



PREVENTICUS
RHYTHM IS LIFE

EN

Preventicus Heartbeats app

Instructions for use

App version: 1.6

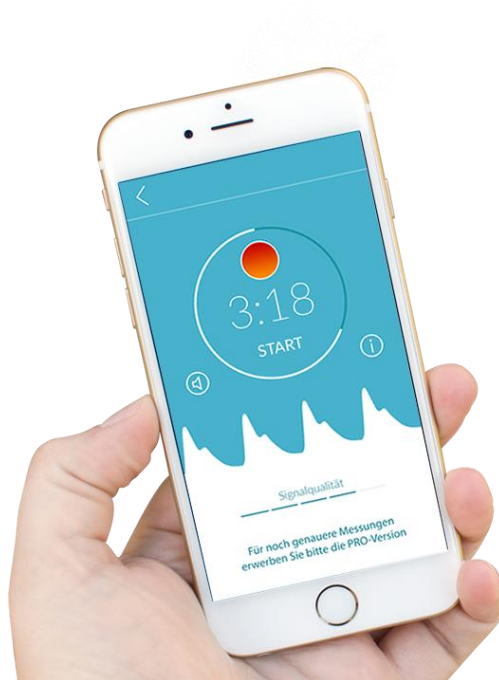


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These instructions for use describe how to use the Preventicus Heartbeats app on smartphone devices with iOS and Android operating systems and how it works.

An up-to-date list can be found on <https://live.preventicus.com/static/app/beats/content/devices>. For ease of use, the term 'smartphone' is exclusively used below.

More information can be found on the Preventicus support website at (<https://www.preventicus.com/support>). You can also order a paper version of these instructions for use from the website free of charge.

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 10 of EU Directive 93/42/EEC, last amended by 2007/47/EC of the European Parliament and Council of 5 September 2007.
	Warning A warning is always related to safety.
	Note A note informs the user of interesting information.
 <div>Preventicus® GmbH Ernst-Abbe-Str. 15, 07743 Jena, Germany</div>	Manufacturer's specifications

2 Introduction

Thank you for your interest in Preventicus Heartbeats. Preventicus Heartbeats not only analyses your heartbeat, but also and especially your heart rhythm - simple and at any time with your smartphone camera, no accessories needed. The app has been validated in clinical studies and detects irregular heartbeats (e.g. extrasystoles) as well as the presence of absolute arrhythmia with suspected atrial fibrillation (AF). However, irregular heartbeats (e.g. extrasystoles) and atrial fibrillation can only be diagnosed in accordance with the guidelines with an ECG of the thoracic wall, generally carried out by cardiologists.

If you are feeling unwell or experience other troubling symptoms, please seek medical advice immediately.

2.1 Purpose

The purpose of the app is to detect signs of the presence of cardiac arrhythmias in a non-clinical environment. This includes the following cardiac arrhythmias: **detection of signs of absolute arrhythmia with suspected atrial fibrillation, detection of signs of extrasystoles as well as measuring the heart rate with signs of bradycardia and tachycardia without further diagnostic differentiation.**

Under no circumstances may this app be used for diagnosis in situations considered to be life-threatening.

Using the smartphone camera, a pulse curve is captured from the fingertip over a period of up to 5 minutes and the heart rate data derived. If any evidence of arrhythmia is found, the user can store the underlying information in a measurement report. The user is also recommended to undergo further medical assessment by professionals. Preventicus has verified the detection of atrial fibrillation and extrasystoles and the accuracy of the heart rate detected with in-house clinical studies (see also: www.preventicus.com/Studien). These have shown that the underlying algorithm of the app can distinguish between atrial fibrillation and a regular heart rhythm with an accuracy of more than 96%.

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. The full version distinguishes between three categories after a measurement of up to 5 minutes: no abnormalities (green traffic light), slight arrhythmia (>5% of all beats are irregular -> yellow traffic light) or the presence of severe arrhythmia (red traffic light) detected. In addition, the user is informed of any suspected relevant bradycardia or tachycardia (without differentiating between possible causes) and is advised that prompt cardiac assessment is necessary if this occurs regularly and is not already under medical observation. Any interferences occurring during the measurement (wobbling, coughing, shaking, etc.) are automatically detected and eliminated.

The full version also links to a measurement report of the results and allows you to print it off. The report shows the original pulse curve over the course of maximum 5 minutes and integrates symbolic R peaks in each cardiac cycle. This allows the treating physician to visually assess the heart rhythm, understand the automatic interpretation and take any further diagnostic measures.

The result obtained merely constitutes a possible suspicion ("Suspected diagnosis"), not a diagnosis in the medical sense. The results obtained are for information purposes only and should under no circumstances replace a personal diagnosis or personal advice, care or treatment by medical or medically trained personnel.

The app should not be used for decision-making in life-threatening situations or for real-time monitoring of vital functions nor should it intervene with existing diagnostic pathways or therapeutic measures according to the guidelines.

A basic distinction should be made between AF detection (screening or progress monitoring) and subsequent AF diagnosis. **AF should be exclusively diagnosed with an ECG of the thoracic wall, generally performed by cardiologists, in accordance with the guidelines.** Preventicus apps are not intended for the final diagnosis of AF with therapeutic implications, but exclusively for AF screening or AF progress monitoring without therapeutic implications. Any therapeutic implications should only arise based on a real ECG, not on plethysmographic technology, as accurate as this may be.

