

Coala Care Manual US Rx

Additions during COVID-19



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1. Introduction

Additional functionalities are added to the Coala Heart Monitor System under the FDA policy 'Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency'. Coala Life are adding functionality, indication and claims under the FDA policy and this temporary manual is an addition to the Coala Care Manual and describes the added functionalities.

2. Temporary Indications for Use

See our Coala Care Manual for Indication for use. Under the 'Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency' the following additional functionalities, indications and claims (not cleared by the FDA) apply:

Additional indications:

The Coala Heart Monitor can be used as a digital stethoscope for remote auscultation of respiratory conditions and heart sounds.

The Coala Heart Monitor can indicate and display heart rhythm deviations. The indicated deviations are atrial fibrillation, skipped heart beats, fast heart rhythm, shorter sequences of faster or slower beats, recurring extra heart beats (Bigemini), recurring extra heart beats (Trigemini), recurring extra heart beats (>5 PAC), recurring extra heart beats (>5 PVC), irregular heart rhythm.

Claims:

The Coala Heart Monitor can be used as an electronic stethoscope.

3. ECG category descriptions

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, are categorized based on any heart rhythm deviations detected.

If no heart rhythm deviations are detected in both the thumb and chest ECG, the combined result will be categorized as Category 1 "Coala indicates a normal result" which will be presented to the patient in Coala App.

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

	Description
1.	Coala indicates a normal result
2.	Coala indicates signs of atrial fibrillation
3.	Coala indicates skipped heart beats
4.	Coala indicates a fast heart rhythm
6.	Coala indicates shorter sequences of faster or slower beats
7.	Coala indicates recurring extra heart beats (Bigemini)
8.	Coala indicates recurring extra heart beats (Trigemini)
10.	Coala indicates recurring extra heart beats (>5 PAC)
11.	Coala indicates recurring extra heart beats (>5 PVC)
12.	Coala indicates an irregular heart rhythm

Individual categorization vs. combined categorization

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

The combined ECG categorization as presented to the patient in Coala App may differ from the individual chest or thumb ECG categorization. The combined result categorization is the most accurate and takes into account both the recorded chest and thumb ECGs.

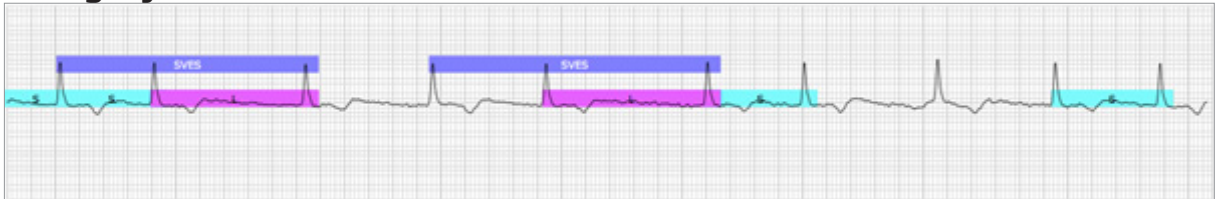
For example; only indicated atrial fibrillation in the chest ECG is not sufficient to indicate an overall result of atrial fibrillation.

Category 1



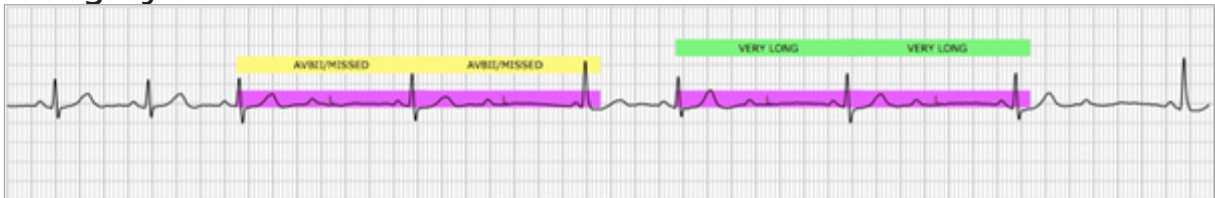
No Rhythm Deviation (Only insignificant irregular beats present).

