PREVENTICUS
RHYTHM IS LIFE

Manual

Preventicus Nightwatch

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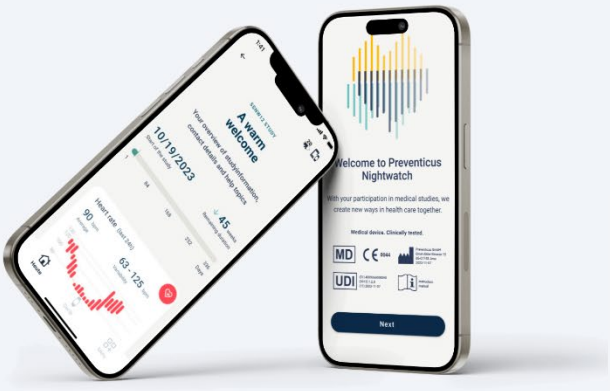

Date
2024-05-21

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

Please read the instructions for use carefully before using the Preventicus Nightwatch.

An up-to-date version of the instructions can always be found at https://www.preventicus.com/manuals-preventicus-nightwatch-app/

The operating instructions are supplied electronically. Upon request, you can obtain a free paper version of the manual at service@preventicus.com.

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1. PRODUCT DESCRIPTION

Preventicus Nightwatch is a software application that can record or receive heart rate data, such as the pulse curve or ECG data, perform a heart rhythm analysis based on the data and provide an overview.

Using a PPG pulse rate sensor from a wearable device, a pulse curve is collected from the wrist over a period of 30 minutes. Based on a blind study, the app Preventicus Nightwatch only shows the heart rhythm, the amount of recorded data and analyzed data by the Preventicus algorithm. Any noise or artifacts that may appear in the data are detected and eliminated. If the algorithm detects indications of a cardiac arrhythmia, the study center will contact the affected person.

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: *www.preventicus.com/Studien*). These have shown that the underlying algorithm of Preventicus can distinguish between atrial fibrillation and a regular heart rhythm with an accuracy of more than 96%.

1.1 Purpose of Preventicus Nightwatch

The purpose of Preventicus Nightwatch is to detect signs of the presence of cardiac arrhythmias in form of a suspected diagnosis and determine and characterize the heart rate. 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 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 Nightwatch is suitable for the following users:

- Individuals who are confident in the use of smartphones and wearables.
- Reading and understanding texts written in Latin letters and Arabic numerals
- Competent language level in German or English

1.3 Indications

Preventicus Nightwatch is suitable for the following individuals:

- Persons, regardless of gender
- Persons aged 18 years and older
- Persons with suspected cardiac arrhythmias such as atrial fibrillation
- No or only minor, corrected visual impairment
- Healthy skin tissue with which the sensor comes into contact

1.4 Contraindications and exclusions

However, Preventicus Nightwatch 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

1.5 User guidelines (intended use)

Preventicus Nightwatch 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.

App Preventicus Nightwatch is compatible with the following wearable devices:

- **Polar Verity Sense (from firmware 2.2.1)**

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 Nightwatch for the required analysis.

1.6 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 Nightwatch 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 quickly to a diagnosis and subsequent therapy by a cardiologist and thus to reduce the risk of stroke.

1.7 Measurement principle: Basics of pulse curve analysis

The Preventicus 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 algorithm. 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.

2. NOTES AND RECOMMENDATIONS

2.1 Warnings

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

1. If the sensor becomes too hot, please stop the measurement and remove the device from your skin
2. 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.

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

2.2 Further notes on performance and residual risks

The Preventicus Nightwatch 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 algorithm 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 algorithm is 99%.

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

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 algorithm.

