run special setup software.
By choosing **COMPUTER** the results will be downloaded to a serial computer port.

If you don't use the port RS232 please choose OFF to avoid disturbances.

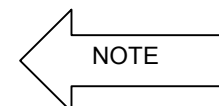


2.5.4 Baud

By pressing the **ENTER-key** the RS232 port setting can be changed. Now the baud rate can be modified to a standard baud rate step. The possible range is displayed in the status line.

Please note!

Only by selecting the correct rate the instruments are able to work together properly.



2.5.5 S.I.

By pressing the **ENTER-key** and scrolling the SI-Units can be switched **ON** or **OFF**. If it is switched **ON** the results are given in SI-Units. Otherwise the results are given in Standard-Units.

2.5.6 HGB

By pressing the **ENTER-key** the HGB-unit **GRAM** can be changed into **MOL**. This is provided only when SI-Units are selected. In newer instruments only the GRAM unit is still possible.

2.5.7 Paper size

By pressing the **ENTER-key** and by scrolling the paper size of 11 or 12 inch can be selected.

2.5.8 Emulation

Depending on the printer you are going to use, you have to select the printer emulation in this menu point. By pressing the **ENTER-key** the printer emulation option can be changed.

You can scroll among **IBM**, **EPSON** and **THERMO** by using the Curser-keys. Depending on your choice the results are printed out in IBM graphic mode, EPSON graphic mode or on the delivered standard thermo printer.

2.5.9 Auto Standby

No function.

2.5.10 Auto clean

No function.

2.5.11 Auto start

By pressing the **ENTER-key** the **Auto start function** can be switched **ON** or **OFF**. If it is switched ON after having dispensed lyse the measurement will be started within a certain time interval (10 seconds) automatically. In the other case you have to press the **Start-key** for starting measurement.

2.5.12 Auto diff

By pressing the **ENTER-key** the **Auto diff function** can be switched **ON** or **OFF**. If it is switched ON for WBC counting an automatic three-part-differentiation (Lymphocytes, Granulocytes and mid cells) is carried out. In the other case no differentiation is done.

2.6 SEX SELECTION

Since most users take the so-called unisex range as norm value the feature of choosing the patient sex by factory setting is not activated.

If you want to use different ranges of normal values for

- male
- female
- child

patients, you can activate this option in the SEX SELECTION submenu in the SYSTEM menu. You have to select once among male, female and child to be able to change later on the sex in the standard measuring display by scrolling by means of the cursor keys at the same time with entering sample and ID number.

In the sex selection sub menu, see Fig 24, you choose the sex by the corresponding **Number-key**.

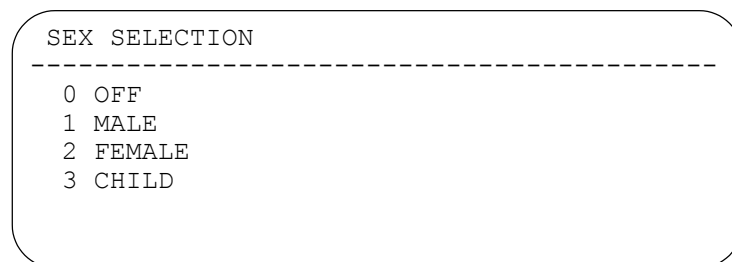


Fig 24: Sex selection sub menu

Attention!

Make sure you don't mistake the patient's sex as this would lead to a wrong marking of measuring results that are not within the normal range for this patient!



2.7 DATABASE

By pressing **Number-key 7** in the system menu the database features are selected. The **database** offers a capacity of up to **250 samples**.

Selecting a number-key (see Fig 25) the corresponding sub menu can be called up:

DATABASE	

1	DATABASE VIEW
2	DATABASE PRINTING
3	SINGLE DATA ERASE
4	ERASE DATABASE
5	DATA SAVING ON

Fig 25: Database sub menu

2.7.1 Database view

By pressing **Number-key 1** the database view menu opens up. Using the cursor-keys samples and parameters can be selected. As for the parameters you can scroll among 3 pages.

BLOCK: 1/1	SAMPLE	5	PAGE	1			
NO.	RBC	WBC	HBG	HCT	MCV	THR	DAT/ID

01	4.52	9.5	13.2	38	87	221	123456
02	4.42	7.5	13.5	37	85	272	345678
03	5.58	9.6	16.4	49	89	424	123561
04	4.22	5.5	12.6	36	87	121	345622
05	3.52	4.5	11.2	30	82	325	123457

Fig 26: Database view

2.7.1.1 Samples marked with "L", "M", "R" or "?"

If a sample is marked with "L", "M", or "R" the **THR-distribution-curve** is not correct. If a result is marked with "?" the corresponding parameter (WBC, RBC, THR, MPV) is out of linearity range (please compare measuring display).

BLOCK: 1/1	SAMPLE	5	PAGE	1			
NO.	RBC	WBC	HBG	HCT	MCV	THR	DAT/ID

01	4.52	9.5	13.2	38	87	221	123456
02L	4.42	7.5	13.5	37	85	272	345678
03M	5.58	9.6?	16.4	49	89	424	123561
04*	4.22	5.5	12.6	36	87	121	345622
05R	3.52	4.5	11.2	30	82	325	123457

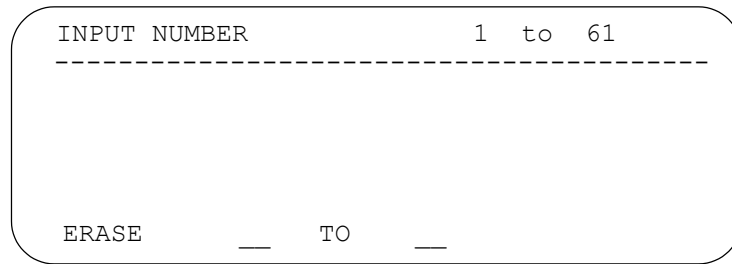
Fig 27: Database view with marks

2.7.2 Database printing

By pressing **Number-key 2** in the database menu the printing of the database is activated. The database is displayed and printed out at once.

2.7.3 Single Data erase

By pressing **Number-key 6** in the database menu you get into the single data erase sub menu.



The screenshot shows a terminal-style interface with a rounded rectangular border. At the top, the text 'INPUT NUMBER' is on the left and '1 to 61' is on the right. A dashed horizontal line is positioned below this text. At the bottom of the screen, the text 'ERASE' is on the left, followed by two underscores, the word 'TO', and another underscore.

Fig 28: Single data erase display

In the blank the database numbers for the range of samples to be erased can be typed in. The possible range is displayed in the status line.

2.7.4 Erase Database

By pressing **Number-key 7** in the database menu you can delete all samples of the database. Please note that the erasure has to be confirmed.

2.7.5 Database saving

By pressing **Number-key 5** in the database menu the saving option can be changed. You can scroll between **ON** and **OFF** by using the **Cursor-keys**.

2.8 SET NORMAL VALUE

By pressing the **Number-key 8** in the system menu the display for changing normal ranges (Fig 29) is called up. Here you can put in different values for male, female or child or, if no sex is selected, for the general settings. Scroll in the different settings by the Number-keys:

- 0 - General,
- 1 - Male,
- 2 - Female,
- 3 - Child.

If a measured value is out of the normal range, the result in the print out will be marked by a “*”.

SET	NORMAL	RANGE	MALE	(1=M 2=F 3=C)		
3.90	RBC	5.90	37.0	HCT	52.0	
150	THR	300	0.015	PCT	0.035	
4.0	WBC	10.0	27.0	MCH	32.0	
12.0	HGB	17.0	32.0	MCHC	36.0	
70	MCV	96	0	RCDW	15.0	
7.2	MPV	35.0	0	LCDW	35.0	

Fig 29: Display for setting normal ranges

2.9 PARAMETERS

By pressing the **Number-key 9** in the system menu the display for switching on or off measuring parameters (Fig 30) is called up. All measuring parameters can be combined the way you like. The calculated parameters correlated to the measured parameters are automatically switched on and off depending on the parameters you have selected.

Pressing the corresponding **Number-key** the measuring parameters can be switched ON or OFF.

PARAMETER SELECTION	
1 RBC:	ON
2 THR:	ON
3 WBC:	ON
4 HGB:	ON

Fig 30: Submenu Parameters

When the entering is completed you can return to the main menu by pressing the **MODE-key**.

2.10 PRINTOUT

By pressing the **Enter-key** in the system menu you can start the printout of the actual measured results manually.

3 DILUTER FUNCTIONS

3.1 DILUTION STEPS

By means of the built-in diluter you can manually dilute the blood for both the RBC and the WBC measurement. You have just to follow the instructions in the service line. Normally to start the next step just press the touch plate when the former step is finished. The normal way for EDTA blood is as follows (**READY FOR WBC-SAMPLE** is displayed in the service line):

1. taking 30 µl of the blood sample,
2. dispensing the first (WBC) dilution (30 µl blood + approx. 4 ml MEDILUID III DIFF),
3. taking 30 µl of the first dilution,
4. dispensing the second (RBC) dilution (30 µl first dilution + 9 ml MEDILUID III DIFF),
5. dispensing 5 ml MEDILYSE III DIFF to the WBC dilution by means of the lyser dispenser (to activate by the micro switch there).

