HemoCue® WBC DIFF

Operating Manual

HemoCue®

Table of Content

HemoCue® WBC DIFF system

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Thank you for choosing the HemoCue® WBC DIFF system.

The HemoCue WBC DIFF system is an *In-Vitro* diagnostic system designed for quantitative determination of white blood cells (WBC) in capillary or venous whole blood. The system provides values for a total white blood cell count and a differential white blood cell count including neutrophil count, lymphocyte count, monocyte count, eosinophil count and basophil count.

The HemoCue WBC DIFF system is indicated for use in clinical laboratories and for point of care testing in professional health care settings on pediatric (≥ 3 months) and adult patients. The HemoCue WBC DIFF Analyzer is only to be used with HemoCue WBC DIFF Microcuvettes for measurement of a total white blood cell count and a differential white blood cell count or with HemoCue WBC Microcuvettes for measurement of a total white blood cell count only.

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

Components

1. HemoCue WBC DIFF Analyzer
2. AC adapter (country specific)
3. Six type C (LR14/HR14) batteries*
4. HemoCue WBC DIFF Quick Reference Guide
5. a. HemoCue WBC DIFF Microcuvettes*
   b. HemoCue WBC Microcuvettes*
6. HemoCue WBC DIFF Operating Manual
7. HemoCue® Cleaner WBC

Place analyzer and accessories on a rigid surface (non-vibrating).

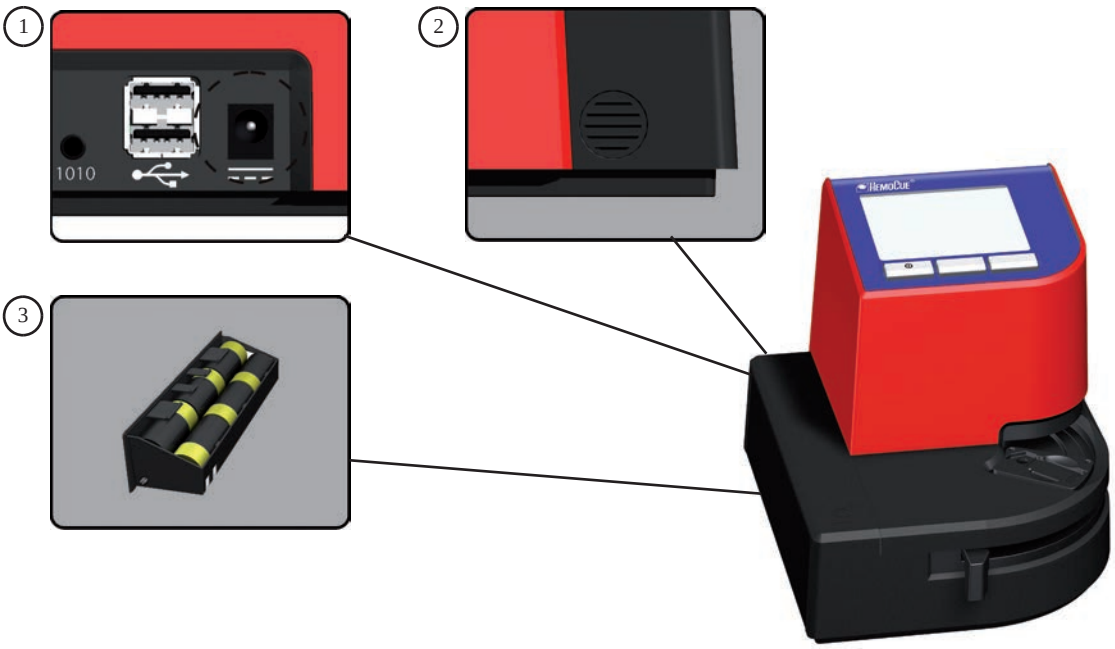
NOTE: Do not open the cover of the analyzer. The warranty is void if the cover of the analyzer is opened.

Only WBC DIFF cuvette holder (marked WBC DIFF) is to be used with the WBC DIFF analyzer.

*Not included.

For infomation about HemoCue WBC DIFF Microcuvettes and HemoCue WBC Microcuvettes, please contact your HemoCue distributor.

Start-Up



 *Only use AC adapters listed under Specifications in the AC Adapters section.*

The analyzer can be powered by either AC adapter or batteries.

Connect the AC Adapter

1. Plug the supplied AC adapter into the power inlet at the back of the analyzer.

Insert Batteries

2. Press the ribbed marked button on the back of the analyzer to open the battery compartment on the left side.
3. Gently take out the battery unit. Insert six type C (LR14/HR14) batteries, 1.5 V. Observe the indication of polarity. Put the battery unit back in the analyzer.

 *Consult local environmental authorities for proper disposal of batteries.*

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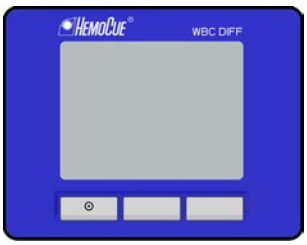
Start the Analyzer

4. Pull the cuvette moving arm out to loading position.
5. Press and hold the left button until the display is activated. A start-up window shows analyzer software version for approximately 15 seconds.
6. The analyzer performs a self test and the hourglass is shown for approximately 30 seconds.
7. The analyzer is ready for use when the main menu is shown.

Turn off the Analyzer

8. Press and hold the left button until the display goes blank.
   The analyzer will automatically turn off when not in use.
   - after 5 min with battery supply
   - after 8 hours with AC adapter

Data Entry & Navigation

1 

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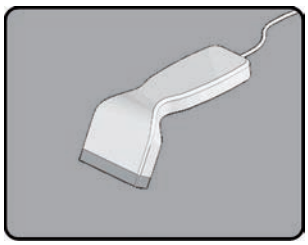
3 

Analyzer buttons

1. The three buttons below the display are for navigating and confirming the choices/symbols displayed above each button. The left button is also for turning on/off.

External keyboard

2. Use the keyboard for data input e.g. Patient ID, Operator ID, Lab ID, Control ID and Site ID. It can also navigate by using F1 for left, F2 for up/down and F3 for right.
   For installation of external keyboard see *Set-Up/Keyboard* section.

External barcode reader

3. Use the barcode reader for data input e.g. Patient ID, Operator ID, Lab ID, Control ID and Site ID.
   For installation of the external barcode reader see *Set-Up/Barcode Reader* section.

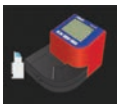
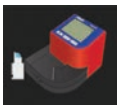
GB Symbols

Navigation Symbols	Designation	Function
	Home	Go to main menu.
	Right	Continue to next number/window.
	Left	Return to previous number/window.
	Up	Scroll up.
	Down	Scroll down.

Navigation Symbols	Designation	Function
	Accept	Accept input.
	Reject	Reject input.
	Switch	Jump between result and data.

Procedure Symbols	Designation	Function
	Patient Test	Go to Patient Test procedure.
	Menu	Go to “Menu” window for Review/Delete/Settings/QC test.
	Review/Delete	Go to “Review/Delete menu” window.
	Review	Go to “Review” window.
	Delete	Go to “Delete Results” window.
	Settings	Go to settings menu.

Display Symbols	Designation	Function
	Connected	Analyzer connected to a PC application.
	Unsent Results	Unsent results stored in the analyzer.
	Accepted	Accepted result.
	Rejected	Rejected result.
	Auto Accepted	Auto accepted result.
	Battery Level	Critical battery level.

Display Symbols	Designation	Function
	Battery Level	Battery level 30%. Battery level indicates 10-100%.
	AC Adapter	Analyzer connected with AC adapter.
	Insert Cuvette	Analyzer ready for measurement. Insert a microcuvette to start measuring.
	Remove Cuvette	Pull the cuvette moving arm to laoding position and remove the cuvettte.
	Measuring	Measuring.
	Hourglass	The analyzer performs a selftest.

Display Symbols	Designation	Function
	Page Number	Current page number/total amount of pages.
	Caution	The results for the WBC differential count are uncertain. The sample may contain pathological, abnormal or unidentified cells. For more information see the *Trouble-shooting Guide* section. The print-out will show an asterisk (*) instead of the display symbol 
	Non-critical Error	An error has occurred. For more information see *Troubleshooting Guide* section.
	Critical Error	A critical error has occurred. For more information see *Troubleshooting Guide* section.

