Corsano

Continuous Patient Monitoring
Anytime, Anywhere

Corsano System Portal Onboarding Manual

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2 Welcome to Corsano's System

We are very pleased that you have chosen to work with the Corsano System, which in our view represents one of the most advanced approaches available today to collect, report and action against a wide range of near real-time physiological data.

This manual is provided to help assure a smooth onboarding process for a System Evaluation Lead (EL) / Study Lead (SL) and any Evaluation Study Participants (ESP). It is also designed to support Evaluation Study data extraction and analysis steps.

While every attempt to make this document as comprehensive as possible, there is considerable additional helpful information available on the Corsano website: https://corsano.com/knowledge-base/.

3 Get started - Installing the Corsano App

An Operating System-specific Corsano App has been developed to enable seamless interaction with the Corsano Health Platform. Based on the type of phone the EL plan to use and where they are located, they can get the right version of the App from the following sources:

Scan the QR Code or click the links to get the App:

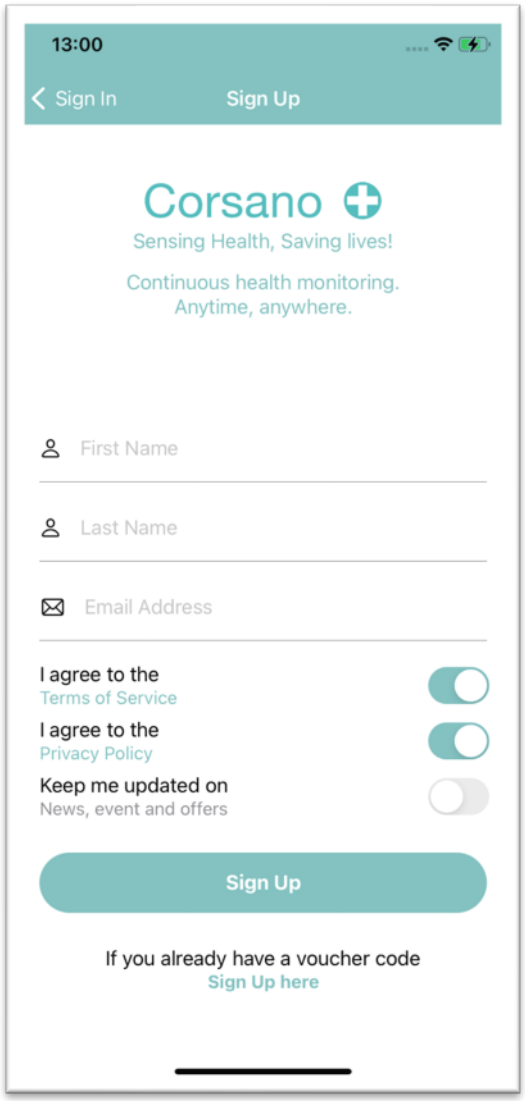
https://play.google.com/store/apps/details?id=com.swisscloudportal.corsanotrials

https://apps.apple.com/app/corsano/id1559005170

To begin, please install and open the App to begin the Registration process.

4 Registering on the Corsano System

EL and ESP (users) need to create a Corsano account, to be able to use the Corsano App and/or the Corsano Research Portal.

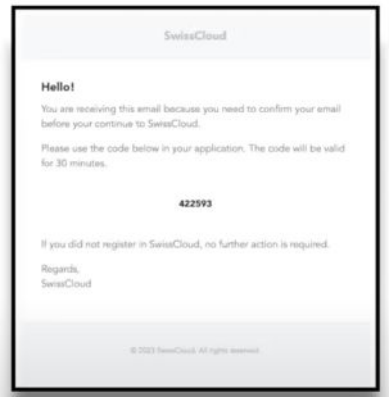


Once opened, the Corsano App displays a Sign-up page where the user can enter their First and Last Name and an email address.
Additional options can also be selected. These include slider buttons to agree to:

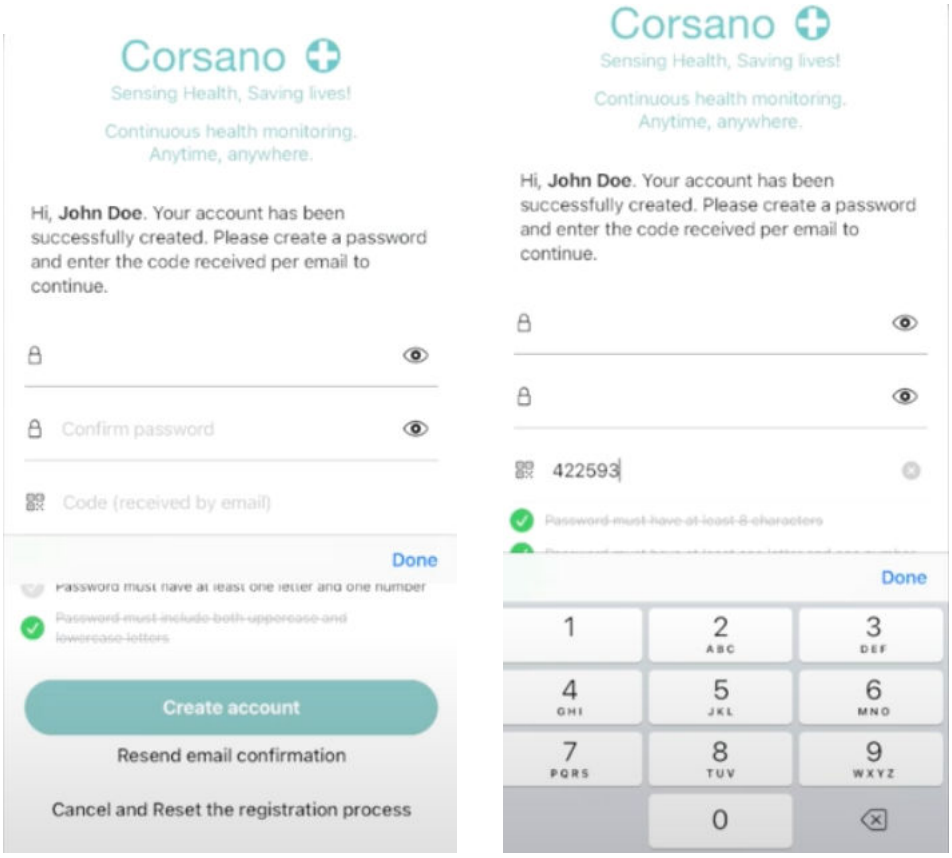
1) The Terms of Service
2) The Privacy policy
3) Receive updates on News, Events and others items

<u>IMPORTANT</u>: Users will not be able to register on the Corsano System if User chooses not to accept the Terms of Service and the Privacy policy.

A 6-digit Confirmation Code will be sent to the User-specified email address.



Enter Voucher Code into appropriate field and input a Password complying with (complex password requirements) in the following screen to complete registration process.



4.1 About password policies, password expiration and auto-logout

A combination of username and password are used to control access to the Web Portal and Corsano App. The App requires that the user creates a strong password (More than eight characters, containing letters, digits, capital and small letters, at least one special character such as "!"#$%&'() +). It is the responsibility of the user to apply the appropriate password policies e.g., password complexity, renewal intervals.

Follow these general recommendations on password:

- Use a minimum password length of 8 characters
- Include lowercase and uppercase alphabetic characters, numbers and symbols
- Generate passwords randomly where feasible
- Passwords should be renewed after 90 days.

5 Creating a User profile

Once registered, a user will be able to create a profile by completing the details shown in the App.

Any profile changes or updates can be made using the App.

A Video Tutorial is available at the following link:
https://corsano.com/knowledge-base/how-to-register-in-the-corsano-app-new/

Note:
User may select alternate Sign-Up process via voucher code if provided with a Voucher Code.
The Voucher code access is described further in the document.

6 Accessing the Research Portal

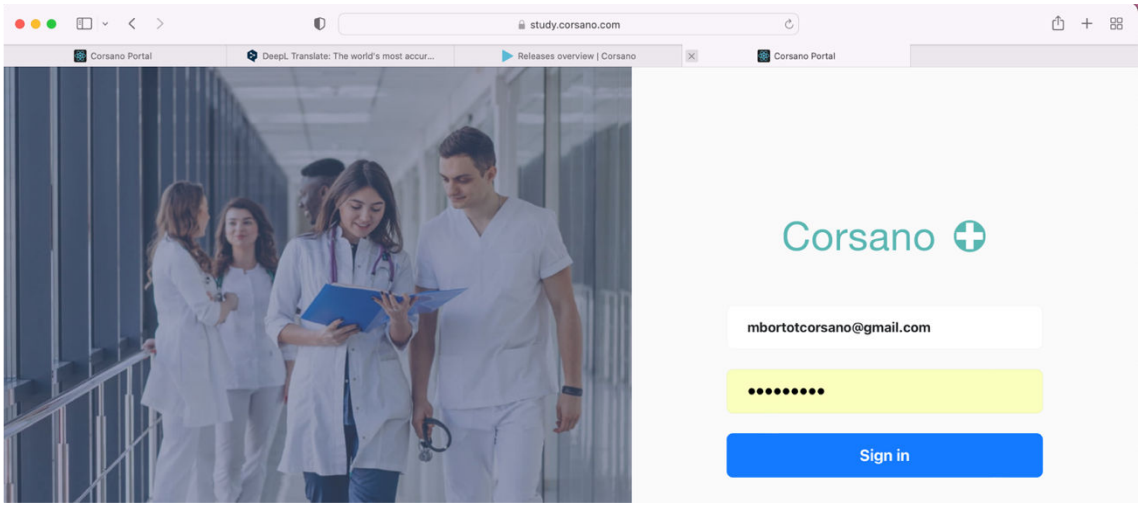
Approved EL Users configure Studies and respective Study Participants via the cloud-based Research Portal. Access to the Research Portal is enabled once the EL completes the Registration Step
The Portal is accessed via a browser at the following address: https://study.corsano.com/

Note:
Continued EL User Research Portal and Study access is linked to valid Corsano Subscription(s). Approved Study Participants may be assigned by an EL to more than one study at a time.

