CZECH TECHNICAL UNIVERSITY IN PRAGUE

FACULTY OF BIOMEDICAL ENGINEERING

Department of Biomedical Technology

Effect of measurement site temperature on perfusion index

Bachelor Thesis

Study program: Biomedical and Clinical Technology

Study branch: Biomedical Technician

Bachelor thesis supervisor: MUDr. Lenka Horáková

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BACHELOR‘S THESIS ASSIGNMENT

I. PERSONAL AND STUDY DETAILS

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II. BACHELOR’S THESIS DETAILS

Bachelor’s thesis title in English:

Effect of measurement site temperature on perfusion index

Bachelor’s thesis title in Czech:

Vliv teploty místa měření na perfuzní index

Guidelines:

Analyze the perfusion index (PI) derived pulse oximetry. Conduct an experiment for analysis of the performance of PI during changes of temperature of the measurement body site. Use the PI measured by advanced pulse oximeters manufactured by the company MASIMO.

Bibliography / sources:

[1] Rafl, J., Kulhanek, F., Kudrna, P., et al., Response time of indirectly accessed gas exchange depends on measurement method, Biomedical Engineering / Biomedizinische Technik, 2017, doi:10.1515/bmt-2017-0070
[2] Walter Boron, Emile L. Boulpaep, Textbook of Medical Physiology, ed. 2nd, Elsevier, 2009, ISBN 978-1-4160-3115-4
[3] Horakova L., Kudrna, P., Roubik, K., Dynamic changes of perfusion index during hypoxemia and hypercapnia in outdoor experiments, International Conference on e-Health and Bioengineering (EHB), ročník 1, číslo 2021, 2021

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DECLARATION

I hereby declare that I have completed this thesis having the topic “Effects of cold and warm environment on PI” independently, and that I have attached an exhaustive list of citations of the employed sources.

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

In Kladno 18.05.2023 …..…….…….....

Abdulrahman Mahmoud Shaat

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I would like to express my gratitude to my extraordinary supervisor MUDr. Lenka Horáková. for her huge and patient support with my project. Her skills and the way she was digesting the topic for me is truly astonishing. I am very proud and fortunate to have an opportunity to work with such a great mind that cares about my work so much and who responds to any questions regardless of their difficulty.

Abstract

The aim of the bachelor thesis was to determine the effect of hand temperature on the perfusion index (PI) parameter. The perfusion index is a parameter derived from pulse oximetry and is clinically used in intensive care and anaesthesia.

The effect of the temperature was examined in a randomized cross-over non-blinded study on eleven healthy subjects, four females and seven males. Each participant underwent both testing phases, cold and warm, in a random order with sufficient recovery time between phases. In the cold phase, ice bags were applied on the tested hand, during the warm phase, heating blankets instead. The perfusion index was measured on the tested hand and simultaneously on the other (reference) hand.

The main finding of the thesis is that the perfusion index is affected and significantly decreased when the measurement site is exposed to cold environment and increased when the measurement site is exposed to warm environment

Key Words:

Perfusion index, Hypothermia, Hyperthermia

Table of Contents

List of symbols and abbreviations

List of Symbols

Symbol	Units	Meaning
A	-	Absorbance
ε	I/mol/cm	Molar attenuation coefficient
c	M	Molar concentration
I	m	Distance
PI	%	Perfusion index
Ip	-	Absorption of the pulsatile component
Inp	-	Absorption of the non-pulsatile component
$EtCO_2$	mmHg	Carbon dioxide at the end of exhalation
SpO_2	%	Blood oxygen saturation
λ	m	Wavelength

List of Abbreviations

Abbreviation	Meaning
CO2	Carbon dioxide
LED	Light emitting diode
Hb	Hemoglobin
O_2Hb	Oxyhemoglobin
SaO_2	Arterial blood oxygen saturation
PaO_2	Partial pressure of oxygen in blood
COHb	Carboxyhemoglobin
MetHb	Methemoglobin

1 Introduction

With the advancement of modern technology, healthcare has made significant progress in the ability to diagnose and treat patients, as for today there are many different tools and techniques that health care providers use to precisely diagnose and monitor a patient's health. Measurements of the body's most fundamental processes, such as heart rate, blood pressure, body temperature, and breathing rate are referred to as vital signs. These measurements are crucial health indicators that aid doctors in spotting potential issues or alterations in a patient's condition.

Hospitals monitors are devices that continuously and periodically measure and display vital signs which are a key indicator to the patient's physiological state, and One of these vital signs is oxygen saturation which is the percentage of oxygen in the blood that is measured by a Pulse oximeter. The perfusion index (PI) was first introduced by Masimo in 1995. Since then, a large number of devices that can measure this parameter have become available on the market. The measurement of PI is a feature of some more advanced pulse oximeters. These devices are available in various forms, including versions for use in clinical settings such as anaesthesiology and intensive care, and versions for use in the field or for home care, such as those manufactured by Masimo.

The goal of this diploma thesis is to shed light on the connections between the perfusion index and other parameters. The initial section of the thesis outlines the fundamental concepts and physical principles involved. Afterwards, an experiment is conducted with the objective of determining the impact of cold and warm environment on the measurement sites for the perfusion index, where the last part will be devoted for the processing and the evaluation of data from the experiment.

1.1 Pulse oximeter

A pulse oximeter is a non-invasive medical device that measures the oxygen saturation level in a patient's blood, pulse oximeter devices use light sensors to investigate the oxygen saturation level and display the saturation level in percentages, normal oxygen saturation levels range from 95% to 100% where oxygen saturation levels below 90% indicates a lack

of oxygen in the blood and indicates a serious medical condition. The physical principle of pulse oximeters is based on Lambert-Beer Law that states the absorbance of a solution is directly proportional to the concentration of the absorbing species in the solution and the path length through which the light travels. In pulse oximetry the blood is considered as a homogenous substance. The mathematical equation for the Lambert-Beer Law is:

$$A = \varepsilon \cdot c \cdot l,$$

Where A is the absorbance, ε is the molar absorptivity (a property of the absorbing species), c is the concentration of the absorbing species, and I is the path length of the light through the solution.

The two physical principles that form the basis of pulse oximetry are the existence of a pulsatile signal produced by arterial blood that is largely independent of non-pulsatile arterial blood, venous and capillary blood, and other tissues, and the second is the fact that O_2Hb and reduced Hb have different absorption spectra [1].

speaking of oximeters and LEDS, pulse oximeter consists of two light-emitting diodes (LEDs) that are used to produce light at a wavelengths of 660 nm (red) and 940 nm (infrared). Because O_2Hb and Hb have distinct absorption spectra at these specific wavelengths, these two wavelengths are utilized. where O_2Hb absorbs less light than Hb in the red zone, while the opposite happens in the infrared region.

The pulse oximeter's digital microprocessor stores the calibration algorithm after the ratio of absorbencies at these two wavelengths is experimentally calibrated using volunteers' direct measurements of arterial blood oxygen saturation (SaO_2) [2-3].The calibration curve is utilized to produce the pulse oximeter's estimated arterial saturation (SpO_2) during future use. Most pulse oximeters also provide a plethysmographic waveform, which can assist physicians discern a false signal from the real signal in addition to the digital readout of oxygen saturation.

The limitations of pulse oximeters might lead to inaccurate results Table 1.1 [4]. According to the O_2Hb dissociation curve, pulse oximeters detect SaO_2, which is physiologically linked to arterial oxygen tension PaO_2. In individuals with high baseline PaO_2 values, oximetry is rather insensitive in identifying the onset of hypoxemia due to the sigmoid form of the O2Hb dissociation curve [5].

Only two light wavelengths are used in pulse oximeters, and as a result, only two chemicals, Hb and O_2Hb, can be distinguished. Four wavelengths are needed to calculate the "fractional SaO_2" when COHb and MetHb are also present [6-7]. Oximetry consistently overestimated the genuine SaO_2 in the presence of increased COHb levels by the quantity of COHb present [8]. Inaccurate oximetry results may also result from elevated MetHb levels [9].

In non-hypoxemic patients with acute anemia, pulse oximetry was accurate in measuring O_2 saturation with a bias of only 0.53%, indicating that anemia does not appear to impact the accuracy of the test [10]. However, compared to a control group of patients without sickle cell anemia, patients with sickle cell anemia who presented with an acute vaso-occlusive crisis had a mean pulse oximetry bias of 4.5% (in some patients, it was as high as 8%). Pulse oximetry accuracy is unaffected by severe hyperbilirubinemia (mean bilirubin, 30.6 mg/dl) [11-12].

Table 1.1: limitations of Pulse Oximetry[4]

Ambient light	Low perfusion state
Anemia	Dyes nail polish
False alarms motion artifacts	Carboxyhemoglobin and Methemoglobin

1.2 Perfusion index (PI)

Perfusion index (PI) is a measure of the amount of blood through tissues in a specific body part, usually on a finger or a toe, this blood flow through the tissues is measured by a Pulse

Oximeter. (PI) is a well-known measure for assessing perfusion changes in peripheral tissues. (PI) is determined as the ratio of the pulsatile to non-pulsatile signal amplitudes of the plethysmography waveform's infrared signal. to calculate PI. The amount of infrared (940 nm) light absorbed by a pulse oximeter determines both signals [13]. The sympathetic reaction to noxious stimuli can be assessed using the pulse oximetric waveform. However, a number of variables, including age, sex, and peripheral perfusion, are known to have an impact on the accuracy of the data produced by pulse oximetry. Moreover, pulse oximetry provides a non-invasive choice for impartially assessing pain perception. It is well established that unpleasant stimuli elicit different autonomic reactions based on a person's age and gender [14].

The PI can range from 0.02 to 20; the greater the PI, the better the perfusion. The metric (PI) is derived as a ratio of the 3-5 s pulse amplitude to the non-pulsatile 30 s average, which may hide extremely fast changes in perfusion [15].

Perfusion pressure is what keeps blood flowing to every part of your body. Lack of perfusion pressure in some parts of your body, could lead to cardiac and circulatory problems or life-threatening conditions. Perfusion tests that don’t involve internal organs usually start with pulse oximetry. This test is carried out using a pulse oximeter that calculates your blood oxygen level to check if there’s enough blood perfusion in an area. This is called the oxygen saturation, This parameter is important as its used to monitor the circulation and oxygenation of patients in intensive care units, operating rooms, and emergency departments as for that its being used more and more in clinical practices.

2 State of the art

Monitoring of Perfusion index is mostly employed in anaesthesia, where increasing PI is connected with vasodilation owing to anaesthetic action and decreasing PI indicates insufficient analgesia. Furthermore, during localized anaesthesia, changes in the perfusion index can be utilized to detect vasodilation produced by local anaesthetics [16]**.**

One of the most important effects on the pulse oximetry, perfusion index (PI), that should be taken into consideration is cold and warm environment, so in order to know how the cold and warm environment have effect on this parameter, based on the sources found an Outdoor experiment imitating respiration beneath avalanche snow was conducted to develop an international criterion for resuscitation of buried avalanche victims. One of the challenges Horáková et al. faced during this study is the accuracy of the pulse oximetry, as well as the performance of pulse oximeters as they have many well-known limitations, which includes low perfusion of the monitored tissues that is caused by the cold environment. Based on the resources found, the degree of redistribution of body heat from the central to the peripheral compartment varies depending on the peripheral perfusion status, PI may be connected with variations in body temperature during general anaesthesia. As a result, the goal of this found study resource is to assess the relationship between the PI and the development of intraoperative hypothermia during general anaesthesia. The source study data suggests that PI is connected to both body temperature and perfusion state, implying that perfusion status should be addressed in body temperature control. There is various reasons why low PI might cause hypothermia. Early hypothermia under general anaesthesia is produced primarily by the transfer of body heat from the central to peripheral compartments as a result of vasodilation after anaesthetic administration. The degree of redistribution of body heat may be influenced by the peripheral perfusion status, which varies across individuals and resulting in a gradient difference in temperature between the central and peripheral compartments. Low peripheral perfusion can result in low peripheral body temperature, reducing total core body temperature. The purpose of this research paper is to evaluate the warm and cold environments effects on perfusion index parameter by conducting an experiment that will be narrated in details [17].

