Ortho-Monitorizer: A Portable Device to Monitor the Use of Upper Limb Orthoses - A Concept Proof

Raquel Gonçalves[1], Carla Quintão[1,2], Ricardo Vigário[1,2] and Cláudia Quaresma[1,2]
[1]*Departamento de Física, Faculdade de Ciências e Tecnologia, Universidade Nova de Lisboa, 2829-516 Caparica, Portugal*
[2]*LIBPhys - UNL, Faculdade de Ciências e Tecnologia, Universidade Nova de Lisboa, 2829-516 Caparica, Portugal*

Keywords: Rehabilitation, Orthoses, Monitorization, Temperature, Pressure, Compliance, Upper-limb, Wearable.

Abstract: This article presents the development of a wearable and portable system, the Ortho-Monitorizer, which allows an objective, continuous and simultaneous monitoration of the temperature and pressure exerted on the skin on the 3 main pressure points derived from the use of a hand and wrist orthosis. It also allows the monitorization of the patient's compliance to the orthosis, providing its time of use. This way, adjustments to the orthosis can be optimized, reducing the discomfort felt by the patient, increasing compliance, reducing the risk of pressure sores' formation derived from inadequate levels of pressure applied, and consequently, increasing the effectiveness of orthosis' use. Therefore, an Arduino Uno, powered by a powerbank, is used as microcontroller. Three force sensors and three temperature sensors are controlled by the microcontroller to detect the pressure and temperature. A Bluetooth Low Energy module is used to send data from the Arduino to an android application under development, which will allow healthcare professionals to consult all the information and clinical history relating to each patient, as well as allowing the patient to develop a greater awareness and sense of responsibility regarding their performance in relation to the guidelines provided by the health professional.

1 INTRODUCTION

Wrist and hand orthoses have been used in hand injury recoveries, pain relieve and prevention of muscular disorders of chronic diseases, such as Carpal Tunnel Syndrome and stroke (Tan et al., 2020).

Orthoses are support technologies that play an important role and are recurrently used. These devices are generally produced using low-temperature thermoplastics to be possible adapt them to each patient's hand and they seek to act in limiting or promoting movement, positioning anatomical structures, protecting body segments and reducing pain (Tan et al., 2020).

The use of orthoses in patients is usually encouraged to be as frequently as possible, normally for a long period of time depending on the injury. For tendon injuries is approximately 4 to 6 weeks whereas for post-stroke patients is perhaps years, for example (Tan et al., 2020).

However, currently, the study of its effectiveness is still insufficient (Pritchard et al., 2019), and it can even be said that studies in the field of rehabilitation need greater solidity, scope and a broad international consensus (Costa, 2019).

One of the main reasons of low patient's compliance is the discomfort experienced by patients, which leads to decreased effectiveness of hand and wrist orthoses and often to the formation of pressure ulcers due to prolonged exposure to inadequate pressure (Tan et al., 2020).

Thus, objective monitoring of patient adherence to orthosis, identification of pressure points and changes in tissue temperature are important areas of study and development in order to solve many of the challenges encountered in clinical practice, such as identifying and minimizing the excessive pressure exerted by the orthosis, as well as, identifying a potential tissue inflammation by a local temperature increasing. This monitoring will also allow efficient orthosis' adjustments, reducing the possible discomfort felt by the patient.

Regarding the objective monitoring of patient's compliance to orthosis, there are already some devices on the market that allow this monitoring, but none is designed for hand orthoses (Benish et al., 2012; Davies et al., 2020). Additionally, there are already some studies that try to develop pressure and/or

Gonçalves, R., Quintão, C., Vigário, R. and Quaresma, C.
Ortho-Monitorizer: A Portable Device to Monitor the Use of Upper Limb Orthoses - A Concept Proof.
DOI: 10.5220/0011012000003123
In *Proceedings of the 15th International Joint Conference on Biomedical Engineering Systems and Technologies (BIOSTEC 2022) - Volume 1: BIODEVICES*, pages 94-101
ISBN: 978-989-758-552-4; ISSN: 2184-4305

temperature monitoring devices, however there are none on the market yet (Lou et al., 2005). Nevertheless, there are studies directed to hand orthoses but only concerning pressure (Tan et al., 2020). As regards the simultaneous study of the three parameters, there are again some studies but none of them allows the monitoring of all three simultaneously on upper-limb orthoses (Lou et al., 2002; Chalmers et al., 2015; Mao et al., 2018).

