5

STAT-ON™: The User Interface and Generated Report

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Abstract

STAT-ON™ is a medical device capable of detecting and measuring the most relevant motor symptoms of Parkinson's disease. This device must be easy to use, both by the patient who must wear it during his normal activity, during the period prescribed by their neurologists, and also by themselves who, based on their interpretation of the measurements provided, will be able to know much better the state and evolution of the disease, in the treated patient.

In order to facilitate the use, an accurate conception and design of the appropriate user interface were done. This interface is based on a physical part (which allows direct interaction with the sensor), and a software part (in the form of an app that must be installed on a smartphone) that allows a series of interactions to get, at the end of the monitoring process, a report on the patient's condition. This chapter describes the details of the STAT-ON™ user interface.

5.1 Introduction

The complete STAT-ON™ system comprises a monitoring device, its base charger, a belt, and a mobile application. The system provides numerical and

graphical information on the motor symptoms associated with Parkinson's disease. Furthermore, data related to the general motor activity of the patient are calculated.

The device continuously collects the inertial signals associated to the patient's movement, processes them in real-time using artificial intelligence algorithms, 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. Therefore, the patient should wear the sensor in their daily activities to provide relevant information to health professionals.

The available smartphone application (the app) connects to the STAT-ON™ device via bluetooth (BLE). The app is used both for configuring the system and downloading the data previously generated by the sensor. In addition, the mobile application can send the data enclosed in a report by e-mail or digital support to any user, caregiver, therapist, or neurologist.

In previous chapters, it is possible to get all the details concerning the internal electronic and processing structure of the device, how it operates, and how the required regulatory process has been followed to obtain the CE marking as a medical device Class IIa. Along this process, it has been already introduced the necessity for a specific software (the app) that will be the necessary interface with the user. Through this software, it is possible to configure the STAT-ON™ correctly and, later, when required by the user to get the results stored in the device's internal memory, which will be processed under the format of a useful and understandable report.

The following sections present the requirements of the implemented software, the details about the functionality and related interface for an easy user experience, details about the generated report, and some hints on how to correctly interpret the contained information.

5.2 Requirements, Interface Description, and Different Modes of the Device

STAT-ON™ is a device designed to be very useful and easy to use. The patients must wear the device, and some interaction could be required from them by the neurologist (be aware of the correct position, to check the battery life of the sensor, to indicate the moment of the medication intake by pushing the device's button, etc.). From their side, the neurologists and healthcare professionals are the main users of STAT-ON™ and should enter the configuration according to the patient to be monitored, and at the end of the testing period, they should obtain the detected and registered information in relation

Table 5.1 Description of the main user requirements.

User requirement	Description
1	The interface must be easy to use and understand.
2	The app must run on Android and IOS smartphones and tablets.
3	The user must to obtain the app by downloading it from the official channels (Google and Apple stores).
4	The interface must be available in different languages.
5	The connection with the STAT-ON™ will be via bluetooth low energy (BLE). This connection must provide access to the results of the monitorization and to the status data.
6	The app must supply error messages to the user whenever needed and will always inform the user of the current status of the connected sensor.
7	The app will be responsible for the generation of a useful report containing all the organized information detected during the testing period. The user (health professional) is only responsible for managing and sending this information.

to the motor symptoms of the patient. This information should be useful and correctly structured for a correct understanding of the information captured by the sensor. Thus, the device's user interface is a very important part and must be carefully designed.

STAT-ON™ is equipped with a physical interface responding to the already discussed electronics presented in Chapter 3 (a press-button and a set of LEDs are part of this human–machine interface – HMI, permitting obtaining internal information about the operation modes and the state of the battery, and/or to enter a signal by pressing the button that indicates an event, like the moment of the medicine intake). Accompanying this physical part, a software interface has been included for the rest of the functionality and a correct interaction with the device. A very important component is the app to be installed in a smartphone, providing a complete human–computer interface (HCI). This software interface should permit the configuration of the device, according to the patients' characteristics, and give information about the state of STAT-ON™ (battery level, connection, etc.). When required by the neurologist, the HCI must be able to present, in an organized and useful way, all the information about the detected and measured PD motor symptoms.

Table 5.1 shows a minimum user requirement list that the implemented user interface must accomplish.

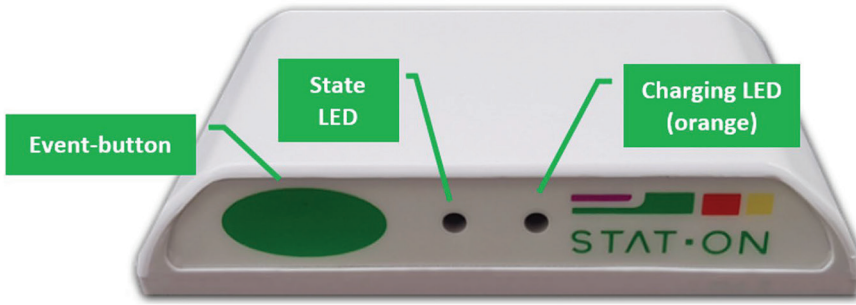

Figure 5.1 Physical interface.

5.2.1 The physical interface (HMI)

The sensor device has a button, and two led indicators next to the STAT-ON™ logo. The device is also equipped with a small vibrator motor and a buzzer (see Figure 5.1 for details).

- **The button**: The functionality of the available button is just for three specific cases:
  - Turn on the sensor when it is in shutdown mode.
  - Stop an alarm after it triggers.
  - Mark user events when specified by the professional (medication intake, sleep, meals, etc.).
- **The state LED indicator**: The color pattern of the State LED specifies the current status of the device. Through a sequence of different blinking colors (black, white, blue, magenta, green, and red), the LED shows the different states of STAT-ON™ (see reference [1] for complete details). The main possible states of the device are the following:

Connected and low battery indication

The sensor will indicate that it has an active Bluetooth connection or a low battery level by blinking the led in blue or magenta color, respectively. These indications will be combined with the sensor's current main state.

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**.

Configuration pending

When the device is in this state, its status LED will blink in white color. 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 and Yahr value. These should be configured through the STAT-ON™ app via Bluetooth.

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

Monitoring, sleep, and standby

When the sensor is correctly configured and has detected some movement, it enters the *MONITORING* state. The patient's movement is monitored in this state, and the algorithms are executed. In addition, the status LED will blink in green color. This normal operation state implies that the sensor is running correctly. However, if no movement is detected for some minutes or 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; **the user does not need to power the device on or off**.

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 in the configuration area in the app. This option forces the sensor to pause monitoring without losing its configuration. Once the sensor's button is pressed, the sensor will resume monitoring.

Full memory

If the internal memory of the device fills up, its status led will blink in red color. 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 can monitor again. Formatting (clearing the sensor's memory) can also be done, but in this case, the stored data not yet synchronized will be completely lost.

Synchronization

The synchronization process involves transferring the stored data from the sensor to the smartphone. This can only be done by using the STAT-ON™ app. While this process is ongoing, the status led will quickly blink in blue, and the app will show a progress bar. After receiving all the data from the sensor, the app will automatically generate the corresponding files and reports (see the following sections for details).

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 must be configured again to re-enable. The format sequence can be started by using the app and pressing the <DELETE> button.

Error

If the sensor detects an internal system malfunction, it will enter *ERROR* state. The status led will stay in red color. Most processes and operations, like monitoring or executing algorithms, are interrupted if an error happens. When the sensor connects with the app while in an error state, it will transfer the error code to the app, and the app will offer to perform a sensor reset.

