



Logging in and account settings

You can find the Beat2Phone ECG Cloud Service at https://www.beat2phone.net

Select language between English and Suomi (Finnish) prior to login.

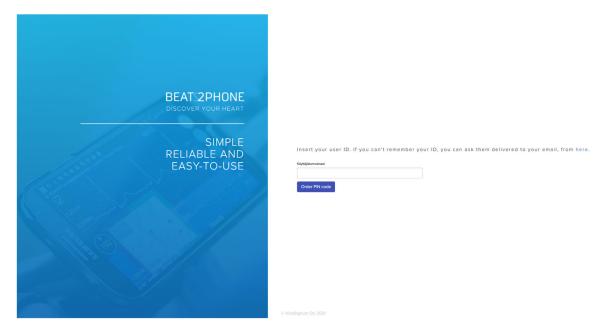
To log in to the cloud service, use the username and password that you have created in the Beat2Phone ECG mobile application. If you try to log in with a wrong password too many times in a row, your user account will be locked for security reasons. You cannot log in to the cloud service or the mobile application with a locked account, you must unlock the account first. The account can be unlocked be following the instruction below, that are also used to restore a forgotten password.



If you have forgotten your password or if your account is locked, choose "Forgot password?" next to the login button. By inserting your user id, the system will send you a PIN code to reset your password. The PIN code will be sent to the email that you used to create your user profile. Password must be at least 6 characters long, and special characters are allowed.







If you cannot remember your user ID, you can order a list of your usernames to your email by clicking the link that says "here".

Insert your user ID. If you can't remember your ID, you can ask them delivered to your email, from here.

A form to input your email opens. By inputting the email that you used to create your profile, the system sends your username(s) to your email.

After successfully logging in, you can change your account settings from the "Account" button in the top right corner.

Account

Activating the purchased license

You can optionally purchase a license for cloud storage¹ and algorithm analysis for the ECG recordings.

NOTE: The license requires the new Beat2Phone ECG sensor- CE_{0598} . It cannot be used with the old Beat2Phone sensor.

To activate your purchased license, log in to the Beat2Phone ECG web service with the profile you wish to use the analytics service² on. After logging in, open your account settings from the "Account" button as instructed earlier. Choose "Add license code" and enter your license key. The license should now be activated.

NOTE! You must also restore the profile in the mobile application before taking any new recordings after the license activation. Go to mobile application PROFILES select NEW PROFILE, select RESTORE

¹ Cloud storage is free for customers that have previously purchased the consumer version of the sensor.

² Analytics service is provided by Cardiolyse CE₀₁₉₇-marked software algorithm

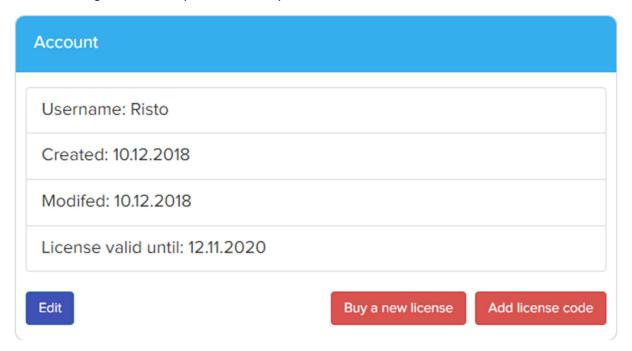




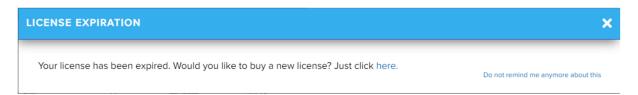
and enter the profile username and password. Only after this the recordings for the profile are stored to the cloud service.

When the license is active, the analytics service will analyze any new recordings that you upload to the cloud.

After the license has expired, you can still access the cloud service and view your old recordings, but new recordings will not be uploaded or analyzed.



If your license has expired the web GUI will remind you to renew. Note that recordings made while having no valid license will not be uploaded and analysed retrospectively, so to avoid service cuts renew the license in time.