2.2 Intended use

The app can be used by anyone, who is confident in the use of smartphones and smartwatches, aged 18 years and over, regardless of sex, for their own self-testing. The measurement should be performed at normal room temperature and under normal lighting conditions. **The camera should be used only on healthy skin tissue on the finger. Users with reduced sensitivity to pain are advised not to use this product.** The app should not be used when the terminal device is charging.

The app is intended for use on a terminal device that has been tested and released for this purpose by Preventicus GmbH. An up-to-date list can be found under the following link <https://live.preventicus.com/static/app/beats/content/devices>

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..

3.2 Additional notes and comments

ECGs are the gold standard for rhythmological diagnostics. An analysis of the heart rhythm based on the pulse curve is an appropriate screening method as a preliminary step to further diagnosis.

Preventicus Heartbeats detects atrial fibrillation with an overall accuracy of 96% according to the studies conducted. The sensitivity (correct positive rate) is approx. 92%. The sensitivity indicates the probability with which atrial fibrillation is detected as such. In parallel, the specificity (true-negative rate) indicates the proportion of users not affected by atrial fibrillation for whom the result is correctly displayed with a green traffic light. The specificity of Preventicus Heartbeats is 99%. Atrial fibrillation can occur sporadically; if it is not present at the moment of measurement, it cannot be detected by Preventicus Heartbeats.

It cannot be ruled out that existing diseases (such as diabetes, vascular diseases or the condition after cardiovascular operations), medications affecting the pulse rate or pacemakers may falsify the accuracy of Preventicus Heartbeats.

4 Service life of the product

The service life of the product is the timeframe until a new version of the app is released. This is indicated by an increase of at least the second digit of the version number. Details of the version number can be found in the relevant app store.

<https://itunes.apple.com/de/app/preventicus-heartbeats-herzstolpern/id1122978949>

https://play.google.com/store/apps/details?id=com.preventicus.heartbeats&referrer=adjust_reftag%3DcnkNmWWmkMJ7H%26utm_source%3DPreventicus.com

Update information is provided by the operating system. Depending on the smartphone's user settings, the update will either be carried out automatically or will have to be actively approved and started by you.

5 Data backup

Data can be backed up in the following way:

The reports can be exported and sent as PDF files, e.g. by email. This allows them to be stored in other databases (e.g. PDMS, Praxis software) or on other storage media (e.g. hard drive, memory card).

6 Measuring principle: basics of the pulse curve analysis

Preventicus Heartbeats is used to capture the so-called pulse curve at the tip of the finger using the camera on your phone. You place your finger on the lens of the camera and light from the lens is radiated into your fingertip. Signal analytical methods are then used to derive the pulse curve from the camera signal, in a similar way to the medical procedure photoplethysmography. The pulse curve corresponds to the blood pulsation resulting from the activity of the heart.

Based on the variability of the heartbeat in combination with biosignal analytical methods, the app can detect any signs of arrhythmia.

7 First-time use

The Preventicus Heartbeats app is compatible with smartphones from operating system iOS 10.3 and Android 5.0 onwards.

When you have installed the Preventicus Heartbeats app and use it for the first time, you must first accept its purpose, including the warnings, Privacy Policy and Terms and Conditions, in order to use the app.

General terms and conditions

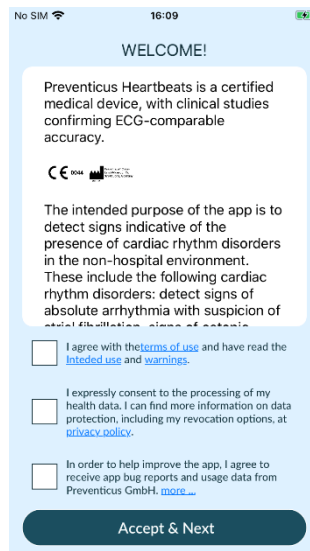
<https://www.preventicus.com/allgemeine-geschaeftsbedingungen/>

Privacy of the Preventicus Heartbeats app

<https://www.preventicus.com/datenschutz-der-app/>

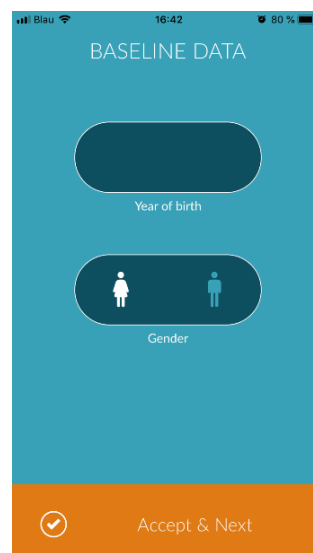
7.1 Reading and accepting the purpose, including the warnings, Terms and Conditions and Privacy Policy

Please read the Terms and Conditions carefully and accept them to continue.



7.2 Entering baseline data

Please enter your year of birth and your gender to continue.



8 Home screen

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

- [Measurement modes](#) (see *Chapter 9.1 Choice of measurement mode*) (1)
- [Reports](#) (see *Chapter 12 Reports & Telecare*) (2)
- [Reminder](#) (see *Chapter 13.2 Reminder function*) (3)
- [Login](#) (see *Chapter 13.3 User account*) (4)
- [Tutorial](#) (see *Chapter 9 Performing a measurement*) (5)
- [What you should know about the app](#) (see *Chapter 13.5 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 13 Menu* for more details.



9 Performing a measurement

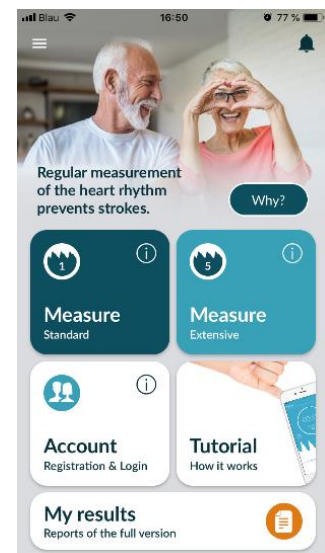
9.1 Choice of measurement mode

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:

- | | |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Standard: | 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.

