

Document History:

Title: HemoCue® WBC System

Site(s): All Applicable Sites

Document #:	140-170-04	Version:	6
Section:	Hematology	Sub-section:	POCT Laboratory

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

Details of Recent Revision

- Addition of LIS Worklist
 - Update to Policy regarding confirmatory testing
 - Addition to Related Procedures
-

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HemoCue® WBC System

Purpose: To provide instructions for using the HemoCue WBC System for WBC testing.

Policy: The system is indicated for use for quantitation determination of white blood cell (WBC) count in capillary or venous whole blood.

The system is factory calibrated and requires no further calibration.

Results displaying LLL or HHH will require confirmatory testing at a hematology site.

Materials:

Reagents:	Supplies:	Equipment:
<ul style="list-style-type: none"> Alcohol (20 – 70%) Mild detergent 	<ul style="list-style-type: none"> HemoCue® WBC microcuvettes HemoCue® WBC Cleanser Lancet Gauze/lint-free wipes Alcohol wipes Glass slides 	<ul style="list-style-type: none"> HemoCue® WBC analyzer Printer Cable

Sample:

- Capillary finger poke
- Venous (EDTA) sample
- The microcuvette accepts 10 uL of blood sample
- Specimen must be mixed thoroughly 10 – 20 times by hand inversion prior to use and store at room temperature (15 – 35°C) or in a refrigerator (2 – 8°C) for 48 hours. If the specimen is refrigerated, bring to room temperature before mixing.

Special Safety

Precautions: As per Routine Practices (Standard Precautions). Mandatory use of gloves and safety glasses.

Storage and Handling:

Microcuvettes:

- Store at 15 - 35°C with < 90% humidity
- Unopened package can be used until expiration date printed on the package
- Opened vial is stable for 3 months once seal is broken
- Keep vial properly closed and unused microcuvettes should remain in the original package.

HemoCue® WBC Analyzer:

- Do NOT use analyzer close to portable communication devices
- Store between 0 - 50°C, < 90% humidity
- Operating temperature is 15 - 35°C, < 90% humidity
- Analyzer must reach room temperature before use

Quality Control:

- Currently, no HemoCue® WBC controls are available for use in Canada.
- Monthly CBC samples (<24 hours old) must be sent from a nearby site to the laboratory using the HemoCue® WBC analyzer. The receiving site will perform a WBC test on the CBC sample to compare the WBC. Results must compare to within 15%.

Self-Test: The analyzer has an internal quality control “self-test” which automatically verifies the measurement performance when the unit is turned on.

If:	Then:
The self-test passes,	The screen will show the HemoCue® symbol and the flashing dashes indicating the unit is ready.
The self-test fails,	An error code will be displayed on the screen

The self-test also performs several condition checks of the HemoCue® WBC microcuvette and the sample itself. The operator’s ability to handle the microcuvette and apply the sample properly is also included in the self-test.

Accessioning: Register the test in Delphic:

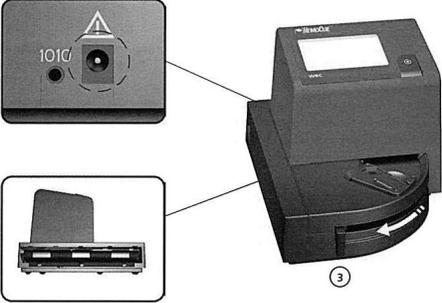
- Test code is **IWBC** (POCT WBC)
- Document LIS sample number onto test requisition

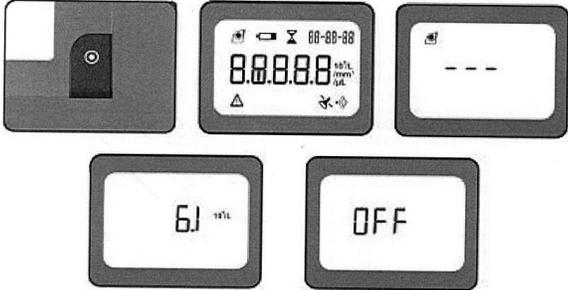
If:	Then:
Test performed by non-DSM laboratory staff,	Order test code POCT (Test performed by non-laboratory personnel)

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).

