Master's thesis

NTNU
Norwegian University of Science and Technology
Faculty of Information Technology and Electrical Engineering
Department of Engineering Cybernetics

Patrick Christian Bösch

Device for Improved Insulin Absorption in Diabetes Type 1

Master's thesis in Cybernetics and Robotics
Supervisor: Øyvind Stavdahl
Co-supervisor: Anders L. Fougner
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Sammendrag

Det har skjedd store forbedringer i behandling av Diabetes Mellitus gjennom de siste årene. Behandlingen har blitt mye mer kompleks og avansert og kommer seg langsomt men sikkert i nærheten av en kunstig bukspyttkjertel, som er "den hellige gral" i diabetes behandling. Men dessverre står den trege subkutane insulin administrasjon i veien ditt.
Det finnes mange måter som er mistenkt å forbedre subkutan insulin absorpsjon. Lysterapi er en av disse og etter den fikk lovende resultater fra en små pilotstudie bestemte den Kunstig Bukspyttkjertel Trondheim (APT) Gruppe seg å undersøke dette teknologi videre. Under pilotstudie ble det oppdaget at de kommersielle lysterapi systemer er ikke særlig egnet til forskning. Det er hovedsaklig på grunn av manglende modularitet og tilpasningsevne. APT bestemte seg derfor å bygge sitt eget lysterapi system som er tilpasset til de planlagte videregående forsøk. Det ble bestemt å legge utviklingsarbeid og prototype bygging ut som studentoppgave. På grunn av oppgavenstørrelse ble den delt opp i en prosjekt- og en masteroppgave. Dette masteroppgave er derfor en direkt fortsettelse av prosjektoppgaven. Den handler hovedsaklig om avslutting av konseptfase og å finne løsninger til de følgende tre deloppgaver: den optimale lyskildeplassering, et tilfredstillende kjølingopplegg og utforming av protypens elektronikk som er alle sammen del av utformingsfasen.
Til slutten presenteres det også veien viddere i prototypenutviklingsprosessen.

Abstract

Over the past decades, Diabetes Mellitus management has advanced dramatically, becoming increasingly complex and refined in order to approach the "Holy Grail" of diabetes management, the Artificial Pancreas. However, the slow dynamics of subcutaneous (SC) insulin have proven to be a significant barrier, and numerous ways are being researched to overcome or mitigate this problem. One of those techniques to reduce the impact of sluggish SC insulin dynamics is being investigated by the Artificial Pancreas Trondheim (APT) Group. Based on the results of a pilot study they previously conducted, they plan to investigate the vasodilating properties of NIR radiation further, as enhanced subcutaneous blood flow would drastically minimise the adsorption delay of SC insulin. When analysing the data from the pilot trial, it was discovered that the commercially available Light-Therapy devices are hard to use and provide only limited functionality. As a result, it was decided to develop and build a Light-Therapy device specifically tailored to the intended future studies that are planned in order to confirm the findings of the pilot study.

The project development of such a device is rather complex and time intensive. It was therefore decided to split the task into a Project and a Master thesis.

This Master thesis is building upon the ground works laid by the Project thesis and is a direct continuation of it. The thesis concludes the Concept Phase of the product development process and solves the challenges of optimal LED placement, appropriate LED cooling and design of the control electronics from the Design Phase.

In the end of this thesis, it provides a detailed outlook of the next steps in the product development process.

Acknowledgement

Diabetes Mellitus, an incurable auto-immune disease puts a burden on the lives of millions of people. Even though diabetes is no longer a death sentence it requires the constant attention of the patient that has to manage the disease with frequent blood glucose measurements and insulin injections in order to achieve a good blood glucose control. A good blood glucose control is essential to reduce the risk of a host of long- and short-term adverse effects. The generally slow time constants for insulin absorption and glucose measurement in the subcutaneous space pose a big challenge to achieving good blood glucose control.
As the development engineer of the Artificial Pancreas Trondheim (APT) Group i am daily confronted with the challenges and implications of diabetes. It is therefore very motivating to contribute to potentially groundbreaking research that has the potential to improve the daily lives of countless people.
First of all i would like to give my gratitude and thanks to my two supervisors, Professor Øyvind Stavdahl and Associate Professor Anders L. Fougner for their supervision, valuable inputs and advice and always having an open ear for me. Furthermore i would like to thank my college Karim B. Davari for supporting me with his expertise when simulating and optimising the LED placement.
A big thanks also goes to my girlfriend Fei Song for having my back through out this thesis project. I would like to thank Misbah Riaz and the other APT members for their valuable feedback and inputs. Lastly i would like to thank the iC-Haus GmbH for supporting this project with free product samples.

Masteravtale/hovedoppgaveavtale

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Oppgaven

Oppstartsdato	**01.02.2021**
Leveringsfrist	**28.06.2021**
Oppgavens arbeidstittel	**Device for improved insulin absorption in diabetes type 1**
Problembeskrivelse	**In treatment of diabetes mellitus type 1 (DM1) a major challenge is the slow absorption of infused insulin and the resulting delay in glucose lowering effect. Thus, any technology that might speed up the insulin absorption has the potential to significantly improve the performance of insulin therapy. The Artificial Pancreas Trondheim (APT) research group is planning to investigate whether exposing the tissue to near-infrared (NIR) light and/or local heating of the tissue can contribute to faster insulin absorption. The hypothesis is that these stimuli will cause local vasodilation (i.e., increase local blood transfusion) and thus facilitate faster transport of the insulin away from the infusion site and into the target tissues. The goal of this project is to build an electronic prototype system for controlled NIR treatment. The long term goal is to produce a physical device that can be used for research into the possibilities and limitations of the technology in the current application. The MSc Thesis is building on a Project Thesis with the same working title conducted during Fall 2020 and its work should include the following: 1. Design and build a prototype. 2. Test the functions and identify the parameters of the prototype in vitro. 2a. (Optional - Test the device in a self-test - in vivo) 3. Identify potential improvements for future iterations.**

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Nomenclature

Z_n Zener Diode, a special type of diode designed to reliably allow current to flow "backwards" when a certain set reverse voltage is reached

Altium Designer An electronic design automation software for printed circuit boards (PCB).

AP The Artificial Pancreas

APT The Artificial Pancreas Trondheim Group

CA California, constituent state of the United States of America

CAD Computer-aided Design

CGM Continuous Glucose Monitor

CSII Continuous Subcutaneous Insulin Infusion

DAC Digital-to-analogue Converter

DC Direct current, a one-directional flow of electric charge

DC/DC converter High-frequency power conversion circuits that use high-frequency switching and inductors, transformers, and capacitors to smooth out switching noise into regulated direct current voltages

DIP switch A manual electric switch that is packaged with others in a group in a standard dual in-line package

DIY "Do it yourself" is the method of building, modifying, or repairing things by oneself without the direct aid of experts or professionals.

ECTS The European Credit Transfer System

EUR Euro, currency of the European Union

FDA The United States Food and Drug Administration

FL Florida, constituent state of the United States of America

FMECA Failure Mode, Effects & Criticality Analysis

FR-4 A composite material composed of woven fiberglass cloth with an epoxy resin binder that is flame resistant.

FWHM Full-Width Half-Maximum

GA	Genetic Algorithm
IC	Integrated Circuit
ICNIRP	The International Commission on Non-Ionizing Radiation Protection
IDF	The International Diabetes Federation
IEC	The International Electrotechnical Commission
In vitro	Processes that happen outside of a living organism
In vivo	Processes that happen inside of a living organism
IO	Input/Output
IP	Intraperitoneal
IP rating	Protection classification established in 1989 by the International Electrotechnical Commission (IEC)
IP52	The protection level of against dust deposits and falling water for a maximum inclination of 15°
IP54	The protection level of against dust deposits and splashing water
IR	Infrared Radiation
ITK	Institutt for teknisk kybernetikk, Department of Engineering Cybernetics in NTNU
LEDs	Light Emitting Diodes
LLLT	Low-Level Light Therapy
Ltd	Limited Company
MATLAB	A programming and numeric computing platform developed by MathWorks
MDI	Multiple Daily Injection
MIRE	Monochromatic Infrared Therapy
MSc	Master of Science
NEK	Norsk Elektroteknisk Komite, The Norwegian Electrotechnical Committee
NIR	Near Infrared Radiation

NO	Nitric Oxide
NOK	Norwegian krone, currency of Norway
NOS	Nitric Oxide synthase
NTNU	The Norwegian university of science and technology
P-MOSFET	The P-channel metal–oxide–semiconductor field-effect transistor
PBM	PhotoBioModulation
PCB	Printed Circuit Board
POM	Polyoxymethylene
PWM	Pulse Width Modulated
REK	The Regional Ethical Committee
RNS	Reactive nitrogen species
RoI	Region of Interest, samples within a data set identified for a particular purpose
ROS	Reactive oxygen species
SC	Subcutaneously
SEK	Swedish krona, currency of Sweden
SELV	Safety extra low voltage
SMD	Surface Mount Device
THD	Trough-Hole Device
TTL	Through the Lens
UML	Unified Modelling Language, a type of programming languages
USA	The United States of America
USD	The United States dollar
VDI	Verein Deutscher Ingenieure, The Association of German Engineers

1 Introduction

Affecting over 463 million people world wide and causing healthcare costs exceeding 760 billion USD annually, Diabetes Mellitus is one of the widest spread and most costly autoimmune diseases. Despite big advances in blood glucose control the disease is still responsible for millions of premature deaths. [1, 2] Those suffering from Diabetes Mellitus are dependent on frequent daily insulin injections to keep their blood glucose levels within the healthy range and avoid complications.
Insulin injections are subject to many issues and complications. One of the most prominent issues is the slow absorption rate to the plasma for Subcutaneously (SC) injected insulin. With a median delay of 7.6min for fast-acting insulin the absorption rate makes it extremely challenging for patients or algorithms to achieve a satisfying blood glucose control.[3, 4]
The main research of the Artificial Pancreas Trondheim Group (APT) is focused around blood glucose control with an Artificial Pancreas (AP). A key element of every AP is the control algorithm. In order to improve the performance of its algorithm, APT is also investigating various ways to to improve the pharmacokinetics of insulin. [5] One way to reduce the time delay for SC insulin is to locally increase the SC blood flow. A previous master thesis and some preliminary experiments showed that Near Infrared Radiation (NIR) could be used to increase the SC blood flow and thereby enhance the insulin absorption. Unfortunately the commercially available equipment used during the preliminary experiments proved to be insufficient for further investigation which resulted in the decision to produce a custom made prototype.[6, 7] Therefor this thesis is aimed at building a customised NIR-Device which would narrow the gap.
Due to the potential for patenting and commercialisation of NIR for absorption enhancement **this thesis is classified as strictly confidential** for 3 years after after handing it in. See Appendix I for more detailed information.

1.1 Aim and Scope

In order to full-fill a 2 year MSc in cybernetics and robotics at the Norwegian university of science and technology (NTNU), one has to complete a master thesis accounting for 30 ECTS. The thesis spans over a period of 20 weeks which amounts to a workload of approximately 800h.[8] It is expected that the reader of this thesis has some basic university level knowledge of electronics, mechanics, control theory as well as bio-medicine, comparable to that of a 2^{nd} year MSc student in cybernetics and robotics at NTNU with a specialisation in biomedical cybernetics.
The APT Group is investigating ways to improve the pharmacokinetics of SC insulin as already stated in the Introduction 1. One promissing approach is the use of a NIR source to locally increase the SC blood flow and thereby reduce the

absorption delay. Previous researches conducted by APT on this topic yielded some promising initial results, and more extensive studies are being planned to properly investigate and quantify the effects of NIR.
Should the use of a NIR source improve the SC insulin uptake as indicated, it would provide a simple and cost-effective way to help patients facilitate their diabetes management and it would allow developers of AP to utilise more aggressive control approaches. This would overall result in a better blood glucose management which would reduce the short and long-term diabetes complications. There are still other factors affecting the pharmacokinetics of SC insulin resulting in a total delay of 40 to 49min between injection and maximum plasma concentration, but being able to reduce the 7.6min between injection and absorption onset would be the first major step.[3, 9]
When researchers of the APT Group performed a pilot study in 2019 it became quickly apparent that the off-the-shelf NIR-Therapy devices available were not suitable for large scale and more detailed investigations as they lack the configurability and were dependent on a stationary power outlet.[10] It was therefore decided that a customised NIR-Device was required.
Due to the sheer size of the prototype development task, the project was split into a semester project and a master thesis. This master thesis is therefore a direct continuation of my project thesis titled "Device for improved insulin absorption in diabetes type 1". [7] The original intend of the master thesis was to complete the entire prototype development task including parameterisation and testing of the completed prototype. However, due to the task being significantly more extensive than anticipated as well as delays caused by corona restrictions, supply shortages and non-thesis related work tasks performed for the APT Group, the progress was not as intended. This thesis did therefore not result in a finished prototype but it managed to address the majority of tasks of the Design Phase and make preparation for having the device built and assembled in the aftermath of the thesis.

1.2 Structure of the Thesis

This MSc thesis consists of 6 main chapters and provides various supporting documents in the appendix. The 1^{st} chapter will provide a brief introduction to thesis as well as a motivation for this thesis. Chapter 2 consists of relevant background theory that will help understanding the thesis content. The 3^{rd} chapter looks deeper into key aspects of the design process while chapter 4 focus on the actual design choices made. Chapter 5 will provide a summary of what was achieved in this MSc thesis while chapter 6 will reflect on the project and highlight remaining work tasks as well as potential improvements.

1.3 Methods

Just like the Project Thesis on which this MSc thesis builds, the work was conducted in accordance with the product development norm VDI 2221/2 - "Design of technical products and systems".[11] Many of the basic development tasks were already performed as part of the Project thesis, so this MSc thesis cover primarily the design aspects of product development. For this, various solutions were identified and evaluated. Electronics were designed in a bottom-up approach and all the required components were identified and purchased. For the electronic design some of the parameters had to be derived through simulation or calculation.
A Gantt-diagram supported by bi-weekly meetings with the two supervisors has ensured project progress as well as frequent exchange with the relevant stakeholders (Appendix H).

2 Theoretical Background

The following section is meant to provide the necessary theoretical background knowledge required to comprehend this thesis. As this master thesis is a direct continuation of my previous project thesis titled "Device for improved insulin absorption in diabetes type 1" [7] the required theoretical background knowledge is for most parts identical. As there is little benefit to rewriting my own words and to improve readability of the thesis it was therefore decided to reuse the relevant theoretical sections by citing them in this thesis.
In order to avoid confusion of what contribution was made during the master thesis the cited sections are written in "*Italic*" and marked with a individual reference to the project thesis at the end of the section.

2.1 Diabetes Mellitus

Diabetes Mellitus is a disease that affects the bodies ability to control the glucose levels in the blood so they end up outside of the healthy range. It is considered one of the biggest health issues of today, affecting over 463 million people which corresponds to about 1 in 11. Furthermore it is the 9th most common cause of death, accounting for 11.3% of deaths, and causes world wide health costs of over 760 billion USD.[12, 13, 14] And we are far from solving the issue as patient numbers and prevalence have been constantly rising, with prevalence nearly doubling in the past 40 years to over 9.3%.[15] Diabetes does not just directly affect the health of the patient through hyper- and hypoglycemia, but poorly controlled blood sugar levels can also cause a variety of long-therm health issues, such as increased risk for cardiovascular diseases such as heart attacks or strokes, high blood pressure, diabetic eye disease (diabetic retinopathy), kidney failure, gum disease, pregnancy complications as well as vascular and nerve damage (usually of the lower limbs).[13] Diabetes can be divided in 3 main types as well as several, more rare types: [7]

Type 1 Diabetes:
Type 1 Diabetes is considered an auto-immune disease where the immune system of the body gradually destroys the β-cells in the pancreas that produce insulin, so the Insulin production will gradually decrease until it becomes non-existent. It can appear at any age, but the majority of patients are diagnosed before the age of 20. With the bodies natural glucose control gone, the patient is dependent on constant monitoring of the blood glucose level and has to inject Insulin accordingly. There is currently no cure for type 1 diabetes and the disease can therefore only be controlled. It is however very demanding for the patient to maintain a good level of control over the blood glucose levels. Type 1 diabetes accounts for approxi-

mately 10% of the total diabetes cases. It is no fully understood what triggers the auto-immune response leading to type 1 diabetes, but it is suspected that it is a combination of genetic susceptibility and environmental factors.[2, 16, 7] [7]

Type 2 Diabetes:
Type 2 diabetes accounts for 90% of the diabetes cases in the world. It is a progressive disease caused by increased Insulin resistance in the body. So the pancreas does not produce enough Insulin or it is not working as well as it should. Most type 2 patients are able to manage their disease in the early stages by eating healthy, weight loss and regular physical activity. However, many will require an insulin regime similar to a type 1 diabetic as the disease progresses. It is also not fully understood what causes type 2 diabetes. However, it is often associated with overweight and physical inactivity, but genetic and environmental factors are also suspected to contribute significantly. [16, 17] [7]

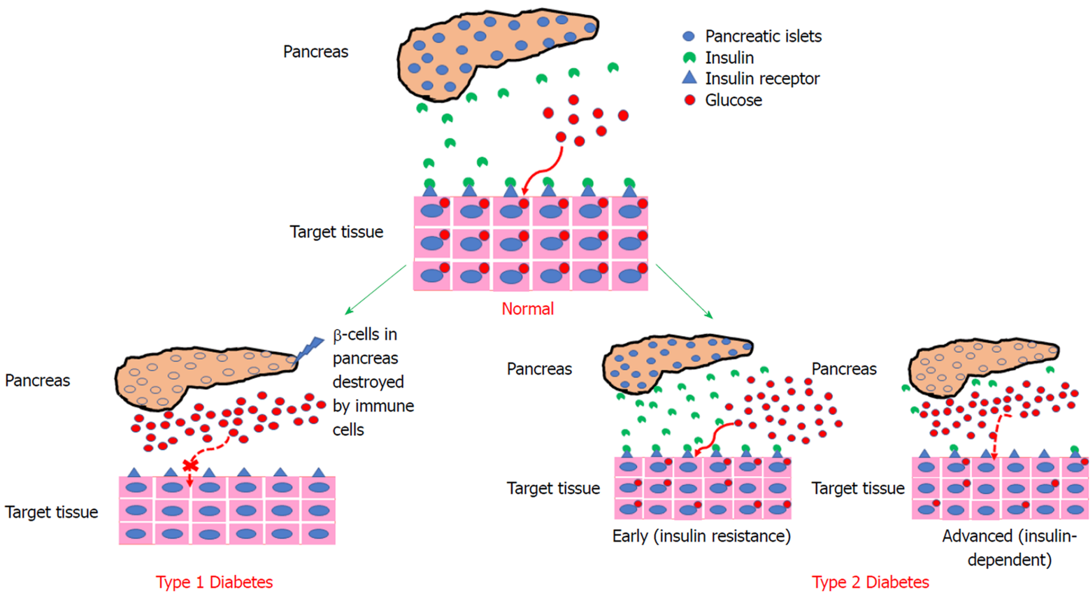


Figure 1: The differences between a normal and a Type 1 and Type 2 Diabetes pancreas [18]

Gestational Diabetes:
This type of diabetes occurs usually during the third trimester of a pregnancy and will resolve itself with the end of the pregnancy. The resulting hyperglycemia however, has to be properly treated and the gestational diabetes has to be well managed as it could otherwise put both mother and child at risk. It is estimated that about 5-10% of pregnant women suffer from gestational diabetes.[19][7]

2.2 State of the Art Diabetes Treatment

Diabetes type 1 is an auto-immune disease which makes it incredibly hard to find a potential cure. So despite a lot of researches in this field it is currently not possible to cure a patient suffering from diabetes type 1. However, much has happened since 1922 when Frederick Banting managed to isolate insulin from the pancreas of a dog and turn diabetes type 1 from a death sentence to a disease that can be managed.[20] Frequent insulin infusion in combination with frequent measurement of the patients blood glucose levels became the norm in managing diabetes type 1. But in order to achieve well controlled blood glucose levels that are close to those of a healthy person it requires a lot of determination and focus on the disease from the patients. In order to simplify the whole processes confronted by patients, there has been a lot of effort put into the development of the "Holy Grail" of diabetes management, the artificial pancreas (AP). So where do we stand now?

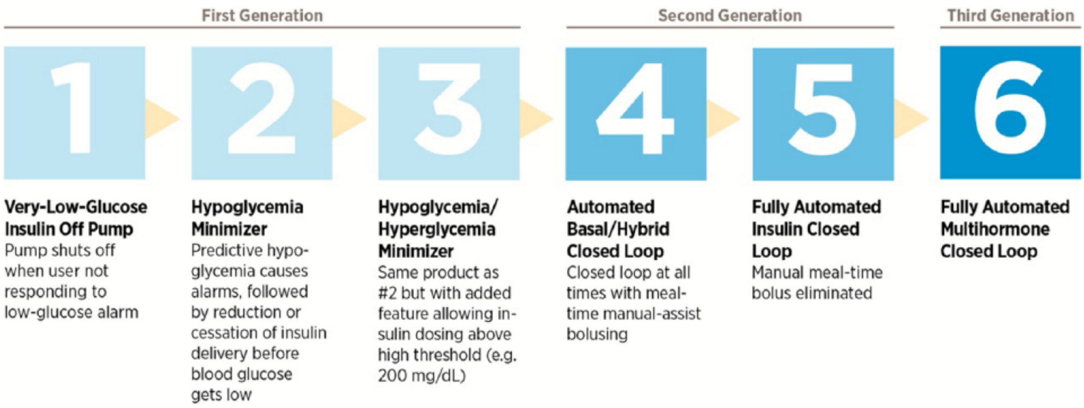


Figure 2: We currently stand at the start of the second generation with the first hybrid closed loop APs being approved and on the market and several other companies not far behind.
[21]

Figure 2 highlights the steps towards this goal. At the time of writing we find ourselves on step 4 at the start of the second generation of AP devices. There are currently two Hybrid Closed Loop APs on the market, the Medtronic MiniMed 670G (Medtronic plc., Minneapolis - USA) and the Tandem Control-IQ (Tandem Diabetes Care, Inc., San Diego - USA). Both systems are single hormone as they only use insulin and consist of an insulin pump, a continuous glucose monitor (CGM) and a control algorithm to adjust the insulin infusion based on the measurements from the CGM. They are also know as double subcutaneous (SC) systems as both insulin administration and glucose monitoring happens via the SC route. They do perform very well in times of low activity, for example at night, but still require a significant amount of attention from the patient during the more active times, especially with

regards to meals and physical activity. So in order to achieve a true closed loop AP, that frees the patient of the majority of the disease burden, there are still a lot of issues that have to be solved. There is also work being done in dual hormonal AP that use Insulin and Glucagon as well as systems using the intraperitoneal (IP) delivery and monitoring route, but these systems are still far away from entering the market.[22, 23, 24][7]
In addition to advanced control, monitoring and infusion systems, there are also faster acting insulin being developed.[20] [7]
Other attempts at halting the progress of diabetes type 1 or even curing it with the help of pancreatic islets or pancreas transplantation as well as immune therapies are also being investigated. However, none of those have so far managed to provide a lasting cure as they struggle with various challenges such as foreign body response, lack of donors and high cell mortality during transplantation.[25] [7]

2.3 Insulin and Glucagon

For our body to function properly it is important to keep the glucose levels in our blood within a rather tight band of 3.5-5.5mmol/l when fasting. Our body adsorbs glucose through the intestines from the food and drink ingested. Glucose provides the main energy source for our muscles, brain and other cells and is metabolised within those. Keeping control of the blood glucose level and keeping it within the healthy zone is one of the most important functions of the pancreas.
The pancreas is a large gland located closely to the stomach and produces enzymes for the digestive system as well as various hormones to keep the blood glucose and salt concentration in the body at balance. The most prominent hormones for blood glucose control are Insulin and Glucagon. Both hormones have their main effect on the liver, which acts as the body's main glucose reservoir and stores the glucose in the form of glycogen.[26, 27][7]
As visualised in figure 3, if the blood glucose rises too high the pancreas releases Insulin from its β-cells which results in glucose being absorbed into tissue and the liver. This would happen, for instance, after a carbohydrate rich meal. Should glucose levels fall below normal, for example due to exercise, the pancreas will release Glucagon produced in its α-cells which prompts the tissue and liver to release the previously stored glucagon and glycogen. Hence Insulin and Glucagon counteract with each other.[26, 28] [7]

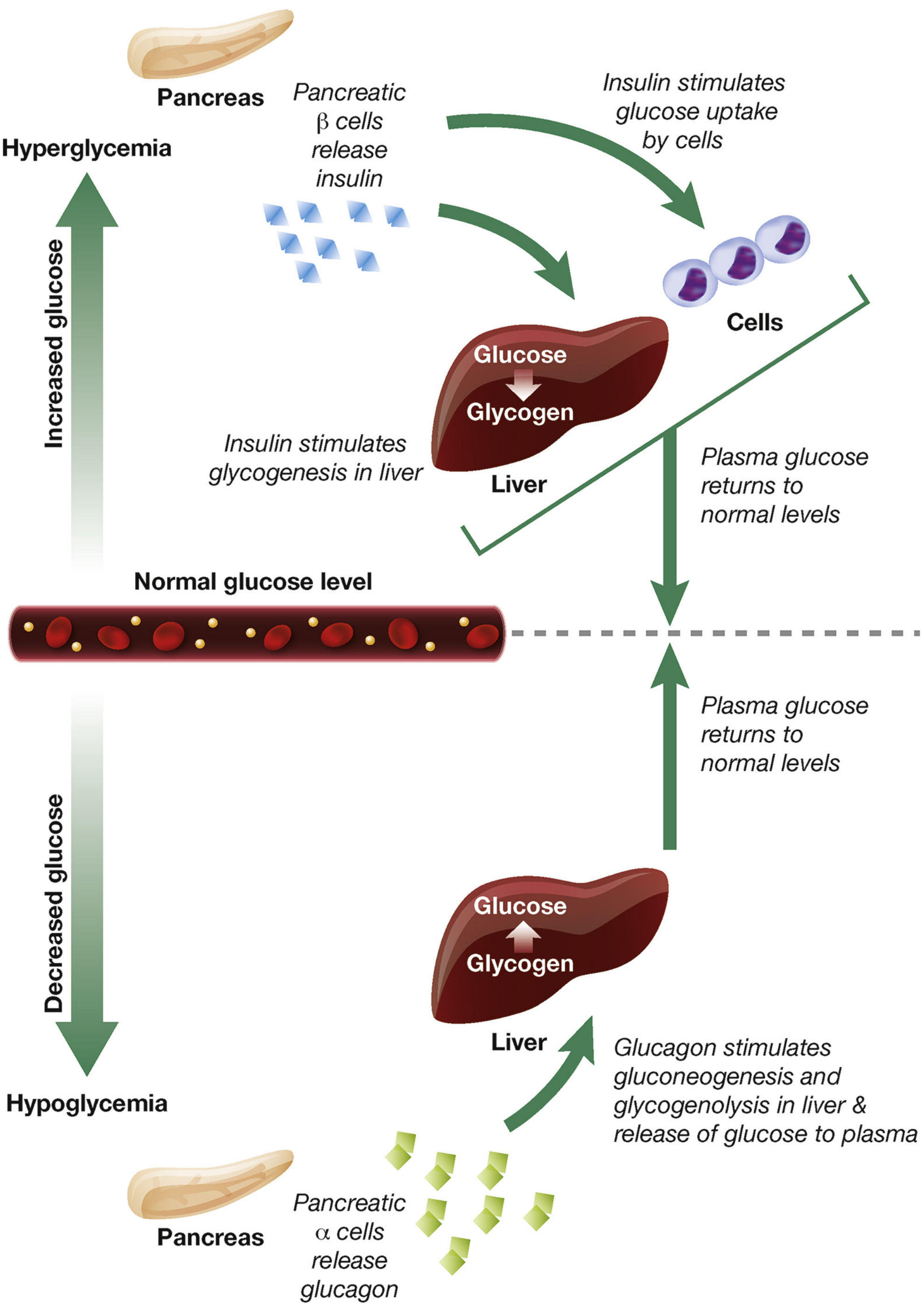


Figure 3: Effects of Insulin and Glucagon on the body's blood glucose level. [16]

2.4 Subcutaneous Tissue

The skin is the biggest organ of the body and covers every part of it. It is made up of several different tissue layers with different functions as shown in figure 4. The subcutaneous tissue, also know as hypodermis, is often described in literature as an adipose tissue layer. However, it is an intricate structure of a variety of cells, tissue and vessels. The subcutaneous tissue consists of a network of loose connective tissue, adipose tissue and unevenly distributed arterioles, venules, capillaries and lymph vessels. Within this comparably loose tissue there is a small quantity of interstitial fluid that allows for transport of nutrients. It is located between the dermis and the fascia, creating a type of gliding surface between the two. This allows the skin to stay elastic and protects the underlying muscles from trauma.[29, 30] The subcutaneous tissue is often used for the injection of small volumes of drugs (<2ml), however, due to the few blood vessels, the transport of the drug to the blood circulation happens primarily through diffusion in the interstitial fluid according to Fick's laws. This results in a slow but continuous absorption. SC tissue suitable for the injection of drugs is primarily located on the abdomen, the thighs, the upper arms and the lower loins. Some of the key drugs administered subcutaneously are vaccines, insulin and growth hormones.[29, 31] [7]

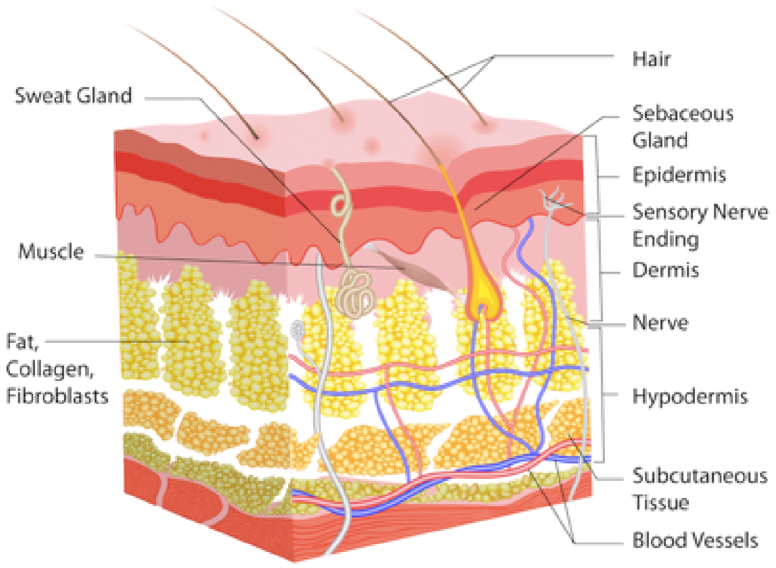


Figure 4: The human skin consisting of the main layers Epidermis, Dermis and Subcutis or Hypodermis lying on top of a fascia and the skeletal muscles. [32]

2.5 Problems with external Insulin Delivery

External, so called exogenous insulin has been the cornerstone of diabetes management for the past 100 years, and massive advances have been made on the insulin types used as animal derived insulin have gradually been replaced by insulin analogues in an attempt to mimic human insulin and to improve diabetes management. As a result there are now four main groups of insulin available, rapid-, short-, intermediate- and long-acting insulin analogues.[33] They are either used individually or in combination with each other and the standard way of administering them is through SC injection. The injection happens either via a pump and so called continuous subcutaneous insulin infusion (CSII) or multiple daily injection (MDI), whereas CSII is the superior treatment with regards to glucose control.[34] [7]

The rapid acting insulin, for example Humalog®or Fiasp®have onset times of 15min, reach their peak action after 1-3h and are no longer active after 3-5h, Which is already a big improvement compared to the early insulin, but nowhere near the endogenous insulin in a healthy person where the onset happens within 1-2min of a meal and up to 80% of it reaches directly the liver where it has its main effect. In addition to that, endogenous insulin has a much shorter half-life time of around 5min which means it is cleared much faster from the system. The exogenous insulin on the other hand is administered by SC and transported by the blood-circulation, consequently the concentration hitting the liver is very low. So when looking at physiological problems for administering exogenous insulin SC, it becomes apparent that the slow onset combined with a long active period causes a lot of problems when managing blood glucose levels. Due to the slow onset, patients have to calculate how much carbs they are going to eat and administer the appropriate amount of insulin 15-30min prior to a meal in order to avoid hyperglycemia after the meal. The other problem stems from the long active duration of exogenous insulin which can cause hypoglycemia long after the insulin has been administered. Those controlling problems can cause other side effects, such as weight gain due to the need of extra glucose to counter hypoglycemia. Another issue can arise lipohypertrophy at the injection site where fat accumulates in the SC tissue and consequently delays the insulin uptake even further.[35, 36, 37, 38, 6] [7]

2.6 Near Infrared Radiation (NIR)

Infrared radiation(IR) is part of the non-ionising part of the electromagnetic spectrum. It starts just above the visible light at a wavelength of 780nm and reaches up to a wavelength of 1mm. The infrared spectrum is subdivided into Near , Mid and Far infrared. IR is also known as thermal radiation and the penetration depth varies greatly from several millimetres for NIR to superficial for Far infrared. Near Infrared radiation (NIR) ranges from 780 to 1400nm and will be the main focus of this thesis due to its higher penetration depth.[39, 40] There are several factors affecting the penetration depth of IR, such as wavelength, energy, coherence, size of the irradiated area, as well as the attenuation coefficient which is defined by refraction, scatter and absorption of the material in question. [7]

Human tissue is a collection of various materials, which makes it hard to calculate exact numbers of the penetration depth. Human tissue has several so called windows that are biologically transparent, meaning that the total attenuation within this bandwidth is comparably small which makes it ideal for optical applications. In case of human tissues there are three such biological windows with the first one lying between 650-950nm, the second between 1100-1350nm and the third one at 1600-1870nm. These windows are readily exploited for diagnostic and treatment purposes. Due to the deeper penetration of the shorter wavelengths, the thesis will focus on the first window. The first window is primarily defined by the absorption of water on its upper end and the absorption of the melanin in the skin on its lower end. This is illustrated by Figures 5A and B with A highlighting the three windows as well as the loss due to scattering while B highlights some of the main attenuation contributors in the first and second window.[41, 42, 43] [7]

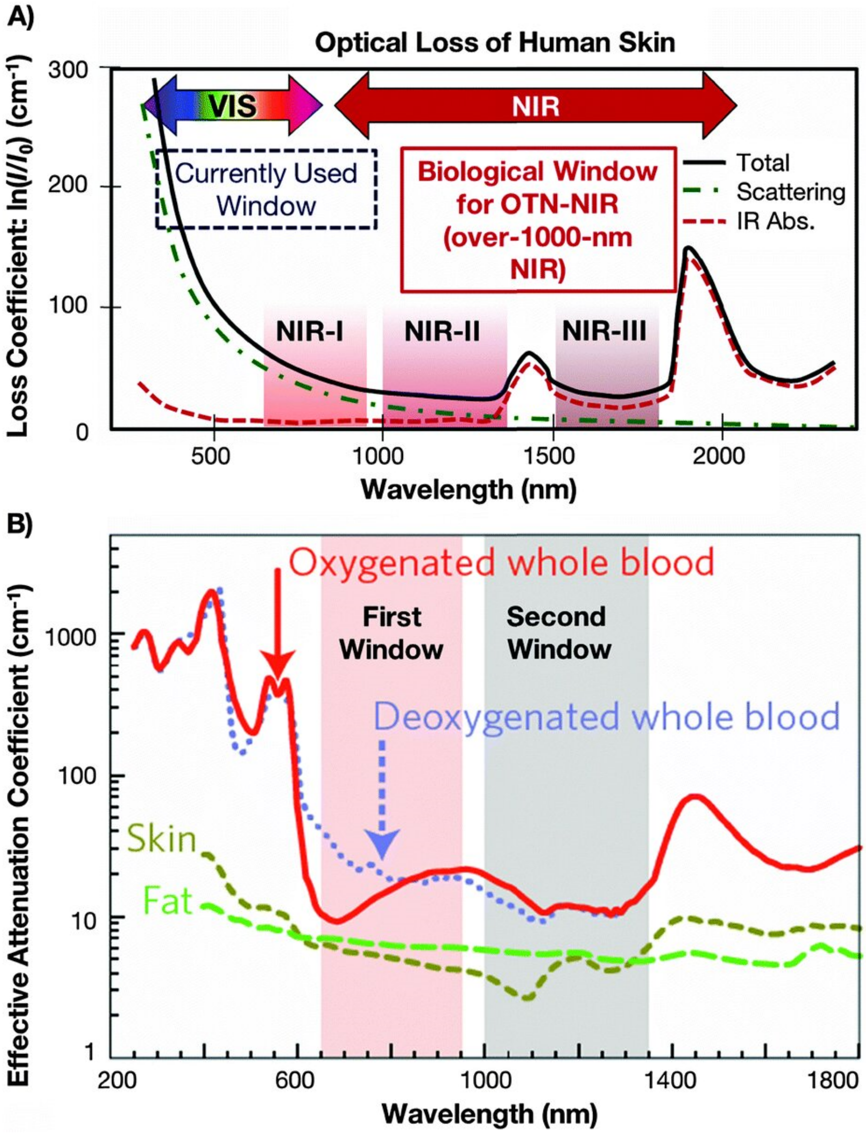


Figure 5: A: Tissue windows and contribution of scattering to optical losses in skin
B: Attenuation contribution of key component in dermal tissue.
[41]

2.7 Medical Thresholds for NIR - Radiation

NIR is located in the invisible, non-ionising part of the electromagnetic spectrum. Its main effect is the depositing of energy in the form of heat in the tissue as the water molecules in the cells absorb the radiation, but it is also able to change protein structures. It is therefore important to assess the potential hazards of handling NIR sources and the maximal medical thresholds that guarantee the safety of the patients.
When assessing the potential dangers of a light source, it is important to distinguish between coherent light sources, such as lasers, and incoherent light sources, like Light Emitting Diodes (LEDs). Due to coherent light sources' focused and directed radiation, a much higher energy density are therefore capable of causing damage within a fraction of a second. It is therefore only logical, that laser applications are much stronger regulated than LED applications. Other factors that determine the risk of NIR exposure are the wavelength, the exposure duration and the type of organ irradiated. As this project uses only LEDs, this section focuses only on dangers and thresholds applicable to LEDs.
As the overall penetration depth of NIR radiation does not exceed a few millimetres, it primarily affects superficial organs like the skin or the eye. The eye is significantly more sensitive than skin as the eye focuses the incoming radiation onto the retina. There exist therefore different thresholds for skin and eye.
In the NIR spectrum the main damage to the eye stems from thermal damage of the iris, thermal damage of the crystaline lense and thermal damage of the retina. In addition to that, there is the risk of photochemical damage to the retina in case of chronic exposure. This chronic exposure can result in cataracts, which is commonly seen in glass workers.
If the source is strong enough it will trigger within a short time a feeling of discomfort and pain, which causes an adverse reaction long before dangerous exposure levels are reached. The same applies to very bright light sources which cause an adverse reaction of the eye. However, the natural protection mechanism for the eye does not work as well for very strong pulsed sources or sources with longer wavelengths that are in the invisible spectrum, such as the longer wavelengths in the first tissue window. In case of LED sources the risk of pulsed radiation can be neglected as the response time of the semiconductor junction is too slow.[39, 44]
The danger of skin damage though a NIR source is significantly lower, as the majority of the NIR is absorbed by blood which is constantly circulating and effectively preventing heat from accumulating. Furthermore, pain and discomfort will appear long before NIR radiation causes damage and will cause an adverse reaction in the patient. If however the radiation source is attached to the skin, there are two heat sources present: one is the radiant heat energy from the NIR, and the other is heat transferred by conduction from the semiconductor junction. The second however is only relevant if the LEDs are in direct contact with the skin. Bozkurt Onaral (2004) [45] showed that the heating of the skin caused by the semiconductor junc-

tion can raise the skin by up to 10°C compared to the increase of 0.5°C cause by the NIR component of the same source. Based on this research it is therefore advisable to avoid direct contact between the skin and the LEDs whenever possible.[45] The medically safe exposure limits are derived from the current knowledge and constantly updated by the International Commission on Non-Ionizing Radiation Protection (ICNIRP).[46] These limits are used by various regulatory bodies and standards. In case of Norway it is the Norsk Elektroteknisk Komite (NEK) that is responsible for the standards involving IR sources. According the the standard NEK IEC 62471:2006 the following exposure limits apply for the NIR application and wavelengths in this project:[47] [7]

Maximal optical exposure for the eye:
For t<1000s:

$$E = \frac{1.8 \cdot 10^4}{t^{\frac{3}{4}}}[W/m^2]$$

For t>1000s:

$$E = 100[W/m^2]\ or\ maximum\ daily\ dose\ H = 3 \cdot 10^6[J/m^2]$$

Thresholds for NIR exposure to skin only exist up to t = 10s as the on-setting pain reaction will cause a human to turn away from the source before the skin can get harmed.
For skin exposures t<10s the maximum daily dose is defined as:

$$H = 2 \cdot 10^4 \cdot t^{\frac{1}{4}}[J/m^2]$$

2.8 Various Factors affecting Insulin Absorption

There are a large variety of factors that can influence the insulin absorption speed both negatively and positively. This creates a large variabillity which in turn complicates diabetes management.The mechanisms behind those factors are often quite complex, so this section will only provide a general overview.
A lot of research has been put towards the development of different insulin formulations with specific pharmacokinetics (section 2.3), ranging from long- to rapid-acting. Those different insulin make use of various additives and different sizes of insulin oligomers. Other factors affecting the absorption are the infused volume and the concentration of the infused insulin, with larger concentrations and volumes resulting in slower diffusion and hence a slower absorption. [7]
A major role in the pharmacokinetics of insulin plays the subcutaneous blood flow,

with increased blood flow resulting in a faster absorption. A wide array of factors can influence the SC blood flow. There are for example various vasodilating drugs, exercise, massage, skin temperature and Nitrous Oxide(NO) release which all improve absorption while smoking for example results in a lower SC blood flow.[7]
The injection site and injection type also influence absorption as different sites have different concentrations of SC capillaries and different amounts of SC adipose tissue. For example an injection into the SC tissue with a high adipose tissue content and few capillaries results in a slower, but more steady and controlled absorption while an intramuscular injection is absorbed much faster but less predicable which can easily result in hypoglycemia.[7]
Other factors are for example the injection technique, needle size or medical conditions, such as lipohypertrophy, where the SC tissue in a local area becomes more fibrous with a lower density of blood vessels.[48, 49]
There are two factors that are especially relevant for this project as the APT Group intends to investigate them with the help of the finished prototype, so the next two subsections will expand on them. [7]

2.9 Nitric Oxide induced Vasodilation

Nitric Oxide (NO) is a crucial chemical messenger in all mammals. It affects directly and indirectly various organs in the body. One of its main effects is the regulation of blood pressure by relaxing the blood vessels, also known as vasodilation. NO is the bodies most potent vasodilator and acts locally by activating enzymes in the vascular smooth muscle cells, rendering them to relax. It inhibits vasoconstriction as well. However, at the same time it also acts as a neurotransmitter and affects among others various functions of the immune system, the gastrointestinal, respiratory, and genitourinary tract. NO is primarily synthesised in the vascular endothelium (the inner cell layer of blood vessels) and possesses an odd number of electrodes, which makes it a highly reactive and radical molecule. The amount of NO synthesised depends heavily on the availability of the amino acid L-arginine, NO synthase (NOS) enzymes and oxygen. However, there are also several non-enzymatic pathways where nitrite is turned into NO that can affect the NO levels. NO can travel comparably large distances of more than 100μm through diffusion. It also diffuses very easily by having 1.4x the diffusion coefficient of oxygen. The half-life time of NO can vary greatly depending on the environment but is generally very low, ranging from 3.8 - 6.2s in an aqueous solution to <1s in blood. This short half-life time can primarily be attributed to the high reactivity of NO and it increases significantly with falling NO or oxygen concentrations.[50, 51, 52, 53, 54]
[7]

