

EN

Manual Preventicus Heartbeats Service



Date 2025-01-31

This user manual describes the use and functions of the Preventicus Heartbeats Service mobile application.



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

The operating instructions are supplied electronically. You can also find an always upto-date version of the operating instructions at <u>https://www.preventicus.com/preventicus-wearable-service/</u>. Upon request, you can obtain a free paper version of the manual at <u>service@preventicus.com</u>.

Table of contents

	1
# 1.1 Product Description	4
# 1.1 Purpose of Preventicus Heartbeats Core	4
# 1.2 Oser/Indications	5
# 1.3 Contraindications and exclusions	5
# 1.4 User guidelines (Intended Use)	5
# 1.5 Clinical benefit	6
# 1.6 Measurement principle: Basics of pulse curve analysis	6
# 2. NOTES AND RECOMMENDATIONS	7
# 2.1 Warnings	7
# 2.2 Further notes on performance and residual risks	7
# 3. LET'S GO - ACTIVATING THE PREVENTICUS SERVICE	8
# 4. HOME PREVENTICUS - HEART RHYTHM AT A GLANCE	10
# 4.1. Additional navigation menu	10
# 4.2. Support area	11
	10
	12
# 5.1 Start measurement # 5.2 How is the beart routhm measurement done	12
# 5.2 How is the heart rhythm measurement done	12
# 6. DISPLAY MEASUREMENT RESULTS	13
# 6.1 Results at a glance	13
# 6.2 Detailed result of a measurement with PDF Report	14
# 6.3 Explanation of the rhythm classifications	16
# 6.4 Explanation measurement result PDF report	17
# 6.5 Not evaluable Results	20
# 7. MANAGE MEASUREMENT DATA	20
	20
# 7.1 Filtering the result lists	21
# 7.2 Save health report and/or forward to third parties	21
# 8. NOTIFICATIONS / MESSAGES	22
# 8.1 Notification of irregular heart rhythm - suspected diagnosis of atrial fibrillation	22))
[#] 0.1 Notification of megalar neart mythin ⁻ suspected diagnosis of athal fibrination	22
# 9. TELECARE SERVICE	23
# 9.1 Order Telecare Service	24

Preventicus	Heartbeats	Service	
			L

	3
# 9.2 Show telecare result	25
# 9.3 Store telecare result or forward to third parties	25
# 10 SUBSCRIBE	27
	27
# 11. TERMINATION OF USE	27
# 11.1 Trial expiration	27
# 11.2 Cancellation of your subscription	27
# 11.3 Delete Preventicus user profile	28
# 12. TROUBLESHOOTING	28
# 13. CYBER-SECURITY	29
# 14. DATA BACKUP	30
# 15. PRODUCT LIFE	30
# 16. APPLICABLE SYMBOLS	31
# 17. MANUFACTURER INFORMATION AND CONTACT DETAILS	32
# 18. REGISTRATION AS A PARTICIPANT OF A STUDY	33
# 18.1 Create user account	33
# 18.2 Link user account with Preventicus	34

1. PRODUCT DESCRIPTION

Preventicus CoreView, hereinafter referred to as Preventicus Heartbeats Service, is available as a mobile application or as an inApp service offering and is able to display the results of the heart rhythm analysis of the medical device Preventicus Heartbeats Core for the user. The Preventicus Heartbeats Service (CoreView) itself is not a medical device, as this application is only used to display results.

With Preventicus Heartbeats Core, an evaluation in three categories is possible: 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 differentiating their cause.

Heart rhythm analysis is performed using one to five minute heart rate data. The results of the heart rhythm analysis can be provided to the user for one to five minutes or summarized over specific time periods. Any noise or artifacts that may appear in the data are detected and eliminated.

If the Preventicus Heartbeats Core algorithm detects indications of a cardiac arrhythmia, the affected person can save the underlying information in the form of a PDF report and share it with third parties if necessary. In addition, the affected person is recommended further medical evaluation by professionals.

Preventicus has verified the detection of atrial fibrillation and extrasystoles as well as the accuracy of the detected heart rate with own clinical studies (see also: <u>www.preventicus.com/Studien</u>). These have shown that the underlying algorithm of Preventicus Heartbeats Core can distinguish between atrial fibrillation and a regular heart rhythm with an accuracy of more than 96%.