- **The charging LED**: This LED indicates when the device is in the correct charging process, if the process had a problem, and when the charging process has finished. See reference [1] for more details. Figure 5.2 shows the correct use of the charging platform.

5.2.2 The sensor modes

The STAT-ON™ has different operational modes: shutdown, configuration, off, on, and sleep. After unpacking the system, the sensor device will stand in shutdown mode. Before using the sensor for first time, it is necessary to fully charge the battery and press the sensor's button to switch it on.

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

Figure 5.2 Device correctly placed on the charging platform (LED always orange while charging and always off when the charge is completed).

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

If the user expects not to use the sensor for long, keeping it in shutdown mode is recommended. Shutdown mode is activated after formatting the device using the STAT-ON™ app. It is recommended to synchronize all the data before formatting in order not to lose all the data stored in the sensor permanently. Charging the device's battery before switching it off is also important.

In the regular use regime, 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, and 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 use the system (worn on the waist) for a minimum of 5 days and 24 h 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 (see next sections). The doctor will download to

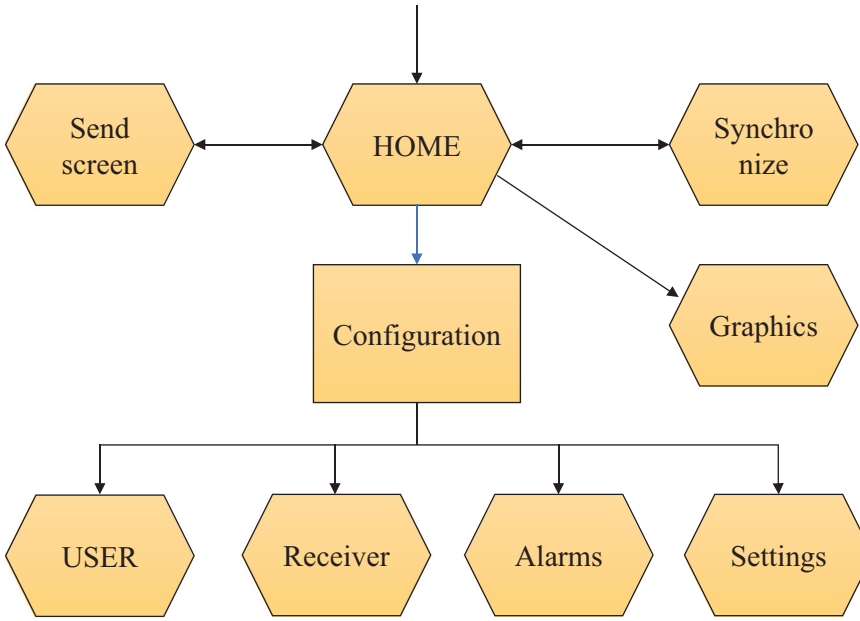

Figure 5.3 Software architecture.

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 the initial state, configuring the required parameters to start a new study period with a new patient.

5.2.3 The software interface (HCI)

The software interface is provided through a specifically designed app to be downloaded and installed in a smartphone. This app must follow the concrete user requirements described in Table 5.1 and should respond to the structure shown in Figure 5.3.

The app was designed to have a home screen from which it is possible to do the following actions:

- Synchronize with the sensors.
- Generate graphics for visualization.
- Send data.
- Configure the device.

The configuration menu is used to set up all required parameters for the proper function of the app and consists of four screens:

- User screen to introduce the user parameters configuration.
- Receiver, to set up the information of the receiver of the generated data.
- Alarms to set up the alarms of the device.
- Settings, for the configuration of the sensor's parameters.

In order to create a multi-platform and multi-device app, the graphic elements must accomplish different requisites. Image quality and resolutions must be well designed and defined to achieve the best quality and good app performance without memory leaks. Appropriate tools have been used for these purposes. The app design was directly implemented by XML in both IDEs (Android Studio layouts and XCode interface builder), accomplishing different screen dimensions and devices. Some elements were also adapted to new design rules by Google in Android (Material Design) and iOS limitations or suggestions by Apple.

5.3 The Application (App) and Its Management

The STAT-ON™ app can be installed on any smartphone or tablet running Android 5 or higher, and the device must support bluetooth low energy (BLE) and have a 1GB RAM minimum. It 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), it must be searched for "STAT-ON," and make sure its developer is Sense4Care.

The STAT-ON™ device is suitable for evaluating the motor state of a patient with PD. 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 to the number of patients registered by the smartphone at the same time, it depends on the memory of the smartphone; however, it is recommended to use no more than six patients.

The **patient ID number must be changed each time a sensor is given to a different patient**.

In order to simplify the situation where a single user (usually a healthcare professional) 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 (the data monitored is used for generating the reports and then

discarded and not used anymore). **However, in the Android version, the app does store all the generated reports** (.pdf and .csv) inside the STAT-ON-specific directory in the smartphone memory. Given that 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.

5.3.1 HOME: Main screen

After opening, the app shows the main screen, which enables access to all the areas and features of the STAT-ON™ app (see Figure 5.4). 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 device is connected, it is announced by Bluetooth and battery indicators (see the top of Figure 5.4). "*Connected*" appears under the Bluetooth logo, and the battery level is also shown.

From this home screen, the professional (user) is able to perform and organize the basic functionalities:

- *Bluetooth:* Establish the correct Bluetooth pairing with a given device.

  The Bluetooth area manages the paired devices and chooses the sensor to connect to. 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 *Stat-On* and then contains the two last digits of its serial number (e.g., "*StatOn00*").

  It is necessary to press on the STAT-ON™ device we wish to pair to, and a PIN/Passkey request may pop up. Each device has a six-digit numerical PIN/Passkey, which is provided with the sensor packaging.

- *Configuration:* Properly configure the device according to the patient data.

  The values inside the configuration area are stored inside the sensor. Thus, an active Bluetooth connection is required for its use. Once the user configures all the parameters, the user has to push the <SAVE> button.