ⓘ **Note:** *Due to the blind study, the results of the above analysis are not shown in the app Preventicus Nightwatch.*

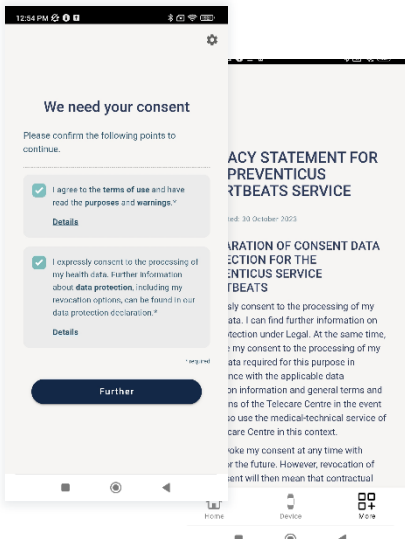
3. LET´S GO

The Preventicus Nightwatch is your very own personalized resource to actively keep track of your heart rate to reduce the risk of stroke.

The Preventicus Nightwatch app can be used on smartphones running iOS 15.0 and Android 8.0 or higher.

3.1 Privacy policy and terms of use

After installing the app Preventicus Nightwatch or if you are not yet logged in, you must first accept the intended use, including the warnings, terms of use and privacy policy, in order to be able to use the application.



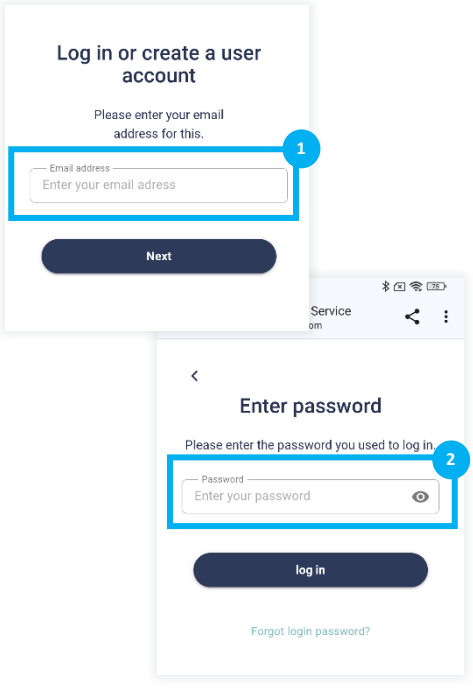
1. Open the app Preventicus Nightwatch on your smartphone and go to "Next" on the start page.

2. Accept the terms of use and privacy policy. You can find detailed descriptions under "Details".

   Note: *You can view the information again later at any time in the "More" section under Legal.*

3.2 Login to Preventicus Nightwatch

Already you have a user account? Simply log in with your e-mail and password.



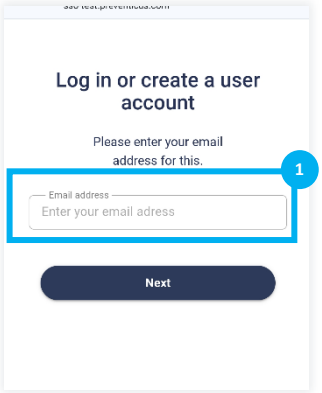
1. Enter your e-mail address and click on "Next"

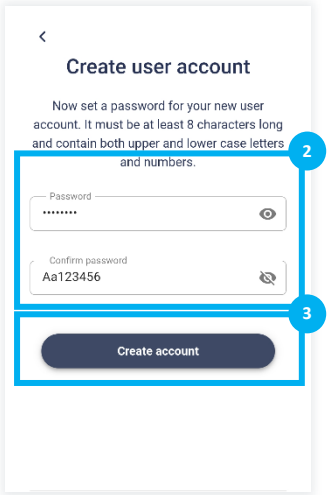
2. Then enter the password you used to login for the app Nightwatch and tap on "Log in"

   You've done it! You have successfully logged in and will be redirected to the start screen.

3.3 Register with Preventicus Nightwatch

Don't have a user account yet? Simply register with your e-mail address and password.





1. Enter your e-mail address and tap on "Next" to continue.

2. set a password of your choice and repeat your password to check it.