1.1 Purpose of Preventicus Heartbeats Core

The purpose of Preventicus Heartbeats Core is to detect signs of the presence of cardiac arrhythmias in a non-clinical setting. This involves the following cardiac arrhythmias: Detection of indications of absolute arrhythmia with suspicion of atrial fibrillation, detection of indications of extrasystoles, and determination of heart rate with indications of bradycardias and tachycardias, without their further diagnostic differentiation.

The determined result is only a possible suspicion (concretely in the sense of DVG: "suspected diagnosis"), but not a diagnosis in the medical sense. The results obtained

Preventicus CoreView, hereinafter referred to as 5

are for information purposes only and under no circumstances replace a personal diagnosis, advice, care or treatment by medical or medically trained personnel.

1.2 Intended Users

Preventicus Heartbeats Core is suitable for the following individuals:

- Individuals who are confident in the use of smartphones and wearables.
- People who can read and understand texts written in Latin letters and Arabic numerals
- A competent level of German and English is required to use Preventicus Heartbeats Core in conjunction with Preventicus Heartbeats Service (CoreView)

1.3 Indications, Contraindications and exclusions

Preventicus Heartbeats Core is suitable for the following persons:

- Persons, regardless of gender
- Persons aged 18 years and over
- Persons with suspected cardiac arrhythmias such as atrial fibrillation
- Persons with no or only slightly corrected visual impairment
- Healthy skin tissue with which the camera comes into contact

However, Preventicus Heartbeats Core is not intended for use by all individuals:

- Individuals with pacemakers, an ICD, or other implanted electronic devices because of their ability to control the heart's natural rhythm
- Persons with cognitive impairments

1.4 User guidelines (intended use)

Preventicus Heartbeats Core can be used in combination with a compatible and functional mobile or wearable device. The intended use of the mobile or portable device used must be followed.

Preventicus Heartbeats Core is compatible with the following wearable devices:

• Corsano CardioWatch Bracelet in conjunction with the Corsano AF App.

Even if there is no internet connection, a measurement can be taken, although the measurement analysis will not be available until the connection is restored, as the information must be sent to the Preventicus Heartbeats Core for the required analysis.

1.5 Clinical benefit

Cardiac arrhythmias, especially undetected atrial fibrillation, are associated with a greatly increased risk of stroke. It is often not noticeable, frequently occurs only sporadically and is thus usually difficult to diagnose.

Cardiological associations therefore recommend independent and regular measurement of the heart rhythm with suitable apps, wearables or smartwatches. If atrial fibrillation is detected and subsequently confirmed by a doctor via ECG, the risk of stroke can be reduced or normalized with medication. The Preventicus Heartbeats Service with Preventicus Heartbeats Core offers a solution for independent and regular measurement of the heart rhythm in order to detect indications of atrial fibrillation at an early stage, to guide those affected more guickly to a diagnosis and subsequent therapy by a cardiologist and thus to reduce the risk of stroke.

1.6 Measurement principle: Basics of pulse curve analysis

The Preventicus Heartbeats Core algorithm is a certified medical device and uses photoplethysmography (PPG) sensor data from compatible wearable devices/models to receive and analyze heart rate data.

Using a PPG pulse rate sensor from a wearable device, such as a smartwatch, a pulse curve is collected from the wrist over a period of up to 5 minutes and transmitted to Preventicus Heartbeats Core. The pulse sensor uses green LEDs in conjunction with light-sensitive photodiodes to record relative changes in blood flow. When the heart beats, it sends a pressure wave through the arterial vasculature, causing a momentary increase in blood volume and a change in light reflection as it passes the sensor.

The pulse curve corresponds to the blood pulsation generated by the heart activity. From the variability of the heartbeat, in combination with biosignal analytical methods, possible indications of cardiac arrhythmias can be detected.

If signs of cardiac arrhythmia are detected, the underlying information is stored in a measurement report.

2. NOTES AND RECOMMENDATIONS

2.1 Warnings



Safe use of Preventicus Heartbeats Core is only guaranteed if the warnings are followed.

1. Drugs that affect the heart rate, pacemakers or defibrillators may defibrillators can possibly distort the results of the rhythm analysis. falsify the result of the rhythm analysis.

