COALA®

USER MANUAL COALA HEART MONITOR Rx

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Introduction

Congratulations on your new Coala. Please read this manual for important safety information and to get the most out of the Coala Heart Monitor.

1. Product Description

The Coala Heart Monitor is an electrocardiogram (ECG) and digital auscultation (stethoscope) recording system that can be used both by medical professionals and health conscious individuals in a home healthcare environment. Both ECG and heart sounds recordings are available for your Healthcare professional.

The Coala Heart Monitor consists of the following parts:

- 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 followed by a thumb ECG measurement.

- The Coala app that is installed on a smartphone and is used to perform measurement together with Coala, collect and view recordings. The Coala app transmits recordings to the Coala Care Portal and receives analyzed results from the same server. It also features a messaging system where you can receive notifications from your Healthcare professional.
- A user-supplied compatible smartphone running iOS or Android, listed on the Coala Life website: www.coalalife.com/device-compatibility
- Coala Care Portal is the server that provides detection of the cardiac rhythm deviations, stores all your recordings and handles your Coala account.
- The Coala Charge Station that is used to charge the battery in the Coala. The Coala can be charged from the supplied wall adapter or any compatible USB outlet. Ensure the battery is charged regularly, and that it is fully charged before first use.
- The Coala cover and the travel bag are provided to protect the Coala device during transportation and storage.

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

- Record simultaneous ECG and heart sounds.
- Receive results from detection of cardiac rhythm deviation.
- Annotate each recording with symptoms or free text.
- Access recordings from the Coala Care Portal and download pdf file recordings.
- Receive messages from your physician. (If connected through the Coala Care Portal)

Chest and thumb ECG recordings

The Coala can measure ECG on the chest and on the thumbs. The measurement on the chest is done by holding the Coala to the chest and the thumb measurement by gently pressing both thumbs on the electrode on the bottom of the Coala.

Since the recorded signal depends on the location on the chest, a finger ECG is also always obtained for reference.

Simultaneous ECG and heart sound recordings

The mechanical movement of the valves in the heart creates 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.

2. Indications for Use

The Coala Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms and heart sound.

The Coala Heart Monitor also displays ECG rhythms and detects the presence of normal sinus rhythm and atrial fibrillation (when prescribed or used under the care of a physician).

The Coala Heart Monitor is intended for use by healthcare professionals and adults with known or suspected heart conditions.

Rx ONLY.

3. Contraindications

There are no known contraindications for Coala Heart Monitor.

4. Cautions

- Do not use this device in a wet environment. Do not use a 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 that the Charge Station, wall adapter and USB cable do not carry an IP rating and are only to be used in a dry environment.
- 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 dustproof.
- Do not use this 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 a device that shows signs of mechanical damage or loose parts.
- Do not sterilize this device with an autoclave, gas sterilizer or using radiation such as gamma or E-beam sterilization.
- 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 expose the device to strong shocks or vibrations.
- Recordings may be interrupted by strong electromagnetic interference, shocks and vibrations.
- Always protect the membrane from sharp objects such as keys, pencils etc.
- Do not disassemble, repair or modify the device in any way.
- This device is not intended to be operated by children, elderly or persons with physical or mental impairment. Let an able accompanying adult operate the device.
- Do not take recordings if the ECG electrodes are dirty. Clean them first.
- Do not use for any purpose other than to obtain ECG and sound recordings.
- The Coala Heart Monitor has not been tested and it is not intended for pediatric use.

- A successful chest recording may not be possible if the device is applied to a chest which has too much body hair or very dry skin. Try to apply moisture to the skin and shave off any body hair to obtain successful recordings.
- The Coala should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).
- Not to be used with a pacemaker. 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.
- 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.
- Not suitable for direct cardiac application (intact skin only).
- To avoid intrusion and leakage of personal data to unauthorized persons lock the phone or logout from Coala App between measurements.

- Contact Coala Life of any signs of malicious system behavior, suspicions of malware or system cybersecurity violations.
- Coala Life does not recommend using on individuals with a cardiac pacemaker, ICDs or other implanted electronic devices.
- Maximum T-wave amplitude is 1.5 times the QRS amplitude for correct display of heart rate.

5. 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. Always consult your Health Care Professional if you experience changes in your health.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Always consult a medical professional.

- Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional.
- Keep out of reach of infants, small children and animals to avoid strangulation by the supplied USB cable.
- Not for pediatric use.
- 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.
- 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.
- Not for use with High Frequency Surgical Equipment.

6. Storage

Store the Coala indoors in the supplied travel bag with the cover to protect the membrane and the electrodes. Temperature +5 °C to +35 °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.
- 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.

7. Cleaning and Maintenance

Use only a wet cloth or alcohol to clean the Coala and accessories. Do not use other solvents like acetone or petroleum based chemicals. There are no parts that need regular service or maintenance.

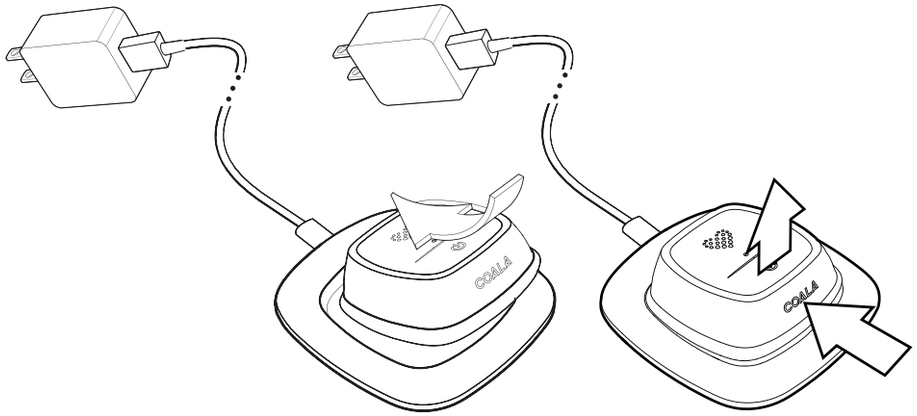
8. Using the Coala

8.1. Check Smartphone Compatibility

The Coala Heart Monitor is compatible with smartphones running iOS (iPhone 5 or later) or Android (4.4 KitKat) listed on the Coala Life website:
https://www.coalalife.com/device-compatibility

8.2. Unpack and Charge the Coala

Unpack the Coala Charge Station from the box and place it flat on a table. Unpack the wall adapter and connect the USB cable between the Coala Charge Station (small USB plug) and the wall adapter (large USB plug). Charge the Coala by sliding it carefully into the Coala Charge Station as shown. You are now ready to charge the Coala and bring it to life.



Make sure the Coala is charged regularly and is fully charged before the first use.

Connect the wall adapter to a mains power outlet. The Coala should now start blinking with a blue light to indicate that it is charging. If not, repeat the steps above and make sure that the Coala has been correctly placed in the Coala Charge Station.

The Coala will show a steady blue light once it is fully charged.

The Coala can also be charged from a laptop, battery pack or other source such as a power supply/wall adapter with a USB port that can support 300 mA of current. Simply plug the USB cable between the Coala Charge Station and the source instead of using the supplied wall adapter.

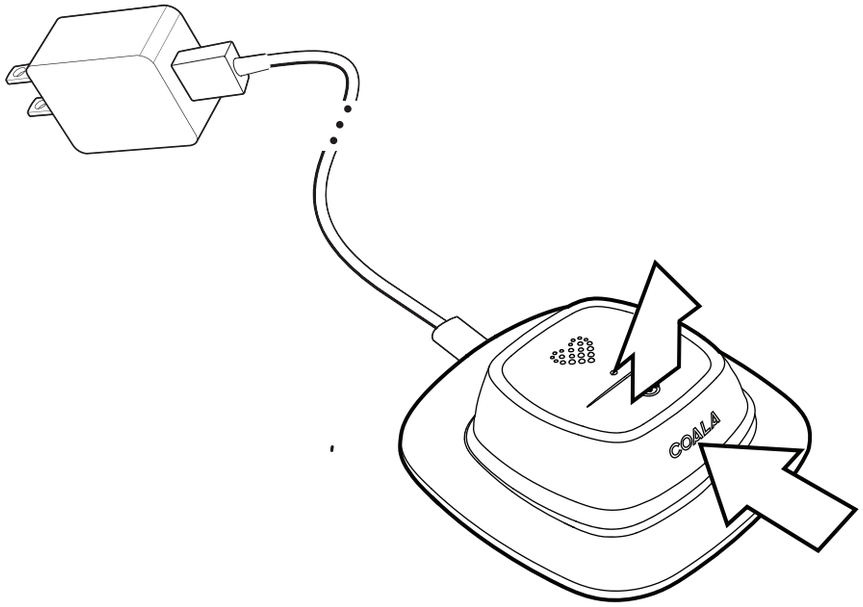
NOTE

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 wall adapter are IT type equipment and do not carry the type BF (Body Floating) medical electrical safety rating that the Coala does.

NOTE

If an external power supply/wall adapter is used it must be a class II power supply (no connection to protective earth) with an output voltage of 5VDC and capable of at least 300 mA of current.

To remove the Coala from the Coala Charge Station, push against it using your thumb. Do not try to lift it directly out of the Coala Charge Station.



8.3. Download the Coala App

Start by downloading the Coala App from the Apple App Store or Google Play depending on your smartphone. Search for ”Coala App”. Follow the instructions for your phone to install the Coala App.

8.4. Coala Account Setup

Enter the username and password you chose when you signed up for the service. Follow the instructions in the app to set up your personal Coala account. If you wish to be included in the Coala Atlas, enter your personal details.

1. Coala Atlas allows your recordings to be used for research. Read text and select to participate or not. This can also be selected later in the app.
2. Health data: Gender, height, weight, medication (add if yes), smoking habits, pacemaker or other implantable device.

8.5. Pair the Coala to your phone

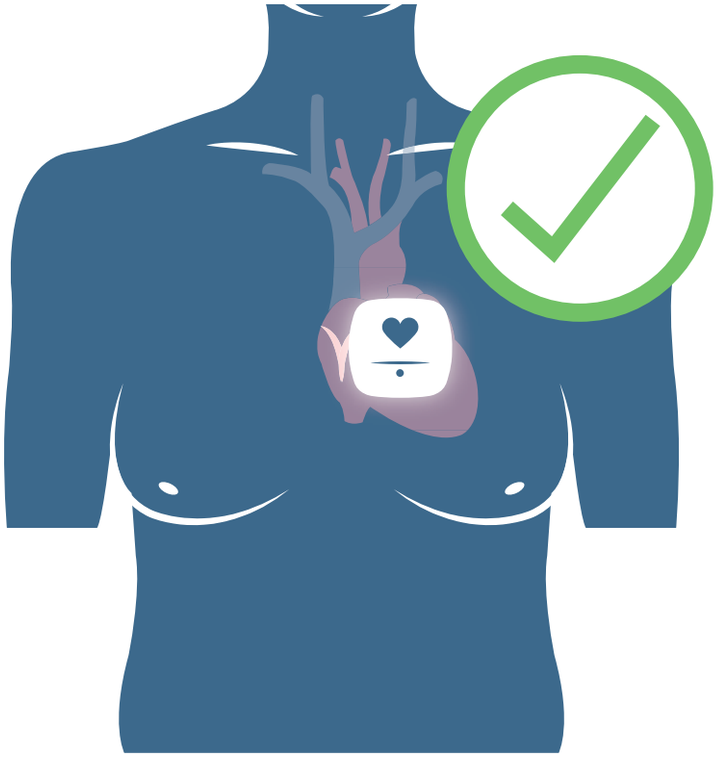
Use these steps to connect your Coala to the Coala App on your phone.

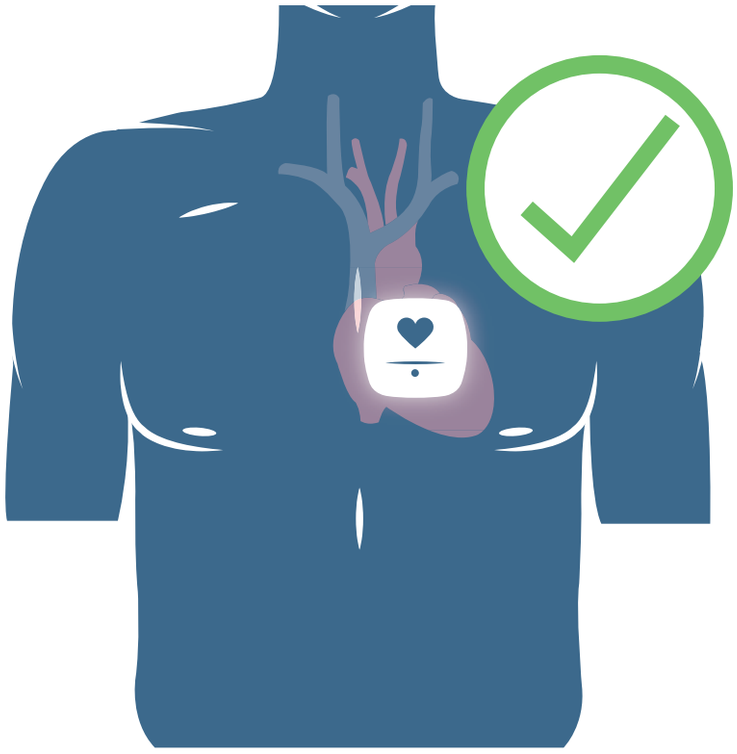
1. Make sure that your Bluetooth is not connected to another device when you make recordings with the Coala Heart Monitor.
2. Make sure that Bluetooth is enabled on your phone. It is found in the Settings tab on your phone.
3. Power on the Coala by briefly pressing the Power button ⏻. Your Coala should now be blinking green in rapid succession.
4. Press the “Connect Coala” button in Coala App and follow the instructions.
5. Press “My Coala is powered on” and then press “Show the list of devices” and select the serial number of your Coala in the list.