2.10 Application of Heat for increased Insulin Absorption

It is a well-known principle that heat affects the uptake of insulin and other SC administered drugs. Higher temperatures lead to vasodilation while lower temperatures result in vasoconstriction. Global heat application results in global vasodilation, while local application will only trigger a local response. A maximal local cutaneous vasodilation can be achieved by continuously applying 42°C to the skin. A strong response can be observed after 3 to 5min of heat exposure and the blood flow reaches a plateau after 25 to 30min of exposure.[55] This heat induced vasodilation has shown to induce faster insulin uptake after a SC infusion. There are also attempts being made to integrate this effect into a diabetes product, such as the InsuPatch™ and the InsuPad™ (both Insuline Medical Ltd., Petach-Tikvah, Israel). During one of their studies they successfully showed that local application of heat at the infusion site can reduce the time to maximum plasma insulin concentration by 42%. In order to achieve this InsuPatch™ was deployed, which consists of a heating element that has been incorporated into the adhesive layer of an infusion set. During those experiments the heating element was activated 15min prior the insulin bolus and turned off 60min after the bolus. During this time it exposed the infusion site to a constant temperature of 40°C.[56, 57] [7]

2.11 Application of NIR - Radiation for increased Insulin Absorption

The investigation of the effects of NIR radiation on the body has its roots over 50 years ago when Mester et al. started investigating the so called Low-Level Light Therapy (LLLT) which is a PhotoBioModulation (PBM) therapy.[58]Those types of therapy employ laser or LED between 600 and 1000nm, exploiting the first tissue window, and apply it locally to the skin in order to modulate biological activity. In order for the emitted NIR radiation to have a biological effect on the skin and the cells below, the radiation has to be absorbed by the cells. So the possible effective depth is directly dependent on the penetration depth of the applied NIR radiation. This penetration depth depends greatly on several factors, such as skin/tissue type, irradiation power, type of irradiation source, skin thickness and skin pigmentation. However, one of the most prominent factors is the wavelength of NIR. For wavelengths and irradiation power inside of the range used by PBM therapy the penetration depth varies greatly, from around 2-3mm for 660nm to about 4-6mm for 830nm with a peak penetration at 800nm. This is represented by the absorption coefficient($1/cm$) for skin. Yoon et al.[59] determined its value for skin with a thickness of 3mm: 0.26 (λ = 660nm), 0.12 (λ = 830nm), and 0.38 (λ = 980nm).[7]

Although a lot of different values for the absorption of skin can be found in literature with Kono & Yamada [60] reporting a 10 times lower absorption coefficient for 800nm compared to 600nm on the inner forearm. Higher penetra-

*tion depths were also achieved by increasing the optical output of the source. Some studies report penetration depths of 50mm when applying 660nm with 100*mW/cm^2*.[61]*[7]
Many health benefits are attributed to therapies using NIR radiation and several of them are rather controversial and disputed. But there as also several health effects that are scientifically supported. Those effects ranging from improved wound healing to neural stimulation and applications in cancer treatment.[62][7]
What makes NIR radiation interesting for potentially improving the pharmacokinetics of insulin is the fact that many of the scientifically proven health benefits of NIR radiation rely on NIR radiation triggering the production of reactive oxygen species (ROS) and reactive nitrogen species (RNS), one of which is NO, a potent vasodilator. However, mechanisms and the extent of this NIR triggered NO production are not yet fully understood.[63, 64] [7]

2.12 Systems used in Previous Studies

In 2019 the APT Group performed a small pilot study with 8 type 1 diabetes patients to investigate the potential of NIR to cause vasodilation and through this a faster uptake of insulin. For this these patients exposed their insulin injection site prior to the injection to NIR for a designated amount of time and the result was monitored through a SC CGM system. This study was based on the Regional Ethical Committee (REK) application No.2018/2468. Two commercial models, approved by the Food and Drug Administration (FDA) were considered for this study: The Anodyne® (Therapy Model 120 Professional), and the Tendlite®(Model 204). Based on the fact that there is more scientific data indicating that the wavelength used by the Anodyne® could have the desired effect, it was decided to use the Anodyne® in the pilot study. The results of this study lead to the desire of further investigating the potential of NIR for enhanced insulin absorption, which is one of the main drivers for this project.[65, 10, 66, 67] [7]

2.12.1 Anodyne® Therapy Model 120 Professional

The Anodyne® Therapy Model 120 Professional (Anodyne Therapy LLC, Oldsmar - FL, USA) as shown in figure 6 is an FDA approved Monochromatic Infrared Therapy (MIRE) System. It is equipped with 4 LED pads comprised of 5x12, so a total of 60 LEDs which are operated at 292Hz with a duty cycle of 50%. The system requires a constant 230V power supply, so it is not suitable for mobile use. The LEDs have a wavelength of 890nm and a radiant intensity of 18.4mW/sr, resulting in a radiant power density of 34.7mW/cm^2 per pad. The LED pads are directly applied to the skin for up to 45min at a time and the intended medical use is to provide pain relief and increase blood circulation.[68, 69] [7]

Figure 6: LED pads and base station of the Anodyne® Therapy Model 120 Professional [70]

2.12.2 Tendlite® Medical Device - Model 204

The Tendlite® Medical Device - Model 204 (Lumina Group Inc, San Diego - CA, USA) is a small, portable and pen-shaped device as seen in figure 7. It is approved by the FDA for pain relief and promotion of faster wound healing by reducing inflammations and increasing blood circulation.
It operates at a wavelength of 660nm and contains one LED with an optical output of 1500mW. It is applied in a 60s interval with up to 3 repetitions. During the application the device is held 1 inch (= 2.54cm) away from the skin, resulting to a radiant power density of 94.04mW/cm^2.[71, 72] [7]

Figure 7: The Tendlite® Medical Device - Model 204 in use. Due to the wavelength of 660nm the radiation is visible to the naked eye.
[71]

2.13 Light Emitting Diode (LED)

Light Emitting Diodes or better known as LEDs have been around since the 1960s. LEDs are part of the wider family of Diodes as they have very similar electrical properties and are therefore often represented in schematics and literature with the diode symbol and two added arrows for the photons emitted as seen in figure 8.[73, 74, 75]

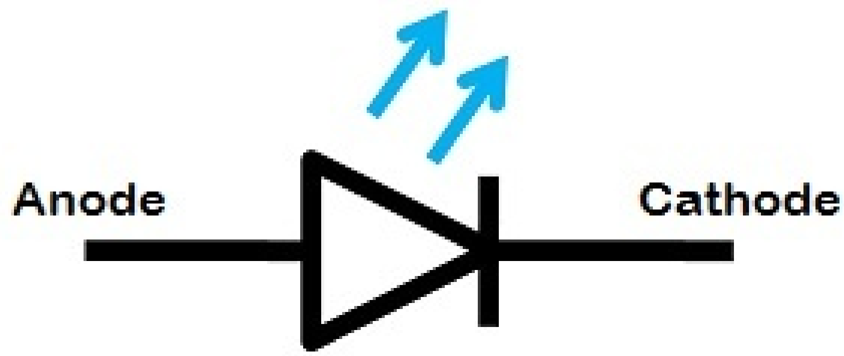


Figure 8: The schematic symbol for LED used in electronic applications. The Forward Current (I_F) flows from Anode to Cathode and the light blue arrows represent the photons emitted.
[74]

However, only in recent years LEDs became omnipresent in daily life and are nowadays found in nearly every device containing electronics. They stand out with their small size and high efficiency compared to traditional incandescent light sources.
An LED is a type of semiconductor that combines a P-Type semiconductor which has a hole surplus with a N-Type semiconductor that has an electron surplus. Applying a sufficient Forward Voltage (V_F) will trigger the electrons to cross the P-N junction and recombine with the holes which results in the flow of a Forward Current I_F. The forward current I_F together with the forward voltage V_F lead to the release of energy in the form of heat and photons. This is illustrated in figure 9.[73, 74, 75]

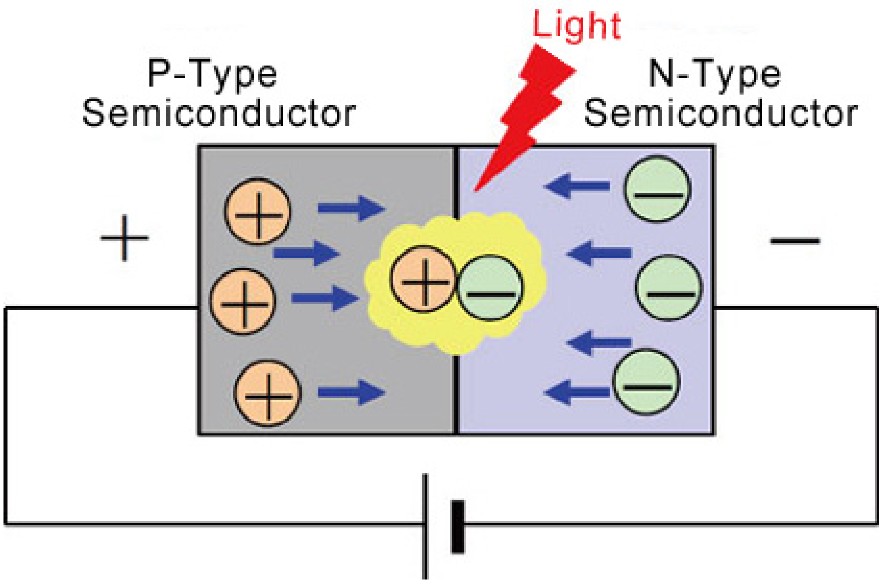


Figure 9: A simplified drawing of an LED-Dice with its P-Type and N-Type layer. [76]

It is possible to alter the wavelength of the photons emitted by doping the semiconductor layer with different elements and thereby cover the entire spectrum goes from Ultra-Violet all the way to Infrared.
The added impurities affect the forward voltage V_F of the LEDs, the forward voltage V_F ranges between approximately 1.2V and 4.0V dependent on the type of impurity added, with the longer wavelengths having a lower forward voltage V_F. Figure 10 provides an overview of the most commonly used elements and how they affect the specifications of an LED.[73, 74, 75]

Typical LED Characteristics			
Semiconductor Material	Wavelength	Colour	V_F @ 20mA
GaAs	850-940nm	Infra-Red	1.2v
GaAsP	630-660nm	Red	1.8v
GaAsP	605-620nm	Amber	2.0v
GaAsP:N	585-595nm	Yellow	2.2v
AlGaP	550-570nm	Green	3.5v
SiC	430-505nm	Blue	3.6v
GaInN	450nm	White	4.0v

Figure 10: A table with the primary elements used for doping the semiconductor layer. It also displays the resulting wavelength and approximate Forward Voltage (V_F).
[73]

As the energy released is directly dependent on the current flowing through the LED, it is essential to limit the forward current I_F and thereby prevent the LED from overheating which would permanently damage it. There are various ways of current control, yet adding a serial resistor R_S is the most basic one. Figure 11 shows an example for such a series circuit.
LEDs can easily be combined to an array by connecting them in series to one another where all LEDs in the array are subject to the same forward current I_F, and adding an additional serial resistor R_S simply results in an additional voltage drop.
LEDs should however never be connected in parallel as no two LEDs are identical. This small difference between LEDs would result in different currents flowing through the parallel LEDs. This current would for one result in different wavelengths being emitted by the parallel branches, and in the worst case the current would lead to one branch overheating.[73]

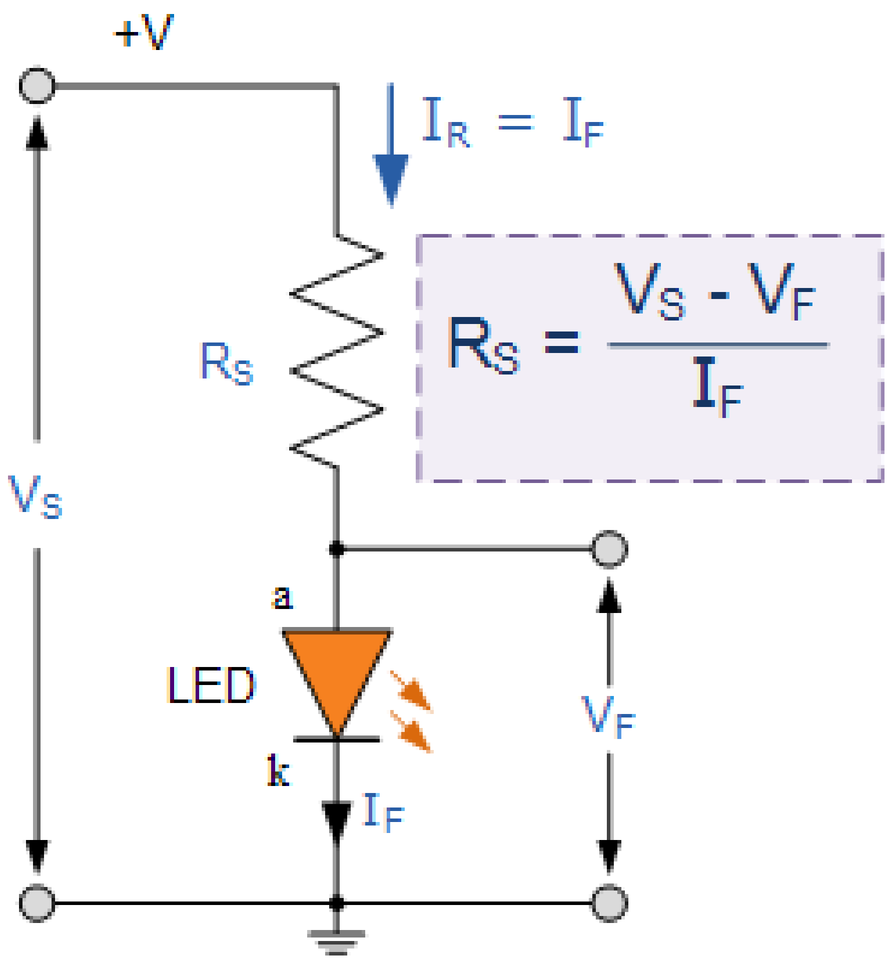


Figure 11: A schematic drawing of the most basic control circuit for LEDs. The serial resistor (R_S) is selected according to the desired voltage drop ($V_S - V_F$) when running the LEDs Forward Current through it.(I_F) [73]

The LED dice itself is tiny, usually less than $1x1mm$. To allow an easier mounting, the dice are usually placed in either a Trough-Hole Device(THD) housing or a Surface Mount Device(SMD) housing. Figure 12 shows a cross section of both housing types with their main components. Both types of housing have an Anode and a Cathode to connect the dice to the circuit. In addition to that a Reflector and a Lens that directs the photons emitted as desired for the intended application can be seen. One big advantage of the SMD housing is the large thermal heatsink that allowes for a much better thermal connection to the environment. This makes SMD housings ideal for high power LEDs that require active cooling to avoid thermal damage as they can easily be attached to an appropriate external heatsink.[77]

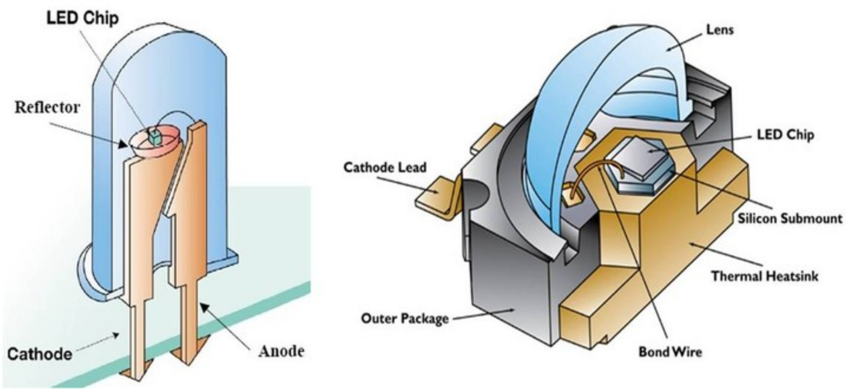


Figure 12: The two main types of LED casing and their construction. With the Trough-Hole housing on the left and the Surface Mount housing on the right. [77]

2.14 Control of Power LED

When dealing with power LED that typically operate with an $I_{\mathrm{F}} \geq 350mA$ it becomes quickly complex if one is to ensure a safe and stable operation. For one, power LEDs require a rather high current and are very demanding on the stability of that current as any variation would change the emitted wavelengths and the brightness. Because of this high stability demand the simple circuit with a serial resistor is no longer usable as the resistance of the resistor is temperature dependent, so it will constantly change while in use. Furthermore are the voltage outputs of most power supplies also not perfectly stable which also affects I_{F}. In addition to what mentioned above, will the V_{F} of the power LED also increase as temperatures rise. We therefore require a circuit that can actively control I_{F} if we are ever to stand a chance at achieving a stable output of the LED.
There are various different ways to create a current control circuit and Figure 13 shows a simple example of such a current controlled circuit. In case of this circuit a fixed value for I_{F} can be chosen by adjusting the value of resistor$R2$. This circuit operates with two transistors, $Q1$ and $Q2$. If the voltage drop over $R2$ exceeds $0.6V$, $Q2$ will start conducting which diverts some of the base current from $Q1$, as a result increasing its resistance, causing I_{F} to drop. The system will stabilise around a voltage drop of $0.6V$ over $R2$. [73, 78]

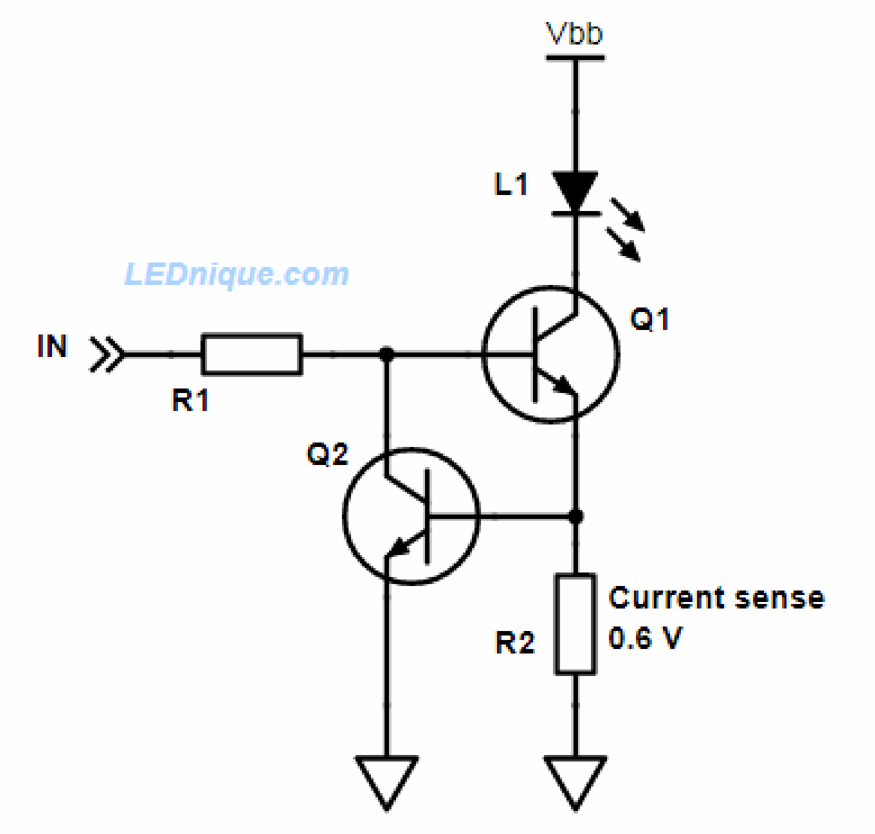


Figure 13: Simple example of a constant current driver for LEDs using two transistors and a resistor $R2$ to select the desired I_{F}.
[79]

If one wants to reduce the optical output of the power LED, one can not simply reduce I_{F} as this would also change the emitted wavelength. So for a dimming power LEDs without changing the emitted wavelength one has to use a Pulse Width Modulated (PWM) input to the control the circuit. A PWM input will turn the power LED on and off in fast succession. By adjusting the time between ON-cycles it is possible to reduce the average current and thereby the total optical output of the LED without interfering with the emitted wavelength. In order to leave the visual impression of a source that is constantly on, the PWM has to have a pulse frequency of at least $400Hz$ as the LED would otherwise be perceived as blinking.Figure 14 shows such a PWM signal.[73, 78]

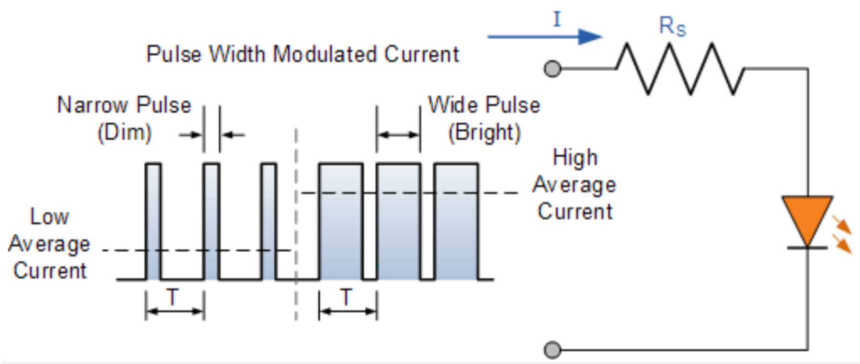


Figure 14: Example of a PWM signal for Dimming of LEDs.T is the also known as Duty Cycle and is defined by the on time. For example if the signal is on for 20% of T, the Duty Cycle will be 20%.
[73]

Another major challenge when controlling power LED is the large amount of heat generated by the semiconductor junction. An increased LED temperature will significantly reduce the LEDs lifetime and can in the worst case destroy it. It is therefore a must to design an adequate cooling system for the power LEDs. It is also possible to reduce the heat generated by operating the power LEDs with a Duty Cycle $< 100\%$ as this gives the power LED time to cool down between pulses.[78]

3 Design Process

This section covers the Design Phase according to the product development norm VDI 2221/2 - "Design of technical products and systems".[11] and builds on the work performed in the project thesis titled "Device for improved insulin absorption in diabetes type 1" [7]. The project thesis covered primarily the Planning Phase and parts of the Concept Phase. As part of the project thesis were among other tasks an FMECA, a patent search and a stakeholder analysis performed. In addition to that some preliminary experiments were conducted to identify the some design parameters of the LED-Head. This information was combined to an extensive Functional Specifications document which in turn provided a base to have a first look into the critical system components. Based on the results of the project thesis, this master thesis will conclude the Concept Phase and address the majority of the Design Phase.

3.1 Desired Application

Based on the findings of the project thesis [7] and feedback from the main stakeholders it became apparent that a final prototype should be a compact, portable and self-contained device with a basic and simple user interface so it can easily be operated by researchers and test subjects without programming knowledge. The device will primarily be used for investigating the effects of NIR on SC insulin absorption-speed in either supervised in-house studies at the clinic or with free-living test subjects with limited supervision. It is therefore essential that the device runs reliably, has strong safety features to protect the user from harm and comes with enough memory space to allow for data collection over the course of several days.
The device should also allow to investigate if the main effect of NIR-Therapy stems from the electro-chemical reactions triggered by the NIR radiation or if the effect is due to heating of the tissue, induced by the heat generated in the semiconductor junctions of the LEDs. This requires a modular system that allows for a swift and easy exchange of the wavelengths used. It is also desirable that beside the thermal and electro-chemical effects the placebo effect can be investigated as well.
To sum it up, the prototype shall be a useful tool in the investigation of the following three medical questions:

- Does NIR radiation increases the local SC blood flow?
- Does increased local SC blood flow stem from en elctro-chemical effect or heat?
- Does the application of NIR radiation improve the pharmacokinetics of SC administered insulin?

3.2 Design Concept for Key Components

The following section will investigate the design concepts for the most crucial elements and components of the prototype.

3.2.1 Simulation of LED Placement

Determining the maximal optical output and where on the PCB to place the LEDs is not an easy task. We desire a uniform distribution of the NIR radiation inside our Region of Interest(RoI) which is made quite challenging by the fact that the optical output of each LED varies greatly depending on the viewing angle. It was therefore decided to simulate the LED arrays for different configurations in MATLAB and use an optimisation algorithm to determine the ideal placement for each LED. It is intuition that for a uniform irradiation of the RoI the LEDs have to be distributed in a somewhat symmetrical manner, so an optimisation algorithm should be able to account for this. With support of Karim Davari, one of APTs Phd candidates, a hybrid optimisation in the form of Mathworks Genetic Algorithm (GA) optimisation was implemented into MATLAB. The Genetic Algorithm combines a binary optimisation executed on the XY-plane to place the LEDs and a variable optimisation executed on the Z-axis to find the optimal distance between workspace and RoI.[80]

The simulation and the algorithm require the following input parameters:

- The function of the power distribution of each LED with regards to the viewing angle
- The LEDs radiant intensity [mW/Sr]
- The LEDs diameter [mm]
- The desired number of LEDs on the workspace
- The size of the Workspace in the XY-plane where the LEDs can be placed [mm]
- The maximal and minimum distance on the Z-axis between LED (Workspace) and Skin (Region of Interest)
- The diameter of the Region of Interest (RoI) where we desire the uniform optical distribution and measure the maximal optical output
- The LED-Penalty that punished the optimisation algorithm when diverging from the desired number of LEDs
- Tuning the parameters of the cost-function (Penalty on quadratic error of uniform distribution of light and the penalty on number of the LEDs)
- The number of initial generation in GA algorithm which are symmetric in order to make the algorithm faster in converging to optimal (sub-optimal) pattern.

Two MATLAB files were created, "PlotLED_circular.m" which is the main program that initialises the simulation, calls the optimisation algorithm and generates the plots. Another file, "LED_Cost_circular.m", contains the cost function for the stochastic optimisation.(see Appendix F)
In a first step, the "PlotLED_circular.m" file approximates the power distribution function for the LED with $\rho = sin(\varphi)$ with φ being the viewing angle. This approximation can be seen in figure 15.

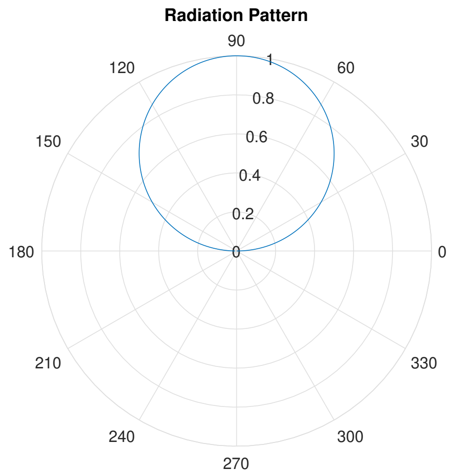


Figure 15: Approximation of the LED Radiation Pattern for the chosen LED product line.
[81, 82, 83]

In a next step, all the parameters are initialised and the maximum number of LEDs on each axis is calculated by dividing the axis length by the LED diameter. Combining the number of LEDs for each axis with their diameter we end up with a matrix that provides all theoretically possible LED positions. However, we should define another space on the PCB that that contains the legal positions for the LEDs to be placed according to the optical lens diameter. In order to introduce this space to the algorithm we defined a workspace in the form of a generated matrix where legal LED coordinates are marked with "1" and illegal coordinates are marked with "0" as shown in figure 16.

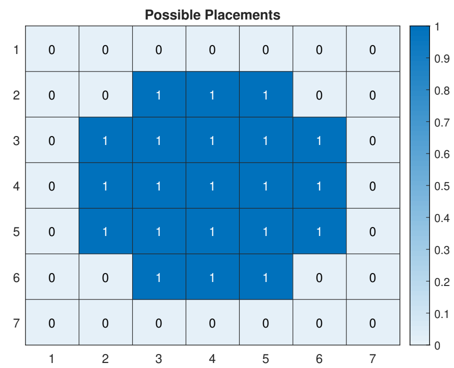


Figure 16: Workspace with where legal LED Coordinates are highlighted in blue and marked with a "1"

Appendix F

As a last initialisation task, the RoI on skin is generated with a resolution of $1mm^2$. The active area, which will be utilised by the cost function, is highlighted in yellow and shown in figure 17.

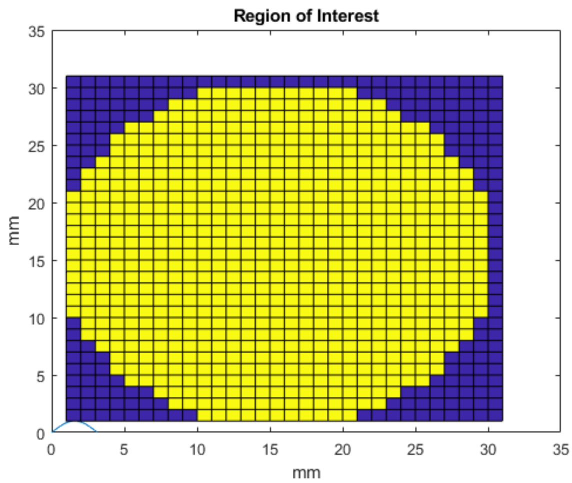


Figure 17: Region of Interest on skin for LED Optimisation algorithm in which we need to have uniform light distribution. The active pixels are highlighted in yellow and have a $1mm^2$ resolution.

Appendix F

With everything initialised, the constraints are created. For this optimisation there is a constraint on the maximum number of LEDs as well as an upper and lower bound for the Z-axis.
With all the basics in place, the optimisation algorithm is put to use. During optimisation the received energy for each pixel in the RoI is calculated and the cost function compares it to the average over the RoI, by running a quadratic cost-function.

The Genetic algorithm starts to test different initial generation and after producing new generation based on the initial generation, it start to seek sub-optimal pattern. The child who has the minimum cost will be saved and the algorithm will continue to seek other possible pattern by creating new generations from that child. Once the improvement between two iterations falls below a threshold or maximum number of iterations is reached, the optimisation terminates. It returns a graph with the final error and the progress as seen in figure 18. It is notable that the user can also terminate the optimisation manually. In that case, the algorithm will return the patter which had the minimum cost.

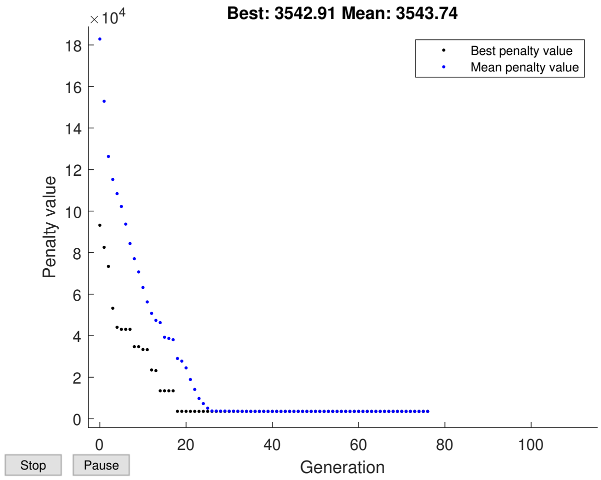


Figure 18: Example for the Penalty of the Optimisation of the LED Placement. In this example 19 LEDs with 810nm were used.
Appendix G

The Genetic Algorithm used in this optimisation task has a few shortcomings. For one it is not able to separate global from local minimum, but there is a simple workaround for that. As we know that any ideal placement will have some symmetry to it, we can push the optimiser into the right direction by forcing it to start with a predefined number of symmetrical placements. By exploiting this we can run the optimisation process several times for each wavelength, comparing the final penalty until we find the lowest value. This is possible as we place the LEDs on a grid with a finite number of possible locations.
The other shortcoming is that the LED-Number constraint is a soft constraint, so the algorithm sometimes ends-up selecting more LEDs than desired. This can be addressed by increasing the LED-Penalty. Another thing noticed is that the optimisation of the Z-axis always ends at on the upper bound. This is due to the fact that the workspace is comparably small compared to the RoI. So with the current constraints one could neglect to optimise the Z-axis, which is the distance of LED and RoI.

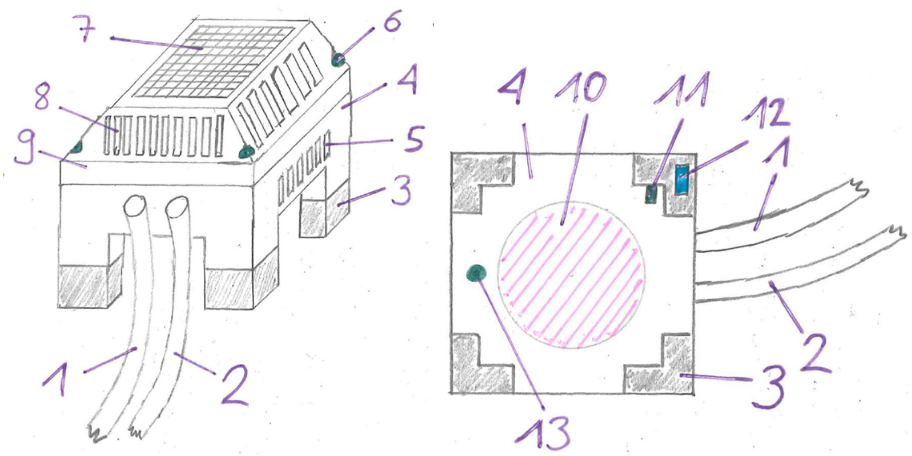
There also more space for improvement. For example, one could use polar coordinates for the workspace instead of a matrix and introduce non-linear constraints for the proximity between LEDs as well as between an LED and the edge of the workspace.
Another option could be using an entirely different optimisation algorithm. Such as a simulated annealing algorithm described by Zhouping Su et al.[84] However the results of the initial optimisation were deemed sufficient, so no further improvement implements were demanded in this thesis.

3.2.2 Cooling

Using such powerful LEDs makes cooling an essential aspect of the prototype to consider. As the device consists of 2 sections containing electronics, the LED-Head housing primarily the LEDs and the control electronics are where we find the whole power management, the processing unit and all relevant control electronics.
The LED-Head is the most demanding when it comes to cooling as a change in temperature would not only result in a shift in the output wavelength, but could easily damage and destroy the costly LEDs as their maximum junction temperature is only 85°C. [81, 82, 83] This combined with the compact size demanded in the system requirements (Appendix A) places quite a challenge. Therefore an active way of cooling is a must. Various options were investigated, but a fan in combination with a large heatsink turned out to be the most efficient and compact solution.
As additional measures one should ensure when designing the LED-Head that no dead space is created where hot air can get trapped. Furthermore one should design a good thermal connection between the 2 sides of the PCB and choose a metal with a high thermal conductivity and low weight, such as aluminium, as a construction material for the housing. To further improve the heat dissipation through passive radiation, the aluminium parts facing away from the RoI could be anodised which would rise their emissivity coefficient from around 0.09 to about 0.77. [85] Lastly one should also consider to thermally decouple the LED-Head from the test subject as it is in direct skin contact and transferring heat to the RoI, especially by conduction, would negatively impact the intended experiments. An easy way to achieve a thermal decoupling could be the addition of a polymer layer between the metal parts of the housing and the skin.
Cooling of the control electronics is not as demanding as it is far more spacious, not in direct dermal contact with the subjects skin and has fewer high power or temperature sensitive components. The majority of the heat in the control electronics is generated by the processor unit, the LED driver and the DC/DC converters. The processor unit and the DC/DC converters come on their own PCBs and are connected to the main control PCB via headers which gives them

extra exposure to the surroundings. Taking this into account, it is considered sufficient to cool the control electronics with the help of a small fan and drop additional heatsinks.

3.2.3 LED Head



(a) (b)

Figure 19: (a) 3D view of the LED-Head (b) Bottom view of the LED-Head.
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The LED-Head has to be as small and compact as possible while still allowing all the necessary components to fit in. The final concept ended up being of a cuboid shape with a leg in each corner and tapered on the top. This design fulfils the most critical requirements and provides a 20mm air-gap between the LEDs and the skin. A first draft of the final design can be seen in figure 19. It consists of the following components:

1. LED cable, this shielded 8x0.22mm^2 multicore cable connects the LEDs to the control electronics.
2. Signal cable, this shielded cable comes with 4 twisted pairs of 0.20mm^2 cores that connect all the sensors in the LED, the fan, the warning LED and the ID-Resistor to the control electronics.
3. Polymer pads for thermal decoupling of the LED-Head from the skin.
4. Bottom half of LED-Head.
5. Air outlet for LED cooling.
6. Screws to connect the two halves.
7. Air intake.
8. Air outlet for air blowing past the heatsink.

9. Upper half of the LED-Head.
10. Optical filter as described in section 3.3.2 and intended to retain IR radiation emitted due to heating-up of the LEDs.
11. Air temperature sensor, a PT1000 resistor monitoring the air temperature.
12. Skin temperature sensor, a PT1000 resistor protecting the subjects skin from taking thermal damage. Furthermore its measurements will be used to evaluate how much heat was transferred to the RoI.
13. Warning LED, a small LED will alert the user if the NIR Power LEDs are turned on.

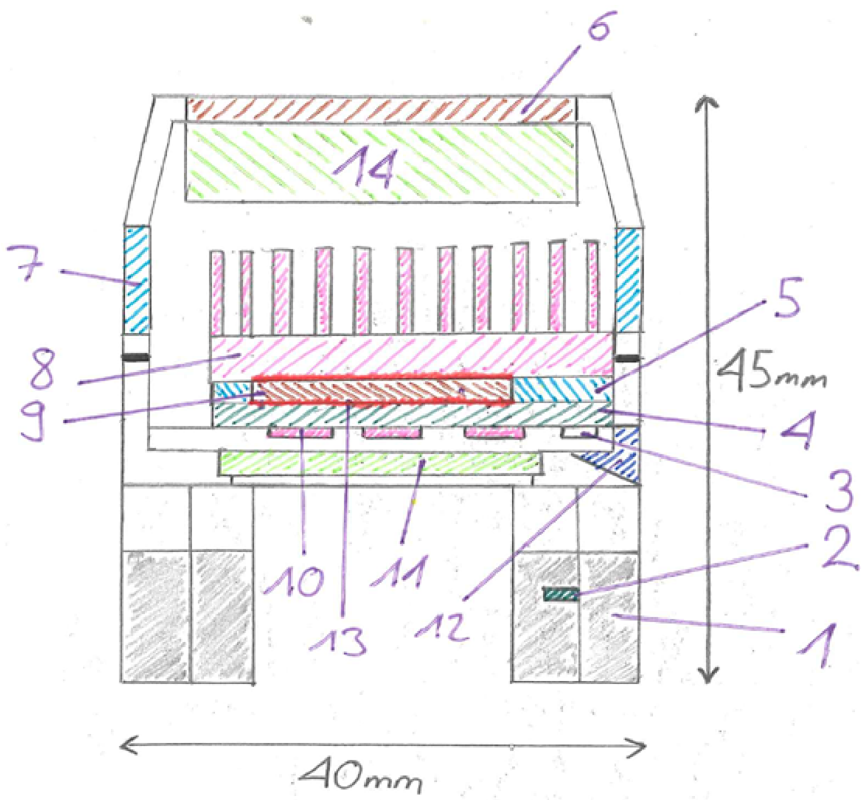

Figure 20: A vertical cut of a proportional model of the LED-Head with all its main components.
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Figure 20 provides another angle of the LED-Head. Here the LED-Head is cut-open vertically to expose the inside. All elements in this figure have the correct proportions. The following main components are visible in this figure:

1. Polymer pads for thermal decoupling of the LED-Head from the skin.
2. Air temperature sensor, a PT1000 sensor monitoring the air temperature.
3. LED temperature sensor, a PT1000 resistor that monitors the temperature of

the LEDs.
4. PCB that carries the LEDs and other electronics.
5. Thermal pad to create a good thermal connection to the heatsink. It is a soft, non-conducting pad with a thermal conductivity of 17.8$W/m * K$.
6. Air intake.
7. Air outlet for air blowing past the heatsink. Outlets are found on all four sides.
8. Heatsink measuring 28x31x10mm with pins that allow the air to blow past it in all directions. The heatsink has a thermal resistance of 5.4°C/W and is made of aluminium.
9. Copper spacer, a 20x20x2mm piece of copper ensures a good thermal connection between the PCB and the heatsink. This set-up allowes to keep the heatsink as large as possible while still providing space for other electronic components on the PCB.
10. NIR Power LEDs.
11. Optical filter as described in section 3.3.2 and intended to retain IR radiation emitted due to heating-up of the LEDs.
12. Air outlet for LED cooling.
13. Thermal paste placed between the PCB and the copper block and between the copper block and the heatsink. The thermal paste has a thermal conductivity of 10$W/m * K$.
14. Fan, a small fan measuring 30x30x6mm provides 8.3m^3/h of air to keep the whole system cool.

3.3 Selection and Design of Key Components

This section highlights how key components and functions of the prototype were chosen and executed. It also provides relevant argumentation on how the conclusion was reached.

3.3.1 NIR LED and their Placement

Table 1: LED Purchased

Manufacturer	**Wave-length** [λ_p]	**FWHM** [$\Delta\lambda$]	**Radiant Intensity** [I_e]	**Forward Voltage** [U_f]	**Forward Current (cont.)** [$I_{f,max}$]	**Forward Current (puls.)** [$I_{f,pulse}$]
EPIGAP [81]	660nm	-	110mW/sr	2.3V	500mA	700mA
EPIGAP [82]	810nm	39nm	25mW/sr	1.7V	350mA	1000mA
EPIGAP [83]	880nm	39nm	30mW/sr	1.5V	350mA	350mA

In the Chapter 3.7.1 of project thesis [7], 2 possible suppliers of power NIR LEDs were found and evaluated. Due to the shorter lead time, EPIGAP was chosen as a supplier. The 3 wavelengths chosen of products from their "EOLS-496" line and their key specifications are displayed in table 1.
The simulation described in section 3.2.1 is initialised with the relevant specifications for each LED and run multiple times for each wavelength with the objective of finding a global minimum for the quadratic regression of the error for the maximum number of LEDs. The optical output of the resulting LED arrays should not exceed the $100[W/m^2] = 100[mW/cm^2] = 1[mW/mm^2]$ that are considered safe for the eye even if the exposure time t>1000s according to the standard NEK IEC 62471:2006.[47] 1000s is equivalent of to approximately 16.5min which we will exceed with planned experiment duration of 30 to 40min. Chapter 2.7 describes the relevant norms and thresholds for NIR sources in more detail.
The results of those simulations are summed-up in Table 2. There you see the results for different numbers of LEDs for all three wavelengths with the resulting maximal optical output as well as the ratio between highest and lowest output inside of the Region of Interest with a 30mm diameter. The most suitable number of LEDs for each wavelength have been highlighted in green. All simulation data is measured at a distance of 20mm from the LED-array.

