Biosen C-Line | Clinic / GP+

Glucose/Lactate Measuring System

User Manual

EKF Diagnostics

Subject to alteration. Errors excepted.

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Manual Revision and Changes
3.0 Complete review and amendment reflecting the changed appearance of the Biosen C-Line, Intended purpose according to IVDR, Restructuring chapter order.

Contents

0. IMPORTANT INFORMATION / SAFETY NOTES

0.1 Symbol

The following symbol is used in this user manual:

Caution
This Symbol indicates that caution is necessary when operating the device, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

0.2 Safety Notes

It is essential that you read the following notes to avoid risks to persons and damage to the device and other equipment. The handling of the device requires full understanding and strict observance of this manual. EKF-diagnostic GmbH does not accept any responsibility for damage arising from non-observance of the following notes.

Danger of infection
The device processes samples of human origin. This involves potential risk of infection. Particularly the sample cannula, the exchanger, the chip sensors, the tray and the waste container can be contaminated. Protective gloves should always be worn when operating the device.

Danger of electric shock
Under no circumstances should you open the device. There are no components inside which require servicing or maintenance. Repairs to the device must only be performed by EKF-diagnostic GmbH or an authorized service partner.

Never use a damaged device. If your device is damaged unplug the power cord from the wall socket and contact service.

The device is not insulated against fluid ingress. If a fluid spillage is suspected unplug the power cord from the wall socket and contact service.

Danger of explosion
The device is not approved for use in areas where there is a risk of explosion.

Only use the Biosen C-Line for the purpose described in section 1. Observe the specifications for the use, storage and transport of products.

Only use equipment and consumables, which are expressly approved by EKF-diagnostic GmbH for use with the Biosen C-Line.

Moving Parts
The device has parts that can move unexpectedly during normal operation. It is recommended not to touch these parts during operation because the device may immediately abort a running measurement operation.

Maintenance
The device should be subject to regular maintenance. It is recommended to make a service contract. Repairs to the device must only be performed by EKF-diagnostic GmbH or an authorized service partner.

For users in the European Union only:
Please report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

0.3 Abbreviations

STD	Standard
C1 / C2	Control 1 and 2
STAT	Urgent sample
Glu	Glucose
Lac	Lactate
QC	Quality control
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
Hct	Hematocrit
UL	Upper limit
LL	Lower limit
P	Position in the tray
No	Running sample number
PID	Sample Identification (from Barcode)
Ref. Type Glu	Reference Type for Glucose testing
GUI	Graphical User Interface

1. INTENDED USE

The Biosen C-Line is an automated analyzer intended to be used for quantitative in-vitro diagnostic determination of chemistry analytes using the Biosen Sensors and Consumables. It is used for near-patient testing by healthcare professionals and laboratory testing by laboratory professionals.

2. DESCRIPTION OF DEVICE COMPONENTS

Figure 1 – Front view

NR.	C-Line Clinic	C-Line GP+
1	Display with touch panel	Display with touch panel
2	Tray for 20 samples	Tray for 5 samples
3, 4	Positions for standard 1 and 2 (STD1, STD2)	Positions for standard 1 and 2 (STD1, STD2)
5, 6	Positions for control 1 and 2 (C1, C2)	Positions for control 1 and 2 (C1, C2)
7	Positions for urgent sample (STAT)	Positions for urgent sample (STAT)
8	Exchanger (maintenance part)	Exchanger (maintenance part)
9	Sample cannula (maintenance part)	Sample cannula (maintenance part)
10	Lifter	Lifter
11	Pivot arm	Pivot arm
12	Pump tube (maintenance part)	Pump tube (maintenance part)
13	Pump with pump flap	Pump with pump flap
14	Sensor holder measuring channel 1	Sensor holder measuring channel 1
15	Sensor holder measuring channel 2 (optional)	Sensor holder measuring channel 2 (optional)
16	Opening for bottle of system solution	Opening for bottle of system solution
17	Opening for waste bottle	Opening for waste bottle
18	Waste bottle with lid, color code black + symbol Biohazard	Waste bottle with lid, color code black + symbol Biohazard
19	Bottle for system solution with lid, color code red	Bottle for system solution with lid, color code red
20	Card reader	Card reader

Figure 2 – Rear view

NR.	Description
1	Mains connection with 2 fuses
2	Serial interface for printer DPU-S445
3	Serial interface for EDP connection
4	Ethernet
5	USB

3. DESCRIPTION OF GRAPHICAL USER INTERFACE

The touch panel is the main interface for the user. The home screen is displayed in **Figure 3**. You can see the status of the device **(1)** and use the main functions to perform measurement **(2)** and access the memory **(3)** directly from this screen.

NR.	Description
1	Status of the device + advice text
2	Perform measurement
3	Memory
4	Date and time
5	Main Menu
6	Info Menu
7	Stand by

Figure 3 – Home screen view

In some instances, additional screens are available by swiping to the side. This is always indicated by page indicators in the form of grey dots at the lower end of the display **(see Figure 4)**.

Figure 4 - Page Indicator

A white arrow on the right indicates, that there are more buttons available **(see Figure 5 and Figure 6)**.

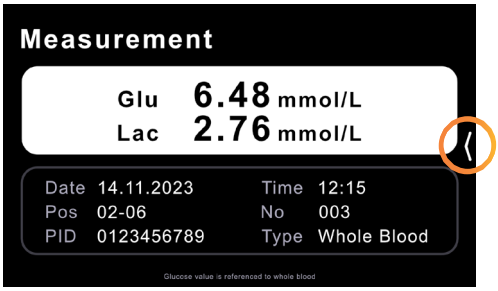


Figure 5 - white arrow at the right

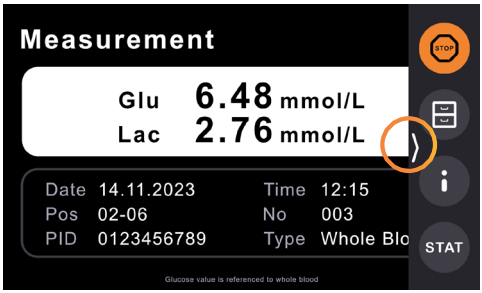
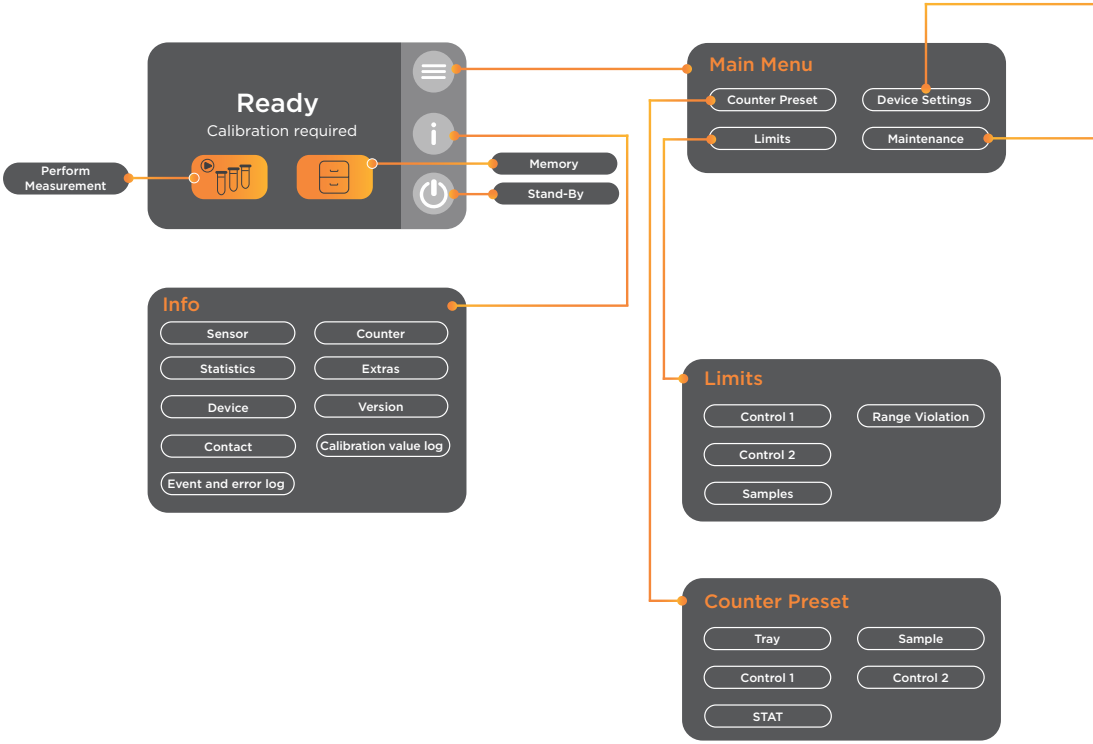


Figure 6 - additional buttons

All functions are available in the main menu. If you look for a specific function, you can use the menu overview to navigate fast to the desired function.