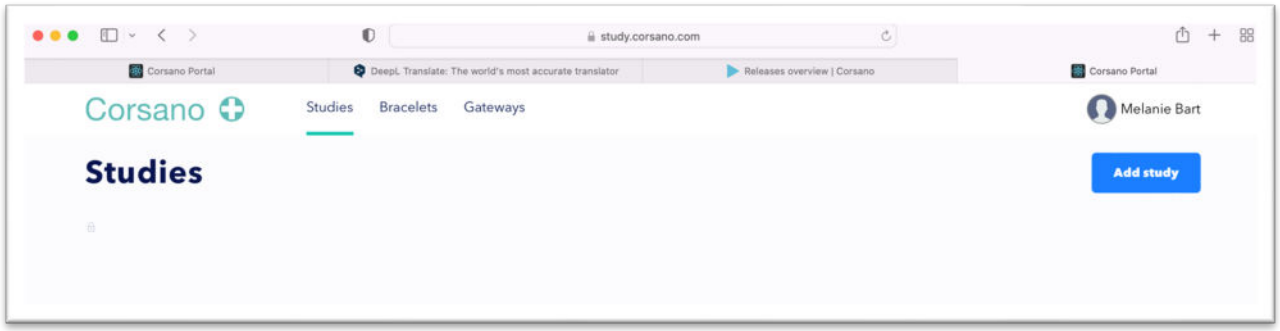
A prompt in provided to the EL to indicate the pending expiration date of the Evaluation Subscription as well as steps to follow to renew or extend the subscription if desired.
Upon Subscription termination, User access to the portal and study(ies) linked to the terminated subscription will also become unavailable. If Study Participant is enrolled in more than one Study and in the case one of the studies is terminated, the Study Participant data remains visible in the other ongoing studies

6.1 Account Sign In:

Enter the email and password details used in the Registration Step then click Sign in.

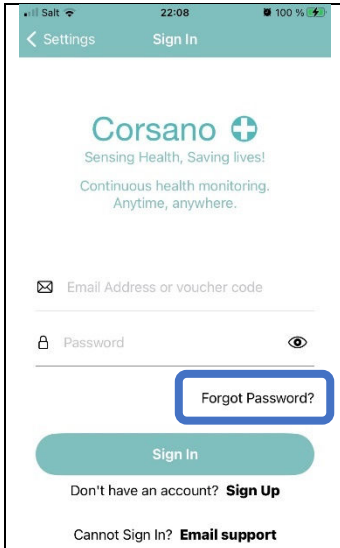
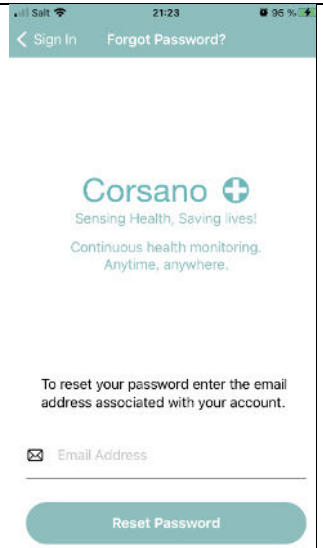
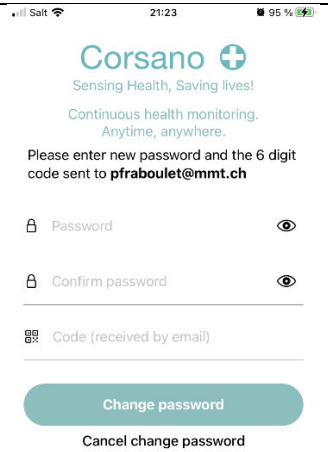
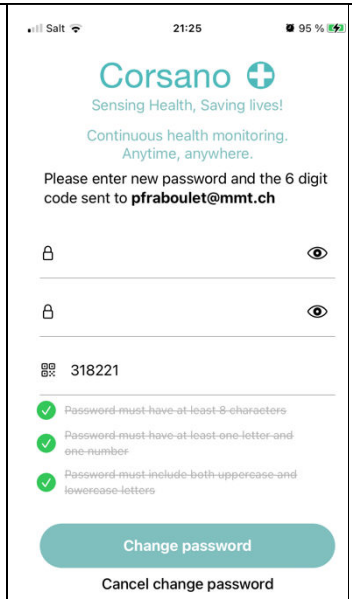


On successful login, the following Home screen is visible to User:



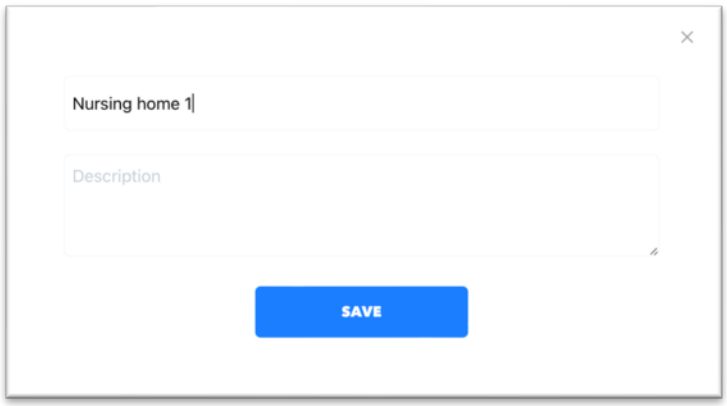
6.2 Account Recovery:

Forgotten User Registration details can be recovered using the following steps.
Contact helpdesk if Account Recovery steps fail.

				NOTE: For Voucher users, there is no email option. The EL / Study Owner must contact Corsano Support and request a new password. Only registered EL / Study Owners are entitled to request a new password. The EL / Study Owner is responsible for keeping user anonymous.
Open the Corsano Trials APP. In the Sign-In page, press Forgot Password?	Enter Email where to receive the verification code.	Enter the new password, complying with complex password requirements steps described in the app.	Enter verification code.	

7 Creating a Study

Click the Add Study Button to begin the create study step.
Enter a Study Name as well as a description in the dialogue box that appears.
To avoid confusion, please make sure your Studies have a Unique identifier. Description field is optional. Click Save to complete step.
A Unique Identifier is created for the Study.



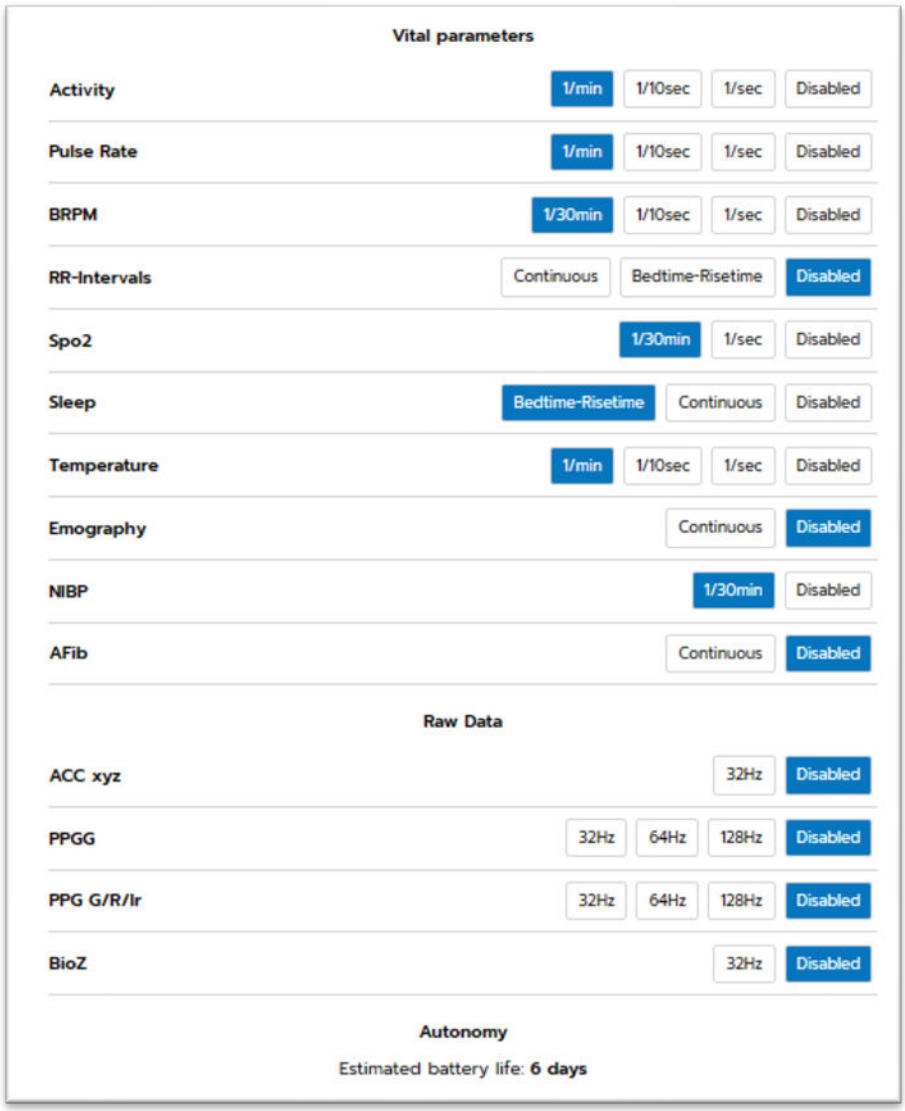
Once saved, Study details will appear on the User's Home screen.
A unique Corsano **Study Tag** (see figure below) is now associated with each study.

