

Instructions for Use



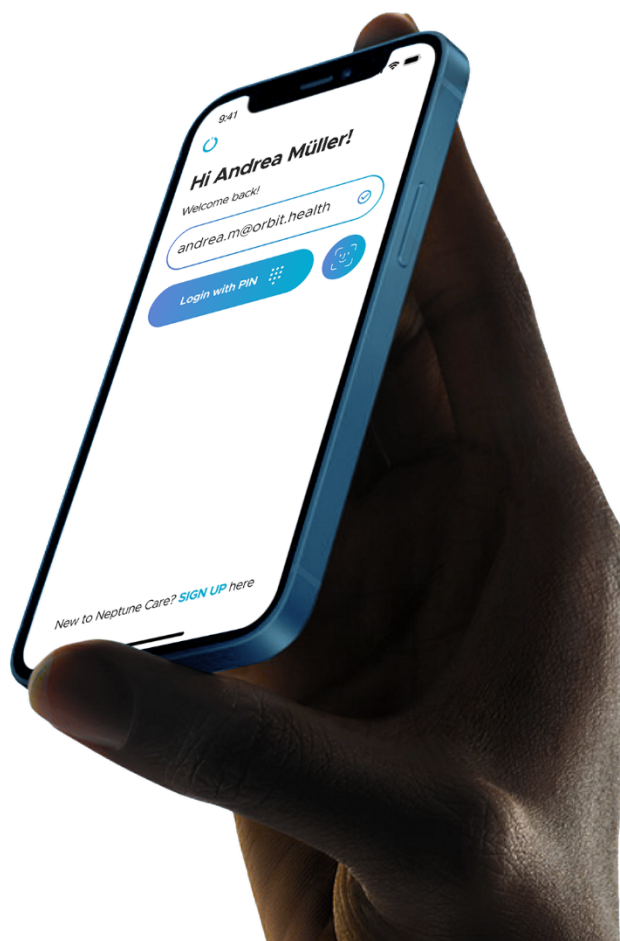
These instructions were put together with great care. If you happen to encounter any discrepancies here in how the system is operating, please inform us promptly for swift correction.

Should there be a serious incident or undesirable side effects during handling and use of the product which are not specified in these instructions for use, please report these to us with a detailed description of the incident or side effects. Please use the contact details below for this purpose.

The specifications and figures in this user manual are subject to change due to optical or further technical developments.

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Note

These instructions for use contain screenshots from the Neptune Care app to make the instructions as specific and clear as possible. However, be aware that the screenshots may deviate slightly from what you see in the app.

Information about the product and the manufacturer

Neptune Care, a product of

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Version of these instructions for use

This is version 4 of this instruction for use from 18th January 2024 valid for version 2.1.x of Neptune Care.



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1 Product Description

1.1 Intended Purpose

Neptune Care is a software as a medical device that enables continuous, objective monitoring of motor symptoms of people suffering from Parkinson's disease as well as daily manual tracking of medication intake, symptoms and disease relevant actions and events. This combined information supports users in objectively monitoring their disease and observing the interplay with disease-relevant daily activities.

1.1.1 Intended Patient Population

The Neptune Care software is intended for adult users (> 18 years).

1.1.2 Medical Indications

Neptune Care is intended to be used by people diagnosed with primary, idiopathic Parkinson's disease (ICD G20).

Contraindications

- Atypical Parkinsonism.
- Medical disorder that prohibits wearing of body-worn-sensors, e.g. bilateral Shunt (dialysis patients)

1.1.3 Intended User

Neptune Care is intended to be used by people suffering from idiopathic Parkinson's disease and/or their caregivers. The intended users are laypersons. They do not require any training.

1.1.4 Intended Use

Neptune Care is a mobile phone application that is used by the intended user under normal daily life conditions. The app can be used continuously and at any time throughout the day.

Required equipment

Neptune Care requires the user to wear a third-party smartwatch or wrist-worn sensor which collects raw motion data (accelerometer and gyroscope).

The user needs a private smartphone (either Android or iOS) to install and use the mobile application.

Compatibilities

Neptune Care is compatible with smartwatches or wrist-worn sensors that possess an inertial measurement unit (IMU) sensor that provides accelerometer and gyroscope raw data.

1.1.5 Product Lifetime

The product lifetime of the Neptune Care device is defined as 3 years starting from the release of the respective software version.

1.2 Precautions/Warnings

Neptune Care is not intended to provide information for diagnosis of Parkinson's disease or provide information which is used to make decisions with diagnosis or therapeutic purposes. Furthermore, Neptune Care shall neither replace physicians' judgments nor be used to provide automatic diagnoses or to automatically deliver therapies or treatments.

1.3 Claims

Benefits

- Neptune Care provides objective motor symptom insights with a frequency of 1/min compared to state of the art consisting of snapshots with a frequency of 1 observation per 3-6 months obtained during clinical visits. In addition, the tracking of medication intake, symptoms and disease relevant actions and events provides more precise information about the disease and disease progression for the patient. This allows patients to better understand and monitor their disease.

Performance claims

- Neptune Care's algorithm can predict the patient's motor state (dyskinesia, ON, and OFF) as well as severity of bradykinesia or dyskinesia

(score from -4 to 4) from raw motion data with a high relaxed accuracy ($\geq 75\%$) and a temporal resolution of 1/minute

Disclaimers

Neptune Care is not intended to provide information for diagnosis of Parkinson's disease or provide information which is used to make decisions with diagnosis or therapeutic purposes. Furthermore, Neptune Care shall neither replace physicians' judgments nor be used to provide automatic diagnoses or to automatically deliver therapies or treatments.

1.4 Functional Description

1.4.1 Modules

- Third-party smartwatch or wrist-worn sensor
- Patient mobile application (available for Android and iPhone)
- AWS cloud for data storage and processing
- Neptune Care's algorithm

1.4.2 Input(s)

- Raw motion data passively captured via the accelerometer and gyroscope of a third-party smartwatch or wrist-worn sensor.
- Users input relevant data for mobile app log-in, data concerning activities, medication intake, symptoms and disease relevant actions and events.

1.4.3 How the Device Achieves its Intended Purpose

The solution (Neptune Care) provides people living with Parkinson's disease with continuous insights into their motor status and insights into manually logged daily activities, medication intake, and symptoms. The additional information enables the user to review and monitor the state of the disease independently.

Neptune Care achieves its purpose by utilizing continuous raw motion data captured passively by a third-party smartwatch or wrist-worn sensor. The raw motion data is transmitted to Neptune Care's AWS cloud processor where it is processed by Neptune Care's algorithm. The algorithm turns the data into motor states, which are illustrated against a scale ranging from -4 to 4. The scale indicates the severity of dyskinesia (1 to 4), bradykinesia or OFF (-4 to -1), and the ON state (-1 to 1). From this rating, the time the patient spends in ON, OFF or Dyskinesia state can be obtained.

The patients enter data on medication intake, symptoms and disease relevant actions and events and the time of their occurrence and their duration if applicable.

The Neptune Care software device combines objective, sensor-based information with user reported data to allow the user to better understand the disease and observe the interplay between motor symptom severity and daily actions and events.

1.4.4 Output(s)

Clinical Output(s)

- Continuous motor state reading based on MDS-UPDRS III and AIMS scale
- % of time patient spends in the Dyskinesia, ON, and OFF states

Non-clinical Output(s)

- Diary of manually logged events and activities
- Visualization of tracked motor states and sleep throughout the day
- Overlay of medication intake times, events and activities on motor state graph
- Aggregated disease report

1.4.5 Variants

There is only one Neptune Care app.

1.4.6 Labeling





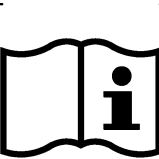


Symbol	Significance
	Manufacturer name and address
	Software release date
	CE label
	Unique Device Identifier (UDI)
	Please see accompanying documents (Instructions for use, IFU).
	Warning (Warnings have their origin in risk assessment. They are necessary to draw the user's attention to residual risks or sources of danger. All warnings are listed in Chapter 2 below each other.)
	Medical Device

Table 1.1: Labeling

2 Safety Instructions

Read these instructions for use carefully. They are part of the device and have to be available at all times. Do only use the device for the intended purpose described in this document (see chapter 1.1).

For your own safety and according to the requirements of the Medical Device Regulation, please observe the following:

WARNING: Important safety or performance information or immediate response from operator required.

CAUTION: Other important information with or without the need of operator response.

2.1 General Remarks




	<p>Neptune Care is not intended to provide information for diagnosis of Parkinson's disease or provide information which is used to make decisions with diagnosis or therapeutic purposes.</p>
	<p>Do not change your prescribed medication or medication schedule based on information provided by Neptune Care. Always consult your treating physician.</p>
	<p>Neptune Care shall neither replace physicians' judgments nor be used to provide automatic diagnoses or to automatically deliver therapies or treatments.</p>

Table:2.1: General remarks

2.2 Side Effects and Contraindications




	<p>Neptune Care is intended to be used by people diagnosed with primary, idiopathic Parkinson's disease (ICD G20).</p>
	<p>Neptune Care is not intended to be used for people suffering from atypical Parkinsonism.</p>
	<p>Neptune Care is not intended to be used by people suffering from a medical disorder that prohibits wearing of body-worn-sensors, e.g. bilateral shunt (dialysis patients).</p>

Table 2.2: Side Effects and Contraindications

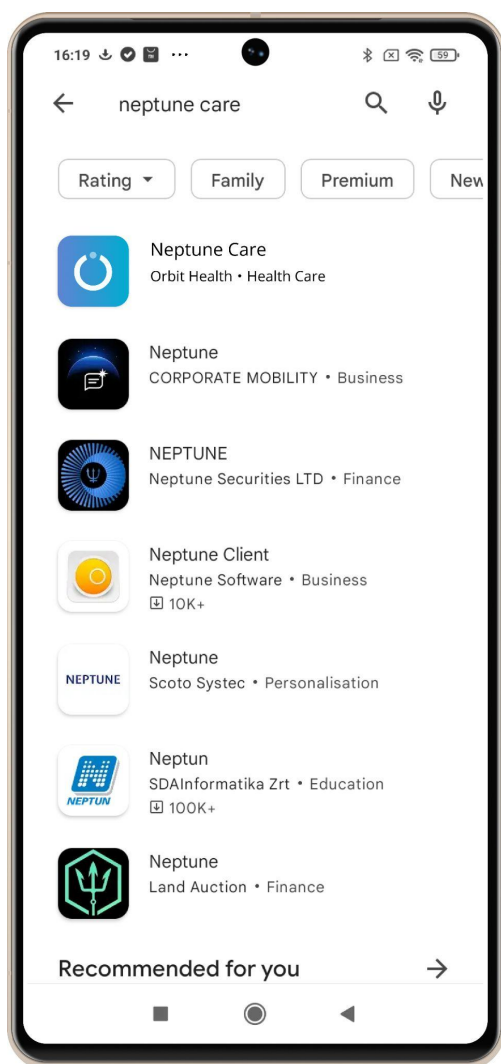
3 Initial Operation

3.1 Installation

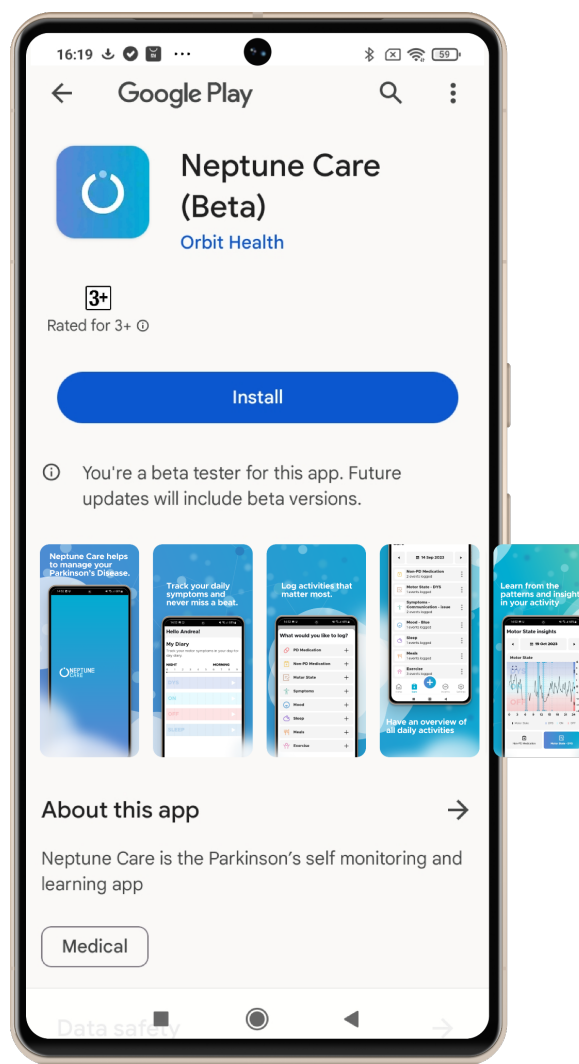
Neptune Care is a mobile phone application that can be downloaded either from the Google Play store for Android devices or the Apple store for iPhones.

3.1.1 Google Play Store

To install the app, open the Google Play store on your phone. Use the search field and search for “Neptune Care”. The app should be shown (LEFT IMAGE), and you can install the app by tapping on “Neptune Care” and then on the “Install” button on the app detail screen (RIGHT IMAGE).



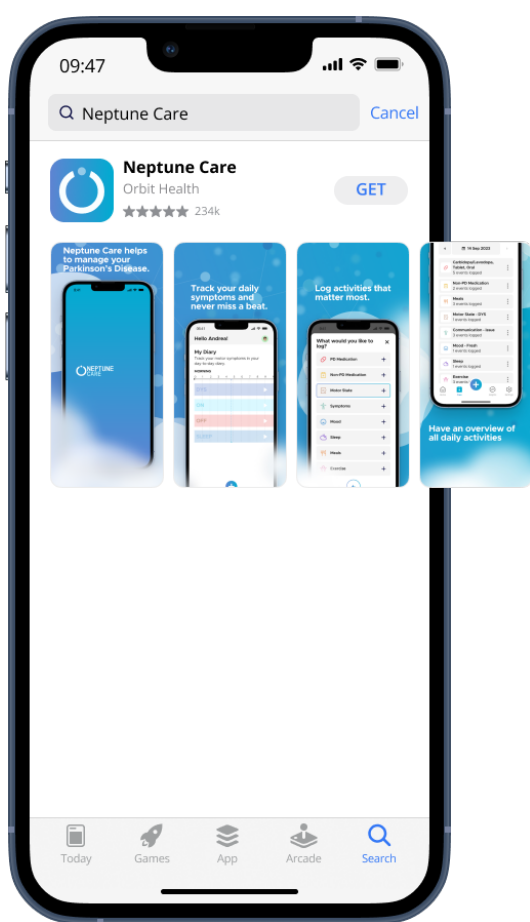
LEFT IMAGE



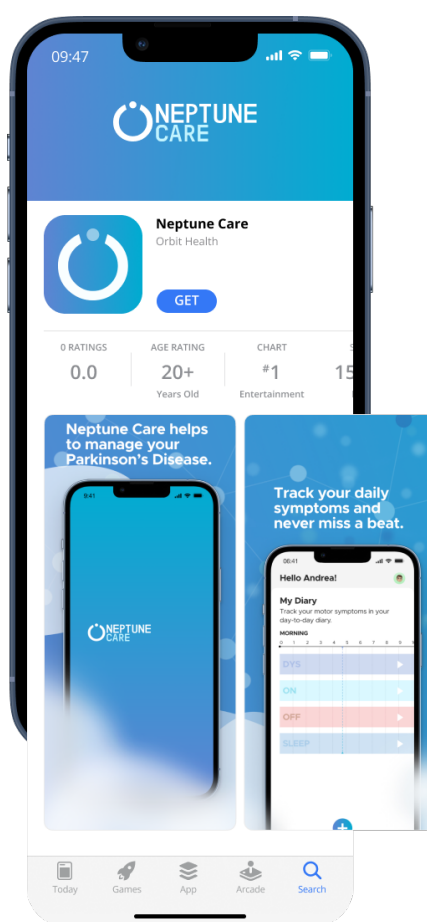
RIGHT IMAGE

3.1.2 Apple Store

To install the app, open the Apple store on your phone. Use the search field and search for “Neptune Care”. The app should be shown (LEFT IMAGE), and you can install the app by tapping on the “GET” button. Alternatively, you can tap on “Neptune Care” and then on the “Get” button on the app detail screen (right image below).



LEFT IMAGE

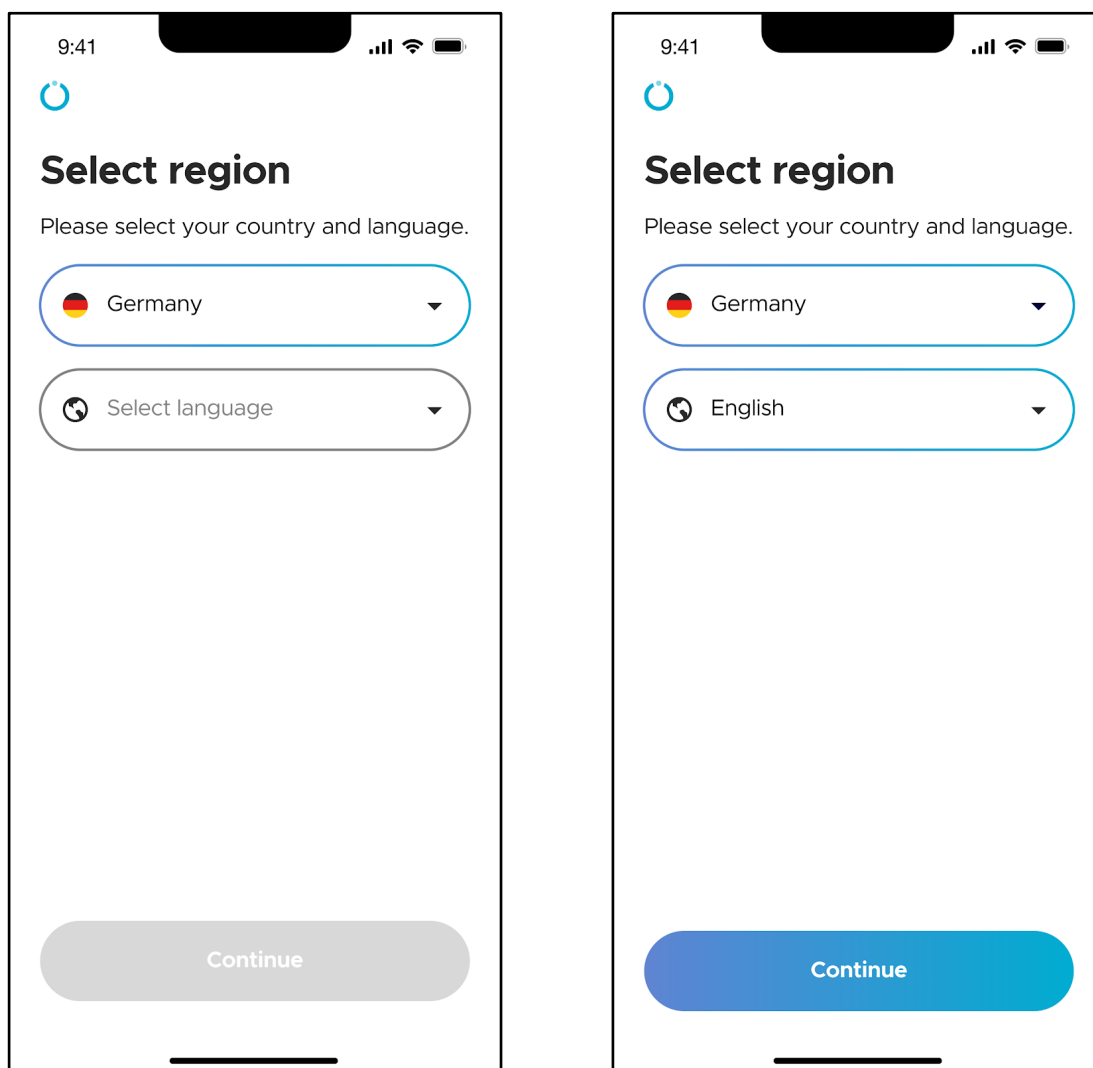


RIGHT IMAGE

4 Operation

4.1 First Time Opening the App - Sign up

4.1.1 Selecting Country and Language



When opening Neptune Care for the first time, select the country in which you are located and the language you want to use inside the app. You may do this by using the dropdown menus shown in the above pictures.

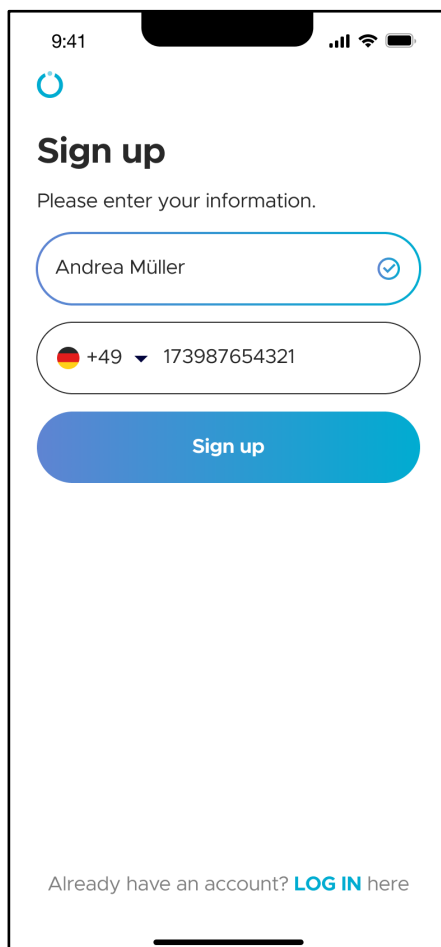
4.1.2 Sign Up

After selecting your country and language, you need to create your personal Neptune Care account by signing up. You can do this by either providing your Email address or your mobile phone number.

This determines the way in which the app can send you required information in the future e.g. for changing PIN codes needed to login to the app. You can either receive this via Email or via SMS directly to your phone.

***Please Note:** You will not be able to change how you login in the future e.g. with your Email vs with your mobile phone number, so think about your choice carefully.

A) Sign Up Using Mobile Phone Number



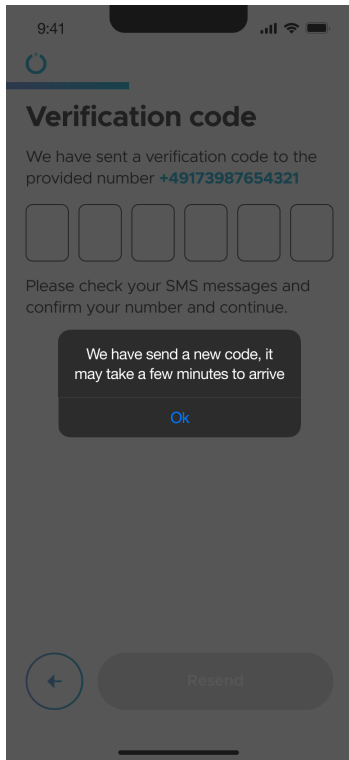
The screenshot shows the 'Sign up' screen in the Neptune Care app. At the top, the time is 9:41 and there are icons for signal strength, Wi-Fi, and battery. Below the status bar is a blue circular refresh icon. The main heading is 'Sign up' in bold black text, followed by the instruction 'Please enter your information.' There are two input fields: the first contains the name 'Andrea Müller' with a checkmark icon on the right; the second contains the country code '+49' (with a German flag icon) and the phone number '173987654321'. Below these fields is a large blue button labeled 'Sign up'. At the bottom of the screen, there is a link: 'Already have an account? [LOG IN](#) here'.

Enter your first and last name into the name field.

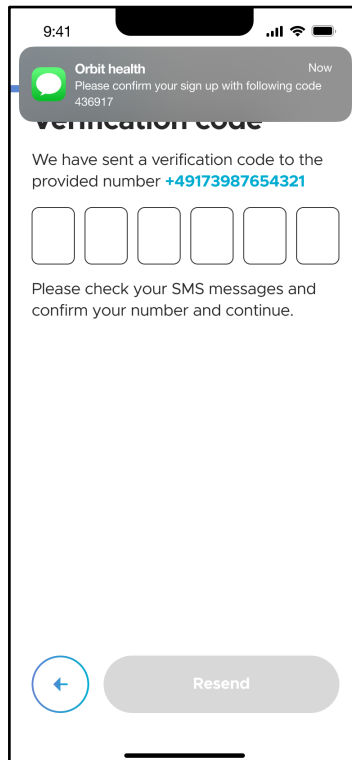
Select the country code for your mobile phone number and then enter your mobile phone number* into the field.

***Please note:** Do not enter "0" at the start of your phone number.

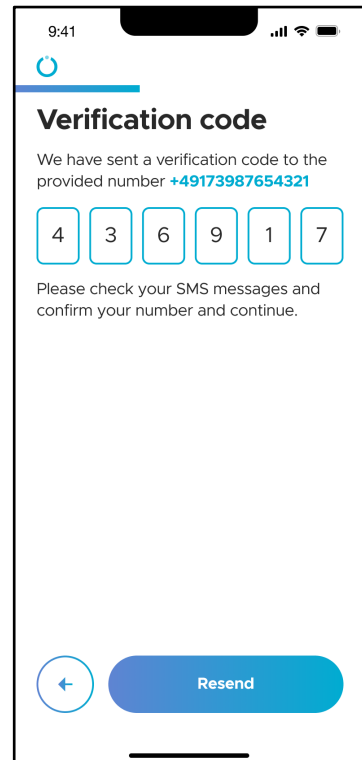
Then you can click "Sign up".



LEFT IMAGE



MIDDLE IMAGE



RIGHT IMAGE

Next, you will need to verify your mobile phone number.

A verification code will be sent as an SMS to the provided mobile phone number (MIDDLE IMAGE). You will then need to enter the verification code in the respective fields (RIGHT IMAGE). In case no code was sent, you can resend a verification code by tapping on the “Resend” button. After entering the code, tap “Verify” to finalize the verification.

B) Sign Up Using Email address

9:41

Sign up

Please enter your information.

