KOIOS CARE

PARKIWATCH

Instructions for Use

Healthcare Professionals

INSTRUCTIONS FOR USE (Healthcare Professionals)

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 healthcare professionals. A separate IFU exists for people with Parkinson's Disease.

IFU PART NUMBER: PARKIWATCH.IFU.EN.002
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Legal notice

KOIOS CARE
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Important Notices

This document is the Instructions for Use of PARKIWATCH intended exclusively for Healthcare Professionals (HCPs). A separate IFU is available for patients. Read this document in full before using the PARKIWATCH system with patients.

WARNING: PARKIWATCH is not a standalone diagnostic tool. It must not be used for the initial diagnosis of Parkinson's Disease and must not be the sole basis for any therapeutic decision. All treatment adjustments must be based on the clinician's independent medical judgment within the context of a full clinical evaluation.

The screenshots in this document are provided for guidance purposes.

Any serious incident that has occurred in relation to the device shall be reported to Koios Care, Filip Williotstraat 9, 2600 Antwerpen, support@koios.care and to the competent authority of the country in which the user and/or the patient is established.

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1. Product Description

1.1 Intended Purpose

PARKIWATCH is a Class IIa 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. The device provides objective, long-term data of the patient's kinematic patterns between clinic visits to assist healthcare professionals in making informed clinical decisions and evaluating treatment effectiveness.

Required equipment (health care professional side): Computer or tablet device with a supported web browser, and a Wi-Fi / ethernet or cellular data connection for access to the dashboard.
Compatibility (healthcare professional side): A list of web browsers and versions that are compatible with the healthcare professional's dashboard can be found in section "Using the Healthcare Professionals Dashboard".

Required equipment (patient-side): PARKIWATCH requires the user to wear a third-party smartwatch or wrist-worn sensor which collects triaxial accelerometer data at a minimum sampling frequency of 18 Hz. The user needs a private smartphone (Android) to install and use the PARKIWATCH smartphone Android application.
Compatibility (patient-side): 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. Its outputs are adjunctive to, and must be interpreted within the context of, standard clinical assessment and the treating healthcare professional's judgment.

1.2 Intended Patient Population

PARKIWATCH is a software-based medical device intended for the automated, objective, and long-term monitoring of kinematic patterns in adult patients diagnosed with Parkinson's disease by a healthcare professional.

The software analyzes kinematic data collected from a third-party smartwatch or wrist-worn sensor device and third-party smartphone device during the daily life activities of patients. It is intended to provide healthcare professionals with longitudinal data on patient kinematic patterns between clinical visits, serving as a clinical decision support tool to assist in the management and optimization of the patient's care plan.

PARKIWATCH automatically monitors kinematic patterns throughout the day to provide insights. These insights can be found in the automatically generated PDF reports accessible via the healthcare professional's dashboard (for the healthcare professional), and the PARKIWATCH android application (for patients that can access it via their PARKIWATCH smartphone application).
The system is intended for use by patients who:

- Are under the active clinical follow-up of a licensed healthcare professional.
- Possess the cognitive and physical capability to operate a smartphone and wear a smartwatch continuously during waking hours.

PARKIWATCH is classified as a Class IIa Software as a Medical Device under EU MDR 2017/745.

1.3 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.

1.4 Intended User

PARKIWATCH is intended for use by licensed healthcare professionals responsible for the management of patients with Parkinson's disease; as defined in the section “Intended Patient Population”. Users must be familiar with clinical assessment of Parkinson's disease before use. No training is required. Interpretation of the report can be found in Section 5, and support in Section 8.

1.5 Use Environment and Required Equipment

Use Environment

Clinicians access the PARKIWATCH Healthcare Professionals dashboard in their usual clinical or office environment via a standard web browser with internet access. No special environmental requirements apply.

The following required equipment should not be mistaken for the Required Equipment regarding the correct operation of the PARKIWATCH Android smartphone mobile application intended for the population of people with Parkinson’s Disease.

Required Equipment

- Computer or tablet device with a supported web browser. A list of web browsers and versions that are compatible with the healthcare professional's dashboard can be found in section “Using the Healthcare Professionals Dashboard”
- Connectivity; Wi-Fi or cellular data for access to the dashboard.

1.6 Performance Claims

The following performance claims are based on PARKIWATCH's ability to accurately infer kinematic patterns representative of tremor; the automatic detection and quantification of reductions in movement velocity and amplitude representative of bradykinesia; and the automatic detection and quantification of irregular, non-rhythmic hyperkinetic movements representative of dyskinesia. The following tables provide the results for each of the kinematic patterns mentioned above. The minimum acceptance criteria that were met for each case are also provided.

(1) For the detection and quantification of oscillatory kinematic patterns representative of tremor.

Item	Metric	Met minimum acceptance criterion
UPDRS II Item 16	Spearman	≥ 0.30 ($p < 0.05$)
UPDRS III Item 20 tremor		
MDS-UPDRS Constancy		

(2) For the detection and quantification of reductions in movement velocity and amplitude representative of bradykinesia.

Item	Metric	Met minimum acceptance criterion
Spearman r (MDS-UPDRS Global Spontaneity of Movement)	Spearman	≥ 0.30 ($p < 0.05$)
Spearman r (UPDRS Part III Item 31)		

(3) For the detection and quantification of irregular, non-rhythmic hyperkinetic movements representative of dyskinesia.

Item	Metric	Met minimum acceptance criterion
Spearman r (UPDRS IV Item 32)	Spearman	≥ 0.30 ($p < 0.05$)
Spearman r (MDS-UPDRS Time Spent with Dyskinesias)		
Spearman r (MDS-UPDRS Functional Impact of Dyskinesias)		

Product Lifetime

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 in Section 11.2.

1.7 Clinical Benefits

Parkinson's management typically relies on observations made during clinic visits that occur every 3–6 months. PARKIWATCH continuously monitors kinematic patterns throughout the day and provides validated kinematic measures with a resolution of 15 minutes, giving the healthcare professional information between clinical visits. This may support more informed decisions regarding the management and care plan of the patient. PARKIWATCH does not diagnose Parkinson's Disease, does not recommend or modify pharmacological therapy, and does not replace the clinical judgment of the healthcare professional.

2. Functional Description

2.1 Key Components and Modules

PARKIWATCH is a Class IIa SaMD comprised of three integrated components:

- Patient mobile application (Android smartphone): passively collects sensor data and patient-reported outcomes; syncs to the cloud.
- Healthcare professional dashboard: secure browser-based interface enabling clinicians to monitor patients, review indicators, and access reports.
- The cloud infrastructure: responsible for producing the validated kinematic measures.

The PARKIWATCH Android smartphone application for the patients with Parkinson’s Disease 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, the PARKIWATCH Android smartphone application for patients 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.

2.2 Inputs

The system accepts the following inputs for the production of the validated kinematic measures:

- Raw 3-axis accelerometer and data from the compatible third-party smartwatch or wrist-worn sensor device;
- Patient-reported outcomes via in-app questionnaires (UPDRS-II) and reminders from the PARKIWATCH Android smartphone application that is used from the patients with Parkinson's Disease;
- Clinician-entered data: patient email address for monitoring initiation; account credentials for healthcare professional dashboard access.

To produce the support digital health measures the system accepts the following inputs:

- Raw 3-axis accelerometer and gyroscope and data from the compatible third-party smartwatch or wrist-worn sensor device worn by the patient with Parkinson's Disease;
- PPG-derived heart rate data from the third-party smartwatch or wrist-worn sensor device worn by the patient with Parkinson's Disease;
- Location-based information from the third-party smartphone used by the patient with Parkinson's Disease;
- Flight and hold time, produced by timestamp-only information from the digital keyboard included in the PARKIWATCH smartphone Android application used by the third-party smartphone of patient with Parkinson's Disease.