Menu Overview



Besides the standard design of the screens, there are two types of screens which need special attention by the user. When the user requests irreversible actions, a turquoise attention screen appears **(see Figure 7)**. Any error will be displayed in red **(see Figure 8)** and includes the header "Error", an exclamation mark, a short failure description, if available a short application for action and an error code.

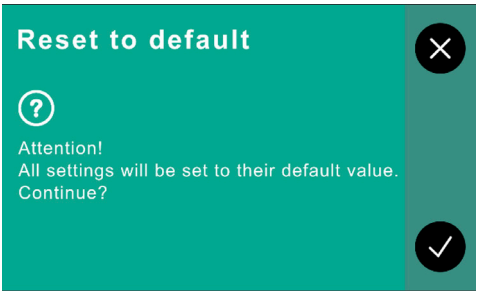


Figure 7- Attention! Screen

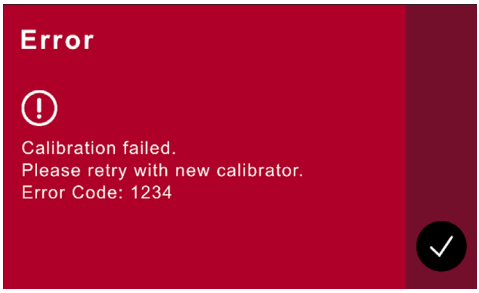
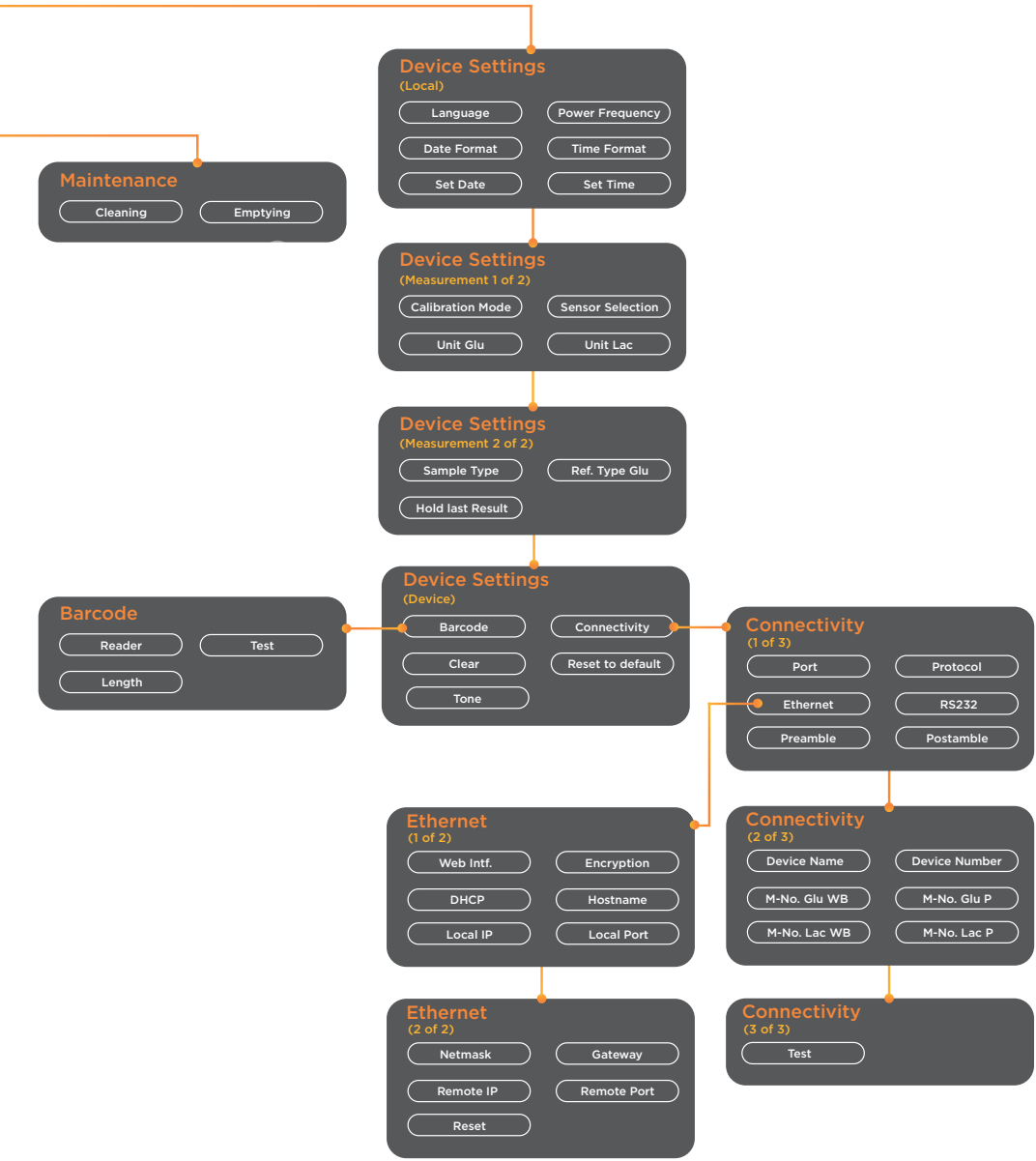


Figure 8- Error screen


Device Settings
(Local)
Language
Power Frequency
Date Format
Time Format
Set Date
Set Time
Maintenance
Cleaning
Emptying
Device Settings
(Measurement 1 of 2)
Calibration Mode
Sensor Selection
Unit Glu
Unit Lac
Device Settings
(Measurement 2 of 2)
Sample Type
Ref. Type Glu
Hold last Result
Device Settings
(Device)
Barcode
Connectivity
Clear
Reset to default
Tone
Barcode
Reader
Test
Length
Connectivity
(1 of 3)
Port
Protocol
Ethernet
RS232
Preamble
Postamble
Ethernet
(1 of 2)
Web Intf.
Encryption
DHCP
Hostname
Local IP
Local Port
Connectivity
(2 of 3)
Device Name
Device Number
M-No. Glu WB
M-No. Glu P
M-No. Lac WB
M-No. Lac P
Ethernet
(2 of 2)
Netmask
Gateway
Remote IP
Remote Port
Reset
Connectivity
(3 of 3)
Test

4. SETTING UP

Before you set up and connect the device, check that you have received all components belonging to the product free of mechanical damage.

- Device Biosen C-Line
- Sample tray (Clinic) respectively sample receptacle (GP+)
- Bottles for system solution and waste
- Power cable

Material required but not provided:

- System solution
- Chip sensors for glucose and / or lactate measurement
- Pre-filled micro test tubes for sampling with capillaries (Hemolyzing Solution)
- Micro test tubes with calibration solution (Multi Standard Solution)
- Blood sampling equipment

4.1 Place of installation

Danger of explosion
The device is not approved for use in areas where there is a risk of explosion.

Select a suitable place for setting up the device and make sure to:

- Check that the room is of an ambient temperature: 15 - 35 °C
- Check that the room is of a humidity of: 20 - 85 %
- Avoid direct influence of damp
- Avoid direct sunlight
- Avoid strong electromagnetic fields
- Avoid direct influence from ionizing radiation
- Avoid rapid temperature variations (keep away from heaters, open windows, ventilators, extraction or air conditioning systems, etc.)
- Operate the device in dry rooms on a flat, waterproof surface
- Free space around the analyzer to ensure good ventilation

Allow the device to equilibrate to room temperature before operating! When changing from a cold into a warm environment condensation can form inside the device. Wait for minimum one hour before you connect the device to the mains.

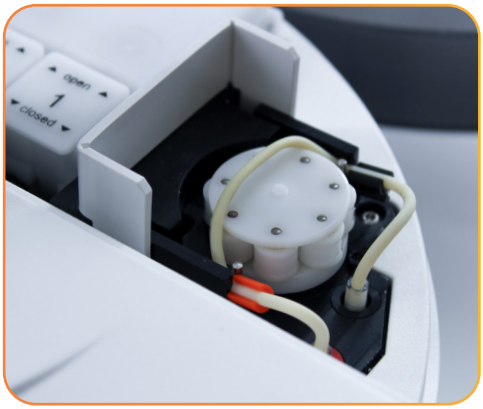
4.2 Preparations for device operation

4.2.1 Bottles

- Pour system solution into the bottle **(Figure 1)** and place in the appropriate opening.
- Place the empty waste bottle **(Figure 1)** in the appropriate opening.

