Abacus 3 Closed Tube

A3CT

Operator’s Manual

Revision 02

Revisions

<table>
<thead>
<tr>
<th>Rev</th>
<th>Author</th>
<th>Changes</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Csaba Magyar</td>
<td>Initial version based on UM-A3CT-01-04</td>
<td>Nov-28-2011</td>
</tr>
<tr>
<td>2</td>
<td>Csaba Magyar</td>
<td>Remove all A3CP references</td>
<td>Nov-28-2011</td>
</tr>
</tbody>
</table>

Approval

<table>
<thead>
<tr>
<th>Ref</th>
<th>Team Role</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>R&amp;D Director</td>
<td>Bálint Mendele</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>QA</td>
<td>Olivér Babinszki</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Abacus 3CT

Hematology Analyzer

Operator’s Manual

1.0 Release

Abacus 3CT software level : 1.3

DIATRON MI PLC
1038 Papírgyár utca 58-59, Budapest
HUNGARY
Tel: +36 1 439800
Fax: +36 1 4369809
www.diatron.com
support@diatron.com
THIS PAGE IS LEFT INTENTIONALLY BLANK
# 1 INTRODUCTION

1.1 Intended Use ............................................................... 1-1
1.2 The Instrument .................................................................. 1-1
1.3 Patient Testing ................................................................... 1-2
1.4 Technical Operation ........................................................... 1-2
1.5 Calibration and Quality Control ......................................... 1-3
1.6 Main parts of the Analyzer .................................................. 1-3
1.7 User interface ...................................................................... 1-3
1.8 Environmental conditions .................................................... 1-4
1.9 Consumables ...................................................................... 1-4
  1.9.1 Reagents ..................................................................... 1-4
  1.9.2 Additional chemicals .................................................... 1-5
  1.9.3 Additional materials ..................................................... 1-5
1.10 General points .................................................................... 1-5

# 2 DESCRIPTION OF THE ABACUS 3CT INSTRUMENT

2.1 Identifying parts of the analyzer .......................................... 2-1
  2.1.1 Front view .................................................................... 2-1
  2.1.2 Rear view ....................................................................... 2-2
    2.1.2.1 Reagent connectors ................................................. 2-3
  2.1.3 Left side ........................................................................ 2-3
  2.1.4 Right side ....................................................................... 2-4
    2.1.4.1 Closed door ............................................................. 2-4
    2.1.4.2 Opened door ............................................................ 2-4
  2.1.5 Printer ............................................................................ 2-5
  2.1.6 External power supply ..................................................... 2-5
2.2 Accessories ......................................................................... 2-6
2.3 Specifications ....................................................................... 2-7
  2.3.1 Temperature & Humidity ................................................ 2-7
  2.3.2 Mechanical data & space requirements ............................ 2-7
  2.3.3 Electrical data ............................................................... 2-8
  2.3.4 Peripherals and external devices ....................................... 2-9
  2.3.5 User Interface .................................................................. 2-10
2.3.6   Reagents and control material ................................................................. 2-11
  2.3.6.1   Reagents................................................................................................. 2-11
  2.3.6.2   Control Material.................................................................................... 2-13
  2.3.6.3   Calibrator ............................................................................................. 2-13
2.3.7   Measurement technology ........................................................................ 2-13
  2.3.7.1   Function of the Fluidics ....................................................................... 2-14
2.3.8   Reagent and waste connections ............................................................... 2-15
2.3.9   Reagent and waste handling ...................................................................... 2-16
2.3.10   Reagent security system .......................................................................... 2-17

3   PERFORMANCE CHARACTERISTICS ......................................................... 3-1
3.1   Device accuracy ............................................................................................. 3-2
3.2   Device precision ............................................................................................ 3-2
3.3   Device linearity .............................................................................................. 3-3
3.4   Device carryover ............................................................................................ 3-3
3.5   Sample Stability ............................................................................................ 3-3
3.6   Mode to Mode ................................................................................................ 3-4
3.7   Reference ranges ........................................................................................... 3-5
3.8   Interfering Substances .................................................................................. 3-6

4   INSTALLATION AND FIRST TIME USE ..................................................... 4-1
4.1   Prior the installation ....................................................................................... 4-1
  4.1.1   Select a suitable location ........................................................................... 4-1
    4.1.1.1   Space requirements ............................................................................. 4-1
    4.1.1.2   Mechanical issues ............................................................................... 4-2
    4.1.1.3   Connecting the reagents ................................................................. 4-2
    4.1.1.4   Power connection .............................................................................. 4-2
    4.1.1.5   Connection to the peripherals ............................................................ 4-3
    4.1.1.6   Environment conditions ................................................................. 4-4
  4.1.2   Checking your analyzer upon arrival ...................................................... 4-4
4.2   Performing the installation ............................................................................ 4-5
  4.2.1   Unpacking ................................................................................................. 4-5
    4.2.1.1   Visual inspection ................................................................................. 4-5
  4.2.2   Moving to the selected location .............................................................. 4-6
4.2.3 Connecting the reagents ........................................................................................................ 4-6
4.2.4 Powering up the ‘Abacus 3CT’ ............................................................................................ 4-7
4.2.5 Connecting the peripherals .................................................................................................. 4-7
4.3 First start-up .............................................................................................................................. 4-8
4.4 Primary settings ....................................................................................................................... 4-9
  4.4.1 Setting date and time ......................................................................................................... 4-9
  4.4.2 Adjusting the normal ranges ............................................................................................. 4-9
  4.4.3 Printer setting .................................................................................................................... 4-9
  4.4.4 Bar-code reader ............................................................................................................... 4-10
  4.4.5 Reagent volumes ............................................................................................................. 4-10
  4.4.6 Other settings ................................................................................................................... 4-10
4.5 Familiarization period .............................................................................................................. 4-10
4.6 Calibration and QC .................................................................................................................... 4-10
4.7 Performance checking .............................................................................................................. 4-10
5  BASIC OPERATIONS .................................................................................................................. 5-1
  5.1 Turning the Instrument ON .................................................................................................. 5-1
  5.2 Turning the Instrument OFF ................................................................................................ 5-2
  5.3 Preparing for shipment ......................................................................................................... 5-3
  5.4 Emergency shut-down .......................................................................................................... 5-3
  5.5 Sample measurement ............................................................................................................ 5-4
  5.6 Refilling the printer .............................................................................................................. 5-5
6  THE MENU SYSTEM .................................................................................................................... 6-1
  6.1 General Information .............................................................................................................. 6-1
  6.2 Navigating in the Menu System ............................................................................................ 6-1
  6.3 Items in the menu structure .................................................................................................. 6-3
    6.3.1 Menu selection .............................................................................................................. 6-3
    6.3.2 Radio buttons ............................................................................................................... 6-4
    6.3.3 Check box .................................................................................................................... 6-4
    6.3.4 List box (roll down menu) ............................................................................................ 6-5
    6.3.5 Edit box (data field) ..................................................................................................... 6-5
  6.4 Panels .................................................................................................................................. 6-6
TABLE OF CONTENTS

6.5 Menu structure........................................................................................................................................6-6

7 OPERATING PRINCIPLES.........................................................................................................................7-1
  7.1 Impedance Method....................................................................................................................................7-1
  7.2 Principle of HGB Measurement...........................................................................................................7-1
  7.3 Parameters .............................................................................................................................................7-2

8 ROUTINE UTILIZATION and MEASUREMENT .........................................................................................8-1
  8.1 Sample handling .....................................................................................................................................8-1
  8.2 Initiate the analysis .................................................................................................................................8-3
  8.3 Sample parameters .................................................................................................................................8-6
    8.3.1 Edit sample information ................................................................................................................8-6
    8.3.2 Measurement local menu ..............................................................................................................8-7
    8.3.3 Patient limits .....................................................................................................................................8-7
  8.4 Results ....................................................................................................................................................8-8
    8.4.1 Range flags .......................................................................................................................................8-8
    8.4.2 Measurement condition flags ........................................................................................................8-8
      8.4.2.1 Problems on the WBC –HGB channel ....................................................................................8-9
      8.4.2.2 Problems on the RBC –PLT channel ....................................................................................8-9
    8.4.3 Parameter warning and error flags .................................................................................................8-10
    8.4.4 Modifying lyse quantity .................................................................................................................8-10
  8.5 Blank measurement ...............................................................................................................................8-11

9 DATABASE ..................................................................................................................................................9-1

10 UTILITIES ...............................................................................................................................................10-1
  10.1 Maintenance ........................................................................................................................................10-1
    10.1.1 Cleaning .........................................................................................................................................10-1
    10.1.2 Priming .........................................................................................................................................10-1
    10.1.3 Draining chamber .........................................................................................................................10-2
    10.1.4 Reagent status & Reagent protection ..........................................................................................10-2
  10.2 Calibration ..........................................................................................................................................10-4
    10.2.1 Perform calibration.......................................................................................................................10-5
# TABLE OF CONTENTS

10.2.1.1 *Manual calibration* .................................................. 10-5
10.2.1.2 *Measurement based calibrations* ................................ 10-6
10.2.2 Review old calibration factors ........................................ 10-7

10.3 Quality Control Procedure .................................................. 10-8
10.3.1 Selecting QC level ....................................................... 10-8
10.3.2 Manual entry of QC parameters ....................................... 10-8
10.3.3 QC measurement ......................................................... 10-9
10.3.4 QC database ............................................................ 10-10
10.3.5 QC diagrams ........................................................... 10-10

10.4 Diagnostics ................................................................. 10-10
10.4.1 Device Information ...................................................... 10-10
10.4.2 Statistics ................................................................. 10-11
10.4.3 Self Test ................................................................. 10-11

10.5 Settings ........................................................................ 10-13
10.5.1 Printer settings .......................................................... 10-13
10.5.2 Customize .................................................................. 10-14
10.5.2.1 *General Settings* .................................................. 10-15
10.5.2.2 *Laboratory information* .......................................... 10-16
10.5.3 Date and time ............................................................ 10-16
10.5.4 Fluid sensors ............................................................ 10-17

10.6 Service ........................................................................ 10-18

10.7 Background functions ....................................................... 10-18
10.7.1 Reagent level monitoring ................................................ 10-18

11 MAINTENANCE .................................................................. 11-1

11.1 User-accessible parts ....................................................... 11-1
11.2 Maintenance schedule .................................................... 11-2
11.2.1 Daily maintenance, before daily routine: ......................... 11-2
11.2.2 Daily maintenance, after daily routine: ......................... 11-2
11.2.3 Weekly: ................................................................. 11-2
11.2.4 Semi-annual: ........................................................... 11-3
11.3 Cleaning ................................................................. 11-3

12 PRINTING ....................................................................... 12-1
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.1</td>
<td>Printouts</td>
<td>12-1</td>
</tr>
<tr>
<td>13</td>
<td>FLUIDIC SCHEMATICS</td>
<td>13-1</td>
</tr>
<tr>
<td>14</td>
<td>WARNING LABELS ON THE ANALYZER</td>
<td>14-1</td>
</tr>
</tbody>
</table>
1 INTRODUCTION

This chapter gives a general overview of the ‘Abacus 3CT’ instrument. For detailed information, please check the referred chapters.

1.1 Intended Use

The ‘Abacus 3CT’ hematology analyzer is a fully automated cell counter with a cap piercing function designed for *in vitro* diagnostic use. The instrument is intended for small clinics or laboratories and as a backup system to a primary hematology analyzer.

1.2 The Instrument

The ‘Abacus 3CT’ is a fully automated, bench top hematology cell counter.

It uses the impedance-method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells using a photometric method.

The analyzer features a color graphical LCD display module and a foil keypad of 29 keys including 6 software buttons (with icons), 6 function keys (above LCD) and has a START button.

The instrument allows printing reports to an external printer (USB port), or can have an optional built-in printer module.

Its internal memory is capable of storing 1000 records with full histograms, and individual patient data. The QC measurements are stored in a separate database. The software operating the instrument can be updated by using a USB flash memory device. The instrument can be connected to a host computer for uploading records stored in its memory through a USB SLAVE port (USB B) or serial link (RS232). Archiving records to an USB flash memory device is also possible.

*NOTE: If equipment operation is different from the manufacturer specifications and intended use, the protection provided by the equipment may be impaired. Misuse of equipment or use other than its intended purpose will invalidate conditions of warranty. The accuracy and precision may also be impaired.*

The manufacturer reserves the right to modify instrument setup and accessories when necessary. Such changes do not influence performance unless indicated differently. When such changes occur, compatibility and functionality are always maintained.
1.3 Patient Testing

The analyzer can process 60 samples per hour. Samples can have individual sample data, and additional parameters. You can print results to an external or to the optional built in printer. The user can customize the report format.

The ‘Abacus 3CT’ determines 20 hematology parameters including three-part WBC differential. The instrument requires 100µl of whole blood sample:

<table>
<thead>
<tr>
<th>WBC</th>
<th>white blood cell count</th>
</tr>
</thead>
<tbody>
<tr>
<td>LYM</td>
<td>lymphocyte count</td>
</tr>
<tr>
<td>MID</td>
<td>mid cell count</td>
</tr>
<tr>
<td>GRA</td>
<td>granulocyte count</td>
</tr>
<tr>
<td>LYM%</td>
<td>lymphocytes percentage</td>
</tr>
<tr>
<td>MID%</td>
<td>mid cell percentage</td>
</tr>
<tr>
<td>GRA%</td>
<td>granulocyte percentage</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RBC</th>
<th>red blood cell count</th>
</tr>
</thead>
<tbody>
<tr>
<td>HGB</td>
<td>hemoglobin</td>
</tr>
<tr>
<td>HCT</td>
<td>hematocrit</td>
</tr>
<tr>
<td>MCV</td>
<td>mean corpuscular volume</td>
</tr>
<tr>
<td>MCH</td>
<td>mean corpuscular hemoglobin</td>
</tr>
<tr>
<td>MCHC</td>
<td>mean corpuscular hemoglobin concentration</td>
</tr>
<tr>
<td>RDW (sd,cv)</td>
<td>red blood cell distribution width</td>
</tr>
<tr>
<td>PLT</td>
<td>platelet count</td>
</tr>
<tr>
<td>PCT</td>
<td>plateletcrit</td>
</tr>
<tr>
<td>PDW (sd, cv)</td>
<td>platelet distribution width</td>
</tr>
<tr>
<td>MPV</td>
<td>mean platelet volume</td>
</tr>
</tbody>
</table>

For details, see chapter 7.3

1.4 Technical Operation

The ‘Abacus 3CT’ is a fully automated instrument, operating it requires minimal training and technical support.

The day-to-day operator interaction requirements are:

- Perform and evaluate a ‘blank measurement’ following prolonged inactivity or after power-up;
- Enter sample and/or patient data;
- Run the sample for analysis;
- Print results either one-by-one, or in groups by selecting records from the database;
- Replace consumables (reagents, printer-paper);
- Perform the QC procedures;
- Recalibrate the instrument if necessary;
- Perform simple weekly maintenance, as described later in this description (11.2.3).
1.5 Calibration and Quality Control

Although the ‘Abacus 3CT’ is a precise, accurate and reliable instrument by design and by manufacturing, it is still necessary to monitor the instrument’s performance and re-calibrate if necessary.

The calibration factors can be changed:

- Manually: based on the calibration data of the user of the ‘Abacus 3CT’;
- Automatically (measurement based): the ‘Abacus 3CT’ calculates the calibrations from the target and measured values.

For details, see chapter 10.2.

1.6 Main parts of the Analyzer

The ‘Abacus 3CT’ hematology analyzer is composed of the following three main units:

- **Fluidic System**: Performs sampling, diluting, mixing, and lysing functions. Generates the regulated vacuum used for moving cells through the aperture during the counting process.

- **Data Processing System**: Derives count data, calculates indirect parameters, and generates and stores numerical results and histograms.

- **Control Panel**: Features an LCD display, a 29-button keypad, and USB ports and serial (computer) interfaces.

1.7 User interface

The user interface of the ‘Abacus 3CT’ is based on an interactive graphical menu-system.

The following input devices are available for the user:

- 29-button keypad;
- The start-button with a built-in control LED;
- External keyboard (USB or PS2) (optional);
- External bar-code reader (optional);

The ‘Abacus 3CT’ gives feedback and provides data to the user using the following devices:

- Color LCD display;
- Control LED on the start-button;
- Audio signals (built-in speaker);
- Printouts (optional built-in and optional external printer).