Category 2



Irregular Sequence (Unexplained irregularities, which may be AF or paroxysmal AF).

Category 3



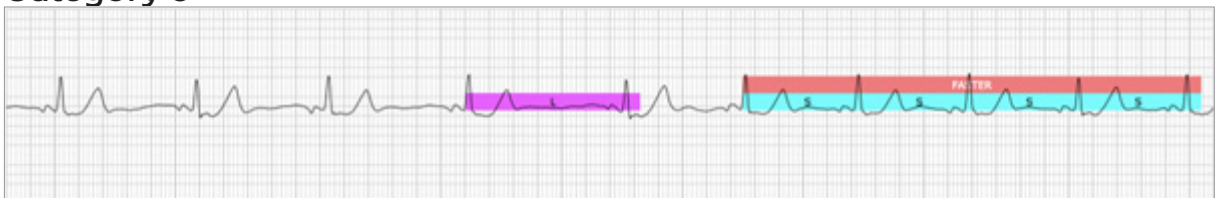
Pause/AV Block II (or beats longer than 2.2s).

Category 4



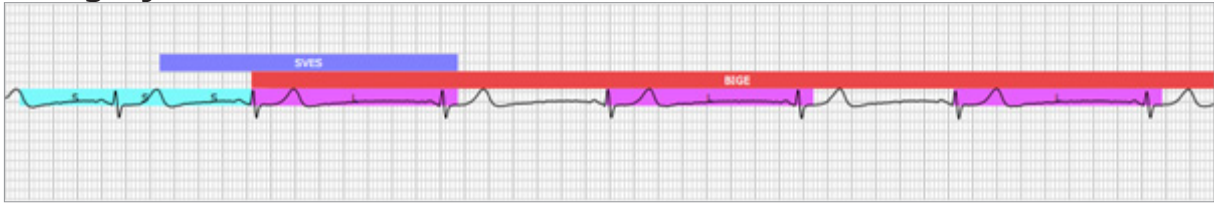
Fast Regular (RR interval shorter than 600ms in entire signal).

Category 6



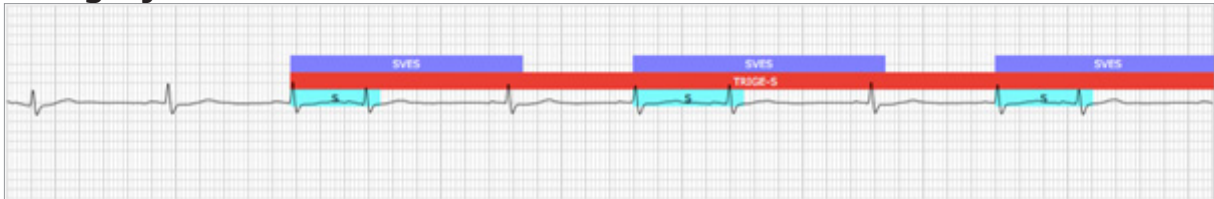
Fast/Slow Sequences (Shorter sequences of faster or slower beats).

Category 7



Bigeminy (patterns with P waves detected).

Category 8



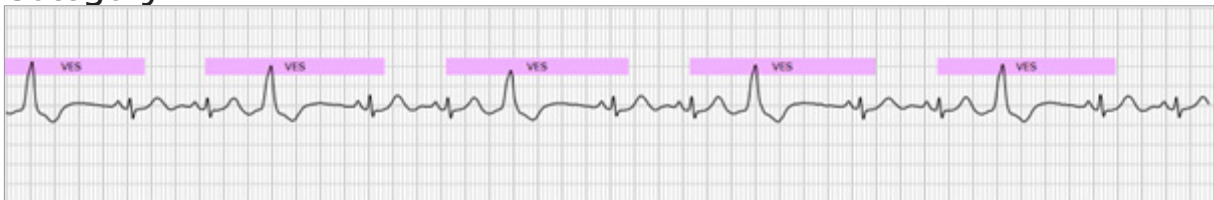
Trigemini (patterns with P waves detected).

