

Corsano Research Portal Onboarding Manual



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2. Welcome to Corsano's Research Platform

We are very pleased that you have chosen to work with the Corsano Research Platform, 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 Research Platform 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:

The Corsano App has been published <u>in Europe</u>. 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

Outside Europe

TestFlight and Firebase distribution while awaiting FDA 510k regulatory clearance





https://appdistribution.firebase.dev/i/34605ad0b0874fb9



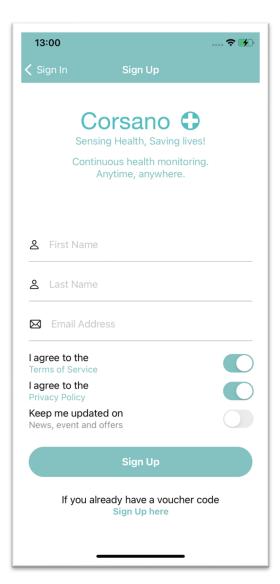


https://testflight.apple.com/join/cuAOjWGs

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

4. Registering on the Corsano Research Platform

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

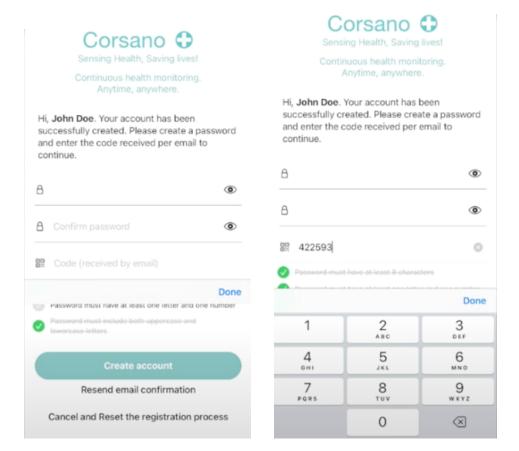
<u>IMPORTANT</u>: Users will not be able to register on the Corsano Research Platform if User chooses not to accept the Terms of Service and the Privacy policy.

A 6-digit Confirmation Code will be sent to the Userspecified 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.



Complete your profile Enter details about your profile to keep track of your stats over time. You can also skip this for now and complete later. Your weight 75 kg Your height 175 cm Gender Male Wrist Left Unit Metric Birthdate 1 January 1970

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:

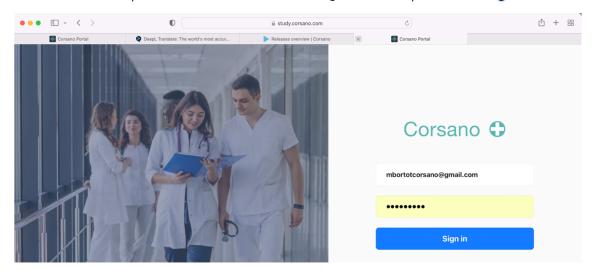
Continued EL User Research Portal and Study access is linked to valid Corsano Subscription(s). Approved Study Participants may be assigned by an EL to more than one study at a time.

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.

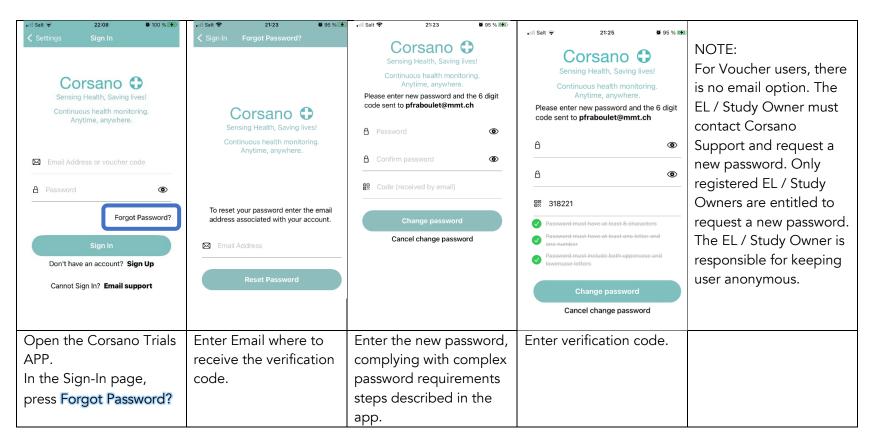


On successful login, the following Home screen is visible to User:



