STAT·ON

USER MANUAL (Rev 1.6)

SENSE4CARE

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User Guide, Rev 1.6. This device has been made under the Council Directive 93/42/EEC, being certified as a Medical Device Class IIa.

Sense4Care guarantees that the device has been built under the ISO 9001:2015 for the design, manufacturing and commercialization of industrial electronic controls. Furthermore, Sense4Care also guarantees that the device has been built under the ISO 13485:2016 for the design and manufacturing of electronic controls as well as medical devices.

Table of content

0. Warnings, care and use instructions

Please, read carefully the user manual before using the device. Check that everything is correct before using the system.

Use only accessories supplied and/or authorized by the manufacturer

The product must be repaired by Authorized staff by the manufacturer

Equipment modifications must be done by Authorized staff by manufacturer

This device must be used by health professional staff.

Indications

STAT-ON is a waist-worn inertial device, configured by a doctor and used by the patient, that collects the movements from patients with Parkinson disease.

Device Sensor

- ❖ Do not expose the system to liquids. Liquid exposure may permanently damage the system.
- ❖ Do not use the system under 0ºC conditions or over 40ºC. Wait at least two hours for the system to return to room temperature before it is turned on.
- ❖ Operate system with room humidity between 45% and 85%.
- ❖ Keep the electrical cord away from walking paths.
- ❖ Improper routing of cabling may result in a choking hazard.
- ❖ Do not put metallic elements on the charging pad.
- ❖ Do not use in oxygen rich-environments.
- ❖ Do not use with inflammable agents.
- ❖ Do not use with flammable anaesthetics.
- ❖ Preferably use in waking hours and daily living activities. Do not use the sensor in sports. If so, inform the health professional about it. Manufacturers recommend not to sleep with the sensor since it can be oppressive and might cause physiological discomfort. The sensor must be managed only in clinical environments.
- ❖ Vehicles (car, motorcycle, bus or train) could affect the output of some algorithms.
- ❖ Do not use the sensor in medical interventions (surgical procedures, X-ray sessions, magnetic resonances…).
- ❖ The sensor and the smartphone must be at a distance of 1.5 meters from any other medical device when they communicate in order to not to produce interferences.
- ❖ Limited warranty covers any defect in the device under normal use during warranty period (2 years). Warranty does not cover any problem that is caused by conditions, malfunctioning or damage not resulting from normal use. It is not allowed to open the enclosure, otherwise, Limited warranty will not be applied.
- ❖ Battery is non-replaceable. The box is closed and it only can be opened by qualified personnel. Contact the manufacturer support in case of some malfunctioning of the battery.
- ❖ Use the battery supplied and/or authorized by the manufacturer
- ❖ There is no risk of reciprocal interference from the presence of the equipment during investigations or treatment

Belt

- ❖ Ironing allowed but use low heat
- ❖ Do not dry clean
- ❖ Maximum washing temperature up to 100ºC
- ❖ Do not bleach
- ❖ Do not tumble dry

Charge system

- ❖ Do not use another charger. The charger base may be damaged.
- ❖ The user must plug the charger system in a position that enables to unplug it easily.
- ❖ The battery has a life expectancy of 6 years.

Disinfection Procedure

- ❖ The device is not in contact with the patient. It is not necessary to clean the device but we recommend to clean it after some use with wet wipes.
- ❖ Do not submerge the device into water for cleaning up the device.
- ❖ Do not use abrasives as they may damage the sensor.
- ❖ The multiple cleaning of the device does not affect the integrity of the case material.

Isolation

- ❖ Type BF. Applicable parts are the sensor device and the belt.

Disposal instructions

Affixed to this device in accordance with European Council Directives 2002/96/EC.

These directives call for separate collection and disposal of electrical and electronic equipment. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Please, return to SENSE4CARE S.L. at the end of its operating life.

Contraindications

- ❖ The STAT-ON device is not indicated for:
  - o Healthy people or people without movement disorders.
  - o Children
  - o Parkinson's Disease patients with Hoehn & Yahr Scale 5.

- ❖ The STAT-ON device does not detect Parkinson's Disease. The device monitors Parkinson's Disease once it is already diagnosed by a Neurologist or an expert.
- ❖ The device and its App must be only used by Neurologists or Health experts (e.g. nurses, rehabilitation experts, therapists).

Secondary or side-effects / Adverse reactions

- ❖ The STAT-ON device cannot be worn by a person in wheelchair or using crutches. The results will not be valid in these conditions.
- ❖ The STAT-ON device must be worn correctly as the Instructions for User indicates. Otherwise, results will not be valid.

1. Quick start

1.1.   Download the app

Please use the QR code or go to:
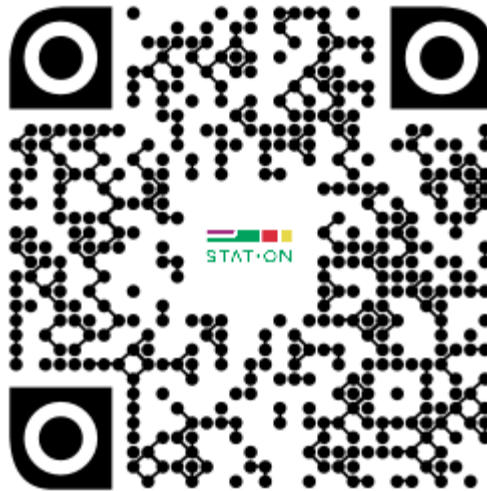
 https://www.sense4care.com/support/

Figure 1.   QR Code to download User Manual and Apps

Download the STAT-ON app. It requires Android 5 or higher or iOS 10.2 or higher.

1.2.   Press the sensor's button

Press the button and wait until the LED blinks in white. **IMPORTANT NOTE:** The button is only used to wake up the system the first time of use and to annotate EVENTS. It is not a "standby" button.

1.3.   Pair the device with your smartphone

Open the app, push the Bluetooth button on the app.

Figure 2.   Upper screen capture: Bluetooth area and Battery indicator

Search your STAT-ON device → "*STATONxx*" where xx are the last 2 numbers of the Serial Number (see STAT-ON label at the sensor, S/N). The pin is formed with the last 6 numbers of the Serial Number.

1.4. Configure your data

Please, fill the missing information in order to adjust the algorithms press the 'save' button. Then the sensor should stop blinking in white colour, meaning it has been configured. Once the sensor detects movement, its LED blinks in Green colour. Now the sensor is already working.

Figure 3. Configuration menu

1.5. Place the sensor

Place the sensor correctly within the belt aperture and put on the belt. The sensor should be placed at the left side of the waist above the iliac crest as shown in the Figure 4.

Figure 4.   Placement of the sensor

2. Intended Use

STAT-ON is a waist-worn inertial recorder, configured by a doctor and used by the patient for clinical, ambulatory, or home environments, that collects the results of the motor disorders and events of the Parkinson's Disease patient's in a period of time.

3. About STAT-ON

The STAT-ON system consists of a monitoring device, its base charger, a belt, and a mobile application. The system provides numerical and graphical information of the motor symptoms associated with Parkinson's disease. Furthermore, data related to the general motor activity of the patient are calculated.

The device collects the inertial signals of the patient's movement continuously, processes it in real time by means of mathematical algorithm classifiers and stores the results in its internal memory. The sensor must be only managed in clinical environments and only health staff can operate the App and the device. The patient should wear the sensor in their daily life activities with the aim of providing relevant information to health professionals.

The smartphone application connects to the STAT-ON device via Bluetooth (BLE). The App is used both for configuring the system and for downloading the data previously generated by the sensor. The mobile application can send the data enclosed into a report by email or digital support to any user, caregiver, therapist or neurologist.

STAT-ON has been developed under the PARK-IT project, funded by the European Commission (Grant Agreement: *756861 — PARK-IT 2.0 — H2020-SMEInst-2016-2017/H2020-SMEINST-2-2016-2017*).

4. STAT-ON kit components

The STAT-ON is composed by the following components:

4.1.   The sensor device

The sensor device (Figure 5), also called STAT-ON, has been developed under the PARK-IT project. The sensor is a 90x12.75x62.5mm^3 device with 83g of weight. It is composed by an ultra-low power high-performance nano-accelerometer, a microcontroller, and a Bluetooth Low Energy system, among others. The sensor has a battery life of seven days continuously in normal conditions. Manufacturer recommends to charge the device every day in case of forgetting doing it every 6-7 days. The system is waterproof with a IP65 protection.

Figure 5.   The sensor device

4.2.   The belt

The belt is made of Polyester (94%) and elastane (6%). Its fabric allows a complete adjustment to the body while being comfortable. Hook and loop fastener is used to fasten the belt securely. The belt has passed the Oeko-Tex® Standard 100 tests, guaranteeing no toxicity of the belt. The belt must be worn directly over a t-shirt or a thin clothing.

Figure 6.   Specific belt

4.3.   The charger system

The STAT-ON device can be charged wirelessly. It is necessary to use a charger compatible with the sensor:

- 5W of power
- Qi communication V1.1

It is mandatory that the charger base system contains a declaration of conformity with FCC regulations for Electromagnetic Compatibility with STAT-ON.

The AC Charger connected to the base charger must have the following parameters:

Standard: IEC-60601 Medical electrical equipment

Output Voltage: 5V

Output current: 2A

Connection: Micro USB – B

A charger kit (Base+AC Charger) might be purchased at **www.sense4care.com.**

Figure 7.   Top and Bottom view of a wireless charger base

5. Operator Use

STAT-ON is a waist-worn inertial device that collects the outcomes of several algorithms that are based on the computation of inertial signal. In other words, it collects data from a triaxial accelerometer, which is embedded within the device. In this section explained, it is the way of using the device.

It is highly recommended to follow the mobile app instructions at the beginning, which will conduct you through the first steps required for the system to work.

5.1.   Location and orientation of the device

The belt, which is provided with the sensor, must be used to attach the sensor to the user. The sensor must be worn on the left hip and its largest flat side should be facing the user. The status LED, the button and the label should be facing upwards. The following image shows how the sensor should be placed.

Figure 8.   Location and orientation of the sensor

The sensor must be placed on the left part of the waist. If the sensor is located in a different way that the showed in Figure 8, measurements collected might not be valid.

The sensor (within the belt) should be worn over a thin clothing as shown in Figure 8. The belt should be fastened tightly to prevent the sensor from moving, but allowing the user to be comfortable with it. The belt has a hole for viewing the status LED and enables pressing the event-button. It was designed to prevent the sensor from sliding out of it.