   Note: *Your password should consist of at least one lowercase letter, one uppercase letter and numbers and contain a total of 8 characters.*

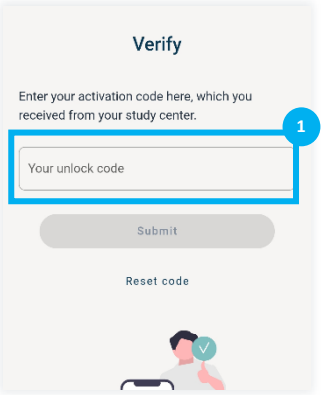
3. Tap on "Create account" to save your data and create the user account.

   Finally, please confirm your e-mail address. An e-mail with a confirmation button will be sent to you.

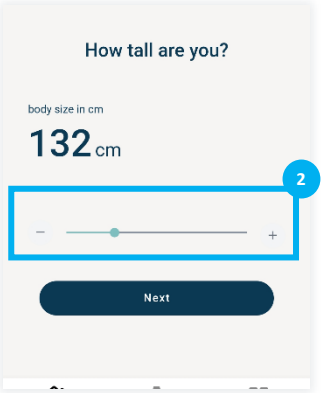
You've done it! You have successfully registered and will be redirected to the start screen.

3.4 Participation in (study) programs

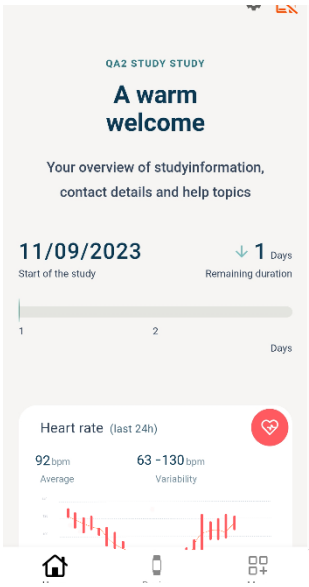
Please note that the mode can only be activated if you have been invited to a program and have received an activation code.



1. As a program participant, you have received a personal activation code to gain access to the program. This code is requested once as part of the registration process. To do this, enter the code you have received in the corresponding field (1). Then tap on "send" to activate the program/access.



2. The next questions help us to create your profile, on the basis of which the individual medical evaluations are then carried out. Follow the instructions on your smartphone display.



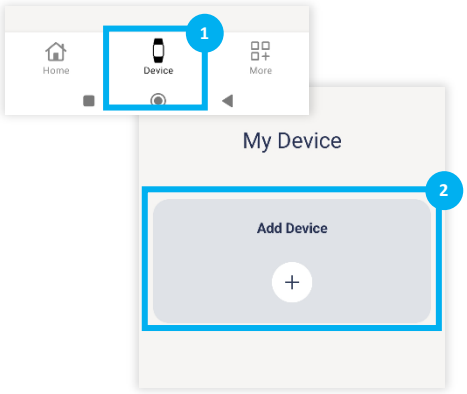
Finished!
All questions have been answered. You are now on your program overview page.

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

You now have access to your personal overview page.

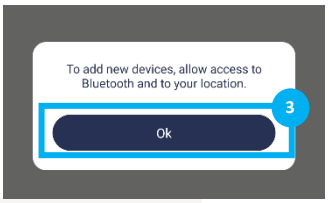
4. CONNECTING THE PORTABLE DEVICE TO THE APP

In order for the data from your wearable device to be transferred to the Preventicus Nightwatch app, both must be connected to each other.

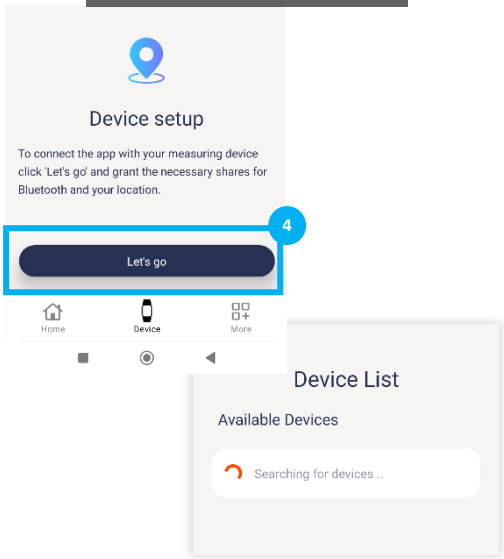


1. Go to "Device" in the menu at the bottom of the screen

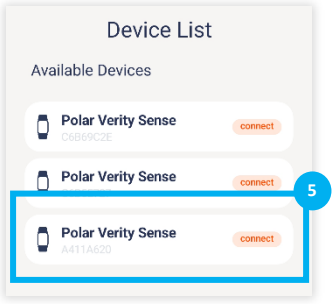
2. Add a new device.