2.3 Outputs

Output of PARKIWATCH are PFD reports that contain validated kinematic measures (section 3.1) and supportive digital health measures (section 3.2).

Reports are accessible from the Recent Reports panel of the assominiciated patient profile in the healthcare professional dashboard. More information on the contents of the dashboard, as well as the content of the report, including the interpretation of the validated kinematic measures, can be found in section 5.

3. Validated kinematic measures

3.1 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.

3.2 Supportive Digital Health Measures:

- The automatic analysis of rhythm and timing during smartphone keyboard interactions to provide insights on the 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 activity levels.
- The logging and visualization of questionnaires' responses

This information is combined into reports to complement the clinical assessment of the healthcare 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 the healthcare professional and does not serve as an emergency response system.

4. Combination with Other Devices

4.1 Compatibility Requirements

To ensure correct operation, PARKIWATCH must only be used on devices that meet the following validated minimum technical requirements.

PARKIWATCH – **Healthcare professional side:**

- Computer or tablet device with a supported web browser. A list of web browsers and versions that are compatible with the healthcare professional's dashboard can be found in section "Using the Healthcare Professionals Dashboard"
- Connectivity; Wi-Fi or cellular data for access to the dashboard.

PARKIWATCH – **patient side:**

- Third-party smartphone Android 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.

PARKIWATCH third-party smartphone android application 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.

WARNING: Ensure the third-party patient android smartphone device meets the minimum specifications listed in section 4.1. Operation on devices that do not meet these specifications may result in unreliable performance.

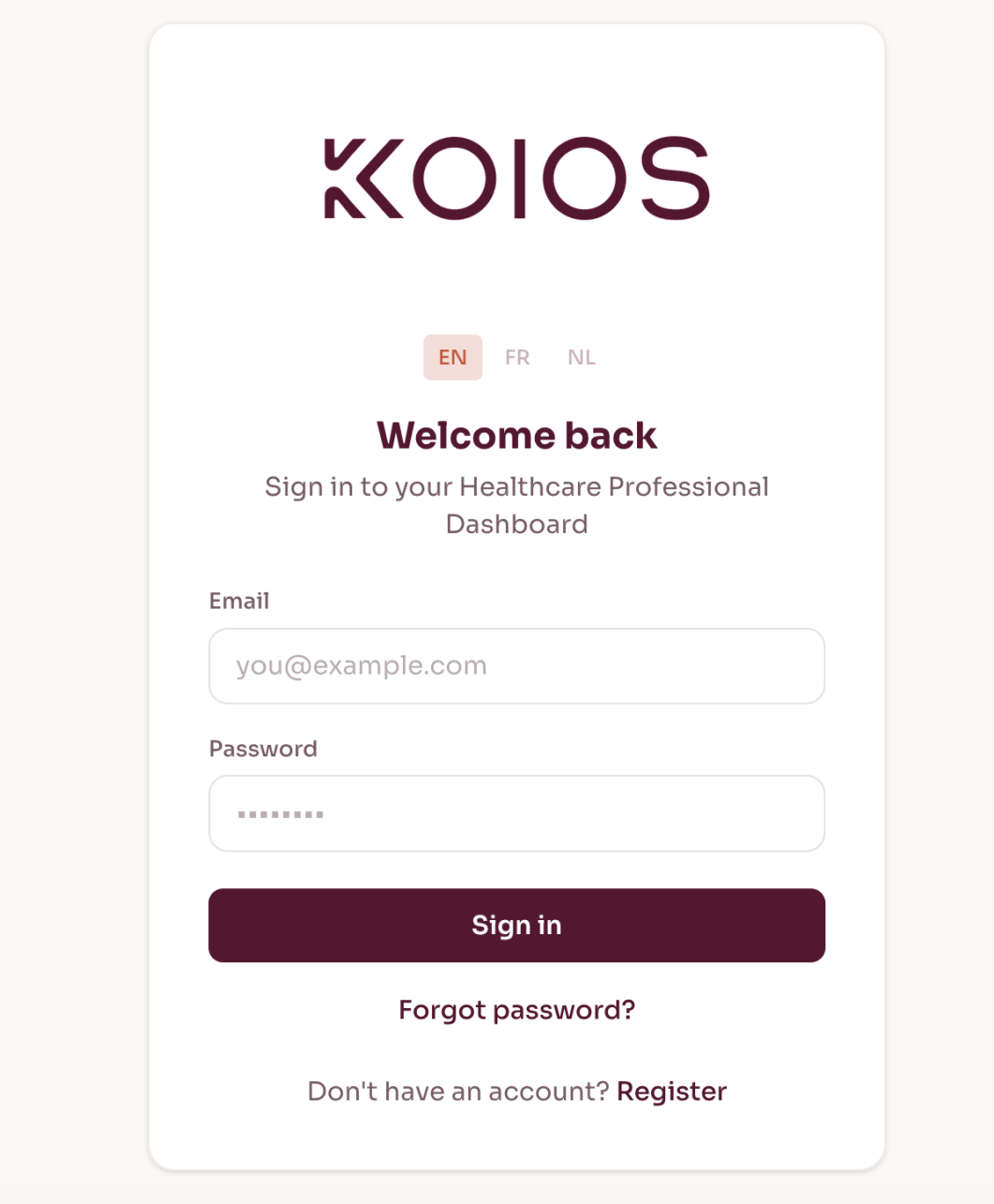
The patient-specific smartwatch must be paired with the respective patient account within the PARKIWATCH app, initiated by the patient, or the healthcare professionals dashboard, initiated by the healthcare professional. Incorrect pairing will result in data not being attributed to the correct patient.

5. Using the Healthcare Professionals Dashboard

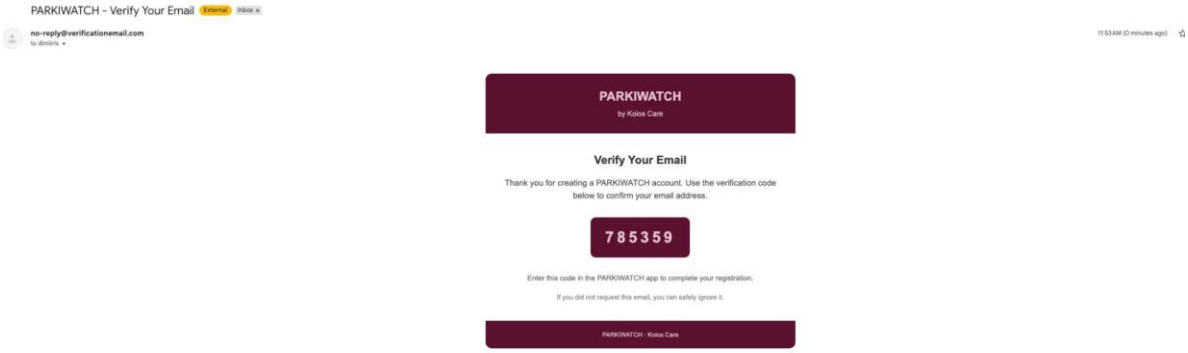
The Healthcare Professionals dashboard is accessible from the Koios Care website. It is compatible with Chrome>= 118, Firefox >=117, Safari >= 17, Edge >=118 based web browsers. The following sub-sections provide a complete walkthrough of the clinician workflow with annotated screenshots.