Category 10



More than 5 PAC detected over 30 seconds (only 10 seconds in the ECG above).

Category 11



More than 5 PVC detected over 30 seconds (only 10 seconds in the ECG above).

Category 12



Irregular sequence with detected P waves.

NOTE: The color bars in the images above are not visible in the PDF presented in the app

4. Coala stethoscope measurements

The Coala Heart Monitor can be used as a digital stethoscope for remote auscultation of respiratory conditions and heart sounds. Through Coala Care a Healthcare Provider may prescribe, auscultate and visually interpret stethoscope measurements of different configurations based on specific patient needs.

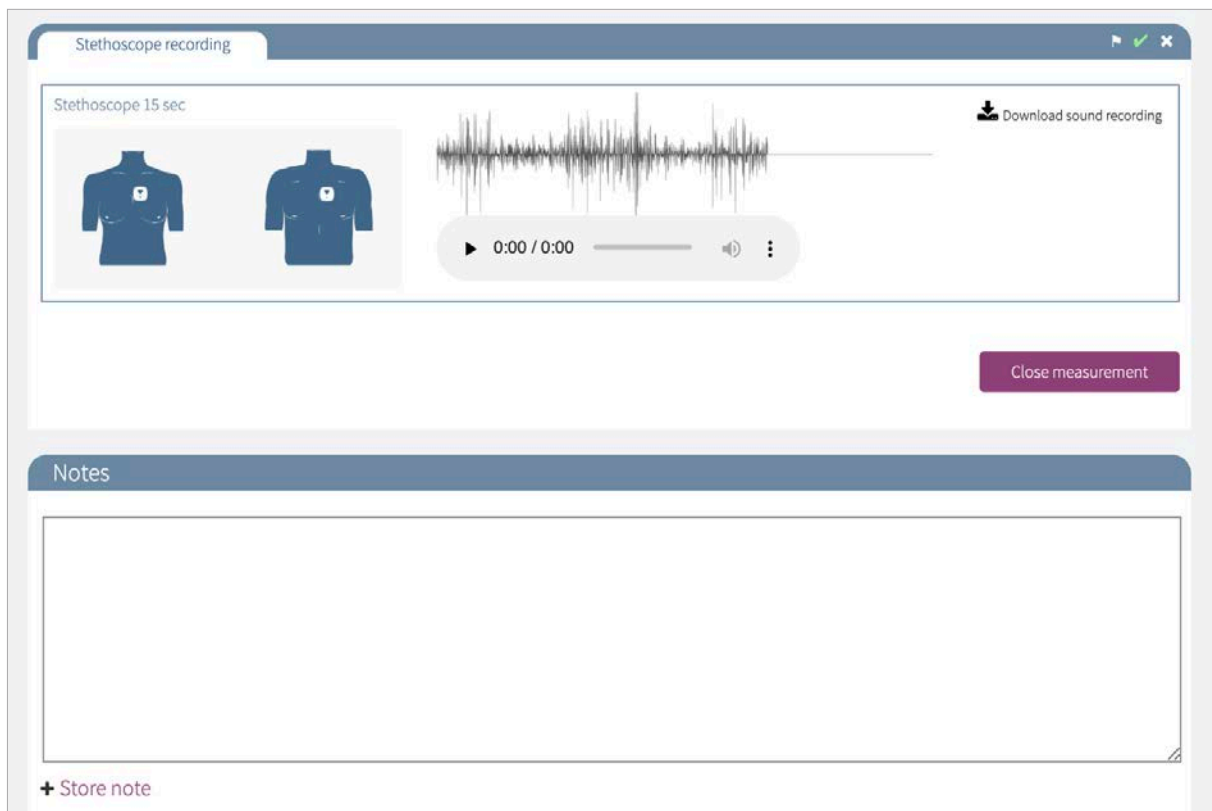
To access any of the stethoscope measurement configurations listed in this instruction for use, contact your Coala Life Inc sales representative.

