COALA®



USER MANUAL COALA HEART MONITOR

CE
2797

INTRODUCTION

Congratulations on your new Coala. Please read this manual before use for important safety information about your Coala.

The Coala is paired to the Coala App on a user supplied compatible smartphone running iOS or Android. Compatible smartphones are listed on Coala Solutions website:
www.coalasolutions.com/device-compatibility.

"Made for iPhone" mean that an electronic accessory has been designed to connect specifically to iPhone and has been certified by the developer to meet Apple performance standards. Apple is not responsible for the operation of this device or its compliance with safety and regulatory standards. Please note that the use of this accessory with iPhone may affect wireless performance. iPhone is a trademark of Apple Inc., registered in the U.S. and other countries.

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01 Product description

The Coala Heart Monitor is a patented medical device that records clinical quality ECG (electrocardiogram) and heart sounds simultaneously. The device can be used by both healthcare professionals and health conscious individuals to record ECG in a home healthcare environment whenever they are feeling symptoms. The ECG and heart sound recordings can easily be shared with your Healthcare provider through the Coala Care Portal.

The Coala Heart Monitor system consists of the following parts:

- The Coala Heart Monitor: A small hand-held device that is pressed against the chest for simultaneous recordings of ECG and heart sounds through electrodes and a stethoscope membrane. The chest measurement is always followed by a thumb ECG recording for the most accurate detection.
- The Coala App: Installed on a compatible smartphone and is used together with the Coala Heart Monitor to record, transmit and view measurements directly on your smartphone. Measurements are transmitted from the app to the Coala Care Portal server for analysis and the user reviews the analyzed result within minutes in the Coala App. The app also features a messaging system where you can receive messages and notifications from your Healthcare provider.
- The Coala Care Portal: The server that provides the automatic analysis of measurements, detection of cardiac rhythm deviations, stores all your recordings and Coala App account information.
- The Coala Charge Station: Used to charge the battery in the Coala Heart Monitor. The Coala can be charged from any compatible USB source (only use the supplied USB cable). Fully charge the battery before the first use and ensure that the battery is charged regularly.

The Coala Heart Monitor is intended to be used by a single individual to:

- Record simultaneous ECG and heart sounds.
- Annotate each recording with symptoms or free text.

- Wirelessly transfer and receive results from detection of cardiac rhythm deviation.
- Access previous Coala recordings from the Coala Care Portal server.
- Print or save ECG recordings to a PDF format, to send to your Clinician or the recipient of choice.
- Receive messages and notifications from your Healthcare provider. (If accepted as a Healthcare provider with access to the Coala Care Portal)

Chest and Thumb ECG

The Coala records ECG measurements on the chest and thumbs. The chest measurement is recorded by pressing the Coala membrane to the chest. The thumb measurement is recorded by firmly pressing both thumbs onto the electrodes located on the bottom of the Coala.

Simultaneous ECG and Heart Sound

The mechanical movement of valves in the heart create heart sounds that can be used for assessing the mechanical condition of the heart. These sounds can be recorded by the Coala and can be used by a trained medical professional for an assessment of the heart (when prescribed or used under the care of a healthcare professional). The unique Coala feature is the ability to record simultaneous ECG and heart sounds. This combined information can be used by a trained cardiologist to give a detailed view of the electrical and mechanical activity of your heart.

02 Intended use

The Coala Heart Monitor is intended for self-testing by patients to record, store, transfer and display surface ECG and sound to aid the detection of heart and respiratory conditions. The Coala Heart Monitor is intended for use by healthcare professionals, individuals with known or suspected heart conditions and health conscious individuals, in the age of 18-100. Use by individuals under 18 years of age should only be done when recommended by health care professionals.

The Coala Heart Monitor is not intended for use for vital monitoring as in intensive care.

03 Contraindications

There are no known contraindications for Coala Heart Monitor

04 Cautions

- Do not use for any purpose other than to obtain ECG and sound recordings.
- The Coala should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).
- Not suitable for direct cardiac application (intact skin only).
- Always protect the membrane from sharp objects such as keys, pencils etc.
- Not to be used with a pacemaker, ICD or other implanted electronic device unless recommended by healtcare professional. If the Coala is used with a pacemaker, pacing pulses may be detected and counted by the heart rate display but may not be displayed in the ECG graphs.
- A successful chest recording may not be possible if the device is applied to a chest which has too much body hair, body fat or very dry skin. Try to apply moisture to the skin and shave off any body hair to obtain successful recordings.
- Do not disassemble, repair or modify the device in any way.
- Do not take recordings if the ECG electrodes are dirty. Clean them first.
- Do not sterilize this device with an autoclave, gas sterilizer or

using radiation such as gamma or E-beam sterilization.

- Do not use device in locations subject to extreme high or low temperatures or humidity. For this reason, do not leave the device in vehicle.
- Do not use device in wet environments. Do not use device that has been submerged in water. The Coala device carries an Ingress Protection (IP) rating of IP22 meaning that vertically dripping water has no harmful effect when the enclosure is tilted at an angle up to 15° relative to its Normal mode (in flat position with stethoscope membrane turned down). Note: The Charge Station and USB cable do not carry an IP rating and are only to be used in a dry environment.
- Do not expose the device to strong shocks or vibrations.
- Recordings may be interrupted by strong electromagnetic interference, shocks and vibrations.
- Do not take recordings in the presence of strong electromagnetic fields such as near an arc welder, high power radio transmitter etc as these can cause disturbances to recorded signals. Note that recordings performed in vehicles (cars, buses, trains, aircraft etc) may
  see disturbances due to electromagnetic interference as from motors and ignition systems.
- Do not use this device in dusty environments such as machine shops. Use the protective cover and bag to keep the device clean. Note that the IP22 rating of the Coala device does not mean that it is dust proof.
- To avoid intrusion and leaks of personal data to unauthorized persons lock the smartphone or logout from the Coala App between measurements.
- Contact Coala Solutions of any signs of malicious system behavior, suspicions of malware or system cybersecurity violations.
- ECG-filters may distort baseline properties and high-frequency response of the ECG signal. The full signal without filters is available for healthcare professionals in the Coala Care Portal. Signal amplitudes for the chest ECG measurement are typically lower (0.1 to 0.4 mV) than on conventional chest leads due to close electrode spacing on the Coala. Chest signal morphology

is also affected by positioning of the Coala on the chest and may not resemble conventional chest leads.
- Maximum T-wave amplitude is 1.5 times the QRS amplitude for correct display of heart rate.
- This device is not intended to be operated by infants, small children or persons with physical or mental impairment. Let an able accompanying adult operate the device.

05 Warnings

- This device is not intended for complete diagnosis of cardiac conditions. This device should never be used as a basis for starting or modifying treatment without independent confirmation by medical examination.
- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions or life threatening arrhythmias. Always consult your Healthcare Professional if you experience changes in your health.
- Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Always consult a medical professional.
- Do not use a device that shows signs of mechanical damage or loose parts.
- Keep out of reach of infants, small children and animals to avoid strangulation by the supplied USB cable.
- The heart rate is based on the heart rhythm; therefore the rate is only valid if there is a valid detected rhythm.
- Warning: MR-unsafe! Do not expose the device to a magnetic resonance (MR) environment. The device may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core. Thermal injury and burns may occur due to the metal components of the device that can heat during MR scanning. The device may generate artifacts in the MR image. The device may not function properly due to the strong magnetic and radiofrequency fields generated by the MR

scanner.