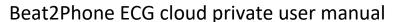


Click the renewal link which will take you to the VitalSignum web-shop for purchasing a new service license. Once the new license is activated the reminder will no longer be shown. New license time will be added on top of the existing license period, so you can renew the license in advance of the expiration of your current license.

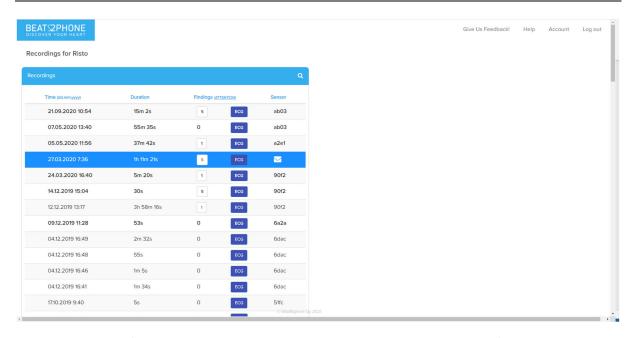
Measurement list view

After logging in, you will see a list of your measurements.









You will see a list of ECG measurements. The measurements have been named after the measurement date and measurement time. The uppermost measurement is the most recent one. The duration of the measurement is shown in the duration field. The findings field displays the number of different annotations made by the user and gives detailed information when hovered over. If you have bought the Beat2Phone ECG analytics service, the findings field will also display those annotations. Hovering over the findings button opens a list of unique annotations. The list includes the source and type of an annotation, and the number of those annotations in the recording. The source of an annotation can be '-', meaning the user, 'alg', meaning algorithm, or the user ID of the user.

Measurements that have not been opened by you are marked with bold text. Once the ECG is opened, the bolding is removed. Just viewing the findings will only temporarily remove the bolding. You can also mark the measurement read or unread by hovering over the line and clicking the envelope symbol at the sensor column.

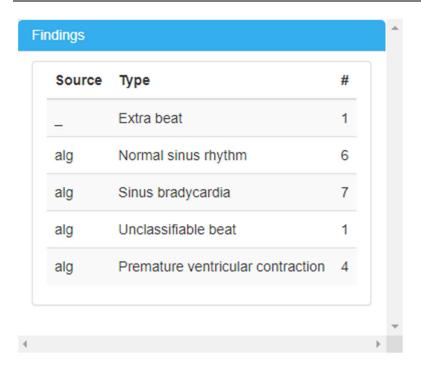


ATTENTION: Algorithm (alg) annotations are not intended to be the sole means of diagnosis for any abnormal ECG. They are offered to physicians on an advisory basis only, in conjunction with the physician's knowledge of ECG.

NOTE! The algorithm (alg) adds N marking of normal beat for first normal beat detected at the beginning of the recording and after each abnormal beat. Algorithm also adds (N marking of normal sinus rhythm detected at the beginning of the recording and after each abnormal rhythm.







Clicking the ECG button on the list of recordings opens the ECG chart view.

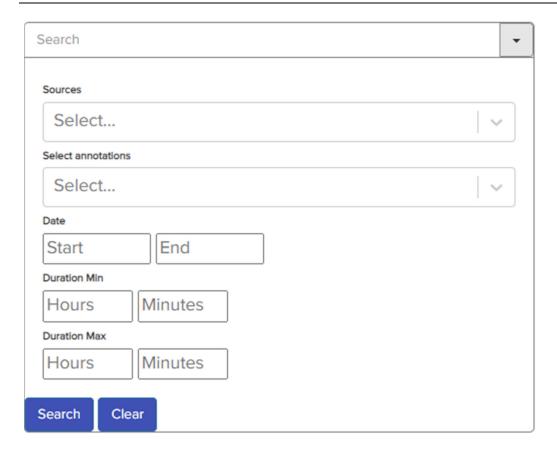


The Sensor column show the sensor ID – the sensor label MAC address last four characters - that was used for the recording.

The measurement list also includes search functions behind the magnifying class symbol that can be used to filter the list of measurements with several different criteria, for example measurement duration and types of annotations.







Choose a recording you wish to examine by clicking the line of the recording.



Details about the measurement open to the right.





