pdmonitor®

PDMonitor_Booklet_v2.0_20210505

Standing by you, at every move you make

A non-invasive continuous monitoring system for patients with Parkinson's disease

powered by

pd neurotechnology®
medical solutions

www.pdneurotechnology.com


Wrist position monitoring devices
pdmonitor


pdmonitor
pdmonitor®
Standing by you, at every move you m
Pdmonitor, a non-invasive, continuous monitoring
for use by patients with Parkinson's diseas
See the video demo for more info about operations a
Consult with your treating physician about how to best utilise


pdmonitor
Physician Tool
Home
Patients
Periods
Overview
Report
> Download PDF
> Select period
> Report Comments
OFF Score
Code
OFF Score
Period
Time when symptom was present
Average Value [Min-Max]
Compare With
Select code to compare...
Reset report
Min
Max
Time of day
Lying
Left
Symptoms
Patient
Overview
Summary
Medications
Messages
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Intro

This brochure is aimed at patients and healthcare professionals treating patients suffering from Parkinson's Disease (PD), such as: neurologists, neurosurgeons, nurses, physiotherapists or other involved specialties.

It describes PDMonitor®'s functionality and what this new, groundbreaking technology is about, in practical terms, and also in ways of instilling confidence in its use. Experts believe that PDMonitor® could enable a paradigm shift in treating complex, chronic conditions, such as PD, through continuous Objective Measurement (OM) and mHealth.

In the first section, you can find the Product Description of PDMonitor®, a CE marked Class IIa Medical Device, which supports physicians in monitoring, following progress and treating patients suffering from PD. Its various parts and the technology and science behind it will help you understand the ecosystem it entails, the product distinct features and capabilities, its intended use and its advantages, and how it can have an impact in the daily living of patients, physicians and caregivers.

In the second section, you can find more about PD Neurotechnology® (PDN), a Medical Device Company, founded in London, in 2015, by a team of experts in the field of movement disorders and wearable patient monitoring systems. A global Medical Advisory Board steers the company's R&D efforts and medical/clinical pipeline.

PDN's headquarters are in the UK, while its state of the art research and development, production, warehouse, distribution, technical support service and medical trial units are in Ioannina, and its Sales and Marketing activities are managed out of Athens, Greece.

Finally, this brochure comes with additional, useful material in the following areas:

a. Medical Advisory Board

b. Evidence and Results

c. Publications

d. Clinical Trial Pipeline

e. Case studies

f. In daily practice

THE PRO-DUCT

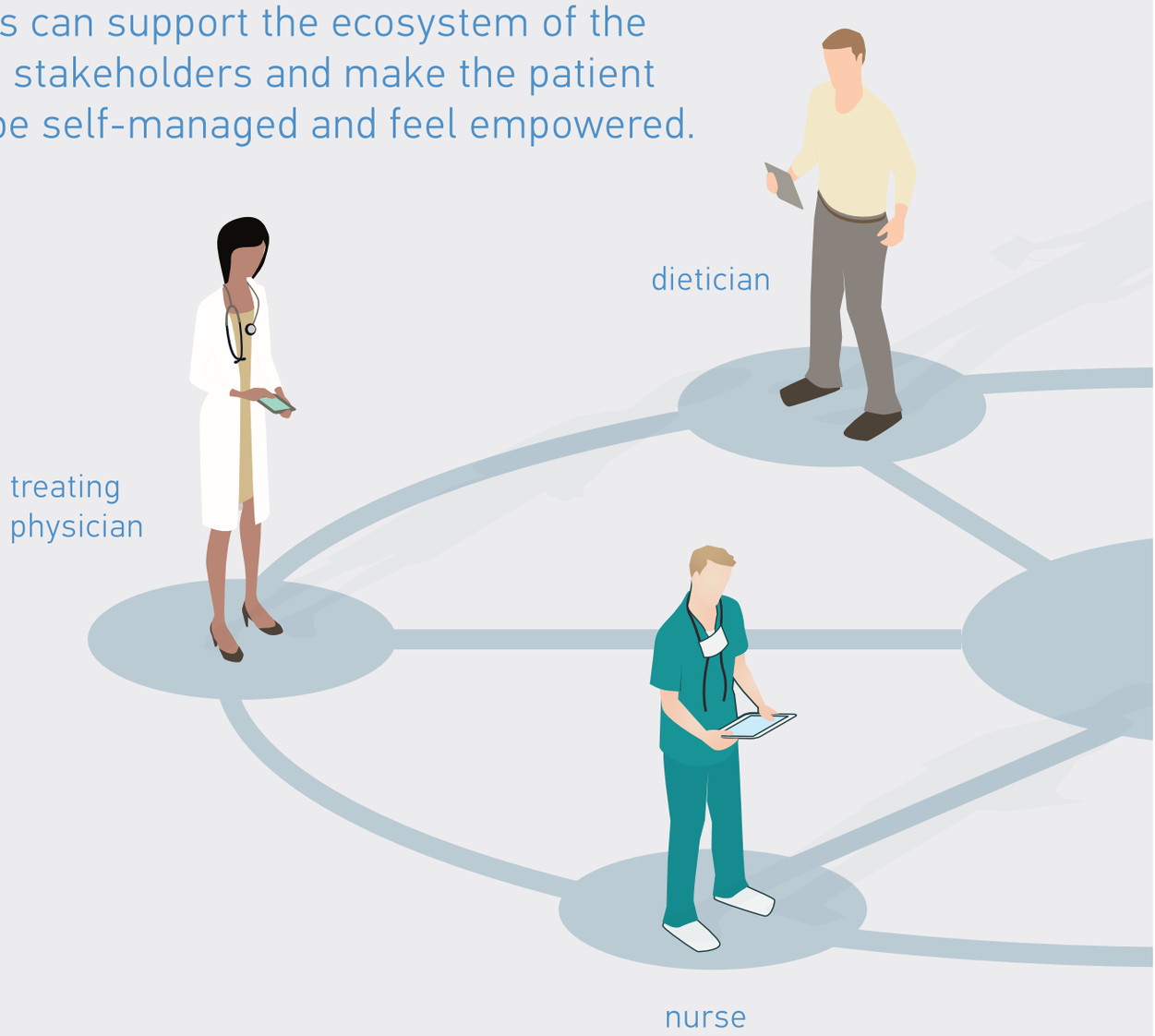
Standing by you, at every move you make

pdmonitor®

Principles for successful mHealth

The Active - Empowered Patient in mHealth

Healthcare patient-centred solutions must involve all stakeholders who influence patients and based on collaborative models can manage patient's monitoring and treatment. Integrated information technology solutions can support the ecosystem of the involved stakeholders and make the patient able to be self-managed and feel empowered.



1 Proactive
Proactive interventions are allowed before symptoms occur.

2 Preventive
Anticipatory actions can be taken for prevention of the disease and reduction and monitoring of developing symptoms risks.

ECOSYSTEM OF STAKEHOLDERS

3 Personalised

Data are collected and are owned by each patient and his/her treatment is based on the characteristics of the individual.

4 Participatory

The patients become drivers of their health and are fully engaged in personal health management.

PDMonitor®: Patient-centered mHealth delivering actionable Knowledge

A New Treatment Paradigm

Currently Treatment based on:

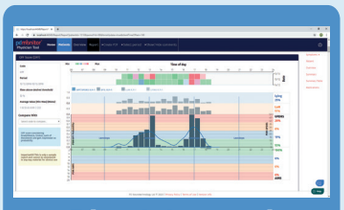
- Subjective diaries
- Routine physician visits
- Ad-hoc communication with the physician

Jan | Feb | Mar | Apr

Routine Doctor visit
- Diary
- Interview
- Examination

With pdmonitor®

- Objective motor symptoms
- Knowledge constantly communicated to the physician
- Patient/caregiver participation