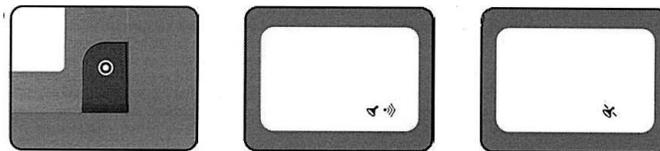
Procedure A: Follow the activities in the table below to start-up the analyzer.

Step:	Action:						
1	Remove the analyzer and ensure the unit remains on a stable surface. <div style="text-align: center;">  </div>						
2	<table border="1"> <thead> <tr> <th>If:</th> <th>Then:</th> </tr> </thead> <tbody> <tr> <td>AC power is available,</td> <td>Plug the adapter into the power outlet at the back of the analyzer.</td> </tr> <tr> <td>Power is not available,</td> <td> Insert 6 type AA batteries, 1.5 v. To open the battery lid on the left side of the unit: <ul style="list-style-type: none"> • Press on the ribbed marking engraved on the battery lid and slide it backwards until it opens. • Gently take out the battery holder; put batteries in. • Place according to the indicated polarity • Replace the holder back into the battery compartment. • Close the lid. </td> </tr> </tbody> </table>	If:	Then:	AC power is available,	Plug the adapter into the power outlet at the back of the analyzer.	Power is not available,	Insert 6 type AA batteries, 1.5 v. To open the battery lid on the left side of the unit: <ul style="list-style-type: none"> • Press on the ribbed marking engraved on the battery lid and slide it backwards until it opens. • Gently take out the battery holder; put batteries in. • Place according to the indicated polarity • Replace the holder back into the battery compartment. • Close the lid.
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3	Pull the cuvette moving arm out of the loading position.
4	<p>Press and hold the button until the screen is activated and all symbols appear.</p> <div style="text-align: center;">  </div>
5	The analyzer will perform a self-test and after ten (10) seconds, the screen will show three (3) flashing dashes and the HemoCue® symbol. The analyzer is ready to use.
6	To turn off the analyzer, press and hold the button until the screen reads "Off" and then goes blank. If the analyzer is operating on battery power, and is not being used, it will automatically turn off after five (5) minutes, but if on AC power, it will take two (2) hours.

Procedure B:
Audible
Signal

Follow the activities in the table below to activate the audible signal. If activated, a signal will be heard when the measurement is completed or if an error code is displayed.

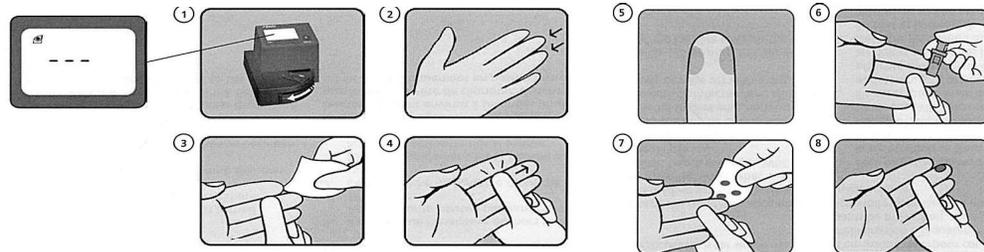


Step:	Action:
1	To activate/deactivate audible signal: <ul style="list-style-type: none"> • Ensure analyzer is turned off. • Press the button for ten (10) seconds <ul style="list-style-type: none"> ○ The screen will show a flashing bell symbol • Press the button rapidly to change between signal on and off.
2	When the setting is complete, press the button for three (3) seconds until the bell stops flashing. The analyzer will return to the ready mode.

Procedure C:
Measuring
Capillary
Blood

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

Note: Always handle blood specimens with care as they could be infectious.

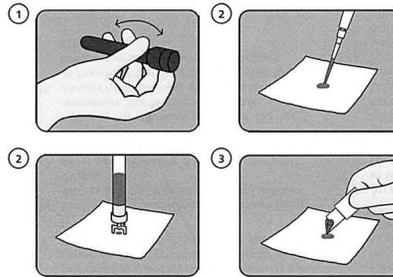


Step:	Action:
1	The cuvette moving arm should be in the loading position. The screen will show three flashing dashes and the hemocue symbol. Take a HemoCue WBC microcuvette from the vial.
2	Ensure patient's hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.
3	Clean fingertip with disinfectant and allow to dry completely or wipe off with a dry, lint-free wipe.
4	Using your thumb, lightly press the finger from the top of the knuckle towards the tip.
5	Sample at the side of the fingertip.
6	After applying light pressure towards the fingertip, puncture the finger using a lancet.
7	Wipe away the first 2-3 drops of blood.
8	Re-apply light pressure towards the fingertip until another drop of blood appears.
9	When drop of blood is large enough, fill the microcuvette in one continuous motion. DO NOT REFILL. Ensure the microcuvette is filled from the tip, placed at about a 45-degree angle towards the blood drop.
10	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.

