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KOIOS CARE PARKIWATCH

INSTRUCTIONS FOR USE

Document

Revision: 2.0

Device

Software

Manufacturer: Koios Care (BV), Filip Williotstraat 9, 2600 Antwerpen, Belgium

Date of Issue: September 11, 2025

About

#:

Name:

Version:

This

KCI-IFU-001

PARKIWATCH

1.0.0

Guide

This document provides essential information for the safe and effective use of the PARKIWATCH system. It is intended for two main user groups:

- **People with Parkinson's Disease:** Please refer to **Section 1**.
- **Healthcare Professionals:** Please refer to **Section 2**.

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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For more information on KOIOS products, please visit <https://www.koios.care>

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Any serious incident that has occurred in relation to the device shall be reported to KOIOS and the competent authority of the country in which the user and/or the patient is established.

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- **Section 1: Guide for People with Parkinson's (Patients)**
 - **1.1 What is PARKI WATCH?**
 - PARKI WATCH is a software application that works with your Android smartphone and a compatible Wear OS smartwatch. It is designed to help you and your healthcare provider get a clearer picture of your Parkinson's symptoms by passively and continuously collecting information from your smartwatch and smartphone as you go about your daily life.
 - **1.2 What PARKI WATCH Does (Intended Use)**
 - The PARKI WATCH system measures and records specific aspects of your daily life that can be affected by Parkinson's. It does this automatically in the background by analyzing signals from the sensors in your devices. The information collected includes:
 - **Hand Steadiness (Tremor):** By analyzing the motion from your smartwatch sensor, the system measures the presence and intensity of tremor throughout the day.
 - **Movement Fluency (Bradykinesia & Dyskinesia):** The watch also measures patterns of slowness (bradykinesia) or involuntary movements (dyskinesia) during your daily activities.
 - **Fine Motor Control (Typing Analysis):** By looking at the rhythm and timing of your taps on the smartphone keyboard, the system provides insight into the fine motor control of your hands.
 - **Eating Behavior:** By using the motion of your wrist, the system measures the time it takes to bring food from your plate to your mouth (**Plate-to-Mouth**). This can be related to slowness or difficulty with utensils.
 - **Sleep Quality:** The system tracks your movements and heart rate during the night to understand how long you sleep, how often you wake up, and the overall quality of your rest.
 - **Daily Activity:** The watch and phone work together to count your steps and (with your permission) use GPS to understand your general mobility patterns, like time spent outside the home.
 - This information is combined into reports that your doctor can use to better understand your condition between your regular clinic visits.
 - **IMPORTANT:** PARKIWATCH is a monitoring tool. It **does not** diagnose Parkinson's Disease, provide medical advice, or recommend treatments. It is designed to support, not replace, the relationship you have with your healthcare provider.
 - **1.3 Who Should Not Use PARKIWATCH (Contraindications)**

You should not use PARKIWATCH if you have significant cognitive difficulties that make it hard to use a smartphone or smartwatch.
 - **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.
 - **Login:** Open the app and follow the on-screen instructions to log in using your Google account.
 - **Permissions:** The app will ask for permissions to access your phone's sensors and to send notifications. These are necessary for the system to work correctly.
 - **Pair Smartwatch:** Follow the app's instructions to connect and sync with your compatible Wear OS smartwatch. Ensure Bluetooth is enabled on both your phone and watch.
 - **Wear Correctly:** For the best results, wear the smartwatch on your dominant hand (the hand you write with).
 - **1.5 Using PARKIWATCH Day-to-Day**
 - **Passive Monitoring:** The system works in the background. Simply wear your smartwatch and keep your smartphone with you as you normally would. Ensure your watch is charged daily.

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- **Questionnaires:** The app will occasionally send you a notification to complete short questionnaires (like the UPDRS-II or PDQ-39) about how you are feeling. Your honest answers provide important context to the sensor data.
- **Viewing Your Data:** The app may show you general trends about your activity or sleep. The detailed clinical reports are designed for your healthcare provider to interpret.

1.6 Troubleshooting

- If you experience an issue with the PARKIWATCH system, please try these simple steps first.
 - **Problem: My watch and phone are not syncing or connecting.**
- **Possible Cause:** Bluetooth may be turned off, or the devices may be too far apart.
- **Solution:**
 - Ensure Bluetooth is turned “ON” on both your smartphone and your smartwatch.
 - Make sure your smartwatch and smartphone are close to each other (within 10 meters / 30 feet).
 - Open the PARKIWATCH app on your phone to encourage it to sync.
 - If the issue continues, restart both your smartphone and your smartwatch by turning them completely off and then on again.
 - **Problem: I don't see any new data in my app.**
- **Possible Cause:** The data has not yet been synced from the watch or uploaded to the cloud.
- **Solution:**
 - First, follow all the steps in "My watch and phone are not syncing" above.
 - Check that your smartphone has an active internet connection (either Wi-Fi or cellular data). The app needs an internet connection to upload data for processing.
 - Ensure your smartwatch battery is charged. Data collection may stop or be paused if the battery level is very low.
 - **Problem: The PARKIWATCH app on my phone is frozen or has closed.**
- **Possible Cause:** A temporary software issue.
- **Solution:**
 - Close the app completely from your phone's recent applications screen.
 - Re-open the PARKIWATCH app.
 - If the problem happens frequently, try restarting your smartphone.
 - **Problem: I am not receiving notifications for my questionnaires.**
- **Possible Cause:** The app's permission to send notifications may have been turned off.
- **Solution:**
 - Go to your smartphone's main **Settings** menu.
 - Tap on "**Apps**" or "**Applications**".
 - Find and tap on "**PARKIWATCH**".
 - Tap on "**Notifications**" and ensure that all switches are turned **ON**.
 - **Problem: My skin is irritated under the smartwatch.**

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- **Possible Cause:** This is a hardware issue related to the watch band or casing, not the PARKI WATCH software.
- **Solution:**
 - Stop wearing the smartwatch immediately.
 - Consult the user manual provided by the smartwatch manufacturer for guidance on materials and cleaning.
 - Inform your healthcare provider of the irritation.

1.7 Support

- For any technical issues that are not resolved by the steps above, please contact Koios Care support through the details provided in the app or at the end of this document.
- **Questions?** For any technical issues, please contact Koios Care support through the details provided in the app or at the end of this document.

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

Device description

PARKIWATCH is a software application that works with your smartphone and a compatible smartwatch. It is designed to help you and your healthcare provider get a clearer picture of your Parkinson's symptoms by passively and continuously collecting information from your smartwatch and smartphone as you go about your daily life.

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Section 2: Guide for Healthcare Professionals (HCPs)

2.1 Intended Use and Indications for Use

- **Intended Use:** The PARKI WATCH is intended to quantify kinematics of movement disorder symptoms including tremor and dyskinesia, in adults with mild to moderate Parkinson's disease.
- **Indications for Use:** Parkiwatch is intended to support the remote monitoring of motor and non-motor symptoms in individuals with Parkinson's disease by collecting and presenting health-related data from smartphones and smartwatches to assist healthcare professionals in evaluating disease status and treatment effectiveness.

2.2 Clinical Principle, Performance, and Methodology

The PARKIWATCH is a SaMD that operates on the Koios Platform. It uses a suite of validated, independent modules to process multi-modal sensor data and patient-reported outcomes. The outputs of these modules are integrated to compute a composite digital biomarker, the **Q-index**, providing a holistic view of the patient's functional status.

The table below summarizes the key system indicators, their description, and clinical validation highlights. Full methodology and validation reports are available in the "System Report: Methodology and Reproduction" document.

