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Annual Maintenance of Pulse Oximeters

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Regular checks of functionality and overall condition are common practise in the aviation sector. Medical devices are no exception, as regular checks are cost effective way to ensure reliability and patient safety.

The goal of this thesis was to produce annual maintenance instruction for two Masimo pulse oximeters, because there was a need for it in the Hospital District of Helsinki and Uusimaa. Regulations and Finnish law demanded to follow the manufacturer's instructions, so further ways to improve the maintenance was searched from literature. Also, the accuracy was tested on a large scale using a simulator, in order to choose a sufficient measuring range for functionality check.

As a result of this work, a checklist was produced with step-by-step maintenance instructions based on literature review, former maintenance practise and manufacturer's instructions. Currently used method to test accuracy was found to be limited to functionality testing. One study claimed that use of the spectrometer could be more valuable, but this requires further investigation as even sensors ages were unknown in the study.

A conclusion from the literature review was that user knowledge of pulse oximeter is important, as it does not only improve effectiveness, but also prolongs the service life of the device.

Keywords	pulse oximeter, annual maintenance, masimo

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Säännölliset toiminnallisuuden ja yleiskunnon tarkastukset ovat yleinen käytäntö ilmailualalla. Lääkintälaitteet eivät ole poikkeus, sillä säännölliset tarkastukset ovat kustannustehokas tapa varmistaa luotettavuus ja potilasturvallisuus.

Tämän opinnäytetyön tavoitteena oli tuottaa vuosihuolto-ohjeet kahdelle Masimo pulssioksimetrille, koska sille oli tarvetta Helsingin ja Uudenmaan sairaanhoitopiirissä. Asetukset ja Suomen laki vaativat seuraamaan valmistajan ohjeita, joten kirjallisuudesta etsittiin muita keinoja edistää huoltoa. Myös tarkkuus testattiin laajamittaisesti simulaattorilla, jotta voitaisiin valita riittävä mittausalue toiminnan tarkastukseen.

Tämän työn tuloksena tehtiin tarkistuslista vaiheittaisilla huolto-ohjeilla, perustuen kirjallisuuskatsaukseen, aikaisempiin huoltokäytäntöihin ja valmistajan ohjeisiin. Tällä hetkellä käytössä oleva menetelmä tarkkuuden testaamiskesi huomattiin rajoittuvan toiminnan testaamiseen. Yhdessä tutkimuksessa väitettiin, että spektrometrin käyttö voi olla arvokkaampaa. Tämä kuitenkin edellyttää lisätutkimuksia, koska jopa anturien iät olivat tuntemattomia.

Päätelmä kirjallisuuskatsauksesta oli, että käyttäjien tieto pulssioksimetristä on tärkeää, koska se ei ainoastaan paranna laitteen tehokkuutta, vaan pidentää myös sen käyttöikää.

Avainsanat	pulssi oksimetri, vuosihuolto, masimo

Contents

1 Introduction

Reliability is an important aspect of medical devices. Unnoticeable error or malfunction can delay treatment, resulting in longer patient recovery. In worst case scenario, device designed to detect life-threatening signs is not alerting about the severe condition with catastrophic consequences. Pulse oximeter is one of these devices, but not as critical, because there are other signs which will indicate about the same problem. Pulse oximeter monitors changes in blood flow, or more precisely oxygen saturation in blood. [1, 10-11; 2, 31]

Regulations play a key role to ensure certain reliability of medical devices. In essence, they are legally binding acts about the use, maintenance and manufacturing of medical devices defining responsibilities for user and manufacturer. [3, viii]

The purpose of this study is to create one step-by-step annual maintenance instruction for Masimo SET Radical and Radical-7 Rainbow pulse oximeters according to local regulations (i.e. Finnish legislation). Also, the question if reliability can be further improved by more extensive maintenance is addressed in this thesis.

The annual maintenance instruction was requested by the Hospital District of Helsinki and Uusimaa (Helsingin ja Uudenmaan sairaanhoitopiiri), as there was a need to improve maintenance procedure for two Masimo pulse oximeters.

2 Background of Pulse Oximeter

Physiological phenomena of oxygen transport and the physics behind the measurement of oxygen saturation have to be familiar subjects before conducting maintenance. This chapter will introduce the underlying theory of them both, as well as the basic structure of pulse oximeter.

Information in this chapter can be found easily in literature as pulse oximeter is widely used and even mandatory in several countries during anaesthesia. This importance has led the World Health Organization (WHO) to publish a training manual for pulse

oximeter [4, 4] with a notation that efficiency depends on understanding of pulse oximeter. However, focus on this chapter will be on the technical side, as it is the nature of this thesis.

2.1 Oxygen and a Human Cell

Human being is a multicellular organism. It consists of multiple cells, where similar cells make up a tissue specialized in a certain function (e.g. muscle tissue). These different tissues together, with their own unique roles, form even greater entities called organs. Among others, such organs are heart, lungs and blood vessels. [5, 14-15]

Proper collaboration of many organs is lifeblood to the human organism. One of such is the cardiovascular system; an organ system which contributes to the metabolism and gas exchange at cellular level. Without it, a cell cannot receive energy to keep its form or to carry out its functions. As oxygen is largely required to derive that energy, lack of it will result in cell damage. Thus, oxygen is an absolute requirement for the life of energy demanding human cell and that way to the human being. [5, 14-15, 460-463]

2.2 Transport of Oxygen in the Blood

Transport of oxygen occurs in the cardiovascular system. As the Latin names *cardio* and *vascular* implies, the heart, blood vessels, and additionally blood itself take their part on oxygen delivery. [6, 689]

The heart is primarily responsible for inflicting force to the blood vessels. The right ventricle pumps blood to the lungs, and the left ventricle to the rest of the body. Frequency of these contractions depends on various matters, presented as heart rate [5, 233]. Contractions of the heart causes pressure differences, and as the cardiovascular system is a closed system, blood travels throughout it. A simplified version in figure 1 illustrates this in more detail. [5, 220-221]

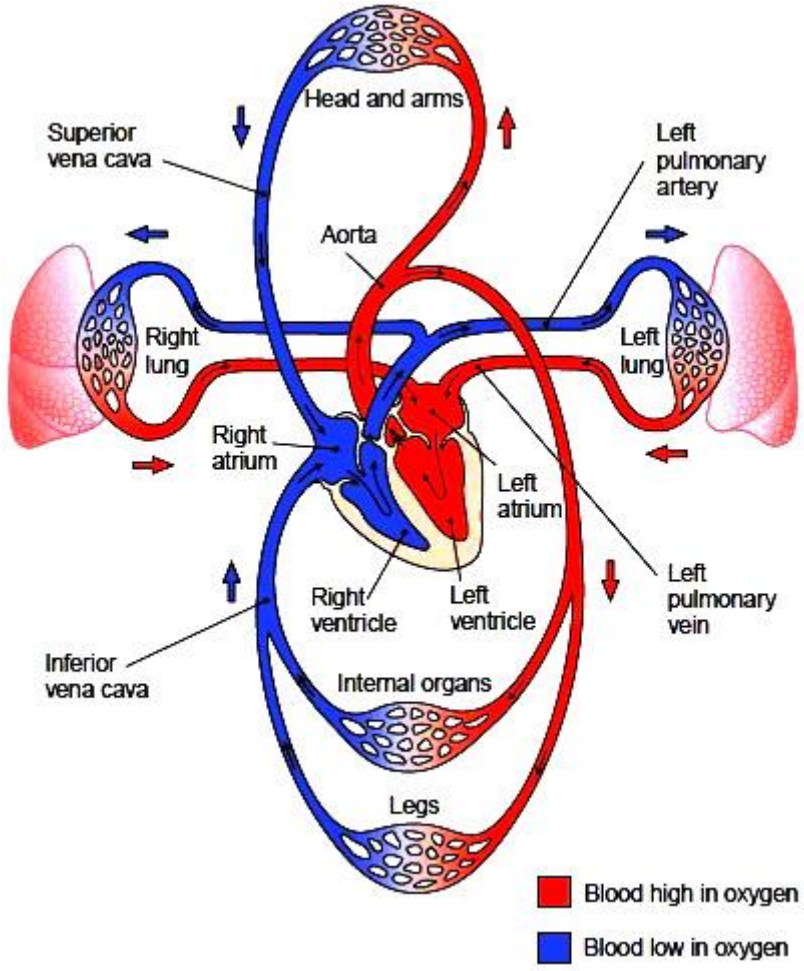

Figure 1. Simplified circulatory system and names of the blood vessels from the heart, copied from Hitachi MRI teaching modules [7]. While resting, it takes about 60 seconds that the equivalent amount of blood in the whole system has passed lungs [5, 221].

Blood vessels are the pipeline which enables blood to reach everywhere in the body. As in figure 2, it is roughly divided in five: arteries, arterioles, capillaries, venules and veins. In first two flows oxygen-rich blood, delivering oxygen and other substances to the cells. From the artery it is possible to measure pulse, as blood flowing through causes it to expand momentarily on every heartbeat [5, 232]. Last two, venules and veins, transport waste products and carbon dioxide out of cells. Consequently, capillaries are the section of the blood veins where gas exchange and cell metabolism occurs. It is also the place in circulatory system where the pulse oximeter makes its measurements, which will be discussed more detailed later on. [5, 237]

A further function of the blood veins is to enable regulation of blood flow. It is a needed function, because the amount of blood is so limited that it has to be prioritized by the demand. This body regulation of blood flow happens by the contraction of smooth

muscle tissues around the smaller arteries (i.e. arterioles, see figure 2). When muscle tissues are active, diameter decreases and causes grater resistance to blood flow [5, 243]. Same applies inversely when smooth muscle tissue relaxes. This enables to utilize “parallel connections” of blood vessels (see simplified figure 1), where blood flow to an organ can be adjusted by the connecting arterioles. The phenomenon can be witnessed while running; digestion slows down because blood is more needed in the leg muscles than in the digestive system. However, blood circulation in brains is not affected by this, as its blood flow is prioritized. Body aims to keep blood flow to the brain at a constant level. [5, 220, 263]

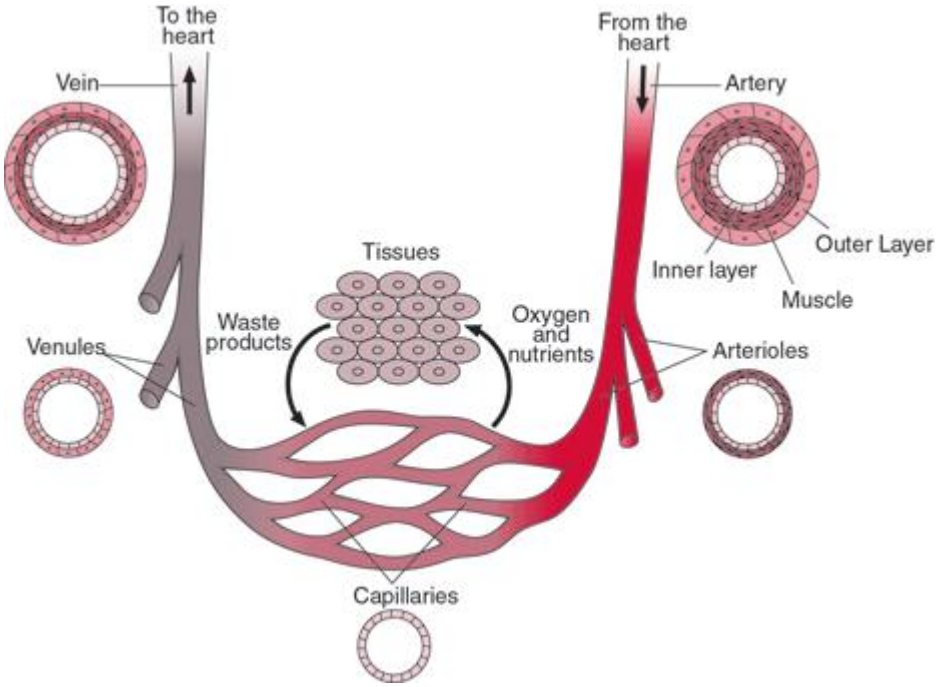

Figure 2. Connection between artery and vein, copied from Merck [8].