One of the interesting links is the relation between tissue hypoxia and impaired organ perfusion recognition that could help doctors to prevent organ failure. For example, Skin blood flow slows during circulatory shock to protect important organ perfusion. As a result, the skin becomes cold, pale, sweaty, and mottled [18], which are clinical symptoms of inadequate peripheral perfusion. In order to detect insufficient perfusion in critically sick patients, indexes of peripheral perfusion have been utilized Clinical indicators, the central-to-toe temperature differential [19-20-21], and methods like laser Doppler and capillary microscopy can all be used to measure peripheral perfusion [22]. Recently, it has been proposed that variations in peripheral perfusion can be detected in the pulse oximetry signal. Additionally, peripheral perfusion has been linked to the pulse oximetry signal's ratio of the pulsatile to non-pulsatile component. Considering that every operating room and intensive care unit has a pulse oximeter [23]**.** Another interesting aspect is the relationship between the PI and perioperative hypothermia. The risk of surgical morbidity and mortality is increased by perioperative hypothermia [24-25-26]. Perioperative hypothermia affects 50–90% of patients on average [27]. The peripheral rapid drop in body temperature occurs during the first hour of general anaesthesia as a result of anaesthetic-induced peripheral vasodilation, which redistributes body heat from the central to the peripheral perfusion index [28],to find the relationship between PI and the body temperature, lee and his colleagues made a study and In this study, it was found that a low pulse index (PI) at the start of surgery was linked to the development of hypothermia during the procedure [29]. The results suggest that PI, which reflects both body temperature and blood flow, may be important in managing body temperature. It is believed that low PI can contribute to hypothermia during surgery due to the dilation of blood vessels caused by anaesthetic drugs, which can shift heat from the core of the body to the periphery and potentially lower overall body temperature. This process may be influenced by the individual's peripheral perfusion, or blood flow, which can vary among patients and impact the temperature difference between the core and periphery of the body. A reduced peripheral perfusion can lead to a lower peripheral body temperature and a decrease in core body temperature. Therefore, Patients with low peripheral to central temperature gradients (as indicated by low peripheral perfusion index, or PI) may experience greater reductions in core temperature. This study also found that patients with lower baseline body temperatures

tended to have lower baseline PIs. However, the relationship between PI and hypothermia was stronger than the relationship between baseline body temperature and hypothermia (as indicated by the higher odds ratio for PI compared to baseline body temperature) [29]. Moving on to the relationship between pain and perfusion index where There is a relationship between pain and perfusion index in that pain can affect perfusion which is A common side effect for critically ill patients. This is a shared and neglected issue amongst many patients. As with anything left untreated, it only gets worse. Unrelieved pain leads to the activation of the sympathetic nervous system as well as many other things such as vasoconstriction, a higher demand for oxygen and damage of the immune system function. The lack of attention to treating pain originated due to the difficulty of its assessment [30]. For example, if a person is experiencing severe pain, it can cause constriction of the blood vessels and decrease perfusion to the affected area. On the other hand, if a person is experiencing improved pain control, it can lead to increased perfusion to the affected area. A hypothesis of the perfusion index being an indirect tool for pain assessment was raised due to the direct relation between sympathetic stimulation and pain. This was because of the fact that it allowed the simultaneously non-invasive and continuous measurement, of the peripheral perfusion, as mentioned previously. The waveform of the pulse oximeter is used to observe the sympathetic response to painful stimuli, whereas, the perfusion index is used to determine the success of peripheral nerve blocks [30].

2.1 limitations of cold and warm environment

The use of a Pulse Oximeter for continuous arterial oxygen saturation monitoring has quickly established itself as a best practice in anaesthesiology. Numerous studies have established that under normal circumstances, co-oximetry of arterial blood is less accurate than pulse oximetry [31].

It is known that temperature affects the peripheral vascular [32]. Hypothermia is common during surgery and anaesthesia and results from exposure to ambient temperature. There is currently no obvious connection between the temperature of the measurement site and the perfusion index parameter. Hypothermia is known to cause vascular constriction in the

periphery of the body. Because the sensor is placed on the finger, the producer Masimo claims that this temperature variation could significantly affect the measurement of PI. However, the precise effects that variations in temperature might have are not mentioned in the device's technical specifications.

Hynson et al. [33]. demonstrated that cooling the whole patient results in a shift of Spo_2 towards higher readings due to vasoconstriction, without a concomitant change in arterial Po_2. There are many studies evaluating the influence of temperature on Spo_2 reading during cardiac surgery

A study was conducted on Ten children who underwent a cardiac surgery, after anaesthesia was induced and given phenoxybenzamine 1mg per kg and morphine , ice packs were removed when the reading of the rectal temperature showed 26 °C after that temperature continued to decrease to 23 °C and lower during the preparations for the surgery , pulse oximeters(Ohmeda 3700 and OSM-2 Hemoximeter) was attached to the palm before induction in all the patients . readings of PSaO2 were made and arterial samples were extracted in every one degree drop in the temperature from 36 °C to 25 °C and sealed in ice slush , after the samples were obtained the analysed, readings showed that SaO_2 were overestimated by the Ohmeda 3700 in the range of 36 degree to 30 degree where on the other hand underestimated by the OSM-2 in the temperature range of 29 °C to 25 °C Further analysis of these oxygen saturations showed in every case the $PSaO_2$ rose, or remained above 97%, as hypothermia developed and this was reflected in the co-oximeter readings. Further examination of these oxygen saturations revealed that as hypothermia set in, the $PSaO_2$ in every case increased or stayed over 97%, which was reflected in the co-oximeter readings, the study findings, when grouped by the degrees of desaturation, revealed that the difference was very slightly negative at 36 °C and slightly positive at 25 °C in patients whose baseline PSaO2 was above 90%. However, the difference was significantly negative (-5%) among individuals whose baseline PSaO2 was ≤ 80% at 36 °C, and significantly positive (+ 7%) at 25 °C [34].

It's critical to understand how a pulse oximeter actually functions in surgery rooms. Pulse oximeter measurements can be affected by hypothermia in a number of ways. A falsely high

measurement could be brought on by peripheral vasoconstriction [35-36], and if it's severe, it could result in signal loss.

Another important parameter that should be taken into consideration is $EtCO_2$, which is the end-tidal carbon dioxide which is a measure of the carbon-dioxide present in a persons exhaled breath and often measured by a device called capnograph, elevated $EtCo_2$ levels may indicate that a person is not breathing effectively and may be at risk of hypercapnia [37]. which is excess carbon dioxide in the blood that could potentially lead and contribute to vasodilation. A study was conducted in 2013 to understand the effect of hypercapnia on perfusion index during anaesthesia and it was concluded in that study that changes in CO_2 levels causes changes in the Perfusion index values and the results showed that when hypercapnia occurred and the $EtCO_2$ value was equal to 45 mmHg an increase in the perfusion index values were detected [38].

3 Aims

The aim of the thesis is to design, realize and conduct an experiment that is focused on the evaluation and analysis of the performance of perfusion index in relation to temperature changes of the measurement site. Additionally, to explore the application of perfusion index as a supplementary diagnostic indicator with a specific focused evaluation of the efficacy of perfusion index as an auxiliary tool for the diagnosis and monitoring patients

4. Methods

4.1 Equipment

There are many types of advanced pulse oximeters that are used to record and display perfusion index and, in this study, Masimo Rad-97 Pulse CO-oximeter was used see Figure 4.1. Masimo rad-97 is a non-invasive device intended to monitor functional oxygen saturation of arterial Hemoglobin (SpO_2), Pulse Rate (PR), Perfusion index (Pi), and Pleth Variability Index (PVi) along with optional non-invasive measurements of total Hemoglobin (SpHb), Carboxyhemoglobin (SpCO), total oxygen content (SpOC), Methemoglobin (SpMet), Acoustic Respiration Rate (RRa), Oxygen Reserve Index (ORi), and Pleth Respiration Rate (RRp). The Rad-97 is a versatile and advanced medical device that offers a range of key features for monitoring vital signs and oxygenation levels. One of its most notable features is its use of Masimo SET and rainbow SET technology, which allows for exceptional performance in SpO2 and pulse rate monitoring, even in challenging environments such as motion and low perfusion. Additionally, the Rad-97 offers continuous and non-invasive monitoring of Carboxyhemoglobin (SpCO), Methemoglobin (SpMet), and total Hemoglobin (SpHb). It also measures respiration rate (RR) through various methods such as acoustic (RRa) and Plethysmographic waveform (RRp). Another important feature is Oxygen Reserve Index (ORi), an index that measures changes in oxygen states under hyperoxic conditions. The device also comes equipped with a wireless radio for easy transfer of parameter data, and has various operational modes such as Sleep Study and Home mode. Additionally, the device can be integrated with Non-invasive Blood Pressure (NIBP) and NomoLine capnography technology. The Rad-97 also has the ability to display data on a secondary display and designed for third party measurement expansion to allow for additional platform measurements [39]. for testing the effects of cold and warm temperatures on perfusion index, there were two other types of equipment's used beside the pulse oximeter Radical-97, which are a medical ice bags [40] and electrical warming blanket [41]. The medical ice bags are filled with cold gel and applied to the testing hand to induce cold temperature on the measuring site. The electrical warming bag were heated up and applied to the testing hand to induce a warm temperature.

Figure 4.1: Masimo Radical 97 (Masimo Corporation, USA) [42].

4.2 Specifications for Pulse Oximeters: Understanding Accuracy, Oxygen Saturation Levels, and Allowable Margins of Error

In medical devices, such as the Radical-97 pulse oximeter, accuracy is an important factor in determining and ensuring that the patient get an accurate diagnoses and treatment. The Accuracy (ARMS*) which is a specification in Radical-97 pulse oximeter that shows how precise the results obtained from the pulse oximeter, where the lower the ARMS value, the more accurate the results are.

an important specification in Radical-97 pulse oximeter is that its accuracy in measuring the SpO2 is 2% or less for adults, pediatric, and infant populations, which means the device's SpO2 measurement can be up to 2% higher or lower than the actual SpO2 level in the patient's blood when the patient is still. In the technical sheet of Radical-97 pulse oximeter the Perfusion index (PI) is not mentioned as it is not considered as a primary measurement, but rather as a secondary

Indicator of the signal quality being measured. Instead, manufacturers provide information about the range and variability of PI values that can be expected in different patient populations which ranges between 0.2% to 20%,

4.3 Description of the measurement and preparation of the measurement

The experiment took place at the faculty of Biomedical Engineering CTU in Prague in the Laboratory A-105, each experimental measurement took a place according to the experimental Protocol (see appendix (A)) , the experiment as determined before will consist of measuring the perfusion index on the left and the right hand of the subject were one hand will be recorded during the(cold/warm) phase , and the other hand will be recorded as a reference. Warming the testing hand during the experiment was achieved by using a warming electrical blanket as illustrated See Figure 4.2 that was heated to a temperature of 40 degree Celsius, while cooling the hand was achieved by using laboratory cooling Ice bags in Figure 4.3.

Figure 4.2: Illustration of Inducing the warm temperature on the testing hand.

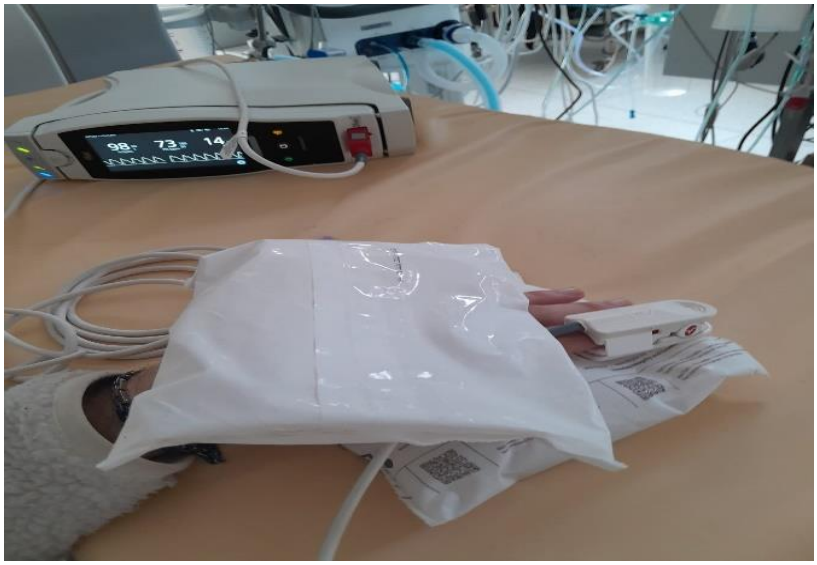

Figure 4.3: Illustration of Inducing the cold temperature on the testing hand.

4.4 Artifacts

During medical examination and monitoring, errors in the data can arise due to many factors such as technical issues , poor signal quality , and external interference, where these factors have a significant and important impact on the accuracy and reliability of measurements leading to misleading results see Table 1.1, for example when using the pulse oximeter , artifacts may occur due to patient movement , low perfusion or ambient light interference , resulting in incorrect results and readings , its important to be aware of these potential artifacts and take account for them in data collection to ensure reliability of the medical data obtained from the pulse oximeter, during the measurement on the subjects a simulated intentional artifact was conducted to analyse or predict the shape of an artefact before the start of the measurement on all the subject in order to filter the unwanted data, see Figure 4.4 and Figure 4.5 for more illustration.

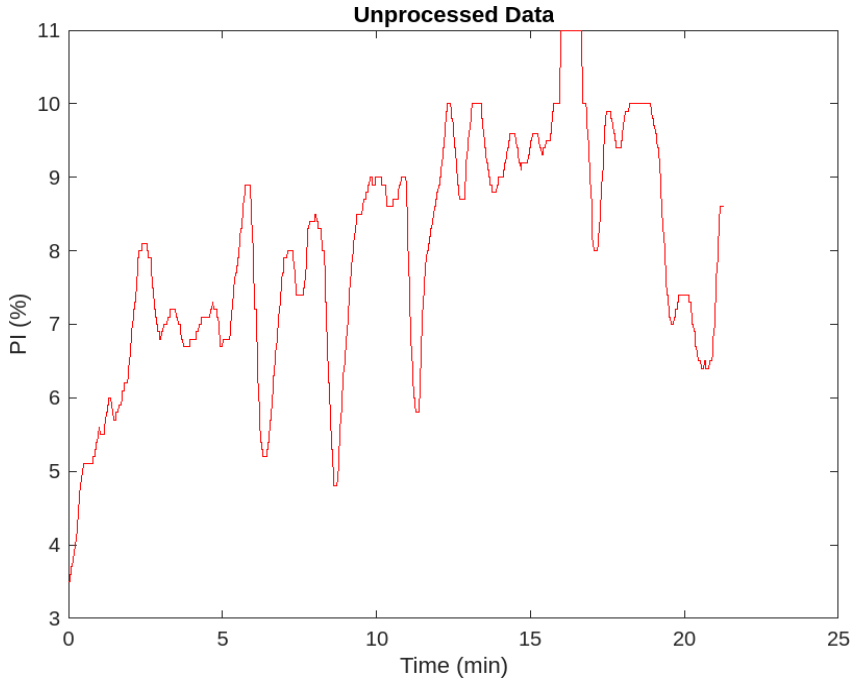

Figure 4.4: a graphical representation of the original data extracted from the pulse oximeter containing artifacts.