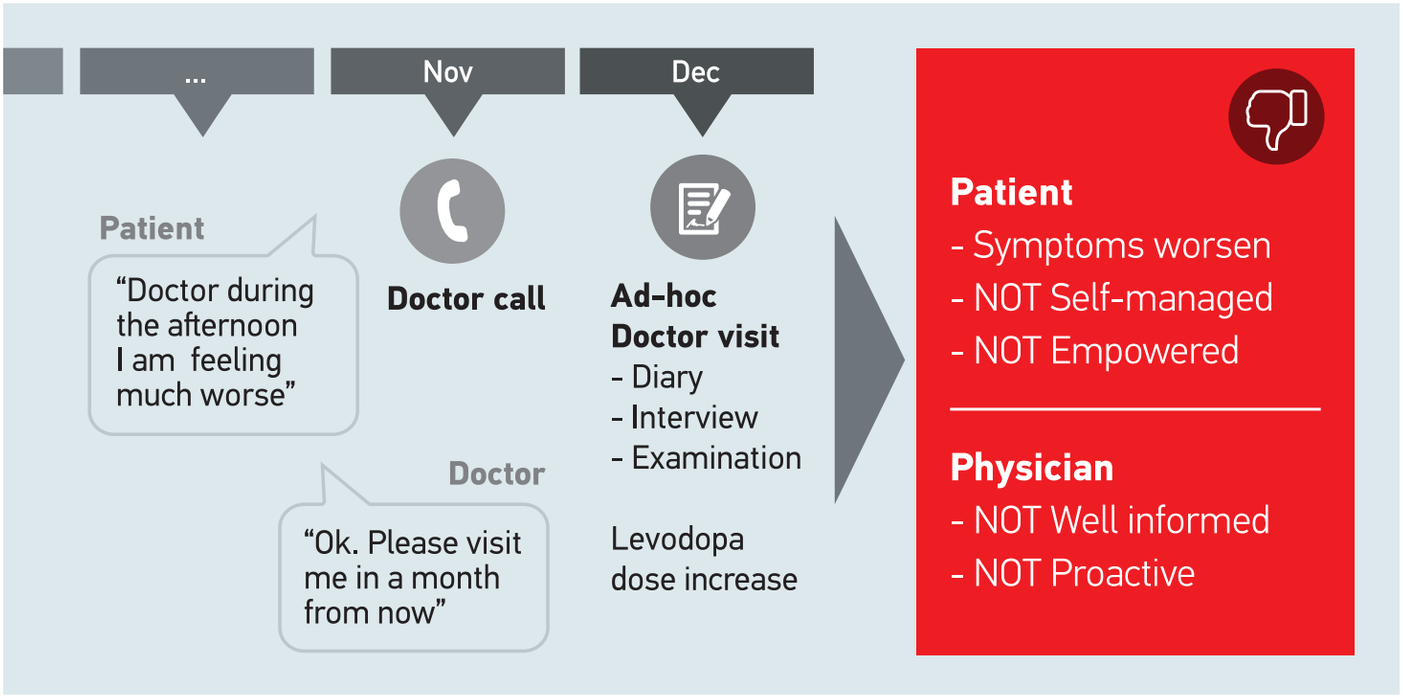


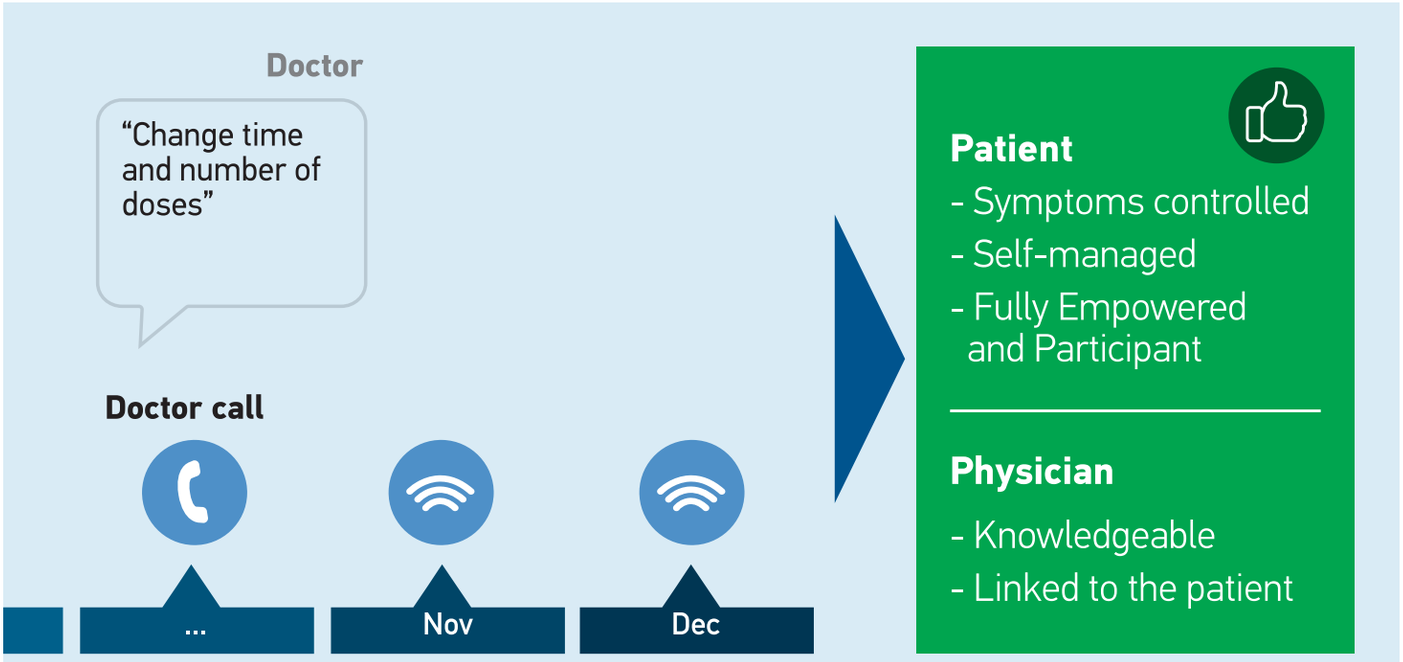
Physician tool

Jan | Feb | Mar | Apr

pdmonitor® 4Ps Compliant treatment | Ecosystem operation |

Routine visits to the physician and ad-hoc interactions give their place to continuous Objective Monitoring and knowledge-based interventions.