Table 2: Simulated LED Output

Wavelength	**Number of LED**	**Max. Output [mW/mm^2]**	**Ratio Max/Min**
660nm	4	0.8368	2.4967
660nm	5	1.0649	2.7036
810nm	18	0.9211	2.7241
810nm	19	0.9799	2.7787
810nm	20	1.0389	2.7721
890nm	14	0.8302	2.6435
890nm	16	0.9639	2.6645
890nm	18	1.1053	2.7241

The results for these simulations show a symmetric LED distribution whenever it was possible based on the number of LEDs chosen. Therefore the resulting received power is also very well distributed as the edge of the RoI still receiving well over 60% of the optical power of the centre. With a circle of more than 10mm diameter in the centre of the RoI receiving 90% of the maximum received within the RoI. This area of nearly uniform optical power is considered sufficient as SC insulin does not diffuse far from the injection site. For example a bolus of 5u of 100u/ml insulin spreads on average 6mm from the infusion site. [86]

The following figures show the simulation results for the number of LEDs chosen for each of the 3 wavelengths. It is important to notice that the penalties can not be compared to one another as each wavelength required different initial penalty weights to avoid ending up in a local minimum. The penalty graph does however show that the algorithm converges rather fast for all the wavelengths. For more simulation results see Appendix G.

Simulation results 4 LED 660nm

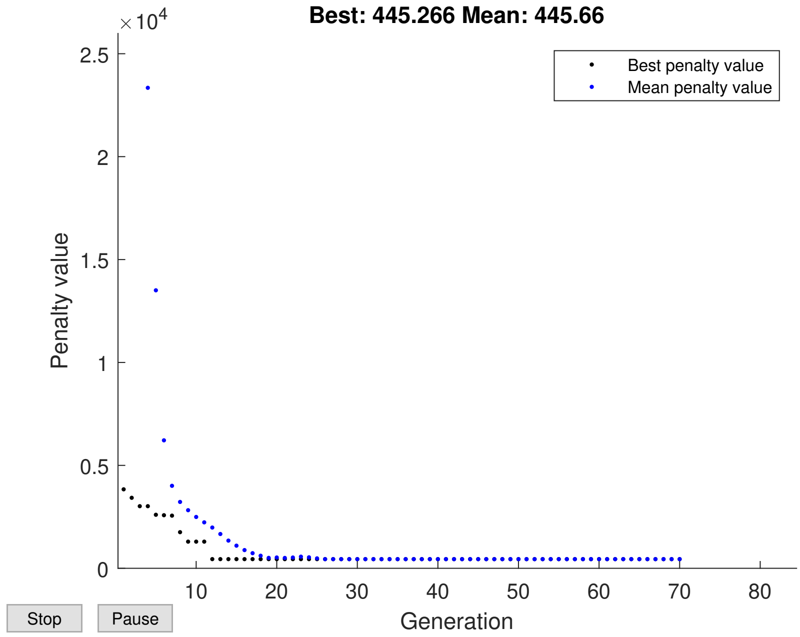

Figure 21: Penalty and conversion rate for 4 LED 660nm.
Appendix G

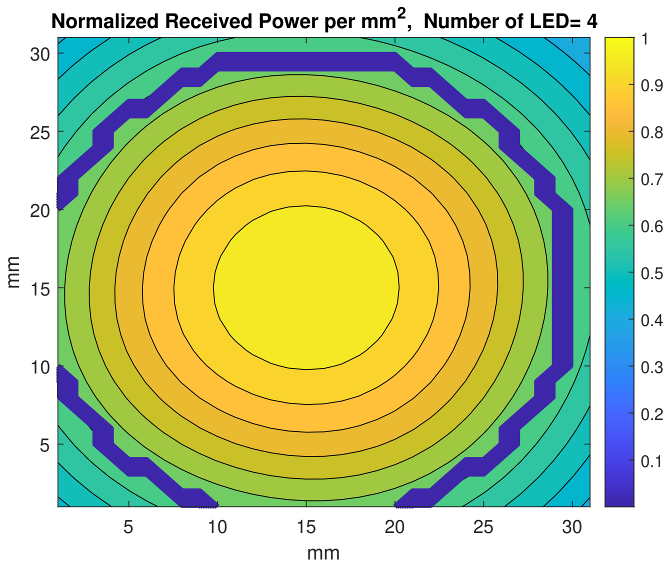

Figure 22: Normalised Received Optical Power for 4 LED 660nm measured at 20mm from the LED-array.
Appendix G

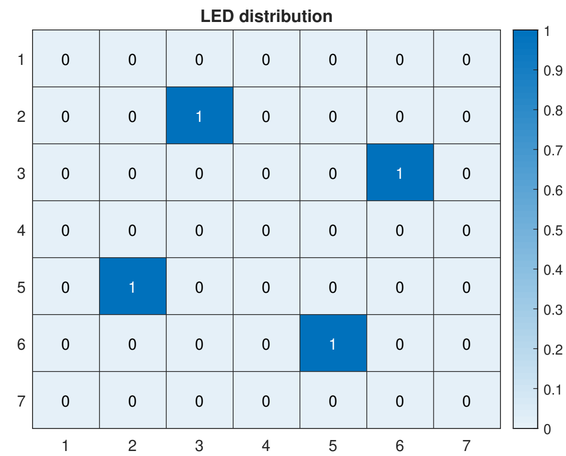

Figure 23: Proposed LED placement for 4 LED 660nm. Each square measuring 4x4mm.
Appendix G

Simulation results 19 LED 810nm

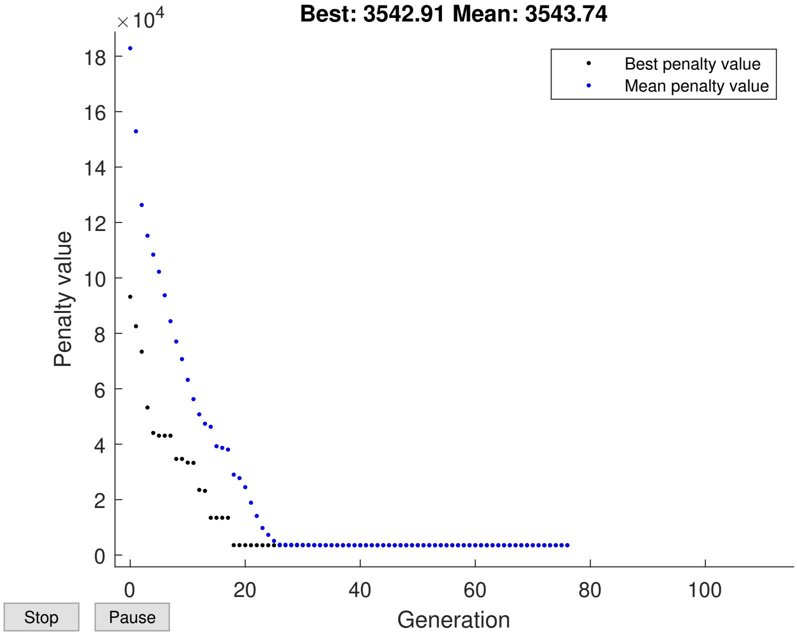

Figure 24: Penalty and conversion rate for 19 LED 810nm.
Appendix G

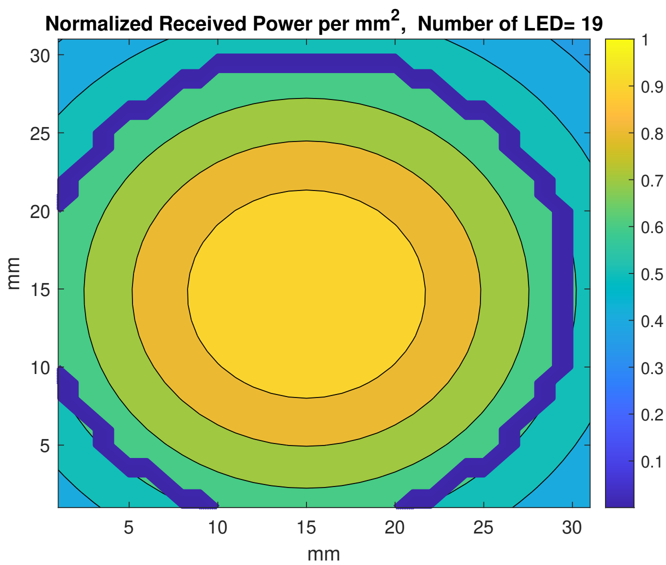

Figure 25: Normalised Received Optical Power for 19 LED 810nm measured at 20mm from the LED-array.
Appendix G

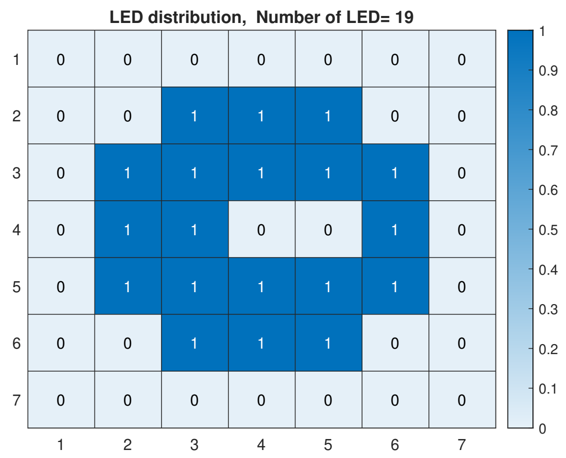

Figure 26: Proposed LED placement for 19 LED 810nm. Each square measuring 4x4mm.
Appendix G

Simulation results 16 LED 880nm

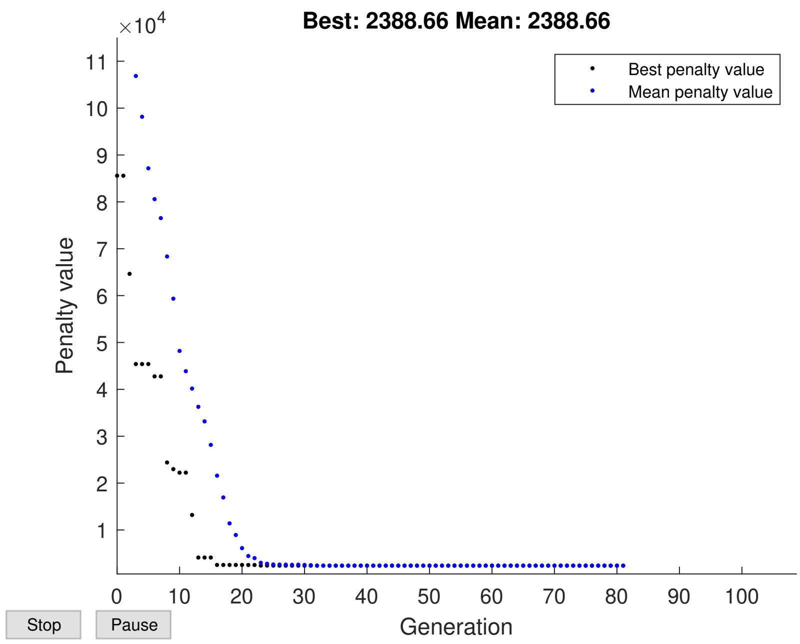

Figure 27: Penalty and conversion rate for 16 LED 880nm.
Appendix G

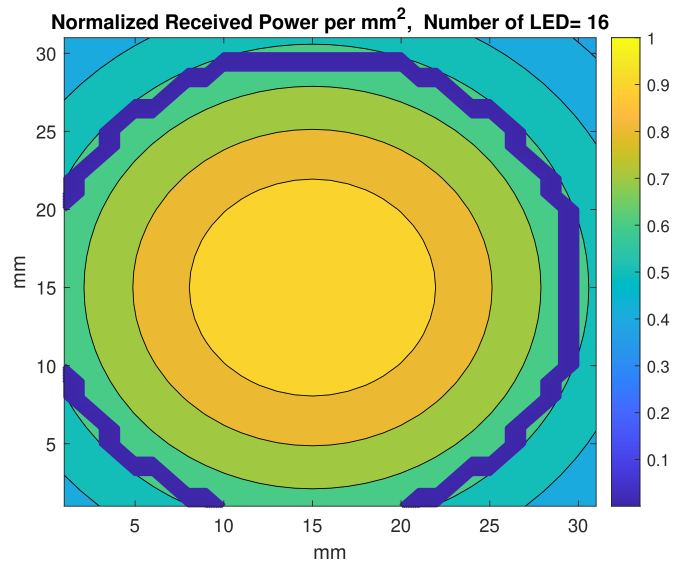

Figure 28: Normalised Received Optical Power for 16 LED 880nm measured at 20mm from the LED-array.

Appendix G

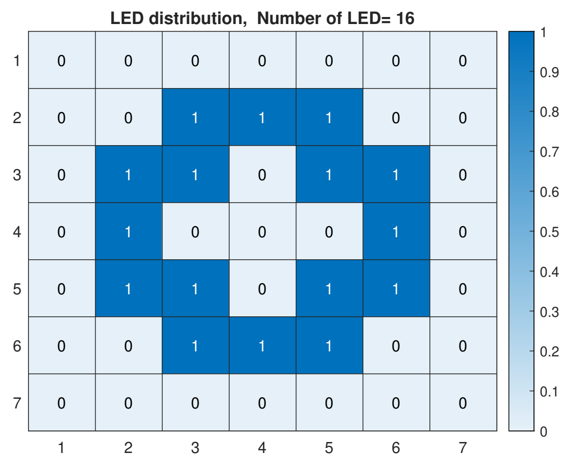

Figure 29: Proposed LED placement for 16 LED 880nm. Each square measuring 4x4mm.

Appendix G

3.3.2 Optical Filters

The optical filter was already thoroughly investigated in the project thesis [7] in Chapter 3.7.3. The 2 lenses chosen, a hot mirror with a cut-off at 690nm for the 660nm LEDs [87] and a shortpass filter with a cut-off at 1000nm. [88] For the 810nm and the 890nm LEDs, those lenses are fulfilling all the essential

requirements for the desired application.
The original plan was to use a 30x30mm filter to maximise the area over which the LEDs could be spread. However, both filters were only available as circular 1". The manufacturer Thorlabs would be able to produce both filters in the desired dimensions at a competitive price per unit, but as the minimum order was 10 units for each filter it was decided go with the off-the-shelf dimensions to stay within budget. It would however be possible to acquired the larger filters for future iterations of the prototype if desired. In the end the filters purchased have a diameter of 25.4mm for the hot mirror and 23.3mm for the shortpass. The shortpass has a slightly smaller diameter as it was only available off-the-shelf as a 1" mounted filter, after removing the mount the actual filter has a diameter that is 2.1mm smaller. For more information on the offer for custom sized filters, please see Appendix J.

3.3.3 Cooling of Electronics

There are 2 subsystems in this project that require cooling: the control electronics and the LED-Head. As the control electronics has few temperature critical components and a comparably low component density as mentioned in section 3.2.2. It was decided that there is no need to run a detailed thermal calculation of the control electronics. It was however decided to equip the control electronics with an air outlet a small 5V fan opposite the outlet that will continuously blow air at 8.3m^3/h through the housing. There is no plan of adding additional heatsinks to the control electronics as the most critical components are already on their own PCBs and connected with headers to the main PCB. This will allow the air to pass easily around those smaller PCBs. In addition to that the Main PCB is equipped with a PT1000 resistor that will be used to constantly monitor the PCB temperature. So should against all expectations the need for additional heatsinks arise, it can easily be detected and corrected at a later point.
The LED-Head cooling however is a far more challenging affair.
A good thermal management is of essence if one is to operate an array of power LEDs as they produce large quantities of heat. For this reason a cooling solution with a heatsink and forced convection was chosen and calculated. Figure 30 provides a cross section of the LED-Head with an indication on how the air blown into the housing will be distributed. The air will be sucked into the housing through the fan in the lid which will supply an approximate airflow of 8.3m^3/h.

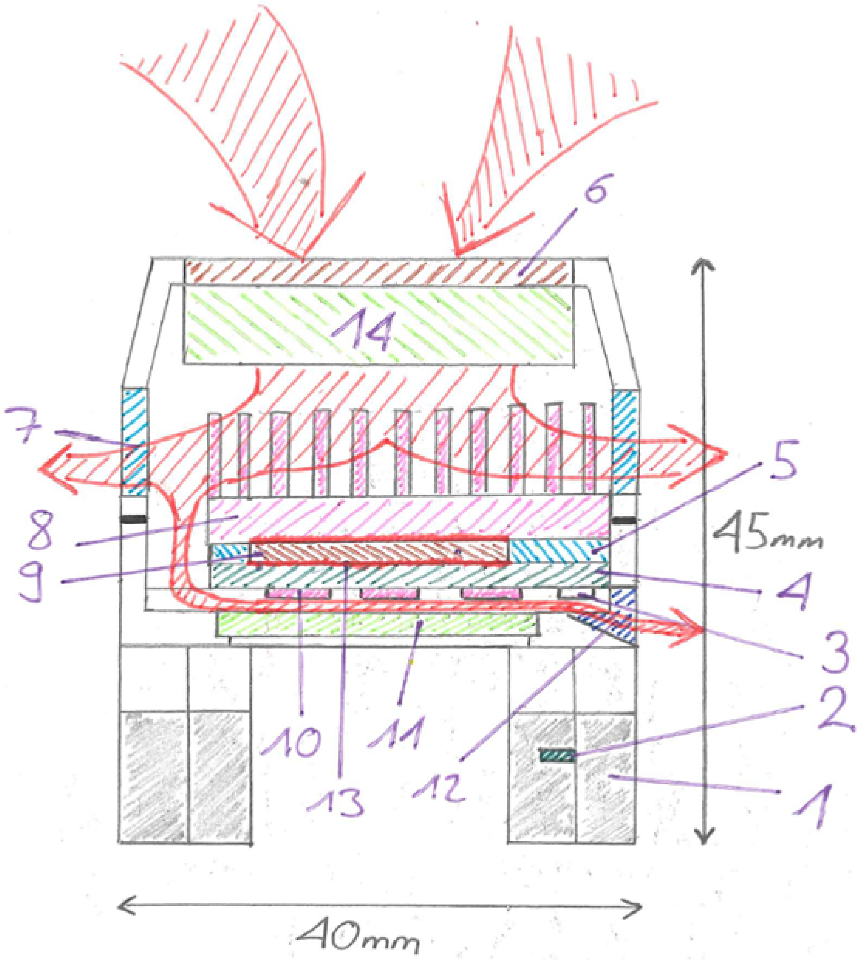

Figure 30: Air flow in the LED-Head. Explanation of the components can be found in section 3.2.3
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LEDs might have a significantly higher luminous efficiency than incandescent light sources. But most LEDs still only achieve a luminous efficiency of approximately 15%.[89] So around 85% of the power consumed by an LED is turned into heat. This heat is generated by the semiconductor junction of the LED dice and transferred to the environment. About 90% of the heat generated are transferred by means of conduction, about 8% are dissipated via convection and the remaining 2% through radiation.[90, 91]
It is therefore obvious that primarily the heat dissipated through conduction has to be addressed. The other 2 thermal paths can be neglected for most applications. In order to calculate the resulting junction temperature of an LED when combined with a cooling set-up one requires 3 values: the ambient temperature in [°C] (T_{amb}), the thermal power dissipated by the LED array in [W] (P_{Heat}) and the total thermal resistance of the cooling set-up in [K/W] (R_{THtot}). Those

values are than plugged into the following formula, providing the expected junction temperature:[92]

$$T_J = T_{amb} + (R_{THtot} \cdot P_{Heat})[^\circ C] \tag{1}$$

To find the thermal power dissipated one can use the following equation:

$$P_{Heat} = V_F \cdot I_F - \Phi_e[W] \tag{2}$$

With V_F being the forward voltage of one LED, I_F the forward current of one LED and Φ_e the radiant power of one LED. To get P_{Heat} for the whole array, just multiply it with the number of LEDs in the array. All this information can be found in the LED datasheets. [81, 82, 83]

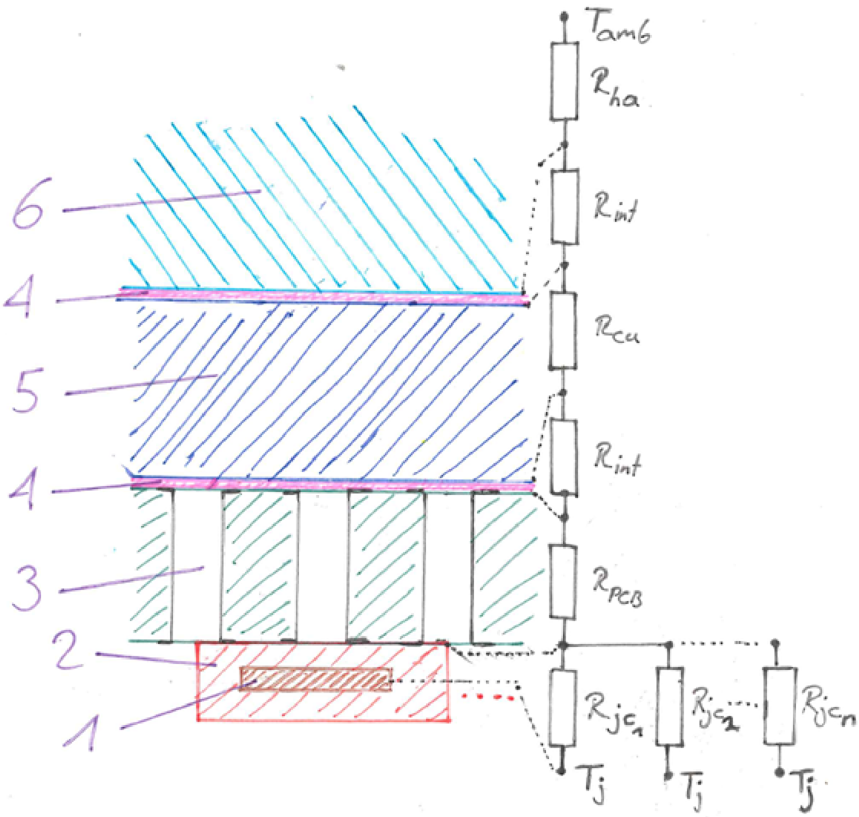

Figure 31: The cooling system is composed of several layers with different thermal properties.Those layers are: 1. LED Junction, 2. LED Case, 3. FR-4 PCB with thermal Vias, 4. Thermal paste, 5. Copper block, 6. Heatsink
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To calculate R_{THtot} one can treat the individual heat resistances on the cooling set up exactly like electrical resistance. Figure 31 provides an overview of our thermal resistance network. Notice that R_{JCn} are parallel resistances as we have several LEDs attached to the same cooling set-up. So the final equation for R_{THtot} is:

$$R_{THtot} = \frac{R_{JC}}{n} + R_{PCB} + R_{Int} + R_{CU} + R_{Int} + R_{HA} \quad (3)$$

The individual thermal resistances are determines as followed:
The Junction-Case resistance R_{JC} can be found in the LED datasheet and is $10K/W$.[81, 82, 83]
Most PCBs consist of FR-4 material which is a rather good insulator. However, the addition of thermal vias can reduce the thermal resistance significantly. For example having 9 thermal vias in close proximity to the LED Footprint reduces the thermal resistance by over 50%.[93] This amount of vias is viable for all the LED array designs, so for this application we calculate with a 50% improvement due to the vias. FR-4 has a thermal conductivity of $0.4W/m \cdot K$ according to its datasheet.[94] So for a 1mm PCB with 9 Thermal vias per LED and a contact area of 20x20mm we get the following thermal resistance:

$$R_{PCB} = \frac{x}{A \cdot K} \cdot 0.5 = \frac{0.001}{0.02^2 \cdot 0.4} \cdot 0.5 = 3.125[K/W] \quad (4)$$

R_{Int} is the thermal resistance of the thermal paste layer between two layers in the cooling set-up. The thermal pasted used in this application has a thermal conductivity of $10W/m \cdot K$ according to its datasheet.[95] Combining this with our 20x20mm contact area and an average past layer thickness of $50\mu m$, we get the following resistance for the thermal paste:[96]

$$R_{Int} = \frac{x}{A \cdot K} = \frac{0.00005}{0.02^2 \cdot 10} = 0.0125[K/W] \quad (5)$$

To calculate the thermal resistance of the 20x20x2mm copper block we use its conductivity of $385W/m \cdot K$: [91]

$$R_{CU} = \frac{x}{A \cdot K} = \frac{0.002}{0.02^2 \cdot 385} = 0.013[K/W] \quad (6)$$

The heatsink has according to its datasheet a thermal resistance of $5.4K/W$. However this value is for passive convection. In out case we have forced convection due to the installed fan. So to determine the thermal resistance for forced convection we have to calculate the air velocity created by the fan and compare it to the table in the heatsinks datasheet.[97]
The air velocity is calculated by dividing the air volume with the area covered by the fans rotor. In our case we have the following:

$$v_{air} = \frac{\frac{8.3}{3600}}{0.014^2 \cdot \pi} = 3.74[m/s] \quad (7)$$

This is the air velocity crated by an unobstructed fan. For a partially obstructed fan we have to adjust for the pressure loss.[98] As we have a heatsink with pins and plenty of openings for the air to exit the LED-Head a factor of 0.75 was chosen. So we are left with an air velocity of 2.8m/s. Comparing this to the datasheet we get a forced convection thermal resistance of R_{HA}= 2.75K/W
We can also calculate the maximum T_J for each type of LED. For this we take equation 6 but now we use the maximum operating temperature of 85°C for T_{amb} and R_{JC} instead of R_{THtot}. Making those adjustments we get a T_{Jmax} of approximately 90°C.
Applying equation 6 to 3 we can calculate the performance of the cooling set-up. The results of this calculations are summarised in table 3:

Table 3: Calculation for LED Junction temperature

λ_{LED}	LED_{No}	η_{optic}	P_F	P_{Heat}	R_{THtot}	T_{Jmax}	T_J
660nm	4	0.180	3.22 W	2.64 W	8.413 K/W	91.6°C	47.21°C
810nm	19	0.114	11.31 W	10.01 W	6.439 K/W	90.3°C	89.45°C
880nm	16	0.161	8.96 W	7.52 W	6.538 K/W	89.7°C	74.17°C

Looking at the result of the calculation it becomes quite obvious that especially the 810nm array is very close to the maximum junction temperature. However, this is only a very rough calculation with many simplifications and assumptions. For instance, we didn't take into account the thermal dissipation of the LED by convection and radiation. In addition to that is the PCB on its edges in direct contact with the aluminium housing which will direct some heat away form the main cooling path.[99] This calculation also assumes that the LEDs will be operated in constant mode at their maximum output. So if the LEDs are operated in pulsed mode their junction temperature with again fall significantly. In addition to that we have a PT1000 resistor close to the LEDs so their temperature can be monitored and should the temperature rise too much a shut-down can be forced to protect the LEDs from thermal damage.
Theoretically it would be possible to get a more accurate estimate of the expected junction temperature, but this is not so straight forward as it requires some complex thermal simulations and is therefore outside of the scope of this thesis.

3.3.4 Processor Unit

The processor unit is the brain of the device. It is possible to design and build this part from scratch which would optimise the space used and the power consumption. However as the control electronics is not so dimension critical and compared to the LEDs all other power consumers in this device are negligible, it was decided to go with an off-the-shelf solution. This also provides the advantage that we know our processing unit works as intended and it comes with tried and tested software and hardware. This leaves us with 2 possible options, Arduino or Raspberry Pi which are both commonly used in DIY and prototyping applications. They are however quite different. While the Arduino is a type of microcontroller development board, the Raspberry Pi is a fully fledged mini computer running Linux as an operating system. This makes the Raspberry Pi a fare more powerful and versatile device with significantly more processing power, memory and RAM compared to the Arduino. This comes however at the cost of increased complexity and power consumption. Furthermore requires the Raspberry Pi a boot and shut-down sequence as otherwise software and hardware could be damaged. Both systems come with digital input and output(IO) pins that allow you to connect sensors or other external hardware. The Arduino has the advantage that it also provides analogue IO pins, is open source, does not require an operating system and power fluctuations do cause any damage to the system. The significantly lower power consumption and the lower price also speak for the Arduino.[100]

It was therefore decided to use the Arduino platform in this project. After further investigation into the different models available, the Arduino Mega 2560 Rev3 was chosen. The key benefits of this model over the others available are the large number of IO pins as well as the analogue IO pins operating on 5V, which is needed for operating the PT1000 and the ID resistor detection.[101]

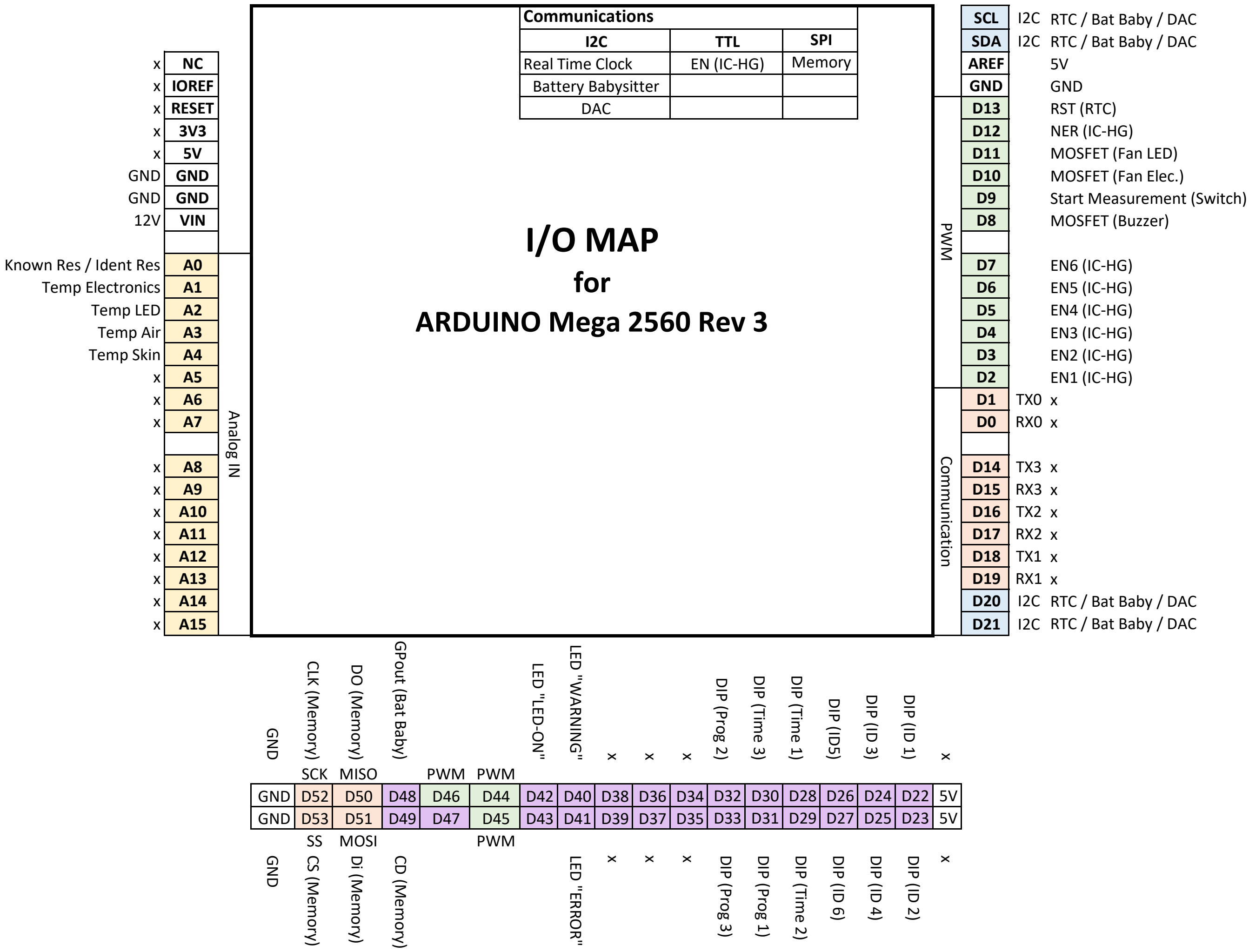

Figure 32: IO ports of the Arduino Mega 2560 Rev3 and how they are being used in this project.
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Figure 32 provides and overview of the IO pins found on the Arduino Mega 2560 Rev3 and how they are being utilised in this project. The analogue IO is used to connect the PT1000 circuits as well as the circuit for the identification resistor on the LED-Head. D2 to D7 connect to the inputs of the LED driver that operates in TTL mode and allow for a pulsed LED operation. It also utilised the serial pins for the memory extension and the I2C pins for various peripheral systems. D22 to D33 connect to the two dip switches that allow the user to give different binary encoded inputs to the Arduino. The remaining IO is primarily used to operate signal and warning devices as well as error handling and receiving of user input.

3.3.5 Power Supply

The power management is an essential part of the prototype. In order to have an appropriately scaled power supply the power consumption of the system was calculated. For this the most power hungry components were analysed and their total power consumption was calculated. A the detailed calculations can be found in Appendix C. Table 4 provides a summary of this calculation. Showing the total power required to run one 30min or 45min measurement with the device in different configurations. All the calculations are done for continuous LED operation with the 660nm and the 810nm, examples were chosen as they contain the least and the most LEDs of the three configurations.

Table 4: Power consumption of system for different configurations

	P_{max} $[Wh]$	P_{av} $[Wh]$	P_{810} $[Wh]$	P_{660} $[Wh]$	C_{max} $[mAh]$	C_{av} $[mAh]$	C_{810} $[mAh]$	C_{660} $[mAh]$
$30min$	25.44	17.00	11.91	4.27	6875	4594	3218	1153
$45min$	38.16	25.50	17.86	6.40	10312	6892	4827	1729

Applying this power consumption per measurement to the battery capacity will provide an indication on how many consecutive measurements can be run before the battery has to be replaced. It was decided to have both an internal and an external battery. The internal battery is a single cell Li-Po with 8200mAh. As an external battery, any of-the-shelf battery bank can be connected through the USB-C port on the control electronics. The system does require for the external battery to be linked in order to function as the power will primarily be drained from the internal battery. The external battery will act as a support for the internal one and charge the internal one during periods of low power consumption. For the following calculations an external battery bank with 10'000mAh was chosen.

Table 5: Consecutive measurements times of system with different batteries

		No. of Meas(max)	No. of Meas(aver)	No. of Meas(810nm)	No. of Meas(660nm)
30min	Internal Battery	1.19	1.78	2.55	7.11
	Internal and External Battery	2.65	3.96	5.66	15.78
45min	Internal Battery	0.80	1.19	1.70	4.74
	Internal and External Battery	1.76	2.64	3.77	10.52

Table 5 shows how many consecutive measurements can be performed before the battery has to be recharged. It is planned to use the device before every meal. So any configuration allowing for 3 or more consecutive measurements is considered good as the battery can simply be recharged over night and is therefore highlighted in green. More than 1 but less than 3 measurements is considered acceptable as the battery can simply be exchanged between measurements and is therefore highlighted in orange. Less than 1 measurement is unacceptable as it can not be used in this configuration,hence with the red highlighting. The battery capacity is only considered insufficient for the configuration 45min measurement with internal battery only and maximal power consumption. This scenario is highly unlikely and can therefor be ignored. So overall the planned power supply is sufficient for the intended task.

3.4 Design Proposal

With the help of the requirements list (see Appendix A), the preparation work from the project thesis [7] and the calculations, simulations and design analysis condted in chapter 3.1,3.2 and 3.3 a Morphological Box was created (Appendix E). Based on this Morphological box 4 different design proposals were created that combine the key design suggestions from the morphological box with each other as seen in table 6. After meeting with the stakeholders within APT for a design review, Design 3 turned out to be the preferred option. Its primary difference to the runner-up, Design 4, is the choice of power supply and the construction material. The presentation of of the design review can be found in Appendix K.
The advantage of using a single cell Li-Po lie primarily with the simplicity of charging them compared to a multi-cell Li-Po. This allows to integrate a charging circuit into the control electronics, reducing the need for the test subjects to open the control electronics and exchange batteries for charging. The different material choice for the LED-Head improves the thermal property of it while keeping it thermally decoupled from the subjects skin.

Table 6: Design Proposals

Design Proposals NIR Device

Function	Design 1	Design 2	Design 3	Design 4
Electronics Housing	Cuboid	Cylinder	Cuboid	Cuboid
Power Supply	External charging	External charging	Integrated charging	External charging
Battery Type (Rechargeable)	LiPo (flat - 2 cell (7.4V))	Lithium-ion (18650)	LiPo (flat - 1 cell (3.7V))	LiPo (flat - 2 cell (7.4V))
User Interface	Analogue (Buttons, Switches and LEDs)	Analogue (Buttons, Switches and LEDs)	Analogue (Buttons, Switches and LEDs)	Analogue (Buttons, Switches and LEDs)
Parameter adjustment	Analogue and Software	Analogue and Software	Analogue and Software	Analogue and Software
User Protection	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact
Control Board	Raspberry Pi	Arduino	Arduino	Arduino
Additional Memory	No	MicroSD	MicroSD	MicroSD
LED Driver	iC-HG 3A Laser Switch	iC-HG 3A Laser Switch	iC-HG 3A Laser Switch	iC-HG 3A Laser Switch
Programing Interface	Micro USB (internal)	Micro USB (internal)	Micro USB (external)	Micro USB (internal)
Connection Electronics to Cable	Round connector	Round connector	Round connector	Round connector
Shielding Connectors	Shielded	Shielded	Shielded	Shielded
Cable / Wire	Twisted-Pairs	Twisted-Pairs	Twisted-Pairs	Twisted-Pairs
Shielding Cable	Shielded-Pairs	Shielded-Pairs	Shielded-Pairs	Shielded-Pairs
Interface Cable - Sensor head	Soldering	Soldering	Soldering	Soldering
Detection LED Head	Resistor	Resistor	Dip Switch to set ID	Resistor
Layout LED-Array	Round	Octagonal	Round	Octagonal
LED Type	SMD	SMD	SMD	SMD
Shape LED Head	Square	Round	Square	Square
Temperature Control LED Head (Sensors)	- Skin - Pad - Chamber	- Skin - Pad - Chamber	- Skin - Pad - Chamber	- Skin - Pad - Chamber
Temperature sensors	Resistive Temperature Detector (RTD)	Resistive Temperature Detector (RTD)	Resistive Temperature Detector (RTD)	Resistive Temperature Detector (RTD)
Filter	- Optical Shortpass Filter - Hot Mirror	- Optical Shortpass Filter - Hot Mirror	- Optical Shortpass Filter - Hot Mirror	- Optical Shortpass Filter - Hot Mirror
Cooling of LED Array	Heatsink + Fan (Active)	Heatsink + Fan (Active)	Heatsink + Fan (Active)	Heatsink + Fan (Active)
Manufacturing Sensor Head	Aluminium (Milled)	POM (Milled)	- Aluminium (Milled) - POM (Milled)	ABS (3D-Print)
Manufacturing Electronics Housing	POM (Milled)	POM (Milled)	POM (Milled)	POM (Milled)

4 Design Choices

This chapter presents the final design choices, decisions and documents that in a next step will be used for purchase and manufacturing of the different system components.

4.1 Mechanical Design

This sub-chapter is meant to present the mechanical design. However, due to time constraints it was not possible to present finished CAD drawings of the device that are of acceptable quality. Nonetheless, figure 33 should provide a first impression of the appearance of finished device. The mechanical parts will be manufactured by ITKs in house mechanical workshop.

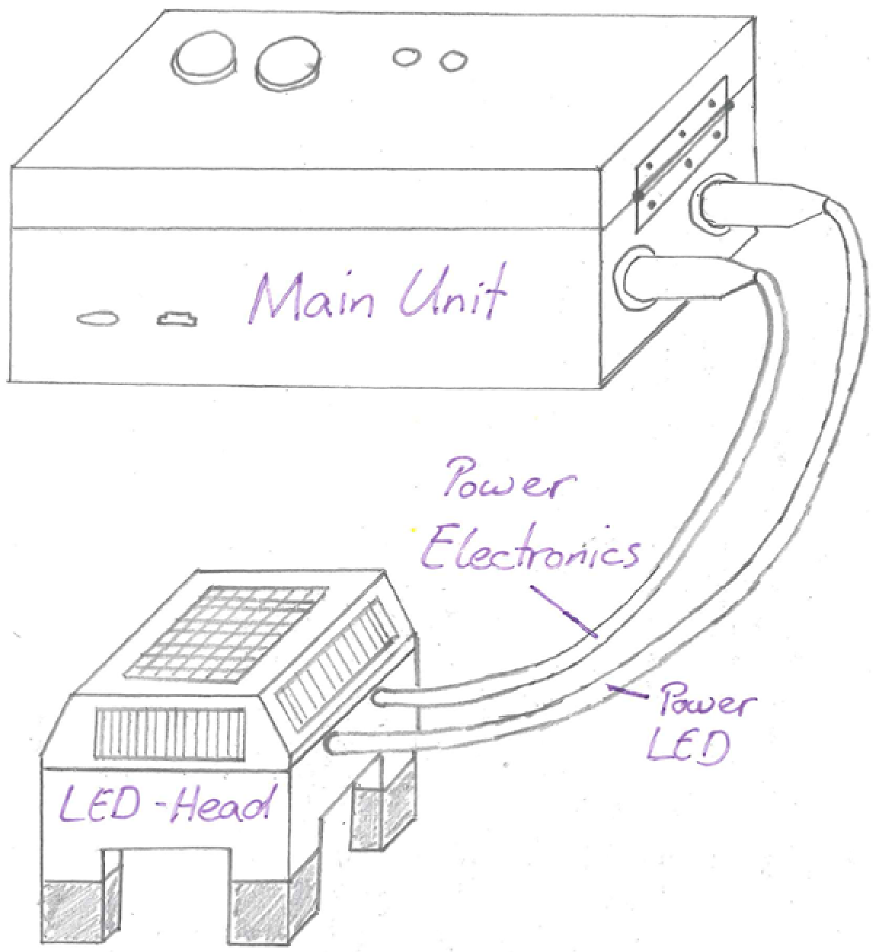


Figure 33: Sketch of Mechanical Design.
©Patrick Bösch 2021

The plan is to create a milled and cuboid shaped box made of Polyoxymethylene(POM) for the control electronics. It will be manufactured in 2 halves that are connected: on one side with a hinge, on the opposite side a latch will be placed to allow for easy access of the battery compartment and the DIP switches. 2 cables with plugs will be used to connect the control electronics to the LED-Head, one to power the LEDs and one to operate the sensors, warning LED and fan.
The LED-Head will consist of 6 parts, a sketch of it can be seen in section 3.2.3: 2 halves milled from aluminium and anodised that are joined together by screws, the aluminium parts make up the main part of the LED-Head and provide some additional heat dissipation; meanwhile 4 feet milled from POM are attached with nylon screws and provide thermal decoupling from the subjects skin.

4.2 Electrical Design

In this part, the electrical design of the prototype is presented from a hardware perspective.

4.2.1 Electronics Overview

The first step of electrical design is to gain an overview of the system on how components are connected to one another and how they interact. For this reason an electronics overview figure 34 was created. In addition to the 2 main compartments the control electronics and the LED-Head, all internal and external connections are depicted. Meanwhile, other crucial components' locations and categories are also illustrated. The colour coding of the arrows indicate the operation voltage of the components.

