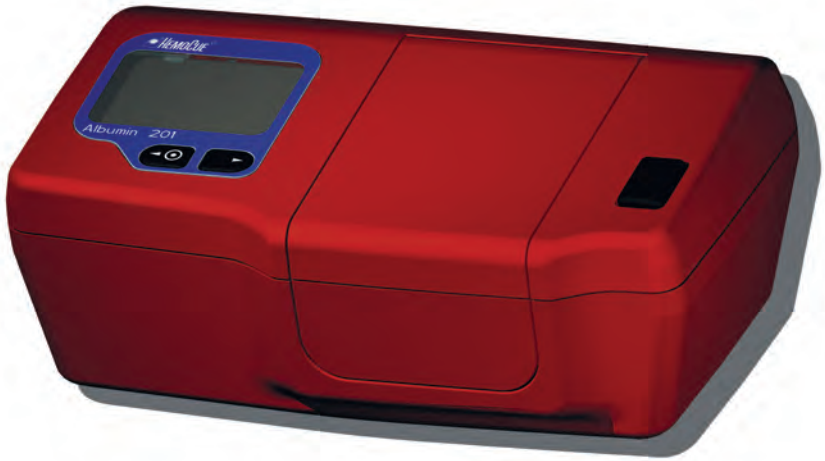
HemoCue® Albumin 201

Operating Manual



HemoCue®

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HemoCue® Albumin 201 system Operating Manual

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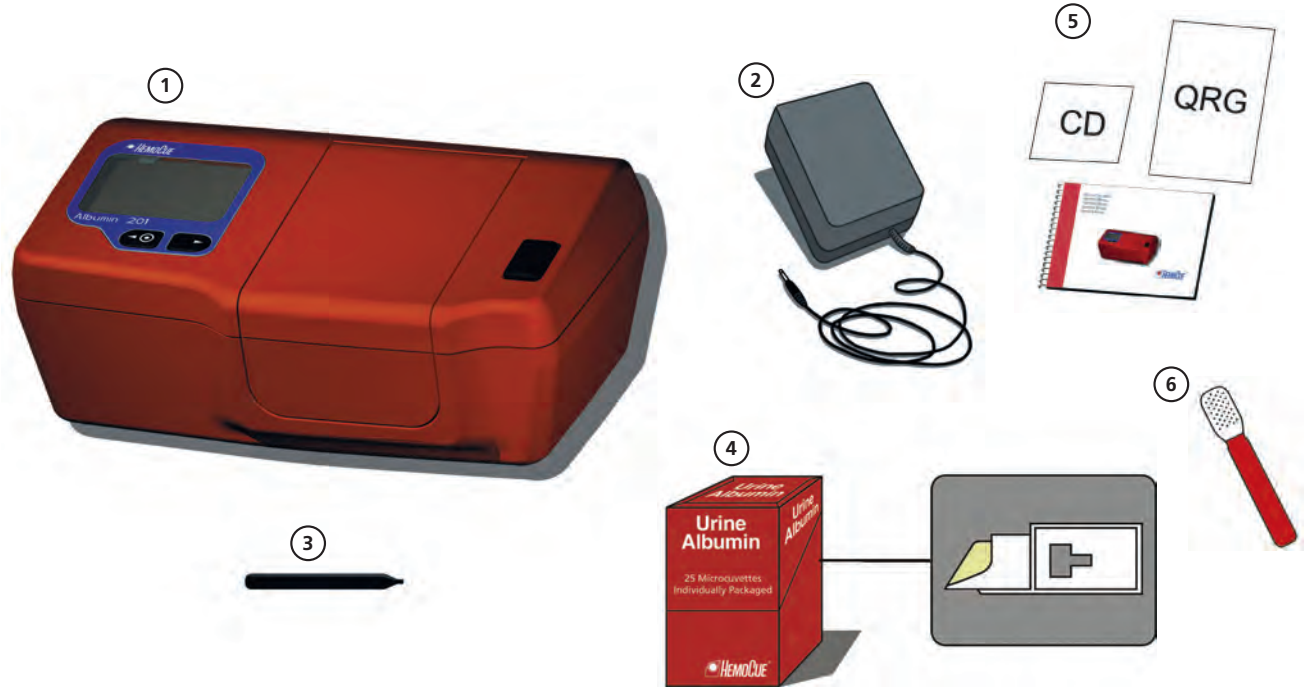
The HemoCue® Albumin 201 system consists of the HemoCue Albumin 201 Analyzer and HemoCue Urine Albumin Microcuvettes.
The system provides rapid, simple and reliable quantitative determination of albumin in urine with results that are precise and accurate.
The system can be used for the purpose of screening, for diagnosis, monitoring and supporting the clinical evidence in the treatment of microalbuminuria.
This manual provides the basic instructions for routine use as well as technical specifications.
Additional information may be obtained from HemoCue America.
The HemoCue Albumin 201 System is classified as Waived under the CLIA Guidelines and can be used by all laboratories holding a CLIA certificate of waiver. Please note that the complete test procedure should be read before performing the test. If the laboratory modifies the HemoCue Albumin 201 test procedure, the test no longer meets the requirements for waived categorization. A modified test is considered to be highly complex and is subject to all applicable CLIA requirements. For information on how to obtain a CLIA Waiver certificate, please refer to CMS CLIA program.

