

# Coala Care Manual



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# 1. Product Description

Coala Care Portal is a part of the Coala Heart Monitor system from Coala Life AB. Coala Care Portal is a standalone web-based software for Portal users to review ECG and heart sound measurements. The measurements are recorded with the Coala device and stored in Coala Care Portal using a compatible smartphone running the Coala App.

*NOTE! The Coala Care Portal is not a regulated Electronic Health Record.*

# 2. Clinical benefits

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

# 3. Intended use

The Coala Heart Monitor is intended for self-testing by patients to record, store, transfer and display surface ECG and sound to aid the detection of heart and respiratory conditions. The Coala Heart Monitor is intended for use by healthcare professionals, individuals with known or suspected heart conditions and health conscious individuals.

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

# 4. Contraindications

There are no known contraindications for Coala Heart Monitor

# 5. Cautions

- 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 Portal users in the Coala Care Portal. Signal amplitudes for the chest ECG measurement are typically lower (0.1 to 0.4 mV) than on conventional chest leads due to close electrode spacing on the Coala. Chest signal morphology is also affected by positioning of the Coala on the chest and may not resemble conventional chest leads.
- Maximum T-wave amplitude is 1.5 times the QRS amplitude for correct display of heart rate.
- Treatment or diagnosis shall not be based on weight or blood pressure parameters alone.
- For Coala device specific cautions see Instructions for use Coala Heart Monitor.

## **6. Compatibility**

The Coala Care Portal software is compatible with Internet Explorer 11 or higher.

*NOTE! The Coala Care Portal is not compatible with tablets as this may offset scaling when reviewing the ECG tracings.*

## **7. Cybersecurity Measures**

To avoid intrusion and leakage of personal data to unauthorized persons, lock the computer or logout from Coala Care Portal between sessions.

Contact Coala Life of any signs of malicious system behavior, suspicions of malware or system cybersecurity violations.

# 8. Getting Started

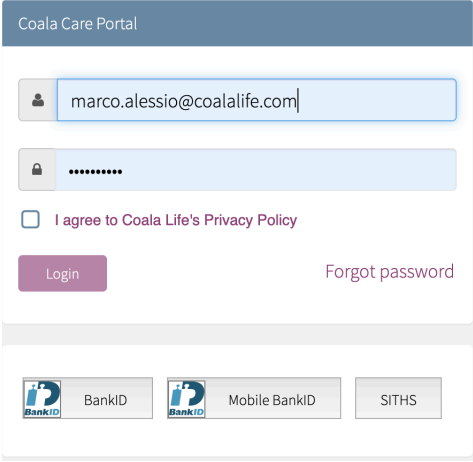
## 8.1 Register an account

For Healthcare professionals interested in using the Coala Heart Monitor and system, a registered user account is required. Contact Coala Life to register a user account.

*NOTE! The account will require authentication through valid identification and email address.*

## 8.2 Login

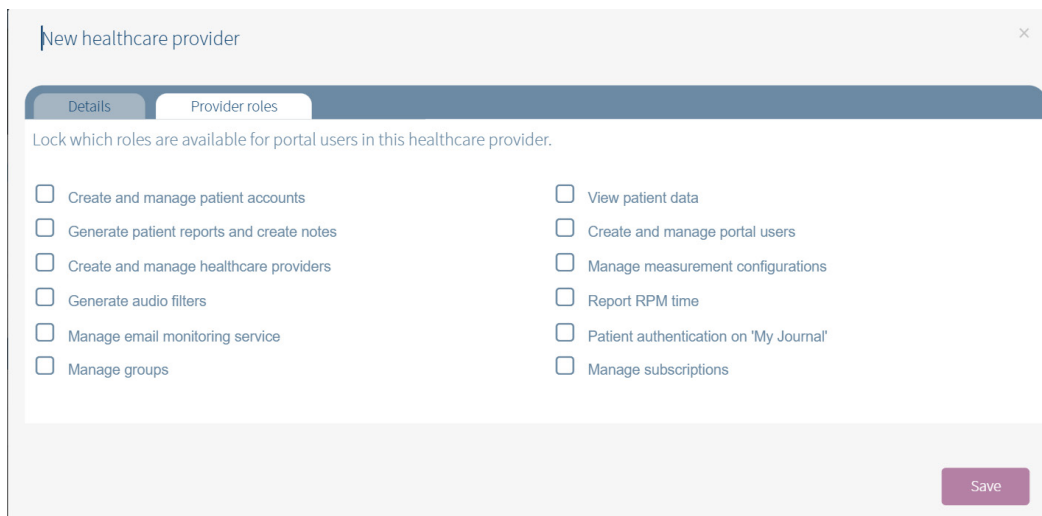
On your device: Visit [www.coalacare.com](http://www.coalacare.com) and login using personal login details provided to you by Coala Life to start using the Coala Care Portal. Your login details will include email and a secure password.



## 8.3 The Healthcare provider

A clinic, organization, or healthcare provider will be set up as a *Healthcare provider* in the Coala Care Portal. The Healthcare provider will contain all of the recorded measurement data and general health information registered by patients and portal users using the Coala App and Coala Care Portal connected to the Healthcare provider.

## 8.4 System roles



New healthcare provider ×

Details Provider roles

Lock which roles are available for portal users in this healthcare provider.

- Create and manage patient accounts
- Generate patient reports and create notes
- Create and manage healthcare providers
- Generate audio filters
- Manage email monitoring service
- Manage groups
- View patient data
- Create and manage portal users
- Manage measurement configurations
- Report RPM time
- Patient authentication on 'My Journal'
- Manage subscriptions

Save

Roles will be assigned when the Healthcare provider is created.

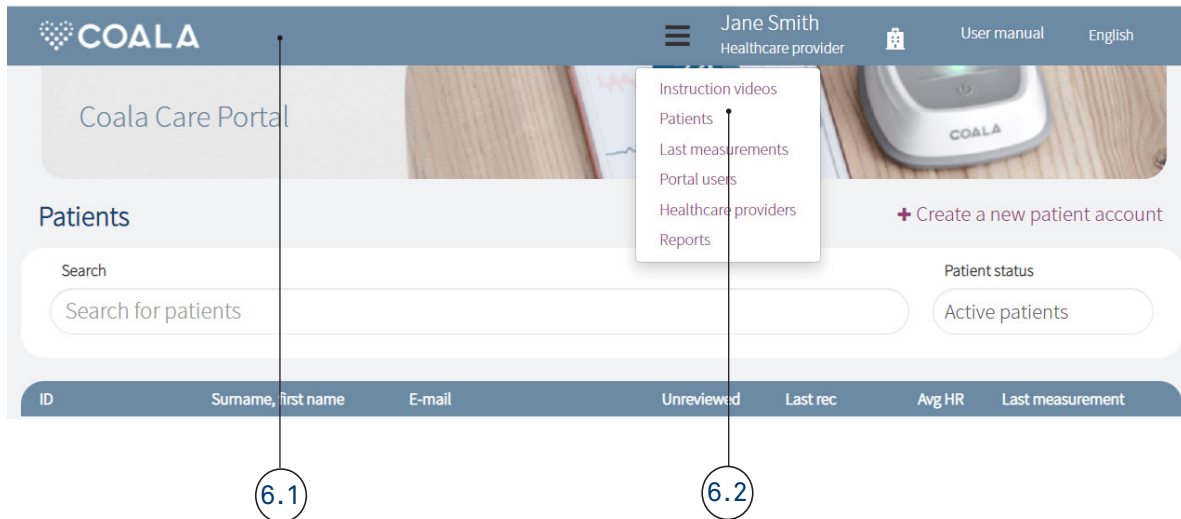
The roles are inherited through a healthcare provider to a portal user. It means that a portal user can only have permissions that its healthcare provider has.

In the portal: hover over the role name for explanation of the role.

## 9. Coala Care Portal menu

A portal user has access to the pages shown in the header menu. *Patients* and *Portal users* is where patients and portal users within the same healthcare provider are listed and where new accounts are created.

The portal username is visible in the header (*Jane Smith*) and the healthcare provider it is connected to (*Healthcare provider*).



### 9.1 Top-bar

The menu and top-bar section are available, at all times when logged into Coala Care Portal and provides the portal users with specific options according to the user admin rights. The top-bar also provides links to the Coala Life website for instruction for use and support. The Coala logo will bring you back to the home *Dashboard*.



#### 1. Log out or change healthcare provider

Click on the hospital icon to access the log out option or to change healthcare provider if connected to more than one. Remember to log out after each complete session.

A portal user can log in to other healthcare providers they are connected to under the hospital symbol. The portal user will only be able to view the patients and portal users that are connected to the chosen healthcare provider.

#### 2. User manual

Access the latest version of the Coala Care Manual on Coala Life website.

*NOTE! Select the correct user manual according to your region.*

### 3. Language settings

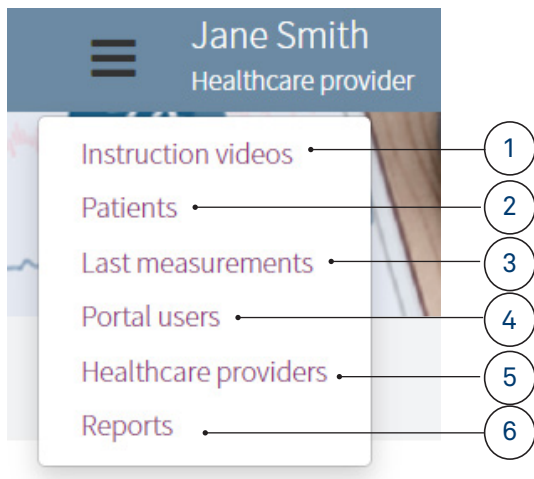
Language settings (by default set according to your region at sign up).

