KOIOS CARE

PARKIWATCH

Instructions for Use

People with Parkinson's Disease

INSTRUCTIONS FOR USE

Device Name: PARKIWATCH
Manufacturer: Koios Care (BV), Filip Williotstraat 9, 2600 Antwerpen, Belgium
Date of Issue: 29/05/2026
IFU Version: 2.0

About This Guide

This document provides essential information for the safe and effective use of the PARKIWATCH system. It is intended for people with Parkinson's Disease. A separate IFU exists for the Healthcare professionals.

General system information, technical specifications, and regulatory details applicable to all users are in **Section 3**.

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Legal notice

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Section 1: Guide for People with Parkinson's (Patients)

1.1 What is PARKIWATCH?

PARKIWATCH is a software application that works with your Android smartphone. PARKIWATCH requires the user to wear a third-party smartwatch or wrist-worn device which collects raw motion data (accelerometery). The user needs a private Android smartphone with minimum technical requirements described in 1.4.2 to install and use PARKIWATCH. It is designed to complement the clinical assessment of your healthcare professional by passively and continuously collecting information outside of a clinical setting, in-between the clinical visits.

1.1.1 Software Version and compliance

This Instructions for Use (IFU) applies specifically to PARKIWATCH Version 1.0.0. Using an outdated version of the software may result in inaccurate data or security vulnerabilities. You can check your current software version within the PARKIWATCH application on your smartphone by accessing the “About” setting on the left-hand menu.

Software updates are mandatory to ensure the continued safety, security, and performance of the device. Ensure that "Auto-Update" is enabled in the Google Play Store for PARKIWATCH.

1.2 What PARKIWATCH Does (Intended Use)

PARKIWATCH is a Software as a Medical Device (SaMD) intended for the continuous, passive detection and quantitative assessment of kinematic patterns representative of (i) tremor, defined as oscillatory movements; (ii) bradykinesia, defined as reductions in movement velocity and amplitude during voluntary upper-limb activity; and (iii) dyskinesia, defined as irregular, non-rhythmic hyperkinetic movements consistent with levodopa-induced involuntary movements; in adults with Parkinson's Disease.

Required equipment: PARKIWATCH requires the user to wear a third-party smartwatch or wrist-worn sensor which collects raw motion data (accelerometery). The user needs a private smartphone (Android) to install and use the PARKIWATCH smartphone Android application.

Compatibility: PARKIWATCH is compatible with third-party smartwatches or wrist-worn sensors that possess an inertial measurement unit (IMU) sensor that provides raw accelerometer data.

PARKIWATCH processes triaxial accelerometer data collected from third-party smartwatch or wrist-worn devices. PARKIWATCH applies validated signal processing and statistical learning algorithms to produce continuous, longitudinal output Validated Kinematic Measures, which are made available to healthcare professionals via a web-based dashboard and PDF reports. The validated kinematic measures are calculated alongside other supportive digital health metrics.

PARKIWATCH is NOT intended to diagnose Parkinson's Disease, to recommend or modify specific pharmacological therapy independently, or to provide real-time clinical alerts. Its outputs are adjunctive to, and must be interpreted within the context of, standard clinical assessment and the treating healthcare professional’s judgment.

1.3.1 Who Should NOT Use PARKIWATCH (Contraindications)

- Atypical Parkinsonism; including Multiple System Atrophy (MSA), Progressive Supranuclear Palsy (PSP), and Corticobasal Degeneration (CBD).
- Secondary Parkinsonian Syndromes; including drug-induced parkinsonism, vascular parkinsonism, or normal pressure hydrocephalus.
- Essential Tremor or other non-Parkinsonian movement disorders that may interfere with kinematic data accuracy.

1.3.2 Who should use PARKIWATCH

This system is intended for you only if:

(A) You are currently being treated and followed by a licensed healthcare professional (such as a neurologist).

(B) You are physically and mentally able to use a smartphone and are willing to wear a third-party smartwatch or wrist-worn device every day during your waking hours.

1.4 Getting Started: Setup and Installation

Download.
Open the Google Play Store on your Android smartphone and search for "PARKIWATCH" by Koios Care. Tap to download and install the application.

Register/Login.
Open the app and follow the on-screen instructions to register using a working e-mail address. A verification email will arrive in your inbox with a confirmation code to validate the e-mail address and will enable to log in using the credentials you have provided during the registration process.

Permissions and info.
The PARKIWATCH Android smartphone application will ask for permissions in order to access sensor information, operate in the background, and to send notifications. These are necessary for the system to work correctly. Additional info will include gender, birth year and the year you were diagnosed with Parkinson's Disease. Finally, additional info includes indicating the wrist (Left or Right) you eat with and the wrist you are wearing the third-party smartwatch or wrist-worn sensor device (Left or Right).

Pair the third-party smartwatch or wrist-worn sensor device.
Consult the third-party smartwatch or wrist-worn sensor device documentation on instructions regarding the correct setup of the device. Additionally, the on-screen instructions are provided in the PARKIWATCH smartphone Android application.

Connect with healthcare professionals.
To share your data, select the Healthcare Professional option from the left-hand menu. If your doctor provided an email address, enter it to send a connection request. If your healthcare professional has already initiated the connection, you can accept or reject their invitation within this same menu. Once a connection is active, your data will be shared automatically with your healthcare professional for their review.

Wear Correctly.
Wear the third-party smartwatch or wrist-worn sensor device snugly (but comfortably) on the wrist of the hand as directed by your doctor. For instructions on how to wear the third-party smartwatch or wrist-worn sensor device, consult the user manual provided by the device's manufacturer.

1.4.1 Data Security and Privacy

You have the right to access your collected data or request account deletion at any time. To do this, please contact support@koios.care.

1.4.2 Hardware and Software Compatibility

PARKIWATCH is compatible with third-party smartwatch devices and wrist-worn sensors that possess an inertial measurement unit (IMU) sensor that can provide 3-dimensional raw motion data from an accelerometer with a sampling frequency of at least 18 Hz.

A list of PARKIWATCH-compatible third-party smartwatch or wrist-worn sensor devices is available on the Koios Care website.

To ensure correct operation, PARKIWATCH must only be used on devices that meet the following validated minimum technical requirements: Operating system should be Android 9.0 (SDK 28) or higher.

- Bluetooth 5.0 (or higher) and an active internet connection (Wi-Fi or Cellular).
- Access to the Google Play Store is required for installation and mandatory updates.

WARNING: Ensure the smartphone device meets the minimum hardware and software specifications listed in section **1.4.2**. Operation on devices that do not meet these specifications may result in unreliable performance.

1.5 Using PARKIWATCH's passive monitoring: PARKIWATCH works in the background and doesn't require your attention besides Questionnaires.

Questionnaires.
If selected by your healthcare professional, PARKIWATCH will periodically notify you to complete short clinical questionnaire, the UPDRS-II with a recall period of seven (7) days. Answering these questions will allow you to report how you are feeling and provide essential, additional, context to the kinematic data captured by the sensors in your third-party smartwatch or wrist-worn sensor device. To ensure the most accurate insights for your healthcare provider, please respond to these notifications promptly and provide honest answers.

Viewing Your Data.
For a comprehensive analysis, the system automatically generates detailed PDF reports on your kinematic patters. These reports are specifically designed for healthcare professional interpretation and should be reviewed with your healthcare professional to guide your care plan.

1.5.1 Maintenance and Care

No manual calibration of the software is required.

1.5.2 Stop using PARKIWATCH

When your healthcare professional indicates that you should no longer use PARKIWATCH, simply uninstall the PARKIWATCH application from your smartphone.

Uninstalling the PARKIWATCH smartphone application stops data collection, but it does not automatically delete your historical data from the secure cloud. If you wish to have your personal health data permanently deleted, please contact support@koios.care in accordance with your privacy rights (GDPR).

1.6 Clinical benefits

Parkinson's management typically relies on observations made during clinic visits that occur every 3-6 months. PARKIWATCH continuously monitors your kinematic patterns throughout the day and provides validated kinematic measures representative of bradykinesia, dyskinesia and tremor with a resolution of every 15 minutes, giving your healthcare professional information in-between clinical visits. This may support more informed decisions about your care between appointments and how your body responds to the treatment plan. PARKIWATCH does not diagnose Parkinson's Disease, does not recommend or change your medication, and does not replace the judgment of your healthcare professional.

1.7 Troubleshooting

If you experience an issue with the PARKIWATCH, please try the steps under the problem that best matches your situation first.

Problem: My smartphone and third-party wrist worn sensor device are not syncing.
Possible Cause: Bluetooth may be turned off, or the devices may be too far apart.
Solution: 1. Verify that the PARKIWATCH application is installed and active on your smartphone. You can confirm the system is working correctly by checking your smartphone's top notification bar; the presence of the "Everything is running smoothly" notification indicates that the software is successfully capturing and processing data. If this notification is missing, open the app on your smartphone to resume monitoring. 2. Ensure that the third-party smartwatch or wrist-worn sensor device is correctly set up. For this, consult the user manual provided by manufacturer for guidance on the set-up process. 3. Ensure Bluetooth is turned "ON" on both your smartphone and the third-party smartwatch or wrist-worn sensor device. 4. Keep your smartphone and the third-party smartwatch or sensor device battery charged, ON and next to each other. 5. The PARKIWATCH smartphone app will automatically sync the device. 6. If the issue continues, restart both your android smartphone and the third-party smartwatch or wrist-worn sensor device by turning them completely off and then on again. Consult the user manual provided by the manufacturer for guidance on the restart process.

Problem: I don't see any new reports in my smartphone PARKIWATCH app.
Possible Cause: New data has not yet been synced from the third-party smartwatch or wrist-worn sensor device or uploaded to the cloud.
Solution: 1. First, consult the user manual provided by the third-party smartwatch or the wrist-worn sensor device manufacturer for guidance on the set-up process. a. Ensure that the battery of third-party smartwatch or wrist-worn sensor device is adequately charged (above 20%). 2. Next, check that your smartphone has an active internet connection (either Wi-Fi or cellular data). PARKIWATCH needs an internet connection to upload data for processing.

Problem: The PARKIWATCH app on my phone is frozen or has closed.
Possible Cause: A temporary software issue.
Solution:

1. Close the app completely from your phone's recent applications screen.
2. Re-open the PARKIWATCH app on your smartphone – the notification bar should now include the “Everything is running smoothly” notification by PARKIWATCH.
3. If the problem happens frequently, try restarting your smartphone.

Problem: The PARKIWATCH app on my phone crashes immediately after launching it.

Possible Cause: A software issue caused by the Android OS.

Solution:

1. Go to your smartphone’s settings and search for ‘Apps’
2. In the list of applications, search for ‘PARKIWATCH'
3. In the menu that opens, find ‘Storage and cache’.
   a. Select clear storage, and clear cache.
4. Go back and select uninstall. This operation will cleanly remove the PARKIWATCH app from your smartphone.
5. Follow the installation instructions to download, install and configure PARKIWATCH again on your phone.

Problem: I am not receiving notifications for my questionnaires.

Possible Cause: The smartphone’s app permission to send notifications may have been turned off.

Solution:

1. Go to your smartphone's main Settings menu.
2. Tap on "Apps" or "Applications".
3. Search and tap on "PARKIWATCH".
4. Tap on "Notifications" and ensure that all switches are turned ON.

Problem: My skin is irritated under the third-parrty smartwatch or the wrist-worn sensor device.

Possible Cause: This is a hardware issue related to the band, or casing, of the third-party smartwatch or wrist-worn sensor device; not the PARKI WATCH software.

Solution:

1. Stop wearing the third-party smartwatch or wrist-worn sensor device immediately.
2. Consult the user manual provided by the third-party smartwatch or the wrist-worn sensor device manufacturer for guidance on materials and cleaning.
3. Inform your healthcare professional of the irritation.

1.8 Support

For any technical issues that are not resolved by the steps above, please contact Koios Care support through the details provided in the smartphone application under “contact” in the left-hand menu, or at the end of this document.

1.9 Regulatory Notifications and Service Life

The product lifetime of PARKIWATCH is defined as five (5) years from the date of release of each respective software version. At the end of the product lifetime, Koios Care will notify registered users and, where applicable, provide guidance on transitioning to a supported version. The current supported software version is specified on the cover page of this document.

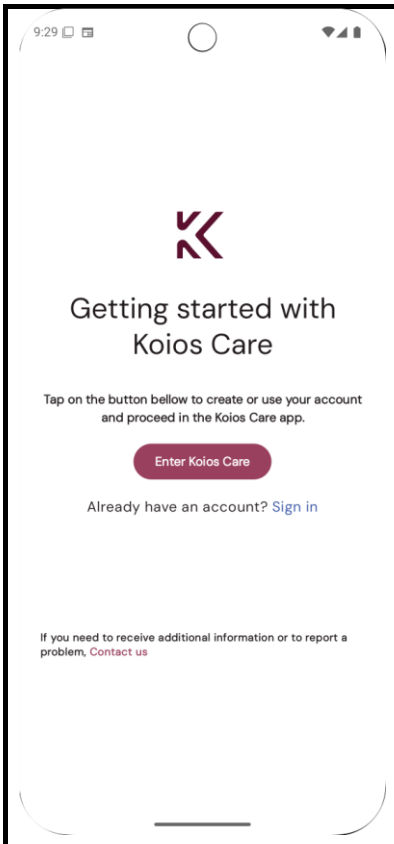
Any serious incident that has occurred in relation to the device must be reported immediately to Koios Care (support@koios.care) and to the competent medical authority in your country of residence.

Your data is hosted on secure cloud servers. Ensure your smartphone maintains at least 500MB of available storage for temporary data buffering.

This manual was created by KOIOS CARE. It is intended to guide the user on how to setup and use PARKIWATCH, developed by KOIOS CARE.

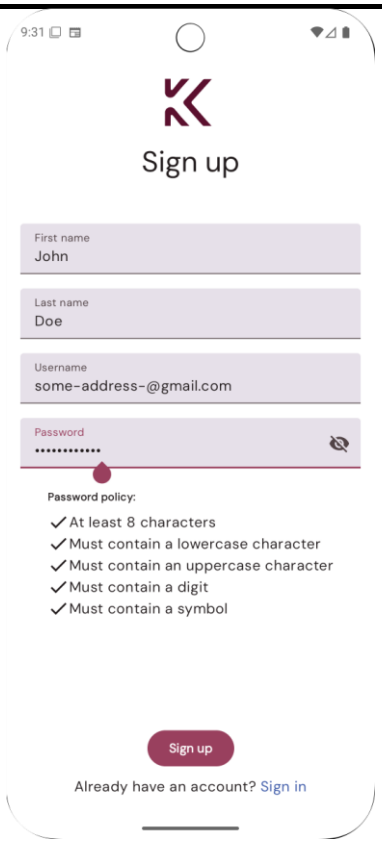
Section 2: Operating instructions - setting up PARKIWATCH

2.1 Setting up the PARKIWATCH app for your Android smartphone



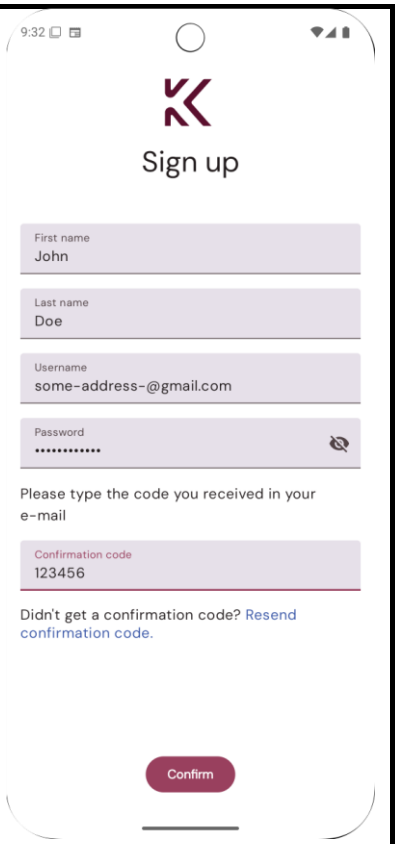
Getting Started Screen

Upon launching the PARKIWATCH app, users are greeted with the Getting started screen. This serves as the main entry point to the application. To begin, the user taps the Enter Koios Care button to either create a new account or access an existing one. Users who already have an account can bypass this by selecting the Sign in link. For additional information or to report an issue, the Contact us link is available at the bottom of the screen.