Stethoscope measurement configurations

Coala provides three measurement configurations intended for remote patient auscultation using the Coala Heart Monitor and App. Stethoscope measurements are prescribed by the Healthcare Provider in Coala Care and the patient follows specific instructions in the Coala App for optimal recording quality and proper placement of the Coala.

15 sec Stethoscope

The Healthcare Provider prescribes the 15 sec stethoscope measurement in Coala Care and the patient uses the Coala App for the recording. The Coala App will provide the patient with instructions on how to operate the Coala during the measurement for optimal recording quality. Placement for this recording is optional and skin contact is not required to proceed with the recording.



160 sec Stethoscope

The Healthcare Provider prescribes the 160 sec stethoscope measurement in Coala Care and the patient uses the Coala App for the recording. The Coala App will provide the patient with instructions on how to operate the Coala during the measurement for optimal recording quality. Placement for this recording is optional and skin contact is not required to proceed with the recording. The Coala may also be adjusted during the measurement to record in several positions.

The screenshot displays the 'Stethoscope recording' interface within the Coala App. At the top, a blue header bar contains the text 'Stethoscope recording' on the left and navigation icons (back, forward, play, checkmark, close) on the right, with '5 of 6' in the center. Below the header, the main content area is titled 'Stethoscope 160 sec'. On the left, there are two blue icons of a human torso showing different chest placements for the stethoscope. To the right of these icons is a waveform visualization of the recorded audio. Below the waveform is a playback control bar showing '0:00 / 0:00', a progress slider, a volume icon, and a menu icon. In the top right corner of the main content area, there is a 'Download sound recording' button with a download icon. Below the main content area, there is a purple button labeled 'Close measurement'. The bottom section of the interface is titled 'Notes' and contains a large, empty white text box for entering notes. At the bottom left of this section, there is a '+ Store note' button.

Posterior lung auscultation

The Healthcare Provider prescribes the 40 sec stethoscope measurement, which measures four 10 sec parts recordings for remote posterior lung auscultation in Coala Care and the patient uses the Coala App for the recording.

The Coala App will provide the patient with instructions on how to operate the Coala during the measurement for optimal recording quality.

The measurement is recorded in four posterior thorax positions (lower right posterior, lower left posterior, upper left posterior, upper right posterior), so the patient will need assist with holding the Coala in each position. For proper placement, the patient will also be instructed with images for each of the 10 sec parts. While the Coala is recording the patient is instructed to take a deep breath and slowly breath out.

The screenshot displays the 'Stethoscope recording' interface within the Coala App. The interface is organized into four horizontal panels, each representing a different recording position. At the top, a blue header bar contains the text 'Stethoscope recording' on the left and '1 of 6' with navigation icons on the right. Each panel includes the following elements:

- Position Label:** The name of the recording position (e.g., 'Right lower posterior').
- Diagram:** Two blue icons of a human torso showing the placement of the Coala device on the chest.
- Waveform:** A black waveform representing the recorded audio signal.
- Download Button:** A button with a download icon and the text 'Download sound recording'.
- Player Controls:** A playback bar showing '0:00 / 0:00', a progress slider, a speaker icon, and a menu icon.

Prescribe stethoscope measurements

To prescribe measurement configurations to target specific patient needs use the tool for prescribing measurement configurations. Measurement configurations may be prescribed when setting up the patient with a Coala App account for the first time or later by editing the prescribed configurations.

If no specific measurement configuration is prescribed to the patient, all measurement configurations available for your healthcare provider will be prescribed.

Create new patient account

amanda.miller@coalalife.com

Amanda Miller

12

03/17/1989

Your password has to be at least 8 characters long. It must contain at least one lower case letter, one upper case letter, and one number.