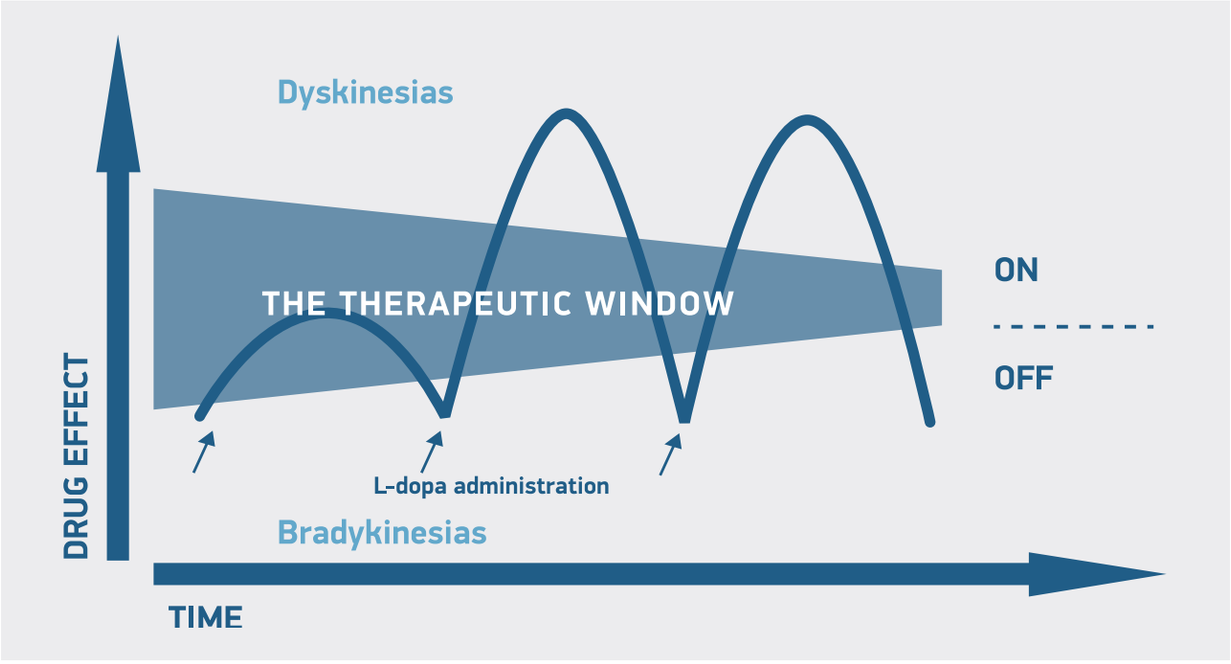


n | Patient - centered | Cost - Effective healthcare provision


pdmonitor

Patient management becomes more effective, keeping the therapeutic window open

Usual disease progression



The PDMonitor® effect

1. Decisions about treatment changes are more frequent and responsive to symptoms worsening.

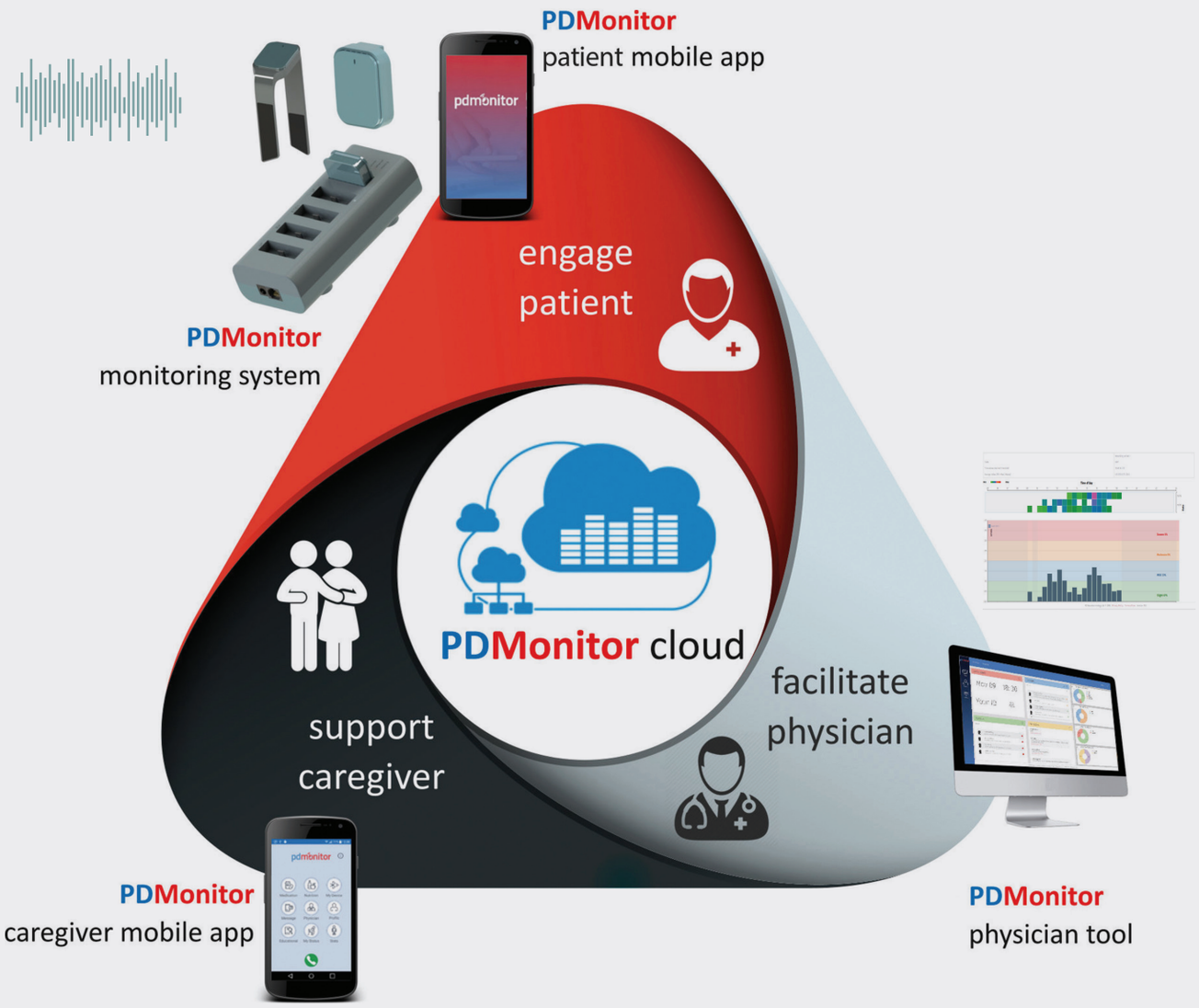
2. Symptoms management is more efficient and timely.

3. Non optimal dosing side effects, such us Dyskinesia, are managed.

4. Disease progresses slower in time, thus the therapeutic window is kept open.

All stakeholders benefit:
Patients, Physicians,
Caregivers, Families,
Hospitals,
Pharma companies,
Medical Devices companies,
Healthcare Maintenance
Organizations (HMOs)
and the Society.

A NOVEL non invasive Medical Device and Ecosystem that revolutionizes the treatment of Parkinson's Disease (PD)



with:

- Wearable devices unobtrusively monitoring patients 24/7.
- Machine Learning and Artificial Intelligence Algorithms to accurately monitor the most significant PD symptoms.
- Mobile apps and cloud infrastructure connecting all involved actors.

offers:

- Continuous, Objective Monitoring (OM) of ALL* motor symptoms.
- Better provision of services by the physician.
- Better treatment for the patient.
- Through mobile apps and cloud infrastructure better support to the caregiver.

***** *Activity, Bradykinesia, Dyskinesia, Tremor, Freezing of Gait, Gait disturbances, Postural instability, ON/OFF conditions, Fluctuations.*

PDMonitor® intended use

PDMonitor® is a non-invasive continuous monitoring system to be used by patients with Parkinson's Disease (PD), with the consultation of their attending physician.

The system consists of:

> a set of five (5) wearable monitoring devices,
> a mobile application, which enables patients/caregivers to record medication, nutrition and non-motor status information as complementary information for the motor symptom assessment, and
> a physician tool, which graphically presents to the physician patient movement and patient related information.

The physician tool reports are at the disposal and judgement of the attending physician and could allow for a better and objective assessment and understanding of the patient's PD symptoms.

The PDMonitor® system can be used at any stage of the disease after its initial diagnosis and when the patients are under medical treatment.

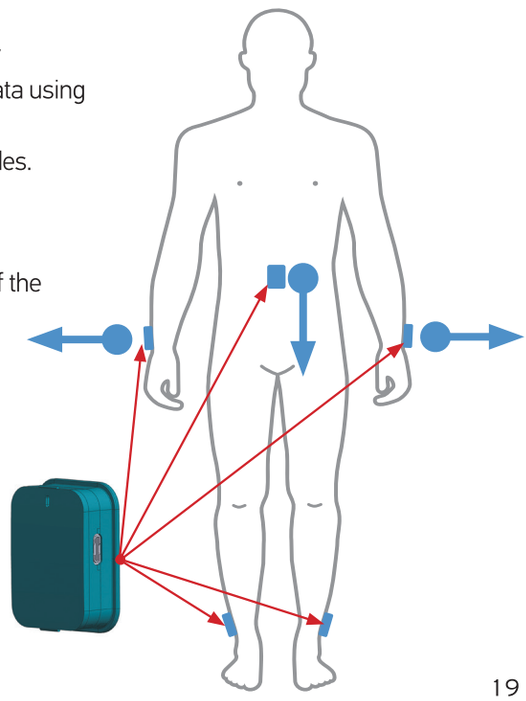
Three actors compose the PDMonitor® user ecosystem:

> patients being at any stage of the disease,
> caregivers – formal (nurses, volunteers) or informal (relatives, family, volunteers) – appointed for specific patients,
> physicians (medical doctors – Neurologists experts in movement disorders or Neurologists or General Practitioners trained to interpret PDMonitor® reports).

PDMonitor® monitoring devices & body position

PDMonitor® monitoring system

The PDMonitor® monitoring devices are mounted on five (5) predefined body positions: Waist (1), Wrists (2), Shanks (2). Each device collects movement data using an accelerometer, a gyroscope and a magnetometer.
Those are used to evaluate the various PD symptoms affecting both body sides.



PDMonitor® body position

Assessing activity, walking and other symptoms requires the identification of the placement of the sensor. This has initially imposed a requirement to have some kind of labeling for sensor body position (left/right, waist/arms/legs).

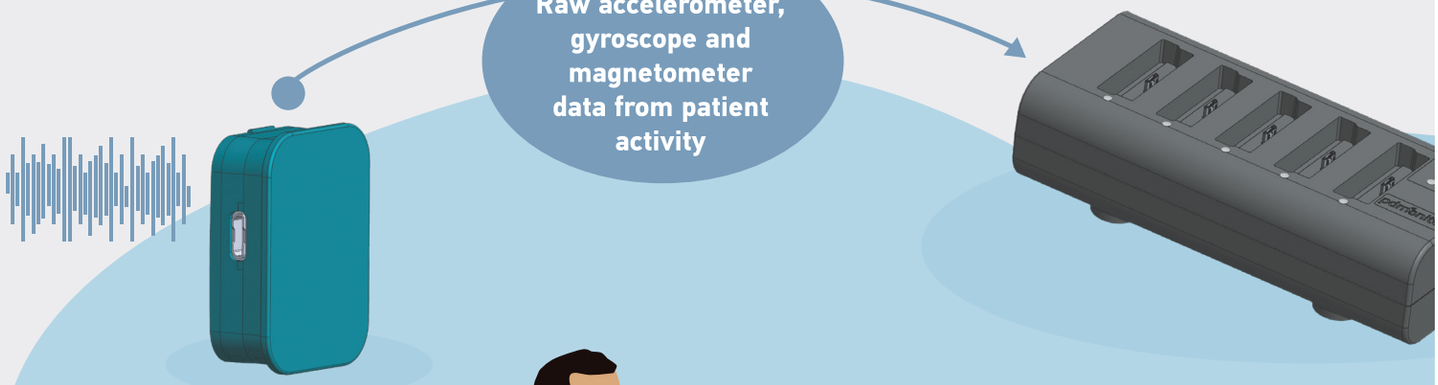
A new method has been developed to identify sensors automatically given correct placement. The method relies on the following observations to identify where the monitoring device is placed (waist/arms/legs):

> Waist accelerometer energy is always less than that of the rest of sensors.
> Hands are facing both upwards and downwards whereas legs are not.
> Left and right sides (legs and arms) have different signs in the correlation of different axes of the gyroscope.

