

Preventicus Heartbeats app

Instructions for use



Table of contents

1	Symbols	5
2	Product description and intended purpose	6
2.1	Intended purpose	6
2.2	Indication / user profile	6
2.3	Contraindication and exclusions	6
2.4	Intended use	7
2.5	Clinical benefit	7
2.6	Measuring principle: Basics of pulse curve analysis	7
3	Notes	7
3.1	Warnings	7
3.2	Additional information and explanations on performance and residual risks	8
4	Product lifespan	8
5	Data backup	8
6	First use	9
6.1	Starting the Preventicus Heartbeats app	10
6.2	Read and accept the purpose statement including warnings, terms of use and privacy policy. 11	
6.3	Enter access code	11
6.4	Register and create user account	12
7	Home screen	12
8	Performing a measurement	13
8.1	Choice of measurement mode	13
8.2	Preparing the device	14
8.3	Correct measuring position	15
8.4	Alternative measuring position	16
8.5	Using the positioning tool	16
8.6	Detecting good signal quality	17
8.7	What to do during the measurement	17
8.8	Starting the measurement	18
9	Creating a measurement report	18

10	Interpretation of the results	19
10.1	Poor signal quality.....	19
11	Reports & Telecare	20
11.1	Overview of the measurement report.....	20
11.2	Measurement report list.....	22
11.3	Telecare - report list	23
11.4	Telecare - order report.....	23
12	Menu.....	25
12.1	Baseline data.....	25
12.2	Reminder function	26
12.3	Login	26
12.3.1	User account.....	27
12.3.2	Changing devices	27
12.3.3	Multiple users - user change.....	28
12.4	Why Heartbeats	29
13	Full version.....	29
13.1	In-app purchases	29
13.2	Purchase of the full version	30
14	Delete user account.....	30
15	Error messages	32
16	Uninstalling the app	33
17	Technical data.....	34
18	Manufacturer information	34

These instructions for use describe the use and functions of the Preventicus Heartbeats app on smartphone devices with iOS or Android operating systems. For the sake of clarity, we only refer to smartphones in the rest of the document.



Please read the instructions for use carefully before using the Preventicus Heartbeats app.







An up-to-date version of the instructions can always be found at

<https://www.preventicus.com/manuals-international-preventicus-heartbeats-app/>

Further information can be found on the Preventicus support website (<https://www.preventicus.com/support-faqs/>). You can also request a paper copy of the user guide free of charge from the support website.

1 Symbols

These instructions for use contain the following symbols (colour and size may vary):

Symbol	Meaning
	This stand-alone software is a medical device classified as risk category IIa, in accordance with rule 11 of Regulation (EU) 2017/745 / risk category B in accordance with rule 11 of MDS-REQ-001.
	Warning A warning is always related to safety.
	Note A note informs the user of interesting information.
 Preventicus® GmbH Ernst-Abbe-Str. 15, 07743 Jena, Germany	Manufacturer's specifications
	Observe the electronic instructions for use.
	Medical device

2 Product description and intended purpose

The Preventicus Heartbeats app is a software application that records the pulse curve, uses the data to analyse heart rhythm, and provides the results.

The pulse curves are recorded in the app using a smartphone camera through contact with the fingertip. A heart rhythm analysis is then performed using the recorded pulse curve. The results of the heart rhythm analysis are provided in the Preventicus Heartbeats app. If signs of a cardiac arrhythmia are detected, if it is not under medical control and if it occurs repeatedly, further medical assessment by a professional is recommended.

If you feel unwell or experience any other worrying symptoms, please seek medical attention immediately.

The Preventicus Heartbeats app can assign you to one of three categories based on the assessment: no abnormalities, suspected extrasystoles (>5% of all beats are irregular) and absolute arrhythmia with suspected atrial fibrillation. In addition, information is provided about suspected relevant bradycardia and tachycardia without further differentiation of their cause.

The heart rhythm is analysed using one-minute and five-minute pulse curves. The results of the heart rhythm analysis can be provided for one and five minutes. Any potential disturbances and artefacts in the data are detected and eliminated.

Preventicus has been proven to detect atrial fibrillation and extrasystoles and to accurately determine heart rate in its own clinical studies (see also: <https://www.preventicus.org/evidence/>). It has been shown that this product's underlying algorithm can differentiate between atrial fibrillation and normal heart rhythm with over 96% accuracy.

2.1 Intended purpose

The Preventicus Heartbeats app is used to detect cardiac arrhythmias in the form of a suspected diagnosis, and to determine and characterise heart rate. The following cardiac arrhythmias can be detected: absolute arrhythmia with suspected atrial fibrillation, extrasystoles and irregular heartbeats, heart rate with signs of bradycardia and tachycardia.

The result obtained is only a possible suspicion ("suspected diagnosis"), not a diagnosis in the medical sense. The results obtained are for information purposes only and under no circumstances a substitute for personal diagnosis, advice, care or treatment from a medical or medically trained professional.

2.2 Indication / user profile

The Preventicus Heartbeats app is suitable for use on themselves by the following people:

- people who are confident using smartphones and wearables
- people with no cognitive impairments
- people of any gender
- people over the age of 18
- people with suspected cardiac arrhythmias such as atrial fibrillation

2.3 Contraindication and exclusions

The Preventicus Heartbeats app is not intended for the following users:

- patients who have a pacemaker or defibrillator implanted
- people with a cognitive impairment

2.4 Intended use

Measurements with the Preventicus Heartbeats app should be performed at normal room temperature and under normal light conditions. The camera should only be used on healthy skin tissue. We do not recommend using this product if you have reduced pain sensitivity. The app must not be used when the device is charging.

The Preventicus Heartbeats app is intended for use on a device tested and approved by Preventicus GmbH for this purpose. An up-to-date list can be found at the following links:

<https://heartbeats.preventicus.com/devices/en>

2.5 Clinical benefit

Cardiac arrhythmias, particularly undetected atrial fibrillation, are associated with a significantly increased risk of stroke. Atrial fibrillation is often not noticeable, frequently only occurs sporadically and is therefore usually difficult to diagnose.

Cardiology associations therefore recommend independent and regular measurement of heart rhythm with suitable apps, wearables or smartwatches. If atrial fibrillation is detected and subsequently confirmed by a doctor with an ECG, the risk of stroke can be reduced or normalised with medication. The Preventicus Heartbeats app provides a solution for independent and regular heart rhythm measurement to detect early signs of atrial fibrillation, to lead people affected to a diagnosis and subsequent therapy by a cardiologist more quickly and, therefore, to reduce the risk of stroke.

2.6 Measuring principle: Basics of pulse curve analysis

With Preventicus Heartbeats, you can record your pulse curve using your fingertip and your smartphone camera by placing your finger on the camera lens and shining the light from the flash onto your fingertip. The pulse curve can be derived from the camera signal using signal analysis methods. This is comparable to the medical procedure photoplethysmography. The pulse curve corresponds to the blood pulsation caused by heart activity.

Potential signs of cardiac arrhythmia can be detected using the variability of the heartbeat in combination with biosignal analytical methods.

3 Notes

3.1 Warnings



For safe use of Preventicus Heartbeats, ensure you follow the warnings.

1. Remove any protective covers from your smartphone.
2. Do not perform the measurement with the power adapter plugged in.
3. If the flash of your smartphone becomes too hot, even while using the app correctly (your finger is positioned on the lens only, not on the flash), you should stop the measurement.
4. Users with reduced sensitivity to pain are advised not to use this product.
5. Medication or drugs affecting the heart rate, pacemakers or defibrillators can potentially falsify the results of the rhythm analysis.

① **Note:** We ask you to report any serious incidents that occur in association with the Preventicus Heartbeats app to us and the competent authority in the country you are resident in. (For detailed contact information, see the “Manufacturer information” section). Mail: support@preventicus.com

3.2 Additional information and explanations on performance and residual risks

The ECG is the gold standard for rhythm diagnostics. An analysis of the heart rhythm from the pulse wave is a suitable screening method for a preliminary stage before further diagnostic procedures. The Preventicus Heartbeats app is used by the patient themselves in a non-clinical environment and is not intended to be used for decision-making in life-threatening situations nor for real-time monitoring of vital functions, nor does it interfere with existing guideline-based diagnostic pathways or therapeutic measures.

A basic distinction must be made between atrial fibrillation (AF) detection (screening or monitoring) and subsequent AF diagnosis. AF should be diagnosed exclusively in accordance with the guidelines with a chest wall ECG, generally by cardiologists. Preventicus applications are not intended for final AF diagnoses with therapeutic implications, rather they are intended solely for AF screening or AF monitoring without therapeutic implications. A therapeutic implication can only be derived from a real ECG.

Preventicus Heartbeats detects atrial fibrillation with an overall accuracy of 96% according to the studies conducted. The sensitivity (true positive rate) is approx. 92%. The sensitivity indicates the probability that atrial fibrillation will be recognised as such. In parallel, the specificity (true negative rate) gives the percentage of users who do not have atrial fibrillation for whom the result (green traffic light) is correct. The specificity of Preventicus Heartbeats is 99%.

