



ENGLISH

INSTRUCTIONS FOR USE

Version: 0.9 | March 20, 2020

powered by



pd neurotechnology[®]
medical solutions

CE 0297

FCC Warning

This device complies with part 15 of the FCC rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator and your body.

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This document may contain technical inaccuracies or typographical errors. Contents of this document are subject to changes without prior notice. Changes will be incorporated in future revisions of this document.

This item is compliant with the Medical Device Directive 93/42/EEC of 14 June 1993.

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1 Intended Use

PDMonitor® is a non-invasive continuous monitoring system for patients with Parkinson's Disease (PD). It is intended to trace, record, process and store a variety of motor symptoms frequently occurring in PD through the continuous use of a set of wearable Monitoring Devices. Comprehensive movement information taken from the recordings as well as information on disease symptoms and their intensities is, following appropriate data processing, sent to the treating physician. The system can be used at any stage of the disease after its initial diagnosis and when the patient is under medical treatment. The PDMonitor® system consists of the SmartBox, five (5) Monitoring Devices and the PDMonitor® mobile application.

The PDMonitor® Monitoring Devices. The devices are mounted on the body and acquire body-motion data for assessing the PD motor-symptoms.

The PDMonitor® SmartBox. The PDMonitor® SmartBox is a small station for charging the Monitoring Devices, collecting, storing and processing the data from all Monitoring Devices and uploading them to the PD Neurotechnology storage service (Cloud).

The PDMonitor® mobile application. The PDMonitor® mobile application is an electronic diary for medications, diet and symptoms related to PD. Moreover, the PDMonitor® mobile application provides a summary of daily activity as recorded by the PDMonitor® system. Additionally, the PDMonitor® device recordings and symptom assessment can be also used for clinical research in movement disorders and collection of motion/movement data.

PDMonitor® system shall be used only after the approval of your treating physician who is registered to PD Neurotechnology Ltd. in the use of the PDMonitor® system.



2 Contraindications

- ⓘ Do not use this system with a defibrillation device.
- ⓘ Do not use this system during MRI scanning.
- ⓘ Do not use during medical procedures.
- ⓘ Do not use this system when patient is in a clinical imaging department with high radiation.
- ⓘ Do not use this system with a pacemaker.
- ⓘ Do not operate this system in an environment containing flammable anesthesia gas.
- ⓘ Do not use it with other devices with high levels of electromagnetic radiation in the vicinity of the Monitoring Device.
- ⓘ Do not use the PDMonitor® Monitoring Devices and all the provided accessories for more than 24 hours continuous use.
- ⓘ Before exercise, it is recommended that you seek appropriate advice from your treating physician on the correct Instructions for Use of PDMonitor®. Failing to follow the proper Instructions for Use could affect the measurement quality and extracted symptom evaluation.

- ⓘ Do not use the system on an open wound.
- ⓘ The environment where the device is used should be reasonably free from vibration, dust, corrosive or combustible matter and avoid extremes of temperature and humidity.
- ⓘ Should there be an allergic reaction or skin irritation, remove the Monitoring Device. Then, take pictures of the affected areas and keep detailed notes on the symptoms.
- ⓘ All adverse events or side effects should be reported immediately to PD Neurotechnology Ltd. This will help PD Neurotechnology Ltd. to analyze and report the case.
- ⓘ PDMonitor® does not administer any medicinal, chemical or biological products.
- ⓘ PDMonitor® does not provide treatment recommendations or instructions.
- ⓘ A consultation by your treating physician is an absolute necessity for the appropriate use of the PDMonitor® system.
- ⓘ PDMonitor® is able to monitor PD symptoms during a range of daily activities including walking. When performing intense fitness activity (running, bicycling etc.) it should either be removed or the treating physician should be informed about those activities.

3 Warnings

- ⓘ Tripping Hazard - keep the electrical cord away from walking paths.
- ⓘ Do NOT expose the SmartBox to liquids. This may permanently damage the system.
- ⓘ Operate the system within relative humidity of 40%-80% and temperature from 5°C to 35°C. If the storage/transport conditions exceed the suggesting operating limits, let the device stand for at least 30 minutes at room temperature before connecting it to the power supply.
- ⓘ PDMonitor® should not be used under any other medical procedure (MRI, CT Scan, PSU, etc.).
- ⓘ If the power supply unit is damaged, do not operate the system (the PSU green led light is off even when this is plugged in the electrical socket).
- ⓘ The PDMonitor® Monitoring Devices are water resistant and NOT waterproof. Therefore, they should not be exposed to liquids or used during swimming, showering, bathing or during any underwater activity.
- ⓘ Use only the accessories provided for PDMonitor® system.
- ⓘ Do not disassemble or remodel the SmartBox or/and the Monitoring Devices.
- ⓘ PDMonitor® Monitoring Devices include rechargeable lithium polymer batteries. Storage, use and transportation outside the instructed environmental conditions and/or exposure to

excessive heat or fire may result in increased risk of device damage, explosion, chemical burn or fire. Do not crush, puncture, or burn as doing so can result in fire, explosion or the release of toxic gases. Do not use the device if it appears to be leaking, damaged, discolored, misshapen, or in any way irregular.

- ⓘ If there are any signs of material degradation on the Monitoring Devices or the SmartBox, avoid using the system and contact PD Neurotechnology HelpDesk (available at www.pdneurotechnology.com).
- ⓘ You can only use the Power Supply Unit (GSM25E05-PIJ) supplied with the PDMonitor® system.
- ⓘ If the device is not going to be used for a long period, it is recommended that the PDMonitor® system is safely shutdown, through a mobile device.
- ⓘ PDMonitor® system (Monitoring Devices are part of PDMonitor® system) may reach temperatures of more than 41°C in accordance with 60601 11.1.1.2 and therefore is not recommended for use with infants or other high risk groups.
- ⓘ The medication list in the PDMonitor® mobile application is not an exhaustive list of medication you could be prescribed at any given time. The PDMonitor® mobile application is not intended to be used as a medication reminder to be relied upon.

4 Precautions

- ⓘ PDMonitor® should NOT be used near radiology modalities or in radiology departments.
- ⓘ Do not leave PDMonitor® Monitoring Devices unattended. They must be either worn or docked in the SmartBox.
- ⓘ PDMonitor® Monitoring Devices should be tightly fitted on the body.
- ⓘ Do not use PDMonitor® system USB ports for other devices.
- ⓘ PDMonitor® Monitoring Devices should not be worn near magnetic accessories (magnetic bracelets, watches etc.).
- ⓘ Clean PDMonitor® Monitoring Devices and SmartBox according to the instructions in section 9.
- ⓘ Keep infants and children away from PDMonitor® accessories to prevent suffocation or choking.
- ⓘ Please keep the PDMonitor® lid on at all times to protect your device from dust and liquids and use the supplied bag for transportation.

For more safety and regulatory information and for battery disposal information, refer to the Regulatory Safety and Environmental Notices provided by PD Neurotechnology Ltd. (see section 16 and Appendix).



5 Package Contents


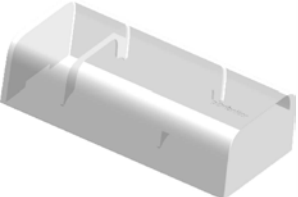

Photo	Description	Qty.
 A black, rectangular, multi-bay device with four slots and a small display on the right side.	SmartBox	1
 A white, rectangular lid with a central slot and two side tabs.	SmartBox lid	1
 A teal, rectangular, rounded device with a small silver latch on the left side.	Monitoring Device	5

Photo	Description	Qty.
	<p>Clipframe</p>	<p>1</p>
	<p>Strapframe</p>	<p>3</p>
	<p>Wristband</p>	<p>2 (small to medium) 2 (medium to large)</p>







Photo	Description	Qty.
	<p>Hook and loop strap</p>	<p>2 (small) 1 (large)</p>
	<p>Power supply unit (GSM25E05-P1J)</p>	<p>1</p>
	<p>Ethernet cable</p>	<p>1</p>
	<p>Instructions for Use</p>	<p>1</p>

Photo	Description	Qty.
	<p>Videobook</p>	<p>1</p>
	<p>Videobook charging USB cable</p>	<p>1</p>
	<p>Carrying Bag</p>	<p>1</p>

6 PDMonitor® System

SmartBox

The SmartBox (Figure 1) is the PDMonitor® unit where the Monitoring Devices should be placed to upload their data to the PD Neurotechnology storage service (Cloud). The SmartBox also charges the PDMonitor® Monitoring Devices.



Figure 1. PDMonitor® SmartBox

Monitoring Devices

The PDMonitor® Monitoring Devices are used to measure body movements during daily life activities.

All Monitoring Devices have a light indicator and a micro USB port for charging and communication purposes, as shown in Figure 2. Monitoring Devices are mounted on the body with PDMonitor® accessories.

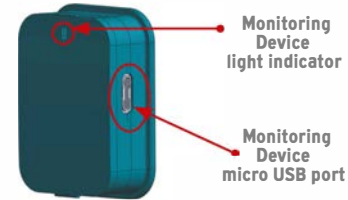


Figure 2. PDMonitor® Monitoring Device

Accessories

The wristband, strapframe and clipframe (Figure 3) are designed to secure the Monitoring Devices to predefined body places. Wristbands are for wrists, strapframes for shanks (legs) and for waist, along with the large strap, and clipframes for waist. Detailed instructions on the usage of the accessories are given in section 8. 1.

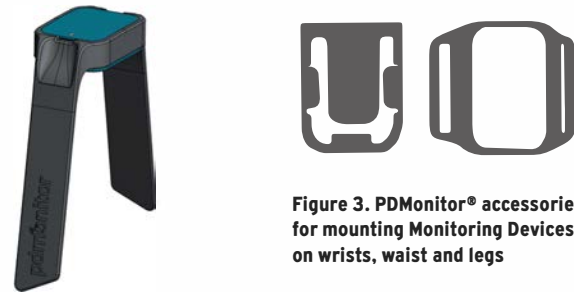


Figure 3. PDMonitor® accessories for mounting Monitoring Devices on wrists, waist and legs

7 Setup Instructions

The SmartBox requires an Internet connection either via an Ethernet cable or an available Wi-Fi network to function properly.

To receive the full benefit of using the PDMonitor® system, the SmartBox should be registered with an account, which in turn will be paired with a treating physician who will evaluate the data produced by the device. For details on how to create an account and pair with a treating physician, consult the PDMonitor® Instructions for Use (section 11.4).

7.1 Unpacking the PDMonitor® System

All Monitoring Devices should be fully charged before use.

