CompoLab TM
Hemoglobin measurement system

EN(CA)

Operating Manual

Measuring instrument: CompoLab TM
Compatible cuvettes: CompoLab TM Cuvettes
Edition: 08/10.20
Part no.: M697171
CE

FRESENIUS
KABI

Table of contents

1 Intended use

The CompoLab TM system is designed for quantitative total hemoglobin determination in human blood, using finger prick capillary samples, in a specifically designed analyzer, the CompoLab TM, using specifically designed disposable cuvettes, the CompoLab TM Cuvette cuvettes.

The CompoLab TM system is to be used in human blood donation settings.

The CompoLab TM analyzer is only to be used with CompoLab TM cuvette.

The CompoLab TM analyzer and the CompoLab TM cuvettes are for in vitro diagnostic use only.

2 In Vitro Diagnostic Directive

The CE marked CompoLab TM analyzer complies with the Directive 98/79/EC on in vitro diagnostic medical devices.

3 Summary and Explanation of the Test

The CompoLab TM system provides instant quantitative total hemoglobin results using capillary samples. The system is based on photometric measurement of hemoglobin in unaltered whole blood and consists of a photometer and cuvettes.

4 Principles of the Procedure

The CompoLab TM analyzer utilizes a broad-spectrum, multi-chromatic sensor which measures the absorbance of whole blood over a wide spectral range. The cuvettes do not contain any reagent.

The exactness of hemoglobin measurement is determined by the length of the light path through the sample in the cuvette, in combination with the measuring principle of the CompoLab TM analyzer.

The system is factory calibrated against the hemoglobincyanide (HiCN) method, the international reference method for the determination of hemoglobin concentration in blood.

5 The CompoLab TM Analyzer

5.1 Hemoglobin Measuring System

Fig. 1 CompoLab TM analyzer (ref. no. 9034000)

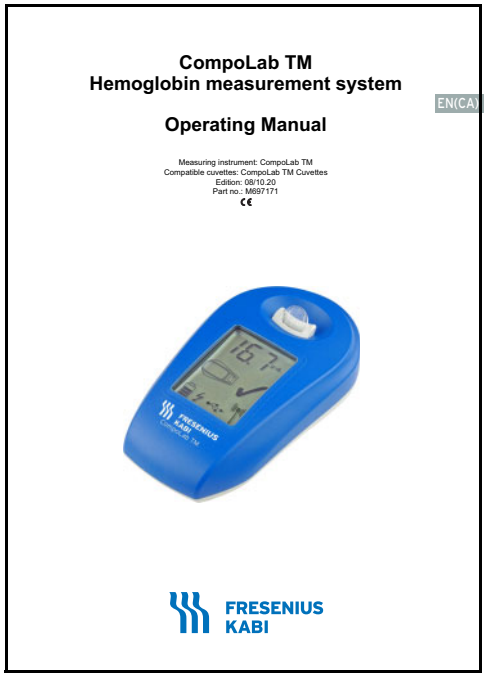


Fig. 2 Operating Manual

- **Accessories Included in the Product**

Fig. 3 USB cable (ref. no 9033050), power supply and adapter plug (ref. no 9033140)

The CompoLab TM analyzer, manual, USB-cable, adapter plug and the power supply are delivered in a carton. 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.

Please contact the manufacturer or your local distributor for replacement spare parts: cuvette holder (ref. no. M693010SP), USB cable (ref. no. 9033050), adapter plug and power supply (ref. no. 9033140) if anything is missing or damaged.

The **CompoLab TM analyzer** can be stored at 0 °C to 50 °C (+32 °F to +122 °F). Temperatures of -30 °C to +70 °C (-22 °F to +158 °F) are temporarily permitted during transport (24 hours max.). Operating temperature is +10 °C to +42 °C (+50 °F to + 108 °F). Allow the analyzer to reach ambient temperature before use.

5.2 Consumables

Not included.

Fig. 4 CompoLab TM Cuvette (ref. no 9034050), Bag of 100 pcs

CompoLab TM Cuvettes are packed in resealable bags containing 100 pieces, 5 bags per box. Store at 0 °C to +50 °C (+32 °F to +122 °F).

Temperatures of -30 °C to +70 °C (-22 °F to +158 °F) are temporarily permitted during transport (24 hours max.) as long as the cuvettes are stored in their original packaging. Use the CompoLab TM Cuvettes prior to the expiry date (the expiry date is the same for unopened or opened bags). Unused cuvettes should be stored in their original bag.