4.2.2 Pump tube

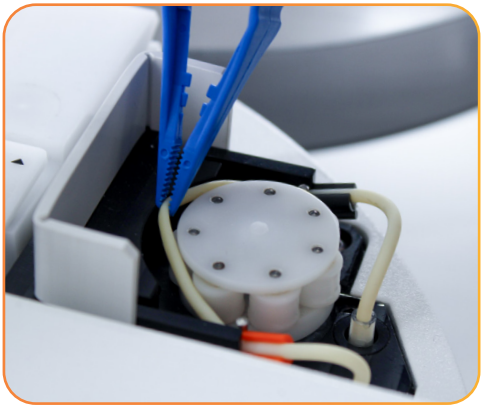
The device is delivered with a pump tube disconnected from the pump rollers, this is in order to avoid the tube becoming stuck when at rest. For initial start-up the pump tube must be looped over the pump rollers.



State on delivery

Open pump latch (raise up from right to left).

Figure 9 – Pump tube disconnected from pump rollers



The pump tube must be looped over and centered on the pump rollers. A rounded pair of tweezers is recommended for this. **Do not use sharp objects.**

Then close the pump latch from left to right.

Figure 10 - Looping over pump tube

4.2.3 Chip Sensor

The chip sensors are the core of the measuring system. They convert the sample concentration into an analyzable, electrical signal.
Only type II chip sensors from EKF-diagnostic GmbH may be used. EKF-diagnostic GmbH offers chips sensors for glucose and lactate determination as well as dummy sensors **(see section 10.1)**.

The device has at least one or optionally two measuring channels. With two measuring channels, glucose and lactate can be measured from one sample at the same time. The device recognizes the chip sensors (glucose, lactate, dummy sensors) automatically. No manual settings are required.

It does not matter which sensor is placed in which measuring channel. The same parameter can be measured on both channels. It is recommended to equip measuring channel 1 with glucose and measuring channel 2 with lactate. If a device with two measuring channels is operated with only one sensor, there needs to be a dummy sensor (accessory) in measuring channel 2. In this case it is recommended to place the active sensor in measuring channel 1 (higher measuring speed).

Plug the power cable in the device and the power socket.

Danger of electric shock
An isolated ground receptacle is mandatory for operating the device. Check whether the mains voltage and frequency printed on the type label match your mains socket.

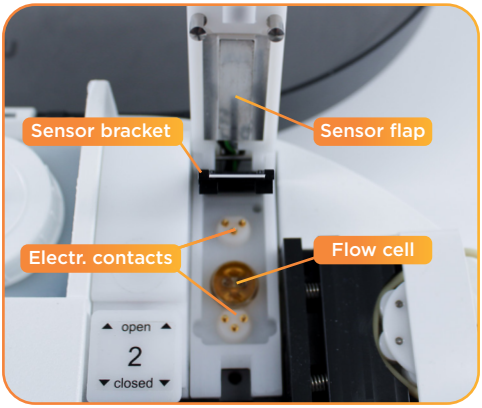
The display will read "`Please insert sensor!`".

Open the sensor latch by pressing it down on the **open** side.

Figure 11 - Opening the sensor latch

Push the latch further up from below to open the sensor holder completely.

Figure 12 - Opening the sensor holder



Opened sensor block.

Figure 13 - Sensor holder open

Do not touch the electrical contacts and do not apply moisture to the electrical contacts. Carefully dab away moisture on the flow cell and sensor bracket using a lint-free cloth.

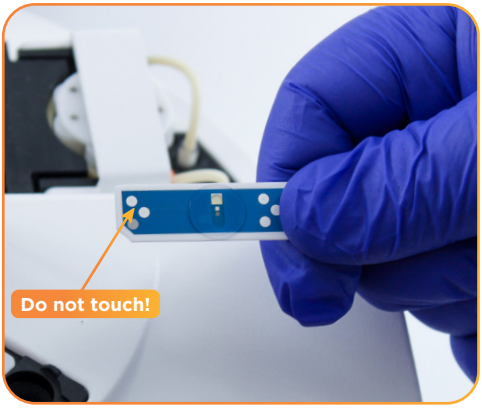


Figure 14 - Sensor

Hold the sensor only as illustrated in the figure. Do not touch the area with the beveled corner!

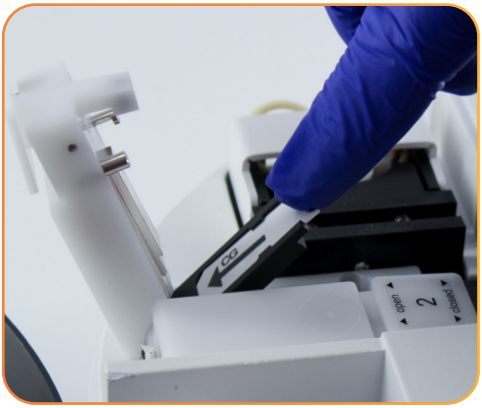


Figure 15 - Inserting the sensor

Insert the sensor into the sensor bracket and press down until it stops. The arrow on the reverse side must be visible and pointing in the direction of insertion.

If the sensor is inserted incorrectly and the sensor latch is forced down, the sensor will be damaged.

Close the sensor holder and press the latch down on the **closed** side until it audibly (click) engages.

Figure 16 - Closing the sensor holder

Repeat this procedure for the second measuring channel if applicable.

Once the measuring channel is equipped correctly, the "`Sensor Replacement`" window opens where the inserted sensors has to be identified as "`New`".
After the sensor is inserted, the device needs some time for sensor conditioning. This time is shown on the display and counts down. During this period it is not possible to conduct measurements.

4.2.4 Mains

It is essential that the actual mains frequency is set in the **main menu/device settings** before measurement.

The device is designed for a mains voltage of 100 to 240 Volt and a frequency of 50 or 60 Hz. Set the mains frequency in the main menu/device settings to the correct value for your region. For further enquiries contact your technical consultant or dealer.

The device is designed for continuous operation. Even in the stand-by state, the chip sensor and flow system use internal device functions, which are available only when the device is connected to the mains supply.

4.3 Barcode (only C-Line Clinic)

If the barcode function is activated (default setting), the barcode scanner reads barcode labels of samples which are placed in the sample tray. In standard, control and STAT positions the barcode cannot be read.

The internal barcode scanner can be activated or deactivated in the **main menu/ device settings/barcode/Reader** menu.

4.3.1 Barcode format

To reduce the risk of incorrectly read barcode values, it is recommended to define the length of the barcode. The length can be adjusted between 0 and 12, where 0 corresponds to a setting with variable barcode length.

All usual barcode formats (Code39, Code93, Codabar, Code128, 2 of 5, Interleaved 2 of 5) with a maximum of 12 characters are supported.

4.3.2 Specification of the barcode label

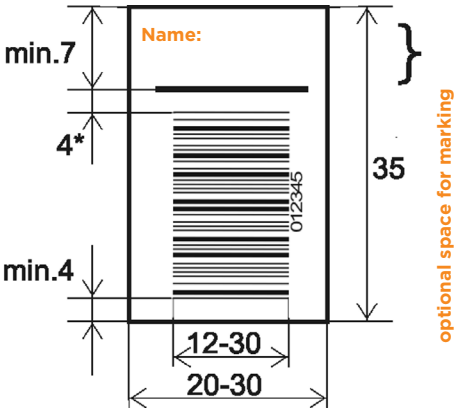
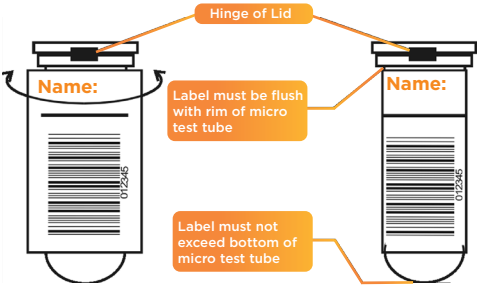


Figure 17 – Barcode label

The gap between the barcode and the upper edge of the sheet must be at least 7 mm, between the barcode and the lower edge of the sheet at least 4 mm. The barcode must be at least 12 mm wide. The label dimensions must not exceed 35 x 30 mm.

The area for the name is optional. If the name does not appear then the borderline and the upper empty area of 4 mm can be omitted, hence the barcode can be extended.

4.3.3 Positioning of the barcode label



The label must be stuck centered to the hinge axis, vertically and without folds. The label must not come off, particularly in the upper area, hence press it on firmly.

Figure 18 - Positioning barcode label

To check the compatibility of barcodes label and the device, a Barcode test can performed. Place a sample tube with barcode label in the sample holder and start the test under **main menu/device settings/barcode/test**.

