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FACULTY OF BIOMEDICAL ENGINEERING

Department of Biomedical Technology

Analysis of the response of pulse oximeters to a step-change in saturation depending on the set averaging time

Bachelor Thesis

Study program: Biomedical and clinical engineering
Study branch: Biomedical technician

Bachelor thesis supervisor: Ing. Veronika Ráfl Huttová

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BACHELOR'S THESIS ASSIGNMENT

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II. BACHELOR'S THESIS DETAILS

Bachelor's thesis title in English:

Analysis of the response of pulse oximeters to changes in oxygen saturation depending on the set averaging time

Bachelor's thesis title in Czech:

Analýza odezvy pulzních oxymetrů na změny saturace v závislosti na nastaveném průměrovacím čase

Guidelines:

Analyze the response of pulse oximeters to change in peripheral oxygen saturation (SpO2) with respect to set averaging time of the oximeters. Design and perform a set of laboratory experiments with several brands of pulse oximeters or vital signs monitors and an SpO2 simulator. Simulate various step changes in oxygen saturation that differ in magnitude, initial level of oxygen saturation or the direction of the change. Validate the output test signal of the SpO2 simulator as a part of the experiment.

Bibliography / sources:

[1] John G. Webster. Encyclopedia of medical devices and instrumentation, ed. 6, Wiley, 2006, ISBN 978-0-471-26358-6
[2] Amal Jubran, Pulse oximetry, Critical Care, ročník 19, číslo 1, 2015
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Date of bachelor's thesis assignment: **15.02.2021**
Assignment valid until: **18.09.2022**

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DECLARATION

I hereby declare that I have completed this project with the topic "Analysis of the response of pulse oximeters to a step-change in saturation depending on the set averaging time" independently and that I have attached an exhaustive list of citations of the employed sources to the bachelor thesis.

I do not have a compelling reason against the use of the project within the meaning of Section 60 of Act No.121 / 2000 Coll., on copyright, rights related to copyright, and amending some laws (Copyright Act).

In Kladno 29/07/2021 Angie Vanessa Gil León.

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ABSTRACT

Title of the Thesis: Analysis of the response of pulse oximeters to a step-change in saturation depending on the set averaging time.

The main principle of signal averaging is that each displayed value is the average value for a given period. This bachelor thesis aims to analyze and compare different averaging methods of one medical pulse oximeter (Masimo Root with Radical 7), and two vital signs monitors (Carescape B650 and Datex Ohmeda S/5), using a SpO_2 simulator (Fluke Biomedical ProSim8) to simulate the oxygen concentration and various step changes. We designed and conducted a laboratory experiment using a SpO_2 simulator, to analyze the response of the mentioned devices to different step changes varying in magnitude, initial oxygen saturation level, or change direction (up and down). We validated the output test signal of the SpO_2 simulator signal to verify if the signal from the SpO_2 simulator presents any delay or different step change. Different averaging times were compared using two different sequences: automatic and manual, and step-changes. The obtained results showed that the fastest response was given by Masimo Root with Radical 7 for automatic, manual sequences, and step-changes. Output signal of the SpO_2 simulator has not presented any delays.

Key words

Pulse oximeter, averaging time, *SpO_2* step-change.

ABSTRAKTNÍ

Název práce: Analýza odezvy pulzních oxymetrů na skokovou změnu sytosti v závislosti na nastaveném průměrném čase.

Hlavním principem průměrování signálu je, že každá zobrazená hodnota je průměrná hodnota za dané období. Tato bakalářská práce si klade za cíl analyzovat a porovnat různé metody průměrování jednoho lékařského pulzního oxymetru (Masimo Root s Radical 7) a dvou monitorů vitálních funkcí (Carescape B650 a Datex Ohmeda S/5) pomocí SpO_2 simulátoru (Fluke Biomedical ProSim8) stimulací koncentrace kyslíku a různých skokových změn. Navrhli a provedli jsme laboratorní experiment pomocí simulátoru SpO_2, abychom analyzovali odezvu zmíněných zařízení na různé skokové změny, které se lišily velikostí, počáteční úrovní nasycení kyslíkem nebo změnou směru (nahoru a dolů). Ověřili jsme výstupní testovací signál simulátoru SpO_2, abychom ověřili, zda signál ze simulátoru SpO_2 vykazuje nějaké zpoždění nebo jinou skokovou změnu. Různé doby průměrování byly porovnány pomocí dvou různých sekvencí: automatické, manuální a skokové změny. Získané výsledky ukázaly, že nejrychlejší odezva byla dána Masimo Root s Radical 7 pro automatické, manuální sekvence a krokové změny. Výstupní signál simulátoru SpO_2 nepředstavuje žádné zpoždění.

Klíčová slova

Pulzní oxymetr, doba průměrování, kroková změna *SpO_2*.

Table of Contents

List of symbols and abbreviations

List of symbols

Symbol	Unit	Importance
SpO_2	%	Oxygen saturation
T	sec	Time constant
PR	bpm	Pulse rate
SpCO	ppm	Carbon monoxide levels

List of abbreviations

Abbreviation	Importance
IR	Infrared light
RRa	Acoustic Respiration Rate
pVI	Pulmonary vein isolation
DeoxyHB	Deoxyhemoglobin
MetHB	Methemoglobin
COHb	Carboxyhemoglobin
HbO2	Oxyhemoglobin

1 Introduction

Nowadays, there are different ways to measure the amount of oxygen in the blood, such as arterial blood gas test (ABG), pulse oximetry, near-infrared spectroscopy, transcutaneous measurement of blood gases, etc. The hindrance is that some of these methods are invasive for the human body to deal with daily, less accurate, and have a slower response. For a blood gas test, a sample of blood is taken from an artery, generally in the wrist. This procedure is accurate, nevertheless, it can be considered invasive and painful for the patient [1]. On the other hand, pulse oximeters are non-invasive devices. They measure the blood oxygen saturation levels and heart rate as well as allow continuous monitoring of oxygenation as opposed to a blood gas test. The normal levels of SpO_2 (peripheral oxygen saturation) in the blood are between 94–100% in a healthy person [1]. The importance of oxygen in the blood is vital to human life; When there are not enough oxygen levels in the human body (Hypoxemia), the main body parts such as the heart, lungs, or brain, might go into organ failure, or when the oxygen levels are too high (Hyperoxemia), the body can be unprotected to pulmonary and ocular toxicity [1]. Oxygen saturation refers to the available hemoglobin that carries oxygen throughout the human body. There are different types of hemoglobin, i.e. oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin, and methemoglobin. Where oxyhemoglobin carries oxygen through the body (oxygen-loaded) and deoxyhemoglobin occurs after the release of oxygen. The saturation of hemoglobin is described in equation 1.1,

$$SpO_2 = \frac{HbO_2}{DeoxyHB + HbO_2 + MetHB + COHb} * 100\%, \qquad (1.1)$$

Where HbO_2 is oxyhemoglobin, DeoxyHB stands for deoxyhemoglobin, MetHB stands for methemoglobin, and COHb is carboxyhemoglobin.

Nonetheless, a traditional pulse oximeter cannot detect methemoglobin or carboxyhemoglobin [2]. A pulse co-oximeter, a system that reads various levels of hemoglobin in the blood, is the best way to test these forms of hemoglobin in a noninvasive way [3]. However, pulse oximeters can detect more types of hemoglobin by working with multiple wavelengths of radiation.

The main setup of a basic pulse oximeter consists of a light source and a light detector. These devices transmit two forms of light, one red light (660 nm) and infrared light (940 nm), from a diode, then, this light is absorbed by a photodiode located in the light detector. This principle is mostly given by a fingertip. Oxygenated and deoxygenated hemoglobin absorbs light differently. Oxyhemoglobin absorbs more IR (Infrared light) because it is full of oxygen, it has a reddish color and it is brighter to the eye [4]. Whereas deoxyhemoglobin absorbs more red light than infrared light.

The accuracy of the pulse oximeters could be affected by different artifacts such as motion artifact i.e. involuntary patient motion or relaxation of the muscle, external light, nail polish, position of the finger during the measurement, low signal, perfusions, etc. Different methods have been discovered throughout the years to remove artifacts and minimize subsequent alarms, such as Fast Fourier Transformation (FFT), Wigner-Wille distribution, or averaging, which can be influenced by the user himself by setting the device. The averaging time is setting depending on the specific artifact or need of the patient, for example, to reduce noise artifacts, it is possible to use a longer averaging time, make sure that the patient is in a steady position, as well as, prevent external light near the sensor.

The most recommendable position to measure oxygen saturation levels is that the person is in a firm position without any external movement affecting the measurement. However, this is not always the case, especially with infants. Therefore, one of the most important questions is how the movement could significantly affect the measurement? It has been proven that pulse oximeters do not show a reliable result in the presence of external movement, causing missed alarms, false or missed transient desaturation, or a misread signal, as well as erratic signal. The pulse oximeter will work properly only if it's able to detect a modulation in transmitted light [5]. Figure 1.1 shows the effect of artifacts on the course of the SpO_2 signal.

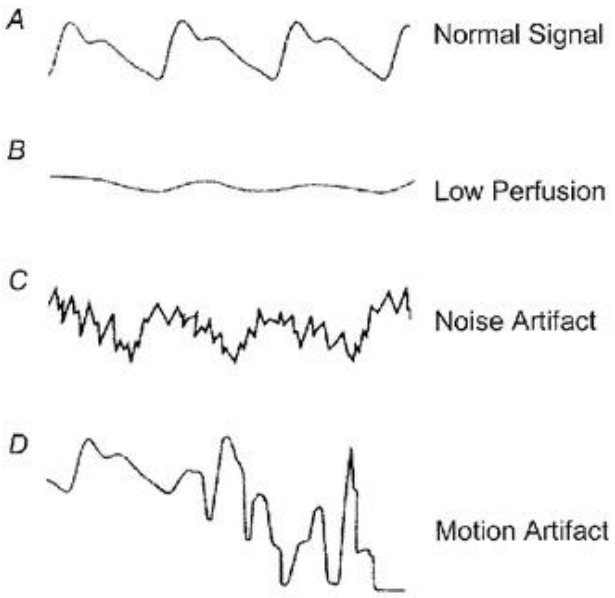

Figure 1.1 Signal Artifacts in Pulse Oximeters. Taken from [5].

During these extraordinary times, it has been proven that COVID-19 can cause silent hypoxemia [6]. A study based in Boston University, USA, showed that many infected individuals with COVID-19 have no signs of lightheadedness or trouble breathing, considering extremely low oxygen concentration, which is acknowledged as hypoxemia, however, this condition can be extremely dangerous in most cases, henceforth, it was vital for the medical researchers and personnel to discover the causes how to monitor and prevent this condition, Biomedical researchers from Boston University, after a few modeling experiments, revealed that the hypoxia was given by a combination of biological mechanisms in the lungs [6]. The importance of pulse oximeters during these times has been shown, hence it helps doctors and nurses to recognize low levels of oxygen <92%, alarming medical personnel of oxygen changes in the blood of patients with COVID-19. In addition, pulse oximeters have been an incredible tool for home-monitoring of patients with or without COVID-19, due to their affordable price, high accuracy when using correctly, alarms, and continuous monitoring of oxygen levels in the blood. [6] this one of the main reasons this experiment has relevance in the present, in order to compare different averaging methods of one medical pulse and the vital signs monitors in different oxygen concentrations, in this way it would be better known and understood which of these devices used in patients would be the best for them and their recovery.

2 Overview of the current state of the art

Different clinical research has been accomplished throughout the years, where, for example, Masimo's clinical research data states that most of the artifacts are given involuntary and/or by random movements of the patient, and they usually last around 30 sec [7]. The other percentage is given by children, if they cannot stay still during the measurement of the oxygen saturation in the blood or they do not want to use the equipment correctly, etc. The removal of artifacts is the key to the medical practice nowadays, thus, artifacts could cause a false alarm or a missed alarm, where before-mentioned could bring severe consequences to the clinical practice. The idea of finding out how averaging affects the measured signal is crucial to this bachelor thesis, at the same time, it is important to know that the display of artifacts and frequency is affected by the averaging setting, considering the common averaging time in clinical practice.

2.1 What is averaging and when do we use it

The main principle of signal averaging is that each displayed value is the average value for the last (2, 8, 16 sec, etc.). The most common averaging time in clinical practice is between 8 seconds and 15 seconds and it is the default value for most pulse oximeters [7]. There are different problems with a long time averaging for the reason that, it changes in the SpO_2 saturation and it could not be detected, such as rapid hypoxemia or hyperoxemia, and the signal is not comprehensible in most cases, thus, can directly affect and influence the diagnosis of the patient. [7]. On the other hand, with a short averaging, the full picture of the SpO_2 signal was demonstrated such as peaks of oxygen saturation during a specific period. However, different problems were faced such as false alarms caused by the different types of artifacts, such as movement, low perfusion, noise, etc. Manufacturers around the world do not suggest an averaging time higher than 16 seconds, thus, with a long time-averaging, the oximeters tend to underestimate brief desaturation lasting [8]. On one side it is important to know that there is not a "recommended averaging signal" because it depends on clinical application. In this way, longer averaging times are usually recommended when there is long-term monitoring of a stable patient for example. On the other side, shorter averaging times are usually recommended for patients with frequent desaturations. Desaturation can happen at any time throughout the day in adults due to a variety of pathological conditions, however, the case is different in children, they

usually occur when they are asleep hence, they have immature lungs. In a study realized by Michael T. Peterson on an infant with sleep apnea, it had been proven that almost all the transient desaturations were detected using a 2–4sec averaging time, whereas it was almost impossible to read the signal using a 16 sec averaging [4]. Figure 2.1 shows saturation vs. time within different averaging times.

