Reducing environmental impact from biomedical devices

- A case study

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Abstract
In the medical industry, environmental considerations have lagged behind in order to focus on patient safety. A combination of both should be possible to achieve. In this report, focus have been on how environmental impacts can be lowered from disposable biomedical devices. In order to quantify the impact from a product, the method Life Cycle Assessment (LCA) was used which gives a full life-cycle perspective. The case chosen was the company Atos's product Life GO HME, a plastic product used by patients with tracheostomy. Using LCA, energy usage and CO_2-emissions for the product's life-cycle was quantified. The life-cycle that could be calculated were between sub-products leaving sub-contractors till the product's end-of-life. Two different scenarios were chosen, the product being shipped to Europe respectively America. One fully loaded cardboard box, containing 1500 HMEs, with destination America led to 10.8 kg CO_2 and 111 MJ used. Transportation was deemed to be the most impacting process. For destination Europe, the values were 2.1 kg CO_2 and 19.8 MJ used. In order to lower the environmental impact from the product, focus should be on the packaging. One solution could be introducing more bio-plastics such as Polylactic Acid (PLA), Bio-PET, Bio-PE or Polyhydroxyalkanoates. However, considerations towards how this would affect the recyclability needs to be further investigated. Another way of lowering the impact could be removing the physical manual and providing instructions another way.
In order for the medical industry to save more lives, environmental efforts could be a great area to focus on.

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Summary

Rising emissions from human society has lead to a greenhouse effect, leading to e.g. the rising of global temperature and sea levels. Furthermore, fossil fuels and polymer plastics are used at unsustainable levels and are predicted to run out. In the biomedical sector, disposable plastics are used in high volumes due to its cheap, lightweight and biocompatible properties. The main concern of the industry has been with patient safety, an alignment which inadvertently has given consequences to the environment. Patient safety should be combined with a mindset that concerns sustainability and the environment. The main focus of this report is investigating how environmental impact from biomedical products can be reduced while also cutting down on plastic usage.

Achieving this goal was done through the case Provox Life Go HMEs, a heat-and-moisture exchanger used by patients with tracheotomy. The product is a disposable plastic which needs to be used everyday for the rest of a patients life, accumulating large amounts of waste. The company Atos produces these and ships them out to patients all over the world from their facility in Hörby. To analyse the environmental impact from these products and quantify it, the method life cycle assessment was utilised. A life cycle assessment (LCA) considers the whole life cycle of a product from raw material production until its end-of-life. To further investigate the parts of the product's life cycle that lead to high impacts, the LCA was split into three different scopes, cradle-to-gate, gate-to-gate and gate-to-grave. The impact categories which were investigated included emissions in kg CO_2 equivalents and energy usage in MJ. Issues with data collection lead to the cradle-to-gate being limited to only containing transportation from sub-contractors to the Atos facility. The analyses considered a full shipping box containing 50 boxes of Provox Life Go HMEs, 1500 HME pieces in total. Two different shipping scenarios were considered, one to Paris,France, and one to Houston, USA. From the defined product life-cycle, sub-contractors to waste management, with destination Paris, the impact totalled to 2.1 kg CO_2 and 19.8 MJ used. For destination Houston, the result showed 10.8 kg CO_2 and 121.3 MJ used. In the latter, transportation to end customer were the dominating factor for both emissions and energy usage. For destination Paris, the waste disposal and transportation to end customer were the largest contributors in emissions. Production at the Atos facility and transportation to end customer were the dominating factors for energy usage.

An attempt to quantify the emissions from plastic production for the product lead to

an extra 11.3 kg CO_2 equivalents. In order to lower the impact from the product, the conclusion were to focus on the blister packaging which contain the HMEs. Material substitutions from conventional plastics to bio-plastics such as PLA, PHA, Bio-PE or Bio-PET were considered. This would not only lower emissions from the product life-cycle significantly but also lower the use of fossil based materials. However, further investigation needs to be done on the consequences that bio-plastics have on recyclability of plastics in the waste stream. Another way of lowering the product impact would be removing the physical manual from the product and instead providing it electronically. It is a fairly simple product and patients who use the product everyday probably only need the manual at the time of their first ever usage.

The medical industry could save even more lives through considering their environmental impact and further investigating plastic substitutions with the goal of a more sustainable future.

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1 Introduction

Humans' impact on the environment is nothing new. Atmospheric measurements have been carried out since the 1950s and an increased carbon dioxide concentration is a fact. There exist natural fluctuations in carbon dioxide, but there exist no doubt in the scientific world that the increase in modern times are due to human interference (Vitousek, 1992). Burning of fossil fuels and large scale deforestation are just some of the ways humans contribute to global warming and the greenhouse effect (Houghton, 2005). Much of these emissions are connected to household consumption. In 2007, China became the country which emit the most greenhouse gases. However, this has mostly to do with their large scale production of household products which are then exported out to the rest of the world. Their own per capita consumption based environmental impact is actually small (Norwegian University of Science and Technology, 2016). According to Ivanova et al. (2016), household consumption contribute to more than 60% of global green house gas (GHG) emissions and highly impacts the world energy, material and water use. The large scale global consumption of products clearly leads to a considerable toll on the environment.

One area which have gained a lot of attention regarding products is waste generation. Global waste generation has been constantly increasing and show no signs of slowing down. It is estimated that 3.5 million tonnes of global solid-waste generation per day would increase to over 6 million tonnes between the years 2010-2025. The estimation to the year 2100 is that this number will increase to around 12 million tonnes of waste (Hoornweg et al., 2013). Waste can end up in dumps or landfills, which can pose a threat to the environment through contamination of water and degradation to toxic pollutants. Incineration of waste is also common which leads to air pollutants and greenhouse gas emissions (Hoornweg and Bhada-Tata, 2012). However alarming this may sound, it has been showed that the environmental impact from a products waste management usually only contributes to less than 5% of its full life-cycle impact (Hoornweg et al., 2013). The largest part of a products impact comes from the production phase and usage. It is therefore crucial to look at the full life-cycle of a product, in order to accurately estimate its environmental impact.

A noteworthy point is that the current plastic usages is not sustainable as the raw material comes from fossil sources. In the report from Thompson et al. (2009) they press on the fact that four percent of the worlds' oil production is used to make plastics, where over a third of the finished products are discarded. Plastics have great capabilities for use in biomedical products. Historically, plastics have dominated the medical field due to being cheap, lightweight and biocompatible (North and Halden, 2013). However, the massive use of disposable plastic suggests to pose a serious threat to the environment. According to the article by Souhrada (1988), 85% of medical equipment is comprised from single-use disposable plastic devices. Gloves, syringes, bags, sterile packaging and countless other products are vital for the medical industry. They are all single-use due to many different factors, such as the inability to properly sterilise them after use, risk of infection transmission and degradation of the plastic which make it lose its inherent function (van de Mortel, 2016). The amount of plastics in medical single-use devices (SUDs) can however vary a lot. In the case-study from Unger et al. (2017), the combined average of seven medical SUDs were shown to have a 52% weight from the plastic polyethylene. However, it did vary between 7-88%.

There are several tools used to analyse environmental systems, e.g. Risk Assessments, Environmental Auditing, Energy Flow Analysis, Material Flow Analysis and Environmental Impact Assessment (EIA). However, since the 90s the Life Cycle Assessment has grown successively more popular and what makes it stand out is that it has a cradle-to-grave perspective and a focus on a product's provided function. These are some properties not believed to be replaced by any other method (Finnveden, 2000a). However, LCA should never be the sole contributor to a decision basis, it may be supplemented with either a risk assessment, cost-/benefit analysis or environmental audit (Rydh et al., 2002).

When Unger et al. (2017) wanted to find out if the use of biopolymers, instead of plastics, would reduce the environmental impact from surgical procedures, a life cycle assessment was used. This was done to more accurately portray the full scope of the environmental load and they were able to show that the use of plastics lead to an approximate increase of 900% in smog-related impact. They also pointed out that the use of biopolymers in medical products correlate with a reduction in carcinogenic respiratory effects. Biopolymers as a substitution for conventional plastics have shown very promising effects so far. Switching out to biopolymers could prove very useful for lowering environmental impacts in the biomedical sector.

1.1 Purpose and Research question

The purpose of this report was to try and increase knowledge of how biomedical devices affect the environment and what positive changes could be implemented.

The main research question that this report will investigate is:

- How can the environmental impact from biomedical devices be reduced while also cutting down on plastic usage?

1.2 Limitations

This project is limited partly by time. Due to the fact that it is a Master's Thesis there is a time limit of less than 20 weeks. This will have an impact on the amount of data that can be collected. Preferably, the LCA would be supplemented by some kind of environmental and/or health-risk assessment. But due to the limited time, the LCA may only be followed by a qualitative discussion and no deeper analysis.

The case used in this study could also be regarded as a limitation. Since the assessment did not consider any other medical devices produced by Atos Medical or any other manufacturer.

The economical limitations may also have an impact on the study. While there are several, practical softwares for performing a Life Cycle Assessment, these are often very expensive. At the same time, open-source software may not contain the in-depth data points required to correctly assess the life cycle of Atos Medical-case, presented in this study. Hence, performing an LCA "by hand" in a more traditional way may produce results that are richer in detail than open-source but at the same time lack the completeness and extra tools that a premium software may provide.

2 Theoretical and methodological framework

Presented below is the literature and theoretical concepts, later built upon in the methodology and assessment.

2.1 Plastics in Healthcare

Historically, plastics have had a great impact on our way of living (Thompson et al., 2009). Plastics have contributed with cheap ways to secure a sterile and safe treatment and enhanced comfort of patients (Kleber and Cohen, 2020). The medical device safety is ultimately considered a risk management issue. However, as a multi-faceted problem one must also consider that absolute safety cannot be guaranteed, the safety is closely aligned with the effectiveness and performance of the device and it must be considered throughout the lifespan of the product. Another important consideration when it comes to medical devices is the risk/benefit relation. By definition, this means that when used in a proper manor, the device may not compromise the clinical condition or safety of the patient. Nor the safety or health of other users unless the risk is acceptable when weighted against the benefits for the persons in question. In short, this means that one strives to maximise benefit and minimise risk of the medical devices (World Health Organisation, 2003).

In the present situation, plastic waste from healthcare may end up on landfills or be incinerated. While waste ending up on landfills occupies big areas and runs the risk of contaminating surrounding water and lands, incineration is not a perfect solution either. Burning the waste do solve the problem of space, but instead contributes to harmful gas-emissions directly into the atmosphere (Kleber and Cohen, 2020). It also consumes resources instead of use the waste stream for productive matters, for example recycling. The current situation with the pandemic of the SARS-COV-19 virus is a good example. Necessary diagnostic equipment is used in great quantities, hence also disposed of. It is estimated that the Real Time-PCR tests' have contributed to 15,439.59 tonnes of plastic waste up til August 2020 (Celis et al., 2021). However, the knowledge of the environmental impact of medical products are lagging behind, especially in relation to other sectors. As legislative pressures are increasing, the medical sector must advance their efforts regarding reductions of environmental impact (Moultrie et al., 2015).

2.2 Life Cycle Assessment

In this report LCAs are used in an attempt to quantify the environmental impact that a product can have. LCA is described by Agarski et al. (2019) as a "scientifically sound and comprehensive approach" to determine environmental impact from processes and products. LCA is defined in the ISO standards ISO 14040 (International Organization for Standardization, 2006b) and ISO 14044 (International Organization for Standardization, 2006a) for environmental management. In ISO 14040 the principles and framework for an LCA is defined and in ISO 14044 the requirements and guidelines for the LCA is laid out. An LCA is generally made up by four different steps which will now be explained further.

2.2.1 Goal and Scope definition of an LCA

In this step, the goal and scope for the LCA is defined. The goal definition is supposed to answer what the objective of the study is, for whom it is conducted and for what purpose it is made. If the LCA is made for comparative purposes, such as the case in this report, then this should also be stated in the goal (Klöpffer and Grahl, 2014).

The scope definition handles the product system and sets boundaries for what will be included in the LCA. An LCA is in many ways an iterative process, which means that the scope may be changed during the assessment. A product system is often visualised with the help of an enclosed flow chart which shows how the product steps are connected. When modelling the product system it is important to consider what functional unit (fU) that will be used for the LCA. This is one of the most important parts of this step. A universal fU needs to be established for the LCA which all systems of the product will be measured in. The fU differs depending on the system, but it could be something along the lines of "number of products produced in a month". To create flow charts for the product system early on can be especially important in the case of comparative LCAs. This is due to finding similar steps between product systems, which can then be omitted from the analysis if they match. For example, transportation of different products have similar environmental impact regardless of what products are being transported. If the sole goal of the analysis is comparing products, this step can then be omitted (Klöpffer and Grahl, 2014).

Omission of other steps can also be justified. Often different cut-off criteria are set in place to hinder the product system from becoming too broad. These criteria often look at one box from the flow chart, called unit process, and see to what extent inputs contribute to the units impact. In order to realise what this contribution actually means, ISO 14044 states three contribution categories which can be used; mass, energy and environmental relevance . One cut-off criteria which is found widespread throughout literature, for instance Curran (2012), is the 1%-rule. This rule works on the basis of negligible contributions from inputs to a unit process. According to the 1%-rule, if the contribution from an input to a unit process is less than 1% for all chosen categories, then the input can be omitted. Curran (2012) states that this often works well, but can occasionally lead to large errors. These errors can occur if, for example, there are many different inputs which each contribute less than 1%, but together adds up to larger sum. Therefore, a complementary criteria exist which is called the 5%-rule. This rule states that omitted inputs due to the 1%-rule are not to total a contribution which exceeds 5% (Klöpffer and Grahl, 2014). If this is the case, then either all inputs need to be included or the cut-off criteria needs to be lowered to a number less than 1%.

Another important distinction that needs to be made is defining the product life cycle which is considered. Many different methods exist here where the most complete one is the "cradle-to-grave"-approach (Von Blottnitz and Curran, 2007). Cradle-to-grave takes all phases of a product life cycle into account and these phases can be categorised differently. For example, in Liebsch (nd) they define the phases to be in the order of; raw material extraction, manufacturing and processing, transportation, usage and retail, and waste disposal. Transportation usually exists between every phase, but can still be categorised as one phase. A cradle-to-grave approach takes in the full amount of environmental impact a product leaves, but also requires a lot of data. There are many other approaches, but for this report the relevant ones are cradle-to-gate, gate-to-gate and gate-to-grave. A cradle-to-gate approach assesses a product from the raw material extraction to the finished product. The referred "gate" is then the factory gate. A gate-to-gate approach is done when you want to look at a single step, for example the manufacturing of a product. This can be useful when the product system is very complex and there exists many value adding steps along the life cycle. The gate-to-grave perspective assesses the impact from the product leaving the factory til its disposal, usually as waste. These different approaches can later be connected, so eventually a full cradle-to-grave analysis is reached (Liebsch, nd).

2.2.2 Life Cycle Inventory Analysis

A Life Cycle Inventory (LCI) Analysis is scientifically based upon the laws; conservation of mass, conservation of energy and increase of entropy. These principles are important in order to understand the maximum amount of a product that can be produced and the minimum amount of energy it takes for a reaction to occur. Estimations done can often be referred back to these laws and the concept of $input = output$ that follows (Klöpffer and Grahl, 2014). An LCI is made to quantify and compile all of the inputs and outputs of a product system. All unit processes are connected with flows to show their inputs and outputs, and much of the work in the LCI is actually quantifying these flows. In the scope definition a broader system analysis and flow chart is made. In the LCI, a more strict identification of the functions is made with focus on what the goal of the study is. This is especially important when doing comparative LCA-studies so that all co-functions and overlaps between the systems become identified (Christiansen et al., 1995).

When mapping out the flows between unit processes, it becomes important to clearly state what flows that are discussed. If a certain amount of oil is set as input in a unit process, that oil needs to be trackable throughout the system. Another important part of the LCI is to consider the waste flow. If parts of the product is reused or recycled then closed loops can become present in the flow chart which reduces the total amount of material needed for the product. The question of waste management is one that quickly can become complicated. When considering products that are sold world-wide, a uniform waste management process for the LCA becomes impossible. With different methods in every country, quantification of environmental impacts need to be split into many different scenarios. For example, according to a report from Eunomia by Gillies et al. (2017) Germany recycles around 56% of their waste which makes it the best country in the world at this. Singapore is found at 10th place with a recycling rate of 34%. Shown from this is how much recycling rate can differ, which complicates averaging a value. Furthermore, many large cities around the world such as, San Francisco and Vancouver, are setting up goals to reduce their waste to zero (Zaman, 2015). With a trend such as this, the quantification of waste can quickly become outdated and so also the LCA.

