

Hemo Control Analyzer



Point of care device providing immediate, lab quality results for hemoglobin and hematocrit from one simple test



Hematology

Product features



Easy to use

Small sample size
(ca. 8µl)

Step by step
instructions,
backlit touch
screen with
adjustable
contrast

User selectable
language



Practical and portable

Compact size

Self-testing

Integrated,
rechargeable
battery (100 hrs)

Operating
temperature up
to 40°C



Fast and accurate

Results in 25-60
seconds

Imprecision:
CV <2%

Soft-close
cuvette loader
minimises risk of
contamination



Hemo Manager

Stores up to
4,000 records;
500 QC results

Barcode
identification

Serial port for PC

Bluetooth
QC lockout
function



Accessories

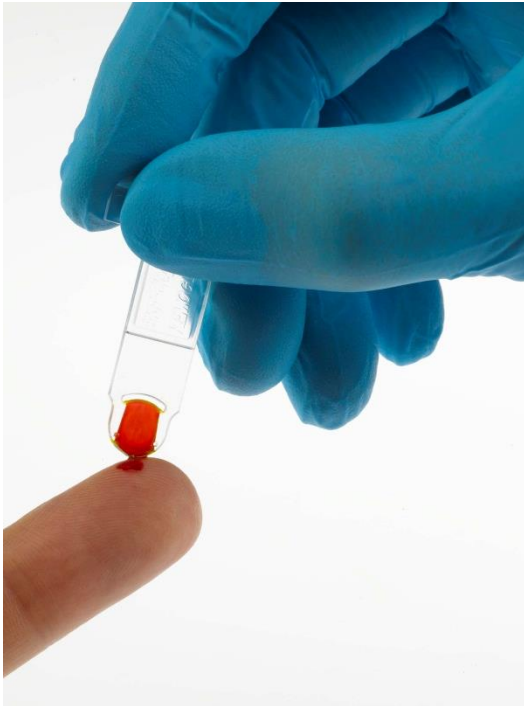
Vials x 50
cuvettes

Single-packed
cuvette option

Control cuvettes
included

Liquid controls
Cleaner

Performing a test



Take a blood sample



Insert cuvette into analyser



Results in ca. 25 – 60 sec

Results in 3 easy steps

Performing a test



Hemo Control devices



Hemo Control

- ✓ Basic analyzer version
- ✓ Stores 4,000 test results with date and time
- ✓ Data export only
- ✓ Data transfer by cable



Hemo Control Manager

- ✓ Preinstalled data management capability
- ✓ Allows direct integration with LIS
- ✓ Bi-directional interface
- ✓ Configuration via LIS POC Manager or Hemo Connect Software (EKF)
- ✓ Barcode scanner included
- ✓ Stores 4,000 patient results and separately 500 QC results
- ✓ Data transfer by cable or integrated Bluetooth

New! Add pack DM for Hemo Control

Basic version of Hemo Control can be upgraded with Data Management (DM) functions at a later point of time

Ideal for customers who are...

- Planning future connection of POC devices to LIS but have not yet decided
- Connection to LIS postponed for budget reasons, option to split costs
- Facing increasing demands for connectivity and want to keep options open

Unique feature in POC devices!

Only available for new release Hemo Control devices.

The “Add pack DM” upgrades a basic Hemo Control to the same functionality as the Hemo Control Manager (except for the integrated Bluetooth module)

Add pack DM for Hemo Control

Content:

- Licence key
- Barcode scanner
- 3fold adapter
- Barcode table
- Manual

Licence key for
Hemo Control Data Management

Website	www.ekfhemocontrol.com/addDM
User name	ADDHC3
Password	
Licence key	NH77S-4U9BJ-T52Q2-VZFZ5



EKF
DIAGNOSTICS
SCIENCE MADE SIMPLE
www.ekfdiagnostics.com

Manufacturer

EKF diagnostic GmbH
Ebendorfer Chaussee 3
39119 Barleben, Germany

Tel +49 (0)39203 7850

3040-0211-0172 - Rev. 1.0-02/2015

Sales

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Fenarth, Cardiff, UK, CF64 2EZ

Tel +44 (0)29 20 710570



How to install the 'Add pack DM'

Once the end user has purchased the upgrade they can follow this **upgrade procedure**:

- Go to www.ekfhemocontrol.com/addDM
- Access with User Name and Password
- Enter Licence Key and serial no. of device
- Print out generated barcode
- Connect scanner to device and scan code
- All DM functions are unlocked and set to optional input (basic configuration)
- Individual configuration of DM functions can be done either by LIS POC Manager or Hemo Connect Software

Data management functions

Hemo Control basic version

- Time and date
- Test result

Hemo Control with DM upgrade or Hemo Control Manager

Lists can be send from LIS to device
Each function can be set as compulsory,
optional or in-active.