5.2. Sensor interface and modes

As shown in the following figure, the sensor device has a button and two led indicators next to the STAT-ON logo. The device also contains a small vibrator motor and a buzzer.
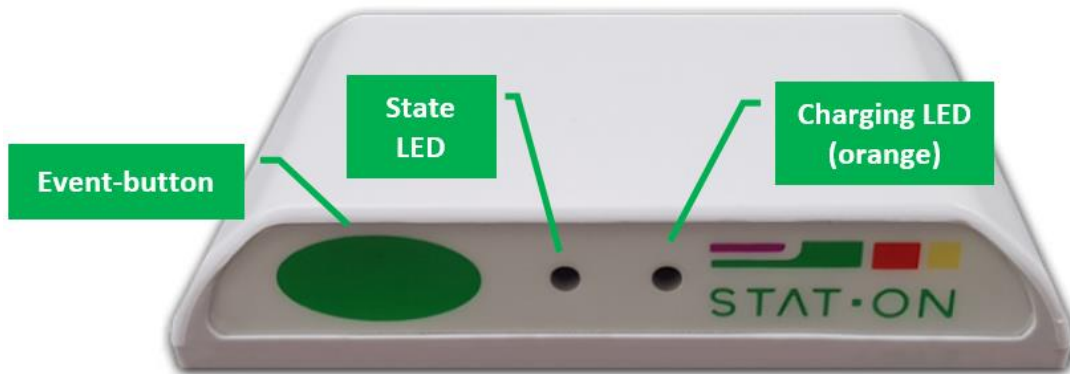

Figure 9.   Sensor's interface

5.2.1. Button

The device button must be pressed by the operator (health professional or caregiver) and not by the patient. It has two uses:
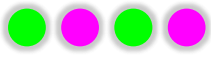
1- Turn on the sensor when it is in shutdown mode (See Section 5.3.2 for Shutdown mode).
2- Mark user events (user events are optionally specified by the medical professional, e.g. mark medication intake events, meals, sleep, etc.).
3- Stop an alarm after it triggers.

The device will vibrate shortly after the button is pressed.

5.2.2. State LED indicator

The colour pattern of the state LED specifies the current status of the sensor device. The following table describes the possible states of the sensor and its colour sequences.

Main state	Secondary state	Sequence	Description
SHUTDOWN	-	⚫⚫⚫⚫	Always off
CONFIGURATION_PENDING	-	⚪⚫⚪⚫	White blink
CONFIGURATION_PENDING	CONNECTED	⚪🔵⚪🔵	White-blue
CONFIGURATION_PENDING	LOW_BATTERY	⚪🟣⚪🟣	White-magenta
MONITORING	-	🟢⚫🟢⚫	Green blink
MONITORING	CONNECTED	🟢🔵🟢🔵	Green-blue

MONITORING	LOW_BATTERY	🟢🟣🟢🟣	Green-magenta
SLEEP	-	⚫⚫⚫⚫	Always off
SLEEP	CONNECTED	⚫🔵⚫🔵	Blue blink
SLEEP	LOW_BATTERY	⚫🟣⚫🟣	Magenta blink
MEMORY_FULL	-	🔴⚫🔴⚫	Red blink
MEMORY_FULL	CONNECTED	🔴🔵🔴🔵	Red-blue
MEMORY_FULL	LOW_BATTERY	🔴🟣🔴🟣	Red-magenta
SYNCHRONIZATION	-	🔵⚫🔵⚫	Fast blue blink
FORMAT	-	🔵🔵🔵🔵	Always blue
ERROR	-	🔴🔴🔴🔴	Always red

5.3.   Possible sensor states

5.3.1. Connected and low battery indication

The sensor will indicate that has an active Bluetooth connection or a low battery level by blinking the led in blue or magenta colour respectively. These indications will be combined with the sensor's current main state. For example, if the sensor is monitoring while having low battery, it will not only blink in green colour but alternate green and magenta colours.

5.3.2. Shutdown

The sensor will come in this state initially. While in this state, the sensor will do nothing until its button is pressed. To power it up, place the sensor on its charging pad and make sure the charging process starts (the orange led must switch on), then wait until the battery is fully charged (the orange led switches off). Then, press the sensor's button and it should enter *CONFIGURATION_PENDING* state.

In addition, the sensor will automatically enter this state if the battery level is too low, to power it up, **the button should be pressed after charging the sensor**.

5.3.3. Configuration pending

When the device is in this state, its status LED will blink in white colour. The device will not record data nor execute algorithms while in this state. In order to leave this state and start monitoring,

the user should configure the following parameters: Patient ID, Age, Leg Length and Hoehn & Yahr value. These should be configured through the STAT-ON App via Bluetooth. Read section *6.6* of this document for detailed information on how to configure the sensor.

Once the sensor is configured, it will alternate *SLEEP* and *MONITORING* states, which are the normal operation states.

5.3.4. Monitoring, sleep and standby

When the sensor is correctly configured and has detected some movement, it enters *MONITORING* state. In this state, the patient's movement is monitored and the algorithms are executed. In addition, its status LED will blink in green colour. This is the normal operation state and implies that the sensor is running correctly. However, if no movement is detected for some minutes or if the sensor is charging, the device may enter *SLEEP* state in order to save power. The device will resume monitoring after detecting any movement.

Given that the power save mode is enabled and disabled automatically; <u>the user does not need to power the device on or off</u>.

The *STANDBY* state is an optional state that can be enabled once the sensor is correctly configured. It can be enabled using the <Standby> button at the configuration area. This option forces the sensor to pause monitoring without losing its configuration (see section *6.6.7*). Once the sensor's button is pressed, the sensor will resume monitoring.

5.3.5. Full memory

If the internal memory of the device fills up, its status led will blink in red colour. Since there is no space in memory, the sensor will not record any new data. It is therefore recommended to synchronize the device data using the STAT-ON App. After the data is sent, the device memory will be automatically cleared and the sensor will be able to monitor again. Formatting (clearing the memory of the sensor) can be also done, but in this case, the stored data not yet synchronized will be completely lost.

5.3.6. Synchronization

The synchronization process consists of transferring the stored data from the sensor to the smartphone. This can only be done by using the STAT-ON App (see section *6.5- Synchronization Area*). While this process is ongoing, the status led will quickly blink in blue colour and the App will show a progress bar. After receiving all the data from the sensor, the app will generate the corresponding files and reports automatically.

5.3.7. Format

The format process completely clears the device memory. Formatting the sensor is only recommended if the device will not be used for a long time. Synchronizing the data contained in the sensor is recommended before starting the format process; otherwise, all the stored data not yet transferred to the smartphone will be lost. After formatting the device, its previous configuration will also be lost, thus the sensor needs to be configured again to re-enable it. The format sequence can be started by using the App, by pressing the <DELETE> button (see section *6.6.8- Delete button*).

5.3.8. Error

If the sensor detects an internal system malfunction, it will enter *ERROR* state. The status led will stay in red colour. Most processes and operations, like monitoring or executing algorithms,

are interrupted if an error happens. When the sensor connects with the STAT-ON App while in error state, it will transfer the error code to the App and the App will offer to perform a sensor reset. If the error persists after the reset or occurs periodically, please write down the error code displayed on the App and contact support@sense4care.com.
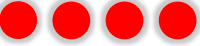
5.4. Charging the device

The following steps describe how to charge the STAT-ON sensor:

1- Place the charging Pad on the table making sure the white part is facing down. Plug the provided USB cable to the charging pad and plug the other end into a power outlet.
2- Place the STAT-ON sensor on the centre of the charging pad. The sensor's largest flat side marked with a ((•)) symbol should be touching the charging pad.
3- While the battery is charging, the sensor's orange LED indicator will illuminate. In addition, the led indicator on the charging pad will blink in yellow colour. The charging process can last up to 8 hours.
4- Once the battery is fully charged, the orange LED indicator from the sensor will switch off. The LED indicator from the charging pad will stay enabled and yellow, without blinking.

Figure 10.   Do's and Don'ts

Charging State	Sensor LED	Charging pad LED
CORRECTLY CHARGING	🟠 (always orange)	⚫🟠⚫🟠 (orange blink)
END OF CHARGE	⚫ (always off)	🟠🟠🟠🟠 (always orange)
POWER SUPPLY ERROR	⚫ (always off)	⚫🔴⚫🔴 (red blink)
GENERAL ERROR	⚫ (always off)	🔴🔴🔴🔴 (always red)

The previous table describes the possible states indicated by the sensor and the charging pad. The sensor does only charge when its LED is ON.

Additional charging considerations:

- <u>Do not place any object on the charging pad</u>, whether the device is being charged or not.
- It is possible to charge the sensor inside the specific belt. However, the sensor may need to be located more precisely at the centre of the charging pad. In addition, its internal temperature may get higher, thus interrupting the charging process.
- In case the *POWER SUPPLY ERROR* occurs, make sure that the AC to USB adapter used is the one provided by Sense4Care.
- In case the *GENERAL ERROR* occurs, check the battery level and, if it is still low, take the sensor from the charging pad and place it again. Make sure the sensor is placed on the centre of the charging pad.
- If any problem persists, contact Sense4Care for technical support.

5.5. Switching On/Off the system

After unpacking the system, the sensor device will stand in shutdown mode. Before using the sensor at first time, please fully charge the device battery and press the sensor's button to switch it on.

Once the button is pressed, the system will enter in the configuration mode, from which the user will be able to configure the sensor with the App. Then, the system will work autonomously. That means that the user will not have to switch it on or off.

The system will enter sleep mode if no movement has been detected for some minutes. It will automatically exit this mode and start monitoring after movement is detected. This work mode allows saving energy, thus extending the autonomy of the sensor.

If the user expects not to use the sensor in a long time, keeping it in shutdown mode is recommended. Shutdown mode is activated after formatting the device using the STAT-ON App (see section *5.3.7- Format*). It is recommended to synchronize all the data before formatting in order not to permanently lose all the data stored in the sensor. It is also important to charge the device battery before switching it off.

5.6.   Regular use

The STAT-ON system is a wearable inertial device that monitors the symptoms of PD patients. **This is a medical device and only health professionals must manage it.** Outcomes of the sensor might be used to adjust or evaluate a therapy, to adjust the diets of the patient, or evaluate the result of the therapy.

The system works autonomously, that is, the patient does not need to interact with the device. The health professional will provide the sensor to the user correctly configured (see sections 5.3.3 and 5.3.4) and previously charged (charge the sensor at least 5 hours during the previous 24hours of using the sensor). The user will wear the sensor for registering the symptoms of PD during the days of the study proposed by the health professional.