For capillary blood the steps vary as follows:

1. Pressing **F1-key** to switch to the capillary blood mode dilution (**READY FOR CAPILLARY RBC-SAMPLE**) is displayed in the service line)
2. dispensing 30 µl MEDILUID III DIFF for the first (WBC) dilution by pressing the red dilution switch (see No 16 in Fig 1),
[Alternatively you can press **F2-key** (see chapter 3.3) and afterwards press the touch plate when you are **not** in capillary blood dilution mode]
3. taking 30 µl of the first dilution,
4. dispensing the second (RBC) dilution (30 µl first dilution + 9 ml MEDILUID III DIFF),
5. dispensing 5 ml MEDILYSE III DIFF to the WBC dilution by means of the lyser dispenser (to activate by the micro switch there)

3.2 CAPILLARY BLOOD MODE

F1

The **F1-key** is used to switch between the dilution steps for EDTA blood and capillary blood.

3.3 DISPENSING DILUTION FOR CAPILLARY BLOOD

F2

The **F2-key** is used to prepare dispensing the right amount of MEDILUID III DIFF for the first capillary blood dilution (WBC). Afterwards by pressing the touch plate MEDILUID III DIFF is dispensed through the sample needle.

3.4 CAPILLARY PRESSURE

F3

The **F3-key** is used to give pressure from inside to the capillaries in order to clean the capillary in case they are partly or completely blocked.

3.5 DILUTER RESET

F4

The **F4-key** is used to reset the diluter to the start position of the diluting cycle. This is used when you made a mistake in the cycle and you want to restart at the right start position.

4 OPERATION

4.1 ENTERING SAMPLE NUMBER AND PATIENT'S ID-NUMBER

For entering the sample or ID number choose the desired input sector in the measuring display by using the cursor and confirm your selection by pushing the **ENTER-key** (see Fig 31).

The chosen sector will now be marked and the desired data can be typed in. Use the **ENTER-key** to confirm the entered data.

Attention!

Make sure you don't mistake the patients and the respectively patients IDs!



4.2 CHOOSING THE PATIENT'S SEX

If you want to use different ranges of normal values for

- male
- female
- child

patients, you can activate this option in the SEX SELECTION submenu (chapter 2.7) of the system menu. You have to select once among male, female and child to be able to change later on the sex in the standard measuring display by scrolling by means of the **Cursor-keys left** and **right** at the same time with entering sample and ID number.

CH2:	0.0	NO:	00000	[10:44]	
CH1:	0.0	ID:	00000	FEMALE	

RBC:	0.0	HCT:	0.0	MCV:	0.0
WBC:	0.0	LYM:	0.0	MPV:	0.0
THR:	0.0	MID:	0.0	MCHC:	0.0
HGB:	0.0	GRA:	0.0	MCH:	0.0
READY FOR WBC-SAMPLE!				<-SEX->	

Fig 31: Measurement display for entering sample number, patient's ID and sex (optional)

Attention!

Make sure you don't mistake the patient's sex as this would lead to a wrong marking of measuring results that are not within the normal range for this patient!



4.3 DISPLAY CONTRAST

You can change the LCD contrast using the **Curser-keys up** and **down** every time you are in the standard or measuring display.

4.4 SYSTEM HANDLING

For testing the instrument fill two measuring cups with isotonic solution and place them underneath the aperture tube with the measuring capillary. Start the blank solution measurement by pressing the **START-key**. This way you can make sure that the aperture-tubes and the measuring solution are in working condition. In the status line MEASURING is displayed.

Pressing the **STOP-key** can interrupt the measurement.

After measurement, the measuring time and the determined background of channel **CH1** (WBC) and channel **CH2** (RBC) are displayed. The system will check the results and reject them with an error-report or accept them by displaying: **BLANK VALUES OK** in the status line.

CH2:	0.0	NO:	00000	[00:00]	
CH1:	0.0	ID:	00000		

RBC:	0.0	HCT:	0.0	MCV:	0.0
WBC:	0.0	LYM:	0.0	MPV:	0.0
THR:	0.0	MID:	0.0	MCHC:	0.0
HGB:	0.0	GRA:	0.0	MCH:	0.0
BLANK VALUES OK!					

Fig 32: standard or measuring menu after blank measurement

4.4.1 The Blank Values

The following blank values are allowed:

RBC	up to	0,07
WBC	up to	0,7
HGB	up to	0,5
THR	up to	50
PRP	up to	45

In case of higher values repeat a zero measurement.

After reaching these values the measuring of samples can be started (compare chapter 4.8).

4.4.2 Make a dilution

The built-in dilution station serves to process the blood samples to the proper dilution ratio semi automatically. When **READY FOR WBC-SAMPLE** is displayed in the status line, take a blood sample under the sample tube and press the touch plate. The sample will be sucked in. Now follow the step instructions in the status line, see chapter 3. Don't forget to dispense lyse reagent into the WBC dilution cup by the lyser dispenser.

4.4.3 Start a measurement

After preparing the two dilutions for RBC and WBC place the measuring cups underneath the corresponding aperture tubes. Either start the measuring by pressing the Start-key or if you activated AUTOSTART in the option settings the measurement starts automatically certain seconds after dispensing the lyse reagent.

The results are displayed as soon as the measurement is finished.

Please note: Every step of the measurement is shown on the status line.

4.5 DOCUMENTATION OF THE MEASUREMENT RESULTS

4.5.1 The Graphic Printout

The first possibility for documentation is the graphic printout, which includes both the series of numbers and the distribution histograms. For obtaining this kind of printout chose GRAHIC in the parallel port settings in the options menu.

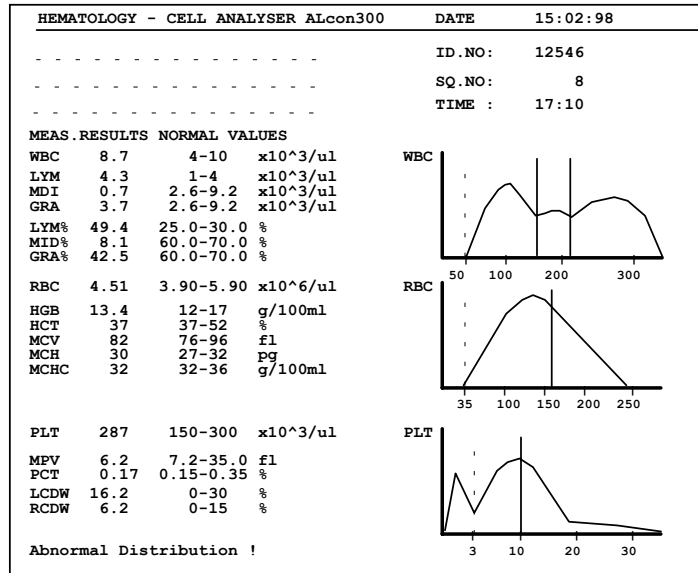


Fig 33: The graphic printout

4.5.2 The Ticket Printout

The other possibility for documentation is the ticket printout, which only includes the series of numbers. For obtaining this kind of printout chose TICKET in the parallel port settings in the options menu.

AL300 CELLCOUNTER			
DATE :	12.02.98		
ID.NO:	12546		
SQ.NO:	16		

MEAS.RESULTS	NORMAL VALUES		
WBC	8.7	4-10	x10 ³ /ul
LYM	4.3	1-4	x10 ³ /ul
MID	0.7	2.6-9.2	x10 ³ /ul
GRA	3.7	2.6-9.2	x10 ³ /ul
LYM%	49.4	25.0-30.0	%
MID%	8.1	60.0-70.0	%
GRA%	42.5	60.0-70.0	%
RBC	4.51	3.90-5.90	x10 ⁶ /ul
HGB	13.4	12-17	g/100ml
HCT	37	37-52	%
MCV	82	76-96	f1
MCH	30	27-32	pg
MCHC	32	32-36	g/100ml
PLT	287	150-300	x10 ³ /ul
MPV	6.2	7.2-35.0	f1
PCT	0.17	0.15-0.35	%
LCDW	16.2	0-30	%
RCDW	6.2	0-15	%

Fig 34: The ticket printout

4.6 WORKING WITH VENOUS- AND CAPILLARY BLOOD

4.6.1 Extraction of Samples

The blood quality is very important for the measuring results. Let us give you some hints! **Haematology-Systems** are suited for the processing of venous blood or capillary blood.

4.6.2 Venous Extraction (EDTA-Blood)

Required are: EDTA coated tubes
 70% Ethanol
 Sterile cannula

After puncturing the vein, let a few ml of blood flow into the EDTA-tube. Then seal it with the stopper and carefully turn over several times (swaying) to enable the anti-coagulence to thoroughly dissolve and mix with the blood. However, shaking and foaming has to be strictly avoided.

Advantages of venous blood over capillary blood:

- (+) Easy further processing of the sample.
- (+) No mistake on the blood volume due to possible tissue fluid flow.
- (+) The EDTA blood will keep for 24 hrs. in a sealed tube at room temperature. Enough sample material for numerous classifications is available.



4.6.3 Capillary-Blood Extraction

Required are: Capillary 20 µl
 Swabs, sterile lancets
 70% Ethanol
 MEDICLEAN

Before extracting capillary-blood, particularly by anemic patients and patients with low skin temperature, it is important to have hyperaemicised finger pads, e.g. by rubbing or by warming them in warm water.

Rub the finger pads well with Ethanol (preferably the ring finger of the left hand) and prick the finger 2-3 mm deep with a sterile lancet. Wipe away the first drop of blood with a swab and take the spontaneous flowing blood to fill the capillary.

Disadvantages and Sources of Error:

Make sure to avoid squeezing and pressing of the finger after pricking. This causes tissue fluid to be mixed with the blood, which can cause a volume error of up to 15 %.

4.7 DILUTION RATIOS

Haematology instruments work at an end-diluting ratio of:

WBC ≈ 1 : 130
RBC ≈ 1 : 40.000

The **primary dilution** is used for determining the values for WBC, HGB:

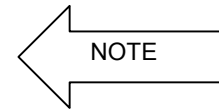
30 µl EDTA-blood + approx. 4.0 ml MEDILUID III DIFF and
5 ml Lyse reagent is added after the 30 µl for secondary dilution is taken away.