Therefore, the need for this project arises, whose objective is to develop a device and an objective and simultaneous analysis methodology of all these parameters, through the coupling of pressure and temperature sensors to the orthoses. This way, it will not only be possible to monitor patient's compliance, identify risk situations through changes in pressure and temperature, but it will also allow the intervention of health professional to adapt the orthoses to the needs of each patient.

2 ORTHO-MONITORIZER

The Ortho-Monitorizer was developed in collaboration with the Department of Physical Medicine and Rehabilitation of Hospital Curry Cabral – Centro Hospitalar de Lisboa Central.

Its main objective is to allow a quantitative, continuous and simultaneous monitoring of patient's compliance to the orthosis (wearing time), as well as the pressure and temperature values associated with the use of the orthosis.

For the development of the system, several prerequisites were taken into account, namely:

- Light and compact device, to make it a wearable and comfortable device;
- Portable device with wireless and real-time data transmission, to allow a satisfactory degree of freedom to the patient while guaranteeing constant monitoring;
- Device with low consumption, to allow greater autonomy;
- Small sensors, so that when inserted in the orthosis, they do not cause discomfort or possible injuries to the patient;
- Device designed by modules, that is, the sensors could be decoupled from the rest of the circuit, to facilitate the removal of the device;
- Application with functionalities adapted to each type of user, namely, patients, therapists and administrator;
- User-friendly interfaces, to be accessible to any user.

Considering all the previous characteristics, the block diagram presented on figure 1, was designed.

It can be observed that the system is divided into two major parts: the device itself and its android application.

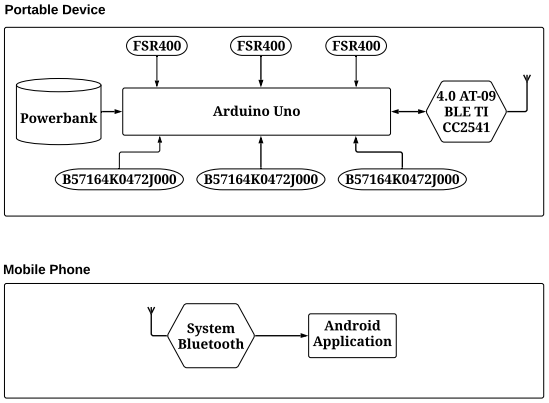


Figure 1: Block diagram of the proposed system.

2.1 Portable Device

Figure 2 shows the implemented circuit. The entire circuit is placed inside a box modelled in 3D that have the ideal dimensions and the necessary holes so that is possible to power the microcontroller using a powerbank, as well as the fitting of the sensors. The device measures 90 mm x 72 mm x 43 mm and weighs, approximately, 112.5 g. However, an industrial implementation and the use of a smaller microcontroller, such as, Arduino IOT, would enable a reduction in its size to an estimate of 49 mm x 22 mm x 30 mm.

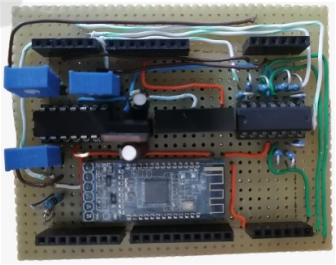


Figure 2: Circuit implementation.

2.1.1 Pressure Sensor

The occurrence of discomfort and pressure sores were conventionally considered in bony prominences, however there are other regions that are also sensitive to the high levels of applied pressure.

A study (Tan et al., 2020) sought to analyse the main critical points of discomfort or those that pre-

sented high pressure magnitudes when using a hand without thumb stabilization orthosis, and concluded that there are 3 critical points, represented in the Figure 3, namely:

- At the most prominent point of the abductor digiti minimi;
- At the distal end of ulna;
- At the distal end of radius and near the anatomic snuffbox.

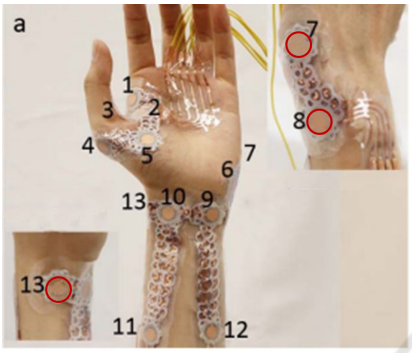


Figure 3: Three main critical points: (7) the most prominent point of the abductor digiti minimi; (8) the distal end of ulna; (13) distal end of radius and near the anatomic snuffbox. Adapted from (Tan et al., 2020).

