Chiron Solutions Inc.

February 21, 2021

Dr. Craig Scratchley
School of Engineering Science
Simon Fraser University
Burnaby, BC, V5A 1S6

Re: ENSC 405W Requirements Specification for Harp Blood Pressure Monitor

Dear Craig Scratchley,

The following document contains the functional specification for the Blood Pressure Measurement Device. Our goal is to design a non-invasive device that can measure diastolic blood pressure continuously. The device is intended to be comfortable enough to be worn throughout the day and be usable during most daily activities.

The functional specification will provide a system overview, the overall system requirements, engineering, medical and safety standards, and the sustainability matters for the proof-of-concept, and future prototypes of this device.

Thank you for taking the time to review our functional specification for BPM Device. If you have any questions or concerns regarding our document, please contact Khalil Ammar, our Chief Executive Officer.
Sincerely

Khalil Ammar
Chief Executive Officer
Chiron Solutions Inc.

Chiron Solutions Inc.

Requirements Specification

Harp Blood Pressure Monitor

Project Members:	Alikhan Zhansykbayev
	Akshay Kumar
	Daniel Wan
	Khalil Ammar
	Licheng Bao
	Tianhao Li
Contact Person:	Khalil Ammar
	kammar@sfu.ca
Submitted to:	Craig Scratchley
	Shervin Jannesar
	Michael Hegedus
	Chris Hynes
	School of Engineering Science
	Simon Fraser University
Issue date:	Feb 21, 2021

Abstract

The blood pressure monitoring market is currently dominated by cuff-based blood pressure monitors which have numerous shortcomings. The current products are not only bulky and restrictive but they also inflate the cuffs to an uncomfortable degree while in use. This leads to the second major drawback, which is the inability to provide the user with continuous readings of their blood pressure.

Our product aims to cover those shortcomings and provide users with a more seamless blood pressure measurement experience that does not hinder their daily lives while providing accurate and continuous measurements of their blood pressure to give them better insight into their health condition. The device will be wearable and will be composed of two main subsystems: The first part is a wearable hardware subsystem which will contain the required sensors, a microcontroller, and a bluetooth module to communicate with the second subsystem. And the second main part is a software subsystem in the form of a mobile app that will receive the data from the wearable device, analyze it, and display the results to the user

The requirements for the different subsystems have been outlined in this document and have been further categorized into the different phases of the development process, namely the alpha, beta, and production phases. Furthermore, the testing plan for our prototype has been listed along with the various engineering standards, sustainability and safety requirements by which our product will abide.

Table of Contents

List of Tables

List of Figures

1. Glossary

Term	**Definition**
DBP (Diastolic Blood Pressure)	The lowest/minimum arterial pressure occurring each heartbeat.
ECG (Electrocardiogram)	A graph of voltage versus time of the electrical activity of the heart using electrodes placed on the skin.
PEP (Pre-Ejection Period)	The time period between the onset of left ventricular depolarization (the onset of QRS complex on electrocardiogram (ECG), and in particular the ECG Q wave when available) and the opening of the aortic valve.
PPG (Photoplethysmography)	Optical technique used to detect volumetric changes in blood in peripheral circulation
PTP (Point-to-Point)	A type of calibration of cuff-less blood pressure (BP) measurement.
PTT (Pulse Travel/Transit Time)	The time it takes a pulse wave to travel between two arterial sites.
SBP (Systolic Blood Pressure)	The highest/maximum arterial pressure occurs in each heartbeat.

SCG (Seismocardiography)	The non-invasive measurement of accelerations in the chest wall produced by myocardial movement

Table 1. Glossary Table

2. Introduction

Hypertension is an ailment that affects **14.4%** of the world's population today [1][2]. Currently, those affected by hypertension and even healthy individuals are measuring their blood pressure at home to either manage their illness or prevent it from developing in the first place.

The current market is filled with manual and automatic cuff-based blood pressure monitors, including ambulatory monitors, which take readings at predefined intervals over 24 hours. This is very useful because a one time reading at the doctor's office is not enough to diagnose hypertension. It also helps with the *white coat effect*, where the patient's readings come out to be either too high or low when they go see a doctor.