6.2. Account Recovery:

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



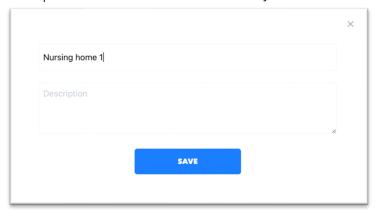
7. Creating a Study

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:

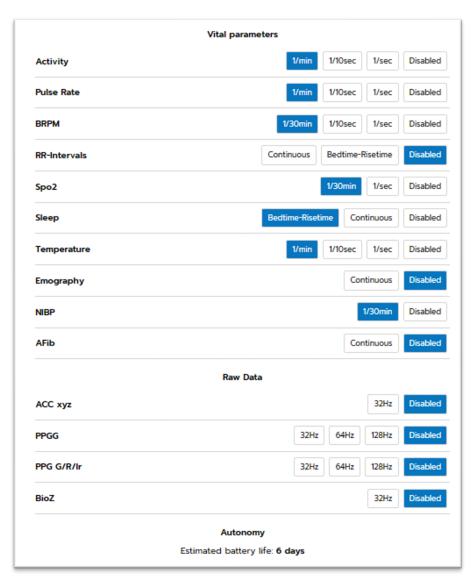
Study name can be edited using the **Pencil**. Study can be customized further using the **settings**.



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.

NOTE:

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

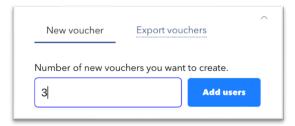
9.1. Anonymous enrollment via Voucher

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

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



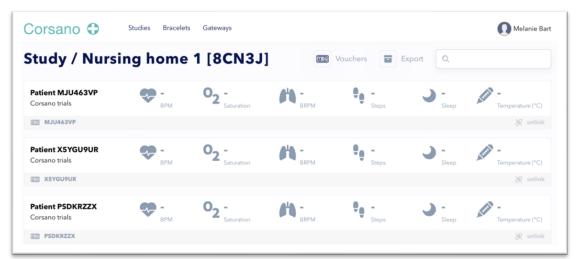
Click on Vouchers. Enter required Study Participant number in the dialogue box. Click Add users.



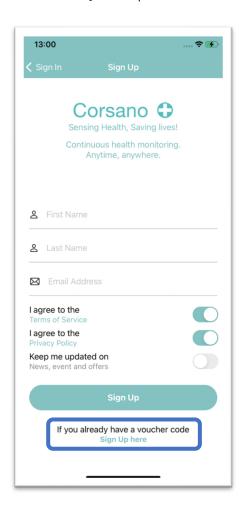
A list of Vouchers is created and can be exported as an XLS file. The resultant Participant Vouchers details are now associated with, and visible in the respective Study and Participant Vouchers are ready to be shared by study admin / EL with potential Study Participants.

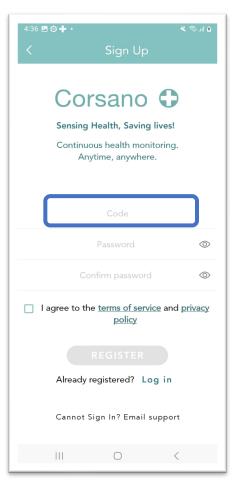


The generated Voucher code shall be used by Study Participant to login to the Corsano App to collect the Bracelet data. The data collected by the Study Participant using the Voucher code will be visible in the Portal under the same Voucher code.



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.

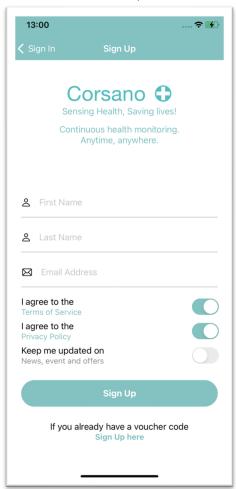
The terms of service and privacy policy box should be checked next.

