Medicine Devices

USER MANUAL

MDC 4000

MDC 4000 (before MEDICON 4000)

Automated hematology analyzer for determination of the small blood picture

Operator manual 1.1
July 2005

Manufacturer:

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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 extend

- 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 automatically. The blood is sampled and diluted with an isotonic particle-free solution. The first dilution is divided into two streams. A lysing reagent is added to one stream to remove RBCs before performing the WBC count. The second stream 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.

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.

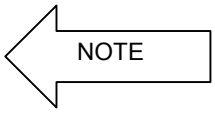
The cell counter is capable of performing a three-part differential. A special reagent is added to the WBC dilution to lyse RBCs and remove intercellular fluid from all WBCs. Due to the differences in their volume these cells are then identified and classified as lymphocytes, monocytes, or granulocytes.

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 (Granolocytes)
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	-	Standard-Deviation of the RBC graph
RDW-CV	-	Coefficient of variation of the RBC graph
PDW	-	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

1.6.1 The Front side

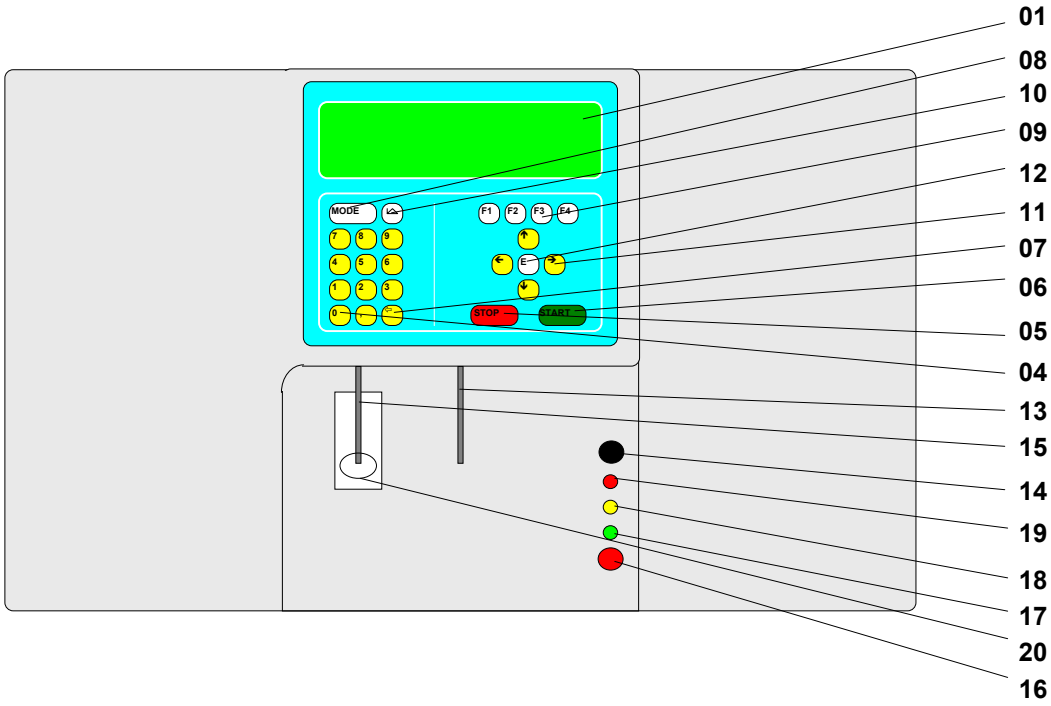


Fig 1: The Instrument and its functions (front side)

The functional units

01.	LC-display	to display measuring results, user information
04.	Number keys 0-9	to enter parameters or select options
05.	Stop-key	to abort activated working cycle
06.	Start-key	to start a working cycle
07.	Enter-key	to enter, confirm and select
08.	Mode-key	to enter into main menu
09.	Diluter-key	to select diluter 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.	Capillary sample tube	to suck in capillary blood dilution
14.	Dispenser -key	to start dispensing isotonic solution
15.	Sample / Dispense tube	to suck in the blood sample 7 to dispense
16.	Man. Sample-key	to initiate working cycles manually
17.	Green light	signals: ready to suck in
18.	Yellow light	signals: system in waiting position
19.	Red light	signals: disturbance in the diluter
20.	Sample / Cleaning plate	for cleaning and for sample

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

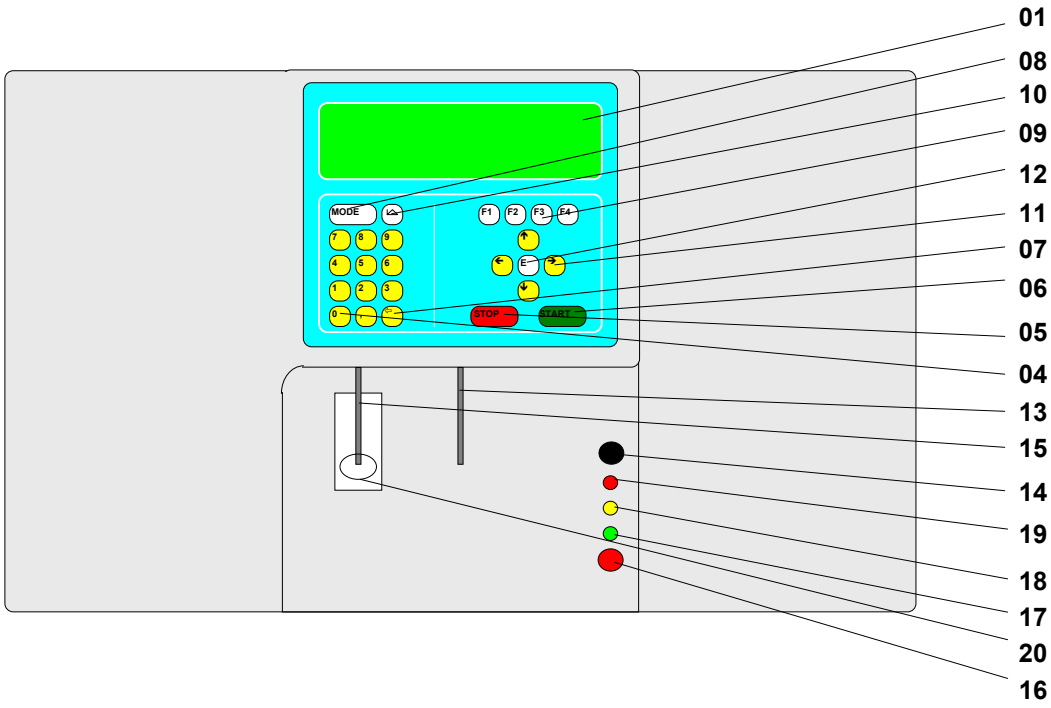


Fig 1: The Instrument and its functions (front side)

The functional units

02.	LC-display	to display measuring results, user information
04.	Number keys 0-9	to enter parameters or select options
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20.	Sample / Cleaning plate	for cleaning and for sample

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

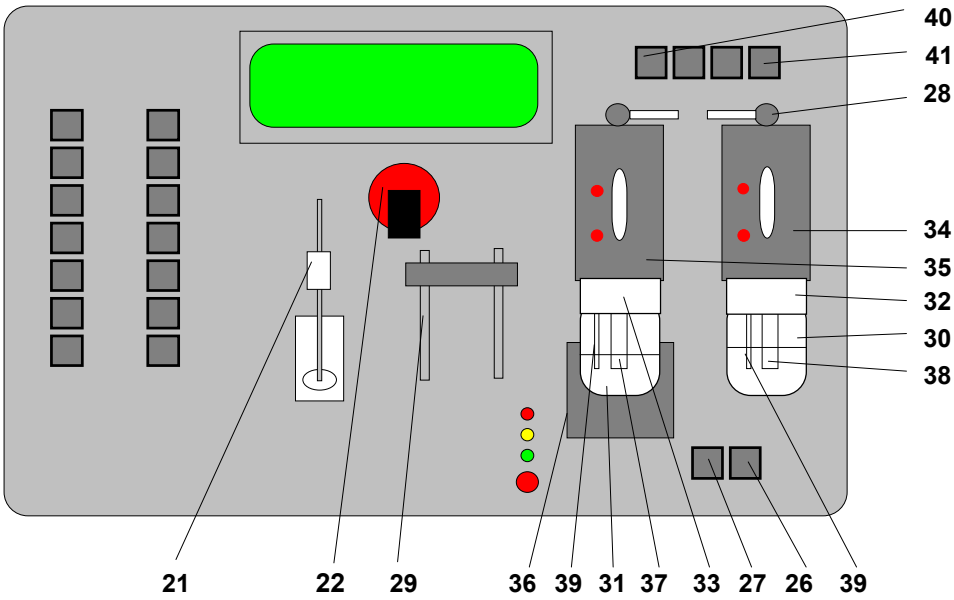
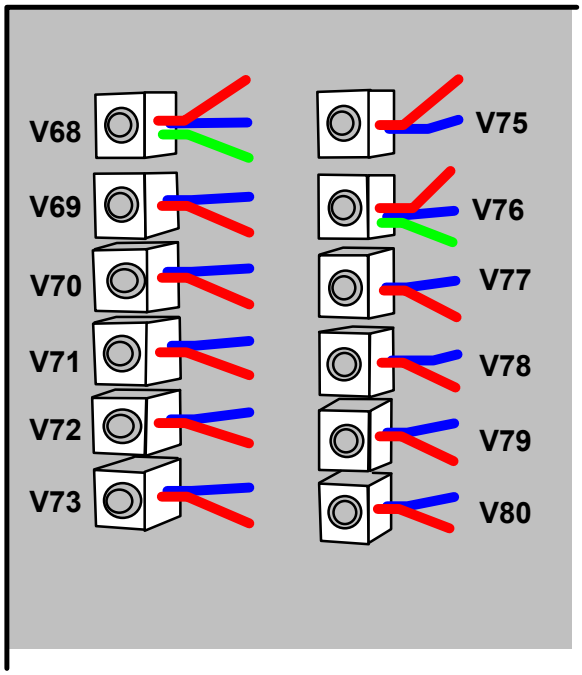


Fig 2: The Instrument and its functions (front side without front cover)

The functional units

21.	Sample cleaner	for cleaning sample tube
22.	RBC-valve	for preparation of RBC-dilution
26.	C2-valve	for manual emptying of measuring chambers (RBC)
27.	C1-valve	for manual emptying of measuring chambers (WBC)
28.	Tube-cap	cover of the volume unit
29.	Cap.-sample taker	for capillary blood method
30.	C2-chamber	RBC-measuring chamber
31.	C1-chamber	WBC-measuring chamber
32.	C2-channel	RBC-measuring channel
33.	C1-channel	WBC-measuring channel
34.	C2-volume unit	for control the RBC-channel
35.	C1-volume unit	for control the WBC-channel
36.	HGB-unit	for HGB measuring
37.	Capillary 100 µl	instrument transformer inside the aperture-tube
38.	Capillary 80 µl	instrument transformer inside the aperture-tube
39.	Electrode	voltage feed
40.	WBC-valve	for measurement
41.	RBC-valve	for measurement

Fehler! Verweisquelle konnte nicht gefunden werden. shows the valve unit situated in the left part on the front side of the instrument:



The functional units

68. Valve Dispense
69. Valve Vacuum (WBC-Inside-Chamber)
70. Valve Pressure (WBC-Inside-Chamber)
71. Valve Cleaning (Sample-Tip)
72. Valve Mixing (WBC-Measuring-Chamber)
73. Valve Mixing (RBC-Measuring-Chamber)
74. Free
75. Valve RBC-Sample
76. Valve Capillary Blood/Air
77. Valve Empty (WBC- Mixing chamber)
78. Valve WBC-Sample
79. Valve Out WBC-Solution (WBC-Measuring chamber)
80. Valve Waste/Sample
81. Free