These devices work by inflating the cuff so that no blood flow occurs through the patient's artery. As the cuff is deflated below the systolic pressure, the reducing pressure on the artery allows blood to flow through which sets up a detectable vibration in the arterial wall. When the cuff pressure falls below the patient's diastolic pressure, blood flows smoothly through the artery without any vibration [3]. Although intuitive to use, these devices can be very uncomfortable for some, and also require the user to stay still for the reading.

We aim to fill this gap in the current marketplace with our own continuous blood pressure monitoring system. The device can be work on either your chest or arm (on your upper bicep, heart-level) and will use 3 sensors, namely Electrocardiogram (ECG),

Seismocardiography (SCG), and Photoplethysmography (PPG) instead of a cuff to take readings which will be then synced to our software application on the user's phone via bluetooth. Once synced, the readings will be used in the PTT-based (Pulse Transit Time) algorithm to estimate the user's diastolic blood pressure. The user can track current trends in their blood pressure, get notified of a too high or low reading or even look at historical data in the software application.

3. Background

Blood pressure (BP) measurement always plays an important role in people's health. As the development of medical science and technology has progressed, there have been several different techniques developed to measure blood pressure. The current devices can measure and monitor the blood pressure, from cuff to cuff-less and from invasive to non-invasive, providing more accurate data with less requirements during the measurement.

Nowadays, hypertension and related cardiovascular diseases are increasing [1], Ambulatory blood pressure measurement (ABPM) has a better performance as a predictor of risk than office blood pressure [4]. The home blood pressure measurement device has become a household necessity.

For pursuing the ambulatory blood pressure measurement [5] and non-invasive blood pressure measurement [6], the measurement of pulse transit time (PTT) has become one of the most popular methods to implement cuff-less continuous BP monitor [6]. According to several papers, PTT can be estimated based on Electrocardiogram (ECG), Seismocardiography (SCG), and Photoplethysmography (PPG) [6].

Currently, most cuff-based devices use oscillometry [7]. As one of the basic blood pressure techniques [4], oscillometry is regarded to be extended to apply for cuff-less and calibration monitoring through an external device such as smartphone [7]. On the other hand, as the method to resolve the problem of initial calibration of cuff-less designs, mean Point-to-Point (mPTP) and factor Point-to-Point (fPTP) have a better

performance than traditional one Point-to-Point (oPTP) [8]. It is also possible to use a deep learning model to implement real-time cuff-less continuous blood pressure estimation [4].

3.1 Market:

For now, there are some wearable products in the market. For example, there are some products that are wireless and able to communicate with the smartphone and send the test results to the application [9]. There are also some products that can continuously record the data when the user is lying on the bed without moving [10]. However, none can record the information continuously while the user is doing something else without interrupting them. Besides, most of the current devices are testing the Systolic blood pressure by increasing the cuff pressure to a high level, which makes the customers uncomfortable. According to the interviews, the target users want a blood pressure testing device that is wearable, continuous, and comfortable to help them prevent the risk of hypertension in daily life. There are still no such products in the market, and our product will fill this gap.

3.2 Customer:

The main target of this product is hypertension patients who need to keep the continuous measurements of their blood pressure during daily life. The product can give them real-time feedback in case of a sudden rise in blood pressure. Another main group of customers is the elders and the adults who are at risk of hypertension. The product can give them the trend of blood pressure, thus helping them prevent or mitigate hypertension. The product also targets the current users who are using other products but feel cuff-based designs are uncomfortable.

4. Scope

The product will focus on continuous blood pressure testing on diastolic pressure. That is the main goal in the developing process. Additionally, the product must be comfortable to wear, as it is a requirement from users. To function correctly as a measuring device, the device should keep the accuracy at ±5 mmHg in reference to current cuff-based monitors [11]. Furthermore, the product will contain an algorithm to analyze the data collected and display the results to the user.

The product will not focus on the standard of hypertension as it has been set by the experts. The standard of defining the trend and advice for the user will also be acquired by consulting the experts. It will not keep track of continuous systolic blood pressure. The device will also not keep track of short-term changes in pulse pressure as that results from changes based on the condition of the artery which do not affect the results. [12]. Finally, the product is designed to track the data and help the user, so the product is not meant to cure patients.

