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Document History:

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

Document #:	**140-170-10**	**Version #:**	**03**
Section:	**Hematology**	**Subsection:**	**POCT Laboratory**

Approved by:	Dr. Ping Sun *(Approval on file)*	**Date:**	7-SEPT-2022
		Effective Date:	1-OCT-2022

Details of Recent Revision

- Update to Quality Control section/requirements (requirements, comparisons, new lots/shipments)
- Addition of LIS worklist
- Update to Policy regarding confirmatory testing
- Addition of Appendix 5
- Update to Related Documents
- Updates to Procedures

HemoCue ® Hb 201 DM Analyzer

Purpose: This procedure provides instructions for determining the hemoglobin value on this point of care device.

This device is CLIA waived.

Policy: This unit can be used in the lab or the bedside. The analyzer stores 4000 test results, date, time, 500 quality control results and 500 error messages (including maintenance).

This system is used for the determination of the total amount of hemoglobin in whole blood. 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.

Only certain staff members will be able to access basic or advanced settings that allows specialized functions to be initiated/added to the analyzer. The settings for most functions arrive from the factory as “Not Used”. Staff who will be allowed to access the settings function (password protected) can enter lot related information about quality control and cuvettes. Instructions can be found in the reference manual. These staff members will be determined by the regional directors.

Results > 235 g/L, < 65 g/L or displaying HHH will result in confirmatory testing at hematology site.

Materials:

Reagents:	Supplies:	Equipment:
• Eurotrol Hemotrol Low, Normal and High Controls • Alcohol • Mild soap solution	• HemoCue hemoglobin cleaner • Microcuvettes • 21-22-gauge Lancets 2 mm depth (as applicable) • Pipette or Diff Safe • Lint-free wipes • Hydrophobic plastic or glass slides	• HemoCue 201 DM • Primary Docking Station

Special Safety Precautions: As per Routine Practices (Standard Precautions). Mandatory use of gloves. Equipment not suitable for use in the presence of flammable mixtures.

Sample:

- Capillary, venous or arterial blood can be used.
- EDTA anticoagulated sample can be used.
    - Mix all specimen samples 8-10 times by hand inversion.
    - If the specimen has been refrigerated, allow sample to warm up to room temperature for 15 minutes before mixing.

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%.
- EPT must be subscribed to (ie. HE). See Appendix 2 to perform Proficiency Testing.
- New lot numbers or new shipment same lot number of QC or cuvettes requires the QC to be run once and documented on the QC log prior to testing patient samples.
- QC values must be within stated insert ranges.

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.

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.

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

Note: Microcuvette must be filled with blood/QC matrix within three (3) minutes of opening the wrapping.

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%).

Accessioning: Register the test in Delphic:

- Test code is **IHGB** (POCT HBG)
- Document LIS sample # onto test requisition.

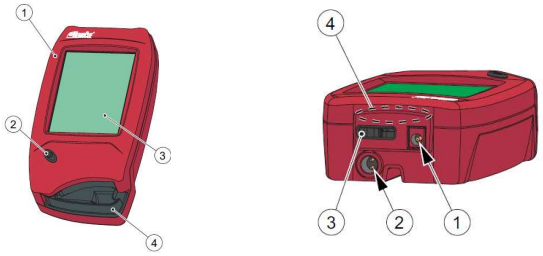
If:	Then:
Test performed by non-laboratory staff,	Order test code **POCT** (test performed by non-laboratory personnel).

IMPORTANT: Lab performed tests **CANNOT** be combined with non-lab performed tests on a single registration as the code applies to all tests under a single request ID.

LIS Worklist: **ICBC** is printed prior to patient testing to record results and staff details for 2-year retention (with printout as applicable).

Analyzer Overview:

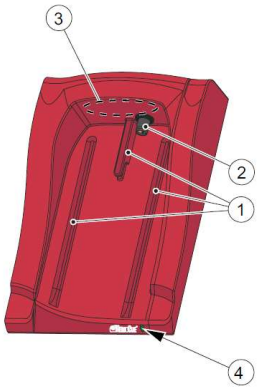
Front Panel: The analyzer (1) is started when the ON/OFF button (2) is pressed. The screen images will be visible on the display (3). See picture below. All navigation and information handling are performed by pressing the appropriate touch buttons on the display. A test measurement is performed using 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:



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)

On the back panel are the following items:

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

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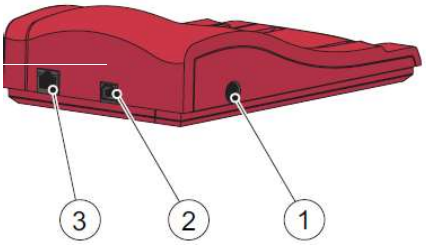
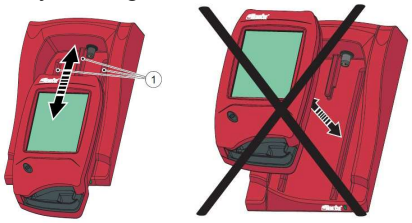


DO NOT cover or block the items on the back panel or a malfunction may occur.

Always slide the analyzer into and out of the docking station using the tracks and ensure the unit is fulling 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



Functions & Features:

The HemoCue 201 DM system is a data management system that has the capability of:

1. Operator ID input, with lockout function if operator ID is not recognized.
2. Patient ID input
3. Cuvette batch data input
4. Lab # input
5. QC with input of lot numbers, ranges and lockout functions.
6. STAT tests
7. Proficiency testing

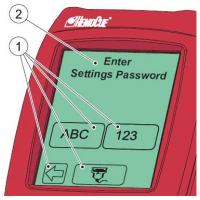
- Approximately the analyzer stores 4000 patient/STAT test results and 500 QC test results including ID, date, time and comments.
- 500 log entries including error messages and maintenance.

The analyzer has a touchscreen display, a built-in barcode scanner and is powered by a rechargeable lithium battery, power adapter or via docking station. The battery is recharged when connected to the docking station.

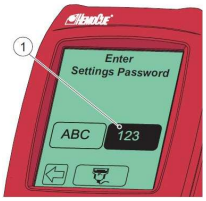
Operating the Display:

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.