- It is not recommended to place a mobile phone directly next to a pacemaker or ICD (Implantable Cardioverter Defibrillator) as this may disturb your implantable device.
- Do not use the Coala with a defibrillator. The Coala is not defibrillator proof and may be damaged or reduce the effectiveness of the defibrillation.
- Do not use device in explosive environments (mines, oil rigs, fueling stations, oxygen rich environments such as hyperbaric chambers or in the presence of flammable anesthetics).
- Do not connect the Coala Charge Station to any power source or external equipment other than described in this manual.
- Do not dispose in fire. Contains lithium battery that may explode. Dispose as electronic waste according to local regulations.
- Not for use with high frequency surgical equipment.

06 Adverse events

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and to the competent authority of the Member State in which the user and/or patient is established.

Sweden:

Swedish Medical Products Agency (Läkemedelsverket)

Address: Box 26, 751 03 Uppsala, Sweden

Phone: +46 18 17 46 00

Email: registrator@mpa.se

Website : https://www.lakemedelsverket.se

07 Clinical benefits

The Coala Heart Monitor enables recording of (i) electrocardiogram (ECG) to aid the detection of rhythm deviations including Atrial Fibrillation and (ii) sound for assessment of heart and lung activity.

08 Before using the Coala

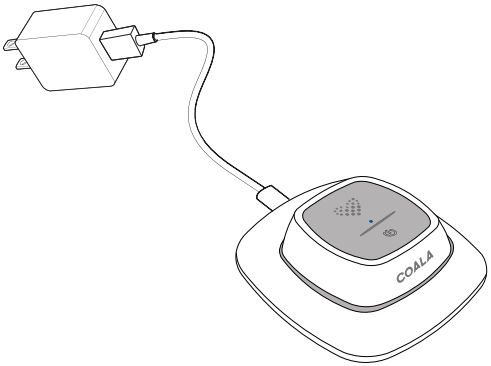
Check smartphone compatibility

The Coala Heart Monitor is compatible with smartphones running iOS or Android listed on the Coala Solutions website: www.coalasolutions.com/device-compatibility

Unpack and charge the Coala

Unpack the Coala and Charge Station and place it on a flat surface.

Unpack and connect the supplied USB cable to the Charge Station using the small USB plug. Connect the large USB plug to a power source such as a; wall adapter, laptop, battery pack or other power supply.



NOTE! The external USB power source, as a supply/wall adapter, must be a CE- marked class II power supply (no connection to protective earth) with an output voltage of 5VDC and capable of at least 300 mA of current.

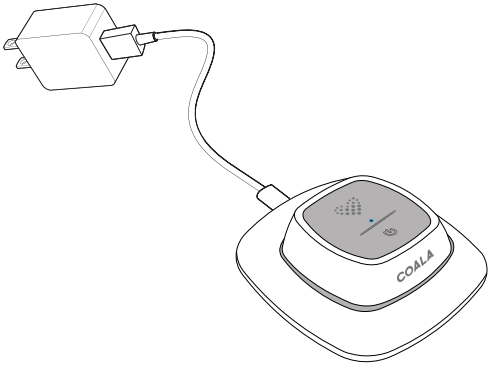
Charge the Coala by sliding it carefully into the Charge Station as shown. Do not use extensive force when placing the Coala into the Charge Station.



NOTE! The Coala should be carefully placed in the Coala Charge Station by noting correct orientation and sliding it into place. Do not use force or press straight down on the Coala to get it in place. For maximum electrical safety the Coala cannot be used for obtaining recordings while charging since the Coala Charge Station and connected USB power source are IO type equipment and do not carry the type BF (Body Floating) medical electrical safety rating that the Coala does.

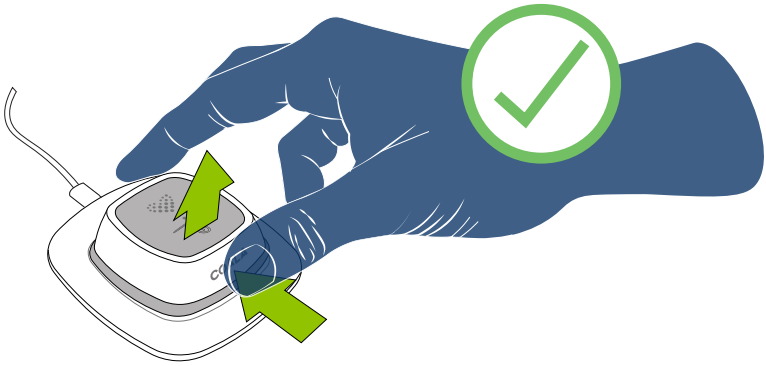
The Coala LED light should start blinking with a blue light to indicate that it is charging. If not, repeat the previous steps and make sure that the Coala has been correctly placed into the Charge Station.

Once the Coala is fully charged the LED light will indicate a steady blue light. Make sure the Coala is charged regularly and is fully charged before the first use.



To remove the Coala from the Charge Station apply light pressure on to the “COALA” text on the front of the Coala using your thumb. Carefully tilt and lift the front of the Coala out of the Charge Station first, as illustrated below.

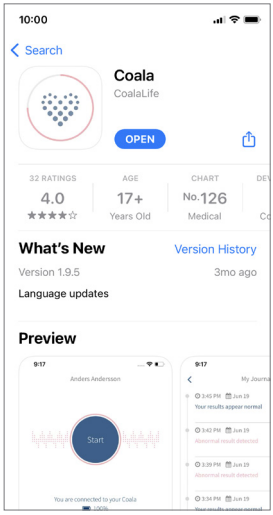
Do not use extensive force when lifting the Coala out of the Charge Station.



09 Getting started

Download the Coala App

Download the Coala App from App Store or Google Play depending on your smartphone. Search for 'Coala Solutions'. Follow instructions on your smartphone to install the app.



Open the app and log in

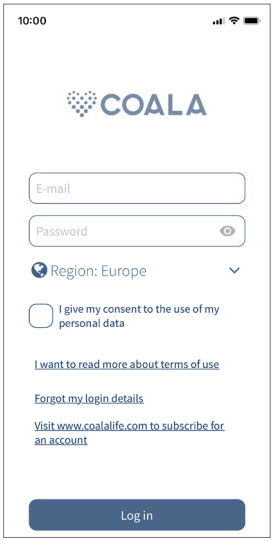
Open the Coala App on your smartphone and login using the email and password* registered when signing up for the service or the details that were provided by your healthcare professional.

The first time the Coala App is opened you will have to allow Coala notifications.

Ensure to enter the correct region. If you signed up for the account in the EU select Europe as your region.

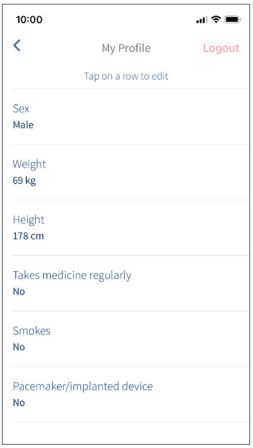
Check the box: "I give my consent to the use of my personal data" to agree to Coala's user and privacy terms. To read the terms click on the text: "I want to read more about the terms of use".

Press: "Log in" when you are ready.



**If you forgot your password click on 'Forgot my login details and follow the on-screen instruction. A link (valid for 30 minutes) will be sent to your registered email to reset the password. If you do not receive the email, check your junk mail folder. For security reasons you will not be able to login into Coala App for 20 minutes if you have entered the wrong password 3 times.*

Health data to ‘My profile’



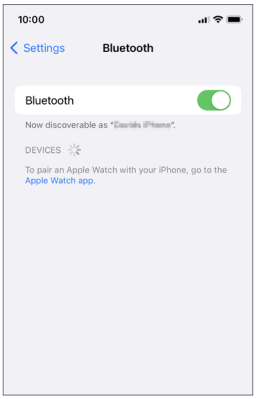
Before you are able to record measurements with the Coala and Coala App you will be required to enter health data to your personal profile.