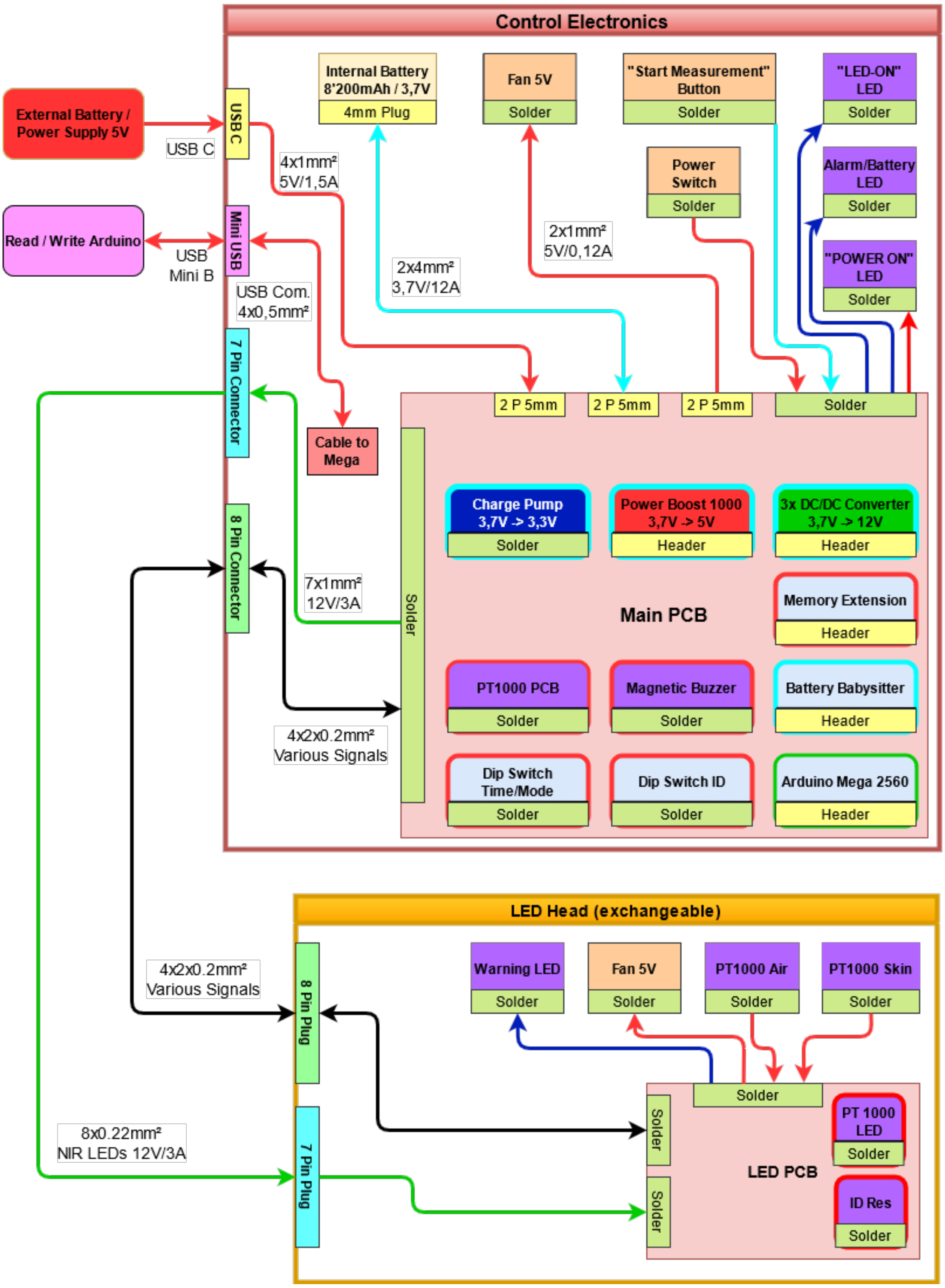


Figure 34: Overview of the electronics in the prototype, showing all the main components, how they are connected and with which voltage they are operated. ©Patrick Bösch 2021

4.2.2 Power Distribution

It is critical to have efficient power management as we are working with rather power demanding LED arrays, which would guarantee that enough power is available to operate the system and provides an overview of the circuit's maximum currents, allowing the most power-hungry components to be positioned close to the source and the track width to be set correspondingly when constructing the PCB. With the help of the electronics overview in 4.2.1 and the power calculation from chapter 3.3.5, the power management in figure 35 was created. It shows the internal and external power supply in addition to the internal charging circuit that monitors the remaining capacity of the internal battery. The 2 P-channel metal–oxide–semiconductor field-effect transistors (P-MOSFET) in the diagram protect the system against reverse currents and voltage in case the battery is being connected with the wrong polarity. P-MOSFETs also ensure that the electronics are power-less while the main switch is in the off position. With the way the power distribution system constructed, it is possible to charge the internal battery through the USB C port while the system is turned off. It also becomes clear that even though the internal battery could provide current as much as 492A, the attached DC/DC converters will never draw more than 13A. It is therefore sufficient to dimension the 3.7V tracks between the battery and the DC/DC converters to 13A, which requires a track width of at least 20mm for a 18μm thick copper layer, which is the standard thickness on a PCB. It could therefore make sense to order a PCB with a copper layer of 35μm as it would reduce the minimal track width to 10mm.

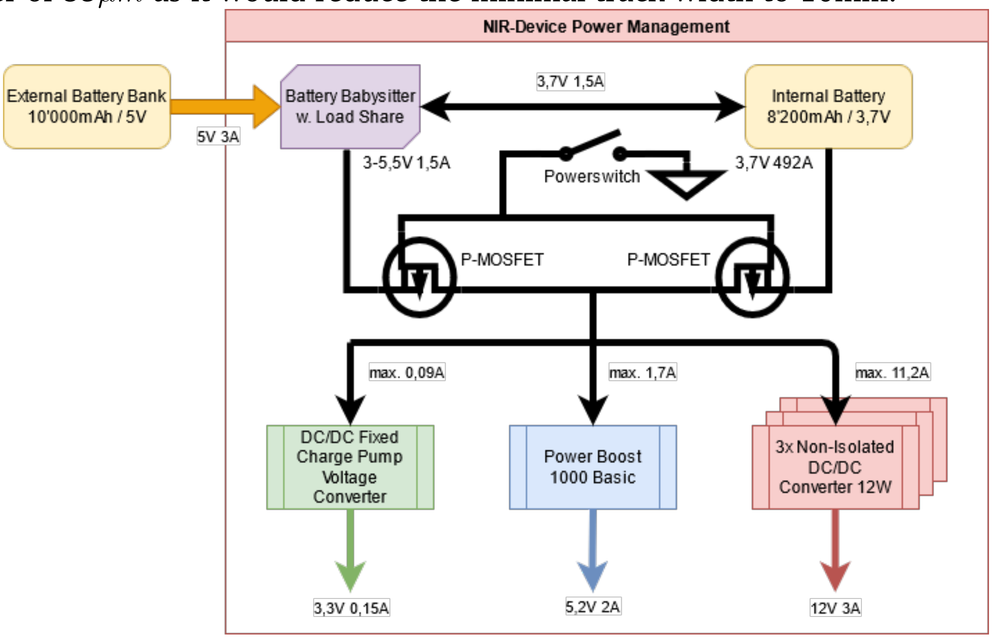


Figure 35: Overview of the electronics in the prototype, showing all the main components, how they are connected and with which voltage they are operated. ©Patrick Bösch 2021

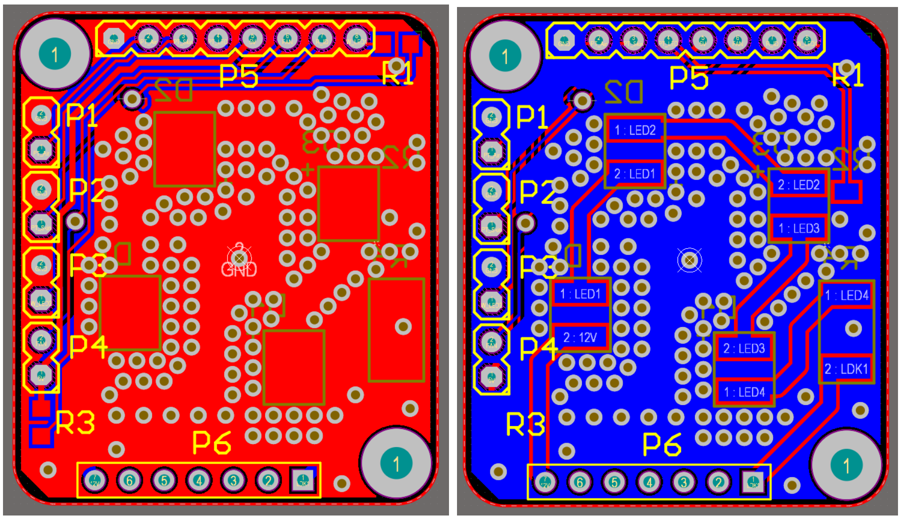
4.2.3 Schematic Drawings

With the basic design laid out, the next step is to produce schematic diagrams as they build the foundation for a later PCB design. Schematics also make the electronics design more readable for technicians. This task can be very complex and time consuming as all the components have to be identified, selected and correctly interfaced with one another. For this master thesis, 2 separate schematics were created, one for the control electronics and one for the LED-Head. Especially the schematics of the control electronics are rather complex and extensive, so some functions were transferred to sub-schematics. The green boxes in the main schematics refer to the corresponding sub-schematics. All the schematic drawings can be found in Appendix L.
The "U_Temp_Meas" blocks provide the reference voltage for the PT1000 measurement and amplify the resistance changes so the resolution of the temperature measurement increases.
The "U_Power_Management" block contains the complete power distribution described in chapter 4.2.2. It is also equipped with several large electrolytic decoupling capacitors for all the supply voltages to avoid voltage drops due to load transients, such as when the LEDs are in pulsed mode. Moreover, there are several smaller ceramic capacitors integrated in the circuit. The combination of the electrolytic and ceramic capacitors not just stabilise the voltage but also provides an efficient 1^{st}-order low-pass filter that reduces ripple and noise in the frequency range between 2-150kHz. As we desire as little variation in optical output from the NIR-LEDs as possible yet fluctuation of the supply voltage can have a large impact on the optical output, an additional π-filter is added to the the 12V path, a powerful 3^{rd}-order low-pass filter that especially addresses the high frequency ripple and noise in the 0.65-1MHz range and reduces noise by at least 20dB. [102]
The "U_Real_Time_Clock" block contains a real-time clock IC with its own power supply that provides a reference time to the Arduino and prevents the Arduinos internal time and date from being re-set when re-starting the system.
Lastly the "U_LED_Control" block contains the LED driver circuits.

4.2.4 Printed Circuit Board(PCB) LED-Head

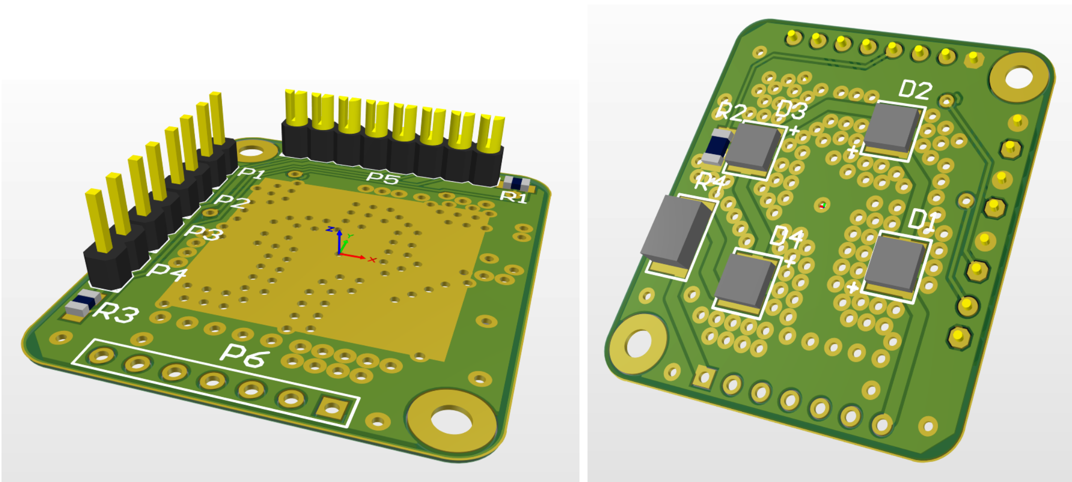
Based on the "LED_Head_660nm" schematics found in Appendix L a PCB for the 660nm LED array was created in Altium Designer and can be seen in figure 36 and 37.
Along the edge of the PCB, solder connections are placed for connecting the cables coming from the control electronics. On the bottom of the PCB, the LEDs are located according to the simulated optimal placement from chapter 3.3.1 with the PT1000 resistor right beside one of the LEDs in order get an accurate temperature reading of the LEDs. Several thermal vias connect the 2 large

ground planes on the bottom and the top. The top ground plane is equipped with a large pad of blank copper to allow for a good thermal connection to the cooling system. This PCB should be manufactured with the 1mm substrate instead of the standard 1.55mm substrate in order to reduce its thermal resistance.



(a) (b)

Figure 36: (a) 2D top-view of the LED-PCB (b) 2D bottom-view of the LED-PCB ©Patrick Bösch 2021



(a) (b)

Figure 37: (a) 3D top-view of the LED-PCB (b) 3D bottom-view of the LED-PCB ©Patrick Bösch 2021

4.3 Control of NIR LED

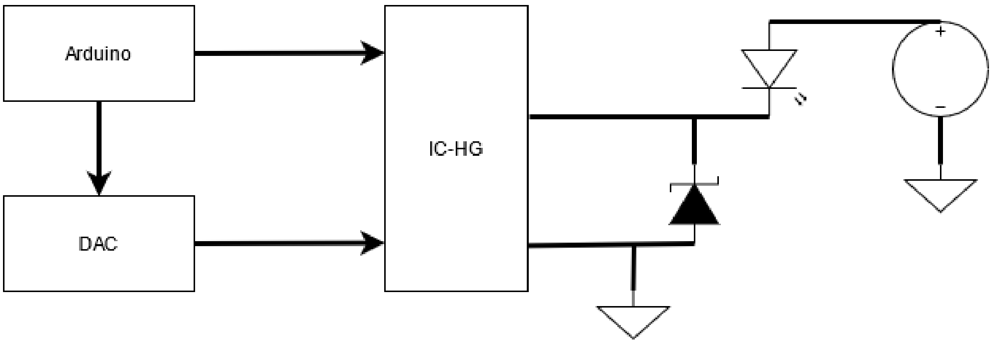


Figure 38: Sketch with all the components required for the LED control
©Patrick Bösch 2021

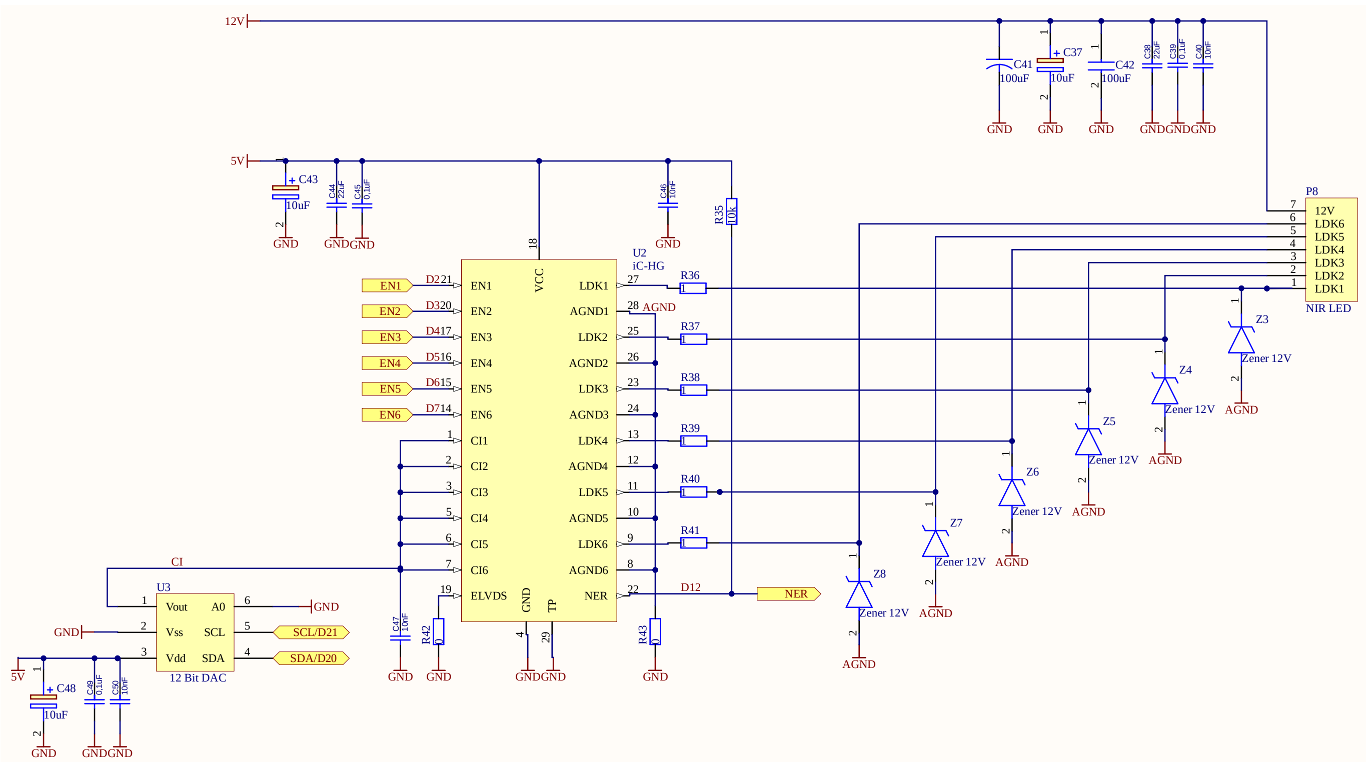


Figure 39: Detailed schematics of the core of the LED control
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Figure 38 provides a simplified overview of the implemented LED control while figure 39 shows a more detailed picture. The LED driver is the heart of the control. It is an “IC-HG”, produced by IC-Haus GmbH, a laser switch with 6 independent channels capable of switching 0.5A per channel continuously and

up to 1.5A per channel in pulsed mode. It provides a very precise inbuilt current control for each channel.[103]
The Arduino is the brain, connecting directly to the "EN" ports of the IC-HG. It is a TTL based input, so as soon as the voltage on an "EN" port rises above the threshold voltage of 2.7V the corresponding "LDK" channel will be turned on.[104] Should the voltage on the "EN" port fall below 0.4V the "LDK" channel will be turned off again. The Arduino is capable of providing a constant or a PWM input. The standard frequency for the PWM provided by the Arduino Mega is 490Hz and the duty-cycle of the signal is variable with an 8 bit resolution. It is possible to adjust the PWM frequency to up to 31.3kHz, however increasing the frequency results in a loss of duty-cycle resolution.[105]
The Arduino also provides the input to the IC-HGs current control, the "Cl" ports. Those ports are voltage controlled, so the size of the applied voltage controls the current that can pass through the "LDK" channel. Unfortunately the Arduino does not provide a true DC output on its analogue IO pins, so a DAC had to be implemented into the system. The DAC is controlled by the Arduino via "I2C" and provides the desired, smooth analogue voltage for the current control.
The LEDs are connected to the 12V power supply while the rest of the components run on 5V. As the V_F of the LEDs is well below 12V the LEDs are connected in series to an array. Each channel should contain as many LEDs as required so the total voltage drop over the serial LEDs is more than 12V. Should this not be possible the circuit is designed to include a serial resistor (R_s) to introduce an additional voltage drop. The composition for the different LEDs is as followed:

- 660nm: 1x4 LED ((R_s) = 0Ω)
- 810nm: 2x6 ((R_s) = 4.2Ω) and 1x7 LED ((R_s) = 0Ω)
- 880nm: 2x5 ((R_s) = 5.7Ω) and 1x6 LED ((R_s) = 0Ω)

When operating the LEDs in pulsed mode, large voltage peaks can occur when switching the LEDs. In order to protect against such voltage peaks, each "LDK" channel is equipped with a Zener Diode (Z_n) that limits the voltage to 12V.

4.4 User Interface

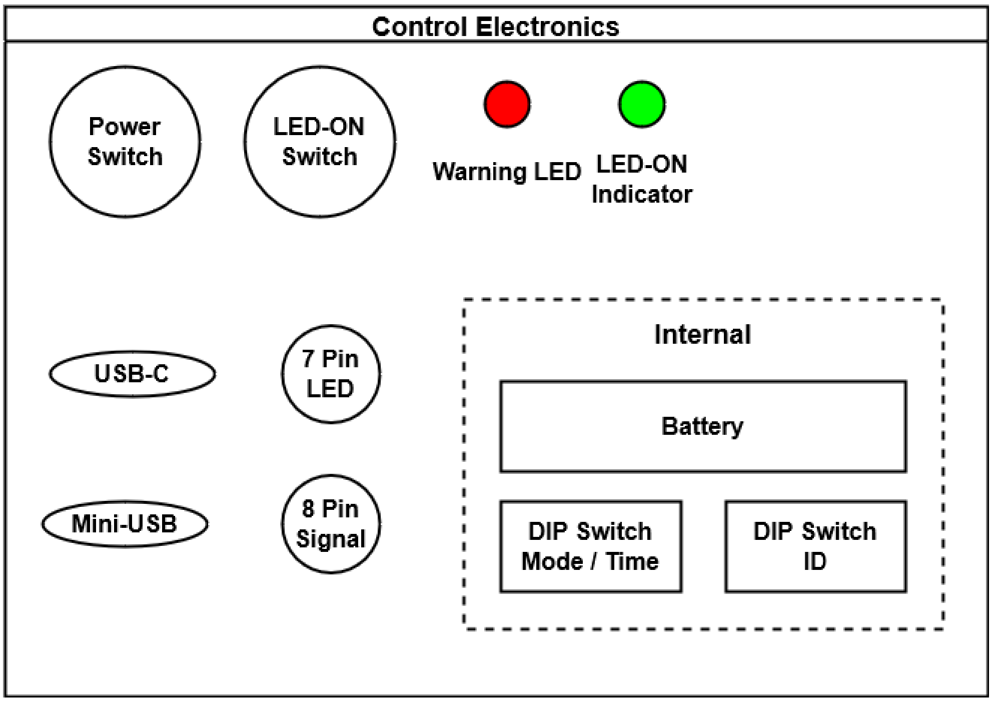

Figure 40: User interface with all its main components.
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As specified in the requirements list (Appendix A) the user interface is supposed to be fairly simple and low tech. It was therefor decided to go with an interface that does not require a screen. Figure 40 provides an overview of the planned interface. The interface has 2 levels: an external one that is accessible from the outside, and an internal one that is only accessible by opening the housing of the control electronics.The interface involves following elements:

- Power Switch: A round push-switch that is flush-mounted to prevent accidental operation.
- LED-ON Switch: A round push-button that will start the measurement sequence, which will in turn start the timer and turn on the LEDs.
- Warning LED: A red LED that will be turned on if an error is triggered and will be blinking if the battery level is too low to run another measurement with the current setting.
- LED-ON Indicator: This green LED will be turned on while a measurement is in progress.
- USB-C: This USB-C connector is used for connecting an external battery bank or for charging the internal battery.

- 7 Pin LED: A socket for the 7-Pin plug that connects the cable for the LEDs.
- Mini USB: This Mini-USB connector is used to connect to the Arduino. It can be used to adjust the Arduinos software or to download data.
- 8 Pin Signal: A socket for the 8-Pin plug that connects the cable for the Signals.
- Battery (INTERNAL): The internal battery that is connected via two 4mm pins and can be exchanged.
- DIP Switch Mode/Time (INTERNAL): This 6 channel dip switch allows the user to choose from pre-programmed measurement duration and operation modes such as constant, pulsed or placebo. It provides 3 bit per setting, so a total of 8 different modes.
- DIP Switch ID (INTERNAL): This 6 channel dip switch gives the user 6 bits to encode a binary patient ID, so a total of 64 IDs.

4.5 Safety Features

Safety is paramount, especially when the intended application of the device involves humans. A good and thorough handling of the safety critical aspects makes it also easier to get the prototype approved by the Regional Ethical Committee (REK). The Failure mode effects and criticality analysis (FMECA) performed during the previous project thesis came to the conclusion that the primary dangers stem from the LEDs and electrical components.(Appendix B) However, good safety features not just protect the user from the device but also the device from the user (e.g. Improper use and operation) and itself (e.g. Overheating). Otherwise small issues can quickly turn into time consuming and costly repairs.

4.5.1 Optical Safety

This is the most critical safety aspect as particularly the invisible NIR radiation could do potentially permanent damage to the eyes as emphasised previously in chapter 2.7. Several safety measures were employed as precaution. For one, all LED arrays are designed in a way that when operated in continuous mode, their optical output in the RoI stays below the $1[mW/mm^2]$ that are considered safe for the eye. Furthermore a warning LED is implemented in the control electronics and in the bottom of the LED-Head and will be turned on while a measurement is in progress. In addition to that the skin temperature sensor in the LED-Head is also used to detect skin contact, so the LEDs can not be turned on unless the skin temperature sensor measures above 28°C. A threshold of 28°C was chosen as firstly in Norway environmental temperatures above 28°C are rare, secondly it is still well above the average room temperature of 18-24°C and well bellow the normal human skin temperature of 33-36.9°C. [106, 107]

4.5.2 Electrical Safety

Electrical safety is another critical aspect highlighted by the FMECA (Appendix B). A Li-Po battery powered medical equipment has to comply with both the norms for batteries (NEK IEC 62133-1:2017) as well as the norm for medical electrical equipment (NEK IEC 60601-1-2:2014A1:2020) if it ever to be CE-Certified.[108, 109] The required testing is rather rigorous and extensive and way out of scope of this thesis. Furthermore, APT is not intending to certify this prototype, so many of the tests and design requirements can be dropped. However a few of them are still worth implementing. For one, the device an be considered a class III medical electrical equipment if it is not operated while charging from a power outlet. As it has no direct ground connection and operates on safety extra low voltage (SELV) (<60V DC). Further precautions that should be taken is a reverse voltage protection in case the battery is connected with the wrong polarity as well as polyfuses after the power supply and DC/DC converters to protect against short circuits of the output side.[110] Polyfuses are of now not part of the design but can easily be implemented as the PCBs are not yet manufactured.
The PCBs are furthermore equipped with PT1000 sensors that allow for monitoring of the PCB temperature as well as the LED temperature in the LED-Head. The DC/DC converters as well as the IC-HG and the Arduino come with inbuilt over temperature protection that will force a shut-down and/or trigger an error. An ID resistor in the LED-Head is used to detect the exact type of LED array and select the correct number of channels and the correct I_F for the LEDs.

4.5.3 Mechanical Safety

To guarantee mechanical safety, all the mechanical parts are executed in durable materials. All the switches, LEDs and sockets mounted on the exterior of the housing should have a low profile and an environmental protection level of at least IP54 (Appendix D). Moreover, rounded edges and compact build reduce snatch hazards.
The only issue regarding mechanical safety stems from the active cooling system as it calls for unobstructed air intakes and outlets which jeopardises especially the fluid protection value of the IP rating classified by IEC. But by using many but narrow in- and outlets for the cooling air and combining them with a smart mechanical design, for example use horizontal openings with an angle so the outside lies slightly below the inside, it should be possible to maintain a minimum IP rating of IP52. To achieve a higher rating the whole system would require a redesign and likely turn out bulkier and heavier.

4.5.4 User Safety

User safety is paramount for all equipment used in human trials and all the other safety aspects discussed previously in chapter 4.5 ultimately contribute to user safety. However, there are a few additional features that primarily target the users. First there is an audio alarm in the form of a buzzer to alert the user of the start and the end of a measurement procedure. Second the LED-head is thermally decoupled from the patients skin so that even if the aluminium parts of the LED-Head get warm it should not affect the user. In addition to that the Li-Po battery is located inside of the control electronics, in case of a battery malfunction it would not be strapped directly to the users body which enables more time to react and remove it.
Over heating of the skin is also a potential risk but according to the regulations it can be neglected as a healthy user would remove the source due to discomfort long before damage could be done.[2.7] However, this adverse reaction to excess heat might not be triggered fast enough in users suffering from neuropathy, which is a serious diabetes complication where the peripheral nerves are being damaged, resulting among other things in decreased temperature sensitivity. It is very common among diabetics, affecting as much as 50% of the diabetics.[111, 112] In order to protect users with neuropathy from thermal skin damage as well a PT1000 resistor is integrated in one of the feet of the LED-Head and monitor the users skin temperature constantly. Should the skin temperature measured rise above 43°C the system will automatically turn of the LEDs to protect against skin damage.

5 Results

This chapter will provide an overview of the projects progress and what has been achieved so far.

5.1 Update on System Requirements

The System Requirements list created during the project thesis was continuously expanded, updated and can be found in Appendix A. Among others, dependencies and colour coding were added. The colour coding should give an indication on how likely it is that a certain requirement will be fulfilled as specified by the final prototype, with green meaning very likely, orange meaning probably and red meaning very unlikely.
The power supply specification is questionable as it heavily depends on the chosen battery and LED configuration. The Dimension of both LED-Head and control electronics are highly likely going to exceed the original requirements due to crucial parts being more space demanding than expected. As for their weight at this point is still open as the housing weight keeps unknown.
On the cooling front, a solution without a peltier element was chosen so the specifications do no longer match and it is questionable if an IPX3 protection can be achieved for the LED-Head due to those many air ducts. The testing and many projects documents are still not started due to the big delays in the project progress. Hence the original time plan is no longer feasible. Regarding the economical side of the budget, here the project went well over board as emphasised in chapter 5.2.
To summarise, the vast majority of the project requirements will be met as specified.

5.2 Project Economy

It quickly became quite clear that the original project budget of 10’000NOK for one control electronics unit and 3 LED-Heads was far from sufficient. As highlighted in table 7, the NIR LEDs and the electronics components turned out to be the big cost drivers. Especially the NIR LEDs price is significantly over the expectation. This is primarily due to a misunderstanding with the supplier. The supplier, which is located in Sweden, sent an original offer without stating the currency. The question asked by us on the currency was not directly replied yet leaving the impression of the price was in SEK, therefor sufficient spare LEDs were ordered. However, when the invoice arrived after receiving the LEDs, it turned out that the price was in EUR, so approximately 10x as much as expected and as they were produced to order, they could not accept a partial

return of the order. Had this been known prior to placing the order the spare LEDs would have been reduced to a minimum cutting the cost by approximately 30%. Fortunately the company granted us a 40% as it was primarily their negligence that was responsible for the misunderstanding.
The electronics cost on the other hand had simply been underestimated as several functions turned out more complex to implement and asking for higher priced components. Large minimal orders for some components also contributed to the elevated price. The PCB costs are based on an estimate made by the manufacturers online tool while the cost for anodising of the aluminium parts was estimated by a local supplier (Appendix J). Lastly the workshop cost are simply a rough estimate for the materials used as the services of the in-house workshop are otherwise free of charge.
Those budget outliers result in a deficit of -20'764NOK. Fortunately 6'000NOK could be charged to the ITK Master Thesis account leaving APT with an estimated 14'764NOK over budget.
On a positive note, due to the many spare parts caused by large minimum orders, the manufacturing of additional devices would turn out significantly cheaper.

Table 7: Updated Project Budget

What	Price [NOK]
Optical Filters	3'383
NIR LED	10'800
Electronic Components	12'481
Control Electronics PCB	1'350
LED PCB	1'150
Anodising LED-Head	600
Material Mech. Workshop	1'000
Total	**30'764**
Contribution ITK	6'000
Original Budget	**10'000**
Difference	**-14'764**

5.3 Development Progress

The project is significantly behind the original schedule as shown in the GANTT Diagram in Appendix H. However, even though the progress was far smaller than anticipated, obvious progress was made. Comparing the project progress to the product development norm VDI 2221/2 - "Design of technical products and systems"[11], the planning and the concept phase have successfully been completed. The design phase has also seen great progress when it comes to the electronics side. The heavy lifting has been done and all the relevant functions have been either calculated or simulated. Furthermore the required externally supplied components with exception of the 2 PCBs have been chosen and ordered and a "Bill of Material" has been generated (Appendix D. On the PCB front, with the schematics finished, the next step will be the design of the control electronics PCB.

6 Discussion and further Work

The last chapter of this master thesis will reflect upon the project and the challenges encountered. It will also provide suggestions for further improvements as well as highlight the remaining tasks.

6.1 Personal Reflection on the Work performed

Overall I am quite happy with the quality and the result of the work that was performed. Especially the electronics design has been very thorough and there was a constant and productive exchange with the stakeholders involved in the project.

However looking at the overall work progress, I am not impressed at all. The thesis started off well, with a high activity, continuing with the drive from the project thesis. However an increasing load of high priority APT and study related work soon pushed the thesis down on the priority list. There were for example 2 full weeks filled with 24h lab experiments which resulted in the project progress stalling. The progress did improve a little around the Easter break but was crippled again by an approaching exam. The constant interruptions together with an ever increasing workload also took a toll on the motivation for the project. This other smaller factors resulted in a rather underwhelming progress in the first two-thirds of the project which is clearly visible in the GANTT Diagram (Appendix H). It was only by the end of May when things finally started picking up; and despite the 4 weeks of extension and the extensive time commitment since the start of June, the overall time spent on the project is falling a few hours short of the 800h target. So the balancing of interests and time management leaves definitely room for improvement.

6.2 Challenges encountered

Several challenges were encountered throughout this Master thesis project. For example are many of the of the physical processes associated with this prototype very complex and would require extensive finite element simulations to be calculated properly. This would have exceeded the scope of the thesis so simpler simulations and calculations were used and many simplifications and assumptions were made. But despite the simplifications, the obtained results seem to be sufficiently accurate for a first prototype.

As this masters was performed part-time beside my engineering position with the APT Group I also had to deal with many unrelated high priority tasks that were interrupting the workflow, causing delays and reducing thereby work efficiency. These delays resulted in the thesis deadline being extended by 4 weeks.

An additional challenge encountered are the worldwide semiconductor shortage cause by the COVID-Lowdowns as it made the sourcing of components very demanding and time consuming since often various suppliers had to be visited to find the correct components. In addition to that the electronic circuits required to provide all the required functions also tuned out far more complex than anticipated, resulting in additional workload.
Last but not least there was also a written exam at the end of May that required a significant amount of my attention.
So overall one can summarise the challenges with the complexity of the project combined with continuous distractions by other high priority tasks and a general electronics supply shortage, which resulted in the experienced delays in the project progress.

6.3 Potential Improvements of the Development Process

From a technical point of view, the development progress went smoothly and was well structured. Although the workload and the cost were both grossly underestimated. It was especially difficult to follow the time schedule due to other competing tasks of high priority.
When it comes to improvements of the design device there are not that many things that stand out and are worth addressing. There are however some possible improvements. For one, polyfuses should be added to the outputs of the DC/DC converters to protect them from short circuits. Furthermore an improvement of the LED simulation as describes in chapter Appendix G could potentially yield a more optimal LED placement and thereby a more uniform optical power distribution in the RoI. When reviewing the LED distribution it would also make sense to invest into the customised 30x30mm optical filters which would increase the legal area of the workspace and thereby improve the the optical power distribution in the RoI.
The project could potentially also benefit from a thorough thermal simulation of the LED-Head in order to ensure that all array designs and operation modes are possible without exceeding the maximal junction temperature. This however is a rather large and complex task and would likely be a project on its own.

6.4 Reminding Work and Timeline

As shown in the GANT diagram (Appendix H) there is still a significant portion of work remaining to reach the goal of a functioning and tested prototype. Holding the position of development engineer in the APT Group it will be my task to continue where the MSc Thesis left off. However, as I will go back to regular workhours and participate in other tasks I have to perform for APT, future progress will be significantly delayed. The most time-consuming aspects of the electronics design have been completed, but it take another full week of regular working hours to finish the control electronics PCB and have all documents up to date so the PCBs can be ordered. Once the PCB dimensions are know, work on the CAD design of the mechanical components can be started. Creating all the CAD models and mechanical drawings will take around 3 workdays. Assuming that the mechanical workshop at ITK has free capacity I am hoping to have the mechanical parts manufactured before my holidays at the end of August so they can be sent off for anodising. With with the mechanical and electronic components finished, the focus can be shifted towards software. As programming is not exactly my strong-suit it is hard to give a time estimate. I do however expect to use around 2-3 weeks to get familiar with the software environment, create an UML diagram and implement everything into stable code. Once the software is ready it should take about 2 days to assemble everything, followed by 2 weeks of testing and de-bugging. The last remainder will be the writing and updating of all the required documentation, such as the User Manual.

Factoring in the 5 weeks of Autumn holidays and assuming i will be the only one working on the project i would estimate the prototype to be assembled and tested by mid-November. This is quite a bit behind the original schedule as it was intended to run some small scale test with APT members as subjects from mid-August onward. It is however possible to cut the time by several weeks if more human (especially programming) resources are assigned to the project.

7 Bibliography

References 6, 7, 10, 66 and 67 are confidential and therefore not publicly available. They are however delivered as individual attachments for the propose of grading of the report.

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Appendix A Requirements List

Requirements List

Device for improved insulin absorption in Diabetes Type 1

ID	Depen-dencies	Update	F, Mi, Ma, D	Requirement	Value	Respon-sibility	Comment / Future Improvement
				General Technical Requirements			
1.1	-	01.10.2020	Mi	Powersupply	6h	Patrick	Inbuilt and rechargeable / exchangeable and rechargeable
1.2	-	15.03.2021	F	Electrical Safety	According to NEK IEC 60601:2014	Patrick	The electrical components shall be designed in a way that they can not harm the user
1.3	1.2	15.03.2021	Ma	Supply voltage	60 V DC	Patrick	Safety extra low voltage (SELV)
1.4	-	01.10.2020	F	Solvent resistant	Ethanol and Isopropanol	Patrick	Rubbing down with a saturated wipe
1.5	-	01.10.2020	F	Environment of use	Indoor	Patrick	Controlled setting and free living subjects
1.6	-	01.10.2020	F	Portability	Yes	Patrick	Main device should fit into a fanny-pack or small handbag
1.7	-	01.10.2020	F	Number of units	1	Patrick	Second unit can be produced once the first prototype works as intended (second unit required for actual patient trials)
1.8	-	~~01.10.2020~~	~~F~~	~~Number of LED pads/unit~~	~~1~~	~~Patrick~~	
		09.03.2021	F	Number of LED pads/unit	1	Patrick	Connect one at a time
1.9	-	~~01.10.2020~~	~~F~~	~~Provided functions~~	~~LEDs and Heat~~	~~Patrick~~	~~Heating effect should correspond to heating caused by LEDs (Placebo)~~
		09.03.2021	F	Provided functions	LEDs or Heat	Patrick	Heating effect should correspond to heating caused by LEDs (Placebo), allow for indipendent investigation of heat and NIR
1.10	-	09.03.2021	F	Modularity of system	Yes	Patrick	Allow interchangeable LED-Heads
1.11	-	15.03.2021	F	System Safety	According to NEK IEC 62471:2006	Patrick	The device shall not exceed the safe optical and thermal output limits for human skin and take measure to prevent harm to the eye
1.12	-	15.03.2021	F	Experiment verification	Yes	Patrick	All device parameters, settings and alarms shall be recorded and have to be intentifiable

				LED - Head			
2.1	2.3, 2.4, 2.5	10.12.2020	D	Dimensions	40x40x40mm	Patrick	Size is very depending on design, application and features: Application: Over infusion sets / for pen injection Design: Single / Multiple wavelength; Illuminated area Features: Active heating / Filters / ...
2.2	2.3, 2.4, 2.5	10.12.2020	Ma	Weight	50g	Patrick	Same as for size
2.3	-	10.12.2020	F	Application	Pen injection and angled infusionsetts	Patrick	
2.4	1.10	01.10.2020	F	Design	Multi-Pad with 1 wavelength each	Patrick	Array

ID	Depen-dencies	Update	F, Mi, Ma, D	Requirement	Value	Respon-sibility	Comment / Future Improvement
2.5	2.3	10.12.2020	Ma	Illuminated area	30cm²	Patrick	1-2cm arund the injection site should be enough (Investigate with a selfstudy how far the effect reaches)
2.6	-	01.10.2020	Mi	Liquid protection electronics	IP X3	Patrick	Spraywater up to 60° angle
2.7	-	01.10.2020	Mi	Solid particles protection	IP 4X	Patrick	Paticles with >d1mm
2.8	-	01.10.2020	Mi	Mechanical protection electronics	IK 04	Patrick	200g from 25cm (EN 62262)
2.9	1.9	01.10.2020	D	Active heating	No active heating (build heating probe once LED works)	Patrick	5 options: 1. Include a heating element, blow warm air over the skin 2. Peltier element instead of heating element 3. Use IR LEDs with a higher wavelength (eg. 1450nm) 4. Pad with resistors instead of LEDs (resistors that produce the same heat as LEDs) 5. No active heating '- should be of similar magnitude to measured heating power of the LED array
2.10	1.9, 1.11	01.10.2020	D	Surface skin temperature	Fixed	Patrick	Monitor the temperature of the skin surface and set to a biologically safe level
2.11	1.9, 1.11	01.10.2020	D	Temperature sensor for active heating	Yes	Patrick	Monitor the temperature for active heating and cooling in the measuring chamber (record temperature)
2.12	1.9	01.10.2020	D	Active cooling of the skin	No	Patrick	3 options: 1. No active cooling 2. Constantly blow environmental air over the excitation area 3. Blow cooled air over the excitation area
2.13	1.9, 2.6, 2.7	01.10.2020	F	Filter unwanted wave-lengths and physical protection	Yes	Patrick	For example a short-pass filter (Wavelengths emitted by temperature increase of LED ~2'000-15'000nm)
2.14	2.2	01.10.2020	F	Connection to main unit	Cable with plug	Patrick	Should be as thin and light as possible
2.15	1.10	01.10.2020	F	Interface to main unit	Plug	Patrick	Allow for easy replacement of the LED-heads
2.16	1.11, 2.10, 3.8	01.10.2020	F	Skin temperature sensor	Yes	Patrick	To monitor skin temperature and prevent dangerous overheating (record temperature)
2.17	1.9	01.10.2020	F	LED placement	Physical gap	Patrick	Air gap to create a uniform illumination, larger distance helps reduce the variability due to changes in skin curvature, avoids heat conduction. Distance depending on LEDs chosen (1-2cm) (remove hair in the exposed area)
2.18	1.9	01.10.2020	F	Cooling of LED array	Active	Patrick	Use a peltier element (TEC) with heatsink and fan to keep the LEDs at a constant temperature (fan should be constantly on, even if not needed - Placebo)

ID	Depen-dencies	Update	F, Mi, Ma, D	Requirement	Value	Respon-sibility	Comment / Future Improvement
2.19	1.9	01.10.2020	F	LED temperature sensor	Yes	Patrick	Temperature sensor to monitor and control the temperature of the LED array
2.20	-	01.10.2020	F	Placing during experiment	Strap and skin marker	Patrick	Subjects complained about itchy velcro strap, we should get a different strap (Strap design not part of the thesis)
2.21	-	01.10.2020	F	Cablelength	1m	Patrick	
2.22	1.9, 1.10	~~01.10.2020~~	~~F~~	~~LED Wavelengths~~	~~660nm, 890nm, 730nm~~	~~Patrick~~	~~Desired wavelengths in the first Tissue Window (650-950nm), 660nm and 890nm should be included as Tendlite and Anodyne use them.~~
		25.01.2021	F	LED Wavelengths	660nm, 810nm, 890nm	Patrick	Desired wavelengths in the first Tissue Window (650-950nm), 660nm and 890nm should be included as Tendlite and Anodyne use them. 810nm chosen based on literature search findings, possible to produce different wavelengths once device built and tested
2.23	-	01.10.2020	Ma	Spectral Bandwith	Δλ30nm	Patrick	
2.24	1.9, 1.11	01.10.2020	D	Radiant Intensity (mW/mm²) on skin	Variable intensity through PWM control (adjusted in software - same for all wavelengths)	Patrick	4 options: 1. Identical intensity by means of varying LED numbers 2. Variable intensity by using the same number of LEDs for every wavelength (variable because of different LED specs) 3. Variable intensity by means of not activating all the LEDs of a certain wavelength (example 2 or 3 steps) 4. Variable intensity by dimming the LEDs(PWM) (will cause minor frequency shift)
2.25	1.11	01.10.2020	Ma	Maximal radiant Intensity (mW/mm²) on skin	According to wavelength and NEK IEC 62471:2006 (Photobiological safety of lamps and lamp systems)	Patrick	Use the safe maximum for the most powerful wavelength, calculate for the different wavelenths
2.26	1.11, 3.8, 3.9	16.03.2021	Ma	Indication LED for LED-on	Yes	Patrick	Include one bright LED in the visible range in the LED array, this LED should flash while the NIR-LEDs are on to allert the user

