DiaSpect Tm

User Manual

EKF Diagnostics

DiaSpect Tm User Manual

Table of Contents

1. Intended Use....2
2. Principles of the Procedure....2
3. The DiaSpect Tm system....3
   - 3.1 DiaSpect Tm Analyzer....3
   - 3.2 DiaSpect Tm Cuvettes....3
4. Control Material....4
5. Safety information, warnings and cautions....5
6. Installation and Operation....6
   - 6.1 Charging....7
   - 6.2 Configuration of analyzer....8
   - 6.3 Data Transfer....10
   - 6.4 Cleaning and Disinfection....11
   - 6.5 Quality Control....11
   - 6.6 Disposal....12
   - 6.7 Service and Maintenance....12
7. Specimen Collection and Preparation....13
   - 7.1 Capillary Sampling....13
   - 7.2 Venous Sampling....15
   - 7.3 Control Sampling....16
8. Measuring....17
9. Troubleshooting Guide....18
10. Expected Values....19
11. Performance Characteristics....19
12. Limitations....20
13. Technical Specifications....21
14. References....22
15. Consumables....22
16. Spare parts and Accessories....22
17. Symbols Used....23

DiaSpect Tm User Manual

1. Intended Use

The DiaSpect Tm is intended for the semi-automated measurement of hemoglobin in capillary whole blood and venous whole blood (K_2EDTA or lithium heparin) using the DiaSpect Hemoglobin Cuvettes.
For screening, monitoring and as an aid to diagnosis of Anemia.
For screening of adult blood donors, for acceptability to give blood.

For near patient testing by healthcare professionals or for laboratory testing by laboratory professionals.

2. Principles of the Procedure

Based on a photometric principle, the DiaSpect Tm analyzer utilizes a broad-spectrum, multi-chromatic sensor with compensation for turbidity and scattering which measures the absorbance of whole blood over a wide spectral range. The light path length through the cuvette cavity of the DiaSpect Hemoglobin Cuvette, in combination with the DiaSpect Tm analyzer, determines the exactness of the hemoglobin measurement. The cuvettes do not contain any reagent. The hemoglobin concentration is calculated from the measured absorbance at multiple wavelengths.

The analyzer is calibrated against the hemoglobincyanide (HiCN) method, the international reference method for the determination of hemoglobin concentration in blood as described in CLSI H15-A3 and ICSH standard 1995.[1,2]
The DiaSpect Tm analyzer is factory calibrated and requires no further calibration.

3. The DiaSpect Tm system

A comprehensive list of consumables, spare parts and accessories for the DiaSpect Tm analyzer can be found in sections 15 and 16.

3.1 DiaSpect Tm analyzer

Upon delivery, open the carton on a stable surface, remove the analyzer and the accessories, and check that all the components are included and undamaged.

The DiaSpect Tm analyzer can be stored at 0 to 50 °C (32 to 122 °F). Temperatures of -30 to 70 °C (-22 to 158 °F) are temporarily permitted during transport (24 hours max.).
The operating temperature of the instrument is 10 to 42 °C (50 to 107 °F). Allow the analyzer to reach ambient temperature before use.

1. *DiaSpect Tm analyzer*

2. *User Manual*

3. *Power supply, adaptor plugs and USB cable*

3.2 DiaSpect Hemoglobin Cuvettes

Cuvettes are ready for use upon removal from the package. A sample volume of 10 µL is required to ensure proper filling of the DiaSpect Hemoglobin Cuvette. The cuvette serves as sample collector and measuring cuvette at the same time. The blood sample is drawn into the cavity by capillary force.

Refer to the product label and package insert of the DiaSpect Hemoglobin Cuvettes for information on storage and expiry. Unused cuvettes should be stored in their original bag.

DiaSpect Tm Cuvettes

Cuvettes in foil bag

4. Control Material

DiaSpect Controls HBT are available to facilitate compliance with local, state and/or federal regulations or accreditation requirements.
The DiaSpect Control HBT is produced in three concentrations that correspond to three known levels of human hemoglobin. Refer to the product label and package insert of the DiaSpect Control HBT for further information on storage and expiry.