8.6. Best Practices

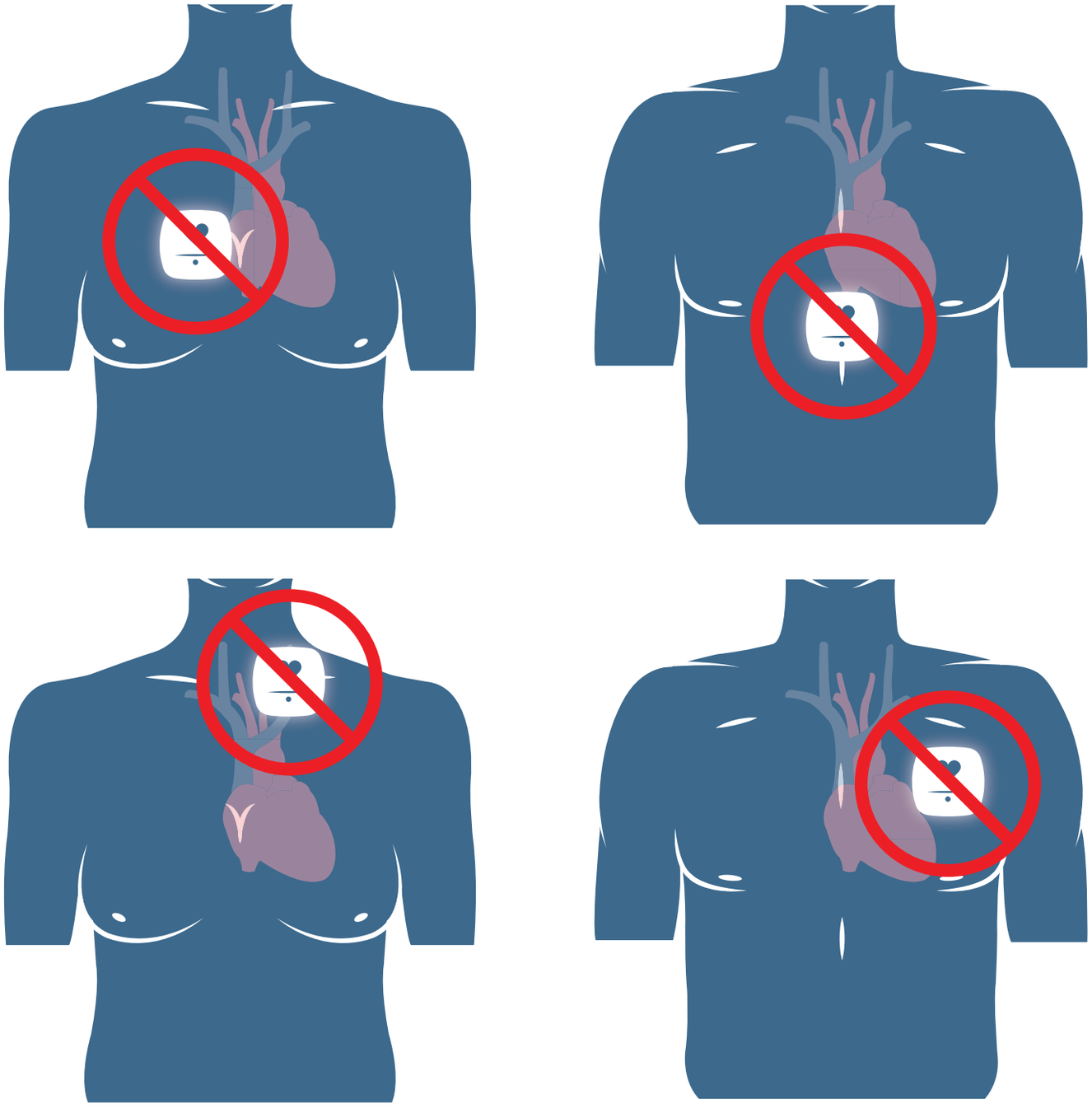
Sit down comfortably during recording for best results. Avoid lying down or standing up. For correct placement of the Coala

for chest ECG, see illustrations below. Hold the Coala between your thumb and middle finger. Place the Coala slightly to the left of your sternum (chest bone) as shown in pictures below. It is important that the Coala is upright (Coala text facing down). Press the heart button with your index finger to start a recording and hold the Coala steady during the recording. Try to relax and breathe normally. Avoid speaking during the measurement to ensure best recording quality.

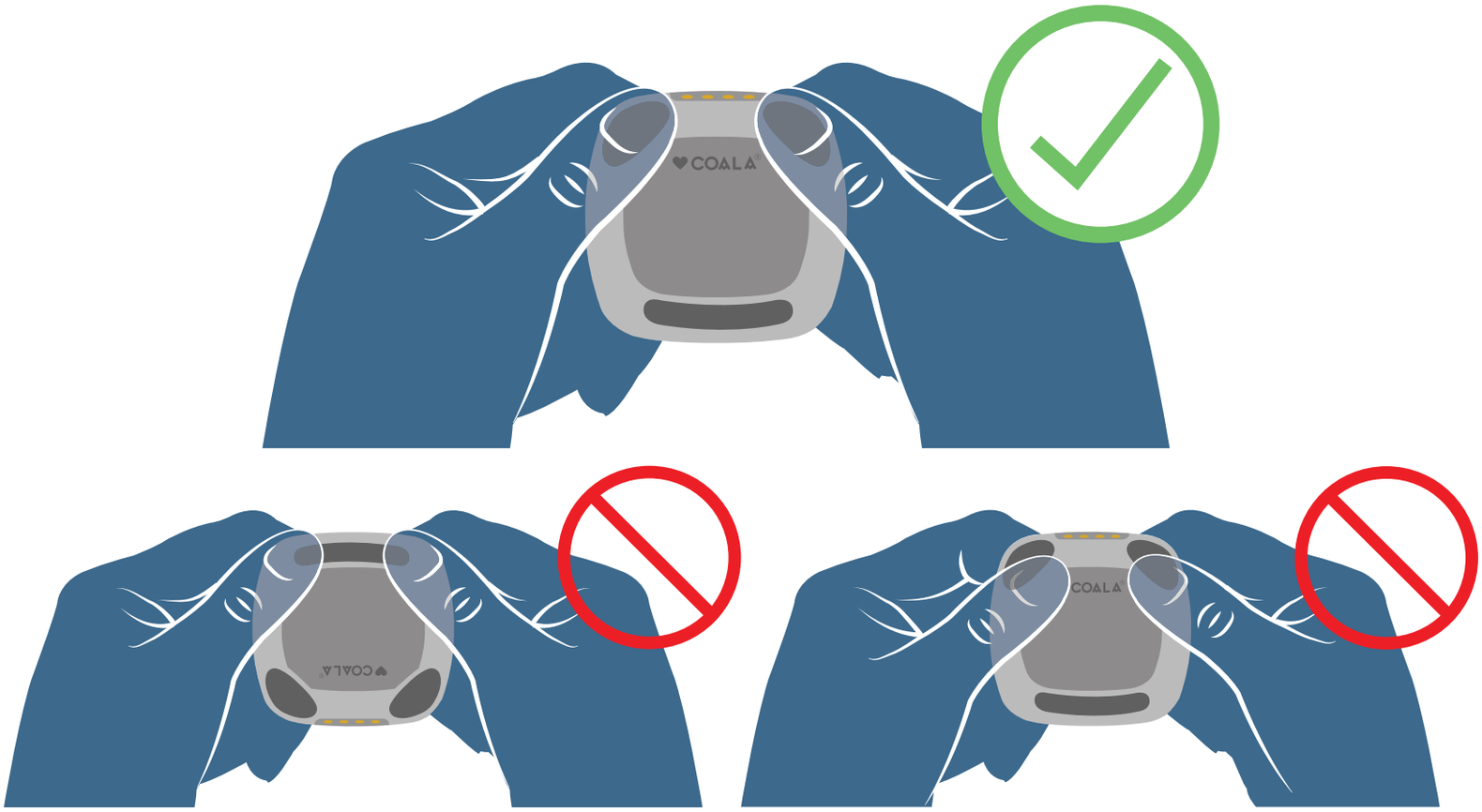




Shown below are the wrong locations for chest measurement with Coala.



Correct placement of fingers for thumb-ECG. Place your thumbs on the top electrodes. Try to hold the Coala in a relaxed position for the best possible recording. Resting your forearms on a table or on your legs when sitting down is the best way to obtain good recordings. Avoid pressing the electrodes hard, just maintain a firm grip.



For more information, see www.coalalife.com

NOTE

This user manual is found in the Coala App under My Coala -> Manual. The serial number and manufacturing date of your Coala is found under My Coala.

8.7. To record ECG and Heart sound

For best results, sit down and relax a few minutes before measuring. Be extra careful to hold the Coala steady, be completely still and do not talk during the recording.

If the Coala indicates an unreadable value make sure to perform an extra measurement.

A deviating value could occur without anything being wrong.

A deviating result could occur with high heart rate from physical activity or from other factors.

Click on the Start button in Coala App. Press the Coala against the chest. Push the ”Heart” button on the Coala to start the recording. A timer will count down during the recording. Keep the Coala as still as possible, breathe normally, sit down, try to relax and avoid talking. The next step is to conduct a thumb-ECG. Place both thumbs against the electrodes with the Coala oriented so you can read the text on the Coala membrane. Keep the Coala as still as possible, breathe normally, sit down and try to relax.

Your phone should always be within reach during the recording to assure proper radio signal transmission from the Coala to Coala App.

8.8. My Journal

My Journal contains all the saved data from all your recordings. Internet access is needed to see recordings since they are not stored on the phone.

8.9. My Inbox

My Inbox contains all sent messages to your Coala account.

8.10. Device settings and data transfer

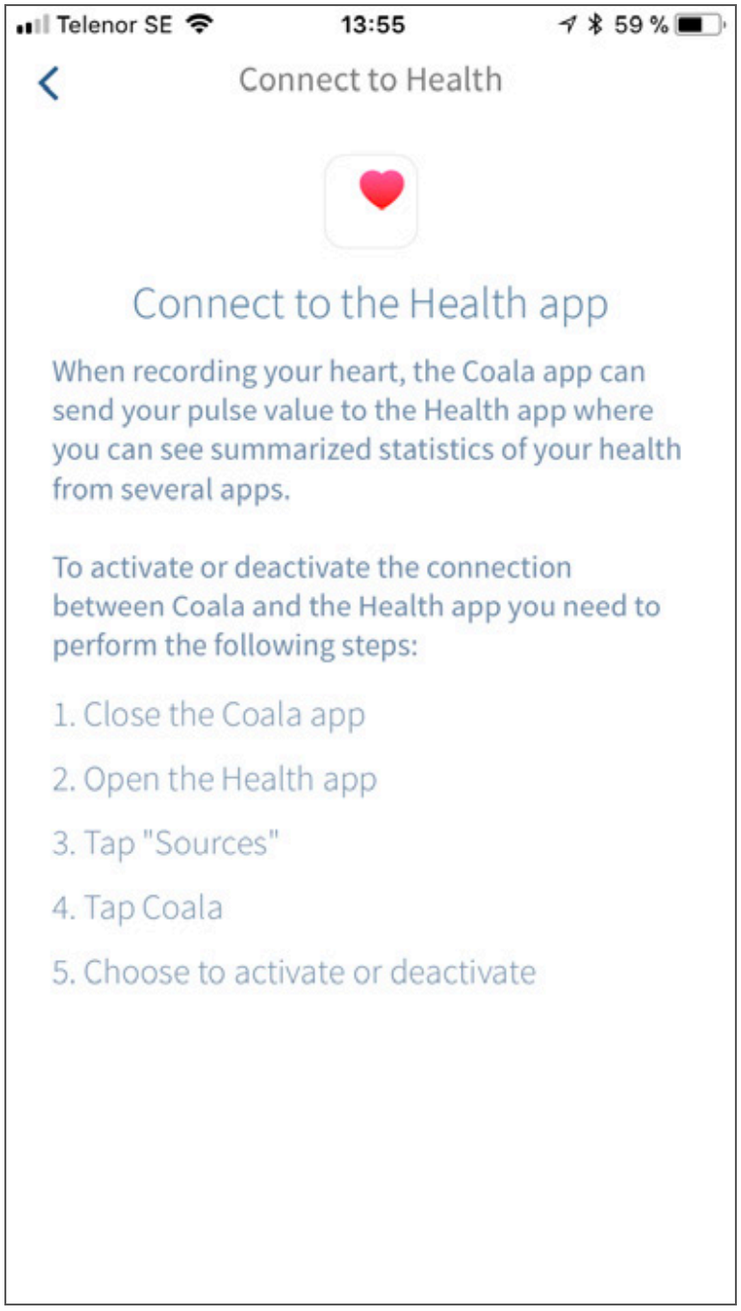
To modify device settings and obtain more information on the Coala device, click on “My Coala” from the main menu of the Coala App.

The settings that can be changed are related to sound recording. If you want to disable recording of heart sounds, activate “Robust Recording Mode”.

You will also be able to accept or decline healthcare providers.

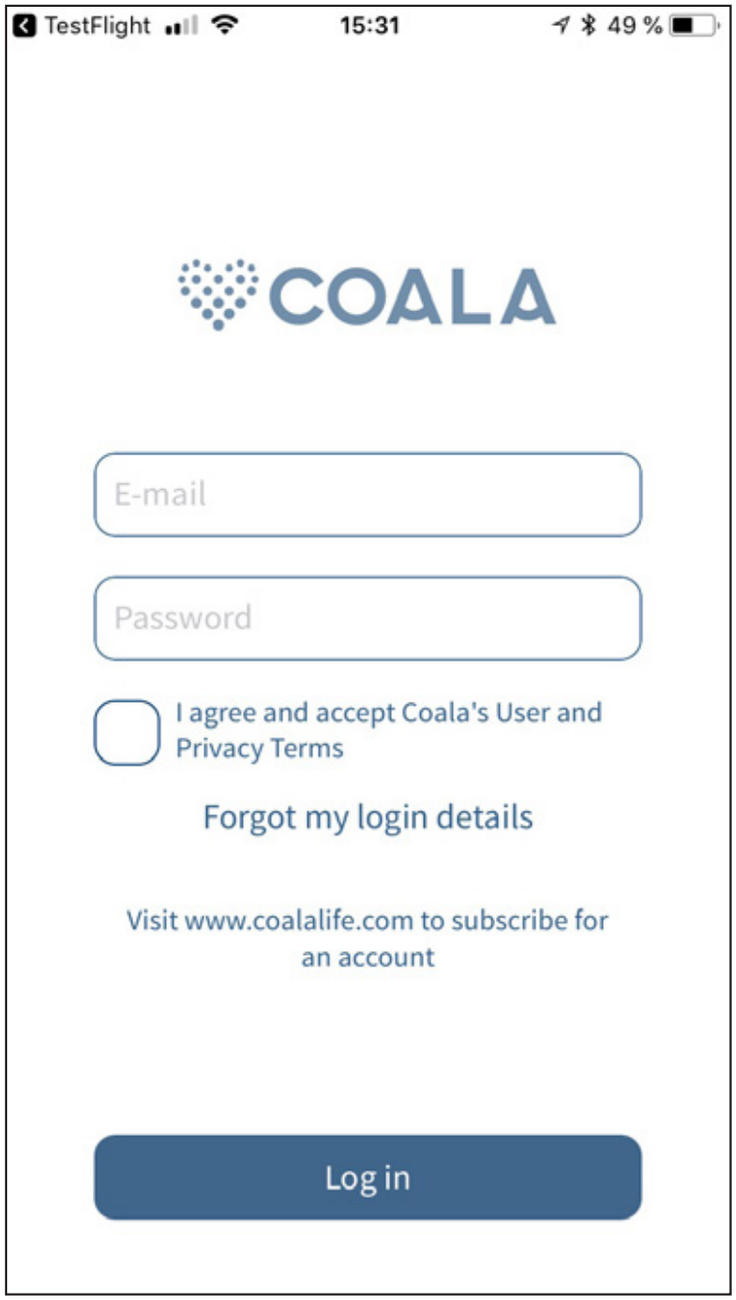
You can choose to show or not show help text (see picture on the right).