2.2.3 Allocation

In an inventory analysis, if all activities can not compare between unit processes, it might be necessary to either allocate the environmental load or change the system boundaries. In allocation, the energy used for the unit process is subtracted from the "problematic" activity and the environmental load is assigned to the end-product (Rydh et al., 2002). In science and standards, it is not recommended to use allocation. Instead, allocation can be avoided by expanding or reducing the system boundaries. However, to always expand the system can make the analysis practically impossible to go through with. So even if the allocation is not always scientifically correct, it is still necessary from a practical standpoint (Klöpffer and Grahl, 2014). What the allocation is realised as in the LCI is splitting up the environmental impact over different parts. For example, if a moving truck is moving a couch and a chair in the same payload, the couch can be allocated a higher impact than the chair in proportion to its weight.

2.2.4 Life Cycle Impact Assessment

What turns a Life Cycle Inventory Analysis to a Life Cycle Assessment is the addition of a Life Cycle Impact Assessment (LCIA). In this important step of the LCA, the purpose is to define the actual environmental footprint (EF) of a product's or process' life-cycle. Up until this step in the process, inputs and outputs have mostly been quantified and this is where an actual impact is related to them (Klöpffer and Grahl, 2014; Walker and Rothman, 2020).

The three mandatory elements of the LCIA is the selection of impact categories, the classification (assignment of LCI results) and the characterisation (calculation of category indicator results). In the impact categorisation, different environmental effect categories that are relevant to the scope and goals of the assessment are established. Also included in the impact categorisation is the impact category indicator and characterisation factor (CF). The indicator must be, according to ISO 14044, a "quantifiable representation" that one can use to directly measure the impact on its respective category. By examples given by Klöpffer and Grahl (2014) this could be carbon emissions, measured in CO_2, if the impact category is "climate change". The CF is important as it is used to convert results from the LCI to the common units previously defined as the impact category indicators. Sometimes the LCI gives quantifiable values which can be used directly in the LCIA. For example, if an impact category is "energy usage", measured Joules from the LCI can be transfered over to the LCIA without any conversion. The ISO-standards does not specify any standardised impact categories, but they do provide assistance in selecting. Impact categories, indicators and CF will therefore vary, depending on the individuals performing the LCA. In the classification, data-categories from the LCI are assigned to their respective impact characterisation. For example, substances found in the LCI which are classified as greenhouse gasses, are assigned to the impact category "climate change" (Klöpffer and Grahl, 2014). The same data-categories can be assigned to several impact categories (Rydh et al., 2002). Lastly comes the characterisation of the impacts. This is the most important step of the LCIA as it is here that the results from the LCI is given comparable units. This is achieved by multiplication of the LCI results and the previously defined CFs (Klöpffer and Grahl, 2014).

Recommendations regarding choice of impact categories can be found in Agarski et al. (2019) and are strengthened by Gironi and Piemonte (2010) and Corbière-Nicollier et al. (2001), among others. In these studies, Global Warming, Acidification and Eutrohpication have been three of the most predominant impact categories. Additionally, the same sources have proven Energy Use or Energy Consumption equally popular. Presented in Table 2.1 are the most commonly used impact categories and their respective characterisation factor. Used as unit per functional unit (Walker and Rothman, 2020).

Table 2.1: Impact categories and their respective characterisation factors (Agarski et al., 2019; Walker and Rothman, 2020).

Impact Categories	CF units
Global Warming Potential	$kg * CO_2$
Acidifying Potential	$kg * SO_2$
Eutrophication Potential	$kg * PO_4^{3-}$
Energy usage	MJ

2.2.5 Life Cycle Interpretation

The last element of the life cycle assessment is the interpretation of results. Here, conclusions that can be drawn from the LCIA are presented in the light of the previously stated goal and scope definition along with the inventory analysis. This contributes with enough substance to constitute recommendations for the intended audience. An important part of the interpretation phase is the sensitivity and uncertainty analysis (Sandin et al., 2016).

In an uncertainty analysis, one seeks to establish intervals wherein important parameters may vary. The uncertainty analysis methodically engage the life cycle assessment in three phases. First, the parameters regarding the product system is evaluated in the phase of goal- and scope definition. Secondly, the uncertainty-intervals of the inventory analysis is created and the then corresponding values for the impact assessment. Lastly, the uncertainties of CFs in the impact assessment are estimated. In the sensitivity analysis, the effects of the chosen methodology and data is evaluated with regard to the complete result of the study. In short, the two methods combine to show how sensitive the end result is to uncertain parameters, which are found in the uncertainty analysis. The results of the sensitivity analysis are often portrayed as a dispersion interval or a diagram (Rydh et al., 2002).

2.2.6 Materials used

In this section, some of the materials that will be present in the life cycle assessment are expanded on. Their properties are written out which will later be used for discussion.

Polyethylene
Polyethylene makes up the highest volume of the worlds plastics (Patel, 2016). There are many different kinds of polyethylene plastics and the capabilities can vary. They are made up from ethylene gas, $(C_2H_4)_n$, which then create long polyethylene chains. Usually for the emergence of a synthetic polymer, the "n" needs to be around $10^2 - 10^4$. These long polymer chains have a high melting point and are very stable (Wieser et al., 2013). The weight of a polyethylene chain is approximately correlated to its chemical composition and is therefore dependent on the weight of carbon and hydrogen atoms. With molar weights taken from the periodic table (Angelo State University, nd), the weight becomes:

$$((12.011\ amu * 2) + (1.008\ amu * 4)) * n = (28.054 * n)\ amu = (28.054 * n)\ g/mol \quad (2.1)$$

To get how many (C_2H_4) constellations per gram of polyethylene, the equation becomes dependent on the Avogadro constant:

$$(6.022 * 10^{23}\ amu/28.054\ amu)\ /g = 2.1466 * 10^{22}/g \quad (2.2)$$

Polyethylene is 100% volatile and burns in one reaction, breaking of carbon-carbon bonds (Shemwell and Levendis, 2000). Assuming that all carbon atoms become CO_2 gas when incinerated, the amount of CO_2 emission from incinerating a gram of polyethylene can be calculated through multiplication of the molar weight for CO_2. The resulting equation becomes:

$$2.1466 * 10^{22} * 2 * (12.011 + 16 * 2)\ amu = 1.89 * 10^{24}\ amu = 3.14\ g \tag{2.3}$$

This would lead to a ratio of around 1:3 CO_2 when burning polyethylene.

Polyethylene terephthalate

Polyethylene terephthalate (PET) are long polymer chains with the chemical composition $(C_{10}H_8O_4)_n$. PET is produced through polymerization of ethylene glycol and terephtalic acid (Britannica, 2020). PET chains can be very long and it is not unusual for them to have a molar weight of 10-50 kg/mol. PET is a more complex material than polyethylene and can therefore not be approximated to CO_2-emissions the same way. Pyrolysis of PET produces different polycyclic hydrocarbons and byphenyl derivates which are dangerous for not only the environment but also human health (Park et al., 2020).

2.2.7 Waste disposal

To be able to quantify the environmental footprint from a product's full life-cycle, the disposal phase needs to be considered. For waste management, several different methods exist. One of these is incineration. During incineration of municipal waste a variety of different climate-relevant emissions are released, such as oxides of nitrogen and ammonia. However, CO_2 is by far the most emitted gas from incineration and is produced more than a hundred times compared to the other emissions (Johnke, 2003). Another widespread method is landfilling. Landfills and incineration of waste will be the main methods discussed in this report. Recycling of materials will also be considered.

According to EPA (2020b), the recycling of 45.97 million tons of paper and paperboard in the US 2018 lead to greenhouse gas benefits of 155.17 million metric tons of carbon dioxide equivalents. So recycling seems to be extremely beneficial for lowering the environmental impact. However, it is important to note what these savings actually mean. The US environmental protection agency takes in to account the savings from a full life-cycle perspective of the recycled paper, e.g. all the emissions that are saved from not producing new paper. However, for every time paper is recycled the fibres shorten and after 5-7 times of recycling it can not be used for new paper (Clark Howard, 2018). So paper considered in an LCA, how many times have it been recycled before entering the product system? Questions like these are present for all processes in an LCA and shines light on the difficulty of the model. The LCA gives an approximate result and it is therefore important to be clear of what assumptions has been made.

3 Methodology

Here, the methodology used to assess the environmental impact from medical devices, is described.

3.1 The Case - Atos Medical and Provox Life Go HME

To address the problems related to waste accumulation, plastic usage and sustainability in the biomedical sector, the case Provox Life Go HME came about. Atos Medical is a company which provides products and help for patients who have received a laryngectomy. Their two largest product categories consists of Heat-and-Moisture Exchangers (HMEs) and adhesives. The purpose of the HME unit is to capture heat and moisture in the exhalation. While bypassing the upper airways, a net loss of heat and moisture is created which may lead to pulmonary complications. During inhalation, the moisture evaporates into the entering gasses. These are also warmed by the heat trapped in the core of the HME unit (Pelosi et al., 1994). The HMEs are largely plastic based, needs to be changed daily and are disposed after each use. An ordered package of HMEs usually contain 30 units, so patients use around one package per month. Each unit is constituted by a housing, lid and foam. In the products in focus, the foam is the functional part of the product that produces its primary function. The product can be seen in Figure 3.1 and Figure 3.2.

Figure 3.1: One box of Provox Life Go HMEs. One box contains three blisters, with 10 HMEs in each.

One model of these HMEs is the Provox Life Go HME, a risk-class I medical device. Classification is made in accordance with the European Commission classification of medical devices (Läkemedlesverket, nd). A full analysis of this product's life-cycle was intended in order to quantify a biomedical product's environmental impact. Due to the HMEs daily and one-time usage, which the patient is dependent on for the rest of their lives, it was seen as a suitable product to analyse since so many units are discarded. To quantify the impact from the HMEs, the method Life Cycle Assesment (LCA) was chosen. In order to not underestimate the impact, a full cradle-to-grave assessment was intended to be performed. Furthermore, a decision was made to divide the full LCA in to three different analysis, cradle-to-gate, gate-to-gate and gate-to-grave, in order to reach a better understanding of where in the products life-cycle the most of its environmental impact is done. To divide an LCA in this way has been preformed in similar reports, such as Mousavi (2013) and Jiménez-González et al. (2000). The intention was that these three analysis would summed together show the full impact of the product.

3.2 LCA Provox Life Go HME, Gate-to-Gate

The first life cycle assessment which was carried out was performed with a gate-to-gate perspective. In accordance with ISO standards, the first step of the LCA was to define the goal and scope (Klöpffer and Grahl, 2014). The goal of this study was to quantify the complete environmental impact of a Provox Life Go HME product. The assessment was done to get a clear understanding of the impact that such a product's life-cycle cause. This first gate-to-gate analysis was carried out with the intention of allocating the product's impact to the different parts of its life-cycle. For the analysis of these HMEs, no comparisons were intended and therefore no production steps would be cut-off due to that reason. The complete environmental impact from the product was desired.

The gate-to-gate perspective chosen to be investigated was the manufacturing and processing, which takes place on site at Atos manufacturing plant in Hörby. The two gates referred to are the gate for incoming goods at the facility and the gate for outgoing finished products. Everything between these doors are considered and everything outside are cut-off in this gate-to-gate analysis. The chosen product system is depicted in Figure 3.3.

Figure 3.2: Provox Life Go HME. Consists of lid, housing and foam. The HME unit is placed on top of the patient's tracheotomy with the help of an adhesive.

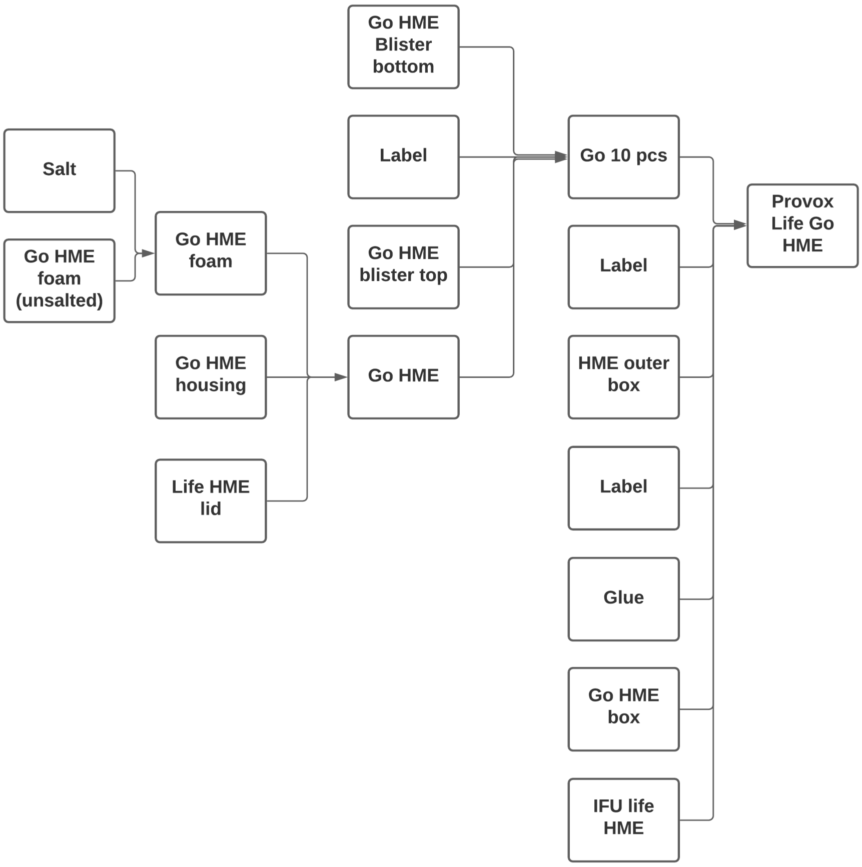

Figure 3.3: Flow chart depicting the product system of a Provox Life Go HME.

The fU chosen for this LCA is "production of 50 Provox Life Go HME boxes ready for shipping". This fU was chosen due to the finished products being shipped in large cardboard boxes which fit 50 HME boxes in each. Each HME box in turn contains 30 pieces of HMEs, which leads to the fU containing a total of 1500 HMEs.

With boundaries and fU defined, impact categories needed to be adressed. The chosen impact categories can be seen in table 3.1. Many other impact categories were considered, such as acidification and eutrophication, but had to be disregarded due to lack of data.

Table 3.1: Impact categories

Impact Category	Substantial LCI Parameter	Unit of Category Indicator
Global warming potential	CO_2, CH_24, N_2O etc	kg CO_2-equivalent
Energy consumption	Joule consumed	Mega Joule

The next step in the LCA was to create the Life Cycle Inventory (LCI) analysis. After having applied the 1% cut-off rule described in section 2.2.1, a new flow chart with the relevant unit processes was created. This can be seen in Figure 3.4. This flow chart depicts the different production steps that happens specifically on site at Atos which for now is the boundary of the system. For example, the Go HME housing and Life HME lid, which can be seen in Figure 3.2, are both produced at a different factory and then shipped to Atos facility in Hörby. The environmental impact from production of these were therefore not accounted for in this step.

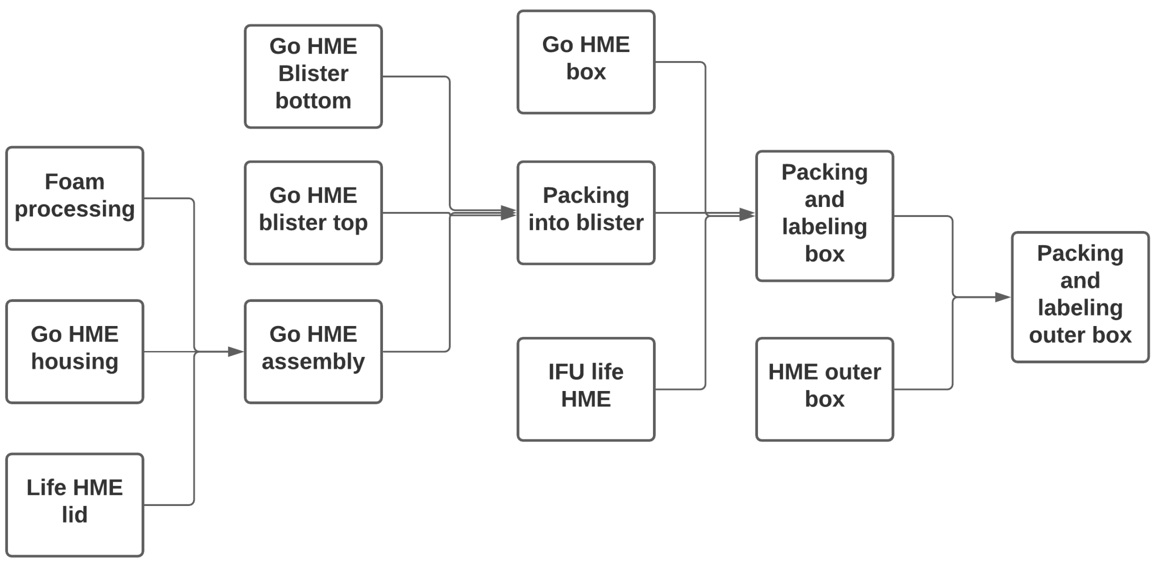

Figure 3.4: Flow chart depicting unit processes in the life cycle inventory. Showing production of one functional unit.