11	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.						
12	The result is obtained in three (3) minutes.						
13	If results are unexpected or unacceptable, repeat the test to ensure pre-analytical factors are not the cause. Poke a second finger.						
14	<p>If results are over 30.0, the measuring range will display as "HHH".</p> <table border="1" data-bbox="500 552 1546 1108"> <thead> <tr> <th data-bbox="500 552 792 590">If:</th> <th data-bbox="792 552 1546 590">Then:</th> </tr> </thead> <tbody> <tr> <td data-bbox="500 590 792 863">WBC is > 30.0 (HHH)</td> <td data-bbox="792 590 1546 863"> <ul style="list-style-type: none"> • Report G30 • In ICOM comment, insert &WBCEP (Preliminary result. WBC count is greater than 30.0. Venous sample is being sent to reference lab for confirmatory testing.) • Draw venous sample and send to reference site for confirmatory testing of WBC. </td> </tr> <tr> <td data-bbox="500 863 792 1108">WBC displays LLL</td> <td data-bbox="792 863 1546 1108"> <ul style="list-style-type: none"> • Place *&DEL in the IWBC box • In ICOM Comment, report "Preliminary result. WBC is less than 0.3. Venous sample is being sent to reference lab for confirmatory testing.) • Draw venous sample and send to reference site for confirmatory testing of WBC. </td> </tr> </tbody> </table>	If:	Then:	WBC is > 30.0 (HHH)	<ul style="list-style-type: none"> • Report G30 • In ICOM comment, insert &WBCEP (Preliminary result. WBC count is greater than 30.0. Venous sample is being sent to reference lab for confirmatory testing.) • Draw venous sample and send to reference site for confirmatory testing of WBC. 	WBC displays LLL	<ul style="list-style-type: none"> • Place *&DEL in the IWBC box • In ICOM Comment, report "Preliminary result. WBC is less than 0.3. Venous sample is being sent to reference lab for confirmatory testing.) • Draw venous sample and send to reference site for confirmatory testing of WBC.
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15	Discard the microcuvette into an autoclave bag and the lancet into a sharp's container.						

Procedure D: Follow the activities in the table below to measure venous samples.

Measuring Venous Samples

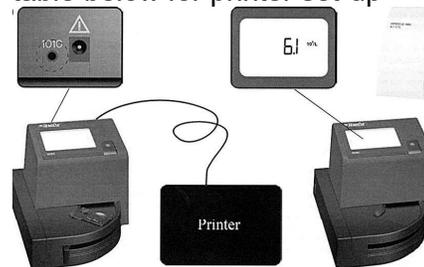


Step:	Action:
1	If the venous blood samples have been stored in a refrigerator (2 – 8 °C), allow it to warm up to room temperature (15 – 35 °C) before mixing. Mix the venous sample tubes thoroughly by inverting the tube 10 – 20 times by hand.
2	Place a drop of blood onto a hydrophobic plastic or glass slide, using a pipette.
3	Fill the microcuvette in one continuous motion. DO NOT REFILL. Make sure that the microcuvette is filled from the tip, placed at about a 45-degree angle towards the blood drop.
4	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.
5	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.
6	Gently push cuvette holder tap to allow magnetic closure of cuvette holder.
7	The result is obtained in three (3) minutes.
8	If results are unexpected or unacceptable, repeat the test to ensure pre-analytical factors are not the cause.