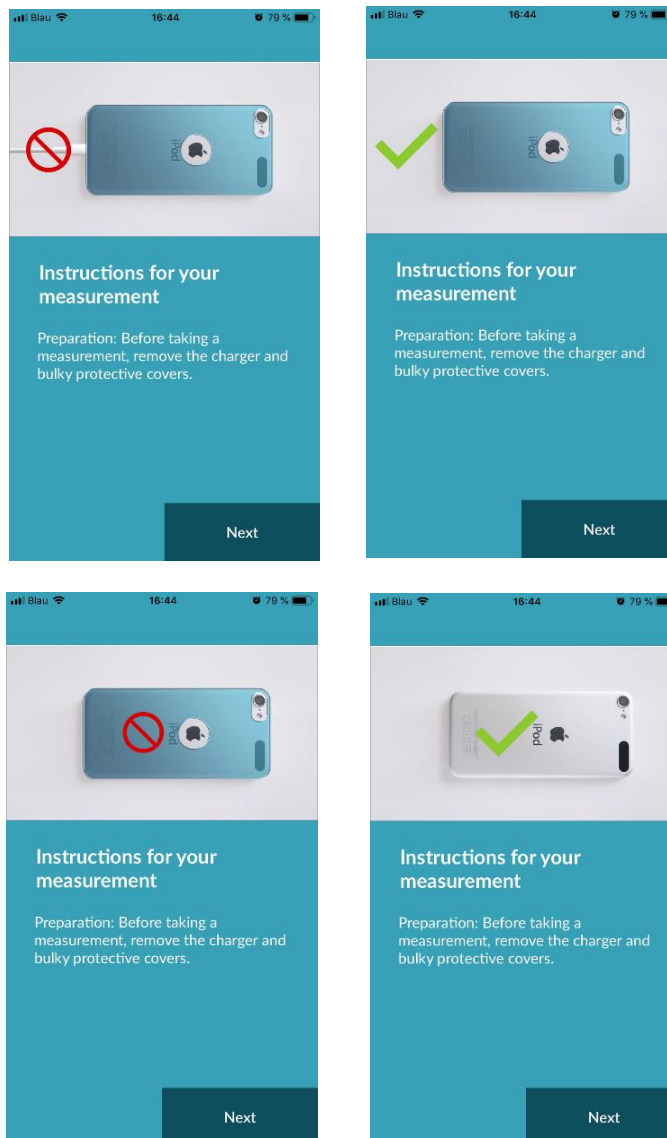
The free version rates the heart rate as normal (grey traffic light) or abnormal (orange traffic light) based on a 1-minute measurement. The result is displayed by means of a traffic light system. A measurement report is only created in the full version.



9.2 Preparing the device

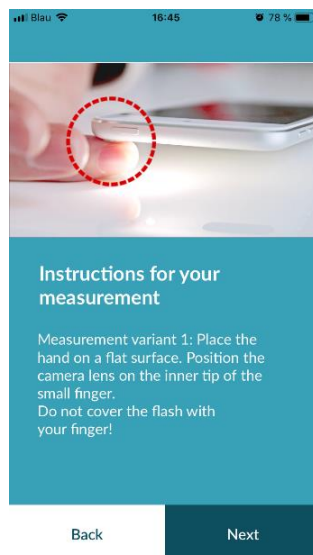
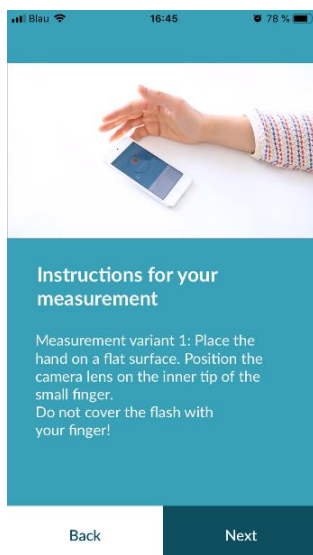
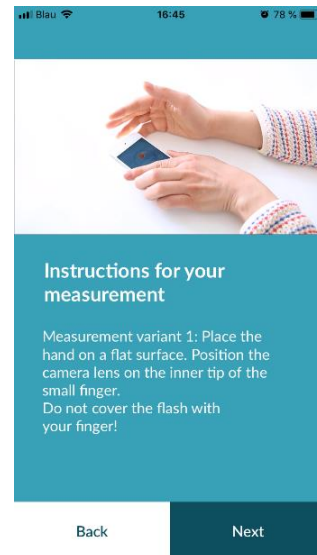
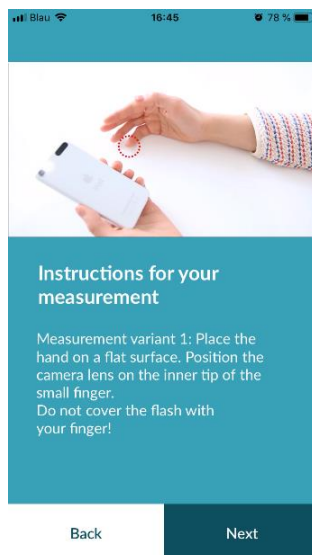
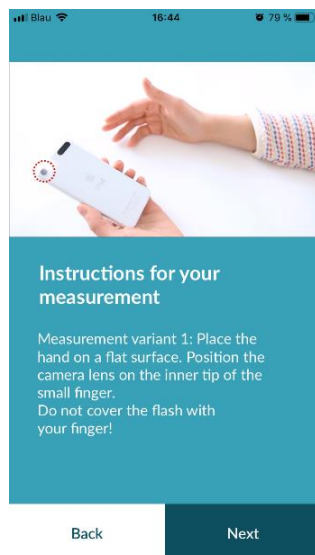
Before the first measurement, you are provided with instructions on how to carry out a measurement (tutorial). Please read these carefully. Once you complete the tutorial, you can either view it again or start a measurement.