5.3 Control Material

Not included.

*Fig. 5 Diaspect Control HBT,**
1.9 ml per vial, 3 vials per package
3 x HBT Low (ref. no 90B.0011)
3 x HBT Medium (ref. no 90B.0012)
3 x HBT High (ref. no 90B.0013)
1 x HBT L, 1 X HBT M, 1 x HBT H (ref. no 90B.0014)

*Fig. 6 Diaspect Control HB,**
1.9 ml per vial, 3 vials per package
3 x HB Low (ref. no 90B.0001)
3 x HB Medium (ref. no 90B.0002)
3 x HB High (ref. no 90B.0003)
1 x HB L, 1 X HB M, 1 x HB H (ref. no 90B.0004)

The **DiaSpect Control HBT** can be stored unopened at +2 °C to +25 °C (+35 °F to +77 °F).

Temperatures of -30 °C to +70 °C (-22° F to +158 °F) are temporarily permitted during transport (24 hours max.) as long as stored in the original packaging. Do not expose the bottles to direct sunlight!

After opening, when properly recapped, the product is stable for 60 days when stored at +2 °C to +35 °C (+35 °F to +95 °F).

** Use the appropriate Control as registered in your country.*

5.4 Installation and Operation

Only qualified/trained personnel may use the CompoLab TM analyzer. Please read the operating manual before using the analyzer for the first time.

The CompoLab 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 measuring, the analyzer remains in a low power mode. The CompoLab TM analyzer may be used as a handheld device.

5.4.1 Display

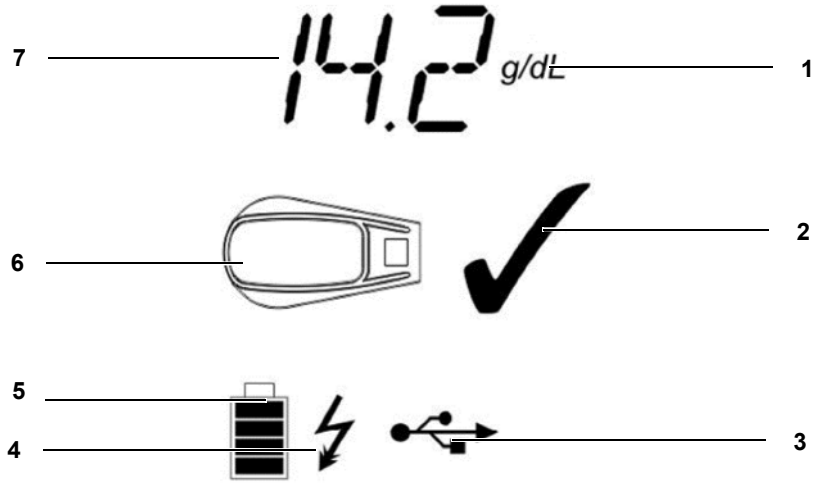


Fig. 7 Display

1 Unit of measure
Options: g/L, g/dL, mmol/L

2 Checkmark

3 USB symbol

4 Flash symbol

5 Battery symbol

6 Cuvette symbol

7 Hemoglobin value

Checkmark Shows valid reading and passed self-check

USB Shows USB connection status:
– Visible: connected to host
– Blinking: data transfer

Flash – Visible: connected to power

Battery Shows battery charge status
– Blinking: battery low

Cuvette

– Visible: please insert cuvette
– Blinking: please remove cuvette

5.5 Charging

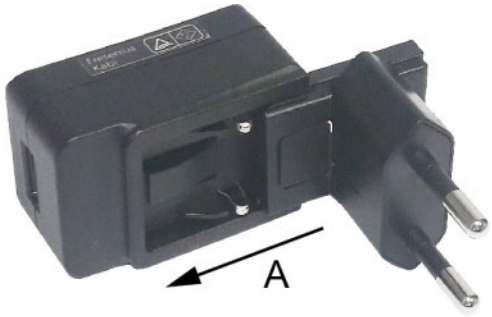
The CompoLab TM analyzer has a built-in rechargeable battery. The battery can be recharged by connection with the power supply or to a computer via a USB cable.

A USB cable and a power supply for charging the battery are supplied.

– Connect the USB cable with the analyzer.

● **Charging by power supply:**

– Connect the adapter plug with the power supply.



– Connect the USB cable with the power supply and plug the power supply into a power outlet.