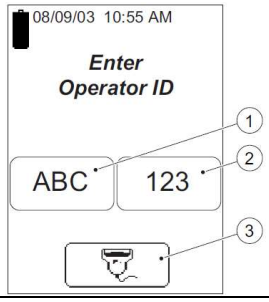
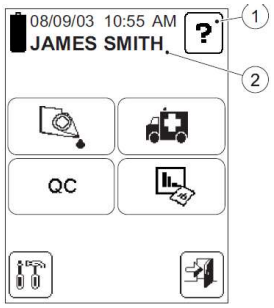
Power Save Mode:

When no procedures have been performed within 30 minutes, the analyzer will switch to power save mode.

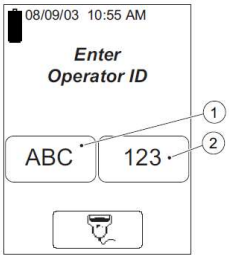
If the analyzer is powered by the battery, the user will be logged off and the analyzer will be switched off. The ON/OFF button must be pressed to reactivate it.

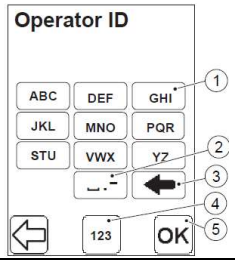
If the analyzer is powered by the Power Adapter, the user will be logged off, the image on the display disappears but the power remains on. Touch the display to reactivate it.

Procedure A: Operating the Analyzer

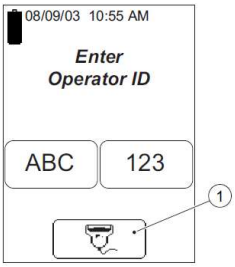
Step:	Action:
1	Turn on the analyzer. The Start image will be displayed including the analyzer type, software version and serial #.
2	The cuvette holder must be in the loading position for the analyzer to perform a self-test. No function can be activated for approximately 20 seconds during the self-test.
3	Operator ID can be set up on the unit. If this function is desired, the login image will be displayed. The Operator ID can be entered via the alphabetical (1) or numeric (2) mode buttons or by the barcode scanner (3). 
4	The main menu screen will appear which includes all necessary procedure buttons to initiate certain functions.  (1) Help Button (2) Operator Name, Operator ID or blank depending on settings activated

Entering Information with Letters and Digits:

Step:	Action:
1	Inputs to the analyzer are made using either the display or barcode scanner.
2	The display can be set up using text mode for entering letters and special characters or numeric mode for entering numbers.
3	Press the text mode button (1) or the numeric button (2) depending on if the first character is a letter or a digit. 

4	Only capital letters and a few special characters can be used in this mode. Lower case letters can only be entered utilizing the barcode scanner.
5	Inputs are made using the letter buttons (1) and the special character button (2). One needs to press the same key one or more times to specify the input character. For example, ABC button, hit it once for A, twice for B and three times for C.
6	The erase button (3) erases the last input.
7	IF a number is required, switch the numeric input mode by pressing the button (4).
8	Press the confirm button (5) when all information has been entered. 

Barcode Scanner:

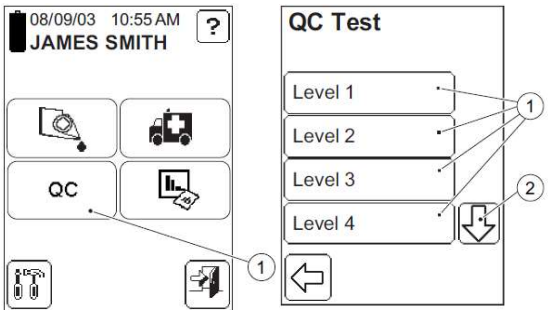
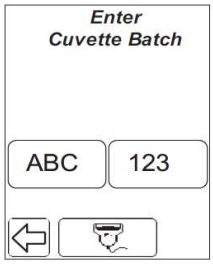
Step:	Action:
1	The barcode scanner (1) can be used for entering letters, digits and special characters. 
2	Use the scanner on the back panel of the analyzer. Scanning range is 4-12 inches from the scanner. Hold the barcode scanner button to initiate scanning and the information from the barcode appears 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.

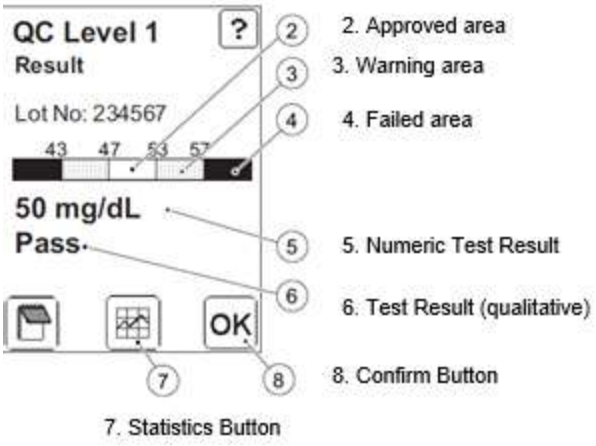
Default Settings:

When this button is pressed in the Settings Menu, confirmation or cancellation of the requested change to the analyzer default setting is necessary and a question will be displayed. This affects analyzer configuration (including passwords) but not measurement results or lists (QC, cuvette batches, operations, comments or logs).

Procedure B: Measuring Control Material

Follow the activities in the table below to measure control material. See Appendix 3 for QC.

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 the QC test button (1). There will be 7 options shown: Levels 1-5, Linearity and Proficiency. If the option that you want is not visible immediately, use the scroll button to find it. Select the option that you are interested in. The concentration level of the QC test will be displayed (i.e. Level 1 or 2 etc). 
4	Using a pipette or transfer device (diff safe), place a drop of control material onto a hydrophobic surface (i.e. plastic film or glass slide) 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.
8	Enter the cuvette batch number either directly on the display via the text/numeric mode buttons or with the barcode scanner using the barcode scanner button. 