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



9.3 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.



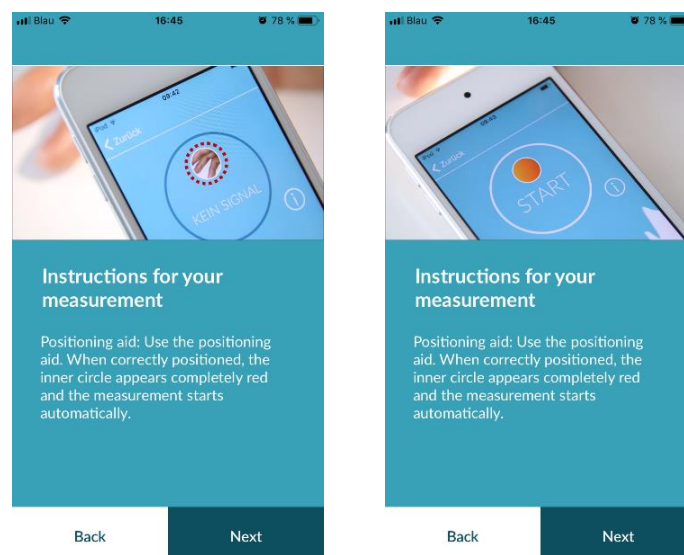
9.4 Alternative measuring position

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.



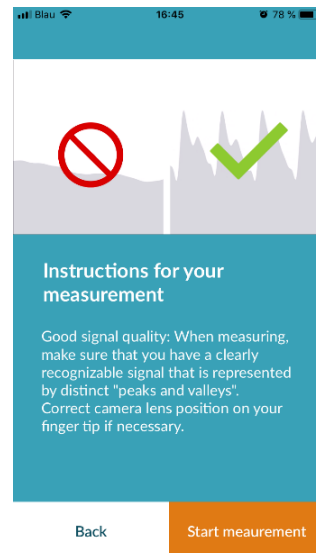
9.5 Using the positioning tool

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. The camera lens is correctly positioned when the entire inner circle of the preview window is red.



9.6 Detecting good signal quality

Next, the system checks the signal quality. Wait until you find an easily detectable signal. Then the measurement will start automatically. To assess the signal quality, please check the bar graph at the bottom. The signal quality indicator should be located in the penultimate or preferably in the last segment. If necessary, correct the position of the camera on your fingertip.

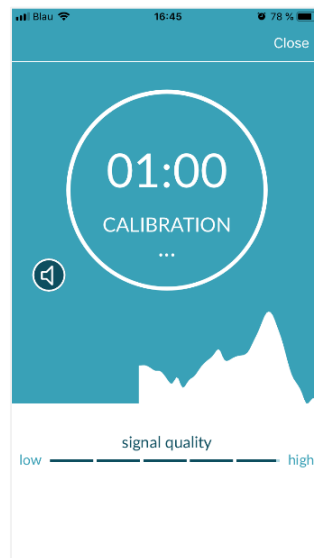


9.7 What to do during the measurement

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

9.8 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 you have an easily detectable signal, the measurement will start automatically.



10 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.

11 Interpretation of the results

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




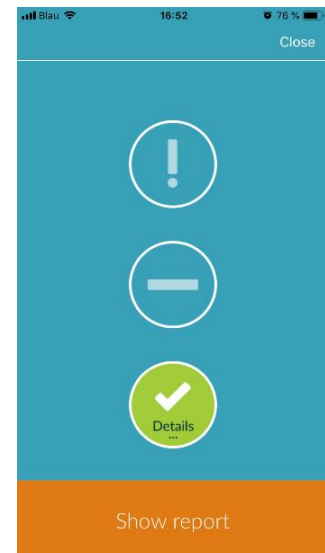
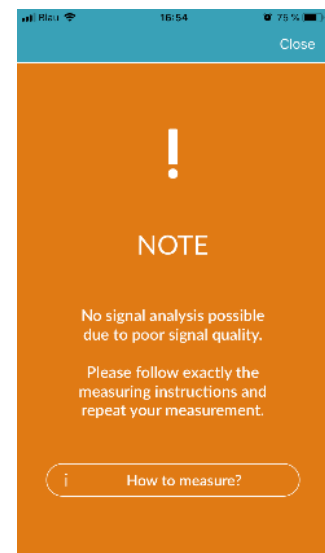
Traffic light colour	Meaning
Green 	Regular heart rhythm and normal heart rate
Yellow 	Slight arrhythmia (>5% of all beats are irregular) and/or a slightly increased or decreased heart rate
Red 	Absolute arrhythmia with suspected atrial fibrillation and/or a significantly increased or decreased heart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

Table 11.1 Colour labels and heart rhythm and heart rate assessment



11.1 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.



12 Reports & Telecare

12.1 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. 12.1).