For the unit processes in Figure 3.4, material flow and energy usage was quantified. The resulting material flow is shown in table 4.1 in the results-section 4.1.1. The material flow was also important for the other perspectives, cradle-to-gate and gate-to-grave. The weights of the different parts were taken from real-life weight measuring on site at Atos.

3.2.1 Energy Usage

In order to quantify the energy usage for the unit processes shown in Figure 3.4, real-life measurements were used. Energy gauges was put on the different production steps and measurements were taken. Many of the unit processes in 3.4, such as the HME housing and lid, do not lead to any energy use in this gate-to-gate analysis since they are produced at a different facility. Only the processing steps lead to any energy expenditure, since that is where machines are used.

One step that needed calculation were the foam processing. Data from Atos lead to the energy expenditure being calculated through:

$$\frac{0.9\ kWh}{3600\ filter} = \frac{0.375}{1500\ filter} = 1350\ kJ \tag{3.1}$$

The resulting energy usage is found in table 4.6. For both energy and temperature at the site, completely renewable sources are used. Their electricity comes from different renewable power sources, such as water and wind. For heating and cooling, geothermal heat is utilised. This is seen as a carbon-neutral fuel. The gate-to-gate production and manufacturing does therefore not lead to any emissions at all, according to the methodology for renewable energy described in Klöpffer and Grahl (2014).

3.3 LCA Provox Life Go HME, Cradle-to-Gate

In the second step of the life cycle assessment, focus was moved back from the production and assembly at Atos, to the manufacturing of subcontractors. This part of the product system is illustrated in Figure 3.5. Herein, sub-parts of the HME Go unit are considered as well as the packaging products. The LCA was then performed in the very same way as previously described for the Gate-to-Gate-analysis. The functional unit was directly related to the previous fU "50 Provox Life Go HME boxes". In contrast to the previous part of the assessment (Gate-to-Gate), transportation to Atos production plant was now included in the calculations.

However, limitations were drawn at the subcontractors. Meaning that only the manufacturing of each sub-unit were looked into and not the next line of suppliers, i.e. the subcontractors of the subcontractors. It proved very difficult to collect data from providers due to various reasons. Then even further limitations had to be drawn. Many subcontractors were unable to provide any data. Therefore no energy consumption of production or processing of materials and parts could be considered. Hence, factors that could be taken into calculations were transportation and the estimated impact of each raw-material, as far to the source as they could be traced.

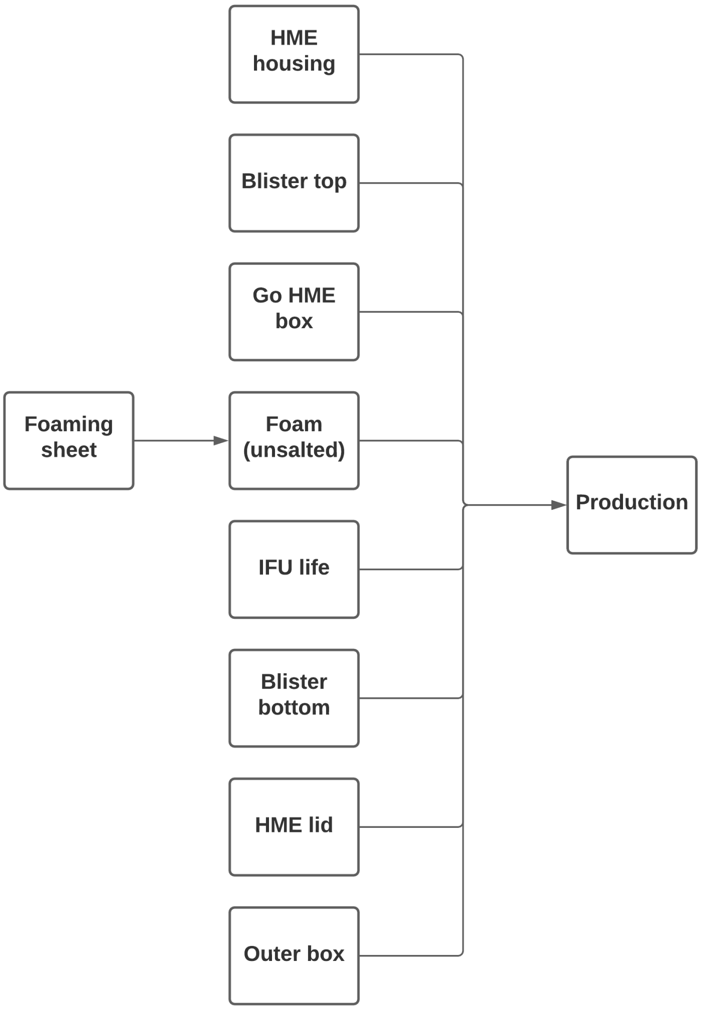

Figure 3.5: Flow chart depicting unit processes in the Cradle-to-Gate phase of the inventory analysis

Constraints were also found. After thorough literature search for environmental impact data, it was only found for some of the materials. Preferably, a material flow would have been used as described in the theoretical framework. However, to perform a fair analysis, one could not take this data any further with regard to the materials remaining non-quantified which would in other cases result in an unbalanced analysis. Instead, the findings from this part of the study were going to constitute substance for the discussion. Hence, this part of the study could only deal with the transportation of materials and sub-parts.

3.3.1 Material

Materials HME Housing and Lid are jet-moulded as the complete sub-units they are. The waste from this processing was relatively small in relation to its shipped quantity and were therefore disregarded. The salt however were shipped to the production facilities in Hörby in much greater quantities than which were finally used in the end-product. Similarly with the blister bottom and top. Although they did not contribute with as much waste as the salt, the difference in weight were still notable enough to be included in the Cradle-to-Grave phase.

3.3.2 Transport

In contrast to the gate-to-gate analysis, there were now a need for quantifying the distance of transport. This was estimated for transport on road. These assumptions were also needed for quantification in the gate-to-grave-analysis. For lorry transportation, an assumption was made that these are done by lorries which fit the "Three Axle Rigid Euro4"-category after investigating Australian Trucking Association (2018). These have a maximal payload of 13.69 tonnes. Using the online tool at SustainableFreight (2021), fuel consumption and CO_2-emissions could be calculated. Another assumption made was that the truck was fully loaded, 13.69 tonnes of payload. Information regarding routes, as well as ways of transportation, were provided directly by Atos and relevant subcontractors and order-information sheets. These routes for the cradle-to-gate were compiled into the results table 4.3.

In some cases, information could be obtained for several links in the manufacturing process and for a few of them, all the way to the manufacturing of raw material. However, to make an as even comparison as possible, limitations had to be drawn at warehouses and suppliers or in some cases, the closest facilities that performed some kind of last processing (before reaching the "gate").

For calculating energy usage for lorry transportation, a report from Davis et al. (2009)

was used to approximate. A heavy single-unit and combination truck during 2007 used around 23328 Btu per vehicle mile. This can be translated to megajoules per km through:

$$23328\ Btu/mile = 23328 \cdot 1055.056\ MJ/1.61\ km = 15.287\ MJ/km \tag{3.2}$$

3.3.3 Impact Assessment

Following the Inventory analysis, the results could now be related to its environmental footprint through division into impact categories. In this study, the carbon footprint equivalents were measured in kg CO_2 and the energy uses in Joule, both recommended in similar studies presented in the Theoretical Framework. These were evaluated to be the most relevant impact categories and also most plausible categories to find information about, with regard to the materials studied in the analysis.

Despite there not being any need for material flow in the Cradle-to-Gate phase, mass data were still usable to correctly assess the individual functional units' impact. The emission data produced with the help of SustainableFreight (2021) and Davis et al. (2009) assumed fully loaded trucks of 13.69 metric tonnes. The weight of the components were then divided by the total freight weight. In this way, a ratio could be produced between the amount of CO_2 equivalents that were released for the whole transport and the functional unit. Similar methodology were applied to the energy-usage data, retrieved from Davis et al. (2009).

3.4 LCA Provox Life Go HME, Gate-to-Grave

For the final step of the full LCA, a gate-to-grave approach was taken. The scope of this analysis was chosen to be between the product leaving the Atos facility til it goes to its grave. The grave was here defined as the disposal phase of the HMEs, meaning different waste options such as incineration, landfilling and recycling. This gate-to-grave scope also defines the product system. According to Atos internal sales data, the largest part of HMEs are delivered to European countries, around 70%. However, the single country with the most orders is the US, where 25% of all products are shipped to. What was decided to be done was to create two scenarios, one where the product was delivered to a customer in Europe and one to a customer in the US. To get somewhat of an average value, the deliverance was chosen to go to a customer in Houston, Texas for the US and

Paris, France for Europe. In regards to sold products in Europe, the largest countries are in order Germany, Spain, the UK, France and Italy. These countries make up over 80% of all European sales, so Paris was seen as a suitable average distance value for all of them.

The functional unit chosen for this LCA is related directly to the previous gate-to-gate analysis, "50 Provox Life Go HME boxes packaged in an outer box". For the life cycle inventory analysis of this LCA, a fairly simple model with only four unit processes was created. Due to the HMEs not having any other inputs or outputs than themselves for the usage phase, that phase was completely disregarded. Left is only transportation, warehouse storage and the disposal of the product. This flow is depicted in Figure 3.6.

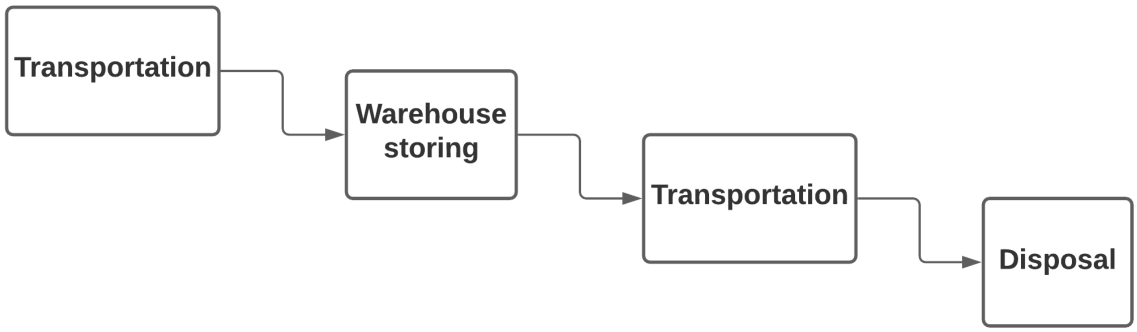

Figure 3.6: Flow chart depicting unit processes in the life cycle inventory. Showing the gate-to-grave perspective.

3.4.1 Material Flow and waste disposal

In regards to the disposal phase, as mentioned in section 2.2.7, there are many different waste disposal methods utilised. According to Eurostat (2020), estimations for 2019 were that municipal waste is dealt with by 24.0% landfilling, 26.7% incineration, 30.2% material recycling, 16.9% composting and 1.8% other ways. In the US these statistics correspond to 50.0% landfilling, 11.8% incineration, 23.6% material recycling, 8.5% composting and 6% other food management for the year 2018 (EPA, 2020b). The statistics that are relevant for the functional unit are landfilling, incineration and material recycling. The HMEs specifically are not to be recycled due to contamination, but the box, outer box, and IFU life manual can in theory be recycled easily. The blister was assumed to not be recycled. The parts of the product that are not recycled are then disposed of through landfills and incineration. Taking the previously mentioned statistics for America and Europe, the disposal of the non-recycled product became:

- In Europe: 47.3% landfilled, 52.7% incinerated
- In the US: 80.9% landfilled, 19.1% incinerated

According to EPA (2020b), 68% of paper and paperboard was recycled 2018 in the US. This number was up to 84.8% in 2017 for Europe and will be used for calculating emissions (Coppola, 2020).

For incineration, an emissions-value of 0.07 kg CO_2 equivalents (CO_2 e) per kg paper and paperboard was used. This value was taken from Hillman et al. (2015) and is a proposed average for incineration in Norway, but lacking other information this value was taken for incineration in both Europe and the US.

For calculating landfill emissions from paper and paperboard, the report from Zhao et al. (2019) was used. There, paper and paperboard are classified as biodegradable waste which produces a maximum of 135 kg methane and 320 kg CO_2 per 368.4 kg of biodegradable waste. They produced these values from stoichiometric calculations. The sum of 135 kg methane and 320 kg CO_2 equals 3695 kg CO_2-equivalents (EPA, 2020a). However, the stoichiometric calculations are not representative for reality and Zhao et al. (2019) mentions that these landfill emissions were only 24% of the estimated maximum in 2015 in the US. Taking this into account, the calculation for CO_2e for landfilled paper and paperboard becomes:

$$\frac{3695\ kg \cdot 0.24}{368.4\ kg} = 2.407\ kg\ CO_2e\ per\ kg \tag{3.3}$$

Specific values for Europe were unable to be found. Therefore, this value was used for paper landfilling in both the US and Europe.

Combining landfill and incineration values, emissions from the disposal of the boxes and manual could be calculated. The calculations were split in to two, one for Europe and one for the US. Recycled paper was approximated as having zero CO_2e emission. First, the recycled part needed to be subtracted from the functional unit and then the emissions from incineration and landfill were calculated. Only the weight from the paper and paperboard parts of the product were taken into account, namely the outer box, Go HME box and IFU life. The equation for Europe then became:

$$3.182\ kg \cdot (1-0.848) \cdot (0.473 \cdot 2.407\ (kg/kg) + 0.527 \cdot 0.07\ (kg/kg)) = 0.5685\ kg\ CO_2e \tag{3.4}$$

Meanwhile, the equation for USA became:

$$3.182\ kg \cdot (1 - 0.68) \cdot (0.809 \cdot 2.407\ (kg/kg) + 0.191 \cdot 0.07\ (kg/kg)) = 2.00\ kg\ CO_2e \quad (3.5)$$

To calculate emissions from disposal of the plastic parts of the product, the same division for incineration and landfilling was used. The assumption was that none of the plastic parts were recycled. Starting with incineration, the article by Chen and Lin (2008) provided emission data for combined plastics. They concluded that for 84334 tonnes of incinerated plastic, 22770.18 tonnes CO_2e was produced. These emissions are taken from waste incinerators in Taipei, but were used for both European and American incineration values. This equals to 0.27 kg CO_2e being produced for every kg of plastic waste. This value is a lot lower than the 1:3 ratio which was calculated stoichiometrically for polyethylene in section 2.2.6. Lower real-life values can come from different carbon catching methods which are frequently used in incineration plants. More on this topic can be found in the discussion. In this assessment, the value 0.27 kg, calculated from Chen and Lin (2008), will be used.

For plastic in landfills, the emission looks different. According to Chen and Lin (2008), landfilled plastics give zero CO_2e due to breaking down so slow in landfills. In Chamas et al. (2020), they estimate that landfilled PET have an estimated half-life of over 2500 years and polyethylene products with similar characteristics of the HMEs have a half-life of 250 years. In regards to emissions from the landfilled HMEs, a value of zero was therefore used. Having plastics in the environment is obviously not desirable, but for the emission category used in this report no emissions are produced.

With information regarding the disposal methods, emissions for the plastic part of the functional unit was then calculated. Just as for the paper and paperboard, two equations for the different locations were needed. Only the weights for the plastic parts HME housing, unsalted HME foam, HME lid, blister top and blister bottom in table 4.1 were taken into account. The first equation for Europe became:

$$3.1035\ kg \cdot 0.527 \cdot 0.27\ (kg/kg) = 0.4416\ kg\ CO_2e \quad (3.6)$$

The equation for the US became:

$$3.1035\ kg \cdot 0.191 \cdot 0.27\ (kg/kg) = 0.1600\ kg\ CO_2e \tag{3.7}$$

The salt in the foam was regarded as having no impact on CO_2-emissions in the disposal phase due to having no carbon. The salt can still have a negative environmental impact, but in regards to the chosen categories in this report it is negligible. It was therefore not taken into account.