The **secondary dilution** is used for determining the values for RBC, HCT, MCV, THR/PLT:

30 µl primary dilution + 9.0 ml MEDILUID III DIFF

Note!

The sample tube of the diluter has to be carefully freed from all external remains with a fluff-free cloth.



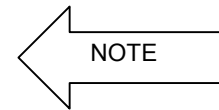
4.7.1 Stability of the samples

The stability of the samples depends on different factors. The data below refer to the capillary-blood method.

Primary dilution:	approx. 4 hours (room temperature)
THR/PLT primary dilution:	approx. 2 hours
THR/PLT secondary dilution:	approx. 15-20 minutes

Notice!

The primary dilution must be mixed up smoothly after a long-standing period. Please use a fluff-free cloth to clean the suck-in tube of the diluter in order to avoid spoiling the sample with cellulose particles. This would lead to a blockage of the capillary.



4.7.2 Commonly occurring errors

Most of the disorders in measurement and results are avoidable. Let us give you some hints!

- **Always use fresh blood.**
- **Avoid squeezing and pressing of the finger when taking capillary extractions.**
- **Always use tested solutions and particle-free one-way material.**

Most errors are caused by partial or complete blockage of the capillary aperture.

Other causes are:

- **Particle-polluted sample containers**
- **Pollution of the reagents**
- **Pollution caused by unsuitable cloths**
- **Unclean aids (pipettes a.s.o.)**

The incorrect wiping of the suck-in tube and consequently the inaccurate dilutions cause further problems. Please remember that the measured material is available in quantities of µl range. Most electronic and mechanical disorders are recognized by the haematology system. This is essential for the correctness of the measuring results.

The following disturbances may occur:

- The aperture-tube is partly or completely blocked.
- Bubbles are in the fluid system.
- The measuring unit is polluted.
- The instrument needs a follow-up calibration.
- A wrong dilution has been measured (compare cap. method).

4.8 PREPARATION OF THE SAMPLE

The blood prepared on the mixer is to be processed as follows:

4.8.1 Primary-Dilution - WBC (Leucocytes)

By pressing the touch plate the blood is taken from the sample needle and the system absorbs approx. 30 µl EDTA-blood.

Attention!

Please make sure not to hurt yourself at the sample needle, which is very sharp!



30 µl blood is diluted with approx. 4.0 ml **MEDILUID III DIFF** and, after pressing the touch plate once again, transferred out in the prepared measuring cup (dilution 1:130).

After the secondary solution is drawn 5 ml lysing reagent have to be added by the lyser dispenser tube. For this activate the micro switch at the lyser dispenser tube.

Important for three-part-differentiation!

**Always use lysing reagents compatible with the instrument.
Always use the correct lysing time.**



Otherwise a three-part-differential cannot be detected!!

4.8.2 Secondary-Dilution - RBC (Erythrocytes)

By pressing the touch plate the diluting station absorbs 30 µl suspension from the first dilution measuring cup (WBC-dilution) and dilutes it with 9.0 ml **MEDILUID III DIFF** after pressing the touch plate once more. Use a new measuring cup for collecting this second dilution. (Dilution referred to EDTA-Blood 1:40.000).

4.8.3 Capillary Blood Dilution

For the use of capillary blood first you have to dispense 4.0 ml **MEDILUID III DIFF** through the sample needle into a cell cup by activating the red dilution switch (see No 16 in Fig 1) and then to add 30 µl capillary blood. So you have the first dilution (WBC). The **dilution ratio** is **1:130**.

Afterwards you switch the built-in diluting station to **capillary blood mode** by pressing **F1-key**, see chapter 3. Now **READY FOR CAPILLARY RBC-SAMPLE** is displayed.

Next, by pressing the touch plate the diluting station absorbs 30 µl suspension from the first dilution measuring cup (WBC-dilution) and dilutes it with 9.0 ml **MEDILUID III DIFF** after pressing the touch plate once more. Use a new measuring cup for collecting this second dilution. (Dilution referred to capillary-Blood 1:40.000).

After the secondary solution is drawn 5 ml lysing reagent have to be added to the first dilution measuring cup (WBC) by the dispenser tube. For this activate the micro switch at the lyser dispenser tube.

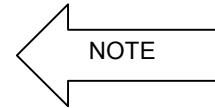
4.9 COUNTING OF PLATELETS WITH THE THR/PLT-ANALYSER

4.9.1 Determination of Platelets from Whole Blood

The haematology system is suited for the determination of platelets from whole blood simultaneously with the RBC-measurement by application of a THR/PLT-analyzer. By means of a microcomputer the platelets are automatically determined and evaluated parallel to the RBC-measurement.

Notice:

However, it has to be noted that with this method not the same precision can be reached as with the PRP-method.



Also, the instrument does not give a specification about the condition of the determined cells, so that with all pathologic cells or extreme concentrations, a faulty determination by the computer might become possible.

However, the system recognizes this and an alarm is given with an error-report on the display.

The evaluation-error outside of the normal measuring range of 150-400.000 platelets/ μ l may be more than 20%.

In extreme cases the PRP-Dextran-method should be used.

4.9.2 Measuring Range with THR/PLT-Analyzer

When THR concentrations of less than 100.000/ μ l are measured an error of more than 20 % can occur due to the dependency on RBC.

With THR values of more than 350.000/ μ l a difference compared to other measuring methods can occur. A possible error of more than 30 % is due to the dependency on RBC.

Of course, the system also determines platelets values that are far below or above the mentioned values and which are still precise.

However, the values mentioned above are given to emphasize the sensitivity of the method and are meant to help you to avoid improper use of the system and of certain values.

ANALYSING RANGE: 3 – 25 fl

NORMAL RANGE: 2 – 35 fl

Attention!

Remember that very small particles are not analysed. In that case the result is normally marked with "I", "L" or "R".



4.9.3 Determination of Blank Values

For the exactness of the measurement it is important to use isotonic solution of high quality in order to have lowest possible blank values. Otherwise the results in the pathological range can be distorted or even be unusable.

Determine the solution blank values carrying out a few measurements without blood. The blank value must be below 50. When the blank value is acceptable blood samples can be measured.

In case of extremely low THR, the blank value - particularly when it is above 10 - has to be taken into consideration for a correct result.

For example:

Sample	value	80
Solution	blank value	-15
<hr/>		
Measuring result		65
<hr/>		

4.10 THE DISPLAY OF THE PLATELET DISTRIBUTION

After the measurement is finished, the THR-histogram can be called up at any time by pressing the **CURVE-key**.

If extremely pathological results are measured an error report with the platelet distribution curve will automatically appear on the display so that the user can decide whether the measured result is acceptable or not.

4.10.1 The standardized Distribution Curve

Fig 35 shows a standardized THR-distribution curve. The numbers 1 to 5 explain the position of the different evaluation parameters.

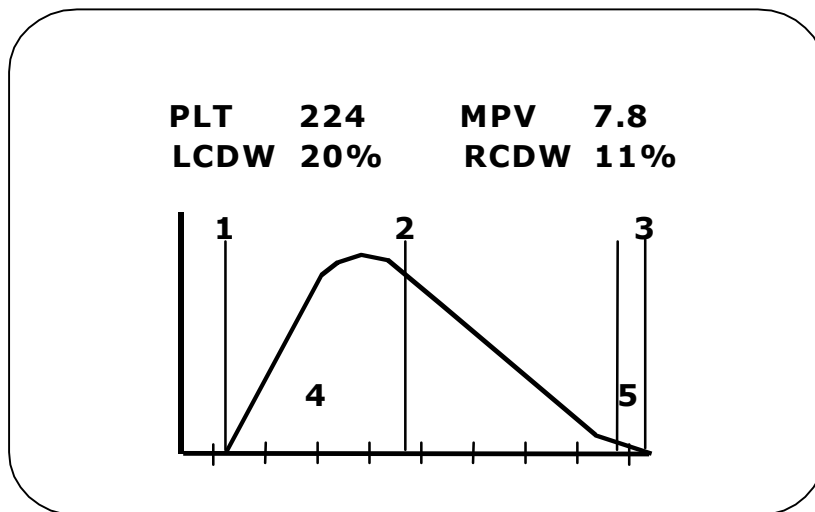


Fig 35: Standardized THR-distribution curve

- | | |
|-------------------------|----------|
| 1 = lower discriminator | 4 = LCDW |
| 2 = MPV | 5 = RCDW |
| 3 = upper discriminator | |

As the standardized curve does not show the background noise, the curve is distorted or even falsified, particularly when low values have been measured. The transition of THR/PLT distribution and electronic noise cannot be visually controlled. Thus, the possibility to detect the loss of very small platelets or electronic disturbances in the measuring system depends entirely on the evaluation parameters.

Therefore, the manufacturer refrained from giving a standardized distribution curve.

4.10.2 The not-standardized Distribution Curve

The advantage of the not standardized curve over the standardized one is that the former corresponds better to the original measurement of the THR-distribution. The electronic noise (6) is also displayed. This way the assessment on whether there is interference due to disturbances or very small particles becomes easy.

