Hemo Control
User Manual

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Hemo Control

User Manual

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Hemo Control

Hemoglobin Measuring System

User Manual

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CE

0. Contents

1. Important Information

1.1 Safety notes

It is essential that you read the following notes in order to avoid risks to persons and damage to the device and other equipment. EKF-diagnostic GmbH does not accept any responsibility for damage arising from non-observance of the following notes.

! Warning !

Follow the user manual!

Each time the device is used precise knowledge of and compliance with this user manual is required. Only use the Hemo Control photometer for the purpose described in Section 2 on page 6.

! Danger !

Danger of fatal electric shock!

Under no circumstances should you open the mains adaptor. There are no components inside which require servicing or maintenance.

Never use a mechanically damaged mains adaptor, live connections might be exposed.

Never let the mains adaptor come into contact with liquids. Note the maintenance instructions in Section 8.1.1 on page 25.

Only use the mains adaptor plug in sockets, which have been installed to IEC guidelines. Check whether the mains voltage and frequency printed on the mains adaptor type label match your mains socket.

! Warning !

Do not use in areas where there is a risk of explosion!

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

Keep the device away from liquids!

The device is not insulated against fluid ingress. Note the maintenance instructions in Section 8.1 on page 25.

Only use original accessories!

Only attach accessories expressly approved for use with the Hemo Control.

Allow the device to reach room temperature!
When changing from a cold into a warm environment condensation can form inside the device. Wait for about one hour before you connect the device to the mains or switch it on.
Do not open the device!
There are no components inside which require maintenance. Repairs must only be performed by authorized service staff. For further maintenance, instructions please refer to Section 8 on page 25.

1.2 Abbreviations

QC	Quality control
Hb	Hemoglobin
Hct	Hematocrit
DM	Data Management
POCT Data Manager	Software to connect the device to an electronic information system as well as for device configuration

2. Intended Use

The Hemo Control measuring system is intended to be used for the quantitative determination of hemoglobin (Hb) concentrations in human blood. It consists of the Hemo Control photometer and Hemo_Control Hemoglobin Microcuvettes.

Using the reagent filled microcuvette a small amount of arterial, venous or capillary blood is taken up by capillary action. The filled microcuvette is inserted into the Hemo Control photometer. The color produced by chemical reaction in the microcuvette is measured and the Hb value is displayed. The microcuvettes are intended for singular use only and must be disposed of after their use as potentially infectious waste in accordance with the current regulations applicable to your establishment.

The Hemo Control photometer is intended for use in medical practices and in clinical laboratories to assist in medical diagnostic investigations. In addition, it can be used in emergency and intensive care units and in medical facilities such as blood donor sessions and blood banks.

Only qualified personnel with profound skills in handling in vitro diagnostic devices and this system should be allowed to take blood samples and operate the Hemo Control photometer.

3. Setting Up

3.1 Components

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

Figure 1 - Hemo Control with mains adaptor, control cuvette and cleaner

- Hemo Control photometer
- Mains adaptor
- Control cuvette
- 2 Cleaner

3.2 Operation

3.2.1 Setting up and initial start up

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

- 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 surface

For initial start-up connect the device to the mains. The device should remain connected to the mains until the integrated rechargeable battery has been fully charged.

! Warning !

The mains adaptor is designed for a mains voltage of 100 - 240 V and a frequency of 50 – 60 Hz. For further information refer to Section 10.1, Technical Data, on page 31.
For further enquiries contact your technical consultant or distributor.

Figure 2 - Connection of mains adaptor

3.2.2 Switching the device on and off

The device is not provided with a separate switch. If the device is not used for a longer period, it automatically switches to the energy-saving **Stand By** mode. This period can be selected in the device menu; refer to Section 6.9.5 on page 21.

The device can be switched on as follows:

- Touch the display
- Open or close the cuvette holder
- Connect the mains adaptor to or disconnect it from the mains

3.2.3 Mains operation

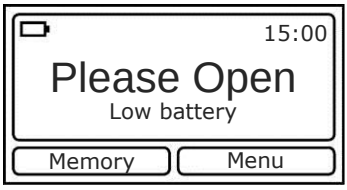
The plug symbol indicates mains operation.
An additional arrow in the battery symbol indicates that the battery is being charged.

Figure 3 - Mains operation

! Note !

The device should remain connected to the mains until the integrated rechargeable battery has been fully charged.
Set the mains frequency in the device menu to the correct value of your region; refer to Section 6.8 on page 20.
(50 Hz or 60 Hz)

3.2.4 Battery operation



The battery symbol indicates its remaining capacity. The device displays the warning “Low battery” at low capacity. If the battery is not recharged, the device switches off after a while.

