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Exploration of Electric Stimulation for Decreasing Pain during Mechanical Hair Removal

Master thesis

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Acknowledgement

It is a pleasure to me to thank those who made this work possible.

My sincerest appreciation to my boyfriend, Gerald Wriessnegger, I wish to say thanks. He was and is a solid anchor on which I rely again and again. Words cannot express how grateful I am to be in his life and how much this work was enhanced and made easier by him being in mine.

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I thank you all!

Exploration of Electric Stimulation for Decreasing Pain during Mechanical Hair Removal

This master thesis was written for Philips Consumer Lifestyle in Klagenfurt. The topic is triggered by the fact that available mechanical hair removal solutions do not satisfy the consumers wish for a pain free application. There are already implemented solutions (thermal and mechanically), but none is focusing on the topic of pain relief due to electric stimulation. The role which electric stimulation can play for pain relief due to mechanical removing of hairs is discussed in this work.

First physiological basics are discussed before the relevant theoretical aspects are described. This information combined with a literature study helps to narrow the available electric stimulation methods to those which can be used in combination with mechanical hair removal. Finally a set of relevant parameters for having a successful application is explored.

Electric stimulation, mechanical hair removal, decreasing pain, Philips

Elektrostimulation zur Schmerzreduktion während mechanischer Haarentfernung

Die Masterarbeit wurde für die Firma Philips im Bereich Consumer Lifestyle in Klagenfurt geschrieben. Das Thema entstammt dem Wunsch der Anwenderinnen, nach einer schmerzfreien Methode zur mechanischen Haarentfernung. Es gibt bereits thermisch und mechanisch basierte Lösungen und daher konzentrierte man sich auf das Thema der Schmerzreduktion mittels elektrischer Stimulation. In dieser Arbeit wird die Rolle, die Stimulation bei der Unterdrückung des Schmerzes, welcher durch die mechanische Haarentfernung ausgelöst wird, spielen kann diskutiert.

Zuerst werden die physiologischen Grundlagen besprochen um danach die relevanten theoretischen Grundlagen zu beschreiben. Diese Informationen in Zusammenhang mit einer Literaturstudie helfen die elektrischen Stimulationsmethoden herauszufiltern, welche in Kombination mit mechanischer Haarentfernung angewendet werden können. Durch diese Informationen können schlussendlich auch die Parameter für eine vielversprechende Anwendung bestimmt werden.

Elektrostimulation, mechanische Haarentfernung, Schmerzreduktion, Philips

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Glossary

CL	Control leg
FES	Functional Electric Stimulation
ICT	Interferential Current Therapy
ISAP	International Association for the Study of Pain
LED	Light Emitting Diode
MDD	Medical Device Directive
OP	Operational Amplifier
PRC	Product Research Center
SG	Substantia Gelatinosa
TENS	Transcutaneous Electric Nerve Stimulation
TL	Test leg
Z_{Skin}	Skin impedance
$Z_{Electrode}$	Electrode impedance

1 Introduction

In the last decades the importance of hair removal business has steadily increased and was triggered by women's major wish to be hair free. Philips is one of the leading companies in serving consumer's needs by placing different solutions, including the mechanical epilation system, on the market. A major drawback for using this mechanical epilating system is the unwelcome occurrence of pain during the hair extraction process. During the application acute pain impacts the experience. Although Philips as well as other companies has paid attention to pain management in general for quite some time there is not yet a solution available to satisfy all consumers. The focus of already implemented solutions is based on thermal or mechanical pain relief methods. Those solutions are mainly used during or after the epilation process. There are also chemical pain relief methods on the market to make the epilation experience less unpleasant, but they are not directly implemented to an epilator.

Philips' strategy to be innovative and to come up with new solutions supporting consumers in their needs led to the decision to carry out a master's study to have more insight in combining electrical pain relief methods with the mechanical hair removal process.

1.1 Objective

The objective of this thesis was to gain knowledge about the role electricity can play in influencing the pain provoked by the mechanical hair removing process. Different possibilities which can be applied to Philips' mechanical hair removal products had to be discussed and evaluated.

First of all relevant knowledge about hair and skin was acquired. Specifically important was to describe and evaluate the process when applying electricity to the skin. Building on that principles of bioelectricity and already available electrically driven pain management solutions were studied. Those insights helped to understand how electric current can have an influence on the felt pain. Bringing all facts together a hypothesis in how electric current can be used to influence acutely occurring pain during mechanical hair removal was made and provided the base for the proposal about how a less painful or even pain-free mechanical hair removing system could be realized.

1.2 Philips pain management products

Philips has been investigating the topic of epilation for a long time. Pain management for mechanical hair removal products was and is one of the main topics for Philips Klagenfurt. This research led to various products that were placed on the market, e.g.

- Cooling ice pack,
- Vibration cap.

Figure 1-1 displays the epilator package including the Satinelle Epilator, an active massage element and the cooling ice pack. The ice pack had to be placed in the fridge for cooling down before starting the application. When clicking it on the epilator the pack is located on the back side and is used to sooth the skin and decrease the pain during the epilation process. The active massage element was used to counteract the painful application by stimulation.

The combined thermal and mechanical pain relief method was not satisfying all consumers, because there were some practical disadvantages. For example the cooling ice pack had to be cooled down in the fridge before each application. Philips Product Research Center (PRC) in Klagenfurt found out that people who do not like the detachability did complain about the practicability of the device.

Figure 1-1 Philips Satinelle Epilator with cooling ice pack and active massage element

Figure 1-2 shows a vibration cap which makes use of mechanical stimulation as pain relief method. The cap could be clicked on the epilation head and is used to counteract the pain during the application.

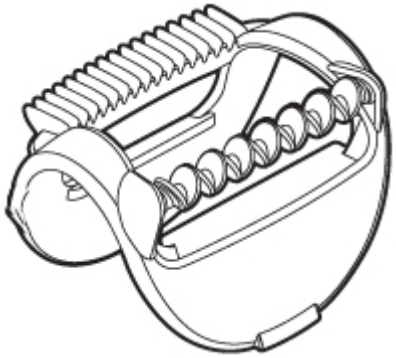

Figure 1-2 Philips vibration cap

Chemical pain management solutions were studied in the past, but there was never a product placed on the market.

1.3 Competitors pain management products

Main competitors of Philips within the epilation business are Braun, Panasonic and Groupe SEB (Calor/Rowenta). All of them have to deal with the same basic problem of pain during mechanical hair removal. However none of the mentioned companies claim with slogans like “to be pain free” or even speak of a painless application. Also none of them do offer any type of electric pain relief in combination with their mechanical hair removal solutions.

Braun offers a massage tool as well to guarantee a more pleasant application. This attachment, which is shown in figure 1-3, could be used in combination with the post-epilation cooling ice glove shown in figure 1-4.

Figure 1-3 Braun massage attachment[1]

[1] http://www.braun.com/de/female-grooming/silk-epil-epilators/silk-epil-5.html, Accessed on July 21, 2013

Figure 1-4 Braun Ice glove[2]

Panasonic does offer a skin protection attachment for their epilation systems to avoid painful skin stretching and claims pain reduction.

Figure 1-5 Panasonic skin protection attachment[3]

Rowenta as another competitor brand claims that their integrated micro massage balls in the epilation head reduce pain actively during the application process.

Figure 1-6 Rowenta epilation head including micro massage balls[4]

In a second product Rowenta makes use of a technology, where fresh air blowing reduces the pain.

Figure 1-7 Rowenta fresh air epilatior[5]

[2] http://www.braun.com/de/female-grooming/silk-epil-epilators/silk-epil-5.html, Accessed on July 21, 2013
[3] http://shop.panasonic.com/shop/model/ES-WD94-P, Accessed on July 21, 2013
[4] http://www.rowenta.de/NR/rdonlyres/B731BB4A-9E62-4BED-A30C-F48837520821/43599/ep8444_main.gif, Accessed on July 21, 2013

2 Physiological basics

Women who want to be hair free for a longer period than razor users and do not want to remove their hair by chemical methods are the target customers for epilator manufacturers. By its definition the intended use of an epilator is to pull body's hair out of the skin. To understand this complex hair removal process this chapter is drawing the connection from skin to hair and further on to the dermal nerve fiber network.

2.1 Skin

"The skin is the largest organ of the human body with its primary function to regulate its temperature, hydration and protection from the external environment." [1]
The protection function acts as barrier against mechanical, chemical or even thermal damage to the skin. Women, indeed, are looking for possibilities to get rid of their hair.

2.1.1 Structure

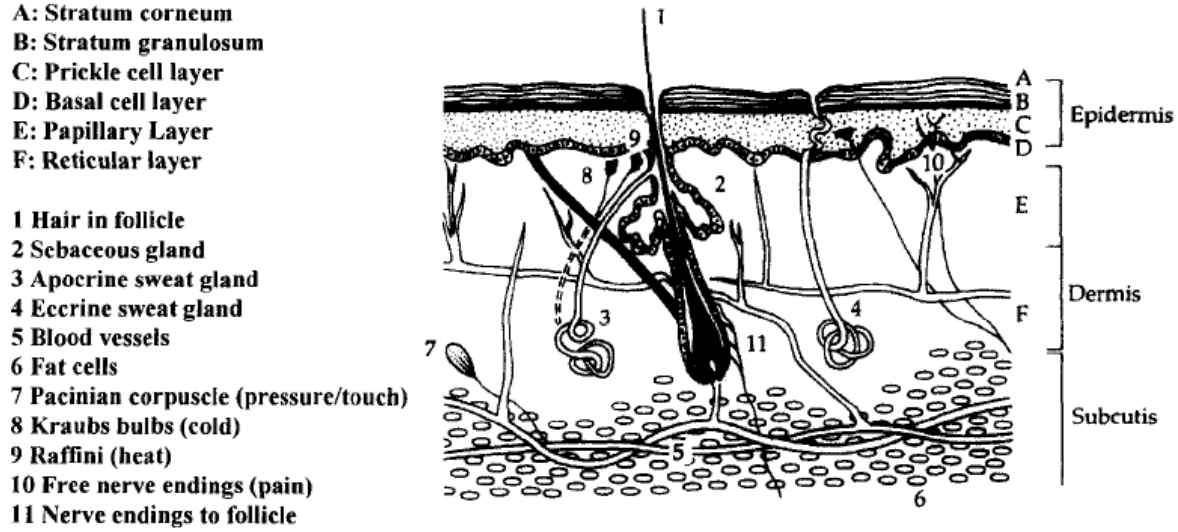

Figure 2-1 Cross section of human skin [15]

Figure 2-1 displays the three skin layers which vary in thickness and structure:

- Epidermis

  It is the outside layer of the skin - the so called protection shield of the body. The thickness varies from 0.05 to 1.5 mm. The epidermis itself is divided into four layers and the skin protection function is achieved by the stratum

[5] http://www.rowenta.com.tr/NR/rdonlyres/F9E1F725-E992-4D27-AFC4-70EE9BDDE5E1/4562/AccessEP7910_FreshAir_USP.gif, Accessed on July 21, 2013

corneum. It consists of dead cells which wear down and are replaced constantly by new ones. The stratum corneum has the highest electrical impedance of all skin layers. [15]

- Dermis

  The dermis is located between the epidermis and the subcutaneous tissue layer. It is composed of connective tissue which is responsible for the mechanical properties of the skin. Furthermore it contains sweat glands, sebaceous glands and is growing tissue for hair follicles and houses the free nerve fiber endings which are responsible for pain transmission. The thickness of the dermis varies from 0.3 mm up to 3.0 mm. [15]

- Subcutaneous tissue

  The subcutaneous tissue layer is a layer of fat and connective tissue that contains larger blood vessels, hair papilla and fat cells. Body's temperature regulation happens there. [15]

Pain relief is the main topic in this thesis and free nerve endings in the dermis are responsible for the detection of pain signals evoked as part of the protection function of the skin.

2.2 Hair

Figure 2-2 points out that a single hair originates in the subcutaneous layer but when the hair starts to grow it penetrates each layer and leaves the skin through the outermost sheath of the skin, the stratum corneum. The main tasks of a single hair are to assist the skin in its protection function against e.g. skin rubbing and to act as a dermal sensor. [15]

Women's wish to get hair free by a sustainable and pain free method is now conflicting the supporting function of a hair.

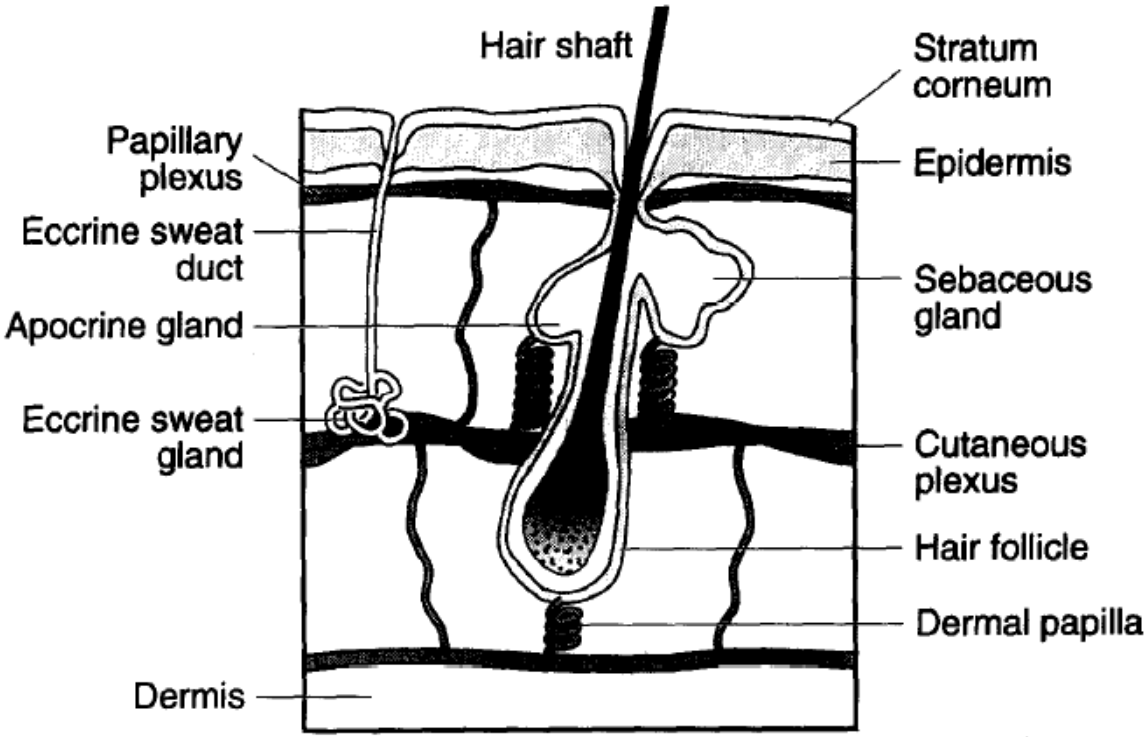

Figure 2-2 Simplified schematic of a hair follicle in the surrounding tissues [1]

2.3 Dermal nerve fiber network

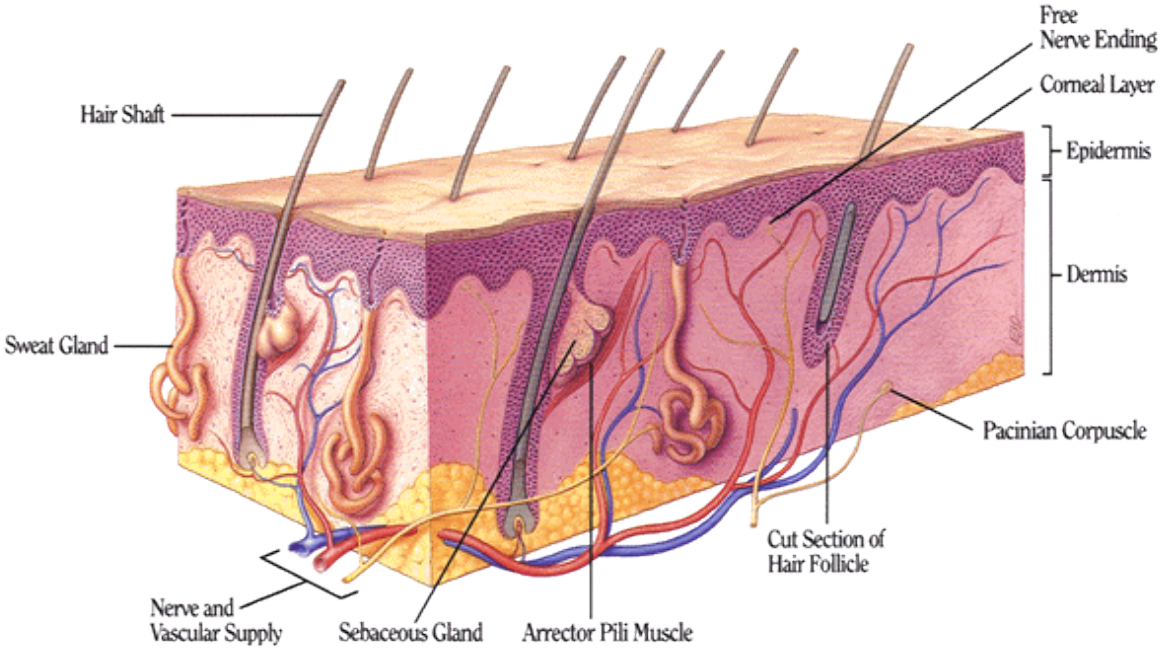

Figure 2-3 Image of hairy skin with detailed illustration of hair follicles, nerve supply, vascular supply and the free nerve endings[6]

[6] http://doctorderm.homestead.com/skinanatomy.html, Accessed on April 13, 2013

Figure 2-3 shows an image of hairy skin with schematically illustration of hair follicles, nerve and vascular supply as well as free nerve endings around the connective tissue between the epidermis and the dermis. Other nerve fibers are located deeper in the dermis at the base of each hair follicle.