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



9.2. Study Participant enrollment via 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.

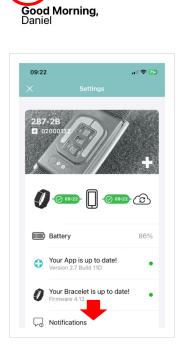
Note:

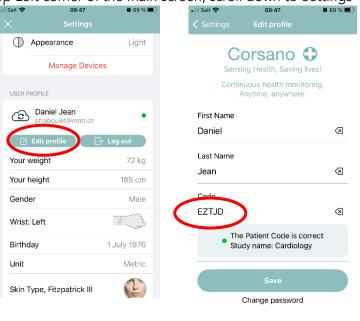
Bracelet have a unique ID. The EL should note the ID as bracelet is distributed to a Study participant.

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 Research Platform 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.

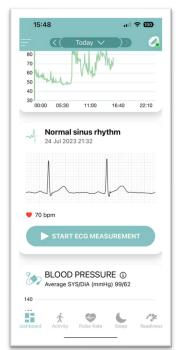
Key steps are illustrated in the Corsano App.

More details on the correct wearing of the bracelet can be found here:

https://corsano.com/knowledge-base/wearing-your-bracelet/

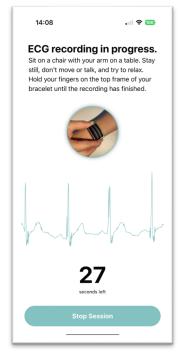
An additional Tutorial Video can be found here: https://corsano.com/knowledge-base/movies/

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













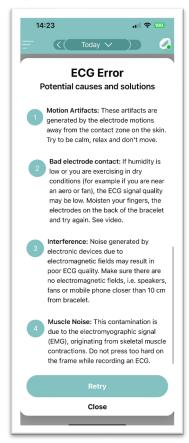
11. Troubleshooting ECG Data Collection issues

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

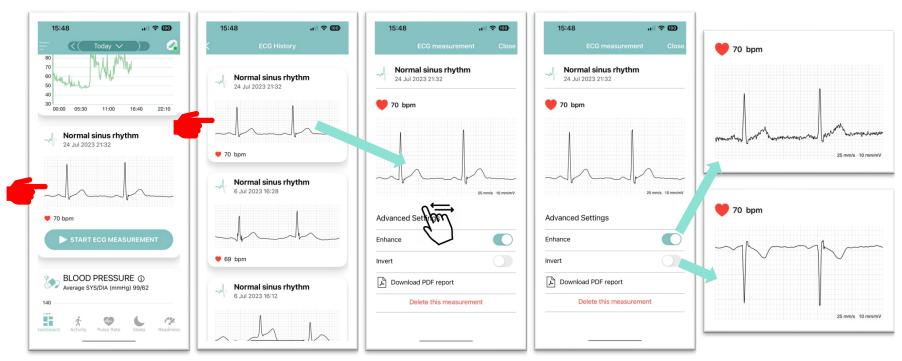


From the App Dashboard, select Menu Icon (top left corner), scroll to User Profile and then edit Wrist



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.

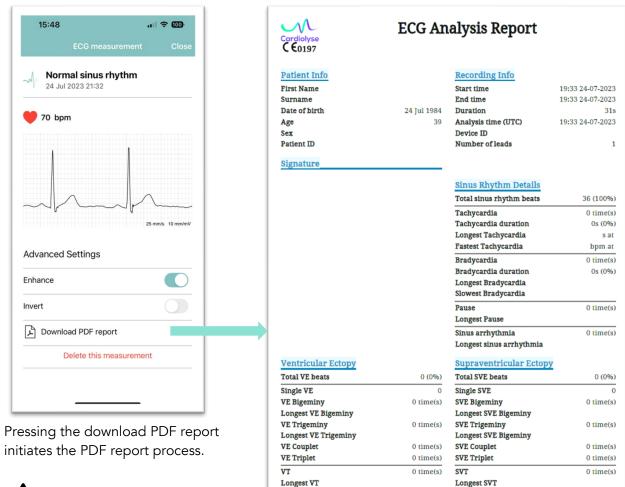
The "Enhance" button shows the filtered or unfiltered signal.

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.



Fastest VT

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



initiates the PDF report process.