- **Charging by computer:**

– Connect the USB cable to the USB port of a computer.

A 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.

5.6 Data Transfer

The CompoLab TM analyzer comes with a USB 2.0 bus. For additional information, e.g. required software for data transfer, please contact the manufacturer.

5.7 Cleaning and Disinfection

The CompoLab TM analyzer is not intended to be sterilized. Sterilization may result in damage to the device.

Equipment cleaning and disinfection should be carried out at the end of the day. When contaminated with blood or body fluids, which may contain blood-borne pathogens, equipment should be cleaned and disinfected immediately.

Disinfecting the equipment without prior cleaning is not effective.

Please use an alcohol based surface disinfectant with 70% isopropyl alcohol / 30% purified water such as, but not limited to, Decon-ahol® (DIN 02351374; DIN 02351382). Alternatively, you may use Super Sani-Cloth germicidal wipes (DIN 02247354).

Warning

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

Only use wipes or lint-free cloth soaked in water / detergent / disinfectant for cleaning and disinfection.

5.7.1 Cleaning instructions

– Wear suitable protective gloves or other personal protective equipment.

– Hold the backside of the cuvette holder and pull it out from the analyzer.

– Clean the cuvette holder with cold water or a mild detergent prior to disinfection, if visibly soiled.

– Reinsert the dry cuvette holder.

5.7.2 Disinfection Instructions

– Wear suitable protective gloves or other personal protective equipment.

– Using 70% Isopropyl alcohol / 30% purified water as disinfectant agent, apply the disinfectant with a wipe or lint-free cloth.

– Wipe the surfaces repeatedly to ensure they remain moist for two (2) minutes while at the same time taking care to avoid seepage of the disinfectant into the device itself. Do not allow any part of the analyzer or cuvette holder to become saturated or submersed in liquid.

– Optionally, use the disinfectant agent, Super Sani-Cloth wipes, follow the vendor's instructions, and ensure that the surfaces remain moist for two (2) minutes.

– Allow the analyzer or cuvette holder to completely dry at ambient room temperature.

5.8 Technical Specifications

Operating temperature	+10 °C to +42 °C (+50 °F to +108 °F)
Operating humidity	0 to 100%, not condensing
Operating air pressure	Not specified
Storage temperature	0 °C to +50 °C (-30 °C to +70 °C during transport, 24 h max.)
Sample volume	< 10 µL
Measurement range	0 to 25.5 g/dL (0 to 255 g/L; 0 to 15.9 mmol/L)
Linearity	1.8 – 23.6 g/dL
Wavelength	Multiple wavelengths ranges, 450 nm to 750 nm
Measuring time	1 – 2 s
Battery	3.6 V integrated lithium-ion rechargeable batteries
Safety	Type of protection against electric shock: class II, IEC 60950-1
Instrument input rating	5 V, 100 mA (PC) / 350 mA (Power supply)
Power supply input rating	4.5 VA, 100–240 V AC, 50–60 Hz
Data interface	USB 2.0
Protection class	IP 21
Supply current	100 mA from USB host, 350 mA from USB power supply
Duration of use	Several weeks for a fully charged battery and continuous use
Analyzer dimensions	L = 15 cm, W = 9 cm, H = 4 cm
Analyzer weight	Approx. 185 g
Dimensions of transport box	L = 23 cm, W = 16.5 cm, H = 7 cm
Weight of analyzer and transport box	Approx. 515 g
	The CompoLab TM analyzer complies with IEC 61326-2-6 for group 1, class B equipment regarding electromagnetic compatibility, emission and interference immunity.

- **Surface Materials Used on CompoLab TM Analyzer and Accessories**

Analyzer surface	Eastman Tritan (TM) Copolyester MX711
Analyzer pane	Polyether Sulfone (PES)
Analyzer feet	Ethylene Propylene Dien Rubber (EPDM)
Cuvette holder	Eastman Tritan (TM) Copolyester MX711
USB cable	Polyvinyl Chloride (PVC)
Adapter plug	Polycarbonate/Acrylonitrile Butadiene Styrene (PC-ABS)
Power supply	Polycarbonate/Acrylonitrile Butadiene Styrene (PC-ABS)

5.9 Calibration and Control

The CompoLab TM analyzer is delivered factory-calibrated and requires no additional calibration prior to operation.

The CompoLab TM analyzer will perform an automatic self-check after each measurement. Passing the self-check verifies the measurement performance and is indicated by a checkmark ✓.