Indicator Category	Specific Metric(s) Measured	Performance & Validation Highlight
Tremor	Probability of tremor presence in 5-second windows from smartwatch accelerometer.	Accuracy: 98%, Sensitivity: 93%, Specificity: 100%, AUC: 0.98 vs. clinical UPDRS scores (Items 16, 20, 21).
Bradykinesia	Probability of bradykinesia presence in 6-minute windows from smartwatch accelerometer/gyroscope.	Accuracy: 87%, Sensitivity: 87%, AUC: 0.93, Pearson ρ = 0.73 vs. Hauser Diary.
Dyskinesia	Probability of dyskinesia presence in 1-minute windows from smartwatch accelerometer.	Sensitivity: 81%, Precision: 79%, Pearson ρ = 0.38 vs. Hauser Diary.
Typing (Fine Motor)	UPDRS-scaled scores for Bradykinesia, Rigidity, and Alternate Finger Tapping from smartphone keystroke dynamics.	Correlates strongly with UPDRS Part III items: Bradykinesia ($\rho=0.58$), Rigidity ($\rho=0.58$), AFT ($\rho=0.61$) . Excellent test-retest reliability (Day-by-Day $\rho > 0.84$).
Sleep	Sleep stages (Wake/Asleep), duration, efficiency, fragmentation, and number of awakenings from smartwatch accelerometer and heart rate.	Epoch-per-epoch Accuracy: 94%, Precision: 97%, Sensitivity: 97% vs. polysomnography-validated methods.
Eating Behavior	Plate-to-Mouth (P2M) duration, number of bites, and meal duration from smartwatch motion sensors.	Bite detection F1-score: 93% . P2M metric shows excellent test-retest reliability (User Avg ρ = 0.98 for filtered meals).

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Activity & Location	Step count (in/out of home), time spent at home, and unique locations visited from smartwatch and smartphone GPS/sensors.	Step count validated with AUC of 0.95 . Home location detection validated with 100% accuracy on internal dataset.
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These validated indicators are integrated into the composite **Q-index**, which has been clinically validated to show:

- **High Test-Retest Reliability (ICC = 0.95).**
- **Strong Correlation with UPDRS-II (Spearman's $\rho > 0.60$) and PDQ-39.**
- **Superior Sensitivity to Change (Cohen's $d = 0.75$).**

2.3 Warnings and Cautions

- **Warning:** The PARKIWATCH is not a standalone diagnostic tool and should not be used for initial diagnosis of Parkinson's Disease.
- **Warning:** The data provided by PARKIWATCH should not be the sole basis for making therapeutic decisions. All treatment adjustments must be based on the clinician's independent medical judgment in the context of a full clinical evaluation.
- **Caution:** Data accuracy may be affected by factors such as improper smartwatch placement, non-dominant hand use, or periods of low device wear time.
- **Caution:** The primary clinical risks are related to the misinterpretation of data. Over-reliance on the device's outputs without adequate clinical correlation could lead to inappropriate treatment adjustments.

– Section 3: General System and Regulatory Information

3.1 Device Description

PARKI WATCH is a SaMD comprised of an Android mobile application and a Wear OS companion application. It passively collects multi-modal data from onboard sensors (e.g., 3-axis accelerometer, gyroscope, PPG heart rate sensor) and smartphone interactions (e.g., GPS, typing patterns). It processes this data through a series of validated modules including Tremor, Bradykinesia, Sleep, and Typing analysis to provide objective health metrics.

3.2 Technical Specifications

- **Smartphone:** Requires Android version 9.0 or higher.
- **Smartwatch:** Requires a compatible smartwatch running Wear OS 3.0 or higher.
- **Connectivity:** Requires Bluetooth for phone-watch synchronization and an internet connection (Wi-Fi or cellular) for data upload.

3.3 Cybersecurity and Data Privacy

The Koios 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

Symbol	Meaning
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CE Mark: Conformity with European Union regulations (MDR 2017/745).

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Manufacturer: Indicates the medical device manufacturer.

Electronic Instructions for Use: Consult the electronic IFU.

REF **Catalogue Number:** The device's reference number.

SN **Serial Number:** The device's serial number.

3.5 Contact Information

Manufacturer:

Koios

Filip

2600

Technical

Website: www.koios.care

Care
Williotstraat
Antwerpen,
Support:

(BV)
9,
Belgium
support@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:** User responsibility for IFU familiarity – The primary user is responsible for ensuring that all users of this application stay informed and up to date with the current version of the instructions for use.
- 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:** Mandatory updates and post-update verification – Device updates are mandatory. 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.

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2 INTRODUCTION

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

For further technical assistance, please contact:



KOIOS
Filip Williotstraat 9, 2600 Antwerpen, Belgium
6982791755
www.koios.care

– PRODUCT COMPLAINTS

Any healthcare professional who has any complaints or has experienced any dissatisfaction with the quality, durability, reliability, safety, effectiveness, or performance of this product must notify KOIOS via info@koios.care

If, during the use of this device or as a result of its use, a serious incident has occurred, please report it to KOIOS and/or its authorised representative or agent and to your national authority.



KOIOS
Filip Williotstraat 9, 2600 Antwerpen, Belgium
6982791755
<https://www.koios.care>

KOIOS Service Support – local support addresses and phone numbers are listed on <https://www.koios.care>

– 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).

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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.

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3 PRODUCT LABELING

This section contains a summary of the labelling found on and in PARKIWATCH and its software. The locations of the labels are also provided.

– ABOUT BOX

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



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PARKIWATCH Version 1.0.0.

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www.koios.care 2797




(01) 123456789 (11) YYYYMMDD (8012) 1.0.0.


Figure 7: About box




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)

– **INSTALLATION AND CONFIGURATION**

When installing PARKIWATCH, the following warnings must be observed:



- CAUTION:** KOIOS does not make any guarantee to the functionality of PARKIWATCH if any other software is installed, with the exception of the [...]
- CAUTION:** Ensure enough storage should be allocated. By default, [XX]GB storage is set.
- CAUTION:** After configuration is complete, test that the PARKIWATCH software has been successfully installed and is functional.

– **HARDWARE MINIMUM REQUIREMENTS**

The PARKIWATCH software should be installed on a smartwatch with the following minimum resource requirements: Android 14. This configuration assumes cloud-based data processing.

– **SUPPORTED OPERATING SYSTEMS**

Android, WearOS.

– **COMPATIBILITY**



- CAUTION:** Android Smartphones and Smartwatch wearables have been fully validated for compatibility with PARKIWATCH.

– **INSTALLATION AND CONFIGURATION**

PARKIWATCH is provided and maintained by KOIOS. After configuration is complete, test that the PARKIWATCH software has been successfully installed and is functional.

