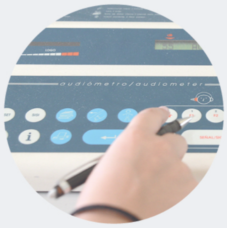
INSTITUTO SUPERIOR DE ENGENHARIA DO PORTO

MESTRADO EM ENGENHARIA BIOMÉDICA



Sistema de apoio ao diagnóstico de sobrecargas plantares

JOÃO VÍTOR DA SILVA COELHO

Outubro de 2021

Plantar Overload Diagnostic Support System

João Vítor da Silva Coelho

Dissertation presented at the Polytechnic of Porto - School of Engineering to obtain the Master's degree in Biomedical Engineering

Scientific guidance: Luiz Faria, Constantino Martins

October, 2021

Acknowledgement

I start by thanking my family, especially my parents and sister, for all the support they gave me in the most difficult moments and for giving me the opportunity to continue studying.

To my girlfriend Ana Ferreira, for always accompanying me and being available in good and bad moments during this master's course.

To Polytechnic of Porto - School of Engineering, for all the formation received.

To the engineers Luiz Faria and Constantino Martins, my advisors, for the support and availability in the guidance of this dissertation.

To all the team involved in the SMART-HEALTH-4-ALL project.

To all my friends and colleagues in the course, who were always present and gave me strength in the moments that I needed the most.

To all who directly or indirectly helped me in this journey.

To all of you, my sincere gratitude.

Abstract

Diabetes Mellitus (DM) is a chronic disease that impacts the quality of life of individuals of various age groups, being listed among the 10 leading causes of death in adults. Associated with this disease are diabetic foot ulcers, which cause a reduction in the patient's mobility, quality of life and even amputation of the affected limb.

In order to prevent this situation, the study in question aims to develop a mobile application to monitor the patient's gait.

The gait data will be collected from a sensorised insole with pressure, temperature, and humidity sensors, with its subsequent analysis and real-time provision of warnings if situations conducive to the formation of a foot ulcer are found.

As this insole has not yet been developed, a second mobile application was created to send data replicating several phases of the human gait.

In addition, a web application was developed for healthcare professionals, where they can access the patient's personal data as well as various types of statistics associated with their gait, helping the professional to make decisions regarding the improvements that can be made regarding the way the patient performs the gait.

All applications were properly tested and proved to be responsive on different devices, environments, and operating system versions. Throughout the development process, it was possible to observe that they will help the healthcare professional to detect more easily patterns in the patient's gait and will alert the patient to the need to change the way he supports the foot, with the provision of information in real time.

In order to continue this study, it is hoped in the future to link this system with a clinical record repository, to create a learning algorithm that can use other parameters besides the reading records to create alerts, and finally, it would be useful to develop the application for the IOS operating system.

Keywords: Technology, mobile applications, web applications, *Diabetes Mellitus*, diabetic foot ulcers, mHealth

Resumo

A Diabetes Mellitus (DM) é uma doença crónica que tem impacto na qualidade de vida de indivíduos de vários grupos etários, estando listada entre as 10 principais causas de morte em adultos. Associadas a esta doença, estão as úlceras do pé diabético, que causam uma redução da mobilidade do paciente, da qualidade de vida e até mesmo a amputação do membro afetado.

Com o objetivo de prevenir esta situação, o estudo em questão visa desenvolver uma aplicação móvel para monitorizar a marcha do paciente.

Os dados da marcha serão recolhidos a partir de uma palmilha sensorizada com sensores de pressão, temperatura e humidade, com a sua posterior análise, e fornecimento, em tempo real, de alertas no caso de serem encontradas situações propícias para a formação de uma úlcera no pé.

Como esta palmilha ainda não foi desenvolvida, foi criada uma segunda aplicação móvel para enviar dados que replicam várias fases da marcha humana.

Além disso, foi desenvolvida uma aplicação Web para profissionais de saúde, onde podem ter acesso aos dados pessoais do paciente, bem como vários tipos de estatísticas associadas à sua marcha, ajudando o profissional a tomar decisões relativamente às melhorias que podem ser feitas em relação à forma de como o paciente executa a marcha.

Todas as aplicações foram devidamente testadas e mostraram-se responsivas em diferentes dispositivos, ambientes e versões de sistema operativo. Ao longo do processo de desenvolvimento, foi possível observar que estas ajudarão o profissional de saúde a detetar mais facilmente padrões na marcha do paciente, e alertarão o mesmo para a necessidade de mudar a forma como apoia o pé, com o fornecimento de informação em tempo real.

De forma a dar continuidade a este estudo, espera-se no futuro interligar este sistema com um repositório de registos clínicos, criar um algoritmo de aprendizagem que possa utilizar outros parâmetros para além dos registos de leituras para criar alertas, e, finalmente, seria útil desenvolver a aplicação para o sistema operativo IOS.

Palavras-chave: Tecnologia, aplicações móveis, aplicações web, *Diabetes Mellitus*, úlceras do pé diabético, mHealth

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List of Abbreviations

API – Application Programming Interface

APP – Application

BMI – Body Mass Index

CART – Classification and Regression Tree

CCCD – Client Characteristics Descriptor

CDA – Clinical Document Architecture

CRUD – Create, Read, Update, and Delete

CSS – Cascading Style Sheets

DCNN – Deep Convolution Neural Networks

DFA – Detrended Fluctuation Analysis

DGS – Directorate General of Health

DM – Diabetes Mellitus

FHIR – Fast Healthcare Interoperability Resources

GRF – Ground Reaction Forces

HATEOAS – Hypertext as the Engine of Application State

HbA1c – glycated hemoglobin

HCA – Hierarchical Cluster Analysis

HCP – Health Cluster Portugal

HIS – Health Information Systems

HL7 – Health Level Seven

HTML – HyperText Markup Language

HTTP – Hypertext Transfer Protocol

ICA – Independent Component Analysis

IDE – Integrated Development Environment

IHE – Integrating the Healthcare Enterprise

ISO – International Organization for Standardization

IT – Information Technology

JSON – JavaScript Object Notation

KPCA – Kernel Principle Component Analysis

LDA – Linear Discriminant Analysis

MAC – Media Access Control

mHealth – mobile Health

MLE – Maximum Lyapunov Exponent

MR – Maximum-Revelance

NHS – National Health Service

OS – Operating System

OSI – Open Systems Interconnection

PCA – Principal Component Analysis

PPCA – Probabilistic Principle Component Analysis

PU – Pressure Ulcer

RAM – Random Access Memory

REST – Representational State Transfer

RFCOMM – Radio Frequency Communication

RIM – Reference Information Model

SDK – Software Development Kit

SDO – Standard Development Organizations

SDP – Service Discovery Protocol

SVM – Support Vector Machine

URI – Uniform Resources Identifier

URL – Uniform Resource Locator

UUID – Universally Unique Identifier

XML – Extensible Markup Language

CHAPTER 1 – INTRODUCTION

1. Introduction

This chapter aims to contextualize the theme of this dissertation, to define the main objectives associated with the work entitled "Plantar overload diagnostic support system", to present the structure in which this thesis is divided and the content of each chapter.

Additionally, the contributions of the study to the field of medical informatics and to the SMART-HEALTH-4-ALL project are listed, and the research methodology used is described.

1.1. Contextualization and motivation

Diabetes Mellitus (DM) is a metabolic disorder, with a major impact on the life and well-being of individuals, families, and societies around the world. It is among the top 10 causes of death in adults and is estimated to have caused 4.2 million deaths worldwide in 2019, in adults aged 20 to 79 years, equivalent to 1 death every 8 seconds. Its prevalence in the same year was about 9.3% (463 million people), and it is estimated to rise to 10.2% (578 million) in 2030 and 10.9% (700 million) in 2045. In 2019, Portugal was the second European country with the highest prevalence of diabetic patients [1].

Diabetic foot is a serious chronic diabetic complication consisting of deep tissue lesions associated with peripheral neurological and vascular diseases of the lower limbs. Among all amputations in diabetic patients, 85% are preceded by a foot ulceration that deteriorates after a severe gangrene or infection [2].

Foot ulcers are the main cause of hospitalization, amputation, reduced mobility, loss of social participation and lower quality of life in people with diabetes, and are caused by repetitive stress under an area subject to high shear stress or vertical force in patients with peripheral neuropathy. It is estimated that up to 34% of all people with diabetes have a foot ulcer during their life [3], [4].

The best form of prevention is to monitor the patient's plantar pressure, since critical areas, or areas with higher pressure, are more prone to pressure ulcers.

As the current risk scales for ulcer development used by healthcare professionals are dependent on their possible subjectivity or the veracity of the patient's report, it is necessary to create a system that monitors, analyses walking data and provides statistics that allow healthcare professionals to overcome the barriers described above.

In addition, these statistics should be able to provide information and patterns that, with the naked eye, the health professional cannot perceive. Thus, to meet these needs, My Care Shoe was created.

1.2. Objectives

The context of this work presupposes a set of information acquired through a piece of equipment that will still be under development within the SMART-HEALTH-4-ALL project, promoted by the Health Cluster Portugal (HCP).

Thus, the main objective of this study is the development of a mobile application targeting patients, which will receive data regarding pressure, humidity and temperature recorded in each foot, and will analyze them in order to create useful statistics and warnings.

These data are displayed to the patient in real time, and whenever hyperpressure records are verified, the application will generate a warning, which will allow the user to know that he needs to change the way he walks and will later allow the healthcare professional to identify and treat this anomaly with greater precision.

In order to achieve the general objective described above, the following specific objectives were required:

- Research into subjects convenient for the understanding of the various subjects covered, such as foot anatomy, gait cycle and types of foot movements. Other subjects such as interoperability in health and learning algorithms are explored, as it is a future goal to design an interconnection of the system with a clinical record repository, as well as to conceive a model for analyzing the collected data together with personal information;

- Survey of the state of the art of mobile applications used to detect and assess ulcers, as well as risk scales used to assess them;
- Design and implementation of a mobile application capable of collecting the data sent, processing and displaying it to the patient. The processing of these data will include the calculation of the number of steps, cadence, pace, stance time on each foot and warnings. This application will display the patient's personal data, which can be changed by the patient, as well as the statistics regarding the gait in a time interval;
- Design and development of a mobile application that will send data aiming to simulate the behavior of the microcontroller, which will be responsible for collecting and sending these data in the future. Each message sent by this application will represent a phase of the gait, and will enable further tests regarding the functionalities of reading, processing and presentation of the data by the application used by the patient;
- Design and implementation of a web application intended mainly for health professional profiles, so that it will be possible to access the patient list, view and change personal information, change the parameters used in the algorithm for the creation of warnings and access statistics regarding the data generated by patient walking. This application is also targeted at administrators, who will be able to assign profiles to users, and manage their access permissions;
- Test and validate the mobile and web application with functional, compatibility and performance tests.

1.3. Contribution

This study contributed to the SMART-HEALTH-4-ALL project, as through this it will be possible to perform a future integration with its sensing system, and tests in situations that represent the daily life of the target users.

The main contribution involved the creation of mobile and web applications, with the objectives described above, and with the requirements previously discussed with the researchers that constitute this project. The mobile application is supported on all Android devices running from version 7 (Application Programming Interface (API) level 24) and above to the most recent one.

With the development of this system with the various applications, this study contributes to medical informatics, in the sense that it presents a useful tool that allows preventing the appearance of diabetic foot ulcers based on the data collected by a sensorised insole, instead of using the common scales of risk of ulcer appearance, which may depend on the veracity of the statements of the patient in question. The algorithms present in the mobile application use the information from the pressure sensors, and through them it calculates several types of variables associated to human gait, and identifies the gait phase in which the user is.

Furthermore, this study constitutes a basis for future developments in this context, combining for example the algorithms developed with upgrades, such as learning algorithms, and interconnecting the system with a real repository of clinical records.

1.4.Research Methodology

This research was carried out in a step-by-step manner, based on the Action Research methodology [5].

This methodology, represented in **Error! Reference source not found.**, consists of proving whether the solution solves the problem, producing highly relevant research results because it is based on practical actions.

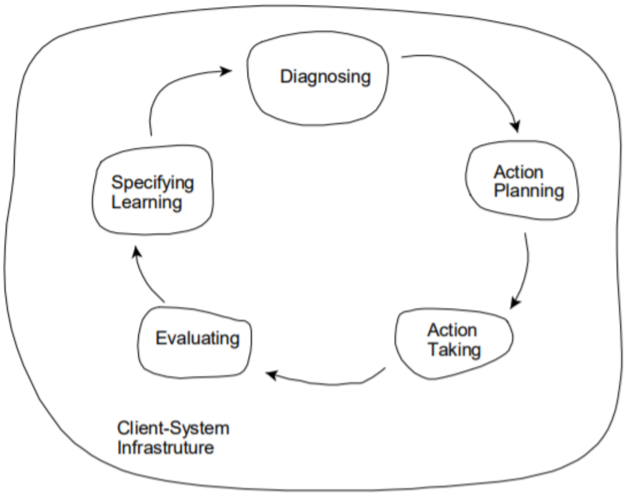

Figure 1.1 - The Action Research Cycle [5]

This approach suggests a cyclical process composed of five steps executed in a given context, also called client-system infrastructure [5]:

- Diagnosing: identification of the problem and the respective motivation to solve it;
- Action Planning: consists in planning the solution to the problem presented, as well as describing what will be necessary to solve it;
- Action Taking: execution of the solution previously described;
- Evaluating: to verify if the solution implemented in the previous step solves the problem;
- Specifying Learning: associated to the recognition of what was learned during the cycle, and preparation of what will be necessary to execute the next iteration.

Every time a cycle is repeated, the improvements introduced tend to stabilize. If this stabilization is significant, the intervention may be considered completed or the redefinition of new objectives is undertaken, leading to the start of a new cycle. The great advantage of using this model is that it warns of the need to comply with the set of steps established, and to reuse the knowledge obtained in the previous iteration in the new iteration [5].

1.5.Report Organization

The dissertation addresses aspects related to gait analysis and what leads to the appearance of ulcers in diabetics, so that, using the analysis of data from the sensors implanted in an insole, it will be possible to prevent the appearance of these ulcers, avoiding subsequent consequences, as like amputation of the foot.

Chapter 1- Introduction

In this chapter, the theme developed in this dissertation is framed, contextualizing its execution, and presenting in a clear and succinct way all the objectives to be achieved, as well as the contribution and the research methodology, ending with a brief description of the report's structure.

Chapter 2 – Interoperability in Healthcare

Regarding this chapter, the concept of interoperability is discussed, as well as the standards that enable the structured exchange of health data.

Chapter 3 – Biomechanical Data

Concerning this chapter, the concept of big data is presented, and the main components of modern data science methods are described. Furthermore, the risk assessment scales for pressure ulcers are addressed.

Chapter 4 – The Foot and the Gait

This chapter discusses the anatomy and possible movements of the foot, as well as the stages of the human gait cycle. At the end, the solutions present on the market for the prevention of ulcers using the analysis of several factors through mobile applications are presented.

Chapter 5 – Project Development

As far as this chapter is concerned, the system architecture and the principle of operation of the applications will be shown. To validate them, several types of tests were performed to ensure their quality, as well as the user experience.

Chapter 6 – Conclusions

Finally, this chapter addresses the concluding aspects of this study, presenting limitations and future work related to it.

CHAPTER 2 – INTEROPERABILITY IN HEALTHCARE

2. Interoperability in Healthcare

With the gradual digitization of medicine, there will be major developments for global health. When data from sensors, wearable devices and electronic medical records are analysed using artificial intelligence, a significant improvement in the lives of a large portion of patients worldwide may be associated, as they will have more accurate diagnoses, customized treatments and early disease prevention [6], [7].

In order to make this medical data into relevant information, good quality datasets, standard data formats and viable communication between IT (Information Technology) systems are required so that humans and machines can process these data [7].

Thus, interoperability is required, which is related to the ability to exchange information between two components or systems, and subsequently use this exchanged information [8].

Among the many advantages of implementing interoperability between different Health Information Systems (HIS) is the ease of data sharing between health and research organizations, as well as faster and more reliable information exchange. Enabling this data sharing will be beneficial to patients as it will help improve their safety and reduce the cost of their treatments [9].

In the specific case of this study, it will be extremely important in the future to be able to interconnect the system created with a clinical records repository shared by the National Health Service (NHS), since in this way the health professional will have access to the most up-to-date and realistic data on the patient, and will not depend on the possibility of the user making a mistake when recording them.

In addition, it will be beneficial for the learning algorithm that will be developed in the future to have access to a reliable source of data, since it will reproduce the warnings or reports much more accurately.

Currently, interoperability can be further divided into the following layers [7]:

- Technical interoperability: using communication channels and data transmission protocols, this layer is related to the ability to exchange basic information between systems. As the exchange of data between two points is not enough, it is necessary to extract and process the information, syntactic and semantic interoperability becomes crucial;

- Syntactic interoperability: specifies the structure and format of the data. The structured exchange of health data is done by standards, for example, Health Level Seven International (HL7), Integrating the Healthcare Enterprise (IHE), openEHR and Fast Healthcare Interoperability Resources (FHIR), which are called standard development organizations (SDO);
- Semantic interoperability: in order to make the exchange of medical concepts between systems possible, and allow concepts to be understandable by man and machines, this layer is necessary, as it includes the domain of medical terminologies, nomenclatures and even ontologies;
- Organizational interoperability: with the purpose of making the work of health professionals more productive, this higher level relates to policies, organizations and associated legislation.

2.1.HL7

Among the previously defined standards are the HL7 standards, created by Health Level Seven International, which was founded in 1987.

The term "Level 7" is a reference to the seventh and last layer of the Open Systems Interconnection - OSI standard defined by ISO (International Organization for Standardization). With this, it seeks to be an application layer integrated in the transport of data and the interpretation of the information sent, supporting functions such as security verification, user identification, availability verification, exchange negotiation mechanisms, and the information exchange structure [10].

Over time, HL7 has produced a group of standards that have changed over the years, namely, HL7 Version 2 (V2), HL7 Version 3 (V3) and HL7 Reference Information Model (RIM), HL7 Version 3 Clinical Document Architecture (CDA®), and more recently, Fast Healthcare Interoperability Resources (FHIR®) [11].

From the second version onwards, HL7 has become the most widely used standard worldwide. Although the standard is in the third version, it has not yet obtained great acceptance by software developers, due to the lack of compatibility between the versions, high complexity of the structure to meet the actions and clinical situations and mainly due to the lack of documentation. [10]

2.2.FHIR

In order to address the gaps present in the HL7 V3 protocol, an independent group of HL7 architects decided to create Fast Healthcare Interoperability Resources - FHIR (pronounced HL7 "Fire"), this being a new model targeted at the interoperability of electronic health systems. With the first version becoming available in 2012, the aim was to use the know-how acquired over the years with other versions of HL7 and develop a new standard with available technologies [12].

2.2.1. Resources

As previously mentioned, the FHIR is a framework standard that aims to provide interoperability mechanisms for HL7, which are based on existing web standards such as XML (Extensible Markup Language), JSON5 (JavaScript Object Notation), HTTP (Hypertext Transfer Protocol), OAuth, and others. It supports RESTful-based architectures and is flexible enough to be used in various contexts, such as mobile applications or even electronic clinical record sharing [12].

Thus, FHIR is intended to map HL7 messages to messages in a format that the organization that defined FHIR sets as standard and that are recognized by other health information systems. These messages can be displayed in XML with JSON and accessed via RESTful, being these standard formats called resources [13].

These resources can represent clinical, administrative and infrastructure data, including single patient consultations and population level consultations. Each resource represents a data structure, expressed in well-defined fields and data types [9].

The definitions of these clinical resources are related to concrete and intuitive concepts, such as medication prescription, adverse reactions, exam prescription, etc. For example, a Medication Prescription resource has information about the prescriber (FHIR Practitioner), the patient (FHIR Patient) and which medicine is prescribed (FHIR Medication). Figure 2.1 shows an sample of a patient resource [14].

```
<Patient xmlns="http://hl7.org/fhir">
  <id value="glossy"/>
  <meta>
    <lastUpdated value="2014-11-13T11:41:00+11:00"/>
  </meta>
  <text>
    <status value="generated"/>
    <div xmlns="http://www.w3.org/1999/xhtml">
      <p>Henry Levin the 7th</p>
      <p>MRN: 123456. Male, 24-Sept 1932</p>
    </div>
  </text>
  <extension url="http://example.org/StructureDefinition/trials">
    <valueCode value="renal"/>
  </extension>
  <identifier>
    <use value="usual"/>
    <type>
      <coding>
        <system value="http://hl7.org/fhir/v2/0203"/>
        <code value="MR"/>
      </coding>
    </type>
    <system value="http://www.goodhealth.org/identifiers/mrn"/>
    <value value="123456"/>
  </identifier>
  <active value="true"/>
  <name>
    <family value="Levin"/>
    <given value="Henry"/>
    <suffix value="The 7th"/>
  </name>
  <gender value="male"/>
  <birthDate value="1932-09-24"/>
  <careProvider>
    <reference value="Organization/2"/>
    <display value="Good Health Clinic"/>
  </careProvider>
</Patient>
```

Resource Identity & Metadata

Human Readable Summary

Extension with URL to definition

Standard Data:
- MRN
- Name
- Gender
- Birth Date
- Provider

Figure 2.1 - Example of a Patient resource [12]

In order to map an HL7 message to an FHIR resource, integration tools can be used, such as Iguana. After this mapping, the FHIR resources are able to be made available abroad, through a Web service [15].

2.2.2. Extensibility

The specification of information exchange with the FHIR is based on the common requirements defined between healthcare facilities, which in turn may consider various approaches. In order to cover all the data that needs to be exchanged, an extension element has been added. In this update, each element of a resource has the choice to have extension elements, which can be presented an arbitrary number of times. [16].

In Figure 2.2, it can be seen that the extension element has two attributes, one being the Uniform Resource Locator (URL), which is mandatory and must be a URL, and the parameter "value[x] ", whose name "value" is constant and the field "[x]" is replaced by the name in the form of a title of the type that is actually used.

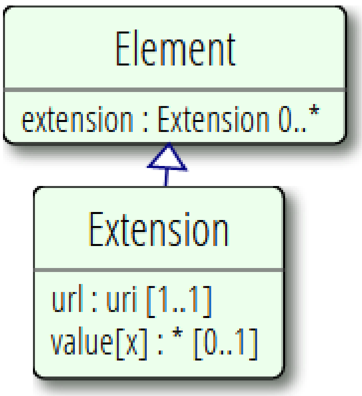

Figure 2.2 - FHIR extension element [16]

This FHIR extension can be represented in XML format, as presented in Figure 2.3.

```
<name>
  <extension url="http://hl7.org/fhir/StructureDefinition/iso-21090-EN-use" >
    <valueCode value="I" />
  </extension>
  <text value="Chief Red Cloud"/>
</name>
```

Figure 2.3 - Example FHIR extension in the XML format

2.2.3. Exchange paradigms

FHIR is modelled on a 'RESTful' specification, given the widely used industry term REST (Representational State Transfer). This term is associated with the collection of architectural principles through which a Web Service can be designed. This has become an alternative to traditional interoperability methods due to its simplicity of use [17].

An implementation of REST follows four basic design principles [18]:

- It uses HTTP (Hypertext Transfer Protocol) methods explicitly;
- It is stateless, that is, whenever the server receives a request from a client, the message must contain all the information necessary for its execution, regardless of other messages sent previously;
- Exposes the directory structure as URI (Uniform Resources Identifier) to resources. These URI's are called endpoints. To manipulate the resource identified in the URI, REST makes use of HTTP protocol methods: POST, GET, PUT and DELETE. These operations are similar to CRUD (Create, Read, Update, and Delete) operations in the database respectively;
- Serializes resources in XML or JSON language.

Even though it is possible to support Level 3 of the REST Maturity model, FHIR only supports Level 2 of this model, as part of the main specification [19].