5.1 Account Setup and Authentication

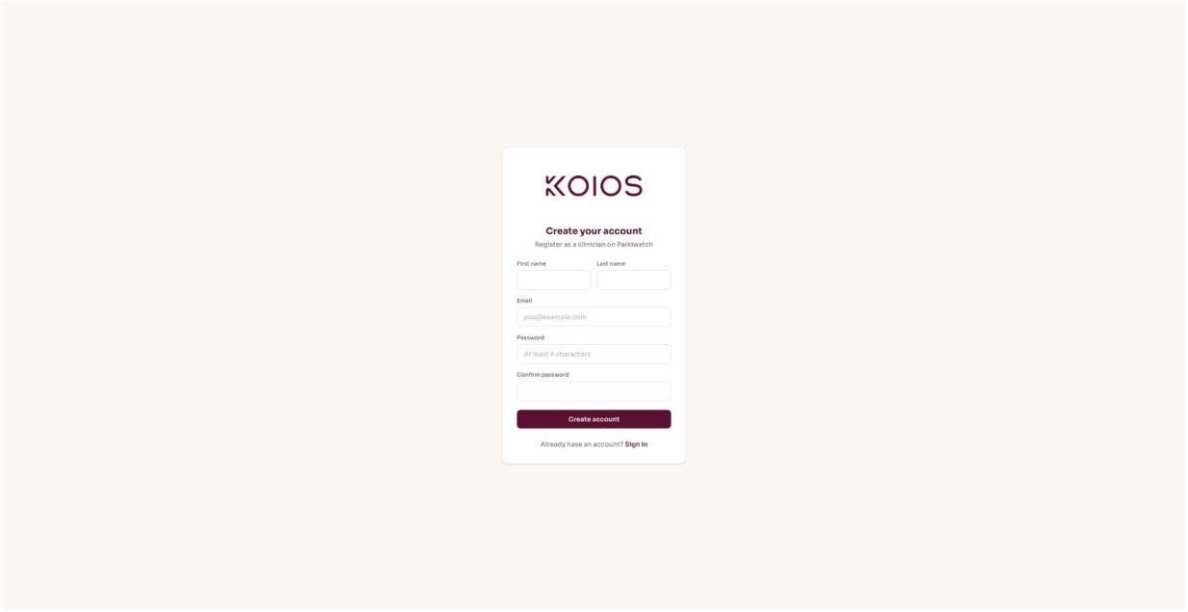
New healthcare professional accounts are created by completing the registration form at the dashboard. After submission, a one-time verification code is sent to the registered email address. The code must be entered in the dashboard to activate the account. Returning users may sign in with their email and password.



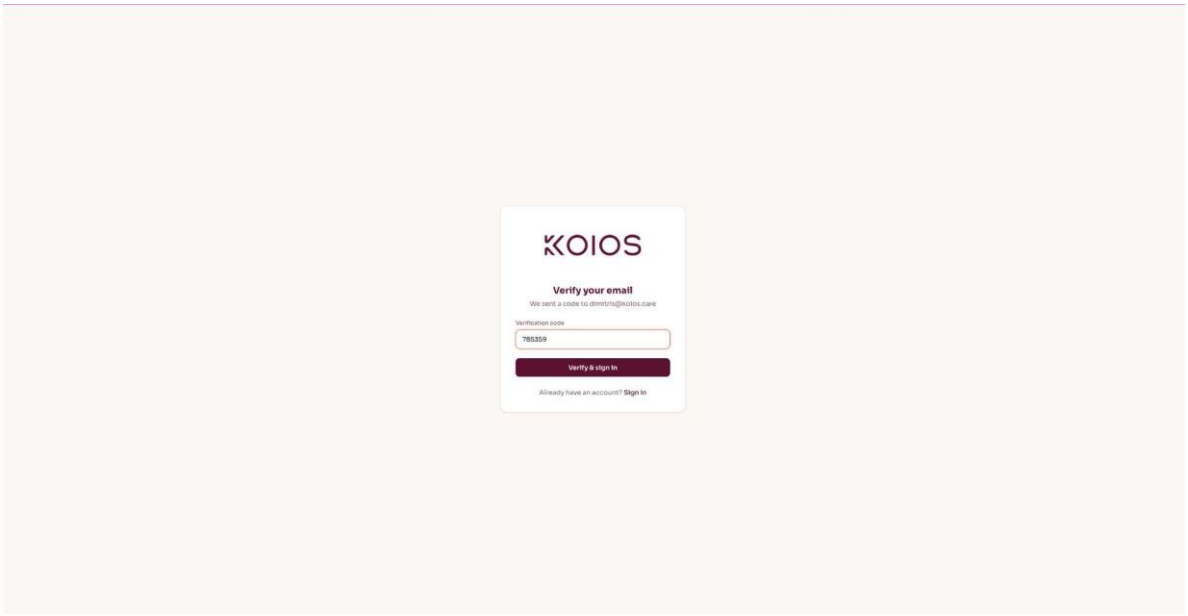
Sign In screen: email/password login.



Account Registration: first name, last name, email, and password (minimum 8 characters).



Email Verification: a one-time code sent by PARKIWATCH to the registered healthcare professional email.



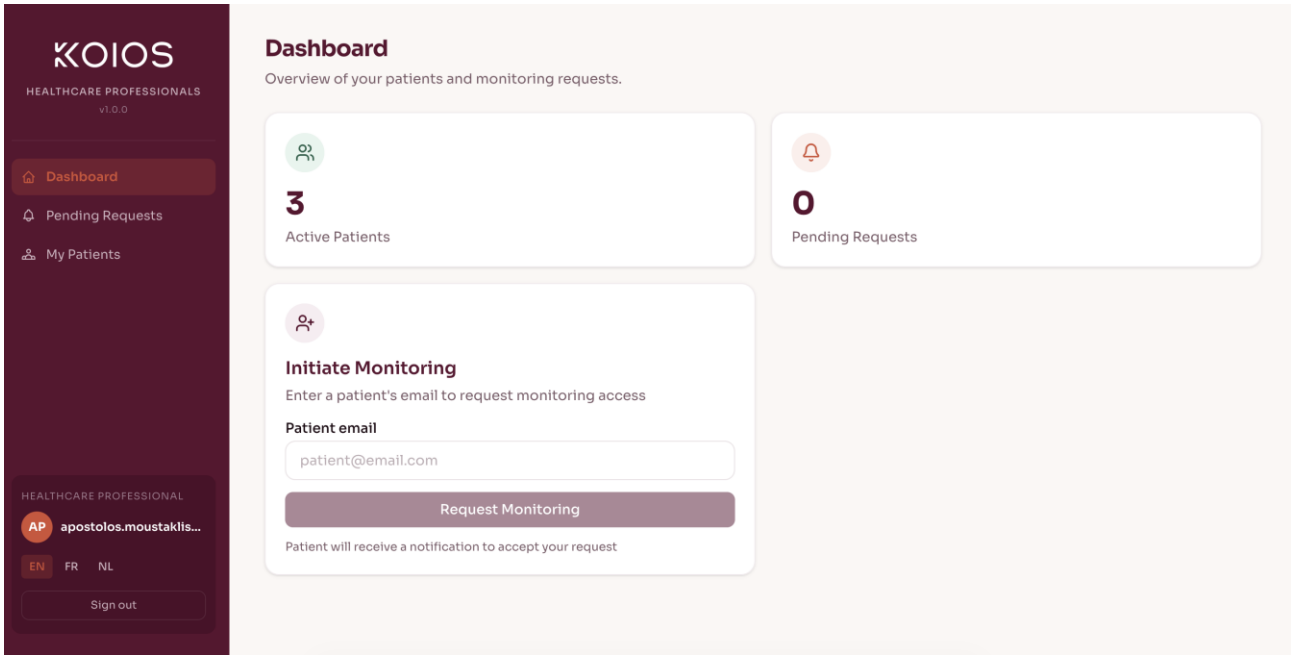
Verification Code Entry: the six-digit code must be entered to complete account activation.

