DiaSpect Tm User Manual

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DiaSpect Tm User Manual

1. Intended Use

The DiaSpect Tm system is intended for the *in vitro* quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA or lithium heparin tubes in point-of-care settings and in non-anticoagulated capillary whole blood and venous whole blood drawn in K2-EDTA tubes in blood bank settings. The DiaSpect Tm system consists of the DiaSpect Tm analyzer and specifically designed disposable cuvettes. The DiaSpect Tm analyzer is only to be used with DiaSpect Tm Cuvettes.

- Caution: Federal law restricts this device for sale by or on the order of a physician or other licensed practitioner (Rx only).
- CLIA Complexity for whole blood: Waived

Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test, or the test will no longer be considered CLIA waived.

2. Principles of the Procedure

Based on a photometric principle, the DiaSpect Tm system 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, in combination with the DiaSpect Tm analyzer, determines the exactness of the hemoglobin measurement. The hemoglobin concentration is calculated from the measured absorbance at multiple wavelengths.

The cuvettes do not contain any reagent. The system is calibrated against the hemoglobincyanide (HiCN) method, the international reference method for the determination of hemoglobin concentration in blood as described in NCCLS/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

3.1 DiaSpect Tm analyzer

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

A comprehensive list (with item numbers) of all parts for the DiaSpect Tm system can be found in sections 15 and 16.

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, adapter plug and USB cable*

3.2 DiaSpect Tm 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 Tm 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 Tm 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: 1.9 mL per vial, 3 vials per package

5. Important Safety Instructions and Notes on Radio Interference

DiaSpect Tm analyzer

- 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.

FCC statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Notes on radio interference

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful. Interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer.

Caution

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

RF exposure info

The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.

Radio equipment	Frequency Bands	Radio Frequency Power
Bluetooth® Low Energy	2.402 - 2.480 GHz	<1 mW

6. Installation and Operation

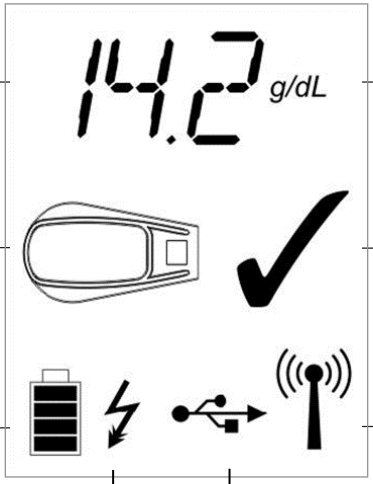
Only healthcare professionals may use the DiaSpect Tm analyzer.

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.

Understanding the DiaSpect Tm Display



Hemoglobin value

Unit of measure

Cuvette symbol

Visible:
Insert cuvette
Blinking:
Remove cuvette

Checkmark
Shows valid reading and passed self-check

Battery symbol
Shows battery charge status

Blinking:
Battery low

Antenna Pole
Shows RF connection status and signal strength (only with activated Bluetooth® option)

Flash Symbol

Visible:
Connected to power

USB symbol
Shows USB connection status

Visible:
Connected to host
Blinking:
Data transfer

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. Check that the adapter plug is connected 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 Data Transfer

The DiaSpect Tm analyzer comes with USB 2.0 and an optional Bluetooth® function.

For additional information on data transfer, please contact the manufacturer.

6.3 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 with cold water or mild detergent, followed by disinfectant.

To disinfect the instrument, use conventional solvent-free surface disinfectants or PDI Super Sani-Cloth® Germicidal Disposable Wipes and follow labeling directions.

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

Only use wipes lightly dampened in water/detergent/disinfectant for cleaning and disinfection.

6.4 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 at 1-800-531-5535.

6.5 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.

6.6 Service and Maintenance

The DiaSpect Tm analyzer does not require maintenance. For cleaning, see 6.3.

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 EKF Diagnostics 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:

EKF Diagnostics, Inc.
1261 North Main Street
Boerne, TX 78006
USA

Phone: 1-800-531-5535
Email: techsupport@ekfdiagnostics.com
www.ekfusa.com

7. Specimen Collection and Preparation for Analysis

Capillary blood or venous whole blood containing K2-EDTA or lithium heparin anticoagulant may be used.

7.1. Capillary Sampling

With gloved hands, take a DiaSpect Tm 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 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.

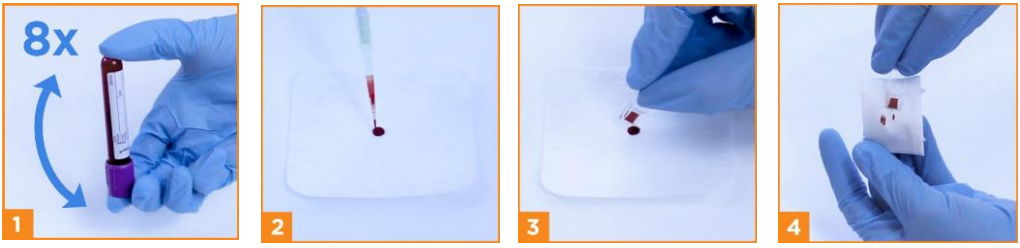
If the blood flow has decreased or stopped, another incision should be made for the confirming sample. Repeat the procedure described in steps 1-6 and record all results from repeated sampling, including relevant information about the reason for retesting.