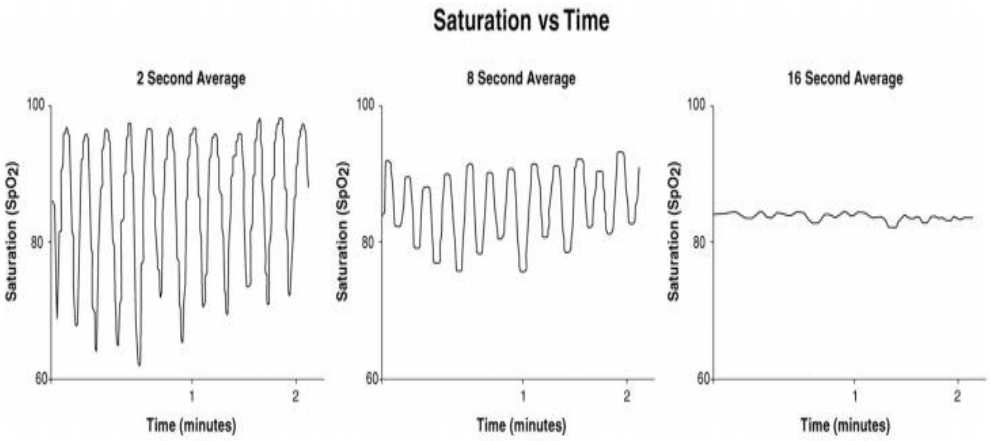

Figure 2.1. Saturation vs. Time within different averaging times. Taken from [7].

2.2 How manufacturers deal with averaging

Masimo Root with Radical 7 pulse oximeter, has an adjustable averaging of 2–4 sec up to 16 sec. The Carescape B650 patient monitor (GE Healthcare, Little Chalfont, UK), have the following range of averaging times: 2 sec, 4 sec, 8 sec, 10 sec, 12 sec, 14 sec, and 16 sec [8] This gives medical staff a wider range of averaging times to choose from, depending on the patient's needs, and according to their user manual, the normal response mode to alarms is 6 to 7 sec for Carescape B650 patient monitor [8].

As it has been discussed before that long-time averaging could lead the medical personnel to miss alarms, being lethal to the patient's health. [6] Masimo's oximeters use a technology that can read through motion, being the most common "Discrete saturation transform", as well as different signals processing, and the after-mentioned algorithm can identify the arterial signal that occurs during motion [3]. Thus, making the device more reliable. However, this case is not the same once we talk about Datex Ohmeda S/5 (Datex – Ohmeda, Inc, Madison, USA), hence these devices are based on a "Variable Cardiac Gated Averaging" algorithm, it tends to attenuate signals that did not occur, and it can

mislead some other signals such as the heart rate waveform [9]. However, it is not completely clear which algorithm they use for specific devices. The

following figure 2.2 shows how averaging time impacts alarms.

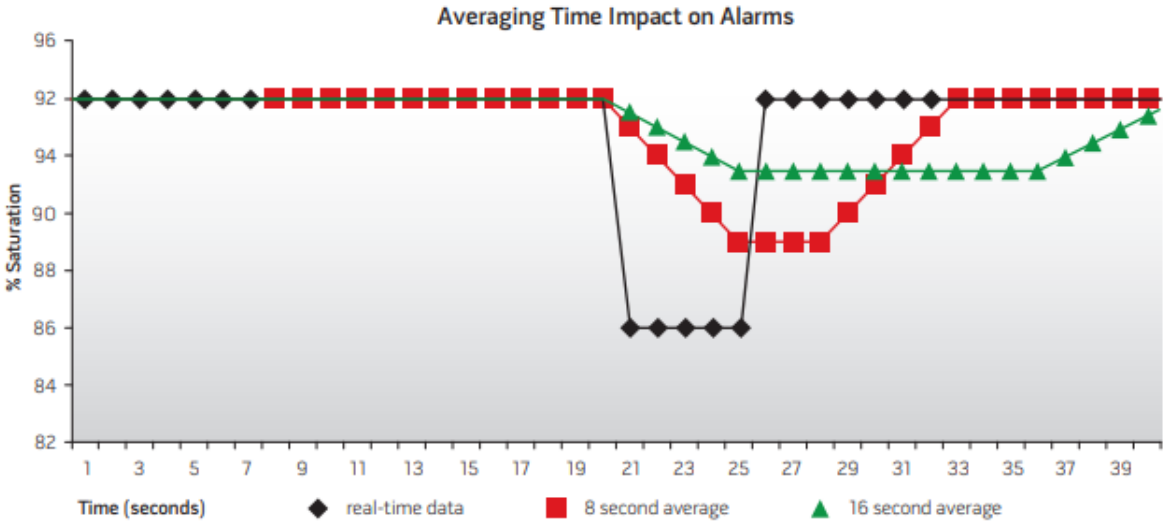

Figure 2.2. Averaging Time Impact on Alarms. Taken from [10].

3 Aims

This bachelor thesis aims to analyze the response of pulse oximeters and vital signs monitor to changes in peripheral oxygen saturation concerning set averaging times of the pulse oximeters. The devices used for this experiment are Masimo Root with Radical 7, Datex Ohmeda S/5, Carescape B650, and Fluke Biomedical ProSim8.

The thesis will be divided into two sections: Sequences and signal validation. 3 different sequences will be implemented: automatic sequences, which is a special function of the Fluke Biomedical ProSim8, manual sequences, where the steps of the signal will be changed manually, and step-changes, which will vary in magnitude, initial oxygen level, and direction. For these sequences, the response of the mentioned devices will be analyzed to different step changes, at different SpO_2 levels and directions (Up and down). For signal validation of the Biomedical ProSim8, the aim is to validate the output test signal of the device and verify if the signal presents any delays or different step changes.

4 Methods

The laboratory experiment was designed and conducted using a SpO_2 simulator. This is to analyze the response of the medical pulse oximeter Masimo Root with Radical 7, vital signs monitor Datex Ohmeda S/5, and Carescape B650 life signs monitor.

The response of the pulse oximeters was analyzed depending on the set averaging time. Three parts of the experiment were performed for this analysis: automatic, manual sequences, and step-changes. For automatic sequences, which is a special function of the SpO_2 simulator, we compared different SpO_2 saturation in different directions and levels. With manual sequences, we adjusted the SpO_2 saturation manually for each step change. For step-changes, we proceeded to simulate different oxygen saturations that differed in magnitude, the initial level of oxygen, and the direction of the change.

The output signal of the SpO_2 simulator was validated. The validation of the signal was performed using a specific sensor USB400 (Ocean Insight, USA), software designed for the recording of the signal OceanView (Ocean Insight, USA), a screen recorder (Bandicam, 5.1.1), and Masimo pulse oximeter. Ocean USB400 measured the spectrum of the light of each wavelength which allowed us to measure the answer on the probe of the simulator. The signal intensity varied according to the finger setting, we worked with 2 intensities: dark, thick finger vs. medium finger.

Furthermore, we used various averaging times in the development of this experiment, for automatic sequences, manual sequences, and step-changes, where for Masimo Root with Radical 7, we used 2–4 sec, 8 sec, and 16-sec averaging times, whereas, with Carescape B650 vital signs monitor, we used 2 sec, 8 sec, and 16-sec averaging times. We set three different average times for the Datex Ohmeda S/5 monitor: beat to beat, normal (10 sec), and slow (20 sec).

The following chapters provide specific information about the devices used in this experiment, as well as detailed information on the experimental setup and results of the experiment.

4.1 Devices used for the experiment

Masimo Root with Radical 7 was the first device, it was used to measure automatic and manual sequences, as well as step-changes. The second section of signal validation goes through the two, vital signs monitors used in the project: Datex Ohmeda S/5 vital signs monitor for automatic and manual sequences, as well as the Carescape B650 for step-changes. The Fluke Biomedical ProSim8 vital signs simulator was the last device used in this bachelor thesis, and it was used to simulate the *SpO2* signal during the experiment.

4.1.1 Masimo Root with Radical 7

Masimo Root with Radical 7 (Masimo Corporation, USA) is a pulse oximeter that is widely used nowadays in hospitals, clinics, and homes throughout the world. The use of this device is intended for adults, infants, and neonates. It can monitor different physiological parameters such as pulse rate, oxygen saturation, perfusion index, and pleth variability index, total hemoglobin concentration, methemoglobin, and carboxyhemoglobin. It also can transmit data for supplemental remote viewing and alarming, i.e. to a central nurse's station [11].

Masimo Root with Radical 7 has a 3D anatomical view of possible alarms [11], meaning that it can show the different states of the alarm when there is no alarm when the alarm is approaching and the alarm state when it is occurring. The device contains different features such as root display, home button, root charging indicator, AC power indicator, speakers, nurse-call button, USB ports, power entry module, and power button. Masimo Root with Radical 7, the accuracy of the signal is given by ± 2 digits, for adults, infants, and neonates [12]. The Masimo technology's SpO_2 sensor works based on isolating the artery signal from several sources of noise [12]. As a result, the sensor's accuracy and reliability are improved.

This device does not contain any contraindication and it possesses a wireless mode, consequently, the device will work properly in case of any emergency or internet complications.

Alarms are a vital feature for any pulse oximeter, therefore one of the main features of the Masimo Root with Radical 7, is an analog view of the signs. Every vital sign has 3 colors in a circular array around a dial, as shown in Table (4.1), this feature indicates

changes that can be interpreted easily and faster. It has an adjustable averaging of 2–4 sec up to 16 sec and Figure 4.1 shows Masimo Root with Radical 7.

Table 4.1. Meaning of each color in Masimo root with radical 7, alarms feature.

Color	Meaning	Alarm
White	Normal value	No alarm
Yellow	Changes in the value	Approaching
Red	Alarming range	ON

Figure 4.1. Masimo root with Radical 7 taken from [13].

The main screen of the device consists of different features, such as shown in Table 4.2.

Table 4.2 Features of Masimo's main screen.

Abbreviation	Meaning	Unit
SpHb	Total hemoglobin	g/dL
PR	Pulse Rate	Bpm
RRa	Acoustic Respiration Rate	Rpm
SpMET	Levels of methemoglobin	%
PI	Perfusion Index	-
SpO_2	Oxygen Saturation	%
pVI	Pulmonary vein isolation	-
SpCO	Carbon monoxide levels	%
SpOC	Spontaneous oscillatory concentration	%

4.1.2 Carescape B650 and Datex Ohmeda S/5

Datex Ohmeda S/5 (Datex Ohmeda, Inc, Madison, USA), is the first vital signs monitor used for the measurement of automatic and manual sequences. Numerous different screens are supported by the Ohmeda S/5, which also has a dedicated warning feature with automatic limitations and advanced reporting options [14]. According to the user manual for Datex Ohmeda S/5, this device works with 3 different averaging times, beat to beat, normal (10 sec), and slow (20 sec) [15]. When comparing the Masimo Root and Radical 7 alarms to the vital signs monitor alarms, all vital signs monitors have two different colors for alarms, red and yellow, where red indicates life-threatening conditions and yellow indicates severe problems [14].

Carescape B650 (GE Healthcare, Little Chalfont, UK) is the second vital signs monitor used during the development of this bachelor thesis, for the single step-changes. This device has high accuracy in detecting cardiac vascular changes, such as arrhythmias. It provides an intelligent and accurate alarm system. This monitor helps to deliver correct doses and to avoid data interruptions. It has a high reliability; thus, this device is intended for use on adults, infants, and neonates. Carescape B650 works with a data module to promote data continuity, the main values of averaging times are 2 sec, 8 sec, and 16 sec [15]. Figure 4.2 shows the setup of Carescape Monitor B650.

The key difference between these two vital signs monitors is the date of introduction to the market. The Carescape B650 was released in 2013 [15], while the Datex Ohmeda S/5 was released in 2003. [14]. Furthermore, the device's manufacturer has been sold to other firms over the years, resulting in a change of name and manufacturer. The main difference between the main functions of these two vital signs monitors is the different averaging time that it provides when measuring oxygen saturation in the blood, as has been mentioned before.

As regards these vital signs monitor, they take a different approach than Masimo in averaging times, as a result, they use three different averaging times, which can be adjustable depending on the patient’s needs. The accuracy of the signal for saturation of oxygen concentration is given by 100-80% ± 2 digits, 80-50%, ± 3 digits, and it is unspecified for lower values than the ones previously stated. [18].

Figure 4.2. Carescape B650 vital signs monitor. Taken from [17].

4.1.3 Fluke Biomedical Prosim8 vital signs monitor

ProSim8 simulator (Fluke Biomedical, USA) was vital for the realization of this experiment. It allows users to set any values and test the reaction of the device being tested. It is an all-in-one patient simulator [12]. The main features are SpO_2, pulse rate, blood pressure, and ECG.

The idea of the use of a simulator is to make the experiment more accurate and reliable, preventing human and external artifacts. In addition, there is no other method to make SpO_2 changes that are clearly defined; hence we can't simulate a step-change in SpO_2 in a volunteer. Figure 4.3 shows Fluke Biomedical ProSim8 vital signs simulator.

According to the user's manual, the accuracy of the SpO_2 saturation depends on the oxygen saturation, for 91% up to 100%, the accuracy is ± 3 counts, for 81% to 90% is ± 5 counts, and 71% to 80% % is ± 7 counts, the accuracy for signals under 71% is not specified [3].

Figure 4.3. Vital signs simulator. Taken from [16].

4.2 Experimental set-up

In the first place, we used the Biomedical ProSim8 simulator with an artificial finger to simulate the exact SpO_2 value according to the measurement protocol and connected it to the sensor of Masimo Root with Radical 7, Datex Ohmeda S/5 monitor, and Carescape B650. In figure 4.4, it is possible to see the general monitoring set-up for Masimo Pulse Oximeter with the Biomedical ProSim8 simulator, in addition, figure 4.5 shows the general monitoring set-up for Datex with the Biomedical ProSim8 simulator.

Figure 4.4. General monitoring setup for Masimo Root with Radical 7.