While Level 2 of the REST Maturity model, represented in Figure 2.4 uses HTTP verbs identically to the way it is used in HTTP itself, Level 3, represented in Figure 2.5 allows the functionality of an API to be extended to other levels through hypermedia. Through the use of HATEOAS (Hypertext as the Engine of Application State), the API can answer to requests with additional information, and bind resources for richer interactions [20].

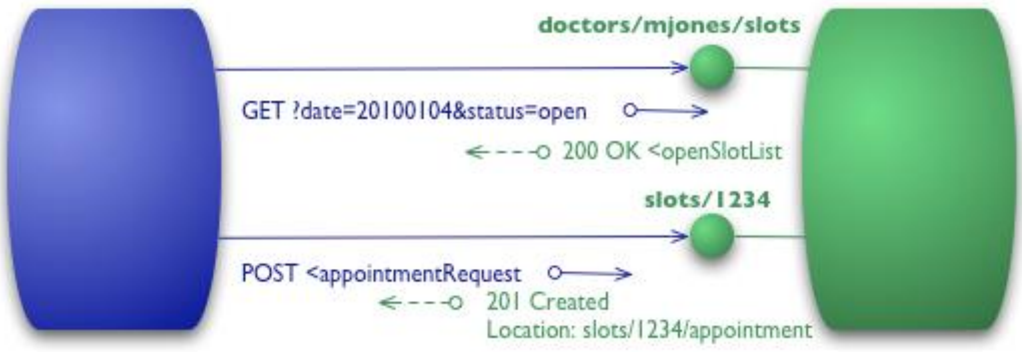

Figure 2.4 - Level 2 of the REST Maturity model [20]

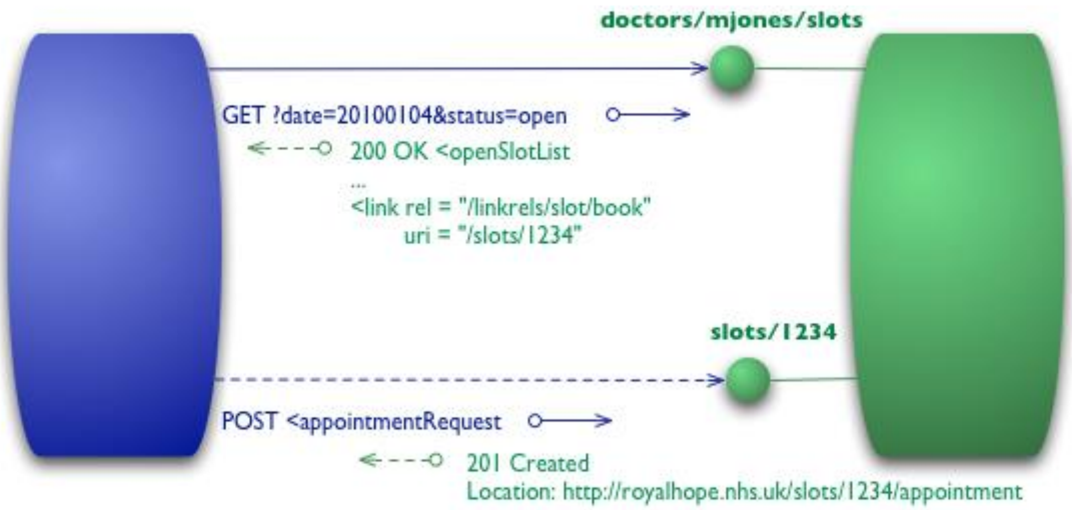

Figure 2.5 - Level 3 of the REST Maturity model [20]

The RESTful API supports FHIR resources in the set of interactions represented in Table 2.1, which they use to manage the resources and communicate with the server, which in turn acknowledges these interactions and which resources they support.

Table 2.1 - FHIR Interactions

Instance Level Interactions	read	Read the current state of the resource
	vread	Read the state of the specific version of the resource
	update	Update an existing resource by its id (or create it if it is new)
	patch	Update an existing resource by posting a set of changes to it
	history	Create a new resource with a server assigned id
	delete	Delete a resource
Types Level Interactions	create	Create a new resource with a server assigned id
	history	Retrieve the change history for a particular resource type
	search	Search the resource type based on some filter criteria
Whole System Interactions	capabilities	Get a capability statement for the system
	batch/transaction	Update, create or delete a set of resources in a single interaction
	history	Search across all resource based on some filter criteria
	Search	Retrieve the change history for all resources

Furthermore, the interactions have the structure shown in Figure 2.6, where what is enclosed by [ ] is mandatory, and if it appears surrounded by { } it is optional. The HTTP verb is one of the HTTP protocol methods, and the remaining elements are:

- Base: refers to the base URL associated with the service;

- Mime-type: related to the type of media;
- Type: associated with the name of a resource type;
- Id: the logical ID of a resource.

```
VERB [base]/[type]/[id] {?_format=[mime-type]}
```

Figure 2.6 - Interaction's structure

In summary, with the use of FHIR, there will be several associated advantages, including [12]:

- Speed and ease of implementation;
- Interoperability and adaptation of basic resources;
- Use of Web standards, such as HTTP, XML and JSON;
- Serialization format presented in a way that can be understood by a human;
- Specifications easy to understand, free and without associated restrictions.

Thus, as the understanding of the whole process inherent to the exchange of data using the mechanisms of the FHIR framework, and the advantages associated with the implementation of interoperability, the need to interconnect the system created in this study with a repository of clinical records becomes evident.

Often, making this happen can be complicated, since this exchange of personal information between different agents presupposes privacy, security and patient consent. Thus, it is necessary to ensure that the data is properly stored and that only authorized entities can have access to it, to ensure patient confidentiality [21].

CHAPTER 3 – BIOMECHANICAL DATA

3. Biomechanical Data

Due to the fact that risk factors associated to human gait are a result of an interaction between multiple clinical and biomechanical variables, traditional biomechanical analysis methods, such as the analysis of peak angles and statistical hypothesis test, are unable to capture the complexity of this interactions [22].

Thus, machine learning methods and multivariate analysis have been used to identify these interactions, allowing for the prevention of injuries such as ulcers. Allied to these methods, there are risk assessment scales that allow classifying the risk of developing ulcers.

In this chapter, the principles of big data will be discussed, as well as what steps should be followed to extract from it information that is important and convenient for the problem at hand. These steps constitute the modern data science methods, and are the initial input features, dimensional reduction techniques and learning algorithms.

Additionally, the main ulcer risk scales that are used by health professionals will be addressed.

3.1.Big Data

Although there is no concrete definition of the term “big data”, it can be referred to datasets that are too big or too complex to be handled by traditional data collection and analysis tools within an acceptable duration [23].

On the other hand, it can also be defined in the lights of the 5 V’s definition, as presented in Figure 3.1: Volume, Velocity, Variety and additionally Value and Veracity [24]:

- Volume – refers to a large quantity of data. The growth of data amount is caused by the increasing generation of data for each subject, by data collection technologies. The number of variables per subject is around 50-150 discrete variables, and it is recommended to increase this number to assert if the results are similar in different populations [24], [25];

- Velocity – big data are often generated at a high rate, due to the data generated by multiple events or by different sensors, and this data needs to be processed in real-time or near real-time. For injuries that are a result of either a walking or running event, the rehabilitation can take weeks or months, in which some data are collected in real-time, and some are collected once every week [24], [25];

- Variety – deals with the complexity of big data, as well as the semantic and information models behind this data, that can be collected as structured, unstructured, semi-structured or even mixed. For gait analysis, data can exist in multiple types and captured from different sources, which involves the data from the sensors as well as clinical data [24], [25];

- Value - is defined as the impact that the data collected may have on the respective process, activity or hypothesis. Although the value of the big data analysis in gait biomechanics has not yet been proven, if the correct information extraction techniques are used, even when the veracity of the data is low, there may be a result with high value [24], [25];

- Veracity - is related to the consistency, authenticity, reliability and security of data throughout its life cycle, from collection to storage. In the area of biomechanics, veracity is related to incomplete data or noise, the result of sources of error, such as electrical interferences or soft tissue artefacts, or incomplete clinical data. In order to handle the lack of data, data science techniques can be used, such as k-nearest neighbors [24], [25].

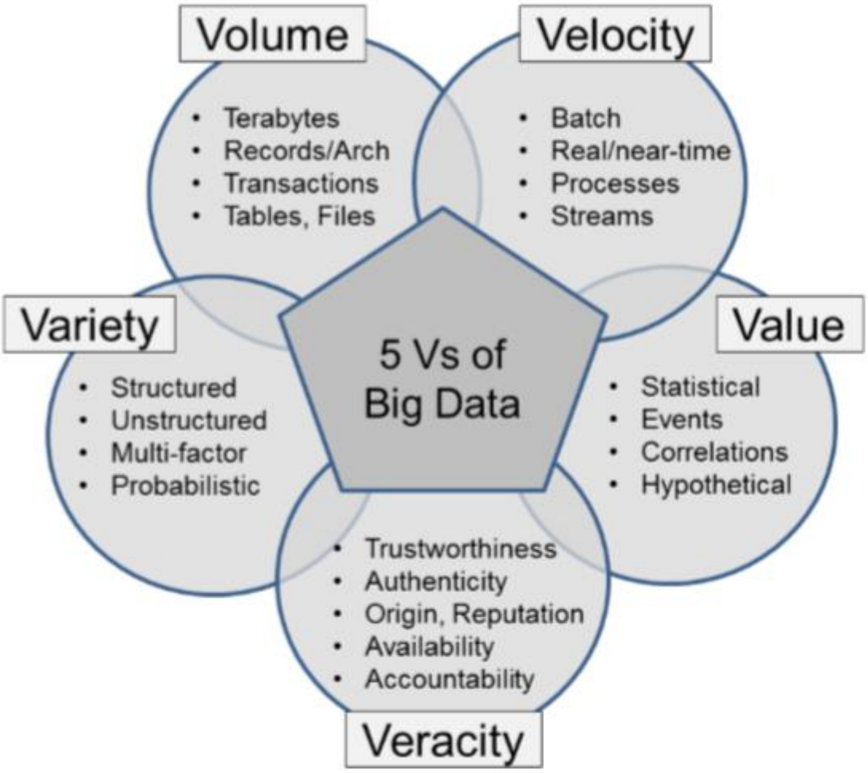

Figure 3.1 - 5Vs of Big Data [24]

Among the main components of modern data science methods, initial input features, dimensional reduction and learning algorithms can be highlighted, as illustrated in Figure 3.2 [25].

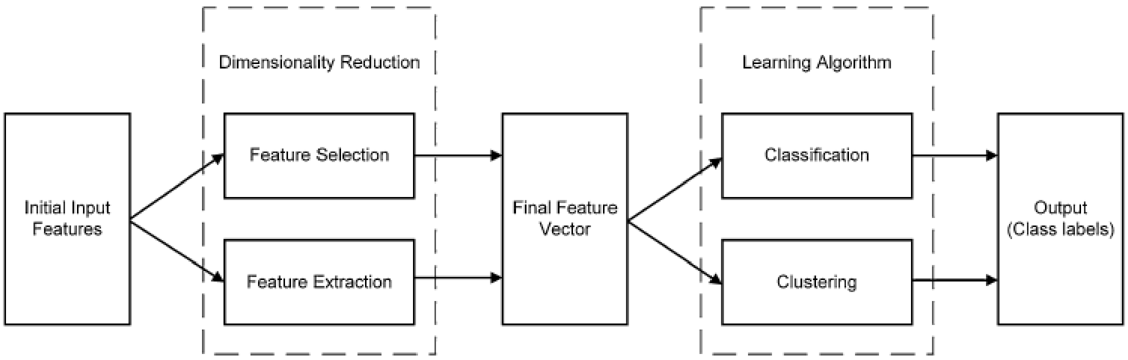

Figure 3.2 - Main components of modern data science methods [25]

3.1.1. Initial input features

As far as initial input features are concerned, they must have an adequate dimensionality, as there are methods of dimensionality reduction that need an adequate number of samples to obtain stable results. However, a larger amount of data does not mean a larger amount of useful information, since it can be associated with an increase of ambiguous data, such as artifacts of soft tissue movements, unnecessary, incomplete or inconsistent [25], [26].

Besides the information from the sensors, there are risk factors that can contribute to the detection of ulcer formation, such as age, height, weight, gender, duration and type of diabetes, body mass index (BMI), value of glycated hemoglobin (HbA1c), vibration perception threshold, cumulative duration of past ulcer records, record of amputation, presence of peripheral arterial disease, smoking, alcohol consumption (>20 milliliters of pure alcohol/day), living alone, being employed, academic degree and the time between curing of the last ulcer until the beginning of the study [27], [28].

Also, Waaijman et al. also included the presence of foot deformity, with the following classification [27]:

- Absent;
- Mild – presence of pes planus, pes cavus, hallux valgus or limitus, hammer toes, or lesser toe amputation;
- Moderate – presence of hallux rigidus, hallux or ray amputation, prominent metatarsal heads, and/or claw toes;
- Severe – presence of Charcot deformity, forefoot amputation, or pes equines.

3.1.2. Dimensionality reduction

In order to be able to predict any type of complications associated with a human disease, more specifically in the case of diabetic ulcers, it is essential that the datasets are pre-processed. Thus, dimensionality reduction techniques arise, whose role is to reduce high dimensionality data to a reduced dimensionality [29].

These techniques can drastically reduce the time complexity of training phase of machine learning algorithms, as well as improve classification accuracy by reducing the noise and improving the clinical relevance of the results with the selection of more interpretable features [25].

3.1.2.1. Feature selection

Feature selection methods can be classified in various ways, with the most common being classifications into filters, wrappers, embedded, and hybrid methods, and assuming independence or near-independence of features [30].

Filtering methods select features based on a performance measure, which in turn is independent of the data modelling algorithm being used. The modelling algorithms can only use the best features once they have been found. Filtering methods can classify individual features or classify entire subsets of features. Thus, it is possible to broadly classify the measures developed for feature filtering into: information, distance, consistency, similarity, and statistical measures [30].

This method offers greater potential when the initial features consist of categorical data, such as demographic or clinical data, as well as continuous or discrete data, as is the case with the values returned by pressure sensors. Although it has lower prediction performance compared to wrapper methods, it is more useful to understand associations between features, being associated to less computational power [25].

Wrappers, on the other hand, will evaluate subsets based on classifier performance (e.g., Naïve Bayes or Support Vector Machine (SVM)) in classifications tasks, while for clustering, a wrapper will evaluate subsets based on the performance of a clustering algorithm (e.g., K-means).

Compared to filtering methods, these methods are much slower when it comes to finding sufficiently good subsets, because they depend on the resource requirements of the modelling algorithm [30].

Another set of methods that can be considered are embedded methods, which are characterized by performing feature selection while executing the modelling algorithm.

These methods are incorporated into the algorithm either as its normal or extended functionality. Common embedded methods include decision tree algorithms such as CART (Classification and Regression Tree), C4.5 (a decision tree algorithm) and random forest, but also other types of algorithms such as multinomial logistic regression [30].

Finally, hybrid methods combine the best features of wrappers and filters, in which a filter method is used to reduce the dimension space, and then a wrapper is used to find the best candidate subset among the subsets generated by the filter method. Among the various recently proposed methodologies for hybrid methods are the fuzzy random forest based feature selection, hybrid genetic algorithms, hybrid ant colony optimization, or even mixed gravity search algorithm [30].

The comparison of each method is presented in Table 3.1.

Table 3.1 - Comparison of feature selection methods

	Filter	**Wrapper**	**Embedded**	**Hybrid**
Technique	Statistical measures	Optimization algorithm	Combination of filter and wrapper methods	Contains the best features of filter and wrapper methods
Computational efficiency	Efficient	Inefficient	Inefficient	Efficient
Computation cost	Cheaper	Expensive	Expensive	Cheaper
Computation space	Low	High	High	Low
Computation time	Time efficient	Slow	Slow	Time efficient
Generality	High	Low	Low	High

Complexity	Low	High	High	High
Suitable for high dimensional data	Yes	No	No	Yes
Advantage	Time efficient	High prediction performance	High prediction performance	Time efficient and high prediction performance
Disadvantage	Low prediction performance	Increased runtime	High computation cost	Dependents of the combination of different feature selection method

Regarding the search strategy, it can be univariate or multivariate. While univariate feature filters evaluate (and usually rank) a single feature, multivariate filters evaluate an entire feature subset.

The most common approach related to search is the maximum-revelance (MR) selection method or also called univariate feature selection, whose purpose is to apply the objective function to each feature and determine its relevance in relation to the ranking variable. At the end of this iterative process, the features with the highest score are chosen [25].

On the other hand, the most common search strategies used with multivariate filters can be divided into the following groups [25], [30]:

- Exponential algorithms - evaluate several subsets that grows exponentially with the feature space size. Examples: exhaustive search and branch-and-bound;
- Sequential algorithms - creates a subset of features by adding or removing one feature at a time, based on a score obtained from a wrapper method, followed by choosing the subset that best increases the classification accuracy while minimizing the size of the feature subset. This algorithm can lead to local minima,

particularly when dimensionality is very high. The most common algorithms that belong to this group are the greedy forward selection or backward elimination, best-first, linear forward selection, floating forward or backward selection, beam search and race search;

- Randomized algorithms - incorporates randomness into the search procedure, avoiding local minima. This group includes algorithms like random generation, simulated annealing, scatter search and evolutionary computation algorithms.

3.1.2.2. Feature extraction

Feature extraction is defined as the transformation of original features into more meaningful ones, where the size of the feature space can often be reduced without losing information from the original feature space [25], [31].

This technique has the advantage of being able to reduce complexity and provide a simpler representation of the data representing each variable in feature space.

These features can be based on either linear or non-linear analysis, as well as supervised or unsupervised learning approach.

Regarding unsupervised linear learning, the method that stands out is Principal Component Analysis (PCA), and this is the one used in most investigations related to gait analysis, both in walking and running, where it has demonstrated accuracies between 80% and 100% in distinguishing between different patterns in running gait. [25].

This method consists of an orthogonal transformation, whose objective is to convert samples belonging to correlated variables into samples of linearly uncorrelated features, where these new features are called principal components. The main reason for using this method is because it is non-parametric and allows extracting the most important information from a set of redundant or noisy data [31].

In order to achieve minimum redundancy and maximum relevant information, PCA eliminates the last principal components that do not contribute significantly to variability.

Even though the first or low-order principal components are related to the most dominant movement patterns, it has been shown that the intermediate and higher order components are useful in monitoring the results of a given treatment in injured patients and can show the success of rehabilitation [32]. Although useful in certain situations, this method has limitations:

1. It assumes that the relationship between variables is linear;
2. Its interpretation is only sensitive if it is assumed that all variables are scalable to the numerical level;
3. It does not have a probabilistic model structure, which is useful when using Bayesian decision.

In order to overcome the first and second limitations described above, the Nonlinear Principle Components Analysis method was created, which differs from the traditional method in that it is suitable for variables of different types, such as nominal, ordinal and numeric. Another difference lies in the fact that in nonlinear PCA, the variables measured are quantified during the analysis, whereas in the traditional method these variables are directly analyzed [31].

Another method that overcomes the first limitation is the Kernel Principle Component Analysis (KPCA). This method, with the use of the kernel function, avoids the direct evaluation of the necessary point product in a high-dimensional feature space, making it so that no explicit nonlinear function is needed that projects the data from the original space to the feature space [31].

Still within the non-linear unsupervised feature extraction methods, there is fractal analysis, whose objective is to evaluate the fractal, or self-similar, characteristics of the data, by determining the fractal dimension of the data. Thus, fractal analysis considers variability as long-term correlations, rather than considering this variability as random [25], [33].

There are several techniques of fractal analysis, in which detrended fluctuation analysis (DFA), maximum Lyapunov exponent (MLE), critical exponent analysis and fractal dimension of variance stand out, being that DFA has been used to quantify stride interval dynamics and MLE to identify local dynamic stability [34], [35].

Finally, to overcome the third limitation, Probabilistic Principle Component Analysis (PPCA) emerges, which allows the sound component to have an isotropic structure. This method departs from the traditional PCA and adds a parameter learning phase for this model using the maximum likelihood estimation method, as well as a maximization algorithm [31].

Regarding supervised feature extraction, the most common method used is Linear Discriminant Analysis (LDA), which takes as input a set of high-dimensional features grouped into classes, finding an optimal transformation (projection) that maps the raw features into a lower-dimensional space, preserving the class structure. This method minimizes the distance within the class and simultaneously maximizes the distance between classes, thus achieving maximum discrimination [36].

On the other hand, a combination of SVM and Independent Component Analysis (ICA) as a supervised and unsupervised feature projection showed better overall performance over the PCA method in classifying running data in two different shoe conditions [25].

3.1.3. Learning algorithms

After creating a final feature vector, it is necessary to choose a supervised or unsupervised learning approach to perform classification, clustering or regression.

Machine learning algorithms can be classified into supervised or unsupervised, as presented in Figure 3.3, although some authors also classify other algorithms as reinforcement, because such techniques learn data and identify patterns for the purpose of reacting to an environment. Even though the latter classification exists, most articles assume that machine learning algorithms can be either supervised or unsupervised [37].

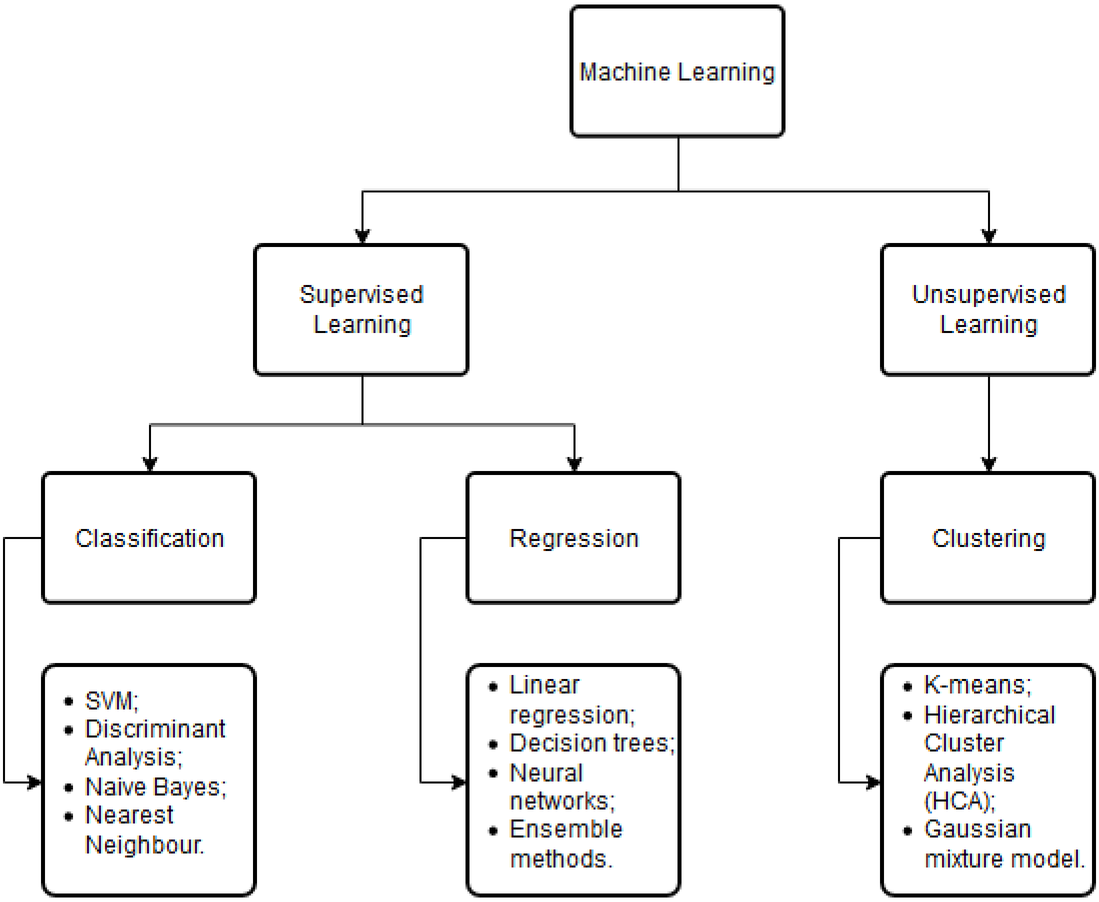

Figure 3.3 - Classification of Machine Learning

3.1.3.1. Supervised learning

Supervised machine learning involves a predetermined output attribute in addition to the use of input attributes.