1.6.2 The back side

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

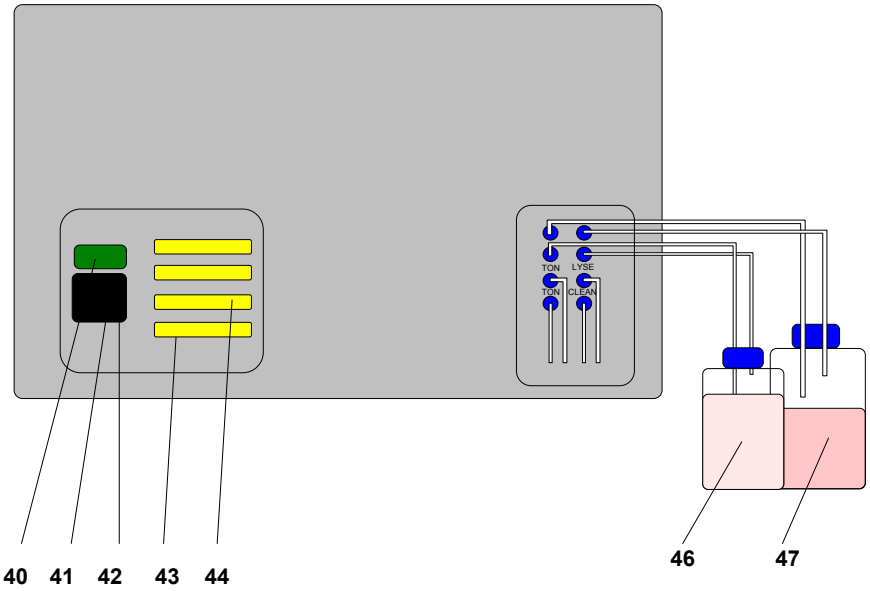


Fig 3: The Instrument and its functions (backside)

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
46.	Waste bottle	for waste fluids
47.	Waste bottle	for waste fluids

1.6.3 The keyboard

Fig 4 shows the keyboard and its components:

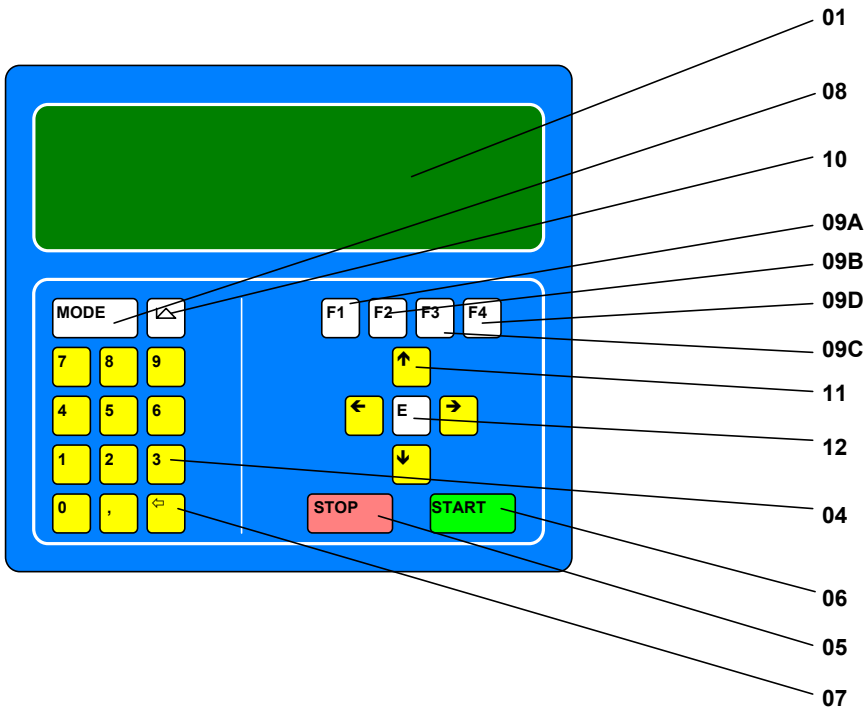


Fig 4: The keyboard

The functional units

01.	Liquid crystal display	to display measurement/ working instructions
04.	Number keys 0-9	to enter parameters
05.	Stop-key	to abort activated working cycle
06.	Start-key	to start all working functions
07.	Enter-key	to enter, confirm, select
08.	Mode-key	to select menu-options
09A	Celloton-key	to fill the system with celloton
09B	Lyser-key	to fill the system with cellolyse
09C	Into operation	to take the system into operation
09D	Out of operation	to take the system out of operation
10.	Curve-key	to display the distribution histograms
11.	Cursor-keys	to select display
12.	Print/Enter-key	for manual print confirmation

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.

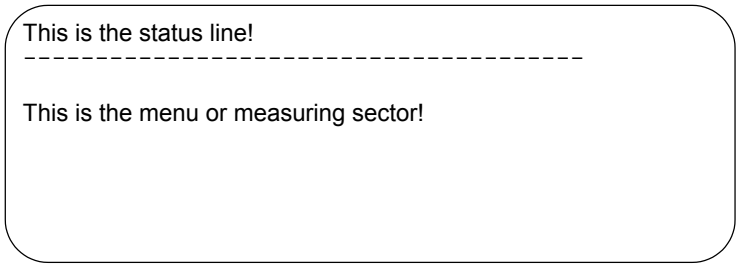


Fig 5: The Display

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.

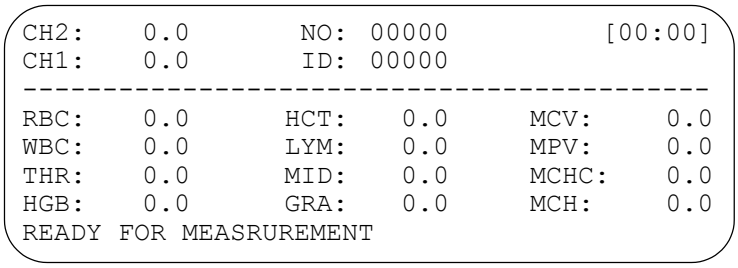


Fig 6: The standard or measuring display

The status line	shows the present working mode
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 and CH2) 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.

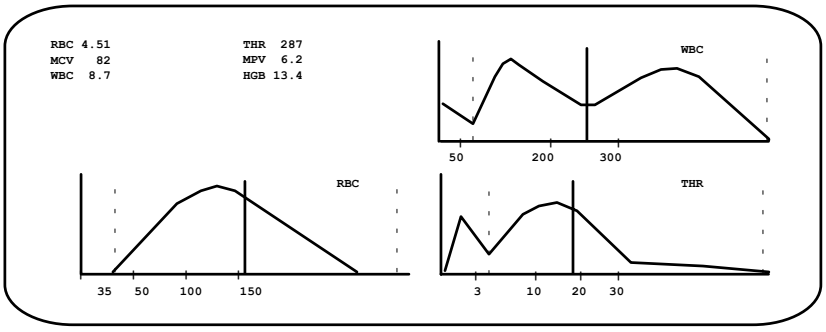


Fig 7: The graphic display

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

MODE

By pressing the MODE-key you reach the main 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

START

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

STOP

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 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.**

1.6.5.7 The E-PRINT-key

E

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.

1.6.5.8 The NUMBER-keys

1

9

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.

1.6.5.9 F1-Key

F1

The F1-key is used to fill the diluter system with **MEDILUID III DIFF** out of the supply canister.

1.6.5.10 F2- Key

F2

The F2-key is used to fill the diluter system with **CELLOLYSE** out of the supply canister.

1.6.5.11 F3-Key

F3

The F3-key is used to take the system **INTO OPERATION**.

1.6.5.12 F4-Key

F4

The F4-key is used to take the system **OUT OF OPERATION**.

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 WBC/HGB - chamber is fixed correctly.

4. Remove the safety screw from the vacuum pump.

5. Check if RBC/WBC-measuring chambers are setted correctly.

6. Connect the waste-bottles, the supply-canisters and the printer. The tubes and connectors at the back side of the instrument are marked accordingly.

7. Connect the instrument and printer with mains and switch on the instrument (backside).

8. Read the manual carefully before you start working.

9. Switch on the instrument. A self-test is started automatically.
   If the instrument works properly, close main cover.

10. Fill the instrument with **MEDILUID III DIFF** by pushing the **F1-key** (or alternatively by selecting command FILL in the system menu) for at least 2-3 times.

11. Fill the counter with **CELLOLYSE** by pushing the **F2-key** for at least 2 times. Afterwards the **red LED** has to be off and the **green LED** has to light up.

12. Push the **F4-key** to take the instrument **out of operation**. Switch off the instrument.

13. Switch on the instrument again. Afterwards the instrument will be **taken into operation** automatically. (If the system does not carry out this cycle, please push the **F3-Key**).

14. Close the front-cover (it is to stuck - not fixed by screws).

15. Carry out some blank measurements.

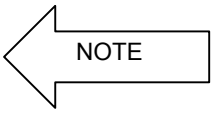
16. Check correct setting of the **C1-channel** with a zero **HGB-measurement**.

17. Check all menu options and settings. **Auto clean** and **Auto standby** should be **chosen**.

18. If the instrument works properly, you can start measuring and calibration.

Adjust blood-, capillary- and dispenser needle if necessary.
For special blood needle ask your distributor.

Important Notice:
When the front cover is removed you can not measure HGB.



The WBC-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. A help-menu which gives explanations and offers problem solutions can be called up.

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 4000   SELFTEST ……  IS FINISHED

-----------------------------------------
RBC        6.09          THR ANA     4.01
WBC        3.01          RBC ANA     3.04
DILUTER    5.05          WBC ANA     3.34
SPOOLER    3.35
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**. Than the **system menu** is displayed, see Fig 9.

```
SYSTEM MENU
                    7 CAPILLARY REPLACE
1 CAP PRESSURE      8 DATABASE / STATISTICS
2 FILL              9 DATE / TIME
3 CLEAN             0 DILUTER INFO
4 CALIBRATION       -> SET NORMAL VALUES
5 SERVICE           <- PARAMETERS
6 OPTIONS           E PRINTOUT
```

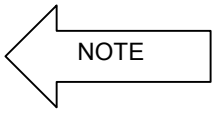
Fig 9: The system menu

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 capillary is reopened or pressure cleaned. This happens when a capillary is blocked.

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



2.2 FILL

From this menu 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.

```
FILLING SYSTEM
                    7 CAPILLARY REPLACE
1 CAP PRESSURE      8 DATABASE / STATISTICS
2 FILL              9 DATE / TIME
3 CLEAN             0 DILUTER INFO
4 CALIBRATION       -> SET NORMAL VALUES
5 SERVICE           <- PARAMETERS
6 OPTIONS           E PRINTOUT
```

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 CLEAN

From this menu the program does not switch to a submenu. When **Number-key 3** is pressed in the system menu, the whole system is cleaned. The same happens during the auto-clean cycle.

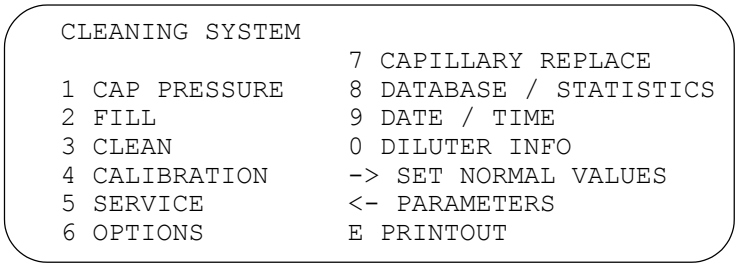


Fig 11: Display during system cleaning

The system is equipped with a cleaning cycle that is sufficient for the normal use of the system. In case of extreme soiling with defective solution or micro clots blocking up the capillary aperture the cleaning cannot be executed automatically. The measuring result would not be reliable.