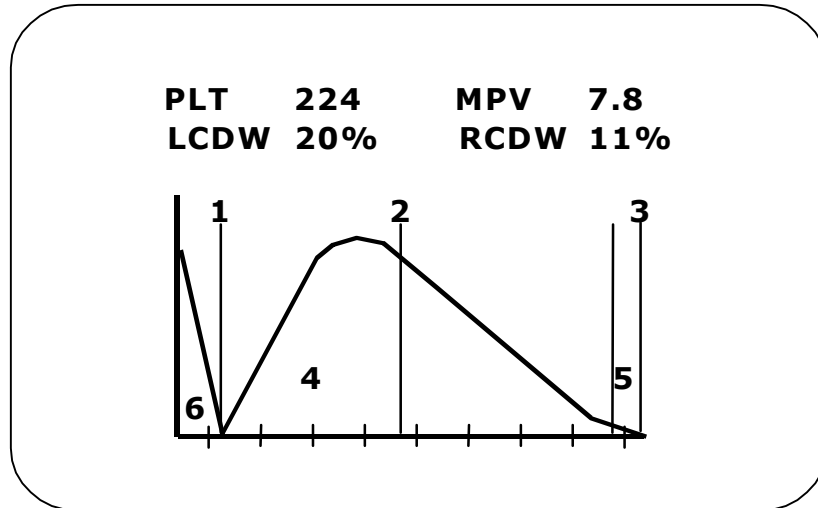


Fig 36: The not-standardized Distribution Curve

- | | |
|-------------------------|----------------------|
| 1 = lower discriminator | 4 = LCDW |
| 2 = MPV | 5 = RCDW |
| 3 = upper discriminator | 6 = Electronic noise |

It occurs that the platelet distribution curve differs from the standard curve, even if the measurement was correct.

The appearance of the curve depends on the total number of particles as well as on the particle size.

See the following chapters to learn more about possible error indications.

4.11 ERROR INDICATIONS WITH THR/PLT-ANALYSER

4.11.1 Results marked with "L" = LCDW

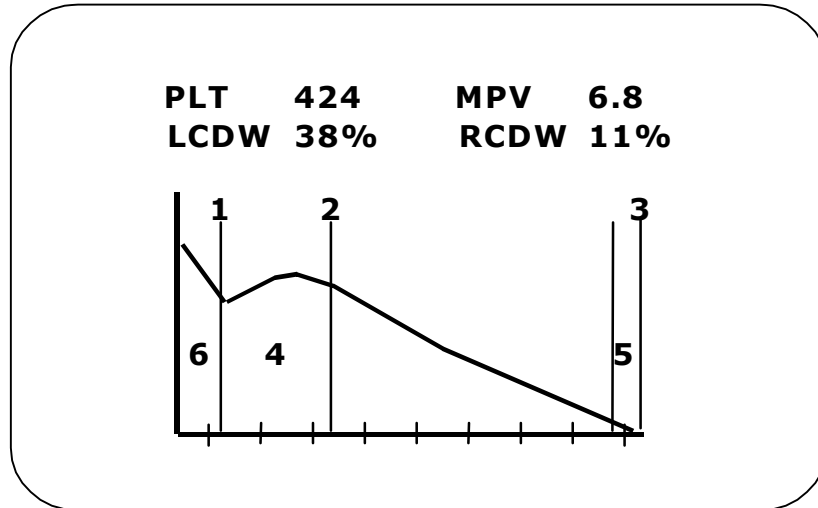


Fig 37: THR/PLT distribution marked with "L"

1 = lower discriminator	4 = LCDW
2 = MPV	5 = RCDW
3 = upper discriminator	6 = Electronic noise

The distribution of platelets does not correspond to an acceptable standard distribution. The number of platelets counted on the left control sector exceeds 30 % (the normal range is 0 – 30 %).

This could be due to pollution, electronic interference that merges with the background noise, or destroyed RBCs and cellular debris that distort the measuring result.

4.11.1.1 Normal or extremely high values that are marked with "L" or "I"

The result can only be used with restrictions. Check the usability of the result by the histogram and the LCDW value!

Clean the system and determine the blank value once or twice to check the system.

Then measure the sample again. If the result is still marked with "L" or "I", the distribution values are abnormal.

A look at the distribution curve will then allow a judgement on whether the results can be used.

If the blank values are not okay, replace the capillary and measure another blank solution.

If no acceptable blank value can be reached, a defect in the system or an unsuitable quality of the isotonic solution could be the reason.

4.11.1.2 Low value marked with "L" = LCDW

The criteria of measuring evaluation were set up for a normal platelet distribution. When a very low concentration of platelets is measured, it can occur that the system gives an error report because the distribution is shifted by more than 30 % to the left.

A check of the distribution curve can help to decide whether the result can be used or a disturbance occurred.

If the electronic noise is not clearly separated from the platelets, rinse the system and determine the blank value.

If the blank value is acceptable, repeat the measurement.

Attention!

If the system continues giving error reports, this could be due to extremely small platelets.

Always check the result by means of an equivalent method!



4.11.2 Results marked with "R" = RCDW

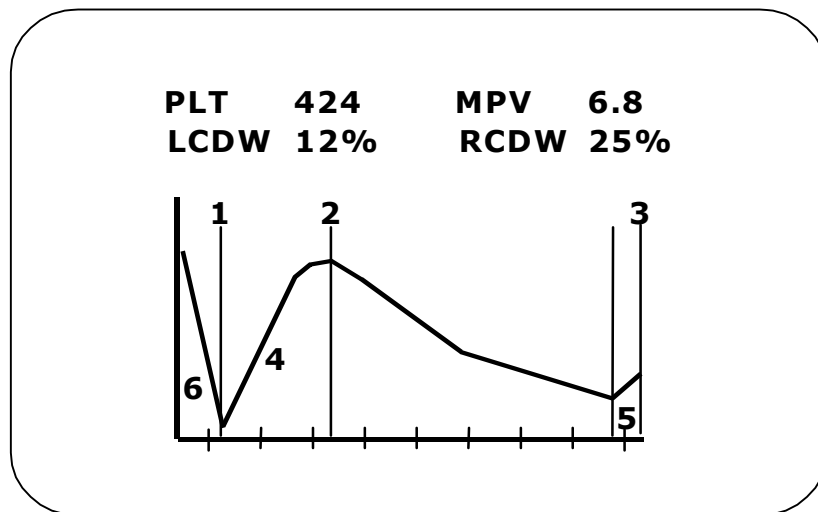


Fig 38: THR/PLT distribution marked with "R"

- | | |
|-------------------------|----------------------|
| 1 = lower discriminator | 4 = LCDW |
| 2 = MPV | 5 = RCDW |
| 3 = upper discriminator | 6 = Electronic noise |

Fig. 44 shows a platelet distribution curve on which more than 15 % of all counted platelets are in the control sector between thrombocytes and erythrocytes. This could be due to abnormally big thrombocytes or an erythrocyte-interference by very small erythrocytes.

Attention!

Always check the result by means of an equivalent method!



4.11.3 Results marked with "M" = MPV-Alarm

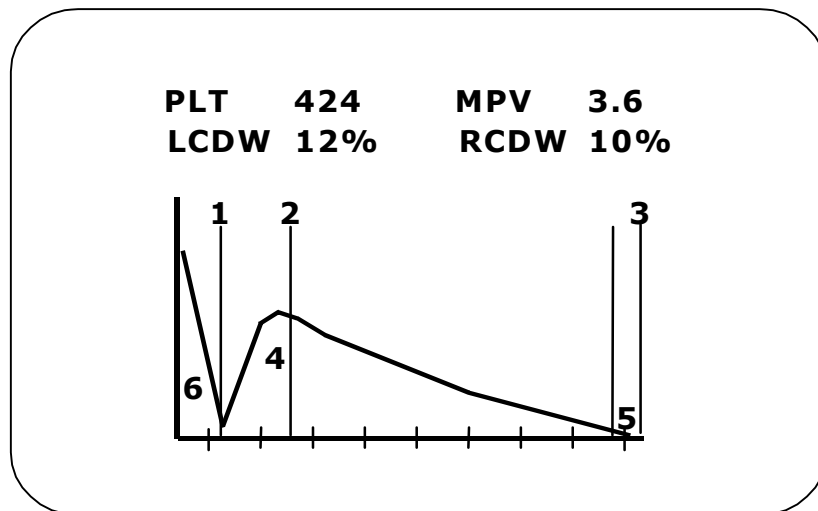


Fig 39: THR/PLT distribution marked with "M"

- | | |
|-------------------------|----------------------|
| 1 = lower discriminator | 4 = LCDW |
| 2 = MPV | 5 = RCDW |
| 3 = upper discriminator | 6 = Electronic noise |

Fig. 45 shows a normal distribution but the average platelet volume (MPV-value) is smaller than 4.5 fl.

This means that, although the distribution of platelets is correct, the MPV is shifted to the left and the LCDW warning cannot react because the deviation in the distribution is less than 30 %.

Attention!
Always check the result by means of an equivalent method!



4.12 RECOGNIZING ERRORS THROUGH THE HISTOGRAM

Errors or disturbances in the measuring cycle will influence the histogram. After gaining some experience you will be able to recognize the cause of the disturbance by studying the distribution curve.

4.12.1 System Error - LCDW

The distribution curve in Fig 40 shows disturbances of the measurement on the left side. The curve can vary depending on the cause of the disturbance.