1. Unpack the contents of the box
2. Place all components on a flat surface and find a nearby power outlet
3. Connect the power supply unit to the power outlet
4. Connect the power cord to the SmartBox adapter (Figure 4)

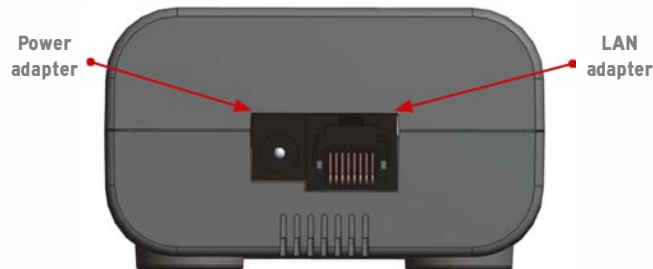


Figure 4. Rear view of PDMonitor® SmartBox

5. All Monitoring Device status light indicators on the SmartBox should be switched off (Figure 5)

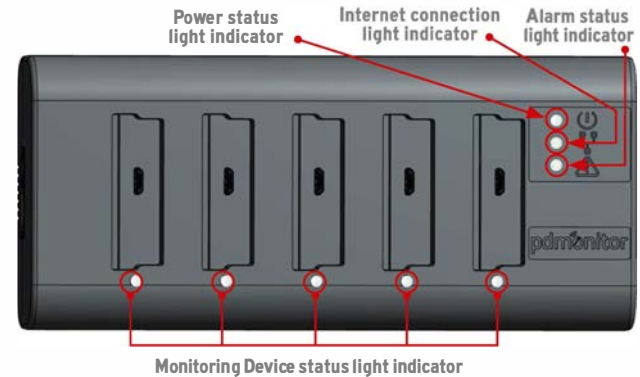


Figure 5. Top View of PDMonitor® SmartBox

6. Place the Monitoring Devices on the SmartBox as shown in Figure 6

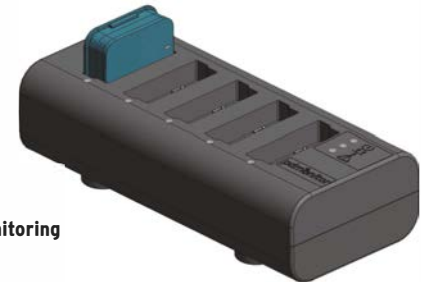


Figure 6. Placing PDMonitor® Monitoring Devices on the SmartBox

7. The Monitoring Devices start charging. When charging, each Monitoring Device is flashing orange.

7.2 Configure SmartBox to the PD Neurotechnology Cloud

The SmartBox must be connected to the PD Neurotechnology storage service (Cloud) to be properly configured either via Ethernet cable or an available Wi-Fi network. This requires an Internet connection.

7.2.1 Register via Ethernet Cable

1. Connect the SmartBox to the power outlet
2. Connect one end of the Ethernet cable to the SmartBox LAN adapter (Figure 4) and the other end to an available wall, modem or router LAN plug
3. Follow the step-by-step procedure on the PDMonitor® mobile application to pair the SmartBox with the mobile phone via Bluetooth (or any of the other options described in section 1.1.3) and register an account on the SmartBox.

If you do not own an Android or iOS SmartPhone, please contact PD Neurotechnology HelpDesk to setup your device for you.



7.2.2 Register via Wi-Fi

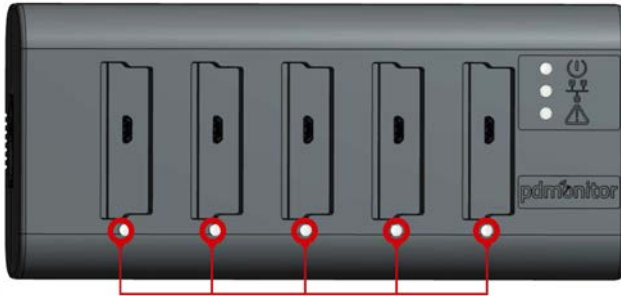
1. Connect the SmartBox to the power outlet
2. Follow the step-by-step procedure on the PDMonitor® mobile application to pair the SmartBox with the mobile phone via Bluetooth. This is necessary for the PDMonitor® mobile application to be used to send the Wi-Fi credentials to the SmartBox and allow it to connect to the available Wi-Fi network. It is advisable that the mobile device is already connected to the same Wi-Fi, however this is not necessary (refer to section 1.1.1.8).

The PDMonitor® system is now ready for use. For details and advice on how often to wear the monitoring devices, please consult your treating physician.



7.3 SmartBox Light Indicator

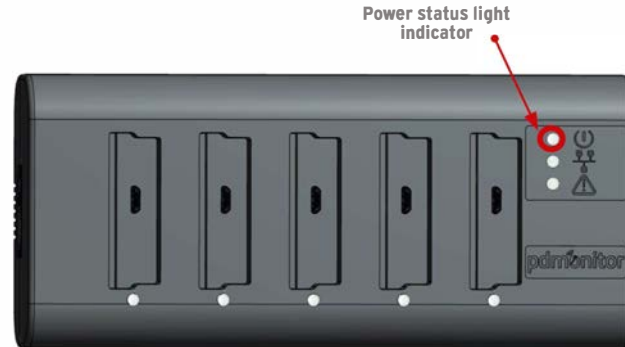
In this section, the light indicator functionalities of the PDMonitor® SmartBox are described at Figure 7, 8, 9 and 10.



Monitoring Device light status indicator

#	Light indicator color	State	Function
1	Green	Constant	Monitoring Device is fully charged and is ready for use
2	Orange	Constant	Monitoring Device is charging and data upload is completed
3	Orange	Flashing	Monitoring Device is charging and uploading data. It SHOULD not be removed
4	OFF	Constant	Monitoring Device is disconnected

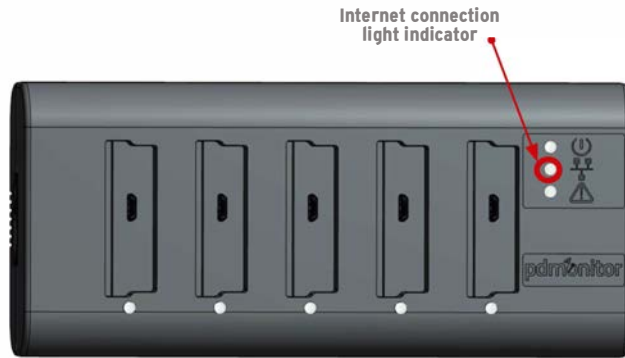
Figure 7. Monitoring Device light status indicator



#	Light indicator color	State	Function
1	Green	Constant	The SmartBox is powered on
2	Orange	Constant	The SmartBox is starting up
3	OFF	Constant	Power off

Figure 8. Power status light indicator

7 Setup Instructions

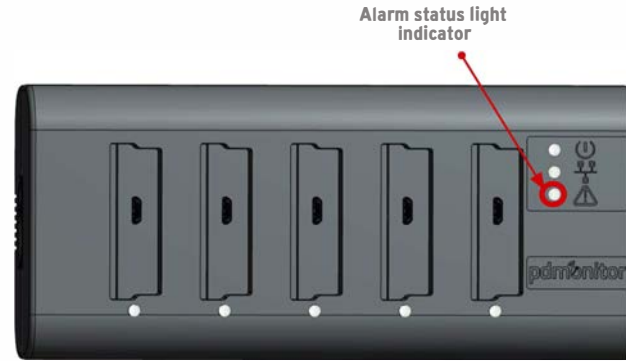


#	Light indicator color	State	Function
1	Blue	Constant	Internet connection is available
2	OFF	Constant	No Internet connection available

Please make sure that all light indicators are green before using the PDMonitor® Monitoring Devices.



Figure 9. Internet connection light indicator



#	Light indicator color	State	Function
1	Red	Constant	The PDMonitor® is NOT functioning properly and you must check the PDMonitor® mobile application for more information and alerts. A list of warnings is included in Device screen (refer to section 11.17)
2	OFF	Constant	PDMonitor® is working properly

Figure 10. Alarm status light indicator

8 Monitoring Device Usage

PDMonitor® system records the symptoms of Parkinson's Disease only while Monitoring Devices are mounted on predefined body locations. PDMonitor® shall only be used when all Monitoring Devices are charged and the light status indicators (Figure 7) are green. This indicates that PDMonitor® system is ready for a new recording.

The PDMonitor® system is ready for use only when all Monitoring Device light status indicators (Figure 7) are green.



The PDMonitor® system should be used only with the strapframes, clipframe, straps, wristbands and power supply included in the original PDMonitor® packaging, or equivalent official components provisioned by PD Neurotechnology Ltd.

The PDMonitor® system should only be used with the strapframes, clipframe, straps and wristbands provided with the device and the Monitoring Devices should be placed in all predefined body locations.



Place the Monitoring Devices on the SmartBox after the recording period is finished.

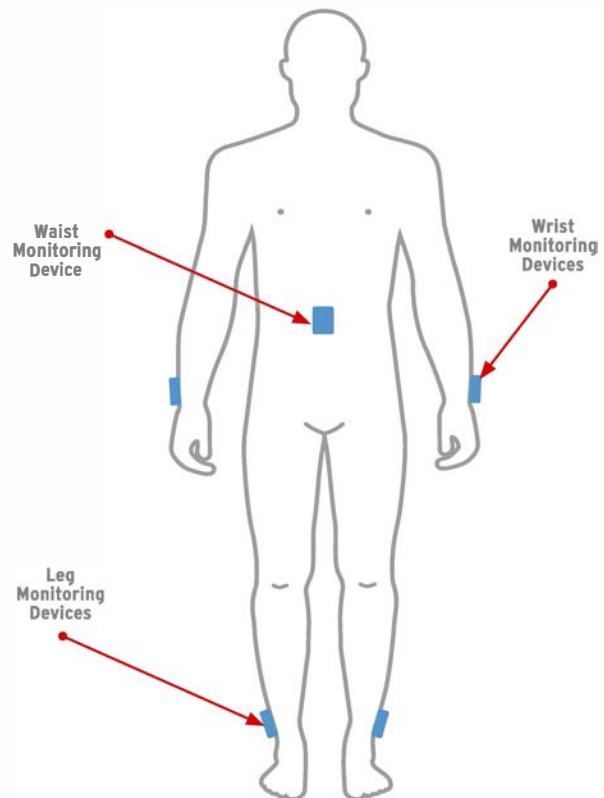


Figure 11. The body parts that PDMonitor® Monitoring Devices should be worn

8 Monitoring Device Usage

8.1 Placing the Monitoring Devices on the Body for a New Recording

The five (5) PDMonitor® Monitoring Devices must be placed on specific body locations for PDMonitor® system to function properly. Those specific body locations are depicted in Figure 11. The following section describes in detail how to properly mount the Monitoring Devices.