The healthcare staff can ask the caregiver to press the button at a certain time, such as lunch, dinner, medicine intake, etc.

The patient should wear use the system a minimum of 5 days and a minimum of 24 hours within these 5 days to generate enough inertial data to personalize the algorithms. It is recommended to use the sensor for 7 days. From this moment, a report can be generated at any time. The doctor will download to his/her mobile phone the information generated by the sensor at the doctor's office with the STAT-ON application, which will automatically generate a report of the motor state and symptoms during the days of study.

After this step, the sensor will enter in the initial state, being necessary to configure the app parameters in order to put on the sensor in other patient.

6. Application management

6.1. Device compatibility and downloading the app

The STAT-ON App can run on any Smartphone or tablet running Android 5 or higher, the device must support Bluetooth Low Energy (BLE) and 1GB RAM minimum.

The STAT-ON device also works in iOS for Apple devices. It is required to use iOS 10.2 or higher.

The app can be downloaded at *Google Play* (Android) or the *App Store* (iOS), search for "STAT-ON", and make sure its developer is Sense4Care. Press <install> and the app will be automatically downloaded and installed.

6.2. Managing multiple patients

As stated in the Section 2 (Intended Use), the STAT-ON device is suitable for evaluating the motor state of a patient with Parkinson's disease. The value of the "*Patient ID*" item, which can be set through the App's *Configuration Area*, is used to associate all the data related to each user. There is no limit of number of patients registered by the smartphone at the same time, it depends on the memory of the smartphone, however, we recommend to use no more than 6 patients.

The **Patient ID number must be changed each time a sensor is given to a different patient**, moreover, it is highly recommended to keep a record containing each patient's personal data together with its Patient ID value in order to **ensure that the same value is not shared by different patients**.

In order to simplify the situation where a single user (usually a healthcare worker) handles various sensors and multiple patients, **the results and reports are obtained solely from the data transferred during the current synchronization event**. Therefore, no historical record is kept inside the App's database (i.e. the data monitored is used for generating the reports and then discarded and not used anymore). **However, the App does store all the generated reports** (.pdf and .csv) inside the STAT-ON specific directory at the smartphone memory. Given the generated reports are tagged using the Patient ID number, it is still important to keep a value for each user and configure the sensor accordingly.

6.3.   Main screen
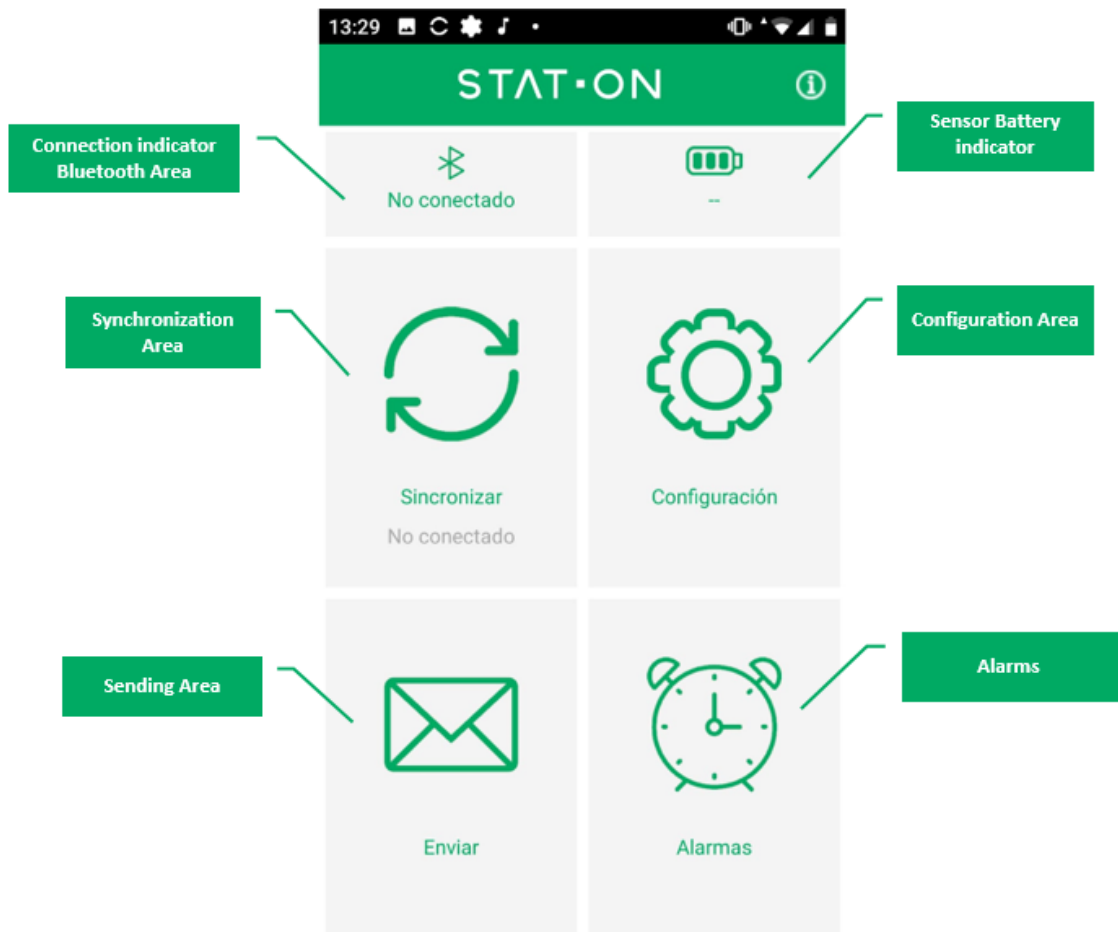
Figure 11.   Main screen caption

After opening the App, it shows the main screen, which enables the access to all the areas and features of the STAT-ON App. It also indicates whether there is an active connection with a sensor and shows its battery level. While on the main screen, the App connects automatically to the paired STAT-ON sensor. When a sensor device is connected, the Bluetooth area and battery indicators change their colour. "*Connected*" appears under the Bluetooth logo and the battery level is shown as well.

Figure 12.   Top of the main screen when connected

6.4. Bluetooth area

The Bluetooth area is used for managing the paired devices and choosing the sensor to connect to. The Bluetooth area is accessed by pressing on the Bluetooth logo on top of the main screen.

The switch on top of the screen is used for enabling and disabling the Bluetooth of the smartphone/tablet. Bluetooth has to be enabled for the app to connect with the sensor.

Below the Bluetooth switch, the currently connected sensor is displayed, if any. Only one STAT-ON sensor should be connected at the same time.

In order to search for the connectable sensors, the scan button should be pressed. Then all the available sensors will appear inside the area below. The device's Bluetooth name starts with *StatOn* and then contains the two last digits of its serial number (e.g. "*StatOn00*").

Press on the STAT-ON device you wish to pair to. A PIN/Passkey request may pop up. If the PIN request does not show up, check the smartphone notifications. Each device has a six-digit numerical PIN/Passkey, which is provided with the sensor packaging.

Before leaving the Bluetooth area, make sure that the correct device appears under the 'connected sensor'.

6.5. Synchronization area

The Synchronize Area can only be used when connected to a sensor. It contains only one button, which starts the synchronization process if the sensor contains any data.

When synchronizing, all the results from the sensor are transferred to the smartphone using Bluetooth. This screen also shows the last time a synchronization had been performed.
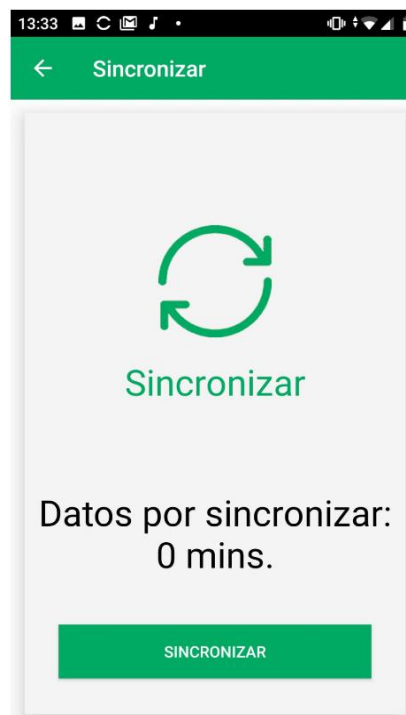
Figure 13.   Synchronization menu caption

The App will notify the user if the synchronization process fails. If the synchronization problems persist, contact Sense4Care for support.

6.6.   Configuration area

The values inside the configuration area are stored inside the sensor, thus an active Bluetooth connection is required for its use. Apart from the pin (which is optional), all the parameters from this area must be configured for the sensor to work correctly and exit the "configuration pending" state. Once the user configures all the parameters, the user has to push the <SAVE> button.

If the sensor has any results from previous stored monitorizations (i.e. is not synchronized), it will not be possible to change some parameters from this area. Synchronizing or deleting the pending results is required before the parameters can be changed.

The following sections explain each parameter in detail.
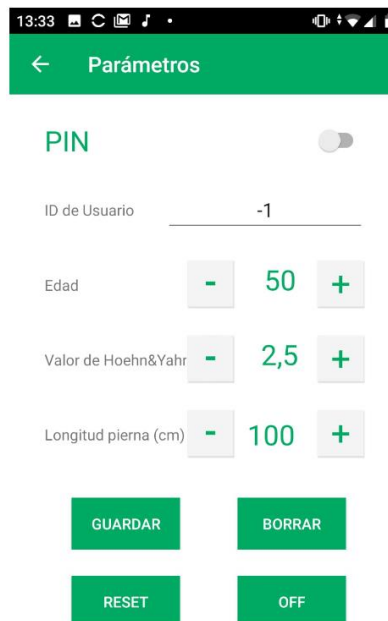
Figure 14.   Configuration menu caption

6.6.1. PIN configuration

This switch enables a 4-digit pin protection for the Configuration area. It is an optional feature, which shall only be used if the access to this area needs to be restricted.

6.6.2. Patient ID

This value identifies the user that wears the sensor. Any value different than -1 should be used. As explained in the section 6.2 (*Managing multiple patients*), the Patient ID is key for keeping the record of each patient correctly related. It can only be modified if it is not yet configured or if the sensor has no pending data to send (i.e. smartphone and sensor have synchronised).

This value must be modified each time the sensor changes from patient to patient, and should be assigned to a sole patient (should not be the same for different patients).