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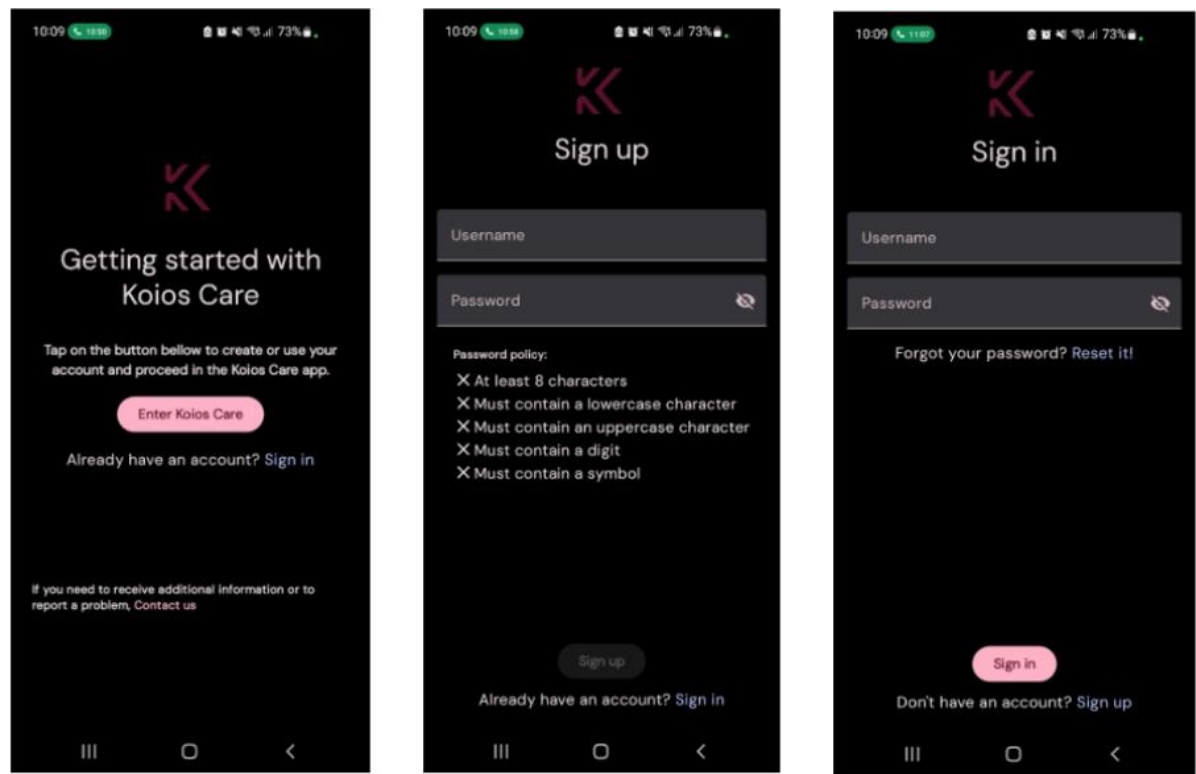
4 **SYSTEM OVERVIEW**

PARKIWATCH is a CE-marked, AI-driven software system designed to monitor the symptoms and signs of Parkinson’s disease.

PARKIWATCH is not intended to replace expert review but rather to support patient management decisions. It should be used in conjunction with other diagnostic tools and clinical information in accordance with its intended purpose.

5 **PRODUCT OPERATION**

- **WORKFLOW OVERVIEW**
- **GRAPHICAL USER INTERFACE (GUI)**
- General Information



Getting Started Screen

Upon launching the Koios Care app, users are greeted with the “Getting started with Koios Care” 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.

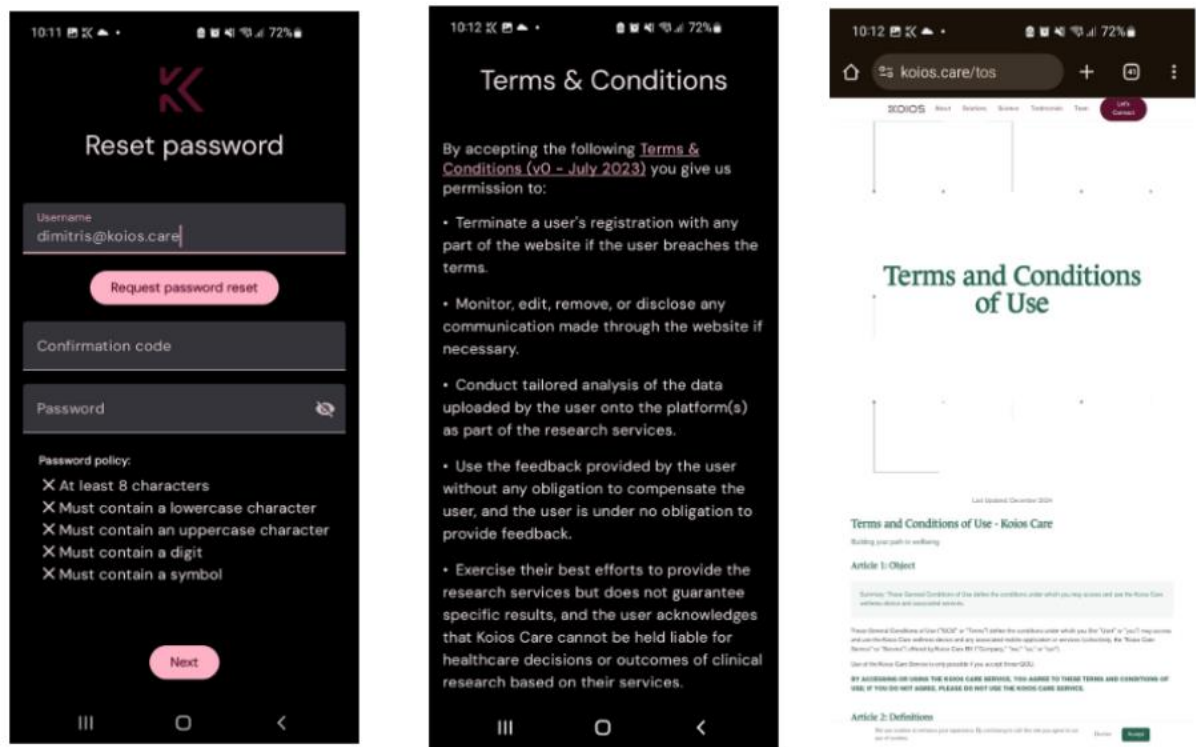
Sign Up Screen

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The “Sign up” screen allows new users to create an account. Users are prompted to enter a username and a password. The password must comply with the defined security requirements, which are displayed beneath the password field. These include a minimum of 8 characters, at least one lowercase letter, one uppercase letter, one digit, and one symbol. The **Sign up** button remains disabled until all password criteria are met. Users who already have an account can tap **Sign in** at the bottom of the screen to return to the login page.

Sign In Screen

The “Sign in” screen is used by existing users to access their Koios Care account. Users must enter their username and password into the respective fields. Once the credentials are entered, the user taps the **Sign in** button to proceed. If the user has forgotten their password, the **Reset it!** link can be used to initiate password recovery. Those without an account can select **Sign up** to begin the registration process.



Reset Password Screen

The “Reset password” screen enables users to restore access to their account in case they have forgotten their credentials. To initiate the reset process, the user enters their registered email address or username and taps **Request password reset**. A confirmation code is then required, which is sent to the user's email. 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 **Next** button becomes active only when all conditions are fulfilled.