9	<table border="1" style="width: 100%;"> <tr> <th style="text-align: left;">If:</th> <th style="text-align: left;">Then:</th> </tr> <tr> <td>WBC is > 30.0,</td> <td> <ul style="list-style-type: none"> • Report G30 • In ICOM comment, insert &WBCP (Preliminary result. WBC count is greater than 30.0 Venous sample is being sent to reference lab for confirmatory testing.) • Send venous sample to reference site for confirmatory testing of WBC. </td> </tr> <tr> <td>WBC displays LLL</td> <td> <ul style="list-style-type: none"> • Place *DEL in the IWBC box • In ICOM Comment, report "Preliminary result: WBC is less than 0.3. Venous sample is being sent to reference lab for confirmatory testing.)" • Send venous sample to reference site for confirmatory testing of WBC. </td> </tr> </table>	If:	Then:	WBC is > 30.0,	<ul style="list-style-type: none"> • Report G30 • In ICOM comment, insert &WBCP (Preliminary result. WBC count is greater than 30.0 Venous sample is being sent to reference lab for confirmatory testing.) • Send venous sample to reference site for confirmatory testing of WBC. 	WBC displays LLL	<ul style="list-style-type: none"> • Place *DEL in the IWBC box • In ICOM Comment, report "Preliminary result: WBC is less than 0.3. Venous sample is being sent to reference lab for confirmatory testing.)" • Send venous sample to reference site for confirmatory testing of WBC.
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10	Discard the microcuvette into an autoclave bag.						

**Procedure E:
Printer Set-Up**

Follow the activities in the table below for printer set-up



Step:	Action:
1	Only the current WBC result can be transferred to the printer directly after the measurement.
2	Connect the cable to the analyzer and the printer before performing the analysis.
3	Perform the analysis.
4	When the result is shown on the screen, it will print automatically.
5	The settings are: Baud Rate: 9600 Databits: 8 Parity: None Stopbits: 1 Flow control: None

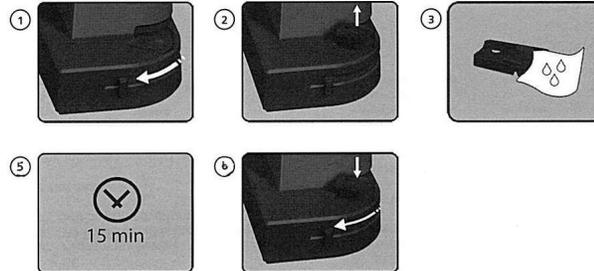
Result

Reporting:

- Document WBC Result into Delphic by inserting POCT WBC value from printer tape into **IWBC** slot on **ICBC** format
- Double check WBC value inserted for transcription errors prior to result release.
- Document any comments in ICOM comment area on ICBC format
- Complete documentation on the ICBC worksheet and file.

Maintenance:

Follow the activities in the table below to clean the cuvette holder after each day of use. Cuvette holder is stored in the closed position when not in use.



Daily:

Step:	Action:
1	Must be cleaned after each day of use
2	Turn the analyzer off and place the cuvette moving arm in the loading position.
3	Remove cuvette holder by lifting it straight up.
4	Clean the cuvette holder with alcohol (20 – 70%) or mild detergent. DO NOT AUTOCLAVE. Do not spray cleaning products directly onto analyzer.
5	If the optical parts get stained an error code is displayed.
6	Wait 15 minutes prior to replacing the cuvette holder.
7	Place the cuvette moving arm in loading position before replacing the cuvette holder.

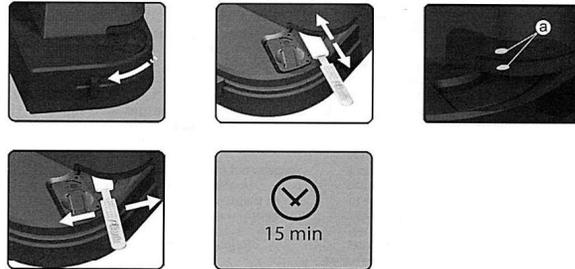
Weekly:

Follow the activities in the table below to clean the cover of the unit.

Step:	Action:
1	Clean the cover with alcohol (20-70%) or a mild detergent. Do not spray cleaning products directly onto analyzer.

Monthly:

Follow the activities in the table below to clean the optical parts of the WBC analyzer monthly or sooner if an error code is displayed on the screen.



Step:	Action:
1	Turn the analyzer off and place the cuvette moving arm in the loading position, leaving the cuvette holder in place.
2	Hold the analyzer with the HemoCue logo facing upwards. Push the cleaner as far as possible into the opening of the optic unit.
3	Move back and forth along the cuvette holder 5-10 times. The optical parts are placed on the left of the opening. Move the cleaner alongside of the cuvette holder to get the right angle for cleaning the optical parts.
4	Move from side to side 5-10 times. If cleaner is stained, repeat the process using a new cleaner.
5	Wait 15 minutes before performing any testing.