Available languages:

- English
- Swedish
- French
- Italian
- German
- Dutch

## 9.2 Menu

Select the menu icon to access menu options available to your current user type. For information on system roles in the Coala Care Portal, see section “5.4 System roles” on page 6. Most common accesses are as follow:



### 1. Instruction videos

Link to video tutorials for using the Coala Care Portal: [www.coalalife.com/coala-care-instructions](http://www.coalalife.com/coala-care-instructions).

### 2. Patients

The main overview for patient administration where portal users may select or search for patients to review their profile, set up new patient accounts and request access from patients already using the Coala services. For information on this view, see chapter “9. Patients” on page 15.

### 3. Last measurements

The measurement overview, listing all measurements recorded by patients connected to the healthcare provider. In this view the portal users may; filter to review measurements from all patients connected to the healthcare provider.

For information on this view, see section “10. Last Measurements” on page 21.

### 4. Portal users

The main overview for portal user administration, where portal users can create and edit portal users accounts for the Coala Care Portal.

For information on this view, see chapter “8. Portal Users” on page 12.



## **5. Healthcare providers**

Overview for healthcare provider administration where all healthcare providers are listed together with a search function. New healthcare providers can be created, see chapter “7. Healthcare Providers” on page 10.

## **6. Reports**

Overview for *Reports* that lists all generated reports for patients within the healthcare provider.

# 10. Healthcare Providers

## 10.1 Create new healthcare provider

Go to *Healthcare providers* in the header menu and select *+ Create healthcare provider*.

The screenshot shows a 'New healthcare provider' form with a progress indicator at the top. The progress indicator has four steps: 1. DETAILS (highlighted with a green circle), 2. MONITORING SETTINGS, 3. PROVIDER ROLES, and 4. a checkmark. Below the progress indicator, the form is divided into two main sections: 'Healthcare provider details' and 'Measurement configurations'. The 'Healthcare provider details' section contains several input fields: 'Name \*', 'Phone \*', 'Email', 'Address 1 \*', 'Address 2', 'City \*', 'Zip \*', 'State/Region \*', and 'Territory ID \*'. The 'Measurement configurations' section contains a checkbox labeled 'Only original configuration' which is checked. At the bottom of the form, there are 'Cancel' and 'Next' buttons.

### 1. Details

Add information regarding the healthcare provider under the tab *Details*. Check *Only original configuration* to limit the configuration to 30 seconds chest measurement and 30 seconds thumbs measurement. No other configuration will be available.

### 2. Monitoring settings

Add information regarding the monitoring settings for the healthcare provider.

Choose to enable automatic email notifications on each deviating measurement for this healthcare provider. Enter the email that shall be notified.

**New healthcare provider** ×

Create a healthcare provider account for a new clinic or hospital with the proper settings to be able to add portal users and patients within the healthcare provider.

1 2 3 4

DETAILS MONITORING SETTINGS PROVIDER ROLES

Email notification service

Do you want automatic email notifications on each deviating measurement?

Enable E-mail monitoring service?  Yes  No

Email notification receiver address  Remove

[+ Add email](#)

Cancel Previous Next

### 3. Provider roles

Choose the roles that the portal users within the healthcare provider will be able to use under the tab *Provider roles*. See section “5.4 System roles” for more information. Press **Save**.

**New healthcare provider** ×

Create a healthcare provider account for a new clinic or hospital with the proper settings to be able to add portal users and patients within the healthcare provider.

1 2 3 4

DETAILS MONITORING SETTINGS PROVIDER ROLES

Provider roles

Lock which roles are available for portal users in this healthcare provider.

<input type="checkbox"/> Create and manage patient accounts	<input type="checkbox"/> View patient data
<input type="checkbox"/> Generate patient reports and create notes	<input type="checkbox"/> Create and manage portal users
<input type="checkbox"/> Create and manage healthcare providers	<input type="checkbox"/> Manage measurement configurations
<input type="checkbox"/> Generate audio filters	<input type="checkbox"/> Report RPM time
<input type="checkbox"/> Manage email monitoring service	<input type="checkbox"/> Patient authentication on 'My Journal'
<input type="checkbox"/> Manage groups	<input type="checkbox"/> Manage subscriptions

Cancel Previous Save

## 10.2 Edit healthcare provider

Go to *Healthcare providers* in the header menu and choose which healthcare provider to edit by clicking on it. Edit the tabs *Details*, *Monitoring settings* and *Provider roles* according to the corresponding steps in “7.1 Create new healthcare provider”.

**Edit healthcare provider** ×

Create a healthcare provider account for a new clinic or hospital with the proper settings to be able to add portal users and patients within the healthcare provider.

Details Monitoring settings Provider roles

# 11. Portal Users

Select *Portal users* to view a list of all portal users with a Coala Care account that are connected to the same healthcare provider.

In this view the portal users can create new or edit portal user accounts, grant portal users access, or remove portal users from the healthcare provider, dependent on their system roles. Read more about roles in section “5.4 System roles” on page 6.

Coala Administration tool v2.4.0

Portal users + Create portal user. **8.1**

Search  
Search portal users

Represent	Name	ID	E-mail	Belongs to
	Clinician, Mikaela	190004045544	mikaela.clinician@coalalife.com	Healthcare provider

**8.2**

## 11.1 Create a new portal user account

### Step 1

Go to *Portal users* in the header menu and choose *+ Create portal user*.

### Step 2

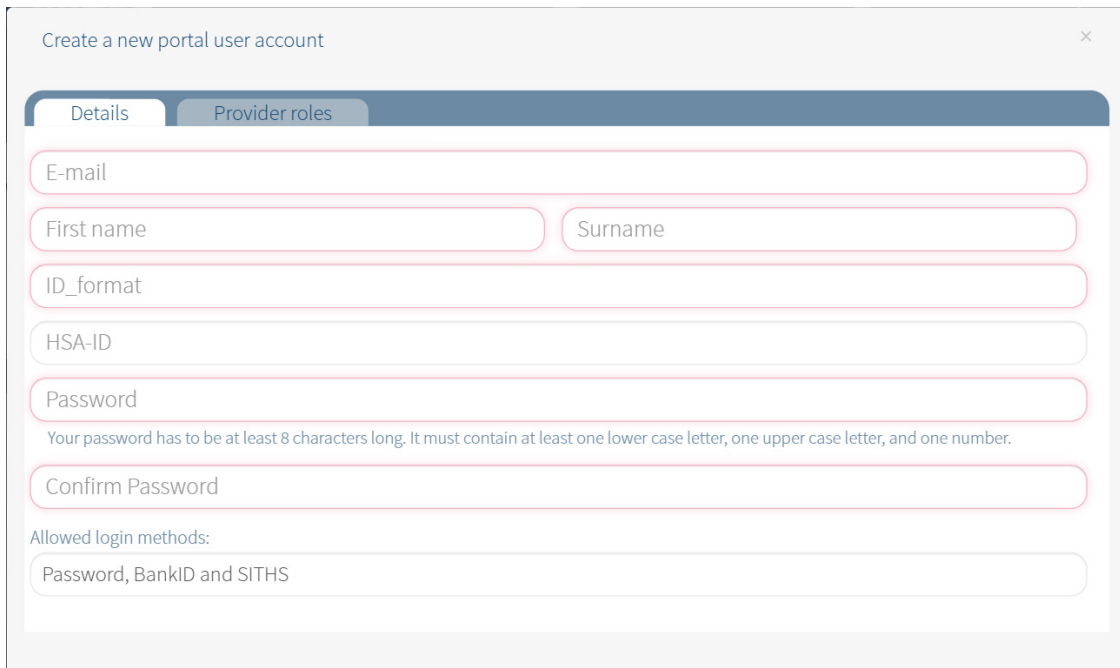
Add information regarding the portal user under the tab *Details*.

### Step 3

Choose the roles that the portal user will be able to use under the tab *Provider roles*. A portal user needs at least one role. Read more about roles in section “5.4 System roles” on page 6.

## Step 4

Press *Save*.



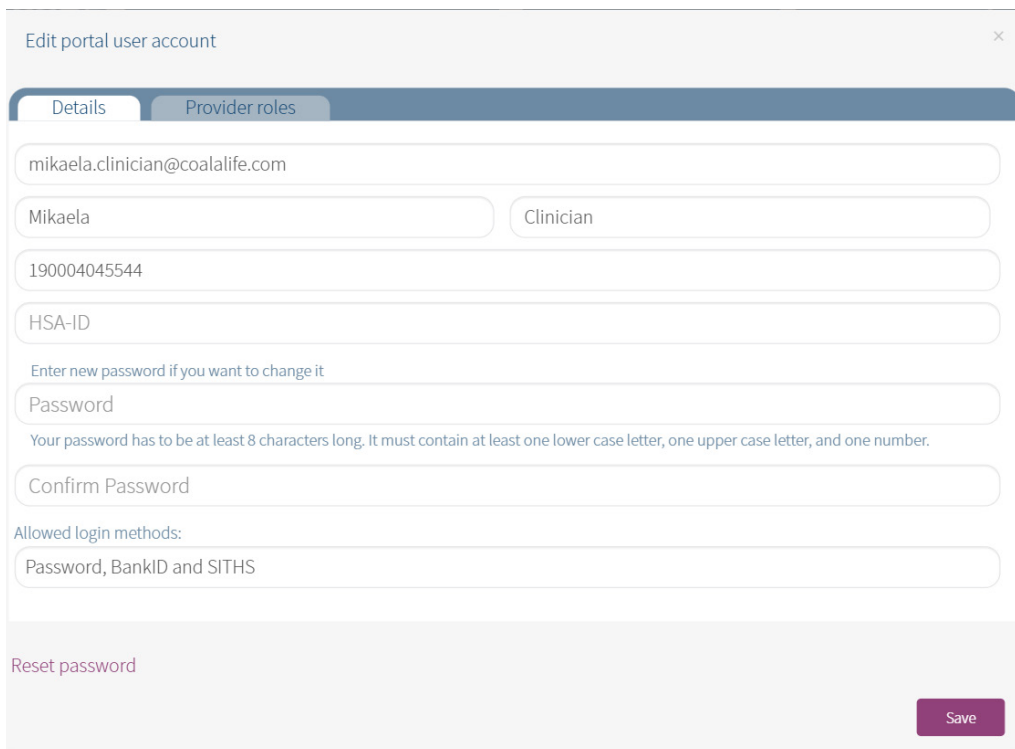
The screenshot shows a dialog window titled "Create a new portal user account" with a close button (X) in the top right corner. The window has two tabs: "Details" (selected) and "Provider roles". The form contains the following fields:

- E-mail
- First name
- Surname
- ID\_format
- HSA-ID
- Password
- Confirm Password

Below the password fields, there is a note: "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." Underneath, there is a section for "Allowed login methods:" with a text input field containing "Password, BankID and SITHS".