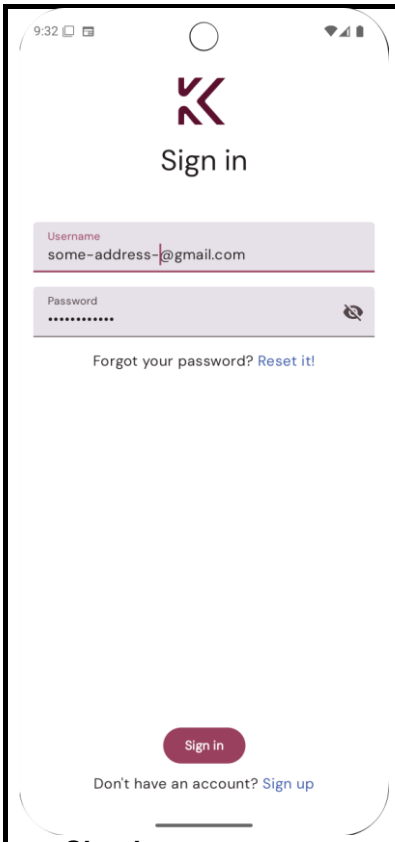
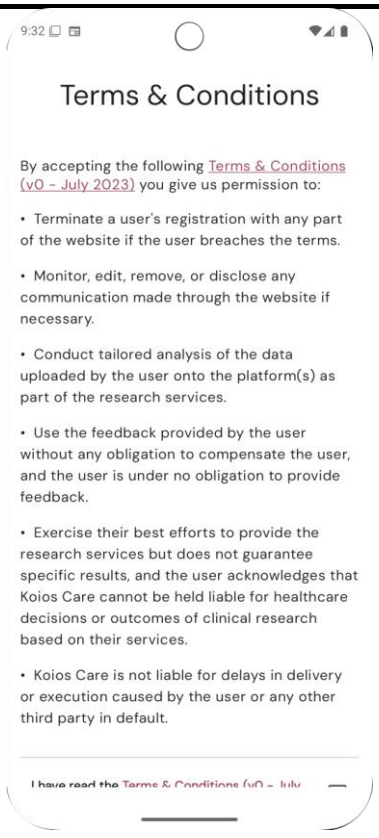
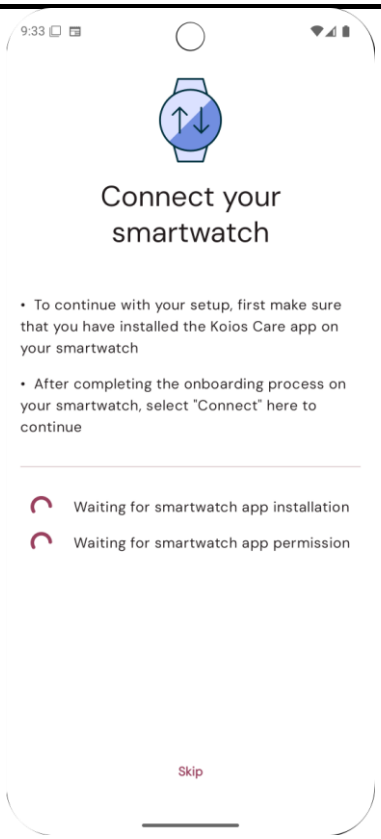
Sign up screen – filling in the details

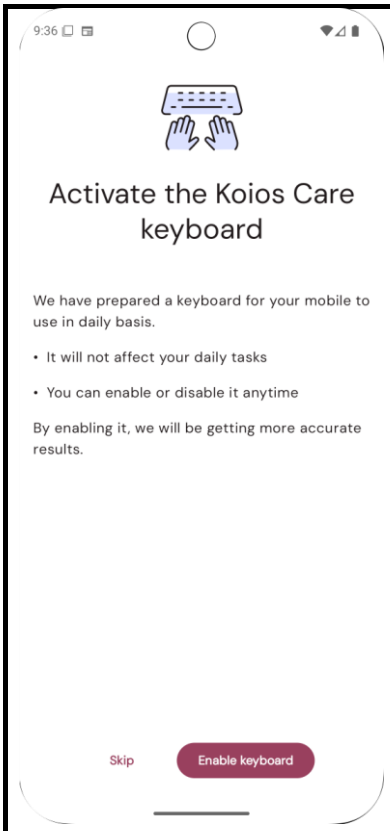
If the user doesn't have an account, the sign-up screen serves as the entry point of creating one. The user fills in the information such as first and last name, e-mail address and presses "sign up" at the bottom. This will send a verification e-mail in the provided address to confirm the details provided.



Sign up screen - using the confirmation code

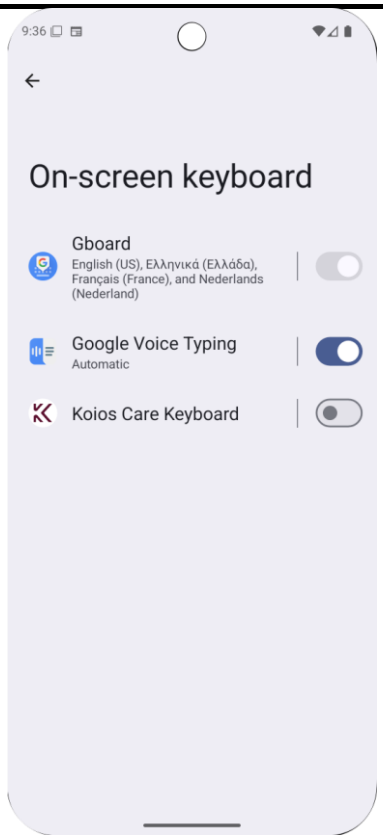
Upon receiving the e-mail, the user can enter the confirmation code in the appropriate field. Once the code is entered, the user must set a new password that complies with the security requirements displayed beneath the password field: a minimum of 8 characters, including at least one lowercase letter, one uppercase letter, one digit, and one symbol. The "Confirm" button becomes active only when all conditions are met. Tapping on the "confirm" button concludes the sign-up process.

		
Sign in screen – user already has an account If the user has already created an account, the sign in screen is the entry point to the PARKIWATCH application. The user types the email address and password that they used during the sign-up process and press sign in to continue with the setup process. In case the user has forgotten their password, the button "Reset it" sends an email to the provided address to perform password reset; i.e., select a new password to sign in. Same condition about the strength of the password applies as the sign-up process.	**Terms and Conditions** After successfully going through the sign in process, the user proceeds with the terms and conditions screen. This screen outlines key legal permissions granted to Koios Care upon acceptance. By agreeing to the terms, users allow Koios Care to terminate registrations for breach of terms, edit or remove user communications when necessary, and conduct personalized data analysis. A link to the full document (e.g., "Terms & Conditions (v0 – July 2023)") is included for users who wish to review the complete terms.	**Connect your smartwatch screen** This screen provides supportive guidelines for users in order to connect their third-party smartwatch or wrist-worn sensor device with the PARKWATCH android smartphone application. For detailed instructions, please consult the documentation provided by the third-party smartwatch or wrist-worn sensor device manufacturer. While you can **temporarily** skip this step to continue the setup process, you will eventually need to connect a compatible device for PARKIWATCH to operate correctly.



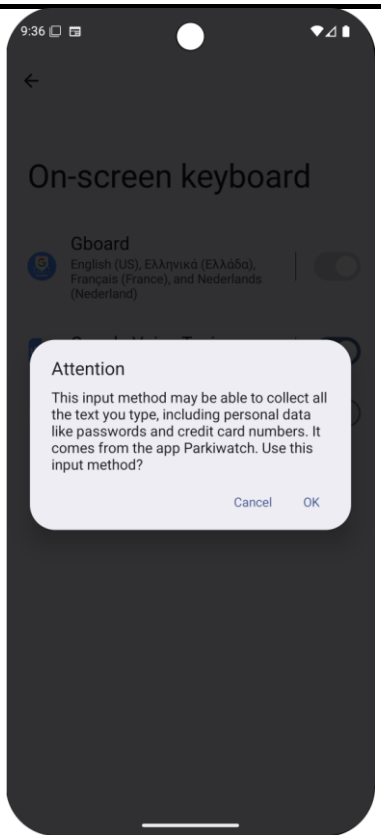
Activate the Koios Care keyboard screen

Next, the users are greeted with the activate the Koios Care keyboard screen. Users have the option of selecting either to skip this step (and enable it later) or skip it completely. The Koios Care keyboard is used to extract **support digital health measures** and does not affect the extraction of the validated kinematic measures. Pressing on “enable keyboard” continues with the setup of the Koios Care keyboard.



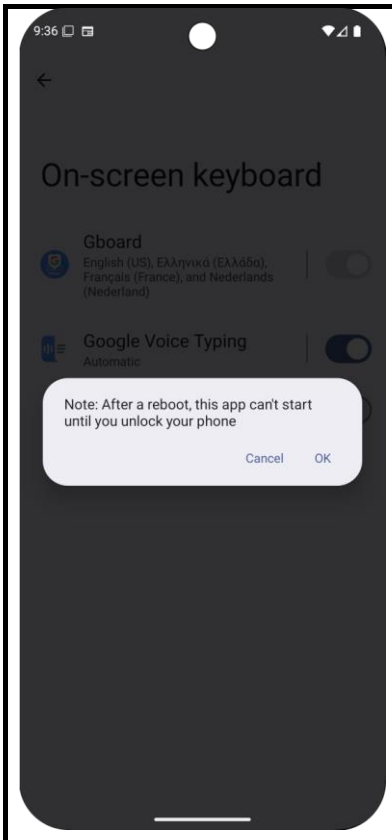
Selecting the on-screen keyboard

The next screen provides the option to the user to enable the keyboard as the primary input method (i.e., primary keyboard) for all standard input/typing processes on their smartphone. By tapping on the sliding bar, users can enable or disable the keyboard and/or replace it with another keyboard that is currently installed on their device. Tapping on the arrow on the top left side of the screen, cancels this process and users can return on the “activate the Koios Care keyboard screen”.



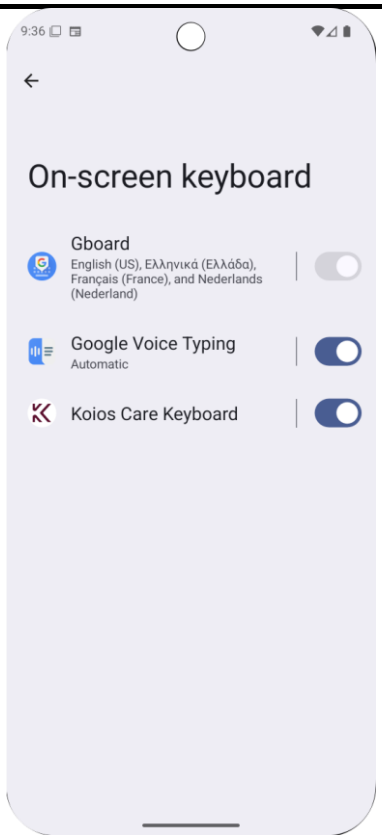
Verifying keyboard selection

The next screen is an Android-related operation that attracts the attention of the user regarding what they need to be aware when selecting a new keyboard; specifically, other than the Google one. Users can select OK to proceed with the keyboard change, or CANCEL to go back to the previous screen and cancel the keyboard verification process.



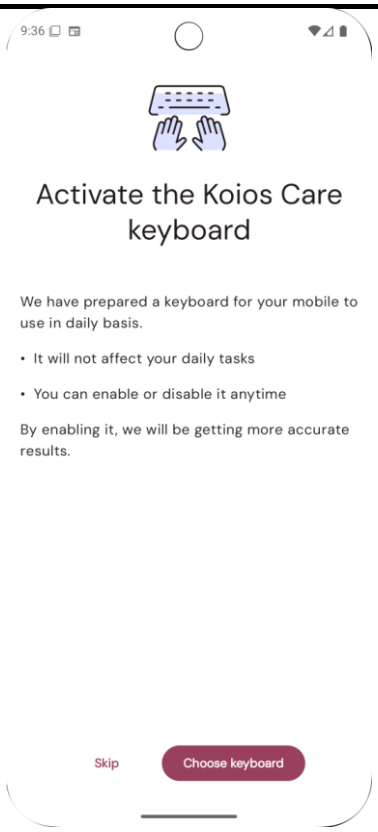
Verifying keyboard process - unlock phone prior to starting the app

The next screen informs the user that after the next reboot of the phone, either initiated by the user of by accepting a prompt to restart by the Android system, a phone unlock, using the Android user-selected password, will be required prior to starting the application. This is a safety mechanism from Android. Users select OK to continue or CANCEL to go back to the “"selecting the on-screen keyboard” screen.



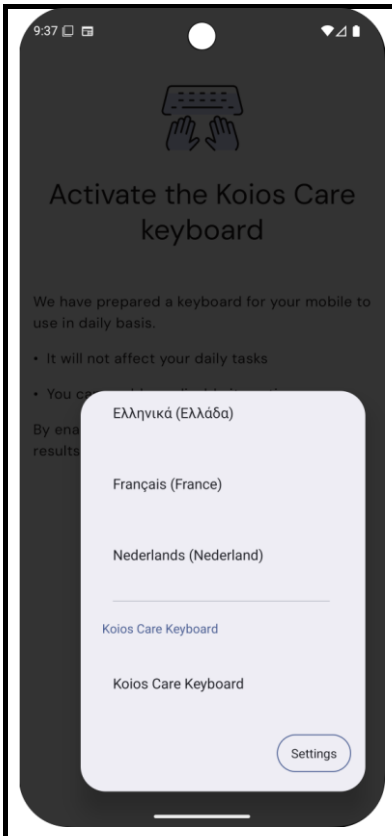
Concluding the on-screen keyboard selection

After successfully going through the selection of the on-screen keyboard and the Android pop-up windows, the next screen verifies that the Koios Care keyboard is enabled and accessible by the user on their phone. The user can again tap on the slider to disable and re-enable the Koios Care keyboard. By tapping on the top-left arrow, the user goes back to the “"activate the Koios Care keyboard” screen, to continue with the setup process.



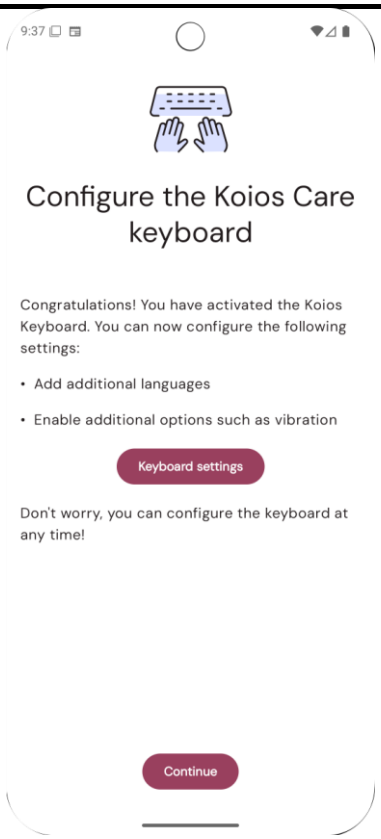
Activate the Koios Care keyboard screen – Koios Care keyboard is enabled

By returning to the “"activate the keyboard”" screen, after successfully going through the steps of selecting the Koios Care keyboard, the user can either select to “Choose keyboard” to continue with the setup of the Koios Care keyboard as an input method for their phone, or skip this process all together.