This type of algorithms attempts to predict and classify the predetermined attribute, and its accuracy and misclassification, as well as other performance measures, depends on whether the predetermined attribute counts correctly predicted, classified, or otherwise. Thus, they perform analytical tasks using the training data first and then build contingent functions to map a new instance of the attribute [37].

Of the supervised machine learning algorithms described above used for classification, the most popular is SVM. This method builds a model that can predict whether in which category a subject best fits, with the design of the edges as the boundary between the classes in the given dataset. The creation of these margins is done so that the distance between each class and the nearest margin is maximized and, consequently, leads to the least possible classification error [37].

Although SVM can perform a nonlinear classification, it is with the use of linear kernel that better performance is obtained in identifying differences caused by age in running and walking gait patterns [25].

In order to obtain a more robust model, it is recommended to use a Linear Discriminant Analysis (LDA), which is able to identify a projection vector to maximize the between-class dispersion matrix while minimizing the within-class dispersion matrix in feature space [38].

This model has not only been able to predict the success of individual treatment in patients with knee osteoarthritis, but also to discriminate between different walking gait patterns without prior knowledge of the load condition [25].

Regarding the techniques used for regression, the use of neural networks stands out, namely Deep Convolution Neural Networks (DCNN). This type of neural networks was used by Lee et al. to classify several types of gait, extracting features based on a deep convolution neural network from data measured using several types of sensor sets mounted on a smart insole [39].

3.1.3.2. Unsupervised learning

Unlike supervised learning, unsupervised data learning involves pattern recognition without the involvement of a target attribute. Thus, all variables used in the analysis are used as inputs and due to the approach, the techniques are suitable for clustering and mine association techniques [37].

The aim of this technique is to identify inherent groupings within the unlabeled data and subsequently assign label to each data value.

Among the clustering algorithms, the one that stands out most in relation to gait analysis is HCA (Hierarchical Cluster Analysis), which has been used to identify subgroups with homogeneous gait patterns. With the use of this technique, Jauhiainen et al. were able to determine whether injured runners exhibit similar kinematic gait patterns [40].

In addition to HCA, there is k-means, which aims to create groups or classes in unlabeled datasets based on the average distance between classes, where k stands for number of clusters. This technique was used in a study by Böhm et al. to identify foot motion patterns in children with flexible flat feet using gait analysis. However, this method should be used with care, as an inappropriate choice of k may yield poor results [41].

3.2. Risk assessment scales for pressure ulcers

Aiming to identify individuals at risk of Pressure Ulcer (PU) development, the use of PU risk assessment tools or scales is necessary.

These risk assessments use checklists that alert professionals to the most common risk factors predisposing individuals to pressure ulcer development. Among the most commonly used tools for this assessment, the Norton, Waterlow and Braden scales stand out [42].

3.2.1. Norton scale

The Norton scale, represented in Table 3.2, was the first scale to be created, where several risk factors were scored, including mobility, incontinence, activity, mental state and physical condition. This score was designed so that the lower the score, the higher the risk of developing PU's [43].

More specifically, if this score is lower than 10, the risk is very high and if it is between 10 and 14, the risk is high. On the other hand, if it is between 14 and 18, the risk is medium, and if it is above 18, the risk is low [43].

Table 3.2 - Representation of the Norton Scale

Risk areas	Score
Mobility	1 - Immobile, 2 – Very Limited, 3 – Slightly Impaired, 4 – Full
Incontinence	1 – Urinary and Faecal, 2 – Usually Urinary, 3 – Occasional, 4 – None
Activity	1 – Bedfast, 2 – Chairbound, 3 – Walks with help, 4 – Ambulant
Mental state	1 – Stuporous, 2 – Confused, 3 - Apathetic, 4 – Alert
Physical condition	1 – Very Bad, 2 – Poor, 3 – Fair, 4 - Good

3.2.2. Waterlow scale

The Waterlow score, whose scale is depicted in Figure 3.4, was created as a practical aid to the preventative aids and treatments available, whilst promoting awareness of the causes of PU's and the determined risk. This score considers the following risk factors: build/weight, continence, skin type, mobility, gender/age, appetite, tissue malnutrition, neurological deficit, surgery/trauma, specific medication and additional risk factors (such as smoking). The higher the score, the higher the risk of PU formation [43].

Build/Weight for Height	*Score*	*Skin type visual risk areas*	*Score*	*Sex & age (Years)*	*Score*	*Special risks*	
Average (BMI= 20-24.9)	0	Healthy	0	Male	1	**Tissue Malnutrition**	**Score**
Above average (BMI= 25-29.9)	1	Tissue paper (Frail)	1	Female	2	Terminal Cachexia	8
Obese BMI= >30	2	Dry	1	14-49	1	Multiple organ failure	8
Below average (BMI = <20)	3	Oedematous	1	50-64	2	Single organ failure (Resp, Renal, Cardiac)	5
(BMI=Wt in kg/Ht in m^2)		Clammy, Pyrexia	1	65-74	3	Peripheral vascular disease	5
		Discoloured grade I	2	75-80	4	Anemia <8gm%	2
		Broken/Spots grade 2-4	3	81+	5	Smoking	1
Continence	*Score*	*Mobility*	*Score*	*Appetite*	*Score*	*Neurological deficit*	*Score*
Complete/ Catheterised	0	Fully	0	Normal	0	Diabetes, MS, CVA	4 to 6
Urine Incontinence	1	Restless/Fidgety	1	Scarce/Feeding tube	1	Motor/Sensory	4 to 6
Fecal Incontinence	2	Apathetic	2	Liquid IV	2	Paraplegia	4 to 6
Urinary + Fecal Incontinence	3	Restricted	3	Anorexia/ Absolute diet	3		
		Bed bound e.g. traction	4			**Major surgery or trauma**	
		Chair bound e.g. wheel chair	5			Orthopedic/Spinal	5
						On table >2 Hrs	5
Interpretation						On table >6 Hrs	8
10+	At Risk						
15+	High Risk						
20+	Very High Risk						

Figure 3.4 - Representation of the Waterlow Scale [44]

3.2.3. Braden scale

This scale, represented in Table 3.3, was validated for the Portuguese population in 2001 and is a standard of the Directorate General of Health (DGS) for its application, presenting the ideal validation and the best sensitivity/specificity balance when compared with the Norton and Waterlow scales [45], [46].

It consists of 6 subscales: sensory perception, moisture, physical activity, mobility, nutrition, and friction and shear forces. Each of these subscales assesses the patient's status, assigning a rating between 1 and 4 (except for the last one, which is 1 to 3), comparing the patient's status with the scale's statement and assigning the respective value [45].

The sum of the value assigned in each of these subscales will be numerically translated into a value between 6 and 23, which translates the risk of PU development. The risk is thus stratified, categorizing them into "high risk of PU development" when the final value is below 16 and "low risk of PU development" when the value is equal to or higher than 17 [45].

Table 3.3 - Representation of the Braden Scale

Risk areas	Score
Sensory perception	1 - Completely Limited, 2 – Very Limited, 3 – Slightly Limited, 4 – No Impairment
Moisture	1 – Constantly Moist, 2 – Very Moist, 3 – Occasionally Moist, 4 – Rarely Moist
Physical Activity	1 – Bedfast, 2 – Chairfast, 3 – Walks Occasionally, 4 – Walks Frequently
Mobility	1 – Completely Immobile, 2 – Very Limited, 3 – Slightly Limited, 4 – No Limitation
Nutrition	1 – Very Poor, 2 – Probably Inadequate, 3 – Adequate, 4 - Excellent
Friction and shear forces	1 – Problem, 2 – Potential problem, 3 – No Apparent Problem

Thus, this chapter has provided insight into the main characteristics for a given dataset to be considered big data, as well as a comparison of the different approaches that can be used in each of the data science methods.

Given that among these methods, there are options with appealing characteristics, such as low computational cost and great efficiency, it becomes evident that the system created in this study will benefit in the future from an implementation of these methods in conjunction with the current functionalities of the applications, making them more effective in discovering patterns on the gait.

In addition to this topic, the different risk scales for ulcer formation were addressed, which allowed elucidating the different parameters used in them. Although they are commonly used by health care professionals, namely the Braden scale in Portugal, it may not be the most reliable as the evaluation of the various parameters of the scales is dependent on the evaluation criteria of each professional, and in addition, there should be more assessment options within a risk area, as the maximum observed is four.

Furthermore, the parameters/factors used in a scale may not be completely related to risk, or even this scale may wrongly assess patients as being at risk (low specificity), and may influence health care resources/professionals, as it will be assigned patients who are not at risk.

In order to overcome possible errors resulting from the subjectivity of these scales, the analysis of gait and foot movements through big data analysis techniques should be used to prevent the appearance of ulcers in a more effective way.

CHAPTER 4 – THE FOOT AND THE GAIT

4. The Foot and the Gait

In order to be able to interpret the sensor values sent to the mobile application, it is crucial to know the anatomy of the foot, its movements and the different phases of human gait. Thus, this chapter will address these topics, as well as solutions already implemented to prevent the appearance of ulcers.

4.1.Foot Anatomy

The osteology of the foot, presented in Figure 4.1, consists of 26 bones, 7 of which belong to the tarsus (talus, calcaneus, cuboid, navicular or scaphoid, lateral cuneiform, intermediate cuneiform and medial cuneiform), 5 bones belong to the metatarsus, denominated as 1st, 2nd, 3rd, 4th and 5th metatarsus, separated by interosseous spaces, and 14 phalanges (3 for each of the fingers, except the hallux which has only 2) [47].

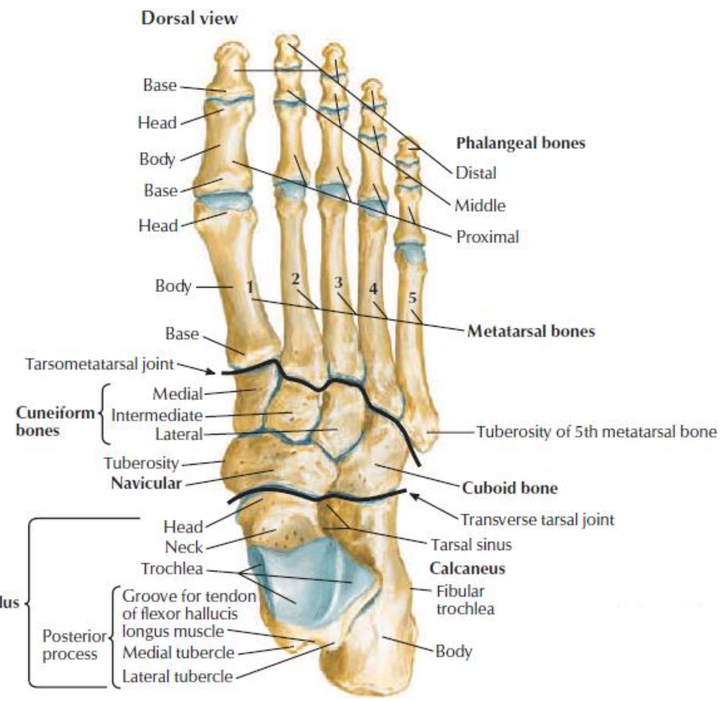

Figure 4.1 - Foot osteology [47]

Thus, the foot can be classified into three segments:

- Hindfoot, which has astragalus and calcaneus bones;
- Mid-foot, consisting of the 3 cuneiform bones, the cuboid and the navicular, being separated from the posterior part of the foot by the transverse joint of the tarsus;
- Forefoot, which contains the 5 metatarsals and 14 phalanges and is separated from the rest of the foot by the tarsometatarsal joint.

4.2.Foot Movements

To ease the understanding of the relationship of structures to each other and the movement of one segment in relation to the other, there are three imaginary reference planes, represented in Figure 4.2, that pass through the body in order to be mutually perpendicular to each other [48], [49]:

- Front plane, or coronal, divides the body in the posterior and anterior parts;
- Sagittal, or median, plane is any plane that divides the body into two symmetrical left and right sub-parts. Any plane parallel to this is called parasagittal or paramedian;
- Transverse plane, or horizontal, is perpendicular to the frontal and sagittal planes, dividing the body into the superior and inferior parts.

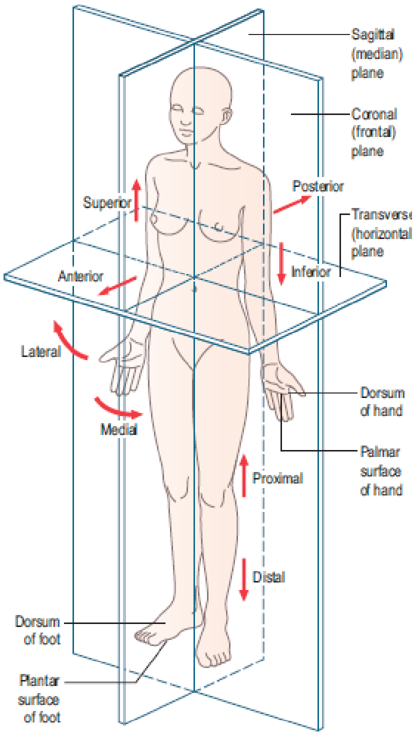

Figure 4.2 - Anatomical planes[48]

There are several movements performed by the foot, and they are only performed in one or two planes described above:

- Abduction and adduction (described in the frontal plane): while the abduction describes the distance of the foot from the median sagittal axis, the adduction describes the approach of the foot to this axis, as illustrated in Figure 4.3.

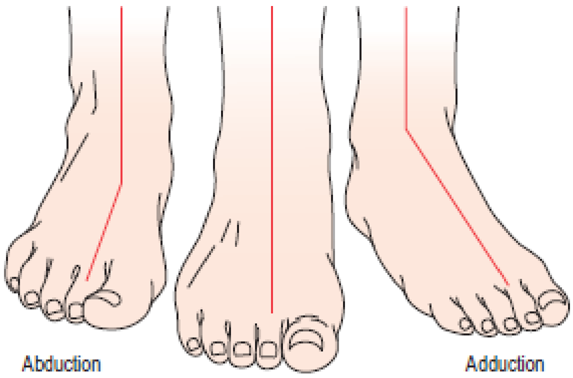

Figure 4.3 - Abduction and adduction [48]

- Dorsiflexion and plantarflexion (described in the sagittal plane): dorsiflexion consists of the approximation of the top (dorsum) of the foot towards the anterior surface of the leg and, on the other hand, plantarflexion consists of moving the dorsum of the foot away from this same surface, as shown in Figure 4.4.

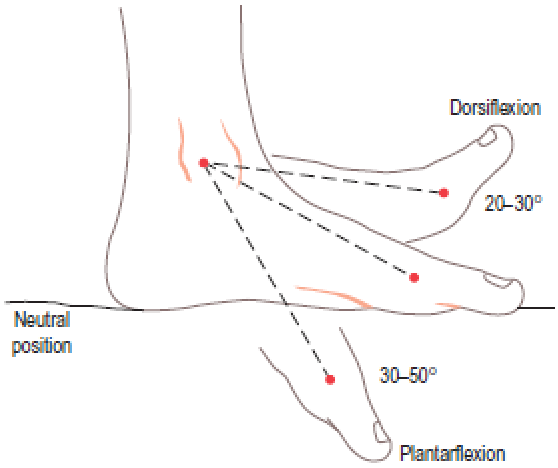

Figure 4.4 - Dorsiflexion and plantarflexion [48]

- Inversion and eversion (occur in the transverse plane): as illustrated in Figure 4.5, while in the inversion (combination of supination and adduction of the forefoot), the movement of the whole foot makes the sole face medially, with a maximum amplitude of 20º, in the eversion (combination of pronation and abduction of the forefoot), the sole comes to face laterally, with a maximum amplitude of only 5º;

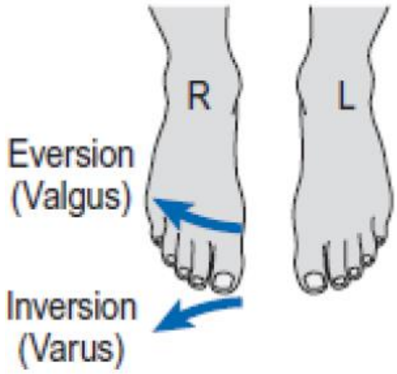

Figure 4.5 Inversion and eversion [49]

- Pronation and supination, represented in Figure 4.6: pronation consists of the combination of abduction, dorsiflexion and eversion, while supination consists of the combination of adduction, plantarflexion and inversion.

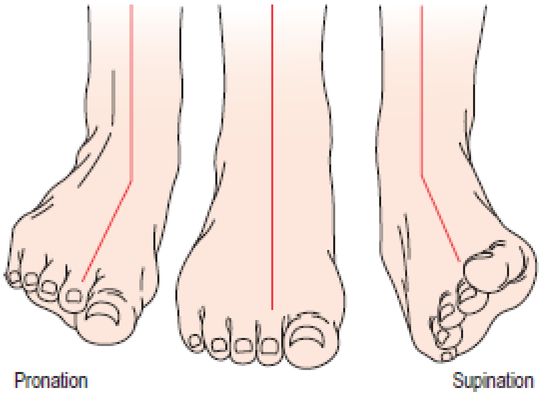

Figure 4.6 - Pronation and supination [48]

4.3.Human Gait Cycle

The human gait is originated through the combination of muscular forces, neuronal motor commands and joint movements. Among the several factors that contribute to the gait are the electromyographic activity, the muscular binary, the ground reaction forces (GRF), the limb movement and the energetic-metabolic cost [50].

The gait cycle, represented in Figure 4.7, refers to the sequence of events that occur between two consecutive repetitions of a given gait event. It usually starts when one foot is in contact with the ground, usually through the heel, until the next heel contact of the same foot [51].

This cycle is divided into two parts, stance phase and swing phase. On average, the total duration is approximately one second, in which 60% correspond to the stance phase, and the other 40% to the swing phase [51].

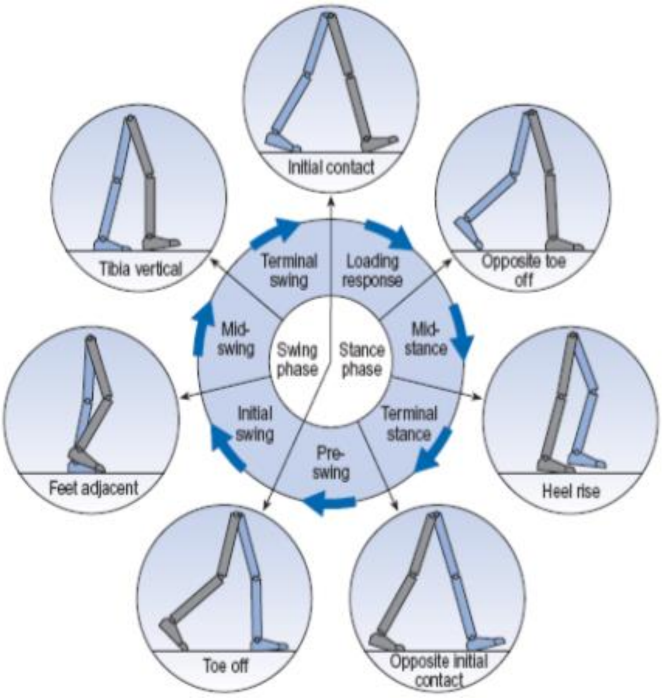

Figure 4.7 - Gait cycle

The stance phase can be subdivided into 5 phases [49], [52]:

- Initial contact: it is the initial phase of the gait cycle, and corresponds to 0-2% of the stance phase and is determined by the moment when the foot contacts the ground through the calcaneus in order to position the limb for posterior heel bearing. At this stage the foot is at 25º to the ground, while the ankle joint is approximately in a neutral position (assuming up to 3º plantar flexion), and the center of gravity is at its lowest position. This position depends on the freedom of movement existing in the ankle joint, as well as the active control of the anterior leg muscles;
- Loading response: This phase extends to 10% of the stance phase and is characterized by providing stabilization and shock absorption, being the phase where there is initial contact with the ground and continues until the foot at the other end enters the swing phase. As soon as the heel contacts the soil, the foot descends to the 10º of plantar flexion through the action of the pretibial muscles that prevent the uncontrolled collapse of the foot;

- Mid-stance: Represents between 10% and 30% of the stance phase and its beginning is marked by the toe off of the contralateral limb. In this phase, the ankle performance occurs maintaining the hip and knee stability, while the body moves on a stationary foot. The force is applied on the static foot at three main points: calcaneus and heads of the first and fifth metatarsals. Simultaneously, the opposite limb begins the oscillation phase and is in a monopodial support phase. The center of mass reaches its maximum when its vertical speed is zero. At the beginning of this phase, the foot presents a slight plantar flexion, gradually moving to dorsal flexion, both flexions presenting a 5º angle, and reaching 10º of dorsal flexion when lifting the heel at the moment the terminal stance phase begins;
- Terminal stance: It happens between 30% and 50% of the stance phase and its main objectives are to produce acceleration and an adequate step length. Acceleration is a consequence of the displacement of the weight of the body forward over the foot, and generates about 80% of the energy needed for walking in so-called normal adults;
- Pre-swing: Corresponding to about 50-60% of the stance phase, it is also known as toe-off, and it is the last part of the propulsion phase, referring to the moment when the reference foot takes off from the ground. In this phase, there is the preparation of the leg for the oscillating phase, and there is contact with the ground through the contralateral foot, thus initiating the middle stance phase, leading to a rapid transfer of weight to that same limb. There is then in this phase a rapid flexion to plant until about 20º.

On the other hand, the swing phase is divided into 3 phases [49], [52]:

- Initial swing: It happens between 60% and 73% of the swing phase and its main objectives are to achieve a sufficient distance of safety between the foot and the ground and reach the desired cadence. This phase starts when the reference foot leaves the ground and ends when it is in front of the support foot;
- Mid-swing: occurs between 73% and 87% of the swing phase and its main goal is to maintain the separation between the foot and the ground. This phase begins when the oscillating foot is in front of the support foot and only ends when there is a projection of the foot forward and the tibia remains vertical;

- Terminal swing: It takes place between 87% and 100% of the cycle and its main objectives are to slow down the leg and try to position the foot correctly for contact with the ground. This starts when the tibia exceeds the vertical position in relation to the ground, and the knee places itself in a position of attack on the ground, and ends when the foot comes into contact with the ground.

Using the different phases of walking, it is possible to delineate various metrics such as steps, cadence and pace.

The distance measured between two consecutive supports of the same foot is called step length. Also, cadence is defined as the number of steps that are performed in a time interval, with your unit being the step per minute. Expressed in steps per second, cadence is twice the inverse of cycle duration [49].

The running speed is the distance travelled by the body in the unit of time in the considered direction. The average speed can be calculated as the product of the cadence by the length of the step [49].

There are some differences in the gait cycle between walking and running.

Figure 4.8 - Forward human locomotion [53]

As illustrated in Figure 4.8, the point A represents the transition from periods of double support (when both feet are in contact with the ground) during the stance phase in the walking gait cycle, to two periods of double float (when neither foot is in contact with the ground) at the beginning and the end of the swing phase of the running gait cycle. Among distance runners, 80% are rearfoot strikers and the remainder are midfoot strikers [53].

In addition, the point B is related to the change in how initial contact is made, from being on the Hindfoot in running gait cycle to the forefoot in sprinting gait cycle [53].

