



Better clinical management
of the patient with
Parkinson's disease



PD-WATCH MEDICAL DEVICE
A SYSTEM FOR PROCESSING MOVEMENT DATA OF
PATIENTS WITH PARKINSON'S DISEASE

AN AID FOR THE HEALTHCARE PROFESSIONAL

The PD-Watch, an acronym for Parkinson's disease watch, is a medical device that allows the processing of data regarding the body movements of adult patients with Parkinson's disease. It provides information on patients' motor states, including tremors, bradykinesia, dyskinesia, and ON/OFF states.

The PD-Watch has been designed and developed to provide medical personnel with aid to refine the patient's treatment plan in order to reduce symptoms and motor complications, ensuring the patient spends more time in a normal motor state.



HOW IT WORKS

A continuous recording session is carried out similar to a "holter". It records the patient's body movements through a wearable system similar to a wristwatch, which includes a triaxial accelerometer and memory support.

This recording occurs at any time and during the patient's daily activity. However, the recorded data comprises both movements of physiological and pathological origin.

Therefore, at the end of the recording, the data stored by the wearable system are processed with the PD-Watch's software, which was designed and developed to provide the doctor with an instrument to support distinguishing the two types of movements.

Data processing takes place automatically through a dedicated cloud platform, and a report containing the primary information on the patient's motor state is generated. This way, the doctor can assess the severity of symptoms and motor signs and study how they vary throughout the day and from day to day.

ON/OFF recap

Duration of OFF state	Duration of ON state	Duration of ON with non-troublesome dyskinesia state	Duration of ON with troublesome dyskinesia state
02:13	04:12	03:05	00:00
hours per day	hours per day	hours per day	hours per day

Global results

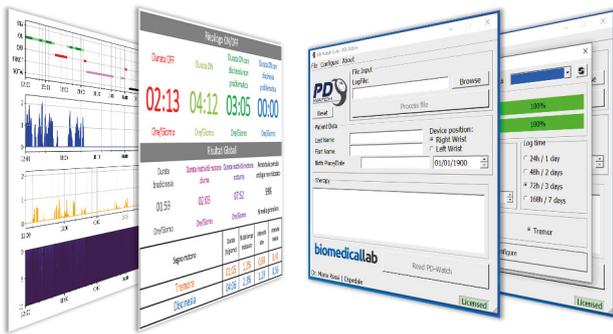
Duration of bradykinesia	Duration of nighttime motor inactivity	Duration of daytime motor inactivity	Percentage of worn time
01:59	02:03	07:52	99%
hours per day	hours per day	hours per day	mean percent daily value

Motor signs	Duration (hours per day)	% of worn time	Maximum Intensity	Mean Intensity
Tremor	01:05	4,2%	0,88	0,41
Dyskinesia	04:06	16,7%	1,29	0,56