## 11.2 Edit Portal users account

Select any portal user account in the list to edit the account. In the dialog window edit any of the following details:



The screenshot shows a dialog window titled "Edit portal user account" with a close button (X) in the top right corner. The window has two tabs: "Details" (selected) and "Provider roles". The form contains the following fields:

- mikaela.clinician@coalalife.com
- Mikaela
- Clinician
- 190004045544
- HSA-ID
- Enter new password if you want to change it
- Password
- Confirm Password

Below the password fields, there is a note: "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." Underneath, there is a section for "Allowed login methods:" with a text input field containing "Password, BankID and SITHS".

At the bottom left, there is a link "Reset password". At the bottom right, there is a purple "Save" button.

**Email and name**

Update and press *Save*. The email address needs to be unique for the system.

**Update password**

Update and confirm the entered password.

*NOTE! The 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.*

**Reset password**

Select *Reset password* to issue a reset password-link to the portal user's registered email address.

**Provider roles**

Update the portal user roles or connect the portal user to other Healthcare providers. For more information on System roles in the Coala Care Portal, see section "5.4 System roles" on page 6.

## 12. Patients

### 12.1 Create a new patient account

The patient account is intended for patients to login to the Coala App and use together with the Coala Heart Monitor to record, store and transfer measurements to the Coala Care Portal. The patient account created will by default be connected to the same healthcare provider as the portal user and listed as a patient.

In the Patient view select *+ Create a new patient account* to create a new patient account for the Coala App.

**Create new patient account**

Create a patient account so the patient will be able to login to the Coala App and record measurements with the Coala Heart Monitor. Portal users within the healthcare provider will be able to see the patient's measurements in the Coala Care Portal.

1 DETAILS 2 ORDER COALA CONNECT

**Patient details**

First name \*  
First name

E-mail \*  
E-mail

Surname \*  
Surname

Phone number \*  
Phone number

Patient Id \*  
PNR (AAAAAMDDXXXX)

**Password**

Password \*  
Password

Confirm Password \*  
Confirm Password

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**

Cancel Next

#### 1. Details

In the details tab, enter the correct patient information, a set password and which *Measurement configurations* to be included for the patient then click *Next*.

Take caution to enter a valid email. The patient will use the email and password registered here to login to the Coala App.

*NOTE! The system will identify portal users already registered with the same email address and residual fields will automatically populate with the details registered for the portal users account. The password will be the same for both the patient account and the Coala Care account.*

A portal user account is already using the E-mail address. The subscription will be activated for this account so that it can be used in the app.

E-mail \*

autotech.unrestricted@coalalife.com

### Message

A healthcare provider account is already using this mail address. The subscription will be activated for this account so that it can be used in the app.

## 2. Order Coala Connect

Select *Yes, please assist with patient training + ship Coala Heart Monitor* to prescribe a Coala Heart Monitor for shipment and education of patient. Fill in the patient's contact details. Check the *I agree to the terms and conditions* box and click *Next*.

### Create new patient account

Create a patient account so the patient will be able to login to the Coala App and record measurements with the Coala Heart Monitor. Portal users within the healthcare provider will be able to see the patient's measurements in the Coala Care Portal.

1 DETAILS 2 ORDER COALA CONNECT ✓

#### Order Coala Connect

Do you want to prescribe a Coala Heart Monitor for Home Enrollment?

Yes, please assist with patient training + ship Coala Heart Monitor

Yes, please assist with patient training

No, I do not want Home enrollment for my patient

Delivery address \*

Delivery address

ZIP code \* City \*

ZIP code City

Mobile number \*

Mobile number

No prescription \*

No prescription

I agree to the terms and conditions

Cancel Previous Next



## 12.2 Edit patient account

Go to *Patients* in the header menu and choose which patient to edit by clicking on it and selecting *Edit patient*.

The screenshot shows the 'Edit patient account' form with the following sections and callouts:

- 1** Points to the 'Details' tab in the top navigation bar.
- 2** Points to the 'Password' section, which includes fields for 'Password' and 'Confirm Password' and a note: '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.'
- 3** Points to the 'Measurement configurations' section, which includes a dropdown menu with 'All' selected and a search input field.
- 4** Points to the 'Reset password | Inactivate patient' link at the bottom left of the form.

At the bottom of the form, there are 'Cancel' and 'Save' buttons.

### 1. Edit

Edit the tabs *Details*, *Home enrollment*, *Monitoring settings* and *Insurance data* according to the corresponding steps in “9.1 Create a new patient account”.

### 2. Change Password

Enter a new password for the patient if you want to change it and confirm by entering the password two times. Select *Save* before exit.

### 3. Measurement configurations

Edit the *Measurement configurations* for the patient.

### 4. Reset password, Inactive patient

Select *Reset password* to issue a reset password-link by email to the patient’s registered email address.

Select *Inactivate patient* to terminate the live connection between the patient and the healthcare provider. The healthcare provider will not have access to the patient’s measurement data recorded after inactivating the patient. Patients that are currently activated for measurements are listed as *Active patients* in the Patients list and patients that are Inactivated are listed as *Inactivate patients*. To activate a Coala App account again as a patient, see “9.3 Request access to list a patient already using the Coala”.

## 12.3 Request access to list a patient already using the Coala

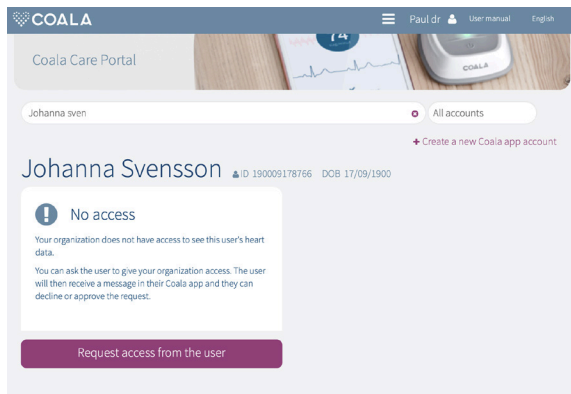
If the patient has already registered with the Coala service through any healthcare provider you have to send a request to access the patient's stored measurement data and general health information. The request must be approved by the patient in the Coala App in order for the patient to be connected to your Healthcare provider.

### Step 1

Enter the patient's: full name or full email in the search bar above the Patients list. Be as specific as possible. Note that only exact matches will be displayed! Multiple matches will not be shown due to integrity reasons.

### Step 2

If the patient is not connected to your Healthcare provider the system will provide you with an option to send a request to access the patient.



### Step 3

Select *Request access from the patient* to submit a request to the patient in the Coala App. The patient will receive a message in the Coala App with the option to 'approve' or 'deny' the healthcare provider.

### Step 4

The Portal users submitting the request will be notified by email when the patient has approved or denied the request.

## 12.4 Patients list

The Patients list will show an overview of all patients connected to the healthcare provider. Select a patient from the list or search for connected patients by entering; full name, patient ID or email in the search bar to display the patient's profile.

*NOTE! To access patient's recorded measurement data and general health information, the patient must be connected to the Healthcare provider, see previous sections of this chapter.*

COALA Jane Smith Healthcare provider User manual English

Coala Care Portal

Patients + Create a new patient account

Search Patient status

Search for patients Active patients

ID	Surname, first name	E-mail	Unreviewed	Last rec	Avg HR	Last measurement
190008281408	20-010, CR	cr20-010@coalalife.com	-			
19890828X002	20-017, CR	cr20-017@coalalife.se	-			
190008280004	20-017, CR		-			
190002020201	21-017, CR	cr21-017@coalalife.se	3/12 rec	128 days ago	74 bpm	Stethoscope
190002020203	21-017, CR	cr21-017@coalalife.se	11/13 rec	128 days ago	78 bpm	Ok
190003030302	21-018, CR	cr21-018@coalalife.com	-			
190008070605	21-020, CR	cr21-020@coalalife.com	0/1 rec	68 days ago	73 bpm	Ok
190007075678	Coala Life, Support	support@coalalife.com	1/2 rec	100 days ago	72 bpm	Stethoscope
200001278225	Engman, Mikaela	minnah00@hotmail.se	2/2 rec	307 days ago	76 bpm	Ok
190008280001	Frank, Olivia	olivia.frank@coalalife.com	0/1 rec	124 days ago	77 bpm	Ok

First 1 2 \* Last

Displaying 15 patients at 2 pages

### 1. Patient list

Patients are listed by: patient ID (if administered), surname, first name, email, fraction of unreviewed measurements, last recorded measurement, average HR (the over all average heart rate of the patients recorded measurements excluding Stethoscope measurements only) and result of the last recorded measurement.

- Click anywhere on the patient-line of interest to display the patient's profile.

### 2. Search patient

Patients can be looked up by patient name, email or ID#. Enter the patient's: full name or full email in the search bar above the Patients list. Be as specific as possible. Exact matches of patients is required when the healthcare provider dont have access to them. When the healthcare provider has access to a patient, writing a part of the name, email or ID will bring up suggestions of patients based on the entered text.

