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luma

Operating Manual

www.lumahealth.uk

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Welcome to Luma

Luma empowers you to track your own health. With Luma, you can manage your anaemia by measuring your haemoglobin levels from the comfort of your home. Luma uses a single drop of blood and gives you a result in 60 seconds.

A mobile app is available to use if you would like to record your results, symptoms and medications to see trends in your health. Please note that the mobile app is not needed to use Luma.

Who is Luma for?

This product is suitable for use by men and non-pregnant women aged over 16 years old. Please note that if you are currently pregnant or have an underlying condition your target range may vary from that indicated by the mobile app. Please consult your healthcare professional before using the device.

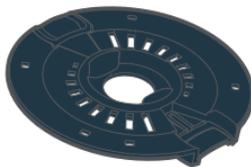
Components

- A. Luma.
- B. Holder - only use the Luma holder manufactured by Entia.
- C. Micro USB cable - only use the cable provided.
- D. Mains plug - only use the plug provided.
- E. Operating manual.
- F. Quick reference guide.

A



B



D



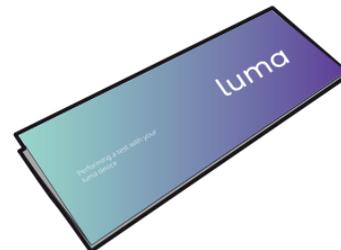
E



C



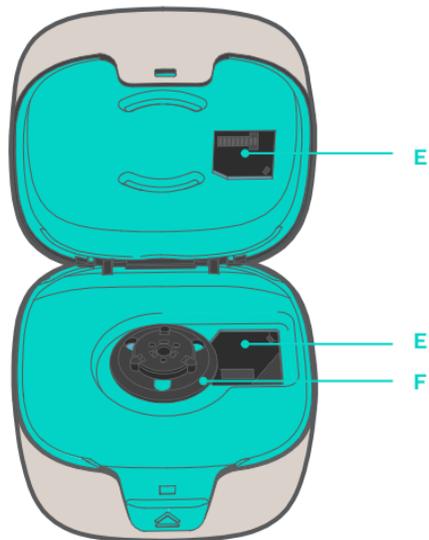
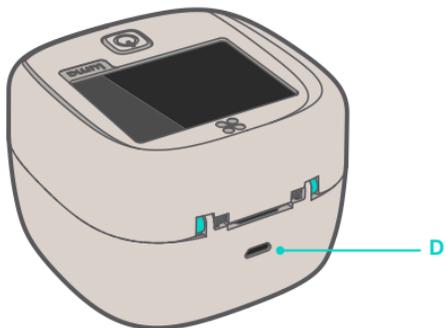
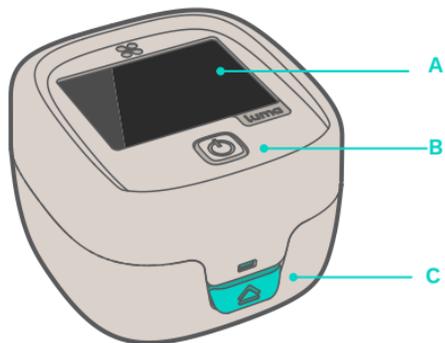
F



⚠ Only use the equipment in accordance with the instructions specified in this operating manual.

Please check that all components are undamaged and in working order. If any components are damaged, contact Entia (page 44).

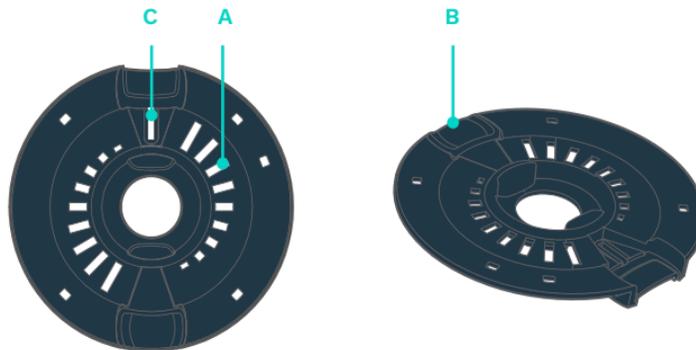
Device Features



- A. Touchscreen.
- B. Power button.
- C. Button: press to open.
- D. Micro USB charging port.
- E. Optical units.
- F. Holder clip.

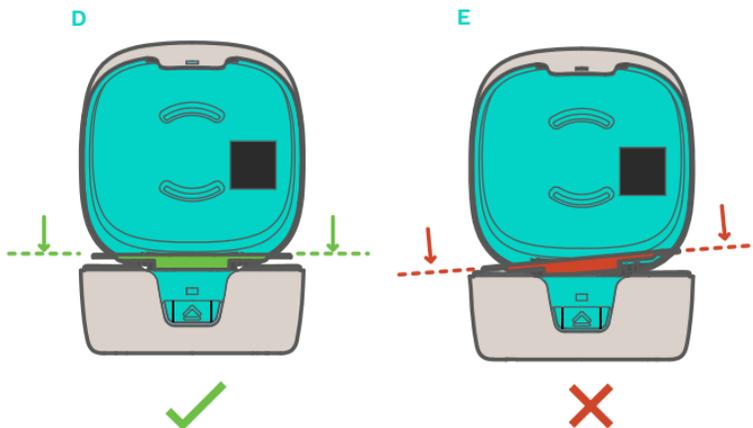
Holder

The holder secures the cuvette and calibrates (A) the device each time a measurement is made. A balance (B) is used for stability during a measurement, **do not** attempt to remove it at any time. The analysis window (C) allows the light from the optical units to go through, which is how the measurement is performed (page 40).



⚠ Position of the Holder

When clipping the holder into the device, ensure that it is level (D). An incorrectly positioned holder (E) may result in a measurement error.



Test Components

Test kits are available on a subscription basis through the Luma website (www.lumahealth.uk). Alternatively you may be receiving them from a healthcare professional on an individual basis.

- A. Cuvette bag
- B. Lancets
- C. Cuvettes

A



Cuvette bag

The cuvette bag contains 15 disposable cuvettes.

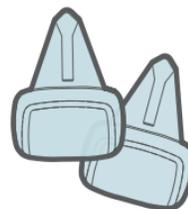
B



Lancets

Lancets are used to prick your finger and create a blood drop. Lancets are sterile and are single use only.

C

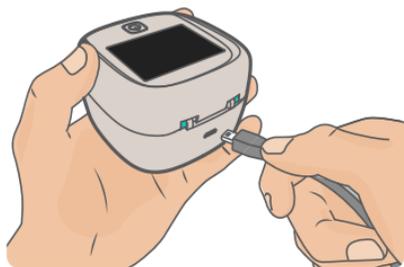


Cuvettes

Cuvettes are used in each test to collect the blood sample and to perform the measurement using the device (page 12). Cuvettes are single use only.

 **Do not** use the equipment in a manner not specified as the protection provided by the equipment may be impaired.

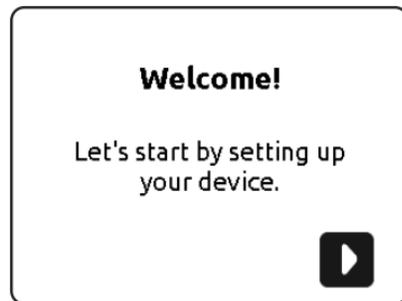
Initial Set-up



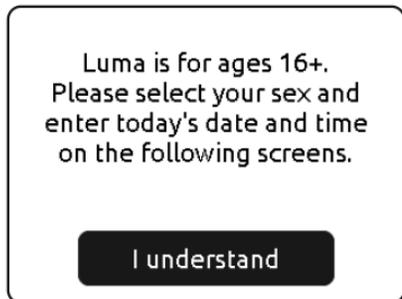
1. Connect the USB cable to the back of Luma and charge for 2 hours before using it for the first time. **Only use** the micro USB cable and mains plug provided (page 3).