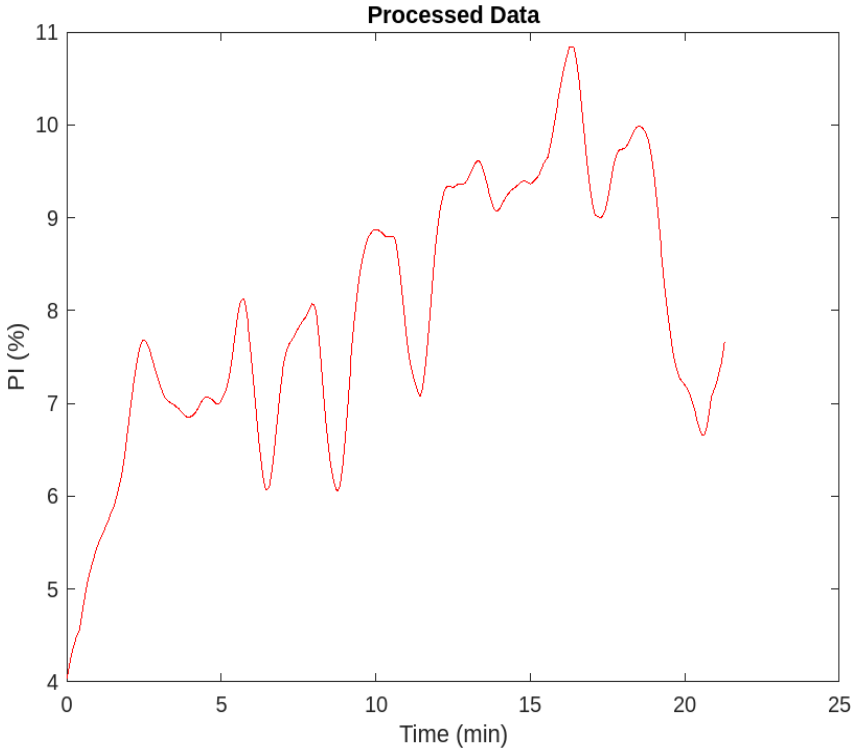

Figure 4.5: a graphical representation of the Perfusion index after filtering and processing the data from unwanted artifacts.

The primary difference between these two figures is the level of noise, as it is important to note that the graph of perfusion index most of the times show fluctuations or irregular patterns that will make it difficult to interpret or analyse the data. However, after filtering, these irregularities may be removed or at least reduced, resulting in a smoother and more consistent graphical representation, which can make it easier to draw a meaningful conclusion from the analysis in summary, by applying regression filtering to all subjects' data, the impact of noise in the data has been minimized, resulting in a more reliable representation of the perfusion index.

4.4 Subjects

The subjects of the study will be a total of 11 participants (both men and women), students and colleagues in the Faculty of Biomedical Engineering at Czech University of Technology in Prague and from third faculty of medicine in Charles university, participated in the clinical study. Participants were divided into two groups according to gender and were required to be in good health and have no skin injuries on their hands. Participation was voluntary and could be withdrawn at any time without explanation. Prior to each measurement, participants completed a participant card, including assigning a unique identification number, and provided informed consent. Personal information such as name, age, and contact information were also collected, along with basic health data such as height, weight, and any pre-existing conditions. The body mass index (BMI) was calculated from this information. The basic characteristics of both groups are presented in Table 4.2.

Table 4.1: Table of participants

Gender	n	Age	Height (cm)	Weight (kg)	BMI (kg/m^2)
Male	7	21.8±2.7	179±7.8	74.7±8.8	22.98±1.46
Female	4	32±16.08	165.5±3.29	59±4.23	21.3±0.76

4.5 Protocol

The protocol for measuring perfusion index (PI) under warm and cold conditions is designed to provide valuable information on the body's response to changes in temperature. The process begins by preparing two Masimo Radical-97 pulse oximeters and attaching the

probes to the subject's index fingers, followed by taking baseline measurements. During the testing phase, the subject is exposed to either a warm or cold environment, with PI measurements taken for seven minutes, followed by a recovery phase that lasts an additional seven minutes. The recovery period allows the subject's circulatory system to return to baseline levels before the next measurement. See Figure 4.4

The protocol includes a randomization process, in which participants are assigned to either begin with the warm phase followed by the cold phase or vice versa, with a 1-hour break between each phase. The study design utilizes MATLAB software for data analysis and focuses on assessing recovery time between the testing phase and the recovery phase. The left hand's index finger is used as the reference finger, while the right-hand index finger is exposed to warm and cold environments. By measuring PI under controlled and randomized conditions, this protocol can provide valuable insights into the circulatory system's response to different temperatures and be used to diagnose and monitor various medical conditions.

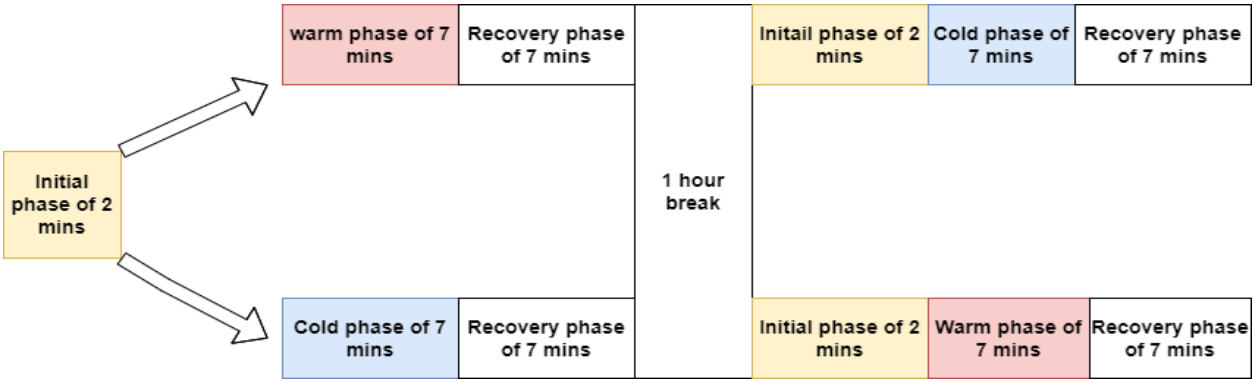

Figure 4.4: step by step diagram illustration of the Protocol.

4.5 Data analysis and processing

The processing of all data taken from the measurement will be analysed, processed, and plotted using MATLAB (version 2022b), plotting the figures and creating Box plots. The results will be presented as a mean ± of the standard deviation.

For the analysis of the data, the data were divided into 3 main sections, the initial phase, testing phase, and the recovery phase, as stated on Figure 4.4, the whole experiment will be conducted in time interval of 16 minutes. The analysis of the experiment will be divided into two branches: Warm phase, and Cold phase and Based on our hypothesis that the maximum effect during each phase will be observed in the last minute a calculation of the mean and the standard deviation of the perfusion index will be calculated in the last minute of the initial phase, testing phase, and recovery phase for the warm phase and the cold phase separately for both the Testing hand and the reference hand.

5 Results

5.1 Cold Temperature effects on PI results

Within this subchapter, a visual depiction illustrating the cold phase experiment is presented for both the Testing hand, as shown in Figure 5.1, and the Reference hand, as displayed in Figure 5. 2.

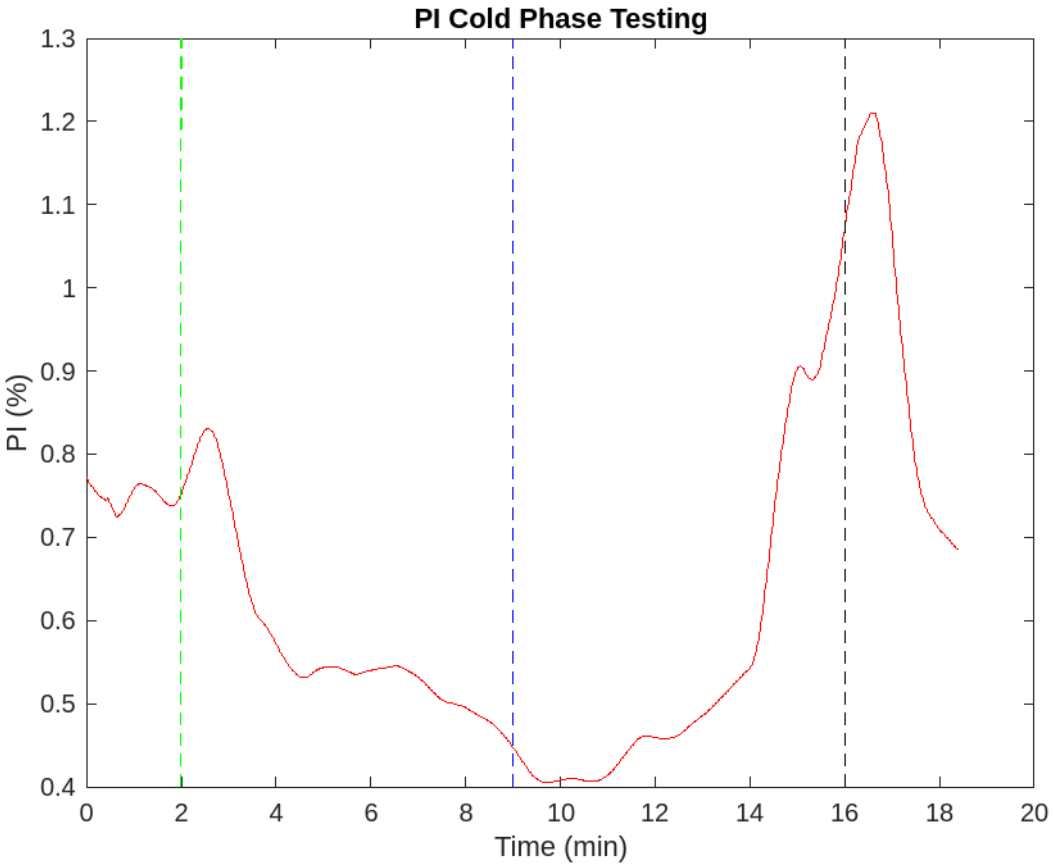

Figure 5.1: a graphical representation of the Perfusion index during applying Ice bags on the Testing hand on one of the subjects.

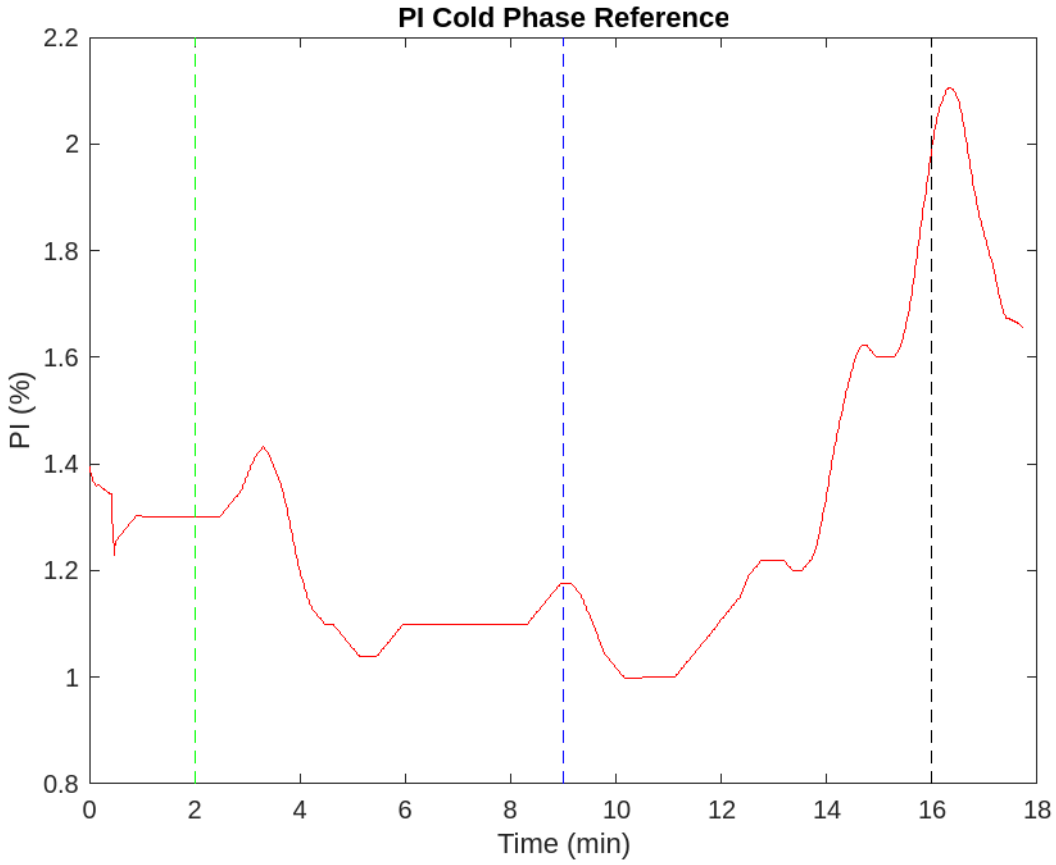

Figure 5.2: a graphical representation of the Perfusion index of the reference hand during applying Ice bags on one of the subjects.