Atrial fibrillation can occur sporadically. If it is not present at the time of measurement, it cannot be detected by Preventicus Heartbeats.

It cannot be ruled out that poor signal quality, pre-existing illnesses (such as diabetes, vascular diseases or prior cardiovascular surgery), medications affecting the pulse rate or pacemakers may distort the accuracy of Preventicus Heartbeats.

4 Product lifespan

The lifespan is defined as the period before a new version of the app is released. This is indicated by an increase of at least the second digit of the version number. The version number is specified in the respective app stores.

https://play.google.com/store/apps/details?id=com.preventicus.heartbeats&hl=en_US

<https://apps.apple.com/de/app/preventicus-heartbeats/id1122978949?l=en>

Information on updates is provided via the operating system. Depending on the corresponding user settings on the smartphone, the update is either performed automatically or must be actively approved and started by you.

5 Data backup

The reports can be exported and sent as PDFs, e.g. by email. The reports can then be saved in other databases (e.g. PDMS, Praxis software) or on other storage media (e.g. hard drive, memory card).

Preventicus GmbH recommends protecting the smartphone that the application is running on with a code (PIN, personal identification number), facial recognition or fingerprint recognition. It is important that your smartphone is protected because personal health information is stored on it.

6 First use

The Preventicus Heartbeats app can be run on smartphones with the following operating systems: iOS 12.1 or higher or Android 7.0 and higher.

The up-to-date list of tested and approved devices can be found at

<https://heartbeats.preventicus.com/devices/en>.

For smartphones for which the application is not demonstrably suitable, the Preventicus Heartbeats app will not be displayed in the corresponding store.

You can download and install the Preventicus Heartbeats app from the following links:

Link to the App Store for iOS devices:

<https://apps.apple.com/de/app/preventicus-heartbeats/id1122978949?l=en>

Link to Play Store for Android devices:

https://play.google.com/store/apps/details?id=com.preventicus.heartbeats&hl=en_US

After installing the Preventicus Heartbeats app and when using it for the first time, you must first read and accept the purpose statement including the warnings, terms of use and privacy policy in order to proceed. If you have an access code, you will then have the option to enter it. You can also skip this step. In both cases, you will then be taken to the registration screen to create an account for the app.


General terms and conditions


<https://www.preventicus.org/terms-and-conditions/>

Privacy policy for the Preventicus Heartbeats app

<https://www.preventicus.org/heartbeats/privacy-policy-of-using-the-app/>

6.1 Starting the Preventicus Heartbeats app

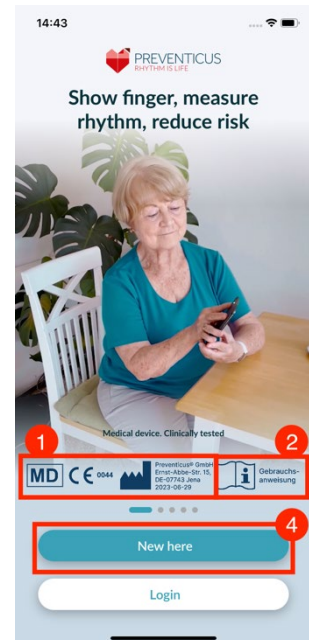
After installing the app, the Preventicus Heartbeats heart  appears on your smartphone display. When you click on the heart, the app will open.

When the app is open, the first screen you will see is the home screen. The screen shows product-relevant icons (1), including an icon for the instructions for use (2). Clicking on the icon  opens the instructions for use in an extra browser window on your smartphone.

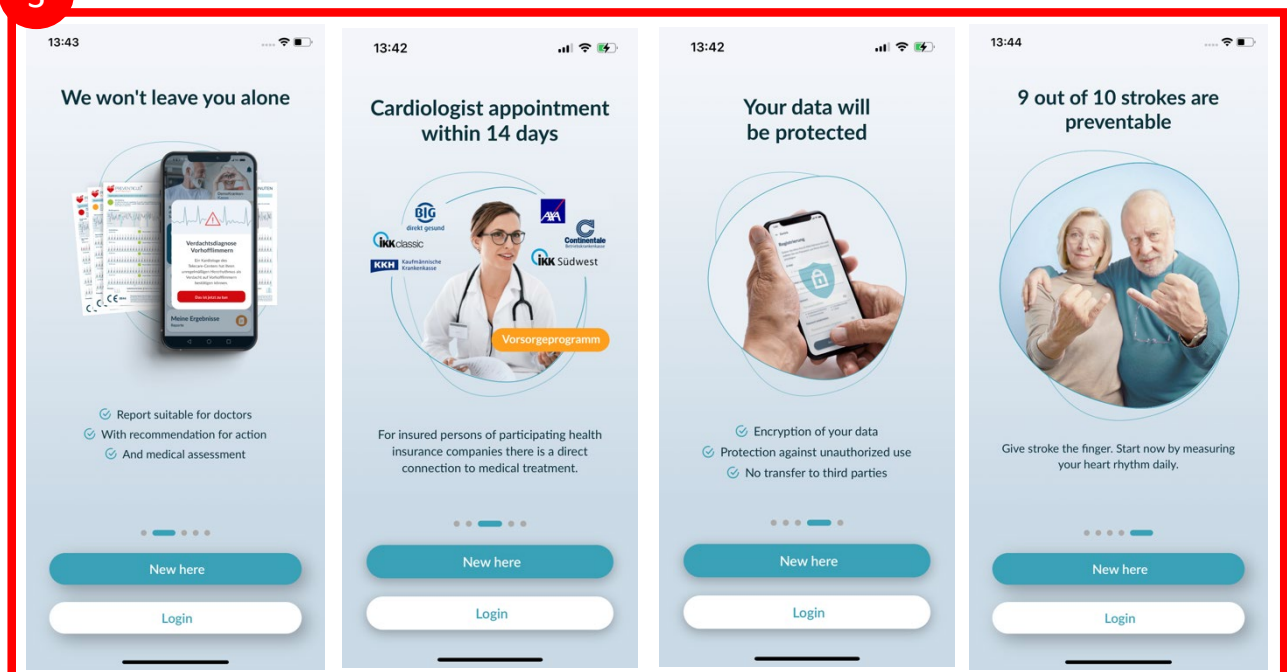
The start screen consists of a total of five pages with information on important functions of the app and, in addition, the preventive care program in cooperation with health insurance companies (3). You can view the individual pages individually by swiping your finger on the display from right to left or left to right.

If you are using the Preventicus Heartbeats app for the first time, please click on the "New here" button to continue (4).

If you are already an active user of the app, please go to chapter 12.3 Login.



3



6.2 Read and accept the purpose statement including warnings, terms of use and privacy policy.

Before you start using Preventicus Heartbeats, it is important to know how it works and what you should pay attention to. Therefore, in the next step, please read carefully the posted terms of use, purpose and warning statements, and privacy information. In order to proceed, you must first agree to these terms. To do so, click on the rectangular boxes to place a check mark indicating that you accept them. Then press the "Continue" button to proceed.

The first two checkboxes on Terms of Use, Purpose including warnings and the Privacy Information are mandatory fields and must be accepted to continue (1). The third checkbox is optional and therefore does not have to be accepted to continue (2).

14:43

< Back

We need your consent

In order to use Preventicus Heartbeats, you must know how Preventicus works and agree to the following.

☐ I agree with the terms of use and have read the intended use and warnings.
[Terms of use, intended use & warnings](#)

☐ I expressly consent to the processing of my health data.
[Data protection information](#)

☐ In order to help improve the app, I agree to receive app bug reports and usage data from Preventicus.
[Detailed information](#)

Continue

6.3 Enter access code

In the next step, you have the option to enter an access code (1) to unlock extended services of the Preventicus Heartbeats App. You can receive an access code from your health insurance company, for example, as part of a preventive care program. In addition, you have the option of using a code generator to check whether you can also obtain such an access code (2).

After entering the access code, click the "Continue with access code" button to continue.

To continue without an access code, click the "Continue without access code" button.

14:43

< Back

Access Code

Have you received an access code? If yes, please enter it here now.

[How do I get an access code?](#)

Access code

Enter code here

Continue with access code

Continue without access code

6.4 Register and create user account

Preventicus Heartbeats app as a user, your user data will be linked to your account in the future. When you change your smartphone, you then only need to log in to the app and your license and data will be automatically restored.

To register, please enter your email address and a password of your choice. The registration can only be completed if all information is filled in correctly written.

Then click on "Register now" to link your user account with your data.

To complete the creation of your user account and to be able to access your data and results at any time, you must confirm your registration at the end. For this purpose, you will receive an e-mail from us with an activation link. By clicking on the link you confirm your registration.

Note: You have 1 month to confirm your e-mail address. If this time expires, you have the option to request the confirmation again and a new e-mail will be sent.