Note:
Study name can be edited using the **Pencil**. Study can be customized further using the **settings**.

8 Vital Parameters Settings

The Vital Parameters Setting can be reached by clicking on the Settings button found on the Research Portal home screen.

Each study has pre-specified vital parameter settings as seen in the figure below.



Parameters can be individually tuned for the study need.

Estimated battery life (or Autonomy) related to selected parameters is also visible on this page.

Data storage available when using maximum data streaming settings is 6 hrs.

<u>NOTE:</u>
Please enable at least one parameter to begin the data collection process. If none are selected, the bracelet will enter sleep mode.

9 Study Participant Enrollment

Evaluation Leader, (and other members of the Evaluation team based on details the EL provides to Corsano) are currently able to enroll participants into a Study.

Note:
The EL must first declare a list of authorized emails.
Corsano will then assign Study Admin rights to the corresponding accounts.

Currently, there are 2 methods to enroll Participants into a Study.

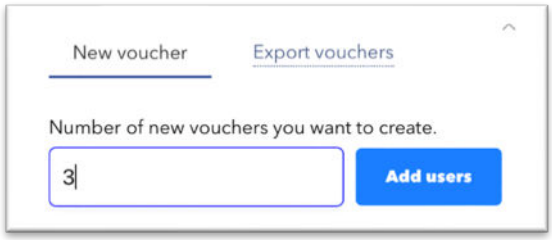
1) Anonymously via registration Voucher
2) Identified via their email

9.1 Anonymous enrollment via Voucher

With an anonymous enrollment method, unique registration Vouchers are generated for each intended participant. Each participant will be provided a Voucher to use for Registration in the Corsano App. There is no upper limit to the number of participants per trial.

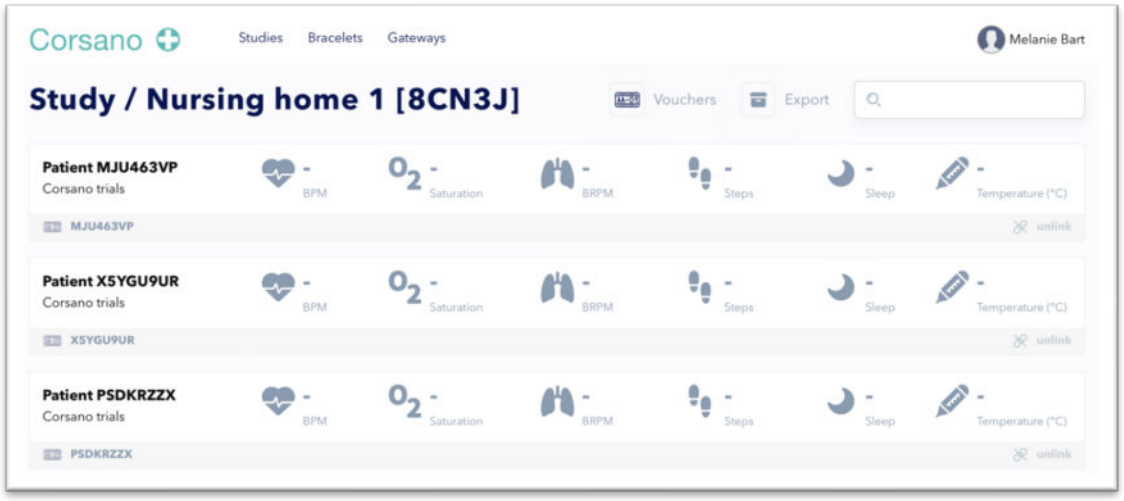
To begin, EL shall click desired Study in the Research Portal. This opens a Study dialog box.

Click on **Vouchers**. Enter required Study Participant number in the dialogue box. Click Add users.

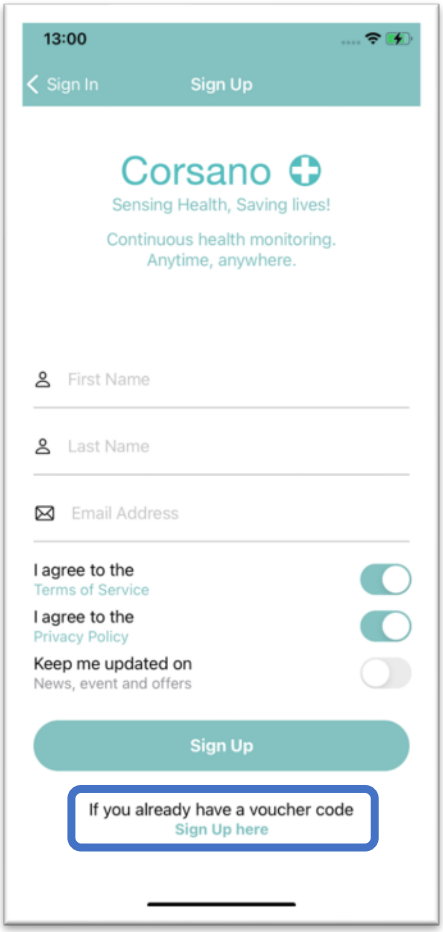


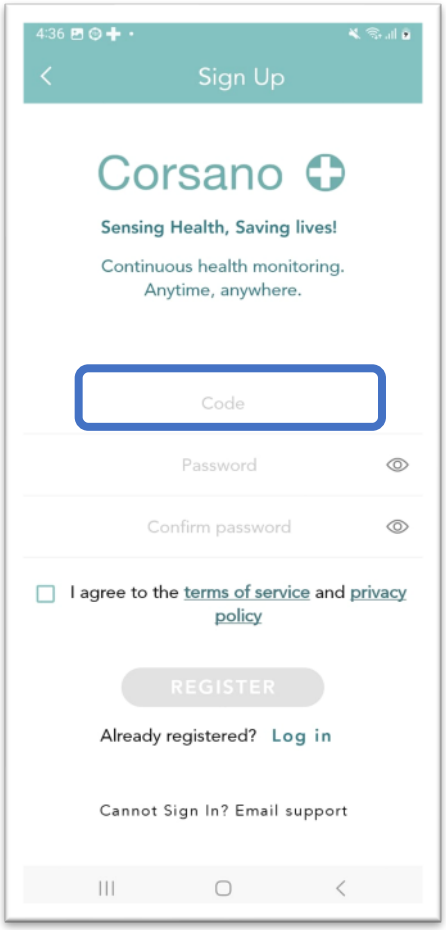
A list of Vouchers is created and can be exported as an XLS file. The resultant Participant Vouchers details are now associated with, and visible in the respective Study and Participant
Vouchers are ready to be shared by study admin / EL with potential Study Participants.

The generated Voucher code shall be used by Study Participant to login to the Corsano App to collect the Bracelet data. The data collected by the Study Participant using the Voucher code will be visible in the Portal under the same Voucher code.



Intended Study Participants should download and open the Corsano App on their smartphone.





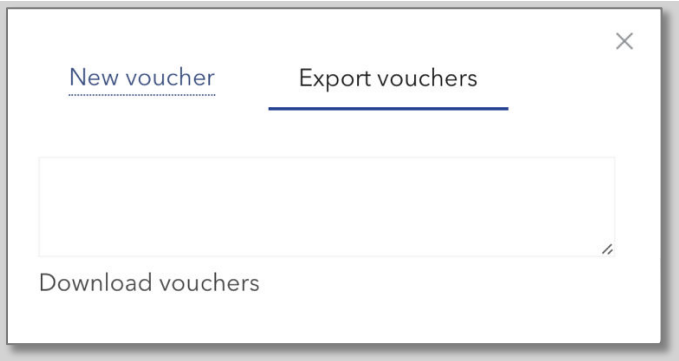
Study Participants with registration Vouchers should click Sign Up here, then enter the Voucher Code and Password of their choice.

The terms of service and privacy policy box should be checked next.

This activates the REGISTER button, which when pressed completes the registration steps.

9.2 Study Participant enrollment via QR Code

Corsano added QR Codes for vouchers. Via the Corsano Research Portal, it will be possible to download QR Codes for each Voucher. The QR Code has links to the Corsano App on the AppStore and GooglePlay, as well as the voucher code. Press 'Download vouchers':



Patient Letter

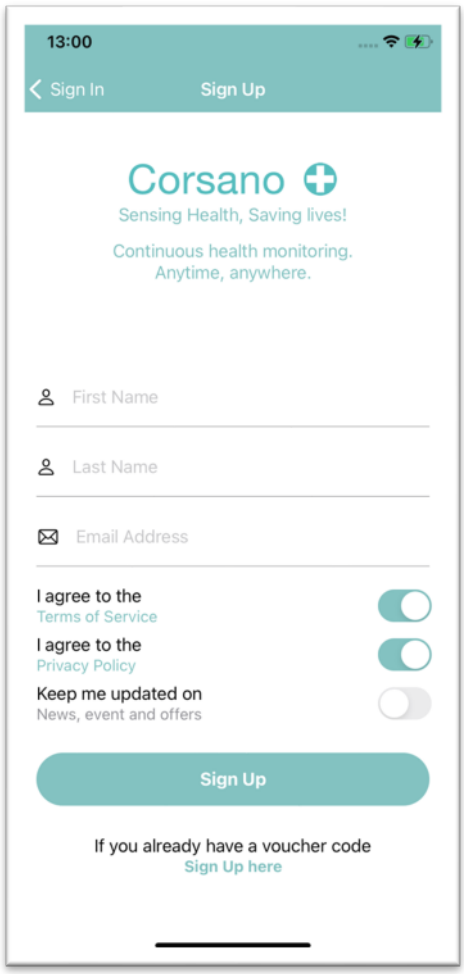
Moreover, there is a sample Patient Letter on the Portal. Principle Investigators can modify this letter directly on the Portal in a text editor. All letters for a study can be exported in PDF format so that they can be printed and send to patients.

