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.

Note
These instructions for use contain screenshots from the Neptune Healthcare Portal 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 portal.

Information about the product and the manufacturer
Neptune, a product of
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Version of these instructions for use
This is version 1 of this instruction for use from 7th July 2025 valid for version 1.4.x of Neptune.

CE 0123 MD

Contents

1 Product Description

1.1. Intended Purpose

Neptune is a software as a medical device that enables continuous monitoring of motor symptoms of Parkinson's patients by transforming raw motion data obtained from a third-party smartwatch or wrist-worn sensor. This continuous information supports healthcare professionals in treatment adjustment and personalization.

1.1.1. Intended Patient Population

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

1.1.2. Medical Conditions and Medical Indications

Neptune is intended to be used with patients 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 is intended to be used by physicians or healthcare professionals in charge of monitoring the patient's symptoms or adjusting the treatment.

1.1.4. Intended Use

Use environment

Physicians and healthcare professionals use Neptune in their usual working environment. There are no special requirements for a use environment.

Required equipment

The solution requires the patient to wear a third-party smartwatch or wrist-worn sensor which collects raw motion data and uploads the data to a cloud data storage from which Neptune can load the data.

The patient needs a stable internet connection to allow for the data upload to the cloud storage.

The physician needs a computer with a web browser and internet access.

1.1.5. Product lifetime

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

1.1.6. Claims

Performance Claims

The following performance claims are based on Neptune's ability to accurately infer motor state severity from raw motion data obtained from a third-party smartwatch as well as the frequency with which the inference can provide information about the motor state severity:

- Neptune'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 ($>$ 75%) and a temporal resolution of 1 data point per minute

Clinical Benefits

Neptune's clinical benefit is that

- Neptune provides motor insights with a frequency of 1/min compared to state of the art consisting of snapshots with a frequency of 1 observation per 3-12 months. This allows physicians to evaluate the influence of medications and daily activities of a patient on the motor states.

2 Functional Description

2.1 Key components and Modules

Key components and modules of the Neptune device include the following:

- Physician/Healthcare professional web application (accessible via web browsers)
- Administrator portal (accessible via web browsers)
- AWS cloud with data storage and Neptune's algorithm for transforming raw motion data into Parkinson's disease motor symptom severity scale

2.2 Input(s)

- Raw motion data passively captured via the accelerometer and gyroscope of a third-party smartwatch or wrist-worn sensor. Neptune loads the raw motion data from the cloud storage where the raw motion data had been uploaded to from the sensor device. There is no direct pairing of Neptune with the sensor devices (e.g. via Bluetooth)
- Physicians or healthcare professionals enter relevant data for web app log-in and can potentially overlay information from the Neptune Care logging in case the patient is using this separate device that is not part of Neptune.
- Administrators set up and manage physician accounts and can connect physicians with a patient's Neptune Care account if available.

Optional input from Neptune Care devices used by the patient:

- Patients reported data concerning medication intake time, symptoms and disease relevant actions and events (e.g. time of sleep, exercise, meals etc.)

3 Combination with other medical devices or non-medical devices

To achieve its intended purpose, Neptune requires raw motion data captured from a third-party smartwatch or wrist-worn device (sensor device). This sensor device is NOT part of the Neptune medical device.

Compatibilities

Neptune is compatible with smartwatches or wrist-worn sensors that possess an inertial measurement unit (IMU) sensor that can provide 3-dimensional raw motion data from an accelerometer and gyroscope with a sampling frequency of at least 20Hz.

Neptune can be paired with medical devices or non-medical devices provided that the smartwatch or wrist-worn sensor device was tested for compatibility and the correct functioning of the combination of Neptune with the sensor was verified.

A list of devices compatible with Neptune is available on the manufacturer's website.

The patient-specific sensor must be paired with the respective patient account. Hence, a combination of Neptune with a non-compatible sensor is not possible.