Note: If you do not receive a confirmation activation link, please contact our customer support: support@preventicus.com.

The registration screen displays the following fields and instructions:

- E-Mail:** Enter email
- Repeat email:** Enter email again
- Password:** Choose password. Requirements: at least 8 characters, 1 lowercase, 1 uppercase, 1 number.
- Repeat password:** Enter password again
- Register now:** A large button at the bottom.

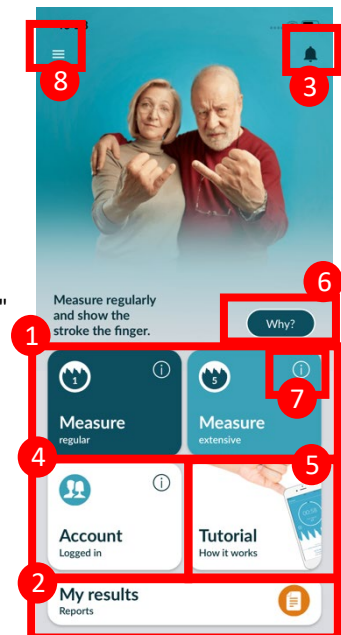
7 Home screen

The home screen displays the main features of the Preventicus Heartbeats app:

- [Measurement modes](#) (see *Chapter 8.1 Choice of measurement mode*) (1)
- [Reports](#) (see *Chapter 11 Reports & Telecare*) (2)
- [Reminder](#) (see *Chapter 12.2 Reminder function*) (3)
- [Login](#) (see *Chapter 12.3.1 User account*) (4)
- [Tutorial](#) (see *Chapter 8 Performing a measurement*) (5)
- [What you should know about the app](#) (see *Chapter 12.5 Why Heartbeats*) (6)

Click the "Info" icon for more information about the measurement modes "Standard" and "Extensive" (7).

Other than the main features, the menu (8) also contains information on the user profile, settings and information on the topic "Full version". See *Chapter 12 Menu* for more details.



8 Performing a measurement

Note: A stable internet connection is required to perform a measurement and subsequent heart rhythm analysis with display of the results. Please ensure a stable internet connection before starting the measurement.

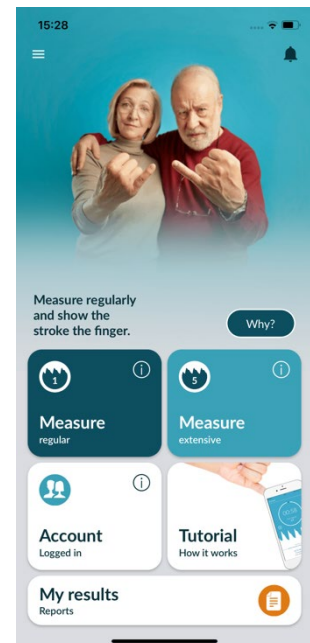
8.1 Choice of measurement mode

Once you have successfully entered your data, you are taken to the general user interface. In the full version, you can choose between two measurement methods:

- | | |
|-------------------|---|
| regular: | one-minute test including full analysis and measurement report. The norm for regular measurement. |
| extensive: | detailed five-minute test including measurement report and the highest accuracy. Recommended in case of abnormalities in the standard test, if recommended by a doctor and especially if you want to utilise a Telecare service assessment as a private user. |

To start the measurement, select one of the two modes.

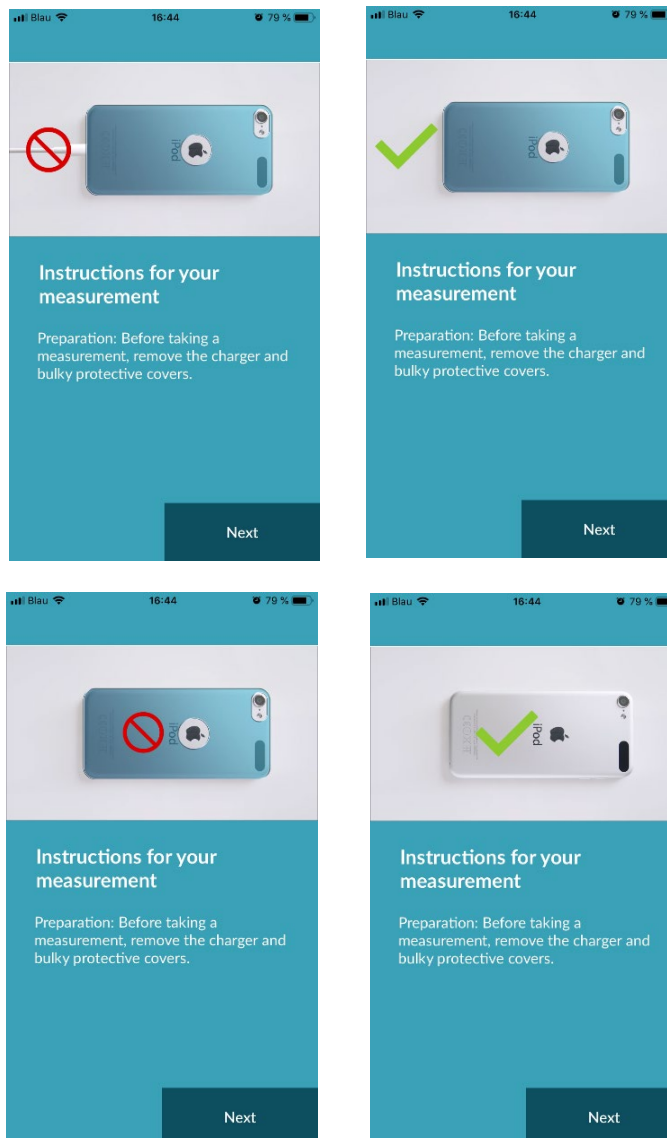
The free version rates the heart rate as normal (grey traffic light) or abnormal (orange traffic light) based on a 1-minute measurement. The result is displayed by means of a traffic light system. A measurement report is only created in the full version.



8.2 Preparing the device

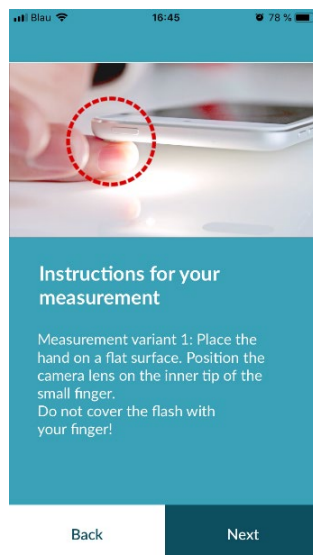
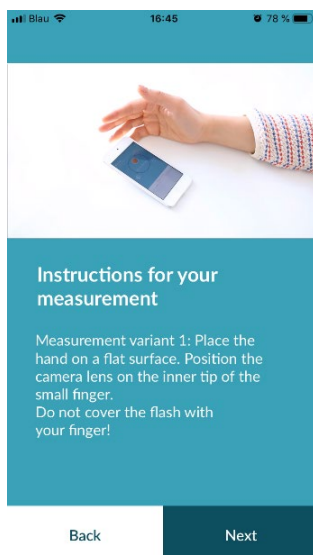
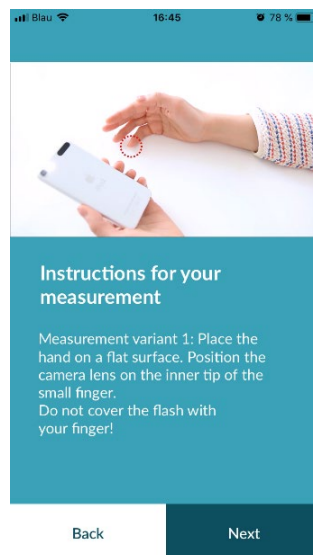
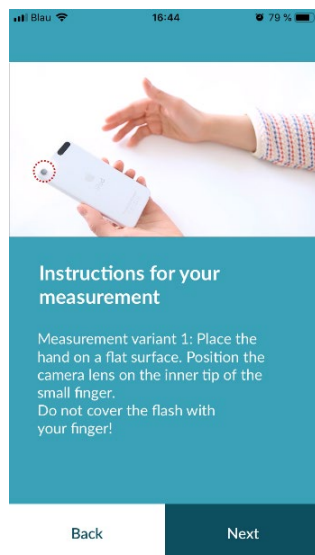
Before the first measurement, you are provided with instructions on how to carry out a measurement (tutorial). Please read these carefully. Once you complete the tutorial, you can either view it again or start a measurement.

Remove the charger and cover (if applicable) before measuring.



