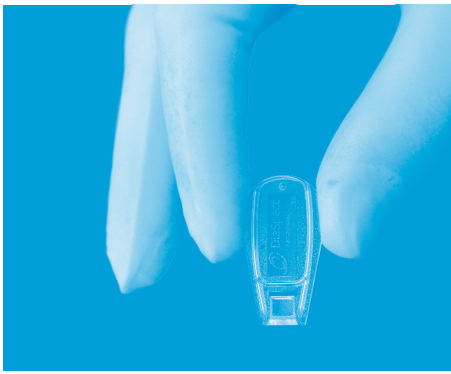
CONSULT®

McKESSON



Consult® Hemoglobin
Testing System

USER MANUAL

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INTENDED USE

The Consult® Hemoglobin Testing System is intended for the *in vitro* quantitative measurement of total hemoglobin in non-anticoagulated capillary whole blood and venous whole blood drawn in K2EDTA 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 Consult® Hemoglobin Testing System consists of the Consult® Hemoglobin analyzer and specifically designed disposable cuvettes, the Consult® Cuvettes. The Consult® Hemoglobin analyzer is only to be used with Consult® Hemoglobin 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.

PRINCIPLES OF THE PROCEDURE

Based on a photometric principle, the Consult® Hemoglobin Testing 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 Consult® Hemoglobin analyzer, determines the exactness of the hemoglobin measurement. The cuvettes do not contain any reagent. The hemoglobin concentration is calculated from the measured absorbency at multiple wavelengths.

The system is factory calibrated (and requires no further calibration) against the hemiglobincyanide (HiCN) method, the international reference method for the determination of hemoglobin concentration in blood as described in NCLLS H15-A3and ICSH standard 1995.[1,2]

A comprehensive list of consumables, spare parts and accessories for the Consult® Hemoglobin analyzer can be found on pages 23 and 24.

THE CONSULT® HEMOGLOBIN TESTING SYSTEM

CONSULT® HEMOGLOBIN 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.

The Consult® Hemoglobin 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. Consult® Hemoglobin analyzer

2. User Manual

3. Power Supply, Adapter Plug and USB Cable

CONSULT® 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 Consult® 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 Consult® Hemoglobin Cuvettes for information on storage and expiry. Unused cuvettes should be stored in their original bag.

Hemoglobin Cuvettes

Cuvettes in foil bag

CONTROL MATERIAL

Consult® Control Solutions are available to facilitate compliance with local, state and/or federal regulations or accreditation requirements.

Consult® Control Solutions are produced to three concentrations that correspond to three known levels of human hemoglobin. Refer to the product label and package insert of the Consult® Control Solution for further information on storage and expiration date.

Contents: 3 vials per package

Package configurations of Consult® Control Solutions	
900-501MCK	3 x Consult® Control Solution Low
900-502MCK	3 x Consult® Control Solution Normal
900-503MCK	3 x Consult® Control Solution High

IMPORTANT SAFETY INSTRUCTIONS AND NOTES ON RADIO INTERFERENCE

Consult® Hemoglobin 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 acclimatize to operating temperature of 10 to 42 °C (50 to 107 °F) to prevent condensation damage.
- Do not place the Consult® Hemoglobin analyzer in direct sunlight or near a heat source.
- Do not place the Consult® Hemoglobin 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 / Consult® Hemoglobin 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