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. K2-EDTA or lithium heparin tubes may be used.

With gloved hands, take a DiaSpect Tm 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 system 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 Tm 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 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.

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 7.1 to 7.3 for more information.
Error E01	Calibration lost	Contact Technical Support at 1-800-531-5535.
Error E02	Sensor read error	Repeat measurement with the same cuvette. If error persists, contact Technical Support at 1-800-531-5535.
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 Technical Support at 1-800-531-5535.
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 Technical Support at 1-800-531-5535.
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 Technical Support at 1-800-531-5535.
Error E07	Battery too low to perform measurements	Recharge the battery.
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 Technical Support at 1-800-531-5535.

10. Expected Values[3 - 8]

The unit of measure for the hemoglobin value is g/dL. 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) Within Run and Total Precision
Repeatability and overall reproducibility of three samples was tested over 20 days.

Sample	Concentration	Within-Run (SD, %CV)	Total (SD, %CV)
Low	7.99 g/dL	(0.085, 1.06%)	(0.11, 1.38%)
Medium	12.58 g/dL	(0.11, 0.88%)	(0.14, 1.09%)
High	15.82 g/dL	(0.15, 0.92%)	(0.22, 1.41%)

b) Accuracy, Point-of-Care
The results of the comparison studies between the DiaSpect Tm and the predicate 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

DiaSpect Tm has not been evaluated for capillary samples with hemoglobin values below 8.5 g/dL as such samples are very rarely seen in the primary care setting. It is recommended that patients showing a capillary hemoglobin of less than 8.5 g/dL are referred to a confirmatory laboratory test.

c) Accuracy, Blood Donation Centers
A method comparison of 150 capillary and 147 venous samples was conducted at two blood bank settings, giving the following results:

Sample Type	N	DiaSpect Tm Minimum	DiaSpect Tm Maximum	Hb301 Minimum	Hb301 Maximum
K2-EDTA	147	10.4 g/dL	22.0 g/dL	11.1 g/dL	20.7 g/dL
Capillary	150	10.5 g/dL	20.6 g/dL	10.7 g/dL	20.7 g/dL

DiaSpect Tm vs HemoCue Hb 301 (linear regression)

Matrix	N	Slope (95% CI)	Intercept (95% CI)	r
Capillary	150	0.9541 (0.9134~0.9948)	0.2619 (-0.3496~0.8733)	0.967
Venous	147	1.1465 (1.1068~1.1863)	-2.5299 (-3.4183~-2.1122)	0.978

DiaSpect Tm vs HemoCue Hb 301 (Passing-Bablok regression)

Matrix	N	Slope (95% CI)	Intercept (95% CI)	r
Capillary	150	1.000 (0.9512~1.032)	-0.45 (-1.011~0.2805)	0.967
Venous	147	1.140 (1.100~1.179)	-2.477 (-3.067~-1.895	0.978

The bias of the DiaSpect Tm at the hemoglobin deferral levels for male and female donors was calculated from the regression curves using the Hb 301 as the reference method.

Donor Cutoff, Hb 301	DiaSpect Tm Capillary		DiaSpect Tm Venous	
	Hb Level	% Bias	Hb Level	% Bias
Adult Female, 12.5 g/dL	12.2 g/dL	-2.4%	11.8	-5.6%
Adult Male, 13 g/dL	12.7 g/dL	-2.3%	12.4	-4.8%

Using the HemoCue Hb301 as the reference method, the agreements for blood donor eligibility are as follows:

Capillary All Donors	Hb 301 ≥Cutoff	Hb 301 <Cutoff
DiaSpect Tm ≥Cutoff	127	2
DiaSpect Tm <Cutoff	7	14

Agreement (Score 95% CI)
Accept = 127/134 = 94.8% (89.6~97.4%)
Reject = 14/16 = 87.5% (64.0~96.5%)
Overall = 141/150 = 94.0% (89.0~96.8%)

Venous All Donors	Hb 301 ≥Cutoff	Hb 301 <Cutoff
DiaSpect Tm ≥Cutoff	120	1
DiaSpect Tm <Cutoff	13	13

Agreement (Score 95% CI)
Accept = 120/133 = 90.2% (84.0~94.2%)
Reject = 13/14 = 92.9% (68.5~98.7%)
Overall = 133/147 = 90.5% (84.6~94.2%)

The discordance observed was investigated by comparison to a laboratory reference method. In a separate study, 100 capillary and 100 venous samples were tested with the DiaSpect Tm, the HemoCue Hb 301 and the Sysmex XP-300. The DiaSpect Tm was found to be substantially equivalent to the Sysmex XP-300 (calibrated to the hemiglobincyanide method, HiCN), while the HemoCue Hb 301 consistently provided results that were higher by approximately 0.6 g/dL. These results are summarized below.