Blood is the carrier of oxygen, carbon dioxide and various other substances. On average, there is about five litres of blood which consists of plasma, and of three different blood cells: platelets, white blood cells and red blood cells. Since plasma is over 90% of water and less than 10 % of blood cells are other than red blood cells, only red blood cells will be examined further. This is also because oxygen is carried specifically in red blood cells, which is area of interest for pulse oximeter measurement. [5, 268-269]

Red blood cells, or erythrocytes, are elastic and disk shaped, where the middle section is slightly flat (see figure 3). It is the part of the blood which main task is to carry oxygen to cells, although it also carries carbon dioxide to the lungs as well. [5, 269]

Erythrocytes are generated in the bone marrow, and kidneys regulate their production with a hormone called erythropoietin. Content of erythropoietin in blood stream depends on the efficiency of oxygen transport; if oxygen demand of the body is not satisfied, erythropoietin elevates. Athletes utilize this phenomenon when training in mountains, which is among the reason for individual differences in the ratio of red blood cells in blood. Other examples are testosterone and dehydration. However, normal ratios are 47 % for men and 42 % for women. [5, 270-271, 273]

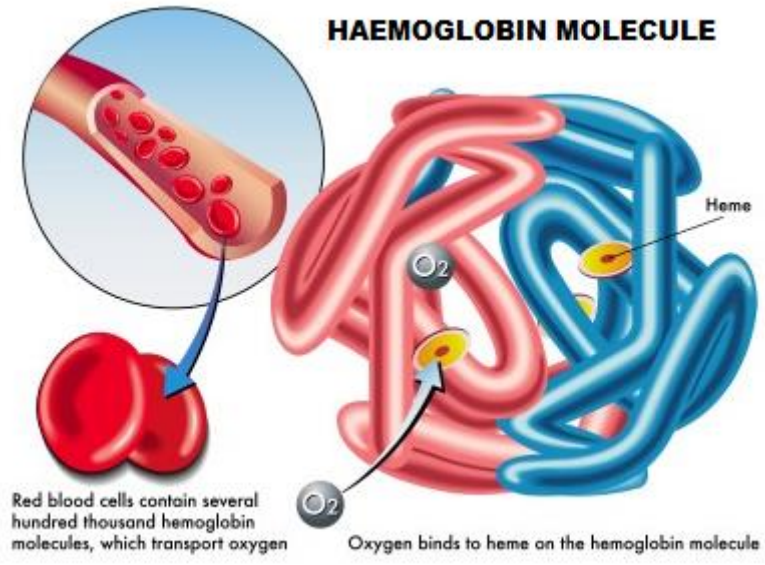

Figure 3. Red blood cells and haemoglobin molecule, copied from Dreamstime [9]. There are four “Heme” in all haemoglobins, where oxygen and carbon dioxide can bind to [5, 269].

The part in the red blood cells that binds oxygen is a haemoglobin protein. As production of red blood cells is controlled by erythropoietin, haemoglobin also varies individually. This also means that men have typically higher haemoglobin values due to testosterone. Roughly speaking, one litre of blood has around 150 grams of haemoglobin, which is around one third of the red blood cells dry weight [10, 168]. [5, 269-270]

The red colour of red blood cells is caused by haemoglobin. Intensity of the red colour depends on the amount of bound oxygens molecules in the haemoglobin molecules,

varying from scarlet to bluish. As one haemoglobin molecule has four heme parts (see figure 3), where each iron atom in the middle of the heme is able to bind one oxygen molecule, it can bind a total of four oxygen molecules. When one oxygen molecule contacts heme, it forms oxyhaemoglobin. This makes haemoglobin molecule more receivable for the next oxygen molecule, and less likely to bind a carbon dioxide. As haemoglobin binds more oxygen, affinity increases even more. This phenomenon is called Haldane effect. [5, 269, 314; 11, 673]

The oxygen binding reaction mentioned above can be expressed as equilibrium reaction, meaning that it occurs in both ways [5, 314]:

$$Hb + O_2 \rightleftharpoons HbO_2 \quad (1)$$

Where O_2 is oxygen, Hb is haemoglobin and HbO_2 is oxyhaemoglobin.

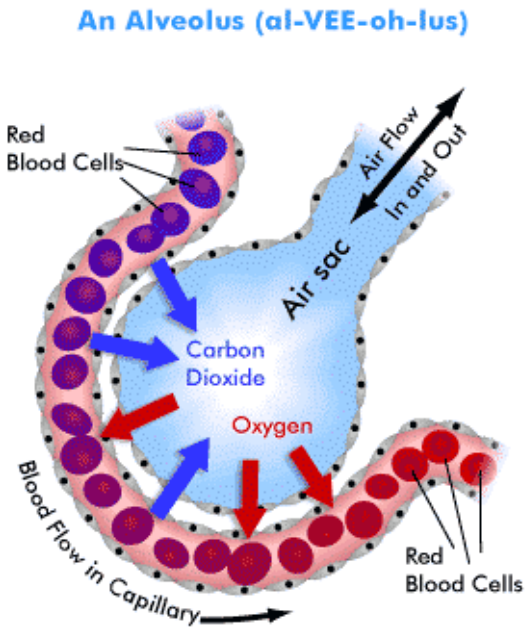

Figure 4. Diffusion in the alveoli, copied from YKSD course material [12]. As in the figure, capillaries are so narrow that red cells squeezes slowly through one by one [5, 245].

Reaction on equation 1 does not take place everywhere in the blood veins, as mentioned on page 4. It happens specifically in capillaries, which is the narrowest section of blood veins, having just 100 nanometres thin walls. And as the network of capillaries is so pervasive that distance to every single cell is non-existing, it is perfect for metabolic

exchange. There the gases are able to diffuse into the cells or the alveoli of lungs (see figure 4). The term diffusion means that concentrated particles prefer to balance the concentration on the whole available volume. So when there is high concentration of oxygen in blood and correspondingly low concentration of oxygen in the cell, oxygen will diffuse (“even out”) into the cell. Carbon dioxide enters to blood by the same principle. Determining factor for the direction of diffusion is the partial pressure (pressure of gas in the volume that it would occupy alone) in the case of gases. [5, 245-246, 314-316, 444]

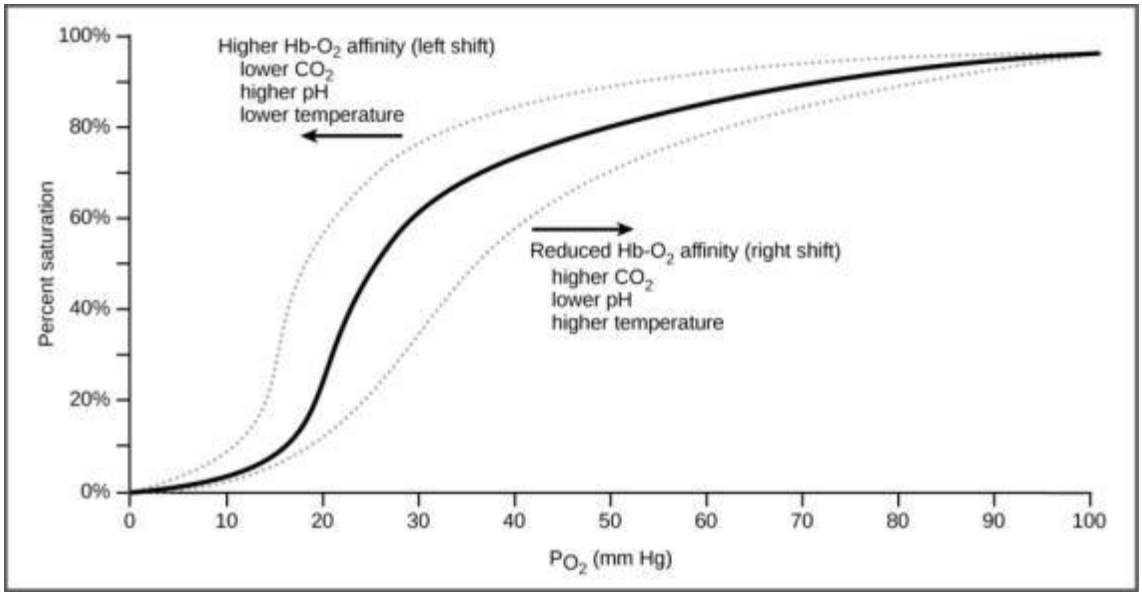

Figure 5. Oxygen-haemoglobin dissociation curve and effect of various factors, copied from GPnotebook [13]. Curve shows the ratio of saturated haemoglobins as a function of the partial pressure of oxygen.

The affinity of haemoglobin to bind oxygen is affected by numerous other factors. As visible in figure 5, the mentioned partial pressure of oxygen (horizontal axel) has considerable effect [5, 315]. Carbon dioxide on the other hand can effect to oxygen binding affinity in three ways. First, it can bind straight to haemoglobin, in a form of carbaminohaemoglobin, although not as commonly as oxygen. This results in less haemoglobins that are able to bind oxygen. Second, it can bind hydrogen ion to haemoglobin and diffuse into the water of plasma as bicarbonate. This is primary way in which carbon dioxide is transported, which also causes less haemoglobins to be available for oxygen. Additionally, the pH lowers because of this, making oxygen contacts looser in the blood, so that oxygen is released where it is needed. Third, higher partial pressure of

carbon dioxide in lungs increases first and second. These three are known as the Bohr effect, which is mirror image of the Haldane effect. [5, 316; 11, 671]

Last major factor affecting the curve in figure 5 is the temperature. Higher temperature shifts the curve to the right and lower to the left. In addition, increase in the concentration of 2,3-dpihosphoglycerate (2,3-DPG) in red blood cells moves the curve to the right. [11, 670-671]

2.3 Measurement of Oxygen Saturation

Stated in simple language, pulse oximeter is a device which measures colour differences in haemoglobin to determine its oxygen saturation (SpO_2) in real-time. The reason to measure oxygen saturation is that it gives moderately sufficient information about the cardiovascular system. More precisely, as pulse oximeter measuring point is in capillaries, it tells if adequate amount of oxygenated blood travels through capillaries. [4, 8-9]

Oxygen saturation values below normal indicate deficiency in some part of the cardiovascular system. This is the very reason why it is a valuable device, and even legal obligation during anaesthesia in few countries (see chapter 3.1.), as deficiency of oxygen at the tissue level (i.e. hypoxia) is hard to determine visually before the life-threatening below 90% saturation. Correspondingly, normal value for oxygen saturation is above 95 %. [4, 7-8]

In addition to oxygen saturation, pulse oximeter is also equipped with pulse measurement. As previously discussed, it tells how frequently heart beats (i.e. heart rate), which is usually indicated as beats per minute (BPM). This tells little more information about the cardiovascular system. For adults, normal heart rate is around 50 to 100 while resting. [4, 12]

Measurement technique

Pulse oximeter measures the peripheral capillary oxygen saturation non-inversely, referred as SpO_2 [4, 9]. It can be used to estimate arterial saturation of oxygen (SaO_2),

which is the ratio of oxyhaemoglobin divided by the total of arterial haemoglobin available [14, 239]:

$$SaO_2 = HbO_2 \,/\, (Hb + HbO_2) \qquad (2)$$

However, correct arterial saturation value can only be achieved by blood gas analysis, which underlines the importance to understand the limitations of pulse oximeter. Limitations will be discussed in the chapter 3. [15, 59, 268].

