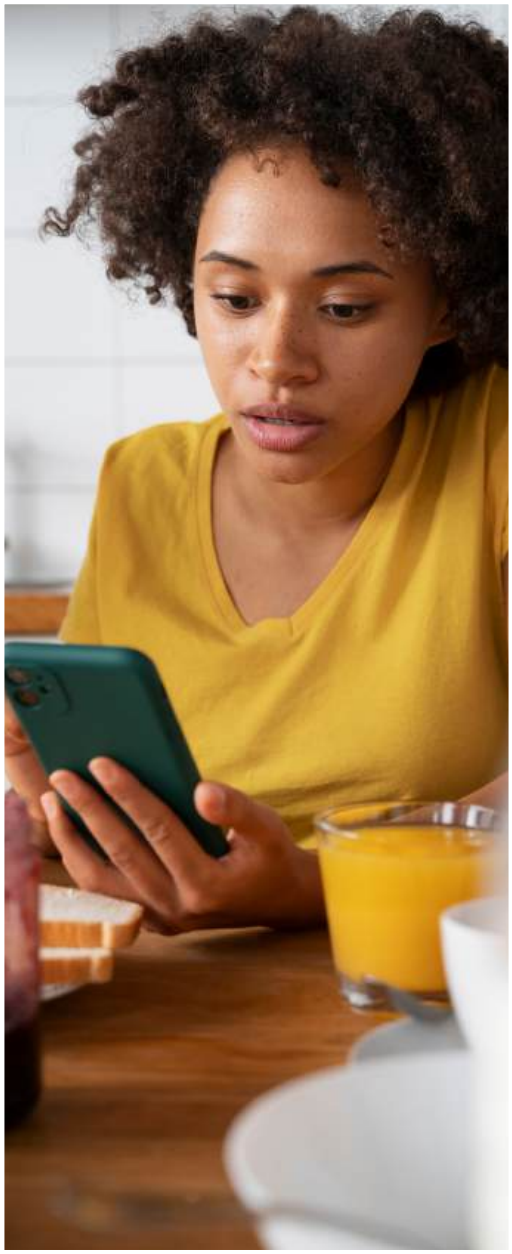
Parky

Welcome to the

# Parky User Guide

v1.5.14



# 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 user guide is intended for Parky app users. The Parky app requires a prescription for access.

If you are a healthcare provider in search of detailed information about the Parky app, please consult the Parky Provider Guide at https://parkynow.com/parky-provider-guide. The Parky Provider Guide is tailored to meet the specific needs of healthcare providers.

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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., 2021 [1])

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 TranslMed. 2021 Feb 3;13(579):eabd7865. doi: 10.1126/scitranslmed.abd7865. PMID: 33536284.*

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# 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 you stay on top of your medication with handy reminders on your 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 you 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 health.

## Activity tracking and mobility support

Parky doesn't just monitor your motor symptoms; it also tracks your daily steps, offering a window into your physical activity levels.

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# Getting started with Parky

Download on the App Store

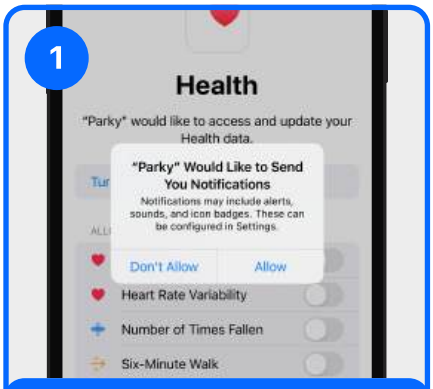
Scan the QR code with your iPhone's camera and follow the pop-up to download Parky from the App store.

You're encouraged to download the Parky app from the App Store to check device compatibility before getting a prescription.

## Granting permissions

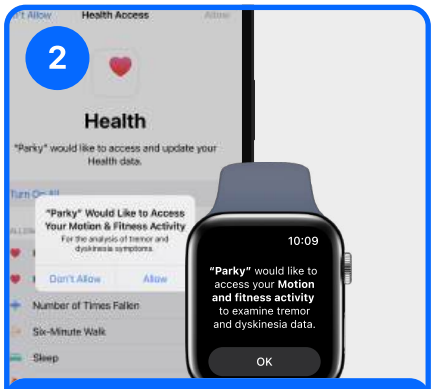
You'll need to grant permissions through the prompts shown below for Parky to function properly. These permissions allow Parky to send notifications and access data for steps, as well as motion tracking for tremor and dyskinesia analysis.

Parky relies on these permissions to provide you with complete insights into your physical activity, symptoms, and medication adherence.



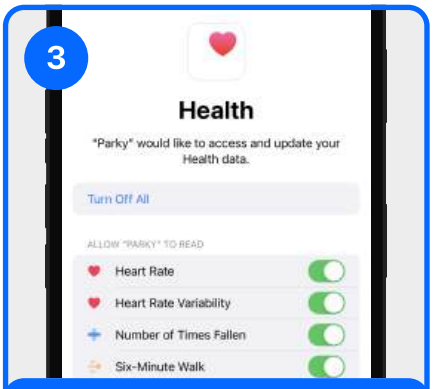

**Notification access**

This permission allows you to receive reminders and updates from Parky. Without it, you won't get notifications for medication schedules and updates.




**Motion data access**

Granting this permission enables Parky to track your movement, which is crucial for monitoring symptoms like tremors and dyskinesia.




**Health data access**

By allowing access to your Health data, Parky can provide insights about your physical activity levels.

