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The STAT-ON™ Industrialization Pathway: From the Research Prototype to the Product

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Abstract

After the technical verification of the REMPARK sensor for the detection and measurement of the motor symptoms associated with Parkinson's disease (PD), a complete redesign process was necessary to obtain a version with feasible industrialization characteristics.

The chapter presents the followed process, with many details about the established final requirements of the system, how the new internal architecture was organized, and how the necessary embedded firmware was implemented.

Details on the mechanical design and the final packaging and labeling of the STAT-ON™ device are included.

3.1 Introduction

The industrialization of a medical device assumes the capacity to organize serial production of a specific device compliant with a list of required and specific standards. In our case, STAT-ON™ is based on the knowledge and technology generated in several Spanish and European-funded research projects such as REMPARK [1,2] and PARK-IT phase I, among others, as has been mentioned in chapter 2.

The industrialization of a medical device must be according to the standard IEC60601-1 for medical electrical equipment. Thus, some requirements

must be defined and specific electrical circuits must be designed accordingly. Additionally, the elements that surround the device, such as the sealing strip, enclosure, packaging, and the accompanying documents, must be defined at the beginning of the project.

In parallel, and as explained in Chapter 4, this process must be aligned with the complete certification process. In the present chapter, it will be described the industrialization process of STAT-ON™, from the prototype to the final product.

The main achievement of the REMPARK project was the development of an algorithmic set capable of detecting Parkinson's Disease (PD) motor symptoms with a sensitivity and specificity greater than 85% for all symptoms of interest. These algorithms, based on machine learning strategies combined with frequency and statistical analysis on inertial signals, also include adaptive techniques that allow to adapt the outcomes to the PD patient profile.

As a continuation of the REMPARK project, a Feasibility Study (PARK-IT phase I) was carried out on the potential market for a medical device to monitor patients with PD, to understand if there was enough demand. The conclusion of this study was positive and indicated, at the same time, that many changes would be necessary to the REMPARK prototype to adapt the device to the market demand.

Originally, the REMPARK proposal assumed a connection between the sensor and a hospital platform, where the data was stored. Clinical professionals could connect to the platform to analyze the data, monitor the patient and manage the concrete treatment. This architecture, at that time, was not feasible for a commercial solution, such as the one proposed, due to the existent interoperability issues among the different hospital systems and the certifications/specifications necessary to connect to them.

For this reason, in the PARK-IT study, a stand-alone system architecture was proposed, where the clinical professional will manage the sensor through a portable device (Smartphone) and where the patient's data is always under the responsibility (in custody), either of the patient himself or of the clinician in charge of the patient care.

After the REMPARK pilot experience and along the Phase I feasibility project, it was concluded that there were two essential aspects to improve on the original sensor: (1) the duration of the monitoring must expand from a few hours to a complete week and (2) the usability of the sensor and its charging system should be improved, when compared to the initial prototype, allowing the patient to wear it more comfortably.

As it is presented in Section 3.1 of Chapter 2, an industrialization process began (PARK-IT2 initiative) that included a general redesign of the initial research prototype towards a medical device, capable of sustaining a feasible business model.

3.2 The Requirements of the STAT-ON™ System

In the PARK-IT phase I feasibility study, the following sensor use scenario was proposed: *the sensor will be under the responsibility and must be configured by the neurologist since the algorithms need a concrete number of clinical data from the patient to adjust the detection algorithms. Once the sensor is configured, it would be delivered to the patient, who would wear it for at least 4 days.*

Monitoring can be extended for as long as the neurologist considers necessary, taking into account that, if necessary, the patient could charge the battery of the sensor at home overnight. Once the monitoring will be finished, the patient or caregiver should send back the device to the neurologist's office, where the sensor's data would be downloaded and, automatically, a complete monitoring report would be generated using a developed Smartphone app.

In this way, the **sensor was conceived as a small portable device that, worn on the left side of the waist, is capable of continuously monitoring and evaluating the PD patient's motor symptoms**. The following requirements are crucial for the presented device concept:

- It must be based on inertial sensors and should have the ability to process data in real time.
- It would include a rechargeable battery providing complete autonomy for several days.
- The data, once processed, would be stored in the internal memory of the device.
- In addition, the sensor must have the ability to communicate wirelessly and safely with a Smartphone and transfer the stored data in a secure way.
- The hardware device must include enough computing capability to embed the signal-processing algorithms and methods developed during the REMPARK project.

The additional pillar of the system should be a mobile application for the generation of complete reports and time distribution of the symptoms in a useful

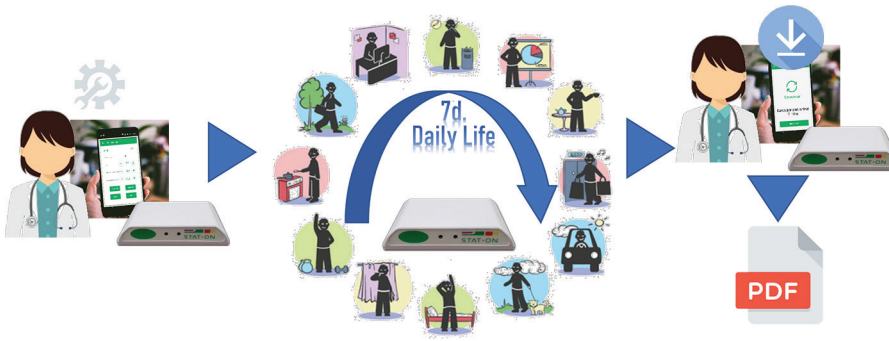


Figure 3.1 STAT-ON™ data flow scheme (patient is wearing the sensor for a period of 7 days while doing normal activities).

format for neurologists. In fact, this application would act as the system's user interface, allowing the neurologist to know the status of the sensor and download the reports generated from the patient's monitoring.

The presented scenario is sketched in Figure 3.1 and the more complete list of requirements is in Table 3.1. According to it, and from a technical perspective, the more challenging aspect to be considered is the reduction of the global consumption of energy, since the original REMPARK prototype had a very high one, due to the main microprocessor used that was the response of many of the internal operations (control aspects and on-line running of the algorithmic set).

The strategy for the consumption reduction was addressed with the use of two different microprocessors, sharing the execution of the different internal processes: the Nordic nRF51822 (nRF), a low-consumption device that will be used for the operational control part of the sensor [3], and the STM32F415 (ST), a high-performance microprocessor that will be responsible for the execution of the algorithmic set in real time [4].

This strategy completely changed the functional scheme of the sensor, evolving towards a hierarchical structure of two different microprocessors. This architecture allowed, on the one hand, to stop the high-performance processor (ST) at convenience when no movement was detected or when the minimum operating conditions were not met. On the other hand, it also allowed the nRF processor to turn on the algorithmic execution, turning on the ST, when necessary.

This scheme requires that each microprocessor must have an independent accelerometer connected. The accelerometer connected to the nRF would allow the data capture and analysis process to be started by turning

Table 3.1 Complete list of the sensor requirements.

Requirements Type	Sensor device requirement description
Functional	The DEVICE must wake up when "wake-up situation" is detected (trembling). The DEVICE must start collecting data after "wake-up situation" and save it in a Flash memory. The DEVICE must store the push button events.
Power management	The DEVICE must have an autonomy of at least 7 days with normal use. The DEVICE's battery must charge with wireless power system (Qi standard). The DEVICE must be fully charged in less than 6 hours. The DEVICE must be able to detect low battery status through a battery gauge.
Communication	The DEVICE must be able to send and receive data using BLE (Bluetooth low Energy). The DEVICE must be able to send the saved data from the Flash memory to the APP (from last synchronized time stamp). The DEVICE must be configurable from the APP to synchronize key parameters and alarms.
Human machine interface (HMI)	The DEVICE must have a RGB LED and a monochromatic ORANGE LED. The ORANGE LED will display information about the status of the charge of the battery (controlled by the charging circuit). The DEVICE will turn on RGB_BLUE LED when connected through Bluetooth. After it will return to GREEN or WHITE. The DEVICE will blink RGB_WHITE LED when it is not yet configured. After it will return to GREEN or OFF. The DEVICE must have a push button. After the button is pushed acoustic or vibration feedback will be activated. The DEVICE must have a buzzer. The buzzer may be replaced by a vibrator if space and the device's autonomy is not affected.
Mechanical	The DEVICE's housing must be IP 65. The DEVICE's housing must be ergonomic. The DEVICE is fixed onto a BELT. The BELT must secure the DEVICE to the hip.

on the ST. The ST microprocessor would use its own accelerometers to capture data and perform the relevant analysis, executing the algorithmic core. When the ST detects a prolonged absence of movement, all internal processes will stop and a request will be sent to the nRF to cut off the power supply.

The complete development of the specified sensor device will suppose, at least, the implementation of the following components:

- An electronic board containing and interconnecting all the required electronic components, with the necessary firmware, to implement the sensor monitoring and the processing and communication functionalities.
- An IP 65 housing to contain the mounted electronic board.
- A resistive keyboard to implement the human-machine interface.
- A belt to attach the sensor device to the human body, in the waist.

The following sections describe the development work done to achieve the mentioned components. Details can be found on hardware electronics, firmware, and mechanical design.

3.3 The STAT-ON™ Hardware Electronics

The application of the above-mentioned requirements in the STAT-ON™ redesign process resulted in a quite complex system with a mandatory reduction of consumption, the wireless battery charge possibility, the use of a microprocessor with enough capability to compute machine learning algorithms with a floating-point unit, the inclusion of a microprocessor with Bluetooth capabilities and low-power capacities to perform the operational control part, the implementation of the necessary human machine interface (HMI), that needed a series of communication buses for its efficient implementation…

The present section describes the electronic circuitry of STAT-ON™, how it was industrialized, and how the design was performed to reduce electromagnetic compatibility problems. It includes a discussion on the main circuit architecture, including the power system as a crucial part of this redesign, the chosen inertial sensors, and how they are used, and the section will finish with the presentation of the designed printed circuit board (PCB).

3.3.1 The main circuit

The complete system is composed of three different subsystems (see Figure 3.2):

- One part, based on the ST microprocessor, is in charge of acquiring the main data and processing it in real time (in yellow).