ID	Depen-dencies	Update	F, Mi, Ma, D	Requirement	Value	Respon-sibility	Comment / Future Improvement
				Control Electronics			
3.1	1.4, 1.6	01.10.2020	Ma	Dimensions	150x100x35mm	Patrick	The smaller the better
3.2	1.4, 1.6	01.10.2020	Ma	Weight	200g	Patrick	The lighter the better
3.3	-	01.10.2020	Mi	Liquid protection electronics	IP X2	Patrick	Spraywater up to 15°
3.4	-	01.10.2020	Mi	Solid particles protection	IP 4X	Patrick	Paticles with >d1mm
3.5	-	01.10.2020	Mi	Mechanical protection electronics	IK 04	Patrick	200g from 25cm (EN 62262)
3.6	1.12, 2.25, 3.8	01.10.2020	F	LED Timer	Yes	Patrick	Change in code, have 3 preprogrammed times that can be turned on via dip-switch
3.7	1.12, 2.25, 4.7	01.10.2020	F	Timer duration	Variable in software, chosen by dip switch	Patrick	1. Have a different length for every wavelength (based on maximum power for that wavelength) 2. Have one (or 2-3) different timers that are changed by changing the code and chosen via dip switch (or buttons accessible for the subject) 3. Have a variable timer that can be set individually for every experiment
3.8	1.11, 2.25	12.10.2020	F	Overexposure protection	Yes	Patrick	Control that user input for duration doesn't result in overexposure for the given wavelength, monitor skintemperature
3.9	1.11, 2.16, 2.25	13.10.2020	F	Eye protection	Yes	Patrick	Use skintemperature sensor to determine if device has skin contact, if not, disable LEDs
3.10	4.1	01.10.2020	F	Signal Buzzer	1	Patrick	Goes off once timer is up
3.11	1.11, 1.12, 3.12	01.10.2020	F	Duty-Cycle control of the LEDs	PWM	Patrick	PWM control for dimming so the treatment has always the same length, (power) indipendent of the wavelength, can be changed in code
3.12	1.12	01.10.2020	D	PWM / LED power variation	Continuous 0-100%	Patrick	Change PWM setting in software
3.13	1.12, 3.12	01.10.2020	F	Pulse length	Variable	Patrick	Change in software
3.14	1.12, 3.12	01.10.2020	Mi	Pulse frequency	0-50Hz	Patrick	Higher frequencys possible, but probably not required as the skin is a rather slow compartment
3.15	1.12, 3.12	01.10.2020	F	Pulse type	Square	Patrick	
3.16	-	01.10.2020	Mi	Internal Memory	50 Treatments	Patrick	Possible to store the output files of at least 50 treatments

ID	Depen-dencies	Update	F, Mi, Ma, D	Requirement	Value	Respon-sibility	Comment / Future Improvement
				Interface (Human / Machine)			
4.1	-	01.10.2020	F	Display	None	Patrick	Aim to keep it simple and fool prove
4.2	1.11, 4.1	01.10.2020	Ma	Indicator LED	3	Patrick	3 indicator LEDs (or fewer, but multi-coloured) to provide information to the user: 1x LED on (always on for the durration of the timer when subjects presses the LED button); 1x Battery level; 1x Error
4.3	4.1	01.10.2020	F	Power switch	Yes	Patrick	Turns device on (use illuminated switch)
4.4	4.1	01.10.2020	F	LED switch	Yes	Patrick	Turns LEDs on (starts the inbuilt timer)
4.5	1.2, 1.11, 1.12, 4.1	25.01.2021	F	Emergency "OFF" switch	Yes	Patrick	Shuts down LEDs / heating instantly
4.6	1.11, 1.12, 4.1	06.10.2020	F	Temperature control	In software	Patrick	Change in the code between experiments if required
4.7	1.12, 4.1	01.10.2020	F	Choosing different operation modes	Dip Switch	Patrick	Dip Switch so the person running the experiments can set a mode without the subject knowing and without need for programming knowledge (Maybe hide it under a lid)
4.8	1.12, 4.1	08.10.2020	F	Setting Patient ID	Dip Switch	Patrick	Dip Switch so the person running the experiments can set the patient ID without programming knowledge (Maybe hide it under a lid)
4.9	1.12, 4.11	01.10.2020	F	Output file Temperature sensors	.csv	Patrick	One file with all the temperature sensors
4.10	1.12, 4.11	01.10.2020	F	Output file device settings	.csv	Patrick	Include all the variable parameters of the device (date, time, patient ID, experiment ID, ...)
4.11	1.12	06.10.2020	F	Output file with LED-ID	.csv	Patrick	Keep exact wavelength used in a separate file and hidden by a code(ID) to allow for double-blinded exeriments
4.12	1.12, 4.5, 5.1, 5.2, 5.3	16.03.2021	F	Output file with Errors and Alarms	.csv	Patrick	Log all alarms and errors
				Errors / Alarms			
5.1	1.11, 2.10, 2.16, 2.25, 3.8, 4.1	01.10.2020	F	Overheating	Indicator LED and buzzer	Patrick	Warn of overheating of LEDs or Skin - cut power to LED if triggered
5.2	4.1	01.10.2020	D	Low Battery	Indicator LED and buzzer	Patrick	Warn user of weak battery
5.3	4.1	06.10.2020	D	LED failure	Indicator LED and buzzer	Patrick	Monitor LED power consumption and warn user if one or more LEDs are not working as intended
				Data Link			
6.1	-	~~01.10.2020~~	~~F~~	~~Interface for data exchange~~	~~Micro-USB~~	~~Patrick~~	Interface to download aquired data and change settings
		26.07.2021	F	Interface for data exchange	Mini-USB	Patrick	

ID	Dependencies	Update	F, Mi, Ma, D	Requirement	Value	Responsibility	Comment / Future Improvement
				Testing			
7.1	1.11	01.10.2020	F	Emmitted wavelength and intensity (including testing of heating effect and temperature dependency of the array)	In vitro	Patrick	Optionally with a photo diode, but it should be sufficient to characterise the arrays in-vitro
7.2	1.1	01.10.2020	F	Battery run-time	In vitro	Patrick	
7.3	1.11	01.10.2020	F	General function test	Yes	Patrick	Including safety features (LED and Skin protection)
7.4	1.11, 2.10, 2.16, 2.19	01.10.2020	F	Temperature of electronics and LED-Array	In vitro	Patrick	Run for 2x max intended usage (or max power) with 100% duty-cycle
7.5	1.11	01.10.2020	Ma	Variation in radiation density	Δ5%	Patrick	Maybe test the existing devices (Anodyne and Tendlite) as well
				Economical			
8.1	-	01.10.2020	Ma	Cost of project	10'000kr	Patrick	Rough estimate and very depending on the amount of features implemented
				Legal			
9.1	-	01.10.2020	D	Patent search	Yes	Patrick	Ensure that no existing patents will be infringed (only relevant for future commercial applications)
				Timing			
10.1	-	01.10.2020	F	Project Start	17.08.2020	Patrick	
10.2	-	01.10.2020	D	Concept Review with APT	08.10.2020	Patrick	
10.3	-	01.10.2020	D	Approval of Technical requirements	29.10.2020	Patrick	
10.4	-	~~01.10.2020~~	~~D~~	~~Design Review~~	~~30.11.2020~~	~~Patrick~~	~~Design part of MSc thesis~~
		25.01.2021	D	Design Review	18.03.2021	Patrick	Master thesis
10.5	-	10.12.2020	F	Hand in of the project report	31.01.2021	Patrick	
10.6	-	16.03.2021	F	Start MSc Thesis	09.02.2021	Patrick	
10.7	-	25.01.2021	F	MSc project Finished	14.06.2021	Patrick	
10.8	-	25.01.2021	F	Hand in MSc Report	28.06.2021	Patrick	
				Documentation			
11.1	-	01.10.2020	F	Report	Yes	Patrick	
11.2	-	01.10.2020	F	User Manual	Yes	Patrick	Master thesis
11.3	-	01.10.2020	F	CAD Files	Yes	Patrick	Master thesis
11.4	-	01.10.2020	F	PCB Files	Yes	Patrick	Master thesis
11.5	-	25.01.2021	F	Electro Scematics	Yes	Patrick	Master thesis
11.6	-	01.10.2020	F	Traceability	Yes	Patrick	
				Organisation			
12.1	-	01.10.2020	F	Biweekly meeting	-	Patrick	

F, Mi, Ma, D	Fixed, Minimal, Maximal, Desired

Appendix B FMECA NIR - Device

FMECA NIR - Device for improved insulinabsorption in diabetes type 1

Description of unit			Description of failure				Effect of Failure		Fault apperance		Risk			Risk reduction measure	Responsible
Ref no	Function	Operational mode	Failure mode	Failure cause	Detection of failure	Circumstance of failure	on the subsystem	on the system function		Number A	Failure rate O	Severity S	Risk priority no RPN = A*O*S		
1.1	LED Array	Treatment of infusion site with NIR	Optical output energy too high	Electrical failure	LED semiconductor junction temperature increases significantly	Too high forward current	LEDs overheat and get damaged	Incorrect optical output	Abrupt	5	2	5	50	Thermal monitoring of LED semiconductor junction temperature	Patrick
1.2							Optical output exceedes safe levels	Pain or thermal injury to user	Gradual	1	1	3	3	Emergency "OFF" button in easy reach of user	Patrick
1.3				Mechanical failure	Undetected	Incorrect LED Array connected for the intended setting	LEDs can receive wrong forward current resulting in incorrect optical output	Pain or thermal injury to user	Gradual	1	7	3	21	Unique coding off the pins of the plug connecting the LED array to the electronics	Patrick
1.4				Controller Failure	Undetected	Duty-Cycle of LEDs too long	Optical output exceedes safe levels	Pain or thermal injury to user	Gradual	1	4	3	12	1. Continuous thermal monitoring of surface temperature in measurement area 2. Audible alarm if surface temperature exceeds limit	Patrick
1.5						Time intervall too long for connected LEDs (faulty programming)			Gradual	1	4	3	12		Patrick
1.7				Electrical failure	Undetected	Broken LED	Insufficient optical output	Invalid experiment	Abrupt	5	2	2	20	1. Frequent manual tests of the LEDs 2. Logging of LED temperature to detect LED failures when analysing experimental data	Patrick
1.8					LED semiconductor junction temperature increases significantly	Insufficient cooling of LED array	Reduced optical output	Invalid experiment	Abrupt	5	2	2	20	Cooling of LED array	Patrick
1.9				Mechanical failure	Undetected	Incorrect LED Array connected for the intended setting	LEDs can receive wrong forward current resulting in incorrect optical output	Invalid experiment	Abrupt	5	7	2	70	Unique coding off the pins of the plug connecting the LED array to the electronics	
1.10				Controller Failure	Undetected	Duty-Cycle of LEDs too short	Reduced optical output	Invalid experiment	Abrupt	5	4	2	40	Logging of experimental parameters such as time, duty-cycle, forward current	
1.11						Time intervall too short for connected LEDs (faulty programming)			Abrupt	5	4	2	40		Patrick
2.1		Accidental activation of LED Array	Exposure of the eye to NIR radiation	Wrong user Input	Indicator LED for "LED ON" activated	LED turned on without being placed correctly	Invisible NIR radiation entering the eye	Eye damage	Intermittent	3	5	5	75	LED can only be activated while surface temperature monitor detects "skin-contact" (measured temperature above certain level)	Patrick
2.2			Exposure of tissue to NIR radiation				Exposure of sensitive tissue areas	Pain or thermal injury to user	Gradual	1	5	3	15	1. Continuous thermal monitoring of surface temperature in measurement area 2. Audible alarm if surface temperature exceeds limit	Patrick
2.3			Exposure of material to NIR radiation				Overheating of material	Thermal damage / fire hazard	Gradual	1	5	2	10	1. Continuous thermal monitoring of surface temperature in measurement area 2. Limit maximal temperature to biologically acceptable levels	Patrick

FMECA NIR - Device for improved insulinabsorption in diabetes type 1

Description of unit			Description of failure				Effect of Failure		Fault apperance		Risk			Risk reduction measure	Responsible
Ref no	**Function**	**Operational mode**	**Failure mode**	**Failure cause**	**Detection of failure**	**Circumstance of failure**	**on the subsystem**	**on the system function**		**Number A**	**Failure rate O**	**Severity S**	**Risk priority no RPN = A*O*S**		
3.1	Heating element	Heat treatment of infusion site	Heat output too high	Electrical failure	Surface temperature probe	Too high forward current	Element overheats and get damaged	Incorrect heat output	Abrupt	5	1	5	25	Thermal monitoring ot heating element	Patrick
3.2							Heat output exceedes safe levels	Pain or thermal injury to user	Gradual	1	1	4	4	Emergency "OFF" button in easy reach of user	Patrick
3.3				Controller Failure		Too long exposure time	Heat output exceedes safe levels	Pain or thermal injury to user	Gradual	1	4	4	16		Patrick
3.4			Heat output too low	Electrical failure		Too low forward current	Heat output below expected levels	Invalid experiment	Abrupt	5	1	2	10	Logging of experimental parameters such as time, surface temperature, forward current	Patrick
3.5				Controller Failure		Too short exposure time			Abrupt	5	4	2	40		Patrick
4.1		Accidental activation of heat treatment	Exposure of tissue to heat treatment	Wrong user Input	Indicator LED for "LED ON" activated	Heating element activated without it being placed properly	Exposure of sensitive tissue areas	Pain or thermal injury to user	Gradual	1	5	3	15	1. Continuous thermal monitoring of surface temperature in measurement area 2. Audible alarm if surface temperature exceeds limit	Patrick
4.2			Exposure of material to heat treatment				Overheating of material	Thermal damage / fire hazard	Gradual	1	5	2	10	1. Continuous thermal monitoring of surface temperature in measurement area 2. Limit maximal temperature to biologically acceptable levels	Patrick
5.1	Electrical charging	Charging of the battery	Short circuit of the battery	Electrical failure	Red Error LED activated	Component failure	Overheating of battery	Permanent damage to battery / fire hazard	Abrupt	5	1	5	25	Fuse	Patrick
5.2				Wrong user Input	Red Error LED activated	Charger connected with wrong polarity	Overheating of battery	Permanent damage to battery / fire hazard	Abrupt	5	5	5	125	1. Battery and charger integrated in design 2. Charging plug that prohibits wrong polarisation	Patrick

Risk ranking (higher means more risk):
- 5: Abrupt fault
- 3: Intermittent fault
- 1: Incipient (gradual) fault

Likelihood of occurrence (qualitative, can vary from patient to patient):

1 less than once a lifetime
2 once a lifetime
3 once a year
4 several times a year
5 Once per month
6 Several times per month
7 Once per week
8 Several times per week
9 Once a day
10 Several times a day

Severity of fault:
- 1: Light or negligible damage to user or device
- 5: Destruction of the device or severe harm to the user

Risk priority number:
- combine the previous numbers by multiplying them. High RPN -> highly critical, low RPN -> less critical
- Failures with RPN >= 50 should be given special attention

Appendix C Power Consumption

Calculation Power Consumption NIR-Device

	What	I(av)[mA]	I(max)[mA]	No. of Dev	No. of Dev(810nm)	No. of Dev(660nm)	I(tot_max)[mA]	I(tot_aver)[mA]	I(tot_810nm)[mA]	I(tot_660nm)[mA]	
12V	NIR LED	350,00	500,00	6,00	4,00	1,00	3000,00	2100,00	1400,00	350,00	
	Arduino	100,00	200,00	1,00	1,00	1,00	200,00	100,00	100,00	100,00	
						I(tot_max)12V[mA]	3200,00	2200,00	1500,00	450,00	
5V	Sunon Fan	112,00	112,00	2,00	2,00	2,00	224,00	224,00	224,00	224,00	
	IC-HG	300,00	750,00	1,00	0,67	0,17	750,00	300,00	200,00	50,00	
	MicroSD card breakout board+	100,00	150,00	1,00	1,00	1,00	150,00	100,00	100,00	100,00	
	Buzzer	1,00	60,00	1,00	1,00	1,00	60,00	1,00	1,00	1,00	
	DAC (from Arduino)	0,20	0,40	1,00	1,00	1,00	0,40	0,20	0,20	0,20	
	Voltage ref PT1000 (Arduino)	0,30	0,30	4,00	4,00	4,00	1,20	1,20	1,20	1,20	
	LED in Power Switch	20,00	20,00	1,00	1,00	1,00	20,00	20,00	20,00	20,00	
						I(tot_max)5V[mA]	1205,60	646,40	546,40	396,40	
3.3V	Warning LED (Head)	20,00	20,00	1,00	1,00	1,00	20,00	20,00	20,00	20,00	
	Real Time Clock	0,20	0,20	1,00	1,00	1,00	0,20	0,20	0,20	0,20	
	Panel LED red	10,00	20,00	1,00	1,00	1,00	20,00	10,00	10,00	10,00	
	Panel LED green	10,00	20,00	1,00	1,00	1,00	20,00	10,00	10,00	10,00	
						I(tot_max)3.3V[mA]	60,20	40,20	40,20	40,20	
		U(out)[V]	I(out_max)[A]	I(out_aver)[A]	I(out_810nm)[A]	I(out_660nm)[A]	n	I(3.7_max)[A]	I(3.7_aver)[A]	I(3.7_810nm)[A]	I(3.7_660nm)[A]
I(tot_max)3.7V	3.7V -> 12V	12,00	3,20	2,20	1,50	0,45	0,87	11,93	8,20	5,59	1,68
	3.7V -> 5V	5,00	1,21	0,65	0,55	0,40	0,94	1,73	0,93	0,79	0,57
	3.7V -> 3.3V	3,30	0,06	0,04	0,04	0,04	0,61	0,09	0,06	0,06	0,06
							I(tot_max)[A]	13,75			
								I(tot_av)[A]	9,19		
									I(tot_810nm)[A]	6,44	
										I(tot_660nm)[A]	2,31
							P(tot_max)[W]	**50,88**			
								P(tot_av)[W]	**34,00**		
	mAh	**C**	**I(max)[A]**						**P(tot_810nm)[W]**	**23,81**	
Battery	8200	60,00	492,00							**P(tot_660nm)[W]**	**8,53**
Battery Bank	10000										
Battery(tot)	18200										
Usage	30min/measurement	P(max)[Wh]	25,44	P(av)[Wh]	17,00	P(810nm)[Wh]	11,91	P(660nm)[Wh]	4,27		
		C(max)[mAh]	6875,19	C(av)[mAh]	4594,68	C(810nm)[mAh]	3218,04	C(660nm)[mAh]	1153,09		
	45min/measurement	P(max)[Wh]	38,16	P(av)[Wh]	25,50	P(810nm)[Wh]	17,86	P(660nm)[Wh]	6,40		
		C(max)[mAh]	10312,78	C(av)[mAh]	6892,01	C(810nm)[mAh]	4827,06	C(660nm)[mAh]	1729,64		

		No. of Meas (max)	No. of Meas (aver)	No. of Meas (810nm)	No. of Meas (660nm)
30min	Battery	1,19	1,78	2,55	7,11
	Battery with Battery Bank	2,65	3,96	5,66	15,78
45min	Battery	0,80	1,19	1,70	4,74
	Battery with Battery Bank	1,76	2,64	3,77	10,52

All values are for CW-mode of LEDs

Appendix D Bill of Material

Bill of Materials

System-Part	What	Where	Manufacturer	Supplier	Price (exc. VAT)	Min. Quantity	Order Quantity	Total/ component	Order Number
Control Electronics	BATTERY BABYSITTER LIPO BATTERY	Charging Battery	SparkFun	Digi-Key	167,38	1	1	167,38	PRT-13777
Control Electronics	PowerBoost 1000 Basic - 5V USB Boost @ 1000mA from 1.8V+	3,7V to 5V	Adafruit	Digi-Key	125,43	1	1	125,43	2030
Control Electronics	Memory Extension Arduino, MicroSD card breakout board+	Arduino	Adafruit	Digi-Key	62,93	1	1	62,93	254
Control Electronics	Development Board, Arduino Mega 2560, ATmega2560 MCU, 54 5V I/O, 16 Analogue Inputs, 4 UARTs	Arduino	Arduino	Digi-Key	323,02	1	1	323,02	A000067
Control Electronics	1s 8200mAh - 120C - Intellect HV Shorty Li-Po	Internal Power	Schumacher	Elefun	495	2	2	990	IPCC1S8200PT1
Control Electronics	Fuse Hardcase strømkabel m. Traxxas	Battery Cable	Fuse	Elefun	52	1	1	52	45087
Control Electronics	Bronto Lipo-Safe Bag 30x23cm (L)	Battery Charging external	Bronto	Elefun	99	1	1	99	21975
Control Electronics	ISDT PD60 60W/4S USB-C	Battery Charging external	ISDT	Elefun	239	1	1	239	PD60
Control Electronics	SkyRC Ladekabel - 2S Hardcase XT60 4/5mm	Battery Charging external	SkyRC	Elefun	69	1	1	69	SK-600023-14
Control Electronics	Circular Connector, 1B Series, Panel Mount Receptacle, 7 Contacts, Solder Socket, Push-Pull	Connect LEDs	Lemo	Farnell	299,43	1	1	299,43	EGG.1B.307.CLL
Control Electronics	Surface Mount Tantalum Capacitor, MICROTAN®, 1 µF, 25 V, 0603 [1608 Metric], 298D Series, ± 20%	RTC	Vishay	Farnell	16,04	1	2	32,08	298D105X0025M2T
Control Electronics	Extreme MicroSDHC Class 10 U3 V30 Memory Card, 32GB 90MB/s 60MB/s	Arduino	SanDisc	Farnell	176,25	1	1	176,25	SDSQXAF-032G-GN6MA
Control Electronics	SMD Chip Resistor, 4.7 kohm, ± 1%, 125 mW, 0603 [1608 Metric], Thick Film, High Power	I2C Pull-up	Multicomp	Farnell	0,104	2	10	1,04	MCWF06P4701FTL
Control Electronics	Battery Holder, Coin Cell - 20mm x 1, SMD	RTC	Multicomp	Farnell	7,68	1	1	7,68	CH7410-2032LF
Control Electronics	N-pol Transistor (MOSFET) 30V 3.2A	Audio Alarm	Vishay	Farnell	4,14	1	2	8,28	SI2304BDS-T1-E3
Control Electronics	N-pol Transistor (MOSFET) 30V 3.2A	LED and Electronics Fan	Vishay	Farnell	4,14	4	4	16,56	SI2304BDS-T1-E3
Control Electronics	Schottky Rectifier, 30 V, 1 A, Single, SMD, 2 Pins, 500 mV	Fly Back Fans and Buzzer	Taiwan Semiconductor	Farnell	7,56	3	5	37,8	SS13L R3
Control Electronics	DIP / SIP Switch, 6 Circuits, Slide, Through Hole, SPST-NO, 24 V, 25 mA	Choose Patient ID, Time, Mode	Multicomp	Farnell	14,81	2	3	44,43	MCNDS-06V
Control Electronics	LED Panel Mount Indicator, Green, 2 VDC, 8 mm, 20 mA, 8 mcd, IP67	Indicator LED	APEM	Farnell	40,05	1	1	40,05	Q8F6CXXG02E
Control Electronics	LED Panel Mount Indicator, Red, 2 VDC, 8 mm, 20 mA, 12 mcd, IP67	Indicator LED	APEM	Farnell	42,01	1	1	42,01	Q8F6BXXR02E
Control Electronics	PTC Thermistor, 1 kohm, SMD, PTS Series	Temp PCB	Vishay	Farnell	18,75	1	1	18,75	PTS120601B1K00P100
Control Electronics	SMD Chip Resistor, 1 ohm, ± 1%, 750 mW, 1206 [3216 Metric], Thick Film, Pulse Proof, High Power	IC-HG	Vishay	Farnell	3,45	6	10	34,5	CRCW12061R00FKEAHP
Control Electronics	Zero Ohm Resistor, Jumper, 0805 [2012 Metric], Thick Film, 500 mW, 6 A, Surface Mount Device	Various	Vishay	Farnell	1,13	3	10	11,3	CRCW08050000Z0EAHP
Control Electronics	SMD Chip Resistor, Ceramic, 100 kohm, ± 1%, 100 mW, 0603 [1608 Metric], Thick Film	MOSFET, 3.3V	Multicomp	Farnell	0,093	8	10	0,93	MCMR06X1003FTL
Control Electronics	SMD Chip Resistor, 100 ohm, ± 0.1%, 100 mW, 0603 [1608 Metric], Thin Film, Precision	IC-HG	Multicomp	Farnell	1,41	3	10	14,1	MCWF06R1000BTL
Control Electronics	SMD Chip Resistor, 10 kohm, ± 5%, 100 mW, 0603 [1608 Metric], Thick Film, General Purpose	IC-HG /MOSFET/Button	Multicomp	Farnell	0,0506	4	10	0,506	MCWR06X103 JTL
Control Electronics	SMD Multilayer Ceramic Capacitor, 10000 pF, 50 V, 0603 [1608 Metric], ± 5%, X7R, VJ Series	IC-HG, LED, Power source	Vishay	Farnell	0,58	6	10	5,8	VJ0603Y103JXACW1BC
Control Electronics	SMD Multilayer Ceramic Capacitor, 0.1 µF, 50 V, 0603 [1608 Metric], ± 5%, X7R, VJ Series	IC-HG, LED, Power source, DAC	Vishay	Farnell	0,566	12	20	11,32	VJ0603Y104JXACW1BC
Control Electronics	Digital to Analogue Converter, 12 bit, I2C, 2.7V to 5.5V, SOT-23, 6 Pins	DAC	Microchip	Farnell	13,09	1	2	26,18	MCP4725A3T-E/CH
Control Electronics	SMD Chip Resistor, 10 kohm, ± 0.01%, 62.5 mW, 0603 [1608 Metric], Thin Film, Precision	PT1000 / ID Resistor	Multicomp	Farnell	10,42	13	14	145,88	MCTF0603TTX1002
Control Electronics	SMD Chip Resistor, 1 kohm, ± 0.01%, 100 mW, 0805 [2012 Metric], Thin Film, Precision	PT1000	Multicomp	Farnell	18,9	4	5	94,5	MCTF0805TTX1001

Bill of Materials

Control Electronics	Operational Amplifier, 2 Amplifier, 1 MHz, 0.1 V/µs, 3V to 32V, ± 1.5V to ± 16V, SOIC, 8 Pins	PT1000	TI	Farnell	11,27	4	5	56,35	LM358MX/NOPB
Control Electronics	Surface Mount Tantalum Capacitor, MnO2, 100 µF, 16 V, 2412 [6032 Metric], T495 Series, ± 10%	3.7V to 12V	Kemet	Farnell	14,3	6	8	114,4	T495C107K016ATE200
Control Electronics	DC/DC Fixed Charge Pump Voltage Converter, 2 V to 5.5 V in, 3.3 V/150 mA out, MSOP-8	3.7V to 3.3V	Microchip	Farnell	18,66	1	2	37,32	MCP1253-33X50I/MS
Control Electronics	Surface Mount Tantalum Capacitor, 2.2 µF, 16 V, 0805 [2012 Metric], TAJ Series, ± 10%, -55 °C	3.7V to 3.3V	AVX	Farnell	3,89	1	5	19,45	TAJR225K016RNJ
Control Electronics	PCB Terminal Block, THT, 5mm Pitch, Horizontal, Screw, 4 Poles	Connect Battery and other I/O	Phoenix Contact	Farnell	33,73	2	4	134,92	MKDS 3/ 4
Control Electronics	Wire-To-Board Terminal Block, 5 mm, 2 Ways, 24 AWG, 12 AWG, 2.5 mm², Screw	Connect Battery and other I/O	Phoenix Contact	Farnell	9,32	4	6	55,92	MKDS 3/ 2
Control Electronics	Pin Header, Board-to-Board, 2.54 mm, 2 Rows, 36 Contacts, Through Hole Straight	Connect Arduino	Molex	Farnell	15,69	1	2	31,38	10-89-7361
Control Electronics	Pin Header, Board-to-Board, 2.54 mm, 1 Rows, 25 Contacts, Through Hole Straight	Connect Arduino	Molex	Farnell	8,63	2	3	25,89	22-28-4250
Control Electronics	SMD Chip Resistor, 270 ohm, ± 1%, 125 mW, 0805 [2012 Metric], Thick Film, General Purpose	MOSFET to Arduino	Multicomp	Farnell	0,101	6	10	1,01	MCWR08X2700FTL
Control Electronics	Power MOSFET, P Channel, 20 V, 18 A, 0.0073 ohm, PowerPAK 1212, Surface Mount	Current Protection Battery	Vishay	Farnell	8,74	5	6	52,44	SIS407ADN-T1-GE3
Control Electronics	Industrial Pushbutton Switch, Miniature, 48-EM Series, 13.6 mm, SPST-NO-DB, Maintained, Round Domed	Start Measurement	ITW Switches	Farnell	124,13	1	1	124,13	48-2-RB-N-BL-B
Control Electronics	Vandal Resistant Switch, Miniature, 57M-EM Series, 16.1 mm, SPST-NO-DB, Maintained, Round, Natural	ON-OFF Switch	ITW Switches	Farnell	228,94	1	1	228,94	57M-211B
Control Electronics	Surface Mount Tantalum Capacitor, MnO2, 220 µF, 10 V, 2917 [7343 Metric], T495 Series, ± 10%	Battery Stabiliser	Kemet	Farnell	23,29	2	3	69,87	T495X227K010ATE100
Control Electronics	Ferrite Bead, 5 A, 78 ohm	12v Smoothing	Fair-Rite	Farnell	6,42	3	4	25,68	2773021447
Control Electronics	SMD Chip Resistor, 84.5 ohm, ± 1%, 500 mW, 0805 [2012 Metric], Thick Film, High Power, Anti-Surge	LED Power-Switch	Panasonic	Farnell	0,829	1	10	8,29	ERJP06F84R5V
Control Electronics	Non-Isolated DC/DC Converters 12W 3.3/5V	3.7V to 12V	TI	Mouser	177,98	3	4	711,92	PTN04050CAZT
Control Electronics	Ansmann 10Ah 5 V, 9 V, 12 V Power Bank Portable Charger	Battery Extension	Ansmann	RS Online	353,76	1	1	353,76	1700-0115
Control Electronics	Binder Panel Mount Connector, 8 Contacts, Miniature Connector	Socket Sensors	Binder	RS Online	135,27	1	1	135,27	99-9128-00-08
Control Electronics	Amphenol ICC, Right Angle, PCB Mount, Socket Type C 3.1 IP67 USB Connector	Charging Battery	Amphenol	RS Online	101,19	1	1	101,19	MUSBR-M1C1-30
Control Electronics	Maxim Integrated DS3231SN#T&R, Real Time Clock, 236B RAM Serial-I2C, 16-Pin SOIC	RTC	Maxim Integrated	RS Online	93,28	1	2	186,56	DS3231SN#T&R
Control Electronics	Panasonic CR2032 Button Battery, 3V, 20mm Diameter	RTC	Panasonic	RS Online	21,63	1	1	21,63	CR-2032/BN
Control Electronics	Sunon, 5 V, dc Axial Fan, 30 x 30 x 6mm, 4.9cfm, 560mW, IP20	Cooling electronics	Sunon	RS Online	128,65	1	1	128,65	MF30060V1-1000U-A99
Control Electronics	RS PRO 93dB, SMD External Magnetic Buzzer Component	Audio Alarm	RS Pro	RS Online	7,96	1	2	15,92	771-6954
Control Electronics	ON Semiconductor, 12V Zener Diode 5% 500 mW SMT 2-Pin SOD-123	IC-HG , flyback	ON Semiconductor	RS Online	1,278	6	50	63,9	MMSZ12T1G
Control Electronics	Nexperia, 5.1V Zener Diode 2% 830 mW SMT 2-Pin SOD-123F	5V	Nexperia	RS Online	2,936	1	5	14,68	BZT52H-B5V1,115
Control Electronics	Nexperia, 3.3V Zener Diode 2% 830 mW SMT 2-Pin SOD-123F	3.3V	Nexperia	RS Online	1,631	1	10	16,31	BZT52H-B3V3,115
Control Electronics	Murata 0805 (2012M) 22µF Multilayer Ceramic Capacitor MLCC 25V dc ±20% SMD	IC-HG, LED, Power source, 3.3V	Murata	RS Online	3,619	14	20	72,38	GRM21BR61E226ME44L
Control Electronics	KEMET, 1210 (3225M) 100µF Multilayer Ceramic Capacitor MLCC 16V dc ±20%	NIR LED	Kemet	RS Online	34,875	1	2	69,75	C1210C107M4PACTU
Control Electronics	Vishay 10µF MnO2 Tantalum Capacitor 25V dc, TR3 Series	DAC, 3.3V	Vishay	RS Online	5,484	4	5	27,42	TR3C106K025C0600
Control Electronics	Panasonic 1.33kΩ, 0603 (1608M) Metal Film SMD Resistor ±0.1% 0.1W	3.7V to 12V	Panasonic	RS Online	0,998	3	10	9,98	ERA3AEB1331V

Bill of Materials

Control Electronics	TDK, 1206 (3216M) 47µF Multilayer Ceramic Capacitor MLCC 25V dc ±20%	3.7V to 12V	TDK	RS Online	12,974	6	8	103,792	C3216X5R1E476M160AC
Control Electronics	Amphenol ICC, Straight, Through Hole, Socket Type B 2.0 USB Connector	Arduino	Arduino	RS Online	127,52	1	1	127,52	MUSBB55104
Control Electronics	Binder, 720 Female Dust Cap IP67 Rated	Connector Sensors	Binder	RS Online	35,73	1	1	35,73	08-2567-000-000
Control Electronics	Resistor to Warning LED, Vishay 68Ω, 0805 (2012M) Thick Film SMD Resistor ±1% 0.5W	Signal LEDs	Vishay	RS Online	0,291	2	0	0	CRCW080568R0FKEAHP
Control Electronics	LED Driver, iC-HG 3 A LASER SWITCH	LED Driver	IC House	AAAAA Nordic AB	120	1	5	600	
LED-Head	THERM PAD A1780 40X40X2MM	Heatsink LED PCB	t-Global	Digi-Key	294,82	3	3	884,46	TG-A1780-40-40-2.0
LED-Head	Heat Sink, Square, Micro Porous, 10.21 °C/W, LED, 30 mm, 5 mm, 30 mm	Cooling LED PCB	AMEC THERMASOL	Farnell	24,72	1	1	24,72	MPC303050WT
LED-Head	Heat Sink, Square, Pin, For CPU, 5.4 °C/W, Universal Processor, 32.7 mm, 10 mm, 32.7 mm	Cooling LED PCB	Fischer Elektronik	Farnell	90,93	3	3	272,79	ICK S 32 X 32 X 10
LED-Head	PTC Thermistor, 1 kohm, SMD, PTS Series, 1206	Temp PCB	Vishay	Farnell	18,75	3	4	75	PTS120601B1K00P100
LED-Head	Circular Connector, 1B Series, Cable Mount Plug, 7 Contacts, Solder Pin, Push-Pull, Brass Body	Connector LEDs	Lemo	Farnell	345,41	3	3	1036,23	FGG.1B.307.CLAD62Z
LED-Head	Multicore Cable, Control, Screened, 8 Core, 24 AWG, 0.22 mm², 100 ft, 30.5 m	Cable LEDs	Alpha Wire	Farnell	511,37	1	1	511,37	6300/8 SL005
LED-Head	Multipair Cable, Communication, Screened, 4 Pair, 24 AWG, 0.2 mm², 100 ft, 30.5 m	Cable Sensors	Alpha Wire	Farnell	589,1	1	1	589,1	5474C SL005
LED-Head	SMD LED 660nm	NIR LED	Epigap	Optonyx	120	4	10	1200	EOLS-660-496
LED-Head	SMD LED 810nm	NIR LED	Epigap	Optonyx	120	19	40	4800	EOLS-810-496
LED-Head	SMD LED 880nm	NIR LED	Epigap	Optonyx	120	16	40	4800	EOLS-880-496
LED-Head	Sunon, 5 V, dc Axial Fan, 30 x 30 x 6mm, 4.9cfm, 560mW, IP20	Cooling electronics	Sunon	RS Online	128,65	3	3	385,95	MF30060V1-1000U-A99
LED-Head	Non-Silicone Thermal Grease, 2.5W/m·K	Heatsink LED PCB	Electrolube	RS Online	96,31	1	1	96,31	ERHTCP02S
LED-Head	Ceramic Synthetic Fluid Thermal Grease, 10W/m·K	Heatsink LED PCB	Fischer Elektronik	RS Online	387,89	1	1	387,89	WLPK 10
LED-Head	TE Connectivity Type PT 1000 Thermocouple 4mm Length, 1.2mm	Temp Air	TE Connectivity	RS Online	49,55	3	4	198,2	NB-PTCO-153
LED-Head	RS PRO Type PT 1000 Thermocouple 1mm Diameter	Temp Air	RS Pro	RS Online	63,71	3	4	254,84	814-0171
LED-Head	Jumo Type PT 1000 Thermocouple 5mm Length, 2mm Diameter (Pack of 5)	Temp Skin	Jumo	RS Online	243,3	1	1	243,3	PCA_1.2005.10S_10_F 0,15
LED-Head	Identification resistor Panasonic 1kΩ, 0805 (2012M)	Identification Resistor	Panasonic	RS Online	7,392	1	5	36,96	ERA6ARW102V
LED-Head	Identification resistor 10kO, Panasonic 10kΩ, 0805 (2012M)	Identification Resistor	Panasonic	RS Online	7,566	1	5	37,83	ERA6ARW103V
LED-Head	Identification resistor 100kO, Panasonic 100kΩ, 0805 (2012M)	Identification Resistor	Panasonic	RS Online	7,524	1	5	37,62	ERA6ARW104V
LED-Head	Serial Resistor LED 0ohm, Isabellenhutte 0Ω, 2512 (6432M)	NIR LED	Isabellenhutte	RS Online	5,125	5	10	51,25	SMS-R000-U
LED-Head	Warning LED, 2.2 V Green LED 2 mm Through Hole	Warning LED for "NIR ON"	Kingbright	RS Online	2,24	3	5	11,2	L-13GD
LED-Head	Resistor to Warning LED, Vishay 68Ω, 0805 (2012M) Thick Film SMD Resistor ±1% 0.5W	Warning LED for "NIR ON"	Vishay	RS Online	0,291	3	25	7,275	CRCW080568R0FKEAHP
LED-Head	Binder Cable Mount Connector, 8 Contacts, Miniature Connector	Connector Sensors	Binder	RS Online	119,69	3	3	359,07	99-9125-00-08
LED-Head	Unmounted, Ø23.3 mm Premium Shortpass Filter, Cut-off: 1000nm	Filter 810nm/880nm	Thorlabs	Thorlabs	1190	2	2	2380	FESH1000-UM-SP
LED-Head	Ø1" High Quality Hot Mirror, AOI: 0°	Filter 660nm	Thorlabs	Thorlabs	1003,3	1	1	1003,3	M254H00
							Total Cost	26664,153	
	Available from previous projects / free samples						Free Parts	1086,42	
							ITK MSc Acc	6000	
							Final Cost APT	**19577,733**	

Appendix E Morphological Box

Morphological box - NIR-Device

Function \ poss. Solution	1	2	3			
Electronics Housing	Cube	Cuboid 1, 3, 4	Cylinder 2			
Power Supply	Integrated charging 3	External charging 1, 2, 4				
Battery Type (Rechargeable)	AA	AAA	Lithium-ion (18650) 2	LiPo (flat - 1 cell (3.7V)) 3	LiPo (flat - 2 cell (7.4V)) 1, 4	
User Interface	Analogue (Buttons, Switches and LEDs) 1, 2, 3, 4	Digital (Touch screen LCD)				
Parameter adjustment	Software only	Analogue and Software 1, 2, 3, 4	Analogue			
User Protection	Digital (limit output power) 1, 2, 3, 4	Monitor Skin Temperature 1, 2, 3, 4	Optical Warning LED (on pad) 1, 2, 3, 4	Timer 1, 2, 3, 4	Skin sensor to detect Body Contact 1, 2, 3, 4	
Control Board	Arduino 2, 3, 4	Raspberry Pi 1	Only necessary ICs on PCB			
Additional Memory	No 1	MicroSD 2, 3, 4	SD			
LED Driver	iC-HG 3A Laser Switch 1, 2, 3, 4					
Programing Interface	Micro USB (external)	Micro USB (internal) 1, 2, 4	Micro USB (external) 3			
Connection Electronics to Cable	Rectangular connector	Round connector 1, 2, 3, 4	Fixed connection			
Shielding Connectors	Unshielded	Shielded 1, 2, 3, 4				
Cable / Wire	Twisted-Pairs 1, 2, 3, 4	Multi-Conductor				
Shielding Cable	Unshielded	Shielded-Pairs 1, 2, 3, 4	Shielded Cable			
Interface Cable - Sensor head	Soldering 1, 2, 3, 4	Connector				
Detection LED Head	Resistor 1, 3, 4	Unique Wireing of Pins in Plug	Dip Switch to set ID 2			
Layout LED-Array	Round 1, 3	Square	Rectangular	Octagonal 2, 4		
LED Type	SMD 1, 2, 3, 4	Through-Hole				
Shape LED Head	Square 1, 3, 4	Rectangular	Round 2			
Temperature Control LED Head (Sensors)	None	Skin 1, 2, 3, 4	Pad 1, 2, 3, 4	Chamber 1, 2, 3, 4		
Temperature sensors	NTC-Thermistor	PTC-Thermistor	Thermocouple	Resistive Temperature Detector (RTD) PT1000 1, 2, 3, 4	Contact less (photodiode)	Semiconductor sensors (Digital)
Filter	None	Optical Shortpass Filter 1, 2, 3, 4	Optical Bandpass Filter	Hot Mirror 1, 2, 3, 4		
Cooling of LED Array	Convection (Passive)	Heatsink (Passive)	Thermo Electric (Heatsink - Passive)	Thermo Electric (Heatsink + Fan - Active)	Heatsink + Fan (Active) 1, 2, 3, 4	
Manufacturing Sensor Head	Aluminium (Milled) 1, 3	ABS (3D-Print) 4	POM (Milled) 2, 3			
Manufacturing Electronics Housing	Aluminium (Milled)	ABS (3D-Print)	POM (Milled) 1, 2, 3, 4			