Simple pulse oximeter measures oxygen saturation (SpO_2) with three diodes. Two LEDs transmit light, where one transmits in the infrared region (940 nm) and the other in the visible light region (660 nm). Photodetector diode detects the transmitted light from both diodes. Figure 6 illustrates the technique. [14, 242; 15, 56]

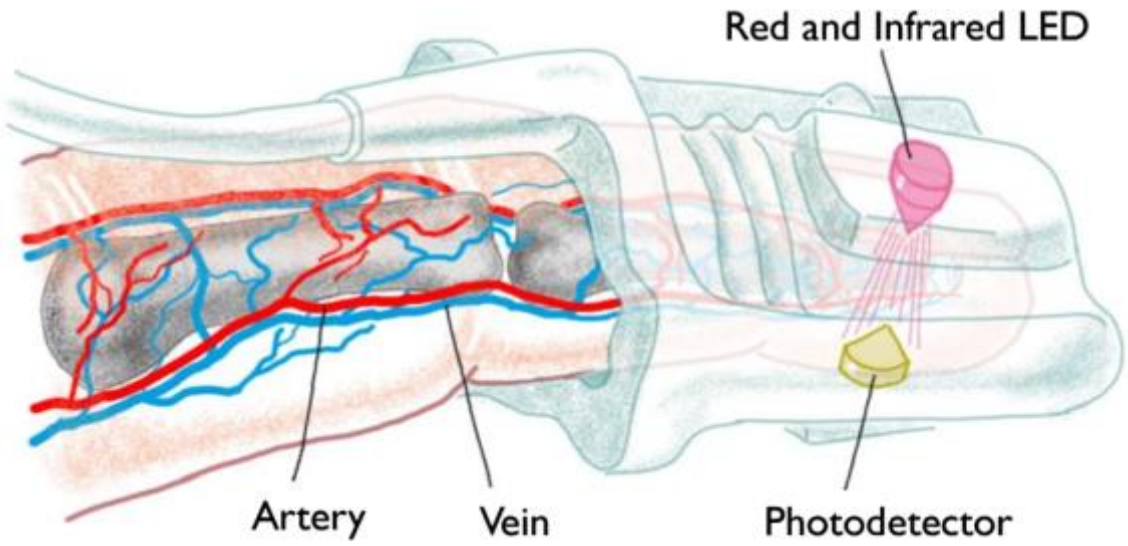

Figure 6. Measurement technique of pulse oximeter from fingertip, copied from Wijshoff (2012) [16].

As the light travels through tissue, it gets absorbed by various substances (see figure 8 for more detail). By utilizing the Beer-Lambert law with the knowledge that haemoglobin colour varies according to bound oxygen molecules (see chapter 2.1.), oxyhaemoglobins can be estimated. [17, 2]

Beer-Lambert law enables the use of light as a way to determine how much absorbance has occurred for a specific medium. It can be presented as an equation [17, 3]:

$$I = I_0 e^{-\varepsilon(\lambda)cd} \quad (3)$$

Where,
I is the intensity of light measured,
I_0 is the original intensity of light,
$\varepsilon(\lambda)$ is the absorptivity of the medium,
c is the concentration of the medium and
d is the length of the optical path.

By dividing I_0 and taking natural log from equation 3 we get the unscattered absorbance (A) [17, 3-4]. This can be further manipulated as a sum of numerous mediums, where $A_t(\lambda)$ is the total absorbance [17, 4]:

$$A_t(\lambda) = \sum_{i=1}^{n} \varepsilon_i(\lambda) \cdot c_i \cdot d_i \quad (4)$$

With this equation, it is possible to separate oxygenated haemoglobin (oxyhaemoglobin, HbO_2), and not oxygenated haemoglobin (deoxyhemoglobin, Hb). Molar absorptivity of these is represented in figure 7, where deoxyhaemoglobin is described as DeOxyHb and oxygenated haemoglobin as OxyHb. As there is sufficient difference in infrared region and visual light region between the two, distinctions can be made to estimate concentration of the two. Thus, placing the measured values on equation 2 gives the oxygen saturation value (SpO_2). [14, 242-243]

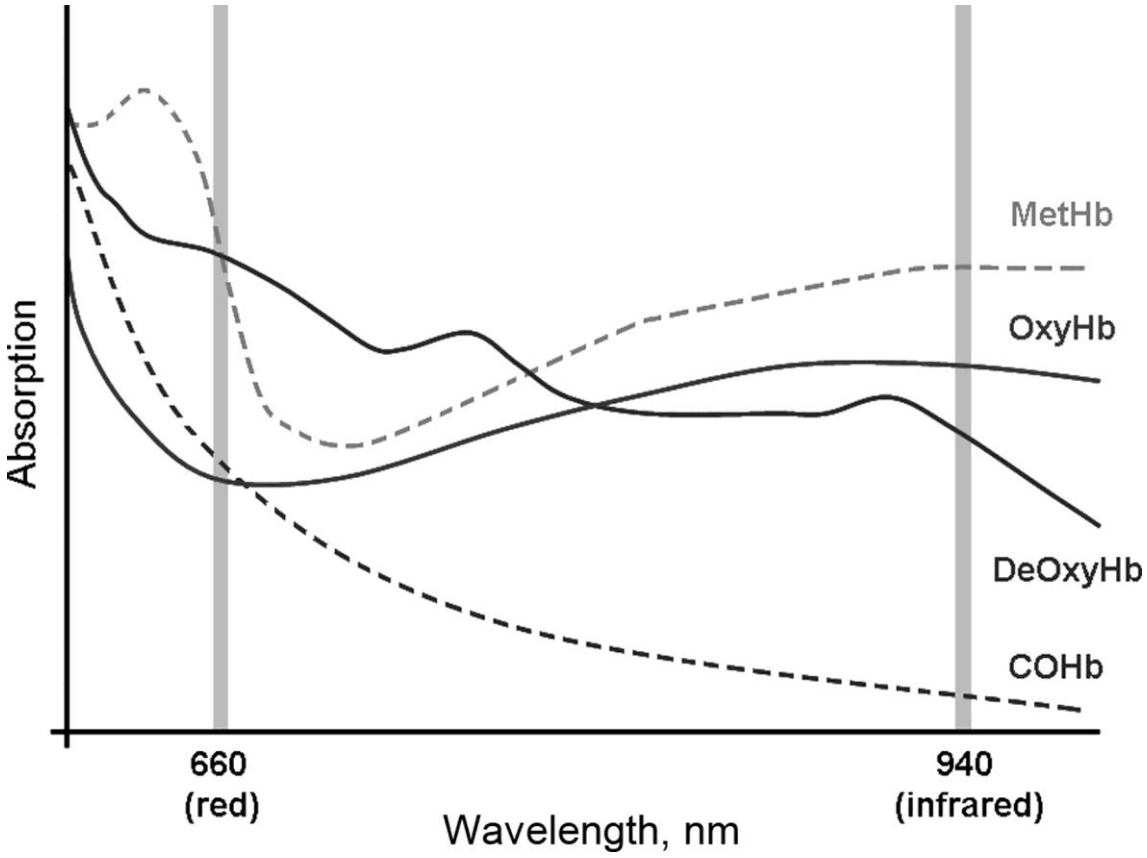

Figure 7. Molar absorptivity of various haemoglobins, copied from Fouzas (2011) [18].

However, accurate estimations are hard to come by with the above technique. One reason is that mix up to other types of haemoglobins is very possible. Such are met-haemoglobin (MetHb) and carboxyhaemoglobin (COHb) visible in figure 7, which will cause error when they are elevated. [19]

Other reason for inaccuracy comes from assumptions made with Beer-Lambert law. A light-emitting diode, which has a main role in pulse oximeter, has qualities that count to substantial error if equation 3 would be used. This is because intensity of light also depends on the wavelength, which is hard to determine as LED is not monochromatic, meaning that it does not form one beautiful spike in the visible spectrum. And even if it could be measured precisely, LED's intensity in specific wavelength varies even in the same production batch. [17, 4-5]

It is also false to assume that blood is one uniform substance of same building blocks. In fact, it is the opposite; a mixture of various substances varying each moment. Therefore it also makes error to all parts of equation 3 and 4, as it is expected to be homoge-

neous medium. Intensity lost due to reflection and scattering are not considered either, but as both counts to acceptable error they can be safely ignored. [17, 4-5]

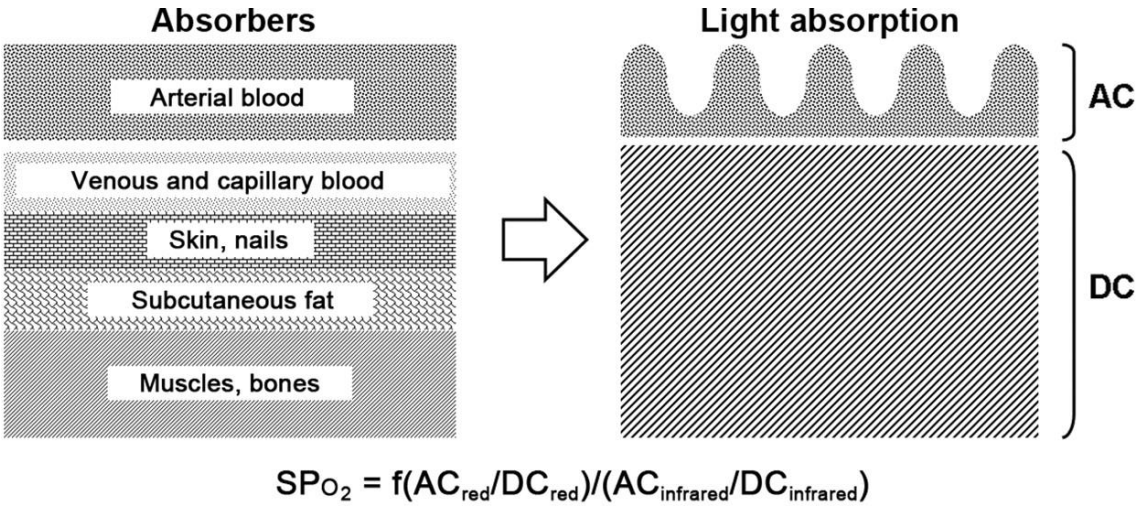

Figure 8. On the left: various substances absorbing light. On the right: AC and DC components. On the bottom: way to calculate SpO_2 based on AC and DC components. Copied from Fouzas (2011) [18].

The insight to tackle inaccuracy came from Takuo Aoyagi [14, 245-246]. He found out that it is sufficient to focus only on the changes of the arterial pulse, or the AC component (see figure 8). This eliminates the need to know light intensity of the LED [17, 5].

The insight can be presented as ratio calculation (R) [14, 246]:

$$R = (\varepsilon_o(\lambda_1) \cdot c_o + \varepsilon_d(\lambda_1) \cdot c_d)/(\varepsilon_0(\lambda_2) \cdot c_o + \varepsilon_d(\lambda_2)c_d) \quad (5)$$

Where,
for oxyhemoglobin: ε_o is absorptivity and c_o the concentration and
for deoxyhaemoglobin: ε_d is absorptivity and c_d the concentration.
The λ_1 is value measured with red LED and
the λ_2 is value with infrared LED.

Estimation of SaO_2 can be calculated with R as follows [14, 246]:

$$SpO_2 = ([\varepsilon_d(\lambda_1) - \varepsilon_d(\lambda_2)]R) \,/\, ([\varepsilon_d(\lambda_1) - \varepsilon_0(\lambda_1)] - [\varepsilon_d(\lambda_2) - \varepsilon_0(\lambda_2)]R) \quad (6)$$

Where SpO_2 represents estimation of SaO_2.

These equations do not solve the LED issue completely, as the molar attenuation coefficient is still needed. As it requires wavelength of the light source to be known by definition [20], Takuo Aoyagi worked around it with an approximation [14, 247]:

$$R \approx \left(I_{AC}(\lambda_1)/I_{DC}(\lambda_1)\right)/\left(I_{AC}(\lambda_2)/I_{DC}(\lambda_2)\right) \quad (7)$$

Where AC is the pulsatile, and DC is the non-pulsatile component.