Andrea Müller ✓

andrea.m@orbit.health ✓

Sign up

Already have an account? **LOG IN** here

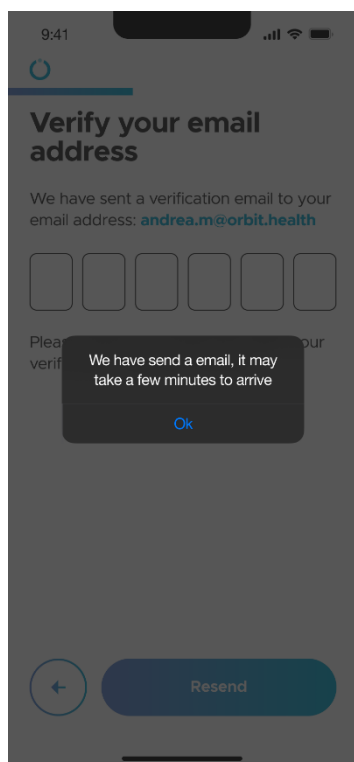
Enter your first and last name into the name field.

Enter your Email address into the Email address field.

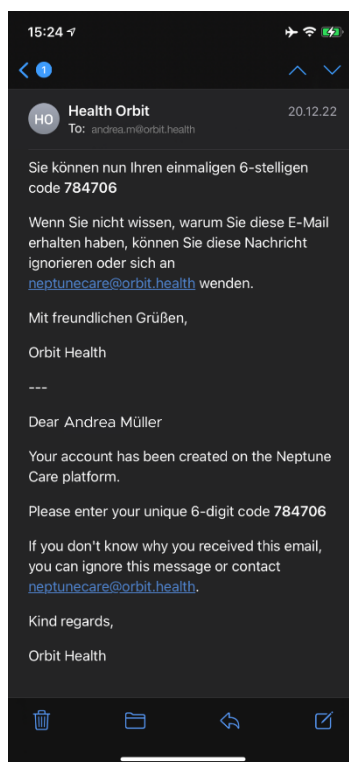
Make sure you have access to the Email inbox as you will receive an Email with a verification code that is needed to complete the signup process.

You can also sign up with your Apple Mail, Google Mail or Facebook account.

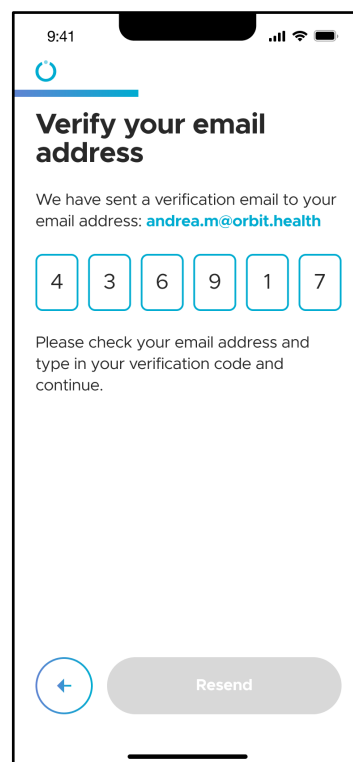
Then you can tap on “Sign up”.



LEFT IMAGE



MIDDLE IMAGE

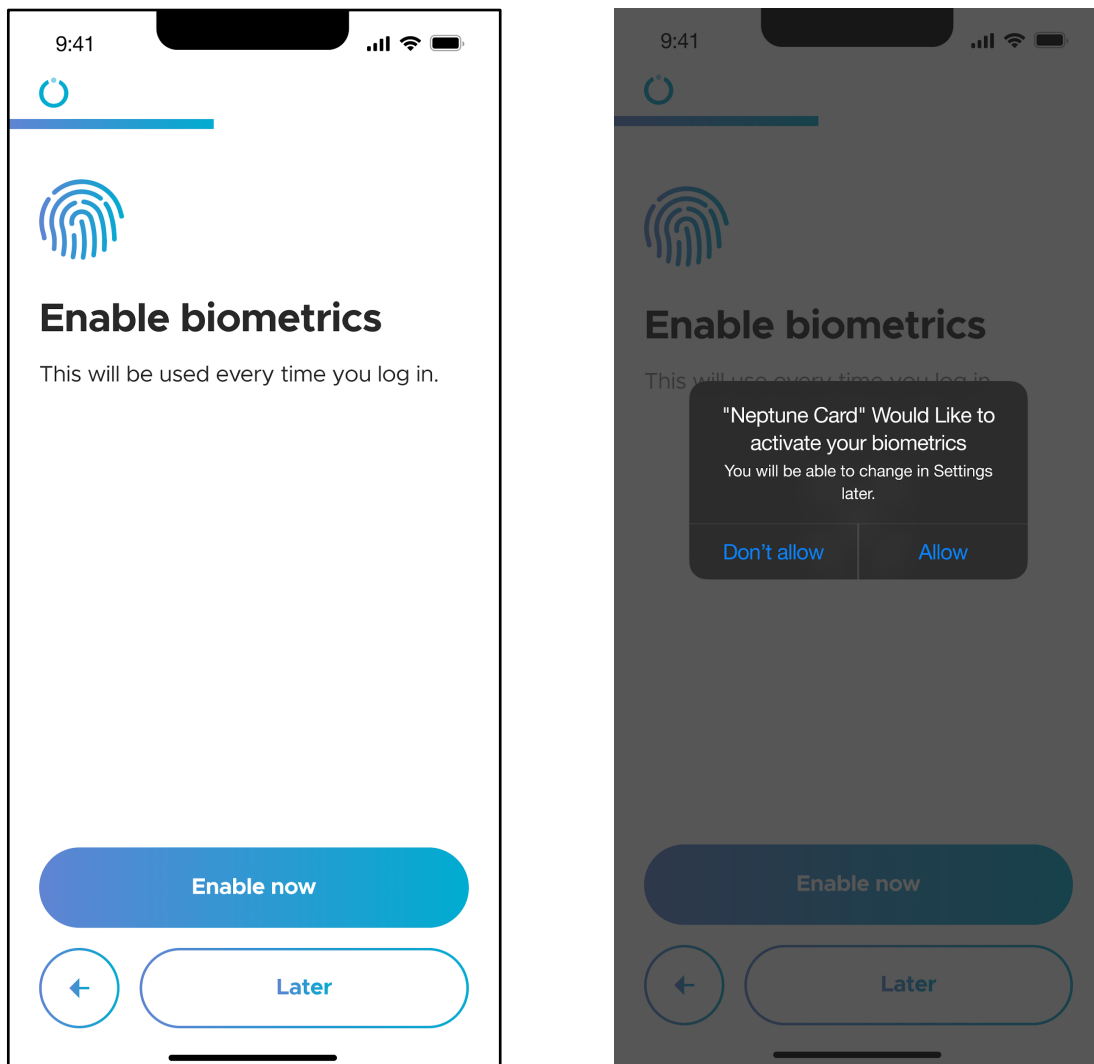


RIGHT IMAGE

Next, you need to verify your Email address.

A verification code will be sent to the Email address you have provided during the signup process (MIDDLE IMAGE). You will need to enter the verification code in the respective fields (RIGHT IMAGE). In case no code was sent, you can resend a verification code by tapping on the “Resend” button. After entering the code, tap on “Verify” to finalize verification.

4.1.3 Biometrics Authentication



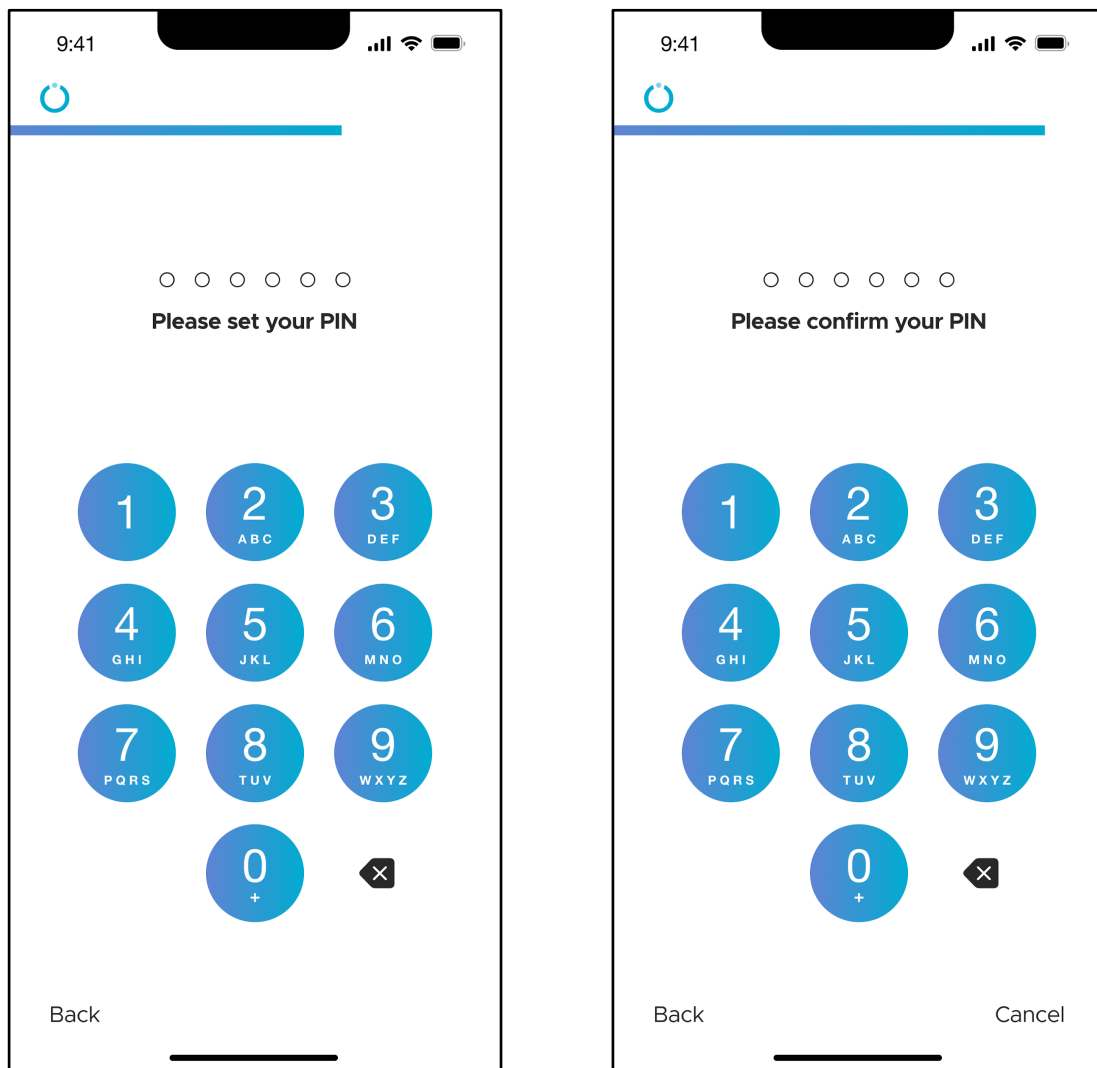
For a simplified login procedure, you can use your mobile phone’s biometrics feature, which can be either fingerprint or face authentication (Face ID). This allows you to login to the app using your phone’s fingerprint sensor or face detection without the need to manually input a PIN code.

To use this feature, tap on “Enable now”. Neptune Care will ask you for the permission to use this feature. If you tap on “Allow”, you can login with biometrics in the future.

If you do not want to use biometrics or would like to set it up later, you can tap on “Later”.

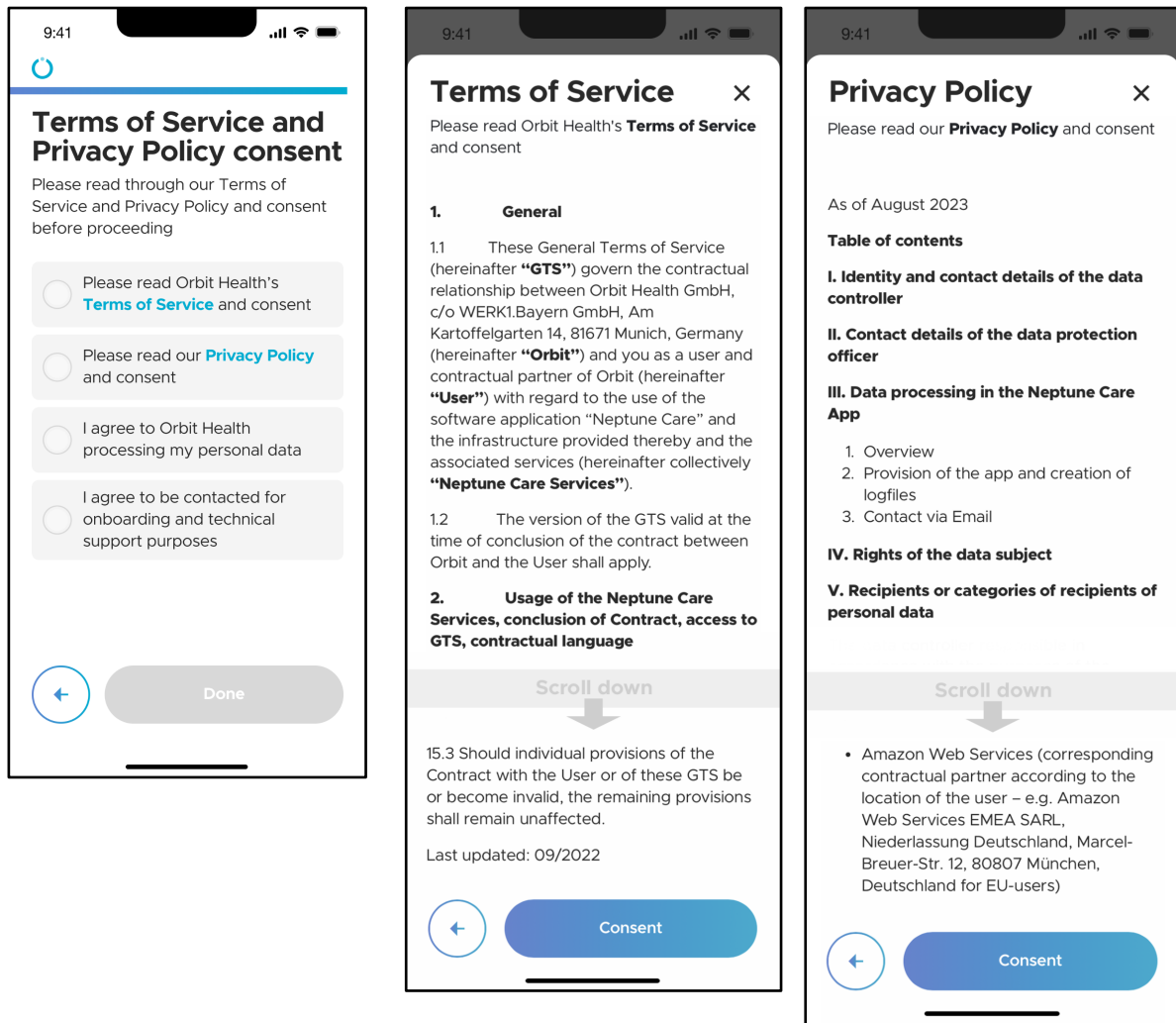
***Please Note:** This function cannot be used if your phone does not support biometrics!

4.1.4 Set Up PIN



You can also login to Neptune Care using a six-digit PIN code. You will first need to enter a six-digit code that you would like to use, then confirm the PIN by re-entering the same PIN again. Once you have successfully re-entered, you will have completed the PIN code setup process.

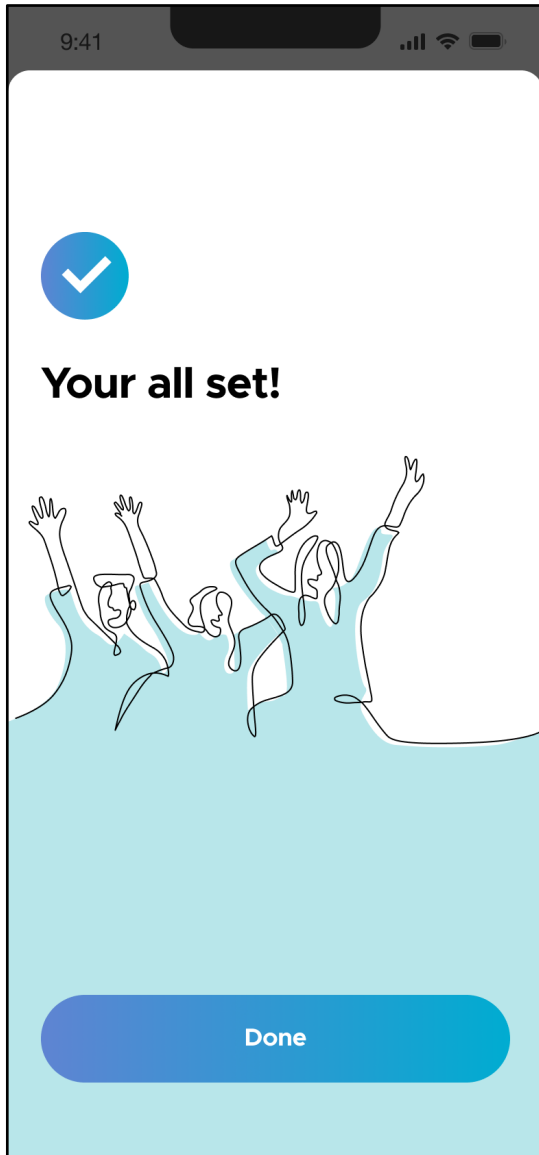
4.1.5 Terms of Service and Data Privacy Policy



To be able to use Neptune Care, you will need to accept the “Terms of Service”, the “Privacy Policy” and consent to the processing of your personal data by Orbit Health. Furthermore, you must consent to being contacted by Orbit Health for technical support purposes.

By tapping on “Terms of Service” and “Privacy Policy”, the respective document opens, and you should read them carefully before consenting. Scroll to the bottom of the document to tap “Consent”. You can consent to data processing and to being contacted by Orbit Health by tapping on the respective tiles.

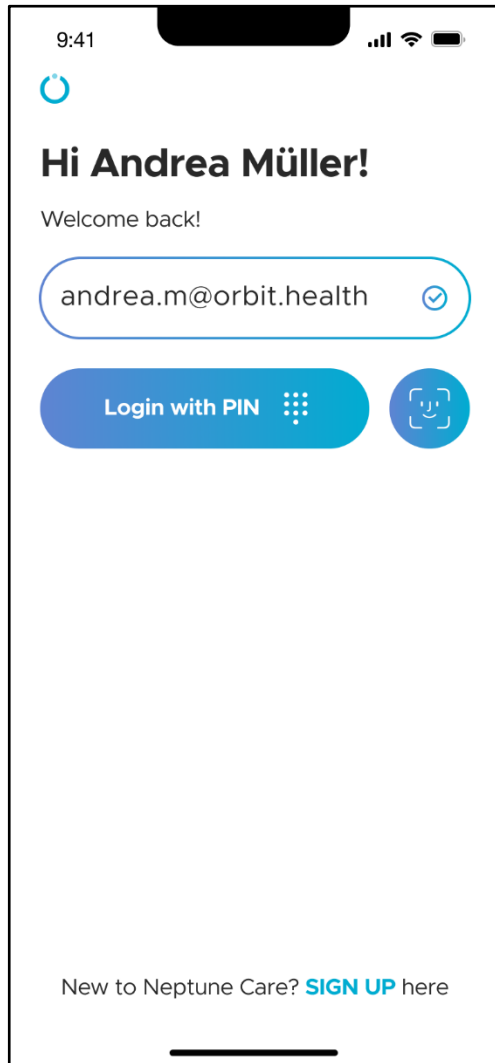
You can revoke your consent to any of the above at any time in the app. However, you may not be able to continue using our services if you choose to revoke consent.



When you tap “Done”, the sign-up process is finished, and you will be brought to the login screen.

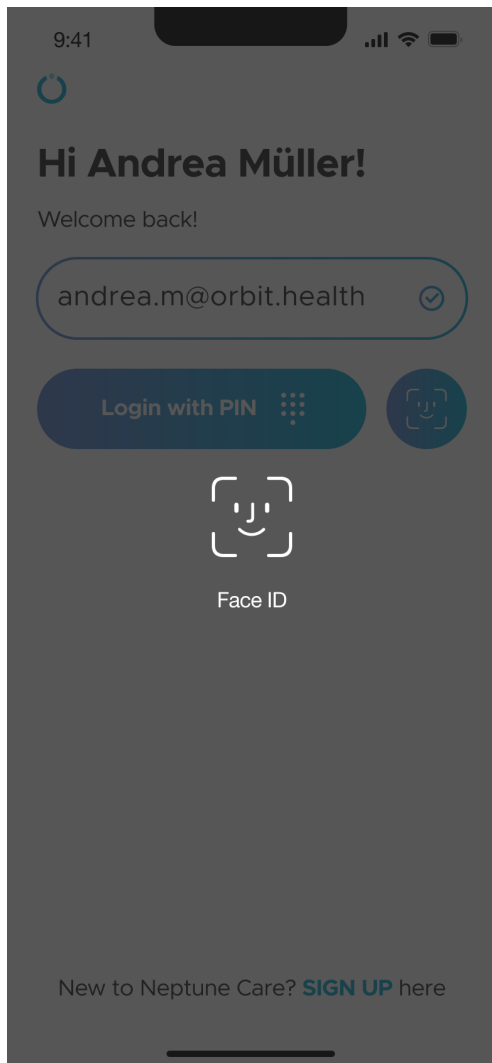
4.2 Login and the Home Screen

4.2.1 Login

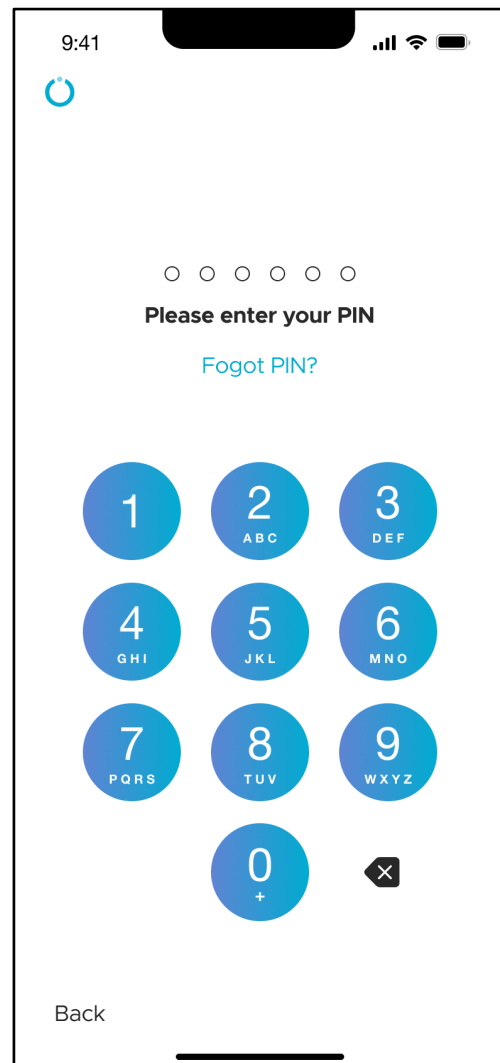


To login to Neptune Care, you need to provide your sign-up information (either mobile phone number or Email address). This information is normally pre-filled for you. You can choose to login with your six-digit PIN or biometrics (blue circle with the face icon).

You can also choose to login using your Apple, Google or Facebook account.



LEFT IMAGE

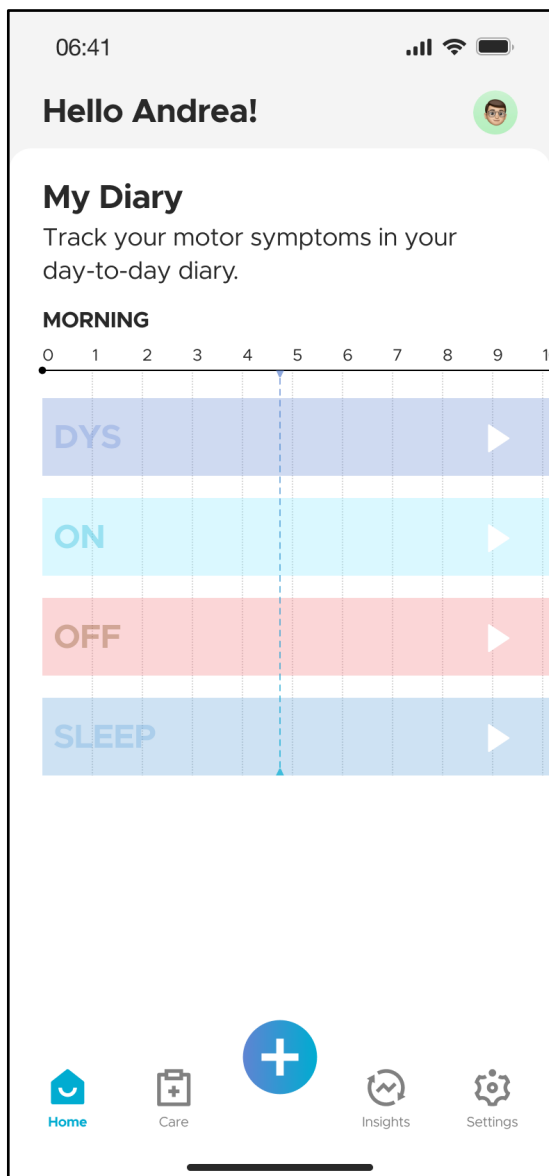


RIGHT IMAGE

If you choose to login with biometrics, you will need to either use your fingerprint or your Face ID to log in (LEFT IMAGE).

If you choose to login with a PIN, you will be required to enter your six-digit PIN to login (RIGHT IMAGE).

4.2.2 Home Screen



After you have logged in successfully, you will be brought to the Home Screen. This screen shows the diary information that you have entered for the current day.