Wrist position Monitoring Devices

- Put the two Monitoring Devices using the appropriate wristbands on the left and right wrist as shown in Figure 12
- Undock the Monitoring Devices from the SmartBox
- Secure the Monitoring Devices to the wristband as shown in Figure 13
- Put the Monitoring Devices on your wrist and make sure that they are comfortable yet tight fitting
- The Monitoring Devices start recording automatically.

The wristbands should not be too tight to avoid other health complications. If you start to experience skin redness or irritation, remove the wristbands and contact PD Neurotechnology Ltd.

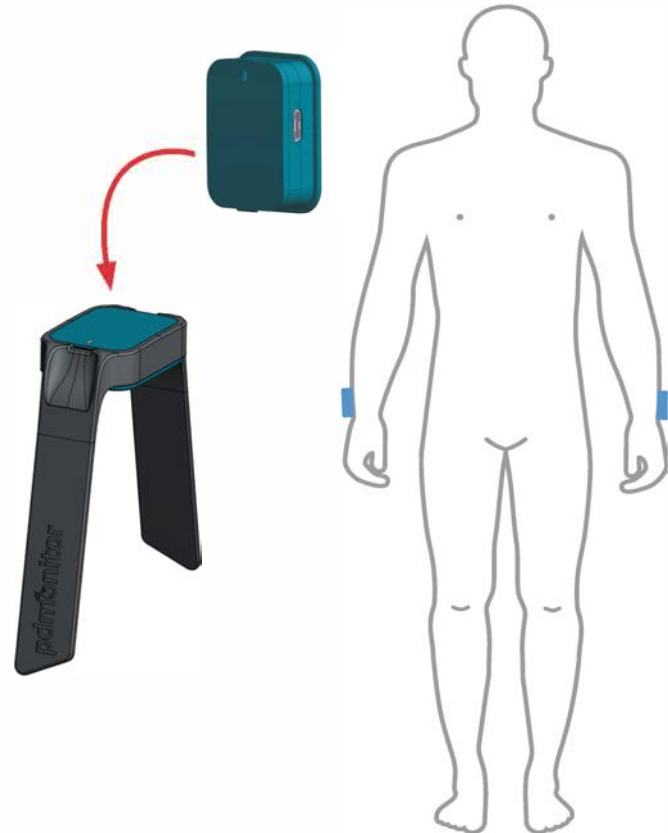


Figure 12. PDMonitor® Monitoring Devices on wrists

Wrist position Monitoring Devices

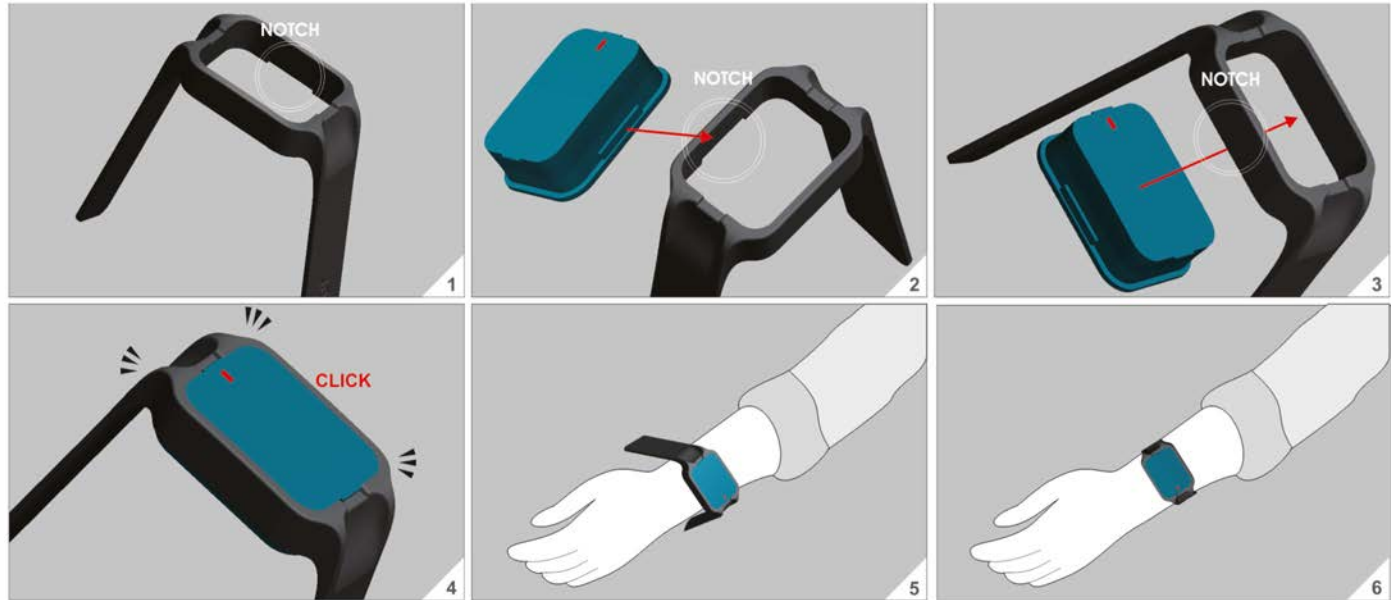


Figure 13. Instructions on mounting PDMonitor® Monitoring Devices on wrists using the wristband

8 Monitoring Device Usage

Leg position Monitoring Devices

- Place the two Monitoring Devices using the appropriate strapframes and straps on the left and right leg as shown in Figure 14
- Undock the Monitoring Devices from the SmartBox
- Secure the Monitoring Devices to the strapframe as shown in Figure 15 by sliding the Monitoring Devices inside the frame and then pushing the strapframe sides until a characteristic “clicking” sound or feeling on the hand occurs
- Place the Monitoring Devices in the correct leg position, as shown in Figure 15
- The Monitoring Devices start recording automatically.

The leg straps should not be too tight to avoid other health complications. If you start to experience skin redness or irritation please remove the straps and contact PD Neurotechnology Ltd.

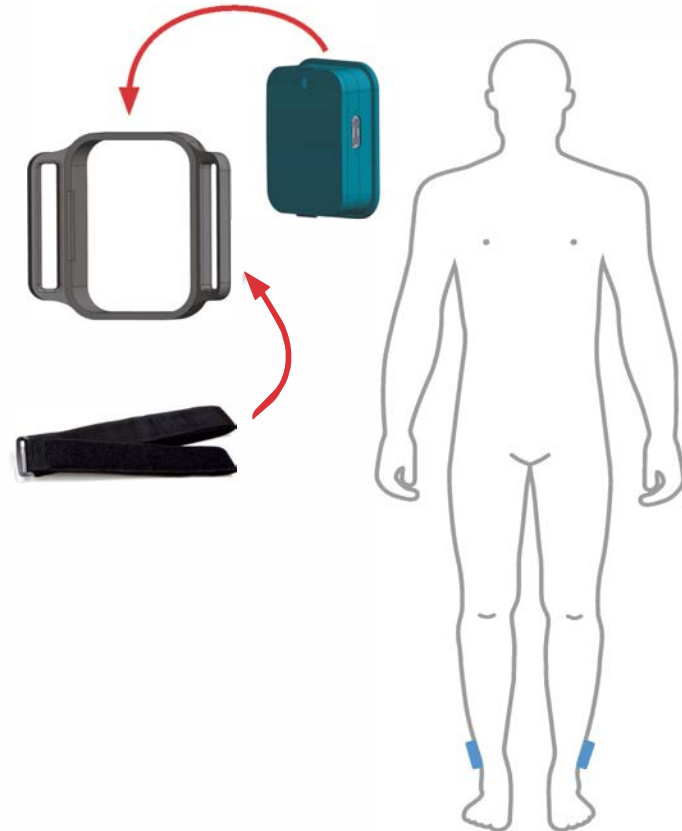


Figure 14. PDMonitor® Monitoring Devices on shanks

Leg position Monitoring Devices

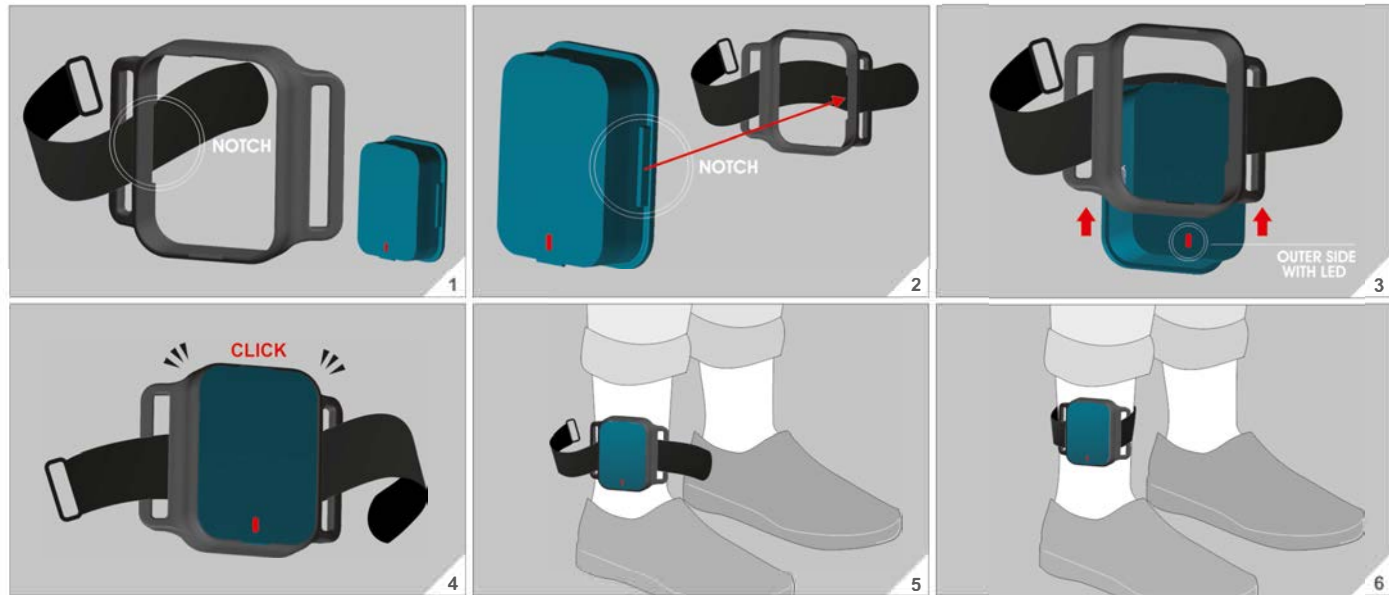


Figure 15. Instructions on mounting PDMonitor® Monitoring Devices on shanks using the strapframe

8 Monitoring Device Usage

Waist position Monitoring Device

- You should wear the last (fifth) Monitoring Device for the waist position using the provided clipframe to the appropriate body position (Figure 16). Another way to wear it, is with the appropriate strapframe and strap to the waist
- Undock the Monitoring Device from the SmartBox
- Secure the Monitoring Device to the clipframe as shown in Figure 17 by sliding the Monitoring Device inside the clipframe and then pushing the clip sides until a characteristic “clicking” sound or feeling on the hand occurs
- Wear the Monitoring Device on your waist and make sure that it is comfortable yet tight fitting
- The Monitoring Device start recording automatically.