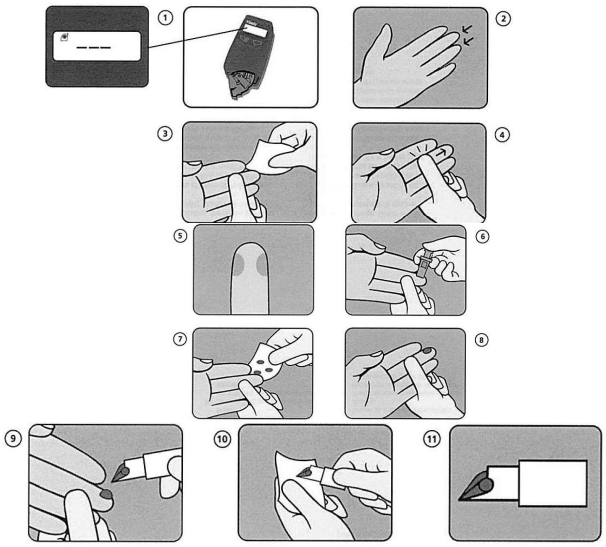
9	Enter the lot number for the liquid control used either directly on the display via the text/numeric mode buttons or with the barcode scanner using the barcode scanner button. If the lot number has not been previously stored or has expired, **Invalid Control Lot** will show up on the display screen.
10	During the measurement phase, "⌛" (hour glass) and three fixed dashes will be seen on the screen.
11	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.
12	Remove the microcuvette from the cuvette holder and discard in an autoclave bag.
13	The numeric test result and qualitative result (Pass/Fail) are displayed in bold text. A result in the approved area will indicate a "Pass"; a result in the warning area (dotted area on the display) will indicate "Pass, Warning" and a result within the failed area (solid area on the display) or 2 consecutive results in the warning area will indicate "Fail". 
14	To avoid or unlock a QC lockout, the qualitative test result must be a Pass (if analyzer is set up with this option).
15	To view a graphic presentation of the most recent QC results, press the Statistics button.
16	Press the Confirm button.
17	**If:** / **Then:** QC within limit range, → • Enter **P** (pass) on Hemocue Log form F140-170-03A • Record hemoglobin value • If all other QC levels are within limit range, process sample. • Comment if trends observed. QC outside limit range, → • Enter **F** (fail) on Hemocue Log form F140-170-03. **Do not process samples.** • Inspect QC specimen (ie. volume, open vial expiry date). • Repeat QC sample with a new microcuvette.

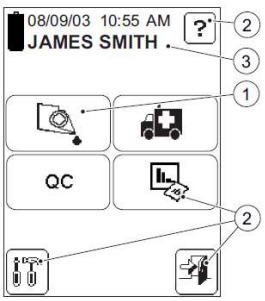
		• Record value in hemoglobin. • Comment on actions/resolution.
	Repeat QC outside limit range,	• **Do not process samples**. Consider instrument problem. Troubleshoot as applicable. • If not resolved, notify Supervisor; implement Contingency Plan. • Charge Technologist or delegate must investigate and comment on specific corrective actions. • Contact technical assistance for help
18	Document hemoglobin results on the HemoCue® Hemoglobin QC log, form F140-170-03A.	

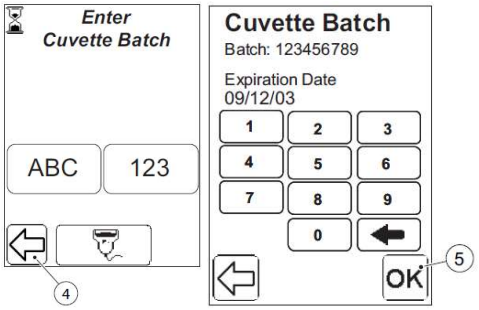
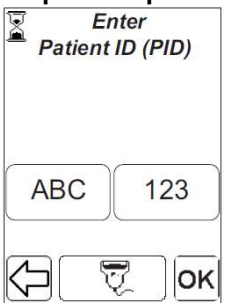
Procedure C: Measuring Capillary Blood

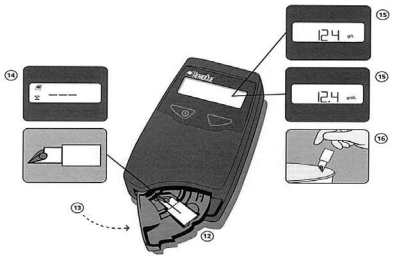
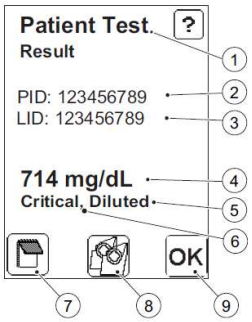
Follow the activities in the table below to measure capillary blood.

Note: Always handle blood carefully as it could be infectious. Wear gloves when handling blood specimens.



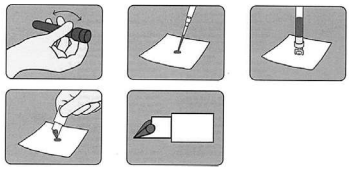
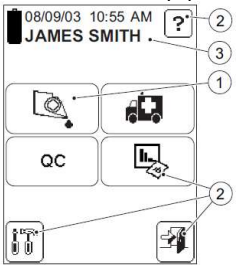
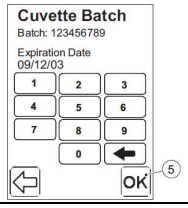
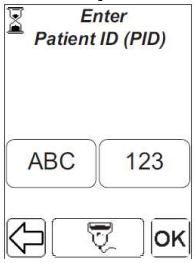
Step:	Action:
1	After start-up is complete, the cuvette holder will be in the loading position. **Note:** The microcuvette must be filled with blood within three (3) minutes of opening the wrapper.
2	In the Main Menu, press the Test Patient button (1).  3. Operator name 1. Patient test button 2. IF hour glass is displayed, only these buttons can be used

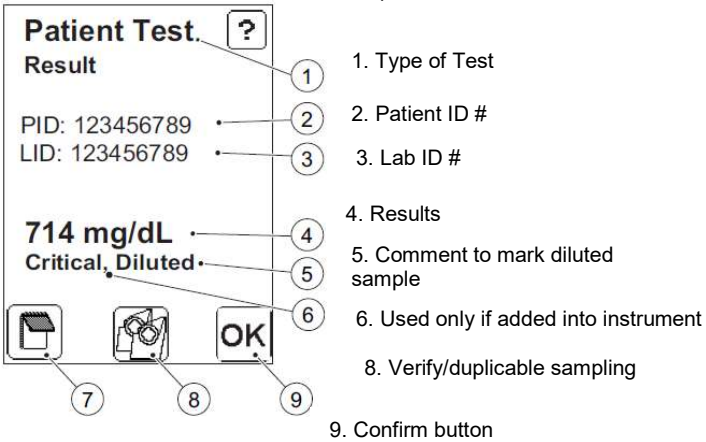
3	If the cuvette batch is set to be required, then enter the cuvette batch number directly onto the display screen using either the text/numeric mode buttons or by using the barcode scanner with the barcode scanner button. If the cuvette batch has not been previously stored or has expired, **Invalid Cuvette Batch** will be displayed.  Enter all cuvette batch information as applicable and press the Confirm button (5).
4	Enter the patient ID via the text/numeric mode buttons or with the barcode scanner using the barcode scanner mode. A display will be shown where it is possible to verify all entered information. If an error is noticed, use the back arrow to go back and re-enter the correct information; otherwise press **OK.** **NOTE: It is recommended to limit the number of characters for Operator ID, patient ID and Lab ID in order to prevent possible mix-up of identification.** 
5	Ensure the patient's hand is warm and relaxed prior to starting the procedure. Use either the middle or ring finger for sampling while avoiding any fingers with jewelry on.
6	Clean the finger with disinfectant and allow to dry or wipe off with a dry, lint-free wipe.
7	Using your thumb, lightly press the finger from the top of the knuckle towards the tip. This motion will stimulate the blood flow towards the sampling point.
8	For best blood flow, use the side of the fingertip and not the center.
9	While lightly pressing towards the fingertip, puncture the finger using a lancet.
10	Wipe away the first 2-3 drops with lint free wipe.
11	Apply light pressure towards the fingertip until another drop of blood appears.