Stimulation of those nerve fibers can be done in different ways. The most common types are mechanical, thermal, electrical and chemical stimulation.

3 Literature study

This chapter points out the steps of the literature research conducted. The main focus was to gain knowledge about electric pain relief and practicable methods which could be combined with mechanical hair removal in future.

There has no project been addressed to the topic of electric pain relief at the innovation site in Klagenfurt yet. The Philips research center in Eindhoven in contrast has already built up a knowledge base in chronic pain management and general facts about hair and skin due to their extensive research in the field of epilation in the past.

The first step was now to look through all the relevant publications which have been written by Philips research teams. A literature search in Philips' internal database was conducted by using the following keywords:

- Skin
    - Electric skin model
    - Electric skin properties
- Hair
    - Hair extraction
    - Mechanical hair removal
- Pain
    - Pain relief
    - Chronic pain
    - Acute pain
- Nerve stimulation

Unfortunately it became clear that Philips research had done extensive research in electric pain relief for chronic back pain and osteoarthritis of the knee only. Although basic facts about skin and its electric behavior as well as information about hair extraction and epilation was found, no relevant information about acute pain relief could be gathered.

The second source for literature was the online and the offline library at Graz University of Technology where most information about anatomy of hair and skin could be found.

As third source the following online databases were used to find relevant material in scientific literature published within the last 20 years:

- IEEE Xplore
- PubMed
- SpringerLink
- Wiley Online Library

By using all the three mentioned sources the following topics could be covered:

- Basics in hair and skin
- Electric stimulation
- Acute pain relief

To provide a more comprehensive search all possible combinations between keywords in some basis sets were used. It turned out that the use of appropriate keywords is pivotal for finding all relevant information. An effective way to retrieve a complete set of information is to use single sets and permute them. As example the set about the role of nerve fibers in combination with the gating mechanism is displayed in table 3-1

Set 1	***Set 2***	***Set 3***
Gate-control-theory	A-beta	fiber
Gate control theory	A-β	nerve fiber
Gating theory	Abeta	fibre
	A beta	

Table 3-1 Example for a complete set of keywords

An important issue in this literature study was to identify the quality of the gathered information. Therefore the search was conducted via common databases with an engineering focus which are established for more than 20 years. Classification of publications was done based on the quality indices of the respective journal. Additionally to the above named methods of quality verification there was also a

critical discussion of literature with the Philips supervisors or some experts in Philips' provided network. To prove the content of the found publications cross-references to original papers have been critically reviewed.

4 Pain

On the website of the International Association for the Study of Pain (ISAP) pain is defined by:

“An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.” [16]

Pain is a barrier for women to start epilating. Although the body gets used to the pain and the subjectively felt pain decreases after a few applications the biggest problem for inexperienced women is to get started with epilating. As described in chapter 1 the current available products on the market are not even claimed to be painless and therefore the market potential of a completely pain free mechanical hair removal method is enormously high.

4.1 Pain measurement

In general pain can be subdivided into two types: acute pain and chronic pain. The intensity as well as the duration of the stimulus can be seen as determining criteria to differentiate between the types of pain. When the reaction to the applied stimulus occurs slowly but with slightly rising intensity it would address to chronic pain. On the contrary acute pain can be described as sharp and fast pain.

So far no method exists to quantify pain objectively. [15]

For this thesis the very intense acute pain is relevant, because hair extraction due to mechanical hair removal is only a short but suddenly appearing stimulus.

4.2 Pain chain

Pain is a multidimensional sensation which is highly influenced by our psychological and physiological condition. To demonstrate it in a more simple way the three sub processes of the pain chain according to Lefki are displayed in figure 4-1 [15]:

Figure 4-1 The pain chain [15]

In table 4-1 each single process of the pain chain is described:

Component	Related physiological structure	Complexity	Physical process	Pain control
Detection	Nerve endings & receptors	High	Tissue damage	Neutralize pain through substances like acetylsalicylic acid
Transmission	Nerve fibers & spinal cord	Very high	Electro-chemical process of cell membrane	Blockage of pain transmission, gate-control theory
Interpretation	Spinal cord & brain	Extremely high	Neural interactions	Opioids, hypnosis

Table 4-1 Detailed description of pain chain components [15]

4.2.1 Pain detection

Detection of pain occurs by free nerve endings in the dermis. Stimulation of these pain reception sensors, so called nociceptors, happens when a possibly dangerous and damaging action is ongoing. They react immediately to the applied stimulus, which further on evokes acute pain signals, but also refers to chronic tissue damage. [15]

Nociceptors belong to the group of peripheral nerve fibers which are responsible for the transmission of perceived pain. Cutaneous nociceptors have different types of nerve fiber filaments, so called axons, which transport the electrical signals between nerve cells. [14]

Substances which activate nociceptors are named agonists. Accordingly antagonists are substances which block nociceptive signals or cause an anti-nociceptive behavior and result in avoiding pain. [13]

As shown in figure 4-2 at the top of each hair follicle there are nerve fibers to detect reactions inside or outside the skin and transmit the signals then to the brain. This behavior is linked again to the main task of a hair: to act as a sensitive touch receptor and support the skin in its protection function. [13]

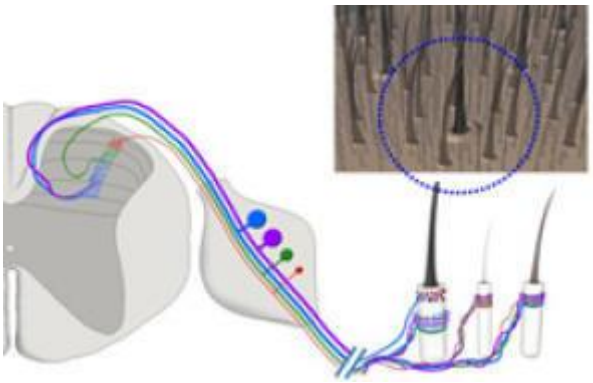

Figure 4-2 Detecting nerves pathway between the periphery and the spinal cord[7]

4.2.2 Pain transmission

The signal is transported from the peripheral site via the spinal cord to the brain by a special type of nerve fibers, which can be categorized, as shown in figure 4-3, by:

- group
- function,
- mean diameter and
- mean conduction velocity.

Another classification, which would differ in the occurrence of the myelin sheath, is not so common in the literature as it would only differentiate between C fibers and the rest.

Fiber group	Innervation / Function	Mean diameter (in microns)	Mean conduction velocity (in m/s)
A-α (alpha)	Primary muscle spindle, motor to skeletal muscles	15 (12-20)	100 (70-120)
A-β (beta)	Cutaneous touch and pressure	8 (5-15)	50 (30-70)
A-γ (gamma)	Motor to muscle spindle	6 (6-8)	20 (15-30)
A-δ (delta)	Mechanoreceptors, nociceptors	<3 (1-4)	15 (15-30)
B	Sympathic pre-ganglionic	3 (1-3)	7 (3-15)
C	Mechanoreceptors, nociceptors sympathic post-ganglionic	1 (0.5-15)	1 (0.5-2)

Figure 4-3 Erlanger/Gasser classification of nerve fibers [15]

Fibers of group A-delta ones are responsible for quick, but short termed pain and can conduct action potentials with a mean speed of about 15 meters per second through the body. [13]

[7] http://www.hopkinsmedicine.org/news/media/releases/touching_a_nerve, Accessed on April 13, 2013

In fibers of group C the signal is transmitted way slower with about only 1 meter per second. These fibers are responsible for the less intense, but longer lasting type of pain. [13]

Fibers of group A-delta and C transmit signals received by the activation of nociceptors, which is an automated reaction on a painful stimulus. The transmission of nerve impulses is determined by the passive electrical cell membrane properties, e.g. resistance and capacitance. [12]

The electrical impulses are characterized by the same amplitude, but differ in frequency as subject of the stimulus amplitude. When increasing the initiating stimulus also the occurrence of the electric impulses gets more frequent, which means that they have a higher firing rate. [15]

4.2.3 Pain interpretation

Interpretation of pain is done by the brain in a highly complex action. According to K. Lefki some general effects can be observed:

- when the pain is expected to be harmless at the first incidence the resulting pain sensation is higher, because of underestimation
- when the painfully treated person can be distracted in a positive way by for example music, light or a nice conversation the subjectively felt pain sensation will be lower [15]

The way of pain interpretation is mostly based on the individual pain sensitivity and is modulated by the interaction of different neurons in the brain. [15]

A more detailed discussion of pain interpretation is not focus of this thesis.

4.3 Pain modulation mechanisms

When studying pain relief due to electrical stimulation of nerves there are two relevant modulation theories described in the literature. Both theories apply to the nerve fibers network including large nerve fibers belonging to the group of A-beta ones and small nerve fibers, which are of type A-delta and C. figure 4-4 explains how the information, which is sent by the different groups of nerve fibers, is transmitted between the spinal cord and the brain and further on influences the descending control and the action system. The large and small types of nerve fibers act directly on the substantia gelatinosa (SG), an inhibitory area within the spinal cord, which subsequently reports further to the central transmission cells (T). The transmission cells belong to the gate control system and are directly linked to the body’s action

system, which is responsible for counteracting the stimulus. This action system affects, in turn, the descending control system to autonomously counteract the stimulation. [17]

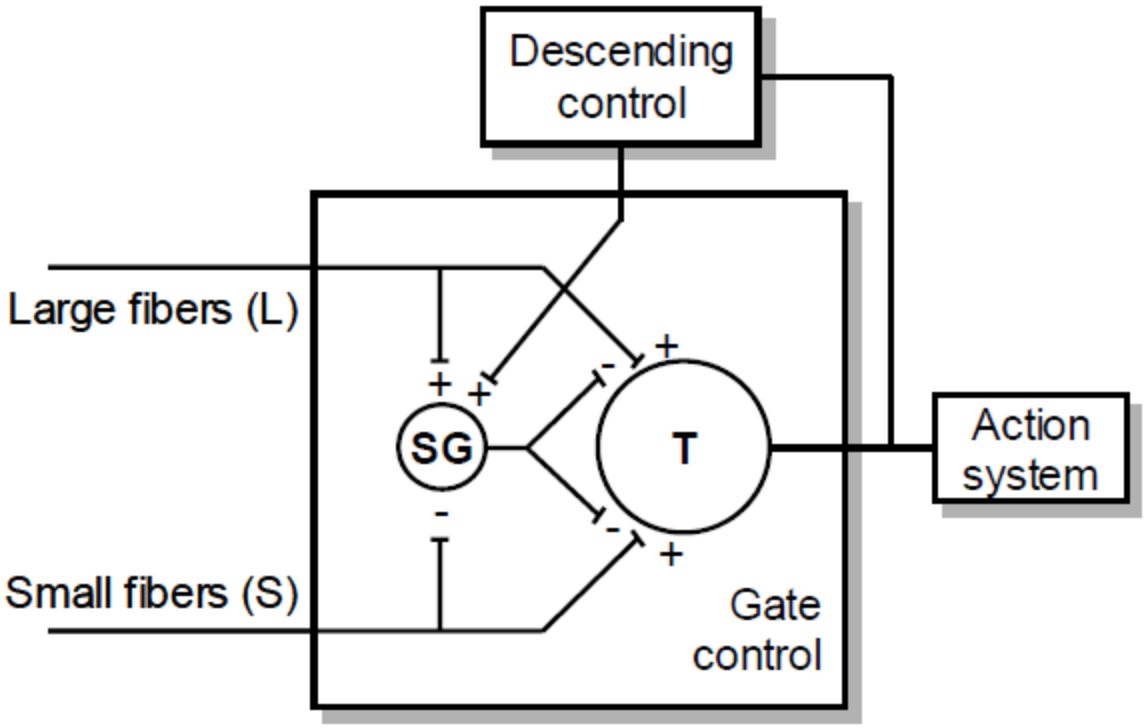

Figure 4-4 Diagram of pain modulation mechanisms: gate control theory and descending control theory [18]

4.3.1 Gate control theory of pain

The gate control theory of pain is described in the paper “Pain Mechanisms: A New Theory”, which was published by Melzack and Wall in 1965. [17]

The authors proved the existence of a gating mechanism which controls the flow of signals sent from the peripheral receptors via nerve fibers to the brain. Three relevant aspects of stimulation were considered:

1) the resting activity which existed before a stimulus happens
2) a stimulus evoking activity
3) the relative balance of activity between large and small fibers. [17]

During resting activity the SG stops the further transmission of signals by deactivating the transmission cell, which would otherwise continuously forward nerve impulses to the action system, as can be seen in figure 4-5. Those forwarded signals are likely to contain useless information. The figure shows that the activation “+” of the transmission cell is neutralized due to deactivation “-“.

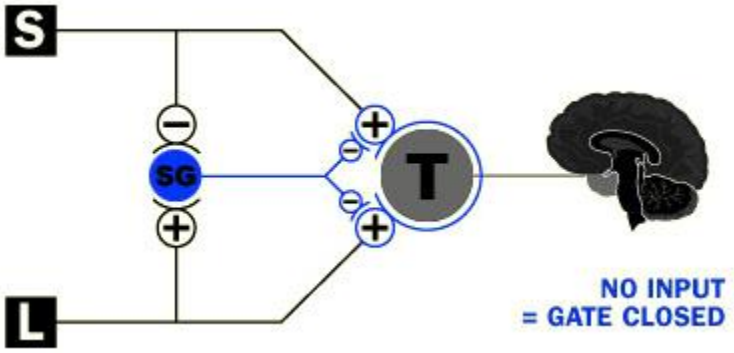

Figure 4-5 Gate control theory without peripheral input[8]

When now an evoking stimulus is applied to small or large nerve fibers they immediately start to transmit the signal further to the transmission cells. When receiving signals the transmission cells get activated, this is characterized by a “+” in front of it, and transmit the signals further to the brain.

The main player in this transmission is the substantia gelatinosa. By either activating “+” or deactivated “-“ the functionality of the transmission cells the SG is triggering the information flow towards the brain.

As can be seen in figure 4-7 the small nerve fibers of type A-delta or C transmit the signal directly to the transmission cells. The substantia gelatinosa does not take action, because it is deactivated and the transmission cells propagate the signals further on to the brain whereas the action system takes action.

The substantia gelatinosa only gets activated by large nerve fiber input as indicated in figure 4-7. The inhibitory effect of SG counteracts the activation of the transmission cells and stops the further transmission of all signals to the brain.

Concluding the publication it can be stated that the transmission cells act as a guard on a gate to the brain. The guards’ task is to make a decision on either further transmitting or blocking the signals arriving at the transmission cells based on the types of transmitting nerve fibers.