Measurement configurations

Original x Stethoscope 15 sec x

Active patient

Event Monitoring Center

Save

♂ Amanda Miller ID 12 DOB 03/17/1989 Create ECG report

Last measurements Patient Info Trends Reports

Health data

- Date of birth: 03/17/1989 (31 years)
- Smokes:
- Pacemaker / implanted unit: No

Medication

- None

Account

- Active Coala Rx patient

Configurations

- Original
- Stethoscope 15 sec

Notes

+ Store note

1. Prescribe measurement configurations

Click Under Measurement configurations to see all measurement configurations available for prescription. Select one or more measurement configurations and click 'Save'. If you enter nothing "All" will be prescribed by default.

NOTE: 'Original' under measurement configurations is for the ECG monitoring.

2. Info section

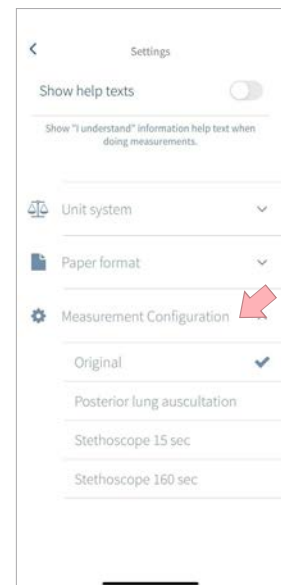
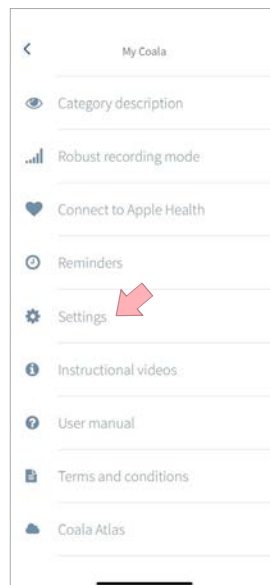
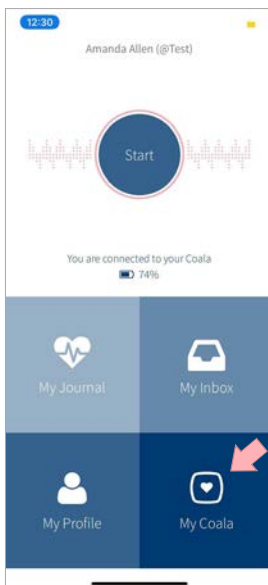
Measurement configurations prescribed to the patient may be reviewed in the Info-tab in the Patient Profile.

Prescribed measurements in the patients Coala App

In the Coala App the patient will have to log out and back into the Coala App to update their prescribed measurement configurations.

If more than one measurement configuration has been prescribed to the patient the patient will have the option to select which measurement configuration to record manually in the Coala App. This can be done by going to 'My Coala' > 'Settings' > 'Measurement configurations'.

NOTE: If a patient has only been prescribed one measurement configuration, the app will run the same configuration every time.



Stethoscope measurements in Coala Care

In the Patient Profile and in Last Measurements view of the Coala Care stethoscope measurements are listed with a stethoscope icon.

The screenshot shows the patient profile for Amanda Miller (ID 12, DOB 03/17/1989). The 'Last measurements' tab is active, displaying a table of measurements. The table includes columns for Time, HR, App result, Chest, Thumb, Feeling, BP, Weight, and PDF. The measurements are as follows:

Time	HR	App result	Chest	Thumb	Feeling	BP	Weight	PDF
05/13/20 2:46PM	109	Ok	Ok	Category 4	Generally well	-	-	<input type="checkbox"/>
05/13/20 2:44PM	92	Ok	Ok	Ok	Generally well	-	-	<input type="checkbox"/>
05/13/20 2:42PM	87	Ok	Ok	Ok	Generally well	-	-	<input type="checkbox"/>
05/13/20 2:14PM	-	Stethoscope	-	-	Generally well	-	-	<input type="checkbox"/>
05/13/20 1:53PM	-	Stethoscope	-	-	Generally well	-	-	<input type="checkbox"/>

Navigation buttons: First, 1, Last. Below the table, it says 'Displays 5 measurements at 1 pages'.