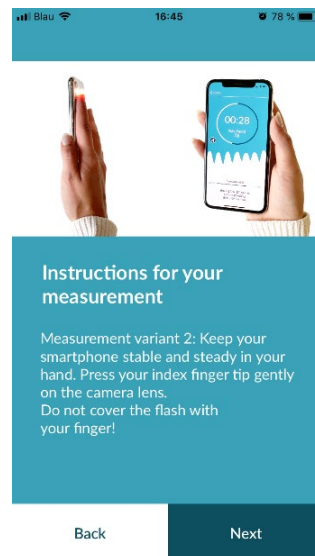
8.3 Correct measuring position

To measure correctly, put your arm and elbow on the table, so you are in a relaxed position. Then take your mobile phone and place it with the camera lens on the tip of your little finger. Make sure the flash LED is not covered. If performed properly, the entire camera lens will be positioned on your finger.



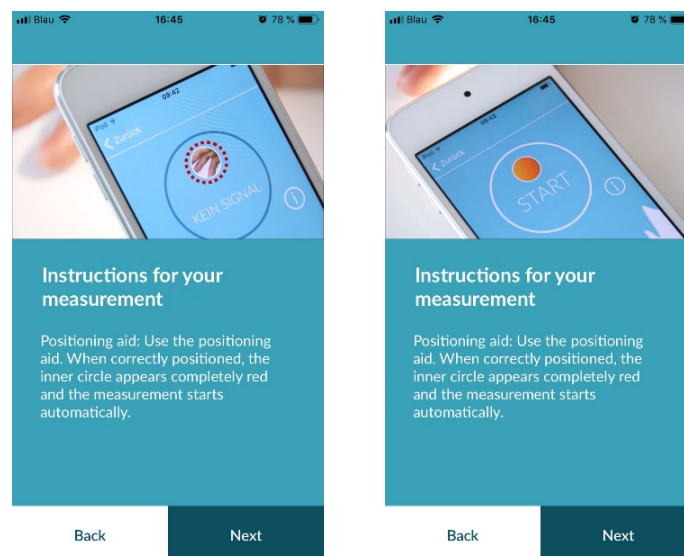
8.4 Alternative measuring position

Alternatively, you can hold the smartphone in your hand. Make sure that you hold the smartphone stable and steady. Place the front part of your index finger on the camera lens. Make sure the flash LED is not covered.



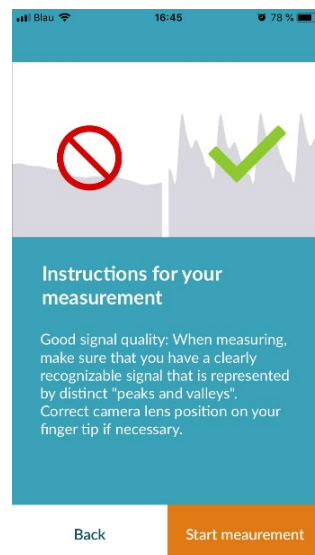
8.5 Using the positioning tool

Correct positioning of the camera lens plays a decisive role for correct measurement. You should therefore use the preview window provided as a positioning tool. With this preview window, you can also identify the correct camera on a smartphone that has more than one camera. The camera lens is correctly positioned when the entire inner circle of the preview window is red.



8.6 Detecting good signal quality

Next, the system checks the signal quality. Place the camera on your fingertip and wait until the system has calibrated the signal quality. The measurement then starts automatically.

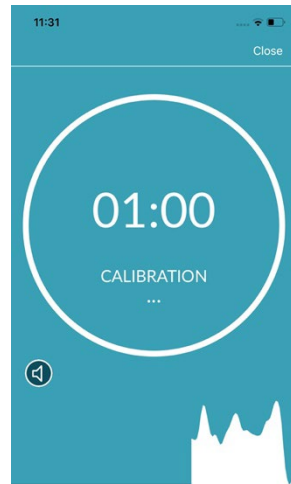


8.7 What to do during the measurement

Maintain a relaxed sitting position during the measurement. Avoid movements and do not talk during the recording.

8.8 Starting the measurement

Once you have pressed “Start measurement”, your device is ready to start measuring. Place the camera lens of the device on the tip of your little finger as described in the tutorial. As soon as the system has calibrated the signal quality, the measurement starts automatically.



THE MEASUREMENT STARTS
as soon as you put your
finger on the camera

9 Creating a measurement report

Once the measurement has been completed, you have the option to enter a title and amend the year of birth and gender, if required. You also have the option to specify how you are feeling (select from a list) and to add your own comments to the measurement (“I’m doing very well today” or “I am feeling unwell today”). This information is then transferred to a report of the measurement. You can then save the measurement report.

10 Interpretation of the results

Once you have saved the measurement, your result is displayed as a traffic light.




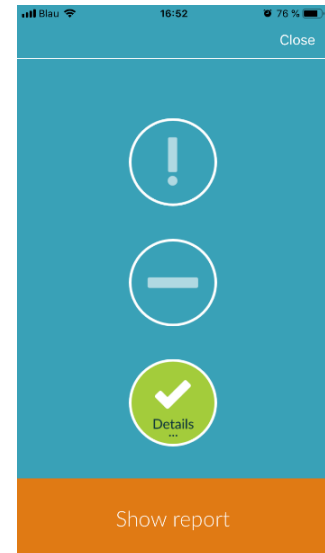
Traffic light colour	Meaning
Green 	Regular heart rhythm and normal heart rate
Yellow 	Slight arrhythmia (>5% of all beats are irregular) and/or a slightly increased or decreased heart rate
Red 	Absolute arrhythmia with suspected atrial fibrillation and/or a significantly increased or decreased heart rate (tachycardia/bradycardia). If you are not under medical observation and if this occurs repeatedly, it is imperative you see the cardiologist immediately.

Table 10.1 Colour labels and heart rhythm and heart rate assessment

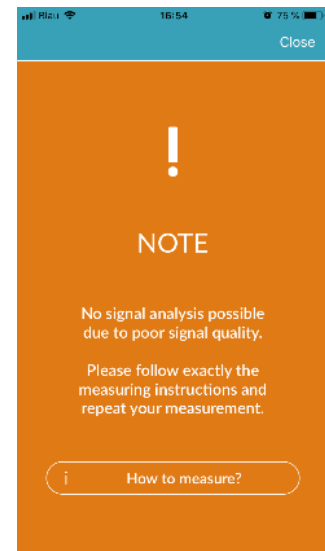


10.1 Poor signal quality

Poor signal quality due to movement, talking, coughing or incorrect positioning of the camera (e.g. on the fingertip) during the measurement makes an assessment impossible. You can take another look at the tutorial under "Correct measurement" and then repeat the measurement.

Reliable evaluation of the heart rhythm with the app depends on good signal quality. Please observe the following when taking a measurement:

1. Sit upright and relaxed.
Measurement variant 1: Place the camera lens on the foremost part of your finger so that it is stable. **Measurement variant 2:** Hold the smartphone steadily and calmly in your hand. Place the tip of your index finger on the camera lens.
2. Do not touch the flash light with your finger!
3. The circle (preview) must be red and completely filled by your finger.
4. The signal quality is then calibrated by the system and after 3sec the measurement starts automatically.
5. If necessary, massage the fingertip of the finger being used for the measurement to increase blood circulation.



If you have any difficulties, please contact Preventicus support at: support@preventicus.com

11 Reports & Telecare

11.1 Overview of the measurement report

After a successful measurement in the full version (1 minute or 5 minutes) you will receive your result as a summary measurement report. This includes the recorded pulse curve, the heart rate (bpm) over time and detailed information about the heart rhythm. The measurement report is made up of three sections (see Fig. 11.1).