[8] modified from http://static.ddmcdn.com/gif/pain-2.gif, Accessed on July 21, 2013

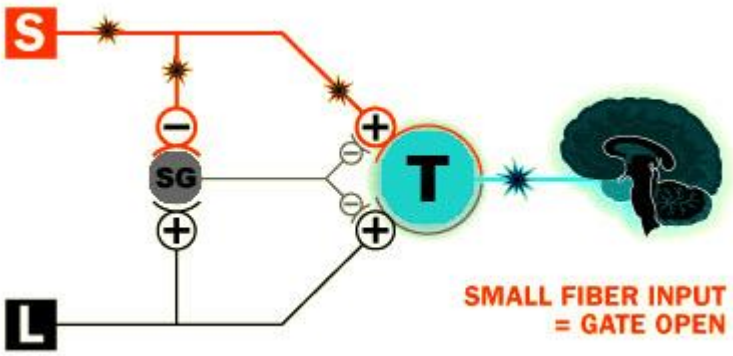

Figure 4-6 Gate control theory at small fiber input[9]

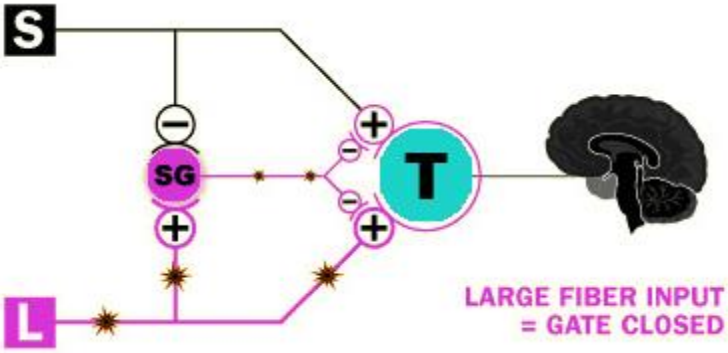

Figure 4-7 Gate control theory at large fiber input[10]

The last stage described by Melzack and Wall is characterized by the disproportional increase of activation in large and small nerve fibers. As transmission is faster in large nerve fibers the amount of information transmitted by these fibers will increase more than in small nerve fibers. [17]

According the gate control theory formulated by Melzack and Wall it can be summarized that the selective activation of large nerve fibers has an inhibitory effect on transmission of pain signals.

4.3.2 Descending pain control theory

The descending pain control theory states that the humans' central nervous system is triggered by the body's action system as shown in figure 4-4. The descending control system then is able to modulate the perceived pain level via the production of natural opioids like endorphin, encephalin and dynorphin. Those substances affect the descending brain signals travelling from the brain to the spinal cord and therefore also influence the intensity of pain signals on to the afferent path. [18]

[9,10] modified from http://static.ddmcdn.com/gif/pain-2.gif, Accessed on July 21, 2013

This means that signals coming from pain sensors also activate a sort of inhibitory mechanism, which starts to suppress the transmission. [17]
This body's autonomously induced action protects the brain from getting overloaded.
The descending path will not be further taken into account in this thesis, because it cannot be controlled by external mechanisms.

4.4 Pain during epilation

Based on the previous information the pain chain during epilation can be described as follows:

1. Nociceptors get activated due to pulling the hairs out of the skin, which generates the initial pain signal.
2. The sum of those signals is now sent to the spinal cord and modulated as described in the gate control theory.
3. The third and last step is characterized by how the brain interprets the signal containing painful related messages.

The different stages of the pain chain can be stated as:

1. Reducing the activation of the nociceptors the deformation and mechanical stress on the skin has to be decreased.
2. According to the gate control theory the transmission of a pain signal can be blocked by stimulation of other types of nerve fibers.
3. The complex mechanism of pain interpretation can only be influenced on emotional or rational base.

The method of influencing the transmission of the signals by selective stimulation of single types of nerve fibers appears very attractive. The next chapter covers the topic of how the activation of nerve fibers takes place.

5 Bioelectricity

This chapter deals with the reaction of our skin to electricity applied and how the activation of nerve fibers takes place. It is important to keep in mind what the body's behavior is before, during and after applying electricity, when thinking of an electric pain relief solution.

The ion mobility determines ones body's resistivity. This mobility is driven by electrostatic forces i.e. force provoked by charged particles on each other [6]

Inside the electrodes the charge is carried by electrons, but when inducing electricity to body's tissue ions take part in carrying the charges. [13]

According to Grimnes' and Martinsen's publication skin is an anisotropic structure and reacts on a potential difference evoked by the application of electricity to the skin. [3]

Two main effects take place:

1) charged particles (ions) begin to move towards the electrodes with opposite electrical sign
2) signals, which are transmitted along nerves, cause depolarization [3]

5.1 Electric properties of the skin

When speaking about the electrical behavior of the skin the complex horizontal layers as well as the skin's vertical structure, as explained in chapter 2, have to be taken into account. When applying a voltage across the skin electrical charges start to move along the vertical and across horizontal skin structures. Electricity does not only provoke a reaction inside the skin, also an reaction outside of the skin under the applied electrodes could be possible. [4]

Tissue cannot be seen as a single, homogenous material. The skin does consist of several layers, which are variously composed and do carry the charges in different ways between those layers. [1]

Out of the foregoing it can be said that tissue components get affected by the applied electricity in a complex way. One possibility to get more information of the skins electrical behavior would be a simulation taking into account the individual behavior of each component during application. But this simulation is not part of the thesis.

5.2 Cell excitation

Electric signals in nerves are transmitted due to a change in membrane potential, which is the difference in electrical potential between the inner and the outer membrane of a nerve cell. In figure 5-1 the time course of the membrane voltage of a nerve cell is shown before, during and after stimulation. The resting potential of a nerve cell is at about -70 mV. When initiating a stimulus the nerve's membrane voltage is going to change up to a maximum of +40 mV.

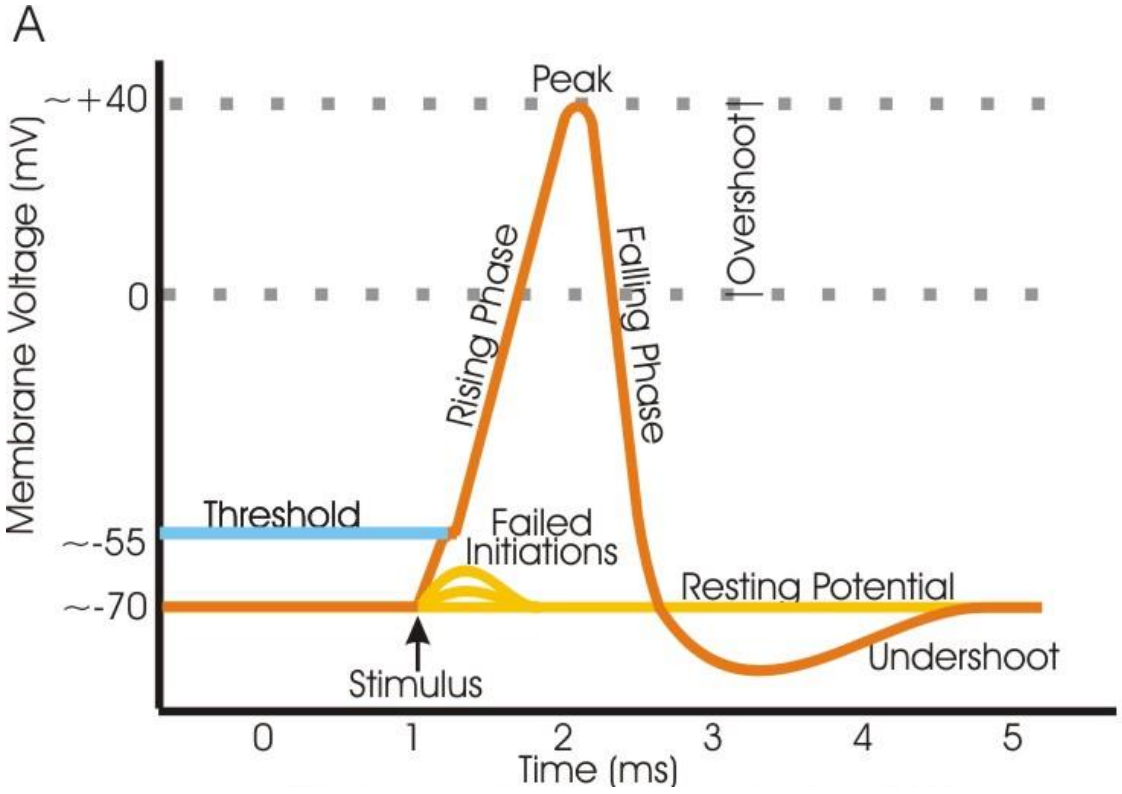

Figure 5-1 Time course of an action potential [11]

To stimulate a nerve cell the membrane must get depolarized, i.e. the potential difference between inner and outer side of the membrane must be increased above the threshold. When the depolarization is too weak to overcome the threshold the stimulus remains unnoticed. On the other hand when exceeding the threshold level a so called action potential is generated and a depolarized wave travels autonomously to the brain. Nerve cells are in direct contact to each other and therefore a change in ones membrane potential also affects other nerve cells, which leads to spreading out of the nerve impulse into the whole body.

[11] http://en.wikipedia.org/wiki/File:Action_potential_vert.png, Accessed on July 31, 2013

The stimulus intensity must be sufficient to reach the threshold otherwise the nerve impulse cannot spread along. The stimulation time has to be long enough to stimulate a nerve cell to transmit the signal. Finally the stimulus has to vary dynamic over time. All three conditions are described in the so called “All-or-none-law”, which states that the stimulus has to fulfill these conditions to spread along the body. When the stimulus remains below the threshold it stays unnoticed. [4]

5.3 Skin impedance

Skin with its layers, the dry stratum corneum, epidermis, dermis and the insulating subcutis layer followed by the muscle tissue can be simplified as the series of skin impedance Z_{Skin} and electrode impedance $Z_{Electrode}$. Both impedances can be modeled as parallel circuit of a capacitor and a resistor as shown in figure 5-2. [1]

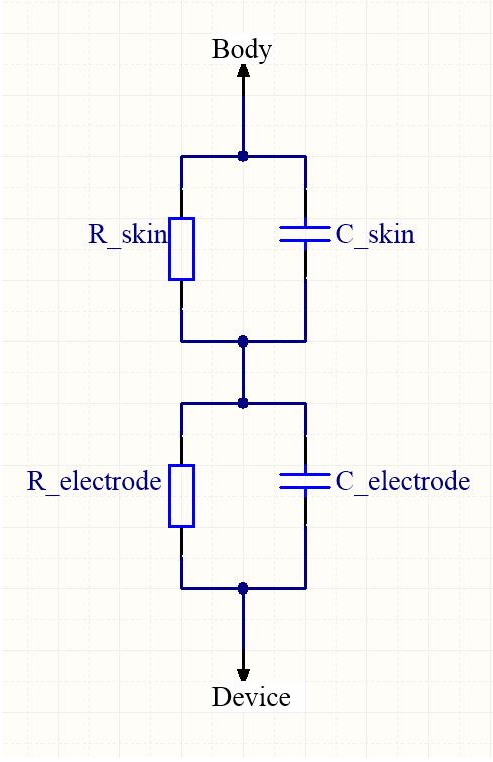

Figure 5-2 Equivalent circuit model of the electrode and skin

Someone’s skin impedance is depended on the applied frequency, the size of the skin area between the measurement electrodes and the skin’s condition. Generally it can be said that skin impedance increases when decreasing the contact area. [1]
The skin condition is furthermore characterized by the perspiratory glands and the blood circulation, as represented in figure 5-3.

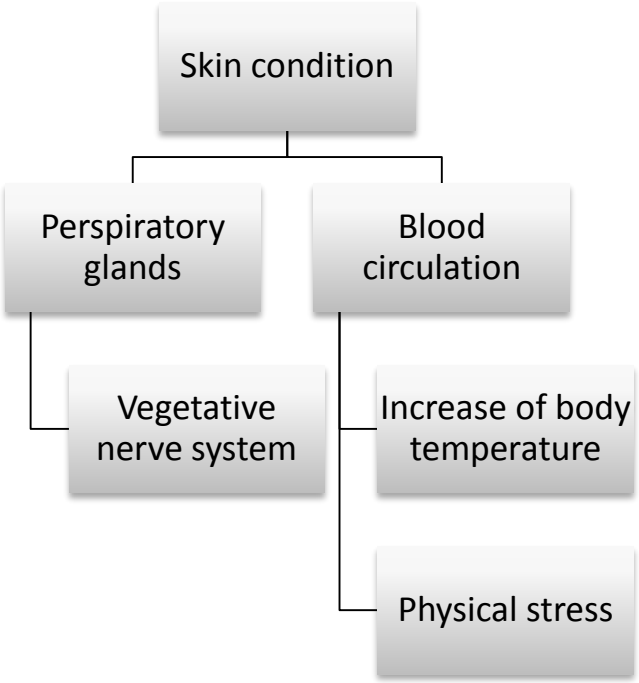

Figure 5-3 Characterization of skin condition [4]

In the literature skin impedance is stated between 100 Ω and several MΩ. [4]
Actually the measured impedance varies between 10 kΩ and 1 MΩ and differs from the literature based values because of facts like

- Electrode area
- Skin temperature
- Vegetative nerve system
- Moisture level of the skin
- Blood circulation inside the skin etc. [4]

In this chapter the basis information about the body and its reaction to electric stimulation has been covered. The next chapter describes the possibilities of electric stimulation in general and focuses in detail on the application of electric stimulation in combination with the mechanical hair removal process.

6 Electric stimulation

In former days electrotherapy, which means the use of electricity for therapeutic issues, was used only for wound healing and muscle regeneration. Due to the extensive use of electricity in the field of rehabilitation and pain management, the term electrotherapy was replaced by a broader one: electric stimulation. [13]
No clear terminology exists and electric stimulation is used synonymously with:

- Functional electric stimulation (FES),
- electrostimulation,
- electrical stimulation

All applications for which the term stimulation in combination with electricity is used have in common that they make use of de- or hyperpolarization of excitable cell membranes by means of applied electricity. [13]
Electric stimulation can be classified according to different medical applications into three classes:

- low frequency stimulation at 0 – 1 kHz,
- mid frequency stimulation using 4 kHz – 10 kHz,
- high frequency stimulation in the range of 10 MHz – 2,5 GHz. [19]

The combination of the gate control theory in chapter 4 and the mechanism of nerve cell stimulation in chapter 5 form the base for an electric approach of pain relief. Sundar and González-Cueto described in their publication "*On the Activation Threshold of Nerve Fibers Using Sinusoidal Electrical Stimulation* " how to make use of electric stimulation for pain relief by the use of selective activation of large A-beta fibers. Their aim was to use alternating current at different frequencies to selectively excite nerve fibers. The individual depolarization threshold depends on the size and conduction velocity of the nerve fibers. Summarizing Sundar and González-Cuetos publication it can be stated that using a sinusoidal waveform at 2 kHz a selective excitation of A-β fibers will take place, i.e. no other fibers will be stimulated. [2]

In the literature study described in chapter 3 the following alternative methods to manage pain by using electric stimulation were identified:

- Electric Acupuncture
- Transcutaneous electric nerve stimulation
- Interferential current therapy

- Russian current stimulation

Electric acupuncture is an invasive method where needles are plugged into the body's electric acupuncture points during the treatment. Due to the invasiveness, it is not applicable to be used together with an epilator and therefore excluded in this thesis. [7]

The other mentioned electrical stimulation methods are non-invasive and have hardly any contraindications. Therefore these methods are used for further discussion in this chapter. [18] [20]

6.1 Transcutaneous electric nerve stimulation (TENS)

Transcutaneous Electrical Nerve Stimulation (TENS) is by definition:

"Electrical stimulation of the skin to relieve pain by interfering with the neural transmission of signals from underlying pain receptors."[12]

It is one of the most used electrical methods for releasing pain. It makes use of pain modulation mechanisms to block signal transmission by selectively stimulating nerve fibers. [18]

TENS also plays an important role in clinical pain management in Western countries. [9]

Transcutaneous electric nerve stimulation is an inexpensive way of non-invasive treatment, as discussed before, and does not have any major side effects. There is no toxic potential and in home-used devices patients can determine their dosage by themselves. Patients using TENS devices are able to administer themselves without medical assistance after conducting a simple training. [8]

Current TENS devices are mostly battery powered electrical units that make use of electrodes to bring electrical impulses inside the skin to affect transcutaneous nerve fibers. People will feel a sort of prickling on their skin and the evoked stimulus is designed to generate a nerve signal which interferes with the transmission of the pain signal to the brain. [18]

In figure 6-1 the principle of transcutaneous nerve stimulation for pain relief by the use of the gate control theory is shown. Low threshold A-beta fibers activate the gating mechanism and the signals, which are transmitted via A-delta and C fibers, get blocked by the closed gate. The painful stimulus is now hindered to reach the brain and the signal transmitted by A-beta fibers evokes a sort of numbness. [8]

[12] http://www.merriam-webster.com/dictionary/tens, Accessed on July 21, 2013

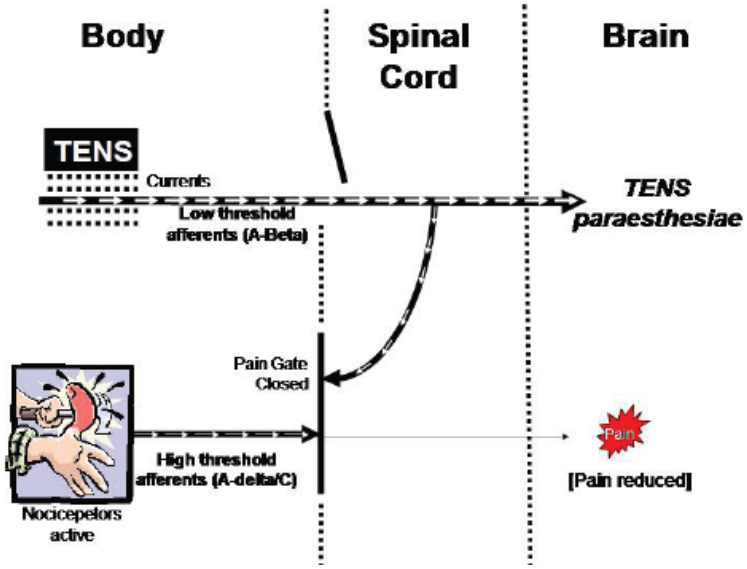

Figure 6-1 The principle of TENS for pain management using the gate control theory [8]

6.1.1 Characteristics of a TENS device

A typical setting for a common TENS device is:

Frequency	1-250 Hz
Amplitude	1-50 mA
Duration	10-1000 µs
Patterns	• Continuous • Burst • Modulated
Modulation in	• Frequency • Amplitude • Pulsewidth

Table 6-1 Pulse parameters of TENS application [18]

Figure 6-2 displays the user's possibility to control parameters like pulse pattern, pulse frequency and pulse duration of a standard 2 channel TENS device.