Set-Up Settings

Settings are made in the Set-Up/Settings menu. Use the left button to confirm/accept input and move backwards. Use the right button to confirm/accept input and move forward. The center button scrolls up/downwards and ticks boxes.

1. Turn on the analyzer as described in the *Start-Up* section.
2. Press the right button.
3. Press right button to chose menu and move to next window.
4. Enter PIN Code window is shown. The Pin Code is used to prevent unauthorized users from entering/changing input in the settings menu. As default, the PIN Code is set to 0000. For change of PIN Code see step 19, *Settings* section.
   Enter the PIN code by pressing the center button to change digit. Press right button to confirm the input and move to the next. After entering the four digit PIN Code press right button to accept and move to next window.
5. If the analyzer is configured for USB - window 5a is shown. If the analyzer is configured for ethernet - window 5b is shown. The display shows: Home, Review/Delete and Settings. Press the right button to enter Settings.

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6. Language set up window is shown. Select language by pressing the center button. Press right button to confirm and move forward.
7. Time Zone window is shown. Select Time Zone input by pressing the button below the up arrow. Press the right button to confirm and move forward.
8. Date Format window is shown. Select Date format by pressing the button below the down arrow. Press right button to confirm and move forward.
9. Date input window is shown. Select Date input by pressing the button below the up arrow to change numbers. Press right button to confirm and move to next number. Press right button to confirm and move forward.
10. Time Format window is shown. Select Time format by pressing the button below the down arrow. Press right button to confirm and move forward.
11. Time input window is shown. Set hours by pressing the button below the up arrow. Press right button to confirm the input and move to minutes. Press right button to confirm and move forward.

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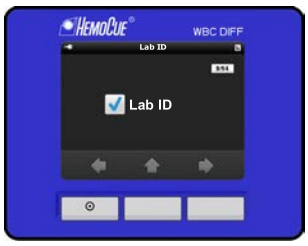

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12. Patient ID window is shown. Select Patient ID on/off by pressing the button below the up arrow. Press right button to confirm and move forward.
13. Operator ID window is shown. Select Operator ID on/off by pressing the button below the up arrow. Press right button to confirm and move forward.
14. Lab ID window is shown. Select Lab ID on/off by pressing the button below the up arrow. Press right button to confirm and move forward.
15. Site ID window is shown. Select Site ID on/off by pressing the button below the up arrow. Press right button to confirm and move forward.
16. Control ID window is shown. Select Control ID on/off by pressing the button below the up arrow. Press right button to confirm and move forward.

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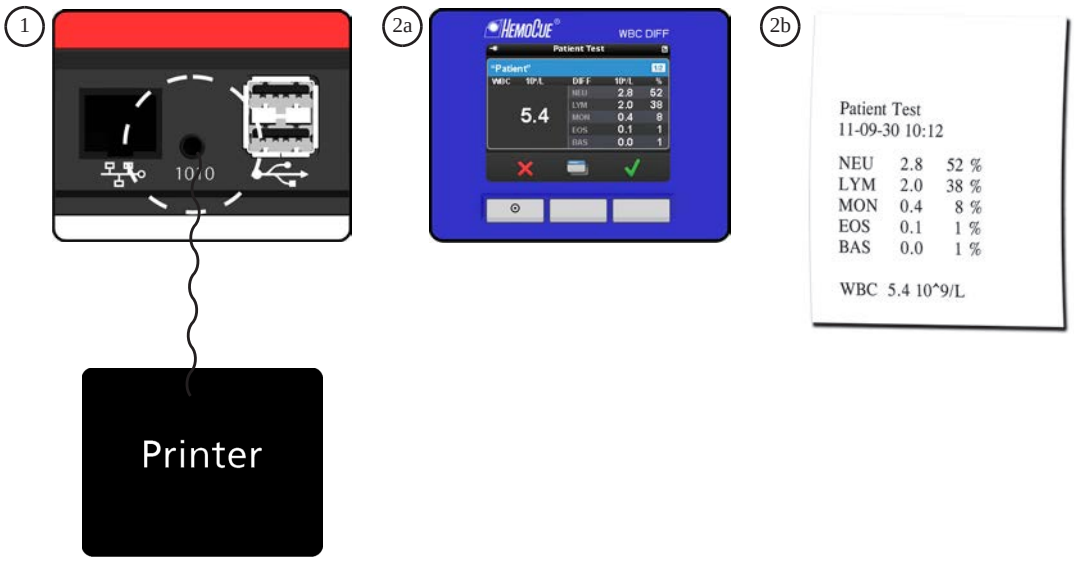
17. Unit window is shown. The results can be presented in
    - absolute numbers together with percentage; 10^9/L, %
    - absolute numbers only; 10^9/L
    - percentage only; %

    Select how to present the result by pressing the button below the down arrow. Press right button to confirm and move forward.
18. Audio Signal window is shown. A soft signal is heard when buttons are pressed, one short signal is heard when a test is ready and a distinct signal is heard when an error has occured. Select Audio Signal on/off by pressing the button below the up arrow. Press right button to confirm and move forward.
19. PIN Code Setting window is shown. Change digits by pressing the button below the up arrow. Press right button to confirm and move to next digit. Press right button to accept the four digit PIN Code.
20. If the PIN Code is changed the Verify Change of PIN Code is shown. Press right button to accept the change. Press left button to reject the change.
21. Main menu is shown.

Set-Up Printer



1. Connect the cable* to the analyzer and ASCII printer* before performing the analysis. Perform the analysis as described in the *Routine Use Patient Test* or *Routine Use QC Test* sections.
2. The result is shown on the display (2a) and will be printed automatically (2b).

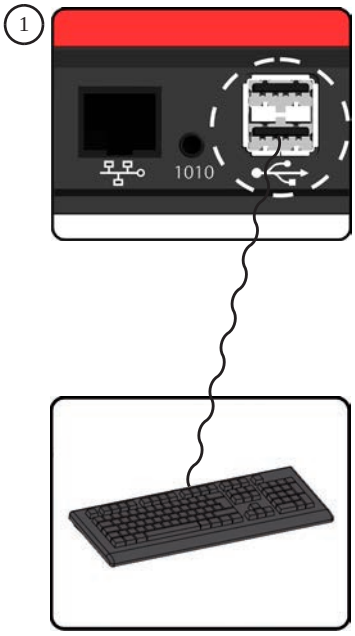
Only current result can be transferred directly to the printer. Stored results can not be printed.

*Must be purchased separately.

Read and follow the printer instructions for use to adjust the following COM-port settings.

- Baud rate 9600
- Databits 8
- Parity None
- Stopbits 1
- Flow control None

Set-Up Keyboard

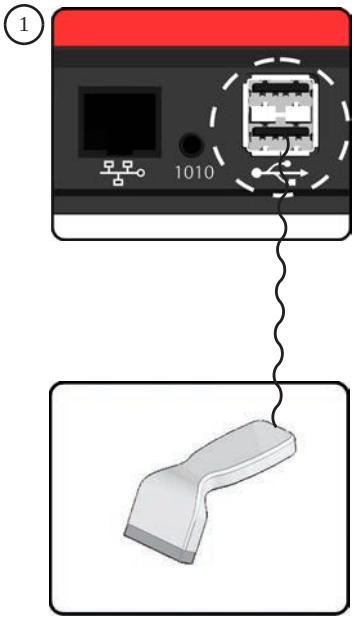


The keyboard can be used for data entry of Patient ID, Operator ID, Lab ID, Control ID and Site ID. To navigate use F1 for left, F2 for up/down and F3 for right.

1. Connect cable from the keyboard* to the USB port connection on the analyzer before performing analysis.

*Must be purchased separately.

