The Importance of Design in the Development of a Portable and Modular Iot-Based Detection Device for Clinical Applications

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Abstract. The integration of human factors engineering methods within the medical device design and development process has been highlighted by international standards organizations. Such methods are contributing to the development of safer medical devices, more suitable to users' needs. Errors during device operation might hamper effective patient diagnosis and treatment, or eventually lead to injury or death. Thus, the designing process of a medical device is indeed crucial to user experience and safety operation. This paper presents a human-centred design analysis of a novel IoT-based screening prototype (iLoF) based on Artificial Intelligence algorithms built-in in a patented-photonics system developed by a deep tech startup. The influence of the design process during the development of the prototype was addressed, based on a human-centred design methodology and considering the device's application environment. iLoF's prototype on-field applicability was evaluated considering a single case-study carried out at one of the main hospitals in Portugal through interviews to ten healthcare professionals with high experience in laboratorial testing. A benchmark assessment and a comparison matrix along with the market products are also presented to fully understand the technology state and to find new solutions that can influence iLoF's product development.

1. Introduction

Medical devices (MDs) are specific tools used for healthcare and medical purposes namely to diagnose, prevent, monitor, treat, alleviate, or compensate for diseases or injuries. As MDs directly or indirectly

interact with human patients, certain construction and design considerations must be complied to ensure efficient and safe medical treatments. Besides the product specifications, an effective MD design should also consider healthcare regulations and practical needs of end-users.

In fact, the development of MDs that integrate technological, performance and/or economic aspects without any design process usually result in products that do not comply with regulatory standards, mainly due to aesthetics, ergonomic, and on-field functionality/usability issues [1,2].

The participation of the end-user during the design process of MDs is crucial to detect and correct operation flaws and user-oriented issues, thus improving the usability and the likelihood of acceptance of the intended solution [3]. According to Norman *et. al* [4], a human-centred design (HCD) stands as the psychological approach of design, enabling the assess to users' needs by observing their interactions with the product. The HCD process includes four interconnected and cyclically repeatable steps: user observation, idea generation, prototyping, and testing, as shown in figure 1. The use of an HCD methodology in the MD design development improves the overall quality and usability of the product and increases the potential to achieve a greater commercial success [4]. The document herein presented aims to reinforce the importance of using a user-centered design process in the product development of a novel screening technology intended to accelerate a new era of personalized therapies.

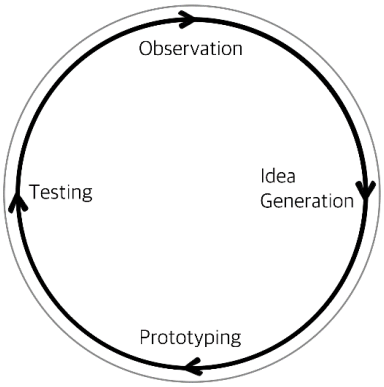

Figure 1. Diagram of the human-centred design process cycle adapted from Norman [4].

1.1. iLoF (Intelligent Lab on Fiber) Technology

iLoF technological platform combines photonic principals, signal processing, and artificial intelligence (AI), to identify disease-associated biomarkers/profiles in human blood-based samples (plasma or serum) through the development of "optical fingerprints". The technology is based on the emission of a highly focused laser beam through an optical fiber with a customized microlens and the acquisition of the back-scattered light resulting from the interaction of the incident light with biological nanostructures of the sample. Such disruptive approach has already shown promising results regarding the identification of optical fingerprints: accuracy above 90% in detecting cells and extracellular vesicles associated with different gastric cancer metastatic degrees; and accuracy above 84% in the detection the Alzheimer's disease profiles for 'beta-amyloid positivity' [5].

To potentiate the acceptance of iLoF technology in healthcare and pharmaceutical settings, scalability and portability were the main requirements pointed by pharmaceutical and medical experts. Thus, the conventional iLoF platform bench setup (figure 2 a)) was converted into a first transportable and miniaturized device (*i.e.* 1st prototype version, figure 2 b)), considering mainly mechanical and electronic aspects. Design features related with human-machine interaction (HMI) and practical requirements of the intended workplaces (mainly laboratories) were neglected at this phase. The current paper presents a user-oriented analysis of this prototype, by evaluating human interaction with field tests and through a benchmark analysis. Such analysis aims to facilitate the development of a new version of this medical device according to the end-user needs, thus improving the usability of iLoF technology in healthcare facilities and accelerating the product roadmap planned for the technology.