12	When blood droplet is large enough, fill the microcuvette in one continuous motion. **DO NOT REFILL!** A total of 10 µL of blood is used.
13	**Wipe away any excess blood from the outside of the microcuvette** with a clean, lint-free wipe. **Note: Do NOT touch the open end of the microcuvette to prevent blood from being drawn into it.**
14	If air bubbles are present in the microcuvette, discard it and fill a new one from a new drop of blood. Small bubbles around the edge can be ignored.
15	Place the filled microcuvette into the cuvette holder and start measurement as soon as possible, but no later than ten (10) minutes after filling the microcuvette.
16	Gently slide the cuvette holder to the measuring position.
17	During the measurement phase, "⌛" (hour glass) and "Please Wait Measuring" will be seen on the screen. 
18	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.
19	If results are unexpected or unacceptable, repeat the test to rule out potential pre-analytical factors as the cause. Perform a second finger poke. Refer to Step 17 Procedure D for additional reporting details.
20	Remove the microcuvette from the cuvette holder and discard in an autoclave bag.
21	The results (4) will be presented in bold print. If critical result (6) values are entered into the unit as defined by Settings, then the word Critical will appear on the display underneath the patient results. (Patient ID is #2 and Lab ID is #3) 

Procedure D: Venous and Arterial Blood

Follow the activities in the table below to measure venous and arterial blood.

Step:	Action:
1	Allow the patient sample to stand for 15 minutes at room temperature (15 – 30 ^{0}C) if coming from the refrigerator.
2	Blood should be gently mixed well prior to performing any testing (8 – 10 times) by hand inversion. 
3	In the Main Menu, press the patient test button (1). 
4	If the cuvette batch is set to be required, then enter the cuvette batch number directly onto the display screen using either the text/numeric mode buttons or by using the barcode scanner with the barcode scanner button. If the cuvette batch has not been previously stored or has expired, **Invalid Cuvette Batch** will be displayed.
5	Enter all cuvette batch information as applicable and press the Confirm button (5). 
6	Enter the patient ID via the text/numeric mode buttons or with the barcode scanner using the barcode scanner mode. A display will be shown where it is possible to verify all entered information. If an error is noticed, use the back arrow to go back and re-enter the correct information; otherwise press **OK.** **NOTE: It is recommended to limit the number of characters for Operator ID, patient ID and Lab ID in order to prevent possible mix-up of identification.** 

7	Using a pipette or transfer device (diff safe), place a drop of blood onto a hydrophobic surface (i.e. plastic film or glass slide).
8	Fill the microcuvette in one continuous motion using 10 uL of blood. **Do NOT refill! Wipe off any excess blood from the microcuvette** with a clean lint-free wipe, ensuring not to touch the open end of the microcuvette. **Note:** The microcuvette must be filled with blood within three (3) minutes of opening the wrapper.
9	If bubbles are present in the microcuvette, discard and fill a new microcuvette from a second drop of blood. Small bubbles around the edge can be ignored.
10	Place the filled microcuvette into the cuvette holder and start measurement as soon as possible, but no later than ten (10) minutes after filling the microcuvette.
11	Gently slide the cuvette holder to the measuring position.
12	During the measurement phase, "⌛" (hour glass) and "Please Wait Message" will be seen on the screen.
13	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.
14	If results are unexpected or unacceptable, repeat the test to rule out potential pre-analytical factors as the cause.
15	Remove the microcuvette from the cuvette holder and discard in an autoclave bag.
16	The results (4) will be presented in bold print. If critical result (6) values are entered into the unit as defined by Settings, then the word Critical will appear on the display underneath the patient results. (Patient ID is #2 and Lab ID is #3)  1. Type of Test 2. Patient ID # 3. Lab ID # 4. Results 5. Comment to mark diluted sample 6. Used only if added into instrument 7. Comment input button 8. Verify/duplicable sampling 9. Confirm button
17	

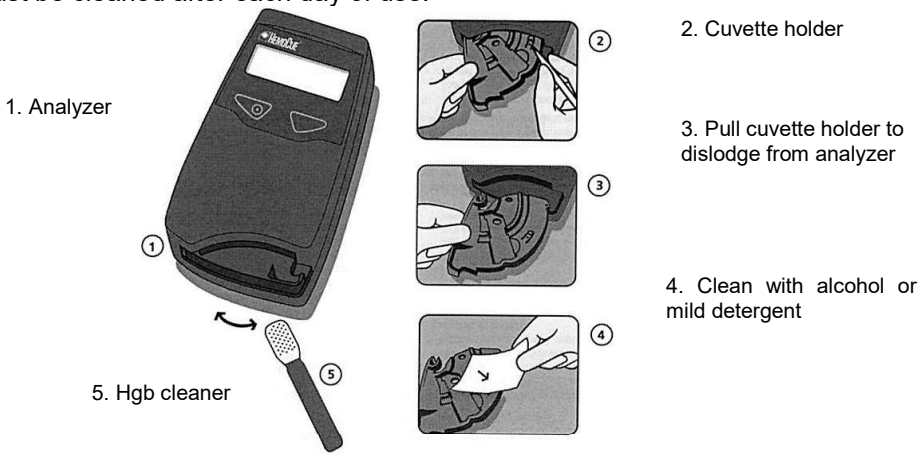
If:	Then:
Hbg is < 65 g/L,	• Report Hbg result • In ICOM comment, insert **&HgbP** (Preliminary result Hbg result is less than 65 g/L. Venous sample is being sent to reference lab for confirmatory testing) • Send sample to reference lab for confirmatory testing of Hgb.
Hgb is >235 g/L	• Report result or if HHH place *&DEL in the IHGB box.

		or displays HHH	• In ICOM enter comment “Preliminary result is >235 g/L. Venous sample is being sent to reference lab for confirmatory testing.”