6.6.3. Age

The Age parameter should be configured before the monitoring starts for the algorithms to work properly.

6.6.4. Hoehn & Yahr value

The algorithms require the patient's stage in the Hoehn & Yahr scale in OFF state. The range of values accepted goes from one to five.

6.6.5. Leg Length

The leg length value (in cm) corresponds to the distance between the ground and the user's hip. By default it is 100cm.

Figure 15.   Leg length, from the ground to the end of the hip (end of the iliac crest)

6.6.6. Save button

After configuring the Patient ID, Age, Hoehn&Yahr and Leg Length parameters, the SAVE button should be pressed. Then the configuration is sent to the sensor. A pop-up will inform of the operation result, if it was successful, the sensor will exit the 'configuration pending' state.

6.6.7. Standby button

This button will only be available once the sensor is correctly configured. Pressing it makes the sensor pause the monitoring process without losing its configuration. The sensor will resume the monitoring process once the button is pressed.

6.6.8. Delete button

Pressing this button will clear all the data currently stored in the sensor whether it has been sent to the App by synchronizing or not. It is important to synchronize the sensor's data before the delete button is pressed in order to ensure that no data is lost. After formatting, the sensor will enter in shutdown mode. And the sensor's button should be pressed to re-enable it.

The previously generated reports and raw data files WILL NOT be deleted, thus, they can still be accessed using the smartphone's file explorer.

6.7. Alarms Area

In the alarms area, the user can configure up to ten alarms each day. The alarms will be stored and will trigger on the STAT-ON sensor, not on the smartphone. The usage of the system alarms is optional.
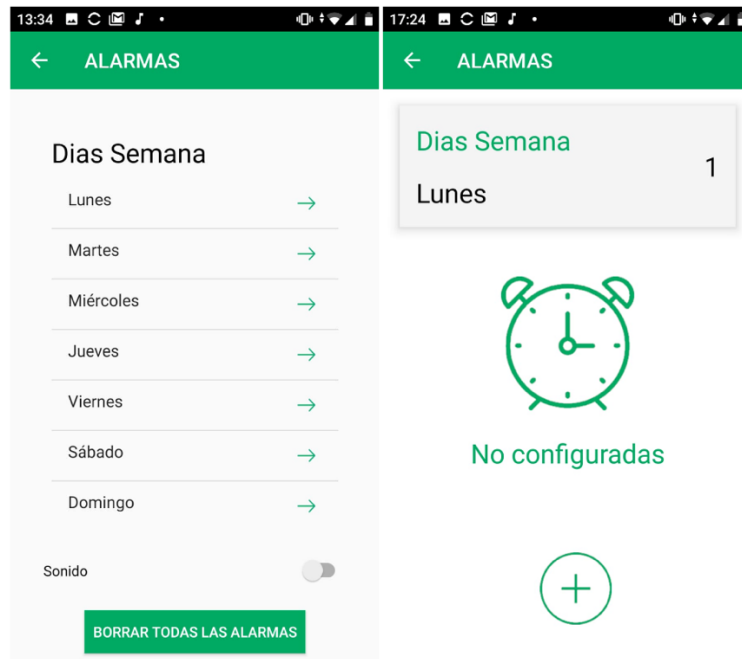
Figure 16.   Alarm screen captions

Programmed alarms can be seen on each day's screen by pressing the left and right arrows, the + symbol is used for creating a new alarm and the trash icon is for deleting the currently viewed alarm. When an alarm triggers, the sensor will vibrate until the sensor's button is pressed. If the "Sound" switch is enabled using the App, the sensor will Beep, too.

6.8. Send area

The send area can be accessed by pressing envelope button of the main screen.
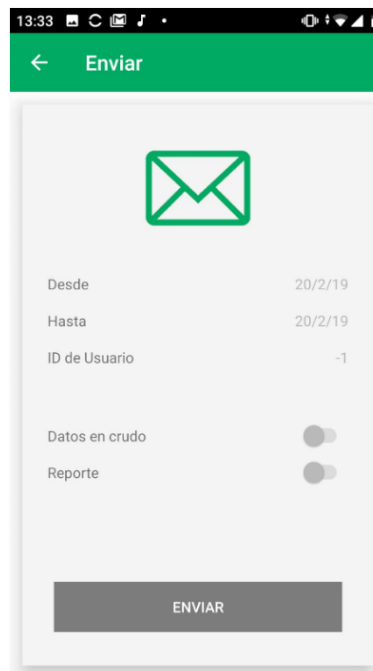
Figure 17.   Send screen caption

On the time period section, the current monitoring process start and end timestamps are displayed.

In addition, two switches can be selected in order to choose which files will be shared.

If "Raw data" is selected, a .csv file containing the algorithm results that were generated each minute of monitoring. If "Report" is selected, a .pdf summary containing several data and graphs will be generated. Both options can be selected at the same time as well. See section 7 for a detailed description of the results generated.

Once the period and the report type have been selected, the <SEND> button should be pressed. It acts like the common "Share buttons", so the user can choose any other communication App (like e-mail) for transferring the documents. A copy of the generated documents is also stored inside the storage of mobile device, under the <STAT-ON> folder.

At the bottom of the screen, the <SEND> button will open a standard 'share' dialog, any mailing or file share method can be used.

7. Reports description

This section describes the reports generated by the STAT-ON device in order to obtain a correct understanding of the variables provided by the sensor.

Through the mobile application two types of reports can be generated that aim to facilitate the task of understanding the data generated by STAT-ON by clinical professionals. The application offers the possibility of generating a summary report of the patient's condition and some graphics that condense the behaviour of the symptoms as well as some gait parameters. The purpose of this first report is of ordinary use for conventional clinical practice. The second report is more extensive, and it includes a large part of the parameters extracted from the algorithms as well as the information contained in the first report. The main purpose of this second mode of reports is its use in the field of research.

The data is presented as a graph with fixed temporal resolution, 30 minutes for data per day, 24 hours for weekly data. In the case of the variables that are presented per day, the average of those higher values of each half hour is computed, obtaining a value every 30 minutes, only those periods greater than 0 being marked on the graph. The values that are presented in format 24h temporary are:

- o Cadence
- o Number of steps
- o Step length
- o SMA (quantity of movement)
- o Stride fluidity
- o Dyskinesia
- o ON state
- o OFF state
- o INT state
- o Number of Freezing of Gait(FoG) episodes
- o Duration of FoG Episodes
- o Falls
- o Events

The weekly-based graphs are processed by means of the average of those values higher than zero per day. Finally, some variables are useful as totalizers during the monitored period. These totalizers can be represented by three methods. The first one is presented by the absolute average (and its standard deviation), for example, hours in OFF state or in ON state or the average length of the stride. Those variables that represent events (e.g. Falls or FoG) are summed with direct summation. Finally, these totalizers can be represented in relative format, this is provided as the percentage of the monitored valid time that presents some symptom.

7.1.   STAT-ON measurements

In PD, various symptoms associated with patient's motor states can be differentiated. One of the most usual clinical practices is visually analysing how patients walk in order to evaluate bradykinesia. In the activity of walking, several symptoms converge with different origins within the neurophysiology of PD. In gait, two movements of different nature are coordinated, on the one hand, automatic movements classically associated with a symptomatology related to

hypokinesia and, on the other hand, voluntary movements that are associated with bradykinesia. It should not be forgotten that the pathophysiology of bradykinesia is the cardinal symptom per excellence of PD and, furthermore, this symptom has a greater degree of correlation with the level of dopamine deficiency and, therefore, with the fluctuations between motor states in PD. Peak-dose dyskinesia is a side effect of the medication that provides a clear indication of the patient's motor status, being associated with ON state.

FoG is another symptom that is of special interest because it is one of the most disabling symptoms of PD. FoG has different characteristics from other parkinsonian symptoms, for example, it has not been possible to clearly correlate the frequency of FoG episodes with other motor symptoms of PD, such as stiffness and bradykinesia. Although in many cases it is not a particularly useful symptom to assess the patient's motor status, it is useful to evaluate the evolution of this symptom and the mobility difficulties of the patient.

The detection method of ON / OFF states in patients with PD depends on the characterization of the motor symptoms that the patient presents in each of the states. In this sense, two specific detectors are used, which analyze the presence of dyskinesia and the bradykinetic gait. The outputs of the detectors are merged into a global classifier that provides the estimation of the motor state.

The bradykinesia detector is based on the analysis of patients' gait and has been validated in several studies that can be found in [1]–[4]. Given that this detector is self-adaptive, it must have a minimum data period of three days.
The detector of choreic dyskinesia is based on the detection of the frequencies of dyskinesia maintained during prolonged periods of time. The outputs of these algorithms are combined through a decision tree, which performs the detection of the motor states. The detail of these algorithms can be found in [5].

The presented architecture has implications for the interpretation of the data presented in the graph. The most relevant is that the sensor emits an OFF verdict when the patient walks. In other words, in those patients who have very deep OFF states in which they cannot move, STAT-ON will not be able to issue a verdict. On the other hand, ON states are associated with the prolonged physical dyskinesias in time, in addition to the bradykinesia level. As aforementioned, since the bradykinesia algorithm is self-adaptive, another implication is that **the system will only show this information if a minimum of 3 days of data has been captured.**

The FoG detector is based on the analysis of windows of 1.6 seconds and, therefore, this is the minimum temporal resolution. This means that, although episodes of freezing lasting less than 1.6 seconds are detected, all of them will be reported as 1.6 seconds long. Another example can be that two episodes of 1.8 seconds and 3.1 seconds will be reported as episodes of 3.2 seconds. This means that when STAT-ON reports a FoG episode of 1.6 seconds it will last from 0 to 1.6 seconds, whereas when a 3.2 seconds episode is reported it will result in a duration between 1.6 seconds to 3.2 seconds. For more details on this detector go to [6].
It must be noted that the total number of reported falls might be confused since the system also analyses the movements when the patient removes the sensor belt or puts it on. These moments involve movements that could be similar to a fall and the system could generate a false positive. The detection of activities, and more specifically the length and speed of the step, are algorithms specifically developed and adjusted with data from patients of PD. You can find the details of

this group in [7]. Below, a detailed description of each of the graphs and data generated by the STAT-ON system is presented.

7.2. Extended report

This report presents two separate parts, on the one hand, the "*summary page*", where a table is presented as a summary and, on the other hand, a series of graphs that are described in the following sections.