Appendix F MATLAB Files LED Simulation

```
clc;
clear all;
close all;

%% Power distribution LED / View Angle
x = [0:0.01:pi/6, pi/6+0.01:0.01:pi] ;
rho = sin(x);  % approximation function of power distribution
polarplot(x,rho)
title('Radiation Pattern')
% Plot Radiation Pattern
figure;
plot(x,rho)

%% Radiant intensity of the LEDs of interest [mW/Sr]
LED660 = 110;
LED810 = 25;
LED880 = 30;
maxPower = LED660; % radiant intensity of the LED [mW/Sr]

%% Define Parameters
global L W D_LED Nx Ny ROI ROIled maxPower LEDpenalty q
L     = 30; % Work space Lenght [mm]
W     = 30; % Work space Width [mm]
D_LED = 4 ; % LED Diameter with its required space with next LED [mm]
h     = 20; % max distance to skin [mm]
Nx    = floor(L/D_LED); %max no of LEDs on x-axis
Ny    = floor(W/D_LED); %max no of LEDs on y-axis
R     = 15; % the radius of attraction region (target area for uniform illumination -↙
in center of workspace)
LEDno = [5]% [4 8 12 16 20 21]; %Desired number of LEDs (or use vector for all↙
possible numbers - should be a multipme of 4!!
LEDpenalty   =   10; %adjust if he refuses to take the desired no of LEDs

% Generate and populate work space for Round Workspace
LED_Plate = zeros(Nx, Ny);
N         = Nx*Ny;
LED_X     = [D_LED/2 : D_LED : L-1]-L/2+1;
LED_X     = repmat(LED_X,floor(W/D_LED),1);
LED_Y     = [D_LED/2 : D_LED : W-1]-W/2+1;
LED_Y     = repmat(LED_Y,floor(L/D_LED),1)';

% Define LED positions that can not be used. (top-bottom / left-right)
Off_LEDs=zeros(size(LED_Plate));
LED_prohibited=[1:9 13 14 15 21 22 28 29 35 36 37 41 42:49]; % Adjust this array when↙
changing Workspace or Lensesize
Off_LEDs(LED_prohibited)=1;

% Generate LED placement matrix
WorkSpace=zeros(L+1,W+1);

% Generate matrix for region of attraction
ROI       = zeros(L+1,W+1);
ROIled    = zeros(Nx,Ny);
for i=1:L+1
    for j=1:W+1
```

```
        if norm([i-L/2 j-W/2],2)<R
            ROI(i,j)=1;
        end
    end
end

for i=1:Nx
    for j=1:Ny
        if norm([LED_X(i,j) LED_Y(i,j)],2)<R
            ROIled(i,j)=1/(norm([LED_X(i,j) LED_Y(i,j)],2)^2/100+0.1);
        end
    end
end

% Plot Region of Interest
surface(ROI)
title('Region of Interest');
xlabel('mm')
ylabel('mm')

MaxRoi=ROIled;
ROIled=ROIled+Off_LEDs*100;
Initial=zeros(200,numel(ROIled));

% Generate initial values for optimiser
qj=1; %counter variable

LED_prohibited=find(Off_LEDs~=1);
for q= LEDno
    Initial=zeros(200,numel(ROIled));

    for i=1:200
     if i<20              % No of initial, symetric generations
         Initial(i,:)=ROIled(:)<(max(MaxRoi(:)))*i/200;
     else
           Initial(LED_prohibited(randi(numel(LED_prohibited),1,4)),:)=1;
     end
    end
    Initial=[Initial,ones(200,1)*h];

% Constraints for optimizer Ax<=b
A=zeros(N+1);
A(end,1:N)=-1;
b=zeros(N+1,1);
b(end)=-q;
lb            =  [zeros(N,1)-0;10]; %lower bound for hight
ub            =  [zeros(N,1)+1;h]; %upper bound for hight

% Create features for Genetic Algorithm
options       =  optimoptions('ga','PlotFcn', @gaplotbestf,↙
'Display','iter','InitialPopulationMatrix',Initial);

% Perform optimisation with a Genetic Algorithm

if q<Nx*Ny
```

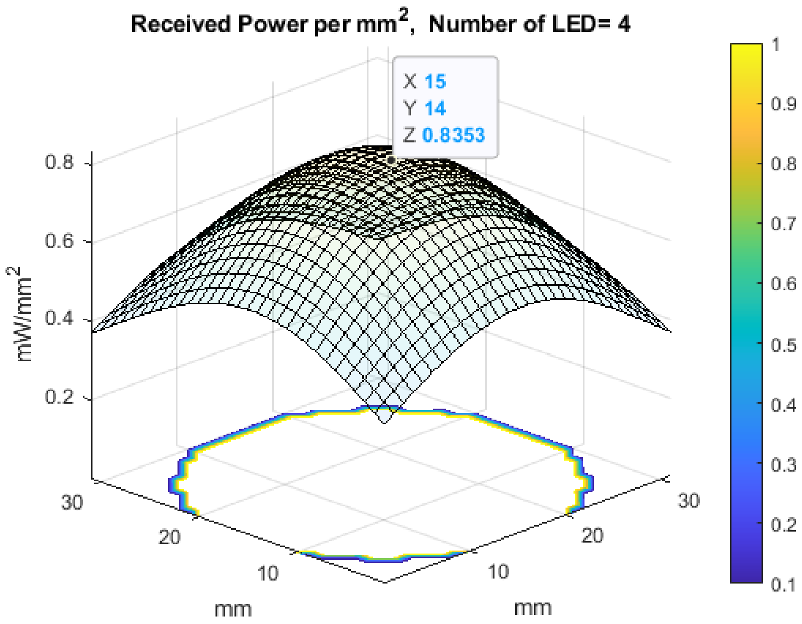
```
    x         =  ga(@LED_Cost_circular,N+1,A,b,[],[],lb,ub,[],1:N,options);
else
    x(:)=1;
    x(N+1)=h;
end

% ga requires vector input (turn matrix into vector)
LED_Plate(:) =  reshape(x(1:N),Nx,Ny);
h            =  x(N+1);

% Calculate the power distribution for each LED and sum all the
% distributions together - Resolution [mm^2]
for i=1:L+1
    for j=1:W+1
        for k=1:Nx
            for l=1:Ny
                a=sqrt((i-15-LED_X(k,l))^2+(j-15-LED_Y(k,l))^2);
                WorkSpace(i,j)= WorkSpace(i,j)+ sin(pi/2-atan2(a,h))* maxPower/↙
(a^2+h^2)*LED_Plate(k,l);
            end
        end
    end
end

%
figure
meshc(WorkSpace./max(WorkSpace(:)))
Num=sum(sum(LED_Plate));
title(['Normalized Received Power per mm^2,  ', 'Number of LED= ', num2str(Num)])
xlabel('mm')
ylabel('mm')
colorbar
% hold all
% contour(0.5+ROI/10000,0.7)

figure
contourf((WorkSpace./max(WorkSpace(:))).^1)
Num=sum(sum(LED_Plate));
title(['Normalized Received Power per mm^2,  ', 'Number of LED= ', num2str(Num)])
xlabel('mm')
ylabel('mm')
colorbar
hold all
[M,c] = contour(0.005*ROI);
c.LineWidth = 3;

figure
surface(WorkSpace,'FaceAlpha',0.1)
title(['Received Power per mm^2,  ', 'Number of LED= ', num2str(Num)])
xlabel('mm')
ylabel('mm')
zlabel('mW/mm^2')
colorbar
view(3)
hold on
```

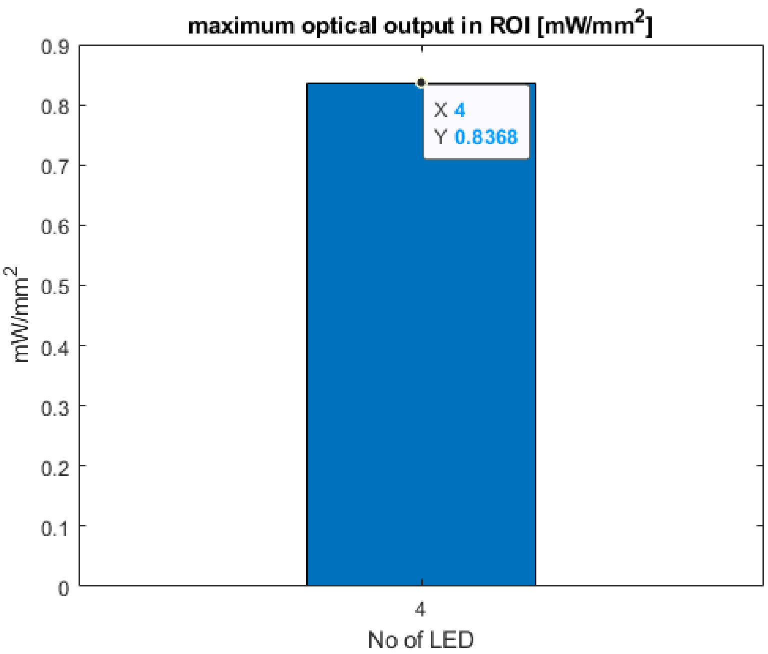
```
contour(ROI)
grid on

figure
heatmap(LED_Plate)
title(['LED distribution,  ', 'Number of LED= ', num2str(Num)])

figure
heatmap(1-Off_LEDs)
title('Possible Placements')
PowerDistur(qj)=max(WorkSpace(:))/min(WorkSpace(:));
maximumpower(qj)=max(WorkSpace(:));
qj=1+qj;
end

figure
bar(LEDno,PowerDistur)
title('Ratio between Max and Min optical output in ROI')
xlabel('No of LED')

figure
bar(LEDno,maximumpower)
title('maximum optical output in ROI [mW/mm^2]')
xlabel('No of LED')
ylabel('mW/mm^2')
```

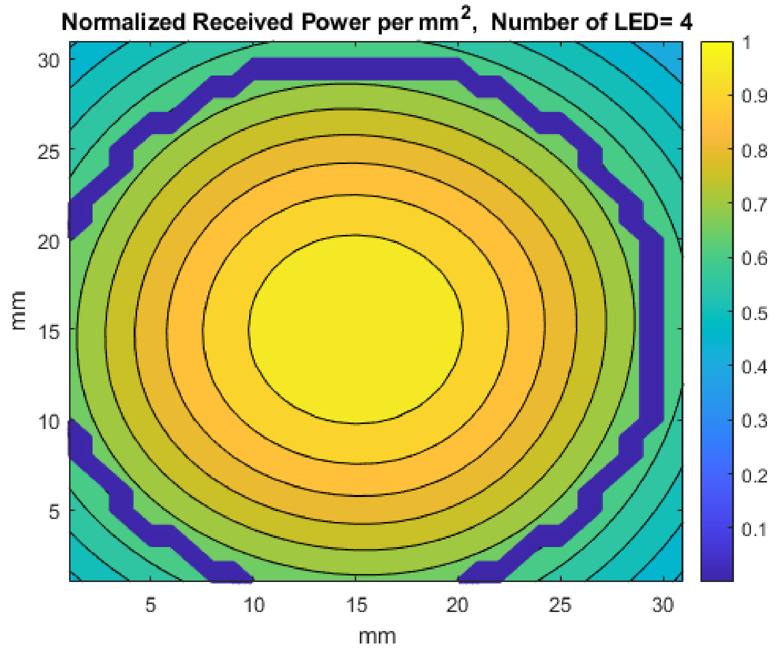
```
%% Cost function for the stochastic optimisation
function [E] = LED_Cost_circular(x)

global L W D_LED Nx Ny ROI ROIled maxPower LEDpenalty q

% Initialise the variables
LED_Plate     =   zeros(Nx, Ny);
N             =   Nx*Ny;
LED_X         =   [D_LED/2 : D_LED : L-1]-L/2+1;
LED_X         =   repmat(LED_X,floor(W/D_LED),1);
LED_Y         =   [D_LED/2 : D_LED : W-1]-W/2+1;
LED_Y         =   repmat(LED_Y,floor(L/D_LED),1)';
WorkSpace     =   zeros(L+1,W+1);
LED_Plate     =   zeros(Nx, Ny);
LED_Plate(:) =    reshape(x(1:N),Nx,Ny);
h             =   x(N+1);

% Calculate the power distribution for each LED and sum all the
% distributions together - Resolution [mm^2]
for i=1:L+1
    for j=1:W+1
        for k=1:Nx
            for l=1:Ny
                 a=sqrt((i-15-LED_X(k,l))^2+(j-15-LED_Y(k,l))^2);
                 WorkSpace(i,j)= WorkSpace(i,j)+ maxPower/(4*pi*(1*h)^2)*sin(pi/2-↙
atan2(a,h))*LED_Plate(k,l);
            end
        end
    end
end

S1=WorkSpace; % put focus on region of attraction
S2=LED_Plate.*1; % generate penalty matrix for LED placement
S2=LED_Plate.*ROIled; % generate penalty matrix for symetric LED placement
avr=mean(S1(find(ROI>0))); % Get referance value for power distribution in region of↙
interest
Dist=(S1-avr).*ROI;

E=(30.*Dist(:))'*(20.*Dist(:))+LEDpenalty*sum(S2(:)) + 300*abs(sum(x(1:end-1))-q); %↙
Cost = Quadratic regression inside workspace + no of available LED

end
```

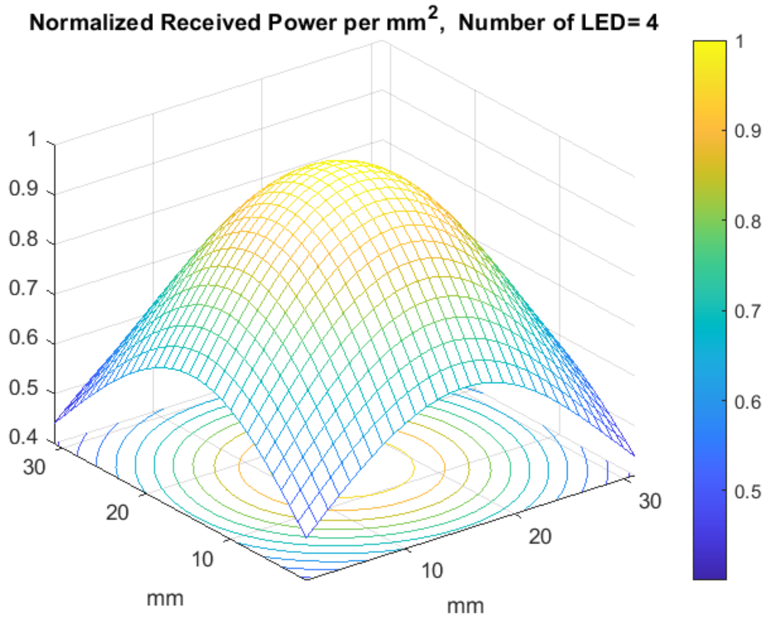
Appendix G Results LED Simulation

660nm 4 LED

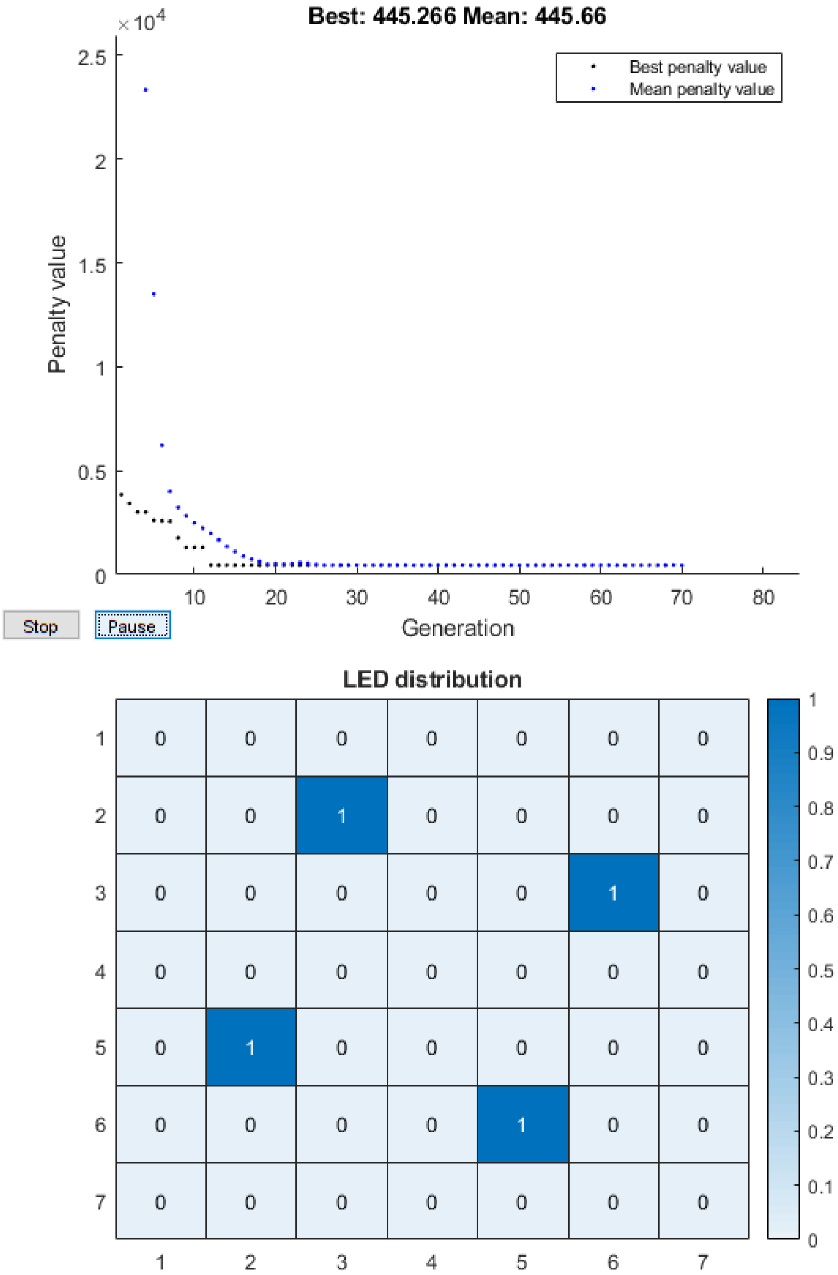

Received Power per mm2, Number of LED= 4
X 15
Y 14
Z 0.8353
mW/mm2
0.8
0.6
0.4
0.2
30
20
10
mm
10
20
30
mm
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1

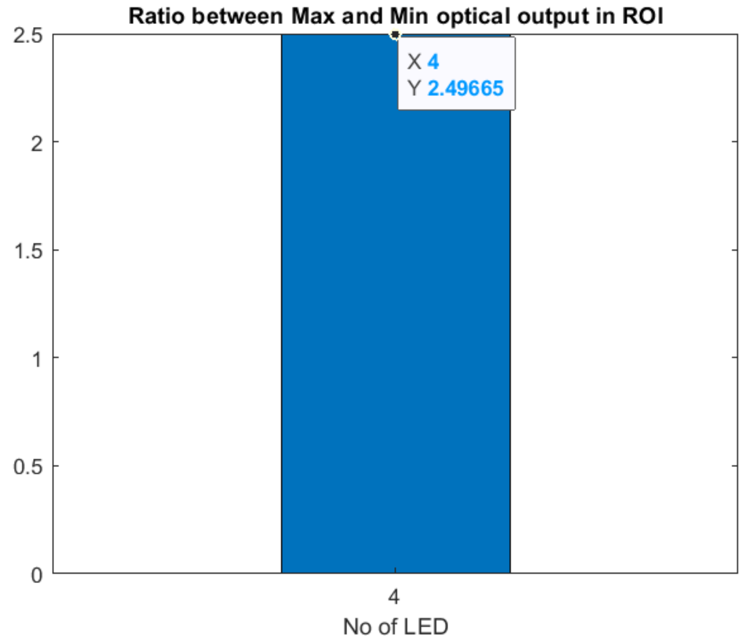

maximum optical output in ROI [mW/mm2]
X 4
Y 0.8368
mW/mm2
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
4
No of LED


Normalized Received Power per mm², Number of LED= 4
mm
mm
30
25
20
15
10
5
5
10
15
20
25
30
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1

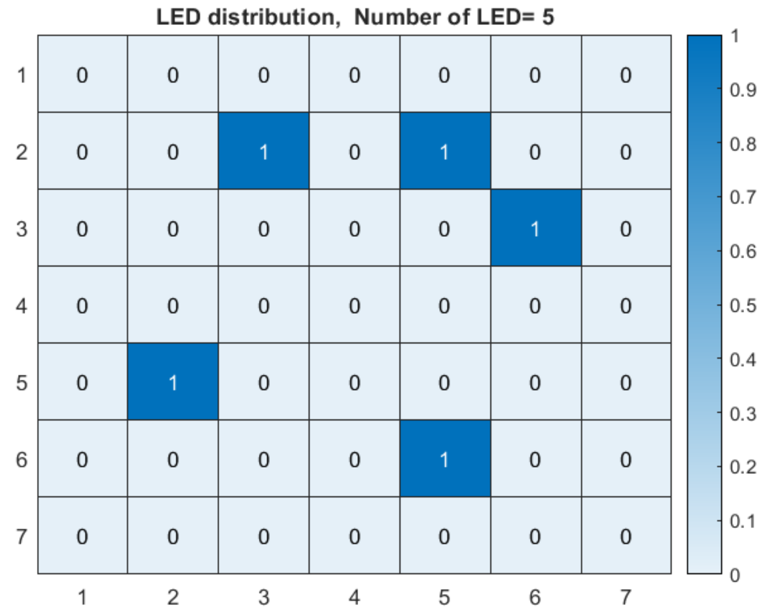

Normalized Received Power per mm², Number of LED= 4
1
0.9
0.8
0.7
0.6
0.5
0.4
30
20
10
mm
10
20
30
mm
1
0.9
0.8
0.7
0.6
0.5

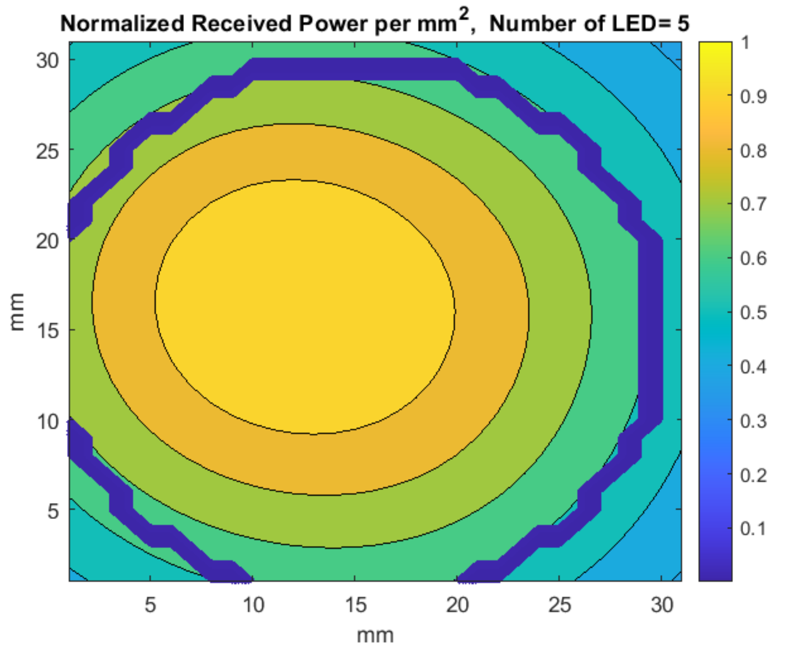
Results LED Simulation



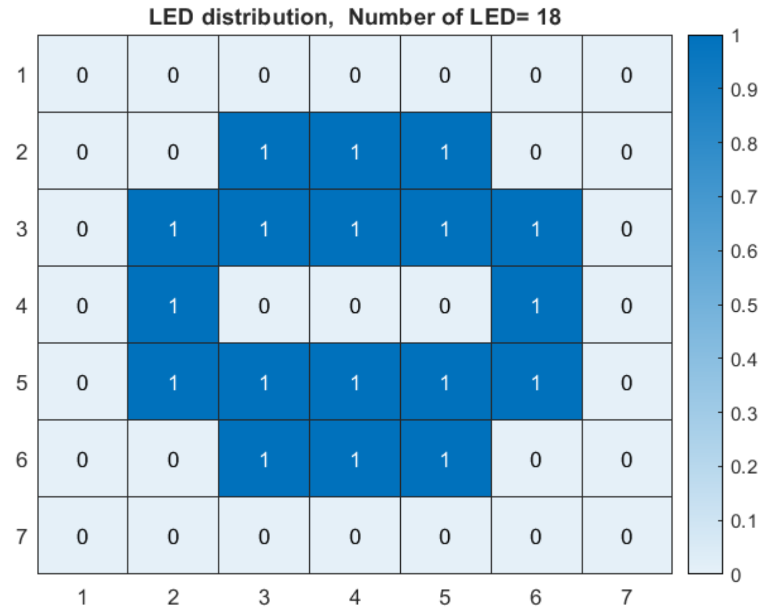

Ratio between Max and Min optical output in ROI
X 4
Y 2.49665
2.5
2
1.5
1
0.5
0
4
No of LED

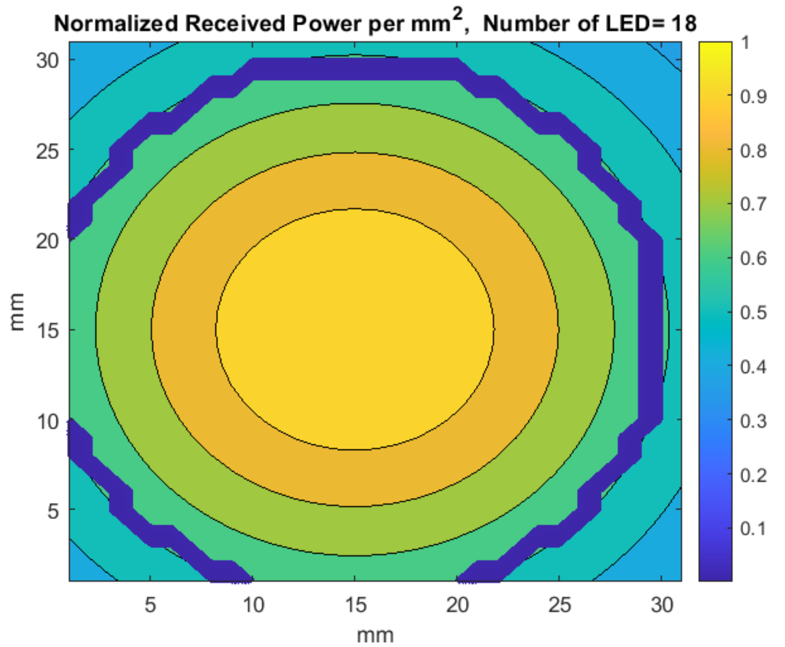
660nm 5 LED


LED distribution, Number of LED= 5

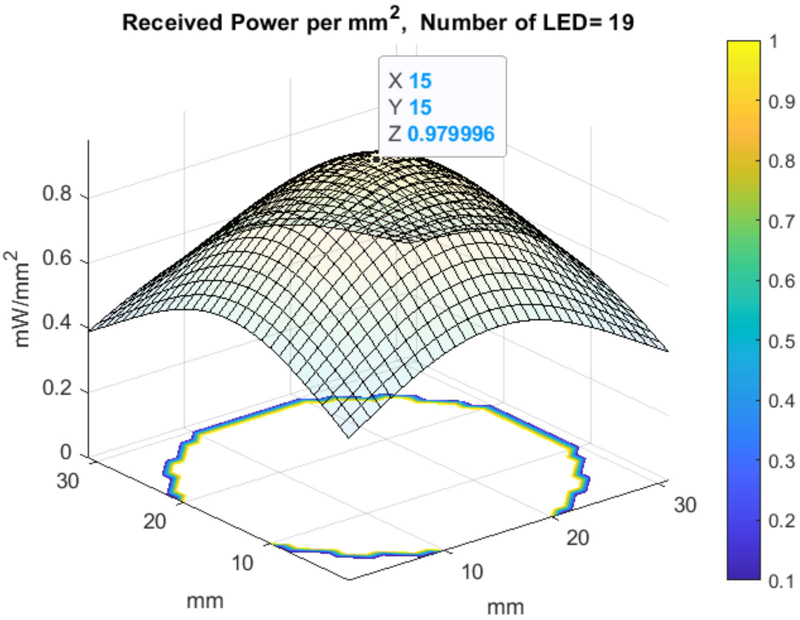

Normalized Received Power per mm^2, Number of LED= 5
mm
mm

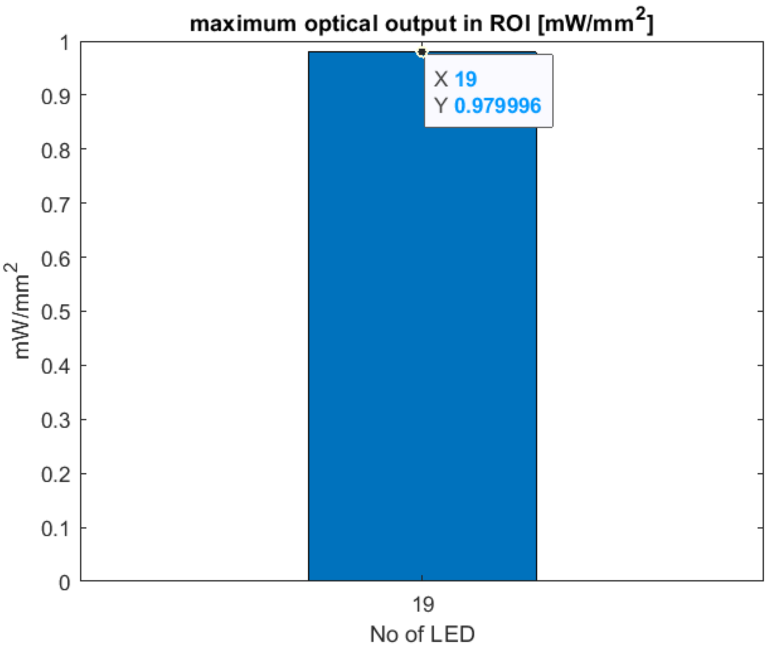
810nm 18 LED

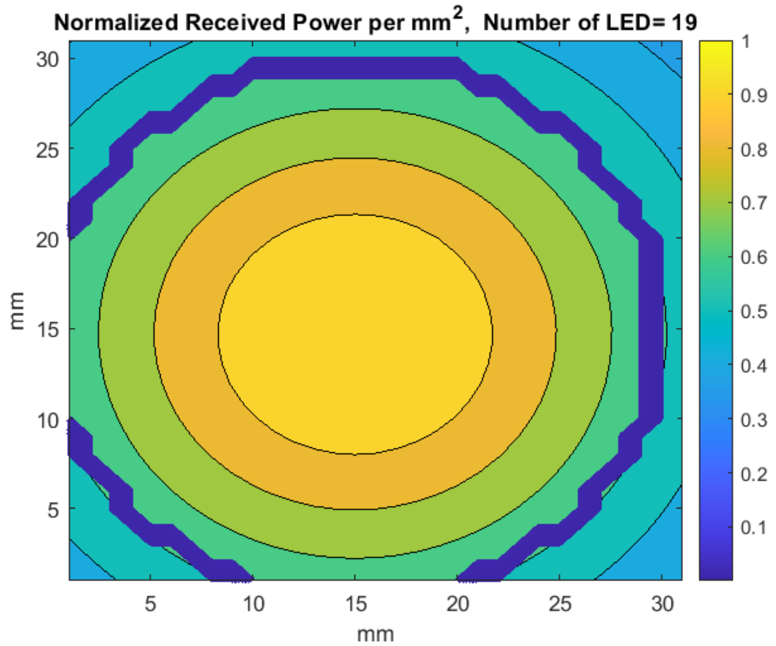

LED distribution, Number of LED= 18
1 2 3 4 5 6 7
0 0 0 0 0 0 0
0 0 1 1 1 0 0
0 1 1 1 1 1 0
0 1 0 0 0 1 0
0 1 1 1 1 1 0
0 0 1 1 1 0 0
0 0 0 0 0 0 0
0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1

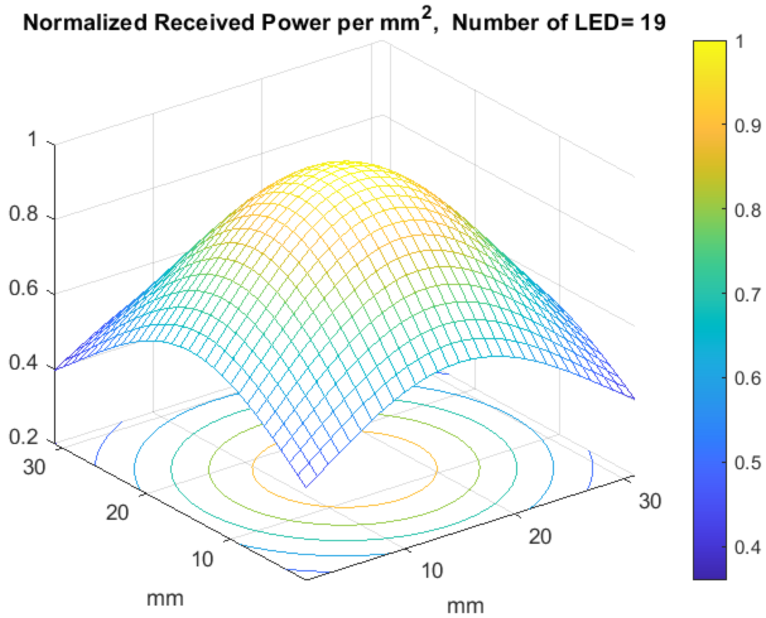

Normalized Received Power per mm2, Number of LED= 18
mm
5 10 15 20 25 30
0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1

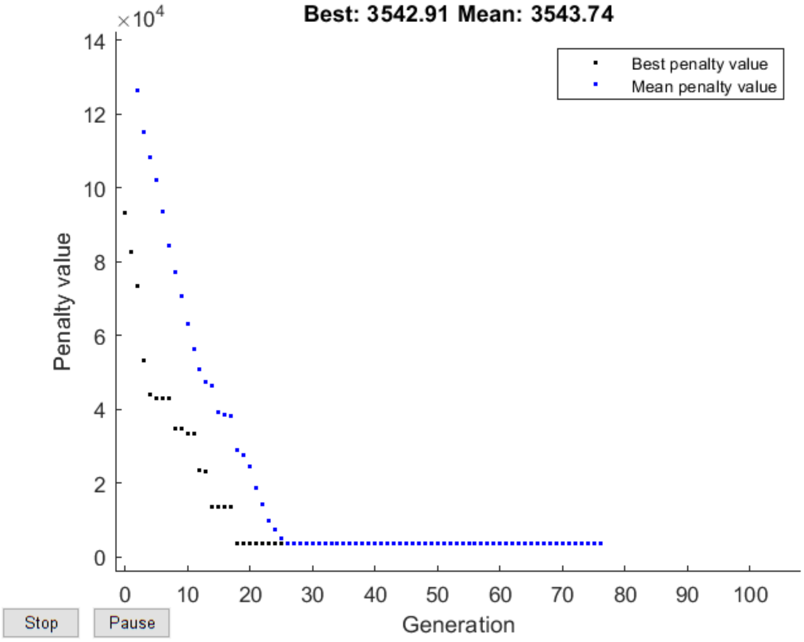
810nm 19 LED

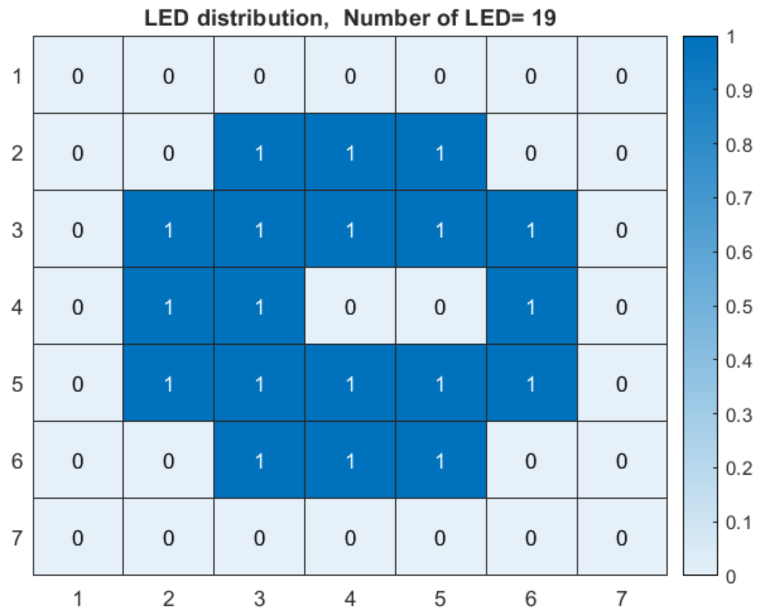

Received Power per mm^2, Number of LED= 19
X 15
Y 15
Z 0.979996
mW/mm^2
0.8
0.6
0.4
0.2
0
30
20
10
mm
30
20
10
mm
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1

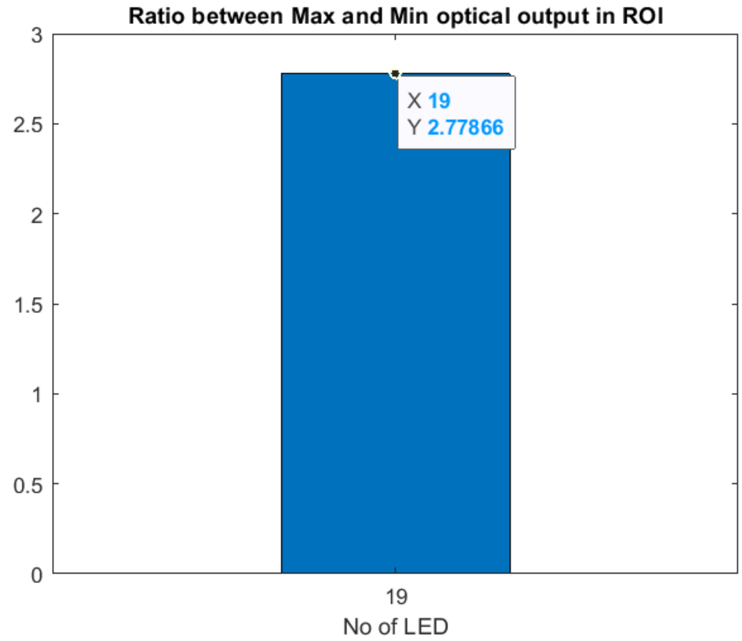

maximum optical output in ROI [mW/mm^2]
X 19
Y 0.979996
mW/mm^2
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
19
No of LED


Normalized Received Power per mm², Number of LED= 19
mm
mm
5
10
15
20
25
30
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1

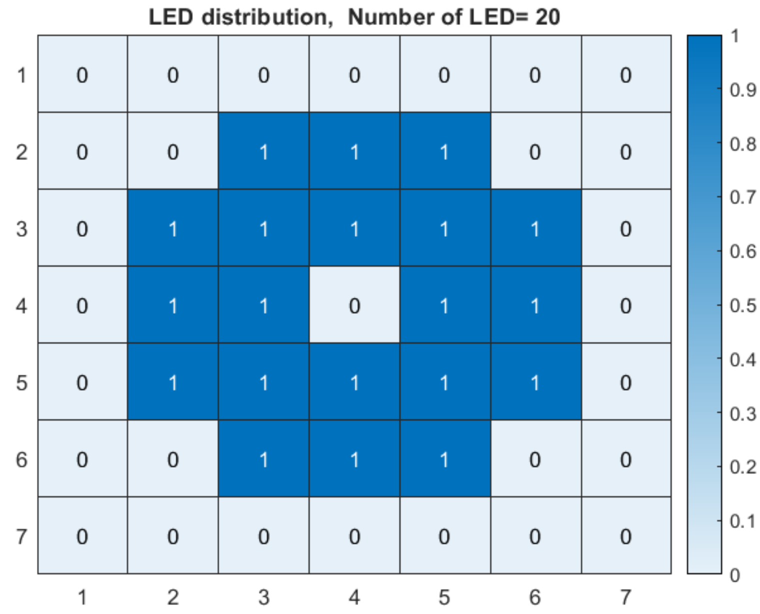

Normalized Received Power per mm², Number of LED= 19
1
0.8
0.6
0.4
0.2
30
20
10
mm
10
20
30
mm
1
0.9
0.8
0.7
0.6
0.5
0.4

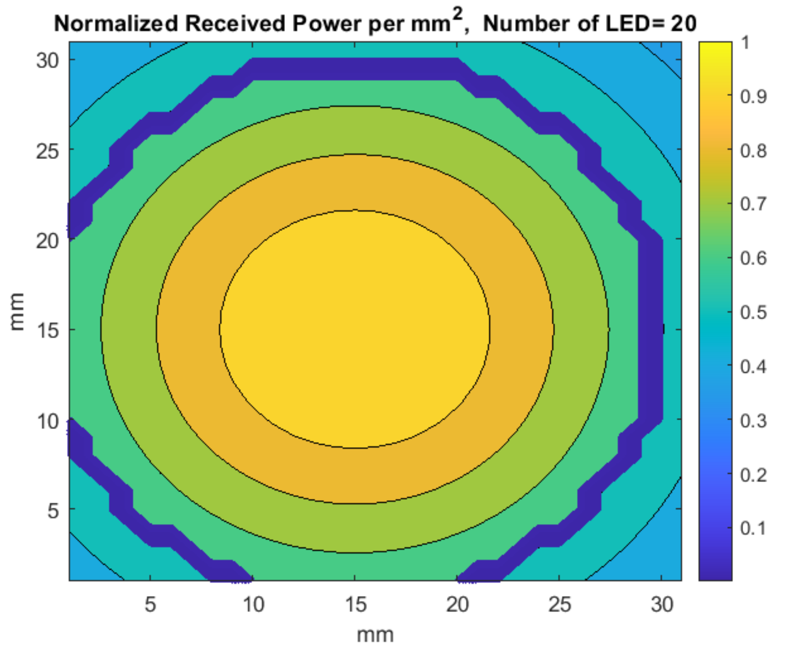

Best: 3542.91 Mean: 3543.74
×10^4
Best penalty value
Mean penalty value
Penalty value
Generation
Stop
Pause


LED distribution, Number of LED= 19

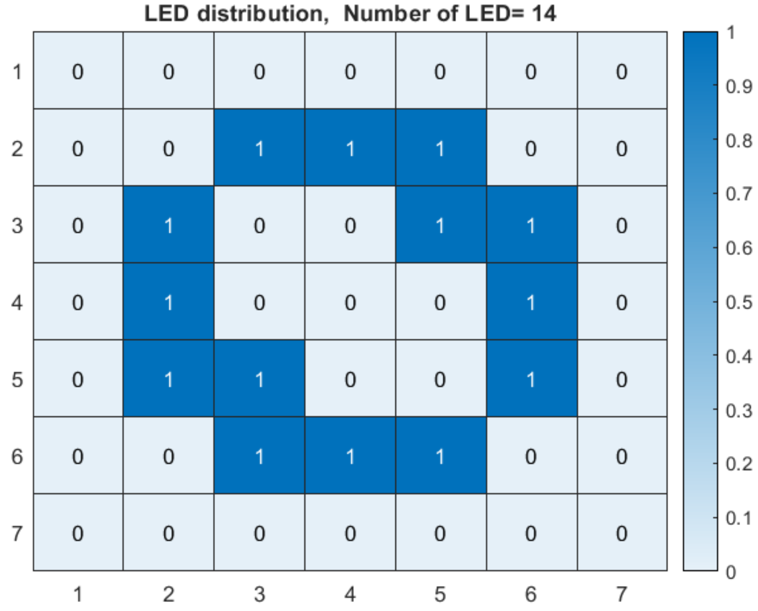

Ratio between Max and Min optical output in ROI
3
2.5
2
1.5
1
0.5
0
X 19
Y 2.77866
19
No of LED