You should pay attention to securing the Monitoring Device firmly inside the clipframe and pushing the clip sides until a characteristic “clicking” sound or feeling on the hand occurs.

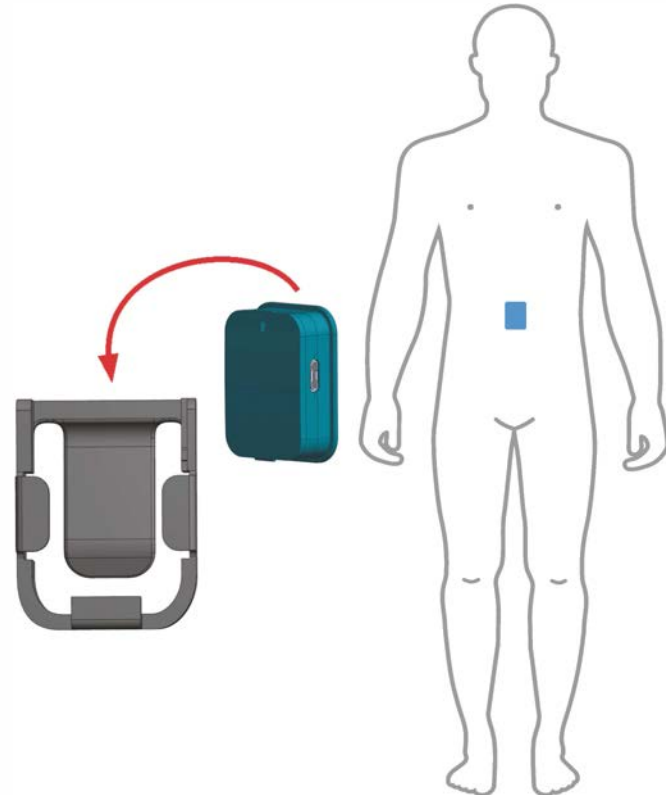


Figure 16. PDMonitor® Monitoring Device on waist

Waist position Monitoring Device



Figure 17. Instructions on mounting PDMonitor® Monitoring Device on waist using the clip

8 Monitoring Device Usage

8.2 Placing the Monitoring Devices on the SmartBox after the Recording Period

After the recording time recommended by your treating physician, take off the Monitoring Devices and put them back in the

PDMonitor® SmartBox. When you place the Monitoring Devices in the SmartBox, the corresponding light status indicator should start flashing orange. While flashing, Monitoring Devices are uploading their data and should not be removed from the SmartBox. When data transfer is completed and the PDMonitor® devices are fully charged, the light status indicators will turn green and the device is ready for a new recording.

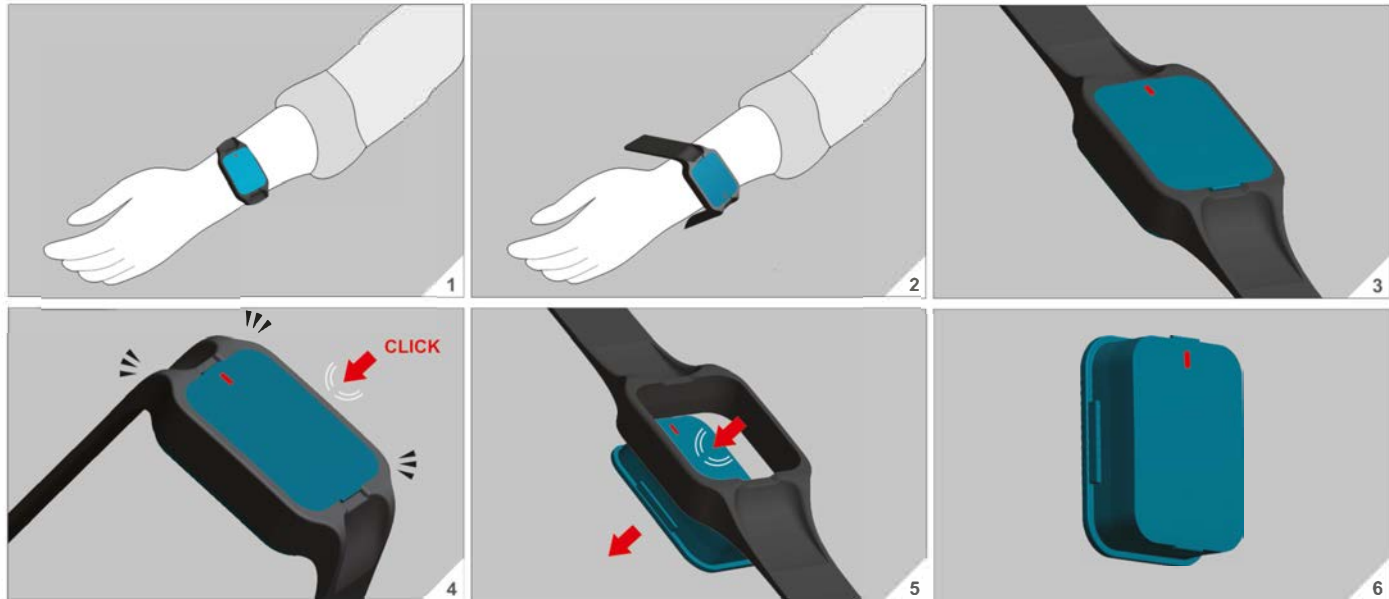


Figure 18. Instructions on removing PDMonitor® Monitoring Devices with wristbands from wrists

Wrist position Monitoring Devices

- Remove each Monitoring Device from the wristbands, as shown in Figure 18
- Place the Monitoring Devices into the slots of the SmartBox, as shown in Figure 19

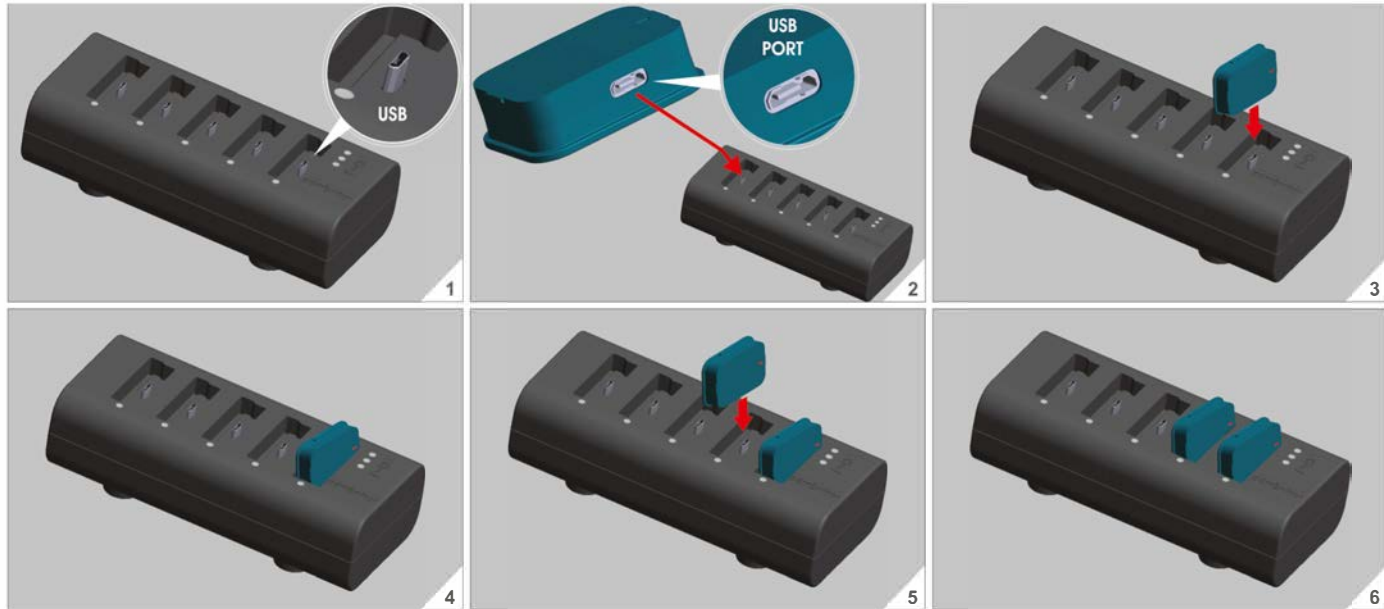


Figure 19. Placing Monitoring Devices into the slots of the SmartBox

8 Monitoring Device Usage

Leg position Monitoring Devices

- Remove each Monitoring Device from the strapframes, as shown in Figure 20
- Place the Monitoring Devices into the slots of the SmartBox, as shown in Figure 21