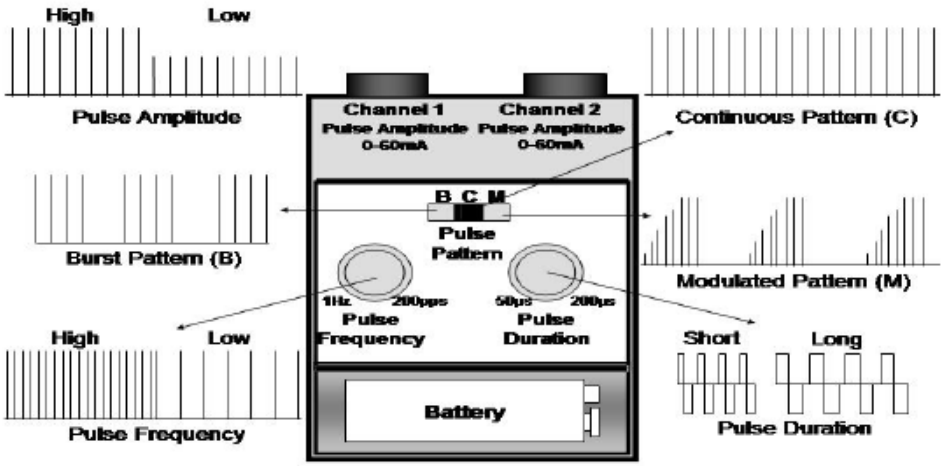

Figure 6-2 Settings of a standard TENS device [8]

Depending on the chosen setting a TENS device can either conduct stimulation at muscular or nervous level. Muscle contraction can be evoked by matching high intensity modes together with lower frequency settings. When, on the other hand, the frequency is increased up to 200 Hz while decreasing the amplitude the stimulation occurs primarily on the nervous level of the body to treat acutely occurring pain.

TENS applications with a frequency range around 100 Hz and intensities between 10 to 35 mA are used for chronic pain management. [18]
There are different types of TENS and the most common ones are:

- continuous (conventional) TENS
- acupuncture-like TENS
- brief (intense) TENS [18]

Each type is characterized by a particular frequency spectrum and intensity (amplitude) level. Acupuncture-like and intense TENS work in higher intensity ranges than the conventional TENS does. The frequency range is lower for acupuncture-like TENS than for the other two application modes. When referring to the statement about the difference in frequency and amplitude between muscle and nerve stimulation it can be stated, that conventional TENS offers the best parameter to provide nerve stimulation - low intensity and high frequency stimulation, which further leads to activation of A-beta fibers. Also the analgesic effect as a result of a common TENS application appears and disappears immediately after the application was started or stopped respectively. This working principle relies on the gate control theory of pain. On the contrary the pain relief principle of acupuncture-like or intense TENS is a prolongation of the felt sensation, which is linked on the descending pain control theory. [8]
Sluka and Walsh did research on how a patient feels during a TENS application. For conventional TENS application they described that the user underwent a strong, but non-painful analgesic experience with minimal muscle activity. The sensation was described as “tingling” or even a pleasant “electrical paraesthesia”. From physiological view conventional TENS achieves the required effect – it activates large diameter fibers, A-beta ones, which trigger the gating mechanism to close the gate for signals transmitted via A-delta or C fibers. [11]

6.2 Interferential current therapy (ICT)

ICT provides a technique where two pairs of electrodes are placed diagonally on the skin so that the treatment area is in the middle, as shown in figure 6-3. The electrodes are supplied by two different electrical currents. When the currents are crossing an interfered current is produced by these two signals. This method is used to excite deep-located nervous tissue, which cannot be excited by conventional

TENS. The ICT method stimulates A-beta fibers, which interfere with the pain signals according to the gate control theory. [18]

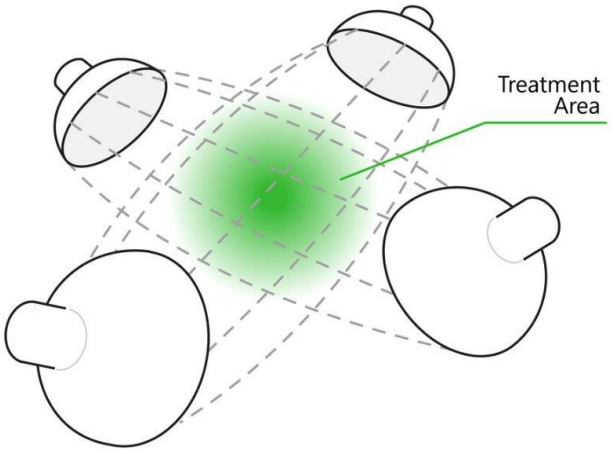

Figure 6-3 Electrode placement for ICT[13]

6.3 Russian Current Stimulation

Another method to stimulate in the kilohertz frequency range is the Russian current stimulation, which was used as physical therapy in elite athletes in Russia. [20]
Originally it was used to perform muscle stimulation at a frequency of 2.5 kHz with rectangular bursts, but there is also evidence that is was used in continuous mode. When using the 2.5 kHz for the purpose of muscle stimulation the electrodes have to be applied very precisely next to the target muscle, which is not trivial. When stimulating muscles in an indirect way via nerve fibers the optimum frequency has to be decreased to 1 kHz. A frequency around 2.5 kHz might not be the ideal one in combination with commonly used electrode positions to conduct muscle stimulation. [20]

6.4 Electrode placement

The intended use of an electric stimulation device is to pass electrical current between two points of the body. To apply the electrical current to the body usually sticking electrodes are used. There are several side effects evoked by the electrodes, which have to be taken into account when speaking about the ideal outcome of the experiment. For this thesis it can be stated that contact area, specified by the electrodes distance on the epilators head, as well as the electrodes placement have major influence on the outcome.

[13] http://i00.i.aliimg.com/img/pb/980/219/107/107219980_197.jpg, accessed on October 23, 2013

Ideally the contact area between the electrodes has to be as small as possible to produce only local analgesia between the two electrodes. One realisation for placing the electrodes as near as possible beside the disks is demonstrated when having an epilator with metal disks is shown in figure 6-4. Here the metal disks could directly be used as electrodes whereas in figure 6-5 the electrodes have to placed on the outer sides of the head.

Figure 6-4 Epilation head including electrodes for metal disks

Figure 6-5 Epilation head including electrodes for glass fibre reinforced plastic disks

In fact for this thesis it is not possible to place the electrodes directly on the epilators head. To exclude having an impact by placing the electrodes differently on the skin it is necessary to specify the application area as good as possible before testing. Also electrode size has to be taken into account.

In the literature current density [S] is stated as the ratio of the applied current [I] to size [A] of the application area.

$$S = \frac{I}{A} \tag{1}$$

This means, that when the electrodes size is decreased by factor 2 the current must be doubled to maintain the same density.

Not only current density, but also electrode placement will have an impact on the effectiveness of nerve stimulation. To guarantee a standardized application the electrodes should be located on the epilation head directly as told before. They get in contact with the skin together with the epilation disks. The geometry of an epilator's head limits the electrode placement position. It is known that any surface change in front of the epilation disks will decrease the hair catching performance. The skin impedance Z_{skin} as function of the current density S and the frequency f is shown in figure 6-6.

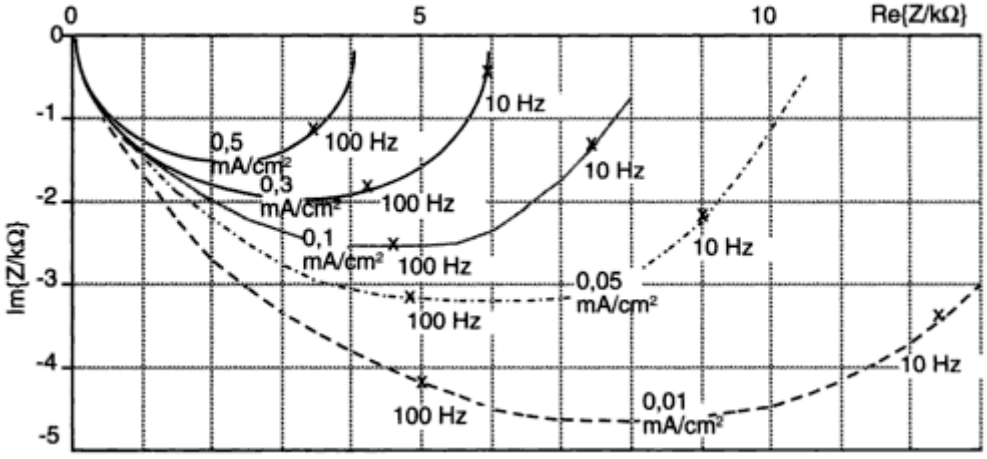

Figure 6-6 Skin impedance as function of current density and frequency[4]

6.5 Safety rules

A consumer product in combination with an electric nerve stimulator should consider also the safety aspect of an electric shock.

The following aspects are determining whether an electric shock is produced or not:

- The amplitude of current that flows through the body.
- The way it takes through the body.
- The duration of the current pulse. [5]

There are more factors that have an influence on how the electricity affects the body:

- The body resistance.
- The moisture level of the skin.
- The health status of the person receiving the shock. [5]

Beneath electric shock several other effects could occur when applying electric current to the body:

- Tingling sensation
- Muscle contractions
- Electrolysis of tissue
- Local burns. [7]

Epilators are used by women mainly in body zones like legs, armpits, face or their bikini zone, which leads to the assumption that a treatment close to the heart region can be almost excluded. Nevertheless it must be stated explicitly in the directions for use and warnings, that the chest region is excluded as region for intended use, as it would be likely for males.
Additionally the device has to keep current and voltage limitations according to the laws and standards.

6.6 Preliminary device classification

In order to have a device classified as medical device according to the MDD it must fulfill the definition of the medical device, which is written in Article 1(2) (a). There is defined, that every instrument, apparatus, appliance or other article intended by its manufacturer to be used specially for diagnostic and/or therapeutic purpose and necessary for its proper application intended by the manufacturer to be used for human beings is a medical device according to the European Medical Device Directive when using it for a purpose of diagnosis, prevention, monitoring, treatment, alleviation or compensation of an disease, for an injury or handicap and investigation, replacement or modification of the anatomy or of a physiological process. [21]
Medical devices are categorized into 4 groups – it can either be a class I, IIa, IIb or class III type of medical device. The classification has influence on the certification process and depends on rules involving:

- duration of body contact,
- invasive character of the device,
- use of any energy source and
- effect on the nervous system. [21]

When the manufacturer defines the intended use of the electric nerve stimulation device for therapeutic purpose the device is clearly classified at least as medical

device category IIa. The categorization on the example of an electric nerve stimulator according to the European MDD can be found in the Appendix. [21]
When focusing on a marketable consumer product, composed by an epilator and an electric stimulator it is not that easy. The intended use for such an application is neither diagnostically nor therapeutically. According to the definition a medical device is defined to be used intendedly for medical purpose, assigned by the manufacturer. The purpose of mechanical hair removal cannot be stated to be medical. These points lead to the argumentation of having a non medical device, but should be clarified with the local government first.

When speaking about placing such a device on the US market the main claim of the product will be determining for its classification. For example the Philips safety, compliance and regulatory affairs officer did explain when claiming the product with a term like “pain suppressing” the device will be classified as a medical product.
The claim is clearly indicating a medical purpose and so the whole system is also again classified as a medical device. Another method to classify devices in the US would be to have a look on similar devices and apply their classification rules by analogy.
Concluding this paragraph it can be stated that in the US the main claim will be indicatory for categorizing the device whereas in Europe the intended use and medical purpose is determining for naming it medical or non-medical.

7 Patentability

Every inventor is looking to create something new, but to grant a patent on an invention the following requirements must be fulfilled:
The invention must be protectable and a novelty. It must include an inventive step and at least also has to be applicable in industry.
In chapter 1 different products providing pain management solutions, placed on the market by Philips and competitor companies like Braun or Panasonic, have been discussed. Although there was not yet an epilator combined with an electric nerve stimulator placed on the market a patent research was conducted. The patent research did light up possibly granted patents related to epilation in combination with electricity. Main focus when reviewing these patents were electrode placement and application settings.

7.1 Patent research

For this thesis the patent search was conducted via Espacenet[14], which is the web based search engine of the European patent office and also used at Philips. Furthermore colleagues from Philips patent department were interviewed, because they deal with this topic every day and sometimes there is not yet a patent filed, but competitors have already published documents.
5 relevant publications could be found on a mechanical hair removal device in combination with electricity for reduction of pain.

7.1.1 Braun EP0986319B1

In this patent an epilation device equipped with a device including at least one electrode to reduce the sense of pain during epilation is characterized in that *“said device is operable to produce an electric spark on the skin, in particular prior to the extraction of the hairs”*. [22]

7.1.2 Braun EP1000562B1

This patent describes a device for plucking hair from human skin including a rotating cylinder and a unit for reducing pain sensation, which is characterized in that *“the clamping device can produce a rotary motion with cyclical plucking of hair and the unit is coupled with the rotary motion of the clamping device immediately before the clamping device is arranged in the rotational direction in such a way that the skin is in*

[14] http://worldwide.espacenet.com/

an operating position by an impulse prior to the plucking of hair" and characterized in that *"the unit delivers a mechanical impuls and/or an electrical impulse"*. [23]

7.1.3 Braun EP1582112B1

In this patent an epilator, a device to generate a current signal and at least two electrodes to bring the current signal into the skin for pain-relieving means are described and characterized in that *"the current signal has a frequency of between 3 kHz and 20 kHz, preferably approximately 10 kHz, and an effective current intensity in the range of between 0.1 mA and 15 mA"* in the main claim. The other claims in this patent are amongst others characterized in that *"the current signal is modulated, preferably amplitude-modulated"*, *"the current signal is sinusoidal and/or sinusoidally modulated" and "the duration of the current signal is approximately 10ms"*. [24]

7.1.4 Matsushita JP8140726A

This patent application describes a device which is claimed to *"an epilation process removing hair by giving an electric stimulus to the skin and systema nervosum peripheric um as stimuli other than a depilation stimulus"* to eliminate the pain during the process of mechanical hair removal. [25]

7.1.5 Braun EP0748174B1

In this patent an epilator to reduce the felt pain characterized in that *"the appliance includes at least two electrically conductive parts which are moveable into engagement with the skin with the clamping device, that the appliance has a related generator producing a stimulator current and that during use of the clamping device the electrically conductive parts are operable to apply a stimulator current in pulse fashion to the skin."* Further claims are characterized in that *"the generator is configured as a preferably adjustable pulse generator with a pulse repetition frequency in the range of between 1 Hz and 500 Hz approximately, a pulse duration of between 1 ms and 0.5 s, approximately, and a pulse amplitude of between 1 V and 100 V, approximately"* and *"the generator supplies unipolar pulses or alternating current of an adjustable intensity varying between 0 and 200 mA, approximately".* [26]

In figure 7-1 a possible execution of such a device is displayed. The conducting parts (26) are located in front and behind the epilation disks.

