ITEA-2019-19008
Inno4Health

Stimulate continuous monitoring in personal and physical health

Deliverable 3.4: Prototype of the wearable in-sole

Due date of deliverable: (31-03-2023)
Actual submission date: (03-07-2023)

Start date of Project: 01 November 2020 Duration: 36 months

Responsible WP3: Karel Electronics

Revision: Final

Dissemination level		
PU	Public	✔
PP	Restricted to other programme participants (including the Commission Service	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (excluding the Commission Services)	

0 DOCUMENT INFO

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Table 1 - Authors

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Documents history

Table 2 - Document History

Document version #	Date	Change
V1.0	03/07/2023	Submitted to ITEA

Document data

Table 3 - Editor's Address

Keywords	
Editor Address data	Name: William Xavier Partner: WISEWARE Address: Zona Industrial da Mota, Rua 12, Lote 51, Fração E, 3830-527 Gafanha da Encarnação Phone: +351964956780 Fax: NA

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1 Executive summary

Deliverable 3.4 is part of WP3 and specifies the technical and design requirements of the prototype of the wearable in-sole. The wearable in-soles will be used in Portuguese use case diabetic foot ulcers.

2 Introduction

2.1 Short description

Nowadays wearable tracking/monitoring health/vital-sign devices are designed to allow measuring of physiological parameters without restricting normal daily activities of the users, providing information that reflects the individual’s health and well-being conditions during its use.
Plantar foot pressure measurement plays a significant role in monitoring both biomechanical posture and neurological performance, in areas such as gait detection/analysis, diabetic foot ulcers and others related to human body posture.

2.2 Functional specifications

To meet wearability standards and medical demands for real time and post-analysis of the data collected, functional specifications were discussed in joint meetings with doctors, caregivers, users, and technical staff, bellow the outcome of specification requirements:

- Both foot sensors should store data synchronously, leading to the development of wireless insole devices, capable of synchronization between at least two devices, and store data from the pressure and temperature sensors embedded on the in-sole.
- Electronics and battery should be as small and lightweight as possible, easy to install and rechargeable, avoiding disposable batteries.
- After installation on the patient, a mobile app should be available to check if the in-soles are installed correctly and measuring expected data, avoiding patients to wear the system for an extended period with bad/incorrect data, needing to repeat the monitoring.
- Some patients wear its own orthopaedic insoles and must keep them when performing in-sole monitoring, thickness of the system should not affect the effect of orthopaedic insoles, a maximum of 1.5mm was defined as absolute maximum thickness.
- Related to comfort, material should have stretchability, bread ability and non-slippery, and in case of direct skin contact it must meet skin compatible materials, if possible washable.

2.3 Technical specifications

With the functional specifications in mind, the technology available at the time of development, a technical specification was done to meet as close as possible all the requirements.

Defined that all the monitoring variables must meet long term acquisitions (power efficient), the electronics processing device should have stand-alone capabilities when monitoring offline (storage capabilities), have wireless connectivity for inter-system synchronization (wireless logical link) and enough throughput for online data view(>1Mbps), the decision for the MCU and wireless communication was to use a chipset which met BLE 5.0 or higher.
As the device must be rechargeable, a compatible USB-C PD 5V charging circuit was designed to meet all USB-C compatible charger specifications.
For long term storage capabilities, 16GB of internal memory was implemented, allowing >30days continuous storage.
Battery lifetime of >100h.
As sensing elements, 8 FSR's were implemented on the insoles for gait analysis, and 8 temperature points with 0.5C error were installed to monitor foot temperature over time, giving and idea of blood irrigation in parallel with foot pressure/movement.

2.4 Preliminary design

When defining functional specifications, initial prototypes were built to understand comfort, easiness of integration and operation.

First sensors were used directly after printing, and due to the plastic finish of the material it was found that after some moisture foot got slippery inside the shoe, bellow image of the RAW printed sensor:

Figure 1 - RAW sensor after printed

To avoid slipperiness, layers of natural leather were added to the top and bottom of the sensor:

Figure 2 - RAW sensor laminated into two layers of natural leather

Figure 3 - Edge view of the leather solution

The above solution seemed OK, but added to the overall thickness 3mm, which proved to be too much when patients need to use special orthopaedic insoles. This lead to find out some material which was skin compatible and comfortable which would not add too much thickness to the final laminated sensor. The solution found was a special type of Alcântara, which added 900um overall thickness.