Furthermore, Neptune is compatible with the Neptune Care medical device. In case a patient uses the Neptune Care device, the logging data can be included into the physician portal so that the physician can look at the logging data and overlay the data onto the motor state graph.

4 How the Device Achieves its Intended Purpose

The solution (Neptune) provides physicians with continuous Parkinson's motor state insights. The additional information, compared to the snapshot obtained during conventional patient visits, enables physicians to adjust, personalize and optimize the medication amount and schedule.

Neptune 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's AWS cloud processor where it is processed by Neptune's algorithm. The algorithm turns the data into motor states, which are illustrated against a continuous 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). These motor state insights can be used to inform medication adjustments. From this rating, the time the patient spends in ON, OFF or dyskinesia state can be obtained.

Optional combination with Neptune Care mobile phone app:

For patients who are using the Neptune Care device and whose account is connected with the respective physician account, physicians can investigate the logged information about medication intake, symptom occurrence and disease relevant actions and events such as sleep, meals exercise in the Neptune physician web portal. Physicians can also overlay such information on top of the motor state graphs to augment the objective motor state data with subjective, patient-reported information.

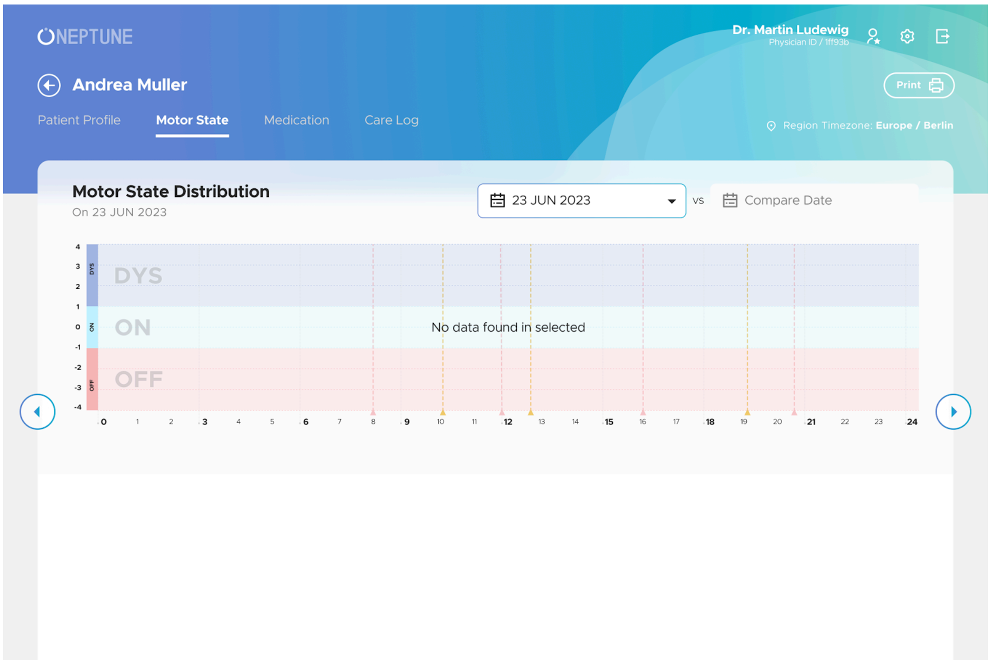


Figure 1: Schematic representation of the motor state graph that is provided by the Neptune device to assist physicians in better understanding a patient's symptoms and to assist in treatment adjustments.