For the last unit process, warehouse storing, real-life data from subcontractors were unable to be obtained. After discussing this with Atos, the warehouse storing was instead approximated as having an environmental impact of zero for the product's life-cycle. The HMEs are not in need of any refrigerated or other special storing alternatives, so the energy usage comes largely from lighting and heating. More on this matter is discussed in section 5.6.

3.4.2 Transport

A fU being transported from the Atos facility in Hörby to Paris was assumed to be transported by a lorry. According to Google (ndc), the driving distance between the two is 1316 km. Using the method described in the section 3.3.2, the online calculator at SustainableFreight (2021) gave an emission of 1969 kg CO_2. From the LCI in table 4.1 one fU had a weight of 6.395 kg. With the assumption that the lorry had a full payload, the fraction of the payload that the fU made out became:

$$6.395\ kg/13690\ kg = 4.672 * 10^{-4} \tag{3.8}$$

The emissions for the fU are then calculated through:

$$4.672 * 10^{-4} \cdot 1969\ kg = 0.9002\ CO_2 \tag{3.9}$$

For calculating the energy usage, the same fraction was used and multiplied with number of kilometres and the value 15.287 MJ/km that was calculated in section 3.3.2. The total amount of energy for the trip to Paris could then be calculated through:

$$4.672 * 10^{-4} \cdot 1316\ km \cdot 15.287\ MJ/km = 9.400\ MJ \tag{3.10}$$

The distance between Hörby and Houston, Texas is 8380 km (Google, ndb). 95% of Go HMEs are transported via container to the US through a combination of boat, train and truck. The routing goes specifically:
Hörby →Helsingborg (by truck) →Reykjavik (by boat) →Halifax (by boat) →Chicago (by train) →New Berlin (by truck)
Atos have a large warehouse in New Berlin where the products are stored. From there, the HMEs are delivered out directly to end customers all over America by UPS or FedEx.

From contacting the subcontractor responsible for shipping to the US, an emission report was received which showed emissions for the full trip between Hörby and the warehouse in New Berlin. This emission report can be found in appendix A0.1. These values represent a full container of Life Go HMEs. In order to get the values representative for one fU, the weight percentage that one fU makes out were taken. The emission report shows two different shipments, one with a higher weight and one with a lower. Since the emissions are the same for both, the one with the lower weight was chosen to be representative, in order to be conservative. The fraction that the fU then makes out becomes:

$$6.395\ kg/36790\ kg = 0.00174 \tag{3.11}$$

This fraction was then multiplied with the emissions and energy usage in the emission-report to produce the results for transportation to New Berlin showed in table 4.5.

The methodology in section 3.3.2 was used to calculate emissions for the last trip from New Berlin to Houston. According to Google (nda), the driving distance between New Berlin and Houston is 1839.3 km. The online calculator at SustainableFreight (2021) gave an emission of 2751 kg CO_2. The fraction of these emissions that the functional unit makes out is the same as mentioned in the previous segment; $4.672 * 10^{-4}$. The emissions for the functional unit are then calculated through:

$$4.672 * 10^{-4} \cdot 2751\ kg = 1.285\ kg\ CO_2 \tag{3.12}$$

For calculating the energy usage, the same methodology as for the trip to Paris was used. The following calculation became:

$$4.672 * 10^{-4} \cdot 1839.3\ km \cdot 15.287\ MJ/km = 13.136\ MJ \tag{3.13}$$

3.5 Sensitivity analysis

As required, the LCA was wrapped up with a sensitivity analysis. With the two different scenarios Paris and Huston, a certain sensitivity could already be said to be investigated. However, several parameters are changed at the same time and a clear understanding of what parameters affect the result the most craves a sensitivity analysis. The four different parameters chosen to be investigated were: how full a loaded truck is, the distance a truck drives to the end customer, the recycling rate of paper and paperboard, and lastly the ratio of landfilling and incineration of waste. The assumption for the trucks were that they were completely loaded. For the sensitivity analysis the scenario investigated were if they instead had a load of 50%. Assuming that a truck is always fully loaded is probably not completely realistic and in for example Kinnon (2011) they instead recommend an assumed payload of 80%. More on this topic in section 5.7.

Varying the distance to the end customer were done through increasing and decreasing the distance by 50%. Important to note is that this increase in distance were taken as ±50% in the distance between New Berlin and Houston, not the total distance between Hörby and Houston. This was investigated in order to see how much the impact would differ if the end customer lived in other places of the US and Europe. Increase and decrease of 50% obviously does not cover all potential destinations, but gives an idea of how the impact could vary with varying end-destinations. For the recycling rate, it was investigated if the recycling of paper and paperboard were 0 respectively 100%. This was done in order to see how much difference it would make for the overall impact if nothing was recycled compared to everything. For the waste disposal, the two scenarios investigated were if everything was landfilled alternatively incinerated. This was done in order to cover more scenarios of waste management. Countries use different combinations of the options, so the result from this analysis would cover a larger range of waste management options. All these parameters were varied and the results are presented in 4.3.1.

As mentioned in 2.2.5, a sensitivity analysis is often accompanied by an uncertainty analysis. However, for this report a sensitivity analysis was deemed as covering enough. Many of the parameters are not that uncertain, such as different distances and production values at Atos. With two different scenarios, a sensitivity analysis and the comparison in section 5.3, a lot of the uncertainties were deemed to be covered and an uncertainty analysis would be redundant.

4 Results

Presented below are the results from the life-cycle assessment presented.

4.1 Life Cycle Inventory Analysis

The results are divided into three subsections, for each life-cycle phase that were investigated.

4.1.1 Gate-to-Gate

Table 4.1: Life Cycle Inventory analysis for unit processes in Figure 3.4. Weighed on site at Atos facility.

Unit process	Material flow
Foam processing	266.55 g foam, Polyurethane and calcium chloride
Go HME assembly	2152.2 g HMEs with 266.55 g foam, 1173.9 g HME housing and 711.75 g HME Lid
Packing into blister	3216.9 g packaged blisters and 502.4 g waste blister material
Packing & labeling box	4513.75 g with 1296.85 g boxes and 3216.9 g
Packing & labeling outer box	5071.75 g full box, 4513.75 g boxes and 558 g cardboard box
Blister bottom	940.9 g containing 80% APET and 20% Polyethylene
Blister top	113.6 g containing 32% Polyester, 2% Polyurethane and 66% Polyethylene
Go HME box	1296.85 g paperboard
IFU life HME	1326.5 g paper
Outer box	558.33 g corrugated fibreboard
HME housing	1150.4 g Polypropylene
HME lid	697.52 g Polypropylene

4.1.2 Cradle-to-Gate

First, presented in Table 4.2 is the inventory of mass-flow from subcontractors to Atos Medical in Hörby. In Table 4.3, the routes and transported distances for each sub-part of the product are presented.

Table 4.2: Environmental impacts of in- and outgoing materials for the Cradle-to-gate phase, portrayed with weights in relation to functional unit

Sub-unit	Material Flow mass (g)
HME Housing jet moulding	1174
HME lid jet moulding	712
Foam manufacturing (unsalted)	163
Salt	1228
Blister Bottom	1389
Blister Top	168
IFU Life HME	1327
Go HME box manufacturing	1297
Outer box manufacturing	558

Table 4.3: Routes and distances for each Unit Process in the Cradle-to-Gate phase.

Unit process	Route	Transport distance (km)
HME Housing & Lid	Ängelholm-Hörby	80
Foam (unsalted)	Mönsterås-Hörby	270
Salt	Darmstadt (Germany)-Hörby	934
Blister Bottom	Lund-Hörby	36
Blister Top	Lund-Halmstad-Hörby	262
IFU- Life HME	Malmö-Hörby	59
Go HME box	Malmö-Hörby	59
Outer box	Malmö-Hörby	59

4.1.3 Gate-to-Grave

Table 4.4: Disposal values for Europe and the US. Reference weights taken from table 4.1

Unit process	Approximated material	Weight (kg)
Go HME box	Paper and paperboard	1.297
Outer box	Paper and paperboard	0.558
IFU life	Paper and paperboard	1.327
HME housing	Plastics	1.174
HME foam (without salt)	Plastics	0.163
HME lid	Plastics	0.712
Blister bottom	Plastics	0.941
Blister top	Plastics	0.114
	Paper and paperboard	Total weight = 3.182
	Plastics	Total weight = 3.104

Table 4.5: Life Cycle Inventory analysis for unit processes in Figure 3.6. Transportation between Hörby and Paris respectively Houston.

Unit process	Transport distance (km)
Transportation of product from Hörby to Paris	1316
Transportation of product from Hörby to New Berlin	6800
Transportation of product from New Berlin to Houston	1839.3
Disposal of product in Paris	-
Disposal of product in Houston	-

4.2 Life Cycle Impact Assessment

4.2.1 Gate-to-Gate

Table 4.6: Energy usage for unit processes in 3.4. Only processes which use energy shown. Some unit processes added together due to the nature of the real-life measurements.

Unit process	Energy usage (MJ)
Foam processing	1.35
Go HME assembly	2.28
Packing into blister	2.16
Packing & labeling of HME box and outer box	2.81
Total energy usage Gate-to-Gate	8.60

4.2.2 Cradle-to-Gate

Data from the Inventory Analysis is here translated into comparable environmental footprints. Presented below in Table 4.7 are the calculated CO_2 emissions from the cradle-to-gate phase of the analysis.

4.7

Table 4.7: Emissions of CO_2 *equivalents* due to transport in the Cradle-to-Gate phase

Unit process	Route	Energy usage (MJ)	Emission ($kg\ CO_2\ equivalent$)
HME Housing & Lid	Ängelholm-Hörby	0.17	$16.53 * 10^{-3}$
Foam (unsalted)	Wetteren (Belgium)-Mönsterås-Hörby	0.049	$4.81 * 10^{-3}$
Salt	Darmstadt (Germany)-Hörby	1.28	$125 * 10^{-3}$
Blister Bottom	Lund-Hörby	0.056	$5.48 * 10^{-3}$
Blister Top	Lund-Halmstad-Hörby	0.049	$4.81 * 10^{-3}$
IFU- Life HME	Malmö-Hörby	0.087	$8.53 * 10^{-3}$
Go HME box	Malmö-Hörby	0.085	$8.34 * 10^{-3}$
Outer box	Malmö-Hörby	0.037	$3.59 * 10^{-3}$
Total impact		1.81	0.177

4.2.3 Gate-to-Grave

Table 4.8: Resulting emissions from disposal in Europe. Calculated through weight fraction times emissions from each respective materials total weight.

Unit process	Emissions (kg CO_2e)
Go HME box	$0.408 \cdot 0.567 = 0.232$
Outer box	$0.175 \cdot 0.567 = 0.100$
IFU life	$0.417 \cdot 0.567 = 0.237$
HME housing	$0.378 \cdot 0.442 = 0.167$
HME foam (without salt)	$0.053 \cdot 0.442 = 0.023$
HME lid	$0.229 \cdot 0.442 = 0.101$
Blister bottom	$0.303 \cdot 0.442 = 0.134$
Blister top	$0.037 \cdot 0.442 = 0.016$
Total emissions	1.01

Table 4.9: Resulting emissions from disposal in the US. Calculated through weight fraction times emissions from each respective materials total weight.

Unit process	Emissions (kg CO_2e)
Go HME box	$0.408 \cdot 2.00 = 0.816$
Outer box	$0.175 \cdot 2.00 = 0.35$
IFU life	$0.417 \cdot 2.00 = 0.834$
HME housing	$0.378 \cdot 0.160 = 0.060$
HME foam (without salt)	$0.053 \cdot 0.160 = 0.008$
HME lid	$0.229 \cdot 0.160 = 0.037$
Blister bottom	$0.303 \cdot 0.160 = 0.048$
Blister top	$0.037 \cdot 0.160 = 0.006$
Total emissions	2.16

Table 4.10: Life Cycle Impact assessment for the Gate-to-grave perspective. Results for destination Paris respectively Houston.

Unit process	Energy usage (MJ)	Emissions (kg CO_2e)
Transportation of product from Hörby to Paris	9.40	0.920
Transportation of product from Hörby to New Berlin	97.79	7.16
Transportation of product from New Berlin to Houston	13.14	1.29
Disposal of product in Paris	-	1.01
Disposal of product in Houston	-	2.16
Total impact Gate-to-grave, destination Paris	9.40	1.93
Total impact Gate-to-grave, destination Houston	110.92	10.61

4.2.4 Total impact

Table 4.11: Total impact cradle-to-grave for Provox Life GO HME.

Unit process	Energy usage (MJ)	Emissions (kg CO_2e)
Cradle-to-Gate	1.81	0.177
Gate-to-Gate	8.6	0
Gate-to-Grave, Paris	9.4	1.93
Gate-to-Grave, Houston	110.92	10.61
Total impact, destination Paris	19.81	2.11
Total impact, destination Houston	121.3	10.79

4.3 Life Cycle Interpretation

When interpreting the result in table 4.11 it seems as though the largest contribution comes from the Gate-to-Grave-phase. Furthermore, the impact is around 5-6 times larger for both impact categories when the destination is set to Houston instead of Paris. When investigating the results in 4.10, this large change can be attributed to the transportation across the Atlantic. This transportation step is by far the largest contributor for the product's life-cycle. But if the product is destined for Paris, a single step becomes less dominant. The energy usage in the Cradle-to-Gate-phase is the smallest while Gate-to-Gate and Gate-to-Grave have somewhat similar energy usages. Regarding the CO_2-emissions, they come largely from the Gate-to-Grave and are split between the transportation phase and waste disposal. 0.92 kg for the transport to Paris and 1.01 kg for the disposal of the product. Allocating the results to different parts of the life-cycle gives the result in Figure 4.1. The figure shows that transportation and disposal are the biggest factors for emissions while transportation and production are the largest contributors to energy usage. This is specific to the destination Paris. With destination Houston, the emissions from disposal are more than doubled. With the added travelling over the Atlantic, the transportation factor becomes completely dominant and is responsible for over 80% of both impact categories.

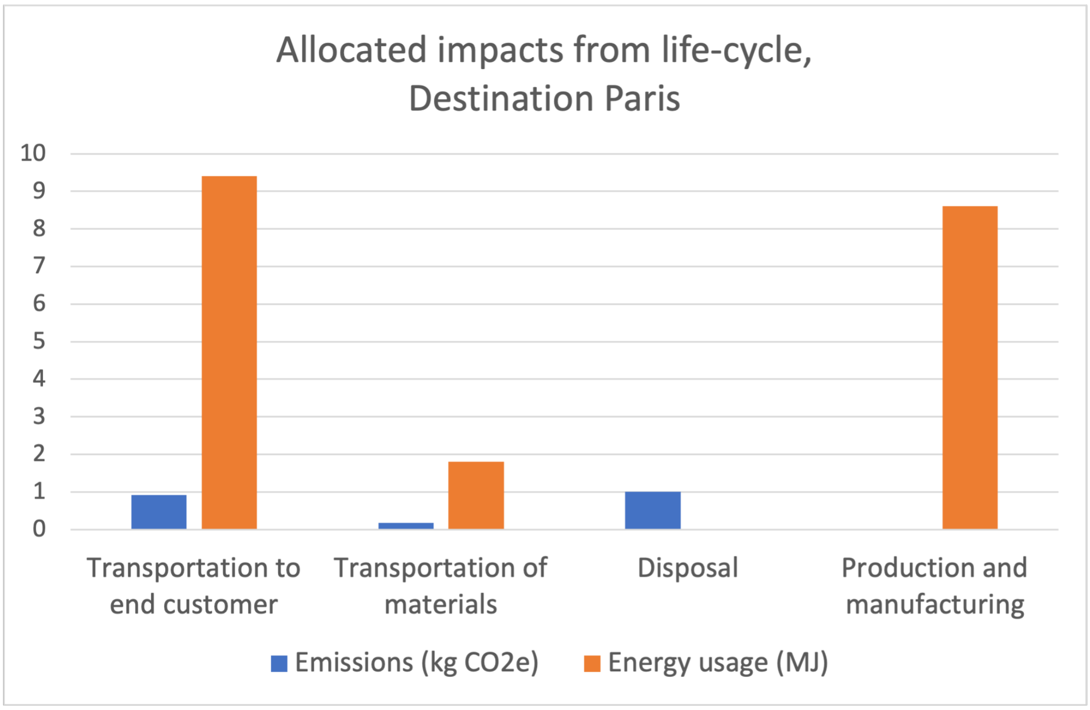

Figure 4.1: Impacts allocated to different steps of the product life-cycle.