Package configurations of DiaSpect Control HBT	
DiaSpect Control HBT1	3 x DiaSpect Control HBT-Low
DiaSpect Control HBT2	3 x DiaSpect Control HBT-Medium
DiaSpect Control HBT3	3 x DiaSpect Control HBT-High
DiaSpect Control HBT4	1 x DiaSpect Control HBT-Low 1 x DiaSpect Control HBT-Medium 1 x DiaSpect Control HBT-High

Contents: 3 vials per package

5. Safety information, warnings and cautions

DiaSpect Tm analyzer

- Only use the analyzer for the purpose described in the intended use.
- Avoid strong mechanical shocks to the analyzer.
- Do not expose the analyzer to liquids.
- After storage or transport, allow the analyzer to acclimate to its operating temperature of 10 to 42 °C (50 to 107 °F) to prevent condensation damage.
- Do not place the DiaSpect Tm analyzer in direct sunlight or near a heat source.
- Do not place the DiaSpect Tm analyzer in, or next to, wet areas such as sinks or wash basins.
- Do not insert anything other than the USB cable into the socket in the back of the analyzer.

Power Supply

- Only use the power supply provided with the instrument.
- Do not expose the power supply to liquids.
- Do not place the power supply near heat sources or expose it to direct sunlight.
- Do not use the power supply if its cable has a visible kink in it or becomes damaged.

Blood

Always handle blood as potentially infectious. Use gloves and avoid direct skin or mucous membrane contact with donated blood, blood specimens, blood from transfer pipettes, DIFF-SAFE® blood dispensers, blood from filled cuvettes or blood on the cuvette holder / DiaSpect Tm analyzer. Dispose of contaminated items in proper hazardous waste containers.

6. Installation and Operation

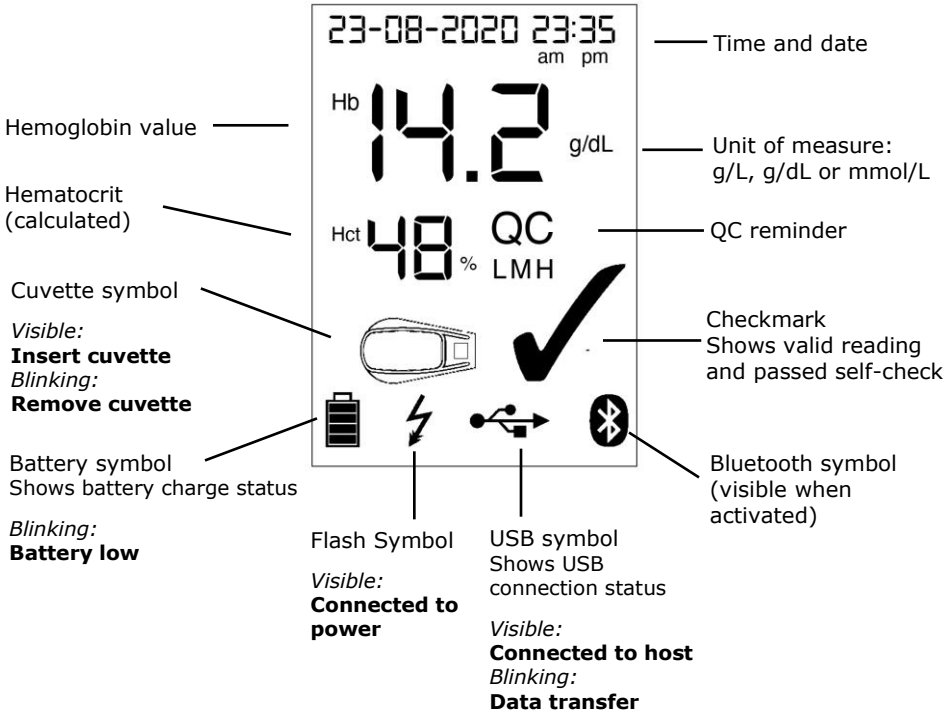
Please read this entire manual before using the analyzer for the first time. Follow the instructions carefully when performing the test as not doing so may result in inaccurate test results.

The DiaSpect Tm analyzer comes ready for use. No installation procedure is necessary. The display is always ON. The analyzer does not have an ON/OFF switch. When not in use, the analyzer remains in a low power mode.

The DiaSpect Tm analyzer may be used as a handheld device.

Overview of the DiaSpect Tm Display*

* Visible information depends on analyzer configuration and status of operation, see section 6.2



6.1 Charging

The DiaSpect Tm analyzer has a built-in rechargeable battery. The battery can be recharged by connecting to a power supply or to a computer via a USB cable. A USB cable and a power supply for charging the battery are supplied.