According to Kelleher J.F., equations 6 and 7 are only accurate for SpO_2 at the range of 90-100% [14, 247]. In order to have the accuracy of sophisticated pulse oximeters, more LEDs are used, which allows better distinctions between different haemoglobins. Yet, the best improvement to the accuracy came from the use of specific calibration curve, which aims to approximate the measured value as close to the real value as possible. Calibration curve is crafted from multiple measurements of a specific build, where R is plotted as a function of measured SaO_2 values (see figure 9). [14, 247]

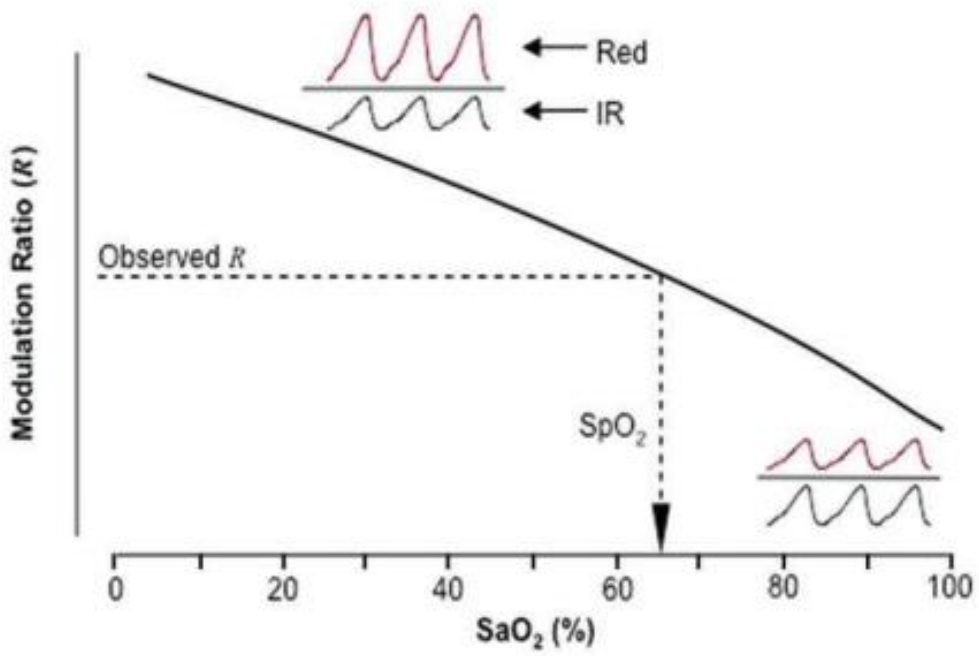

Figure 9. Sample calibration curve (R-curve), copied from Oak (2015) [21].

This technique only takes into account the R (equation 7) and the calibration curve. Same expressed as an equation, with simplified equation 7 [14, 247]:

$$SpO_2 = f \cdot \frac{AC(red)/DC(red)}{AC(infrared)/DC(infrared)} \quad (8)$$

Where,
f is coefficient based on empirical measurements and
AC(red) and AC(infrared) are RMS values. [21, 1]

With these two improvements, multi-wavelengths and a software lookup table, pulse oximeters of today are accurate at the range of 70-100 %. However, multiple artefacts affect to the measurement by creating noise, such as movement. Manufactures correct these with algorithms, which are specific calculations done by the microcontroller. Chapter 3.2 will briefly examine such algorithms. [14, 248-250]

Lastly, pulse oximeter also measures pulse from the AC peaks of absorbed light, represented in figure 8. This gives information about heart rate. As it is based on same phenomenon as the saturation measurement, no further explanation is necessary.

2.4 Basic Structure of Pulse Oximeter

There are four types of oximeters, if divided by their configuration. Pulse oximeter can be built entirely on the finger clip, leaving out all wires. Or it can be a wrist model, with just one wire from the “watch” to the fingertip sensor. Pulse oximeters built with these two structures are hardly accurate models and lack all the qualities of medical device, which is the reason that they are not frequently used in hospital environment. [22, 272]

Two models mostly used in the hospital environment are the handheld and table top model. Masimo pulse oximeters used in this thesis are hybrids, as they are handhelds plugged to a docking station. [22, 272]

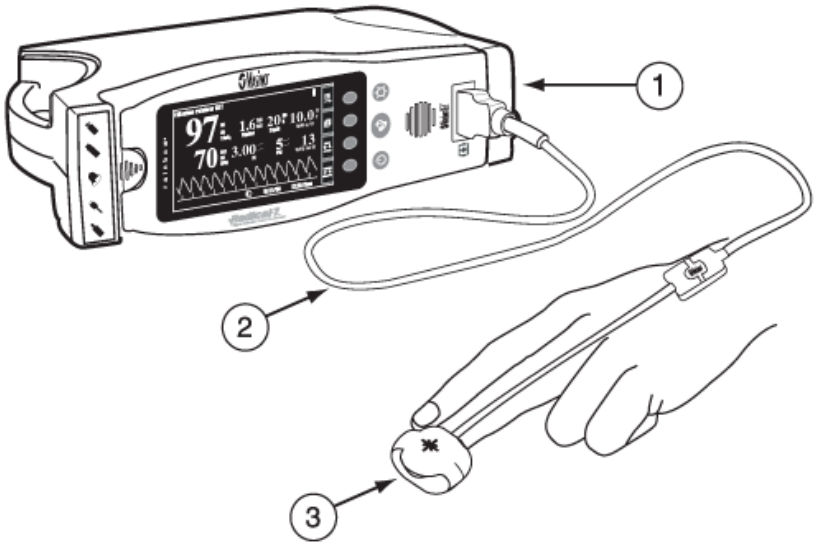

Figure 10. Pulse oximeter with three parts: 1) Handheld with docking station, 2) patient cable and 3) fingertip sensor. Figure copied from Masimo [23].

Figure 10 represents Masimo pulse oximeter. All the other manufacturers have roughly the same parts: the display terminal with user interface to change parameters and to display various audio-visual alarms. Commonly the pulse oximeter shows pulse, oxygen saturation and the quality of signal as waveform. There is also audible information about the saturation, which is a beeping sound. The pitch of the beep follows the saturation value: dropping saturation is indicated with dropping pitch. [4, 9-10]

Then there is the patient cable, which is or is not fixed to the fingertip sensor. Although finger is the most common measurement place, other places to connect pulse oximeter are: toe, earlobe, outer wall of the nostril or the lip. [22, 272]

Sensor Types

Each connection point has its own advantages and it alters the design of the sensor. The most common types, which are 2 and 3 in the figure 11, are slowest to measure (half minute delay). Signal is also prone to distort due to movement and they can easily move out of place. Good thing about the sensors is their protection against ambient lighting and reusability. Measuring point is toe or finger. [22, 271]

Figure 11. Various pulse oximeter sensor types, modified from EMP catalogue [24]. 1, 2 and 3 are finger sensors. 4 is for the nostril, 5 is for the earlobe and 6 is Y sensor. Latter gives freedom to choose the measuring point.

A step further is the sensor type 1 in figure 11. It addresses the movement issue, as it is securely fixed in place with adhesive tape. Disadvantages are the lower protection against ambient lighting and that they are not reusable. Also the measurement delay is same, as it usually is placed on toe or finger. [22, 271]

Faster measurement time comes with sensor type 5 (figure 11), cutting the measurement time to one third. It is like clothespin, which is attached to the earlobe and it is reusable. The signal is not as easily interfered by movement, like in sensors 2 or 3, but it does not stay in place as secure as sensor 1. However, there is less movement in that measuring point than in finger or toe. Downsize is ambient light, which may cause problems. [22, 271]

Type 4 provides the best option considering the signal integrity. It measures from the nostril, making it well protected from ambient light. Movement hardly distracts the signal of type 4, and it is as fast measuring point as the earlobe. Disadvantages is that it is not reusable. [22, 217]

Lastly, type 6 is the joker card, as it gives the luxury to connect it anywhere where the signal can be obtained. It has to be secured with adhesive tape, and it has no protection against ambient light. [22, 271]

System overview

It is hard to explain pulse oximeter system in more detail, as there is variance between manufactures. In outline it may be explained as in figure 12.

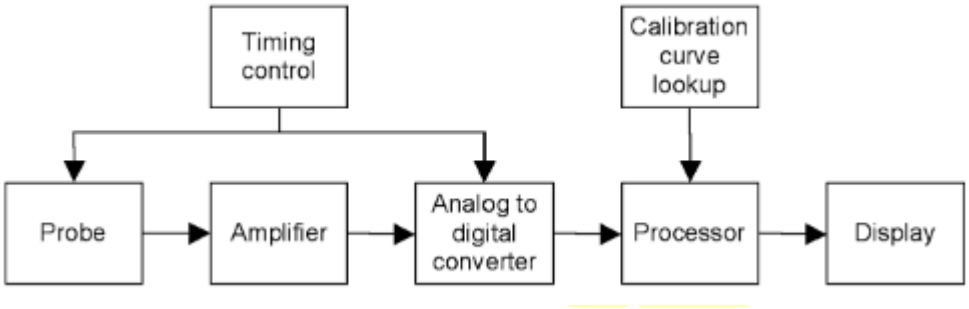

Figure 12. Block Diagram of Pulse Oximeter, copied from Chan (2016) [25, 559].

Analog information about light absorption is measured with the LEDs of the probe. Absorption is different between different haemoglobins, so the timer will change on and off the infrared and visible red LEDs. As distinction between different haemoglobins is improved with multiple LEDs, timer controls multiple LEDs. The data from each LED is then amplified and transferred to the digital converter. There it continues in digital form to the processor, which evaluates it and compares measured R value to the calibration curve. Lastly, information is displayed in the screen. [25, 558-559]

To end up with, pulse oximeter does not have to be an external device. It can also be a part of the patient monitor, which covers more parameters at once. According to one comparison study, GE health monitor had almost equivalent performance with Masimo Radical-7 under motion conditions. [26, 2-3]

3 Signal Integrity

This chapter reviews the environment where the pulse oximeter is used and concerns of it. Also the movement artifact will be discussed briefly, as well as the limitations of pulse oximeter.

3.1 Operating Environment

Oxygenation monitoring is mandatory in several countries during anaesthesia [27, 28, 29]. WHO placed the pulse oximeter in its directive for surgical safety checklist as well [30]. Thus, pulse oximeters are usually found at the operating rooms, which are tightly regulated environments. These regulations demand, for example, that a medical device cannot interfere other vital devices, and has to withstand possible interference coming from other sources. If a device does not meet this basic requirement, it is not allowed into the clinical environment. Other regulations and requirements set for medical devices are discussed on chapter 4. [31]

Pulse oximeter is not only limited to the operating rooms alone. It has become quite popular device due to its simplicity and information value. That is why it is being used around the hospitals, ambulances and in homecare. These various kinds of environments set different demands, such as endurance and reliability while moving, which are more of a problem to manufacturers to solve. These harsh environments bring more noise to the measurement, which manufacturers may try to correct with algorithms. But some errors are simply in the scale of technical limitations, which emphasizes the importance to understand the environment and how the pulse oximeter works. The next two subchapters will discuss the known artifacts and the limitations. [29]

3.2 Motion artifact

One significant artifact for pulse oximeter is created by motion. Jubran Amal [32] investigated in 1999 four different researches to conclude that motion was the main cause for many false alarms and incorrect readings regarding pulse oximeter. To a degree this might be true nowadays, but work has been done on this matter. However, it only concerns those manufactures that have made a claim of accuracy while patient moves. Only in that case accuracy has to be provided in the instructions of use, based on sufficient clinical proof. [14, 251]

Movement artifact is due to absorption changes caused by venous blood. Masimo was first to counter this effectively, with their adaptive filtering technique called Singal Extraction Technology (SET). Masimo claims that this has enabled measurement possible in low peripheral perfusion, during movement and in many low signal-to-noise situa-

tions. Research done by Hay and colleagues seems to confirm that it is remarkably effective, by causing fewer alarms and better detection of hypoxia [33]. [34]

User can also affect to the alarms in case of high motion artifacts, by setting long averaging times. Main downfall of this is that it will also delay alarms. [22, 275]

3.3 Limitations

There are several limitations for pulse oximeter. As explained in chapter 2.2, measurement requires sufficient perfusion to begin with. This is because AC component is required, which is where the measurement is conducted from (see figure 8). One example of low perfusion case is the hyperthermia, where blood is prioritized internal organs at the cost of low perfusion to the limbs. [15, 60]

As light is the determining factor in the measurement, everything interfering with it can alter the results. At normal levels of oxygen saturation Official guidelines from the Thoracic Society of Australia and New Zealand [35] states that skin colour does not have an effect. In low saturations however, very dark skin leads to overestimation of around 2%. According to the same guideline, nail polish and acrylic nails have mostly decreasing effect on SpO_2 reading. Additionally, ambient light was recognized as a source of error. Newer sensors have screens to prevent interference of ambient light.