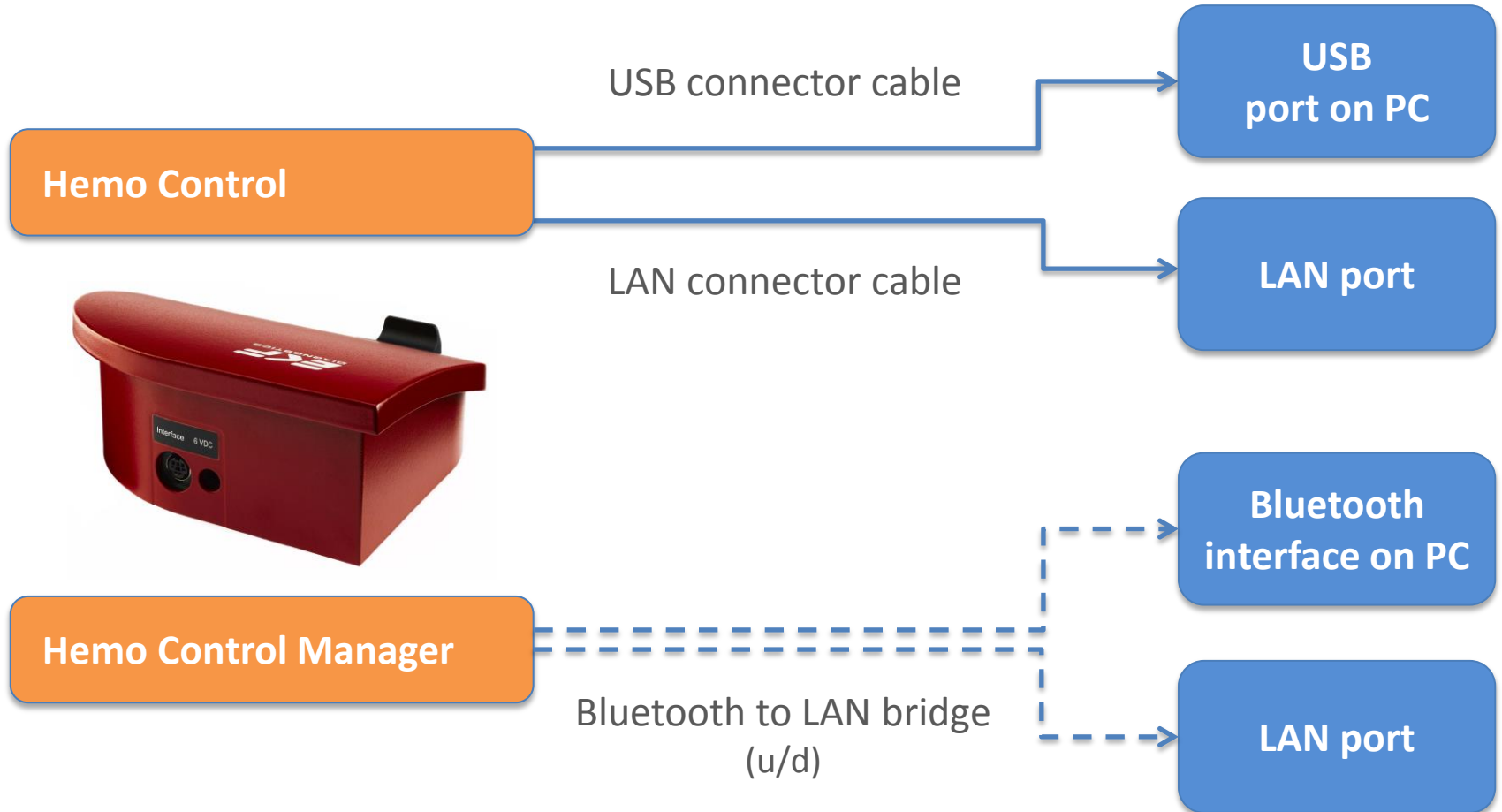
- | | |
|-----------------------------------|-----------------------------|
| - Operator-ID | - Test result |
| - Patient-ID | - QC results and batch info |
| - Cuvette LOT | - QC LOT, Level and Range |
| - QC scheme and lock-out function | - Comments |
| - Time and date | |