In Figures 5.1 and 5.2, vertical lines were drawn to illustrate the three distinct phases of the experiment undertaken by the participants. The green vertical line, located at the 2nd minute, signifies the end of the initial phase and the commencement of the cold phase, where the testing hand was chilled with ice bags. Similarly, the blue vertical line placed at the 9th minute marks the end of the cold phase and the beginning of the recovery phase, which concludes at the black vertical line at the 16th minute of the experiment.

5.1.2 Cold Temperature effect on PI results displayed in Box plots

This section presents the findings of the experiment aimed at examining the influence of hand

temperature on perfusion index during the cold phase. The results are presented graphically through box plots, as illustrated in Figure 5.3, Figure 5.4, and Figure 5.5. Additionally, Table 5.1 displays the median, upper-quantile, and lower-quantile values of the perfusion index for all the subjects during the three phases of the experiment.

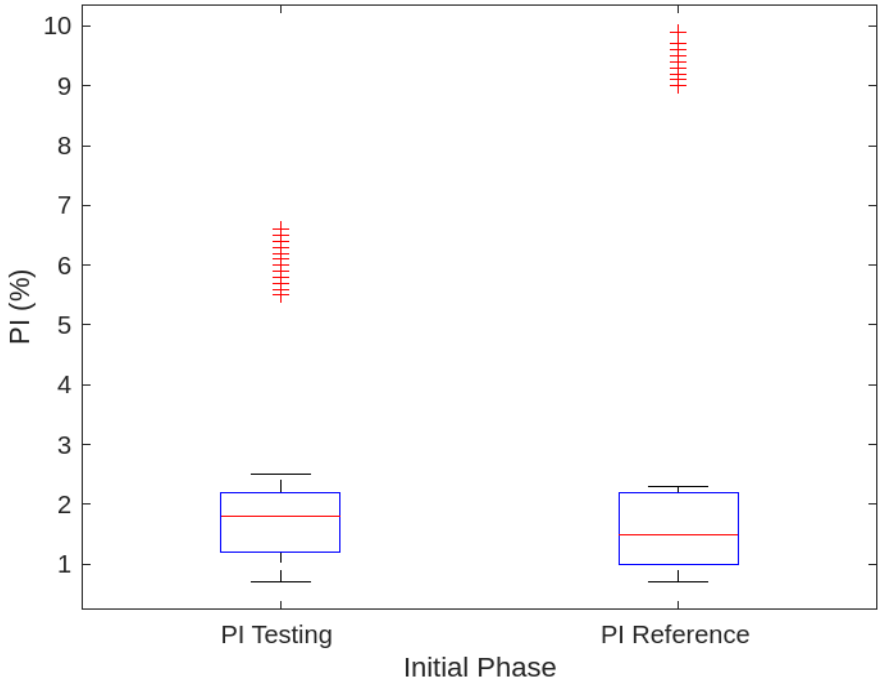

Figure 5.3: Box plot of PI (%) during the Initial phase.

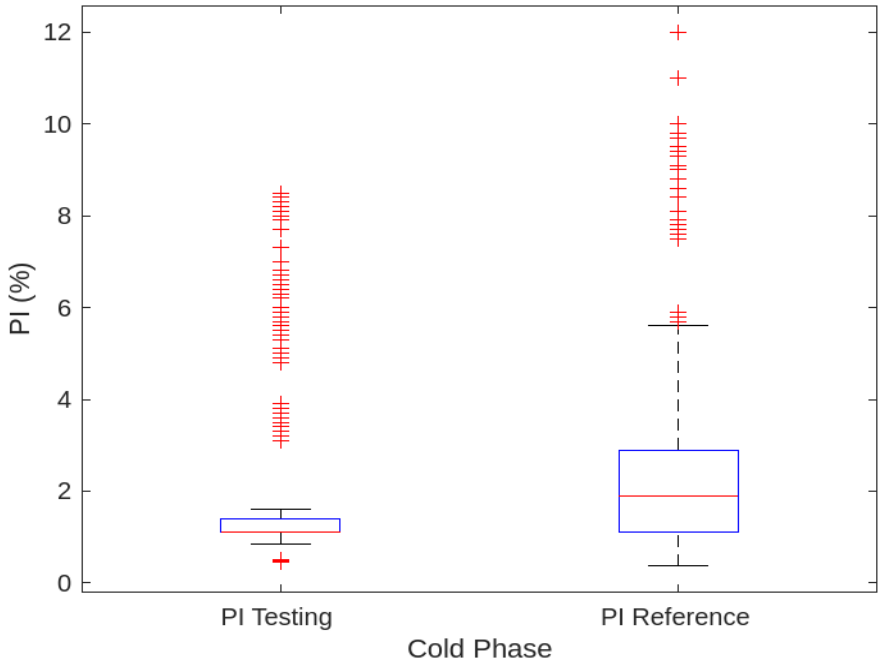

Figure 5.4: Box plot of PI (%) during the Testing phase by applying of the Ice bags.

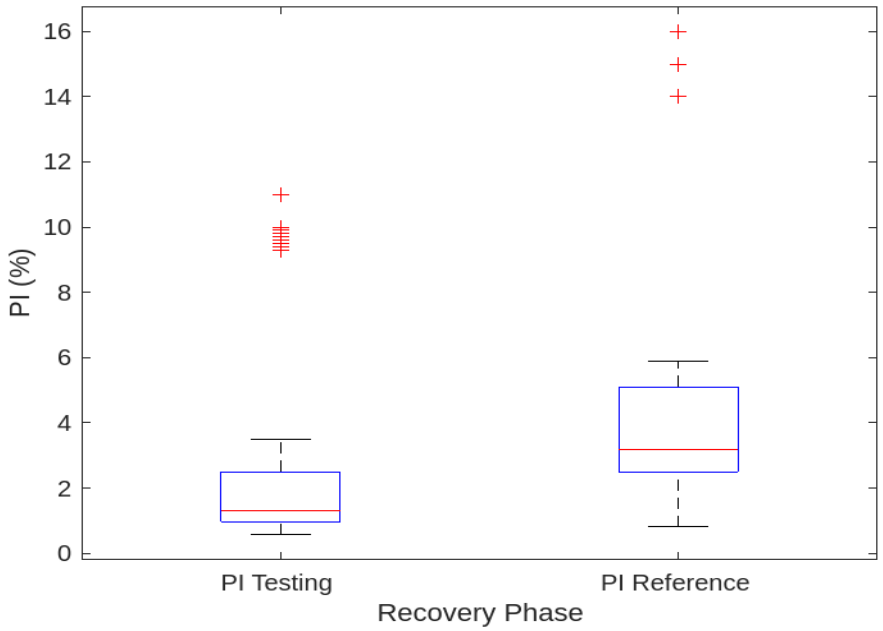

Figure 5.5: Box plot of PI (%) during the Recovery phase.

Table 5.1: Results of Median, Upper-quantile, and lower-quantile during the cold temperature experiment on all the subjects.

Phase/Hand	Median	Upper-quantile	Lower-Quantile
Initial /Testing	1.8	2.2	1.2
Initial /Reference	1.5	2.2	1
Cold /Testing	1.1	1.4	1.1
Cold /Reference	1.9	2.9	1.1
Recovery /Testing	1.3	2.5	0.98
Recovery /Reference	3.2	5.1	2.5

5.2 Warm Temperatures effects on PI results

This subchapter features graphical representations of the warm phase for both the Testing and Reference hands, as illustrated in Figures 5.6 and 5.7, respectively.

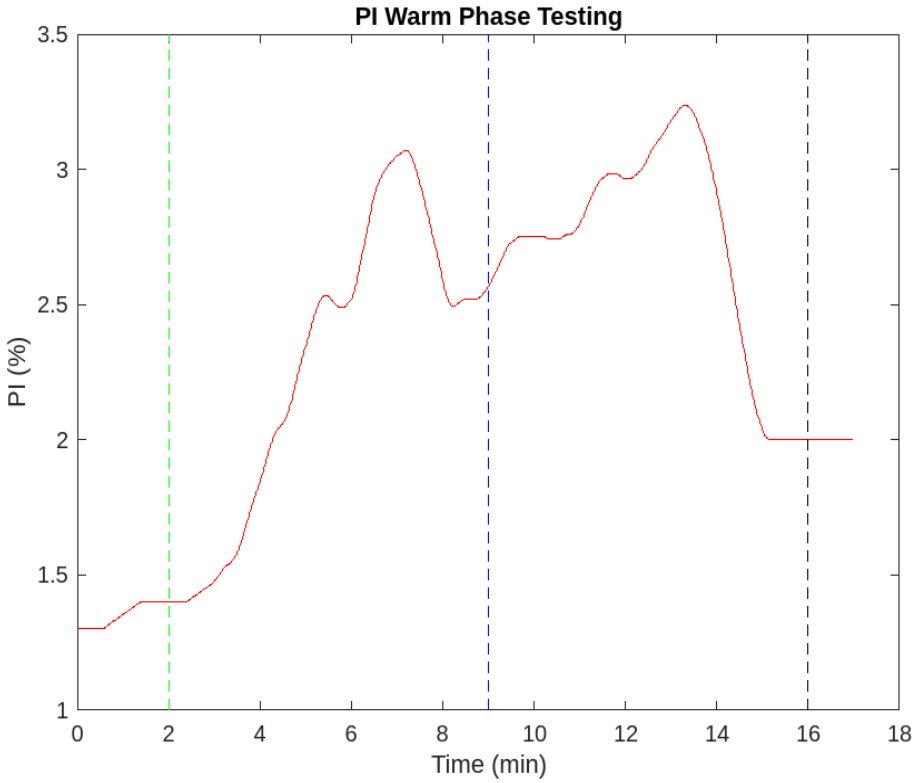

Figure 5.6: a graphical representation of the Perfusion index of the Testing hand during the applying of the warm blanket on one of the subjects.

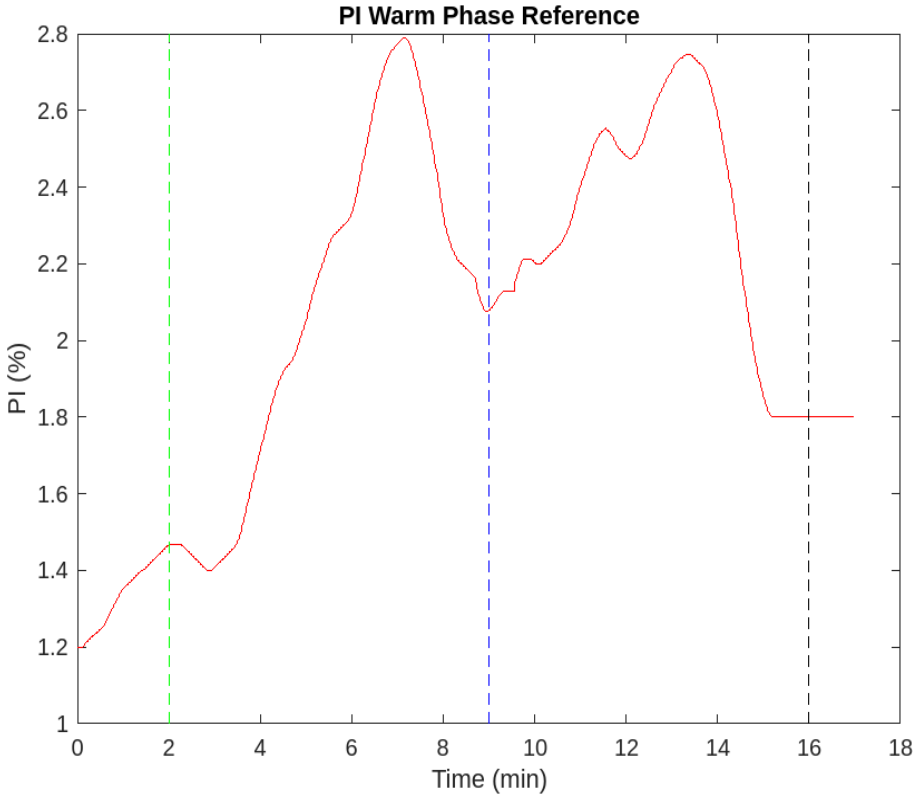

Figure 5.7: a graphical representation of the Perfusion index of the Reference hand during the applying of the warm blanket on one of the subjects.