Set-Up Barcode Reader



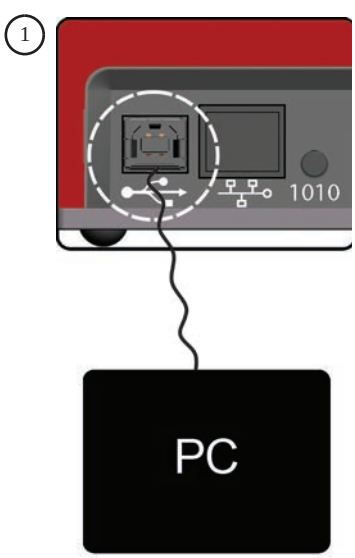
The barcode reader can be used for data entry of Patient ID, Operator ID, Lab ID, Control ID and Site ID

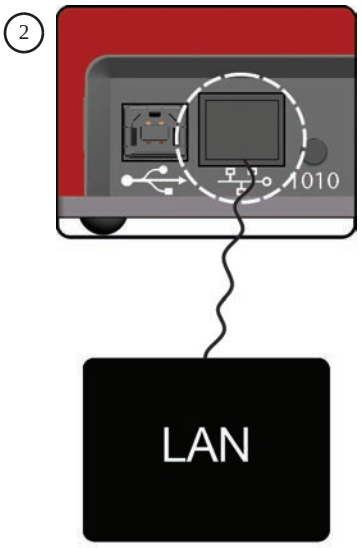
1. Connect cable from the barcode reader* to the USB port connection on the analyzer before performing analysis.

For barcode reader settings refer to barcode reader operating manual.

*Must be purchased separately.

Set-Up Connectivity





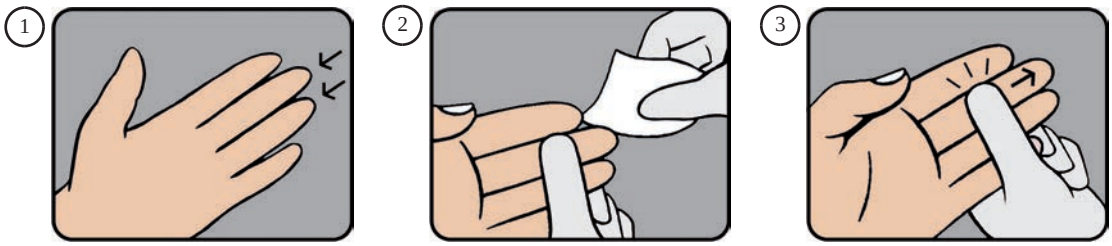
The analyzer can be connected to a PC/Server for transfer of data via USB cable* or LAN cable*.

1. Connection via USB: Connect cable* from the PC* to the USB B connection on the analyzer.
2. Connection via LAN: Connect cable* from the LAN port to the LAN connection on the analyzer.

The data is sent according to the POCT1-A standard. For more information about the connectivity and how to configure the IP address settings when connecting via the LAN port, please contact HemoCue AB.

*Must be purchased separately.

Blood Collection Capillary Sample



⚠ *Important! Always handle blood specimens with care, they might be infectious. Consult local environmental authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvette is for single use only.*

For measuring procedure see *Routine Use/Patient Test* section.

1. Make sure the patient's hand is warm and relaxed. Use only the middle or ring finger for sampling. Avoid fingers with rings on.
2. Clean fingertip with disinfectant and allow to dry completely or wipe off with a dry, lint-free wipe.
3. Using your thumb, lightly press the finger from the top of the knuckle towards the tip.

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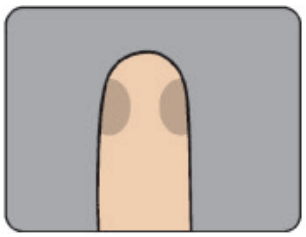

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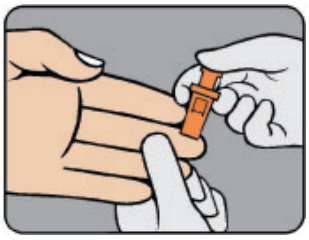

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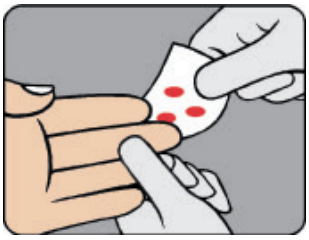

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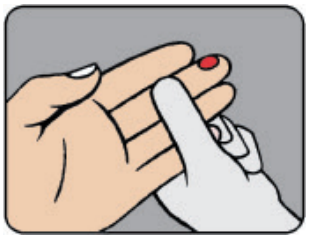

4. Sample at the side of the fingertip.
5. While applying light pressure towards the fingertip, puncture the finger using a lancet*.
6. Wipe away the first two or three drops of blood.
7. Re-apply light pressure towards the fingertip until another drop of blood appears.

*In order to obtain a sufficient blood flow and representative sample, high flow lancet with blade is preferred.

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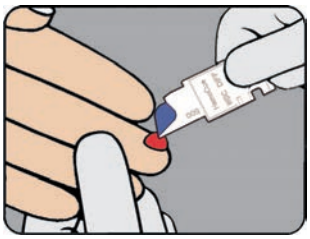

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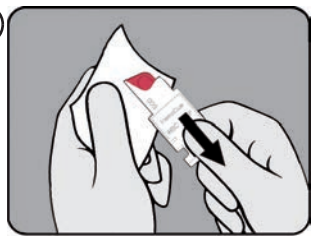

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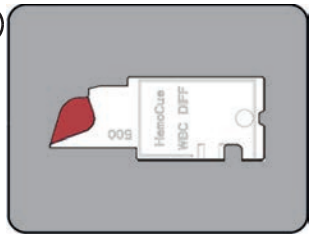


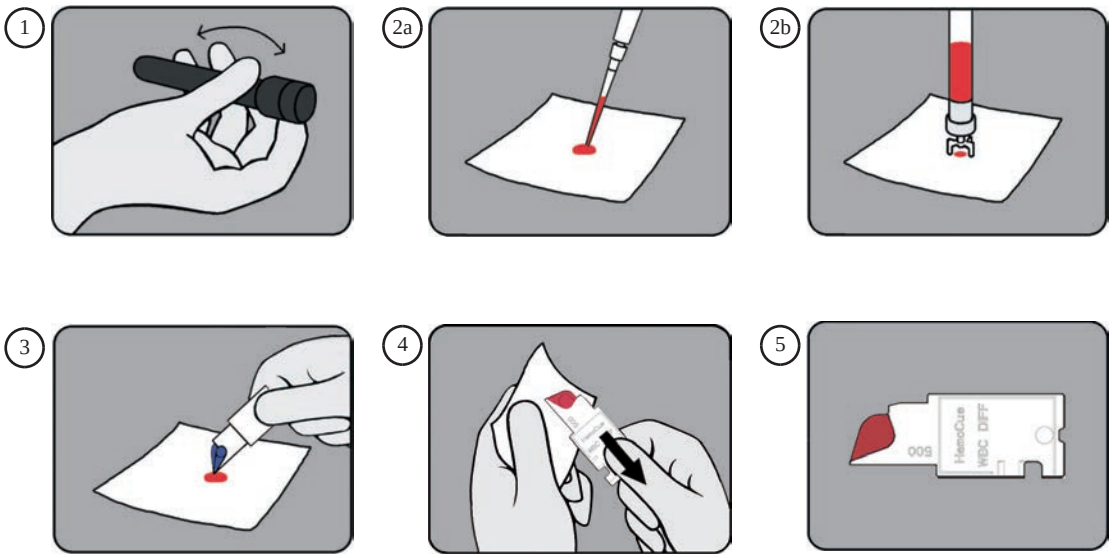
8. When the blood drop is large enough, fill the microcuvette in one continuous process. Do NOT refill!
   NOTE: Make sure that the microcuvette is filled from the tip, forming an angle (about 45 °) with the blood drop.
9. Wipe off excess blood from the outside of the microcuvette with a clean, lint-free wipe. Do not touch the open end of the microcuvette.
10. Look for air bubbles in the filled microcuvette. If present, discard the microcuvette and fill a new microcuvette from a new drop of blood.

NOTE: Make sure that the microcuvette is filled correctly as an improper filling angle might cause air bubbles.

NOTE: If a second sample is to be taken, it is important that this is done after the measurement of the first sample is completed. Wipe away the remains of the drop of blood and fill the second microcuvette from a new drop of blood as per steps 8–10 above.

NOTE: HemoCue WBC DIFF is not validated for heel stick.

Blood Collection Venous Sample and Control Material



⚠ *Important! Always handle blood specimens with care, they might be infectious. Consult local environmental authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvette is for single use only.*

For the measuring procedure see *Routine Use/QC Test* or *Routine Use/Patient Test*.
Control material shall always be measured using QC test procedure.