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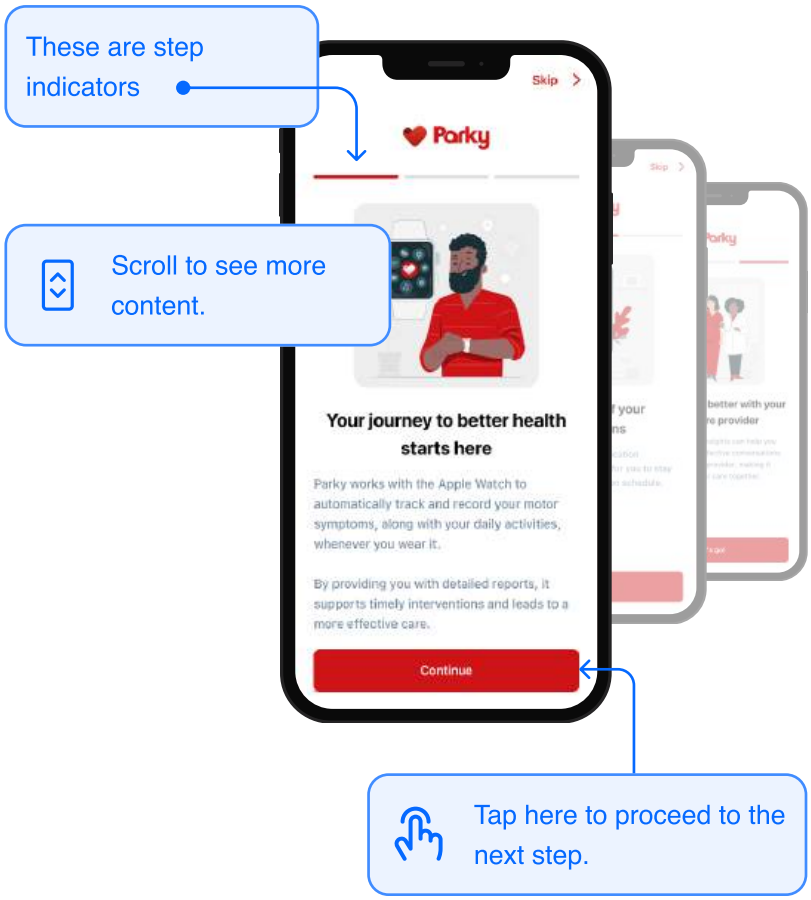
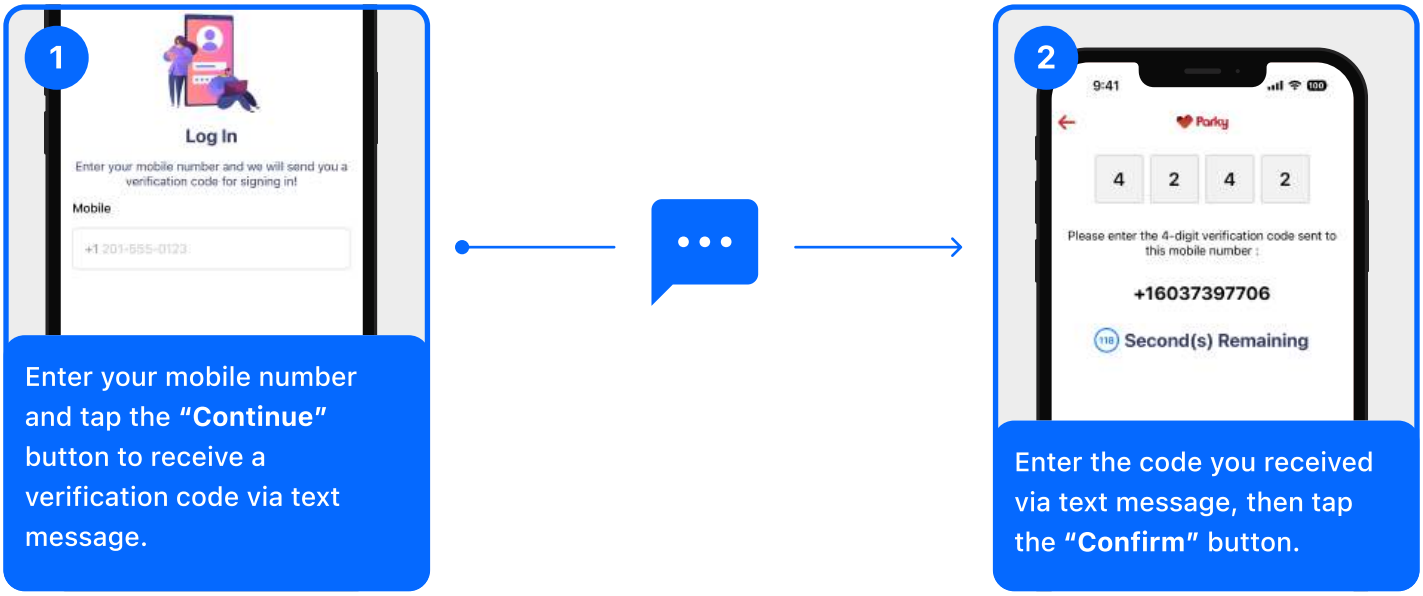
## Onboarding

You'll start with an onboarding process that covers how to use Parky, important safety information, and how we protect your data.




## Logging in

Upon onboarding, you'll enter your mobile number and receive a verification code via text message. **Make sure to use the mobile number provided on your prescription.**

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# Setting up the watch face complications

Follow the steps below to add Parky to watch face complications. Parky can only monitor motor symptoms when watch face complications are added.

1

Tap and hold on the screen.

2

Tap **“Edit”.**

3

Swipe left until the **“Complications”** title appears and select any slot.

4

Scroll until **“Parky”** appears, then tap.

**Parky** complication added.

**Done**

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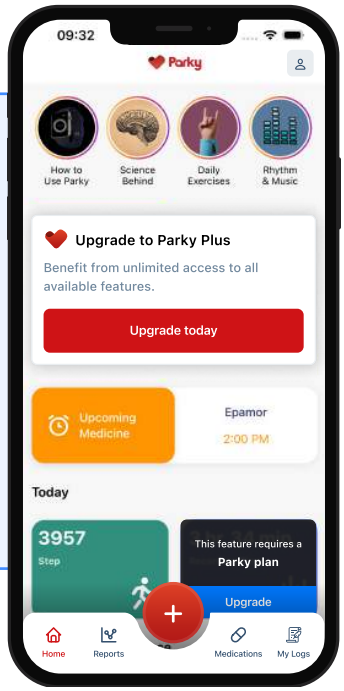
# Inside Parky

## Home screen

The home screen of Parky offers a user-friendly dashboard where you'll find reminders for upcoming medications, track your daily steps, monitor recording times, and view weekly and monthly medication adherence information. Plus, you'll have access to a hub of resources for further information.