Also, in running, toe off occurs before 50% of the gait cycle in contrast to walking, and in sprinting this event takes place even earlier. In a study made by Novacheck, the toe off event occurred in 39% and 36% of this cycle, for running and sprinting, respectively. For elite sprinters, this percentage can be as low as 22% [53].

As represented in Figure 4.9, where for each condition it is represented the timeline of events in two complete gait cycles, as the speed increases, time spent in swing (represented as clear) increases, stance time (represented as shaded) decreases, double float increases, and cycle time shortens.

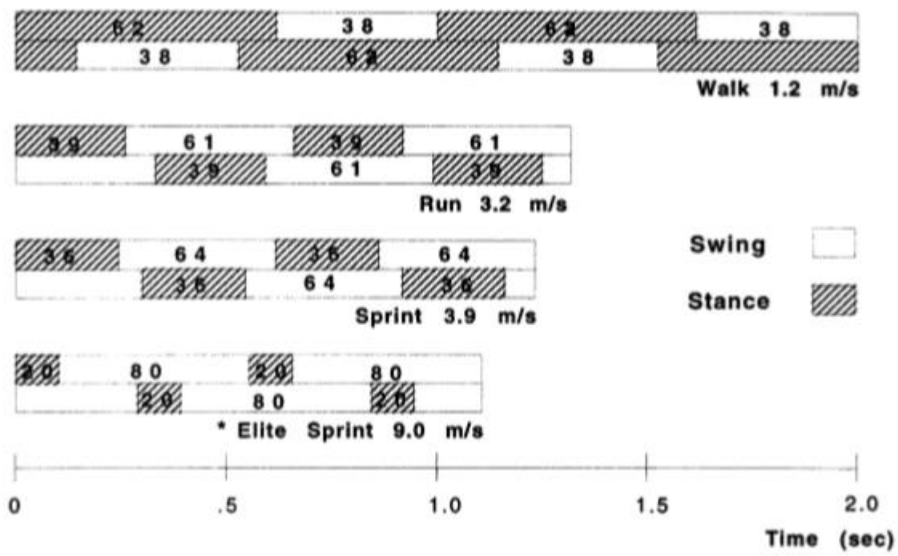

Figure 4.9 - The influence of velocity variation in gait cycle parameters [53]

With the knowledge of foot movements and the human gait cycle, the task of data analysis and processing will be done with better detail and accuracy, since certain patterns measured by pressure sensors can be identified and compared with what is expected. Therefore, over time, several solutions have been created with the aim of doing this analysis and drawing important conclusions that can prevent a possible injury.

4.4. State of the Art Solutions

Currently, there is a widespread increase in the use of APP's (Application) for different health conditions. The main reason for this is due to the various resources available on smartphones, where there is a quick adaptation by the user.

With the introduction of mobile health (mHealth) and the increasing popularity of mobile devices in clinics and hospitals, a team of healthcare professionals will be able to remotely assess and monitor the evolution of the wound through APP's [54].

There are several developments of APPs targeting foot ulcers on the market. Kulkarni, who has implemented an application on Android to facilitate connection, use and mobility by the patient and the healthcare professional, presents one of these solutions. This application was developed with Android Studio IDE (Integrated Development Environment) (version 3.5.1), and the target version was 6.0 and higher. Its purpose was to show temperature, pressure and accelerometer data collected, which were being continuously updated through the Client Characteristics Descriptor (CCCD) defined in Bluetooth protocol [55].

However, there are limitations associated with this development, related to the ending of the Bluetooth connection on changes of orientation, or even when the mobile phone screen was locked, and this connection has to be manually made by the user [55].

In another work developed by Bencheikh and Boukhenous, a system consisting of an instrumented sole was presented, which allowed the reading of pressure, humidity and temperature, whose purpose was to communicate through Bluetooth with an Android mobile application in real time and alert to points of higher risk of ulceration, as shown in Figure 4.10. In addition to the continuous monitoring, this application allowed access to records and graphs of the temporal evolution of these values [56].

Figure 4.10 - Application interface developed by Bencheikh and Boukhenous [56]

Regarding the risk assessment scales for pressure ulcers, there are several mobile applications implemented in the market that have an algorithm that allows determining the scores, using the Braden scale usually, related to the risk of developing ulcers [54].

In addition to this classification algorithm, other algorithms are available to identify the probable stage of the lesion through image analysis. Tibes, in which he developed a prototype of a mobile application, presented in Figure 4.11, capable of preventing and classifying PUs, using Android Studio and the Android SDK (Software Development Kit) and Java language, developed one of these works and the k-nearest neighbors classification algorithm was used as the classification algorithm. Among the limitations of this work is the development of the application exclusively for Android and the lack of automatic system updates [57].

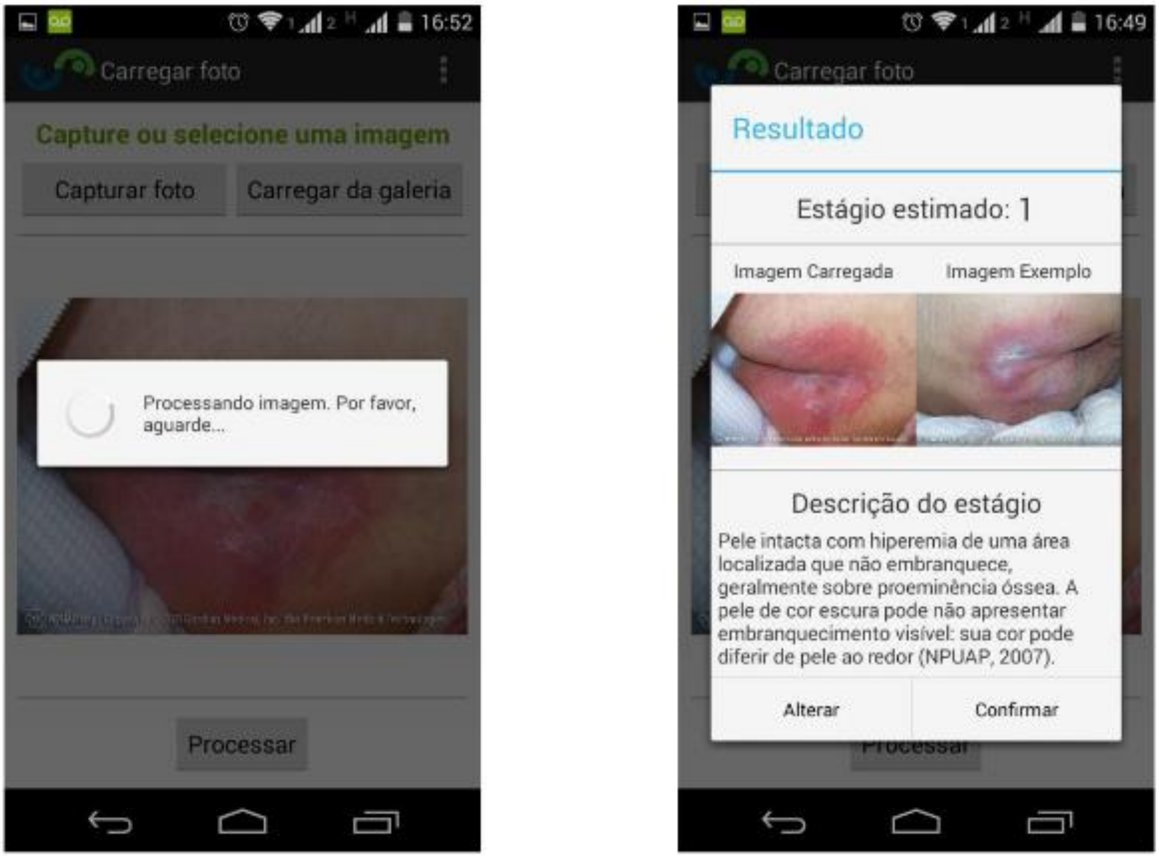

Figure 4.11 - Interface of the automatic ulcer classification developed by Tibes [57]

Thus, it is possible to verify that there are several approaches to prevent the appearance of ulcers, which include using risk assessment scales, where the Braden scale stands out, as well as monitoring the pressure, temperature and humidity existing in the foot in real time. For the classification of the injury stage, image analysis methods are commonly used.

In summary, this chapter has provided details about the foot, its movements and the different phases of the human gait cycle. These topics are extremely relevant, since, for example, an incorrect interpretation of a step count will influence the pace, cadence and stance time values of each foot, causing the patient to have a wrong perception of the monitoring.

Another consequence of not knowing these topics may be to wrongly identify the area of the foot associated to the values of a sensor, causing the healthcare professional to subsequently make a wrong prognosis and not treat the solution in the correct way.

In addition to these topics, some solutions that prevent the appearance of ulcers using a mobile application were explored. However, the application developed in this study has a wider range of functionalities, and overcomes some limitations presented by other authors, such as Kulkarni, namely the ending of the Bluetooth connection on changes of orientation, or even when the mobile phone screen was locked [55].

CHAPTER 5 – PROJECT DEVELOPMENT

5. Project Development

This chapter was created with the aim of explaining the system referred to throughout this study, consisting of a mobile application used by the patient, a mobile application used to test the previous one, and a web application aimed at health professionals and administrators.

In this way, a description of the My Care Shoe project will be initially made, followed by the different components, algorithms and users of the system, which will be detailed. After these explanations, the different tests performed to each of the applications directed to the patient and health professional are listed.

5.1. Overview

Given the growing need to prevent the onset of foot ulcers in diabetics, a smart footwear for diabetics has been devised to fulfil this purpose, called My Care Shoe.

One of the main focuses of this product is its daily applicability, with the respective monitoring and prolonged action of different parameters associated with the user, ensuring minimum impact on comfort compared to conventional footwear.

Regarding the architecture of the solution of diabetic footwear to be developed, it is necessary to highlight the set of technologies and systems to be incorporated into the solution, these being:

- Sensors and systems for measuring plantar and dorsal pressure;
- Temperature and humidity sensors;
- Actuators for relief/adjustment of the pressure evaluated;
- Actuators for stimulation of blood circulation;
- Control electronics (hardware and respective firmware) to control all the above-mentioned systems;
- Functional finishes (antimicrobial) in the materials that constitute the footwear;

- Footwear with customized design to accommodate all the systems;
- Software and user interface (external component to the system).

Based on all the systems mentioned above, a first study was carried out about the possible architecture of the system/solution My Care Shoe, which is illustrated in Figure 5.1.

Figure 5.1 - Illustration of the overall concept of the My Care Shoe solution

By analyzing the figure, it is possible to conclude that the main approach consists in maintaining the visual aspect already implemented previously, optimizing and adjusting all the shoe's materials and components (e.g., sole, insole, vamp) in order to allow for the accommodation of the remaining systems. In this way, it is intended to accommodate the action systems for pressure adjustment and stimulation of blood circulation in the region of the insole and sole, thus readjusting the dimensions and structure of these components. This same region will also serve as a basis for the integration of part of the pressure sensing systems, which is why a careful study was necessary from the design point of view of these components.

The sole, in turn, is the main component with enough size to accommodate the control electronics, being that different encapsulation solutions were explored to ensure not only the robustness and durability of the hardware, but also the comfort of the user, a crucial factor to the whole concept once any degree of discomfort may lead to serious injuries to the target audience (diabetic patients). The location of the hardware in the sole is thus thought in the heel region, since the application of the same in other areas can compromise the flexibility of the shoe, and consequently the locomotion of the user.

In the context of the application of functional finishes, the insole presents itself as the area of greatest interest of functionalization, including anti-microbial and anti-fungal finishes.

Additionally, the system illustrated in the figure includes the software component that will communicate wirelessly (Bluetooth) with the My Care Shoe solution, thus serving as the user interface system, which will be explored in more detail.

5.2.Methods

In order to achieve the proposed objectives, it was necessary to design several components that are represented in Figure 5.2 and make up the system, such as the microcontroller, the APP, the Web API, the Web Client and the respective database (represented as My Care Shoe DB).

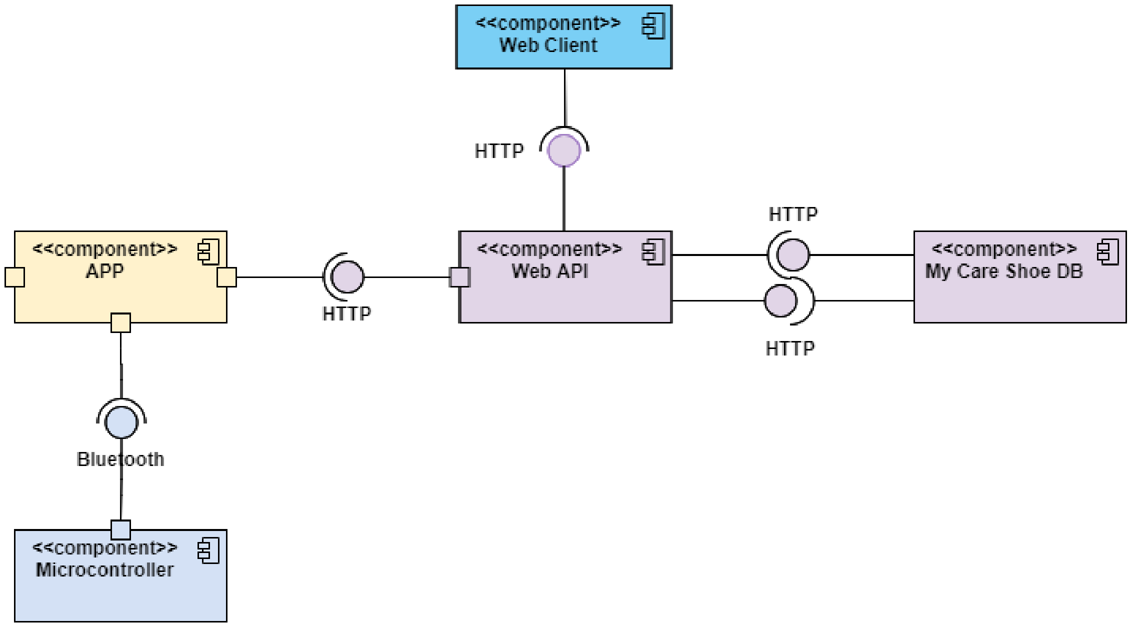

Figure 5.2 - Unified Modelling Language (UML) system diagram

As can be seen in this figure, the operation of the system assumes the existence of a microcontroller, which will be responsible for sending the data collected by the insole sensors, through communication via Bluetooth protocol. Then, the mobile application receives this data, processes it and sends a request through the HTTP protocol to the API, described as Web API in the previous figure.

This component is responsible for processing these requests and performing queries to the database through the HTTP protocol. This action will serve both to save records in the database and to return them.

This process will be similar for the interaction between the Web Client and the API, however, there is no communication between this and the microcontroller. The tools used to develop the various components are listed in Table 5.1.

Table 5.1 - Tools used for the development of the components

Component	Tools used	IDE/ Administration User Interface
Database	MySQL database management system	phpMyAdmin
API	PHP	Atom, v1.58.0
Web application	Cascading Style Sheets (CSS), Bootstrap, JavaScript, HyperText Markup Language (HTML)	Atom, v1.58.0
Mobile application	Java	Android Studio, v4.2.1
Apache Web Server	XAMPP, v3.3.0	-

To achieve an effective interaction of the various users in the architecture of the whole system, it is necessary to share some useful information. This information will be stored in multiple variables consisting of personal information, data from the monitoring system which will later be processed and analyzed to produce some statistics of interest.

The interface software allows access to various actors with different profiles, such as: Diabetic patient (user); Clinical professional (doctor, etc.) and Manager or Administrator. Each user of the various applications (Web and Android) is considered an actor who will have their own use cases regarding their interactions that are intended for them. All the items previously mentioned are presented in more detail below.

5.2.1. System variables

5.2.1.1. Personal information

To register a new user, some personal data and other data characterizing a certain patient who will be the user of the pressure monitoring system are required. These data mentioned are the name, patient number, date of birth, height, weight, size of the foot, presence of diabetes and type of foot.

This information is currently inserted after the moment of registration and later validation by the administrator and is stored in a table of the database used for this project, however, the future goal is to be able to be accessed through the patient's clinical history, which may be stored in an NHS database, if the proper intercommunication authorizations are in place.

5.2.1.2. Information collected by the monitoring system

Regarding the information collected by the pressure monitoring system, it will be necessary to record several metrics. Some of these metrics will be summarized for the system user through the Android APP and the clinician will have access to all the information through the Web application. Some of the data that will be recorded, referring to human gait are, for example:

- The number of steps and the average contact time of each foot per step, which will be estimated through the analysis of the sensors that will be pressed;
- Cadence, which will be calculated through the number of steps per unit of time;
- Speed, which will be calculated with the number of steps and the approximate stride length for each gender;
- Balance, which will be based on an analysis of the support times of each foot normalized to the walking cycle time.

Besides this information, data concerning the amplitude of the pressures involved between the foot and the shoe will also be collected, corresponding to the values measured by each sensor. These data will be further processed and will also be registered in the Android application's database so that the clinician can then access them through his/her Web application.

5.2.1.3. Information processing

After processing the data, it is necessary to have a register and analysis of them. The Android application will be responsible for collecting the sensing data and calculating the several metrics previously mentioned, and then generating some statistics, some of which will be more relevant for the health professional, because they will be extremely useful to help him/her in the patient support process.

These statistics will be divided into two topics, depending on the degree of detail that you want to be observed: illustrative view and graphical view. In the illustrative view, it will be possible to access the average values of plantar and dorsal pressure in both feet, average cadence, number of steps and temperature and humidity values in each foot, while in the graphic view, it will be possible to observe the evolution in detail of the average value of the sensors in each foot, in a determined time interval.

Besides the statistics, the application is responsible for generating warnings whenever overpressure conditions are observed in the data collected by the sensors.

These overpressure conditions vary between patients, and it will be up to the healthcare professional to define them according to each case. These variables are the defined overpressure value, which defines the pressure threshold that can be reached by each sensor, as well as the number of occurrences and time interval.

Whenever the value of a sensor exceeds this threshold a certain number of times, in a certain time interval, an alert is created, which can be consulted later by the patient.

5.2.2. User profiles

The interface software consists of an android application and a web application. The Android mobile application will be used by the diabetic patient, who will use the monitoring system inserted in the footwear. This application monitors the data received by the pressure system control unit, analyses, displays, and issues information with metrics of interest and alerts in case of hyperpressure.

The Web application will be used by the healthcare professional, who will have access to the personal data of the user in question, as well as the data collected by the Android application. This Web application will be managed by an administrator who has high-level privileges for registering new clinicians and users, as well as assigning permissions.

Thus, the users of the whole system and software boil down to the following:

- Diabetic patient (wearer): end user of the shoe with the built-in pressure system and user of the Android mobile smartphone application;
- Clinical professional (doctor, etc.): user of the web application where you can manage patients and analyze the data collected by the pressure system for each patient;
- Manager or Administrator: user of the web application that manages clinical professionals and patients.

5.2.3. Use cases

Each user of the various applications will be considered an actor who will have their own use cases regarding their interactions that are intended for them. The Use Cases (UC) inherent to the interaction of the user (patient) with the Android mobile application are presented in Table 5.2. In Table 5.3 the use cases of the execution of the APP itself are described. The use cases inherent to the use of the Web application by the administrator and by the clinical professional are presented in Table 5.4 and Table 5.5, respectively.

Table 5.2 - Description of typical patient use cases (mobile APP)

Software: Mobile *APP* **Actor:** Diabetic patient		
#UC	**UC name**	**Description**
UC-1	Change credentials	Change username; change password; change e-mail
UC-2	Start monitoring	Initiate monitoring process
UC-3	Real-time data visualisation	View real-time pressure levels, humidity and temperature values and gait information such as number of steps, cadence, balance between the two feet, speed, and average stance time
UC-4	Consult statistics	Consult information generated during a monitoring period (pressure levels, humidity and temperature values and gait information such as number of steps, cadence, balance between the two feet, speed, and average stance time)
UC-5	View warnings	View previous warnings (description of these)
UC-6	End monitoring	End monitoring process
UC-7	Consulting personal information	Query personal data parameters (weight, height, foot size, presence of diabetes, name, gender, patient number and date of birth)
UC-8	Update personal information	Update personal information such as weight, height, foot size, presence of diabetes and foot type
UC-9	Create an account	Register an account with username, e-mail, and password

UC-10	Establish Bluetooth connection	Establish Bluetooth connection with the microcontroller of each foot
UC-11	Sensor value interpretation help	Existence of an aid for interpreting the colour gradient referring to the sensor values in real time

Table 5.3 - Description of typical use cases of the system (mobile APP)

Software: Mobile *APP* Actor: Execution by the mobile APP *software*		
#UC	**UC name**	**Description**
UC-1	Monitorization	Monitoring of user activity: recording and analysis of measurements obtained; generation of warnings
UC-2	Data processing	Organize and structure the different metrics to present in statistical form
UC-3	Sending data to the DB	Sending of sensing data and statistics to the database

Table 5.4 - Description of typical administrator use cases (Web application)

Software: *Web* application Actor: Administrator/Manager		
#UC	**UC name**	**Description**
UC-1	Access permissions management	Restricting or authorizing a user's access to the system
UC-2	Profile management	Assigning a certain profile to a registered user

UC-3	Monitoring DB Changes	View and act upon suspicious data alteration

Table 5.5 - Description of typical use cases of the clinical professional (Web application)

Software: *Web* application **Actor: Clinical Professional**		
#UC	**UC name**	**Description**
UC-1	Changing access credentials	Ability to change your username, e-mail, and password
UC-2	Setting pressure thresholds	Modify/Update pressure thresholds for each patient
UC-3	Assigning warning generation conditions	Assign the number of occurrences of hyper pressure of a sense in a time interval, so that a warning is generated
UC-4	Accessing the patient list	Access the list of registered patients on the My Care Shoe application
UC-5	Adding, viewing and editing patient data	Adding, viewing and editing the patient's personal data like weight, height, foot size, type of foot, presence of diabetes, name, gender, patient number and date of birth
UC-6	Consult statistical data	Ability to generate graphs at a given time interval relating to the evolution of cadence, balance, number of steps, as well as left and right foot pressure, temperature, humidity, and stance time values
UC-7	Consult warnings	Access to the list of warnings at a given time interval, with a picture helping the professional to locate each sensor

On the other hand, Table 5.6 lists some aspects related to non-functional requirements that must be taken into consideration aiming to obtain system security, performance, usability and reliability.

Table 5.6 - Non-functional system requirements

#UC	UC name	Description
UC-1	Security	To ensure data security and avoid storing data locally, it was decided that the APP only works connected to the internet
UC-2	APP and web interface usability	Error prevention, good aesthetics and design, user help, documentation, consistency, and standards
UC-3	System reliability	Minimize system failures
UC-4	Performance	Good response time, resource consumption (power, phone battery, etc.), capacity and scalability

In this way, to better understand all the possible actions to be done by the patient, health professional and administrator, a diagram of use cases present in Figure 5.3 was created.