INSTALLATION AND OPERATION

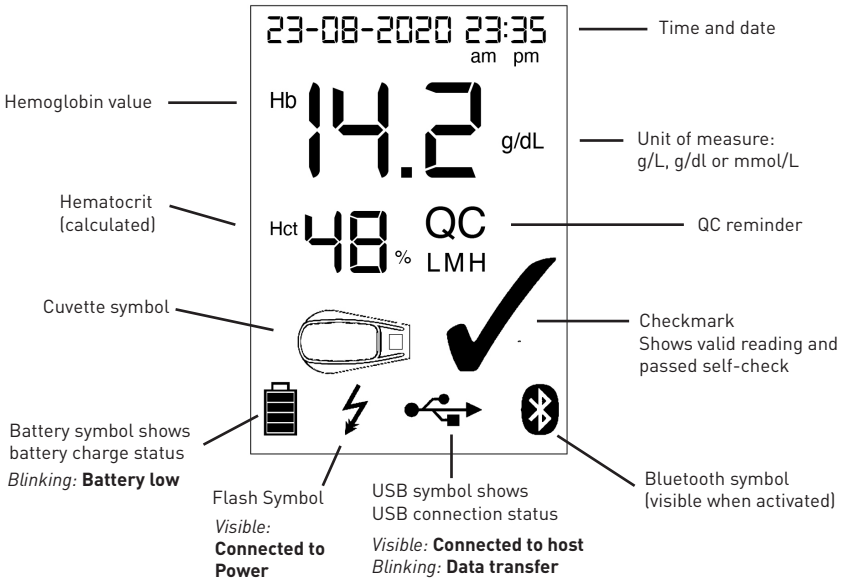
Only healthcare professionals may use the Consult® Hemoglobin analyzer.

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 Consult® Hemoglobin 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 Consult® Hemoglobin analyzer may be used as a hand-held device**

OVERVIEW OF THE CONSULT HEMOGLOBIN ANALYZER DISPLAY

*** VISIBLE INFORMATION DEPENDS ON ANALYZER CONFIGURATION AND STATUS OF OPERATION, SEE SECTION 6.2**



6.1 CHARGING

The Consult® Hemoglobin 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 computer:

1. Connect the USB cable to the analyzer.
2. Connect the USB cable to the USB port of a 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 page 19, Troubleshooting Guide (section 9).

• After 9 months, the battery must be fully charged, whether or not the instrument has been in use.

6.2 CONFIGURATION OF ANALYZER

The Consult® Hemoglobin analyzer is delivered with the following default configuration:

- Unit of measurement: g/dL
- Displayed result: Hb only
- Bluetooth function: off
- Time & date: 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 Consult® Hemoglobin 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 2.943. 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.

6.3 DATA TRANSFER

The Consult® analyzer comes with a USB 2.0 bus.

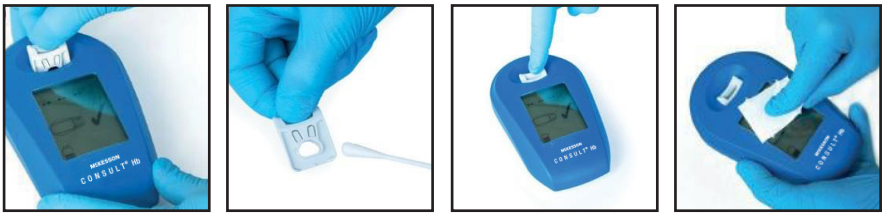
For additional information on data transfer, please contact or visit www.ekflink.com for information on EKF Link software.

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. Reinsert 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, disposable germicidal surface wipes, 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.

6.5 QUALITY CONTROL

The Consult® Hemoglobin Testing System is delivered factory-calibrated and requires no additional calibration prior to operation.

The Consult® Hemoglobin 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.

The Consult® Controls Solution is available to facilitate compliance with local, state and/or federal regulations or accreditation requirements.

Run the controls as described on page 13. Control values must fall within the ranges stated on the vial labels and insert. 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.

6.6 DISPOSAL

Used Cuvettes

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

Consult® Analyzer

The lithium-ion battery in the Consult® Hemoglobin 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.

Consult® Control Solution

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

6.7 SERVICE AND MAINTENANCE

The Consult® Hemoglobin analyzer does not require maintenance. For cleaning, see page 12.

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

Should the Consult® Hemoglobin analyzer fail to function as intended, try to solve the issue by using the Troubleshooting Guide, see page 19.

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.