Charging by power supply:

1. Connect the USB cable to the analyzer.
2. Connect the respective adaptor plug to the power supply.
3. Connect the USB cable to the power supply and plug the power supply into a power outlet.

Charging by power supply

Charging by computer:

1. Connect the USB cable to the analyzer.
2. Connect the USB cable to the USB port of a computer.

Charging by computer

- The battery symbol in the display shows the current charging state.
- The flash symbol indicates that the instrument is connected to power. Leaving the instrument connected to a power source when the battery is fully charged will neither overcharge the battery nor decrease its lifespan.

- A fully charged battery lasts up to 40 days / 10,000 tests of continuous use. The battery must be charged when the last status bar is shown, at the latest when E07 is indicated on the display, see Troubleshooting Guide (section 9).
- Fully charge the battery after 9 months, whether or not the instrument has been in use.

6.2 Configuration of analyzer

The DiaSpect Tm analyzer is delivered with the following default configuration:

- Unit of measurement: g/dL
- Displayed result: Hb only
- Bluetooth function: off
- Time & date: off
- QC reminder: off

The actual result is displayed and transmitted at the time of measurement. It is replaced by the next measurement without saving to the device memory.

The following additional functions can be activated and configured using EKF Link software for basic and advanced settings (available features depending on software license). Please visit www.ekflink.com for information on EKF Link software, or contact EKF Diagnostics or your local distributor.

Basic settings

Date & time:
The time format can be set as 24 hours or 12 hours with am/pm indicator.
The date format can be set to display the following formats:

YYYY-MM-DD
DD-MM-YYYY
MM-DD-YYYY

with the variables Y for year, M for month and D for day.

Note! The use of the device memory function requires the activation of the date and time function prior to use.

Memory:
Up to 4,000 results with date and time can be stored in the memory of the analyzer. Results from the memory can be transferred to a PC using the EKF Link software. When the memory of the DiaSpect Tm analyzer is full, the oldest results will be overwritten consecutively.

Unit setting:
The unit of measurement can be set to g/L, mmol/L or g/dL.
Values are kept in the memory using the unit set at time of measurement.

Bluetooth function:
The Bluetooth function can be activated or deactivated.

Advanced settings

Hematocrit:
Approximate hematocrit value. If this option is activated, the hematocrit value is calculated and displayed for hemoglobin values between 12.0 and 18.0 g/dL.
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[3]. This calculation should not be used outside the normal range of hemoglobin in humans, e.g. under 12.0 g/dL (7.44 mmol/L) and above 18.0 g/dL (11.16 mmol/L). It should not be used in anemic conditions. The hematocrit is displayed for information only and should not be used for clinical decisions.

QC reminder and QC lock-out:
The DiaSpect Tm allows the performance and evaluation of QC measurements by means of DiaSpect HBT control material. Three QC levels (low, medium and high) are defined in the device.

A QC reminder and a lead time can be set individually for each QC level.

The activation of the reminder and the lead time before activation can be set as:
Reminder for a defined working day with lead time in working days
Reminder after lapsed time with lead time in hours (and minutes)
Reminder after a number of patient test with lead time in remaining number of patient tests

When the lead-time for the reminder is reached, a reminder will be shown for each QC level, which is due to be performed. (QC L, M, or H shown on the display) The reminder is displayed permanently during the lead-time and starts blinking after the lead-time has expired.
The QC reminder will disappear when the QC measurement for the configured target level was performed successfully and the result is within the reference range of the target level.

Follow the appropriate steps as detailed in the DiaSpect Control HBT Insert in case the QC result is out of range.

QC lock-out:
A QC lock-out function can be activated to prevent the user from doing further patient tests when the scheduled QC is over-due or has failed. No patient test result will be displayed, before the QC test has been successfully performed. Instead, an error message will be displayed, when attempts for patient measurements are made. When QC measurements have been performed successfully for the requested target levels, the device will be unlocked and the QC reminder will disappear.

6.3 Data Transfer

The DiaSpect Tm analyzer comes with a USB 2.0 and integrated Bluetooth® function.
Hereby, DiaSpect Medical GmbH declares that the radio equipment type DiaSpect Tm system is in compliance with Directive 2014/53/EU. For the full text of the EU declaration of conformity please contact: support@ekf-diagnostic.de

Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment

Radio equipment	Frequency Bands	Radio Frequency Power
Bluetooth®	2.402 - 2.480 GHz	10 mW

For additional information on data transfer, please contact the manufacturer or visit www.ekflink.com for information on EKF Link software.