1. Venous blood samples shall be stored at room temperature (18–30 °C, 64–86°F) and analyzed within eight hours after sample collection. Mix the venous sample tubes thoroughly using a roller mixer for 1-2 minutes or invert the tube 10–20 times by hand. Samples may not be diluted. For control material always follow instructions for use provided by the manufacturer.
2. Place a drop of blood or control material onto a hydrophobic surface using a pipette (2a) or other suitable transfer device (2b).
3. Fill the microcuvette in one continuous process. Do NOT refill!
   NOTE: Make sure that the microcuvette is filled from the tip, forming an angle (about 45 °) with the blood drop.
4. Wipe off excess blood from the outside of the microcuvette with a clean, lint-free wipe. Do not touch the open end of the microcuvette.
5. Look for air bubbles in the filled microcuvette. If present, discard the microcuvette and fill a new microcuvette from a new drop of blood.

Routine Use Patient Test

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Patient Test stands for performing tests on samples from patients.

1. Start the analyzer as described in *Start-Up* section. Place the cuvette moving arm in loading position.
2. The display will show the main menu. Take a microcuvette from the package (HemoCue WBC DIFF Microcuvette or HemoCue WBC Microcuvette). For single packaged microcuvettes; open the inner wrapping and take out the microcuvette.
3. Press the button below Patient Test symbol.
4. Enter required data (selected in settings) e.g. Operator ID, Patient ID, Lab ID, and Site ID. To enter data see *Data Entry* section.
5. If data has been entered the data confirmation window is shown. Press right button to confirm. To change information, press left button until the desired window is shown.

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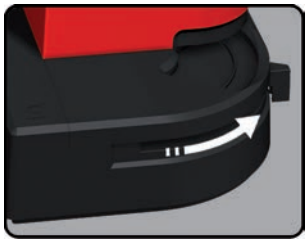

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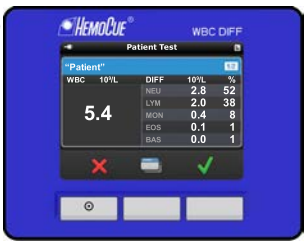
6. Insert cuvette symbol is shown.
7. Take a sample according to *Blood Collection Capillary Sample* or *Blood Collection Venous Sample and Control Material* sections. Place the microcuvette into the cuvette holder (7a) and start measurement as soon as possible but no later than 1 minute after filling the microcuvette by gently pushing the cuvette holder to its measuring position (7b).
8. During measurement the measuring window is shown.

9a



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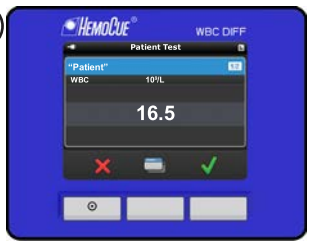

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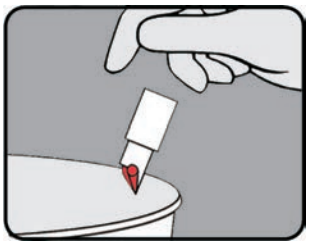

9. The results are displayed within < 5 minutes,
   9a. WBC DIFF result window
   9b. WBC result window
   9c. Entered data
   The result windows may differ due to data entered and choice of microcuvette. To jump between the result and data entered windows press button below the Switch symbol. Confirm result by pressing button below the Accept symbol. Reject result by pressing button below the Reject symbol. A rejected result will be saved but marked with a flag as rejected. The display shows the main menu.
   NOTE: Do not remeasure the filled microcuvette.
10. Always handle blood specimens with care, they might be infectious. Consult local environmental authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvette is for single use only.

Routine Use QC Test

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QC Test means performing tests on control material.

NOTE: Do not analyse patient samples in QC Test mode.

1. Start the analyzer as described in the *Start-Up* section. Place the cuvette moving arm in loading position.
2. The display will show the main menu. Take a microcuvette from the package (HemoCue WBC DIFF Microcuvette or HemoCue WBC Microcuvette). For single packaged microcuvettes; open the wrapping and take out the microcuvette.
3. Press right button for Menu/QC Test.
4. Press center button to scroll down and choose QC Test. Press right button to accept QC Test and move to the next window.
5. Press right button to confirm QC test.
6. Enter required data (selected in settings) e.g. Operator ID, Control ID.

7

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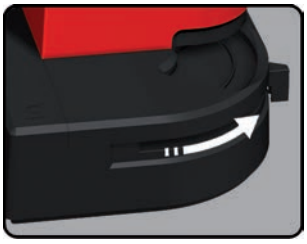
9b



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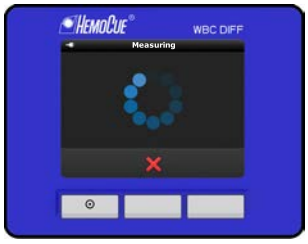


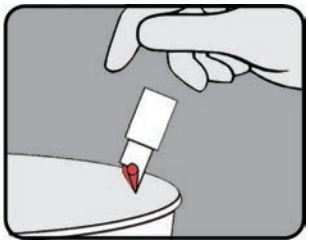
7. If data has been entered the data confirmation window is shown. Press right button to confirm. To change information, press left button until the desired window is displayed.
8. Insert cuvette symbol is shown.
9. Take a sample according to *Blood Collection Venous Sample and Control Material* sections. Place the microcuvette into the cuvette holder (9a) and start measurement as soon as possible but no later than 1 minute after filling the microcuvette by gently pushing the cuvette holder to its measuring position (9b). It will automatically slide into the correct position and the measurement starts.
10. During measurement the measuring window is displayed.

11a

11b

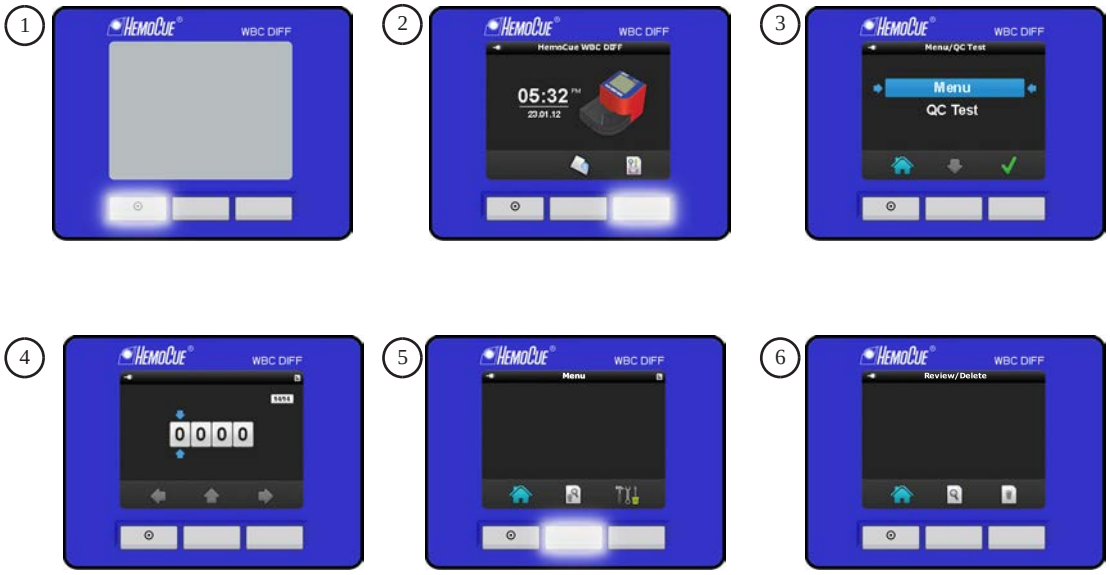
11c

12



11. The results are displayed within < 5 minutes,
    11a. WBC DIFF result window
    11b. WBC result window
    11c. Entered data
    The result windows may differ due to data entered and choice of microcuvette. To jump between result and data windows; press the center button.
    Confirm result by pressing button below the Accept symbol. Reject result by pressing button below the Reject symbol. A rejected result will be saved but marked with a flag as rejected. After rejecting the result main menu is shown.
    NOTE: Do not remeasure the filled microcuvette.
12. Always handle blood specimens with care, they might be infectious. Consult local environmental authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvette is for single use only.