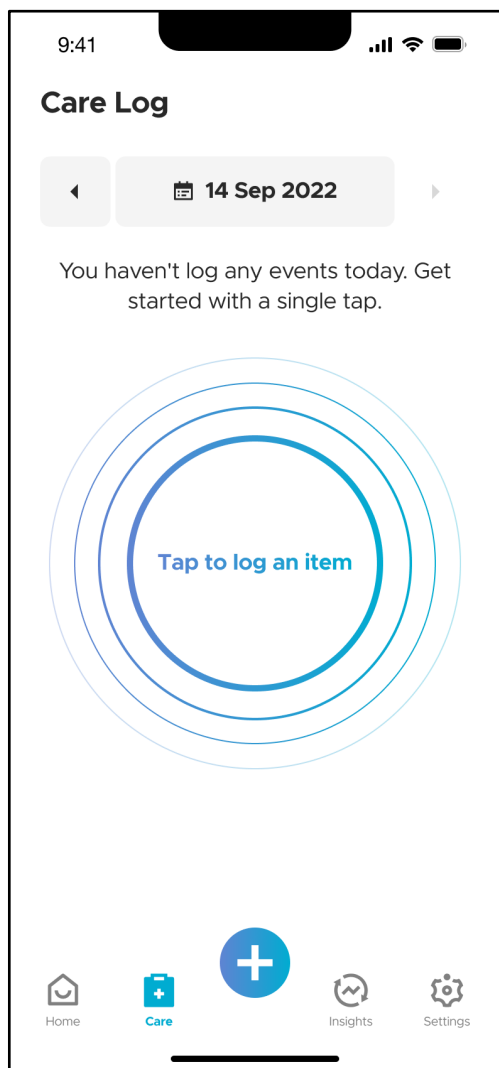
The diary is a timeline that shows periods of DYS, ON, OFF, and SLEEP that you have entered via the motor state event and sleep logging (See sections 4.3.6 and 4.3.9).

The diary is empty upon initial login. As soon as you input a motor state or sleep event, these events will be highlighted in this timeline via a blue bar in the respective row, depending on the type of event that you logged.

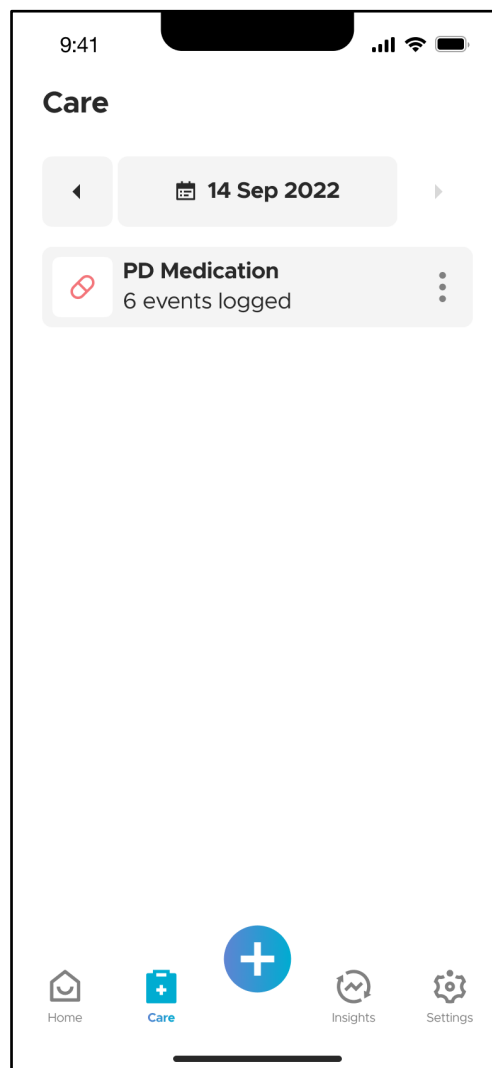
At the bottom, you will see the navigation bar which allows you to switch between the different screens (Home, Care, Insights and Settings). Furthermore, the "+" button allows you to log events related to your disease (See section 4.3.2).

4.3 Event Logging

4.3.1 The Care Screen



LEFT IMAGE



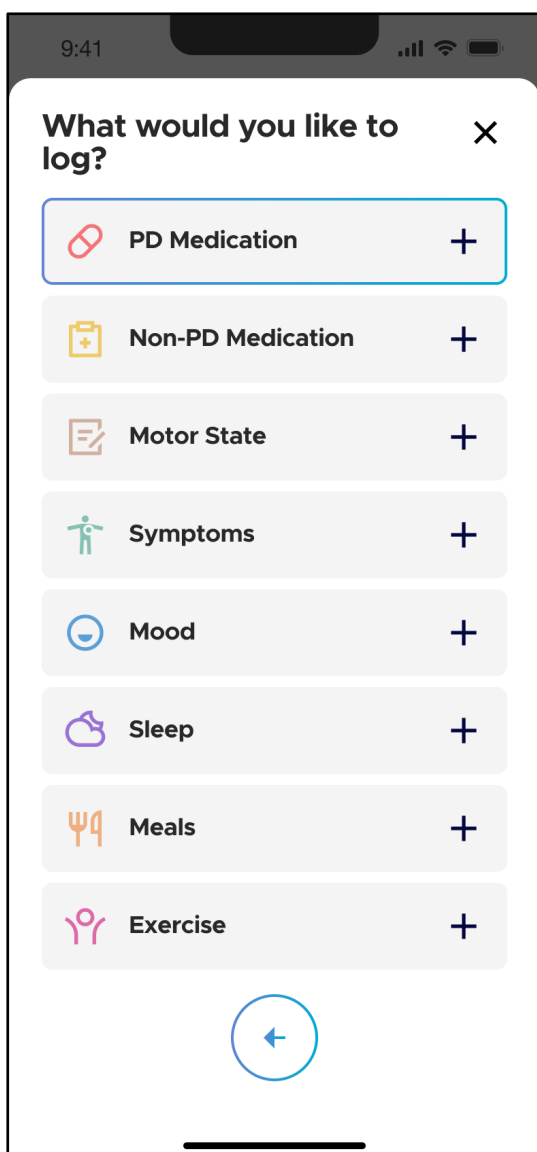
RIGHT IMAGE

You can access the “Care” screen by tapping on the “Care” icon in the bottom navigation bar. The “Care” tab shows all events that you have logged for a day grouped by event type. For example, in the RIGHT IMAGE, you can see six medication events have been logged by the user earlier for the 14th September, 2022. At the top of the image, you can see the current selected date. To change the date, tap on the arrows to select the day before or the day after. You can also change the date by tapping on the date itself. The latter opens a calendar (not shown) to select the desired date. If you have not logged any events for the day, an animation with “Tap to log item” is shown (LEFT

IMAGE). If you tap on this animation, you can log one or more events as described in section 4.3.2.

After you have logged events, they are listed on the “Care” screen (RIGHT IMAGE). You can modify the logged events by tapping on the three dots on the event tile.

4.3.2 Event Types



The current version of Neptune Care allows you to log eight different events. The **PD Medication** event enables you to record the timing of your intake of medications specifically designed to address your Parkinson’s disease (e.g. Levodopa).

Non-PD Medication refers to medication that *does not* target your Parkinson’s disease but may target other diseases or temporary symptoms (e.g. medication to decrease blood pressure, aspirin etc.)*.

***Please note:** You cannot log the specific type or name of medication you take in the current version of Neptune Care.

Motor State events enable you to log the duration of OFF, ON, and DYS episodes as you may be familiar with when completing a Parkinson’s disease diary. You can also log the duration of each of your **Symptoms** such as headache, freezing etc. You can additionally track your mood and

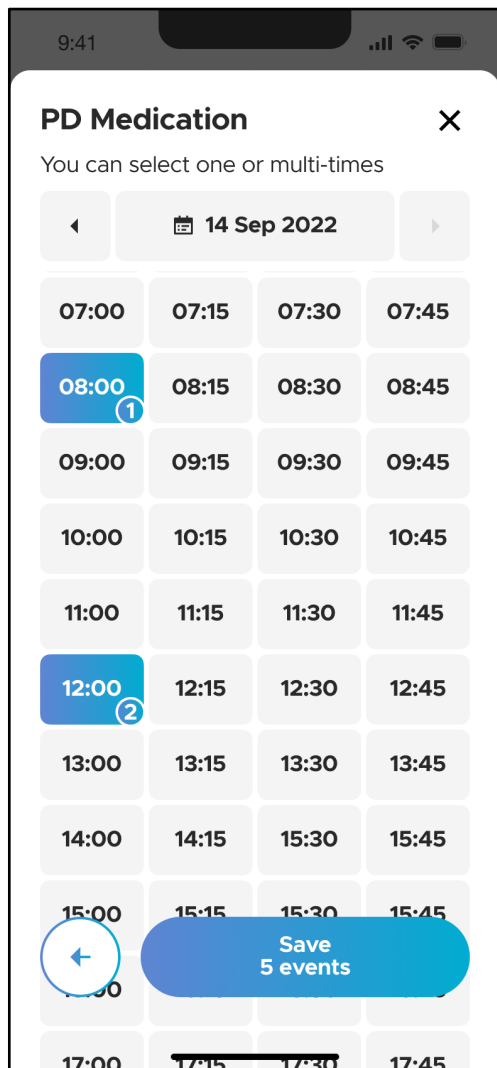
the duration of different moods (sad, happy etc.) under **Mood**. Lastly, you can log the duration of **Sleep** and **Meals** as well as **Exercise**.

The event types described above are part of two categories:

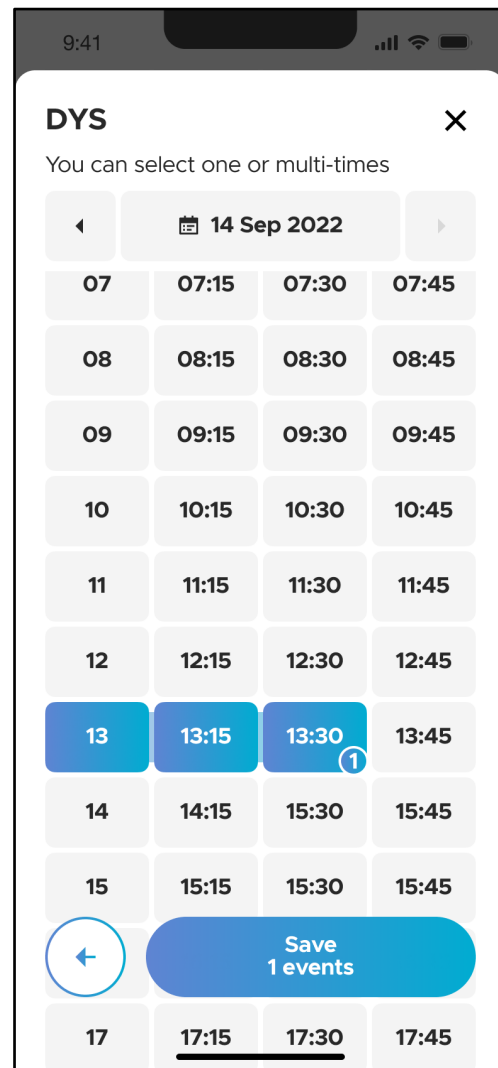
- **Simple Events:** These events happen at a specific point in time but have no duration (e.g. medication intake at 3:45 pm) and
- **Duration Events:** These events have a start time and a duration (e.g. an OFF episode from 3:45 pm to 4:45 pm).

4.3.3 Select Events, Times and Durations

To record events, select the **Event Type** by tapping on the respective entry in the “What would you like to log?” screen (See section 4.3.2.). Depending on the event type, you must then specify the exact type you would like to log as explained in upcoming sections. For all events, you must either log the time of occurrence (simple events) or the duration (duration events) as described in section 4.3.2. You may do this using the time selectors shown in the following:



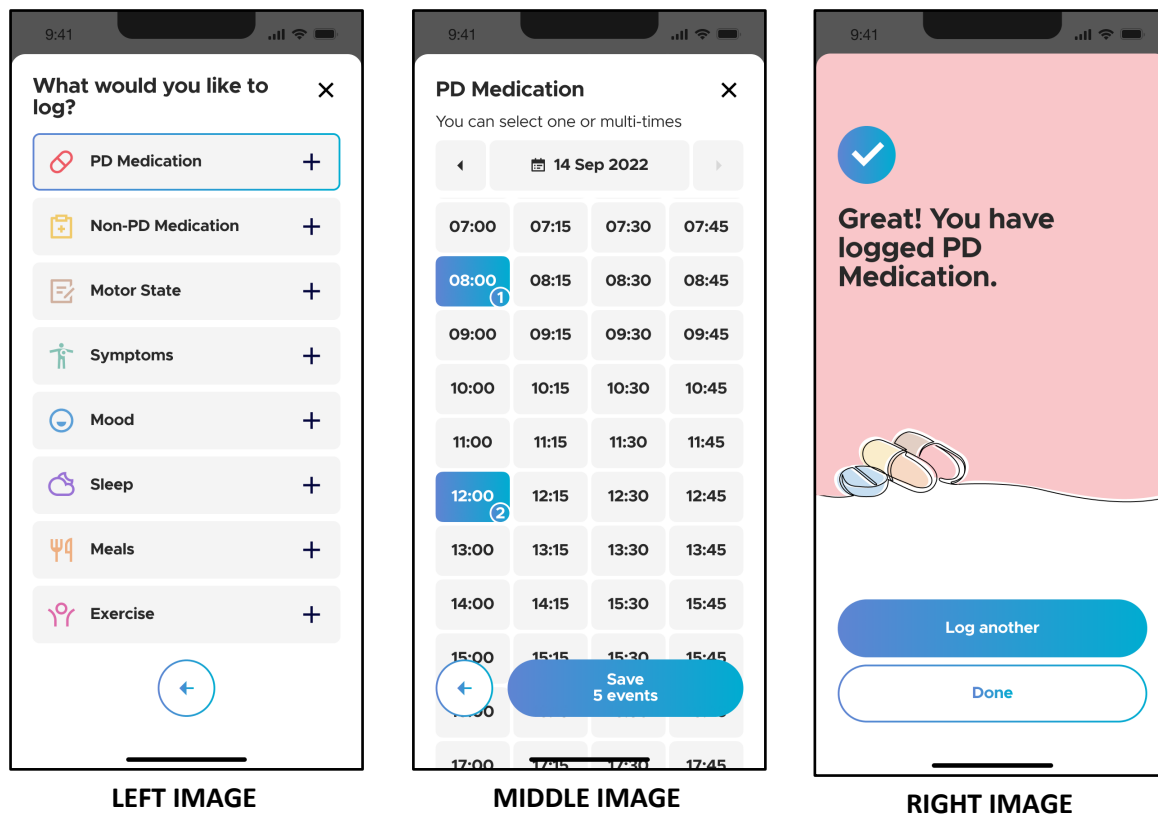
LEFT IMAGE



RIGHT IMAGE

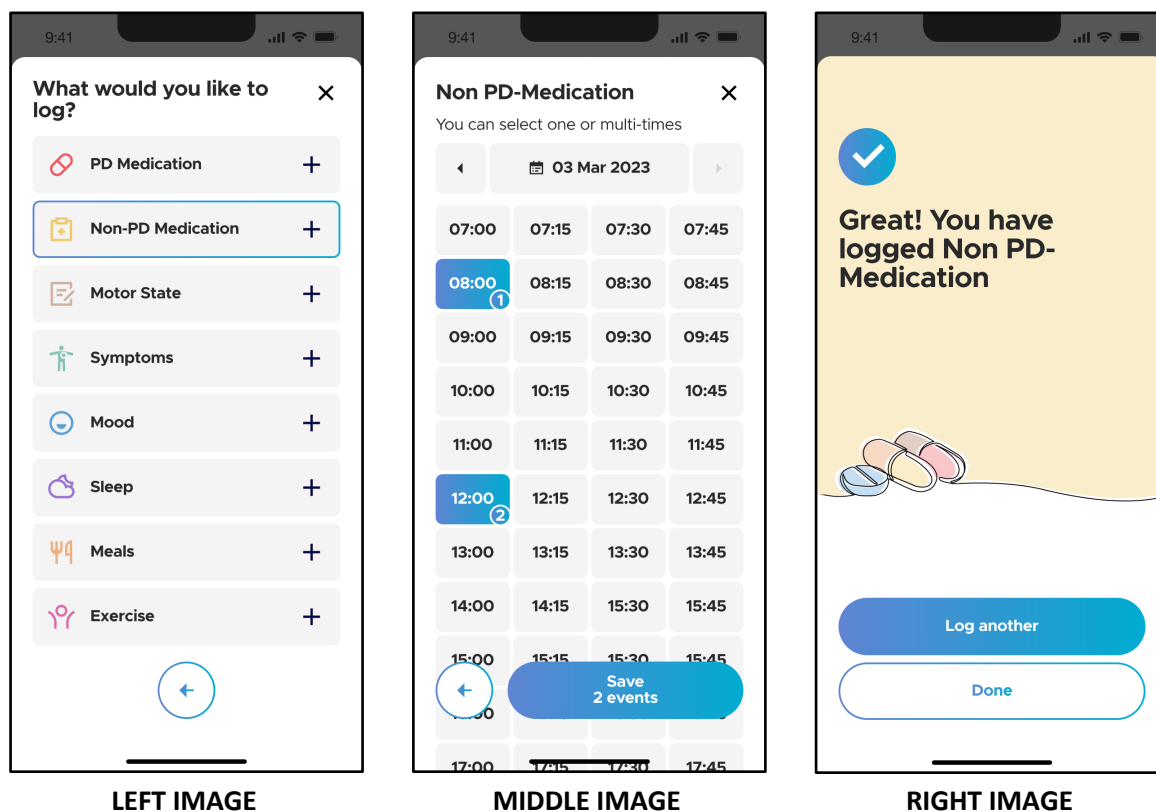
You can select multiple time periods in 15 minute increments by tapping on the respective tile. The tiles you have selected will turn blue and contain the event count. For simple events, you can select multiple subsequent time events that are counted as separated events. For example, if you tap on 08 am, 12:00 pm, 18:00 pm, 20:00 pm and 22:00 pm, you have selected *five simple events* (LEFT IMAGE). In case of a duration, selecting 13, 13:15 and 13:30 would result in *one event*, starting at 13:00 with a duration of 45 minutes (RIGHT IMAGE).

4.3.4 Log PD Medication



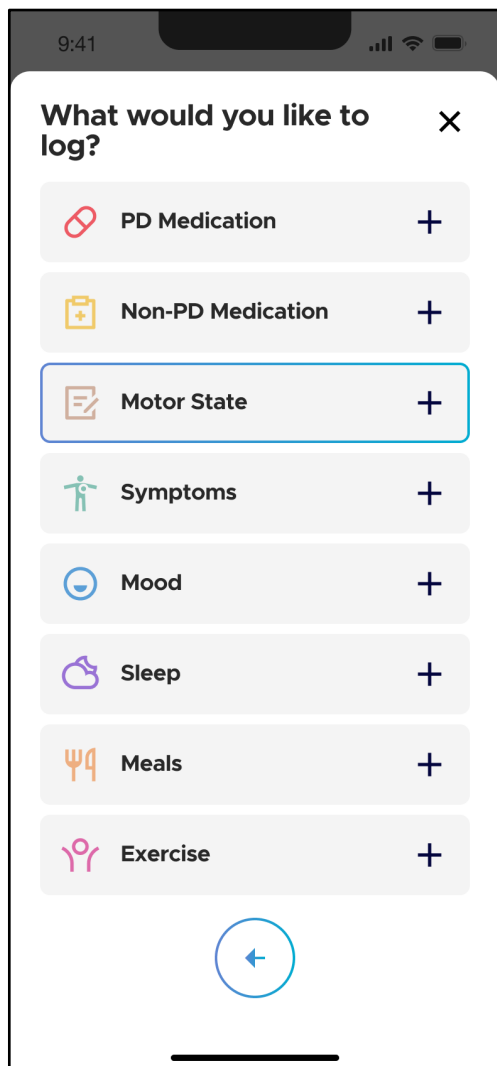
To record your PD medication, navigate to the event log screen and tap on “PD Medication” (LEFT IMAGE). Select the time points in which you have taken the medication(s) and tap the “Save” button (MIDDLE IMAGE). The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap “Done” to go back to the “Care” screen and view your logged events.

4.3.5 Log Non-PD Medication

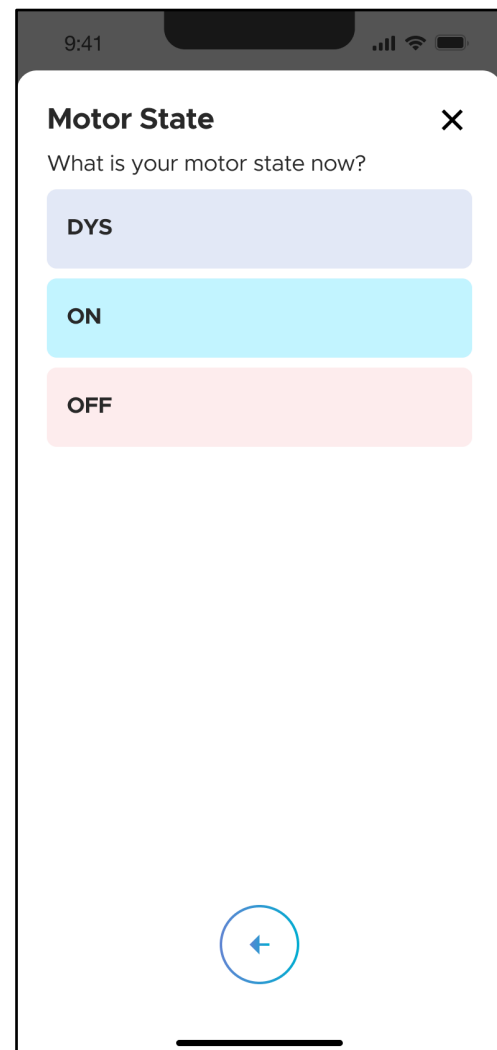


To record your Non-PD medication intakes, navigate to the event log screen and tap on "Non-PD Medication" (LEFT IMAGE). Select the times in which you have taken the medication(s) and tap the "Save" button (MIDDLE IMAGE). The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap "Done" to go back to the "Care" screen and view your logged events.

4.3.6 Log Motor State



LEFT IMAGE

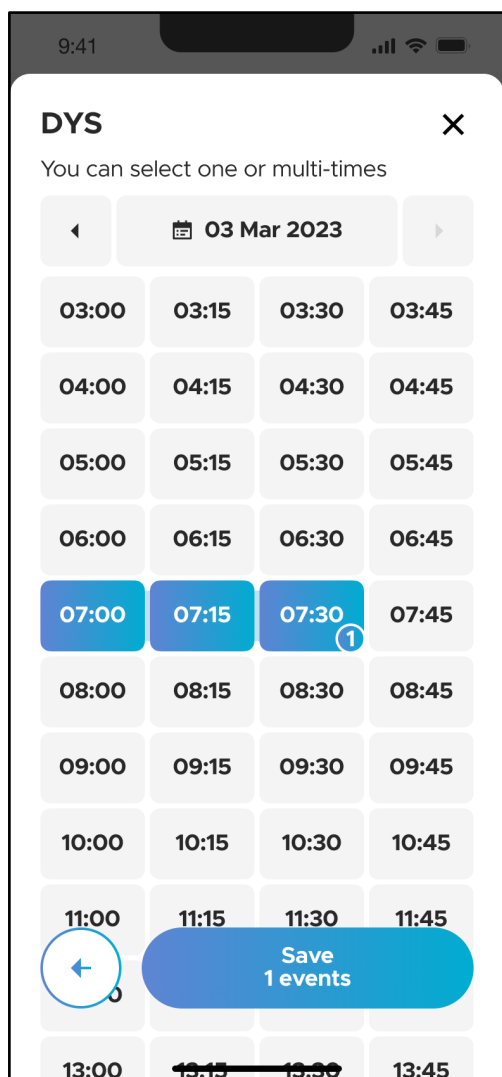


RIGHT IMAGE

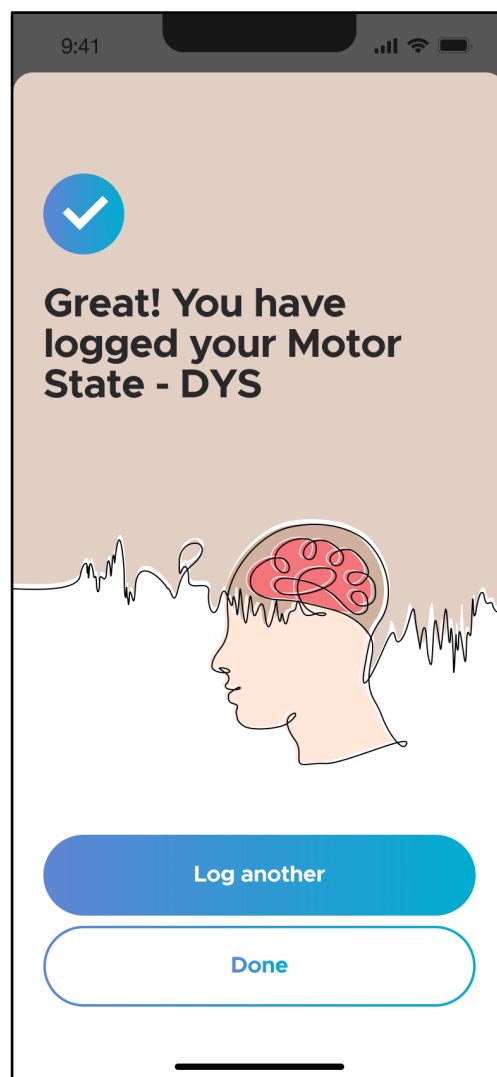
To record your motor state, navigate to the event log screen and tap on “Motor State” (LEFT IMAGE). Select which type of motor state you would like to log (RIGHT IMAGE):

- **DYS:** The “DYS” state is characterized by involuntary movements such as twitches, jerks, twisting or writhing movements often occurring at peak medication concentrations that you perceive as troublesome, e.g. as they interfere with your daily activities.
- **ON:** The “ON” state is the state in which your medication is effective, and your symptoms are under good control.

- **OFF:** The “OFF” state is characterized by the recurrence of Parkinson disease symptoms and functional disability that occurs when the medication effectiveness is wearing off. This may potentially occur during the time period before your next medication dose is due.