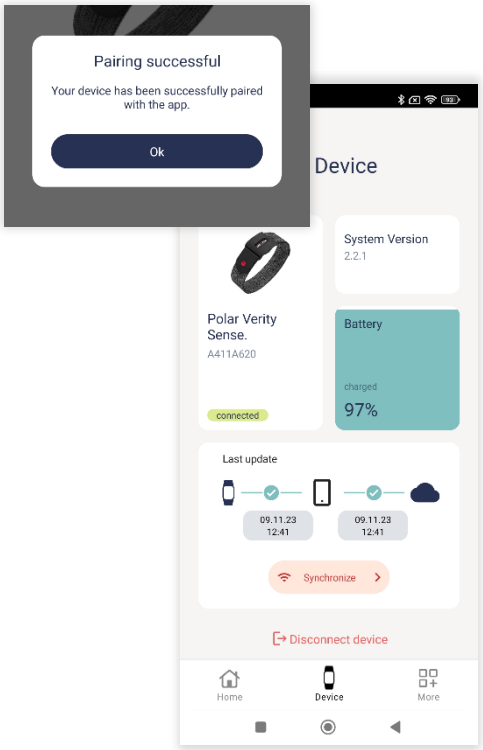
3. To establish a connection between your wearable device and the app Preventicus Nightwatch, Bluetooth and location must be enabled. Allow the app to access Bluetooth and location.



4. Start the device setup. The search for your wearable device is started.



5. While the search is running, your device is displayed in the list. Click on "Connect" to connect your wearable device to the Preventicus Nightwatch.



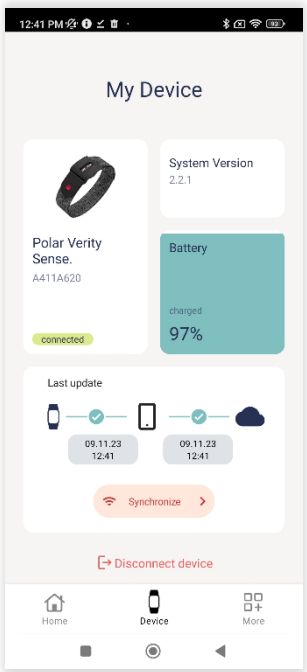
Done!
The connection is successful.

You now have access to your personal overview page.

You can also view information such as the battery status of your wearable device or the last data synchronization under "Devices".

5. INFORMATION ABOUT THE DEVICE IN THE APP

You can find information about your portable device in the "Device" section:

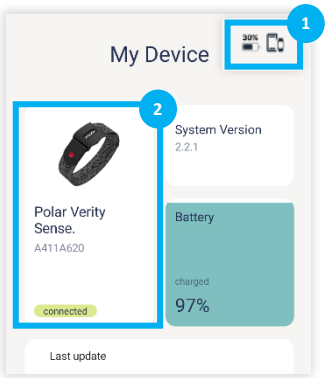


- Battery level
- System version of the device
- Connection between the device and the app
- Last update of the recorded data

You can also disconnect the device from the app here.

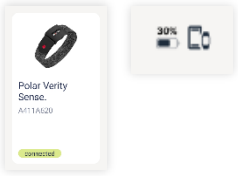
5.1 Checking the connection - device to app

A connection between your portable device is important so that your recorded data can be transmitted and analyzed.

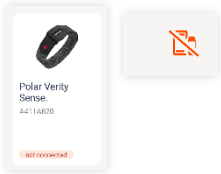


1. You will always be informed about the connection status between your portable device and the app in the top right-hand corner.
2. You can also view this in the "Devices" area.