The blockage of the capillary is detected by the system. In this case "over time" is displayed. The system automatically switches to an error menu so that you do not have to jump to the system menu.

A possible blocking of the capillary aperture is removed through pressure from inside, see chapter 2.1.

2.4.1 Control blood

For calibration 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. If you use different blood samples, we recommend cleaning the needle with **MEDILUID III DIFF** (by carrying out a blank-value measurement) after measuring the control blood sample in order to avoid a carry-over.

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!

2.4.2 General

From this menu the program switches to the **one-point** or **three-point calibration** menu, according to the selected mode in the system settings (Main menu → Options).

In this menu the results for all activated parameters can be adjusted. Indispensable condition for it is that a pre-diluted sample has been measured, and that the values have been within normal range. Depending on the last measured sample the blank values or the standard values can be calibrated.

After having confirmed the selection for the value-modification by **ENTER-key**, the acceptable range of adjustment will be displayed in the status line.

2.4.3 Calibration of Standard Values (one-point-mode)

First of al the calibration mode has to be switched on by the **ENTER-key**. Pushing the **ENTER-key** once more makes switching it OFF.

```
CALIBRATE          (N)
-----------------------------------------
ENABLE CALIBRATION:


                   CALIBRATION:      OFF
                   RECOVER / ERASE
```

Fig 12: Display in Calibration of standard values

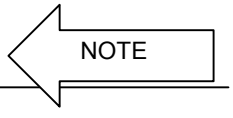
Afterwards the program branches into the following menu. Start a measurement with **control blood** in the **normal-blood mode**.

```
CALIBRATE
-----------------------------------------
N   RBC:    4.56          LYM:    5.50
N   WBC:     225          MID:     2.6
N   THR:     8.0          MCV:    90.0
N   HGB:    14.5          MPV:     8.2
N   HCT:    42.0          CALIBRATION: ON
                          RECOVER / ERASE
```

Fig 13: Calibration display

In this menu the measured values can be calibrated or adjusted. To do this you have to place the cursor on the required value and push the **ENTER-key**. The value is now in modification mode and can be adjusted. You can return to the measuring menu by selecting the **MODE-key.**

Notice:



The calibration can be carried out in this one-point calibration only for normal range blood!

2.4.4 Calibration of Standard Values (three-point-mode)

This menu point serves to adjust three levels of standard values.

```
CALIBRATE                (1=L, 2=N, 3=H)
-----------------------------------------
CONTROL BLOOD:            NORMAL LEVEL



N   HCT:    42.0          CALIBRATION: ON
                          RECOVER / ERASE
```

Fig 14: Display for 3 point calibration

Number-key 1	=	low level control blood
Number-key 2	=	normal level control blood
Number-key 3	=	high level control blood

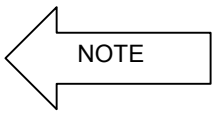
After switching ON the calibration mode by pushing the **ENTER-key** and selecting the blood level by the respectively letter start a measuring with control blood in the selected range. After the measurement the program will switch into the following menu.

```
CALIBRATE                (1=L, 2=N, 3=H)
-----------------------------------------
N   RBC:    4.56          LYM:    5.50
N   WBC:     225          MID:     2.6
N   THR:     8.0          MCV:    90.0
N   HGB:    14.5          MPV:     8.2
N   HCT:    42.0          CALIBRATION: ON
                          RECOVER / ERASE
```

Fig 15: Display for three-point calibration

In this menu the measured values can be calibrated or adjusted. Place the cursor on the required value and press the **ENTER-key**. The value is now in modification mode and can be adjusted. Return to the measuring menu by pushing the **MODE-key.**

Important information:
If the calibration is not correct the linearity of the instrument is wrong!



2.4.5 Calibration of Standard Values (capillary-blood-mode)

After switching ON the calibration mode by pushing the **ENTER-key** start a measurement with **control blood** in the **capillary-blood mode**. As soon as the measurement is carried out the program switches into the following menu.

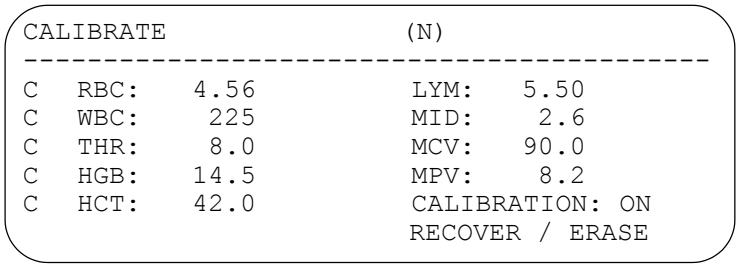
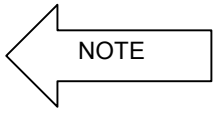


Fig 16: display in capillary-blood mode calibration

In this menu, the measured values can be calibrated or adjusted. Choose a value and press the **ENTER-key**. The value is now in modification mode and can be adjusted. Return to the measuring menu by pushing the **MODE-key.**

Notice:
In this capillary-blood mode calibration can be carried out in the normal range only!



2.4.6 Recover / Erase

For all kinds of calibrations explained above the RECOVER / ERASE option can be selected at the calibration display. In this case the program will branch to the submenu **RECOVER / ERASE.** If the calibration was wrong the previous value can be set again.

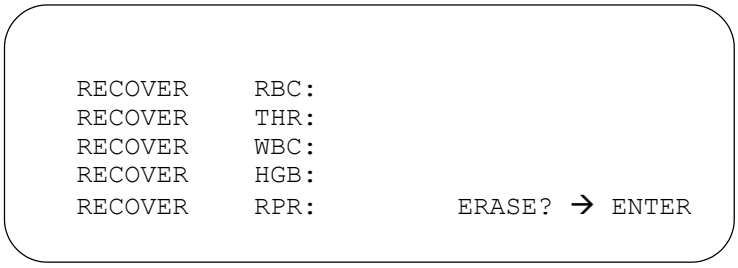


Fig 17: display in recover / erase mode

If **RECOVER** is chosen the previous value will be set. If **ERASE** is chosen, the factory setting will be used.

Place the cursor on the menu point **ERASE** and press the **ENTER-key**. From now on the factory setting for all parameters and levels will be used.

Place the cursor on **RECOVER** of the chosen parameter and press the **ENTER-key**. From now on the previous setting for this parameters will be used.

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

2.5 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.

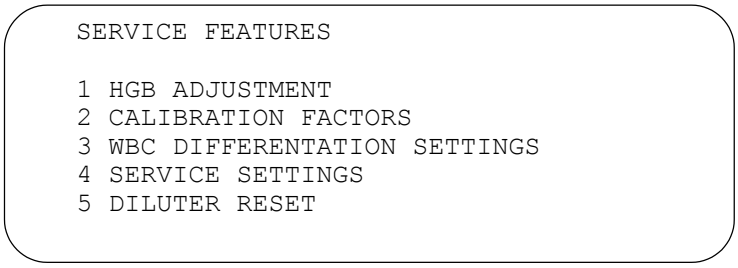


Fig 18: Display Service Menu

NOTE

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.

2.5.1 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.

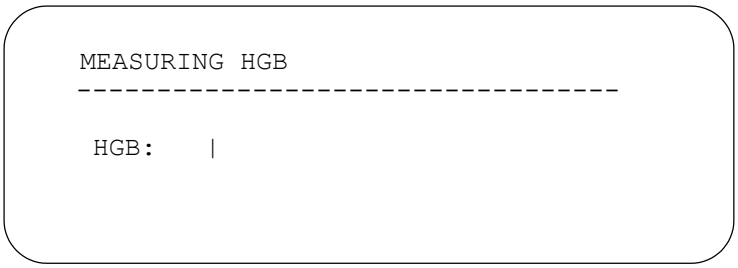


Fig 19: HGB adjustment

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

2.5.2 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.

There are two pages of factors. The values given in brackets are the standard factory calibrations. By activating the menu point **ERASE CALIBRATIONS** at the second page all entered calibrations are set back to the standard factory calibration.

```
        FACTORS:          PAGE 1 / 2

        LOW     NORM    HIGH     1PCAL    CAPBL
RBC     48.0    45.0    46.0     1.000    1.000
WBC     68.0    62.0    56.0     1.000    1.000
PLT     4.70    3.80    3.50     1.000    1.000
HGB     185     200     195      1.000    1.000
PRP     4.70    3.80    3.50     1.000    1.000
```

Fig 20: Calibration of calculation factors

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

2.5.3 WBC-differentiation settings

```
WBC-DIFFERENTATION SETTINGS
-----------------------------------
G         6 (    6)    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 21: 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 are set back to the standard factory calibration.

2.5.4 Service Settings

```
SERVICE SETTINGS
-------------------------------------
LYSING   :   15.0   PLT-CHECK :    20.0
TRANSFER :      6   PLT-CURVE :    ORIG
RBC-TMIN :   10.0   BEEP      :      10
RBC-TMAX :   15.0   PASSWORD  :  000000
WBC-TMIN :    6.0
WBC-TMAX :   14.0
```

Fig 22: 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 22, 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.

2.5.5 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 measurement" and the next sample can be processed.

2.6 OPTIONS

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