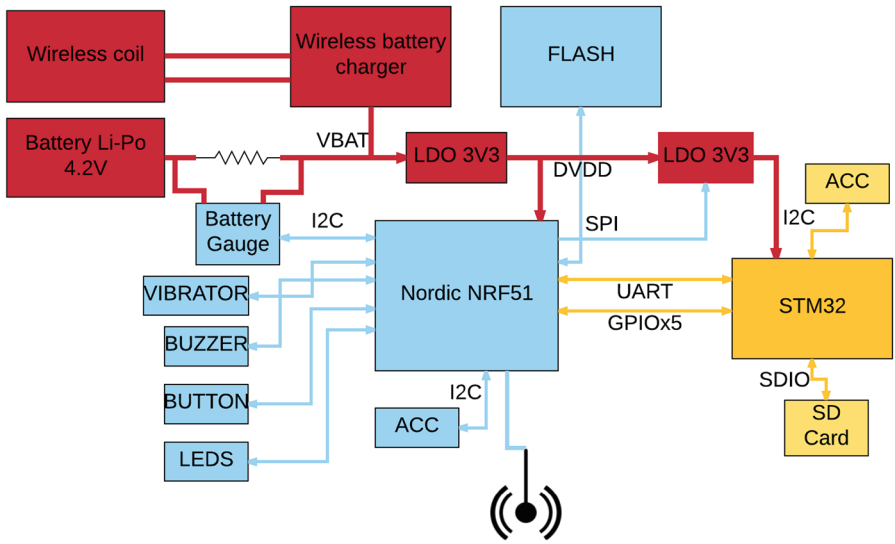


Figure 3.2 Sensor device architecture.

- The second part is based on the nRF microcontroller, in charge of controlling the complete system and sending the data through a Bluetooth communication link (in blue).
- The third subsystem is the power management one to supply all parts of the circuit and the battery (in red).

The chosen ST microprocessor for the online data processing was already used in the REMPARK prototype and this decision facilitated the migration of the developed algorithms to the new platform. This microprocessor will be in charge of reading the accelerometer sensor data, processing them by the embedded algorithmic core developed in REMPARK, storing them in the SD card, and sending them to the nRF microcontroller, when necessary.

The ST microprocessor is part of the STM32F415xx family and is based on the high-performance ARM® Cortex®-M4 32-bit RISC core, operating at a frequency of up to 168 MHz. The Cortex-M4 core features a floating-point unit (FPU) single precision which supports all ARM single-precision data-processing instructions and data types. It also implements a full set of DSP instructions and a memory protection unit (MPU) which enhances application security. In concrete, the STM32F415RGT6 incorporates high-speed embedded memories with 1 Mbyte of Flash and 192 Kbytes of SRAM, and an extensive range of enhanced I/O. This model offers three

12-bit ADCs, two DACs, a low-power RTC, 12 general-purpose 16-bit timers including two PWM timers for motor control, two general-purpose 32-bit timers, a true random number generator (RNG), and a cryptographic acceleration cell. For our redesign, their included communication interfaces capabilities are of special interest:

- up to three I2Cs,
- three SPIs,
- four USARTs plus two UARTs,
- an USB OTG full-speed and a USB OTG high-speed with the full-speed capability, and
- an SDIO/MMC interface (for SD card).

From a more general point of view, this microprocessor's family operates in the temperature range –40 to +105 °C, from a 1.8 to 3.6 V power supply. The supply voltage can drop to 1.7 V when the device operates in the 0 to 70 °C temperature range. A comprehensive set of power-saving modes allows the design of low-power applications.

The chosen microprocessor to manage the whole system and establish a connection to external devices (using Bluetooth 4 protocol) is an nRF51822 from Nordic [3]. This microcontroller is a powerful multiprotocol single-chip solution for Ultra Low Power (ULP) wireless applications. It incorporates Nordic's latest best-in-class performance radio transceiver, a 32-bit ARM® Cortex™ M0 CPU, and 256kB/128kB flash and 32kB RAM memory. The nRF51822 supports Bluetooth® low energy (formerly known as Bluetooth Smart) and 2.4 GHz protocol stacks.

The Programmable Peripheral Interconnect (PPI) system provides a 16-channel bus for direct and autonomous system peripheral communication without CPU intervention. This brings predictable latency times for peripheral-to-peripheral interaction and power-saving benefits when the CPU is in an idle state.

It is interesting to note that the nRF microcontroller has two global power modes ON/OFF, but permitting individual power management and control for all the internal blocks and peripherals. This allows the designer to switch RUN/IDLE the system blocks based on specific requirements derived from particular tasks. These characteristics' set is the basic reason for choosing this microcontroller for the redesign process.

In relation to the power management part (the red part of Figure 3.2), a 3.3V constant voltage is used to supply the nRF through Low Dropout

Regulators (LDO). A second LDO is used as a power switch to supply the ST microprocessor and implement an active low-power strategy (the ST microprocessor is only supplied when necessary).

The Nordic nRF sub-system is composed of the following devices (blue part of Figure 3.2):

- A wake-up accelerometer so the nRF (and complete system) is awoken when movement is detected in the device.
- Flash memory to store all the required data received from the ST or the external App.
- A battery gauge to monitor the battery level.
- A conditioning input circuit to detect when an external button is pushed.
- An enabling circuit to activate the buzzer and vibrator.
- A circuit to control the LEDs.

The nRF microcontroller communicates with the ST microprocessor through a UART port along with two signals that allow proper implementation of an interruption-based communication. Finally, the ST sub-system is composed of the (yellow part in Figure 3.2):

- An accelerometer to read all movements detected by the sensor, when it is awake.
- A slot for flash memory to store all the generated data from the algorithms implemented and executed in the microprocessor. This memory has an additional debugging purpose.

3.3.2 The power system

As mentioned before, the power system is a critical part of the STAT-ON™ redesign. It has been designed considering that it must supply three different parts, with different characteristics: the digital and analog parts corresponding to both microcontrollers (nRF and ST) and the power supply system.

The three systems are separated by ferrite beads to prevent electromagnetic interferences (EMI) and the voltage level is established by means of LDO. Additional ferrite beads have been included between the regulators and the different loads as a preventive measure.

The control and stabilization of the voltage in the inputs and outputs of the included regulators is done, as usual, by capacitors. These controls are

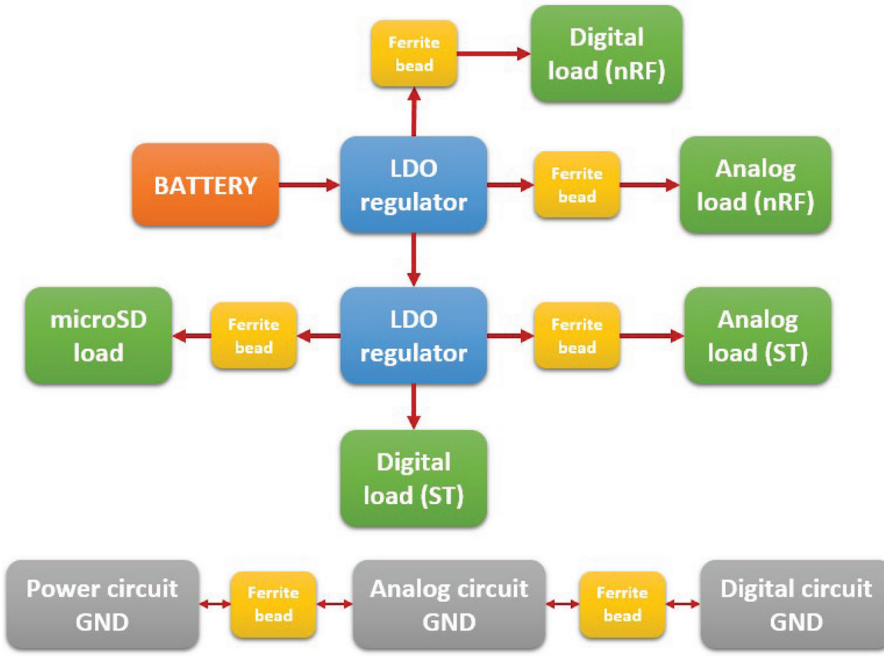


Figure 3.3 The power system and regulator management scheme.

very useful for highly demanding components, like the used microcontrollers, flash memory, or SD Card.

Figure 3.3 shows the main scheme of the STAT-ON™ power system, separated by the different zones.

As shown in Table 3.1, the STAT-ON™ must be a wirelessly charged device according to the Qi standard, and more concretely, with WPC v1.1 Qi Industry Standard. Following the strict requirements of this standard, the redesign must guarantee that the device will work correctly and will not have problems with electromagnetic emissions or other external agents.

As the wireless power charger, the BQ51050BRHLR from Texas Instruments was chosen due to its integrated dual functionality: Qi-receiver and battery charger (integrates the digital controller required to comply with Qi v1.2 communication protocol, and provides all necessary control algorithms needed for efficient and safe Li-Ion and Li-Pol battery charging). The wireless charger system is completely autonomous, starts a charging cycle if the battery voltage is above a threshold, and detects if the device is placed on a charging platform.

For the design of load modulation capacitors, which are in charge of the correct communication between the emitter and receiver, the instructions

provided by Texas Instruments were strictly followed. A specific design was done for STAT-ON™ system to test and adjust the correct values for the capacitors and resistors as it is shown in Figure 3.4.

The battery is a fundamental internal element of the sensor redesign. It should be selected maintaining a balance between two essential design restrictions:

- On the one hand, its capacity must be maximum, to increase the autonomy of the sensor.
- On the other hand, the size of the global system must be restrained as much as possible to increase user comfort.

A lithium polymer battery was selected, according to the specifications in Table 3.2.

The selected battery is a lithium polymer battery with a size of $50 \times 34 \times 6.5$ mm^3 and a weight of 24 g, which guarantees safety, it is compliant with all the related regulations, and its size is correct for the designed enclosure. This battery is certified with different standards, specially IEC62133 which is specific for medical device purposes. It includes a short-circuit protection circuit and power is cut under 2.7 V to avoid malfunctioning of the battery and dangerous conditions. The working temperature range and the charging mode must be carefully considered since there exist some strict limitations: from 10 to 45°C when in charging mode and from 10 to 60°C when in discharging mode.

The battery gauge is a device included in the system (see Figure 3.2) to provide information about the battery capacity and its state of charge, using internal processing algorithms. The device will send the information to the nRF microcontroller.