Figure 4 - Battery operation

In the battery mode the Hemo Control photometer can be operated for about 100 hours. This value strongly depends on the utilization of the device, and hence may vary.

! Note !

Continuous display backlighting is not possible under battery operation. A temporary, energy saving lighting can be activated in the device menu; refer to Section 6.9.4 on page 21.

4. Sampling

4.1 Handling of the microcuvette

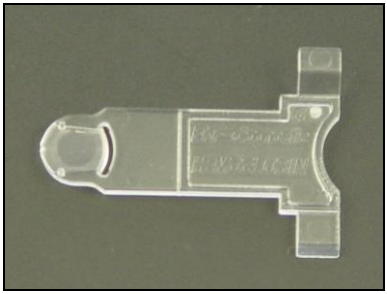


Figure 5 - Microcuvette

The following rules should be observed when handling microcuvettes:

- Microcuvettes are intended for singular use only.
- Store the microcuvettes exclusively in their original box at room temperature.
- Remove only one microcuvette at a time from the box and close the box immediately. The lid must be carefully closed all around.
- Only use the handle and do not touch the optical eye of the microcuvette.
- The microcuvette is intended for in-vitro diagnostic use only.
- Do not swallow the reagents.

4.2 Taking a sample of capillary blood

! Warning !

Risk of infection, please wear suitable gloves!

1. Take out a microcuvette from the supply box and close it again tightly.

2. Lightly massage the fingers to stimulate circulation.
   Only use the middle or ring finger. The patient should not wear a ring on that finger.

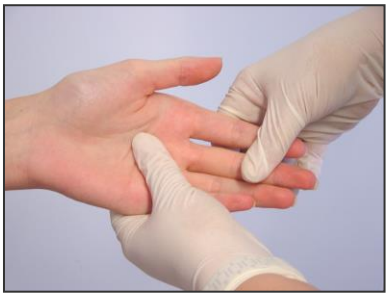


Figure 6 - Stimulation of circulation

3. Disinfect the puncture site and allow it to dry.

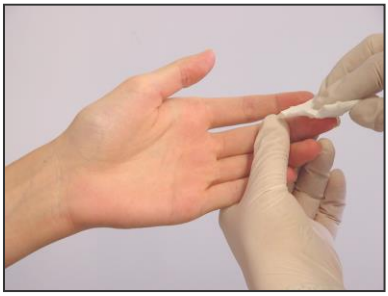


Figure7 - Disinfection

4. Press lightly on the finger tip and puncture from the side to a depth of about 2 mm.

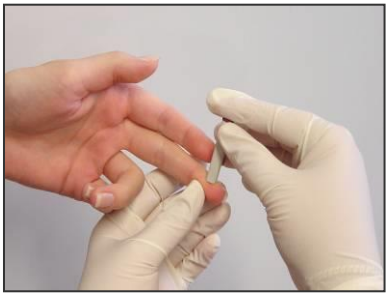


Figure 8 - Puncturing of finger

5. Blot away the first drop of blood and press lightly again. The second drop must be large enough to fill the microcuvette in one step.

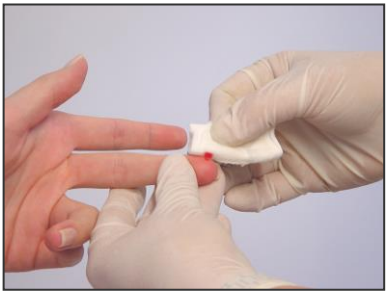


Figure9 - Blotting away blood

6. Hold the tip of the microcuvette in the middle of the drop of blood and let the cavity fill completely in one step. The microcuvette must be filled bubble-free.

Figure10 - Filling the cuvette

7. Remove any excessive blood from the outside of the microcuvette. Be careful to prevent sucking out and emptying of the microcuvette cavity.

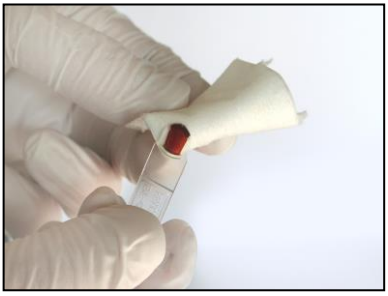


Figure 11 - Removing excessive blood

The microcuvette sample prepared in this way can be measured immediately or within 10 minutes at the latest.

4.3 Taking a sample of venous or arterial blood

The Hemo Control can be used for determination of venous or arterial blood samples if the blood was sampled not longer than 24 hours ago and the sample material has been stored in a fridge. Prepare the sample for the measurement as follows:

! Warning !

Risk of infection, please wear suitable gloves!

1. 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.

2. Take out a microcuvette from the supply box and close it again tightly.

3. Pipette a sufficiently large drop of blood (about 15 µL) on a clean, non-absorbent material (e.g. PE film).

4. Hold the tip of the microcuvette in the middle of the drop of blood and let the cavity fill completely in one step. The microcuvette must be filled bubble free.