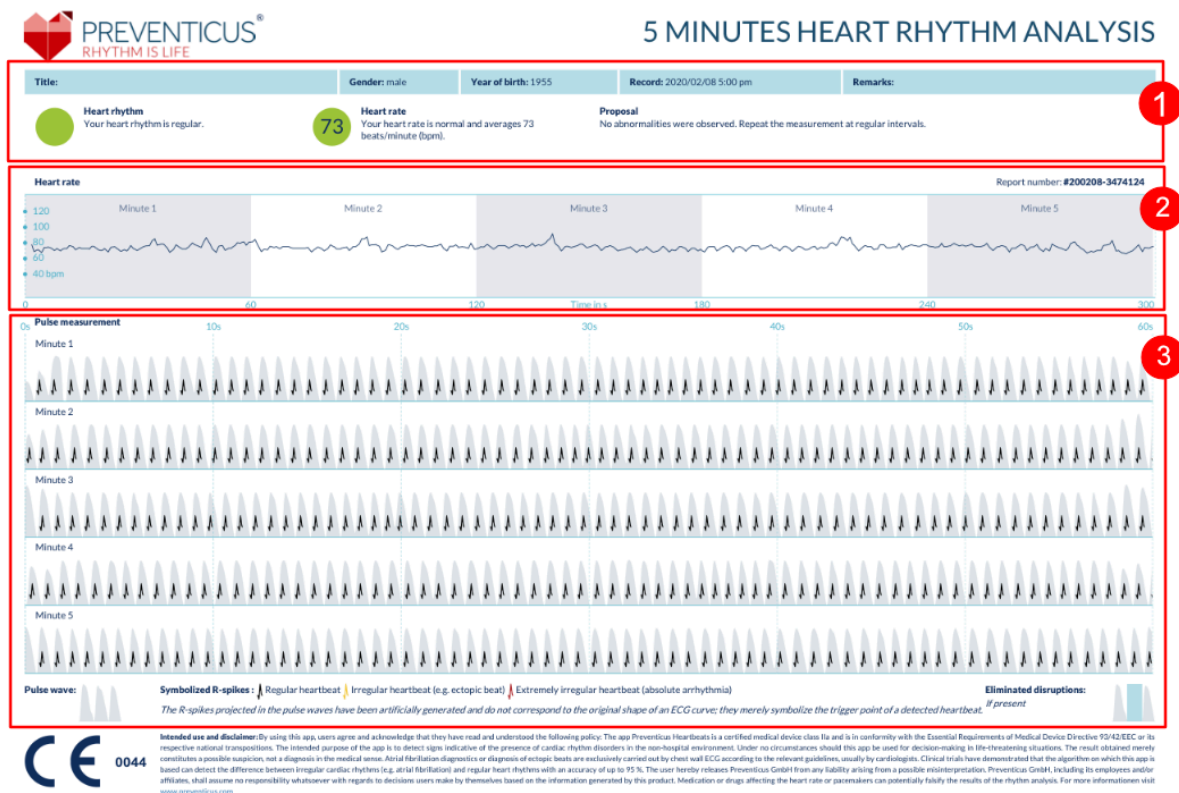


Fig. 11.1 Preventicus Heartbeats measurement report consisting of three sections: 1 – Summarised results of the heart rhythm analysis, 2 – Heart rate in beats per minute (bpm) over the entire measurement, 3 – Original pulse curve over the entire measurement

The summarised results of the heart rhythm analysis (see Fig. 11.1/section 1) contain both baseline data and optional information, such as name and comments on the measurement. In addition, the heart rate and heart rhythm results are made available to you in text form, including colour label. The coloured labels correspond to the traffic light colours in the results screen of the app (see Table 10.1). Depending on the result, you are offered an additional medical assessment by a medical professional.

In the second part of the report (see Fig. 11.1/section 2), the heart rate is displayed in beats per minute (bpm) over the entire measurement. Slight and regular fluctuations in heart rate, as shown in Fig. 11.1/section 2, are normal and are usually caused by the interaction between breathing and heartbeat.

Sudden positive or negative peaks, as shown in Fig. 11.2, however, are caused by individual irregular heartbeats and may be evidence of extrasystoles.



Fig. 11.2 Summarised results of the heart rhythm analysis and heart rate in beats per minute (bpm) over the entire measurement of a report with slight arrhythmia

Positive peaks result from irregular heartbeats, which have a significantly reduced time interval from the previous heartbeat compared to the average. Negative peaks in the pulse rate, on the other hand, indicate a significantly greater time interval between the irregular heartbeat and the previous normal heart rate, compared to the average.

Fig. 11.3 shows a heart rate with the presence of atrial fibrillation. The heart rate is strongly irregular over the entire measurement. The fluctuations of the heart rate occur chaotically throughout the entire measurement.

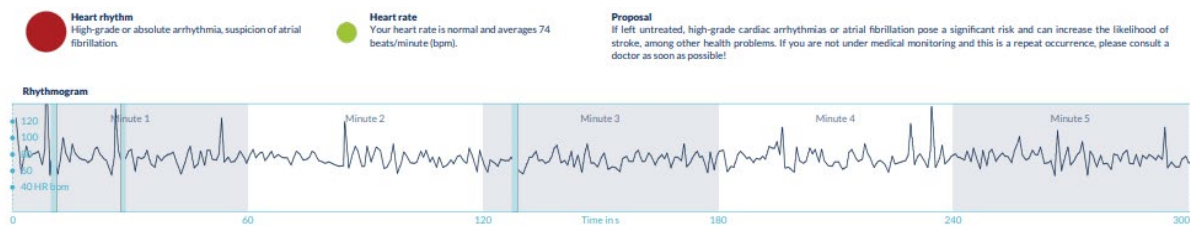


Fig. 11.3 Summarised results of the heart rhythm analysis and heart rate in beats per minute (bpm) over the entire measurement of a report with absolute arrhythmia

The third section of the measurement report consists of the original pulse curve. A wave in the pulse curve represents one heartbeat. For the heart rhythm analysis, points are detected in the pulse curve, which behave equivalent to the R peaks in an ECG. These points are shown in the form of R peaks in the original pulse curve to illustrate a detected/recognised heartbeat (see Fig. 11.4). Black R peaks symbolise a regular heartbeat, yellow an irregular heartbeat (such as extrasystole) and red R peaks an extremely irregular heartbeat based on absolute arrhythmia (suspected atrial fibrillation).

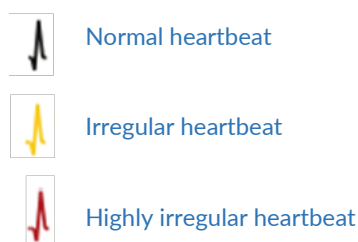


Fig. 11.4 Legend of the R peaks in the original pulse curve

Blue bars in the pulse curve (see Fig. 11.5) indicate an automatically detected disruption, which could be caused by movement, environmental light or camera readjustments.

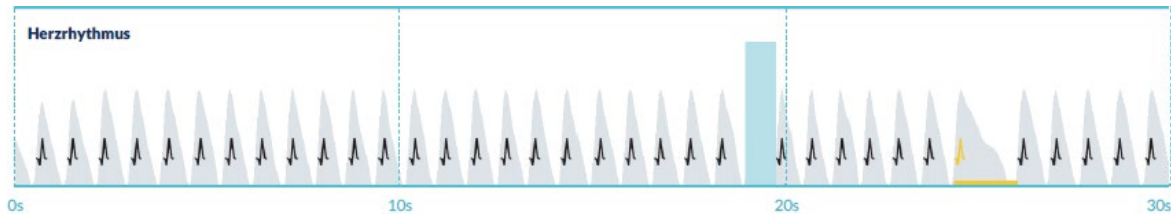


Fig. 11.5 Original pulse curve of the measurement report with detected disruption (blue bar)


11.2 Measurement report list

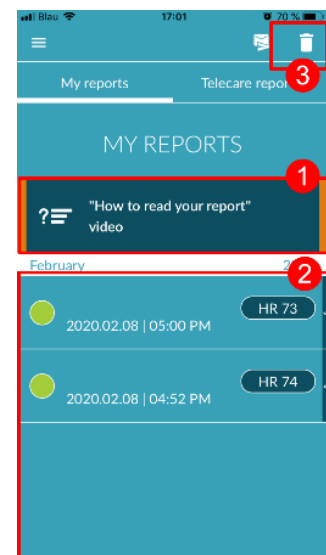
After each measurement, the reports are stored in a list and can be viewed via the menu item "My results".



To better understand how to read such a report, see the video guide in the "My reports" area (1).

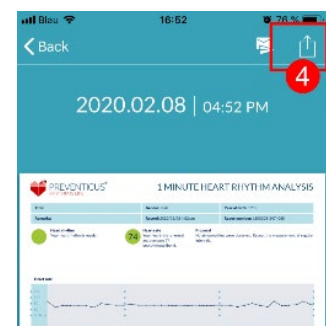
The list shows the reports and their main information in sequence: heart rate measurement, the corresponding traffic light colour of the measurement, comments and time of the measurement (2).

The measurement report is displayed in detail by tapping on the relevant report.

Measurement reports can be deleted from the list at any time (3). To do this, go to the bin icon . Now you can select individual reports in the list that should be deleted. In this mode, you can cancel your selection at any time by tapping on a new report. To cancel the entire selection, tap the "Cancel" button. Press "Delete" to delete the reports. The reports will be deleted immediately.



In the detailed view, you can share a report with other people (4). To do this, tap the "Share" button (iOS:  // Android: ). You can then choose from a selection of services to send the report or store it on your smartphone outside of the app. You receive a message that encryption or password protection of the document is recommended when sending the report.



11.3 Telecare - report list

If you have one or more reports with suspected mild arrhythmia (yellow traffic light) or absolute arrhythmia (red traffic light), you have the option to send these reports to the Telecare service for a fee.

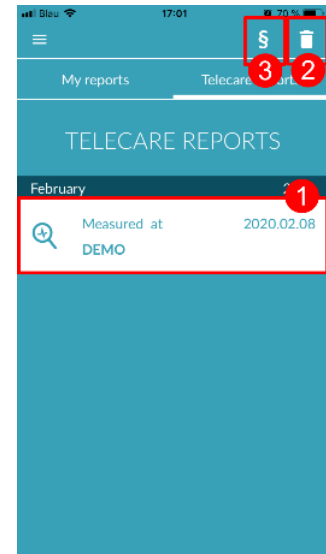
The Telecare service offers you a direct medical assessment of your measurements by Telecare employees who specialise in heart rhythm analyses of heart rate data.