The following is the default Patient Letter on the Portal:

> Dear Patient,
>
> Thank you for your participation in the study.
>
> Please find instructions to download the Corsano App and register your anonymized voucher code [VOUCHER CODE]. Please follow these steps:
>
> 1) Take your mobile phone and scan the QR Code with your camera:
>
> [QR CODE]
>
> 2) You will be directed to the Corsano App on the store. Please download and install the Corsano App on your phone.
>
> 3) Open the Corsano App on your mobile phone and press the [VOUCHER] button. You can now scan the QR Code again and your voucher code will be registered.
>
> 4) Please follow all instructions in the Corsano App to create a password and then pair the bracelet.
>
> Please contact us any time if you are having questions via: https://corsano.com/knowledge-base/
>
> Best regards,
>
> Your Research Team

9.3 Study Participant enrollment via email

Intended Study Participants should download and open the Corsano App on their smartphone.

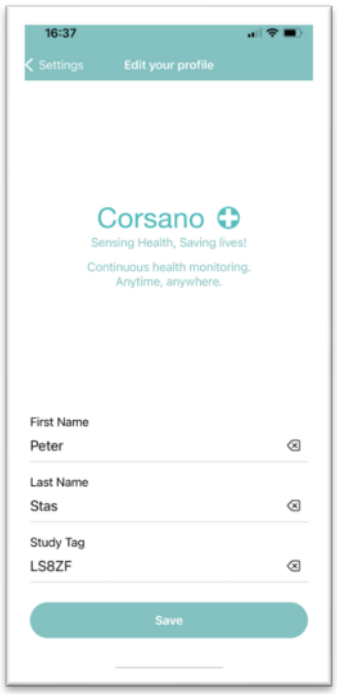


Once opened, the Corsano App displays a Sign-up page for Study Participants to enter First and Last Name and an email address.

Additional options can be selected using Slider Buttons:

1) The Terms of Service
2) The Privacy policy
3) Receiving updates on News, Events and others items

IMPORTANT:
Registration is only possible if Study Participant accepts the Terms of Service and the Privacy policy



A Confirmation Code is sent to the email address Study Participant has entered. This Code needs to be entered to complete the Registration process. The Study Tag can be entered at this stage.

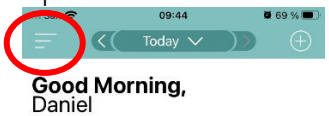
A Participant can now enter the Study Tag and pair their bracelet in the user profile found in the Settings screen. The Study Tag is generated from the Research Portal by the Evaluation Leader (EL) and provided to the Study Participant.

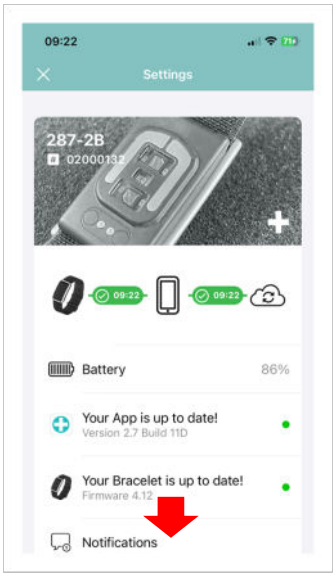
User profiles can be edited using the App's Setting link.

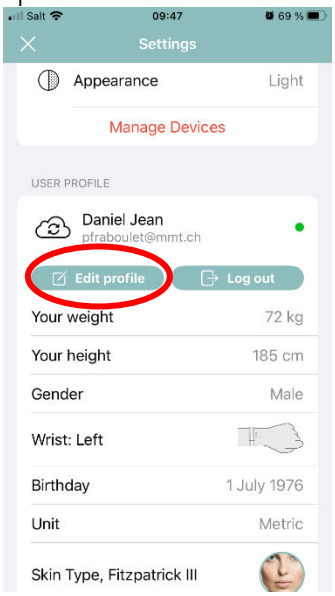
<u>Note:</u>
Bracelet have a unique ID. The EL should note the ID as bracelet is distributed to a Study participant.

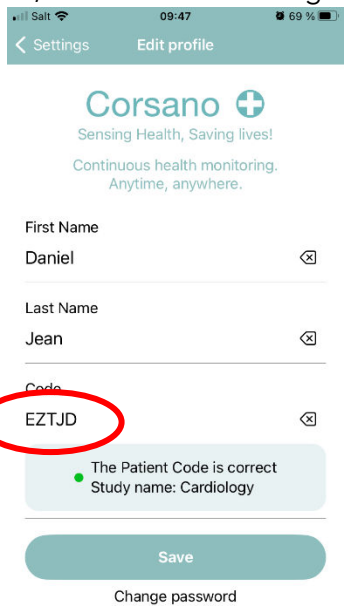
A video tutorial is available on this link:
https://corsano.com/knowledge-base/pair-your-cardiowatch-2/

User Profile and Study Tag can also be edited from the Corsano Trials App menu. To do so, they shall press the Menu icon in the Top Left corner of the main screen, scroll down to Settings









10 ECG Recording

An important step in assessing health status is based on the proper collection of electrocardiogram (ECG) data. The Corsano Bracelet and System provide a best-in-class approach to achieve this. The ECG data collection process lasts about 40seconds. In addition to the Bracelet and Phone, a comfortable chair and table are required for the recording.

To begin:

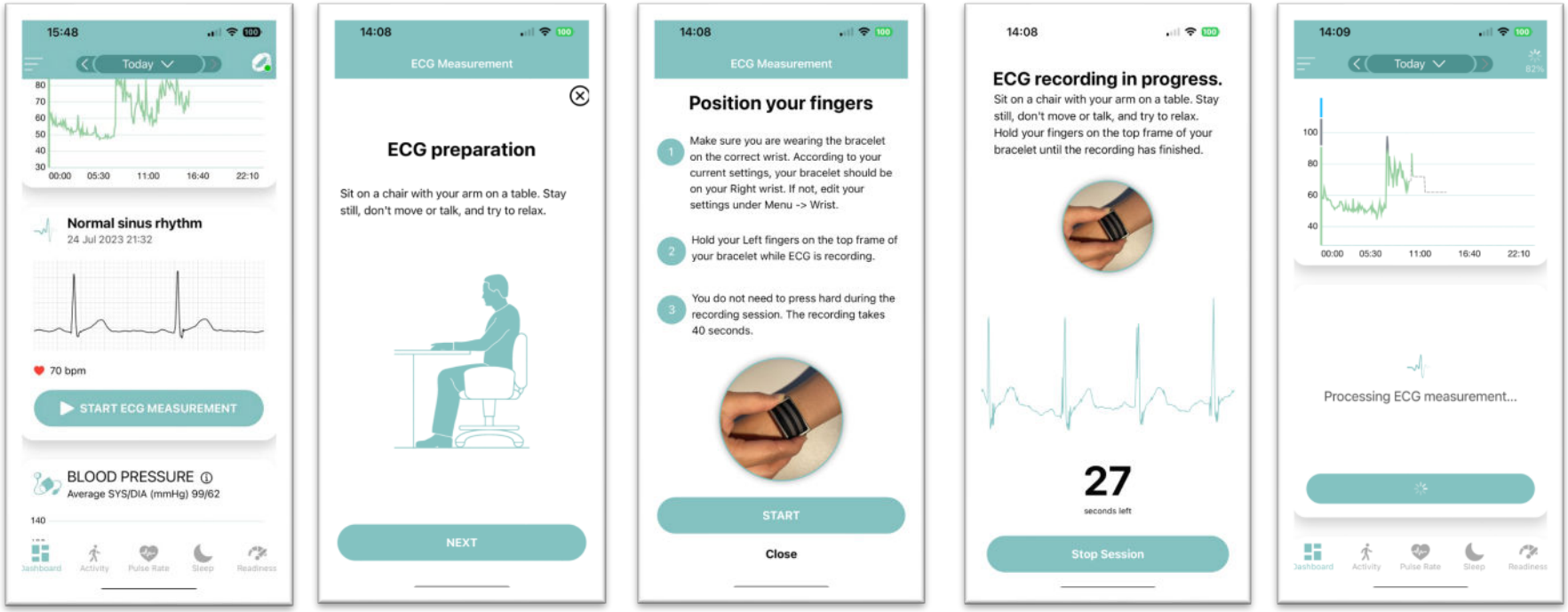
1) Sit in chair and place your arms on the table
2) Open the Corsano App. In the App Dashboard menu click START ECG MEASUREMENT
3) Check position of the Corsano Bracelet and adjust as needed.
4) Follow screen prompts. Remain still and relaxed to optimize signal collection.

Once the recording step is complete, the Corsano software processes the collected ECG data. This step may take several seconds to complete.

Key steps are illustrated in the Corsano App.
More details on the correct wearing of the bracelet can be found here:
https://corsano.com/knowledge-base/wearing-your-bracelet/

An additional Tutorial Video can be found here:
https://corsano.com/knowledge-base/movies/

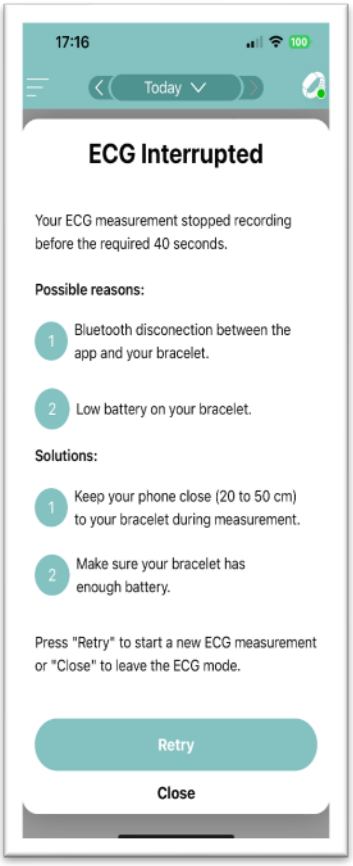
10.1 Illistration of the ECG process as provided by the Corsano App.