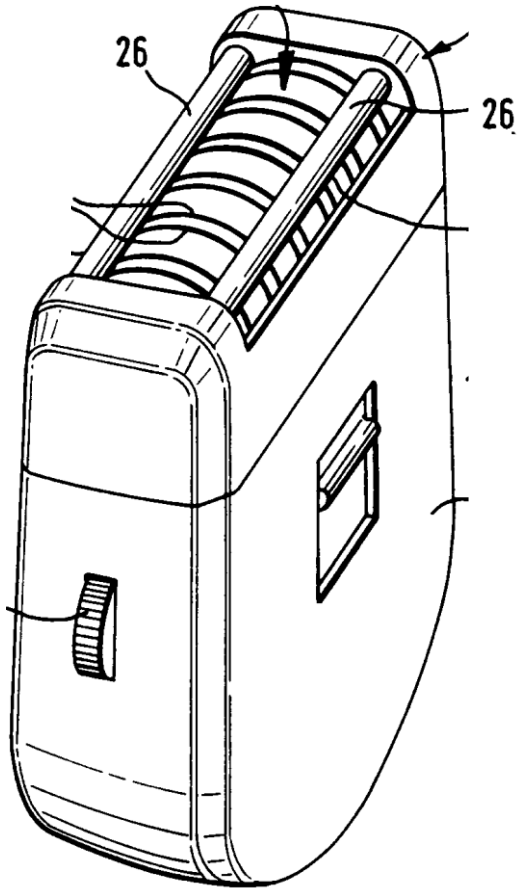

Figure 7-1 Epilator including electric conductive parts [26]

Figure 7-2 shows the realization of the device with the electric impulse generator (38) and the two conductive parts (26) in contact to the skin.

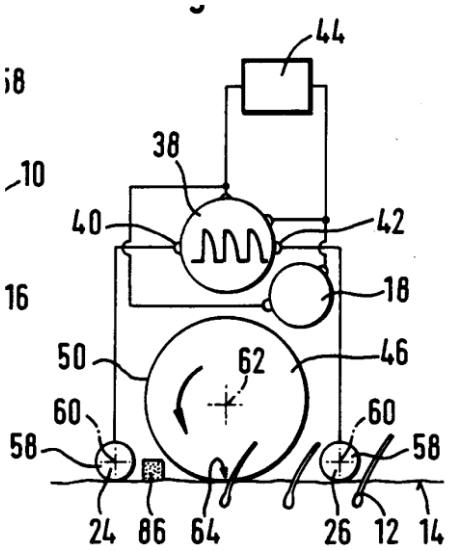

Figure 7-2 Epilator head in combination with an electric impulse generator [26]

7.2 Discussion of the relevant patents

The publications EP0748174B1 and EP1582112B1 very well describe what an application combining a mechanical hair removal device with a frequency generator could look like. The patents themselves do distinguish mostly in their parameter specification. As it was stated before stimulation at high frequency and low intensity will show different results than stimulation with low frequency and high intensity. Out of the previous it seems that the 500 Hz frequency of EP0748174B1 as well as the 3 kHz frequency of EP1582112B1 is not optimal to make use of the analgesic effect.

The intensity range of 0 up to 200 mA stated in EP0748174B1 is poorly specified, however in EP1582112B1 it is limited between 0.1 and 15 mA, which could address to the right intensity.

The placement of the electrodes in figure 7-1 is not ideal, because they represent a barrier influencing the hair catching mechanism. Such a barrier will further directly affect the device's performance and lead to a negative customer impression.

It is not known whether Braun performed tests in different frequency and intensity ranges, but they never placed such a product on the market, which, in the end, leads to the assumption that the parameters specified in the patient might be inappropriate.

The following chapters 8 and 9 focus on the implementation and outcome of indicative tests, based on the parameters found in the extensive literature and patent research.

8 Test preparation

In this chapter the chosen test devices and the indicative test setup are described. The information gathered in chapter 1 to 5, the chosen electric stimulation methods from chapter 6 and the patent research of chapter 7 built up the decision base. Impulsive for generally having those tests conducted was the fact that there is not yet a mechanic hair removal product in combination with a electric stimulator available.

8.1 Device specification

Summarizing all the information from the chapters before the specifications of a test device were defined as follows:

- Frequency: ~ 2 kHz
- Intensity: 0 - 100 mA
- Amplitude: 0 - 50 V
- Pulse form: rectangular
- Continuous stimulation

Philips in general has no experience in the area of electric stimulation for acute pain relief and therefore no device for testing was available. The devices used by Philips research in Eindhoven are designed for chronic pain relief and have inappropriate parameter settings. Due to the very high intensity level of > 100 mA and the limited frequency range up to 150 Hz that they do not meet the needed specifications at all. The Schwa Medico device provided by the Medical University Graz did not fulfill the requirements neither. Furthermore the purchased Hydas device was also not ideal for the purpose of continuous stimulation and so the decision was made to build a laboratory setup of a frequency generator which meets all the above specified criteria.

8.2 Schwa Medico TNS SM 2 MF

The transcutaneous nerve stimulator designed by Schwa Medico as can be seen in figure 8-1 is a device to conduct electric stimulation. It can be operated easily and was initially designed for using a home based medical device of class IIa. The specified upper frequency limit of the device is 100 Hz, which is completely out of specification. Although the device did not meet the specification it was used to have insights about using such a device for further tests.

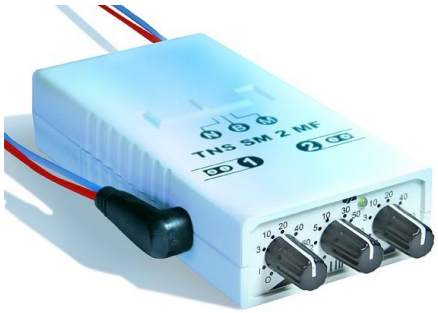

Figure 8-1 Schwa Medico TNS SM 2 MF [15]

8.3 Hydas 4513 electrical impulse stimulator

The Hydas 4513 TENS/EMS device as shown in figure 8-2 is a digital, 4 channel electrical impulse stimulator. There are 30 preset stimulation programs, which should be selected according to the individual medical indication. In each single program mode the intensity level can be adjusted individually. On request the company provided the information that program number 10 stimulates with a 2 kHz rectangular pulse whose amplitude could be adjusted individually in 10 steps between 0 and 20 V. Unfortunately the important information that the stimulation is not provided continuously was not given and so, depending on the selected speed level, there was a 2.5 to 4 seconds break between the stimulation phases. Because of the very limited availability of test persons and the last minute information about the discontinuous stimulation the first indicative test was conducted anyhow with this device. Due to this not expected behavior of this device it could not be used for the second indicative test and it was decided to build up a laboratory test to meet the specified criteria.

Figure 8-2 Hydas 4513[16]

http://shop.schwa-medico.de/media/catalog/product/cache/1/image/9df78eab33525d08d6e5fb8d27136e95/t/n/tns_sm2_mf.jpg, Accessed on October 23, 2013[15]
http://www.hydas.de/group_view,tens_reizstromgeraete,8NEK03F9NR9Y6FWHQV53O0TPXESWB0VI,de,504c80d186863e25325a482febd658d9.html, Accessed on July 25, 2013

8.4 Philips electrical stimulator laboratory setup

As mentioned before the available devices did not meet the specification and so the decision was made to build a setup of a frequency generator that would meet all the desired specifications for further testing.

8.4.1 Hardware overview

The laboratory setup consists of three main parts, which are shown in the block schematic in figure 8-3:

1. protection circuit
2. oscillator and
3. amplifier.

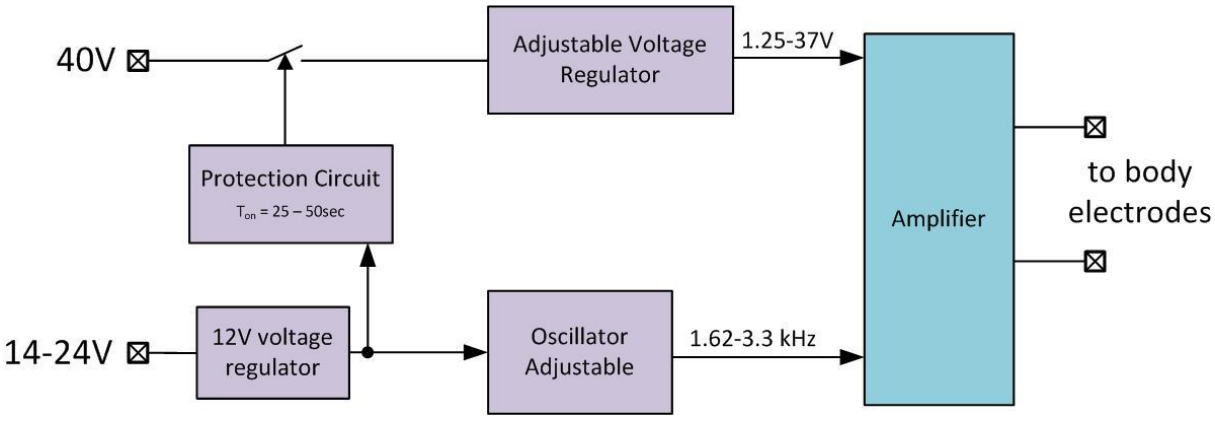

Figure 8-3 Laboratory setup hardware concept

In figure 8-4 the physical realization of the stimulator is shown. Its user interface parts are described as follows:

1. The logic parts are supplied via the connectors on the left side top view of the device with a voltage between 14 and 24 V.
2. The connectors on the right side are used for supplying the output stage with any voltage from 0 up to 40 V.
3. The LED on the top indicates the active mode.
4. The Button is used to start the active cycle and resets the protection circuit.

16 http://www.hydas.de/group_view,tens_reizstromgeraete,8NEK03F9NR9Y6FWHQV53O0TPXESWB0VI,de,504c80d186863e25325a482febd658d9.html, Accessed on July 25, 2013

5. Adjustable stimulation control
   5.1 Stimulus duration from 25 to 50 s
   5.2 Amplifier output level from 1.25 to 37 V
   5.3 Frequency range from 1.62 to 3.3 kHz
6. Body electrodes connector

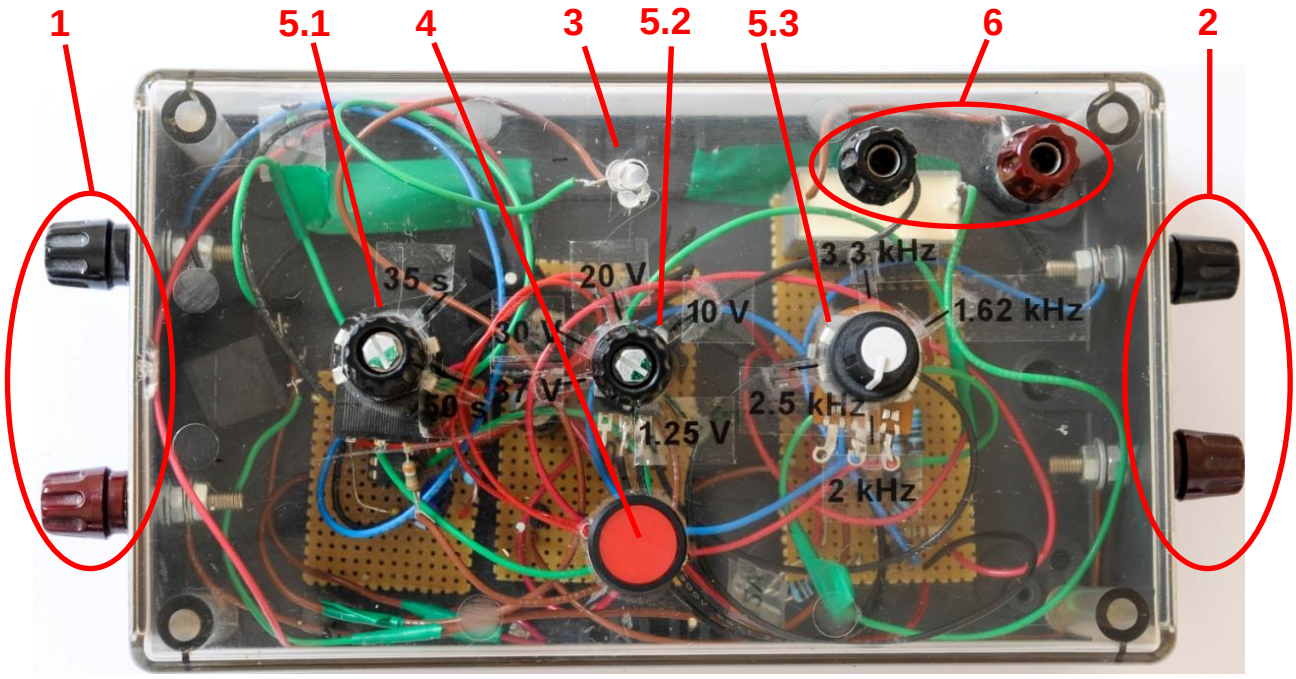

Figure 8-4 Philips electric stimulation laboratory setup

All following simulation have been done with Altium Designer 13.2.

8.4.2 Protection circuit

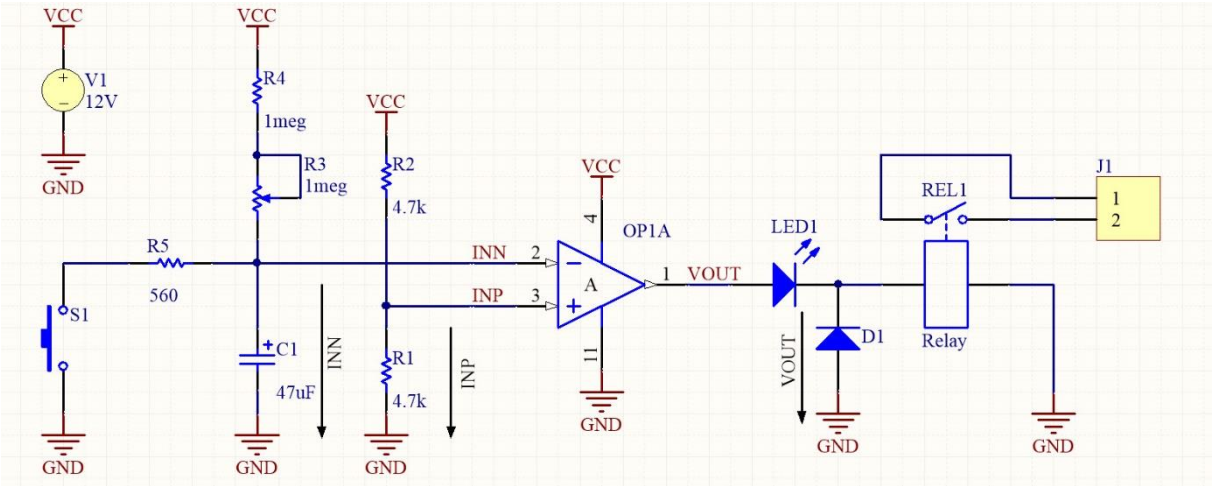

Figure 8-5 Protection circuit

The protection circuit, which is shown in figure 8-5 acts as the security feature of the impulse generator. The circuits' purpose is to turn off the circuit power supply automatically after a predefined time span. During this time span, the circuit is actively supplied and in operating condition, which is indicated by the illuminated LED. By pressing the red button S1, which is number 4 of figure 8-4, the capacitor C1 is discharged and resets the time span.

After releasing the button S1 the capacitor C1 is charged from the 12 V supply through resistors R4 and potentiometer R3, which are used to limit the charging current. The charging voltage of the capacitor C1 increases slowly. Operational amplifier OP1 acts as a comparator and switches the relay Rel1 off, if the voltage at capacitor C1 exceeds the level of the positive input. The reference level on the positive input in this case is 6V, set by the resistors R1 and R2. With the potentiometer R3, set with number 5.5.1 in figure 8-4, the charging current of the capacitor C1 is adjusted, which results in the change of the time constant of the RC-circuit. The time constant t_{on} determines the online time of the circuit.