6.4 Cleaning and Disinfection

1. Pull the backside of the cuvette holder slightly towards you and lift up.
2. Using a swab, clean the cuvette holder with cold water or a mild detergent, followed by disinfectant. Dry thoroughly.
3. Re-insert the dry cuvette holder by pressing down until you feel a "click".
4. Clean device housing with cold water or mild detergent, followed by disinfectant. Only use wipes lightly dampened in water/detergent/disinfectant for cleaning and disinfection.

To disinfect the instrument, use conventional solvent-free surface disinfectants, or alcohol based substances such as 70% isopropyl alcohol. Please note the application instructions of the Manufacturer.

Do not spray the instrument when cleaning, as this will damage the instrument! Wipe only!

6.5 Quality Control

The DiaSpect Tm system is factory calibrated and requires no further calibration.

The DiaSpect Tm analyzer will perform an automatic self-check after each measurement. Passing the self-check verifies the measurement performance and is indicated by a check-mark. An error code is displayed if the self-check fails and the analyzer will cease measuring, so there is no risk of an incorrect result being displayed.

DiaSpect Controls HBT are available to facilitate compliance with local, state and/or federal regulations or accreditation requirements.

Run the controls as described in section 7.3. Control values must fall within the ranges stated on the vial labels. If controls are not in range, repeat with a new cuvette. If values are still out of range, contact Technical Support department.

6.6 Disposal

Used Cuvettes

Dispose of used cuvettes in a container for potentially infectious waste. Consult local environmental authorities for adequate disposal.

DiaSpect Tm Analyzer

The lithium-ion battery in the DiaSpect Tm analyzer has to be disposed of separately. For disposal of the battery, analyzer and power supply, follow the relevant regional or local waste disposal regulations. If you require the manufacturer to dispose of the instrument and its components, please return them to EKF Diagnostics (see section 6.6). Confirmation of appropriate disinfection of the instrument should be included in the shipment.

DiaSpect Control HBT

For disposal of the control material refer to the respective instructions for use.

6.7 Service and Maintenance

The DiaSpect Tm analyzer does not require maintenance. For cleaning, see 6.4.

If damaged, the cuvette holder, USB cable, adaptor plug and the power supply can be replaced by the user.

Should the DiaSpect Tm analyzer fail to function as intended, try to solve the issue by using the Troubleshooting Guide, (Section 9). If this is not possible, return the DiaSpect Tm analyzer to DiaSpect Medical GmbH or your local distributor.

Never open the analyzer or the power supply.

Any repairs which may be necessary must be carried out by the manufacturer or by authorized personnel only.

Failure to follow the specific instructions for use may result in warranty services offered by the manufacturer being restricted.

For Technical Support, please contact:

DiaSpect Medical GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

Phone: +49 39203 511 414

or your local customer service department

Email: support@ekf-diagnostic.de

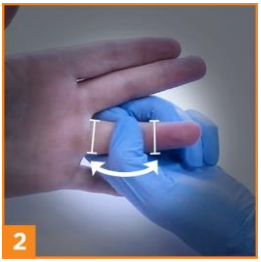
7. Specimen Collection and Preparation for Analysis

Capillary blood or venous whole blood containing K_2EDTA or lithium heparin anticoagulant may be used.

7.1. Capillary Sampling

With gloved hands, take a DiaSpect Hemoglobin Cuvette out of the foil bag and close the bag. Make sure the hand is warm and relaxed. Use the middle or ring finger for sampling. Avoid fingers with rings on.

1. Disinfect and dry the puncture site.
2. Gently massage the finger towards the tip to increase blood flow. Avoid going past the first knuckle.
3. Make the incision on the upward-facing side of the fingertip, so that the blood drop sits on top of the finger, to facilitate filling of the cuvette.



4. Apply light pressure towards the fingertip (but not past the first knuckle) until a blood drop appears. Wipe away the first 3 drops and make sure there is a free blood flow before filling the cuvette with the fourth drop.
5. Be sure to have a sufficient sized blood drop to fill the cuvette. Fill the cuvette completely by touching the corner of the cuvette to the blood drop. Do not refill the cuvette. If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one, repeating steps 4 and 5.
6. Gently wipe off the excess blood on the outside of the cuvette with a gauze pad. Be sure to gently wipe both sides.
   Do not wipe too close to the open end of the cuvette as this can draw blood out of the cuvette.