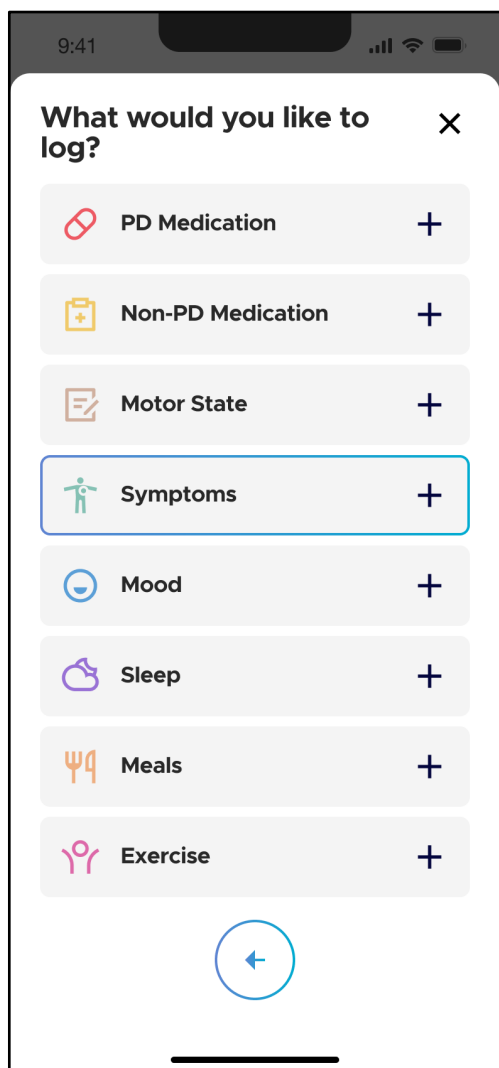
LEFT IMAGE



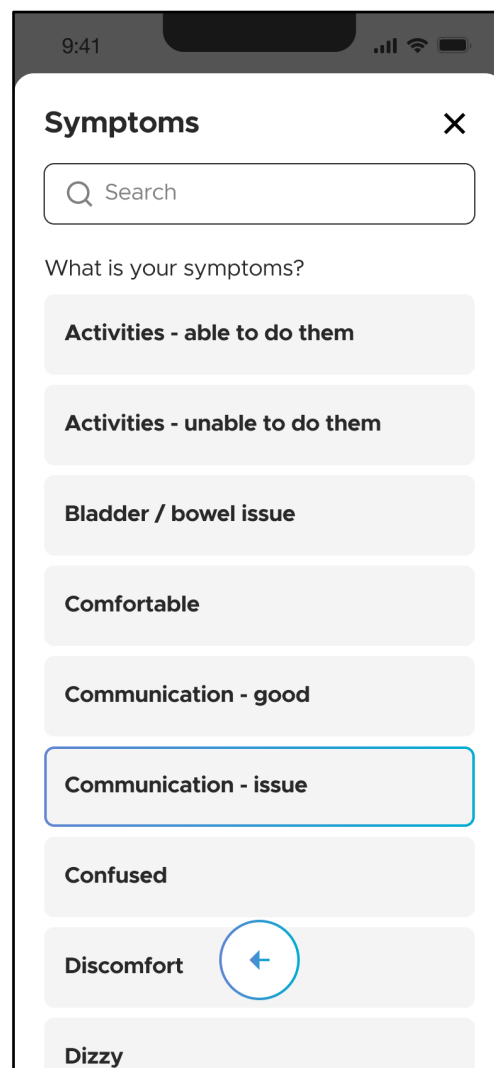
RIGHT IMAGE

Next, select the times and durations in which you have experienced the motor state and tap the “Save” button (LEFT IMAGE). The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap “Done” to go back to the “Care” screen and view your logged events.

4.3.7 Log Symptoms

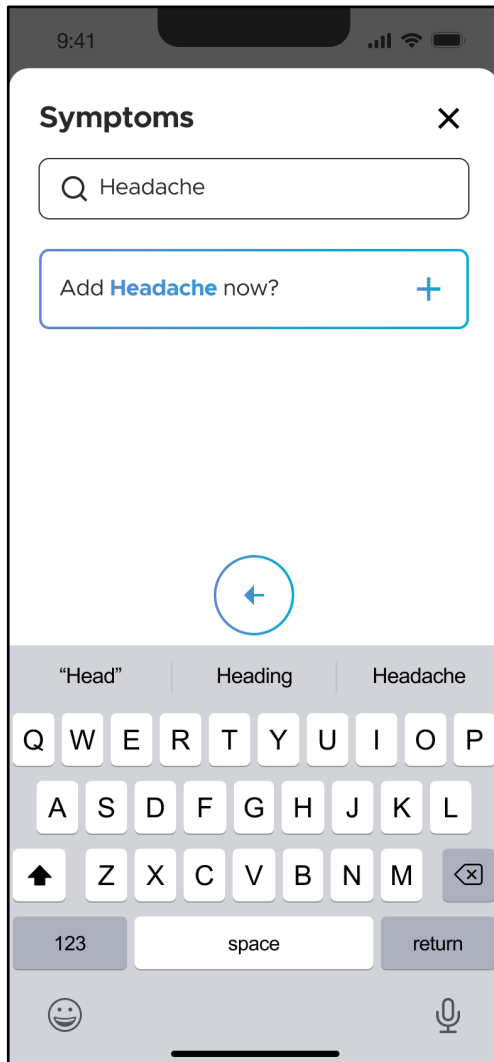


LEFT IMAGE



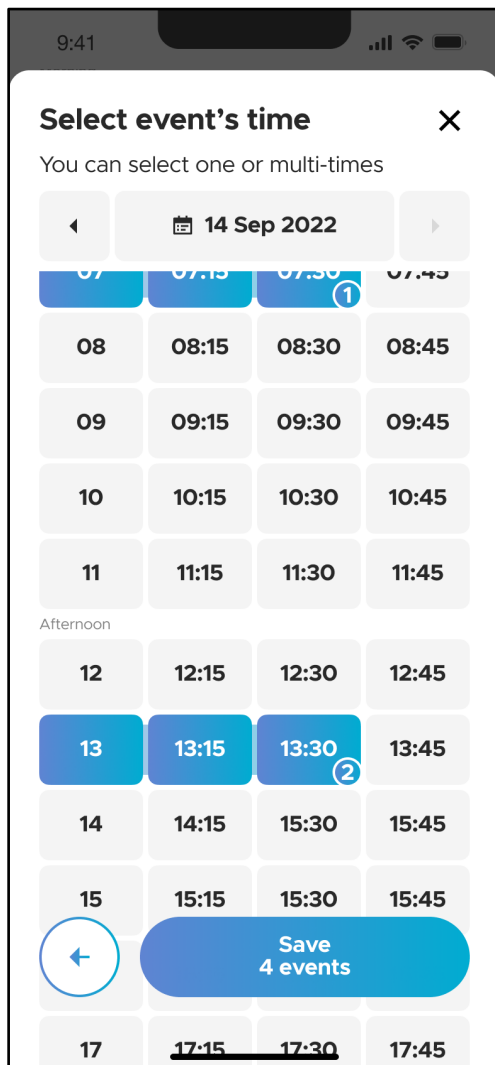
RIGHT IMAGE

To record a symptom, navigate to the event log screen and tap on “Symptoms” (LEFT IMAGE). Select the type of symptom you want to log from the provided list. Additionally, there is a search field in which you can use to search for the symptom that you would like to log.

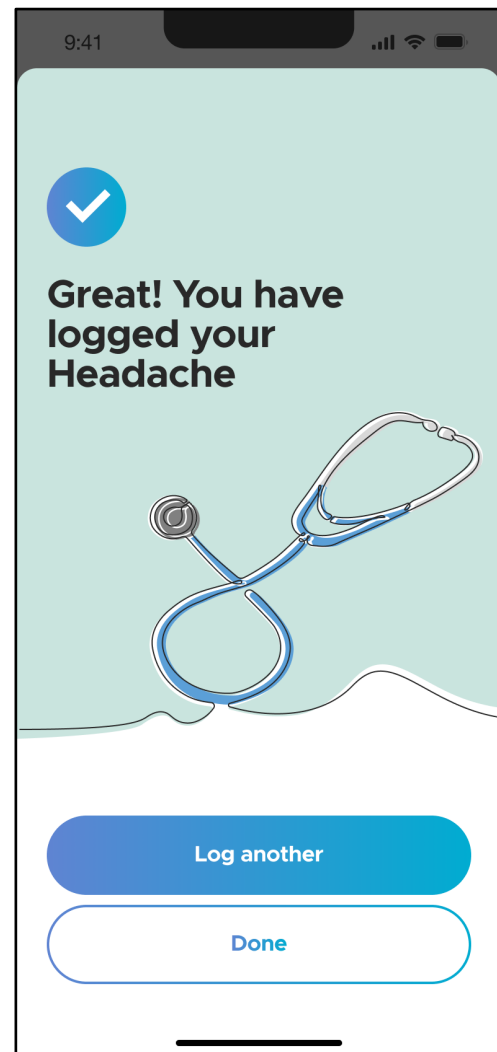


If a particular symptom you would like to log is not already part of the symptom list, you can add it as a new entry. Enter the full symptom name to the search field and then tap “Add ‘symptom’ now” as shown on the left panel. For example, to add “headache” as a symptom, the button will read “Add Headache now”).

The newly added symptom will then be available for future logging.



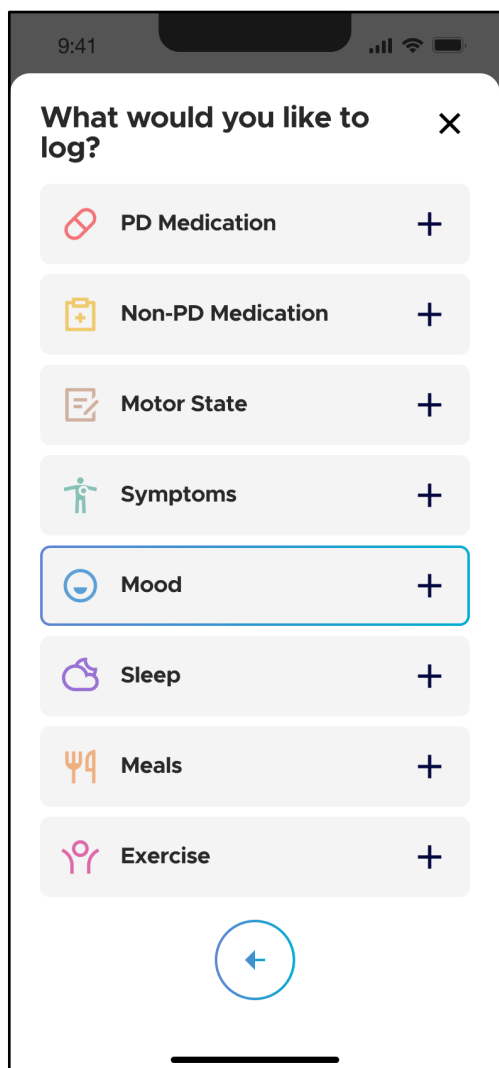
LEFT IMAGE



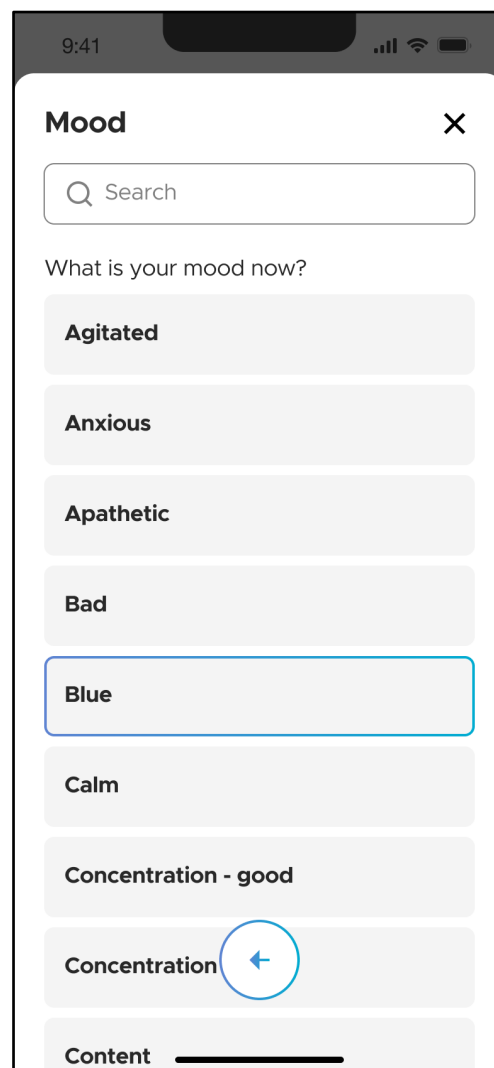
RIGHT IMAGE

After you have selected the symptom you would like to log, select the times in which you experienced the symptoms and tap the "Save" button (LEFT IMAGE). The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap "Done" to go back to the "Care" screen and view your logged events.

4.3.8 Log Mood

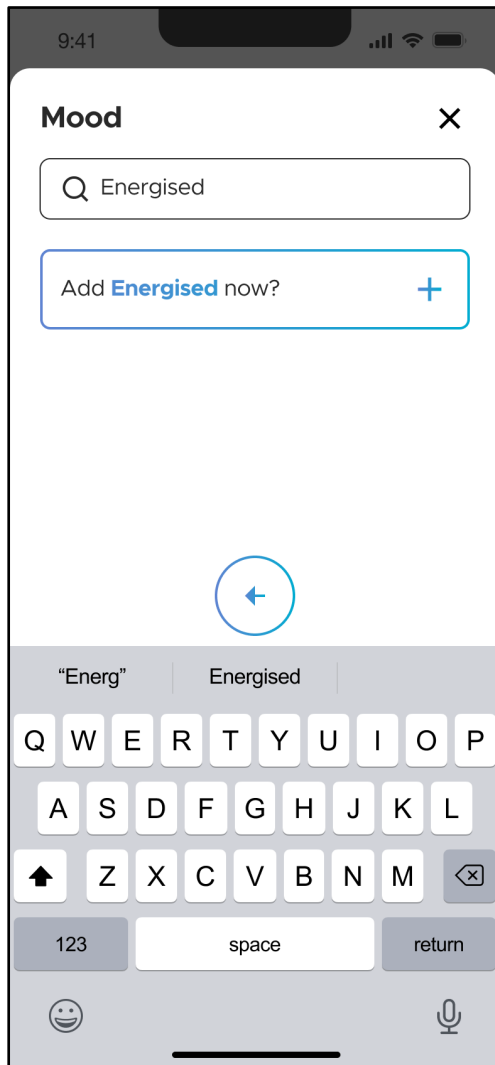


LEFT IMAGE



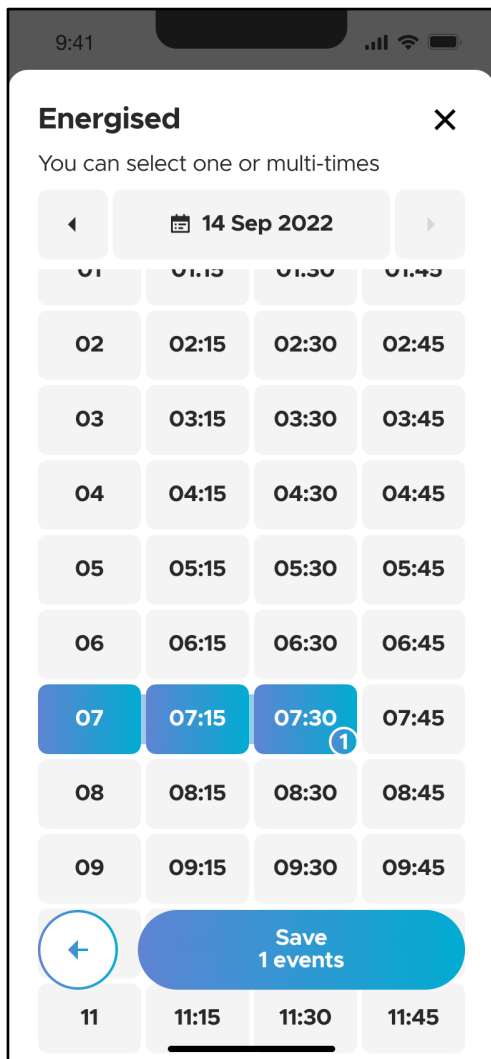
RIGHT IMAGE

To record your mood, navigate to the event log screen and tap on “Mood” (LEFT IMAGE). Select the mood you want to log from the provided list (RIGHT IMAGE). There is a search field which you can use to search for the mood that you would like to log to help you navigate the long list of moods.

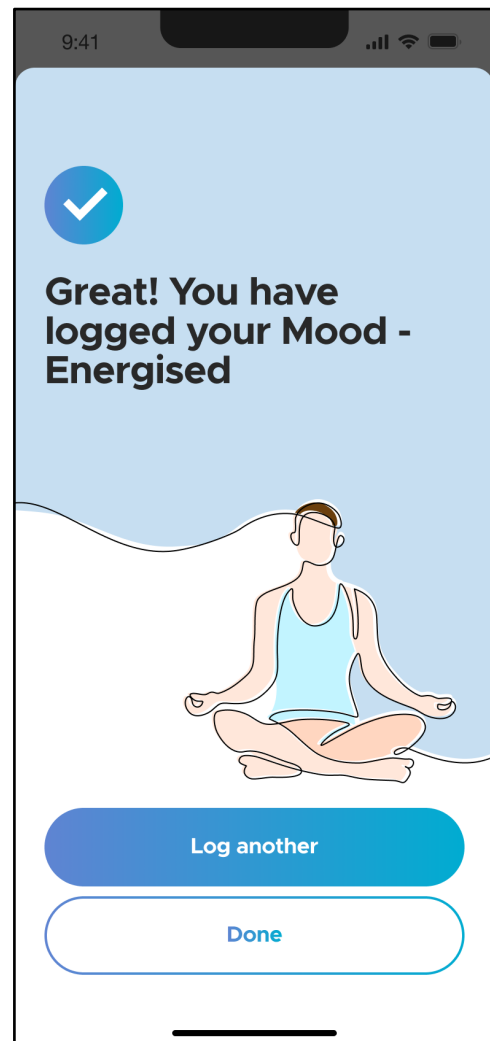


If the mood you would like to log is not already part of the mood list, you can include it as a new entry. Enter the full mood name to the search field and then press “Add *mood* now” as shown on the left panel. For example, to add “Energised” as a symptom, the button will read “Add Energised now”).

The newly added mood will be available for future logging.



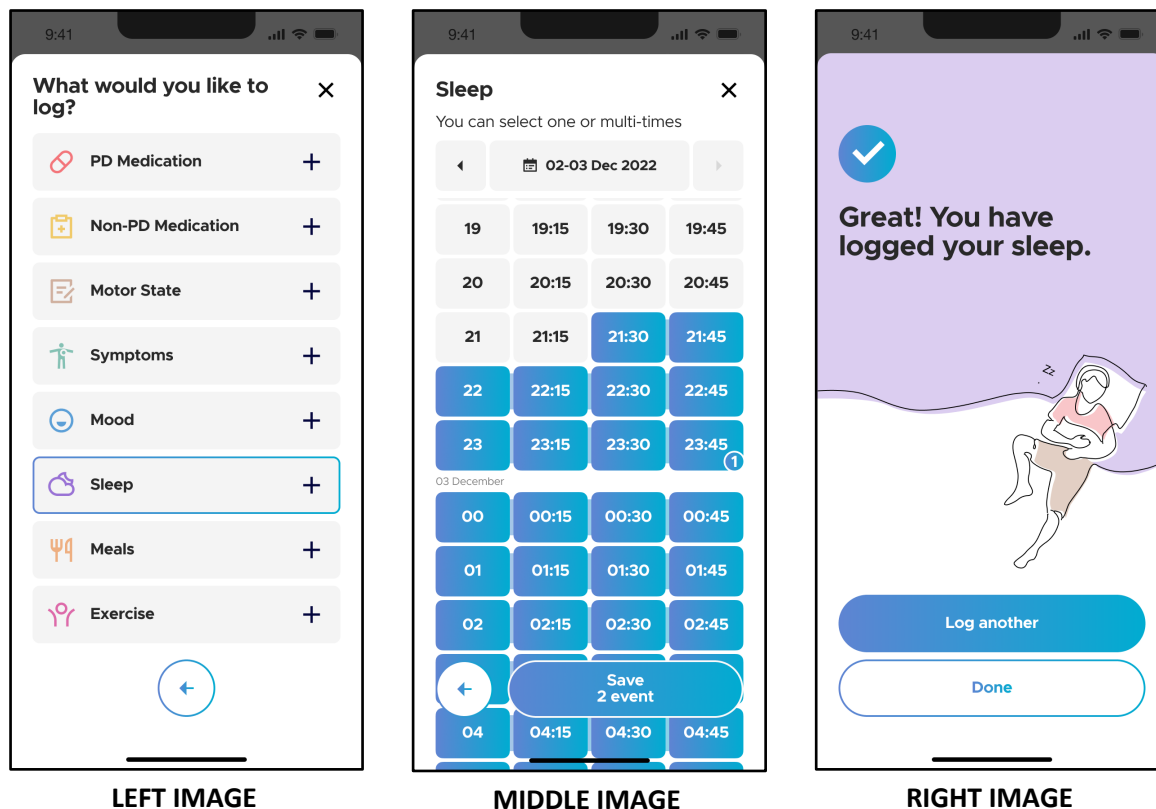
LEFT IMAGE



RIGHT IMAGE

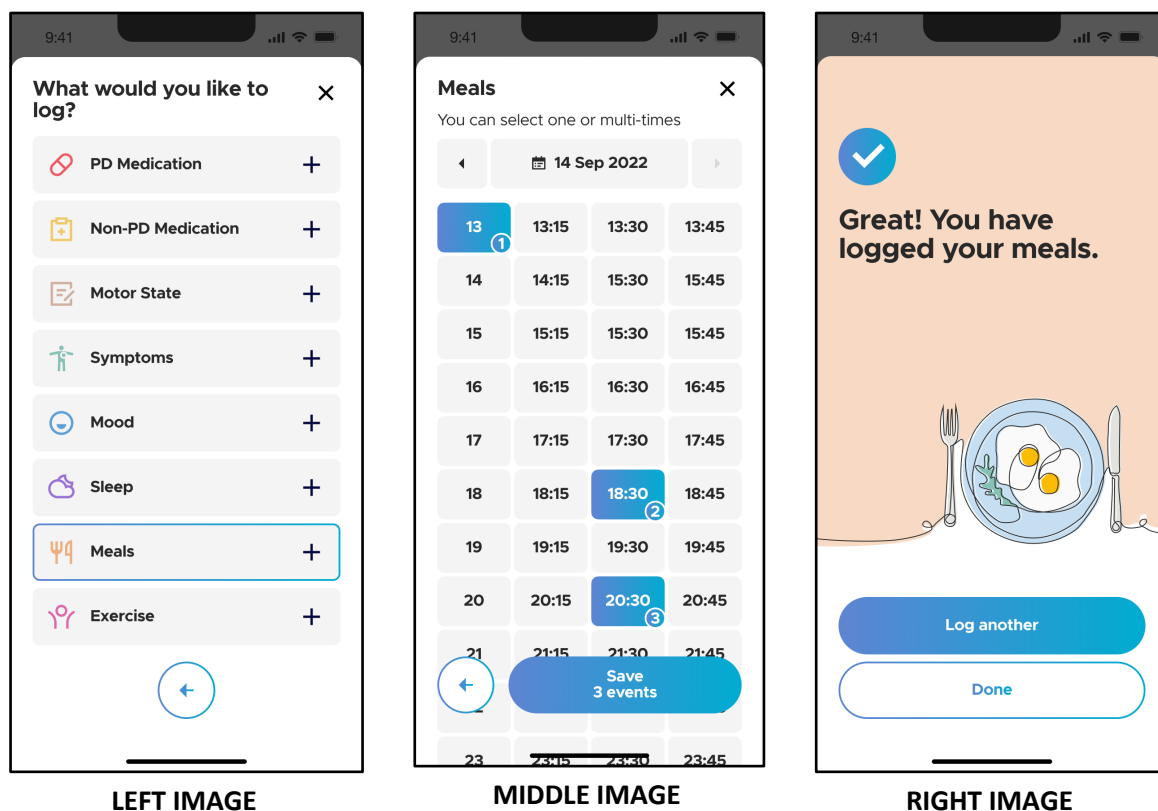
After you have selected the mood you would like to log, select the duration at which you experienced the mood and tap the "Save" button (LEFT IMAGE). The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap "Done" to go back to the "Care" screen and view your logged events.

4.3.9 Log Sleep



To record your sleep periods, navigate to the event log screen and tap on “Sleep”. Select the times and durations at which you slept and tap the “Save” button. The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap “Done” to go back to the “Care” screen and view your logged events.

4.3.10 Log Meals



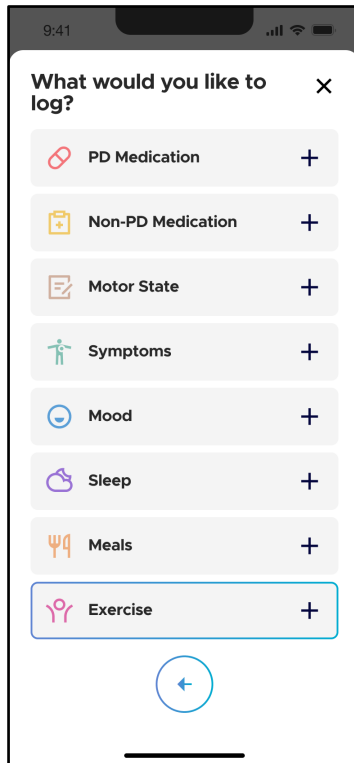
LEFT IMAGE

MIDDLE IMAGE

RIGHT IMAGE

To record your meal times, navigate to the event log screen and tap on “Meals”. Select the time at which you ate and then tap the “Save” button. The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap “Done” to go back to the “Care” screen and view your logged events.