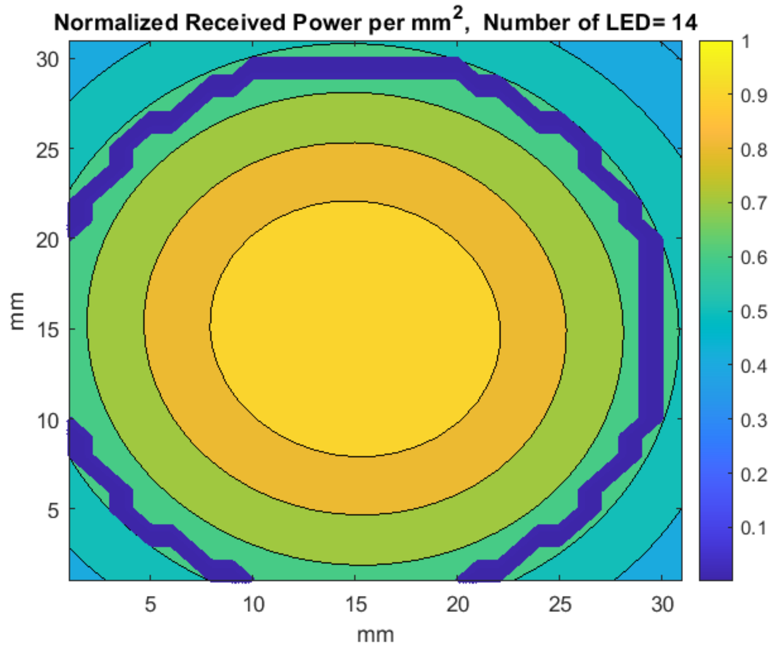
810nm 20 LED


LED distribution, Number of LED= 20
1
2
3
4
5
6
7
0
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1

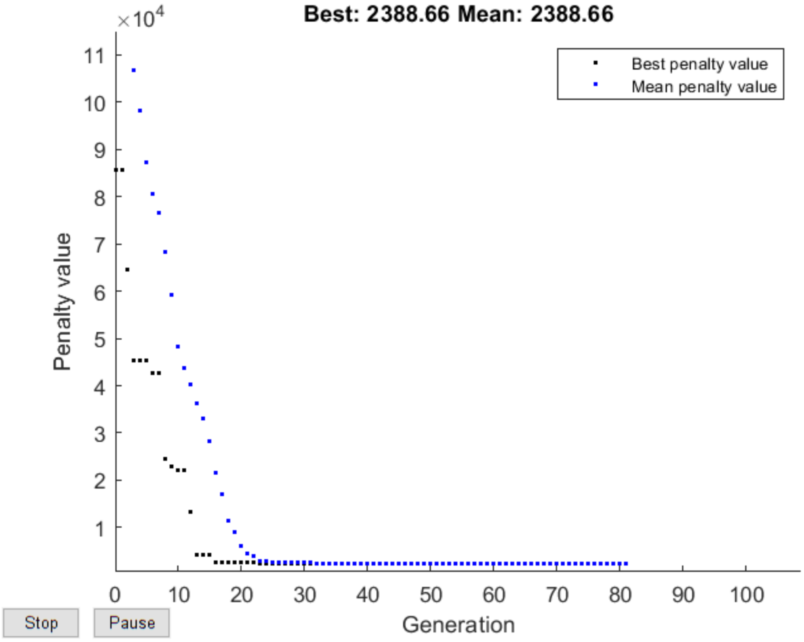

Normalized Received Power per mm², Number of LED= 20
mm
mm
5
10
15
20
25
30
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1

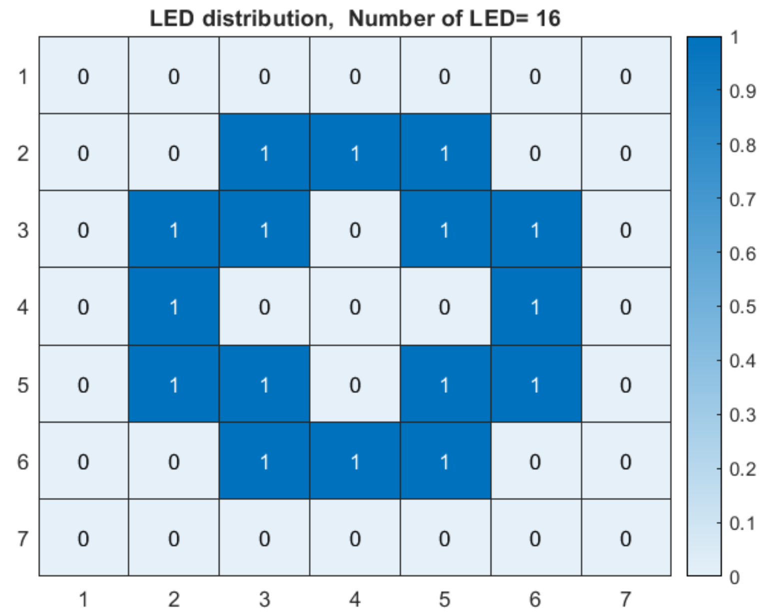
880nm 14 LED

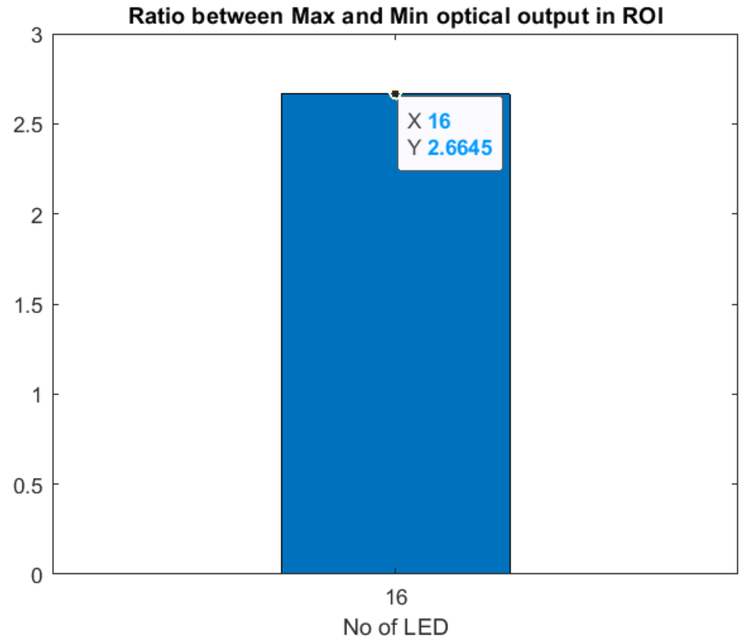

LED distribution, Number of LED= 14
0 0 0 0 0 0 0
0 0 1 1 1 0 0
0 1 0 0 1 1 0
0 1 0 0 0 1 0
0 1 1 0 0 1 0
0 0 1 1 1 0 0
0 0 0 0 0 0 0
1 2 3 4 5 6 7
0 0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1


Normalized Received Power per mm2, Number of LED= 14
mm
5 10 15 20 25 30
mm
0.1 0.2 0.3 0.4 0.5 0.6 0.7 0.8 0.9 1

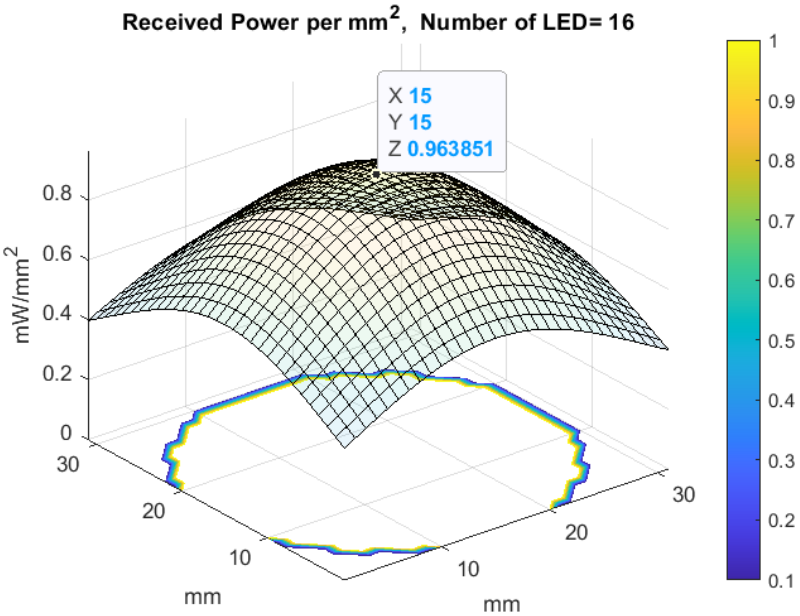
880nm 16 LED


Best: 2388.66 Mean: 2388.66
Best penalty value
Mean penalty value
Penalty value
×10^4
Generation
Stop
Pause

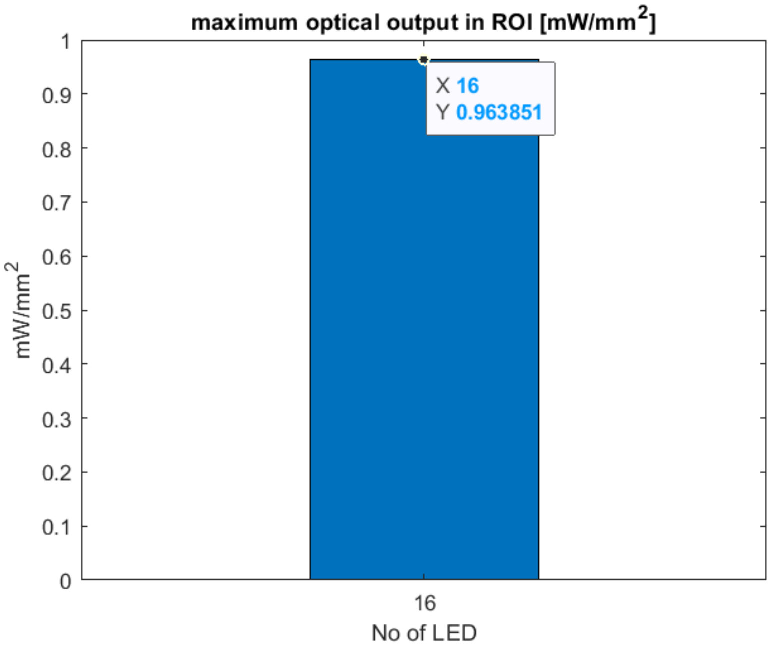

LED distribution, Number of LED= 16
0 0 0 0 0 0 0
0 0 1 1 1 0 0
0 1 1 0 1 1 0
0 1 0 0 0 1 0
0 1 1 0 1 1 0
0 0 1 1 1 0 0
0 0 0 0 0 0 0

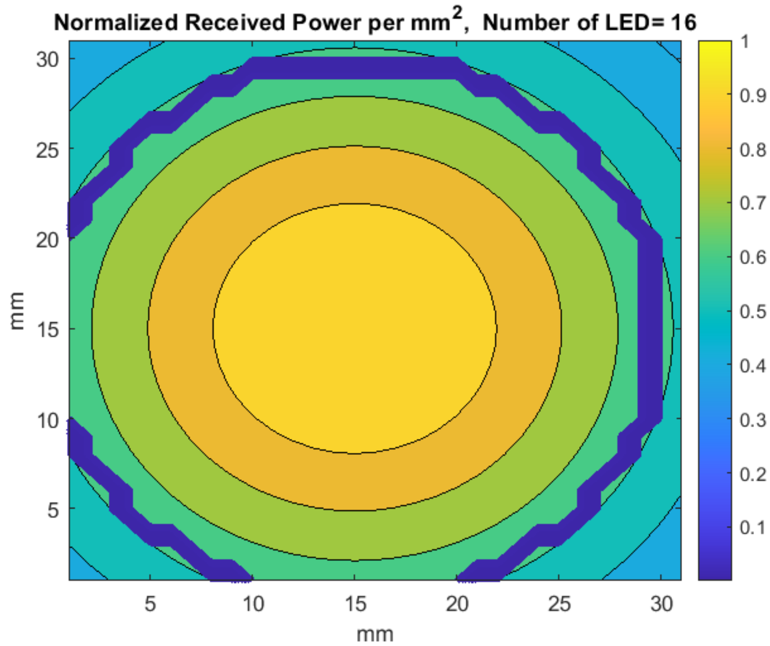


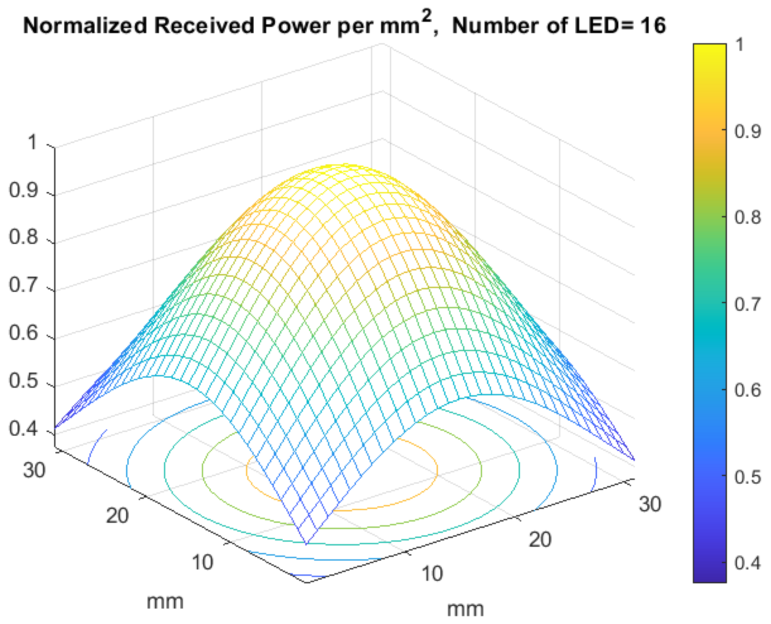
Ratio between Max and Min optical output in ROI
X 16
Y 2.6645
3
2.5
2
1.5
1
0.5
0
16
No of LED



Received Power per mm², Number of LED= 16
X 15
Y 15
Z 0.963851
mW/mm²
0.8
0.6
0.4
0.2
0
30
20
10
mm
10
20
30
mm
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1

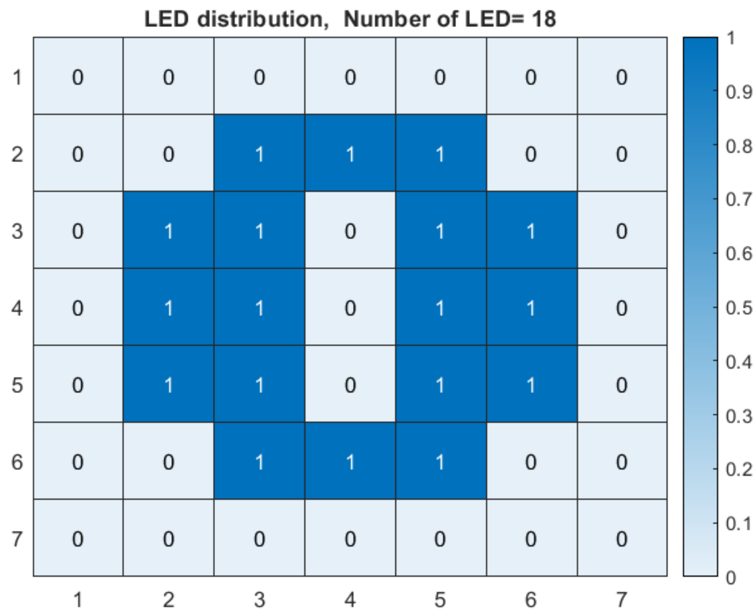

maximum optical output in ROI [mW/mm²]
mW/mm²
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
X 16
Y 0.963851
16
No of LED

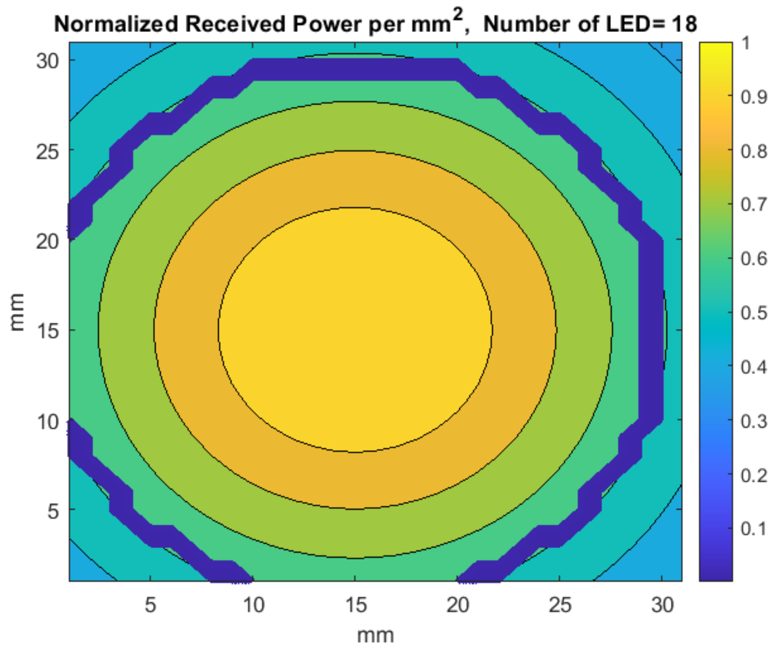

Normalized Received Power per mm², Number of LED= 16
mm
30
25
20
15
10
5
5
10
15
20
25
30
mm
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1



Normalized Received Power per mm^2, Number of LED= 16
1
0.9
0.8
0.7
0.6
0.5
0.4
30
20
10
mm
10
20
30
mm

880nm 18 LED


LED distribution, Number of LED= 18
1
2
3
4
5
6
7
0
1
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9


Normalized Received Power per mm^2, Number of LED= 18
mm
5
10
15
20
25
30
0.1
0.2
0.3
0.4
0.5
0.6
0.7
0.8
0.9
1

Appendix H GANTT Diagram

Procedure- and Time schedule - GANTT Diagram

30ECTS*26.6h = 800h Total Hours = 800h

Project title	"Apparat for forbedret insulinabsorpsjon i diabetes type 1"
Date	26.07.2021

No.	Task	Worktime [h] Is	Target	Due Date	Staff resource schedule Responsible	Support	Status
	Total	**768,5**	**808,5**				
1.	**Planning phase**	**50,0**	**49,0**				
1.1	Kick off meeting	2,0	2,0	02.02.2021	Stavdahl	Bösch, Fougner	
1.2	Clarify the tasks	8,0	8,0	12.02.2021	Bösch	-	
1.3	Develop and update time schedule (GANT)	12,0	10,0	28.06.2021	Bösch	-	
1.4	Thesisstructure ready	12,0	6,0	12.02.2021	Bösch	-	
1.5	Literature Search on Bioheat	6,0	15,0	19.02.2021	Bösch	-	
1.6	Requirements list (improve and update)	10,0	8,0	25.06.2021	Bösch	-	
2.	**Concept phase**	**148,0**	**66,0**				
2.1	Morphological box	30,0	20,0	22.02.2021	Bösch	-	
2.2	Creation of design proposals	10,0	8,0	23.02.2021	Bösch	-	
2.3	Selection of key components	100,0	30,0	05.03.2021	Bösch	-	
2.4	Evaluation of design proposals	8,0	8,0	04.03.2021	Bösch	-	
3.	**Design phase**	**252,0**	**230,0**				
3.1	Design LED Panel (incl. calc. and sim.)	120,0	40,0	12.03.2021	Bösch	-	
3.2	Connection plan	25,0	20,0	12.03.2021	Bösch	-	
3.3	Scematics control electronics	80,0	30,0	19.03.2021	Bösch	-	
3.4	Design PCB	15,0	60,0	13.04.2021	Bösch	-	
3.5	Mechanical design (CAD)	2,0	40,0	13.04.2021	Bösch	-	
3.6	UML	0,0	20,0	12.04.2021	Bösch	-	
3.7	IO overview	10,0	8,0	14.04.2021	Bösch	-	
3.8	Structure data aquisition	0,0	12,0	19.04.2021	Bösch	-	
4.	**Development phase**	**80,0**	**181,0**				
4.1	Various orders	80,0	40,0	21.05.2021	Bösch	-	
4.2	Manufacturing PCB	0,0	1,0	07.05.2021	Bösch	-	
4.3	Manufacturing mechanical components	0,0	2,0	07.05.2021	Bösch	-	
4.4	Programing User interface and software	0,0	70,0	07.05.2021	Bösch	-	
4.5	Assembly PCB	0,0	20,0	10.05.2021	Bösch	-	
4.6	Assembly Mechanics	0,0	16,0	12.05.2021	Bösch	-	
4.7	Assembling of the device	0,0	16,0	26.05.2021	Bösch	-	
4.8	Start-up procedure and debugging	0,0	16,0	30.05.2021	Bösch	-	
5.	**Test phase**	**208,5**	**40,0**				
5.1	Function control	0,0	12,0	02.06.2021	Bösch	-	
5.2	Deriving of parameters	0,0	12,0	04.06.2021	Bösch	-	
5.3	In Vivo testing (if time permits)	0,0	16,0	11.06.2021	Bösch	-	
6.	**Documentation**	**208,5**	**210,5**				
6.1	Writing of MSc Thesis	180,0	150,0	27.06.2021	Bösch	-	
6.2	Write user manual	0,0	36,0	18.06.2021	Bösch	-	
6.3	Final draft finished	0,0	0,0	21.06.2021	Bösch	-	
6.4	Thesis printed	0,5	0,5	28.06.2021	Bösch	-	
6.5	Documentation finished	8,0	8,0	27.06.2021	Bösch	-	
6.6	Thesis finished	0,0	0,0	27.06.2021	Bösch	-	
6.7	Handing in Thesis	2,0	2,0	28.06.2021	Bösch	-	
6.8	Preparation Presentation	16,0	12,0	26.05.2021	Bösch	-	
6.9	Presentation APT Meeting	2,0	2,0	27.05.2021	Bösch	-	
7.	**Meetings**	**30,0**	**30,0**				
7.1	Meeting	30,0	30,0	10.12.2020	Bösch	Stavdahl, Fougner	
8.	**Milestones**	**2,0**	**2,0**				
8.1	Design Review with APT	2,0	2,0	04.03.2021	Bösch	Stavdahl, Fougner, Christiansen, APT	
8.2	Design phase finished	0,0	0,0	19.04.2021	Bösch	-	
8.3	PCB ordered	0,0	0,0	26.04.2021	Bösch	-	
8.4	Electronical components ordered	0,0	0,0	26.04.2021	Bösch	-	
8.5	Device assembled	0,0	0,0	26.05.2021	Bösch	-	
8.6	Development phase finished	0,0	0,0	30.05.2021	Bösch	-	
8.7	Test phase finished	0,0	0,0	11.06.2021	Bösch	-	
8.8	Final Draft of Thesis to Supervisors	0,0	0,0	21.06.2021	Bösch	-	
8.9	Hand-in Thesis	0,0	0,0	28.06.2021	Bösch	-	

Calendar week 2021

5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29
1-7.02	8-14.02	15-21.02	22-28.02	1-7.03	8-14.03	15-21.03	22-28.03	29-4.04	5-11.04	12-18.04	19-25.04	26-2.05	3-9.05	10-16.05	17-23.05	24-30.05	31-5.06	7-13.06	14-20.06	21-27.06	28-04.7	5-11.07	12-18.07	19-25.07

Scheduled Work
Executed Work
Easter Holiday
Preparation ModSim Exam

Status legend
1 = complete
2 = in progress
3 = on hold
4 = delayed

Appendix I Master Agreement

Masteravtale/hovedoppgaveavtale

Sist oppdatert 11. november 2020

Fakultet	**Fakultet for informasjonsteknologi og elektroteknikk**
Institutt	**Institutt for teknisk kybernetikk**
Studieprogram	**MITK**
Emnekode	**TTK4900**

Studenten

Etternavn, fornavn	**Bösch, Patrick Christian**
Fødselsdato	**03.03.1990**
E-postadresse ved NTNU	**patrick.c.bosch@ntnu.no**

Tilknyttede ressurser

Veileder	**Øyvind Stavdahl**
Eventuelle medveiledere	**Anders Lyngvi Fougner**
Eventuelle medstudenter	

Oppgaven

Oppstartsdato	**01.02.2021**
Leveringsfrist	**28.06.2021**
Oppgavens arbeidstittel	**Device for improved insulin absorption in diabetes type 1**
Problembeskrivelse	**In treatment of diabetes mellitus type 1 (DM1) a major challenge is the slow absorption of infused insulin and the resulting delay in glucose lowering effect. Thus, any technology that might speed up the insulin absorption has the potential to significantly improve the performance of insulin therapy. The Artificial Pancreas Trondheim (APT) research group is planning to investigate whether exposing the tissue to near-infrared (NIR) light and/or local heating of the tissue can contribute to faster insulin absorption. The hypothesis is that these stimuli will cause local vasodilation (i.e., increase local blood transfusion) and thus facilitate faster transport of the insulin away from the infusion site and into the target tissues. The goal of this project is to build an electronic prototype system for controlled NIR treatment. The long term goal is to produce a physical device that can be used for research into the possibilities and limitations of the technology in the current application. The MSc Thesis is building on a Project Thesis with the same working title conducted during Fall 2020 and its work should include the following: 1. Design and build a prototype. 2. Test the functions and identify the parameters of the prototype in vitro. 2a. (Optional - Test the device in a self-test - in vivo) 3. Identify potential improvements for future iterations.**

Risikovurdering og datahåndtering

Skal det gjennomføres risikovurdering? **Dersom «ja», har det blitt gjennomført?**	**Ja** **Nei**
Skal det søkes om godkjenninger? (REK*, NSD)**	**Nei**
Skal det skrives en konfidensialitetsavtale i forbindelse med oppgaven? **Hvis «ja», har det blitt gjort?**	**Ja** **Ja**

* Regionale komiteer for medisinsk og helsefaglig forskningsetikk (https://rekportalen.no)

** Norsk senter for forskningsdata (https://nsd.no/)

Eventuelle emner som skal inngå i mastergraden

Retningslinjer - rettigheter og plikter

Formål

Avtale om veiledning av masteroppgaven/hovedoppgaven er en samarbeidsavtale mellom student, veileder og institutt. Avtalen regulerer veiledningsforholdet, omfang, art og ansvarsfordeling.

Studieprogrammet og arbeidet med oppgaven er regulert av Universitets- og høgskoleloven, NTNUs studieforskrift og gjeldende studieplan. Informasjon om emnet, som oppgaven inngår i, finner du i emnebeskrivelsen.

Veiledning

Studenten har ansvar for å

- Avtale veiledningstimer med veileder innenfor rammene master-/hovedoppgaveavtalen gir.
- Utarbeide framdriftsplan for arbeidet i samråd med veileder, inkludert veiledningsplan.
- Holde oversikt over antall brukte veiledningstimer sammen med veileder.
- Gi veileder nødvendig skriftlig materiale i rimelig tid før veiledning.
- Holde instituttet og veileder orientert om eventuelle forsinkelser.
- Inkludere eventuell(e) medstudent(er) i avtalen.

Veileder har ansvar for å

- Avklare forventninger om veiledningsforholdet.
- Sørge for at det søkes om eventuelle nødvendige godkjenninger (etikk, personvernhensyn).
- Gi råd om formulering og avgrensning av tema og problemstilling, slik at arbeidet er gjennomførbart innenfor normert eller avtalt studietid.
- Drøfte og vurdere hypoteser og metoder.
- Gi råd vedrørende faglitteratur, kildemateriale, datagrunnlag, dokumentasjon og eventuelt ressursbehov.
- Drøfte framstillingsform (eksempelvis disposisjon og språklig form).
- Drøfte resultater og tolkninger.
- Holde seg orientert om progresjonen i studentens arbeid i henhold til avtalt tids- og arbeidsplan, og følge opp studenten ved behov.
- Sammen med studenten holde oversikt over antall brukte veiledningstimer.

Instituttet har ansvar for å

- Sørge for at avtalen blir inngått.
- Finne og oppnevne veileder(e).
- Inngå avtale med annet institutt/ fakultet/institusjon dersom det er oppnevnt ekstern medveileder.
- I samarbeid med veileder holde oversikt over studentens framdrift, antall brukte veiledningstimer, og følge opp dersom studenten er forsinket i henhold til avtalen.
- Oppnevne ny veileder og sørge for inngåelse av ny avtale dersom:
    - Veileder blir fraværende på grunn av eksempelvis forskningstermin, sykdom, eller reiser.
    - Student eller veileder ber om å få avslutte avtalen fordi en av partene ikke følger den.
    - Andre forhold gjør at partene finner det hensiktsmessig med ny veileder.
- Gi studenten beskjed når veiledningsforholdet opphører.
- Informere veileder(e) om ansvaret for å ivareta forskningsetiske forhold, personvernhensyn og veiledningsetiske forhold.
- Ønsker student, eller veileder, å bli løst fra avtalen må det søkes til instituttet. Instituttet må i et slikt tilfelle oppnevne ny veileder.

Avtaleskjemaet skal godkjennes når retningslinjene er gjennomgått.

Godkjent av

Patrick Christian Bösch
Student

10.12.2020
Digitalt godkjent

Øyvind Stavdahl
Veileder

11.12.2020
Digitalt godkjent

Lill Hege Pedersen
Institutt

11.12.2020
Digitalt godkjent

Fastsatt av Rektor 20.01.2012

STANDARDAVTALE

om utføring av masteroppgave/prosjektoppgave (oppgave) i samarbeid med bedrift/ekstern virksomhet (bedrift).

Avtalen er ufravikelig for studentoppgaver ved NTNU som utføres i samarbeid med bedrift.

Partene har ansvar for å klarere eventuelle immaterielle rettigheter som tredjeperson (som ikke er part i avtalen) kan ha til prosjektbakgrunn før bruk i forbindelse med utførelse av oppgaven.

Avtale mellom

Student: **Bösch, Patrick Christian**	født: **03.03.1990**

Veileder ved NTNU: **Øyvind Stavdahl**

Bedrift/ekstern virksomhet: **Artificial Pancreas Trondheim (APT) Group**

og

Norges teknisk-naturvitenskapelige universitet (NTNU) v/instituttleder

om bruk og utnyttelse av resultater fra masteroppgave/prosjektoppgave.

1. Utførelse av oppgave

Studenten skal utføre masteroppgave i samarbeid med

Artificial Pancreas Trondheim (APT) Group

bedrift/ekstern virksomhet

01.02.2021- 28.06.2021

startdato – sluttdato

Oppgavens tittel er:

Device for improved insulin absorption in diabetes type 1

Ansvarlig veileder ved NTNU har det overordnede faglige ansvaret for utforming og godkjenning av prosjektbeskrivelse og studentens læring.

2. Bedriftens plikter

Bedriften skal stille med en kontaktperson som har nødvendig veiledningskompetanse og gi studenten tilstrekkelig veiledning i samarbeid med veileder ved NTNU. Bedriftens kontaktperson er:

Sven Magnus Carlsen

Formålet med oppgaven er studentarbeid. Oppgaven utføres som ledd i studiet, og studenten skal ikke motta lønn eller lignende godtgjørelse fra bedriften. Bedriften skal dekke følgende utgifter knyttet til utførelse av oppgaven:

Parts for the prototypes (10'000kr)

3. Partenes rettigheter

a) Studenten

Studenten har opphavsrett til oppgaven. Alle immaterielle rettigheter til resultater av oppgaven skapt av studenten alene gjennom oppgavearbeidet, eies av studenten med de reservasjoner som følger av punktene b) og c) nedenfor.

Studenten har rett til å inngå egen avtale med NTNU om publisering av sin oppgave i NTNUs institusjonelle arkiv på internett. Studenten har også rett til å publisere oppgaven eller deler av den i andre sammenhenger dersom det ikke i denne avtalen er avtalt begrensninger i adgangen til å publisere, jf punkt 4.

b) Bedriften

Der oppgaven bygger på, eller videreutvikler materiale og/eller metoder (prosjektbakgrunn) som eies av bedriften, eies prosjektbakgrunnen fortsatt av bedriften. Eventuell utnyttelse av videreutviklingen, som inkluderer prosjektbakgrunnen, forutsetter at det inngås egen avtale om dette mellom student og bedrift.

Bedriften skal ha rett til å benytte resultatene av oppgaven i egen virksomhet dersom utnyttelsen faller innenfor bedriftens virksomhetsområde. Dette skal fortolkes i samsvar med begrepets innhold i Arbeidstakeroppfinnelsesloven[1] § 4. Retten er ikke-eksklusiv.

[1] Lov av 17. april 1970 om retten til oppfinnelser som er gjort av arbeidstakere

Bruk av resultatet av oppgaven utenfor bedriften sitt virksomhetsområde, jf avsnittet ovenfor, forutsetter at det inngås egen avtale mellom studenten og bedriften. Avtale mellom bedrift og student om rettigheter til oppgaveresultater som er skapt av studenten, skal inngås skriftlig og er ikke gyldig inngått før NTNU har mottatt skriftlig gjenpart av avtalen.

Dersom verdien av bruken av resultatene av oppgaven er betydelig, dvs overstiger NOK 100.000 (kommentert i veiledningen[2] til avtalen), er studenten berettiget til et rimelig vederlag. Arbeidstakeroppfinnelsesloven § 7 gis anvendelse på vederlagsberegningen. Denne vederlagsretten gjelder også for ikke-patenterbare resultater. Fristbestemmelsene i § 7 gis tilsvarende anvendelse.

c) NTNU

De innleverte eksemplarer/filer av oppgaven med vedlegg, som er nødvendig for sensur og arkivering ved NTNU, tilhører NTNU. NTNU får en vederlagsfri bruksrett til resultatene av oppgaven, inkludert vedlegg til denne, og kan benytte dette til undervisnings- og forskningsformål med de eventuelle begrensninger som fremgår i punkt 4.

4. Utsatt offentliggjøring

Hovedregelen er at studentoppgaver skal være offentlige. I særlige tilfeller kan partene bli enig om at hele eller deler av oppgaven skal være undergitt utsatt offentliggjøring i maksimalt 3 år, dvs. ikke tilgjengelig for andre enn student og bedrift i denne perioden.

Oppgaven skal være undergitt utsatt offentliggjøring i

tre år

Behovet for utsatt offentliggjøring er begrunnet ut fra følgende:

The application for which the prototype is designed for is currently being investigated by the APT and NTNUs TTO for potential patents.

De delene av oppgaven som ikke er undergitt utsatt offentliggjøring, kan publiseres i NTNUs institusjonelle arkiv, jf punkt 3 a), andre avsnitt.

http://www.lovdata.no/all/hl-19700417-021.html

[2] Veiledning til NTNUs standardavtale om masteroppgave/prosjektoppgave i samarbeid med bedrift http://www.ntnu.no/studier/standardavtaler

Selv om oppgaven er undergitt utsatt offentliggjøring, skal bedriften legge til rette for at studenten kan benytte hele eller deler av oppgaven i forbindelse med jobbsøknader samt videreføring i et doktorgradsarbeid.

5. Generelt

Denne avtalen skal ha gyldighet foran andre avtaler som er eller blir opprettet mellom to av partene som er nevnt ovenfor. Dersom student og bedrift skal inngå avtale om konfidensialitet om det som studenten får kjennskap til i bedriften, skal NTNUs standardmal for konfidensialitetsavtale benyttes. Eventuell avtale om dette skal vedlegges denne avtalen.

Eventuell uenighet som følge av denne avtalen skal søkes løst ved forhandlinger. Hvis dette ikke fører frem, er partene enige om at tvisten avgjøres ved voldgift i henhold til norsk lov. Tvisten avgjøres av sorenskriveren ved Sør-Trøndelag tingrett eller den han/hun oppnevner.

Denne avtale er underskrevet i 4 - fire - eksemplarer hvor partene skal ha hvert sitt eksemplar.
Avtalen er gyldig når den er godkjent og underskrevet av NTNU v/instituttleder.

10.12.2020	Patrick Christian Bösch

Elektronisk godkjent, dato student

11.12.2020	Øyvind Stavdahl

Elektronisk godkjent, dato veileder ved NTNU

11.12.2020	Lill Hege Pedersen

Elektronisk godkjent, dato instituttleder, NTNU institutt

Elektronisk godkjent, dato for bedriften/institusjonen
stempel og signatur

Master`s Agreement / Main Thesis Agreement

Faculty	**Faculty of Information Technology and Electrical Engineering**
Institute	**Department of Engineering Cybernetics**
Programme Code	**MITK**
Course Code	**TTK4900**

Personal Information

Surname, First Name	**Bösch, Patrick Christian**
Date of Birth	**03.03.1990**
Email	**patrick.c.bosch@ntnu.no**

Supervision and Co-authors

Supervisor	**Øyvind Stavdahl**
Co-supervisors (if applicable)	**Anders Lyngvi Fougner**
Co-authors (if applicable)	

The Master`s thesis

Starting Date	**01.02.2021**
Submission Deadline	**28.06.2021**
Thesis Working Title	**Device for improved insulin absorption in diabetes type 1**
Problem Description	**In treatment of diabetes mellitus type 1 (DM1) a major challenge is the slow absorption of infused insulin and the resulting delay in glucose lowering effect. Thus, any technology that might speed up the insulin absorption has the potential to significantly improve the performance of insulin therapy. The Artificial Pancreas Trondheim (APT) research group is planning to investigate whether exposing the tissue to near-infrared (NIR) light and/or local heating of the tissue can contribute to faster insulin absorption. The hypothesis is that these stimuli will cause local vasodilation (i.e., increase local blood transfusion) and thus facilitate faster transport of the insulin away from the infusion site and into the target tissues. The goal of this project is to build an electronic prototype system for controlled NIR treatment. The long term goal is to produce a physical device that can be used for research into the possibilities and limitations of the technology in the current application. The MSc Thesis is building on a Project Thesis with the same working title conducted during Fall 2020 and its work should include the**

	following: 1. Design and build a prototype. 2. Test the functions and identify the parameters of the prototype in vitro. 2a. (Optional - Test the device in a self-test - in vivo) 3. Identify potential improvements for future iterations.

Risk Assessment and Data Management	
Will you conduct a Risk Assessment? **If "Yes", Is the Risk Assessment Conducted?**	**Yes** **No**
Will you Apply for Data Management? **(REK*, NSD**)**	**No**
Will You Write a Confidentiality Agreement? **If "Yes", Is the Confidentiality Agreement Conducted?**	**Yes** **Yes**

* REK -- https://rekportalen.no/

** Norwegian Centre for Research Data (https://nsd.no/nsd/english/index.html)

Topics to be included in the Master`s Degree (if applicable)

Guidelines – Rights and Obligations

Purpose

The Master's Agreement/ Main Thesis Agreement is an agreement between the student, supervisor, and department. The agreement regulates supervision conditions, scope, nature, and responsibilities concerning the thesis.

The study programme and the thesis are regulated by the Universities and University Colleges Act, NTNU's study regulations, and the current curriculum for the study programme.

Supervision

The student is responsible for

- Arranging the supervision within the framework provided by the agreement.
- Preparing a plan of progress in cooperation with the supervisor, including a supervision schedule.
- Keeping track of the counselling hours.
- Providing the supervisor with the necessary written material in a timely manner before the supervision.
- Keeping the institute and supervisor informed of any delays.
- Adding fellow student(s) to the agreement, if the thesis has more than one author.

The supervisor is responsible for

- Clarifying expectations and how the supervision should take place.
- Ensuring that any necessary approvals are acquired (REC, ethics, privacy).
- Advising on the demarcation of the topic and the thesis statement to ensure that the work is feasible within agreed upon time frame.
- Discussing and evaluating hypotheses and methods.
- Advising on literature, source material, data, documentation, and resource requirements.
- Discussing the layout of the thesis with the student (disposition, linguistic form, etcetera).
- Discussing the results and the interpretation of them.
- Staying informed about the work progress and assist the student if necessary.
- Together with the student, keeping track of supervision hours spent.

The institute is responsible for

- Ensuring that the agreement is entered into.
- Find and appoint supervisor(s).
- Enter into an agreement with another department / faculty / institution if there is an external co-supervisor.
- In cooperation with the supervisor, keep an overview of the student's progress, the number of supervision hours. spent, and assist if the student is delayed by appointment.
- Appoint a new supervisor and arrange for a new agreement if:
    - The supervisor will be absent due to research term, illness, travel, etcetera.
    - The student or supervisor requests to terminate the agreement due to lack of adherence from either party.
    - Other circumstances where it is appropriate with a new supervisor.
- Notify the student when the agreement terminates.
- Inform supervisors about the responsibility for safeguarding ethical issues, privacy and guidance ethics
- Should the cooperation between student and supervisor become problematic, either party may apply to the department to be freed from the agreement. In such occurrence, the department must appoint a new supervisor

This Master`s agreement must be signed when the guidelines have been reviewed.

Signatures

Patrick Christian Bösch
Student

10.12.2020
Digitally approved

Øyvind Stavdahl
Supervisor

11.12.2020
Digitally approved

Lill Hege Pedersen
Department

11.12.2020
Digitally approved

By order of Rector: 20 January 2012

STANDARD AGREEMENT

concerning work on a master's thesis/project assignment (academic work) done in cooperation with a company/external organization (organization).

This is the authoritative agreement that governs academic work by students at the Norwegian University of Science and Technology (NTNU) that is carried out in cooperation with an organization.

The involved parties have the responsibility to clarify whether or not a third party (that is not a party to this agreement) may have intellectual property rights to the project background before the latter is used in connection with the academic work.

Agreement between

Student: **Bösch, Patrick Christian**	Date of birth: **03.03.1990**

Supervisor at NTNU: **Øyvind Stavdahl**

Company/external organization: **Artificial Pancreas Trondheim (APT) Group**

and

Norwegian University of Science and Technology (NTNU), represented by the Head of Department

concerning the use and exploitation of the results from a master's thesis/project assignment.

1. Description of the academic work

The student is to carry out Master`s thesis in cooperation with

Artificial Pancreas Trondheim (APT) Group

company/external organization

01.02.2021– 28.06.2021

starting date – completion date

Title of the academic work:

Device for improved insulin absorption in diabetes type 1

The responsible supervisor at NTNU has overall academic responsibility for structuring and approving the description of the academic work and the student's learning.

2. Responsibilities of the organization

The organization is to appoint a contact person who has the necessary experience in supervision and will give the student adequate supervision in cooperation with the supervisor at NTNU. The contact person at the organization is:

Sven Magnus Carlsen

The purpose of completing the academic work is academic training for the student. The academic work is part of a student's course of study and the student is not to receive wages or similar compensation from the organization. The organization agrees to cover the following expenses that are associated with carrying out the academic work:

Parts for the prototypes (10'000kr)

3. Rights of the parties

a) The student

The student holds the copyright to his/her academic work. All intellectual property rights to the results of the academic work done by the student alone during the academic work are held by the student with the reservations stated in points b) and c) below.

The student has the right to enter into an agreement with NTNU concerning the publication of his/her academic work in NTNU's institutional archive on the Internet. The student has also the right to publish his/her academic work or parts of it in other media providing the present agreement has not imposed restriction concerning publication, cf. Clause 4.

b) the organization

If the academic work is based on or develops materials and/or methods (project background) that are owned by the organization, the project background is owned by the organization. If the development work that includes the project background can be commercially exploited, it is assumed that a separate agreement will be drawn up concerning this between the student and the organization.