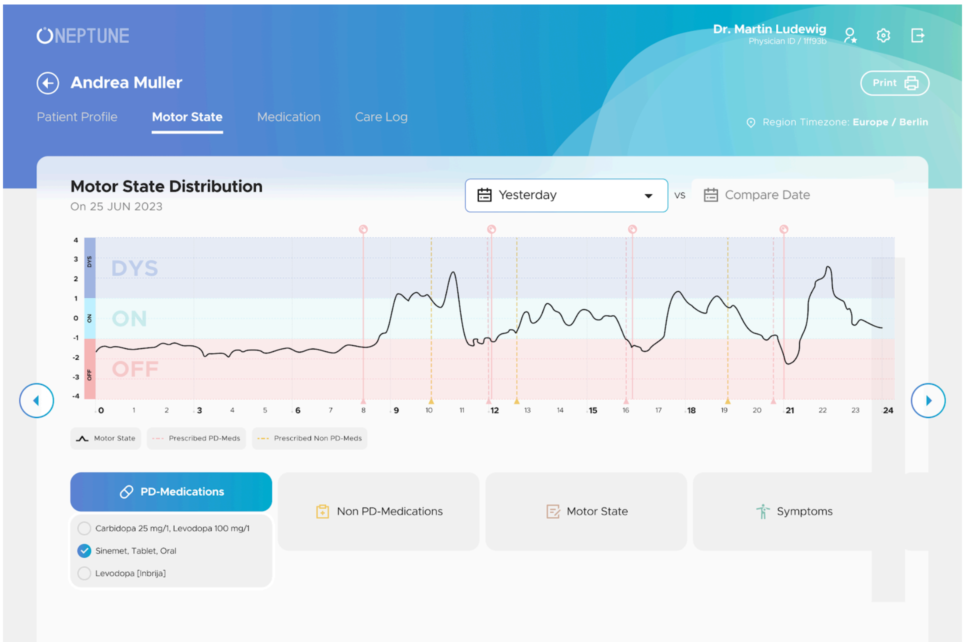


Figure 2: Schematic representation of the motor state graph that is provided by the Neptune device. Here the figure shows how the incorporation of data from the Neptune Care patient mobile app will work. Below the motor state graph, the physician can see the data that the patient logged for that specific day. The Physician can overlay this information onto the motor state graph to better understand the influence on the timing of medication intake and symptoms and activities on the motor symptoms. In the "medication" tab, the physician can view the medication plan that the patient logged in the app and in the "Care log" tab, all logged events and activities from the patient app are listed.

5 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

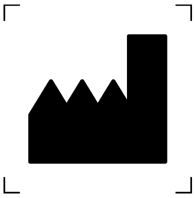
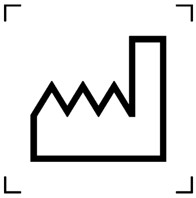
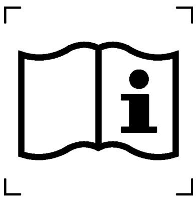
Optional non-clinical Output(s) (when Neptune Care is used by the patient)

- Tracking of medication intake based on patient's input
- Tracking of symptoms, disease relevant actions and events based on patient's input

6 Variants

There is only one Neptune device.

6.1 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 7 below each other.)

Symbol	Significance
MD	Medical Device

Table 1.1: Labeling

7 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.

7.1 General Remarks

	Neptune is not intended to replace physicians' judgments nor to be used to provide automatic diagnoses or to automatically deliver therapies or treatments.
	This system is intended for use by the assigned patient only. The sensor must be worn on the side of their body most affected by Parkinson's disease symptoms to ensure accurate analysis. Use by unauthorized individuals or incorrect placement (e.g., on body parts other than instructed) may result in unreliable data interpretation and should be avoided.
	This system is trained on datasets representing common patient activity profiles. In certain atypical or non-routine scenarios (e.g., prolonged physical activity, extended rest), variations in input patterns may influence classification performance. Clinicians are advised to interpret results in conjunction with their clinical judgment and the overall patient context.

Table 2.1: General remarks

7.2 Side Effects and Contraindications

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

Table 2.2: Side Effects and Contraindications

8 Maintenance

8.1 Maintenance

Neptune will be updated on an as-needed basis to ensure that it continually complies with all regulations, is safe, effective and protects your data.

8.2 Technical Parameters

Feature	Value
Product class according to Regulation EU 2017/245 (MDR)	Class IIa
Software version	1.4.x
Operating systems	Operable on Chrome based browsers.
Product life time	3 years

Table 3.1: Technical Data