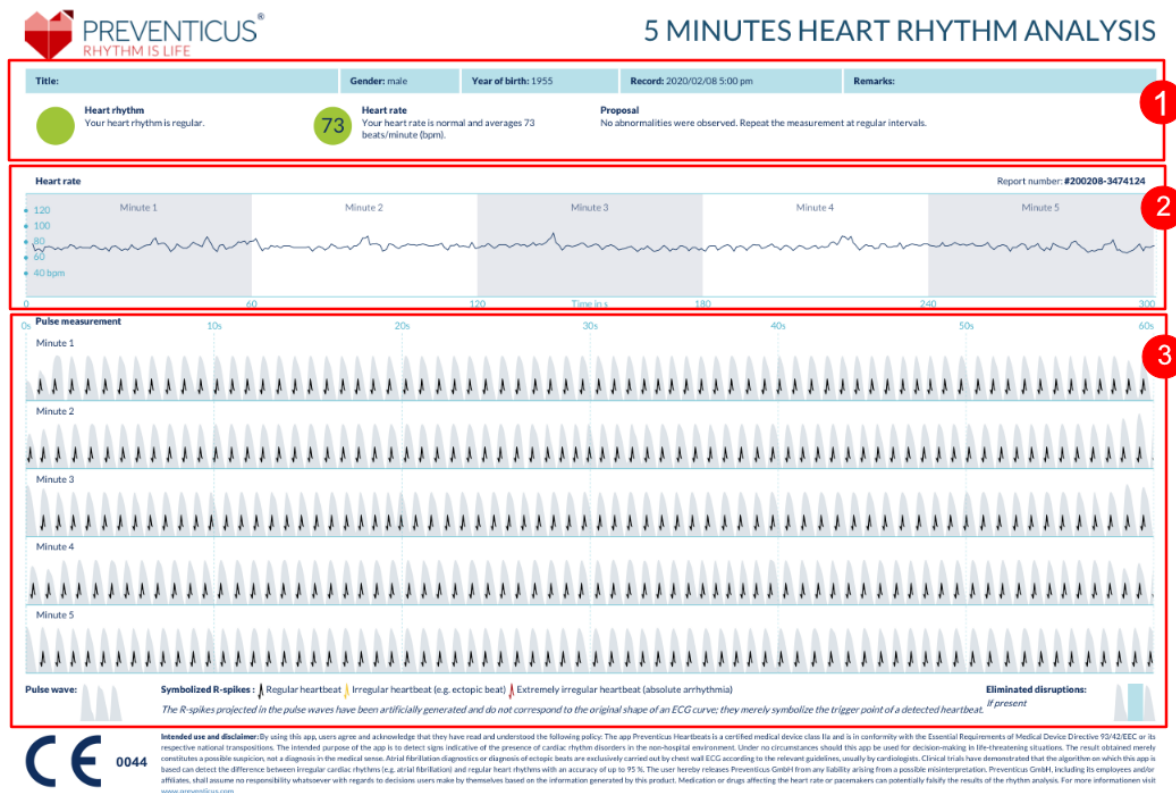


Fig. 12.1 Preventicus Heartbeats measurement report consisting of three sections: 1 - Summarised results of the heart rhythm analysis, 2 - Heart rate in beats per minute (bpm) over the entire measurement, 3 - Original pulse curve over the entire measurement

The summarised results of the heart rhythm analysis (see Fig. 12.1/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 11.1). Depending on the result, you are offered an additional medical assessment by a medical professional.

In the second part of the report (see Fig. 12.1/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. 12.1/section 2, are normal and are usually caused by the interaction between breathing and heartbeat.

Sudden positive or negative peaks, as shown in Fig. 12.2, however, are caused by individual irregular heartbeats and may be evidence of extrasystoles.

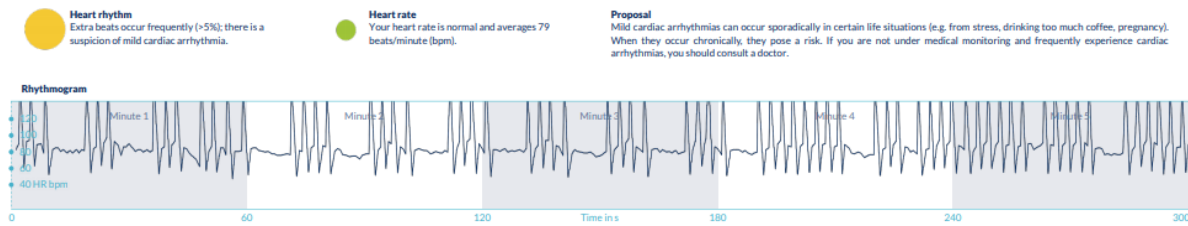


Fig. 12.2 Summarised results of the heart rhythm analysis and heart rate in beats per minute (bpm) over the entire measurement of a report with slight arrhythmia

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. 12.3 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.

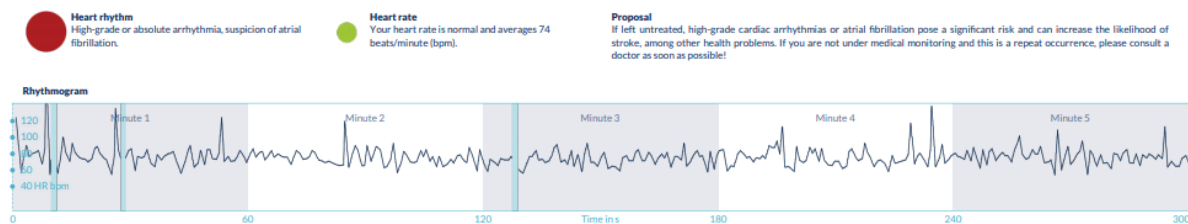


Fig. 12.3 Summarised results of the heart rhythm analysis and heart rate in beats per minute (bpm) over the entire measurement of a report with absolute arrhythmia

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. 12.4). 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).