In-App Terms & Conditions Screen

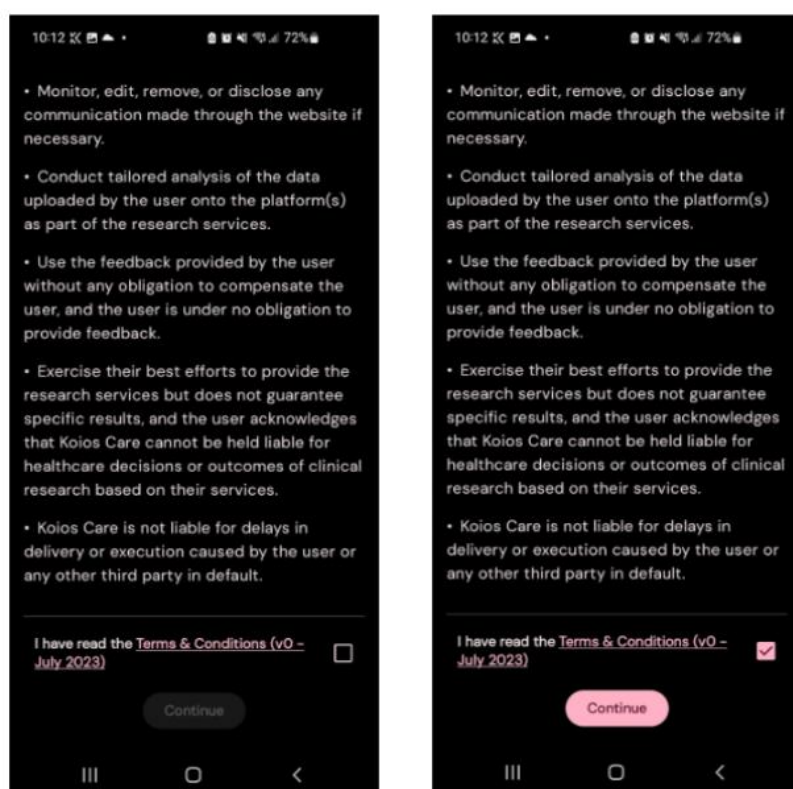
Users are presented with the “Terms & Conditions” screen during account creation or as part of the login process. This screen outlines key legal permissions granted to

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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. The company is also permitted to use user-provided feedback without obligation and to provide research services without guaranteeing specific results. A link to the full document (e.g., “Terms & Conditions (v0 – July 2023)”) is included for users who wish to review the complete terms.

Web-Based Terms and Conditions Page

For full legal transparency, the complete Terms and Conditions of Use are also accessible via the Koios Care website (koios.care/tos). This page includes all applicable clauses, such as the object of the agreement, definitions, and detailed legal stipulations regarding user responsibilities, limitations of liability, and data use. Users are encouraged to consult this web-based version for the most current and comprehensive terms, especially prior to accepting them within the app.

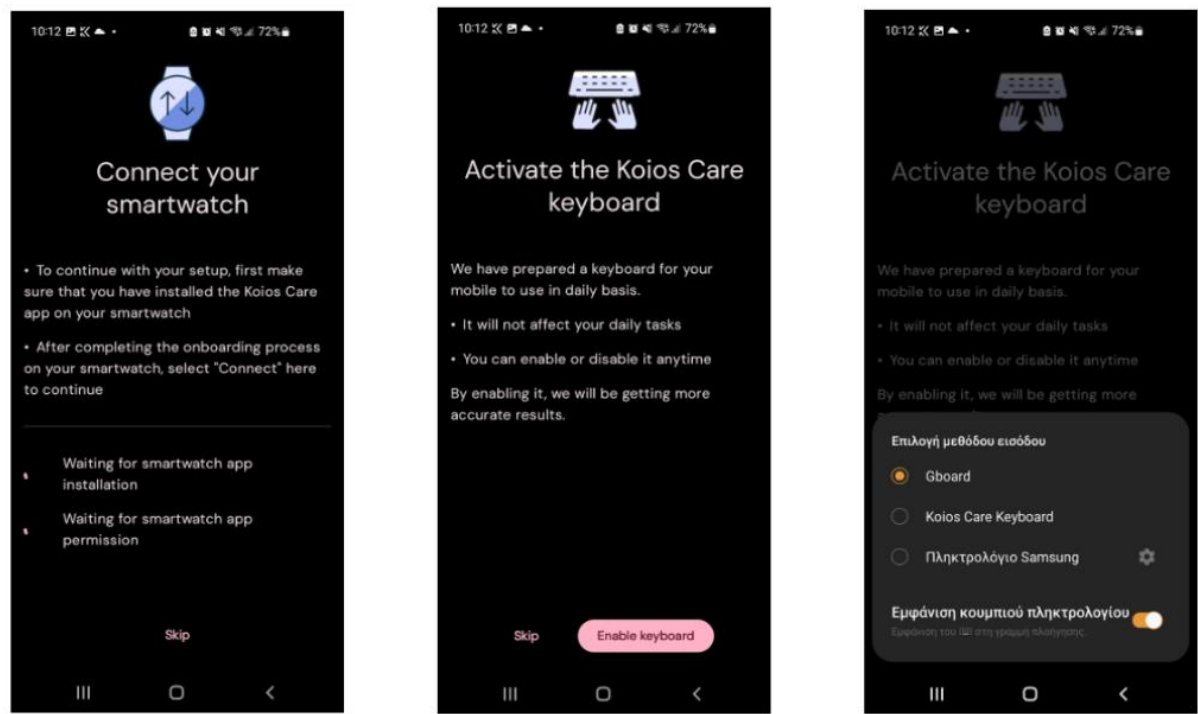


Terms & Conditions Consent Screen

Before proceeding, users are required to review and accept the Terms & Conditions of Koios Care. The screen displays key terms, including Koios Care’s right to monitor or remove communications, perform tailored analysis of uploaded data, and use user feedback without compensation. It also clarifies that Koios Care does not guarantee specific research outcomes and cannot be held liable for clinical decisions or delays caused by the user or third parties.

At the bottom of the screen, users must confirm that they have read the applicable version of the Terms & Conditions by ticking the checkbox next to the statement “I

have read the Terms & Conditions (v0 – July 2023).” The **Continue** button remains inactive until this box is checked. Once selected, the button becomes active and allows the user to proceed.



Connect Your Smartwatch Screen

This screen guides users through connecting their smartwatch to the Koios Care app. To proceed, the Koios Care app must first be installed on the smartwatch. After completing the smartwatch’s pairing process, users are instructed to return to this screen and select **Connect** to continue. Status indicators at the bottom show whether the smartwatch app has been installed and whether the necessary permissions have been granted. Users who wish to skip this step can tap **Skip** to proceed without connecting a smartwatch.