Review/Delete Results



Use Set-Up/Settings menu to review/delete results. The analyzer can store up to 600 results.

1. Start the analyzer as described in the *Start-Up* section.
2. Press the button below the Menu/QC Test symbol.
3. Press right button to accept menu and to move to next window.
4. Enter PIN Code window is shown. The Pin Code is used to prevent unauthorized users from entering/changing input in the settings menu. As default, the PIN Code is set to 0000. For changing the PIN Code see step 19 in the *Settings* section.
   Enter PIN code by pressing the button below up arrow to change digit. Press right button to confirm and move to next digit. After entering the four digit PIN Code press right button to accept and move to next window.
5. The display shows: Home, Review/Delete and Settings. Press center button to enter Review/Delete.
6. The display shows Review/Delete window. Select review by pressing the button below Review symbol and move to number 7. Select Delete by pressing the button below Delete symbol and move to number 9.

7

8

9

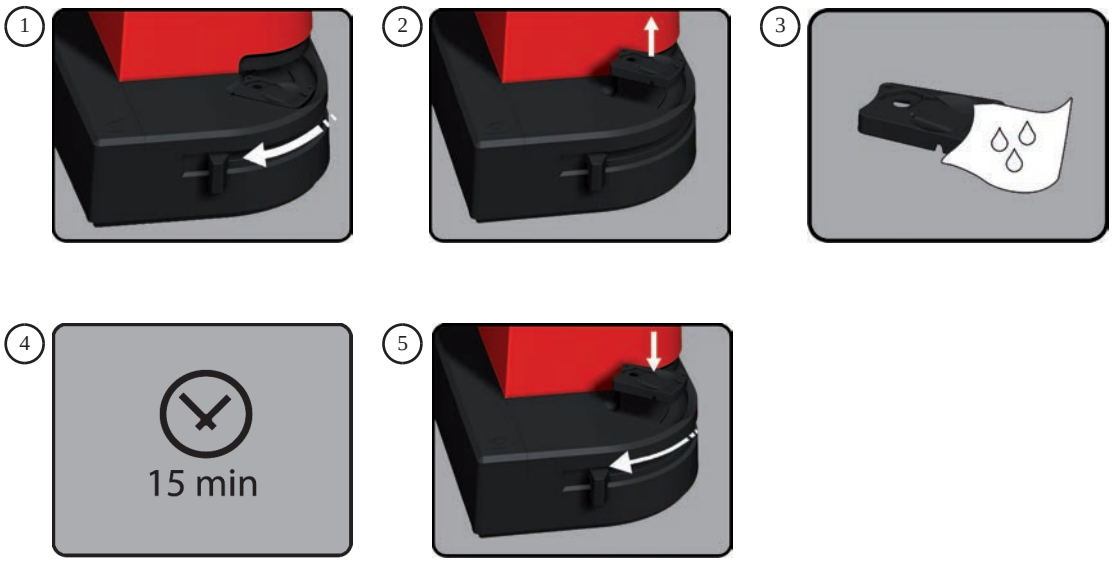
Review Results

7. The latest results are displayed. To jump between result and data windows; press center button. The result windows may differ due to data entered and type of microcuvette. Return to main menu by pressing center button and then left button.
8. To jump between result and data windows; press center button. Press left button to return to main menu.

Delete Results

9. Delete window is shown. Press right button to delete all results stored in the analyzer. To cancel press left button. The main menu is shown.
   NOTE: Single results can not be deleted.

Maintenance Daily Maintenance

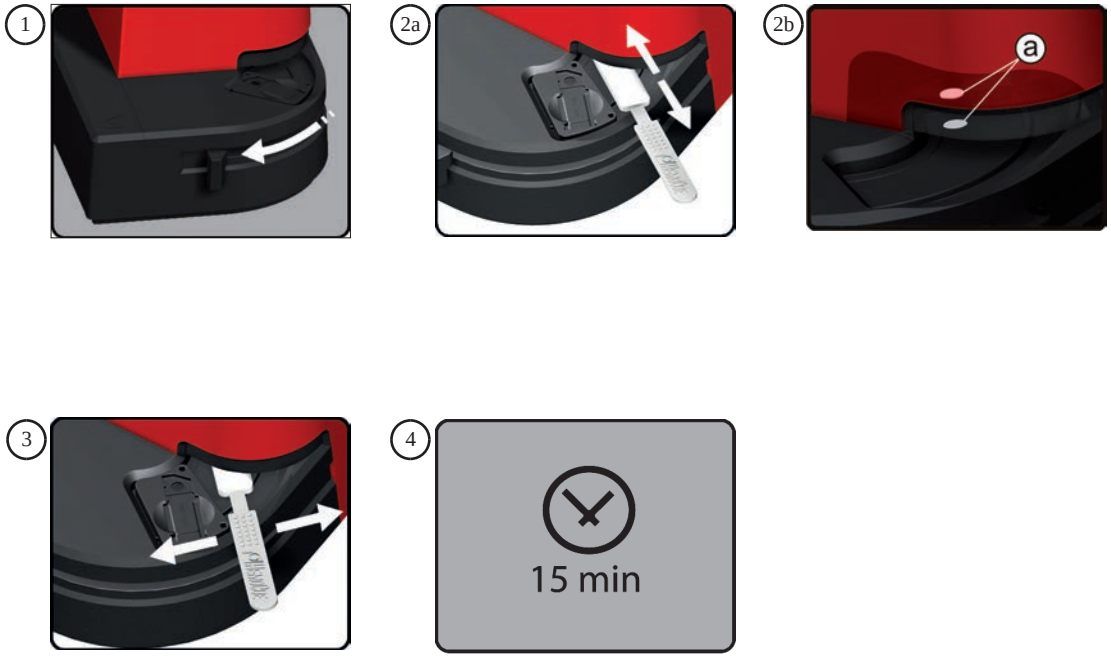


Clean the cuvette holder after each day of use.

1. Turn off the analyzer. Place the cuvette moving arm in loading position.
2. Remove cuvette holder by lifting it straight up.
3. Clean the cuvette holder with alcohol (20-70%) or mild detergent.
   NOTE: Do not autoclave.
   If the optical parts are stained an error code is displayed. Clean according to *Maintenance/Optical Parts* section.
4. Wait 15 minutes before replacing the cuvette holder.
5. Place the cuvette moving arm in loading position before replacing the cuvette holder.
   Clean the cover with alcohol (20-70%) or a mild detergent.

Only the WBC DIFF cuvette holder is to be used with the WBC DIFF analyzer. The WBC DIFF cuvette holder is marked WBC DIFF.

Maintenance Optical Parts



If the optical parts of the WBC DIFF Analyzer are dirty an error code is displayed. Use the HemoCue Cleaner WBC for cleaning optical parts.

1. Turn off the analyzer. Place the cuvette moving arm in loading position, leave cuvette holder in place.
2. Hold HemoCue Cleaner WBC* with the HemoCue logotype facing upwards. Push the cleaner as far as possible into the opening of the optic unit. Move back and forth along the cuvette holder 5-10 times (2a). The optical parts are placed on the left in the opening. Move the cleaner alongside of the cuvetteholder to get the right angle for cleaning the optical parts (2b).
3. Move from side to side 5-10 times.
   If the cleaner is stained, repeat using a new cleaner.
4. Wait 15 minutes before performing a new measurement.

*One HemoCue Cleaner WBC is included with the analyzer. Contact your local distributor to order additional cleaners.

NOTE: Make sure the cuvette moving arm is in loading position with cuvette holder in place.

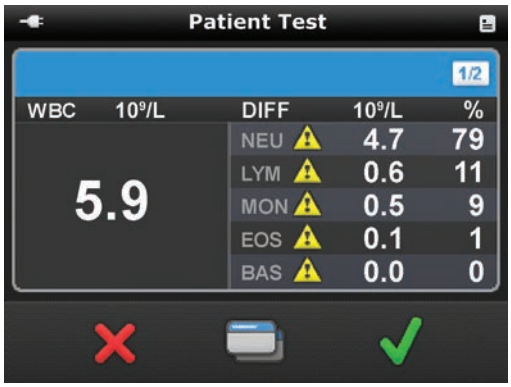
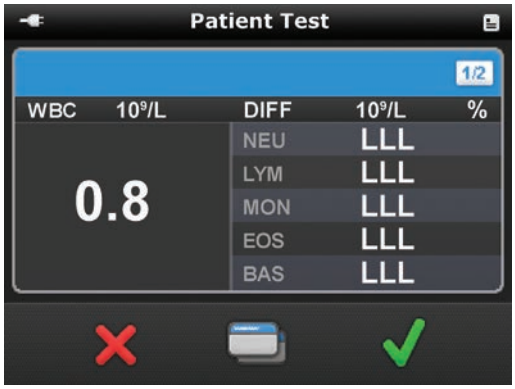
NOTE: Dispose of the cleaner as potentially infectious waste. Do not reuse.

