

Document History:

Title: HemoCue®Hb 201 Analyzer
(includes Hb 201 and Hb 201 DM) **Site(s):** All Sites

Document #:	140-170-03	Version #:	08
Section:	Hematology	Subsection:	POCT Laboratory

Approved by: <i>(approval on file)</i>	Dr. Ping Sun	Date:	17-JUN-2025
		Effective Date:	17-JUL-2025

Details of Recent Revision:

- Clarifications throughout all processes including SOP order of information for clarity.
- Incorporation of validation/verification processes for new or replacement/moved analyzers.
- Addition of previous Job Aids into this document as Appendices for quick processing reference guides.
- Updates to Appendix 1 System set up to streamline device operation.
- Addition that hydrophobic surface must be one of three listed items only.

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HemoCue® Hb 201 DM Analyzer (for Hb 201, refer to Appendix 5)

Purpose: To provide instructions for using the HemoCue Hb 201 and DM 201 System for Hemoglobin testing.

Policy: This unit can be used in the lab or at the bedside. The system is indicated for use for quantitation determination of total Hemoglobin in capillary, venous or arterial blood.

Principle: The system consists of an analyzer with microcuvettes containing dried reagents. The microcuvette acts as a pipette, reaction chamber and as a measuring device. No dilution is required. The hemoglobin measurement occurs in the analyzer, which follows the progress of the reaction until a steady state is reached. The system is factory calibrated against the hemoglobin cyanide (HiCN) method (the international reference method) and thus requires no further calibration.

The reaction in the microcuvette is a modified azidemethemoglobin reaction. The red blood cell membranes are disintegrated by sodium deoxycholate, releasing the hemoglobin. Sodium nitrate converts the hemoglobin iron from the ferrous to the ferric state to form methemoglobin which then combines with azide to form azidemethemoglobin.

Materials:

Reagents:	Supplies:	Equipment:
<ul style="list-style-type: none"> Eurotrol Hemotrol Low, Normal and High Controls 	<ul style="list-style-type: none"> HemoCue Hemoglobin Cleaner HemoCue Hb Microcuvettes Lancet Pipette or Diff Safe Gauze/Lint-free wipes Alcohol wipes Hydrophobic surface (glass slide, Bloodbloc or parafilm only) 	<ul style="list-style-type: none"> HemoCue 201 or DM 201 Primary Docking Station

Special Safety Precautions:

As per Routine Practices (Standard Precautions). Mandatory use of gloves.

Sample:

- Capillary
- Venous (EDTA)
- Arterial (EDTA)

Storage and Handling:

Microcuvettes:

- Must be used prior to the expiration date printed on each package.
- Store at room temperature (15-30°C).
- Do **NOT** refrigerate.
- Expiration date of the microcuvette in a sealed vial is printed on the vial.
- Once seal is broken on a vial, stable for three (3) months.
- Keep vial container closed at all times.
- Must be filled with blood three (3) minutes of opening wrapper.
- The microcuvette accepts 10 uL of sample.

Individual Packages of Cuvettes:

- Store at room temperature (15-30°C).
- Do **NOT** refrigerate.
- Stable until expiry date printed on each individual package

HemoCue® Analyzer:

- Store at 0-50°C.
- Operating temperature is 15-30°C.
- Allow unit to reach room temperature before use.
- Should not be used at high humidity (>90%).
- Keep unit away from portable and RF communication equipment (transmitters)

Measuring Range:

- Measuring range: 0 – 256 g/L

Instrument Set-Up:

Follow Appendix 1.

These requirements are to ensure that the new or replacement analyzers are functioning as expected. Samples used for validation must be less than 24 hours old.

All Data to be logged in workbook F170-140-03C – select appropriate tab.

Validation:

Context	Validation requirements before use
Brand New instrument that has never been validated	<p><u>Accuracy Study</u> Eurotrol QC- 3 levels – 10 times each</p> <p><u>Comparison Study</u> Using samples previously analyzed at referral lab for comparison 2 x samples with Hb <80g/L 3 x samples with Hb 80-120g/L 3 x samples with Hb 120-160g/L 2 x samples with Hb >160g/L Results within +/- 7% from reference Lab analyzer</p> <p><u>Precision Study</u> Test the Hemoglobin from one CBC patient sample ten (10) times</p> <p>Approval by Hematology Discipline</p>
Replacement instrument (Previously validated/moved)	<p><u>Accuracy Study</u> Eurotrol QC – 3 levels -1 time each</p> <p><u>Comparison Study</u> Using samples previously analyzed at referral lab for comparison 1 x sample <80g/L 1 x sample 120-150g/L 1 x sample >150g/L Results within +/- 7% from reference Lab analyzer</p> <p><u>Precision Study</u> Test the Hemoglobin from one CBC patient sample three (3) times</p>

Once complete, workbook is sent via e-mail to POCT@sharedhealthmb.ca for final approval.