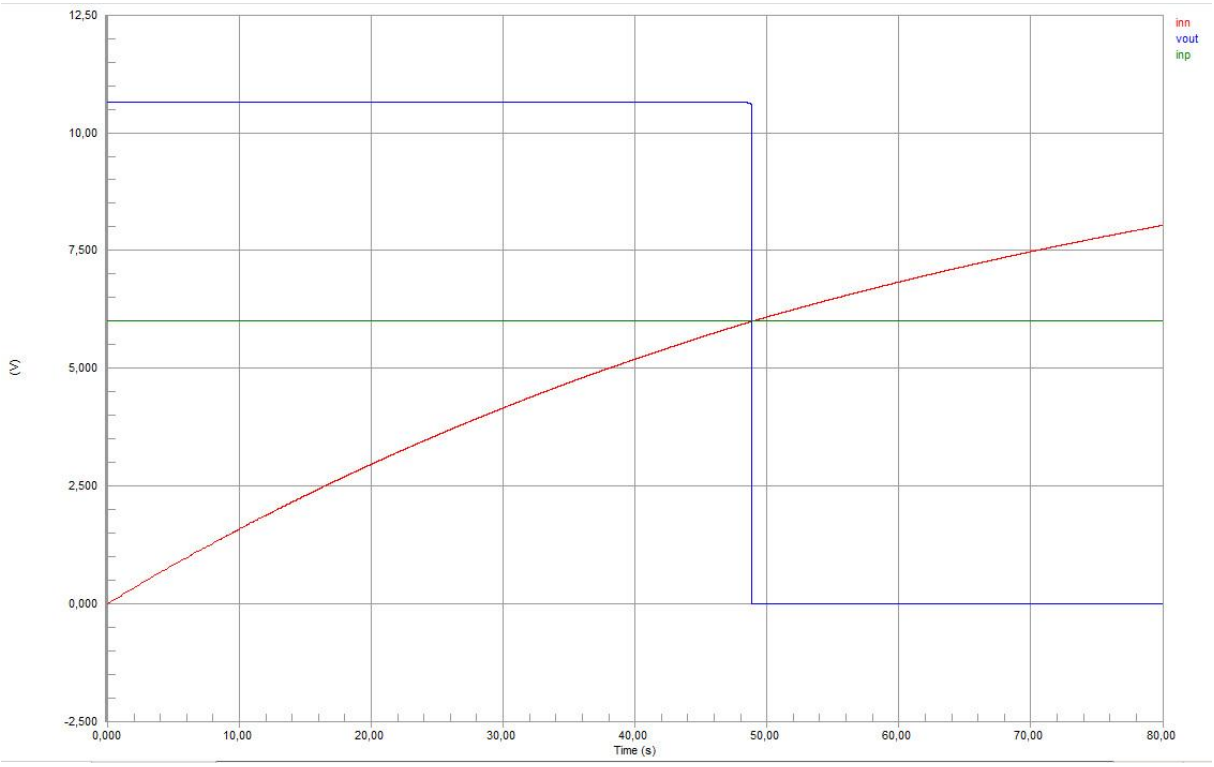

Figure 8-6 Simulation of protection circuit

The simulation of the protection circuit as shown in figure 8-6 displays the voltage across the relay coil, labeled as VOUT, with its maximum time span of ~65 seconds with a charging resistance of 2 MΩ and a supply of 12 V.

The charging slope of the capacitor voltage can be described as:

$$u(t) = U_{in} * \left(1 - e^{-\frac{t}{\tau}}\right) \quad (2)$$

Out of equation (2) the time span when the capacitor voltage reaches the threshold voltage U_{th} of OP1 is calculated:

$$U_{Th} = 12V * \frac{R_1}{R_1+R_2} = 6V \equiv u(t) \quad (3)$$

$$t = R * C * (-\ln\left(1 - \frac{u(t)}{U_{in}}\right)) = 1.5M\Omega * 47\mu\text{F} * -\ln\left(1 - \frac{6\text{V}}{12\text{V}}\right) = 48.86\ \text{s} \quad (4)$$

The voltage across the capacitor, labeled as INN, starts to rise immediately when the button is released. When reaching the point where the capacitor voltage crosses the reference level of 6 V, displayed as INP, the protection circuit turns the relay off and shuts down the power supply of the setup immediately.

8.4.3 Oscillation circuit

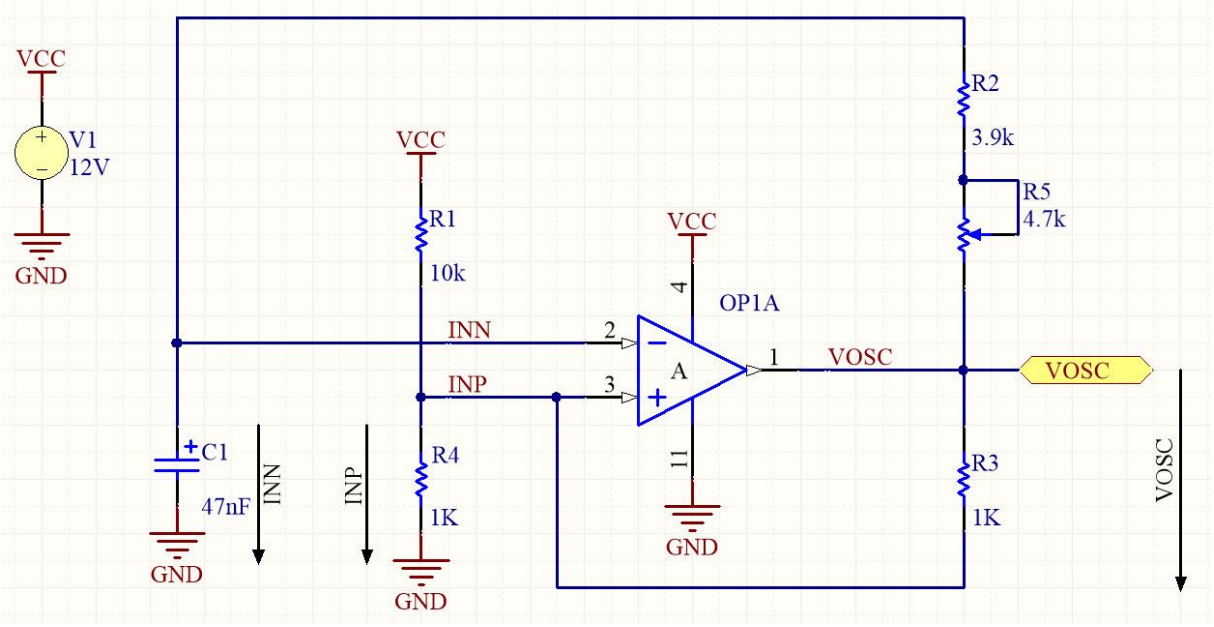

Figure 8-7 Oscillator

In figure 8-7 the oscillation circuit is shown. The circuit is supplied via 12 V for the time span which is adjusted in the protection circuit. The oscillation frequency is adjustable via potentiometer R5, number 5.5.3 in figure 8-4, between a range from 1.62 to 3.3 kHz.

The switching thresholds of the operational amplifier are defined as:

$$U_{Threshold\_pos} = \frac{R_4 * U_{in}}{R_4 + R_1 \| R_3} = \frac{1k * 12V}{1k + 0.909k} = 6.286\ V \quad (5)$$

$$U_{Threshold\_neg} = \frac{R_4 \| R_3 * U_{in}}{R_1 + R_4 \| R_3} = \frac{0.5k * 12V}{10k + 0.5k} = 0.571\,V \quad (6)$$

$$R_{Charge} = R_5 + R_2 = 8.6\,k\Omega \quad (7)$$

$$R_{Discharge} = R_5 + R_2 = 8.6\,k\Omega \quad (8)$$

Out of equations (3), (6) and (8) follows for the charging slope of the capacitor:

$$t_{rise} = R_{Charge} * C_1 * \left(-\ln\left(1 - \frac{U_{Threshold\_pos}}{U_{in}}\right)\right) =$$

$$= 8.6k\Omega * 47\text{nF} * \left(-\ln\left(1 - \frac{6{,}286\text{V}}{12\text{V}}\right)\right) = 299\ \mu\text{s} \quad (9)$$

The discharging of the capacitor starts immediately after reaching the positive threshold voltage. Therefore the discharging slope is calculated from the positive to the negative threshold voltage and out of equation (5), (6) and (8) the discharging slope of the capacitor can be calculated as:

$$t_{fall} = R_{Discharge} * C_1 * \left(-\ln\left(1 - \frac{U_{Threshold\_pos} - U_{Threshold\_neg}}{U_{Threshold\_pos}}\right)\right) =$$

$$= 8.6k\Omega * 47\text{nF} * \left(-\ln\left(1 - \frac{5.715\text{V}}{6.286\text{V}}\right)\right) = 0.99\ \text{ms} \quad (10)$$

The output frequency depends on the charging and discharging time of the capacitor C1. As the output of the operational amplifier OP1 is either high or low, the capacitor is charging or discharging. This results in a change of the voltage level on the positive input of the operational amplifier OP1. The output voltage of this circuit block V_{osc} is connected further on to the amplifier.

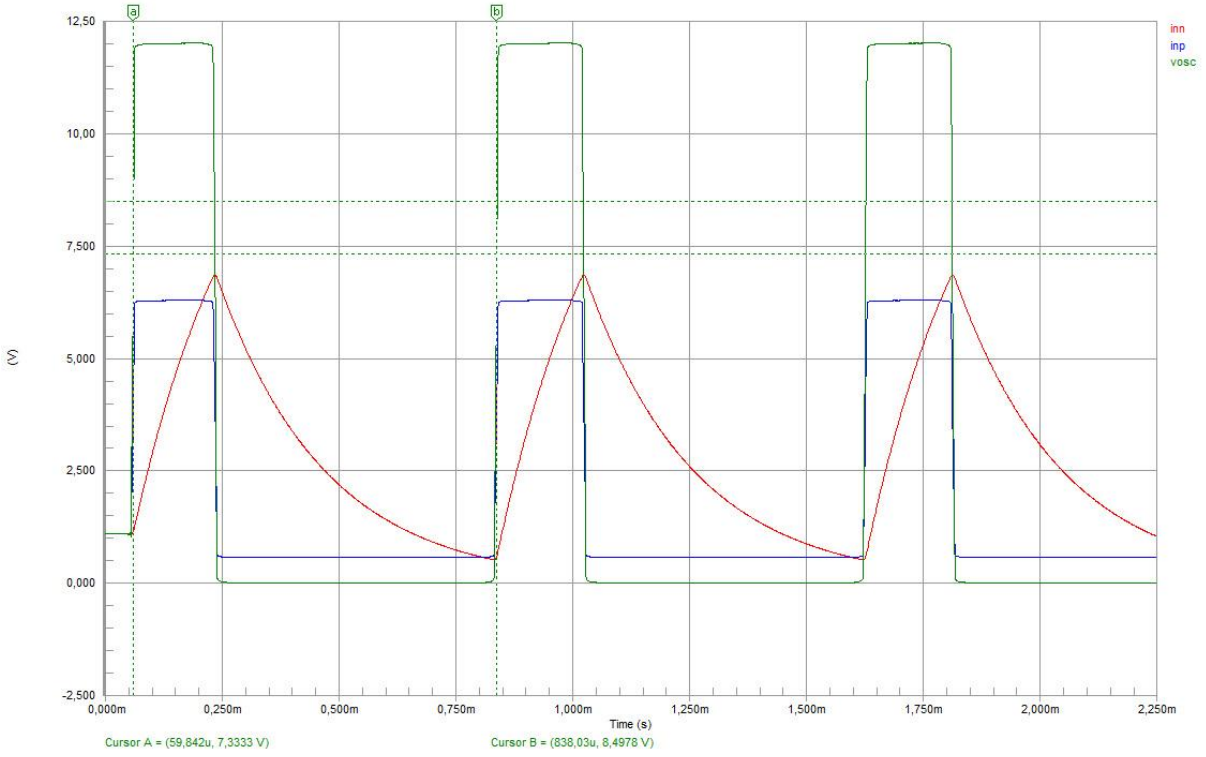

Figure 8-8 Simulation of oscillator output, positive and negative OP input at 1 kΩ

The simulation results of the oscillator output voltage, labeled as VOSC, together with the positive, INP and negative, INN operational amplifier input are shown in figure 8-8 and figure 8-9. In both figures it is shown that if the capacitor voltage INN crosses the positive operational amplifier input voltage INP a transition of the output signal VOSC is created. The period, which can be adjusted with potentiometer R5, varies between 778 µs in the simulation results in figure 8-8 with a resistance of 1 kΩ and 1.3 ms in the simulation results in figure 8-9 by using a resistance of 4.7 kΩ

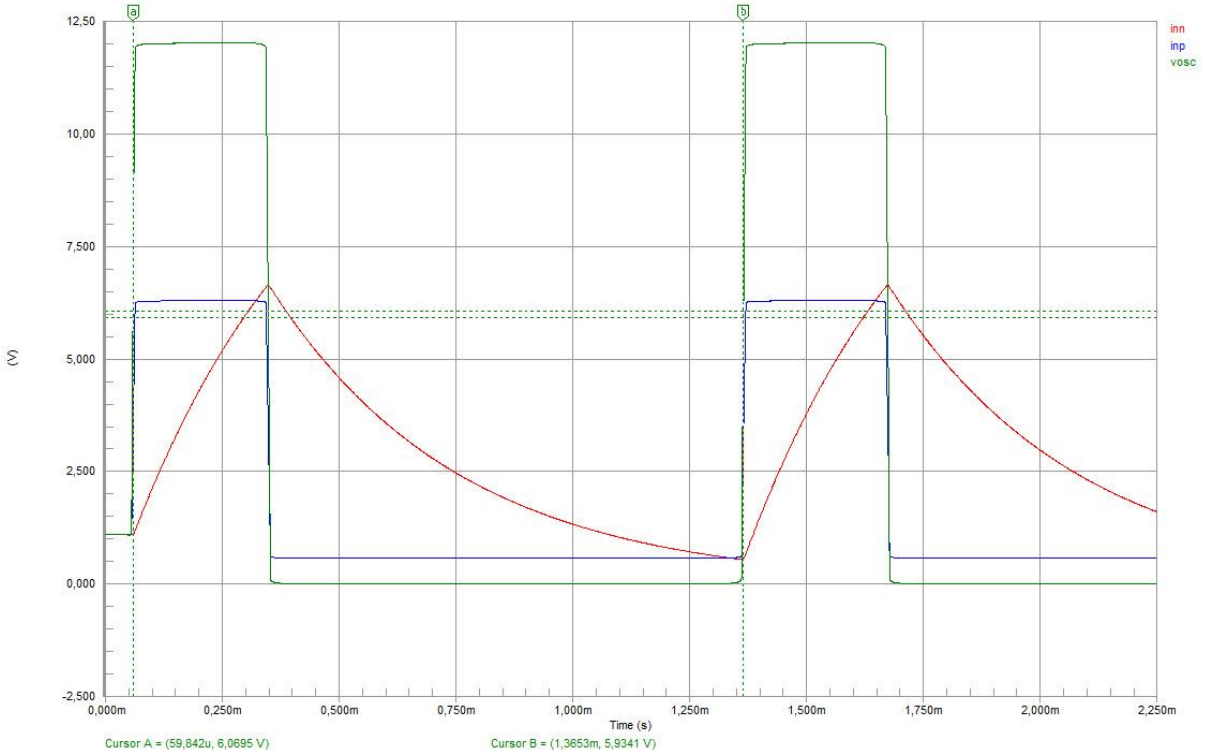

Figure 8-9 Simulation of oscillator output, positive and negative OP input at 4.7 kΩ

8.4.4 Amplifier

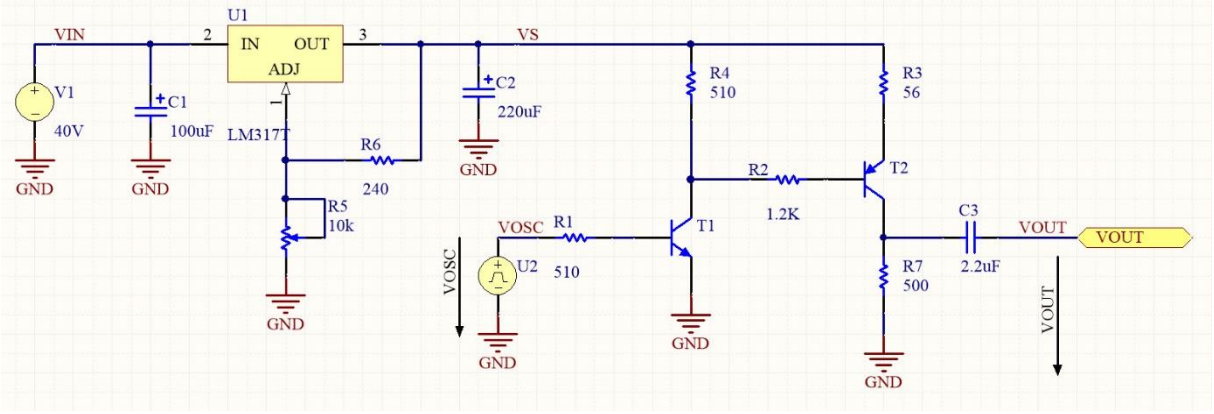

Figure 8-10 Amplifier

The amplifier is the last part of the setup and is using the adjustable voltage regulator LM317 for setting the output voltage up to 37 V (with 40 V supply voltage). The input voltage of the amplifier V_{osc} is the 12 V output signal from the oscillator circuit. Therefore this input signal has to be level shifted to the supply rail of the amplifier circuit by using the npn transistor T1. The pnp transistor T2 is then switching the output according to the shifted oscillator voltage. The potentiometer R5, number 5.5.2 in figure 8-4 regulates the output voltage of the regulator LM317 and is adjustable between 1.25 and 37 V. C3 is used as a decoupling capacitor to block the DC parts of the circuit. Finally the signal is fed into the body via electrodes.