The organization is to have the right to use the results of the academic work in its own activities providing the commercial exploitation falls within the activities of the organization. This is to be interpreted in accordance with the terminology used in Section 4 of the Act Respecting the Right to Employees' Inventions (Arbeidstakeroppfinnelsesloven). This right is non-exclusive.

The use of the results of the academic work outside of the activities of the organization, cf. the last paragraph above, assumes that a separate agreement will be drawn up between the student and the organization. The agreement between the student and the organization concerning the rights to the results of the academic work produced by the student is to be in writing and the agreement is invalid until NTNU has received a copy of the agreement in writing.

If the value of the results of the academic work is considerable, i.e. it is more than NOK 100 000, the student is entitled to receive reasonable compensation. Section 7 of the Act Respecting the Right to Employees' Inventions states how the amount of compensation is to be calculated. This right to compensation also applies to non-patentable results. Section 7 of the Act also states the applicable deadlines.

c) NTNU

All copies of the submitted academic work/files containing the academic work and any appendices that are necessary for determining a grade and for the records at NTNU, are the property of NTNU. The academic work and any appendices to it can be used by NTNU for educational and scientific purposes free of charge, except when the restrictions specified in Clause 4 are applicable.

4. Delayed publication

The general rule is that academic work by students is to be available in the public domain. If there are specific circumstances, the parties can agree to delay the publication of all or part of the academic work for a maximum of 3 years, i.e. the work is not available for other students or organizations during this period.

The academic work is subject to delayed publication for:

three years

The grounds for delayed publication are as follows:

The application for which the prototype is designed for is currently being investigated by the APT and NTNUs TTO for potential patents.

The parts of the academic work that are not subject to delayed publication can be published in NTNU’s institutional archive, cf. Clause 3 a) second paragraph.

Even if the academic work is subject to delayed publication, the organization is to make it possible for the student to use all or part of his/her academic work in connection with a job application or follow-up work in connection with doctoral study.

5. General

This agreement takes precedence over any other agreements that are or will be entered into by two of the parties mentioned above. In case the student and the organization are to enter into a confidentiality agreement concerning information the student obtains while he/she is at the organization, NTNU's template for a confidentiality agreement is to be used for this purpose. If there is such an agreement, it is to be appended to the present agreement.

Should there be any dispute relating to this agreement, it should be resolved by negotiation. If this does not lead to a solution, the parties agree to the matter being resolved by arbitration in accordance with Norwegian law. Any such dispute is to be decided by Sør-Trøndelag District Court or a body appointed by this court.

This agreement is signed in 4 - four - copies, where each party to this agreement is to keep one copy. The agreement comes into effect when it has been approved and signed by NTNU represented by the Head of Department.

Note that the Norwegian version of this standard agreement is the authoritative version.

10.12.2020	Patrick Christian Bösch

Digitally approved, date (dd.mm.yy) student

11.12.2020	Øyvind Stavdahl

Digitally approved, date (dd.mm.yy) supervisor at NTNU

11.12.2020	Lill Hege Pedersen

Digitally approved, date (dd.mm.yy) Head of Department, NTNU

place, date (dd.mm.yy) for company/organization
signed and stamped

Appendix J Email Correspondence

Patrick Christian Bösch

From: Patrick Christian Bösch
Sent: onsdag 28. april 2021 13:55
To: 'post@trondheimeloksering.no'
Subject: RE: Eloksering

Hi Kim

Tusen takk for svaret. Det høres greit ut. Da kommer jeg å ta kontakt igjen når delen er klart.
Ved hensyn til rigging. Hvilken geometrier gjør rigging enkelt eller vanskelig? Er fortsatt i design fase, så kan kanskje ta hensyn til det.

Mvh

Patrick

From: post@trondheimeloksering.no <post@trondheimeloksering.no>
Sent: Wednesday, April 28, 2021 8:23 AM
To: Patrick Christian Bösch <patrick.c.bosch@ntnu.no>
Subject: SV: Eloksering

Hei.
Hvis disse delene er forholdsvis enkle å rigge vil disse komme innenfor oppstart/minstepris for sort eloksering, kr 595,- eks. mva. Ved mere utfordrende geometri, komplisert rigging og lengre håndteringstid kan det komme til anslagsvis 1-300,- ekstra. Ledetid på sort eloksering i denne størrelsesordenen er for tiden 5-10 virkedager.

Med vennlig hilsen
Kim Johansen
Daglig leder

Trondheim Eloksering AS | Søbstadvegen 19A | 7088 Heimdal
Telefon +47 453 80 506 | Org. nr. 920 688 985 | www.trondheimeloksering.no

Fra: Patrick Christian Bösch <patrick.c.bosch@ntnu.no>
Sendt: tirsdag 27. april 2021 18:24
Til: post@trondheimeloksering.no
Emne: Eloksering

Hi

Jeg bygget et prototype som masteroppgaven min og har behov til å eloksere noen aluminiumsdeler svart.
Det snakkes om 3x2 deler (totalt 6 deler) som måler maks 50x50x30mm hver.

Kan dere gjøre det? Hvis ja, hvor langt tar det og hva koster det?

Tusen takk for svaret.

Mvh

Patrick Bösch

Patrick Christian Bösch

From: Markus Wyndhamn (Optonyx AB) <markus@optonyx.com>
Sent: torsdag 18. februar 2021 11:33
To: Patrick Christian Bösch
Subject: VB: Request for EOLS-660-496
Attachments: EOLS-660-496.pdf; EOLS-810-496.pdf; EOLS-880-496.pdf

Hello Patrick,

We received your request for the EpiGap LEDs. I will send you quotation for these LEDs as soon as I have the pricing.

In the mean time, I here send you the data sheets for all three LEDs.

Also, there is one issue I need to inform you of.
The marking for the EOLS-880-496 is at the cathode (n-up) and not at the anode (p-up) as indicated in the data sheet. EpiGap is working to correct this and will update the data sheet. As soon as I have it I will send the updated version to you. The data sheet you receive now is the old one. I hope this is ok for you.

Best regards / Med vänlig hälsning,

Markus Wyndhamn
Regional Sales Manager
Business Area Photonics
markus@optonyx.com
Direct +46 8 55 11 14 16
Mobile +46 720 799 376

OPTONYX
– part of Hugo Tillquist AB

Von: Patrick Christian Bösch <patrick.c.bosch@ntnu.no>
Gesendet: Mittwoch, 17. Februar 2021 18:08
An: sales@epigap-optronic.de
Betreff: Request for EOLS-660-496

Hi

As part of my MSc Thesis at the Norwegian University of Science and Technology (NTNU) in Trondheim, Norway, i am to design and build a prototype using NIR- LEDs.
I came across your product and it seems like it could work for the intended application.
I will probably need somewhere between 20 and 30 LEDs for each wavelength.

Could you also provide me with additional quotes for the following LEDs:
- EOLS-810-496
- EOLS-880-496

Would you be able to send me a quote for this, including an estimated lead time?
Furthermore, would you be able to send them to Norway?

Thank you very much for your reply

Best regards

Patrick

Patrick Bösch

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Patrick Christian Bösch

From: SE Tech Support <techsupport.se@thorlabs.com>
Sent: tirsdag 6. april 2021 08:44
To: Patrick Christian Bösch
Subject: Re: [CAS-360219-X7C7K3] FESH1000 and M254H00

Hi again Patrick,

I have now received some answers from our optics department and the good news is that they can offer the special sizes, but we do have a minimum order quantity of 10 pcs of each. So I guess this will be too much for you, but I'll send the prices and part descriptions to you any way. Please see below.

Let me know if this is at all interesting and you would like to receive a formal quote.

FESH1000-30x30MM-UM-SP: 30x30mm Premium Shortpass, 1000nm Cut-Off, Unmounted

Price: 167 EUR each
Quantity: 10
Lead Time: 7-8 weeks after drawing approval

Description:
CLEAR APERTURE: 90% OF AREA
TRANSMITTED WAVEFRONT ERROR: ≥λ/4 AT 632.8nm OVER CLEAR APERTURE
SURFACE QUALITY (S1, S2) 40-20 SCRATCH-DIG
COATING: SHORTPASS FILTER, HARDCOATED
TRANSMISSION: >90% ABSOLUTE 500-987nm
BLOCKING: >OD5 1013-1500nm
FILTER SLOPE: (OD5-50%
TRANSMISSION): <1.0%
AOI: 0

M254H00-30x30MM-SP
30x30MM UVFS Hot Mirror, AOI: 0°, 5 mm Thick

Price: 146 EUR each
Quantity: 10
Lead Time: 7-8 Weeks if all components are in stock

30x30MM UVFS Hot Mirror, AOI: 0°, 5 mm Thick
CLEAR APERTURE: > 90% of the physical diameter
SURFACE QUALITY: 20-10 SCRATCH-DIG
SURFACE FLATNESS: <λ/10 AT 633nm
DIAMETER TOLERANCE: ±0.20mm
THICKNESS TOLERANCE: ±0.40mm
WEDGE TOLERANCE: ±10arcmin
FILTER COATING (S1):
REFLECTION BAND (R): >97% AVERAGE, 710-1200nm
TRANSMISSION BAND (T): >92% AVERAGE, 400-690nm
0° AOI

Let me know if you have any further questions.

Best Regards,

Frida Nero
Technical Support
THORLABS Sweden AB

Appendix K Presentation Design Review

NIR-Device for enhanced Insulin Absorption
Project and MSc Thesis H20/V21
Design Review

APT meeting
18.03.2021
Patrick Bösch

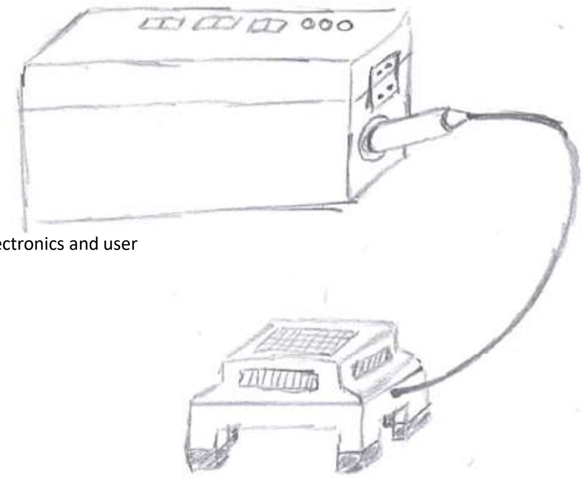
1

Aim

- Discuss different design proposals
- Gather input from different APT members
- Use this input to finalise design of the protoype

2

First principle Draft



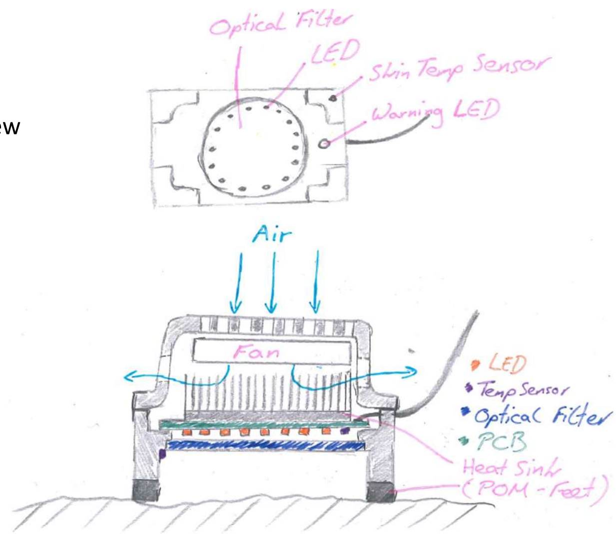
- Box to hold batteries, control electronics and user interface
  - 150x100x40mm
  - 500g max
- Wire with plug
  - 1m
- Interchangeable LED-Head
  - 40x40x40mm
  - 50g max

3

Details for first principle Draft

- Bottom view

- Cut of side view



4

Different Designs

- 4 different designs created based on a Morphological box that provides different solutions for system components
- Key design questions:
  - Arduino or Raspberry Pi
    - Battery choice
    - Memory choice
    - Interface choice
  - Shape and Material LED- Head

5

Different Design Proposals 1/2

Function	Design 1	Design 2	Design 3	Design 4
Electronics Housing	Cuboid	Cylinder	Cuboid	Cuboid
Power Supply	External charging	External charging	Integrated charging	External charging
Battery Type (Rechargeable)	LiPo (flat - 2 cell (7.4V))	Lithium-ion (18650)	LiPo (flat - 1 cell (3.7V))	LiPo (flat - 2 cell (7.4V))
User Interface	Analogue (Buttons, Switches and LEDs)	Analogue (Buttons, Switches and LEDs)	Analogue (Buttons, Switches and LEDs)	Analogue (Buttons, Switches and LEDs)
Parameter adjustment	Analogue and Software	Analogue and Software	Analogue and Software	Analogue and Software
User Protection	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact	- Digital (limit output power) - Monitor Skin Temperature - Optical Warning LED (on pad) - Timer - Skin Sensor to detect Body Contact
Control Board	Raspberry Pi	Arduino	Arduino	Arduino
Additional Memory	No	MicroSD	MicroSD	MicroSD
LED Driver	iC-HG 3A Laser Switch	iC-HG 3A Laser Switch	iC-HG 3A Laser Switch	iC-HG 3A Laser Switch
Programing Interface	Micro USB (internal)	Micro USB (internal)	USB C (external)	Micro USB (internal)

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Different Design Proposals 2/2

Function	Design 1	Design 2	Design 3	Design 4
Connection Electronics to Cable	Round connector	Round connector	Round connector	Round connector
Shielding Connectors	Shielded	Shielded	Shielded	Shielded
Cable / Wire	Twisted-Pairs	Twisted-Pairs	Twisted-Pairs	Twisted-Pairs
Shielding Cable	Shielded-Pairs	Shielded-Pairs	Shielded-Pairs	Shielded-Pairs
Interface Cable - Sensor head	Soldering	Soldering	Soldering	Soldering
Detection LED Head	Resistor	Resistor	Dip Switch to set ID	Resistor
Layout LED-Array	Round	Octagonal	Round	Octagonal
LED Type	SMD	SMD	SMD	SMD
Shape LED Head	Square	Round	Square	Square
Temperature Control LED Head (Sensors)	- Skin - Pad - Chamber	- Skin - Pad - Chamber	- Skin - Pad - Chamber	- Skin - Pad - Chamber
Temperature sensors	Resistive Temperature Detector (RTD)	Resistive Temperature Detector (RTD)	Resistive Temperature Detector (RTD)	Resistive Temperature Detector (RTD)
Filter	- Optical Shortpass Filter - Hot Mirror	- Optical Shortpass Filter - Hot Mirror	- Optical Shortpass Filter - Hot Mirror	- Optical Shortpass Filter - Hot Mirror
Cooling of LED Array	Heatsink + Fan (Active)	Heatsink + Fan (Active)	Heatsink + Fan (Active)	Heatsink + Fan (Active)
Manufacturing Sensor Head	Aluminium (Milled)	POM (Milled)	- Aluminium (Milled) - POM (Milled)	ABS (3D-Print)
Manufacturing Electronics Housing	POM (Milled)	POM (Milled)	POM (Milled)	POM (Milled)

Prefered Design: Design 3

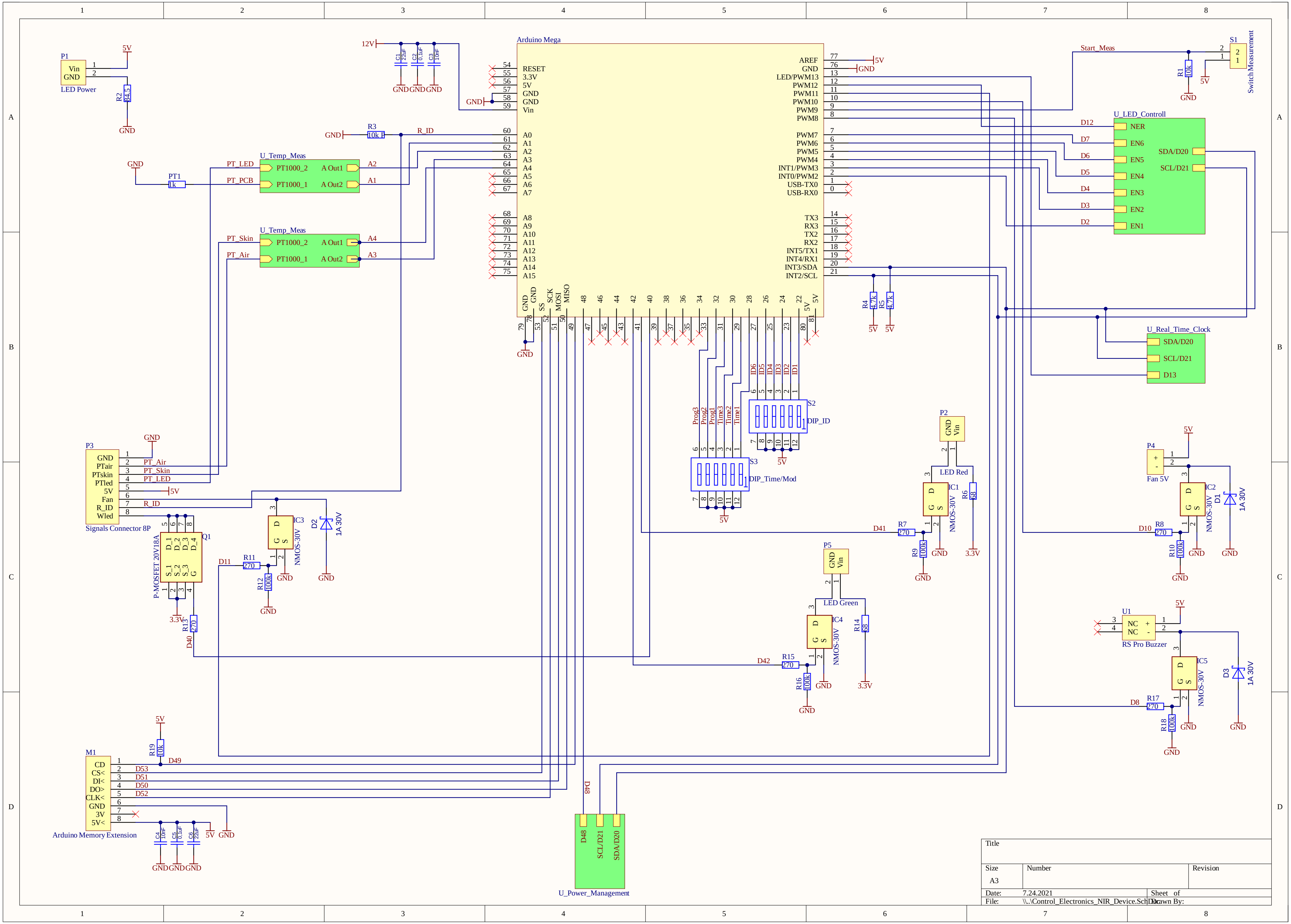
- internal charging removes need for frequent battery exchange by patient
- Analogue interface will keep it simple and easy for the user / patient
  - Internal Dip-Switches allow quick setting of Patient ID and choice of operation mode (power, duration)
- Variety of features to protect the user against eye damage (skin is not relevant as the user would feel pain before real damage can occur)
- Arduino is simple to use as well as small and light and comes with analogue and digital I/O
  - Downside, it requires additional memory
- iC-HG 3A Laser Switch allows for PWM modulation and current control of LEDs with up to 3A
- Round plug will lock itself and guarantee secure fit while individually twisted and shielded pairs will reduce noise induced by the PWM signal
- Resistors of different values allow to clearly identify different LED pads and adjust settings
- Square LED-Head allows for easy attachment of holders (for example for a Velcro strap)
- Resistive Temperature Detector (likely PT1000) monitor temperature to keep system and patient safe
- Filter provide physical protection of LEDs and filter out the majority of heat radiated by the semiconductor junction
- Air-Gap between the LEDs and the skin removes heat conduction from the LEDs and helps create a uniform lightdistribution in the target area
- A heatsink together with a fan will cool down the LEDs and the temperature can be controlled by a simple control loop with the PCB temperature sensor
- Aluminium housing helps remove the heat from the LED-PCB while POM feet isolate the system towards the body and make application more pleasant

Key Components

- LEDs
  - 660nm – 110mW/sr
  - 810nm – 25mW/sr
  - 880nm – 28mW/sr
    - 120° View Angle
- Filter
  - Short pass with cut-off 1000nm (810/880nm)
  - Hot Mirror cut-off 690nm (660nm)
  - Temp LEDs <85°C (cooled to around body temperature ~37°C) -> emitted wavelengths ~2'500-20'000nm with peak around 7'500nm

Questions and Inputs?

Appendix L Schematic Drawings of Electronics



Arduino Mega
P1
LED Power
Vin
GND
5V
R2
84.5
GND
12V
C1 22uF
C2 0.1uF
C3 10nF
RESET
3.3V
5V
GND
Vin
AREF
LED/PWM13
PWM12
PWM11
PWM10
PWM9
PWM8
PWM7
PWM6
PWM5
PWM4
INT1/PWM3
INT0/PWM2
USB-TX0
USB-RX0
TX3
RX3
TX2
RX2
INT5/TX1
INT4/RX1
INT3/SDA
INT2/SCL
A0
A1
A2
A3
A4
A5
A6
A7
A8
A9
A10
A11
A12
A13
A14
A15
SS
SCK
MOSI
MISO
R3
10k
R_ID
Start_Meas
S1
Switch Measurement
R1
10k
U_LED_Controll
NER
EN6
EN5
EN4
EN3
EN2
EN1
SDA/D20
SCL/D21
D12
D7
D6
D5
D4
D3
D2
U_Temp_Meas
PT1000_2
PT1000_1
A Out1
A Out2
PT_LED
PT_PCB
PT_Skin
PT_Air
PT1
1k
R4 4.7k
R5 4.7k
U_Real_Time_Clock
SDA/D20
SCL/D21
D13
S2
DIP_ID
ID6
ID5
ID4
ID3
ID2
ID1
S3
DIP_Time/Mod
Prog3
Prog2
Prog1
Time3
Time2
Time1
P2
LED Red
IC1
NMOS-30V
R6
68
R7
270
R9
100k
D41
P4
Fan 5V
IC2
D1
1A 30V
R8
270
R10
100k
D10
P3
Signals Connector 8P
GND
PTair
PTskin
PTled
5V
Fan
R_ID
Wled
Q1
P-MOSFET 20V18A
IC3
D2
1A 30V
R11
270
R12
100k
D11
R13
270
D40
P5
LED Green
IC4
R14
68
R15
270
R16
100k
D42
U1
RS Pro Buzzer
NC
IC5
D3
1A 30V
R17
270
R18
100k
D8
M1
Arduino Memory Extension
CD
CS<
DI<
DO>
CLK<
GND
3V
5V<
D49
D53
D51
D50
D52
R19
10k
C4 10nF
C5 0.1uF
C6 22uF
D48
U_Power_Management
D48
SCL/D21
SDA/D20
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Revision
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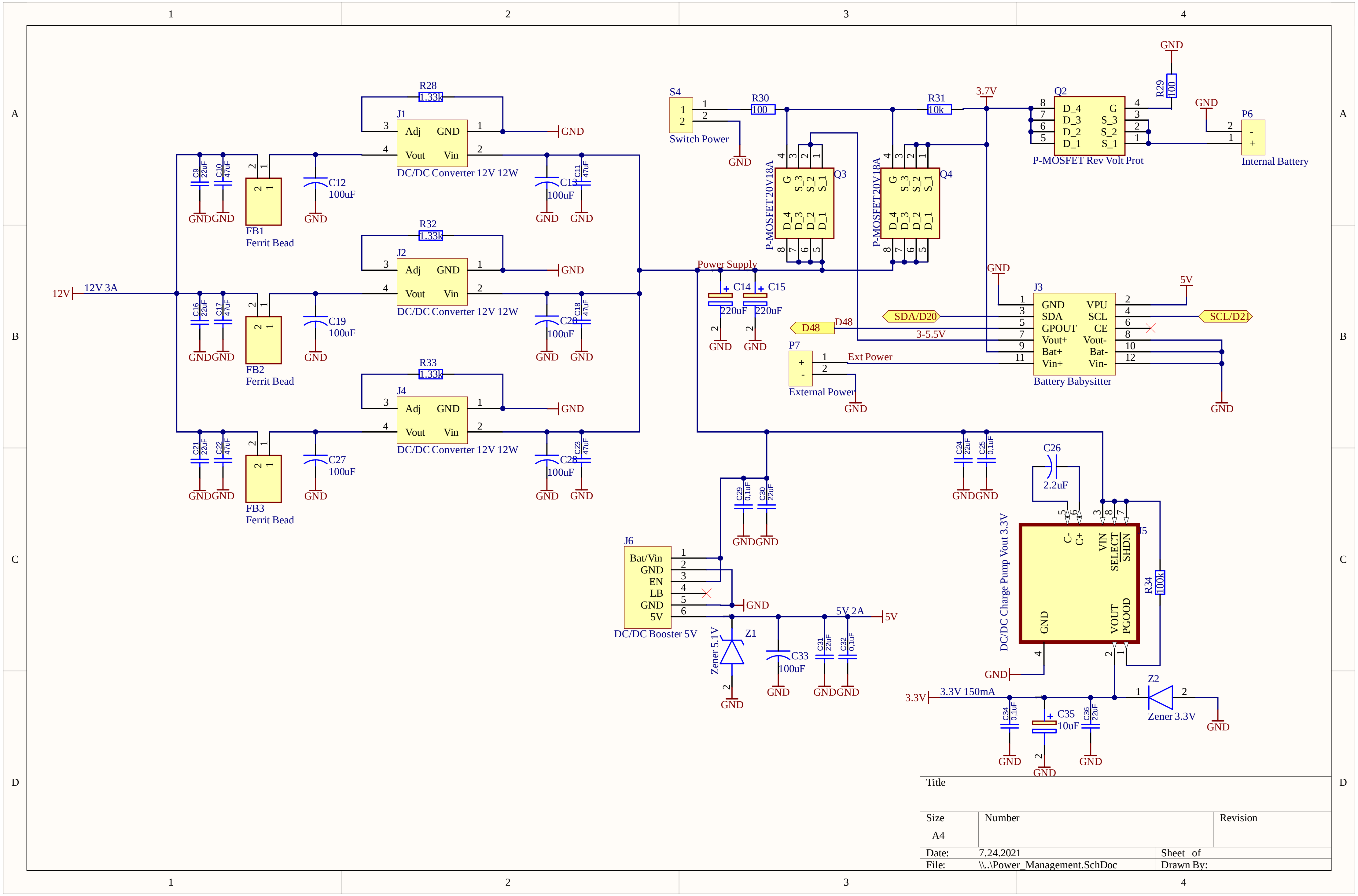
12V
12V 3A
R28 1.33k
J1
Adj GND
Vout Vin
DC/DC Converter 12V 12W
R32 1.33k
J2
R33 1.33k
J4
FB1 Ferrit Bead
FB2 Ferrit Bead
FB3 Ferrit Bead
C9 22uF
C10 47uF
C11 47uF
C12 100uF
C13 100uF
C16 22uF
C17 47uF
C18 47uF
C19 100uF
C20 100uF
C21 22uF
C22 47uF
C23 47uF
C27 100uF
C28 100uF
GND
S4
Switch Power
R30 100
R31 10k
3.7V
Q2
D_4 D_3 D_2 D_1 G S_3 S_2 S_1
P-MOSFET Rev Volt Prot
R29 100
P6
Internal Battery
Q3
Q4
P-MOSFET 20V18A
Power Supply
C14 220uF
C15 220uF
J3
GND SDA GPOUT Vout+ Bat+ Vin+
VPU SCL CE Vout- Bat- Vin-
Battery Babysitter
5V
SDA/D20
SCL/D21
D48
3-5.5V
P7
Ext Power
External Power
C24 22uF
C25 0.1uF
C26 2.2uF
J5
C- C+ VIN SELECT SHDN
GND VOUT PGOOD
DC/DC Charge Pump Vout 3.3V
R34 100k
J6
Bat/Vin GND EN LB GND 5V
DC/DC Booster 5V
C29 0.1uF
C30 22uF
Z1
Zener 5.1V
C33 100uF
5V 2A
C31 22uF
C32 0.1uF
3.3V
3.3V 150mA
C34 0.1uF
C35 10uF
C36 22uF
Z2
Zener 3.3V
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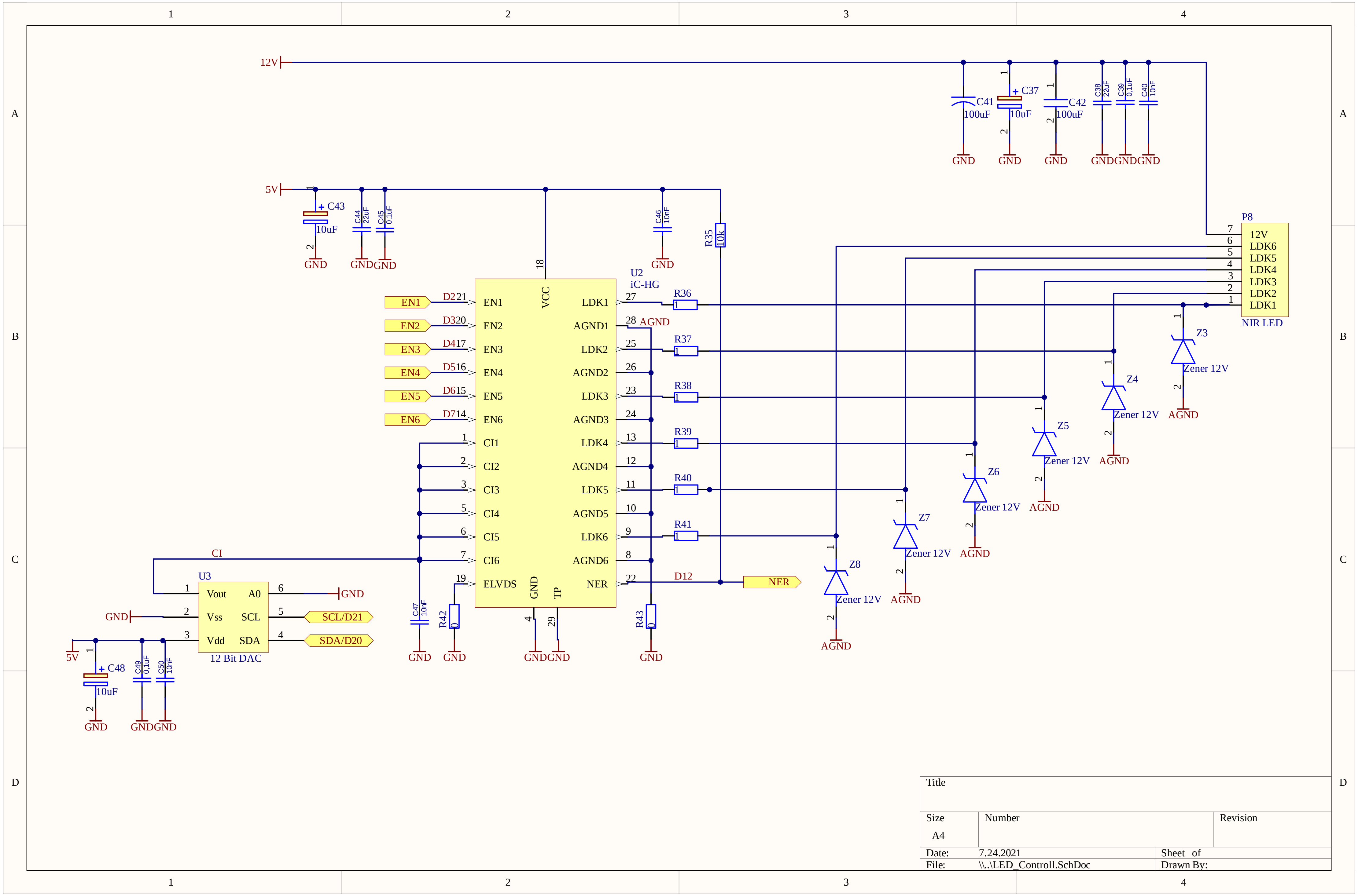
12V
5V
C41 100uF
C37 10uF
C42 100uF
C38 22uF
C39 0.1uF
C40 10nF
C43 10uF
C44 22uF
C45 0.1uF
C46 10nF
C47 10nF
C48 10uF
C49 0.1uF
C50 10nF
GND
AGND
R35 10k
R36
R37
R38
R39
R40
R41
R42
R43
U2
iC-HG
VCC
EN1 EN2 EN3 EN4 EN5 EN6
D2 D3 D4 D5 D6 D7
CI1 CI2 CI3 CI4 CI5 CI6
ELVDS
TP
LDK1 AGND1 LDK2 AGND2 LDK3 AGND3 LDK4 AGND4 LDK5 AGND5 LDK6 AGND6
NER
D12
P8
12V LDK6 LDK5 LDK4 LDK3 LDK2 LDK1
NIR LED
Z3 Z4 Z5 Z6 Z7 Z8
Zener 12V
CI
U3
Vout A0
Vss SCL
Vdd SDA
12 Bit DAC
SCL/D21
SDA/D20
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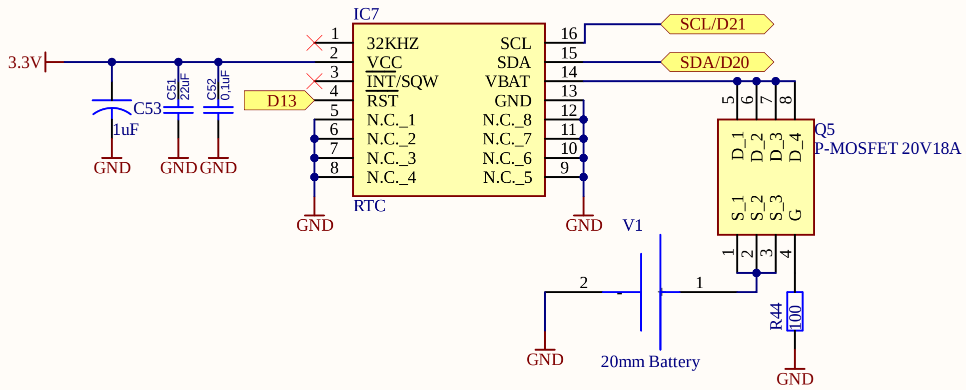

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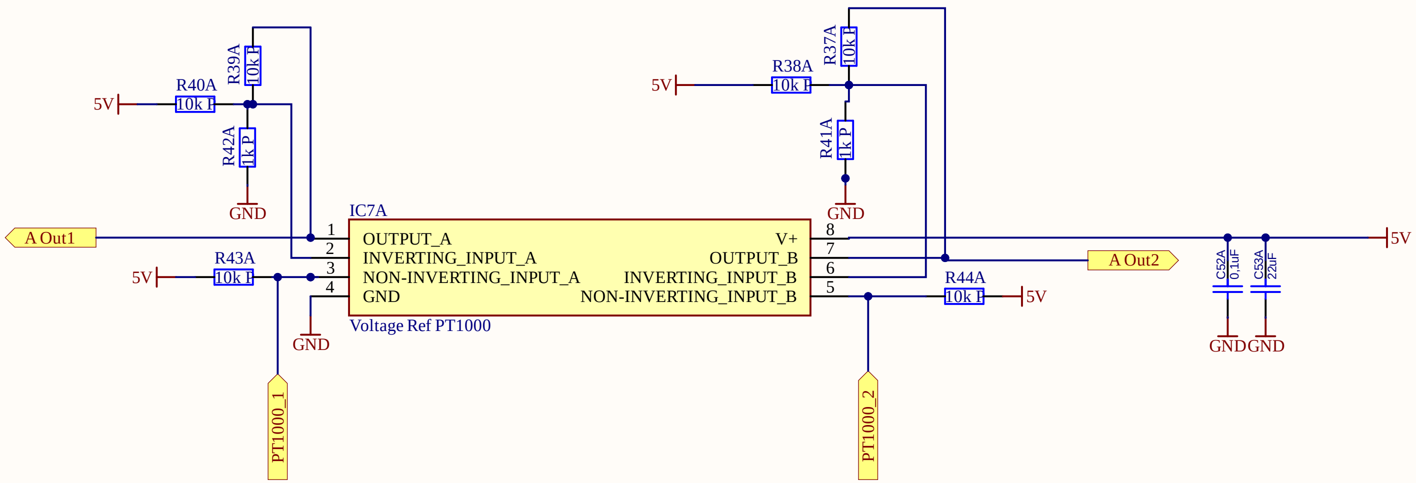

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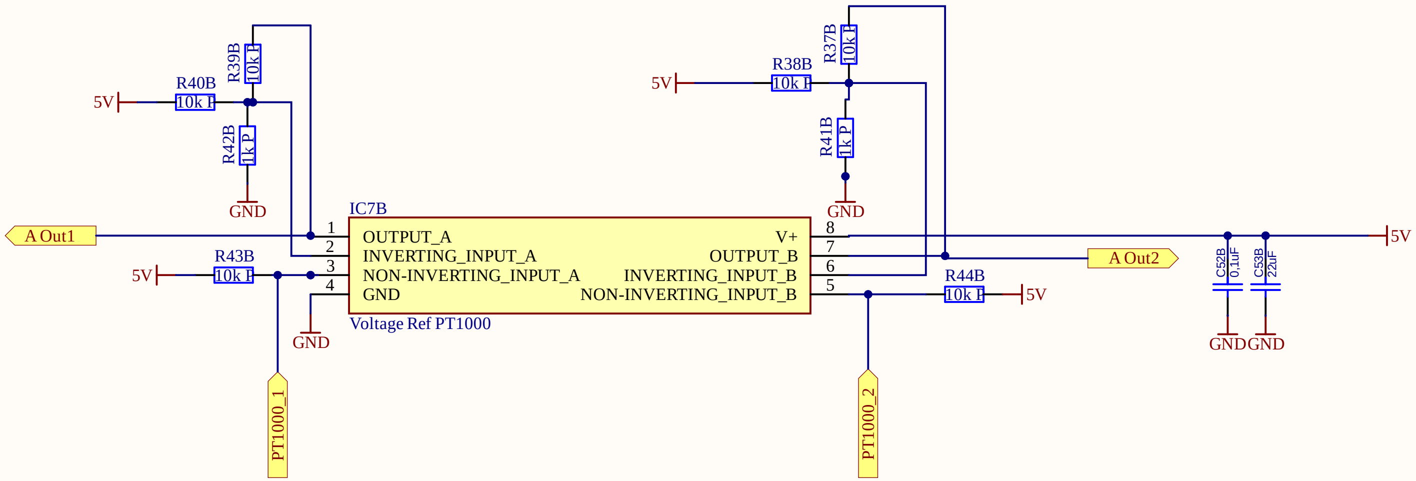

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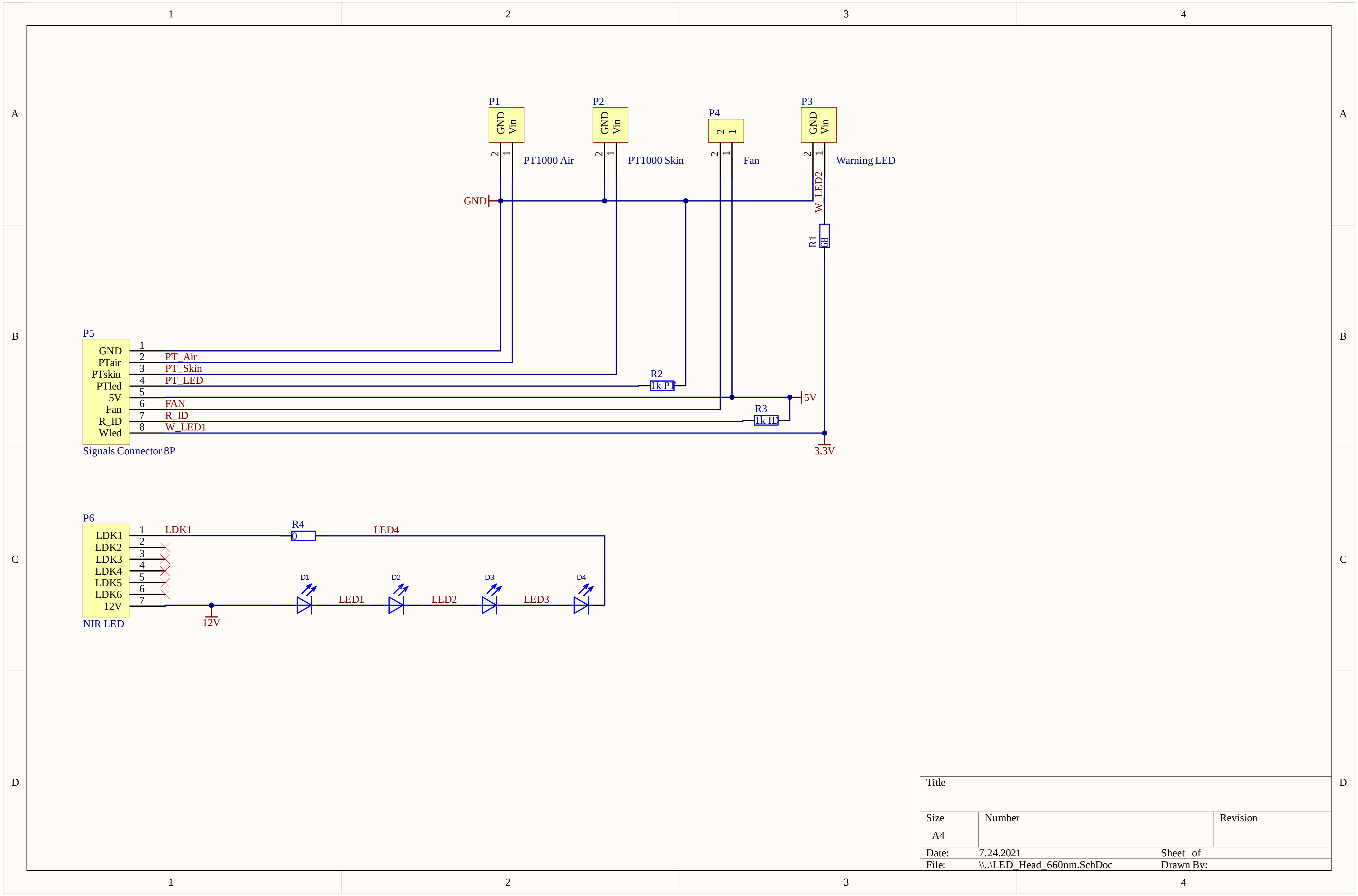
P1
GND
Vin
PT1000 Air
P2
GND
Vin
PT1000 Skin
P4
Fan
P3
GND
Vin
Warning LED
W_LED2
R1
68
GND
P5
GND
PTair
PTskin
PTled
5V
Fan
R_ID
Wled
PT_Air
PT_Skin
PT_LED
FAN
R_ID
W_LED1
R2
1k PT
R3
1k ID
5V
3.3V
Signals Connector 8P
P6
LDK1
LDK2
LDK3
LDK4
LDK5
LDK6
12V
LDK1
R4
0
LED4
D1
D2
D3
D4
LED1
LED2
LED3
12V
NIR LED
Title
Size
A4
Number
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Patrick Christian Bösch

Device for Improved Insulin Absorption in Diabetes Type 1

NTNU
Norwegian University of
Science and Technology