The structure of the menu and the function of the short-cut keys are optimized for everyday usage.

For details of the menu system and the usage of the ‘Abacus 3CT’, see chapters: 1.
1.8 Environmental conditions
The ‘Abacus 3CT’ is designed for laboratory use.

Operating conditions for the ‘Abacus 3CT’ are:

- Temperature: 59–86 °F (15–30 °C). Optimal temperature is 77 °F (25 °C);
- Relative humidity: 65% ± 20% non-condensing;
- Direct power input; 12 VDC fused at 7 A;
- Power input of the external power supply 100/240 VAC.

The ‘Abacus 3CT’ should be used in a clean environment free from vibrations and dust.

For detailed specifications, see chapters 2.3, 4.1.

1.9 Consumables
The ‘Abacus 3CT’ requires the following consumables for proper operation:

1.9.1 Reagents
The performance and lifespan of the ‘Abacus 3CT’ can be guaranteed only if reagents supplied by the manufacturer are used. System performance is optimized using manufacturer’s reagent formulations.

The below reagents are required for the ‘every-day’ routine operation of the ‘Abacus 3CT’.

<table>
<thead>
<tr>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diatro●Dil-DIFF (diluent)</td>
<td>Isotonic saline solution, used to dilute whole blood samples and to rinse the fluidic system between measuring procedures. (Color code: green.)</td>
</tr>
<tr>
<td>Diatro●Lyse-DIFF (lyse)</td>
<td>Creates hemolysate for 3-part WBC differential and for total WBC and HGB. (Color code: yellow.)</td>
</tr>
<tr>
<td>Diatro●Cleaner (cleaner)</td>
<td>Cleaning process of the fluidics. (Color code: blue.)</td>
</tr>
</tbody>
</table>

For details, see chapter 2.3.6.1.
1.9.2 Additional chemicals
These generally available materials listed in this chapter are required occasionally.

<table>
<thead>
<tr>
<th>Name</th>
<th>Material</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hard-cleaner</td>
<td>2% Sodium Hypochlorite solution</td>
<td>Remove clogging, cleaning</td>
</tr>
<tr>
<td>Distilled water</td>
<td>Distilled water</td>
<td>Remove salts, reagents. (“Preparing for shipment” procedure. See: 0)</td>
</tr>
</tbody>
</table>

1.9.3 Additional materials

<table>
<thead>
<tr>
<th>Material</th>
<th>Purpose</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermal paper roll</td>
<td>Printing media for the internal printer</td>
<td>sales representative, dealer</td>
</tr>
<tr>
<td>See chapter 5.6</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QC material (low, normal, high)</td>
<td>Performance checking of the ‘Abacus 3CT’, See chapter 10.3</td>
<td>R &amp;D Systems, CBC-3D</td>
</tr>
<tr>
<td>Calibrator Material</td>
<td>Performing calibration of the ‘Abacus 3CT’</td>
<td>R&amp;D Systems, CBC-CAL PLUS</td>
</tr>
<tr>
<td>General cleaning materials</td>
<td>Cleaning the ‘Abacus 3CT’</td>
<td>general</td>
</tr>
</tbody>
</table>

1.10 General points
The manufacturer guarantees work, safety, reliability and general characteristics under the following conditions only:

- Services and repairs are performed by an authorized technician;
- The electrical system of the laboratory follows national and/or international regulations;
- The system is operated according to instructions contained herein.
2 DESCRIPTION OF THE ABACUS 3CT INSTRUMENT

In this chapter, you can find details about the ‘Abacus 3CT’ instrument.

2.1 Identifying parts of the analyzer

2.1.1 Front view
2.1.2 Rear view

- Vent holes
- Additional grounding point
- Instrument label
- Reagent & waste connections
- Warning labels
- USB-A ports (printer, keyboard, bar-code reader)
- USB-B port (host connection)
- PS-2 port (keyboard)
- Power switch
- Power supply connector
- RS-232 port (host connection)
2.1.2.1 Reagent connectors

The reagent manifolds are located in the bottom, left corner of the rear panel of the ‘Abacus 3 CT’.

2.1.3 Left side
2.1.4 Right side

2.1.4.1 Closed door

The user accessible parts are behind the right-hand side door. See chapter 11.1 for details.

2.1.4.2 Opened door
2.1.5 Printer
The (optional) built-in printer is located on the top of the ‘Abacus 3CT’ instrument.

You can configure this printer in the “Printer Settings” menu (see chapter 10.5.1).

2.1.6 External power supply
The analyzer works with an external power supply. The power supply unit generates 12VDC. The power supply module has an auto range input, allowing operation on 100V - 240V power system. The power supply fulfills the CE and UL safety requirements.

The input socket is a standard power cable connection shipped with the analyzer; the output is a special, lockable socket as shown in the picture.

Only the provided power supply shall be used with the instrument. (“GLOBTEK INC”, Model ID: GT-9100P10012)
2.2 Accessories

Below is a list of accessories shipped with your ‘Abacus 3CT’.

- ‘Abacus 3CT’ Hematology Analyzer;
- ‘Abacus 3CT’ Operator’s Manual;
- ‘Abacus 3CT’ Reagent Pickup Tubes (with colored connector caps)
  - Diluent tube (green)
  - Lyse tube (yellow)
  - Clean tube (blue)
  - 2x Waste tube (red)
- ‘Abacus 3CT’ Cleaning Tube Kit.
- Caps for reagent containers (matching connector colors);
- Waste Container (20 L);
- External power supply for ‘Abacus 3CT’ and localized power cord;
- Thermal roll-paper;
- 3 sample adapters (different sizes).

1. Reagent tubing kit
2. Cleaning Tube kit
2.3 Specifications

In this chapter, you can find technical details about the ‘Abacus 3CT’ instrument.

2.3.1 Temperature & Humidity

<table>
<thead>
<tr>
<th>Operating conditions</th>
<th>Temperature: 59–86 °F (15–30 °C). Optimal temperature is 77 °F (25 °C). Relative humidity: 65% ± 20% non-condensing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Storage conditions</td>
<td>Temperature: 41–95 °F (5–35 °C). Relative humidity: 15% - 90% non-condensing</td>
</tr>
</tbody>
</table>

Avoid using the instrument in areas of extremely high or low temperatures or where it is exposed to direct sunlight. If the ‘Abacus 3CT’ was kept at a temperature lower than 50°F (10°C), then the instrument should sit for 2 hours at the correct room temperature before use.

If the ‘Abacus 3CT’ is moved to a warmer place, be sure that no condensation can happen on or inside the ‘Abacus 3CT’.

Reagents should be stored at a temperature range of 59–86 °F (15-30°C).

2.3.2 Mechanical data & space requirements

<table>
<thead>
<tr>
<th>Dimensions (W x D x H)</th>
<th>340 x 414 x 380 mm (13.4” * 16.1” * 14.9”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net weight</td>
<td>17 kg (37.5 LBS)</td>
</tr>
</tbody>
</table>

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance. Consider the following space requirements:

- Select a location near a power source and close to a suitable drain;
- Place the unit on a clean and level surface;
- Leave at least 20” (0.5m) space on both sides and above the instrument to access pneumatics and (optional) built in printer. Provide a minimum of 7” (20cm)between the rear panel and the wall to allow for heat dissipation and tube clearance;
- Install the reagents in a suitable place with easy access. The best place is on the ground, below the supporting desk of the instrument. The pneumatics system is capable of aspirating reagents from containers being 3.3ft (1m) below the reagent inputs. Make sure the reagent tubes are not bent, broken, twisted or blocked in between the desk the instrument is on and the wall behind. Such circumstances can result in instrument operation failure;
- DO NOT PLACE the reagents above the instrument, as there can be a risk of falling and spilling;

**WARNING:** Install the unit on a table or workbench. If the unit was installed without a supporting desktop under the unit, there is a possibility that the analyzer could accidentally fall.
## 2.3.3 Electrical data

<table>
<thead>
<tr>
<th>Power requirement</th>
<th>12VDC, fused at 7A.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power supply unit</td>
<td>External, auto-ranging power unit.</td>
</tr>
<tr>
<td></td>
<td>Input: 100-240 VAC, 47–63Hz, Maximum input current: 6.0A at 90VAC and 3.0A at 240VAC.</td>
</tr>
<tr>
<td></td>
<td>Output: 12VDC/0-8.34A/0-100W.</td>
</tr>
</tbody>
</table>

The ‘Abacus 3CT’ is delivered with an auto-range external power supply (Input 100 – 240 VAC, 47 – 63 Hz, maximum input current 6.0A at 90VAC and 3.0A at 240VAC; Output 12VDC, maximum output current 8.34 A) and a localized power cord.

![Diagram](image)

The analyzer should only be operated from a wall outlet meeting general specifications of power input requirements: 110/240VAC; 47Hz to 63Hz.

If the power network is not reliable, contact your representative for options (e.g. installation of an external UPS module).

Only the power cord supplied with the instrument should be used. Avoid using extension cords.

Please check the power consumption of the additional devices (printer) as well.
The grounding of the ‘Abacus 3CT’ instrument can be ensured via:

- The power supply and the appropriate power cord;
  - and/or
- The additional grounding point (See chapter 2.1.2, rear-view).

If you decide to use both grounding methods then please consider the effects of the ground looping. Ask for support of a qualified electrician.

| ![Warning] | Improper grounding of ‘Abacus 3CT’ bypasses important safety features and may result in electrical hazard. |
| ![Warning] | If a device directly connected to the ‘Abacus 3CT’ (USB, serial port) has its own power supply then use the same ground-point! (Use the same wall-socket group.) Contact a qualified electrician if you have doubts about the quality of the grounding. |

The ‘Abacus 3CT’ is safe for transient voltages to INSTALLATION CATEGORY II and POLLUTION DEGREE 2.

### 2.3.4 Peripherals and external devices

You can connect several peripherals to the ‘Abacus 3CT’ instrument.

| ![Warning] | As a general rule: if the peripheral you want to connect has its own power source / power supply then turn off both the peripheral device to be connected and the ‘Abacus 3CT’ instrument as well before connecting the peripheral device. |
| ![Warning] | The peripheral connectors on the ‘Abacus 3CT’ are SELV (safety extra low voltage) connectors, only connect external devices that are SELV rated to the instrument. |

You can connect the following devices:

- **Printers:**
  - Please contact Diatron or your sales/service representative for the list of supported printers;
  - Please ensure that the selected printer has CE/UL mark;

- **Keyboards:** you shall not connect more than 1 external keyboard at a time:
  - Keyboards with PS2 connector:
    - Possible to connect if the ‘Abacus 3CT’ is powered off;
  - Keyboards with USB connector:
    - Possible to connect if the ‘Abacus 3CT’ is powered on or powered off;

- **Bar-code readers with USB connector:**
  - Please contact Diatron or your sales/service representative for the list of supported bar-code readers;
  - Please ensure that the selected bar-code reader has CE/UL mark (leaser radiation);
  - Please ensure that the selected bar-code reader supports the bar-code format used at your site;
  - Possible to connect if the ‘Abacus 3CT’ is powered on;

- **USB memory devices:**
  - USB memory sticks
    - Up to 2 GB (2048 MB);
- Possible to connect if the ‘Abacus 3CT’ is powered on, wait for end of activity;
- Host computer
  - Via serial (RS-232) link;
  - Via USB link
    - USB-B port on the ‘Abacus 3CT’ side, USB-A port on the host side; To utilize this USB connection, you may need to install a suitable driver on the computer. Refer to your Service Engineer for instructions
    - USB A-B cable required.

2.3.5 User Interface

<table>
<thead>
<tr>
<th>User interface</th>
<th>Easy-to-use, menu driven user interface with 6 software buttons (with graphic icons), 6 hardware function buttons, cursor and numeric keys.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Languages available</td>
<td>English</td>
</tr>
<tr>
<td>Data capacity</td>
<td>1000 results with RBC, PLT, WBC 3-part histogram</td>
</tr>
<tr>
<td>Host computer interface</td>
<td>USB B port or RS-232 serial link.</td>
</tr>
<tr>
<td>Data back-up method</td>
<td>USB mass storage device</td>
</tr>
<tr>
<td>Printer interface</td>
<td>USB with support for printers, color and monochrome printout.</td>
</tr>
<tr>
<td>Built-in printer</td>
<td>“Easy Paper Operation” thermal printer module, 58 mm (2.3”) wide roll paper, full report with histograms.</td>
</tr>
<tr>
<td>Display</td>
<td>320x240-dots, high-contrast, backlit, color graphics LCD</td>
</tr>
<tr>
<td>Keypad</td>
<td>29 foil keys + separate START button, red/green/orange machine state light.</td>
</tr>
<tr>
<td>External keyboard</td>
<td>Standard PS/2 compatible or USB</td>
</tr>
</tbody>
</table>

The user interface is a graphical menu system. The first level menu items are accessible from any other menu-points via the hard short-cut keys (6 pieces) located over the LCD screen.

The user can navigate in the menu-tree using the built-in keypad and/or an external keyboard.

**START button** - If the analyzer is in measurement-ready mode then pressing and releasing the START button triggers an analysis cycle (Measurement screen displayed and START button lit green).

**Status indicator** - A two-color (red/green) LED is located near the START button.

The actual color indicates the status of the analyzer.

<table>
<thead>
<tr>
<th>LED color</th>
<th>Analyzer status</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Green</td>
<td>The analyzer is ready to work. Analysis can be initiated.</td>
</tr>
<tr>
<td>• Red blinking</td>
<td>Blood sample can be removed when the LED blinks red 3 times and the instrument beeps 3 times.</td>
</tr>
<tr>
<td>• Red</td>
<td>The analyzer is currently performing an analysis. No new measurement can be started.</td>
</tr>
<tr>
<td>• Orange</td>
<td>The analyzer is performing a maintenance process.</td>
</tr>
<tr>
<td>• Orange blinking</td>
<td>The instrument is in stand-by and display (LCD) light is off.</td>
</tr>
</tbody>
</table>
2.3.6 Reagents and control material
Always use reagents and control materials recommended and approved by the manufacturer. The analyzer, the control material and the reagents form a system. Each component of this system is carefully selected and designed to meet certain criteria, which can very sensitively indicate and validate system operation.

Using non-approved components of this system can cause false indications or incorrect, inaccurate measurements.

2.3.6.1 Reagents
In order to operate correctly and accurately the following reagents must be used.

All these reagents are manufactured and provided by Diatron MI Plc.

All these reagents are for in vitro use only!

![Warning]

- If the eyes or skin comes into contact with any of the reagents, flush abundantly with water.
- If a large quantity is ingested, drink water immediately and contact a doctor.

Ask for the MSDS (Material Safety Data Sheet) for the reagents from your dealer or they can be downloaded from the WWW pages of Diatron MI Plc. (www.diatron.com)

You can find useful information on the “PACKAGE INSERT” notes as well.

2.3.6.1.1 Diatro•Dil-DIFF diluent

<table>
<thead>
<tr>
<th>Description</th>
<th>Multiple micro-filtered, particle free, buffered isotonic solution, containing stabilizers, special additives and preservatives.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td>Quantitative and qualitative determination of RBC, WBC, PLT and HGB concentration measurement.</td>
</tr>
<tr>
<td>Appearance</td>
<td>Colorless, odorless solution.</td>
</tr>
<tr>
<td>Shelf-life</td>
<td>36 months</td>
</tr>
<tr>
<td>Open container stability</td>
<td>120 days</td>
</tr>
<tr>
<td>Storage</td>
<td>Between 15 °C - 30 °C. (59-86 °F)</td>
</tr>
<tr>
<td>Diatron reagent code</td>
<td>D1012 (20L cubitainer) optional: D1015: 5L cubitainer</td>
</tr>
<tr>
<td>Color code</td>
<td>Green</td>
</tr>
</tbody>
</table>

The product is environmental-friendly, since does not contain azide nor cyanide.
2.3.6.1.2 Diatro•Lyse-DIFF lysing agent

<table>
<thead>
<tr>
<th>Description</th>
<th>Stabilized and micro-filtered lysing agent.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td>Stromatolysis of erythrocytes (RBC), for quantitative determination of leukocytes (WBC), leukocyte three-part differentiation (LYM, MID, GRAN) and hemoglobin (HGB) concentration measurement in human blood on Diatron hematology analyzers.</td>
</tr>
<tr>
<td>Appearance</td>
<td>Colorless solution with characteristic odor</td>
</tr>
<tr>
<td>Shelf-life</td>
<td>48 months</td>
</tr>
<tr>
<td>Open container stability</td>
<td>120 days</td>
</tr>
<tr>
<td>Storage</td>
<td>15 °C - 30 °C. (59-86 °F)</td>
</tr>
<tr>
<td>Diatron reagent code</td>
<td>D2011 (1L bottle) optional: D2015 – 5L cubitainer</td>
</tr>
<tr>
<td>Color code</td>
<td>Yellow</td>
</tr>
</tbody>
</table>

The product is environmental-friendly, since does not contain azide nor cyanide.