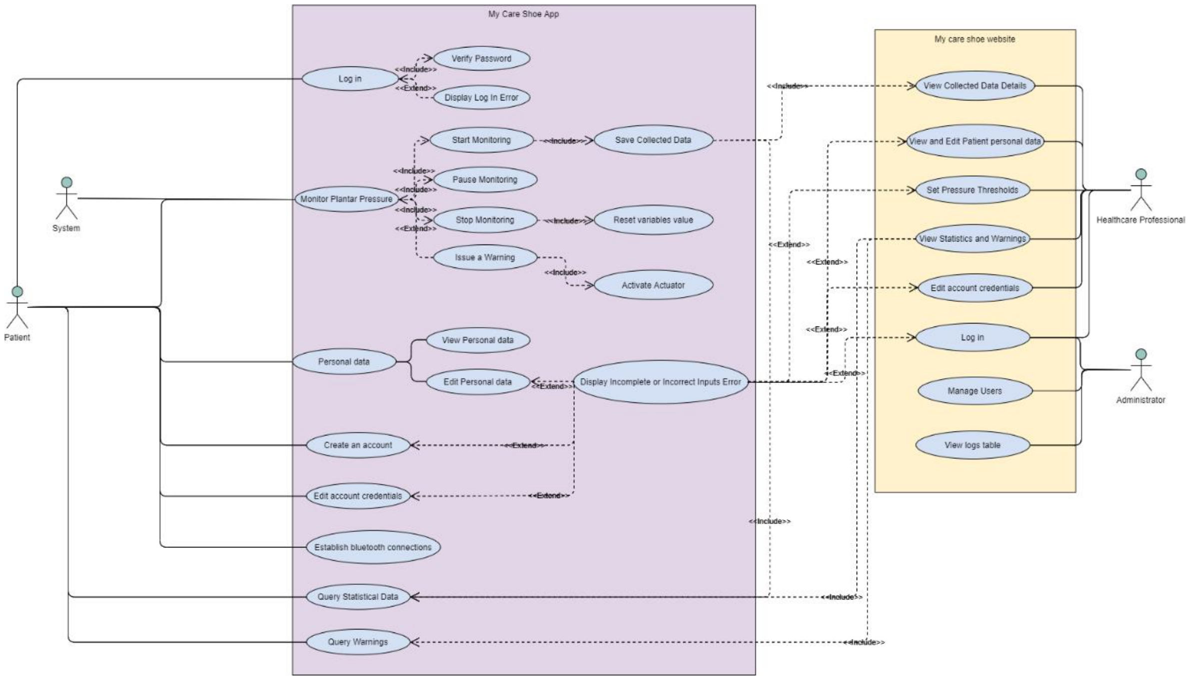

Figure 5.3 - My care shoe use case diagram

5.2.4. Database architecture

The constitution of the database is represented in Figure 5.4, where it consists of seven tables interconnected by several variables.

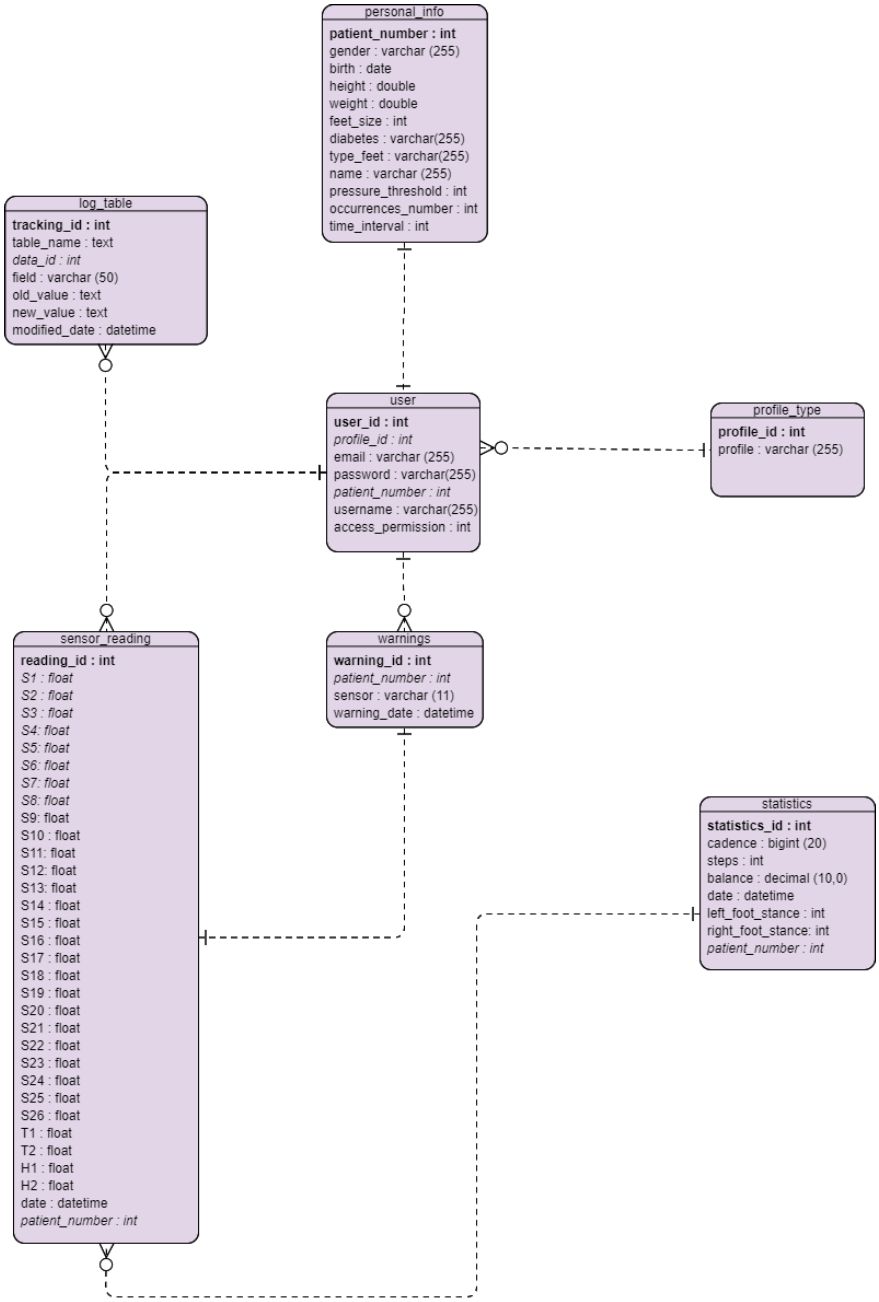

Figure 5.4 - Entity Relationship Diagram

The *user* table (Table 5.7) houses the data related to the user account in question, which has a secondary key to access the profile variable of the *profile_type* table (Table 5.8) that will define the user type, for example, if the user is a patient, a healthcare professional or an administrator. In addition, this table contains the *access_permission* column, which relates to the permission to access the software.

Table 5.7 - Description of the user table columns

Column	**Description**
user_id	Unique *user* identifier (primary key)
profile_id	Secondary key for *profile_type* table
email	User email (unique)
password	User password
username	Unique sequence of characters that identifies a user
patient_number	Patient’s number
access_permission	Variable related to the user access permissions, having a value of 0 for access denied, and 1 for access allowed

Table 5.8 - Description of the profile_type table columns

Column	**Description**
profile_id	Unique *profile_type* identifier (primary key)
profile	Type of user profile: healthcare professional, user or administrator

The *personal_info* table (Table 5.9) stores the user's personal variables, variables that will be provided in the future by an external entity, as well as the *pressure_threshold*, *occurrences_number* and *time_interval* variables that are directly associated with the creation of warnings.

Table 5.9 - Description of the personal_info table columns

Column	Description
patient_number	Patient’s number (primary key)
gender	Patient’s gender
birth	Date of birth/age of patient
height	Patient’s heigth
weight	Patient’s weight
feet	Size of the patient's foot
diabetes	Presence of diabetes
type_feet	Patient’s foot type
name	Patient’s name
pressure_threshold	Pressure value that exceeded constitutes an overpressure value
occurrences_number	Limit to the number of times a sensor can show overpressure values in a given interval
time_interval	The above-mentioned time interval, in seconds, in which the number of times a sensor shows overpressure values is counted

The table *sensor_reading* (Table 5.10) stores the pressure, humidity and temperature values, which are received by the monitoring system. Two variables are also added, representing the time in which the readings were received and the patient number, which represents the secondary key that points to the *user* and *personal_info* tables.

Table 5.10 - Description of the sensor_reading table columns

Column	Description
reading_id	Unique *sensor_reading* identifier (primary key)
S1, S2, S3, S4, S5, S6, S7, S8, S9, S10, S11, S12, S13, S14, S15, S16, S17, S18, S19, S20, S21, S22, S23, S24, S25, S26	Readings received from each pressure sensor, in Kilopascal (kPa)
T1, T2	Received readings from each temperature sensor, in degree Celsius (ºC)
H1, H2	Received readings from each humidity sensor, in percentage (%)
date	Date/Time the readings were received
patient_number	Number of the patient that produced this reading (secondary key to *personal_info* and *user* tables)

The *warnings* table (Table 5.11) houses the variables necessary for the creation of the warning in case of hyperpressure. After analyzing the values received from each sensor, if within a time interval (variable *time_interval* of the *personal_info* table) one or more values reach the threshold (variable *pressure_threshold* of the *personal_info* table) a certain number of times (variable *occurrences_number* of the *personal_info* table), a new warning is created with the description of the sensors, patient number and creation date.

Table 5.11 - Description of the warnings table columns

Column	Description
warning_id	Unique *warnings* identifier (primary key)
sensor	Sensors that have reached the overpressure value, in a certain number of occurrences in a time interval
warning_date	Date/Time the warning was produced
patient_number	Number of the patient that produced this warning (secondary key to *personal_info* and *user* tables)

The *log_table* (Table 5.12) will be the table that allows the administrator to have access to the changes made to the database, to make it easier to understand if it has suffered a computer attack or even to understand what may be wrong, relative to the *personal_info* and *user* tables.

Table 5.12 - Description of the log_table table columns

Column	Description
tracking_id	Unique *log_table* identifier (primary key)
table_name	Name of the table whose record was changed
data_id	Primary key value of the table row that was changed
field	Table column that was modified in the record
old_value	Previous value of the variable
new_value	New value of the variable
modified	Date of modification

The *statistics* table (Table 5.13) will be responsible for keeping the information concerning the statistics (such as cadence, steps, balance, as well as left and right foot stance time) every second whenever the stopwatch is being run. In addition to these variables, the date of creation of this statistic and the patient number with which it is associated are also saved.

Table 5.13 - Description of the statistics table columns

Column	Description
statistics_id	Unique *statistics* identifier (primary key)
cadence	Total number of steps taken per minute
steps	Number of steps made in this record
balance	Percentage of the left foot load distribution over the total load
date	Date/Time the statistic record was created
left_foot_stance	Determined as the time that the left foot was in contact with the floor, in seconds
right_foot_stance	Determined as the time that the right foot was in contact with the floor, in seconds
patient_number	Number of the patient that produced this statistic (secondary key to *personal_info* and *user* tables)

5.2.5. Bluetooth Communication

With the goal to send information about the sensor reading from the microcontroller to the mobile phone, the Bluetooth communication protocol is used. Since the Android platform is compatible with the Bluetooth network stack, it becomes possible for a given device to communicate with another Bluetooth device wirelessly.

Using the Bluetooth APIs present in Android, several features can be accessed, including [58]:

- Search for other Bluetooth devices;

- Consult the paired Bluetooth devices;
- Create and establish RFCOMM (Radio Frequency Communication) channels;
- Establish a connection with other devices and exchange data;
- Managing the various connections.

In order to explain how communication is done in the My Care Shoe application, a UML Sequence Diagram was created, represented in Figure 5.5, which uses the functionalities previously described.

In aiming to search for Bluetooth devices, the following objects described in Table 5.14 are used: *BluetoothFragment*, *BluetoothController* and *BluetoothAdapter*.

Table 5.14 - Main Objects used throughout the Bluetooth communication and connection

Object	Description
BluetoothFragment	It will serve as a user interface, where it will display the paired devices and trigger the connections between them
BluetoothController	Contains the various threads that will be used, being responsible for managing them
BluetoothAdapter	Necessary for any activity involving Bluetooth, this adapter is unique in the system and is used by the APP to interact with Bluetooth. In order to return its instance, the getDefaultAdapter() method is used, which if it returns null means that the device does not support Bluetooth.

Using *BluetoothAdapter* it is possible to discover and access the list of paired devices.

This discovery consists of searching locally for Bluetooth devices that are discoverable and then requesting some information from them, namely the MAC (Media Access Control) address, which is unique, and the name of the device.

After this list is presented to the user using the *getBondedDevices*() method, the user may choose the device with which to initiate a connection.

With the purpose to initiate the connection process, there is logic on the server side as well as the client side. On the server side, it will be necessary to create a server socket, and on the client side, it will be necessary to make the connection using the server MAC address.

Thus, it will be necessary that a device assumes the role of the server, instantiating and opening a *BluetoothServerSocket*. This object will listen for connection requests, and its purpose is to return a *BluetoothSocket* once the connection is established.

This process, managed by *AcceptThread*, can be summarized in the following steps [58]:

- Use of the *listenUsingInsecureRfcommWithServiceRecord*(APP_NAME, MY_UUID) method to get the *BluetoothServerSocket*: the use of the UUID (Universally Unique Identifier) is for the purpose of identifying an information that needs to be unique within the same system, and in this case it is provided by the client in the connection process;
- Use of the *serverSocket.accept()* method, in order to receive possible connection requests from the client;
- Use of the *close*() method, which will dispense with the server socket if no additional connections are needed, and the connected socket will not be closed.

On the client side, the following steps will need to be followed [58]:

- Find the device that is receptive to new connections via the server socket (*BluetoothDevice*), and get the *BluetoothSocket* via the *createInsecureRfcommSocketToServiceRecord* (MY_UUID) method;

- Using the *connect*() method, of the previously instantiated *ConnectThread* object, the connection is established.

The UUID is stored in the Service Discovery Protocol (SDP) database in the *listenUsingInsecureRfcommWithServiceRecord*(APP_NAME, MY_UUID) method on the server side, and this value is searched in this same database as soon as the client invokes the *connect*() method, in order to find the device on the server side that holds the same value for the variable [58].

After this connection is properly established, a *ConnectedThread* is instantiated and the *BluetoothSocket* created can be used to exchange information between devices. There are two actions that can be performed for the exchange of information: read data (using the *read*(byte[] method) or send data (using the *write*(byte[] method)).

In order to manage these operations, the *InputStream* and *OutputStream* are used, returned through the *getInputStream*() and *getOutputStream*() methods, respectively.

At the end, when the user wishes to terminate the connection, the *cancel*() method is used on each instantiated thread, and the *close*() method is used on the socket to close the *BluetoothSocket* created.

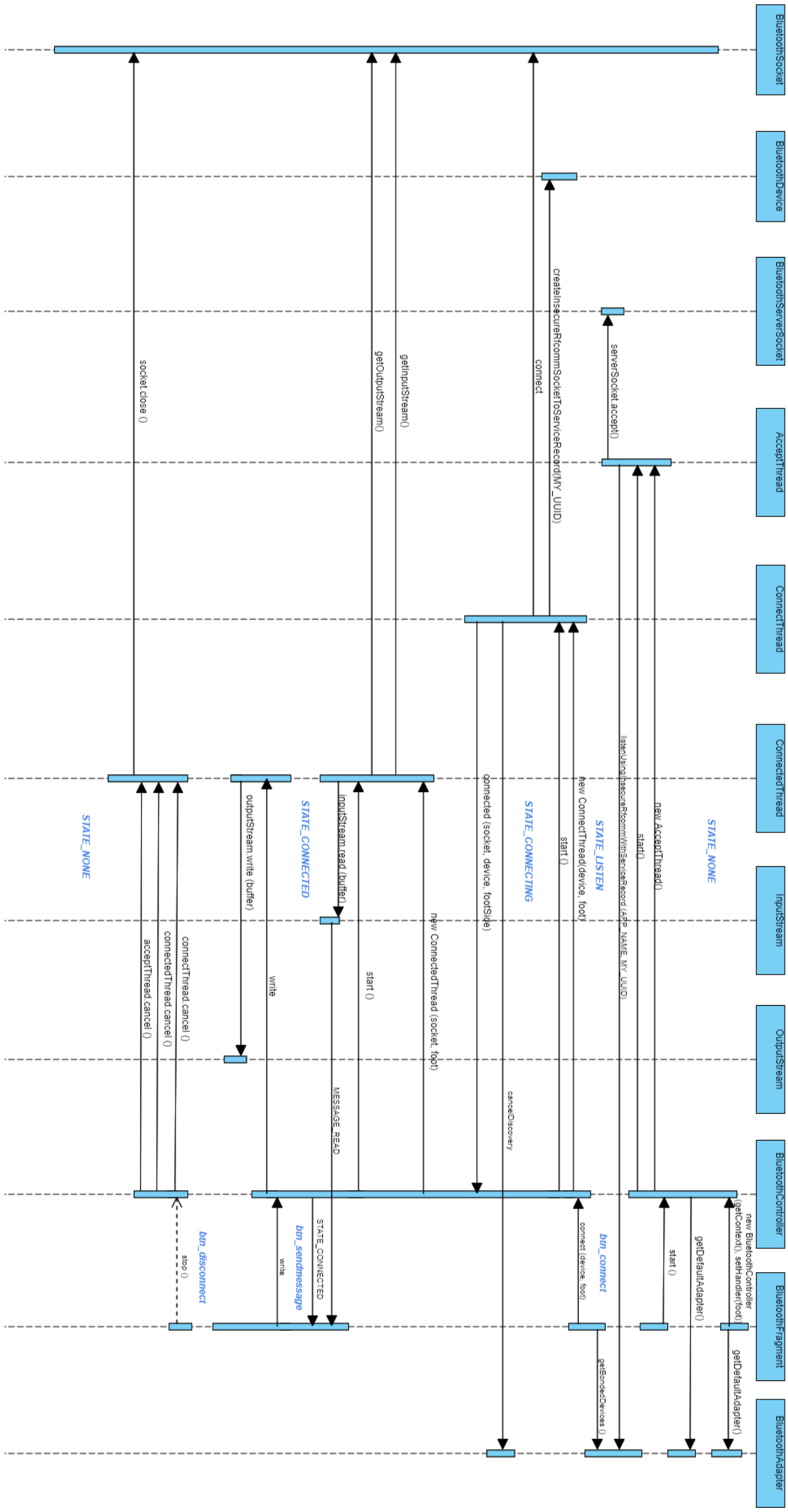

Figure 5.5 - Bluetooth UML Sequence Diagram

5.2.6. Monitoring process

After the data is sent by the microcontroller via the *InputStream*, whose format is represented in Figure 5.6 and in Figure 5.7, these are processed, stored in the database, and immediately presented to the user.

S1|S2|S3|S4|S5|S6|S7|S8|S9|S19|S20|S21|S22|H1|T1

Figure 5.6 - Right foot monitoring data format

S10|S11|S12|S13|S14|S15|S16|S17|S18|S23|S24|S25|S26|H2|T2

Figure 5.7 - Left foot monitoring data format

All the values shown in the previous figures S_x, refer to the pressure values of the sensors of each foot, in kPa. On the other hand, the T_x values refer to the temperature values, in degrees Celsius, and H_x refers to the humidity values, in percentage (%).

In order to make the data display easier for the patient, these pressure values are displayed in a graphic representation of the foot and converted into a color gradient, which will fill in the location of the sensor, as shown in the Figure 5.8.

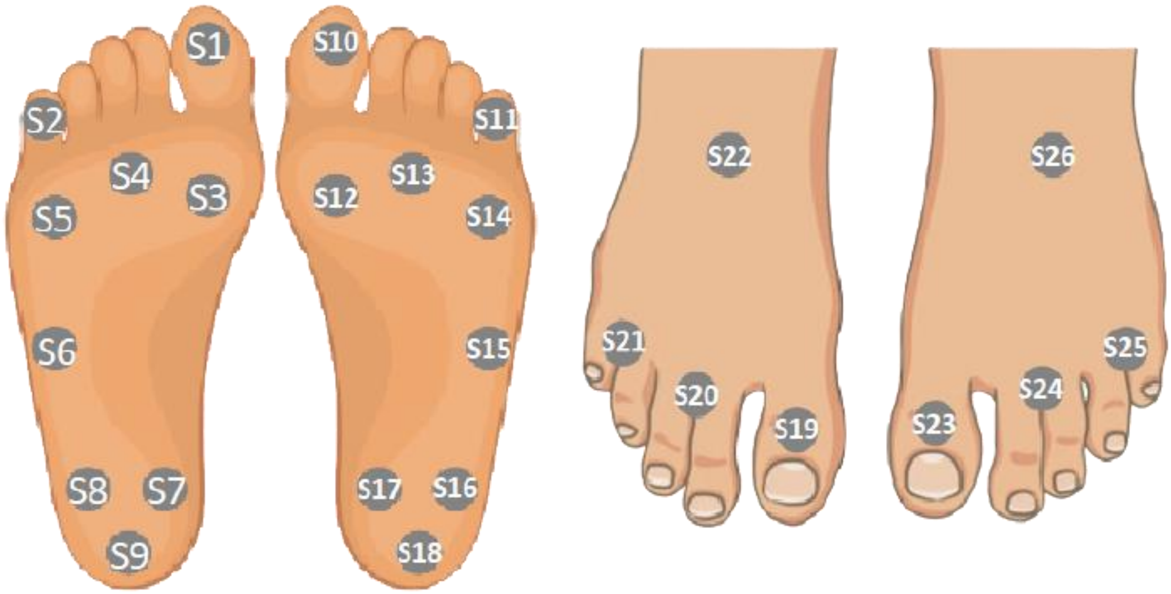

Figure 5.8 - Graphical representation of the sensors on each foot

As previously mentioned, each sensor represented in the figure will have a color, which will be associated with the pressure value. This gradient is represented in Figure 5.9.

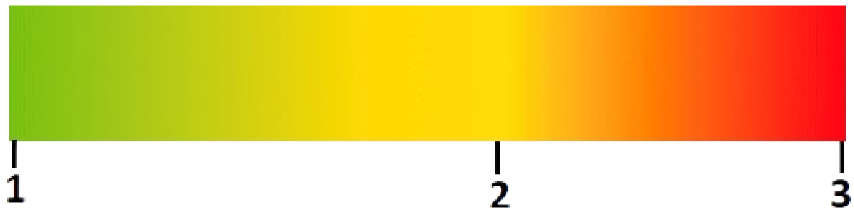

Figure 5.9 - Sensor pressure value color gradient

To define the intervals that are numbered in this figure, it is necessary to consider the hyperpressure value defined by the healthcare professional:

1. Value corresponding to 0 kPa;
2. Value corresponding to one third of the hyperpressure value;
3. Value corresponding to the hyperpressure value

If this value is not yet set, the system assumes that this variable has a default value of 200 kPa.

Thus, if the default value mentioned above is assumed, the range between point 1 and 2 in this figure refers to the range of values between 0 and approximately 66.7 kPa, and the range between point 2 and 3 refers to the values between 66.7 and 200 kPa.

All values equal to or greater than the hyperpressure value will have the same red coloring.

On the other hand, the temperature and humidity values are presented to the patient as represented in Figure 5.10.

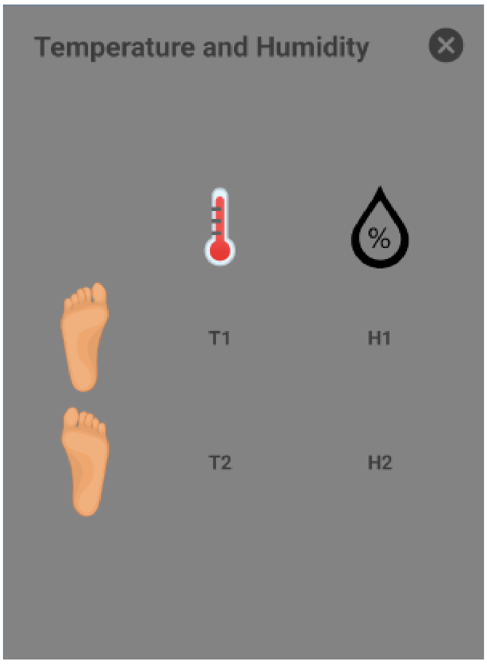

Figure 5.10 Illustrative presentation of temperature and humidity values

For the remaining variables, a timer was set to update the value presented to the user. Every 2 seconds a statistical record is calculated and saved, if the stopwatch is counting, and the number of steps and the stance time of each foot is updated on the user interface.

On the other hand, every 3 seconds, the cadence and pace values are updated on this same interface.

5.2.7. API specification

To be able to interpret the requests made by each application, and return the desired data from the database, it is necessary to create an API.