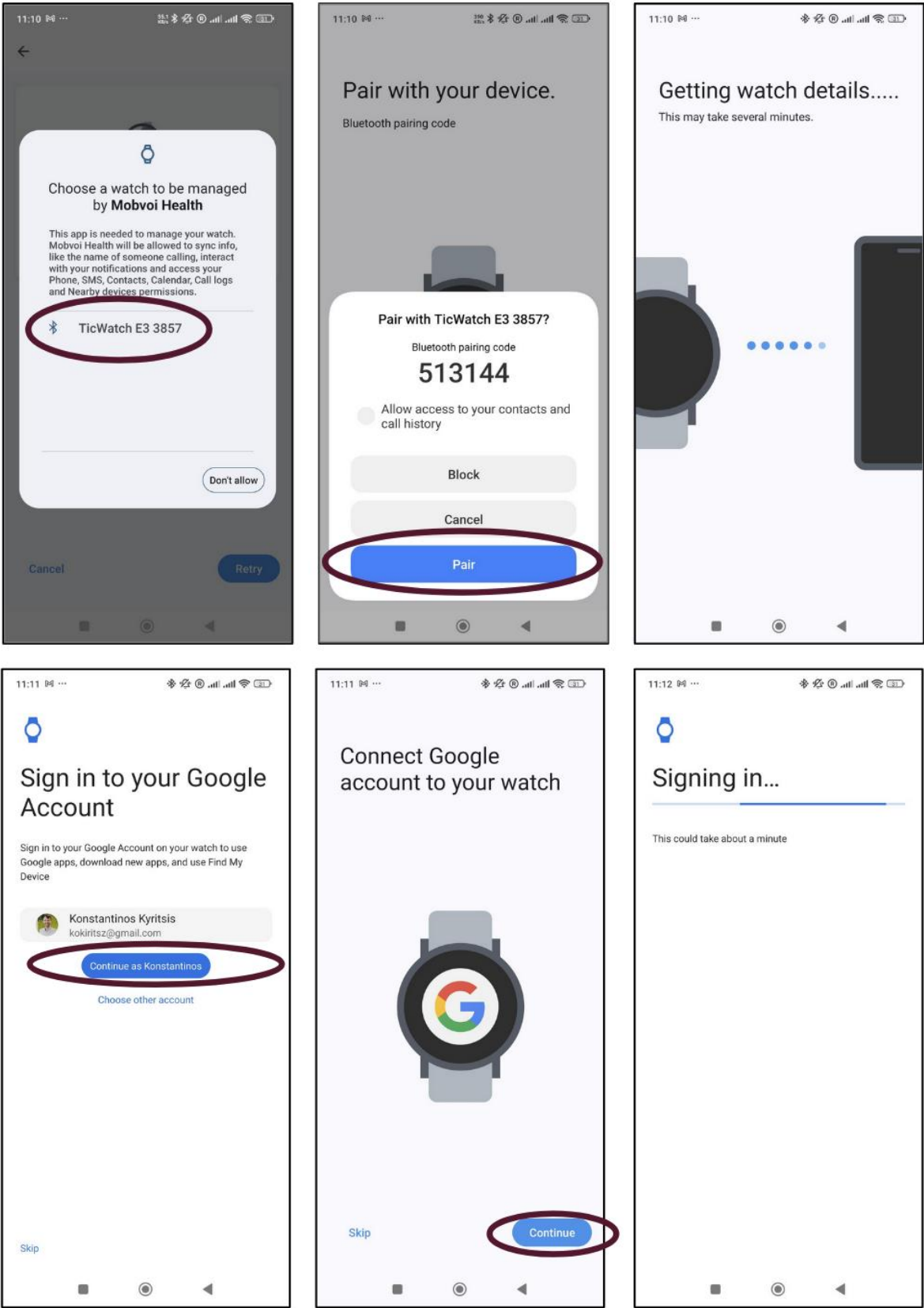


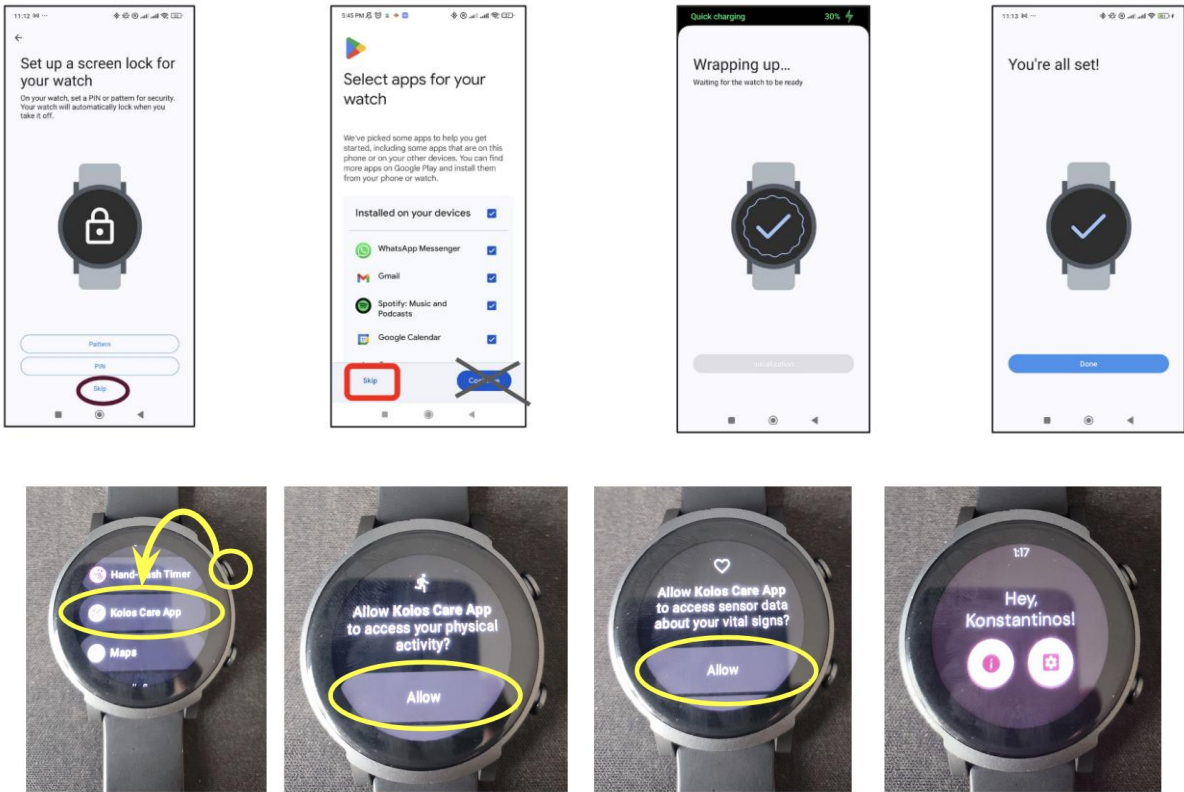
Start by powering-on the smartwatch by long-pressing the top right button.

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”.



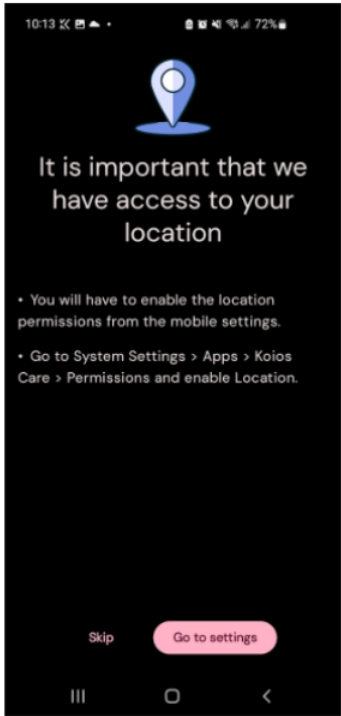
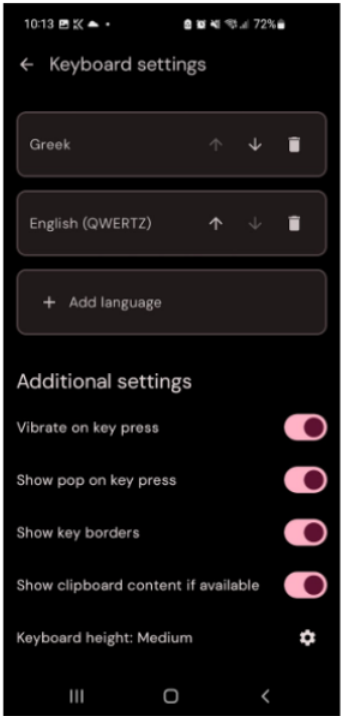
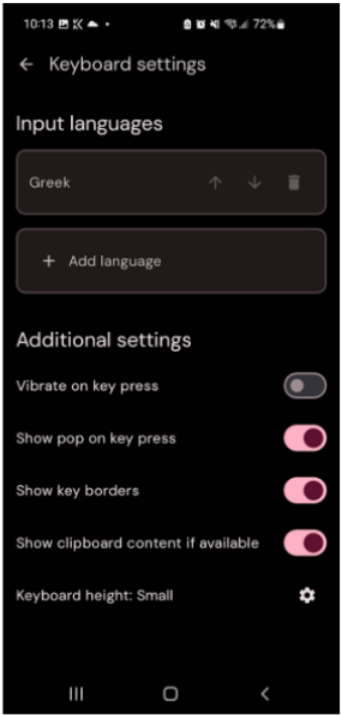


Activate the Koios Care Keyboard – Introduction Screen

This screen introduces users to the custom Koios Care keyboard, which is designed for use during daily mobile tasks. The keyboard does not interfere with standard phone functionality and can be enabled or disabled at any time. Activating the keyboard supports more accurate data capture by the app. Users can tap **Enable keyboard** to proceed with activation, or choose **Skip** to move on without enabling it.