2. To turn on the device, press the power button for 2 seconds.



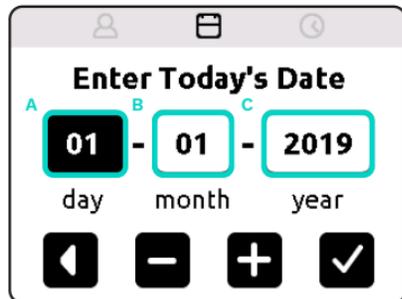
3. When turned on for the first time, the device will run the initial set-up.



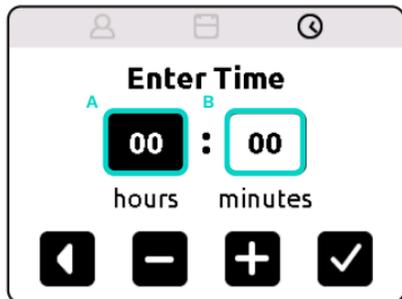
4. This message describes the information you need to enter to set up your device correctly.



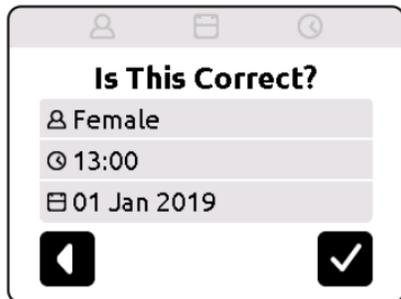
5. Select your biological sex.



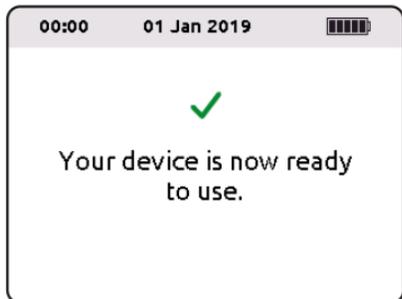
6. Set the date. Select day (A), month (B) or year (C). Set values using +/- . Press +.



7. Set the time. Select hours (A) or minutes (B). Set values using +/- . Press +.



8. Verify your information. If everything is correct, press +. Your profile information can be changed later in Settings (page 24).



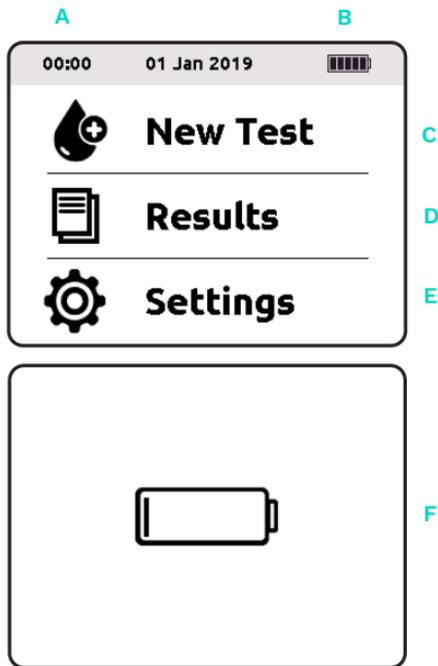
9. The set-up is complete.

3

Using the Device

Home Screen

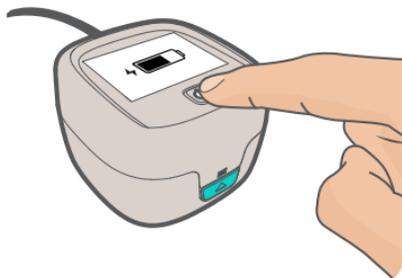
After completing the initial set-up, the home screen should show the following:



- A. Time.
- B. Battery status.
The different icons displayed here indicate the:
 - i.  Charge bars which represent 20%, 40%, 60%, 80%, 100% of battery charge.
 - ii.  Battery is critically low (<10%). Charge the device.
 - iii.  Device is 100% charged.
 - iv.  Device is plugged in and charging.
 - v.  Device is plugged in, but not charging.
- C. New Test. Select to perform a test.
- D. Results. Select to access previous test results and to access the QR code if you are using the mobile app. The device can be used without the app.
- E. Settings. Select to change sex, change time and date, view software licences and perform a factory reset.
- F. A full screen notification will show when the battery charge drops to 10%. Charge the device.

Battery Notifications

When the device is plugged in and charging, the battery status can be checked by tapping the power button. A full screen battery notification will be displayed.



- A. ✓  Fully charged.
- B. ⚡  Charging.
- C.  Battery status (not charging).
- D.  Battery is empty (not charging).
- E. !  ⚠ The device is connected to the charger but not charging:
 1. Check that you are using the mains plug and micro USB cable provided.
 2. Do not charge Luma from a computer.
 3. Verify that the cable and the mains plug are not damaged.
 4. If the problem persists, contact Entia (page 44).

Using the Cuvette

The Cuvette

The cuvette is used to analyse the blood sample in the device. It is composed of a top chamber (A), where the blood sample is collected, a bottom chamber (B) where the blood sample is analysed, and a base (C) where the cuvette should be held.

⚠ **The cuvette is for single use only. Discard the cuvette after use. Only use Luma cuvettes manufactured by Entia.**



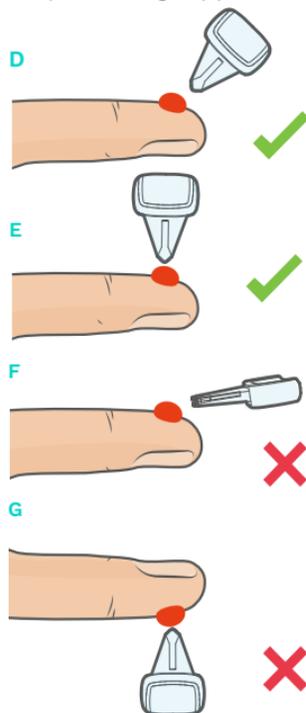
Sample Volume

The sample volume should be adequate for the test to be completed successfully.



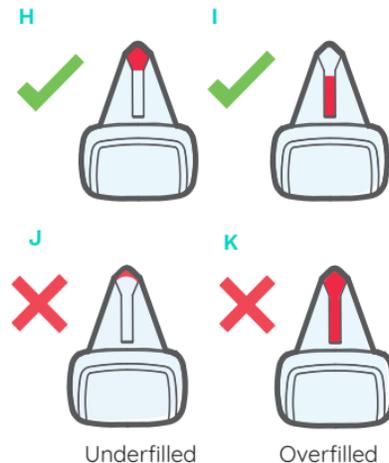
Filling the Cuvette

To fill correctly, hold by the base (C) and position at 90° or at 45° to the pricked finger (D, E). Do not use the cuvette upside down (G), or parallel to the pricked finger (F).



Fill the top chamber (H). The sample may fall into the second chamber (I), if this happens do not continue to fill the cuvette. Do not underfill or overfill cuvettes. Underfilled (J) and overfilled (K) cuvettes will be detected by the device, and an error message will be displayed.