Procedure E: Daily Maintenance - Cuvette Holder

Follow the steps in the table below for maintenance of **cuvette holder**. Cuvette holder is stored in the closed position when not in use.

Note: Must be cleaned after each day of use.



Step:	Action:
1	Turn analyzer off. The screen should be blank.
2	Pull the cuvette holder out to its loading position. Carefully press the small catch positioned in the upper right corner of the cuvette holder.
3	While pressing the catch, carefully rotate the cuvette holder towards the left as far as possible. Carefully pull the cuvette holder away from the analyzer.
4	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.
5	Document on HemoCue® Hemoglobin Maintenance Log, form F140-170-03B.

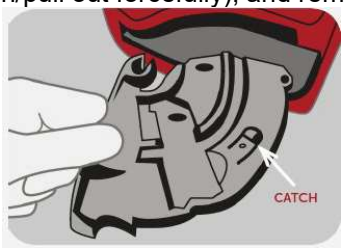
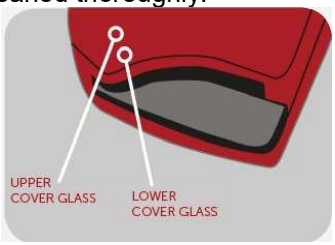
Cleaning Display and Analyzer Outer Case

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.

Screen Calibration:

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.

Optical Parts: ***(How to locate and clean)***

Step:	Action:
1	Remove the microcuvette holder. Check that the analyzer is turned off. Pull the cuvette holder out to its loading position. Carefully press the small catch positioned in the upper right corner and rotate the cuvette holder toward the left. Carefully pull the cuvette holder away from the analyzer (towards your body, **DO NOT** pull upwards/downwards or push/pull out forcefully), and remove it. 
2	The optical parts are located behind the pivot point of the tray. On the top and bottom, about ¾" inside the opening of the cuvette holder. The upper and lower cover glasses need to be cleaned thoroughly. 
3	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. As an alternative to the Hemocue Cleaner, a cotton tip swab moistened with alcohol (20-*70% without additive) or water may also be used for cleaning. If a cotton swab is used, make sure it is not too wet and not too dry. 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.

Result Reporting:

1. Document Hgb result into Delphic by inserting POCT Hgb value from analyzer using the LIS generated worksheet or patient worksheet into IHgb slot on ICBC format.
2. To print a LIS generated worksheet from Delphic go to:
   - Results Entry
   - Click on Printing on the left-hand side
   - Click on Print Tab at the top bar
   - In 'Worksheet to be printed' field, type **ICBC,** press F12 or click Print button on your favorites screen if site has it set up
3. Double check IHgb value inserted for transcription errors PRIOR to result release.
4. Document any comments in ICOM comment area on ICBC format
5. Complete documentation on ICBC worksheet and file.

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.

Interpretation/ 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" **&RB** of results, date and time in ICOM comment area. Ensure "Read back" is stated to indicate the results were read back.

Measuring Range:

0 – 256 g/L
Results above 235 g/L or with a "HHH" must be confirmed by sending a CBC sample to the nearest reference laboratory or site-based laboratory. Report the result from the analyzer, if provided, and in ICOM, free text "Preliminary result. Sample being sent to reference lab for confirmatory testing." No result can be provided for HGB values with HHH as none will be given by the unit.

References: HemoCue® 201 DM Reference Manual

Related Documents:

Form F140-170-03A: HemoCue® Hemoglobin QC Log
Form F140-170-03B: HemoCue® Maintenance Log
Form F100-140-04: HemoCue®/i-STAT Requisition/Report
Job Aid JA100-140-16: HemoCue Hb DM Analyzer Job Aid

Appendixes:

Appendix 1: Troubleshooting Guide
Appendix 2: Proficiency Testing
Appendix 3: Reviewing Quality Control Data and Set Up New Lot Number
Appendix 4: Display Buttons and Symbols
Appendix 5: Analyzer Set-up

Procedural Notes:

Procedural Note #1:

Theory:

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.

Procedural Note #2:
Pre-analytical Variables:

- 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.
- **Confirmation of an unacceptable or unexpected result is required to rule out potential pre-analytical factors causes. Repeat sample using a second finger poke.**
- Keep unit away from portable and RF communication equipment (transmitters)

Procedural Note #3:
Retention Policy:

Since all results and QC are not going directly into the LIS using an interface, these results are being manually entered onto a log sheet or into the LIS and therefore must be kept for 2 years as per accreditation. Therefore, place QC results from the analyzer onto the QC log (if this is what the site wants to use) or requisition or LIS generated worksheet. Scan the image into the computer and keep it in a QC file folder with month and year for easy retrieval. After the 2-year mark, the oldest information can be deleted month by month as time progresses.

Procedural Note # 4:
When Confirmatory Testing Can't be Sent to Referral Site:

This scenario might occur in some of our sites because: a) techs do not work weekends/STAT days and b) no availability of other couriers than lab truck or volunteer drivers.

In these situations, where a confirmatory testing sample is required for Hemocue results, upon the MLTs return to the lab and after entering the POCT result, free text this sentence in the associated POCT test comment field: "Confirmatory sample is greater than 48 hours old and is not suitable for confirmatory testing."

If your referral site is WL, then the comment would state 72 hours instead of 48 hours because their analyzer has been validated to that timeframe.