Figure 4.2 and Figure 4.3 presented in this section show the allocated emissions to each part of the product. The transportation of the finished product was disregarded. This was done due to the difficulty of allocating impacts from the transportation step to certain parts of the product. For instance, if the IFU life manual was removed from the product, the transportation emissions for the finished product would still be the same. Therefore allocating these emissions to parts of the product seemed misinformative and was chosen to be removed from these specific figures. For energy usage, allocating to the different parts of the product was disregarded. Figure 4.1 shows that most of the energy usage comes from the production and manufacturing, if the transportation to end customer is disregarded. These steps, shown in table 4.6, are mostly representative for the full functional unit and was therefore not allocated to parts of the product.

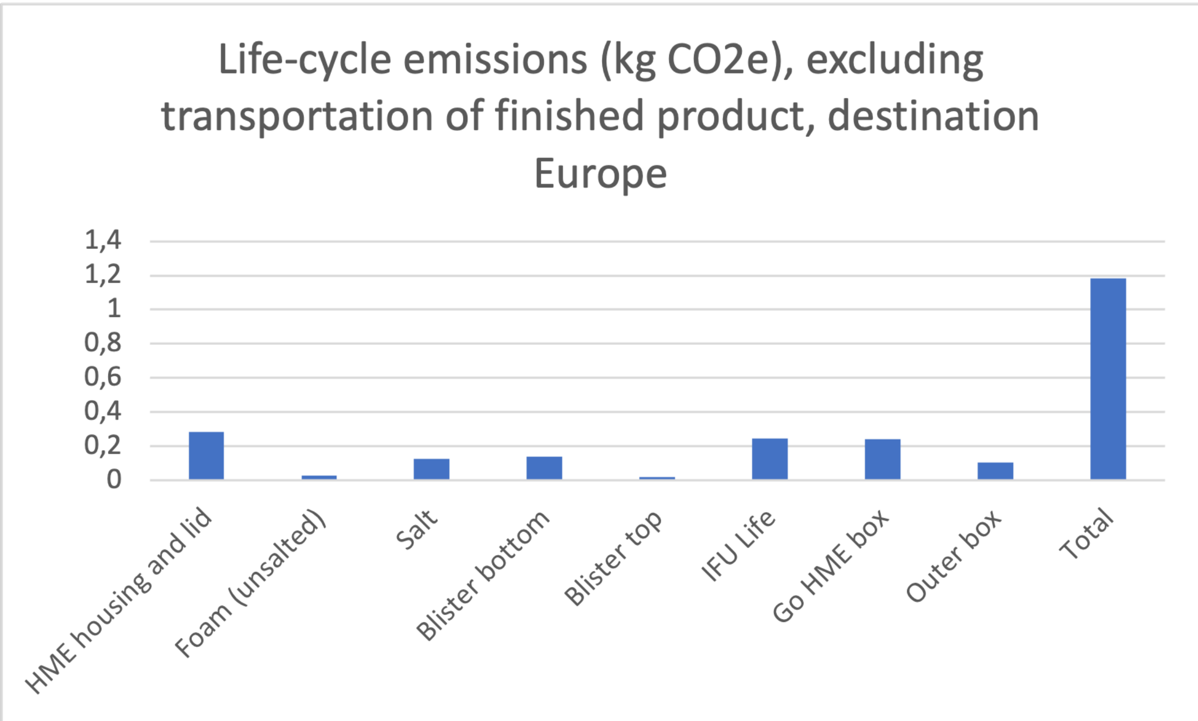

Figure 4.2: Emissions from the life-cycle allocated to different parts of the product.

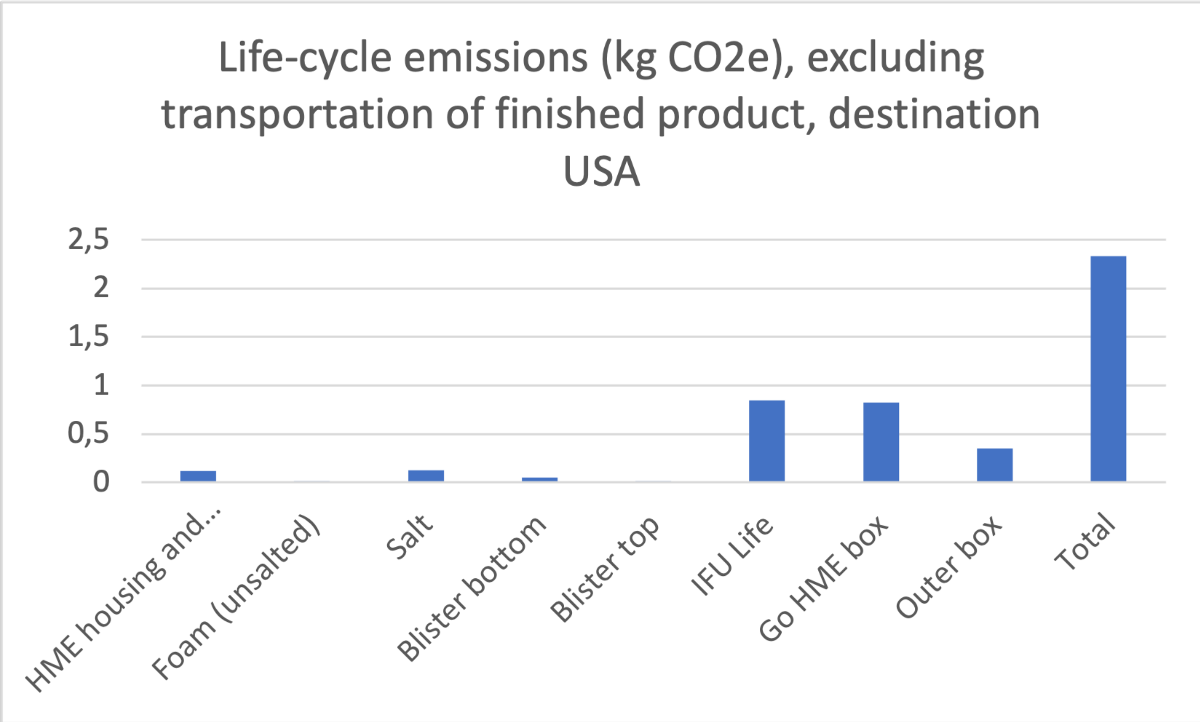

Figure 4.3: Emissions from the life-cycle allocated to different parts of the product.

4.3.1 Sensitivity analysis

In Figures 4.4-4.7 the sensitivity analyses are presented and shows how the changing of four different parameters affect the total life-cycle impacts. The middle line in each of the figures represent the resulting values from the total impacts in section 4.2.4. The waste incineration represents the lower values in the graphs and landfilling the higher. The "distance to the end customer" is simply varied by 50% in the European case. But in the case for destination US, the distance varied is the one from New Berlin to Houston. The recycling rate is specifically for paper and paperboard.

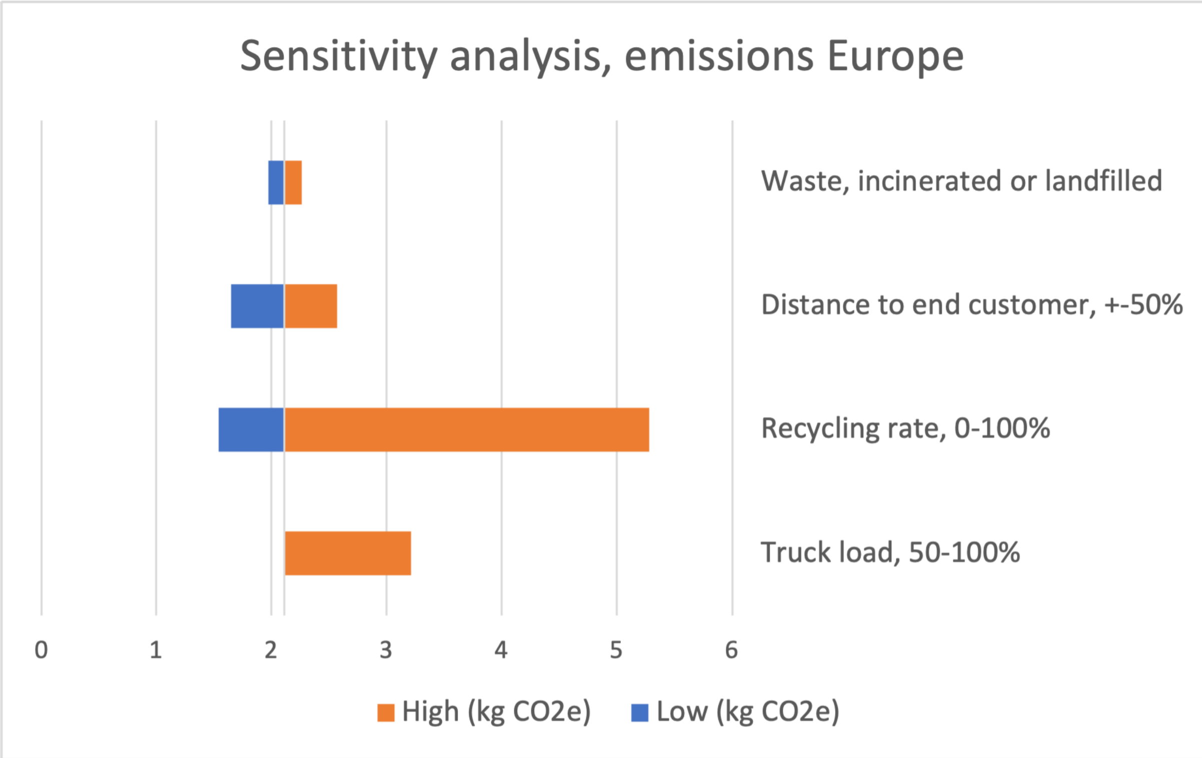

Figure 4.4: Sensitivity analysis investigating how four different parameters affect the total life-cycle impact.

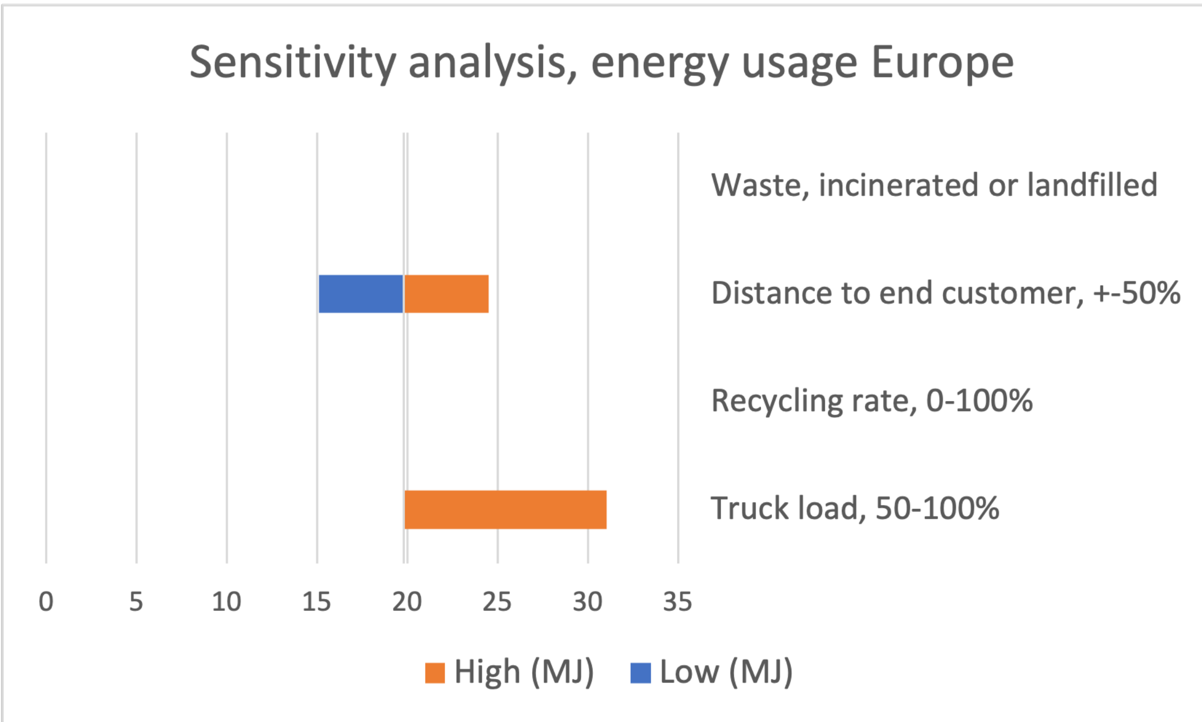

Figure 4.5: Sensitivity analysis investigating how four different parameters affect the total life-cycle impact.

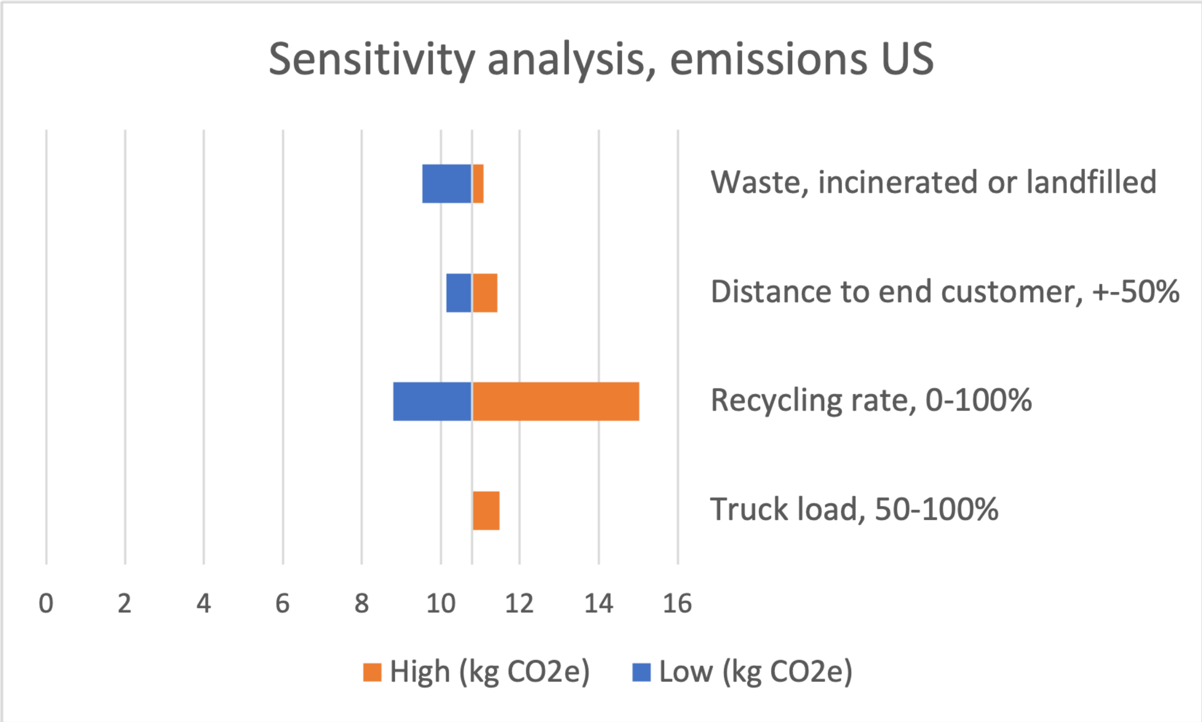

Figure 4.6: Sensitivity analysis investigating how four different parameters affect the total life-cycle impact.