The chosen battery gauge is the BQ27441DRZR-G1 from Texas Instruments. This device includes a patented embedded algorithm to estimate the battery capacity. This device has an I2C bus for configuration and information purposes.

The temperature control of the battery is essential and mandatory for a medical device. Modes of charge not only depend on the phase of charge but also directly depend on the temperature. The used power charger (BQ51050B) is JEITA standard compliant and this implies a series of rules to charge the battery in a safe way: current and voltage limitations depending on the temperature (details are in Figure 3.5). Nevertheless, the battery manufacturer strongly recommends not to charge the battery over 45°C, and this is the reason why, in the redesign process, we do not allow the battery to charge over 45°C.

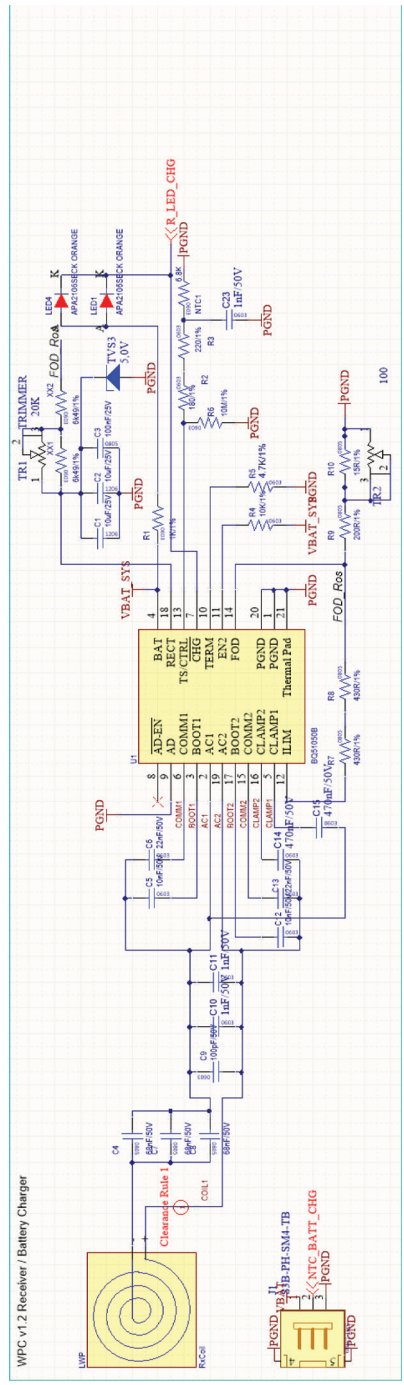


Figure 3.4 WPC V1.2 receiver power system.

Table 3.2 Battery specifications.

Name	Lithium-ion polymer battery
Voltage	3.7 V
Capacity	1150 mAh
Dimensions ($L \times W \times$ T) mm	50 × 34 × 6.0
Standard charge current	0.2/0.5C
Maximum charge current	1A
Open circuit voltage	3.7–3.9 V
Cut off voltage	2.75/4.2 V
Cycle life	500 times
Appearance	Without scratch, distortion, contamination , and leakage
Certifications	CE, RoHS Directive-compliant, UL, SGS, BIS, CB, IEC 62133

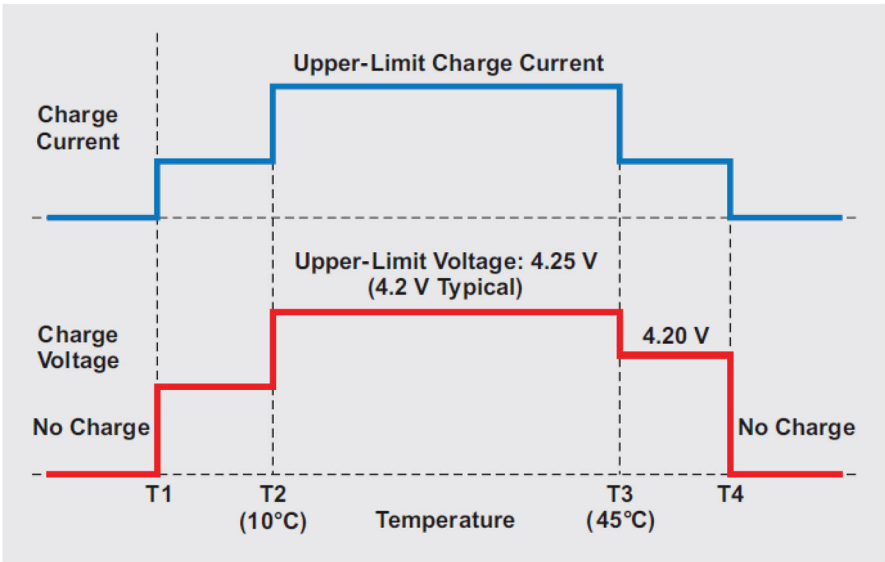


Figure 3.5 JEITA guidelines for charging Li-ion batteries (notebook applications).

To implement the control of the battery temperature and according to the BQ51050B datasheet, the circuit of Figure 3.6 is used. It is necessary to calculate resistors R1 and R3 according to a specific range of temperatures and regarding a specific NTC.

Following the equations on the BQ51050B datasheet, a thermistor with R_0 = 6.8 KΩ and K = 4480, and using the application provided by the

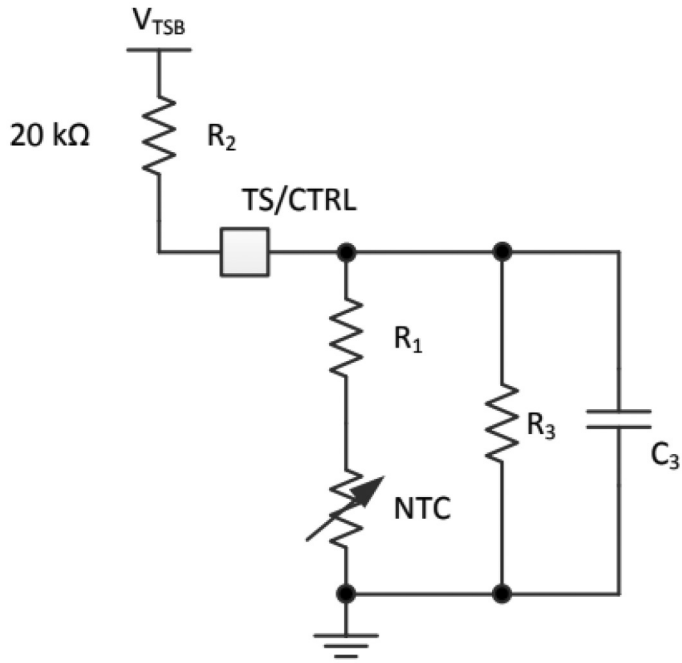


Figure 3.6 Circuit to control the battery's temperature. Source: Texas Instruments.

Table 3.3 LDO's dropout voltage specification.

Output current, T_j = –40°C to 125°C	**Dropout voltage**
1 mA	5 mV
200 mA	133 mV
300 mA	200 mV

manufacturer to compute R_1 and R_3 (BQ5105XB NTC Calculator Tool, (SLUS629)), we determined the following values: R_1 = 400 Ω and R_3 = 10M Ω. This way, the device allows the charge of the battery process from –0.58°C to 45.4°C, being the used thermistor an NT, Serie B57371V2, which is compatible with the Qi charger and the used battery.

The chosen LDO is an LP3981IMM-3.3/NOPB from Texas Instruments, able to provide a maximum output current of 300 mA. This LDO has been chosen due to its ultra-low voltage dropout (to maximize battery capacity) (see Table 3.3).

From current consumption measurements, it is possible to observe that the maximum current will be 200 mA and the voltage dropout will be around 130 mV. This LDO has an *Enable* pin to turn the LDO regulator off. This pin

is used to disconnect the ST microprocessor during some operation modes when the nRF performs the control and management of the system.

3.3.3 The inertial sensors

According to the specifications, the system will use two accelerometers: one connected to the nRF and the other to the ST.

The chosen accelerometer is a LIS3DHTR from an STMicroelectronics manufacturer. This accelerometer has dynamically user-selectable full scales of ±2G/±4G/±8G/±16G and is capable of measuring accelerations with output data rates from 1 Hz to 5.3 kHz. The self-test capability allows the user to check the functioning of the sensor in the final application. The device may be configured to generate interrupt signals using two independent inertial wake-up/free-fall events as well as by the position of the device itself.

The LIS3DH has an integrated 32-level "first-in-first-out" (FIFO) buffer, allowing the user to store data to limit the intervention of the host processor. The LIS3DH is available in a small thin plastic land grid array (LGA) package and has a guaranteed operation over an extended temperature range (from -40 °C to +85 °C). The internal embedded registers may be accessed through both the I2C and SPI serial interfaces.

This flexibility and the rest of exhibited characteristics motivated the selection of this accelerometer for its use in this redesign:

- The automatic detection of events and the ability to generate interrupts make it an ideal option for the functionality associated with the nRF microcontroller.
- The option of using a FIFO to store data autonomously, the great variety of selectable full scales, and the possible sampling frequencies make it an ideal option for the continuous data capture to be processed by the ST microprocessor.

In addition, the possibility of using two different serial communication interfaces (I^2C or SPI), allows us to use the most convenient one, depending on the data transfer requirements.

3.3.4 The printed circuit board (PCB)

The final version of the PCB is based on the design done for the REMPARK prototype. Several modifications were introduced to guarantee the correct

Figure 3.7 Antenna connection and isolation using vias connected to ground.

functionality, reduce the production cost by setting a strict "design rules" requirement, and delete redundant or unused components. Some of the most relevant characteristics of the final industrialized PCB version are:

- The board has two layers, top and bottom. All the components have been included in the top layer to cheapen the manufacturing process in series production.
- All the power lines must have a width of 0.5 mm maximum and 0.2 mm minimum, while the signal lines cannot be wider than 0.3 mm and the preferred width is 0.2 mm.
- Vias must be 0.55 mm width in diameter with a hole of 0.2 mm minimum.
- Clearance between tracks must be 0.15 mm minimum.
- Vias have a direct connection to obtain a better distribution of the current between the top and bottom layers.
- The antenna must be isolated by a line of vias connected to the ground as the Bluetooth BLE requirements suggest (see Figure 3.7).