5. System Overview

Our product will allow the user to get a continuous stream of blood pressure reading throughout the day. There are more than 17.9 millions people [1] who are at risk of cardiovascular disease and having this data can help them and their doctors to detect important signs and act accordingly. The product will consist of a module that will be placed either on the patient's chest or around their upper arm with the help of a comfortable strap. This placement was chosen because it has been proven that placing a blood pressure monitor at heart level yields the best accuracy [4]. Therefore, having the device around the upper arm or on the chest ensures that it will always function at its optimal potential regardless of the posture of the wearer.

The device will be easily wearable throughout the day and will not hinder the user's daily activities and it will be composed of 3 different sensors to collect data that will be used to calculate the blood pressure at any given time: An Electrocardiogram (ECG), a Photoplethysmography (PPG) and a Seismocardiography (SCG) [6]. The raw data will then be processed and analyzed on the user's mobile phone and the results can be seen through the accompanying app. The system will communicate with the app using Bluetooth and is therefore self-contained and does not require any external connections or tethers. This ensures that the product's wearability is optimized and allows it to be used comfortably under various circumstances such as sleep, desk-related work, and light physical activities.

6. System Diagram

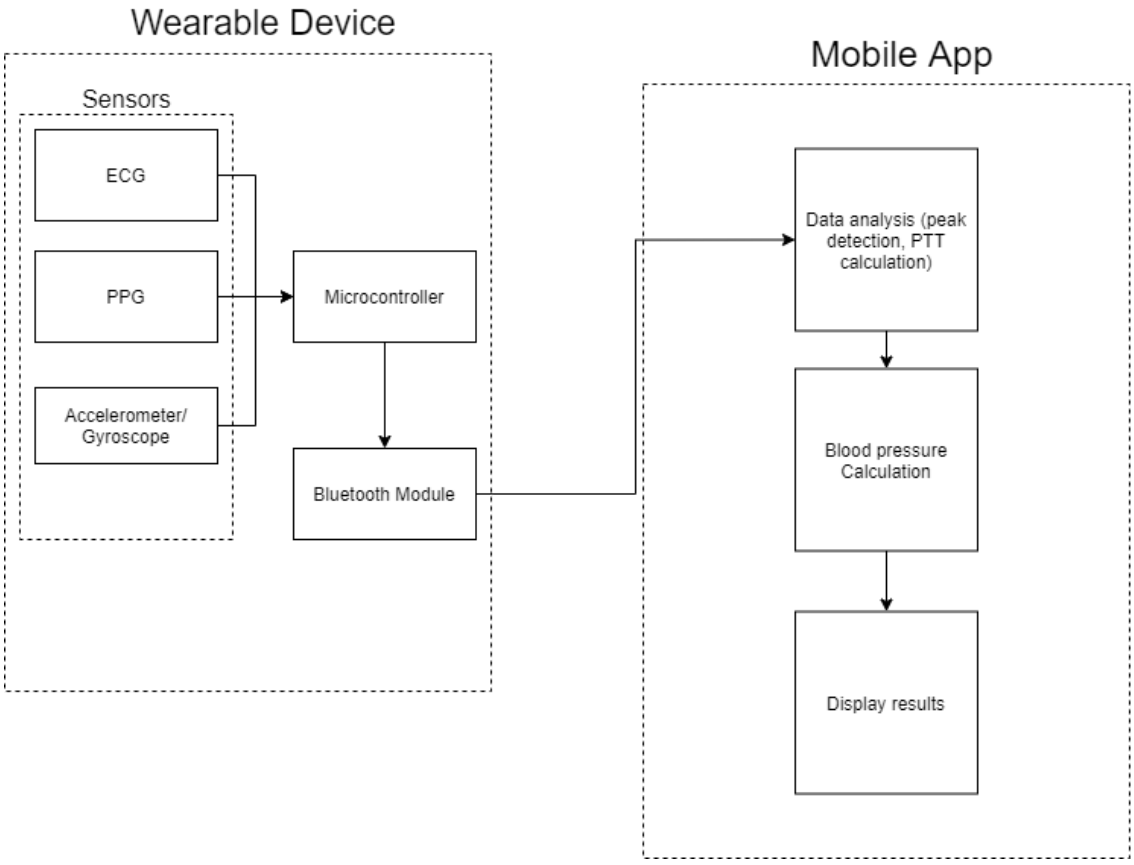

Figure 6. System diagram

7. System Requirements

This section outlines the requirements for the hardware components and the associated software system that will be used to take automated readings. Our product will attach on to either an arm band or a chest band, which the user will wear either on their upper bicep/tricep area (at heart level) or on their chest. It will use three sensors to collect ECG, PPG and SCG data. This data will not be displayed on the device and instead will be synced via bluetooth to our application installed on the user's phone. Our app will then use the PTT algorithm to estimate the user's blood pressure and display alerts or readings on the user's phone based on their preferences/settings.