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

Components


1
Albumin 201
2
5
CD
QRG
3
4
Urine Albumin
25 Microcuvettes Individually Packaged
6

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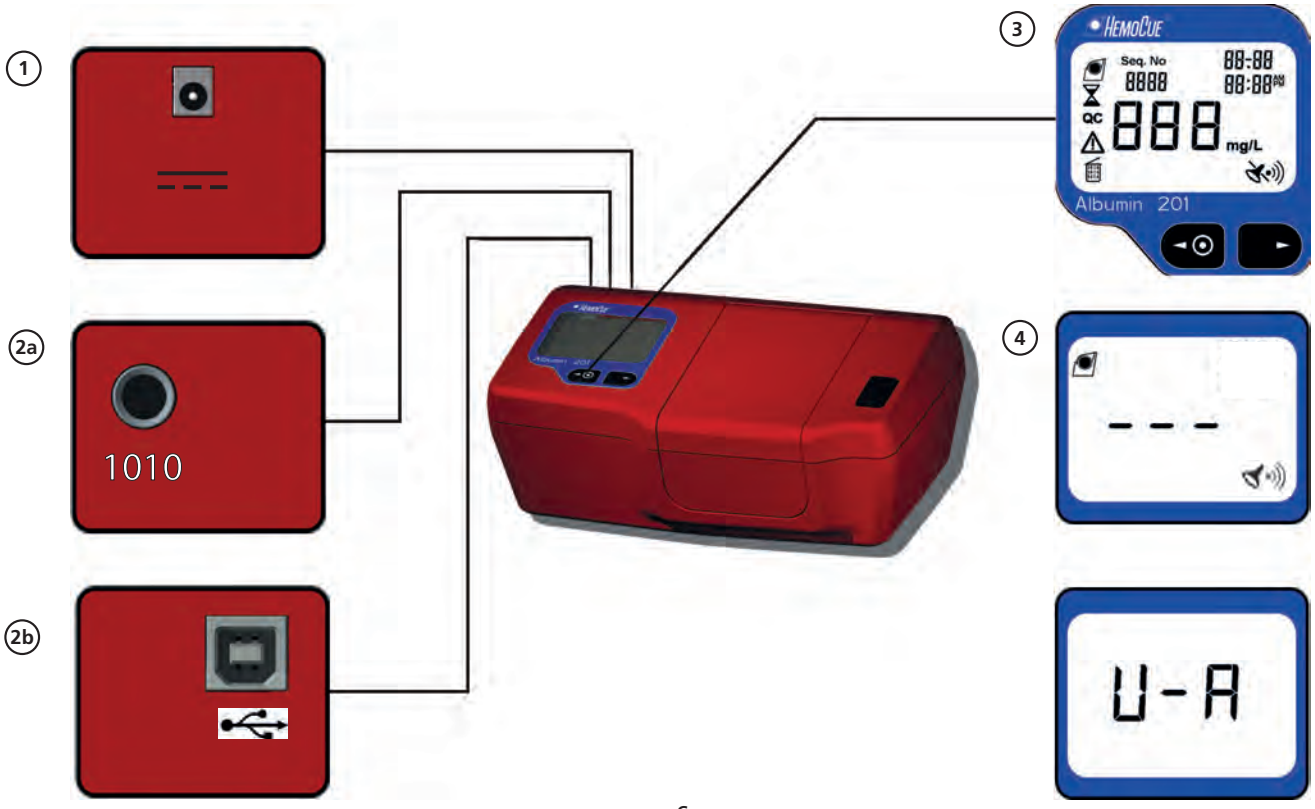
1. The HemoCue Albumin 201 Analyzer*.
2. Power Adapter**.
3. Device for removing the cuvette holder.
4. HemoCue Urine Albumin Microcuvettes***.
5. HemoCue Albumin 201 Operating Manual, Quick Reference Guide and Instruction CD.
6. HemoCue Cleaner.