4.3.11 Log Exercise



LEFT IMAGE



MIDDLE IMAGE



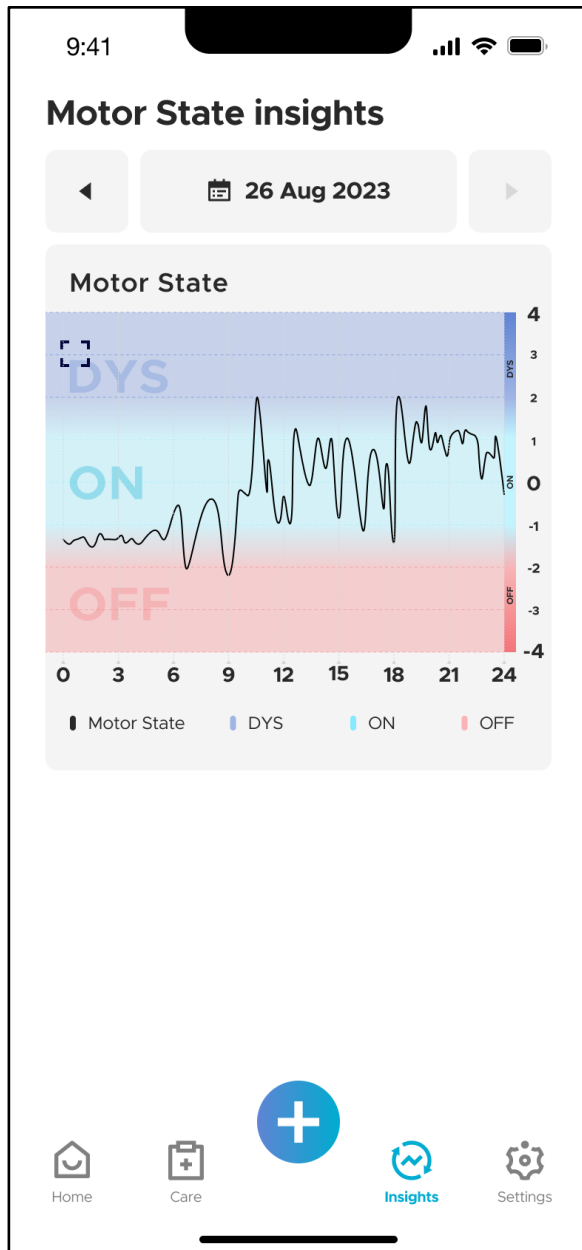
RIGHT IMAGE

To record your exercise times, navigate to the event log screen and tap on “Exercise”. Select the times and durations during which you have exercised and tap the “Save” button. The events are successfully logged when you see the completion screen (RIGHT IMAGE). Here, you can choose to log more events or tap “Done” to go back to the “Care” screen and view your logged events.

4.4 Disease Insights

4.4.1 The Motor State Graph

Neptune Care's main feature is its ability to obtain data from a third-party sensor and transform it into a scale that identifies and reflects the severity of motor symptoms, those being bradykinesia, dyskinesia and the symptom free ON-state. Symptoms are displayed minute by minute in a motor state graph. The symptom severity scale ranges from -4 to +4. Values from 1 to 4 indicate Dyskinesia, i.e., the presence of involuntary movement (Note: 1 is less severe and 4 is the most severe). Values between -1 to -4 indicate a state of Bradykinesia, i.e., slowness of movement (Note: -1 is less severe and -4 is the most severe). Values ranging from -1 to 1 are considered to be in the symptom free "ON" state.

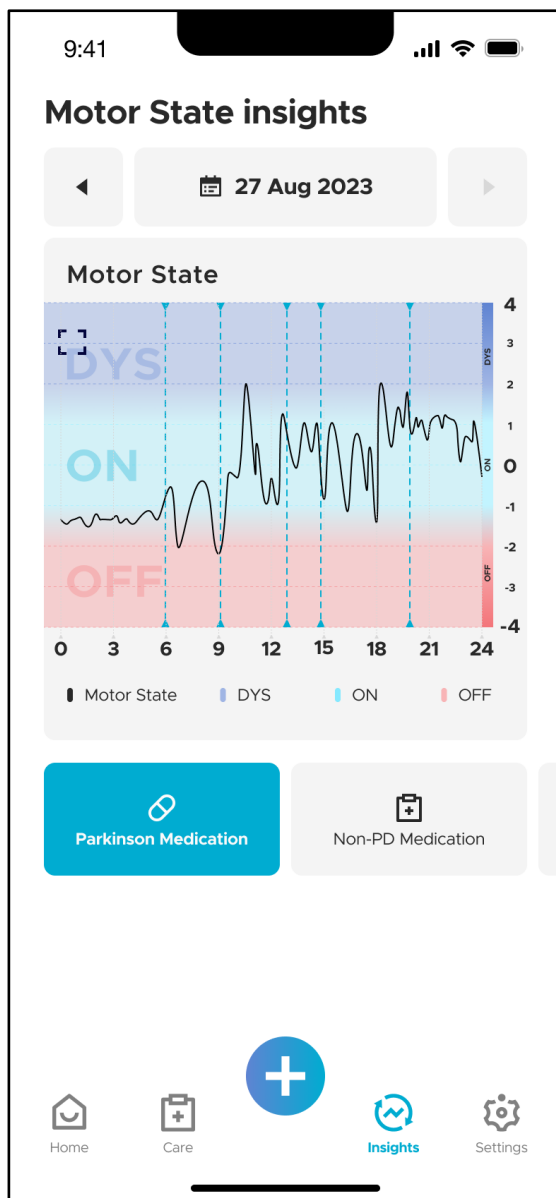


To see your motor state data, navigate to the “Insights” tab using the bottom navigation bar. On the top of the screen, you will see the date or the date range that is currently displayed (In the left panel, it is 26th August 2023). You can change the date by using the arrows or you can also select date ranges by tapping on the date field as described in section 4.4.3.*

***Please note:** You can only see your motor state insights data for days on which you have worn the sensor. You will only be able to see data up to 24 hours prior, i.e., up to the day before the current date. This is because data gathered by the sensor, for the current day, will only be processed after midnight Central European Time.

The motor state graph is displayed as a function of the hours in a given day. The ON (teal color), OFF (red color) and DYS (blue color) regions are highlighted for easy understanding of your motor states.

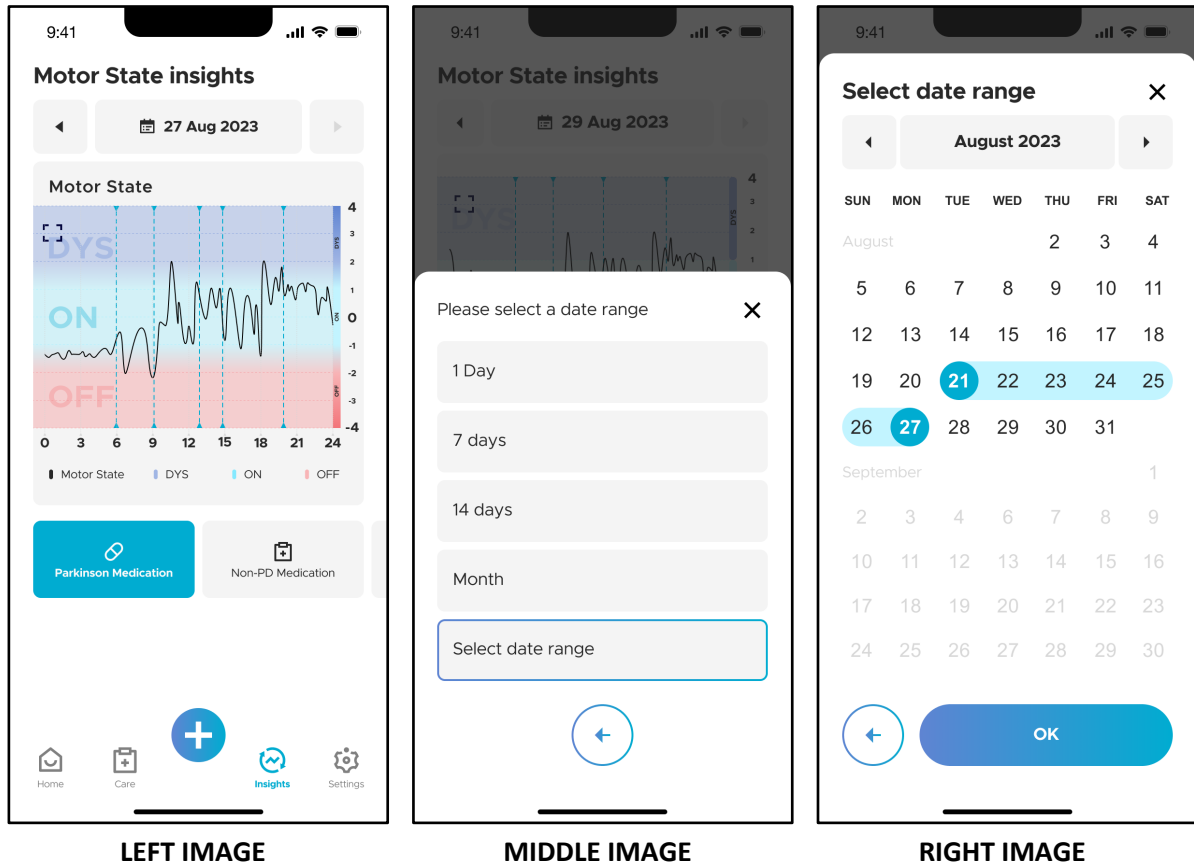
4.4.2 Overlaying Logged Events



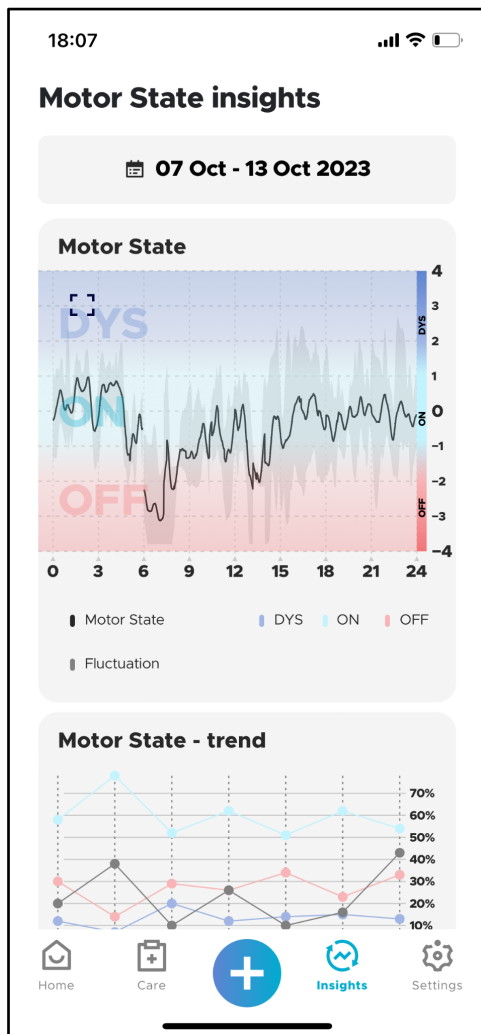
When you have logged events on days that you have worn the sensor, you can view the corresponding event types below the motor state graph. Additionally, you can overlay the occurrence of these events onto the motor state graph by tapping on the corresponding event type. In the example on the left panel, you will see that the event “Parkinson Medication” is selected. The times and/or durations of these events are then displayed on the motor state graph as vertical blue dashed lines (for time instances), or blue rectangles (for duration events, not shown here).

You can select multiple event types which will be shown on the graphic. This information can help you learn more about how the timing of certain events may influence your motor states and your PD symptoms. If you only want to see the motor state graph (without any event overlays), tap again on the selected event type to deselect it.

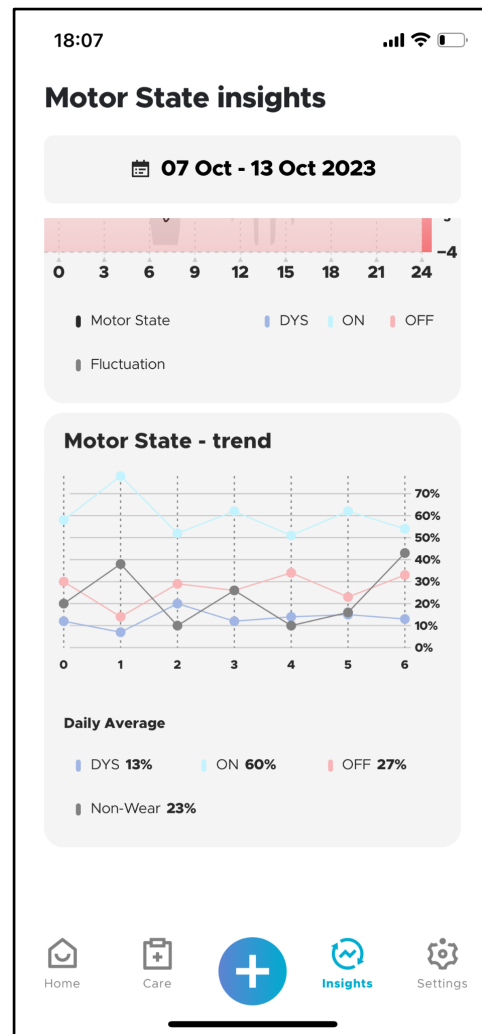
4.4.3 Motor State Insights Report



You can gain insights into your motor states by looking at aggregated data over longer periods of time. To see your aggregated data, tap on the field in which the date is displayed. A dropdown menu will open where you can select the date range. There are pre-specified ranges (1 day, 7 days, 14 days, Month) which you can select (MIDDLE IMAGE). These will aggregate your data over the specified range until the day before the current day. You can also select a custom date range by tapping on “Select date range”. A calendar will open where you can select the custom date range (RIGHT IMAGE).



LEFT IMAGE



RIGHT IMAGE

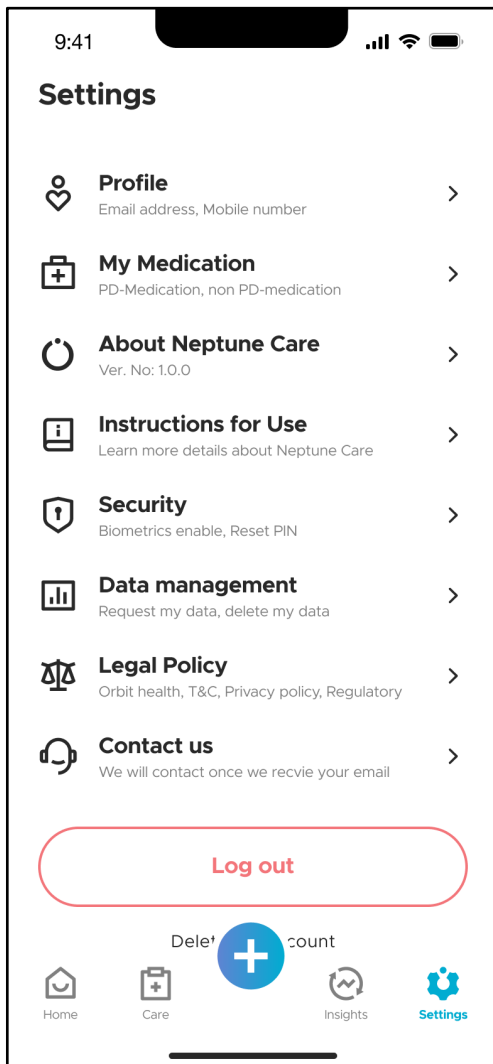
When you select a date range, an aggregated motor state graph is displayed (LEFT IMAGE). This aggregated view displays the average motor state calculated over all the days in the selected date range (for each minute of a day, the mean value over all days is calculated) and is displayed as the black line. The shaded area around this black line highlights the fluctuation around this mean value (i.e. the standard deviation around the mean). This fluctuation informs you about how different your motor state is when you compare the same time for different days. High fluctuations (larger shaded areas) mean that your motor state differs when comparing different days while small fluctuations (smaller shaded areas) mean that your motor state is very similar when comparing the same time for different days.

Beneath the aggregated motor state graph, a motor state trend graph is displayed (RIGHT IMAGE). For each day, the graphic displays the percentage of time you have spent in each of the different motor states (ON, OFF, DYS) or when you did not wear the sensor (Non-wear). This allows you to monitor the change of your motor symptoms over longer periods of time.

***Please note:** The Motor State - trend category (DYS, ON, and OFF) percentages are based on the percent of time of active wear. For example if you experience 23% of non-wear, the DYS, ON, and OFF percentages are calculated based on the remaining 77% of the time when you were actively using the device.

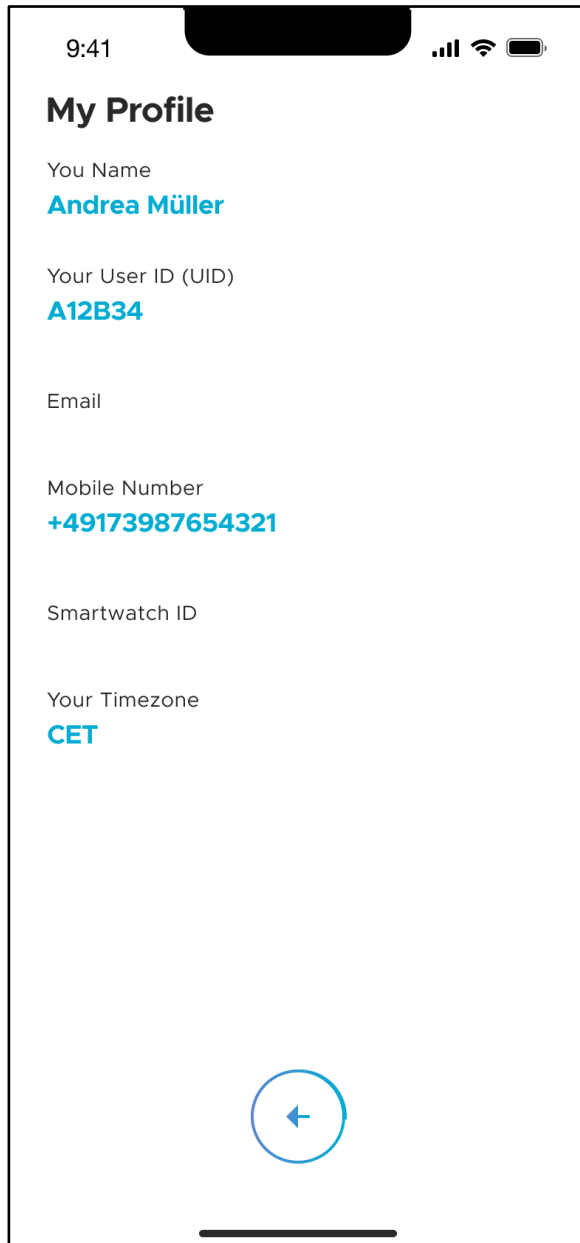
4.5 Settings

4.5.1 The Settings Screen



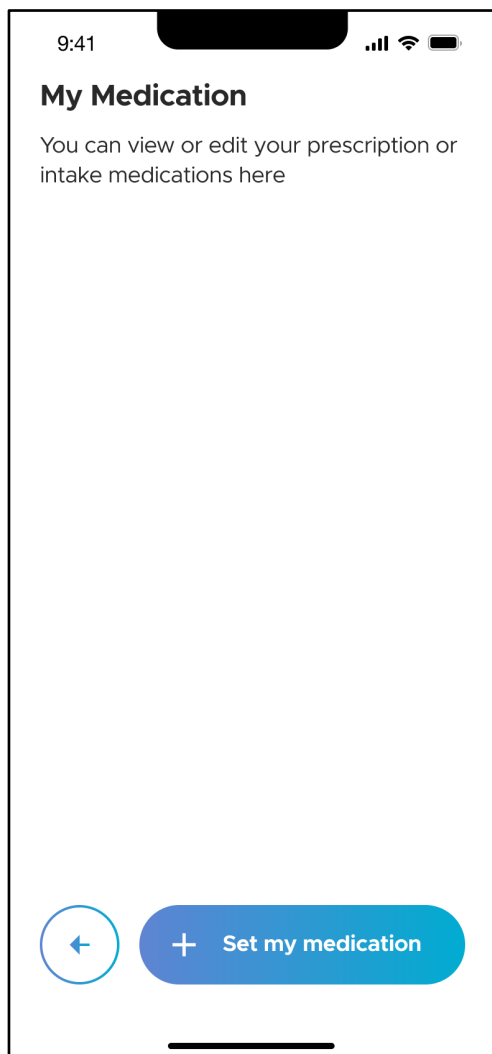
To access the settings screen, tap on the “Settings” icon in the bottom navigation bar. The settings screen allows you to get information about your profile (**Profile**), medication information (**My Medication**) and Neptune Care (**About Neptune Care**). You can also change your security settings (**Security**), manage your data (**Data management**), manage your consent to Terms of Service and Data Processing (**Legal Policy**), and view Orbit Health contact information (**Contact us**). Furthermore, you can log out (**Log out**) and delete your account (**Delete my account**).

4.5.2 My Profile

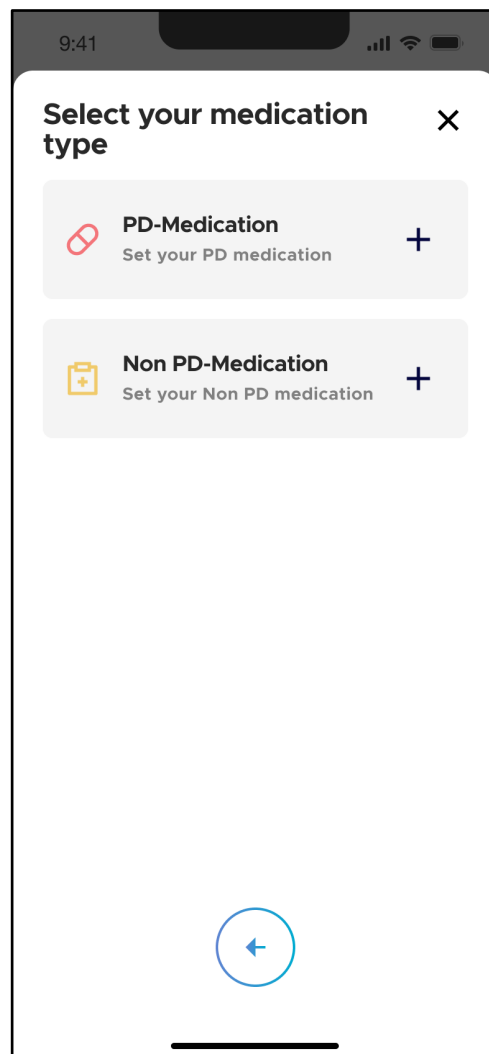


The “My Profile” screen shows information about your Neptune Care account. This includes the name you provided during sign-up, Email address and mobile phone number you provided, your Smartwatch ID, your time zone and your unique identification code (UID). The UID is a random code that is generated by Neptune Care during sign-up. You will need this code to access your personal data as described in section 4.5.7.

4.5.3 My Medication



LEFT IMAGE

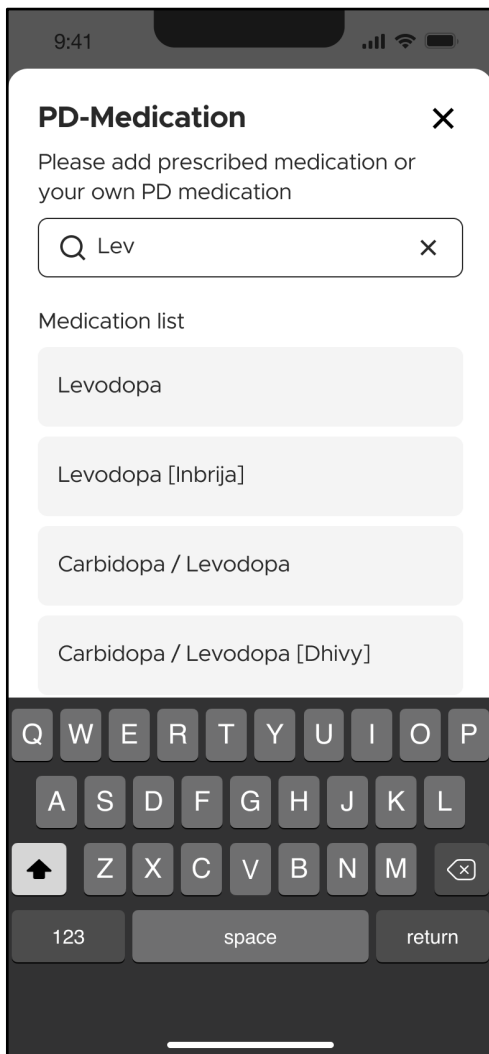


RIGHT IMAGE

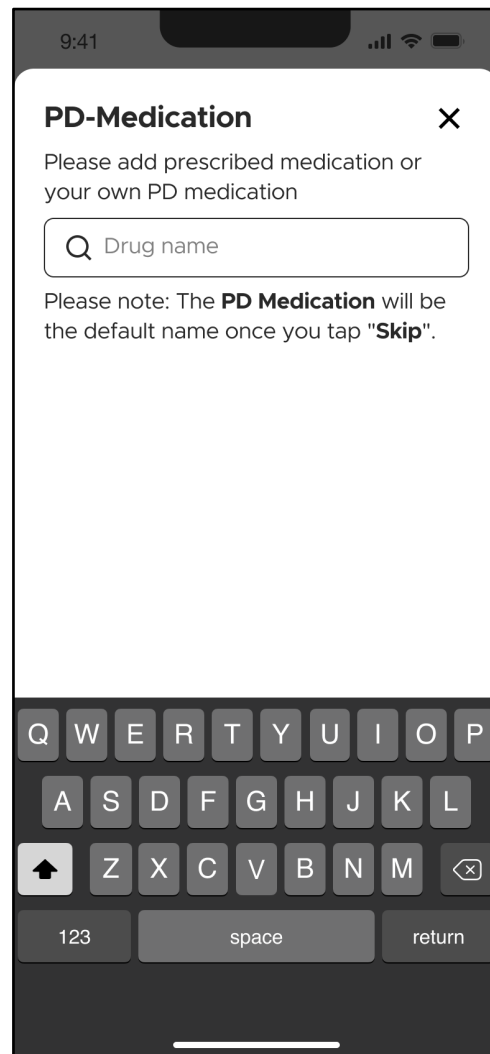
The “My Medication” screen shows information about your medication plan. To set up your medication plan, tap “+ Set my medication” (LEFT IMAGE). You will now be able to input “PD-Medication” and/or “Non PD-Medication” under the “Select your medication type” screen (RIGHT IMAGE).