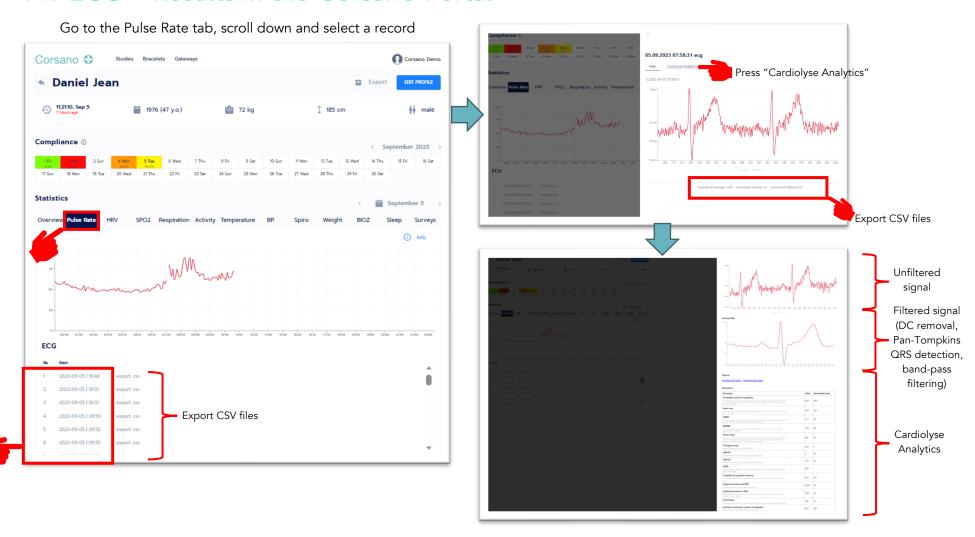


CAUTION: Once delete a deleted measurement cannot be undone.

Fastest SVT



14. ECG – Results in the Corsano Portal





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".



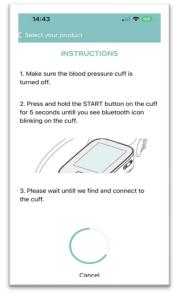
Press "Blood Pressure Cuff"



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.

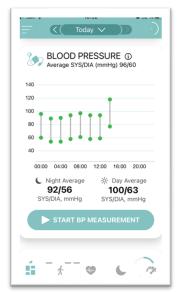
Press the "Done" button.



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 <u>internal batteries</u> or an external <u>USB cable</u> plugged to a power source.



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

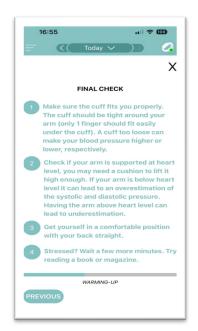


Prepare for the Blood Pressure Cuff measurement.

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.

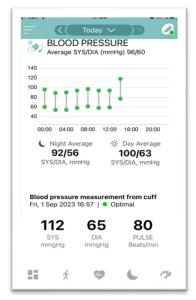
This takes about 30s. Once completed, a new BP measurement is possible.

A total of <u>3 BP readings</u> 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.



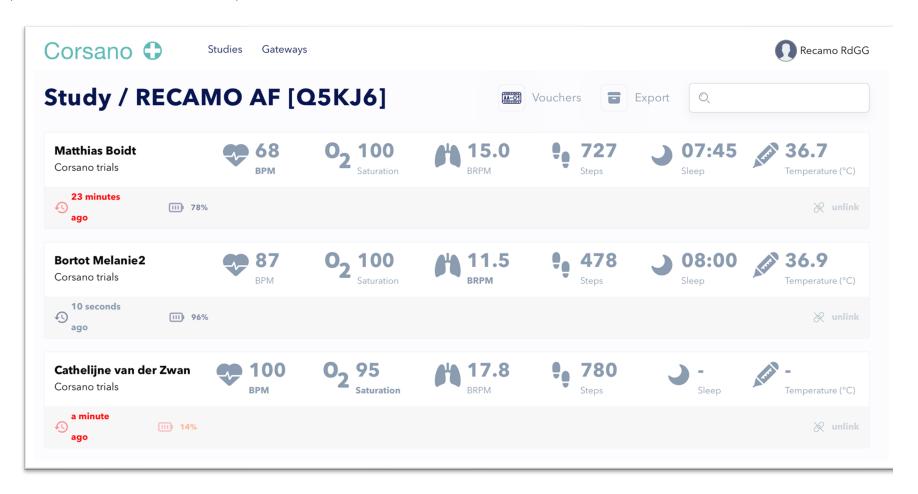
Non-Invasive Blood Pressure (NIBP) calibration with the external BP Cuff should be performed once per month.