The HemoCue Albumin 201 Analyzer and a power adapter are delivered in a carton. Open the carton on a stable surface and lift out the analyzer and the accessories.

* Do not open the cover of the analyzer. Note: The warranty will be voided if the cover of the analyzer has been opened.
** Only use adapters, as listed under specifications.
*** Not included.
For infomation about HemoCue Urine Albumin Microcuvettes please contact HemoCue America.

Start-up


1
2a
1010
2b
3
HEMOCUE
Seq. No
8888
88:88
88:88 PM
QC
888
mg/L
Albumin 201
4
U-A

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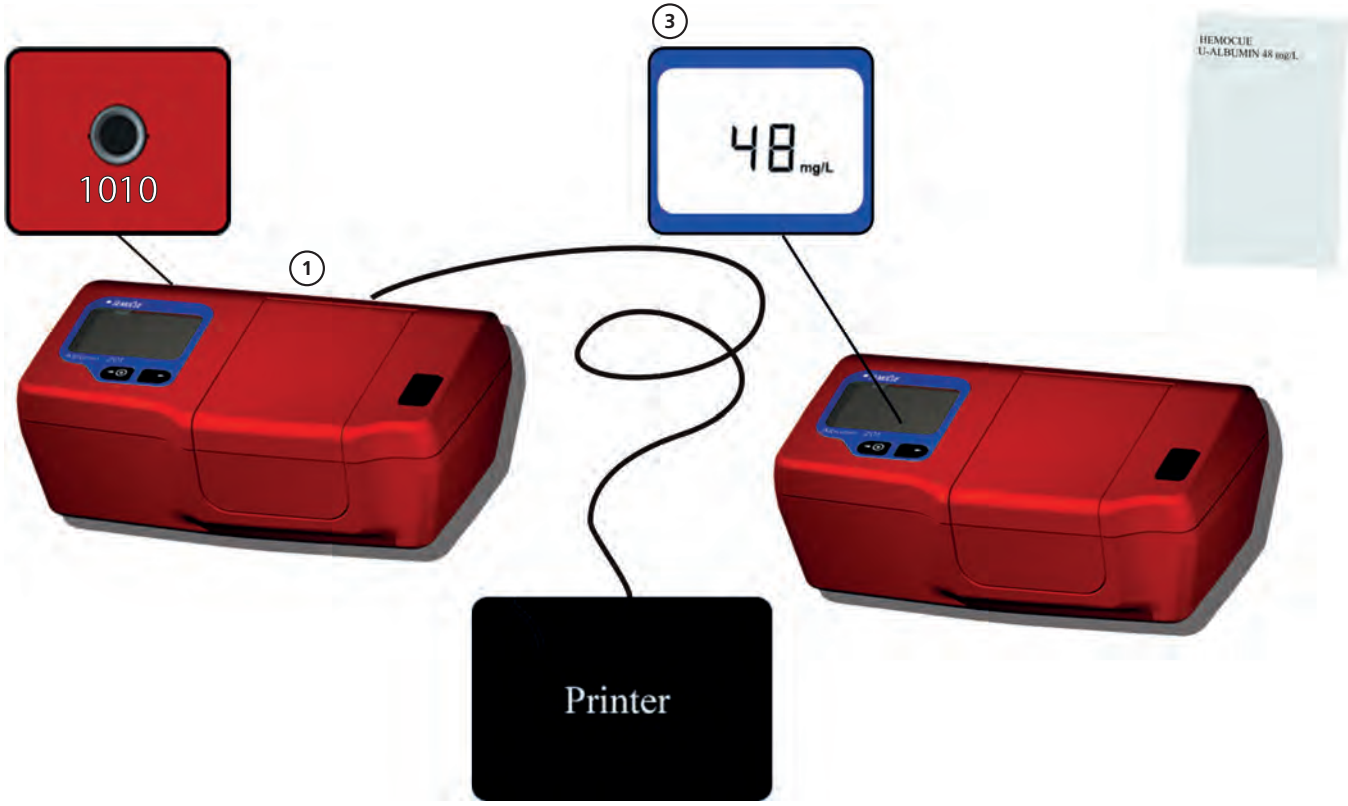
1. Attach the power adapter to the "POWER INLET" at the back of the analyzer. Make sure that the lid on top of the analyzer is closed.
2. a. Serial port. The analyzer can be connected to a printer (for further information, see Set up Printer function).
2. b. USB port. (Used for PC-connection – only outside US)
3. Press and hold the left button until the display is activated (all symbols appear on the display). The display shows the version number of the program, audio signal and the HemoCue symbol. During this time the analyzer will automatically verify the performance of the optical unit.
4. After this the display will show three flashing dashes. This indicates that the HemoCue Albumin 201 Analyzer is ready for use.