(i) Note: We ask you to report all serious incidents that have occurred in connection with the mobile application or the in-app service Preventicus Heartbeats Service to us and the competent authority in the country where you are located. (For detailed contact, see the item "Manufacturer information"). Mail: <u>service@preventicus.com</u>

2.2 Further notes on performance and residual risks

The Preventicus Heartbeats Core is used in the out-of-hospital setting as a stand-alone application and is not used for decision making in life-threatening situations, nor for real-time monitoring of vital signs, nor does it interfere with existing guideline-based diagnostic pathways or therapeutic measures.

Basically, a distinction must be made between atrial fibrillation (AF) detection (screening or follow-up) and subsequent AF diagnosis. AF diagnostics are performed exclusively according to guidelines with a chest wall ECG, usually by cardiologists. Preventicus applications are not intended for final AF diagnosis with therapeutic implications, but exclusively for AF screening or follow-up without therapeutic implications. A therapeutic implication can only be made on the basis of a real ECG.

Preventicus Heartbeats Core 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 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 Core is 99%.

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

It cannot be excluded that poor signal quality, existing diseases (such as diabetes, vascular diseases or the condition after cardiovascular surgery), medications affecting the pulse rate or pacemakers may distort the accuracy of Preventicus Heartbeats Core.

3. Let's go - Activating the Preventicus Service

The Preventicus Heartbeats Service is your very own personalized resource to actively keep track of your heart rhythm to reduce the risk of stroke.

The Preventicus Service is a premium service that is activated and purchased directly through the app on your mobile or wearable device.

3.1 Activation of the Preventicus service

In order to use the Preventicus service, you must initially activate the service and connect your user account to Preventicus.

Corsano CardioWatch Bracelet:



 Open the Corsano app of your smartphone. Tap on the Preventicus icon in the lower navigation area to open the Preventicus service.

Preventicus Heartbeats Service

3. Let's go - Activating the Preventicus Service 9

- <complex-block><complex-block><complex-block>
- 2. You have the possibility to test the full Preventicus Heartbeats service free of charge at first. After the trial period has expired, you will have to pay for the service. In order to use the Preventicus service permanently, you will need to purchase a subscription.

Follow the instructions on your smartphone screen to continue.

 In order to use the Preventicus service, you must first consent to the transmission and processing of your heart rhythm data from your wearable device to and by Preventicus. Please read the information before accepting the Terms of Use and Privacy Information.

Done! When this process is complete, you have successfully connected your user account to Preventicus and unlocked the Preventicus Heartbeats service.

From now on you have access to your personal overview page of your Preventicus Service - My heart rhythm at a glance.

3.2 Synchronize data with Preventicus service

The data from your portable device is automatically synchronized with your smartphone and so is the Preventicus service. This means that your information is always up to date, you always have an overview and not the slightest change escapes you.

It is important that your portable device is paired with the device app (e.g. Corsano AF) and that you have an active internet connection. For more information, see the user notes of your device app.

4. Home Preventicus - Heart rhythm at a glance

When you switch to the Preventicus section of your wearable device's app, you first come to an overview page - My Heart Rhythm at a Glance.



Here you will find:

- (1) Latest measurements
- (2) Health Insights Highlighted data that is especially important to your health.
- (3) Notifications of abnormal measurements with suspected atrial fibrillation
- (4) Notifications and useful information about the product "Preventicus Heartbeats Service"
- (5) Additional menu to reach further functions and information

4.1. Additional navigation menu

On the overview page - My heart rhythm at a glance - you will find access to an additional navigation menu in the upper area.

Via the navigation menu you can reach:

- My Preventicus subscription (information about your subscription)
- Help section of Preventicus
- Privacy policy
- Terms of use
- Information about Preventicus



- 1. Go to your Preventicus overview page My heart rhythm at a glance
- 2. Select the 3 points in the upper area and click on them.



3. Now the additional menu area opens.

4.2. Support area

The Support area provides supporting and technical information. This section contains the following information:

- Instruction manual
- Frequently Asked Questions (FAQs)
- Support contact option



- 1. Go to your Preventicus overview page -My heart rhythm at a glance.
- 2. Open the additional navigation menu there. To do this, select the 3 points in the upper area and click on them.
- In the menu view, you will find the item "Support area". If you select this, you will be taken directly to the Preventicus support area.