### 3. Sort patients

Click on the title of any column to sort patients by: patient ID, surname, or email.

#### **4. Filter patients**

Patients may be filtered according to account status administered to the patient:

- *All Accounts* - displays all patients connected to the Healthcare provider.
- *Active Patients* - displays patients that are currently activated for measurements.
- *Inactive Patients* - displays patients that have not yet been activated for measurements or that have been de-activated after a completed measurement period.
- *Coala Connect* - Lists all patients that have been ordered an Coala Connect where Coala Life AB sends a monitor directly to the patient, see section “11.1 Patient administration” on page 24.

## 13. Last Measurements

In the top bar menu, select *Last measurements* to review all measurements recorded by all patients using Coala Heart Monitor and app connected to the current healthcare provider with a maximum of 20 measurements per page.

In this view the portal users may; review and filter measurements recorded by all connected patients. The portal user may select any measurement from the list to review the full details of the measurement and the result of the automated analysis.

Coala Care Portal

Last measurements  Auto refresh

From To Evaluation period in days

From To Evaluation period in days

Review status Category Feeling Measurement config

All All All All

Surname, first name	Time	HR	App result	Feeling	PDF
✓ 21-020, CR	2021-12-03 08:51	73	🟢 Ok	iOS 15.1.1	<input type="checkbox"/>
Coala Life, Support	2021-11-01 10:24	-	👂 Stethoscope	Generally well	<input type="checkbox"/>

### 1. Filters

Use the filters to sort the listed measurements according to:

#### 1.1 From-To and Evaluation period in Days

Enter date ranges to filter for a specific date. Enter a specific number of days to review measurements during that time period.

#### 1.2 Review Status

Select from the dropdown the status of measurements; Show only flagged 🚩, Show only unreviewed, Show only commented. Remove filter by selecting *Uncheck all*.

#### 1.3 Category

Select one or more categories from the drop-down list to show only results from these categories. Remove the filter by selecting *Uncheck all*.

#### 1.4 Feeling

Select one or more *Feelings* from the drop-down list to filter measurements by *Feeling* entered by the patient in the Coala App in attachment to the measurement. Remove the filter by selecting *Uncheck all*.

#### 1.5 Measurement configuration

Select *Measurement configurations* to filter measurements by configuration. Remove the filter by selecting *Uncheck all*.

### 2. Measurement List

Measurements are listed in chronological order with the patient ID, name, date and time of recorded measurement, average heart rate of the measurement, app result (the combined categorization of the measurement as indicated to the patient in the Coala App) and feeling (as entered by the patient in the Coala App). Select any measurement in the list for further analysis of the Measurement screen.

### 3. Auto refresh

Check the box to enable automatic refresh of the measurement list, measurements will appear in the list as they are transmitted to the Coala Care Portal in real-time.

### 4. Quick review Thumbnails

Select the *thumbnails symbol* to display thumbnails of each ECG tracing for more efficient review. Select the symbol again to view measurements as a list.



### 5. Create PDF

Check the boxes in the PDF column for one or more measurements of interest and select *Create PDF* to generate a PDF file of the ECG tracings of each measurement. The name of the PDF file will be the date and time from when the PDF was generated.

## 14. Patient profile

*CAUTION! Make sure that the patient names and emails are correct.*

Select a patient from the patient overview to view the *Patient profile*.

In the Patient profile menu the portal users may review all data registered through the Coala services by the current patient; all measurements recorded, general health information entered by the patient in the Coala App, and account status as well as details entered on behalf of the patient by a Healthcare provider.

In the Patient profile menu the portal users will also be able to access tools for patient administration and reimbursement reporting.

Select 'X' in the search bar or select *Patients* in the menu to exit the current patient profile and return to the patient overview.

11.1

11.2

11.3

11.4

12

190002021221

+ Create a new patient account | Edit patient

♀ John Smith

ID 190002021221 DOB 1900-02-02

Contact patient

Last measurements		Patient info		Trends		Reports			
Time	HR	App result	Chest	Thumb	Feeling	BP	Weight	PDF	
2020-04-28 13:56	62	Ok	Category 2	Ok	Generally well	-	-	<input type="checkbox"/>	
2020-04-28 13:53	98	Ok	Ok	Ok	Generally well	-	-	<input type="checkbox"/>	
2020-04-28 13:49	87	Ok	Category 2	Ok	Generally well	-	-	<input type="checkbox"/>	
2020-04-28 12:23	75	Ok	Ok	Category 2	Generally well	-	-	<input type="checkbox"/>	
2020-04-28 12:20	77	Ok	Ok	Ok	Generally well	-	-	<input type="checkbox"/>	
2020-04-28 12:15	80	Ok	Measurement error	Ok	Hand	-	-	<input type="checkbox"/>	
2020-04-28 12:13	79	Ok	Ok	Ok	Generally well	120/80	81.6kg	<input type="checkbox"/>	
2020-04-28 12:08	85	Ok	Ok	Ok	Generally well	-	-	<input type="checkbox"/>	

First 1 Last

Displays 8 measurements at 1 pages

## 14.1 Patient administration

*CAUTION! Make sure that the patient names and ID:s are correct.*

In the top section of the patient profile the portal users may access tools for patient administration and reimbursement reporting.

The screenshot shows a patient profile for John Smith. At the top right, there are links for '+ Create a new patient account' (callout 2) and 'Edit patient' (callout 3). Below the patient name 'John Smith' (callout 1), there is a 'Contact patient' button (callout 4). The patient ID is 190002021221 and the date of birth is 1900-02-02. Below this is a table of last measurements.

Time	HR	App result	Chest	Thumb	Feeling	BP	Weight	PDF
2020-04-28 13:56	62	Ok	Category 2	Ok	Generally well	-	-	<input type="checkbox"/>
2020-04-28 13:53	98	Ok	Ok	Ok	Generally well	-	-	<input type="checkbox"/>
2020-04-28 13:49	87	Ok	Category 2	Ok	Generally well	-	-	<input type="checkbox"/>
2020-04-28 12:23	75	Ok	Ok	Category 2	Generally well	-	-	<input type="checkbox"/>

### 1. Patient details

Shows the patient's personal details: full name, patient ID and date of birth.

### 2. Create a new patient account

Select *+ Create a new patient account* to create a new Coala App account for another patient. For information on creating a new patient account for the Coala App, see chapter: "9.1 Create a new patient account".

### 3. Edit patient

Select *Edit patient* to edit the patient's information, see chapter "9.2 Edit patient account" for more information.

### 4. Contact patient

Select *Contact patient* to find the patient's contact information and be able to send a message to the patient. The message will appear in the inbox of the Coala App on the patient's smartphone. Messages sent to the patient may be reviewed under *Patient info*.

*CAUTION! Use this message function for non-critical information only.*

*NOTE! The patient cannot reply to sent messages.*



## 14.2 Patient measurements

Select the tab *Last measurements* in the Patient profile to view the patient's recorded measurements.

In the *Last measurements* view the portal users may review all measurements recorded by the current patient using the Coala Heart Monitor and app with a maximum of 10 measurements per page, apply filters to the list and select any measurement from the list to review the full details of the measurement and the automated analysis.

Time	HR	App result	Chest	Thumb	Feeling	BP	Weight	PDF
2020-04-28 13:56	62	Ok	Category 2	Ok	Generally well	-	-	<input type="checkbox"/>
✓ 2020-04-28 13:53	98	Ok	Ok	Ok	Generally well	-	-	<input type="checkbox"/>
2020-04-28 13:49	87	Ok	Category 2	Ok	Generally well	-	-	<input type="checkbox"/>
✓ 2020-04-28 12:23	75	Ok	Ok	Category 2	Generally well	-	-	<input type="checkbox"/>

### 1. Measurement list

Measurements are listed in chronological order with a maximum of 10 measurements per page. Select any measurement of interest to analyze the measurement in detail. For information on the detailed analysis of the measurement, see chapter “13. Review patient ECG” on page 34.

### 2. HR - heart rate

Shows the average heart rate of the measurement as a whole as returned to the patient in the Coala App in BPM.

### 3. App result, Chest- and Thumb -result

*App result* - the combined categorization of both the chest and thumb recording indicative of the measurement as a whole. This is also the result indicated to the patient in the Coala App. For information on the individual versus the combined result, see chapter “14. ECG Categorization” on page 42.

### 4. Feeling

Shows the *Feeling* entered by the patient in the Coala App in attachment to the recorded measurement to describe his/her state of health during the measurement. This field can also contain free text entered by the patient in the Coala App.

### 5. Blood Pressure and Weight

Values for blood pressure and weight if the patient manually entered values into the Coala App after taking their measurement.

### 6. Create PDF

Tick the check boxes of one or more measurements in the PDF column and select *Create PDF* to generate a PDF file from one or more measurements. The name of the PDF file will contain patient name, patient ID, date and time of generated PDF.

*NOTE! The option Create PDF will only be visible when one or more measurements have been selected.*

## 7. Quick review Thumbnails

Select the *Quick review thumbnails* symbol to display thumbnail plots of the thumb and chest ECG recordings for all entries in the measurement list. Select the symbol again to hide the thumbnails. For a deeper analysis of any measurement's recordings, select the applicable measurement to open the Measurement screen.



## 14.3 Patient Info

Select the tab: *Patient Info* in the patient profile to view general patient info.

In the *Info* view the portal users may review the patient's general health information, account status, sent messages, general notes and notes attached to specific measurements.

