



Parky



Welcome to the
Healthcare Provider Guide

v1.5.2



INDICATIONS FOR USE STATEMENT

The Parky App is intended to quantify kinematics of movement disorder symptoms including tremor and dyskinesia, in adults (45 years of age or older) with mild to moderate Parkinson's disease.

INTENDED AUDIENCE

This guide is intended for healthcare providers. The Parky app requires a prescription for access.

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Meet Parky

Parky is a remote monitoring tool designed for the continuous, objective assessment of Parkinson's Disease motor symptoms, like tremors and dyskinesia. It quantifies motion sensor data through the Apple Watch and delivers real-time symptom profile reports, supporting patient management.

Parky leverages the clinically validated Motor Fluctuations Monitor for Parkinson's Disease (MM4PD) algorithm developed by Apple Inc. (Powers et al., 2021¹)

For the clinical study report, please visit <https://pubmed.ncbi.nlm.nih.gov/33536284/>

Who is Parky intended for?

- Parky is intended only for clinically diagnosed idiopathic Parkinson's Disease users who are competent enough to use an Apple Watch and an iPhone.
- Parky works best for individuals who primarily experience tremor and dyskinesia symptoms.
- Parky is not designed to assess Parkinsonian syndromes such as Multiple System Atrophy (MSA), Progressive Supranuclear Palsy (PSP), Corticobasal Degeneration (CBD), or Lewy Body Dementia.

¹ Powers R, Etezadi-Amoli M, Arnold EM, Kianian S, Mance I, Gibiansky M, Trietsch D, Alvarado AS, Kretlow JD, Herrington TM, Brillman S, Huang N, Lin PT, Pham HA, Ullal AV. Smartwatch inertial sensors continuously monitor real-world motor fluctuations in Parkinson's disease. *Sci Transl. Med.* 2021 Feb 3;13(579):eabd7865. doi: 10.1126/scitranslmed.abd7865. PMID: 33536284.

A quick look at Parky

Innovative monitoring and assessment

Parky provides valuable insights by detecting tremors and dyskinesia at various stages of the disease. It collects accurate, all-day data on motor symptoms and allows for assessments anywhere, even outside of supervised settings.

Medication management and symptom insights

Parky ensures patients to stay on top of their medication with handy reminders on their iPhone and Apple Watch, and combines symptom reports with medication usage data. This blend provides clear, objective insights, aiding healthcare providers in detecting any changes in symptoms, thereby enhancing treatment plans.

Empowerment through technology

Parky integrates wearable sensors to offer a reliable alternative to patient diaries, addressing the subjective nature of self-evaluation and preventing data gaps commonly found in diary-keeping. This integration offers continuous, passive tracking, ensuring seamless monitoring of your patients' health.

Activity tracking and mobility support

Parky doesn't just monitor your patients' motor symptoms; it also tracks their daily steps, offering a window into their physical activity levels. Additionally, Foggy, an innovative feature in Parky, utilizes haptic feedback to support your mobility, which may contribute to an improved quality of life.

Meet Foggy - Haptic cue generation

We've integrated Foggy into Parky, an Apple Watch-based feature that generates haptic cues to support patients during freezing episodes. It aims to make movement easier, helping your patients to carry on with their daily life..

- Patients can activate haptic cues by tapping their Apple Watch, which then sends vibrations to prompt movement.
- Foggy is accessible only through prescription. With a prescription for Parky, patients can unlock this feature.



Foggy


How to Prescribe Parky for your patients?

1. As the initial step in considering a prescription for Parky, it is crucial to ensure device compatibility. Patients are strongly encouraged to download the Parky app from the App Store before the prescription process begins.
2. Healthcare providers (HCPs) are offered a convenient online platform, Parky Provider Portal, to prescribe Parky and track their patients' reports online
3. Healthcare providers can sign up on Parky Provider Portal by creating a provider account. In the account creation process, HCPs are required to provide their full name, email address, NPI, phone number, address and organization. Additionally, they must create a new password. Once the account is created, HCPs are required to confirm their email address by clicking the verification link sent to them.
4. Healthcare providers have the option to generate an e-prescription both for a new patient and/or for existing patients. To complete the e-prescription submission, HCPs are required to provide the relevant patient information that includes the correct mobile number of their patient.
5. Healthcare providers have the flexibility to specify the number of refills for the prescribed Parky app. Additionally, they are encouraged to communicate with their patients about the prescribed application and assure them that they will be kept informed by the Parky team, regarding the prescription.