2.3.6.1.3 Diatro•Cleaner cleaning agent

<table>
<thead>
<tr>
<th>Description</th>
<th>Stabilized and micro-filtered detergent solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td>Regular automated cleaning, rinsing and washing of hematology analyzers’ capillaries, tubing and chambers, removing blood component precipitates and lipoprotein deposits on Diatron hematology analyzers.</td>
</tr>
<tr>
<td>Appearance</td>
<td>Colorless solution with characteristic odor.</td>
</tr>
<tr>
<td>Shelf-life</td>
<td>48 months</td>
</tr>
<tr>
<td>Open container stability</td>
<td>120 days</td>
</tr>
<tr>
<td>Storage</td>
<td>15 °C - 30 °C. (59-86 °F)</td>
</tr>
<tr>
<td>Diatron reagent code</td>
<td>D5011 (1L bottle) optional: D5015 – 5L cubitainer</td>
</tr>
<tr>
<td>Color code</td>
<td>Dark blue</td>
</tr>
</tbody>
</table>

The product is environmental-friendly, since does not contain azide nor cyanide.
2.3.6.2 Control Material
The R&D Systems, ‘CBC-3D’ control material (control blood) is selected to perform the QC measurements on the ‘Abacus 3CT’ instrument.

Please note that the specifications (target values) of the control materials can change lot-by-lot. The actual values can be found on the enclosed package insert.

2.3.6.3 Calibrator
The R&D Systems, ‘CBC-CAL PLUS’ calibrator is the selected material to perform measurement based calibrations. See chapter 10.2.

Please note that the specifications (target values) of the calibrator material can change lot-by-lot. The actual values can be found on the enclosed package insert.

2.3.7 Measurement technology

<table>
<thead>
<tr>
<th>Sample volume</th>
<th>100 μl of whole blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chambers</td>
<td>3 chambers for diluting whole blood and counting; 1:MIX, 1:RBC, 1:WBC, +1 needle-washing chamber</td>
</tr>
<tr>
<td>Reagent system</td>
<td>Isotonic Diluent, Lyse, Cleaner</td>
</tr>
<tr>
<td>Aperture diameter</td>
<td>80 μm (RBC/PLT), 100 μm (WBC)</td>
</tr>
<tr>
<td>Throughput</td>
<td>60 tests/hour</td>
</tr>
<tr>
<td>Sampling method</td>
<td>Open or closed tube system with automatic sample rotor.</td>
</tr>
<tr>
<td>Sample types</td>
<td>Human(general), Male, Female, “Alternate 1”, “Alternate 2”, (built-in reference ranges) See chapter 2.3.7.2</td>
</tr>
<tr>
<td>Clog prevention</td>
<td>High-voltage pulse on aperture in each analysis cycle; chemical cleaning; high-pressure back flush of aperture with Cleaner reagent.</td>
</tr>
<tr>
<td>Cleaning procedure</td>
<td>High-voltage burst of the aperture, high-pressure back-flush, chemical cleaning of the aperture using Cleaner reagent.</td>
</tr>
<tr>
<td>Quality control</td>
<td>6 QC levels, QC parameters include: mean, ± range, SD and CV for all measured and calculated parameters, 16- and 64-day Levey-Jennings charts, and separate QC database.</td>
</tr>
<tr>
<td>Calibration</td>
<td>1 or 3-measurement automatic and manual (factors) calibration of WBC, HGB, RBC, PLT, MCV and MPV absolute.</td>
</tr>
</tbody>
</table>
2.3.7.1 **Function of the Fluidics**

For the Schematics of the fluidics system, see Section1.

Stages of the blood testing process:

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>100 µl of anti-coagulated (K3-EDTA) whole blood sample is aspirated through the sampling needle, mixed with diluent and stored in the mixing chamber.</td>
</tr>
<tr>
<td>b</td>
<td>A part of primary diluted sample is then aspirated and mixed with more diluent into the RBC chamber.</td>
</tr>
<tr>
<td>c</td>
<td>The primary dilution remaining in the mixing chamber flows into the WBC chamber where the necessary amount of lysing reagent is added.</td>
</tr>
<tr>
<td>d</td>
<td>WBC cell counting is started. HGB is measured at the end of the WBC counting process</td>
</tr>
<tr>
<td>e</td>
<td>RBC and PLT measurement is run</td>
</tr>
<tr>
<td>f</td>
<td>The system drains and cleans measuring chambers and related tubing system, and prepares for the next blood sample</td>
</tr>
</tbody>
</table>

**Table 1.**

Nominal dilution rates used within ‘Abacus 3CT’:

- Primary dilution 1:160
- Total RBC dilution 1:25 600
- WBC dilution 1:196

Measurement times:

- WBC count 2-6 seconds
- HGB measurement 2 seconds
- RBC/PLT count 5 seconds
2.3.8  Reagent and waste connections
The reagents and the waste (2 connectors) connected to the ‘Abacus 3CT’ via plastic connectors. The fluid path is grounded inside the ‘Abacus 3CT’ instrument.

The reagent tubing can be connected by pushing the tubes onto the stainless steel manifold. If you want to remove the tubing then it is better to push it at the edge of the tube than simply pull the tube, because the elastic tube will shrink as you pull it and bond stronger to the manifold.

Place the reagent and waste containers near the instrument, to an accessible location. Do not place the containers to a higher position than that of ‘Abacus 3CT’, because if a tube comes off its connector, the fluids would spill out. Use the supplied connecting tubes and special bottle caps. Be sure that the color on each tube, cap and connector in the back of the instrument match. You can place the reagent containers below the desk the analyzer is installed on, as the instrument has sufficient power to draw the liquids from a lower location.

WARNING!  Reagents may cause corrosion and skin irritation. If any liquids leak onto the cover of analyzer or the furniture, it has to be wiped down immediately. In case of skin contact, the liquid has to be flushed with plenty of water.

The two waste connectors of the ‘Abacus 3CT’ must not be connected together before the Waste container! If 2 separate connections are not used then the performance of ‘Abacus 3CT’ and the lifetime of the pumps can be degraded, and some internal tube-connections can leak.
2.3.9 **Reagent and waste handling**

The reagents and the waste should be handled according to the applicable local regulations.

If there is a difference between the different regulations (MSDS, hospital, state, federal level regulations), then always follow the ‘stricter’ regulation.

---

**WARNING!** Reagents may cause corrosion and skin irritation. If any of the liquids leaked onto the cover of analyzer or the furniture, wipe it off immediately. In case of skin contact, flush with plenty of water.

Waste generated by the unit is biohazard material. Handling and disposal must happen according to local regulations regarding reagent systems.

**WARNING!** The waste contains hazardous substances because of chemical content and human blood. These substances are representing a potential hazard to the environment. For this reason, safe handling of the waste liquid is very important.
2.3.10 **Reagent security system**

The ‘Abacus 3CT’ is equipped with a reagent security system.

The ‘Abacus 3CT’ will reject your measurement requests if the allotted amount of reagent has been fully utilized and the reagent container is empty. You can refill your account using the ‘hardware keys’ (identifier module) provided with the lysing reagent. Each supplied hardware key contains a specific number of measurements. After connecting the ‘hardware key’ to the ‘Abacus 3CT’, you can ‘upload’ the measurement allowance.

By default, a hardware key (identifier module), containing 800 measurements, is attached to the 5L lyse container. The 1L bottle is delivered along with a hardware key containing 300 measurements.

See chapter 10.1.4 about the technical steps to activate the purchased measurement allowance.
3 PERFORMANCE CHARACTERISTICS

The performance characteristics of the ‘Abacus 3CT’ are described below:

- Accuracy:
- Precision:
- Linearity:
- Carryover:
- Sample Stability:
- Mode to Mode:
- Reference ranges:
- Interfering Substances:
### 3.1 Device accuracy

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Difference Criteria</th>
<th>Evaluation Levels</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absolute ±</td>
<td>Percent ±</td>
</tr>
<tr>
<td>WBC (10^3/µl)</td>
<td>0.30</td>
<td>6.00%</td>
</tr>
<tr>
<td>GRA% (%)</td>
<td>3.00</td>
<td>10.00%</td>
</tr>
<tr>
<td>LYM% (%)</td>
<td>3.00</td>
<td>10.00%</td>
</tr>
<tr>
<td>MID% (%)</td>
<td>3.00</td>
<td>10.00%</td>
</tr>
<tr>
<td>RBC (10^6/µl)</td>
<td>0.15</td>
<td>6.00%</td>
</tr>
<tr>
<td>HGB (g/dl)</td>
<td>0.30</td>
<td>6.00%</td>
</tr>
<tr>
<td>MCV (fl)</td>
<td>1.00</td>
<td>6.00%</td>
</tr>
<tr>
<td>RDW (%)</td>
<td>0.50</td>
<td>6.00%</td>
</tr>
<tr>
<td>PLT (10^3/µl)</td>
<td>15.00</td>
<td>8.00%</td>
</tr>
<tr>
<td>MPV (fl)</td>
<td>0.50</td>
<td>10.00%</td>
</tr>
</tbody>
</table>

### 3.2 Device precision

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Repeatability</th>
<th>Within-Device Precision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>SD</td>
<td>CV%</td>
</tr>
<tr>
<td>WBC (10^3/µl)</td>
<td>&lt; 0.18</td>
<td>&lt; 2.7 %</td>
</tr>
<tr>
<td>GRA% (%)</td>
<td>&lt; 3.5</td>
<td>N/A</td>
</tr>
<tr>
<td>LYM% (%)</td>
<td>&lt; 3.1</td>
<td>N/A</td>
</tr>
<tr>
<td>MID% (%)</td>
<td>&lt; 2.0</td>
<td>N/A</td>
</tr>
<tr>
<td>RBC (10^6/µl)</td>
<td>&lt; 0.11</td>
<td>&lt; 1.7 %</td>
</tr>
<tr>
<td>HGB (g/dl)</td>
<td>&lt; 0.20</td>
<td>&lt; 2.0 %</td>
</tr>
<tr>
<td>MCV (fl)</td>
<td>&lt; 1.0</td>
<td>&lt; 1.7 %</td>
</tr>
<tr>
<td>RDW (%)</td>
<td>&lt; 0.4</td>
<td>&lt; 2.5 %</td>
</tr>
<tr>
<td>PLT (10^3/µl)</td>
<td>&lt; 23</td>
<td>&lt; 6.0 %</td>
</tr>
<tr>
<td>MPV (fl)</td>
<td>&lt; 0.45</td>
<td>&lt; 8.7 %</td>
</tr>
</tbody>
</table>
### 3.3 Device linearity

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Determination $\left( R^2 \right)$</th>
<th>Nonlinearity absolute error</th>
<th>Nonlinearity relative error</th>
<th>Reportable Low</th>
<th>Reportable High</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC $\left( 10^3/\mu l \right)$</td>
<td>&gt; 0.95</td>
<td>&lt; 0.80</td>
<td>&lt; 3.0 %</td>
<td>0.0</td>
<td>85.0</td>
</tr>
<tr>
<td>HGB (g/dl)</td>
<td>&gt; 0.95</td>
<td>&lt; 0.27</td>
<td>&lt; 3.0 %</td>
<td>1.0</td>
<td>25.0</td>
</tr>
<tr>
<td>RBC $\left( 10^6/\mu l \right)$</td>
<td>&gt; 0.95</td>
<td>&lt; 0.20</td>
<td>&lt; 3.0 %</td>
<td>0.00</td>
<td>8.00</td>
</tr>
<tr>
<td>PLT $\left( 10^3/\mu l \right)$</td>
<td>&gt; 0.95</td>
<td>&lt; 35</td>
<td>&lt; 3.0 %</td>
<td>0</td>
<td>1000</td>
</tr>
</tbody>
</table>

### 3.4 Device carryover

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Maximum Carryover (%)</th>
<th>Reportable Low</th>
<th>Reportable High</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC $\left( 10^3/\mu l \right)$</td>
<td>&lt; 1.0%</td>
<td>0.0</td>
<td>85.0</td>
</tr>
<tr>
<td>HGB (g/dl)</td>
<td>&lt; 0.8%</td>
<td>1.0</td>
<td>25.0</td>
</tr>
<tr>
<td>RBC $\left( 10^6/\mu l \right)$</td>
<td>&lt; 0.5%</td>
<td>0.00</td>
<td>8.00</td>
</tr>
<tr>
<td>PLT $\left( 10^3/\mu l \right)$</td>
<td>&lt; 1.0%</td>
<td>0</td>
<td>1000</td>
</tr>
</tbody>
</table>

### 3.5 Sample Stability

Long-term sample stability studies on blood specimens drawn in K$_3$EDTA collection tubes at room temperature showed no significant clinical variation for all parameters between 30 minutes and 7 hours post phlebotomy. MPV results can show an unstability in the first two hours but are stable afterwards.
### 3.6 Mode to Mode

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Difference Criteria</th>
<th>Evaluation Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Absolute ±</td>
<td>Percent ±</td>
</tr>
<tr>
<td>WBC (10^3/µl)</td>
<td>0.30</td>
<td>6.00%</td>
</tr>
<tr>
<td>GRA% (%)</td>
<td>3.00</td>
<td>10.00%</td>
</tr>
<tr>
<td>LYM% (%)</td>
<td>3.00</td>
<td>10.00%</td>
</tr>
<tr>
<td>MID% (%)</td>
<td>3.00</td>
<td>10.00%</td>
</tr>
<tr>
<td>RBC (10^6/µl)</td>
<td>0.15</td>
<td>6.00%</td>
</tr>
<tr>
<td>HGB (g/dl)</td>
<td>0.30</td>
<td>6.00%</td>
</tr>
<tr>
<td>MCV (fl)</td>
<td>1.00</td>
<td>6.00%</td>
</tr>
<tr>
<td>RDW (%)</td>
<td>0.50</td>
<td>6.00%</td>
</tr>
<tr>
<td>PLT (10^3/µl)</td>
<td>15.00</td>
<td>8.00%</td>
</tr>
<tr>
<td>MPV (fl)</td>
<td>0.50</td>
<td>10.00%</td>
</tr>
</tbody>
</table>
### 3.7 Reference ranges

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Male</th>
<th>Female</th>
<th>Human</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>WBC</td>
<td>4.0</td>
<td>11.7</td>
<td>4.0</td>
<td>11.7</td>
</tr>
<tr>
<td>LYM%</td>
<td>7.1</td>
<td>43.1</td>
<td>7.1</td>
<td>43.1</td>
</tr>
<tr>
<td>MID%</td>
<td>0.0</td>
<td>18.8</td>
<td>0.0</td>
<td>18.8</td>
</tr>
<tr>
<td>GRA%</td>
<td>44.4</td>
<td>86.4</td>
<td>44.4</td>
<td>86.4</td>
</tr>
<tr>
<td>LYM</td>
<td>0.6</td>
<td>3.1</td>
<td>0.6</td>
<td>3.1</td>
</tr>
<tr>
<td>MID</td>
<td>0.2</td>
<td>1.8</td>
<td>0.2</td>
<td>1.8</td>
</tr>
<tr>
<td>GRA</td>
<td>2.4</td>
<td>9.2</td>
<td>2.4</td>
<td>9.2</td>
</tr>
<tr>
<td>RBC</td>
<td>3.26</td>
<td>5.73</td>
<td>2.75</td>
<td>5.59</td>
</tr>
<tr>
<td>HGB</td>
<td>10.1</td>
<td>16.5</td>
<td>8.8</td>
<td>15.5</td>
</tr>
<tr>
<td>HCT</td>
<td>30.6</td>
<td>49.6</td>
<td>26.1</td>
<td>47.4</td>
</tr>
<tr>
<td>MCV</td>
<td>76.4</td>
<td>102.0</td>
<td>76.4</td>
<td>102.0</td>
</tr>
<tr>
<td>MCH</td>
<td>23.3</td>
<td>36.1</td>
<td>23.3</td>
<td>36.1</td>
</tr>
<tr>
<td>MCHC</td>
<td>29.7</td>
<td>36.7</td>
<td>29.7</td>
<td>36.7</td>
</tr>
<tr>
<td>RDW</td>
<td>12.2</td>
<td>16.6</td>
<td>12.2</td>
<td>16.6</td>
</tr>
<tr>
<td>PLT</td>
<td>97</td>
<td>390</td>
<td>97</td>
<td>390</td>
</tr>
<tr>
<td>MPV</td>
<td>7.1</td>
<td>10.9</td>
<td>7.1</td>
<td>10.9</td>
</tr>
</tbody>
</table>
### 3.8 Interfering Substances

The following substances can interfere with parameter measurement and alternate measurement procedures may be required.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>WBC</td>
<td>&gt; 5 NRBC’s/100 WBC’s, PLT clumps/large PLTs</td>
</tr>
<tr>
<td>RBC</td>
<td>WBC Count &gt; 50.0 x10³/µL</td>
</tr>
<tr>
<td>MCV</td>
<td>WBC Count &gt; 50.0 x10³/µL</td>
</tr>
<tr>
<td>PLT</td>
<td>PLT clumps/large PLTs (Abnormal histogram)</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>WBC count &gt; 50.0 x10³/µL, Lipids &gt; 270 mg/dL</td>
</tr>
<tr>
<td>Differential</td>
<td>&gt; 5 NRBC’s/100 WBC’s, PLT clumps/large PLTs (Abnormal histogram)</td>
</tr>
</tbody>
</table>
4 INSTALLATION AND FIRST TIME USE

The ‘Abacus 3CT’ is a complex medical device. You must take some precautions before turning the analyzer on. First, you should read this manual, especially this chapter.

