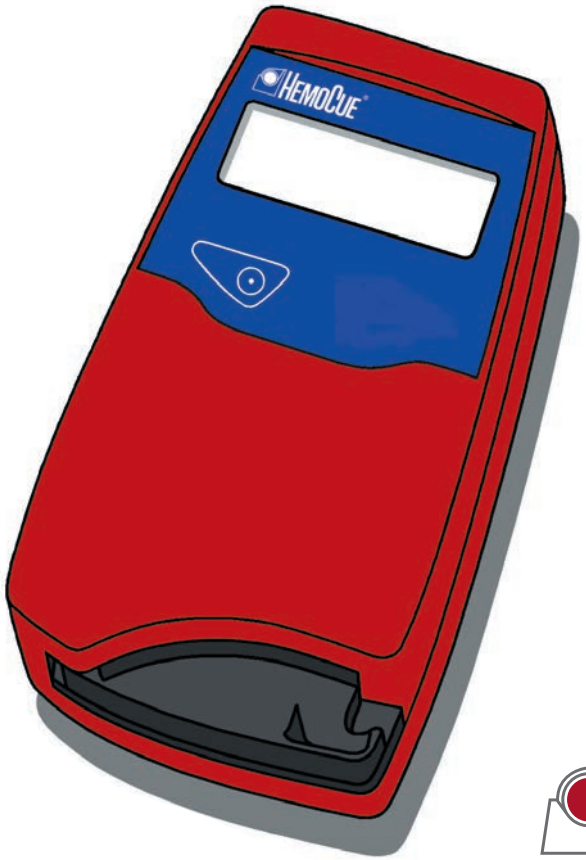
HemoCue Glucose 201 with Plasma Conversion

Operating Manual



HemoCue®

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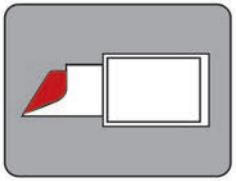
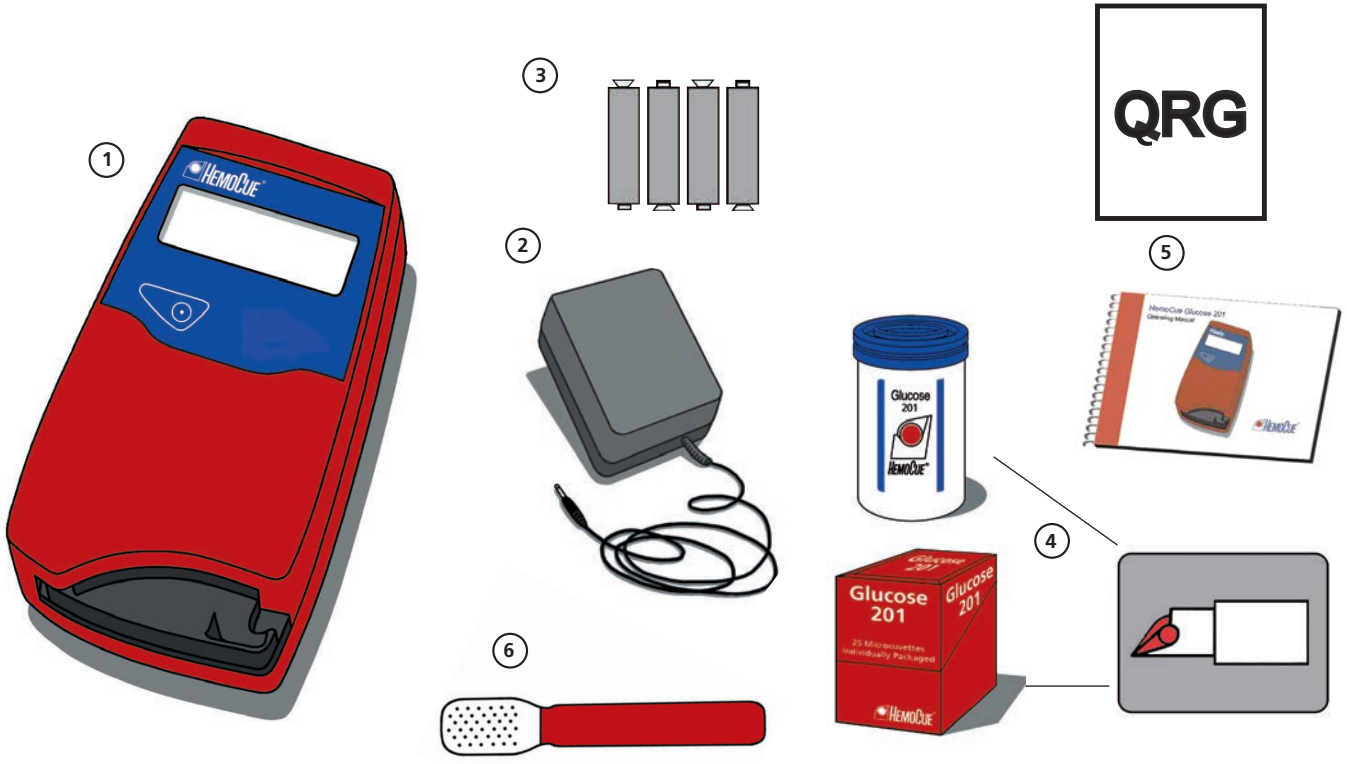
HemoCue Glucose 201 with Plasma Conversion *Operating Manual*

The HemoCue® Glucose 201 Analyzer with plasma conversion provides laboratory quality analysis of glucose in whole blood, easily, quickly and conveniently. Utilization of a conversion factor allows the measured whole blood result to be displayed as a plasma equivalent glucose value. Capillary, venous or arterial whole blood may be used. This manual provides the basic instructions for routine use as well as technical specifications. Further information may be obtained from HemoCue America or your local distributor.