Quality Control:

- Eurotrol Hemotrol is an assayed hemoglobin control with a known concentration.
- To be performed prior to testing the first patient sample of the day or at least one (1) times per week if testing not performed daily.
- 10 µL of control material is used per run.
- Each level contains 1 mL of purified bovine hemolysate.
- Store unopened in the refrigerator at 2-8°C until expiration date.
- After vial is opened, stability is one (1) month if properly capped and stored at 2-30°C.
- Monthly comparison of a previously processed hemoglobin result from HemoCue and main analyzer from a nearby laboratory must be performed. The CBC sample must be less than 24 hours post collection at the time that is processed on the HemoCue. The comparison results must be within 7%.
- New lot numbers and new shipment same lot number of QC or cuvettes require the QC to be run once and documented on the QC log prior to testing patient samples.
- QC values must be within package insert ranges.

External Proficiency Testing (EPT):

- Each site should subscribe to an external proficiency testing program
- Samples must be tested according to instructions included with each kit, and treated the same as all patient samples.

Self-Test:

Analyzer has an internal quality control or “self-test”. When 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 unit is left on.

If:	Then:
“Self-test” passes,	Screen will display HemoCue® symbol and states “Please Wait – Self-Testing”. The unit is ready to perform testing when it changes to the main screen that requests the operator ID be entered.
“Self-Test” fails,	An error code will appear on the screen.

Accessioning: Delphic Sites only:

- Register sample in Delphic. Test code is **IHGB** (POCT HBG)
- Document LIS sample number onto test requisition.

If test is performed by non-Shared Health staff, order test code POCT (Test performed by non-laboratory personnel).

ICBC is printed prior to patient testing to record results and staff details for 2-year retention (if site procedure and with printout as applicable).

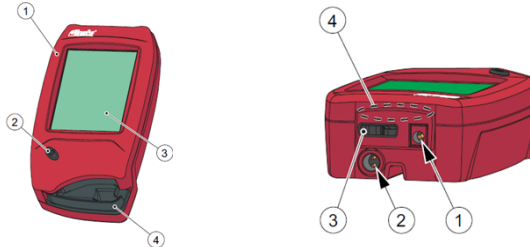
Non- Shared Health/Non-Delphic Sites only:

Using Requisition/Report F100-140-04, fill out all required sections including:

- Patient demographics.
- Ordering practitioner name and location.
- Collection date and time.
- Test ordered and resulted.

Analyzer Overview: Front Panel:

The analyzer (1) is started when the ON/OFF button (2) is pressed. The screen images will be visible on the display (3). See picture below. All navigation and information handling are performed by pressing the appropriate touch buttons on the display. A test measurement is performed using a cuvette filled with a sample material which is then placed in the cuvette holder (4) and inserted into the analyzer. Once testing is complete, the analyzer can be turned OFF by pressing the ON/OFF button.

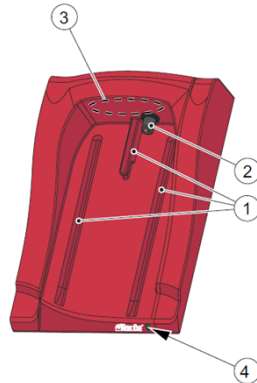


Back Panel:

The following items are found on the back panel:

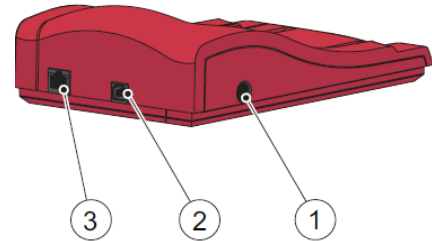
- Power inlet (1) for power adapter.
- Power and USB signal inlet (2) for connector to docking station.
- Built in barcode scanner (3), Infrared transmitter/receiver (4).
- **DO NOT** cover or block the items on the back panel as doing so could result in malfunction.

Primary Docking Station Overview:



On the back panel are the following items:

- Power inlet (1) for power adaption
- USB port (2) for setting up primary docking station



The docking station consists of the following items:

- Tracks (1) for the analyzer
- Power and USB signal outlet (2) which connects to the corresponding connector on the analyzer.
- LED (4)
- Receiver (3) for data transmission to/from analyzer (N/A at this time)

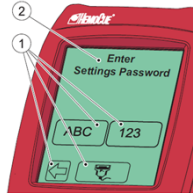
DO NOT cover or block the items on the back panel or a malfunction may occur.

Always slide the analyzer into and out of the docking station using the tracks and ensure the unit is fully inserted. Never try to lift the analyzer out of the docking station or press the unit downwards into the station as these actions may damage the casing and power outlets on both equipment

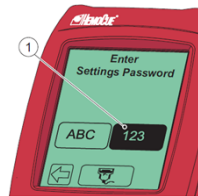
Operating the Display:

Display Buttons:

The buttons (1) appearing on the display (2) activate specific functions symbolized by the image on the button. Do not use any sharp objects on the buttons, only the fingertip to prevent damaging the buttons.