7.1 Hardware Requirements

7.1.1 ECG, PPG and SCG sensors

[Req7.1.1-a]: Each sensor must require at most an initial calibration and must be able to operate without recalibration during daily use.
[Req7.1.1-b]: The sensors must be able to provide sufficiently continuous and accurate readings (±10mmHg) under average human skin temperature and humidity (sweat).
[Req7.1.1-b]: The system must not use too much power (>50mAh).

7.1.2 Microcontroller/Bluetooth Module

[Req7.1.2-a]: The microcontroller/bluetooth module should be able to interface with the sensors through physical connections and the software application via bluetooth.
[Req7.1.2-b]: It should support Bluetooth Low Energy (BLE) for power efficiency.
[Req7.1.2-c]: The system must not use too much power (>50mAh).

7.1.3 Battery

[Req7.1.3-a]: Battery must support the continuous operation of the system for a minimum of 12 hours.

[Req7.1.3-b]: The battery must be safe and light enough to be used as a wearable for humans.

7.1.4 Bands

[Req7.1.4-a]: The bands should be comfortable and easy to wear.
[Req7.1.4-b]:It should be easy to switch/interchange bands.

7.2 Software Requirements

The application software plays a critical role in providing data and alerts to the user related to their blood pressure. The requirements for the software are summarized in the list below:

[Req7.2-a]: The application must be easy and intuitive to use.
[Req7.2-b]: The application must be able to use bluetooth to communicate with the device at predefined intervals and collect the sensor readings.
[Req7.2-b]: It must use the PTT algorithm and the data to accurately estimate the user's blood pressure.
[Req7.2-b]: It must send the user notifications related to readings or alerts based on predefined minimum and maximum readings based on the user's settings.
[Req7.2-c]: It should also store historical data and show the user graphs based on this data when requested.

8. Safety Requirements

8.1.1	The device must not contain any hazardous and dangerous materials

8.1.2	All electronic connections must be contained
8.1.3	The device instructions should be easy to understand
8.1.4	The app must secure the user's privacy and confidential data
8.1.5	The device must not have any sharp edges to prevent patient from getting hurt
8.1.6	The device should not pose any risk to the user if exposed to water
8.1.7	The temperature of the sensors must not exceed 80 degrees Celsius

Table 8. Safety Requirements

9. Sustainability

Our team would like to make it easier for the user to control the continuous blood pressure reading throughout their daily life. The design of this product focuses on the ability to measure the blood pressure using the comfortable-to-wear module that will be placed on the patient's chest or around their upper arm with the help of a strap. Our team will respect the standards of the Canadian Standards Association by following their rules and regulations.

The proof-of-concept of the Blood Pressure Measurement Device consists of a few sensors, such as Electrocardiogram(ECG), Photoplethysmography(PPG),

Seismocardiography(SCG), and the mobile app that will display the Blood Pressure of the user.

The ECG, SCG, gyroscope, and accelerometer sensors will consist of a printed circuit board, microcontrollers, wires, and plastic. The PCB, microcontroller, and wires can be disposed of at electronic waste depots, and the plastic can be recycled at plastic recycle stores.

In order to be wearable on the patient throughout the day, the battery is required for this device. The most suitable option is rechargeable lithium-ion batteries, which can be disposed of at special battery disposal depots.

10. Engineering Standards

The continuous diastolic blood pressure measurement device is intended to be worn by the general public, thus, it must adhere to certain engineering standards. These include safety, quality, and device standards. The types of standards that are relevant belong to the International Electrotechnical Commission (IEC), Organization of Standardization (ISO), and the Institute of Electrical and Electronics Engineers (IEEE). Specifically being that the device is intended to be a medical device, every precaution must be taken to ensure its reliability, accuracy and safety. Some additional guidelines can also be found from WHO technical specifications for automated non-invasive blood pressure measuring devices [13]. The following standards will be met as closely as possible.