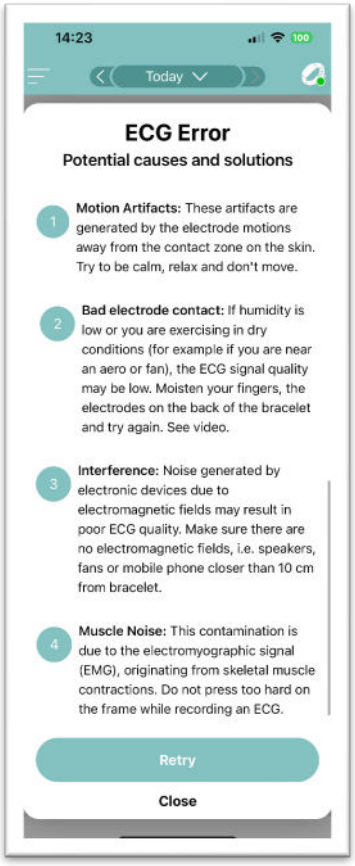
11 Troubleshooting ECG Data Collection issues

Three common problems are seen when collecting ECG data for monitoring.
The Corsano App provides information to the user based on each of the possible conditions.
In the case where the problem persists, please call the helpdesk.

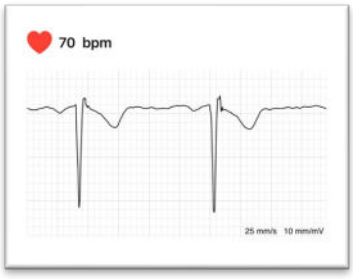
1) Interrupted ECG



2) An ECG Error

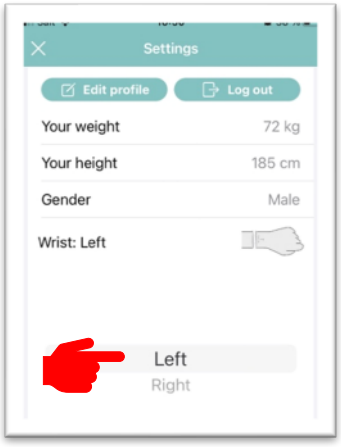


3) An Inverted ECG



Likely cause is bracelet is worn on the wrong wrist.
Switch wrists and retry

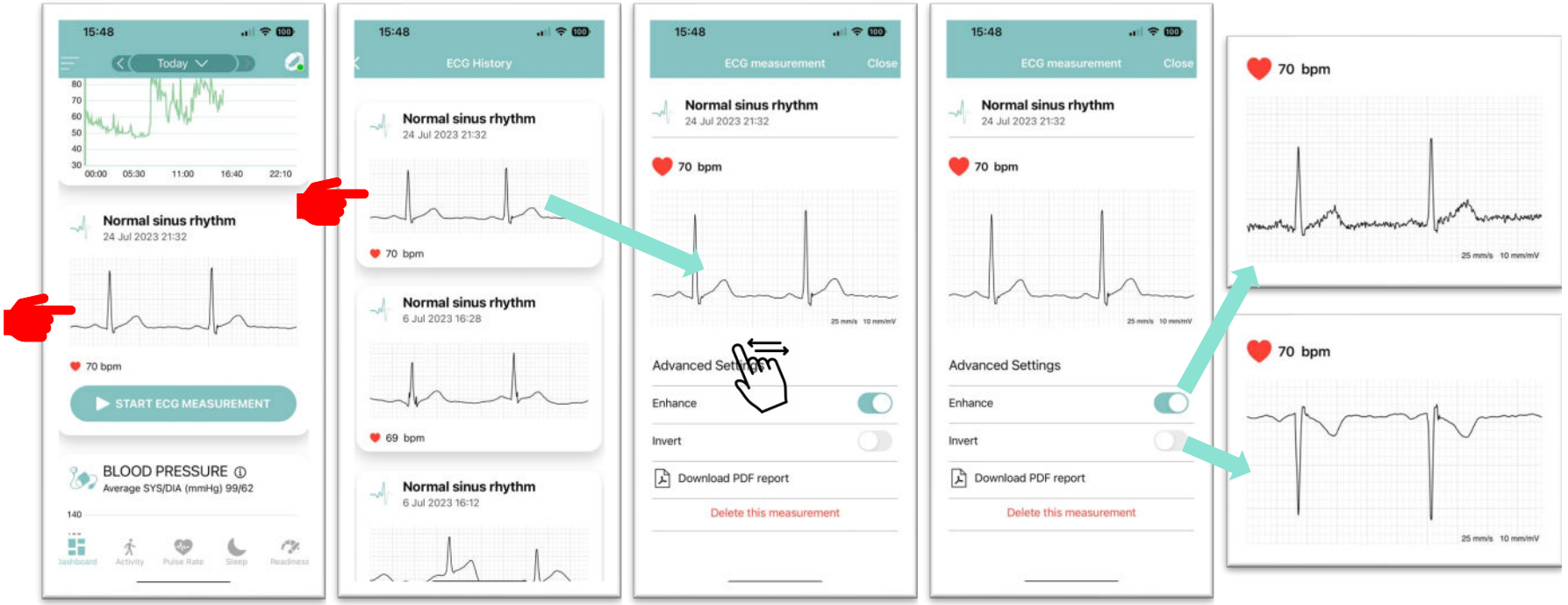
Alternative Approach:
Use App to select correct wrist



From the App Dashboard, select Menu Icon (top left corner), scroll to User Profile and then edit Wrist

12 ECG - App Results

The following are steps to obtain ECG histories and examples of ECG data results provided via the Corsano App.



Access the history of an ECG recordings by pressing the ECG window in the APP Dashboard,

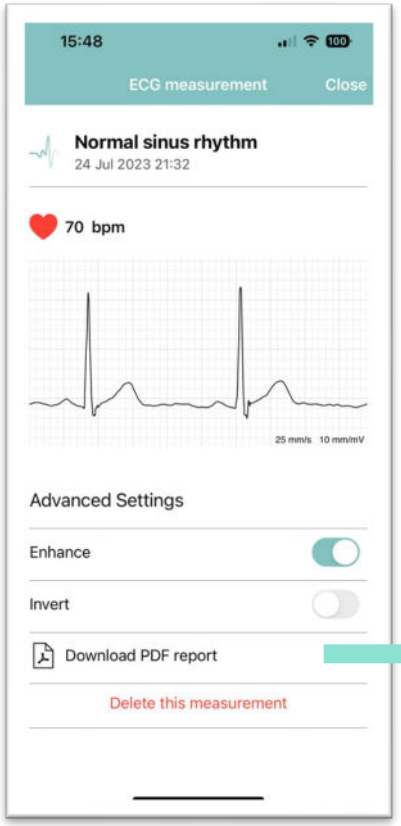
Select recording by tapping on it.

Swipe left and right to scroll through the recording.

The "Enhance" button shows the filtered or unfiltered signal.
The "Invert" button shows the inverted signal.

13 ECG - Analysis Report

The following are additional options available for working with the ECG data via the Corsano App.



Pressing the download PDF report initiates the PDF report process.

ECG Analysis Report

Cardiolyse CE0197

Patient Info		Recording Info	
First Name		Start time	19:33 24-07-2023
Surname		End time	19:33 24-07-2023
Date of birth	24 Jul 1984	Duration	31s
Age	39	Analysis time (UTC)	19:33 24-07-2023
Sex		Device ID	
Patient ID		Number of leads	1

Signature

Sinus Rhythm Details	
Total sinus rhythm beats	36 (100%)
Tachycardia	0 time(s)
Tachycardia duration	0s (0%)
Longest Tachycardia	s at
Fastest Tachycardia	bpm at
Bradycardia	0 time(s)
Bradycardia duration	0s (0%)
Longest Bradycardia	
Slowest Bradycardia	
Pause	0 time(s)
Longest Pause	
Sinus arrhythmia	0 time(s)
Longest sinus arrhythmia	

Ventricular Ectopy		Supraventricular Ectopy	
Total VE beats	0 (0%)	Total SVE beats	0 (0%)
Single VE	0	Single SVE	0
VE Bigeminy	0 time(s)	SVE Bigeminy	0 time(s)
Longest VE Bigeminy		Longest SVE Bigeminy	
VE Trigeminy	0 time(s)	SVE Trigeminy	0 time(s)
Longest VE Trigeminy		Longest SVE Bigeminy	
VE Couplet	0 time(s)	SVE Couplet	0 time(s)
VE Triplet	0 time(s)	SVE Triplet	0 time(s)
VT	0 time(s)	SVT	0 time(s)
Longest VT		Longest SVT	
Fastest VT		Fastest SVT	

A detailed PDF report is generated by the Corsano Platform. The platform leverages a cloud-based, CE MDR-certified algorithm developed by Cardiolyse

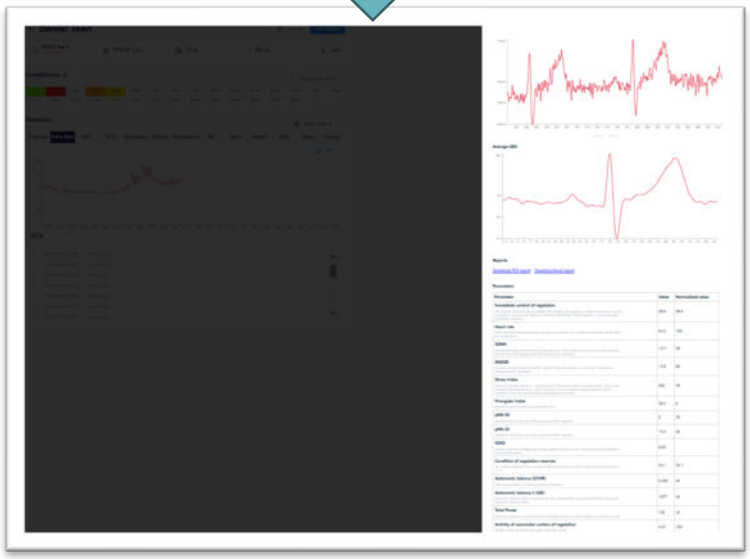
Cardiolyse

⚠

CAUTION: Once delete a deleted measurement cannot be undone.