Public standard protocol

LIS2-A2 communication standard

- Successor of the well known ASTM (E1381/E1394) standard
- Common for small to mid size analyzers, easier to integrate than POCT-1A, public protocol available from EKF
- **Bi-directional interface** allows direct connection to third party software
- Protocol is basis for interfacing with the customers LIS system via the existing middleware or with other 3rd party software
- EKF Hemo Connect and Hemo Connect light software continue to be available for configuration and data export in case no direct connection to customer data system is planned

Data connections



Accessories

BT printer MCP 1880

- Small, lightweight
- Communication via printer cable or Bluetooth (HCM only)

Barcode scanner

- Lightweight, flexible

3x adapter

- To connect BC scanner and PC/LIS simultaneously
- Alternatively connect barcode scanner and printer

Connection options to IT systems

- USB connector cable, serial cable (HC + HCM)
- BT dongle to PC (HCM only)
- Options for serial-to-LAN and BT-to-LAN are under investigation

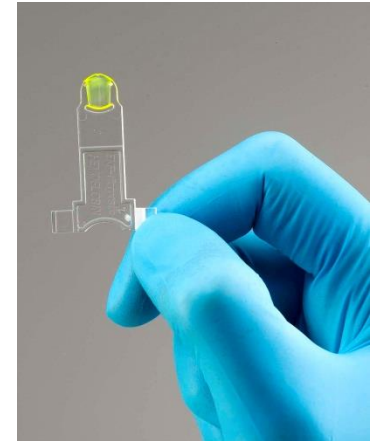


EKF nxt Microcuvette

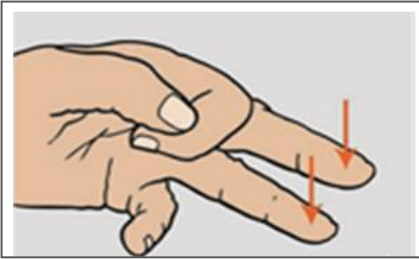
Unique design minimises risk of air bubbles in the sample:

- A slot at the rear of the sample chamber allows trapped air to escape
- Round tip and wide opening for sample uptake
- Users can hold the cuvette at any angle to the blood droplet
- Desiccant conveniently integrated in canister
- Total shelf-life up to 24 months, 3 months after opening of canister
- Package configuration 50 pcs per canister (4x50pcs)

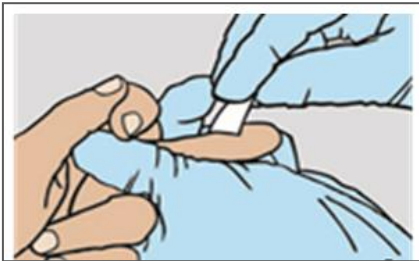
Note: cuvettes are susceptible to humidity, only remove cuvettes for direct use and close canister immediately after!



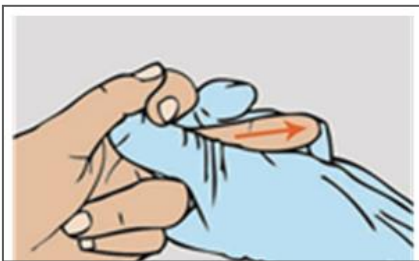
Capillary sampling



1. Hand must be warm and relaxed . Use the middle or ring finger. The patient should not be wearing a ring on the finger.