Follow the on screen instructions in the Coala App and enter sex, length, weight, medication, smoking habits, pacemaker or other implanted device.

This data will be available to your approved healthcare provider in the Coala Care Portal if you are connected to an healthcare provider.

The profile may be edited at any time under ‘My Profile’.

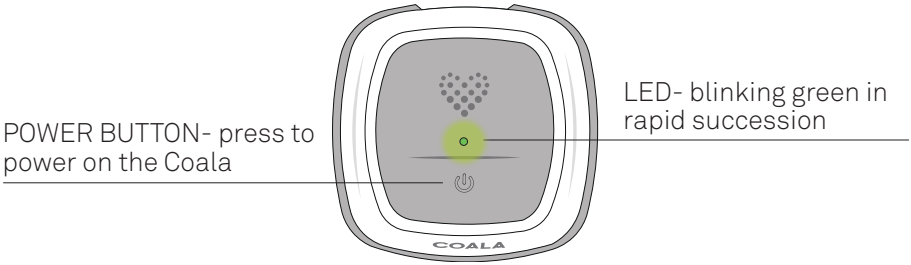
Pair the Coala to a Smartphone



To record measurements with the Coala and Coala App the Coala must be paired to your smartphone.

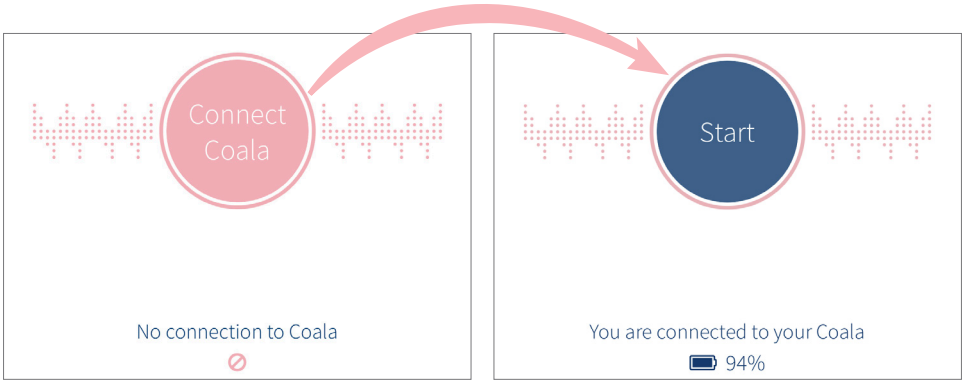
Follow these steps to pair the Coala to your smartphone:

1. Ensure Bluetooth is enabled on your smartphone:
   Bluetooth is found under ‘Settings’ on your smartphone.
2. Ensure to disable all Bluetooth connections to other devices when connecting your Coala for the first time: Go to ‘Settings’ on your smartphone to disconnect Bluetooth devices.



3. Power on the Coala by briefly pressing the Power button ⏻ on top of the Coala. Your Coala should now be blinking green in rapid succession.
4. In the Coala App press 'Connect my Coala now' and follow the on screen instructions.
5. When the Coala is connected, the large circle in the app turns blue. This indicates successful pairing between the Coala and your smartphone.





You are now ready to record your first measurement.

Please read the next chapter: 'Best practices' before initiating your first measurement recording in order to ensure the most accurate result.

10 Best practices

Sit down and relax a few minutes before recording measurements with the Coala to ensure the most accurate reading.

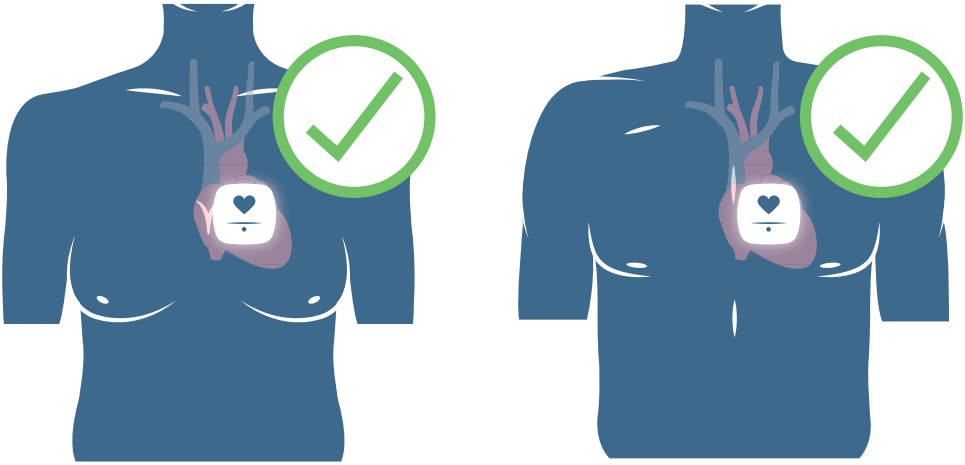
Before executing measurement recordings, make sure to:

- Sit down comfortably during the entire recording.
- Avoid lying down or standing up.
- Be extra careful to; hold Coala steady, be completely still and do not talk during the measurement recording. Do not stand up or move around.
- Keep your phone within reaching distance to ensure proper radio signal transmission from the Coala to the Coala App.

If Coala indicates an unreadable value, make sure to perform another measurement.

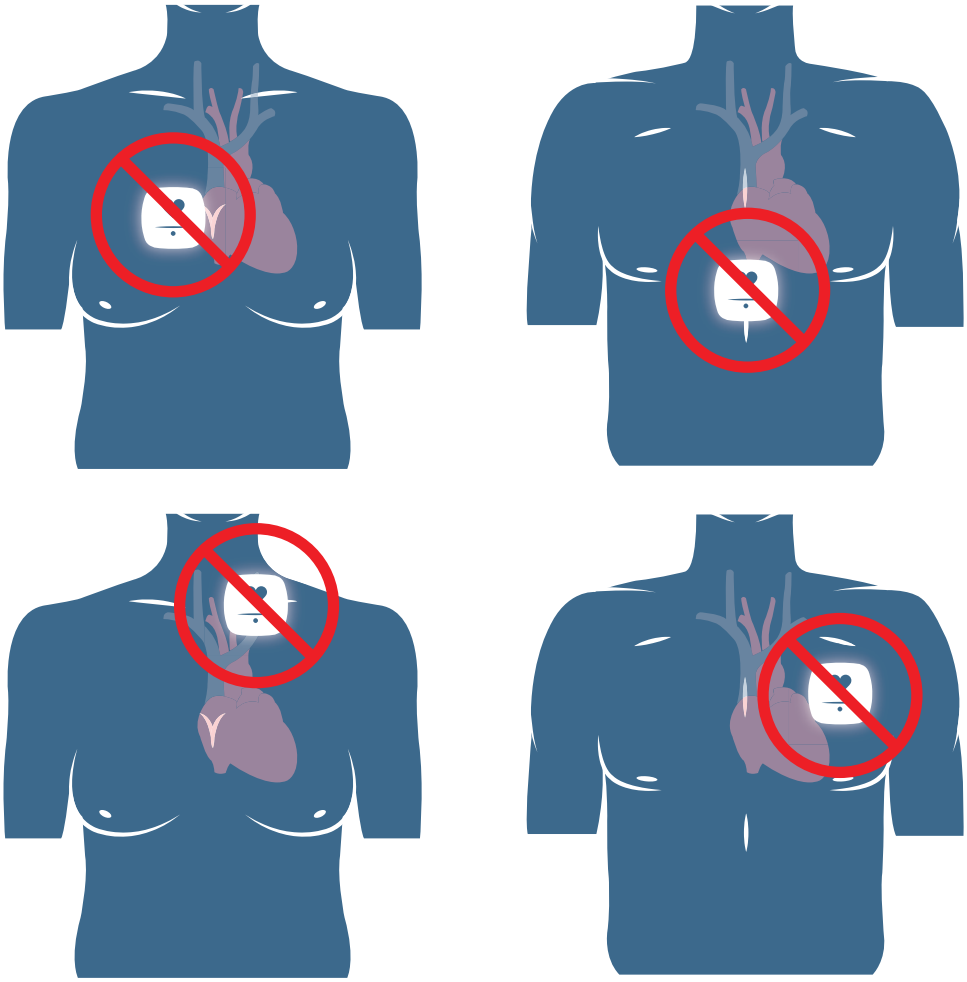
A deviating value could occur without anything being wrong, high heart rate from physical activity or from other factors.