5.2 Healthcare professional Dashboard and Patient Monitoring

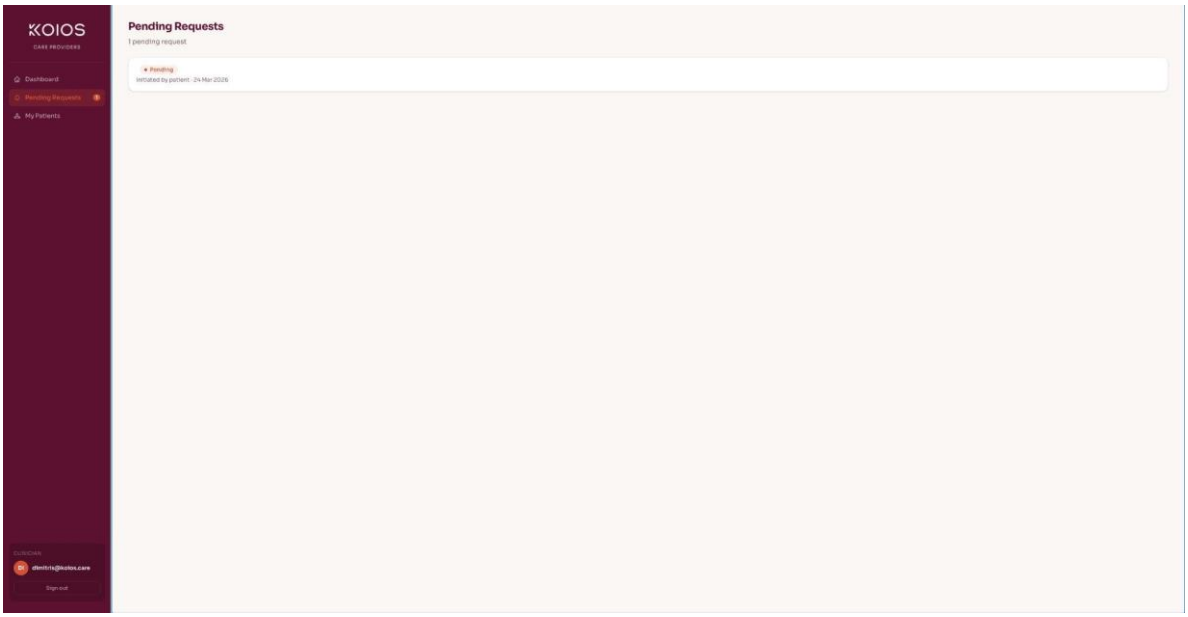
Upon login, the healthcare professional dashboard provides an at-a-glance overview of active patients and pending monitoring requests. To begin monitoring a new patient:

- Navigate to the Dashboard.

- Enter the patient's registered PARKIWATCH email address in the Initiate Monitoring panel and click Request Monitoring.
- The patient receives a notification in their Android smartphone PARKIWATCH app. The healthcare professional gains access to the patient's data only after the patient accepts the request.
- Pending requests are visible in the Pending Requests section and include the date of initiation.



Health care professional Dashboard: active patient count, pending requests, and the Initiate Monitoring panel.



Pending Requests: monitoring requests awaiting patient acceptance are listed with status and date.

To terminate monitoring for a patient, navigate to the patient's profile and click Terminate Monitoring. The patient will be notified, and data sharing will cease immediately.

5.3 Accessing and content of the activity report

PARKIWATCH generates scheduled PDF activity reports for any selected observation period. Reports are listed in the Recent Reports panel on the patient profile. To access a report:

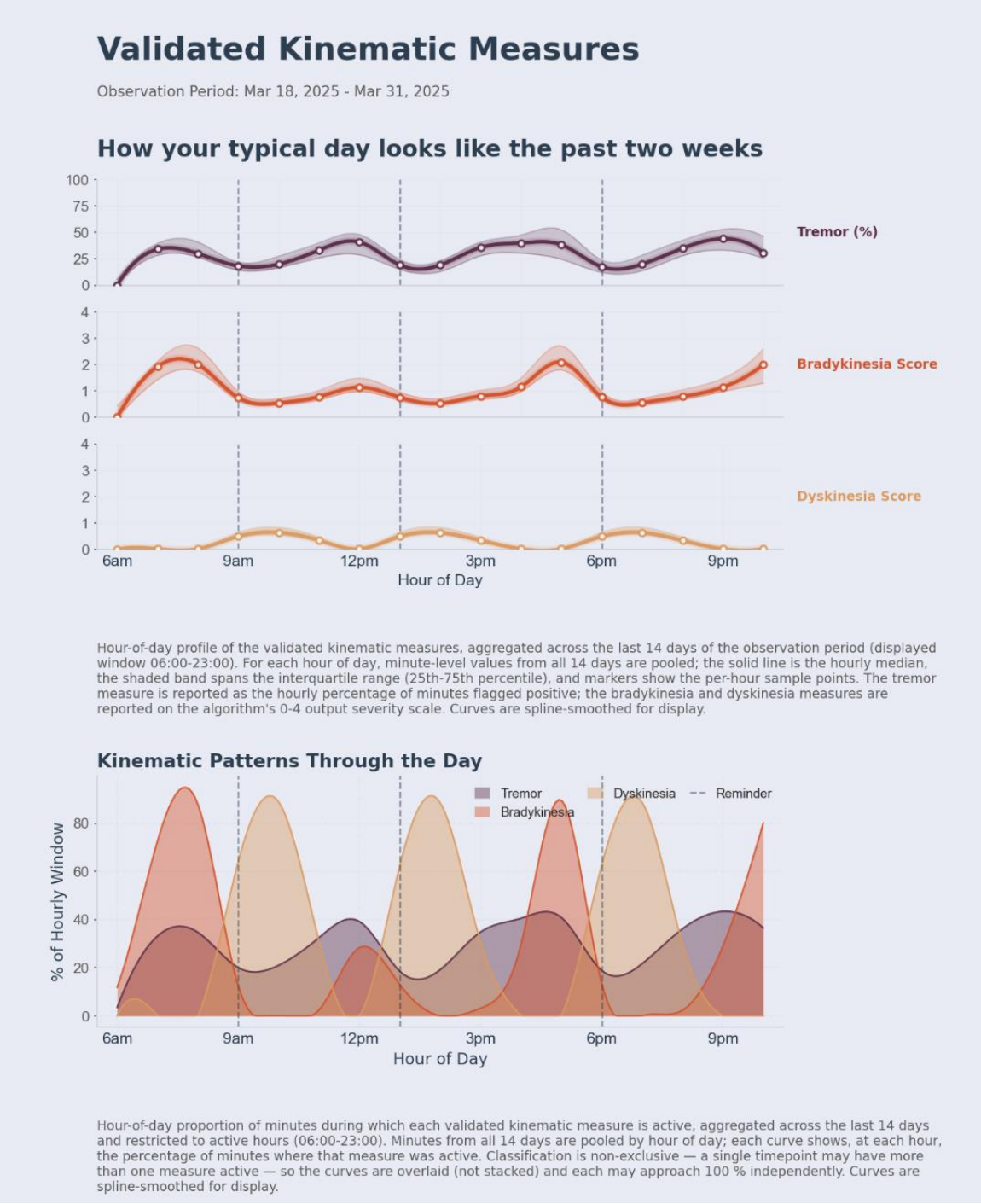
- Click on the report date range listed under Recent Reports to open the PDF viewer.
- Use the download button in the PDF viewer to save a local copy.