Another limitation is caused by the similarities between different types of haemoglobins. Methaemoglobin (MetHb) and Carboxyhaemoglobin (COHb) (see figure 7) share the same light absorption characteristic with either the oxyhaemoglobin or the deoxyhaemoblobin. Normally they do not interfere with the measurement much, but as they elevate, SpO_2 value changes correspondingly. For Masimo Radical-7 pulse oximeter, higher methaemoglobin lowers SpO_2 value by 10-15% and higher carboxyhaemoglobin raises SpO_2 value directly proportionally to the COHb value. [23, ii]

What comes to the body temperature, Ralston, Webb and Runciman [36] concluded on their study in 1991 that overall error caused by high or low body temperature are clinically insignificant when measuring with pulse oximeter. This is of course if perfusion in measuring point is sufficient. It was also concluded in the same study that accuracy of pulse oximeter should not be affected by the pH in the blood.

4 Medical Device Regulations

Authors of the book Medical Devices: Use and Safety, Bertil Jacobson and Alan Murray, stated in the preface that many reported accidents involving medical devices could have been avoidable. Further, they concluded that risk associated to medical devices is relatively small in developed countries due to well-established safety procedures. It is therefore apparent that regulations play a key role at controlling the risk associated to medical devices. [37, xi, 1]

As regulations and standards are such important aspect regarding patient safety, the WHO has taken initiative to harmonize medical device regulations [3, vii]. The work is yet undone, giving many countries freedom to practise their own judgment. Countries with established safety producers are not in the clear either, according the authors mentioned above. Numerous documented accidents give room for improvement regarding responsibilities, as they are far from well-defined when dealing with complex devices. However, authors also noted that European Union did take significant step forward in this matter with the harmonized practices. [37, 325-327]

European Medical Device Regulations is lawful in Finland. It is primarily created from the perspective of the internal market, but it also harmonizes standards between the member states. The Finnish Medical Device Act goes more in detail, but it mainly follows European regulations. [38]

According to Medical Device Directive 93/42/EEC a medical device is [38, Article 1, Section 2]:

> any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
> - diagnosis, prevention, monitoring, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
> - investigation, replacement or modification of the anatomy or of a physiological process,
> - control of conception,
>
> and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; ---

Regarding this thesis, CE-marking is the most significant aspect of EU legislation. It verifies that a medical device complies with the regulation, which consist several requirements depending on the risk class. Among many other, requirements are placed for EMC and the protection of electric shock. First means that other electrical devices near-by the product must not be affected, and the latter is for user safety. Overall, without the CE-marking, it is not allowed to use or sell the device in Finland or the rest of European member states. [38, Article 12]

The most significant aspect of Finnish Medical Device Act (629/2010) for this thesis is the statement in chapter 5, article 24, and section 4. It requires that the maintenance, adjustments and maintaining is done according to the manufacturer's instructions. Sections 1 and 7 of the same article, define that only qualified personnel can use and conduct maintenances to the device. [39]

Lastly, there are two standards from IEC (International Electrotechnical Comisson) for electromechanical testing: IEC 60601-1 and IEC 62353. These are guidelines for testing of medical electrical equipment and medical electrical systems; with defined measurements and limits to ensure safety.

According to Havia Antti, author of thesis which deals with SFS-EN 62353-standard in medical device maintenance (content is identical with IEC 62353), these two standards mostly overlap with each other in guidance and test limits [40, Abstract]. However, Havia noted that IEC 62353 is more focused for the end-user and end-user environment, where IEC 60601-1 is more to the manufacturers and lab environment [40, 1]. Havia also listed the major difference. The most relevant to this thesis is the protective earth test which is done with only 200 mA compared to minimum of 10 A in the older standard [40, 10]. Protective earth means safe measure to protect from electric shock, where touchable parts are connected to the earth. In the case of insulation fail, current will flow through the earth's low potential and trip the fuse.

Other relevant difference in Havia's list is the amount of leakage current measurements, which has come down from five measurements to only two with the newer standard [40, 17]. These two measurements are the device leakage current and the connecting element leakage current. First measures the total current flowing from the parts connected to supply mains to the earth, where high values indicate a problem in

the insulation [40, 21-22]. In practise, currents flowing through casing's connecting parts and connecting elements to the ground are measured.

Second one means unwanted current reaching the patient via patient connection [40, 25]. In this measurement, currents coming to patient connection through supply mains or casing are measured. Actual measuring techniques will be discussed more detailed later on, but Havia made important observation that with direct measurement technique, the device leakage currents are comparable with the older standard [40, 22].

So the four measurements to ensure electrical safety, according to Havia, in standard SFS-EN 62353 are: resistance of protective grounding, device leakage current, connecting element leakage current and insulation resistance [40, 17]. Last one is only one left to be introduced, which is self-explanatory. Resistance is measured from the places which should be insulated from each other, such as casing and supply mains [40, 27].

This thesis will not go through with great detail about the standards, as there are plenty of other theses and literature which solely cover the IEC 62353 standard and its differences to the older IEC 60601-1. The focus in the thesis is in the actual electrical safety measurements that are conducted to Masimo pulse oximeter. This will be discussed in the next chapter.

5 Maintenance of Pulse Oximeter

The previous chapter, as well as the introduction of this thesis, have discussed the risk associated to medical devices and the content of regulations aimed to reduce them. This chapter shifts to the actual measures by which patient safety and reliability of a specific medical device (i.e. pulse oximeter) is improved in accordance to the regulations.

Major influence for next subchapter comes from WHO guideline titled as *Medical equipment maintenance programme overview*. It has been written "to aid a health facility or a national ministry of health to establish or improve a medical equipment maintenance programme" [41, 5].

5.1 Preventive Maintenance

The objective of this thesis is to produce annual maintenance instructions for two pulse oximeters. This type of maintenance is in the category of preventive maintenance, as the main goal is not to fix anything, but to ensure that everything works as described in the user manual. [41, 10]

Value of preventive maintenance is evident. It helps to lower the risk of unexpected failures, increasing patient safety. Furthermore, it expands the lifetime of a device, which saves money. Longer lifetime may be especially achieved if user is delegated to do minor maintenance procedures, as it should create a sense of ownership which is fruitful in handling and upkeep of the device [41, 31]. [41, 10]

When preventive maintenance is accompanied with sufficient documenting and digital records, it provides valuable knowledge. This is true in corrective maintenance, meaning maintenance after a failure, where previously recorded values in preventive maintenances may give insight where the problem lays. [41, 37]

On the other hand, management can make a few valuable calculations from the service history database. These are, for example, the upkeep expenses considering a specific device, effectiveness of preventive maintenance and durability of different parts. Latter comes handy in predicting when specific part is about to fail, so that the maintenance interval can be adjusted accordingly to exchange the specific part before any failure occurs. Additionally, management can increase inventory of that exchange part beforehand, cutting downtime and utilizing possible volume discounts. [41, 13, 19, 32-33, 37]

Lastly, the report form for the annual maintenance was requested to be a checklist. The very reason to create checklist type maintenance procedure is that in that way it is easy to see what was done, and more importantly, it speeds up the maintenance process by cutting time from documentation and service manual reading. [41, 37]

5.2 Masimo Radical Hybrids

Founders of Masimo Corporation, Joe Kiana and Mohammed Diab, invented SET-technology in 1998 [14, 248; 42, 1]. Their first product line of pulse oximeters utilized this technology, being the first pulse oximeter to have accurate readings while patient

moved [43]. Their product, Masimo SET Radical (see figure 13), also won silver award in the 2001 Medical Design Excellence Awards [44].

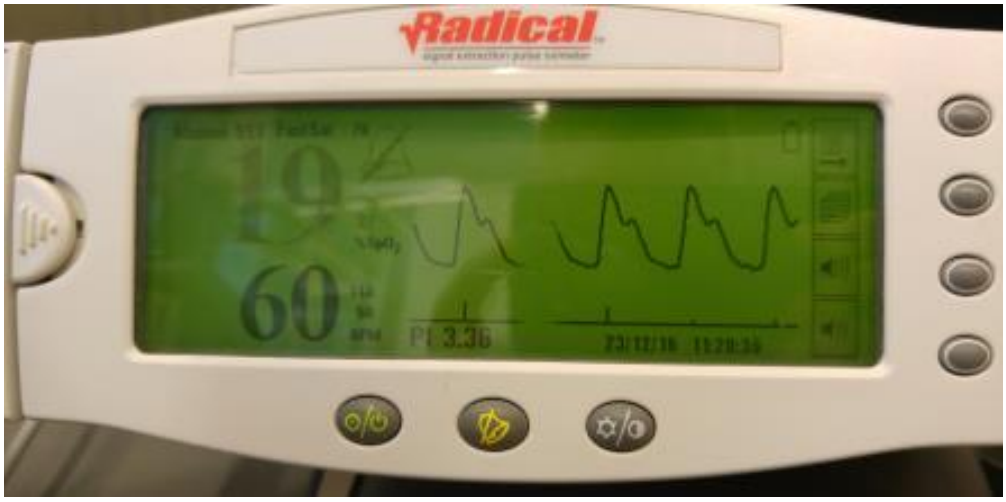

Figure 13. Masimo SET Radical (2003).

As explained in chapter 2.4, Masimo SET Radical is a hybrid, meaning that it consists of the handheld part and the docking station. The information it measures can be seen in figure 13, where oxygen saturation is on the left side (19 %) and pulse is below it (60 BPM). PI of 3.36, on the right side of BPM, indicates arterial pulse signal strength. The device also draws waveform to represent signal quality, visible on the right side of figure 13.

Next radical change to Masimo pulse oximeters came in 2005, when Rainbow technology was released [43]. Having the same SET functionality as previously, it also introduced more wavelengths, allowing the measuring of carboxyhaemoglobin, methaemoglobin and total haemoglobin. Masimo Radical-7 Rainbow is capable of measuring those three, using at least seven different wavelengths [23, section 1, page 3]. Only downsize is that it requires a special sensor for that. The device can be seen in figure 14.

Figure 14. Masimo Radical-7 Rainbow (2011) hybrid in vertical mode, attached to docking station. Note that the device is upright. Text in the screen will turn, if the whole device is turned 90 degrees counter clockwise (default horizontal mode).

As it can be seen from figure 14, there are almost no differences to the older model. Most notable difference is the buttons, where three buttons from the bottom have changed their place to the right side. LCD display has also been updated, but other than that, there are no major changes to the look.

Functionally, the interface is also same. There are new features, as expected with additional measurements, but it is safe to conclude that user would not notice the difference in basic oxygen saturation usage.

5.2.1 Instructions by Manufacturer

Manufacturer has released service manual for Masimo Radical-7. It contains comprehensive instruction how to conduct maintenance for the Radical-7, with additional troubleshooting aid and other information. As Finnish law requires following manufacturer's instructions (see chapter 4), it is therefore strictly followed when constructing the

checklist. However, as the functionality is same with Masimo Radical-7 Rainbow and Masimo SET Radical, only Radical-7 service manual will be used.

The contents of service manual will be divided further in subheadings, where general explanation of each part will be given.

Cleaning

Cleaning is obviously an important part, as spilled blood or other body fluids can pose infection hazard. Manufacturer has given instructions how to properly decontaminate after such incident [45, Section 2.2]. However, WHO manual encourages clinical staff to conduct decontamination, as they have the best knowledge of infection risks [41, 38].

Battery Check

Being a hybrid device, Radical pulse oximeter can be powered with just the battery. If the battery life is severely decreased, it causes a risk. This is the reason that it is usually replaced in the preventive maintenance, so that such a risk can be decreased. [45, Section 3]

Visual Inspection

This requires no additional explanation, as it is the best way to find if something is or is about to break down.

Functionality Tests

In functionality tests, all lights and buttons will be tested. Also the alarms in various instances will be tested, which are the saturation limit, pulse limit and when cable is removed. These procedures ensure that the device works as it should. [45, Section 5]

Testing saturation with a measuring device is also part of the functionality test, which will be discussed more on the chapter 5.2.2.