*Always handle the instrument with care.*

4.1 Prior the installation

Before you start the installation procedure, please ensure that the following conditions are fulfilled:

- A suitable location is found for the ‘Abacus 3CT’ instrument;
- You will have time enough to perform the necessary steps precisely. The installation and the first start-up takes approximately 2-3 hours;
- At least 2 persons are available to perform the installation. (Not including the Diatron qualified service personnel);
- You have the contact information to the Diatron representative/service;
- Local support (i.e. electrician) is available if necessary during the installation;
- Check chapter 2.3 (precautions, limits, specification).

It is also beneficiary if the ‘normal ranges’ are decided as well. See chapter 3.53.7.

4.1.1 Select a suitable location

When selecting a location for the ‘Abacus 3CT’ please take into account your requirements (safety, ergonomics, and logistics of blood-samples) and the requirement of the ‘Abacus 3CT’ (safety, operation, environment). Check chapter 2.3.

> It is important to install the instrument in a suitable location. A poor location can adversely affect its performance. Consider the space requirements.

4.1.1.1 Space requirements

It is important to install the instrument in a suitable location. A poor location can adversely affect its performance.

See chapter 2.3.2 for details and site drawing.

Please check that there is space enough for your additional tools, devices as well, like printer, sample holders, printed reports etc.
4.1.1.2 Mechanical issues

The ‘Abacus 3CT’ weighs 17 Kg (~38 lbs), the weight of the ‘Abacus 3CT’ with external keyboard, documents etc. can weigh 25 Kg (~55 lbs). If you decide to store the reagents on the same table, laboratory shelf, workbench where the ‘Abacus 3CT’ is installed, then the weight of whole system can reach 65 Kg (~144 lbs).

Diatron recommends placing the reagents under the table where the ‘Abacus 3CT’ is installed. (You can save table-space, you do not need to lift the reagent containers, and you can store a spare set of reagents under the table as well.

Please select a table, laboratory shelf, or other location that can support the weight of the ‘Abacus 3CT’ and the accessories and is free from vibrations.

Although a single person can carry the ‘Abacus 3CT’, it is still recommended that 2 people carry the ‘Abacus 3CT’.

- To keep the instrument leveled and prevent the content of measuring chambers from spilling out;
- Move the instrument to a precise location especially if cables, power-cords, reagent tubing are present.

If you decide to run the reagent tubing through the tabletop, then please drill the holes before the installation process starts.

| ! | To allow reliable operation and to provide a safe working environment, make sure that the table supporting the unit is stable enough to carry the weight of the instrument and necessary accessories. Reagents should be placed below the supporting desk, or next to the analyzer on the same level, not above the analyzer. Reagents below the analyzer save desk space. |

4.1.1.3 Connecting the reagents

The ‘Abacus 3CT’ is capable to aspirate reagents from 1.0m (~3.3’). (Measured from the bottom of the reagent container to the table level where the ‘Abacus 3CT’ is installed.)

You will use 3 input reagents and two waste outputs. Select a location close to a suitable drain. The waste container should be periodically emptied.

You can place the reagents below or on the same level where the ‘Abacus 3CT’ is installed. Do not place the reagents to a higher location than the bottom of the ‘Abacus 3CT’, because in case of any tubing problem, valve error etc. the reagent can spill out.
4.1.1.4 Power connection

The ‘Abacus 3CT’ is delivered with an auto-range external power supply (Input 100 - 240, 47 – 63 Hz, maximum input current 6.0A at 90VAC and 3.0A at 240VAC; Output 12VDC, maximum output current 8.34 A) and a localized power cord.

The analyzer should only be operated from a wall outlet meeting general specifications of power input requirements: 110/220VAC; 47Hz to 63Hz
If the power network is not reliable, contact your representative for options (e.g. installation of an external UPS module).
Only the power cord supplied with the instrument should be used. Avoid using extension cords.

Please check the power consumption of the additional devices (printer) as well.

The ‘Abacus 3CT’ instrument can be grounded through the power supply and / or by using the additional grounding point (See chapter 02.1.2, rear-view). If you decide to use both grounding methods, then please contact a qualified electrician (clarify the effect of “ground looping”).

WARNING: Improper grounding of ‘Abacus 3CT’ bypasses important safety features and may result in electrical hazard.

Note: If a device directly connected to the ‘Abacus 3CT’ (USB, serial port) and has its own power supply then use the same ground-point! (Use the same wall-socket group.) Contact a qualified electrician if you have doubts about the quality of the grounding.

The ‘Abacus 3CT’ is safe for transient voltages to INSTALLATION CATEGORY II and POLLUTION DEGREE 2.

4.1.1.5 Connection to the peripherals

If you plan to connect the ‘Abacus 3CT’ to any external devices (printer, host-computer etc.) then prior the installation please check the possible cable paths. If it is necessary then make all the preparations (cable-channels, cable-binders, drilling trough tables, walls etc.) before the installation starts.
4.1.1.6 Environment conditions

<table>
<thead>
<tr>
<th>The ‘Abacus 3CT’ is designed for laboratory operation. Mobile operation is not supported. Operate ‘Abacus 3CT’ within the ambient temperature range of 59–86 °F (15–30 °C). Optimal temperature is 77 °F (25 °C) and relative humidity: 65% ± 20% non-condensing.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reagents should be stored at a temperature range of 59–86 °F (15–30 °C).</td>
</tr>
<tr>
<td>The ‘Abacus 3CT’ operates properly up to 9800 ft (3000 m) above sea level.</td>
</tr>
<tr>
<td>Do not place the reagent containers to a higher position than the ‘Abacus 3CT’. This is to avoid unintentional spilling of reagents. The vertical distance between the reagent container and ‘Abacus 3CT’ must not be more than 3.3 ft (1 m).</td>
</tr>
</tbody>
</table>

The instrument should be placed in a well-ventilated location. The instrument should not be placed near potentially interfering devices capable of emitting radio frequencies (e.g. radio or television transmitters/receivers, radars, centrifuge, X-ray devices, fans, mobile phones, electric Christmas decorations etc.).

Operation at an altitude over 3000 meters (9800 ft) is not recommended.

4.1.2 Checking your analyzer upon arrival

Upon receiving your ‘Abacus 3CT’ instrument, check that the shipping carton is not damaged;

If there is external damage to the package, immediately file a claim to the freight shipping company.

In case of any problem, please contact your sales representative, the service representative, or the forwarding company.

Please do not open the package unless you have prior approval from your sales/service representative.
4.2 Performing the installation

Start the installation only if all the pre-conditions are met. Trained and approved service personnel should install the ‘Abacus 3CT’.

4.2.1 Unpacking

Carefully remove ‘Abacus 3CT’ from the shipping carton. Inspect the instrument for any visible signs of damage incurred during shipping. Should you find any damage, file a claim with the carrier or your distributor immediately. Check the accessories received (See chapter 2.2.) against the packing list. Contact Service if anything is missing.

**CAUTION! Prior to initial operation, allow the instrument to reach room temperature (approx. 2 hours). Rapid temperature changes in an operating unit can lead to water condensation, which may damage electronic parts.**

Should any of the above be missing or damaged, please inform your Sales Representative for further instructions.

4.2.1.1 Visual inspection

To ensure correct operation, and to check that the instrument has been delivered to you without any damage, please check the following before starting the unit for the first time:

- The front panel should have no cracks;
- The screen should have no cracks;
- No visible dents or bumps on instrument housing (front, side, rear, top cover, bottom plate);
- Open the side panel of the unit:
  - The side panel is easy to open and close (see section 0);
  - Inspect that the syringes are not cracked;
  - Check if there are no fluid inside the tubing;
  - Check if there are no salt build-ups inside the tubing.
4.2.2 Moving to the selected location

Check the presence of all necessary connections.

Move the ‘Abacus 3CT’ to the selected location.

Be sure that the main switch (right next to the power connector) is in off position.

4.2.3 Connecting the reagents

- Connect the reagent tubes to the ‘Abacus 3CT’:
  - Use the supplied connecting tubes and special bottle caps;
  - Be sure that the color on each tube, cap and connector in the back of the instrument match;
- Connect the reagent containers to the reagent tubes;
- Connect the waste connectors to the waste-container. Use 2 separate tubes; do not ‘merge’ the tubes. See chapter 2.3.8!

The analyzer operates with chemically and biologically active reagents. Direct skin contact with these reagents should be avoided. Please read reagent descriptions carefully for possible emergency actions. Only original reagents are usable with ‘Abacus 3CT’, available from Diatron.

Place the reagent containers near the instrument, to an accessible location. Do not place the containers to a higher position than ‘Abacus 3CT’. This is to avoid unintentional spilling of reagents.
4.2.4  **Powering up the ‘Abacus 3CT’**

In order to power up the ‘Abacus 3CT’ perform the following steps:

- Be sure that the main switch (right next to the power connector) is in off position;
- Connect the DC cable of the external power supply to the ‘Abacus 3CT’. Hand-tight the securing screw (2.5 – 3 turns).
- Connect the localized power cord to the external power supply;
- If it is necessary then connect the additional grounding point to the grounding system;

**The ‘Abacus 3CT’ instrument must be grounded!**
(Using the power supply and/or the additional grounding point.) See chapter 2.3.3!

- Plug-in the power-cord into the wall-outlet;
- Power up the ‘Abacus 3CT’ see chapter 5.1 for details:
  - Check if the software starts up without any problem;
  - Check the serial number and the software revision. See chapter 10.4.1;
- Shut down the ‘Abacus 3CT’ for details see chapter 5.2.

At this stage do not perform any other operations, just ensure that the ‘Abacus 3CT’ is operational.

4.2.5  **Connecting the peripherals**

To connect the desired peripherals perform the following steps:

- Shut down the ‘Abacus 3CT’ for details see chapter 5.2;
- Connect the desired peripherals;
- Power up the ‘Abacus 3CT’ see chapter 5.1 for details;
  - Check if the software starts up without any problem;
- Check the operational status of the peripherals;
- Shut down the ‘Abacus 3CT’ for details see chapter 5.2.

**If a peripheral directly connected to the ‘Abacus 3CT’ (USB, serial port) and has its own power supply then use the same ground-point!** (Use the same wall-socket group.) Contact an electrician if you doubts about the quality of the grounding.

**Check the manual of the connected external device / peripheral.**

You can connect/ disconnect peripherals / external devices to the ‘Abacus 3CT’ instrument after the installation procedure as well.
4.3 **First start-up**

Make sure that the reagents are connected and the tubes are not kinked or blocked (visual inspection of lines).

Check the power connection (wall-outlet-> power supply -> ‘Abacus 3CT’).

First startup is special, because ‘Abacus 3CT’ arrives to your laboratory drained, without reagents. To avoid warning messages about missing reagents, you have to fill-up the analyzer with reagents.

Although your ‘Abacus 3CT’ was quality checked and calibrated at Diatron it is necessary to check the reagent level and fill up the measurement account in case of locked reagent system.

- Power up the ‘Abacus 3CT’ see chapter 5.1 for details;
  - Check if the software starts up without any problem;
- In the Utilities (the screw-nut key) / Maintenance / Reagent status menu:
  - If your instrument is sold with the ‘locked reagent system’ then activate the hardware key and upload the required measurements. See details in chapter 10.1.4;
  - Check the nominal size of the reagent containers. If necessary, a qualified service person can adjust the volumes. See details in chapter 10.1.4;
  - Reset the reagent levels (you have freshly connected reagent containers);
- In the Utilities / Maintenance / Priming menu prime all reagents;
- In the Utilities / Maintenance / Cleaning menu initiate 3 cleaning cycles;
- Switch to the measurement panel (the blood-drop key):
  - The ‘Abacus 3CT’ automatically performs a ‘blank’ measurement. (See chapter 8.5);
  - Even if the result are acceptable please perform 5 blank measurements;
  - If the ‘blank results’ are not acceptable after 10 cycles or the out-of-range results are not improving then the service personnel on site should investigate the situation;
- As an optional step measure a QC sample (see chapter 10.3) or a human sample with known parameters (measured on an another hematological instrument):
  - Be aware that the calibration is not necessarily correct;
  - The purpose of this measurement is to check the operational status of the ‘Abacus 3CT’ instrument.

After completing these steps, you can proceed to the primary settings.
4.4 Primary settings
After filling up and checking the ‘Abacus 3CT’ it is time to go through the “Settings” menus.

It is suggested to adjust the:

- Date and time;
- The operation mode of the bar-code reader (if in use);
- Laboratory header;
- Contact information to the service by a qualified service person;
- The nominal volume of the reagent packs by a qualified service person;
- Printers;
- Normal ranges.

The adjustment of the listed items requires action made by a qualified service person or it is important to adjust them as soon as possible.

4.4.1 Setting date and time
You can adjust the date /time format and value in the ‘Utilities / Settings / Date and time’ menu.

Please take in to consideration that at the current software level the ‘Abacus 3CT’ does not support the automatic daylight-saving changes.

See chapter 10.5.3 for details.

4.4.2 Adjusting the normal ranges
If you already know / decided the normal ranges to be used, then you can adjust them at this point. You can modify the normal ranges at a later time. See chapter: 8.3.3.

The changes in the normal ranges will not affect the previously made measurements.

4.4.3 Printer setting
You can adjust the:

- The used device, see chapter 10.5.1
- Laboratory header (the data about the laboratory/ instrument which made the print-out) see chapter 0;
- Printing format see chapter 10.5.1;
- Printing details (you can switch on/off parts of the printout, like normal ranges, histograms etc. see chapter 10.5.1.)
4.4.4 **Bar-code reader**
If you plan to use a bar code reader then you should adjust if the barcode identifies the sample or the patient. See chapter 10.5.2.1.

4.4.5 **Reagent volumes**
The volumes of the used reagent containers are preset to the standard delivery size. If you will use reagent containers with different volumes then a qualified service person can adjust these volumes.

4.4.6 **Other settings**
You can walk through the settings and adjust all items of interest.

4.5 **Familiarization period**
It is suggested to measure 10-20 ‘spare’ hematology samples leftover from other tests in order to gain some experience before measuring ‘real’ samples.

4.6 **Calibration and QC**
After the ‘Abacus 3CT’ is installed and configured according to your needs perform the following tasks before ‘real’ samples analyzed on the ‘Abacus 3CT’.