```
SYSTEM SETTINGS
---------------------------------------
AUTO     :      ON   PAPER SIZE   :    12''
PARALLEL:GRAPHIC   EMULATION     :     IBM
RS232    :     OFF   AUTO STANDBY:     OFF
BAUD     :    9600   AUTOCLEAN    : ON(30)
S.I.     :     OFF   BLOOD SAVING:     OFF
HGB      :    GRAM   3-POINT-CAL.:      ON
```

Fig 23: The sub-menu Options

2.6.1 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.

2.6.2 Parallel

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

2.6.3 RS 232

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

By choosing **PRINTER** the results are downloaded to a serial printer.
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.

NOTE

2.6.4 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.

NOTE

2.6.5 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.

2.6.6 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.

2.6.7 Paper size

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

2.6.8 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.

2.6.9 Auto Standby

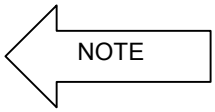
By activating the standby-mode the solution in the measuring chambers and in the capillaries will be replaced to avoid a pollution. The standby-mode does not set the system into a different working condition but is meant to allow a continuation of sample processing after interruption. When the system is in standby-mode there have no extra steps to be done to continue measuring. Just start a normal measurement.

The system is always in a standby position when no samples are measured. However, as blood samples always cause pollution it should be avoided to let blood samples in the instrument for a longer period of time. When the system is not used for several time and the automatic standby-mode is switched on, the system carries out the standby-mode procedure after 20 minutes automatically. This way, it is not necessary to take the instrument out of operation for a smaller measurements interruption.

In this menu point the auto standby mode can be changed by pressing the **ENTER-key**. You can scroll between **ON** and **OFF** by using the **Curser-keys**.

Notice:

The STANDBY-mode should always be activated by interruptions in the daily measuring routine. This way problems of pollution that might influence the next measurement can be avoided.



2.6.10 Auto clean

The human blood contains proteins, grease and micro clods. These can block the capillary. For a good running of the instrument the system has to be cleaned during the daily routine. Is the **AUTOCLEAN MODE ON**, the system will be cleaned after the registered sample sequence. A message which you have to confirm by YES or NO will be displayed.

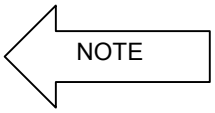
By activating the AUTOCLEAN MODE the solution in the measuring chambers and in the capillaries will be replaced, so that possible pollution is avoided. If cleaning is activated the sample tube should be also cleaned with MEDICLEAN^{E}. This function is displayed.

The AUTOCLEAN MODE does not bring the system into a different working condition but is meant to allow a continuation of sample processing after interruption. When the system is cleaned by the **AUTOCLEAN MODE** no extra steps are necessary to continue measuring. Just start a normal measurement.

In this menu point the AUTOCLEAN MODE can be switched **on** and **off** by pressing the **ENTER-key.** If it is switched **ON** you can change the amount of samples after which the auto-cleaning should start by entering a new number. Following values are displayed in the status line: (1) actual amount of samples and (2) possible maximum value to type in.

Notice:

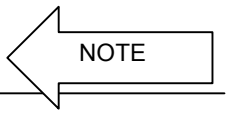
The AUTOCLEAN MODE should always be chosen when the system offers this menu point. This way pollution problems which might affect the next measurement will be avoided. You can start the next measurement without any further procedures.



2.6.11 Blood saving

In this menu point the blood saving mode can be selected by pressing the **ENTER-key.** You can scroll between **ON** and **OFF** by using the Curser-keys. If the blood saving mode is activated the used blood volume will be reduced to a minimum.

Notice:



By using this option, the accuracy of the instrument might not be correct. For adjustment of the blood collecting, use the transfer-time setting

Is the **BLOOD-SAVING MODE** switched on, blood will be sucked only to the first sample detector. After removing the sample the system sucks the blood up to the second sample detector. Thereby the blood consumption will be reduced. This option is suitable especially for the working with control-blood. As control blood samples have different viscosity it is possible to adjust the transfer time in the service settings of the service menu. An adjustment could be executed only experimentally.

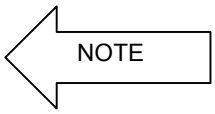
A change from control to human blood could make it necessarily to change the adjustment of the transfer time too.

2.6.12 3-Point cal.

In this menu point the 3-Point calibration mode can be switched **on** and **off** by pressing the **ENTER-key.** If ON is selected the instrument uses the three-point calibration mode, otherwise the one point calibration mode for calibration will be used, see chapter 2.4.

The kind of calibration mode is displayed in the corresponding calibration menu.

Notice:
If the application of three-point-calibration is chosen, one mistake by calibration of the measuring levels might it make necessary to delete the calibration complete because the linearity of the system is no longer correct.



2.7 CAPILLARY REPLACEMENT

If a capillary replacing is necessary, menu point 7 in the system menu should be called up. After pressing **Number-key 7**, the measuring chambers will be emptied. Now a removing of the capillaries is possible.

For capillary replacing follow the instruction displayed in the status line.

Fig 24 shows how the aperture-tube is mounted into the measuring chamber:

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

Aperture diameter for WBC-channel (left) C1 = 100 um
Aperture diameter for RBC-channel (right) C2 = 80 um

NOTE

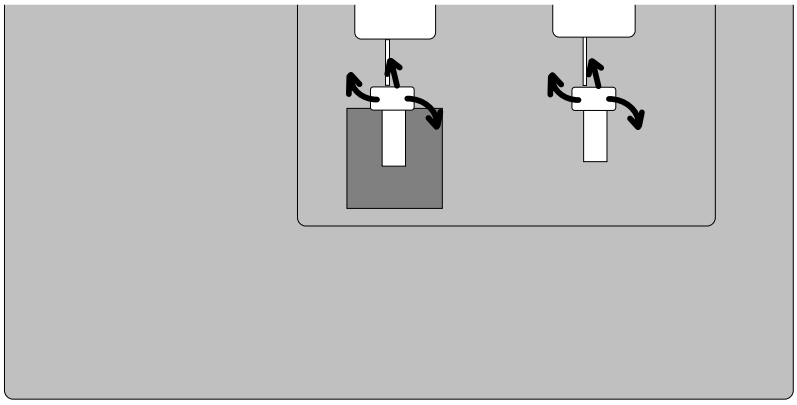


Fig 24: Fitting the capillary

<u>Important Notice!</u>

NOTE

After having carried out a capillary replacement the correct fixing of the capillary has to be checked for a wrong fixing will influence the HGB-measurement.

The measuring chamber must fit closely to the reverse-side/right side. Make sure the chamber fits properly starting a blank solution measurement in the menu "HGB-Adjustment" (see chapter 2.5.1).

The chamber is properly adjusted when the measured result varies between – 1.5 and +1.5.

Please note that no light source will shine on the measuring chamber directly.

2.8 DATABASE / STATISTICS

By pressing **Number-key 8** 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. 26) the corresponding sub menu can be called up:

```
DATABASE / STATISTICS
--------------------------------------
1 DATABASE VIEW       7 ERASE DATABASE
2 DATABASE PRINTING
3 STATISTICS VIEW
4 STATISTICS PRINTING
5 DATA SAVING    ON
6 SINGLE DATA ERASE
```

Fig 25: Database sub menu

2.8.1 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

2.8.1.1 Exclude a sample

If you have a sample that you don't want to use for the statistical analysis you can exclude it as follows:

- Select the corresponding block by finding the ID sample number
- Press the last figure of the sample number in the statistic database (e.g. "4" for sample No. "04"
- The sample should now be marked by an "*", see Fig 27.

```
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 27: Database view with excluded sample

2.8.1.2 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 28: Database view with marks

2.8.2 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.

2.8.3 Statistics view

By pressing **Number-key 3** in the database menu the statistic is displayed. You can scroll by using the **Curser-keys** among 3 parameter pages.

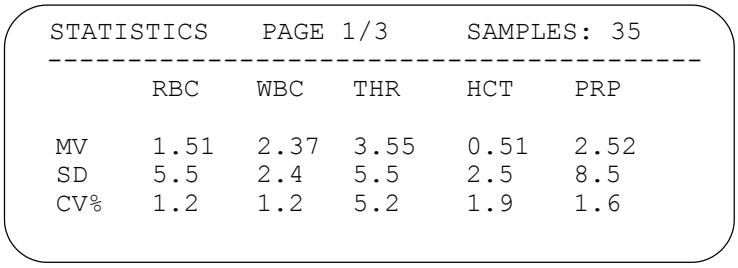


Fig 29: Statistic view

Fig. 30 shows the statistic of the samples in the database that have not been deselected:

MV	=	Mean value
SD	=	Standard deviation
CV %	=	Coefficient of variation in %

2.8.4 Statistics printing

By pressing **Number-key 4** in the database menu the printing of the statistics is activated. The statistics is displayed and printed out at once.

2.8.5 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**.

2.8.6 Single Data erase

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

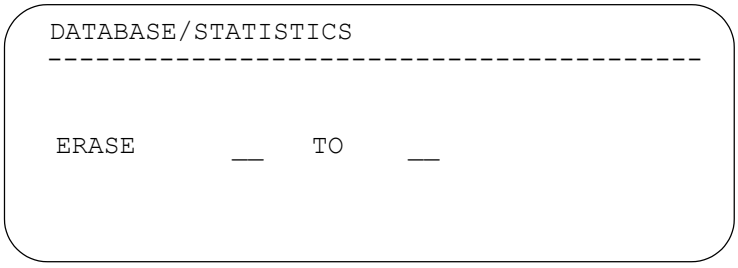


Fig 30: Single data erase display

In the blank the database numbers for the range of samples to be erased can be typed in.

2.8.7 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.

2.9 SETTING TIME AND DATE

By pressing **Number-key 9** 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 figures
- (4) Accept/confirm the changes by pressing the **Enter-key**

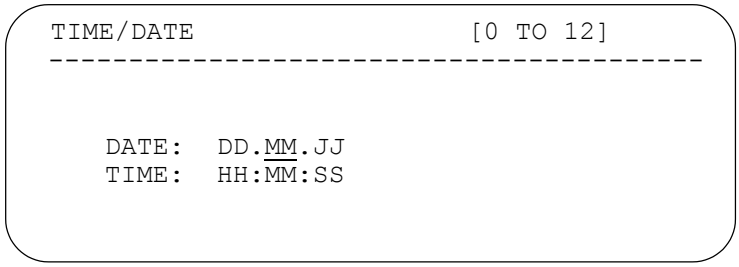


Fig 31: Setting time and date

2.10 DILUTER INFOS

In this sub menu the diluter information can be checked.

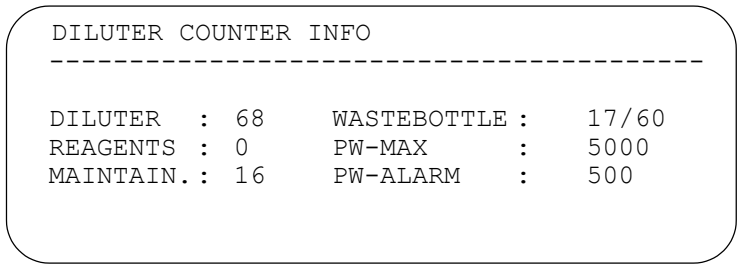


Fig 32: Display for diluter counter infos

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

2.11 SET NORMAL VALUE

By pressing the **Cursor-key right** in the system menu the display for changing normal ranges (Fig. 34) is called up.

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

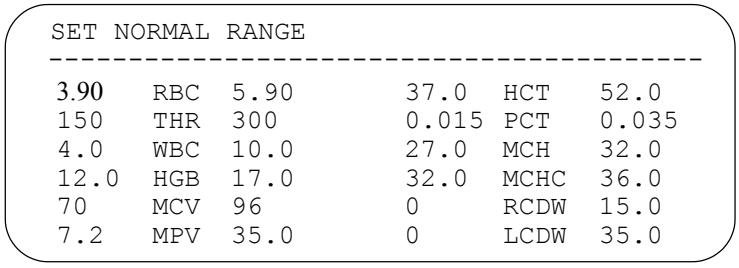


Fig 33: Display for setting normal ranges

2.12 PARAMETERS

By pressing the **Cursor-key left** in the system menu the display for switching on or off measuring parameter (Fig. 35) is called up.

- Pressing the **Cursor-keys** the measuring parameter can be selected
- Pressing the **Enter-key** you can switch between ON / OFF.

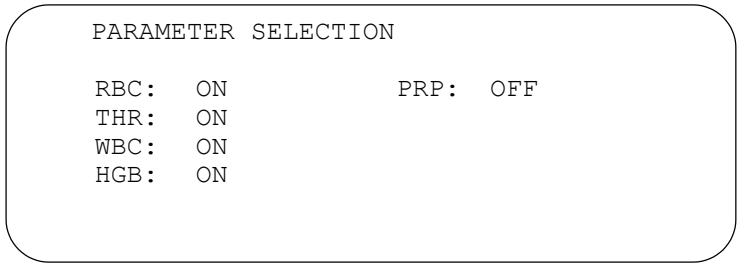


Fig 34: Submenu Parameters

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

2.12.1 PRP Blood

If the PRP-blood-mode is switched on, all other measuring parameters are automatically switched off.

The PRP-mode is used to determine Platelets (Thrombozytes) from Platelet Rich Plasma (PRP) according to the Dextran T 500 method (See section "preparing samples").

2.12.2 RBC, THR/PLT, WBC, HGB

If the PRP-blood-mode is switched off all other 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.

2.13 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 FILLING THE DILUTER WITH MEDILUID III DIFF

F1

The **F1-key** is used to fill the tube system with isotonic solution, e.g. in case the supply bottle is empty.

The supply of the measuring system with **MEDILUID III DIFF** (isotonic solution) is system controlled. In case the **MEDILUID III DIFF** supply is empty, it will be signalled on display. The supply bottle has to be replaced. After that the **F1-key** has to be pushed and the diluting station as well as the tube system will be filled. Please note: Every step of the procedure is shown on the status line.

Notice:
After installing a new CELLOTON supply bottle, a control measurement for all parameters must be carried out using a blank solution.
This way the user becomes aware of possible changes in the quality of the isotonic solution which would affect the results.