The registration process is shown in three sequential screenshots:


- Step 1: Create A Provider Account**
This screen shows a progress bar with 'Account setup' as the active step. It includes a 'Submit' button and a 'Log In' link for existing users.
- Step 2: Welcome here!**
This screen shows a progress bar with 'Practice information' as the active step. It contains a 'Sign Up!' button.
- Step 3: It's Verify Your Email**
This screen shows a progress bar with 'Account activation' as the active step. It contains instructions to check email for a verification link.

Follow the steps and create a provider account in **Parky Provider Portal**

 Once your account has been created, click the **"Create New Prescription"** button to submit an e-prescription for your patient.

The dashboard shows the following elements:

- Header:** Parky Clinician / dev, Home icon, 'Your Prescriptions' title, and '+ Create New Prescription' button.
- Message:** 'Welcome To Parky HCP Portal!' with a checkmark icon and text: 'You have successfully completed your sign up. You may now start prescribing Parky to your patients by clicking on the "Create New Prescription" button below.'
- Section: Your Prescriptions**
Text: 'You can see the list of prescriptions that you have created on this page.'
Text: 'To create a new prescription, click on the "Create New Prescription" button that is on the top-right corner of this page.'
- Action:** '+ Create New Prescription' button.
- Footer:** 'Once you have created one or more prescriptions, you will be able to list them here.' and 'Archived Prescriptions' link.

 Clinician / dev

Your Prescriptions / Create New Prescription

Your Prescriptions

Create New Prescription

You may use this page to create a new prescription for your patients.

Prescribe For A New Patient
 Prescribe For An Existing Patient

Patient Information

| | |
|----------------------|----------------------|
| First Name | Last Name |
| <input type="text"/> | <input type="text"/> |
| Mobile Phone | Email |
| <input type="text"/> | <input type="text"/> |
| Gender (at birth) | Date of Birth |
| <input type="text"/> | <input type="text"/> |

Contact Address

Address

City

State

Zip Code

Prescription Information

Refills

Patient has been informed about and provided consent to receive communications regarding their Parky4Parkinsons prescription via email, SMS and / or phone call.

[Cancel](#) [Create Prescription](#)