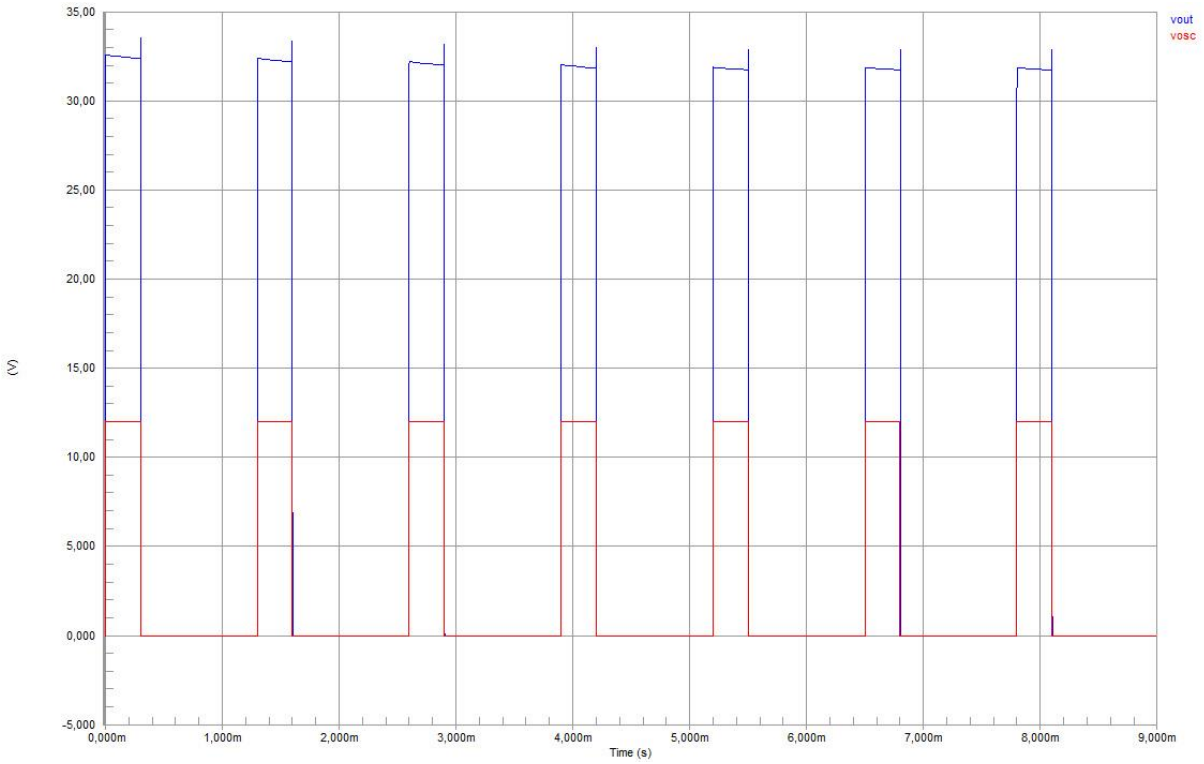

Figure 8-11 Simulation of amplifier output before the decoupling capacitor

The simulation result in figure 8-11 displays the output voltage of the amplifier before the decoupling capacitor, labeled as VOUT, together with the input oscillator voltage VOSC.

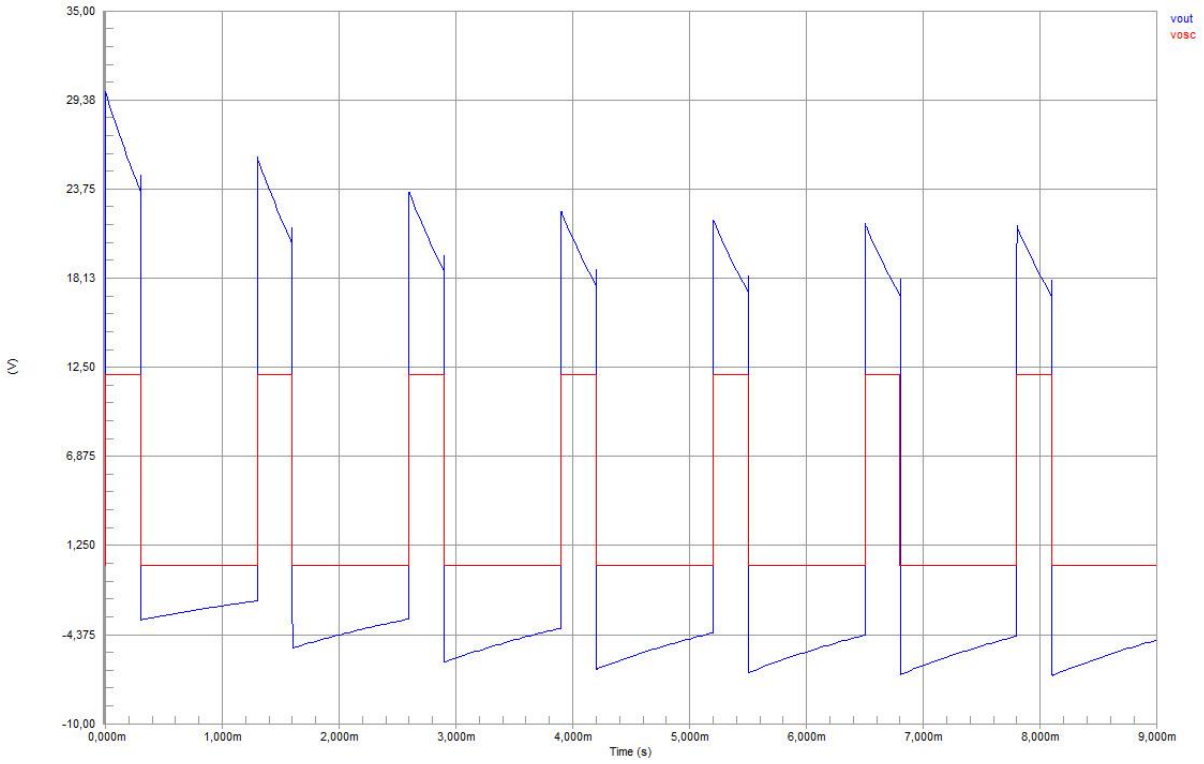

Figure 8-12 Simulation of loaded amplifier output after the decoupling capacitor

In figure 8-12 the amplifier output is loaded with a 550 Ω resistor to ground. The curve labeled as VOUT is measured after the decoupling capacitor.

9 Indicative testing

To have a better understanding of what users experience and think Philips Klagenfurt has a Product Research Centre (PRC) in house. Users are asked about their opinion about products developed by Philips, but also opinions to competitor devices. They are also welcomed to test new products or act as decision makers for innovative projects.

The previous chapters showed that the usage of electric counter stimulation looks most promising on the way to a pain free epilation experience. Although scientific facts may be strong, the user's opinion is a knock-out criterion for Philips. To test if such a device should really be developed indicative tests were conducted. Indicative tests at Philips are done in a development project already before prototypes are built to get an indication for further research directions or to test a hypothesis. The improved test setup is further used after a prototype has been built to have further indications of functionality and input for modifications and implementation variations.

The tests conducted for this thesis should indicate whether Philips can think of starting a project and do further research on the topic of electric pain relief or to leave it completely out of their development scope for the next years.

The subjective felt pain had to be ranked between 1 and 7 according to the Philips pain scale as can be seen in figure 9-1. Whereas the number 1 indicates a very painfully application and choosing number 7 indicates to have a pain free application according to this scale.

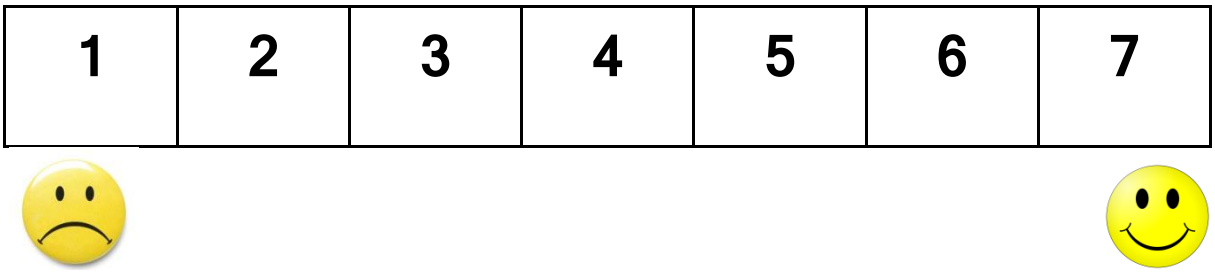

Figure 9-1 Philips subjectively felt pain scale

9.1 Test #1

The first test set up was already planned and test persons were scheduled when it became clear that the Hydas device does not meet the stimulation criteria as described in detail in paragraph 8.3. The device made use of discontinuous pulsation instead of continuous one with a time span of 2.5 seconds between the pulses.

However, the decision was made to do the test in order to get more experience in the field of testing with application of electricity and to get first opinions by test users about the presented idea in general. The test criteria for the first test had to be changed respectively – the testing questionnaire can be found in the appendix.
Main thought when setting up this questionnaire was to compare two types of applications. The first application makes use of electric pulses and the second one is a normal set up without electric influences.

9.1.1 Test equipment

The test equipment consisted of:

- Philips precision epilator type HP6365
- Hydas 4513 electric impulse generator
- Insulating transformer
- disinfection bath
- self-adhesive electrodes, square-cut, 4.5 x 4.5 cm edge length
- electrode wires

Figure 9-2 Philips precision epilator HP6365

The Hydas device is able to switch between 10 intensity levels in the range from 2 to 20 V. For each test person the level was adjusted by himself or herself on advice according their subjectively maximum possible tolerance level. Frequency was fixed by choosing program number 10 to 2 kHz and could not be adjusted. Also the pulse duration was predefined by a 1 second pulsation phase followed by a 2 second break.

As can be seen in figure 9-3 and figure 9-4 square electrodes of 4.5 x 4.5 cm edge length where placed with an edge to edge distance of 5 cm on the test person's outer and inner side of the lower leg. The distance of 5 cm was chosen to provide an application with the shortest possible electrode distance, as given by the epilator head. This point was proposed in chapter 5 for further implementation.

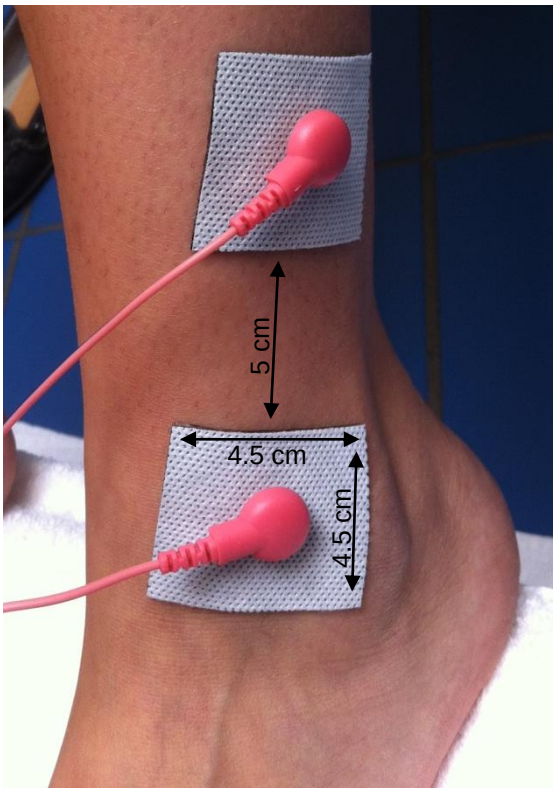

Figure 9-3 Electrodes placed on the outer side of a test person's leg

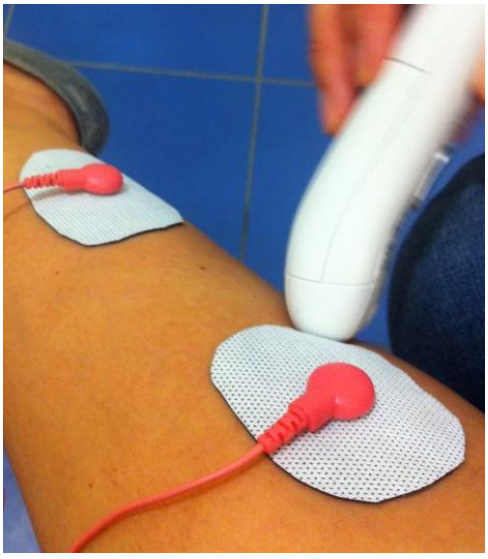

Figure 9-4 Electrodes placed on the inner side of a test person's leg

One leg was used as test leg (TL) whereas the other leg served as control leg (CL). On both legs the test person had to epilate their skin in between the electrodes. After the application was finished the test persons had to score her felt pain in the range between 1 and 7. The data are summarized in table 9-1 and table 9-2.

9.1.2 Test procedure

Six people out of the PRC database could be recruited to attend this indicative test. The test was observed by the PRC manager. Four of them were categorized as experts; two were listed as normal epilator users. People are classified as experts within Philips when they have already taken part in various tests at PRC in the same sector (e.g. epilation, shaving etc.) or have also joined discussion groups and got special trainings on a topic.

After a short instruction the test persons carried out the epilation process and filled in the questionnaire by themselves. They were asked to comment the application and their opinion in general about such an application.

9.1.3 Test result

According to the results represented in table 9-1 and table 9-2 none of the test persons indicated to have a pain free application, which would mean a score of 7, on the control leg on the inner side of their lower leg. However 4 out of 6 mentioned to have a pain free application on the inner side of the test leg. When switching to the outer side of the leg the same 4 test persons did indicate a pain free application. In summary 3 out of 6 test persons indicated that the subjectively felt pain level during the application in combination with an electric counter stimulation on the inner side of the leg was somewhat less, whereas 3 indicated an obviously less felt pain. On the outer side of the lower leg 1 out of 6 test persons did indicate that there is no difference between a counter stimulation and no stimulation.

The intensity was adjustable in the range from 1 up to 10 and chosen amongst the test persons subjective tolerance level.

The test person did comment the application with terms like “distracting, pulsing, massage like, prickling”.

TP #	Pain score CL	Pain score TL	Intensity	Subjective felt pain	TP categorization
1	5	6	4	Somewhat less	Expert
2	5	7	5	Obvious less	Non-expert
3	6	5	7	Somewhat more	Non-expert
4	6	7	7	Somewhat less	Expert
5	5	7	4	Obvious less	Expert
6	4	7	4	Obvious less	Expert

Table 9-1 Indicative test #1 results at inner side of lower leg

TP #	Pain score CL	Pain score TL	Intensity	Subjective felt pain	TP categorization
1	5	6	4	Somewhat less	Expert
2	6	7	6	Obvious less	Non-expert
3	6	6	5	Equal	Non-expert
4	7	7	5	Somewhat less	Expert
5	4	7	4	Obvious less	Expert
6	5	7	5	Obvious less	Expert

Table 9-2 Indicative test #1 results at outer side of lower leg

9.2 Test #2

For the second test the Philips laboratory setup of the electrical stimulator was used. This time the test was conducted to prove the assumption of pain relief due to electric counter stimulation at the frequency range around 2 kHz with continuously pulsed signals. Also very interesting was the consumer opinion to this type of stimulation as a potential pain relief method for experiencing a more pleasant application.

9.2.1 Test equipment

The test setup consisted of:

- Philips precision epilator type HP6365
- Philips electrical stimulator laboratory setup
- PeakTech 6000A power supply
- Philips HQ8505 15V power supply
- Insulating transformer
- Elektro-Automatik EA-PS2316-050 power supply
- disinfection bath
- self-adhesive electrodes, square-cut, 4.5 cm
- electrode wires

The setup was supplied by a 15 V power supply and the insulating transformer separating the circuit from the mains voltage and limiting the current for security purposes. The maximal output voltage of the setup was 36 V, being supplied by the PeakTech 6000S power supply with 40 V. The time span for active supply of the setup was set to 50 seconds at each application.