The report contains the following regarding the validated kinematic measures (Medical Device Functions):

- Quantification of kinematic patterns (kinematic patterns representative of tremor; reductions in movement velocity and amplitude representative of bradykinesia; irregular, non-rhythmic hyperkinetic movements representative of dyskinesia) in 15-minute intervals through the day.

And the supportive digital health measures:

- Slowness of movements via analysis of hold and flight timestamps while typing using the digital keyboard per day.
- Duration of plate-to-mouth during meals
- Daily heart rate, sleep duration, frequency of awakenings, and rest quality.
- Daily step counts, time spent outside of home.
- Patient-Reported Outcomes (PROs) via standardized clinical questionnaires.



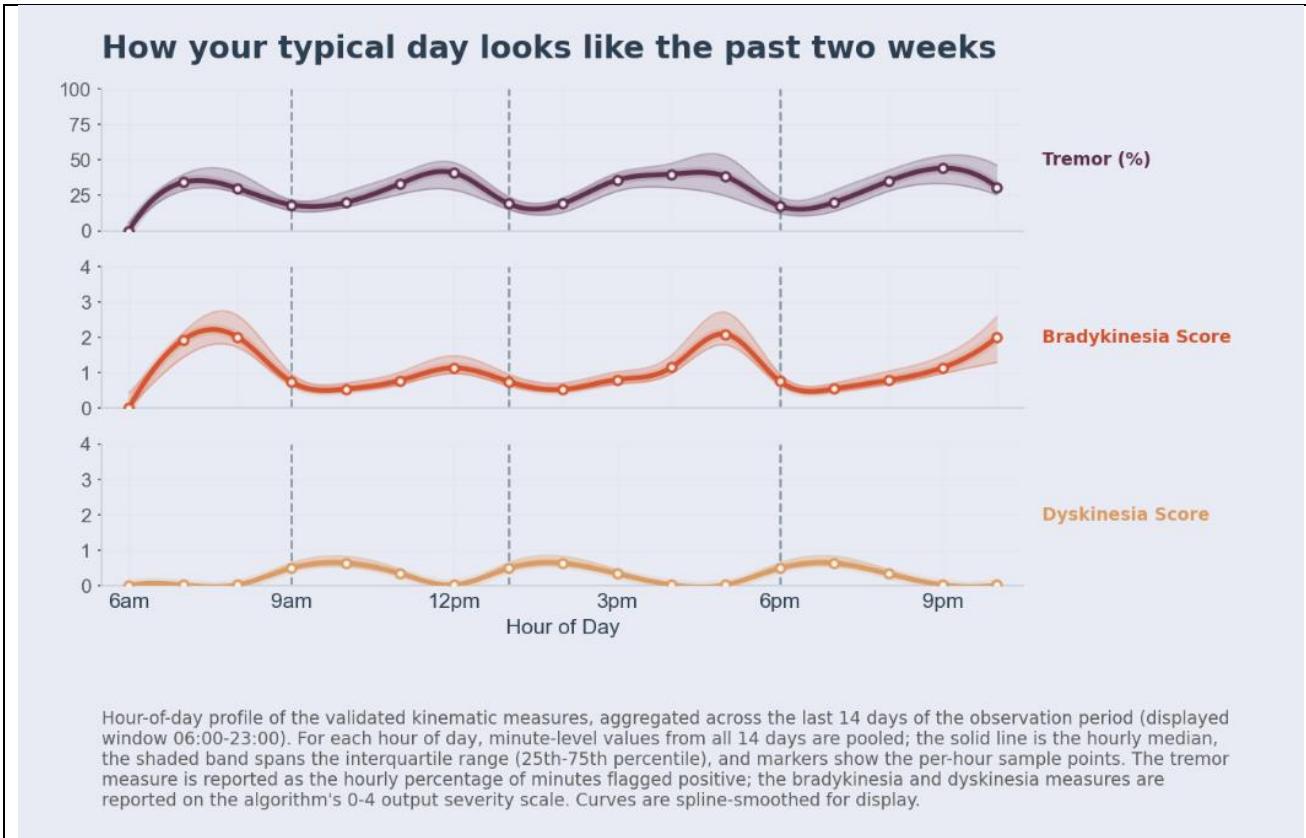
Example Activity Report (PDF). The figure shows page one of the validated kinematic measures.

5.4 Contents

The PARKIWATCH activity report is a scheduled PDF document structured in two sections. The first covers the validated kinematic measures and the second covers the supportive digital health measures.

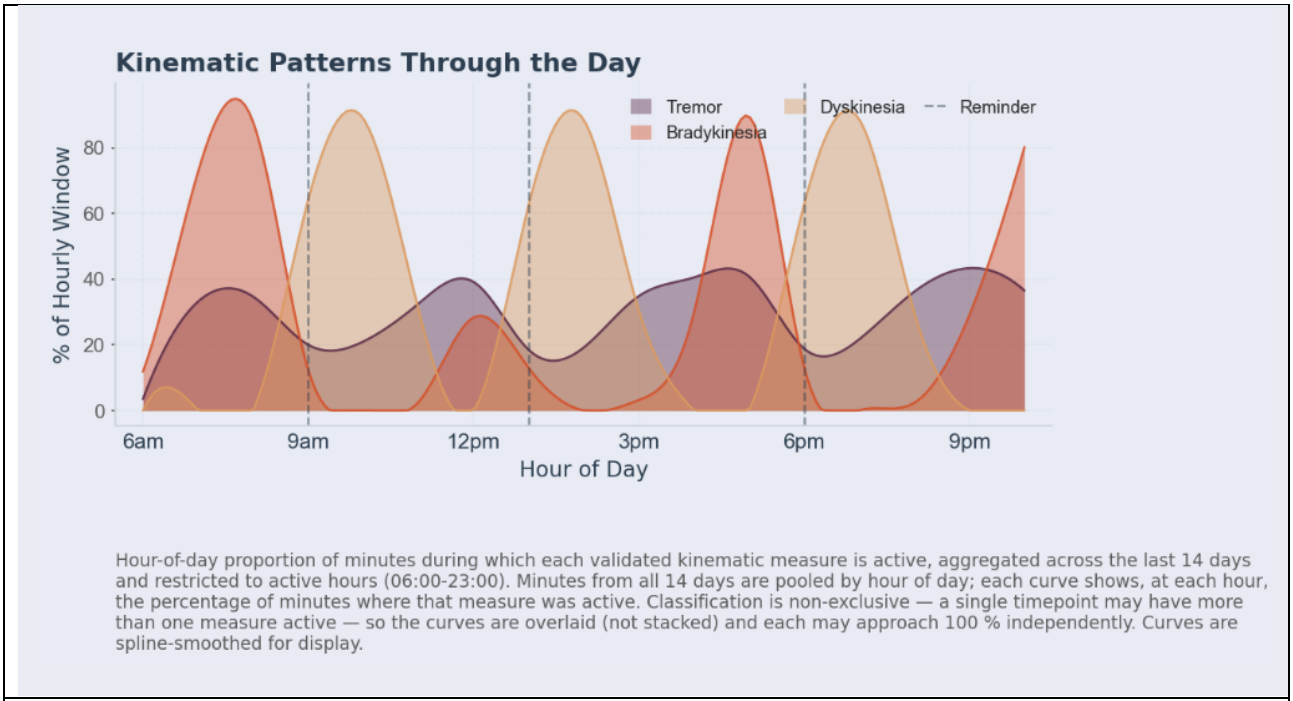
5.4.1 Validated Kinematic Measures

This section of the report provides the validated, accelerometer-derived quantification of three kinematic patterns; oscillatory patterns representative of tremor, reductions in movement velocity and amplitude representative of bradykinesia, and irregular non-rhythmic hyperkinetic movements representative of dyskinesia. All outputs are derived from continuous passive monitoring and processed entirely in the Koios Care cloud infrastructure.