According to this study, the sensors should cover the range of values between 0.02 MPa to 0.078 MPa.

After searching the market for a sensor with dimensions and cost suitable for the intended purpose, it was concluded that the FSR-400 sensor would be a good candidate.

The FSR-400's active area is a circle and its area is 20.26 mm^2.

As it was mentioned the intensity of minimum pressure P_{min} applied on the skin should be 0.02 MPa, i.e. 0.02 N/mm^2. Thus, the minimum force F_{min} that FSR400 should measure is 0.4 N.

Likewise, the intensity of maximum pressure P_{max} and maximum force F_{max} that will be applied on FSR400 are 0.078 N/mm^2 and 1.58 N, respectively.

Since, the range of force sensor FSR400 is 0.1 N - 20 N, it is suitable for this purpose. The FSR's features are provided in Table 1.

To implement the FSRs, a current-to-voltage converter circuit was used. The implementation circuit of one single FSR is shown in Figure 4.

In this circuit the sensor is the input of the current-to-voltage converter and its supply voltage is -5 V.

The op-amp LM324N must be able to swing below ground, from 0 V to 5 V, therefore dual sided supplies are necessary.

The criteria for choosing R_{13} was to maximize sensor's accuracy according to the defined range of

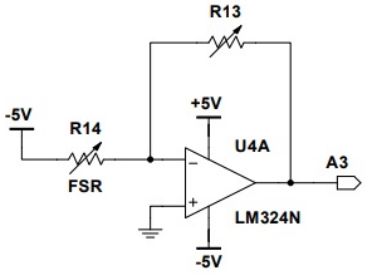


Figure 4: The circuit diagram of a current to voltage converter that was used for a single FSR Sensor.

values (0.4 N – 1.58 N). Thus, $R_{13} = 2150\ \Omega$.

The relation between output voltage V_{Out} and the value read by Arduino's ADC (V_A) is given by:

$$V_{Out} = \frac{5 \times V_A}{1023} \quad (1)$$

By replacing the V_{Out} value in the constructed calibration curve, the pressure value is obtained.

This calibration curve was previously constructed by collecting the voltage values from the Arduino, when placing progressively various weights on the active area of the sensor.

Table 1: Pressure Sensor Parameters.

Manufacturer	Interlink Electronics
Model	FSR-400
Force Sensitivity Range	0.1 - 20 N
Diameter	7.62 mm
Active Area	5.08 mm
Nominal Thickness	0.3 mm
Temp Operating Range	-30 ºC to +70 ºC (Recommended)
Number of Actuations (Life time)	10 Million tested, Without failure

2.1.2 Temperature Sensor

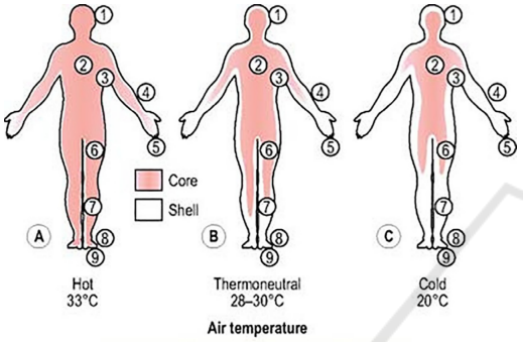
The normal human skin temperature on the trunk is 36-37 °C, however, since blood circulation is faster near the heart than in other parts of the body, the trunk's skin temperature is always higher than the skin temperature of the limbs, being lower, namely on protruding and markedly curved parts, such as the fingers (Bierman, 1936).

The temperature of the surface of the skin varies with the temperature of the body and with conditions in the skin and in the structures lying beneath. It also shows large fluctuations when the body is exposed to changes in environmental temperatures (Childs, 2018). In Figure 5, there are the skin surface temperatures at nine body sites in hot (A: 33 °C) ther-

moneutral (B: 28–30 °C), and cool (C: 20 °C) ambient conditions (Childs, 2018).

From the table provided by Figure 5, although they correspond to values from a sample that may not represent the general population, it shows that the temperature of the fingers can vary from 21.0 ºC in cold environments to 35.9 ºC in hot environments, similarly, the arm can vary from 27.6 ºC and 35.9 ºC, in cold and hot environments, respectively.

Thus, it is possible to realize that the choice of temperature sensors that will measure the temperature of the skin of the upper limb should cover, at least, the range of values from 21 °C to 36°C.