4.5.3.1 PD Medications

To input PD medications, tap on “PD-Medication” (RIGHT IMAGE).



LEFT IMAGE



RIGHT IMAGE

Under the “PD-medication” screen, type in the name of the PD medication in the input field (LEFT IMAGE). A drop down list will be populated after you have entered at least 3 characters of the medication name. For example, after entering “Lev” into the field, a few possible drug candidates will be populated in the drop down list. Select the appropriate medication from the drop down list. If the drug that you are trying to add is not already part of the drop down list, you can include it as a new entry (RIGHT IMAGE).

9:41

PD-Medication ×

Please add prescribed medication or your own PD medication

Carbidopa / Levodopa ×

Route (e.g.oral, enteral, etc.)

Oral ▾

Strength

25mg / 100mg ▾

Product list

- Carbidopa and levodopa Tablet, Oral
ScieGen Pharmaceuticals Inc
- Carbidopa-levodopa Tablet, Oral
Advagen Pharma Ltd.,
- Sinemet, Tablet, Oral
Organon LLC
- Sinemet, Tablet, Oral
Merck Sharp & Dohme Corp.

← Skip

LEFT IMAGE

9:41

Carbidopa 25 mg/1- Levodopa 100 mg/1, Oral ×

Dosage (e.g. pill, teaspoon, etc.)

— 1 (Tablet) +

← Next

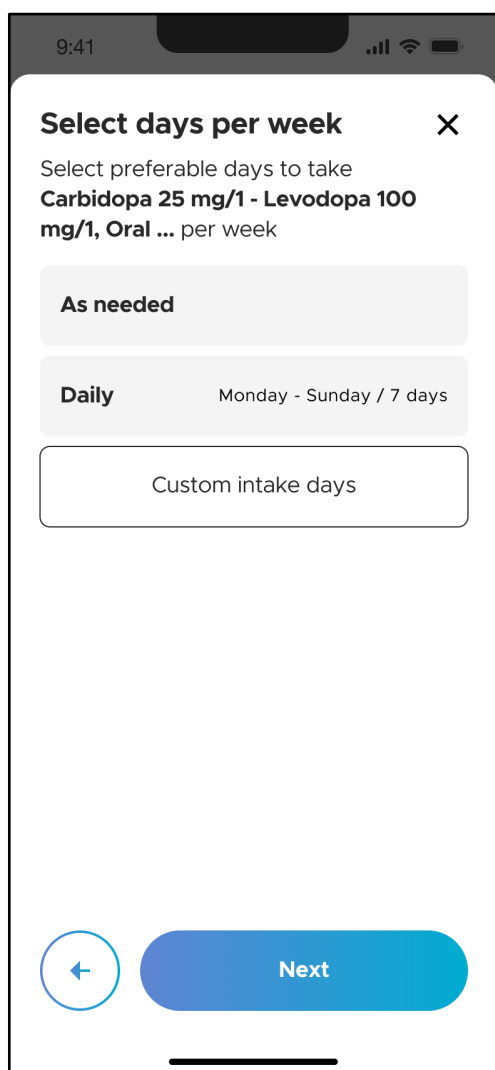
Skip

RIGHT IMAGE

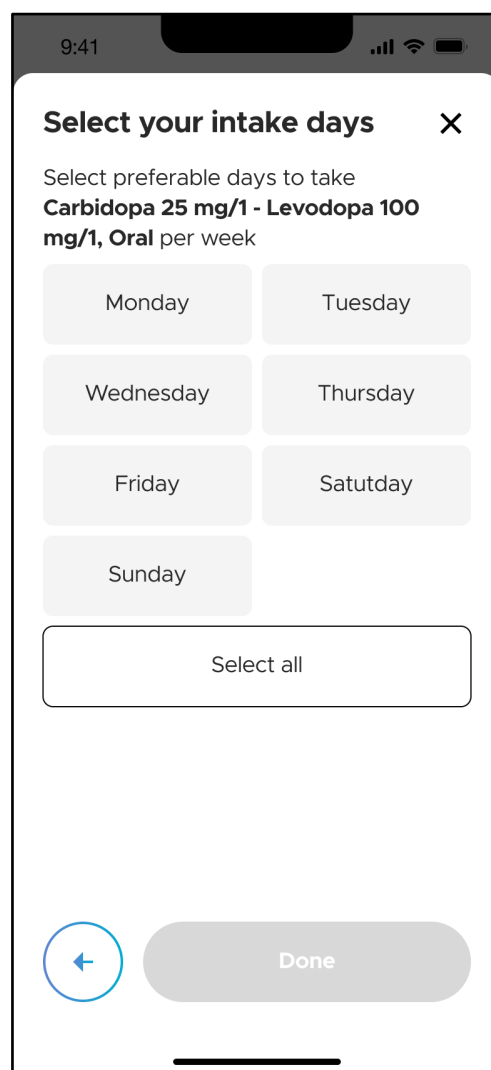
Next, select the appropriate route of administration under “Route”, followed by the medication strength under “Strength” from their respective drop down lists (LEFT IMAGE). Select the appropriate medication name from the “Product list” (LEFT IMAGE).

***Please note:** The product list will not show up if you have added the drug as a new entry.

Once selected, you will be brought to the next screen to input the dosage of the medication (RIGHT IMAGE). There is a “-” or “+” button to edit the dosage if needed. Tap on “Next” to continue.

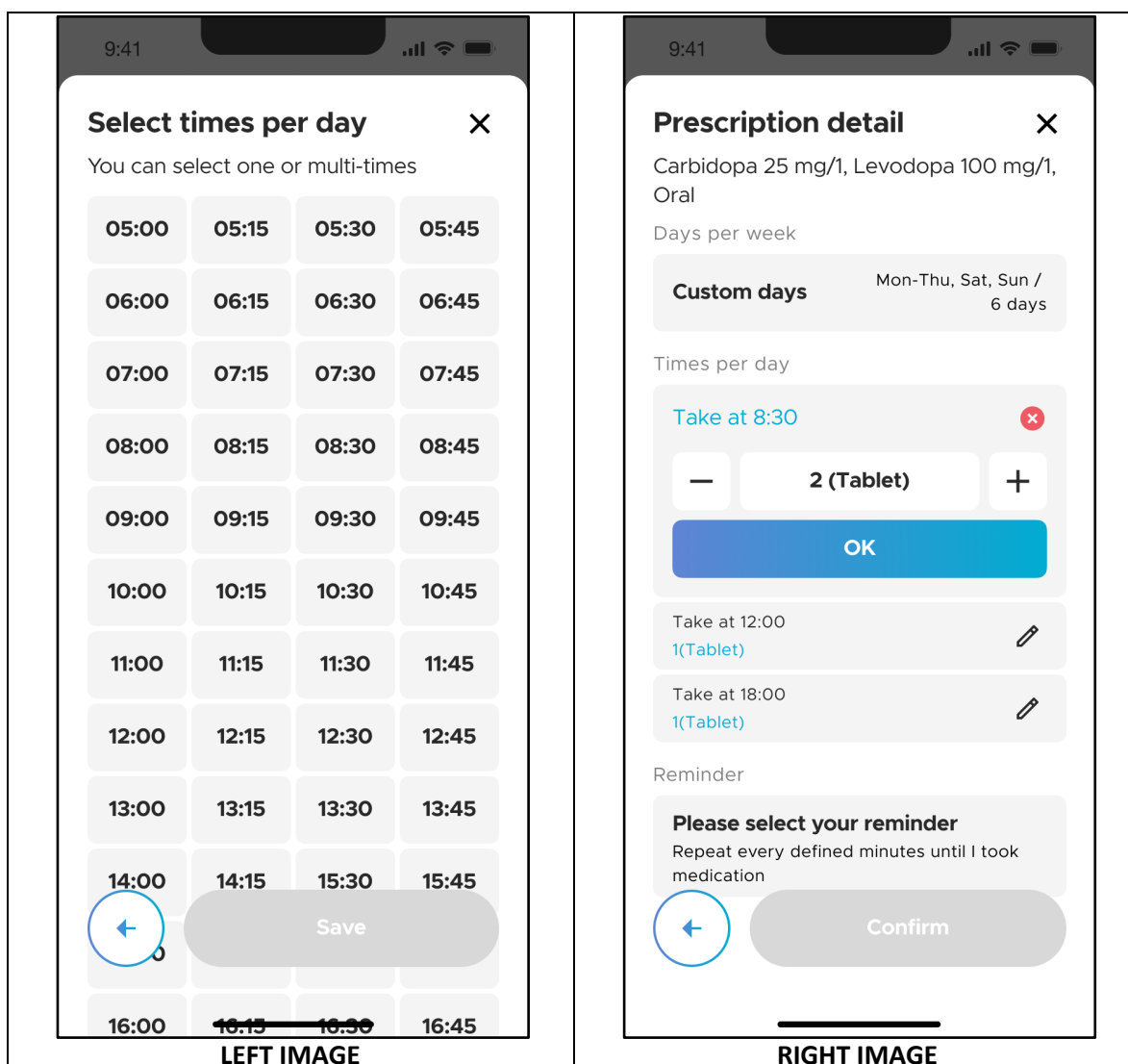


LEFT IMAGE



RIGHT IMAGE

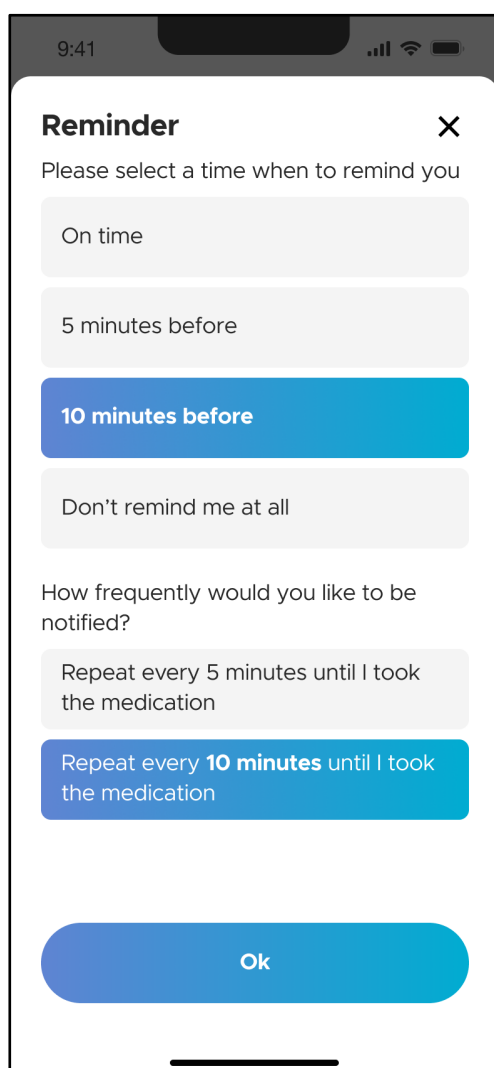
Under the “Select days per week” screen, specify the number of days per week for which the medication needs to be taken (LEFT IMAGE). The possible selections are “As needed”, “Daily” and “Custom intake days”. To customize specific days on which the medication needs to be taken, tap on “Custom intake days” to go to the “Select your intake days” screen (RIGHT IMAGE). Specify the days of the week and tap “Done” to continue.



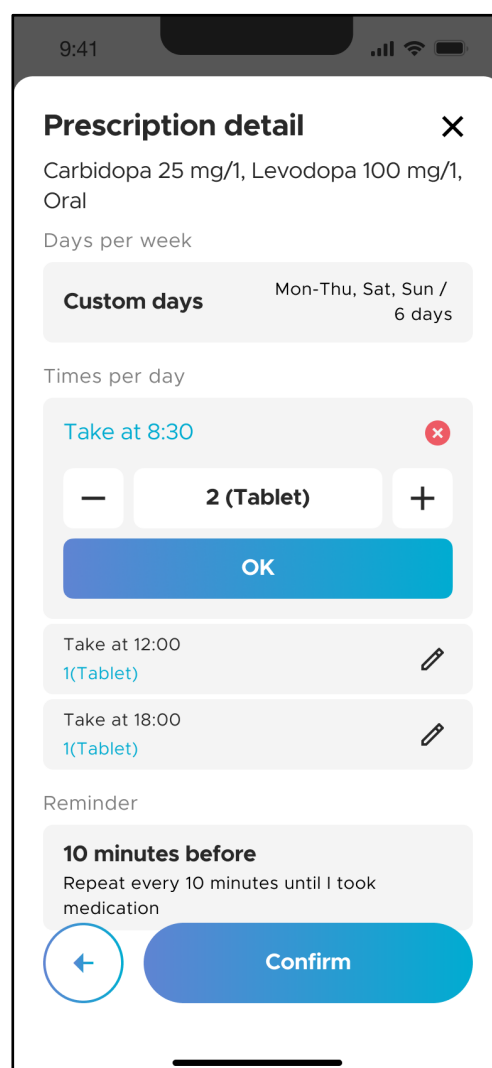
Under the “Select times per day screen”, select the time points in which you have taken the medication(s) and tap the “Save” button.

Once completed, you will be brought to the "Prescription detail" screen with an overview of your inputs for that medication (RIGHT IMAGE). If necessary, you can edit each intake time and dosage individually by tapping the “Edit” icon on each panel.

At the bottom of the screen is the “Reminder” section (RIGHT IMAGE). Tap on “Please select your reminder”.



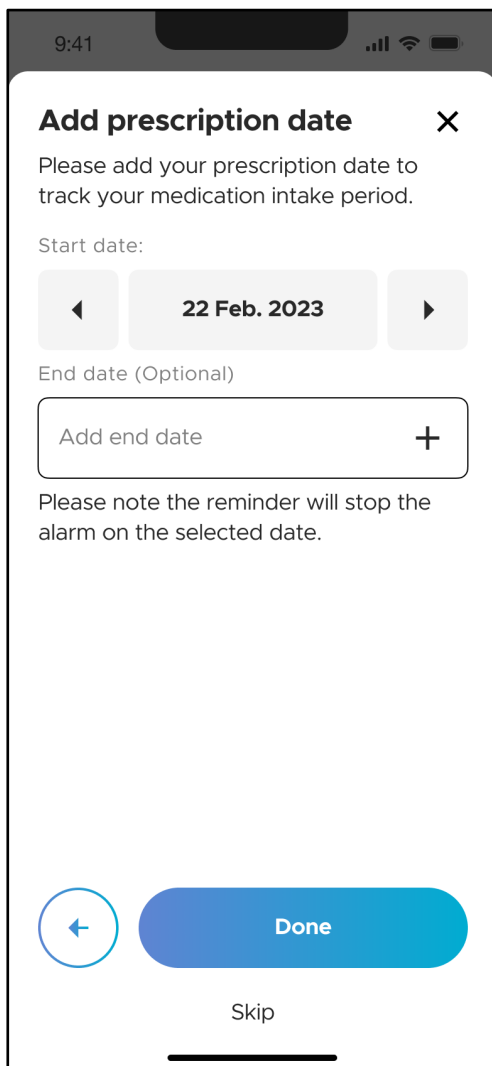
LEFT IMAGE



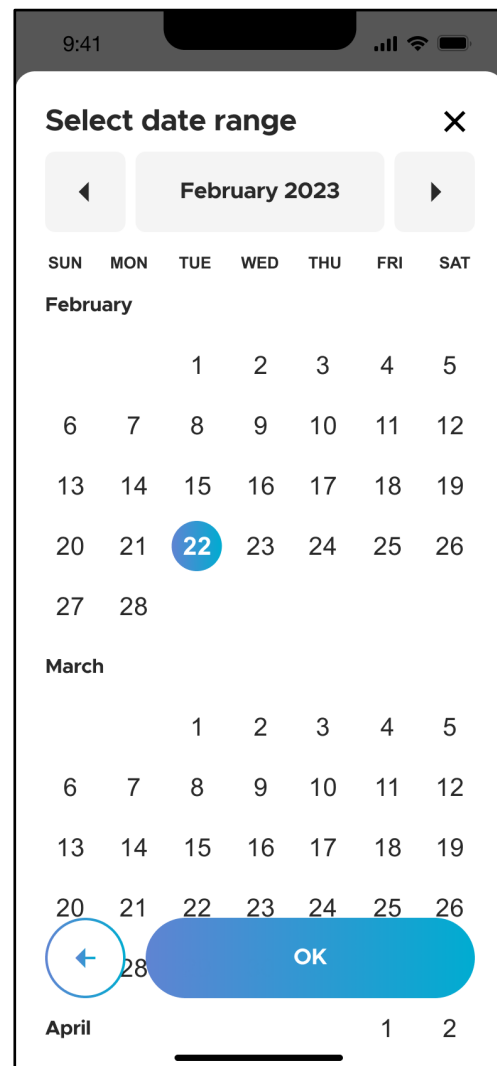
RIGHT IMAGE

Under the “Reminder” screen (LEFT IMAGE), you can customize the reminder times and frequency of reminders for each medication. The possible selections for reminder times are “On-time”, “5 minutes before”, “10 minutes before” and “Don't remind me at all”. The reminder is set to “10 minutes before” by default.

The possible selections for frequency of reminders are “Repeat every 5 minutes” and “Repeat every 10 minutes”. The frequency of reminders is set to “Repeat every 10 minutes” by default. Tap “OK” to complete the reminder setting and return to the “Prescription detail” screen (RIGHT IMAGE). Tap “Confirm” to save this medication input.



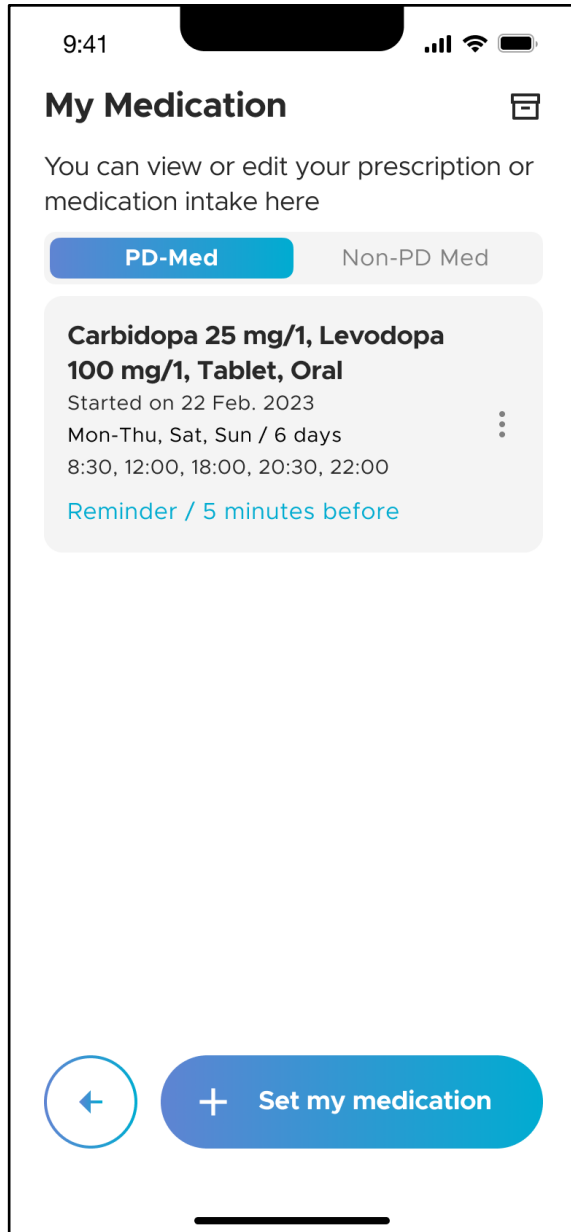
LEFT IMAGE



RIGHT IMAGE

You will then be brought to a “Add prescription date” screen for you to track the start and end dates of the medication intake. “Start date” is defaulted to the current date (according to your mobile device setting). You can set the “Start date” by tapping the forward and backward arrows. You can also change the date by tapping on the date tile itself. The latter opens a calendar (RIGHT IMAGE) to select the desired date.

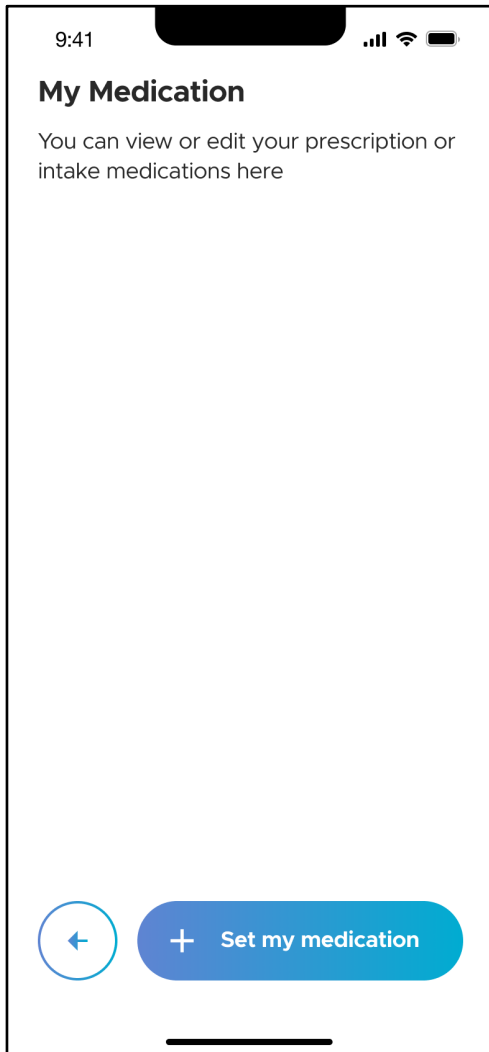
It is not mandatory to add the “End date” for your prescription. However, please note that if you have added an “End date”, the medication reminder will stop the alarm on this date.



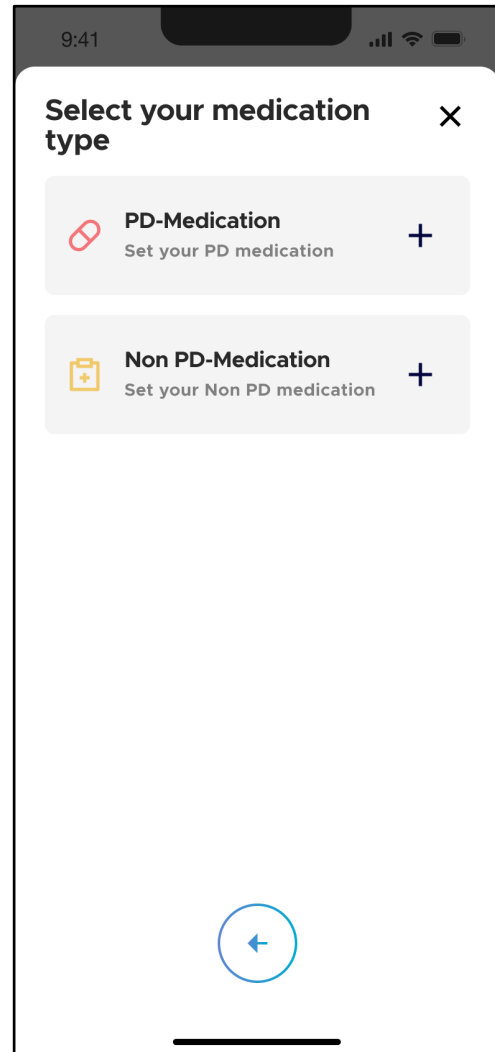
Upon completion, you will then be brought back to the “My Medication” screen. There are 2 tabs under the “My Medication”, namely “PD-Med” and “Non-PD Med”. To add another PD medication into your medication plan, tap “+ Set my medication” and repeat the instructions described in section 4.5.3.1. To add non-PD medications, refer to section 4.5.3.2.

4.5.3.2 Non-PD Medications

To input Non PD-medications into your medication plan, tap “+ Set my medication” (LEFT IMAGE) and tap on “Non PD-Medication” (RIGHT IMAGE).



LEFT IMAGE



RIGHT IMAGE

9:41

Non PD-Medication

Please add prescribed medication or your own Non PD-Medication

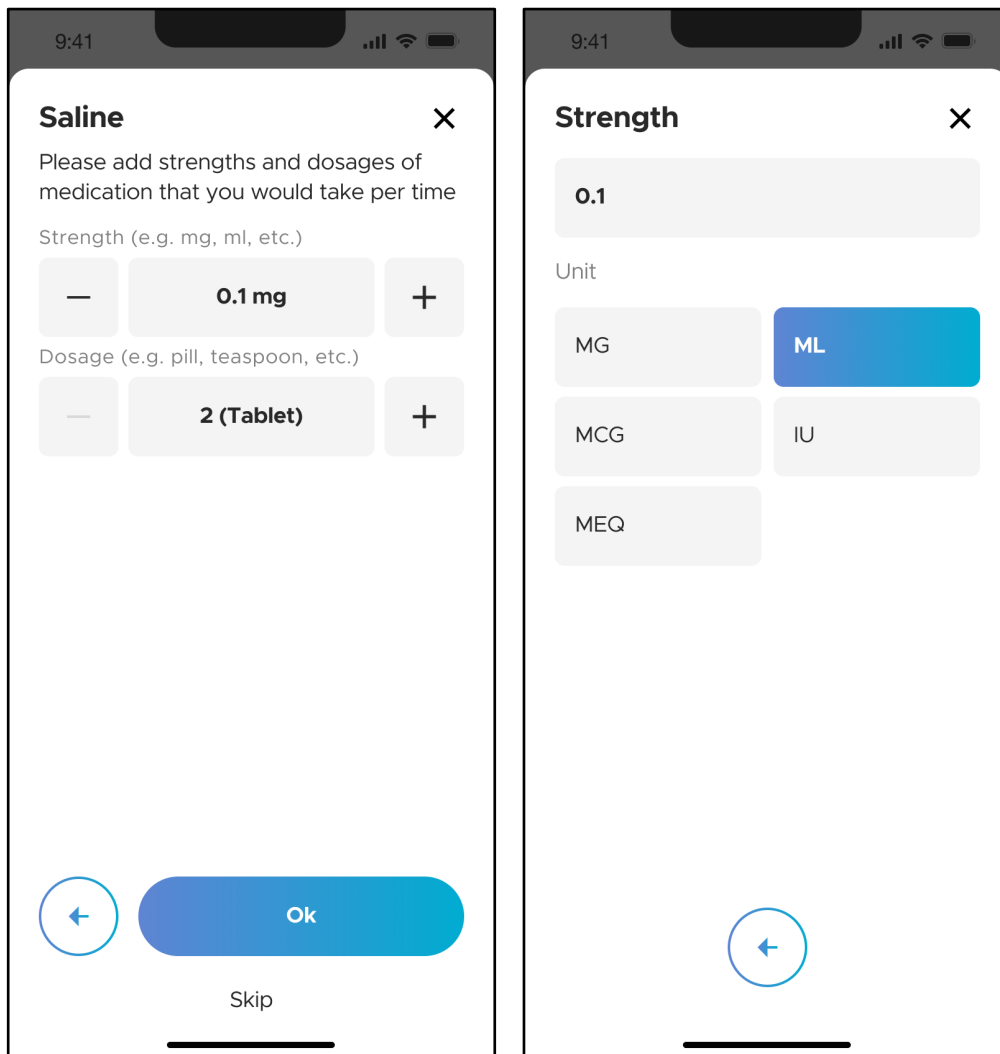
Q Saline

What is your medication?