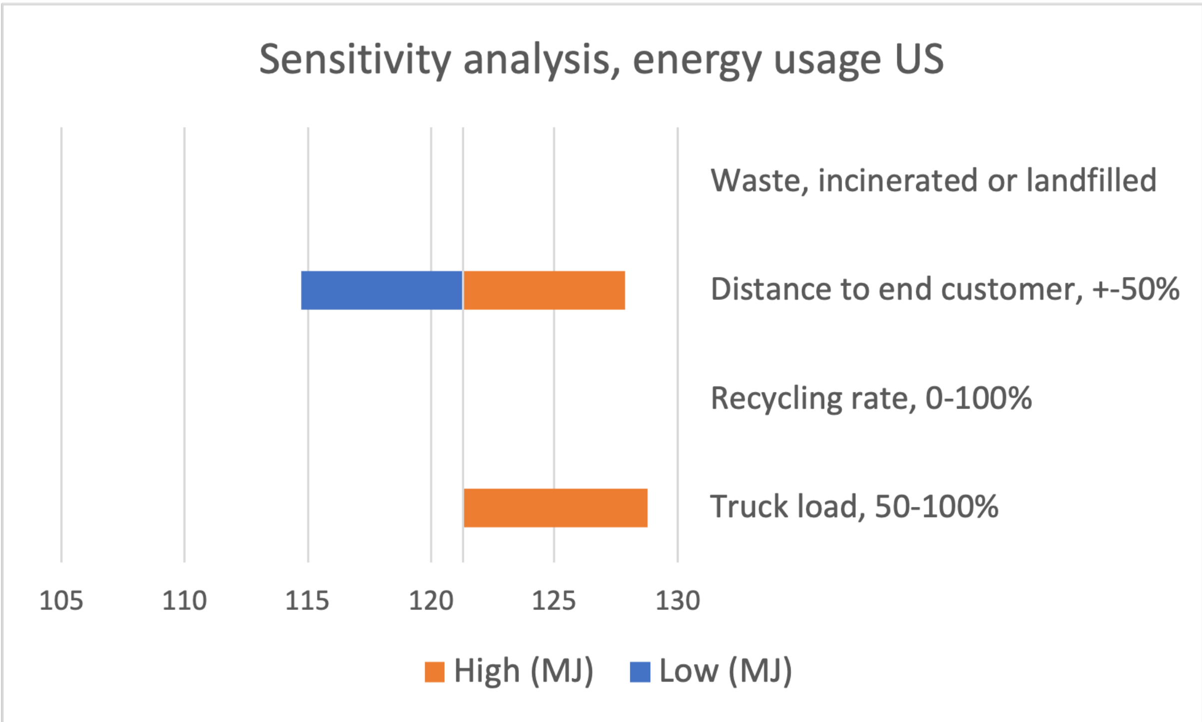

Figure 4.7: Sensitivity analysis investigating how four different parameters affect the total life-cycle impact.

5 Discussion

In this section, results and flaws in the analysis will be discussed. Furthermore, ways forward are discussed with how the environmental impact can be lowered.

5.1 Lowering the product's environmental impact

In an attempt to lower the environmental impact of the product, potential solutions were investigated. First, all parts of the products were considered in order to find where a change could be made. The main way of change which was considered was material substitutions. The regulations regarding biomedical products are very robust and set demands on the actual HMEs. The different plastics in the HME could perhaps be changed, but since these have physical contact with the patient the material would also need to be biocompatible. Furthermore, the subcontractor were unable to give out the information needed to properly calculate the environmental impact these plastic parts lead to. This means that even if other materials were considered, a true comparison would be impossible.

The HME and outer boxes are already made in fairly environmentally friendly materials and use no plastic. According to the product data sheets, the HME boxes are made from wood fibres which are sustainably grown with a controlled origin, in accordance with the EU timber regulations. The adhesive used is starch adhesive which have the benefit of being renewable and biodegradable (Dan, 2014). Specific information regarding the outer box were unable to be obtained from the subcontractor, but corrugated fiberboard as a material is made from paper which is renewable and recyclable. The IFU life paper manual is also made from paper and the best way to remove impact from this would probably be to remove it and instead have manuals electronically available online. However, not everyone has the opportunity to use online resources which complicates the removal. Customers who buy the HMEs get a manual in every new box they buy. Considering they often use these products throughout their lives, it becomes even less necessary to get a new manual each month or week. From the result in the graphs 4.2 and 4.3, the IFU life manual is actually one of the parts which performs the worst. Removing it would also not compromise the rest of the product in any way. HME housing and lid in graph 4.2 perform the worst, but removing it would take away the product's function. Removing the boxes would hinder the transportation of the HMEs. The manual on the other hand is not essential for the product's functioning or the transportation. An option could be to make it possible to order the product with or without manual, so long-time users could chose to not receive one. Another option could be to shorten the manual. At the time of this writing, the manual provided is 52 pages with instructions in 13 different languages. Considering the product is classified as a class 1 medical device and is fairly easy to use, the manual could perhaps be shortened. An alternative could also be splitting up the manual in fewer languages or in the language the customer wants. Considering the accumulating nature of the manuals over a patient's life-time, the best option in regards to environmental impact would probably be to remove it all together.

The blister top and bottom are made from plastics where a change could also be considered. The blister top use a film from AR packaging which use 39% renewable plastic. The subcontractor were unable to give out actual data, but according to their website they have tried to optimise carbon emissions and minimise use of fossil oil (AR packaging, nda). The last unit process left is the blister bottom. This one is also provided by AR packaging and according to their webpage, they use up to 50% recycled PET from certified and approved sources in the making of the product (AR packaging, ndb). It seems as though much thought is already made regarding the environmental impact. The blister bottom has a weight of around nine times that of the blister top, so a change would be more impactful here. Therefore, an attempt to lessen the impact from the blister bottom would be substituting the material. Lowering the plastic use for renewable materials would also be a more sustainable alternative.

One material substitution which was considered were using Polylactic Acid (PLA) instead of PET. PLA is usually made from corn, starch or sugarcane. It is compostable, recyclable and does not need to be cleaned before thrown. However, it can not be recycled together with other sorts of plastics (Bio Plastic News, nd). PLA is more permeable than PET and is therefore not suitable for humid conditions. The boxes are however not exposed to any abnormal levels of humidity. In the report from Madival et al. (2009), a comparison between PET- and PLA-packaging of strawberries were made. They made a full cradle-to-grave life cycle assessment for both of the materials. Growing of corn with inclusion of pesticides and fertilisers were included. They mention how PLA is used in blisters and packaging and according to Vink et al. (2007) PLA have a lower environmental footprint than PET. In Madival et al. (2009), the cradle-to-grave analysis showed a similar result where PET had the highest impact in most of their chosen impact categories. However, if transportation would be excluded from the analysis the result would look different. Considering only resin production, extrusion, thermoforming and electricity, the CO_2-emissions become 100 kg for PLA and 109 kg for PET. This number were for the functional unit of 1000 containers. So the difference was only 9% and a similar difference can be seen for the other categories. The authors also largely contribute this to the PET boxes higher weight. PLA could be a considered material substitution for the blister bottom, but it does not reduce CO_2-emissions in a large way. The main benefit would be from a sustainability perspective, where renewable materials are used instead of petroleum based. It should also be noted that the company BioPak claim that production of Ingeos' PLA emits 75% less CO_2-emissions compared to conventional plastics (BioPak, 2017). What a company claims and what is the objective truth could be different, but it is worth a mention. It is however a quickly growing field and companies have large monetary incentives to keep their secrets to themselves. Another thing to note is that PLA have weaker mechanical properties than PET. It is not as elastic and can not be elongated to the levels that PET can (MakeItFrom, 2020). This could lead to problems in Atos' manufacturing process if the material was chosen to be implemented.

Another bioplastic which can be considered is thermoplastic starch (TPS). TPS as a plastic can be created as 100% renewable and completely biodegradable (Humphreys, 2013). TPS also cause less environmental burden than PLA (Mahalle et al., 2014). However, TPS as a plastic have very poor stability and easily becomes brittle when it is the sole material used. Instead it is usually combined with other plastics, both bio- and petroleum-based. It is currently mostly used in fields where biodegradation is seen as an important feature, such as food packaging and compostable films (Humphreys, 2013). In Mahalle et al. (2014), a bioplastic using around a third each of wood fibres, PLA and TPS was compared against a polypropylene-plastic (PP). Their cradle-to-gate analysis showed that the bioplastic actually had a negative effect of -0.41 kg CO_2e compared to PPs 1.45 kg. The composite also performed better than PP in almost every impact categories. What should be noted here is that the end-of-life phase is not included in this analysis, it is only cradle-to-gate. Bioplastics do see some complications in waste disposal phase, more on this in section 5.8. The biggest drawback in physical property between the composite and polypropylene is that its moisture and water absorption capabilities are much worse. But this should not be a problem for usage as a HME blister bottom, since they are not exposed to any large quantities of moisture.

Polyhydroxyalkanoate (PHA) is another potential bioplastic that could be considered. It is created through bacterial fermentation and is both biodegradable and bio-based (Creative Mechanisms Staff, 2017). It has been used for single use packaging of different food products since it has the benefit of waste sorting in food waste.

A benefit PHA shows which PLA lack is that it can be produced from food waste. The environmental impact from PLA mostly comes from the fact that sugar cane or corn needs to be grown. However, since production of PHA can be made from the organic part of municipal waste, an otherwise overlooked resource could instead be used to create plastic (Colombo et al., 2017). This usage of food waste for PHA mostly seems to be found in literature though and is not widely implemented yet.

More on the actual quantification of these bioplastics and how it would influence the Provox Life's impact is found in 5.2.

5.2 Cradle-to-Gate analysis: Materials

As explained in section 3.3, enough data could not be found to support a inventory-, and later on impact-analysis of the material flow. However, some EF data were found and had relevance for some of the materials used in the blister packaging. From Gironi and Piemonte (2011) extensive information about the environmental impact of manufacturing different plastics could be found. Presented in table 5.1 are data retrieved from this article, among other sources. For Polypropylene, data were retrieved from Chen and Patel (2012). This source were also the main provider for several of the bio-based plastics. As can be seen in Table 5.1, different sources for bio-material have different environmental impact.

According to Stefan (2019), suitable substitutes for PET would be PLA, PHA and Bio-PET. This view is strengthened by Lackner (2015) where the substitute potential is ranked moderate to high for PLA and PHA. Meanwhile, PE have different levels of substitution potential depending on which form of PE that is manufactured. Still, most bio-based materials, this including PLA, PHA and Bio-PE, have a high to medium substitution potential for Low-Density-PE, Linear-Low-Density-PE and High-Density-PE. The case is similar for PP as PLA and PHA have a medium to high substitution potential (Lackner, 2015).

Table 5.1: Environmental impacts for manufacturing of different plastics

Material	kg CO_2 eq /(kg manufactured material)	MJ/(kg manufactured material)
PET	4.93	77
PE	4.94	80.3
PP	2.0	73.4
Alternative material	kg CO_2 eq /(kg manufactured material)	MJ/(kg manufactured material)
PLA	3.84	57.0
PHA	-	57.0
Bio-PET		
Maize	1.4	58.7
Sugar Cane	0.8	48.0
Bio-PE		
Maize	2.81	43.4
Sugar Cane	-0.37	-6.4
Bio-PP		
Maize	-0.25	42

Using the general data from table 5.1, emission values could easily be calculated in relation to the functional unit. This was performed by multiplication of the emissions values with the material weights from the Cradle-to-Gate phase. These were seen as the best representatives for the amount of manufactured material that is needed to make up one functional unit. The usage of these materials were, as previously described, mostly divided between blister bottom, blister top, HME housing and lid. Seen in Figure 5.1-5.6 are climate impact and energy demand, presented as they would have been in this study. Also seen is the impact of their corresponding substitute, the impact from each unit process and their total impact. The "total" category represents a scenario where all the conventional materials would be exchanged for one of the substitutes. Meanwhile each component category portrays the impact of exchanging the materials in only one component. Observe that Figure 5.1 and 5.2 has one category, as PET were only present in one product, and the "Total" category would hence be rendered unnecessary. Also, as the CO_2 emissions data for manufacturing of PHA were unknown, this pile is set to zero for all left graphs of Figure 5.1 to 5.6.

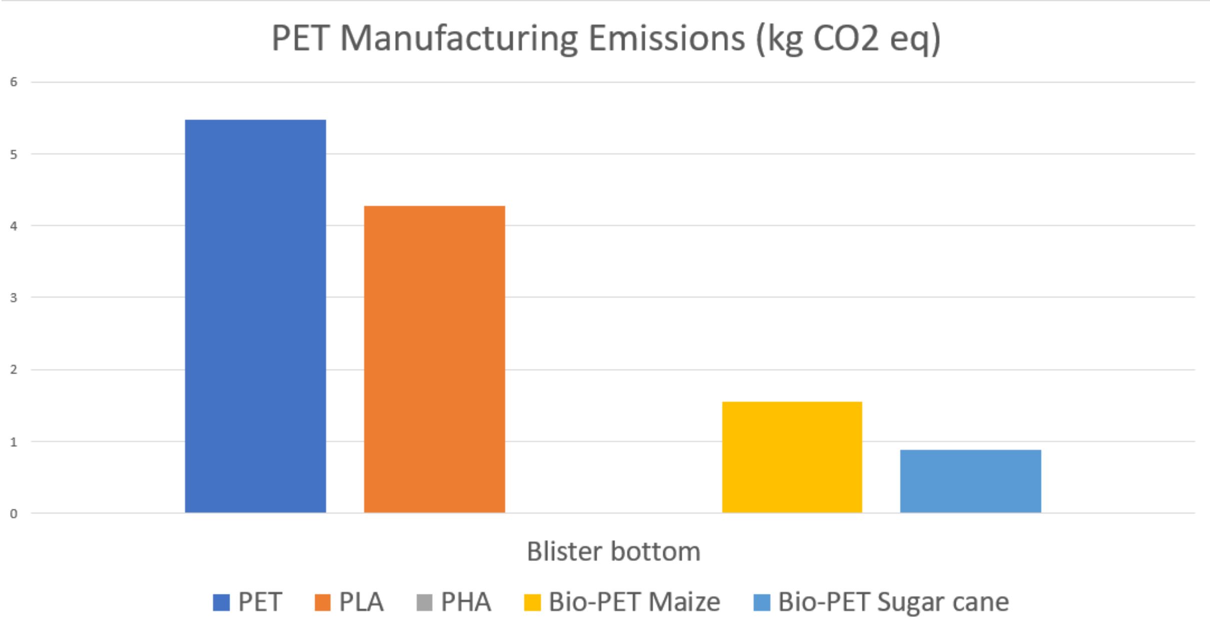

Figure 5.1: Impacts of CO_2 emissions from manufacturing of polyethylene terephtalate now in use and its substituents

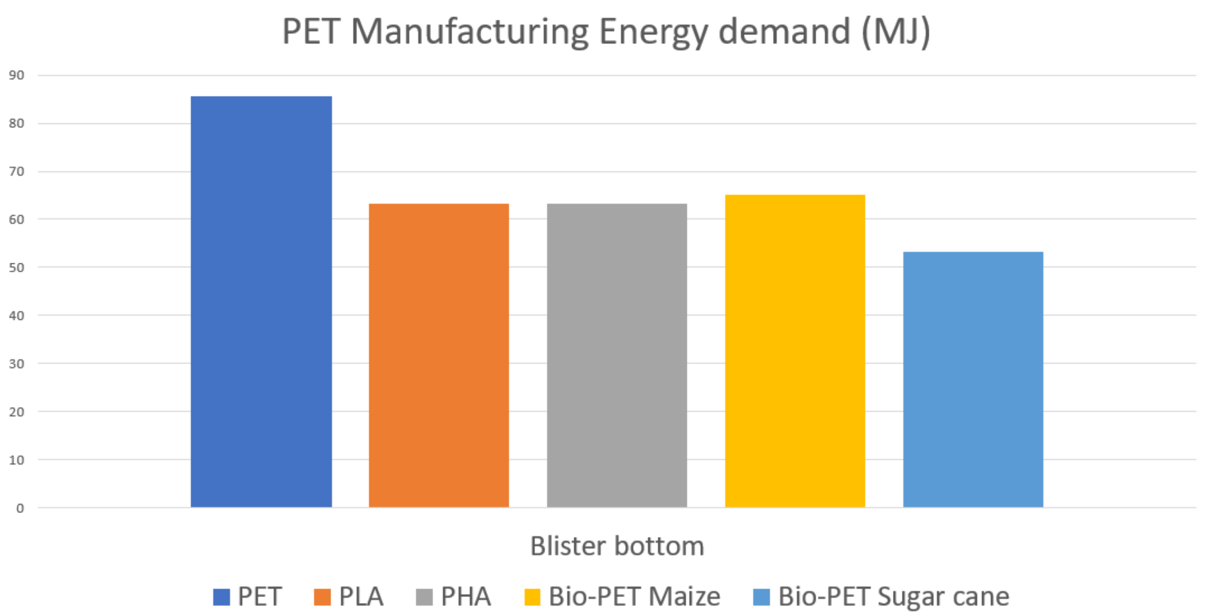

Figure 5.2: Impacts of energy demand in manufacturing of polyethylene terephtalate now in use and its substituents