Electrical Safety

This is the last part, which will be discussed more in depth. Standards have guidelines for conducting electrical safety measures, which are introduced in the end of chapter 4.

Masimo Radical-7 Rainbow and SET Radical are in the protection class 1, meaning basic insulation in which all touchable or internal metallic parts are grounded. Its patient connection is BF-type (Body Float), indicating isolation where only small patient leakage current (i.e. leakage current to the ground) is allowed to flow in the connection [46, 53]. In single fault condition, maximum of 5 milliamps (AC) is allowed to flow through [46, 171].

Electrical safety measurements can be done with the ESA620 Electrical Safety Analyzer from Fluke. It is an electrical safety tester, intended for medical devices, which can be used to measure various things. Among others, such are the resistance and leak currents according to standards. ESA620 is specially built for ECG measuring and its characteristic look comes from ECG connection posts, visible in upper parts of the ESA620 (see figure 15). [47, 1]

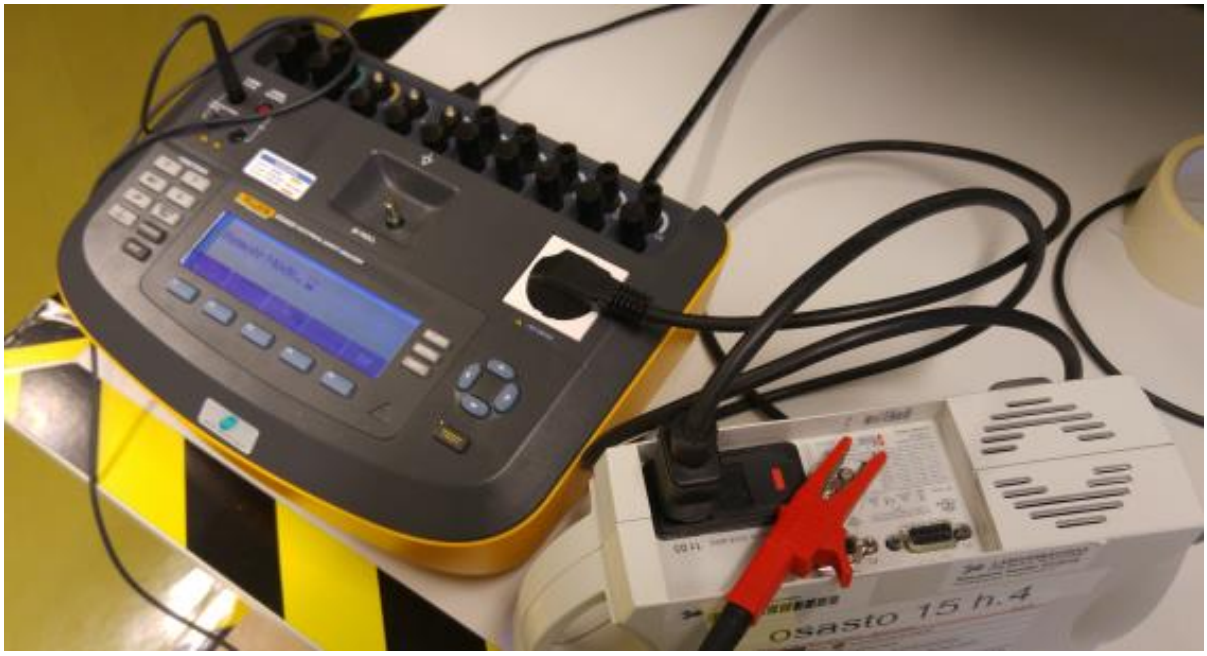

Figure 15. Fluke ESA620 Electrical Safety Analyzer on the left and back of the pulse oximeter on the right. Note: Pulse oximeter is upside down only to allow better picture.

Standard SFS-EN 62353 guides to conduct four different measurements listed at the end of chapter four. These measurements where done with the aid of computer, which was used to control remotely the ESA620. This enabled automation testing according to chosen standard, SFS-EN 62353, leaving user only to connect power cable and test lead between the ESA620 and the device, which is subject to measurement. This eliminates any possibility to user error in the measurement, which in return enhances the reliability of the electrical safety measurements.

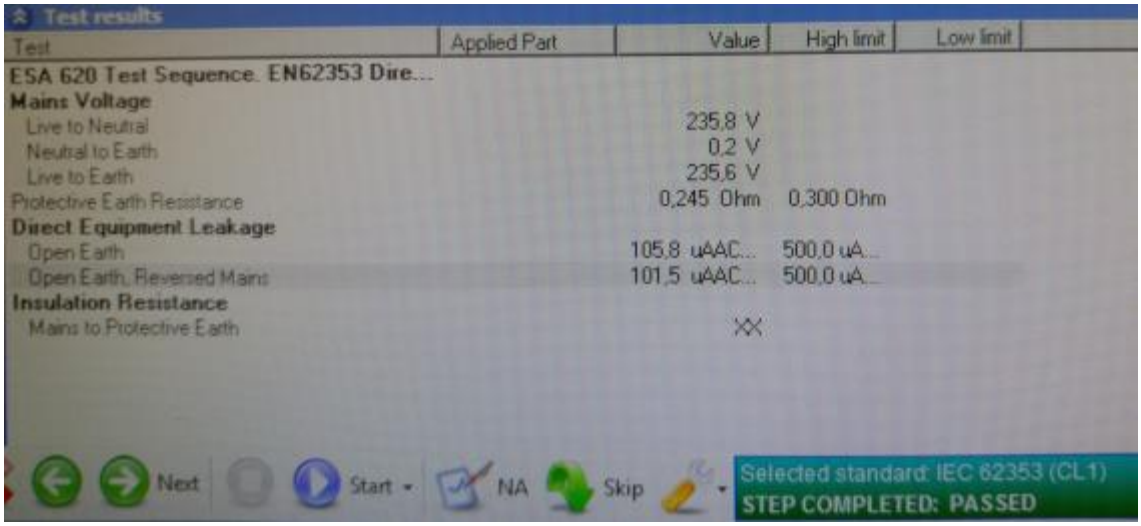

Figure 16. Test results of Fluke ESA 620 in Ansur software.

As what measurements were actually involved in the standard were not many. First there was the measurement of protective earth resistance with a current of 200 mA, where the limit was 300 mΩ. Then, as the Rainbow was class 1 device, leakage current was measured with direct method. Figure below illustrates the connection, where mains were reversed to have two values. Results and limits of all measurement can be seen on figure 16.

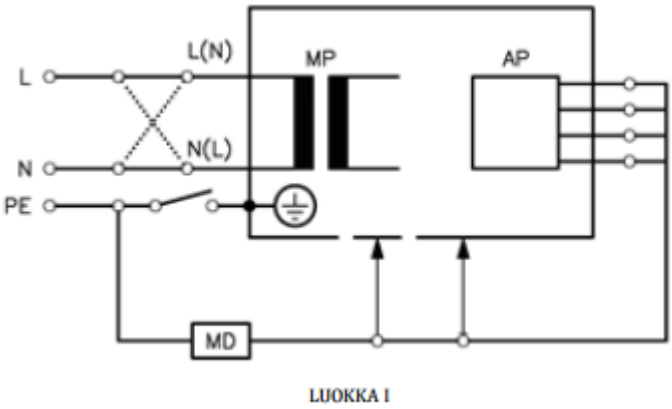

Figure 17. Direct measurement technique for class 1 medical device, copied from SFS [48]. MP stands for power supply unit, AP stands for connecting parts and MD stands for measuring device.

Insulation resistance was not measured, as it was not necessary according to the manufacturer. Standard SFS-EN 62353 also retains it as optional, with a notation that it can be even forbidden by manufacturer [48, 19]. It was also noted in the standard that patient connection leakage current is already part of leakage current measurement, so there is no need for separate measurement. On top of that, manufacturer did not give any instructions about these two measurements, so they can be safely ignored. [48, 29]

5.2.2 Saturation Measurements

Testing saturation is part of functionality test. But as there was no optional Masimo SET tester described in the service manual available, different tool was utilized [45, Section 5]. To see how the measuring device behaves in different saturations, profound testing was conducted.

Masimo Radical-7 Rainbow

The device used to validate pulse oximeter saturation reading was ProSim 8 Vital Signs Simulator. It is a device which can simulate various kinds of physiological parameters: respiration, temperature, blood pressure (invasive and non-invasive), cardiac output and SpO_2 [49, 1]. Additionally, it can be used to test Masimo multi-wavelength Rainbow SET and ECG. As ProSim 8 had R-curve (see figure 9 for more detail) for both Masimo and Masimo Rainbow (see figure 18), it was possible to test saturation values.

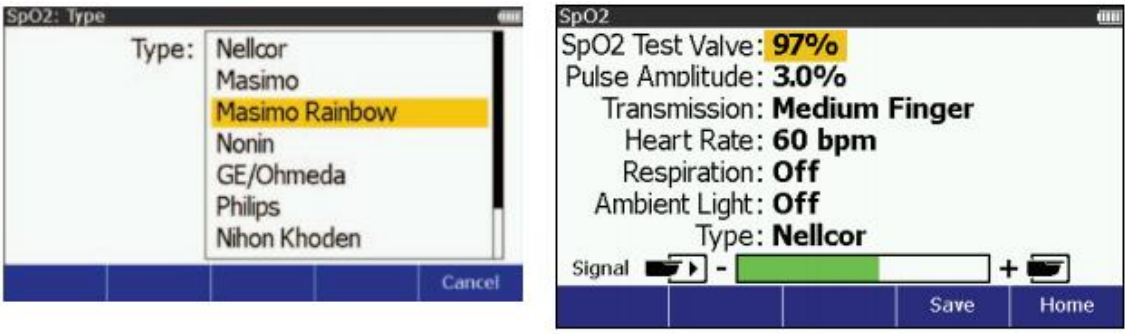

Figure 18. Type selection of SpO_2 and measurement parameters in ProSim 8.

ProSim 8 needs an external optical emitter and detector for SpO_2 measurement to mimic a finger. It attenuates the light according to the R-curve (see figure 9 for more detail), after which it sends the attenuated light back to the receiving LED of the pulse oximeter. This makes it possible to compare in real time the calculated, and the measured saturation values. [49, 52]

The artificial finger can be seen in the figure 19 on the right side, attached to pulse oximeter sensor. In the same figure, values set for ProSim 8 are 92% saturation and 60 bpm (beats per minute). Accordingly, the display of pulse oximeter shows the same values.