Findings						
Time: 21.09.2020 10:54, Sensor: ab03						
PAPER	Time	Source	Туре	Description		
	10:54	Algorithm	(SBR	Sinus bradycardia		
	10:56	Algorithm	(N	Normal sinus rhythm		
	10:56	Algorithm	(SBR	Sinus bradycardia		
	11:01	Algorithm	(N	Normal sinus rhythm		
	11:01	Algorithm	(SBR	Sinus bradycardia		
	11:03	Algorithm	V	Premature ventricular contraction		
	11:03	Algorithm	V	Premature ventricular contraction		

In this list, each annotation made by the user or the Beat2Phone ECG analytics service algorithm is displayed along with its time, type and description. By choosing an annotation from the list, the ECG graph view opens, and the ECG graph will be centered around the chosen annotation.

ATTENTION: Algorithm (alg) annotations are not intended to be the sole means of diagnosis for any abnormal ECG. They are offered to physicians on an advisory basis only, in conjunction with the physician's knowledge of ECG.

NOTE! The algorithm (alg) adds N marking of normal beat for first normal beat detected at the beginning of the recording and after each abnormal beat. Algorithm also adds (N marking of normal sinus rhythm detected at the beginning of the recording and after each abnormal rhythm.

You can download the ECG recording to your computer as an EDF file by selecting the EDF -button. The EDF file may be useful for a medical professional ECG analysis. You find the file named with the recording ID and file type .edf at your computer's downloaded files -folder. You can create a millimeter paper report from the chosen annotations from the PAPER button and print it to a file or on paper from your computer.

WARNING

Do not attempt self-diagnostics based on the device recordings or the algorithm markings, always consult a competent medical professional for the needed actions. Recordings and markings can only be offered on advisory basis to qualified physicians for interpretation.

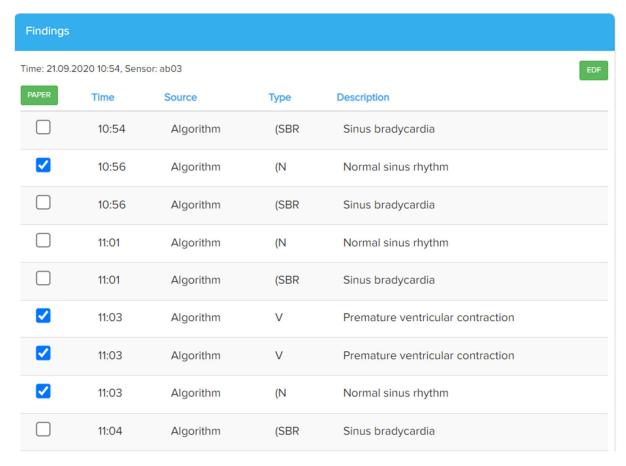
If you have heart symptoms contact a medical professional even if the recordings and markings appear to be normal.





Millimeter paper report from annotations

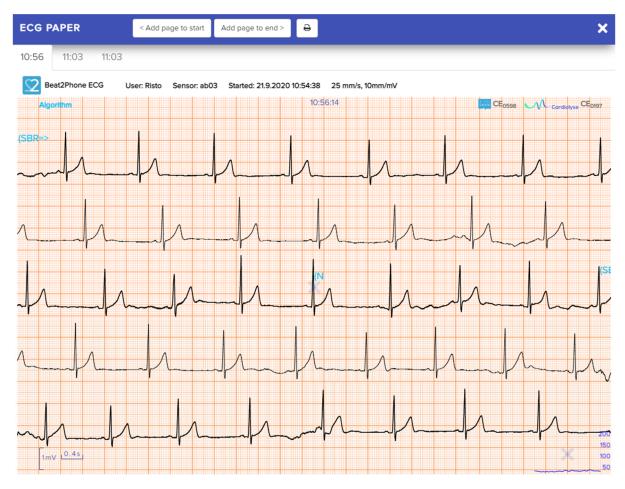
You can create a millimeter paper report from chosen annotations from the annotation list view. First, choose the annotations you want to include by using the check box. Then, click the PAPER button.



After clicking the button, the report from the chosen annotations opens.