The screenshot shows the filter and waveform view for stethoscope measurements. The 'Category' dropdown is set to 'Stethoscope'. The 'Feeling' dropdown is empty. The table below shows the filtered measurements:

Time	HR	App result	Chest	Thumb	Feeling	BP	Weight	PDF
2020-05-08 11:44	-	Stethoscope	-	-	Generally well	-	-	<input type="checkbox"/>
2020-05-08 11:34	-	Stethoscope	-	-	Generally well	-	-	<input type="checkbox"/>
2020-05-07 18:07	-	Stethoscope	-	-	Generally well	-	-	<input type="checkbox"/>

Below the table, there are three waveform thumbnails. The first waveform is highlighted with a circled '1'. The second waveform is highlighted with a circled '2'.

1. Thumbnails

If thumbnails are enabled the waveform of the stethoscope measurement will be displayed as the thumbnail of each recorded part of the measurement.

2. Filter by Stethoscope

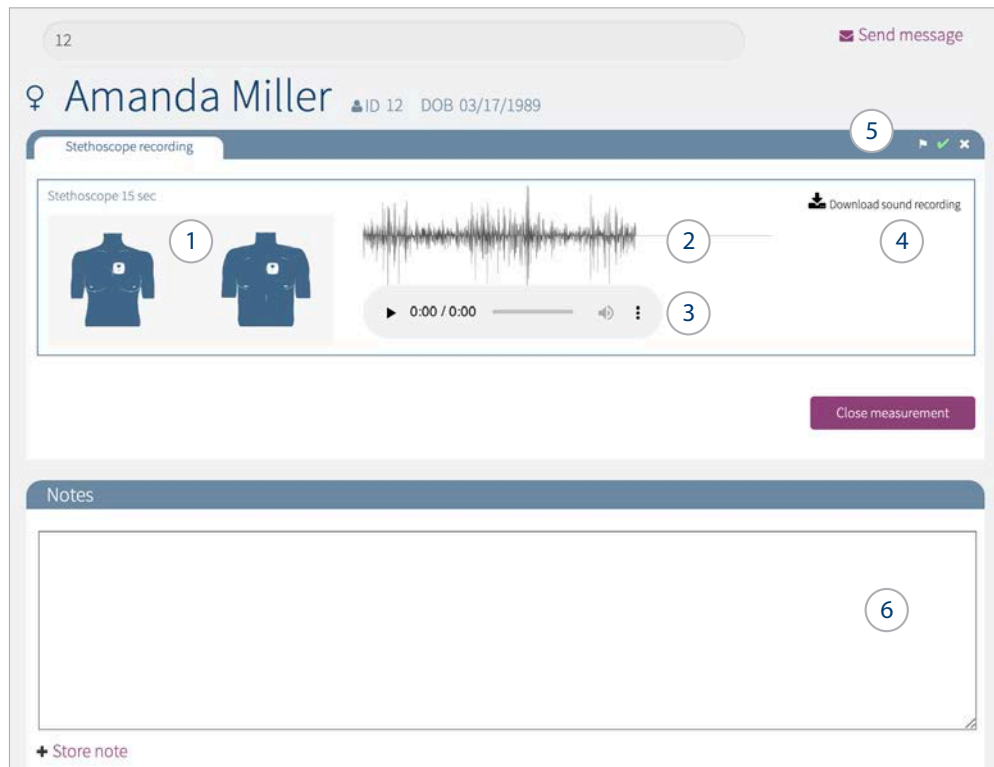
Click on the funnel. In 'Category' you will find 'Stethoscope' to filter the list for only stethoscope measurements.

Measurement screen for stethoscope

To review the stethoscope recording, click on the measurement to review the details of the measurement. The images of the Coala placement and text indicating the position of each recording based on the instruction provided to the patient in the Coala App.

In the Measurement Screen the Healthcare professional may listen to each recording while visually inspecting the waveform.

NOTE: For stethoscope measurements there is no automated analysis. Interpretation and quality assessment has to be done manually by a trained Healthcare professional.