How PDMonitor® works

Smart Box
Processes motion data and extracts PD symptoms

Raw accelerometer, gyroscope and magnetometer data from patient activity



Monitoring Devices
Acquire and store raw motion data

Patient Mobile App
Patient Diary, Medication/ Nutrition data

Patient mobile App data

PDMonitor®
Physician Tool

- Patient symptom reports and statistics
- Grouping functionality
- Graphical User Interface
- Summary Reports

Actionable knowledge

PDMonitor® Cloud

Aggregate symptoms and Mobile App input integrated in a powerful knowledge base

Caregiver
Mobile App

Patient Diary,
Medication/Nutrition data

PDMonitor® System

1

Monitoring Devices

The PDMonitor® Monitoring Devices are used to measure body movements in everyday activities. All Monitoring Devices have a light indicator and a micro USB port for charging and communication purposes. Monitoring Devices are mounted on the body with PDMonitor® Accessories.

2

SmartBox

The SmartBox is the PDMonitor® unit where the Monitoring Devices should be placed to get charged and to upload the collected data. The data are then processed to extract the Parkinson's Disease symptoms. The symptoms are then uploaded to the cloud via ethernet cable or WiFi.

3

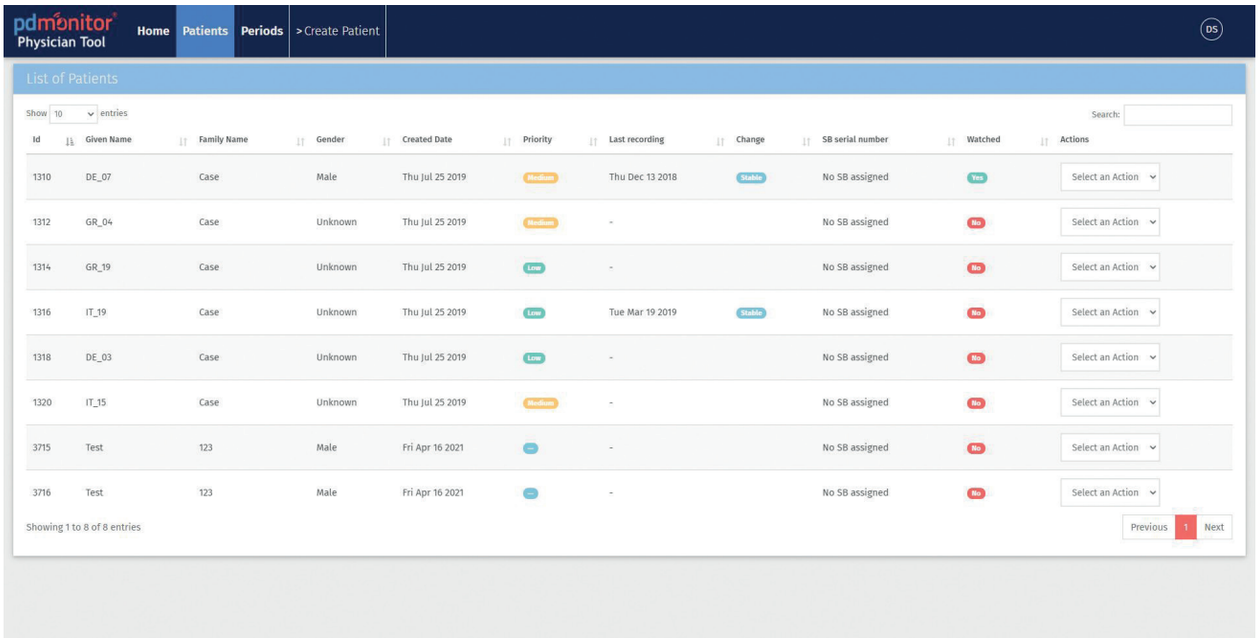
Accessories

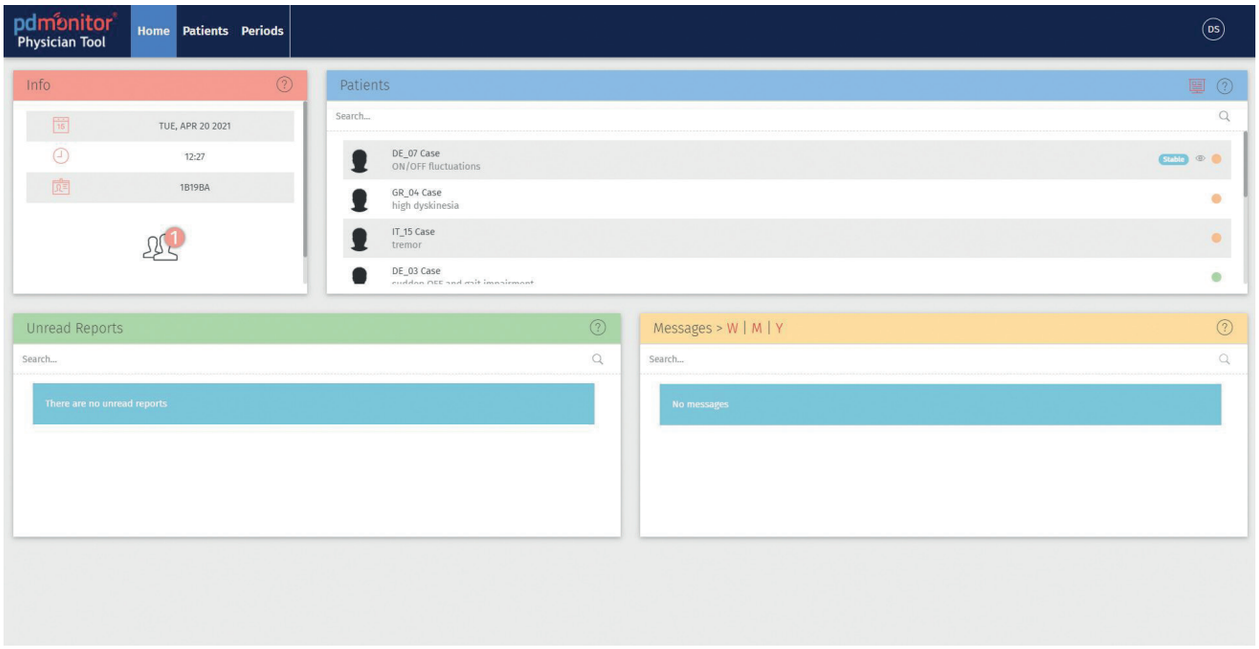
The wristband, strap frame and clip frame are designed to secure the Monitoring Devices to predefined body places. Wristbands are for wrists, strap frames for shanks (legs) and the large strap and clip frame for waist.

PDMonitor® Physician Tool

The PDMonitor® web enabled software interface is the main tool for the treating physician allowing the management of his or her patients.

The physician has access to a dashboard for each patient with information provided by his or her PDMonitor® monitoring system and mobile application.