All system components are designed and manufactured to provide maximum safety. Any other use of the system may impair the safety.

Components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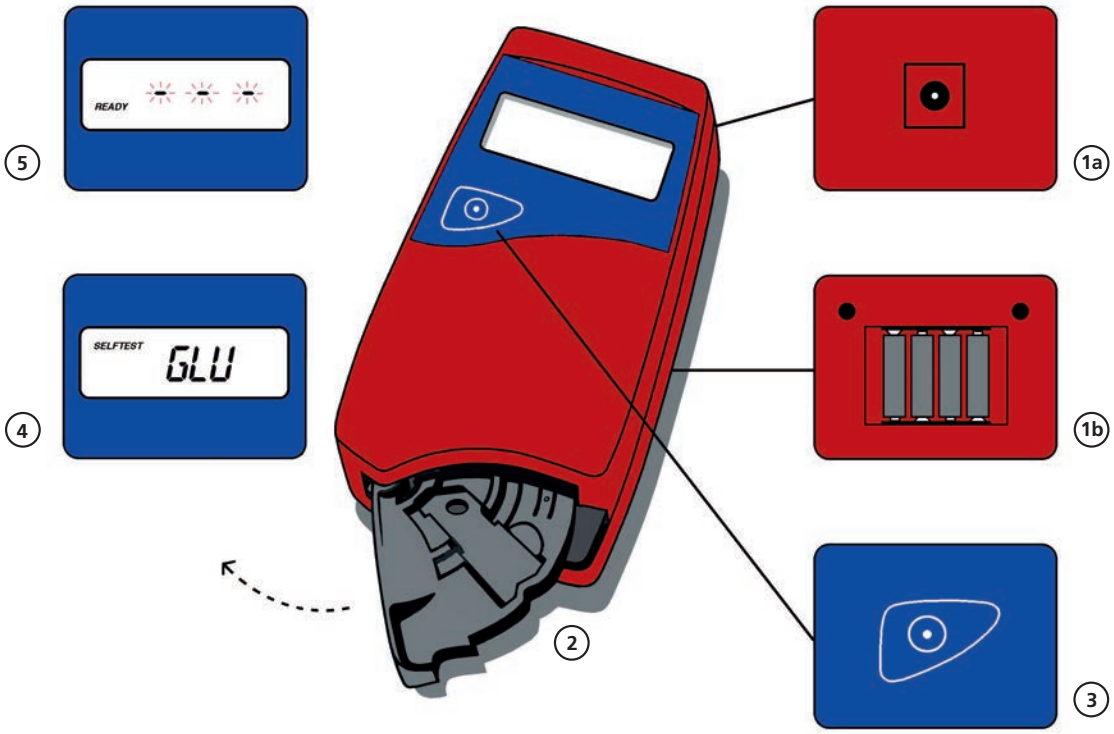
1. The HemoCue Glucose 201 Analyzer*
2. AC adapter.**
3. 4 type AA or R6 batteries, 1.5 V.***
4. A vial of HemoCue Glucose 201 Microcuvettes. Individually packaged HemoCue Glucose 201 Microcuvettes.***
5. HemoCue Glucose 201 Operating manual and Quick Reference Guide.
6. HemoCue Cleaner.

The HemoCue Glucose 201 Analyzer and power adapter are delivered in a carton. Open the carton on a stable surface and lift out the analyzer and the accessories. Consult local environmental authorities for proper disposal of batteries.

* Do not open the cover of the analyzer.
Note: The warranty is voided if the analyzer has been opened
** ⚠ Only use adapters as listed under Specifications.
*** Not included.

Start-up



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1a. If A/C power is available, plug the power adapter into the power inlet at the back of the analyzer.

1b. If A/C power is not available, install 4 type AA batteries in the battery compartment as shown.

2. Pull the cuvette holder out to the loading position.

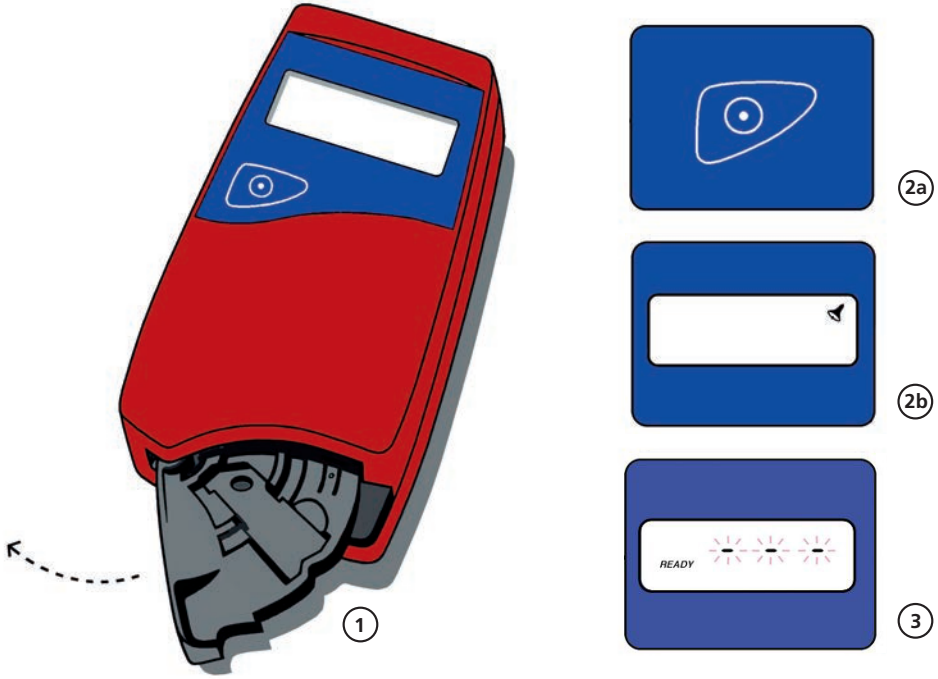
3. Press and hold the on/off button until the display is activated.