The Telecare service will verify your measurement report. You will receive the result directly on your smartphone under Telecare reports.

See the "Telecare reports" section for a sample report (1).

Just like the measurement reports, you can also delete the Telecare reports (2).

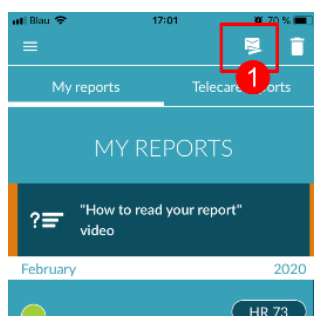
In addition, the General Terms and Conditions and Privacy Policy of the Telecare service can be found in this section (3).



You can also share the detailed view of the Telecare report with others. To do this, select a Telecare report from the list and go to the detailed view. Tap the "Share" button (iOS:  // Android: ) to subsequently receive a selection of services to send the report or store it on your smartphone outside of the app.

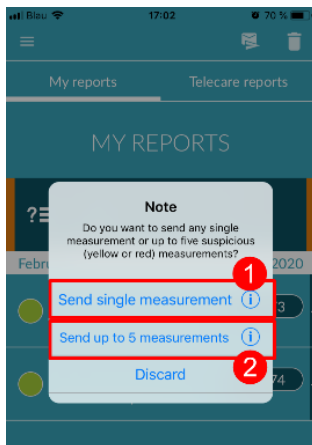


11.4 Telecare - order report



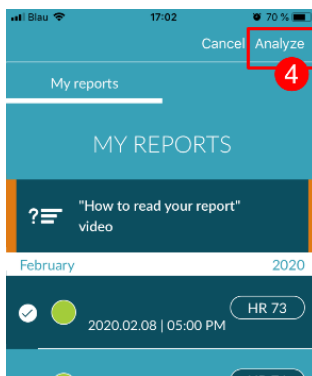
To order a Telecare report you have to be in the "My reports" list. Next, select the "Send" icon (1).

You can send a single measurement or up to 5 measurement reports.



Single measurement: select "Single measurement" if you only want to send one report (2). Keep in mind that you can send each report only once.

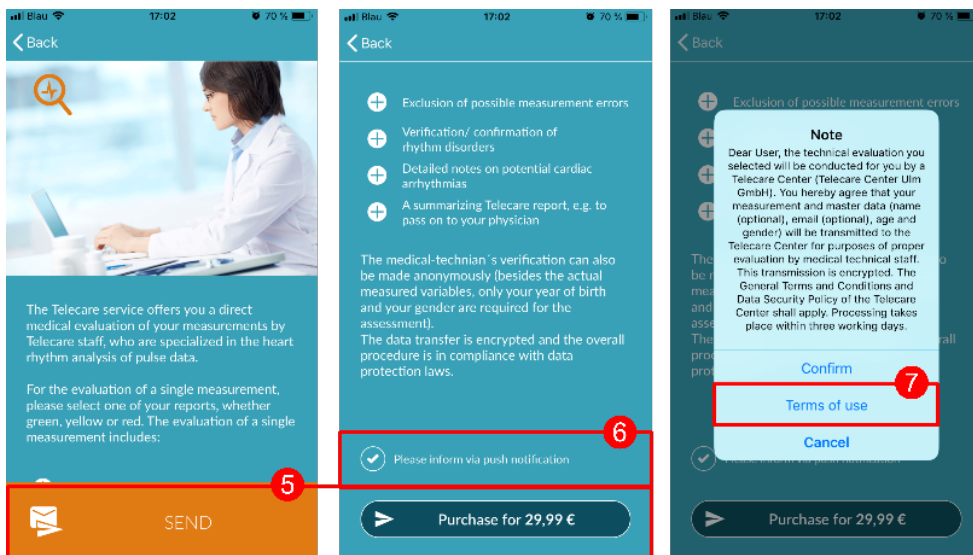
Several measurements: if you want to send several measurements at the same time, select "Send up to 5 measurements" (3). Please note that you can only select abnormal measurements (red and yellow traffic lights).



Select the report(s) you want to send and then tap "Analyze" (4).

You can now send the report(s) for a fee (5). The cost will be deducted from your specified payment method in the store.

Please note that to obtain a corresponding analysis you must give your consent (6) for the selected measurements and your baseline data (age and gender) to be sent to the Telecare centre. The transmission is encrypted.



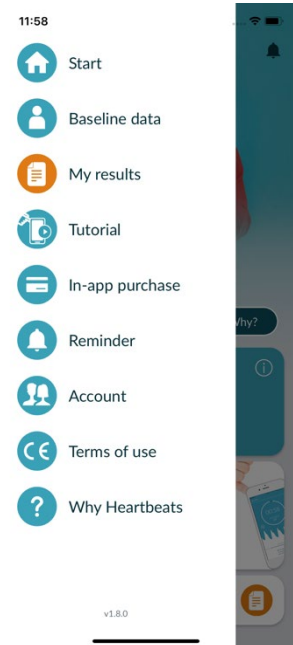
You will receive your personal Telecare report within 3 working days. You have the option to receive information to your smartphone via email or push notifications (7).

12 Menu

The menu consists of the following items:

- [Start](#): back to the home screen (see Chapter 7 Home screen)
- [Baseline data](#): personal information (see Chapter 12.1 Baseline data)
- [My results](#): overview of measurement results and Telecare reports (Chapter 11 Reports & Telecare)
- [In-App purchase](#): overview of the range of functions of the pre-test and full version (see section 13.1 In-app purchases)
- [Reminder](#): reminder function for regular measurements (see chapter 12.2 Reminder function)
- [User account](#): login and registration (see Chapter 12.3.1 User account and Chapter 14 Delete user account)
- [Legal](#): information on the topics - Purpose, Terms and Conditions, Privacy Policy, etc.
- [Why Heartbeats](#): information on the Preventicus Heartbeats app (see section 12.5 Why Heartbeats)
- [Version number](#)

You can reach the menu via the home screen (see Chapter 7 Home screen)

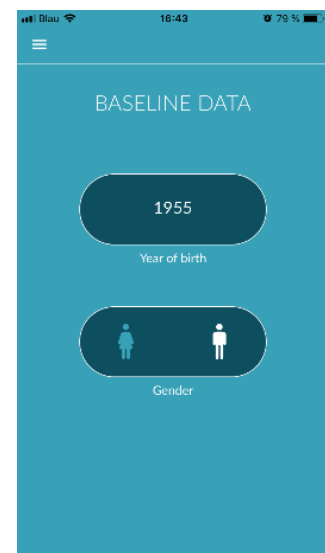


12.1 Baseline data

The base data is composed of gender and year of birth. After the first completed measurement, you must provide your basic data when creating the measurement report so that it can be used for analysis.

As a participant in the screening program, you enter this data in the course of enrollment.

In the menu item Basic data, you can view the information at any time and still change it afterwards.



12.2 Reminder function

In the "Reminder" menu item you have the option to be reminded of your daily measurements. You will receive push notifications on your smartphone to remind you to perform the measurement.

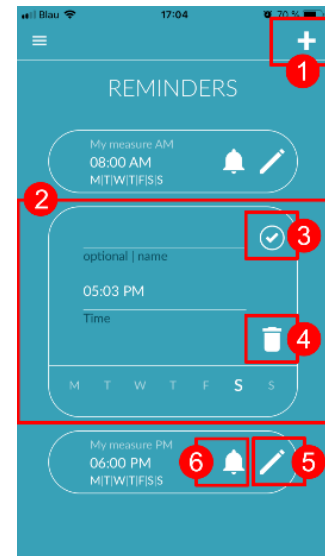
(i) Please note: To be able to use the reminder function, you must be registered.

You have the option to create your own reminders. To do this, click on the "+" icon (1).

A new reminder will appear (2). Enter a name, such as "Daily measurement early", then select a time and the day of the week. Confirm the reminder to create it (3) by pressing the "OK" icon.

You can edit (4) and delete (5) the reminder at any time. To delete the entry, press the "Edit" icon (4) and select the "Bin" symbol. The reminder will be permanently deleted.