The bias of the DiaSpect Tm at donor eligibility cutoffs was calculated from the regression curves using the Sysmex XP-300 as the reference method.

Donor Cutoff, XP-300	DiaSpect Tm Capillary		DiaSpect Tm Venous	
	Hb Level	% Bias	Hb Level	% Bias
Adult Female, 12.5 g/dL	12.56	0.5%	12.53	0.2%
Adult Male, 13 g/dL	13.05	0.4%	13.07	0.7%

The positive bias of the Hb 301 at donor eligibility cutoffs was calculated using the Sysmex XP-300 as the reference method. The positive bias of the Hb 301 is consistent with its higher acceptance rate of donors near the eligibility cutoff, and is supported by the literature.[9,10]

Donor Cutoff, XP-300	Hb 301 Capillary		Hb 301 Venous	
	Hb Level	% Bias	Hb Level	% Bias
Adult Female, 12.5 g/dL	13.12	5.0%	13.03	4.2%
Adult Male, 13 g/dL	13.62	4.8%	13.55	4.2%

12. Technical Specifications

Operating temperature	10 to 42 °C (50 to 107 °F)
Operating humidity	0 to 100%, non-condensing
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
Measurement range	1.2–25.5 g/dL
Wavelength	Multiple wavelengths ranges, 450 nm to 750 nm
Measuring time	1 second
Battery	3.6 V integrated lithium-ion rechargeable batteries
Safety	Tested in accordance with IEC 61010
Instrument input rating	5 V, 100 mA (PC) / 350 mA (power supply)
Power supply input rating	125mA, 100–240 V AC, 50–60 Hz
Data interface	USB 2.0, Bluetooth® Smart (optional)
Protection class	IP 21
Supply current	Max. 100 mA from USB host Max 350 mA from USB power supply
Duration of use	A fully charged battery lasts up to 40 days / 10,000 tests
Analyzer dimensions	L = 6 in, W = 3.5 in, H = 1.6 in
Analyzer weight	0.4 lb
Dimensions of transport box	L = 9 in, W = 6.5 in, H = 2.8 in
Weight of analyzer and transport box	1.3 lb

13. Limitations

Specificity & Disease States

The following substances and disease states do not affect the test results.

Potential Interferent	Test Concentration	Potential Interferent	Test Concentration
Bilirubin	20.0 mg/dL	Ferrous Fumarate	30 mg/dL
Cholesterol	500 mg/dL	Iron Dextran	284 mg/dL
Creatinine	5 mg/dL	Folic Acid	1000 ng/dL
Protein	12 mg/dL	Vitamin B12	2500 ng/dL
Triglyceride	1000 mg/dL	Lithium Carbonate	23 mg/dL
Urea	258 mg/dL	Immunoglobin	500 mg/dL
Uric Acid	24 mg/dL	Methyldopa	1.7 mg/dL
Acetaminophen	2 mg/dL	Salicylic Acid	100 mg/dL
Ascorbic Acid	6 mg/dL	5x EDTA	Tube filled to 1/5 volume
Dopamine	0.1 mg/dL	Hypochromia	Disease state
Ibuprofen	55 mg/dL	High WBC Count	Disease state
Tetracycline	1.5 mg/dL	Polycythemia	Disease state
Ferrous Sulfate	22 mg/dL	Sickle Cell	Disease state
Ammonium Ferric Citrate	30 mg/dL		

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

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)
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Other:

DiaSpect Tm Cuvettes package insert
DiaSpect Control HBT package Insert

The following consumables, spare parts and accessories may be used with the DiaSpect Tm analyzer REF 7049-0013-0264 / Cat. 900-001.

15. Consumables

DiaSpect Tm Cuvettes (1x100 pcs)	REF 7049-3013-0584 / Cat.900-100
DiaSpect Tm Cuvettes (5x100pcs)	REF 7049-3013-0369 / Cat.900-500
DiaSpect Control HBT1	REF 90B.0011 / Cat.900-501
DiaSpect Control HBT2	REF 90B.0012 / Cat.900-502
DiaSpect Control HBT3	REF 90B.0013 / Cat.900-503
DiaSpect Control HBT4	REF 90B.0014 / Cat.900-504

16. Spare parts and accessories

Cuvette Holder	REF 7049-1011-0145
USB Cable	REF 7049-7021-0161
Power supply with US adapter	REF 7049-7013-0187
Carrying case for DiaSpect Tm (plastic)	REF 7049-8011-0179

17. Symbols Used

IP21	Protection of electrical equipment against foreign objects, water and access
SN	Serial number
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
	Antenna Pole, Shows RF connection status and signal strength (only with activated Bluetooth® option)
	Temperature limitation

USA Contact

EKF Diagnostics, Inc.
1261 North Main Street
Boerne, TX 78006
USA
Phone 1-800-531-5535
Email: techsupport@ekfdiagnostics.com
www.ekfusa.com

EKF-diagnostic GmbH
Ebendorfer Chaussee 3
39179 Barleben
Germany

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