5. Check/record heart rhythm

5.1 Start measurement

Preventicus **automatically** checks your heart rhythm while you sleep, watching for an irregular heart rhythm that could be atrial fibrillation.

- 1. Before going to bed, check if your portable device is charged and turned on.
- 2. Check that your portable device is connected to the app.
- 3. Check if the correct sleep period is set in the app (if available) only within this period data for the Preventicus service will be recorded automatically.

Done! No further action is necessary to start a measurement. The measurement and check of your heart rhythm is now done automatically in the background while you sleep.

Once Preventicus has started recording your heart rhythm, a report card will appear on your overview page in the Preventicus area.

(i) Note: Please observe the information provided by the device manufacturer on the correct donning and wearing of your portable device.

5.2 How is the heart rhythm measurement done

Your wearable device uses a PPG (photoplethysmography) sensor that emits light and measures its reflections off the blood vessels of the wrist. As the blood flows, the light reflection changes.

The unique Preventicus Core algorithm collects their data and analyzes each measurement based on specific algorithms. When an irregular rhythm is detected, you receive a notification.

The recording of your heart rhythm usually happens at night, when you are calm, to ensure the most accurate measurement. It is done automatically in the background while you sleep.

The time from 10 pm to 7 am is preset as the sleep time. During this time, a 5-minute measurement of your heart rhythm takes place every 30 minutes. You can adjust changes to your sleep time at any time in the app of your wearable or mobile device.

After each measurement, you will first receive an automatic interpretation of the Preventicus Core algorithm in relation to your heart rhythm and pulse.

6. Display measurement results

Actively track your heart rhythm. After each measurement, you will first receive an automatic interpretation by the Preventicus Core algorithm regarding your heart rhythm and pulse.

6.1 Results at a glance

The measurements and analysis results performed during the night can be displayed in detail the next morning (prerequisite: stable Bluetooth and Internet connection). Depending on how active you are during the night, the number of collected and analyzable measurements varies.



 Open your personal Preventicus area - "My heart rhythm at a glance"- of your device app. Here you will find a summary of your night measurements.

In the overview card (1) you can see if your heart rhythm shows any abnormalities during the last night, how many measurements could be successfully evaluated during the night and how high your pulse rate was and if it was also abnormal.

It is possible to view every single measurement of a night in detail and to generate an ECGcomparable report with the results of your heart rhythm measurement.

In the overview area, select the night that you would like to view in more detail. Click on the respective map.



- 2. Now all single measurements of the selected night are displayed, which have been recorded and evaluated by Preventicus.
- To get to the detailed information of an individual measurement, select the respective card (2) that you want to have a closer look at.

15:35		🕈 🔳
=	Preven	ticus 🔗
🖌 Zurück		Oberblick 🝙
Ihr Messe 04.10.2022	rgebnis , 23:30 U	s hr
Es wurden kei	ne Auffalligk	ietten festgestellt.
	•	62
Regelmäßig Herzrhythmi	er JS	Normaler Puls
unauffal	19	unsuffällig
Report		
Report		
Auswertungsre oder speichern	eport diese	r Messung ansehen

4. The detailed view of the selected individual measurement then opens.

6.2 Detailed result of a measurement with PDF Report

In the detailed result you will find all information about your "heart rhythm" and "pulse" for the selected 5 min measurement as well as a summary evaluation(1).

Clicking on the "Heart rhythm" (2) and "Pulse" (3) fields will take you to detailed explanations and assessments of your result values as well as detailed recommendations for next steps. Depending on the result, a further medical evaluation by specialists will be suggested to you.





 15:33
 ● Preventicus
 ● ●

 ✓ zuricuk
 ● Deublicuk ●
 ●

 ✓ zuricuk
 ● Deublicuk ●
 ●

 Otto 2002 of 21:30 Uhr
 ●
 ●

 ● Brunden Auffälligkeiten im Herzrhythmut Bestellt. Zuden munde ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden munde ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden munde ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden munde ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden munde ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten im Herzrhythmut Bestellt. Zuden ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten ein Herzrhythmut Bestellt. Zuden ein erhöhter Pulse
 ●
 ●

 ● Munden Auffälligkeiten ein Herzrhythm

All data analyzed by Preventicus Heartbeats Core can be compiled into an ECG-comparable report. You can generate and display the report by clicking on the report window (4).