IEC 80601-2-30:2018	Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers [14]

ISO 81060-2:2018	Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent automated measurement type [15]
IEEE 1708-2014	IEEE Standard for Wearable Cuff-less Blood Pressure Measuring Devices [16]
IEEE 1708a-2019	IEEE Standard for Wearable, Cuff-less Blood Pressure Measuring Devices - Amendment 1 [17]
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes [18]
ISO 16142-1:2016	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards [19]
ISO/IEEE 11073-10407:2010	Health informatics — Personal health device communication — Part 10407: Device specialization — Blood pressure monitor [20]
ISO 14971:2019	Medical devices— Application of risk management to medical devices [21]
ISO 14155:2011	Clinical investigation of medical devices for human subjects — Good clinical practice [22]
IEC 62304:2006	Medical device software — Software life cycle processes [23]

Table 10. Engineering Standards

11. Acceptance Test Plan

The acceptance test plan for the proof of concept prototype deliverable will be outlined in this section. It is sufficient for the prototype to only satisfy the basic requirements of the specifications outlined. This means the main focus of the prototype will be validating whether the devices can feasibly measure a person's blood pressure reliably.

The device must use the ECG, PPG, accelerometer, and gyroscope sensors which all feed data to the microcontroller. The data collected must feasibly be able to calculate the corresponding blood pressure measurement. To test if this was accomplished, the prototype must be built and tested on at least 5 different patients. Blood pressure measurements taken must be reasonably close to a consumer based sphygmometer as defined above. Based on the feedback of testing, necessary changes will be made to the device. An app need not be developed at this stage, as the main concern is with the feasibility of the hardware system.

The acceptance test plan for the final product will be stricter than the acceptance test plan of the prototype. One of the differences being that physical dimensions of the product need to be within the specified bounds. The device must be wearable on a person's body. An app must be developed which will be able to receive the data from the microcontroller. The app then must calculate the blood pressure measurement from the received data and display it appropriately.

12. Conclusion

This document outlines all the requirements specifications and is intended to be used as a guideline when developing the prototype blood pressure measurement device. The document provides insight into certain hardware and software requirements, as well as categorizes the essential versus less essential requirements.

These requirements include hardware requirements such as battery life, equipment accuracy, comfort, efficiency, and compatibility. Software requirements like user interface intuitiveness and usability are also addressed. In addition to these system requirements, safety requirements are also listed, examples of which include material selection and securing user data. Next, sustainability is discussed as to hopefully make the least amount of waste as possible. Lasty, engineering standards from IEEE, IEC, and ISO which are relevant to the development of the device are listed.

The specifications listed in this document are only meant to be used as guidelines when developing the prototype, therefore as development progresses on the devices, there may be changes to the details in this document, and requirements may be slightly modified to fit the updated needs.

13. References

[1] Li, Y. H., Harfiya, L. N., Purwandari, K., & Lin, Y. D. (2020). Real-Time Cuffless Continuous Blood Pressure Estimation Using Deep Learning Model. Sensors (Basel, Switzerland), 20(19), 5606. [Online]. Available: https://doi.org/10.3390/s20195606.

[2] “Hypertension.” *World Health Organization*, World Health Organization. [Online]. Available: https://www.who.int/en/news-room/fact-sheets/detail/hypertension [Accessed 18 Feb 2021]

[3] Berger, Abi. (2001). Oscillatory Blood Pressure Monitoring Devices. BMJ, 323(7318), 919. [Online]. Available: https://doi.org/10.1136/bmj.323.7318.919.

[4] Ogedegbe, G., & Pickering, T. (2010). Principles and techniques of blood pressure measurement. Cardiology clinics, 28(4), 571–586. https://doi.org/10.1016/j.ccl.2010.07.006.

[5] Vischer, Annina S, & Burkard, Thilo. (2017). Principles of Blood Pressure Measurement – Current Techniques, Office vs Ambulatory Blood Pressure Measurement. Hypertension: From Basic Research to Clinical Practice, 956, 85–96. [Online]. Available: https://doi.org/10.1007/5584_2016_49.