4.4 Calibration

The device calibrates iself using multi standard solutions with a known concentration. All measurements are related to this calibration and three calibration modes can be selected to control the calibration functions. The multi standard solution must be obtained from EKF-diagnostic GmbH in ready-to-use form **(see section 10.1)**.

Place the multi standard solution in the STD1 or STD2 position **(see Figure 1)**.

The desired calibration mode can be set in the **main menu/device settings/calibration mode**:

"`Before Measurement`"
The device calibrates itself before every measurement starts. In the home screen the following is always displayed: "`Ready Calibration required`"

"`Periodic`"
The device calibrates itself automatically every 60 min. At measurement start the samples are measured immediately. In the home screen the following is displayed: "`Ready Next calibration in xx min`", where xx stands for the time until the next automatic calibration. If the calibration time runs out while samples are still being measured, the sample measurement is interrupted, and continued after successful calibration.
If a calibration was not successful, an error message appears. This needs to be confirmed then the device changes to the Ready state. The home screen now shows "`Ready Calibration required`". At measurement start a calibration takes place first.

"Time account"
The device is ready to measure for 60 minutes after a calibration. At measurement start the samples are measured immediately. In the home screen the following is displayed: "Ready Calibration valid xx min". Once the 60 min have elapsed calibration does not take place automatically. The home screen now shows "Ready Calibration required". At next measurement start, a calibration takes place first.

4.5 Adjustment whole blood glucose/plasma glucose (optional)

The devices are measuring glucose in various sample materials such as whole blood, serum and plasma. At default settings, the measured glucose concentration of the respective sample material is displayed. Based on the different content of water respectively solids, the measurement result from serum/plasma is about 11 % higher than from whole blood.

To avoid confusion between whole blood glucose and serum/plasma glucose the IFCC recommends the general declaration of glucose values as plasma glucose. To this end, it is possible to display values, measured in whole blood, as calculative corrected plasma glucose values. The calculation is carried out with a constant factor of 1,11 according to the current recommendation of the IFCC.

The adjustment of whole blood glucose/plasma glucose can be activated in the **main menu/device settings/Ref. Type Glu**. The default is whole blood glucose. The activation can be checked in the **Info Menu** "Info-4 Extras".

Be aware of the different Glucose reference Types plasma or whole blood for glucose values. You can check in the Info menu, if whole blood samples are displayed as plasma referenced.

If the adjustment is activated, the sample type has to be set correctly in the **main menu/device settings/sample type** If the sample type whole blood is selected, the displayed value is calculative increased by 11 %. If the sample type plasma is selected, no value correction occurs. The adjustment is valid for all sample positions as well as the urgent sample position. The control and standard positions will not be affected.

In order to avoid erroneous measurement results, carefully select the corresponding sample type for the used sample material. Do not mix the sample type during a measuring series.

4.6 Quality control

EKF-diagnostic GmbH recommends regular performance of quality control measurements.

EKF-diagnostic GmbH offers different control materials **(see section 10.1)** to facilitate compliance with local, state and/or federal regulations or accreditation requirements. For handling the control material refer to the respective operating instructions. It is recommended to use EasyCon norm and EasyCon pat for daily control.

The measurement of controls is carried out on positions C1 and C2 **(Figure 1)**. If the control positions are equipped, they are measured and evaluated after every successful calibration. If control measurements are not desired after every calibration, the controls must be removed from the positions C1 and C2.

The control value limits, as well as the action taken in case of range violation, can be set in the **main menu/limits**.

4.6.1 Limits

The upper limit (UL) and lower limit (LL) can be defined for control 1, control 2 and sample.

4.6.1.1 Samples

Setting of warning limits for sample measurements for both measuring channels. Possible settings are:

Glucose	0,5 mmol/l (9 mg/dl) – 50 mmol/l (900 mg/dl)
Lactate	0,5 mmol/l (5 mg/dl) – 40 mmol/l (360 mg/dl)

4.6.1.2 Control 1

Setting of warning limits for special position C1. The defined upper and lower limit must agree with the permitted limits of the used control material.

4.6.1.3 Control 2

Setting of warning limits for special position C2. The defined upper and lower limit must agree with the permitted limits of the used control material.

4.6.1.4 Range Violation

These settings control the action taken, when defined limits are exceeded.

"Continue even if QC fails"
If limits are exceeded in controls C1 or C2, measurement of the samples can be aborted or continued.

"Double determination""
If limits are exceeded during sample measurement, a second measurement of this sample can be carried out (double determination).

4.7 Prepaid Mode (optional)

In the prepaid mode, measurements are only possible when the device is in credit.

Credit is paid to the device using a Prepaid Card. Prepaid Cards always belong to a particular device by means of the serial number and are available with different amounts of credit. The number of measurements by which the device is in credit is displayed in the home screen as advice text.

The displayed credit is reduced by 1 with:

- each sample measurement
- each urgent sample measurement

The displayed credit is not reduced for:

- control measurements in positions C1 and C2
- calibrations
- double determination of the same sample

Once the credit is used up, no measurements or calibrations are possible. A new credit can be topped up at any time. Existing credit is retained.

To top up the credit, proceed as follows:
The device must show the home screen. Push the Prepaid Card into the slot of the card reader. The chip on the card has to face upwards. The slot is located on the front of the device below the display. Follow the instructions on the display.

When topping up is complete, the device returns to its initial mode and the new balance is displayed. The used Prepaid Card is now devalued.

4.8 Printer

Printer and serial printer cable can be obtained from EKF-diagnostic GmbH **(see section 10.1)**. The printers and printer cable are preconfigured and need only be plugged into the printer port **(see Figure 2)**.
The device prints measurement results directly after each measurement.

Use only printers supplied by EKF-diagnostic GmbH. Standard printer cables and standard printers are not compatible.

Printing is also possible utilising EKF Link Lite when connected to a PC or laptop through one of the available connection ports. See section 4.9 for more details on connectivity.

4.9 Connectivity

A connection can be established via USB, serial or ethernet connection. Use the plugs at the rear of the device **(see Figure 2)**.

Under menu item **main menu/device settings/connectivity** all parameters for data exchange can be set.

This menu item contains all relevant parameters for connecting the device with the hospital's laboratory or POCT data management software and also EKF Link or EKF Link Lite. Changes should only be made by competent personnel.

4.9.1 Device ID

Setting of the name, which the device uses to identify itself to the EDP. The name is transmitted in the first part of the data protocol. Moreover, a device number between 01 and 99 can be assigned.

Possible device IDs:	5030, 5040, 5130, 5140, BIOS, 6664, 6667, EBIO, CARE, SG01, SGL2

4.9.2 Method number

Method numbers can be assigned for glucose and lactate in whole blood and in plasma, which are transferred within the data protocol. According to the selected sample type, the set method number is transferred. Method numbers can be set between 000 and 999.

4.9.3 Test

This menu item is for testing the connectivity settings selected. When confirmed a data test is sent to the data management software.

5. MEASUREMENT

5.1 Sampling

The sample is taken up with an end-to-end capillary and hemolyzed in a micro test tube, pre-filled with a hemolyzing solution. This involves thinning the sample by 1:51. Capillary blood, venous blood, plasma or serum can be used as sample material.

Refer to the instructions for use of the used chip sensor.

Sampling errors directly lead to erroneous measurement results. Always observe the following instructions.

For sample collection, you should have ready an opened prefilled micro test tube, a capillary, and possibly a capillary holder **(see section 10.1)**.
When opening and closing the micro test tube, take caution so as not to splash or spill the solution.

5.1.1 Taking a sample of capillary blood

With poor peripheral circulation, glucose concentrations in capillary blood may deviate greatly from concentrations in venous blood. Examples are critically ill patients, shock, severe hypotension, severe dehydration or hyperosmolar hyperglycemia. In these cases measurement of glucose from capillary blood is not clinically recommended and should be done from venous blood [i,ii].

[i]Atkin SH, Dasmahapatra A, Jaker MA, Chorost MI, Reddy S., Fingerstick glucose determination in shock, Ann Intern Med. 1991 Jun 15;114(12):1020-4.Links
[ii]Desachy A, Vuagnat AC, Ghazali AD, Baudin OT, Longuet OH, Calvat SN, Gissot V. Accuracy of bedside glucometry in critically ill patients: influence of clinical characteristics and perfusion index, Mayo Clin Proc. 2008 Apr. 83(4):400-5.

Risk of infection, wear protective gloves!

Figure 19 - Disinfection

Clean and disinfect the puncture site and allow it to dry. Residues of sweat and disinfecting solution can falsify the results.