In addition to the detailed information about the measurement result, tips and articles are provided at the end of the page to support you in the best possible way with questions about the service offer..

(i) Note: This analysis does not represent a diagnosis and does not replace medical advice. If you have or experience any symptoms, you must consult a physician. The interpretation is based solely on the PPG recording used for the analysis.

6.3 Explanation of the rhythm classifications

Immediately after the 5-minute measurement, the Preventicus Heartbeats Core algorithm automatically interprets the data. The following alarm messages may appear:

Traffic ligh	t color	Meaning
Green	Regular heart rhythm normal	 Your heart rhythm is regular. However, if you feel unwell or experience other worrying symptoms, please contact your doctor directly. Note: This analysis does not represent a diagnosis and does not replace medical advice. If you have or experience any symptoms, you must consult a physician.
Yellow	Irregular heart rhythm conspicuous	Irregular beats occur frequently (>5%), mild cardiac arrhythmias are suspected. Mild cardiac arrhythmias can occur situationally in certain life situations (e.g. stress, caffeine consumption, pregnancy). If they occur permanently, they are a risk. In case of repeated occurrence, you should discuss this measurement with your doctor if you are not yet familiar with cardiac arrhythmias. Note : <i>This analysis does not represent a diagnosis and does not replace medical advice. If you have or experience any symptoms, you must consult</i>
		a physician.
Red	ossible trial firillation consplauous	High-grade or absolute arrhythmia, suspected atrial fibrillation. High- grade arrhythmias or atrial fibrillation are a considerable risk if left untreated and promote, among other things, a stroke. In case of recurrent occurrence, you should discuss this measurement with your physician if you are not already familiar with cardiac arrhythmias.
		If not under medical control and in case of repeated occurrence, immediate cardiologic evaluation is necessary .

Tab. 1 Color coding and evaluation of heart rhythm and heart rate

6.4 Explanation measurement result PDF report

After each successful measurement, the result is saved in the form of a summary measurement result report. This contains the recorded pulse curve, the pulse (in bpm) over time and detailed information on the heart rhythm. The measurement result report consists of three sections (see Fig. 1.1).



Fig. 1 Measurement result report of Preventicus Heartbeats Core consisting of three sections: 1- Summary result of heart rhythm analysis, 2 - Pulse in beats per minute (BPM) over the entire measurement, 3 - Original pulse curve over the entire measurement incl. result.

The summary of the results of the heart rhythm analysis (see Fig. 1 / area 1) contains the basic data. Furthermore, the results of the pulse and the heart rhythm are each provided in text form including color coding. The color coding corresponds to the color of the traffic light - see Table 1 Rhythm classification. Depending on the result, a further medical evaluation by specialists will be suggested.

In the second part of the report (see Fig. 1 / area 2), the pulse is shown in beats per minute (bpm) over the entire measurement. Slight and regular fluctuations in the pulse, as shown in Fig. 1/ Area 2, are normal and are usually due to the interaction between respiration and heartbeat.

In contrast, sudden positive or negative spikes, as shown in Fig. 2, are due to single irregular heartbeats and may indicate extrasystoles.



Fig. 2 Summary result of the heart rhythm analysis and pulse in beats per minute (BPM) over the entire measurement from a measurement result report with mild cardiac arrhythmia

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

Fig. 3 shows the pulse in the presence of atrial fibrillation. The pulse is highly irregular over the entire measurement. The fluctuations of the pulse occur chaotically over the entire measurement.



Abb. 3 Summary result of the heart rhythm analysis and the pulse in beats per minute (BPM) over the entire measurement from a measurement result report with absolute arrhythmia

The third area of the measurement result report consists of the original pulse curve. One wave of the pulse curve corresponds to one heartbeat. For the analysis of the heart rhythm, points are detected in the pulse curve that are equivalent to the R-wave in the ECG. These points are drawn in the form of R-prongs in the original pulse curve to indicate a detected/recognized heartbeat (see Fig. 4). Black R-spikes symbolize a regular heartbeat, yellow ones an irregular heartbeat (e.g. extrasystole) and red R-spikes an extremely irregular heartbeat due to absolute arrhythmia (suspected atrial fibrillation).