You can move between annotations by clicking the numbered tabs. "Add page to start" and "Add page to end" buttons are used to add ECG signal around the chosen annotation, either before the annotation or after the annotation. The print button (printer) is used for printing the ECG signal to either paper or pdf. The prevalent rhythm algorithm marking is shown at the first beat of the ECG mmpaper sample. The scales of the mm-paper sample are at the bottom left corner.

ECG graph view

The ECG graph view opens from the start of the measurement by default. If you opened it by choosing an annotation from the list view, the graph will be centered around the chosen annotation.

The white graph in the middle is the ECG graph, the yellow one below is the HR graph, and the red one is the HRV graph displaying the changes and variation in the heart rate.

The horizontal bars between the ECG and HR/HRV graphs highlight the detected rhythm periods – sinus bradycardia in this example – however an AF rhythm period would be similarly highlighted from the beginning of the rhythm to the end of it.

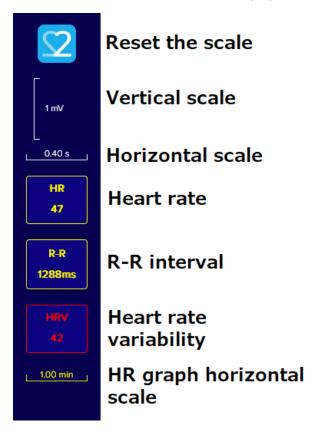
ATTENTION: Sometimes annotations made by the algorithm (alg) might be slightly off, e.g. off by one beat on the ECG.







On the left of the screen, you can see the scale of the measurement view. Two squares vertically are 1.00 millivolts, and two squares horizontally are 0.400 seconds. The horizontal scale can be zoomed in and out with the mouse scroll wheel. You can reset the scale by clicking the Beat2Phone logo on the left. In addition, the heart rate is displayed on the left.



On the top of the screen, there are controls for moving between annotations and automatically playing the ECG graph. From 'Annotations', you can filter the annotations by type and source and use the arrows to move between annotations. From 'Play/Pause' you can choose whether to play

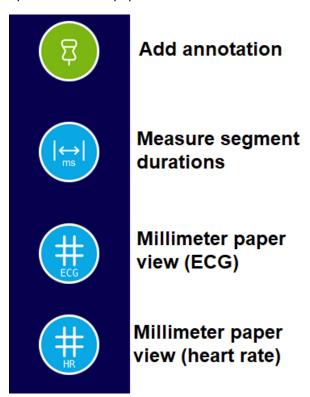




the ECG graph or the HR graph. After that, the arrow keys are used to control whether the playback is forwards or backwards. From 'Speed Control' you can adjust the playback speed. The Start and End -buttons take you to the beginning or end of the recording.



On the right, there are various buttons. From the first button, annotations can be added to the registration. Free text annotation is the last choice on the list of possible markings. From the next button (ms), you can open a tool for measuring the duration of different segments in the ECG. From the middle button (ECG), you can open a millimeter paper view of the ECG. The last button (HR) opens millimeter paper view of the heart rate.



Warning

WARNING: Do not attempt to do any self-diagnosis based on the ECG recordings or the algorithm markings. They can only be offered on advisory basis to qualified physicians for interpretation.

Measure segment durations

The segment duration measurement tool can be used to estimate the duration of different waves and segments. You use the tool by first dragging the vertical dotted line to the correct spot, for example to the onset of the P wave, and then clicking the corresponding button from the top. By repeating this step for all points, the tool calculates the durations.



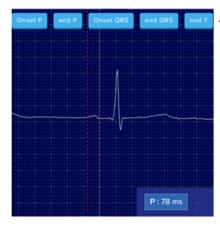




Drag the dotted line to the onset of the P wave and choose 'Onset P'



Drag the dotted line to the end of the P wave and choose 'end P'



The tool displays the duration of the P wave in milliseconds

Warning

WARNING: Do not attempt to do any self-diagnosis based on the ECG recordings or the algorithm markings. They can only be offered on advisory basis to qualified physicians for interpretation.