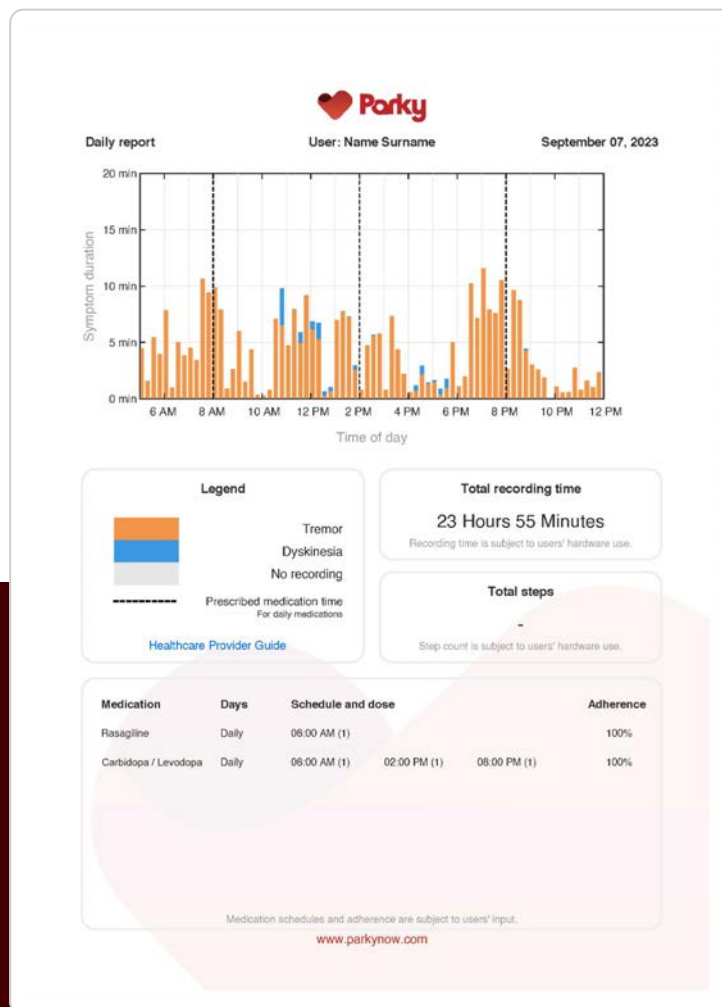
Eric Clarkson
Logout



Submitted prescriptions will be verified by the authorized online pharmacy. Upon prescription confirmation, the patient will be notified via a text message and they will be sent verification code to log in to their account. Given that communication will be facilitated through a text message, ensuring the accuracy of the patient's mobile number is highly important.

Making the most of symptom profile reports

1. When a patient starts using Parky, their reports are automatically uploaded to the Parky Provider Portal.
2. Healthcare providers can access Parky Provider Portal at any time.
3. Each report includes tremor and dyskinesia charts, daily activity(step counts), recording time and if provided by the patient, the medication adherence information.
4. It's essential to note that reports cannot be generated by Parky until a sufficient recording time has been reached.

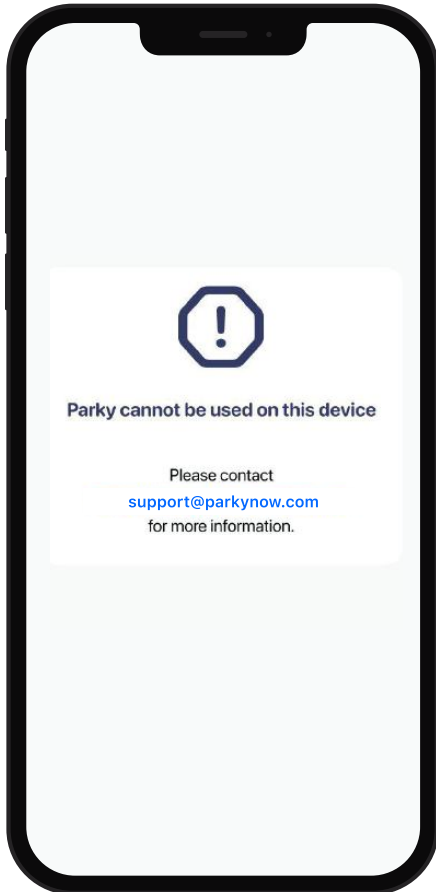


[Click here to full page preview](#)

Support and troubleshooting

1. In case you need support, go to the "Support & Troubleshooting" section in the "Profile" tab, click "Send Support Request," describe your issue briefly, and send us your request.
2. You can reach out to us about a variety of issues, including but not limited to:
 - Questions about using the Parky app or hardware
 - Issues with recording symptoms
 - Issues with payments

IMPORTANT IN-APP WARNING



Upon initialization, Parky conducts a verification process for any MM4PD version changes and confirms device compatibility to ensure the secure and efficient operation of its functions.

Should an error screen, as displayed to the left in the Parky application, emerge, this signifies that Parky is incompatible with the current device, operating system, or software version.

HARDWARE AND SOFTWARE REQUIREMENTS

Parky is supported on:

- Apple Watch Series 3 (and newer) devices with WatchOS 8+.
- iPhone 6s (and newer) devices with iOS 15+.