Figure 20 - Puncturing of finger

Press lightly on the fingertip and puncture from the side using a suitable lancing device.
Press out a drop of blood which is large enough to fill the capillary.

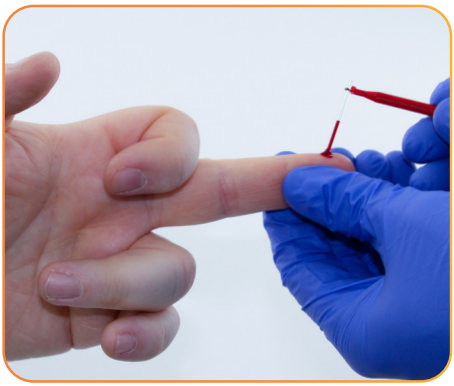


Figure 21 - Filling the capillary

Hold the capillary on the blood drop and fill correctly as shown in **Figure 22**
Hold the capillary slightly oblique.

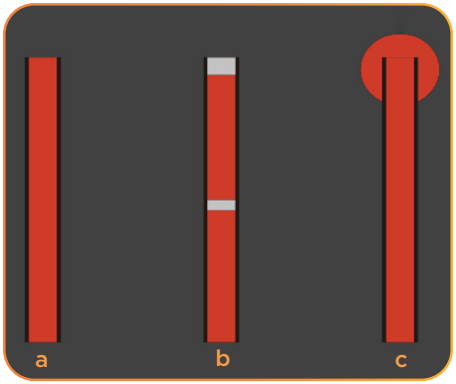


Figure 22 - Filled capillaries

a. Correctly filled capillary.

b. Capillary is not completely filled and contains air bubbles. This capillary must be disposed of.

c. Capillary with excess blood at the end. This capillary must be carefully wiped off.

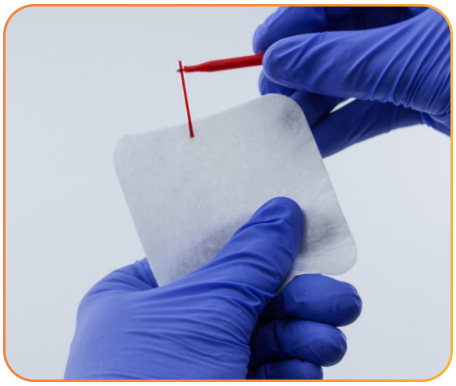


Figure 23 - Removing blood

Remove excess blood at the end of the capillary. Use caution so as not to empty the capillary.

Figure 24 - Prepared sample

Place the capillary into the prefilled micro test tube, close tight, and shake about 10 times. The capillary must be completely emptied and the hemolyzing solution must be homogenously stained.

The sample prepared in this way can be measured immediately.

It is recommended to measure as soon as possible.
The glucose and lactate concentration in hemolyzed sample, in closed and not punctured micro test tubes, is stable at room temperature for a storage period of 5 days. However, it is recommended to store the samples in a refrigerator if possible.

5.1.2 Other sample materials

The glucose and lactate concentration can also be determined in venous samples as well as in plasma or serum. The blood collection systems should be prepared with suitable additives to avoid alteration of glucose or lactate values over the time period until measurement. If the blood vessel does not contain a glycolysis inhibitor, the sample must be processed immediately. The blood may contain the following anticoagulants / glycolysis inhibitors: heparin, fluoride, EDTA, citrate or a combination of these.

Please follow the instructions of the blood collection system manufacturers for factor correction if applicable.

Risk of infection, wear protective gloves!

Take out the sample tube from the fridge and allow it to warm up to room temperature. Mix the sample carefully by repeated rotating and rolling.

Pipette a sufficiently large drop of blood (about 30 µL) on a non-absorbent material (e.g. PE film).
Hold the capillary on the blood drop and fill correctly as shown in **Figure 22**.

Figure 25 - Fill capillary

Then insert the capillary into the pre-filled micro test tube as described above.

5.2 Sample measurement

Place the samples to be measured in the sample positions.

Pressing the Perform measurement button (2) starts the measurement process.

Figure 26 – Home screen view

The device recognizes and runs inserted micro test tubes automatically. Depending on the state of calibration, either the calibration of the device takes place first and then the sample measurement, or the sample measurement takes place directly. If calibration is necessary, the standard positions have to be equipped **(see Figure 1)**.

The standard positions can be equipped in any way, even together. If a micro test tube with multi standard solution is empty, a corresponding error message occurs. If a second micro test tube with multi standard solution is available, this is automatically used. For a calibration, the last used STD position is preferably used.

Use punctured micro test tubes with multi standard solution for a maximum of 8 hours. Do not pour together the contents of opened micro test tubes with multi standard solution.

In order to avoid erroneous measurement results, carefully select the corresponding sample type for the used sample material. Do not mix the sample type during a measuring series.

The adjustment of whole blood glucose/plasma glucose can be activated in the **main menu/device settings/ref. type glu**. The default is whole blood glucose. The activation can be checked in the **Info Menu** "`Info-4 Extras`".

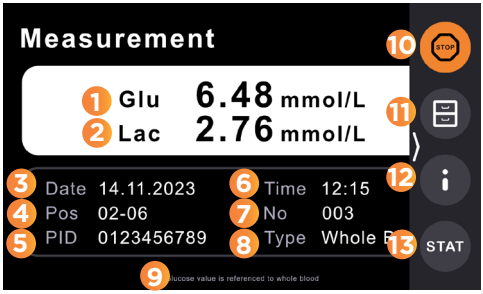


Figure 27 - Measurement Screen

The screen shown in **Figure 27** is shown at the end of the measurement process. The information that is shown is described below.

No.	Item	Description
1	Measuring Channel 1	Shows the measured parameter, the current measurement value and the unit in channel 1.
2	Measuring Channel 2	Shows the measured parameter, the current measurement value and the unit in channel 2.
3	Current date	Date and format can be changed in the **main menu/device settings**.
4	Sample Position (Tray-Position)	The current tray number is raised by 1 every time measurement starts. This can be pre-allocated in the **main menu/counter preset**, and is automatically set to 1 with every cold start or change of date (at midnight). The position shown here corresponds with the number on the tray.
5	Barcode PID	If the Barcode scanner is activated and a valid barcode is read, the barcode value is shown here.
6	Current time	Time and format can be changed in the **main menu/device settings**.
7	Running sample number	Running numbering of the measurement samples, the urgent samples and the control samples. Each sample type has its own circle of numbers which can be pre-allocated in the **main menu/ counter preset**. These circles of numbers are automatically set to 1 with every cold start or change of date (at midnight). An asterisk here indicates, that this a double determination measurement due to a range violation.
8	Sample Type	Sample type: whole blood or plasma
9	Reference of Glucose value	The Glucose measurement value is referenced to plasma/whole blood.
10	Stop after this sample	Stop the measurement series after this measurement. After hitting the button, a tick is visible on the button.
11	Memory	Show sample and quality control results of performed measurements.
12	Info	Info menu
13	Stat measurement	An inserted urgent sample in the STAT position is automatically recognized by the device and processed as quickly as possible. If a stat measurement is marked a tick is visible on the STAT button. Depending on the calibration mode, in the Ready state the calibration of the device takes place first.

5.3 Urgent samples (STAT)

To measure an urgent sample, put the sample in the STAT position **(see Nr. 7 in Figure 1)**. The inserted urgent sample is automatically recognized by the device and processed as quickly as possible.

5.4 Memory screen

The following figure shows the stored test results. You can swipe to reach the QC results.

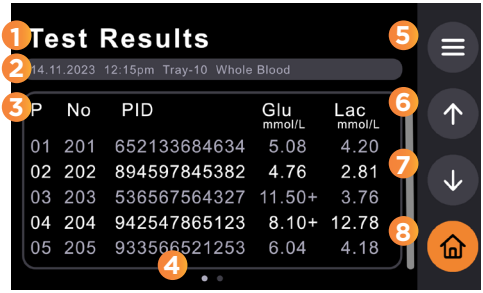


Figure 28 - Test Results screen

No.	Item	Description
1	Test Results / Quality Control Results	The headline indicates if test results or Quality Control results are shown. You can swipe to switch between test results and QC results.
2	• Date and Time • Tray number • Sample Type	• Shows the date and time, when this measurement series started. • Running number of trays measured at this day • Shows the selected sample type: whole blood or plasma
3	Results table	• P - Position in tray • No – Running sample number of this date • PID – If the Barcode scanner is activated and a valid barcode is read, the barcode value is shown here. • Glu – Glucose value and selected unit • Lac – Lactate value and selected unit "+" or "-" behind the value signalizes that the value has exceeded or fallen below the warning limits **(see section 4.6.1)** "+++" or "−−−" instead of a value signalizes a value higher or lower than the measurement range **(see section 8)**. "***" instead of a value signalizes that the sample could not be measured correctly, hence no value could be determined.