The screenshot displays the patient profile for John Smith. At the top, there is a header with the patient's name, ID (190002021221), and DOB (1900-02-02). A 'Contact patient' button is located in the top right. Below the header is a navigation bar with tabs for 'Last measurements', 'Patient info', 'Trends', and 'Reports'. The 'Patient info' tab is active. The main content area is divided into several sections:

- Health data** (Changed 2020-11-13): Includes fields for Date of birth (1900-02-02, 122 years), Height (177.8cm), Weight (81.6kg), Smokes (No), and Pacemaker / implanted unit (Yes).
- Medication** (Changed 2020-11-13): Shows 'None'.
- Account**: Shows 'Disconnected from you: 2020-11-13' and 'Agreed to Coala Life's Terms and Privacy Policy on 2019-10-18 15:15'.
- Measurement config**: Shows 'Original'.
- Messages**: Shows '4 messages sent' and a recent message from '13 Nov 2020 17:12' with the subject 'EU verification requesting access'.
- Time report**: Includes a filter for '+ 1 min + 2 min + 5 min + 10 min + 20 min' and a 'Total review time: 00:01:00'.
- Notes**: A large empty text area with a '+ Store note' button below it.

Numbered callouts 1 through 6 point to the following elements:

- 1: Health data section header
- 2: Medication section header
- 3: Account section header
- 4: Measurement config section header
- 5: Messages section header
- 6: Time report section header

### 1. Health data

Shows general health information entered by the patient in the Coala App including; date of birth, age, height, weight, smoking habits, and pacemaker/implanted unit status.

### 2. Medication

Shows regularly taken medications, as entered by the patient in the Coala App.

### 3. Account

Shows date and time when the patient logged in to the Coala app for the first time and accepted the Coala terms and conditions.

### 4. Measurement configuration

*Original* configuration is default and contain a 30 sec. chest ECG- and phono measurement plus a 30 sec. thumb measurement.

**5. Sent messages**

Shows all messages sent to the patient using the Coala App.

**6. Time report**

Time report for the patient. Add to the total review time by clicking on *+ 1 min*, *+ 2 min*, *+ 5min*, *+ 10 min*, or *+ 20min*.

**7. Store notes**

To attach a general note to the patient's profile, enter the note in the text-box and select *+Store note*. Stored notes are listed below the text-box together with specific notes attached to measurements recorded by the patient. Specific notes attached to measurements will provide a link to the specific measurement: *Show measurement*. For instructions on how to attach a note to a specific measurement see chapter "13. Review patient ECG" on page 34.

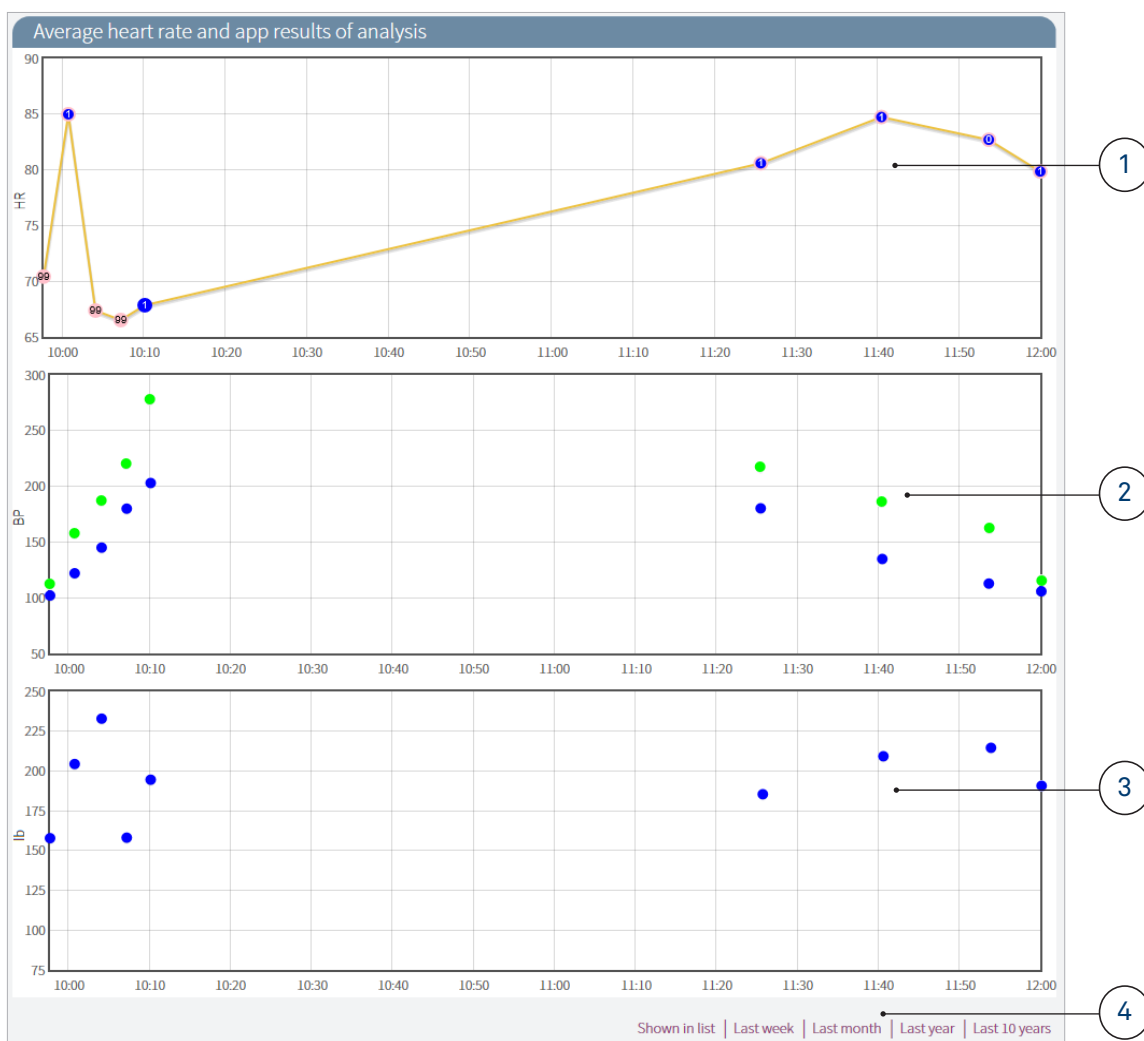
## 14.4 Patient trends

Select the tab: *Trends* in the Patient profile to review trends in the patient's recorded measurement data.

In the Trends view, the portal users may review the patients recorded data plotted as trends in three sections. The first section will display a plot of the patient's *App result* including: categorization, average heart rate, and *Feeling*. The second and third section will display plots of blood pressure and weight entered by the patient in attachment to the measurement respectively.

*NOTE! Measurement data plotted in the Trends tab is entered in attachment to each measurement. It is not a representation of the general health information displayed in the Patient info tab of the patient profile.*

*CAUTION! The weights and blood pressures plotted in the graph section should not be used as a sole basis for diagnosis.*



## 1. App result graph

The first graph will plot the average heart rates of the patients recorded measurements. The configuration of the plotted data points are also indicative of:

- ② Pink center and a pink border indicates the detection of a measurement anomaly and that the *Feeling* entered by the patient is anything other than *Generally well*. The categorization indicated as the *App result* is shown by the number.
- ① Blue center and a blue border indicates a normal *App result* and that the *Feeling* entered by the patient is *Generally well*. The number indicated as the *App result* will be category 1.
- ① Blue center with a pink border indicates a normal categorization result, and that the *Feeling* entered by the patient is anything other than *Generally well*. The number indicated as the *App result* will be category 1.

## 2. Blood pressure graph

The second graph will plot the systolic (green) and diastolic (blue) blood pressure entered in by the patient in Coala App in attachment to the measurement. This entry is optional to the patient in the Coala App and will only be plotted when entered.

## 3. Weight graph

The third graph will plot weights in pounds as entered in by the patient in Coala App in attachment to the measurement. This entry is optional to the patient in the Coala App and will only be plotted when entered.

## 4. Filter measurements

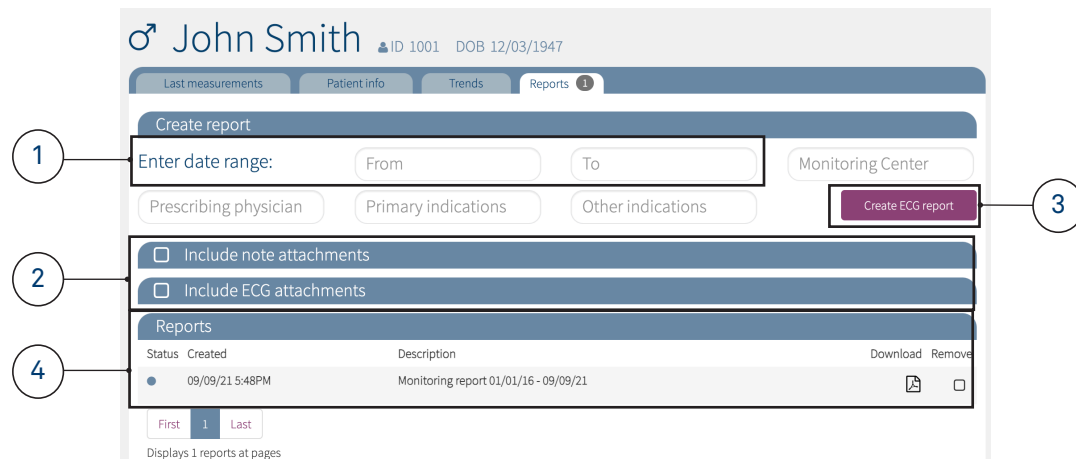
Select one of the options ; *Shown in list*, *Last week*, *Last month*, *Last year* or *Last 10 years* to filter measurements by a specific time period.

Measurements will by default be plotted as *Shown in list*. This will plot the patient's 10 most recent measurements from the Last measurements list in the patient profile with any filters intact.

# 15. Coala ECG Monitoring Report

## 15.1 Generate report

Generate a patient monitoring report by first selecting *Patients* in the top bar menu and then selecting the patient in the patient list. Download the generated report under the tab *Reports*. A number next to the tab name indicates that there is one or more monitoring reports that have not yet been downloaded. The report contains general patient information and a summary of findings.