⚠ **If you get this error, use a new cuvette to perform another test.**

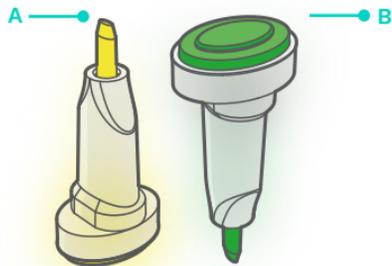


⚠ **Reseal the cuvette packet after use.**

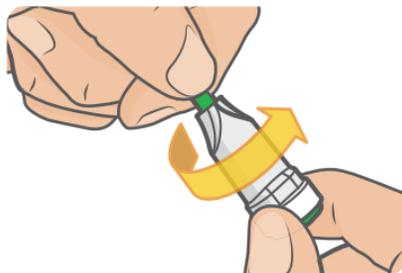
Using the Lancet

The Lancet

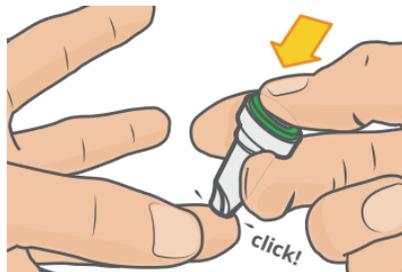
The push-button-activated lancet is used to perform finger pricks to collect blood samples. It is composed of a protective cap (A) and a push button (B).



⚠ The lancet is for single use only.
Discard the lancet after use.



a. Twist the lancet's green protective cap (A) until it is loose and pull it out.



b. Place the lancet **firmly** on the desired finger and press the button (B) to prick yourself.

Performing a Test

We've made it simple so you can do the test from the comfort of your home. Your subscription kit contains everything you need to perform a haemoglobin (Hb) test. Make sure you read the instructions carefully.

It will be quick and easy and will only take a couple of minutes.

Phases:

01. Preparing

02. Pricking

03. Sampling

04. Analysing

Items You Need Before Performing a Test



01. Luma

To perform a measurement.



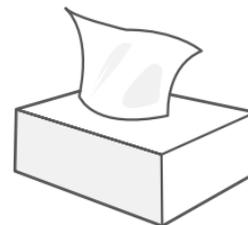
02. Cuvette

To collect the blood sample.



03. Lancet

To prick your finger.



04. Tissues

To wipe blood.

Things You Need to Know before You Do a Test



01. Time and position

Perform every test at the same time and in the same position. We recommend doing tests in the morning, in a seated position.



02. Stay hydrated

If you are dehydrated your haemoglobin result will be higher than it really is.



03. Dry your hands

If your hands are wet, the drop of blood may be diluted which could cause a false low reading.



04. Warm your hands

By running them under warm water. Having warm hands allows the blood drop to form easily. Wearing a ring and having cold hands can decrease blood flow, which can affect results.



05. Don't squeeze

Allow the drop to form naturally. Don't squeeze your finger. Squeezing can damage red blood cells, creating a false result.



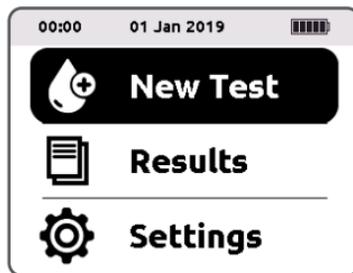
06. Below elbow level

To increase blood flow, you can maintain your finger below elbow level.

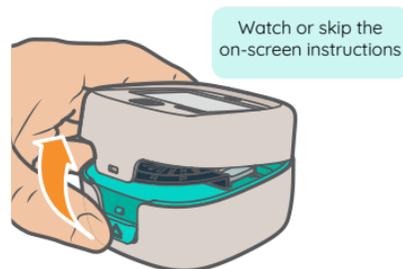
01. Preparing



a. Warm your hands by washing them in warm water for **two minutes**.



b. Select **New Test** on the device's home screen.



c. Open your Luma device.

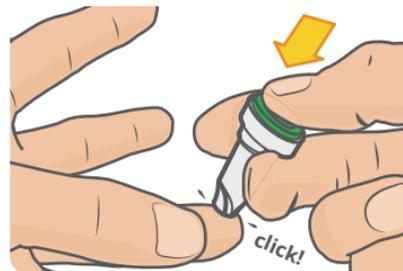
02. Pricking Complete steps 02, 03, 04(a) in less than 1 minute



a. Make sure your hands are dry. If your hands are still cold, warm them by rubbing them together.

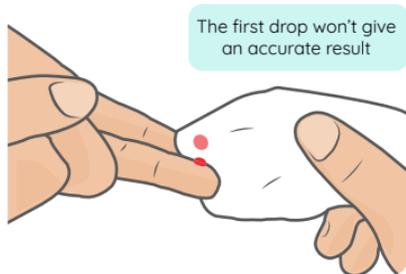


b. We advise to prick the side of the **3rd or 4th finger** of your non-dominant hand.

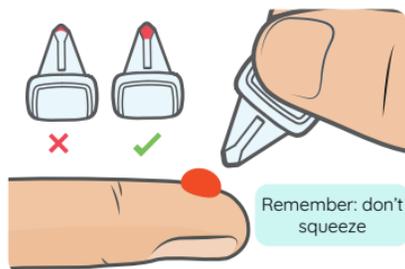


c. Twist off the lancet's protective cap. Press the lancet firmly into the side of your finger. Press the button to prick.

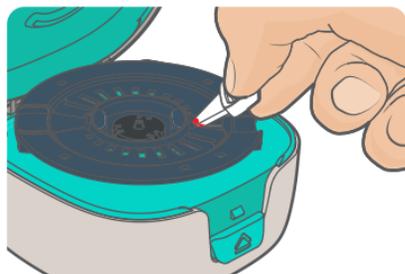
03. Sampling



- a. Wipe the first drop of blood. Hold your finger below elbow level to increase blood flow.

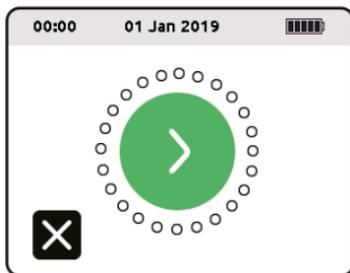


- b. Fill the cuvette with the **2nd drop of blood**. Wait until the drop is a similar size to the diagram above.



- c. Place the cuvette in the device holder. Close the device. Use a tissue to apply pressure to your finger.

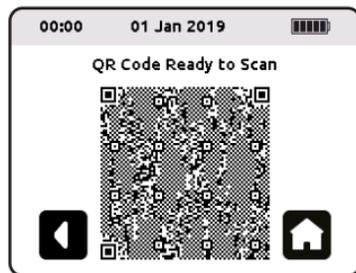
04. Analysing



- a. Press the green button to start. You will get your result in 60 seconds.

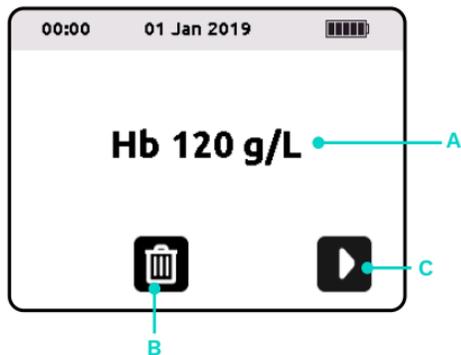


- b. Your result will be shown on screen. Dispose of the lancet and cuvette as they are single use.



- c. If you are using the app you can scan the QR code. The device can be used without the mobile app.