4. The display shows "SELFTEST" and the version number of the program, after which it will say "GLU". During the "SELFTEST" the analyzer will automatically verify the performance of the optronic unit.

5. After 15 seconds the display will show "READY" and three flashing dashes. This indicates that the HemoCue Glucose 201 Analyzer is ready for use.

To turn the analyzer off, press and hold the on/off button until the display is turned off.

Audio signal



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To activate an audio signal which will indicate when the result is displayed, follow the instructions below.

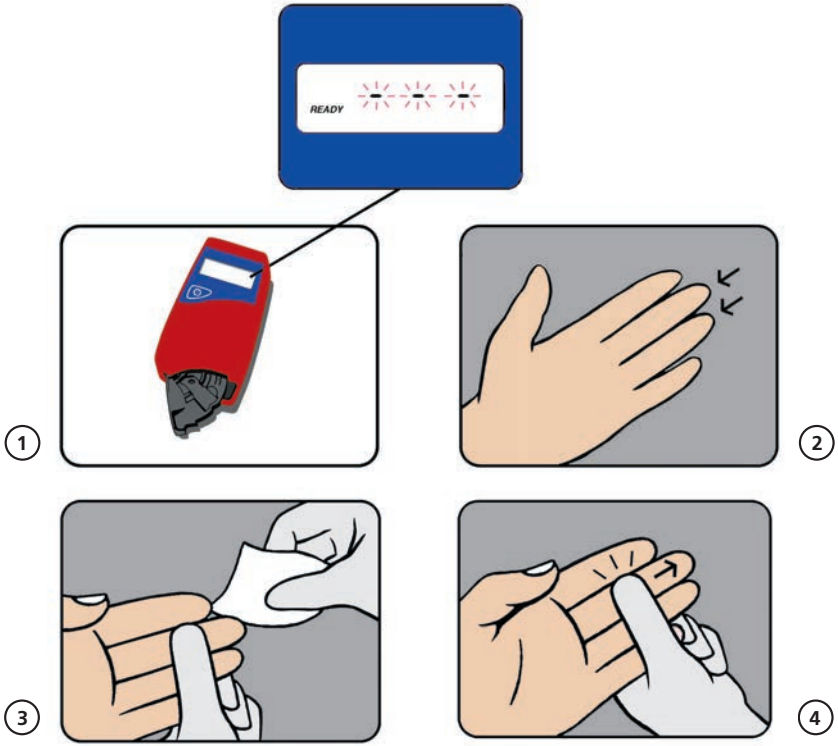
1. Check that the analyzer is turned off. The display should be blank. Pull the cuvette holder out to the loading position.

2a,b. Press and hold the on/off button until the display shows a bell in the upper right corner. The audio signal is now activated.

3. Wait until the analyzer display says "READY" before performing an analysis.

To turn off the audio signal follow steps 1–3 until the bell in the upper right corner disappears. The analyzer is delivered with the audio signal turned off.

Measuring Capillary blood



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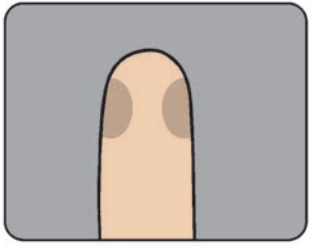
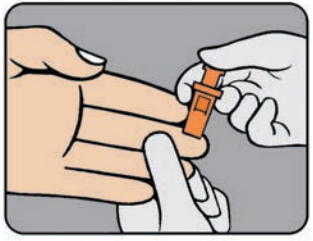
Note: In cases of severe hypotension or peripheral circulatory failure, glucose measurement from capillary samples may be misleading. In such circumstances it is recommended that venous or arterial whole blood be used.[1]

1. After start-up, the cuvette holder should be in the loading position. The display will show "READY" and three flashing dashes.
2. Make sure the patient's hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.
3. Clean with disinfectant and allow to dry or wipe off with a dry, lint free tissue.
4. Using your thumb, lightly press the finger from the top knuckle towards the tip. This stimulates the blood flow towards the sampling point.

5





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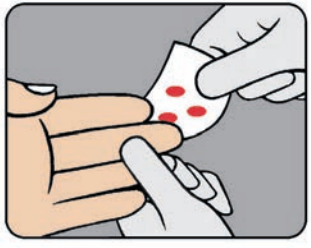

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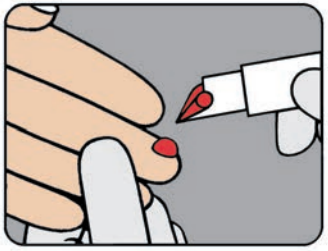
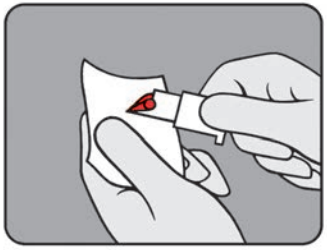
5. For best blood flow and least pain, sample at the side of the fingertip, not in the center.
6. While applying light pressure towards the fingertip, puncture the finger using the lancet.
7. Wipe away the first 2 or 3 drops of blood.
8. Re-apply light pressure towards the fingertip until another drop of blood appears.