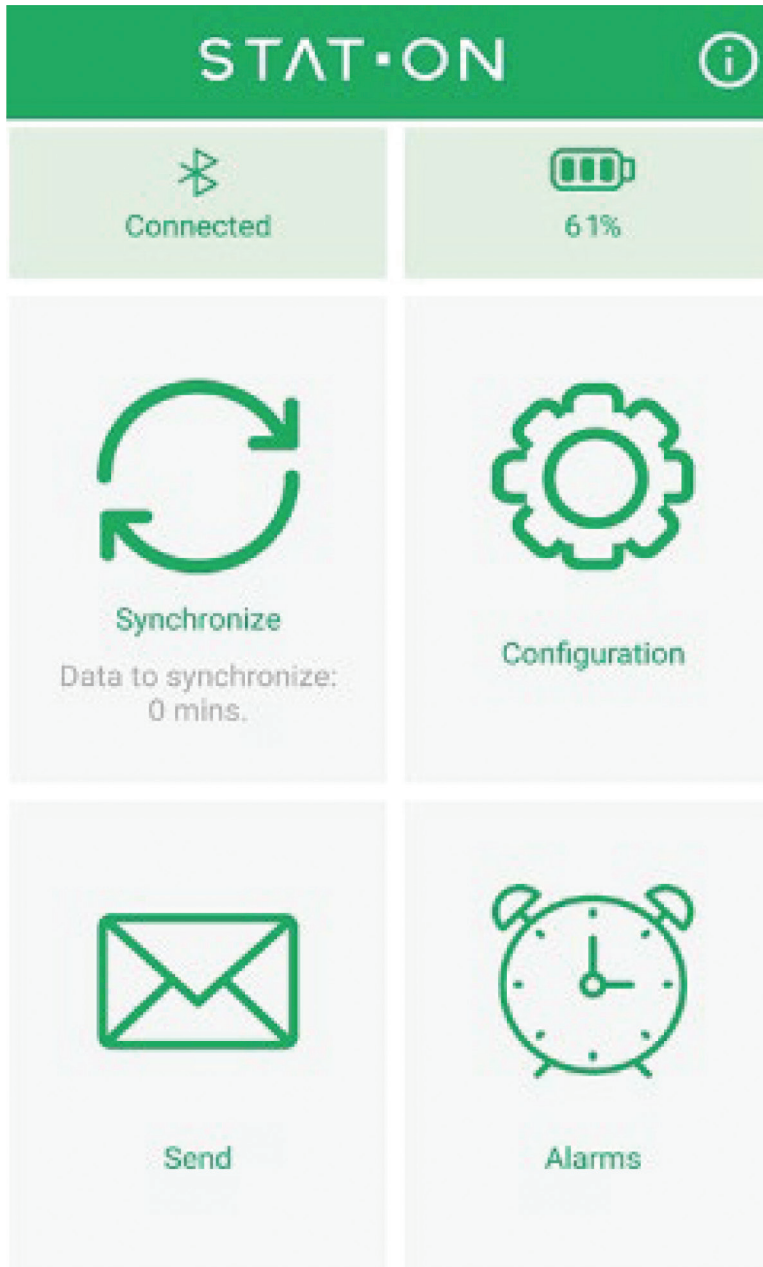

Figure 5.4 Main screen aspect.

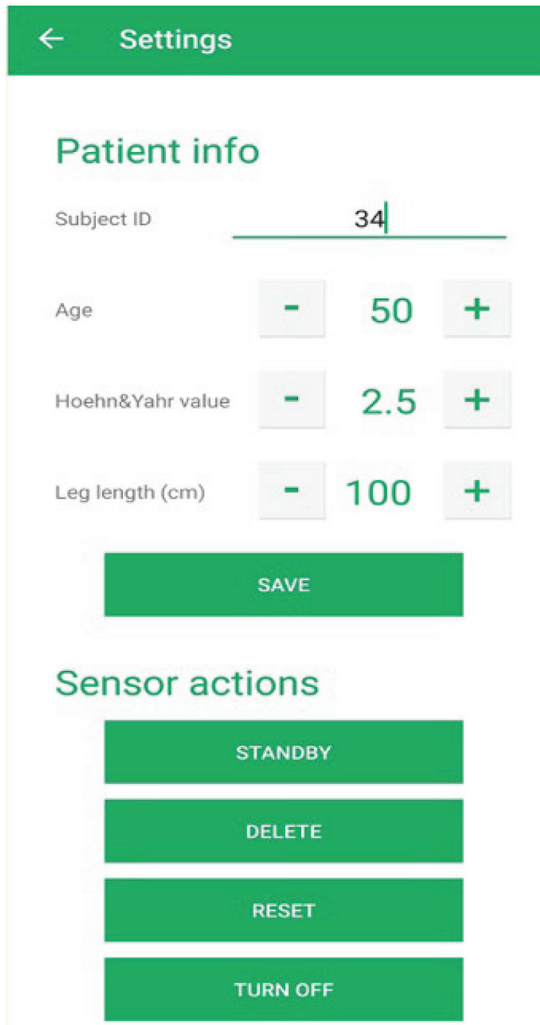

Figure 5.5 Configuration menu.

If the sensor has any results from previously stored monitorizations (i.e., not synchronized), changing some parameters from this area will not be possible. Synchronizing or deleting the pending results is required before changing the parameters. In reference to Figure 5.5, it can be mentioned:

- The patient ID value identifies the patient that wears the sensor. Patient ID is key for keeping the record of each patient correctly

related and must be modified each time the sensor changes from patient to patient.

- The age, the Hoehn and Yahr value, and the leg length of the patient must be introduced.
- The SAVE button must be pressed after the introduction of the above parameters. This way, the configuration parameters are sent to the device and start the monitoring process. A green blinking light appears in the sensor Status LED.
- The STANDBY button is available only when the device is correctly configured and permits to pause the monitoring process of the sensor.
- The DELETE button permits clearing all the data currently stored in the sensor, whether it has been sent to the app by synchronizing or not.
- The RESET button resets the sensor. This option is used in case the sensor blocks or has an error. It does not lose any data.
- TURN OFF the sensor switches OFF totally. The timestamp is lost, but the internal data is not lost. It might be used when STAT-ON™ is not used for a long time.

- *Synchronization:* This option enables downloading the information that has been computed in real-time in STAT-ON™. With this option, once downloaded, the app generates the report and the CSV file (see Figure 5.6).

  This option can only be used when connected to a sensor. The menu generates a basic five-page or extended report with all the daily information.

  There is also an option to adjust the date and time of the desired monitoring period. This is used, for example, to delete data at the beginning or at the end of the monitoring period, which is not useful (i.e., the sensor has been sent through the post office, and there are 2 days of useless data). This way, the report generated only contains important information.

  The synchronization button enables the download of all the sensor's 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.

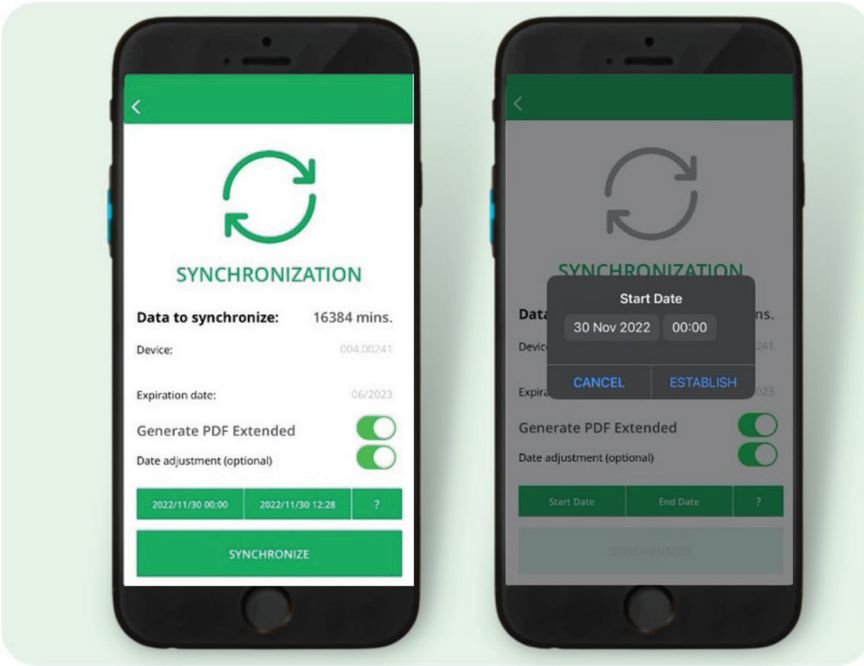

Figure 5.6 Synchronization menu,

- *Send:* Establish the sending functionality of the app.

  When the user synchronizes the device and downloads all the data, the app directly allows sending the information to a digital platform. However, if the user desires to send this information to another user later, then the "Send" option must be used. 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 mobile device's storage, 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.

- *Alarms:* It permits the optional configuration of alarms to be received on the device. The alarms will be stored and will trigger on the STAT-ON™, not the smartphone. 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. For example, alarms can be used to remember the patient's medication intake.