For the design of the API, a division of the different files by folders was considered, according to the context in which they are inserted, these folders being called db, logs, patient, readings, statistics, user, and warnings. All these files start from the same directory, whose *host* variable has the value *IP_ADDRESS/mycareshoeapi/*, where the *IP_ADDRESS* value is 10.8.129.207.

However, there is one feature, shown in Table 5.15, that cuts across many of these contexts, and so has not been placed in any specific subdirectory.

Table 5.15 - URIs relative to http://{host}/search.php

Name	HTTP request	Description
search	GET ?start_date=yyyy-MM-dd & end_date= yyy-MM-dd & topic= {*topic*} & patient_number= patient_number	Returns the data generated between *start_date* and *end_date*. The data type is set by the *topic* and can take the value of "*logs*" to return the logs, the value of "s*ensorsReading*" to return the sensor readings, the value "*warnings*" to return the generated warnings and the value "*statistics*" to return the generated statistics. Apart from *topic*=logs, all other values require the patient number *(patient_number*) to return records.

Regarding the patient, there are 3 actions, described in Table 5.16, which are used in the system: searching for a specific patient, updating personal information, and returning all existing patients.

Table 5.16 - URIs relative to http://{host}/patient

Name	HTTP request	Description
patient_search	GET /patient_search.php?patient_number= patient_number	Returns the patient's personal information with patient number equal to *patient_number*
update_patient _info	PUT /update_patient_info.php ? patient_number= patient_number & updated_parameters = updated_parameters	Updates patient personal information with patient number equal to patient_number. The variable updated_info corresponds to the variables that the user wished to update such as "gender", "height", "weight", "feet_size", "diabetes", "type_feet", "patient_number", "pressure_threshold", "occurences_number", "time_interval", "name" and "birth".
patient_search _all	GET /patient_search_all.php	Returns the data of all the patients entered

In the case of sensor readings and statistics, in addition to their search in a specific range already mentioned, it is necessary to create new entries, whose action is described in Table 5.17 and Table 5.18, respectively.

Table 5.17 - URIs relative to http://{host}/readings

Name	HTTP request	Description
create_reading	POST /create_reading.php?patient_number= patient_number&S[1…26]=S[1…26]	Inserts a record of a sensor reading, having as parameters the patient_number, date, the

	&T1=T1&T2=T2&H1=H1&H2=H2& date=yyyy-MM-dd hh:mm:ss	value of sensors S1 to S26, the value of temperature T1 and T2 and the value of humidity H2 and H2

Table 5.18 - URIs relative to http://{host}/statistics

Name	HTTP request	Description
create_statistics	POST /create_statistics.php?patient_number = patient_number&cadence=cadence& balance=balance & steps=steps & left_foot_stance=left_foot_stance & right_foot_stance=right_foot_stance & date=yyyy-MM-dd hh:mm:ss	Inserts a statistic calculated from patient number (*patient_number*), *date*, cadence value (*cadence*), *steps*, *balance* and stance time in each foot (*left_stance_time* and *right_stance_time*)

Concerning the user, operations such as login, registration and updating of personal information are required and are documented in Table 5.19.

Table 5.19 - URIs relative to http://{host}/user

Name	HTTP request	Description
login	POST /login.php?usernameEmail=usernameEma il & password=password	Verification that the user data is present in the database. The *usernameEmail* parameter refers to the common field for both username and email, and the *password*

		parameter refers to the password
registration	POST /registration.php?email=email&username=username&password=password&patient_number=patient_number	Creation of a new user record with the parameters email, password, username, and patient_number
update_user_info	PUT /update_user_info?email=email&username=username&password=password&patient_number=patient_number	Changing user data with the parameters email, password, username and patient_number

Finally, with respect to warnings, procedures such as creating and collecting all warnings entered are required and are documented in Table 5.20.

Table 5.20 - URIs relative to http://{host}/warnings

Name	HTTP request	Description
create_warning	POST /create_warning.php?patient_number=patient_number&sensor=sensors&warning_date=date	Creation of a new warning record, with the parameters *patient_number*, comma separated sensor description (*sensor*) and creation date (*warning_date*)
warnings_search	GET /warnings_search.php?patient_number=patient_number	Returns all warnings created by the patient

All the feature's details for the mobile application and web application are further explored in Appendix A and Appendix B, respectively.

5.3. Microcontroller Simulator

With the purpose of testing the mobile application, it was previously necessary to find a device that replicated the microcontroller's function, that is, a Bluetooth server, and could connect with the application and send data that simulated human walking.

Thus, during the development of the project, two of these devices (mobile phones) were used, each one simulating the source of data of a particular foot (right or left).

In this way, another application was created with the interface identical to the one in the Figure 5.11, which has the following functionalities:

1. Listing of the device to which it is connected;
2. Possibility to connect autonomously to any device;
3. Listing of sent and received messages;
4. Possibility of sending personalized messages.

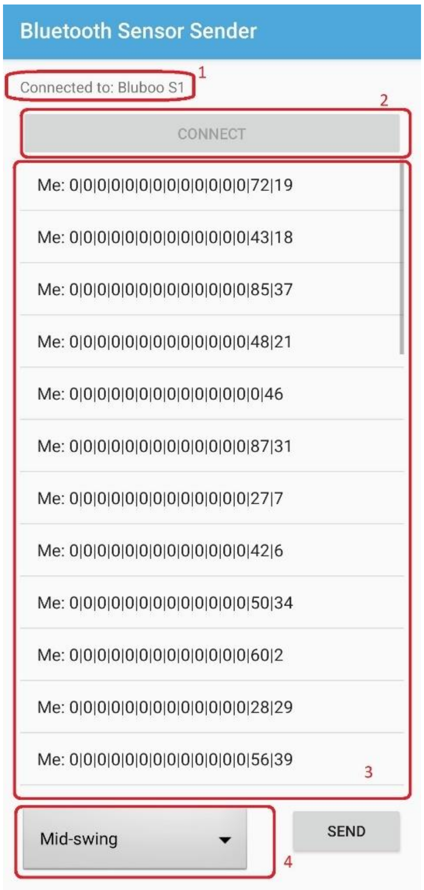

Figure 5.11 - Interface of the application used to mimic the Bluetooth server

With the aim of being able to replicate the different types of data generated on the gait, the different customized message options were created, as shown in the Table 5.21.

Table 5.21 - Different types of sent data

Name	**Pressure sensor values**	**Humidity values**	**Temperature values**
Random values	Between 0 and 300 kPa	Between 0 and 100%	Between 0 and 50ºC
Mid-swing	0 kPa	Between 0 and 100%	Between 0 and 50ºC

Random values without warning	Between 0 and 199 kPa	Between 0 and 100%	Between 0 and 50ºC
Heel strike	S7, S8 and S9 or S16, S17 and S18 with values between 0 and 100 kPa, and all the others with 0 kPa value	Between 0 and 100%	Between 0 and 50ºC
Toe off	S1 or S10 greater than 0, and all the others equal to zero	Between 0 and 100%	Between 0 and 50ºC
Walk simulation - Left foot; **Walk simulation - Right foot**	Sending information to simulate heel strike, foot support, toe off and swing, being delayed on each foot	Between 0 and 100%	Between 0 and 50ºC

To validate the correct functioning of the functionalities listed above and ensure the quality of the product, it is necessary to perform tests that fulfil this purpose.

5.4.Mobile Application Tests

Software testing consists of a process of executing a product, with the objective of checking whether it meets the specifications previously described, and whether this same product works as expected in the environment for which it was designed. Thus, before the product is deployed to production, it is crucial to detect all faults and correct them before final delivery. Thus, the tests performed on the system to ensure its quality will be specified.

5.4.1. Functional testing

This type of test aims to test what the application should do, as described in the functional requirements of the system. Thus, the evaluation, represented in Table 5.22 is carried out according to the following nomenclature: W - Works; WR - Works with some restrictions; NW - Does not work; NT - Not tested.

Table 5.22 - Functional testing of the mobile application

Requirements	Result	Test scenario
1. Login	W	**Table 5.23**
2. Change credentials	W	**Table 5.26**
3. Start monitoring	W	-
4. Real-time data visualisation	W	**Table 5.30**
5. Consult statistics	W	**Table 5.28**, **Table 5.29**
6. View warnings	W	-
7. End monitoring	W	-
8. Consulting personal information	W	**Table 5.27**
9. Update personal information	W	
10. Create an account	W	**Table 5.24**

11. Establish Bluetooth connection	W	**Table 5.25**
12. Sensor value interpretation help	W	-

Table 5.23 - Test scenario related to login functionality

Pre-conditions			
Accessing My Care Shoe mobile application			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify login with the valid patient credentials with access permission	1. Enter valid username/e-mail and password; 2. Click login button	Monitorization landing fragment is displayed, as well as the message “Successful logged in”	Pass
Verify login with the invalid patient credentials	1. Enter invalid username/e-mail and password; 2. Click login button	The message “Invalid username or password” is displayed	Pass
Verify login with the valid patient credentials but with no access permission	1. Enter username/e-mail and password with no access permission; 2. Click login button	The message “Access denied” is displayed	Pass
Verify login with the valid professional or	1. Enter professional or administrator	The message “The APP is only meant to be used by a patient. Contact the	Pass

administrator credentials	username/e-mail and password; 2. Click login button	administrator.” is displayed	

Table 5.24 - Test scenario related to registration functionality

Pre-conditions			
Accessing My Care Shoe mobile application and opening Registration activity			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify registration with all fields filled, and with a unique username, patient number and e-mail	1. Enter valid username, patient number, e-mail and password; 2. Click save button	The message “Successfully registered the user” is displayed	Pass
Verify registration with an already existing username	1. Enter existing username, patient number, e-mail and password; 2. Click save button	The message “Error in registering. The following fields already exists: username” is displayed	Pass
Verify registration with an already existing patient number	1. Enter username, existing patient number, e-mail and password; 2. Click save button	The message “Error in registering. The following fields already exists: patient_number” is displayed	Pass
Verify registration with	1. Enter username, invalid patient	The message “Invalid patient_number value” is displayed next to the	Pass

an invalid patient number	number, e-mail and password; 2. Click save button	field and save button is disabled	
Verify registration with an already existing e-mail	1. Enter username, patient number, existing e-mail and password; 2. Click save button	The message "Error in registering. The following fields already exists: email" is displayed	Pass
Verify registration with an invalid e-mail	1. Enter username, patient number, invalid e-mail and password; 2. Click save button	The message "Invalid email value" is displayed next to the field and save button is disabled	Pass
Verify registration with at least one missing field	1. Enter username and patient number;	The save button is disabled	Pass

Table 5.25 - Test scenario related to the Bluetooth connection functionality

Pre-conditions			
Accessing My Care Shoe mobile application, login, then open sliding menu and choose "Settings". After that, click on "Choose Bluetooth devices for each foot".			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify if the Bluetooth connection is working when selecting two devices	1. Select a valid device from each dropdown;	The status label in each foot will turn green, with the text "Connected"	Pass

that will connect successfully	2. Click Save button		
Verify Bluetooth connection with only one selected device	1. Select only a device from one dropdown; 2. Click Save button	The save button will be disabled	Pass
Verify if the Bluetooth connection is working when selecting two devices that will connect unsuccessfully	1. Select invalid device from each dropdown; 2. Click Save button	The message “Unable to connect device” is displayed and the status labels in each foot will remain red, with the text “Disconnected”	Pass
Verify Bluetooth connection is working when one connected device gets unavailable	1. Disconnect/turn off connected device	Device connection was lost in L/R foot	Pass

Table 5.26 - Test scenario related to credentials modification functionality

Pre-conditions			
Accessing My Care Shoe mobile application, login, then open sliding menu and choose “Settings”. After that, click on “Account settings”.			
Test Case	**Test Steps**	**Expected Result**	**Status**
Check that the functionality of changing access credentials works	1. Fill in valid username, e-mail and password;	Message “Successfully updated the user information” is displayed	Pass

	2. Click Save button		
Check the behaviour of the functionality of changing access credentials with an existing username	1. Fill in an already taken username, e-mail and password; 2. Click Save button	Message “Error in updating user info. The following fields already exists: username.” is displayed	Pass
Check the behaviour of the functionality of changing access credentials with an existing e-mail	1. Fill in username, an already taken e-mail and password; 2. Click Save button	Message “Error in updating user info. The following fields already exists: e-mail.” is displayed	Pass
Check the behaviour of the functionality of typing an e-mail with an incorrect format	1. Fill in username, an incorrect e-mail and password; 2. Click Save button	The message “Invalid email value” is displayed next to the field and save button is disabled	Pass

Table 5.27 - Test scenario related to personal information feature

Pre-conditions			
Accessing My Care Shoe mobile application, login, then open sliding menu and choose “Personal Information”.			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify if the personal information is retrieved successfully	1. Check the consistency of the data presented	The correct patient personal information’s are displayed, and fields “Name”, “Patient Number” and	Pass

		"Birth Date" are disabled	
Verify if weight field only accepts a interval of values (20 – 700kg)	1. Edit "Weight" field with a value below 20 kg or above 700 kg.	An error message should popup next to the field saying "Invalid weight value" and save button is disabled	Pass
Verify if height field only accepts an interval of values (0.5 – 3m)	1. Edit "Height" field with a value below 0.5m or above 3m.	An error message should popup next to the field saying "Invalid heigth value" and save button is disabled	Pass
Verify if feet size field only accepts an interval of values (15 – 75 European Size)	1. Edit "Feet Size" field with a value below 15 or above 75.	An error message should popup next to the field saying "Invalid feet_size value" and save button is disabled	Pass
Verify if form doesn't consider a change replacing an existing value with the same one	1. Edit any field with the same value.	Save button is disabled	Pass
Verify if any alteration is successfully saved	1. Edit any field; 2. Click save button; 3. Re-open this menu.	The changed field should have the most recent value	Pass

Table 5.28 - Test scenario related to the plotted statistics feature

Pre-conditions			
Accessing My Care Shoe mobile application, login, then open sliding menu and choose "Statistics". After that, select "Pressure statistic (plot)".			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify if pressure plotted statistics are retrieved successfully from an interval with at least one entry	1. Select a start and end date with at least one entry; 2. Click search button.	Each plot is created with the respective data, title, and x-axis label ("Sensor reading records")	Pass
Verify if pressure plotted statistics are retrieved successfully from a day with at least one entry	1. Select the same start and end date with at least one entry; 2. Click search button.	Each plot is created with the respective data, title and x-axis label ("Hours", referring to hours of the day)	Pass
Verify if it is not allowed to choose an end date that is older than the start date	1. Select a start date and try to select an end date older than the start date.	All the days before the start date are disabled and cannot assume the end date value	Pass
Verify if it is not allowed to choose a start date that is more recent than the end date	2. Select an end date and try to select a start date more recent than the end date.	All the days after the end date are disabled and cannot assume the start date value	Pass

Verify the behaviour of the plots when the interval doesn't contain any result	1. Select a start and end date with no entries; 2. Click search button.	Message "There is no sensor reading in this time gap!" is presented, and the previous plot data is deleted	Pass

Table 5.29 - Test scenario related to the illustrated statistics feature

Pre-conditions			
Accessing My Care Shoe mobile application, login, then open sliding menu and choose "Statistics". After that, select "Pressure statistic (illustrated)".			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify if pressure illustrated statistics are retrieved successfully from an interval with at least one entry	1. Select a start and end date with at least one entry; 2. Click search button.	Sensors dots are coloured depending on the value, and data as cadence, number of steps, humidity and temperature in each foot are presented	Pass
Verify if it is not allowed to choose an end date that is older than the start date	1. Select a start date and try to select an end date older than the start date.	All the days before the start date are disabled and cannot assume the end date value	Pass
Verify if it is not allowed to choose a start date that is more recent than the end date	1. Select an end date and try to select a start date more	All the days after the end date are disabled and cannot assume the start date value	Pass

	recent than the end date.		
Verify the behaviour of the menu when the interval doesn't contain any result	1. Select a start and end date with no entries; 2. Click search button.	Message "There is no sensor reading in this time gap!" is presented	Pass

Table 5.30 - Test scenario related to monitorization functionality

Pre-conditions			
Access My Care Shoe mobile application and login			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify if monitorization process is working correctly	1. Open sliding menu; 2. Select "Settings"; 3. Select "Choose Bluetooth devices for each foot"; 4. Select a device for each foot; 5. Click save button; 6. Open sliding menu; 7. Select "Monitorization"	Sensors dots are coloured depending on the value, and data as cadence, stance time, number of steps, pace and time is updated. When clicking the temperature icon, the most recent information about temperature and humidity should be shown.	Pass
Verify the behaviour with screen rotation or	1. Rotate the screen orientation, or switch to another	The monitorization process and data visualization should	Pass

fragment swapping	fragment and then return to the same	be preserved and not affected	
Check warnings list functionality, with the respective access to a warning	1. Click on the warnings button; 2. Select a warning from the list	If the button is previously red, it should turn grey again. The list should be displayed, and withing each warning, should be stated the sensors responsible for the warning creation as well as the date of occurrence.	Pass

5.4.2. Compatibility testing

With the aim of ensuring the compatibility of the application in different environments and platforms, it is necessary to perform compatibility tests. Thus, it will be necessary to perform these tests on different mobile devices with Android OS (Operating System), and in different versions of this same OS.

Thus, the following devices were used for these tests:

- Xiaomi Mi 10T Lite – Android 10;
- HUAWEI P8 lite 2017 – Android 7.0;
- Bluboo S1 – Android 7.0.

After running the application on each of these devices, no error or abnormality of the application was detected.

5.4.3. Performance Testing

With the purpose of checking whether the application satisfies specific performance requirements, such as the response time of requests made by users, performance tests were implemented.

The following devices were used for this test: Xiaomi Mi 10T lite with 128GB internal memory and 6GB RAM (Random Access Memory), Huawei P8 lite 2017 with 16GB internal memory and 3GB RAM, and the Bluboo S1 with 64GB internal memory and 4GB RAM.

Thus, Table 5.31 was created where the response times for each action in each device performed by the user are listed.

Table 5.31 - Response time in each major action with different devices

Action	**Response time**		
	Xiaomi Mi 10T lite	Huawei P8 lite 2017	Bluboo S1
Change credentials	321 milliseconds (ms)	112 ms	163 ms
Data processing	508 ms	154 ms	842 ms
Consult statistics (illustrated view)	387 ms	327 ms	519 ms
Consult statistics (plot view)	4349 ms	539 ms	682 ms
Log in	347 ms	228 ms	1821 ms

View warnings	237 ms	116 ms	266 ms
Consulting personal information	98 ms	68 ms	105 ms
Update personal information	103 ms	137 ms	188 ms
Create an account	228 ms	81 ms	300 ms
Establish Bluetooth connection	3790 ms	4500 ms	7940 ms

5.5. Web Application Testing

Regarding the web application, it was also necessary to ensure that its functionalities performed as expected. Thus, functional and compatibility tests were performed to achieve the desired product quality.

5.5.1. Functional testing

With the objective of checking whether the main functionalities of the web application are as expected, Table 5.32 was constructed, which lists the functional requirements previously specified. To each requirement, a more detailed exploration is associated within a test scenario, present in Appendix C of the document. As in Table 5.22, an evaluation is performed according to the following nomenclature: W - Works; WR - Works with some restrictions; NW - Does not work; NT - Not tested.

Table 5.32 - Functional testing of the web application

Requirements	Result	Test scenario
Access permissions management	W	Table C.1
Profile management	W	
Monitoring DB Changes	W	
Changing access credentials	W	**Table C.4**
Setting pressure thresholds	W	Table C.2
Assigning warning generation conditions	W	
Accessing the patient list	W	
Viewing and editing patient data	W	
Consult statistical data	W	**Table C.3**
Consult warnings	W	

5.5.2. Compatibility testing

With the aim of ensuring that the web application is responsive on different devices and browsers, compatibility tests were performed.

Thus, the Google Chrome, Microsoft Edge and Mozilla Firefox browsers were used, and every requirement of this application worked as expected in them.

In addition to this, the application was tested on a desktop device with the Dell Precision 3551 model, with Windows 10, as well as the mobile devices previously mentioned, Xiaomi Mi 10T Lite, HUAWEI P8 lite 2017 and Bluboo S1. On all these devices, the APP proved responsive, and all the requirements worked as expected.

To summarise this chapter, it is now possible to understand the functioning of the system, as well as the different components that constitute it, such as the database architecture, the API, the system requirements and the respective algorithms. Regarding the communication process, the Bluetooth communication protocol used to communicate between the microcontroller and the application is now clear.

With all the functionalities described, it will be advantageous for both the healthcare professional and the patient to use these applications, since they have access to the same data, allowing the professional to have knowledge of the patient's statistical and personal data, and because they allow them to recognise hyperpressure patterns and alert the areas that triggered the respective warnings.

To ensure the quality of the system developed, different types of tests were developed for the web and android applications, which passed without showing any anomaly, both being ready to be used by the end-user.

Chapter 6 – Conclusions

6. Conclusions

Throughout this work, an application capable of preventing the appearance of ulcers in diabetics was developed. This application allows patients to be aware of what needs to be corrected in their gait and then, using the medical opinion obtained using the web application, to obtain indicators resulting from the analysis of this data, which will allow the healthcare professional to have a visibility of some pattern that is not easily detectable without this tool.

Once the implementation of the application was completed, it is time to take a view of the general ideas that emerged throughout the process of analysis and design of the system.

Given that the overall objective was to develop a system capable of helping to prevent the appearance of ulcers, it was necessary to research several topics that helped to better understand the problem and how to reach its solution.

Thus, research was initially carried out on topics that were not implemented in the present study, but which will be of great use for the continuation of this work.

The first is related to interoperability in health, where the research about the different frameworks used and the data exchange mechanism was carried out, and the need to interconnect the system created in this study with a repository of clinical records was highlighted, given the speed of data exchange and the safety and cost reduction of patient treatment. In this topic, the reasons that are associated with the lack of adherence to data sharing between agents were found to be privacy, security and user consent. In order to overcome this barrier, it is necessary that the system that will handle these data stores them correctly and securely, as well as belonging to the set of entities authorized to access this type of data.

The second topic is related to biomechanical data, as well as its processing. The different methods regarding data science were researched, and comparisons were made, and scenarios were found where a certain method stood out from the others. Thus, it became evident the need for the creation of an analysis model of the collected data, which could help in the creation of warnings in a more precise way. Different types of ulcer risk scales were also found, and, although they are effective in some cases, they have the disadvantages of subjectivity in parameter assessment and the fact that they may not be directly related to ulcer risk.

Subsequently, to help interpreting the sensor data, it was necessary to understand the anatomy of the foot, its movements and the different phases of the gait cycle. With this knowledge, it was possible to integrate in the algorithm for the creation of warnings the recognition of the different phases of the cycle, allowing the accurate calculation of several gait variables and the correct identification of the affected foot area. In addition, by researching other ulcer prevention systems, it was possible to identify which gaps need to be addressed and to understand that the system in this study has more useful functionalities.

Finally, the system was explained, and more specifically the software developed, where the different components of each application were addressed, and their operation was explained in detail. Next, to ensure the quality of the system, tests were performed to the applications used by the end user, and functional, compatibility and performance tests were performed to the mobile application, and functional and compatibility tests to the web application. After these tests, it was possible to ensure that all functionalities had the expected behavior, even in different versions, equipment and browsers.

6.1.Limitations

Even though the web and mobile application was successfully developed, there were some validations that needed to be done. The most important was to understand the behavior of the analysis made by the application, in a real context, where the insole and the whole sensing system had already been developed. This step would be important because the user of the insole may not have such a linear walking behavior as assumed in this project.

Another limitation was that it was decided that the application would only work with an internet connection. Although the offline use of the application would be important, it was decided to ensure the privacy of the data, which would need to be stored until a connection was established. Thus, in order to make this functionality possible, it is necessary in the future to meticulously ensure the security of this data, given its importance.

6.2.Future work

As far as future work is concerned, there are several options that could be implemented.