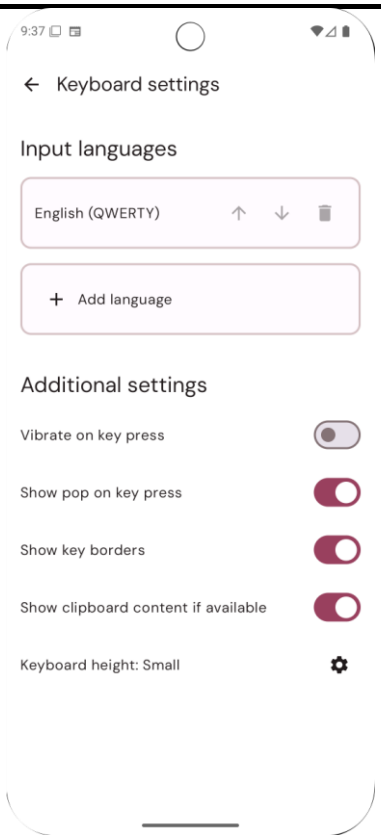
Setting up the Koios Care keyboard

Next, the users are greeted with the option of selecting to initiate the configuration process of the Koios Care keyboard, by tapping on “Settings” button on the bottom right. The information on the screen showcases the languages that are included in the Koios Care keyboard – French, Dutch and Greek.



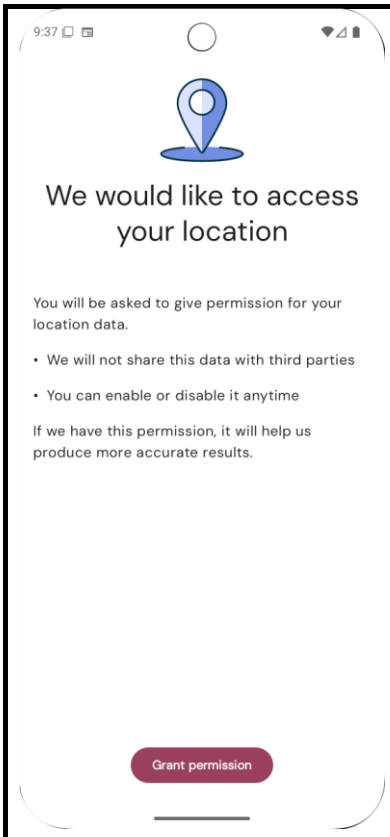
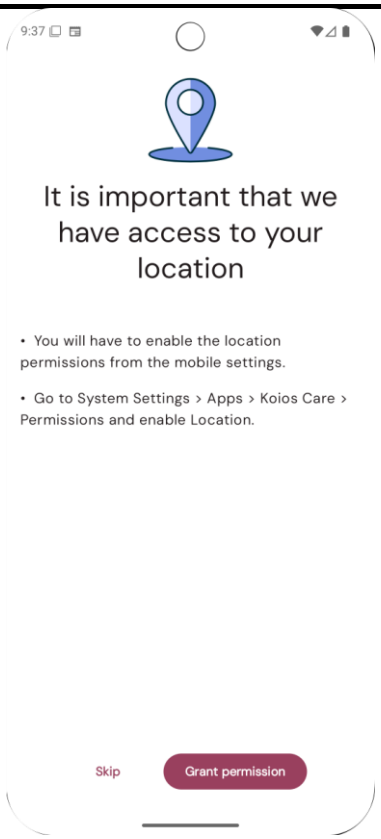
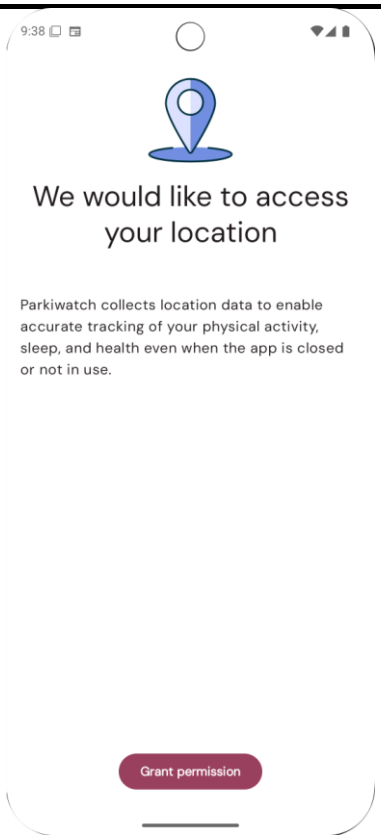
Setting up the Koios Care keyboard (cont.)

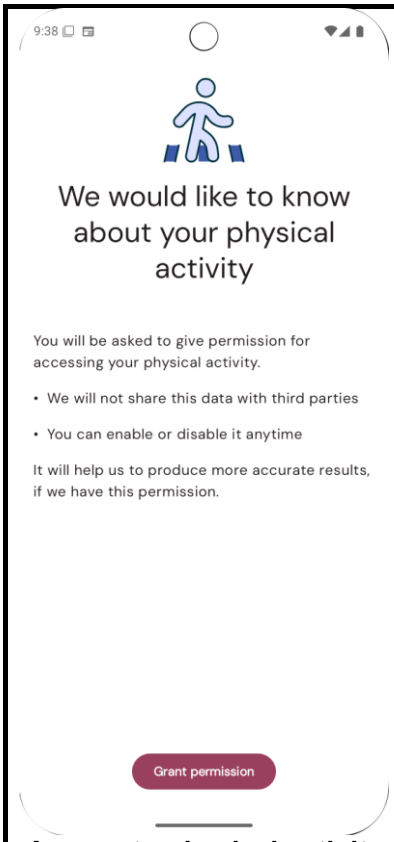
In the next screen, the user can continue with the keyboard setup process, by tapping on “Keyboard settings” or select “Continue” at the bottom of the screen to continue with the app setup process with the default settings of the keyboard.



Setting up the Koios Care keyboard (cont.)

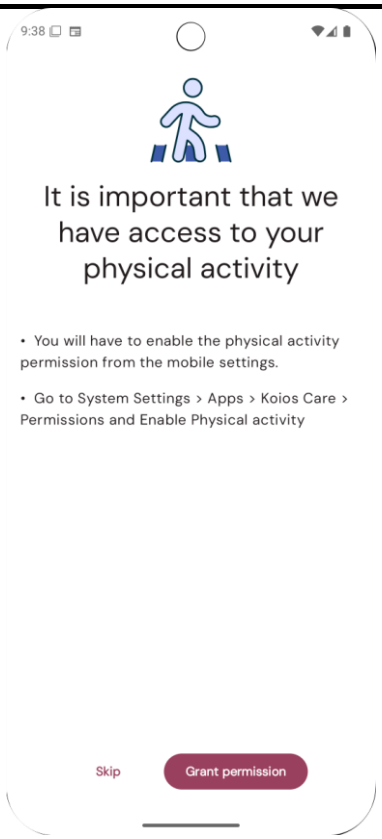
By selecting “"Keyboard Settings” the user can add or remove languages and change how the languages are sorted when cycling through them. This can be done by tapping on the “add language button” (to add languages), the garbage bin icon (to remove a language) or the up and down arrows to change the sorting. Additional settings, such as (1) vibrate on keypress, (2) show pop on keypress, (3) show key boarders, (4) show clipboard content if available, and (5) parameterize the height of the keyboard by tapping on the gear icon. After the user finishes personalizing their keyboard, they can select the arrow on the top left to conclude the keyboard selection and setup process and continue with the next steps of setting up PARKIWATCH.

		
Setting up access to location The next screen initiates the process of granting access to the location via the GPS of the smartphone. In the first screen, the user can be informed about how Koios Care uses the location information to extract **support digital health measures**. After going through the information on the screen, the user can continue by selecting the “grant access” button at the bottom of the screen.	**Setting up access to location (cont.)** Next, the user is presented with information on how to enable or disable the access of PARKIWATCH to the location data, by accessing the system settings on their smartphone. They can select to continue with granting access to the location information they can select "grant permission” at the bottom right of the screen. If they don’t wish to grant location permission, then they can select “"skip” at the bottom left of the screen and continue with the next steps of the PARKIWATCH app setup process. Important to note that location information is not required to calculate the validated kinematic measures and is **only** used for the calculation of the **support digital health measures**.	**Setting up access to location (cont.)** The final screen of setting up the location access, presents to the user the final piece of info regarding how PARKIWATCH is collecting location information in the background (i.e., without the app being actively used by the user). The “"grant permission” button at the bottom of the screen prompts the user for a final confirmation on granting access to the location data. This step concludes the setting up of the access to location. Now the PARKIWATCH app can access the user’s location information to extract **support digital health measures**.



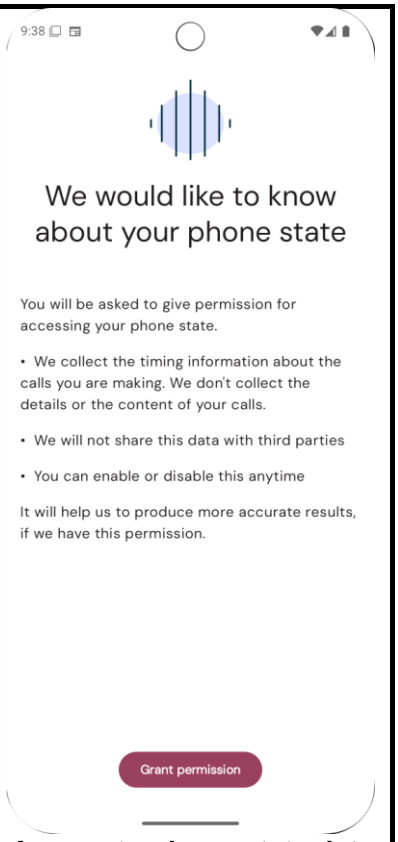
Access to physical activity data

Next, the user is provided with information regarding PARKIWATCH's access to physical activity data. Information includes that this information is not to be shared with third parties and that the user it free to disable access whenever they want. Access to physical activity data is solely used for the extraction of **support digital health measures**. By tapping on the "grant access"" button the user continues with the process of granting, or not, permission to the physical activity data to PARKIWATCH.



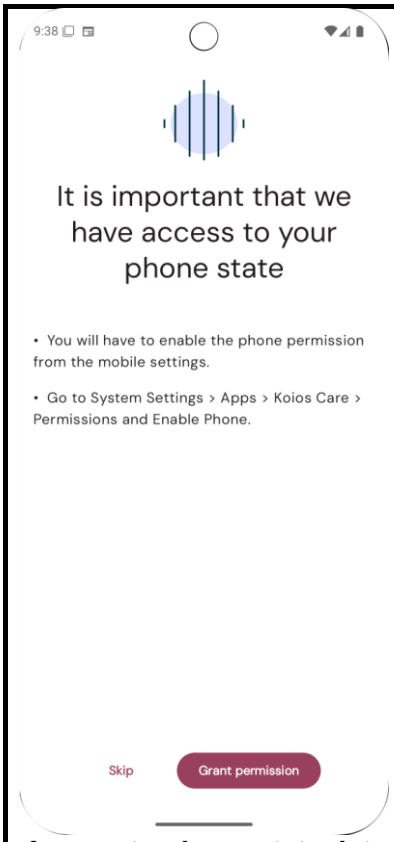
Access to physical activity data (cont.)

The next screen offers more information on the usage of physical activity data. More specifically, that by selecting to grant access, Android will prompt a final yes/no towards granting permission. If the user doesn't want to provide physical activity access, they can select the ""skip" button at the bottom left and proceed with the next steps of the PARKIWATCH app setup process. If they want to proceed with granting physical activity access, they can select "grant permission" at the bottom right and then Android will prompt with a final window to provide, or not, access. This action concludes the process of providing, or not, access to the physical activity data to PARKIWATCH.



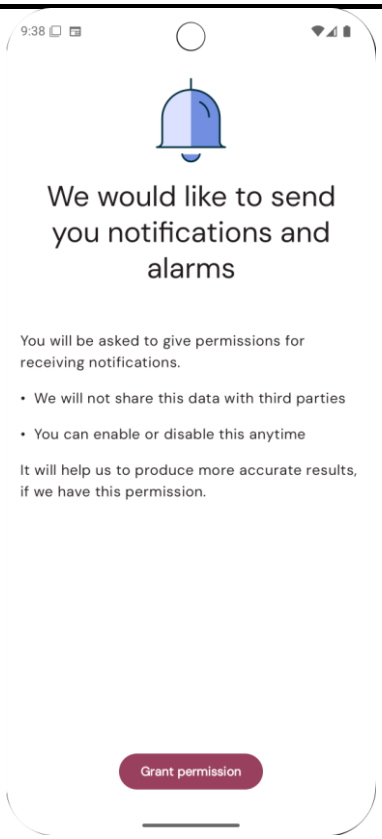
Access to phone state data

Next, the user is presented with information regarding access to the phone state. More specifically, the user is informed that phone state data means the timing of the phone calls and in no way the content of the calls. Moreover, information contains that access can be disabled at any time after the app setup process, and that the data will not be shared with third parties. Access to phone state is used **solely** for the extraction of **support digital health measures**. The user can select ""grant access" at the bottom of the screen to continue.



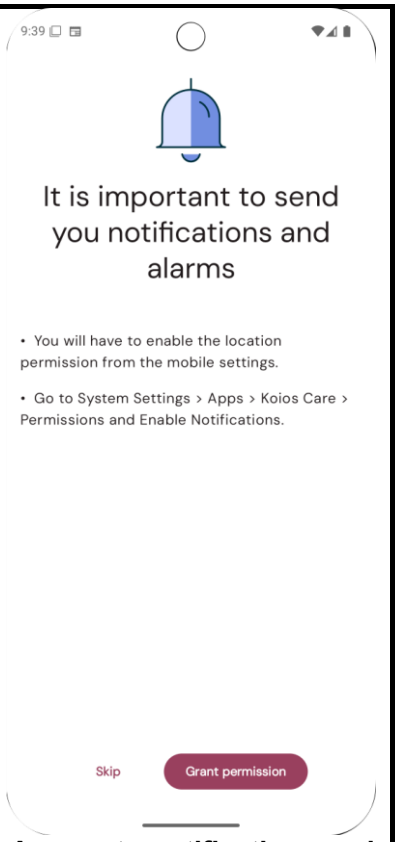
Access to phone state data (cont.)

The next screen provides more information on how the user can enable or disable the access to phone state data. If they don't wish to provide access to PARKIWATCH to this information, the user can select "skip" at the bottom left of the screen to continue with the setup process of PARKIWATCH without granting access to phone state info. If they wish to grant access, they can select "grant permission" at the bottom right. After selecting ""grant permission" Android will prompt for a final yes/no on granting access. This concludes the process of phone state info access to PARKIWATCH, and the app setup process continues with the next steps.