5.3.2 The reports

5.3.2.1 Introduction

When required by the professional, it is possible the generate a complete report about the patient's status. The application offers the possibility of generating two kinds of reports:

- A *Basic report* of the patient's condition and some graphics that condense the behavior of the symptoms and some gait parameters. The purpose of this first kind of report is of ordinary use for conventional clinical practice.
- An *Extended report* includes a large part of the parameters extracted from the algorithms and the information contained in the first type of report. The main purpose of this second mode of reports is its use in the field of research or for a more accurate analysis of the condition.

In order to ease the use and the correct understanding of these reports by professionals, graphic representations are extensively used. Therefore, the data are presented in four sections.

- Summary page
- Distribution and severity summaries
- Weekly summaries
- Daily information

The information provided in the report is the following:

- ON state
- OFF state
- INT state
- Dyskinesia
- Number of freezing of Gait (FoG) episodes
- Duration of FoG episodes
- Stride fluidity (bradykinesia index, BI)
- SMA (quantity of movement)
- Falls

- Events (indicated by pressing the button)
- Number of steps
- Step length
- Cadence

5.3.2.2 Summary of the STAT-ON™ measurements

Various symptoms associated with the patient's motor states can be differentiated in PD. One of the most common clinical practices is visually analyzing 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 natures are coordinated. On the one hand, automatic movements are classically associated with 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. 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 clearly indicates the patient's motor status associated with the ON state.

FoG is another symptom that is of special interest because it is one of the most disabling symptoms of PD. In addition, 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 state. 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 estimates 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 [2]–[5]. Since this detector is self-adaptive, it must have a minimum data period of three days. From this analysis, an important index is shown in the reports called stride fluidity or bradykinesia index, which is correlated with subscales of the UPDRS concerning bradykinesia and gait [6, 7].

The detector of choreic dyskinesia is mainly based on detecting 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 [8].

The presented architecture has implications for interpreting 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 with 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 prolonged physical dyskinesias in time, in addition to the bradykinesia level.

As presented in [3], 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 s; therefore, this is the minimum temporal resolution. This means that although freezing episodes lasting less than 1.6 s are detected, all of them will be reported as 1.6 s long. Another example can be that two episodes of 1.8 and 3.1 s will be notified as episodes of 3.2 s. This means that when STAT-ON™ reports a FoG episode of 1.6 s, it will last from 0 to 1.6 seconds, whereas when a 3.2 s episode is reported, it will result in a duration between 1.6 and 3.2 s. For more details on this detector, go to [9].

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. Details of this group can be found in [10]. Below, a detailed description of each of the graphs and data generated by the STAT-ON™ system is presented.

In the following sections, the different parts of the basic and extended report are presented and discussed. Every section title announces the content, also mentioning if corresponds to the basic or extended reports.

5.3.2.3 The summary page (basic and extended report)

The report's summary page 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 (see an example in Figure 5.7).

User ID:	4
Age:	72
Hoehn & Yahr:	2.0
Study start:	21/02/2022
Study end:	01/03/2022
Days monitored:	9
Time Monitored:	97 hours

N° FoG Episodes:	28
Average FoG Episodes/day:	3.1±2.3
Average minutes walking/day:	87.4±38
Average number of steps/day:	9783.6±4389.1
Motor inactivity (% time monitored):	20.5 hours (21.1 %)
Total Time in OFF (% time monitored):	35.5 hours (36.6 %)
Total Time in Intermediate (% time monitored):	16.5 hours (17 %)
Total Time in ON (% time monitored):	24.5 hours (25.3 %)
Total Time with dyskinesias (% time monitored):	27.5 hours (28.4 %)
Bradykinesia index (Stride fluidity) >8.5 optimal; <6.5 suboptimal	6.6±0.4

Figure 5.7 Summary page example.

In the first table, the specific data from the patient and the monitored period is shown:

- User ID: Numeric identifier of the patient, introduced through the app by the professional.
- Age: Age of the patient.
- Hoehn and Yarh: PD stage evaluation.
- 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 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.
- *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 the 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.
- *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 an 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.
- *Bradykinesia index (stride fluidity)*: this index represents the patient's state after the monitored period. It is considered that an index below 6.5 is considered a patient in a suboptimal state. Conversely, a patient who is over 8.5 is considered a patient in an optimal state.

5.3.2.4 Symptoms distribution graph (basic and extended report)

One of the most relevant graphs presented in the report is the weekly representation of the patient's motor symptoms. An example is shown in Figure 5.8.

The daily time is included on the horizontal axis, while the monitored days are indicated on the vertical axis. The colors in the graph represent the different states of the patient according to the following code:

- Green: The patient is in ON state.

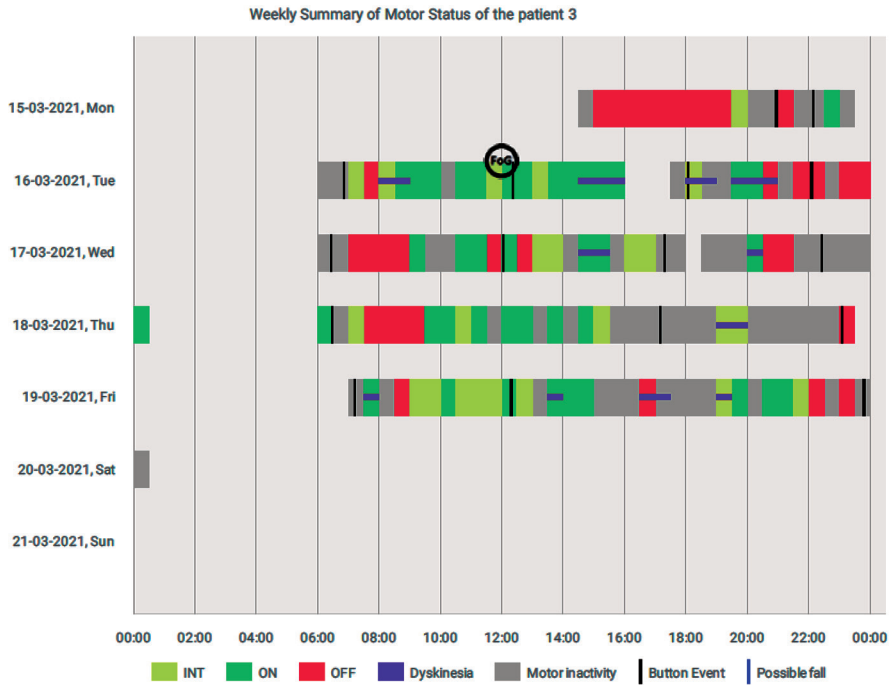

Figure 5.8 Weekly motor state. The presence of FoG is indicated. In this case, the button was pressed at medication intake.

- Red: The patient is in OFF state.
- Yellow: The patient is in an intermediate state.
- Magenta: It has been detected as choreic dyskinesias.
- Gray: No state has been detected (no dyskinesias, no walking detection).
- FoG circle: Detection of FoG episode.
- Blue vertical line: indicates a possible fall.
- Black vertical line: indicates an event. The patient pressed the button in that moment. It might indicate that the patient has taken the medication. The clinician might suggest the patient do so to see the correlation between the symptoms and the medication effect. It can be used for other purposes such as eating, feeling bad, falling, or sleeping.