2. Clean and dry puncture site.



3. Gently massage the finger towards the tip

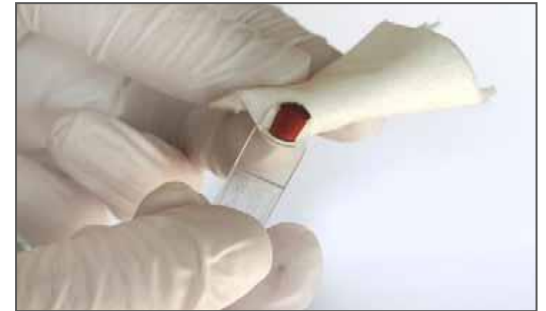


4. Incision should be done on the *side* of the finger tip

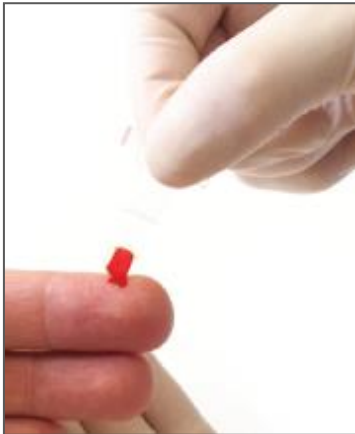
Capillary sampling



5. Discard the first 2- 3 drops



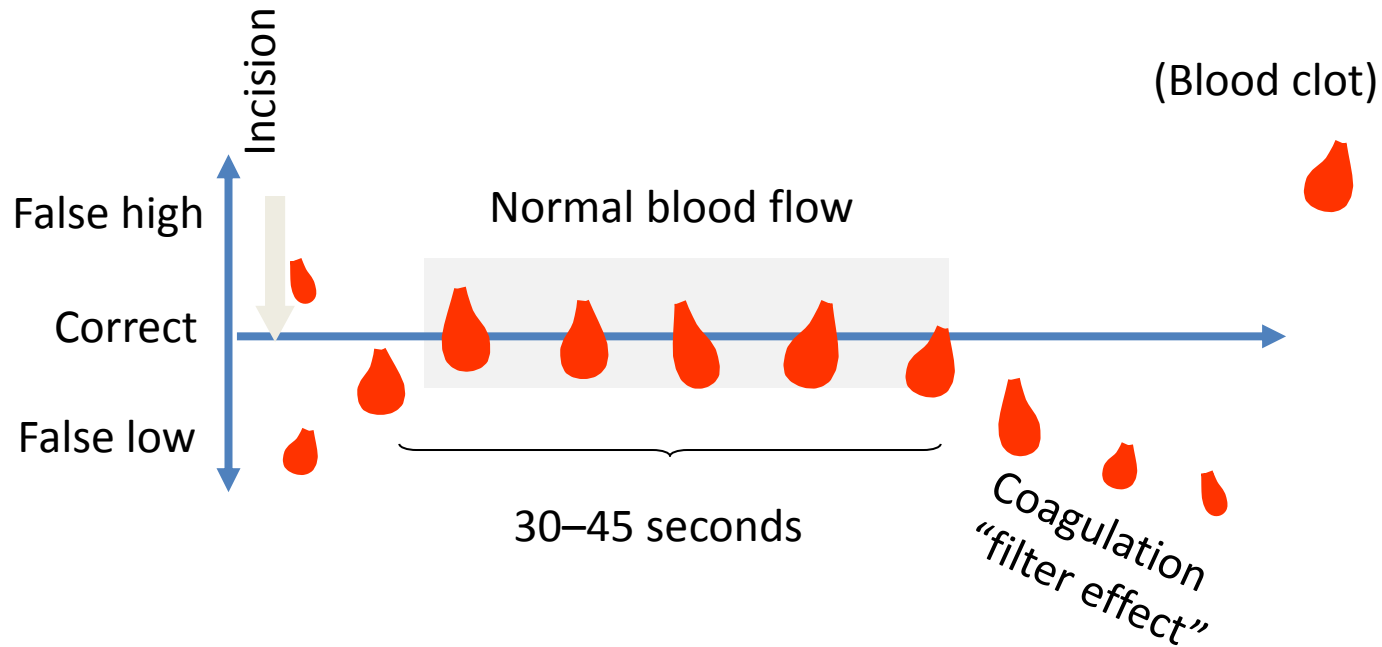
7. Wipe off the *outside* of the cuvette



6. Touch blood drop with the tip of the cuvette. Blood drop must fill the cuvette .
Fill completely in one continuous process - do not refill!