Normaler Herzschlag
 Unregelmäßiger Herzschlag
 Äußerst unregelmäßiger Herzschlag

Fig. 4. Legend of the R-spikes in the original pulse curve

Blue bars in the pulse curve (see Fig. 5) indicate a detected disturbance, which can be caused by movement or ambient light, among other things.



Fig. 5 Original pulse curve of the measurement result report with detected fault (blue bar)

6.5 Not evaluable Results

Not evaluable - This result means that the Preventicus Heartbeats Core algorithm was not able to analyze the data.

Not evaluable > 09/30/2022 | 00:09 AM

A "not evaluable" recording can be caused by a "signal interference". This usually happens if you moved a lot during the recording, the sensor is dirty or your wearable device did not have enough skin contact on your wrist.

7. Manage measurement data

You have the possibility to manage your measurement data individually. If desired, you can pre-filter your measurement results. Each result report can be easily transmitted to third parties such as a doctor or health expert. Alternatively, you can save the report and print it out at home.

7.1 Filtering the result lists

You have the possibility to pre-select your measurement data according to individual needs.

	0	Preventicus	~
		✓ Zurück	
4ein Herzrhythmus m Überblick	1	Meine Nachtmessungen 05.10.2022, 21:00 - 00:00	l Uhr
Alle Reports Filte	er >	Zeitraum Messur 3 Stunden 6	igen
5. Oktober 2022	1 a	Puls 62 - 107 bpm	
Zettraum Messungen Puls * 3 Stunden 1915 62 - 107 bpm		Regelmäßig	,
		04.10.2022 [23.30 UII	
3. Oktober 2022		Messdauer Puls	
Regelmäßig 03.10.2022 17:00 - 20:00 Uhr	>	Messidauer Puls 4 Minuten 62 bpr	
S. UKTODER 2U22 Regelmäßig 03.10.2022 17:00 - 20:00 Uhr Zeitraam Messangen 3 Stunden 0 62 bpm	*	Messatauer Puls 4 Minuten 62 bpr Regelmäßig 04:10.2022 23:00 Uhr	n >
S. UKTODET 20/22 Regelmäßig 03.10.2021 (17.00 - 20:00 Uhr 2ditzam Standen Pub 52 bpm 2. Oktober 2022	,	Masshaver Pula 4 Minuten 62 bpr Regelmäßig 04.10.2022 23:00 Uhr Messdaver Fula 62 bpr Ei	

- First go to the respective overview page where you want to filter the results.
- Then use the corresponding filter (1a + 1b) above the results list to limit your view to the desired content.

7.2 Save health report and/or forward to third parties

You would like to save a selected measurement report in a personal location, in order to view it in detail on your own PC or to print it out. Forwarding selected measurement reports to a third party, such as your doctor or family members, is also possible without any problems.



- 1. First go to the detailed result that you would like to save or download.
- 2. Then press the "Share report" button (1).

Alternatively, you can also open the report directly. You will find an additional menu (2) in the upper area of the report page. If you select this, you will also get to the "Share report" function (2).



3. A function area (3) then opens, offering you various options for saving your report, sending it or transferring it to the PC.

8. Notifications / Messages

8.1 Notification of irregular heart rhythm - suspected diagnosis of atrial fibrillation



If the Preventicus Core algorithm has detected an irregular heart rhythm that could be atrial fibrillation, you will receive a corresponding message on the "My heart rhythm at a glance" overview page. Pressing the information cards will then take you directly to the conspicuous measurement. Here you will receive all the information about what to do then.

Information on how to activate the notifications can be found on the corresponding information and help pages of the app of your portable device.

9. Telecare Service

If you have one or more reports with a suspected mild cardiac arrhythmia (yellow result) or absolute arrhythmia, suspected atrial fibrillation (red result), you have the option of sending these reports to our Telecare Service for a fee.

The Telecare Service offers you a direct medical evaluation of your measurements by medical technicians specialized in heart rhythm analysis of pulse data.

The Telecare Service verifies your measurement result report. You will receive the result directly on your smartphone at Telecare Reports.

9.1 Order Telecare Service



- 1. Go to the detailed result that you would like to have evaluated by the medical technician.
- 2. Select the Telecare Service (1).