- Calibrate the ‘Abacus 3CT’. See chapter 10.2.
- Run a QC series (low/ normal/ high). See chapter 10.3.

4.7 **Performance checking**
If you wish to check the performance of the ‘Abacus 3CT’ instrument, then please use the related CLSI (NCCLS) guidelines.
5 BASIC OPERATIONS
In this chapter, you will find information how to perform the basic operations on the ‘Abacus 3CT’ instrument.

5.1 Turning the Instrument ON
If you use any external device / peripheral that has its own power supply, then first turn on these devices. (Printer, host computer.)

Turn on the ‘Abacus 3CT’ using the power switch on the rear panel.
The ‘On’ position is marked by the ( I ) symbol.

During start-up, the following screen is displayed. A progress bar is displayed in the bottom part of the display.

A few second later, the software version number appears and the name of actually loaded module is displayed.

When the software version is loaded, the DATABASE panel is displayed without any pneumatic initialization (default setting). Pneumatic movement is initiated only when necessary for the relating process.

The default setting can be changed by a qualified service person; in this case, the instrument will perform the pneumatic initialization automatically and open the MEASUREMENT panel. No further user action required (except accepting the blank results) to start the daily routine.

See details in chapter 5.5!

CAUTION! Wait 5 minutes before initiating any measuring process to allow the instrument to reach the optimal working temperature.

In some cases, a priming cycle is necessary prior to sample introduction. The instrument will perform the cycle automatically if the fluid sensors are on and additional liquid in the tubing system is required. Run a priming cycle in case of:
5.2 Turning the Instrument OFF
Do not turn off the instrument by simply flipping the power switch on the rear panel. Doing so may result in erroneous operation and/or prolonged start-up cycle during later use.

This special “turning off” procedure avoids the below consequences:

- It takes time until the software operating the ‘Abacus 3CT’ saves the changed data, settings, closes the databases and/ or files. If the power is simply cut before all data items are secured then some data might be lost;
- If the ‘Abacus 3CT’ can’t properly fill or empty tubes and chambers then as the water evaporates salt build-up can block fluid-paths, or sensitive parts (like the measuring capillaries) can be exposed and dust particles can pass into the measurement system. Also the blood-sample can remain inside the instrument increasing the risk of contamination and/ or the dried-in blood can permanently block the sample-paths;
- If the mechanical parts (sample needle, syringes, valves) are not moved to their ‘home’ position before powering off the ‘Abacus 3CT’ then at next startup it takes considerably longer time until the ‘Abacus 3CT’ can initiate the mechanics and flush the pneumatics system.

Therefore always follow the instructions below when switching the instrument off.

Press EXIT key on the front panel. The following screen is displayed.

Select Shut down. A message appears: (Warning 5905). When prompted, press to confirm. The ‘Abacus 3CT’ will display a message (Warning 5906) and give a tone indicating that it is safe to shut it off.

Turn off the instrument using the power switch on the rear panel. The Off position is marked by O symbol.
5.3 Preparing for shipment

The second item in the shut down menu should be used when the instrument is to be shipped or left unused for a longer time (more than 1 week). The instrument will ask you to use the cleaning tube kit and 100ml of distilled water.

Press EXIT key on the front panel.

Select ‘Preparing for shipment’ option.

Follow the instructions:

- Remove the reagent tubing, but leave the waste connected. (Emptying the reagent lines);
- Connect the cleaning tube kit to the reagent inputs, submerging the free end in a bottle containing at least 100 ml of distilled water. (Washing out all salt remains, flushing the fluidics part.);
- Remove the cleaning tube; (Empty the fluidics);
- Power off and disconnect the waste connector.

5.4 Emergency shut-down

Turning off the ‘Abacus 3CT’:

- By simply flipping the power switch on the rear panel;
- Turn off the circuit breaker to the work area or the whole laboratory. (Most of the laboratories are equipped with emergency circuit breakers.)

It is entirely your decision and responsibility when and how to perform an emergency shutdown.

The following list provides some examples for emergency shutdown:

- Personal injury / risk of personal injury:
  o Someone opened the instrument enclosure and put his/ her finger between moving parts;
- Fire or flood in the laboratory;
- Risk of high over-voltage on the electric-grid that the ‘Abacus 3CT’ can sustain permanent damage. (Suddenly developed thunderstorm.)
- It is discovered that wrong reagent connected to the ‘Abacus 3CT’. 
5.5 Sample measurement

After powering up the ‘Abacus 3CT’, you need to perform the following steps in order to perform a measurement.

It is assumed that:

- All reagents and the waste are properly connected;
- The calibration was performed, checked and meets requirements;
- All environment conditions are met.

A qualified service person can adjust which stage is reached after powering up the ‘Abacus 3CT’:

- The pneumatics is NOT initialized and the DATABASE panel is active;
- The Pneumatics is activated and the ‘Abacus 3CT’ performed the 1st blank measurement.

If the DATABASE panel is active then press the blood-drop hard short-cut key. The ‘Abacus 3CT’ will check the status the pneumatics and perform the pneumatics initialization sequence if necessary. At the end of the pneumatics initialization sequence the ‘Abacus 3CT’ performs a blank measurement.

If the alternate power-up sequence was selected, then the ‘Abacus 3CT’ automatically reaches this stage.

As the 1st blank measurement completed:

- if the results are good then accept the blank measurement (See chapter 8.5);
- If results are outside tolerance ranges then the blank measurement shall be repeated.

It is acceptable to perform 2-4 blank measurements before the results are within the tolerance range. See details in chapter 8.5.

After accepting the blank measurement, the measurement result panel is displayed with no results.
You can enter the sample/patient info, but the measurement can be started without it, the ‘Abacus 3CT’ will automatically assign a sample ID. See details in chapter 8.3.1.

Place the sample-tube into the sample holder, and press the ‘START’ button. The ‘Abacus 3CT’ will automatically perform the measuring sequence. When the sampling procedure has completed the ‘Abacus 3CT’ returns the sample-tube. As soon as the results are available, they are displayed on the measurement panel.

Please note that the displaying of the results does not mean the completion of the measuring process. The ‘Abacus 3CT’ shall complete some cleaning, flushing sequences before a new measurement can be initiated.

### 5.6 Refilling the printer

Use the specified (58 mm (2.3’’) wide) thermal paper roll. See chapter 1.7; built in printer)

![Press the protruding button to open the lid](image)

![Remove the coil former](image)

![Place the paper roll over the paper holding space of the printer. Pull out 5-6” of paper UNDER the roll.](image)

![Let the thermal printer paper fall into the printer housing.](image)

![Hold the open end of the paper and close the lid so that the end of the paper is clipped between the black paper guide and the printer mechanics.](image)
6 THE MENU SYSTEM

6.1 General Information
This chapter contains information about the structure and usage of the software implemented menu structure.

This integrated software controls instrument operations including calculation and evaluation of measured data, displaying results and information screens, storage and recalling of data.

6.2 Navigating in the Menu System
The instrument uses a menu system to initiate actions and to access settings.

You can navigate in the menu system, activate/deactivate settings, enter data on the following ways:

- Using the hard short-cut keys (fixed function buttons)
  - These keys are located above the LCD screen;
  - The function of each key is fixed;
  - By pressing any of them, you can directly access their functions, regardless whichever submenu you are in;
  - If you use an external keyboard, you can access these functions with keys F7 through F12;

- Using the soft short-cut keys (variable function buttons)
  - These keys are located under the LCD screen;
  - They actual function is marked by an icon right over the physical button;
  - If you use an external keyboard, you can access these functions with keys F1 through F6;

- Using the cursor keys and the ‘OK’ button
  - You can navigate in menus by using the ‘arrows’
  - You can mark your chose by pressing the ‘OK’ button;
  - If you use an external keyboard, you can access these functions with the cursor keys and the ‘ENTER’ button.

- Numeric keypad:
  - You can select menu items by pressing the related number;
  - You can enter numeric/alpha-numeric data;
  - You can use an external keyboard as well.
Below is a list of icons and functions assigned to the soft short-cut keys (function keys):

<table>
<thead>
<tr>
<th>Function key</th>
<th>Action triggered</th>
</tr>
</thead>
<tbody>
<tr>
<td>🔄</td>
<td>Exit from actual menu or action</td>
</tr>
<tr>
<td>🗑️</td>
<td>Leave data-entry menu without saving changes (Cancel)</td>
</tr>
<tr>
<td>✅</td>
<td>Confirm the results or changes made (OK)</td>
</tr>
<tr>
<td>🔄↑</td>
<td>Repeat action (e.g. Blank measurement)</td>
</tr>
<tr>
<td>📊</td>
<td>Display details of the highlighted patient or QC sample.</td>
</tr>
<tr>
<td>📋</td>
<td>Enter/modify/ review the sample/patient data, patient type selection</td>
</tr>
<tr>
<td>🔄↑↓</td>
<td>PAGE-UP / PAGE-DOWN key in a multi-page menu</td>
</tr>
<tr>
<td>16  64</td>
<td>Change scaling of Levey-Jennings chart (16 or 64 entries)</td>
</tr>
<tr>
<td>🕒</td>
<td>Confirm error</td>
</tr>
<tr>
<td>📜</td>
<td>Go to local menu (database measurement)</td>
</tr>
<tr>
<td>🕗</td>
<td>Patient limits (normal ranges)</td>
</tr>
<tr>
<td>❌</td>
<td>Stop a running process</td>
</tr>
<tr>
<td>📐</td>
<td>Show data in table format</td>
</tr>
<tr>
<td>🥤</td>
<td>Initiates the reagent replacement</td>
</tr>
<tr>
<td>🔨</td>
<td>Initiates allotting measurement counts.</td>
</tr>
</tbody>
</table>
Below we list the icons and functions assigned to hardware function buttons

<table>
<thead>
<tr>
<th>Function key</th>
<th>Action triggered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Information</td>
</tr>
<tr>
<td></td>
<td>Measuring process at once</td>
</tr>
<tr>
<td></td>
<td>Database</td>
</tr>
<tr>
<td></td>
<td>Utilities menu</td>
</tr>
<tr>
<td></td>
<td>Printing function</td>
</tr>
<tr>
<td></td>
<td>Exit menu</td>
</tr>
</tbody>
</table>

6.3 Items in the menu structure
Navigating in the menu structure you can find different menu/function items. In this chapter, you can find information about their usage.

6.3.1 Menu selection
After opening a menu (i.e.: pressing the utilities short-cut key) you can reach the desired menu item by:

- Selecting a menu item (move highlight) with the ↑ and ↓ keys and press the OK key to enter or activate the highlighted item;
- Pressing the numeric key corresponding to the menu item allows selection and access of an item without the need to press the OK key. This method is more efficient after the user knows the menu structure.

To return to a higher level in the menu hierarchy (return to the previous menu) use the \(\text{←} \) or the \(\text{X} \) soft short-cut key. (The return arrow is used on menu the ‘X’ (cancel) is used on data panels.)

If a menu item opens a submenu, then the item has a \(\Rightarrow\) symbol on the right of the menu line.

If the functionality behind a menu item is not available, then the color of the item changes to gray.
6.3.2 Radio buttons
The function of these groups is that only one item of the group can be selected, and this is indicated with a filled circle in front of the selected item.

To highlight an item:
- Use arrow-keys;
- Press the related numeric key.

To select the highlighted item:
- Press the ‘OK’ button;
- Press the ‘Enter’ key on an external keyboard.

Selecting an item of the group will move the filled circle in front of this item, emptying the circle of the old selected item.

6.3.3 Check box
The function of these items is to enable / disable a given feature/ behavior of the ‘Abacus 3CT’.

To highlight an item:
- Use arrow-keys;
- Press the related numeric key.

To select the highlighted item:
- Press the ‘OK’ button;
- Press the ‘Enter’ key on an external keyboard.

Even if the check boxes are grouped, you can still select/ unselect any combination of them.
6.3.4 List box (roll down menu)
Using the list boxes, you can assign value to a parameter from a given list.

- To select a list box use the arrow/ cursor key on the keypad on an external keyboard.
- To open the list, press the ‘OK’ button or the ‘ENTER’ key on an external keyboard.
- Select between the possible values by using the up/down arrow/ cursor key on the keypad or on an external keyboard;
  - The previous selection is marked with the ‘\ ’ symbol;
  - The pointed value is marked with the ‘← ’ symbol;
- To cancel the operation and return to the original value:
  - Press the ‘Esc’ key on an external keyboard;
  - Press the soft short-cut key. (It will close the menu/ panel as well.)

6.3.5 Edit box (data field)
Using edit boxes, you can assign the desired value to a parameter. In case of the edit boxes, there are no rules about the content but the format and the range of the data. In the menu structure of the ‘Abacus 3CT’, you can find the following box types.

- Numeric boxes;
- Date / time boxes;
- Alphanumeric boxes.

You can use both the built-in keypad and an external keyboard to enter values.

Please note that in case of the alphanumeric boxes you can type-in letters using the built-in keypad by repeatedly pressing a given key. (Just like creating a text message on a cell phone.)
6.4 Panels
While using the menu structure of the ‘Abacus 3CT’ you open different panels. A panel can contain more types of menu items.

A panel can be build from one or more pages. If a panel has more pages, then you can change the active page by:

- Using the soft short-cut keys;
- Using the page up/ page down button on an external keyboard.

6.5 Menu structure
The following outlines ‘Abacus 3CT’ menu functions/ panels.

<table>
<thead>
<tr>
<th>Information/Help</th>
<th>Displays help for the current screen.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>After pressing the soft short-cut key, it returns to the menu where it was activated.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Analysis/Measurement</th>
<th>Opens the measurement panel</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>X</th>
<th>Measurement local menu</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Repeat last sample</td>
<td>Repeats last sample tested. Previously filled in sample parameters (sample ID, Patient ID, etc.) will be used for the consecutive sample. “Repeat mode” appears in lower left section of the screen. (You have to press the ‘START’ button to initiate the measurement.)</td>
</tr>
<tr>
<td>2 Measure blank</td>
<td>Performs a Blank measurement</td>
</tr>
<tr>
<td>Patient information screen</td>
<td></td>
</tr>
<tr>
<td>-----------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Date (read only)</strong></td>
<td>Actual time stamp of sample (always synchronized with system time)</td>
</tr>
<tr>
<td><strong>Sample ID</strong></td>
<td>Alphanumeric field to enter specific sample identification. The last numeric value +1 is offered automatically.</td>
</tr>
<tr>
<td><strong>Patient ID</strong></td>
<td>Alphanumeric field to store additional ID</td>
</tr>
<tr>
<td><strong>Patient type</strong></td>
<td>Selects the patient type (Human, Male, Female, Alternate1, Alternate 2). The patient type assigns the actual normal ranges to the sample as well.</td>
</tr>
<tr>
<td><strong>Patient name</strong></td>
<td>Alphanumeric field for storing Patient name</td>
</tr>
<tr>
<td><strong>Birth date</strong></td>
<td>Birth date of the Patient</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td>Selectable male/female</td>
</tr>
<tr>
<td><strong>Doctor</strong></td>
<td>Alphanumeric field</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reference ranges for selected profile.</th>
</tr>
</thead>
<tbody>
<tr>
<td>On this panel, you can adjust the reference / normal ranges for the selected patient type.</td>
</tr>
<tr>
<td>If any of the 16 reported parameters is outside the defined range then the result will be ‘flagged.’</td>
</tr>
<tr>
<td><strong>Database</strong></td>
</tr>
<tr>
<td>--------------</td>
</tr>
<tr>
<td><strong>Detailed view</strong></td>
</tr>
<tr>
<td><strong>Table view</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Database local menu</strong></td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>3</td>
</tr>
<tr>
<td>4</td>
</tr>
<tr>
<td>5</td>
</tr>
</tbody>
</table>
### THE MENU SYSTEM

**Edit sample info**

- Opens dialog for editing patient information. (Patient ID, Patient name, birth-date, sex, doctor).
- The date-stamp, the Sample ID and the Patient type is displayed as read-only parameter.