APPENDIX 1

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.	Save test results by placing the analyzer in a Docking Station connected to DMS Software or OR. For the following, supervisory authority is needed. 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).
E27	The QC memory is full. No more QC data can be saved.	Save test results by placing the analyzer in a Docking Station connected to DMS software or OR. For the following, supervisory authority is needed. a) Delete all or part of the QC tests stored in the analyzer (see 7.3 Delete Stored Data) b) Change analyzer settings regarding full internal memory for QC 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.	Save test results by placing the analyzer in a Docking Station connected to DMS software or an OR. For the following, supervisory authority is needed. 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.	a) Turn off the analyzer and clean the optronic unit as described in the Instructions for Use. b) Analyzer needs service. Contact distributor.
E31	Communication Error	a) Check that the LED on the Docking station does not show a red light (stable or flashing). See Symptom "Docking Station LED red". b) See Symptom "No transfer of data" If problems remain contact distributor.
E70/E71*	The cuvette is faulty or the sample might be grossly lipemic. *this error code is only displayed in HemoCue Glucose 201 DM Analyzer and HemoCue Glucose 201 DM RT Analyzer	Check that the system is used according to the Instructions for Use. Fill a new cuvette and perform a measurement. If the error code appears again, use a suitable laboratory reference method to analyze the specimen.
Overrange	**HemoCue Hb 201 DM:** Measured value exceeds 25.6 g/dL (256 g/L, 15.9 mmol/L	**HemoCue Hb 201 DM and HemoCue Glucose 201 DM RT:** 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.
No characters on display	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.	1. 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.
The display gives erroneous characters.	1) The display is out of order. 2) The microprocessor is out of order.	1) & 2) analyzer needs service. Contact distributor.

Scanner is malfunctioning	1) The incorrect barcode is being scanned. 2) The product has expired. 3) The analyzer is too close or too far from the barcode. 4) The barcode is indistinct. 5) The scanner glass is dirty. 6) The barcode is not compatible with the scanner. 7) The scanner is broken.	1) Check that you are reading the barcode from the correct product. 2) Check the expiration date of the product. 3) Hold the analyzer within 10-30 cm (4-12 inches) from the barcode. 4) Enter the information manually. 5) Clean the scanner glass according to relevant section in Instructions for Use. 6) The standards that can be scanned are listed in section 10.1 Technical Specifications. 7) Analyzer needs service. Contact distributor.
Docking Station LED red	1) Flashing red light – external communication error. 2) Steady red light – internal error in the Docking Station.	1) See Symptom “No transfer of data”. 2) A) Disconnect and then reconnect the Power Adaptor. B) Contact HemoCue AB or the distributor.
No transfer of data via USB	No USB-communication.	a) Check that the analyzer is properly docked. b) Check the cable connections in both the Docking Station and the PC. c) Check that the Docking Station is not a Primary Docking Station. d) Check that all Docking Stations that should communicate are connected with a USB cable to the PC. e) Check the DMS software is properly installed and that the USB driver is installed. f) Check the electrical connection. The LED on the docking station should give a stable or flashing green light.

No transfer of data	1) No network communication with OR or PC. 2) Communication error. 3) No communication. 4) No communication between the first and second docking station. 5) No communication between the secondary docking stations. 6) No communication with any docking station.	1) A) Check that the LED on the docking station does not show a flashing red light. B) check the network configuration of PDS/PDS+ C) If multiple docking stations are used, make sure not to mix docking stations labelled PDS+/SDS+ D) Check the external set up and settings (OR/PC, firewall, network infrastructure). 2) A) More than 5 docking stations are docked together. B) If multiple docking stations are used, make sure not to mix docking stations labelled PDS+/SDS+ 3) A) check that a USB connection is not used for communication in a Primary Docking Station. B) If multiple docking stations are used, make sure not to mix docking stations labelled PDS+/SDS+ with unlabeled docking stations. 4) Check that two primary stations aren't docked together. 5) A) Check the electrical connections. The LED on the docking station should give either a stable green light or a flashing green light. B) If multiple docking stations are used, make sure not to mix docking stations labeled PDS+/SDS+ with unlabeled docking stations. 6) Check the electrical connection. The LED on the docking station should give either a stable green light or a flashing green light. If problems remain, contact distributor.
Analyzer not charged	No charging of the battery.	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.

Empty cuvette*	1) The cuvette is empty. Empty cuvette function captures primarily empty cuvettes, not under-filled cuvettes. 2) No chemical reaction is identified in the blood-filled cuvette. *this error code is only displayed in HemoCue Glucose 201 DM analyzer and HemoCue Glucose 201 DM RT analyzer	1-2) Fill a new cuvette and perform a measurement as described in relevant sections of Instructions for Use. 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.
Unexpected patient or control results	Patient or control samples 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. 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 Control Samples 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.	Patient or control samples 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. 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. Control Samples 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.

APPENDIX 2
PROFICIENCY TESTING

Background:

Proficiency testing is performed on samples from external sources. The expected value is unknown to the site that is performing the analysis. The purpose of the test is to ensure that the systems enrolled in the proficiency testing all have the same level of calibration.

Procedure: Follow the steps below to process an EPT sample.

NOTE: Follow SOP 140-10-20 first to register the survey samples.

Step:	Action:
1	Press the Proficiency Test button in the QC Test options display.
2	Fill a cuvette with the survey sample.
3	Place the cuvette in the cuvette holder and gently insert it into the measuring position.
4	Enter the cuvette batch number of the cuvette used via text, numeric or barcode scanner.
5	Enter the specimen ID of the sample and then press the **CONFIRM** button.

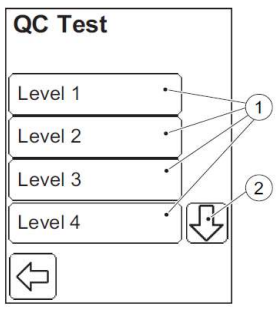


FIGURE 6-6

There are 7 QC Test options (1):

- Level 1 (See *6.2.1 QC Tests at a specific concentration level*)
- Level 2
- Level 3
- Level 4
- Level 5
- Linearity (see *6.2.2 Linearity Test*)
- Proficiency (see *6.2.3 Proficiency Test*)

a) View options (1) not initially visible by pressing the Scroll bar arrow (2).

b) Select a QC Test option by pressing it.

Level 1, Level 2, Level 3, Level 4 and Level 5, refer to the different concentration levels of Liquid Controls used in QC tests. The procedure for performing a QC test is the same for all the concentration levels. Therefore only one, Level 1, is described.

1 QC Test options
2 Scroll bar arrow

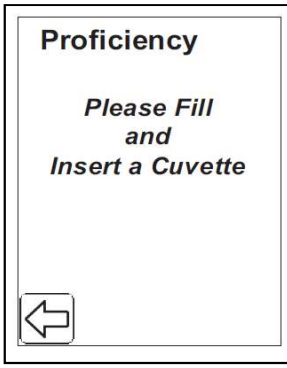


FIGURE 6-27

a) To perform a Proficiency Test, press the Proficiency button in the QC test options display, see *FIGURE 6-6*.

b) Fill a Cuvette with the proficiency sample.

c) Place the Cuvette in the Cuvette holder and gently insert it into the measuring position.
FIGURE 6-28 will be displayed.