1. Placement image

Image indicating the placement of the recorded measurement. This is also the image shown to the patient in the Coala App to instruct the patient on proper placement of the Coala.

2. Waveform

The recorded stethoscope signal plotted as a waveform for visual interpretation of the recorded signal.

3. Player

Listen to the recorded signal for auscultation through high quality headphones. For auscultation in Coala Care it is recommended to use Bluetooth headphones with active and passive noise canceling, and a flat frequency response between 20 Hz and 20kHz.

4. Download .wav

Download the recorded signal as a .wav file that may be filtered and reviewed, see chapter 5. Audio filters.

5. Mark the measurement

Mark the measurement with a flag by clicking to activate the flag-icon. When flagged, the measurement is clearly distinguished in any list and can be filtered to display only flagged measurements.

The green check will be activated automatically when the measurement has been viewed. Click on the green check to deactivate. This will make the measurement appear as if it has never been viewed.

6. Attach a note to the measurement

Attach a note to the measurement that you may return to at a later stage. The notes will be date and time stamped when the notes were saved. Measurements with notes attached can be revisited and found in the info section of the Patient Profile.

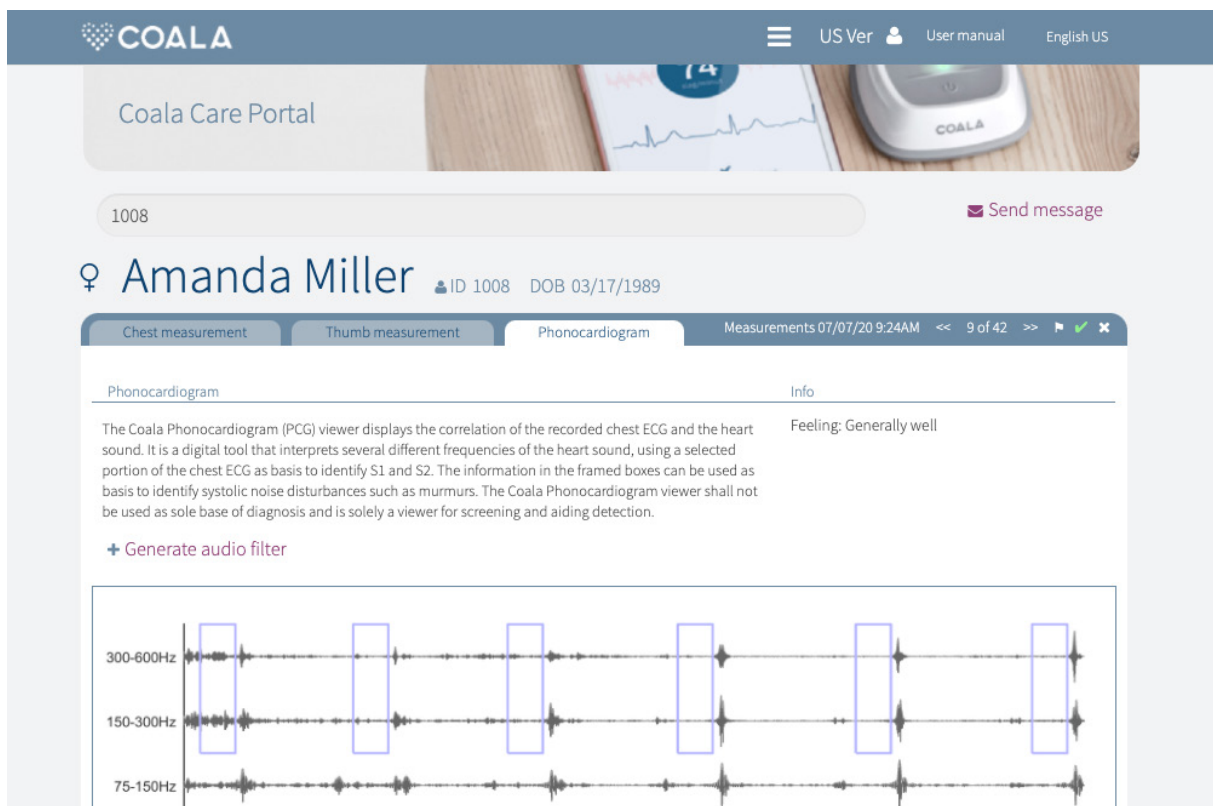
5. Audio filters

The Coala Heart Monitor can be used as a digital stethoscope for remote auscultation of respiratory conditions and heart sounds. Through Coala Care a Healthcare Provider may view and interpret audio recordings with filtered sound.