Activate the Koios Care Keyboard – Selection Screen

Once the keyboard activation is initiated, users are prompted to select the Koios Care Keyboard from their device’s list of available input methods. A system dialogue appears, displaying options such as “Gboard,” “Koios Care Keyboard,” and the default keyboard (e.g., Samsung Keyboard). Users must select **Koios Care Keyboard** to enable it. This step completes the keyboard setup, which can be reversed or changed at any time through the device settings.



Keyboard Settings Screen

The “Keyboard settings” screen allows users to customize the Koios Care Keyboard according to their preferences. Users can manage **Input languages** by adding, removing, or reordering them. In the examples shown, both Greek and English (QWERTZ layout) are available.

Under **Additional settings**, users can toggle features such as:

- **Vibrate on key press**
- **Show pop on key press**
- **Show key borders**
- **Show clipboard content if available**

The **Keyboard height** can also be adjusted (e.g. Small or Medium). These settings allow for personalization of the typing experience to suit individual needs and habits.

Location Access Permission Screen

To ensure full functionality of the Koios Care app, users are prompted to enable location services. The screen informs users that access to location data is necessary and must be granted via the device’s system settings.

Instructions are provided:

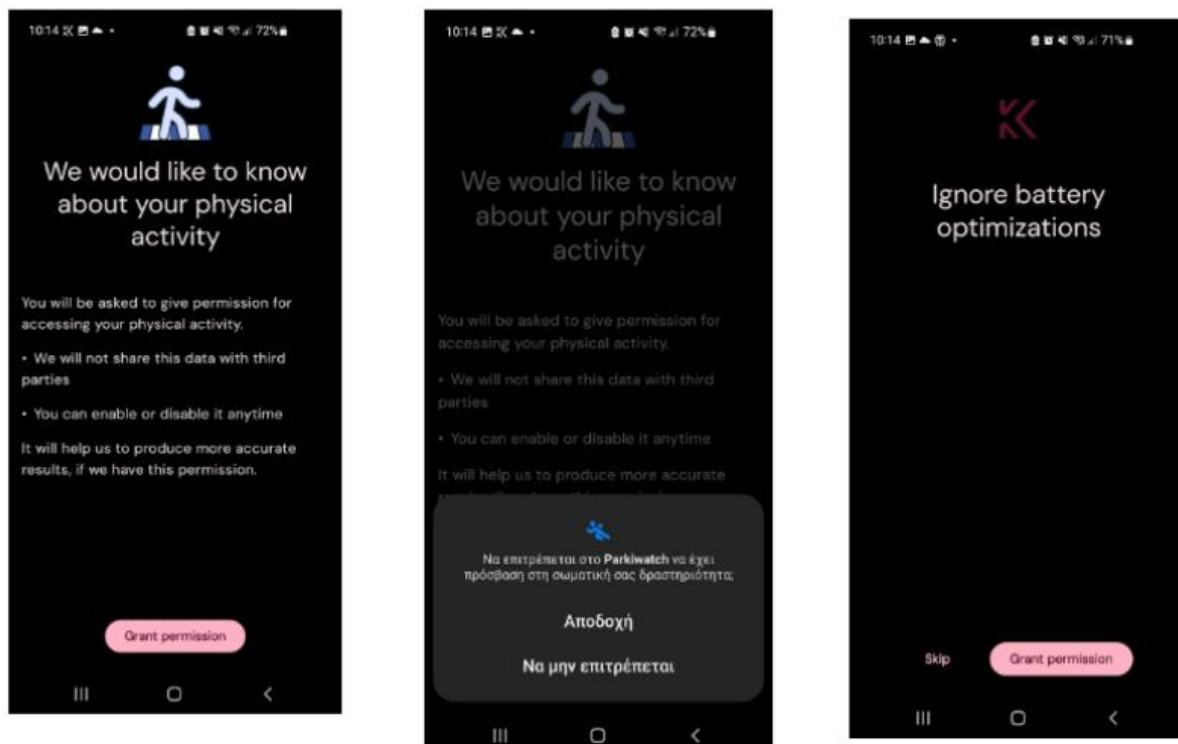
Navigate to **System Settings > Apps > Koios Care > Permissions**, and enable **Location**.

Two buttons are available:

- **Go to settings**, which takes the user directly to the permissions page

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- **Skip**, allowing the user to continue without enabling location access (which may limit some features)



Physical Activity Permission Screen

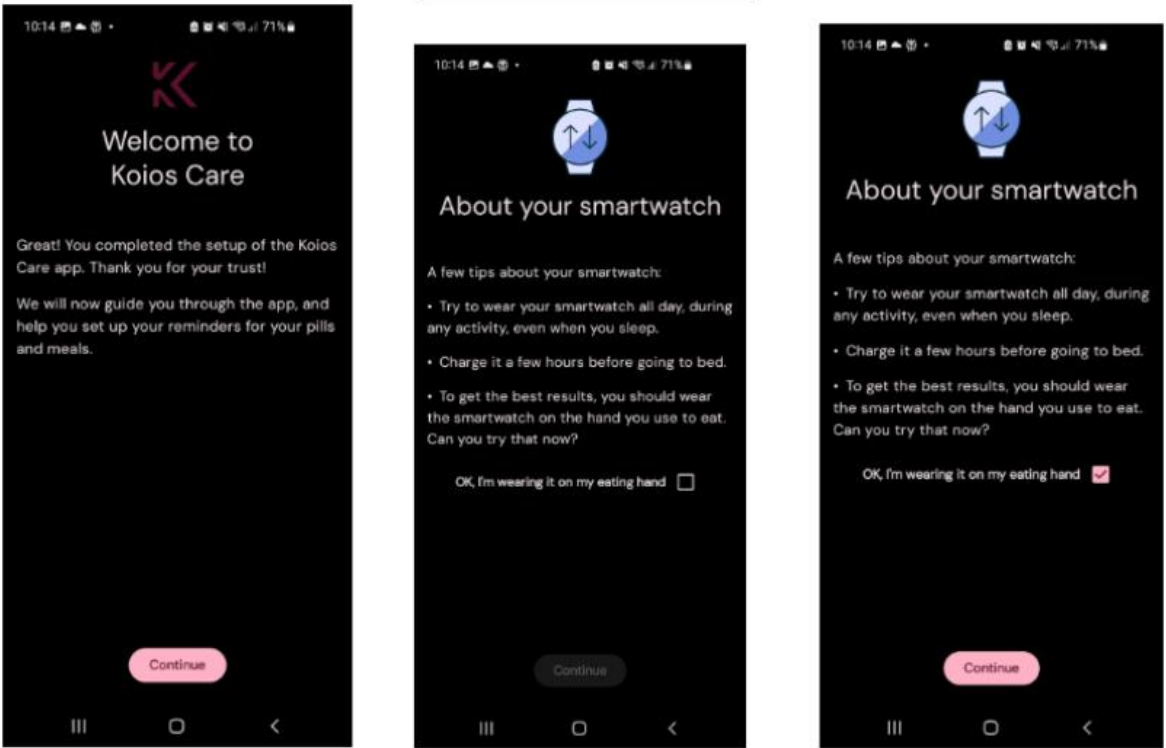
This screen requests user consent to access physical activity data from the device. The Koios Care app uses this information to improve the accuracy of its results. Users are assured that this data will not be shared with third parties, and they retain the ability to enable or disable this permission at any time.