To turn the analyzer off, press and hold the left button until the display reads OFF and then goes blank. Disconnect the analyzer from the power source by removing the power adapter from the outlet.

Note! Make sure that the lid is closed. If the lid is open for more than one minute, the display will show "U-A". Once the lid is closed, the analyzer will perform an electronic "self test".

Set-up Printer function



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The analyzer can be on or off when connecting the printer to the analyzer. A printer can be used to print out the current result immediately after completion of the measurement. Previously obtained results cannot be printed.

1. Connect the cable* to the analyzer and printer*.
2. Perform the analysis by following the steps 1-6 in Measurement.
3. When the result is shown on the display, the printer will automatically print the result.

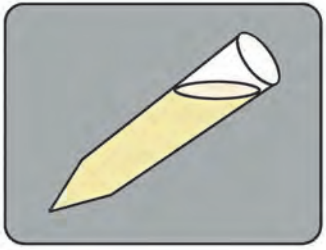
Note! Only use ASCII printers. Contact HemoCue America for information.

*Not included.

The following comport settings are used:

- Baudrite 9600
- Databits 8
- Parity None
- Stopbits 1
- Flowcontrol None

Specimen collection U-Albumin – Spot urine, morning urine



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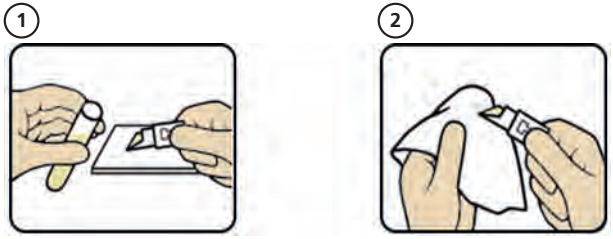
Specimen collection
Spot urine, preferably the first morning urine may be used.

Specimen collection for U-Albumin, spot urine
Collect the first morning urine. The analysis is performed as described below. The result is read directly from the instrument in mg/L.

Measurement



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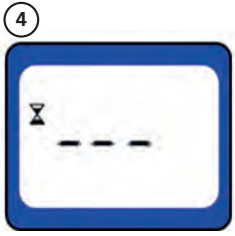
Open the microcuvette package and carefully remove the cuvette.
Pipette a drop of urine onto a hydrophobic surface (for example, Parafilm).
It is also possible to fill the cuvette directly from the sample, if it is not to be used for any other analysis.

1. Hold the cuvette opposite the filling end. The filling end is brought into contact with the urine sample. Allow the cavity of the cuvette to fill completely in one step. Do NOT refill the cuvette! Always avoid contamination of the outside of the cuvette.
2. When completely filled, carefully wipe off the excess urine from the outside of the cuvette with a clean lint free wipe. Make sure that no sample is drawn out of the cuvette during this procedure. The filled cuvette should be visually inspected to check that the cuvette is properly filled, i.e. completely filled up to the edge and without air bubbles in the optical eye. If air bubbles are seen in the optical eye of a filled cuvette, discard the cuvette and fill another cuvette from a second drop of specimen.