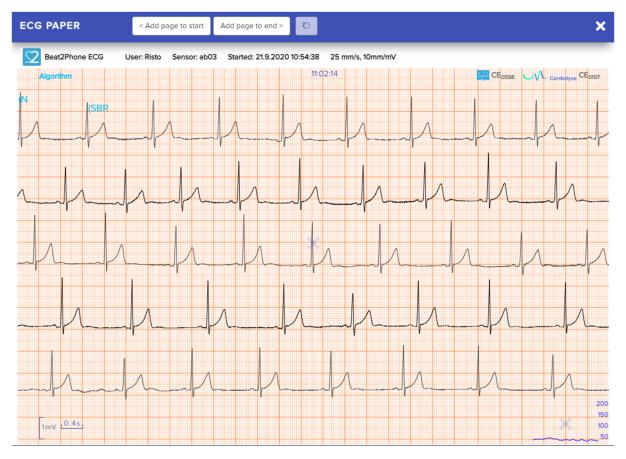
Millimeter paper view

The millimeter paper view shows 30 seconds of ECG from the selected spot on the ECG view, 15 seconds backwards and 15 seconds forwards from the spot. A cross X is visible on the millimeter paper to indicate the selected spot. The HR graph from the whole recording is displayed on the bottom right corner of the millimeter paper. The HR graph also includes the cross X that indicates the selected spot. The time for the





selected spot is shown on the top of the mm-paper. Annotations are also available on the millimeter paper. The prevalent rhythm algorithm marking is shown at the first beat of the ECG mm-paper sample.



The scales of the mm-paper sample are at the bottom left corner. The millimeter paper can be saved as an image by selecting the save button (floppy disk).



The millimeter paper can be printed or saved as pdf by right clicking the millimeter paper and selecting Print... or by using the shortcut ctrl+P.

To exit the millimeter paper view back to ECG view click the cross on top right corner of the mm-paper window or the ECG view on the background. Using the back button of the browser returns you to the recordings list.

Warning

WARNING: Do not attempt to do any self-diagnosis based on the ECG recordings or the algorithm markings. They can only be offered on advisory basis to qualified physicians for interpretation.





Sharing access to data

You can share your data to a trusted person through your web access by providing web access to her email address in the "Account" settings "Permission granting" dialogue.

Permission granting	
Grant permission to access your data for	
email@address.com	
For today and next 0 days (max. 30)	

Write the email address for the trusted person, define the permission length in days, and save permission. If you give no length the permission will expire by the end of the day. The email addresses you have given permission to your recording data are listed along with their permission status.

Your trusted person will receive an email from <u>info@vitalsignum.com</u> with the login credentials – username is this person's email address and password is generated by the service. A professional user account¹ is created for the trusted person.

"You have been shared access to the Beat2Phone ECG measurements of "YourID". You can see the measurements by logging in to https://beat2phone.net/, your userid is "trusted.person@email.*" and your password is "longCrypticString"². You can find the measurements with the patient id "YourID"."

You can cancel the permission any time by clicking the CANCEL button on the list of email addresses.

Used annotation abbreviations

The Beat2Phone ECG analytics service uses abbreviations for annotations in the millimeter paper view and in some lists. The full list of annotation abbreviations is as follows:

'F1': 'Irregular rhythm',

'F2': 'Extra beat',

'F3': 'Palpitation',

¹ In case the trusted person already has a Beat2Phone ECG professional account registered for the email, the shared data will appear on the existing account patient list, and no new login information is shared.

² Meaning a strong autogenerated password.