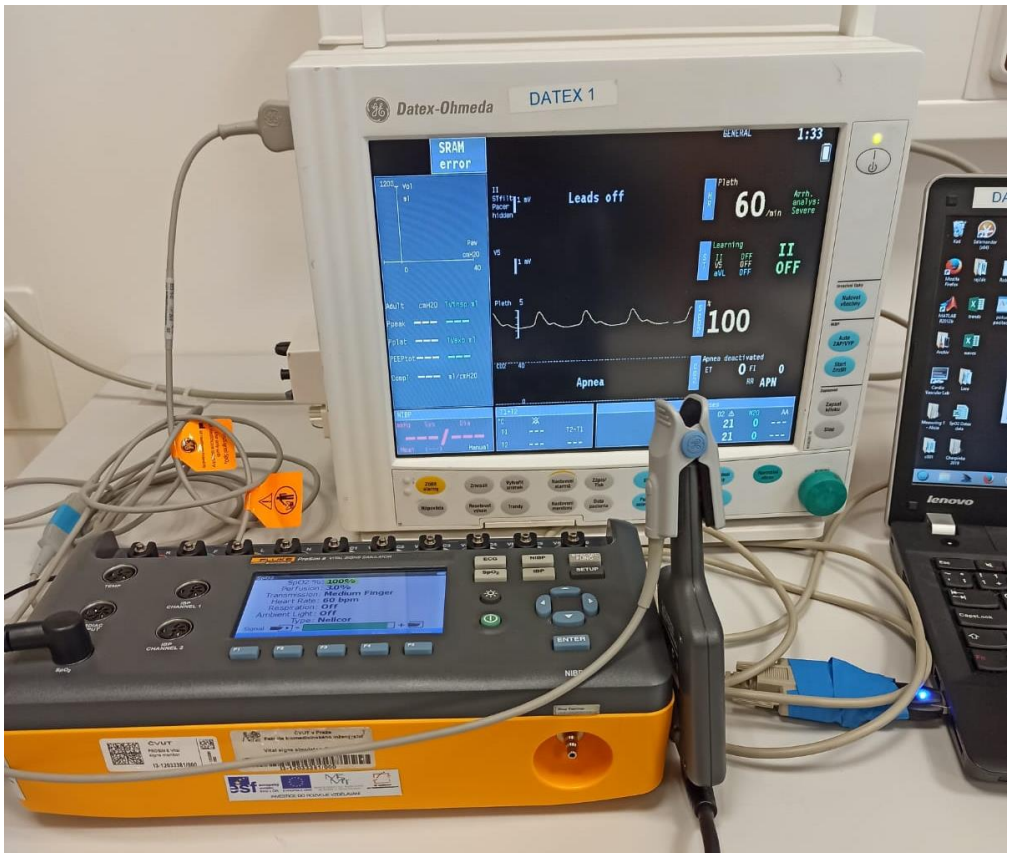

Figure 4.5. General monitoring setup for Datex Ohmeda S/5 monitor.

There were set 3 averaging times in the pulse oximeter (2–4 sec, 8 secs, and 16 sec), for Masimo pulse oximeter, and as regards Datex Ohmeda S/5 vital signs monitor, there were set 3 averaging times, beat to beat, normal (10 sec), and slow (20 sec), for both automatic and manual sequence. Where, automatic sequence had 19 steps sequences and a signal duration of 45 sec, the simulator function for testing pulse oximeter was used, and the steps down were completed automatically, and the steps up were done manually. As regards the manual sequence, it consisted of 7 steps sequences that were manually performed, having a signal duration of 45 sec each. As regards the step-changes, there were set 2 averaging times in the pulse oximeter (2–4 sec and 12 sec) for Masimo Root with Radical 7, and (2 sec and 12 sec) for Carescape B650 vital signs monitor, comparing 4 different magnitudes of simulated SpO_2, 20%, 15%, 10%, and 5%, for each averaging time.

4.3 Measurement procedure

This section of the bachelor thesis explains in detail the individual parts of the experiment, the firstly, it shows the measurement of the response of the pulse oximeters to SpO_2 change at different averaging times, which consists of automatic sequences, manual sequences, step-changes. Consequently, it describes in detail the verification of the output signal of the SpO_2 simulator

4.3.1 Automatic sequences

The automatic sequence is mostly used for the testing of the device. This special feature of the SpO_2 simulator changes the oxygen saturation in the blood from 100, 95, 90, 85, 84, 83, 82, 81, and 79%. After obtaining the descending sequence, we proceeded to implement manually the ascending sequence, obtaining a total of 19 steps sequences, and changing each step every 45 sec. This first part of the bachelor thesis was completed using both a SpO_2 simulator, Datex Ohmeda S/5 vital signs monitor, and Masimo Root with Radical 7, using an averaging time of 2–4 sec, 8 sec, and 16 sec for Masimo, and using an averaging time of B-TO-B (beat to beat changes), normal (10 sec), and, slow (20 sec) averaging time for Datex Ohmeda S/5. The simulated signal of SpO_2 for the automatic sequence is shown in the following Figure 4.6.

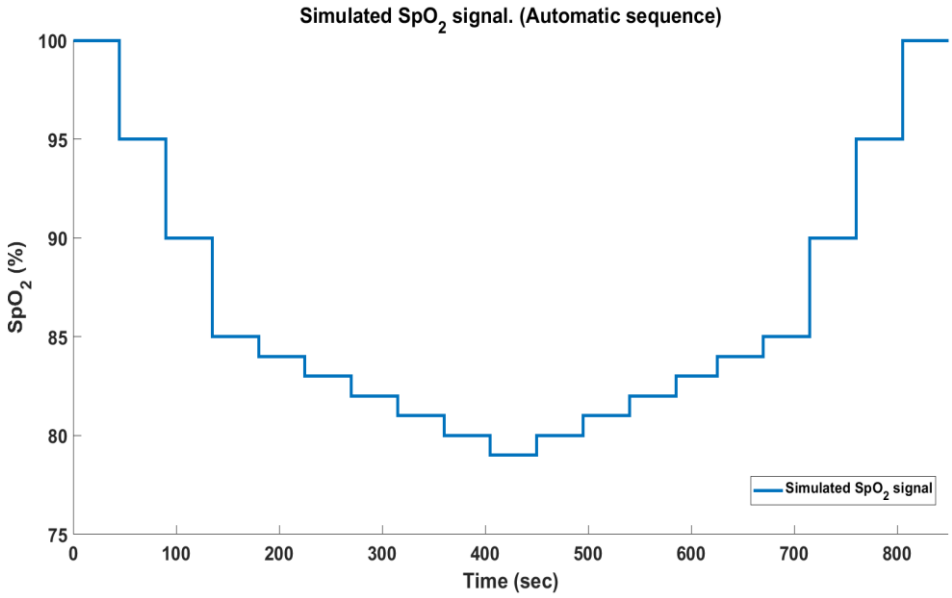

Figure 4.6. Simulated SpO_2 signal for automatic sequence

4.3.2 Manual sequences

As respects manual sequences, the oxygen saturation was changed using 7 different steps, 100, 98, 95, 91, 95, 98, and 100 (%), these steps sequences were given every 45 sec, for both, Datex Ohmeda S/5 and Masimo Root with Radical 7, using an averaging time of 2–4 sec, 8 sec, and 16 sec for Masimo and, using an averaging time of B-TO-B (beat to beat changes), normal (10 sec), and, slow (20 sec) averaging time for Datex Ohmeda S/5. The simulated signal of SpO_2 for the manual sequence is shown in the following figure 4.7.

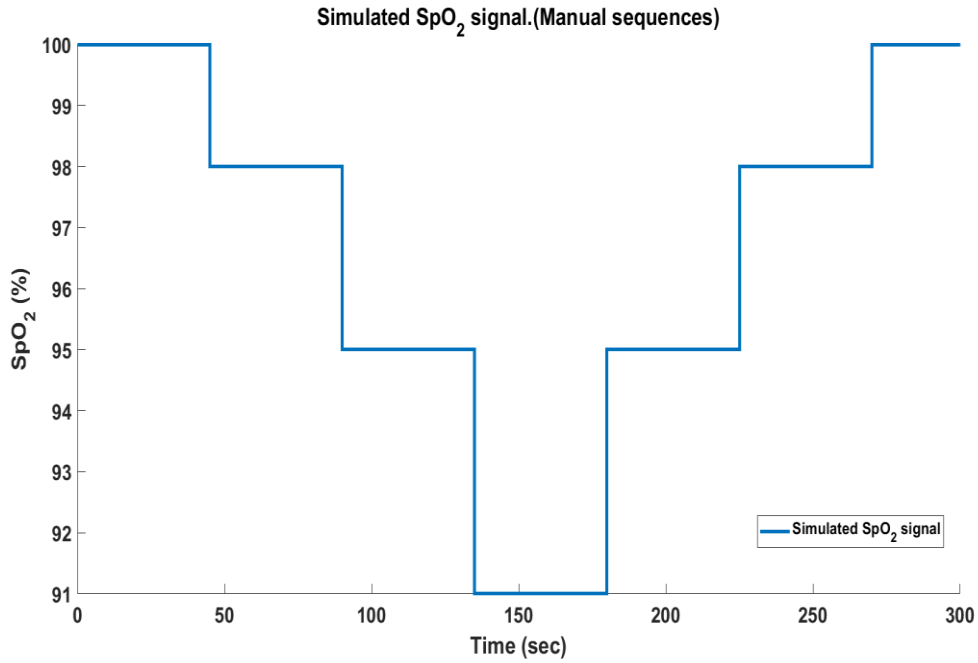

Figure 4.7. Simulated SpO_2 signal for manual sequences.

4.3.3 Step–changes

Regarding step-changes, we developed a way to compare 4 different step changes of SpO_2, these were given every 20%, 15%, 10%, and 5%, and each step had a duration of 60 sec. The goal was to see whether the pulse oximeter response would be the same or different for the same step changes from different initial saturation values and in different directions (up/down). For each step-change, we set two different averaging times (2 sec and 12 sec). Table 4.3. shows the initial saturation values and the combinations performed during the step-changes. Figure 4.8 shows a step-changes of 20% difference

Table 4.3. Initial saturation values and the combinations performed during the step-changes.

SpO_2 difference	Saturation values
20%	100 – 80 – 60 – 80 – 100 (%).
20%	90 – 70 – 90 (%).
15%	100 – 85 – 70 – 85 – 100 (%).
15%	95 – 80 – 95 (%).
15%	90 – 75 – 90 (%).
10%	100 – 90 – 80 – 70 – 80 – 90 – 100 (%).
10%	95 – 85 – 75 – 85 – 95 (%).
5%	100 – 95 – 90 – 85 – 80 – 85 – 90 – 95 – 100 (%)

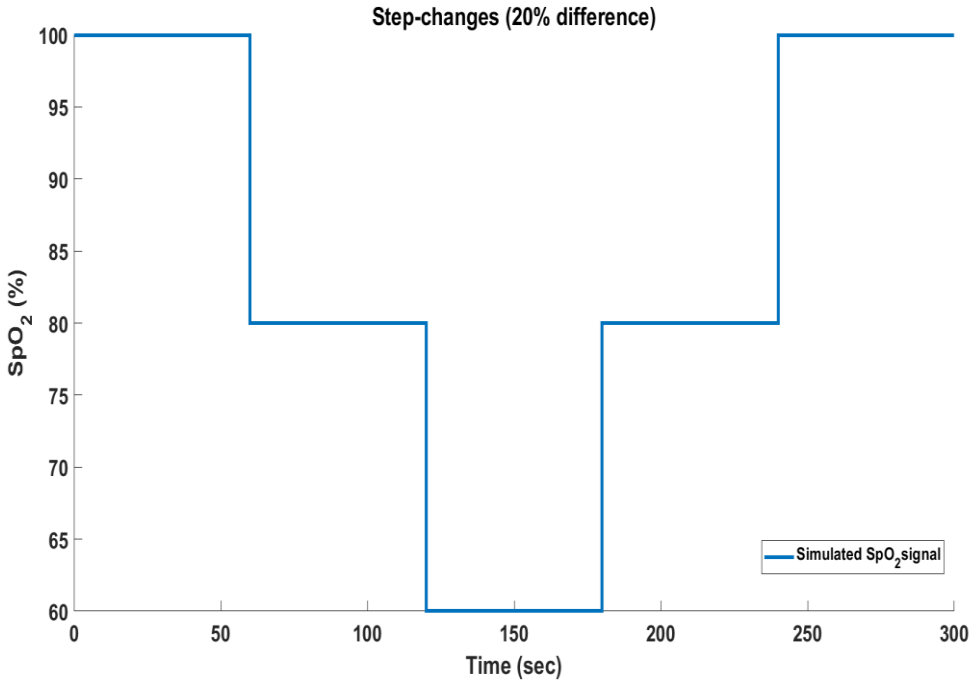

Figure 4.8. 20% difference step-changes.

4.3.4 Signal validation

The last part of this project consisted in the validation of the signal from the SpO_2 simulator (Biomedical ProSim8 simulator), this was given by the software OceanView (Ocean Insight, USA), a specific probe USB400 (Ocean Insight, USA), and a screen recording program (Bandicam, USA). In addition, a video was made in which the computer screen can be seen simultaneously, along with a simulator in which we changed the settings. The main principle of this part of the project was to show how quickly the simulator reacts to a step-change if it shows any delay or different change when changing the oxygen saturation.

To test the SpO_2 simulator's output signal, the device was inserted into the sensor of Masimo Root with Radical 7 pulse oximeter, the sensor USB400 from Ocean Insights, and the artificial finger of the SpO_2 simulator. We set two transmissions of light in the SpO_2 simulator: “Dark, thick finger”, and “Medium finger”, where the program OceanView displayed the change between each transmission, and the screen recording program allowed us to see how quickly the change between each transmission was. Each change between dark, thick finger and medium finger was performed twice.

This second part of the bachelor thesis had to be completed in a dark environment, to assure that no external artifacts would affect the signal. The probe of the signal validation is shown in figure 4.9

Figure 4.9. The probe of the sensor USB400.

4.4 Methods for data analysis

Methods for data analysis are divided into 3 steps. The first step for data analysis was to implement a MATLAB (The MathWorks, USA, 2020) script for automatic and manual sequences. Firstly, the code processes the *.xlsx document from the measured data by Masimo Root with Radical 7 and Datex Ohmeda S/5 vital signs monitor in MATLAB and excludes the N/A (not available) values that were found during the experiment. The code is written in a way to emit these values; therefore, the user can see the whole waveform for the respective averaging time. Subsequently, after omitting all the N/A values, we created different plots which contain: One simulated signal and three measured SpO_2 saturation depending on the set averaging time and the device, separated from each other by different colors.