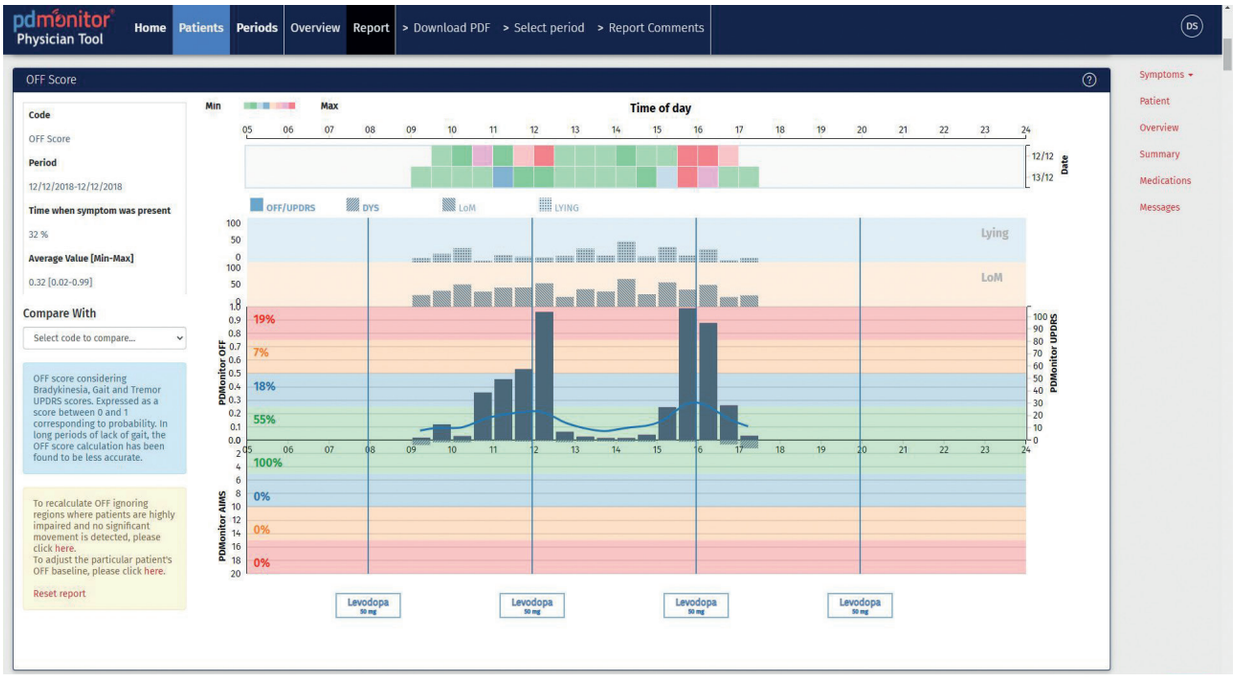




The PDMonitor® detects/quantifies:

> Activity
> Bradykinesia
> Dyskinesia
> Tremor
> Freezing of Gait
> Gait Disturbances
> Postural Instability
> ON/OFF conditions
> Fluctuations

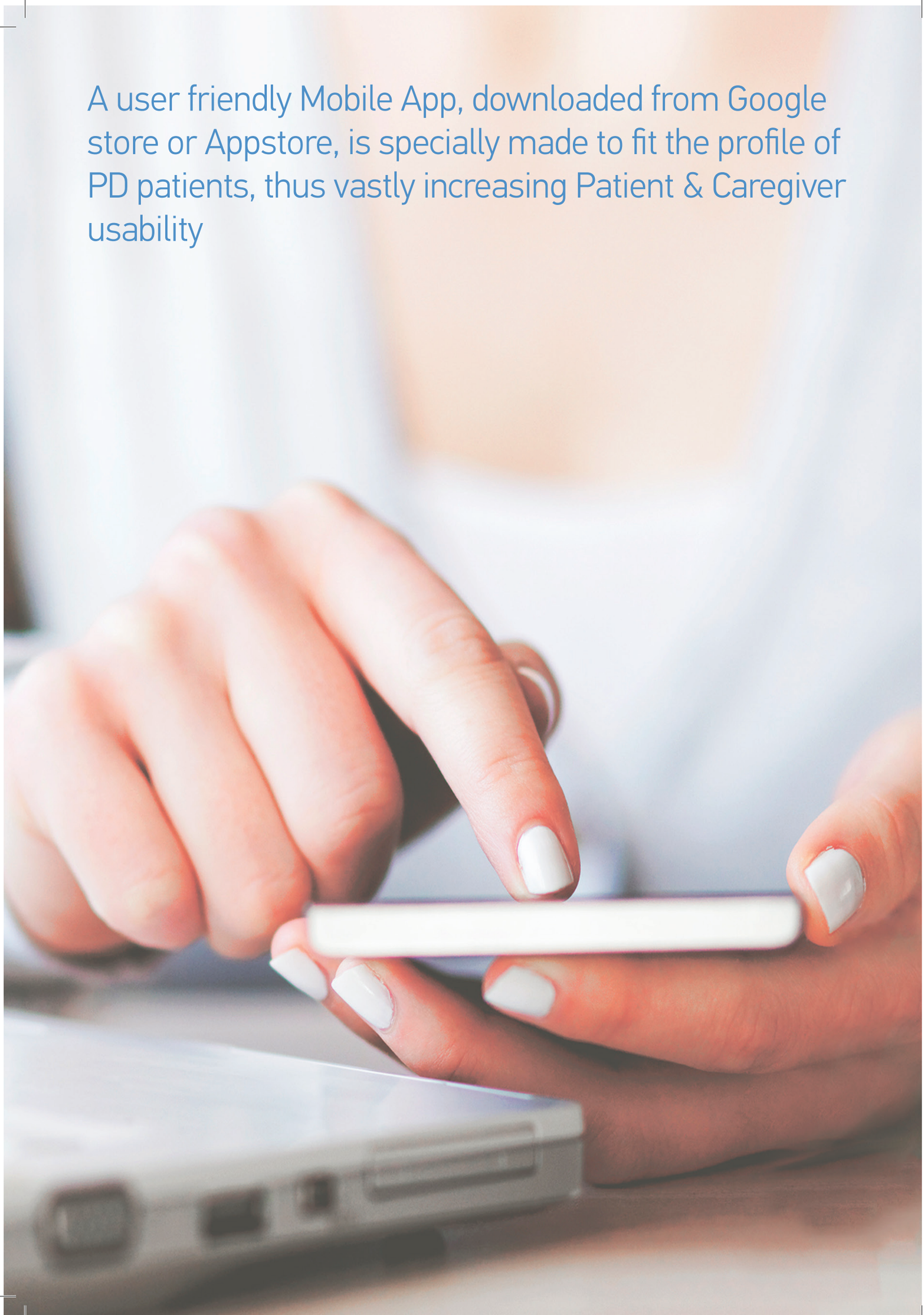
The symptoms are translated to clinically relevant scales and aggregated for the entire recording period (bars) and per day (heatmap).



PDMonitor® Activity detection:

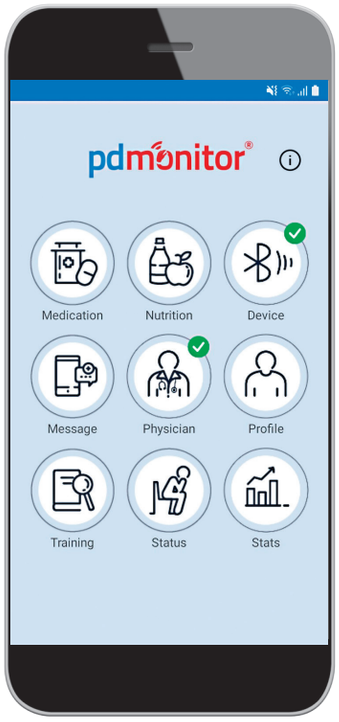
> Activity detection is fundamental for both patient assessment and also for symptom evaluation.
> PDMonitor® detects main activity (resting/walking) and posture (lying/sitting).
> This enables the better assessment of symptom impact on patient quality of life.
> The use of 5 monitoring devices enables the accurate detection of activity.

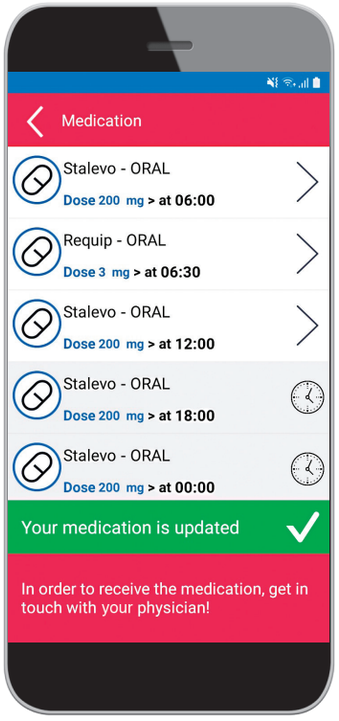
A user friendly Mobile App, downloaded from Google store or Appstore, is specially made to fit the profile of PD patients, thus vastly increasing Patient & Caregiver usability