7.2.1. Summary page

The summary page of the report presents a series of numerical data as a summary of the physical activity of the patient and the prevalence of symptoms that the patient has presented during the monitored period.

User ID:	171113-S01
Age:	68
Hoehn & Yahr:	OFF: 3, ON: 2
Study start date:	3/28/2018
Study ending date:	4/1/2018
Total days monitored	5

Total FoG Episodes	87
Average FoG Episodes per day	18±4
Average minutes walking per day	58±19
Average number of steps per day	3094±560
Number of falls	4
Time in OFF (% regarding total time monitored)	7.2 hours (34.5 %)
Time in Intermediate (% regarding total time monitored)	9.6 hours (43.6 %)
Time in ON (% regarding total time monitored)	8.4 hours (38.2%)
Time with dyskinesias (% regarding total time monitored)	1.6 hours (7.3 %)
Total time monitored	22 hours

Figure 18.   Summary page example

In the first table you can find the minimum necessary data of the patient and the monitored period:

- User ID: Numeric identifier of the patient, this is a number configurable from the app that serves to anonymize the patient's data and that only clinical professionals have access to the relationship between the captured data and the identity of the patient.
- Age: Age of the patient.
- Hoehn & Yarh: PD stage evaluation, provided are the values in OFF and ON state.
- e-mail: e-mail to where the report will be sent.
- Study start date: Day and Hour of the start of the monitored phase.
- Study ending date: Day and Hour of the end of the monitored phase.
- Total days monitored: Total number of days in which the patient has been monitored.

In the second table a summary of the symptoms and physical activity during the monitored period is shown:

- Total FoG Episodes: Total number of FoG episodes that have been measured during the monitored period. It is a totalizer which has a strong dependence on the length of time monitored.
- Average FoG Episodes per day: It is a comparable relative measure between patients or separate monitoring periods. Standard deviation is also provided, which gives evidences as to whether the patient has FoG episodes consistently every day or whether there are days that show more than others.
- Average minutes walking per day: It is a good indicator of physical activity presented by the patient.
- Average number of steps per day: In patients without gait disorders, it provides very similar information to walking minutes, but in the case of presenting gait disorders this parameter is significant to assess the disease.
- Number of falls: Number of falls that the patient has presented during the monitoring period. Given the aforementioned factors, it must be noted that this monitoring system does not present a feedback system with the user, so the system can confuse actions such as removing or putting the sensor on the waist as a fall generating false positives.
- Time in OFF (% regarding total time monitored): Percentage of time monitored in which the patient presents OFF state.*
- Time in Intermediate (% regarding total time monitored): Percentage of time monitored in which the patient presents INTERMEDIATE state.*
- Time in ON (% regarding total time monitored): Percentage of time monitored in which the patient presents ON state.*
- Time with dyskinesia (% regarding total time monitored): Percentage of time monitored in which the patient has evidenced dyskinesia episodes.*
- Total time monitored: Total monitored time in hours.

*For an extended explanation of the measurement, see the explanation of the corresponding graph.

7.2.2. Graphs

7.2.2.1.   Weekly Motor State

One of the most relevant graphs in which it shows the motor state of the patient in periods of maximum 7 days. This means that a graph is generated for every 7 days (or less) of monitoring. Below, it is shown an example of the motor state.
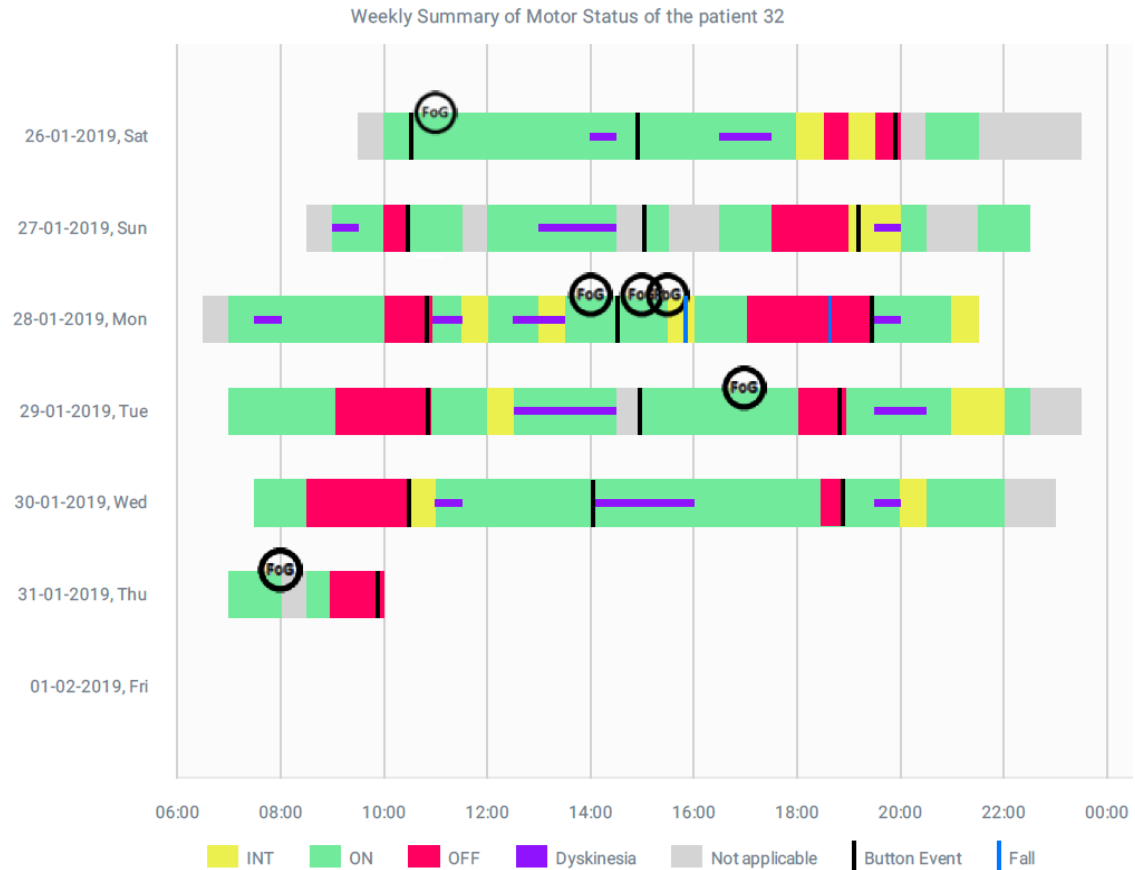
Figure 19.   Weekly motor state. Button event was pressed at medication intake

The daily time is included on the horizontal axis, while the monitored days are indicated on the vertical axis. The colours in the graph represent the different states of the patient regarding the colour in which they are represented:

- Green: The patient is in ON state.
- Red: The patient is in OFF state.
- Yellow: The patient is in an intermediate state.
- Magenta: It has been detected choreic dyskinesias.
- Grey: No state has been detected (no dyskinesias, no walking detection).

7.2.2.2. Weekly Time in OFF state

This graph shows the daily-accumulated time in OFF state that has been detected. On the horizontal axis, it is shown the days monitored (maximum one week) and on the vertical axis the percentage of monitored time that the patient has been in OFF state. Although the bars are based on the percentage of monitored time that has been detected as OFF state, information is added about the number of hours the patient has been in this state. This graph must be carefully analysed, although it can be very useful, it can present aberrant data due to very short periods of monitoring or very long periods of inactivity. Whenever this graph is analysed, three factors must be taken into account: the total monitoring time, the sum of hours in OFF state and the total time with any motor state verdict. It is highly recommended to analyse this graph jointly with the weekly motor state.

Figure 20. Time in OFF state
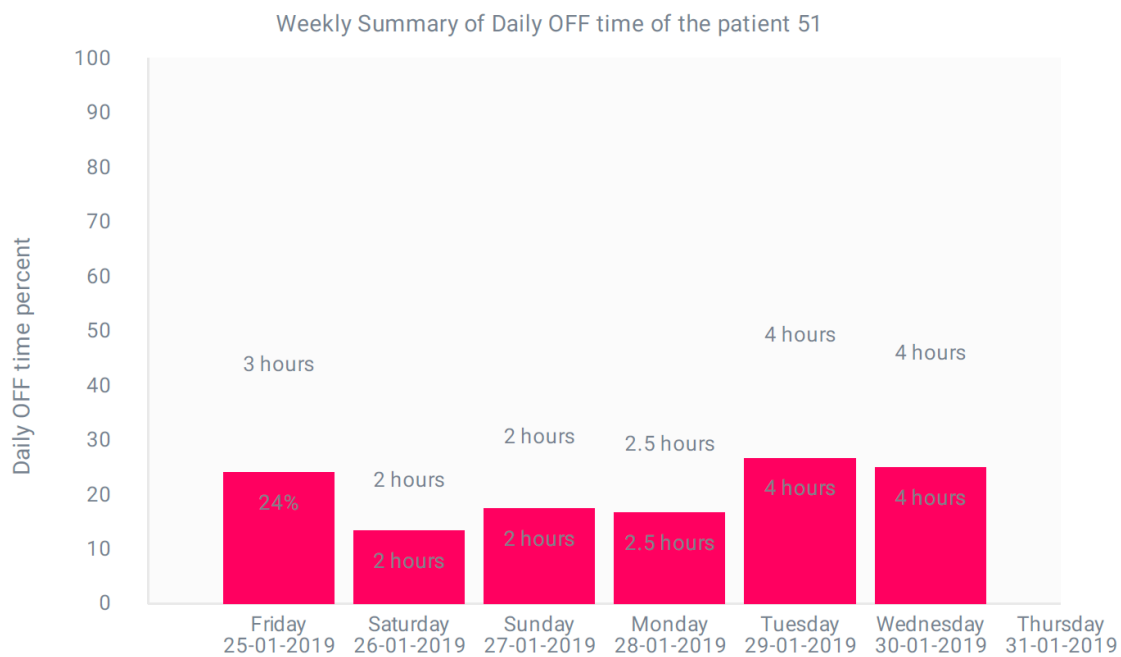
7.2.2.3. Weekly FoG episodes