Masimo Root with Radical 7 pulse oximeter, has an internal memory from which the data is transferred to a computer using a USB cable and software MICT (Masimo Instruments Configuration Tool, Masimo Corporation, USA) which records the signal from different parameters, heart rate, pulse rate, oxygen saturation, etc. MICT can be easily downloaded into any computer by installing the program on a computer [19]. This program records the signal into a *.csv file every 2 seconds. Datex Ohmeda S/5 records signal every 1 second. [20]. It uses a special program Datex – Ohmeda S/5 Collect online (Datex Ohmeda, Inc, Madison, USA), where the computer and the vital signs monitor are connected via the RS-232 – USB interface, thus the files can be saved into an ASCII file

The second step for data analysis was to write a MATLAB code to plot the different step-changes from Masimo Root with Radical 7 and Carescape B650 vital signs monitor, this data was saved into a *.xlsx document and written in the code, to visualize 4 different lines: Simulated signal, moving average, measured signal by Masimo Root with Radical 7, and Carescape B650 vital signs monitor, for two different averaging times (2–4 sec, and 12 sec).

The ideal simulated signal was used to calculate the moving average according to the set averaging time, using the obtained results from Masimo and Datex pulse oximeters, where, the result is a signal that we would expect as ideal measured by pulse oximeters. To which the moving average function in MATLAB will be applied with a window length equal to the averaging time, by which the average was calculated from the last point of the window.

According to the set averaging time, we can assume that each calculated SpO_2 value corresponds to the average SpO_2 simulated in the last 2–4 sec and 12 sec. The main task is to create different graphs that will display the simulated SpO_2 value, the measured for one averaging time, and a curve that is the product of applying the moving average function to the simulated signal with the length of the window corresponding to the chosen averaging time. We proceeded to compare the ideal measured signal (simulated signal after moving mean filtration) with the measured signal for a given averaging (Measured values by pulse oximeter without any filtration) using the obtained graphs. As regards the value for the different windows, we used 2–4 sec, and 12 sec, respectively, to respect the set averaging from the pulse oximeter. In addition, it is important to remark that the moving average is calculated for the last sample of the window. To compare the ideal measured signal with the measured signal for a given averaging, we proceeded to use the function '*movmean'* in MATLAB. The used codes can be found in Appendix B. Where we sampled the simulated signal after 1 sec and the length of the window corresponding to the averaging time. For example, 2-sec averaging time, window length will be 2 samples. Appendix A contains the MATLAB script for automatic sequences and Appendix B contains the code findings for manual sequences.

4.5 Calculations of parameters

This subchapter contains information regarding the calculations performed during this bachelor thesis, which were, the measured delay by which the pulse oximeter/vital signs monitor measures the simulated value after the SpO_2 change, delay by which the pulse oximeter began to respond to the SpO_2 on the simulator, and the rate of change. These calculations were performed for automatic sequences, manual sequences, and step-changes. Each one of the following subchapters (4.5.1, 4.5.2, and 4.5.3) contains detailed information regarding the mathematical equations, as well as, an example of each calculation.

4.5.1 Measured delay by which the pulse oximeter/vital signs monitor measures the simulated value after the SpO_2 change

The first calculation was the delay after the SpO_2 change for each SpO_2 waveform (depending on the set averaging time) to the simulated signal, for both automatic and manual sequence. For this measurement, we applied equation 4.1. to measure the delay by which the pulse oximeter measures the simulated value after the SpO_2 change.

$$Delay = Time\ Measured - Time\ simulated, \tag{4.1}$$

Where time measured is measured by the pulse oximeter/vital signs monitor for a specific averaging time and time simulated is the simulated SpO_2 signal. Figure 4.10 shows an example of the calculation for the time delay between a simulated signal and a measured SpO_2 signal with averaging time set to 2 s.

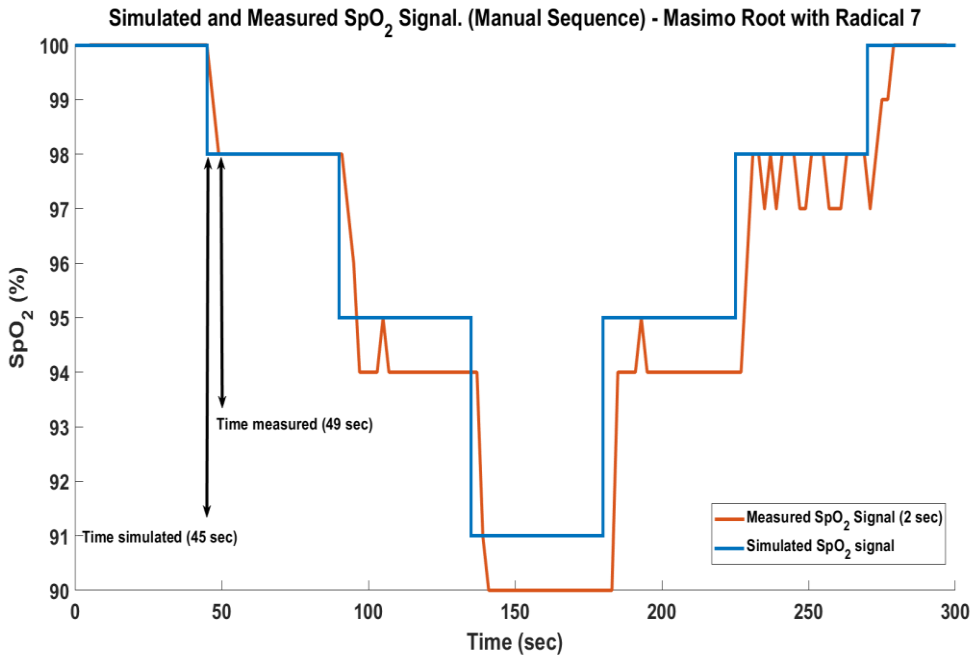

Figure 4.10 Delay for one-step sequence of manual sequence.

4.5.2 Delay by which the pulse oximeter/vital signs monitor began to respond to the SpO_2 on the simulator

We used equation 4.2 to calculate the delay by which the pulse oximeter began to respond to the SpO_2 change on the simulator. This parameter was measured for all three devices, Masimo Root with Radical 7, Carescape B650, and Datex Ohmeda S/5. Figure **4.11** shows an example of how to calculate the delay by which the pulse oximeter/ vital signs monitor began to respond to the SpO_2 change on the simulator,

$$Delay = Measured\ time - Time\ simulated \quad (4.2)$$

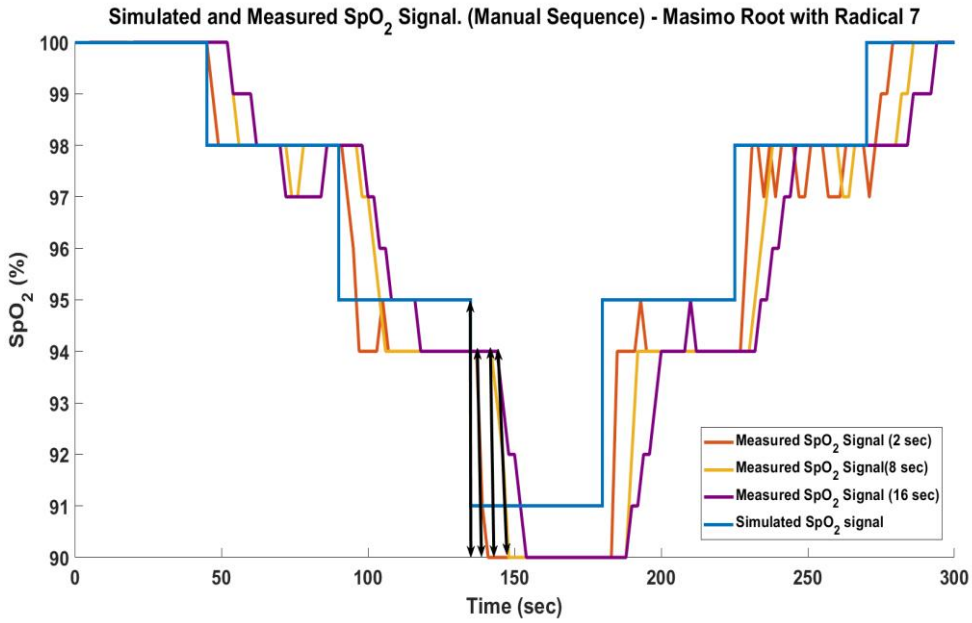

Figure 4.11 Delay by which the pulse oximeter began to respond to the SpO_2 change on the simulator.

Order of the SpO_2 change from left to right

↓Time of simulated SpO_2 signal

↓Time of the pulse oximeter reaction for 2 sec averaging time

↓ Time of the pulse oximeter reaction for 8 sec averaging time

↓ Time of the pulse oximeter reaction for 16 sec averaging time

4.5.3 Rate by which the pulse oximeter/vital signs monitor changes the SpO_2 during one step

The next calculation in this project was the rate by which the pulse oximeter changes the SpO_2 during one step. Figure 4.12 shows the explanation of this calculation and equation 4.3 shows the rate of change

$$Rate\ of\ change = \frac{SpO_2 0 - SpO_2 1}{T1 - T0}, \qquad (4.3)$$

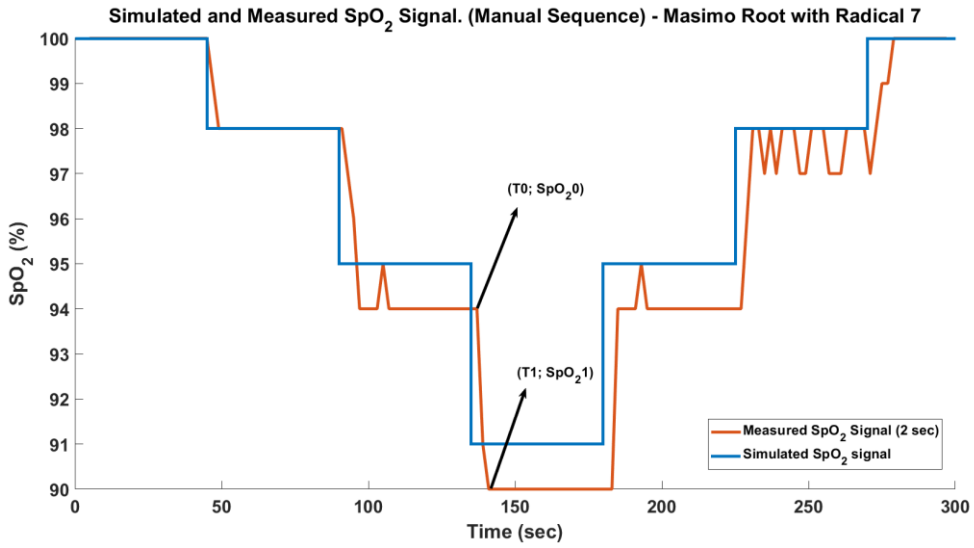

Figure 4.12. Rate of change by which the pulse oximeter changes the SpO_2 during one step of manual sequence between 2 sec averaging time and simulated signal.

4.5.4 Evaluation of parameters

To gain a better understanding of the signal, it was computed the average for all the parameters. Different averages were calculated for the measured delay by which the pulse oximeter/vital signs monitor measures the simulated value after the SpO_2 change for automatic sequence, delay by which the pulse oximeter/vital signs monitor began to respond to the SpO_2 on the simulator and the rate by which the pulse oximeter/vital signs monitor changes the SpO_2 during one step, for automatic sequences, manual sequences and step-changes for different averaging times.

5 Results

This section contains graphs and tables of the obtained results using Masimo Root with Radical 7, Datex Ohmeda monitor, and Carescape B650. Results show how averaging affects the reading of the simulated signal and the specific calculations of parameters for each task. The performed calculations include the delay by which the pulse oximeter measures the simulated values after the SpO_2 changes, the delay by which the pulse oximeter began to respond to the SpO_2 change in the simulator, and the rate by which the pulse oximeter changes the SpO_2 during one step. To have a better understanding of the signal, the average for all steps of this experiment was calculated using different averaging times. This section of the bachelor thesis will be separated into 4 parts, results for automatic sequences, manual sequences, step-changes, and signal validation.

5.1 Results for automatic sequences

This subchapter contains detailed information regarding the signal responses for automatic sequences, comparing 2 different devices Masimo Root with Radical 7 and Datex Ohmeda S/5) and their different averaging times. Figure 5.1 shows an automatic sequence for Masimo Root with Radical 7, showing one simulated SpO_2 signal and three SpO_2 signals for three different averaging times 2–4 sec, 8 sec, and 16 sec. Figure 5.2. Shows an automatic sequence for Datex Ohmeda S/5, showing one simulated SpO_2 signal, and three different averaging times beat to beat, normal (10 sec), and slow (20 sec).

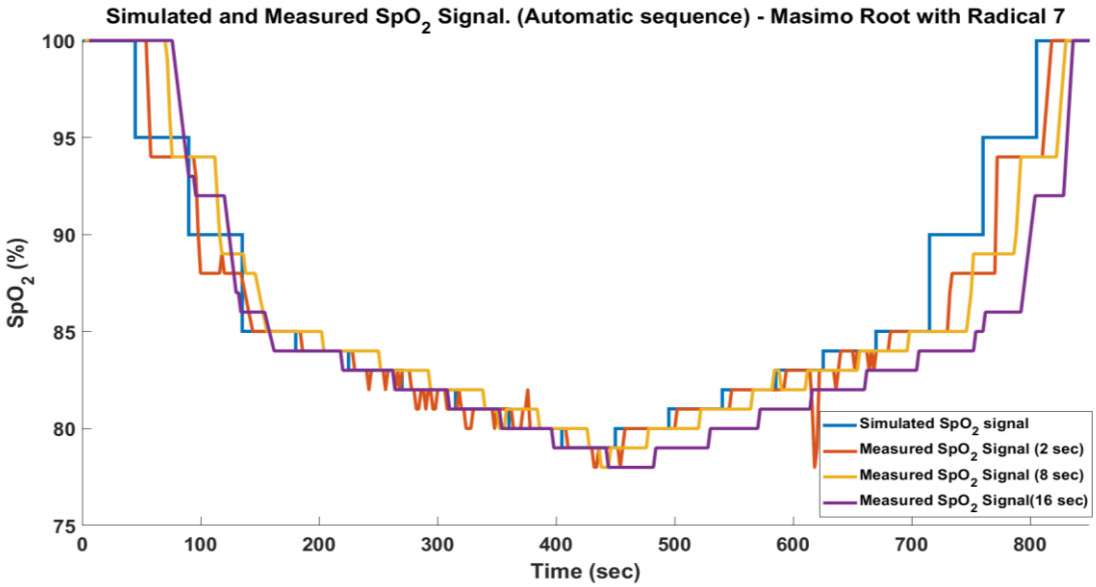

Figure 5.1. Results for simulated and measured *SpO2* signal (Automatic sequence) – Masimo.