Connection exists



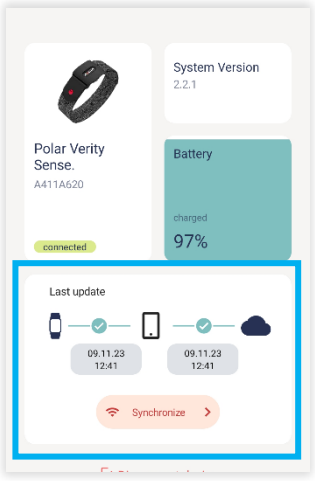
No Connection



5.2 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 and that you have an active internet connection.



You can see the last synchronization under "Device".

You can also start synchronization manually.

6. Check/record heart rhythm

6.1 Start measurement

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

1. Check if your portable device is charged and turned on.

2. Check that your portable device is connected to the app.

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 app Preventicus Nightwatch has started recording the data, you will appear on your overview page in the Home area.

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

6.2 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.

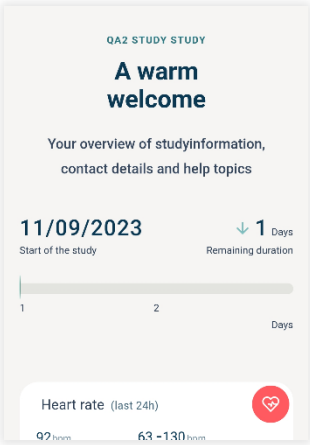
The unique Preventicus Core algorithm collects their data and analyzes each measurement based on specific algorithms. When an irregular rhythm is detected, you receive a notification from your study center.

The recording of your heart rhythm is continuous. It is done automatically in the background.

The measured data is transmitted to the Preventicus algorithm after a full 30 minutes. After each measurement, you will first receive an automatic interpretation of the Preventicus Core algorithm in relation to your heart rhythm and pulse.

7. HOME AREA

When you switch to the Preventicus section of your wearable device's app, you first come to an overview page.



Here you will find:

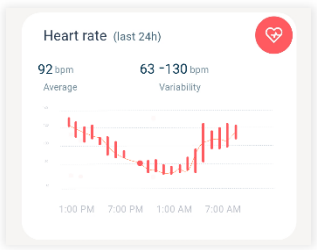
(1) Information about the (study) program
(2) Health Insights - Highlighted data that is especially important to your health.

Actively track your heart rate and keep an eye on the measurement data you receive.

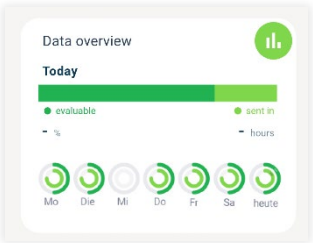
7.1 Results at a glance

You can display the measurements taken and your heart rate in the home area (prerequisite: stable Bluetooth and Internet connection). The number of measurements collected and analyzable varies depending on how actively you wear your measuring device.

(1)



(2)



Open the app Preventicus Nightwatch and you will automatically be taken to the Home area.

Prerequisite: You must be logged in.

In the heart rate overview card (1) you will see an average value and the variability of the last 24 hours.

In the overview card Data overview (2) you can see the measurements of the last 7 days that have been received and could be evaluated.

Note: *The data is not displayed in real time. The data is updated after each synchronization.*

7.2 Not evaluable Results

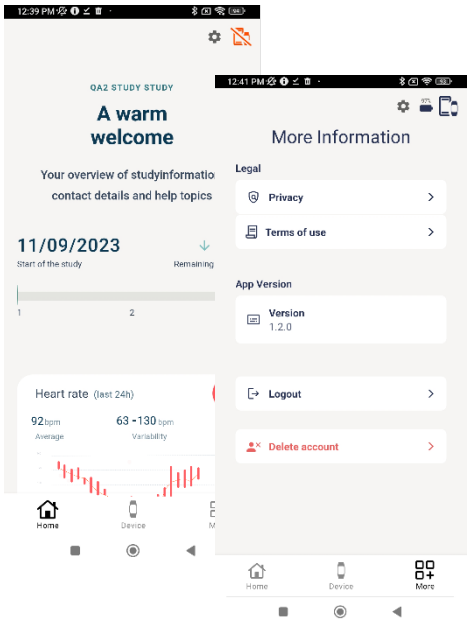
This result means that the Preventicus algorithm was not able to analyze the data.