Your Test Results



A. The value for haemoglobin (A) is displayed. Haemoglobin results above 250 g/L and below 50g/L will create Error 11 and Error 12 (page 37). The device will not give a numerical result for results outside of the 50 to 250 g/L range.

B. Press the bin symbol (B) to delete a result.

C. The ▶ button (C) reveals a QR code that can be scanned if you are using the app.

What to Do If You Have an Unusual Result

1. If you get an unusual result or one that is outside of the range provided by your healthcare professional, we recommend you perform a second test. Test result accuracy is dependent on following the advice and instructions provided in this manual (pages 15-17).
2. Use a new cuvette and prick a different finger.
3. Do not make changes to your medication without first speaking to your healthcare professional.

Variability in Results

A blood test using a capillary sample (typically obtained from a finger) may differ slightly from one using a venous sample (obtained through direct puncture to a vein, most often on the inside of the arm).

A difference of up to 7% in results obtained from tests performed on different capillary samples is considered normal. Even within a venous sample, a difference of up to 3.5% in results is considered normal. [1] Your haemoglobin concentration can differ from one drop of blood to the next.

Results can vary due to a variety of factors, including:

- Natural variations in haemoglobin concentration in different parts of your body (e.g. right hand versus left hand).
- Your position (whether you are standing, sitting, or laying down).
- The time of day when you perform your test (morning vs. evening).
- Your level of hydration.
- The altitude of your location.

For best results, we advise that you perform all tests:

- In the same position (seated or standing) and having maintained this position for 2-3 minutes prior to taking each measurement.
- At the same time of day (preferably in the morning before breakfast).
- Using the sampling technique outlined on pages 16-17.

[1] Morris SS, Ruel MT, Cohen RJ, et al. Precision, accuracy, and reliability of hemoglobin assessment with use of capillary blood. *Am J Clin Nutr.* 1999;69:1243-1248.

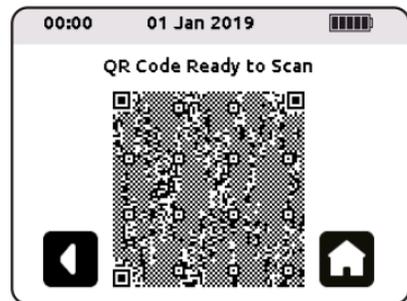
Uploading Results to the Mobile App

A Luma QR code can store up to 35 test results. Once the memory is full, the Luma QR code will automatically delete the oldest results.

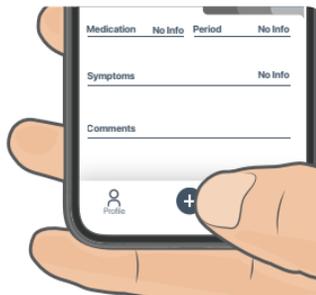
If you are using the mobile app and would like to track your results there, make sure to scan the QR code regularly. The device will remind you to scan results every 50 tests. The device can be used without the app.

Please note, the app displays haemoglobin results against a target range based on the Dacie and Lewis Practical Haematology target ranges (page 42). Your target range may vary if you have underlying health conditions. Please seek advice from your healthcare professional if in doubt.

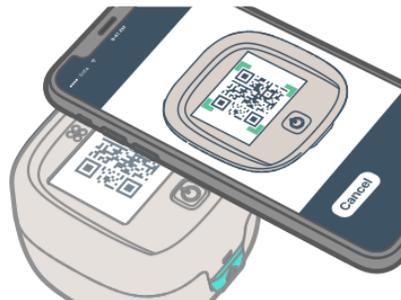
Scanning Results to the Mobile App



1. After you perform a test, you will see the QR code screen.



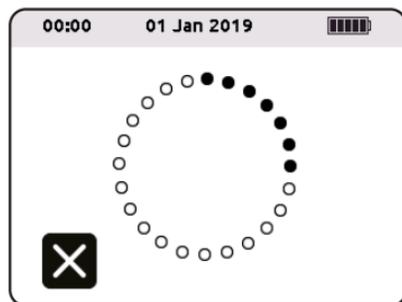
2. Open the mobile app, and click on the + in the bottom bar to open your camera.



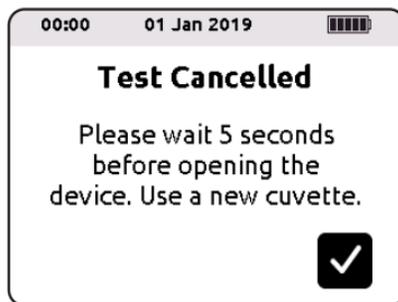
3. Capture the QR code using the camera within the mobile app.

Canceling a Test

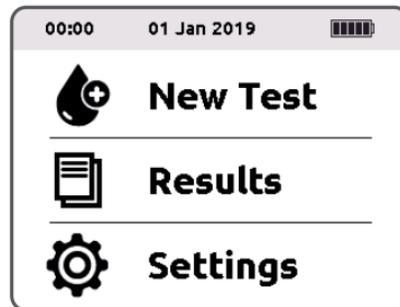
You can use this feature to cancel a test.



1. Press **X** at any time to cancel the test.



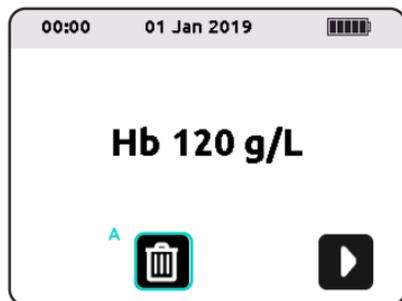
2. A prompt will appear. Wait 5 seconds before opening the device to allow the holder to stop spinning. Dispose of the cuvette.



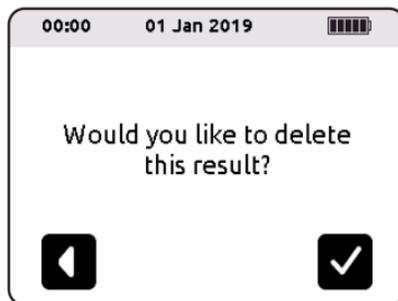
3. You will be redirected to the home screen. Perform a new test using a new cuvette (page 16).

Deleting a Result

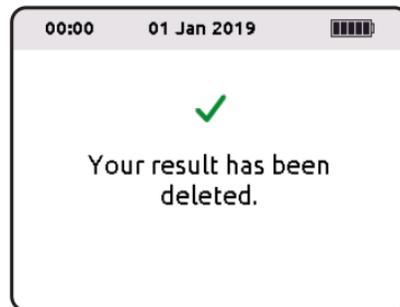
You can use this feature to delete a result. ⚠ Deleting a result is permanent - a deleted result cannot be recovered.



1. Press the bin symbol (A) to delete a result.



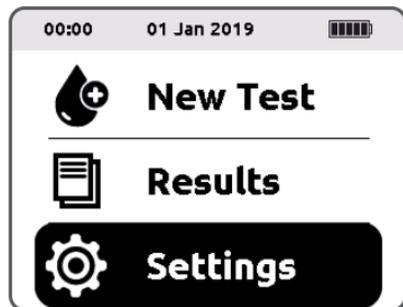
2. A prompt will appear. Press + to confirm your selection.



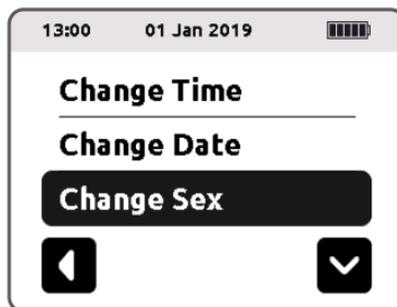
3. A confirmation will appear and you will be redirected to the home screen.