You will also be able to Connect to Apple Health (see instruction under “Connect to the Health app”).

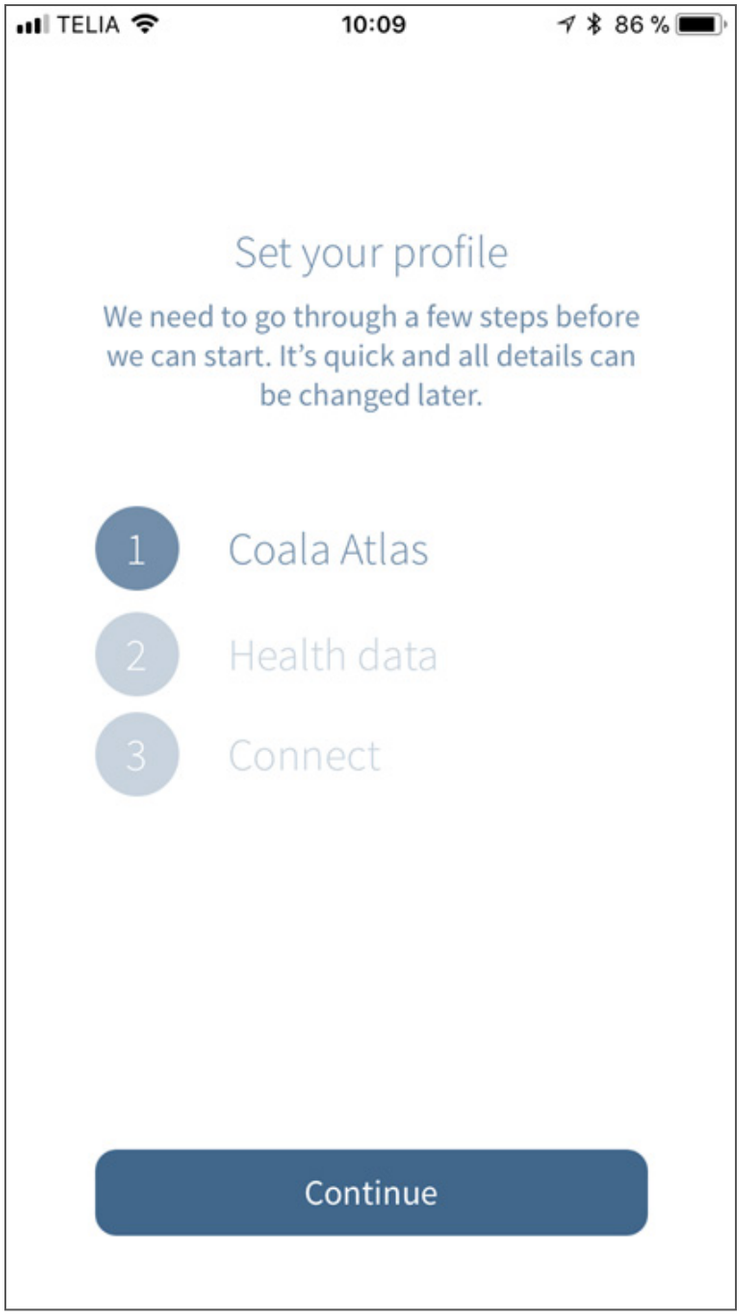


8.11. Step-by-step instructions

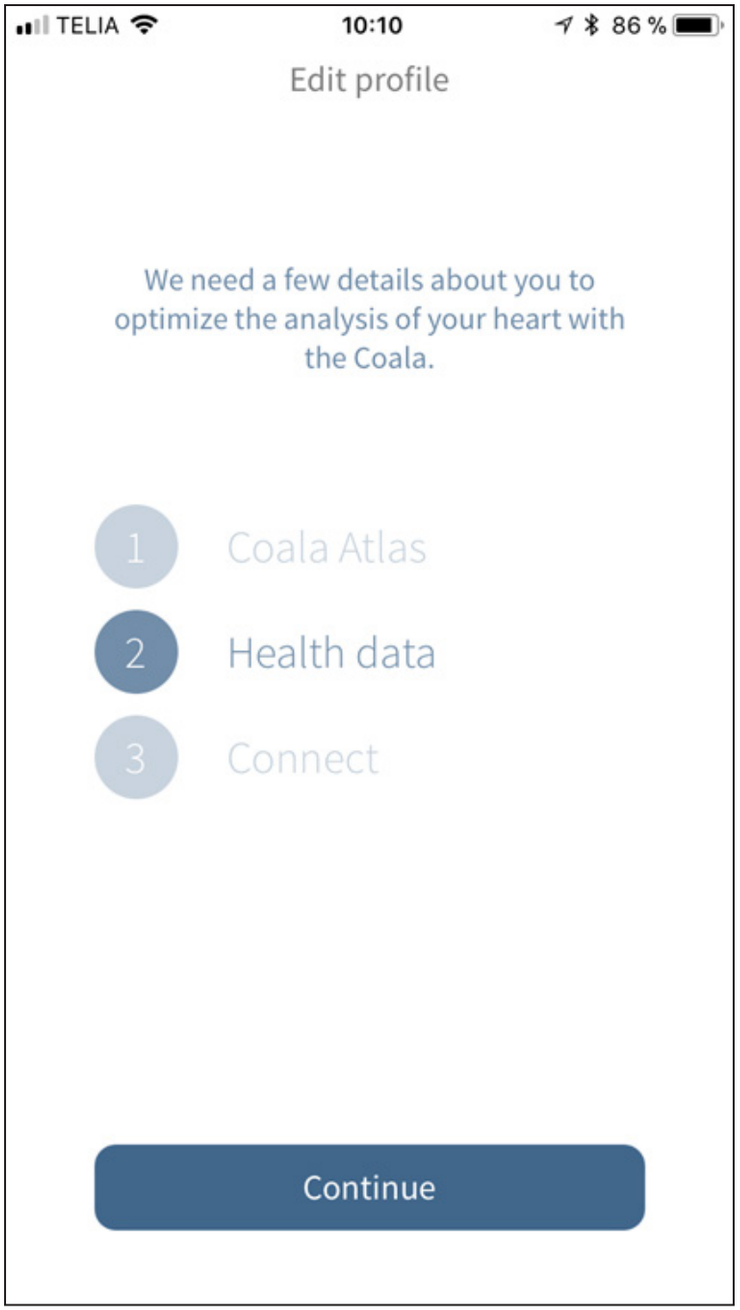
1. Log in with the username and password you entered when you registered your Coala account. If you have forgotten the password, tap the “Forgot my login details” and follow the on-screen instructions. You will then receive an email with a link to change the password (valid for 30 minutes). If you have not received the email, please check your junkmail folder. For security reasons you will not be able to login to Coala App for 20 minutes if you have entered the wrong password 3 times. You need to agree and accept Coalas User and Privacy terms to be able to log in to your account by checking the checkbox (you can read the terms if you click on the text “ Coala User and Privacy Terms”).



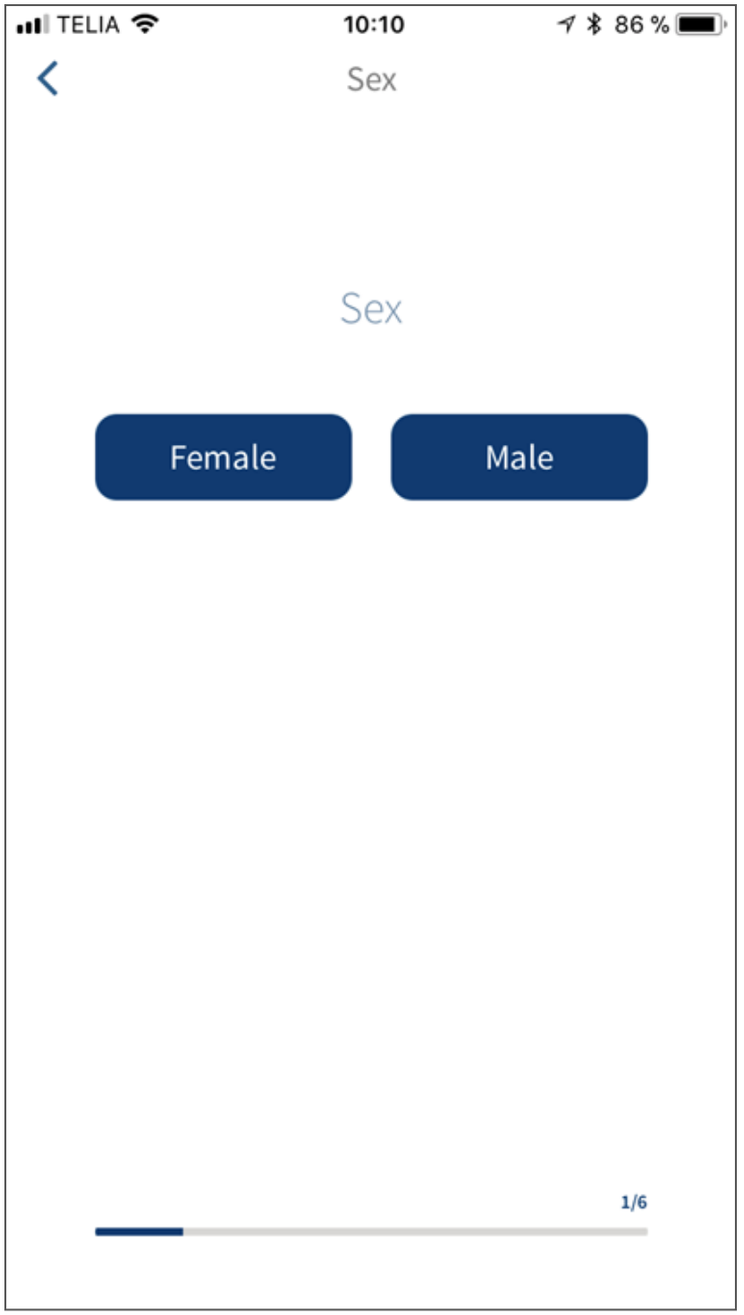
Before you can connect your Coala and perform your first measurement you will be prompted to enter some health data. Start by pressing Continue.



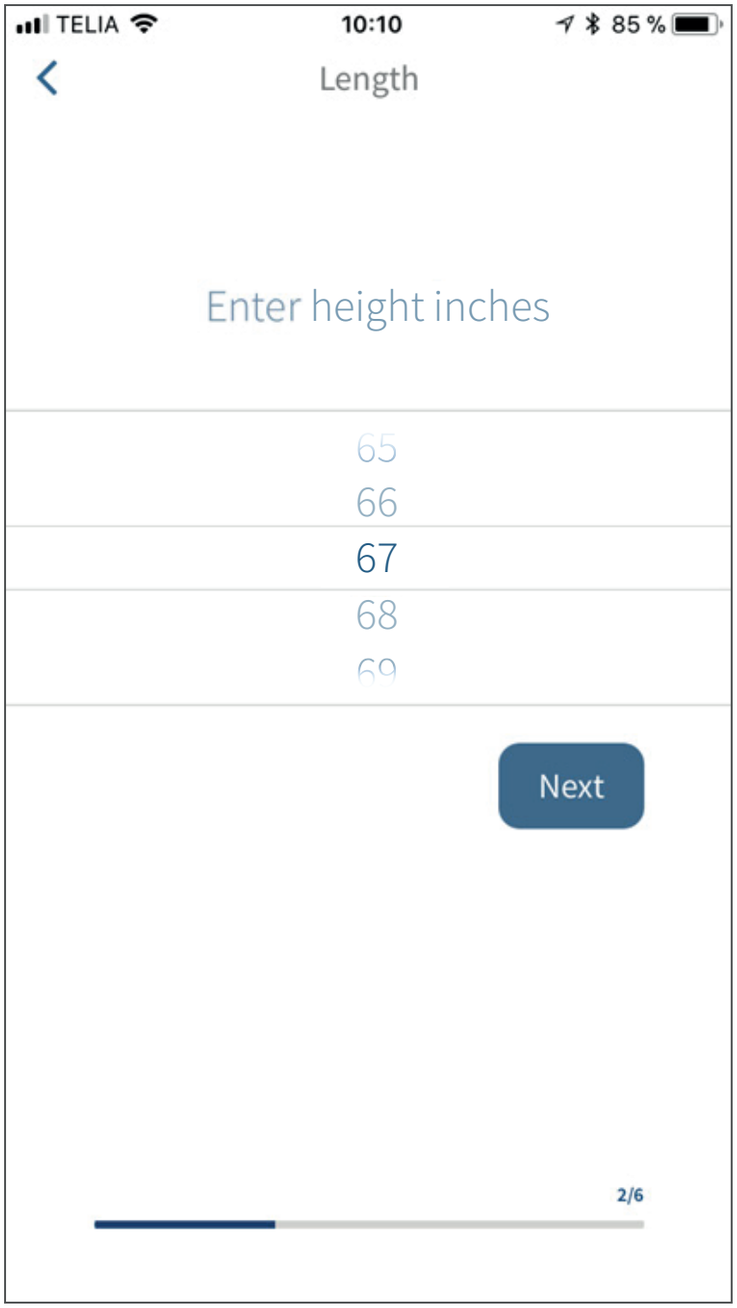
The first question is if you would like to participate in the Coala Atlas. If you want to participate anonymously, that can be set in the app settings later.