2.5 Final design

Bellow, the final design of the wearable in-soles:

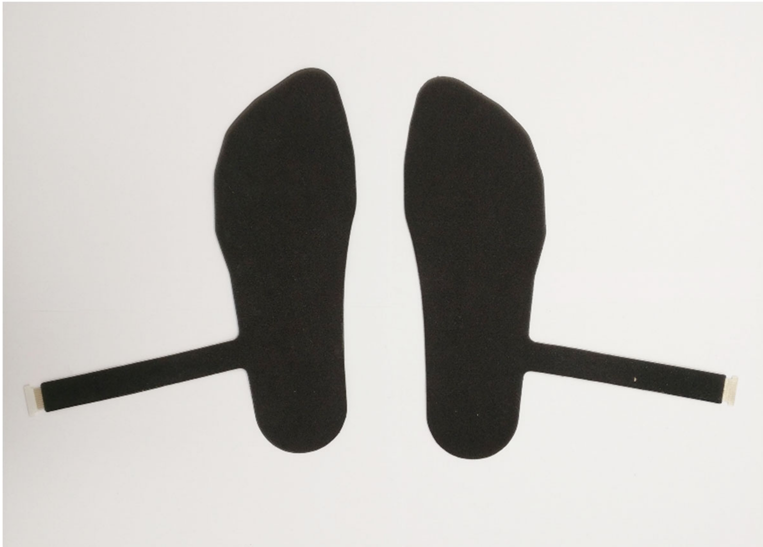

Figure 4 - RAW sensor laminated into two layers of Alcântara

Figure 5 - Edge view of the Alcântara solution

With the latest solution, we found that the insoles integration seems to be compatible with mostly any use case of shoes and foot sizes.

The insoles sensors are connected to the electronics via the assembled USB-C male connector to FFC adapter. When testing started on a controlled and indoor environment the mechanical fixing/behaviour seemed sufficient to avoid it to disconnect while in use; but when testing started outdoor and on tougher environments it was observed that on more demanding movements and some micro-disconnects exist. These microdisconnections could affect the overall signal acquisition and loss of signal logging, leading to poor acquisitions and in some cases difficulty to merge all data into one synchronized file.

Figure 6 - Initial Insoles sensor inter-connection to electronics enclosure

With the above findings, biomechanical team started to develop a locking mechanism between the electronics enclosure, and the insoles sensor USB-C male connector to FFC adapter, which would guarantee enough mechanical fixing but at the same time not too difficult to remove and insert when needed.
As the previous design was already tested with produced tooling for the initial enclosure, some care had to be taken while redesigning the USB-C cover and the locking mechanism on the electronics enclosure. The solution at the end was able to reuse original tooling, adding the needed mechanical fixing to avoid any possibility of poor contact even in tough environments.

Figure 7 - Re-designed Insoles sensor inter-connection to electronics enclosure

3 Conclusions

This deliverable has documented the requirements and specifications for the sensors which are to be developed and used within INNO4HEALTH project, namely the wearable in-sole system.

The outputs of the wearable in-soles systems were enough to measure the required variables for clinicians to understand how to improve healing process. Meanwhile, the overall system was submitted for CE/RED Certification, bellow the certification approval.

CE

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CERTIFICATION OF TESTING

Under EU RED - DIRECTIVE 2014/53/EU –
Under EU-LOW VOLTAGE DIRECTIVE 2014/35/EU

This certifies that the following designated product

BLE Insoles Gateway
Model No. : WW#001#
Brand Name : WISEWARE

(Product identification)

Has been tested in accordance to essential protection requirements of the RED - DIRECTIVE 2014/53/EU, EU-LOW VOLTAGE DIRECTIVE 2014/35/EU and found the test results indeed meet the limitation of the relevant test standard(s) listed below:

EMC	Radio Spectrum	Safety
EN 301 489-1: V2.2.3 (2019-11)	EN 300 328 : V2.2.2 (2019-07)	IEC 62368-1:2014/COR1:2015
EN 301 489-17: V3.2.4 (2020-09)		and EN 62368-1:2014/A11:2017
		Health
		EN 62479 (2010)

(Identification of regulations / standards)

This certificate is issued for

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(Name / Address)

SPECIAL STATEMENT:
THE CONFIRMATION IS VALID ONLY IF THE PRODUCT IS MANUFACTURED IN ACCORDANCE WITH THE TEST REPORT NO. W6M22105-20968-E-16, W6M22105-20968-T-45, W6M22105-20968-62479, W6M22105-20968-L AND TO THE SAMPLE HAS BEEN TESTED BY WORLDWIDE TESTING SERVICES (TAIWAN) CO., LTD..

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June 18, 2022
(Date)

Rex Kao
Rex Kao, Laboratory Director

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Figure 8 - Certification of Testing