	Site	A (°C)	B (°C)	C (°C)
1	Scalp	36.0	34.8	32.8
2	Chest	35.8	34.5	31.3
3	Axilla	36.5	36.4	36.4
4	Arm	35.9	33.5	27.6
5	Finger	35.9	33.2	21.0
6	Thigh	35.2	33.4	27.8
7	Leg	35.3	30.1	25.2
8	Foot	35.5	29.7	22.7
9	Toe	36.2	29.1	21.4

Figure 5: Distribution of temperatures within the human body into core and shell during exposure to cold, thermoneutral and warm environments (Childs, 2018).

The most common temperature sensors are ICs, RTDs, thermocouples and thermistors.

These represent contact sensors that measure the average temperature between the sensor and the skin surface.

Considering the characteristics presented in Table 2, it appears that all types of sensors have value ranges that include the values needed to be measured.

However, a good precision is important, since there is a need to detect small temperature variations at the points where we will measure the temperature.

Table 2: Comparing temperature sensing technologies. Adapted from (Texas Instruments, 2019).

	IC Sensors	Thermistors	RTDs	Thermocouples
Range	-55 ºC to 200 ºC	-100 ºC to 500 ºC	-240 ºC to 600 ºC	-260 ºC to 2,300 ºC
Accuracy	Good/Best	Calibration-dependent	Best	Better
Size	Smallest	Small	Moderate	Large
Complexity	Easy	Moderate	Complex	Complex
Linearity	Best	Low	Best	Better
Price	Low to moderate	Low to moderate	Expensive	Expensive

For this reason, due to its accuracy, price and size, both ICs and thermistors would be good options.

For this reason, B57164K0472J000 thermistors were implemented since they were available in the laboratory, the size was adequate, they had a range of values that allows measuring the desired values, they were low cost, easy to implement and already had a calibration curve that facilitated the conversion of the obtained values to temperature values. The thermistors' features are presented in Table 3.

Table 3: Temperature Sensor Parameters.

Manufacturer	EPCOS/TDK
Product Category	NTC Thermistors
Operating Temperature	-55 ºC to +125 ºC
Diameter	5.5 mm
Length	2 mm
Width	5 mm

A voltage divider converter circuit followed by a 1.5x amplification circuit was used to implement the temperature sensors. The implementation circuit of one single B57164K0472J000 thermistor is shown in Figure 6.

The amplification circuit was used to achieve the desired accuracy (0.2 °C).

The relation between output voltage V_{Out} and the value read by Arduino's ADC (V_A) is given by:

$$V_{Out} = \frac{5 \times V_A}{1023 \times 1.5} \quad (2)$$

Then, it is possible to obtain the value of thermistor resistance R using the voltage divider expression:

$$R = R2 \times \frac{5}{V_{Out} - 1} \quad (3)$$

The calibration curve was constructed from the resistance values for each temperature, given by the manufacturer, followed by the adjustment of a exponential curve in order to obtain its equation.

By replacing the R in the previously constructed calibration curve the temperature value is obtained.

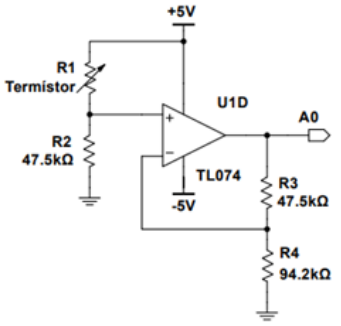


Figure 6: The circuit diagram of the voltage divider for a single B57164K0472J000 thermistor.

2.1.3 Power Supply

Several circuits were implemented in order to optimize the accuracy of the sensors. Even single supply circuits were tested to try to reduce the power supply complexity. However, through the use of a dual supply better results were found. Once Arduino is only capable of providing positive voltage, a voltage regulator and conversor were used to produce the required negative voltage value. The power supply circuit used is presented on figure 7.

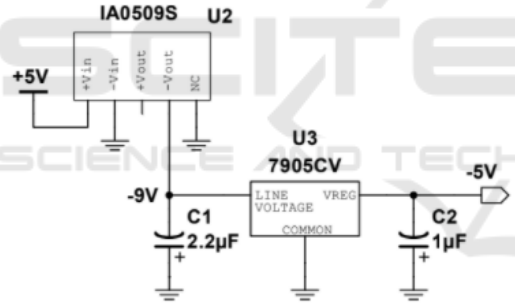


Figure 7: Power supply circuitry.