In Figures 5.6 and 5.7, vertical lines were drawn to illustrate the three distinct phases of the experiment undertaken by the participants. The green vertical line, located at the 2nd minute, signifies the end of the initial phase and the commencement of the Warm phase, where the testing hand was warmed by electrical warming blanket. Similarly, the blue vertical line placed at the 9th minute marks the end of the warm phase and the beginning of the recovery phase, which concludes at the black vertical line at the 16th minute of the experiment.

5.2.1 Warm Temperature effect on PI results displayed in Box plots

This section presents the findings of the experiment aimed at examining the influence of hand temperature on perfusion index during the Warm phase. The results are presented graphically through box plots, as illustrated in Figure 5.8, Figure 5.9, and Figure 5.10. Additionally, Table 5.2 displays the median, upper-quantile, and lower-quantile values of the perfusion index for all the subjects during the three phases of the experiment.

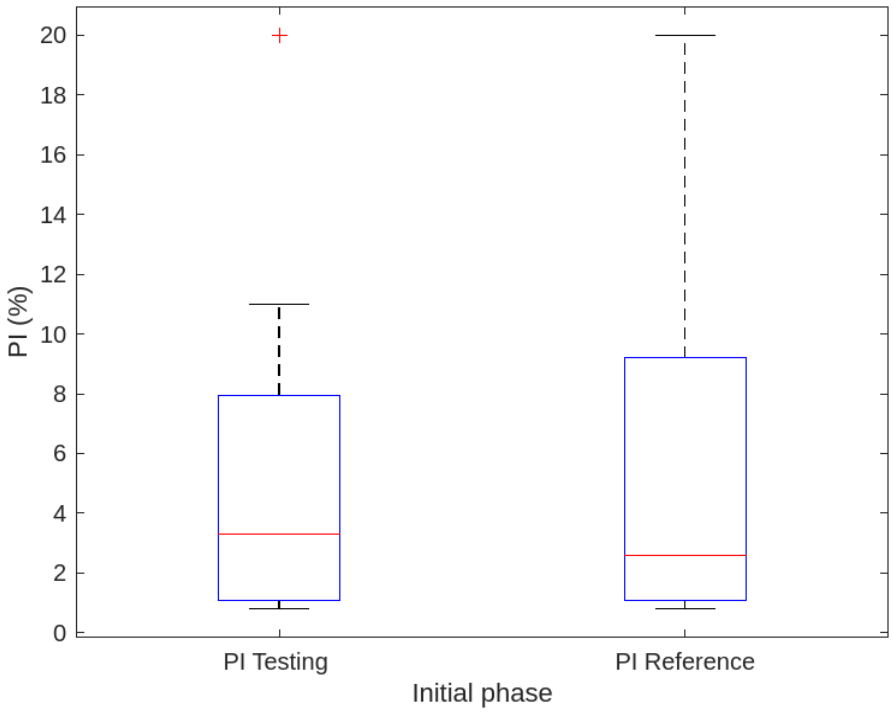

Figure 5.8: Box plot of PI (%) during the Initial phase.

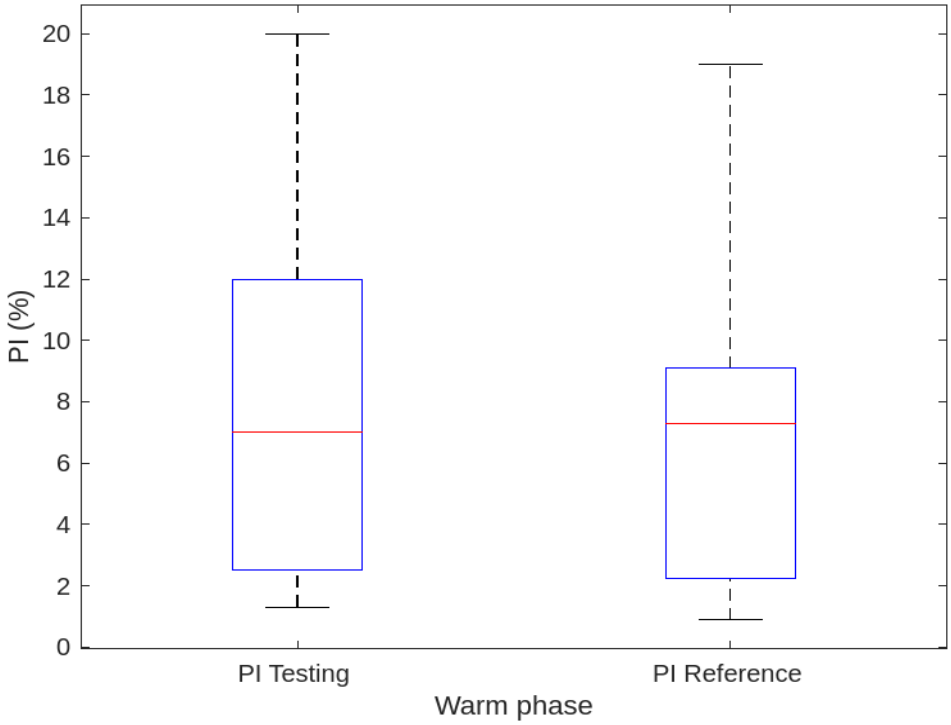

Figure 5.9: Box plot of PI (%) during the Testing phase by applying of the warm electrical blanket.

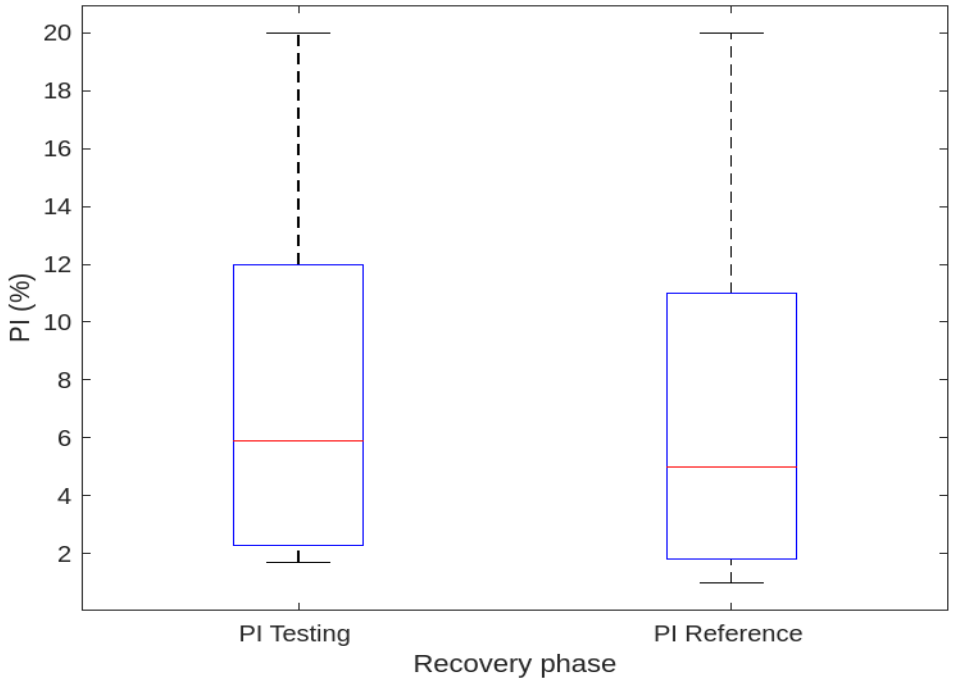

Figure 5.10: Box plot of PI (%) during the Recovery phase.

Table 5.2: Results of Median, Upper-quantile, and lower-quantile during the warm temperature experiment on all the subjects.

Phase/Hand	Median	Upper-quantile	Lower-Quantile
Initial /Testing	3.3	7.95	1.1
Initial /Reference	2.6	9.2	1.1
Cold /Testing	7	12	2.5
Cold /Reference	7.3	9.1	2.2
Recovery /Testing	5.9	12	2.3
Recovery /Reference	5	11	1.8

5.3 Statistical comparison between effects of cold and warm temperatures

The mean values and standard deviations for the experiment's three separate phases—the Initial phase, the (Cold/Warm) phase, and the recovery phase—were determined after the data on the perfusion index were gathered and analysed. At the minute mark of each phase, the perfusion index was measured and noted in order to calculate the overall mean and standard deviation. Table 5.3 and Table 5.4, which present a clear summary of the findings, was then created from these results. We were able to learn a lot about the physiological changes that took place during the experiment by adopting this method, and we were also able to think about possible clinical practice implications.

Table 5.3: Mean Values and Standard Deviations of Perfusion Index for Initial, Cold, and Recovery Phases of Experiment.

	Testing Hand		Reference Hand	
	PI mean values (%)	PI STD values	PI mean values (%)	PI STD values
Base-line phase	1.87	0.062	1.98	0.076
Testing-phase	1.81	0.686	1.85	0.428
Recovery-phase	2.22	0.285	2.09	±0.132

Table 5.4: Mean Values and Standard Deviations of Perfusion Index for Initial, Warm, and Recovery Phases of Experiment.

	Testing Hand		Reference Hand	
	PI mean values (%)	PI STD values	PI mean values (%)	PI STD values
Base-line phase	5.2	0.469	5.09	0.4491
Testing-phase	7.6	0.577	6.70	0.4651
Recovery-phase	6.16	0.401	6.77	0.1956

Before the start of the statistical study, a statistical assessment was conducted to assess the normality of the data during the application of cold temperatures induced by the ice bags at the last minutes of each of the three phases of the experiment- initial phase, testing phase, and recovery phase, and this was done by using the Jarque-Bera test which is a statistical test used for the determination of the normality distribution of a given data by calculating the data sample skewness and kurtosis after that these values will be to calculate the test statistics , which is given by

$$JB = n/6 * (S\text{^}2 + (K-3)\text{^}2/4)$$

Where n is the sample size, S is the sample skewness, and K is the sample kurtosis. A comparison of the test statistic to a chi-squared distribution with 2 degrees of freedom and if the calculated chi-squared value is less than the critical value from the chi-squared distribution table for a given significance level of 0.05 then we accept the null hypothesis that the data is normally distributed, otherwise the null hypothesis is rejected.

5.4 Assessing the Normality of the Cold Phase Data: A Statistical Testing Approach

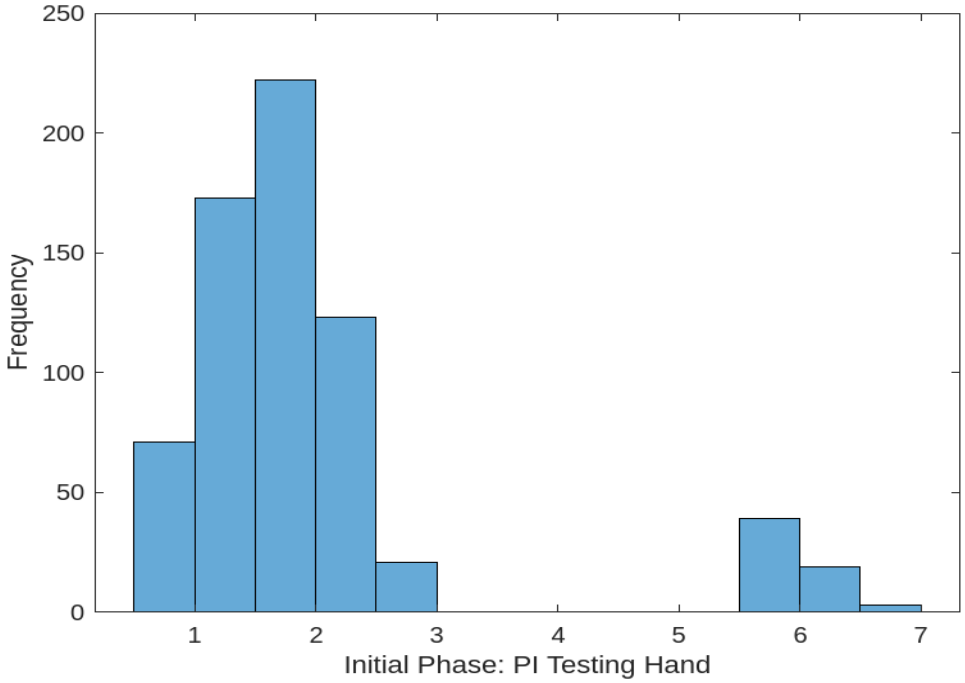

Figure 5.11: Histogram of Initial phase of the Testing Hand.