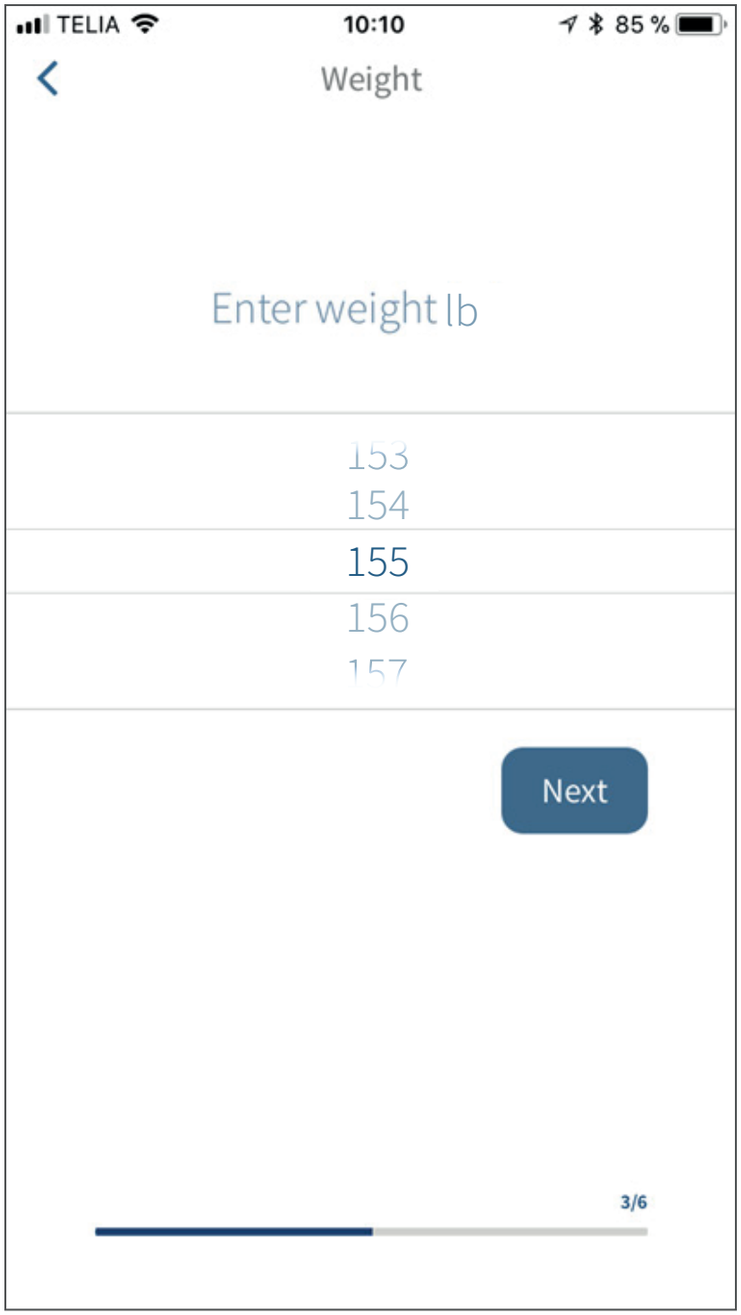
Next step is to start filling in your health data.



Select gender.

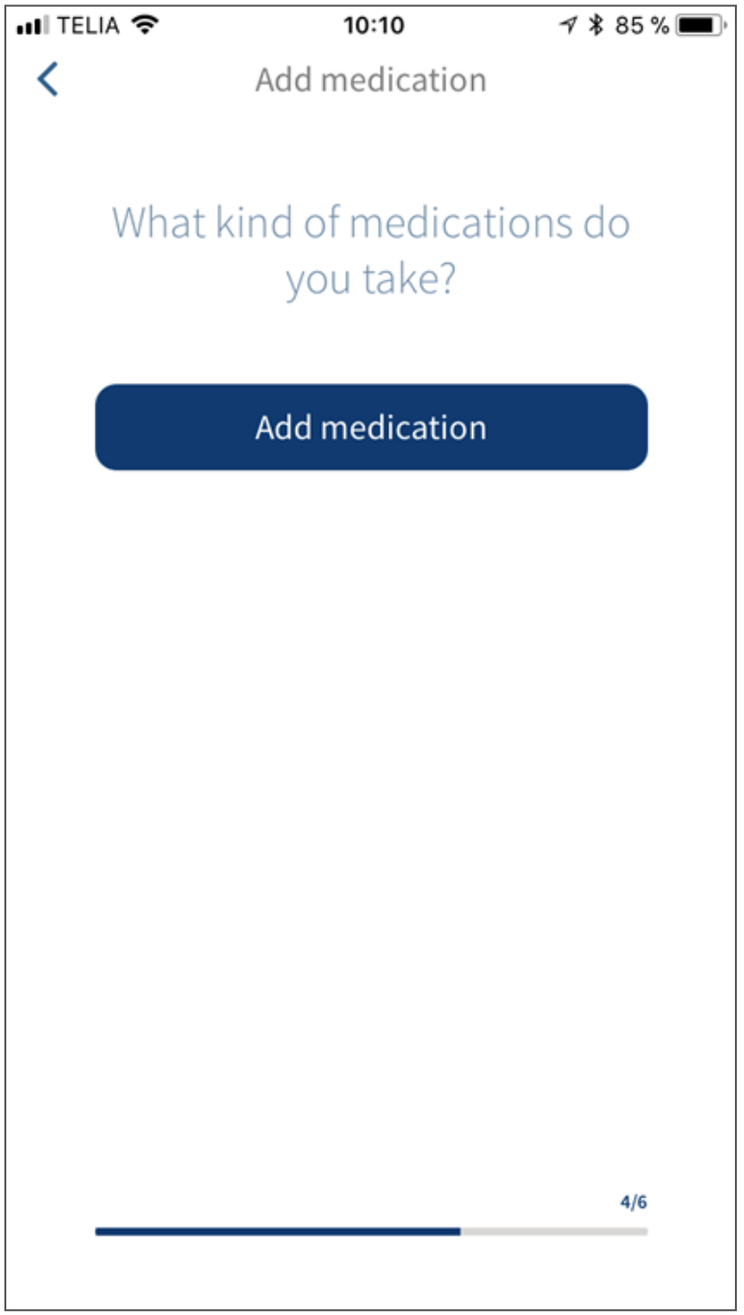


Input your height. Scroll up or down and press next.

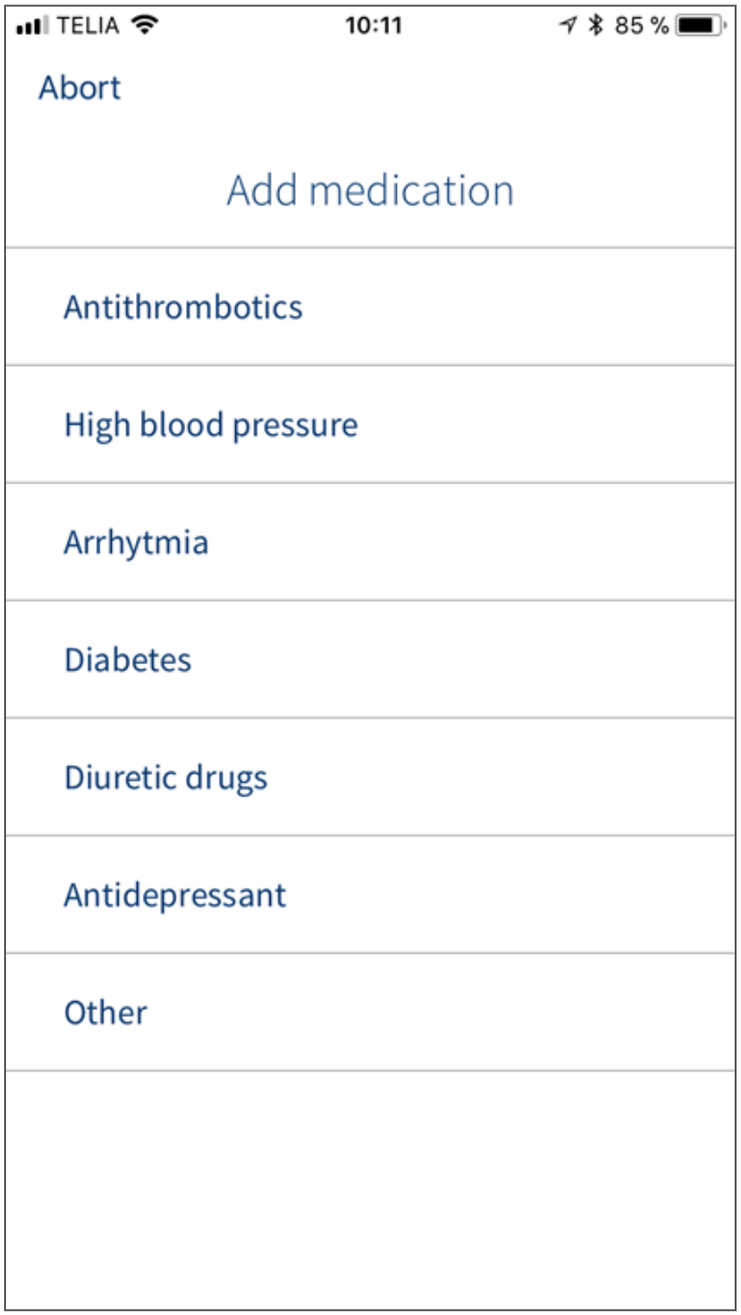


Input your weight. Scroll up or down and press next.

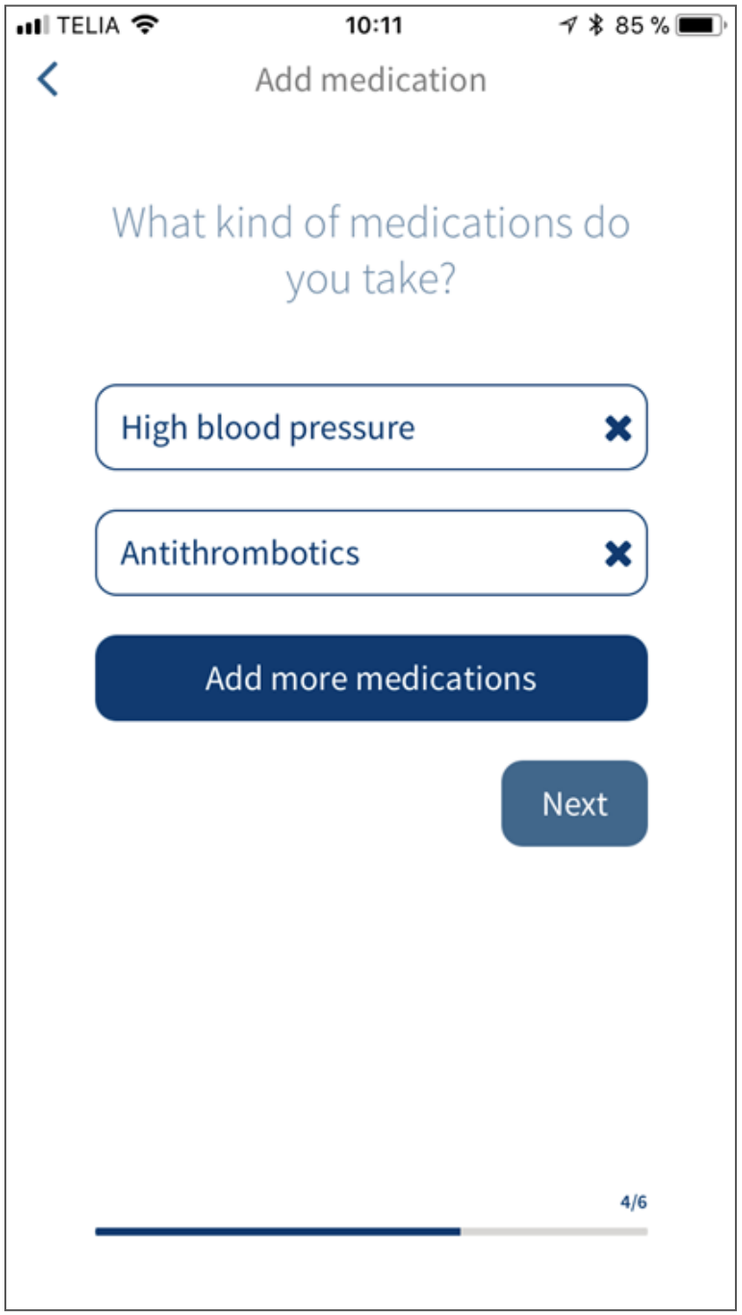
Medication status. If yes, fill in the following steps.



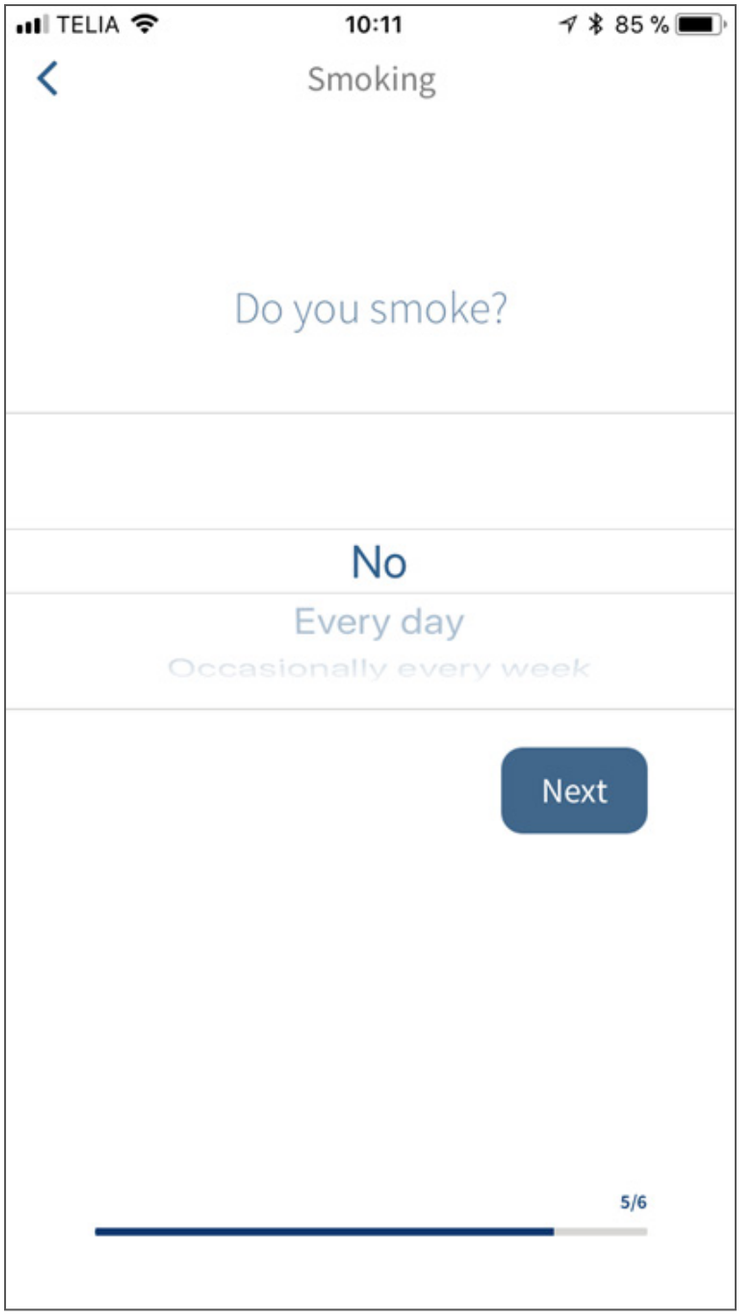
Press Add Medication.