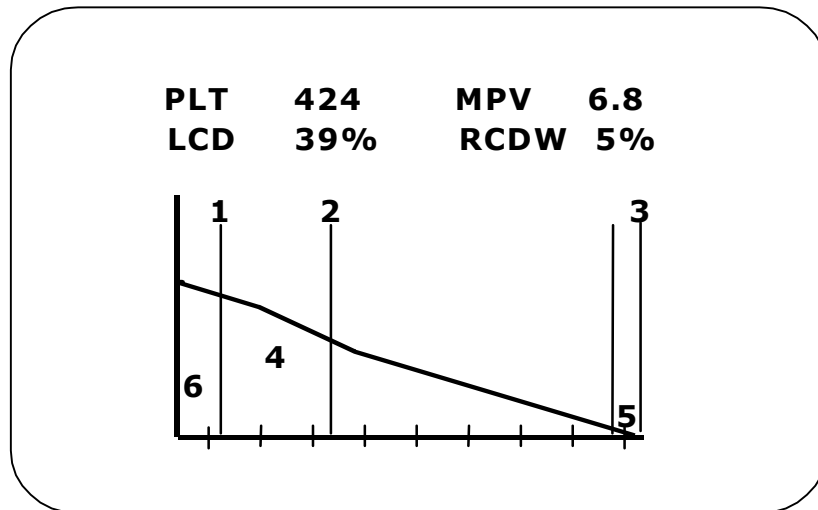


Fig 40: Histogram with disturbances on the left side

- | | |
|-------------------------|----------------------|
| 1 = lower discriminator | 4 = LCDW |
| 2 = MPV | 5 = RCDW |
| 3 = upper discriminator | 6 = Electronic noise |

Possible causes are:

- Pollution of the capillary due to particles or cleaning solution.
- Short-time blockage of the capillary aperture due to a micro-clot or a bit of fluff.
- Too high electronic noise.
- Defective capillary, short-circuits are caused by cracks in the glass.
- Defective measuring solution.

4.12.2 System Error - RCDW

The distribution curve in Fig 41 shows disturbances in the measurement on the right side. The curve can vary depending on the cause of the disturbance.

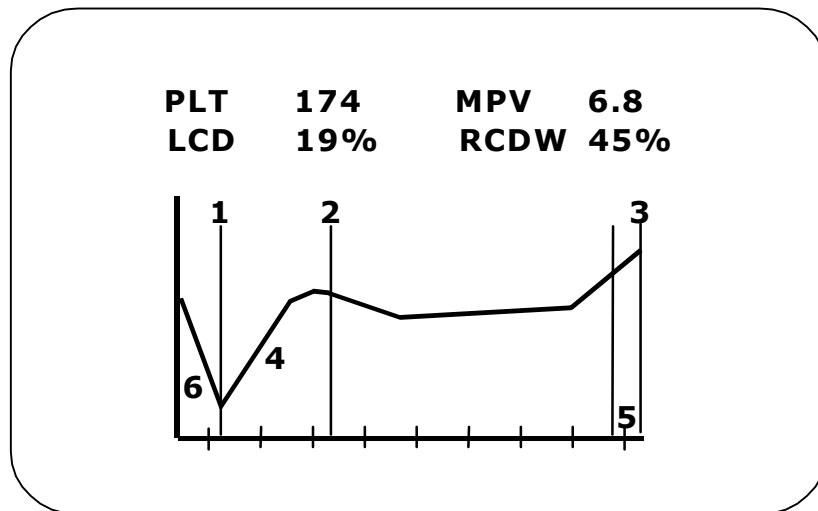


Fig 41: Histogram with disturbances on the right side

1 = lower discriminator 4 = LCDW
2 = MPV 5 = RCDW
3 = upper discriminator 6 = Electronic noise

Possible causes are:

- Defective capillary, short-circuits through cracks in the ruby or plastic
- Defective isotonic solution
- Defective capillary aperture, possibly worn
- Defective measuring sample, interference of erythrocytes (RBC)
- Electronic defect, capillary tension too low

4.12.3 System Error - "?" or "00"

The distribution curve in Fig 42 shows disturbances of the measurement in the middle range and the result is marked with "?" or the result is "00".

The course of the curve can be higher or lower, depending on the cause of the disturbance.

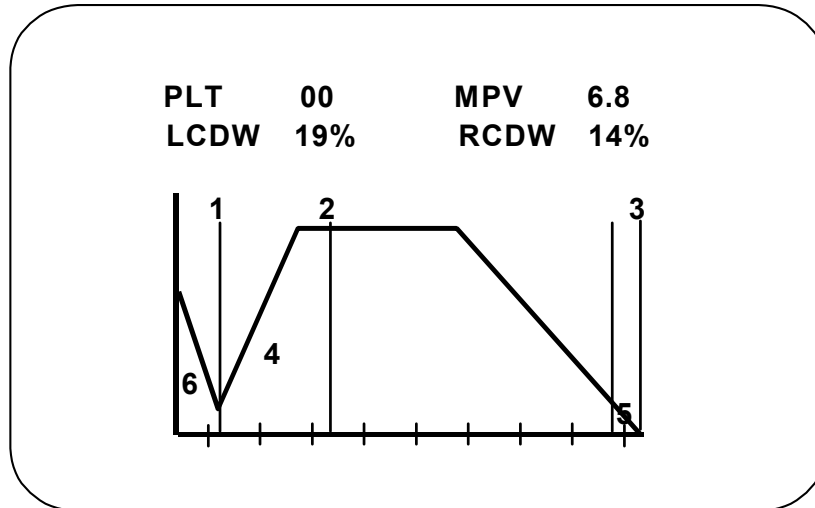


Fig 42: Histogram with disturbances in the middle range

- | | |
|-------------------------|----------------------|
| 1 = lower discriminator | 4 = LCDW |
| 2 = MPV | 5 = RCDW |
| 3 = upper discriminator | 6 = Electronic noise |

Possible causes are :

- Overflow of the distribution curve because of too high measuring results.
- Sample is too high, dilution must be checked.
- Defective measuring solution (diluent)
- Defective or possibly worn capillary aperture (ruby)
- Defective measuring sample
- Electronic defect, analyzer board does not work properly.

4.13 THE DISPLAY OF THE RBC-DISTRIBUTION CURVE

The RBC-distribution curve in Fig. 49 has no diagnostic value and serves only for checking the particle distribution, e.g. for THR/PLT interference, and for checking the MCV-value.

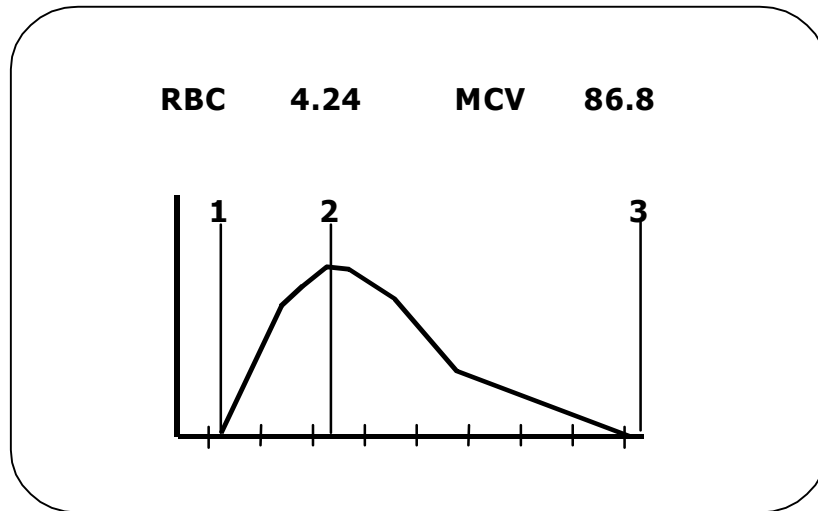


Fig 43: RBC distribution curve

- 1 = lower discriminator
- 2 = MCV
- 3 = upper discriminator

4.14 THE DISPLAY OF THE WBC-DISTRIBUTION CURVE

The **WBC-distribution curve** is needed for checking the particle distribution in order to calculate **Lymphocytes, Granulocytes** and **MID cells**.

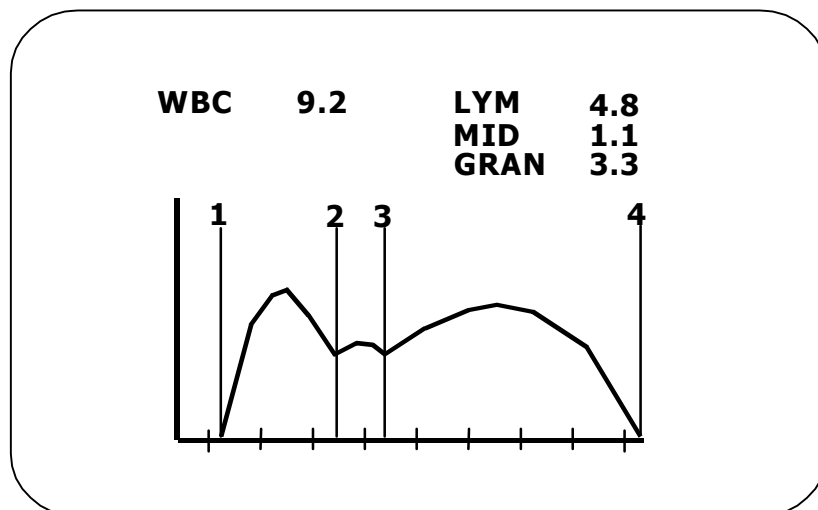


Fig 44: WBC distribution curve

- 1 = lower discriminator
- 2 = middle discriminator 1
- 3 = middle discriminator 2
- 4 = upper discriminator

4.14.1 Setting the WBC-Discriminator

The results of **Lymphocytes**, **Granulocytes** and **MID cells** are calculated automatically by using fix discriminators. However if necessary the result can be changed by moving the discriminator. Chose the WBC histogram among the three available histograms in the graphic display by pressing **Cursor-key up**. When the WBC-distribution is displayed, press the **Enter-key**.