For correct placement of the Coala for chest ECG and heart sound recordings, see diagram below. Hold the Coala between your thumb and middle finger. Place the Coala slightly to the left of your sternum (chest bone) as shown.

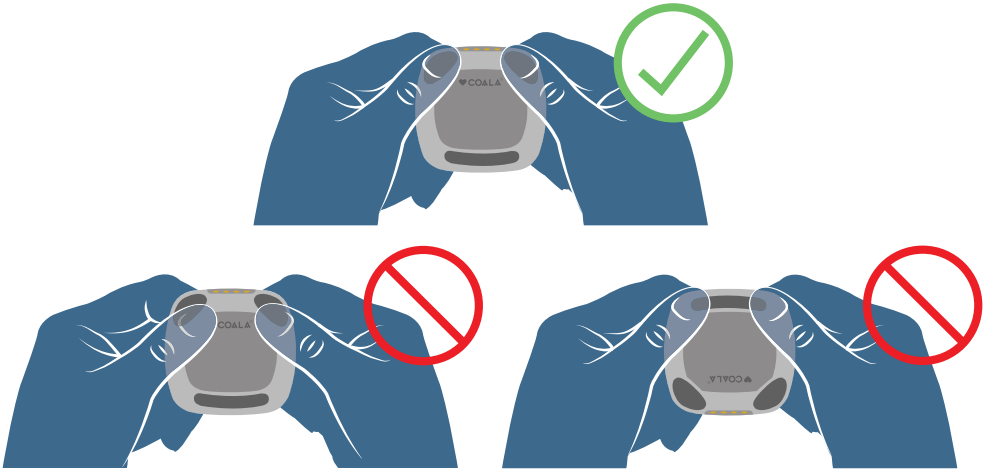


It is important that the Coala is held upright (COALA text facing down). Press the heart button with your index finger to start recording and hold Coala steady during the entire recording. Try to relax and breathe normally. Avoid speaking during measurement to ensure best recording quality.

The diagram below shows incorrect placement of the Coala for chest ECG and heart sound recordings.



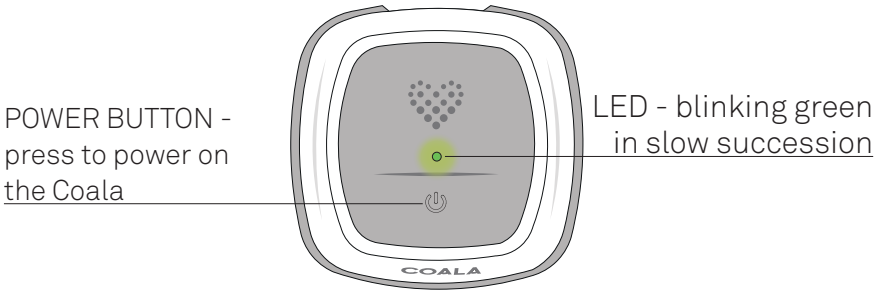
For correct finger placement for thumb ECG recording. Place your thumbs on top of electrodes as shown in diagram below. For best possible recording, hold Coala in a relaxed position resting your forearms on a table or on your legs when sitting down. Avoid pressing the electrodes too hard, just maintain a firm grip.



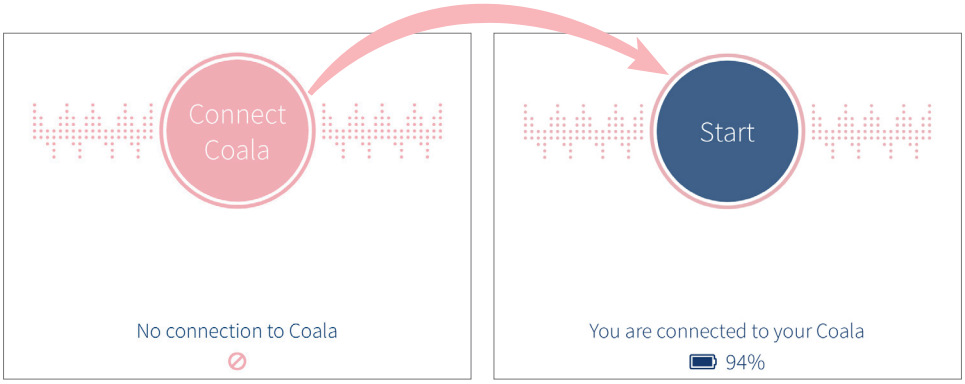
11 Record the first measurement

Follow these steps to record your first measurement:

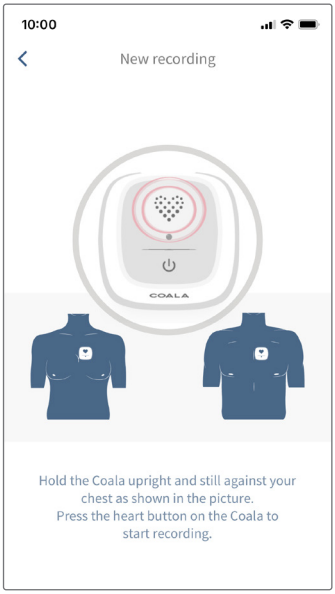
1. Power on the Coala by briefly pressing the Power button ⏻. Your Coala LED light should be blinking green in slow succession.



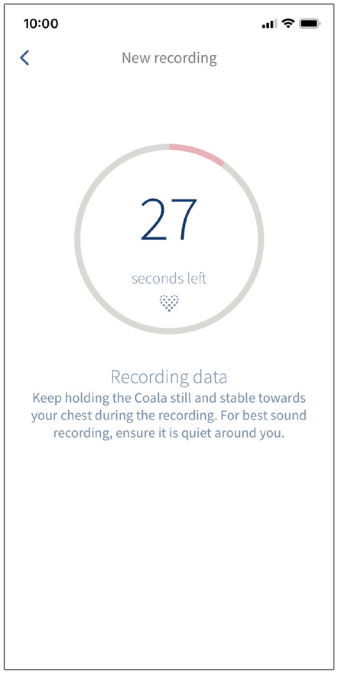
2. The large circle in the main screen of the Coala App should turn blue to indicate that the Coala has connected (if the circle remains pink please see “Pair the Coala to your smartphone”. Sit down and relax for a few minutes before starting the recording to ensure that your heart rate is at rest and for the most accurate reading.
   Press ’Start‘ to start a new recording.



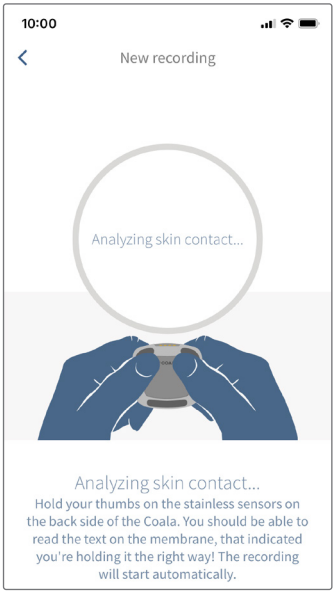
3. Sit down (do not stand or lie down). Hold the Coala firmly against your upper chest slightly to left of sternum as shown in the image in the app. Press ‘I understand’ in the app and then the ’Heart button‘ on the Coala to start recording.