### Utilities

- Opens the utilities menus

### 1. Maintenance

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Cleaning</td>
<td>You can start cleaning (on line cleaner) or hard cleaning sequences (external hard cleaner solution).</td>
</tr>
<tr>
<td>2. Priming</td>
<td>You can prime (initial fill) a selected or all the reagents.</td>
</tr>
<tr>
<td>3. Drain chamber</td>
<td>The measuring chambers emptied. (Preparation for maintenance or service.)</td>
</tr>
<tr>
<td>4. Reagent Status</td>
<td>The actual level of the reagent and waste containers are displayed.</td>
</tr>
</tbody>
</table>

- Initiates the uploading of measurement counts
- Initiates the reagent replacement.
- You can mark the replacement (reset liquid level) of the diluent, lyse, cleaner and waste container.
- Mark the desired check boxes and perform the reset by pressing the soft short-cut key.
### 2. Calibrate

In this part of the menu system, you can change/review the calibration of the ‘Abacus 3CT’. See chapter 10.2 for details.

<table>
<thead>
<tr>
<th>1. Calibrate</th>
<th>The calibration factors entered manually.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Factorial calibration</td>
<td>The calibration factors calculated from a single measurement result.</td>
</tr>
<tr>
<td>2. Calibration from 1 measurement</td>
<td>The calibration factors calculated from the average of 3 measurement results.</td>
</tr>
</tbody>
</table>

| 2. View Calibrations | The values of the former calibration settings are visible. |

### 3. Quality control

In this part of the menu system, you can perform different QC related operations. See details in chapter 10.3

<table>
<thead>
<tr>
<th>1. Enter reference manually</th>
<th>You can manually copy the parameters of the QC material.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Enter reference via barcode</td>
<td>Enter QC target values from bar-code sheet if available.</td>
</tr>
<tr>
<td>3. Measure</td>
<td>Start a QC measurement</td>
</tr>
<tr>
<td>4. QC database</td>
<td>Open the database of QC results</td>
</tr>
<tr>
<td>5. QC diagram</td>
<td>View the QC result on Levey-Jennings chart</td>
</tr>
<tr>
<td>6. Set level</td>
<td>Select the desired QC level.</td>
</tr>
</tbody>
</table>

### 4. Diagnostics

<table>
<thead>
<tr>
<th>1. Device information</th>
<th>Read-only device information</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Statistics</td>
<td>Read only statistical data</td>
</tr>
<tr>
<td>3. Self test</td>
<td>Initiates the self-test sequence. See chapter 10.4.3 for details.</td>
</tr>
</tbody>
</table>
## 5. Settings

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Printers</strong></td>
<td>On this panel you can select the printer device adjust printing format and content.</td>
</tr>
<tr>
<td><strong>2. Customize</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>1. General settings</strong></td>
</tr>
<tr>
<td></td>
<td>Play sound</td>
</tr>
<tr>
<td></td>
<td>Serial (RS232) link speed</td>
</tr>
<tr>
<td></td>
<td>Display turnoff time (screen saver)</td>
</tr>
<tr>
<td></td>
<td>Barcode reader mode</td>
</tr>
<tr>
<td><strong>2. Laboratory</strong></td>
<td>The content of header of the printed report.</td>
</tr>
<tr>
<td><strong>3. Date and time</strong></td>
<td>On this panel you can adjust the date, time, date format and time mode.</td>
</tr>
<tr>
<td><strong>4 Fluid sensors</strong></td>
<td>On this panel, you can enable/ disable and recalibrate the fluid sensors.</td>
</tr>
</tbody>
</table>

## 6. Service

|   | Contact information of the service / dealer/ sales representative. |

### Printing

Initiates the printing of the active / selected measurement result or the content of the setting panels.

### Exit

1. **Shutdown**
   - Shuts down the ‘Abacus 3CT’ instrument. (Use if the unit will not be used for over 72 hours.)

2. **Preparing for shipment**
   - Drains and shuts down the ‘Abacus 3CT’ instrument. (Use if the unit will be unused for more than 2 weeks, or if it will be shipped.)
7 OPERATING PRINCIPLES

7.1 Impedance Method
The impedance method counts and sizes cells by detecting and measuring changes in electrical impedance when a particle in a conductive liquid passes through a small aperture.

![Impedance method diagram](image)

Each cell passing through the aperture — there is a constant DC current flowing between the external and internal electrodes — causes some change in the impedance of the conductive blood cell suspension.

These changes are recorded as increases in the voltage between the electrodes.

The number of pulses is proportional to the number of particles. The intensity of each pulse is proportional to the volume of that particle. The volume distribution of the cells are displayed on the WBC, RBC, and PLT histograms.

7.2 Principle of HGB Measurement
The HGB concentration of the lysed and diluted sample can be measured by a photometric method. The reagent lyses the red blood cells, which release hemoglobin. The chemical process forms a stable form of methemoglobin.

All Diatron branded reagents are cyanide and azide free, and thus are environment-friendly.
### 7.3 Parameters

The ‘Abacus 3CT’ measures and calculates parameters, listed below. For each parameter, we list the name, abbreviation and measurement unit in the first column. Short description for each parameter is in the second column.

<table>
<thead>
<tr>
<th>White Blood Cells – WBC</th>
<th>Number of leukocytes</th>
</tr>
</thead>
<tbody>
<tr>
<td>(10^3 cells/µL)</td>
<td>WBC = WBC&lt;sub&gt;cal&lt;/sub&gt; x (10^3 cells/µL)</td>
</tr>
<tr>
<td>Red Blood Cells – RBC</td>
<td>Number of erythrocytes</td>
</tr>
<tr>
<td>(10^6 cells/µL)</td>
<td>RBC = RBC&lt;sub&gt;cal&lt;/sub&gt; x (10^6 cells/µL)</td>
</tr>
<tr>
<td>Hemoglobin concentration - HGB</td>
<td>Measured photometrically at 568 nm; in each cycle blank measurement is performed on diluent</td>
</tr>
<tr>
<td>(g/dl)</td>
<td>HGB = HGB&lt;sub&gt;cal&lt;/sub&gt; x (HGB&lt;sub&gt;measured&lt;/sub&gt; - HGB&lt;sub&gt;blank&lt;/sub&gt;)</td>
</tr>
<tr>
<td>Mean Corpuscular Volume - MCV</td>
<td>Average volume of individual erythrocytes derived from the RBC histogram.</td>
</tr>
<tr>
<td>(fl)</td>
<td></td>
</tr>
<tr>
<td>Hematocrit – HCT</td>
<td>Calculated from the RBC and MCV values.</td>
</tr>
<tr>
<td>(percentage, absolute)</td>
<td>HCT&lt;sub&gt;percentage&lt;/sub&gt; = RBC x MCV x 100</td>
</tr>
<tr>
<td>Mean Corpuscular Hemoglobin – MCH</td>
<td>Average hemoglobin content of erythrocytes, calculated from RBC and HGB values.</td>
</tr>
<tr>
<td>(pg)</td>
<td>MCH = HGB / RBC</td>
</tr>
<tr>
<td>Mean Corpuscular Hemoglobin Concentration – MCHC</td>
<td>Calculated from the HGB and HCT values.</td>
</tr>
<tr>
<td>(g/dl)</td>
<td>MCHC = HGB / HCT&lt;sub&gt;absolute&lt;/sub&gt;</td>
</tr>
<tr>
<td>Red Cell Distribution Width – RDW-SD (%)</td>
<td>The distribution width of the erythrocyte population derived from the histogram at 20% of peak</td>
</tr>
<tr>
<td>Red Cell Distribution Width – RDW-CV (fl)</td>
<td></td>
</tr>
<tr>
<td>Platelet distribution width – PDW-SD (%)</td>
<td></td>
</tr>
<tr>
<td>Platelet distribution width – PDW-CV (fl)</td>
<td></td>
</tr>
<tr>
<td>Platelet – PLT</td>
<td>Number of thrombocytes (platelets)</td>
</tr>
<tr>
<td>(10^3 cells/µL)</td>
<td>PLT = PLT&lt;sub&gt;cal&lt;/sub&gt; x (10^3 cells/µL)</td>
</tr>
<tr>
<td>Plateletcrit - PCT</td>
<td>Calculated from the PLT and MPV values</td>
</tr>
<tr>
<td></td>
<td>PCT&lt;sub&gt;percentage&lt;/sub&gt; = PLT x MPV x 100</td>
</tr>
<tr>
<td>Mean Platelet Volume – MPV</td>
<td>Average volume of individual platelets derived from the PLT histogram.</td>
</tr>
<tr>
<td>(fl)</td>
<td></td>
</tr>
<tr>
<td>White blood cell differential:</td>
<td>Percentage values derived in the WBC sizing channels determined by the three WBC discriminators:</td>
</tr>
<tr>
<td>• LYM, LYM%: lymphocytes</td>
<td></td>
</tr>
<tr>
<td>• MID, MID%: middle size cells</td>
<td></td>
</tr>
<tr>
<td>• GRA, GRA%: granulocytes</td>
<td></td>
</tr>
<tr>
<td>Absolute values calculated from the WBC value x the differential percentages.</td>
<td></td>
</tr>
<tr>
<td>The Diatron Abacus 3 System uses electronic sizing to determine three distinct white cell subpopulations. Cells correlating to lymphocytes are included in the small cell subpopulation. Cells correlating to granulocytes (neutrophils) are included in the large cell population. The remaining cells correlating to monocytes, basophils, eosinophils, blasts, and other precursor white cells are included in the mid-size cell population.</td>
<td></td>
</tr>
</tbody>
</table>
8 ROUTINE UTILIZATION and MEASUREMENT

8.1 Sample handling
In order to obtain proper results, stabilized and anti-coagulated sample shall be analyzed on the ‘Abacus 3CT’ instrument.

Use K3-EDTA (liquid) based sample tubes! The ‘Abacus 3CT’ system (the instrument, the reagents, the controls and the calibrator materials) was designed and tested for K3-EDTA treated blood-samples.

<table>
<thead>
<tr>
<th>Warning</th>
<th>The reagent system is designed and tested, to be used with K3-EDTA-treated blood-samples. Other anti-coagulants may chemically react with the reagents.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warning</td>
<td>Follow the instructions of the producer of the sample-tube!</td>
</tr>
<tr>
<td></td>
<td>• Keep the impact time of the anti-coagulant! (There should be no clumps in the sample.)</td>
</tr>
<tr>
<td></td>
<td>• Fill the tube up to the prescribed volume!</td>
</tr>
<tr>
<td></td>
<td>o The over/ under filled samples tubes can provide distorted results because of the changed dilution ratio;</td>
</tr>
<tr>
<td></td>
<td>o If the EDTA concentration is too high (very low filling of the sample tube) then the blood-cells can damage before the analysis;</td>
</tr>
<tr>
<td></td>
<td>• Follow the mixing / inverting instructions!</td>
</tr>
<tr>
<td>Warning</td>
<td>Do not shake the sample! Do not use ‘vortex’ mixers!</td>
</tr>
<tr>
<td></td>
<td>• The shaking creates micro-bubbles which can falsify the results;</td>
</tr>
<tr>
<td></td>
<td>• Strong shaking can even damage / break the blood cells.</td>
</tr>
<tr>
<td>Warning</td>
<td>If you suspect that the sample was shaken (i.e.: during transportation) or the sample was fallen from the table then keep the sample at room temperature for 10 minutes. (Let the micro bubbles to disperse or leave the blood sample.)</td>
</tr>
</tbody>
</table>
Homogenize the sample by mixing before analyzing on the ‘Abacus 3CT’ instrument. The sample should be at room temperature.

<table>
<thead>
<tr>
<th>Refrigerated sample</th>
<th>Suggested manual mixing</th>
<th>Suggested mechanical mixing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Keep the sample at room temperature for 10 minutes.</td>
<td>Mix the sample for 15-20 minutes.</td>
</tr>
<tr>
<td></td>
<td>Roll the sample between our palms for 1 minute.</td>
<td>Ensure that the sample can reach room temperature.</td>
</tr>
<tr>
<td></td>
<td>Invert the sample 3 times.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Keep the sample at room temperature for 5 minutes.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Invert the sample 7-8 times.</td>
<td></td>
</tr>
<tr>
<td>Sample at room temperature</td>
<td>Invert the sample 3 times.</td>
<td>Mix the sample for 10-15 minutes.</td>
</tr>
<tr>
<td></td>
<td>Keep the sample at room temperature for 1 minute.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Invert the sample 7-8 times.</td>
<td></td>
</tr>
</tbody>
</table>

Note: the control and calibrator materials require different mixing procedure. Always follow the instruction of the manufacturer! (These instructions are included in the package insert of the control material.)

Always handle the blood-samples as potentially infectious material!

Follow safety rules of your laboratory!
8.2 Initiate the analysis

To initiate analysis:

1. Homogenize (mix, invert) the sample. Do not shake the sample, because micro-bubbles can form inside, which may cause erroneous results!
2. Position the sample tube in the sample rotor.
   You have the possibility to use 3 different interchangeable adapters for different tube types.
   Tube types are shown in figures below.
   The cap-piercing mechanism is designed for the ‘BD Vacutainer®’ and mechanically equivalent (like Venosafe Terumo®) sample-tubes. Tubes with different cap design/ layout (like the Sarstedt Monovette®) and the non-pierce-able tubes (like the hard-cap QC blood tubes) shall be used in open mode only.
3. Adjust the sample parameters (See chapters 8.3.3)
4. Push START key.

The ‘standard’ adapter.

Vacutainer with sample blood (cap removed)  Vacutainer with sample blood (with cap)  5ml tube for control material (screw-cap removed)

Please wipe the mouth of the tube because the bursting bubble can dirt the sample-needle with blood which can cause measurement error at next sample

Below you can see 3 types of tubes (microtainers) used in micro adapters.
Be careful to place the tube with the cap always in the position shown above, otherwise the cap can get stuck when the sample holder turns.

Wide adapter for 2ml screw-cap bottles.

*Remove non-pierce-able and non-compatible caps! It is very important because the tip can pierce the adequate caps only!*
After pressing the ‘START’ button, the sample rotor will turn into the inside of the instrument and the needle draws sample from the tube. The aspirating needle is retracted, while its outer surface is automatically rinsed with diluent. This insures the low cross-contamination between samples. After a few seconds, the rotor turns out. Now you can remove the sample tube from the adapter of the sample rotor.

WARNING! Do not reach inside the instrument, as the needle can cause injury!
8.3 Sample parameters

8.3.1 Edit sample information
The software allows the user to enter information for each sample that has been, or will be measured.

Two options exist for sample information entry:

- immediately before analysis
- in the Database menu

To enter sample information prior to sample analysis, press the Measurement/Analysis key, and press the button on the screen. The following panel appears:

Use the build in keypad or an external keyboard to select and change the desired parameter. (See chapters 6.2 & 6.3 how select and edit the parameters of interest.)

The ‘Date’ parameter is read only, derived from the system clock.

Press the to accept data, cancel with button. Both options will return to the measurement (database) panel.

Note: If this function called from the database panel then the ‘Date’, ‘Patient ID’ and ‘Patient type’ parameters are read only.
8.3.2 Measurement local menu

To access the ‘Measurement local’ menu press the short-cut key. The following panel will be displayed:

If the ‘Repeat last sample’ check box is selected then all sample data (except the date/time stamp) will copied from the previous sample. This feature is a very useful tool to make parallel measurements from the same sample.

By selecting the ‘Measure blank’ menu option, the ‘Abacus 3 CT’ will perform a blank measurement.

You can return to the measurement panel by pressing the short-cut key.

8.3.3 Patient limits

To access the patient limits table press the short-cut key. The following panel will be displayed:

The actual/ active profile is selected on the ‘Edit sample information’ panel.

In order to gain proper reports the normal ranges shall be adjusted according to the local conditions, because the applicable normal ranges vary site-by-site (genetic background of the population, altitude from sea level etc.). It is completely your duty and responsibility to determine the normal ranges applicable at your site. Please follow the CLSI (NCCLS) and FDA regulations/recommendations.
8.4 Results

When analysis is complete, the measurement panel is filled out to show all measured and calculated parameters as well as the WBC, RBC and PLT histograms. Results, histograms and other terms will be stored automatically in the memory.

Use ▼ and ▲ keys on the screen to move through the results and histograms.

The following chapters summarize flags, and explains possible causes and suggests hints to overcome the problem.

The flags are grouped according to measurement conditions and according to the problems relating to the blood sample.