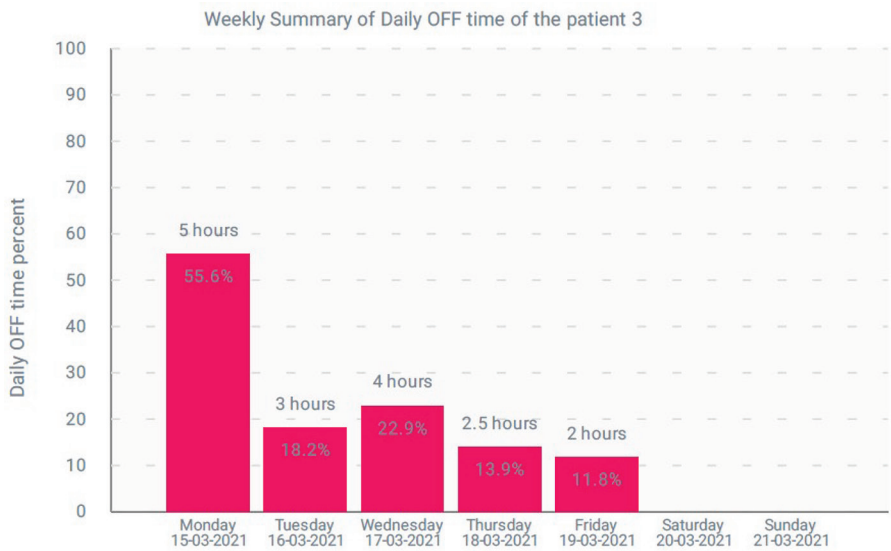

Figure 5.9 Time in OFF state.

5.3.2.5 Graph of the weekly time in OFF state (basic and extended report)

This graph (see an example in Figure 5.9) shows the daily-accumulated time in OFF every day and the percentage of OFF time regarding the total time monitored every day.

On the horizontal axis, the days monitored (maximum 1 week) are shown, and on the vertical axis is the percentage of monitored time that the patient has been in OFF state. Although the bars are based on the percentage of monitored time detected as OFF state, information is added about the number of hours the patient has been in this state. Whenever this graph is analyzed, 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. Analyzing this graph jointly with the weekly motor state is highly recommended.

5.3.2.6 Graph of the weekly FoG episodes (basic and extended report)

On the horizontal axis (see Figure 5.10), the days monitored (maximum 1 week) and the number of episodes detected per day can be observed on the vertical axis.

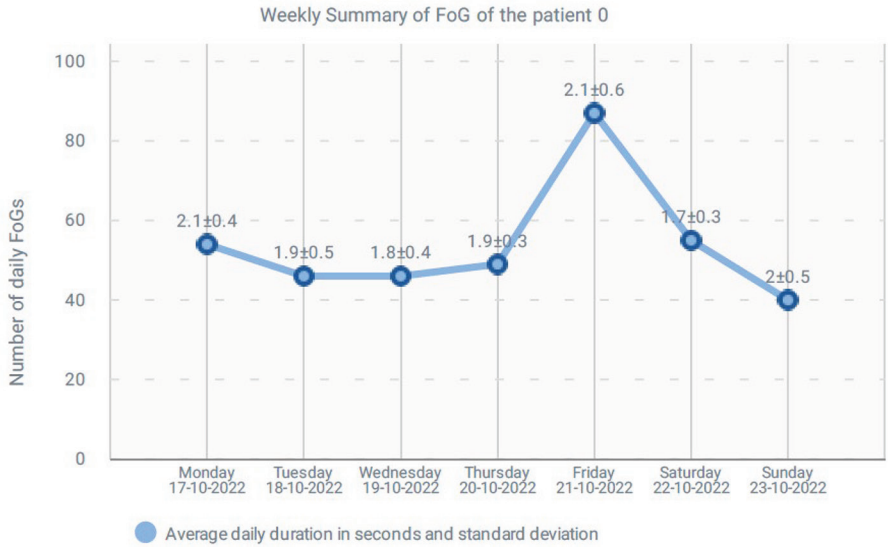

Figure 5.10 Weekly FoG episode detection.

This graph shows the number of episodes detected per day, the average length (as explained above in a resolution of 1.6 s), and the maximum duration of an episode of FoG per day.

5.3.2.7 Graph of the weekly stride fluidity (basic and extended report)

The graph presents the weekly evolution of the median stride fluidity that the monitored patient presents. The arrows represent the best and worst fluctuations of the patient throughout the day. The personalized thresholds for the ON and OFF are also indicated with a red and green line. The average of these two numbers is the bradykinesia index parameter found on the summary page. The red and green zone indicates the mentioned optimal and suboptimal zone. When the patient is over 8.5, it is considered an optimal motor state. However, when the patient is below 6.5, the patient is considered to be in a suboptimal zone. This graph is very useful for seeing the patient's daily fluctuations and severity. It permits comparing with other patients and the same patient after a medication adjustment.

The stride fluidity is a measure of acceleration obtained as an intermediate result of the bradykinesia detector (ranging from 2 to 25), which is related to the fluidity of the patient's movement when walking. This way, this evaluates the evolution of the patient's difficulty when walking as an average per day (the greater the value, the greater the fluidity).

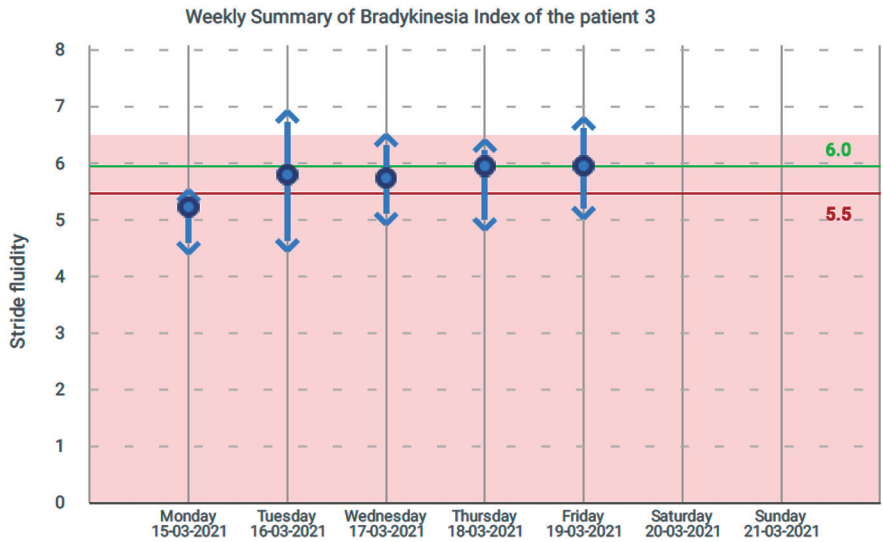

Figure 5.11 Weekly bradykinesia index (stride fluidity).

This value is correlated with the so-called factor 1 of UPDRS-III (see [2]). Figure 5.11 shows the days monitored (maximum 1 week) on the horizontal axis and on the vertical axis the measure of fluidity.

5.3.2.8 Clinical interpretation guideline (basic and extended report)

At the end of each report, basic or extended, a quick guideline is presented that indicates some of the ranges for considering the warnings of the summary page (see Figure 5.12). Given that some graphs might provide a lot of information, this guideline is useful as support for the clinician to interpret the patient's state with more quality.