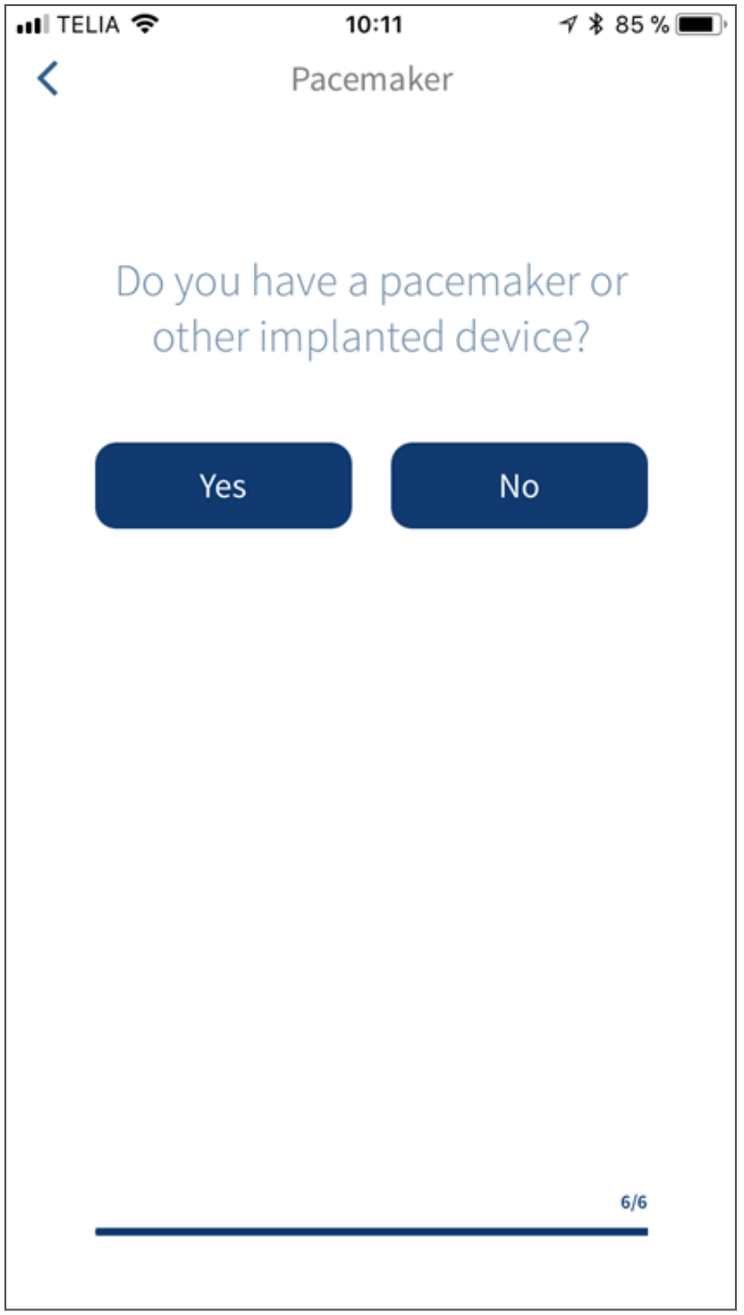
Select the medication type that you use. You cannot fill in the exact name of your pre-scripted medication.



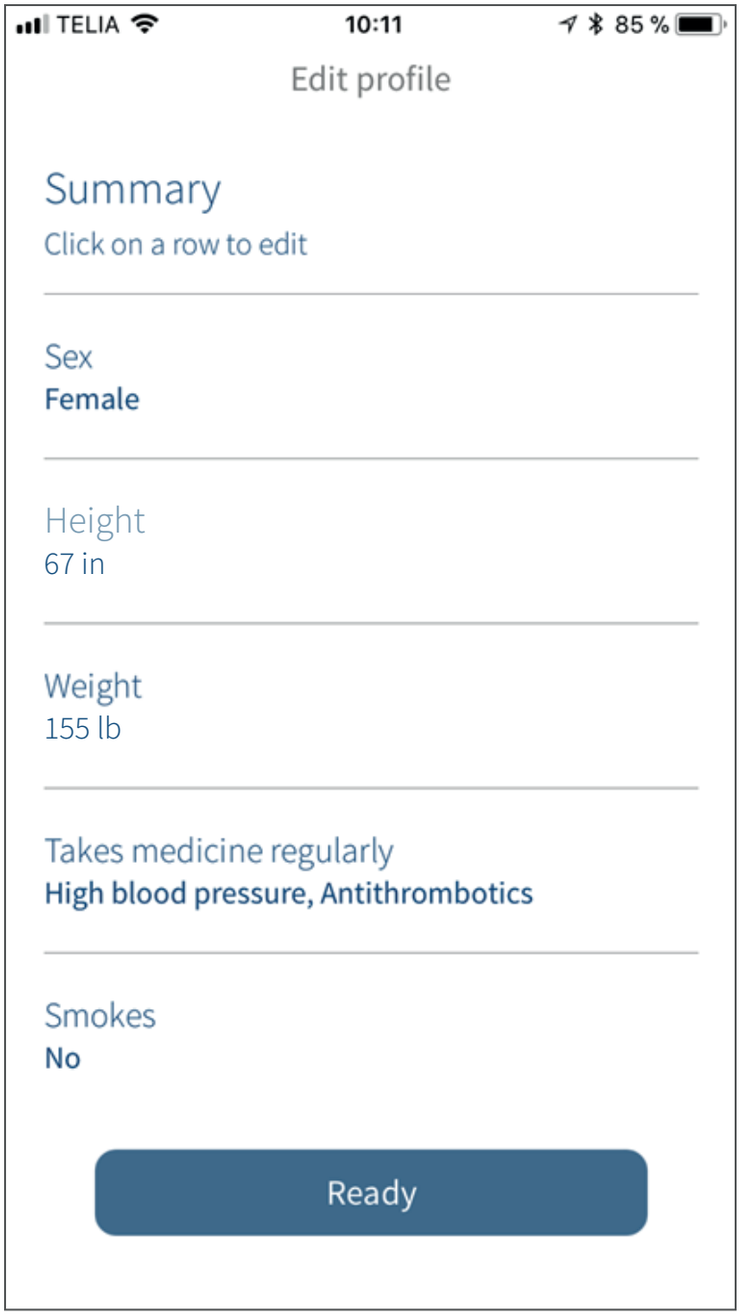
Add the medication that you use by pressing Add more medications. Once done press next.



Smoking status.

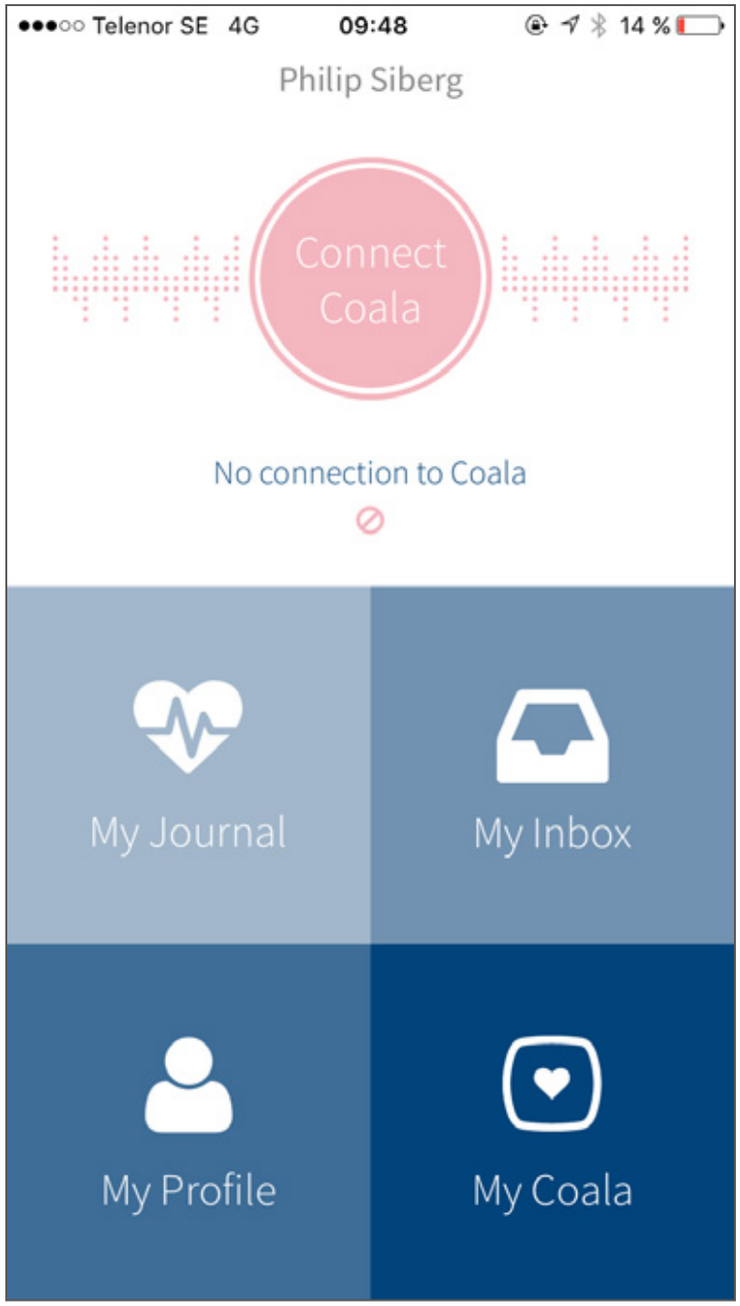


Pacemaker status.

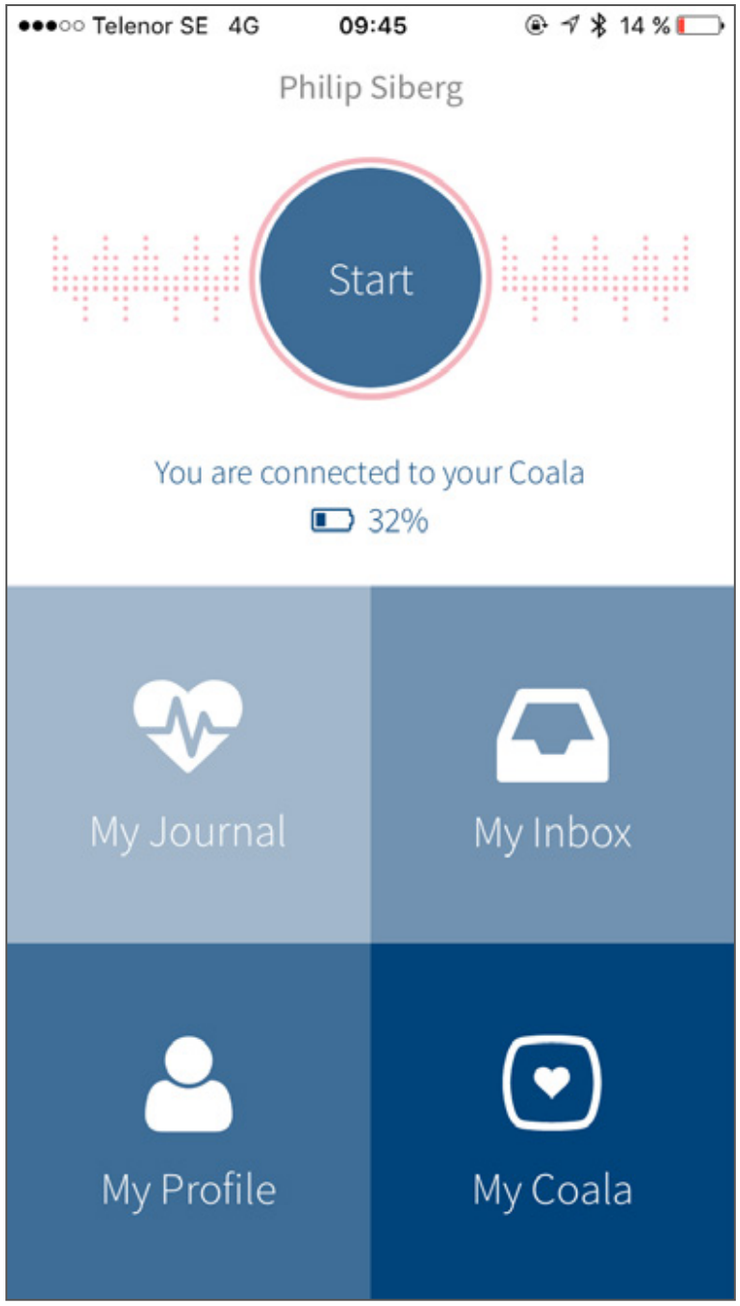


This is a summary of all the data you have entered. Confirm by pressing Ready.