8.4.1 Range flags

The first flagging method is evaluation against the normal ranges. If some of the parameters out of range, it gets a (L) flag if under the range, or gets (H) if over the range. (In addition, the given parameter will be highlighted (orange) as well.) You can customize ranges for all kind of patients by setting the corresponding lower and upper ranges. If you set 0 for a range limit, it will be not verified. (See chapter 3.5 about the ranges.)

8.4.2 Measurement condition flags

If there is some problem and / or doubt about the correctness of the measurement process then measurement warning flags can be attached to the result. These flags are displayed in the bottom left corner of the result screen. (See the ‘lp’ mark in the screen shot above.)
8.4.2.1 Problems on the WBC – HGB channel

Uppercase letters refer to WBC or HGB problems:

<table>
<thead>
<tr>
<th>Flag</th>
<th>Meaning</th>
<th>Recommended user action</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>No WBC 3-part differential</td>
<td>Possible lyse problem. May occur in pathological lymphocytosis.</td>
</tr>
<tr>
<td>H</td>
<td>HGB blank is high, or no HGB blank</td>
<td>Repeat the blank measurement. If the HGB blank is not stable, there are probably bubbles in the WBC chamber: Run a cleaning and try blank again. Close the side door if open during measurement.</td>
</tr>
<tr>
<td>B</td>
<td>WBC blank is high, or no WBC blank</td>
<td>Repeat the blank measurement, or run prime lyse and try blank again. Possible lyse contamination, or noise problem.</td>
</tr>
<tr>
<td>C</td>
<td>WBC clogging</td>
<td>Aperture clogging. Perform cleaning and repeat the measurement. If it is a general problem, please contact your Service Personnel. Low temperature reagents can cause it as well (mainly diluent), in this case, you will have to wait until they reach room temperature.</td>
</tr>
<tr>
<td>M</td>
<td>WBC coincidence is too high. Linearity error.</td>
<td>Please manually pre-dilute the sample using isotonic solution, and calculate the results.</td>
</tr>
<tr>
<td>L</td>
<td>WBC/RBC Threshold Interference</td>
<td>The RBC-WBC discriminator is over 45 fl on the histogram</td>
</tr>
</tbody>
</table>

If the flags are related to clogging (C), or probably lysing problems (E, B), or pressure problems (pressure error), then it is suggested to repeat the measurement.

8.4.2.2 Problems on the RBC – PLT channel

Lowercase letters refer to RBC or PLT problems:

<table>
<thead>
<tr>
<th>Flag</th>
<th>Meaning</th>
<th>Recommended user action</th>
</tr>
</thead>
<tbody>
<tr>
<td>p</td>
<td>PLT blank is high, or no PLT blank</td>
<td>Run cleaning and repeat the blank measurement. Diluent or system cleanliness problem. If it is stable high, replace the diluent by opening a new tank.</td>
</tr>
<tr>
<td>b</td>
<td>RBC blank is high, or no RBC blank</td>
<td>Same action as in case of warning flag p.</td>
</tr>
<tr>
<td>c</td>
<td>RBC/PLT clogging</td>
<td>The same action as in case of the C warning flag.</td>
</tr>
<tr>
<td>m</td>
<td>RBC/PLT coincidence is too high. Linearity error.</td>
<td>Please manually pre-dilute the sample using isotonic solution, and calculate the results.</td>
</tr>
<tr>
<td>l</td>
<td>RBC/PLT Threshold Interference</td>
<td>The analytical software could not separate RBC’s from PLT’s because of a population overlap.</td>
</tr>
</tbody>
</table>

If the flags are related to clogging (c), or probably lysing problems (b, p), or pressure problems (pressure error), then it is suggested to repeat the measurement.
8.4.3 Parameter warning and error flags

If there is some doubt about the correctness of a given parameter then the ‘Abacus 3CT’ will mark the affected parameter:

- **Level 1, warning:**
  - The parameter is flagged with an exclamation mark flag (!) and highlighted (yellow);
  - Measurement and/or calculation result is suspicious;

- **Level 2, error:**
  - The parameter is flagged with an uppercase ‘E’ and highlighted (red);
  - Measurement and/or calculation error. The parameter is displayable;

- **Level 3, no result**
  - The result is not displayed;
  - Measurement and/or calculation result cannot be displayed.

8.4.4 Modifying lyse quantity

The default lyse quantity can be adjusted by pressing on the MEASURE screen. Another option is to modify the lyse quantity by ± 0.1 ml or ± 0.2 ml is available during analysis.

Press ↑ to increase the lyse quantity (+0.1/0.2 ml) if the separation between lysed RBCs and WBC populations is poorly differentiated, resulting in increased WBC and LYM counts.

Press ↓ to decrease the lyse amount (-0.1/0.2 ml) if the WBC histogram seems to be shrunk to the left, i.e. the different WBC populations are overlapped. This can inhibit proper separation of WBC populations.
8.5 Blank measurement

The system uses blank measurements to check cleanliness of the system and reagents. Blank measurement must be performed:

- Once daily, before sample analysis (this is done automatically before the first analysis in MEASURE function).
- After any reagent change (activated manually from the MEASURE/MEASURE BLANK menu).
- After the replacement of any hardware component that is closely related to the measuring process (aspiration, dilution, counting, rinsing).

Press the Measure key and press the \( \square \) button on the screen and select Measure blank.

If the blank measurement was OK, press \( \checkmark \) to accept the result. The ‘Abacus 3CT’ is then ready for analysis. The instrument then displays a sample measurement screen, as shown, and is now ready to perform an analysis.

If the blank results are not acceptable or you want to repeat the blank measurement (i.e.: checking blank stability) then press the \( \uparrow \downarrow \) button to repeat the blank measurement.
There are 3 regions for blank value handling:

1. **Optimal** - all results are within acceptable ranges.

2. **Blank is high** - ! flag is displayed at relevant results.

3. **Blank exceeds acceptability** - no results displayed.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>1. No flag at parameter</th>
<th>2. ! flag at result</th>
<th>3. E (error) flag at result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HGB</td>
<td>0-1 g/dl</td>
<td>1 – 2.5 g/dl</td>
<td>&gt; 2.5 g/dl</td>
</tr>
<tr>
<td>WBC</td>
<td>0 - 0.5 x10^3 cells/µL</td>
<td>0.5 - 1.0 x10^3 cells/µL</td>
<td>&gt; 1.0 x10^3 cells/µL</td>
</tr>
<tr>
<td>PLT</td>
<td>0 - 25 x10^3 cells/µL</td>
<td>25 - 50 x10^3 cells/µL</td>
<td>&gt; 50 x10^3 cells/µL</td>
</tr>
<tr>
<td>RBC</td>
<td>0 - 0.05 x10^6 cells/µL</td>
<td>0.05 - 0.5 x10^6 cells/µL</td>
<td>&gt; 0.5 x10^6 cells/µL</td>
</tr>
</tbody>
</table>

See chapter 8.4.2 about the flagging cases.

Accepted blank values are essential for proper calibration and quality control measurement. For this reason, no calibration or QC measurement can be performed without accepted blank values.

Quality control measurement and calibration can be performed **only** if all blank values are in the first region (receiving no flags or errors).

If analysis errors occur or the blank measurement is too high, an E error flag appears along with the affected parameter and “---” is displayed instead of results. In this situation, perform a cleaning.
9 DATABASE

Patient results are stored in the memory in chronological order, and can be retrieved at any time. Memorizing capacity is 1,000 measurements, including the complete parameter list, histograms, flags, sample data, and date/time of measurements. If memory is full, latest (actual) record will overwrite oldest record.

To access the Database table, press the Database key on the front panel. The first screen that appears shows the most recent saved tests.

To display the histograms, press the soft key.

To print an individual result, highlight the result and press Print.

DATABASE LOCAL MENU

From the database table screen, enter the Database local menu by pressing the Menu key.

The menu contains the following items:

1. Go to specified record
2. Selection
3. Change sort order
4. Manage selected records
5. Back up to USB drive
<table>
<thead>
<tr>
<th>Command</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Go to specified record</td>
<td>Jumps to a particular sample record. Enter the date, sample ID, and patient ID of the sample you want to view, and press ✓. The first sample meeting your parameters is then displayed. If you leave any ID blank (0), records are searched by date/time only.</td>
</tr>
<tr>
<td>Selection</td>
<td><strong>Selects all</strong> sample records in memory, or all having a specific date, time and ID. <strong>Select by date, time and ID</strong> allows you to select a range of specific records, and <strong>Deselects all</strong> deselects all records. Entering 0 as an ID searches by date/time only. Corresponding results are marked with a filled box.</td>
</tr>
<tr>
<td>Change sort order</td>
<td>Changes the order in which results are displayed: by time, sample ID or patient ID.</td>
</tr>
<tr>
<td>Manage selected records</td>
<td>Sends selected records to a PC, deletes them, or saves them to a USB device. Before selecting ‘Backup selected records’, connect a USB storage device.</td>
</tr>
<tr>
<td>Backup to USB drive</td>
<td>Backs up all records from a specified day to USB storage device. Select a day to backup, then press ✓ to confirm.</td>
</tr>
</tbody>
</table>
10 UTILITIES

The ‘Abacus 3CT’ is equipped with a wide range of function to:

- Support daily operation;
- Check performance;
- Keep the instrument calibrated;
- Tailor the behavior of the ‘Abacus 3CT’ according to your needs.

10.1 Maintenance

By selecting item (1) of the UTILITIES, you can access the MAINTENANCE menu.

From Maintenance submenu, the user can initiate maintenance procedures such as cleaning, priming, draining chamber, reagent status.

10.1.1 Cleaning

Item 1 in the above menu brings up cleaning functions.

Item 1 starts a washing cycle using the system cleaner reagent. This action is recommended if clogging problems are experienced (C or Q error flag).

Item 2 initiates a process that uses a light solution of hypochlorite (NaOCl), and washes the entire system with it. The instrument will ask for the cleaning solution in a sampling tube. (See chapter 1.9.2.)

10.1.2 Priming
During the priming cycle, the fluidic system is rinsed with a large amount of diluent. It differs from the process in a start-up procedure; as in the latter case, a simple filling of the fluidics is performed. If fluid sensors are on, the analyzer makes these procedures automatically; otherwise, the User must initiate them activating the appropriate item within this submenu.

10.1.3 Draining chamber
Draining of the chamber should be run before removal or replacement of parts related to the measuring chambers or apertures (Service personnel task).

10.1.4 Reagent status & Reagent protection
The panel shows the estimated reagent / waste volumes in the containers, as calculated by the instrument. As measurements are performed, the volumes are changing accordingly. When reagent volume in a container is running low, instrument will notify user, and ask replacement.
A qualified service person can adjust the volume of the containers.

Press the soft key, select the reagent(s) to be replaced (reset status) then press to confirm.

If the lyse reagent is replaced and the ‘Abacus 3CT’ has a closed reagent system, then the ‘Abacus 3CT’ will ask for the hardware key.
In order to access the reagent protection panel press the soft key, the following panel will be displayed:

Module state:

- Open: there are no limitation about the number of measurements;
- Close: the measurement account is in use;

Available measurements: the number of remaining measurements. (Displayed in case of closed modules only.)

Identifier Module: the detection of the HW key.

If you want to upload the content of the hardware key (identification module) then insert the hardware key to the slot on the left hand side of the ‘Abacus 3CT’ and press the button. The status and the content of the hardware key will be checked.

Press the button to initiate the uploading process.

Confirm your choice by pressing the button.
After uploading the measurement rights, the empty hardware key will be reported as “identifier module not present”.

As the uploading procedure is initiated, the number of remaining measurements is truncated to 50. The content of the hardware key will be added later.

If there are more than 50 measurements left then the new number of available measurements will be 50 + content of the hardware key.

If there are 50 or less measurements left then the new number of available measurements will be the actual number + content of the hardware key.

As a default commercial procedure the hardware key is attached to the lyse container. (800 measurements with the 5L lyse container.) It is recommended to initiate the upload procedure if the lyse container is replaced.

10.2 Calibration

By selecting item (1) of the UTILITIES, you can access the Calibration submenu.

From the Calibration submenu, the user can initiate the calibration of the ‘Abacus 3CT’ instrument or can review the calibration history.
10.2.1 Perform calibration

Calibration can be performed in two ways:

1. User can manually enter calibration factors using the numerical keypad. In this case the user shall calculate and verify the new factors;

2. One, or three-fold measurements of calibration material with known parameters. In this case, the instrument automatically calculates new factors using the following formula:

\[
\text{New factor} = \frac{\text{Assigned value} \times \text{Stored factor}}{\text{Measured value(s) (or average of those)}}
\]

CAUTION! New calibration will invalidate the previous factors. Old values cannot be retrieved, but can be reviewed in the VIEW CALIBRATIONS menu.

It is recommended to do calibration in the following cases:

1. At analyzer installation, before beginning the analyses.

2. After replacing any component, related to the process of dilution or measurement.

3. When quality control measurements show any systematic error, (bias) or they are outside predefined limits.

4. At regular time intervals (determined by the lab itself).

10.2.1.1 Manual calibration

If you calculate the calibration factors from measurement results then you can put them into force on the ‘Set calibration factor’ panel. In order to access this panel, choose option ‘1 Factorial calibration’ on the Calibration settings panel and press the key.
Accept the new factors by pressing the ✔ key or discard them and return to the Calibration settings panel by pressing the ✗ button.

10.2.1.2 Measurement based calibrations
If you want the ‘Abacus 3CT’ to determine the calibration factors from single or 3 point measurements then choose option ‘2’ or option ‘3’ on the Calibration settings panel and press the ✔ key.

Use approved calibrator material (see chapter 2.3.6.3.) to perform the measurement-based calibration.

As the ‘Set calibrator’ panel opens, you can enter the target values. (The target values are listed on the package insert of the calibrator material.) If a target value is set to 0 then the given parameter will not be calibrated. Target values for calibrated parameters can be set within the following ranges:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Low limit</th>
<th>High limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>RBC (10^6/µL)</td>
<td>1.00</td>
<td>8.00</td>
</tr>
<tr>
<td>MCV (fl)</td>
<td>50</td>
<td>120</td>
</tr>
<tr>
<td>PLT (10^3/µL)</td>
<td>30</td>
<td>800</td>
</tr>
<tr>
<td>MPV (fl)</td>
<td>5</td>
<td>15</td>
</tr>
<tr>
<td>HGB (g/dl)</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>WBC (10^3/µL)</td>
<td>1.0</td>
<td>30.0</td>
</tr>
</tbody>
</table>

Table 7. Calibration ranges

When all parameters are set, press the ✔ soft key.
An empty (no measurement result) measurement panel opens, but the header refers to calibration sample.

Perform the measurement(s). See chapter 1. Follow the manufacturer's instructions about the sample preparation (mixing.)

10.2.2 Review old calibration factors
If the “2. View calibrations” option was selected on the ‘Calibration’ panel then the former calibration factors are displayed.

You cannot directly recall old calibrations, but you can manually copy / reuse old factors.
10.3 Quality Control Procedure

By analyzing control materials, the day-to-day reproducibility, accuracy, carryover and the general performance of the ‘Abacus 3CT’ can be monitored. Before performing QC measurements the target values and tolerance ranges for each parameter shall be specified for the given QC levels.

The target values and tolerance ranges are listed on the package-insert of the QC material.

### NOTE:
Target values of the control material should be set only once, when you start to use the given lot. Resetting parameters deletes previous QC results of the active level.

### CAUTION!
Any change in the QC material setting deletes previous QC results. It is strongly recommended to print results prior to changes.

The QC functions are located in the ‘Utilities / 3. Calibration control’ structure.

#### 10.3.1 Selecting QC level

First, select the desired ‘level’ if the actual value (displayed under the menu selections) is not adequate. (The practical reason for the 6 levels/ QC lots is old/active lot for low/normal/ high level.)

Set the reference data (target, tolerance) before using the QC lot. You can set the reference data manually.

#### 10.3.2 Manual entry of QC parameters

In the Quality Control menu, select ‘Set reference manually’:

Enter the value ranges for each test parameter and the lot identification (lot#, expiry date) as indicated on the paperwork accompanying the QC lot number you are using.

use the keypad or the external keyboard to change the values.

use the PGDN and PGUP to view additional parameters.

Enter 0.0 to disable the quality check of a parameter.
Press 🔴 to accept the data, then press 🔴 again to confirm.