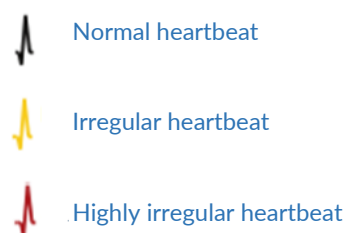


Fig. 12.4 Legend of the R peaks in the original pulse curve

Blue bars in the pulse curve (see Fig. 12.5) indicate an automatically detected disruption, which could be caused by movement, environmental light or camera readjustments.

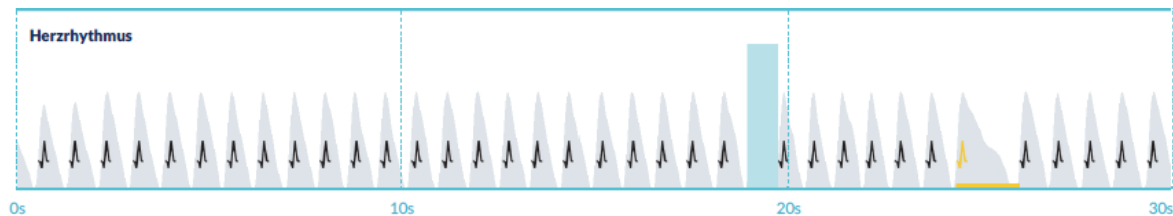


Fig. 12.5 Original pulse curve of the measurement report with detected disruption (blue bar)


12.2 Measurement report list

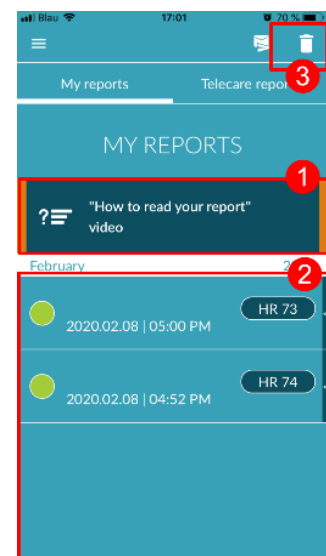
After each measurement, the reports are stored in a list and can be viewed via the menu item “My results”.



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

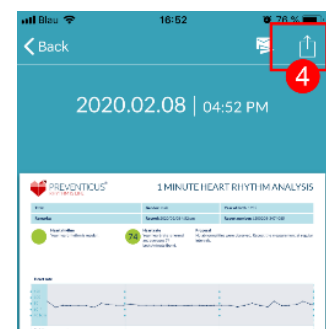
The list shows the reports and their main information in sequence: heart rate measurement, the corresponding traffic light colour of the measurement, comments and time of the measurement (2).

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.



12.3 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.

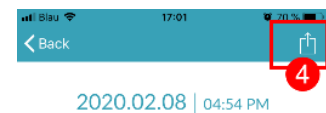
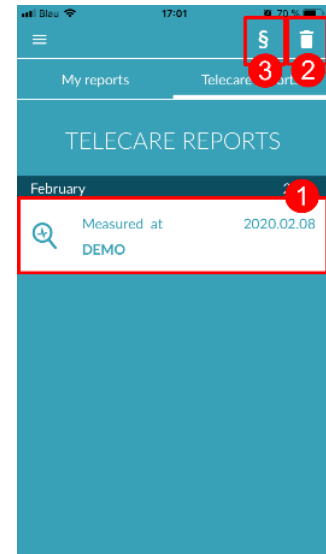
The Telecare service offers you a direct medical assessment of your measurements by Telecare employees who specialise in heart rhythm analyses of heart rate data.



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).

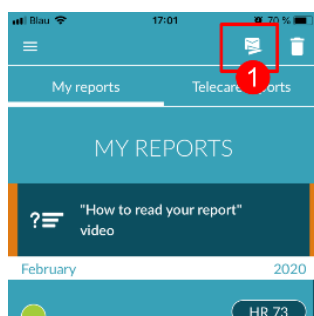
In addition, the General Terms and Conditions and Privacy Policy of the Telecare service can be found in this section (3).



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.

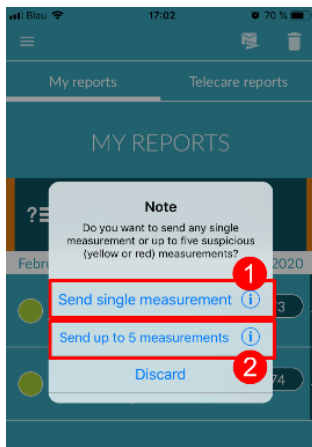


12.4 Telecare - order report



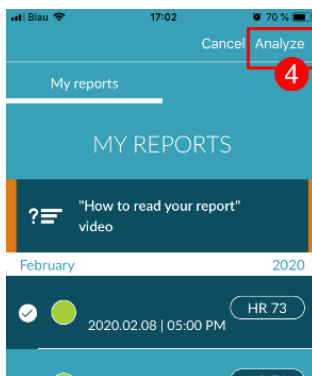
To order a Telecare report you have to be in the "My reports" list. Next, select the "Send" icon (1).

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.