Repeat Testing

Be careful to apply the procedure described in step 1-6 correctly when collecting capillary blood for hemoglobin measurements.

The most common causes for erroneous results are choice of an unsuitable size or type of lancet, incorrect capillary sampling technique, restricted capillary blood flow, or the presence of tissue fluid in the sample after pressing the fingertip too hard. These factors commonly affect the result.

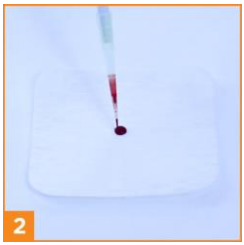
Confirmation of an unexpected or unacceptable result can exclude sampling mistakes as the cause. As the DiaSpect method is very fast, this confirmatory test can probably be done using the same incision. Further drops following the 4th drop may be used for testing as long as there is still a free flow of blood.
If the blood flow has decreased or stopped, another incision should be made for the confirming sample. Repeat the procedure described in steps 1-6 and record all results from repeated sampling, including relevant information about the reason for retesting.

7.2 Venous Sampling

If a venous sample cannot be run immediately, it may be refrigerated up to 72 hours. If the blood is refrigerated, then the blood should be allowed to reach room temperature before testing. K_2EDTA or lithium heparin tubes may be used.

With gloved hands, take a DiaSpect Hemoglobin Cuvette out of the foil bag and close the bag.

1. Make sure the sample is at room temperature before testing. Mix the tube by gentle inversion at least 8 times.
2. Place a drop of blood on to a hydrophobic surface (e.g. Parafilm) using a commercially available transfer pipette or DIFF-SAFE® Blood Dispenser.
3. Fill the cuvette completely by touching the corner of the cuvette to the blood drop. Do not refill the cuvette. If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one, repeating steps 2 and 3.
4. Gently wipe off the excess blood on the outside of the cuvette with a gauze pad. Be sure to gently wipe both sides. Do not wipe too close to the open end as this can draw blood out of the cuvette.



7.3 Control Sampling

1. The DiaSpect Tm analyzer can be verified by use of DiaSpect Control HBT. If stored refrigerated, allow the control solution to reach room temperature first.
   With gloved hands, take a DiaSpect Hemoglobin Cuvette out of the foil bag and close the bag.

   Mix the control solution by gentle inversion 5 times immediately before sampling. Open the vial, wipe any excess material from the vial tip and cap with a clean tissue and discard the first drop.

2. Dispense a second drop of the control solution on to a hydrophobic surface (e.g. Parafilm).

   Fill the cuvette completely by touching the corner of the cuvette to the drop. Do not refill the cuvette. If a cuvette cannot be filled in one continuous process, or if the cuvette contains air bubbles, discard the cuvette and use a new one with a new drop of control solution.

3. Gently wipe off the excess control solution on the outside of the cuvette with a gauze pad. Be sure to gently wipe both sides. Do not wipe too close to the open end as this can draw control solution out of the cuvette.

4. Wipe any excess material from the vial tip and cap with a clean tissue and recap the vial tightly, immediately.

8. Measuring

1. Insert the filled cuvette in the cuvette holder.
2. Press down gently until you feel a "click" and hold in position until the result appears on the screen. **Pull the cuvette out of the DiaSpect Tm quickly.**
3. Dispose of the used cuvette in a container for potentially infectious waste. Record the test result as soon as the checkmark is shown.
4. The result will remain on the display until replaced by the next measurement. To erase the latest result, press down on the empty cuvette holder.

Use only completely filled cuvettes for measuring. A filled cuvette should be analyzed within 1 minute after filling. A filled cuvette should be kept in a horizontal position until measurement.

If the DiaSpect Tm analyzer has been out of use for a couple of hours, an error code may appear after the first measurement. Remove the filled cuvette, make a "blank" measurement by pressing down the empty cuvette holder and then reinsert the filled cuvette for measurement.