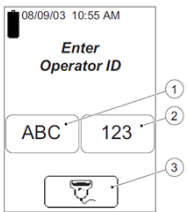
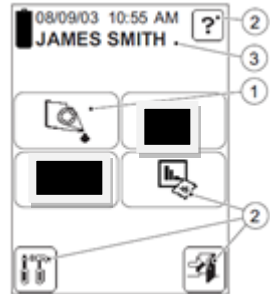



When a button (1) is pressed, it will be highlighted as long as it is kept pressed. When it is released, the function is **activated**. An audio signal will sound if previously activated.



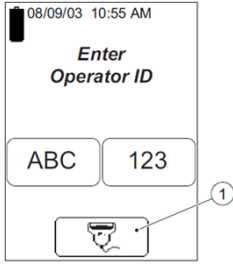
To cancel a function, continue pressing while moving the fingertip over an area without buttons. No buttons will be highlighted when the finger is released. The first button choice will be ignored and no action will be activated.

Procedure A: Operating the Analyzer


Step:	Action:
1	Turn on the analyzer. The Start image will be displayed including the analyzer type, software version and serial #.
2	The cuvette holder must be in the loading position for the analyzer to perform a self-test. No function can be activated for approximately 20 seconds during the self-test.
3	The Operator ID can be entered via the alphabetical (1) or numeric (2) mode buttons or by the barcode scanner (3). <div style="text-align: center;">  </div>
4	The main menu screen will appear which includes all necessary procedure buttons to initiate certain functions. <div style="text-align: center;">  </div>

	(1) QC and Test Patient Button (2) Help Button – For data review, settings and logging out. Data review button, the analyzer stores 4000 patient/QC test results can go back to at any time (3) Operator ID or blank depending on settings activated (4)  Buttons not used
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Barcode Scanner:

Step:	Action:
1	The barcode scanner (1) can be used for entering letters, digits and special characters. 
2	Use the scanner on the back panel of the analyzer. Scanning range is 4-12 inches from the scanner. Hold the barcode scanner button to initiate scanning and the information from the barcode appears on the display when the analyzer identifies the barcode. The information remains displayed as long as the barcode scanner button is pressed. To cancel reading, move the fingertip to an area without any buttons before releasing. The information will be stored in the analyzer, but not displayed on the screen.

Procedure B: Measuring control material.

Step:	Action:
1	Allow the vial to stand for 15 minutes at room temperature (15 – 30°C) if coming from the refrigerator.
2	Control material should be gently mixed well prior to performing any testing (8 – 10 times) by hand inversion. Note: The microcuvette must be filled with QC material within three (3) minutes of opening the wrapper.
3	In the main menu, press QC & Patient Test Button. 
4	Place a drop of control material onto a hydrophobic surface. Fill the microcuvette in one continuous motion. Do NOT refill! Wipe off any excess control material from the microcuvette with a clean lint-free wipe, ensuring not to touch the open end of the microcuvette.
5	If bubbles are present in the microcuvette, discard and fill a new microcuvette from a second drop of control material. Small bubbles around the edge can be ignored.

6	Place the filled microcuvette into the cuvette holder.
7	Gently slide the cuvette holder to the measuring position and start measurement as soon as possible, but no later than ten (10) minutes after filling the microcuvette.
9	During the measurement phase, “⌚” (hour glass) and three fixed dashes will be seen on the screen.
10	After 15 – 60 seconds, the hemoglobin value will be displayed. This result will remain on the screen as long as the cuvette holder is in the measuring position.
11	Remove the microcuvette from the cuvette holder and discard in an sharps container. autoclave bag.
12	Repeat for all three levels, Document hemoglobin results on the HemoCue® Hemoglobin QC log F140-170-03A. If QC failures, troubleshoot by following scenarios listed in Appendix 6.

Procedure C: Document all maintenance tasks on HemoCue® Hemoglobin Maintenance Log, form F140-170-03B
Daily Maintenance – Cuvette holder
 Cuvette holder is stored in the closed position when not in use.



Step:	Action:
1	Must be cleaned after each day of use
2	Turn analyzer off. The screen should be blank.
3	Pull the cuvette holder out to its loading position. Carefully press the small catch positioned in the upper right corner of the cuvette holder.
4	While pressing the catch, rotate the cuvette holder towards the left as far as possible and pull the cuvette holder away from the analyzer.
5	Clean the cuvette holder with alcohol or mild detergent. It is essential that the holder is allowed to dry completely before being replaced – approximately 15 minutes. Do not spray cleaning products directly onto analyzer.

Weekly Cleaning – Display and Analyzer outer case

Step:	Action:
1	Clean the outer case of the analyzer with alcohol or mild detergent. Do not spray cleaning products directly onto analyzer.
2	Wipe the display off with a lint free wipe.