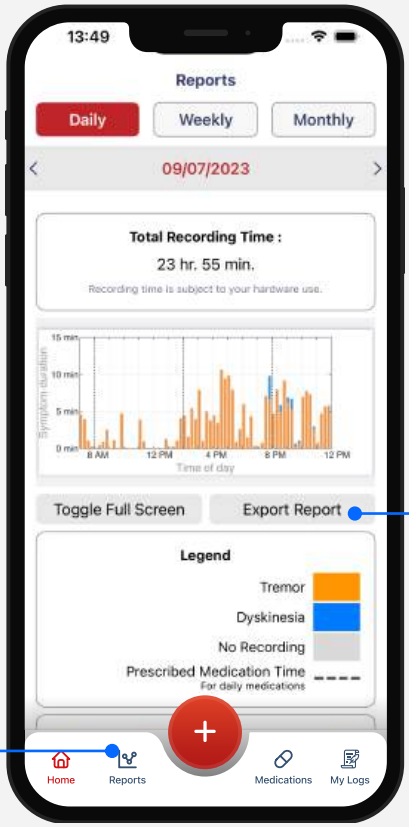



## Accessing the reports

Available with **Parky Plus**

Reports will be shown as daily by default.

View your symptom reports on the “Reports” tab.




Select the tab menu to view weekly and monthly reports, including retrospective dates.

Tap the export button to download a specific report as a PDF anytime.

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Available with **Parky Plus**

These reports will be accessible to your prescribing healthcare provider through the Parky Provider Portal. They include tremor and dyskinesia charts, medication adherence data, step counts, and recording times for a given period.

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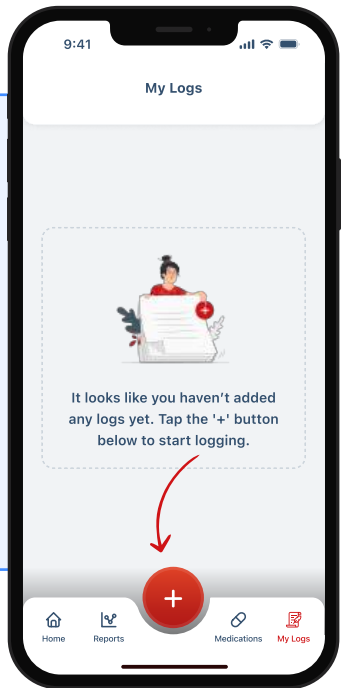
## Logging

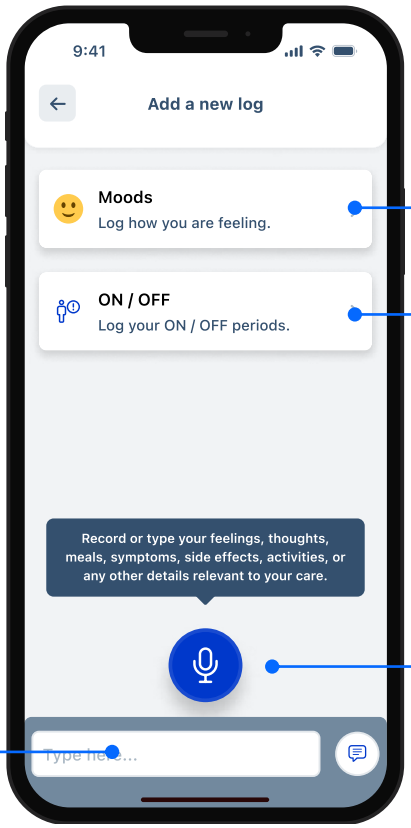
You can easily record how you're feeling throughout the day. Helps you stay in tune with your emotional state and build a better understanding of your moods over time. Start tracking your emotional patterns today to enhance self-awareness and support personalized care.




## Adding Logs

You can log your Mood, On/Off periods or free custom log relevant to your care.

Tap log any details you want with typing.




Mood selection.

On / Off selection.

Tap log any details you want with voice record.

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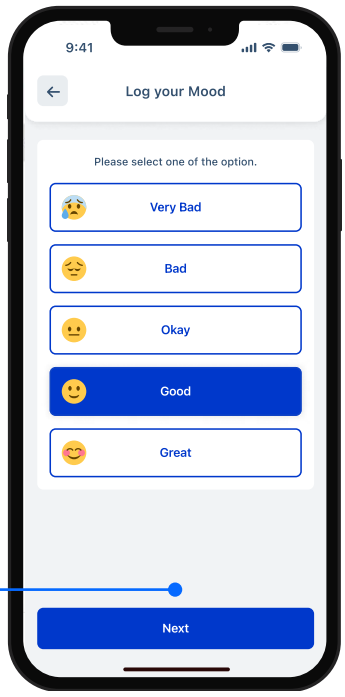
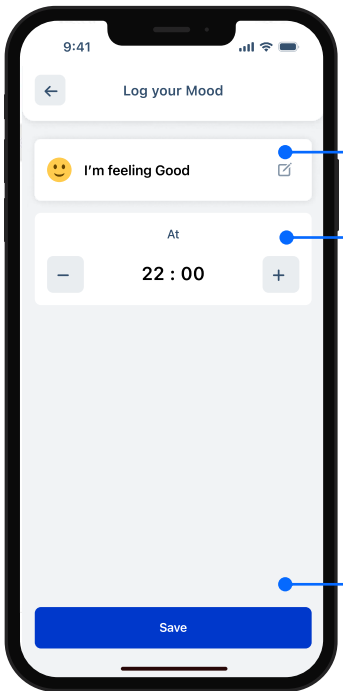
# Moods

Select the most suitable option for you

Tap Next to adjust your time settings.




You can edit your previous settings by tapping here.

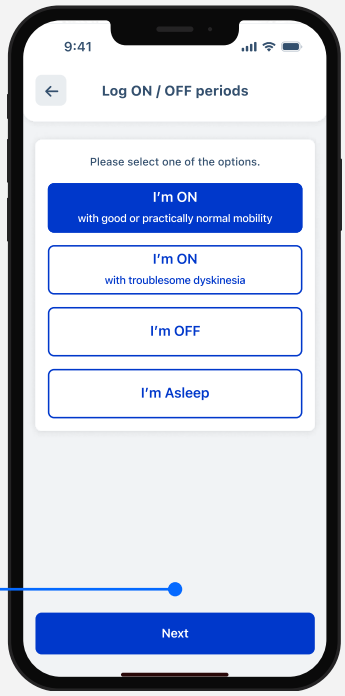
Adjust your time of your log.