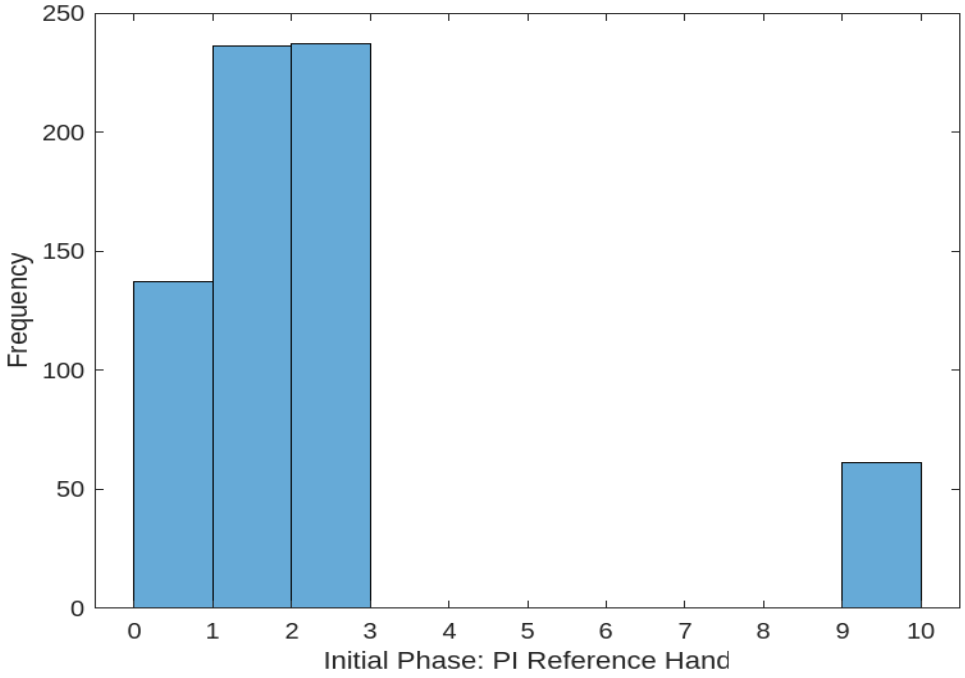

Figure 5.12: Histogram of Initial phase of the Reference Hand.

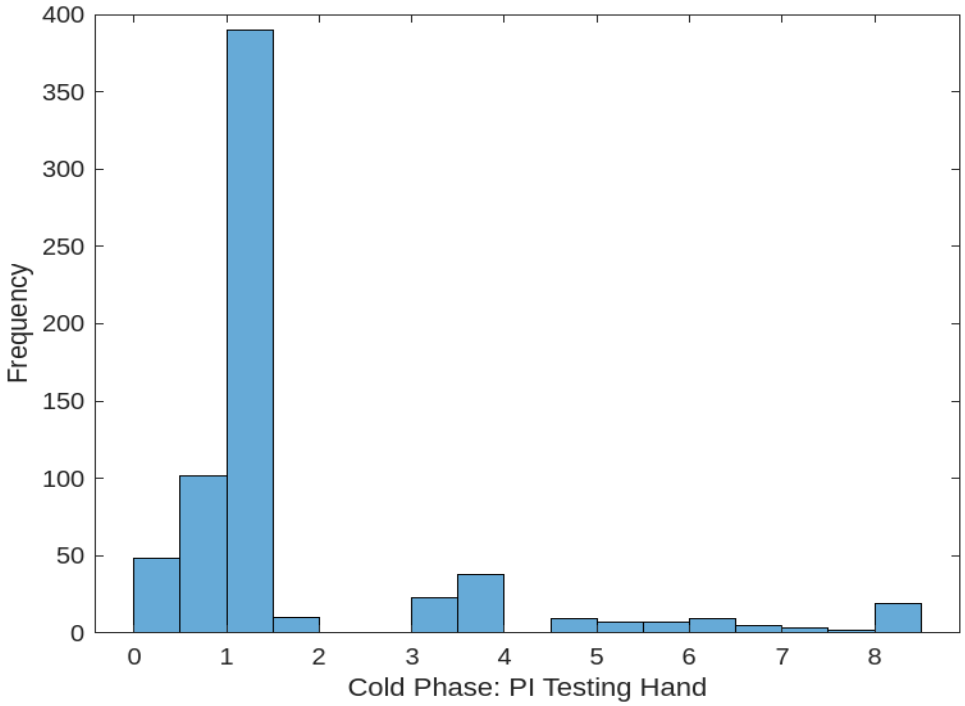

Figure 5.12: Histogram of Cold phase of the Testing Hand.

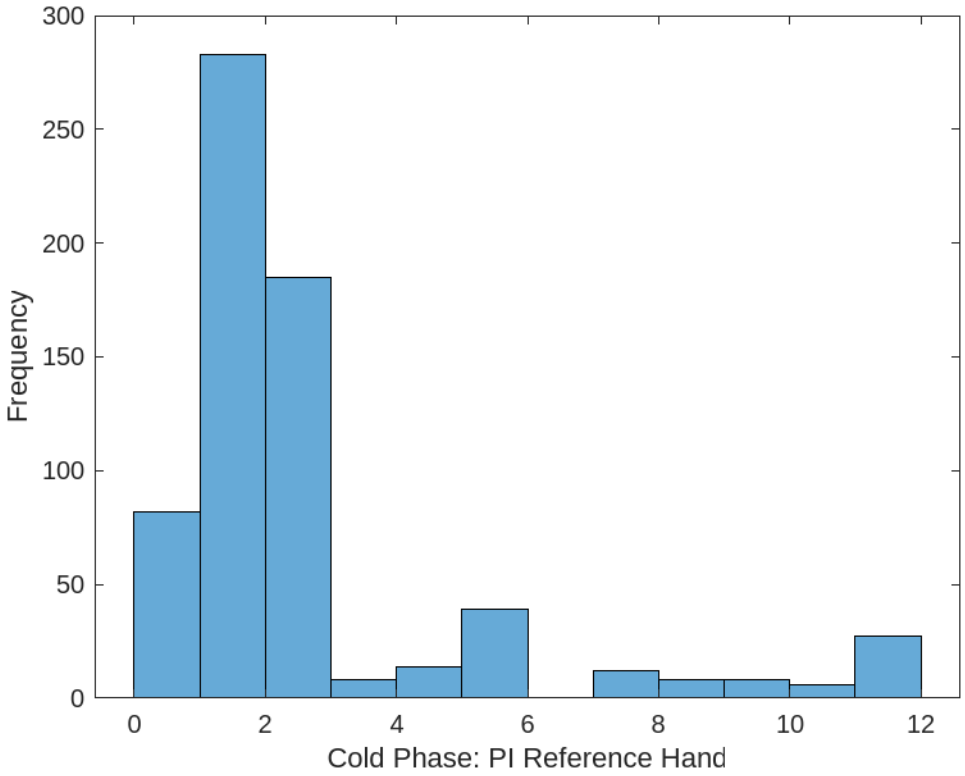

Figure 5.13: Histogram of Cold phase of the Reference Hand

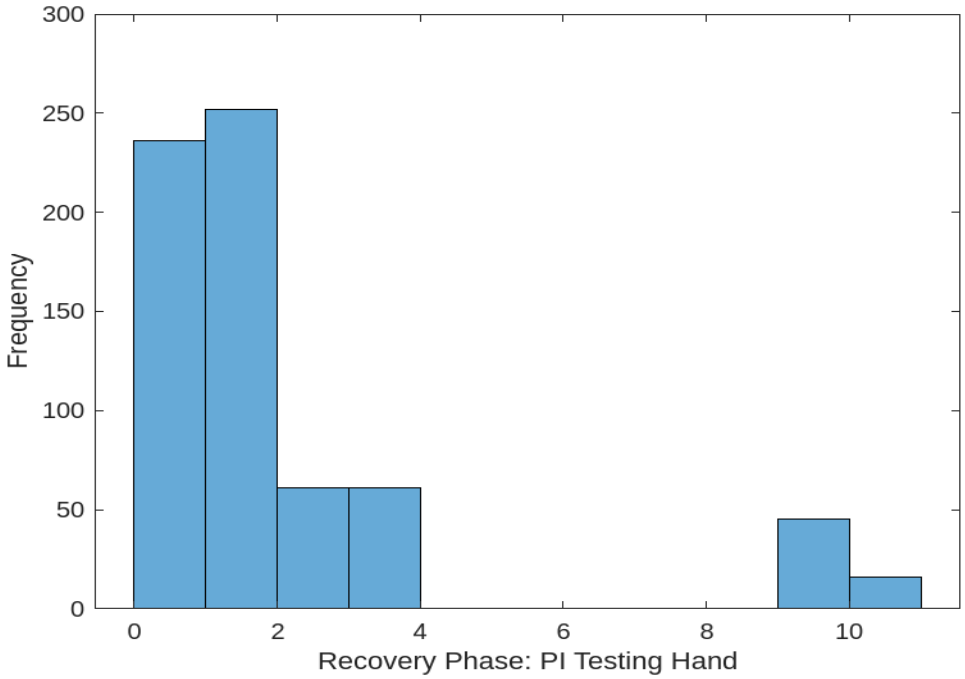

Figure 5.14: Histogram of Recovery phase of the Testing Hand

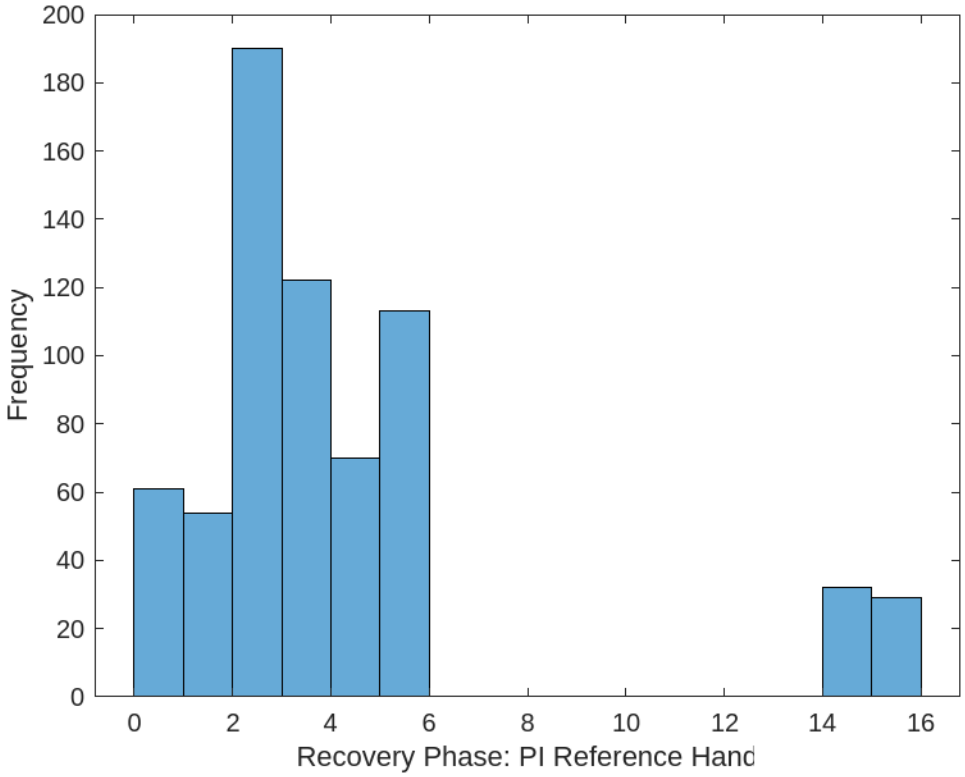

Figure 5.15: Histogram of Recovery phase of the Reference Hand

Table 5.5: Jarque-Bera normality testing results during the Cold Phase measurement.

Phase	Variable	p-value	isNormal
Initial	PI Testing	0.001	False
Initial	PI Reference	0.001	False
Cold	PI Testing	0.001	False
Cold	PI Reference	0.001	False
Recovery	PI Testing	0.001	False
Recovery	PI Reference	0.001	False

5.5 Assessing the Normality of the Warm Phase Data: A Statistical Testing Approach

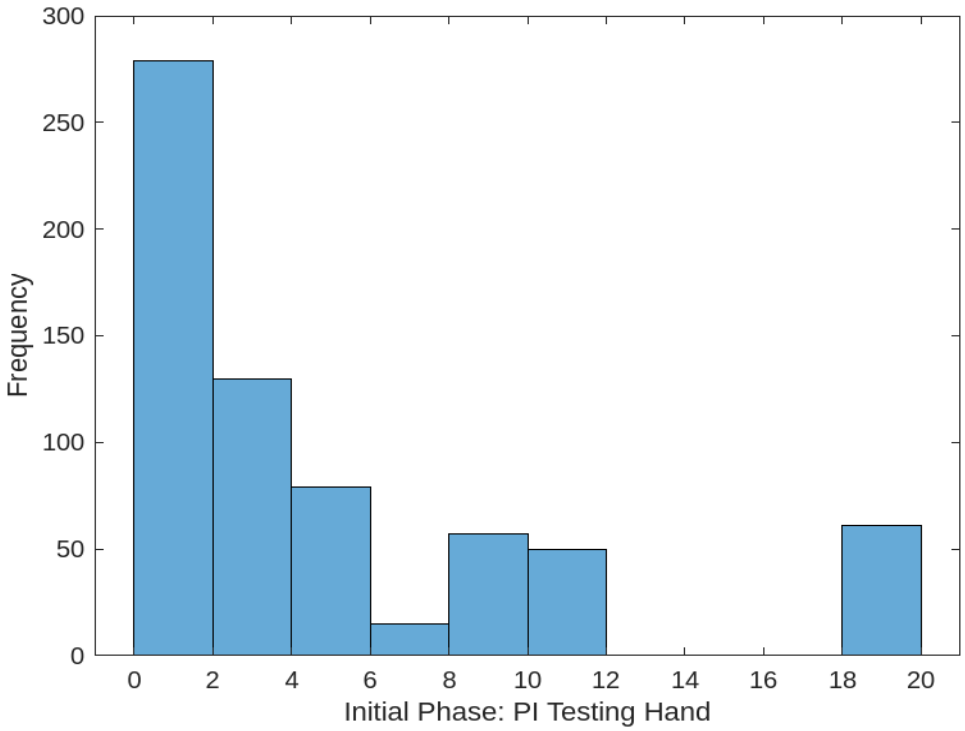

Figure 5.16: Histogram of Initial phase of the Testing Hand.