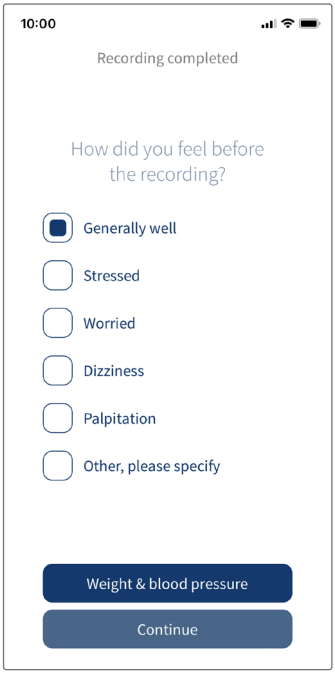
4. Before recording the Coala checks for adequate skin contact and then starts the 30 second recording with a visual countdown. Breathe calmly, relax and stay quiet. Do not talk and remain seated during recording. Continue to hold Coala firm and steady to your chest until recording is complete, and then remove the Coala from your chest.



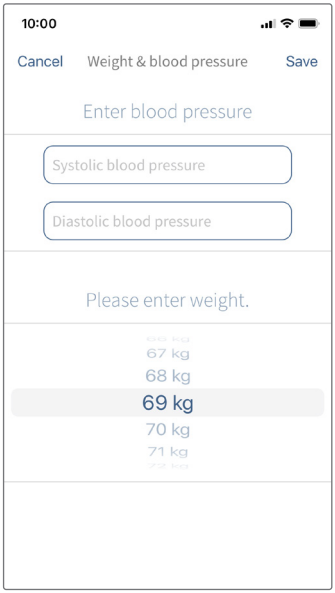
5. Follow the instructions in the app and click ‘I understand’. Place thumbs on electrodes and hold the Coala firmly to perform a 30 second thumb recording as shown. For the most accurate result; rest your forearms on a table, breathe calmly, relax and stay quiet. Do not talk during recording. Continue to press thumbs firm and steady onto the electrodes until recording is complete.



6. Once the recording is complete, select the correct description of how you felt before the recording. Select ‘Other, please specify’ to enter free text.

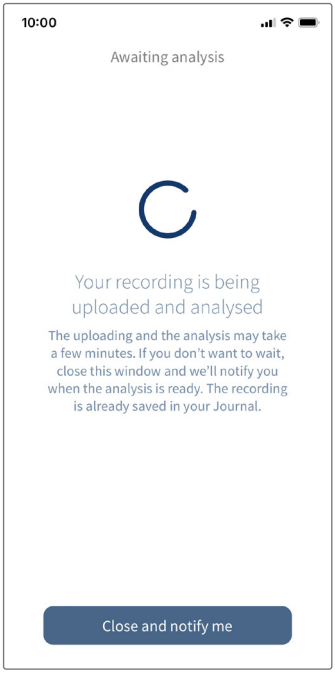


7. There is also an option to enter blood pressure (Systolic and Diastolic) and weight in attachment to the recording. Take caution to enter correct values and press 'Save'.
(To modify unit settings for weight and height entries in the Coala App go to 'My Coala').
Press 'Continue' when your entry is complete.



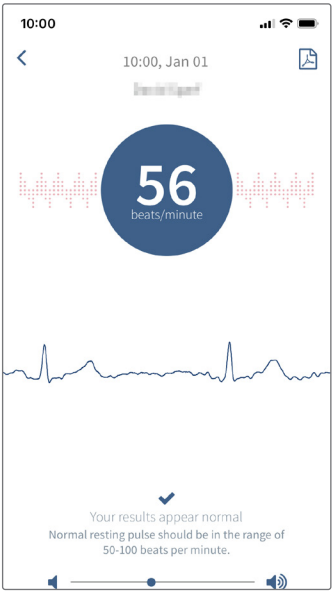
8. The recording is now sent for analysis in the Coala Care Portal. Ensure you have sufficient internet access, so the recording can be sent to the server. If not, the recording will be sent once you have sufficient internet access.

Note: Coala Solutions is not responsible for any additional charges your cellphone provider may charge for sending recordings to Coala Care Portal.

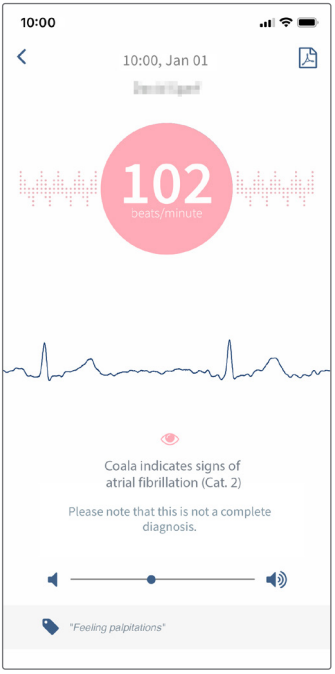


9. When the analysis is complete, the user will be notified of the result in the Coala App.
   If the result is normal, the user is informed by a blue circle indicating average heart rate of the 30 sec thumb recording. The visible ECG tracing in the app is from the thumb recording.

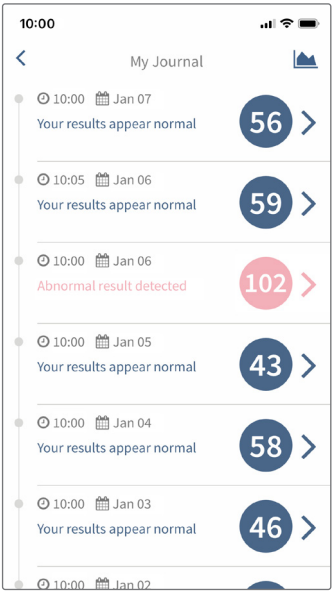
Note that the result indicated in the Coala App is a combined analysis of the thumb and chest ECG.



10. If the Coala detects an abnormal result, the user is informed of the deviating result by a pink circle indicating the average heart rate of the 30 sec thumb recording. There is also be a short description of the result below the ECG-tracing of the thumb recording.
    When a deviating result occurs, always conduct a second recording to verify the result and pay particular attention to holding Coala steady during recording.



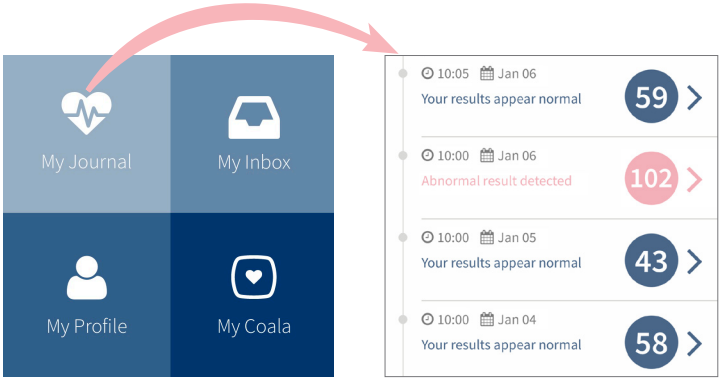
11. Your first recording is now complete. Find previous recordings along with measurement result under ‘My Journal’ in the Coala App on your smartphone. Note: Internet access is needed to access recordings. Please see the next chapter “My Journal” for more information.



12 My Journal

To review previous recordings, return to the home screen in the Coala App and select 'My Journal'.

