COALA®



USER MANUAL COALA GO!

Including Coala Heart Monitor paired with Coala Go! tablet

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Introduction

Congratulations on your new Coala Go!

The Coala Go! includes everything you need to perform measurements of your heart, a Coala Heart Monitor and a preconfigured Coala Go! tablet.

Please read this manual before use for important safety information about your Coala Heart Monitor, Coala Go! tablet and app.

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O1 Product description

The Coala Go! 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. The Coala Go! system consists of the following parts:

- The Coala Heart Monitor: A small hand-held device that is held against the chest for simultaneous recordings of ECG and heart sounds through electrodes and a stethoscope membrane. The chest recording is always followed by a thumb ECG recording for the most accurate detection.
- The Coala Go! Tablet: A tablet with the pre-installed Coala Go! app that is used together with the Coala Heart Monitor to perform measurements. Please ensure the tablet is charged prior to use.
- The Coala Go! App: Preinstalled on the enclosed tablet and used together with the Coala Heart Monitor to record, store and transmit measurements. Measurements are transmitted from the app to the Coala server for analysis. The app also features a messaging system where you can receive messages and notifications from your Healthcare provider.
- The Coala Charge Station: Used to charge the battery in the Coala Heart Monitor. The Coala can be charged using the supplied wall adapter or any compatible USB outlet (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 and Coala Go! app 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 results from detection of cardiac rhythm deviation
- Receive messages and notifications from a Healthcare professional .

Chest and thumb ECG

Coala measurements consist of two consecutive recordings; the chest recording followed by the thumb recording. The chest recording is performed first by holding the Coala membrane firmly to the chest, slightly to the left of your sternum. The thumb recording is performed by firmly pressing both thumbs onto the electrodes located on the bottom of the Coala.

Simultaneous ECG and audio recordings

A unique Coala feature is the ability to simultaneous record ECG and heart sounds during a chest recording. This combined information can be used by a trained cardiologist to give a detailed view of the electrical and mechanical activity of the heart.

02 Indications for use

The Coala Heart Monitor is intended to record, store, display and transfer single-channel electrocardiogram (ECG) waveforms, as well as heart sounds.

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.

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 heart sound recordings.
- The Coala should be applied only to intact and clean skin (e.g., not over open wounds, lesions or 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. 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, wall adapter 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 or high power radio transmitter as these can cause disturbances to recorded signals. Note that recordings performed in vehicles (cars, buses, trains, aircrafts) may see disturbances due to electromagnetic interference 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 tablet between measurements.
- Contact Coala Life of any signs of malicious system behavior, suspicions of malware or system cybersecurity violations.
- 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 Healthcare 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.
- Not for pediatric use.
- 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 tablet directly next to a pacemaker or ICD (Implantable Cardioverter Defibrillator) as this may interfere with 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 Before using the Coala Go!

Unpack the Coala and Charge Station

Read the instruction sleeve carefully before removing it. When the sleeve has been removed place the Coala and Charge Station on a flat surface and remove the Coala from the Charge Station by following the instructions on the next page.

Apply light pressure onto the "COALA" text on the front of the Coala using your thumb. Carefully lift, and tilt the front of the Coala out of the Charge Station as illustrated below.

Unpack the supplied Wall Adapter and connect the USB Cable



between the Charge Station (small USB plug) and Wall Adapter (large USB plug). Connect the Wall Adapter to the power outlet.

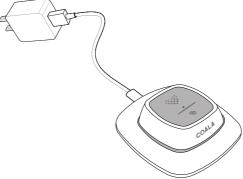
NOTE! If an external power supply/wall adapter is used it must be a class II power supply (no connection to protective earth) with an output voltage of 5VDC and capable of at least 300 mA of current.

Charge the Coala by sliding it carefully back into the Charge Station as illustrated below. Do not use excessive force when placing the Coala into the Charge Station.



NOTE! The correct orientation of the Coala when placing it into the Coala Charge Station. Do not use force or press straight down on to the Coala when placing it into the Charge Station. For maximum electrical safety, the Coala cannot be used while charging. 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.

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 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 excessive force when lifting the Coala out of the Charge Station as this will damage the device

Handling the Coala Go! tablet

In order to push and retrieve data between the server and the tablet please make sure to keep the tablet charged and powered on at all times. The tablet should be charged with the included charging device. The battery level is indicated in the top right corner of the display window .

Your charging port could be located on the top or bottom of your tablet. Once located, plug the charging cable into the tablet.



Make sure you have enough cellular reception to be able to upload your measurement. Cellular reception is indicated by the reception bars **...Il** found in the top right corner of the display window.