To proceed, the user taps **Grant permission**, which triggers the system permission dialogue. This dialogue asks the user whether to allow the associated app (e.g., Parkiwatch) access to physical activity data, with options to **Allow** or **Deny**.

Battery Optimization Screen

This screen encourages users to disable battery optimizations for the Koios Care app. Disabling such optimizations ensures that the app can operate continuously in the background without interruption from the operating system's power-saving functions.

Users can choose to tap **Grant permission** to proceed to system settings and disable battery optimization for Koios Care. Alternatively, they may tap **Skip** to continue without making changes, although this may affect the app's performance in background operation.



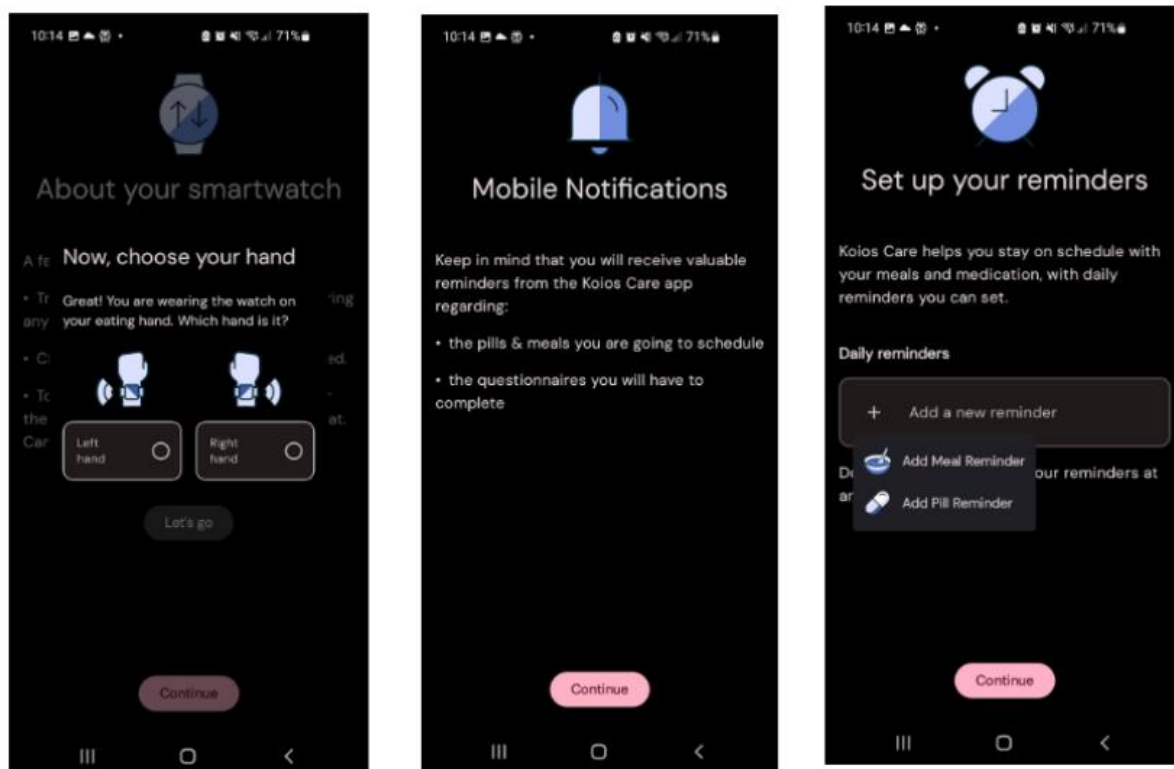
Welcome Screen

After successfully completing the initial setup, users are greeted with a “Welcome to Koios Care” message. This screen confirms that setup is complete and thanks the user for their trust. It also informs users that the app will now guide them through setting up reminders for medication and meals. To proceed, users tap the **Continue** button.

Smartwatch Usage Guidance Screen

This screen provides practical advice for using the smartwatch effectively with Koios Care. Users are encouraged to wear their smartwatch throughout the entire day, including during physical activity and sleep, for optimal data capture. It is also recommended that the device be charged a few hours before bedtime. For best results, the user is advised to wear the smartwatch on the hand they typically use to eat. A checkbox allows users to confirm: “OK, I'm wearing it on my eating hand.” The **Continue** button becomes active once the checkbox is selected.

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Smartwatch Hand Selection Screen

This screen finalizes the smartwatch configuration by asking users to confirm which wrist the watch is worn on. Since the user has already indicated they are wearing it on their eating hand, they are now prompted to specify whether that is the **Left hand** or the **Right hand**. Once selected, the **Continue** button becomes active, and the user can proceed by tapping **Let's go**.

Mobile Notifications Screen

This screen informs users that they will receive helpful mobile notifications from the Koios Care app. These alerts serve two key functions:

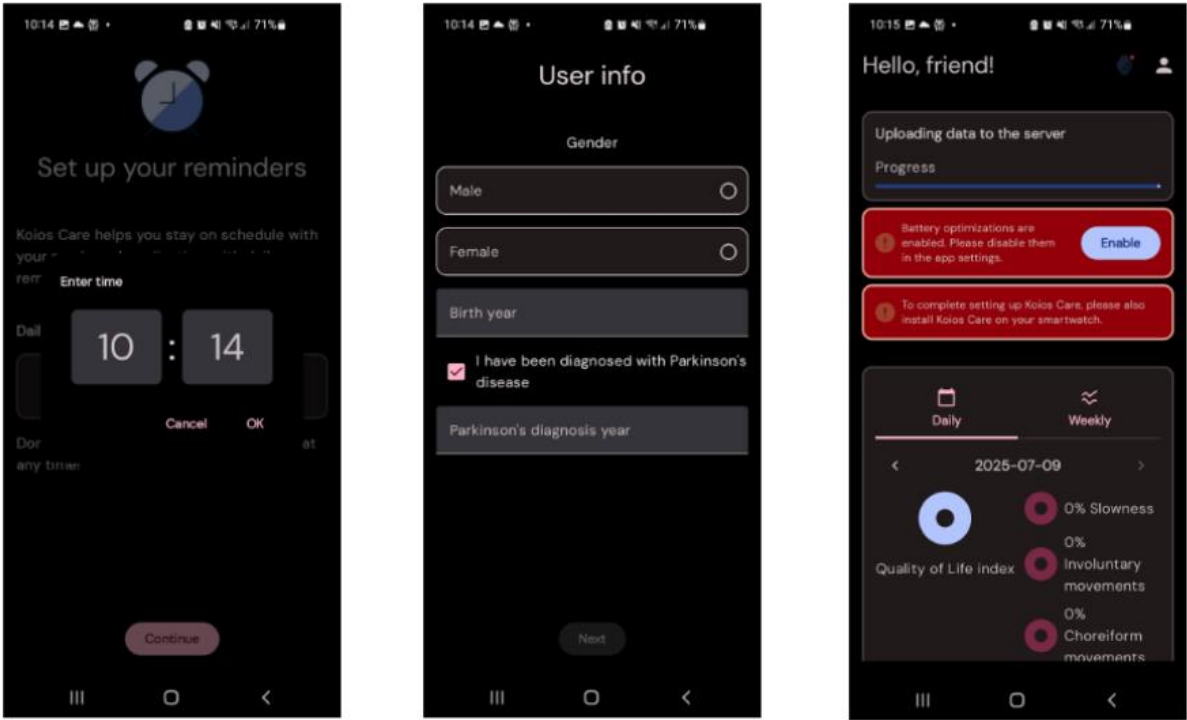
- Reminding users about scheduled pills and meals
- Notifying users about questionnaires they need to complete
- The user acknowledges this by tapping the **Continue** button to proceed.