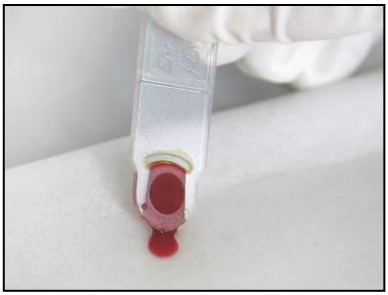


Figure 12 - Filling the cuvette

5. Remove any excessive blood from the outside of the microcuvette.
   Be careful to prevent sucking out and emptying of the microcuvette cavity.

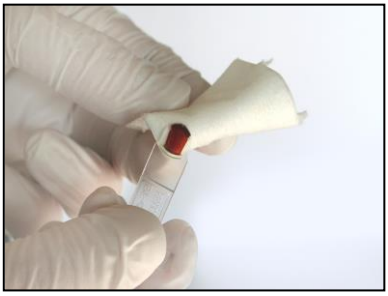


Figure13 - Removing excessive blood

The microcuvette sample prepared in this way can be measured immediately or within 10 minutes at the latest.

5. Measurement

5.1 Switching on the device

If the device is not used for a longer period, it automatically switches to the energy saving **Stand By** mode.

The device can be switched on as follows:

- Touch the display
- Open or close the cuvette holder
- Connect the mains adaptor to or disconnect it from the mains

Screen explanation

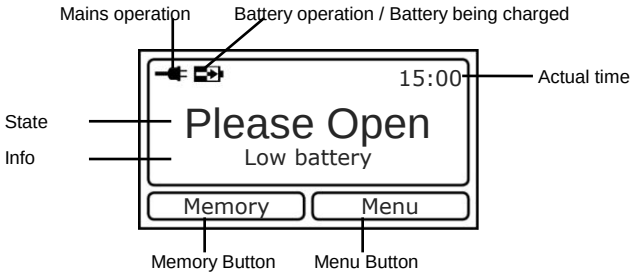


Figure 14 - Screen

Mains operation: The plug symbol indicates that the device is under mains operation. If this symbol is not displayed, the device is under battery operation.

Battery operation: This symbol indicates the battery state of charge.

Battery being charged: An arrow in the battery symbol indicates that the battery is being charged when connected to the mains.

Info: Information, as may be required, is displayed here.

Opening the cuvette holder sets the device ready for measurement.

5.2 Measurement

Inserting the microcuvette and closing the cuvette holder starts the measurement. Depending on the configuration, several options are available prior to the measurement.

! Warning !

Ensure the cuvette is correctly positioned in the cuvette holder. The microcuvette must be inserted flat. The angled handle of the microcuvette must point to the right, see Figure 15.

Figure 15 - Correctly positioned cuvette

Figure 16 - Incorrectly positioned cuvette

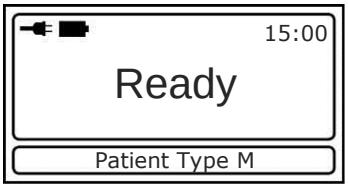
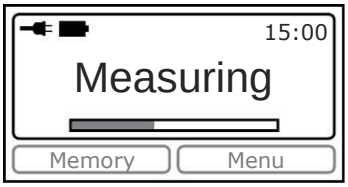


Figure 17 - Ready

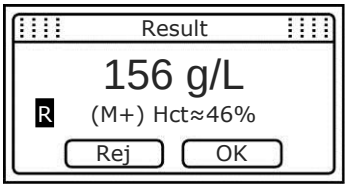
PT: *Selection of patient type*. This button is only displayed if measurement with Hb limit values is activated. This function is activated in the Menu under item 6.6, Hb limits. If a patient type has been selected, this type is displayed by an accordant symbol in the PT button. (M=male, F=female, C=child)



Closing the cuvette holder starts the measurement.

Figure 18 - Measuring

5.3 Result screen



The number of symbols displayed may vary depending on the options selected prior to the measurement.

Figure 19 - Patient result

(M): A patient type (male) has been selected. **+** or **–** behind the PT signalises that the value has exceeded or fallen below the limit value.

Hct: Approximate hematocrit value. If the option is activated in the device menu under item 6.9.1, the hematocrit value is calculated and displayed for measured values between 120 and 180 g/L.

Rej: A measured value can be rejected by the operator by pressing **Rej**. A rejected value is marked accordingly.

R: The measured value has been rejected by the operator.

OK: Press to leave the result screen.

Showing **+++** or **−−−** instead of a value indicates a value higher or lower than the measurement range (see Section 10, page 31, Technical Data). In this case, the used microcuvette and the blood sample should be checked critically. Further it should be checked if an Adaptation is applied (see Section 6.1, page 19, Information), which has an influence on the displayed values.