NOTE

3.2 FILLING THE DILUTER WITH LYSING REAGENT

F2

The **F2-key** is used to fill the tube system with lysing reagent, e.g. in case the lysing reagent supply bottle is empty.

The supply of the measuring system with lysing reagent is system controlled. In case the system runs without lysing reagent an alarm is given on display. When the need of lysing reagent is signalled, replenish the supply bottle.

After pressing **F2-key** the tube system is filled. The process can be observed in channel C2. If necessary, repeat the procedure.

Lysing Time
In case a different lysing reagent is used, it may be necessary to adjust the lysing time according to the lysing reagent. This adjustment can be carried out entering sub menu **Service settings** (chapter 2.5.4). The adjustable time varies between 2 and 50 seconds.

Attention!
In case the lysing or haemoglobin reaction time is not adjusted, this can lead to wrong or irreproducible results in the leukocytes or haemoglobin range.

3.3 TAKING INTO OPERATION

F3

By pressing **F3-key** the whole system can be taken from mode **Out of operation** into operation. During this step the cleaning solution is taken out of the whole system and is replaced by isotonic solution.

If the instrument was taken out of operation before switching off, the **Taking into operation** (chapter 3.4) procedure must not be performed. In this case, after switching on the instrument by pressing the mains switch, the cleaning solution is automatically replaced by isotonic solution.

3.4 TAKING OUT OF OPERATION

F4

After the daily working routine, the whole system should be cleaned by activating the menu point **TAKING OUT OF OPERATION** before switching it off.

After pressing **F4-key** the whole system is filled with cleaning solution and refilled for totally dissolving strong pollution. Please note: Every step of the procedure is shown on the status line. The supply of the measuring system with cleaning solution is system controlled and the need for new supply is displayed. In that case the supply bottle must be replaced and the procedure must be restarted.

If the **Out of operation** mode is activated the sample tube must be cleaned manually with **MEDICLEAN^{E}**.

After the cleaning is over the instrument signals on display that the system is out of operation and asks to be turned off by switching off power.

3.5 DISPENSER FUNCTION

When the dispense-switch is pressed, the diluter prepares manually MEDILUID III DIFF in a cell cup.

Hold the cell cup underneath the needle for dispenses. The dispensing is started automatically by activating the micro switch.

After the dispensing is finished, remove the cell cup. Now prepare the sample for capillary blood.

3.6 CAPILLARY BLOOD FUNCTION

When the capillary-switch is pressed, a manually prepared sample can be processed. (Check preparing samples)

- Hold the cell cup underneath the needle for capillary blood.
- By activating the micro switch, sucking in is started automatically.

After the sucking in is finished, remove the cell cup. The system now processes the sample and displays the results or prints them out.

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 35).

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

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 SET NORMAL VALUE submenu (chapter 2.11) 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 choosing 1 (male), 2 (female) or 3 (child) at the same time with entering sample and ID number.

```
CH2:    0.0        NO: 00000          [00:00]
CH1:    0.0        ID: 00000       FEMALE (2)
-----------------------------------------
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 MEASRUREMENT
```

Fig 35: 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.

Check if there is solution in the measuring chambers. This happens when the instrument is gone through the cycles:

TAKING OUT OF OPERATION or **TAKING INTO OPERATION**

by switching the instrument on or off.

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:

The measuring can be interrupted by pressing the **STOP-key**. After measuring, the measuring time and the determined background of channel **C1** and **C2** are displayed. The system will check the results and reject them with an error-report or accept them by displaying: **READY FOR MEASUREMENT** 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
READY FOR MEASRUREMENT
```

Fig 36: standard or measuring menu

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 section sample preparation).

4.4.2 The Dilution Station

The built-in dilution station serves to process the blood samples to the proper dilution ratio. The green light signals that the diluting station is ready.

In the status line **READY FOR MEASUREMENT** is displayed.

Now take a blood sample under the sample tube. The sample will be sucked in as soon as the light barrier is activated. Afterwards the sample tube will be cleaned automatically.

After the sample tube is cleaned, the next sample measure can be started placing the next blood sample under the sample tube. The sample is processed automatically and the results are displayed as soon as the measurement is finished.

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

4.4.3 The Sample Sequence

Usually the lysing reagent requires a waiting period of about 5 to 20 seconds for processing the leukocyte / haemoglobin measuring solution (check manufacturer notice "lysing reagent").

It is recommended to use this time for sucking in the next sample. This way the sample sequence can be increased considerably.

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.

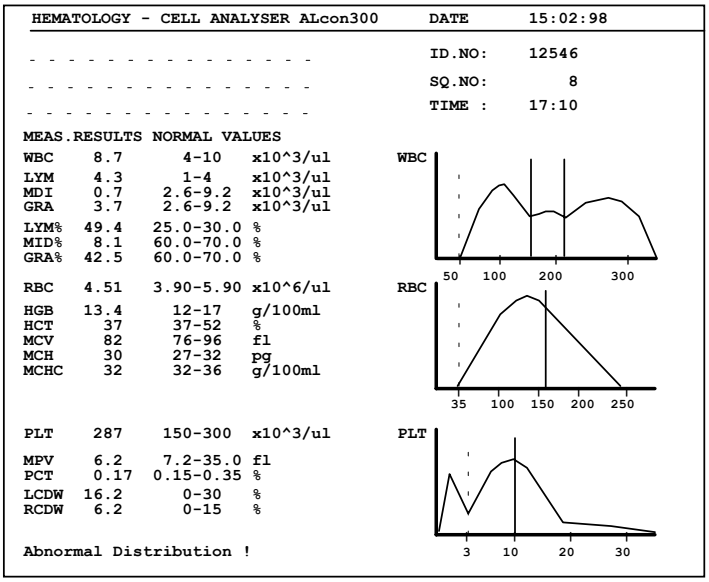


Fig 37: The graphic printout

4.5.2 The Ticket Printout

The other possibility for documentation is the ticket printout which only includes the series of numbers.

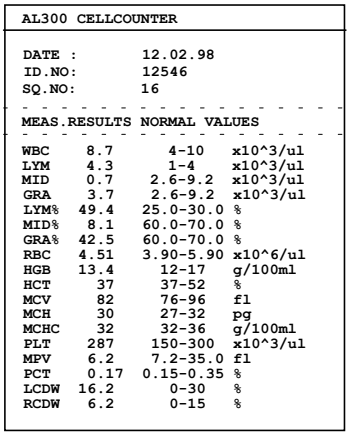


Fig 38: The ticket printout

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	1:300 or 1:350
RBC	1:45.000

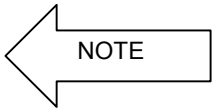
The **primary dilution** is used for determining the values for WBC, HGB:

20 µl EDTA-blood + 6.0 ml MEDILUID III DIFF and
0.6 ml Lyse is added after the 20 µl foe secondary dilution is token away.

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

20 µl primary dilution + 3.0 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.

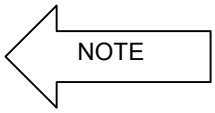


4.7.1 Stability of the samples

The stability of the samples depends on different factors. The data below refer to the capillary-blood method and are not applicable to the automatic system.

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 suction sonde and consequently 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 sample button or activating the light barrier, the blood is taken from the sample needle and the system absorbs approx. 20 µl EDTA-blood.

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

20 µl blood is diluted with 6.0 ml **MEDILUID III DIFF** and transferred into the mixing chamber (dilution 1:300), alternatively mix 20 µl capillary blood with 6.0 ml isotonic solution for capillary blood.

After the secondary solution is drawn 0.6 ml lysing reagent is added during the transfer into the WBC-Measuring-chamber.

4.8.2 Secondary-Dilution - RBC (Erythrocytes)

The diluting station absorbs 20 µl suspension from the mixing chamber (WBC-dilution) and dilutes it with 3.0 ml **MEDILUID III DIFF**. Then the dilution is transferred into the RBC-mixing-chamber (Dilution referred to EDTA-Blood 1:45.000).

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 !!

4.8.3 Capillary Blood Dilution

For the use of capillary blood first you have to dispense 6.0 ml **MEDILUID III DIFF** through the sample / dispenser tube into a cell cup by activating the micro switch and then add 20 µl capillary blood.

In this case the **dilution ratio** is **1:300**.

Next you activate the micro switch on capillary-blood-needle (number 1 in Fig 39) with the cell cup and suck in the complete solution.

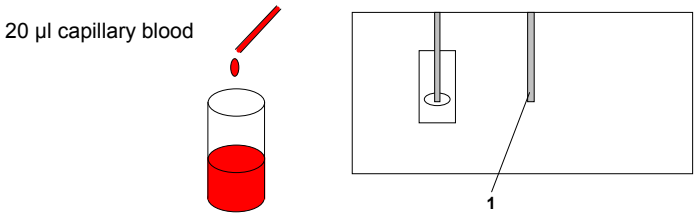


Fig 39: dilution of capillary blood

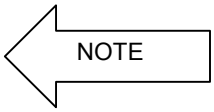
After removing the sample cup the further internal diluting cycle and the complete measurement will be started.

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/µl may be more than 20%.

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

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.

4.9.2 Measuring Range with THR/PLT-Analyzer

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

With THR values of more than 350.000/µl 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
Measuring result		**65**

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

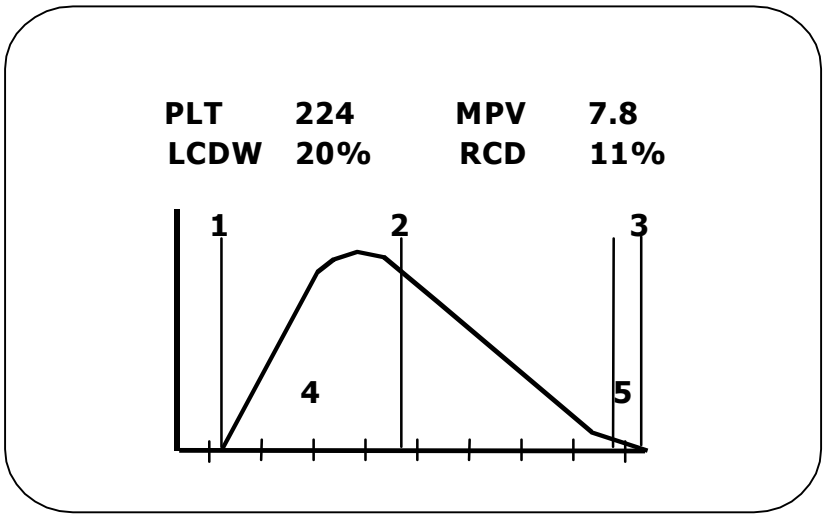


Fig 40: Standardized THR-distribution curve

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

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.

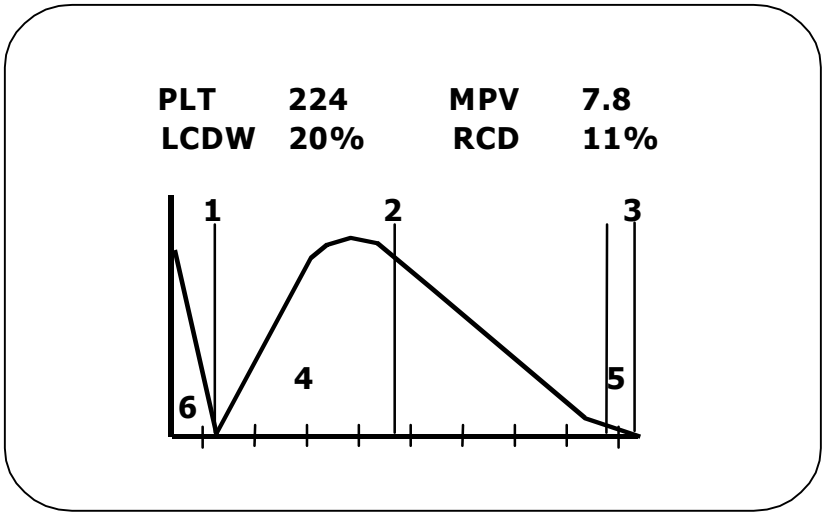


Fig 41: The not-standardized Distribution Curve

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.

4.11.1 Results marked with "L" = LCDW

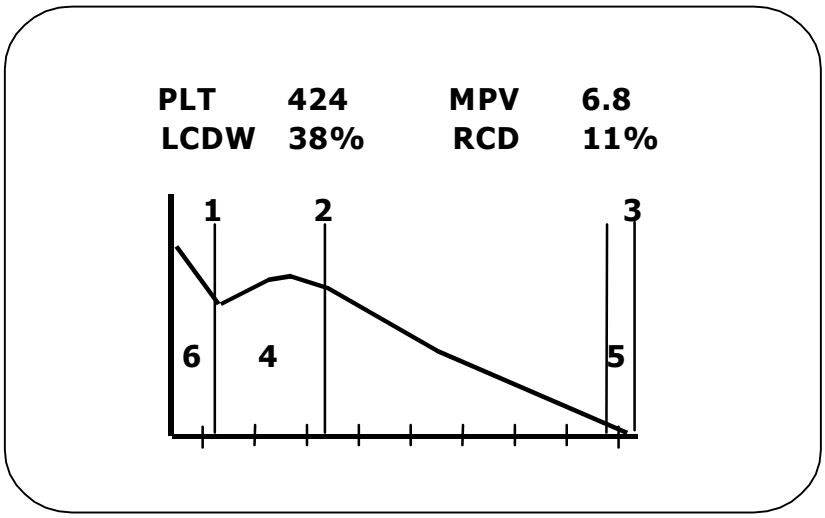


Fig 42: THR/PLT distribution marked with "L"

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 occured.

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

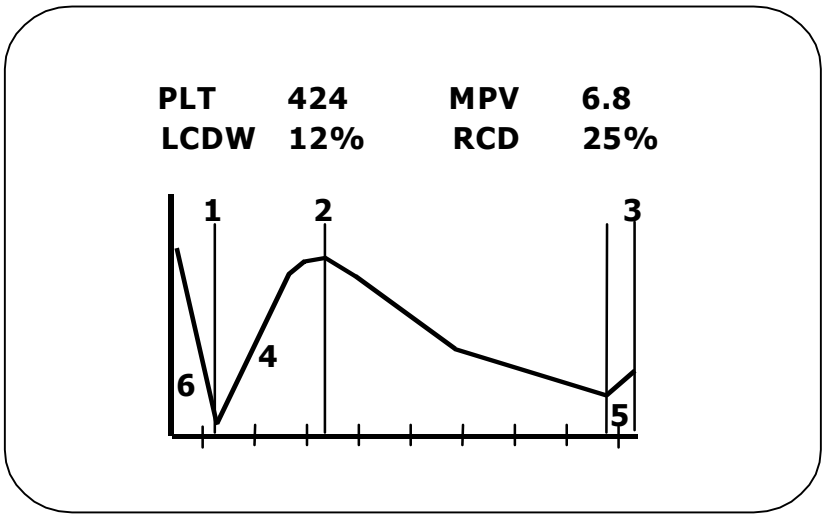


Fig 43: THR/PLT distribution marked with "R"

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

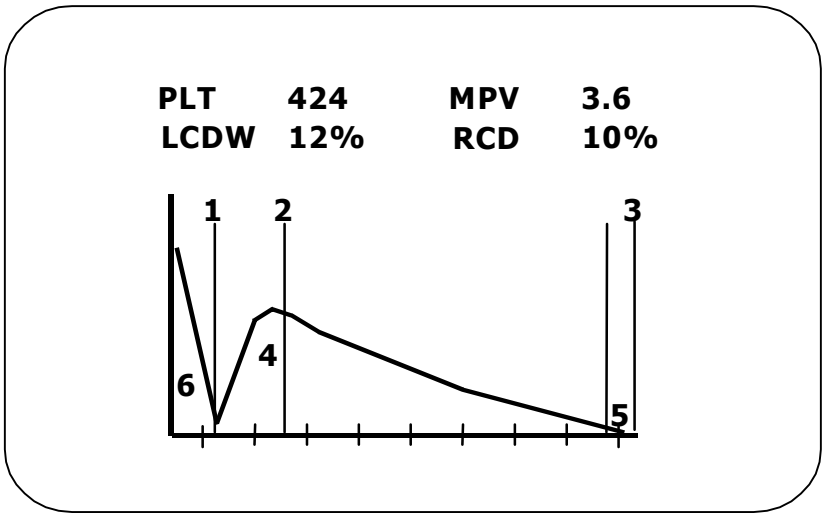


Fig 44: THR/PLT distribution marked with "M"

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 45 shows disturbances of the measurement on the left side. The curve can vary depending on the cause of the disturbance.

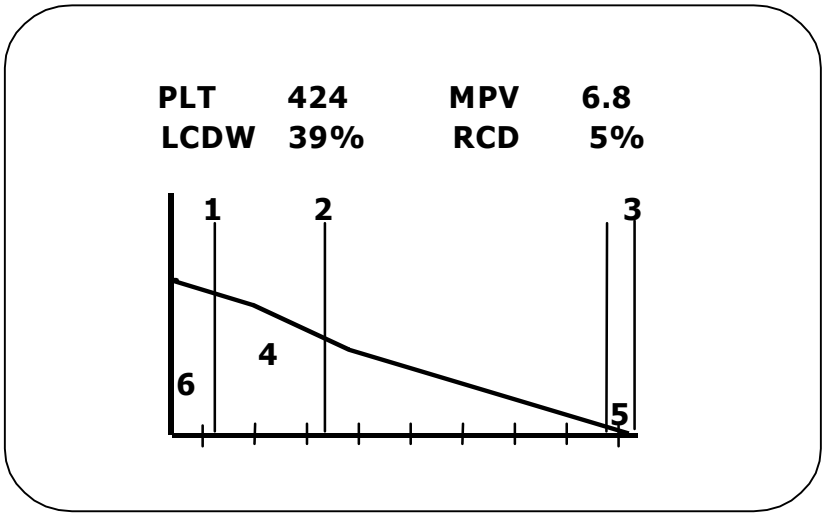


Fig 45: Histogram with disturbances on the left side

1 = lower discriminator
2 = MPV
3 = upper discriminator
4 = LCDW
5 = RCDW
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 46 shows disturbances in the measurement on the right side. The curve can vary depending on the cause of the disturbance.

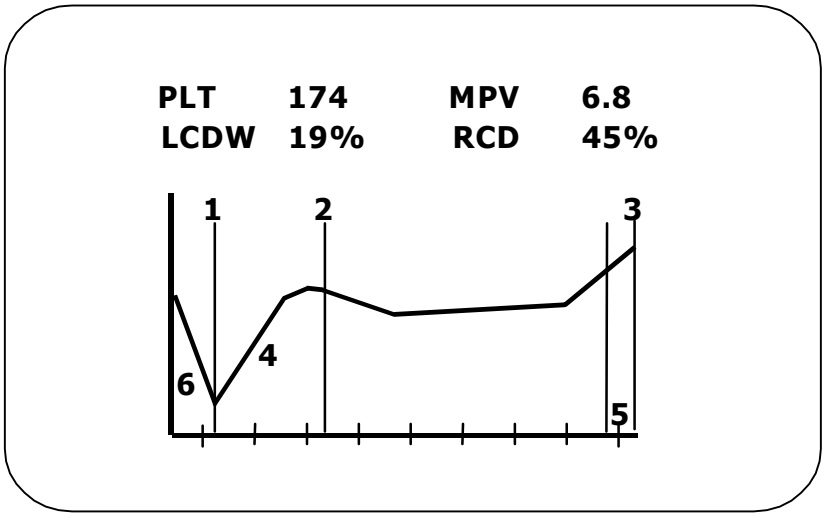


Fig 46: Histogram with disturbances on the right side

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 47 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.

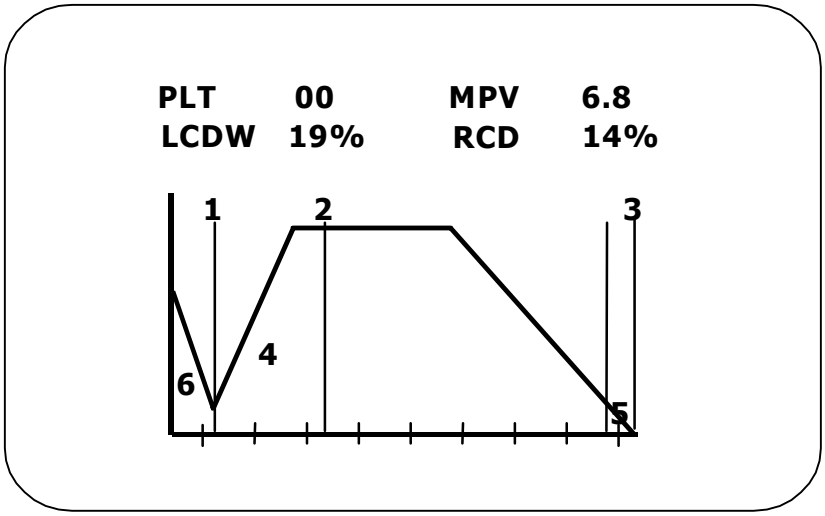


Fig 47: Histogram with disturbances in the middle range

1 = lower discriminator
2 = MPV
3 = upper discriminator
4 = LCDW
5 = RCDW
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.
- Defective capillary aperture, possibly worn.
- 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 diagnostical value and serves only for checking the particle distribution, e.g. for THR/PLT interference, and for checking the MCV-value.

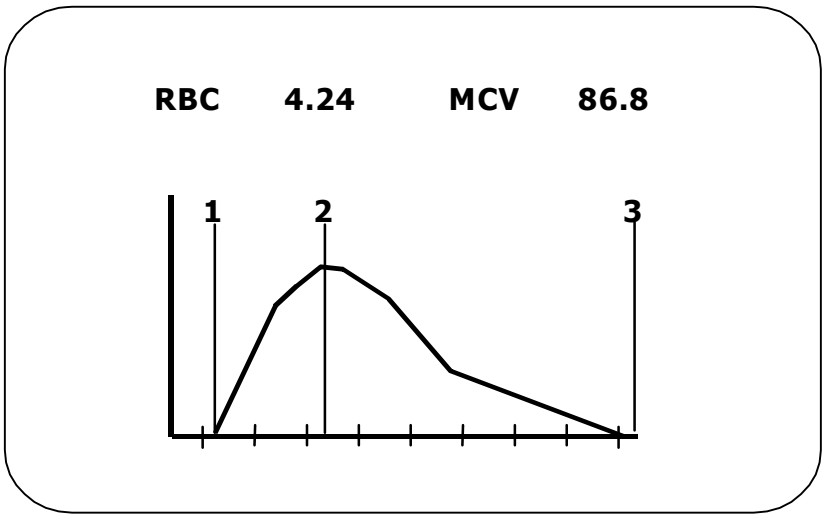


Fig 48: RBC distribution curve

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**.

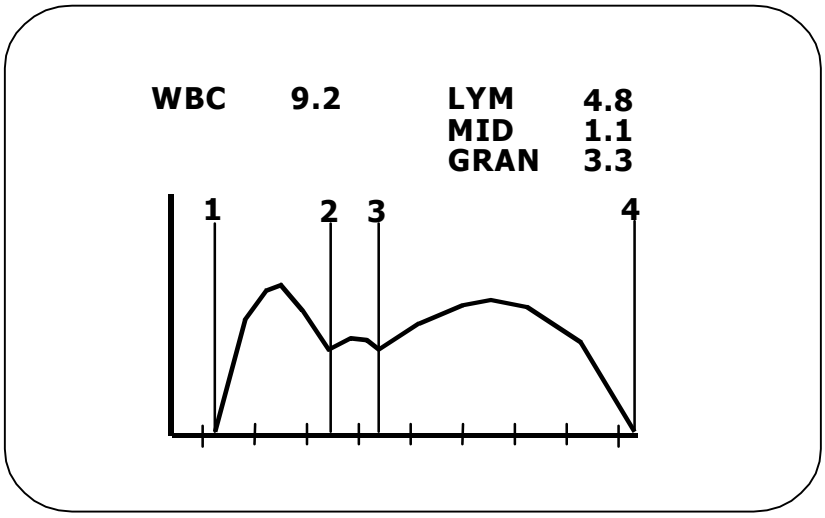


Fig 49: WBC distribution curve

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

4.14.1 Setting the WBC-Discriminator

The results of **Lymphocytes, Granulocytes** and **Mid cells** are calculated automatically when the distribution of the WBC-curve is well structured, i.e. showing clear valleys and maximum values. 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**.

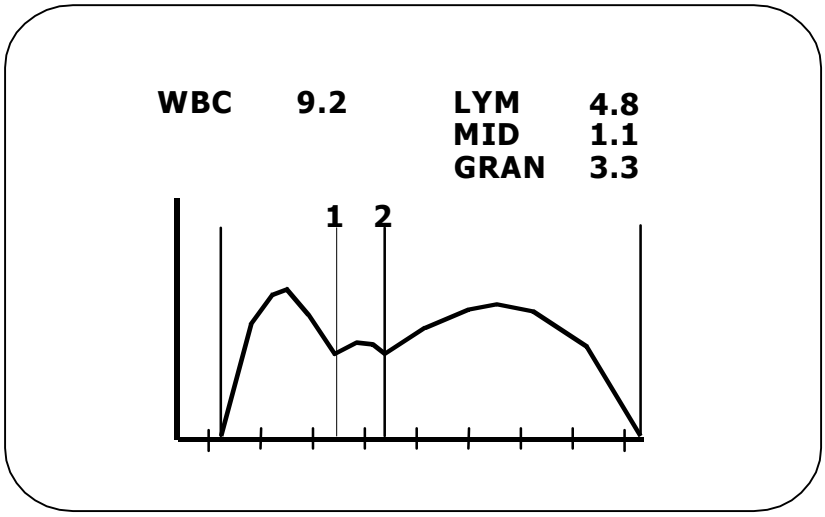


Fig 50: WBC distribution curve moving discriminator 1

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.

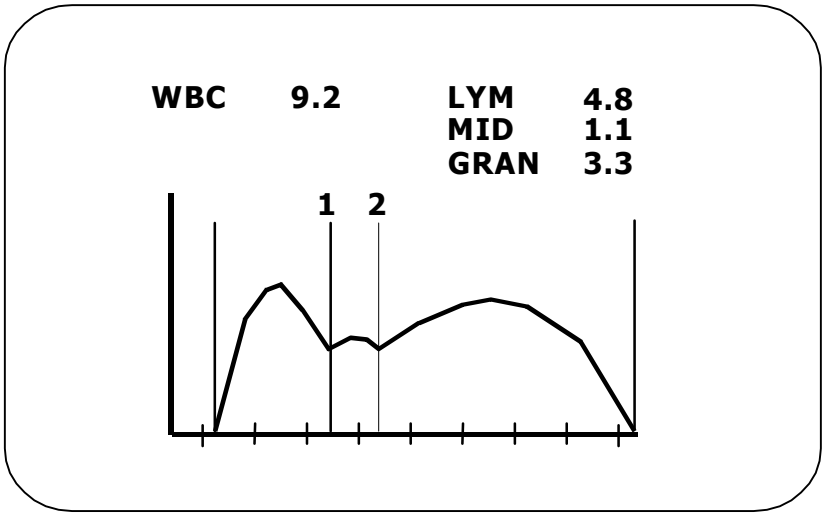


Fig 51: WBC distribution curve moving discriminator 2

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 Thrombocytes from Dextran solution. Because of appropriate window-discriminators it can be guaranteed that only particles of the size of the thrombocytes 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.
- After the centrifugation take the sample with the sample needle from the middle of the solution by pushing the sample bottom.
- 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 **PRP ON** in the system menu under Parameters. All other parameters should now be off. 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:

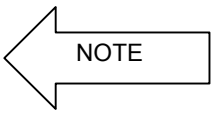
Sample	Value	80	
Solution	Blank value	15	-
Measuring result		**65**	

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

- Always close the waste containers tightly as the system works with vacuum that is made at the empty part of the waste-containers.