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

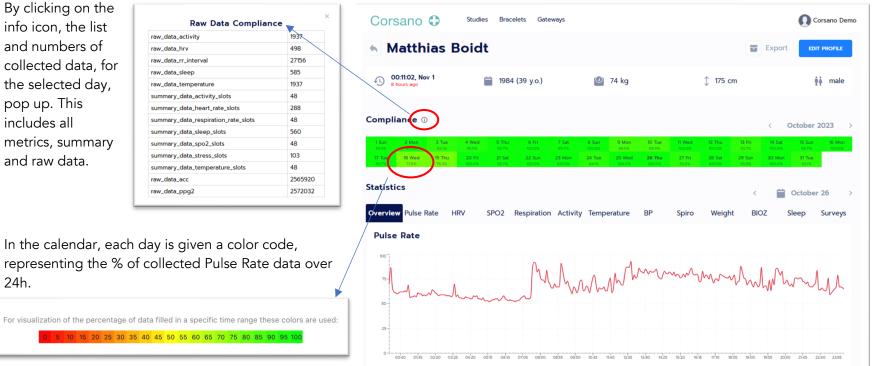




18. Data Collection Compliance

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.

24h.





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/

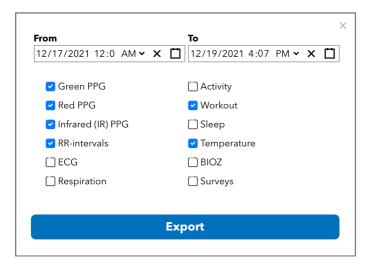
Remote Patient Mo	onitoring					
Autonomy (days)						
No Raw Data to Cloud						
	Activity (steps, calories, speed, activity type)	HR, RR, BRPM (PPGG Intermittent)	SpO2 (PPG G/R/Ir Intermittent, 32Hz)	Sleep (PPGG Continuous, PPGR/Ir Intermittent)	Emography (Continuous)	BP (PPG G/R/Ir Intermittent, 128Hz) 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	

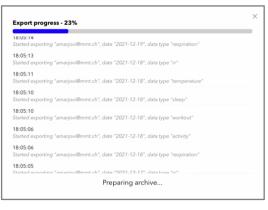


20. Data Exports – Study Level

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



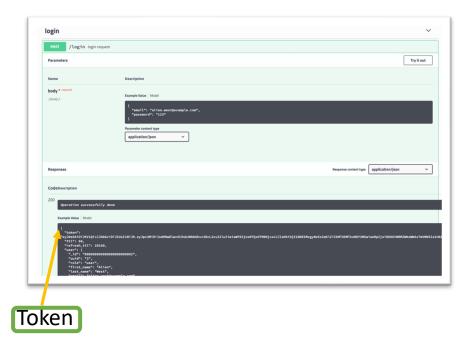


22. REST API and Token Refresh (Authentication Data)

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:

<u>Token must be REFRESHED every 30 minutes with this request</u>

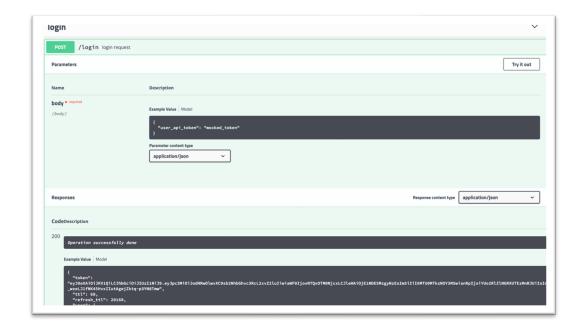
step is often overlooked>



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.

<u>General:</u>	
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/
ISO certificates	
Cardiolyse	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:

Technical Support: philippe.fraboulet@corsano.com

Support Admin Support:

ademir@corsano.com