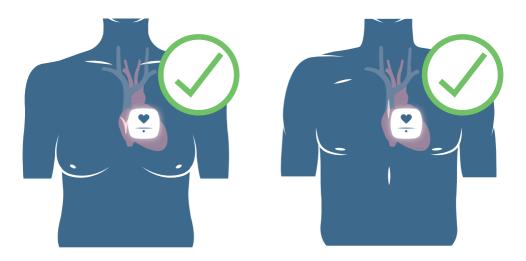
07 Best practices

Sit down and relax a few minutes before recording measurements with the Coala to ensure the most accurate reading. Before initiating the 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 recordings. Do not stand up or move around.
- Keep your tablet within reaching distance to ensure proper radio signal transmission from the Coala Heart Monitor to the Coala Go! App.

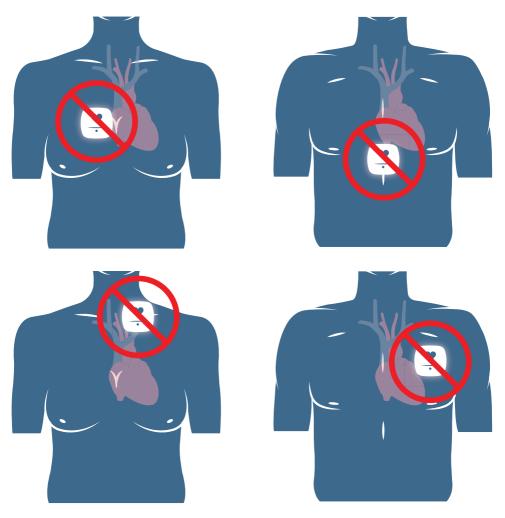
If Coala indicates an unreadable value make sure to perform a second measurement to verify the result.

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 firmly to the left of your sternum (chest bone) as shown below.

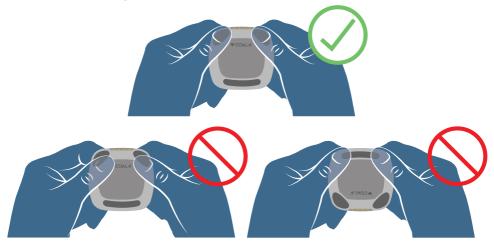


It is important that the Coala is held upright (COALA text facing down). Press the heart button with your index finger to start recording and hold Coala steady during the entire recording. Try to relax and breathe normally. Avoid speaking during measurement recordings to ensure best quality recording.

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



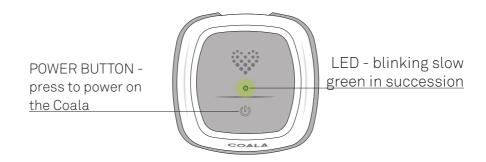
For correct finger placement for thumb ECG recording, see diagram below. Place your thumbs on top of electrodes as shown in diagram below. For best possible recording, hold Coala in a relaxed position resting your forearms on a table or on your legs when sitting down. Avoid pressing the electrodes too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



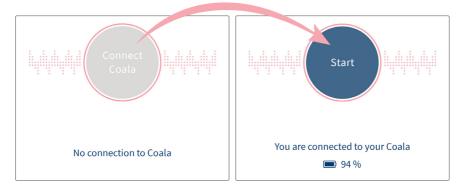
08 Record your first measurement

Follow these steps to record your first measurement with the Coala Heart Monitor and Coala Go! App:

- 1. Activate your tablet by pressing the lower button on the righthand side. If the screen does not light up, assure you have pushed the lower of the two buttons. If the tablet still does not start, please charge the tablet and retry.
- 2. 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.
- 3. Power on the Coala by briefly pressing the Power button ⁽⁾. Your Coala LED light should be blinking slow green.



4. The large circle in the main screen of the Coala Go! App should turn blue to indicate that the Coala has connected (if the circle remains gray please contact Coala Life for support). Click 'Start' to start a new recording.



- 5. Follow the instructions in the app. Sit down (do not stand or lie down) and hold the Coala firmly against your upper chest, slightly to the left of your sternum as shown in the diagram. Click 'I understand' in the app and then the 'Heart button' on the Coala to start recording.
- New recording

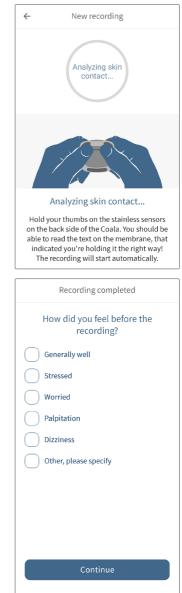
 Image: Control of the control

Recording data

Keep holding the Coala still and stable towards your chest during the recording. For best sound recording, ensure it is quiet around you.

6. 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.

- 7. Read further instructions and click 'I understand' in the app and then 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.
- 8. Once the recording is complete, enter a "feeling" to describe how you felt before the recording. To enter free text in attachment to the recording select 'Other, please specify' and enter text. Press 'Continue'.



- 9. The recording is now sent to the Coala server for analysis. Ensure you have sufficient cellular reception, indicated by the bars ...l in the top right corner of the display, so the recording can be sent. If you do not have cellular reception you will get a message telling you to move to a different location and the recording will be sent once you have sufficient reception. You can click 'Close and notify me' or 'OK' and the recording will continue to be uploaded in the background.
- 10. Your first recording is now complete.