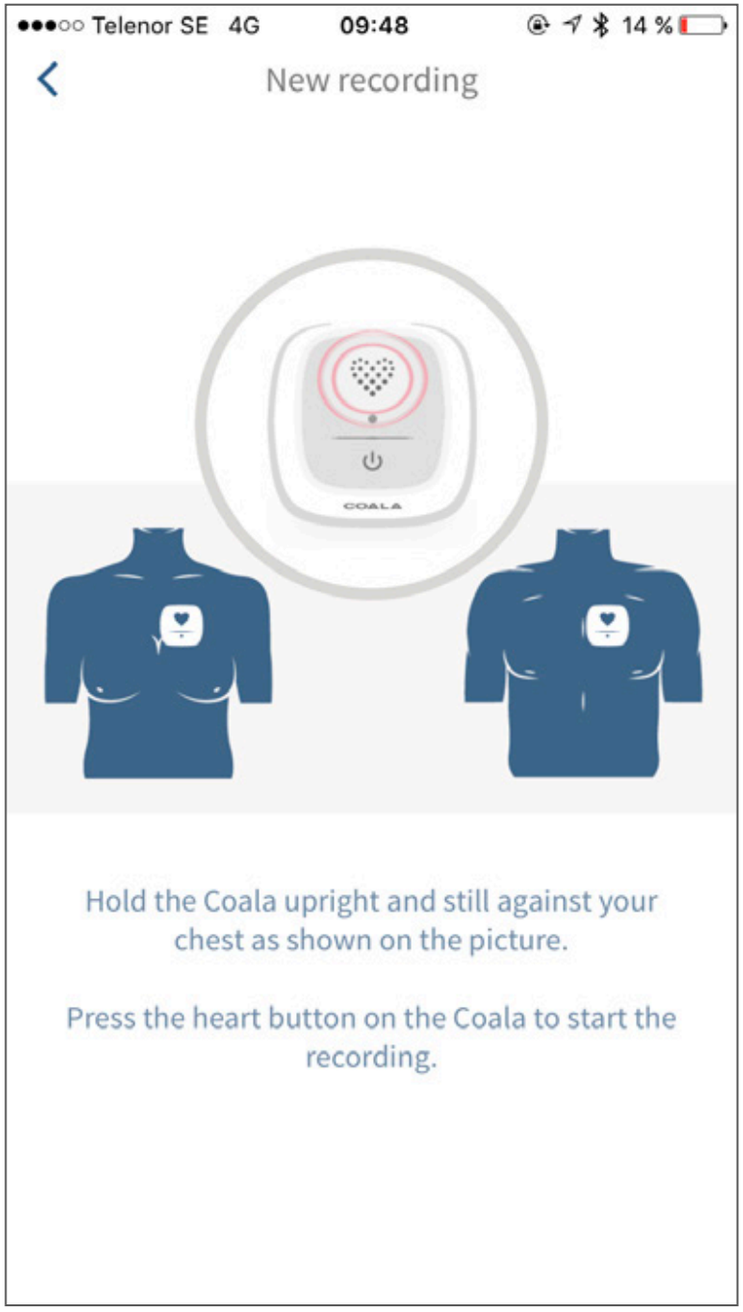
2. Switch on your Coala by pressing the On-button, ⏻, on the Coala. Ensure you have Bluetooth enabled on your smartphone (this is found under “settings” on your smartphone).



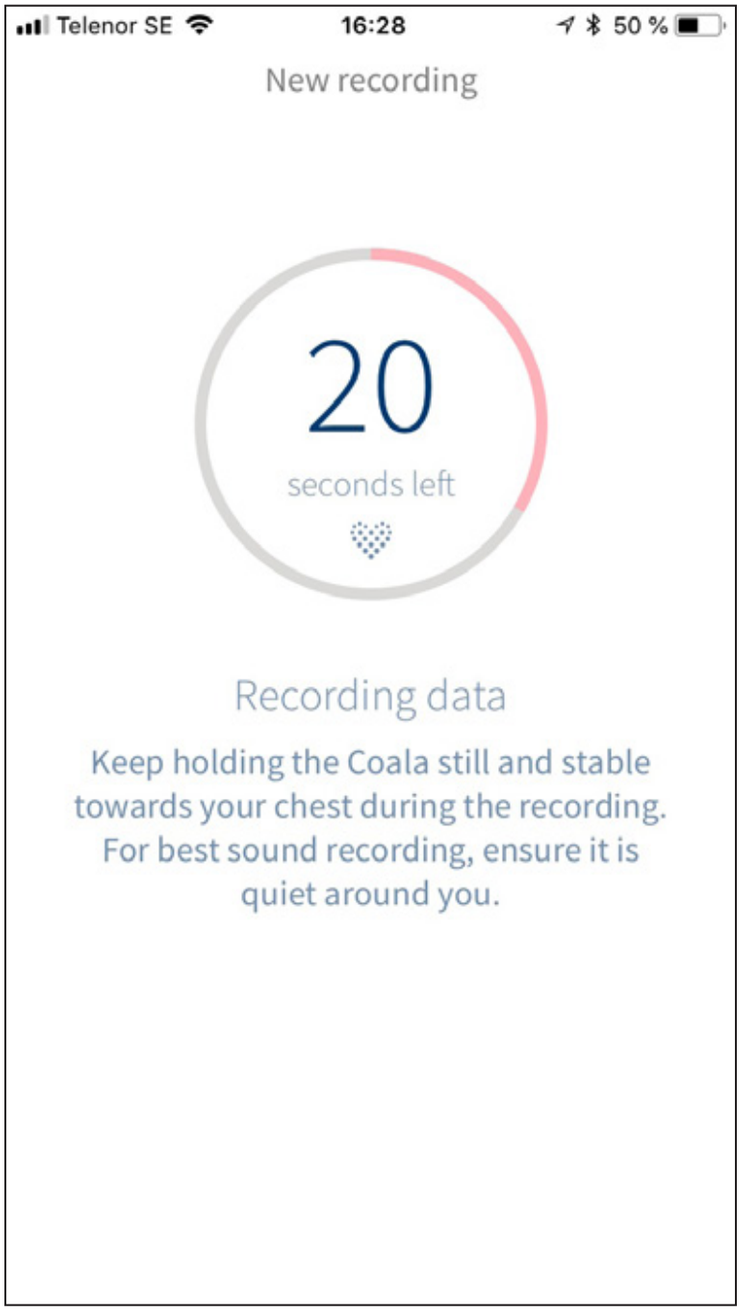
3. When the Coala is connected, the large circle turns blue. Relax and sit down for a minute before starting a new recording to ensure that your heartrate is at rest. This is important in order for the analysis to be accurate. Tap “Start” to start a new recording.



4. Sit down comfortably (do not stand or lie down). Hold the Coala firmly against your chest as indicated on the picture. Place and hold the Coala against your upper chest slightly right of the sternum according to the picture. Press the ”Heart”-button on the Coala to start recording.

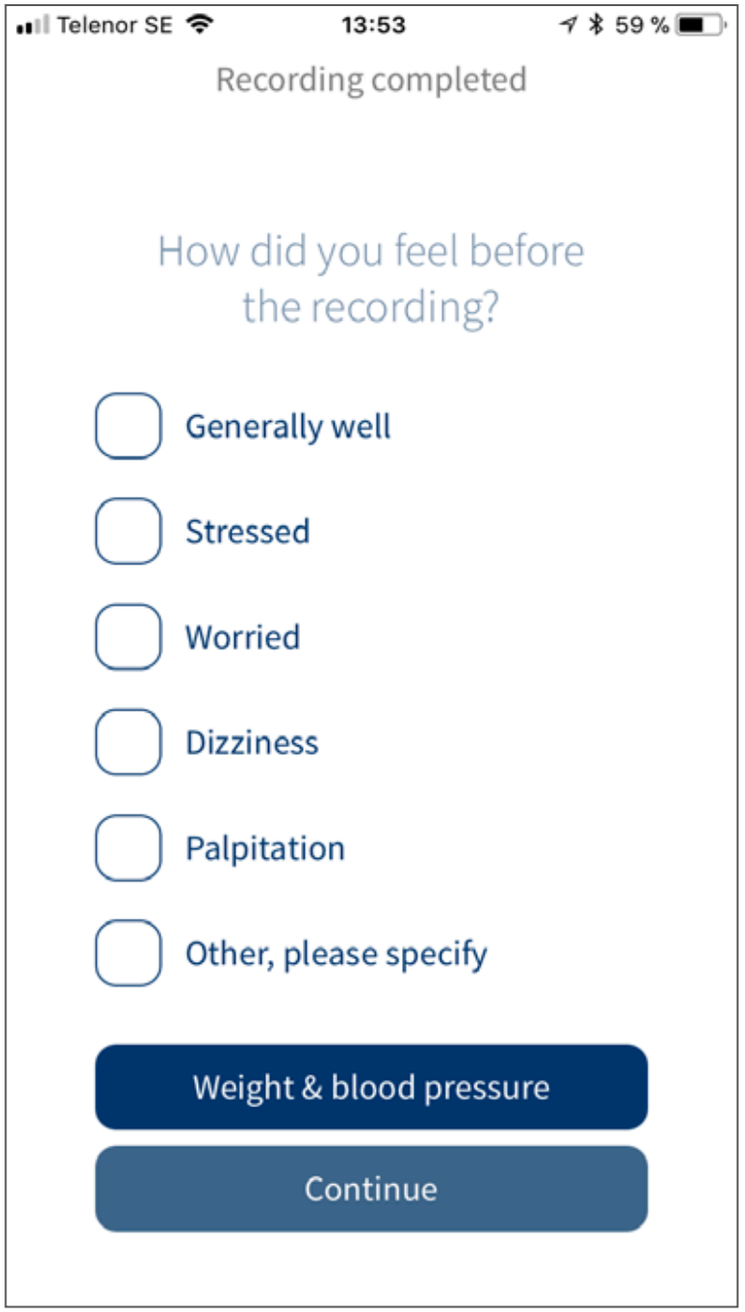


5. The Coala first checks for proper skin contact and then starts the 30 second recording with a visual countdown. Breathe calmly, relax and stay quiet. Do not talk during recording. Remain seated during recording. Continue to hold the Coala firm and steadily to your chest.

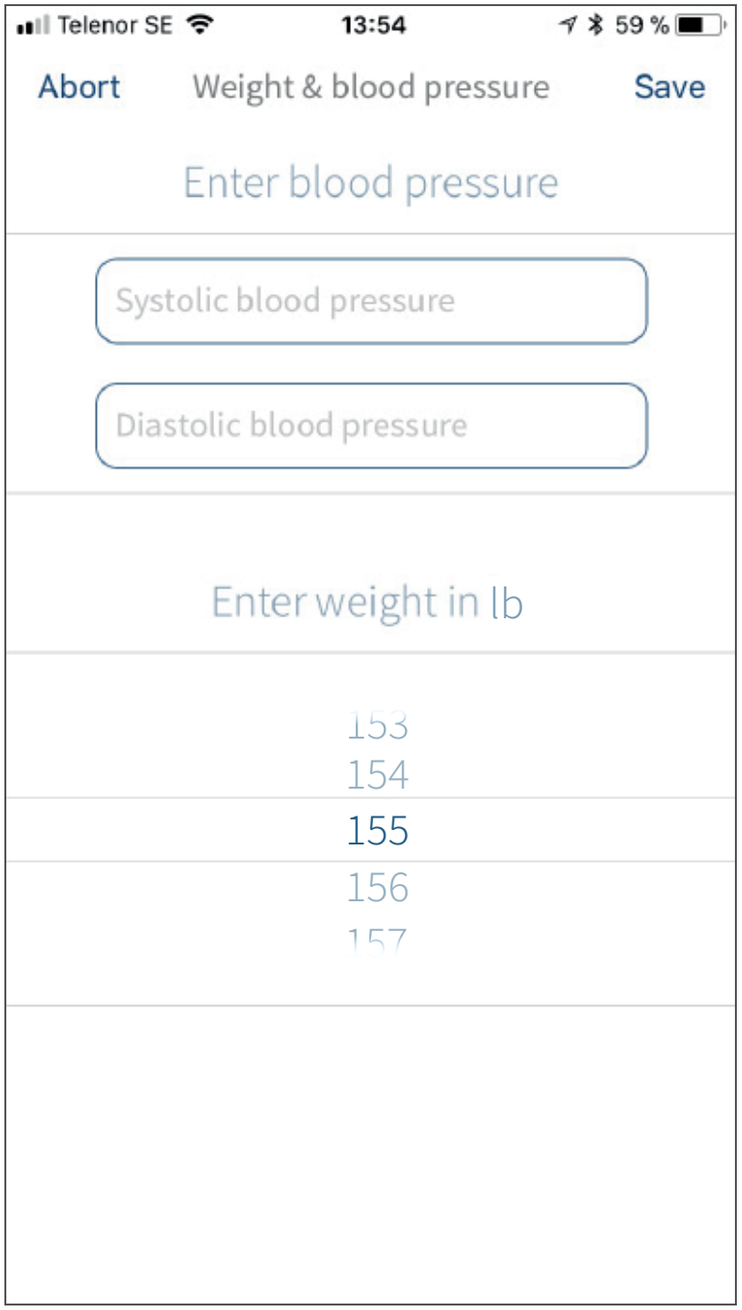


6. Next step is to perform a 30 second thumb-recording. Hold the Coala firmly as instructed in the picture. For the most accurate result, rest your forearms on a table. Breathe calmly, relax and stay quiet. Do not talk during recording. Continue to press your thumbs on the Coala firmly and steadily.