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.

8. FURTHER INFORMATION AND HELP SECTION

You can access further information via the navigation menu below. This section contains the following information, among others:

- Privacy policy
- Terms of use



1. When you start the app, you are in the "Home" area. Select "More" in the lower menu.
2. The "More" area will open.
3. Select one of the items above.
4. The respective page opens.

Do you need help? Please feel free to contact us. Go to the home area, scroll down and click on the "Preventicus Support" tile in the help area.

9. TERMINATION OF USE

9.1 Delete your Preventicus user profile

You can delete your user profile at any time. To delete your user account and your user data at Preventicus, please contact our customer service at: service@preventicus.com.

ⓘ **Note:** ***Please note that this action is final. Your data can no longer be recovered if you change your mind.***

What happens if you delete your account?

- All data associated with this account will be lost.
- You will no longer have access to past measurements.
- You will lose access to your (study) program.

What to do before you delete your account:

- Check the data in your Home area.

10. FAQs

If the connection between the app Preventicus Nightwatch and the measuring device does not work properly, read the following troubleshooting steps.

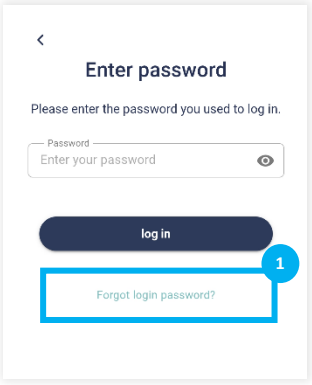
I can't log in to the app.

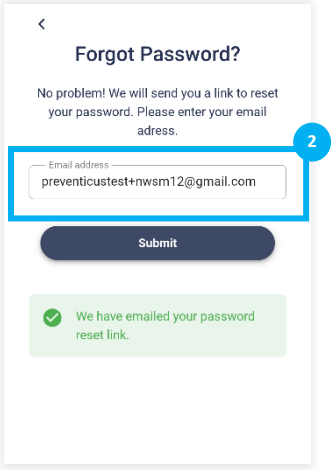
Do you already have a user account but cannot log in? Check that your e-mail and password are correct and try again.

If this does not work, please contact your study center.

I have forgotten my password.

You already have a user account but have forgotten your password? You can reset your password at any time.





1. Contact your study center. They will guide you through the process.
2. Go to "Forgot your password?"
3. Enter the email address you received from your study center and click on "Submit"
4. Study center: Open your and go to the password reset email.
5. Study Center: Click on the button to reset your password.
6. The Preventicus Service website opens.
7. Study Center: Enter a new password and repeat it.
8. study center: Share this with the participant.

Done! Once this process is complete, you have successfully reset the password and can now log in to the app Preventicus Nightwatch with your new password.

Measuring device is not found in the list.

Make sure that your wearable device is charged and that you have activated Bluetooth and the location and go to "Search again".

If the error persists, please contact our customer service (service@preventicus.com).

You have not received heart rate values.

Make sure that your wearable is connected to your smartphone and synchronized using Bluetooth and location. If you still do not receive any heart rate data, the Preventicus Service has unfortunately not received any analyzable data.

Please try the following:

- Check that the wearable device is charged.
- Make sure that your device is connected to the app Preventicus Nightwatch and has a stable Bluetooth and internet connection.
- Clean the back of the wearable device.
- Make sure that your wearable is in permanent contact with your skin. It should not be able to move around the applied area.

If problems continue to occur, refer to the device manufacturer's help pages or contact their customer service.

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 with the following note: Error code: 401.