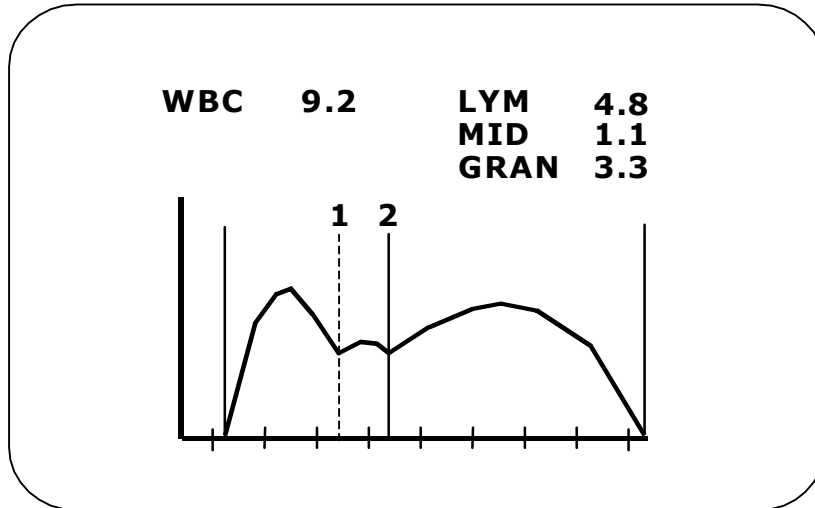


Fig 45: WBC distribution curve moving discriminator 1

Use the **Cursor-keys left and right** to move the discriminator number 1. When the discriminator is located in the correct position press the **Enter-key** again.

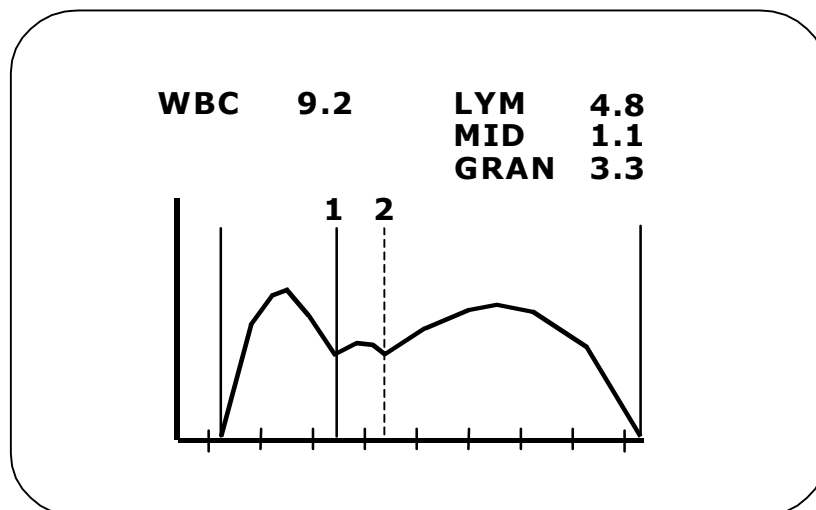


Fig 46: WBC distribution curve moving discriminator 2

Use **CURSOR-key left and right** to move the discriminator number 2. When the discriminator is located in the correct position press the **Enter-key** again.

The results will be calculated once again.

4.15 PLATELETS COUNTING BY THE PRP-DEXTRAN-METHOD

4.15.1 General

The Haematology System is generally suited for counting the platelets from Dextran solution. Because of appropriate window-discriminators it can be guaranteed that only particles of the size of the platelets are counted. Larger particles exceed the higher threshold-value and are not counted.

Attention!

This method is very sensitive. Absolute cleanliness is an indispensable prerequisite as well as completely particle-free solutions and materials.



4.15.2 Process-Description

The EDTA-Blood is diluted with a Dextran solution, which has a high molecular weight. Dextran causes the coagulation of the erythrocytes. They are then separated by an appropriate centrifugation.

Thrombocytes are left over in the solution and keep floating for quite some time in the solution because of their specific gravity.

Attention!

The use of EDTA blood samples is recommended!

4.15.3 Preparation of Samples

- Dilute 60 µl of well-mixed EDTA-Blood with 1.5 ml (1:25) of Thrombocent in a Thrombo-tube or Eppendorf-tube.
- Mix this dilution shortly and let it stand for 5 min.
- Thereafter, put the Thrombo-tubes into the Thrombo-centrifuge and centrifuge the diluted samples for 3-5 min.
- On the cell counter switch on the Capillary blood method by pressing **Key-F1** and proceed with the steps for the RBC dilution.
- Now you have the measuring Solution.

Attention!

Please avoid squirting the dilution into the cup, so that the sensitive Thrombocytes will not be destroyed. Best if you slant the cup slightly.



Always use a centrifuge with 900 R/Min with 100 g.! Otherwise the measured solution will not correspond to the actual platelet number and the result will be unusable.

4.15.4 Handling of the Instrument

Switch **RBC and WBC ON** in the system menu under Parameters. All other parameters should now be off. After measurement, the value for RBC has no meaning.

For the background measurement, determine the blank solution by measuring **MEDILUID III DIFF**. It occurs that a low blank-value is not attainable because of a possible contamination of the measuring solution or possible pollution at the aperture-tube. In this case repeat the measurement with fresh blank solution until a blank value not exceeding 25-30 is reached. If necessary, check aperture-tube and solution.

When the blank value is acceptable the sample can be measured.

In case of extremely low Thrombocytes, the blank value can be considered as a correct result, for example:

Sample	Value	80	
Solution	Blank value	15	-
<hr/>			
Measuring result		65	
<hr/>			

Attention!

The instrument must be checked only with control substance for pure Platelets-control that does not contain any erythrocytes (RBC).

If centrifuged control-blood or control-blood with Latex-particles is used, you will measure wrong results! Different control substances can lead to different results depending on the used particles.

The system is adjusted on human-platelets.

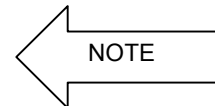
The measured values do not have to correspond to control-blood but rather to measured human-blood.



Note!

The calibration of the instrument is made for whole blood.

For PRP-method the first calibration must be changed to the corresponding result.



5 MAINTENANCE

5.1 GENERAL

The quality of the measurement results are strongly depending on

- the system handling,
- the system maintenance,
- the quality of the used solutions.

Therefore the system must always be in a very clean condition. As the system works with pressure and vacuum, all mechanical parts have to fit and close correctly.

5.1.1 The most important points for maintenance

- Always close the waste bottle tightly as the system works with vacuum that is made at the empty part of the waste bottle.
- Check the safety waste bottle regularly for an overflow of this bottle will cause the destruction of the vacuum unit.
- Check and clean the capillaries regularly since cracks or pollution will corrupt the measuring results.
- Check the supply bottles for contamination and clean or replace them if necessary.
- Always use original solutions or solutions of approved quality.
- Always use solutions with an acceptable blank value. After replacing the supply container, always check carrying out a blank value determination.
- Let check the instrument by a service technician regularly.
- Do not make any changes in the service menu.
- Clean the O-ring at the waste-bottle regularly using acid-free grease or silicon-paste.
- Check valves and tubes regularly - if necessary, replace them!

5.1.2 The reagent's and waste bottle monitoring

By means of optical and pressure sensors the microprocessor can control the fluids in the supply and waste containers detecting major errors. When errors occur a report is displayed.

In order to avoid unnecessary disturbances in the working routine the control units are set up to accept a certain range of tolerance. For this reason it is particularly important that the waste bottle is closed tightly, for even a very small leak not recognized by the system might cause problems in the measuring routine.

The overflow of the waste bottles is photo-optically controlled, therefore drops on the control sensors can make the system wrongly report an error.

If such an error report occurs and you are sure that the waste bottles are empty, press the Enter-key. The alarm display will be deleted and you can continue working.

Attention!

An overfilling of the waste bottle can cause the destruction of the vacuum pump!



5.1.3 The aperture-tube

To enable the equipment to run free of disturbances, the aperture-tube must be kept in good condition. In the surrounding of the capillary aperture and in the aperture tube itself protein deposits can occur, especially when counting white blood corpuscles.

The following guidelines are to be kept:



- Never let the aperture-tube dry out.
- Never let the aperture-tube stand in a blood sample for too long.
- Rinse the system well with MEDILUID III DIFF and cleaning solution between work phases or when the cell counter is not going to be used for a longer period of time.
- Inspect the aperture-tube regularly under a microscope with a 10 times enlargement for deposits or cracks in the glass around the sapphire.

5.1.4 System cleaning

The valves, tubes, glass parts and several other parts of the instrument will be soiled during the working routine. For cleaning the whole system you fill two measuring cups with MEDICLEAN^E, put them under the two aperture tubes and start several measurements. So the whole measuring system will be cleaned.

Before you continue measuring blood samples you have to do some blank measurements. For this you fill two measuring cups with MEDILUID III DIFF, put them underneath the aperture tubes and start several measurements. This way no residues of MEDICLEAN^E should remain and the system is in best measuring condition.

You should perform this procedure depending on your sample throughput. Recommended is the cleaning procedure before a longer break in measuring as well.

5.2 DAILY MAINTENANCE

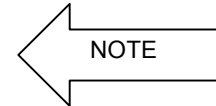
5.2.1 The waist and supply bottles

The cell counter controls the waste and supply bottles as well as the system pressure. Nevertheless in order to avoid disruptions it is important to include the following points into the routine.

- Check the waste bottle daily and empty it if necessary.
- Check the supply bottles daily and replace or fill them if necessary.

Notice:

Empty the supply bottle of all residues, so that new supplies are not polluted by possible spoiled residue.



5.2.2 The Capillaries

The capillaries must always be covered by isotonic solution. The capillary must never be dried unless it was carefully rinsed with distilled water.

To enable the equipment to run free of disturbances, the capillary must be kept in good condition. In the surrounding of the aperture and in the aperture, protein deposits can occur, especially when white blood corpuscles are counted.

The following guidelines are to be kept:

Never let the capillary dry out.

Never let the capillary stand in a blood sample for too long.