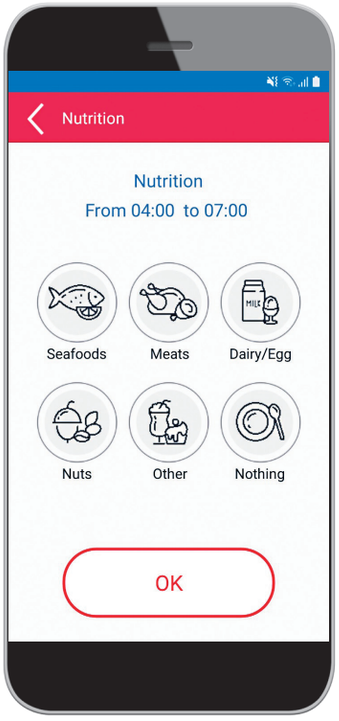


PDMonitor® Mobile APP

- > Medication input
- > Nutrition input
- > Message of the Day
- > Symptom (ON/OFF/ Dyskinesia) diary input
- > Activity statistics
- > Educational sessions





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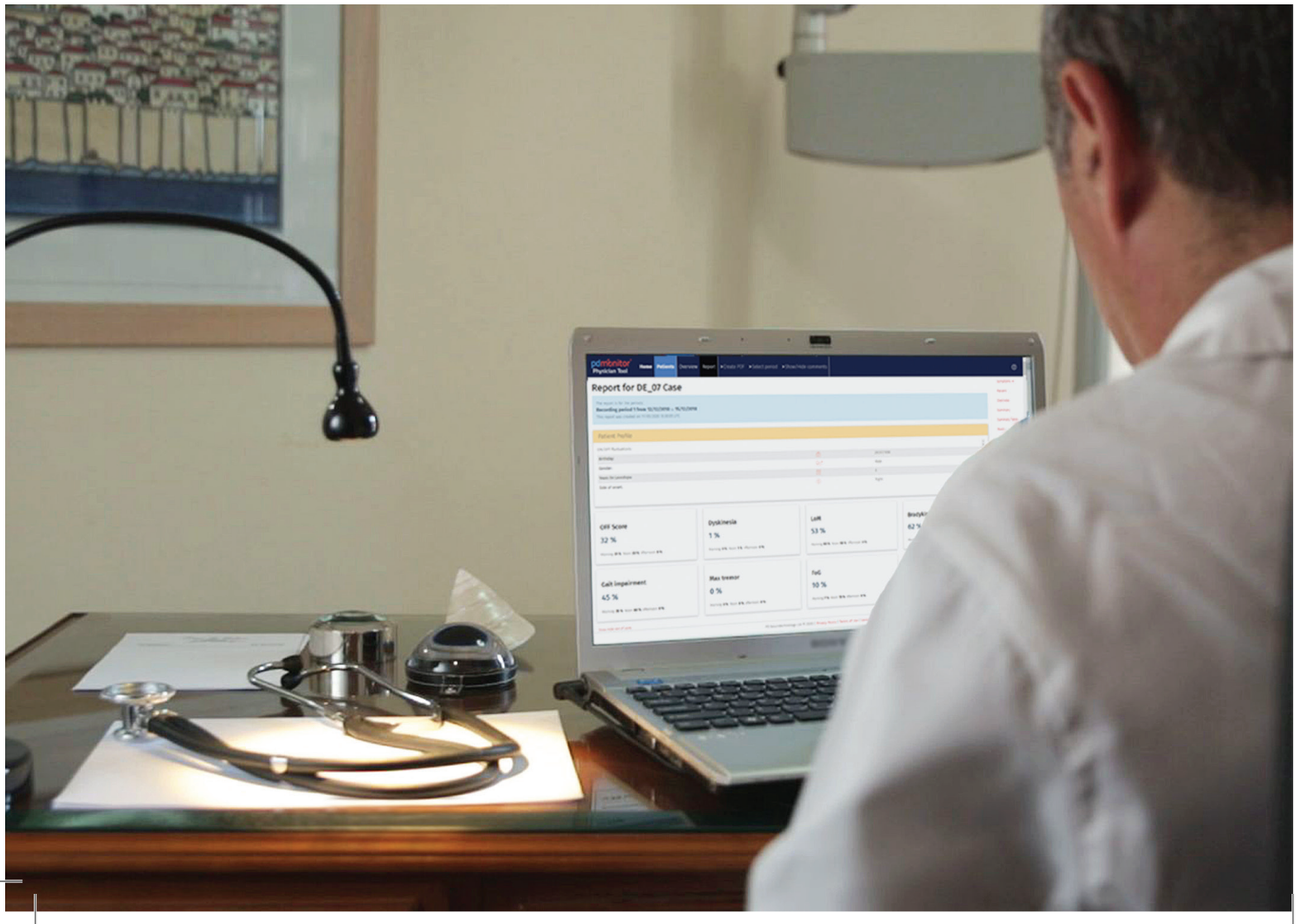

Report for DE_07 Case
Patient Profile
OFF Score
32 %
Dyskinesia
1 %
LoM
53 %
Gait impairment
45 %
Max tremor
0 %
FoG
10 %

PDMonitor®'s advantages, in daily practice, are summarized as follows

1 Prompt disease staging driving decision making about major treatment alterations

a. It provides accurate assessment of ALL* motor symptoms. The use of more sensors and the proper processing of their data provide superior symptom detection accuracy and disease insights that cannot be assessed with a single (wrist or waist) sensor.

b. It evaluates motor symptoms bilaterally. This is very important, given that PD symptoms do not affect both body sides the same and that the onset of symptoms on the less affected side is related to the progress of the disease.

c. Please also consult with the "In daily Practice" brochure, for additional info.

2 Continuous dosage fine tuning in the fluctuations stage

a. The Physician has unique tools for fine tuning of the treatment of the patient.

b. PDMonitor® provides continuous and progressive monitoring of the health status of the patient, leading to a holistic temporal and spatial understanding of his/her condition.

c. It accurately detects activity. Activity detection is a very important prerequisite for accurate symptom severity estimation. The more the sensors, the more accurate the activity detection.

d. Please also consult with the "In daily Practice" brochure, for additional info.

3 User friendly

a. Automated continuous processing requires minimum interaction with the end-user/patient.

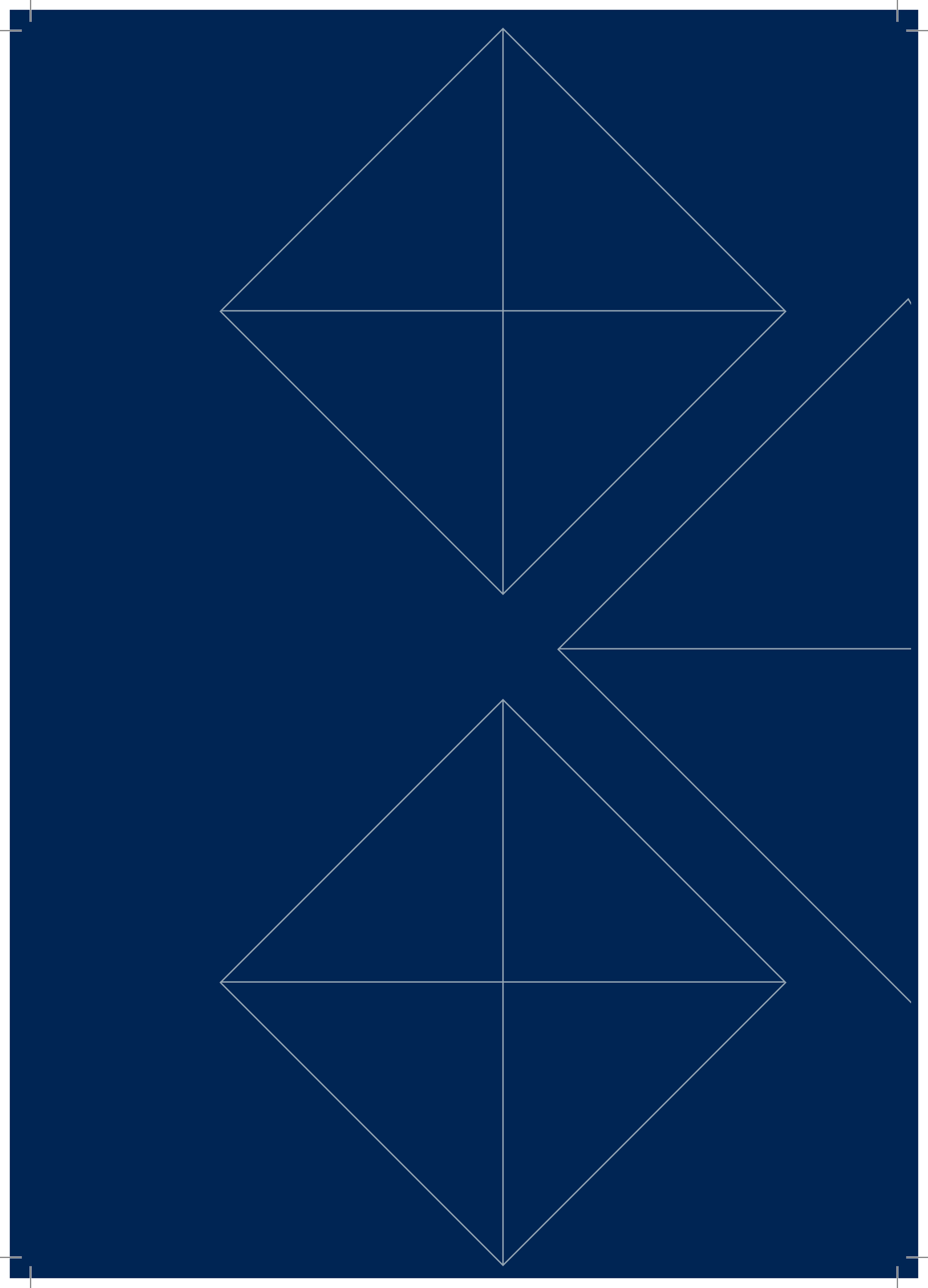
b. It provides comprehensive symptom reporting for physicians, through a very intuitive to use Physician Tool.

