



FREQUENTLY ASKED QUESTIONS

Measurement

Q: What does Hemo Control measure?

A: The EKF Hemo Control measures total hemoglobin.

Q: How long is the typical measuring time?

A: The typical measuring time is in the range of 25 to 60 seconds.

Q: What measuring method is used?

A: The azide methemoglobin method is used.

Q: What is the reference method?

A: The Hemo Control photometer is calibrated against the cyanmethemoglobin reference method, known as NCCLS (now CLSI) reference method and yields results comparable with ICSH standards. A maximum tolerance of 0.3 g/dL (3 g/L or 0.2 mmol/L) at 15.0 g/dL (150 g/L or 9.3 mmol/L) is accepted.

Q: What is the measuring range of the instrument?

A: From 0 - 256 g/L; 0 - 25.6 g/dL; 0 - 15.9 mmol/L

Q: What is the conversion factor for calculating the hematocrit value?

A: Hb in g/dL x 2.94 (% in hematocrit)

Q: What are the factors for conversion into the various Hb units?

A: Conversion:
 · g/L in mmol/L: 1 g/L = 0.062 mmol/L
 · mmol/L in g/L: 1 mmol/L = 16.129 g/L

Connectivity

Q: How can Hemo Control be connected to lab information systems (LIS) or PC environments?

A: The Hemo Control device (REF 3040-0010-0218) can easily be upgraded with on-board data management (DM) functions for instance in the case of implementing a LIS solution at a later stage. The Hemo Control Manager device already features data management functions at delivery. The bidirectional interface simplifies the connection to LIS solutions

using a public standard protocol (LIS2-A2). Connection to LIS is subjected to an adaptation of the local installation or middleware to use the Hemo Control interface. EKF Diagnostics provides support to connect to specific LIS solutions.

A USB connector cable or a serial Sub-D-9 cable can be used to establish the physical PC connection. On Hemo Control Manager an integrated Bluetooth interface is available, too. Alternative connection solutions can be realized using serial-to-LAN or BT-to-LAN bridges.

The Hemo Connect software allows the configuration of DM enabled Hemo Control devices and the data export to a standard file format, while the Hemo Connect light version (freeware) supports data export only. The Hemo Connect software can be used in case the device configuration and data management is not already taken care of by the LIS POCT data manager.

Q: What data management functions are available?

A: Barcode identification of patients, access control and identification of operators, recognition of cuvette LOT and control materials, definition of Quality Control scheme and QC lockout function, addition of comments to test results, flagging of rejected values and range violations. Barcodes are conveniently read into the device using an ergonomic hand-held scanner.

Maintenance

Q: Does the device need to be calibrated?

A: No, it is factory calibrated.

Q: How often should the optics be cleaned?

A: We recommend that the optics of the device are cleaned at least once each month and if the control cuvette or the control solutions cannot be measured correctly. Depending on usage and sample throughput more frequent cleaning may be required. The EKF Cleaner should be used for cleaning the optics. Doing this the cuvette holder must be removed from the instrument and should be cleaned with a cleaning solution or an aqueous disinfectant solution.

Q: How long is the life span of a fully charged battery?

A: Typical values:
· Continuous operation: 100 hours
· Stand-by mode: 30 days

Q: Is it necessary to replace the integrated rechargeable battery?

A: It is not necessary to replace the battery.

Q: What happens if the reset button is pressed?

A: The date and time must be re-entered. All other settings remain as they were.

Q: Why is the hematocrit value not shown on the display?

A: The display must be set up to show the hemocrit result. If this has been done but the hemocrit still does not appear, the value is out of normal range for hemoglobin (120 - 180 g/L or 7.44 - 11.16 mmol/L).

Sampling and Control

Q: How many tests may be taken per puncture?

A: We recommend only 1 test per puncture.

Q: Are there any problems associated with using blood from blood collection systems with coagulation inhibitors?

A: EDTA, NaF and heparin have been shown not to influence test results. Care should be taken to ensure the sample is thoroughly mixed prior to testing.

Q: How soon should a microcuvette be used after it has been removed from the container?

A: Even if several measurements are carried out one after the other, only one cuvette should be removed from the container at a time. The microcuvette should be used immediately after it has been removed from the container. The container must be closed immediately afterwards because the cuvettes are sensitive to humidity.

Q: What is the CV of Hemo Control? How big are the typical fluctuations of measured values?

A: Hemo Control guarantees a CV of $\leq 2\%$. During evaluation the values shown in table 1.0 were determined,

Table 1.0

Hemoglobin/high (15.7 g/dL) Total imprecision (EP5-A)	S _T 0.174 g/dL, CV 1.1%
Hemoglobin/normal (13.3 g/dL) Total imprecision (EP5-A)	S _T 0.165 g/dL, CV 1.3%
Hemoglobin/normal (11.8 g/dL) Total imprecision (EP5-A)	S _T 0.162 g/dL, CV 1.4%
Hemoglobin/low (8.0 g/dL) Total imprecision (EP5-A)	S _T 0.122 g/dL, CV 1.5%

Q: What control features are available with the Hemo Control?

A: Unlike other brands, Hemo Control comes with 3 methods for quality control:
1) Each time the device is turned on a self test is performed automatically.
2) The control cuvette can be used. This is not compulsory but we do recommend the control cuvette is used as a visible quality control.
3) Liquid quality controls (Hb-con) are available. Please ask your distributor.

Microcuvettes

Q: Are there any differences between microcuvettes fresh from production and older ones (that have not expired)?

A: There are no significant differences.

Q: What is the impact of air bubbles on the measured result?

A: Air bubbles can affect the measured result. We recommend that if an air bubble is present the cuvette should be disposed of. The rounded tip of EKF n.x.t cuvettes allows holding of the cuvette in any angle to the sample. An air vent (opening) at the rear of the sample cavity reduces the risk of introducing air bubbles nearly to zero.