Manufacturer of ProSim 8 has stated on their manual that artificial finger is not intended to any other use than to "verify that the electronics within the pulse oximeter probe are functional". Therefore, the tests done in this thesis do not resemble SpO_2 accuracy or the accuracy of the calibration curve, as there is no clinical verification done on that matter. Measurements are purely intended to aid in the selection of sufficient test range to verify functionality. [49, 52]

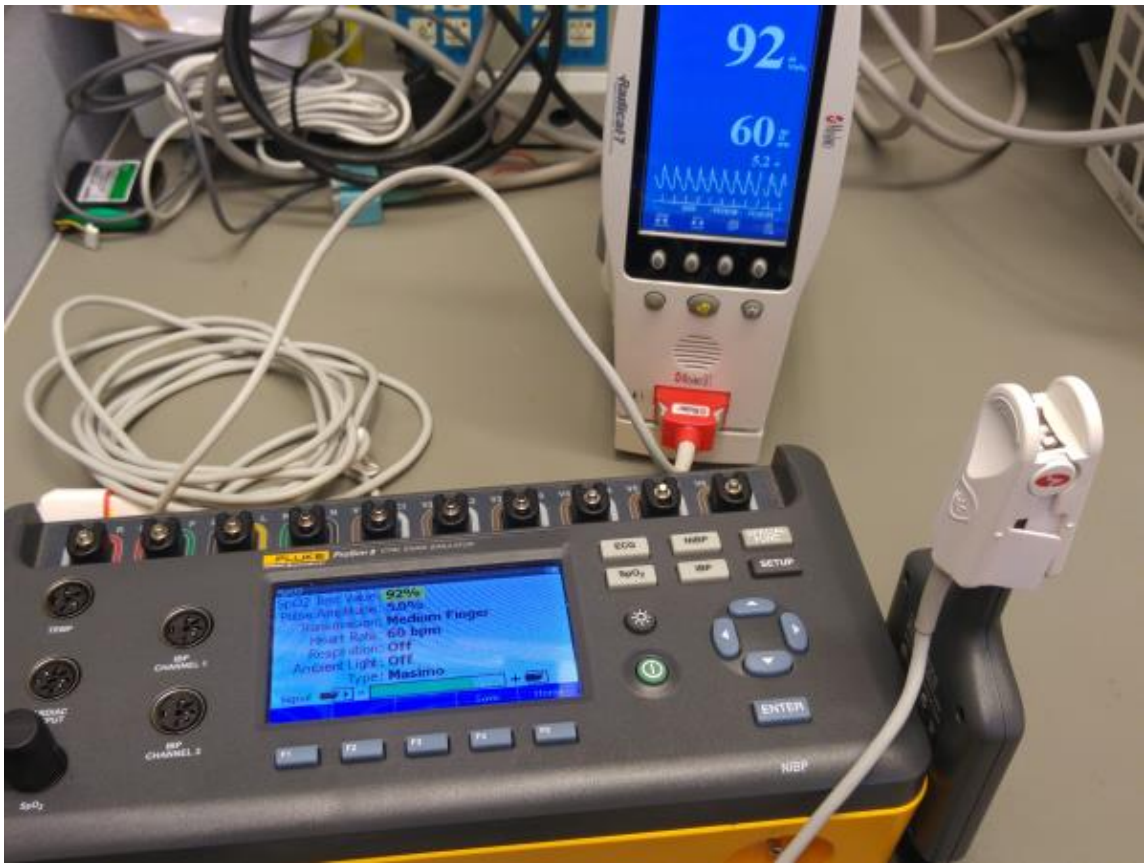

Figure 19. Measurement setting for Radical-7. Below is the ProSim 8, above is the Radical-7 Rainbow.

Five measurement series were done with Fluke ProSim 8 (Serial Number: 2048026) and with Masimo Radical-7 Rainbow (SN: T060920). The bpm was set to 60, while saturation was brought down from 100 % in 2 % increments, all the way to ProSim 8 limit: 30 %. After the measurement was done, devices were both restarted, and the measurement was repeated. The measurement setting can be seen from the figure 19.

Results of the measurement are on the appendix 1, where “Actual” stands for value set in ProSim 8. One column represents one measurement. Difference between the actual value and the measured value is in separate column, with red number colouring.

Masimo SET Radical

As with Rainbow model, saturation measurements were also done to this model. Aberrantly only three series measurement was done, because there was no difference between the measurements on the Rainbow model.

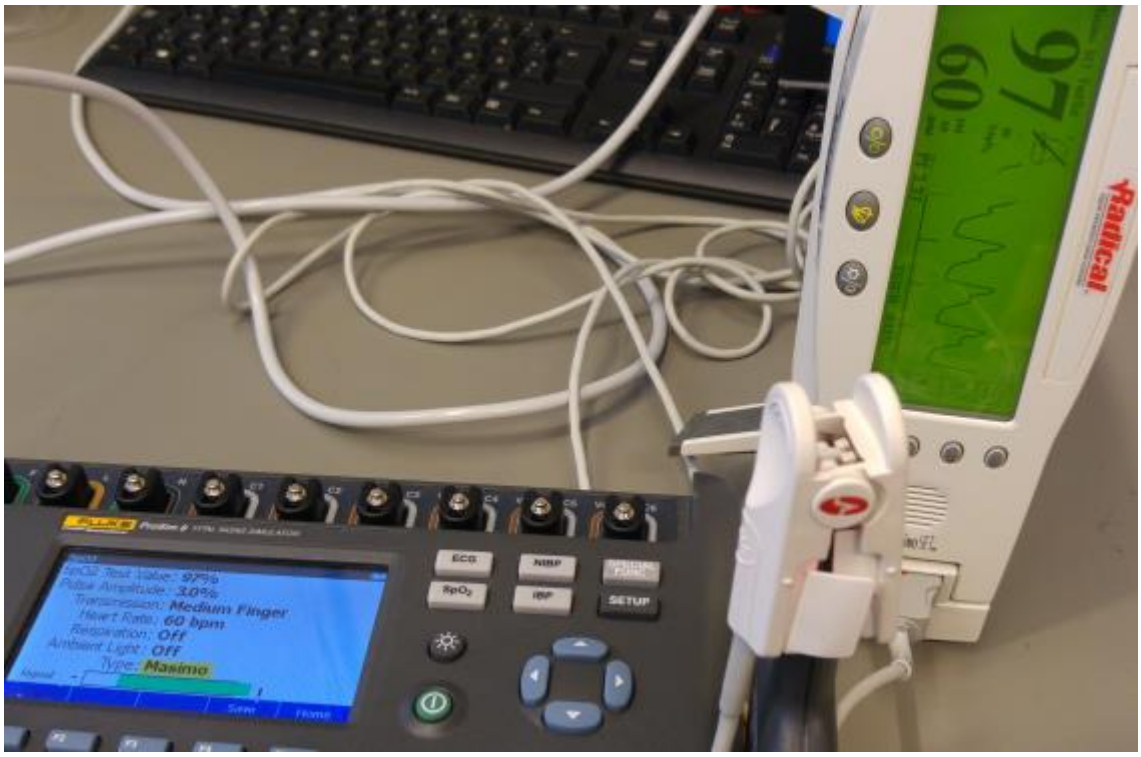

Figure 20. Measurement setting for SET Radical. Below is the ProSim 8 and above is the SET Radical.

The measuring device was the same model as in Rainbow measurements and the measurement setting was also same, visible in figure 20. There was no difference to the measurement technique either. The devices in the measurement were ProSim 8 Vital Signs Simulator (SN: 2799065) and Masimo Radical-7 (SN: 1080550).

Results of the measurement are on the appendix 2. An explanation of the appendix is on the end of chapter 5.1.1.

5.2.3 Results of the Measurements

First notice of the Masimo Radical-7 Rainbow results (appendix 1) is that there is no variation between the separate measurement events. This means that pulse oximeter seems to have high precision (repeatability). Accuracy of the saturation also seems to be according to Masimo's manual, which is ±2% at the range of 70 - 100 % without motion [23, Section 7]. Error comes also from the test device, which is ±1 count, meaning a total of ±3 % [49, 80]. However, as stated in chapter 5.1.1 about the use of ProSim 8, accuracy statements are not valid to make with these measurements. This is fine, as service manual of Radical-7 says that recalibration is not required. Therefore, it

can be stated that the Radical-7 Rainbow pulse oximeter is responding as it is expected to. [45, Section 2]

For the older Masimo SET Radical (appendix 2), conclusions are the same. It is even in the ±3% error margin at the range of 70 - 100 % (no motion). For a device manufactured in 2003, it is a great result. Saturation values below 60 % saturation on the appendix 2 are drastically decreasing. This can be explained by the fact that manufacturer has not made any claim of accuracy; naturally as values below 60 % saturation does not have clinical value.

6 Suggestion for Maintenance Procedure

On the basis of manufacturer's instruction, a checklist was produced. No conclusion was reached with saturation measurements, so the best way is to test manufacturers' promised range of 70-100 %, where maximum error is ±2%. Acquiring an optional Masimo SET tester would also be advisable, as it leaves the sensor out and tests solely the device.

To further improve the maintenance, literature review was done to see if there are any aspects which should be taken in account. Three instances were found, which will be introduced shortly.

Based on two comprehensive studies about the correlation between SpO_2 and SaO_2 in the intensive care unit, one conducted in 2001 [50] and other in 2011 [51], it seems that SpO_2 alarm needs to be set higher to ensure safe limit above 90% SaO_2 value. According to the later study, 92% alarm threshold should be adequate in the intensive care unit.

Milner and Mathews [52] conducted spectrograph analysis for 758 pulse oximeter sensors in use in the UK hospitals. They found out that a total of 169 (22%) sensors were not corresponding with manufacture specified SpO_2 accuracy at the range of 70 % to 100 %.

Study conducted by Crede and colleagues [53] in 2014 found out that the most common point of failure in pulse oximeter probes was the probe wiring. That was the case

for over half of the probes sent to repair shop. Further, the neonatal wrap version was most commonly broken at the strap.

The recommendation of the first two studies, raising saturation alarm limit to 92 %, should be checked with intensive care units if necessary. However, this thesis did not survey user knowledge in any way and current procedures with alarm limits are unknown.

Study of Milner and Mathews published in 2012 is directly a matter of preventive maintenance. As discussed in chapter 5.2.2, currently used method to test sensors was limited to functionality testing only. This method may overlook incipient faults of sensors, especially when considering LEDs. The study of Milner and Mathews indicates that acquiring a spectrometer has benefits, but as stated in the study, age or time of usage of the sensors were unclear. This means that the problem might be corrected by following strictly the lifetime of sensors, specified by manufacturer. Also, it was not specified which types of pulse oximeter sensors were tested. Obliviously there are quality differences between different price ranges. However, as study also implies that functionality testers were used in UK hospitals, further investigation if spectrometer is really needed, should be conducted.

Crede and colleges study was about the most common point of failure considering pulse oximeter sensors. As wiring was the most common to break, and with neonatal wrap probes the strap, extra care is recommended when visually inspecting the sensors.

Lastly, experienced technician found out by practice that connection between handheld and docking station had usually contact failures due to stained dirt. Also the locking mechanism was found out to be among the common parts to break. Inspecting of them both was already routine practice, so no further action is recommended.

7 Conclusion

Goal of this thesis was to improve maintenance for two Masimo pulse oximeters, by producing annual maintenance instructions. Legal boundaries obligated to follow manu-

facturer’s instructions and to have electrical safety measurements according to standard. Literature was also reviewed to find more ways to improve overall maintenance.

As a result of this thesis, a checklist was made based on Masimo’s manual, former maintenance practise and literature review. In structure it followed previously made checklist for different device, having detailed instructions for each part. Literature review on the other hand raised a question if acquiring spectrometer is needed. Also, it was found that to have safe limit of 90 % saturation for intensive care patients, pulse oximeter alarm threshold needs to be raised to 92 % saturation. These findings have a direct effect to patient safety, so the relevance of them is recommended to be investigated further. Moreover, proper user knowledge will, without doubt, prolong the service life of pulse oximeter.

This thesis was limited to two pulse oximeters of the same manufacturer. More pulse oximeters could have been fruitful to test, especially if spectrometer would have been available. This would have allowed making a more general checklist, and answered the question if spectrometer is really needed. However, as many pulse oximeters have same basic features and structure, produced checklist could be trialled for the other manufacturers’ devices as well.

References

1 European Commission. Guidelines on a Medical Devices Vigilance System. Unit F3- Cosmetic and Medical Devices; 2009.

2 World Health Organization. Using the Pulse Oximeter Tutorial 2 - Advanced. WHO; 2011.

3 World Health Organization. Medical Device Regulations Global overview and guiding principles. WHO; 2003.

4 World Health Organization. Pulse Oximetry Training Manual. WHO; 2011.

5 Bjålie JG, Haug E, Sand O, Sjaastad ØV, Toverud KC. Ihminen fysiologia ja anatomia. Porvoo: WSOY; 1999.

6 Tortora GJ, Derrickson BH. Principles of Anatomy and Physiology: Maintenance and Continuity of the Human Body, volume 2. 12th ed. New York: John Wiley & Sons; 2009.

7 Hitachi Medical Systems America, Inc. Circulatory System [online]. URL: http://www.hitachimed.com/self-learning-activity/docs/MRAImagingModule/images/figure41.jpg. Accessed: 7 December 2016.

8 Darling, David. Blood Vessel [online]. URL: http://www.daviddarling.info/encyclopedia/B/blood_vessel.html. Accessed: 8 December 2016.

9 Dreamstime. Hemoglobin [online]. URL: https://thumbs.dreamstime.com/x/hemoglobin-23464646.jpg. Accessed: 8 December 2016.