4	Page Indicator	Indicates can swipe to the side to switch from test results to QC test results.
5	Result Menu	Result context menu. You can send and print the results here. “Sends values to EDP” *Last tray* Sends the last measured series *Selected tray* Sends the series, currently selected in the memory *Selected value* Sends the value, currently selected in the memory By pressing the **ok button** the selected action is performed immediately. “Print values” *Last tray* Prints the last measured series *Selected tray* Prints the series, currently selected in the memory *Selected value* Prints the value, currently selected in the memory By pressing the **ok button** the selected action is performed immediately.
6	Arrow up	You can change the view to the previous tray (if available).
7	Arrow down	You can change the view to the next tray (if available).
8	Home	Button to the home screen.

6. MAINTENANCE

The device should be subject to regular maintenance. Table 1 gives an overview of the required maintenance frequency.

Table 1 - Overview of required maintenance actions

Action	Description
Surface cleaning	Daily
Surface disinfection	If contaminated
Disinfection of the flow system	Before change of any maintenance part
Exchange of Lactate sensor	See IFU of sensor
Exchange of Glucose sensor	See IFU of sensor
Cleaning of the flow system	3 months
Exchange pump tube	6 months
Exchange exchanger	6 months
Exchange sample cannula	12 months

The needed system functions are available via touch screen. Choose **main menu/ maintenance** for all maintenance functions.

Danger of infection
The device processes samples of human origin. This involves potential risk of infection. Particularly the sample cannula, the exchanger, the chip sensors, the tray and the waste container can be contaminated. Protective gloves should always be worn when operating the device.

Danger of electric shock
Under no circumstances should you open the device. There are no components inside which require servicing or maintenance. Repairs to the device must only be performed by EKF-diagnostic GmbH or an authorized service partner.

6.1 Surface Cleaning and disinfection

Surface cleaning of the device should accomplished with a lint-free cloth, lightly dampened with clear water. For more stubborn soiling, a mild soap solution may be used.
To avoid operation of buttons when cleaning the display, remove the bottle of system solution.

If surface disinfection is required, following wipe disinfectants are recommended: Bacillol AF Tissues or PDI Super Sani-Cloth Germicidal Disposable Wipes.

6.2 Cleaning / Disinfection of the flow system

The chip sensor is destroyed by the used solutions. However, a chip sensor has to be in the measuring channel. Only carry out this procedure if the sensor needs to be changed or an old sensor or dummy sensor is available.

The solutions to use must be obtained from EKF-diagnostic GmbH **(see section 10.1)** and be prepared according to the enclosed operating instructions. Afterwards place the micro test tube in position C1, start the procedure under **main menu/ maintenance/cleaning** and follow the instructions on the display.

6.3 Sensor replacement

Chips sensors are subject to deterioration and must be replaced at regular intervals. Dummy sensors can be used as long as there are no leaks in the flow system.

It is possible to check the chip sensors with a sensor test solution or a linearity solution **(see section 10.1)**.

Ensure that the right sample type is chosen before you start a measurement. The sample type must be set as Plasma for measurement of sensor test solution or linearity solution.

Only Replace sensors when the device is connected to the mains supply.
Open the sensor holder as described in **section 4.2.3** and remove the old sensor. The display will read "`Please insert sensor!`".

Do not touch the electrical contacts and do not apply moisture to the electrical contacts. Carefully dab away moisture on the flow cell and sensor bracket using a lint-free cloth.

Insert the new sensor as illustrated in **Figure 14 to 16**. Once the measuring channel is equipped correctly, the "`Sensor Replacement`" window opens.

Here, you must enter whether the sensor you just inserted is "`New`" or "`Used`". It is very important to enter correctly as the device runs different conditioning programs. A "`Used`" sensor is a sensor that has already been used in the device, was removed, and was stored correctly.

Sensors removed for later use must be stored correctly **(see storage information on the package)**. The lifetime of a sensor in the device is not extended by removal. This procedure should not be repeated more than twice for each sensor.

The device is ready for measurement once the sensor conditioning time has expired.

6.4 Exchange pump tube

It is recommended to perform cleaning and disinfection of the flow system before the pump tube is exchanged.

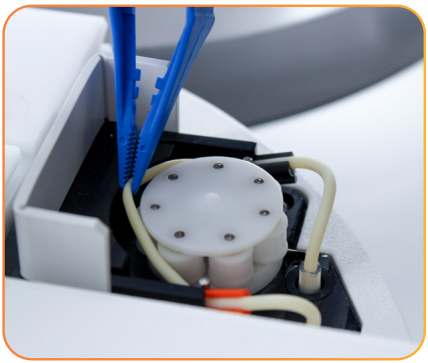


Figure 29 - Remove pump tube

Open pump flap (turn up from right to left). Grab the pump tube, preferably with a rounded pair of tweezers, and unhook from the pump wheel. Pull the ends of the tube out of the pump connections.

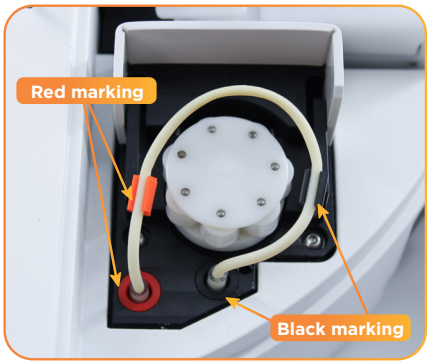
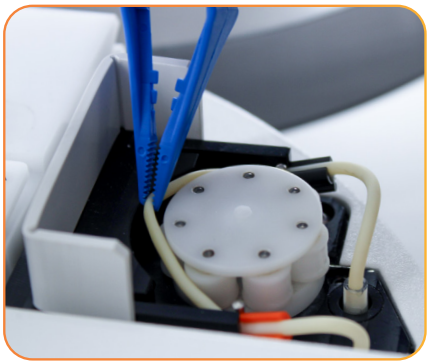


Figure 30 - Insert tube ends

The new tube has a red and black marking. Push the red side of the new pump tube on the red tube connection. When the pump tube is pushed sufficiently (approx. 5mm) on the connection, a rising resistance can be felt. Repeat this for the other end of the pump tube and the black pump connection.

Push the tube into the constriction between the metal rod and the housing. Make sure that the red and black markings remain on the side of the tube connections.

Figure 31 – push tube into the constriction



The pump tube must be looped over and centered on the pump rollers. A rounded pair of tweezers is recommended for this.

Do not use sharp objects.

Then close the pump flap from left to right.

Figure 32 – looping over pump tube

6.5 Exchanger and sample cannula

The exchanger should be changed in a 6 month cycle. The sample cannula should be changed in a 12 month cycle.

Empty the whole flow system using the menu item
main menu/maintenance/emptying and follow the instructions on the screen.

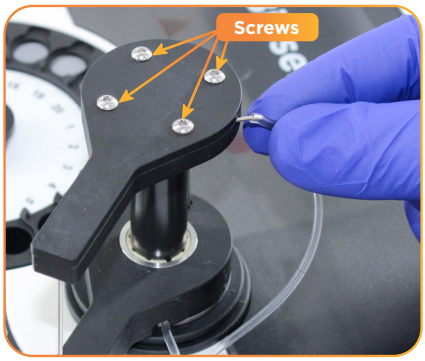


Figure 33 - loosen screws

Pull the tube away from the sample cannula and loosen the fastening screws.

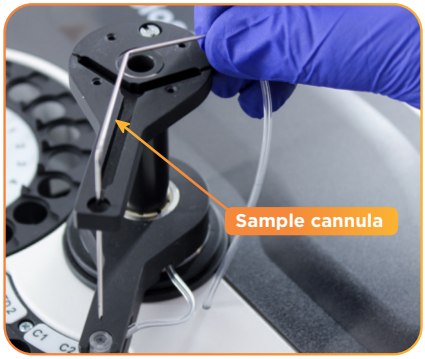


Figure 34 - pull out sample cannula

Take off the cover plate of the pivot arm and pull out the sample cannula upwards.

Figure 35- pull out exchanger

Turn the exchanger at the tube connection until it is at right angles to the pivot and then pull it out forwards.

Pull the exchanger out of the tube and put on a new exchanger. Push the tube as far as it will go.

Figure 36 - change exchanger

Construction is in the opposite order. Turn the exchanger-tube connection in the direction of the pivot arm until it noticeably engages. Then insert the sample cannula carefully from the top. Screw on the cover plate and push the tube on the sample cannula.