Monthly/As required - Optical Parts

Step:	Action:
2	The optical parts are located behind the pivot point of the tray. On the top and bottom, about 3/4” inside the opening of the cuvette holder. The upper and lower cover glasses need to be cleaned thoroughly.

3	<p>With the cuvette holder removed from the analyzer push the HemoCue Cleaner into the opening of the optic unit, as far in as possible. Move from side to side 5-10 times. Then, placed to the left, push the HemoCue Cleaner back and forth 5-10 times. If the swab is stained, repeat the process using a new swab each time, until it is clean. Be sure to clean well in the area of the optical parts. The optronic unit should be cleaned when directed to do so in the troubleshooting guide or as desired. Wait 15 minutes before replacing the cuvette holder and using the analyzer. Make sure the cuvette holder is dry before reinserting. Please refer to the Operating Manual for further instructions.</p> <div style="text-align: center;"> </div>
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Procedure D: Screen Calibration - Only done as required

Step:	Action:
1	Press and hold on/off button until analyzer version is displayed.
2	Use a pointy object and press on each "+" that appears. While being careful not to puncture the screen.

Expected Values:

Adult males: 130 – 170 g/L
 Adult females: 120 – 150 g/L
 Infants, after neonatal period: 110 – 140 g/L
 Children, two years to teenage: Gradual increase to adult normal

Manufacturer does not provide ranges between the ages of children to teenager. Based on the range verification, the values are comparable to standard analyzers and suggest pediatric ranges could be used for these ages.

Processing Samples:

Follow Appendix 2 for HemoCue 201 DM
 Follow Appendix 5 for HemoCue 201 +

Result Reporting:

Delphic Sites Only:

- Document Hgb Result into Delphic by inserting POCT Hgb value from analyzer into **IHGB** slot on **ICBC** format.
- Always double check Hgb value for transcription error prior to releasing result
- Document any comments in ICOM comment area on ICBC format
- Complete documentation on the ICBC worksheet (or F100-140-03A) and file (if applicable)

Non-Shared Health sites only:

- Transcribe Hgb result to your Requisition/Report F100-140-04
- Date and time of collection documented
- Sign at bottom of Requisition/Report
- Follow site procedures for final reporting process (ie: leave for a copy for lab to back enter, scan to Medical records and/or place copy in chart)
- Always double check Hgb value for transcription errors

Confirmatory Testing:

Required when Hgb is <65 g/L, >235 g/L or 'Overrange'

If:	Then:
Hgb is <65 g/L	<ul style="list-style-type: none"> • Report Hgb result • In ICOM comment, insert &HgbP (Preliminary result Hgb result is less than 65 g/L. Venous sample is being sent to reference lab for confirmatory testing) • If not already done so draw venous sample and send to reference lab for confirmatory testing of Hgb. • Delphic sites label tube with the barcode that includes 'LV'. Test alter, adding a CBC. Ensure that CBC is test assigned to the correct Lab. • New registration is required if testing is performed by non-Lab staff, as lab performed tests cannot be combined with non-lab performed tests. • Non-Delphic sites document on requisition/patient log that sample has been sent for confirmatory testing (if applicable) • Ensure to make a peripheral blood smear to send with original CBC sample (If sites usual practice)
Hgb is >235 g/L or displays 'Overrange'	<ul style="list-style-type: none"> • Report result, or if 'Overrange' place *&DEL in the IGB box • In ICOM comment, report "Preliminary result is >235 g/L. Venous sample is being sent to reference lab for confirmatory testing." • If not already done so draw venous sample and send to reference lab for confirmatory testing of Hgb. • Delphic sites label tube with the barcode that includes 'LV'. Test alter, adding a CBC. Ensure that CBC is test assigned to correct Lab. • New registration is required if testing is performed by non-Lab staff, as lab performed tests cannot be combined with non-lab performed tests. • Non-Delphic sites document on requisition/patient log that sample has been sent for confirmatory testing (if applicable) • Ensure to make a peripheral blood smear to send with original CBC sample (If sites usual practice)

When Confirmatory Testing Can't be Sent to Referral Site (Delphic sites only):

This scenario may occur in some of our sites because technologists might not work weekends/STAT days and no courier is available. CBC sample stability is 72 hours refrigerated. In these situations, where a confirmatory testing is required for Hemocue results but cannot be confirmed a comment needs to be added. Upon the MLTs return to the lab and after entering the POCT result, free text this in the associated POCT test comment field: "Confirmatory sample is greater than 72 hours old and is not suitable for testing."

Manual Transcription:

Results are not going directly into the LIS using an interface, these results are being manually entered onto a log sheet, patient requisition /report or into the LIS and therefore must be kept for 2 years as per accreditation. When printer is in place (Hb 201+), all documents must be photocopied/scanned into filing system as the ticker tape will fade and disappear over time. Option to place the ticker tape onto a plain white piece of paper, ensure patient identifier is documented, sign and date.