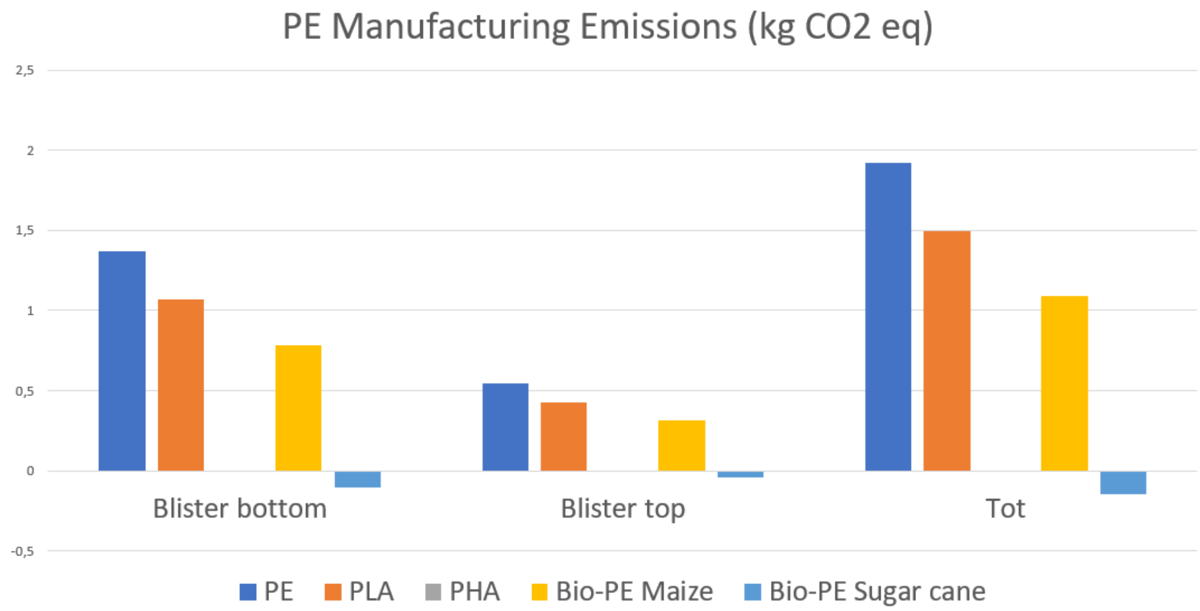

Figure 5.3: Impacts of CO_2 emissions from manufacturing of polyethylene now in use and its substituents

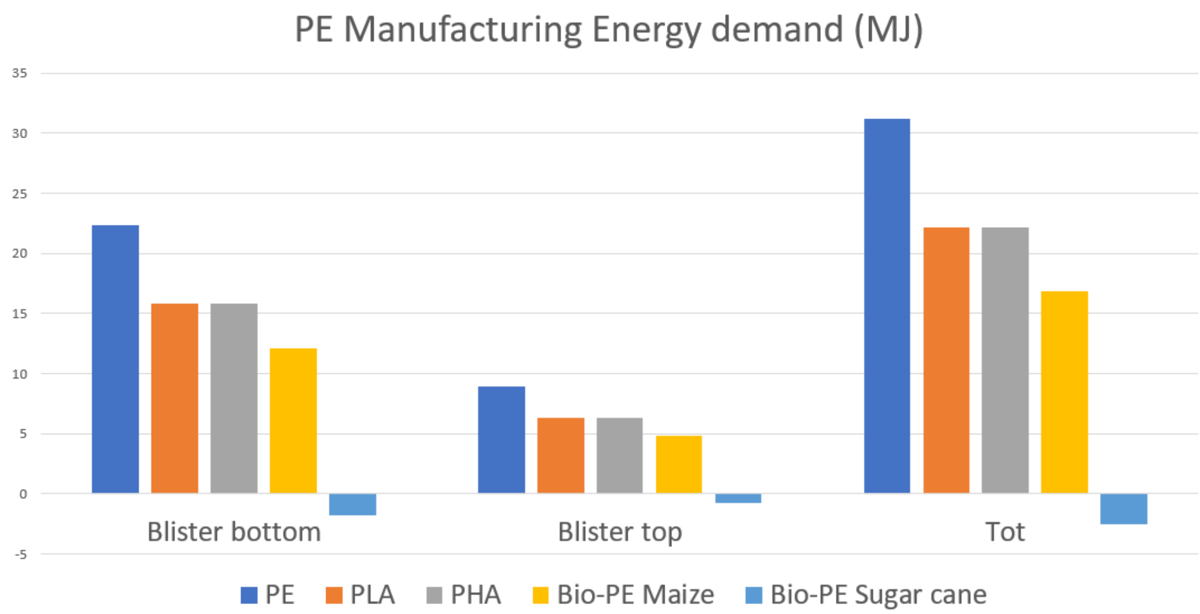

Figure 5.4: Impacts of energy demand in manufacturing of polyethylene now in use and its substituents

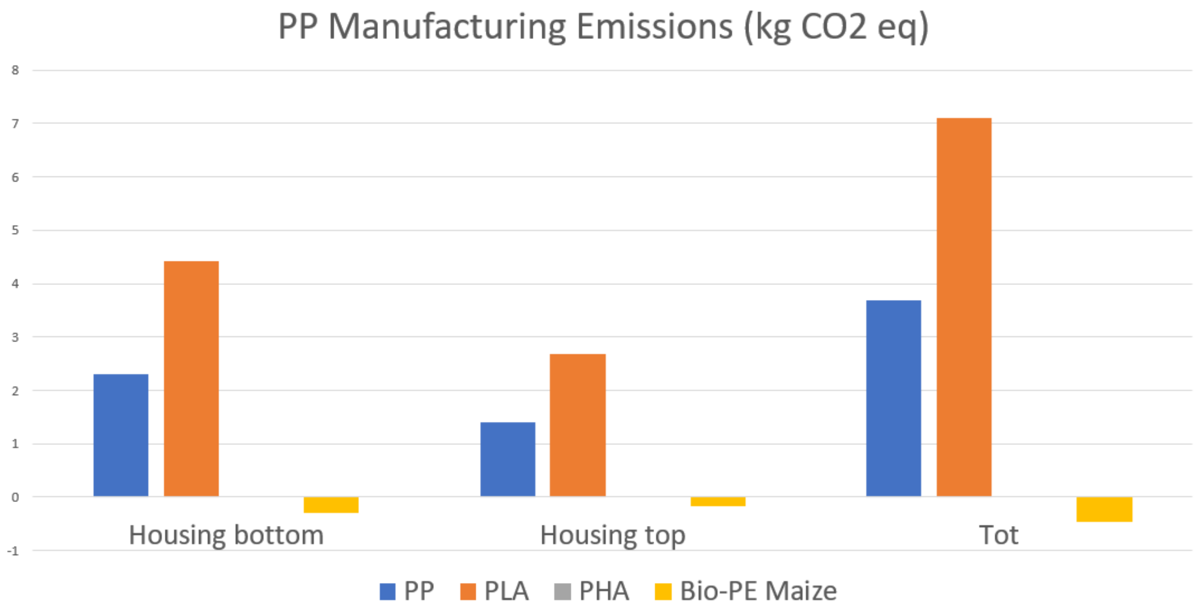

Figure 5.5: Impacts of CO_2 emissions from manufacturing of polypropylene now in use and its substituents

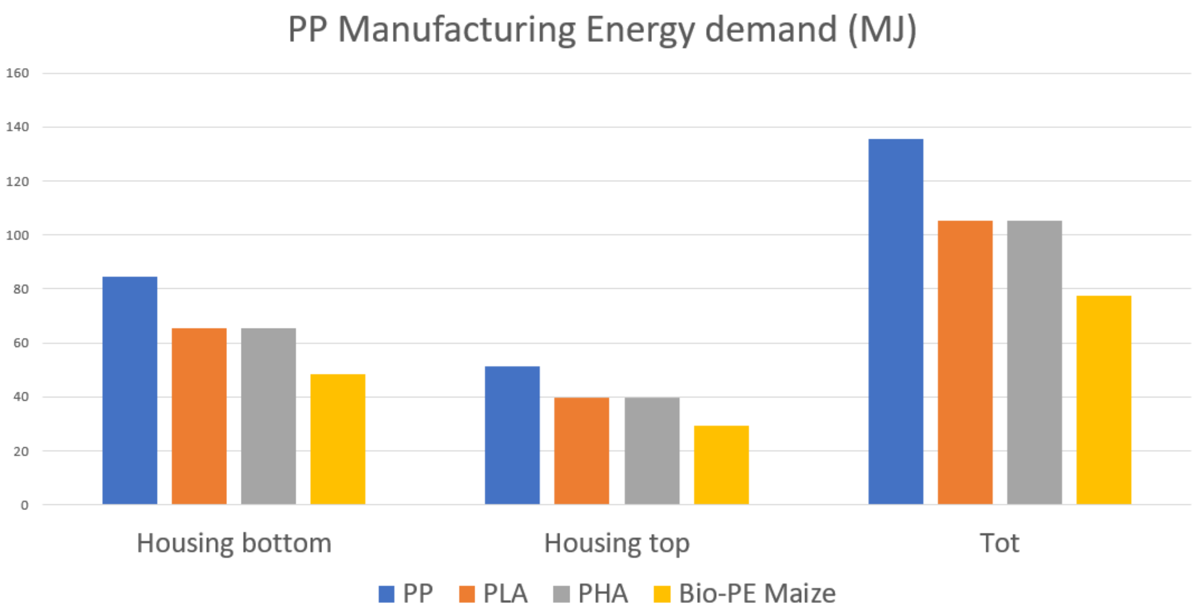

Figure 5.6: Impacts of energy demand in manufacturing of polypropylene now in use and its substituents

Common for most of the graphs is that substituting the conventional, petroleum-based materials would reduce the environmental impact in both terms of CO_2 emissions and energy usage. However, one must acknowledge Figure 5.5 where this is not the case as PLA have a significantly higher carbon dioxide emission than polypropylene. At the same time, PP can be seen to require the most energy of all materials in the manufacturing. This is however partly due to the large amount of PP used. Also common for all graphs is that a substitution to Bio-PET, Bio-PE and Bio-PP from sugar cane (and maize where data is not provided) would contribute most to the reduced environmental impact. Some production values for both energy demand and GHG emissions are fairly low and even negative. This is because the studies that data were retrieved from included energy recovery in their Cradle-to-Gate phase instead of allocating its impact to recycling in the end of the study. E.g. sugar cane have proven to contribute a lot to the energy recovery due to the amounts of bagasse and biological waste (Chen and Patel, 2012).

As previously discussed, the data presented here could favourably have been presented in the Cradle-to-Gate phase of the analysis. It was instead chosen to not be included since it would produce a unbalanced analysis. However, considering an inclusion of the data along with similar results for all components in the analysis, the cradle-to-gate phase would probably have a more proportionate impact than it has now. Further, the data is of good use here when compared to the parallel study performed by the students at Linköping University mentioned in section 5.3. They concluded that the polypropylene in the HME housing component contributed most to the environmental impact, followed by the polyethylene terephthalate used in the blister bottom. From the results in Figures 5.1-5.6, the ranking of components placed the same in top two, but 1st and 2nd had switched place. This could be because the software used in the parallel study used more impact categories which portrayed the scenario differently. Also, the product weight seemed to be portioned differently between the different components in the parallel study. In the study from Linköping, the weight of blister bottom were relative low in relation to the weight of HME housing components. With different weights used, a true comparison becomes harder to make.

An important point of discussion, when it comes to impact categories, is that while bio-based plastics have less CO_2-emissions than petroleum-based materials, it often has a larger potential for acidification and eutrophication (Gironi and Piemonte, 2011). This is discussed to a greater extent later on in the report.

Also important to note regarding this impact comparison is that in the Atos case, some portion of the blister top is already Bio-based. However, this is not taken into account in the calculations above and the results therefore become a bit misleading. Result from the blister top shows that it is not the most urgent component to further implement changes on. It would rather be more impactful to focus on the blister bottom and the HME housing. As presented in the introduction, there are high demands on performance in biomedical products and this could create many obstacles when trying to substitute the materials in class I medical devices such as the HME unit. An easier approach would hence be to focus on reducing the impact from the packaging and the blister bottom.

Also, as discussed later on in the text, some of the substitution-materials do not perform well on their own or are not suitable in medical devices. In the estimations performed above, it is assumed that all conventional material is completely exchanged for a bio-based. However, as this is not possible in reality a more sensitive assessment would be to estimate a partial mix of both conventional and bio-based plastic. This would result in a lesser reduction of environmental impact.

5.3 Analysis comparison

Subsequently as this report was written, four students from Linköping University also made an LCA on the Provox Life GO HME. This was done as a part of an LCA course. In their analysis, the software SimaPro was used and they made a full cradle-to-grave-analysis with destination Germany. The one part which was not included were the manufacturing and processing at the Atos facility. Their result, translated to the functional unit in this report, was that the full life-cycle impact lead to 16.56 kg CO_2e, with 12.88 kg represented for the raw material production, manufacturing and transportation of the finished product. The last 3.68 kg came from waste disposal were everything was incinerated or recycled. Using the same scope as in this report for their analysis, the total emissions became around 4.6 kg CO_2e. Comparing that to the results in section 4.2.4, their emissions for the European case were almost doubled. The impact from transportation were similar in both analyses, the largest difference came from the waste disposal. Their emission-factor for incineration of plastics were around 7 times higher per kg than the one used in this report. Incineration data in this report was taken from a study done on waste incinerators in Taipei and does not necessarily represent the European case that well. However, a factor change of 7 seems fairly high. The values calculated stoichiometric in section 2.2.6 for polyethylene were more in line with the analysis from the Linköping students. These values were calculated under the assumption that only CO_2 is created from the carbon atoms. This was however a simplification made. It was built upon the information from section 2.2.7, that municipal waste creates CO_2 a hundred times more than other gases. However, this was the case for municipal waste and does not have to be applicable for plastics.

According to Weatherby, Courtney (2019), the problem with assessing waste incineration is that it is very dependent on what the waste stream contains. With more "wet" waste, high temperatures become harder to reach in the incinerators. The high temperature is needed to get rid of key pollutants and the energy gained from incinerators also become higher with better waste sorting. Further investigation into the incineration values would be needed in order to find out what results are most representing of the truth.

While the study from Linköping had significantly higher CO_2 emissions in the Cradle-to-Gate phase than in this study, some of the lacking data can be compensated for in section 5.2. With total emissions of $5.5/CO_2e$ from PET, $1.9/CO_2e$ from PE and $3.9/CO_2e$ from PP, only the plastic production adds up to ca $11.3/CO_2e$. Taking these emission values into account, a more comparable analysis to the one produced from the Linköping-students can be made. Also, bear in mind that this excludes other materials in the product, such as polyurethane foam and different qualities of cardboard and paper. Also the transport and production which, on the other hand, was not included to the same extent in the Linköping study. This highlights one of the problems with LCAs, comparing them can often be difficult since the scope is rarely the same.

Before taking the complete assessment into account, the results from Linköping agrees well with the impact estimations in 5.2 where environmental impact where shown to be lower when using bio-based polymers rather than fossil-based. This further underlines the fact that plastic is a problem in medical device.

In the Linköping analysis, energy usage was not considered and hence, that impact category could not be compared.

5.4 Sensitivity analysis

The sensitivity analysis in Figures 4.4-4.7 show that changing the parameter recycling rate is the factor that affect emissions the most. Not recycling anything would more than double the full life-cycle emissions for the European scenario. For destination US, the recycling rate gives an even higher net gain of recycling compared to not recycling, around 1,5 kg CO_2e. One have to note that the model is simplified and counts a 100% recycling rate as having no emissions. This is a simplification, but it is still apparent that recycling does save a lot of emissions. The result from the sensitivity analysis show that recycling rate is important in order to reduce the emissions from the product's whole life-cycle.

Regarding the waste management, incineration or landfilling of the waste does not seem to impact the full life-cycle that much. Incineration seem to produce less emissions than landfilling. Furthermore, this analysis disregards the energy savings which can come from incineration. Compared to landfills, incineration is often used to produce electricity. However, this would only further favour incineration compared to landfills, something that the sensitivity analysis already shows.

Regarding the parameter "distance to end customer", a change in around ±5 MJ and $\pm 0,5 - 1$ kg CO_2 are present for both destinations. For the European case, this represents a change of ±25% for both impact categories, which is fairly significant. It can therefore be concluded that the end destination has a large impact on the environmental consequences for the full life-cycle. This conclusion was also very visible in the different scenarios, Europe and the US. The waste disposal contributes to the difference, but the transportation to America is by far the largest factor for the environmental impact.

The assumption for trucks were that they had a full payload. How well this represents the real-life is not obvious though. For example, in Kinnon (2011) it is recommended to use a payload of 80%, more on this in section 5.7. According to the sensitivity analysis, a load of 50% would increase the European emissions by around 50%. This is a large increase, but the emissions there are strongly connected to different truck transportations. It is therefore not surprising to give such a large increase. For the American case, the change in truck load gives a relatively low total increase in impact. To asses the full life-cycle impact, the truck load is important but does not dominate the analysis.