Displays all three kinematic measures on separate axes, aggregated across the preceding two weeks (14 days) of the observation period, hour by hour, restricted to active hours (06:00 – 23:00).

The top sub-figure, oscillatory patterns representative of tremor, is expressed as the percentage of minutes per hour flagged as tremor-like (scale 0–100%). The percentage is the proportion of minute-windows classified positively by the validated binary tremor detector. Reductions in movement velocity and amplitude representative of bradykinesia (middle sub-figure) and irregular, non-rhythmic hyperkinetic movements representative of dyskinesia (bottom sub-figure), are each expressed on the algorithm's 0-4 output severity scale. At each hour, the solid line in each sub-figure represents the median value across all days in the observation window. The shaded band spans the interquartile range (25th–75th percentile), providing a direct visual of both the kinematic measures and the degree of day-to-day variability at each time of day.

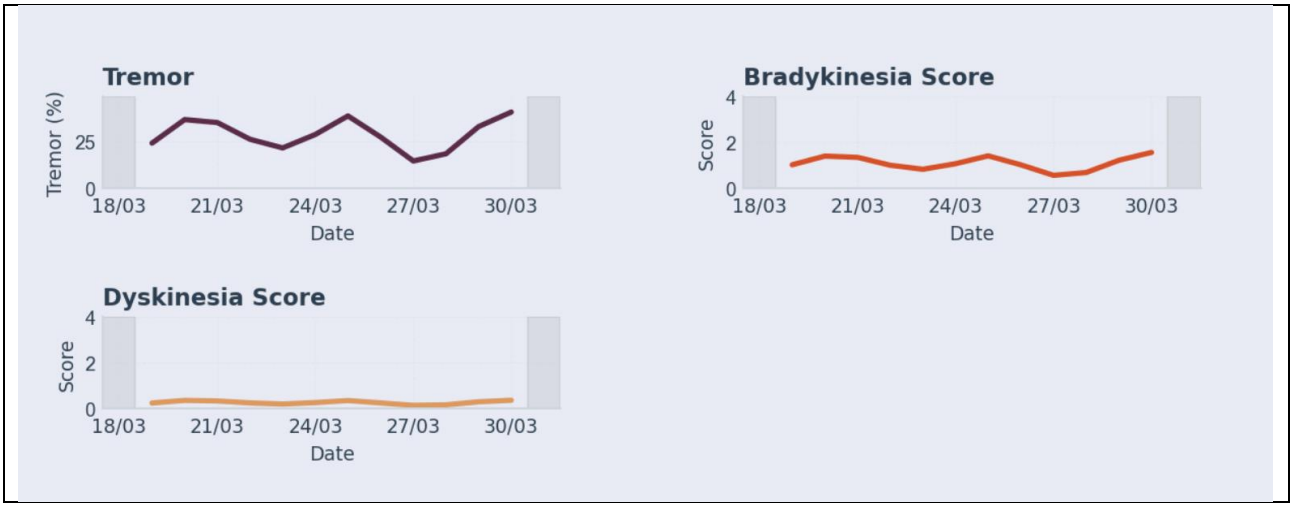


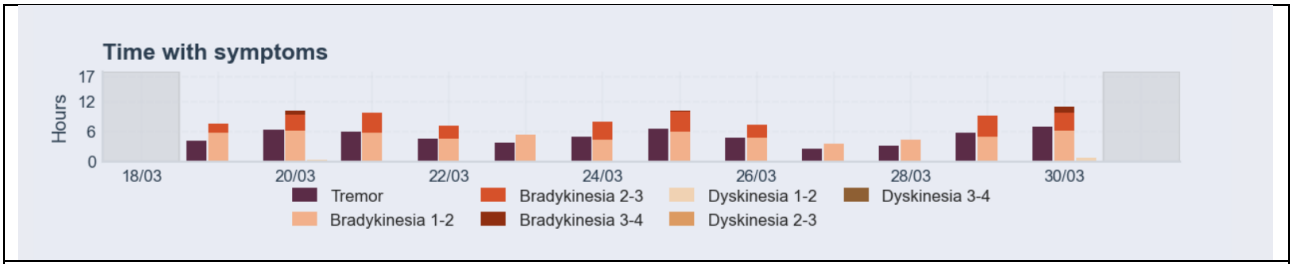
Displays the hour-of-day proportion of classified minutes during which each kinematic measures detector flagged its target pattern, aggregated across the preceding 14 days of the observation period, restricted to active hours (06:00 – 23:00).

Key interpretation guidance:

(1) The three curves (oscillatory kinematic patterns representative of tremor, reductions in movement velocity and amplitude representative of bradykinesia and irregular, non-rhythmic hyperkinetic movements representative of dyskinesia) are overlaid rather than stacked as in the first figure, since classification is non-exclusive.

(2) A single minute may be simultaneously flagged by more than one detector; each curve may independently approach 100% at any given hour. This representation allows identification of windows of isolated or co-occurring kinematic activity.





The top figure showcases the daily values for each of the three kinematic measures that are presented as individual sub-figures over the preceding 14 days, one data point per day.

The second figure, a stacked bar chart titled “time with symptoms”, shows, for each day, the number of active hours during which the bradykinesia or dyskinesia score fell within each output band on the 0–4 scale:

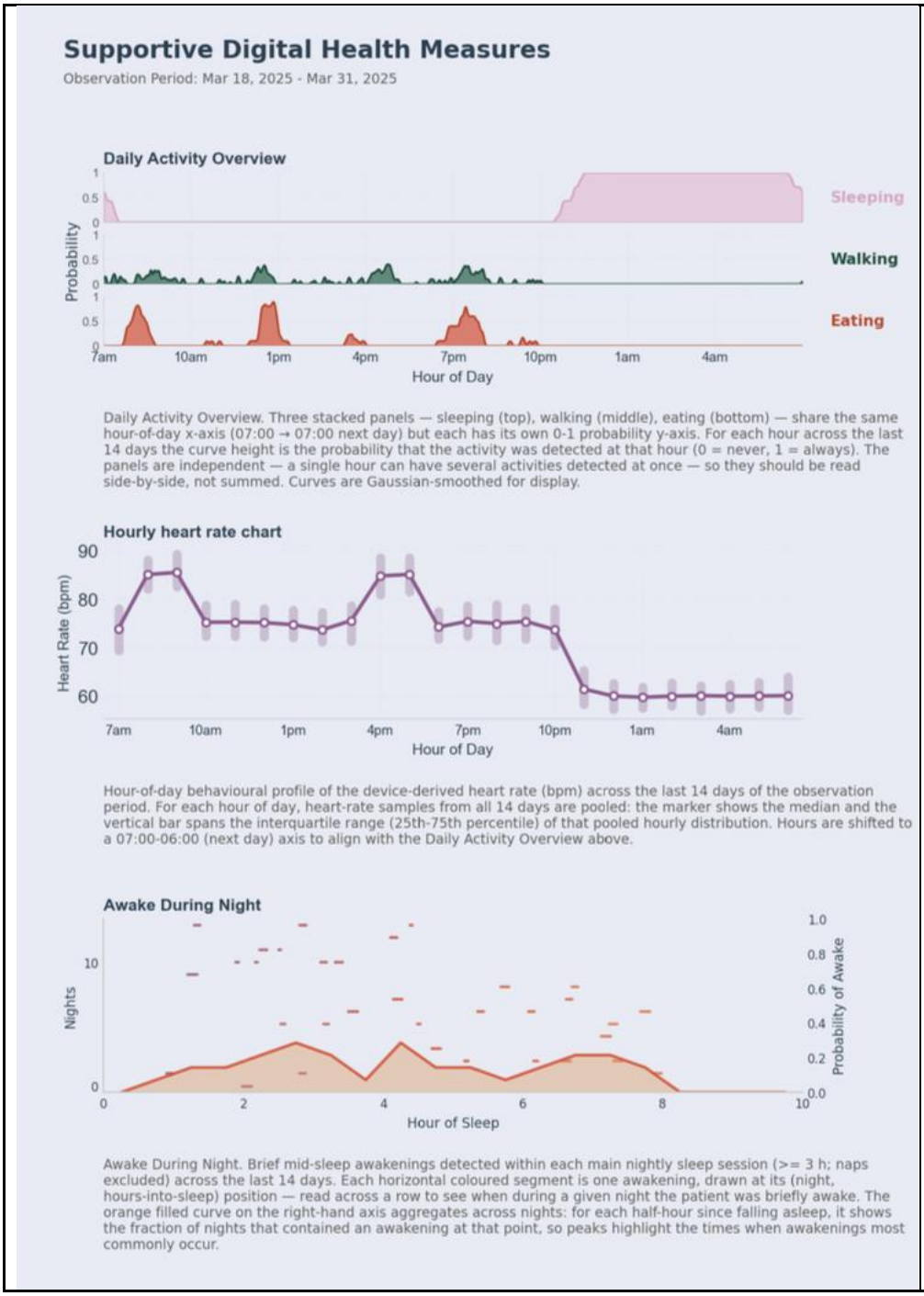
- Band 1–2: mild
- Band 2–3: moderate
- Band 3–4: severe