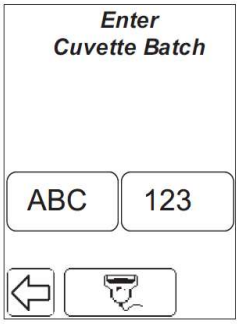


FIGURE 6-28

d) Enter the Cuvette Batch No. of the Cuvette used, either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.
FIGURE 6-29 will be displayed.

If the Cuvette Batch No. requirement is set to *Approved only* (see *3.4.1 General Settings*), and a Cuvette Batch No. that was not previously stored in the Analyzer (see *3.2.2 Cuvette Batches*) is entered, or the Cuvette Batch has expired, the following text will be displayed:
Invalid Cuvette Batch.

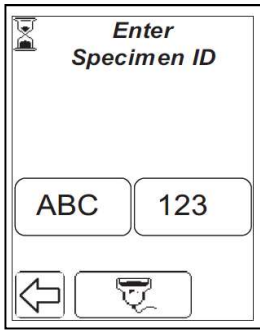


FIGURE 6-29

The Specimen ID is the ID of the proficiency sample.

e) Enter the Specimen ID either directly on the Display via the Text mode and Numeric mode buttons, or with the Barcode Scanner via the Barcode Scanner button.
When finished, *FIGURE 6-30* will be displayed.

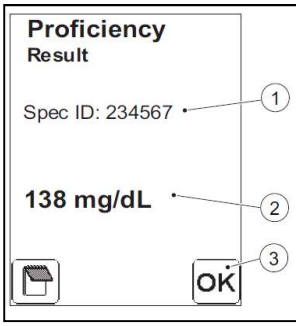


FIGURE 6-30

f) Press the Confirm button (3) to return to *FIGURE 6-27*.

1 Specimen ID
2 Test Result
3 Confirm button

APPENDIX 3

REVIEWING QUALITY CONTROL DATA

Step:	Action:
1	Press the QC Test button in the Review menu (Go to Stored Data menu)

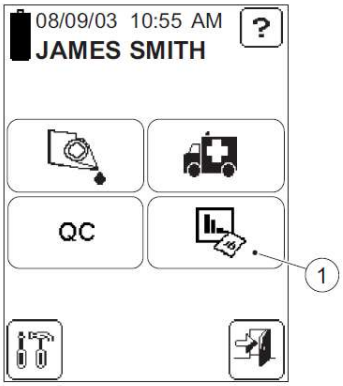


FIGURE 7-1

Access to the Stored Data functions is dependent on the operator's user level and on the existing requirement for an Operator ID. Only a Supervisor can delete data, change an accepted or rejected result or add comments.

a) In the Main Menu, press the Stored Data button (1).

b) If the entry requirement for an Operator ID is set to "Not Used" (see *3 Settings*), *FIGURE 7-2* will be displayed, as this is a password protected function.

Otherwise the Analyzer can respond in two different ways:

If the operator's user level does not permit access to the Stored Data (see *FIGURE 3-22*), *FIGURE 7-3* will be displayed.
If the operator's user level permits access to the Stored Data, *FIGURE 7-4* will be displayed.

1 Stored Data button

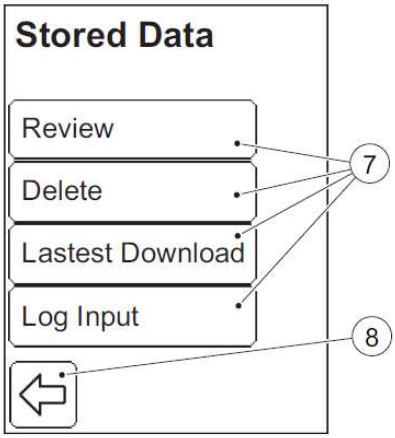


FIGURE 7-4

The following options are displayed:

- Review (see *7.2 Review Stored Data*)
- Delete (see *7.3 Delete Stored Data*)
- Latest Download (see *7.4 Review Latest Download*)
- Log Input (see *7.5 Log Input*)

The Stored Data options (7) are explained in the pages that follow.

f) Select an option by pressing it.

g) To return to the previous image, press the Previous image button (8).

7 Stored Data options
8 Previous image button

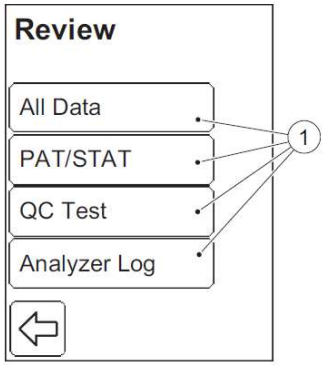


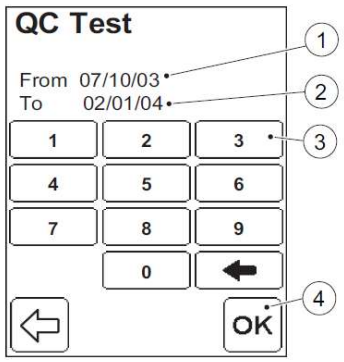
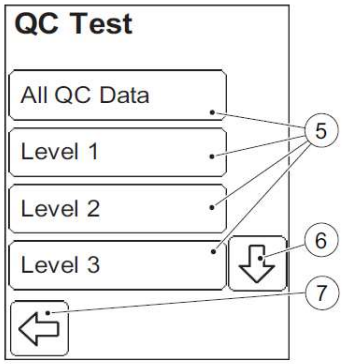
FIGURE 7-5

When the Review button is pressed in the Stored Data menu (see *FIGURE 7-4*), the following options are displayed:

- All Data (see *7.2.1 Review All Data*)
- PAT/STAT (see *7.2.2 Review PAT/STAT*)
- QC Test (see *7.2.3 Review QC Tests*)
- Analyzer Log (see *7.2.4 Review Analyzer Log*)

a) Select an option by pressing it.