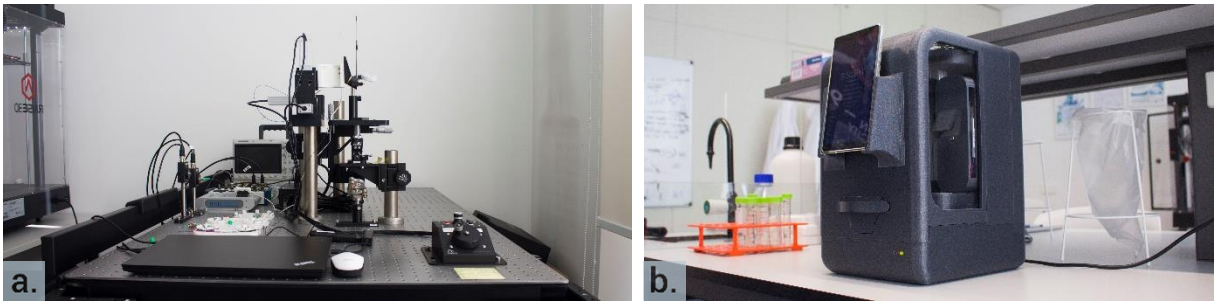

Figure 2. iLoF IoT-based medical device for clinical applications: a) bench setup; b) prototype.

2. End-users and Prototype Evaluation Methods

The observation phase of the HCD methodology was carried out through a case study in a public hospital – Centro Hospitalar Universitário São João (CHUSJ, Porto, Portugal). Therefore, ten volunteers (90% women), aged between twenty-one and sixty-nine years old were interviewed and asked to operate the iLoF prototype in the laboratories of the immunology service of CHUSJ. The participants included healthcare personnel with high expertise in operating MDs, mainly medical doctors, lab technicians, and internees. Participants' behaviours and difficulties/problems of operation were observed and recorded, while operating the device. During the interviews, a trust relationship with the interviewees was built to easly assess information related to needs and emotions during its operation. Besides the main functionality of the prototype (analysing biological samples), questions were asked about workplace restrictions that might influence the design of a MD. Considerations related with prototype colour, shape, sample draw handling, place of the screen, power button and status lights were also addressed in the surveys. All interviews were recorded, upon consent of the participant, to avoid neglectable details.

Additionally, a visit was made to three laboratories of the immunology service of CHUSJ to analyse the usual working conditions (mainly space requirements and MDs placement) on laboratory benches.

A comparison with other products on the market was performed through a benchmark assessment, where 15 MDs performing blood-based tests were compared resorting to a set of criteria (ergonomics, aesthetics, portability, and user friendliness) defined according to user-needs.

3. Results of iLoF Prototype Manipulation

The visit to CHUSJ laboratories pointed the lack of space on the laboratory benches as the major challenge to overcome for new MDs placement, as shown in figure 3 a). Such restriction was also the most highlighted during interviews. Participants mentioned the need of acquiring compact and small-sized MDs to facilitate the positioning of devices on the laboratory benches. Considerations as the need to have side-by-side MDs, the lack of shells, and the high depth of the laboratory benches also indicated that MDs should present a vertical design (*i.e.* shorter in length and larger in height). Odours related with disinfection agents were also noticed and highlighted the requirement to decontaminate both laboratory benches and MDs. The lack of space also forced to place the iLoF prototype on a desk (smaller than laboratorial benches) to perform the interviews and user behaviour analysis.

When asked to turn on the prototype, seven participants were unable to find the power button, and the majority instinctively search the power button in the back of the device. Even after not being found, some participants tried to look at the prototype's back, as seen in figure 3 b). This occurred because MDs usually present their power button at the back, next to the power cable. However, iLoF prototype power button and power cord are located on the left side of the device.

Two main features of the prototype's sample input were addressed: the sample drawer and the sample holder. After being asked to open and close the prototype drawer (where the sample holder is placed), and despite being considered an easy task, two main usability issues were found. Firstly, all participants denoted difficulty to grab the drawer handler while pulling or pushing it, due to a lack of the ergonomics of the drawer handle, which should be resized. The other issue related with the drawer handling was that all participants were unable to open the drawer with a single hand. Ten participants needed to use both

hands to hold the prototype while opening the drawer. Such evidence indicates that the force required to open or close the prototype drawer should be decreased to facilitate the sliding of the drawer, without spilling the sample. When asked to remove the sample holder from the drawer, the participant representing the 95th percentile was unable to effectively grab the sample holder without tilting it. This difficulty arose from the lack of space to place the fingers between the sides of the sample holder and the walls of the drawer where the holder is placed (figure 3 c)). This arose the need to redesign the sample holder to facilitate the placement of the sample without spilling or contaminating the surroundings.

By observing participants operating the device, a misposition of the sample drawer was noticed. The screen of the prototype is located near and above the drawer, leaving limited space for the user to access the inside of the drawer for sample replacement.