9





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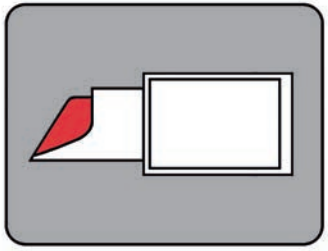

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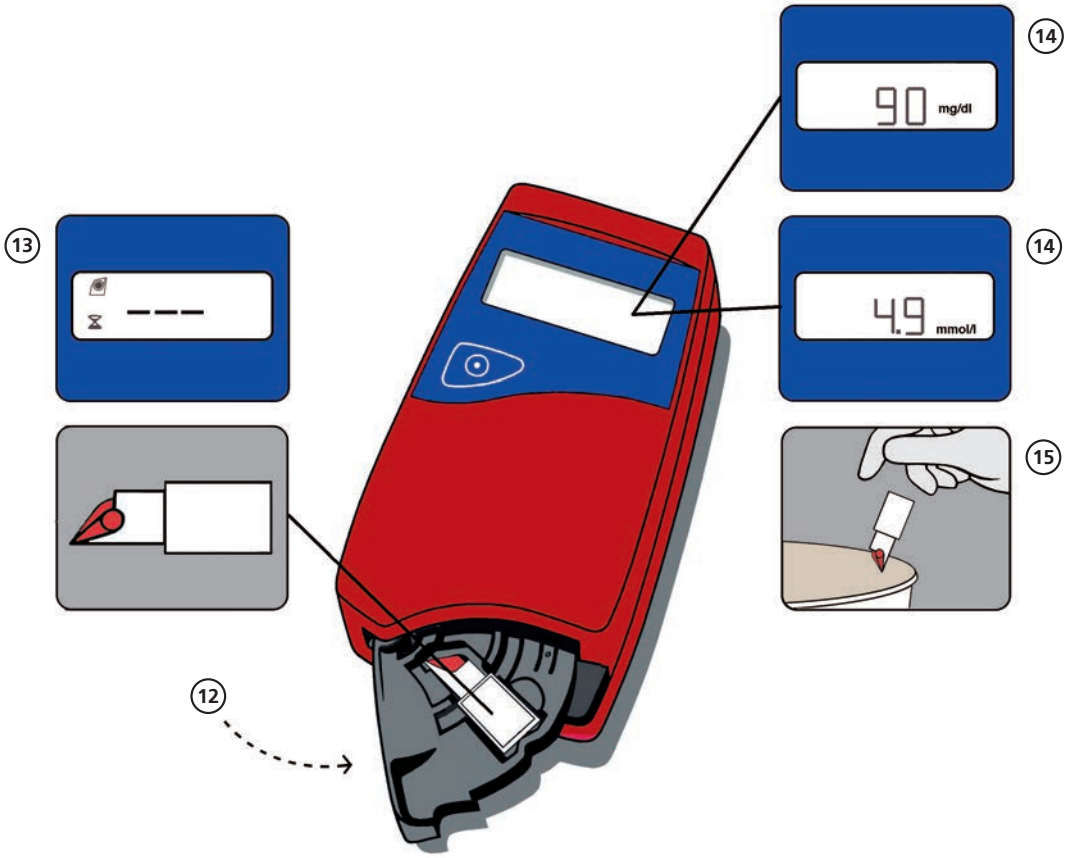
9. When the blood drop is large enough, fill the microcuvette in one continuous process. The microcuvette shall be completely filled. Do NOT refill!
10. Wipe off excess blood from the outer surface of the microcuvette with lint free tissue, being careful not to touch the open end of the microcuvette.
11. Look for air bubbles in the filled microcuvette. If present, take a new sample. Small bubbles around the edge can be ignored.

Note: If a second sample is to be taken from the same fingerstick, it is important that this should be done after the first sample has been read. Wipe away the remains of the first sample and take a second one from a new drop of blood.


13
12
14
90 mg/dl
14
4.9 mmol/l
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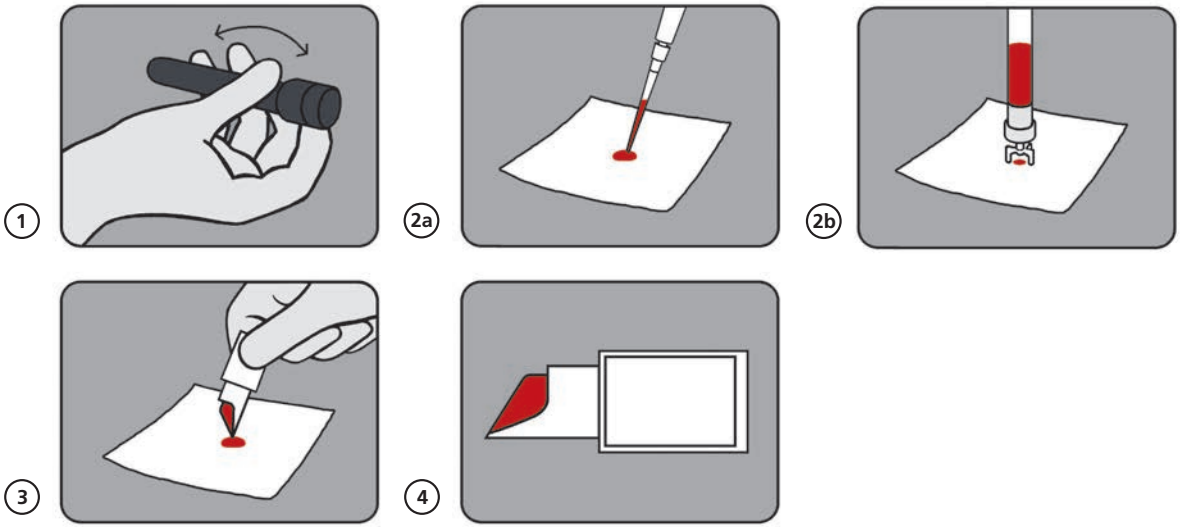
12. Place the microcuvette into the cuvette holder and start measurement as soon as possible but no later than 40 seconds after filling the microcuvette by gently pushing the cuvette holder to its measuring position.
13. During the measurement, "⧖" will be shown in the display.
14. After 40–240 seconds, the glucose value of the sample is displayed. The result will remain on the display as long as the cuvette holder is in the mesuring position. When operating on battery power, the analyzer will automatically turn off after approximately 10 minutes. The result can be retrieved by pressing the on/off button until the display is reactivated. DO NOT remeasure the microcuvette!
15. Although the reagents are present in the microcuvette in extremely low quantities, consult local environmental authorities for proper disposal. Always handle blood specimens with care, as they might be infectious.