[6] Lee, J., Sohn, J., Park, J., Yang, S., Lee, S., & Kim, H. C. (2018). Novel blood pressure and pulse pressure estimation based on pulse transit time and stroke volume approximation. Biomedical engineering online, 17(1), 81. [Online]. Available: https://doi.org/10.1186/s12938-018-0510-8.

[7] Chandrasekhar, A., Yavarimanesh, M., Hahn, J., Sung, S., Chen, C., Cheng, H., & Mukkamala, R. (2019, October 31). Formulas to Explain Popular Oscillometric Blood Pressure Estimation Algorithms. [Online]. Available: https://www.frontiersin.org/articles/10.3389/fphys.2019.01415/full.

[8] Shao, J., Shi, P., Hu, S., & Yu, H. (2020). A Revised Point-to-Point Calibration Approach with Adaptive Errors Correction to Weaken Initial Sensitivity of Cuff-Less Blood Pressure Estimation. Sensors (Basel, Switzerland), 20(8), 2205. [Online]. Available: https://doi.org/10.3390/s20082205.

[9] *Wellue Armfit Plus™ Blood Pressure Monitor Bluetooth, Upper Arm Cuff, Accurate Digital BP Machine, Heart Health Monitoring Device, Free for iOS & Android: Amazon.ca: Health & Personal Care*. [Online]. Available: https://www.amazon.ca/gp/product/B08L5YKCZY?pf_rd_r=B5GKZZVCHGEY8C32M3WF&pf_rd_p=05326fd5-c43e-4948-99b1-a65b129fdd73&pd_rd_r=e93167a7-be2a-475d-b80f-740b4cad134b&pd_rd_w=rfpFb&pd_rd_wg=knZei&ref_=pd_gw_unk.

[10] “CareTaker Medical's continuous blood pressure monitor gets 2nd FDA clearance,” *MobiHealthNews*, 05-May-2017. [Online]. Available: https://www.mobihealthnews.com/content/caretaker-medicals-continuous-blood-pressure-monitor-gets-2nd-fda-clearance.

[11] J. A. Hodgkinson, M.-M. Lee, S. Milner, P. Bradburn, R. Stevens, F. D. R. Hobbs, C. Koshiaris, S. Grant, J. Mant, and R. J. McManus, “Accuracy of blood-pressure monitors owned by patients with hypertension (ACCU-RATE study): a cross-sectional, observational study in central England,” *British Journal of General Practice*, vol. 70, no. 697, 2020.

[12] R. E. Klabunde, “Arterial and Aortic Pulse Pressure,” *Image for Cardiovascular Physiology Concepts, Richard E Klabunde PhD*, 12-Jul-2016. [Online]. Available: https://www.cvphysiology.com/Blood%20Pressure/BP003.

[13] “WHO Technical Specifications for Automated Non-Invasive Blood Pressure Measuring Devices with Cuff.” [Online]. Available: https://www.who.int/docs/default-source/searo/indonesia/who-tech-spec-for-automated-non-invasive-blood-pressure-measuring-devices-with-cuff.pdf?sfvrsn=b112be47_2 [Accessed 18 Feb 2021]

[14] IEC 80601-2-30:2018 [Online]. Available: https://www.iso.org/standard/70653.html. [Accessed 18 Feb 2021]

[15] ISO 81060-2:2018 [Online]. Available: https://www.iso.org/standard/73339.html. [Accessed 18 Feb 2021]

[16] IEEE 1708-2014 [Online]. Available: https://standards.ieee.org/standard/1708-2014.html. [Accessed 18 Feb 2021]

[17] IEEE 1708a-2019 [Online]. Available: https://standards.ieee.org/standard/1708a-2019.html. [Accessed 18 Feb 2021]

[18] ISO 13485:2016 [Online]. Available: https://www.iso.org/standard/59752.html. [Accessed 18 Feb 2021]

[19] ISO 16142-1:2016 [Online]. Available: https://www.iso.org/standard/63939.html. [Accessed 18 Feb 2021]

[20] ISO/IEEE 11073-10407:2010 [Online]. Available: https://www.iso.org/standard/54573.html. [Accessed 18 Feb 2021]

[21] ISO 14971:2019 [Online]. Available: https://www.iso.org/standard/72704.html. [Accessed 18 Feb 2021]

[22] ISO 14155:2011 [Online]. Available: https://www.iso.org/standard/45557.html. [Accessed 18 Feb 2021]