As discussed in the theoretical introduction, it will be important in the future to interconnect this system with a clinical record repository, and it will be necessary to use an interoperability standard, to access previously existing data regarding patient information using the patient number.

In addition, it would be useful to develop a model to analyze the data from the sensing mechanism and the patient's personal information, such as foot type and presence of diabetes, which would allow warnings to be created based on the output of this model.

Furthermore, since the mobile application was designed for the Android operating system and only in English language, the next step would be to create a version for the IOS operating system and add an additional language that can be supported by the mobile application, in order to reach a larger number of users.

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Appendices

Appendix A – User manual for the mobile application

Guidance for My Care Shoe Mobile Application Users

COELHO João
1160796@isep.ipp.pt

INDEX

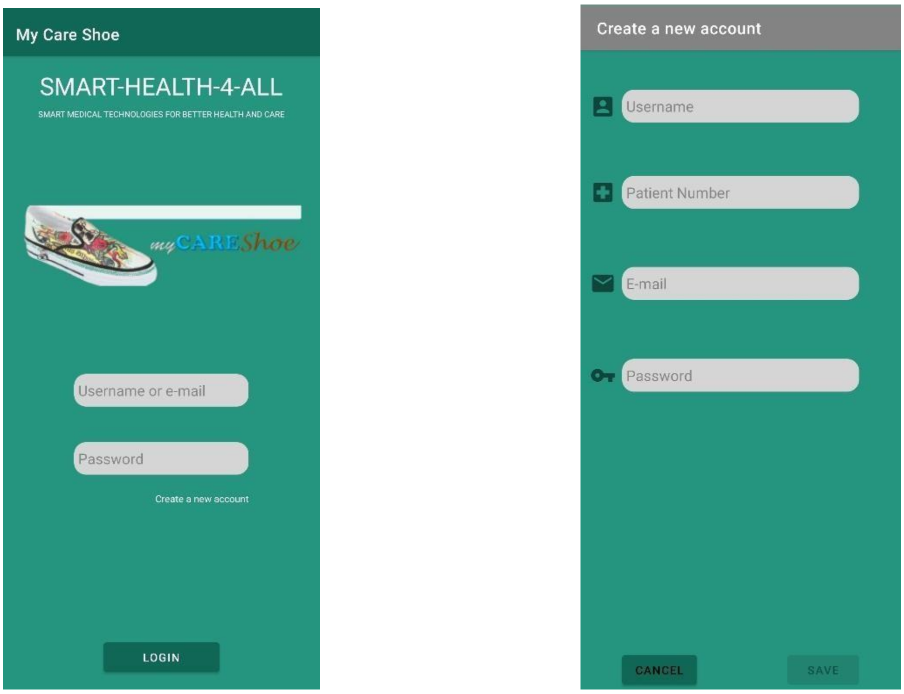
1. Mobile application usage instructions

1.1.Login and registration

When starting the application, the user is faced with Figure 1 (a), which represents the login activity, where only patients can connect. If the credentials are not found in the database, an error message will be exposed, and access will be denied. The same will happen to healthcare professionals or administrators who attempt the same, however this message will say that access is restricted to patients.

If the patient has not yet registered, he will have the option "Create a new account", whose activity is illustrated in Figure 1 (b).

In this registration, if the patient inserts a patient number, e-mail or username already used by someone else, there will be an error message precisely informing this. The same will happen if the patient number does not have 9 digits or if the e-mail does not have an adequate format.



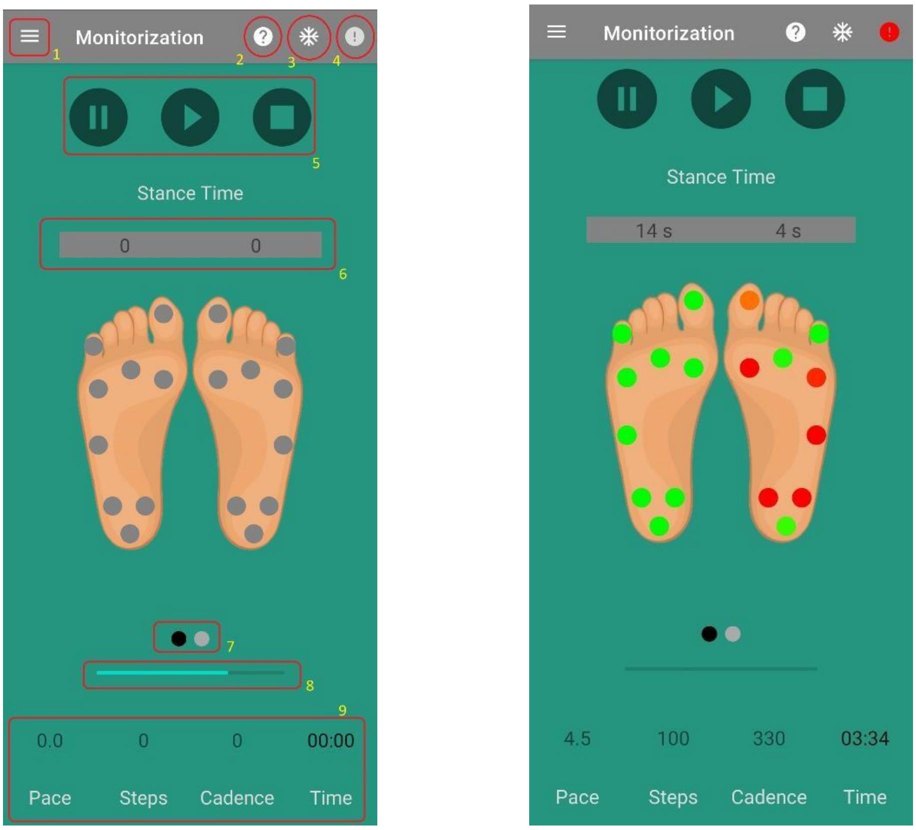
(a) (b)

Figure 1 - APP opening activity view: (a) - Login user interface; (b) - Registration user interface

After registration, the patient will have to wait for the administrator's permission to access the application, otherwise, even if the correct credentials are entered, an error message will be displayed saying “Access denied”.

1.2.Patient landing page

Once the patient enters the correct credentials and has permission to do so, they will encounter Figure 2 (a). If Bluetooth connections are established, and the stopwatch is counting, the interface will look like Figure 2 (b).



(a) (b)

Figure 2 - Monitorization interface: (a) - Patient's landing page; (b) – example of the interface when the patient is being monitored.

As can be seen in the Figure 2 (a) above, there are several sections numbered 1 to 9, which correspond to:

1. My care shoe navigation drawer: once opened, several menu options will be displayed that can be accessed by the patient, described in Figure 3, which are: Monitorization, Statistics, Personal Information, Settings and Log Out.

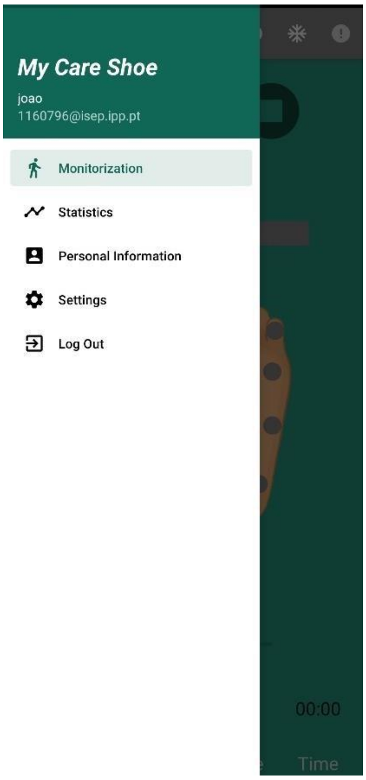


Figure 3 - APP navigation drawer

2. Additional information: when pressed, it will provide the user with an explanation of how the color gradient relating to the pressure values of the sensors is calculated and displayed, an illustration of which is shown in Figure 4.

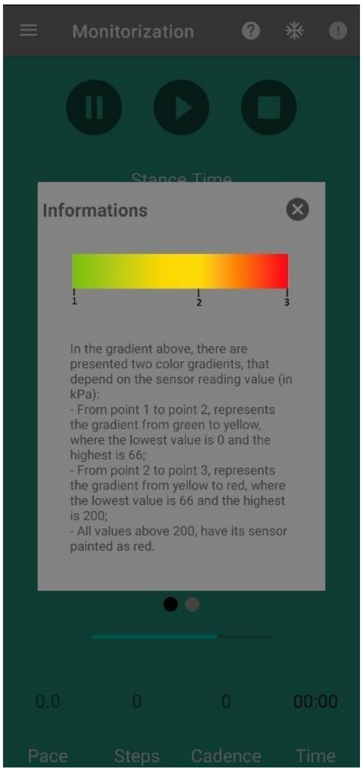


Figure 4 - Addition information's popup

3. Temperature and humidity values: this pop-up will only be displayed if there is monitoring data collected in this session, with the appearance shown in Figure 5.

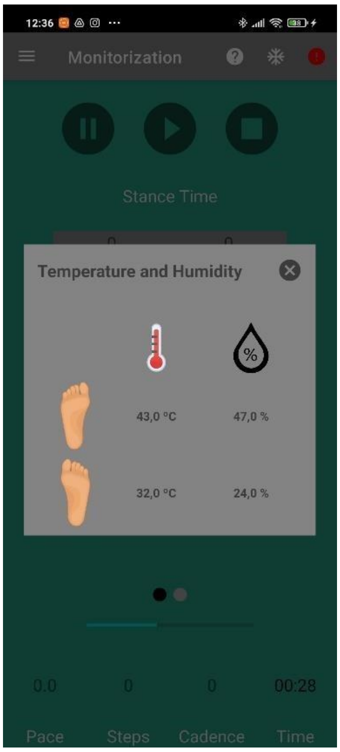
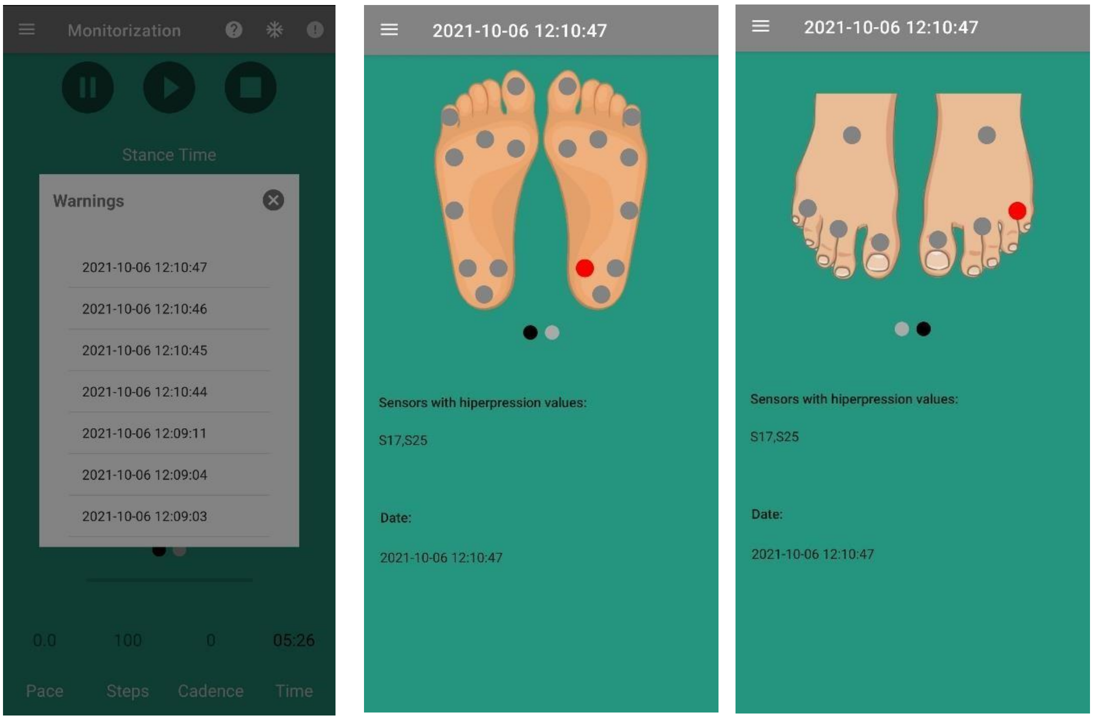


Figure 5 - Temperature and humidity values pop-up

4. List of warnings generated: in this menu, the user may access the warnings that have been generated, as shown on Figure 6 (a), ordered from the most recent to the oldest. Whenever a new warning was created, the button that generate this list will become red. Once the patient clicks on a warning, they will be taken to the screen as shown in Figure 6 (b) and (c) with details about the warning such as time and the sensors that caused it to be created, filled with red color.



(a) (b) (c)

Figure 6 - List of warnings: (a) – List of warnings; (b) – once a warning is selected, the details are shown with front view, and in (c) with upper view.

5. Stopwatch-related action buttons, such as play, pause, and stop.
6. Stance time of each foot in seconds. This value is only updated when on one foot there is a heel strike situation, followed by the toe off phase, and the value displayed is the time difference between these events.
7. Foot view that is selected. In this situation, it was used a ViewPager that serves as a slider between different images, in this case, when the left point is black, it means that the bottom view is visible, and when the right point is black, it means that the top view is visible.
8. Illustrative representation of the balance sheet value. This value is calculated based on the portion of the total pressure of the two feet that is exerted by the left foot, ranging from 0 to 100%.

9. Variables that are updated every time the stopwatch is running, these being pace (in minutes per kilometer), number of steps, cadence (in number of steps per minute) and time.

1.3. Personal Information's view

Once the user accesses the "Personal Information" menu in Figure 3, his personal information will be displayed, as shown in Figure 7, and the following information cannot be changed: name, patient number and date of birth. This is due to the fact that they are data that can only be changed under very specific conditions, and therefore who can do it is exclusively the health professional.

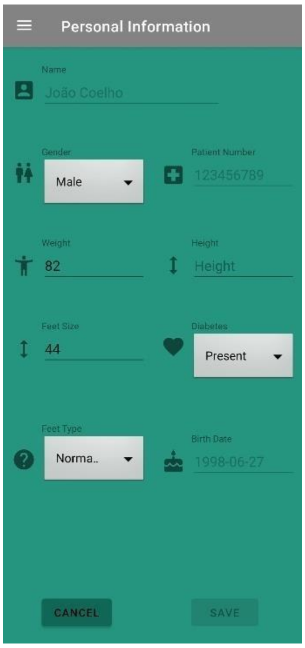


Figure 7 - Patient's personal information interface

There are some restrictions regarding the inputs of some fields that are displayed in this figure, such as:

- Weight cannot be less than 20kg nor more than 700kg, as it is considered the range where the target population will be inserted;

- The height must be between 0.5m and 3m;
- The foot size must be between 15 and 75 (using European foot size scale).

This way, the "Save" button will only be enabled when at least one field has its value changed from the previous value, and there is no input with a value outside the established ranges.

1.4. Settings view

If the patient clicks in the "Settings" menu, he will find the option to choose the Bluetooth devices "Choose Bluetooth devices for each foot" and the option to change his access credentials "Account settings", as shown in Figure 8.

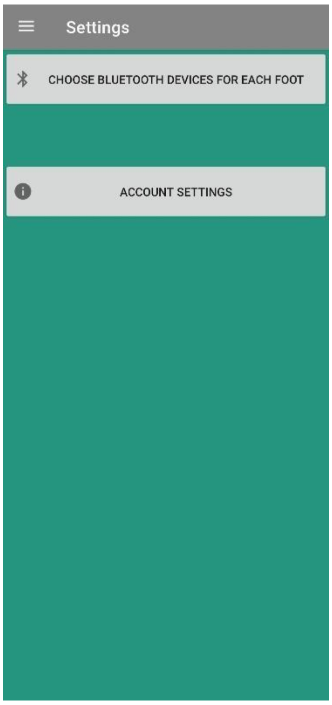
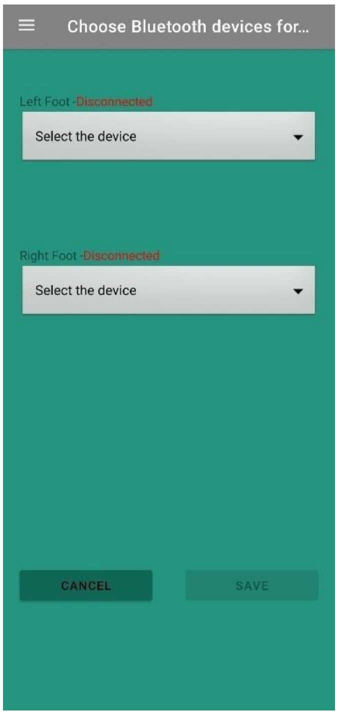
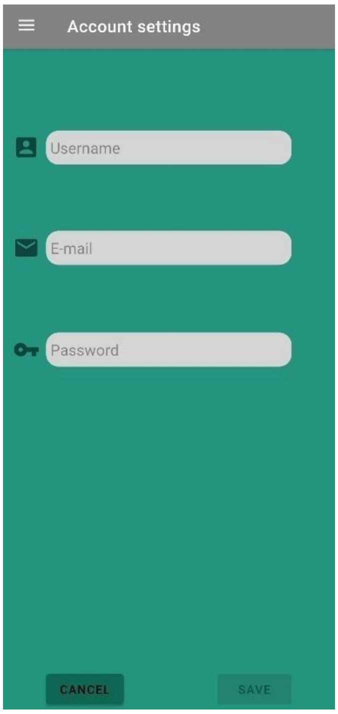


Figure 8 - Settings menu interface

In Figure 9, it is possible to visualize the two menus available in the settings. In Figure 9 (a), it is possible to choose the Bluetooth device to associate to each foot, and the list shows the device name and the MAC address. In Figure 9 (b), the patient can change the credentials, as long as the username and e-mail are not already being used by another user.



(a)



(b)

Figure 9 - Settings menu options: (a) - user interface for choosing Bluetooth connections; (b) - interface for changing credentials.

1.5.Statistics menu interface

Inside the statistics menu, the user is faced with two possible views to be displayed: a view with graphs ("Pressure statistics (plot)"), and another view that is illustrated and easier to understand ("Pressure statistics (illustrated)"), as shown in Figure 10.

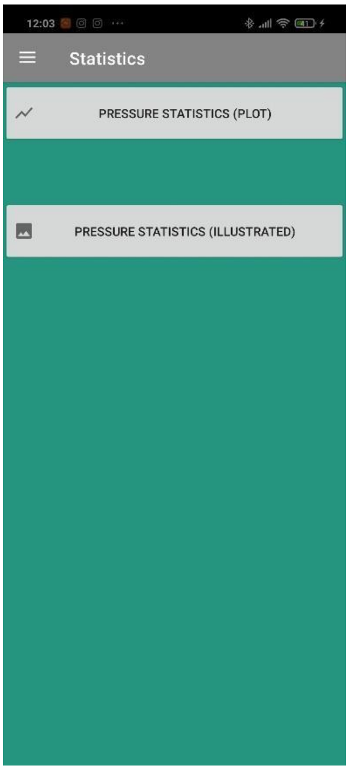
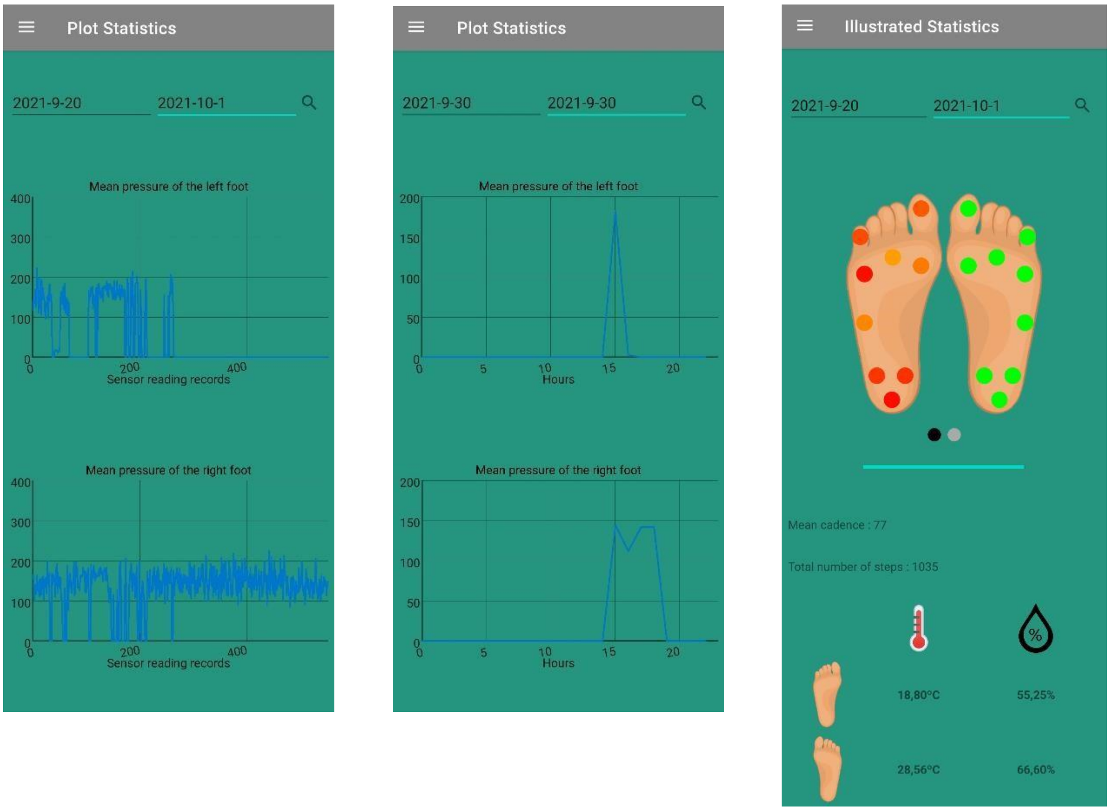


Figure 10 Statistics menu interface

Figure 11 shows the different perspectives of the statistics. In both Figure 11 (a) and (b), the statistics are presented in graphical form, but while in (a) the x-axis is in order of the number of records, in (b) as it is a one-day perspective, the x-axis is in order of the time of day. In Figure 11 (c), the average values of the sensors, number of steps, average cadence, and temperature and humidity values in each foot are shown.



(a) (b) (c)

Figure 11 - Representation of the different types of statistics views: (a) and (b) - in these figures the view of these statistics with graphs is represented; (c) - represents the illustrative view of statistics.

Appendix B – User manual for the web application

Guidance for My care shoe Web Application users

COELHO João

INDEX

1. Application usage instructions

In order for the user to access the web application, he needs to access the address http://10.8.129.207/mycareshoewebsite/site/log_in.php.

1.1. Page structure and common pages

After this page loads, the structure of the login page shown in Figure 1, which is common to any other of this application, will be displayed, consisting of:

1. Header: where information such as telephone number, e-mail, address is presented, as well as the different menus that you will have access to, and which vary from user to user;
2. Body: where the body of the functionality relative to the chosen menu is presented;
3. Footer: where similar information to the one on the header is presented: quick links and contact information.