Measuring Venous and arterial blood



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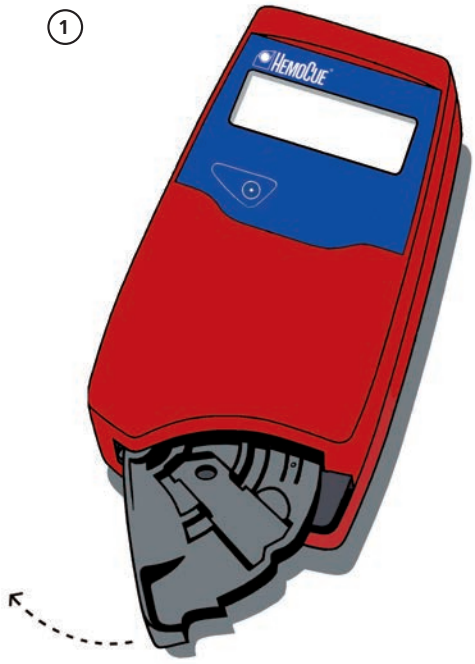
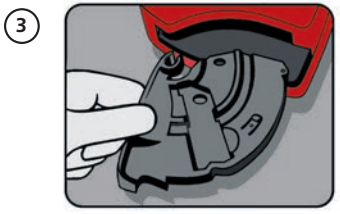
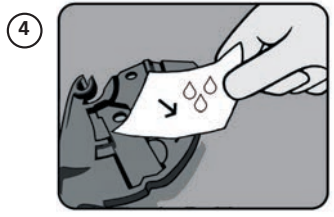
1. The blood should be well mixed prior to performing the measurement.
2a,b. Place a drop of blood onto a hydrophobic surface, e.g., a plastic film, using a pipette, a DIFF-Safe™ or directly from a syringe.
3. Fill the microcuvette in one continuous process. The microcuvette shall be completely filled. Do NOT refill! Wipe off excess blood from the outer surface of the microcuvette with lint free tissue, being careful not to touch the open end of the microcuvette.
4. Look for air bubbles in the filled microcuvette. If present, take a new sample. Small bubbles around the edge can be ignored.

Perform the analysis as per steps 12–15 on page 17.

Maintenance Daily maintenance







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The cuvette holder should be cleaned after each day of use.

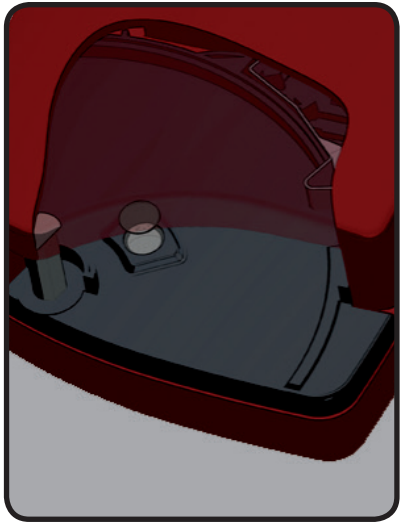
1. Pull the cuvette holder out to the loading position.
2. While pressing the catch, carefully rotate the cuvette holder sideways in open position as far as possible to the left.
3. Remove the cuvette holder from the analyzer, it will come off the stainless steel pin it rotates on.
4. Clean the cuvette holder with alcohol (20–70 %) or mild detergent.

Wait 15 minutes before replacing the cuvette holder and using the analyzer. Make sure the cuvette holder is dry before inserting.

The optical parts should be cleaned when directed to do so in the Troubleshooting Guide, see Maintenance Optical parts.

Maintenance Optical parts

5a



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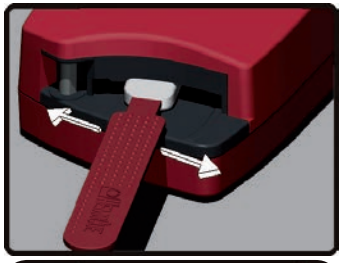

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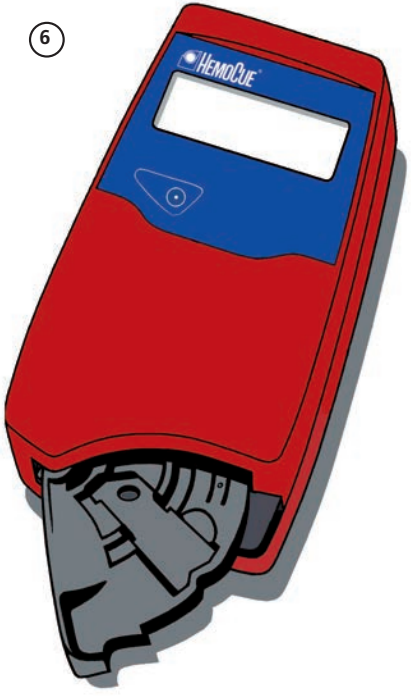

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Dirty optical parts may cause an error code. Follow step 1–3 under Daily maintenance and then clean optical parts as follows. Note! Make sure that the HemoCue® Cleaner reaches both upper and lower cover glasses, see pictures 5a and 5c.