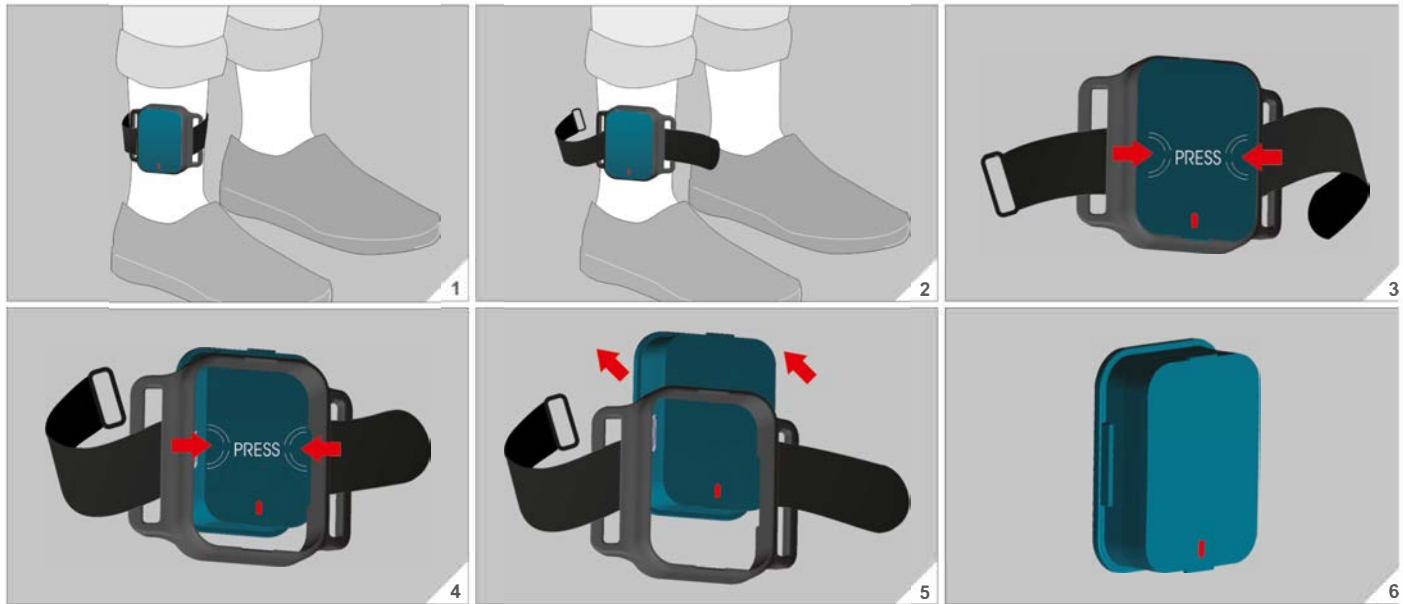


Figure 20. Instructions on removing PDMonitor® Monitoring Devices with strapframe from shanks

Leg position Monitoring Devices

Place the Monitoring Devices into the slots of the SmartBox

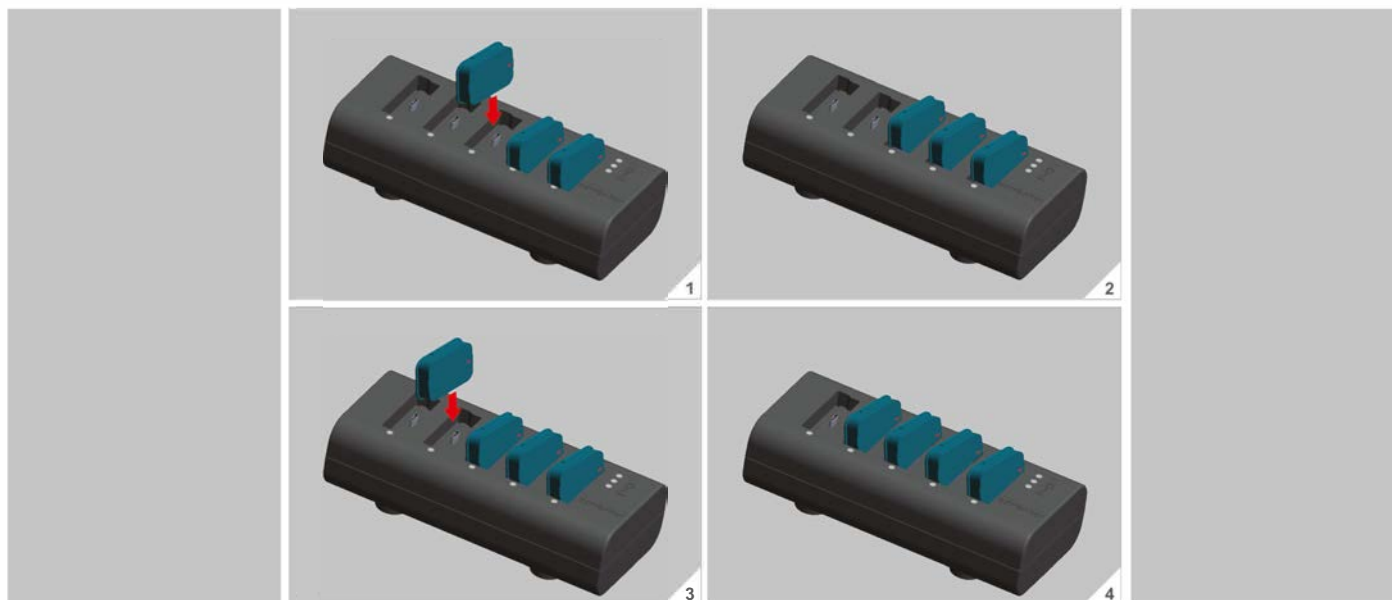


Figure 21. Placing Monitoring Devices into the slots of SmartBox

8 Monitoring Device Usage

Waist position Monitoring Device

- Remove the Monitoring Device from the clipframe, as shown in Figure 22
- Place the Monitoring Device into the last slot of the SmartBox, as shown in Figure 23



Figure 22. Instructions on removing PDMonitor® Monitoring Device with clipframe from waist

Waist position Monitoring Device

Place the Monitoring Device into the slot of the SmartBox

Upon placing the Monitoring Devices into the SmartBox the corresponding light status indicator should start flashing orange. While flashing orange, the devices should not be removed from the SmartBox.

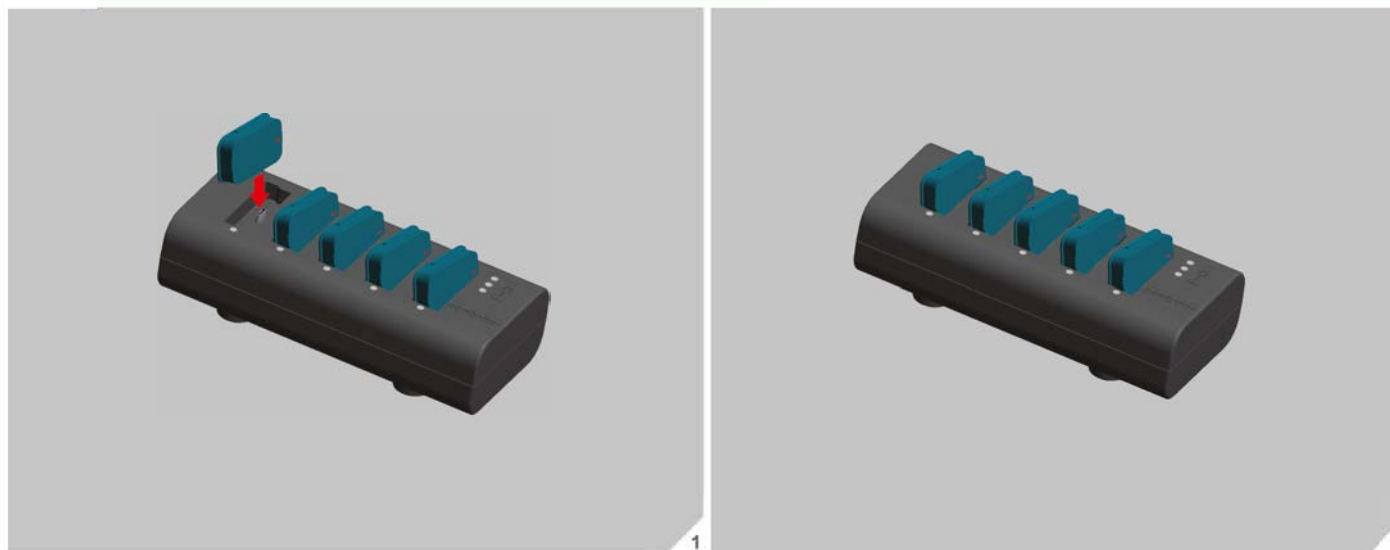


Figure 23. Placing Monitoring Device into the slot of the SmartBox

8 Monitoring Device Usage

8.3 Monitoring Device Light Indicator Functionality

The functionality of the Monitoring Device light indicator is shown in Figure 24.



9 System Maintenance

9.1 Cleaning Monitoring Devices

The Monitoring Devices should be regularly cleaned after any intense activity. To clean each Monitoring Device, household cleansers should be avoided. Use a soft towel preferably. For tough spots or stains, try scrubbing with a soft, wet cloth.

9.2 Disinfecting Monitoring Devices

A disinfecting solution can be applied to the Monitoring Devices, using a soft cloth. Abrasives should be avoided as they could damage the surface of the Monitoring Devices. Ensure that all cleaning fluid is removed by wiping each Monitoring Device carefully with a soft cloth.

#	Light indicator color	State	Function	
1	Blue	Enabled for 3 seconds when device quickly turned towards patient's face	Monitoring Device is working properly	
2	Blue	Flashing every 1 second	Monitoring Device battery is low. Charging is needed	

Figure 24. Monitoring Device light indicator functionality

9.3 Cleaning the SmartBox

The SmartBox can be cleaned by using a soft damp towel. Household cleansers should be avoided.

When the PDMonitor® system is used in hospitals, clinics or healthcare environments it must be disinfected, using disinfecting solution regularly and especially after being used by each individual patient.



10 Troubleshooting

10.1 Troubleshooting SmartBox

After plugging the power cable and the Ethernet Cable in the SmartBox, the following sequence of events should occur:

1. The light indicator (Power) will turn on and the color will be orange for no more than 5 minutes
2. Then, the first light indicator (Power) will stay green and the second (Internet) will be blue.

Should this fail to happen, the power and the Ethernet cables should be unplugged and re-plugged. If the error persists, contact the PD Neurotechnology HelpDesk.

10.2 Troubleshooting Monitoring Devices

After the successful setup of the SmartBox, the Monitoring Devices should be placed on the SmartBox to be fully charged for the first time. The Monitoring Devices are ready for use when each corresponding light indicator on the SmartBox (Figure 9) is a constant green.

After a full charge the Monitoring Devices can record symptoms for more than 24 hours. If the battery is running low, the light indicator of the Monitoring Device will start blinking as illustrated in Figure 24.

After the Monitoring Devices have been worn for the hours indicated by the treating physician, they must be placed on the SmartBox to upload the recorded data. When all five Monitoring Devices are placed on the SmartBox, the following should occur:

1. For every Monitoring Device its corresponding light indicator should be blinking orange (charging and uploading data). If the light indicator does not turn orange, check that the Monitoring Device is properly docked. Undock and re-dock the Monitoring Device in the SmartBox. If the light indicator on the SmartBox is still not orange, unplug and plug again the power supply of the PDMonitor® device to restart the SmartBox. If the problem persists then you should contact the PD Neurotechnology HelpDesk
2. When the light indicator is a constant orange it means that the data have been uploaded and the Monitoring Devices are charging
3. When the light indicator is a constant green the corresponding Monitoring Device is ready for use (charging and data uploading could last for up to 3 hours). If after more than three hours the light indicators on the SmartBox do not turn green then contact the PD Neurotechnology HelpDesk.