3. Then follow the instructions on your display to order the paid evaluation of your report from the Telecare Service.

The cost will be deducted from your specified payment method in the store.

Please note that you must give your consent for your selected measurements and your master data (age and gender) to be sent to the Telecare Center for the purpose of an appropriate evaluation. The transmission is encrypted.

Within 3 working days you will then receive your personal Telecare report.



4. If you would like to get basic information about Telecare Service and its services, please use the link (2) to your offer page.

Alternatively, you can always reach our Telecare information page via the additional menu (3) on your overview page.

9.2 Show telecare result

The processing status of your Telecare reviews is displayed at all times on your overview pages and on the details page.

Possible atrial fibriallion > 09/30/2022 9:00 PM - 01:00 AM	Possible atrial fibriallion > 09/30/2022 9:00 PM - 01:00 AM	Telecare Service	>
Period Measuremenets Heart rate • 5 hours 2 10 54 - 110 (bpm	Period Measuremenets Heart rate • 5 hours 20 10 54 - 110 (bpm	Report is now available	Telecare
Telecare Report: in progress	Telecare: report analysed 1 von 2		

Fig. 7. Telecare Status Information Preventicus Heartbeats Service

Once the Telecare Service has completed its analysis and evaluation, you will receive a notification via the app of your portable device.



Abb. 8 Telecare Mitteilungen von Preventicus Heartbeats Service

9.3 Store telecare result or forward to third parties

As with any results report, the Telecare Report can be easily sent to a third party such as a doctor or family member. Alternatively, you can save the report and print it out at home.



- First go to the detailed result for which you had ordered an evaluation at Telecare and whose Telecare Report you would like to save or transmit to third parties.
- In the upper area of the detail view you will find a clickable map (1), which leads you directly to your Telecare Report.

Alternatively, you can also select the report preview window (2a) in the center of the screen or the "Share measurement result report" button (2b).

Your Telecare Report will then open.



- 3. In the upper part of the report page (3), you will find an additional menu that allows you to select the "Share report" function.
- 4. A function area (4) then opens, offering you various options for saving your report, sending it or transferring it to the PC.

10. Subscribe

The Preventicus service is a premium service that can be activated and purchased directly through the app on your mobile or wearable device. You can choose to subscribe to the service monthly or annually.

- 1. Go to the overview page of the Preventicus service in the app of your portable device. 2.
- 2. There, open the additional menu by clicking on the three dots in the upper area of your overview page. 3.
- 3. Then select "My Preventicus Subscription" from the menu list to get to your subscription area. 4.
- 4. To subscribe, please select one of the two billing periods monthly or annual subscription. 5.
- 5. Then follow the instructions on your screen to complete the purchase.

11. TERMINATION OF USE

11.1 Trial expiration

After expiration of the free trial version, you have to subscribe to continue using your Preventicus service.

The measurement results recorded until then will still be available to you in your overview view.

11.2 Cancellation of your subscription

You can cancel your subscription at any time.

In your account information in Apple's App Store or Google's Play Store, you can view your purchases and manage the respective subscriptions and cancel them at any time in due time. You can also deactivate automatic renewals. For information on how to cancel your Preventicus subscription early, please refer to our terms and conditions on the following link https://www.preventicus.com/allgemeine-geschaeftsbedingungen/.

11.3 Delete Preventicus user profile

Deletion of your user profile is possible at any time. To delete your user account and your user data at Preventicus, please contact our customer service at: <u>service@preventicus.com</u>.

i Note: Please note that this action is final. Your data can no longer be restored in case you change your mind.

What happens if you delete your account?

- All data, reports and purchases associated with this account will be lost.
- You no longer have access to past measurements and reports.
- You will lose access to the purchases you have made from the Apple Store or Google Play.

What to do before you have your account deleted:

- Review the data in your Preventicus area.
- Reports that you would like to keep should either be saved, transferred to another PC, or forwarded before deletion.
- To do this, use the "Share" function on the individual reports.

12. Troubleshooting

If the Preventicus Heartbeats service is not working properly, read the following troubleshooting steps.

You have not received heart rhythm values.

Using Bluetooth, make sure your wearable is connected to your smartphone and has synced. If you still do not receive heart rhythm data, unfortunately the Preventicus service has not received any analyzable data for the night you are looking for.