5. With the cuvette holder removed from the analyzer push the Cleaner into the opening of the optic unit, as far in as possible. Move from side to side 5–10 times, see picture 5b and thereafter push in and pull out the Cleaner 5–10 times, cleaning the cover glasses, placed to the left, see picture 5c. If the Cleaner is stained, repeat with a new Cleaner.
6. Wait 15 minutes before replacing the cuvette holder and using the analyzer. Make sure the cuvette holder is dry before inserting.

The cover may be cleaned with alcohol (20–70 %) or mild detergent.

Note! As an alternative to the HemoCue® Cleaner, a lint free cotton swab, non-pretreated, moistened with alcohol (20–70 % without additive) or water may also be used. If a cotton swab is used make sure it is not too wet and not too dry. Use a dry swab to wipe away excess liquid in the optic house after cleaning with a moistened swab. To avoid scratches on the cover glasses, only the cotton part of the swab should come in contact with the cover glasses.

US Troubleshooting Guide

If you are unable to resolve the problem by following this Troubleshooting Guide, please call your HemoCue distributor or HemoCue America.
LED = Light Emitting Diode. Note! Do not open the cover of the analyzer. The warranty is voided if the analyzer has been opened.

Symptom	Explanation	Action
The analyzer shows "ERROR" and a digit code 900–930.	May be an occasional fault.	Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement. If the problem continues, see specific error code below.
900	No stable endpoint found within the time range. 1. The microcuvette is faulty. 2. The circuit board is out of order.	1a. Check expiration date for the microcuvettes. 1b. Take a new microcuvette and repeat the measurement. 2. The analyzer needs service. Call your distributor.
901	Light intensity for the compensating LED is too low. 1. The optronic unit is dirty. 2. The optronic unit is out of order.	1. Clean the optronic unit, as described in the Maintenance section. 2. The analyzer needs service. Call your distributor.
902	Light intensity for the measuring LED is too low. 1. The optronic unit is dirty. 2. The optronic unit is out of order.	1. Clean the optronic unit, as described in the Maintenance section. 2. The analyzer needs service. Call your distributor.
903	1. The optronic unit is out of order.	1. The analyzer needs service. Call your distributor.
905	1. Light intensity for one of the LED´s is too high.	1. The analyzer needs service. Call your distributor.
906	1. Unstable blank value. The analyzer might be cold.	1. Turn off the analyzer and allow it to reach room temperature. If the problem continues, the analyzer needs service. Call your distributor.
907	1. The battery power is too low.	1a. The batteries need to be replaced. Turn off the analyzer and replace the batteries, 4 type AA. 1b. Use the power adapter.
908	The absorbance is too high. 1. Light blocking item in the cuvette holder.	1a. Check that the analyzer and microcuvettes are used according to the HemoCue Glucose 201 operating manual and instruction for use. 1b. The analyzer needs service. Call your distributor.
910	Seen during all phases of use, and is a fatal error. A read or write operation to the EEPROM did not succeed. 1. The EEPROM memory is out of order.	1a. Turn off the analyzer and turn it on again after 30 seconds and retry testing. 1b. The analyzer needs service. Call your distributor.

Symptom	Explanation	Action
911	Seen during start up and is a fatal error. 1. The analyzer cannot detect a valid EEPROM memory configuration.	1a. Turn off the analyzer and turn it on again after 30 seconds and retry testing. 1b. The analyzer needs service. Call your distributor.
913	Seen during start up and is a fatal error. Self test of RAM memory failed. 1. The electronics are out of order.	1. The analyzer needs service. Call your distributor.
925	Seen at start up and is a fatal error. Calibration checksum is not valid. 1. The analyzer needs calibration.	1. The analyzer needs service. Call your distributor.
929	1. Communication error during internal hardware test.	1. The analyzer needs service. Call your distributor.
930	1. The electronic “SELFTEST” failed.	1a. Turn off the analyzer and allow it to reach room temperature. 1b. If the problem continues, the analyzer needs service. Call your distributor.
HHH	1. Measured value exceeds 444 mg/dL (24.6 mmol/L).	1. Check the expiration date of the microcuvettes. 2. Remeasure sample with fresh microcuvette.
No characters on the display.	1. The analyzer is not receiving power. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order.	1a. Check that the power adapter is connected to the power source. 1b. Check that the power adapter is securely connected to the analyzer. 1c. Check that the adapter wire is not damaged. 2. Turn off the analyzer and replace the batteries, 4 type AA. 3. The analyzer needs service. Call your distributor.
The display gives erroneous characters.	1. The display is out of order. 2. The microprocessor is out of order.	1. The analyzer needs service. Call your distributor. 2. The analyzer needs service. Call your distributor.