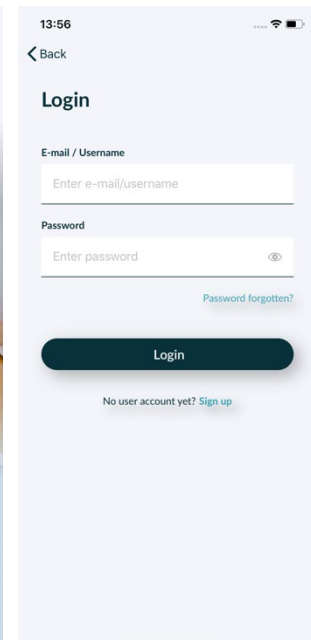
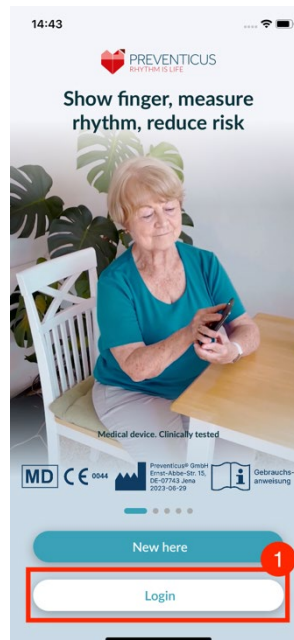
A reminder can also be deactivated (6) by tapping on the "Bell" icon. This button is automatically activated whenever a new reminder is created.



12.3 Login

If you have registered and thus have a user account, you can log in at any time with your e-mail or username and password and gain access to your measurements, reports and activated services.

1. To log in, select the "Login" button on the start screen (1).
2. You will then be taken to the login screen, where you can enter your e-mail or username and password. Click the "Login" button to complete the process. If you forget your password, you can reset it at any time and choose a new one by clicking "Forgot password?".
3. After successful login you will get to the overview page with all functions.



(i) Note: If you have made a mistake when entering your password or have entered an incorrect password, the system will inform you of this. In this case, please enter your password again.

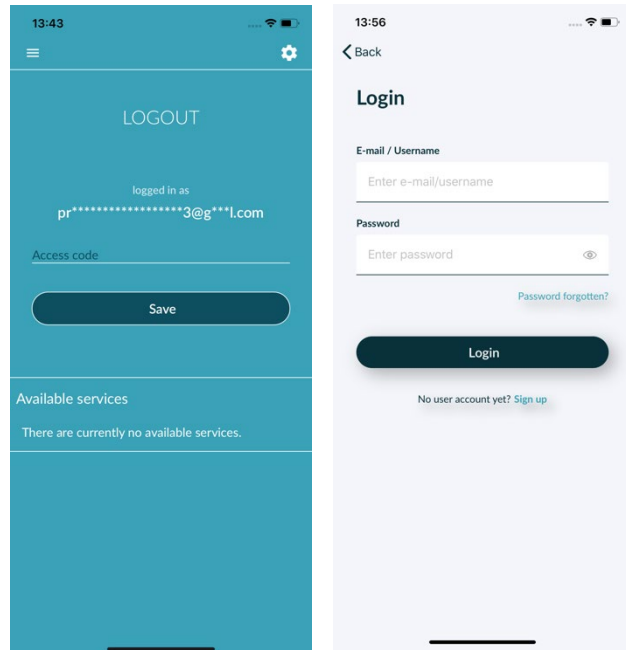
(i) Note: If your password cannot be reset, it is very likely that you are not yet registered as a user after all. In this case, click on the "No user account yet? Sign up" and register as a new user.

12.3.1 User account

The "User account" area is a part of the menu and shows you all the data associated with your user account. Here you can see if you are logged in to your user account and with which email address. Also shown are all services associated with your user account that are active for you.

If you have received an access code, e.g. by letter from your health insurance company, you can also enter this in the user account and thus activate the additional services.

Note: The information will only be displayed if you have logged in with your access data - e-mail or user name and password. Furthermore, a user account only exists if you have registered as a user.



12.3.2 Changing devices

Note: The transfer of the account including any existing user license as well as all reports is only possible when changing the smartphone if you have registered before.

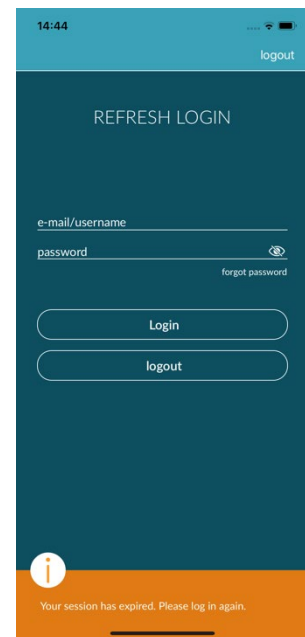
With the following steps you transfer your Preventicus user account including all data to your new smartphone:

1. Install the Preventicus Heartbeats app on your new smartphone.
2. Open the Preventicus Heartbeats app.
3. On the home screen, select the "Sign In" button to log in to your new device.
4. Enter your email and password that you used to register with Preventicus.
5. Then click on "Log in".

If you have forgotten your password, please use the "Forgot your password?" option. This will allow you to reset your password and choose a new one.

If you have completely forgotten your login details or are not sure if you are already registered, please contact our customer support: support@preventicus.com.

Note: It is not possible to log in on two devices at the same time. You will be automatically logged out on the second device when you log in on another device.



12.3.3 Multiple users - user change

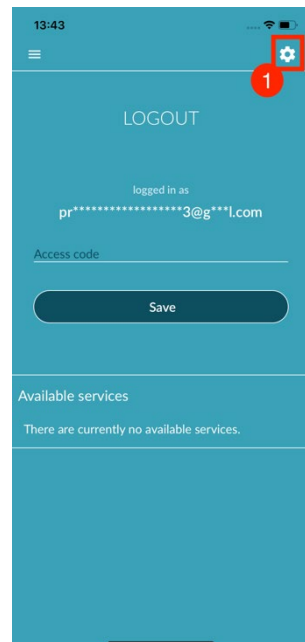
You have the option to set up the Preventicus Heartbeats app for multiple users.

To do this, use the option to create a user account for each user to ensure that each user's data is private and customized for them.

Once you have created the new account, you can change the account and thus the access at any time.

Initial situation - A user is already logged in:

1. On the overview page, select the "Profile" tile and click on it.
2. In the displayed user account you can see if and which account is currently logged in.
3. To change the user account, select the icon in the upper right corner (1). You have the option to choose between "Logout" and "Delete user account". Please, choose the "Logout" option.
4. After successfully logging out, you will be returned to the start screen. Here you can now log in to the app with your own access data via the "Log in" button. After successful login, you will see all your personal measurements as well as your individually unlocked services.

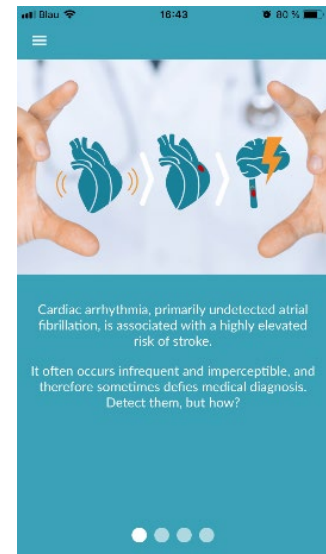


Note: Activated services such as full version licenses or participation in the preventive care program of a health insurance company are user account-bound and cannot be transferred or shared.

12.4 Why Heartbeats

In the “Why Heartbeats” section, you can find information on the consequences of arrhythmias as well as about the functions and content of the Preventicus Heartbeats app.

You can get to this section in the Home screen under “Why” as well as in the menu under “Why Heartbeats”.



13 Full version

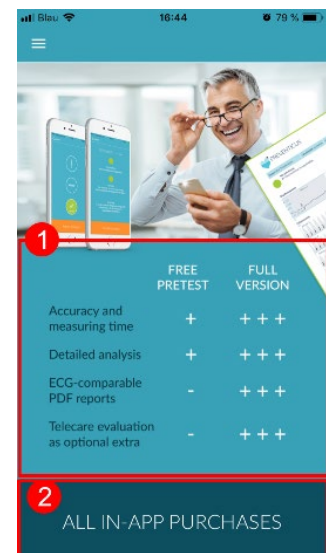
13.1 In-app purchases

The “In-app purchases” is a sub-item of the menu. This overview shows the different products offered and a comparison between their ranges of function (1).

The app is available as a free and full version. The free version rates the heart rate as normal (grey traffic light) or abnormal (orange traffic light) based on a 1-minute measurement.

In the full version, you can choose between a 1- minute and 5-minute measurement. After the measurement, you will receive a detailed analysis. The measured data and analysis are saved as a report. The reports can be viewed in menu item “My results” (see *Chapter 11 Reports & Telecare*).

You can find more information about purchasing the full version under “All In-app purchases” (2). You can trial the full version for 30 minutes.



13.2 Purchase of the full version

To buy the full version, open menu item "In-app purchase" ([Chapter 13.1 In-app purchases](#)).