/Critical Values:

Test	Result	Encounter
Hgb	< /=65 g/L	First time, same day

Phoning Critical Values: Immediate notification is required when any results of tests exceed established critical values. Report must include person notified (first and last name), test result, verification of “read back”.

Delphic Sites only: &RB of results, date and time in ICOM comment area. Ensure “Read back” is stated to indicate the results were read back.

Non Shared Health/Non-Delphic sites: Documentation of critical results notification is captured at the bottom of the Requisition/Report F100-140-04.

Limitations:

- Hemoglobin measurements from capillary sampling may be misleading in cases of peripheral circulatory failure
- Extra cellular fluid present in capillary samples due to patient physiology or unacceptable capillary technique can cause false hemoglobin results.
- Another pre-analytical factor associated with sampling techniques is in regards to the size and proper use of the lancet. Proper technique has a direct effect on the puncture, blood flow, and therefore results obtained.
- Do not remeasure the filled microcuvette. Always fill a new, fresh microcuvette.
- **Confirmation of an unacceptable or unexpected result is required to rule out potential pre-analytical factors causes. Repeat using a fresh sample.**

References: [HemoCue® 201 DM Reference Manual](#)

Related Documents:

- Form F140-170-03A: [HemoCue® Hemoglobin QC Log](#)
 Form F140-170-03B: [HemoCue® Maintenance Log](#)
 Form F140-170-03C: Hemocue Validation Workbook
 Form F100-140-03A: HemoCue POC Patient Log
 Form F100-140-04: [HemoCue/i-STAT Requisition/ Report](#)

Appendixes:

- Appendix 1: Instrument Set Up
 Appendix 2: Specimen Processing for Hemoglobin using HemoCue 201 DM
 Appendix 3: Troubleshooting Guide
 Appendix 4: Display Buttons and Symbols
 Appendix 5: Specimen Processing for Hemoglobin using HemoCue 201+

APPENDIX 1

ANALYZER SET-UP

Technical Support:

Phone #: 1-800-426-7256

Email: technicalsupport@hemocue.com

Password:

Default Password: 0000



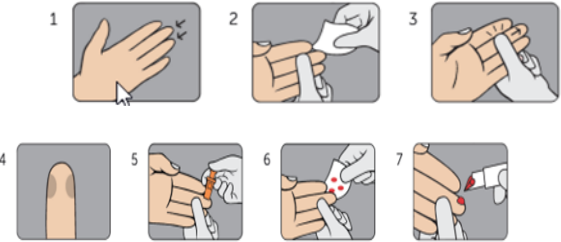
Master Operator ID: SUPERVISOR

Please set up instrument as follows:

Customization Action	Explanation
<p>Operator ID Settings → Advanced Settings → General Settings → Operator ID → Change to “Entry Required”</p>	<p>All users must enter their operator ID prior to use. This is the first request on the home screen.</p>
<p>Cuvette Batch Using Master Operator ID → Settings → Advanced Settings → General Settings → Cuvette Batch → Change to “Not Used”</p>	<p>As we don’t have supervisors at all sites, we will not be inputting the Cuvette Batch lot# and expiry.</p>
<p>Specimen ID Using Master Operator ID → Settings → Advanced Setting → Patient Test → Patient ID → Change to ‘Required’ Using Master Operator ID → Settings → Advanced Setting → Patient Test → Lab Number → Change to ‘Not Used’</p>	<p>Shared Health site with Delphic request number, scan barcode. Non-SH or no Delphic request number available enter in patients PHIN.</p>
<p>QC Test Using Master Operator ID → Settings → Advanced Settings → QC Test → Level 1, 2 and 3, change to “Not Used” Under Define Lists → Liquid Controls → Leave this blank</p>	<p>We will not be inputting QC lot# or expiry dates. All samples will be run as Patient Tests and compared with QC log using package insert ranges.</p>
<p>Date/Time Master Operator ID → Settings → Basic Settings → Date/Time → Change as needed</p>	<p>Ensure instrument is at correct date and time</p>
<p>Operators Master Operator ID → Setting → Define Lists → Define Operators = Not used, leave blank</p>	<p>Only SUPERVISOR should be listed</p>