On the vertical axis, it can be observed the days monitored (maximum one week) and on the horizontal axis the number of episodes detected per day. In this graph, it is shown the number of episodes detected per day, the average length of these episodes (as explained above in a resolution of 1.6 seconds) and the maximum duration of an episode of FoG per day.
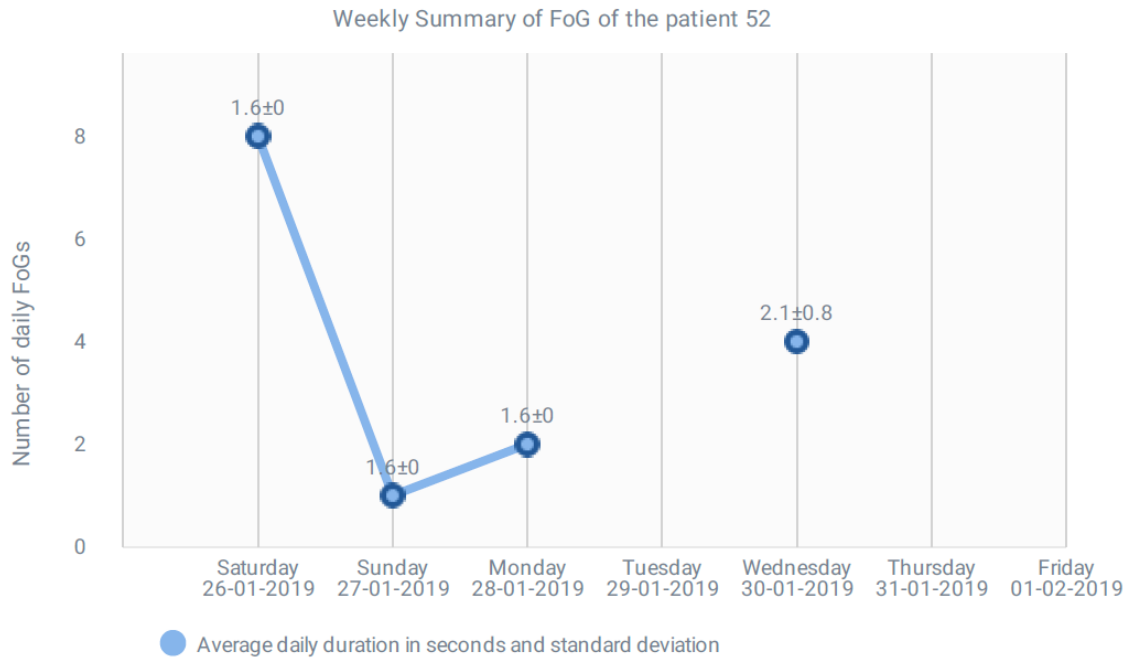
Weekly Summary of FoG of the patient 52

Figure 21.   Number of FoG episodes

7.2.2.4.   Weekly stride fluidity

The following graph presents the weekly evolution of the average stride fluidity that the patient presents during the monitoring period. The stride fluidity is a measure of acceleration that is obtained as an intermediate result of the bradykinesia detector, which has a value (ranging from 2 to 25) and which is related to the fluidity of the movement that the patient presents when walking. This way, we can evaluate the evolution of the difficulty that the patient has when walking as an average per day, the greater the value the greater the fluidity. This value is correlated with the so-called Factor 1 of UPDRS III (see Analysis of Correlation between an Accelerometer-Based Algorithm for Detecting Parkinsonian Gait and UPDRS Subscales) On the horizontal axis you can see the days monitored (maximum one week) and on the vertical axis the measure of fluidity. Below an example is shown:
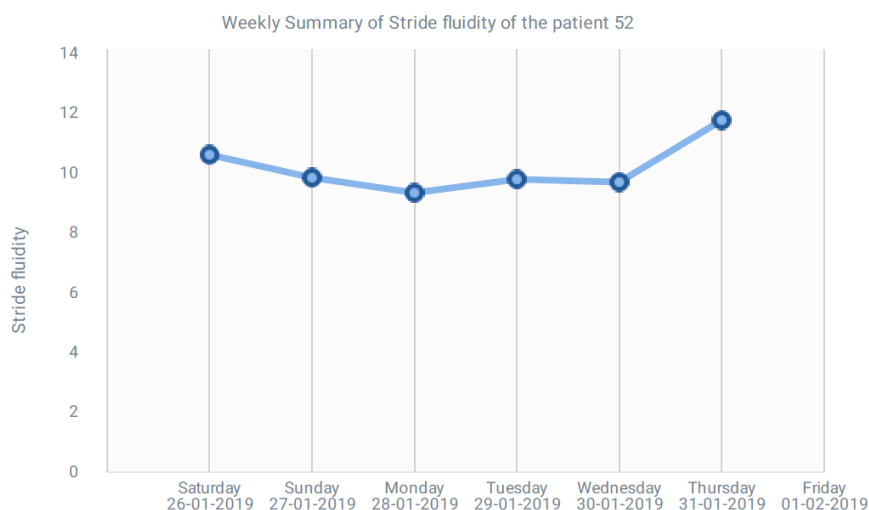
Figure 22.   Weekly stride fluidity

7.2.2.5. Weekly physical activity

Among the sensor output parameters, there are also data about the physical activity that the patient has performed during the entire monitoring period. The variables shown are:

- Step length
- Stride speed
- Cadence
- Energy expenditure
- Number of steps

In each of the graphs, on the horizontal axis, all the monitored days are shown, and on the vertical axis, the average per day of the units corresponding to each one of the measurements. Here are some examples:

Figure 23.   Weekly average cadence

Figure 24.   Weekly average Stride speed

7.2.2.6. Daily motor symptoms

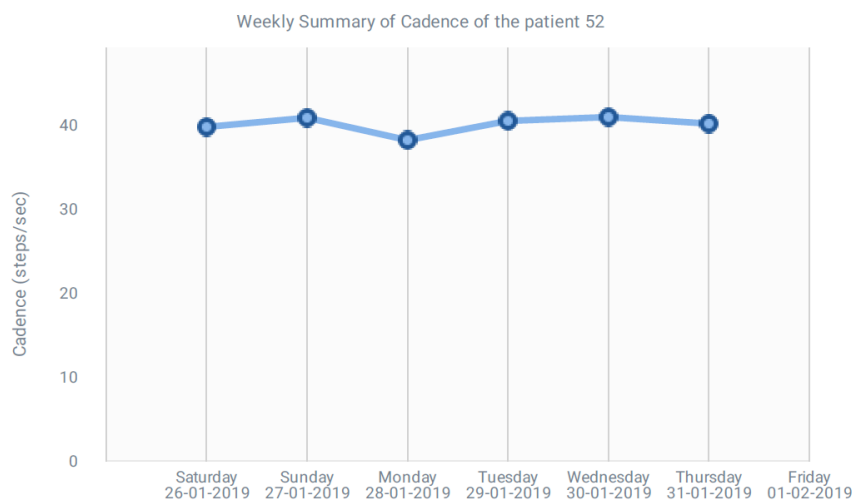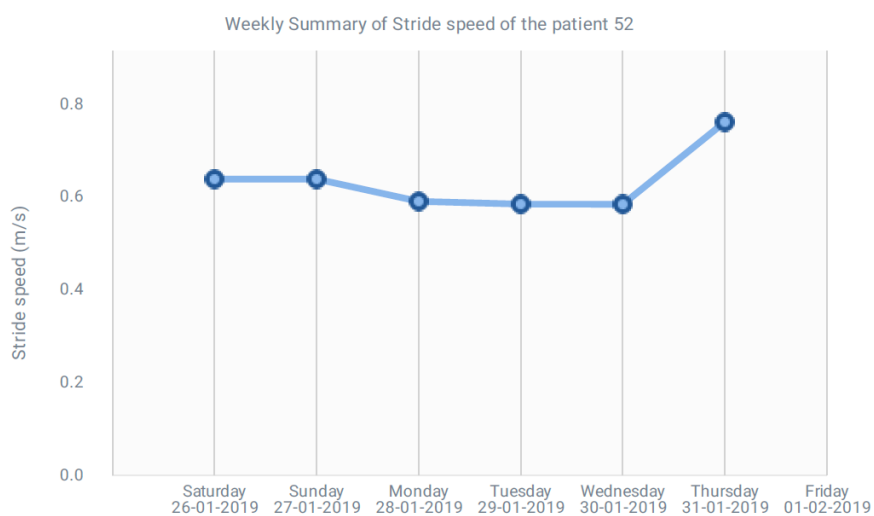STAT-ON, in the extended report, generates a graph of motor symptoms per monitored day where it can be seen, in addition to the motor status, the dyskinesia and the number of FoG episodes that the patient has suffered as well as the hours of appearance. The resolution in all the daily charts corresponds to half an hour. In the following figure, an example of this graph is shown.
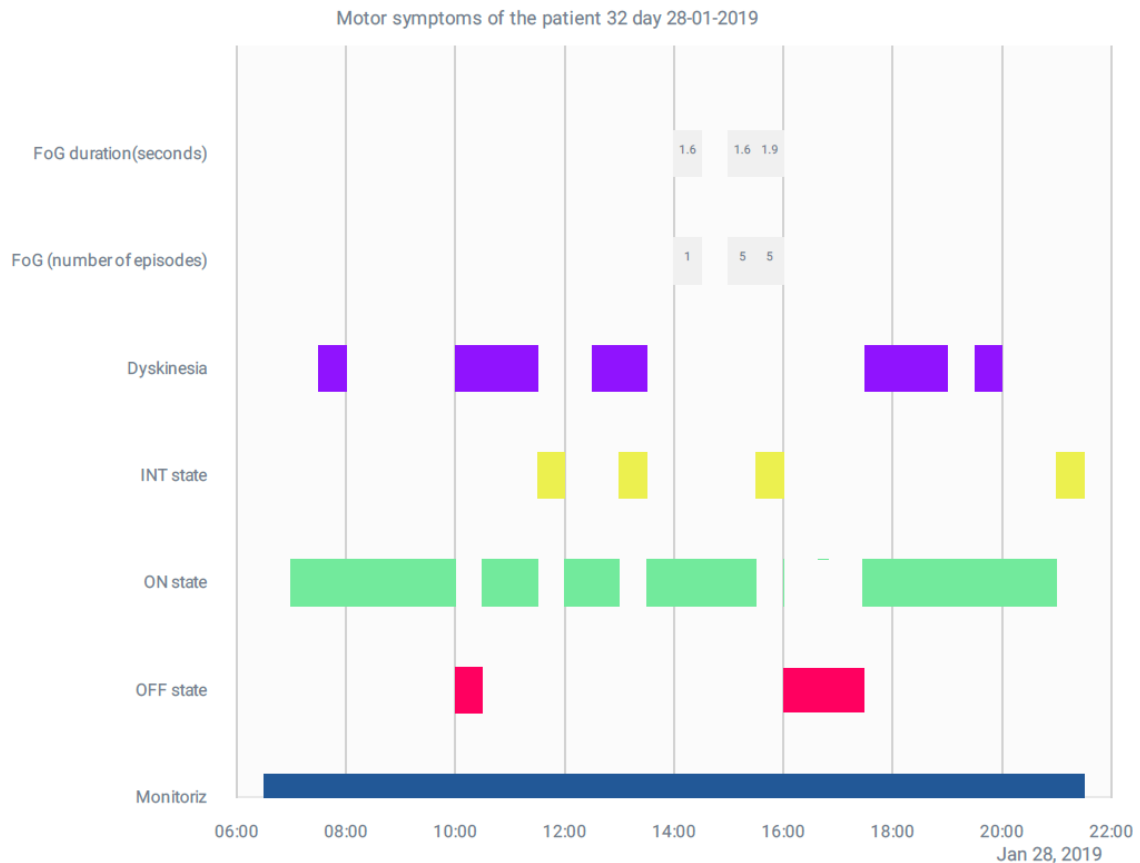
Figure 25. Daily motor states and FoG episodes