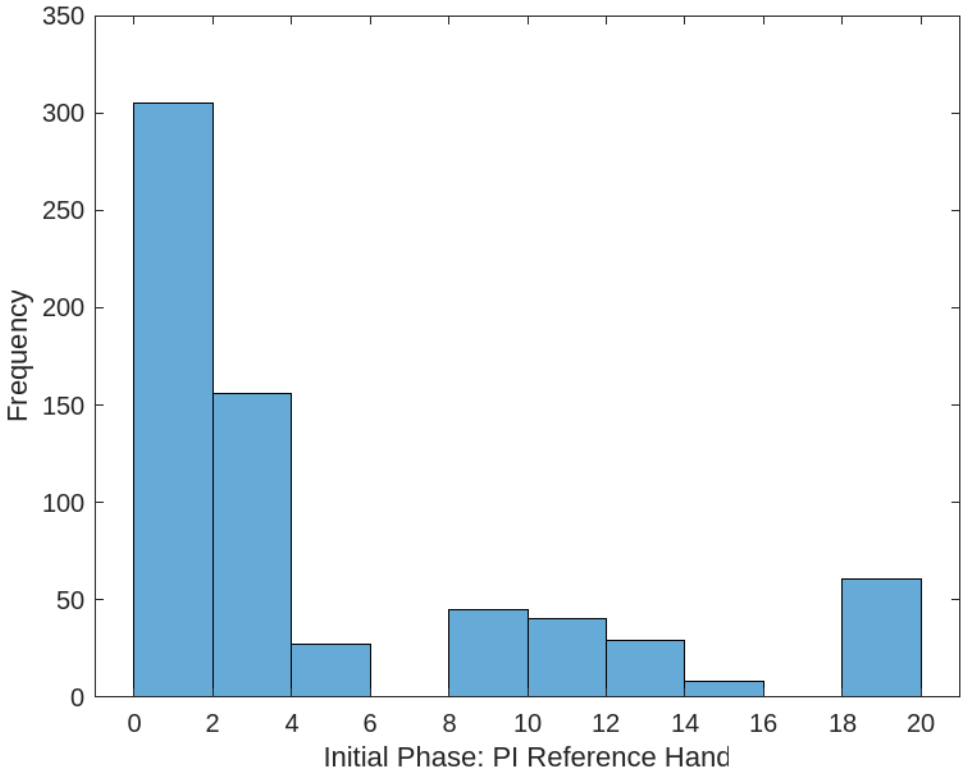

Figure 5.17: Histogram of Initial phase of the Reference Hand.

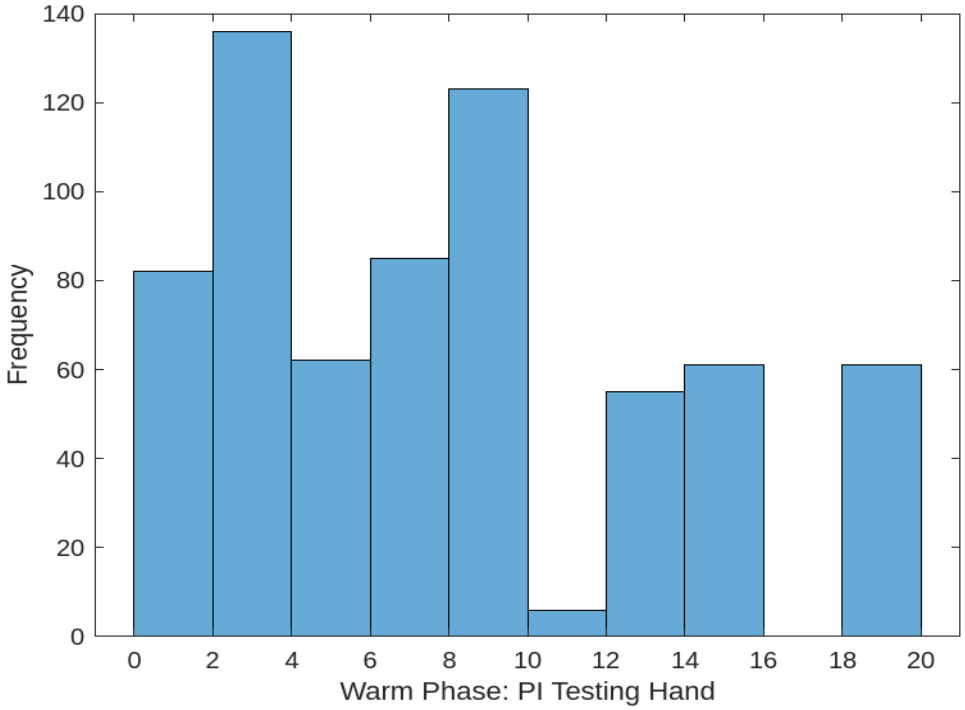

Figure 5.18: Histogram of Warm phase of the Testing Hand.

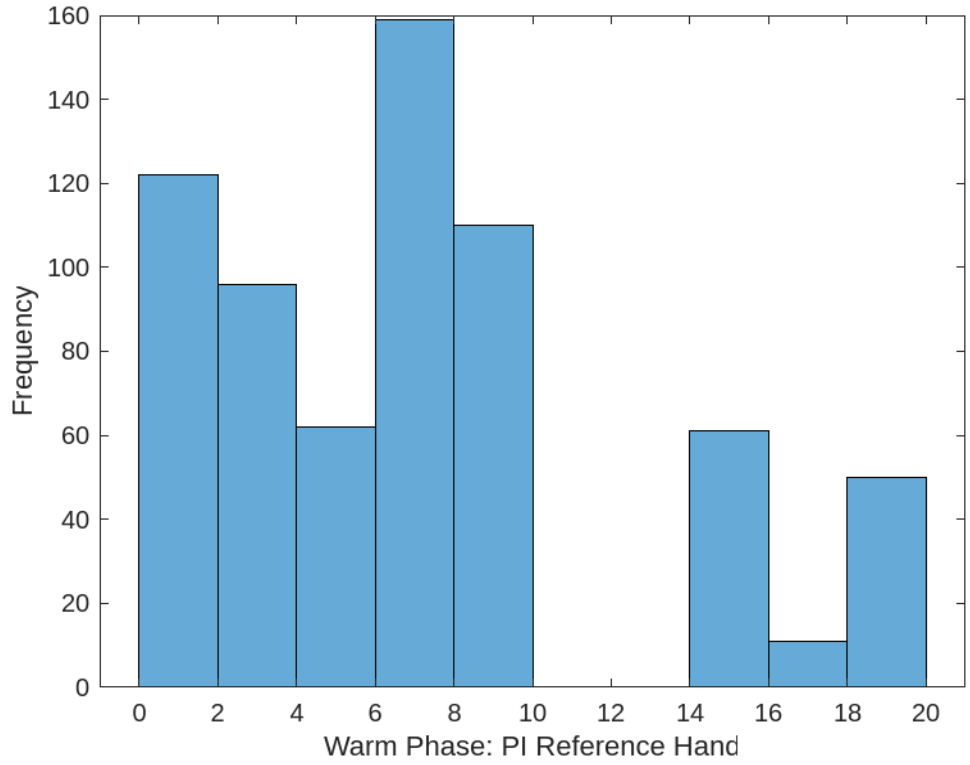

Figure 5.19: Histogram of Warm phase of the Reference Hand.

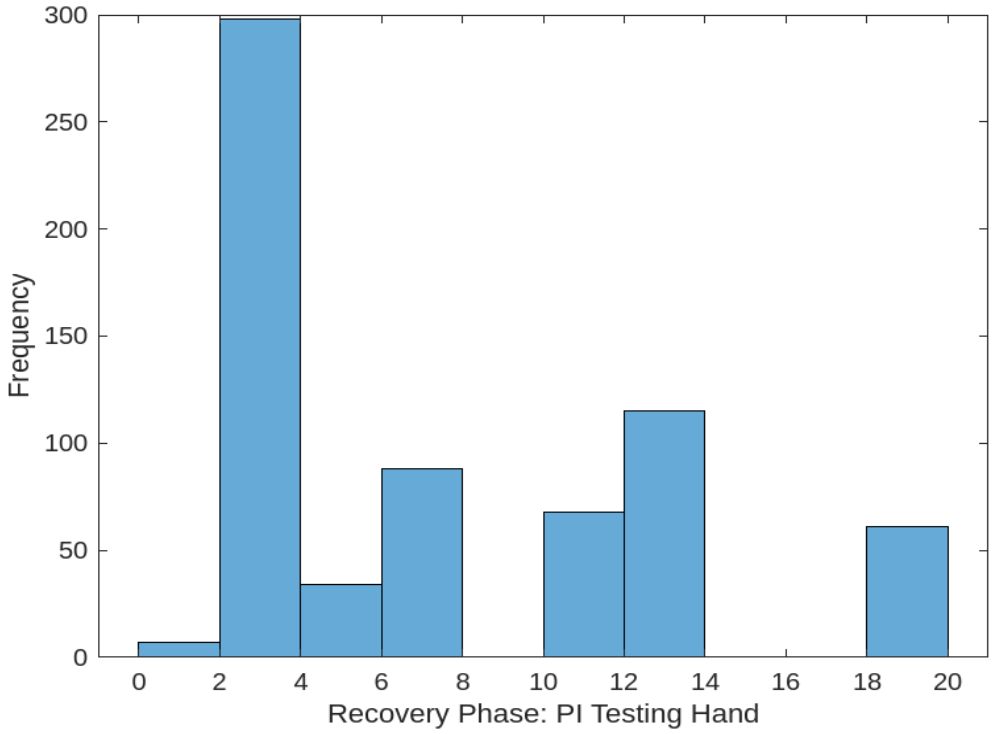

Figure 5.20: Histogram of Recovery phase of the Testing Hand.

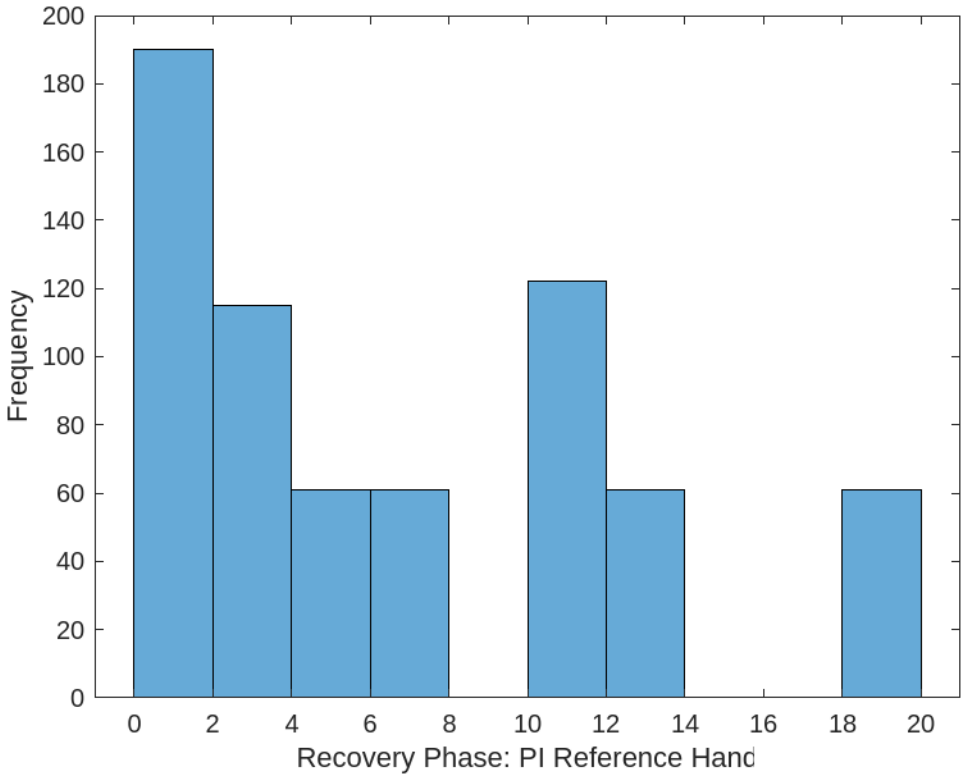

Figure 5.19: Histogram of Recovery phase of the Reference Hand

Table 5.6: Jarque-Bera normality testing results during the Warm Phase measurement.

Phase	Variable	p-value	isNormal
Initial	PI Testing	0.001	False
Initial	PI Reference	0.001	False
Warm	PI Testing	0.001	False
Warm	PI Reference	0.001	False
Recovery	PI Testing	0.001	False
Recovery	PI Reference	0.001	False

5.5 Statistical Analysis of the Experiment Using the Wilcoxon Test

After conducting the normality test, it was determined that the data didn't follow a normal distribution. See Table 5.5 and Table 5.6. the subsequent step is to conduct a non-parametrical statistical test, and the appropriate test for this analysis is the Wilcoxon statistical test where a significance level of 0.05 (or 5%) is used, meaning that if the p-value (calculated from the Wilcoxon test) is less than 0.05, the null hypothesis is rejected and the alternative hypothesis is accepted., where the initial phase will be compared to the cold phase, the cold phase will be compared to the recovery phase, and finally, the initial phase will be compared to the recovery phase, and this will be applied as well to the warm temperature experiment on its three phases. Results of the statistical test will be illustrated in Table 5.7 and Table 5.8.