5.4 Quality Control (QC)

EKF-diagnostic GmbH recommends regular performance of quality control measurements, unless local laws, guidelines and orders will demand it anyway.

5.4.1 Self test

The Hemo Control photometer has implemented an integrated algorithm for checking the optical and electronic components of the device. This self test is carried out automatically in regular intervals and demands no operator action.

5.4.2 Control cuvette

The control cuvette is a physical standard for a comfortable and cheap check of the device. We recommend measuring the control cuvette once a day.

Store the control cuvette always in the original box. Avoid contamination of the control cuvette with potential infectious material. Clean and disinfect the cuvette holder and the device before using the control cuvette (see section 8.1, page 25). Keep away humidity (air humidity >85%) from the control cuvette. Do not clean the control cuvette with any solutions. If necessary clean the control cuvette carefully with a dry cotton bud.

! Warning !

Each control cuvette with indicated limit values belongs to a specific device. Hence, do not confuse control cuvettes. If a new control cuvette is needed, it must be ordered as a set and needs to be calibrated to the device.

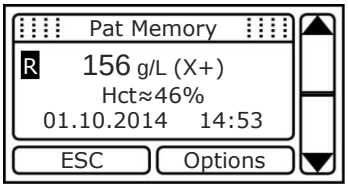
The control cuvette is measured like a normal sample, refer to Section 5.2 on page 15. Thereafter it needs to be checked, whether the result is within the limit values indicated on the box of the control cuvette. If the value is outside the limits refer to Section 9, Troubleshooting.

5.4.3 Control solutions

To verify the complete measuring system including the microcuvette liquid control materials are used, which are very similar to the patient sample. We recommend measuring the control solutions once a week.
For handling the control material refer to the respective instructions for use. We recommend using the control material Hb-con, which is offered in various concentrations (see Section 12.1, page 36). If you use other control material we cannot guarantee for the accuracy of the results.

5.5 Measured value memory

In the **Open** state the **Memory** button can be used to open the measured value memory with various functions.



The number of symbols displayed may vary depending on the options selected prior to measurement.

Figure 20 – Patient memory

(X) (X+) (X-): Selected patient type and if value has exceeded or fallen below the limit values.
X stands for M [male], F [female] or C [child].

R: The measured value has been rejected by the operator.

Options: Further options; refer to next figure.

Arrow: Scrolls through measured value memory.

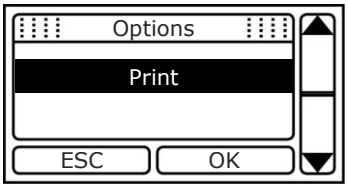


Figure 21 - Options

Print: Print currently selected value. This option is only available if print is activated (see Section 6.9.2, page 21)

6. Device Menu

In the **Open** state the **Menu** button can be used for opening the menu of the device. Any alterations of settings need to be confirmed by pressing **OK**. By pressing **ESC** the menu is left to the next higher menu level without incorporating any alterations.

6.1 Information

-Measurements-

Total:	Total number of measurements performed on this device
Today:	Number of measurements performed this day
Battery:	Total number of measurements with battery

-Battery- Remaining capacity in %

-Memory- *Pat:* Number of new data / number of total data

-Serial number-
-Model number-

-Version- Software
Electronic hardware
Mechanical hardware

-DM- indicates if the DM function is activated.
The Hemo Control offers the option to enable later the data management function by using a licence key offered by EKF-diagnostic GmbH. In delivery state, the DM function is not activated.

-Adaptation- Measured values can be adapted to other Hb measuring methods. The measured values are converted by using the entered equation and displayed.
Modifications can only be made by service staff. The default setting is **y=1.00x+0**; no adaptation of the measured value.

-SPN- **S**ervice**P**rocess**N**umber; required by service staff only.

6.2 Connect

Selecting this menu item establishes a connection via cable to a POCT Data Manager. Measured values and errors messages can be transmitted.

6.3 Date

Entering the date. The format depends on the regional settings under the menu item Region (6.8 on page 20).

6.4 Time

Entering the time. The format depends on the regional settings under the menu item Region (6.8 on page 20).

6.5 Unit

Changing the displayed unit. This change affects the whole measured value memory.

6.6 Hb limits

a. Activates/deactivates the entry of patient type prior to each measurement.
b. Defines the desired upper limit (UL) and lower limit (LL) for the patient types male, female and child.

6.7 Contrast

Setting of the desired display contrast.

6.8 Region

a. Setting of language
b. Setting of date format
c. Setting of time format
d. Setting of local mains frequency

6.9 Options

6.9.1 Hematocrit

Activates/deactivates the hematocrit calculation.
If this option is activated, the hematocrit value is calculated and displayed for measured values between 120 and 180 g/L.