Expected Values:

Adults:	4.0 – 10.0 x 10 ⁹ /L
Children (1 yr):	6.0 – 16.0 x 10 ⁹ /L
Children (2 – 6 yrs):	5.0 – 15.0 x 10 ⁹ /L
Children (6 – 12 yrs):	5.0 – 13.0 x 10 ⁹ /L
Infant (1 mo):	5.0 – 19.0 x 10 ⁹ /L
Infant (2 mo):	5.0 – 15.0 x 10 ⁹ /L
Infant (3 – 6 mo):	6.0 – 18.0 x 10 ⁹ /L

These values may vary due to a variety of factors such as gender, exercise, pregnancy, food, smoking, and trauma.

Interpretation/ Critical Values:	Test	Result	Encounter
		WBC	≤ 2.0 or $> 30 \times 10^9/L$

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:

Displayed range: $0.3 - 30.0 \times 10^9/L$
 Results above the measuring range will be displayed as “HHH”
 Results below the measuring range will be displayed as “LLL”
 Confirmatory testing required for any HHH or LLL results.

Limitations:

1. The measurement of the WBC sample must be started no later than one minute after filling the microcuvette.
2. Do NOT remeasure the filled microcuvette.
3. Mixing samples for an extended period may affect the result
4. Results above the measuring range will be displayed as “HHH”
Results below the measuring range will be displayed as “LLL”
5. Studies have shown that patient samples with $> 2\%$ nucleated red blood cells (NRBC's) may give falsely elevated white blood cell count.

References:

HemoCue® WBC Operating Manual

Related Documents:

Form F100-140-04: HemoCue/i-STAT Requisition/ Report
 Form F140-170-03B: HemoCue® Maintenance Log
 Job Aid JA100-140-04: HemoCue WBC system

Appendixes:

Appendix 1: Troubleshooting Guide

Procedural Note:

Procedural Note #1:

Principle:

A hemolyzing agent lyses the red cells in the microcuvette and a staining agent colors the white cells. An image is taken of the stained white cells and the number of cells is counted by image analysis in the analyzer.

The microcuvette serves as a sample and reaction container. A blood sample ($10 \mu L$) is drawn into the cavity by capillary action and then the microcuvette is placed into the analyzer.

Procedural Note #2:
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 ticker tape onto the QC log (if this is what the site wants to use), place the ticker tape onto a plain white piece of paper, scan the image into the computer and keep it in a QC file folder with month and year for easy retrieval. The original ticker tape results can then be discarded after it is confirmed that the results have been captured in the computer file. After the 2-year mark, the oldest information can be deleted month by month as time progresses. If one wishes to keep the results in paper format, then photocopy the image of the paper with the results on it and place in a binder under month and year. The issue is that the ticker tape will fade and disappear over time and is useless in less than one year, which doesn't meet accreditation policy.