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 Control HB or HBT can be used for system control (analyzer, cuvette, sample collection, and operator).

– Follow all local, state and federal regulations, and other accreditation requirements.

– Contact Fresenius Kabi for additional information.

5.10 Disposal

- **Used cuvettes**

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

- **CompoLab TM Analyzer**

Fresenius Kabi accepts the CompoLab TM with power adapter for cost-free recycling or proper disposal in accordance with pertinent recycling regulations, subject to the following conditions:

Free return to:

Fresenius Kabi AG
61346 Bad Homburg
Germany

– Written confirmation from the user that the instrument has been properly cleaned and disinfected. Before disposing of the instrument, any infection risk has to be removed by appropriate disinfection procedures.

– No third-party tampering with the instrument, other than a service company authorized by Fresenius Kabi.

- **For disposal by customer**

The **lithium-ion battery** in the CompoLab 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.

5.11 Hazards

- **CompoLab TM Analyzer**

Avoid strong mechanical shocks to the analyzer.

Do not expose the analyzer to liquids.

After storage or transport, allow the analyzer to acclimatize to room temperature of +10 °C to +42 °C (+50 °F to +108 °F) to prevent condensation damage.

Do not place the CompoLab TM analyzer in direct sunlight or near a heat source.

Do not place the CompoLab 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 to 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 suitable protective gloves and avoid direct skin or mucous membrane contact with donated blood, blood specimens, blood from filled cuvettes or blood on the cuvette holder/CompoLab TM analyzer.

5.12 Service and Maintenance

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.

Regularly inspect the device for visual damage.

The CompoLab TM analyzer does not require maintenance. For cleaning, see chap. 5.7.

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

Should the CompoLab TM analyzer fail to function as intended, try to solve the issue by using the troubleshooting guide, see chap. 7.3. If this is not possible, return the CompoLab TM analyzer to the manufacturer.

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 operating instructions may result in warranty services offered by the manufacturer being restricted.

For service and maintenance information, please contact your distributor:

Fresenius Kabi Canada Ltd.

Customer Service Department
165 Galaxy Blvd. Suite 100
Toronto, ON M9W 0C8
Canada

Phone: 1-877-821-7724
Fax: 1-877-821-2108
E-mail: Canada_customerservice@fresenius-kabi.com

6 Specimen Collection & Preparation for Analysis

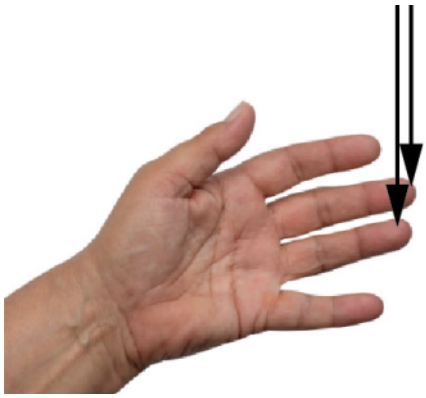
Use capillary blood specimen.

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.

6.1 Capillary Sampling

– Wear suitable protective gloves or other protective equipment. Change gloves before progressing to the next donor.

– Make sure the hand is warm and relaxed. Use the middle or ring finger for sampling. Avoid fingers with rings on.



– Disinfect and dry the puncture site

– Gently massage the finger towards the tip to increase blood flow.

– Make the incision on the side of the finger tip. Use the ‘upward side’ of the finger to facilitate filling of the cuvette.

– Apply light pressure towards the fingertip until a blood drop appears. Discard the first 3 drops and make sure there is a free blood flow before filling the cuvette with the sample drop.

– Be sure to have a sufficient sized blood drop to fill the cuvette. Fill the cuvette by touching the corner of the cuvette to the blood drop. Fill the cuvette without interruption.

– Wipe off the outside of the cuvette. Check that the cuvette is completely filled.

- **Repeated Sampling**

Due to pre-analytical factors, hemoglobin measurements from capillary samples may sometimes be misleading. Typically, pre-analytical factors can include use of the lancet, capillary sampling technique, restricted capillary blood flow, or the presence of extra-cellular fluid in the sample.

These factors commonly affect the result towards too low results. Confirmation of an unexpected or unacceptable result can exclude potential pre-analytical factors as the cause. As the CompoLab method is very fast, this confirmatory test can preferably be done using the same incision, as long as there is still a free flow of blood.