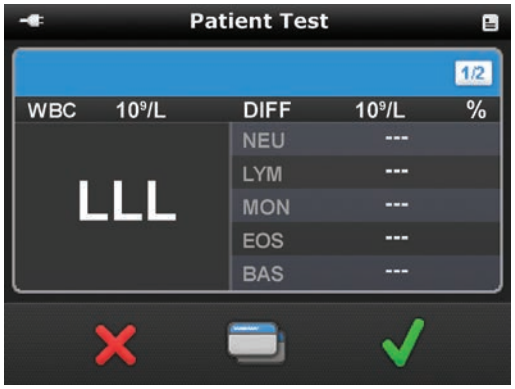
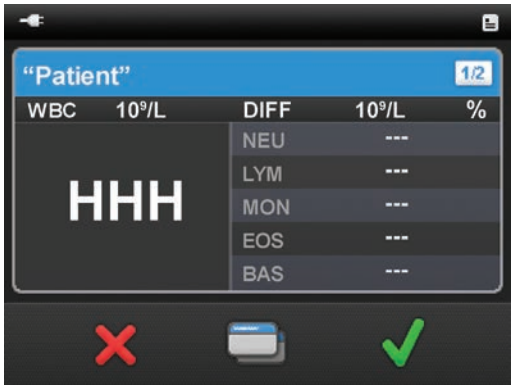
Only the WBC DIFF cuvette holder is to be used with the WBC DIFF analyzer. The WBC DIFF cuvette holder is marked WBC DIFF.

GB Troubleshooting Guide

The HemoCue WBC DIFF system will display a flag or an Error Code if a problem is detected within the system or the sample. In the trouble shooting guide are explanations and recommended actions for each flag or Error Code described.
If the Troubleshooting Guide is unable to resolve the problem, please contact your local HemoCue distributor or HemoCue AB. The analyzer should be cleaned as described in the Maintenance section prior to service or disposal. The analyzer has no serviceable parts.

NOTE: Do not open the cover of the analyzer. The warranty is void if the cover of the analyzer is opened.

Flag	Explanation
	The results in the differential count are uncertain. The sample may contain pathological, abnormal or unidentified cells. The sample should be verified with a suitable laboratory method and be questioned as to the pathological condition of the patient. The printout will show an asterisk (*) instead of the display symbol ⚠
	The differential count is not presented when the total WBC is below 1 x 10^9/L. If a differential count is required the sample should be verified with a suitable laboratory method.

Flag	Explanation
	The measured total white blood cell count is below 0.3 x 10^9/L. The sample should be verified with a suitable laboratory method.
	The measured white blood cell count is above 30.0 x 10^9/L. The sample should be verified with a suitable laboratory method

The HemoCue WBC DIFF system will display an Error Code if a problem occurs impacting the performance of an analysis. Each error code is numbered and related to a specific cause. If an error code appears, accept the error code and continue according to the action described for the specific error code in the trouble shooting guide.

Error code	Explanation	Action
	Non-critical error (Err01, Err02, Err04, Err05, Err31, Err33)	Confirm error code. Continue according to action described for error code shown.
	Critical error (Err03, Err30, Err34, Err35, Err60, Err69, Err90)	Confirm error code. The analyzer will automatically turn off. Restart the analyzer and continue according to action described for error code shown.
Err01	Part of the image area can not be analyzed. Potential causes may be: • Airbubbles in the sample. • Incorrect handling of the sample • Abnormalities in sample.	1. Take a new microcuvette, repeat the measurement as described in *Routine Use Patient Test* or *QC Test* sections. 2. If the problem persists, the sample should be verified with a suitable laboratory method.
Err02	Uneven spatial distribution of detected cells.	Take a new microcuvette, repeat the measurement as described in *Routine Use Patient Test* or *QC Test* sections.
Err03	Image, or part of the image area is out-of-focus.	1. Take a new microcuvette, repeat the measurement as described in *Routine Use Patient Test* or *QC Test* sections. 2. If the problem persists, the analyzer needs service. Contact your local distributor.
Err04	Acceptable light level cannot be achieved.	1. Take a new microcuvette, repeat the measurement as described in *Routine Use Patient Test* or *QC Test* sections. 2. If the problem continues, the analyzer needs service. Contact your local distributor.
Err05	Cuvette holder is inserted before *Patient Test* is selected.	Remove the microcuvette. Take a new microcuvette, repeat the measurement as described in *Routine Use Patient Test* or *QC Test* sections. NOTE: Make sure the “insert cuvette” symbol is displayed before inserting a new microcuvette.

Error code	Explanation	Action
Err30	The optical parts are dirty or wet after cleaning.	1. Clean the optical parts as described in the *Maintenance* section. Wait 15 minutes before starting the analyzer after cleaning to make sure that the optical parts are dry. 2. If the problem persists, the analyzer needs service. Contact your local distributor.
Err31	Memory error.	1. Restart the analyzer as described in the *Start-Up* section. 2. If the problem persists, choose one of the alternatives: · Remove all measurements as decribed in *Review/Delete Results* section. NOTE: All stored data will be deleted. · The analyzer needs service. Contact your local distributor.
Err33	Empty microcuvette, not filled with sample.	Take a new microcuvette, repeat the measurement as described in *Routine Use Patient Test* or *QC Test* sections. Make sure that the microcuvette is filled with sample.
Err34	Stray light detected.	1. Make sure that the analyzer is not exposed to any bright light sources. 2. If the problem continues, the analyzer needs service. Contact your local distributor.
Err35	The battery power is too low.	Replace the batteries, six type C (LR14/HR14) batteries, 1.5 V or use the AC adapter. All described in the *Start-Up* section.
Err60	General hardware error.	Try one or more of the following: 1a) Clean the optical parts as described in *Maintenance* section. 1b) If an error code appears when connecting a USB device, remove the device and start the analyzer as described in *Start-Up* section. 1c) Wait 30 seconds and start the analyzer. 2 If the problem persists, the analyzer needs service. Contact your local distributor.
Err69	Configuration error.	The analyzer needs service. Contact your local distributor.

Error code	Explanation	Action
Err90	Internal error.	1. Wait 30 seconds, start the analyzer as decribed in *Start-Up* section. Take a new microcuvette, repeat the measurement as described in *Routine Use Patient Test or QC Test* sections 2. If the problem persists, the analyzer needs service. Contact your local distributor.
Other Errors		
No characters on the display	1. No power. 2. If on battery power, the batteries need to be replaced. 3. The display is not working.	1a. Check that the AC adapter is properly connected to the analyzer. 1b. Check the cable for damages. 2. Replace the batteries, six type C (LR14/HR14) batteries, 1.5 V as described in *Start-Up* section. 3. The analyzer needs service. Contact your local distributor.
The display shows erroneous characters	1. The display is out of order. 2. The microprocessor is out of order.	The analyzer needs service. Contact your local distributor.
The cuvette holder is not moving into 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.	1. Improper sampling technique. 2. The microcuvettes are damaged, not properly stored or have passed the expiry date. 3. The sample has not been properly stored.	1. Take a new microcuvette, repeat the measurement, as described in *Routine Use Patient Test* section. 2. Check expiry date and storage conditions of the microcvettes. 3. Check storage conditions of the sample.

GB

Specifications

Intended Purpose/Intended Use
The HemoCue WBC DIFF system is an *In-Vitro* diagnostic system designed for quantitative determination of white blood cells (WBC) in capillary or venous whole blood. The system provides values for a total white blood cell count and a differential count including neutrophil count, lymphocyte count, monocyte count, eosinophil count and basophil count.