Another aspect to take into consideration is the isolation of the critical and vulnerable zones in the PCB, such as the crystal clocks, which oscillate to several Mhz, since the design must secure the electromagnetic isolation to not interfere the general clocks of the microcontrollers. A specific ring has been included for the improvement of the clocks' performance, as can be seen in the Figure 3.8.

The final PCB, as mentioned, has been organized into two layers, with all the components mounted in the top layer for making the assembly process cheaper. The shape of the PCB has been designed to correctly fit and adapt to the enclosure, also providing enough space for the battery. Short connection wires are used between the PCB and the battery, the coil of the charger, and the membrane button. See the final aspect in Figure 3.9.

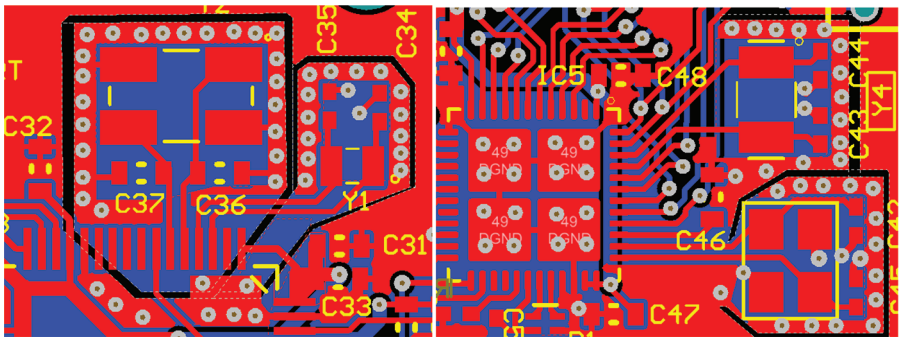


Figure 3.8 Crystal circuit rings.

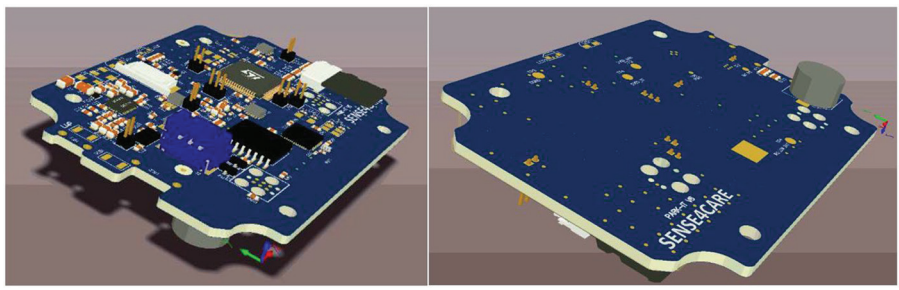


Figure 3.9 3D circuit model views.

3.4 The STAT-ON™ Firmware

As specified above, the STAT-ON™ architecture includes two different processors:

- the nRF microcontroller for the general system control and wireless communication with the external user's Smartphone device, and
- the ST microprocessor for acquiring data from the accelerometer and processing them in real-time for obtaining relevant information about the PD symptoms.

The present section describes the implemented firmware for both processors, including, the implemented protocol for data transfer between both, when required.

3.4.1 Firmware for the Nordic nRF51822

The concrete Nordic microcontroller used is the nRF51822 (nRF). To implement the required and scheduled functionality, it must manage a number of

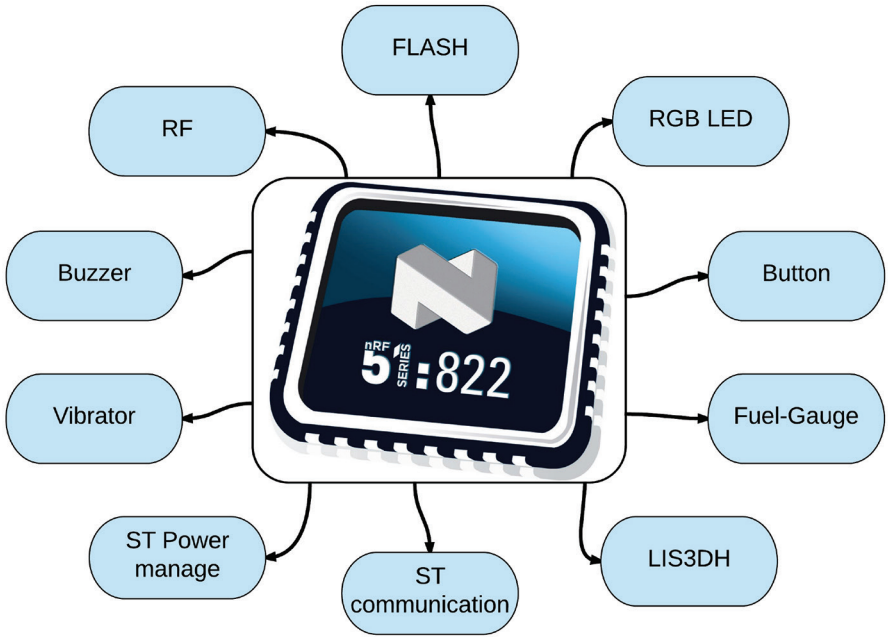


Figure 3.10 nRF51822 system with related modules.

modules (the human interface with the machine (HMI), the internal interconnection with the ST microprocessor, and the management of the Flash memory…). An overview of the nRF-related modules is shown in Figure 3.10.

A brief explanation of the purpose of each module is following:

- RF: It is the block to manage wireless communication, which in this case it is Bluetooth low energy (BLE).
- Buzzer: The buzzer is used for notifications and/or alarms to the user.
- Vibrator: The vibrator is used for notifications and/or alarms to the user.
- ST power management: The nRF is able to switch ON/OFF the ST microprocessor. This module is very useful for minimizing power consumption.
- ST communication: A protocol for serial communication, using UART, between the two microcontrollers was developed from scratch.
- LIS3DH: For the management of the used accelerometer.
- Fuel-Gauge: This module provides the possibility to be aware of the battery level in a very precise way.

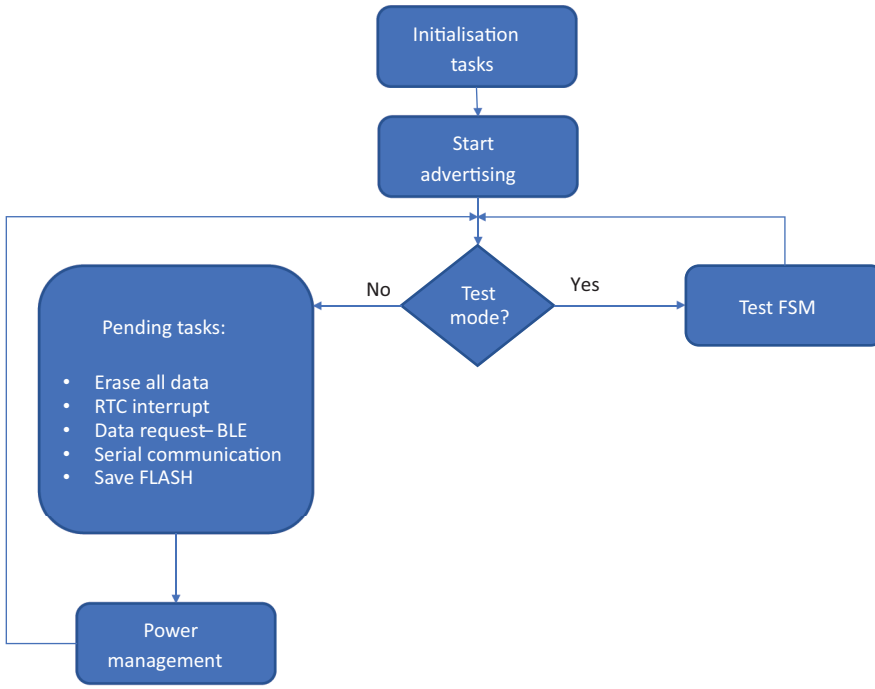


Figure 3.11 nRF firmware structure FSM.

- Button: Provides the management of the mounted button.
- RGB LED: Provides the management of an RGB LED.
- FLASH: For the management of the Flash memory.

3.4.1.1 Main structure of the nRF firmware

The nRF firmware is implemented following the structure and organization of a typical Finite State Machine (FSM), as indicated in Figure 3.11, and according to the following functionality:

Initialization Tasks Block

This block is in charge of the correct initialization of all the peripherals in the system and the correct assignment of the initial values to the variables used in the program. The different tasks executed are:

- **Clock**: It is to notify the nRF that a 32 MHz crystal is being used, start the external high-frequency crystal and wait for its stabilization.

- **Alarms**: Selection of the default mode of the alarms (vibrator and two beeps). The counter's variable for the number of beeps within an alarm is reset.
- **GPIOs**: Configuration of all the general-purpose input/output pins used in this application that are not configured on the particular initializations' blocks.
- **ST interrupt pins**: Interrupt and handling capabilities configuration of the pins used by the ST microprocessor to notify the nRF about new data or no more data. The interrupt is set every time one of these pins changes its state from low to high.
- **Flags**: Clear all the used flags.
- **Data management**: It resets the circular buffer used in the serial communication between ST and nRF microcontrollers.
- **Timers create**: Three different timers for the correct management of the Real Time Counter (RTC), the timeout of the serial communication, and the alarms are created.
- **Buttons and LEDs**: Initialization of the button and the RGB LED.
- **BLE functions**: All this functionality is provided by the manufacturer and the purpose of this task is to initialize the GATT table, the stack, and other parameters regarding the Bluetooth LE protocol and connection parameters/states.
- **Timer starts**: Only the RTC timer is started.
- **LIS3DH**: Configuration, via the serial port I2C, of the accelerometer to generate an interrupt when movement is detected.
- **Fuel-gauge**: Configuration, via I2C, of the fuel-gauge device BQ24771 for the used battery.
- **FLASH**: Initialization of the flash memory.

Start advertising block
Once the initialization process is finished, the device starts advertising via Bluetooth. This makes the device discoverable and connectable.

Test mode block
The program checks whether the device is in test mode (for technical issues) or in normal operation mode.