APPENDIX 2

Specimen Processing for Hemoglobin using Hemocue 201 DM

Step	Action	
1	Ensure the analyzer is placed horizontally and on a stable surface. Pull the cuvette moving arm out of the loading position.	
2	Press and hold the button until the screen is activated and all symbols appear. The analyzer will perform a self-test. Enter or scan your operator ID. On the main menu, press the "QC & Patient Test" button Scan barcode or enter in patient PHIN	
3	Venous/Arterial blood samples (EDTA tube) – If stored in a refrigerator (2 – 8°C), allow it to warm up to room temperature (15 – 35°C) before mixing or use freshly drawn blood sample. Mix the venous sample tubes thoroughly by inverting the tube 10–20 times by hand. Place a drop of blood onto a hydrophobic plastic surface, using a pipette or diff Safe.	
4	Capillary puncture - ensure patients hand is warm and relaxed, use only the middle or ring finger for sampling. Clean fingertip with disinfectant and allow to dry completely. Using your thumb, lightly press the finger from the top of the knuckle towards the tip. Puncture the side of the fingertip using a lancet. Wipe away the first 2-3 drops of blood. Re-apply light pressure towards the fingertip until another drop of blood appears.	
5	Fill the microcuvette in one continuous motion, from finger or hydrophobic surface by holding the microcuvette at a 45-degree angle towards the blood drop. DO NOT REFILL.	
6	Wipe off excess blood from the outside of the microcuvette with a clean lint-free wipe. Be careful not to touch the open tip of the microcuvette.	
7	Be aware of air bubbles in the filled microcuvette unless they are around the edge. If present, discard the microcuvette and fill up a new one from a new drop of blood.	
8	The result is obtained in 15-60 seconds. If results are unexpected or unacceptable, repeat the test to ensure pre-analytical factors are not the cause. Perform another capillary or venipuncture.	
9	Discard the microcuvette into a sharps container.	
10	Transcribe results to HemoCue® Analyzer Report form F100-140-04, requisition, or Delphic worksheet. Sign and date.	
11	Report results as per sites process.	

APPENDIX 3

TROUBLESHOOTING GUIDE

Symptom	Explanation	Action
Analyzer shows an error code,	May be an occasional fault.	Turn off the Analyzer and turn it on again after 30 seconds. Take a new cuvette and repeat the measurement. If problem continues, see the specific error codes below.
E00	No stable endpoint found within the time range. 1) The cuvette is faulty. 2) The circuit board is out of order.	1. A) Check the expiration date for the cuvettes. 1. B) Take a new cuvette and repeat the measurement. 2. Analyzer needs service. Contact the distributor.
E01-E02	1) Dirty optical parts. 2) Analyzer too hot/cold. 3) Magnet missing in cuvette holder.	1) Clean optical parts as described in Instructions for Use. 2) Turn analyzer off, allow to reach operating temperature before use. 3) Order new cuvette holder.
E03	Analyzer exposed to direct light.	Avoid direct light exposure.
E05-E06	Analyzer too hot/cold or exposed to direct light.	a) Turn analyzer off, allow to reach operating temperature before use. b) Avoid direct light exposure. If the problem continues, Analyzer needs service. Contact the distributor.
E08	The absorbance is too high. Light blocking item in the cuvette holder.	a) Check that the analyzer and cuvettes are used according to the Instructions for Use. b) Analyzer needs service. Contact the distributor.
E11	Hardware Error	Analyzer needs service. Contact distributor.
E17	Internal Error	Analyzer needs service. Contact distributor.
E23	Data Error Real Time Clock Real Time Clock backup battery has been drained.	The backup battery needs to be replaced. Contact distributor.
E25	Analyzer not calibrated.	Analyzer needs service. Contact distributor.




E26	The Patient test memory is full. No more patient data can be saved.	<p>Save test results by placing the analyzer in a Docking Station connected to DMS Software or OR.</p> <p>For the following, supervisory authority is needed.</p> <ul style="list-style-type: none"> a) Delete all or part of the Patient Tests stored in the analyzer (see 7.3 Delete Stored Data) b) Change analyzer settings regarding full internal memory for Patient tests to “overwrite” (see 3.4.1 General Settings).
E28	The analyzer log memory is full. No more Error codes and Log Notes can be saved.	<p>Save test results by placing the analyzer in a Docking Station connected to DMS software or an OR.</p> <p>For the following, supervisory authority is needed.</p> <ul style="list-style-type: none"> a) Delete all or part of the analyzer logs stored in the analyzer (see 7.3 Delete Stored Data) b) As the analyzer settings regarding full memory for analyzer logs is the same as the setting for full memory of QC tests, change analyzer behavior for QC tests to “overwrite” (see 3.4.1 General Settings).
E29	The electronic self-test failed. The communication self-test failed. The analyzer may not work properly when connected to a docking station. The is stored as a failed Electronic QC Test (EQC) in the analyzer log book.	Analyzer needs service. Contact distributor.
E30	The electronic self-test failed. The optical self-test failed. The analyzer may not work properly when measuring. This is stored as a failed Electronic QC Test (EQC) in the analyzer log book.	<ul style="list-style-type: none"> a) Turn off the analyzer and clean the optronic unit as described in the Instructions for Use. b) Analyzer needs service. Contact distributor.
Overrange	HemoCue Hb 201 DM: Measured value exceeds 256 g/L	HemoCue Hb 201 DM The result is above the measuring range.
Non-responsive display	Display needs recalibration.	Follow section 5.4 Calibrating the Display in Instructions for Use. If the recalibration fails, the analyzer needs service. Contact the distributor.