6.6 Switching the device off

The device is designed for continuous operation. Even in the stand-by state, the chip sensor and flow system use internal device functions, which are available only when the device is connected to the mains supply. The following problems can occur if the device is disconnected from the mains supply without further provisions.

Chip sensor stability:
After each disconnection from the mains supply, the chip sensor needs some conditioning time for stabilization. The conditioning time depends on how long the device was disconnected from the mains supply.

Flow system:
If the device is disconnected from the mains supply for more than 72 hours, the system solution becomes completely crystallized. This may in certain circumstances lead to blockage of the flow system.

Pump tube:
If the device is disconnected from the mains supply for more than 72 hours, the pump tube can become stuck and prevent flow movement.

If the device is not used, it should be put into **stand-by mode**. In this mode, the use of energy and system solution is reduced to its minimum.

The device does not have a separate power switch but is separated from or connected to the mains by the mains plug **(cold start)**. A disconnection from the mains supply is only recommended if the device will not be used for an extended period **(more than four weeks)**. However, the device must not be simply disconnected from the mains. It must be shut down correctly **(see section 6.8)**.

6.7 Brief separation from the mains (<72h)

For shipment or transport, the device can be separated from the mains for a maximum period of 72 hours.

The bottles for system solution and waste must be emptied. All micro test tubes must be removed.

6.8 Longer separation from the mains (>72h)

If the device is not used for some days, it should be put into **stand-by mode**. A disconnection from the mains supply is only recommended if the device will not be used for an extended period **(more than four weeks)**.

Empty the whole flow system using the menu item **main menu/maintenance/emptying** and follow the instructions on the screen. The bottles for system solution and waste must be emptied, as well as the sample and special positions. Then remove the chip sensor(s) as described in **Section 6.3**.

Remove the pump tube in the following way:

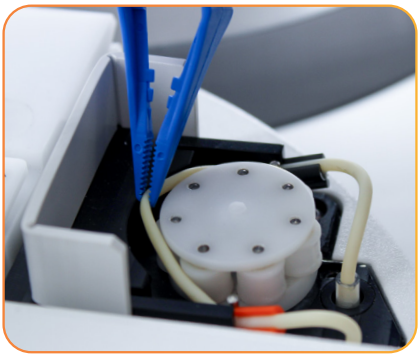


Figure 37 - Removing the pump tube

Open pump flap **(turn up from right to left).**

Grab the pump tube, preferably with a rounded pair of tweezers, and unhook from the pump wheel.

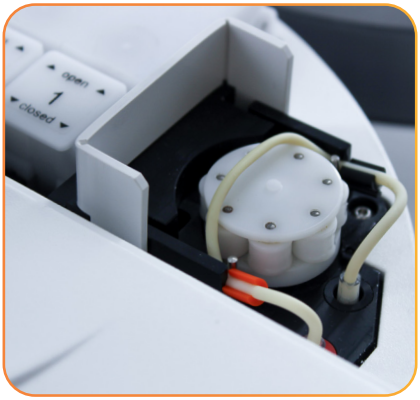


Figure 38 - Pump tube removed

Then close the pump flap again. The tube must not be completely removed.

Finally, separate the device from the mains.

6.9 Disposal

Comply with the applicable local disposal regulations. The user is responsible to ensure proper disposal of the individual components.

Dispose of containers of potentially infectious solutions (micro test tubes, hemolysate, control blood, etc.) in accordance with the current regulations applicable to your establishment.

The device must be carefully disinfected before disposal **(see section 6.1 and 6.2)**.

Electrical and electronic equipment may contain dangerous substances impacting on the environment and human health. Never dispose of old electrical and electronic equipment into unsorted domestic garbage.

Collect such used devices and provide them to local disposal systems. If not possible in other ways, return your Biosen C-Line to the manufacturer for disposal.

7. TROUBLESHOOTING

Before you call the hotline or send the device in for repair, please try to identify or solve the problem with the help of this section.

Error text	Explanation and rectification
Device is off	Please follow these steps, until the problem is solved 1. Check if the power cable plug is correctly plugged into the power socket. 2. Check if the power cable plug is correctly pushed into the device. 3. Remove the power cable from the power socket and check whether the socket works with another device. If not, choose another socket. 4. Remove the power cable from the device. Press the small lever above the cable connection upwards and pull on the black box. Remove both fuses and replace the with new ones **(see section 10.1; Service box)**. Push the fuse box back into position. Plug the power cable in the device and socket. 5. If the device is still not working call service
HMIC default parameter have been loaded	System error → Service required, no measurement possible
PIC is unknown	System error → Service required, no measurement possible
HMIC CRC-Code of ROM is wrong	System error → Service required, no measurement possible
PIC does not response	System error → Service required, no measurement possible
System error – with error number and without confirmation	System error → Service required, no measurement possible
System error – with error number and with confirmation	Noncritical System error → Measurement possible after confirmation
Rinsing error	System solution empty or unsuitable → refill fresh system solution Chip sensor defect or too old → Change chip sensor Leaky flow system. Exchanger, sample cannula or pump tube worn out or defect → Control flow system, change exchanger, sample cannula or pump tube if required

Error text	Explanation and rectification
Sensor current too high	Device was removed from the mains for some hours or days → Chip sensor stabilizes. Wait until device automatically goes into readiness to measure. Chip sensor has been changed → Chip sensor stabilizes. Wait until device automatically goes into readiness to measure. → Check for small air bubbles in the flow system → Perform Sensor conditioning again and select new to perform the full conditioning cycle. See Section 6.3. Chip sensor defect or too old → Change chip sensor System solution empty or unsuitable → Refill fresh system solution
No standard	At measurement start or calibration the device cannot find any multi standard micro test tube, or the multi standard micro test tube inserted is empty. → Insert multi standard micro test tube → Replace empty multi standard micro test tube with a full one → Remove multi standard micro test tube briefly and insert it again After each action start measurement again.
Calibration value sensor1(2) too low	Multi standard micro test tube is empty → Exchange multi standard micro test tube Incorrect or unsuitable multi standard → Use a new original multi standard micro test tube, if possible from new packaging Chip sensor defect or too old → Change chip sensor Leaky flow system. Exchanger, sample cannula or pump tube worn out or defect → Control flow system, change exchanger, sample cannula or pump tube if required → Perform Sensor conditioning again and select new to perform the full conditioning cycle. See Section 6.3.
Calibration value sensor1(2) too high	When the sensor has been changed → Perform Sensor conditioning again and select new to perform the full conditioning cycle. See Section 6.3. Incorrect or unsuitable multi standard → Use a new original multi standard micro test tube, if possible from new packaging Chip sensor defect or too old → Change chip sensor

Error text	Explanation and rectification
Calibration value sensor1(2) instable	Incorrect or unsuitable multi standard → Use a new original multi standard micro test tube, if possible from new packaging Leaky flow system. Exchanger, sample cannula or pump tube worn out or defect → Control flow system, change exchanger, sample cannula or pump tube if required System solution unsuitable → Refill fresh system solution Chip sensor defect or too old → Change chip sensor
No sensor found	No chip sensor equipped in device with one measuring channel. → Insert chip sensor No chip sensors or only one chip sensor equipped in device with two measuring channels → Insert second chip sensor or dummy sensor.
No system solution	System solution empty → Refill fresh system solution
Waste bottle is full	→ Empty waste bottle
Pump error, pump is blocked	The tube is not inserted correctly → Examine the position of the tube Pump defect → Service required
Tray error, tray is blocked	The tray has been blocked and was unable to reach its position. → Remove the cause and confirm error with ok The device tries to remove the error and if it manages goes into readiness to measure. If the attempt is not successful, the device returns to the error message.
Pivot arm error, pivot arm is blocked	The pivot arm was blocked and was unable to reach its position. → Remove the cause and confirm error with ok The device tries to remove the error and if it manages goes into readiness to measure. If the attempt is not successful, the device returns to the error message.
Balance used up	Measurement started although balance = 0 → Top up balance
Balance is too high	Too many Prepaid Cards were inserted in succession → Remove Prepaid Card