Therefore, please try the following for the next night:

- Check if the portable device is charged.
- Make sure your device is connected to the associated device app and has a stable Bluetooth and Internet connection.
- Clean the back of the wearable.
- Make sure your wearable has permanent skin contact. It should not be able to move around your wrist.

If problems persist, refer to the help pages of the device manufacturer or contact their customer service (e.g. Corsano Support).

Something went wrong with the connection to the Preventicus service

Please restart the app.

If the error persists, please contact customer service of the device app (e.g. Corsano Support) with the following note: Error code: 401.

Download not successful

Please try again at a later time. If the error persists, please contact our customer service at: <u>service@preventicus.com</u>.

For problems with the portable device and the associated app, please contact the respective device manufacturer.

No internet connection

Make sure that WIFI or mobile data is activated on your smartphone. Please try again afterwards.

If the error persists, please contact customer service of the device app (e.g. Corsano Support).

13. CYBER-SECURITY

Preventicus uses industry standard encryption protocols to protect all products and data in transit and at rest. Preventicus uses best practices. Detailed measurement data is stored only on secure and encrypted servers and not on the user's device itself. These

databases contain encrypted user data that is encrypted at rest or in transmission. A continuous backup system is used to ensure that all data is secure.

Preventicus GmbH recommends protecting the smartphone running the application with a code (PIN, Personal Identification Number), Face ID or Touch ID (fingerprint). It is important to protect the smartphone because personal health information is stored on it.

Preventicus makes every effort to ensure the security of your data.

14. Data backup

The data backup can be done in the following way:

The reports can be exported and sent via e-mail as a PDF, for example. This can then be used to save them in other databases (e.g. PDMS, practice software) or on other storage media (e.g. hard disk, memory card).

15. Product life

The lifetime is defined as the span until the release of a new version of the mobile application or the in-app service. This is indicated by an increase of at least the second digit of the version number.



The version number information is given at the end of the FAQ section (1).

Information about performed updates is provided automatically via the app of your portable device.

#16. APPLICABLE SYMBOLS

The following symbols may be found in these instructions for use (color and size may vary):

Symbol	Meaning
i	Observe operating instructions
í	Note A note draws attention to information worth knowing .
<u>(</u>)	Warning A warning is always of safety relevance.
Preventicus* GmbH Ernst-Abbe-Str. 15, 07743 Jena, Germany	Manufacturer's marking

17. Manufacturer information and contact details



The Preventicus Heartbeats Service is a product of Preventicus GmbH.

The contact details are

Preventicus GmbH Ernst-Abbe-Straße 15 DE-07743 Jena Telefon: 03641 /55 98 45 -0 Fax: 036 41/55 98 45-9 Web: <u>www.preventicus.com</u> Mail: <u>info@preventicus.com</u>

For questions about the product and the application, please contact our customer service department:

Mail: service@preventicus.com

18. Registration as a participant of a study

18.1 Create user account

To be able to use the Preventicus service in the context of a study, you have to activate the study mode at the beginning and create a user account.

Please note that the mode can only be activated if you have been invited to a study and have received an activation code.



1. The first step is to create a new user account. To do this, click on the word "Login" (1) on the Corsano home.

2. In the next step, switch to the "Managed Care and Study Mode" (2)..



3. Follow the instructions on the smartphone display. Please read the privacy information and terms of use before accepting them. To continue, you agree to the terms of use and privacy information..

4. In the next step enter your first and last name and email address (3).

Optionally, you have the possibility to additionally use all functions of the wearable during the study. You will find information about the functionalities if you click on the info-lcon.

If you want to use the functionalities, you can enable them by pressing the switch.

Complete the registration process by clicking the "Register" button.

18.2 Link user account with Preventicus

Through your user account, the data of your mobile device and smartphone will be synchronized and identified. For this purpose, your account still needs to be connected to Preventicus.



Wie groß sind Sie?

0 6

170 cm

addaed Adixia

6. As a study participant, you have received a personal activation code. Please enter this code in the field.

 The next questions will help us to create your profile, on the basis of which the individual medical evaluations will be made afterwards. To do this, follow the instructions on your smartphone display.



Done!

All questions have been answered. Now you are on your study overview page.

Here you will find an overview of all current profile information as well as important contact information.