'My Journal' displays all previously recorded measurements along with features for reviewing the recorded data.

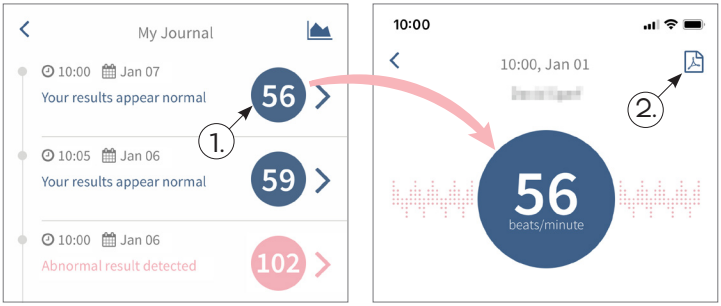


NOTE! Recordings are not stored on your smartphone, so Internet access is needed to view recordings.

Download measurement PDF

Follow these steps to download or your ECG in a PDF format to; print, save or send to your healthcare professional:

1. Select a measurement of interest from the list in 'My Journal'. This will display the result screen shown at the end of a completed measurement.
2. In the result screen; select the PDF symbol in the upper right corner to download a PDF file of the current measurement. Note: The smartphone used must have PDF reader, which does not come with the Coala App.

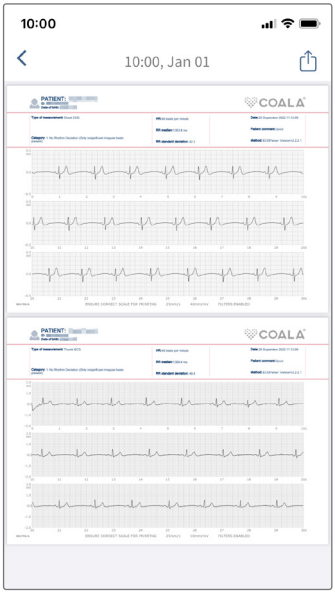


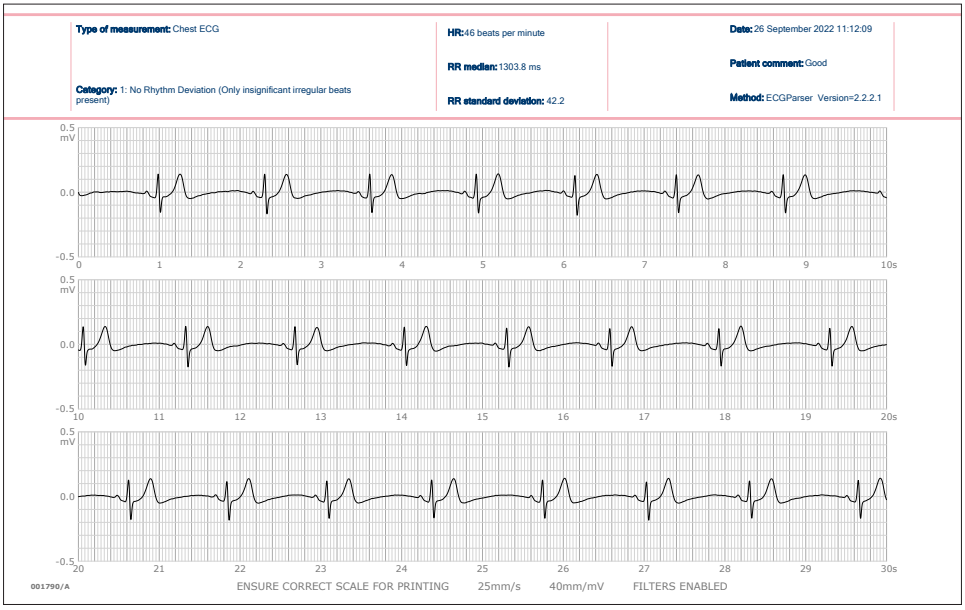
3. The downloaded PDF can be saved on to your smartphone, printed or sent by text message or email.

   The first page of the PDF is the chest ECG tracing, and the second page is the thumb ECG tracing. Default settings for ECG tracings in PDF file format will be:

   Chest measurement, 40 mm/mV, 25 mm/s, filters affecting signal representation enabled.

   Thumb measurement, 10 mm/mV, 25 mm/s, filters affecting signal representation enabled.





For more information about the ECG tracings and how to interpret them see the chapter "ECG Categorization" or visit www.coalasolutions.com/categories.

Trend plot measurements

Return to 'My Journal' and select the trend plot symbol (upper right corner) to trend plot; measurements, blood pressure and weight as shown in the diagram below.



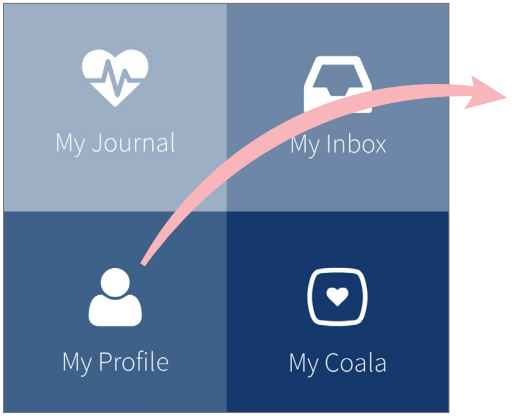
13 My Profile

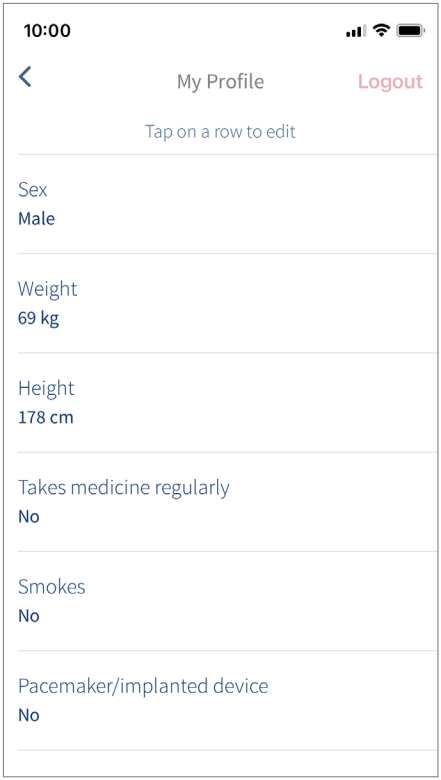
To edit your Coala profile, return to the home screen in the Coala App and select 'My Profile'.

'My Profile' contains all the information attached to the Coala profile. This was entered when logging in to the Coala App for the first time and may be edited at any time.

Edit profile: press on the row and enter the new value. Select: "Save" to edit.

If you would like to modify unit settings for weight and height entries go to 'My Coala' > 'Settings'.

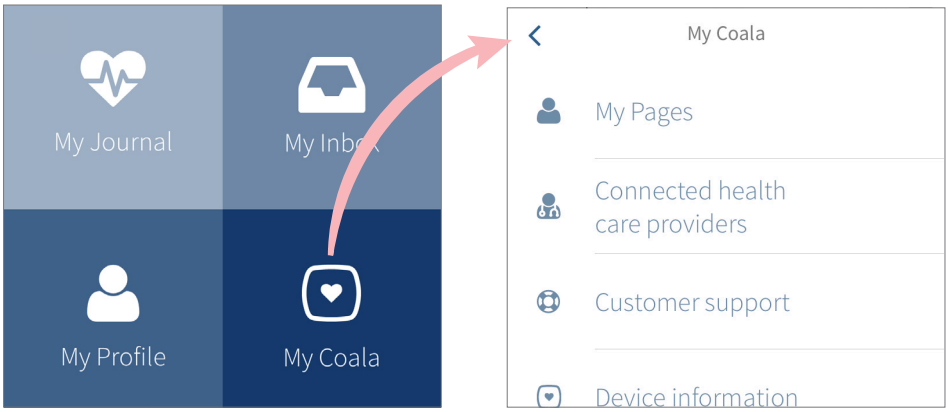




14 My Coala

To modify settings and obtain more information about the Coala Heart Monitor, return to the home screen in the Coala App and select 'My Coala'.