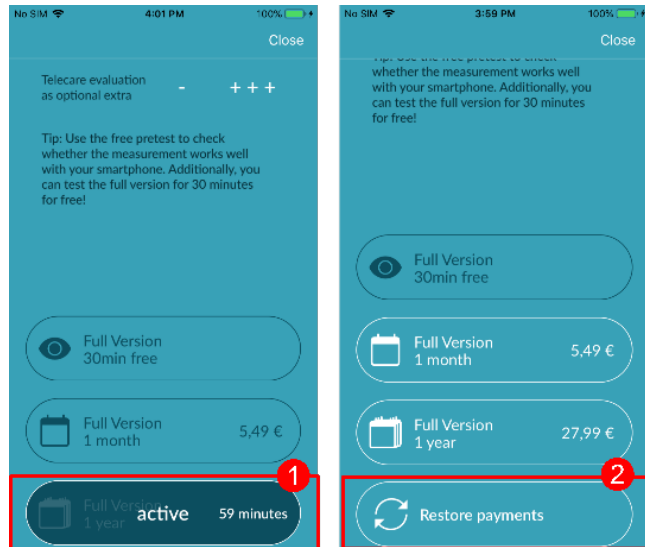
Under "All in-app purchases", you can choose between two prices, based on the period of validity – 1 month or 1 year.

This is not a subscription. Once the period of validity expires, it will not be automatically renewed.

The current period of validity will be shown in "All in-app purchases" (1).

i Please note: these are in-app purchases. You can only make a purchase if you have an active store account on your operating system.

i Please note: you do not have to be registered to complete a purchase.



Completed purchases can be restored in the "In-app purchases" area as long as their period of validity has not yet expired (2).

i Please note: iOS customers have the option to restore all in-app purchases on the new device when they change their device, provided the Apple ID of all in-app purchases remains the same. Otherwise all purchases will be lost together with the old device. We use iCloud Drive to be able to link the "Purchase complete" information with your account. Having an iCloud Drive is therefore a prerequisite for in-app purchases from Preventicus Heartbeats.

i Please note: if you cannot access the full version, please check if you are logged into the app. If you haven't registered in the app yet, please close all apps on your smartphone. Close the app and restart it. Open the "In-app purchase" field in the menu. Find the "Restore purchases" button at the bottom. This should restore your access to the full version.

14 Delete user account

If you are registered as a user in the Preventicus Heartbeats App, you can delete your user account and the associated information and documents at any time.

Please note that this action is final. Your data cannot be restored if you change your mind.

Step 1: What happens if you delete your account?

- All data, reports and purchases associated with this account will be lost.
- You will no longer have access to past measurements and reports.
- You will lose access to purchases you have made and content you have purchased from the AppStore or Google Play, e.g. Telecare reviews.

i Note for participants in the preventive care program: Deletion of your user account always goes hand in hand with cancellation and thus termination of your preventive care program.

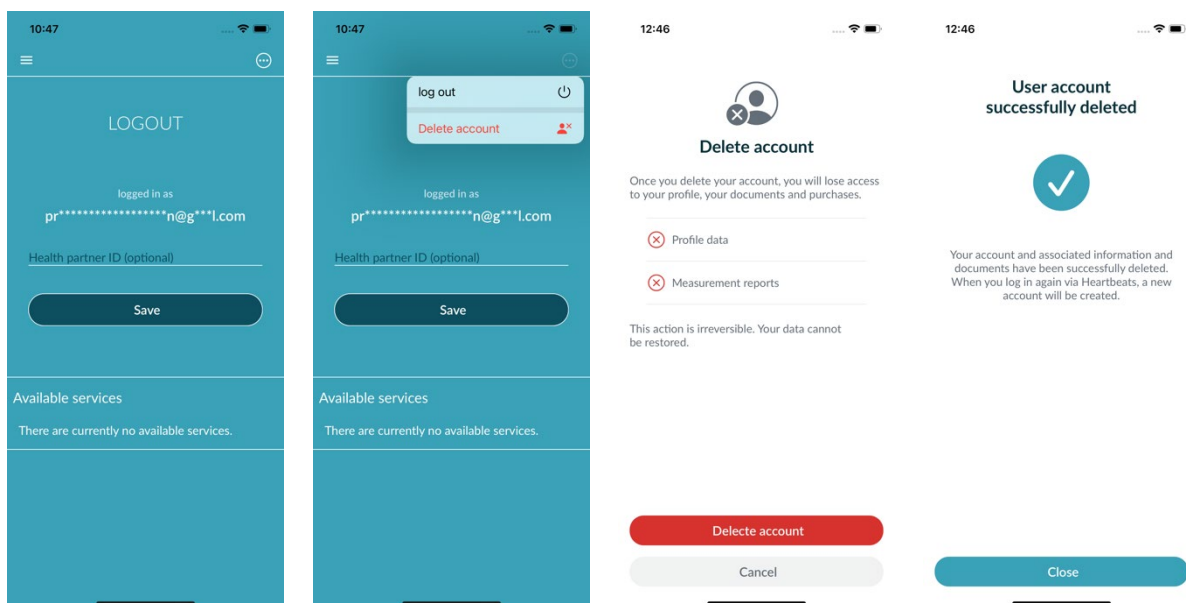
Step 2: Verify and download data

Before you delete your account:

- Review the data in your account.
- Reports that you would like to keep should either be saved, transferred to another PC, or forwarded before deleting.
- To do this, use the "Share" function on each report.

Step 3: Delete account

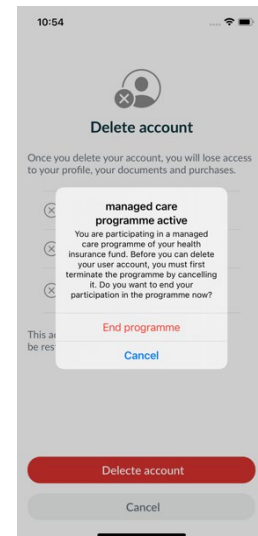
1. Open the menu.
2. Select the "User account" section in the menu.
3. In the upper part of your user account view you will find an icon with three dots, behind which an additional navigation menu is hidden.
4. Click the three dots icon to open the additional navigation menu.
5. Then select the option "Delete account". The following screen will list all the data that will be deleted.
6. To delete your user account permanently, click on the "Delete account" button and follow the instructions on your screen.
7. If your account has been successfully deleted, you will see a hint message.



NOTICE for participants in the health insurance prevention program

As a registered user in the preventive care program, you must first revoke or cancel your contract in order to delete your account. To do this, you will see a message when you click on the "Delete account" button.

Select "End programme" and revoke/terminate your contract. Then follow the instructions on your display to permanently delete your user account.



15 Error messages

How do I get to the Preventicus Heartbeats app? How do I install the Preventicus Heartbeats app on my phone?

This is how you install Preventicus Heartbeats:

1. On your Android smartphone (e.g. Samsung or Huawei device), please open the Google Play Store or on your iOS smartphone (iPhone), please open the App Store.
2. Enter "Preventicus Heartbeats" in the search box.
3. Tap "Download" or "Install" and watch the progress.
4. Once the app is installed, the description will change from "Install" to "Open".
5. Tap "Open" to launch Preventicus Heartbeats. Likewise, the app will appear as a heart icon on your smartphone home screen. By tapping the logo, they can also launch the app.

What should I do if the internet connection is weak (error code 500)?

Please try to position yourself close to your WLAN router or switch on mobile data for your smartphone for use by Heartbeats. If the connection is still poor, switch flight mode on your smartphone on and off again.

What should I do if I cannot update the app?

Please contact support@preventicus.com.

What should I do if the app displays a jumble of letters or a different language?

Please contact support@preventicus.com.

What should I do if the app displays the following message: "Session token not found"?

Please contact support@preventicus.com.

What should I do if I do not have a connection to the server? (Message: "Problems communicating with the server")

Please contact support@preventicus.com.

What should I do if the app does not open or crashes?

Please close the app and open it again. If the app still does work, please uninstall it. Install it again from the corresponding app store and log into the app again with your email address and your password. If that does not help either, please switch your smartphone off and on again and then open the app again.

16 Uninstalling the app

The Preventicus Heartbeats app is stand-alone software that can be used with a smartphone, but it is not ME equipment in the sense of IEC 60601-1. The product can be disposed of by uninstalling the app from the user's smartphone. If you remove an app you have paid for, you can re-install it for free.

17 Technical data

	iOS	Android
Language	German English French Spanish Italian Polish Greek Dutch Hungarian Danish Arabic*	German English French Spanish Italian Polish Greek Dutch Hungarian Danish Arabic*
Required operating system	iOS 12.1	Android 7.0

*SFDA approval pending, Arabic language will be released in the Preventicus Heartbeats App after SFDA approval



Preventicus® GmbH
Ernst-Abbe-Str. 15,
DE-07743 Jena

This stand-alone software is a medical device classified as risk category IIa, in accordance with rule 11 of Regulation (EU) 2017/745 / risk category B in accordance with rule 11 of MDS-REQ-001.

18 Manufacturer information

The Preventicus Heartbeats app is a product by Preventicus GmbH. Their contact details are

Preventicus GmbH
Ernst-Abbe-Strasse 15
DE-07743 Jena
Germany
Phone: +49 (0) 3641 55 98 45 0
Internet: www.preventicus.com
Email: info@preventicus.com

If you have any questions relating to the product or application, please contact our customer service:

Email: support@preventicus.com