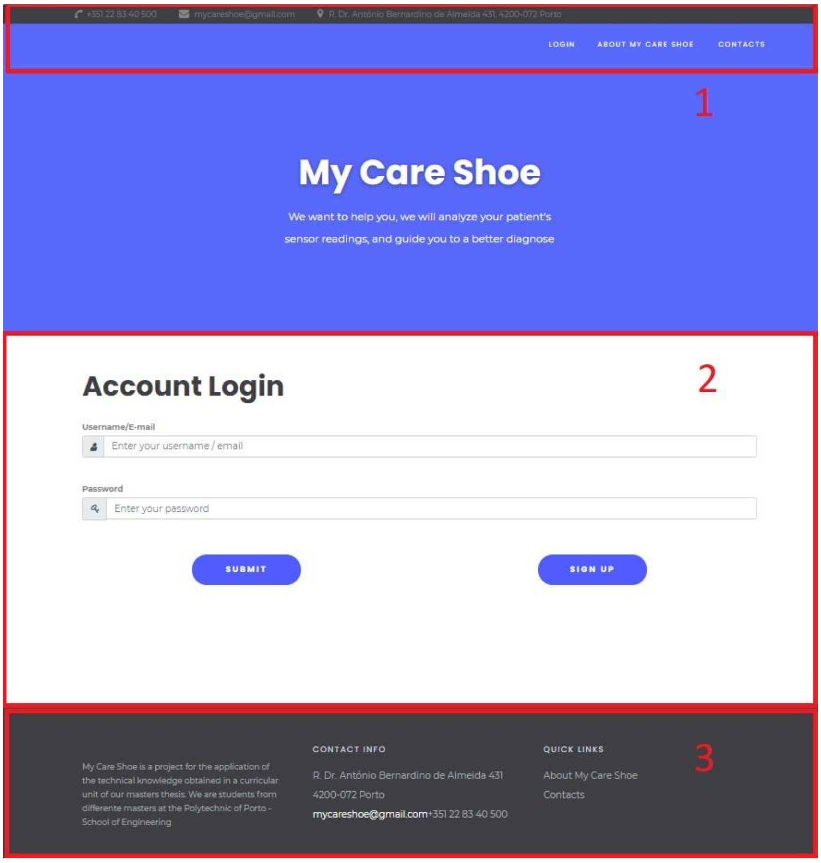


Figure 1 - Login page structure

In this page, it will be possible to log in to the application or proceed to the user registration.

In the case of registration, the user needs to enter a username and e-mail address which have not yet been entered. A valid email address consists of an email prefix and an email domain, both in acceptable formats, separated by the "@" symbol.

After this process, the user needs to obtain permission from the administrator to access this application. In addition, the user must have the profile of a healthcare professional or administrator.

On the other hand, there are two menus that are transversal to the whole application, with the user logged in or not: Contacts and About. In the contacts menu, the members belonging to the My care shoe project will be listed.

The About menu presented in Figure 2, on the other hand, will consist of two sections. In the "Why choose us" section, there will be reasons that explain the mindset used to develop the whole project, and in the "My care shoe APP" section, there will be a preview of the mobile application, as well as links to download it, and the user manuals for this application and the web application.

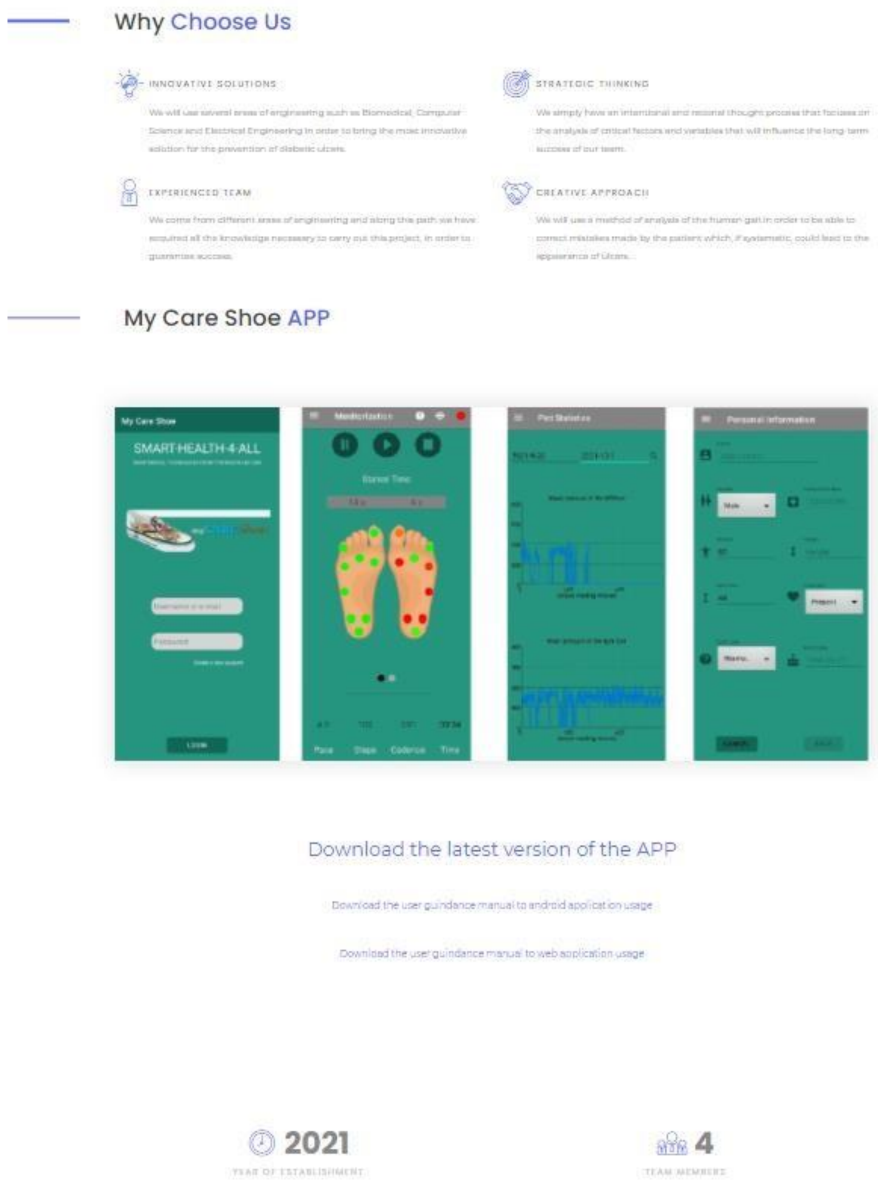


Figure 2 - About page

1.2.Healthcare professional view

In case the user can log in and is a health professional, Figure 3 will be displayed. In the header, different menu options will be presented, such as:

All Patients: where all the patients entered in the database and their data will be listed. If the professional wants to access the patient's profile, the patient will need to click on the corresponding line of the table.

- Add a Patient: where the data of the patient who has just been registered will be added;
- Account settings: in this menu it will be possible to change the professional's username, email and password;

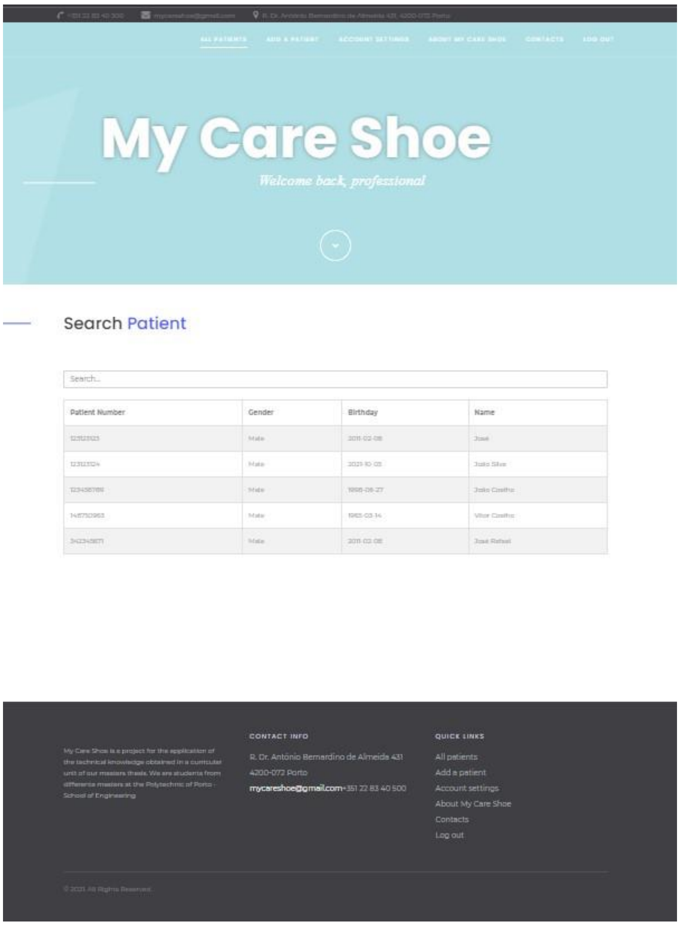


Figure 3 - All patients' page

After the professional clicks on a patient, the screen of Figure 4 will be displayed, with the following sections shown:

Patient's Personal Information: the patient's profile details are shown, and through the "Edit patient information" button, it will be possible to edit this information;

- Warning specifications: where you can configure the parameters that will trigger a warning;
- Patient's statistics and warnings: in this section, the professional may access statistics or warnings within a chosen time interval.

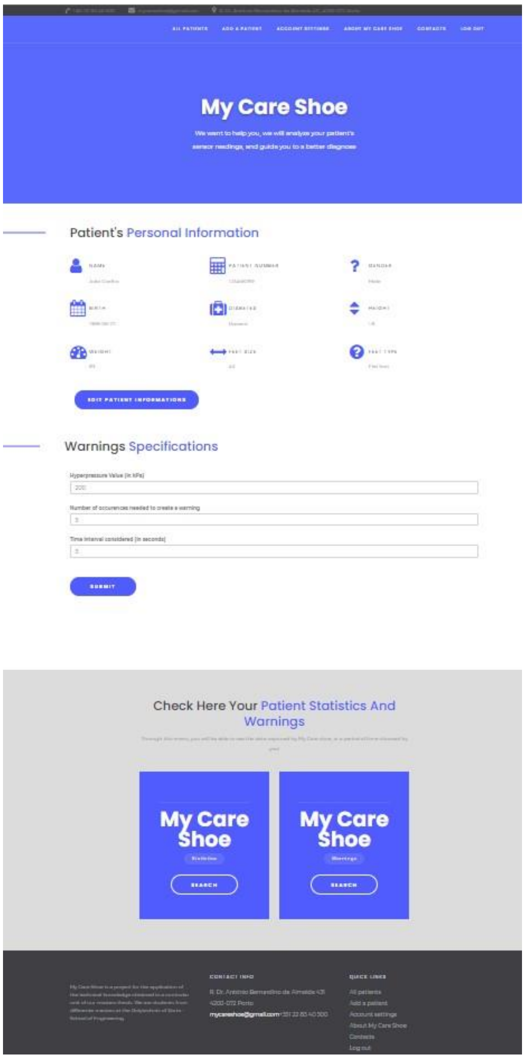


Figure 4 - Patient specifications page

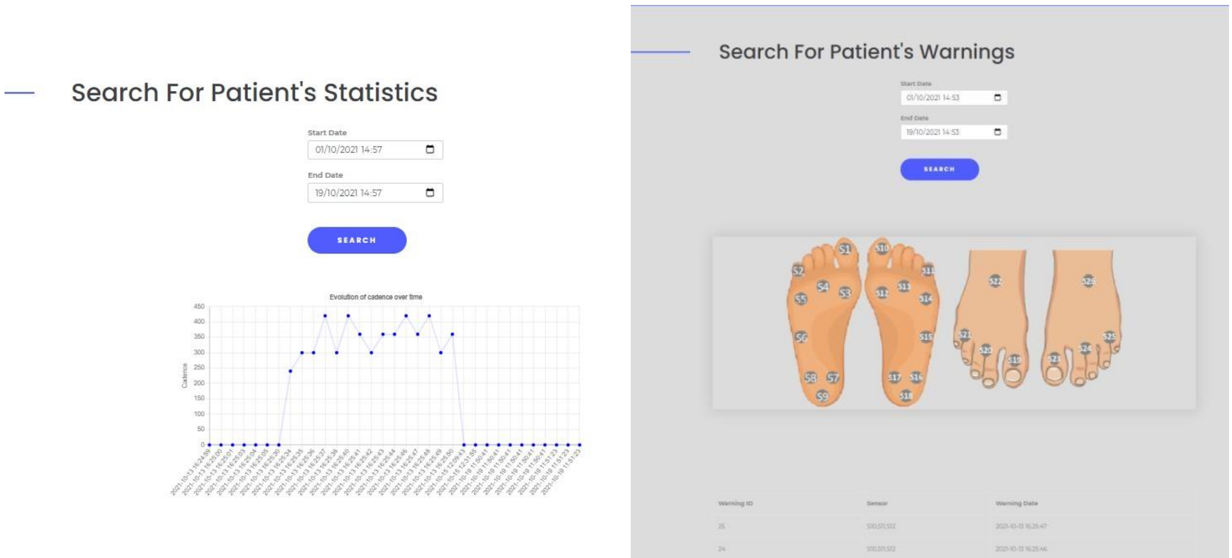
There are some restrictions regarding the inputs of some fields that are displayed in "Edit patient information" page, such as:

Weight cannot be less than 20kg nor more than 700kg, as it is considered the range where the target population will be inserted;

- The height must be between 0.5m and 3m;
- The foot size must be between 15 and 75 (using European foot size scale).

If the professional accesses the statistics or warnings, the pages will have the structure of Figure 5. Thus, it is possible to select the time interval and obtain the results produced in this same interval. In the case of statistics, 11 graphs identical to the one in Figure 5 (a) will be presented, referring to the variables: cadence, balance, steps, as well as left and right foot pressure sensors values, temperature, humidity, and stance time values.

In the warnings page, it will be first shown an image that locates the sensors according to the nomenclature presented in the table below, with the warnings register and the date of their creation.



(a) (b)

Figure 5 - Searching functionality in: (a) - statistics; (b) - warnings

1.3.Administrator view

Once the administrator logs in, the options shown in Figure 6 will be displayed.

Figure 6 - Administrator operations page

On the "Logs table" page presented in Figure 7, the administrator can view the changes made to the users and personal information tables of the database, in a certain time interval. On the other hand, on the "Permissions" page represented in Figure 8, it will be possible to assign a profile to a registered user and give him access permissions.

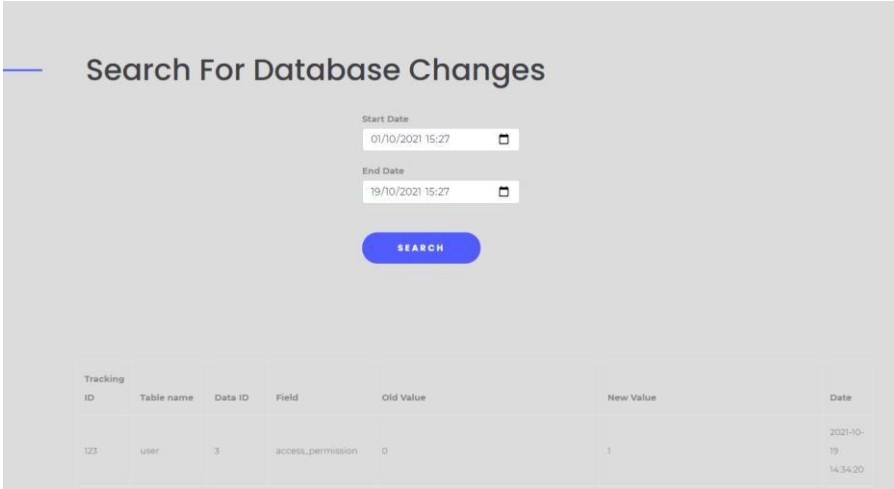


Figure 7 - Logs table page

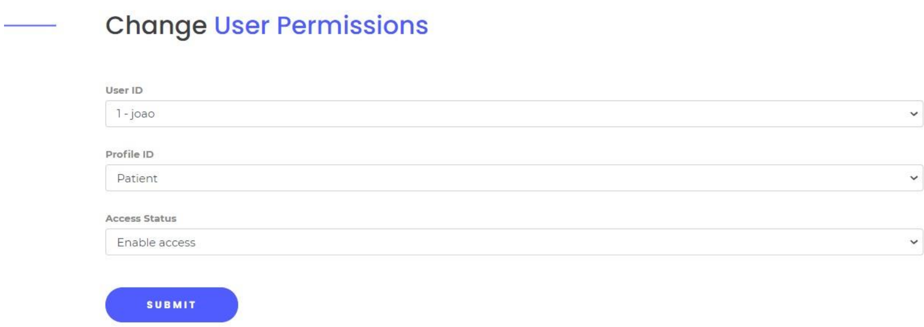


Figure 8 - User permissions page

Appendix C – Test scenarios related to the web application

Table C.1 - Test scenario related to administrator actions

Pre-conditions			
Accessing http://10.8.129.207/mycareshoewebsite/site/log_in.php and entering with administrator credentials			
Test Case	**Test Steps**	**Expected Result**	**Status**
Check if the functionality of enabling access permission works	1. Under administrator permissions, click Permissions box; 2. Choose a user, and set “Access Status” to “Enable access”; 3. Click Submit button	Message “Permissions updated” is displayed and the user can have access	Pass
Check if the functionality of disabling access permission works	1. Under administrator permissions, click Permissions box; 2. Choose a user, and set “Access Status” to “Disable access”; 3. Click Submit button	Message “Permissions updated” is displayed and the user cannot have access	Pass
Check if the functionality of changing profile works	1. Under administrator permissions, click Permissions box; 2. Choose a user, and set “Profile ID” to a different profile;	Message “Permissions updated” is displayed and the user now has a	Pass

	3. Click Submit button	different profile	
Check if the functionality of accessing logs table with a time interval with at least one entry works	1. Under administrator permissions, click Logs table box; 2. Select a start and end date; 3. Click Search button	The table with the correspondi ng searched values is displayed	Pass
Check if the functionality of accessing logs table with a time interval with no entry works	1. Under administrator permissions, click Logs table box; 2. Select a start and end date; 3. Click Search button	Message "No data found!" is displayed	Pass

Table C.2 - Test scenario related to healthcare professional actions regarding patient's data manipulation

Pre-conditions			
Accessing http://10.8.129.207/mycareshoewebsite/site/log_in.php and entering with healthcare professional credentials			
Test Case	**Test Steps**	**Expected Result**	**Status**
Check if the functionality of searching by an existing patient works	1. Click on the search bar; 2. Enter a field that is already present on the table; 3. Click Enter.	The patients with the corresponding field are returned	Pass
Check if the functionality of	1. Click on the search bar;	No patients are displayed	Pass

searching by a non-existing patient works	2. Enter a field that is not present on the table; 3. Click Enter.		
Check if the functionality of changing the warning generation conditions works	1. Click on a patient from the table; 2. Scroll to the "Warnings Specifications" section; 3. Update all of the field presented in that section; 4. Update the page.	The fields are updated with the latest values	Pass
Check if the functionality of changing the patient's personal information works	1. Click a patient from the table; 2. Scroll to "Patient's personal information" section; 3. Click "Edit personal informations" button; 4. Change at least one field to a different value; 5. Click submit button.	The fields are updated with the latest values	Pass
Verify if weight field only accepts a interval of values (20 – 700kg)	1. Click a patient from the table; 2. Scroll to "Patient's personal information" section; 3. Click "Edit personal informations" button; 4. Edit "Weight" field; 5. Click submit button.	An error message should popup next to the field containing the expected range of values	Pass

Verify if height field only accepts an interval of values (0.5 – 3m)	1. Click a patient from the table; 2. Scroll to "Patient's personal information" section; 3. Click "Edit personal informations" button; 4. Edit "Height" field; 5. Click submit button.	An error message should popup next to the field containing the expected range of values	Pass
Verify if feet size field only accepts an interval of values (15 – 75 European Size)	1. Click a patient from the table; 2. Scroll to "Patient's personal information" section; 3. Click "Edit personal informations" button; 4. Edit "Feet Size" field; 5. Click submit button.	An error message should popup next to the field containing the expected range of values	Pass

Table C.3 - Test scenario related to healthcare professional actions regarding patient's warnings and statistics

Pre-conditions			
Accessing http://10.8.129.207/mycareshoewebsite/site/log_in.php and entering with healthcare professional credentials. Furthermore, a patient from the table is clicked.			
Test Case	**Test Steps**	**Expected Result**	**Status**
Check if the functionality of accessing warnings table with a time interval with at least one entry works	1. Scroll to "Patient's statistics and warnings" section; 2. Click Warnings box; 3. Select a start and end date; 4. Click Search button.	The table with the correspondi ng searched values is displayed	Pass
Check if the functionality of accessing warnings table with a time interval with no entry works	1. Scroll to "Patient's statistics and warnings" section; 2. Click Warnings box; 3. Select a start and end date; 4. Click Search button.	Message "No data found!" is displayed	Pass
Check if the functionality of accessing statistics table with a time interval with at least one entry works	1. Scroll to "Patient's statistics and warnings" section; 2. Click Statistics box; 3. Select a start and end date; 5. Click Search button.	The table with the correspondi ng searched values is displayed	Pass
Check if the functionality of accessing statistics table with a time	1. Scroll to "Patient's statistics and warnings" section; 2. Click Statistics box; 3. Select a start and end date;	Message "No data found!" is displayed	Pass

interval with no entry works	4. Click Search button.		

Table C.4 - Test scenario related to healthcare professional account information changes

Pre-conditions			
Accessing http://10.8.129.207/mycareshoewebsite/site/log_in.php and entering with healthcare professional credentials and click Account Settings header button			
Test Case	**Test Steps**	**Expected Result**	**Status**
Check that the functionality of changing access credentials works	1. Fill in a valid username, e-mail and password; 2. Click Save button	Message “Successfully updated the user information” is displayed	Pass
Check the behaviour of the functionality of changing access credentials with an existing username	1. Fill in an already taken username, e-mail and password; 2. Click Save button	Message “Error in updating user info. The following fields already exists: username.” is displayed	Pass
Check the behaviour of the functionality of changing access credentials with an existing e-mail	1. Fill in username, an already taken e-mail and password; 2. Click Save button	Message “Error in updating user info. The following fields already exists: e-mail.” is displayed	Pass

Check the behaviour of the functionality of typing an e-mail with an incorrect format	1. Fill in username, an incorrect e-mail and password; 2. Click Save button	The message “Invalid email value” is displayed next to the field and save button is disabled	Pass

Table C.5 - Test scenario related to healthcare professional/administrator login

Pre-conditions			
Accessing http://10.8.129.207/mycareshoewebsite/site/log_in.php			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify login with the valid healthcare professional / administrator credentials with access permission	1. Enter username/e-mail and password; 2. Click login button	The browser redirects the user to a welcome page	Pass
Verify login with the invalid healthcare professional / administrator credentials	1. Enter invalid username/e-mail and password; 2. Click login button	The message “Invalid username or password” is displayed	Pass
Verify login with the valid healthcare professional /	1. Enter valid username/e-mail and password;	The message “Access denied” is displayed	Pass

administrator credentials but with no access permission	2. Click login button		
Verify login with the valid patient credentials	1. Enter username/e-mail and password; 2. Click login button	The message “You don't have access. This view is only meant to be accessed by your healthcare professional or the administrator!” is displayed	Pass

Table C.6 - Test scenarios regarding sign up in the web application

Pre-conditions			
Accessing **http://10.8.129.207/mycareshoewebsite/site/log_in.php** and clicking Sign up button			
Test Case	**Test Steps**	**Expected Result**	**Status**
Verify registration with all fields filled, and with a unique username, patient number and e-mail	1. Enter username, patient number, e-mail and password; 2. Click save button	The message “Successfully registered the user” is displayed	Pass
Verify registration with	1. Enter username, patient number, e-mail and password;	The message “Error in registering. The following fields	Pass

an already existing username	2. Click save button	already exists: username" is displayed	
Verify registration with an already existing patient number	1. Enter username, patient number, e-mail and password; 2. Click save button	The message "Error in registering. The following fields already exists: patient_number" is displayed	Pass
Verify registration with an invalid patient number	1. Enter username, patient number, e-mail and password; 2. Click save button	An error message should popup next to the field containing the expected number length	Pass
Verify registration with an already existing e-mail	1. Enter username, patient number, e-mail and password; 2. Click save button	The message "Error in registering. The following fields already exists: email" is displayed	Pass
Verify registration with an invalid e-mail	1. Enter username, patient number, e-mail and password; 2. Click save button	An error message should popup next to the field containing the expected e-mail format	Pass