Pending tasks block
This block is especially useful to avoid timeouts (mainly, during BLE connection or serial communication) while executing actions that may take a significant amount of time. The tasks that may be executed inside this block or function are discussed in the following points:

Erase all data task
When a "deleting all data" request is received from Bluetooth, the pending tasks block waits until the entire Flash memory is completely erased. Therefore, no other task within this block is performed. If any other action is requested on the BLE service, the device notifies that is busy erasing the Flash and discards any request. While this task is being executed, the RGB LED is in blue color (without blinking).

RTC interrupt task
Several actions are systematically done every certain time and for correct synchronization, an RTC is used. This counter is incremented every second and is used for:

- The correct management of the alarms: it checks whether the alarms have been configured via Bluetooth or if any alarm should trigger or is ongoing.
- Battery level checking: Every 10 seconds the battery level is read from the fuel gauge.
- Average current test: Every 10 seconds the current value is read from the fuel gauge. This value is used to know whether the device is in charging state or not.

Additionally, every second the following conditions are checked:

- LED blinking:
    - If the device is connected to the Smartphone, the blue LED blinks every second.
    - If the device is assessing symptoms, the green LED blinks every second.
    - If the battery is beyond 20%, the pink LED blinks every second.
    - If the device doesn't have all the configuration parameters, the LED blinks white every second. Otherwise, the LED does not blink. Indicating that the device is in battery-saving mode.

- Serial communication blocked: When movement has been detected and the ST has been powered, the nRF microcontroller expects new data every minute or the indication that it has no more data. If the ST is woken up but there hasn't been any communication for 90 seconds, the ST is switched off. This feature has been implemented to avoid a limbo state.

Data request – BLE task
When the external Smartphone requests new data, the nRF transfers all the data from the Flash memory minute by minute.

Serial communication messages task
This task is responsible for the serial communications in the system. There are communications between the system and the App installed in the Smartphone for configuration purposes and internal communications between both microcontrollers.

- The date and time are sent to the device once the App is connected. Then, the flag indicating that there is a valid timestamp is set. Nevertheless, the timestamp will be sent only when the ST is switched on, and this happens only when movement is detected. It can be updated at any time and can be read by the App via BLE.
- The patient configuration parameters are sent after the date and time message. Some patient-specific parameters are required for the correct running of the algorithms. This information is sent and can be updated and read at any time by the App.
- The communication between both processors is very important and messages via the UART communication channel are shared:
    - **Start recording data:** The nRF microcontroller will transfer all the configuration parameters to the ST to start recording movement data and executing the algorithms. This is also used for checking that both microcontrollers have their timestamp correctly synchronized.
    - **Transfer results:** every minute, the ST will transfer the recoded data and results to the nRF, which is in charge of storing them in the internal memory.
    - Other **data transfers for debugging purposes** (Error logs, time synchronization checking).

Save FLASH information task
It is triggered every time new data has been received from the ST microprocessor and must be stored. This task updates also the Flash memory general information.

Power management block
When executing this block, the nRF microcontroller is entering in low power mode and waits for certain events to wake up. This functionality is provided by the manufacturer.

The possible events for the wake-up condition are:

- BLE events (message received, disconnection, timeout, etc.).
- LIS3DH's interrupt pin for movement detection.
- Button pressed.
- ST pin activation to notify that there's new data.
- ST pin activation to notify that there's no more data to be stored and it is ready to be switched off.
- RTC timer interrupts, occurring every second.

3.4.1.2 The Flash memory

The Flash memory is used to store all the data provided by the ST microprocessor to the nRF microcontroller and, afterward, deliver it to the mobile App. The Flash memory has been mapped in several sectors as follows:

- **Sector 0**: It contains general information (the address of the first empty slot to store new data and the address of the slot that will be delivered to the App when it would request it). Once data is requested, this last address is incremented. It also contains the current patient-specific configuration parameters.
- **Sector 1**: License-related information.
- **Sectors 2–253**: Data. This space is able to store data for nearly 1 year in a continuously saving data regime.
- **Sector 254:** Alarms information.
- **Sector 255**: Sector reserved for error logging and debugging purposes.

Once the nRF is powered up, it initializes the data structure on the Flash memory. This initialization involves:

- Read and check the manufacturer ID, device ID memory interface type, and device ID density.
- Read the first sector to update the patient-related information.

3.4.1.3 The LIS3DH accelerometer

Two specific layers (lis3dh_driver and nrf_LIS3DH) provide the programming and the proper interface with the LIS3DH accelerometer:

The lis3dh_driver

The manufacturer of this accelerometer provides a nearly complete driver. The programmer has to implement two functions: LIS3DH_ReadReg and LIS3DH_WriteReg. These are microcontroller dependent and are implemented in the following nrf_LIS3DH file. The functions allowing the setting of the internal registers ACT_THS and ACT_DUR have been specifically implemented since they were not included in the driver.

The nrf_LIS3DH file

This file provides the initialization, configuration of the LIS3DH, and interface pins. Given that the purpose of this accelerometer is to detect movement and notify the nRF, it is set in low-power mode and low-frequency measurements (10 Hz). Regarding the full scale, it is set at 8G.

Detecting movement is the main function of this accelerometer. To decide if there is movement or not, a threshold of 0.04G has been established with a duration of two consecutive readings. When movement is detected, the INT1 pin is set.

This driver also contains the functions that will be used in the test of the accelerometer, involving a new configuration and reading of new measurements.

3.4.1.4 The management of the ST microprocessor

The nRF microcontroller is in charge of the ST microprocessor management. Given the complexity, the communication between both processors is different from other peripherals. The management is done through two specific functions: ST power management and ST serial communication.

ST power management

The nRF can enable the pin in the LDO that supplies the power to the ST (see Figure 3.3). Since the ST is switched off by default, to reduce power

consumption, it is only awakened whenever the nRF-associated accelerometer detects movement.

Once awaken, it starts the communication between the ST and the nRF. After a while, when the ST sets a certain pin high to indicate that there is no more movement, the nRF cuts the supply of the ST. If by, any chance, the communication gets stuck for over 90 seconds, the ST is switched off.

ST communication management
A module that implements the protocol designed for this application has been developed from scratch. To avoid unnecessary data, the ST will not be awakened until the device has had the timestamp updated at least once and the patient leg length's value is set. In addition, if the device is being synchronized or charged, it will stop assessing symptoms.

3.4.1.5 Alarms

The alarms module allows the user to implement an alarm using three parameters:

- **Mode**: Use the buzzer, the vibrator, or both.
- **Beeps**: Select the number of beeps.
- **Millis**: Duration of the beeps and the silent period in between the beeps.

The alarm configuration by default is Buzzer, two beeps, and a duration of 150 ms. The alarms are triggered once an alarm matches the timestamp and only are executed once.

3.4.1.6 Fuel gauge

To control the battery status, the BQ27441 fuel gauge has been used, and the necessary interface software has been developed (files bq27441_driver and bq27441_fuelgauge). The first contains the functions that deploy the commands, protocol, and timings necessary to interface the BQ27441 and the other one contains the initialization of the BQ27441 and its configuration according to the battery used.

To track the battery level, it is requested by the BQ27441 every 10 seconds. If the battery level has changed, the Smartphone (if it is connected and notifications are enabled) is notified. On the other hand, every 10 seconds the average current is read from the BQ27441. This value is used to be aware that the device is being charged and therefore the ST can be switched off.

3.4.1.7 Bluetooth protocol

This device has four services implemented for the correct management of Bluetooth BLE: the Generic Access Service (generic information about the

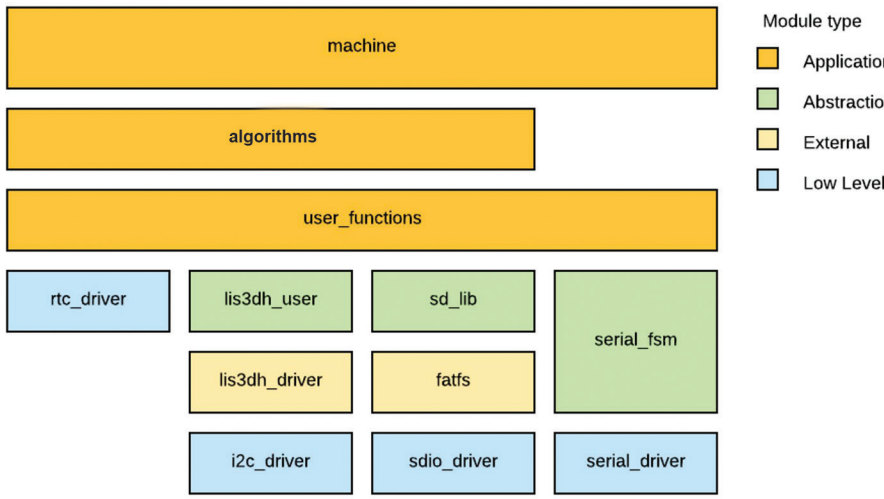


Figure 3.12 ST firmware code architecture.

device), the Generic Attribute Service (defines the GATT hierarchical data structure, the one used on BLE devices), the BAS service (the battery service to monitor its status) and the H4P (holter-for-parkinson) service, designed from scratch to accommodate the nRF to the needs of the new sensor.

3.4.2 Firmware for the STM32F415RGT6

The firmware for the ST microprocessor includes many of the algorithms already developed for the prototype obtained in the REMPARK project and have been refined according to the new structure. So, the main objective was to adapt them to the newly redesigned hardware and allow them to share algorithm results with the rest of the system (nRF microcontroller).

The firmware updating consists of adding a serial communication port to transmit processed data to the nRF and developing a driver for the newly used accelerometer (LISD3H).

3.4.2.1 Firmware code architecture

The ST firmware code architecture is organized into three different layers, as it is presented in Figure 3.12.

- The **application layer** is responsible for the execution of the final user actions. All of the actions executed in this layer shall not depend on peripheral configuration or data adaptation.

- The **abstraction layer** is used to adapt the information from low-level layers to the application layer. In this layer, a specific device setup and data adaptation are performed.
- The **low-level layer** is very dependent on the specific hardware used. Each action relies directly on the different peripherals used.

3.4.2.2 Code modules

A code module is a piece of source code focused on the implementation of certain defined functionalities. The ST firmware includes a number of them. Some modules were designed from scratch, but some others were adapted from the manufacturer's library:

- **Driver_I2C**: it handles the I2C peripheral in the system, allowing access to the accelerometer device lis3dh.
- **Driver_serial**: it provides communication with the nRF microcontroller using the USART peripheral.
- **Serial_fsm**: this module implements the defined communication protocol between ST and nRF processors.
- **lis3dh_user**: this module abstracts the use of the vendor accelerometer library to the application.
- **User_functions**: this is a set of functions used at the application level to handle all the actions that interact with the lower layers. These functions involve, for example, the SD read/write actions, the serial communication, or the accelerometer data acquisition.