5.3.2.9 Graph of physical activity (extended report)

In the extended report, the sensor also gives data about the physical activity that the patient has performed during the entire monitoring period. The measured variables shown are:

- Step length
- Stride speed
- Cadence

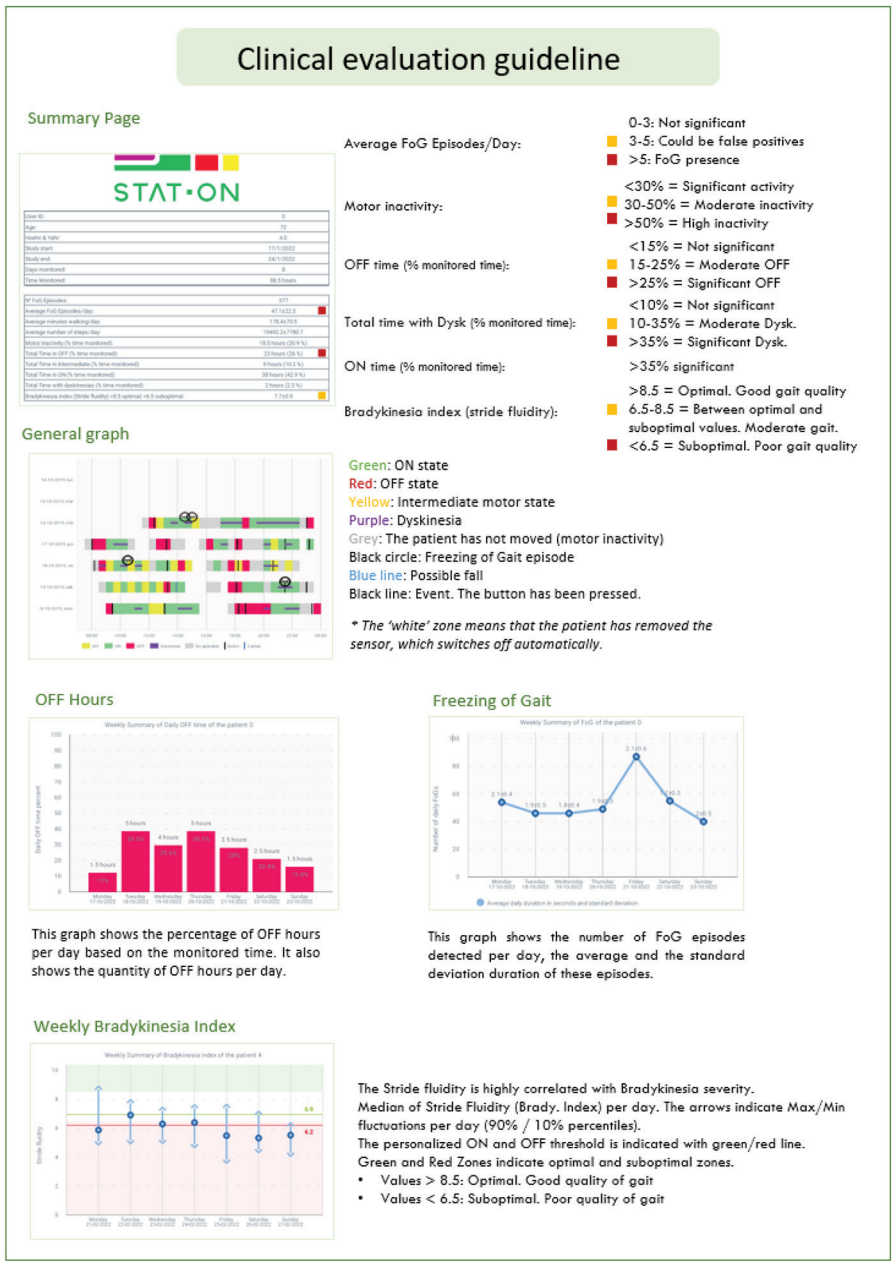

Figure 5.12 Clinical evaluation guideline.

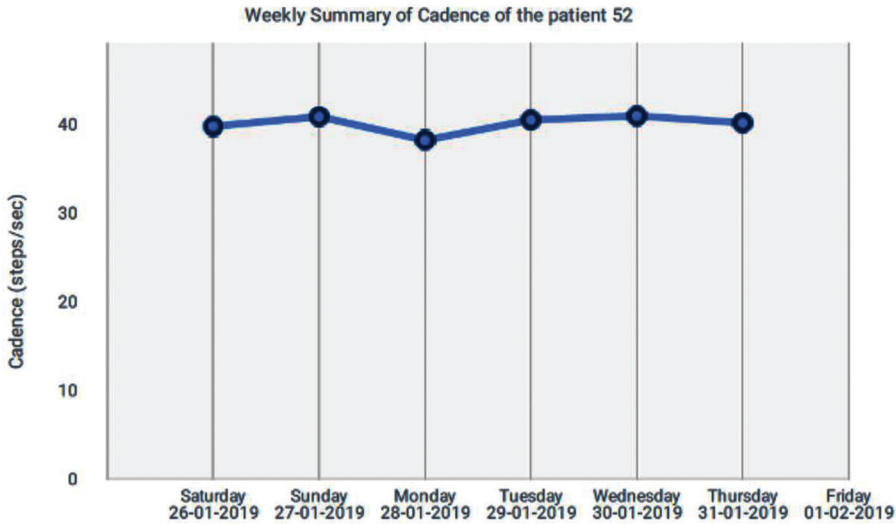

Figure 5.13 Weekly average cadence.

- Quantity of movement
- Number of steps

In each of the related graphs, it is shown, on the horizontal axis, all the monitored days, and on the vertical axis, the average per day of the units corresponding to each one of the measurements. For example, Figures 5.13 and 5.14 show a couple of examples.

5.3.2.10 Graph of daily motor symptoms (extended report)

STAT-ON™ generates a graph of motor symptoms per monitored day where it can be seen, in addition to the motor status, the dyskinesia occurrence, and the number of FoG episodes the patient has suffered, informing the hours of appearance. The resolution in all the daily charts corresponds to half an hour. Figure 5.15 shows an example.

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 at 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 the intermediate state.

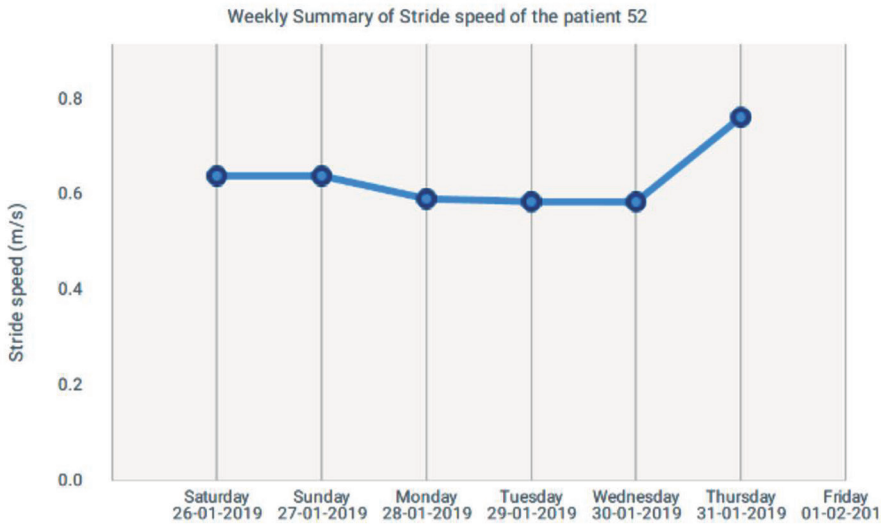

Figure 5.14 Weekly average of stride speed.

- Dyskinesia: periods in which choreic dyskinesias have been detected in the patient.
- FoG episodes: The number of FoG episodes is represented in this row. If an FoG episode is detected, a box with the number of episodes is drawn.