09 Settings

Return to the home screen in the Coala Go! App and select 'Settings' to modify any settings for the Coala Heart Monitor and app,

Wifi settings

Select 'Wifi settings' to view and manage your wifi connection.

Screen brightness

Adjust the screen brightness on your tablet .

Display scaling

Adjust the font size of the Coala App interface.

Language

Select your language. The Coala Go! app supports English and Spanish.

Sex

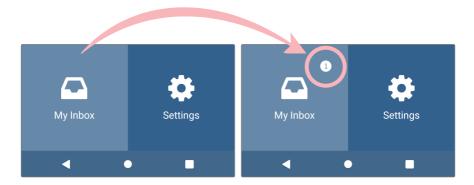
Select your gender, male or female.

Pacemaker/implanted device

Select the box if you have a pacemaker or implanted device. This will not have any effect on the functionality of the app. But 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.

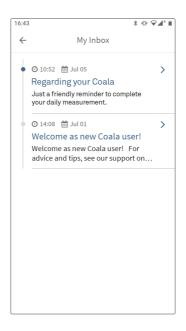
10 My inbox

Return to the home screen in the Coala Go! App and select 'My Inbox' to access messages sent to your app from Coala Life or any approved Healthcare provider in the Coala Care Portal. New messages will be indicated by a number in connection to the 'My Inbox' button.



When entering your inbox you will be prompted to enter a pin code. The pin code is set to your birth month and year in the format MMYY.





11 Coala LED indications

Blinking blue	Coala is charging.
Solid blue	Coala has finished charging and is now fully charged.
Slow blinking green	Powered on and connected to your tablet.
Rapid blinking green	Bluetooth pairing mode. If your Coala goes to pairing mode please contact Coala customer support.
Solid green	Active recording of ECG and audio.
Blinking yellow	Low battery indication.
Solid yellow	Battery empty or internal error. Do not use Coala and consult Troubleshooting section of this manual.

12 Troubleshooting

The Coala Go! App provides you with step-by-step instructions and best practices when recording measurements with the Coala Heart Monitor.

Issue	Solution
Unable to start a new measurement recording.	Make sure that you have sufficient cellular reception, indicated by the cellular reception bars
	If problem persists, contact Coala customer support.
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	Check that the USB cable is correctly connected between the Charge Station and a power source.
placed in the Coala Charge Station.	Check that the Coala is correctly placed in the Charge Station.
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.
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.

Issue	Solution
The Coala LED indicates a steady yellow light or shows signs of internal error.	Please contact Coala customer support and send the Coala Go package back for replacement.
Unable to power on the tablet.	Make sure you activate your tablet by pressing the lower button on the right-hand side.
	If the tablet still does not start, please make sure that the battery has not depleted. Connect the tablet to a power outlet using the included USB charging device. To start it up again long press power button (lower button on the right-hand side).
	If the problem remains contact Coala customer support.

13 Storage

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.
- 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.

14 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.

15 Electrical safety

The Coala Heart Monitor is in compliance with:

- 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 μ A.

16 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

17 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
- FCC 47 CFR Part 15 Subpart B Class B

18 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 \pm 2,0 kV

• IEC 61000-4-5: Surge immunity test

Test levels on AC Power input port: AC Power input port, $\pm0,5$ kV and $\pm1,0$ 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 $\frac{1}{2}$ cycle positive and negative half period.
- 60 % for 10 cycles.
- 30 % for 25 cycles.
- 100 % for 250 s.

19 Warnings related to electromagnetic compatibility

Coala is designed to withstand expected electromagnetic interference. If 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 verified that it is 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.

20 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
C E 2797	European Conformity Mark
	Radio transmitter
\bigcirc	Stand-by on/off
IP22	IP (Ingress Protection) Class 22.
R	WEEE – Properly Dispose of Electronic Waste
5V <u> </u>	Input/output voltage and current
SN	Serial number. The serial number for your Coala is found under Settings* in Coala Go! App.
LOT	Batch number

M	Manufacturer/manufacturing date. The manufacturing date of your Coala is found under Settings* in Coala Go! App.
	Manufacturer
R Only	Caution: Federal (USA) law restricts this device to be sold by or sold on the order of a physician
Ť	Keep dry
Ţ	Fragile, handle with care
	Do not use if package is damaged
	Consult instructions for use
REF	Part number
MR	MR unsafe
FCC ID: 2AL07CHM	FCC ID

*Only available to Admin users of the Coala Go! App.

21 Specifications

Performance Characteristics	
ECG	

ECG Channels	Single channel with noise suppression electrode
Frequency Response	DC to 150 Hz (raw data in Coala Care Portal)
Amplitude Accuracy	Better than 2% for a 500 μV signal
Input Impedance	> 100 MQ
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 Properti	es
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.

22 Contact information to the manufacturer

Coala Life AB Kålsängsgränd 10B 753 19 Uppsala Sweden

www.coalalife.com

info@coalalife.com