Changing the Sex

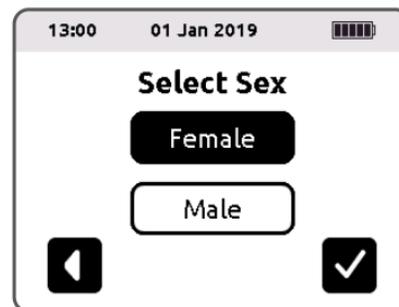
If the sex on your device is incorrect, you can use this feature to change it.



1. From the home screen, select Settings.



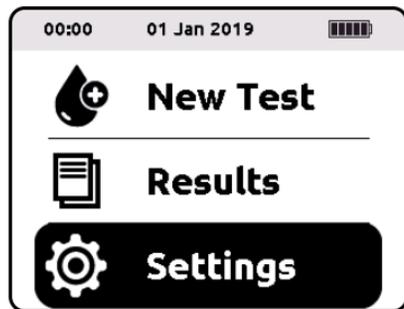
2. Select Change Sex.



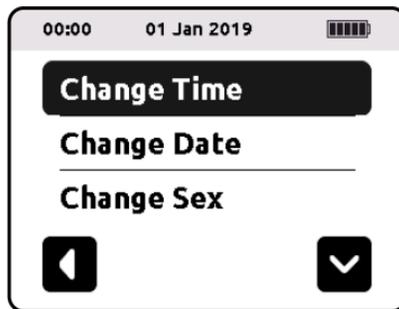
3. Select sex. Press +.

Changing the Time

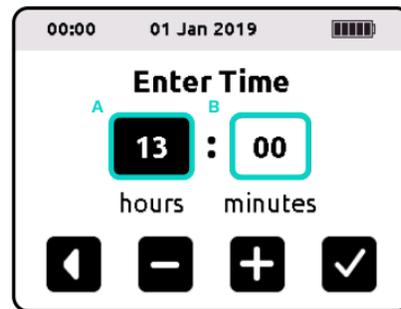
If the time on your device is incorrect, you can use this feature to change it.



1. From the home screen, select Settings.



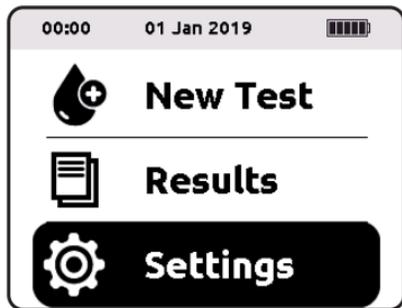
2. Select Change Time.



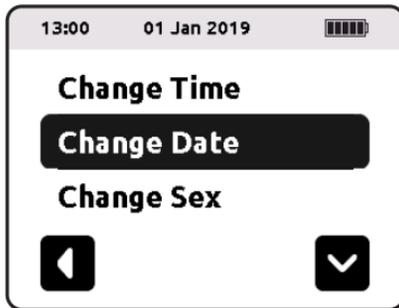
3. Select hours (A), or minutes (B). Set values using +/- . Press +.

Changing the Date

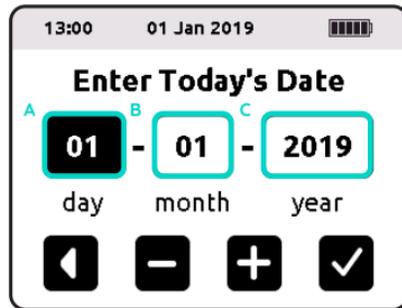
If the date on your device is incorrect, you can use this feature to change it.



1. From the home screen, select Settings.



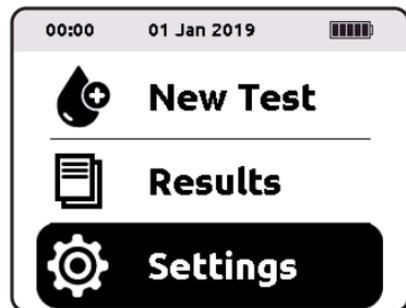
2. Select Change Date.



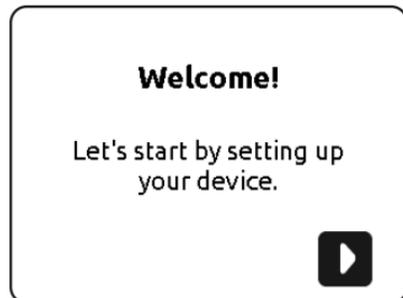
3. Select day (A), month (B) or year (C). Set values using +/- . Press +.

Performing a Factory Reset

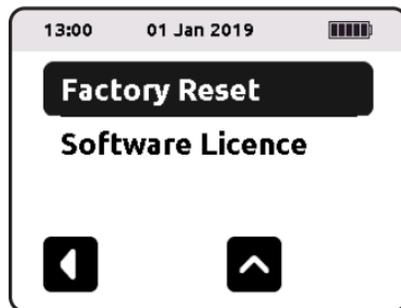
You can use this feature to delete all saved results and settings on the device.



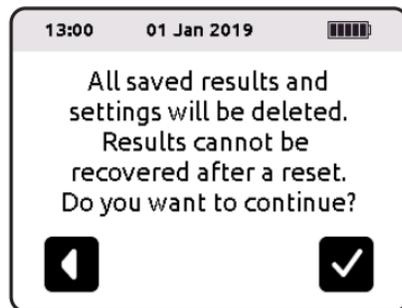
1. From the home screen, select Settings.



4. Wait for the device to reboot. Complete the initial set-up (page 8).



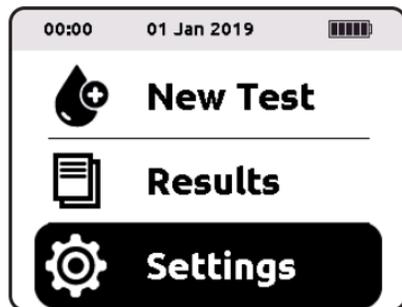
2. Use the arrow to scroll to the second page of the Settings. Select Factory Reset.



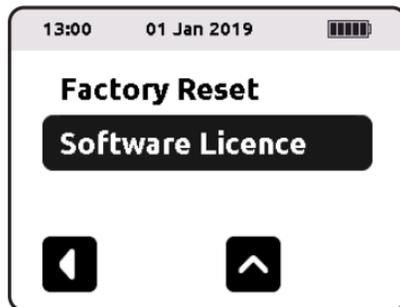
3. ⚠️ Doing this will erase all saved results and settings. Press + to confirm factory reset.

Viewing the Software Licence

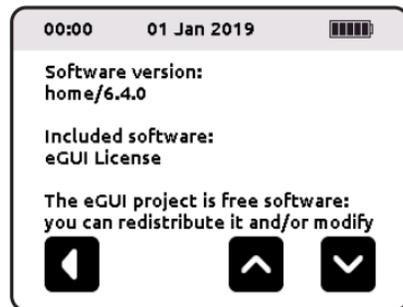
You can use this feature to view the device's software licence.



1. From the home screen, select Settings.



2. Use the arrow to scroll to the second page of the Settings menu. Select Software Licence.



3. Use arrows to scroll up and down.

Cleaning

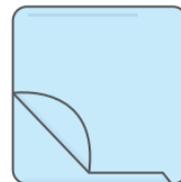
If you need to clean your device due to mild blood splatters, please follow the instructions below.

We recommend using an alcohol wipe, wet wipe or a tissue with mild soap to clean the device. To clean the optical unit we recommend using a microfibre cloth.