### Step 1 (optional)

Enter a date range of interest and free text in the assigned fields for: *Prescribing Portal user*, *Primary indications*, and *Other indications*.

### Step 2 (optional)

Select *Include note attachments* to include all notes generated for the patient and select *Include ECG attachments* to display filtering options for ECG attachments. Use the filters to determine which information to include in the report, such as flagged, unreviewed or commented results, specific result categories or *Feeling* entered by the patient in attachment to the measurement.

### Step 3

Select *Create ECG report* to generate the report. When the report is ready to be downloaded, the PDF icon will appear in the download line. Click on the icon to download the report in a PDF format.

*NOTE! Generating the report may take several minutes. It is ok to leave the Create report screen before the report has been generated. The report is also listed in the Reports tab in the Patient profile when ready for download.*

### Step 4

All previously generated reports will be listed with the option to download the report again in the list below the report generator.

To remove previously generated reports: Tick the check boxes for one or more reports in the remove column and select *Remove selected* to remove all the reports that have been selected.

- Indicates that the monitoring report has not yet been downloaded.
- Indicates that the monitoring report has been downloaded.

## 15.2 Report content

The automated monitoring report includes summarized information from a patient's measurements.

Information and ECG strips regarding most frequent *Algorithm detections*, that is correlation between experienced symptoms during measurement and measurement result, *Heart rate summary* and *Ectopic beats*. The same information is also written in linear format under *Preliminary findings* and there is a section for manual input, *Final interpretation*.

### Coala Automated ECG Monitoring Report

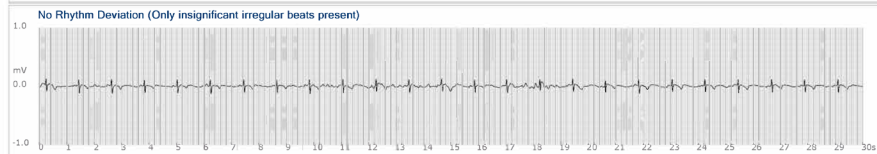
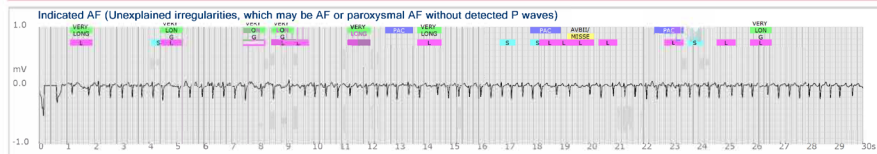
John Smith DOB: 5/14/1965, Male, 66 years, ID:



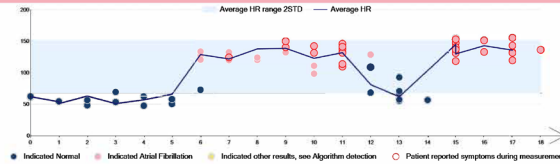
Coala Life Inc. 3333 Michelson Dr. 92612 CA, USA  
Tel 858-579-4441 www.coalalife.com info.us@coalalife.com

Report generated: Tuesday, August 3, 2021 4:12 PM

Physician:	Test clinician	First ECG:	7/16/2021	Patient reported information:
Healthcare provider:	VA Long Beach	Last ECG:	8/3/2021	Height:
Primary indications:		ECG recordings:	77	Weight:
Other indications:		Reported RPM:	35 min	Pacemaker:
				No



Algorithm detection		
	Recordings	%
● Indicated AF	43	64 %
● Normal	22	33 %
● Poor signal	2	3 %
● -	-	-
● -	-	-



Heart rate summary			
During AF		During non-AF	
Max:	156 bpm	Max:	156 bpm
Min:	59 bpm	Min:	48 bpm
Mean:	134 bpm	Mean:	110 bpm
Overview all recordings			
Mean HR:	110 bpm	RR Median:	530 ms
Std dev:	21 bpm	Std dev:	103 ms

**Preliminary findings**  
Patient had a min HR of 48 bpm, max HR of 156 bpm, and avg. HR of 110 bpm.  
43 recordings with Indicated AF

Ectopic beats per 30 sec - all recordings		
	Total count	Mean count
● PVCs	179	2
● PACs	169	2
● Bigemini	0	0
● Trigemini	0	0

**Final Interpretation**  
 Sinus     AF     Agree with findings     Other, specify:  
 \_\_\_\_\_  
 \_\_\_\_\_  
 Signature: \_\_\_\_\_

Stethoscope recordings are not included in this report. Heart rate and RR intervals are calculated from 30-second ECG recordings only. Detected categories are based on both chest and thumb ECG recordings. DIVERSES counts are based on both chest and thumb ECG recordings as detected during the 30-second recording. These measurements are indicative for the duration of the recording only. Diagnosis should be based on assessment of individual recordings. Representative ECG during AF and normal sinus rhythm are gathered from the last representative recording within the enrollment of the report. Measurements with poor quality signal are excluded from any calculations and are not provided on the due to insufficient information.  
© Coala Heart Monitor - Monitoring Report - Coala Life AB 005100N



## 15.3 Notes attachments

All notes generated for the patient, in the measurement view or patient info section, will be generated in a list as attachment to the monitoring report.

### Coala Automated ECG Monitoring Report

JohanUs US, DOB: 5/3/1979, Male, 42 years, ID: 12451335478124



Report generated: Tuesday, June 29, 2021 8:56 AM

<b>Physician:</b>	Test clinician	<b>First ECG:</b>	9/25/2019	<b>Patient reported information:</b>
<b>Healthcare provider:</b>	SeededHealthcareProvider	<b>Last ECG:</b>	4/13/2021	<b>Height:</b> 6' 8"
<b>Primary indications:</b>	An apple a day keeps the doctor away.	<b>ECG recordings:</b>	17	<b>Weight:</b> 170 lb
<b>Other indications:</b>	My opinions may have changed, but not the fact that I'm right.	<b>Reported RPM:</b>	35 min	<b>Pacemaker:</b> No

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 and here is a long row if the Windows Forms Designer fails to load due to an error in your code, in a third-party component, or elsewhere, you'll see an error page instead of the designer. This error page does not necessarily signify a bug in the designer! If the Windows Forms Designer fails to load due to an error in your code, in a third-party component, or elsewhere, you'll see an error page instead of the designer. This error page does not necessarily signify a bug in the designer! If the Windows Forms Designer fails to load due to an error in your code, in a third-party component, or elsewhere, you'll see an error page instead of the designer. This error page does not necessarily signify a bug in the designer.  
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## 16. Review patient ECG

Select a measurement for review in the in the Patient profile or in the Last measurements view to display the measurement screen. The measurement screen will show the complete details of each recorded ECG and/or stethoscope part included in the measurement and the complete details of the automated analysis.

In the measurement screen the portal users may review the recorded parts of the measurement in detail, using the tabs.

- Chest measurement
- Thumb measurement
- Phonocardiogram

To exit the measurement screen: Select 'X' in the upper right corner and return to the previous page.

The screenshot displays the ECG review interface for a patient named John Smith. At the top, patient information includes the name, ID (19650505X001), and DOB (1965-05-05). The measurement date and time are 2021-09-09 10:13. The screen is divided into several sections:

- Measurement Tabs:** Chest measurement (selected), Thumb measurement, and Phonocardiogram.
- Result chest measurement:** A summary section with four status indicators: "No rhythm deviation" (highlighted by callout 13.2), "Irregular Sequence", "Other deviation", and "Poor data quality".
- Info:** Patient status: "Feeling: Generally well", "HR: 73 beats per minute", and "No rhythm deviations".
- ECG Waveform:** A graph showing the ECG signal in mV over time (16 to 21 seconds). Callout 13.1 points to the waveform.
- Heart sound:** A section with a play button, volume control, and a "0:00 / 0:00" timer.
- Annotations:** A section with a "Hide automatic annotations" checkbox.
- Detailed analysis result:** A table with three columns: "Detailed analysis result", "Detailed analysis result more", and "Analysis parameters".

Detailed analysis result	Detailed analysis result more	Analysis parameters
No rhythm deviations	RR median: 822.8 ms	Sample rate: 1000 Hz
Category 1: No Rhythm Deviation (Only Insignificant Irregular beats present)	RR std dev: 36.6	Signal length: 30.103 s
	Heart rate: 72.9 beats per minute	Method: ECGParser Version-1.1.1.0
	Strong P waves	Serial number: 10012401.728000443
		Coala Life*

At the bottom right, there is a "Close measurement" button. A "Notes" section is visible at the very bottom of the screen.

Callouts in the image:

- 13.3: Points to the patient name "John Smith".
- 13.2: Points to the "No rhythm deviation" status indicator.
- 13.1: Points to the ECG waveform.
- 13.4: Points to the "Info" section.

## 16.1 The ECG Graph

The ECG graph will plot the ECG tracing for each part with default scale  $\pm 1$  mV for chest ECG tracings and  $\pm 2$  mV for thumb ECG tracings and provide the portal users with tools for detailed review of the ECG recording.



### 1. Add caliper

Tick the check box *Caliper* to add a digital caliper to the ECG graph.

Click on the graph once to add a starting point to the caliper, click again to add an end point. The caliper will present the total time between the two points selected (in milliseconds). Move the caliper along the X-axis of the ECG graph. Click again to lock the caliper in place.

Deselect the box to remove the caliper.

### 2. Invert graph

Tick the check box *Invert* to invert ECG in graph. Deselect the box to remove inversion.

### 3. Pan ECG graph

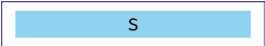
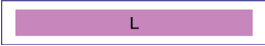

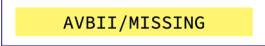

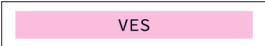
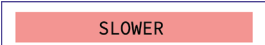
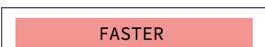
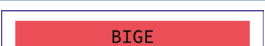


Pan by clicking the double arrows in the upper right corner of the graph.