On the horizontal axis it is shown the hours of the day and on the vertical axis a series of labels that describe the corresponding row:

- Time Monitored: Time in which the sensor is running.
- ON/OFF/INT state: representation of the motor state detected in the patient. Red corresponds to OFF state, Green to ON state and yellow to Intermediate state.
- Dyskinesia: periods in which choreic dyskinesias have been detected in the patient.
- FoG Episodes: In this row, the number of FoG episodes are represented. In case that a FoG episode is detected, a box with the number of episodes is drawn.

7.2.2.7. Daily stride fluidity

The system generates a graph of stride fluidity when the patient is walking where the daily evolution of the stride fluidity of the patient's gait can be assessed. In addition, in the

background of the graph, the detected motor state is also drawn (red OFF, green ON, yellow INT). Finally, note that the thresholds calculated (as self-adaptive algorithm with regression model), upper (green) or lower (red), are also drawn. These thresholds indicate when bradykinesia is considered and, given that patients do not walk in the same way, they are patient-dependent. On the horizontal axis it can be observed the hours of the day and on the vertical axis the units corresponding to the stride fluidity (m/s^2).
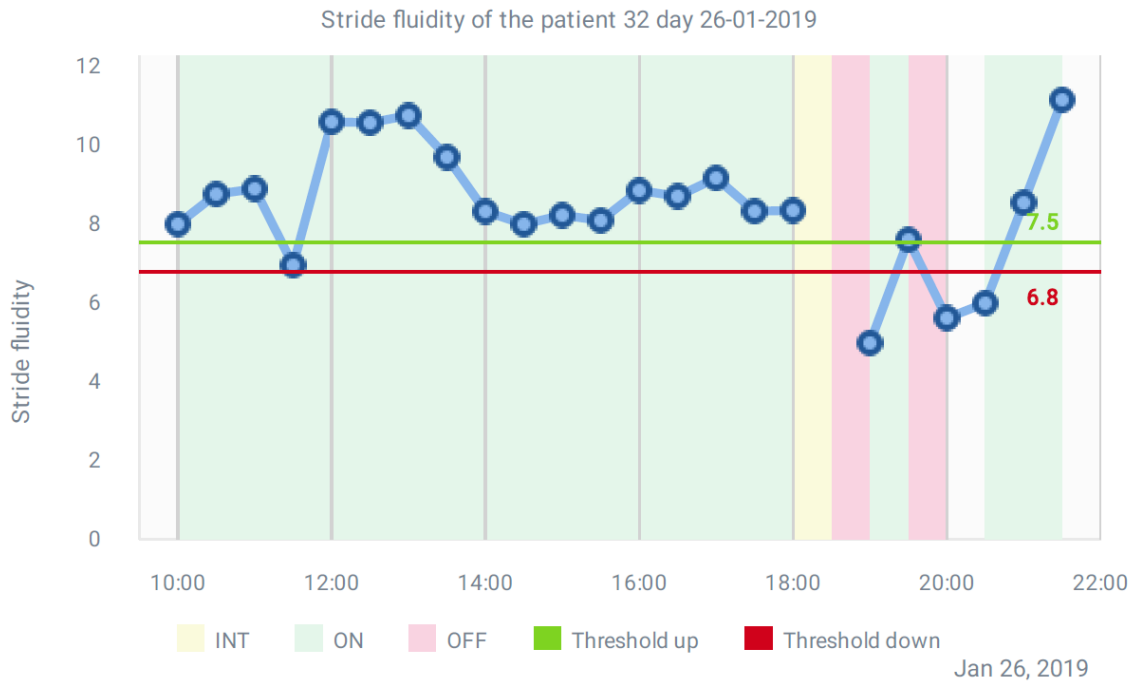
Figure 26.   Daily stride fluidity and motor states

7.2.2.8.   Daily physical activity

This group of indicators provide information about physical activity that the patient has performed along the day and the days that he/she has been monitored. These variables are:

- Step length
- Cadence
- Energy expenditure
- Number of steps

In each of the graphs, the hours of the day are shown on the horizontal axis, and the units corresponding to each of the measurements are shown on the vertical axis. In addition, the detected motor state is added in the background of the graph (red is for OFF state, green is for ON state, and yellow for INT state). Here are some examples:

Energy expenditure of the patient 51 day 25-01-2019

Figure 27.   Daily energy expenditure and motor states

Number of steps of the patient 51 day 25-01-2019

Figure 28.   Daily number of steps

7.3. Reduced report

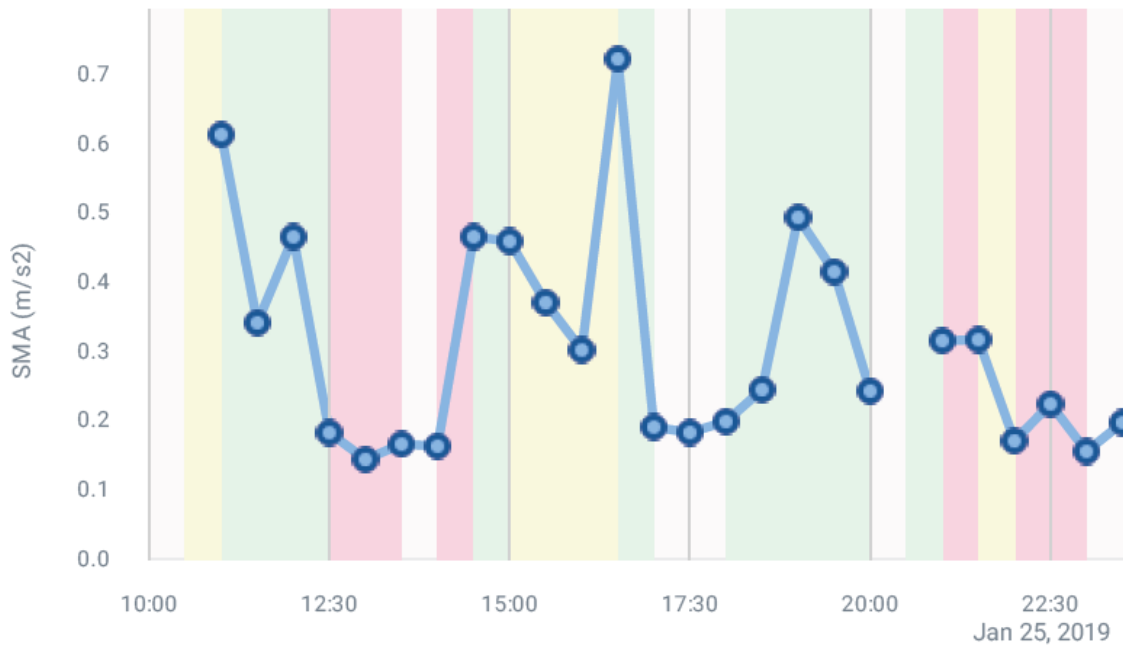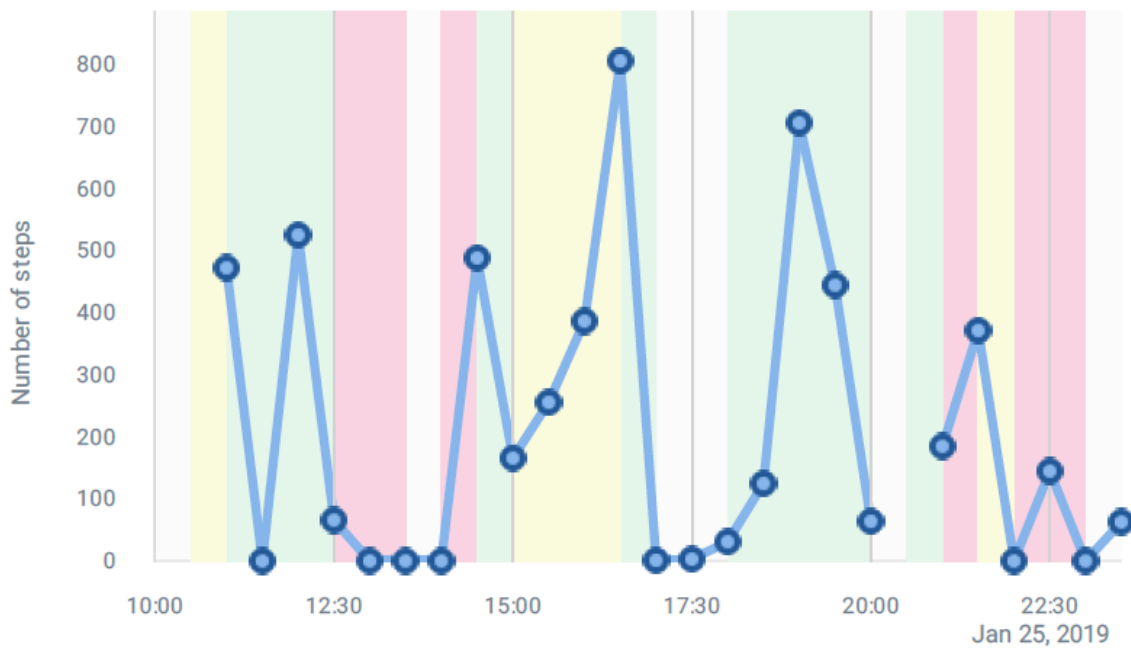This report is a selection of the extended report that includes all those graphs that are of special interest in order to help the clinical professionals to have a more complete and objective view of the state of their patient:

- Summary page (7.2.1)
- Weekly motor state (7.2.2.1)
- Weekly time in OFF state (7.2.2.2)
- Weekly FoG episodes (7.2.2.3)

REFERENCES

[1] C. Pérez-López *et al.*, "Assessing Motor Fluctuations in Parkinson's Disease Patients Based on a Single Inertial Sensor," *Sensors*, vol. 16, no. 12, p. 2132, Dec. 2016.