Capillary sampling

Blood flow in the fingertip



**Pre-analysis is the key to accurate measurements
regardless of measuring system used!**

Method

Vanzetti's azide methemoglobin method

G. Vanzetti, An azide-methemoglobin method for hemoglobin determination in blood
Am. J. Lab. & Clin. Med. 67 (1966) 116

Advantages:

- Azide methemoglobin is a stable coloured complex
- All Hb-variants* are converted
* except SulfHb (SHb)
- Stable results within 10 min after sample uptake into cuvette, shown in repetitive measurements
- High accuracy and precision



Method

1. Sodium desoxycholate dissolves the walls of the red blood cells making hemoglobin available for analysis in the sample.
2. Sodium nitrite oxidises Hemoglobin (Fe^{2+}) to Methhemoglobin (Fe^{3+})
3. Sodium azide ions and Methhemoglobin form azide methemoglobin, a stable coloured complex
4. This complex is then measured photometrically at 570 nm (and 880 nm for compensation of turbidity)



Calibration

The „International Committee for Standardization in Haematology“ (ICSH) was founded in 1964 and given the task to develop recommendations for hemoglobin measurements. Those recommendations were accepted in 1966 and published in 1967.

The CLSI (at that time NCCLS) converted these recommendations into a formal standard named NCCLS H15-A3.

Both, NCCLS and ICSH are describing the same method.

Hemo Control is factory calibrated according NCCLS H15-A3. (= Cyanmethemoglobin reference method)



NCCLS: National Committee for Clinical Laboratory Standards (USA)

CLSI: Clinical and Laboratory Standards Institute (since 2005)

Analytical performance

- ✓ Correlation with NCCLS H15-13 ≥ 0.98
- ✓ Imprecision: CV <2%
- ✓ Measuring range: 0-25.6 g/dL (0-15.9 mmol/L)
- ✓ Linearity:
 - 0-20g/dL = +/- 0.3g/dL
 - >20g/dL = +/- 0.7g/dL



Hematocrit

- Hematocrit (Hct) is the volume of red blood cells within a sample
- Hematocrit is an essential measurement in emergency and transfusion medicine as well as in therapeutic blood dilution
- Hematocrit readings also support the diagnosis of conditions such as anemia and polycythemia
- On Hemo Control the Hct value is derived from the hemoglobin result using the factor 2,94.
- Readings are only provided for normal hemoglobin ranges i.e. **12 - 18 g/dL**. Abnormal values will not be reported.



Control materials

Control cuvette

- Included with each analyser
- Physical standard to check the optical unit
- Using the control cuvettes provides additional safety but means no limitation of device function
- Protect of humidity > 85%
- Avoid damage (e.g. scratches)



Control materials

Control material (Hb-Con)

- Liquid control made of bovine hemolysate
- 1 ml dropper bottle, ready-to-use
- Storage temperature (unopened) 2°C – 8°C . Guaranteed shelf-life at delivery: 6 months
- Shelf-life after opening: 30 days at 2°C – 30°C
- Three levels available (low, norm, high)



Cleaning procedure



Clean **the optical unit once per month or if:**

- The displayed value of the control cuvette differs from the value shown on the label
- The error message “intensity too low” appears

Cleaning method

- Open the cuvette holder until there is a noticeable resistance
- Press down the latch on the left-hand side of the cuvette holder with the help of a pointed object
- At the same time, pull the cuvette holder forward

Cleaning procedure



1. Insert the cleaner carefully into the opening of the cuvette holder until you feel a smooth resistance.
2. Slightly push down on the cleaner and then push it deeper into the opening. Use minimal force, only a slight resistance should be felt.
3. Wipe the optical unit several times in order to clean it. Remove the cleaner when complete.
4. If the cleaner is soiled repeat the cleaning process with a new one.
5. To replace the cuvette holder push it into the opening of the housing until it locks in place.