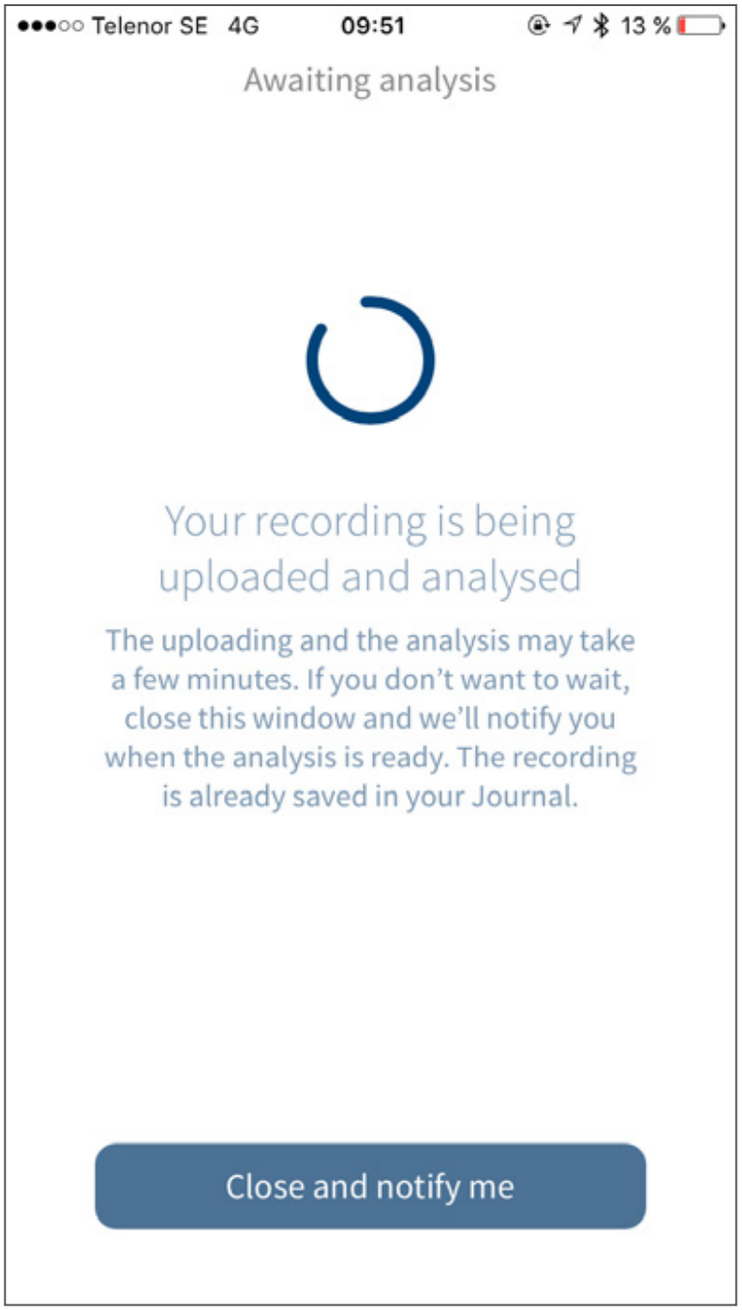
7. Once the recording is completed, specify how you felt before the recording.



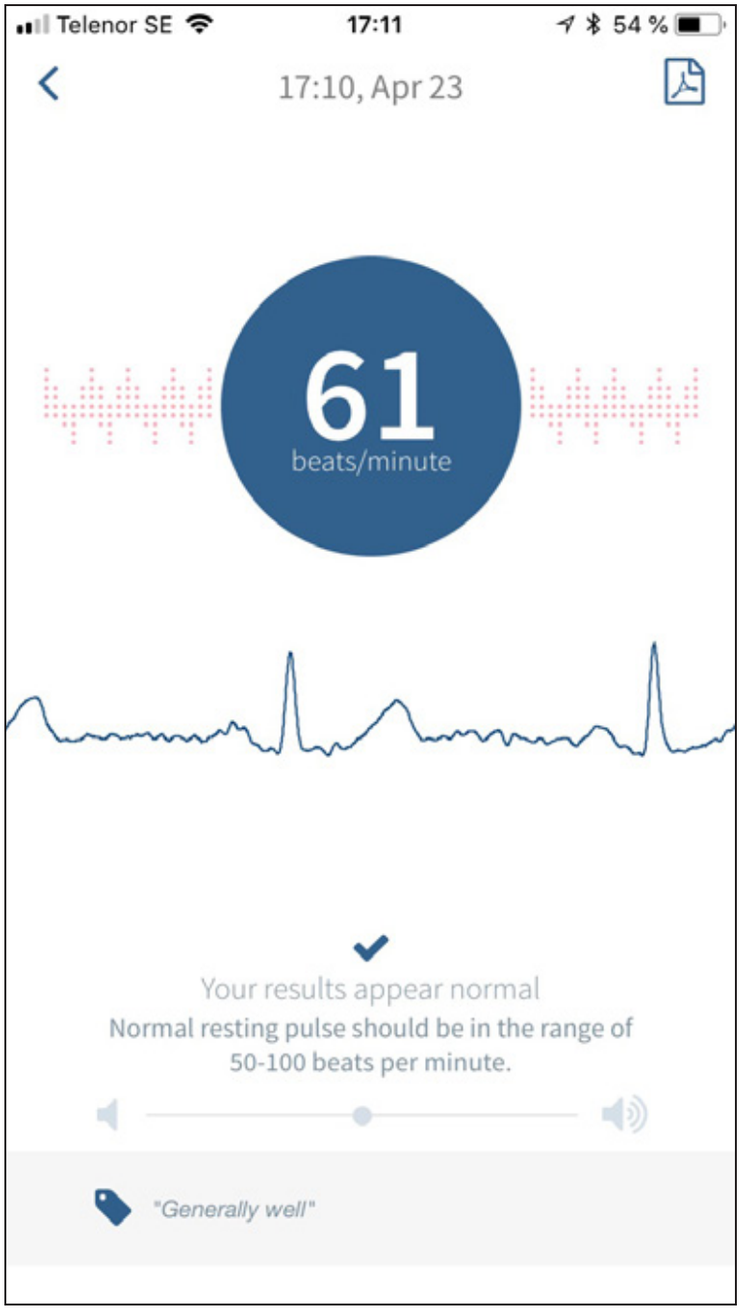
8. You can also enter the blood pressure (Systolic and Diastolic) and weight. Take caution to enter correct values.



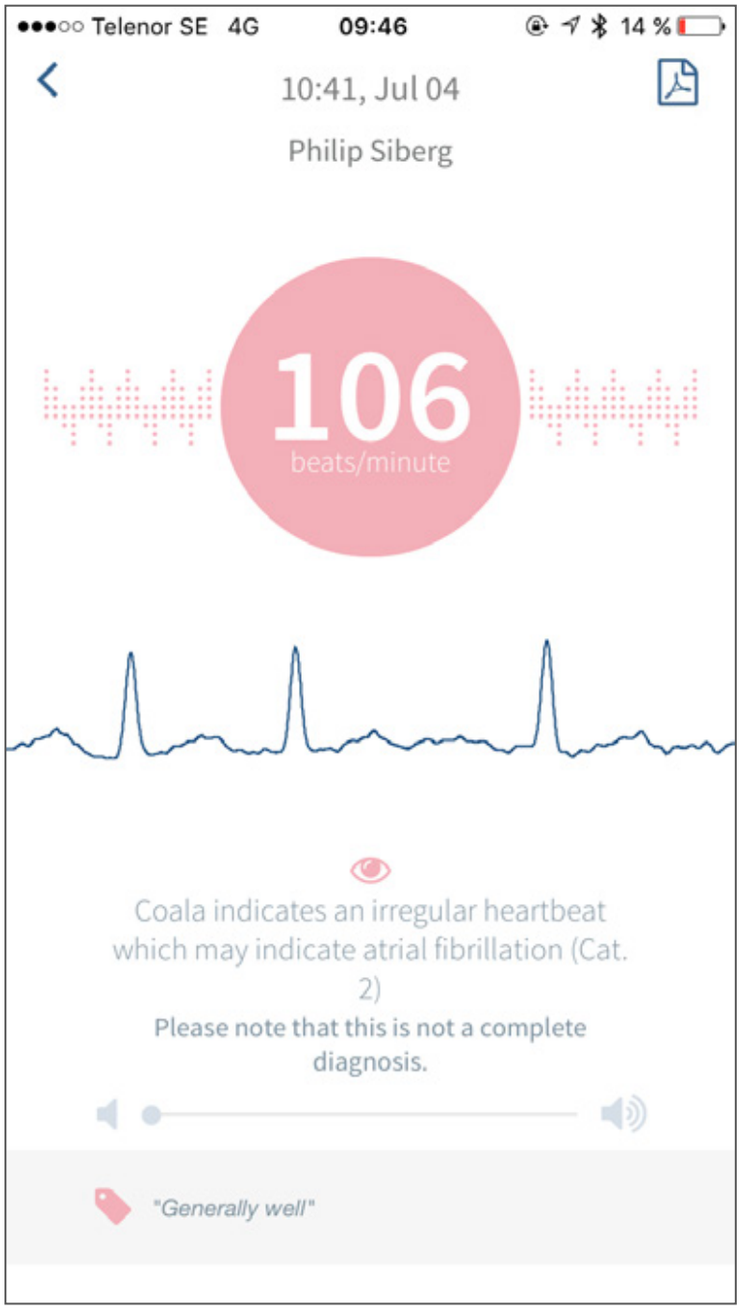
9. Your recording is now sent for analysis in the Coala Care Portal. Ensure you have sufficient internet access. If not, the recording will be held in a queue. Try again later to send the recording. Note that Coala Life is not responsible for any additional extra cost to your internet provider.



10. The analysis is ready. If a normal result is found, then the user is informed and a blue circle appears with average heart rate of the 30 sec thumb recording. The visible ECG-tracing in the app is from the thumb measurement.

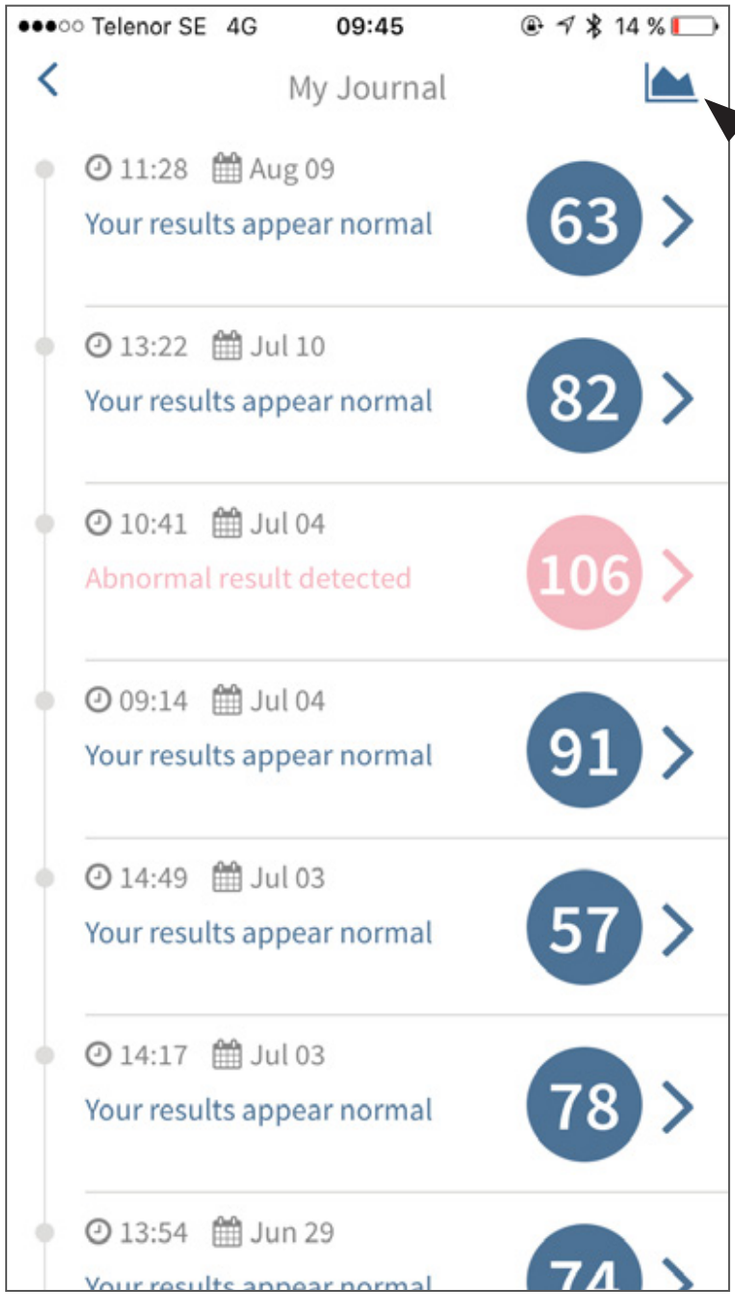


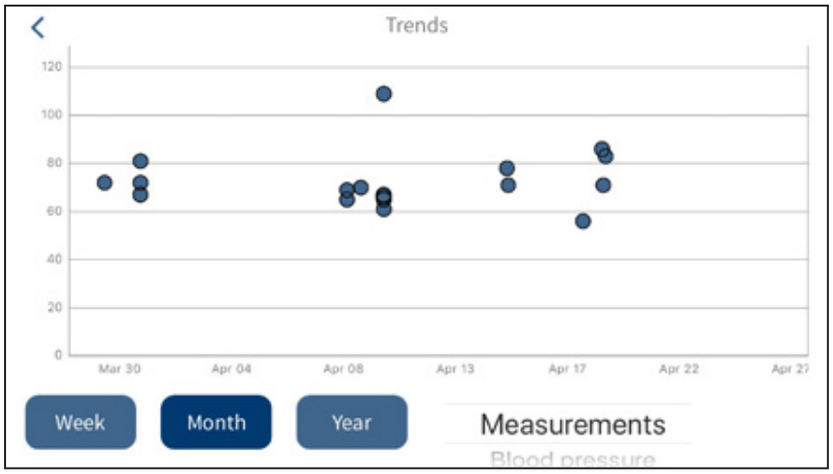
11. If Coala detects an abnormal result, the user is notified of the result. In such case, always conduct a second recording to verify the result and pay particular attention to hold the Coala steady during the recording.