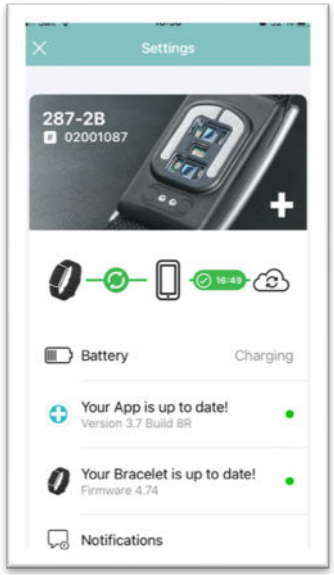
14 ECG – Results in the Corsano Portal

Go to the Pulse Rate tab, scroll down and select a record



15 NIBP – Pairing the BP Cuff

The following describes the steps to pair the blood pressure cuff to enable non-invasive blood pressure (NIBP) measurement capabilities



In the Dashboard, select the Menu icon, in the top left corner.

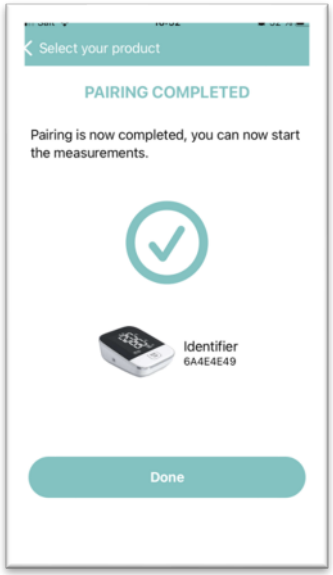
Scroll down to reach “Manage Devices”.

Press “Blood Pressure Cuff”

Press the “Start Paring” button

Do not press the “START” button on the BP Cuff monitor.

If the BP device does not connect, press “Cancel” to abort the current pairing process and restart the process.



Once the Corsano APP detects the BP monitor, it will show a unique identifier number.

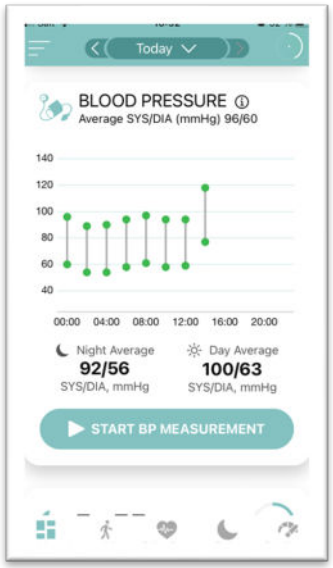
Verify this is your BP monitor by checking your BP monitor unique identifier number located on the back of the BP device.

Press the “Done” button.

16 NIBP – Calibration.

16.1 Bracelet Preparation

A tutorial video can be found here: https://corsano.com/knowledge-base/movies/



From the App Dashboard view, press "START BP MEASUREMENT".

Tick the box if you take medication to lower Blood Pressure.

Make sure a Blood Pressure Cuff is paired to your Corsano APP.

Follow the instructions to properly position the bracelet.

Follow the instructions to properly adjust the tightness of the bracelet.

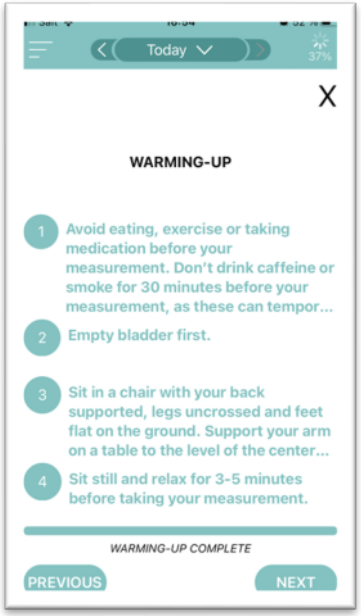
16.2 Properly positioning and preparing the arm

A tutorial video can be found here: https://corsano.com/knowledge-base/movies/

Make sure the Blood Pressure Cuff is powered with internal batteries or an external USB cable plugged to a power source.

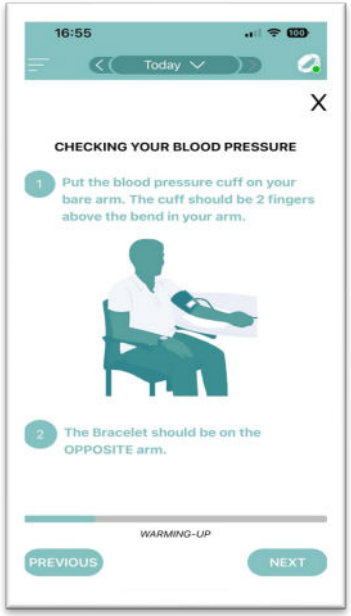
⚠

Wear the Blood Pressure Cuff and the Corsano Bracelet on **opposite arms!**

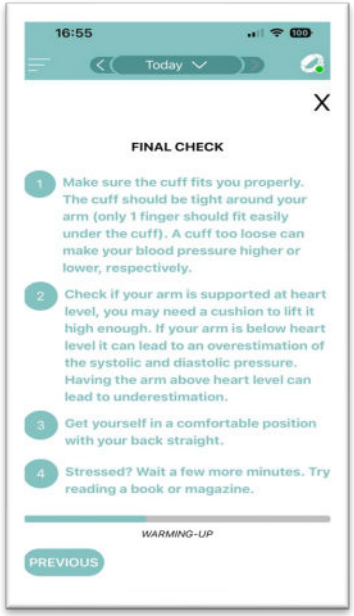


Prepare for the Blood Pressure Cuff measurement.

Sit and follow the instructions.



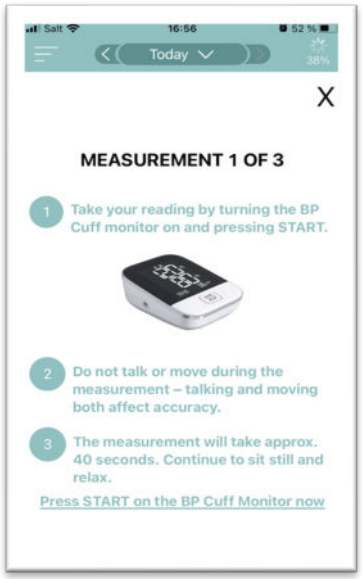
Rest your **arm** on a table at the **same level as your heart**.



Check the tightness of the Cuff. Sit still, don't move and relax.

16.3 Blood Pressure Cuff Monitor measurements

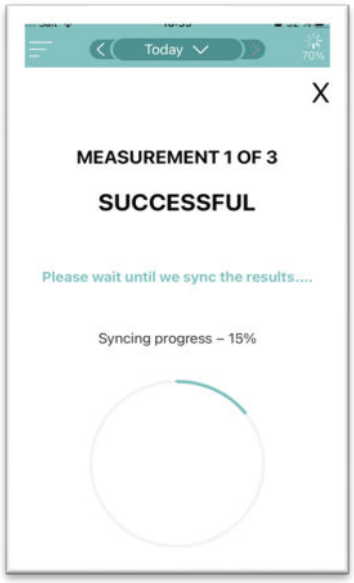
A tutorial video can be found here: https://corsano.com/knowledge-base/movies/



Press the "START" button on the Cuff monitor.

The Cuff will inflate and measure your Blood Pressure.

Wait for the measurement step to finish. This takes about 30s.



A data synchronization step is required with the BP Cuff and the Corsano App.

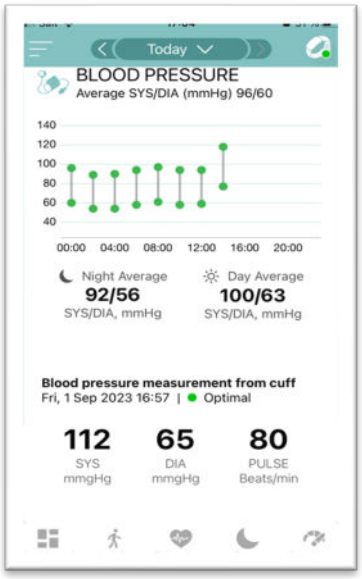
This takes about 30s. Once completed, a new BP measurement is possible.

A total of **3 BP readings** with 30s intervals between readings are required for proper calibration,

App will indicate progress against the required number of readings

Repeat BP measurement as instructed by the Corsano App

Calibration step will be automatically aborted and will need to be restarted if time between intervals is exceeded or interrupted.



Non-Invasive Blood Pressure (NIBP) is calibrated once third BP measurement is completed. Result is available in the APP.