9.2.2 Test procedure

For this indicative test 5 experts and 5 normal epilator users were asked to participate. The questions of the test can be found in the Appendix. Again the test users had to epilate their control leg (CL) and then the test leg (TL), which was connected to the laboratory setup and stimulated electrically.
The intensity was adjusted to their subjective tolerance level and noted for each test person individually. The frequency was set to 2 kHz for the first run and either 3.3 or 1.6 kHz for a second try to test if the test persons do feel a difference between this two values. Also the side of the leg for the 3.3 and 1.6 kHz trial was switched across the test persons to have more variation within the test results.
The test person did not know the selected frequency in any time of the test.

9.2.3 Test result

As can be seen in table 9-3 and table 9-4 none of the 10 test persons indicated that an application with 2 kHz at the test leg was more painful than the application without stimulation at the control leg. At least 7 out of 10 indicated that the pain, when

counteracting the test leg with electric stimulation, is obvious less than without electric stimulation at inner side of the control leg. 3 out of 10 felt somewhat less pain when comparing the control leg with the test leg at the inner side of the leg. On the outer side of the leg 5 out of 10 indicated that the pain as obvious less during the counteracting application and 5 out of 10 felt somewhat less pain when comparing the control leg with the test leg.

Stimulation at 3.3 kHz as well as 1.6 kHz did not increase the subjectively felt pain.

The tolerable amplitudes varied from 19 V to 37 V on the outer side of the leg and from 22 V to 37 V on the inner side of the leg.

The test person did comment the application combined with the 2 kHz stimulation as “distracting, like a massage, numbing, very locally, feels like stretching”.

When applying the 1.6 kHz stimulation the test persons named terms like „pulsing, pulsation, it’s intense, twitching, the skin is prickling”.

People which have been stimulated by the 3.3 kHz signal did mention that their skin felt like someone would stitch in with a needle.

TP #	Pain score CL	Pain score TL at 2 kHz	Pain score TL at 1.6 kHz	Pain score TL at 3.3 kHz	Intensity TL [V]	Subjective felt pain	TP categorization
01	5	6	-	-	22	Somewhat less	Non-expert
02	6	7	5	-	37	Obvious less	Expert
03	5	6	-	4	26	Somewhat less	Non-expert
04	5	6	-	-	37	Obvious less	Non-expert
05	5	6	-	-	25	Somewhat less	Non-expert
06	5	6	5	-	28	Obvious less	Expert
07	6	7	-	-	37	Obvious less	Non-expert
08	5	7	-	-	37	Obvious less	Expert
09	5	6	5	-	25	Obvious less	Expert
10	5	6	-	5	37	Obvious less	Expert

Table 9-3 Indicative test #2 results at inner side of lower leg

TP #	Pain score CL	Pain score TL at 2 kHz	Pain score TL at 1.6 kHz	Pain score TL at 3.3 kHz	Intensity TL [V]	Subjective felt pain	TP categorization
01	5	6	-	5	19	Somewhat less	Non-expert
02	5	7	-	-	32	Somewhat less	Expert
03	5	5	-	-	28	Somewhat less	Non-expert
04	4	6	4	-	37	Obvious less	Non-expert
05	5	6	-	5	27	Somewhat less	Non-expert
06	5	6	-	-	25	Obvious less	Expert
07	6	7	5	-	37	Obvious less	Non-expert
08	5	7	-	5	37	Obvious less	Expert
09	5	6	-	-	22	Somewhat less	Expert
10	6	7	-	-	37	Obvious less	Expert

Table 9-4 Indicative test #2 results at outer side of lower leg

10 Summary

Although Philips did already place pain relief products on the market the actual situation is not satisfying the consumers' needs completely. The wish for a pain free mechanical hair removal solution is still unsatisfied. Philips' available products on the market have solutions in the category of thermal (cooling ice pack) and mechanical stimulation (massage attachment). Also competitors did place several products on the market – e.g. Braun does offer a massage attachment and a cooling ice glove, Panasonic sells a skin protection attachment and Rowenta offers a device including micro massage balls in the head.

There is no product known which is successful in electrical pain relief in combination with epilation. Therefore the goal of this thesis is to gain knowledge about the role electricity can play in influencing the pain in skin due to mechanically removing of hairs, which means by definition to pull the hair out of the skin. The hair penetrates all three layers of the skin and those layers in interaction with the surrounding tissue and its components are all concerned in this hair removal technique.

For gaining knowledge in the field of electric pain relief and practicable stimulation methods a literature study gave the insight to focus on the gate control theory as pain modulation mechanism and that electric stimulation for pain relief makes use of selective activation of nerve fibers.

The meaning of pain is described by the International Association for the Study of Pain as: *"Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"*.

Generally pain can be divided into three mechanisms:

1. Pain detection
2. Pain transmission
3. Pain interpretation

By pain detection the signal detection at the skin level is meant. The detection itself is done by nociceptive sensors (pain sensors). The detected pain can be either in form of an extreme stimulus (acute pain) or tissue damage (chronic pain).

To have a pain free application free nerve endings in the skin have to be treated mechanically, thermically, chemically or even electrically, like using electric stimulation for decreasing the pain.

The transmission of the painful signal goes from the skin to the brain along the spinal cord. The transmission activity is performed by nerve fibers that carry the signal.

Nerve fibers can be classified in fiber groups along the Erlanger/Gasser classification.

Signals are carried by either A-delta or C fibers depending on their mean diameter and conduction velocity. The acute pain signals are carried by the large A-delta fibers whereas the slower transmission of chronic pain signals is conducted by the smaller C fibers.

Along the pain transmission path there exist pain modulation mechanisms. The gate control theory describes the inhibition or transmission of the stimulus. Small nerve fiber input carried by C fibers keeps the gate to the brain open. Signals conducted via large fibers of type A (A-beta, A-delta etc.) are likely to close the gate.

Pain interpretation happens on the level between spinal cord and the brain and is a highly complex interaction of neurons. The individual pain perception makes it even more complex.

Pain relief evoked by electric stimulation is based on the gate control theory. The counter stimulation is achieved by a current sent to the body and carried via A-beta fibers with low threshold afferents. These counteracting signals close the pain gate for signals with higher threshold, for example those sent by pain sensors. The brain reaches a condition of so called paraesthesiae.

In addition also the topic of bioelectricity was part of the literature research. The skin itself consists of multiple complex structures and when applying electricity to the skin these structures start to interact, based on cell excitation and will result a change in skins impedance. Tissue and skin characteristics in general are a function of physiological condition, blood circulation and the perspiratory glands.

Electric stimulation for pain relief can be achieved by electric nerve stimulation in different ways and the most common ones are:

- Conventional transcutaneous electric nerve stimulation (TENS)
- Russian current stimulation
- Interferential current therapy (ICT)

Through comparison of the different stimulation methods the best setting for electric pain relief during epilation was developed:

- Rectangular stimulation
- 2 kHz frequency
- 1-40 V amplitude

Furthermore it is also important to take the size and placement of the electrodes into account, as these parameters will have an impact on the effectiveness of the electric nerve stimulation.

According to the medical device directive electric stimulation devices for therapeutic or diagnostic purpose are classified as medical devices of class IIa. Medical devices are under the premise that their intended use can be named as a medical one. The intended use is defined by the manufacturer. The intended use of an mechanical hair removal device cannot be stated as medical purpose. Also combining it with electric stimulation cannot be seen as diagnostic or therapeutic application.

So the interpretation of the term medical device leads to the assumption that an electric stimulation device for pain relief during epilation is not classified as a medical device.

Although there is no device known which has already been developed and placed on the market there are several patents written on this topic. Braun describes in EP0748174B1 and EP1582112B1 what the application of mechanical hair removal combined with a frequency generator could look like. The parameters suggested in these publications do not seem to be appropriate according to the research conducted in this thesis.

The stimulation settings which could be figured out after comparing the electric pain relief methods and compared with the results from the literature research were evaluated in indicative tests. The first test was performed with 6 people recruited through the Philips test panel. Test device was the Hydas 4531 which was not ideal because of the discontinued pulsation. The reason for this test was to indicate whether there is an impact of electric stimulation on pain relief during epilation or not.

In this first test 3 people had obvious less pain on the leg which was electrically stimulated during the application, 2 had somewhat less pain and 1 did indicate that the felt pain on the inner side of the lower leg was somewhat less and the felt pain on the outer side of the lower leg was equal to the control leg. The indications lead to the decision to perform a second test with better test equipment.

For the second indicative test an electric stimulator laboratory setup was developed in order to fulfill the condition of continuous rectangular stimulation. Further on with this device it was possible to adjust the frequency between 1.62 and 3.3 kHz and the amplitude between 1.25 and 37 V.

10 people participated in this test to find out if they confirm a correlation of decreased pain with a stimulation at 2 kHz frequency compared with an out of range frequency stimulation at 1.6 or 3.3 kHz.

None of the test persons indicated that they had more pain during the application with electric stimulation at 2 kHz. For all test persons the counter stimulation with 1.6 or 3.3 kHz did not increase their subjective felt pain level. On the inner side of the lower leg 7 test persons did tell about obviously less felt pain whereas 5 did tell about it on the outer side of the lower leg. 3 test persons felt somewhat less pain on the inner side of the lower leg and 5 test persons did indicate the same feeling on the outer side of the lower leg.

In summary the thesis supports the theory that stimulation at 2 kHz do have influence on the felt pain. This is a clear indication for further investigation.

11 Discussion

In this thesis it could be shown that there is a potential for using electric nerve stimulation as pain relief method during mechanical hair removal. In the literature electric counter stimulation is described as a means for inhibiting the pain sensation and through indicative tests this theory was strengthened.

Through the tests it was shown in which sections there is still information lacking and further research has to be done.

One point will be hardware improvements. For the next generation of testing a functional prototype should be considered. The following changes should be implemented before further tests can be conducted:

- Implementation of a current source driven circuit
- Battery supplied device
- Precise visualization of amplitude and frequency range – for better adjustment and usability
- Expansion of amplitude range– in order to fulfill the users need for individual adjustment
- Accuracy of amplitude – to satisfy the individual users need, as every user has its own optimized amplitude value
- Limitation of frequency range – according to the tests the optimal frequency range was defined as 2 kHz +/- 250 Hz
- Green LED to indicate the active circuit supply – in the current implementation a red LED was implemented.

Through the indicative tests also additional questions for further research topics in this field arose. It would be interesting to investigate more the impact of amplitude, frequency range and skin resistance. Another aspect would be to define a calibration method for thresholding different skin types to achieve the best result amongst all consumers.

Every approach should again be conducted via tests in Philips PRC under improved conditions like:

- New prototype which includes the electrodes on the stimulation device
- Increased test panel of > 50 test persons to have a broader distribution of different users
- Expansion of the application area to the complete surface of the lower legs

The last step before a product development project can really be started would be to develop a functional model and test it again via a broad panel for its opportunity to finally come to a consumer product on the worldwide epilation market.

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Appendix

Indicative test questionnaire #1

DA Testing #1

Statistical data

TP-Nr: ..... Datum: .....

Test leg (TL) right ❑ left ❑
Starting at: inside ❑ outside ❑

Comparison leg (CL) right ❑ left ❑

Application at comparison leg

How would you describe the pain level at the inner site?

1	2	3	4	5	6	7
Totally painful						Not painful at all

How would you describe the pain level at the outer site?

1	2	3	4	5	6	7
Totally painful						Not painful at all

Application at test leg part A

Test leg (TL) right ❑ left ❑
Application site: inside ❑ outside ❑

Used intensity: .....

How would you describe the pain?

1	2	3	4	5	6	7
Totally painful						Not painful at all

How is your feeling during the application?

.....
.....
.....
.....

Observation (by supervisor)

.....
.....
.....
.....

1

DA Testing #1

Application at test leg part B

Test leg (TL) right ❑ left ❑
Application site: inside ❑ outside ❑

Used intensity: .....

How would you describe the level of pain?

1	2	3	4	5	6	7

Totally painful — Not painful at all

How is your feeling during the application?

.....
.....
.....
.....

Observation (by supervisor)

.....
.....
.....
.....

Application at test leg part C

Test leg (TL) right ❑ left ❑
Application site: inside ❑ outside ❑

Used intensity: .....
Used frequency (~ 1kHz): .....

How would you describe the level of pain?

1	2	3	4	5	6	7

Totally painful — Not painful at all

How is your feeling during the application?

.....
.....
.....
.....

Observation (by supervisor)

.....
.....
.....
.....

2

DA Testing #1

AFTER Application

How would you describe the pain at application INCLUDING electric stimulation in comparison to the application WITHOUT electric stimulation?

Obvious less	Somewhat less	Equal	Somewhat more	Obvious more

3

Indicative test questionnaire #2

DA Testing #2

Statistical data

TP-Nr: ..... Datum: .....

Test leg (TL) right ❑ left ❑
Starting at: inside ❑ outside ❑

Comparison leg (CL) right ❑ left ❑

Application at comparison leg

How would you describe the pain level at the inner site?

1	2	3	4	5	6	7
Totally painful						Not painful at all

How would you describe the pain level at the outer site?

1	2	3	4	5	6	7
Totally painful						Not painful at all

Application at test leg part A

Test leg (TL) right ❑ left ❑
Application site: inside ❑ outside ❑

Used intensity: .....
Used frequency (~ 2kHz): .....

How would you describe the pain?

1	2	3	4	5	6	7
Totally painful						Not painful at all

How is your feeling during the application?

.....
.....
.....
.....

Observation (by supervisor)

.....
.....
.....
.....

1

DA Testing #2

Application at test leg part B

Test leg (TL) right ❑ left ❑
Application site: inside ❑ outside ❑

Used intensity: .....
Used frequency (~ 2kHz): .....

How would you describe the level of pain?

1	2	3	4	5	6	7

Totally painful — Not painful at all

How is your feeling during the application?

.....
.....
.....
.....

Observation (by supervisor)

.....
.....
.....
.....

Application at test leg part C

Test leg (TL) right ❑ left ❑
Application site: inside ❑ outside ❑

Used intensity: .....
Used frequency (~ 1kHz): .....

How would you describe the level of pain?

1	2	3	4	5	6	7

Totally painful — Not painful at all

How is your feeling during the application?

.....
.....
.....
.....

Observation (by supervisor)

.....
.....
.....
.....

2

DA Testing #2

AFTER Application

How would you describe the pain at application INCLUDING electric stimulation in comparison to the application WITHOUT electric stimulation?

Obvious less	Somewhat less	Equal	Somewhat more	Obvious more

3

MDD Classification rules

Non-invasive devices			
Rule #	Rule	Y	N
1	All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.	x	
2	All non-invasive devices intended for channeling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa: • if they may be connected to an active medical device in Class IIa or a higher class, • if they are intended for use for storing or channeling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class I.		x
3	All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.		x
4	All non-invasive devices which come into contact with injured skin: • are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, • are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, • are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.		x
Invasive devices			
Rule #	Rule	Y	N
5	All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I: • are in Class I if they are intended for transient use, • are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I, • are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.		x
6	All surgically invasive devices intended for transient use are in Class IIa unless they are: • intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, • reusable surgical instruments, in which case they are in Class I, • intended specifically for use in direct contact with the central nervous system, in which case they are in Class III, • intended to supply energy in the form of ionizing radiation in which case they are in Class IIb, • intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb, • intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.		x

7	All surgically invasive devices intended for short-term use are in Class IIa unless they are intended: • either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, • or specifically for use in direct contact with the central nervous system, in which case they are in Class III, • or to supply energy in the form of ionizing radiation in which case they are in Class IIb, • or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III, or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.		x
8	All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: • to be placed in the teeth, in which case they are in Class IIa, • to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III, • to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III, or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.		x
Additional rules applicable to active devices			
Rule #	Rule	Y	N
9	All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb. All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.	x	
10	Active devices intended for diagnosis are in Class IIa: • if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum, • if they are intended to image in vivo distribution of radiopharmaceuticals, • if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.		x
11	All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner: • that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.		x
12	All other active devices are in Class I.		x
Special rules			
Rule #	Rule	Y	N

13	All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC and which is liable to act on the human body with action ancillary to that of the devices, are in Class III. All devices incorporating, as an integral part, a human blood derivative are in Class III.		x
14	All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.		x
15	All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb. All devices intended specifically to be used for disinfecting medical devices are in Class IIa, unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb. This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.		x
16	Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.		x
17	All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.		x
18	By derogation from other rules, blood bags are in Class IIb.		x