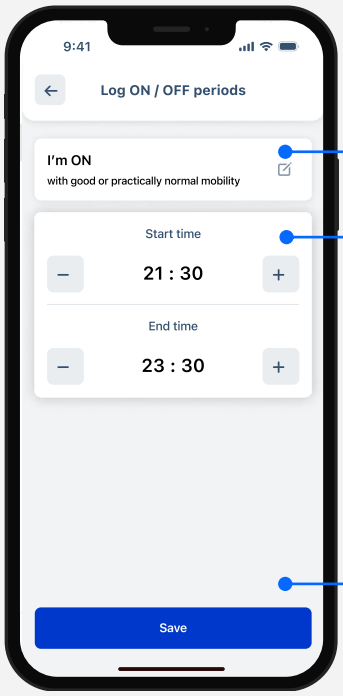
Tap Save to record your log and preview it in "My Logs" tab.

# On / Off Periods

Select the most suitable option for you

Tap Next to adjust your time settings.




You can edit your previous settings by tapping here.

Adjust your time of your log.

Tap Save to record your log and preview it in "My Logs" tab.

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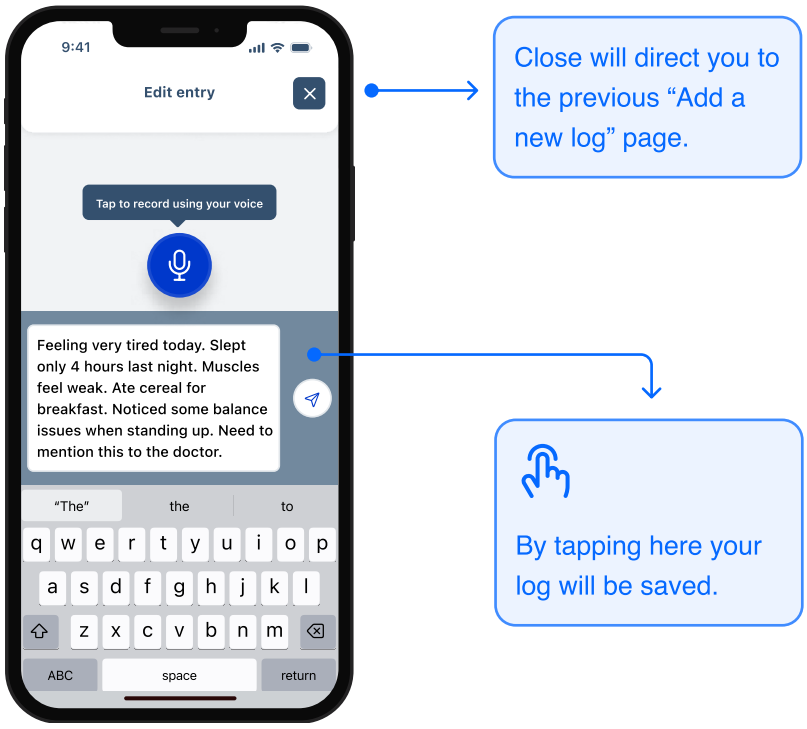
# Custom Log

## with Text

You can type freely about your feelings, thoughts, meals or any details you think it is important to log.

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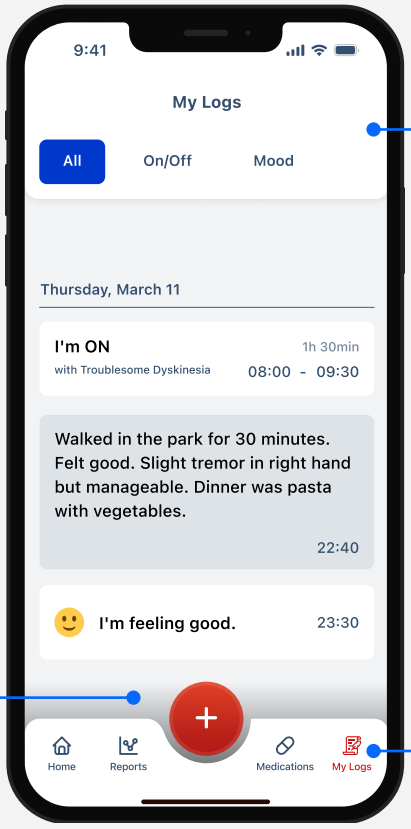
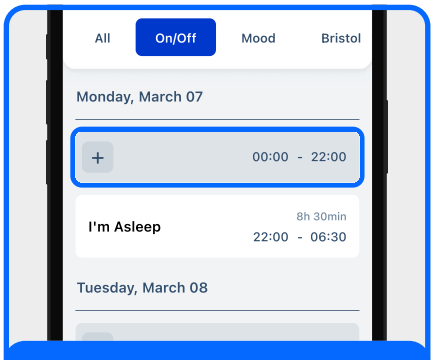
# My Logs



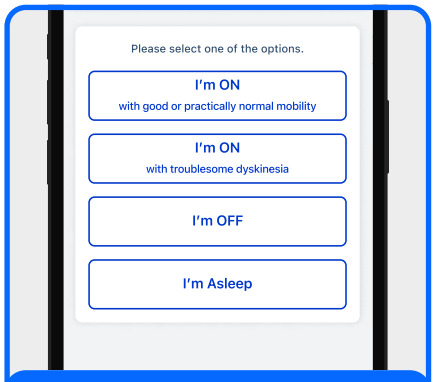

You can filter the preview of your feed.

You can start adding your logs by simply tapping “Plus” icon.

