What Do We Mean by the Validation of Activity Monitoring Devices?

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Abstract—**Various device validation methodologies for activity monitoring are growing in number, but the information about the regulation and rules of recognition for the software and hardware used with these devices is not presented. There are different characteristics that should be evaluated to prove the reliability of these devices, including different security and privacy parameters. Activity monitoring can be performed with mobile devices and other devices whose software versions are updated regularly. That is why these devices should be regulated, including the devices implemented in smart environments, containing the ones implemented in furniture, which are important for the monitoring of ageing people. The regulation of these devices and mobile applications has been discussed, but there are no specific rules. This study presents some possible methods for the regulation of mobile devices and applications for activity monitoring of ageing people, which can also be influenced by environmental conditions.**

Keywords-regulation; mobile technologies; activity monitoring; security; privacy.

I. INTRODUCTION

Activity monitoring is a subject that has been growing with mobile devices and other specific devices. The validation of these devices is important because it is estimated that the number of ageing people and those who need special assistance is increasing [1]. Compared with the need for the validation of the medical devices, these devices need to be validated by several rules for safety and accessible use [1]. Some validation rules of the medical devices have been created by the Food and Drug Administration (FDA) [2] in the United States, and CE Marking [3] in European Union (EU), but only few rules were defined for the validation of the mobile applications according to the severity level of their risks.

There are many studies about the validation of activity monitoring systems, especially wearable technology [4]. Most research in this area has been done without mentioning which regulation and software version was considered.

There are no concrete rules for the validation of the activity monitoring devices and the mobile applications available on the market. In 2010, Unites States of America's (USA) government started the regulation of mobile medical applications. While the suggestion of regulation is rooted in patient safety, concerns about limits on innovation and discovery, as well as the evolving nature of both mobile health and current healthcare delivery have emerged [5]. Currently, the EU countries are working on such laws [6].

Activity monitoring devices are very important for the monitoring of ageing people, where their correct functionality should be validated. In USA, FDA is validating these devices and mobile applications, and this is subject to reimbursement as a medical device [7]. These procedures should be implemented in other countries in order to improve the safety and correct use of this equipment.

The rest of this paper is organized as follows. Section II describes the different methodologies used for the validation of the activity monitoring devices and mobile applications. Section III proposes a validation schema for the mobile applications and devices for activity monitoring. Section IV presents the discussion and conclusions of this study. The acknowledgment and references close the article.

II. METHODS

U.S. Department of Health and Human Services implements a variety of regulations for Products and Medical Procedures, Medical Device Safety, Device Advice, Comprehensive Regulatory Assistance, and Digital Health. Therefore, we are concentrating on Medical Devices which include Mobile Medical Applications [8].

 ISBN: 978-1-61208-660-6

Mobile medical applications are mobile applications that meet the definition of a medical device and are an accessory to a regulated medical device or transform it into a regulated medical device [9]. Some mobile medical apps can diagnose heart rate abnormalities by using an Activity Tracker, whose software versions are updated periodically. For example, the fitness watch Vivosmart HR uses the software Garmin Express for synchronizing the date from devices. It updated from version 2.10 to 4.30, so it is important to clarify which version of the software was used in the research. Also, it is important to control that a device does not update itself during the experimental work.

In 2012, the R package 'fda.usc' was eliminated, which included some utilities for functional data analysis. It also contained functions to compute functional regression models and basic functional principal components analysis [10]. In 2014, an article was published, which shows that "Electronic and mobile systems play pivotal roles in healthcare delivery. A classification system for healthcare applications should be developed that recognizes and delineates the difference between apps that support decision-making, and those which purport to intervene in clinical decisions" [11].

In 2017, the FDA created a pilot study for the validation of some products from large companies, including Apple, Fitbit, Samsung and others [12]. The software and hardware for activity monitoring should be validated according to different perspectives, including Organizational Resource Perspective, Customer Perspective, Learning and Growth Perspective and Process Perspective, based on different principles, including Patient Safety, Product Quality, Clinical Responsibility, Cybersecurity Responsibility and Proactive Culture [13]-[15]. The frequency of the updates of these mobile applications and devices should be reduced to guarantee their correct validation.

FDA was the first agency that started the validation for medical devices and applications during the last years in United States. Currently, in the European Union, the CE Marking started the development of strict rules related to the digital health application and devices [16].

Combining the information mentioned above, some rules will be introduced in the next section related to high-risk and moderate-risk recalls of the mobile devices and applications, especially for the activity monitoring systems for ageing people [22][23].