Non-Invasive Blood Pressure (NIBP) calibration with the external BP Cuff should be performed once per month.

Always follow the Corsano APP instructions

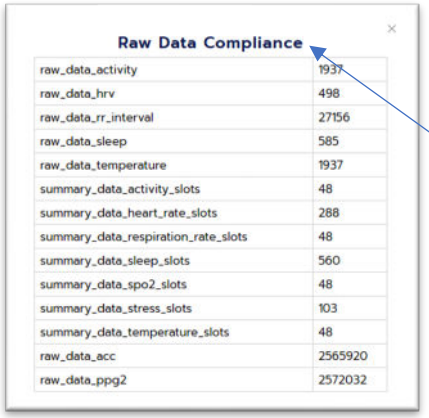
17 Monitoring a Study

Once a participant has signed up via the Corsano App, permitted User(s) can monitor Participant activity on aggregated level or at a single patient level by clicking the desired patient identifier via the Corsano Research Portal

18 Data Collection Compliance

The patient compliance module in the Corsano CardioWatch system offers insight in the continuous data that is stored in the Corsano Health Cloud. Principle Investigators can set limits and receive alerts if data from a patient is below the minimum number of datapoints. This module involves several key features.

By clicking on the info icon, the list and numbers of collected data, for the selected day, pop up. This includes all metrics, summary and raw data.



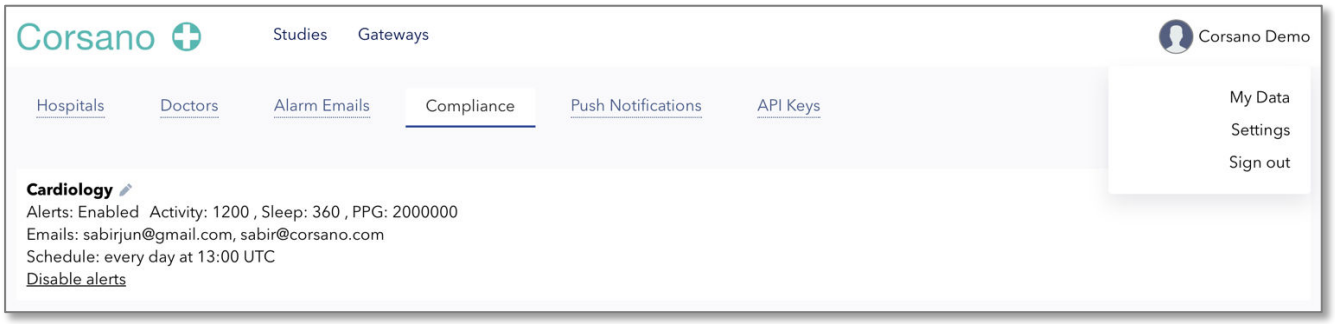
In the calendar, each day is given a color code, representing the % of collected Pulse Rate data over 24h.

18.1 Customizable Alerts

To support compliance, the system can send customizable alerts to the Principle Investigator or HCP. This ensures that they are notified daily if data from a patient is below the minimum a number of datapoints.

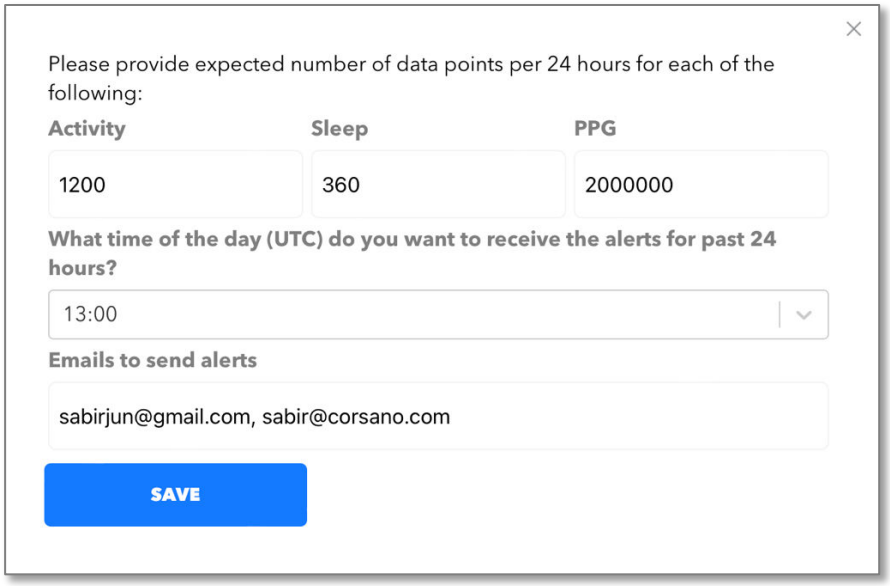
Setting Limits

Click on the Account in right upper corner and select Settings. Then choose Compliance:



The limits for the alert may be adjusted by pressing on the icon right next to 'Cardiology' (name of the study).

Minimum daily datapoints can be set for the Activity File (includes a.o. Pulse Rate, Respiration rate, SpO2), Sleep and raw PPG. These minimums can be set for each study.



Activity

The Activity File is the main datafile in the CardioWatch System and includes a.o. PR, SpO2, Respiration Rate, Steps. Activity Files by default arrive 1/min when 1/min is set in Study Settings. In other words, if the study has a frequency set at 1/min, the Activity File will be generated each minute. Consequently, in 24 hours there will be 60 min * 24 hr = 1'440 datapoints. Please note that every 30 min, the CardioWatch Bracelet also records and saves 2 min at 128 Hz, resulting in an extra 6 * 2 = 12. Hence the maximum for the day is 1'452 datapoints.

Please note that limits may be set at 80% to avoid getting an alert when i.e. patients take the bracelet off when they are under the shower or for when they charge the bracelet.

Sleep

By default, sleep is recorded at 1/min. A minimum of 6 hours of sleep will generate 60 * 6 = 360 datapoints per day.

PPG

Finally, the minimum number of PPG datapoints can be set. Typically, PPG is recorded at 32Hz resulting in 32 * 60 sec * 60 min * 24 hours = 2'764'800 datapoints per day.

Time Alert
Set time for when the system should send a Compliance Alert

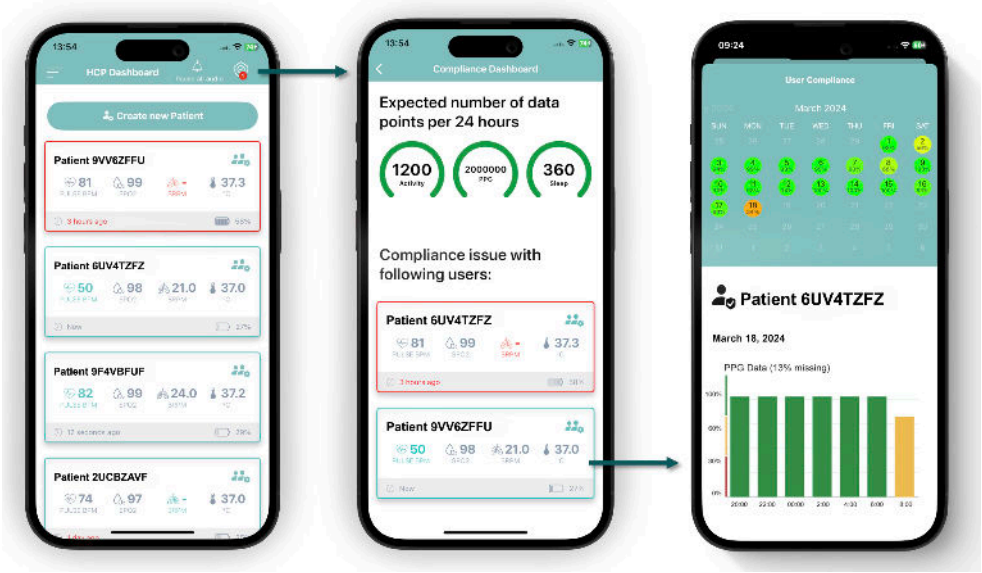
Emails
Type emails where the alert should be send separated by commas. Multiple emails are possible.

Compliance Alert
The Corsano System will send a Compliance Alert every day indicating which patient metric is below the set number of datapoints. The following is an example alert email:

Date: 2023-09-06 01:00:00 (UTC) - 2023-09-07 01:00:00 (UTC)

Name	Type	Actual value	Expected value
Peter Smith	Sleep	325	400
Peter Smith	PPG	0	2000000
Alison Boyd	Sleep	325	400
Alison Boyd	PPG	0	2000000
Atanur Deloitte	Activity	0	1800

Compliance Dashboard in the HCP App
Compliance can be easily followed in the HCP App