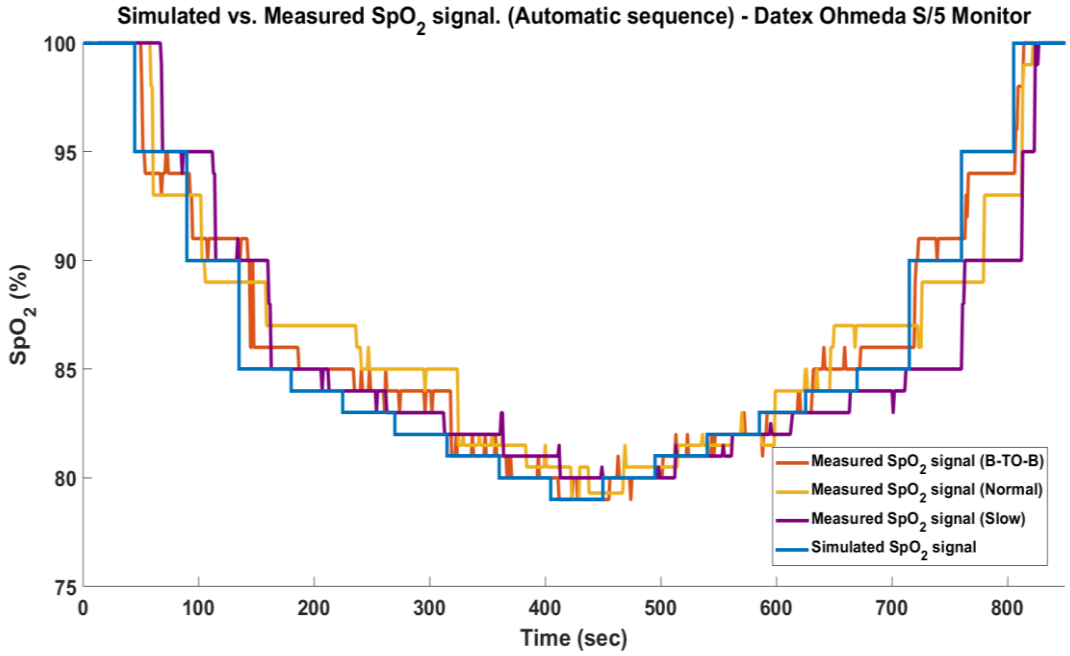

Figure 5.2. Results for simulated and measured *SpO2* signal (Automatic sequence) – Datex Ohmeda S/5.

Table 5.1. Measured delay by which the pulse oximeter measures the simulated value after the SpO_2 change for automatic sequence.

19 steps (Averaging time)	Masimo Root with Radical 7 (Mean average)	19 steps (Averaging time)	Datex Ohmeda S/5 (Mean average)
2–4 sec	7 sec	Beat to beat	9 sec
8 sec	16 sec	Normal (10 sec)	25 sec
16 sec	23 sec	Slow (20 sec)	31 sec

Table 5.2. Delay by which the pulse oximeter began to respond to SpO_2 change in the simulator for automatic sequence.

19 steps (Averaging time)	Masimo Root with Radical 7 (Mean average)	19 steps (Averaging time)	Datex Ohmeda S/5 (Mean average)
2–4 sec	7 sec	Beat to beat	9 sec
8 sec	16 sec	Normal (10 sec)	31 sec
16 sec	24 sec	Slow (20 sec)	38 sec

Table 5.3. Rate by which the pulse oximeter/vital signs monitor changes the SpO_2 during one step.

19 steps (Averaging time)	Masimo Root with Radical 7 (Mean average)	19 steps (Averaging time)	Datex Ohmeda S/5 (Mean average)
2–4 sec	0.4 %/s	Beat to beat	0.5 %/s
8 sec	0.2 %/s	Normal (10 sec)	0.4 %/s
16 sec	0.1 %/s	Slow (20 sec)	0.1 %/s

5.2 Results for manual sequences

As respects manual sequences, the oxygen saturation was changed using 7 different steps, 100, 98, 95, 91, 95, 98, and 100 (%), these steps sequences were given every 45 sec, for both, Datex Ohmeda S/5 and Masimo Root with Radical 7, using an averaging time of 2–4 sec, 8 sec, and 16 sec for Masimo and, using an averaging time of B-TO-B (beat to beat changes), normal (10 sec), and, slow (20 sec) averaging time for Datex Ohmeda S/5. Figures 5.3 and 5.4 show the results for the simulated and measured signal SpO_2 signal for Masimo Root with Radical 7 and Datex Ohmeda S/5.

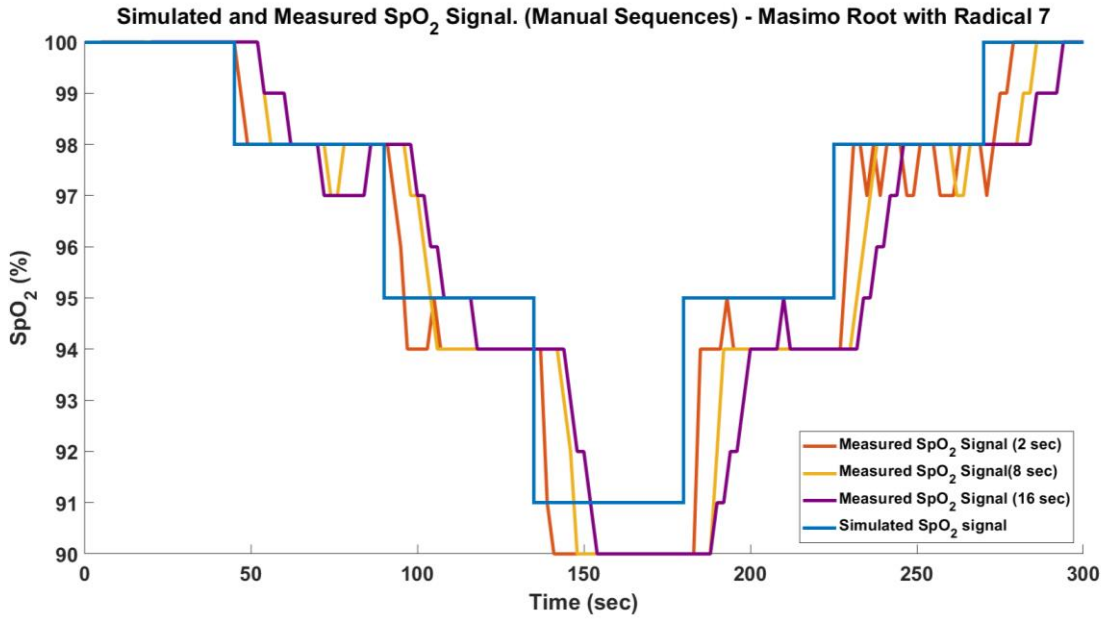

Figure 5.3. Results for simulated and measured *SpO2* signal (Manual sequences) – Masimo.

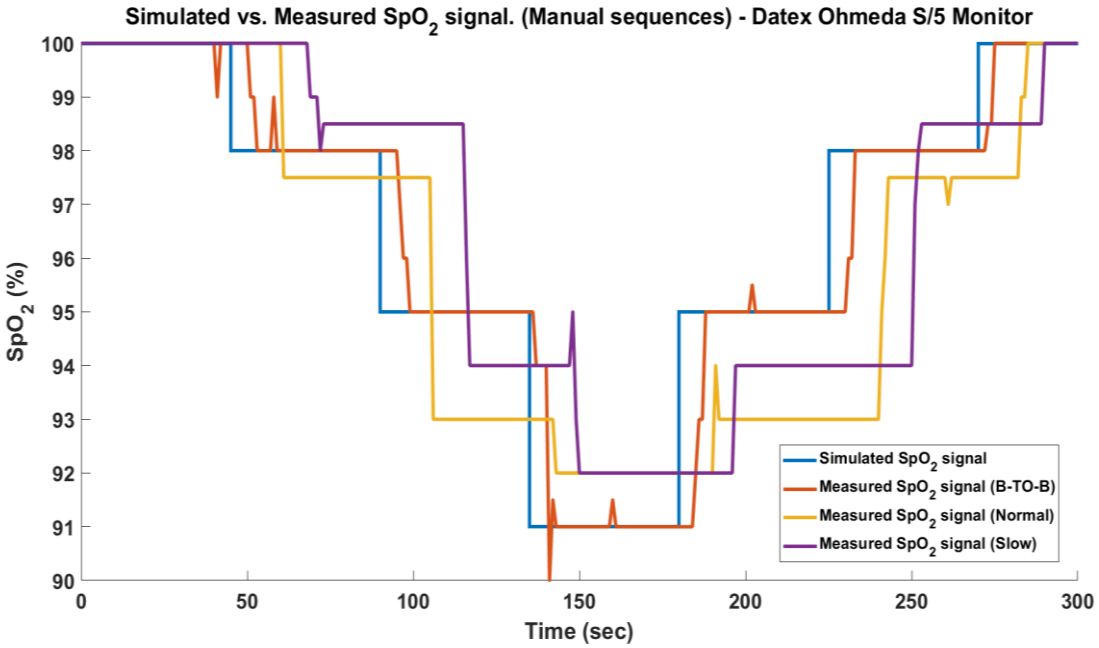

Figure 5.4. Results for simulated and measured *SpO2* signal (Manual sequences) – Datex Ohmeda S/5.

Table 5.4. Measured delay by which the pulse oximeter measures the simulated value after the SpO_2 change for manual sequence.

7 steps (Averaging time)	Masimo Root with Radical 7 (Mean average)	7 steps (Averaging time)	Datex Ohmeda S/5 (Mean average)
2–4 sec	2.5 sec	Beat to beat	6 sec
8 sec	6 sec	Normal (10 sec)	14 sec
16 sec	8 sec	Slow (20 sec)	25 sec

Table 5.5. Delay by which the pulse oximeter began to respond to SpO_2 change in the simulator for manual sequence.

7 steps (Averaging time)	Masimo Root with Radical 7 (Mean average)	7 steps (Averaging time)	Datex Ohmeda S/5 (Mean average)
2–4 sec	4 sec	Beat to beat	5 sec
8 sec	11 sec	Normal (10 sec)	10 sec
16 sec	15 sec	Slow (20 sec)	22 sec

Table 5.6. Rate by which the pulse oximeter/vital signs monitor changes the SpO_2 during one step.

Average (7 steps) (Averaging time)	Masimo Root with Radical 7 (Mean average)	7 steps (Averaging time)	Datex – Ohmeda S/5 (Mean average)
2–4 sec	0.5 %/s	Beat to beat	0.7 %/s
8 sec	0.2 %/s	Normal (10 sec)	0.3 %/s
16 sec	0.1 %/s	Slow (20 sec)	0.2 %/s

5.3 Results for step changes

This section also compares two different devices (Masimo Root with Radical 7 and Carescape B650) and their signal responses for different SpO_2 steps changes 20%, 15%, 10%, 5%. To compare the behavior and response of the devices, having results for different initial SpO_2, and getting directions of change, it was calculated the delay by which Masimo Root with Radical 7 and Carescape B650 change the SpO_2 during one step for manual sequence against, delay by which Masimo Root with Radical 7 and Carescape B650 began to respond to the step-change value after the SpO_2 change for the measured sequence, and rate by which Masimo Root with Radical 7 and Carescape B650 changes the SpO_2 during one step, all parameters were calculated versus the simulated signal. The tables below (5.7, 5.8, 5.9) display two different averaging times (2–4 sec and 12 sec), for different step changes, from different SpO_2 levels and different directions of change, with a 20% difference in amplitude.

The following figures (5.5 up to 5.12) show 4 different step changes, 20% difference, 15% difference, 10% difference, and 5% difference, using 2 pulse oximeters Masimo Root with Radical 7, as well as Carescape B650. These results show one simulated signal for each step-change, one moving average, and two measured signals, one for Masimo Root with Radical 7, and one for Carescape B650 vital signs monitor using 2-4 sec averaging time, and 12 sec averaging time. Table 5.10 compares the delay between the moving average (2–4 sec, 12 sec) and the measured signal after the SpO_2 change.