9. Troubleshooting Guide

Symptom	Possible Cause	Correction
Unexpectedly high / low result	Improper sample	Repeat the sampling. Make sure that the sampling is done correctly. See sections 7.1 to 7.3 for more information.
Hct -- %	Hemoglobin value below 12.0 or above 18.0 g/dL.	None. See section 6.2 for more information.
Error E01	Calibration lost	Contact the DiaSpect customer service department.
Error E02	Sensor read error	Repeat measurement with the same cuvette. If error persists, contact the DiaSpect customer service department.
Error E03	Self-check failed	E03 may be displayed if a filled cuvette is left in the cuvette holder, or was removed too slowly. In order to reset the self-check function, press down on the empty cuvette holder. The screen should display "---" and a "√". If error persists, contact the DiaSpect customer service department.
Error E04	Light source too dark	Remove cuvette from cuvette holder. Press cuvette holder several times until the screen reads "---" and a "√" appears. If error persists, contact the DiaSpect customer service department.
Error E05	Light source too bright	Remove cuvette from cuvette holder. Press cuvette holder several times until the screen reads "---" and a "√" appears. If error persists, contact the DiaSpect customer service department.
Error E07	Battery too low to perform measurements	Recharge the battery.
Error E08	measurement value too high	Measurement value outside the measuring range.
Error E09	Patient measurement during active QC Lock	Successfully perform QC measurement for the requested target level.
Display blank, measuring not possible	Battery completely discharged	To recharge the battery, connect with a power outlet or computer and charge for a minimum of 4 hours. If recharging fails, contact the DiaSpect customer service department.

10. Expected Values[4]

The following hemoglobin values are considered normal:

Population	Age Range	Cited Reference Range*
Adult Male	≥ 22 years	13.0 – 17.0 g/dL
Adult Female	≥ 22 years	12.0 – 15.0 g/dL
Child/Adolescent	> 2 years to 21 years	11.0 – 15.5 g/dL
Infant	1 month to 2 years	9.4 – 16.5 g/dL

* Reference ranges are based on medically accepted published reference ranges (Dacie and Lewis, Practical Haematology, Twelfth Edition, Elsevier Limited 2017). These ranges are for general guidance only. Each laboratory should establish its own normal range.

11. Performance Characteristics

a) Precision

This precision was tested in accordance with CLSI guideline EP5-A2 with 3 lots and 3 blood samples with different hemoglobin levels and confirmed the claimed CV of ≤ 1 % (for hemoglobin values ≥ 10 g/dL) or standard deviation of ≤ 0.1 g/dL (for hemoglobin values < 10 g/dL) for within-run, within-device and within-single run precision as well as for lot-to-lot and analyzer to analyzer variability.

	Claim	High sample CV [%]	Mid sample CV [%]	Low Sample SD [g/dL]
Within-run precision	SD ≤ 0.1 g/dL for Hb < 100 g/L CV ≤ 1% for Hb ≥ 100 g/L	0.5	0.8	0.05
within-device precision		0.6	0.8	0.06
within-single run precision		0.9	0.7	0.06
lot-to-lot variability		0.2	0.6	0.05
analyzer to analyzer variability		0.2	0.6	0.05

b) Accuracy

The trueness was tested and confirmed in accordance to the protocol of CLIA (Clinical Laboratory Improvement Act) and CAP (College of American Pathologists) by direct method comparison against the international reference method HiCN in a hemoglobin range of 1-255 g/L.

	N	Min [g/L]	Max [g/L]	Slope 95th percentile	Correlation coefficient (r)
DiaSpect Tm 1	22	1	255	0.978 0.971-0.985	1.000
DiaSpect Tm 2	22	1	255	0.979 0.971-0.987	1.000

The results of the comparison studies between the DiaSpect Tm and a comparative device performed at the point-of-care are summarized in the following table. The study was performed across four external sites.

Sample Type	N	Min	Max	Slope	Correlation Coefficient (r)
EDTA	344	4.1 g/dL	24.5 g/dL	0.9858	0.986
Li-heparin	120	10.4 g/dL	20.0 g/dL	0.9834	0.987
Capillary	363	8.5 g/dL	20.1 g/dL	0.9903	0.963

12. Limitations

Interferences

The following substances do not affect the test results.

endogene interferents	**Test Concentration**	**exogene interferents**	**Test Concentration**
conjugated Bilirubin	37 mg/dL	Acetaminophen	19 mg/dL
unconjugated Bilirubin	37 mg/dL	Acetylsalicylic acid	4 mg/dL
total Cholesterol	482 mg/dL	Ascorbic Acid	6 mg/dL
Intralipid	2366 mg/dL	Dopamine	0.1 mg/dL
Hemolysis (free hemoglobin)	100% 18,900 mg/dL	Ibuprofen	26 mg/dL
Creatinine	16 mg/dL	Tetracycline	2.6 mg/dL
Urea	129 mg/dL	3x EDTA	Tube filled to 1/3 volume
Uric Acid	29 mg/dL	3x Li-heparin	Tube filled to 1/3 volume

For further limitations of the procedure, see the DiaSpect Hemoglobin Cuvettes package insert.