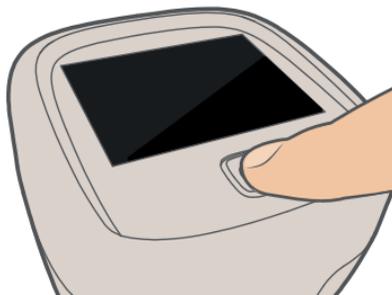
Items you need



01. Tissue



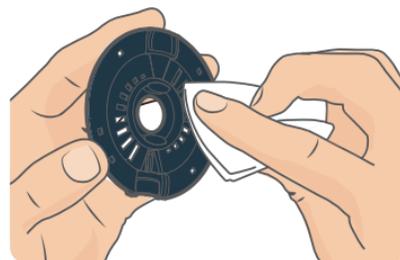
02. Microfibre cloth



1. Turn off the device by pressing the power button for 2 seconds.



2. Remove the holder.

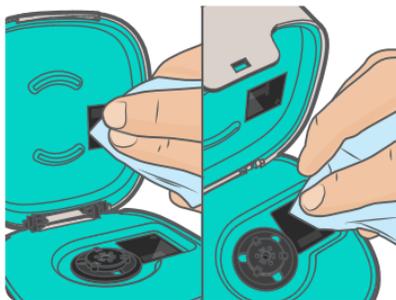


3. Use an alcohol wipe, a wet wipe or a tissue with mild soap to clean the holder.

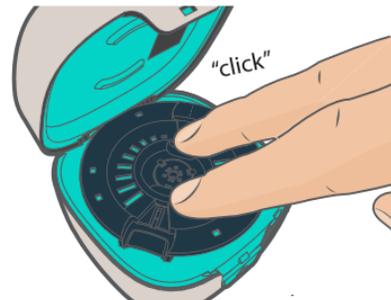
Cleaning ⚠



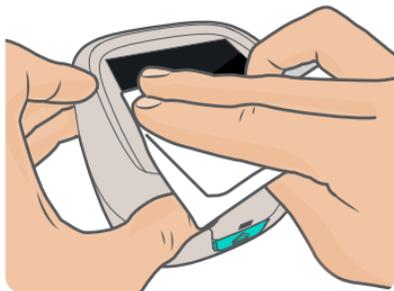
4. Use an alcohol wipe, a wet wipe or a tissue with mild soap to clean the interior surfaces of the device. ⚠ **Do not exert pressure on the holder clip.**



5. Use a microfibre cloth to clean the optical units. ⚠ **Do not scratch the optical units.**



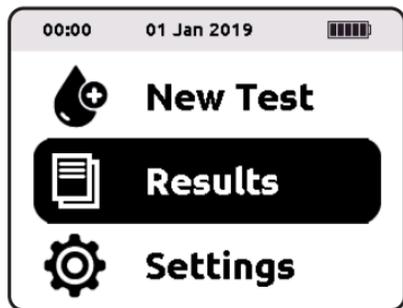
6. Clip the holder back onto the holder clip. ⚠ **Allow to dry for 5 minutes before using the device.**



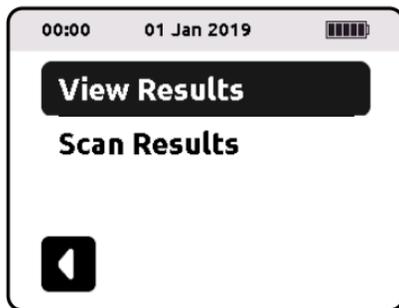
7. Use an alcohol wipe, a wet wipe or a tissue with mild soap to clean the outside of the device.

6

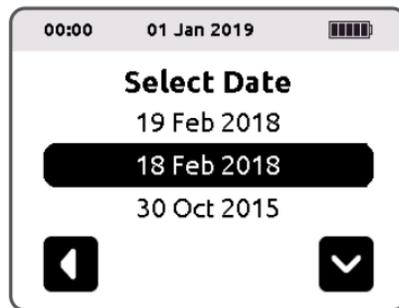
Accessing Results



1. From the home screen, select Results.



2. Select View Results.



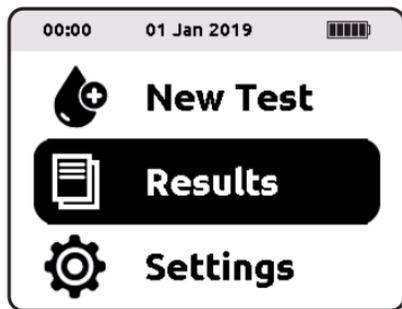
3. Select a date to see a previous measurement. Use the arrows to scroll to additional dates.



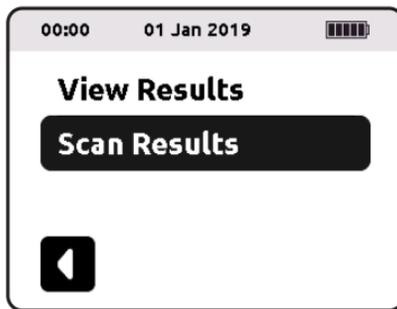
4. Use the arrows to scroll to additional measurements.

Previous Test Results

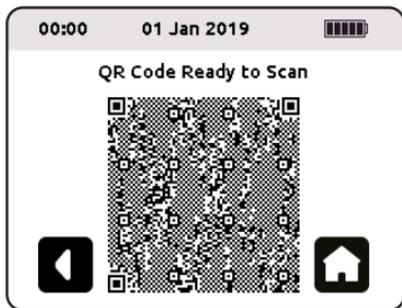
Scanning Results to the App



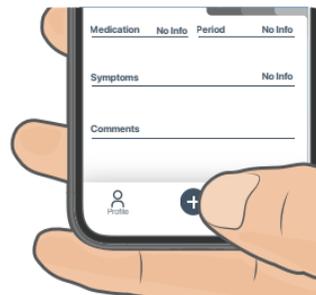
1. From the home screen, select Results.



2. Select Scan Results.



4. Capture the QR code using the camera within the mobile app.

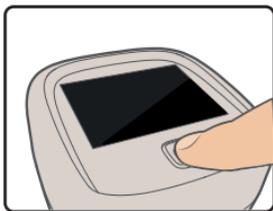


3. Open the mobile app, and click on the + in the bottom bar to open your camera.

Message

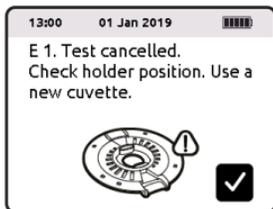
Issue

Action



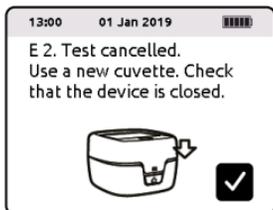
The device screen has frozen.

- 1 - Press the power button for 10 seconds to restart the device.
- 2 - If you were doing a test, use a new cuvette and a new blood sample.
- 3 - If the problem persists, contact Entia (page 44).



The device has encountered a mechanical problem which is preventing the measurement. The test has been cancelled.

- 1 - Use a new cuvette and a new blood sample.
- 2 - Check that the holder and cuvette are inserted properly in the device (pages 5, 17).
- 3 - Check that the holder is free to rotate.
- 4 - If the problem persists, contact Entia (page 44).



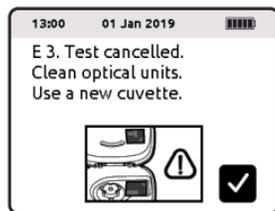
The device has been opened during the measurement, or the device has not been closed properly before the measurement. The test has been cancelled.