6.9.2 Print

Activates/deactivates printing.
When print function is activated the measurement result will be printed after measurement by pressing OK or opening the cuvette holder.
If the device is operated without a printer, the print function should be deactivated.

6.9.3 Sound

Activates/deactivates the sound.

6.9.4 Backlight

Activates/deactivates the display backlight under battery operation. If activated, the backlight is temporary switched on for entries and actions.

! Note !

The backlight consumes power from the battery and shortens the operation time of the device under battery operation. Under mains operation the light is always on with full intensity.

6.9.5 Stand By

A time between 1 and 15 minutes can be set after which the device, if not used, switches to the energy saving **Stand By** mode.

6.9.6 Connection

6.9.6.1 Broadcast

Can be used for setting up data transfer when the device is connected to a POCT Data Manager for the first time.

6.9.6.2 Protocol

Selection of protocol type for data transfer.

LIS2-A2:	Protocol according to LIS2-A2 Standard
EKF-TP:	EKF specific transfer protocol for the use of the Software *HemoConnect light*

6.9.7 Maintenance

Delete complete measured value memory.

6.9.8 Scan Service BC

Is used for the activation of the DM function. Refer to the Add Pack Hemo Control user manual.

6.9.9 Service

For service staff only.

6.10 Contact

Contact data

7. Accessories and Connections

The device is provided with an interface on its rear side. The following components may be connected. The order numbers of the individual accessories can be found in Section 12.1, page 36.

! Note !

Only use the components below with their proper connecting cables. Otherwise, the device may be damaged.

7.1 Data cable

The data cable serves to establish a connection between Hemo Control and a POCT Data Manager. Depending on the cable type, connection is via a serial D-sub 9 port or a USB interface.

7.2 Printer

Measurement results can be printed with the thermal printer MCP1880. Print function is activated in the **Print** menu. See Section 6.9.2, page 21.

Figure 22 - Thermal printer

7.3 Hemo Dock

7.3.1 Description

The docking station Hemo Dock allows a simplified connection of Hemo Control to a POCT Data Manager.

Figure 23 – Hemo Dock

To this end, the device is placed into the Hemo Dock. An automatic connection to the POCT Data Manager and the transmission of measured values occurs. Manual entries are not necessary.

7.3.2 Technical parameters

Ambient temperature	10 – 40 °C
Rel. humidity	10 – 85 %
Power supply	none
Dimensions (L x W x H)	152 x 146 x 25 mm
Weight	100 g

8. Maintenance

8.1 Cleaning and disinfection

8.1.1 Mains adaptor, housing and display

Cleaning the mains adaptor, housing and display is best accomplished with a cloth, lightly dampened with clear water. For more stubborn soiling, a mild soap solution may be used. For disinfection, commercially available solutions intended for surface disinfection can be used if they do not contain alcohol or other solvents. EKF-diagnostic GmbH recommends the use of Kohrsolin® FF. Please note the application instructions of the Manufacturer.

! Note !

To avoid operation of buttons when cleaning the touchscreen, move the cuvette holder into half open position.

8.1.2 Cuvette holder

The cuvette holder can be removed from the device for cleaning. Proceed as follows:

Open the cuvette holder until you feel resistance.
Press down the latch on the left-hand side of the cuvettte holder with a ball-point pen and concurrently retract the cuvette holder to the front side.

Figure 24 - Cuvette holder

The cuvette holder can be cleaned with a mild soap solution. For disinfection commercially available, solvent-free agents intended for surface disinfection can be used.
Wait until the cuvette holder is completely dry before reinserting it into the device. For reinserting the cuvette holder, push it in the correct position into the opening in the housing until it has noticeably engaged.

8.1.3 Internal optical unit

The internal optical unit should be cleaned at least monthly. The internal optical unit should also be cleaned if the displayed value of the control cuvette differs from the value on the label, if control solutions cannot be measured correctly or if the following error message is displayed:

“Dirty optics”

A special cleaner is required for cleaning the optical unit (see Section 12.1, S.36). Proceed as described in the operating instructions attached to the cleaner.

8.2 Integrated rechargeable battery

The device is provided with a rechargeable NiMH battery. The Hemo Control can be operated for about 100 hours. This value strongly depends on the utilization of the device and may vary depending on the following circumstances:

a. Activation of the display backlight reduces the operation time.
b. Depending on the intensity of its use, the battery capacity may noticeably reduce after 2 to 3 years due to ageing. If the battery operation time is no longer sufficient, it needs to be replaced by a service engineer.

! Note !