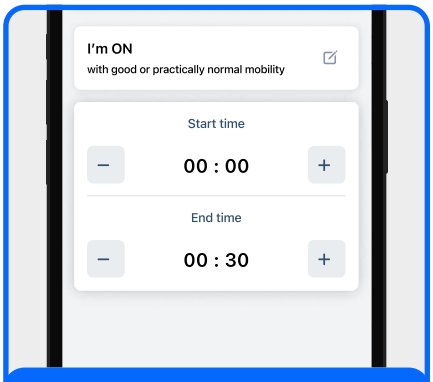
You can preview your logged items as a feed from “My Logs” in the navigation.




In categories where continuity is important you can easily spot your missing entries




You can start filling your missing entries by tapping them.




It will automatically start it with the beginning of your absent time.

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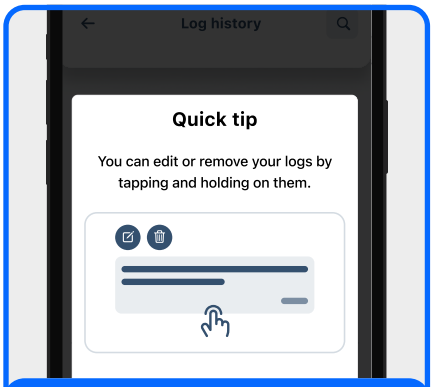
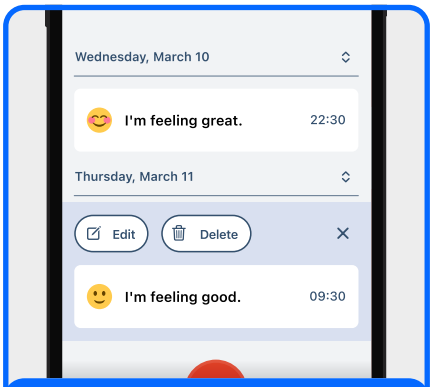
# Editing your logged items

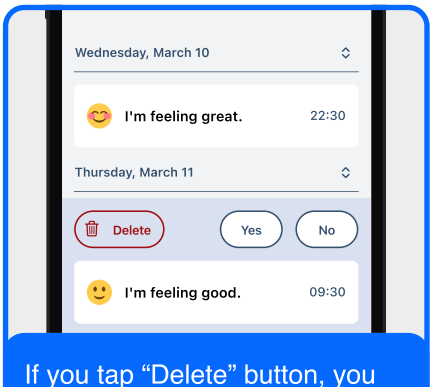
**Start by tap and holding the logged item you want to edit.**



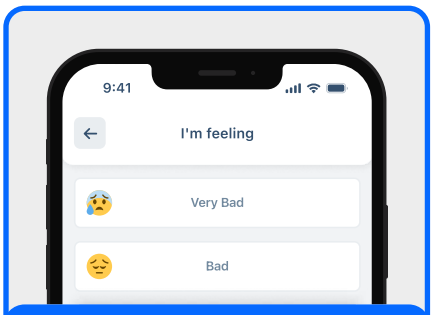

You can edit your logged items by tapping and holding on them.




You can either edit your log or delete them from the overlay menu.




If you tap “Delete” button, you will be asked to confirm your action. Because it will delete the log permanently.




If you tap the 'Edit' button, you will be directed to the same page, just like when you added it before.

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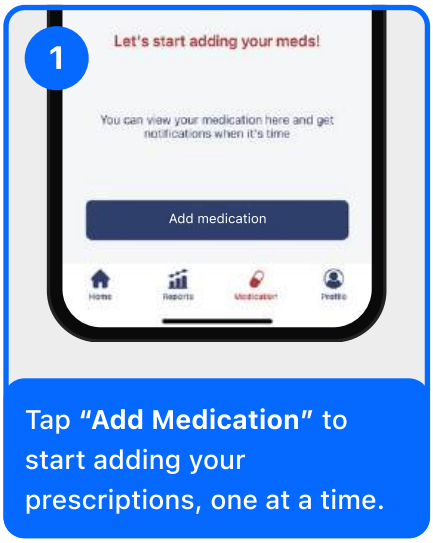
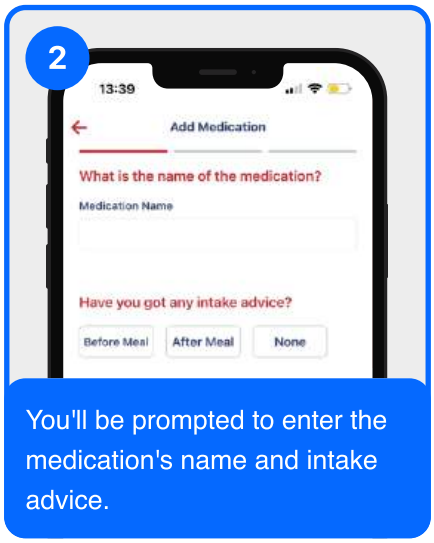
# Setting up your medication schedule

You'll need to enter your correct medication schedule to make the most of Parky. If your treatment plan changes, you can edit or remove your medication schedule at any time.

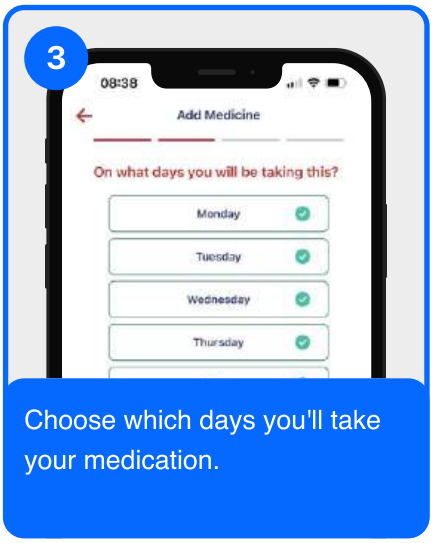
**Start by tapping "Medication" in the bottom menu.**



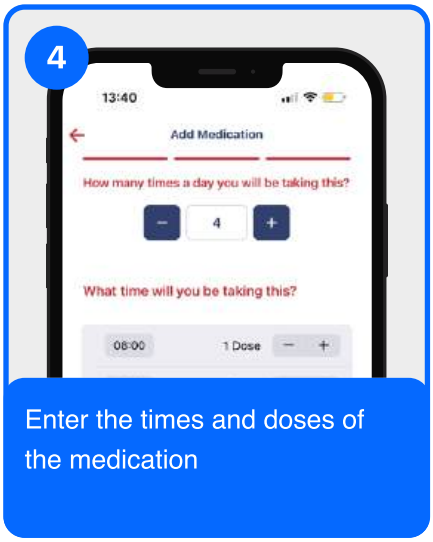

Tap **"Add Medication"** to start adding your prescriptions, one at a time.