During the prototype operation tasks, the visibility of the screen was also evaluated. About 90% of users pointed out the lack of visibility of the graphical interface on the prototype screen. Such difficulties were mainly due to the small size of the interface's text and buttons and to the short tilt angle (9º instead of the 35º) suggested for an ergonomic screen, as show in figure 4).

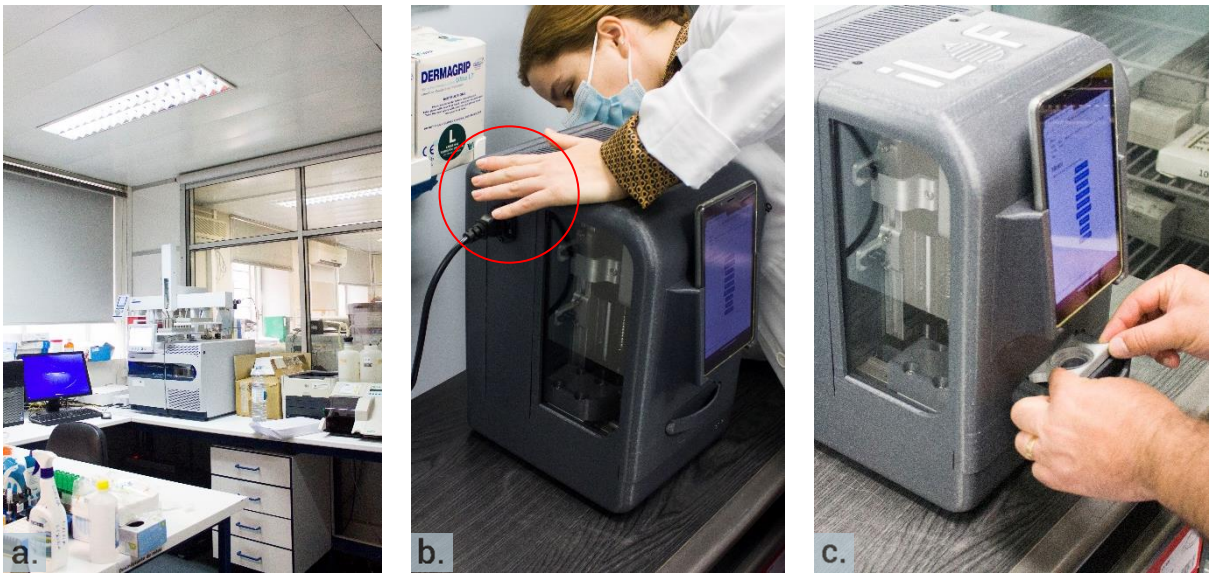

Figure 3. Observations in the laboratory of immunology service of CHUSJ: a) benches presenting a high occupancy density of MDs and it's restricted for the placement of a new device; b) try to find the power button on the prototype; c) grabbing the sample holder.

The light interface, that provides feedback related with operation state, was also unnoticed by 3 participants. It was suggested to increase light size region and change location to enable an intuitive feedback on the operation state. However, and besides user-related operation issues, other improvement suggestions were obtained for the design process of the next version of iLoF prototype:

- The material must be resistant to bleach due to frequent disinfection procedures (daily).
- MD surfaces should not be embossed, preventing dust accumulation, and facilitating disinfection.
- The screen should be incorporated in the prototype, to provide a constant interface to control prototype's operation, without the risk of losing it. Horizontal orientation of the interface should be adopted to improve the visualization of the graphical interface.
- The most recommended colours for MDs are white and blue, because white conveys purity and gives the idea of cleanliness, while blue is usually related with medical equipment.
- The power cable MDs should be easily plugged/unplugged, to facilitate MDs replacement.
- An automatic drawer (or equivalent system) to ensure a better and safer replacement of samples.