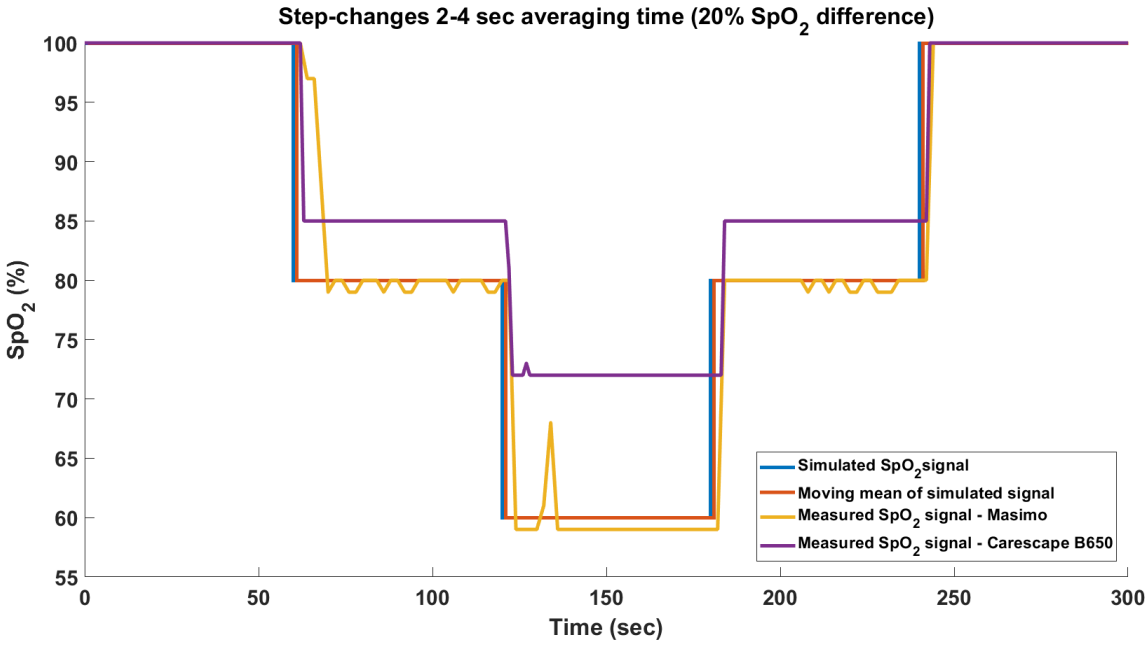

Figure 5.5. Step-changes 2-4 sec averaging time (20% *SpO2* difference)

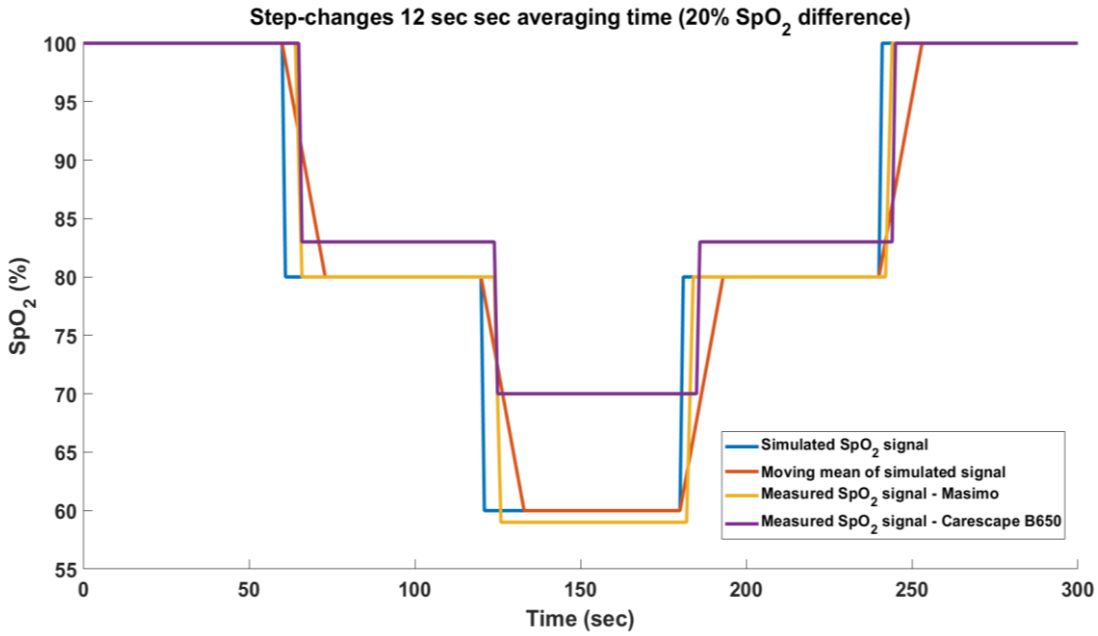

Figure 5.6. Step-changes 12 sec averaging time (20% *SpO2* difference)

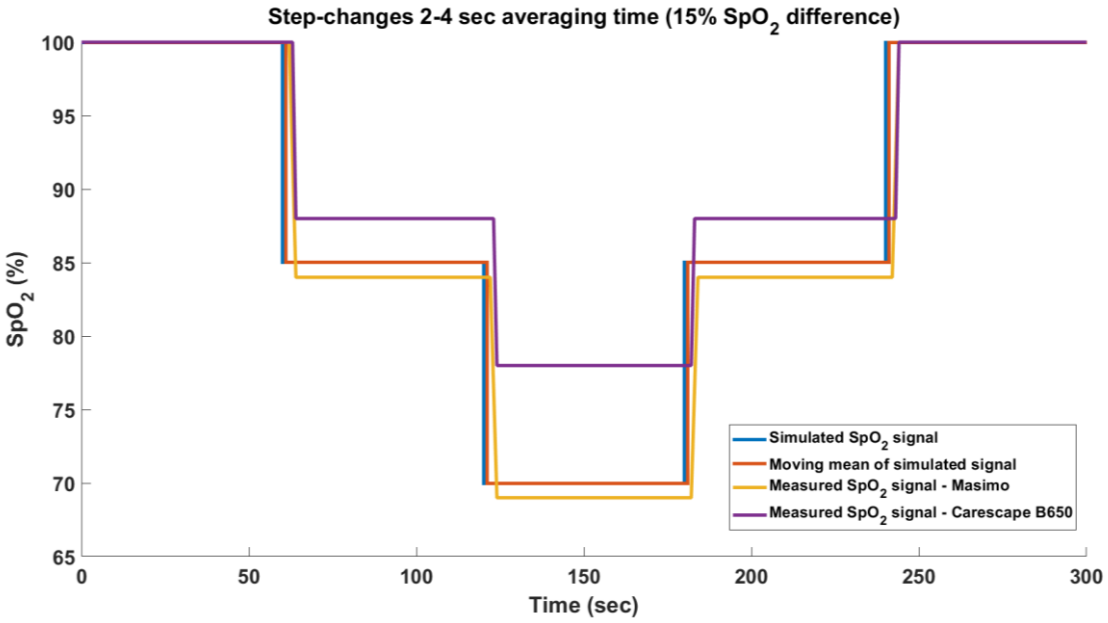

Figure 5.7. Step-changes 2-4 sec averaging time (15% *SpO2* difference)

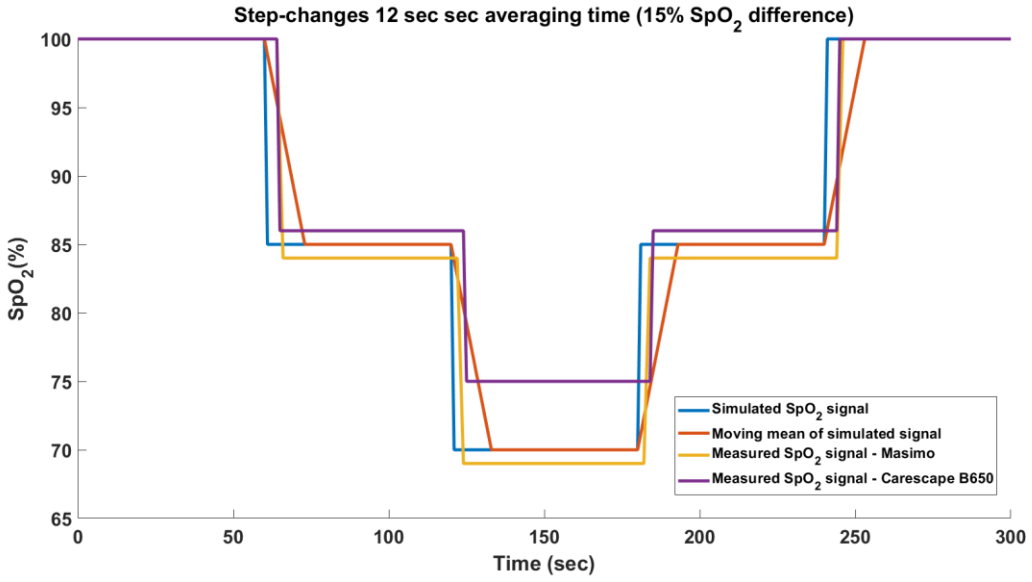

Figure 5.8. Step-changes 12 sec averaging time (15% *SpO2* difference)

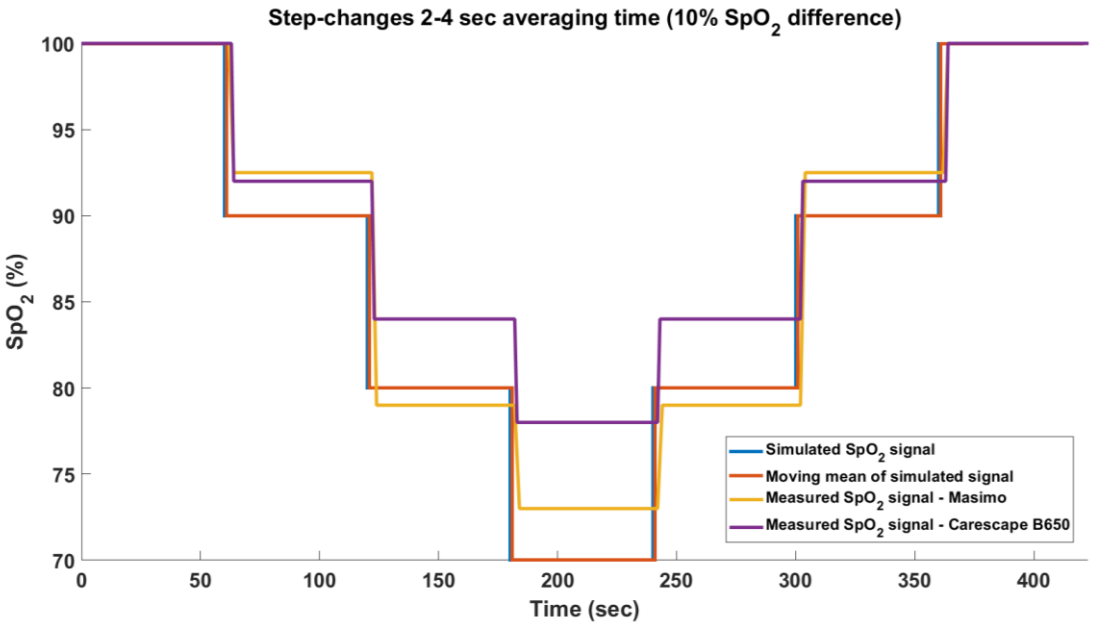

Figure 5.9. Step-changes 2-4 sec averaging time (10% *SpO2* difference)

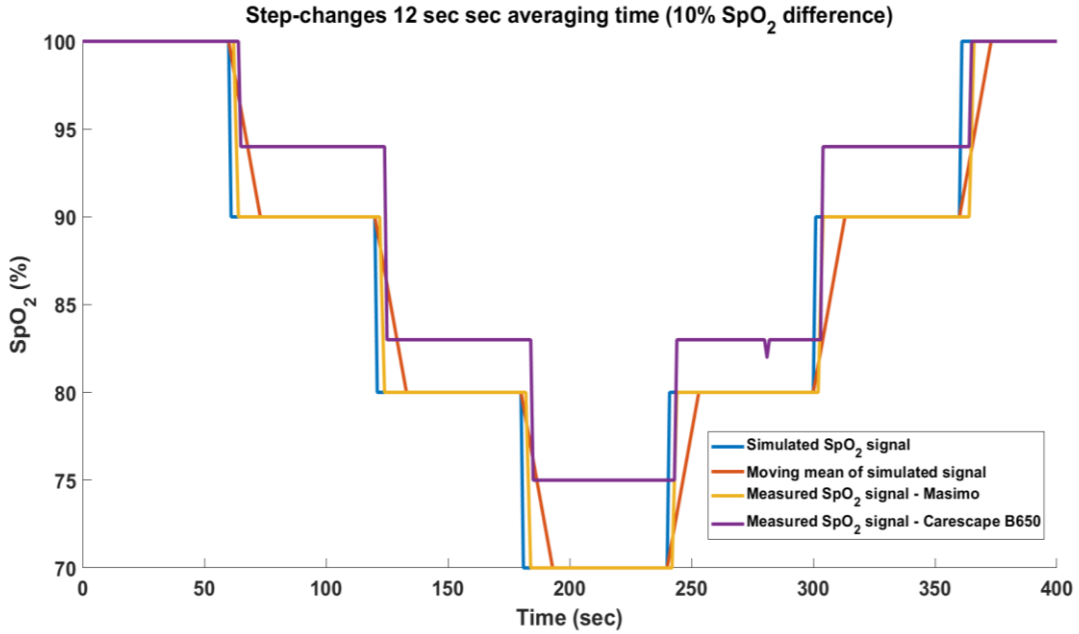

Figure 5.10. Step-changes 12 sec averaging time (10% *SpO2* difference)

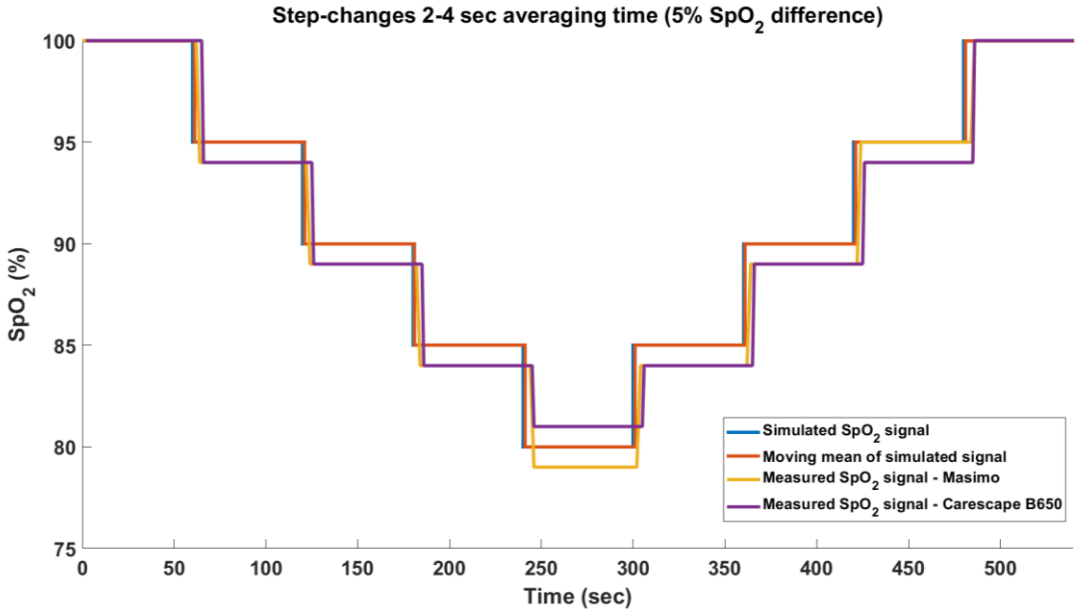

Figure 5.11. Step-changes 2-4 sec averaging time (5% *SpO2* difference)

