



woman²

USING THE HEMOCUE HB 201 ANALYSER

Protocol number: ISRCTN62396133
Version 1.0; Date 05 April 2019

SCREENING FOR ANAEMIA

- A HemoCue Hb 201 analyser has been provided
- The HemoCue Hb 201 analyser is a handheld device used for standard point of care haemoglobin testing:
 - A small sample of blood, taken from the participant's finger, is tested in the analyser
 - Results are available in 15 – 60 seconds

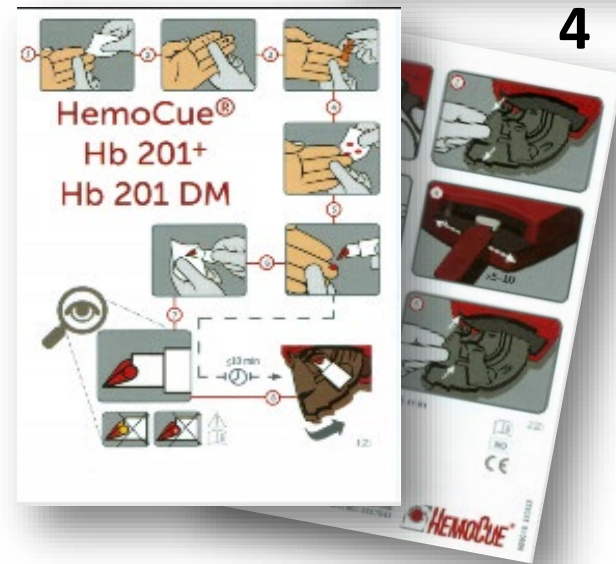


HEMOCUE HB 201 ANALYSER HAS BEEN PROVIDED TO:

- ✓ **Test haemoglobin levels on admission to hospital for all women:**
 - In active labour and
 - Planning to give birth vaginally
- ✓ **Test haemoglobin levels at 24 hours after randomisation or at discharge, whichever comes first**
 - The test is provided is provided free of charge
 - A woman have the right to accept or decline

HEMOCUE HB 201 ANALYSER BOX CONTENTS

1. HemoCue Hb 201 analyser
2. AC power adapter
3. HemoCue Hb 201 Operating manual
4. Quick reference guide
5. 1 x HemoCue Hb 201 cleaner



HOW TO USE THE HEMOCUE HB 201 ANALYSER TO MEASURE HAEMOGLOBIN LEVELS

WHAT MATERIALS WILL YOU NEED?

- **HemoCue Hb 201 analyser and consumables**
 1. HemoCue Hb 201 analyser
 2. Batteries / power adapter
 3. HemoCue Hb 201 microcuvettes (*to collect the blood sample for analysing*)
 4. Gloves
 5. Skin cleaning swabs
 6. Lancets (*for capillary samples*)
 7. Gauze/ lint free wipe (*non-fraying*)
 8. Biohazard disposal (*follow hospital protocol for hazardous waste disposal*)

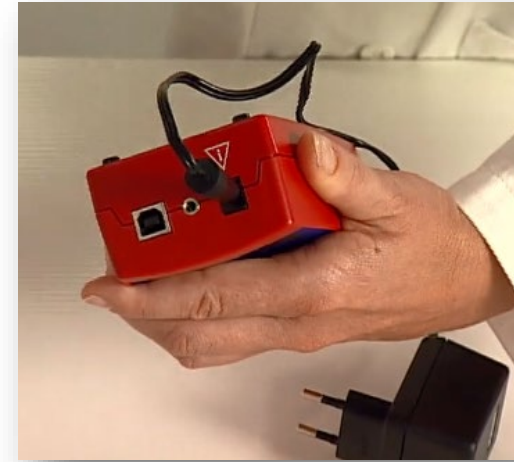


USING THE HEMOCUE ANALYSER

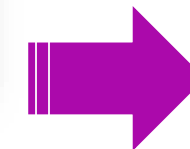
- The HemoCue Hb 201 analyser can be powered by either:
 - The AC power adapter
 - 4 x AA batteries
- Before preparing a blood sample for testing, take the container of microcuvettes and check:
 1. **date of opening.** If it has been 90 days since opening, DO NOT USE
 2. **expiry date**