For Technical Support, please contact:

Phone: 1-800-531-5535

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

Capillary blood or venous whole blood containing K2EDTA or lithium heparin anticoagulant may be used.

7.1 CAPILLARY SAMPLING

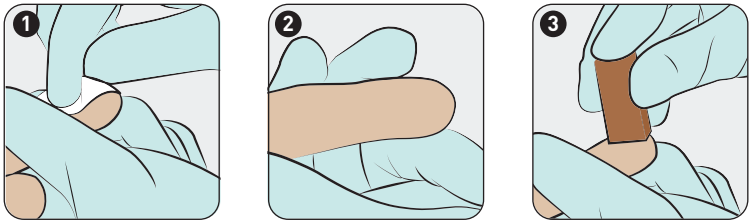
With gloved hands, take a Consult® Hemoglobin Cuvette out of the foil bag and close the bag. Make sure the hand is warm and relaxed. Use the middle or ring finger for sampling. Avoid fingers with rings on.

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.

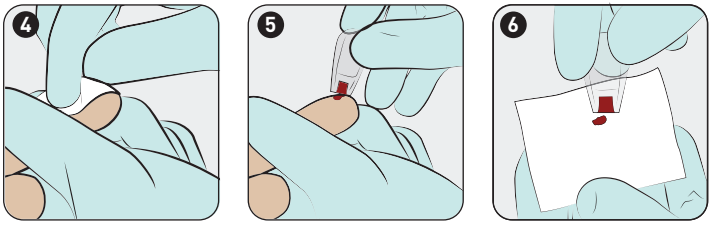
3. Make the incision on the upward-facing side of the fingertip, so that the blood drop sits on top of the finger, to facilitate filling of the cuvette.

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 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 the 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 Consult® Hemoglobin testing method is very fast, this confirmatory test can preferably 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

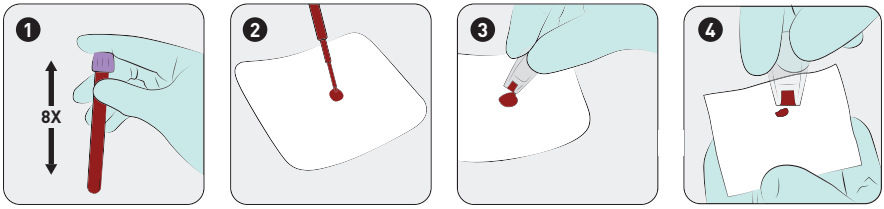
If a venous sample cannot be run immediately, it may be refrigerated up to 72 hours. If the blood is refrigerated, then the blood should be allowed to reach room temperature before testing. K2EDTA or lithium heparin tubes may be used.

With gloved hands, take a Consult® 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.

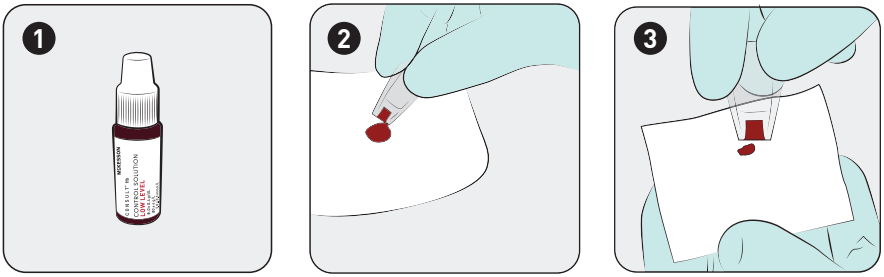


7.3 CONTROL SAMPLING

1. The Consult® Hemoglobin Testing System can be verified by use of Consult® Hemoglobin Control Solution. If stored refrigerated, allow the control solution to reach room temperature first. With gloved hands, take a Consult® 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 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.