The device should remain connected to the mains until the integrated rechargeable battery has been fully charged. The end of the charging process is indicated by a full battery symbol without charging arrow in the Operating mode or without a charging symbol in the **Stand By** mode. Depending on the battery's state of charge, recharging takes up to 5 hours.

8.3 Disposal

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

Dispose of microcuvettes and containers of potentially infectious solutions (control material, etc.) in accordance with the current regulations applicable to your establishment.

Electrical and electronic equipment may contain dangerous substances impacting on the environment and human health. Your Hemo Control photometer contains, amongst others, a rechargeable NiMH battery with such properties. Never dispose of old electrical and electronic equipment into unsorted domestic garbage.
Dispose of the Hemo Control photometer and any electrical accessories after having removed the rechargeable battery in compliance with the applicable regulations for disposing of electronic components.
Dispose of the rechargeable battery in compliance with the regulations for the disposal of waste batteries and rechargeable batteries.
If not possible in other ways, return your Hemo Control photometer to the manufacturer for disposal.

9. 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	Explanation and rectification
No Display, no response to entries	Battery is empty. ⇒ Power the device from the mains. ⇒ Allow the battery to recharge completely. Battery is defect. ⇒ Device can only be operated when powered from the mains. Software does not respond. ⇒ Perform a reset of the device (see section 9.1, page 30).
Error message *"Defective battery"*	Following this message the battery is switched off. The device can only be operated when powered from the mains. ⇒ Service required.
No battery symbol displayed	The battery has been switched off by the device. The device can only be operated when powered from the mains. ⇒ Service required.
Short battery operation time, device switches off without previous warning.	⇒ Always leave the device connected to the mains until the end of the charging process. ⇒ The battery has aged and should be replaced by a service engineer.
Information message *"Low battery"*	Low battery operation time left. ⇒ Power the device from the mains. ⇒ Allow the battery to recharge completely.
No plug symbol displayed	Mains adaptor not powered from the mains. Device plug not connected. Wrong mains adaptor connected. ⇒ Connect EKF mains adaptor. Defective mains adaptor. ⇒ Service required.
Error message *"Wrong mains adaptor"*	Wrong mains adaptor connected. ⇒ **Immediately** disconnect the wrong mains adaptor and connect the correct EKF mains adaptor.
Error message *"User error, voltage too low"*	Wrong mains adaptor connected. ⇒ **Immediately** disconnect the wrong mains adaptor and connect the correct EKF mains adaptor.

Error	**Explanation and rectification**
Limit values of the control cuvette are violated	Wrong control cuvette used. ⇒ Use control cuvette with correct serial number. Damaged control cuvette. ⇒ Order new control cuvette and calibrate it to the device. Cuvette holder not properly engaged. ⇒ Properly engage the cuvette holder. Optical unit soiled. ⇒ Clean optical unit. Control cuvette is not correctly positioned into the cuvette holder. ⇒ Place the control cuvette in the correct position.
Measurement values are not plausible. Limit values during control solution measurements are violated.	Defective or superimposed microcuvette used. Sampling error. Air bubbles in the microcuvette. ⇒ Prepare new microcuvette for measuring. Unsuitable or superimposed control solution. Confused control level. ⇒ Use correct control solution. Cuvette holder not properly engaged. ⇒ Properly engage the cuvette holder. Optical unit soiled. ⇒ Clean optical unit. Control cuvette is not correctly positioned into the cuvette holder. ⇒ Place the control cuvette in the correct position. The Hemo Control photometer must be only used with Hemo_Control Hemoglobin Microcuvettes.
Information message *"Temp. too high"*	Ambient temperature is too high. ⇒ Measurements are still possible, however measurement quality may deteriorate.
Information message *"Temp. too low"*	Ambient temperature is too low. ⇒ Measurements are still possible, however measurement quality may deteriorate.
Error message *"Measured value too high"*	Defective or superimposed microcuvette used. Wrong or unsuitable sample material. Sampling error. ⇒ Prepare new microcuvette for measuring.
Error message *"Memory is full"*	At least 4,000 measured values have been stored. ⇒ Delete memory.

Error	Explanation and rectification
Error message *"Intensity too low"*	Cuvette holder not properly opened or closed. ⇒ Repeat measurement procedure. Cuvette holder not properly engaged. ⇒ Properly engage the cuvette holder. Optical unit soiled. ⇒ Clean optical unit. Defective optical unit. ⇒ Service required. Ambient temperature too high.
Error message when establishing connection via cable *"Timeout"*	No connection to the POCT Data Manager comes off. ⇒ Use correct cable. ⇒ Connect device to a POCT Data Manager. ⇒ Use to the operating instructions and troubleshooting of the POCT Data Manager.
Error message *"CRC ROM"* *"CRC RAM"* *"CRC EEPROM"*	Internal problem of device, no operation possible. ⇒ Service required.
Error message *"Defective electronics"*	Control cuvette or microcuvette in the closed cuvette holder when the device is switched on. ⇒ Remove cuvette. Optical unit soiled. ⇒ Clean optical unit. Internal problem of device, no operation possible. ⇒ Service required.