Device no longer wants to connect.

Your measuring device was already connected to the app Preventicus Nightwatch, but no longer connects?

First go to the device area of the app. Disconnect the device there.

Then go to the Bluetooth settings of your smartphone. All devices that are connected or paired with your phone will be displayed there. Select your measuring device by clicking on it and disconnect the measuring device from the smartphone using "Ignore the device" (iOS) or "Disconnect the device" (Android).

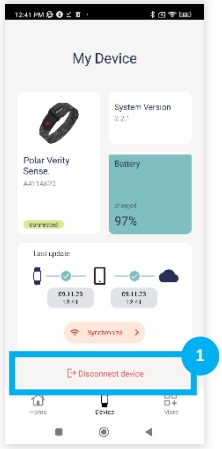
Then go back to the app Nightwatch in the device area. Add your measuring device again. If everything worked, your meter should now have reconnected. All your data will be resynchronized and displayed.

Device is displayed as not connected

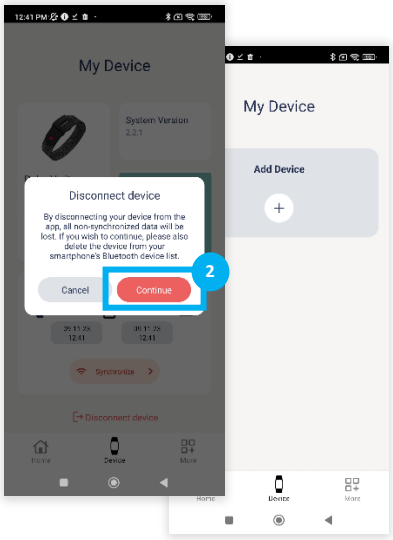
Make sure that your wearable device is charged and that you have activated Bluetooth and the location and go to the device area and click “sync”.

I want to disconnect my wearable device from my smartphone.

Do you want your wearable device to no longer be connected to the app Preventicus Nightwatch? You can disconnect your device in the "Device" section.



1. To disconnect your device from the app Preventicus Nightwatch, go to "Disconnect device" in the "Devices" area



1. please confirm the disconnection
   Your device has been successfully disconnected from the app Preventicus Nightwatch. No more information about the device is displayed or recorded data is synchronized with the app.

   You can now add a new device.

My data cannot be analyzed

This result means that the Preventicus algorithm was not able to analyze the data.

A "not analyzable" recording can be caused by "signal interference". This usually happens if you have moved a lot during the recording, the sensor is dirty or your wearable device has not had sufficient skin contact.

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 our customer service (service@preventicus.com).

11. CYBER-SECURITY

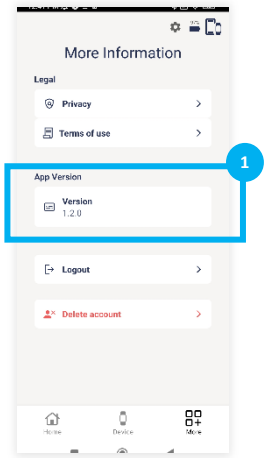
Preventicus uses industry standard encryption protocols to protect all products and data in transit and at rest. Preventicus uses best practices. Detailed measurement data is stored only on secure and encrypted servers and not on the user's device itself. These databases contain encrypted user data that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

12. 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 section “More” (1).

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

13. APPLICABLE SYMBOLS

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

Symbol	Meaning
	Observe operating instructions
	Note A note draws attention to information worth knowing .
	Warning A warning is always of safety relevance.
	Manufacturer's marking
	This stand-alone software is a certified medical device of risk class IIa in accordance with Rule 11 of Regulation (EU) 2017/745.
	Medical product

14. Manufacturer information and contact details

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

The app Preventicus Nightwatch is a product of Preventicus GmbH.

The contact details are

Preventicus GmbH
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DE-07743 Jena
Telefon: 03641 /55 98 45 -0
Fax: 036 41/55 98 45-9
Web: *www.preventicus.com*
Mail: *info@preventicus.com*

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

Mail: *service@preventicus.com*