NOTE:

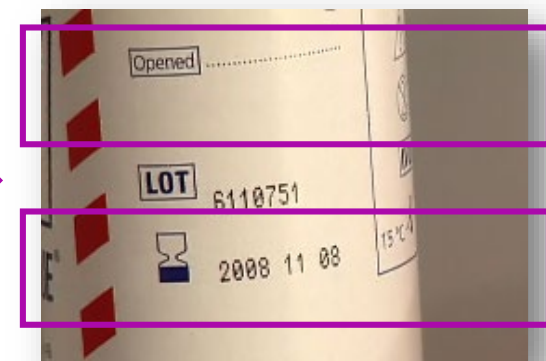
- *After use, always replace the lid to the microcuvettes and make sure it is properly sealed to protect their shelf life*
- *Store microcuvettes at room temperature (do not refrigerate)*



date of
opening



expiry
date



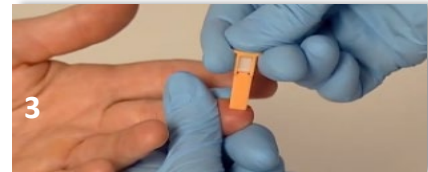
USING THE HEMOCUE ANALYSER

TAKING A BLOOD SAMPLE FOR TESTING (1/2) :

Explain to the woman what is going to happen before you start

Follow standard hand hygiene procedure and put on gloves then:

1. **Clean woman's finger** with alcohol swab and allow to dry or wipe with dry gauze/lint free wipe
2. **Stimulate blood flow**, use your thumb to gently press the finger from the top of the knuckle to the tip
3. **Puncture the SIDE of the finger (not the centre) with the lancet**, while applying pressure to towards the finger tip
4. **Wipe away the first 2-3 drops of blood** with dry gauze/lint free wipe

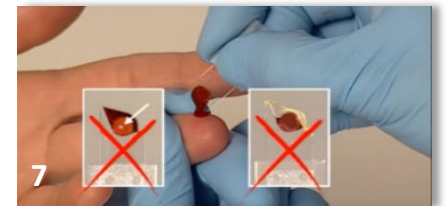
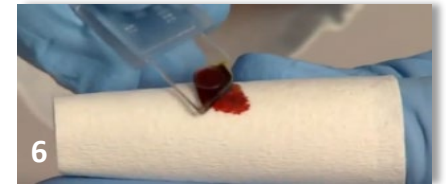
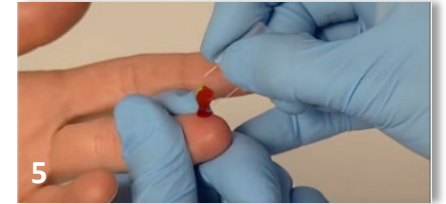


USING THE HEMOCUE ANALYSER

TAKING A BLOOD SAMPLE FOR TESTING (2/2) :

5. **Apply light pressure to fingertip until another drop of blood appears, fill the microcuvette** in one continuous process. Hold the cuvette in the centre of the drop for 2 seconds (count to 2 slowly). **Note!** *If the blood drop is not large enough you will get a false low reading*
6. **Wipe off excess blood from the outer surface of the cuvette** with dry gauze/lint free wipe, be careful not to touch the open end of the cuvette. **Note!** *Make sure that blood is not drawn out from the cuvette during this procedure!*
7. **Look for air bubbles in the filled cuvette.** If any air bubbles are present, fill a new cuvette. Small bubbles around the outer edge can be ignored

NOTE: The microcuvette should be filled within 3 minutes of taking it out from the microcuvette tub



USING THE HEMOCUE ANALYSER

ANALYSING THE BLOOD SAMPLE:

1. Turn on the HemoCue Hb 201 analyser
2. Open the cuvette holder and place filled microcuvette into the cuvette holder.
3. Close the cuvette holder and wait 15-60 seconds for the result

Note! This should be performed within ten minutes after filling the cuvette!