If the blood flow has stopped, another incision should be made for the confirming sample.

– Record all results from repeated sampling, including relevant information about the reason for re-testing.

6.2 Control Sampling

The CompoLab TM system can be verified by use of DiaSpect Control HBT. Allow the control solution to reach room temperature first.

– Wear suitable protective gloves or other personal protective equipment.

– Mix the control solution by gentle inversion before sampling.

– Open the vial and discard the first drop.

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

– Fill the cuvette by touching the corner of the cuvette to the drop. Fill the cuvette without interruption.

– Wipe off the outside of the cuvette.
– Check that the cuvette is completely filled.

7 Procedure

7.1 Required Materials

CompoLab TM analyzer

CompoLab TM Cuvettes

7.2 Measuring

– Wear suitable protective gloves or other protective equipment. Change gloves before progressing to the next donor.

– Place the filled cuvette in the cuvette holder and press down gently until you feel a “click”.

– The hemoglobin value will be displayed instantly.

– Pull out the cuvette quickly.
– Dispose of the used cuvette in a container for potentially infectious waste.
– Record the test result as soon as the checkmark ✓ is shown. The result will remain on the display until replaced by the next measurement.

– To erase the latest result, simply make a “blank” measurement by pressing down 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. Do not re-measure a cuvette.

If the CompoLab 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.

7.3 Troubleshooting Guide

Symptom	Possible Cause	Correction
Unexpectedly high/low result	Improper sample	Redo the sampling. Make sure that the sampling is done in a correct way. See pages 17 –20 for more information.
Error E01	Calibration lost	Contact the CompoLab TM customer service department.
Error E02	Sensor read error	Repeat measurement with the same cuvette. If ‘error’ persists, contact the CompoLab TM customer service department.
Error E03	Self-check failed	In order to reset the self-check function, perform a “blank” measurement*. E03 may be displayed if a filled cuvette is left in the cuvette holder, or was removed too slowly.
Error E04	Lightsource too dark	Perform a “blank” measurement*. If error persists contact the CompoLab TM customer service department.
Error E05	Lightsource too bright	Perform a “blank” measurement*. If error persists contact the CompoLab TM customer service department.
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 (see chap. 5.5) and charge for a minimum of 4 hours. If recharging fails, contact the CompoLab TM customer service department.
** “blank” measurement: Press down the empty cuvette holder (without cuvette inserted) until you feel a “click”.*		

8 Results

The end of a measurement is signaled by a “beep”. The hemoglobin value will instantly be displayed by the CompoLab TM analyzer. When the checkmark ✓ is displayed, the hemoglobin value can be recorded without any additional calculations.

The hemoglobin value is displayed in g/dL by default. The result can also be displayed in g/L or mmol/L.

– Please contact the manufacturer if you require a change of the measuring units.

9 Limitations

The CompoLab TM analyzer is only to be used with CompoLab TM Cuvettes.

Neither the CompoLab TM Cuvettes nor the CompoLab TM analyzer may be used for any purposes other than those specified.

The CompoLab TM analyzer and the CompoLab TM Cuvettes are for in vitro diagnostic use only.

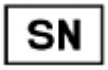
For further limitations of the procedure, see the CompoLab TM Cuvette package insert.

The CompoLab TM analyzer and the CompoLab TM Cuvettes may only be used by professionals.

10 Bibliography

1. CompoLab TM Cuvettes Instruction for use
2. NCLLS document H15-A3, Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard-Third Edition
3. Dacie and Lewis, Practical Haematology, 11th edition, 2012

11 Symbol used

	On Instrument/Accessories and in the Operating Manual
IPX2	Protection of electrical equipment against foreign objects, water and access
	Instrument's serial number
	The CE mark documents the conformance of the CompoLab TM with the essential requirements of the directive on in vitro diagnostic medical devices
REF	Reference number
	For in vitro diagnostic testing
	Dispose of the instrument in compliance with local regulations for the disposal of electronic equipment. Do not put in domestic waste!
	Read the supplied Operating Manual before starting
	Attention, see the instructions for use
	Manufacturer
	Class II equipment
	Biohazard
	Direct current

12 Notes

Fresenius Kabi AG

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Germany

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Web: www.fresenius-kabi.com

The soft copy of the Operational Manual (ENG/FRE) is available at www.fresenius-kabi.ca

La copie électronique du Manuel opérationnel (ENG / FRE) est disponible sur www.fresenius-kabi.ca