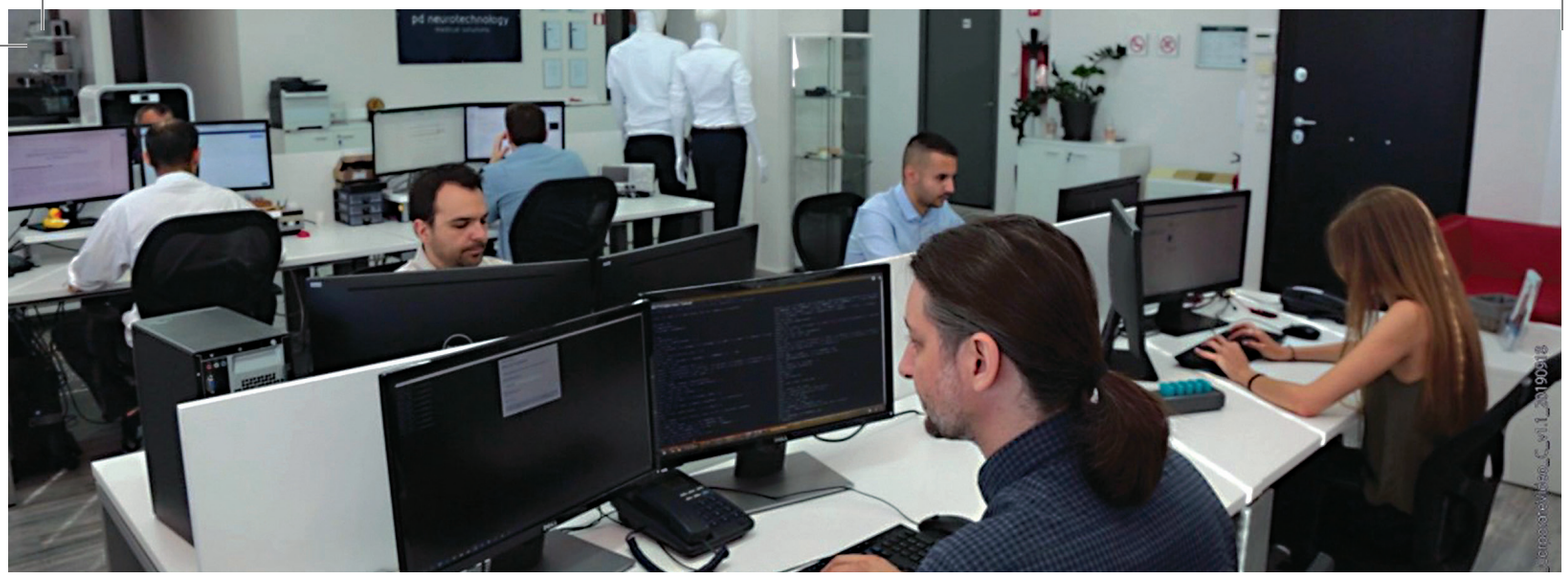
c. PDMonitor® provides digital biomarkers, which otherwise are not possible to be detected and quantified.

***** *Activity, Bradykinesia, Dyskinesia, Tremor, Freezing of Gait, Gait disturbances, Postural instability, ON/OFF conditions, Fluctuations.*

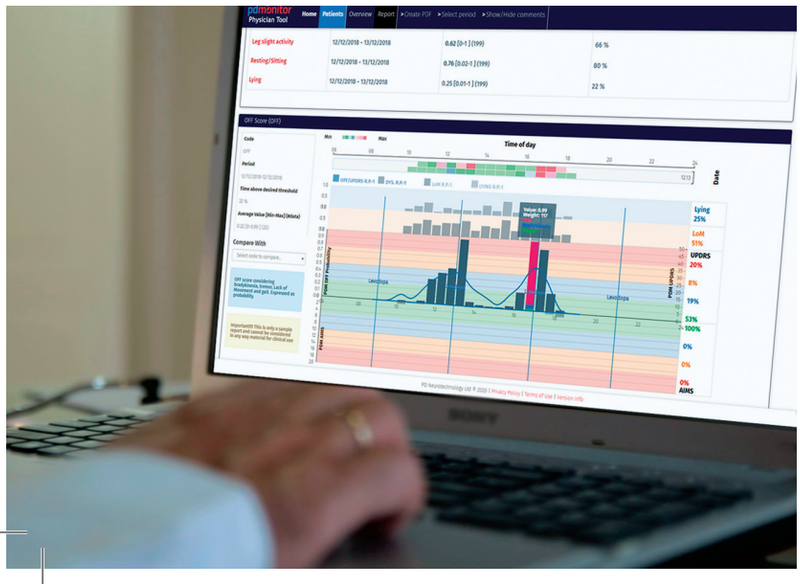
THE COM-PANY

pd neurotechnology® medical solutions




pd neurotechnology


pdmonitor
BULLE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Off Score (off)
Time of day
Lying 25%
LoM 51%
UPDRS 20%
8%
19%
53%
100%
0%
0%
AIMS

About PD Neurotechnology®

PD Neurotechnology® (PDN) is a high-tech company founded in London, UK, with R&D, Production, Tecnical Support, Medical Trials and Distribution units located in Ioannina, Greece. In Athens, PDN operates the sales/marketing services.

Its product lines include but are not limited to medical devices, sensors and software for the monitoring, diagnosis and treatment of patients suffering from Parkinson's Disease (PD) and other movement disorders.

PDN implements and maintains a quality management system according to ISO 9001:2015, an information security management system according to ISO 27001:2013 and a quality management system for research, development, production, distribution, sales, marketing, scientific and technical support of products related to medical technology, according to ISO 13485:2016. All audits were performed by DQS Med and DQS Hellas.

PDN's first product, the PDMonitor®, was certified with a medical CE Class IIa by DQS Med in June 2019.

CE 0297

Awards

NATIONAL BANK OF GREECE

National Bank of Greece GROUP is a partner to PDN LTD

Endeavor - Scale up program participant (Dec. 2020)

Winner of MIT Enterprise Forum competition July 2019

The Hellenic Initiative

Winner - Venture Fair 2018 (July 18)
Winner – ENVOLVE AWARD 2018 (Dec 18)