5.3.2.11 Graph of daily stride fluidity (extended report)

The system generates a graph of the 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 for OFF, green for ON, and yellow for INT). Finally, note that the thresholds calculated (by a self-adaptive algorithm), upper (green) or lower (red), are also drawn. These thresholds indicate when the patient is in its OFF zone or ON zone. The threshold changes between patients, given that the sensor learns how the patient walks. The thresholds are set based on machine learning methods and establish the patient's ON and OFF zones. This graphic is very interesting in understanding how the patient fluctuates and how much fluctuates.

On the horizontal axis, it can be observed the hours of the day and on the vertical axis, the units correspond to the stride fluidity (m/s^2).

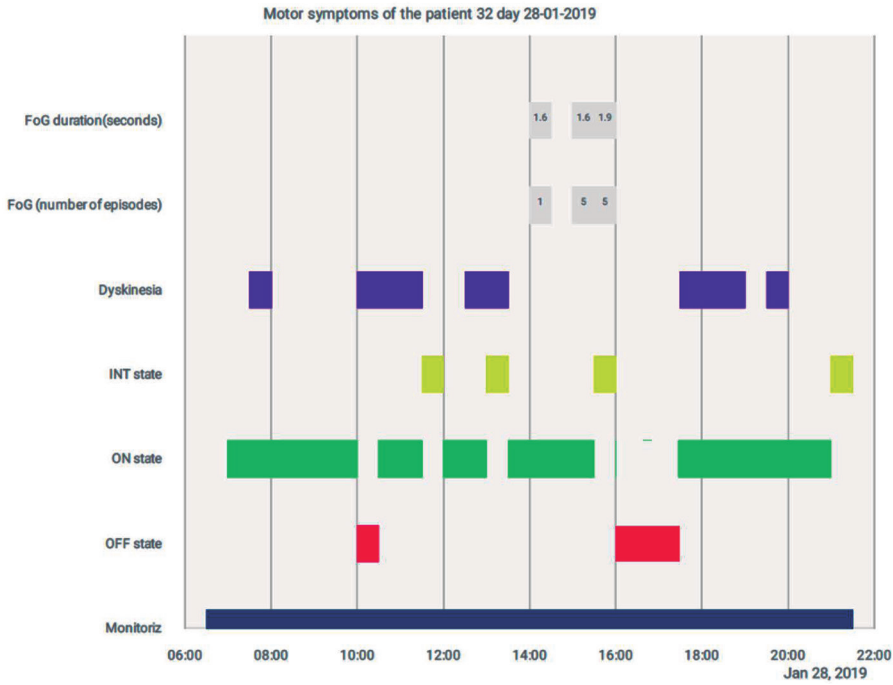

Figure 5.15 Daily motor states, including information about FoG episodes.

5.3.2.12 Graph of daily physical activity (extended report)

This group of indicators provides detailed information about the physical activity the patient has performed throughout the day and during the days they have 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 measurement are shown on the vertical axis. Figure 5.17 shows the daily energy expenditure as an example.

As it was also introduced above, the system can produce a reduced version of this complete report. The reduced report is just a selection of the information and graphs contained in the extended report.

Information with special interest in order to help the clinical professionals to have a more complete and objective view of the state of the PD

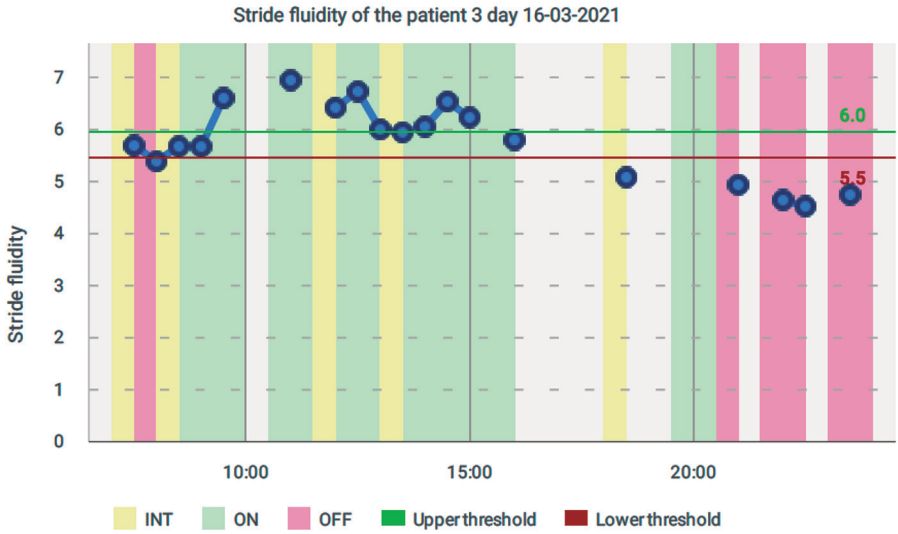

Figure 5.16 Daily stride fluidity and motor states.

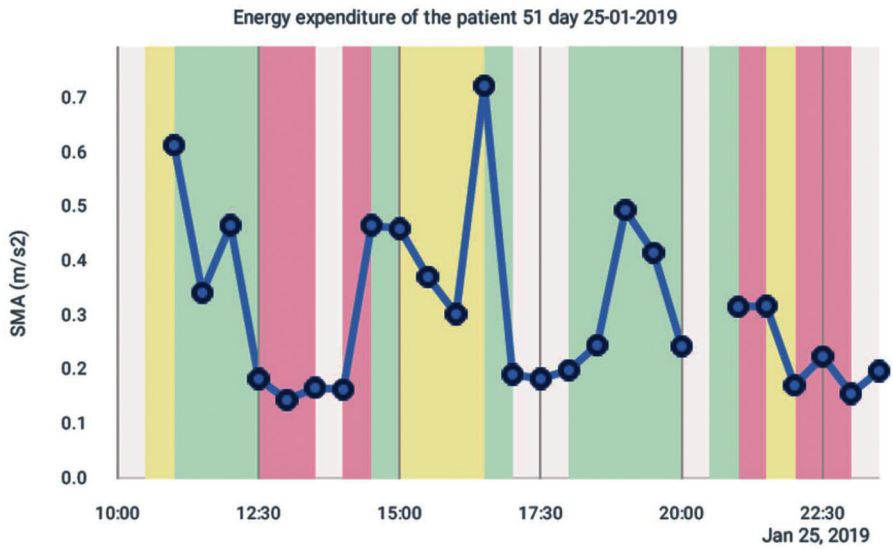

Figure 5.17 Daily energy expenditure and the motor states in the background.

patient, was selected. In concrete: the Summary page (Section 5.2.2.3), the weekly motor state (Section 5.2.2.4), the weekly time in OFF state (Section 5.2.2.5), the weekly FoG episodes (Section 5.2.2.6), and the bradykinesia index weekly graphic (Section 5.2.2.7).

5.4 Report Hints and Interpretation

As a part of the user (mainly the health professional) interface of the STAT-ON™ device, the contents of the extended report have been presented in previous sections. This report and the graphical representation of the captured and measured data was determined according to the list of the users' requirement, shown in Table 5.1, and after many discussions and professional opinions from several cooperating neurologists.

The measured data of the different relevant motor PD symptoms and the calculations and algorithms applied to them, in order to be stored in the device, and represented under the form of a report when required from the app, is explained and presented in [9].

The objective of this section is to try to clarify some of the contents of the report to make their correct interpretation easier for the proper use of this information (and the contained data) for the correct management of the PD patient.