Bars are stacked by score band and colour-coded by severity, enabling rapid visual identification of days with a high proportion of moderate-to-severe motor burden versus days dominated by lower-severity or absent scores. Tremor is shown separately as a continuous daily line given its distinct percentage-based metric format.

For each figure, the grey vertical bands indicate days on which data were absent or insufficient for extracting kinematic measures. **These should not be interpreted as days without kinematic activity; they reflect days with missing data.**

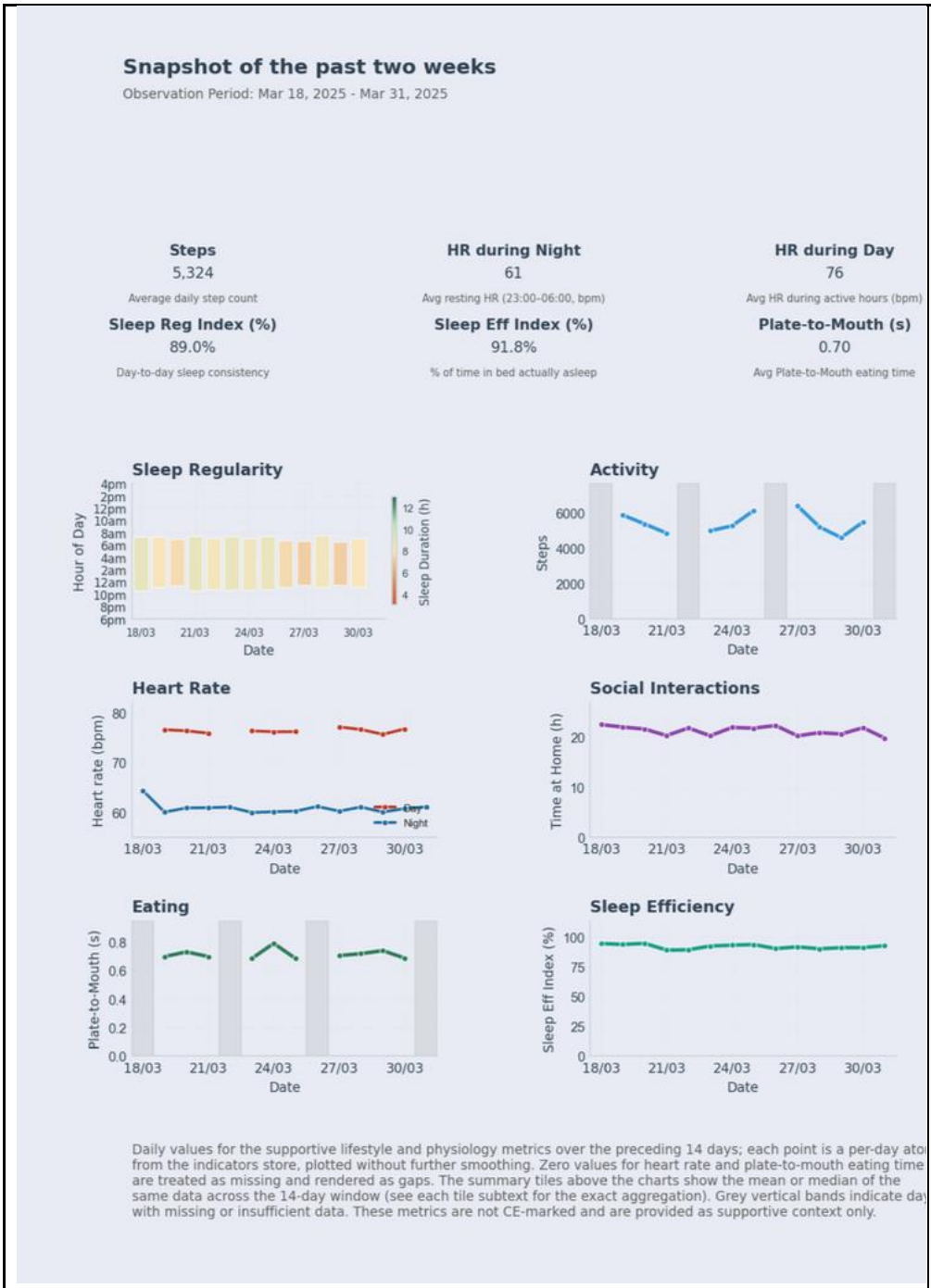
Daily aggregates of the three kinematic outputs across the 14-day snapshot, with stratified time-in-band analysis (1–2, 2–3, 3–4) for bradykinesia and dyskinesia over the active-hours window. The long-term panel shows the 7-day moving average and linear trend fit across the full observation period for each kinematic metric, displayed alongside the weekly UPDRS Part II self-report to support concordance review between passive digital measurement and patient-reported outcome. Grey vertical bands indicate missing or insufficient data.

5.4.2 Supportive digital health measures



Supportive digital health measures for sleep/walking/eating activity, heart-rate clock (median ± IQR across days), and a wake-event map over main nightly sleep sessions (≥3 h) with the fraction-of-nights curve per 0.5 h bin into sleep.

These measures are not validated kinematic measures and are provided as adjunctive context only; they are not intended to support clinical decisions.



Two-week summary of supportive digital health measures: average daily step count, nocturnal (22:00–07:00) and diurnal heart rate, Sleep Regularity Index (day-to-day timing consistency), Sleep Efficiency Index (% time in bed asleep), and Plate-to-Mouth interval as a feeding-rate proxy. Daily time-series panels accompany each summary value.

These measures are not validated kinematic measures and are provided as adjunctive context only; they are not intended to support clinical decisions. Grey vertical bands are used to mark the days with insufficient-data.