3.5 Device Mechanical Design

The enclosure of the product is one of the most important elements and requires careful consideration of its design. Some generally considered characteristics are: it must offer a friendly image, must have a discreet color, and must be usable.

Additionally, it must guarantee robustness against shocks, the enclosure must protect the internal circuitry against dust and water to comply with the IP65 standard. Moreover, as it has been discussed, it must offer solutions to be able to interact with the user by means of a button.

The sensor will have two multicolor LEDs to indicate the device's state. The main specifications defined for the STAT-ON™ case are described in Table 3.4. In these specifications, the characteristics of the

Table 3.4 Electromechanical requirements.

TAG	Component	Requirements definition	Required	Casing design
1	**Case**	Overall dimension	–	90 × 63 ×
		Depth × width × heigh		21.5 mm
		IP	65	65
		Material	–	ABS
		IK	07	09
2	**Battery**	Load/charge	1 Ah	
		Overall dimensions	53 × 35 × 5	
3	**Push button**	Usage		Resistive keypad
6	**Buzzer**	Overall dimensions (mm)	Ø10 × 3	OK
7	**Vibrator**	Overall dimensions (mm)	10 × 10 × 12	OK
8	**Coil**	Overall dimensions (mm)	30 × 30× 1	OK
9	**PCB board**	Overall dimensions (mm)	73 × 51,25 × 1.65	OK
10	**Intermediate ring**	Ensure IP	IP 65	
11	**Threaded insert**	Ensure well joint		

electromechanical components, assembled in the custom plastic casing, are defined.

One of the main items to consider in the mechanical design of the plastic casing is the degree of protection against dust and water intrusion. For STAT-ON™, the level is IP65 (see Table 3.5).

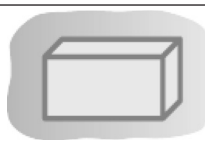
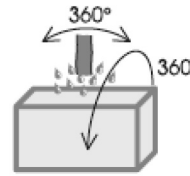
3.5.1 Components selection

According to the already defined requirements, the electromechanical components were defined as part of the redesign process. In concrete, the resistive keypad, the sealing strip, the ironmongery/inserts, and the complete housing were specified.

3.5.1.1 The resistive keypad

For the resistive keypad selection, a test with different users was carried out. Finally, the keypad with 230 μm of the gap was selected. For the adhesive paste, a stronger material has been used to guarantee the tightness of the enclosure according to the IP65 regulation. The membrane is done from polyester (0.15 mm) and the size is 80 × 13 mm^2. Figure 3.13 shows the details and the shape.

Table 3.5 The IP code for STAT-ON™ is IP65.

IP 65 First digit – Protection against solids		IP Second digit – Protection against water	
	A round body, 1.0 mm in diameter, must not be able to penetrate.		A water jet directed at the enclosure from any direction must not have any harmful effects.

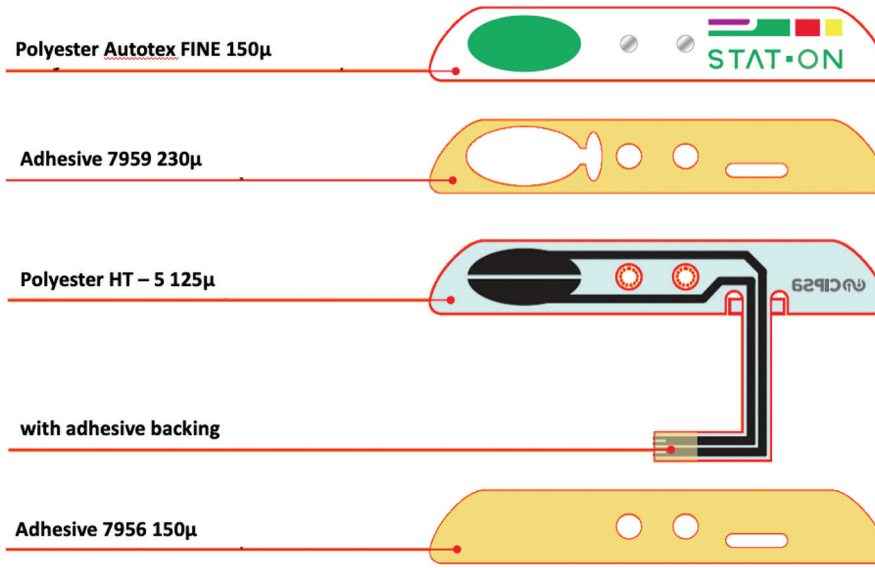


Figure 3.13 View of resistive keypad.

3.5.1.2 The sealing strip

The sealing strip must guarantee that the device is waterproof. The design of the sealing strip must fit the groove constructed in the enclosure for this purpose.

A total of five materials were tested for massive production. Two of them were made of tough silicone and were directly rejected since the enclosure was deformed when screws were inserted. The remaining three materials were: Bisco BF-1000 (white), Bisco HT-800 (black), and Bisco HT-840 (grey). The last one was also tested with glue on one of the sides for better fixation. Technicians found out that the assembly of the sealing strip with glue was uncomfortable and several times had to remove it from the enclosure since it stuck to the walls of the enclosure.

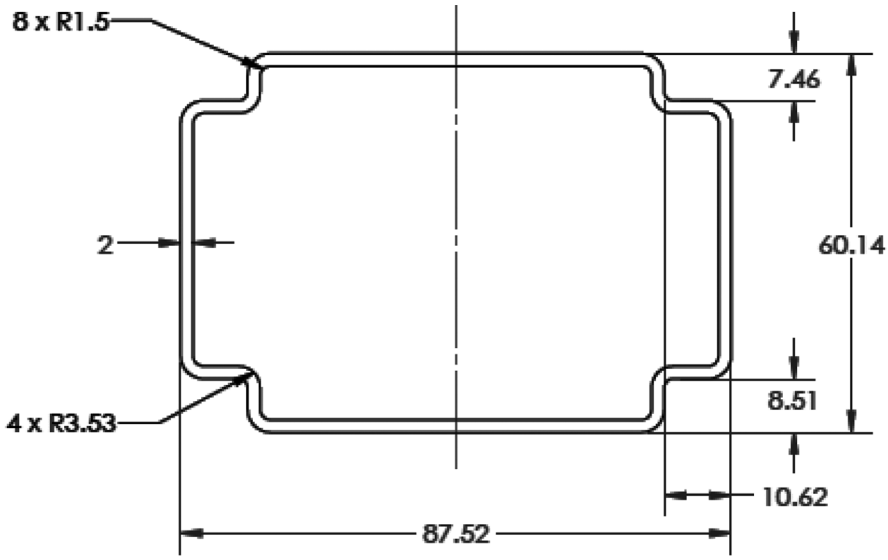


Figure 3.14 Sealing strip shape and dimensions.

Different waterproof tests were performed. Although the three materials worked fine, the most reliable was Bisco HT-840. See Figure 3.14 for shape details.

3.5.1.3 Ironmongery – Inserts

A heat installation insert was selected due to the fact that it ensures a longer useful life than the press insertion models. The selected model is used to increase resistance to torque. See Figure 3.15 for insert performance details and Table 3.6 for the details on inserts.

3.5.1.4 Housing design

With all the selected components, the housing was designed, consisting of two parts. See the initial design idea in Figure 3.16.

The main component of the enclosure is the thermoplastic polymer, called Acrylonitrile Butadiene Styrene (ABS) since it has good mechanical and impact strength, combined with ease of processing (reducing the injection costs).

This material is operable with a wide range of temperatures (-20 ºC until 80 ºC), more than enough for the purpose of this case. The wall thickness that is possible to obtain, depending on the manufacturing process finally decided, has been taken into consideration (> 1 mm if a silicone mold is used

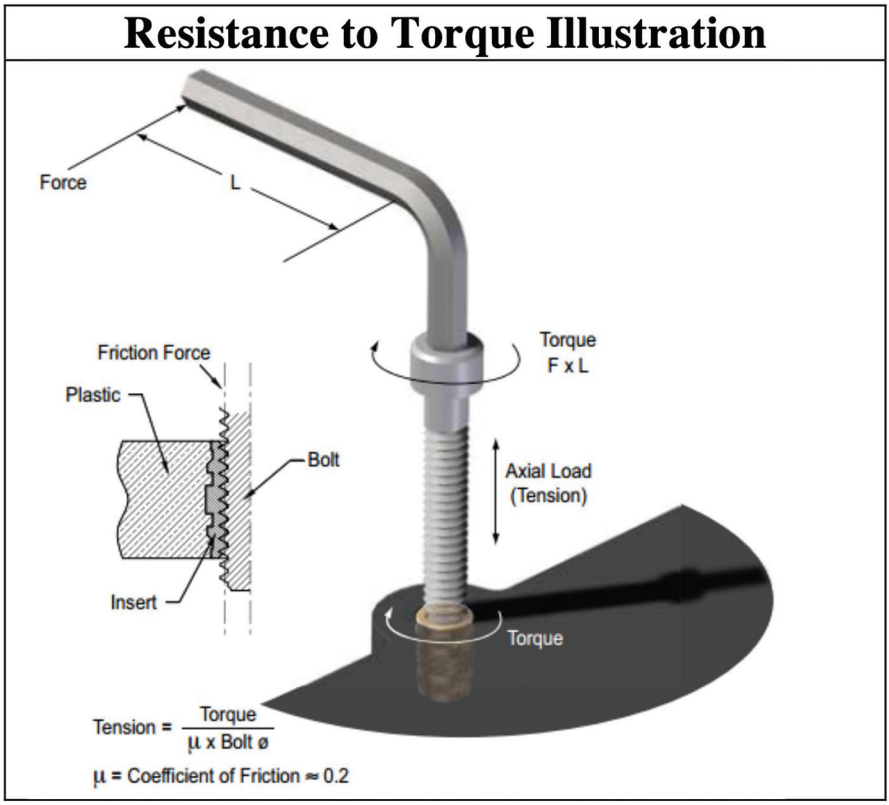


Figure 3.15 Insert performance.