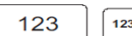




<p>No characters on display</p>	<ol style="list-style-type: none"> 1) The analyzer is not receiving power. 2) If on battery power, the battery needs to be recharged. 3) The display is out of order. 	<ol style="list-style-type: none"> 1. <ol style="list-style-type: none"> A) Check that the Power Adapter is connected to the power supply. B) Check that the Power Adapter is securely connected to the analyzer or Docking Station C) If the analyzer is docked, check the green LED on the Docking Station gives a flashing green light. D) Check that the adapter is not damaged. 2. Recharge the battery via a power adapter or a docking station. 3. Analyzer needs service. Contact distributor.
<p>The display gives erroneous characters.</p>	<ol style="list-style-type: none"> 1) The display is out of order. 2) The microprocessor is out of order. 	<ol style="list-style-type: none"> 1) & 2) analyzer needs service. Contact distributor.
<p>Analyzer not charged</p>	<p>No charging of the battery.</p>	<ol style="list-style-type: none"> a) Check that the analyzer is properly docked. b) Check that the green LED on the docking station gives a flashing green light when docking the analyzer. c) Replace the battery.
<p>Empty cuvette*</p>	<ol style="list-style-type: none"> 1) The cuvette is empty. <p>Empty cuvette function captures primarily empty cuvettes, not under-filled cuvettes.</p> <ol style="list-style-type: none"> 2) No chemical reaction is identified in the blood-filled cuvette. <p>*this error code is only displayed in HemoCue Glucose 201 DM analyzer and HemoCue Glucose 201 DM RT analyzer</p>	<p>1-2) Fill a new cuvette and perform a measurement as described in relevant sections of Instructions for Use.</p> <p>If the Empty Cuvette message appears again, contact your local distributor or HemoCue AB. Use another HemoCue analyzer or a suitable laboratory reference method to analyze the specimen.</p>
<p>Unexpected patient or control results</p>	<p>Patient or control samples</p> <ol style="list-style-type: none"> 1) Improper sampling technique. 2) The cuvettes have passed the expiry date, are faulty or have been improperly stored. 3) The optical eye of the cuvette is contaminated. 4) Air bubbles in the cuvette. 	<p>Patient or control samples</p> <ol style="list-style-type: none"> 1) See relevant section in Instructions for Use. 2) Check the expiry date and the storage conditions of the cuvettes 3) Fill a new cuvette and perform a new measurement. 4) Check the cuvette for air bubbles. Re-measure the control/sample with a new cuvette.




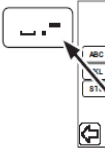
	<ul style="list-style-type: none"> 5) The optical parts are dirty. 6) Incompletely filled cuvette. 7) The measurement needs to be started no later than 40 seconds (for Glucose 201 DM and Glucose 201 DM RT) or 10 minutes (for Hb201 DM) after filling the cuvette. 8) The analyzer is damaged or malfunctioning <p>Control Samples</p> <ul style="list-style-type: none"> 9) The control has not been properly mixed and/or has not reached room temperature. 10) A) Control solution not compatible. B) Control solution expired or improperly stored. 	<ul style="list-style-type: none"> 5) Clean the optical parts as described in relevant section of Instructions for Use. 6) Fill a new cuvette and perform a new measurement. 7) Fill a new cuvette and perform a new measurement. 8) The analyzer needs service. Contact the distributor. <p>Control Samples</p> <ul style="list-style-type: none"> 9) Make sure that the control is properly mixed and that it has reached room temperature. If the problem continues, contact the manufacturer of the control. 10) A) if a quality control test is to be performed, only use quality controls recommended by HemoCue, see relevant package insert for more information. B) Check the expiry date and the storage conditions of the control. Repeat the measurement with a new control/sample. If the problem continues, contact the manufacturer of the control.
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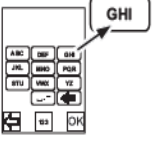
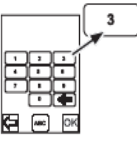
APPENDIX 4
DISPLAY BUTTONS AND SYMBOLS









Navigation Buttons:





Button	Designation	Function
	QC and Patient sample test button	ALL sample will be run in this mode using sample test button. QC data will be compared and accepted using QC Appendix 6
	Settings Button	Used to set up the instruments as per Appendix 1 Analyzer Set-Up.
	Stored data Button	Activates the Stored Data function

Button	Designation	Function
	Erase button	Erases the last input.
	Previous image button	Returns to the previous image Note that inputs/changes made in the current image will not be saved.
	Text mode button	Switches to text input mode.
	Numeric mode button	Switches to the numeric input mode.
	Barcode Scanner button	Activates the Barcode Scanner.
	Scroll bar arrow (Up)	Scrolls upwards in a list of different options or in a text.
	Scroll bar arrow (Down)	Scrolls downwards in a list of different options or in a text.
	Next image button	Continues to the next image in the Help sequence.