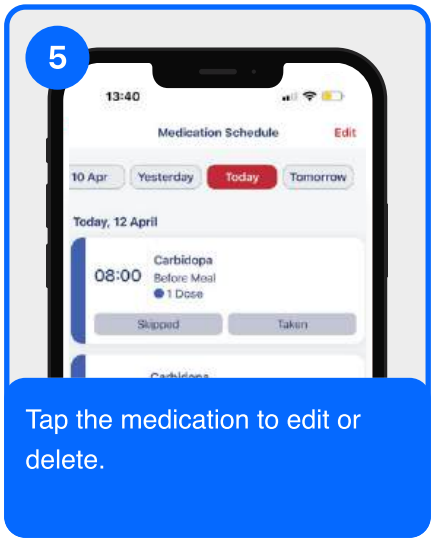

You'll be prompted to enter the medication's name and intake advice.



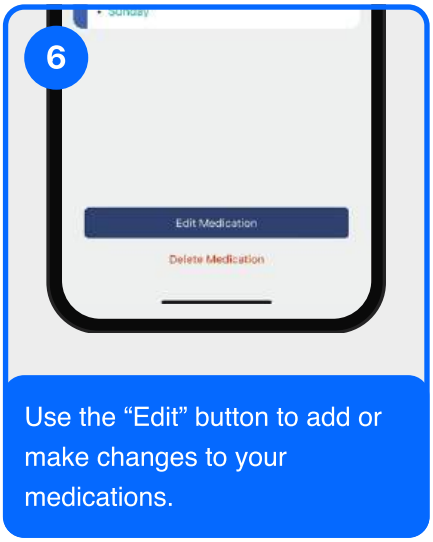

Choose which days you'll take your medication.




Enter the times and doses of the medication




Tap the medication to edit or delete.




Use the "Edit" button to add or make changes to your medications.

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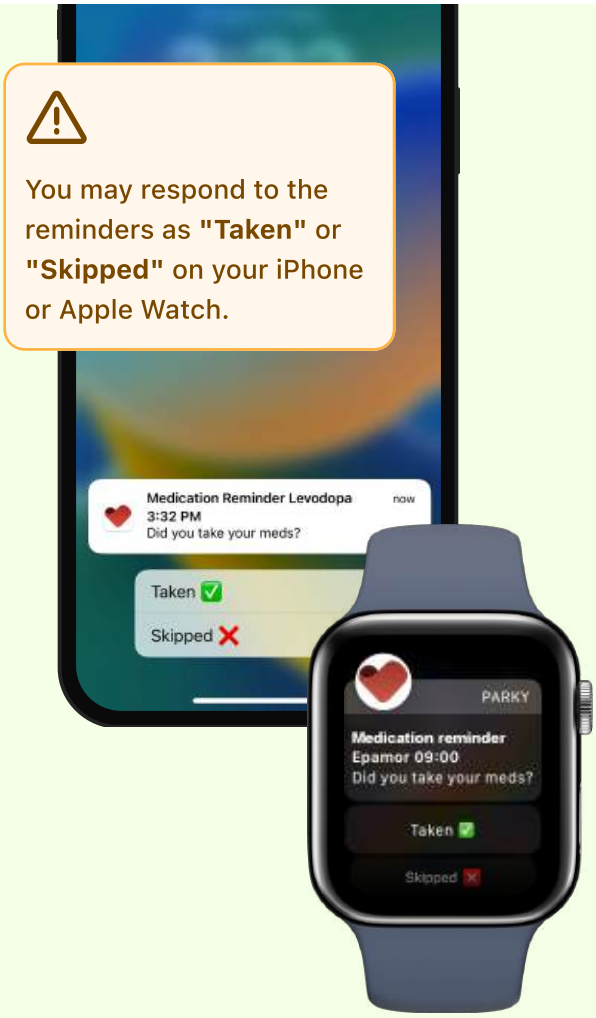
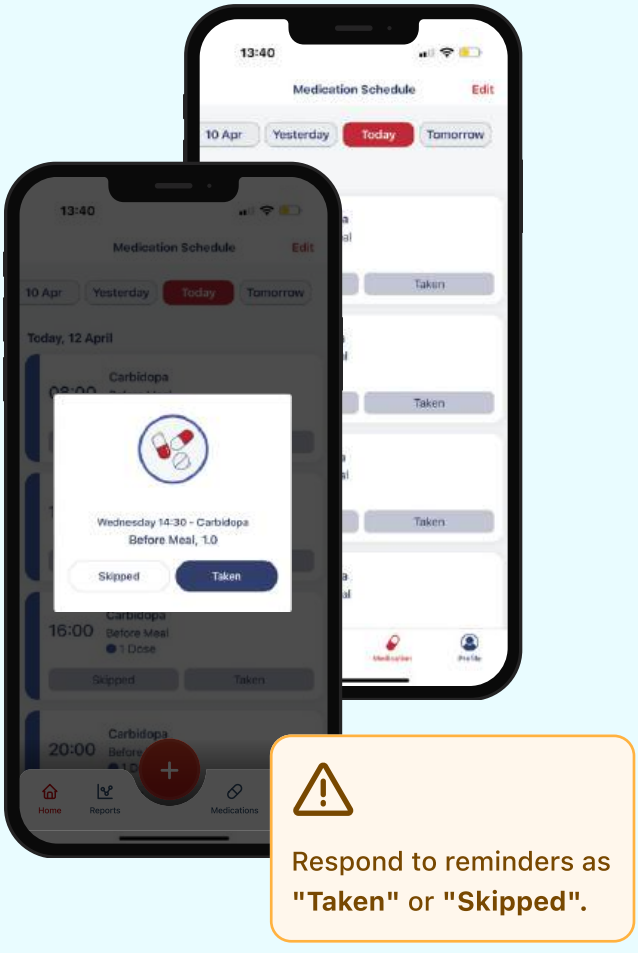
# Using medication reminders