Cleaning procedure

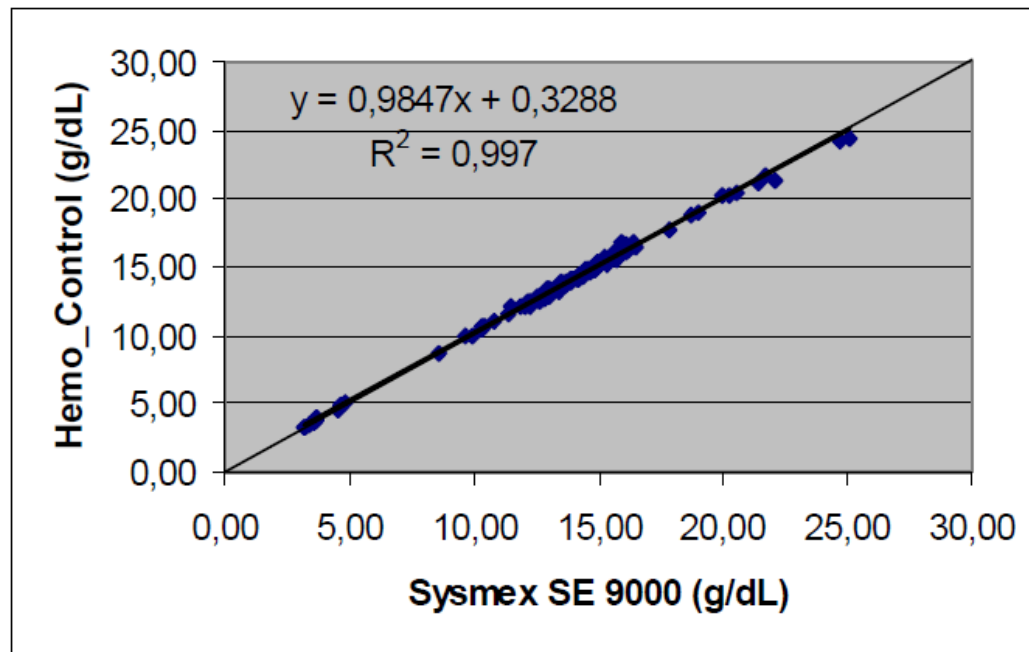


1. The cuvette holder can be cleaned with a mild soap solution. For disinfection, products similar to those used for surface disinfection can be used.
2. Wait at least 15 minutes until the cuvette holder is dry before re-inserting it into the photometer.
3. Clean the housing and touch screen with a lint free cloth lightly dampened with clean water, a mild soap solution or products similar to those used for surface disinfection.

Evaluations

Report on the evaluation: Comparison with Swelab AC 910, Sysmex XE 2100, Sysmex SE 9500, Sysmex SE 9000 = 4 study sites, parallel measurements on Hemo Control and HemoCue B Photometer

Example:



For detailed information see
Report from the evaluation

2004 SKUP Report (Scandinavia)

„Hemo_Control is quick and easy to use and well suited for the Primary health care.”

EKF Hemo_Control evaluation in Taipei Blood Center

Test period: February 1st to February 28th, 2003

Test place: Nan Hai Blood Donation Center, Taipei Blood Center- Chinese Blood Service Foundation (CBSF)

E. Result and Analysis

1. Hb con-low, deviation 1.44 %, CV: 1.08%. **(Meet our requirement)**
2. Hb con-norm, deviation 0.44 %, CV: 0.79%. **(Meet our requirement)**
3. Hb con-high, deviation 0.22 %, CV: 0.79%. **(Meet our requirement)**
4. Parallel test with current HemoCue[®], no significant statistics error
5. Parallel test with Nihon-Koden cell[®] counter, no significant statistics error

Differentiation of DiaSpect Tm vs Hemo Control

Feature	Hemo Control	DiaSpect Tm
Memory	4,000 patient results 500 QC results (DM) > Data can be transferred online or retrospectively, ideal for field use	None > need to have PC connected at test site to save data
Data management	On-board > ID's can be linked to result onsite, QC lock-out	External only > ID's can only be assigned in PC, requires software solution, no QC lock-out
Interfaces	Bi-directional with LIS or Hemo Connect	Send only

Summary on Hemo Control

- ✓ Uses the most established technology
- ✓ Highest degree of flexibility for data management and connectivity
- ✓ Maximum user comfort
- ✓ Excellent product quality
- ✓ Well suited for field and stationary use





Thank you