Measurement



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3. Open the lid and place the filled cuvette into the cuvette holder (3a). It is important that the cuvette "snaps" properly into the cuvette holder (3b). Start measurement as soon as possible but no later than 30 seconds after filling the microcuvette by gently closing the lid (3c).
4. During measurement the hour glass ⌛ is displayed with three fixed dashes.
5. Within 90 seconds, the result is displayed in mg/L. The result will remain on the display until the lid is opened.
   Measurements below 7 mg/L are displayed as "LLL".
   Measurements above 150 mg/L are displayed as "HHH".
   If the display shows an error code, an error has occurred. See the Troubleshooting Guide. Do not remeasure the cuvette. Note that the measurement is not completed until the steps in paragraph 8 have been performed and the display shows three flashing dashes.

Measurement

6a

6b

6c

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6. a, b, c. Open the lid and discard the cuvette. Close the lid and wait until three flashing dashes are shown in the display.
7. Although the reagents are present in the cuvette in extremely low quantities, consult local environmental authorities for proper disposal.Always handle urine with care, as it might be infectious.
   When the measurements for the day have been completed, switch off the analyzer with the ON/OFF button.

Maintenance

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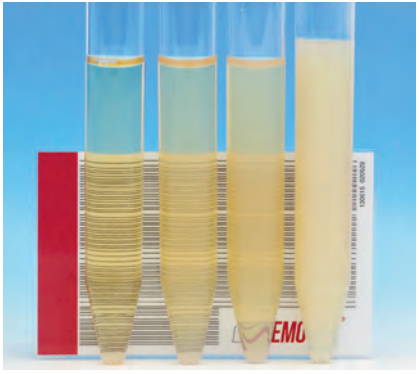
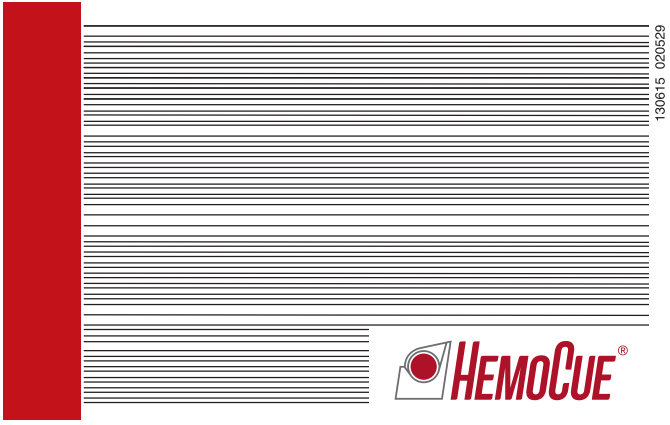
The cuvette holder should be cleaned after each day of use. The cover glasses of the optical unit should be cleaned when directed to do so in the Troubleshooting Guide.
Make sure that the analyzer is switched off and that the display is blank.
Open the lid.

1. The cuvette holder is released by pressing the area marked with arrows using the device included with the system.
2. Press the tab downwards and draw the cuvette holder towards you until it becomes detached. Use a mild detergent or alcohol to clean the cuvette holder.
3. The cover glasses of the optical unit, both beneath and above the cuvette holder area, may be cleaned using the HemoCue Cleaner*. If a HemoCue Cleaner is not available, a cotton tipped swab moistured with water or alcohol without additives may be used.
4. Wait 15 minutes before replacing the cuvette holder.
   Use alcohol or mild soap detergent for cleaning the outer surface of the instrument.

* One HemoCue Cleaner is included with the analyzer. Contact HemoCue America to order more.

Turbidity scale





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The turbidity scale provides guidance as to whether or not the sample may be used for analysis.

– Hold the turbidity scale directly behind the sample.
– If the stripes are well separated, proceed with the analysis.
– If the stripes are not well separated, do not proceed with the analysis.

Note! This scale should serve only as a guide – if there is any doubt, do not proceed with the analysis.

US Troubleshooting guide

If you are unable to resolve a problem by following this "Troubleshooting Guide", please contact HemoCue America. The analyzer has no serviceable parts. Note: Do not open the cover of the analyzer. The warranty will be voided if the cover of the analyzer has been opened.