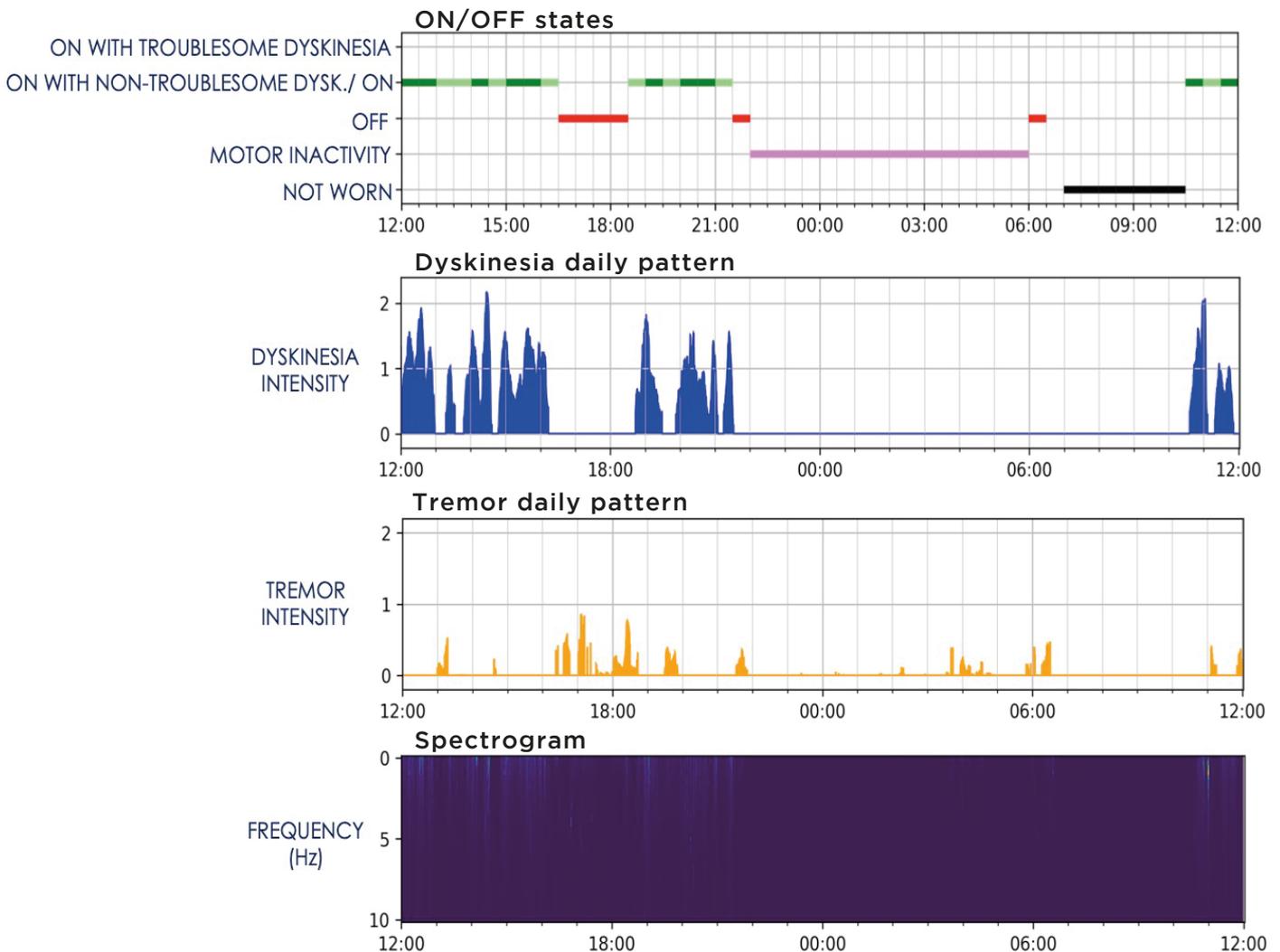
THE EXCLUSIVE PROCESSING METHOD



Symptoms and motor complications can occur with frequency values that can be superimposed on voluntary movements, making it very difficult to distinguish one from the other with only frequency analysis. Therefore, to reduce the probability of error in the distinction between physiological and pathological movements, the PD-Watch's processing method, besides verifying that the frequency of the movement falls within the characteristic values of tremor, bradykinesia and dyskinesia, also performs an analysis of the movement pattern to confirm that it is actually due to a pathological movement. For example, in the case of the assessment of tremor, the PD-Watch's processing method also checks that the movement occurs with the pronation-supination pattern characteristic of a tremor at rest, in addition to verifying that the frequency of the movement is that typical of Parkinsonian tremor.



Daily results



Main Technical Features

General features

Device model	PD-Watch Medical device compliant with EU Regulation no. 745/2017 (MDR)
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PD-Watch Report: main information

Main summary data:

- ✓ The overall duration for each motor state:
 - OFF state
 - ON state
 - ON with non-troublesome dyskinesia state
 - ON with troublesome dyskinesia state
 - Motor inactivity (day/night)
 - Not worn
- ✓ Duration, the mean and maximum intensity of dyskinesia
- ✓ Duration, the mean and maximum intensity of tremor
- ✓ Duration of bradykinesia
- ✓ The duration during standing and non-sedentary condition
- ✓ Histogram with the duration of tremor and dyskinesia for each level of severity expressed in values from 0 to 4, just like the UPDRS "Unified Parkinson's Disease Rating Scale"

Main temporal patterns:

- ✓ Temporal patterns of motor states with the indication of the daily moments of the recording in which the patient experiences an ON and OFF state
- ✓ Temporal patterns of tremor intensity and dyskinesia intensity
- ✓ Spectrogram

The temporal pattern of tremor and dyskinesia, as well as their mean and maximum intensity, are expressed in values from 0 to 4, just like the UPDRS "Unified Parkinson's Disease Rating Scale" and AIMS "Abnormal Involuntary Movement Scale".

The information above refers to the reports obtained for patients with motor fluctuations. For patients without motor fluctuations, the report contains information on tremors and bradykinesia only.

Registration system: main features

Dimensions of the GENEActiv wearable registration system (watch case without strap)	43mm x 40mm x 13mm
Mass of the GENEActiv wearable registration system (watch case without strap)	16 g
GENEActiv main envelope material	PC/ABS
GENEActiv transparent window material	PC
Contact material for physical connection to the 4-way station	Gold plated
Strap material	PU resin
IP protection degree	IP67
Operational temperature	5-40 °C
Mechanical impact	1m drop resistance
Rechargeable lithium polymer battery	Power supply voltage: 3.7V Capacity: 190mAh (typical)
Battery charging time	2 hours to reach 90% of the total charge 3 hours to reach 100% of the total charge
Battery charging mode	Through 4way station connected to PC with PD-Watch software

Input

Acceleration	MEMS triaxial accelerometer Range: -8g to 8g Resolution: 3.9 mg
Illuminance	Range: 0 lux to 3000 lux
Temperature	Range: 0 to 60 °C
Switch status	Membrane switch

Performance related to configuration, recording and storage

Recording duration settings	from 1 day to 15 consecutive days
Recording start mode	On button press, Upon disconnection from the 4-way station, At a set time.
Percentage of battery used during recording (typical values)	5% for a 24 h recording starting from a fully charged battery

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The images shown in this manual are purely illustrative.

The decision to use the PD-Watch to record and process patient data is made exclusively by or by order of a physician.

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