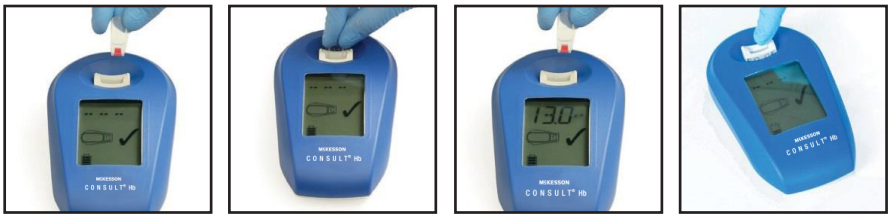
MEASURING

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 Consult® Hemoglobin 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 Consult® Hemoglobin 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.

TROUBLESHOOTING GUIDE

Symptom	Possible Cause	Correction
Unexpectedly hight / low results	Improper sample	Repeat the sampling. Make sure that the sampling is done correctly. See pages 12 – 15 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 measurments	Recharge the battery.
Error E08	Measurement value too high	Measurement value outside the measuring range.
Display blank, measuing 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.
Hct -- %	Hemoglobin value below 12.0 or above 18.0 g/dL	None. See section 6.2 for more information.

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	Potential Interferent
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.*

PERFORMANCE CHARACTERISTICS

a) Within Run and Total Precision

Repeatability and overall reproducibility of three samples was tested over 20 days.

Sample	Mean Hb Concentration	Within-Run (SD, %CV)	Total (SD, %CV)
Level 1	7.99 g/dL	(0.085, 1.06%)	(0.11, 1.38%)
Level 2	12.58 g/dL	(0.11, 0.88%)	(0.14, 1.09%)
Level 3	15.82 g/dL	(0.15, 0.92%)	(0.22, 1.41%)

b) Accuracy

The results of the comparison studies between the Consult® Hemoglobin and the predicate device 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	4.1g/dL	24.5g/dL	0.9858	0.986
Capillary	363	8.5g/dL	20.1g/dL	0.9903	0.963

Consult® Hemoglobin 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.

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	1.2–25.5 g/dL (12–255 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 = 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
	1.3 lb

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

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 Consult® Cuvettes package insert.

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. Dacie and Lewis, Practical Haematology, 121th edition, 2017

4. Fandek N, Moreau D, Newell K C, Ofner A, eds. Clinical Laboratory Tests - Values and Implications.

2nd ed. Springhouse: Springhouse Corporation, 1995: 328pp.

5. DeMott Wayne R, Tilzer Lowell L, Hematology. In: Jacobs DS, DeMott WR, Finley PR, Horvat RT, Kasten Jr BL, Tilzer LL, eds. Laboratory Test Handbook. Hudson: Lexi-Comp, 1992: 517-626.

6. Wallach J. eds. Interpretation of Diagnostic Tests - A Synopsis of Laboratory Medicine, 4th ed. Boston/ Toronto: Little Brown and Co. 1986: 6pp.

7. Painter Pennell C, Cope June Y, Smith Jane L, Appendix. In: Burtis CA, Ashwood ER, eds. Tietz Textbook of Clinical Chemistry. Philadelphia: WB Saunders, 1994: 2161-2217.

8. Tietz N, ed. Clinical Guide To Laboratory Tests, WB Saunders, 1983: 258-259.

Other:

Consult® Hemoglobin Cuvettes package insert

Consult® Control Solution package Insert

The following consumables, spare parts and accessories may be used with the Consult® Hemoglobin Analyzer.

CONSUMABLES

Consult® Hemoglobin Cuvettes (1x100 pcs)	MFR # 900-100MCK
Consult® Control Solution	MFR # 900-501MCK
Consult® Control Solution	MFR # 900-502MCK
Consult® Control Solution	MFR # 900-503MCK

SPARE PARTS AND ACCESSORIES

Cuvette Holder	MFR # 900-902MCK
USB Cable	MFR # 900-901MCK
Power supply with US adapter	MFR # 900-900MCK

SYMBOLS USED

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
	Class II equipment
	Bluetooth® symbol
	Temperature limitation

Techical Support? Call 1-800-531-5535
General Questions? Call 1-800-777-4908

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