CLINICAL INTERPRETATION OF REPORTS

1. Each report includes data on motor fluctuation symptoms, recording time, and steps counted. If the user logs in to the medication plan and provides information on taking the medications, adherence can also be seen.
2. In the symptom report, the x-axis indicates the time, and the y-axis indicates the symptom duration.
3. The legend for tremor, dyskinesia, no recording times, and prescribed medication times are shown under the graph.
4. Symptoms are collected and measured throughout the recording time and are provided in the graph at 15-minute intervals.
5. The reported symptoms are the mean symptom durations of dyskinesia and tremor.
6. The reports exclude data that are unlikely to represent any motor symptom. An empty bar chart is expected for an asymptomatic user or a user lacking any recording.
7. Recording time indicates the total time the user has used the device correctly and that there were no technical issues regarding symptom monitoring. Please refer to the "Limitations" section.
8. Without sufficient recording times, no reports will be generated, as indicated above.
9. Dashed lines indicate the scheduled medication times.
10. Medication adherence information shows the number of "taken" medications over the number of scheduled medications for a given time interval (weekly as the last seven days or monthly as the last 30 days). "Taken" medications are calculated based on user input.
11. Step count information indicates the user's mobility and is shown as the total amount within a given time interval (daily, weekly, or monthly).

THE USE OF COLLECTED DATA

Remote monitoring of tremor and dyskinesia symptoms provides the healthcare provider with an objective view of the user's motor symptoms of Parkinson's Disease while outside of the clinic. When evaluated with non-motor symptoms, user insights, and in-clinic visit findings, Parky supports patient management. In addition to symptom monitoring, steps and medication adherence data helps indicate user mobility and treatment efficacy.

GENERAL INSTRUCTIONS

1. Users must wear the Apple Watch on their most affected arm at all times.
2. Charging the Apple Watch is recommended during user's inactive hours (Preferably during night sleep).
3. Parky cannot monitor symptoms when the Apple Watch is not worn which would cause data gaps.
4. Without sufficient recording times, Parky will be unable to generate symptom reports. Please see the "Limitations" section for more information.
5. Parky App should not be deleted either on the iPhone or on Apple Watch.
6. Users should enter the correct medication schedule to ensure the reliability of medication adherence outputs. Medication scheduling is recommended to be set up in a clinical environment if the user or the caregiver can not do it alone.
7. Users should respond to medication reminders in a timely and correct manner.

LIMITATIONS

1. Parky operates under the following constraints:

- Parky only operates on Apple Watch and iPhone using the MM4PD algorithm developed by Apple.
- Parky does not operate on unsupported devices.
- Parky is advised to be used for idiopathic Parkinson's Disease, and not to be used on other Parkinsonian syndromes such as progressive supranuclear palsy (PSP), multiple system atrophy (MSA), Lewy, and corticobasal degeneration (CBD).
- The user should wear the Apple Watch on the most affected arm.
- Dyskinetic symptom tracking should be considered only for users with chorea on the affected arm, either self-reported or diagnosed by a healthcare provider.
- Parky explicitly tracks resting tremor; it does not track action tremor or postural tremor, and it may not track finger tremor.
- Parky does not explicitly track dystonia or bradykinesia.
- The results may include false positives and false negatives. The user's activity, watch band fit, and concomitant conditions (such as restless legs syndrome and non-Parkinsonian tremor) can affect the quality of the results.
- Parky only explicitly measures symptoms from the wrist while wearing the Apple Watch. However, Apple Watch may sense symptoms transmitted through the body from other affected body parts, possibly resulting in misleading or false metrics.

2. Parky cannot collect data when Apple Watch is turned off and cannot transmit data when iPhone is turned off.

3. Without adequate recording durations, Parky will not be able to generate symptom reports. The reports are generated utilizing the following methodology:
 - Intervals of fifteen minutes, covering the entire duration of the recording, are organized according to the user's local time.
 - Intervals with less than 50% of the required data are excluded.
 - The weekly and monthly reports display the mean tremor and dyskinesia symptom durations from all days with data.
 - In the weekly and monthly reports, only the intervals with data collected from at least five days or representing over 20% of the total period are displayed.
4. Medication schedules are subject to the correctness of data entered by the user. If the user has difficulties in using the app, it is strongly advised to provide support in-clinic settings.
5. The accuracy of medication adherence information relies on the user's prompt and accurate response to medication reminder notifications. Failure to respond or providing inaccurate interactions may lead to incorrect medication adherence outputs. To mitigate this risk, healthcare providers are strongly encouraged to emphasize the crucial importance of accurate reminder responses to users.
6. The step information relies on the user's consistent use of both Apple Watch and iPhone. Parky cannot collect step data if the user is not utilizing either of these devices.
7. Specific to Foggy: Haptic cueing sessions are restricted to a maximum duration of 10 minutes. To maintain uninterrupted cueing sessions, users should avoid sending the app to the background, minimizing view changes, and refraining from app termination, as these actions will halt the sessions.