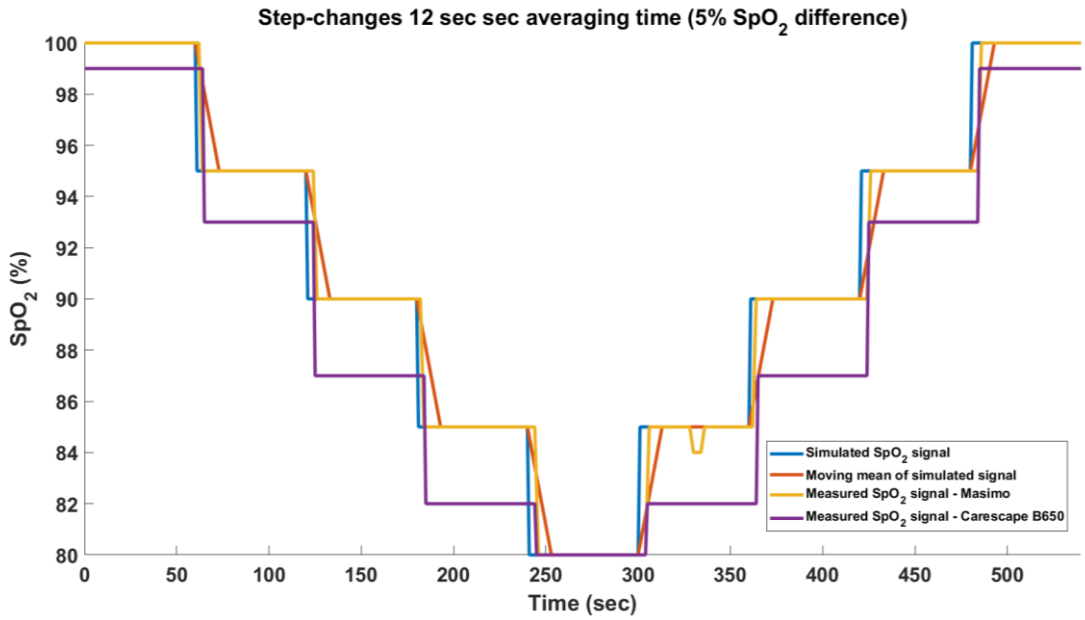

Figure 5.12. Step-changes 12 sec averaging time (5% *SpO2* difference)

Table 5.7. Measured delay by which the pulse oximeter measures the simulated value after the *SpO₂* change.

ΔSpO₂	Steps	Averaging time	Masimo (Mean Average)	Carescape B650 (Mean Average)	Averaging time	Masimo (Mean Average)	Carescape B650 (Mean Average)
20%	100% - 60%	2–4 sec	2 sec	1.5 sec	12 sec	3 sec	3.5
15%	90% - 70%	2–4 sec	2 sec	2.25 sec	12 sec	4.75 sec	4.75 sec
	100% - 70%	2–4 sec	2 sec	3 sec	12 sec	4 sec	3 sec
	95% - 80%	2–4 sec	2 sec	3 sec	12 sec	4 sec	4 sec
10%	90% - 75%	2–4 sec	2 sec	2.5 sec	12 sec	2.25 sec	2.5 sec
	100% - 70%	2–4 sec	1.5 sec	1 sec	12 sec	1.5 sec	4 sec
5%	95% - 75%	2–4 sec	2 sec	2 sec	12 sec	2 sec	3 sec
	100% - 80%	2–4 sec	1 sec	2 sec	12 sec	1.25 sec	1.75 sec

Table 5.8. Delay by which the pulse oximeter began to respond to *SpO₂* change in the simulator.

ΔSpO₂	Steps	Averaging time	Masimo (Mean Average)	Carescape B650 (Mean Average)	Averaging time	Masimo (Mean Average)	Carescape B650 (Mean Average)
20%	100% - 60%	2–4 sec	2 sec	2 sec	12 sec	3 sec	3.5 sec
	90% - 70%	2–4 sec	2 sec	2.25 sec	12 sec	4.25 sec	4.75 sec
15%	100% - 70%	2–4 sec	2 sec	3 sec	12 sec	2 sec	3 sec
	95% - 80%	2–4 sec	2 sec	2.5 sec	12 sec	2 sec	2 sec
	90% - 75%	2–4 sec	2 sec	2.5 sec	12 sec	2.25	2.25 sec
10%	100% - 70%	2–4 sec	1.5 sec	1 sec	12 sec	1.5 sec	4 sec
	95% - 75%	2–4 sec	2 sec	2 sec	12 sec	2 sec	3 sec
5%	100% - 80%	2–4 sec	1 sec	2 sec	12 sec	1.25 sec	1.75 sec

Table 5.9. Rate by which the pulse oximeter/vital signs monitor changes the *SpO₂* during one step.

ΔSpO₂	Steps	Averaging time	Masimo (Mean Average)	Carescape B650 (Mean Average)	Averaging time	Masimo (Mean Average)	Carescape B650 (Mean Average)
20%	100% - 60%	2–4 sec	10%/s	5.83%/s	12 sec	10%/s	3.6%/s
	90% - 70%	2–4 sec	8.33%/s	7%/s	12 sec	10%/s	8.25%/s
15%	100% - 70%	2–4 sec	5.41%/s	5.5%/s	12 sec	8%/s	7%/s
	95% - 80%	2–4 sec	7.5%/s	5.6%/s	12 sec	7.5%/s	6%/s
	90% - 75%	2–4 sec	10.5%/s	8%/s	12 sec	15%/s	14%/s
10%	100% - 70%	2–4 sec	5.5%/s	5.25%/s	12 sec	5%/s	3.5%/s
	95% - 75%	2–4 sec	5%/s	4%/s	12 sec	10%/s	6%/s
5%	100% - 80%	2–4 sec	1.6%/s	2%/s	12 sec	3.3%/s	4.% /s

Table 5.10. Shows the delay between the moving average (2-4 sec, and 12 sec).

Table 5.10. The measured delay between the moving average and the measured *SpO_2* signal, where movmean-instrument was calculated.

ΔSpO_2			Carescape			Carescape
	Window	Masimo	B650	Window	Masimo	B650
20%	2 sec	1 sec	1.5 sec	12 sec	1 sec	1.5
	2 sec	1.25 sec	0.75 sec	12 sec	0.25 sec	1.75 sec
15%	2 sec	1 sec	2 sec	12 sec	2 sec	3 sec
	2 sec	1 sec	2.5 sec	12 sec	2.25 sec	3 sec
	2 sec	1 sec	1.5 sec	12 sec	2 sec	2.5 sec
10%	2 sec	1.5 sec	2 sec	12 sec	2 sec	3.5 sec
	2 sec	1 sec	1 sec	12 sec	2 sec	3 sec
5%	2 sec	2 sec	2.5 sec	12 sec	1.75 sec	3 sec

5.4 Results for signal validation

This subchapter contains detailed information regarding the signal validation performed by the program OceanView and USB400, as well as, the Biomedical ProSim8 simulator and Masimo Root with Radical 7. In order to analyze and compare the different averaging methods of the medical oximeter and the two vital signs monitors. Two different fingers were set: medium finger and dark, thick finger. Figure 5.13 and figure 5.14 show the obtained results for medium finger and figure 5.15. shows the obtained results for dark, thick fingers. It was made a step-change in the intensity of the radiation using a change in the type of fingers, then it was recorded the response speed with a recording of the computer surface and camera of a mobile phone. In the video from this mobile phone, it was appreciated the immediate change of the measured intensity when changing the settings on the simulator. Additionally, in the next figures (5.13, 5.14, and 5.15) it can be appreciated y-axis - intensity (counts) x-axis - wavelength (nm).

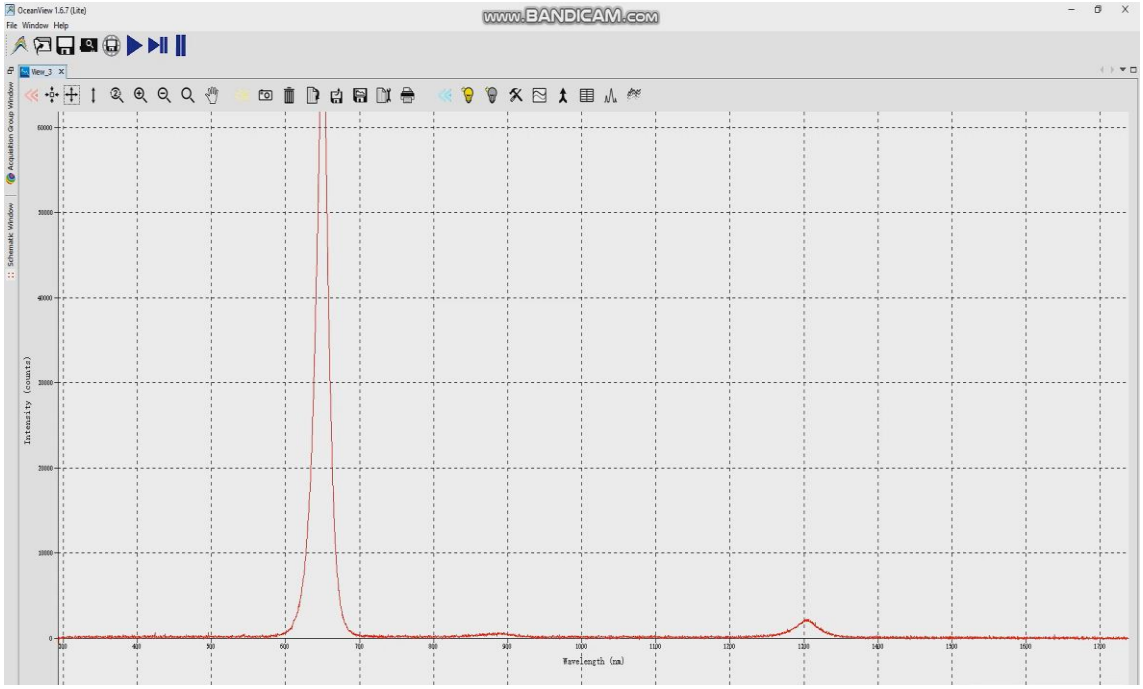

Figure 5.13. Transmission of "Medium finger" performed by Biomedical ProSim8 simulator.

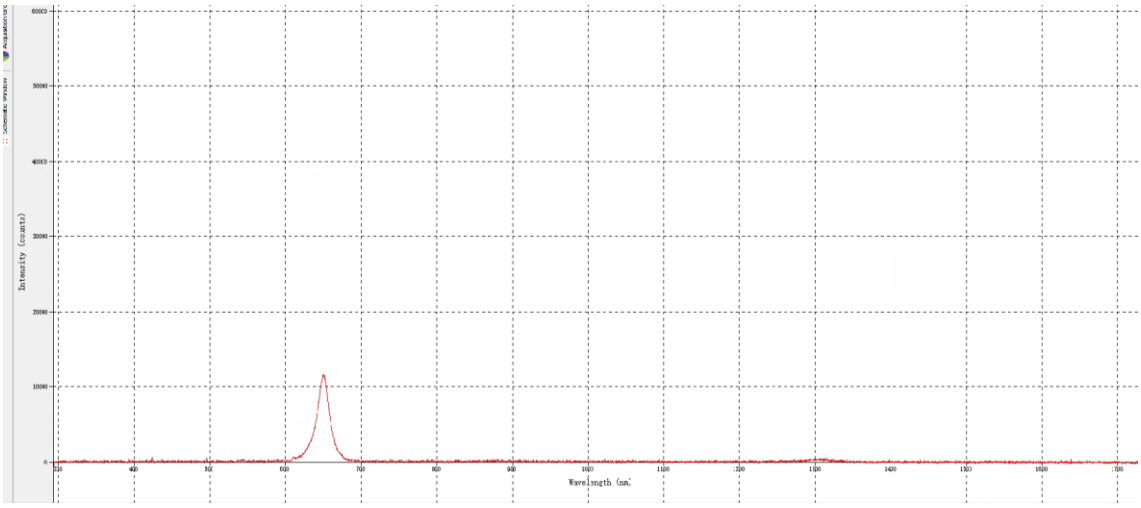

Figure 5.14. Transmission of "Medium finger" performed by Biomedical ProSim8 simulator after 2 sec.

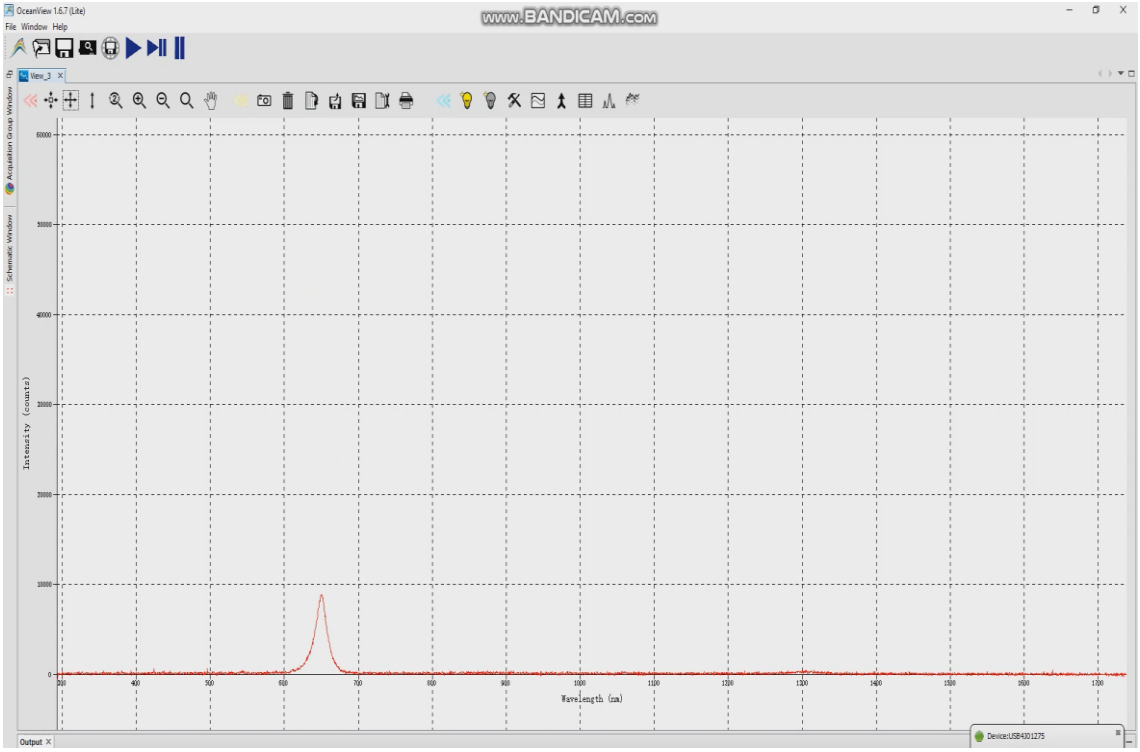

Figure 5.15 Transmission of "Dark, thick finger" performed by Biomedical ProSim8 simulator.