- You'll receive reminder notifications based on the days and times set in your medication schedule.
- You can mark your medication as **“Taken”** or **“Skipped”** on your iPhone or Apple Watch.
- If you miss responding to a notification, you can still respond later via the "Medication" tab.
- To ensure that your medication adherence information is accurate, it's important that you respond to medication reminders promptly and correctly

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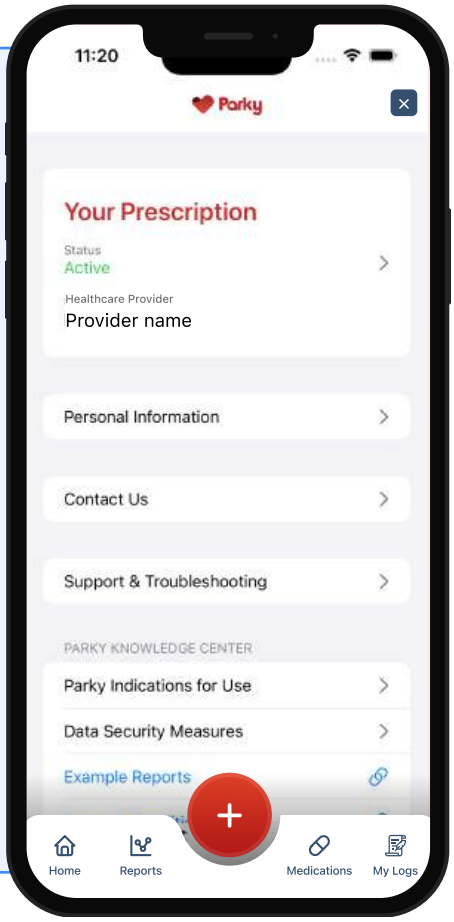
## Profile screen

- You can view your status, prescribing healthcare provider's details, personal information, and time zone in the **"Profile"** tab.
- You can contact us for help or find solutions to common problems in the **"Contact Us"** and **"Support & Troubleshooting"** sections.
- Don't miss our **"Knowledge center"** on the same tab, where you'll find important information about Parky, how to keep your data safe, sample reports, and our terms and conditions along with the privacy policy.




## 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

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# Parky Plus

Parky Plus is a premium membership of Parky that offers advanced features to enhance your experience and provide more detailed insights into your condition. To access Parky Plus, you'll need a prescription. Once you get your prescription from your clinician, you're ready to upgrade your Parky Starter membership to Parky Plus.

## Exclusive benefits of Parky Plus

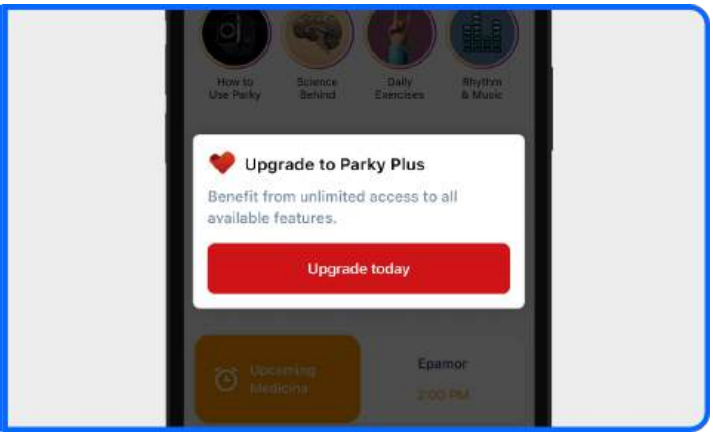
Upgrading to Parky Plus unlocks a suite of advanced features to help you better manage and understand your symptoms. These include:

**Tracking dyskinesia and tremor:** Detect and track tremors and dyskinesia throughout the day, offering valuable insights into the stages of the disease.

**Daily reports:** Receive comprehensive daily reports to track your symptoms, helping you and your healthcare provider stay informed.

**Access to report history:** Review your historical data to track changes over time, better understand your condition, and identify patterns over time.

To enjoy these exclusive benefits, simply tap **"Upgrade today"** after getting your prescription.

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# Setting up your prescription

1. Once your healthcare provider prescribes Parky for you, you'll receive a welcome text message. After getting this message, you can proceed to the payment process.

2. To start the payment process, verify the healthcare provider's information on the screen. By clicking the confirmation button, you confirm your consent to share your data with the healthcare provider and agree to the terms and conditions, including the privacy policy.

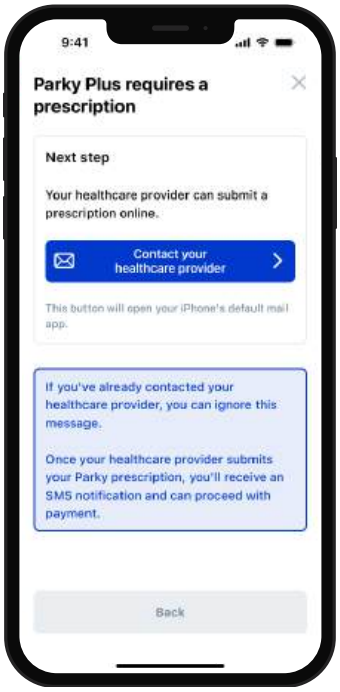
3. After confirming your information and the disclaimer, you'll see various payment options to access Parky for 3, 6, 9, or 12 months, based on your available prescription refill amount. Simply choose the plan that suits you best.

4. After selecting your option and clicking the “Start my journey” button, you'll move to the purchase screen from Apple Inc.

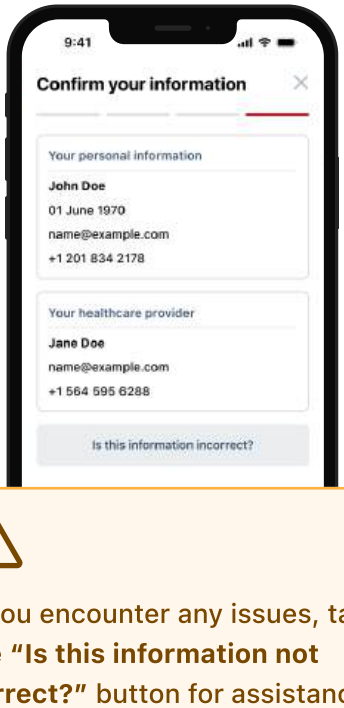
5. Follow the provided instructions to complete your payment.