'F4': 'Chest pain', 'N': 'Normal beat', 'L': 'Left bundle branch block beat', 'R': 'Right bundle branch block beat', 'B': 'Bundle branch block beat (unspecified)', 'A': 'Atrial premature beat', 'a': 'Aberrated atrial premature beat', 'J': 'Nodal (junctional) premature beat', 'S': 'Supraventricular premature or ectopic beat (atrial or nodal)', 'V': 'Premature ventricular contraction', 'r': 'R-on-T premature ventricular contraction', 'F': 'Fusion of ventricular and normal beat', 'e': 'Atrial escape beat', 'j': 'Nodal (junctional) escape beat', 'n': 'Supraventricular escape beat (atrial or nodal)', 'E': 'Ventricular escape beat', '/': 'Paced beat', 'f': 'Fusion of paced and normal beat', 'Q': 'Unclassifiable beat', '?': 'Beat not classified during learning', '(AB': 'Atrial bigeminy', '(AFIB': 'Atrial fibrillation', '(AFL': 'Atrial flutter', '(B': 'Ventricular bigeminy', '(BII': '2° heart block', '(IVR': 'Idioventricular rhythm', '(N': 'Normal sinus rhythm', '(NOD': 'Nodal (A-V junctional) rhythm', '(P': 'Paced rhythm',

'(PREX': 'Pre-excitation (WPW)',

'(SBR': 'Sinus bradycardia',

15





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'(STH': 'Sinus tachycardia',
 '(SVTA': 'Supraventricular tachyarrhythmia',
 '(T': 'Ventricular trigeminy',
 '(VFL': 'Ventricular flutter',
 '(VT': 'Ventricular tachycardia',
'[': 'Start of ventricular flutter/fibrillation',
'!': 'Ventricular flutter wave',
 ']': 'End of ventricular flutter/fibrillation',
 'x': 'Non-conducted P-wave (blocked APC)',
 '(': 'Waveform onset',
 ')': 'Waveform end',
 'p': 'Peak of P-wave',
 't': 'Peak of T-wave',
 'u': 'Peak of U-wave',
 ": 'PQ junction',
 '\": 'J-point',
 '^': '(Non-captured) pacemaker artifact',
 '|': 'Isolated QRS-like artifact',
 '~': 'Change in signal quality',
 '+': 'Rhythm change',
 's': 'ST segment change',
 'T': 'T-wave change',
 '*': 'Systole',
'D': 'Diastole',
'=': 'Measurement annotation',
 'DEV': 'Deviation from normal',
" ": 'Comment annotation'
```

'audio': 'Audio annotation'

The analytics service algorithm sometimes fails to classify beats due to signal artefacts. The algorithm annotation 'Unclassified beat' is filtered out from the GUI for the sake of clarity.





Cardiolyse information

Software for ECG signal analysis Cardiolyse, v 1.0



Cardiolyse Oy Fabianinkatu 29 B 00100 Helsinki





03.2019



Cardiolyse CE₀₁₉₇ Standalone software for ECG signal analysis – HD 60145512 0001

Cardiolyse instructions for use:

https://docs.google.com/document/d/1SwFXwcrBjzvh3EIFcNKHz3f5OzTWID-x4qCy3qnM7dw

CONTACT INFORMATION

CARDIOLYSE OY,

GE Health Innovation Village, 2 Kuortaneenkatu, Helsinki, 00510.

https://cardiolyse.com

Contact: info@cardiolyse.com

INTENDED USE

The Cardiolyse is intended to record, store, analyze, display and transfer up to twelve (12) leads electrocardiogram (ECG).

The Cardiolyse software performs QRS, Ventricular Ectopic Beats, Supraventricular ectopic beats detection, QRS feature extraction, interval measurement, heart rate measurement, rhythm analysis and abnormal ST-T changes for up to 12 leads ECG.

Cardiolyse software also performs automatic ECG interpretation of common abnormalities, including ventricular hypertrophy and myocardial infarction for 12 leads ECG.

The Cardiolyse interpretation results are not intended to be the sole means of diagnosis for any abnormal ECG. They are offered to physicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

The device has not been tested and it is not intended for pediatric use.

CONTRAINDICATIONS

People below 18 years old

SAFETY AND PERFORMANCE





Cardiolyse.me software as a medical device safety and performance was validated based on device's equivalence and clinical evaluation data.

ECG algorithms were validated on widely acceptable databases MIT-BIH, NST, CU, ESC as well as CSE.

Algorithm's sensitivity and specificity is highly dependent on signal quality provided by device.

VitalSignum Information

Beat2Phone ECG Service

VitalSignum Oy
Health Innovation Village,
Kuortaneenkatu 2,
00510 Helsinki, Finland.
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