Symptom	Explanation	Action
The display shows "  "	1. The batteries need to be replaced. 2. If using power adapter, the adapter or circuit board is out of order.	1. Turn the analyzer off and replace the batteries, 4 type AA. 2a. Check that the power adaptor is properly connected and working. 2b. The analyzer needs service. Call your distributor.
The display does not switch from "SELFTEST" to "READY" or from "READY" to "  " (measuring).	1. The magnet in the cuvette holder may be missing. 2. The magnetic sensor is out of order.	1. The analyzer needs service. Call your distributor. 2. The analyzer needs service. Call your distributor.
Measurements on control materials out of range – either too HIGH or too LOW.	1. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 2. The optical eye of the microcuvette is contaminated. 3. The control has not been mixed well and/or is not at room temperature. 4. Air bubbles are present in the microcuvette. 5. The optronic unit is dirty. 6. The control is not suitable for use with the HemoCue Glucose 201 system. 7. The calibration of the analyzer has been changed. 8. The controls are beyond their expiration dates or have been improperly stored.	1. Check the expiration date and the storage conditions of the microcuvettes. 2. Remeasure the sample with a new microcuvette. 3. Make sure that the control is mixed well and at room temperature. 4. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 5. Clean the optronic unit, as described in the Maintenance section. 6. Only use controls intended for the HemoCue Glucose 201 system recommended by HemoCue. 7. The analyzer needs service. Call your distributor. 8. Check the expiration date and the storage conditions of the control. Take a new microcuvette and repeat the measurement.
Measurements on patient samples are higher or lower than anticipated.	1. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 2. The optical eye of the microcuvette is contaminated. 3. Air bubbles are present in the microcuvette. 4. The optronic unit is dirty. 5. The calibration of the analyzer has been changed.	1. Check the expiration date and the storage conditions of the microcuvettes. 2. Remeasure the sample with a new microcuvette. 3. Check the microcuvette for air bubbles. Remeasure the sample with a new microcuvette. 4. Clean the optronic unit, as described in the Maintenance section. 5. The analyzer needs service. Call your distributor.

US Specifications

General

The HemoCue Glucose 201 with plasma conversion is a system for the determination of the total amount of glucose in whole blood. The measured whole blood value is converted to a plasma equivalent glucose result which is displayed on the analyzer. The system consists of a specially designed analyzer with specially designed microcuvettes containing dried reagents. The microcuvette serves as pipette, reaction vessel and as a measuring microcuvette. No dilution is required. The glucose measurement takes place in the analyzer, which follows the progress of the reaction and presents the result only when the end point of the reaction has been reached. The system is factory calibrated and needs no further calibration. The HemoCue glucose reference system is traceable to an Isotope Dilution Gas Chromatography - Mass Spectrometry (ID GC-MS) method.

Intended use

Quantitative determination of glucose in whole blood using a specially designed analyzer, the HemoCue Glucose 201 with plasma conversion. The quantitative determination of the instant blood glucose concentration in circulation supplements the clinical evidence in the diagnosis and treatment of patients with diabetes as well as monitoring of neonatal blood glucose levels. The HemoCue Glucose 201 Analyzer with plasma conversion multiplies the measured whole blood glucose value by a factor of 1.11[2] and displays a plasma equivalent glucose result. HemoCue Glucose 201 Microcuvettes are for In Vitro Diagnostic use only, and are only to be used with the HemoCue Glucose 201 Analyzer. For professional use only.

Theory

The chemistry method utilized by the HemoCue Glucose 201 Microcuvette is a modified glucose dehydrogenase method described by Banauch et al.[3] A chromogen compound is added to the reagents according to the principle outlined by Bergmeyer[4] with saponin used for hemolyzing the erythrocytes. The absorbance is measured at two wavelengths (667 and 840 nm) to compensate for turbidity.

Reagents

Saponin, NAD, MTT and NaF
Enzyme mix: Glucose Dehydrogenase, Diaphorase and Mutarotase

Specimen collection and preparation

Capillary, venous or arterial whole blood may be used. The anticoagulants EDTA or sodium heparin and the glycolysis inhibitors sodium fluoride, sodium oxalate or potassium oxalate shall be used. Glycolysis is a major concern in all glucose measurements. To minimize the effect of glycolysis, measure the blood sample as soon as possible after taking the sample. Samples of blood collected in vials with recommended anticoagulants should be analyzed within 30 minutes. If the blood has been kept in a refrigerator, it must be allowed to reach room temperature 64 – 86 °F (18 – 30 °C) before analysis. Mix all anticoagulated samples thoroughly on a mechanical mixer for at least 2 minutes or invert the tube 8–10 times by hand before measurement. Alternatively follow local recommendations. In cases of severe hypotension and peripheral circulatory failure, glucose measurement from capillary samples may be misleading. In such circumstances we recommend that an analysis be made of the glucose level using venous or arterial whole blood.

Storage and handling of the HemoCue Glucose 201 Microcuvettes

Storage for microcuvettes kept in a vial

Store unopened HemoCue Glucose 201 Microcuvettes below 46 °F (8° C) (incl. storage in a freezer). Note, microcuvettes stored in a freezer must be allowed to reach room temperature (approx. 30 minutes) before analysis. Microcuvettes kept in an opened vial are stable for 30 days when stored in a refrigerator at 35–46 °F (2–8 °C). After breaking the seal, the vial can be stored at room temperature at 59–86 °F (15–30 °C) for up to 3 days. Close the lid immediately after microcuvettes are removed from the vial.

Storage for individually packaged microcuvettes

Store unopened HemoCue Glucose 201 Microcuvettes below 46 °F (8° C) (incl. storage in a freezer). Note, microcuvettes stored in a freezer must be allowed to reach room temperature (approx. 30 minutes) before analysis. The individually packaged microcuvettes can be stored at room temperature at 59–86 °F (15–30 °C) for up to 3 days.

HemoCue Glucose 201 Analyzer

The analyzer can be stored at 32 – 122 °F (0 – 50 °C). The HemoCue Glucose 201 system is designed for use at room temperature 64 – 86 °F (18 – 30 °C). The analyzer should not be operated at high (i.e. > 90 % non-condensing) humidity.

Quality Control

The HemoCue Glucose 201 Analyzer has an internal quality control, the ”selftest”. Every time the analyzer is turned on, it will automatically verify the performance of the optronic unit of the analyzer. This test is performed every second hour if the analyzer is left turned on. The HemoCue Glucose 201 system must be verified on the day of testing using commercially available controls, recommended by HemoCue. Contact HemoCue America, Technical Support, for advice.