Set Up Your Reminders Screen

Koios Care allows users to configure daily reminders to help them stay on track with meals and medication. On this screen, users can tap **Add a new reminder** to select from two options:

- Add Meal Reminder
- Add Pill Reminder

Users can create multiple reminders and manage them later within the app. After setting up at least one reminder, the user taps **Continue** to move forward.



Reminder Time Selection Screen

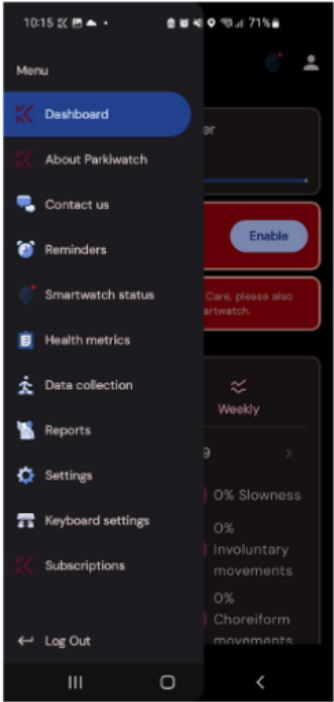
This screen allows users to configure the exact time for their daily reminders. After choosing to add a new reminder, a time picker interface appears where users can select the hour and minutes. Once the preferred time is set, the user confirms by selecting OK or cancels by selecting Cancel. After confirmation, the Continue button becomes active.

User Info Screen

The User info screen collects basic demographic and medical background information. Users are asked to select their gender and enter their birth year. There is also a checkbox to indicate if the user has been diagnosed with Parkinson's disease. If selected, a field appears prompting the user to enter the year of diagnosis. The Next button becomes available once all required fields are completed.

Main Dashboard Screen

After setup is complete, users are taken to the main dashboard of the Koios Care app. The top section shows the progress of data being uploaded to the server. If battery optimizations are still active, a red warning box appears, advising the user to disable these settings via the Enable button. A second red alert appears if the smartwatch app is not yet installed, instructing the user to complete setup. Below these alerts, the user sees a visual overview of their Quality of Life index, including metrics such as slowness, involuntary movements, and choreiform movements. The user can toggle between daily and weekly data views using the buttons at the top of the chart.



Navigation Menu

The main navigation menu provides access to all core features of the Koios Care app. It can be opened from the dashboard view and appears as a sidebar. The following items are available in the menu:

- **Dashboard:** returns the user to the main overview screen showing quality of life and movement data.
- **About Parkiwatch:** provides information about the Parkiwatch system.
- **Contact us:** allows the user to reach out for support or inquiries.
- **Reminders:** leads to the section where daily reminders can be reviewed or edited.
- **Smartwatch status:** displays the connection and activity status of the smartwatch.
- **Health metrics:** presents health-related indices collected by the system.
- **Data collection:** shows which types of data are being gathered.
- **Reports:** provides access to historical summaries or exported data.
- **Settings:** general configuration options for the app.
- **Keyboard settings:** opens configuration options for the Koios Care keyboard.
- **Subscriptions:** manages user access and any applicable subscription plans.
- **Log out:** securely signs the user out of the Koios Care app.

Users can return to any section of the app by selecting the corresponding item from this menu.

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- **ANALYSIS TIMING AND NETWORK REQUIREMENTS**
- **DATA PROTECTION AND PRIVACY**

The system is designed to align with applicable data protection regulations, including those concerning the processing of personal health data. During operation, limited personal data may be processed for essential functions such as image identification, logging of workflow steps, or diagnostic inference. This processing is restricted to what is strictly necessary to support traceability and the clinical utility of the system.

To safeguard patient privacy, the cloud-based components of the workflow implement pseudonymisation techniques where applicable. This ensures that identifiable information is either masked or replaced with coded references prior to processing, thereby minimizing the risk of unauthorized disclosure. Pseudonymisation is especially critical when data is transmitted to external services or analysis engines.

Additionally, to prevent errors in data attribution, all data is validated prior to transmission. This validation step checks for consistency in identifiers, file integrity, and alignment with the associated metadata. It plays a critical role in ensuring that the data remains accurately linked to the correct case, thereby reducing the risk of data mix-ups and ensuring reliable diagnostic output.

These privacy-preserving measures form part of the system's broader compliance with institutional, national, and international standards for data protection in medical environments.

- **TECHNICAL SPECIFICATIONS**
- **TROUBLESHOOTING AND UNINSTALLATION**

In the event that the system exhibits unexpected behaviour following installation or a software update, users are advised to perform a full uninstallation followed by a clean reinstallation. This procedure can resolve common compatibility issues or configuration errors that may arise during system updates or changes in network conditions. Reinstallation ensures that the core components are reset to their default states while preserving system stability.

When removing the software from a device, it is critical to follow the dedicated uninstallation guide provided with the system. This guide outlines the steps required to securely delete all stored patient data and any related diagnostic output. Ensuring that no residual data remains on the local system is essential for maintaining compliance with data protection policies and institutional security standards. Following the guide helps prevent unintentional data retention and supports the responsible handling of sensitive health information.

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6 SAFETY AND CYBERSECURITY

This section describes the safety precautions and training that must be observed to operate the system. Please read the entire safety section before operation.

– GENERAL SAFETY



WARNING: Strictly observe all warnings, cautions, notes and safety markings within this document and on the product.

– TRAINING

The user must have received adequate training in the safe and effective use of the system before attempting to work with it. Training requirements may vary from country to country. The user must make sure that training is received in accordance with local laws or regulations that have the force of law.

– CYBERSECURITY

The General Data Protection Regulation (GDPR) that came into force on May 25, 2018 and stipulates how patient data is handled and stored. It is the customer's responsibility to ensure that the way you use the software and device and how you share information within your organization and with third parties is complaint with the guidelines set out in the GDPR. It is also the customer's responsibility to clean up any computer where the PARKIWATCH is installed or any PARKIWATCH where patient data is present prior to disposal, in accordance with the GDPR guidelines.

– Cybersecurity Controls of the PARKIWATCH

KOIOS maintains a set of cybersecurity controls to improve the cybersecurity of its units and to maintain their functionality and safety. The PARKIWATCH implements the following measures to reduce the attack surface exposed by the system to the outside world:

– Cybersecurity Controls to be Observed by the Customer



WARNING: Access to the user password of the system should be controlled as this account has access to patient health information (PHI).

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The customer should further control who has access to the primary user password of the system. This user necessarily has access to patient health information (PHI) as they will potentially be retrieving this information through use of the Software and any connected modality worklist.

- In case of a Cybersecurity Event

In case of a cybersecurity event, disconnect PARKIWATCH from the network and contact KOIOS immediately.

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7 REGULATORY AND COMPLIANCE

– COMPLIANCE

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

– GENERAL

- [ISO 13485:2016 – Medical devices – Quality management systems – Requirements for regulatory purposes](#)
- [ISO 14971:2019 - Medical devices — Application of risk management to medical devices](#)
- [IEC 62304:2006 - Medical device software — Software life cycle processes](#)
- [IEC 62366-1:2015 - Medical devices — Part 1: Application of usability engineering to medical devices](#)
- [ISO 15223-1:2022 on Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements](#)
- [IEC 82304-1:2017 Health software – Part 1: General requirements for product safety](#)
- [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

- EU Regulation 2017/745 (MDR)
- The product has been designed in accordance with EU Guidelines regarding Medical Devices.

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8 **APPENDIX**

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9 **REVISION HISTORY**

Version	Date of last issue	Change description
1	10/10/2025	Initiation