Full observation-period trajectories (7-day moving average with linear trend fit) for sleep duration, sleep efficiency, step activity, day- and night-time heart rate, time-at-home, and Plate-to-Mouth.

These measures are not validated kinematic measures and are provided as adjunctive context only; they are not intended to support clinical decisions.

6. Variants

There is currently one version of PARKIWATCH. The system is distributed as a unified software package comprising the third-party Android smartphone application, the cloud infrastructure and the healthcare professional dashboard. No hardware variants, configuration variants, or accessory components are supplied by Koios Care.

7. Labeling

The following symbols appear in PARKIWATCH product labeling and documentation.

Symbol	Meaning
	CE Mark – Conformity with EU Medical Device Regulation 2017/745.
	Manufacturer – Indicates the medical device manufacturer (ISO 15223-1, 5.1.1).
	Consult Instructions for Use – User must consult the IFU in all relevant cases (ISO 7000-1051; ISO 15223-1, 5.4.3).
	Medical Device – Indicates the product is a medical device (ISO 15223-1, 5.5.1).
	Unique Device Identifier – Carrier containing UDI information (ISO 15223-1, 5.7.10).
	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.

7.1 About Box

The PARKIWATCH About Box is accessible from within the application and displays the device name, software version, manufacturer details, and document reference number.

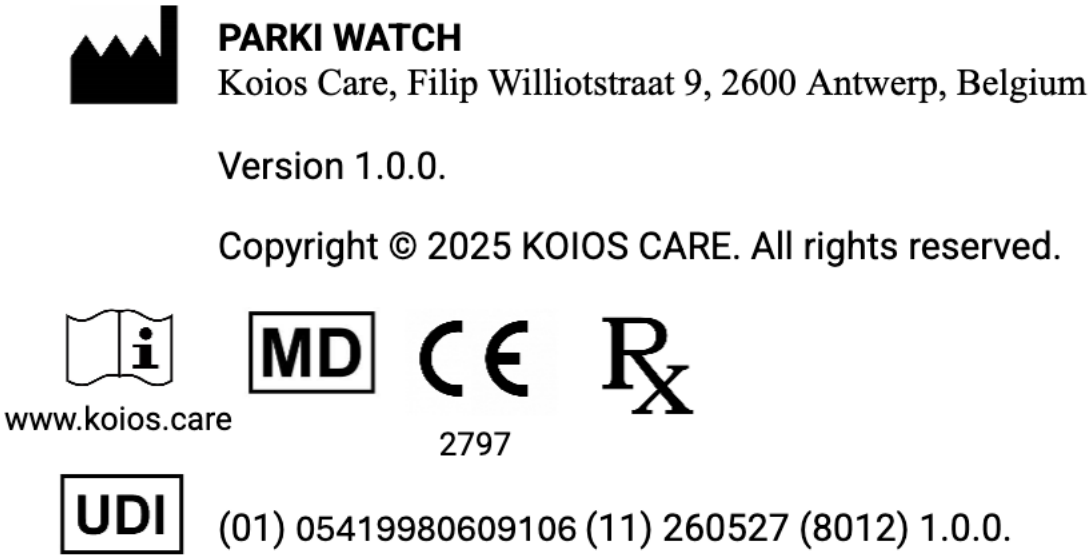


Figure 6.1-1: PARKIWATCH About Box displayed within the application.

8. Safety Instructions

Read these instructions for use carefully before operating PARKIWATCH with patients. This document must be accessible at all times in the clinical setting. Use PARKIWATCH only for the intended purpose described in Section 1.1.

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.

8.1 General Remarks

WARNING: PARKIWATCH is not intended to replace the health care professional's clinical judgment, to provide automatic diagnoses, or to automatically deliver or adjust therapies or treatments.

WARNING: The data provided by PARKIWATCH should not be the sole basis for therapeutic decisions. All treatment adjustments must be based on the health care professional's independent medical judgment in the context of a full clinical evaluation.

WARNING: Results are subject to limitations and may include false positives or false negatives. Always consider the full clinical context when making decisions.

CAUTION: Access to the healthcare professional dashboard account should be controlled. This account has access to patient health information (PHI). Ensure credentials are not shared and are protected in accordance with your institution's data security policies.

WARNING: PARKIWATCH is not intended for use in patients with atypical Parkinsonism.

WARNING: PARKIWATCH is not intended for use in patients with a medical disorder that prohibits continuous wearing of a third-party smartwatch or wrist-worn sensor device (e.g., bilateral arteriovenous shunts, severe dermatological conditions at the wrist site).

CAUTION: Skin irritation at the third-party smartwatch or wrist-worn sensor device contact site is a hardware issue related to the band or casing. If a patient reports irritation, advise them to stop wearing the device and consult the smartwatch manufacturer's guidance. Inform Koios Care support.

CAUTION: Data accuracy may be affected by improper third-party smartwatch or wrist-worn sensor placement, always consider the manufacturer of the device for proper placement on the wrist.

8.2 Side Effects

No direct side effects are associated with the PARKIWATCH software itself.

8.3 Training and Support

No training is required.

Accessing support: For any potential support on the use of the device contact support@koios.care.

8.4 Healthcare professional responsibilities

The healthcare professional is responsible for:

- Controlling access to the healthcare professional dashboard account and not sharing credentials with unauthorised individuals.
- In the event of a suspected breach, disconnect from the network and contact support@koios.care.

9. Uninstalling and Patient offboarding

When a patient is to be permanently removed from PARKIWATCH monitoring, the following steps must be followed to ensure complete removal of patient-related data:

The healthcare professional should:

1. Navigate to the patient's profile in the Healthcare professional dashboard.
2. Click Terminate Monitoring to immediately cease data sharing.
3. Contact support@koios.care to request permanent deletion of the patient's data from Koios Care cloud infrastructure, in accordance with GDPR Article 17 (right to erasure), if applicable.
4. Instruct the patient to uninstall the PARKIWATCH application from their Android smartphone.

10. Maintenance and Technical Parameters

10.1 Maintenance

PARKIWATCH is a SaMD. All server-side maintenance and security patching are managed by Koios Care. No manual installation or maintenance is required from the healthcare professional's side.

WARNING: Software updates to the PARKIWATCH Healthcare Professionals dashboard are managed automatically by Koios Care and require no action from the healthcare professional. After any update, verify that the dashboard is displaying patient data correctly and that reports are accessible before continuing clinical use with patients. If any issue is detected, contact support@koios.care before continuing clinical use.

10.2 Technical Parameters

Parameter	Value
Product class (EU MDR 2017/745)	Class IIa
Software version	1.0.0
Smartphone OS	Android 9.0 or higher
Connectivity	Bluetooth (phone–watch sync); Wi-Fi or cellular (cloud upload)
Cloud infrastructure	AWS – AES-256 encryption at rest and in transit (HTTPS/TLS)
Authentication	Email/password; role-based access control
Product lifetime	5 years from software version release
IFU document number	PARKIWATCH.IFU.EN.002
IFU revision	2.0

11. Regulatory 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)

12. Contact Information

Manufacturer

Koios Care BV

Filip Williotstraat 9

2600 Antwerpen, Belgium

Technical Support: support@koios.care

Product Complaints: info@koios.care

Website: www.koios.care

Product Complaints

Any healthcare professional who has any complaint or has experienced any dissatisfaction with the quality, durability, reliability, safety, effectiveness, or performance of this product must notify Koios Care 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 Care and to your national competent authority.

Appendix: Revision History

Version	Date of Issue	Author	Change Description
1.0	22/05/2026	Kyritsis Konstantinos	Initial release.
2.0	29/05/2026	Kyritsis Konstantinosyrits	Added UDI number in about box figure