Symptom	Explanation	Action
Instrument shows "ERROR" and a digit code E00-E51.	May be an occasional fault.	Turn off the instrument and turn it on again after 30 seconds. Take a new cuvette and repeat the measurement. If the problem continues, see specific error code below.
E00	No end point has been reached within the specified timeframe. 1. The cuvette is damaged. 2. Printed circuit board is out of order.	Check expiration date of the cuvettes. 1. Take a new cuvette and repeat the measurement. 2. The instrument needs service. Contact HemoCue America.
E02	Light intensity of the measuring diode is too low. 1. A cuvette remains in the measuring position. 2. Dirt on the optical unit. 3. The optical unit is out of order. 4. Wrong power adapter is used.	1. Remove cuvette. 2. Clean the cuvette holder and the cover glasses of the optical unit as described in the Maintenance section. 3. The instrument needs service. Contact HemoCue America. 4. Check that the power adapter is recommended by HemoCue.
E03	1. Disturbance on the AC power supply. 2. The optical unit is out of order.	1. Use a different wall outlet. 2. The instrument needs service. Contact HemoCue America.
E04	1. The dark current measured on the detector is too low.	1. The instrument needs service. Contact HemoCue America.
E05	1. Light intensity of the measuring diode is too high.	1. The instrument needs service. Contact HemoCue America.
E06	1. Unstable blank value. The instrument may be too cold.	1a. Check that the instrument and cuvettes are being used according to the HemoCue Albumin 201 system Operating Manual and instructions for use. 1b. The instrument needs service. Contact HemoCue America.

Symptom	Explanation	Action
E08	The absorbance is too high. 1. Light blocking item in the cuvette holder.	1a. Check that the instrument and cuvettes are being used according to the HemoCue Albumin 201 system Operating Manual and instructions for use. 1b. The instrument needs service. Contact HemoCue America.
E09	1. This is caused by high absorbance-values due to immunoinhibition.	1. The albumin concentration is too high to be quantified by the HemoCue Albumin 201 Analyzer.
E10	This can happen during use and is an error that prevents further measurements. A read or write operation to the EEPROM did not succeed. 1. The EEPROM is out of order.	1a. Turn off the instrument and turn it on again after 30 seconds. Take a new cuvette and repeat the measurement. 1b. The instrument needs service. Contact HemoCue America.
E13	1. This can be seen during use and is an error that prevents further measurements. A read or write operation to the RAM did not succeed.	1. The instrument needs service. Contact HemoCue America.
E21	1. Testing a configuration area in EEPROM returned as an erroneous checksum.	1. Turn off the instrument and turn it on again after 30 seconds. If the problem continues, the instrument needs service. Contact HemoCue America.
E23	Data Error Real Time Clock. Real Time Clock backup battery has been drained.	The backup battery needs to be replaced. Contact HemoCue America.
E25	Can be seen when starting the instrument and is an error that prevents further measurements. The checksum of the calibration area is not valid. 1. The instrument needs to be calibrated.	1. The instrument needs service. Contact HemoCue America.
E30	1. Fault or dirt in the optic or electronic units.	1a. Turn off the analyzer and clean the optic unit using the HemoCue Cleaner. 1b. The analyzer needs service. Contact HemoCue America.

Symptom	Explanation	Action
E50	1. The stepper motor causing the cuvette holder to vibrate is out of order. 2. Wrong power adapter is used.	1. The instrument needs service. Contact HemoCue America. 2. Check that the power adapter is recommended by HemoCue.
E51	1. The cuvette holder is in the wrong position when measuring. 2. Wrong power adapter is used.	1. The instrument needs service. Contact HemoCue America. 2. Check that the power adapter is recommended by HemoCue.
LLL	1. Measuring value <7 mg/L.	1. The result is below the measuring range.
HHH	1. Measuring value >150 mg/L.	1. The result is above the measuring range.
No characters in the display.	1. The instrument is not receiving power. 2. The display is out of order.	1a. Check that the power adapter is connected to the AC supply. 1b. Check that the the power adapter is suitable for the instrument. 1c. Check that the cable to the power adapter is not damaged. 1d. Check that the the power adapter is suitable for the power supply. 2. The instrument needs service. Contact HemoCue America.
The display gives erroneous characters.	1. The display is out of order. 2. The micro processor is out of order.	1. The instrument needs service. Contact HemoCue America. 2. The instrument needs service. Contact HemoCue America.