### 4. Annotations and markers

The automated analysis will annotate the ECG recording with markers based on anomalies detected in the signal to aid the portal users in screening and detection of anomalies.

To disable automatic annotations in the ECG graph select *Hide automatic annotations*.

*NOTE! If annotations are disabled these will not be included in the downloaded measurement PDF file.*

Annotation	Meaning	Description
	Short beat	Shorter R-R interval than other beats.
	Long beat	Longer R-R interval than other beats.
	Very long beat	Much longer R-R interval than other beats.
	AV-block/missed beat	AV-block type II or completely missed beat.
	SVES/PAC	Supra-ventricular extra beat.
	VES/PVC	Ventricular extra beat.
	Slower	Sudden slower series of beats than the rest.
	Faster	Sudden faster series of beats than the rest.
	Bigemini	Twin rhythm
	Trigemini	Triplet rhythm
	Trigemini	Triplet rhythm

## 5. Zoom

X-axis - Select: '+' or '-' buttons to zoom on the X-axis.

Y-axis - Select: the  $\pm$ mV setting (full scale) to zoom on the Y-axis.

*NOTE! The scalings set for the Y-axis in the ECG graph will be used for the downloaded measurement PDF file.*

## 16.2 Chest measurements

Select the *Chest Measurement* tab in the measurement screen to view the ECG tracing and the detailed analysis of the chest ECG recording.

In this view the Portal users may access all the same information and tools available in the Thumb measurement view with the addition of options for reviewing the sound recording of the chest measurement.

The screenshot displays the 'Chest measurement' screen for a patient named John Smith. The interface includes a patient header with ID and DOB, a 'Send message' button, and navigation tabs for 'Chest measurement', 'Thumb measurement', and 'Phonocardiogram'. The main content area shows a 'Result chest measurement' section with four status indicators: 'No rhythm deviation' (selected), 'Irregular sequence', 'Other deviation', and 'Poor data quality'. An 'Info' box provides details: 'Feeling: Generally well', 'HR: 73 beats per minute', and 'No rhythm deviations'. Below this is an ECG tracing with a heart rate of 73 bpm. A 'Heart sound' player is visible with a play button and volume control. The bottom section contains a 'Detailed analysis result' table, a 'Close measurement' button, and a 'Notes' text area.

Detailed analysis result	Detailed analysis result more	Analysis parameters
No rhythm deviations	RR median: 822.8 ms	Sample rate: 1000 Hz
Category 1: No Rhythm Deviation (Only insignificant irregular beats present)	RR std dev: 36.6	Signal length: 30.103 s
	Heart rate: 72.9 beats per minute	Method: ECGParser Version: 1.1.1.0
	Strong P waves	Serial number: 10012401728000443
		Coala Life

### 1. Attach notes to the measurement

To attach a note to the specific measurement: enter note in the text-box and select *+Store note* to save the note. Notes attached to specific measurements will be listed with a link to the measurement in the *Patient Info* tab in the patient profile with a link to the measurement screen. Click the link *Show measurement* to display the measurement screen.

## 2. Detailed analysis results and Analysis parameters

The detailed analysis includes the following information:

- Rythm deviations
- RR median
- RR std dev
- Heart rate
- P Waves

The Analysis paramets lists the:

- Sample rate
- Signal length
- Measurement method
- Serial number of the Coala product

## 3. Playback heart sound

Select the play-icon for auscultation of the synchronously recorded heart sound of the chest ECG part. The heart sound recorded can be used to assess the mechanical functionality of the heart. It is strongly advised to use high quality headphones or speaker connected to computer for best audio quality.

## 4. ECG analysis

Shows the detailed results of the ECG analysis, including:

- Heartbeat QRS marker (+), beats that are included in the beat analysis
- (l) all identified beats (including possible noise)
- Beat classification based on morphology
- RR interval (in milliseconds and percentage deviation from average)
- Time marker in seconds (x-axis)
- Voltage marker in mV (y-axis).

## 5. Result group

Indicates the suggested *Result group* of the recording based on the categorization made by the automated analysis. For information on the categorizations see chapter “14. ECG Categorization” on page 42.



Indicates *No Rythm Deviation*. Category 1.



Indicates *Irregular Sequence*. Category 2.



Indicates *Unclassified*. Category 3 - 12.




Indicates *Poor Data Quality*. Poor quality recording, not possible to categorize.

## 6. Send message

Select *Send message* to send a message to the patient in the Coala App. The message will appear in the inbox of the Coala App on the patient’s smartphone. Previously sent messages can be found under *Messages* in the *Info* tab in the patient profile view. Note that the patient cannot reply to sent messages.



*CAUTION! Use this message function for non-critical information only.*

## 7. Flag the measurement

To flag the measurement, click on the flag icon in the upper right corner of the measurement screen. Flagged measurements are marked with a red flag  in the patient profile and *Last measurements* view.

Un-mark by re-clicking the flag icon.

## 8. Reviewed measurement

Once a measurement has been read, the measurement will automatically be marked with a green check  in the upper right corner. Reviewed measurements are marked with a green check  in the Patient profile and Last measurements view.

Un-mark the measurement as reviewed by clicking on the green check icon in the top right corner of the measurement screen.

## 9. Download PDF

Select *Create PDF* to download a PDF file containing both the thumb and chest recording of the current measurement for print, filing of manual interpretation. The PDF will use fix 25mm/s scaling for x-axis and current settings for y-axis for the ECG tracing. The pdf will be saved as: “{patient name}\_{ID}\_{date}\_{time}”.

Ensure your printer settings are set to Letter landscape before printing in order to achieve 25 mm/s.

## 10. Download raw data

Select *Download raw data* to download raw data for analysis in an external program. The sampled raw data of the ECG tracing will be expressed in mV with sample rate 1000 Hz.

## 11. Download heart sound

Select: *Download heart sound* to download the heart sound in digital waveform format (.wav) to a computer for archiving or analysis in an external program.

## 12. Info

Shows a short summary of the automated analysis, *Feeling* entered by patient in the Coala App in attachment to the measurement and the average heart rate of the thumb ECG recording.

## 13. Close measurement

Click *Close measurement* or ‘X’ in the upper right corner of the measurement to return to the previous view.

### 16.3 Thumb measurement

Select the *Thumb measurement* tab to view the ECG tracing and detailed analysis of the thumb ECG recording.

In the Thumb measurement view the portal users may review the thumb ECG tracing with the assistance of the automated ECG analysis, download the raw sample data for review in an external program, or create a PDF file from the measurement for print or filing, see section “13.2 Chest measurements” on page 37 for information on these features.

The screenshot displays a patient's ECG measurement interface. At the top, the patient's ID (19650505X001) and name (John Smith) are visible. The interface is divided into tabs: Chest measurement, Thumb measurement (selected), and Phonocardiogram. The main area shows the 'Result thumb measurement' with four status indicators: 'No rhythm deviation' (selected), 'Irregular Sequence', 'Other deviation', and 'Poor data quality'. The 'Info' section provides clinical data: 'Feeling: Generally well', 'HR: 76 beats per minute', and '3 Minor irregularities'. Below this is a large ECG tracing plot with a y-axis in mV (ranging from -2.0 to 2.0) and an x-axis in seconds (ranging from 19 to 27). The plot includes a grid and a cyan highlight on a portion of the tracing. Below the plot are controls for 'Add Caliper', 'Invert graph', 'Zoom x-axis', 'Zoom y-axis', and 'Annotations'. The 'Detailed analysis result' section is divided into three columns: 'Detailed analysis result' (3 Minor irregularities, Category 1: No Rhythm Deviation), 'Detailed analysis result more' (RR median: 787.2 ms, RR std dev: 40.9, Heart rate: 76.2 beats per minute, Strong P waves), and 'Analysis parameters' (Sample rate: 1000 Hz, Signal length: 30.048 s, Method: ECGParser Version-1.1.1.0, Serial number: 10012401728000443, Coala Life). A 'Close measurement' button is located at the bottom right. A 'Notes' section is at the very bottom.

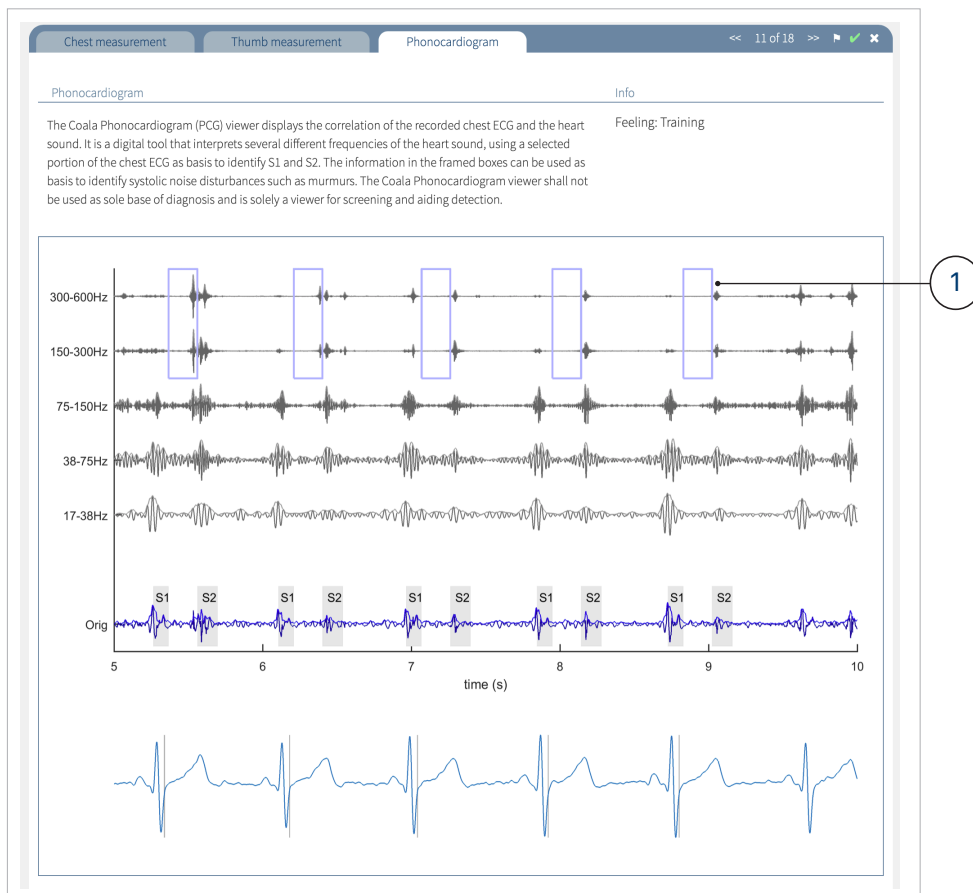


## 16.4 Phonocardiogram

Select the *Phonocardiogram* tab in the measurement screen to view the phonocardiogram analysis of the synchronized chest ECG and heart sound recording.