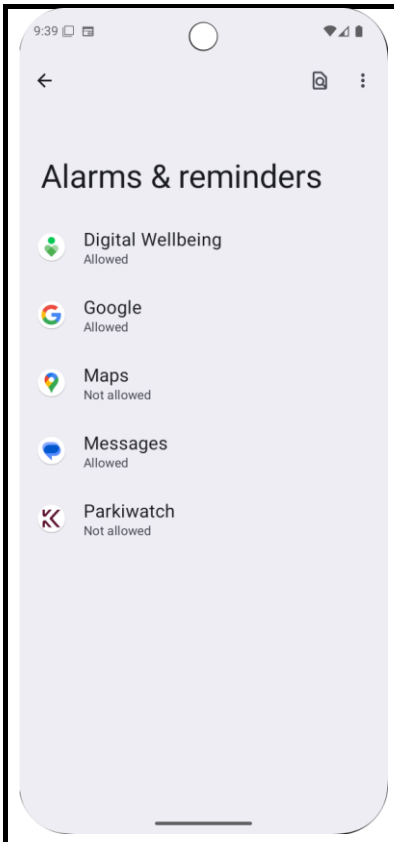
Access to notifications and alarms

The next screen provides information to the user regarding access to sending notifications and enabling alarms. Information includes that no data will be shares with third parties and that the user is free to disable at any time. This information is used **solely** for the extraction of **support digital health measures** and doesn't affect the extraction of validated kinematic measures. Selecting ""grant permission"" at the bottom continues with the next step of granting, or not, notification access to PARKIWATCH.



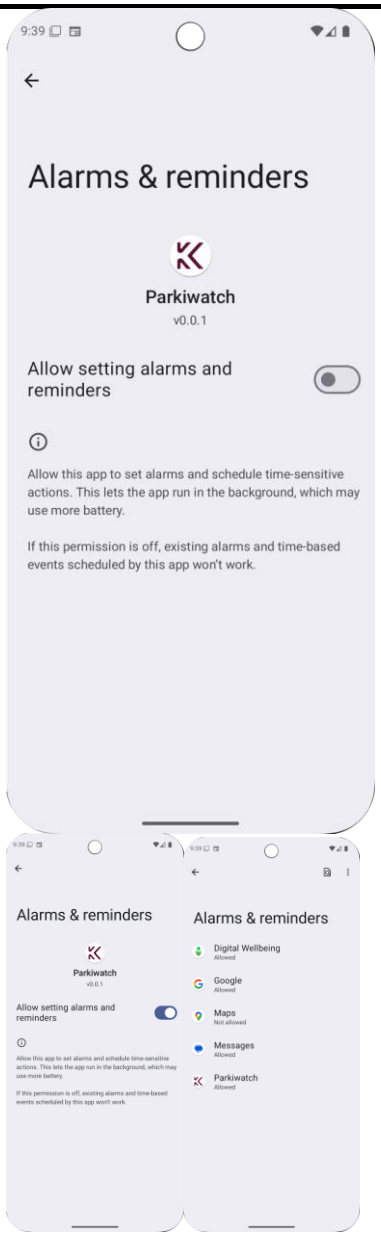
Access to notifications and alarms (cont.)

Next, information of how to grant and disable permission can be done. The user can select "skip" at the bottom left to continue with the next steps of the PARKIWATCH app setup process or select "grant permission"" in the bottom right to initiate the process for providing access.



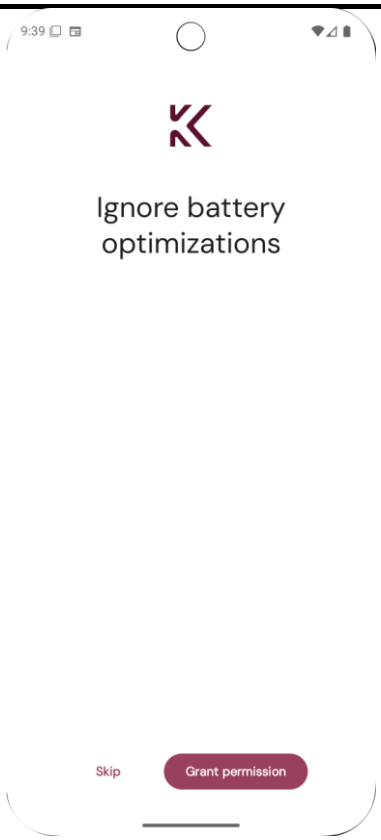
Access to notifications and alarms (cont.)

The next screen follows the Android path for enabling notification and alarm access to PARKIWATCH. From the provided menu, the user can see the applications that are installed to the system that have asked for such permission; in the figure above its Digital Wellbeing, Google, Maps, Messages and PARKIWATCH, along with an indication of access being allowed or not. By tapping on the



Access to notifications and alarms (cont.)

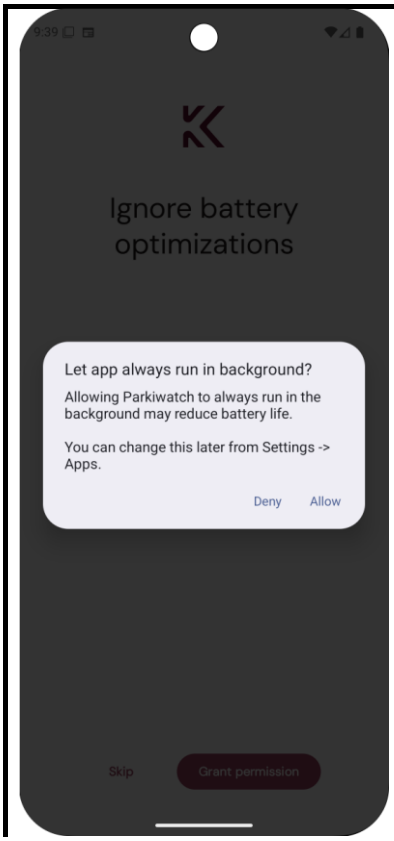
The final screen for providing notification and alarm access is presented to the user. This screen includes a slider that can be tapped to allow, or disable, access to notifications and alarms. Information from the system is also provided that informs the user about how battery life can be affected as the access to notifications and alarms allows the app to operate in the background. Providing access by using the

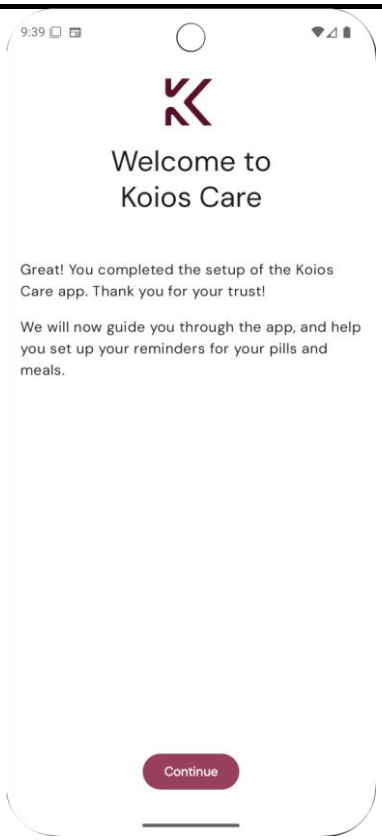


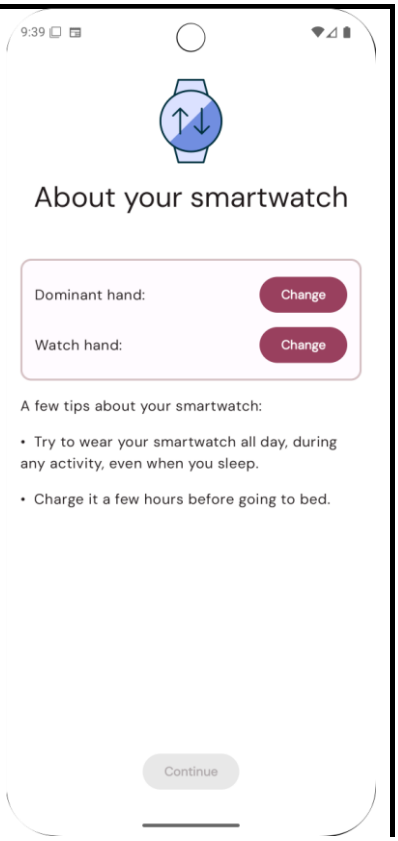
Ignore battery optimizations

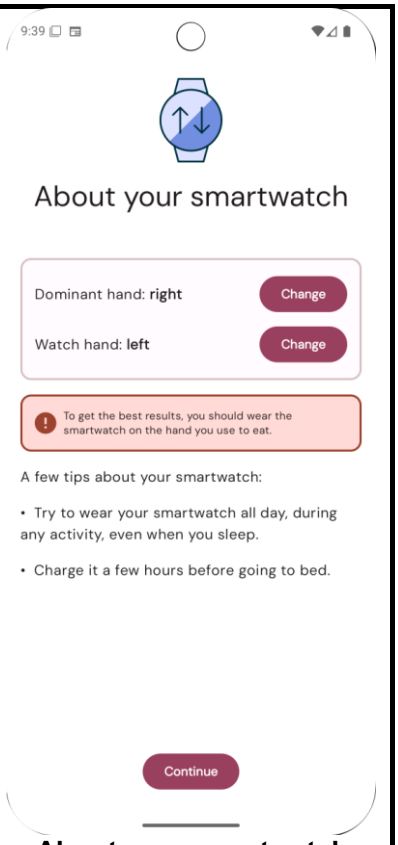
The next step has to do with disabling the battery optimizations. Granting such access allows PARKIWATCH to operate optimally in the background without being affected by the battery optimizations by the Android system. User can select “skip” to proceed to the next step of the PARKIWATCH app setup process or select “"grant permission"” at the bottom right to continue with

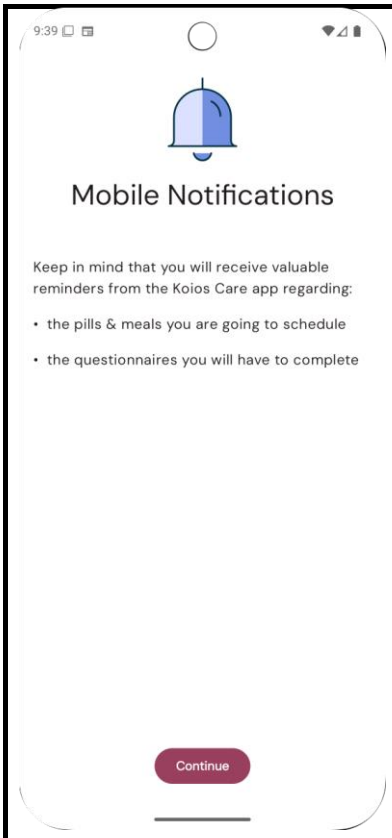
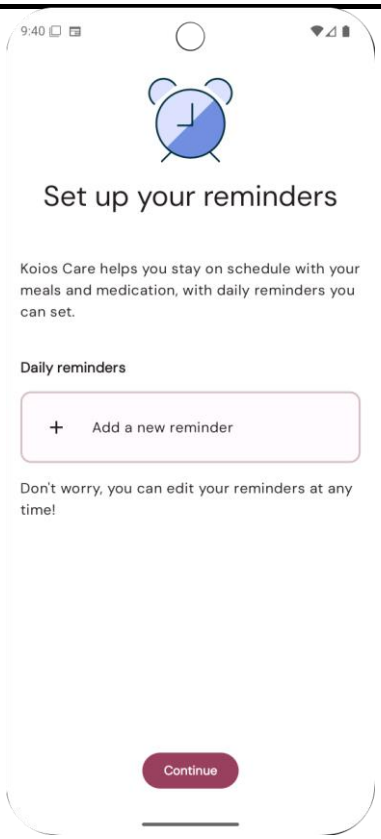
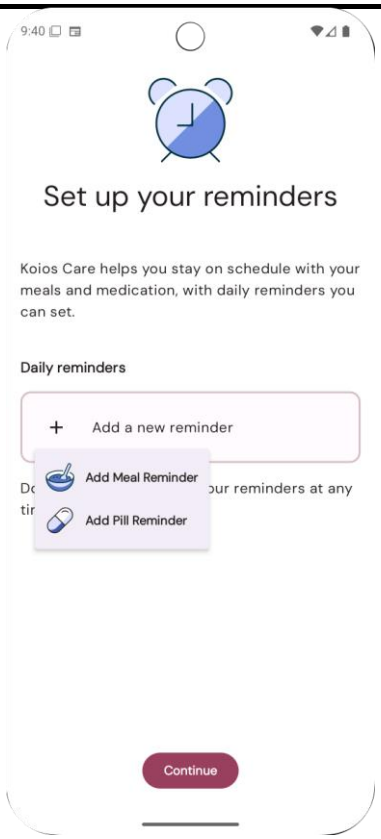
PARKIWATCH app the user can proceed with the next steps of granting notification and alarm access to PARKIWATCH. If the user doesn't want to provide access, they can tap on the arrow on the top left side of the screen and return to the screen that they can select ""skip" to continue with the next steps of the PARKIWATCH app setup process.	slider or selecting the top left arrow to not grant access, concludes the access to notifications and alarms process. From there, the user can select the arrow on the top left to go back to the list of applications that are allowed access. And from there, the user can tap again on the arrow on the top left to finalize the process of granting access to notifications and alarms continue with the next steps of the PARKIWATCH app setup process.	the steps of disabling battery optimizations.