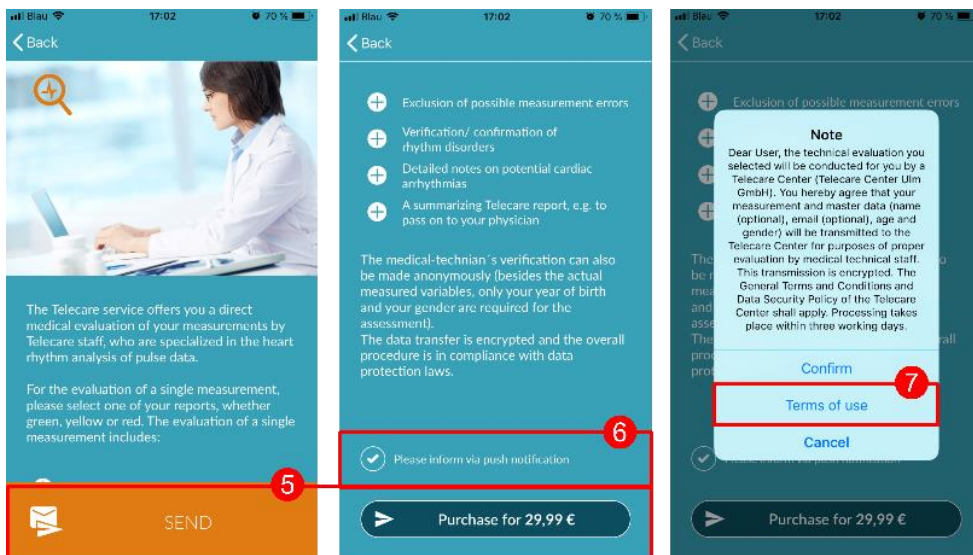
Several measurements: if you want to send several measurements at the same time, select "Send up to 5 measurements" (3). Please note that you can only select abnormal measurements (red and yellow traffic lights).



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.

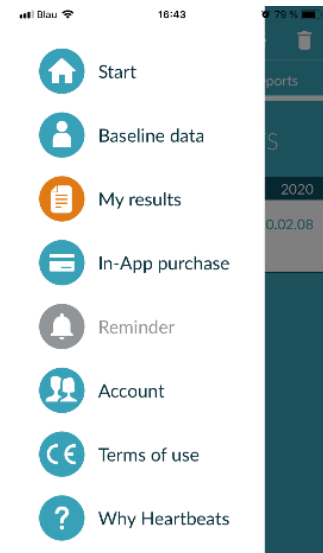


You will receive your personal Telecare report within 3 working days. You have the option to receive information to your smartphone via email or push notifications (7).

13 Menu

The menu consists of the following items:

- [Start](#): back to the home screen (*see Chapter 8 Home screen*)
- [Baseline data](#): personal information (*see Chapter 13.1 Baseline data*)
- [My results](#): overview of measurement results and Telecare reports (*Chapter 12 Reports & Telecare*)
- [In-App purchase](#): overview of the range of functions of the pre-test and full version (*see section 14.1 In-app purchases*)
- [Reminder](#): reminder function for regular measurements (*see chapter 13.2 Reminder function*)
- [User account](#): login and registration (*see Chapter 13.3 User account*)
- [Legal](#): information on the topics - Purpose, Terms and Conditions, Privacy Policy, etc.
- [Why Heartbeats](#): information on the Preventicus Heartbeats app (*see section 13.5 Why Heartbeats*)

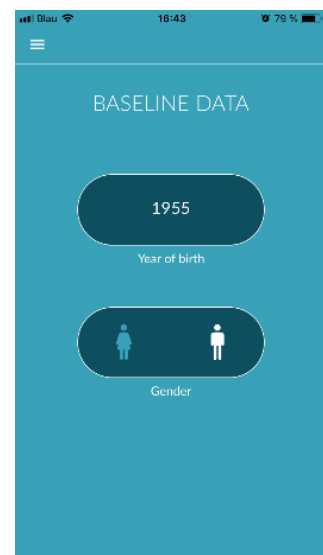


You can reach the menu via the home screen (*see Chapter 8 Home screen*)

13.1 Baseline data

Baseline data include gender and year of birth. These are specified during first use (*Chapter 7 First-time use*).

You can access the data at any time and subsequently change them in the menu item Baseline data.



13.2 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.

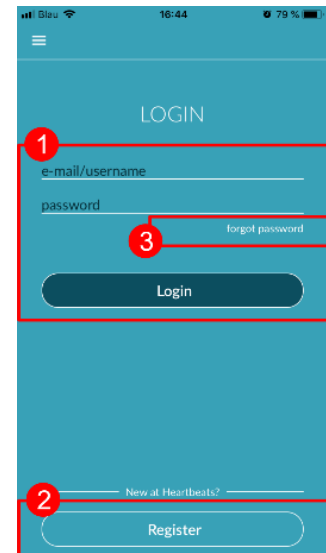


13.3 User account

The "User account" area is part of the menu. Here you can log in (1) if you already have an account or you can create an account (2). If you have forgotten your password (3), you can reset it here.

More information can be found in the individual sections.

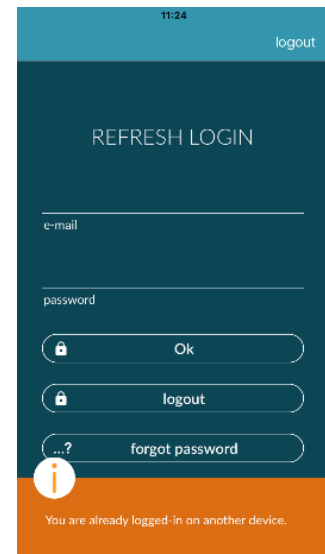
(i) Please note: If you are unable to reset your password, it is very likely that you are not a registered user yet. Simply create a new login.