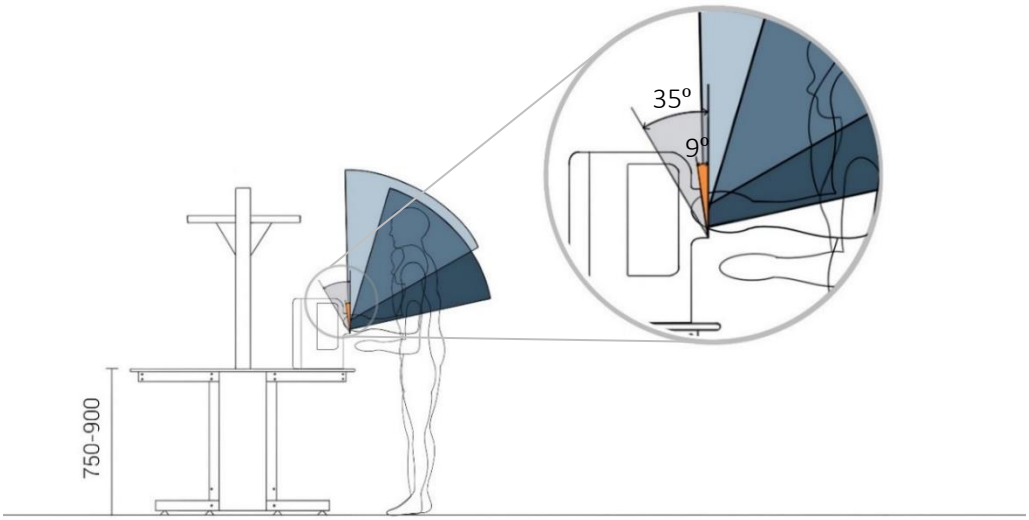

Figure 4. Representation of iLoF prototype placed on a laboratory bench, with the current angle (9º) and the ergonomically recommended angle (35º) with the illustration of fields of vision for the 5th percentile (darker blue) and the 95th percentile (lighter blue) (see online version for colours).

4. Benchmarking Assessment

Table 1. Benchmark comparison considering the criteria under evaluation (A – very good, B – good, C – sufficient and D – enough). The filled rectangles indicate the best options, while the underlined identify the weakest MD. The iLoF prototype is also filled with a thinner rectangle.

	ERGONOMIC	AESTHETIC	PORTABILITY	USER FRIENDLY
Life Tech	A	B	D	B
Droplite	B	C	A	D
FUJIFILM DRI-CHEM IMMUNO AG2	A	A	A	A
Diatron: Aquila	B	B	C	A
Bosh: Vivalytic	B	A	A	A
LG Life Sciences	B	B	C	B
Nicoya Alto	B	C	C	A
BluBox	B	B	A	A
Samsung: LABGEO PT10S	B	B	A	B
Samsung: LABGEO A20A	B	C	A	B
Fluidigm: Juno	B	C	C	B
CRUX: CMD	A	C	B	B
Samsung: LABGEO HC10	D	D	B	C
Samsung: LABGEO IB 10	B	C	A	C
iLoF Prototype	C	C	B	C

The evaluation of the 15 MDs showed that all systems were designed according to some of the already mentioned ergonomic considerations, as the tilted screen for easy visualization of the MDs graphical interface. In terms of aesthetics, some MDs included a simple and attractive design with smooth surfaces, allowing efficient cleaning procedures. Ten MDs also had a built-in handle to improve product portability. A MDs comparison summary is displayed in table 1, where a score from A to D was assigned to each MD according to the criteria selected (ergonomics, portability, aesthetic, and user-friendliness).

The device *DRI-CHEM IMMUNO AG2* from FujiFilm, designed by Hirotoshi Ono presented the best evaluation. This MD has a vertical design which enables to position the equipment on a bench laboratory. Besides having a simple design, with smooth surfaces, the sample drawer is automatic,

avoiding sample spilling and product contamination. The IXDS design team with Bosch R&D team developed the *Vivalytic* also resorts to a vertical and simple design with smooth and ergonomic surfaces. It presents a good human interface, and the buttons have light to provide an instantaneous feedback to the user. The devices with the lowest rating were Samsung *LABGEO HC10*. This MD presents a poor design, coupling the lack of handles for easy transport with a fragile human interface.

Despite being only the first prototype version, iLoF prototype already presents a better evaluation than Samsung *LABGEO HC10*. However, there are some issues to solve, and user needs to attend.

5. Conclusions

A benchmarking assessment and a case study (at CHUSJ hospital) were carried out to demonstrate the relevance of the end-user during the development of a new medical device. The implementation of the iLoF prototype in healthcare facilities allowed the identification of limitations in the operation of the device that must be addressed in the following versions of the equipment. The inclusion of end-users in these tests allowed the identification unperceived of needs. Therefore, and although iLoF prototype did not follow the usual development process of an MD (in accordance with regulatory standards), aesthetic and ergonomic considerations must be addressed in the following iterations of this MD.

The combination of science and technology coupled with user-centric design approaches play crucial role in a MD commercial success. Therefore, the user's needs gathered in the case study, related to sample holders, screen position, shape, colour, and handling of the drawer need to be considered and sorted out in the iLoF prototype project while maintaining an HCD approach.

6. Future work

This work was part of a master's thesis that aimed to develop a new design for the iLoF medical device. Based on the findings of this paper, the next steps include the development of a new prototype, following the human-centred design methodology. The new design of this MD should address the priorly identified user needs, ergonomic considerations and constructive solutions for the drawer and sample holder. The new version must also be built with materials highly resistant to cleaning agents. The end-user must be continuously included during such development to test the new versions, increase technology acceptance and to find new needs and challenges to incorporate in the product development roadmap.

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