1 — 2 — 3

**Request Rx**

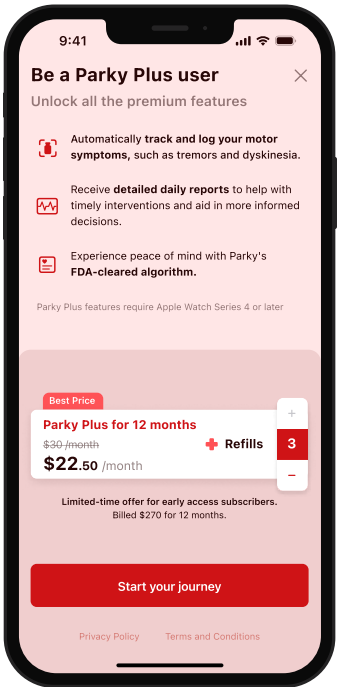



**Activate your Rx**




If you encounter any issues, tap the **“Is this information not correct?”** button for assistance.

**Proceed to Payment**

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# Managing your prescription

- A prescription in Parky is valid for three months.
- Each prescription includes a specific number of refills, and each refill extends the validity of Parky prescription for an additional three months.
- You'll start getting a reminder on your home screen 28 days before your prescription or refill expires to ensure you don't miss out on Parky.
- To keep using Parky, you'll need to refill your prescription or request a new prescription from your healthcare provider if you've used all your refills.

*If you'd like to cancel your prescription, tap the "Your Prescription" button on the "Profile" screen, and then tap the "Cancel Prescription" button. When you cancel your prescription, you'll be considered as dropout, your prescription will become invalid immediately, and your healthcare provider will no longer have access to your Parky reports.*

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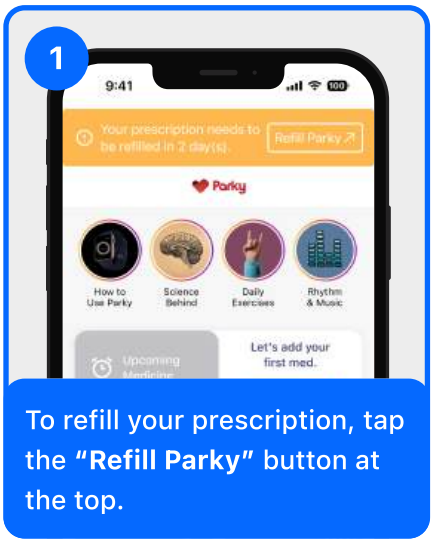
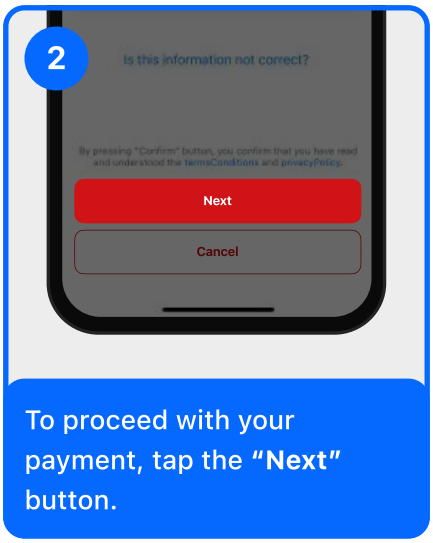
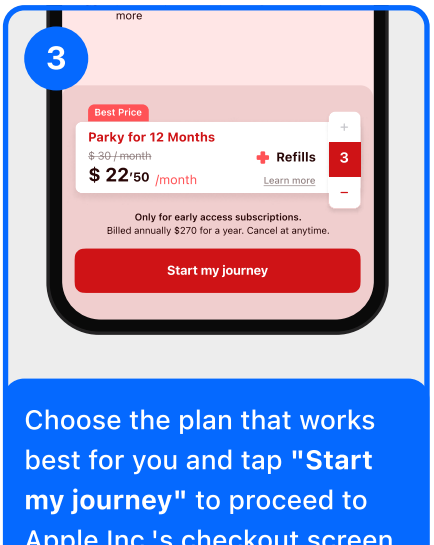
# Refilling your prescription



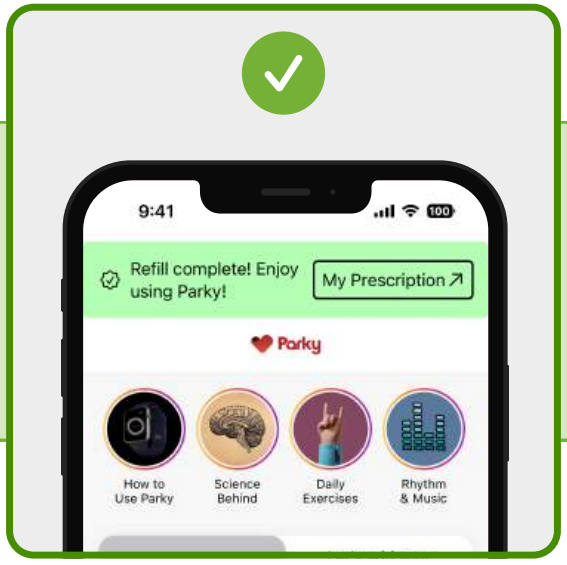

To refill your prescription, tap the **"Refill Parky"** button at the top.




To proceed with your payment, tap the **"Next"** button.




Choose the plan that works best for you and tap **"Start my journey"** to proceed to Apple Inc.'s checkout screen.




**Once you complete the checkout, you're all set!**

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# 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 4 (or newer) devices with WatchOS 10+.
- iPhone XS (or newer) devices with iOS 17+.

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# 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).

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## 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 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.

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# 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.

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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.

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8. 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.

9. 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).

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# 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.

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# DATA SECURITY

1. Parky collects motion data only when the user wears an Apple Watch.

2. Besides motion data, Parky does not collect 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

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