Procedural Note #3:
When Confirmatory Testing Can't be Sent to Referral Site

This scenario might occur in some of our sites because: a) techs might 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
Err01	A portion of the image area is unable to be analyzed. 1. Due to measurement error. 2. Due to abnormal sample.	1. Take a new microcuvette and repeat the measurement, as described in the Measuring section. 2. NOTE! The blood sample should be verified with a suitable laboratory method and be questioned as to the pathological condition of the patient.
Err02	Uneven spatial distribution of detected cells.	Take a new microcuvette and repeat the measurement, as described in the Measuring section.
Err03	Image, or part of the image area is detected as out-of-focus.	Take a new microcuvette and repeat the measurement, as described in the Measuring section.
Err30	1. Optical parts dirty. 2. Optical parts wet after cleaning.	1. Turn off the analyzer and clean the optical parts as described in the Maintenance section. 2a. Wait 15 minutes before turning on the analyzer after cleaning to make sure that the optical parts are dry. 2b. If the problem continues, the analyzer needs service. Contact your local distributor.
Err33	Empty microcuvette, not filled with sample.	Take a new microcuvette and repeat the measurement, as described in the Measuring section and make sure that the microcuvette is filled with sample.
Err34	Stray light detected.	a. Turn off the analyzer and make sure the analyzer is not exposed to any bright light sources. b. If the problem continues, the analyzer needs service. Contact your local distributor.
Err35	The battery power is too low.	Turn off the analyzer. a. Replace the batteries, six type AA, as described in the Start Up section. b. Use the power adapter as described in the Start Up section.
Err60	General hardware error.	a. Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement, as described in the Measuring section. b. If the problem continues, the analyzer needs service. Contact your local distributor.
Err61	Self test error during start up of analyzer.	a. Turn off the analyzer and turn it on again after 30 seconds. Take a microcuvette and perform the measurement, as described in the Measuring section. b. If the problem continues, the analyzer needs service. Contact your local distributor.
Err62	1. Blanking test failed. 2. Optical parts dirty	1. Turn off the analyzer and turn it on again after 30 seconds. Take a new microcuvette and repeat the measurement, as described in the Measuring section. 2a. Turn off the analyzer and clean the optical parts as described in the Maintenance section. 2b. If the problem continues, the analyzer needs service. Contact your local distributor
WbC	Empty cuvette holder.	Take a microcuvette and perform the measurement, as described in the Measuring section.
LLL	1. Measured value is below $0.3 \times 10^9/L$ ($300/mm^3$, $300/\mu L$). 2. Empty microcuvette, not filled with sample.	1. NOTE! Results exceeding the LLL limit should be verified with a suitable laboratory method and be questioned as to the pathological condition of the patient. 2. Take a new microcuvette and repeat the measurement, as described in the Measuring section and make sure that the microcuvette is filled with sample.
HHH	Measured value exceeds $30.0 \times 10^9/L$ ($30000/mm^3$, $30000/\mu L$).	NOTE! Results exceeding the HHH limit should be verified with a suitable laboratory method and be questioned as to the pathological condition of the patient.

Symptom	Explanation	Action
No characters on the display.	<ol style="list-style-type: none"> 1. Power is not received. 2. If on battery power, the batteries need to be replaced. 3. The display is out of order. 	<ol style="list-style-type: none"> 1a. Check that the power adapter is properly connected to the analyzer and the AC power supply, as described in the Start Up section. 1b. Check that the cable is not damaged. 2. Replace the batteries, six type AA, as described in the Start Up section. 3. The analyzer needs service. Contact your local distributor.
The display gives erroneous characters.	<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. The analyzer needs service. Contact your local distributor.
The display shows "FIR".	General analyzer software error.	<ol style="list-style-type: none"> a. Remove and replace all cables and/or batteries, and restart, as described in the Start Up section. b. The analyzer needs service. Contact your local distributor.
The display shows "■".	<ol style="list-style-type: none"> 1. The batteries need to be replaced. 2. If on AC power, the power adapter or the circuit board is out of order. 	<ol style="list-style-type: none"> 1. Turn off the analyzer and replace the batteries, six type AA, as described in the Start Up section. 2a. Check that the correct power adapter is used and properly connected and working, as described in the Start Up section. 2b. The analyzer needs service. Contact your local distributor.
The display does not switch from "2" and "WbC" to three flashing dashes and "■" (ready for measuring).	The cuvette holder sensor is out of order.	The analyzer needs service. Contact your local distributor.
The cuvette holder is not moving into the correct position.	The magnet in the cuvette holder is missing.	The analyzer needs service. Contact your local distributor.
Measurement on patient samples are higher or lower than anticipated.	<ol style="list-style-type: none"> 1. Improper sampling technique. 2. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 	<ol style="list-style-type: none"> 1. Take a new microcuvette and repeat the measurement, as described in the Measuring section. 2. Check the expiration date and the storage conditions of the microcuvettes.
Measurement on control materials are out of range, either too high or too low.	<ol style="list-style-type: none"> 1. Improper sampling technique. 2. The microcuvettes are beyond their expiration date, damaged or have been improperly stored. 3. The control material is beyond its expiration date or has been improperly stored. 4. The control material has not been mixed properly and/or is not at room temperature. 5. The control material is not suitable for use with the HemoCue WBC system. 	<ol style="list-style-type: none"> 1. Take a new microcuvette and repeat the measurement, as described in the Measuring section. 2. Check the expiration date and the storage conditions of the microcuvettes. 3. Check the expiration date and the storage conditions of the control material. If the problem continues, contact the manufacturer of the control material. 4. Make sure that the control material is mixed properly and at room temperature. If the problem continues, contact the manufacturer of the control material. 5. Only use controls recommended by HemoCue, see relevant package insert for more information.