2.1.4 Wireless Communication

Wireless communication techniques are required to transfer the data acquired by the sensors to the android application.

There are several wireless technologies, and the characteristics of the main wireless communication technologies used in wearable devices are presented in Table 4.

Ideally, a low-cost, low energy-consuming and with a high level of security was sought, since the objective will be the transmission of patient clinical data, .

It is also intended a wide range of communication, which allows a satisfactory degree of freedom to the patient while ensuring constant monitoring. Considering the above characteristics, there is a preferential selection for *ZigBee*, 2.4G *Wireless* and *Bluetooth*.

It was decided to use a Bluetooth module, since it is the communication where there was a greater degree of familiarity. However, due to its consumption, a Bluetooth Low Energy (BLE) module was chosen because it has significantly lower consumption.

The module used was the 4.0 AT-09 BLE TI CC2541 and its features are presented in Table 5.

Table 5: BLE Module Parameters.

Input Voltage	3.3 V/ 5 V
Power consumption	8.5 mA (Transfer)
	90 μA $\sim$ μA (Sleep mode)
Coverage up to 60 m	

2.2 Android Application

Ortho-Monitorizer also has an application that is under development.

The main goal of this application is to allow healthcare professionals to consult easily all the in-

Table 4: Main wireless communication technologies' characteristics. Adapted from (Yu et al., 2016).

	ZigBee	**Bluetooth**	**UWB**	**Wi-Fi**	**NFC**
Price	Low	Low	Moderate	Moderate	Low
Safety	High	High	High	Low	Very-High
Data rate (max)	250 Kb/s	3 Mb/s	480 Mb/s	54 Mb/s	420 Mb/s
Max range	75 m	10 m	10 m	100 m	20 cm
Frequency	2.4 GHz 915 MHz (America) 868 MHz (Europe)	2.4 GHz	3.1 GHz - 10.6 GHz	2.4/5 GHz	13.56 MHz
Power Consumption	30 mW	2.5 - 100 mW	30 mW	1W	Low
IEE Standard	IEEE 802.15.4	IEEE 802.15.1x	IEEE 802.15.4a	IEEE 802.11	ISO/IEC 18092
Diffraction penetrating barriers	Not good	Not good	Not good	Not very good	Not good

formation and clinical history relating to each patient, as well as allowing the patient to develop a greater awareness and sense of responsibility regarding their performance in relation to the guidelines provided by the health professional.

The interfaces of this application are simple and intuitive to facilitate its use by any user.

The application has 3 types of users, namely, patients, therapists and administrators, and each of these types have access to different functionalities adapted to their needs.

When starting the application, the user will need to register, being able to register either as a patient or as a therapist. However, if the user registers as a therapist, he will need to be authenticated by the administrator to get access to therapist functionalities.

Regarding the features of each type of user:

- Pacient: Able to change his personal information, have access to instructions for use and cleaning of orthosis and also receive alerts derived from inadequate pressure and temperature values.
- Therapist: Able to change his personal information and has access to all patients data including the info about the injury, the orthosis applied and clinical history.
- Administrator: Has all the functionalities of the therapist, but is still able to manage the functionalities of all health professionals registered in the application. It means that he can provide or remove access to functionalities of therapists or even administrator.

The application is linked to a database, so that the storage of user's data and clinical data, as well as their consultation, are possible.

In addition, the application receives pressure and temperature data from the portable device, via Bluetooth, and is primarily responsible for its processing and for displaying some graphics.

These charts will facilitate the analysis of each patient's clinical history by the responsible therapist, because it will allow the therapist to easily see in which days there were inadequate values of applied pressure and temperature, as well as verifying patient's compliance.

2.3 Measured Results

In order to show the results and the performance of the portable device, data was collected for a period of 30 minutes in a volunteer.

Figure 8 shows the experimental setup used for data acquisition.

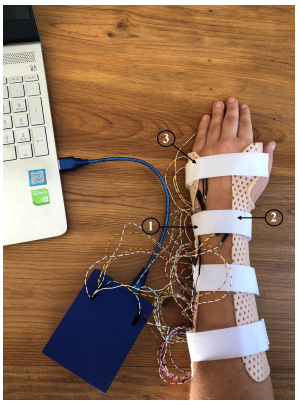


Figure 8: Experimental setup and implementation of the whole prototype. Pressure and temperature values were obtained at the end of ulna (1), at the distal end of radius and near the anatomic snuffbox (2) and at the most prominent point of the abductor digiti minimi (3).