The HemoCue WBC DIFF system is indicated for use in clinical laboratories and for point of care testing in professional health care settings on pediatric (≥ 3 months) and adult patients.
The HemoCue WBC DIFF Analyzer is only to be used with HemoCue WBC DIFF Microcuvettes for measurement of a total white blood cell count and a differential white blood cell count or with HemoCue WBC Microcuvettes for measurement of a total white blood cell count only.

IVD Medical Device Directive
The HemoCue WBC DIFF system complies with the IVD Medical Device Directive 98/79/EC and carries the CE mark.

Principles of the Method/Procedure
Principle of the method
A hemolyzing agent lyses the red cells in the microcuvette and a staining agent colours the white cells. Several images are taken of the stained white cells and cells are classified. The number of cells are counted by image analysis in the analyzer.
Principle of the procedure
The microcuvette is for single-use only and serves as a sample container and reaction chamber. A blood sample of approximately 10 µL is drawn into the cavity by capillary action. The microcuvette is placed in the analyzer and within <5 minutes the result is obtained. The system is designed to establish agreement with:
- Manual method for the differential white blood cell count.
- Manual method for total white blood cell count.

No calibration is needed as the system is factory calibrated

Warning and Precaution
The microcuvettes are for *In Vitro* Diagnostic use only. Always handle blood specimens with care, they may be infectious. Consult local environment authorities for proper disposal. Always wear protective gloves when handling blood specimens. The microcuvettes are for single-use only. Do not analyse patient samples in QC test mode.

Storage and Handling
Microcuvettes
The microcuvettes are to be stored at 15–35 °C (59–95 °F), <90% non-condensing humidity. An unopened vial/capsule of microcuvettes can be stored for a shorter period of time (4 weeks) outside the specified storage conditions, down to 4 °C (39 °F) and up to 50 °C (122 °F). Allow the microcuvettes to reach 18-30° C (64-86 °F) before use. For *individually packaged microcuvettes*: once the wrapping of a single packaged microcuvette is opened it shall be used within 10 minutes. For *microcuvettes packaged in vial*: once the seal of the vial is broken, the microcuvettes shall be used within 3 months. Always keep the vial properly closed.
Use the microcuvettes prior to the expiry date which is printed on the package. The microcuvettes should be stored in the original package.
Analyzer
The analyzer can be stored at 4–50 °C (39–122 °F), <90% non-condensing humidity for four weeks.
Allow the analyzer to reach ambient temperature before use.
Operating temperature
For optimal performance of the HemoCue WBC DIFF system, the operating temperature should be:
Venous/capillary sample in EDTA tube: 18 - 30° C (64-86 °F), <90% non-condensing humidity
Capillary sample from fingerstick: 18 - 25° C (64-77 °F), <90% non-condensing humidity.

Specimen Collection and Preparation
Capillary or venous whole blood may be used. EDTA anti-coagulant should be used. Do not dilute sample.
Venous blood samples and capillary blood samples in EDTA tubes shall be stored at room temperature 18–30°C, (64–86°F).
Stability: venous samples 8h, capillary samples 4h.

Materials Required
- HemoCue WBC DIFF Analyzer
- HemoCue WBC DIFF Microcuvettes and/or HemoCue WBC Microcuvettes
- Lancet (capillary samples)
- Pipette or other transfer device (venous samples)
- Lint-free tissue (non-fraying)

Quality Control
When the HemoCue WBC DIFF Analyzer is started, a quality control (self-test) is automatically performed to verify performance. If the test fails, an error code will be displayed.
For each measurement, quality controls are made on:
- The HemoCue WBC DIFF Analyzer.
- The HemoCue WBC DIFF Microcuvettes or WBC Microcuvettes.
- The sample.
- The handling of microcuvettes and sample.

No additional quality controls performed by the operator are required for functionality verification.

Expected Values (Dacie and Lewis Practical Haematology)

White Blood Cell values for normal children expressed as a mean ±2SD (95% Range)

	3-6 Months	**1 Year**	**2-6 Years**	**6-12 Years**
White Blood Cell Count $x10^9$/L	12±6	11±5	10±5	9±4
Neutrophils $x10^9$/L	1-6	1-7	1.5-8	2-8
Lymphocytes $x10^9$/L	4-12	3.5-11	6-9	1-5
Monocytes $x10^9$/L	0.2-1.2	0.2-1.0	0.2-1.0	0.2-1.0
Eosinophils $x10^9$/L	0.1-1.0	0.1-1.0	0.1-1.0	0.1-1.0

Expected Values (Dacie and Lewis Practical Haematology)

White Blood Cell values for normal adults expressed as a mean ±2SD (95% Range)

	Adults ($x10^9/L$)	**Adults** (%)
White Blood Cell Count	4.0-10.0	NA
Neutrophils	2.0-7.0	40-80
Lymphocytes	1.0-3.0	20-40
Monocytes	0.2-1.0	2-10
Eosinophils	0.02-0.5	1-6
Basophils	0.02-0.1	<1-2

The values above may vary due to a wide range of factors, such as sex, diurnal variations, exercise, physical stress or trauma, pregnancy, indigestion of food, and cigarette smoking.

Measuring Range
Displayed range for total WBC count: 0.3–30.0 x10^9/L (300–30000/mm^3, 300–30000/µL) Results above the measuring range will be displayed as HHH. Results below measuring range will be displayed as LLL.

The differential cell count will be presented when the total white blood cell count is between 1.0–30.0 x 10^9/L.

Limit of Detection
Limit of Detection is defined as the lowest amount of analyte that can be detected with probability.
Limit of Detection has been determined to be 0.3 x 10^9/L. (CLSI Document EP17-A) for WBC count.

Limitations of the Method/Procedure
a) The measurement needs to be started no later than 1 minute after filling the microcuvette.
b) Do not remeasure a filled microcuvette.
c) Mixing samples for an extended period may affect the result.
d) Results above the measuring range will be displayed as HHH. Results below the measuring range will be displayed as LLL.
e) Discard sample if clots.
f) For interference studies see chapter *Known Interferences*.

Specific Performance Characteristics
Linearity
The white blood cell count for the WBC DIFF system has according to the FDA Guidance Premarket Notification for Automated Differential Cell Counters for Immature or Abnormal Blood Cells, been demonstrated to be linear between 0.3 – 30.0 x 10^9/L with a correlation coefficient (r) to 0.999.

Capillary Sampling
When a capillary skin puncture is performed, several defense systems in the body are activated very quickly. These defense systems cause an increase in the number of WBCs in the blood closest to the wound, leading to greater differences in results from several samples taken from the same finger stick.

Repeatability

A study has been performed according to CLSI Document H26-A2 using fresh blood samples to determine repeatability at low, normal and high concentrations. The study was performed on venous whole blood samples tested with 31 replicates per sample using 1 analyzer and 1 batch of cuvettes.

N	WBC Level	Total WBC			Neutrophils			Lymfocytes			Monocytes		Eosinophils	
		Mean ($x10^9$/L)	SD ($x10^9$/L)	CV (%)	Mean ($x10^9$/L)	SD ($x10^9$/L)	CV (%)	Mean ($x10^9$/L)	SD ($x10^9$/L)	CV (%)	Mean ($x10^9$/L)	SD ($x10^9$/L)	Mean ($x10^9$/L)	SD ($x10^9$/L)
31	Low	2.8	0.14	5.0	1.5	0.11	7.3	1.0	0.08	7.8	0.2	0.03	0.1	0.02
31	Normal	6.1	0.17	2.8	3.4	0.13	3.7	2.2	0.10	4.6	0.3	0.07	0.1	0.03
31	High	18.1	0.57	3.1	14.4	0.61	4.3	2.8	0.26	9.5	0.8	0.14	0.1	0.05

Method Comparison Study - Venous Samples

Results from a method comparison study performed according to CLSI Document EP 9-A2 on the HemoCue WBC DIFF system and the Beckman Coulter LH750 are shown for total WBC count in Figure 1, for neutrophil count in Figure 2 and for lymphocytes in Figure 3.