To access the audio filters listed in this instruction for use, contact your Coala Life Inc sales representative.

Generate audio filters

Go to the Phonocardiogram- or Stethoscope tab depending on measurement configuration, to generate filters for an audio recording. The picture below shows the 'Generate audio filters' link for a chest measurement from the measurement configuration 'Original'. It is similar in other configurations.



The screenshot displays the Coala Care Portal interface. At the top, the Coala logo is visible on the left, and navigation links for 'US Ver', 'User manual', and 'English US' are on the right. Below the header, the 'Coala Care Portal' title is shown. A search bar contains the ID '1008', and a 'Send message' button is to its right. The patient's name 'Amanda Miller' is displayed, along with her ID '1008' and DOB '03/17/1989'. The interface shows three tabs: 'Chest measurement', 'Thumb measurement', and 'Phonocardiogram'. The 'Phonocardiogram' tab is active, showing a waveform with six blue rectangular filters overlaid. The filters are labeled with frequency ranges: '300-600Hz', '150-300Hz', and '75-150Hz'. To the right of the waveform, the text 'Feeling: Generally well' is visible. Below the waveform, a '+ Generate audio filter' button is present.

Download and listen to filtered audio

The filtered audio recordings can be listened to through audio players or downloaded as .wav files. The audio players may look different, depending on computer and preferred audio player. The audio files are best listened to through high quality headphones.

Chest measurement | Thumb measurement | **Phonocardiogram** | Measurements 07/07/20 9:24AM

Phonocardiogram Info

The Coala Phonocardiogram (PCG) viewer displays the correlation of the recorded chest ECG and the heart sound. It is a digital tool that interprets several different frequencies of the heart sound, using a selected portion of the chest ECG as basis to identify S1 and S2. The information in the framed boxes can be used as basis to identify systolic noise disturbances such as murmurs. The Coala Phonocardiogram viewer shall not be used as sole base of diagnosis and is solely a viewer for screening and aiding detection.

Feeling: Generally well

Original Download heart sound

1 0:00 / 0:00

60-1500 Hz Download heart sound

3 0:00 / 0:00

100-1500 Hz Download heart sound

5 0:00 / 0:00

30-1500 Hz Download heart sound

2 0:00 / 0:00

80-1500 Hz Download heart sound

4 0:00 / 0:00

20-1500 Hz full bandwidth Download heart sound

6 0:00 / 0:00

Filter applications

The generated filters have different applications, marked with a heart- or lungs symbol as shown in the picture above. The provided audio filters are:

- 1. Original - unfiltered sound**
- 2. 30-1500 Hz optimized for heart sounds**
 Strong, low frequencies.
 + Identification of S3.
 - Not all external devices and headphones can reproduce the low frequencies.
- 3. 60-1500 Hz optimized for heart sounds**
 Medium low frequencies, equal to no 2 but not as intense.
- 4. 80-1500 Hz optimized for heart and lung sounds**
 Medium frequencies.
 + Identification of S2 splits, heart valve clicks and lung sounds. Filter out lower heart sound frequencies.
- 5. 100-1500 Hz optimized for lung sounds**
 Medium high frequencies.
 + Filter out lower heart sound frequencies and vibrations.
 - Slightly increase of ambient sounds.
- 6. 20-1500 Hz full bandwidth**
 Wideband mode.
 + Very sensitive, intended for research use.
 - Listen at lower volumes.

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For more support please visit www.coalalife.com

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