The Coala phonocardiogram (PCG) viewer will display the correlation of the recorded chest ECG and heart sound signal. The Phonocardiogram 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.

*NOTE! The Coala Phonocardiogram viewer shall not be used as sole base of diagnosis and is only intended as a viewer for screening and aiding detection.*



### 1. The framed boxes

The framed boxes can be used to identify systolic noise disturbances such as murmurs.

## 17. ECG Categorization

Coala's automated analysis detects heart rhythm deviations based on two consecutive ECG recordings. Each measurement recording is categorized by the automated analysis into individual results as well as into a combined result on the basis of both ECG recordings.

The thumb and chest ECG recordings are categorized individually into a: "Thumb result" and a "Chest result".

The combined result of both is then categorized into an *App result*. This is the result indicated to the patient in the Coala App. The combined *App result* is categorized based on the detailed analysis of both recordings:

- If no heart rhythm deviations are detected in either of the ECG recordings the App result will indicate Category 1 "Your results appear normal".
- If heart rhythm deviations are detected in both thumb and chest ECG recordings the App result will indicate the categorization of the thumb recording.
- If heart rhythm deviations are detected in both ECG recordings and the Thumb result is Category 2, with the addition of detected p waves in either of the recordings the App result will indicate Category 12 "Irregular heart rhythm".

CATEGORY	DESCRIPTION
0.	Poor quality (Difficult to follow the beat sequence)
1.	Your results appear normal
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
8.	Coala indicates recurring extra heart beats
10.	Coala indicates recurring extra heart beats
11.	Coala indicates recurring extra heart beats
12.	Coala indicates an irregular heart rhythm

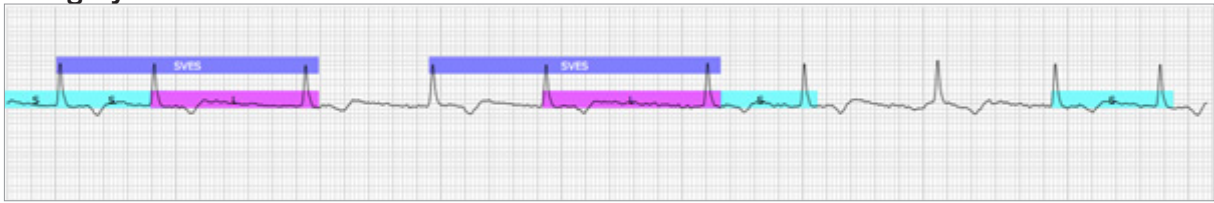
More information about ECG categorizations can be found in the app under *My Coala > Documentation > Category description*. Or visit [www.coalalife.com/categories](http://www.coalalife.com/categories)

### Category 1



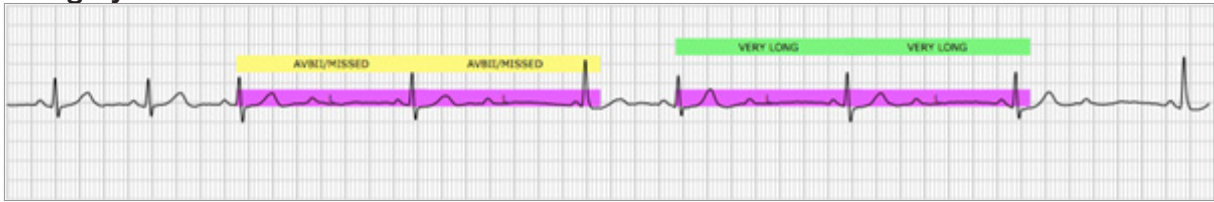
No Rhythm Deviation (Only insignificant irregular beats present).

### Category 2



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

### Category 3



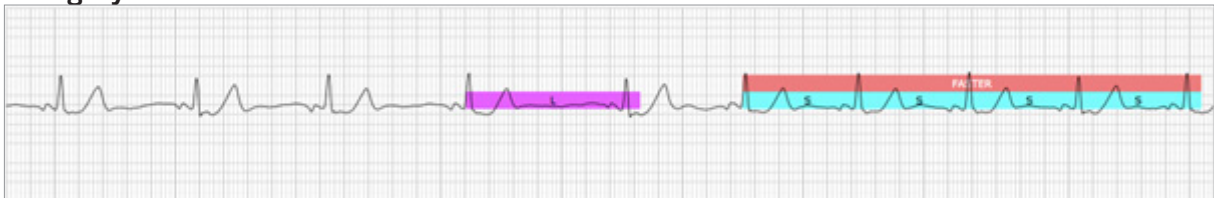
Pause/AV Block II (or beats longer than 2.2s).

### Category 4



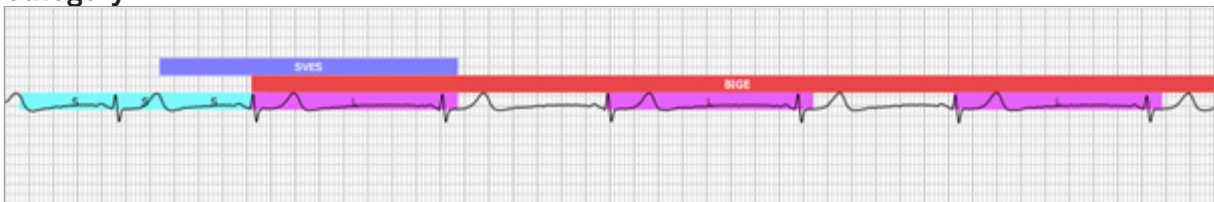
Fast Regular (RR interval shorter than 600ms in entire signal).

### Category 6



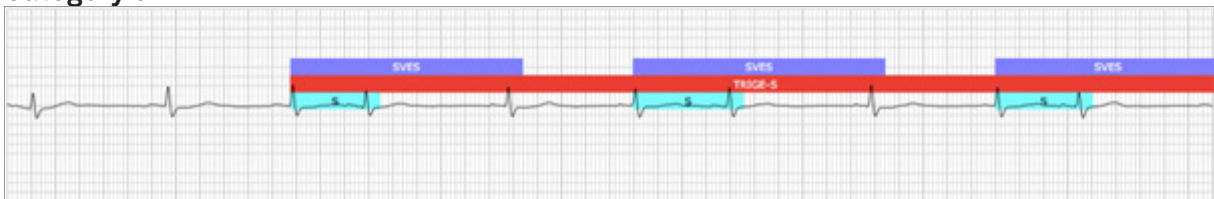
Fast/Slow Sequences (Shorter sequences of faster or slower beats).

### Category 7



Bigemini (patterns with P waves detected).

### Category 8



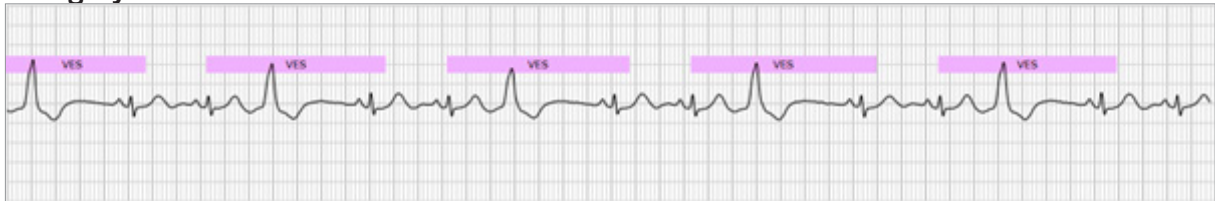
Trigemini (patterns with P waves detected).

### Category 10



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

### Category 11



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

### Category 12



Irregular sequence with detected P waves.

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

## 18. Close and Logout

Press 'x' on tab to exit. Note that any graph settings applied to are not saved at exit. Log out after session by selecting the user account at the top bar and clicking *Log out*.

## 19. Explanations of Symbols



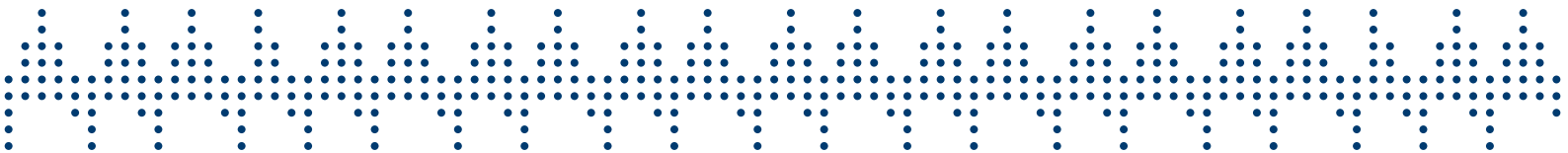
Manufacturer



2797 CE-mark

001787/J 2022-12-09

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