5.5 Usage of LCA

LCA is widely used due to its full cradle-to-grave perspective and ability to catch the full scope of a product's environmental impact. However, it is not without critique. In Matthews et al. (2015) they raise many important problems with LCA, such as the difficulty of setting consistent system boundaries and not letting the practitioner's bias affect the analysis. If the practitioner want to push for a certain decision, it can very easily be done by making small changes in the methodology. Since so much responsibility is on the practitioner it becomes very important to be clear about what method and scope that has been used. This is tied into another problem which Matthews mentions, namely the differing results that can be yielded from an LCA. 10 different practitioners who all follow the ISO standards for LCA are still very likely to reach different results on the same system. The way this report has dealt with these sorts of issues is by having a clear scope of the system and being as transparent as possible with perceived flaws of the analysis.

In Michalski (2015) an attempt was done to summarise many of the problems with an LCA and address their severity. One of the problems, which they ranked as most severe, was data availability and quality. Since an LCA attempts to cover the whole life-cycle, very large amounts of data are needed. To combat these issues in this report, new measurements were taken to an as large extent as possible. However, this task was only surmountable in the gate-to-gate analysis where Atos employees could help with measurements of different energy consuming processes and weights of materials. Getting data from subcontractors proved to be more difficult and certain information, such as material compositions, were confidential. The solution for problems such as these were then to, if possible, make assumptions built on available data from literature and be clear about what information is conveyed in the assessment and what is left out. If assumptions were not able to be made, the boundaries for the assessment instead had to be moved.

In Reap et al. (2008) the problem of standardisation in LCA impact categories is emphasised. There are many different impact categories to choose from and some of them are hard to separate from others. One problem, which was also brought up in Finnveden (2000b), is that different organisations have differently defined standards for impact categories and their values. The issue with this is that comparison of products and processes between organisations can be misleading and not show a truthful image of reality. It therefore becomes difficult to use the results in this report as basis for anything else than Atos' own environmental work.

5.6 Warehouse storing

In the LCA for gate-to-grave, section 3.4, warehouse storing of the HMEs were approximated as having an environmental impact of 0. A reason to why this distinction was made were due to the difficulty of approximating warehouse storing for the product. Considering the HMEs full life-cycle, the finished product is not the only one which get stored. Every sub-component of the HMEs have been stored along the life-cycle and storing is a present step in all parts of the LCA. These storing times and their following environmental impact had to be disregarded due to their intangible nature. However, disregarding the impact from storing could be a very significant flaw in the analysis. Therefore, some analysis of the environmental impact of storing will be done in this section. This is done in order to asses the magnitude of disregarding warehouse storing.

A non-refrigerated warehouse in the US use around 65.66 kWh and 144236 Btu of natural gas per square meter annually (Maras, 2016). In order to estimate the environmental impact of these values, references from EPA (2019a) were used. Note that these values are specifically produced for the US. According to EPA, the burning of 0.1 mmBtu for heating leads to 0.0053 metric tons of CO_2. The CO_2-emission from 144236 Btu natural gas therefore equals:

$$1.44\ (\frac{mmBtu}{m^2 \cdot year}) \cdot 5.3\ (\frac{kg}{mmBtu}) = 7.64\ (\frac{kg}{m^2 \cdot year}) \tag{5.1}$$

The energy usage of 65.66 kWh equals 236 MJ. However, it can also be converted to CO_2-emissions. According to U.S. Energy Information Administration (2020), only 12% of energy consumption comes from renewable energy and over 60% comes from fossil based sources. The energy were therefore chosen to be calculated as its corresponding CO_2-emissions instead. EPA (2019a) use a value of 0.707 kg CO_2 per kWh when considering emissions saved from electricity reductions. Using this number to calculate emissions from the energy usage gives:

$$0.71\ (\frac{kg}{kWh}) \cdot 65.66\ (\frac{kWh}{m^2 \cdot year}) = 46.42\ (\frac{kg}{m^2 \cdot year}) \tag{5.2}$$

The total value of CO_2 produced per year and m^2 for warehouse storing then becomes $7.64 + 46.42 = 54.1$. In warehouse storing, a pedestal with outer boxes take up around 2 m^2. 25 boxes are stacked on each of these pedestals, so one outer box takes up around $2/25 = 0.08m^2$. However, in a warehouse boxes are often stacked on top of each other in shelves. Not all areas of a warehouse are goods though, so these two factors were approximated as cancelling each other out. Therefore, an assumption can be made that storing one outer box in a warehouse leads to:

$$0.08\ (m^2) \cdot 54.1\ (\frac{kg}{m^2 \cdot year}) = 4.328\ kg\ CO_2\ per\ year\ or\ 0.36\ kg\ per\ month \tag{5.3}$$

This is a rough estimation, but gives an idea of the impact that the warehouse storing has on the environment. According to Atos, the finished products are stored around 6 months in total before reaching the customer. This would give a total of around 2 kg CO_2-emitted from storing during the product's life-cycle.

Everything was here transformed to the impact category CO_2-emissions. If instead considering the storing as a combination of emissions and energy usage, the emission calculation becomes:

$$\frac{7.6445 \cdot 0.08}{12} = 0.051\ kg\ CO_2\ per\ month \tag{5.4}$$

For energy usage in MJ the calculation becomes:

$$\frac{65.66 \cdot 3.6 \cdot 0.08}{12} = 19.7\ MJ\ per\ month \tag{5.5}$$

Storing the finished product for 6 months would then lead to an energy usage of 118 MJ and 0.3 kg CO_2. These values compared to the results in table 4.11 do seem very significant. The energy usage is almost the same as the usage for the product's full life-cycle with destination Houston. These data are not taken from the products' actual storing conditions, but they still show a potential magnitude of the problem. The different storing periods during the product's life-cycle could be a very significant portion of its impact, at least in regards to energy usage. Using clean energy for the storing conditions could therefore be a substantial help in lowering the impact for the whole life-cycle.

5.7 Transport

In regards to emissions from transportation, different methods could have been used. In McKinnon (2007) a big distinction is made between transportations by van compared to Heavy Goods Vehicles (HGVs). CO_2-emissions from HGVs are around 138 grams per tonne-km while vans release 360 grams per tonne-km under similar circumstances.

In this report, an assumption was made about the lorries having a full payload and CO_2-emissions were calculated from this assumption. This was done due to the chosen online emission-calculator which only calculated through full payloads. However, the recommendation in Kinnon (2011) is to base the load factor to 80% but also add on 25% of empty running. This method could have been used, but since many other assumptions and approximations were made, such as having the products be delivered to specifically Paris, a decision was made to have a full payload and no empty running.

5.8 Complications from bioplastics

Bioplastics are a more sustainable alternative compared to conventional plastics, but suddenly introducing a lot of bioplastic on the market could lead to complications. In Åkesson et al. (2021) they investigated the effect that mixing of bioplastics and conventional plastics would lead to. They mixed different amounts of a starch-based plastic with PP, PET and PE respectively. They then investigated the effect that this had on the recycled new plastic. At already 1% of bioplastic contamination, PET had lost most of its impact strength. For a 5% contamination, PE and PP saw a strong reduction in elongation ability but were otherwise not significantly affected. What this shows is that the mixing of bioplastics with conventional plastics in the recycling stream could significantly impact the properties of recycled plastics. It is therefore not obvious if a product's substitution to bioplastics would lead to an environmental benefit in the waste system that exists today. Important to note however is that recycled, conventional polymers can also strongly affect other polymers in the waste stream. The mixing of polymers can lead to large losses of their mechanical properties. So this problem is not only present for bioplastics, but also for some conventional polymers. Note however that what the authors Åkesson et al. (2021) press upon is that more research is needed before a definite answer can be given regarding the effects of bioplastics on recycled plastics. If it hinders the recycling of large quantities of polymers, the introduction may lead to a net loss of environmental impact. A critique which bioplastics have received is that it uses food feedstock to be created. 82.5 tonnes of sugar cane can give around 3 tonnes of green polyethylene (Gotro, 2013). This feedstock could be used as food for people instead.

An important issue when trying to replace materials in medical devices, is the regulatory requirements facing choice of material. As lifted earlier in the report and in Bernard et al. (2018), the issues of bio-compatibility of medical materials are complex. The materials must handle chemical and physical properties, as well as duration of contact with tissue. Now, this is often a more delicate problem when it comes to medical devices of a higher risk-category, i.e. for *in vivo* use, and the literature are also more focused on these. Still, the problem remains for class I devices such as the HME unit. This further strengthens the argument to focus on the packaging materials in order to reduce the environmental impact.

As the bio-based materials presented in table 5.1 were not chosen on the grounds of bio-compatibility or regulatory compliance, they should not be viewed as a complete solution for reducing environmental impact. They should rather be seen as possibilities for potential reduction which need further investigation. Some of the materials do show potential for biomedical use. PHA is a good substituent as it has both good barrier properties and is biodegradable (Lackner, 2015). PLA on the other hand have lesser barrier properties and is in its current state not a very popular choice for medical products and devices. It is still a popular choice for packaging when seeking to replace petrochemical plastic (Jem and Tan, 2020).

To assist in the material choice process, risk management has proven to play an important role. Implementing a risk management approach in the *in vitro* phase of production and development of medical devices is common. This helps with attaining regulatory approval and hence also a safer product for the end-user. In the ISO-documentation, several different chapters describe useful ways of implementing a risk-approach into product development (Bernard et al., 2018). Often, when talking about risk in a context similar to the one above, environmental risk is not touched upon. Risk management is implemented to secure a device's usability and safety while ensuring that they comply with regulatory demands (Palanichamy, nd). The common-ground between environmental risk and patient safety is perhaps not found anywhere other than in residual risk. What is certain is that environment and sustainability seem to have very low levels of priority in early phases of product development and one could even be more blunt and say that the ISO-framework is lacking in this specific area. However, the risk-management process is driven by values, established by what is considered worthy of protection at a societal level (Schmuland, 2005). It seems reasonable to suggest a re-evaluation of value-prioritisation while living in a time where environment is a very up-to-date subject. Still, do consider that LCA and RA:s are not as far apart as might be portrayed here. Regulatory Risk Assessments and Life Cycle Impact Assessments share similar properties when determining e.g. toxic impact according to Flemström et al. (2004).

This has further contributed to previous research making requests for integrated approaches of both environmental and health impacts, without any assessments being performed on the account of the other(Flemström et al., 2004). Regardless of whether environmental risk management should be included in medical device development or implemented together with an LCA, it remains an important complement to Life Cycle Assessments.

5.9 Broader perspective

Approximating the total impact from the Provox Life-product can be done in order to put it into a larger context. If considering only CO_2-emissions and including the cradle-to-gate values for plastics mentioned in section 5.2, the total emissions for destination US becomes: $10.79 + 11.3 = 22.1$ kg CO_2e for one functional unit. The same emissions for destination Europe becomes: $11.3 + 2.11 = 13.4$ kg. After talks with Atos and using the results from this report, the approximated emissions over a year from the Life GO HMEs equals to approximately 1500 kg of CO_2-emissions.

Many of the employees at Atos does not live in Hörby. Some of them live in Malmö, a large city approximately 60 km away. Assume that they drive back and forth to the facility 200 days a year. From EPA (2019b) an assumption was made that a car uses an average of 9.4 l/100 km of petrol. Using the CO_2-calculator at MyClimate (Nd), the emissions for travelling back and forth from Malmö to Hörby by car leads to 47 kg CO_2-emissions every day. For one employee with 200 working days a year leads to 9400 kg CO_2-emissions every year. This means that the commuting of only one employee lead to significantly higher emissions then what comes from the HMEs produced. This is however only for one HME-model and Atos produces many different HMEs. With this in mind, if lowering emissions is the main goal then commuting could be looked into. With the ongoing Covid-pandemic most workers instead work from home. This is perhaps one of the easiest and most effective ways of reducing total emissions. This is not directly related to the product, but when using a fully expanded life-cycle perspective it becomes apparent how areas like this can have large effects on the environment.

Meanwhile, as we face an upwards trend for electric- and hybrid vehicles, these should also be considered in a broader perspective. Still, long-range electrical truck and maritime transport are not as developed or commercially abundant as e.g. private vehicles (International Energy Agency, 2020). Once again using the MyClimate (Nd) CO_2 calculator, fuel-consumption and CO_2 emissions could be calculated. Choosing the same distance as above and a plug-in hybrid car, with a fuel-consumption of 1.82 l/100 km and the Swedish electricity-mix, the emissions added up to 30 kg CO_2 equivalents a day. Similar calculations with an all-electric plug-in hybrid (consuming 19.9 kWh/100 km), the emissions became 11 kg of CO_2 equivalents a day. During a year with 200 working days, this would contribute with emissions of 6000 and 2200 kg CO_2 respectively. As can be seen, the general Swedish power-mix does not reflect Atos Medical's own energy mix with completely renewable energy sources. This may however be a small contributor to the problem, since the total emissions still greatly exceeds the yearly emissions coupled to the Life GO HME product. Still, encouraging employees that have the means to invest in hybrid- or electric vehicles would further reduce the environmental impact, which can indirectly be coupled to the production.

6 Conclusion

Cutting down emissions and plastic usage is essential if we want to hinder global warming and live sustainable. Disposable plastic products are a big part of the medical industry and much can be done to improve them from an environmental stand-point. The Provox Life HMEs' life-cycles lead to around 10.8 kg CO_2-emissions and 121 MJ energy consumed per fU. These values are for the life-cycle scope "subcontractors to end-of-life" with destination USA. In order to lower the environmental impact from the product, focus was deemed to be most efficient on the blister packaging. By switching out conventional polymer plastics for bioplastics, environmental gains could be made. The PET in the product could be switched out for Bio-PET with a 75% decrease of CO_2-emissions and around 30% energy use reduction. Switching out Polyethylene for bio-based alternatives showed similar environmental wins with Bio-PE from sugar cane even leading to a net reduction in emissions and energy usage. Switching out the polypropylene in the product for the bio-based material polylactic acid would almost double the emissions, but lowers the use of fossil-based plastic. Material substitutions for more sustainable and lower emissions alternatives needs to still have the intended product function without risk to the patients. Literature shows more promising results with materials that combine bio- and conventional plastics. Important to note however, is the effect on the material recycling which introducing bio-plastics into the waste stream leads to. Lowering emissions through material combinations does not have to give an environmental net gain if the recycling capabilities are removed.

Another way of lowering the product impact would be removing the included product manual which recurring customers have little use for. It is a fairly simple product and instructions could perhaps be provided electronically or solved in a different way.

In the medical industry, focus have always been on helping patients and saving lives. However, neglecting the environmental impact from medical products can indirectly lead to many lost lives through e.g. global warming. The risk-aspect of medical device development is centred around the health-risk factor and effects on the environment are seldom considered. This is also reflected in the writings of ISO-standards and other regulatory frameworks. It is important to constantly keep working towards a more environmentally friendly medical industry and a more integrated approach where human safety can be prioritised without it being on the expense of the environment.

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Appendix

Figure A0.1: Emission Shipment Listing Report

GREENCARRIER FREIGHT SERVICES SWEDEN AB
Strandbadsvägen 13d
Box 945
251 09 Helsingborg

Tel: +46 42 40 04 150
VAT No. SE556382732701

GREENCARRIER

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Emission Shipment Listing Report - ATOS MEDICAL AB (ATOMEDHOO)

Report Shipments where Client is: Consignor, Consignee, Freight Direction: Export Only
Shipment Transport: SEA,

Shipment ETD: From: 01-Jan-21 To: 28-Feb-21,

Shipment Listing Report Printed by: Jonas Lundgren 16-Mar-21 07:59 AM

Shipment	Trans	Mode	House	ETD	ETA	Origin name	Dest name	Volume	Weight	UQ	UQ	Shipper	Consignee Name	TEU	Emissions CO2 tons	Emissions CO2E tons	Emission Energy MJ	Emission NMHC kg	Emission NOx kg	Emission PM kg	Emission SO2 kg
SJHE01437519	SEA	FCL		14-Jan-21	28-Jan-21	Helsingborg	New Be	40.00	3992.00	KG	M3	ATOS MEDICAL AB	ATOS MEDICAL INC.	2.0	4.060	4.120	56,251.790	1.230	34.460	0.000	17.420
SJHE01465618	SEA	FCL	SJHE01465618	18-Feb-21	4-Mar-21	Helsingborg	New Be	40.00	3679.00	KG	M3	ATOS MEDICAL AB	ATOS MEDICAL INC.	2.0	4.060	4.120	56,251.790	1.230	34.460	0.000	17.420