[2] A. Rodríguez-Molinero *et al.*, "Analysis of correlation between an accelerometer-Based algorithm for Detecting Parkinsonian gait and UPDRS subscales," *Front. Neurol.*, vol. 8, no. SEP, pp. 3–8, 2017.

[3] A. Rodríguez-Molinero *et al.*, "A Kinematic Sensor and Algorithm to Detect Motor Fluctuations in Parkinson Disease: Validation Study Under Real Conditions of Use," *JMIR Rehabil. Assist. Technol.*, vol. 5, no. 1, p. e8, Apr. 2018.

[4] À. Bayés *et al.*, "A 'HOLTER' for Parkinson's disease: Validation of the ability to detect on-off states using the REMPARK system," *Gait Posture*, vol. 59, no. September 2017, pp. 1–6, 2018.

[5] C. Pérez-López *et al.*, "Dopaminergic-induced dyskinesia assessment based on a single belt-worn accelerometer," *Artif. Intell. Med.*, vol. 67, pp. 47–56, Feb. 2016.

[6] D. Rodríguez-Martín *et al.*, "Home detection of freezing of gait using support vector machines through a single waist-worn triaxial accelerometer," *PLoS One*, vol. 12, no. 2, 2017.

[7] T. Sayeed, A. Samà, A. Català, A. Rodríguez-Molinero, and J. Cabestany, "Adapted step length estimators for patients with Parkinson's disease using a lateral belt worn accelerometer.," *Technol. Health Care*, vol. 23, no. 2, pp. 179–94, 2015.

8. Frequently asked questions (FAQs)

Q: I have pressed the button but the sensor does not turn on (its LED does not blink):
Place the sensor on a charging pad, the orange led may light up. After a few minutes, press the sensor's button.

Q: When do I have to press the button?
The button is only pressed when the sensor is in shutdown Mode or standby mode. This is not a ON/OFF button. To switch the sensor OFF, do it with the App.

Q: How do I stop the sensor?
In order to save power, the sensor enters *sleep mode* automatically when no movement is detected for some minutes and wakes up automatically as well, thus, there is no need to turn the sensor ON/OFF. However, if the sensor will not be used for a long period of time it can be shut down by clearing its memory (see the *Format* section 5.3.7).

Q: Which is the minimum time that the user should wear the sensor?
The sensor needs a minimum of 24 hours of data, which should be captured within three different days (i.e. 8h/day * 5 days approx.). However, it is recommended to wear the sensor, at least, for a week. The user must use it during the activities of daily living.

Contact support@sense4care.com for any other issues.

9. Device Labelling
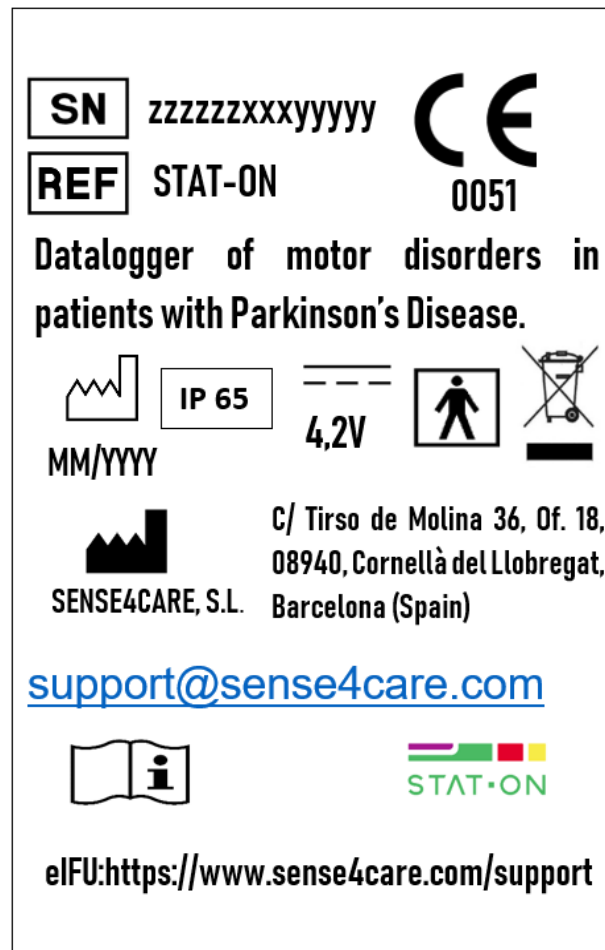
x: stands for the lot number

y: stands for the number of device within the lot

z: stands for month and year of fabrication (MMYYYY)

10. Symbols and labels

Manufacturer

Date of manufacture

SN   Serial Number

REF   Reference number

Input power

Shock protected, type BF.

Consult instructions for use

Do not dispose (excluding belt)

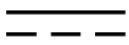93/42/EEC Directive compliance – IMQ Notified Body

0051

11. Privacy

In compliance with the General Data Protection Regulations (GDPR), SENSE4CARE, S.L guarantees that collected data is uniquely stored within the device and that only the user is responsible of the use of these data. In its present form, STAT-ON is not capable to share the collected data to a third party without the user consent.

Sense4Care S.L. will only access to data under the expressly consent of the user and the owner of the STAT-ON device. Shared data to Sense4Care S.L. will be always pseudonymised, in any case. Pseudonymised data that the user provides us will be incorporated into a file of our responsibility and will be kept under the strictest measures of security and confidentiality.

You can exercise the rights of access, rectification, deletion, opposition and portability by contacting C / Tirso de Molina 36, Of.18; 08940 - Cornellà de Llobregat, Barcelona; or to the following email: info@sense4care.com.

12. Technical specifications

Communications	
Bluetooth specification	Bluetooth 4.0 (Bluetooth Low Energy)
Bluetooth bandwidth	2,4 GHz
Wireless charging standard	WPC v1.1 Qi Industry Standard
Wireless charging bandwidth	100-205 kHz
Electrical features	
Power Supply (charger)	100-240 Vac, 0.3-0.6 A, 50-60 Hz
Battery: Type	Lithium-Polymer
Battery: Capacity	1100 mAh
Battery: Charging time	<6 h
Battery: Maximum charging current	500 mA
Battery: Maximum discharge current (peak)	135 mA
Average consumption (normal use)	2.5 mA
Physical features	
Height	62,5 mm
Width	90 mm
Depth	21,20 mm
Weight	86 g
Enclosure material	ABS-FR(17) UL94, UV Protection White - Matte
Environment specifications	
Temperature operation range	From 0°C to 40°C
Temperature in charging conditions	From 0°C to 40°C
Storing conditions	The system must be stored at a temperature close to 20ºC and with batteries charged about 30% to 50% of capacity. We recommend relative humidity storage from 45 to 85%. We recommend that batteries be charged about every half year to prevent over discharge. Directly heat cell body is strictly prohibited. Battery may be damaged by heat above 100ºC.
Atmospheric pressure conditions	700hPa to 1060hPa
Certification	
Protection against and dust and water	IP65
Battery in medical use	IEC62133
Design, fabrication and commercialization of industrial electronic controls.	ISO 9001:2015
Medical Quality Management System and Medical Devices sales, development, manufacturing, delivery and maintenance including related services	ISO 13485:2016
Medical Device certification	CE Marked number: 0051

13. Certification

#	Standard	Harmonized	Application
1	EN 1041:2008 Information supplied by the manufacturer of medical devices	YES	Used to establish the information needed for product use and general aspects of the presentation of information
2	EN 15223-1:2016 Symbols for use in the labelling of medical devices	YES	Used to set the appearance of graphical symbols included in the labelling of our product.
3	EN ISO 60601-1:2006/A1:2013 Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.	YES	Used for establishing the basic safety and essential performance. Date of cessation of conformity for previous ed. 31.12.2017
4	EN ISO 60601-1-2:2015 Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests.	YES	Used for establishing the safety and functionality EMC requirements
5	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	YES	Used for establishing usability requirements for medical electrical equipment
6	EN 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	NO	Se utiliza para establecer los requisitos y las pruebas para el dispositivo como equipo eléctrico médico y sistemas médicos eléctricos utilizados en el entorno de atención médica domiciliaria.
7	EN 62304:2006+/AC:2008 Medical device software. Software life cycle processes.	YES	Used for establishing the life-cycle of software
8	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices	YES	Used for establishing the risk management process for the product
9	EN 80002-1:2009 Medical devices software. Guidance on application of ISO 14971 to medical device software	NO	Used for establishing the risk management process for the software
10	EN ISO 62366:2008 Medical devices. Application of usability engineering to medical devices	YES	Used to minimize use-errors
11	MEDDEV 2.7.1 (2016) Clinical Evaluation Clinical Evaluation – A guide for manufacturers and notified bodies	NO	Guidance for device Clinical Evaluation
12	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects. General requirements	YES	Applies only chapter 4 and recommendations for the review of data and medical and scientific information published / available as Annex A.
13	EN 62353:2014 Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment.	NO	Used for establishing the test after repair and preventive maintenance plans
14	RED 2014/53/EU The Radio Equipment Directive	YES	Used for establishing the radio Equipment requirements

15	ETSI EN 300 328 V2.1.1 Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	YES	Wide Band Data Transmission equipment standard.
16	ETSI EN 301 489-1 V2.2.0 Article 3.1b Directive 2014/53/EU - RED	NO	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements;
17	ETSI EN 301 489-3 V2.1.1 Article 3.1b Directive 2014/53/EU - RED	NO	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD)
18	ETSI EN 301 489-17 V3.2.0 Article 3.1b Directive 2014/53/EU - RED	NO	ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems;
19	ETSI EN 303 417 V1.1.1 Wireless power transmission systems Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU	NO	Wireless power transmission systems, using technologies other than radio frequency beam, in the 19 - 21 kHz, 59 - 61 kHz, 79 - 90 kHz, 100 - 300 kHz, 6 765 - 6 795 kHz ranges;
20	EN 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	NO	It is used to establish the requirements and tests for the device such as medical electrical equipment and electrical medical systems used in home environments.