Rinse the system well with Isotonic diluent and cleaning solution between working phases or when the Cell counter is not going to be used for some time.

Inspect the aperture regularly under a microscope with a 10 times enlargement for deposits or cracks.

Cleaning of the Capillary:

Depending on the amount of samples that are measured, the capillary should be replaced from time to time. For cleaning, the capillary is emptied and put into fresh Celloclean E, so that the inside of the capillary is filled with the cleaning solution through the aperture which is thus rinsed and freed of albumin deposits.

Then rinse well with distilled water and keep the capillary stored dry.

Notice:

For cleaning the capillary do never use any cleaning agents that contain alcohol or other aggressive substances that could attack plastic materials and Plexiglas!

The Cell counter is equipped with two capillaries. However to be safe, a spare capillary should always be at hand.

Before reinstalling, the capillary must be well rinsed. Never let any cleaning solution enter the tube system.

Important!

The capillary must never be cleaned mechanically or with ultrasound. Do not use alcohol or other cleaning solutions that attack plastic materials.

5.3 WEEKLY MAINTENANCE

5.3.1 Cleaning of the aperture-tube

Depending on the amount of samples, the capillary should be replaced and cleaned weekly. For cleaning, the aperture-tube is emptied and put into fresh **MEDICLEAN^E**, so that the inside of the capillary is filled with the cleaning solution through the aperture. This way the aperture opening is rinsed and freed of albumin deposit.

The Cell counter is supplied with one aperture-tube for each measuring channel. Nevertheless spare aperture-tubes should always be at hand.



When the Cell counter is not used for longer period of time, the tube has to be cleaned in **MEDICLEAN^E** and rinsed with aqua-dest.

IMPORTANT!

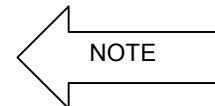
The Cell counter must never be rinsed with bleaching substances (alcohol) or other synthetic cleaning solutions.



Never use cleaning solutions based on ultrasonic waves as this will cause cracks and destroy the capillary-tube.

Notice:

For cleaning the aperture-tube from extreme dirt, Dichromate-Sulfuric-Acid can be used. **For outside use only!**

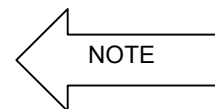


5.3.2 Measuring and Volume Unit

The measuring and volume unit is to be inspected occasionally by opening the front cover of the instrument. The inside walls of the volume tubes must not show any signs of stains or deposits.

Notice:

In extreme cases the cap of the volume unit can be removed and the glass-tube can be cleaned with a small tube brush or a pipe-cleaning brush.



The formation of deposits can be avoided when using an appropriate cleaning reagent.

5.3.3 System cleaning

The valves, tubes, glass parts and several other parts of the instrument will be soiled in spite of the daily cleaning procedures with cleaning solution. Therefore the system should be regularly checked and soiled parts should be cleaned or replaced. The fluid system must always be cleaned with a proper cleaning solution.

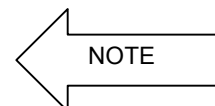
Attention!

Never rinse the Cell counter with other fluids such as concentrated bleaching agents.



Notice:

Before starting the next measurement after cleaning the analyzer, the system has to be rinsed with **MEDILUID III DIFF**.



5.3.4 The Valves

Check tubes and rubber on valves for correct setting, if necessary replace them. Always use the correct size and length, otherwise the system will not work properly.

5.3.5 Reagent- and Lysing Syringes

The isotonic and lyser syringes can only be checked after removing the main cover. Check them only if necessary.

If the syringes are leaking they have to be replaced and adjusted by a technician.

5.3.6 The sample taker

Clean the sample-taker with alcohol so that protein deposits can be dissolved.

6 ERROR DESCRIPTIONS

6.1 WHAT TO DO IF A CAPILLARY IS BLOCKED?

When a capillary is blocked use the CAP PRESSURE procedure (see chapter 2.1) or manual cleaning. If the pressure of the built-in pump is not strong enough to remove extreme blockages, remove the aperture tube and clean the capillary manually.

6.1.1 Aperture tube removing

Fig 47 shows how the aperture-tube is mounted.

1. The aperture-tube is inserted into the screw-lid.
2. The aperture-tube is mounted into the socket with moderate strength.

Capillary diameter for WBC-channel (left)
Capillary diameter for RBC-channel (right)

C1 = 100 μm
C2 = 80 μm

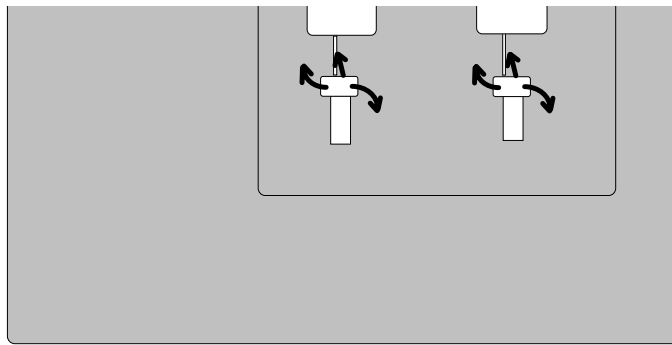
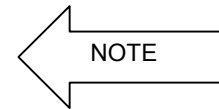


Fig 47: Fitting the capillary

6.1.2 Manual cleaning

- Use a (10 ml) syringe filled up with MEDICLEAN^E and connect it tightly with the top aperture of the aperture tube by means of a tube (rubber), see Fig 48.
- Push and pull using the syringe piston to remove the blockage.
- Remove the syringe and fix the capillary in original position.
- Carry out a blank measurement.
- If the measuring time is correct, fix the front cover.

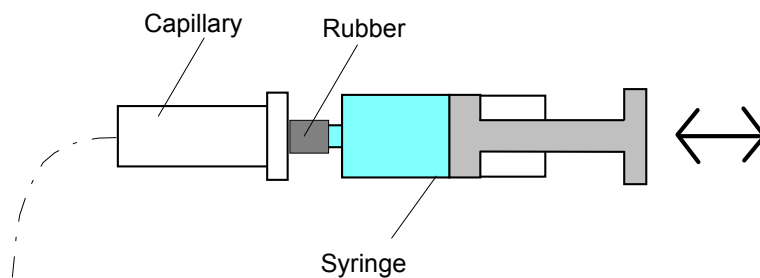


Fig 48: Cleaning the capillary manually

6.2 PROBLEMS DURING MEASURING

Situation	Possible Reason	Solution
The instrument does not work.	Loose wire or plug and mains plug.	Check the wire and the plug of instrument.
No display.	Mains switch is off or the fuse is defective.	Turn on the mains switch, check the fuse. If necessary replace it (pay attention to the correct value!)
	An electrical defect.	Inform the service.
The instrument is out of action, no display.	The fuse on the power board is defective.	Replace the fuse (pay attention to correct value!)
	Wires are loose at a PC- board or at an aggregate.	Check the correct placement of the wire and connect to the correct plug, if necessary.
	There are loose mechanical parts or aggregate of the motor is defective.	Inform the service.
The instrument works but it turns off after a short time.	There is no vacuum.	Check the measuring system for leaks.
	The aperture-tube is placed incorrectly.	Check the placement of the aperture-tube.
	The aperture-tube is blocked.	Clean the aperture-tube if necessary replace it by a clean aperture-tube
	Any electronic defect.	Inform the service.
Filling cycle does not start.	The supply bottle is empty.	Fill the bottle.
	The tube is not deep enough in the supply bottle.	Sink the tube to the bottom of the bottle.
	Mechanical defect.	Inform the service.
The system asks always for FILL.	The tube is not deep enough in the supply bottle.	Sink the tube to the bottom of the bottle.
	The aperture-tube leaks.	Check the aperture-tube for correct placement.
	Mechanical defect.	Inform the service.

Situation	Possible Reason	Solution
The blank values are too high.	The aperture-tube is blocked or unclean.	Replace or clean the aperture-tube.
	The aperture-tube or the seal is broken.	Check the seal, replace it if necessary, and check the aperture-tube.
	The solution is soiled.	Replace the solution.
	The diluter is soiled.	Clean the diluter.
	There are bubbles in the solution.	Repeat the measurement, try new diluents.
	Electronic defect.	Inform the service.
The measuring value is too high.	The blood sample is defective or a wrong sample volume was used.	Check the blood extraction system (blood tubes). Check the diluter. If necessary carry out a counter control.
	The measuring cup is soiled.	Check the cup for cleanliness (blank value).
	The wrong sample was measured.	Check the single measuring cups and the channels.
	Too little lyser was used.	Use more lyser. The technician has to make a little change at the built-in diluter.
	The lysing time was too short.	Wait for the complete lysing time.
	The lyser is empty or the lysing reagent is wrong or defective.	Replace the lysing-reagent.
	Electrical or mechanical defect.	Inform the service.
	The measuring value is too low.	The blood sample is defective or a wrong measuring volume was used.
A wrong dilution ratio was used.		Check the diluter. Check the solution.
The lysing reagent is too strong.		Change the lysing reagent.
Electrical defect.		Inform the service.

Situation	Possible Reason	Solution
The instrument does not measure.	The measuring system is not filled.	Fill the system by means of the filling cycle.
	The aperture-tube is blocked.	Replace or clean the aperture-tube.
	The measuring optic is soiled.	Clean the measuring tube.
	Electronic defect.	Inform the service.
"Function break" is displayed.	The upper light barrier is defective or the glass tubes are soiled.	Clean the glass tube. Clean the system.
	The aperture-tube is placed incorrectly.	Place the aperture-tube correctly.
	Electronic or mechanical defect.	Inform the service.
HGB shows only "00".	Electrical or mechanical defect.	Inform service.
The HGB-Zero display is not reproducible.	The measuring heat is not clean.	Check and clean the suction sonde, if necessary.
	The measuring head is defective.	Inform the service.
The HGB-values are too low.	The calibration is incorrect.	Change the setting.
	A wrong sample was used.	Prepare a new sample. Check the diluter and the tube on the valve.
	The used solution is defective.	Use new solution.
	Electronic defect.	Inform the service.