10.3 Possible Damage

If any kind of damage is detected on any of the Monitoring Devices or a Monitoring Device cannot be placed on the SmartBox correctly, contact the PD Neurotechnology HelpDesk.

11 App

11.1 Introduction

PDMonitor® mobile application has two versions, one for the Patient and one for the Caregiver:

- **Patient Application:** The patient application is required for the initial patient account registration and device set up. It also allows for medication intake, nutrition and general symptom self-assessment recording
- **Caregiver Application:** The caregiver application allows caregivers to act on behalf of their patients to register an account, set up the device, and record complementary information regarding medication, nutrition and symptoms.

11.2 Installation

To install the PDMonitor® mobile application on an Android/ iOS device, open the Google Play Store/ Apple App Store and search for "PDMonitor app". Then, the PDMonitor® mobile application is ready for use.

11.3 Setup

11.3.1 SmartBox Internet Connectivity

As described in section 7.2 before its first use, the SmartBox needs to be connected to the Internet and synchronized with a patient account. The PDMonitor® mobile application must be used for that:

- Ethernet:** As described in section 7.2 before its first use, the SmartBox needs to be connected to the Internet and synchronized with a patient account
- Wi-Fi:** If Wi-Fi is supported and preferred, the PDMonitor® mobile application must be used to send the credentials of the Wi-Fi connection to the SmartBox. For Wi-Fi set up, see section 11.18. Then go on to SmartBox account synchronization.

11.3.2 SmartBox Account Synchronization

As described in section 7.2 the SmartBox needs to be registered with an account. There are three ways to configure the SmartBox patient account, using the PDMonitor® mobile application (Figure 25):

- **Bluetooth:** This screen opens a wizard that guides the user to setup the device
- **QR Scan:** This screen shows how to use the QR code that can be found in the PDMonitor® system original packaging (Figure 26)
- **Manual input:** On this screen, the number corresponding to the QR code which can also be found in the PDMonitor® system's original packaging can be manually filled in (Figure 27).

If the SmartBox is already synchronized with a patient account and you want to synchronize it with a different account, or you have no longer access to your credentials you should contact the PD Neurotechnology Helpdesk.

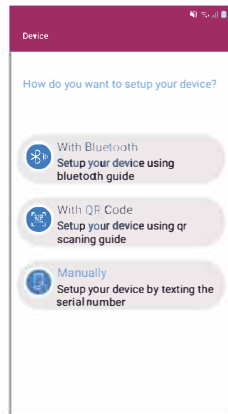


Figure 25



Figure 26

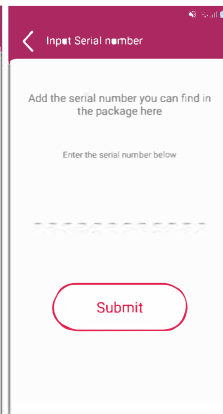


Figure 27

11.4 Pairing

Patient with Treating Physician (Patient Application)

A registered physician owns a unique ID. You can obtain this ID by contacting your treating physician directly. You can then use the physician screen (Figure 41) to send a pairing invitation (section 11.10). Once your physician accepts the pairing invitation, you will receive an e-mail that the pairing was successful.

Caregiver with Patient (Caregiver Application)

Your PDMonitor® account is linked up with your unique e-mail. Your caregiver must obtain this e-mail by directly contacting you. Using this e-mail in the Patient screen, your caregiver can then send you a pairing invitation. Once you accept the invitation through your PDMonitor® mobile application, the caregiver application will inform your caregiver that the pairing was successful.

11 App

11.5 Welcome Page

The Welcome screen appears only while the PDMonitor® mobile application is loading (Figure 28).



Figure 28

11.6 Login

a) Privacy Policy

During the first use of the PDMonitor® mobile application you have to read the Privacy Policy, enabling the “Switch Button”  (Figure 29) and tapping on the “Next Button”  (Figure 30).

Please make sure you read the Privacy Policy carefully as it contains important information you need to be aware of when using the PDMonitor® system and the PDMonitor® mobile application.

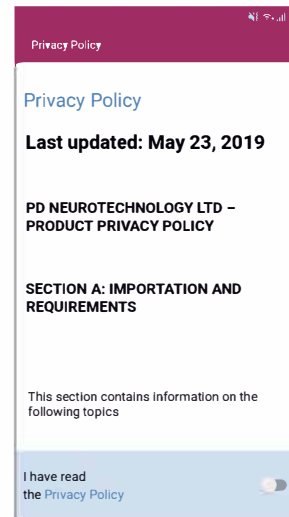


Figure 29

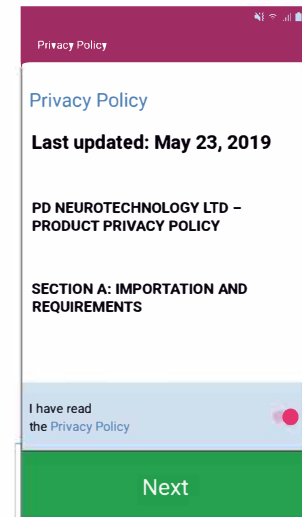


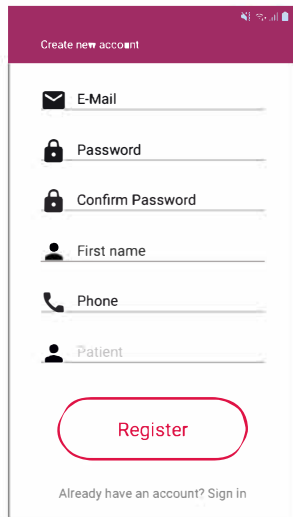
Figure 30

b) Registration

You can register through the application form that appears when the application starts for the first time (Figure 31). Upon successful registration, you will receive a confirmation e-mail.

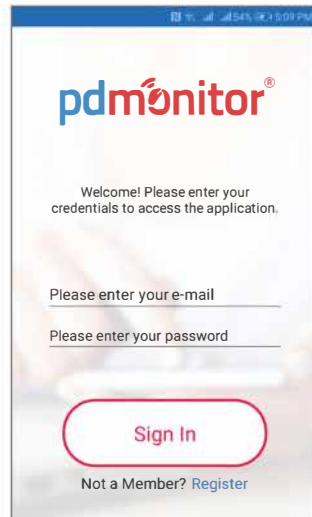
c) Login

In the next login attempts, a Login screen (Figure 32) appears where you must provide your account credentials to access the main menu screen.



The registration form is titled "Create new account" and features a purple header. It contains several input fields: "E-Mail", "Password", "Confirm Password", "First name", "Phone", and "Patient". A red "Register" button is positioned at the bottom, with a link "Already have an account? Sign in" below it.

Figure 31



The login screen displays the "pdmonitor" logo and a welcome message: "Welcome! Please enter your credentials to access the application." It includes input fields for "Please enter your e-mail" and "Please enter your password", followed by a red "Sign In" button. A link "Not a Member? Register" is located at the bottom.

Figure 32

11.7 Main Menu

From the main menu screen (Figure 33) navigate through the application's available features.

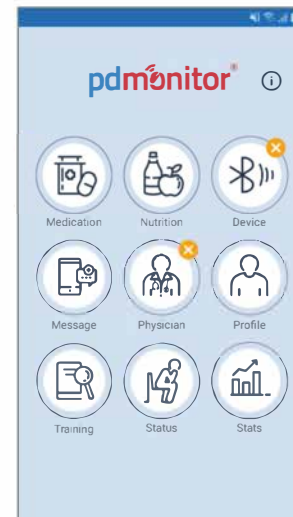


Figure 33

11 App

11.8 Medication

By tapping on the medication icon on the main menu screen, your physician's prescribed medication list appears (Figure 34). This is a list of medicines to be taken during the day. When you choose a specific medicine, the medicine details appear (Figure 35). Then, confirm whether the medicine has been taken or not. As a result, you can see the updated medication list (Figure 36).

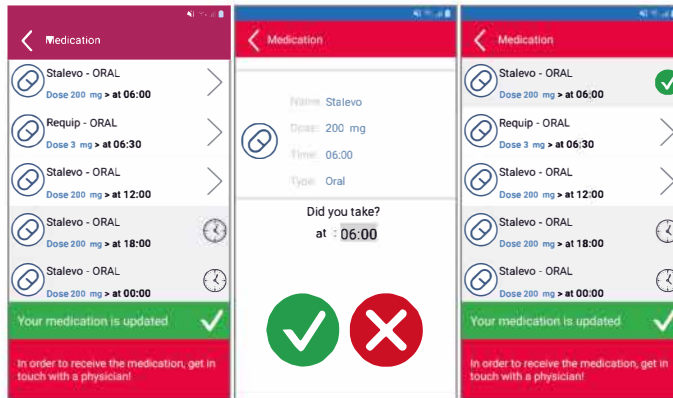


Figure 34

Figure 35

Figure 36

11.9 Nutrition

By tapping the nutrition icon in the main menu screen, you can change the time of your last meal by tapping the clock icon (Figure 37). By setting the time and clicking the OK button the next screen separates the food in protein-based products or other products (Figure 38) and you must record the food you ate 2 hours before and 1 hour after taking medication.

The screen in Figure 39 is also loaded as a part of the medication functionality, after the screen in Figure 35.

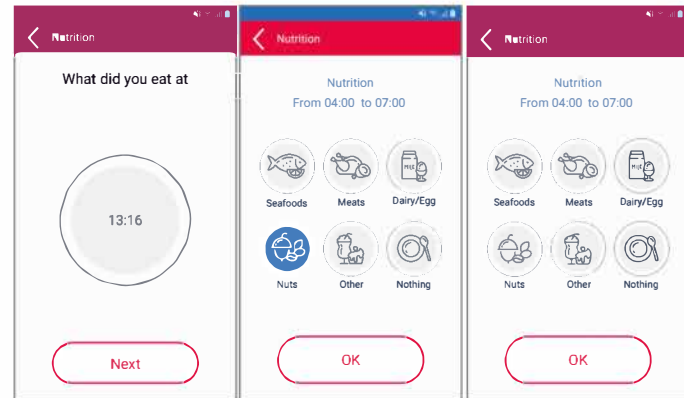


Figure 37

Figure 38

Figure 39



11.10 Invite Physician/ Patient

To use the PDMonitor® system properly, you need to be paired with a physician. To initiate the physician pairing invitation procedure, tap on the Physician icon in the main menu screen (Figure 40). In the next screen (Figure 41), send a pairing invitation (Figure 42) by filling in the unique 6-digit ID you received directly from your treating physician.

After confirmation, the invitation will be sent to the physician. Once your physician accepts the pairing invitation, in the next screen (Figure 43) you will see that the Physician icon in the main menu is slightly altered, with a green tick mark appearing at the top right-hand corner, indicating a successful pairing.