Results

The measuring range is 0–444 mg/dL (24.6 mmol/L). Results above 444 mg/dL (24.6 mmol/L) will be displayed as HHH and should be confirmed with another laboratory method. To establish HemoCue glucose reference values and an intervention level, neonatal blood samples should be evaluated against a suitable laboratory method taking into consideration the difference between whole blood and plasma reference values. Any results with HemoCue Glucose Systems suggesting clinical intervention in the hyperglycemic range on pre-term neonates (<37 weeks), should be verified against a suitable laboratory reference method. For specific performance characteristics, see the package insert for the HemoCue Glucose 201 Microcuvettes.

Limitations

HemoCue Glucose 201 Microcuvettes are for In Vitro Diagnostic use only. The HemoCue Glucose 201 Analyzer is only to be used together with HemoCue Glucose 201 Microcuvettes. For additional limitations of the procedure, see the package insert for the HemoCue Glucose 201 Microcuvettes. The HemoCue Glucose 201 Analyzer with plasma conversion multiplies the obtained whole blood glucose value by a factor and displays a plasma equivalent glucose result. Since this factor is based on the relationship between plasma and whole blood at normal hematocrit, care should be taken when evaluating results in situations where the hematocrit may be extreme.

Expected values

Fasting plasma blood glucose, adults 74–106 mg/dL (4.5-5.9 mmol/L).[5]
For diagnosis of diabetes mellitus, follow local recommendations or use the following value according to WHO:
Fasting plasma glucose, capillary or venous ≥126 mg/dL (≥7.0 mmol/L).[6]

Technical Specifications

Dimension: 3.35x6.30x1.69 inches (85x160x43 mm)
Weight: 0.77 pounds (350 g, batteries included)
4 batteries type AA, 1.5 V
Only use adapters as listed under “AC Adapters”.
Pollution degree: 2

Overvoltage category: II

Equipment not suitable for use in the presence of flammable mixtures. The instrument is tested according to IEC 61010-1, Second edition: 2001 and EN 61010-1: 2001, IEC/EN 61010-2-101: 2002, UL 61010-1: 2004, CAN/CSA-C22.2 no.61010-1: 2004, IEC 61326-1: 2005 and EN 61326-1: 2006, IEC 61326-2-6, First edition: 2005 and EN 61326-2-6: 2006, IEC 60601-1-2, Third edition: 2007 and EN 60601-1-2: 2007 and complies with the IVD Medical Device Directive 98/79/EC.

The instrument is made for continous mode.

AC Adapters

Adaptor HemoCue HCA01 or Friwo FW7333/SM12 can also be used, input 100V~ - 240V~/50-60 Hz/200mA (<500mA, HCA01).

Essential Performance

The essential performance is quantitative determination of glucose in capillary, venous or arterial whole blood.

Warranty

The analyzer carries a 24-month warranty from the day of receipt. After the warranty period, service/repair is carried out at fixed prices. Any other use of the system than recommended by the manufacturer will void the warranty. For technical difficulties or repair contact HemoCue America.

Service and Disposal

The analyzer should be cleaned and disinfected as recommended under Maintenance prior to service or disposal. Consult your local environmental authorities for proper disposal.

Spare parts

The following spare parts are available:

Power adapter

Battery Lid

Cuvette holder

Recommended separation distance between Portable and mobile RF communications equipment and HemoCue® Glucose 201 Analyzer.

The HemoCue systems are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of HemoCue systems can help prevent electromagnetic interference by maintaining a minimum distance between portable and RF communications equipment (transmitters) and HemoCue systems as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distances (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where (P) is the maximum output power rating of the transmitter in watts (W) according to transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequencyrange applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – Electromagnetic immunity

The HemoCue systems are intended for use in the electromagnetic environment specified below. The customer or user of the HemoCue systems should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	<5 %U (>95 % dip in U) for a 0.5 cycle 40 %U (60 % dip in U) for 5 cycles 70 %U (30 % dip in U) for 25 cycles <5 %U (>95 % dip in U) for 5 seconds For explanation of U see NOTE 1.	<5 %U (>95 % dip in U) for a 0.5 cycle 40 %U (60 % dip in U) for 5 cycles 70 %U (30 % dip in U) for 25 cycles <5 %U (>95 % dip in U) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HemoCue systems requires continued operation during power mains interruptions, it is recommended that the HemoCue systems be powered from an uninterruptible power supply or a battery.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz See NOTE 2 and NOTE 3.	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the HemoCue systems, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where (P) is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (a), should be less than the compliance level in each frequency range (b). Interference may occur in the vicinity of equipment marked with the following symbol. 

NOTE 1 U is the a.c. mains voltage prior to application of the test level.

NOTE 2 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 3 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HemoCue systems are used exceeds the applicable RF compliance level above, the HemoCue systems should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the systems.
b) Over the frequency range 150 KHz to 80 Mhz, field strength should be less than 3 V/m.

Technical specifications (EMC-RF)

Use only cables with the following specification:

USB shielded maximum 2 m

Serial shielded maximum 1.5 m

Guidance and manufacturer´s declaration – electromagnetic emissions The HemoCue systems are intended for use in the electromagnetic environment specified below. The customer or the user of the HemoCue systems should assure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions	Group 1	The HemoCue systems uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment
RF emissions	Class B	The HemoCue systems are suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

NOTE 1 It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

NOTE 2 It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended

Symbols used


Caution


Consult instructions for use


CE mark


Class II equipment


Only valid within the European Community. Indicates separate collection for waste of electrical and electronic equipment.


Serial port


Temperature limitation


To maintain safety use only adapter marked HCA01


DC inlet


Efficiency level


Relative humidity, non-condensing

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