<table>
<tr><th>Error text</th><th>Explanation and rectification</th></tr>
<tr><td>Device is locked</td><td>Several attempts with manipulated Prepaid-Cards
→ Service required</td></tr>
<tr><td>Smart card access interrupted</td><td>Prepaid Card was removed without advice
→ Insert Prepaid Card again</td></tr>
<tr><td>Invalid smart card</td><td>Devaluated or unknown Prepaid Card
→ Remove Prepaid Card</td></tr>
<tr><td>Invalid serial no.</td><td>Serial number of Prepaid Card does not match serial number of the device.
→ Remove Prepaid Card. Insert a Prepaid Card with correct serial number.</td></tr>
<tr><td>No barcode is read</td><td>Barcode label does not comply with the specifications made in section 4.3. or is not correctly positioned on the vessel.
→ Stuck correctly formatted barcode label in the correct way
→ Proceed barcode test</td></tr>
<tr><td>The printer does not work</td><td>Check the power supply of the printer.
The printer software switches are normally set correctly. If printer problems occur these settings should be checked (refer to the operating instruction of the printer DPU-S445):
<table><tr><th>SW1</th><th>SW2</th><th>SW3</th></tr><tr><td>1-OFF</td><td>1-OFF</td><td>1-ON</td></tr><tr><td>2-OFF</td><td>2-ON</td><td>2-ON</td></tr><tr><td>3-ON</td><td>3-ON</td><td>3-ON</td></tr><tr><td>4-ON</td><td>4-ON</td><td>4-ON</td></tr><tr><td>5-ON</td><td>5-ON</td><td>5-OFF</td></tr><tr><td>6-OFF</td><td>6-ON</td><td>6-ON</td></tr><tr><td>7-ON</td><td>7-OFF</td><td>7-ON</td></tr><tr><td>8-ON</td><td>8-ON</td><td>8-ON</td></tr></table></td></tr>
</table>

8. TECHNICAL DATA

Measurement principle	Enzymatic - amperometric
Measurement range	Glucose: 0,5-50 mmol/l (9-900 mg/dl) Lactate: 0,5-40 mmol/l (5-360 mg/dl)
Sample material	Blood, plasma or serum
Sample volume	20 µl / 10 µl
Expected lifetime	5 years
Ambient conditions during operation	
Temperature Relative humidity	+15 °C to +35 °C 20 % to 85 %
Ambient conditions during storage and transport	
Temperature Relative humidity	-20 °C to +50 °C 20 % to 85 %
Mains power	100 – 240 VAC 50/60 Hz
Fuse	2 x T2A H250V
Power consumption	≤ 40 VA
Dimensions (LxWxH)	280 x 280 x 95 mm
Weight	Ca. 4,5 kg
EDP	RS 232C/USB/Ethernet
Printer	RS 232C
Display / keyboard	Graphic touch panel (800 x 480 Pixel)
Memory	2000 values

9. THEORETICAL PRINCIPLES

9.1 Reference ranges

For specification of reference ranges there must be differentiated between whole blood glucose and serum/plasma glucose.

Based on the different content of water depending on the hematocrit (Hct: solid parts) value, the measured glucose value in hemolysed whole blood is always lower than in plasma and serum, which show the same glucose value.

Normal values of a healthy adult are specified as follows[iii].

Glucose in whole blood:	3,5 - 5,3 mmol/l (65-95 mg/dl)
Glucose in serum/plasma:	4,1 - 5,6 mmol/l (74-100 mg/dl)

For general comparability the IFCC recommends the declaration of plasma glucose values, which can be calculated from whole blood values.

To this end the IFCC recommends a constant calculation factor of 1,11. This calculation factor relates to a normal hematocrite value of 43 %. A calculation via hematocrite value is not recommended because it can be a source of additional mistakes. The calculated plasma glucose value is moderately affected by the hematocrite value.

At hematocrite of 59 % the displayed value is about 5 % too low and at hematocrite of 18 % it is about 6 % too high.

9.2 Description of measuring procedure

The measurement of glucose and lactate is based on an electrochemical measuring principle with a chip sensor specially developed for this purpose.

The sample is automatically collected by the device and led into the system. Here the ß-D glucose / L-lactate contained in the sample, is converted enzymatically with the help of the immobilized enzyme glucose oxidase / lactate oxidase. The products of the reaction are gluconic acid/ pyruvate and hydrogen peroxide. The hydrogen peroxide is detected at the electrode.

The resulting current is proportional to the glucose/lactate concentration. Unknown glucose/lactate concentrations can be determined relative to a calibration with a solution of known concentration. After each measurement the chip sensor is automatically cleaned with a buffer solution. This washes out the old sample substance.

The sensor system is then ready for the next measurement.

[iii] *Tietz, Fundamentals of Clinical Chemistry, Saunders Elsevier, St. Louis, 2008*

9.3 Calibration

The calibration of the device takes place shortly before measurement. A glucose/lactate solution of known concentration (12 mmol/l, thinned 1:51) is measured on the device. The measured current signal and the corresponding glucose/lactate concentration are used as base for calculation of unknown concentrations.

The value of the calibrator for glucose is traceable to NIST (National Institute of Standards & Technology, Gaithersburg USA) Standard Reference Material 917d (D-Glucose).

10.1 Replacement parts and consumer materials

Order No.	Designation	Unit
	Sensors	
5206-3011	**Chip sensor glucose Type II**	1 piece
5206-3029	**Chip sensor lactate Type II**	1 piece
5206-3115	**Dummy to insert into the sensor-block (type II)**	1 piece
	Consumables	
5211-3015	**Multi Standard Solution 12 mmol/l** 2 ml in micro test tube	50 pieces
5211-3017	**Multi Standard Solution 12 mmol/l** 2 ml in micro test tube	100 pieces
5130-6055	**Sensor test solution** Glucose/lactate, 1 ml in micro test tube	20 pieces
0209-0102-391	**Linearity test kit** Glucose/lactate, Set of 3x1 ml (2 mmol/l), 3x1 ml (7 mmol/l	1 Set
0201-0005-012P6	**EasyCon NORM Quality control material** Glucose/lactate, 1 ml in micro test tube, for thinning in sample tubes	6 pieces
0201-0005-013P6	**EasyCon PAT Quality control material** Glucose/lactate, 1 ml in micro test tube, for thinning in sample tubes	6 pieces
5130-6152	**ReadyCon NORM Test solution** Glucose/lactate, 1ml in micro test tube, 1:51 ready to use	25 pieces
5130-6162	**ReadyCon PAT Test solution** Glucose/lactate, 1ml in micro test tube, 1:51 ready to use	25 pieces
0209-0100-013	**Glucose / Lactate hemolyzing solution** 1000 µl in micro test tube 2,0 mL, 20 µl end-to-end capillaries	200 pieces
0209-0100-014	**Glucose / Lactate hemolyzing solution** 1000 µl in micro test tube 2,0 mL, 20µl end-to-end capillaries	5 x 200 pieces
0209-0100-012	**Glucose / Lactate hemolyzing solution** 1000 µl in micro test tube 2,0 mL, 20 µl end-to-end capillaries	1000 pieces
0201-0002-025	**Glucose / Lactate system solution**	Bottle 0,5 l
0201-0002-024	**Glucose / Lactate system solution**	Canister 2,5 l
0201-0002-026	**Glucose / Lactate system solution**	Canister 5,0 l
0201-0003-001	**Disinfectant solution** 100 µl in micro test tube, not ready to use	5 pieces
0201-0004-001	**Cleaning solution** 30 µl in micro test tube, not ready to use	5 pieces

Order No.	Designation	Unit
	Equipment	
0620-0106-0070	**Printer cable**	1 Piece
0620-0105-0334	**Thermal Printer DPU-S445** Thermal printer with mains adaptor and printer	1 Set
0203-0100-204	**Thermal paper** Suitable for DPU-S445, Set of 5 rolls	1 Set
5211-8019	**Transport case for Biosen C-Line**	1 piece
0720-0100-0283	**EDP serial Cable, 3 m**	1 piece
0901-0200-002	**Capillary holder**	1 piece
	Maintenance/Replacement	
5208-1094	**Pump tube with stopper**	1 piece
5211-1735	**Exchanger**	1 piece
5211-1719	**Sample cannula for Biosen C-Line**	1 piece
5211-7303-0664	**Service box for Biosen C-Line** Consisting of sample canula, pump tube, 2x fuse 250V/T2A, hexagon wrench key, exchanger	1 set

10.2 Contact

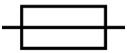
If you have any questions beyond this manual, we will be pleased to help you. Here is all important contact information for you at a glance:

Postal address:
EKF-diagnostic GmbH
Ebendorfer Chaussee 3,
39179 Barleben
Germany

Service hotline: +49 39203 511 414
email: support@ekf-diagnostic.de

10.3 Symbols

 Manufacturer	 Storage temperature
 Consult instructions for use	 Do not reuse
 Caution	 Use-by-date
 Biological Risks	 Dispose of electric and electronic devices separatelys
 Contains sufficient for <n> tests	 Reference number
 Lot number	 In vitro diagnostic medical device
 Serial number	 Control

 Date of manufacture	 Unique Device Identifier
 Device for near-patient testing	 Fuse
 Alternating current	 Keep dry
 CE mark	

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