13.3.1 Login

If you already have an account, you can easily log in with your email or username and password.

You cannot log into two devices at the same time. You will be signed out automatically on the second device if you log in on a different device.



13.3.2 Registration

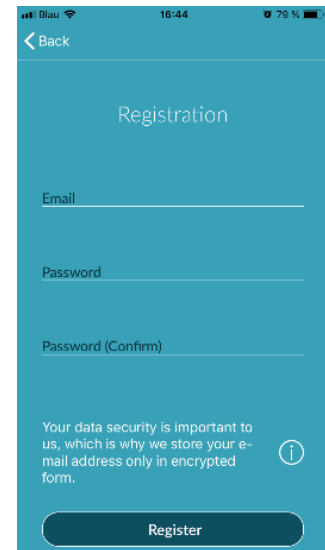
When you register as a user on the Preventicus Heartbeats app, your user data will be linked to your account from then on. If you get a new smartphone, you will only have to log into the app and your licence and data will be automatically restored.

To register, enter an email address, choose a password and confirm. Entering a username, name and first name is optional. Registration can only be completed if all data has been entered correctly.

You will receive an email with an activation link to confirm your registration.

i Please note: you have to confirm your email address within 48 hours. After this time, you have the option to request confirmation again and you will be sent a new email.

i Please note: if you do not receive an activation link to confirm, please contact our customer service: support@preventicus.com.



13.3.3 Changing devices

If you change your device, you will only be able to transfer your account, including any available user licence and all reports, if you have a registered account.

13.4 ID of your health partner (only for members of the prevention programme)

If you are a member of a prevention programme run by your health insurance or other insurance company, you will have received login data (also called ID) from your health partner by post or by email. These login data can be entered in the field "Health partner ID" during your registration (1).

(i) Please note: you need to register to enter your ID.

If you already have an account, you can store the ID in the login area.

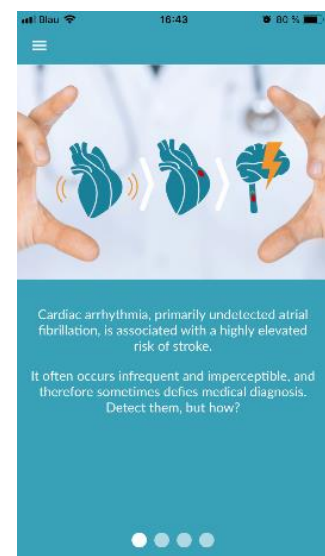
(i) Please note: to do this, please log in (2).

The image contains two screenshots of the Preventicus Heartbeats app interface. The left screenshot is titled 'REGISTRATION' and shows a form with a 'Health Partner ID' field highlighted by a red rectangle and a red circle with the number '1'. The right screenshot is titled 'LOGOUT' and shows a 'Health partner ID (optional)' field highlighted by a red rectangle and a red circle with the number '2'.

13.5 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".



14 Full version

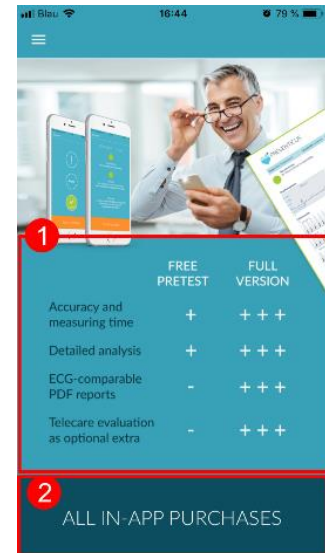
14.1 In-app purchases

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 12 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.



14.2 Purchase of the full version

To buy the full version, open menu item “In-app purchase” (*Chapter 14.1 In-app purchases*).

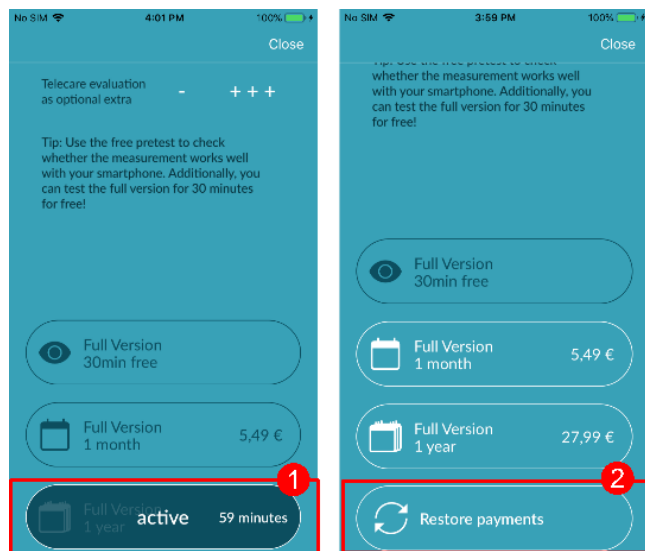
Under "All in-app purchases", you can choose between two prices, based on the period of validity – 1 month or 1 year.

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).

① **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.

① **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.

15 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.

16 Technical data

	iOS	Android
Current version	1.6	1.6
Language	German English French Spanish Italian Polish Greek Dutch Serbian Hungarian Danish	German English French Spanish Italian Polish Greek Dutch Serbian Hungarian Danish
Required operating system	iOS 12.1	Android 7.0



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2017-11

This stand-alone software is a medical device classified as risk category IIa, in accordance with rule 10 of EU Directive 93/42/EEC, last amended by 2007/47/EC of the European Parliament and Council of 5 September 2007.

17 Manufacturer information

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

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Email: support@preventicus.com