'My Coala' contains information and settings as well as useful links to the Coala Solutions website for more information.



My Pages

Here the user may access a link to 'My Pages':

Reset password or review your contact information available to your healthcare professional in the Coala Care Portal.

Approved healthcare providers

Here the user may review approved healthcare providers:

Approved healthcare providers will have access to your recorded measurement data and general health information.

Click the "X" next to the healthcare provider's name to revoke acceptance.

Device information

Here the user may review information about the Coala Heart Monitor and App.

Note that the Coala Heart Monitor needs to be powered on and paired to your smartphone for information to be displayed.

Robust recording mode

Here the user may adjust sound recording of the measurement:

Activate to disable the recording of heart sounds.

Health App integration*

Here the user may connect the Coala App to Apple Health:

Follow the on screen instruction to transfer your heart rate recorded with the Coala App to Apple Health on your iPhone.

**Health app integration only available for Apple Health.*

Reminders*

Here the user may set reminders:

Follow the on screen instruction to set regular reminders for recording measurements with the Coala or for taking your medications. Reminders will send a notification to your smartphone and may be set to any time and frequency.

**Reminders are only available for the iOS App.*

Settings

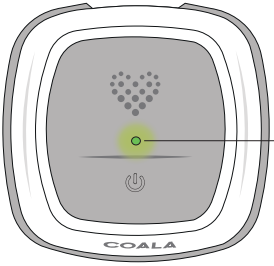
Here the user may set:

- Units for weight and height entries may be set to; "US/Imperial" or "SI/Metric".
- Paper size for the downloaded measurement PDF may be set to; "Letter" or "A4".
- Show help texts; activate to show help texts guiding you through the measurement recording, deactivate-to hide help texts.

15 My Inbox

To view messages sent to your Coala App from Coala Solutions or any approved healthcare provider, return to the home screen and select 'My Inbox'.

16 Coala LED indications



LED - indicates the status of your Coala

Blinking blue	Coala is charging.
Solid blue	Coala has finished charging and is now fully charged.
Slow blinking green	Powered on and connected to smartphone.
Rapid blinking green	Bluetooth pairing mode for pairing with a smartphone.
Solid green	Active recording of ECG and heart sounds.
Blinking yellow	Low battery indication.
Solid yellow	Battery empty or internal error. Do not use Coala and consult Troubleshooting section of this manual.

17 Coala ECG categorization

The Coala Heart Monitor System detects heart rhythm deviations based on both the thumb and chest ECG recorded.

Each recorded measurement, consisting of both chest and thumb ECG, is categorized based on any heart rhythm deviations detected.

If no heart rhythm deviations are detected in the recorded measurement the measurement will be categorized as Category 1 “Your results appear normal”.

Cat.	Description	Details
1.	Your results appear normal	No Rhythm Deviation (Only insignificant l regular beats present).
2.	Coala indicates signs of atrial fibrillation	Irregular Sequence (Unexplained irregularities, which may be AF or paroxysmal AF with or without P waves).
3.	Coala indicates skipped heart beats	Pause/AV Block II (or beats longer than 2.2s).
4.	Coala indicates a fast heart rhythm	Fast Regular (RR interval shorter than 600ms in entire signal).
6.	Coala indicates shorter sequences of faster or slower beats	Fast/Slow Sequences (Shorter sequences of faster or slower beats).
7.	Coala indicates recurring extra heart beats	Bimini (patterns with P waves detected).
8.	Coala indicates recurring extra heart beats	Trigemini (patterns with P waves detected).
10.	Coala indicates recurring extra heart beats	More than 5 SVES detected over 30 seconds (only 10 seconds in the ECG above).
11.	Coala indicates recurring extra heart beats	More than 5 VES detected over 30 seconds (only 10 seconds in the ECG above).
12.	Coala indicates an irregular heart rhythm	Irregular sequence with detected P waves.

For more information on Coala ECG categorization go to www.coalasolutions.com/categories/.

Note that the color bars in the images above are not visible in the PDF presented in the app.

Individual categorization vs. combined categorization

The result categories found in/for individual ECG s (chest ECG or thumb ECG), as available in the downloaded PDF are not the equivalent of the combined ECG categorization of the measurement as a whole.

The combined result categorization is always the most accurate and takes into account both the chest and thumb ECG s recorded.

For example, if atrial fibrillation is detected only in chest ECG, this should not be seen as an indicator of atrial fibrillation, thus is not sufficient to get the overall result of atrial fibrillation.

The combined result categorization is always the most accurate.

18 Troubleshooting

The Coala App provides the user with step-by-step instructions on how to record and where to hold Coala when measurements are recorded.

If you experience difficulties using your Coala, refer to the troubleshooting guide below or contact Coala Solutions support at support@coalasolutions.com. In case of any adverse event or serious health deterioration caused by our device contact us and your medical agency.

Issue	Solution
Unable login to the Coala App.	Make sure that you have the correct user name and password. Note that password is cap sensitive. Make sure that you have sufficient internet access. Make sure that your subscription has not expired. If problem persists, contact Coala customer support.
Unable to start a new measurement recording.	Make sure that Coala unit is powered on and connected to the smartphone. The circle in the app needs to be blue before you can start a recording.
Unable to find my previous recordings.	All recordings are stored in the Coala Care Server and are only accessible if the smartphone is connected to the Internet.
I forgot my password to login in to the app.	Press 'I forgot my login details' on the login screen and follow the instructions. You will receive an email to the email address you used to setup the Coala App.

Issue	Solution
Unable to power on the Coala.	Make sure that the battery has not depleted. Place Coala into Coala Charge Station and connect to a power source. The Coala should start blinking blue indicating that it is being charged, if not contact Coala customer support.
The Coala does not indicate a blue charging light when placed in the Coala Charge Station.	Check that the USB cable is correctly connected between the Charge Station and a power source. Check that the Coala is correctly placed in the Charge Station.
Unable to pair the Coala to smartphone.	Place Coala into the Charge Station and connect the USB cable between the Coala and a power source. The Coala should start blinking slow blue. Hold down the power button for 8 seconds and take the Coala out of the Charge Station. The Coala should now be blinking green in rapid succession. Enable Bluetooth on your smartphone and try to connect the Coala to your smartphone again. If problem persists, do not use device and contact Coala customer support.
The Coala LED indicates a steady yellow light followed by auto-power off.	Battery empty or the Coala has detected an internal error. Place in Coala Charge Station for charging. If problem persists, do not use device and contact Coala customer support.

Issue	Solution
The recording stopped in the middle of the measurement.	Coala needs to have full contact with skin on chest or thumbs. If the skin contact is lost the recording will stop. Make sure to follow the instructions given in instructions for recording.
Recording failed-notification in app “The phone failed to receive enough data. Robust recording mode will be activated and the recording restarted”.	This means that your smartphone does not support enough data transfer to record the heart sounds. The application will automatically be set to Robust recording mode. This will enable normal ECG recording but heart sounds will not be recorded. Restart the measurement.
Unable to open the PDF measurement file.	Make sure that smartphone has a program to read PDF. This does not come with the Coala App.
The Coala LED indicates a steady yellow light or shows signs of internal error.	1. Place the Coala into the Charge Station and connect to a power source. 2. Hold down both buttons (on/off button and heart button) for more than 10 seconds. 3. When Coala LED shows a blue light, release the ’on/off button‘ and hold down ’heart button‘ until a steady yellow light is shown. 4. Remove the Coala from the Charge Station. 5. Shut off the Coala by holding down the ‘on/off button’ for at least 10 seconds. 6. Restart Coala by briefly pressing power on.