13. Technical Specifications

Operating temperature	10 to 42 °C (50 to 107 °F)
Operating humidity	20 to 85 % rH, non-condensing
Storage Humidity	5 to 95 % rH, non-condensing
Altitude during operation	3000 m (with power supply) 4000 m (without power supply)
Altitude during transport	4000 m
Storage temperature	0 to 50 °C (32 to 122 °F) -30 to 70 °C (-22 to 158°F) during transport, 24 hour max.)
Sample volume	10 µL
Linear measurement range	0.5–25.5 g/dL (5–255 g/L)
Wavelength	Multiple wavelengths ranges, 450 nm to 750 nm
Measuring time	1 second
Displayed result	Hemoglobin, optional calculated Hematocrit*
Memory	Up to 4,000 results with date and time*
Battery	3.6 V integrated lithium-ion rechargeable batteries
Instrument input rating	5 V, 100 mA (PC) / 350 mA (USB power supply)
Power supply input rating	Mains Adaptor: Input: 4.5 – 5 VA, 100–240 V AC, 50–60 Hz Output: 350 mA Suitable Power supply: Model: CUI, SMI5-5-V-I38 USB The adapter is only for indoor use
Data interface	USB 2.0, Bluetooth® Smart* Equipment connected to the interface must be compliant to IEC 60950 or IEC 62368
Overvoltage category	II
Pollution degree	2
Duration of use	40 days / 10,000 tests of continuous use, Standby time: 9 months for a fully charged battery
Analyzer dimensions	L = 15 cm, W = 9 cm, H = 4 cm
Analyzer weight	180 g
Dimensions of transport box	L = 23 cm, W = 16.5 cm, H = 7 cm
Weight of analyzer and transport box	570 g

The DiaSpect Tm analyzer complies with IEC 61326-2-6 for group 1, class B equipment regarding electromagnetic compatibility, emission and interference immunity.

*) Function requires activation by EKF Link light / EKF Link software, see section 6.2 for details.

14. References

1. NCCLS/CLSI document H15-A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition
2. Recommendations for reference method for haemoglobinometry in human blood (ICSH standard 1995) and specifications for international haemiglobincyanide standard (4th edition)
3. J.D Bauer, P.G Ackermann, G. Toro, Clinical laboratory methods. The C. V. Mosby Company, Saint Luis 1974, S. 156
4. Dacie and Lewis, Practical Haematology, 12th edition, 2017

The following consumables, spare parts and accessories may be used with the DiaSpect Tm analyzer.

15. Consumables

DiaSpect Hemoglobin Cuvettes (5x100pcs)	REF 90C.0001
DiaSpect Control HBT1	REF 90B.0011
DiaSpect Control HBT2	REF 90B.0012
DiaSpect Control HBT3	REF 90B.0013
DiaSpect Control HBT4	REF 90B.0014

16. Spare parts and accessories

Cuvette Holder	REF 91B.0005
USB Cable	REF 91C.0005
Carrying case for DiaSpect Tm (plastic)	REF 7049-8011-0179

17. Symbols Used

SN	Serial number
CE	The CE mark documents the conformance of the DiaSpect Tm with the essential requirements of the applicable directives/regulations
IVD	In-vitro-Diagnostic Medical Device
REF	Reference Number
	Dispose of the instrument in compliance with local regulations for the disposal of electronic equipment. Do not put in domestic waste!
	Consult Instructions for Use
	Caution
	Manufacturer
	Direct current
	Class II equipment
	Bluetooth® symbol, Shows RF connection status and signal strength
	Temperature limitation

DiaSpect Tm User Manual

DiaSpect Medical GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

DiaSpect Tm-2 manual EN
Revision: 1.01
Issue date: 09/2022

DiaSpect Medical GmbH

Ebendorfer Chaussee 3
39179 Barleben
Germany

3200-9001-0201 EN.1.01 09/2022