- 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 containers for contamination and clean or replace them if necessary.
- Check and clean the mixing and the measuring chambers regularly.
- Always use original solutions or solution 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.
- Clean the instrument regularly using proper cleaning solutions.
- Never leave measuring solutions inside the system for a longer period of time.
- Clean the HGB cuvette using special cleaning solution every week.
- Do not make any changes in the service menu.
- Clean the 0-ring at the waste-bottle regularly using acid-free grease or silicon-paste.
- Check valves and tubes regularly - if necessary, replace them!

Attention!
Make sure not to leave measuring solution in the system for a longer period, as cells and proteins will deposite on the system walls.

These deposits will cause a pollution of the capillaries, particularly of the WBC-measuring-channel and HGB-cuvette. This pollution will also lead to not-reproducible measuring results.

5.1.2 MEDICLEAN^{E}

Always use **MEDICLEAN^{E}** to clean the system. A special tube sucks in the cleaning solution (see marks at the backside of the instrument).

MEDICLEAN^{E} is usable for a maximum of 4 weeks. Please check the cleaning solution regularly (a fluffy cleaning solution might block the tubes or valves)!

5.1.3 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 containers are 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 bottles can cause the destruction of the vacuum pump!

5.1.4 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:

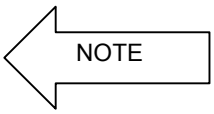
- Never let the aperture-tube dry out.
- Never let the aperture-tube stand in a blood sample for too long.
- Rinse the system well with MEDILUID III DIFF and cleaning solution between work phases or when the cell counter is not going to be used for a longer period of time.
- Inspect the aperture-tube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

5.2 DAILY MAINTENANCE

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

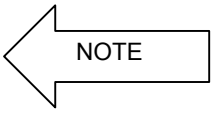
Notice:
Empty the supply bottle of all residues, so that new supplies are not polluted by possible spoiled residue.



5.2.1 Standby-Mode

If you do not run the systems for a short period of time, do not take it out of operation. You should activate the STANDBY- Mode. Thus all measuring solutions inside the system are replaced by isotonic solution.

Notice:
Activating the STANDBY-Mode the system is not really brought into a different operation mode. This means that even over a longer interruption of the working routine the system is permanently ready to measure the next sample without any further procedures.



5.2.2 The Capillaries

The capillaries must always be covered by isotonic solution or by enzymatic cleaning solution **MEDICLEAN^{E}**.

The capillary must never be dried unless it was carefully rinsed with distilled water.

Please activate the dispenser for capillary blood at least once a day for otherwise salt-crystals will start to form which might block the metal-tube.

5.2.3 The HGB/WBC-Chamber

Before each longer interruption of the measuring routine a blank solution must be measured or the system must be put into the standby mode (compare chapter 2.6.9).

After the measuring routine clean the HGB-cuvette starting the **TAKING OUT OF OPERATION** mode with **Function-key 4.**

5.2.4 After the daily working routine

After the daily working routine, the whole system must be cleaned by activating the **F4-key** for **taking** the system **out of operation** before switching it off.

Make sure that there is sufficient solution in the measuring chambers, so that the aperture of the capillary is always filled with **MEDICLEAN^{E}** and protein deposits can be dissolved.

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.

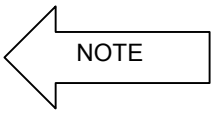
The Cell counter is supplied with one aperture-tube for each measuring channel. Nevertheless spare aperture-tubes should always be at hand.

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.

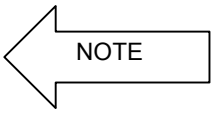
Notice:
For cleaning the aperture-tube from extreme dirt, Dichromate-Sulfuric-Acid can be used. For outside use only!



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 can be removed and the glass-tube cleaned with a small tube brush or a pipe-cleaning brush.



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

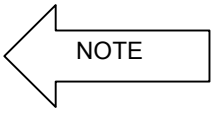
5.3.3 System cleaning

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.

In case the photometer unit gives not-reproducible results or shows too high or unstable blank values, it must be cleaned with special 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.



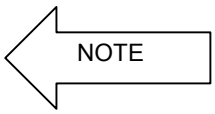
5.3.4 The RBC/WBC-Valve

Moving the red lever upwards until it is horizontal you can open the cap of the RBC/WBC-valve. A slight turn to the left will open the bayonet lock so that the valve cap can be removed.

The rotary valve can now be taken from the socket. It must be cleaned with alcohol and distilled water (aqua-dest) and all salt-crystals must be removed.

To support a long lifetime of the RBC and WBC-valve you can use silicon paste. Always use a film, so that the holes will not be blocked.

Notice:
Regular cleaning will considerably increase the life expectation of the valve!



5.3.5 Cleaning of the diluting and measuring Chambers

The system has one chamber to contain the blood sample, one mixing chamber and two measuring chambers all of them made of Plexiglas.

The using of the system implies the creation of deposits and pollution over a certain period of time. Therefore the chambers must be cleaned about once a week. For cleaning use a soapy cleaner and afterwards rinse the system with distilled water.

Attention!
Never use alcohol for cleaning!
Alcohol destroys Plexiglas!

5.3.6 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.

5.3.7 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.

5.3.8 The sample taker

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

5.4 LONG PERIOD USAGE BREAK

In case of not using the system for a longer period of time switch off the instrument after it has gone through **TAKING OUT OF OPERATION**. This way the system will be automatically cleaned.

5.4.1 Taking the System out of Operation for a Week

Firsts clean the system as usual with cleaning solution by activating the **F4-key: TAKING OUT OF OPERATION**.

- Empty the waste-bottle and fill the supply bottle with aqua-dest.
- Fill the instrument by activating the **F3-key TAKING INTO OPERATION**.
- Rinse the tube system of the lysing reagent supply with aqua-dest by activating the menu point **FILL LYSER**.
- Clean the **WBC-valve**.
- Clean the **RBC-valve**.
- Clean the capillaries with aqua-dest and dry them.
- The procedure is now finished and the instrument can be switched off.

5.4.2 Starting the Instrument after a longer Break

When the instrument is taken back into operation after a longer period of time, the capillaries must be reinstalled and the supply bottles filled and properly connected. Check all parts for correct connection, particularly the tube-valves.

Attention!
Do not mix up the tubes because the safety-tube will otherwise be pressed off from its socket.

The tubes are correctly connected when the tube that leads to the sample tube is connected on the front side.

Afterwards switch on the instrument and activate **F3-key TAKING INTO OPERATION**.

6 ERROR DESCRIPTIONS

6.1 WHAT TO DO WHEN THE SAMPLE TAKER IS BLOCKED?

- Switch off the instrument, Remove the cover (front side). Now remove the tube from the nipple (2) or needle (4).
- Remove the tube from the valve nipple (1) or clean plate (3)
- Take a syringe and clean the tube. Push the Valve manually if is necessary.

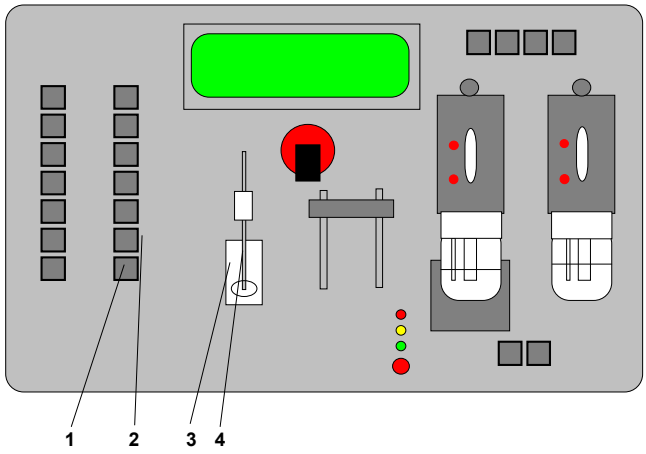


Fig 52: Front view without front cover

6.2 WHAT TO DO WHEN THE RBC- SAMPLE TUBE IS BLOCKED?

- Switch off the instrument
- Remove the cover (front side)
- Remove the tube from the nipple (2) and the RBC-sample valve (1)
- Take a syringe (3) filled with **MEDICLEAN^{E}** and fix it on the tube (4).
- Clean the tube with **MEDICLEAN^{E}** by pushing and pulling.