6 Discussion

It was discovered that Masimo Root with Radical 7 reacted faster (eight out of eight times) than Carescape B650 based on the comparison of the delay between moving average (Table 5.7). The waveform presented by Massimo Root Radical 7 demonstrated a high similarity to the moving average of the simulated signals for different averaging times. As a result, it was concluded that Massimo Root with Radical 7 generated the best results for the experiment.

For the two different sequences that were implemented during this bachelor thesis, automatic and manual sequences, it was discovered that Masimo Root with Radical 7 also presented the most accurate results for 3 different averaging times: 2–4 sec, 8 sec, and 16 sec, for both delayed calculations; the measured delay by which the pulse oximeter measures the simulated value after the SpO2 change and the measured delay by which the pulse oximeter began to respond to SpO2 change in the simulator and rate. The quickest response was discovered to be for 2–4 sec averaging time for all the parameters. Nevertheless, it is important to remark a few differences during this task. For instance, there were applied different averaging times for Masimo and Datex Ohmeda S/5 (beat to beat, normal, and slow), and the accuracy of each device is different, as it has been stated in methods (4 chapter), Masimo Root with Radical 7 presents an accuracy of ±2 digits for any oxygen saturation higher than 70%, whereas, Datex Ohmeda S/5 presents different levels of accuracy depending on the oxygen saturation approximately ±5 digits, the aim of this is discussing the different accuracy of the SpO_2 and the signal (measured by the pulse oximeter) might be different than the simulated one. The last different parameter is the way that the monitor/pulse oximeter recorded the signal, hence Masimo Root with Radical 7 records signal every 2 secs and Datex Ohmeda S/5 every 1 sec, these variables may have affected parameter calculations presented in Chapter 5, It affected the signal because the equipment has more time to process the new step-change and analyze the signal for a longer time. Frequency of the signal in MATLAB needed to be changed to be able to compare the graph with that of Datex Ohmeda S/5.

In regards to the step-changes, 4 different step changes were measured (20%, 15%, 10%, and 5% SpO_2 difference) of oxygen concentration. For this section of the bachelor thesis, 2 different averaging times, 2–4 sec, and 12 sec were used. It was calculated the moving mean of the simulated signal on MATLAB, the windows used were depending

on the averaging times, in most cases, MATLAB documentation suggested an odd window for the averaging of the signal, nevertheless, it was needed to respect the averaging signal of the monitors. The moving mean was not centered, hence, the SpO_2 always averages the signal backward, it was necessary to work with a trailing moving average vector, this MATLAB code can be found in Appendix C. Based on the calculations of parameters, the fastest response was given by Masimo Root with Radical 7, for a 5% SpO_2 difference. The results from table 5.8 show the response of the SpO_2 signal from different steps, for example, from 100% down to 80%, or 90% to 70%, consequently, the pulse oximeter did not present any the same delay regardless of the beginning of the SpO_2 concentration, and it did not present any difference in steps (up or down), but for 10% difference.

The second part of this bachelor thesis was based on the validation of the output signal of the SpO_2 simulator. The primary idea was to measure the change in SpO_2 for 100% oxygen saturation to 30%, however, there were no visible changes in the signal. Nevertheless, the SpO_2 simulator provides different options for signal transmissions, and according to these settings, the simulator provided us different saturations of light. The simulator is controlled electronically and there is no reason why the change in the oxygen saturation wouldn't be the same for a step-change between 100% and 30% oxygen saturation. It is referring to the same nature of the response, i.e.., that when measured was done a step-change in radiation intensity without visible delay, it was assumed that the rate of change of the set saturation at the simulator output will have the same course. The change between "Dark, thick finger" and "Medium finger", was rapid and did not present any delay.

When it comes to time delay and rate estimates, it's important to note that the results aren't always as expected regarding artifacts – motion, sound, light, etc. The most common issue is that the pulse oximeter measured a different SpO_2 value than the simulator for one simulated segment, to solve this, what was done was waiting for the most obvious change in the signal. Averaging creates a small delay in the signal, and different averaging times cause different delays. Between some of the difficulties doing this experiment there would be mentioned two of them:

1) Problems of signal synchronization. The signal synchronization was hard because it had to be done manually and there was no way to ensure that the change was every 60 or 45 sec.

2) Limitations of the experiment: Ensure that the step change is every 45 or 60 sec, try to get equipment that has the same averaging time and that reads the signal at the same frequency. It would also be good to add another device.

It is also important to say that the fastest averaging time was 2–4 sec for Masimo Root with Radical 7 and a beat-to-beat averaging time for Datex Ohmeda S/5.

Finally, it is advised to be cautious with signal synchronization in future experiments for the analysis of the response of pulse oximeters to a step-change in saturation depending on the set averaging time, as a result, signal synchronization is critical for calculating delay, rate, and analyzing the signal.

7 Conclusion

It has been concluded that the fastest averaging time is 2–4 sec for Masimo Root with Radical 7, and a beat to beat averaging time for Datex Ohmeda S/5, hence, both devices presented fewer signal desaturations, and some of the signal features become easier to read, such as step sequences, duration of the signal and maximum, and minimum points of the signal, and they did not miss any alarms during this period, as it demonstrated figure 5.3 and figure 5.4, which is an important study for medical personnel nowadays around the world. Nevertheless, there is not a recommended averaging time, hence it depends on the medical application, for instance, a 2–4 sec averaging time can be used in patients who suffer from desaturations of oxygen concentration, and, along averaging time can be used for stable patients who need continuous monitoring.

After a few mathematical calculations, it was discovered that for Masimo Root with Radical 7, the longest delay and highest rate was found in 16 sec averaging time, for both, automatic and manual sequences. In addition, the signal showed the fastest response in 2–4 seconds averaging time. However, the longest delay and higher rate were given by Datex – Ohmeda S/5 for all calculations, where this monitor presented missed signals and desaturations due to some problems with automatic sequences of the simulator during specific step-changes, mostly in automatic sequences.

Based on mathematical calculations, it may be concluded that Masimo Root with Radical 7 is the pulse oximeter with the fastest time response and best rate and all of the objectives were fulfilled, with a successful comparison of 3 different medical devices using different averaging times.

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Appendix A: MATLAB scripts for automatic sequences

```
clc
close all
clear all

%Set averaging 2-4sec
numData = xlsread('Measured1.xlsx'); %measured signal
SpO2ForMeasuredSignal1=numData(:,2);
TimeMeasuredSignal1=numData(:,3);
idx=find(~isnan(SpO2ForMeasuredSignal1));
Normal=interp1(TimeMeasuredSignal1(idx),SpO2ForMeasuredSignal1(i
dx),TimeMeasuredSignal1,'linear');

%Set averaging 8sec
numData = xlsread('Measured8.xlsx'); %measured signal
SpO2MeasuredSignal3=numData(:,2);
TimeMeasuredSignal3=numData(:,3);
idx=find(~isnan(SpO2MeasuredSignal3));
Normal3=interp1(TimeMeasuredSignal3(idx),SpO2MeasuredSignal3(idx
),TimeMeasuredSignal3,'linear');
shift2=-0.020;
SimulatedData1 = xlsread('Simulated8.xlsx'); %simulated signal
TimeForMeasuredData3=SimulatedData1(:,1);
SpO2ForMeasuredData3=SimulatedData1(:,2);

%Set averaging 16ec
numData = xlsread('Measured16.xlsx'); %measured signal
SpO2MeasuredSignal4=numData(:,2);
TimeMeasuredSignal4=numData(:,3);
idx=find(~isnan(SpO2MeasuredSignal4));
Normal4=interp1(TimeMeasuredSignal4(idx),SpO2MeasuredSignal4(idx
),TimeMeasuredSignal4,'linear');
shift3=-0.0312;
SimulatedData1 = xlsread('Simulated16.xlsx'); %simulated signal
TimeForMeasuredData4=SimulatedData1(:,1);
SpO2ForMeasuredData4=SimulatedData1(:,2);

%SimulatedData
SimulatedData1 = xlsread('Simulated1.xlsx'); %simulated signal
TimeForSimulatedData1=SimulatedData1(:,1);
SpO2ForSimulatedData1=SimulatedData1(:,2);
%Measured Sequences
numData = xlsread('AUTOMATICSEQUENCES.xlsx'); %measured signal
Time1=numData(:,1);
SpO21=numData(:,2);
% idx=find(~isnan(SpO2ForMeasuredSignal1));
%
Normal=interp1(TimeMeasuredSignal1(idx),SpO2ForMeasuredSignal1(i
dx),TimeMeasuredSignal1,'linear');

%Set averaging time 8sec
```

```
AverageTime3 = xlsread('AUTOMATICSEQUENCES.xlsx');
Time2=AverageTime3(:,3);
SpO22=AverageTime3(:,4);

%Set averaging time 16sec
AverageTime4 = xlsread('AUTOMATICSEQUENCES.xlsx');
Time3=AverageTime4(:,5);
SpO23=AverageTime4(:,6);

%SIMULATED
AverageTime2 = xlsread('ManualSequences.xlsx');
TimeSIMULATED=AverageTime2(:,3);
SpO2SIMULATED=AverageTime2(:,4);

%%Plot figures
figure;
hold on
stairs (TimeForSimulatedData1,
SpO2ForSimulatedData1,'LineWidth',3)
plot (TimeMeasuredSignal1+30, Normal, 'LineWidth',3)
plot (TimeMeasuredSignal3+2, Normal3, 'LineWidth',3)
plot (TimeMeasuredSignal4+6, Normal4, 'LineWidth',3)
hold off
xlim ([0 850])
title('Simulated and Measured SpO_{2} Signal. (Automatic
sequence) - Masimo Root with Radical 7'); xlabel ('Time
(sec)');ylabel('SpO_{2} (%)','FontSize',14);
legend('Simulated SpO_{2} signal', 'Measured SpO_{2} Signal (2
sec)', 'Measured SpO_{2} Signal (8 sec)', 'Measured SpO_{2}
Signal(16 sec)', 'FontSize',14);
set(gca,'Fontsize', 18, 'FontWeight', 'bold')

figure;
hold on
plot (Time1+5, SpO21, 'LineWidth',3,'Color', '
[0.85,0.33,0.10]')
plot (Time2+18, SpO22, 'LineWidth',3, 'Color','[0.9290, 0.6940,
0.1250]')
plot (Time3+20, SpO23, 'LineWidth',3,'Color', '[.5 0 .5]')
stairs (TimeSIMULATED, SpO2SIMULATED,'LineWidth',3, 'Color',
'[0, 0.4470, 0.7410]')
xlim ([0 300])
%legend('Measured SpO_{2} Signal (2 sec)','Simulated SpO_{2}
signal','FontSize',14);
title('Simulated and Measured SpO_{2} Signal. (Manual Sequences)
- Masimo Root with Radical 7'); xlabel ('Time
(sec)');ylabel('SpO_{2} (%)','FontSize',14);
legend('Measured SpO_{2} Signal (2 sec)','Measured SpO_{2}
Signal(8 sec)', 'Measured SpO_{2} Signal (16 sec)','Simulated
SpO_{2} signal','FontSize',14);
set(gca,'Fontsize', 18, 'FontWeight', 'bold')
hold off
```

Appendix B: MATLAB scrips for manual sequences.

```
clc
clear all
close all

% %Simulated signal - MovMean - Masimo - Datex signal. (Same
averaging time)
%
%1. %SimulatedData - 20 sec - 2-4 sec averaging time

SimulatedData1 = xlsread('stepchanges-simulatedsignal');
%simulated signal
Time=SimulatedData1(:,1);
SpO2=SimulatedData1(:,2);
%
% 2. MovMean - 2 sec averaging time
window2 = [2 0]; %average time for 2 sec
Anoise2 = movmean(SpO2,window2,2);

%3. Masimo
SimulatedData1 = xlsread('Masimo-StepChanges'); %simulated
signal
Time1=SimulatedData1(:,1);
SpO21=SimulatedData1(:,2);

%4. Datex
SimulatedData1 = xlsread('DatexStepChanges'); %simulated signal
Time2=SimulatedData1(:,1);
SpO22=SimulatedData1(:,2);

figure;
hold on
stairs (Time,SpO2,'linewidth',3);
stairs(Time+1,Anoise2, 'linewidth',3)
plot (Time1, SpO21,'linewidth',3)
plot (Time2, SpO22,'linewidth',3)
xlim ([0 300])
title('Step-changes 2-4 sec averaging time (20% SpO_{2}
difference)'); xlabel ('Time (sec)');ylabel('SpO_{2}
(%)','FontSize',18);
legend('Simulated SpO_{2}signal','Moving mean of simulated
signal','Measured SpO_{2} signal - Masimo','Measured SpO_{2}
signal - Carescape B650','FontSize',14)
set(gca,'Fontsize', 18, 'FontWeight', 'bold')
hold off
```