19 Storage

Store the Coala indoors in the supplied travel bag with the cover to protect the membrane and the electrodes.

Temperature +5 °C to +40 °C / 41 to 95 °F.

Humidity 15 % to 90 %, non-condensing.

Air Pressure 700 to 1060 hPa /10.2 to 15.4 psi.

Do not store the device in:

- Locations exposed to direct sunlight.
- Locations subject to high temperatures such as in vehicles (high and low temperatures) and high humidity.
- Wet or damp locations where the device may be in contact with water.
- Dusty locations.
- Locations near fires or open flames.
- Locations exposed to strong vibration.
- Locations exposed to strong electromagnetic fields.
- Locations exposed to chemicals or solvents of any kind.

20 Cleaning and maintenance

Use only a damp cloth or alcohol to clean Coala and accessories. Do not use other solvents like acetone or petroleum-based chemicals. For Multi use Coala please clean the Coala between different users with 70% Alcohol.

There are no parts that need regular service or maintenance.

The device should be recycled as electronic waste in accordance with local regulations for electronic waste.

21 Electrical safety

The Coala Heart Monitor fulfills the European Medical Device Directive. :

- IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-11, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.

Noise suppression electrode: A voltage is applied to the noise suppression electrode for active noise suppression of the sensing electrodes. The maximum current on the noise suppression electrode is limited to <10 µA.

22 Transceiver properties

The Coala device has an integrated radio transceiver with the properties:

Frequency band: 2400 – 2483.5 MHz.

Maximum emitted radiation power: Less than 10 mW.

Hereby, Coala Solutions AB declares that the radio equipment type Coala Heart Monitor is in compliance with Directive 2014/53/EU. The full text of the EU declaration of conformity is available at the following internet address: www.coalasolutions.com/docred.

23 Electrical emission

The Coala fulfills:

CISPR 11 Class B: Radiated and conducted emission

IEC 61000-3-2: Harmonic current emission

IEC 61000-3-3: Voltage fluctuations and flicker

24 Electrical immunity

The Coala fulfills:

- IEC 61000-4-2: Immunity to electrostatic discharge.
  Test level ±8 kV contact discharge ±2, ±4, ±8 and ±15 kV air discharge.
- IEC 61000-4-3: Immunity to radiated electromagnetic fields in the frequency range 80 – 1000 MHz and 1,0 – 2, 7GHz.
  Test levels:
  80 – 1000 MHz 10 V/m with 80 % AM @ 2 Hz.
  1,0 – 2,7 GHz 10 V/m with 80 % AM @ 2 Hz.
- IEC 60601-1-2: Table 9 (up to 28 V/m pulse modulation at frequencies in ISM bands)
- IEC 61000-4-4: Immunity to fast transients/burst.
  Test levels on AC Power input port: AC input/output power input port ± 2,0 kV
- IEC 61000-4-5: Surge immunity test.
  Test levels on AC Power input port: AC Power input port, ±0,5 kV and ±1,0 kV differential mode.
- IEC 61000-4-6: Immunity to conducted disturbances in the frequency range 0,15 – 80 MHz.
  Test levels on AC Power input port: 6 Vrms with 80 % AM @ 2 Hz.
- IEC 61000-4-8: Immunity to power frequency magnetic fields.
  Test level: 30 A/m, 50 Hz and 60 Hz
- IEC 61000-4-11: Voltage Dips and Interruptions.
  Test levels on AC Power input port: Test frequency: 50 Hz. Test voltages: 100 and 230 V.
  100 % for ½ cycle positive and negative half period.
  60 % for 10 cycles.
  30 % for 25 cycles.
  100 % for 250 s.

25 Warnings related to electromagnetic compatibility

The Coala is designed to withstand expected electromagnetic interference. If the Coala is exposed to electromagnetic interference exceeding what is expected, corrupted measurements could occur or even permanent failures.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (1 foot) to any part of the Coala, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

26 Symbols used in system and package labels

	Type BF (Body Floating) Applied Part (Coala device). Note that the Coala Charge Station is IT-equipment and not type BF.
	Refer to instruction manual
CE 2797	European Conformity Mark
	Radio transmitter
	Stand-by on/off
IP22	IP (Ingress Protection) Class 22.
	WEEE – Properly Dispose of Electronic Waste
5V ⎓ 300mA	Input/output voltage and current
SN	Serial number. The serial number for your Coala is found under My Coala in the Coala App.
LOT	Batch number
	Manufacturer/manufacturing date. The manufacturing date of your Coala is found under My Coala in Coala App.

	Manufacturer
	Temperature limits
	Humidity limits
	Atmospheric pressure limits
	Keep dry
	Fragile, handle with care
	Do not use if package is damaged
	Consult instructions for use
	Part number
	MR unsafe
	Unique Device Identification
	Medical Device

27 Specifications

Performance Characteristics

ECG

ECG Channels	Single channel with noise suppression electrode
Frequency Response	DC to 150 Hz (chest mode only)
Amplitude Accuracy	Better than 2% for a 500 µV signal
Input Impedance	> 100 MΩ
Sampling Frequency	1 kHz
Resolution	24 bit
DC Input Offset Range	± 300 mV
Heart Rate Range	30 to 200 BPM
Pacemaker Compatible	No

Heart sound

Frequency Range	20 – 1500 Hz
Sampling Frequency	4 kHz

Power Requirements

Battery Type	Internal rechargeable lithium-polymer (Non replaceable)
Battery Life	Minimum of 40 recordings per charge. Make sure the battery is charged regularly and fully charged before first use

Coala Charge Station Input	5 VDC, 300 mA minimum, Micro-USB connector. Any external wall adapter used to power the Charge Station must be a Class II power supply (no connection to protective earth).
Wall Adapter Input	100-240 VAC, 50-60 Hz, 0.3 A max

Radio Transceiver Properties

Frequency Band	2.400-2.4835 GHz
Maximum Emitted Radiation Power	< 10 mW
Radio Protocol	Bluetooth
Transceiver Compliance	EN 300 328, EN 301489-1 and EN 301489-17. FCC 47 CFR Part 15.247 Subpart C

FCC NOTE:
This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

– Reorient or relocate the receiving antenna.

– Increase the separation between the equipment and receiver.

– Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

– Consult the dealer or an experienced radio/TV technician for help.

The user is cautioned that any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Physical Characteristics

Coala	49×51×18 mm, 36 grams / 1.93x2.01x0.71 in, 1.27 oz
Coala Charge Station	71×73×12 mm, 50 grams / 2.80x2.87x0.47 1.76 oz
USB Cable	3 ft length, USB in, type A to Micro-USB connectors

Environmental Specifications	
Operating Temperature	+5 °C to +35 °C / 41 to 95 °F
Operating Humidity	15 % to 90 %, non-condensing
Operating Air Pressure	700 to 1060 hPa /10,2 to 15,4 psi
Expected Service Life	3 years
Shelf life	3 years

Body Interface	
Electrical safety	Coala device is type BF (Body Floating)
ECG	Three surgical-grade stainless steel (316L) ECG electrodes in contact with the skin.
Membrane	Polymer membrane in contact with the skin.

28 Contact information to the manufacturer

Coala Solutions AB
Bangårdsgatan 13
753 20 Uppsala
Sweden

www.coalasolutions.com

info@coalasolutions.com

COALA®