Symptom	Explanation	Action
Too high or too low values for controls or patient samples compared to expected values.	1. The cuvettes are damaged, beyond their expiration date or have been improperly stored. 2. The optical eye of the cuvette is contaminated. 3. The control has not been properly mixed and/or has not reached room temperature. 4. Air bubbles are present in the cuvette. 5. The optical unit is contaminated. 6a. The control used is not suitable for the HemoCue Albumin system. 6b. The control is beyond its expiration date or has been stored incorrectly. 7. Incompletely filled cuvette. 8. The measurement needs to be started no later than 30 seconds after filling the microcuvette. 9. Use of frozen specimen/control.	1. Check the expiration date and the storage conditions of the cuvettes. 2. Measure the control/sample with a new cuvette. 3. Make sure that the control is properly mixed and that it has reached room temperature. 4. Check the cuvette for air bubbles. Remeasure the control/sample with a new cuvette. 5. Clean the optical unit as instructed under "Maintenance". 6a. If a quality control test is to be performed, only use controls recommended by HemoCue, see relevant package insert for more information. 6b. Check the expiration date and the storage conditions of the control. Repeat the measurement with a new control/sample. 7. Measure the control/sample with a new cuvette. It is important that the cuvette "snaps" properly into the cuvette holder. 8. Measure the control/sample with a new cuvette. 9. The system is intended to be used with fresh specimen. Use of frozen specimen should be avoided as this may affect results.

US Specifications

General
The HemoCue Albumin 201 system is intended to be used for the determination of low levels of albumin in urine, microalbuminuria. The system consists of a specially designed analyzer, HemoCue Albumin 201 Analyzer, and specially designed microcuvettes, HemoCue Urine Albumin Microcuvettes, containing dried reagent. The cuvettes serve as pipette, reaction vessel and as a measuring cuvette. No dilution is required. The result of the albumin measurement is shown on the display when the reaction has been completed. The system is factory calibrated against a turbidimetric method with traceability to CRM 470 (Certified Reference Material) and needs no further calibration.

Intended purpose
The quantitative, rapid, turbidimetric immunoassay of albumin in human urine using a specially designed system, the HemoCue Albumin 201 system. The system is designed to be used for the quantitative determination of low levels of albumin in urine at the point-of-care for the purpose of screening for, diagnosing, monitoring and to supplement the clinical evidence in the treatment of microalbuminuria. The system is designed for testing using spot samples or timed collections. A quantitative result is obtained within 90 seconds. HemoCue Urine Albumin Microcuvettes are for *In Vitro* diagnostic use only. The HemoCue Albumin 201 Analyzer is only to be used with HemoCue Urine Albumin Microcuvettes.

Theory
A specific rabbit anti-human albumin antibody (polyclonal) forms an agglutinate with the human albumin in the sample. The agglutination is enhanced by polymers. The turbidity of the agglutinates, once formed, is measured photometrically at 610 nm.

Reagents
11 % w/w rabbit anti-human albumin antibody (polyclonal), 35 % w/w PEG, 18 % w/w Tris /HCl-buffer, 2 % w/w polymer and 33 % w/w non-reactive ingredients.

Specimen collection and preparation
Collect the first voided morning urine. Morning urine after rest is recommended since muscle activity influences the albumin excretion rate. Spot samples during the day may be used, but higher results can be expected. Note: The system is intended to be used with fresh specimen. Use of frozen specimen should be avoided as this may affect results.

Storage and environmental requirements

HemoCue Urine Albumin Microcuvettes
Store the HemoCue Urine Albumin Microcuvettes in their package in a refrigerator, at 35 – 46 °F, (2– 8 °C). The individually packaged cuvettes can be stored at room temperature for up to 3 days. Do not store the cuvettes in the freezer. Unused HemoCue Urine Albumin Microcuvettes should be kept in the original package but once a individual package is opened, the cuvette must be used immediately or discarded.

HemoCue Albumin 201 Analyzer
The analyzer can be stored and transported in temperatures between 32–122°F (0 –50 °C). The operating temperature is 59 – 86°F, (15-30°C). The analyzer should be allowed to equilibrate at room temperature prior to use. The analyzer should not be used in extremes of humidity (>80 % relative moisture up to 86°F (30°C)).

Quality Control
• The system can be verified by measuring a commercially available urine albumin control. Note that local, state, or other accreditating agencies may require additional

quality control testing. If the control result is out of range, please refer to the Operating Manual for corrective action. Do not run patient samples unless the quality control results are in the expected range. For CLIA waived laboratories, HemoCue recommends the control material Eurotrol AlbuTrol to be used on the days of testing, for each new shipment of cuvettes and new lots.