9.1 Device reset

A reset serves to return the device into a defined state. All user-specific settings remain unchanged. However, the date and time need to be entered again.
You find the reset button on the underside of the device.

! Note !

If a reset is performed while the mains adaptor is connected to the mains, the current battery capacity is reset, and hence charging is forced. To save the battery, this should be done in exceptional cases only.

10. Technical Data

10.1 Hemo Control Photometer

Measuring procedure	Optical absorption photometry
Source	Dual-color LED 570 / 880 nm
Dominant wavelengths	1st Wavelength: 570 ± 5 nm 2nd Wavelength: 880 ± 10 nm
Spectral half-value widths	1st Wavelength: 15 ± 3 nm 2nd Wavelength: 50 nm
Measuring range	0 – 256 g/L
Linearity	Measured value 0 – 200 g/L: ± 3 g/L Measured value > 200 g/L: ± 7 g/L
Variation coefficient	≤ 2%
Correlation coefficient with reference to NCCLS method	≥ 0.98
Sample material	Venous, arterial or capillary human blood
Sample carrier	Hemoglobin Microcuvette
Mean measuring time	25 – 60 s depending on concentration
Interfaces	RS232
Measured value memory	4000 measured values
Ambient temperature	Room temperature 15 – 40 °C
Transport temperature	-20 to +50°C
Humidity	10 – 85 % relative humidity

Power supply	Mains adaptor: Input: 100 - 240 VAC / 50 - 60 Hz Output: 6 VDC Integrated NiMH battery: Voltage: 3.6 V Capacity: 2000 mAh (about 100 h operation time)
Power take up	max. 6 W
Dimensions (L x W x H)	160 mm x 160 mm x 68 mm
Weight	about 700 g

10.2 Microcuvette

Type	Microcuvette, coated with reagents for determining hemoglobin
Sample volume	about 8 µL
Reagents	Sodium desoxycholate, sodium nitrite, sodium azide, non-reactive additives
Material	Polystyrene
Storage	At room temperature 15 – 30 °C, only in original box
Dimensions (L x W x H)	about 35 mm x 24 mm x 4 mm

11. Theoretical Principles

11.1 Reference ranges

The physiological concentration of the total hemoglobin is specific for age and sex[i,ii].
Women: 110 – 160 g/L
Men: 130 – 180 g/L
Children after neonatal period: 100 – 140 g/L,
The highest Hb concentration is measured in neonates.

11.2 Description of the measuring process

11.2.1 Reaction in the microcuvette

In the microcuvette, a modified form of Vanzetti's azide methemoglobin method is used[iii].
In order to use the azide methemoglobin method in undiluted blood, three reagents are necessary.
Sodium desoxycholate dissolves and disperses the cell walls of the red blood corpuscles. The hemoglobin formerly contained in the erythrocytes is now available free in the solution.
The bivalent iron of the oxyhemoglobin and the desoxyhemoglobin becomes oxidised by sodium nitrite to trivalent iron, in methemoglobin.
Existing and formed methemoglobin and azide ions from sodium azide form a coloured complex, which exhibits maximum absorption at 540 and 575 nm and hence can be quantitatively determined photometrically.

11.2.2 Principle of photometric measurement

In the Hemo Control photometer the absorbance of transmitted light is measured. The use of microcuvettes with short light pathways makes it possible to analyse undiluted blood.
Light of definite wavelength with or without the analyte is directed to a photo detector and the absorbance A is determined. To compensate turbidity and the basic absorption of the measuring system two wavelengths are used for measurement.

[i] H. Greiling, A. Gressner, eds., Lehrbuch der Klinischen Chemie und Pathobiochemie, [*Textbook of Clinical Chemistry and Pathobiochemistry*] F. K. Schattauer Verlagsgesellschaft, Stuttgart, 3. Auflage, 1995, S. 521, 818-819
[ii] Lothar Thomas, ed., Labor und Diagnose Indikation und Bewertung von Laborbefunden für die medizinische Diagnostik [*Laboratory and diagnostic indications and assessment of laboratory findings for clinical investigation*], TH-Books Verlagsgesellschaft mbH, Frankfurt/Main, 5. Auflage, 1998, S. 485, 488
[iii] G. Vanzetti, An azide-methemoglobin method for hemoglobin determination in blood, Am. J. Lab. & Clin. Med. 67 (1966) 116