Table 3.6 Inserts parameters.

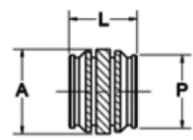
INSERTS Heat Installation	
Manufacturer/Supplier	Spirol
Model	INS 29/M2,5
Reference	150924
	
Metric size (mm)	2.5
A (mm)	4.7
P (mm)	3.9
Recommended hole (mm)	4
L (mm)	3.5

Figure 3.16 Designed housing. Initial design.

or between 1.143 and 3.556 mm if we decide on the option of injected ABS).

The final industrial design of the housing is shown in Figures 3.17 and 3.18. The surface of the device enclosure was designed, in one of its first prototypes, totally smooth. However, it has been proved that this surface type caused scratches very easily. In addition, the continuous use of the device fouled the surface in contrast to the white color resulting in a degraded image of the sensor. For that reason, a matt surface and a darker white color were finally decided.

3.5.2 Enclosure industrialization

In the previous section, the complete design of the STAT-ON™ enclosure has been presented, and is ready for industrial production. The plan was to produce several series in an aluminum mold.

Adjusting of the thickness of the plastic walls is very important to avoid problems coming from the extraction of the enclosure from the mold and the possible sudden and aggressive changes of temperatures that could severely affect the shape of the case.

Figure 3.19 shows the final enclosure, ready for its industrialization, with the final measurements. It is interesting to note that the final shape of the enclosure was maintained after the satisfactory results obtained in a usability test.

The thickness of the wall must be as uniform as possible. The part of the screws had a solid area of plastic that had to be redesigned from the original design, to remove the plastic without affecting the structure of the enclosure. Figure 3.20 shows the details of the parts allocating the screws.

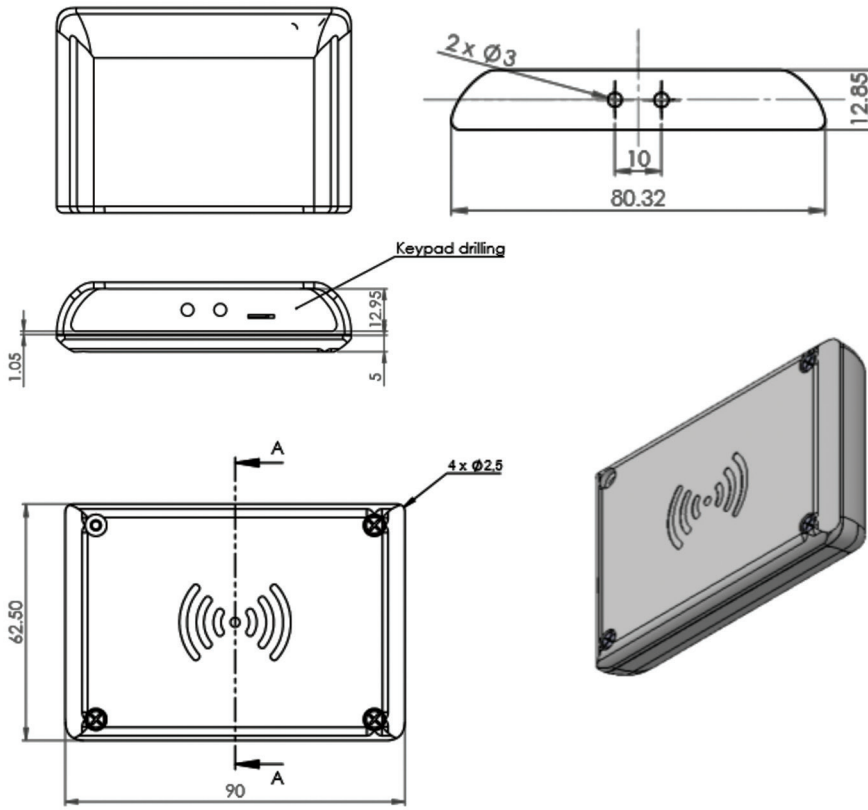


Figure 3.17 Housing overall dimensions.

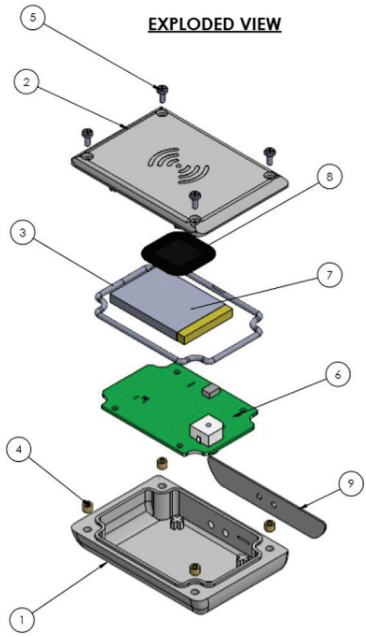
It has also been selected key points to eject the plastic of the mold with the aim of not generating irregularities on the shape of the case in the ejection phase. Figure 3.21 shows the points of ejection of the case.

Figure 3.22 shows the final industrialized enclosure for STAT-ON™ commercialized device.

3.5.3 The belt

A belt is necessary to fix the STAT-ON™ in its correct position, in the waist, and slightly displaced to the left. The belt must have a pocket for an easy insertion of the device giving access to the top bouton for its pressing, when necessary, with a velcro tap for easy fixation.

The belt is made of Polyester (94%) and elastane (6%). Its fabric allows a complete adjustment to the body while being comfortable. A hook and loop



NO. OF ELEMENTO	NAME OF ELEMENT	QUANTITY
1	PARK-IT_CASE_BASE-PART	1
2	PARK-IT_CASE_TOP-PART	1
3	PARK-IT_HOUSING_O-RING	1
4	PARK-IT_HOUSING_INSERT-	4
5	STAINLESS STEEL SCREW M2,5 X 6	4
6	PARK-IT_PCB	1
7	PARK-IT_HOUSING_BATTERY	1
8	Park-It_Coil	1
9	PARK-IT_HOUSING_RESISTIVE-KEYPAD	1

Figure 3.18 View of the different parts forming the complete housing.

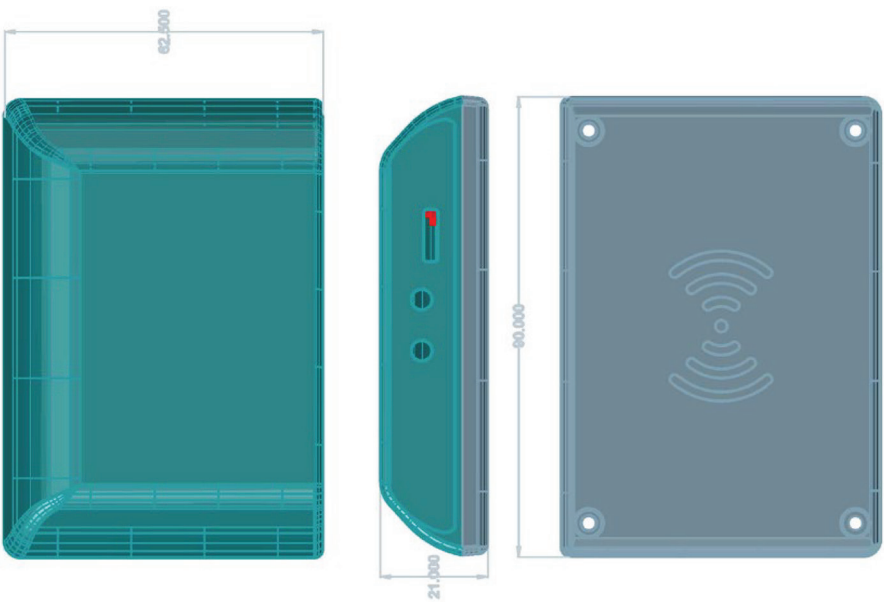


Figure 3.19 General measurements of the box.

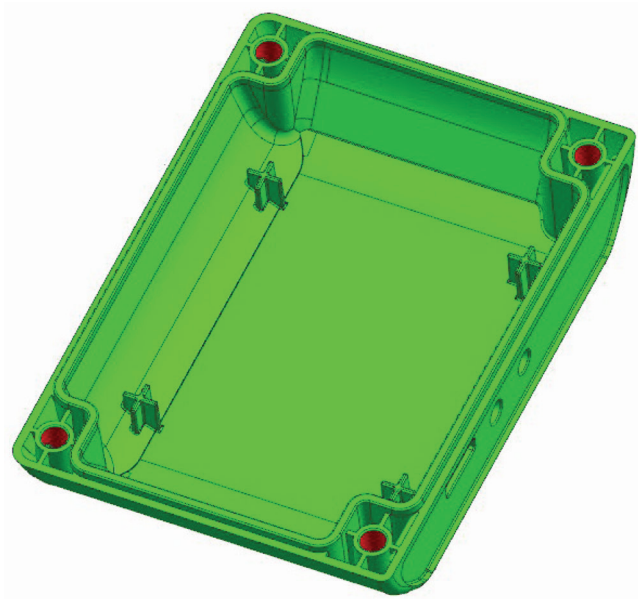


Figure 3.20 Bottom view of the enclosure showing the part of the screws.

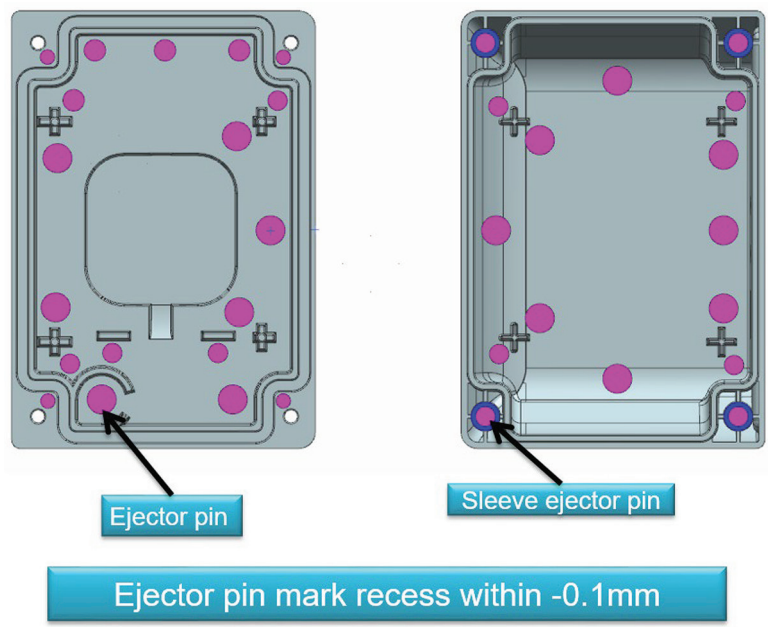


Figure 3.21 Ejection points.