- Insert the tube of the RBC-valve (1) and connect the tube (4) with the nipple (2).
- If necessary, check the RBC-valve (3) by removing the cap.
- Fix the front-cover of the instrument.
- Switch on the instrument and carry out a blank solution.

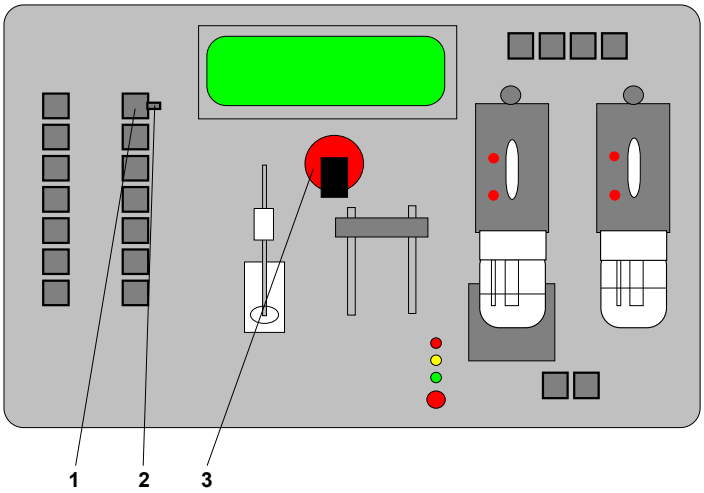


Fig 53: Front view without cover

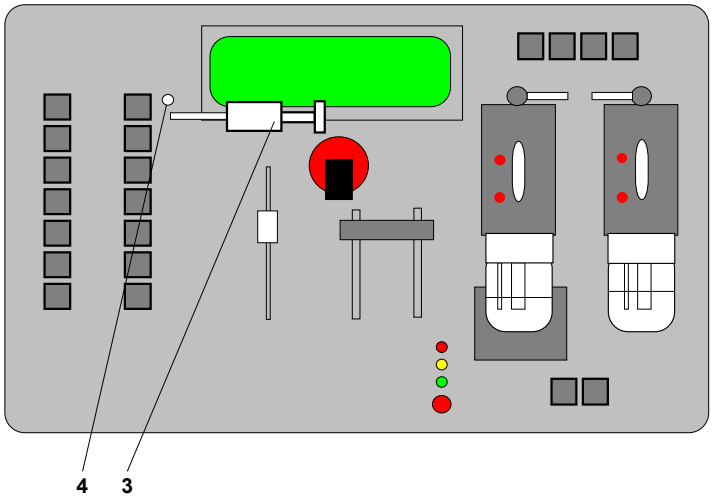


Fig 54: Front view without cover

6.3 WHAT TO DO IF THE WBC-CAPILLARY IS BLOCKED?

Use the auto-cleaning procedure or manual cleaning.

Manual-cleaning:
If the pressure of the built-in pump is not strong enough to remove extreme blockages, remove capillary and clean it manually.

- Use a (10 ml) syringe filled up with MEDICLEAN^{E} and connect it with tube (rubber).
- 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.

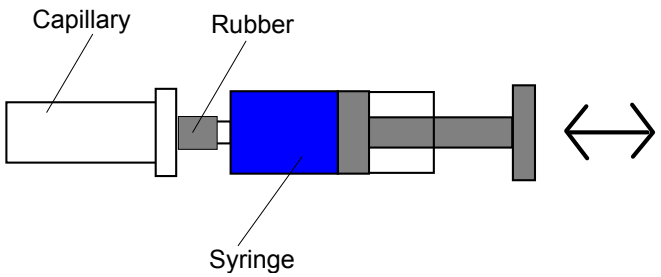
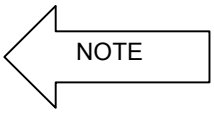


Fig 55: Cleaning the capillary manually

Note:
The replacement of the WBC-capillary always implies a check of the HGB-adjustment.



Solution-cleaning:
If the capillary is not completely blocked, the following steps can be performed:

- Fill ca. 6.0 ml MEDICLEAN^{E} in a cell cup.
- Hold the cell cup underneath the needle for capillary blood.
- By activating the micro switch, the extraction is automatically started.
- After the extraction is finished, remove the cell cup.
- The system now processes the solution.
- Wait for one or two minutes and start a few manual measurements.
- Measuring will clean the capillary.
- Then carry out a blank measurement.

6.4 WHAT TO DO IF THE RBC-CAPILLARY IS BLOCKED?

Use the auto-cleaning procedure or manual cleaning.

Manual-cleaning:
If the pressure of the built-in pump is not strong enough to remove extreme blockages, remove capillary and clean it manually.

- Use a (10 ml) syringe filled up with MEDICLEAN^{E} and connect it with tube (rubber).
- 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.

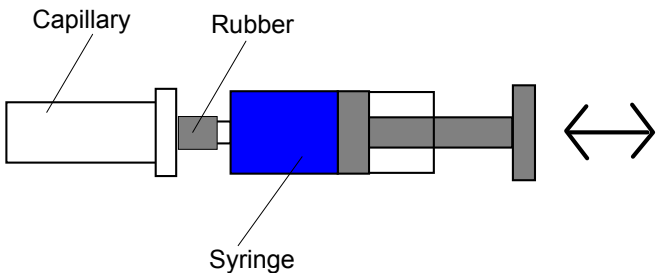


Fig 56: Cleaning the capillary manually

Solution-cleaning:
If the capillary is not completely blocked, the following steps can be performed:

- Remove the RBC-measuring-chamber and fill it with MEDICLEAN^{E}.
- Place the RBC-measuring-chamber in its original position.
- Press the **Start-Button**, the system now processes the solution.
- Wait for one or two minutes and start some manual measurement.
- Measuring will clean the capillary.
- Carry out a blank measurement.

6.5 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 ask always for FILL.	The tube is not deep enough in the supply bottle.	Sink 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, check the aperture-tube.
	The solution is soiled.	Replace the solution.
	The diluter 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 RBC valve.
	Too little lyser was used.	Use more lyser.
	The lysing time was too short.	Wait for a complete lysis:
	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.	Check the blood extraction system (blood tubes).
	A wrong dilution ratio was used.	Check the diluter.
		Check by using the capillary-tube.
		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 WBC-chamber is not in the correct position.	Check the WBC-chamber for correct setting.
	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 occured.	The mechanism does not work properly.
	Defective valve or tube, electronic defect.	Inform the service.

6.6 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 are no mixing bubbles in the WBC-chamber.	There is no pressure.	Check the mixing tube on the WBC-chamber and on valve (70), replace or clean tube if necessary.
	The tube is blocked.	
	Defective pump / electrical defect.	Inform the service.
Cleaning of the sample taker does not work.	The tube is blocked or there is no vacuum.	Check the cleaning tube, the mixing tube and the valve (71). If necessary, replace or clean the tubes.
There are drops at the sample cleaner.	There is a defective valve or an electrical defect.	Inform the service.
There is no change in the HGB value or there is no solution in the WBC-chamber.	The tube is blocked, there is no vacuum.	Check valve (73/82). If necessary, replace the tube.
	There is a defective valve or an electrical defect.	Inform the service.
There is no solution in the RBC-chamber.	The tube is blocked.	Check the tube on valve (74, 84). If necessary, replace the tube
	There is a defective valve or an electrical defect.	Inform the service.
There is no cleaning solution on sample taker.	The tube blocked.	Check the tube on valve (71). If necessary, replace the tube.
	There is a defective valve or an electrical defect.	Inform the service.

Situation	Possible Reason	Solution
There is an overflow of the mixing chambers.	There is no pressure.	Check the mixing chamber.
	The tube is not tight.	Check the tube connectors.
	The tube on the valves is blocked.	Check the tube on Valve (78/79). If necessary, replace the tube.
	The tube is blocked.	Check the tube on valve (80/81). 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 isotonic or clean 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 cleaning solution in the mixing chamber.	There is no vacuum.	Check the mixing chamber.
	A tube is not tight.	Check the tubes connectors.
	A tube is blocked.	Check the tube on valve (69/72/76). If necessary, replace the tube.
	A valve is defective or there is an electrical defect.	Inform the service.
There is no solution aspirating from sample chamber.	There is no vacuum.	Check the tube on valve (73/74). If necessary, replace the tube.
There are no mixing bubbles in the WBC-chamber.	There is no pressure or a tube is blocked.	Check the mixing tube on the WBC chamber and the tube on valve (70). Replace or clean the tube if necessary.
	The pump is defective or there is an electrical defect.	Inform the service.

Situation	Possible Reason	Solution
There is no or not enough solution in the WBC-measuring chamber.	There is no pressure. A tube is not tight.	Check the mixing. Check the tube connectors.
	The tube on valve (73) is blocked.	Check the tube on valve (73/79). If necessary, replace the tube.
	A valve is defective, the pressure pump is defective, or there is an electrical defect.	Inform the service.
The RBC-chamber was not or not completely empty when the sample was changed.	The tube on valve (79) is blocked.	Check the tube on valve (79). If necessary, replace the tube.
	There is a valve defective or an electrical defect.	Inform the service.
The WBC-chamber is not or not completely empty when the sample was changed.	The tube on valve (79) is blocked.	Check the tube on valve (79). Change the tube if necessary.
	There is a valve defective, or an electrical defect.	Inform the service.
There is no suction of the capillary sample.	The micro switch is blocked.	Check the micro switch on the capillary sample taker.
	The tube on valve (69) or on valve (77) is blocked.	Check the tube on valves (69, 77). If necessary, replace the tube.
	There is a valve defective or an electrical defect	Inform the service.

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. capacitators) 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
78415	MEDICLEAN^{E}	cleaning solution	3 x 500 ml
For capillary blood method			
78664	MEDICUPS	particle free cell cups	1.800 pcs
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 Fully 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	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
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	20 µl capillary blood 150 µl whole blood
Needed reagents	Isotonic diluent: 24 ml per sample Haemolyzing reagent: 0.7 ml per sample
Calibration	Keyboard calibration, with 3 point calibration for low, normal and high level control blood
Software	Loaded in memory
Display	LCD: 8 lines each 40 characters
Processor	7 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 Thermoprinter: DPU 414
Noise	Very low noise
Additional Features	Blood saving mode Possibility of instrument coding Built-in Dispenser Programmable auto clean Sample cleaner Adapter for closed tubes available 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	28 kg

7.5 SAFETY SPECIFICATIONS

The MDC 4000 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,

AL Systeme and 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:

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

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