Add **Saline** now?

← Skip

Under the “Non PD-medication” screen, type in the name of the non-PD medication in the input field. A drop down list will be populated after you have entered at least 3 characters of the medication name. For example, after entering “Sal” into the field, a few possible drug candidates will be populated in the drop down list. Select the appropriate medication from the drop down list. If the drug that you are trying to add is not already part of the drop down list, you can include it as a new entry.



LEFT IMAGE

RIGHT IMAGE

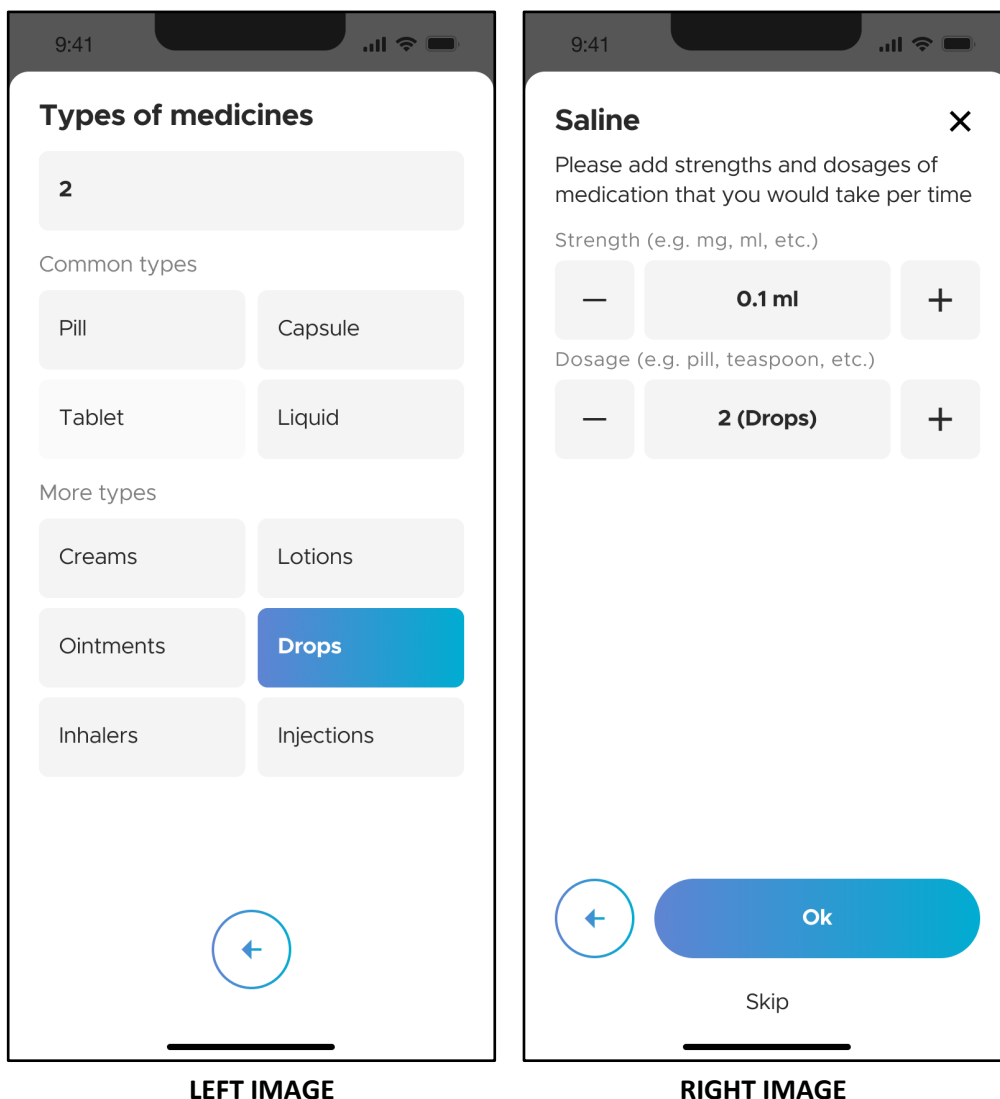
Next, input the strength of the medication under “Strength” (LEFT IMAGE). There is a “-” or “+” button to edit the strength if needed. To edit the units of measurement, tap on the strength tile itself. For example, in the LEFT IMAGE, tap on “0.1 mg”. You will then be brought to a page (RIGHT IMAGE) where you can select the appropriate units of measurement (e.g. mg, ml, etc.). You can also edit the strength of the medication by manually typing in the numeric value right above the “Unit” selections.

Once completed, tap on “<--” to return to the previous screen.

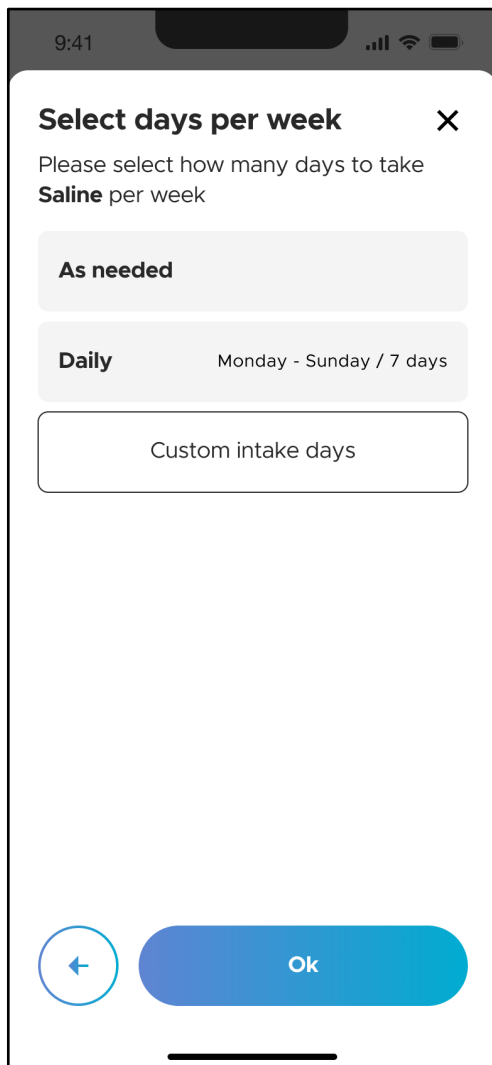
Next, input the dosage of the medication under “Dosage” (LEFT IMAGE). There is a “-” or “+” button to edit the dosage if needed. To edit the units of measurement, tap on the dosage tile itself. For example, in the LEFT IMAGE above, tap on “2 (Tablet)”.

You will then be brought to a page (LEFT IMAGE) where you can select the appropriate type of medicine (e.g. tablet, capsule, etc.). You can also edit the dosage of the medication by manually typing in the numeric value right above the “Common types” selections.

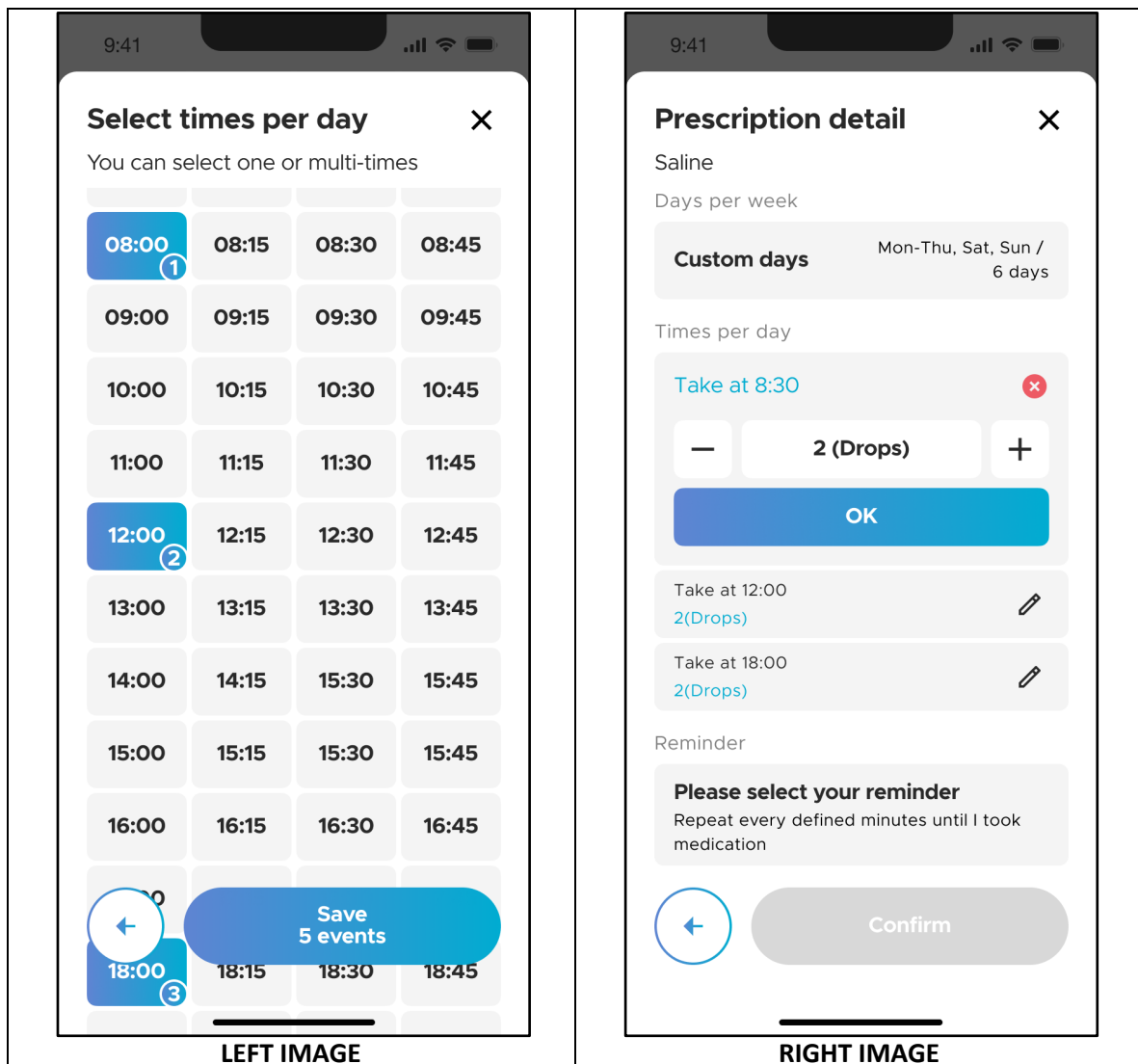
Once completed, tap on “<--” to return to the previous screen.



Tap on “OK” to continue (RIGHT IMAGE).



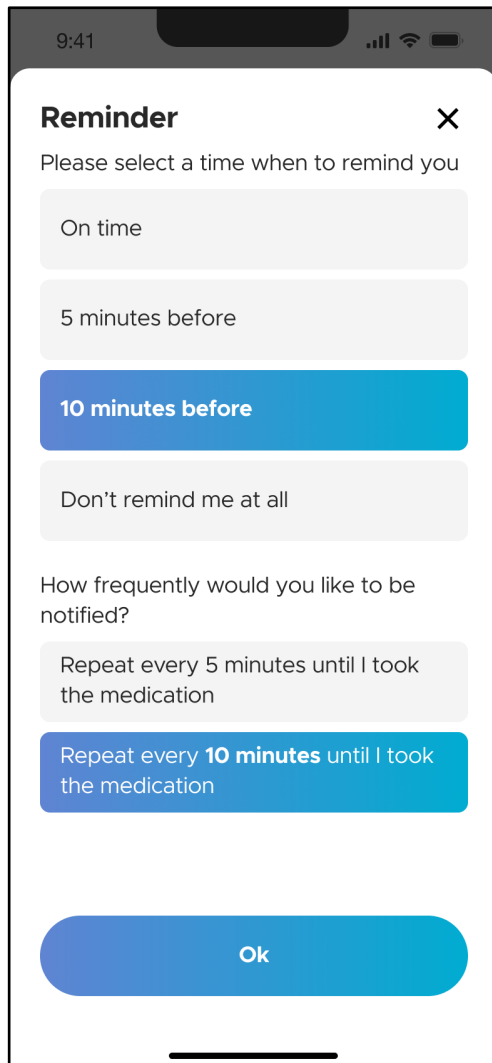
Under the “Select days per week” screen, specify the number of days per week for which the medication needs to be taken. The possible selections are “As needed”, “Daily” and “Custom intake days”. To customize specific days on which the medication needs to be taken, refer to section 4.5.3.1.



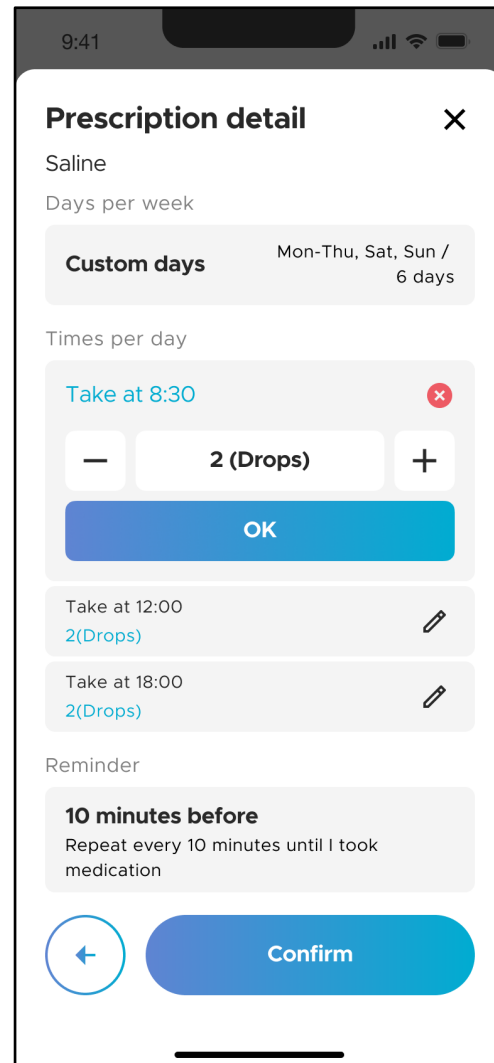
Under the “Select times per day screen” (LEFT IMAGE), select the time points in which you have taken the medication(s) and tap the “Save” button.

Once completed, you will be brought to the "Prescription detail" screen with an overview of your inputs for that medication (RIGHT IMAGE). If necessary, you can edit each intake time and dosage individually by tapping the “Edit” icon on each panel.

At the bottom of the screen is the “Reminder” section. Tap on “Please select your reminder”.



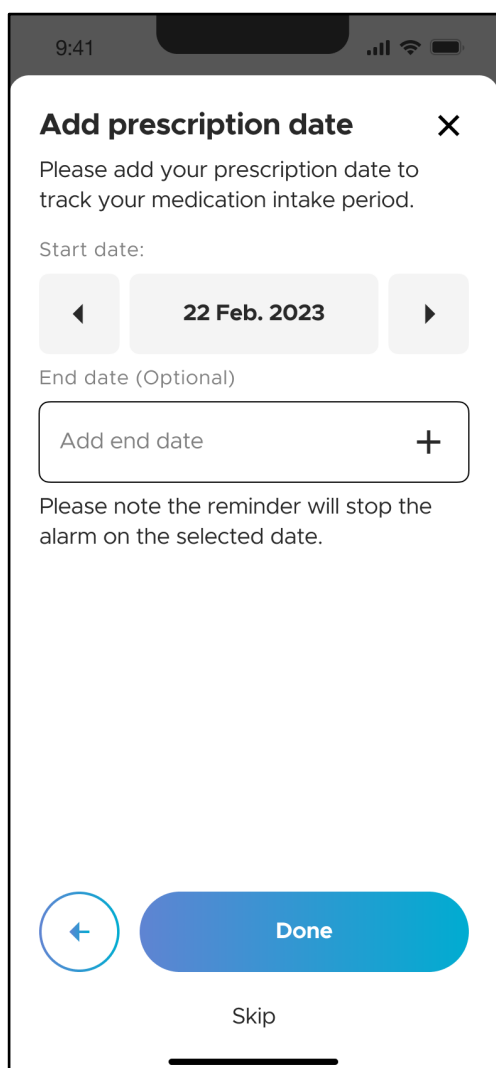
LEFT IMAGE



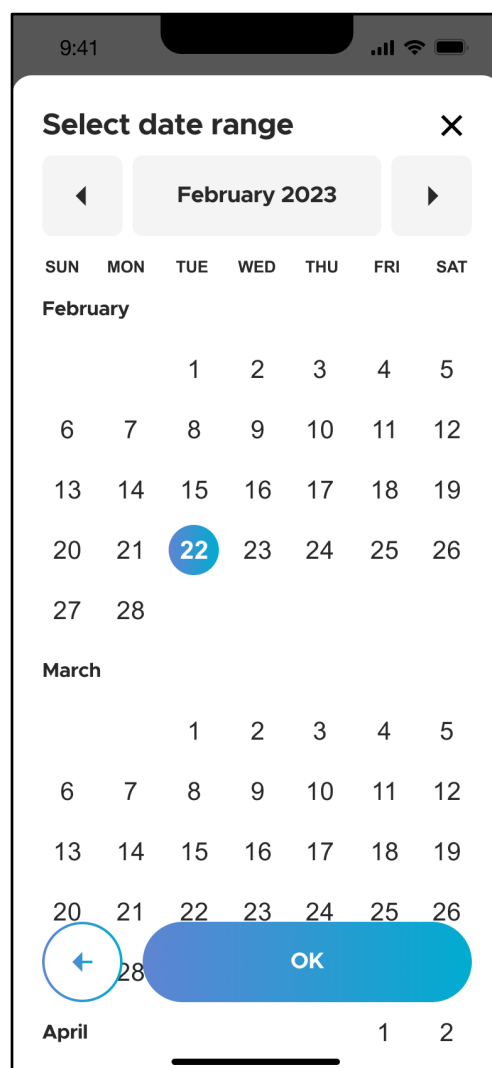
RIGHT IMAGE

Under the “Reminder” screen (LEFT IMAGE), you can customize the reminder times and frequency of reminders for each medication. The possible selections for reminder times are “On-time”, “5 minutes before”, “10 minutes before” and “Don't remind me at all”. The reminder is set to “10 minutes before” by default.

The possible selections for frequency of reminders are “Repeat every 5 minutes” and “Repeat every 10 minutes”. The frequency of reminders is set to “Repeat every 10 minutes” by default. Tap “OK” to complete the reminder setting and return to the “Prescription detail” screen (RIGHT IMAGE). Tap “Confirm” to save this medication input.



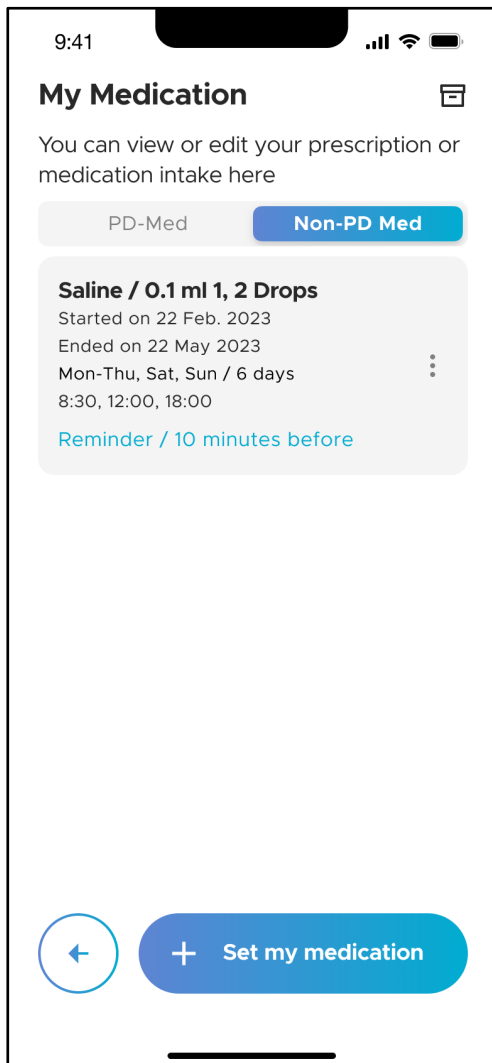
LEFT IMAGE



RIGHT IMAGE

Next, you will see the “Add prescription date” screen where you can track the start and end dates of the medication intake (LEFT IMAGE). “Start date” is defaulted to the current date (according to your mobile device setting). You can set the “Start date” by tapping the forward and backward arrows. You can also change the date by tapping on the date tile itself. The latter opens a calendar (RIGHT IMAGE) to select the desired date.

It is not mandatory to add the “End date” for your prescription. However, please note that if you have added an “End date”, the medication reminder will stop the alarm on this date.

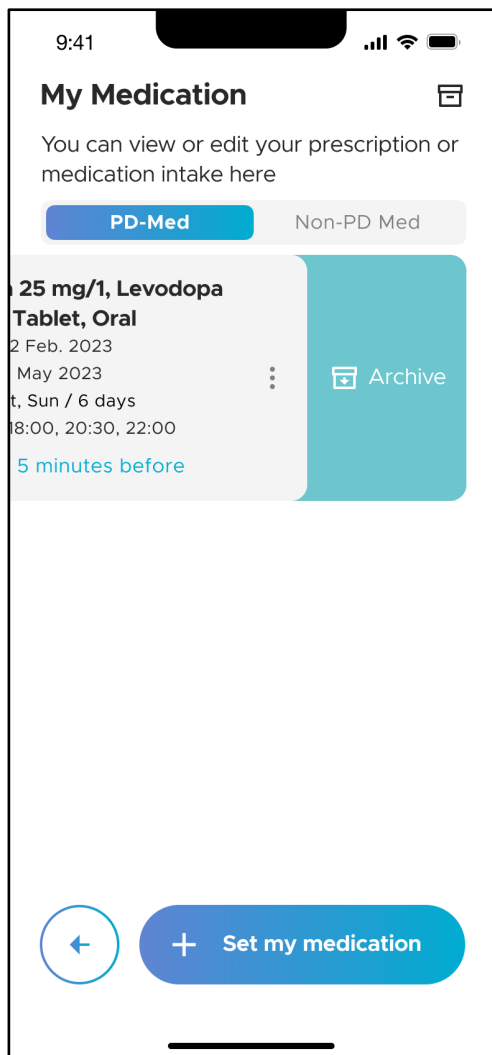


Upon completion, you will then be brought back to the “My Medication” screen. There are 2 tabs under the “My Medication”, namely “PD-Med” and “Non-PD Med”. To add another PD medication into your medication plan, tap “+ Set my medication” and repeat the instructions described in section 4.5.3.1. To add non-PD medications, refer to section 4.5.3.2.

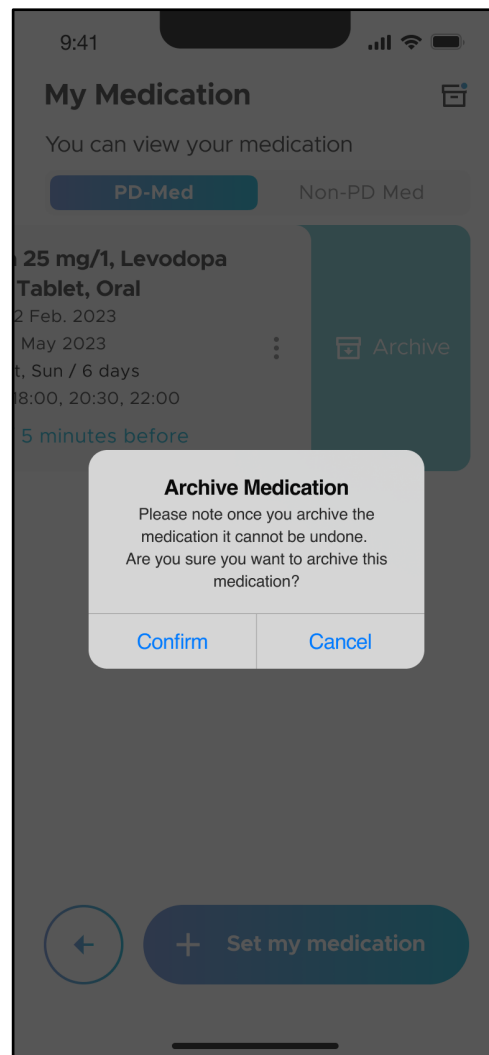
4.5.3.3 Archiving PD Medications

After the end date of each medication that was set up in your medication plan, that medication will be automatically archived.

To manually archive a PD medication from your medication plan, navigate to the “My medication” screen and tap on the “PD-Med” tab. Swipe left on the medication which you would like to archive (LEFT IMAGE). Tap “Confirm” in the pop-up window (RIGHT IMAGE).