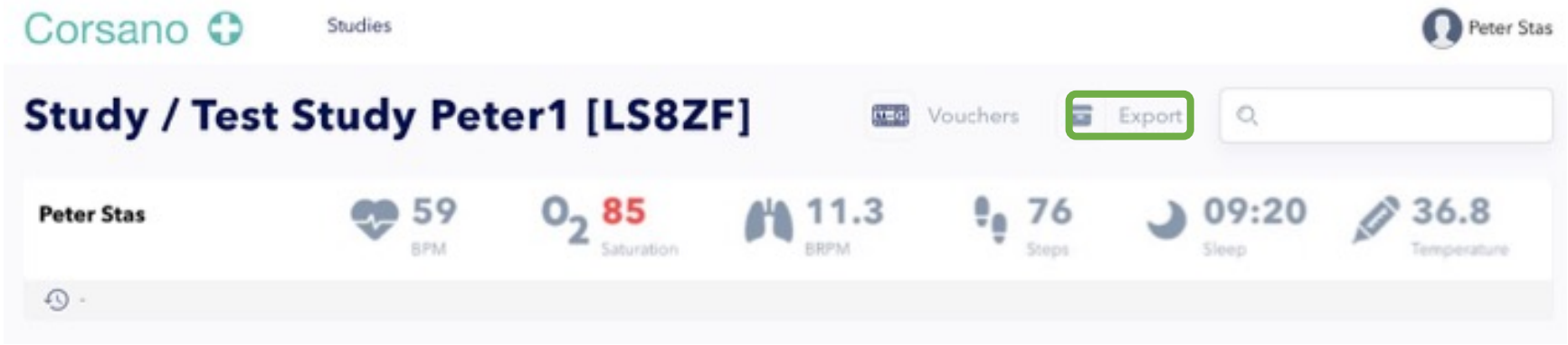
19 Battery Life

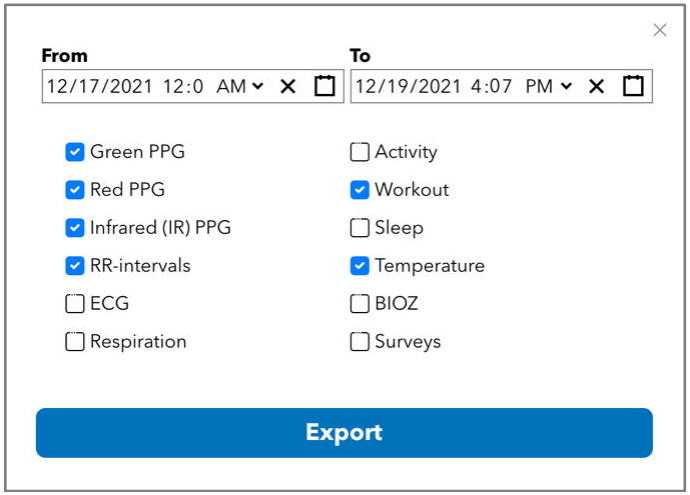
The following table describes how measurements using the Corsano Bracelet currently impact its battery life. Corsano continues to innovate in how to optimise Bracelet battery use, therefore please check the Corsano Website for updates to this data;
https://corsano.com/knowledge-base/set-your-vital-parameters-in-the-study-portal/

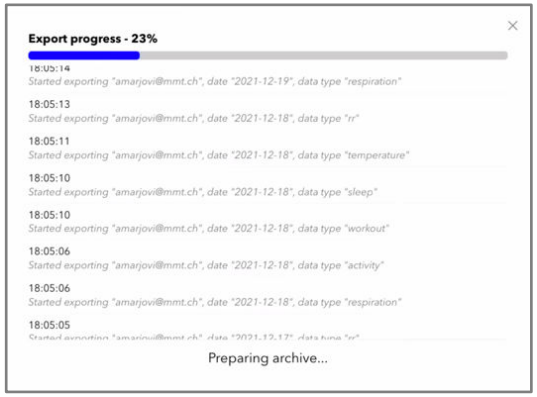
Remote Patient Monitoring						
Autonomy (days)						
No Raw Data to Cloud						
	Activity (steps, calories, speed, activity type)	**HR, RR, BRPM (PPGG Intermittent)**	**SpO2 (PPG G/R/Ir Intermittent, 32Hz)**	**Sleep (PPGG Continuous, PPGR/Ir Intermittent)**	**Emography (Continuous)**	**BP (PPG G/R/Ir Intermittent, 128Hz) in development**
1/hour	15	10	7	6	4	5
1/30min	14	9	6	5	4	5
1/min	13	7	4	4	4	N/A
1/sec	12	6	4	N/A	4	N/A
Raw Data Recording						
	ACC	**PPG G Continuous**	**PPG G Continous, PPG R/Ir Intermittent**	**PPG G/R/Ir Continuous**	**BIOZ**	
25Hz	N/A	N/A	N/A	N/A	3	
32Hz	9	5	4	3	N/A	
128Hz	N/A	3	3	2	N/A	

20 Data Exports – Study Level

Data **export** for all Study Participants and for multiple days is possible from the respective Study entry in the Corsano Research Portal.







21 Data Exports – Participant Level

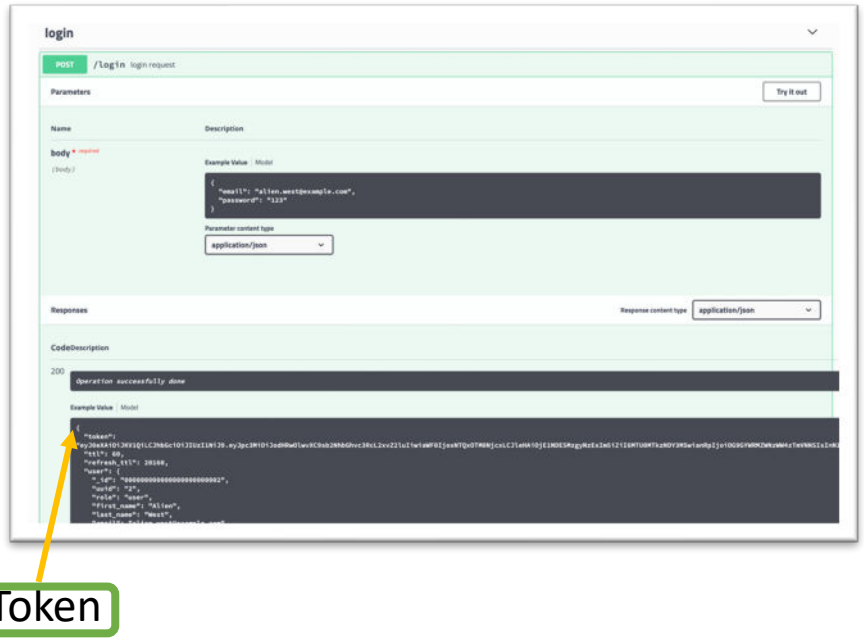
Data can be **exported** for an individual Participant and for each Vital Parameter

22 REST API and Token Refresh (Authentication Data)

With same Portal account credentials (registration email and password), you can get an access token, see LOGIN request in API documentation

Note: The Rest-API requires an annual license, please contact Corsano.

Detailed information on Corsano's Rest-API is available at the following location: https://api.users.cloud.corsano.com



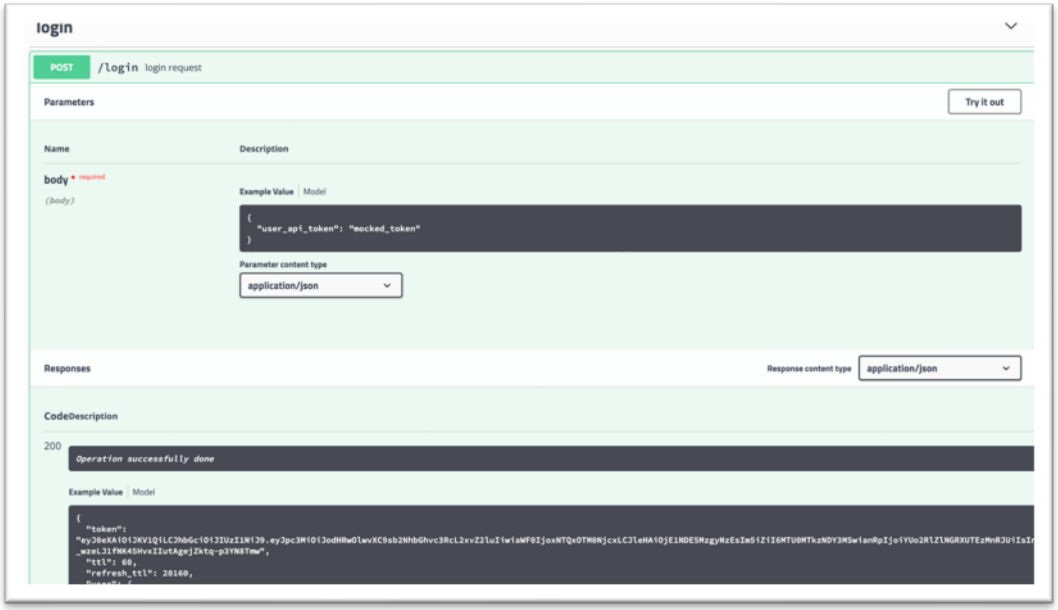
NOTE:

Token must be REFRESHED every 30 minutes with this request

<this step is often overlooked>

23 REST API – Get Health Cloud Token (Health Data)

Exchange Users Cloud Token to Health Cloud Token by making LOGIN request to Health Cloud
Note: The Rest-API requires an annual license, please contact Corsano.
Detailed information on Corsano's Rest-API is available at the following location: https://api.health.cloud.corsano.com



NOTE:
Token must be REFRESHED every 30 minutes with this request
<this step is often overlooked>

24 General Information and Support

The following is a list of relevant details that can be leveraged by Corsano Users and Study Participants.

General:	
Corsano Knowledge Base:	https://corsano.com/knowledge-base/
Video tutorials:	https://corsano.com/knowledge-base/movies/
Study Portal:	https://study.corsano.com
Web Portal:	https://portal.corsano.com

Additional details:

Indication for Use (IFU)	
Bracelet:	https://corsano.com/knowledge-base/ifu-cardiowatch-287-2b/
Research Portal	https://corsano.com/knowledge-base/ifu-research-portal/
Certificates	24.1.1.1 https://corsano.com/knowledge-base/certificates/
Cardiolyse	24.1.1.2 https://www.certipedia.com/companies/635128/system_certificates?locale=en

API documentation	
Users Cloud API:	https://api.users.cloud.corsano.com
Health Cloud API	https://api.health.cloud.corsano.com

For Support related questions:

Support	Technical Support: philippe.fraboulet@corsano.com Admin Support: ademir@corsano.com