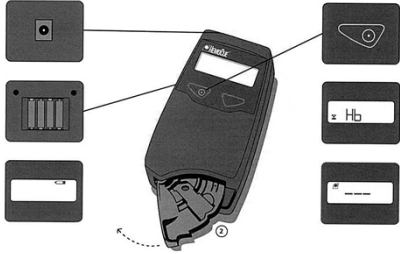

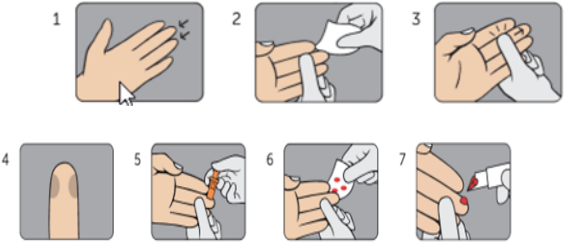
Button	Designation	Function
	Help button	Displays help regarding other buttons, procedures, etc.
	Confirm button	Saves text or numbers and/or displays the next screen image. All inputs/changes will be saved.
	Log Out button	Logs out the operator. The Log Out button is only displayed if the Operator ID is required.
	Special Character button	Enters a special character (see explanations below) Other special characters can only be loaded into the Analyzer by means of the Barcode Scanner.

Button	Designation	Function
	Letter buttons	Allows input of a text Example: To enter a "G" – press once To enter an "H" – press twice To enter an "I" – press three times Only capital letters will be entered. Lower-case letters can be entered into the Analyzer by means of the Barcode Scanner.
	Digit buttons	Allows input of a digit.

Button	Designation	Function
	Reject button	Rejects a result. A rejected result will be saved and flagged as rejected.
	Save button	Stores the entered information.
	No button	The entered information will not be stored.
	Continue button	Continues the current operation.
	Statistics button	Displays statistics on the chosen subject.
	Date format button	Switches between the following date formats: <ul style="list-style-type: none"> • YYMMDD • DD.MM.YY • MM/DD/YY
	Time format button	Switches between the following time formats: <ul style="list-style-type: none"> • 12 hours • 24 hours
	AM/PM button	Enables adding "AM/PM" (only 12-hour format)

Symbol	Designation	Function
	Battery	Indicates the voltage status of the Battery in four levels. The furthest to the left is fully charged, the one to the right is almost empty.
03/03/04	Date	Indicates the Date format chosen (from three possibilities) in the Settings Menu.
	Big Hourglass	The big hourglass is displayed when the Analyzer is in the measuring or selftesting state.
	(rotating)	The big hourglass is rotating when displayed.
	Small hourglass	When the small hourglass is displayed, the instrument is in a measuring or blanking state. When displayed in the Main Menu, only Settings and Stored Data functions are available. It is also possible to log out.

APPENDIX 5
Specimen Processing for Hemoglobin using Hemocue 201 +

Step	Action	
1	Ensure the analyzer is placed horizontally and on a stable surface. Pull the cuvette moving arm out of the loading position.	
2	Press and hold the left button until the display is activated and all symbols appear on the screen. The display shows the version number of the program, after which it will show "E" and "Hb" and "d".	
3	The analyzer will automatically start performing the self-test. After ten seconds, three flashing dashes and the HemoCue® symbol will appear on the screen. These symbols indicate the self-test passed and the unit is ready to use. If the self-test fails, an error code will be displayed.	
4	Venous/Arterial blood samples (EDTA tube) – If stored in a refrigerator (2 – 8°C), allow it to warm up to room temperature (15 – 35°C) before mixing or use freshly drawn blood sample. Mix the venous sample tubes thoroughly by inverting the tube 10–20 times by hand. Place a drop of blood onto a hydrophobic plastic surface, using a pipette or diff Safe.	
5	Capillary puncture - ensure patients hand is warm and relaxed, use only the middle or ring finger for sampling. Clean fingertip with disinfectant and allow to dry completely. Using your thumb, lightly press the finger from the top of the knuckle towards the tip. Puncture the side of the fingertip using a lancet. Wipe away the first 2-3 drops of blood. Re-apply light pressure towards the fingertip until another drop of blood appears.	
6	Fill the microcuvette in one continuous motion, from finger or hydrophobic surface by holding the microcuvette at a 45-degree angle towards the blood drop. DO NOT REFILL.	
7	Wipe off excess blood from the outside of the microcuvette with a clean lint-free wipe. Be careful not to touch the open tip of the microcuvette.	
8	Be aware of air bubbles in the filled microcuvette unless they are around the edge. If present, discard the microcuvette and fill up a new one from a new drop of blood.	
9	The result is obtained in 15-60 seconds. This result will remain on the screen as long as the cuvette holder is in the measuring position. If results are unexpected or unacceptable, repeat the test to ensure pre-analytical factors are not the cause. Perform another capillary or venipuncture.	
10	Discard the microcuvette into a sharps container.	
11	Transcribe results to HemoCue® Analyzer Report form F100-140-04, requisition, or Delphic worksheet. Sign and date.	
12	Report results as per sites process.	