1 Review option buttons

	 FIGURE 7-9 Press the QC Test button in the Review menu, *FIGURE 7-5*. The From date (1) and To date (2) displayed represent the earliest and latest stored QC tests. It is possible to change the date interval. If no change is required, press the Confirm button (4). *FIGURE 7-10* will then be displayed. a) If required, change the From date (1) via the Digit buttons (3). When finished, press the Confirm button (4). b) Repeat instruction "a)" to change the To date (2). c) *FIGURE 7-10* will be displayed. 1 From date 2 To date 3 Digit button 4 Confirm button
2	Figure 7-9: The **From** Date (1) and **To** Date (2) displayed represent the earliest and latest stored QC tests. It is possible to change the date interval. If no change is required, press the **Confirm (OK)** button. If the date must be changed, use the numeric buttons to do so and then press the **Confirm (OK)** button.
3	Choose the correct level of QC that you wish to review by using the scroll down arrow and selecting the category.
4	All QC tests within that category and date interval will be available for review. The latest test is displayed first.  FIGURE 7-11 The categories Level 1, Level 2, Level 3, Level 4 and Level 5, refer to the different concentration levels of Liquid Controls used in a QC test. Linearity and Proficiency define other types of tests. The procedure for reviewing QC Tests is the same for all the concentration levels. Therefore only one, Level 1, is described. a) To view categories not initially visible, press the Scroll bar arrow (6). b) Select a category by pressing it. c) All QC tests within the selected category and the defined date interval will be available for review. The latest test is displayed first. For Level 1, Level 2, Level 3, Level 4 and Level 5 see *FIGURE 7-12*. For Linearity see *FIGURE 7-15*. For Proficiency see *FIGURE 7-17*. If no data within the date interval is found, the following message will be displayed: *No Records Found* The Previous image button (7) must be pressed to return to the QC Test categories image, *FIGURE 7-10*. 5 QC categories 6 Scroll bar arrow 7 Previous image button
5	If no data is available for the date interval input, the following message will display: **No Results Found.** The back arrow (Previous Image button) must be pressed to return to the QC Test category display screen.
6	To browse through all available records instead of date dependent ones, use the scroll bar arrows.

7	A graphic presentation of the most recent QC tests can also be viewed by pressing the **Statistics** button.
8	To return back to the QC Test category menu, press **Confirm (OK).**

To Set up a New Lot # of Controls:

Step:	Action:
1	Select settings → Define lists → Liquid controls → Add
2	Select the level
3	Scan the package insert barcode
4	Set the warning min and max value to the package insert ranges
5	Run the new lot of controls prior to routine use to confirm they are acceptable. Record on QC log.

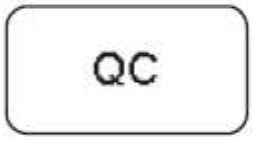
APPENDIX 4

DISPLAY BUTTONS AND SYMBOLS

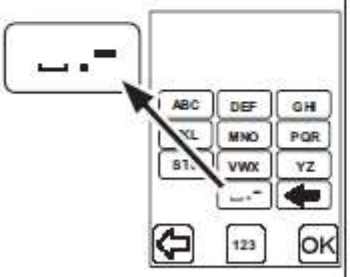
Navigation Buttons:

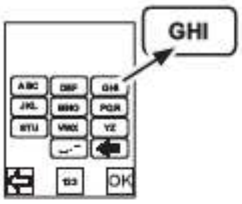
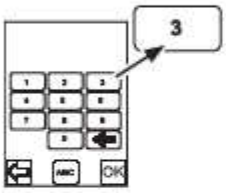
Button	Designation	Function
	Erase button	Erases the last input.
	Previous image button	Returns to the previous image Note that Inputs/changes made in the current image will not be saved.
	Text mode button	Switches to text input mode.
	Numeric mode button	Switches to the numeric input mode.
	Barcode 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.

Procedure Buttons:

Button	Designation	Function
	Patient test button	Activates the Patient Test procedure.
	STAT test button	Activates the STAT (Short Turn Around Time) Test procedure.
	QC test button	Activates the QC (Quality Control) Test procedure.
	Stored data button	Activates the Stored Data function.
	Settings button	Activates the Settings menu.
	Verify/Duplicate sampling button	Allows for the performance of a second test, on the same patient, using a new Cuvette, without the need for re-entering the Patient ID and other information.
	Comment input button	Allows a comment to be added to the current result.
	Comment input button (dotted)	Button appearance confirms that comments have been added to the result.

Other Display Buttons:

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.
	See above	Space – press once
	See above	Period – press twice
	See above	Hyphen – press three times
	View button	Provides a more detailed description of the highlighted item.

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.
	Dilution button*	Allows measurement of a diluted sample. The Dilution button is only displayed if activated in the Settings menu. **only applicable for HemoCue Glucose 201 DM Analyzer* *The Dilution function is not available in all markets.*
Add	Add button	Allows addition of a comment to a result, an item to a list, etc.
Delete	Delete button	Allows deletion of a comment from a result, an item from a list, etc.
Accept	Accept button	Accepts a result. An accepted result will be saved and flagged as accepted.

Button	Designation	Function
Reject	Reject button	Rejects a result. A rejected result will be saved and flagged as rejected.
Save	Save button	Stores the entered information.
No	No button	The entered information will not be stored.
Continue	Continue button	Continues the current operation.
	Statistics button	Displays statitics on the chosen subject.
	Date format button	Switches between the following date formats: • YYMMDD • DD.MM.YY • MM/DD/YY
	Time format button	Switches between the following time formats: • 12 hours • 24 hours
AM/PM	AM/PM button	Enables adding "AM/PM" (only 12-hour format)

Display Symbols:

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.
	Waste bin	Indicates that a result has been rejected. The result is stored in the Analyzer.
	QC Reminder	Reminder that a QC Test will be required within stated time or number of measurements.
	QC Lockout	QC Lockout, i.e. no more Patient Test measurements can be made. The required QC Test has not been performed.
	Lockout	Supervisory Lockout The Analyzer has been locked by the Supervisor.

APPENDIX 5

ANALYZER SET-UP

Technical Support:

Phone #: 1-800-426-7256

Email: technicalsupport@hemocue.com

Password:

Default Password: 0000

Master Operator ID: SUPERVISOR

- Settings → Advanced Settings → General Settings → Operator ID → Change to 'Entry Required'
- Settings → Advanced Settings → General Settings → Cuvette Batch → Change to 'Approved Only'
- Settings → Advanced Settings → QC Test → Level 1, 2 and 3 → 'Not Used'
- Settings → Basic Settings → Date/Time → Change as appropriate
- Settings → Basic Settings → Power Save → Change to 30 minutes
- Settings → Basic Settings → Audible Signals → Button Click → Volume 4
- Settings → Define Lists → Define Operators → Add operators as required – (Supervisors)
- Settings → Define Lists → Cuvette Batches → Add as required
- Settings → Define Lists → Liquid Controls → Add as required
    - Add → Level → Scan package insert barcode

Settings may be transferred between analyzers using Infrared transfer. See section 3.6 of user manual.