The same procedure can be followed by your caregiver to invite you by filling in your unique e-mail.

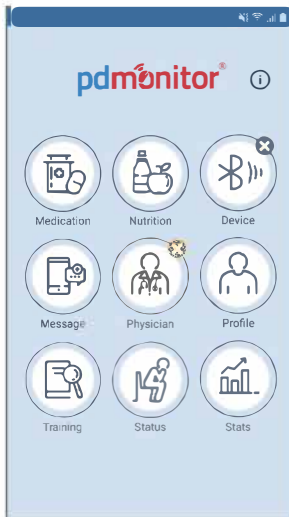


Figure 40

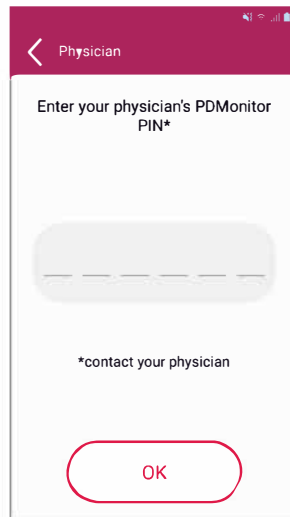


Figure 41

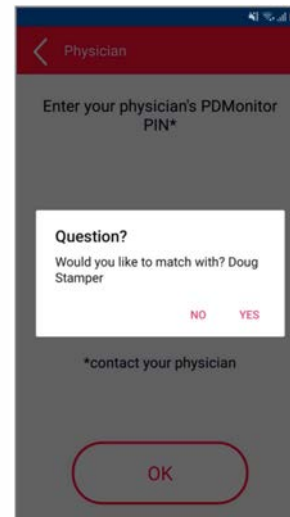


Figure 42

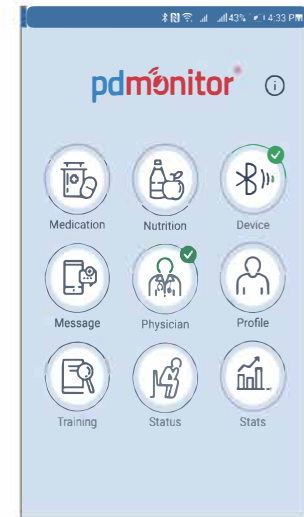


Figure 43

11 App

11.11 Status

On this screen, you can record your physical condition over the previous half-hour (Figure 44). By tapping the ON icon you will be redirected to a new screen, asking you about your symptoms (Figure 45).

After that, a reward message will appear on the screen (Figure 46) to encourage you to keep tracking your physical condition on a daily basis.



Figure 44

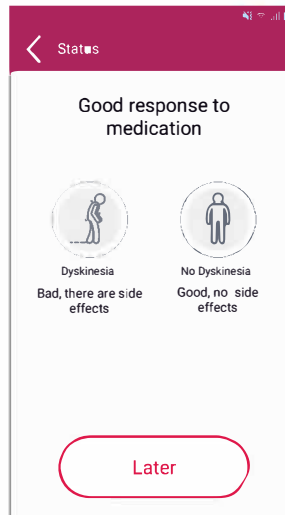


Figure 45

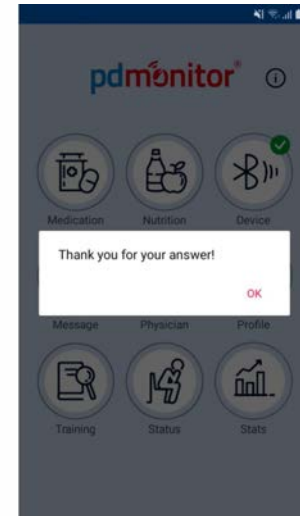


Figure 46



11.12 Profile

On this screen, you can edit and view your personal details. You can also sign out from the PDMonitor® mobile application (Figure 47).



11.13 Stats

On this screen, you can find a summary of your activity statistics, such as percentage of lying down, standing/sitting and walking during the day (Figure 48). The information for this functionality is generated by the PDMonitor® Monitoring Devices.



11.14 Message of the Day

You can send messages to your treating paired physician (Figure 49).

This functionality should only be used to send short communication messages to your treating paired physician, relative to your disease.

Be advised, the physician has no way to respond to the messages, other than contact you directly through telephone or e-mail. This is asynchronous communication and should not be used for emergencies. should not be used for emergencies.

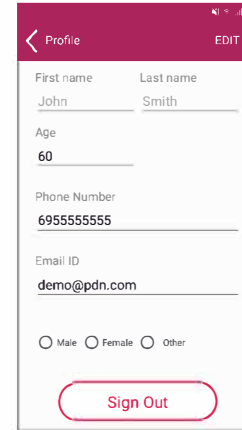


Figure 47

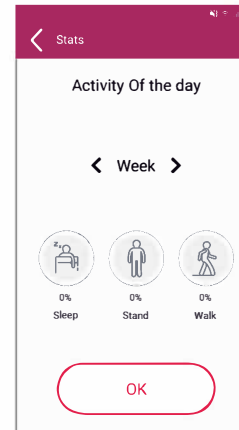


Figure 48



Figure 49

11 App

11.15 Version

By tapping the info icon (i) on the main menu screen, you can navigate to the version page. On this screen you can check the current PDMonitor® mobile application version (Figure 50) and the available new updates (Figure 51).



Figure 50



Figure 51

11.16 Training

In the educational screen, a list with educational videos appears, (Figure 52 and Figure 53).



Figure 52

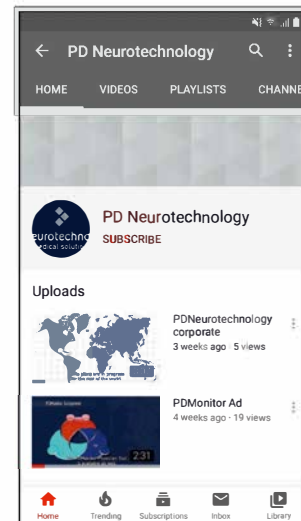


Figure 53

11.17 Device

To register the patient account in the SmartBox, follow the pairing process described in section 11.3. If there is no Ethernet connection, you need the Wi-Fi code to proceed (see section 11.3.1). If the alarm status indicator (Figure 10) is enabled on PDMonitor® device the user must check the alert message provided at the device screen (Figure 54) in order to handle the error.

If the device is not used for a long period, it is recommended that the PDMonitor® system is safely shut down through the PDMonitor® mobile application (Figure 55).

#	Possible warnings
1.	Internet connection appears to be offline.
2.	The Monitoring Devices are neither worn nor placed on the SmartBox.
3.	A problem occurred, please contact PD Neurotechnology HelpDesk.

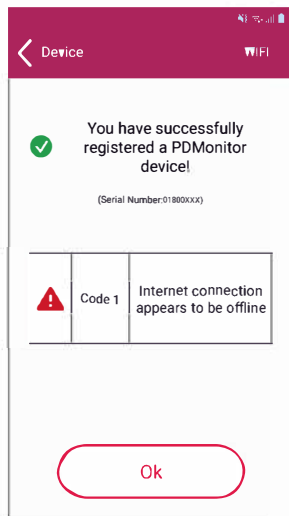


Figure 54

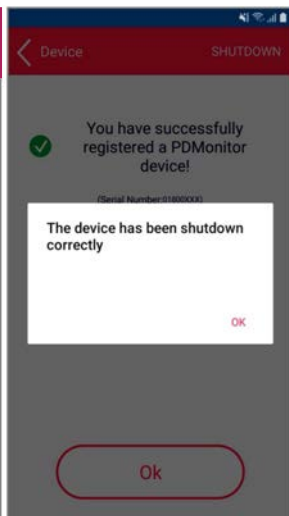


Figure 55

11 App

11.18 Wi-Fi Setup

To Setup the Wi-Fi connection in your PDMonitor® device, first make sure that your mobile phone is already connected to a Wi-Fi network. Then, in the main menu of the PDMonitor® mobile application, press the Device icon and on the Device screen, select the Wi-Fi menu on the top right (Figure 56).

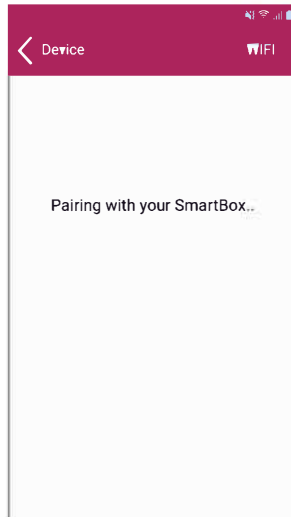


Figure 56

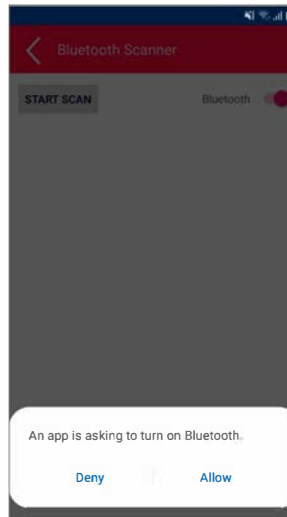


Figure 57



Figure 58

By tapping the “Start Scan” the application will try to connect to PDMonitor® device.

Before scanning, make sure that the “Bluetooth” option is enabled. A confirmation dialog will ask your permission to enable the Bluetooth on your mobile phone (Figure 57). If your device is in range and properly detected, a new screen will appear where you need to fill in the Wi-Fi details (Figure 58). Press the “Connect” button to set the Wi-Fi connection to your PDMonitor® device. Finally, check that the Internet connection light indicator is blue (Figure 9).

12 Mobile Application Troubleshooting

If the application is not responding or shows some dysfunction, restart the application. If the problem persists, contact PD Neurotechnology HelpDesk.

13 System Requirements for Your Smartphone

PDMonitor® mobile application is available on iOS (iOS 10 and higher) and Android (4.4 and higher).

14 Technical Specifications

Battery	
Operating time with full charge	30h
Type	190 mAH Lithium-polymer, rechargeable, non-replaceable
Charging time to full	3h
MD Battery Service Life	500 cycles/MD usages
Communication	
USB	Monitoring device USB port for the connection with the SmartBox
Internet wired connection	RJ45 connector
General	
Operating temperature	5-35°C
Charging temperature	0-35°C
Operating humidity	40-80%
Water ingress rating for SB	IPx21
Water ingress rating for MD	IPx24
Operating Atmospheric pressure	700 hPa to 1060 hPa
Storage/Transport Environmental Conditions	
Storage temperature	-10-60°C
Storage humidity	40-80%
Power supply	
In	230 V AC / 0.35 A
Out	5 V DC / 4 A
SmartBox size	
(length x width x height)	(168 x 74 x 43.5) mm
Monitor device size	
(length x width x height)	(41 x 31 x 12.5) mm
Sensors	
9 DoF IMU sensor	

15 Warranty and Service

The PDMonitor® device requires no calibration to operate properly. Should you have any problems operating the device contact:

PD Neurotechnology Ltd. for customer support at support@pdneurotechnology.com or +30 265 10 01300.