9. If users would like to stop using Parky, they can cancel their prescription. Upon prescription cancellation, the user is considered as a dropout, and the prescription is immediately switched to an invalid state. Users maintain access to the app to review their existing information and previous reports. However, post-cancellation, the app will not generate new reports. Additionally, the prescribing healthcare provider loses access to the user's Parky reports. A new prescription will be required for the user to restart using Parky.
10. If users would like to stop using Parky permanently, they can permanently delete their account. Upon account deletion, the user is considered as a dropout, and the health and personal data of the user will permanently be removed. Both the user and healthcare provider will lose access to the user's Parky reports.

SAFETY

1. The use of Parky and Apple Watch does not affect users with Deep Brain Stimulation (DBS) implants.
2. Apple Watch is water-resistant but not waterproof. It can be worn and used during exercise (exposure to sweat is OK), in the rain and while washing hands.
3. Please refer to the original manufacturer document regarding the user manual and guides for Apple Watch hardware user manual:
https://help.apple.com/pdf/watch/8/en_US/apple-watch-user-guide
4. Guide for Apple Watch: <https://support.apple.com/en-us/HT204665>
5. Apple Watch conforms to the following EMC and Electrical Standards: Electrical safety was assessed according to IEC 62368-1 (2014), "Audio/video, information and communication technology equipment – Part 1: Safety requirements." Apple Watch conforms to EU standards EN 301 489-1 (V2.2.20), EN 301 489-3 (V2.1.1), EN 301 489-17 (V3.2.0), and EN 301 489-52 (V1.1.0).

GENERAL WARNINGS AND PRECAUTIONS

- The Parky App is to be used and interpreted only by trained healthcare providers or technicians.
- Do not use the Parky App for any purpose other than to record the movement of a patient with a movement disorder.
- The Parky App is intended only as an aid to existing clinical methods. It is not intended to be the sole or primary means of clinical assessment.
- h2o therapeutics does not recommend employing the Parky App for patients who lack the capability to interact with either the Parky App on iOS or WatchOS.
- Non-motor findings, patient insights, and in-clinical visits should always be involved in decision-making.
- It is strongly advised to compare Parky results with clinical findings and patient reported insights.
- At initial use to verify data flow consistency, patient results are recommended to be observed closely for 3 to 5 days per patient. This period would also allow the detection of any technical issues.
- Patients should be advised to wear the Apple Watch on the most affected arm.
- Patients or caregivers are encouraged to input the medication schedule. If the patient is unable to do so independently or with the help of their caregivers, healthcare providers are recommended to offer assistance in clinic settings.
- Patients should not self-evaluate their disease progress solely with Parky app data.
- In case of Parky App failure, patients should take medication as prescribed.
- There is no implied drug evaluation by the Parky App.

DATA SECURITY

1. Parky collects motion data only when the user wears an Apple Watch.
2. Besides motion data, Parky does not collect heart rate, voice, mobile & phone activities, screen, or app usage data.
3. User data can only be shared with the prescribing healthcare provider for whom the user or caregiver provided consent and can only be shared with one healthcare provider at a time.
4. User data, including personally identifiable information, is stored on HIPAA compliant servers using Advanced Encryption Standard (AES256). User data is never shared with a third party except for authorized healthcare provider.
5. It is advised to install a mobile security software to further ensure the security of the device.

ADVERSE EVENTS

1. If the user's symptom reports do not match healthcare provider expectations, immediately stop using Parky during clinical practice.
2. In case of any suspected miscalculations, technical problems, and other events, contact support@parkynow.com

MANUFACTURER CONTACT



h2o Therapeutics

Mustafa Kemal Mah 2119 Sok. No 3
Cankaya / Ankara/ Turkey

+903122196219

support@parkynow.com

Rx only