10 Nienstedt W, Hänninen O, Arstila A, Björkqvist S-E. Ihmisen fysiologia ja anatomia. 18th ed. Helsinki: WSOY; 2009.

11 Ganong WF. Review of Medical Physiology. 21st ed. San Francisco, CA: The McGraw-Hill Companies; 2003.

12 Yukon-Koyukuk School District. Chapter 8 Lesson 3 “How We Breathe” [online]. URL: http://ykonline.yksd.com/distanceedcourses/Courses/Biology/lessons/ThirdQuarterLessons/Chapter08/8-3/images/alveolus.gif. Accessed: 11 December 2016.

13 General Practice Notebook. Oxygen-Haemoglobin Dissociation [online]. URL: http://www.gpnotebook.co.uk/oxygen-dissociation%20curve.jpg. Accessed: 12 December 2016.

14 Baura GD. Medical Device Technologies. Waltham, MA: Academic Press; 2012.

15 Duodecim. Akuuttihoidon laitteet. Helsinki: Kustannus Oy Duodecim; 2013.

16 Wijshoff RWCGR, Michi M, Veen J, Van der Lee AM, Aarts RM. Reducing motion artifacts in photoplethysmograms by using relative sensor motion: phantom study. J. Biomed. Opt. 17(11), 117007 (Nov 29, 2012).

17 Kennedy SM. An Introduction to Pulse Oximeters: Equations and Theory [online]. University of Wisconsin-Madison; April 2015. URL: http://www.imt.liu.se/FoUtb/kurser/oxikurs/restricted/pulseoximetersequationsandtheory-stephenkennedy.pdf. Accessed: 12 December 2016.

18 Fouzas S, Priftis KN, Anthracopoulos MB. Pulse Oximetry in Pediatric Practice. Pediatrics. 2011 Oct;128(4):740-52.

19 South Tees Hospitals UK. COHb & MetHB [online]. URL: https://www.southtees.nhs.uk/services/pathology/tests/methaemoglobin-methb/. Accessed: 12 December 2016.

20 University of Texas Libraries. Molar Absorption Coefficients [online]. URL: https://www.lib.utexas.edu/chem/info/molabscoeff.html. Accessed: 4 February 2017.

21 Oak S-S, Aroul P. How to Design Peripheral Oxygen Saturation (SpO2) and Opctial Heart Rate Monitoring (OHRM) System Using the AFE4403. Texas Instruments; 2015.

22 Baheti DK, Laheri VV, editors. Understanding Anesthetic Equipment & Procedures: A Practical Approach. New Delhi: Jaypee Brothers Medical Publishers; 2015

23 Masimo. Radical-7 Signal Extraction –pulssioksimetri & Rainbow –tekniikka Käyttöopas. Irvine, CA: Masimo Corporation; 2008.

24 Emergency Medical Products, Inc. Pulse Oximeter Sensors [online]. URL: http://www.buyemp.com/category/pulse-oximeter-sensors/. Accessed: 17 February 2017.

25 Cha, Anthony YK. Biomedical Device Technology: Principles and Design. 2nd ed. Illinois: Charles C. Thomas Publisher; 2016.

26 General Electric Company. SpO2 performance in clinical motion conditions Comparison study [online]. 2012. URL: http://www3.gehealthcare.co.uk/~/media/downloads/uk/product/clinical%20consumables/spio2/clinical%20emea%20english%20white%20paper%20spo2%20performance%20in%20clinical%20motion%20conditions%2009-2012.pdf?Parent=%7BECFA4AD9-A486-4508-B42C-9C76454DCF31%7D. Accessed: 17 February 2017.

27 Divatia JV. Pulse oximetry: Mandatory for sedation during regional/local Anaesthesia (but watch for hypoventilation!). Indian J Anaesth 2011;55:217-9.

28 American Society of Anaesthesiologists. Standards for Basic Aesthetic Monitoring [online]. 28 October 2015. URL: http://www.asahq.org/~/media/Sites/ASAHQ/Files/Public/Resources/standards-

guidelines/standards-for-basic-anesthetic-monitoring.pdf. Accessed: 14 December 2016.

29 Pretto JJ, Roebuck T, Beckert L, Hamilton G. Clinical use of pulse oximetry: Official guidelines from the Thoracic Society of Australia and New Zealand. Respirology 2014;19:38–46.

30 World Health Organization. Surgical Safety Checklist [online]. WHO; 2009. URL: http://apps.who.int/iris/bitstream/10665/44186/2/9789241598590_eng_Checklist.pdf. Accessed: 14 December 2016.

31 European Comission. Electromagnetic Compatibility (EMC) Directive [online]. URL: https://ec.europa.eu/growth/sectors/electrical-engineering/emc-directive_en. Accessed: 14 December 2016.

32 Jubran A. Pulse oximetry. Critical Care. 1999;3(2):R11-R17.

33 Hay WW Jr, Rodden DJ, Collins SM, Melara DL, Hale KA, Fashaw LM. Reliability of conventional and new pulse oximetry in neonatal patients. J Perinatol 2002: Jul-Aug;22(5):360-6.

34 Masimo Corporation. Signal Extraction Technology [online]. Masimo; 2008. URL: http://www.masimo.fr/pdf/whitepaper/LAB1035R.pdf. Accessed: 14 December 2016.

35 Milner QJW, Mathews GR. An assessment of the accuracy of pulse oximeters. Anaesthesia 2012;Feb;67:396–401.

36 Ralston AC, Webb RK, Runciman WB. Potential Errors in Pulse Oximetry. I. Pulse oximeter evaluation. Anaesthesia 1991; Mar;46(3):202-6.

37 Jacobson B, Murray A. Medical Devices: Use and Safety. Edinburgh: Churchill Livingstone; 2007.

38 European Union. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [online]. URL: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31993L0042. Accessed: 23 November 2016.

39 Finlex. 629/2010 Laki terveydenhuollon laitteista ja tarvikkeista [online]. Naantali, 24 June 2010. URL: http://www.finlex.fi/fi/laki/alkup/2010/20100629. Accessed: 13 December 2016.

40 Havia, Antti. 2011. SFS-EN 62353 -standardi lääkintälaitehuollossa. Thesis, Bachelor. Applied Science of Metropolia, Electrical Engineering. URL: https://www.theseus.fi/bitstream/handle/10024/39498/Havia_Antti.pdf?sequence=1. Accessed: 13 December 2016.

41 World Health Organization. Medical Equipment Maintenance Programme Overview WHO Medical Device Technical Series. URL: http://apps.who.int/medicinedocs/documents/s21566en/s21566en.pdf. WHO, Switzerland; 2011.

42 Masimo Corporation. Masimo Signal Extraction Technology [online]. 2001. URL: http://www.masimo.com/pdf/technology/lab1959.pdf. Accessed: 14 February 2017.

43 Masimo Corporation. Masimo Recognized as Top 10 Innovator in Medical Device Industry [online]. 28 June 2006. URL: http://www.masimo.cn/news/2006.htm#06282006. Accessed: 14 February 2017.

44 UBM Canon. 2001 Winners and their Suppliers [online]. URL: http://www.devicelink.com/expo/awards/awards/index.php?catId=-1&year=2001&view=View&c=off. Accessed: 14 February 2017.

45 Masimo Corporation. Radical-7 Service Manual (2007). Masimo, Irvine; 2007.

46 International Electrotechnical Commission. IEC 60601-1:2005. 3rd ed. IEC, Switzerland; 2005.

47 Fluke Biomedical. ESA520 Electrical Safety Analyzer. URL: http://support.fluke.com/biomedical/Download/Asset/3086339_6150_ENG_C_W.PDF. Accessed: 10.2.2016.

48 Suomen Standardisoimisliitto SFS. SFS-EN 62353:2014. Medical electrical equipment – Recurrent test and test after repair of medical electrical equipment. 2nd ed. Helsinki: SFS ry. 2015.

49 Fluke Biomedical. ProSim 6/8 Vital Signs Simulator Users Manual. Rev. 2, 9/11. Fluke; 2011.

50 Louw A, Cracco C, Cerf C et al. Intensive Care Med 2001;Oct;27:1606-1613.

51 Kanai R, Moriyama K, Kohyama T, Yorozu T. Reliability of Oxygen Saturation by Pulse Oximeter to Detect Hypoxemia of Patients in the Intensive Care Unit. Anesth Analg 2012;113;S-159.

52 Milner QJW, Mathews GR. An assessment of the accuracy of pulse oximeters. Anaesthesia 2012;Feb;67:396–401.

53 Crede S, Van der Merwe G, Hutchinson J et al. “Where do pulse oximeters probes break?”. J Clin Monit Comput 2014;28:309-314.

Measurement Records of Radical-7 Rainbow

HELSINGIN AMMATTIKORKEAKOULU/ ***Tekniikan ja liikenteen toimiala/mittauspöytäkirja by Esa Peljo***	_25__ / _11__ 201 _6_ _____
Masimo Radical 7 Rainbow N:o ___1___	Tehneet Luokka _____
_____SN: T060920 _____	____Piiroinen Stefan___ _____
_____Manufactured in 2011_____	_____ _____
_____	_____ _____

Kaaviot: ----------

							Difference	Comments:
Actual		**1**	**2**	**3**	**4**	**5**		Five measurments. Measurements are
100		100	100	100	100	100		SpO2 in percentage.
98		98	98	98	98	98		
96		96	96	96	96	96		BPM was set to 60 in measurments.
94		94	94	94	94	94		
92		92	92	92	92	92		
90		90	90	90	90	90		
88		88	88	88	88	88		
86		86	86	86	86	86		
84		84	84	84	84	84		
82		82	82	82	82	82		
80		80	80	80	80	80		
78		78	78	78	78	78		
76		75	75	75	75	75	-1	
74		73	73	73	73	73	-1	
72		71	71	71	71	71	-1	
70		69	69	69	69	69	-1	
68		67	67	67	67	67	-1	
66		65	65	65	65	65	-1	
64		63	63	63	63	63	-1	
62		61	61	61	61	61	-1	
60		59	59	59	59	59	-1	
58		56	56	56	56	56	-2	
56		54	54	54	54	54	-2	
54		52	52	52	52	52	-2	
52		50	50	50	50	50	-2	
50		48	48	48	48	48	-2	
48		46	46	46	46	46	-2	
46		44	44	44	44	44	-2	
44		42	42	42	42	42	-2	
42		39	39	39	39	39	-3	
40		37	37	37	37	37	-3	
38		35	35	35	35	35	-3	
36		33	33	33	33	33	-3	
34		31	31	31	31	31	-3	
32		29	29	29	29	29	-3	
30		26	26	26	26	26	-4	

Measurement Records of SET Radical

HELSINGIN AMMATTIKORKEAKOULU/ ***Tekniikan ja liikenteen toimiala/mittauspöytäkirja by Esa Peljo*** Masimo SET Radical N:o ___2___ _____SN: 108550 _____ _____Manufactured in 2003_____ _____	_23__ / _12__ 201 _6_ _____ Tehneet Luokka _____ ____Piiroinen Stefan___ _____ _____ _____ _____ _____

Kaaviot: ----------

								Comments:
Actual		**1**	**2**	**3**			**Difference**	Three measurments. Measurements are
100		100	100	100				SpO2 in percentage.
98		98	98	98				
96		96	96	96				BPM was set to 60 in measurments.
94		94	94	94				
92		92	92	92				
90		90	90	90				
88		88	88	88				
86		85	85	85			-1	
84		83	83	83			-1	
82		81	81	81			-1	
80		79	79	79			-1	
78		77	77	77			-1	
76		74	74	74			-2	
74		72	72	72			-2	
72		70	70	70			-2	
70		68	68	68			-2	
68		66	66	66			-2	
66		63	63	63			-3	
64		61	61	61			-3	
62		59	59	59			-3	
60		56	56	56			-4	
58		54	54	54			-4	
56		52	52	52			-4	
54		50	50	50			-4	
52		47	47	47			-5	
50		45	45	45			-5	
48		42	42	42			-6	
46		39	39	39			-7	
44		36	36	36			-7	
42		35	35	35			-7	
40		32	32	32			-8	
38		30	30	30			-8	
36		27	27	27			-9	
34		24	24	24			-10	
32		22	22	22			-10	
30		20	20	20			-10	