10.3.3 QC measurement
Before performing QC measurements:

- Select the desired QC level (high, low, normal);
- Define the parameters of the given QC material. (Should be done only once.) In case of any doubt, please check the lot number and/or the parameters.

On the ‘Quality Control’ panel select the ‘3. Measure’ option.

There are differences in the handling of the QC materials and the ‘ordinary’ blood samples. The quality control materials are artificial/semi-artificial blood samples. They require different homogenization/mixing procedures.

| ! | Always follow the manufacturer’s instructions about the homogenization/preparation of the QC material! |
| ! | Keep track of the expiration date and open-bottle stability of the QC material! |
| ! | Most of the QC materials shipped with non-piercable hard cap. Measure the QC samples in open mode! |

If the QC material is properly defined, then:

- Homogenize the QC material;
- Open the Quality control/Measure panel;
- Remove the cap; insert the sample tube into the sample rotor. (You may need to use a different sample holder.)
- Press the ‘START’ button;
- Check the results.
10.3.4 QC database
The QC database contains the results of the QC measurement.

See chapter 1 for the available database options, functions.

To access the QC database open the Quality control / QC database function.

Note: This function is available only if there are valid QC measurements.

10.3.5 QC diagrams
On the QC diagrams are Levey-Jennings charts built from the QC results.

- Please ensure that the correct level is selected before checking the QC diagrams;
- Each monitored parameter has its own diagram. You can scroll the pages to access all the diagrams;
- You can swap between the 16 and 64 days modes.

10.4 Diagnostics
The diagnostics panel is accessible as: ‘Utilities / 4. Diagnostics.

On the panels, opening from the diagnostics panel you can find useful information about the ‘health’ of your instrument.

10.4.1 Device Information
The device information panel is accessible as: ‘Utilities / 4. Diagnostics / 1. Device information

On this panel, the SW/HW identification of your instrument is displayed:

- Model;
- Serial number;
- Software version;
- Compile date of the software.
10.4.2 **Statistics**

The statistics panel is accessible as: ‘Utilities / 4. Diagnostics / 2. Statistics

On this panel, you can find statistical information about your ‘Abacus 3CT’ instrument.

10.4.3 **Self Test**

The self-test procedure can be started as: ‘Utilities / 4. Diagnostics / 3. Self-test

After selecting this option the ‘Abacus 3CT’ will perform the self-test procedure. The results are displayed on the self-test panel.

The Self-test is a procedure to verify the proper operation of essential components of the instrument.

The Self-test should be performed:

- At installation.
- After replacing any component.
- After extended time out of use.

When the test is finished, the ‘Abacus 3CT’ displays a summary of the results.
The results are acceptable within the following ranges:

<table>
<thead>
<tr>
<th>Test parameter</th>
<th>Low limit</th>
<th>High limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electrode voltage [V]</td>
<td>45</td>
<td>55</td>
</tr>
<tr>
<td>Electrode current [uA]</td>
<td>830</td>
<td>930</td>
</tr>
<tr>
<td>Amplifier offset [mV]</td>
<td>-5</td>
<td>5</td>
</tr>
<tr>
<td>Noise [pls]</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>Pulse [pls]</td>
<td>19995</td>
<td>20005</td>
</tr>
<tr>
<td>Peak [mV]</td>
<td>1500</td>
<td>1800</td>
</tr>
<tr>
<td>Deviance [mV]</td>
<td>0</td>
<td>80</td>
</tr>
<tr>
<td>Power +12V [V]</td>
<td>11</td>
<td>12.5</td>
</tr>
<tr>
<td>Power -12V [V]</td>
<td>-13</td>
<td>-11</td>
</tr>
<tr>
<td>Battery [V]</td>
<td>2.2</td>
<td>4.5</td>
</tr>
<tr>
<td>Atm. pressure [mBar]</td>
<td>500</td>
<td>1050</td>
</tr>
<tr>
<td>Vacuum [mBar]</td>
<td>350</td>
<td>600</td>
</tr>
<tr>
<td>Drift [mBar / 5 sec]</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>HGB dark</td>
<td>0</td>
<td>3000</td>
</tr>
<tr>
<td>HGB light</td>
<td>3000</td>
<td>60000</td>
</tr>
</tbody>
</table>

If any of the parameters tests fails then contact your service representative!

After the self-test procedure completed you can:

- Repeat the test;
  - or
- Return the ‘Diagnostics’ panel/ menu.
10.5 Settings
Selecting item five (5.Settings) of the UTILITIES you can access to this menu. Using this menu:

- Printers;
- Customization;
- Date and time;
- Fluid sensors;

can be set and defined

10.5.1 Printer settings
Selecting item one (1.Printers) from Settings menu brings up the Printers submenu.

Printer: you can choose between a built-in printer or a USB connected external printer. If the name of the USB printer appears in the list, the printer is supported.

Margin unit: this one can be inch or cm.

Top margin: is used for determining the distance between the upper edge of the sheet and the printed report.

Left margin: is used for determining the distance between the left edge of the sheet and the printed report.

Quality: you can choose between the Normal or a Draft mode of printing.

1. Enable color print: The printout can be color or monochrome.

2. Enable auto print: If enabled, instrument prints results automatically at the end of analysis.

3. Print parameter limits: Enable or disable parameter limit printing.

4. Print warnings: Select to print warning flags that appeared in the result.

5. Print histograms: Enable / disable graph printing.
6. **Print technical information**: If selecting then probe voltages (WBC, RBC), and software / firmware version appear in the printout.

7. **Print logo**: If selecting then the Diatron logo will be printed on the printout.

Press the ✅ soft key to save the settings.

### 10.5.2 Customize

Use the Customize menu to the ‘Abacus 3CT’ according to your needs.

Press the **Utilities** key ➕.

Select **Settings**

Select **Customize**
### 10.5.2.1 General Settings

Select General Settings

This is a collection of settings influencing instrument operation, customization.

The table below describes available settings.

<table>
<thead>
<tr>
<th>Setting</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Play sound</strong></td>
<td>Allows switching the sound signal on/off</td>
</tr>
<tr>
<td><strong>Serial I/O speed (Baud)</strong></td>
<td>Offline, USB, Baud rate (9600, 115200). Protocol used by ‘Abacus 3CT’ to communicate with a connected computer.</td>
</tr>
<tr>
<td></td>
<td>- if the instrument is not connected to a computer, choose Offline;</td>
</tr>
<tr>
<td></td>
<td>- if the instrument is connected computer using USB cable, choose USB.</td>
</tr>
<tr>
<td><strong>Display turnoff time</strong></td>
<td>You can set the time after how many minutes the LCD light will turn off when not using the instrument</td>
</tr>
<tr>
<td><strong>Barcode reader mode</strong></td>
<td>Possible values:</td>
</tr>
<tr>
<td></td>
<td>- Sample ID;</td>
</tr>
<tr>
<td></td>
<td>- Patient ID;</td>
</tr>
<tr>
<td></td>
<td>- Disabled</td>
</tr>
<tr>
<td></td>
<td>This setting has meaning on the Measurement panel only: If the Sample ID mode or the Patient ID mode is selected then the data, read by the bar-code reader will be directly inserted into corresponding (Sample ID / Patient ID) field, without opening the ‘Sample information’ panel.</td>
</tr>
<tr>
<td></td>
<td>In all other cases the bar code reader works as a virtual keyboard, the read data is entered into the active field.</td>
</tr>
</tbody>
</table>
10.5.2.2 Laboratory information

Enter your clinic or laboratory information as follows, to be printed automatically on report headers. You can also use this procedure to edit or change this information.

Enter the name and address of your clinic or laboratory.
Press OK to move to the next line.
Press ✓ to accept the settings.

10.5.3 Date and time

The date and time of each analysis is stored with the results. This menu allows setting the built-in clock and the format of the date displayed.

Press the Utilities key, and then select Settings.

Select Date and time.

Type in the date and time, then press ✓.

Select formats for displaying the date and time, then press ✓ to accept the settings.
10.5.4 Fluid sensors
The ‘Abacus 3CT’ is equipped with several sensors. 4 of them can be enabled/disabled from the user interface. These sensors are the Diluent, Lyse, Cleaner and Blood sensors. Each of them is monitoring the presence of the corresponding liquid at a given point of the fluidics system. This monitoring reduces the risk to perform a measurement without the adequate amount reagent/blood sample, and has other technology functions as well.

| You can perform measurements (blood-sample, QC, calibration blank) only if all the fluid sensors are turned on (enabled) (the check box is set). |

You can perform maintenance style sequences only, if one or more of the sensors are disabled.

Turn off/disable) one or more sensors and perform the related maintenance operations if:

- There is foaming inside the ‘Abacus 3CT’ or some of the reagent inputs have foam inside the tubing. The typical reason for foaming if wrong reagent is used with the ‘Abacus 3CT’ instrument. In case of foaming, there are too many liquid-air changes and the fluid detectors cannot reliably detect the presence of the fluid. In this case, turn off the affected sensors and perform cleaning/hard cleaning sequences until the foaming stopped and the ‘Abacus 3CT’ operational again. Afterwards enable all sensors again and calibrate them.

- Some contamination dried in or accumulated, in such a position that it blocks the sensor. (The sensors always detect liquid.) In this case, turn off the affected sensor(s) and perform cleaning/hard cleaning sequences until the contamination removed and the ‘Abacus 3CT’ operational again. Afterwards enable all sensors again and calibrate them.

- If the support/service person instructs you to do so. In this case, follow his/her instructions.

The ‘Calibrate sensors’ function start a procedure which re-adjust the trigger/threshold setting of the fluid sensors to able to clearly distinguish liquid and air.
10.6 Service
The ‘Utilities/service’ panel shall be filled out by the installation personnel. On this panel, you should find the contact information to your service/distributor.

10.7 Background functions
The ‘Abacus 3CT’ has background/automated functions as well. Most of these functions are practically invisible for the user. In the following chapters describe some of these functions.

10.7.1 Reagent level monitoring
The ‘Abacus 3CT’ keeps track of the used reagents and the generated waste. If the liquid levels reach the preset limit then the ‘Abacus 3CT’ prompts the user to replace the given container before the reagent runs out in a measurement cycle or the waste spills out. See chapter 10.1.4
11 MAINTENANCE

11.1 User-accessible parts
On the right-hand side of instrument there is a side door, which allows reaching the fluidic system and the mechanical parts easily.

Figure 7. Fluidic and mechanical parts

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reagent sensor</td>
<td>7</td>
<td>Valve block 7 - 10</td>
</tr>
<tr>
<td>2</td>
<td>Mixing head</td>
<td>8</td>
<td>Valve block 11 - 16</td>
</tr>
<tr>
<td>3</td>
<td>Needle moving mechanics</td>
<td>9</td>
<td>Vacuum Chamber</td>
</tr>
<tr>
<td>4</td>
<td>Amplifier assembly</td>
<td>10</td>
<td>Fivefold dilutor</td>
</tr>
<tr>
<td>5</td>
<td>Chambers and apertures</td>
<td>11</td>
<td>Double dilutor</td>
</tr>
<tr>
<td>6</td>
<td>Valve block 1 - 6</td>
<td>12</td>
<td>Reagent inlets</td>
</tr>
</tbody>
</table>
11.2 Maintenance schedule

- The user must not remove any covers of the ‘Abacus 3CT’ analyzer!
- User must not disassemble the power supply unit!
- The user is allowed to access/ maintain/ check the following parts behind the side-door of the ‘Abacus 3CT’ instrument:
  - Tubing;
  - X-Y mechanism.
- The following parts must NOT be opened or serviced by the user:
  - power supply
  - instrument housing, and electronic boards

11.2.1 Daily maintenance, before daily routine:
- Check reagent condition: go to reagent status screen, check if the liquid amount in reagent containers is enough for the expected number of daily measurements.
- Check the content of waste tank, if the level is above 80% it is recommended to empty the waste container. See chapters 2.3.9 & 10.1.4!
- Check the existence of air bubbles at rear reagent liquid connectors and syringes (except waste line). In case of bubbles run prime reagent function at regarding reagent
- Check the blank results: if the results of the automatic blank measure (at the first accessing the measurement panel) are within range, accept the results and proceed with your routine. See details in chapter 8.5;
- Run QC samples according to the regulations of laboratory. If there are no other rules, run at least normal control, and check if the results are in range. Use the QC menu of instrument!

11.2.2 Daily maintenance, after daily routine:
- Run cleaning process in Maintenance menu.

11.2.3 Weekly:
- Hard cleaning: pour 1ml of 2% Sodium Hypochlorite solution into a sampling tube, run hard cleaning procedure (See: 10.1.1). It removes remainders of blood samples measured during the daily routine;
- Check tubing system – by opening the side door and looking for any liquid leakage. If you experience leakage, contact authorized technician.
11.2.4 **Semi-annual:**

**Run self test:** as it is written in chapter 10.4.3. If the overall result is “Errors”, print out the result and call service.

11.3 **Cleaning**

![Warning]

Disconnect the ‘Abacus 3CT’ and the power supply from the electric network before cleaning it!

Clean the instrument and its power supply on the outside only, using a damp cloth with a soft detergent. DO NOT let liquids get inside the units.
12 PRINTING

This chapter covers information on making reports on measured samples.

12.1 Printouts

When required, the following items can be sent to an external printer or to a built-in printer by pressing the function key button.

* Database result(s) (table format)
  - Database (specified patient results with histograms)
  - QC result (Levey-Jennings chart)
  - QC result(s) (table format)
  - Calibration results
  - Last measured blank result
  - Last measured patient result (with histograms)
  - Last measured QC result
  - Device information and statistics
  - Self test result
  - Set parameters

The appropriate printout format can be selected in UTILITIES/SETTINGS/PRINTER SETTINGS).
Thermal paper printout

Printout on external printer (color)

Sample ID: 5942507
Name: JOHN SMITH JR.
Date of Birth: 1977-07-07
Type: Male
Sex: Male

Test date: 2010-05-30 4:39 PM
Report date: 2010-07-08 1:04 PM
Serial No.: 296005

WBC 8.82 (10^3) / µL
LYM 4.60 (10^3) / µL
MID 0.65 (10^3) / µL
GRA 4.24 (10^3) / µL
LYM% 45.1% ± 5%
MID% 7.3% ± 5%
GRA% 47.6% ± 5%
RBC 4.50 (10^6) / µL
HGB 12.5 g/dL
HCT 38.5% ± 5%
MCV 88 fL ± 5%
MCH 27.7 pg ± 5%
MCHC 31.5 g/dL ± 5%
PLT 250 (10^3) / µL
MPV 12.3 fL ± 5%

Platelet counts (min/hr):
WBC
RBC
PLT

Abacus 3CT
Ditron

Thermal paper printout

Sample ID: 5943369
Name:
Type: Human
Sex:
Doctor:

Test date: 01.07.2010 16:49
Report date: 16.07.2010 14:31
Serial No.: 1

WBC 8.44 (10^3) / µL
LYM 2.59 (10^3) / µL
MID 0.74 (10^3) / µL
GRA 4.14 (10^3) / µL
LYM% 42.2% ± 5%
MID% 1.4% ± 7%
GRA% 49.6% ± 7%
RBC 4.65 (10^6) / µL
HGB 11.4 g/dL
HCT 37.1% ± 5%
MCV 80 fL ± 5%
MCH 25.1 pg ± 5%
MCHC 31.6 g/dL ± 5%
PLT 344 (10^3) / µL
MPV 11.1 fL ± 15%

WBC
RBC
PLT

Abacus 3CT
Ditron
Abacus 3CT  Fluidic Schematics
THIS PAGE IS LEFT INTENTIONALLY BLANK
# 14 WARNING LABELS ON THE ANALYZER

<table>
<thead>
<tr>
<th>Label</th>
<th>Meaning</th>
<th>Explanation</th>
<th>Chapter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biohazard</td>
<td></td>
<td>The sample and the waste are potentially infectious material</td>
<td></td>
</tr>
<tr>
<td>Corrosive</td>
<td></td>
<td>Reagents may cause corrosion or skin irritation.</td>
<td></td>
</tr>
<tr>
<td>Warning</td>
<td></td>
<td>General warning of injury.</td>
<td></td>
</tr>
<tr>
<td>Sharp needle warning</td>
<td></td>
<td>The sampling needle may cause injury.</td>
<td></td>
</tr>
</tbody>
</table>