The following hypothesis will be used for the testing:

H0: The perfusion index is the same across all phases, and the order of the phases has no effect on the outcome.

H1: The perfusion index is different across phases, and the order of the phases affects the outcome.

Table 5.7: illustration of the results after conducting Wilcoxon testing, on the cold phases showing the p values for the compared phases.

Comparison of phases	Testing Hand	Reference Hand
Initial to Cold	$p < 0.001$	$p < 0.001$
Cold to Recovery	$p < 0.001$	$p < 0.001$
Initial to Recovery	$p < 0.0054$	$p < 0.001$

Table 5.8: illustration of the results after conducting Wilcoxon testing, on the warm phases showing the p values for the compared phases.

Comparison of phases	Testing Hand	Reference Hand
Initial to Warm	$p < 0.001$	$p < 0.001$
Warm to Recovery	$p < 0.001$	$p < 0.001$
Initial to Recovery	$p < 0.001$	$p < 0.001$

6 Discussion

The main finding of this bachelor thesis experimental study of the effects of cold and warm environment on PI is that the perfusion index is highly affected and significantly decreased when exposed to cold environment and increased when exposed to warm environment.

The results from the tables 5.1 and 5.2 provide an interesting and important information regarding the effects of temperature on perfusion index (PI). The first table 5.1 display the results of the cold temperature experiment, while the second table 5.2 display the results of the warm temperature experiment. In the induction of the cold temperature experiment, the median PI for the testing hand decreased from 1.8 during the initial phase to 1.1 during the cold phase, which implies that the exposure to cold temperatures caused a decrease in PI, where the median PI for the reference hand on the other side, increased from 1.5 during the initial phase to 1.9 during the cold phase , this increase in PI was maybe due to compensatory vasoconstriction in response to the cold exposure of the testing hand.

During the recovery phase , the testing hand PI increased to 1.3, while the median PI for the reference hand remained stayed high at 3.2, which suggest that the PI for the testing hand started to recover after the exposure to the cold temperature induced by the ice bags , but didn’t fully return to the initial level at the start of the experiment meanwhile the reference hand showed a noticeable increase in PI during the recovery phase , which was an indication that compensatory vasodilation occurred in response to the previous vasoconstriction. Speaking of the upper-quantile and lower-quantile values for the reference hand during the recovery phase, it was observed that they were higher than those for the testing hand, which indicated the great degree of variability in PI measurement of the reference hand among the subjects.

Moving on to the warm temperature experiment which imply that exposure to warm temperatures resulted in an increase in PI for both the testing and the reference hands. During the initial phase, the median PI for the testing hand was 3.3, which is higher than the median PI for the reference hand at a value of 2.6. During the warm phase, the median PI for the testing hand increased to 7 meanwhile the median PI for the reference hand was 7.3, these

results suggest that the exposure to warm temperature induced by the electrical warming blanket resulted in an increase in PI for both hands. During the recovery phase, the median PI for the testing hand decreased to 5.9, while the median PI for the reference hand remained high at 5, these results suggest that PI for the testing hand started to recover after the exposure to the warm temperatures, but didn't fully return to the initial level, On the other hand, the reference hand showed a slight decrease in PI during the recovery phase, but remained higher than the initial level. These results are consistent with past researches on the effects of temperature on PI. Exposure to cold temperature causes vasoconstriction, which results in reduction of the blood flow and also a decrease in PI. On the other hand, exposure to warm temperatures causes vasodilation which increase blood flow and results in an increase in PI. These observations mark the importance of keeping and maintaining an optimal tissue perfusion and PI during surgical procedures by controlling and regulating the temperature in the operating rooms. After the conduction of the normality test on the data, a non-parametrical test was used specifically the Wilcoxon test with a significance level of 0.05. and a hypothesis of:

H0: The perfusion index is the same across all phases, and the order of the phases has no effect on the outcome.

H1: The perfusion index is different across phases, and the order of the phases affects the outcome.

Where if the p-value obtained from the test was less than 0.05, the null hypothesis would be rejected and the alternative hypothesis would be accepted. The testing was applied to compare the initial phase to the cold phase, the cold phase to the recovery phase, and the initial phase to the recovery phase, the same comparison was applied to the warm experiment on its three phases.

Table 5.7 presents the results obtained on the cold experiment phases, indicating the p-values for the compared phases, the results show for both the testing and reference hands that there was significant difference in the PI between the initial phase and the cold phase ($p < 0.001$); between the cold phase and the recovery phase ($p < 0.001$), and between the initial phase

and the recovery phase ($p < 0.0054$ for the testing hand, and $p < 0.001$ for the reference hand).

Table 5.8 illustrates the results of the Wilcoxon test on the warm phases, showing the p-values for the compared phases. The results indicate that for both the testing hand and the reference hand, there is a significant difference in the perfusion index between the initial phase and the warm phase ($p < 0.001$), between the warm phase and the recovery phase ($p < 0.001$), and between the initial phase and the recovery phase ($p < 0.001$ for both hands).

The Wilcoxon statistical test p-values were less than the significant level of 0.05 indicating the rejection of the null hypothesis and implies that the different phases had a significant impact on the PI values. The PI values were found to be significantly different between the initial and the cold/warm, cold/warm and recovery, and initial and recovery phases. These results suggest that changes in the temperature of the environment affect PI values, and the recovery phase may not completely restore PI values to their initial levels.

7 Conclusion

In conclusion, this study investigated the effects of cold and warm environment on PI during different phases. The results showed that the perfusion index is significantly affected by the cold and the warm environments, with higher values recorded during the warm phases and lower values during the cold phases. Additionally, the non-parametrical test conducted earlier implies that the perfusion index is significantly different across phases. These findings suggest the importance for close regulation and monitoring of the temperature in surgical rooms to reduce any risk of complications during the surgery, overall the study provides important insights into the effects of cold and warm environment on perfusion index and highlights a further research in this area. At last it should be noted that the study acknowledges that the impact of artifacts on the findings might not be eliminated entirely by filtering the results. However, the study emphasizes the importance of maintaining a consistent temperature in operating rooms to reduce the risks of complications and to point out the need for additional studies in this field to clarify the connection between the temperature variations and the perfusion index. Overall This study provides valuable information regarding the impact of temperature on perfusion index and its potential implications for clinical practice, offering insightful findings.

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Appendix (A): the experimental Protocol

17ABBBP – Bachelor thesis

Effect of measurement site temperature on perfusion index

The protocol has been drawn up by	
Name and surname:	Abdulrahman shaat
Study field / Study group	Biomedical Technician
The measurements were carried out in cooperation with	
Name and surname	
Serial Number and total number of log pages	
Serial Number:	
Number of pages:	5
Place and date of measurement	
Date / Measurement site:	
Signature of the student who carried out the measurement and the protocol	

Study Protocol: Perfusion Index under Cold and Warm Conditions

Date:
Time (Beginning, End):
Subject ID:
Randomization Key:
Phases: Warm to Cold (W->C), Cold to Warm (C->W)
Test hand: Right/Left
Reference hand: Right/Left
Room temperature: 21 °C
Laboratory:
Examiner:

1) Preparation of Measurement:

□ Turn on Both Masimo Radical 97

□ Check synchronisation time and date: Settings – Device Settings – Localisation – Current Time and Current Date

□ Check the format of output IAP: Settings – Device Settings – Device Output – USB Port – IAP

□ Turn on heating blanket to maximum heating

□ Measure the room temperature

2) (Warm, Cold) Phase:

□ The subject sits comfortably at the laboratory table.

□ Place the Masimo Radical 97 finger probe on the subject's Test hand middle finger.

□ Instruct the subject to rest both hands comfortably and reduce movement to minimum.

□ Measure the Perfusion Index (PI) for 2 minutes.

□ Place the heating blanket around the subject's Test hand while leaving the Masimo finger probe on.

□ Measure the PI for 7 minutes.

□ Remove the heating blanket.

□ Measure the PI for an additional 7 minutes.

□ Remove both finger probes exactly at the end of this phase, by removing them simultaneously at the same moment.

□ Ask the subject to relax in a recovery room for 60 minutes.

3) (Warm, Cold) Phase:

□ The subject sits comfortably at the laboratory table.

□ Place the Masimo Radical 97 finger probe on the subject's Test hand middle finger.

□ Measure the PI for 7 minutes.

□ Place ice bags wrapped in towels around the subject's Test hand while leaving the Masimo finger probe on.

□ Measure the PI for 7 minutes.

□ Remove the ice bags.

□ Measure the PI for an additional 7 minutes.

4) Data Export:

□ Plug in the REFERENCE Masimo Radical 97 Reference hand to the USB port of a computer using a USB cable. Check the connection of Masimo to port COM3 – Device Manager – Ports (COM, LPT) – COM3.
□ Create a new folder with Subject's ID: This Computer – Disc C – MICT – Trend – Ref_ID, Ph1_ID, Ph2_ID.
□ Turn on program MICT on the computer.
□ Choose Options – Setup Connection:
Instrument: Rad 97
Connection: Serial
Config: Port – COM 3; BaudRate – 921600 –> OK
□ OK
□ Options – Download Trend – Trend – file with Subject ID – into file Ref_ID.
□ Disconnect the Masimo from the computer.
□ Plug in the TEST Masimo Radical 97 (which was attached to the LEFT hand) to the USB port of a computer using a USB cable. Check the connection of Masimo to port COM3 – Device Manager – Ports (COM, LPT) – COM3.
□ Turn on program MICT on the computer.
□ Choose Options – Setup Connection:
Instrument: Rad 97
Connection: Serial
Config: Port – COM 3; BaudRate – 921600 –> OK
OK
□ Options – Download Trend – Trend – file with Subject ID – into file Ph1_ID or Ph2_ID according to the study phase.
□ Disconnect the Masimo from the computer.
□ Turn off all devices if experiments are over.

Appendix (B): Approval of research project in the FBMI Ethics Committee of CTU

ČESKÉ VYSOKÉ UČENÍ TECHNICKÉ V PRAZE
Fakulta biomedicínského inženýrství
nám. Sítná 3105, 272 01 Kladno

Žádost o projednání výzkumného projektu v etické komisi FBMI ČVUT

Application for approval of a research project by FBMI CTU Institutional Ethical/Review Board

Název projektu: Vliv teploty místa měření na perfuzní index
Name of the project: Effect of measurement site temperature on perfusion index

Hlavní řešitel projektu (Jméno, pracoviště, e-mail): Abdulrahman Mahmoud M Shaat, KBT, shaatalc1@fbmi.cvut.cz
Vedoucí kvalifikační práce (Jméno, pracoviště, e-mail): MUDr. Lenka Horáková, KBT, horakle5@fbmi.cvut.cz

Stručný popis projektu:
Perfuzní index (PI) stanovený pomocí pulzní oxymetrie je bezpečná neinvazivní metoda široce používaná mimo jiné v anesteziologii a intenzivní péči. Cílem projektu je experimentální vyhodnocení vlivu teploty místa měření na hodnotu perfuzního indexu. Ohřátí místa měření bude provedeno pomocí elektrické ohřívací dečky, ochlazení pomocí gelových chladících polštářků. Subjekty experimentu budou dobrovolníci z řad studentů FBMI. Studie navazuje na výzkumný projekt, k němuž bylo vydáno souhlasné stanovisko Etickou komisí FBMI ČVUT dne 5.3.2020 (č.j. C13/2020).

Charakter projektu:
- ☐ Grantová úloha (název agentury):
- ☐ Výzkum výzkumného týmu (specifikace):
- X Kvalifikační práce (specifikace): Bakalářská práce (Abdulrahman Mahmoud M Shaat)
- ☐ Jiné:

Seznam přikládaných dokumentů:
- sylabus projektu
- informovaný souhlas vč. informace pro subjekt hodnocení

V Kladně dne 6.4.2023

podpis hlavního řešitele

Vyjádření souhlasu etické komise FBMI ČVUT

FBMI CTU Institutional Ethical/Review Board approval

Projekt byl schválen etickou komisí FBMI ČVUT dne: 10. 5. 2023 **platný do:** 6/2024
pod číslem: C38/2023

Etická komise FBMI ČVUT v Praze, ve složení Mgr. Martina Dingová Šliková, Ph.D. (předsedkyně), prof. Ing. Karel Roubík, Ph.D., RNDr. Táňa Jarošíková, CSc., doc. Ing. Petr Kudrna, Ph.D., MUDr. Tomáš Heřman a Ing. Lucie Šedzmáková, zhodnotila předložený projekt a neshledala žádné rozpory s platnými zásadami, předpisy a mezinárodními směrnicemi pro provádění biomedicínského výzkumu zahrnujícího lidské účastníky nebo laboratorní zvířata.

Řešitel projektu splnil podmínky nutné k získání souhlasu etické komise.

V Kladně dne 15. 5. 2023

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Fakulta biomedicínského inženýrství
nám. Sítná 3105
272 01 Kladno

razítko etické komise FBMI ČVUT

Mgr. Martina Dingová Šliková, Ph.D.

podpis předsedy etické komise

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