• The HemoCue Albumin 201 Analyzer has an internal electronic self test. Every time the analyzer is turned on it will automatically perform the self test. The self test verifies the performance of the optical unit of the analyzer.

Measuring range

7 –150 mg/L. The system is linear between 7-150 mg/L. Results below 7 mg/L are displayed as "LLL". Results above 150 mg/L are displayed as "HHH".

Limitations of the procedure

The HemoCue Urine Albumin Microcuvettes are for *In Vitro* Diagnostic use only. The HemoCue Albumin 201 Analyzer is only to be used with HemoCue Urine Albumin Microcuvettes. For further limitations, see the package insert of the HemoCue Urine Albumin Microcuvettes. For specific performance characteristics, see the package insert for HemoCue Urine Albumin Microcuvettes.

Expected values

According to the literature, the following results are indicators for normal and pathological urine albumin results respectively.

U-Albumin Spot sample (morning urine)	U-Albumin/overnight Urine collected overnight	Interpretation
<20 mg/L	<20 µg/min	normal
20–200 mg/L	20–200 µg/min	microalbuminuria
>200 mg/L	>200 µg/min	albuminuria

Measurements from spot urine during the day may give slightly higher results due to physical activity. In these circumstances, normal values are less than 30 mg/L[1].

Technical Specifications

Dimensions: 6.89x2.56x4.53 inches
Weight: 0.77 lbs

Power Adapter

Type: HCA01
Input: 100-240 V
Output: 12 V DC/0.45 A
Pollution Degree: 2
Over voltage category: II
Atmospheric pressure: 700hPa to 1060 hPa
The instrument is made for continuous mode.

Choose power adapter according to the technical specifications above. The analyzer is CE marked.
Attention! See instructions for use. Equipment not suitable for use in the presence of flammable mixtures.
The analyzer is tested according to EN 60601-1 and IEC 60601-1-2 and complies with the IVD Directive 98/79/EC.

Country	Type	Input
USA	FW7333M/12 HCA01	100-240 V

Warranty
The analyzer has a 24-month warranty from the date of receiving the instrument. After the expiration date of the warranty, maintenance and repairs are offered at a fixed price. For technical difficulties or repair contact HemoCue America, Technical Support. Any other use of the system than recommended by the manufacturer will void the warranty.

Spare parts – Accessories
The following spare parts are available:

- Power adapter
- Device for removing the cuvette holder.
- Cuvette holder

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

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.


Temperature limitation


To maintain safety use only adapter marked HCA01


Efficiency Level


DC Inlet


USB port

1010 Serial port

References

1. Rowe, D.J.F., Dawnay, A., Watts, G.F.: Microalbuminuria in diabetes mellitus: review and recommendations for the measurement of albumin in urine. Ann. Clin. Biochem. 27, 297– 312 (1990).
2. Savage, S., Jeffers, B., Estacio, R.O., Schrier, R.W.: Urinary Albumin Excretion as a Predictor of Diabetic Retinopathy, Neuropathy and Cardiovascular Disease in NIDDM. Diabetes Care, v 19:11; 1243-1248 (1996).

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Warning

The device is tested according to standard IEC 60601-1 and IEC 60601 and is found to comply with the standard. Despite this compliance it is impossible to predict any possible effects by other near by standing instruments or the possible impact of electromagnetic radiance. This is the reason we need to inform users of this analyzer that disturbance from other equipment might affect the performance of the analyzer. Should you note that this is the fact, please contact HemoCue America.

The HemoCue Albumin 201 system is intended for use in the electromagnetic environment specified in Technical specifications. The customer or user of the HemoCue Albumin 201 system should assure that it is used in such an environment. The HemoCue Albumin 201 system 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.

The HemoCue Albumin 201 system is 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.

Accessories connected to analog and digital ports must be certified according to IEC 60601-1. All configurations must comply to the IEC 60601-1-1. Further connection to in or output are considered ”configuring a medical system”, and must comply with IEC 60601-1-1.

For further information, please see Technical Specifications or contact HemoCue America.

Recommended separation distance between Portable and mobile RF communications equipment and HemoCue Albumin 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 3V/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 80MHz and 800MHz, 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	

CE
IVD

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