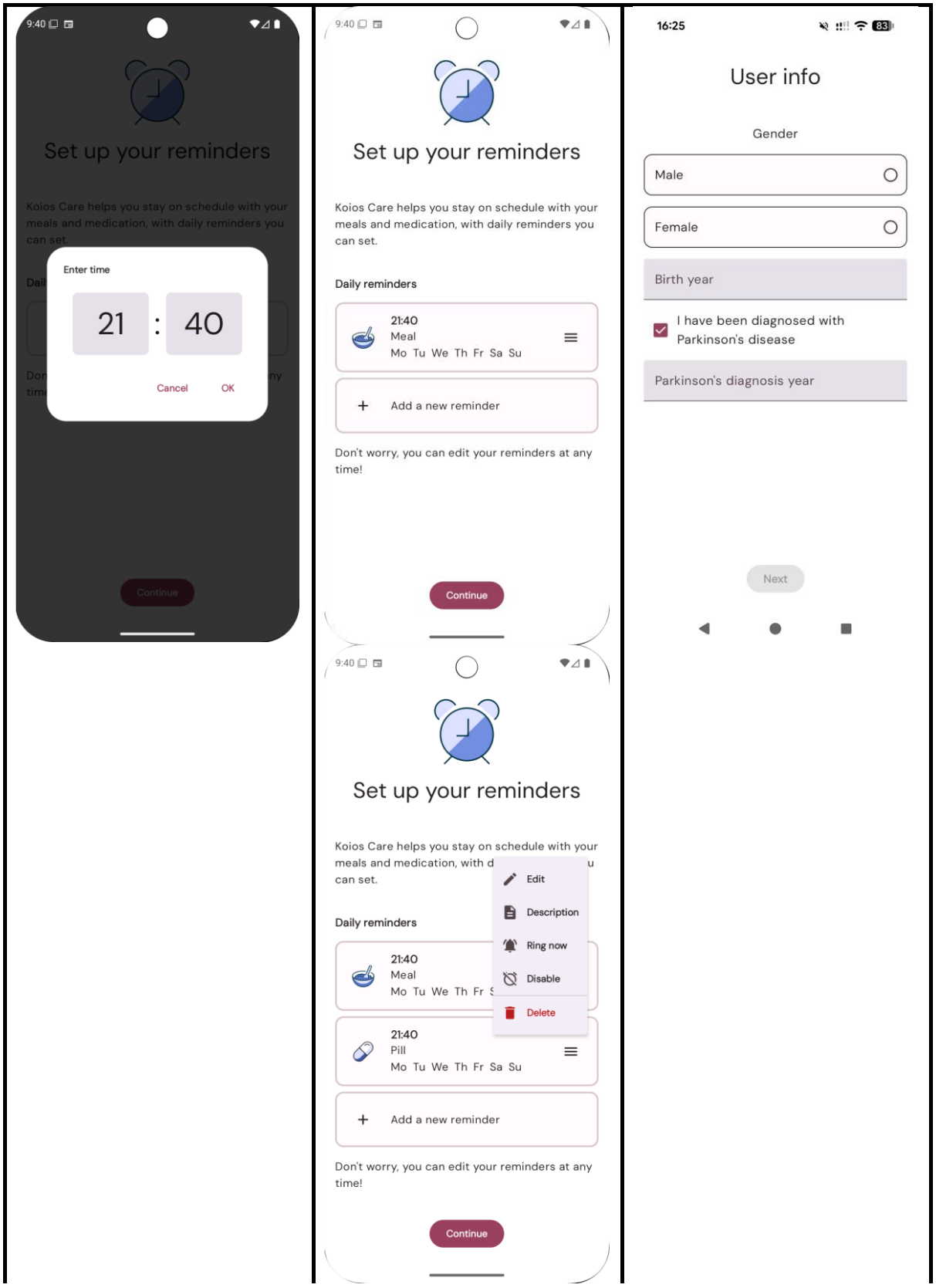




Ignore battery optimizations (cont.) The next screen is an Android prompt that informs the user that by selecting to disable battery optimizations enables the app to always run in the background - and this has the possibility of reducing battery life. The user is also informed that this can be turned off and on again by the settings menu on their smartphone. The user can finalize their option to grant or not access by selecting “deny” or “allow”. This concludes the step of disabling battery optimizations and the user proceeds with the next steps of the PARKIWATCH app setup process.	**Welcome to Koios Care** The next screen informs the user that they successfully went through the part of the PARKIWATCH app setup process that relates to creating account, logging in, agreeing, or not, to the terms and conditions and granting, or not, permissions to PARKIWATCH for extracting support digital health measures. The user can select “continue” on the bottom of the screen to continue with the next steps of the PARKIWATCH app setup process.	 **About your smartwatch** After selecting “continue” on the welcome screen, the next screen asks the user for information on how their wear the third-party smartwatch or wrist-worn sensor device. The top part of the screen asks the user to input which is their dominant hand - this can be selected by the “change” button where a prompt will ask the user to select left or right. The second option deals with the watch hand – which means on which wrist the user is wearing the third-party smartwatch or wrist-worn sensor device. This can also be adjusted by tapping on the associated “change” button. An information box will pop and indicate that for the best results, the user should wear the third-party smartwatch or wrist-worn sensor device on the wrist of the hand that they use to operate the eating utensils (mainly the fork or

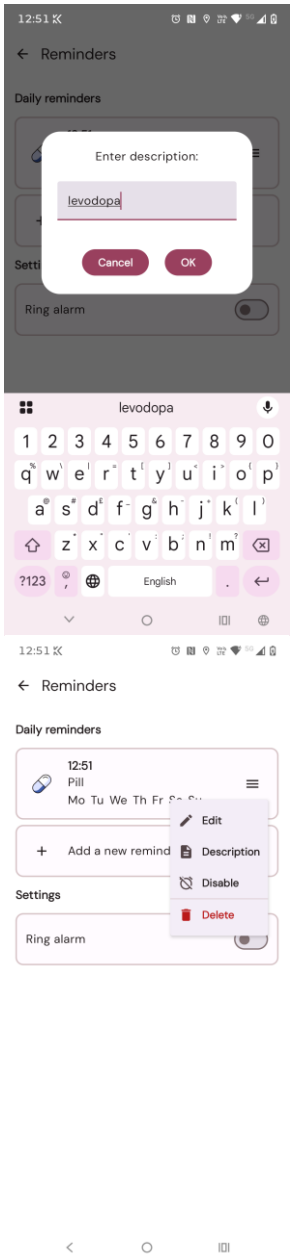
		the spoon). The latter is **solely** for the calculation of the **support digital health metrics** that are associated with eating behavior. The second half of the screen provides tips; specifically, that the user should try and wear it throughout the day, during any activity and during sleep. Also, the user should try to charge the third-party smartwatch or wrist-worn sensor device for a couple of hours prior to wearing it again and going to bed. After selecting the dominant and watch wear wrists, the greyed out “continue” button at the bottom of the screen becomes active and the user can tap on it to continue to the next steps.
 **Mobile notifications screen** The next screen informs the user on how PARKIWATCH uses the notifications engine of Android to remind the user. Specifically, the user can	 **Setting up the reminders** This screen allows the user to set up reminders. The top part of the screen informs the user that setting up reminders helps stay on schedule with	 **Setting up the reminders (cont.)** By selecting “add a new reminder” in the previous screen the user is prompted to select what this reminder is

schedule pills and meals (and reminded of them when the time arrives), as well as prompting the user to fill questionnaires when the scheduled time has arrived. By tapping on “continue” the user proceeds with the next screens of setting up the reminders.	meals and medications. The bottom half allows to add new alarms and informs the user that new alarms can be added, changed or deleted. By pressing continue the user continues with the next steps of the PARKIWATCH setup process. By tapping on “add a new reminder” they are guided to the next screen that allows to setup the reminder.	for; specifically, a meal or a pill reminder. By tapping on either, the user is led to the next screen that allows setting up the specific reminder.


9:40
Set up your reminders
Koios Care helps you stay on schedule with your meals and medication, with daily reminders you can set.
Enter time
21 : 40
Cancel
OK
Continue
9:40
Set up your reminders
Koios Care helps you stay on schedule with your meals and medication, with daily reminders you can set.
Daily reminders
21:40
Meal
Mo Tu We Th Fr Sa Su
Add a new reminder
Don't worry, you can edit your reminders at any time!
Continue
16:25
User info
Gender
Male
Female
Birth year
I have been diagnosed with Parkinson's disease
Parkinson's diagnosis year
Next
9:40
Set up your reminders
Koios Care helps you stay on schedule with your meals and medication, with d u can set.
Edit
Description
Ring now
Disable
Delete
Daily reminders
21:40
Meal
Mo Tu We Th Fr
21:40
Pill
Mo Tu We Th Fr Sa Su
Add a new reminder
Don't worry, you can edit your reminders at any time!
Continue

Setting up the reminders (cont.)

After selecting either the meal or pill reminder, the user can set up the reminder time. In this specific example, when the time is 21:40 local time, the Android smartphone device will trigger an alarm to notify the user that the time for the pill or meal has arrived. The user can cancel the operation by selecting “cancel” or verify it by tapping “OK”.



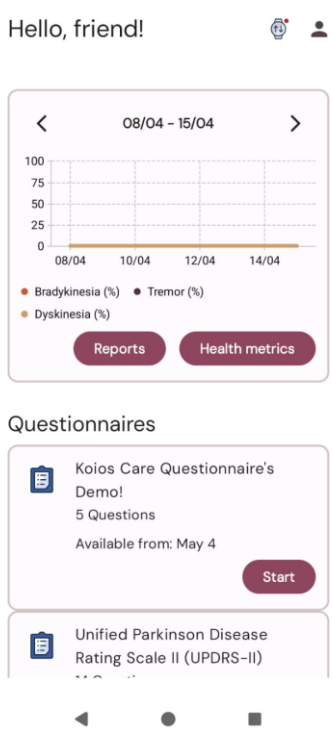
Setting up the reminders (cont.)

By selecting the time for the alarm, the user is led to the previous screen that lists the daily reminders. For each set reminder, information on the time, type of reminder (meal/pill) and the days of the week that the reminder will be triggered. The sandwich menu on the right of each reminder allows the user to explore more options when it comes to setting up the reminder. Options include edit the time, description of

Adding user info

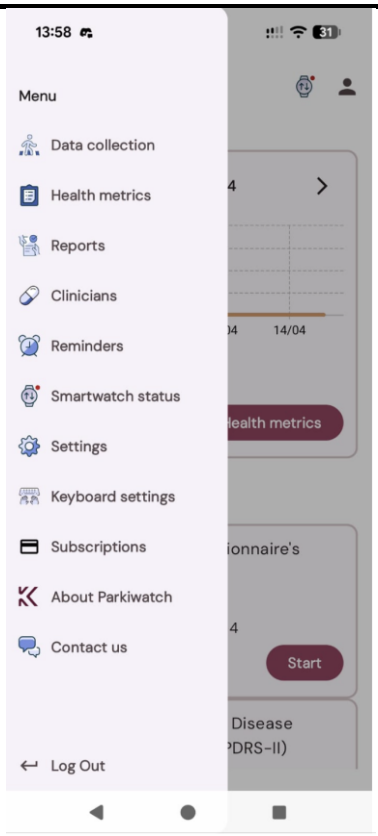
The final screen before reaching the PARKIWATCH dashboard is the user info. From top to bottom the user is asked to select the gender, input the year they were born, and select whether or not they are diagnosed with Parkinson’s Disease by tapping on the checkbox. If they select that they have been diagnosed, then it’s necessary to fill in the year they were diagnosed. The “Next” button is greyed out until all information has been filled. After filling in all information and tapping on “next” the user is greeted with the PARKIWATCH dashboard. This concludes the PARKIWATCH app setup process.

	the pill reminder and days of the week that will trigger the reminder, add a description for the reminder, ring now to verify the correct operation of the reminder, “disable” to temporarily deactivate the reminder, and delete to remove it completely. By pressing the “continue” button, the user continues to the user info screen.	



The PARKIWATCH smartphone app dashboard

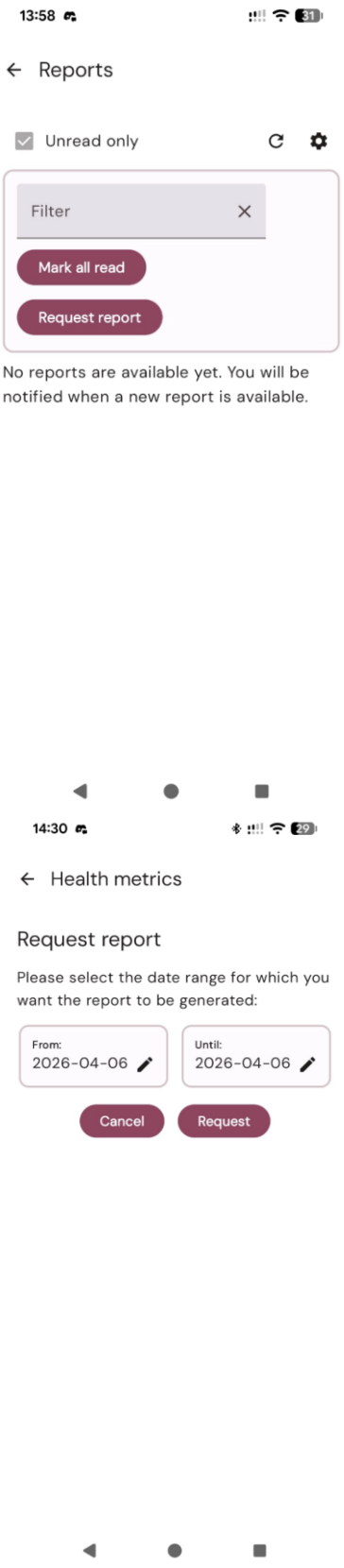
After the user completes the setup process, they are greeted by the dashboard. In the dashboard you can view different items that can help guide you navigate the functionalities of PARKIWATCH. The figure at the top showcases the percentage of time spent with bradykinesia, tremor and dyskinesia during the day, for the period that appears on the top of the figure. The Reports button will take you to the screen that gives access to the generated PDF reports (continue reading the



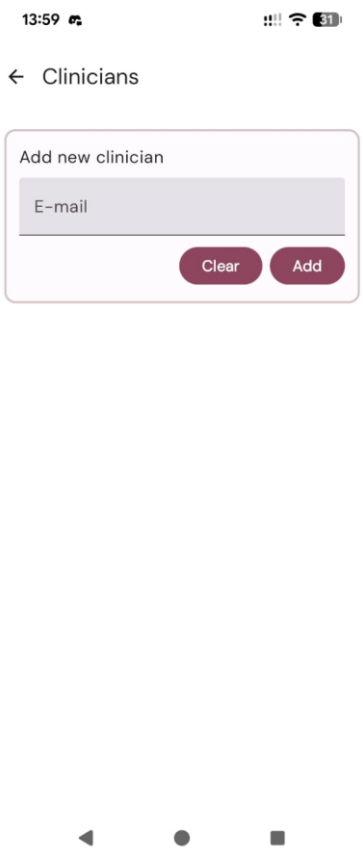
The left-hand side menu

By sliding from the left side of the screen towards the right, you gain access to the left-hand side menu. The items of the menu give you access to different screens. Starting with the “data collection” item you gain access to the screen that showcases how many questionnaires you completed were answered and skipped. As well as

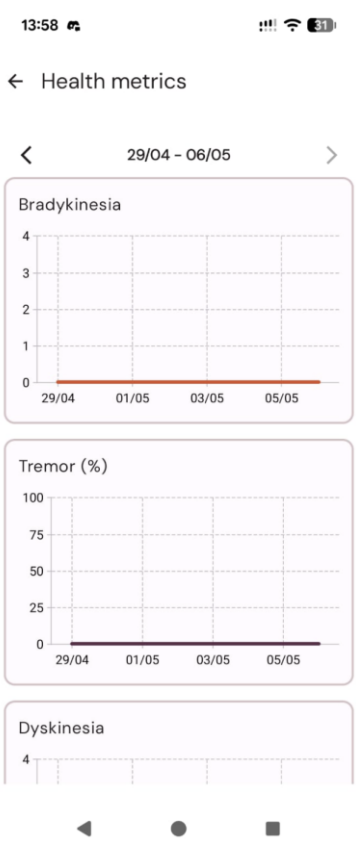
instructions for additional details on that screen), the health metrics button gives access to individual validated kinematic measures (bradykinesia score, tremor %, dyskinesia score – continue reading the instruction for additional details on that screen). Always consult your healthcare professional on how to interpret the different kinematic measures. If your healthcare professional has selected that you should answer questionnaires the questionnaire frame will appear at the bottom of the screen alongside a demo questionnaire that explains the process of answering a questionnaire. By sliding from the left side of the screen to the right, you gain access to the left-hand side menu that contains additional options (keep reading the instructions on information on this).	the amount of data that you have collected and uploaded to the PARKIWATCH cloud infrastructure for further processing and analysis.  The “reports” item gives you access to the generated reports, and you have the option of marking them as read or unread. Additional options on filtering the list of reports (e.g., show only the unread reports), refreshing the list of reports and the gear icon to hide or show the “mark all read” or “request report” options are available. The “request report” button allows you to select the period (from and to, range of dates)	

The PARKIWATCH dashboard screen	that the PDF report should be generated from. 	

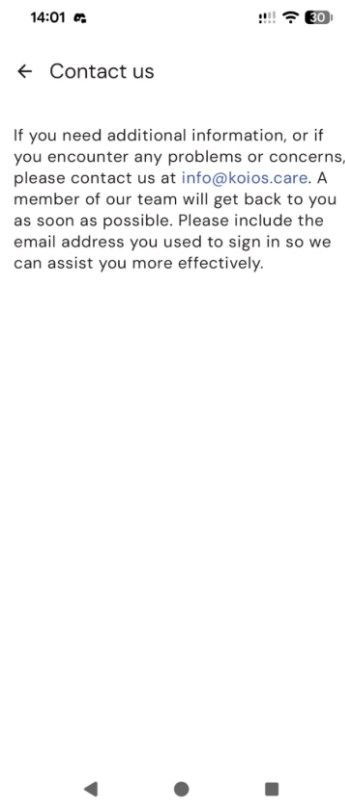
The “clinicians” item gives you access to the menu that you can include the information on your healthcare professional and allows you to connect with them. Connecting with them implies that they will get access to your PDF reports. You should solely provide the email address of your healthcare professional. This feature is designed specifically for their information, so avoid adding personal contacts or unofficial email addresses. To add a new healthcare professional simply type their email in the box and then tap on “add”. Tapping on “clear” simply clears the text already in the box.