PDMonitor® system Two (2) Years Limited Warranty.

PD Neurotechnology Ltd. warrants the PDMonitor® System branded hardware product (PDMonitor®) against defects in materials and workmanship when used normally in accordance with the PDMonitor® published guidelines for a period of TWO (2) YEARS from the date of original retail purchase by the end-user purchaser (“Warranty Period”).

PD Neurotechnology Ltd. does not warrant that the operation of the PDMonitor® will be uninterrupted or error-free.

Should the PDMonitor® system fail to work properly during its useful life, contact PD Neurotechnology Ltd., at +30 265 10 01300 to arrange for repair and/or replacement. There are no user-serviceable parts.

Removal of the void warranty label from the SmartBox voids the warranty of the device.

PD Neurotechnology Ltd. is not liable for any damage arising from the failure to follow instructions relating to the PDMonitor® system use.

The service life of the PDMonitor® device is expected to be five (5) years.

16 Disposal

Application of European directives 2002/95/EC, 2002/96/EC, 2003/108/EC, 2011/65/EU and 2012/19/EU, for reduction in the use of dangerous substances in electric and electronic devices and for garbage disposal.









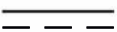
The symbol appearing on the device or its packaging indicates that at the end of its useful life the product must not be disposed of together with domestic waste. It must therefore be delivered to the competent collecting centers for electric and electronic garbage or returned it to the retailer when purchasing a new device. Disposing of the product separately prevents potential environmental and health hazards. In the case of improper disposal, administrative sanctions in compliance with current standards will apply. The device and its parts are marked for disposal, as appropriate, in accordance with national or regional regulations.









17 Version

The current version of Instructions for Use corresponds to the PDMonitor® device version 0.1.6. The contents of this document are subject to changes without prior notice. Changes will be incorporated in future revisions of this document. For the latest version and all revisions of PDMonitor® Instructions for Use please visit <http://www.pdneurotechnology.com>.

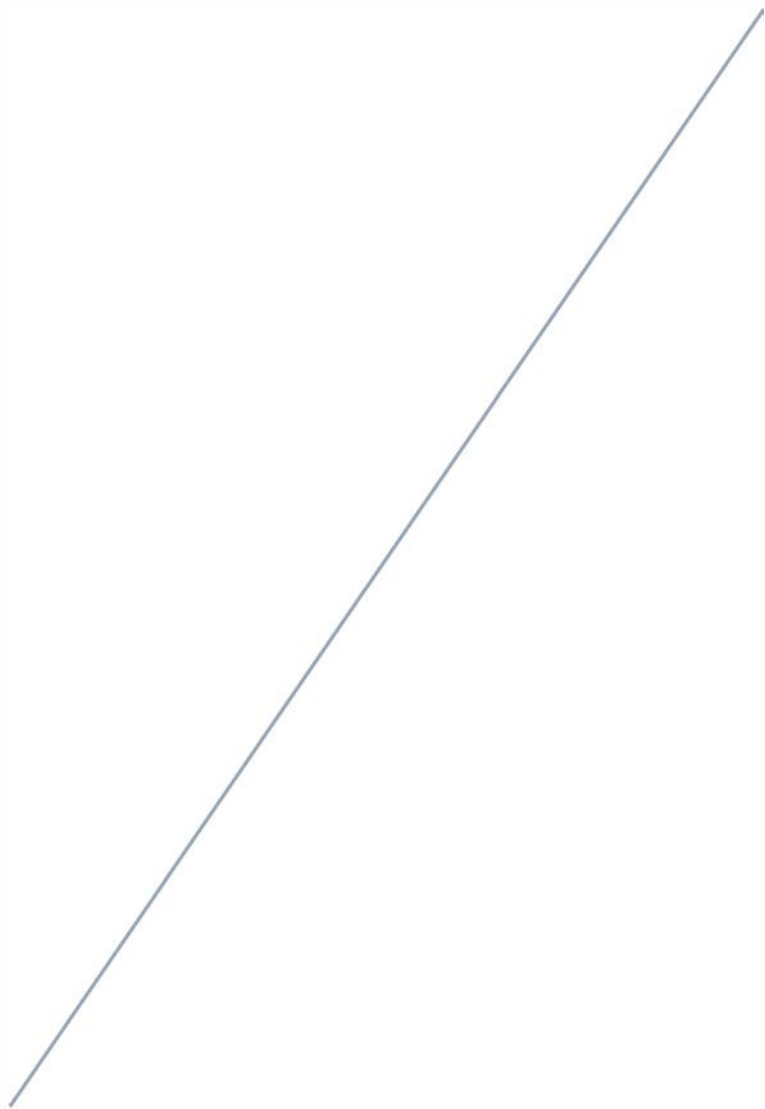
18 Symbol Table

The symbol table contains information to locate and relocate symbolic definitions and references

	Manufacturer
	Date of manufacture
	Batch code
	Serial number
	Fragile, handle with care
	Temperature limits to which the medical device can be safely exposed
	Humidity limits
	Consult the instructions that accompany the PDMonitor® system
	The equipment is suitable for direct current only

	To identify the positive and negative connections (the polarity) of a DC power supply
IP21	Non water resistant (Water ingress protection)
IP22	Protected against insertion of fingers and will not be damaged or become unsafe during a specified test in which it is exposed to vertically or nearly vertically dripping water
IP24	Protected against splashing of water (Water ingress protection)
	Non sterile product
	Do not use, if package is damaged
	Keep dry
	Consult the instructions for use for important cautionary information, such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
CE 0297	These systems have been approved to be sold as medical devices according to the European Union's regulatory requirements
	Class II equipment
	For indoor use only
	Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

50





APPENDIX

powered by



pd neurotechnology[®]
medical solutions

Appendix A: EMC Information

PDMonitor® system

Attention should be paid to the following EMC information prior to installing or using the PDMonitor® system.

- Portable and mobile Radio Frequency (RF) communication equipment may interfere with the operation of the PDMonitor® system.
- The PDMonitor® system has been tested and found to comply with IEC/ EN 60601-1-2.
- Computers, cables and accessories not tested to 60601-1-2 may result in increased emissions or decreased immunity of the PDMonitor® system.

Verify normal operation if utilizing the PDMonitor® system adjacent to or stacked with other electrical equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The PDMonitor® is intended for use in the electromagnetic environment specified below. The customer or user of the PDMonitor® should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	PDMonitor® uses RF energy only for its internal function. Therefore, its RF emissions are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	PDMonitor® is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions	Not applicable	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Not applicable	


**Guidance and manufacturer's
declaration – electromagnetic emissions**

The PDMonitor® is intended for use in the electromagnetic environment specified below. The customer or user of the PDMonitor® should ensure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD IEC 61000-4-2)	± 6k V contact ± 8k V air	± 6k V contact ± 8k V air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC 61000-4-4	Not applicable	Not applicable. No cables exceed 3 m	Mains power quality should be that of a typical domestic or hospital environment.
Surge EN 61000-4- 5: 2014+A1: 2017	± 1 k V Pulse Voltage	± 1 k V Pulse Voltage	
Voltage Fluctuations/ flicker emissions IEC 61000-3-3	N/A	N/A	N/A
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical domestic or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The PDMonitor® is intended for use in the electromagnetic environment specified below. The customer or user of the PDMonitor® should ensure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p style="text-align: center;">Conducted RF EN 61000-4-6</p> <p style="text-align: center;">Radiated RF EN 61000-4-3</p>	<p style="text-align: center;">3 Vrms 150 kHz to 80 MHz</p> <p style="text-align: center;">10 V/m 80 MHz to 2,5 GHz</p>	<p style="text-align: center;">3 V</p> <p style="text-align: center;">10 V/m</p>	<p>Portable and mobile communications equipment should be used no closer to any part of the PDMonitor®, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p style="text-align: center;">Recommended separation distance $d = 1.2\sqrt{P}$</p> <p style="text-align: center;">$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a) should be less than the compliance level in each frequency range. b) Interference may occur in the vicinity of equipment marked with the following symbol: </p>

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PDMonitor® is used exceeds the applicable RF compliance level above, the PDMonitor® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the PDMonitor®.
- b) Over frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the PDMonitor®

The PDMonitor® is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the PDMonitor® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PDMonitor® as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter		
	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	150 KHz to 80 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix B: Clinical Validation

PDMonitor® system

The current version of PDMonitor® has been validated through a clinical trial performed in three sites (Greece, Italy, Germany). The study consisted of two phases. The first phase of the study (Phase I) was conducted in a hospital environment, with detailed (video) monitoring, recording and assessment of a wide range of symptoms by experts. The second phase of the study (Phase II) was conducted in a home environment. The data acquired during Phase II were used to validate the outcomes of the PDMonitor® system against patient/caregiver/nurse diaries. The dataset used for the symptom evaluation for the current version of the PDMonitor® system consists of 50 subjects (94 recording sessions).

NOTE. The reported accuracy of the system is subject to change as a result of a new clinical validation analysis or with software updates including improved symptom monitoring algorithms.

PDMonitor® Performance

PDMonitor® Outcome	Result (comparison to expert rating)
Activity/Posture	Accuracy 0.93
Bradykinesia	$R^2 = 0.46$
Bradykinesia + Gait	$R^2 = 0.79$
Wrist Tremor Detection	Accuracy 0.89, Correlation $R^2 = 0.67$
Leg Tremor Detection	Accuracy 0.93
Gait Disturbances	$R^2 = 0.60$
Freezing of Gait	Accuracy 0.93
Postural Instability	0.90 Accuracy with 1 specificity and 0.33 sensitivity in postural instability detection
Dyskinesia Presence	Accuracy 0.90
Time spent with Dyskinesia	$R^2 = 0.91$
Time spent in OFF state	$R^2 = 0.46$

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**Greece
R&D unit**

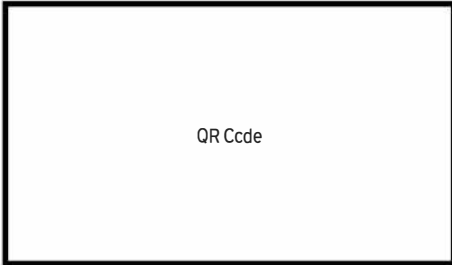
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Monitoring Devices Label



QR Code



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