4. Dispose of the microcuvette (*follow hospital protocol for hazardous waste disposal*)



NOTE: If the HemoCue analyser shows an error message, turn the analyser OFF and ON and retry. If the problem continues, speak to the trial team member responsible for outcome data collection as they will be trained to troubleshoot the issue for you.

HEMOCUE HB 201 ANALYSER QUALITY CONTROL /MAINTENANCE

HEMOCUE HB 201 ANALYSER: QUALITY CONTROL

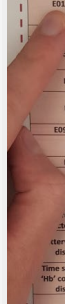
There are two quality control tests for the HemoCue Hb 201 analyser:

1. INTERNAL ELECTRONIC SELF-TEST

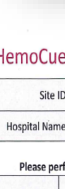
- Performed automatically each time the analyser is turned on.
- If the self-test produces an error code, check the code number against the troubleshooting guidance table in Trial Procedures File, guidance number 4.4 and follow the recommended action.


2. LIQUID QUALITY CONTROL (QC) TEST

- The Liquid QC Test should be performed **ONCE EVERY 3 MONTHS** and the results should be documented in the HemoCue Hb 201 Quality Control Log, available in the Investigator Site File section, section 4 (see Trial Procedures File, guidance number 4.4)



GUIDANCE NUMBER 4.4		
HEMOCUE HB 201 ANALYSER TROUBLESHOOTING		
ERROR CODE/ MEASURING DEVIATION	EXPLANATION	ACTION*
Error code is displayed	May be temporary fault or faulty electronics/optical parts	Turn analyser off. Turn on after 30 seconds. If problem continues, see specific error code below
E00	1. Faulty microcuvette	1. Check expiry date 2. Fill new microcuvette and perform measurement
E01-E02	1. Dirty optical parts 2. Analyser too hot/cold 3. Magnet missing in cuvette holder	1. Clean optical parts** 2. Turn analyser off, allow to reach operating temperature before use 3. Order new cuvette holder (contact your NCC, details in ISF)
E03	1. Analyser exposed to direct light	1. Avoid direct light exposure
E04, E06	1. Analyser too hot/cold or exposed to direct light	1a. Turn analyser off and allow it to reach operating temperature before use 1b. Avoid direct light exposure
E07	1. Battery too low	1a. Batteries need replaced 1b. Use AC power adapter
E08	1a. The absorbance is too high 1b. Faulty microcuvette or sample 1c. Dirty or blocked optical parts	1a and 1b. Ensure the analyser and microcuvettes are used according to the operating manual and relevant package insert 2a and 1c. Clean optical parts**
E09-E30	1. Internal error in analyser	1. Clean optical parts
E35	1. Current measurement incorrectly stored	1. Delete all stored results
HHH	Result exceed measuring range	1. Fill a new microcuvette and perform measurement
Power supply indicators are displayed	1. Analyser not receiving power 2. Faulty display	1a. Ensure AC adapter is properly connected and cable not damaged 1b. Batteries need replaced 2. Analyser needs serviced (contact your NCC, details in ISF)
Warning symbol is displayed	1. Faulty display/electronic	1. Analyser needs serviced (contact your NCC, details in ISF)
Low battery symbol is displayed	1. Low battery 2. Faulty AC adapter	1. Batteries need to be replaced 2. Ensure AC adapter is properly connected and cable not damaged
Time symbol and "H" continuously displayed	1. Faulty cuvette holder/analyser	1. Analyser needs serviced (contact your NCC, details in ISF)
Patient and control samples	1. Microcuvettes have expired, damaged or improperly stored 2. Microcuvette contaminated 3. Dirty optical parts 4. Air bubbles in filled microcuvette 5. Faulty optical parts 6. Incorrect sampling techniques 7. Measurement started later than 10 minutes after filling the microcuvette	1. Check expiry date and storage conditions 2. Fill a new microcuvette and perform measurement 3. Clean optical parts** 4. Fill a new microcuvette and perform measurement 5. Analyser needs service 6. Fill a new microcuvette and perform measurement 7. Start measurement no later than 10 minutes after filling the microcuvette
Unexpected patient or control results	Control samples 1. Control samples not compatible 2. Improper handling of control solutions 3. Control solution expired or improperly stored	Control samples 8. Only use controls recommended for HemoCue 9. Always follow instructions for use of control solution 10. Check expiry date and storage conditions