	The “reminders” button takes you to the screen that is already described in the part of the instructions titled as “Setting up the reminders” (that appears earlier in the instructions). The “keyboard settings” button takes you to the screen that is already described in the part of the instructions titled as “Setting up the Koios Care keyboard”. The “health metrics” button takes you to a screen that showcases the individual validated kinematic measures in each figure, along with the period for which the validated kinematic measures are extracted from (in this case 29/4 till 06/05 of the running year). Always consult your healthcare professional on how to interpret the results. Additional information on these figures is included in the PFD report explanation found in the following pages of the instructions.	



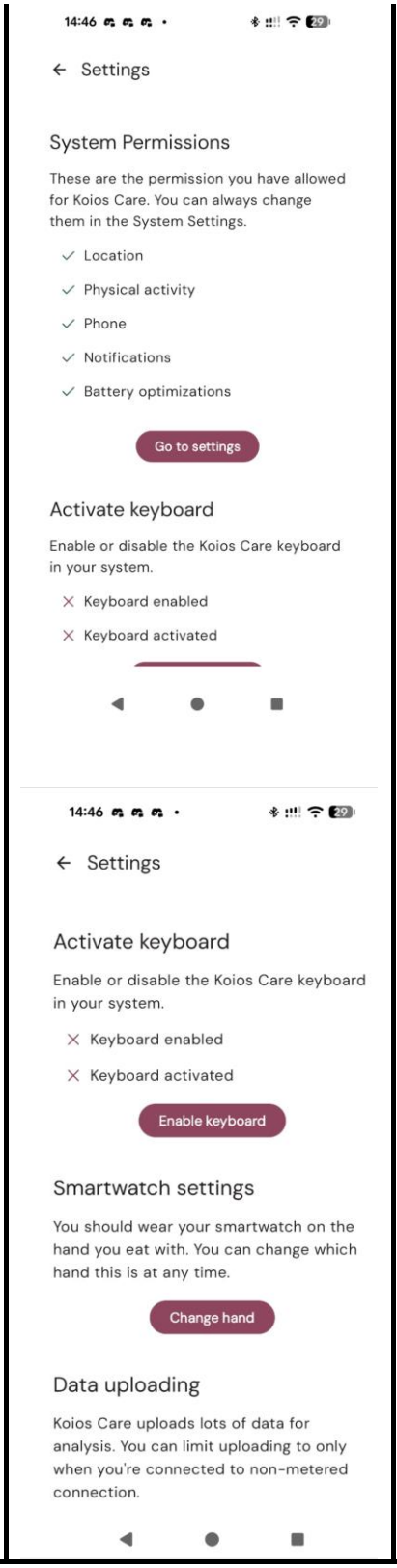
The “contact us” button takes you to the screen that includes information on how to contact Koios Care.

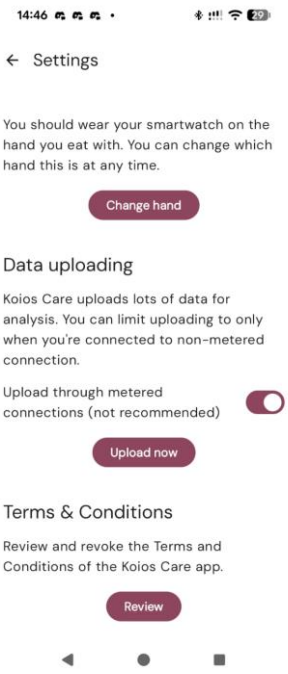


The “about PARKIWATCH” menu item provides access to the information on PARKIWATCH and Koios Care. An additional link leading to the digital version of the instructions is also found.

The “settings” item takes you to a menu that allows

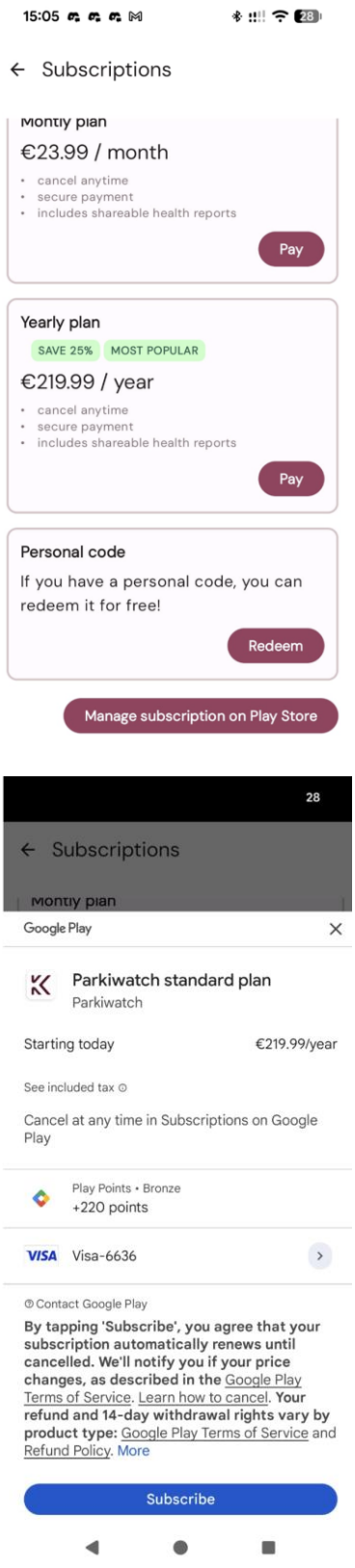
	an overview of the permissions provided (or not provided), access to the keyboard options screen, access to the screen with the wrist (Right/Left) on which you wear the third-party smartwatch or wrist-worn device (and re-adjust them – always consult your healthcare professional on instruction on the wrist you should wear the third-party smartwatch or wrist-worn sensor device), a data upload menu that allows you to enable or disable the data upload to the Koios Care server via metered connection and an “upload now” button to initiate an upload of the so-far collected data to the Koios Care cloud infrastructure for analysis; the terms and conditions menu gives you access to the “terms and conditions” screen that was already mentioned in the instructions. The “subscriptions” button gives access to the different subscription options (monthly, yearly) for accessing the Parkiwatch services. An additional field	


14:46
Settings
System Permissions
These are the permission you have allowed for Koios Care. You can always change them in the System Settings.
Location
Physical activity
Phone
Notifications
Battery optimizations
Go to settings
Activate keyboard
Enable or disable the Koios Care keyboard in your system.
Keyboard enabled
Keyboard activated
14:46
Settings
Activate keyboard
Enable or disable the Koios Care keyboard in your system.
Keyboard enabled
Keyboard activated
Enable keyboard
Smartwatch settings
You should wear your smartwatch on the hand you eat with. You can change which hand this is at any time.
Change hand
Data uploading
Koios Care uploads lots of data for analysis. You can limit uploading to only when you're connected to non-metered connection.



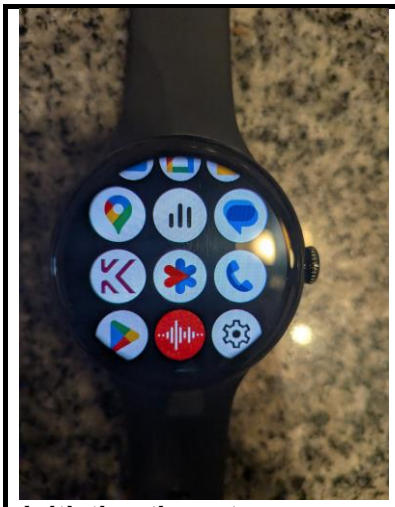
The “smartwatch” menu item will lead you to information on wheather or not your third-party smartwatch or wrist-worn device is connected to the PARKIWATCH android application. If it is not synced a red X will, appear, otherwise a green tick will showcase a correct connection between the third-party smartwatch or wrist-worn device and the PARKIWATCH android smartphone application.

The “subscriptions” button takes you to the page where you can initiate you PARKIWATCH subscription by selecting the monthly or yearly fee. An additional box that allows you to input a redeemable personal code is available (this will allow you to get access to the PARKIWATCH features by bypassing the required subscription). The manage subscriptions button takes you to the screen that allows you to manage (including cancelling) your active subscription. By tapping on the “Pay” button next to either the monthly or yearly subscription you are led to the Google supported page where a secure payment can be performed.


15:05
Subscriptions
Monthly plan
€23.99 / month
cancel anytime
secure payment
includes shareable health reports
Pay
Yearly plan
SAVE 25%
MOST POPULAR
€219.99 / year
cancel anytime
secure payment
includes shareable health reports
Pay
Personal code
If you have a personal code, you can redeem it for free!
Redeem
Manage subscription on Play Store
28
Subscriptions
Monthly plan
Google Play
Parkiwatch standard plan
Parkiwatch
Starting today
€219.99/year
See included tax
Cancel at any time in Subscriptions on Google Play
Play Points • Bronze
+220 points
VISA
Visa-6636
Contact Google Play
By tapping 'Subscribe', you agree that your subscription automatically renews until cancelled. We'll notify you if your price changes, as described in the Google Play Terms of Service. Learn how to cancel. Your refund and 14-day withdrawal rights vary by product type: Google Play Terms of Service and Refund Policy. More
Subscribe

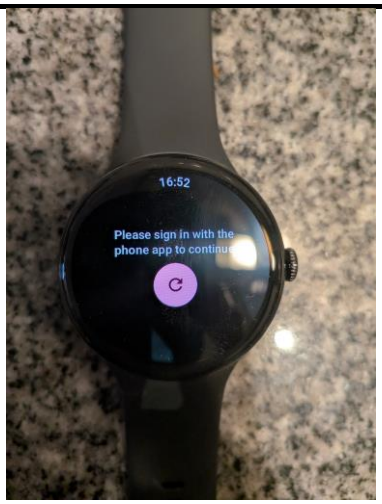
2.2 Example set up, for connecting the PARKIWATCH android smartphone application with a third-party WearOS smartwatch device.

This example aims at showcasing the connection process of the PARKIWATCH android smartphone application with a third-party smartwatch device – in this case a Google Pixel Watch 4. For instructions on how to use your third-party smartwatch or wrist-worn sensor device, consult the manufacturer's documentation.



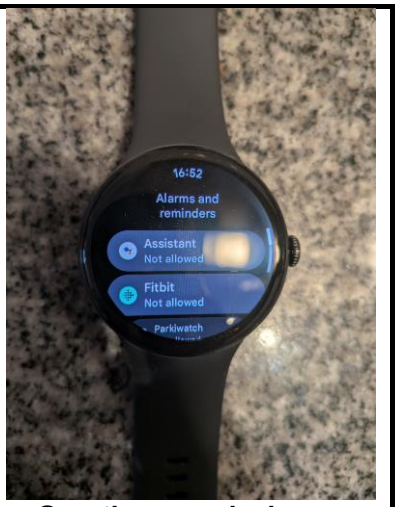
Initiating the setup process

The first step in the process is pairing the third-party smartwatch by following the instructions of the manufacturer (for reference, an example can be found in the appendix 1). By accessing the list of installed applications (this is typically accessible by pressing the physical button of the third-party smartwatch device) the user should be able to find the PARKIWATCH application among the other installed apps. The setup process begins by tapping on the PARKIWATCH icon.



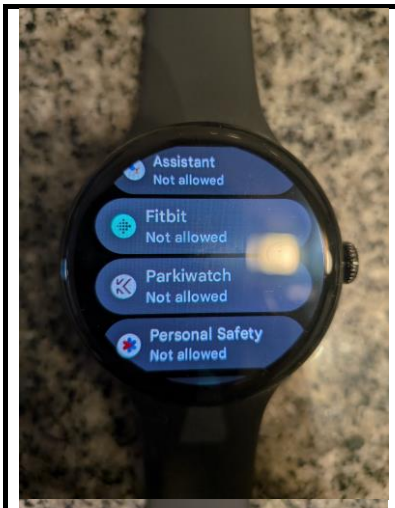
Signing in

The first screen indicates that the user needs to sign in first in the PARKIWATCH smartphone application. After completing this step, the user will be automatically guided to the next screen to begin the process of granting permissions to PARKIWATCH.

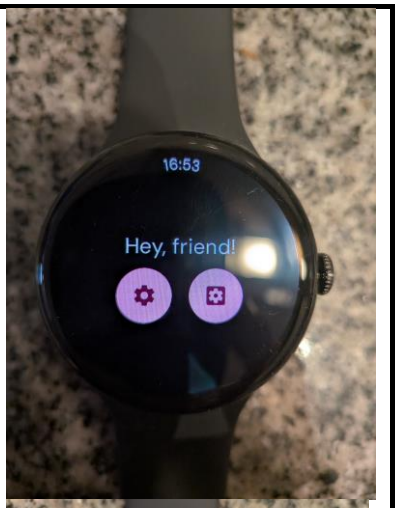


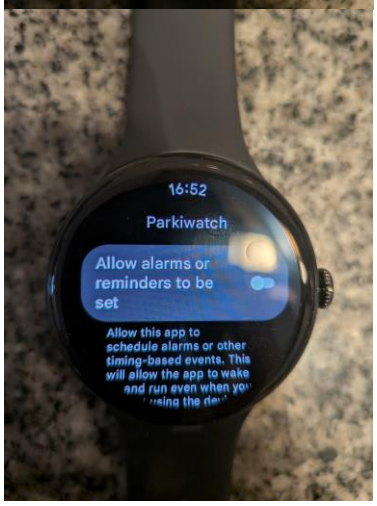
Granting permissions – alarms and reminders

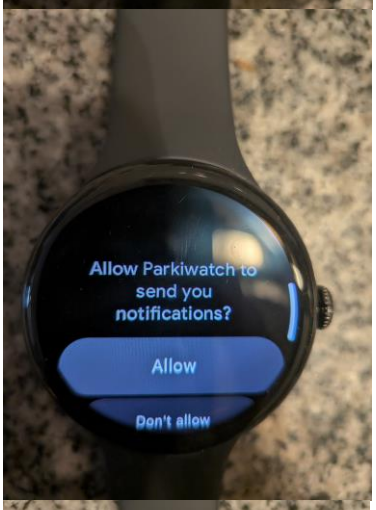
A series of screens will be prompted to the user. The first one being the alarms and reminders. Similar to the PARKIWATCH smartphone app setup a list of applications that ask for access to alarms and reminders can be found. In order to grant access to PARKIWATCH, the user should scroll through the list of apps and locate the PARKIWATCH application.