Figure 3.22 Final industrialized enclosure of the STAT-ON™ device.

fastener is used to fasten the belt securely. The belt has passed the Oeko-Tex® Standard 100 tests, guaranteeing the safety of the textile and the perfect compatibility with the skin. The belt can be worn directly on the skin or above a t-shirt. Figure 3.23 shows the final industrialized belt.

3.5.4 Packaging and labeling

To commercialize and ship correctly the STAT-ON™, a specific package, containing the sensor, has been designed. The accompanying belt is packaged in a specific separated bag, since in this way, is easier to serve a sensor accompanied by several belts to a given customer.

The package has been specifically designed to fit the sensor and be optimal with the space for shipping. The design consists of three pieces (Figure 3.24):

- Base: one model open size 25.5 × 32 cm in Inverkote Mat paper of 350 g in 4+0 inks. Matte laminate on one side. Self-assembling die cut.

Figure 3.23 The belt.

- Band: one model open size 29.5 × 12.4 cm in Inverkote Mat paper of 300 g in 4+0 inks. Matte laminate on one side. Split + apply adhesive tape to one end and close.
- Nest: one model open size 19 × 16.8 cm in Inverkote Mat paper of 350 g in 4+0 inks. Matte laminate on one side. Die-cut with hole for sensor (to be inclined) and adhesive inside the base.

Figure 3.25 shows the aspect of the assembled packaging, ready for distribution. The package's total weight is 330 g and it has an eco-solvent print with matte polypropylene.

The sensor labeling must be according to the medical device regulation and contain the required data. Figure 3.26 shows the label for the STAT-ON™ in the left side and the device with its label on the right.

3.5.5 Battery charging system

The charge of the STAT-ON™ battery is done wirelessly and for this operation, a standard wireless base charger was selected, with the following main features (Figure 3.27):

- Qi-certified charging pad,
- stylish and portable design
- compatible with any Qi-enabled smartphone or device
- including Micro-USB to USB-A cable, and
- requires 2A.

The accompanying AC charger is the GSM12E05-USB, a medical AC charger that is compatible with any charger base with the presented features.

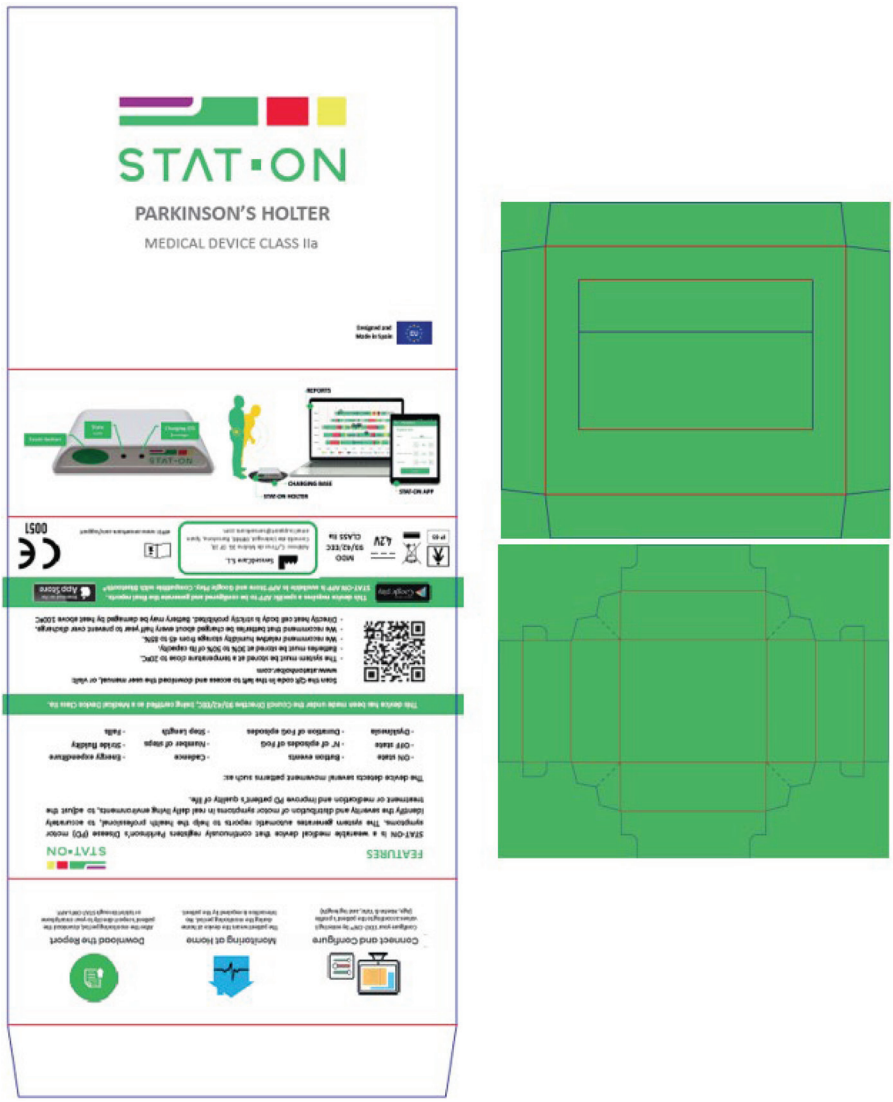


Figure 3.24 The STAT-ON™ packaging.

The AC charger can be used at home since it is compliant with the EN/ EN60601-1/ EN/EN60601-1-11.

3.6 Certification and Characteristics

The industrialized and produced final device is presented with the features specified in Table 3.7, and is certified under the standards indicated in Table 3.8:

Figure 3.25 Assembled packaging ready to go.

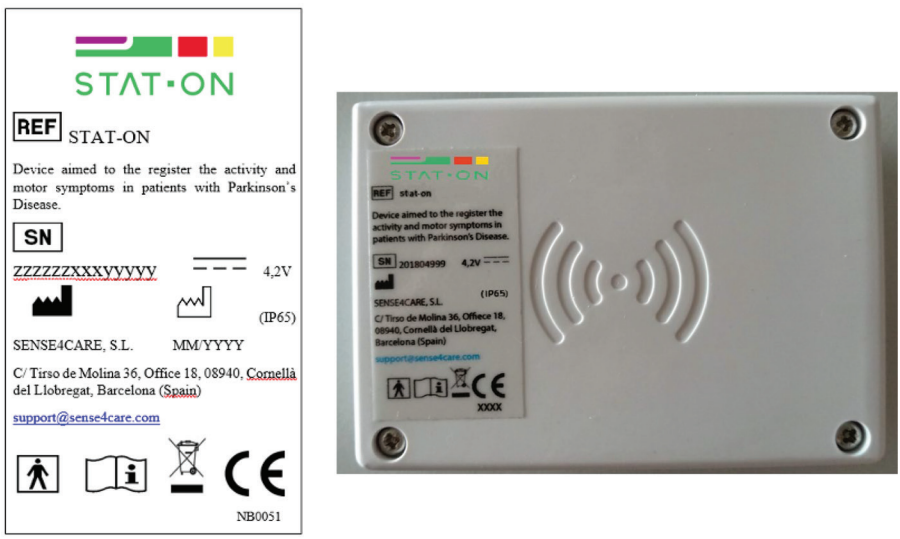


Figure 3.26 The STAT-ON™ labeling.

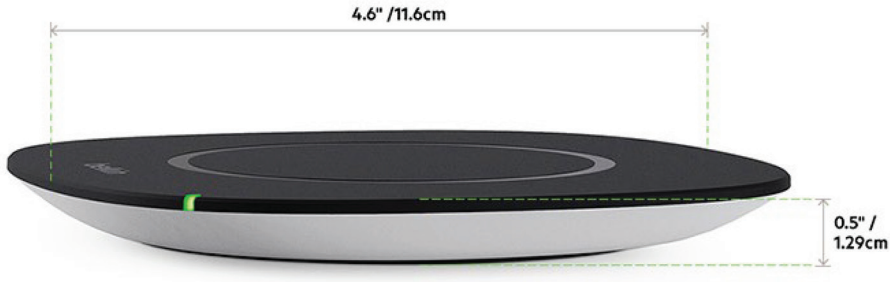


Figure 3.27 Charging pad aspect and dimensions.

3.7 Conclusions

The present chapter presented the complete redesign and industrialization process of the prototype developed in the frame of the REMPARK project [1], enabling the embedding of the complete developed algorithmic set, based on machine learning techniques.

The achieved product is STAT-ON™, a medical device Class IIa, able to act as a Holter for Parkinson's Disease, detecting and measuring, in real time, the motor symptoms associated with PD [5,6].

The redesign process of the device was based on the knowledge achieved on the REMPARK's prototype, but also considering that the device has to be assembled by a third party and must be manufactured in a series of hundreds of units when commercialized.

The cost of the manufacturing process and compliance with the regulatory standards are crucial challenges. In concrete, the mentioned PARK-IT2 project had a whole work package focused on industrialization, covering the certification and the redesign process of the device.

Very demanding specifications were raised from the redesign of the hardware to the mechanical design with the objective that the REMPARK prototype could reach the market. The change in data flow and the new user interface were major technical challenges. Throughout the process, efforts were made to follow the highest quality standards, and multiple tests were carried out, which in many cases forced long redesign processes. For these reasons, the industrialization stage of the sensor lasted for a long time of work in the different lines of the design. But all this work was worth it and STAT-ON™ was born, a sensor that, from a technical point of view, represented a great advance compared to previous models and the competitive landscape surrounding STAT-ON™, both in performance and in reliability and hardness.

Table 3.7 STAT-ON™ characteristics.

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	700 hPa to 1060 hPa
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

Table 3.8 Standards affecting STAT-ON™.

#	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. Parts 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. Parts 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. Parts 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 Harmonized 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 Harmonized 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, 6765–6795 kHz ranges;
20	EN 60601-1-11:2015 Medical electrical equipment. Parts 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.

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