HemoCue Hb 201 Liquid Quality Control Log							
Site ID	002	Principal Investigator Name:	R. Rudolph				
Hospital Name	WOMAN-2 HOSPITAL						
Please perform liquid quality control (QC) tests on all HemoCue Hb 201 analysers EVERY 3 MONTHS.							
Date (dd/mm/yyyy)	Time (hh:mm)	Analyser Serial number	Liquid Control Values			If control values are out of range, note action taken	Signature of person performing QC
			L1	L2	L3		
30/01/2019	11:40	xxxxxxxx	7.9	12.0	16.1	/	

If you have any issues that you are unable to resolve, contact your **National Coordinating Centre (NCC)** (see ISF for details) or the CTU at woman2@lshtm.ac.uk

HEMOCUE HB 210 ANALYSER: MAINTENANCE (1/2)

Disinfect the Cuvette holder DAILY

1. Check that the analyser is turned off. The display should go blank.
2. To remove the cuvette holder, pull it out into its loading position.

Use a pointed object to carefully depress the small catch positioned in the upper right corner of the cuvette holder. While pressing the catch, carefully rotate the cuvette holder sideways as far as possible to the left.

3. Remove the Cuvette holder from the analyser and clean with an alcohol wipe. Wait for the cuvette holder to dry before replacing it.



HEMOCUE HB 210 ANALYSER: MAINTENANCE (2/2)

If troubleshooting for an error → clean the analyser's optical parts:

1. With the cuvette holder removed (see previous slide) **take the HemoCue Cleaner and move from the right to the left 5-10 times, and then pull it out.**

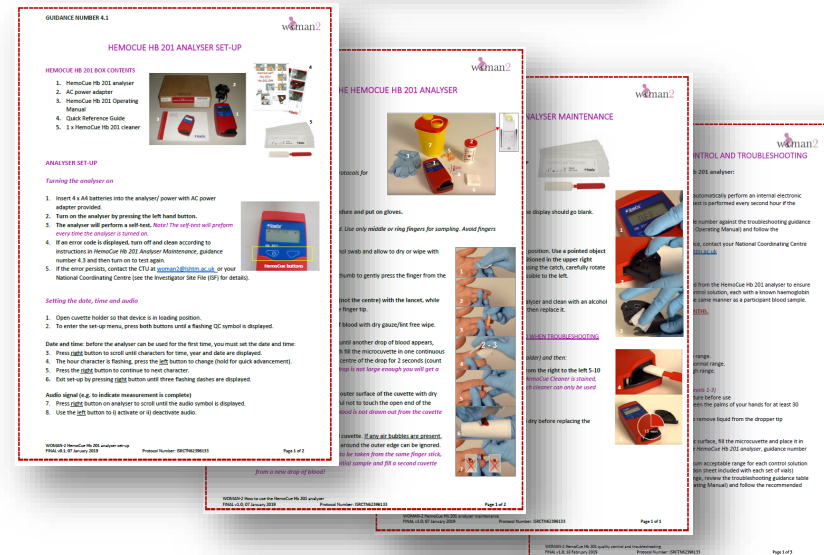
Note! If the HemoCue Cleaner is stained, repeat with a new HemoCue Cleaner. Each cleaner can only be used ONCE.

2. **Wait 15 minutes for the optical parts to dry** before replacing the cuvette holder and using the analyser.



FOR FURTHER GUIDANCE SEE:

1. **HemoCue Hb 201 Operating Manual**
2. **HemoCue HB 201 videos** (available on USB stick provided)
3. **Trial Procedures File, Section 4, Guidance Numbers 4.1- 4.4: HemoCue set up, use and maintenance**





Clinical Trials Unit
London School of Hygiene & Tropical Medicine
Keppel Street, London WC1E 7HT

Tel: +44(0)20 7299 4684
Email: woman2@Lshtm.ac.uk
Website: woman2.Lshtm.ac.uk



LONDON
SCHOOL of
HYGIENE
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