III. RESULTS

This study presents a proposal of validation rules and regulations for mobile and wearable technology that is used by ageing people.

There is much research showing mobile devices or activity monitoring systems validation, but they usually present only brand names and do not demonstrate exactly which tool was used for the experimental work, what was the device serial number, generation, and date of issue [17]. Thus, it is important to clarify serial number, generation, and date of issue of the user device in the research.

An important fact is that, when researchers validate devices, they do not write about the software version of the tool. Smartwatches use their own operating system and mobile applications for synchronizing the raw data to a server and the server gives us access to work with inputs. If the scientist did not mention which software was used and some reader will check artifacts of the study, the results will not the same because programs of mobile applications and device are updating themselves from time to time. So, it is important for researchers to provide information on the software version of the device and operation program for synchronizing the data.

Commonly, the mobile applications and computer programs are updated from time to time. Sometimes, this activity is happening during a very short period. So, it is natural that the software version is the difference in the start and end periods of the research. This case creates a confusing situation, as the data from start steps is not the same then data from the last stages of the study. Therefore, the results of this type of research with be false, because the start and end stages validation were done using a different version. We suggest stopping software updates during the experimental work of any study.

One example of a validated medical device that may be used for activity monitoring is the Everion device, developed by Biovotion [18]. It passed the rules from FDA and it is validated as a medical device in the USA. However, this validation is not valid worldwide. Therefore, common rules should be developed for all countries.

Based on the validation rules created by FDA, the validation process should be executed in three stages [19], as follows:

1. Process Design;
2. Process Qualification;
3. Continued Process Verification.

First, stage 1 should include the research about the Building and Capturing Process Knowledge and Understanding, and the Establishment of a Strategy for Process Control. Second, stage 2 should include the research about the Design of a Facility and Qualification of Utilities and Equipment, the Process Performance Qualification (PPQ), the PPQ Protocol, and the PPQ Protocol Execution and Report. Finally, stage 3 should guarantee the continuous validation during software and hardware updates. The main rules commonly adopted are described in [19].

Also, Boston Technology Corporation offers an end to end mobile application testing services which include the following [20]:

- Testing Strategy should focus on two factors – reducing testing costs and improving 'Time to Market' for the mobile applications;
- Functional Testing verifies that the Mobile Application meets the functional requirements. This testing step is critical to ensure that the functionality built to meet the stated business requirements and objectives works correctly as designed. Functional testing leverages automation tools, but many of the testing steps

 ISBN: 978-1-61208-660-6

require manual testing to effectively mimic App user behavior;

- Non-Functional Testing covers testing mobile applications for usability, performance, scalability, security, as well as compatibility on different devices and Operating Systems (OS) platforms. This testing is typically done after the application has been tested for functional requirements and provides insight into the production readiness of the application. Non-functional testing can be effectively carried out by using testing tools, unlike functional testing, which is largely manual. For this type of testing to be effective, it is important to create specific measurable test objectives [20].

IV. DISCUSSION AND CONCLUSION

The results and methodology discussed here are not limited to regulation of mobile applications and wearable technology validation. They provide the basis to develop this field in European and Asian countries. The validation rules and schema of this research are based on studies of U.S. FDA Registration [21] and CE Marking [16].

Also, software problems in medical devices are very frequent and have the potential to negatively influence mHealth care. “Premarket regulation has not captured all the software issues that could harm patients, evidenced by the potentially large number of patients exposed to software products later subject to high-risk and moderate-risk recalls” [22][23].

The population using mobile applications and programs for activity monitoring is growing every day. So, it is necessary to address legal aspects for their validation.

The correct validation of these devices will increase the confidence in them by patients and healthcare professionals. The recognition of the activities can be a critical area, because the recognition of the activities can be used for the monitoring of risk situations, including the falling of ageing people. In the future, the institutions for the ageing people can be more proactive, combining several sensors for the recognition of different activities, and this can be implemented with sensors available in the mobile devices and sensors placed in the furniture, among others. The validation of these devices should be specified and adapted to their purpose, as their risks may increase with the creation of intelligent systems to monitor and help ageing people [24].

ACKNOWLEDGMENT

This work was supported by FCT project UID/EEA/50008/2013. The authors would also like to acknowledge the contribution of the COST Actions IC1303 – AAPELE – Architectures, Algorithms, and Protocols for Enhanced Living Environments, and CA16226 – Indoor living space improvement: Smart Habitat for the Elderly.

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