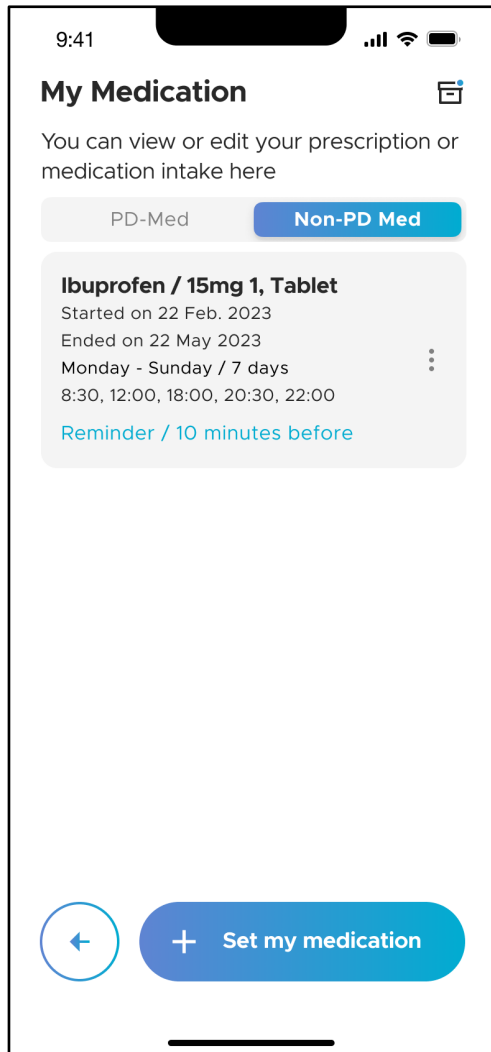
LEFT IMAGE



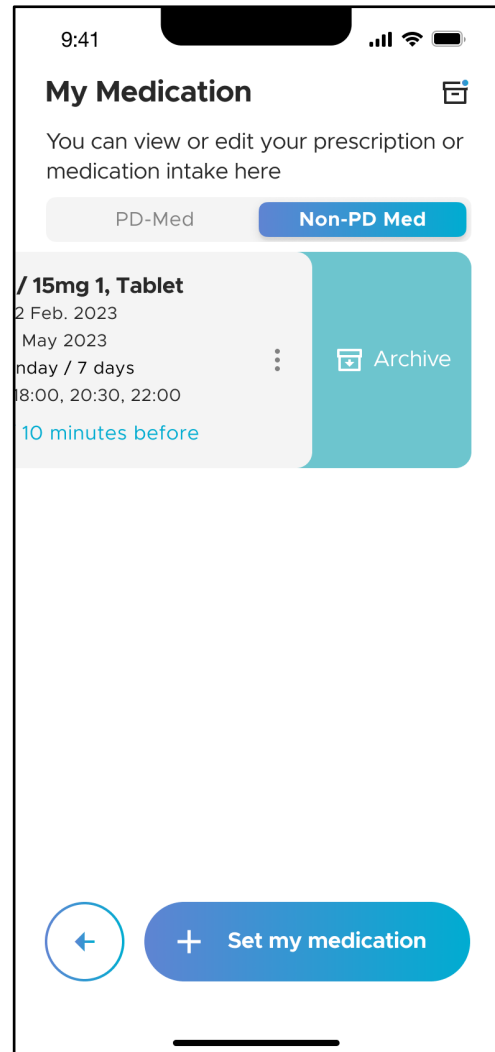
RIGHT IMAGE

4.5.3.4 Archiving Non-PD Medications

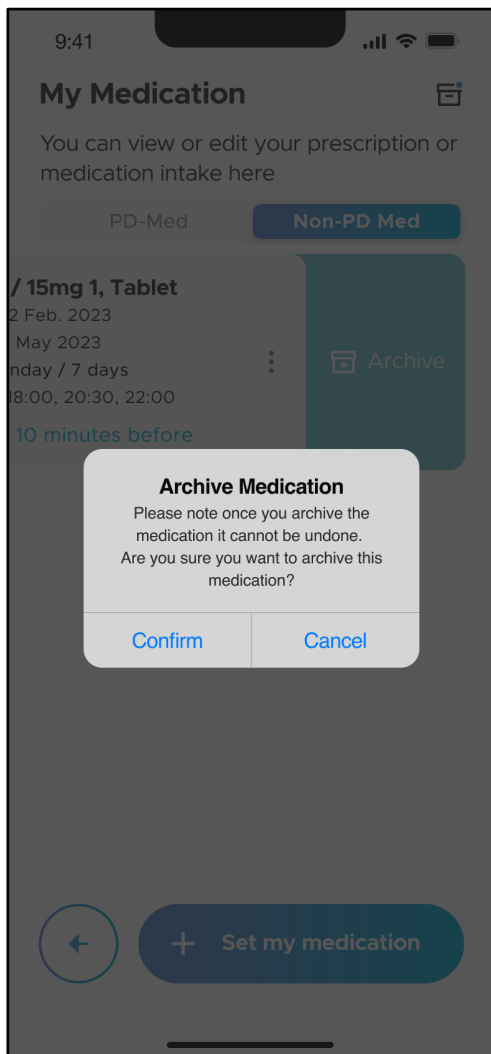
To manually archive a Non-PD medication from your medication plan, navigate to the “My medication” screen and tap on the “Non-PD Med” tab (LEFT IMAGE). Swipe left on the medication which you would like to archive (RIGHT IMAGE).



LEFT IMAGE



RIGHT IMAGE

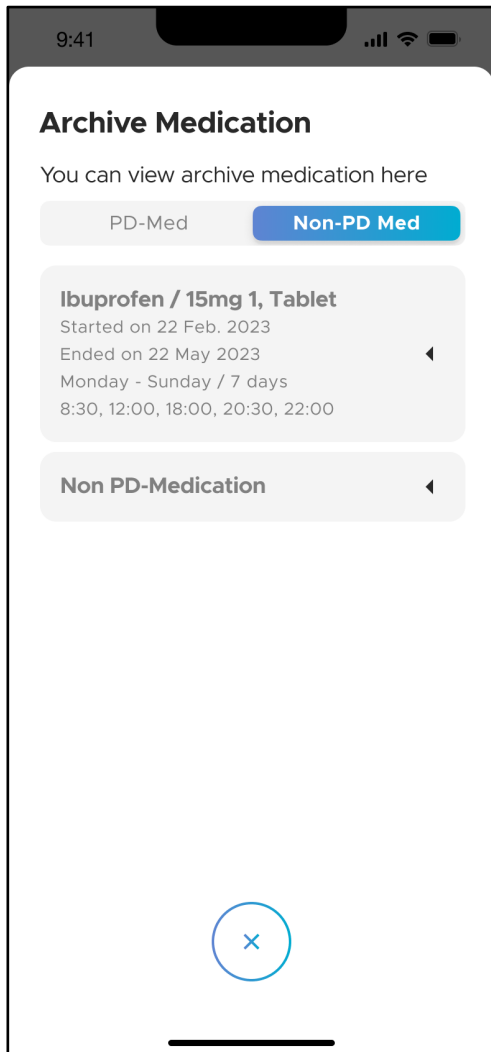


LEFT IMAGE



RIGHT IMAGE

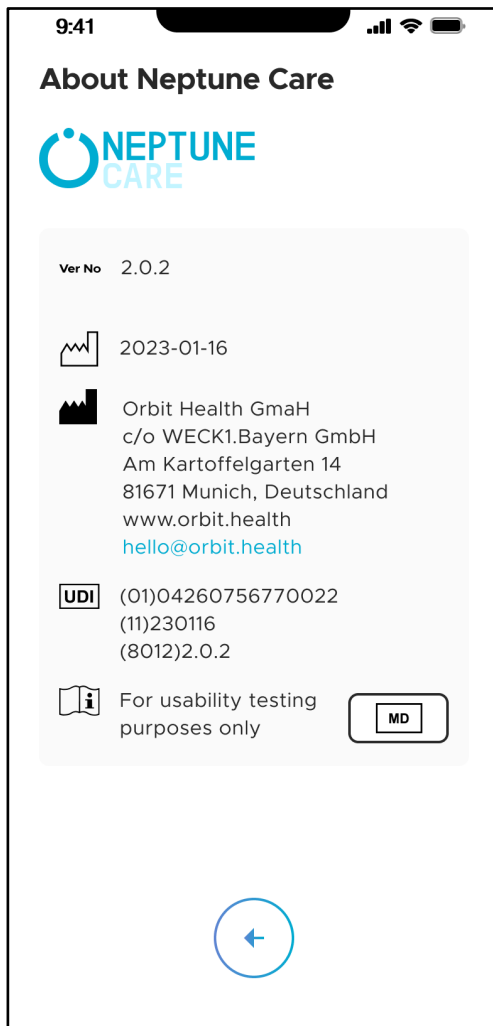
Tap "Confirm" in the pop-up window (LEFT IMAGE). You will then be redirected to the "Archive Medication" screen (RIGHT IMAGE) where the medication plan is shown in the list of archived medications.



To view the details of each medication, tapping on the respective tile to expand it.

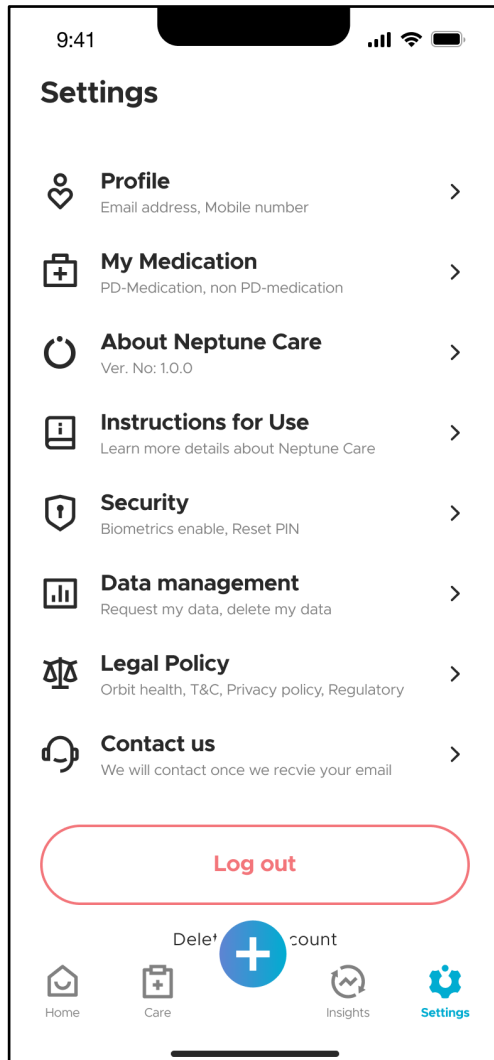
Tap the “x” icon to return to the “My Medication” screen.

4.5.4 About Neptune Care



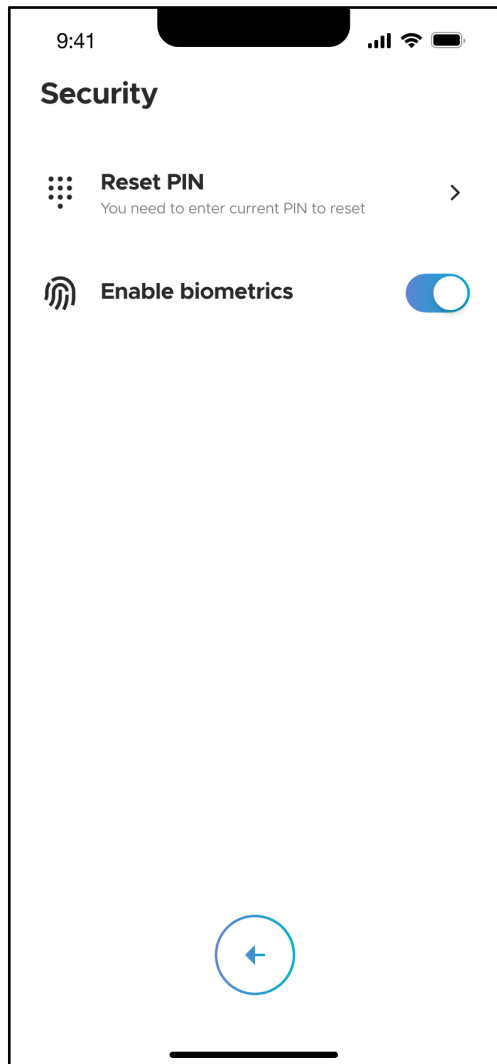
The “About Neptune Care” screen shows information about the Neptune Care application. This screen fulfills the regulatory requirements for medical devices as set out by the medical device regulation REGULATION (EU) 2017/ 745 for medical device labeling. It contains the software version number, release date of the software, information about the manufacturer Orbit Health, and the unique device identifier (UDI).

4.5.5 Instructions for Use

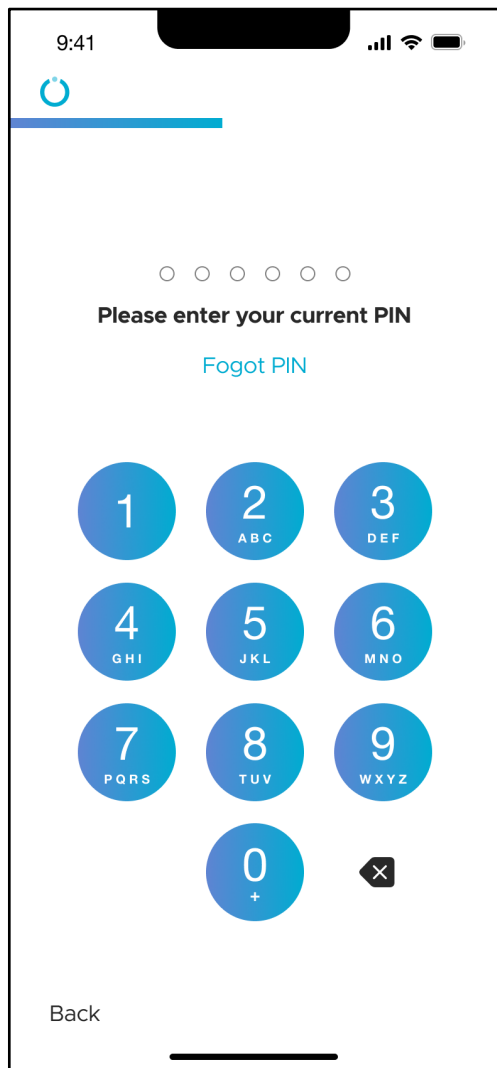


For an electronic version of this set of “Instructions for Use” document, navigate to the “Setting” screen and tap on the “Instructions for Use”. The “Instructions for Use” document for Neptune Care will be opened and viewed on your mobile phone.

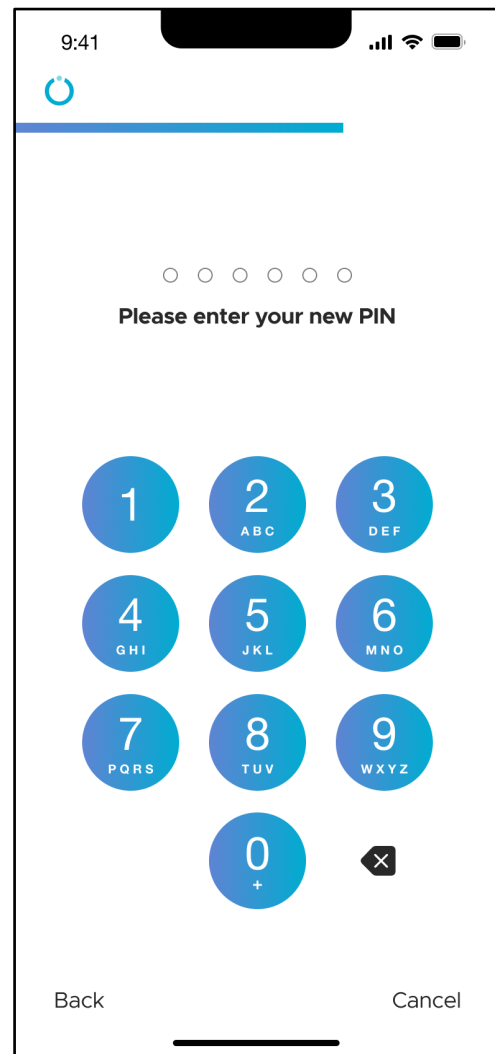
4.5.6 Security



The “Security” screen allows you to reset your PIN, and either enable or disable biometrics for login.



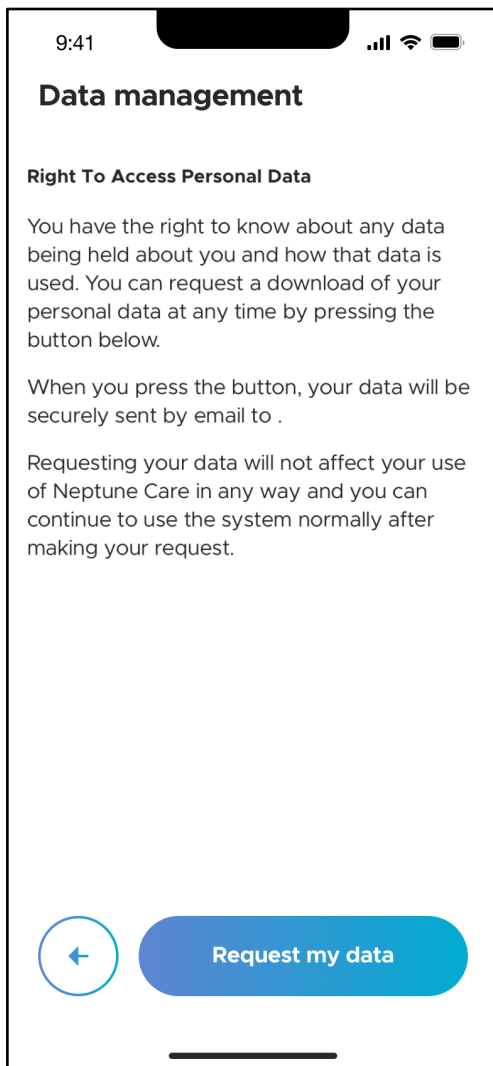
LEFT IMAGE



RIGHT IMAGE

When you tap on “Reset PIN” you will first be required to enter your current PIN. You will then be asked to enter a new PIN and to confirm it. Confirm your new PIN by re-entering it. If you correctly re-entered the PIN, you will have successfully reset the PIN and can now login with your new PIN.

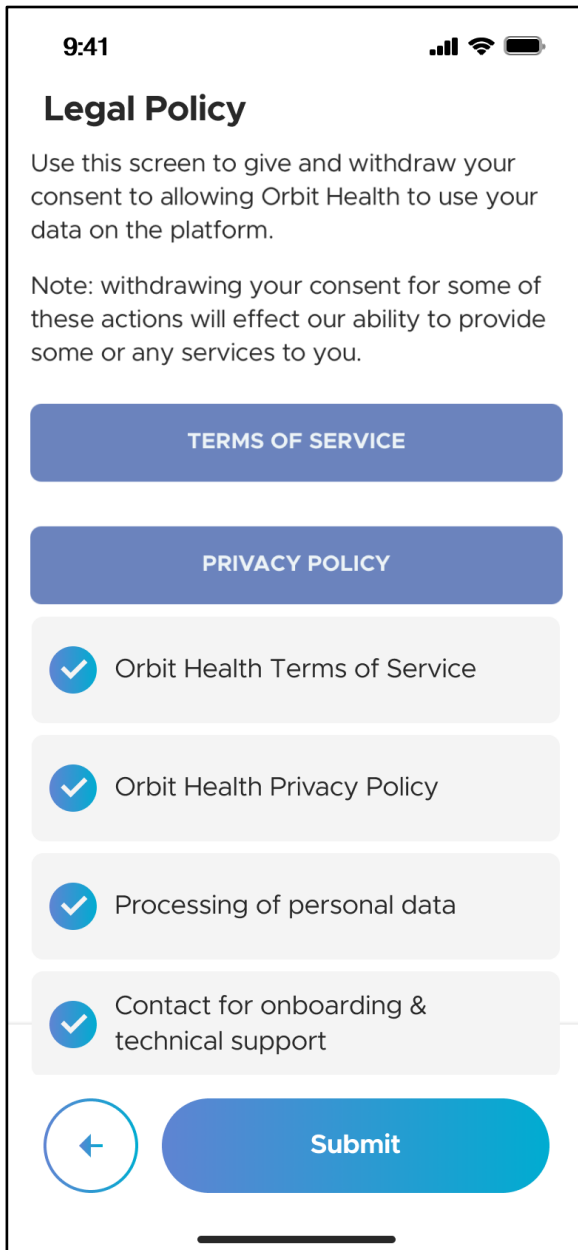
4.5.7 Data Management



The “Data management” screen allows you to download your personal data that is stored in Neptune Care as a password protected ZIP file. When you request your personal data, an Email containing a ZIP file will be sent to the Email address you provided during registration. If you have signed up with a mobile phone number, you will need to input an Email address first after you have tapped on “Request my data”.

You will then receive an Email with a ZIP file attachment. To open the ZIP file, double click on the file and input the UID as a password. You can find the UID in your profile as described in section 4.5.2.

4.5.8 Legal Policy



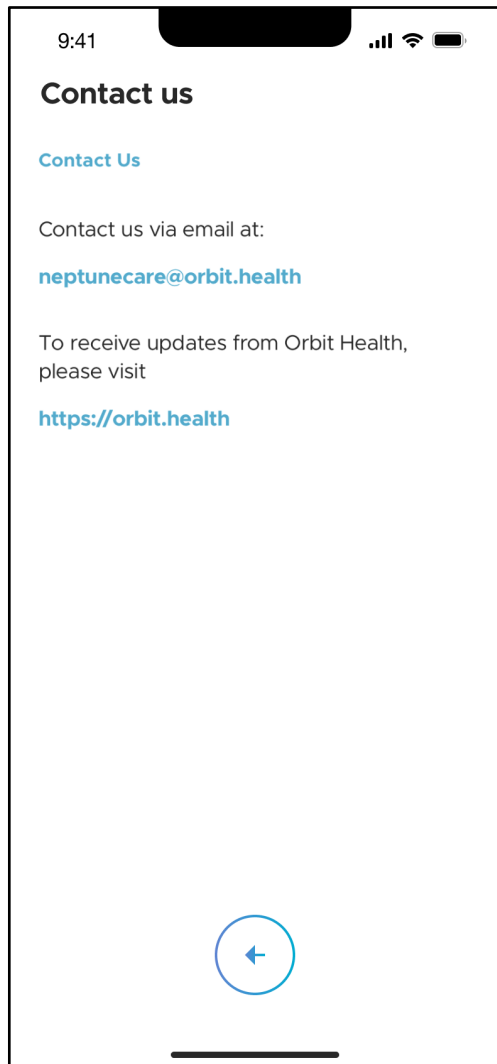
The “Legal Policy” screen allows you to manage your consent to the following:

- 1) Orbit Health Terms of Service
- 2) Orbit Health Privacy Policy
- 3) Processing of personal data
- 4) Contact for onboarding & technical support

You are required to give consent to complete the initial sign up of Neptune Care. However, you can revoke your consent at any time by unchecking the respective checkboxes in the list as shown on the left.

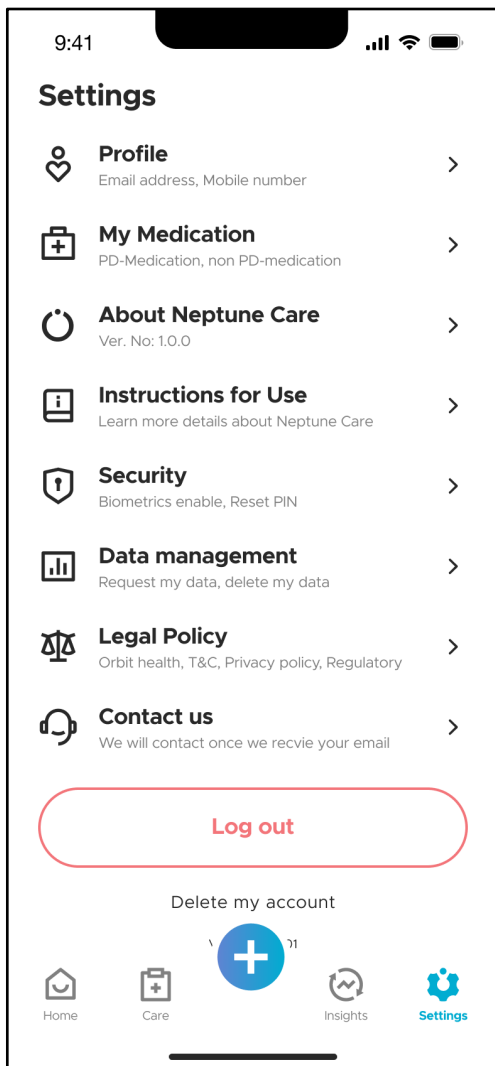
***Please note:** Your use of Neptune Care will be revoked if you withdraw your consent to any of the bullet points.

4.5.9 Contact Us



The “Contact us” screen displays contact details that will help you to get in touch with Orbit Health if you have any issues, questions or feedback.

4.5.10 Logout and Delete Account



By tapping on “Log out”, you will be logged out of the app. Once logged out, you will need to provide your login credentials (PIN or biometrics) to access your data in the app again.

You can delete your Neptune Care account by tapping on “Delete my account”. You will then be asked to confirm your choice before your account is deleted.

***Please note:** All your data stored on the app will be deleted and cannot be restored once you finish deleting your account!

5 Malfunctions and Their Removal

If you encounter any problems with Neptune Care, please contact us using the contact details below. This can also be found in the Neptune Care app, under the “About Neptune Care” and the “Contact us” sections:

Address:

Orbit Health GmbH

Innere Wiener Straße 17,

81667 Munich, Germany

Website: <https://orbit.health>

Email: neptunecare@orbit.health

6 Maintenance

6.1 Maintenance

Neptune Care will be updated on an as-needed basis to ensure that it continually complies with all regulations, is safe, effective and protects your data. You should always have the latest version of Neptune Care installed to ensure continued safe and effective usage and to benefit from the latest feature updates.

7 Technical Data

7.1 Technical Parameters

Feature	Value
Product class according to Regulation EU 2017/245 (MDR)	Class I
Software version	2.1.x
Operating systems	Available for Android (>5.0) and iOS (>12.0)
Product life time	3 years