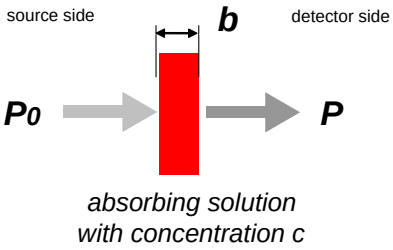


Figure 25 – Principle of photometric measurement

P_0: 100 % - light intensity,
P: remaining light intensity,
b: distance through the solution

$$A = \log \frac{P_0}{P}$$

Equation 1 – Absorbance A

$$A = \varepsilon bc$$

Equation 2 - Lambert-Beers Law

ε: molar extinction coefficient
b: distance through solution in the microcuvette
c: concentration of solution

Using Lambert-Beers Law, (refer to Equation 2) the concentration of the hemoglobin in the microcuvette can be determined. To this end the equations are solved for the concentration c.

$$c = K * \log \frac{P_0}{P} \qquad \text{where} \quad K = \frac{k}{b\varepsilon}$$

Equation 3 - Calculation of concentration

k: proportionality factor for measurement method correction
(taking into account design conditions)

11.3 Calibration

The Hemo Control photometer is calibrated against the reference cyanmethemoglobin method to determine the proportionality factor K. This factor is fixed in the device as an individual parameter.
Calibration is performed by the manufacturer against the NCCLS reference method[iv] and yields results comparable with ICSH (1995)[v]. A maximum tolerance of 0.3 g/dL (0.2 mmol/L) at 15.0 g/dL (9.3 mmol/L) is accepted.

11.4 Calculation of hematocrit value

Hematocrit (Hct) is synonym to PCV (Packed Cell Volume) and means cell volume of red blood corpuscle (erythrocrit).
If the hemoglobin is inside the normal range, an estimation of the hematocrit is obtained by multiplying the measured hemoglobin concentration (expressed in g/dL) by factor 2.94[vi].
This calculation should not be used outside the normal range of hemoglobin in humans, e.g. under 120 g/L (7.44 mmol/L) and above 180 g/L (11.16 mmol/L). It should also not be used in anemic conditions (genetic or caused on serious diseases).

[iv] NCCLS, Reference and selected procedures for the quantitative determination of hemoglobin in blood; approved standard – third edition, NCCLS Document H15-A3, 2000

[v] Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specifications for international haemiglobincyanide standard (4th edition)

[vi] J.D Bauer, P.G Ackermann, G. Toro, Clinical laboratory methods. The C. V. Mosby Company, Saint Luis 1974, S. 156

12. Appendix

12.1 Replacement parts and consumer materials

Order No.	Designation	Unit
3000-3012-0765	**Hemoglobin Microcuvettes** Box at 50 cuvettes	4 pc.
3000-3013-0278	**Hemoglobin Microcuvettes** 50 cuvettes, single packed	1 pc.
3000-6121	**Control solution Hb-con low** 1ml in dropper bottle	1 pc.
3000-6128	**Control solution Hb-con Set 2** Set of 2 dropper bottles 1 ml with 1x Hb-con norm, 1x Hb-con high	1 set
3000-6232	**Cleaner** for cleaning the optical unit Set of 5 Cleaners	1 set
3000-6138	**Control cuvette set** Control cuvette with auxiliaries for calibration 1x control cuvette, 2x cleaner, 1x calibrator	1 set
3000-1104	**Cuvette holder** for Hemo Family	1 pc.
3005-8106-0165	**Carrying plastic case** with inlay	1 pc.
3040-7011-0452	**BT Printer MCP 1880** Thermal printer with mains adaptor	1 pc.
3040-7021-0463	**Printer cable MCP 1880** For Hemo Family	1 pc.
3005-7011-0039	**Data Cable D-Sub 9** for Hemo Family, Data Cable with serial interface	1 pc.
3000-7051-0028	**Data Cable USB** for Hemo Family, Data Cable with USB interface	1 pc.
3005-7074-0156	**Hemo Dock** docking station	1 pc.
Download www.ekfdiagnostics.com	**HemoConnect light** Software for downloading test results	1 pc.

12.2 Contact

If you have any questions over and above 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

Telephone: +49-(0)39203-511-0

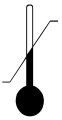
Fax: +49-(0)39203-511-171

Service hotline: +49-(0)39203-511-414

email: info@ekf-diagnostic.de
support@ekf-diagnostic.de

Internet: www.ekfdiagnostics.de
www.ekfdiagnostics.com

12.3 Symbols

 Manufacturer	 Storage temperature
 Follow instructions for use	 Do not reuse
 Warning! See accompanying documents	 Expires on
 Contents will last for <N> measurements	 Dispose of electric and electronic devices separately
LOT Lot number	REF Reference number
CONTROL Test material	IVD In vitro diagnostics
SN Serial number	CONT Contents