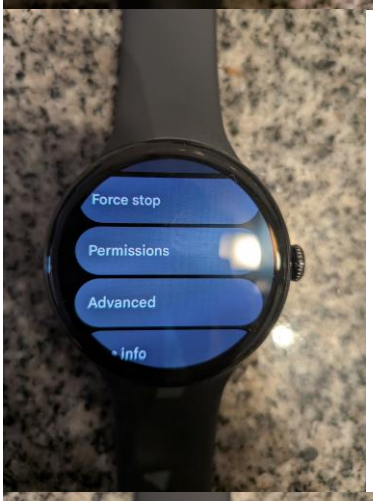

Assistant
Not allowed
Fitbit
Not allowed
Parkiwatch
Not allowed
Personal Safety
Not allowed

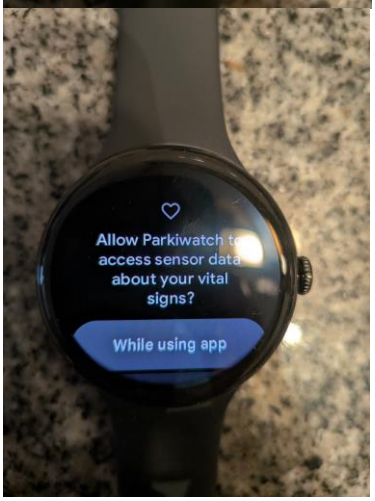

Allow Parkiwatch to access your physical activity?
Allow
Don't allow

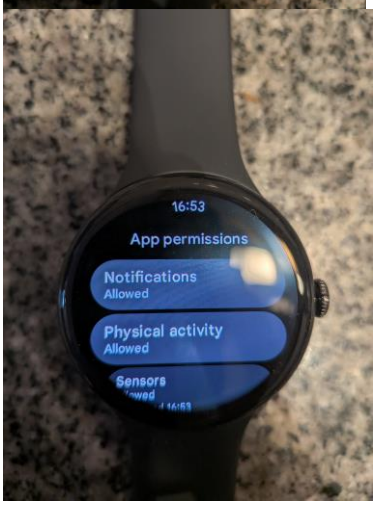

16:53
Hey, friend!

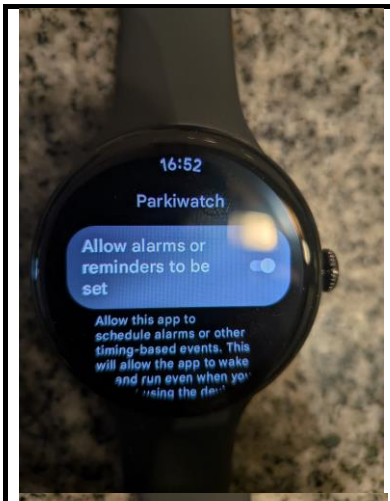

16:52
Parkiwatch
Allow alarms or reminders to be set
Allow this app to schedule alarms or other timing-based events. This will allow the app to wake and run even when you

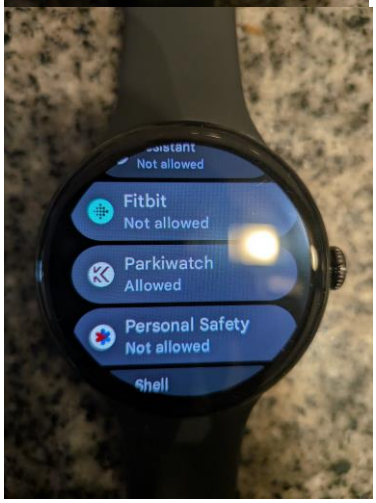

Allow Parkiwatch to send you notifications?
Allow
Don't allow


Force stop
Permissions
Advanced
App info


Allow Parkiwatch to access sensor data about your vital signs?
While using app


16:53
App permissions
Notifications
Allowed
Physical activity
Allowed
Sensors





Granting permissions – alarms and reminders (cont.)

After locating the PARKIWATCH app, the user should tap on it to access the next screen that allows or disables access to alarms and reminders using a toggle switch. After tapping on the toggle switch, and grant permissions, the user can slide right on the third-party smartwatch screen to go back to the previous screen that lists all installed apps that ask for this permission – this time, PARKIWATCH will indicate that is allowed to use alarms and reminders.

Granting permissions – physical activity, notifications and vital signs

The next series of screens will automatically appear asking for three permissions, one at a time. The first permission is the physical activity one. This permission is required **solely** for the calculation of **support digital health measures**; tapping on "allow" grants permission. The next permission is related to notifications. This permission is for showing notifications related with meals and medication reminders (if the user has them set up). Once again, the user can select "allow" to provide access. The final permission relates with the vital signs (PPG sensor). This permission is required **solely**

Main screen and menu

If the user wants, they can access the permissions menu on the right. In this menu, they can access options such as force stopping the app, permissions, advanced features, app info, and uninstall. By access the permissions menu, the user can change permissions for alarms & reminders, physical activity, notifications and vital signs. Force stopping immediately stops the execution of the application and needs to be re-loaded in order to operate in the background again (this can be done by accessing the list of apps and tapping on the PARKIWATCH icon).

	for the calculation of **support digital health measures**; tapping on “allow” grants permission.	

Section 3: General System and Regulatory Information

3.1 Device Description

PARKIWATCH is a Software as a Medical Device (SaMD) intended for the continuous, passive detection and quantitative assessment of kinematic patterns representative of (i) tremor, defined as oscillatory movements; (ii) bradykinesia, defined as reductions in movement velocity and amplitude during voluntary upper-limb activity; and (iii) dyskinesia, defined as irregular, non-rhythmic hyperkinetic movements consistent with levodopa-induced involuntary movements; in adults with Parkinson's Disease.

Required equipment: PARKIWATCH requires the user to wear a third-party smartwatch or wrist-worn sensor which collects raw motion data (accelerometery). The user needs a private smartphone (Android) to install and use the PARKIWATCH smartphone Android application.

Compatibilities: PARKIWATCH is compatible with third-party smartwatches or wrist-worn sensors that possess an inertial measurement unit (IMU) sensor that provides accelerometer raw data.

Modules: PARKIWATCH android smartphone application; healthcare professional dashboard; a cloud infrastructure system for data storage and processing; **t**hird-party smartwatch or wrist-worn sensor device.

PARKIWATCH processes triaxial accelerometer data collected from third-party smartwatch or wrist-worn devices. PARKIWATCH applies validated signal processing and statistical learning algorithms to produce continuous, longitudinal output Validated Kinematic Measures, which are made available to healthcare professionals via a web-based dashboard and PDF reports. The validated kinematic measures are calculated alongside other supportive digital health metrics. PARKIWATCH analyzes data collected from your third-party smartwatch or wrist-worn sensor device and smartphone during your normal daily activities.

PARKIWATCH is NOT intended to diagnose Parkinson's Disease, to recommend or modify specific pharmacological therapy independently, or to provide real-time clinical alerts. Its outputs are adjunctive to, and must be interpreted within the context of, standard clinical assessment and the treating healthcare professional’s judgment.

Validated Kinematic Measures:

- The automatic detection and quantification of oscillatory kinematic patterns representative of tremor;
- The automatic detection and quantification of reductions in movement velocity and amplitude representative of bradykinesia;
- The automatic detection and quantification of irregular, non-rhythmic hyperkinetic movements representative of dyskinesia.

These measures are presented alongside supportive digital health metrics to provide a contextualized view of the patient’s kinematic profile.

Supportive Digital Health Measures:

- The automatic analysis of rhythm and timing during smartphone keyboard interactions to provide insights your ability to type using the digital keyboard of the smartphone.
- The automatic measurement of wrist motion patterns to quantify the duration of plate-to-mouth movements during meals.

- The automatic tracking of nocturnal movement and heart rate to measure sleep duration, frequency of awakenings, and rest quality.
- The automatic quantification of step counts and socialization patterns, including time spent outside the home, to provide an overview of your activity levels.
- The logging and visualization of questionnaires' responses

This information is combined into reports to complement the clinical assessment of your health care professional outside of the clinical setting, in-between clinical visits.

IMPORTANT:
PARKIWATCH is a monitoring tool only. It does not diagnose Parkinson's Disease, provide medical advice, or recommend treatment changes. This device is designed to support, not replace, the professional judgment of your healthcare professional and does not serve as an emergency response system.

3.2 Technical Specifications

Android smartphone operating system should be Android 9.0 (SDK 28) or higher.
Bluetooth 5.0 (or higher) and an active internet connection (Wi-Fi or Cellular).
Access to the Google Play Store is required for installation and mandatory updates.

Required equipment: The user needs a private android smartphone to install and use the PARKIWATCH smartphone application. PARKIWATCH requires the user to wear a third-party smartwatch or wrist-worn sensor which collects raw motion data (accelerometer); PARKIWATCH is compatible with third-party smartwatches or wrist-worn sensor devices that possess an inertial measurement unit (IMU) sensor that provides accelerometer raw data.

3.3 Cybersecurity and Data Privacy

The Koios Care Platform is designed for compliance with HIPAA and GDPR.

Encryption	All data is protected with AES-256 encryption both at rest and in transit (HTTPS/TLS).
Authentication	Multi-factor authentication and role-based access controls are enforced for all users.
Data storage	Data is stored in a secure, hierarchical structure on AWS cloud services.

3.4 Symbols Glossary

WARNING AND CAUTION SYMBOLS

The following symbols show how warnings, cautions, instructions and notes appear in this document. The text explains their intended use.

DANGER/WARNING/CAUTION
The manual shall be consulted in all cases where this symbol is marked, to find out the nature of the potential hazards and any actions which have to be taken to avoid them (ISO 7010, W001).

DANGER: A danger safety notice indicates a hazardous situation of direct, immediate danger for a potential serious injury to a user, engineer, patient or any other person.

WARNING: A warning safety notice indicates a hazardous situation which can lead to a potential serious injury to a user, engineer, patient or any other person.

CAUTION: A caution safety notice indicates a hazardous situation which can lead to a potential minor injury to a user, engineer, patient or any other person.

PRODUCT LABELING

ABOUT BOX

This section describes labels applicable to the overall system and product.

PARKI WATCH
Koios Care, Filip Williotstraat 9, 2600 Antwerp, Belgium

Version 1.0.0.

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www.koios.care

2797

(01) 05419980609106 (11) 260527 (8012) 1.0.0.

CONSULT INSTRUCTIONS FOR USE
Indicates the need for the user to consult the instructions for use (ISO 7000, 1051; ISO 15223-1, 5.4.3).

CE MARKING OF CONFORMITY
Indicates compliance of the device with EU Medical Device Regulation 2016/745.

MEDICAL DEVICE
Indicates a medical device that is intended to be used as a medical device or its accessories (ISO 15223-1, 5.5.1).

UNIQUE DEVICE IDENTIFIER
Indicates a carrier that contains Unique Device Identifier information (ISO 15223-1, 5.7.10).

MANUFACTURER
Indicates the medical device manufacturer (ISO 15223-1, 5.1.1)

PRESCRIPTION USE
Indicates that the device is to be used by, or on the order of, a licensed healthcare professional. This symbol is not listed in EN ISO 15223-1.

3.5 Contact Information

Manufacturer:
Koios Care (BV)
Filip Williotstraat 9,
2600 Antwerpen, Belgium
Technical Support: support@koios.care
Website: www.koios.care

WARNING: Validated hardware only – Use only validated hardware configurations as listed in the documentation. Operation on unsupported hardware may lead to compatibility issues or unreliable performance.

WARNING: Personal health data processing – This device processes personal health information. Whether used on-premise or via a cloud service, data such as study metadata and patient identifiers may be processed for workflow purposes. Pseudonymisation is applied where required.

WARNING: Uninstallation and data removal – To ensure complete removal of patient-related data, follow the detailed uninstallation steps provided. These steps are designed to securely delete all associated information from the system during the removal process.

WARNING: Software updates are mandatory for the correct operation of the device. After each update, verify that the device is functioning correctly. If installation fails, uninstall and reinstall the application. If the issue persists, contact technical support at the provided address.

WARNING: Interpreting AI results – AI-generated results should be interpreted cautiously. Users must understand that these results are subject to limitations and may include false positives or false negatives. Always consider the full clinical context when making decisions based on AI analysis.

WARNING: PARKIWATCH is not intended for individuals with significant cognitive impairments that prevent the safe and consistent operation of a smartphone. The device should not be used by patients who have not received a formal diagnosis of Parkinson's Disease from a qualified medical professional. Additionally, it is not suitable for users with physical conditions or skin sensitivities that prevent the continuous wearing of a third-party smartwatch or wrist-worn sensor device as directed. Consult the user manual provided by the third-party smartwatch or the wrist-worn sensor device manufacturer for guidance on materials and cleaning.

WARNING: Because PARKIWATCH processes sensitive information, you must follow the following security practices. Always protect your smartphone with a secure passcode, PIN, or fingerprint. This can be done by accessing the "security and privacy" menu on the settings screen of your smartphone device. Make sure that you do not share your login credentials with anyone; Koios Care will never ask for your password. Only sync your data over a trusted, private Wi-Fi or cellular network. Avoid using public, unencrypted Wi-Fi hotspots (e.g., in cafes or airports). In case of a cybersecurity event, disconnect PARKIWATCH from the network and contact KOIOS CARE immediately at support@koios.care.

WARNING: Ensure your smartphone and the third-party smartwatch or wrist-worn sensor device charged daily and is battery level is kept above 20%.

WARNING: Certain activities (e.g., using power tools, riding a bike on a bumpy road, or playing a musical instrument) may be incorrectly identified by PARKIWATCH as kinematic patterns associated with Parkinson's Disease. Also, if you do not wear the third-party smartwatch or wrist-worn sensor device, or if the battery of the third-party device depletes, the system cannot collect data. Gaps in your reports are usually due to the third-party smartwatch or wrist-worn sensor device not being worn correctly or being uncharged. Consult the user manual provided by the third-party smartwatch or wrist-worn sensor device manufacturer on instruction for charging and wearing their third-party smartwatch or wrist-worn sensor device properly.

WARNING: Keep the sensors on the back of the third-party smartwatch or wrist-worn device clean and free of debris (such as lotion or sweat) using a soft, lint-free cloth. Refer to the

third-party smartwatch or wrist-worn sensor device manufacturer's guide for specific cleaning instructions to avoid skin irritation.

1 REGULATORY AND COMPLIANCE

The system is compliant with the following specific legislation and standards.

GENERAL (INTERNATIONAL STANDARDS)

- ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes
- ISO 14971:2019 + A11:2021 – Medical devices – Application of risk management to medical devices
- EN IEC 62304:2006 + A1:2015 – Medical device software – Software life cycle processes
- EN IEC 62366-1:2015 + A1:2020 – Medical devices – Part 1: Application of usability engineering to medical devices
- EN ISO 15223-1:2021 – Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
- EN IEC 82304-1:2016 – Health software – Part 1: General requirements for product safety
- EN IEC 81001-5-1:2021 – Health software and health IT systems safety, effectiveness and security – Part 5-1: Security – Activities in the product life cycle

EUROPEAN UNION LEGISLATION

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR).

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation - GDPR)

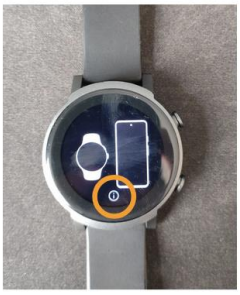
Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)

The product has been designed in accordance with EU Guidelines regarding Medical Devices.

APPENDIX 1

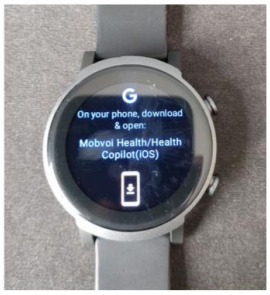
The following example showcases how a third-party WearOS smartwatch device can be initially paired with your Android smartphone device. For detailed information please consult the guidelines provided by the manufacturer of the third-party smartwatch device. The figures below showcase an example on how this can be done using a compatible MOBVOI Ticwatch E3 device.

Start by powering-on the smartwatch by long-pressing the top right button.