Situation	Possible Reason	Solution
The HGB-values are too high.	The dilution concentration is incorrect.	Prepare a new sample.
	The system is incorrectly calibrated.	Change the setting.
	The lysing reagent is defective.	Replace the lysing reagent.
	Electronic defective.	Inform the service.
The HGB-solution is unstable.	The system is not airtight.	Check the air tightness of the system.
	The used lysing reagent is defective.	Check the lysing reagent.
	Spreading between samples occurred.	The mechanism does not work properly.
	Defective valve or tube, electronic defect.	Inform the service.

6.3 PROBLEMS WITH VALVS AND TUBES

Situation	Possible Reason	Solution
The system has no vacuum.	The bottles are not airtight.	Check tubes and bottles.
There is no lyser or not enough lyser is used.	The lyser tube is blocked.	Check the lyser tube. If necessary, replace the tube.
	Defective valve, electrical defect.	Inform service.
There is no change in the HGB value.	The tube is blocked, there is no vacuum.	Check the corresponding valve. If necessary, replace the tube.
	There is a defective valve or an electrical defect.	Inform the service.
There is no isotonic solution.	There is a tube blocked.	Check the respective tube. If necessary, replace the tube.
	A valve is defective, the pressure pump is defective, or there is an electrical defect.	Inform the service.
There is no solution aspirating from measuring cup.	There is no vacuum.	Check the tube on the corresponding valve. If necessary, replace the tube.

7 APPENDIX

7.1 SAFETY ISSUES

The following **caution and safety regulations have always to be observed:**

7.1.1 **Electrical safety**

To connect the device to the power supply, always use **grounded** sockets in order to keep the risk of an electrical shock as low as possible.

Always use **grounded** extension cables.

Never intentionally disconnect the grounding contacts. There is the risk of electrical shock if

- the protective conductor is interrupted within or outside the device, and/or
- the grounded contact has been disconnected from the line.

Never remove protective guards or secured components since you could be exposed to electrically live parts.

Electrical connection contacts (plugs, sockets, etc.) can be electrically live.

Even after a device has been switched off, components (e.g. capacitors) can be under voltage as the result of an electrical charge.

All current carrying parts are sources of danger for an electrical shock.

Surfaces (floors, work table) must not be moist when you are working with any electrical device.

Carry out only the maintenance work and/or the replacement of parts described in these operating instructions.

Unauthorized work on the device can make the guarantee obligation null and void.

Only a technician who is familiar with all risks can work on the opened analyzer.

Always use **replacement fuses** of the stated type and with the stated nominal current. Never use fuses, which have been "repaired". Never short-circuit the fuse holder.

7.1.2 **Fire and explosion hazards**

Do not place any flammable or hazardous explosive material in the proximity of the analyzer. Electrical sparks could cause fire or explosions.

7.1.3 **Mechanical safety (analyzer is operating)**

Never open screw-attached housing parts while the instrument is ON. There is a risk of injury due to moving parts (fan, motor, drives).



7.1.4 Risk of infections

7.1.4.1 Samples

Avoid any direct contact with samples which are potentially infectious or which may generate other risks to the human body. If sample material is spilled onto the analyzer, wipe it off immediately and decontaminate the surface.



7.1.4.2 Reagents

Observe the instruction leaflets for a correct use of the reagents.

7.1.5 Accuracy and precision of the measured results

In order to ensure a flawless operation of the analyzer measure control samples and check the instrument closely. Faulty measurement results may lead to an incorrect diagnosis or range danger for patient.



7.1.6 Operator qualification

Only trained staff should operate the analyzer.



7.1.7 Maintenance and Hygiene

No organic acid based cleaning substances should be applied to the housing of the instrument. Use only cleaner designed for cleaning and disinfecting laboratory instruments. Always use a dampened cloth to clean the instrument. Never spray or pour cleaning solution directly onto the instrument. Otherwise the analyzer's functions will be significantly impaired.



Keep the instrument clean and do not spill liquids onto the analyzer. To protect the instrument from dust, cover it with the supplied dust cover or store the instrument in a cabinet.

7.2 REQUIRED MATERIALS AND REAGENTS

To operate the instrument, high quality particle-free solutions and disposable materials are required. These solutions must always be of the same quality.

On principle the instrument is a so-called open system which allows the user free choice of reagents. However the measuring results for this instrument are of best quality when using the reagents tested by the manufacturer. Using other reagents small variations in the measuring results are possible.

If you are in doubt, always use the original manufacturer accessories. In the following table, you will find names and order numbers as well as packing amounts of all manufacturer accessories.

ARTICLE #	NAME	USING	PACK SIZE
78311	MEDILUID III DIFF	Isotonic solution, diluent	20 l
78310	MEDILYSE III DIFF	lysing / HGB-Reagent	1 l
78664	MEDICUPS	particle free cell cups	1.800 pcs.
78415	MEDICLEAN ^E	cleaning solution	3 x 500 ml

For PRP-method

78413	Thrombocent	Thrombocytes reagent	200 ml
78004	Sample rack	stand for samples	
8240	Sample-mixer	Mixer for samples	

For calibration

Control blood	Calibration blood	3 x 2.5 ml
---------------	-------------------	------------

In addition you need following equipment and reagents, which are not supplied by the manufacturer:

ARTICLE #	NAME	USING	PACK SIZE
	AQUADEST	distilled water	

For PRP-method

EDTA-Tubes 4ml or 20µl Capillaries			
Thrombocups	Particle-free cell cups		
Thrombocyte centrifuge			
Centrifuge-tubes (for example Eppendorf-tubes)			

For samples we recommend venous blood, which contains **K-EDTA** as blood clotting inhibitor.

7.3 MATHEMATICS

The parameters that are measured by the instrument are:

RBC, WBC, PLT, MCV, MPV, HGB.

Others are calculated as follows:

$$HCT = RBC \cdot MCV$$

$$PCT = MPV \cdot THR$$

$$MCH = \frac{HGB}{RBC}$$

$$MCHC = \frac{HGB}{HCT} \cdot 100$$

$$MCH = \frac{HGB}{RBC} \cdot 10$$

The following parameters are determined by a curve analysis:

LYM, MID, GRAN, RCDW, LCDW, RDW-SD, RDW-CV, PDW

7.4 TECHNICAL DATA

Instrument type	Cellcounter Semi automated 21-parameter haematology analyser
Application	Determination of following parameters: RBC, PLT, MPV, HCT, MCV, WBC, HGB, MCH, MCHC, PCT, RDW-SD, RDW-CV, PDW, RCDW, LCDW, LYM#, LYM%, MID#, MID%, GRAN#, GRAN%
Operation	Semi-automatic
Start-up time	2 min
Measuring Principle	Volumetric impedance method (change of electrical resistance), Colorimetric haemoglobine determination by built-in photometer
Sensitivity	RBC: < 1.5 % WBC: < 2.0 % HB: < 1.0 % PLT: < 5.0 %
Result presentation	Numbers with marks for abnormalities 3 Histograms
Number of channels	2
Mean counting time	RBC channel 11 s WBC channel 8 s
Sample throughput	60/h
Transducer (capillary)	RBC/PLT 80 µm WBC 100 µm
Sample Volume	30 µl capillary blood 30 µl whole blood
Needed reagents	Isotonic diluent: 13 ml per sample Haemolyzing reagent (diluted): 5 ml per sample
Calibration	Keyboard calibration, for normal level control blood
Software	Loaded in memory
Display	LCD: 8 lines each 40 characters
Processor	5 x 80C32 microcontroller
Memory	for 250 patient data
Interfaces	1 x RS 232 1 x LPT

Printer	External via LPT Dot matrix printer: OKI, EPSON, IBM Thermo printer: DPU 414
Noise	Very low noise
Additional Features	Possibility of instrument coding Built-in Dispenser WINDOWS®-based patient management software
Power consumption	40 W
Voltage	220/110 V, 50 Hz 60 Hz on special request
Fuses	2 A slow blowing 4 A slow blowing
Environmental conditions	Temperature: -10 to 30°C Relative humidity: < 85%, no condensation
System time	Real-time clock for time and date
Dimensions	490 x 335 x 350 mm ³ (W x D x H)
Weight	22 kg

7.5 SAFETY SPECIFICATIONS



The MDC 2000 haematology analyzer meets all requirements according to EMC-guidelines and Directive 98/79/EC for in vitro diagnostic medical devices.



CE Declaration of conformity

We,

Medicine Devices
Unterer Dammweg 12
76149 Karlsruhe
Germany

herewith declare that the products

**MDC 400, 700, 800, 1000, 2000, 4000
and ALCON 4, 7, 8, 10, 200, 300
and their accessories**

are in conformity with the relevant regulations of the following directives:

98/79/EC **for in-vitro-diagnostics appendix III (1998/10/27)**
89/336/EEC **for electromagnetic compatibility (1989/05/03)**

Conformity is guaranteed by meeting the following harmonised standards:

EN 61010	Safety requirements for electrical equipment, for measurement, control and laboratory use
EN 50081	Electromagnetic compatibility Generic emission standard
EN 50082	Electromagnetic compatibility Generic immunity standard

Signatory of the declaration:

Medicine Devices

Karlsruhe, 2004-06-06
(Place and date of issue)

A handwritten signature in blue ink, appearing to be "J. P. ...", is written over the printed name "Medicine Devices".

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