Although the graphical appearance is not yet what it will look like in the end, the pressure and temperature graphs were obtained, which are shown in Figure 9 and 10, respectively.

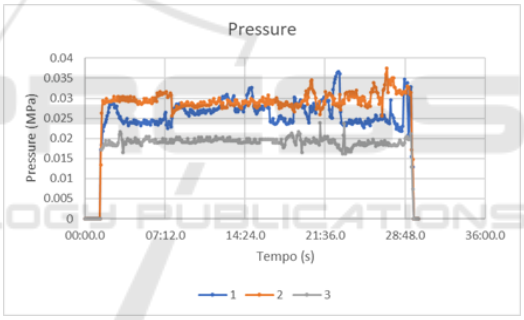


Figure 9: Pressure values obtained during 30 minutes at the distal end of ulna (1), at the distal end of radius and near the anatomic snuffbox (2) and at the most prominent point of the abductor digiti minimi (3).

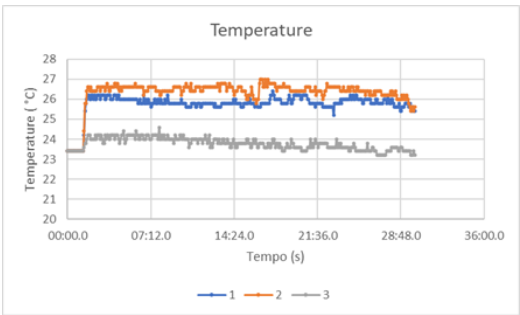


Figure 10: Temperature values obtained during 30 minutes at the distal end of ulna (1), at the distal end of radius and near the anatomic snuffbox (2) and at the most prominent point of the abductor digiti minimi (3).

From the results expressed in both graphs it is possible to see that both the pressure and temperature values are within the expected values according to the study carried out by X. Tan (Tan et al., 2020).

Observing the graphs, it can also be seen that at the pressure graphic, time series 1 showed the greatest variations in pressure values, which can be explained because it corresponds to a place where there is more movement. This is observable at a quantitative level, since by looking at the standard deviations (SD) of each time series (from 1 to 3) (0.026 ± 0.003 MPa), (0.029 ± 0.002 MPa) and (0.019 ± 0.001 MPa), we conclude that the first one shows the biggest SD.

Regarding temperature, it can be observed that time series 1 and 2 have relatively close temperature values, whereas the values of time series 3 are significantly lower than the previous ones. The qualitative results are supported by the mean and SD of temperature values, (25.9 ± 0.2 °C), (26.5 ± 0.3 °C), (23.8 ± 0.3 °C), from 1 to 3 time series, respectively. This can be justified by the fact that the sensor on the abductor digiti minimum is near to the end of the upper limb, and consequently more exposed to environmental temperature, while the others, in addition to being further away from the upper-limb end, were also relatively covered by the patient's sweatshirt.

A slight temperature decrease over time can be also detected in time series 3 since when the hand was still, it started to cool off, tending its temperature to the value of the environmental temperature ($\approx$ 23 ºC).

Through a continuous analysis of the pressure and the temperature it will be possible to detect inadequate values of pressure and variation of temperature values which may indicate inflammation on the tissues. The combination of the analysis of both types of sensors will allow a more accurate assessment of patient's compliance.

These results prove that the equipment is functional, demonstrating that the prototype is viable to be tested in real situations.

3 CONCLUSIONS AND FUTURE WORK

This article presents a portable system capable of objectively, continuously and simultaneously doing the monitorization of pressure and temperature values. Through the processing of these data, it will also allow monitoring the patient's compliance, that is, its time of use. The portable device can be adapted to monitor these parameters in other types of orthotics.

Regarding the application, it is in the development stage, and at this moment its graphic appearance and user interface are being improved.

After concluding the development of the application, the next step will be to apply the device in real situations.

By using this approach, the device will allow a greater and better monitoring of the treatment, as well as reducing discomfort and the formation of pressure sore, since it will not only allow improving adjustments in the preparation of the orthosis, but also the detection of risky situations.

In addition, it will also make possible to store and manage the patient's clinical history, in order to facilitate and assist health professionals, as well as allowing the patient to develop a greater awareness and sense of responsibility regarding their performance in relation to the guidelines provided by the health professional.

ACKNOWLEDGEMENTS

The authors would like to thank all the healthcare professionals of Hospital Curry Cabral - Centro Hospitalar Lisboa Central.

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