The following text presents some hints and comments on the interpretation of some parts of the report. This is not a complete list, but some specific aspects have been identified:

5.4.1 Some interpretations on the weekly summary of motor state graph

We refer to the graph presented in Section 5.2.2.4. It is necessary to remember that green color corresponds to the ON state, red to OFF, yellow corresponds to the intermediate state and gray means that the period is not applicable since the patient is not walking. The magenta line represents the presence of dyskinesia, the black line corresponds to pressing the button, and the blue line indicates the occurrence of a fall.

Figure 5.18 corresponds to a couple of days of the complete monitored period of a patient presenting some interesting particularities:

- It can be seen how the patient has presented dyskinesias at some moments of the monitoring, but that he **presents an OFF-motor state during a great part of it**.
- On the other hand, it presents some isolated FoG episodes, which means that, during the half-hour of resolution that the graph has, at least 1 FoG episode has been detected.
- In this representation, several conditions must be taken into account. One of the most important is that the **diagnosis of OFF can only be**

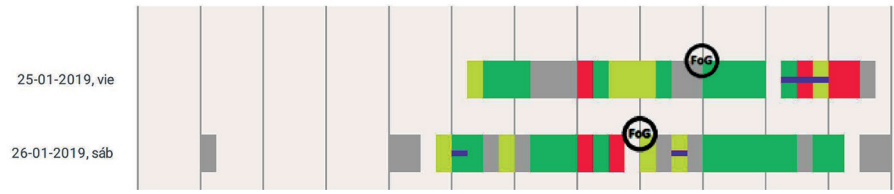

Figure 5.18 Part of the weekly summary graph of a patient.

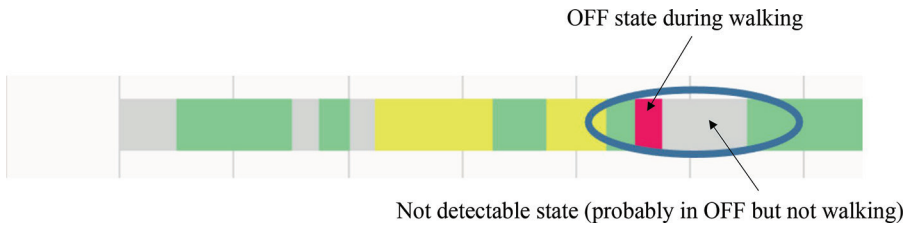

Figure 5.19 Example of active periods followed by inactive ones.

issued when the patient is walking due to the functioning characteristics of the sensor based on accelerometers. Therefore, in moments when a verdict cannot be issued, the monitoring zones without diagnosis appear (in gray).

- Some patients do not walk or walk less during episodes of deep OFF. This means that these **episodes in gray may be long periods of inactivity, or the patient is so bad that he cannot even walk**.

Another interesting aspect to be discussed can be seen in Figure 5.19, where the patient walks a lot throughout the day, and although he presents intermediate states, he continues walking. However, when it goes into an OFF state, he stops walking for a long time.

When the system issues the diagnosis again, it is already in ON state again. We can appreciate how the OFF state is only counted for half an hour, although it may take longer (remember that the sensor can only detect and measure when the patient is moving). In these cases, **it is important to consult with the patient if, during the OFF periods, he tries to walk or not**.

A comment and explanation must be made on the fall detection capabilities of STAT-ON™. It is convenient to consider Fall detection as an indicative mark since it can generate some false positives in specific situations such as when the patient lies down in bed or on the sofa very abruptly or when the patient leaves or puts on the seatbelt due to the manipulation movements.

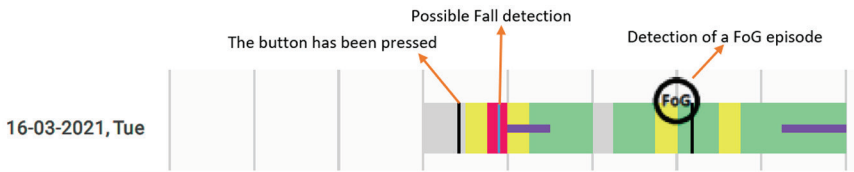

Figure 5.20 Some details related to fall detection, the existence of FoG, and pressing the button situation.

Figure 5.21 A false positive was observed in a healthy person wearing STAT-ON™.

This is a possible consequence of not receiving any feedback from the user (the patient wearing the system).

Figure 5.20 shows a day distribution of a given patient where FoG appeared at a given moment, and a fall has been indicated during an ON state, and at a given moment, the patient pressed the button.

Concerning the presence of FoG, this kind of graph shows that in the half-hour slot around the indicated circle, at least one FoG episode has occurred. For more details and information, it is necessary to consult the specific information detailed in section 5.2.2.6.

The button press mark (black vertical line) appears each time the patient presses the button. This functionality can be used as desired and according to the indications done by the neurologist. For example, in the concrete study shown in Figure 5.20, the user was asked to press it when he took medication.

During the validation of the system, monitoring tests were carried out with healthy patients, obtaining profiles of activity. It should be noted that on certain occasions (such as shown in Figure 5.21), there may be false detections depending on the activity that is taking place (in this case, it is a bus trip).

In healthy individuals, false positives of some symptoms (especially dyskinesia and FoG) have been observed when performing activities such as scrubbing the floor, cleaning the oven, **or taking some public transport such as a train or bus**. *It is relevant to advise patients to try to carry out*

their activities of daily living normally, but to remove the sensor if they are going to carry out physical activities (e.g., going to the gym) or activities with highly repetitive movements such as scrubbing the floor. It is suggested to clinicians that they ask the patient to fill in a simple diary explaining if they take some transport or do sport.

5.4.2 Some details on the weekly FoG episodes

This comment is referred to the detection of FoG episodes and their weekly representation (see Figure 5.10). On the horizontal axis, the monitored days (maximum one week) can be observed, and on the vertical axis, the number of episodes detected per day. This chart shows the number of episodes detected per day, the average duration (as explained in Section 5.2.2.6 at 1.6-s resolution), and the standard deviation of the duration per day.

FoG detection is based on the movement patients make when they are blocked, which can be similar to some movements carried out in physical activities such as the gym or classes of various dance disciplines. ***Therefore, it is necessary to ask the user if they have carried out these activities during the monitoring process and to recommend that they remove the sensor when they are going to carry them out***. Furthermore, in the same way as the previous section, it is recommended to fill in a simple diary explaining if they perform some activity such as sport or taking some transport.

5.4.3 Some recommendations for a correct use of STAT-ON™

Due to the internal design of the device, based on accelerometry and the treating algorithms for the detection of PD-related motor problems, it is very convenient to be aware of some basic recommendations.

These recommendations are formulated in base on the acquired knowledge during the design process and the user experience in real cases:

- The STAT-ON™ system is a human movement analyzer; therefore, it is completely discouraged to carry it for long periods in public and private transport as it can cause false positives in some detectors.
- Patients should be advised to try to carry out their activities of daily living usually, but to remove the sensor if they are going to perform physical activities (e.g., going to the gym) or activities with highly repetitive movements such as scrubbing the floor.

- The patient may be required to press the button to indicate any circumstances the neurologist indicates (e.g., taking the medication, thinking he is entering an OFF period, etc.). He should, therefore, avoid pressing it in any other circumstance.

5.5 Conclusion

The chapter has presented the complete user interface for the correct use and reported measurement understanding. For more detail, it is recommended to access the STAT-ON™ user manual [1] or the product's website [12].

References

[1] STAT-ON™ user manual. Available from Sense4Care website.
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[11] J. Cabestany, A. Bayés (editors), 'Parkinson's Disease Management through ICT: The REMPARK Approach' River Pub. 2017.
[12] statonholter@sense4care.com