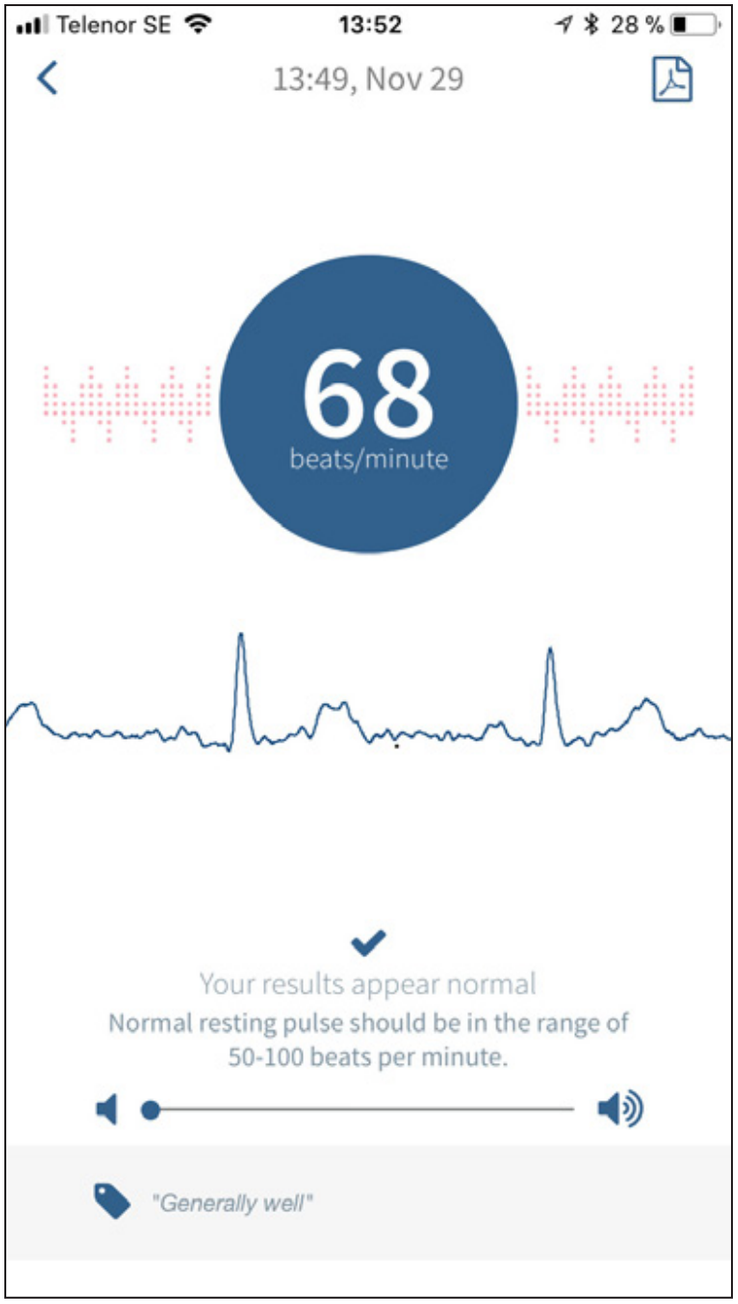
12. All your recordings are saved in your Journal which is easily accessed from the Main Menu. Note: Internet access is needed to access recordings.

13. Click on the trend plot symbol (upper right corner) then you have the possibilty to trend measurements, blood pressure and weight see figure below.





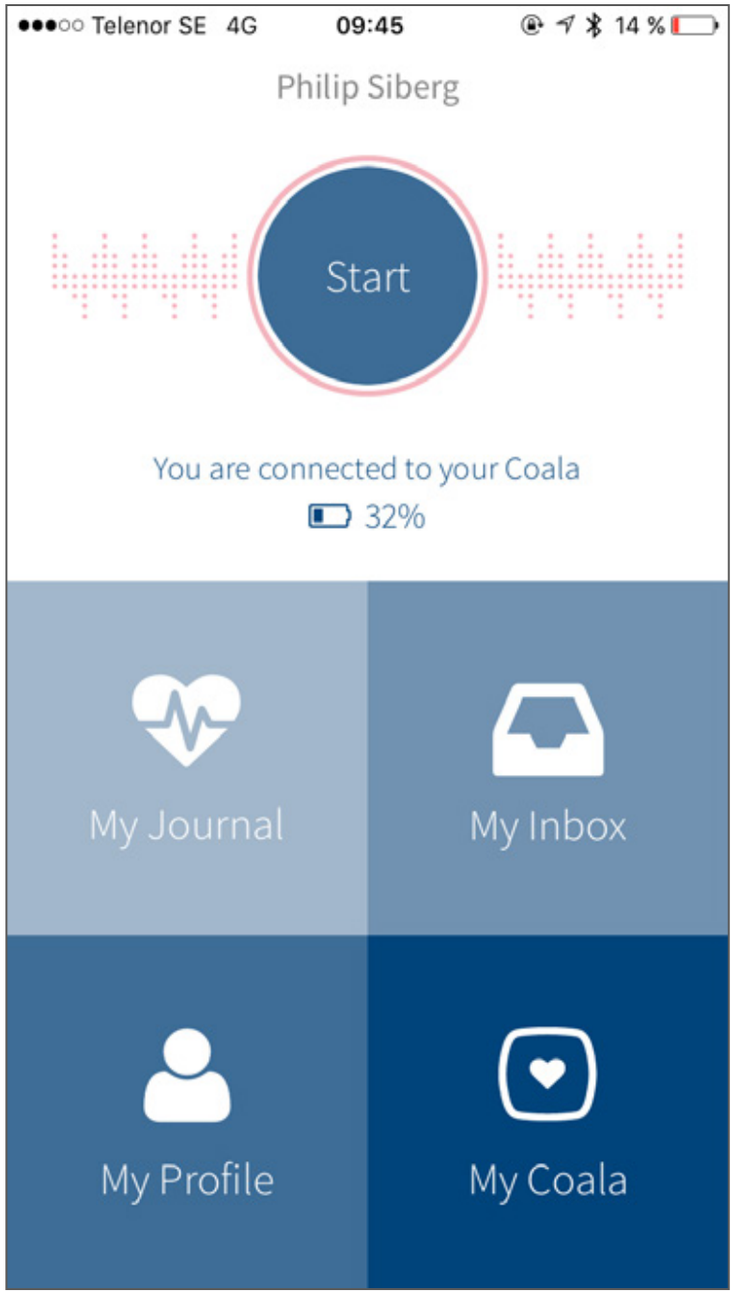
14. To access your ECG in a PDF-format, click on the symbol in the upper right corner of the results screen. The mobile device used needs to have a pdf reader. This does not come with the Coala application.



15. A PDF is generated that can be saved on your mobile device or sent by message or email. The mobile device used needs to have a pdf reader. This does not come with the Coala application. The first page of the PDF is the chest-ECG and the second page the thumb-ECG. Default settings for ECGs in the PDF report:Thumb measurement, 10 mm/mV, 25 mm/s, filters affecting signal representation enabled. Chest measurement, 40 mm/mV, 25 mm/s, filters affecting signal representation enabled.

For more infomation about the ECG curve and how to interpret them see section 10. ECG Categorization.

16. Back to the main menu. The Coala will turn off automatically after 10 minutes. Close the App when not in use.
My Inbox: Messages and caregiver access requests from your physican. My Profile: Personal information and log out from Coala App. My Coala: Connected health care providers, device information, more information about analysis categories, Robust Recording mode, Connected to Apple Health, reminders*, settings, instructional movies, user manual, terms and conditions, settings and participation in Coala Atlas can be found here.



**reminders are only available for iOS App.*

9. Coala LED indications

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

10. ECG Categorization

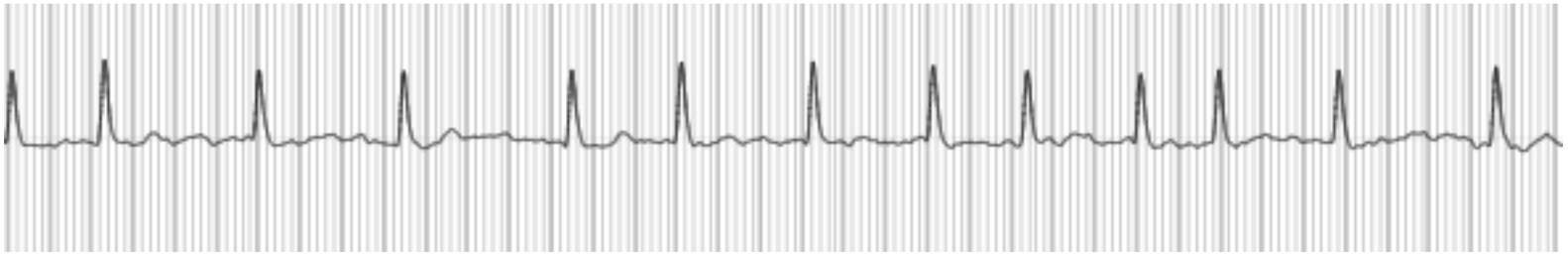
More information about dectected categories can be found under “My Coala” or visit www.coalalife.com.

Category	*Description*
0.	Poor quality (Difficult to follow the beat sequence)
1.	Your results appear normal
2.	Coala indicates an irregular heartbeat which may indicate atrial fibrillation (Cat. 2)
99.	Coala indicates an unclassified heart rhythm (Cat. 99)

Category 1

No Rhythm Deviation (Only insignificant irregular beats present)

Category 2



Irregular Sequence (Unexplained irregularities, which may be AF or paroxysmal AF with or without P waves)

11. Troubleshooting

11.1. Troubleshooting

The Coala App helps the user by step-by-step instructions how to perform a recording and where to apply the Coala. To access Device information such as firmware and software revisions, please see “Device Information” under “My Coala” found in the main menu of the Coala App.

Issue	*Solution*
Can’t login to the app.	Make sure that you have the correct user name and password. Note that the password is cap sensitive. Make sure that you are connected to the internet. Make sure that your subscription hasn’t expired. If problem persists, contact Coala customer support.

Issue	*Solution*
I can’t start a recording.	Make sure that the Coala unit is powered on and connected to the mobile unit. The circle in the app needs to be blue before you can start a recording.
I can’t find my previous recordings.	All recordings are stored in the Coala Care Server and are only accessible if the mobile unit is connected to internet or Wi-Fi.
I forgot my password to login in to the application.	Press “I forgot my login details” on the landing page of the application and follow the instructions. You will receive an email to the email address you use to login in to the application.

Issue	*Solution*
I cannot power on the Coala.	Make sure that the battery hasn't depleted. Place the Coala in the charge station and make sure that the station is powered. The Coala should start blinking blue indicating that it is being charged, if not contact Coala customer support.
Blue charging light does not come on when placed in the Coala Charge Station.	Check that the USB cable and wall adapter is correctly connected to the Coala Charge Station. Check that the Coala is correctly placed in the Coala Charge Station.

Issue	*Solution*
The Coala cannot connect to mobile device.	Make sure Bluetooth is enabled on the phone. Make sure that the Coala is in connection mode. This is done by placing the Coala in the charge station. Make sure that the charge station is powered and the Coala is blinking blue. Hold down the power on button for 8 seconds and take out the Coala from the charge station. Your Coala should now be blinking green in rapid succession. Now try to connect the Coala to your mobile device again. If problem persists, do not use device and contact Coala customer support.

Issue	*Solution*
Steady yellow light followed by auto-power off.	Battery empty or the Coala has detected an internal error. Place in the Coala Charge Station for charging. If problem persists, do not use device and contact Coala customer support.
The recording stopped in the middle of the measurement.	The Coala needs to have full contact with the skin of the chest or of the fingers. If the skin contact is lost the recording will stop. Make sure to follow the instructions given in the application.

Issue	*Solution*
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 mobile device does not support enough data transfer to record the heart sounds. The application will be set in Robust recording mode automatically. This will enable normal ECG-recording but no heart sounds will be recorded. Restart the measurement.
I cannot open the PDF-files.	Make sure that the mobile unit has a program to open pdf-files. This does not come with the Coala application.

Issue	*Solution*
If the Coala have a steady yellow light.	Place the Coala in your charge station. 2. Hold down both buttons (on/off button and heart button) for more than 10 seconds. 3. When the Coala lights blue, release the “on/off button” and hold down the “heart button” until it begins to light yellow constantly. 4. Remove the Coala from the charge station. 5. Shut down the Coala by holding down the button for at least 10 seconds. 6. Then restart the Coala.

For a list of current Software Anomalies see website:
www.coalalife.com/SoftwareAnomalies

12. Electrical safety

The Coala Heart Monitor is in compliance with:

- IEC 60601-1:2006 and amendment 1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-11:2015, 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 60601-1-2:2014 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.

13. 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

14. Electrical emission

The Coala fulfills:
CISPR 11 Class B (2009): Radiated and conducted emission
IEC 61000-3-2 (2014): Harmonic current emission
IEC 61000-3-3 (2013): Voltage fluctuations and flicker
FCC 47 CFR Part 15 Subpart B Class B

15. Electrical immunity

The Coala fulfills:
IEC 61000-4-2 (2008): Immunity to electrostatic discharge
Test level ±8 kV contact discharge ±2, ±4, ±8 and ±15 kV air discharge.

IEC 61000-4-3 (2006 + A1 + A2): 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 60601-1-2:2014: Table 9 (up to 28 V/m pulse modulation at frequencies in ISM bands)

IEC 61000-4-4 (2012): 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 (2006): 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 (2014): 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 (2009): Immunity to power frequency magnetic fields
Test level: 30 A/m, 50 Hz and 60 Hz

IEC 61000-4-11 (2004): 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.

16. Warning related to electromagnetic compatibility

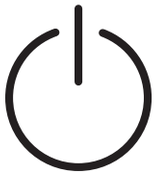
The Coala is designed to withstand expected electromagnetic interference. If the Coala is exposed to electromagnetic interference exceeding what is expected corrupted measurements could occur or even permanent failures.

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 feet) to any part of the Coala, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

17. Symbols used on system and package label

	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 0086	European Conformity Mark
	Radio transmitter
	Stand-by on/off
IP22	IP (Ingress Protection) Class 22.

	WEEE – Properly Dispose of Electronic Waste
5V ⎓ 300 mA	Input/output voltage and current
SN	Serial number. The serial number for your Coala is found under My Coala in Coala App.
LOT	Batch number
	Manufacturer/manufacturing date. The manufacturing date of your Coala is found under My Coala in Coala App.
	Manufacturer
℞ Only	Caution: Federal (USA) law restricts this device to be sold by or sold on the order of a physician

	Keep dry
	Fragile, handle with care
	Do not use if package is damaged
	Consult instructions for use
REF	Partnumber
MR	MR unsafe
FCC ID: 2ALO7CHM	FCC ID

18. 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 – 500 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 charged to full at 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 Amax

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	1 year
Shelf life	1 year

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.

Compatible with iPhone 5 or later with iOS8.x or later or smart phone with Android 4.4 KitKat and all later versions.

For a list of compatible devices see website:
www.coalalife.com/device-compatibility

19. Contact information to the Manufacturer

Coala Life AB
Riddargatan 18
114 51 Stockholm
Sweden

www.coalalife.com
info@coalalife.com

For the latest manual and current information on your product, please visit www.coalalife.com/usermanual. For support or a printed copy of this manual, please email support@coalalife.com or visit www.coalalife.com

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