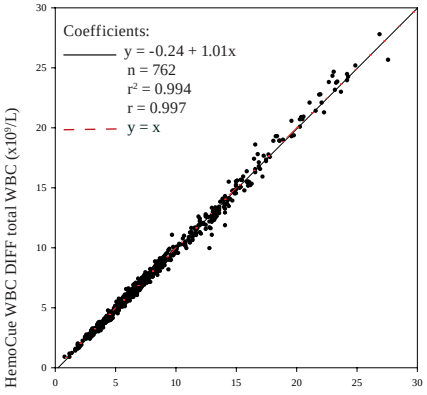


Figure 1 Total WBC

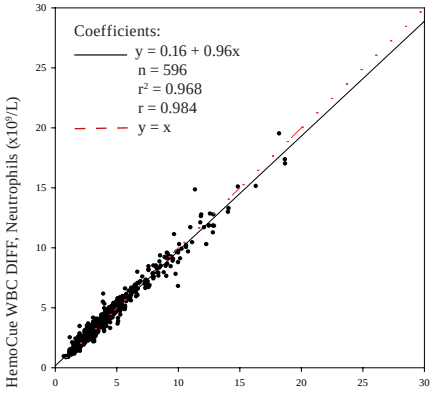


Figure 2 Neutrophils

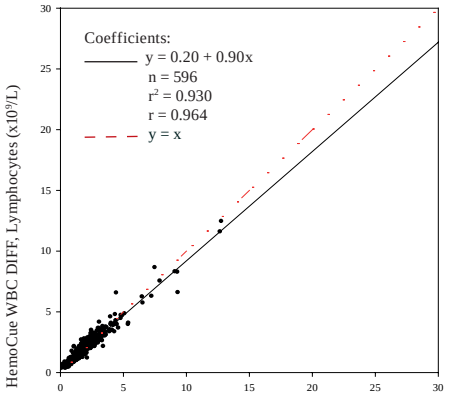


Figure 3 Lymphocytes

Method Comparison Study - Capillary Samples Direct from Finger

Results from a method comparison study performed on the HemoCue WBC DIFF system and the Sysmex XS-1000i are shown for total WBC count in Figure 1, for neutrophil count in Figure 2 and for lymphocytes in Figure 3. Capillary sample for Sysmex was taken in a microtube.

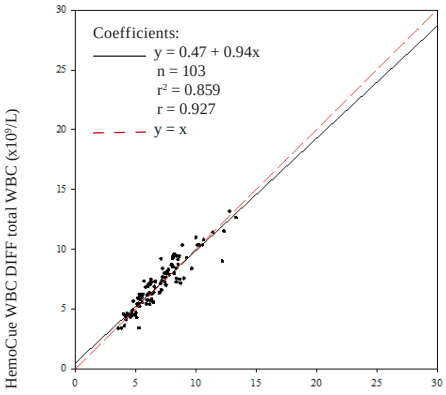


Figure 1 Total WBC

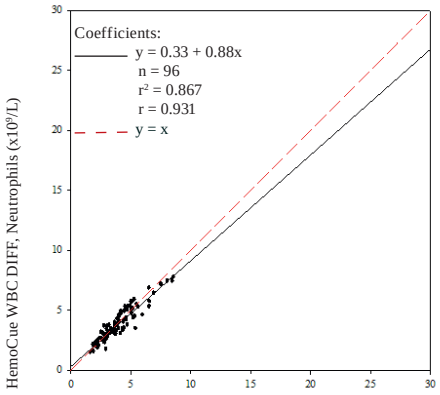


Figure 2 Neutrophils

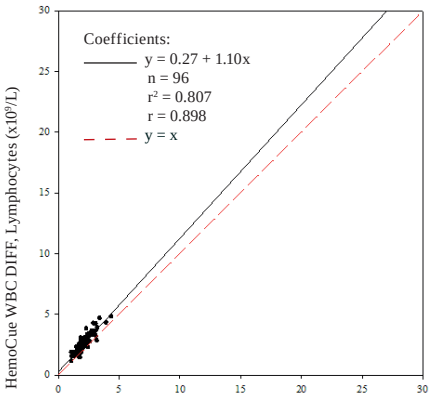


Figure 3 Lymphocytes

Known Interference
Nucleated red blood cells (NRBC) may be counted as white blood cells and give falsely elevated total leukocyte count. This will mainly be reflected in the differential count as an elevated lymphocyte count.
Cold agglutination or cryoglobulin may interfere.
Low Hb (<80 g/L) may cause an increased level of flags.
NOTE: Discard sample if clots.

Technical Specifications
Dimensions: 188x157x155 mm (7.40 x 6.18 x 6.10 inches)
Weight: 1300 g (2.87 pounds) (with 6 C (LR14/HR14) batteries installed)
AC adapter: CE marked
Only use AC adapters listed under AC Adapters.
Pollution degree: 2
Overvoltage category: II
Atmospheric pressure: 700 hPa to 1060 hPa.

Equipment not suitable for use in the presence of flammable mixtures.

The HemoCue WBC DIFF system has been tested for electrical safety and EMC according to the following standards:
- IEC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010-2-101 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.
- UL 61010/CSA-C22.2 No. 61010-1 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements.
- IEC/EN 60601-1-2 Ed 3.0 Medical electrical equipment-Part 1: General requirements for Safety – Part 1-2: Collateral Standard: Electromagnetic compability – requirements and tests.

Essential Performance
The HemoCue WBC DIFF system is an *In-Vitro* diagnostic system designed for quantitative determination of white blood cells (WBC) in capillary or venous whole blood. The system provides values for a total white blood cell count and a differential white blood cell count including neutrophil count, lymphocyte count, monocyte count, eosinophil count and basophil count.

Recommended separation distance between Portable and mobile RF communications equipment and HemoCue WBC DIFF Analyzer

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

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

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

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

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

Guidance and manufacturer's declaration – Electromagnetic immunity
The HemoCue systems are intended for use in the electromagnetic environment specified below. The customer or user of the HemoCue systems should assure that it is used in such an environment.

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

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

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

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

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

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

Technical specifications (EMC-RF)
Use only cables with the following specification:

USB shielded maximum 2 m

Serial shielded maximun 1.5 m

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

AC Adapters
Country: EU/US/GB
Type: HCA01
Input: 100V~ - 240V~/50-60 Hz/< 500mA

Warning
The device is tested according to standard IEC 61010-2-101 and is found to comply with the standard.
Despite this compliance it is impossible to predict any possible effects by other nearby standing instruments, (stationary, portable or mobile units) or the possible impact of electromagnetic radiance. This is the reason we need to inform users of this analyzer that disturbance from other equipment might affect the performance of the analyzer. Should you note that this is the fact, please contact your local HemoCue distributor.
The HemoCue WBC DIFF system is intended for use in the electromagnetic environment specified in Technical specifications. The customer or user of the HemoCue WBC DIFF system should assure that it is used in such an environment. The HemoCue WBC DIFF Analyzer uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
The HemoCue WBC DIFF system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Warranty
The analyzer carries a 24-month warranty from the day of receipt. After the warranty period service/repair is carried out at fixed prices. Any other use of the system than recommended by the manufacturer will void the warranty.

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

Spare Parts and Accessories
The following accessories and spare parts are available:
- AC adapter
- Cuvette holder
- HemoCue Cleaner WBC
- Printer

Patents
The product is protected by the following patents (or patents pending):
SE 0601575-4, SE 0700958-2, US 11/822,159, EP 07808762.4, SE 0601576-2, US 7,633,615, EP 07768988.3, SE 0800117-4, US 8,009,894, EP 09702056.4, SE 0500549-1, US 7,521,243, US 8,092,758

Symbols Used

Caution

CE mark

Class II equipment

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

1010 Serial port

USB

Relative humidity, non-condensing

DC inlet

Temperature

IV Efficiency Level

Consult instructions for use.

To maintain safety use only AC adapter marked HCA01.

References

- HemoCue WBC DIFF Microcuvettes package insert
- HemoCue WBC Microcuvettes package insert
- Dacie and Lewis, Practical Haematology Tenth edition.
- Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA, Document issued at December 4, 2001
- CSLI Document H26-A2, Vol. 30, No. 14, Validation, Verification, and Quality Assurance of Automated Hematology Analyzers
- CLSI Document EP09-A2-IR, Vol. 30, No. 17, Method Comparison and Bias Estimation Using Patient Samples
- CLSI Document EP17-A, Vol. 24, No. 34, Protocols for Determination of Limits of Detection and Limits of Quantitation

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