- 1 - Use a new cuvette and a new blood sample.
- 2 - Check that the holder and cuvette are inserted properly in the device (pages 5, 17).
- 3 - Check that the device door can close.
- 4 - Do not open the device at any time during the measurement.
- 5 - If the problem persists, contact Entia (page 44).

Message

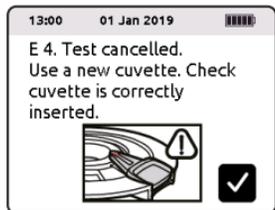
Issue

Action



The optical units may need cleaning. The optical units may be scratched. The test has been cancelled.

- 1 - Turn off the device by pressing the power button for 2 seconds.
- 2 - Check that the optical units are clear of marks.
- 3 - Clean the optical units (page 30).
- 4 - If the problem persists, contact Entia (page 44)



No cuvette is loaded or the cuvette has not been inserted correctly. The test has been cancelled.

- 1 - Use a new cuvette and a new blood sample.
- 2 - Ensure the cuvette is properly inserted in the holder (page 5, 17).
- 3 - If the problem persists, contact Entia (page 44).



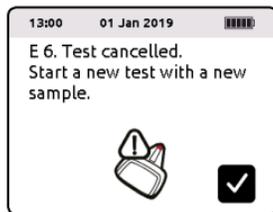
The measurement can not be made because the device is not level. The test has been cancelled.

- 1 - Verify that the device is stable.
- 2 - Use a new cuvette and a new blood sample.
- 3 - If the problem persists, contact Entia (page 44).

Message

Issue

Action



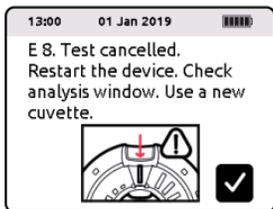
There may be a problem with the blood sample. It may be clotted, or the sample volume in the cuvette is too small or too great. There may be a fault with the cuvette. The test has been cancelled.

- 1 - Check the expiry date on the back of the test kit.
- 2 - Use a new cuvette and a new blood sample.
- 3 - Ensure that the cuvette contains the correct sample volume (page 12). Start the measurement within 1 minute of collecting the blood sample.
- 4 - If the problem persists, contact Entia (page 44).



The device has encountered an issue. The test has been cancelled.

- 1 - Press and hold the power button for 10 seconds to reset the device.
- 2 - Turn on the device by pressing the power button for 2 seconds.
- 3 - Use a new cuvette and a new blood sample.
- 4 - If the problem persists, contact Entia (page 44).



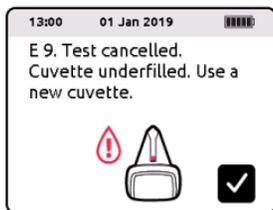
The holder analysis window may be obstructed or the cuvette may be damaged. The test has been cancelled.

- 1 - Press and hold the power button for 10 seconds to reset the device.
- 2 - Turn on the device by pressing the power button for 2 seconds.
- 3 - Clean the holder (page 30) and check the analysis window.
- 4 - Use a new cuvette and a new blood sample.
- 5 - If the problem persists, contact Entia (page 44).

Message

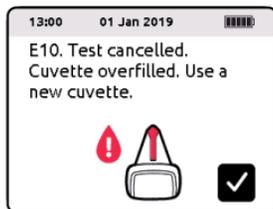
Issue

Action



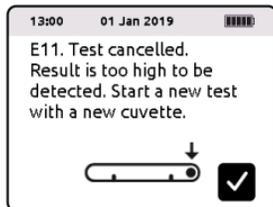
There may be a problem with the blood sample. The sample may have clotted or the sample volume in the cuvette is too small. The test has been cancelled.

- 1 - Use a new cuvette and a new blood sample.
- 2 - Ensure that the cuvette contains the correct sample volume (page 12). Start the measurement within 1 minute of collecting the sample.
- 3 - If the problem persists, contact Entia (page 44).



There may be a problem with the blood sample. The sample may have clotted or the sample volume in the cuvette is too large. The test has been cancelled.

- 1 - Use a new cuvette and a new blood sample.
- 2 - Ensure that the cuvette contains the correct sample volume (page 12). Start the measurement within 1 minute of collecting the sample.
- 3 - If the problem persists, contact Entia (page 44).



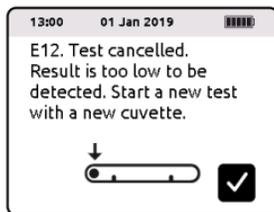
The device will not give a numerical result for results outside of the 50 to 250 g/L range. This may be due to a device error, or to your result being excessively high. If the result is unusual, perform another test.

- 1 - Press and hold the power button for 10 seconds to reset the device.
- 2 - Turn on the device by pressing the power button for 2 seconds.
- 3 - Perform another test. Use a new cuvette and a new blood sample.
- 4 - If the problem persists, contact Entia (page 44).

Message

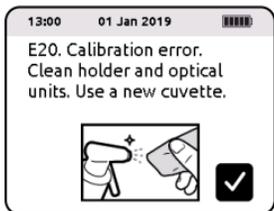
Issue

Action



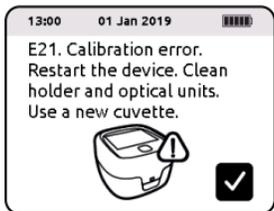
The device will not give a numerical result for results outside of the 50 to 250 g/L range. This may be due to a device error, or to your result being excessively low. If the result is unusual, perform another test.

- 1 - Press and hold the power button for 10 seconds to reset the device.
- 2 - Turn on the device by pressing the power button for 2 seconds.
- 3 - Perform another test. Use a new cuvette and a new blood sample.
- 4 - If the problem persists, contact Entia (page 44).



The holder and/or optical units encountered an issue. The test has been cancelled.

- 1 - Clean the optical units and holder (page 30).
- 2 - Check the holder for damage.
- 3 - Use a new cuvette and a new blood sample.
- 4 - If the problem persists, contact Entia (page 44).



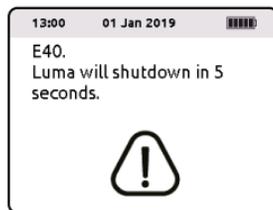
The device encountered a hardware problem. The test has been cancelled.

- 1 - Press and hold the power button for 10 seconds to reset the device.
- 2 - Turn on the device by pressing the power button for 2 seconds.
- 3 - Clean the optical units and holder (page 30).
- 4 - Use a new cuvette and a new blood sample.
- 5 - If the problem persists, contact Entia (page 44).

Message

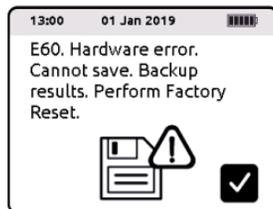
Issue

Action



This error message will also be shown for errors: E41, E42, E43, E44, E45 and E46. The device has encountered a hardware or software problem.

- 1 - Back up previous results by uploading them into the app (page 33).
- 2 - Perform a Factory Reset (page 27).
- 3 - If the problem persists, contact Entia (page 44).



The device memory is corrupted. The device has encountered a hardware problem.

- 1 - Back up previous results by uploading them into the app (page 33).
- 2 - Perform a Factory Reset (page 27).
- 3 - If the problem persists, contact Entia (page 44).



The device memory is corrupted. The device has encountered a hardware problem. In order to solve the problem, the memory has been reset.