INTERNATIONAL ACCELERATOR

PD Neurotechnology among the winners of IQ 2019 at SXSW2019 Austin, Texas

R&D Projects

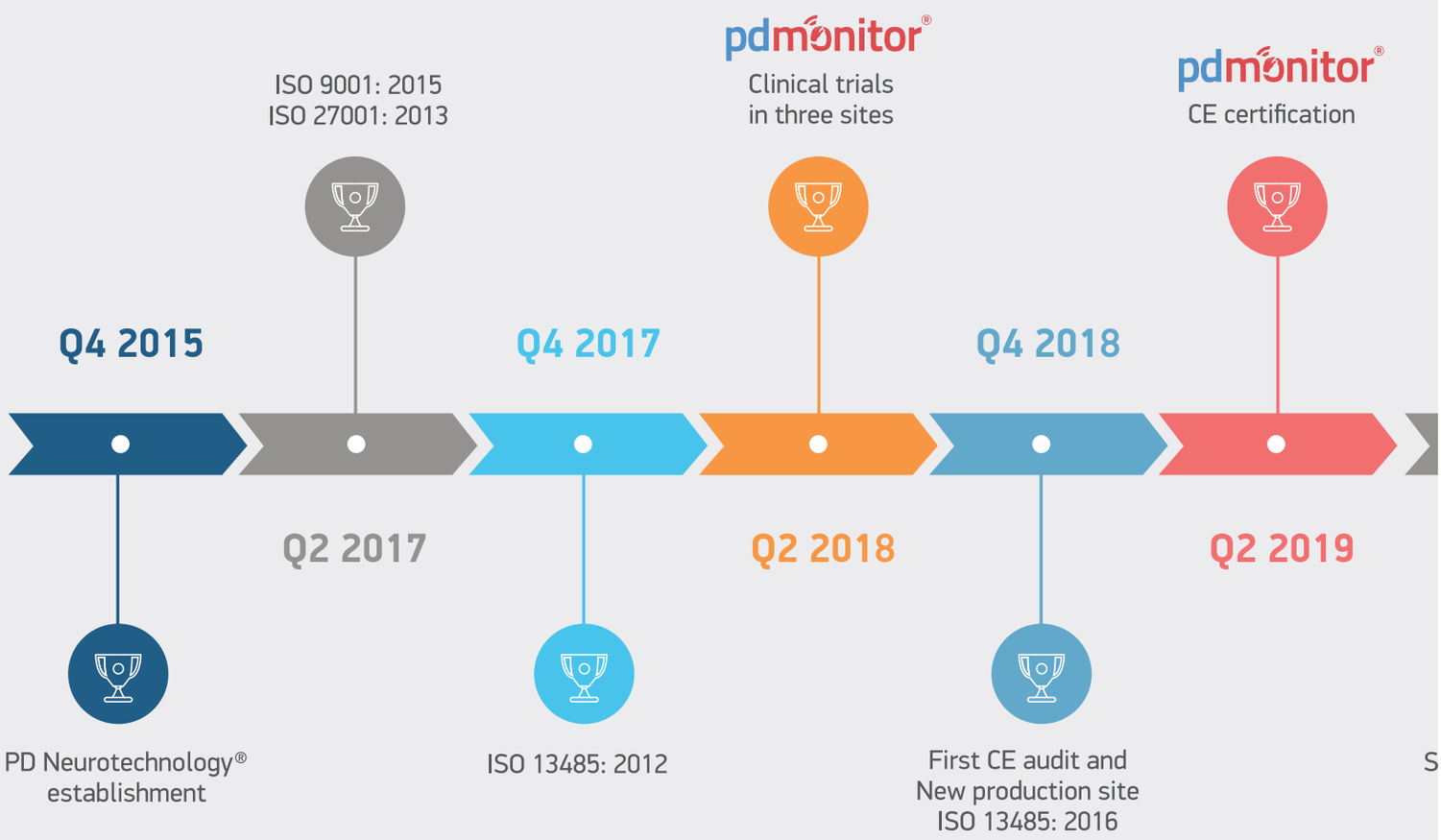
PD_PAL PROJECT
Developing new standards for palliative care in Parkinson's disease

ICARE-PD
Addressing complex care in Parkinson's disease in contemporary society

SMARTINSOLE
A novel wearable sensor for continuous human gait analysis and evaluation

HEALTHSONAR
A system for monitoring sleep and healthy living with low energy radio technology

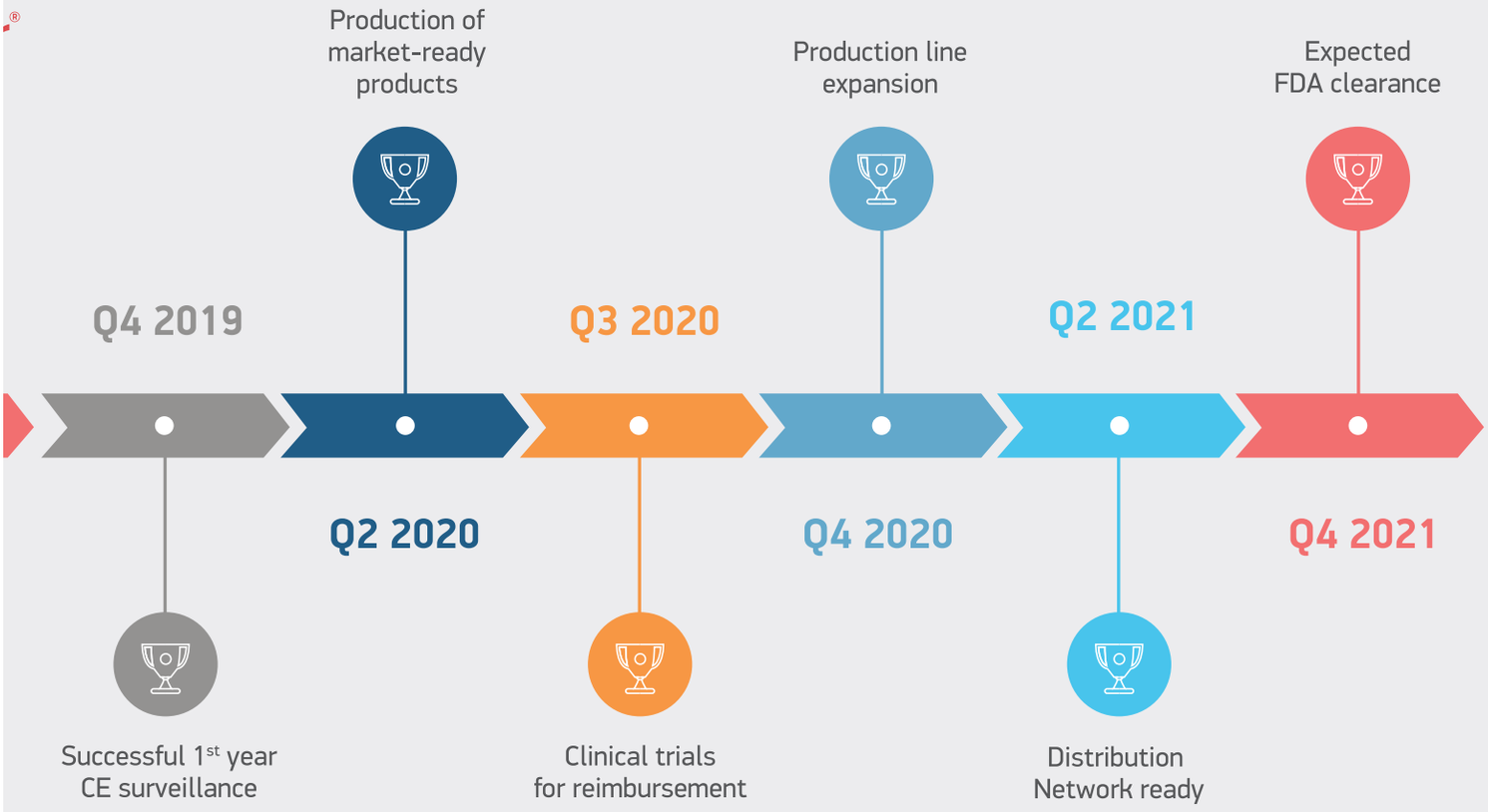
Major milestones



The Regulatory Framework

- > Compliance with the Medical Device Directive (MDD - 93/42/EEC)
- > Soon, PD Neurotechnology® and PDMonitor® will comply with Medical Device Regulation (MDR - 2017/746)
- > In progress-Application to FDA to "Expected clearance is 2021"

EN 1041:2008+A1:2013
IEC 60601-1:2005
EN 60601-1:2006+A12:2014
EN 60601-1-2:2015
EN 60601-1-6:2010+A1:2015
EN 62304:2006+A1:2015
EN ISO 10993-1:2009
EN ISO 10993-10:2010
EN ISO 10993-12:2012
EN ISO 10993-5:2009
EN ISO 13485:2016



EN ISO 14155:2011
EN ISO 14971:2012
EN ISO 15223-1:2016
EN ISO 300 328-1 V2.1.1
ETSI EN 301 489-1 V2.1.1
ETSI EN 301 489-17 V3.1.1
EN ISO 55024 :2010+A1:2105
EN ISO 55032:2015
IEC 62321-3-1:2013
EC 62321-5:2013
IEC 62321-4:2013+AMD1:2017 CSV

IIEC 62321-6:2015
IEC 62321-7-1:2015
IEC 62321-7-2:2017
EN ISO 60529:1989+A1:1999+A2:2013
IEC 60601-1-11:2015
IEC 62366-1:2015
IEC 62311:2018
IEC 62368-1:2014
EN 55011:2016+A1:2017
EN ISO 61000-3-2:2014
EN ISO 61000-3-3:2013

EN ISO 61000-4-6
EN ISO 61000-4-8
EU MEDDEV 2.7.1 rev 4
EU MEDDEV 2-12-1 rev 8
EU DIRECTIVE 2014/30/EMC
EU DIRECTIVE 2014/53/EU
EU DIRECTIVE 2011/65/EU
EN ISO 9001:2015
ISO/IEC 27001:2013
ISO/IEC 27701:2019
ISO 22301:2019

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CE 0297

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