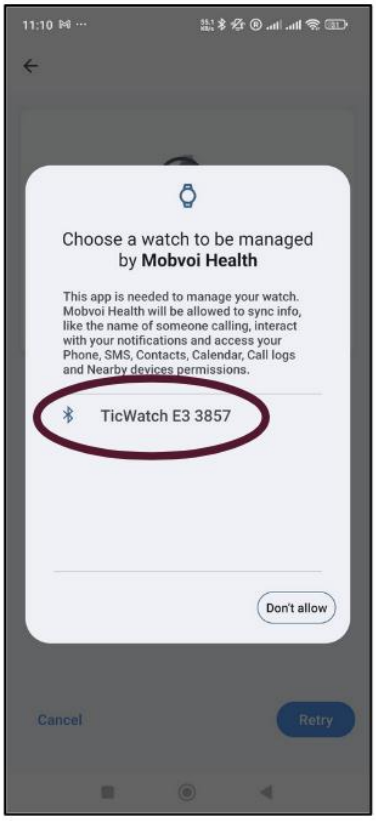


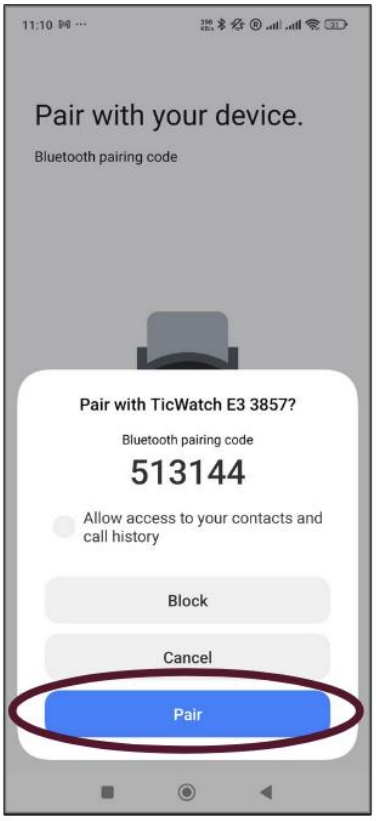
When you see the above screen press the (i) button at the bottom.

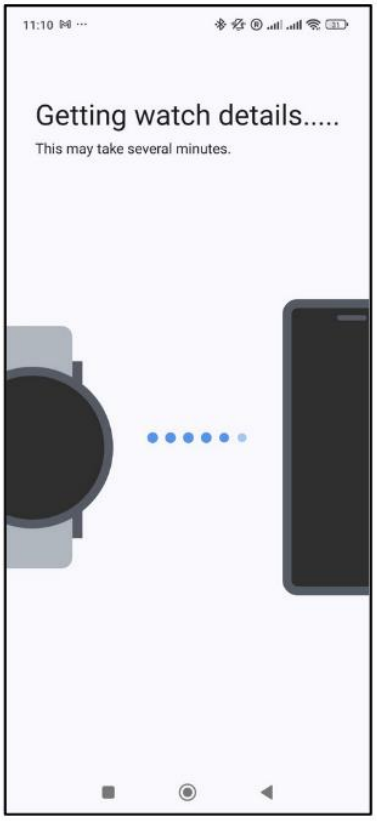
Select the language of interest. You can scroll below for more options.

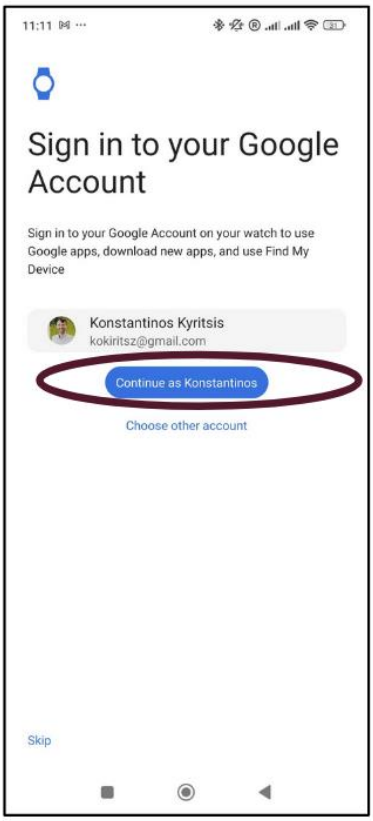


The next screen is the Terms of Service (ToS) by Mobvoi (the manufacturer of the watch). Scroll all the way to the bottom and select "I've read it".





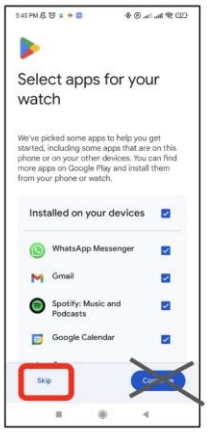



Sign in to your Google Account
Sign in to your Google Account on your watch to use Google apps, download new apps, and use Find My Device
Konstantinos Kyritsis
kokiritsz@gmail.com
Continue as Konstantinos
Choose other account
Skip


Connect Google account to your watch
Skip
Continue


Signing in...
This could take about a minute


Set up a screen lock for your watch
Skip


Select apps for your watch
Installed on your devices
WhatsApp Messenger
Gmail
Spotify: Music and Podcasts
Google Calendar
Skip


Quick charging
30%
Wrapping up...
Waiting for the watch to be ready

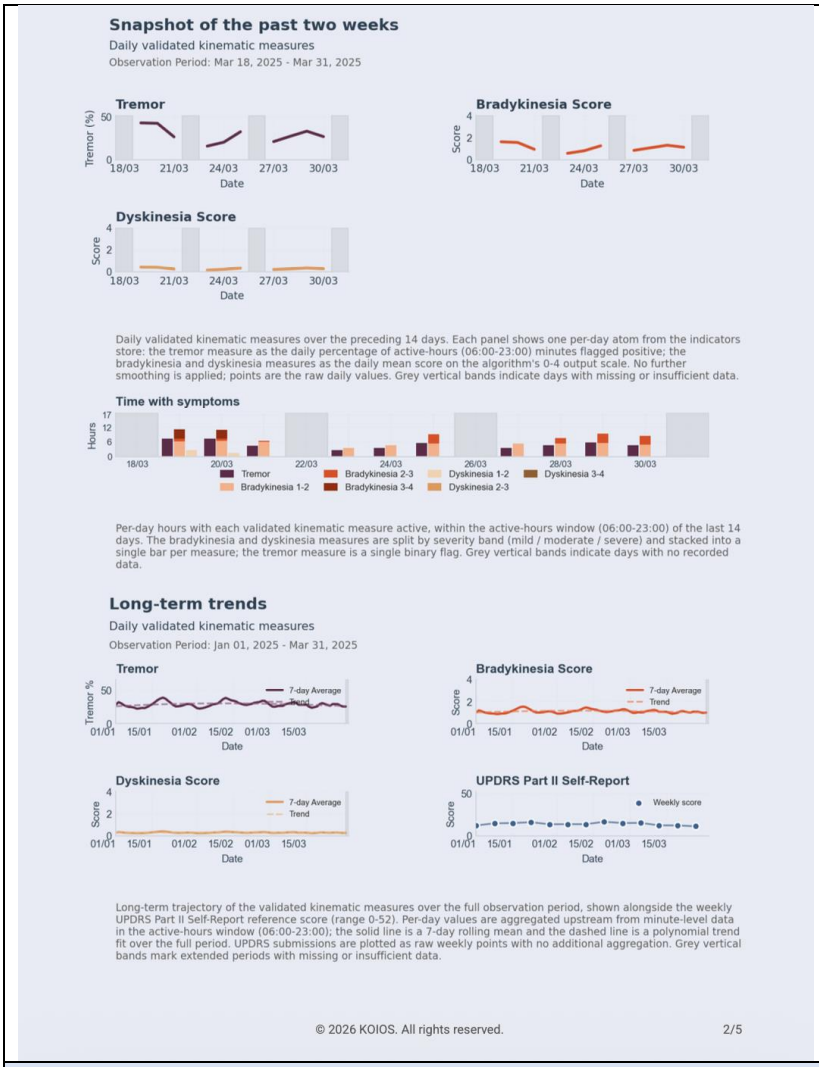

You're all set!
Done

APPENDIX 2

This part of the Instructions for Use deals with the explanation of the contents of the PDF report produced by PARKIWATCH. Consult your healthcare professional regarding the interpretation of the report.

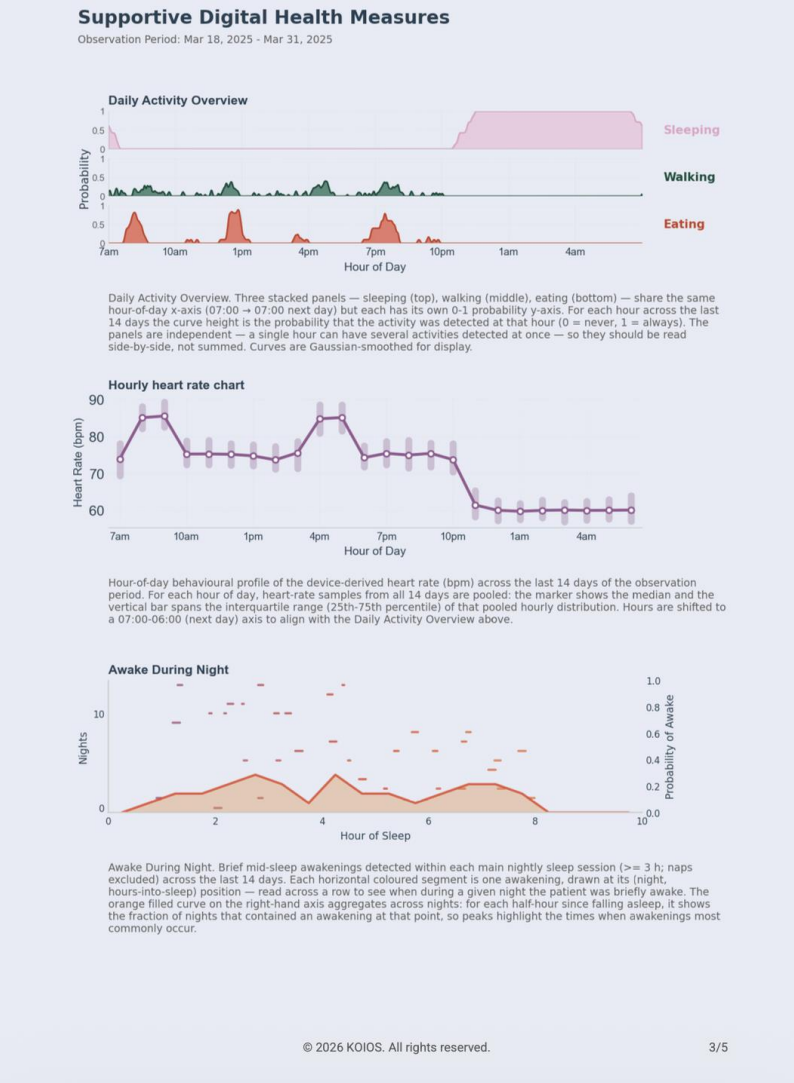
REPORT

This page shows what your typical day looked like over the past two weeks. The top chart tracks how tremor, bradykinesia, and dyskinesia rose and fell through the day — the darker line is your usual level, and the shaded band shows how much this varied from one day to the next. The bottom chart shows, hour by hour, how often each type of movement was picked up, so you can see when your symptoms tend to be most and least noticeable. Always consult your healthcare professional on how to interpret any of the results in the PDF report.



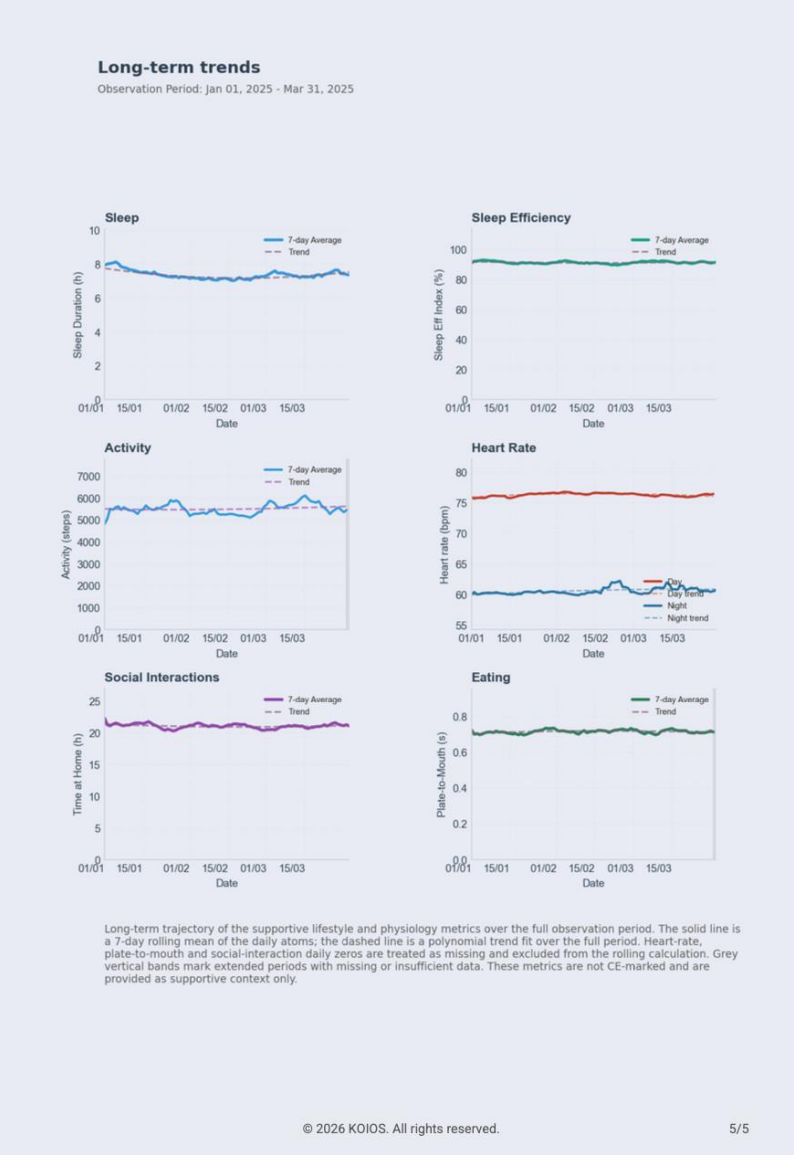
Here you see your day-by-day numbers for the past two weeks, plus a longer view over the past month. The bar chart shows how many hours each day you spent with mild, moderate, or stronger symptoms. The bottom charts put the watch-measured symptoms next to the weekly questionnaire you fill in yourself, so you can see whether how you feel matches what the watch recorded. Grey bands mark days with not enough data. Always consult your healthcare professional on how to interpret any of the results in the PDF report.

The next PDF report pages deal with the supportive digital health metrics and NOT with validated kinematic measures. This means that while these insights offer helpful context regarding your daily activity levels, they are intended for informational purposes only.



These extra charts look at your daily routine, when you sleep, walk, and eat, along with your heart rate through the day and any times you woke up during the night. They are there to provide background information as supportive digital health measures. Always consult your healthcare professional on how to interpret any of the results in the PDF report.

A quick summary of your lifestyle numbers: steps, heart rate during the day and at night, how consistent your sleep schedule was, how well you actually slept while in bed, and how quickly you tend to eat. The smaller charts show how each of these changed day by day. They give supportive information, but they are not validated kinematic measures. Always consult your healthcare professional on how to interpret any of the results in the PDF report.



The longer view of your lifestyle: sleep length, sleep quality, activity, heart rate (day and night), time spent at home, and eating speed across the past month. The solid line is the running average, and the dashed line shows whether things are drifting up or down over time. As on the previous pages information in this page gives background supportive digital health measures information, but they are not validated kinematic measures. Always consult your healthcare professional on how to interpret any of the results in the PDF report.

REVISION HISTORY

Version	Date of last issue	Author	Change description
1	22/05/2026	Konstantinos Kyritsis	Initiation
2	29/05/2026	Konstantinos Kyritsis	Added UDI number in about box figure