- 1 - No action required.
- 2 - If the problem persists, contact Entia (page 44).

Theory

Haemoglobin is the protein found inside red blood cells which is responsible for carrying oxygen around the body. Luma measures haemoglobin concentration in your blood sample.

Luma operates on the principles of centrifugation and photometric measurements to determine haemoglobin. Centrifugation enables the separation of whole blood into cellular constituents (red blood cells, white blood cells and platelets) and plasma. The ratio of volume occupied by red blood cells to the total volume provides a haematocrit.

Luma then shines light through the blood sample, which enables it to calculate haemoglobin concentration within the red blood cells (this figure is called mean corpuscular haemoglobin concentration or MCHC).

The blood sample's haemoglobin concentration can be derived from the haematocrit and MCHC.

Blood Sample Collection

Capillary blood samples (typically collected from a finger) may be used with Luma.

Intended Use

The intended use of this product is for the measurement of haemoglobin in a capillary sample (typically obtained from a finger) using a specifically designed device, Luma, and specifically designed cuvettes, Luma cuvettes. Luma is only to be used with Luma cuvettes. The device is intended for self-testing. No additional training is required beyond the instructions for use.

Storage and Handling

The operating temperature of Luma is 5-45 °C (41-113 °F). Allow Luma to reach ambient temperature before use. Luma can be stored and transported at 0-50 °C (32-122°F).

The expiry date for the cuvettes is the same for unopened and opened bags though the cuvette pack must be resealed when not in use. Luma cuvettes can be stored and transported at 0-50 °C (32-122 °F) and 0-90% humidity. Luma cuvettes can be used at 5-45 °C (41-113 °F) and 0-90% humidity.

If opened during operation, Luma will stop running the measurement. If Luma is dropped or is in free-fall, the device will switch off to reduce the risk of damage to the device.

Memory

Luma can store up to 1000 test results. Once the memory is full, Luma will automatically delete the oldest results. If using the app you can upload your results in the mobile app to save them.

A Luma QR code can store up to 35 test results. Once the memory is full, the Luma QR code will automatically delete the oldest results. Scan results regularly if you would like to track them in the mobile app. The device will notify you every time you have performed 50 tests to remind you to scan.

Limitations

Luma is only to be used with Luma cuvettes that have not passed their expiry date. Luma and Luma cuvettes may only be used for the purposes specified. Results provided by Luma should not be used to make a diagnosis, or to replace or overrule a qualified healthcare provider's judgment.

Service and Disposal

In the event of changes in the analytical performance or operation of the device, please contact Entia (page 44).

Prior to servicing or disposal, Luma should be cleaned as outlined in Maintenance (page 30). Consult environmental authorities to ensure correct disposal of Luma.

Used Luma cuvettes contain blood specimens and as such should be handled and disposed of with care, as they might be infectious. Consult environmental authorities to ensure correct disposal of used Luma cuvettes.

Calibration

Luma has an internal quality control, which enables it to account for physical and environmental changes to the system prior to each measurement.

Materials Required

- Luma.
- Luma cuvettes.
- Lancets.
- Tissues.

Expected Values

Based on the sex you entered, the Luma app is able to display haemoglobin measurements with respect to the Dacie and Lewis Practical Haematology target ranges. Please note that if you are currently pregnant or have an underlying condition your target range may vary from that indicated.

Dacie and Lewis Practical Haematology Target Ranges

	Normal Hb (g/L)
Men (≥ 16 yrs)	130-170
Non-pregnant women (≥ 16 yrs)	120-150

Target ranges in the Luma mobile app are adapted from Bhatnagar, N. (2017), Dacie and Lewis Practical Haematology (12th edition) By B. J. Bain, I. Bates and M. A. Laffan, Elsevier, London, 2017. Br J Haematol, 178: 652-652. doi:10.1111/bjh.14872.

Measurement Range

Haemoglobin 50-250 g/L.

Accuracy

Luma has been tested against gold standard lab methods and demonstrates that measurements are accurate and repeatable.

Technical Specifications Summary

Haemoglobin measurement range	50-250 g/L (5.0-25.0 g/dL, 3.1-15.5 mmol/L)
Operating temperature	5-45 °C
Operating humidity	0-90 %
Storage temperature	0-50 °C
Storage humidity	0-90%
Altitude	≤ 4500 m (mains plug ≤ 2000 m)
Sample volume	4-8 µL
Measurement time	60 seconds
Wavelength	515 nm, 660 nm and 940 nm
Battery	4.2 V Integrated lithium-ion rechargeable battery
Connector	Micro USB B
Instrument input rating	5 V (power supply) 2.0 A
Power supply input rating	0.35 A, 100-240 Vac, 50/60 Hz
Protection class	IP2X
Dimensions	W = 78 mm, L = 83 mm, H = 52 mm
Weight	96 g
Carry case dimensions	W = 230 mm, L = 160 mm, H = 70 mm
Weight of analyser + carry case	500 g

Luma is tested to:
IEC 61326-1: 2013,
IEC 61326-2-6: 2013,
IEC 61010-1: 2010,
IEC 61010-2-101: 2015.

Warranty

Entia Ltd warrants to the original purchaser that this device will be free from defects in materials and workmanship for a period of two years (24 months). The period starts from the date of original purchase. During the period, Entia Ltd shall replace the device under warranty with a reconditioned device or, at its option, repair or replace at no charge a device that is found to be defective.

This warranty is subject to the following exceptions and limitations:

This warranty is limited to repair or replacement due to defects in parts or workmanship. Parts required which were not defective shall be replaced at additional cost. Entia shall not be required to make any repairs or replace any parts that are necessitated by abuse, accidents, alteration, misuse, neglect or failure to operate the device in accordance with the users manual. Furthermore, Entia assumes no liability from malfunction or damage to devices caused by the use of cuvettes other than cuvettes manufactured by Entia. Entia reserves the right to make changes in the design of this device without obligation to incorporate such changes into previously manufactured devices.

Disclaimer of Warranties:

This warranty is expressly made in lieu of any and all other warranties expressed or implied (either in fact or by operation of law) including the warranties of merchantability and fitness for use, which are expressly excluded, and is the only warranty given by Entia.

Limitations of Liability:

In no event shall Entia be liable for indirect, special or consequential damages, even if Entia has been advised of the possibility of such damages. For warranty service, please contact Entia (see below).

Please report any serious incident that has occurred in relation to the device to Entia and the competent authority of the Member State in which you are established.

Support

For technical support or to purchase further products please contact Entia.

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60 Gray's Inn Road,
London
WC1X 8LU, UK

 +44 (0) 20 3020 0031

 support@lumahealth.uk

 www.lumahealth.uk

Spare parts and further products available:

Holder

Operating manual & Quick reference guide

Mains plug & Micro USB cable

Carry case

Test components (cuvettes and lancets)

Symbols Used



Do not use if package is damaged



Handle with care



Do not re-use



Biological risks



Caution: consult operating manual



Consult operating manual



Manufacturer



Date of manufacture



Manufacturer and date of manufacture

MM YYYY



Temperature limitation



Humidity limitation



Use-by date



Direct current



Keep dry



CE Mark. Luma complies with 98/79/EC directive for in vitro diagnostic medical devices.



Dispose of the instrument in compliance with local regulations for the disposal of electronic equipment. Do not put in domestic waste!



In vitro diagnostic medical device



Batch code



Sterilised by radiation



Reference number



Authorised Representative in the European Community

List of Abbreviations

Hb		Haemoglobin
E.		Error

Notes

Notes

Notes