# APPENDIX

Graduation report

Jasper Schuddeboom

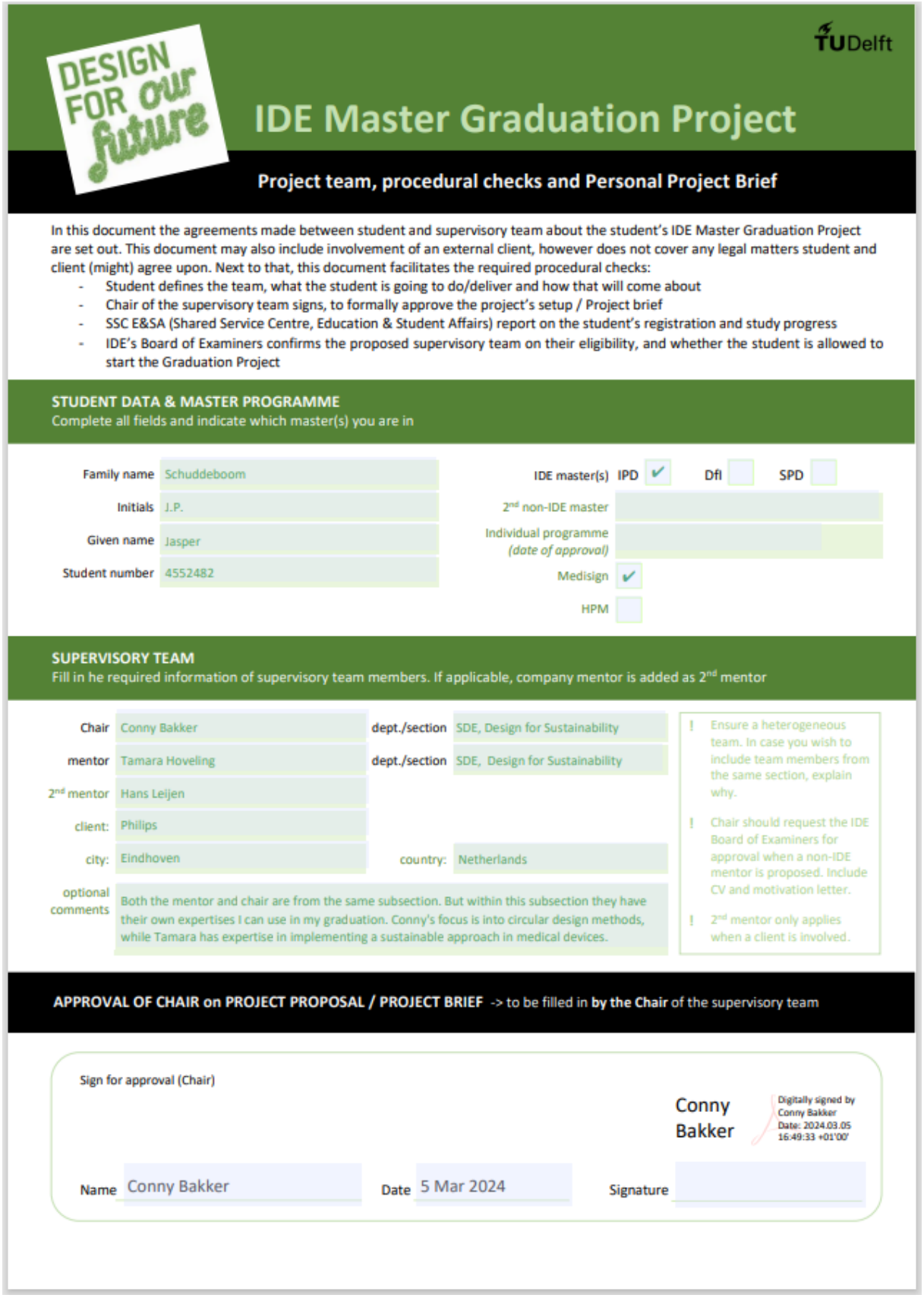
4552482

Chair: Conny Bakker

Mentor: Tamara Hoveling

**Appendix**

## Appendix A



DESIGN FOR our future

TU Delft

# IDE Master Graduation Project

## Project team, procedural checks and Personal Project Brief

In this document the agreements made between student and supervisory team about the student's IDE Master Graduation Project are set out. This document may also include involvement of an external client, however does not cover any legal matters student and client (might) agree upon. Next to that, this document facilitates the required procedural checks:

- Student defines the team, what the student is going to do/deliver and how that will come about
- Chair of the supervisory team signs, to formally approve the project's setup / Project brief
- SSC E&SA (Shared Service Centre, Education & Student Affairs) report on the student's registration and study progress
- IDE's Board of Examiners confirms the proposed supervisory team on their eligibility, and whether the student is allowed to start the Graduation Project

### STUDENT DATA & MASTER PROGRAMME

Complete all fields and indicate which master(s) you are in

| | |
|---|---|
| Family name | Schuddeboom |
| Initials | J.P. |
| Given name | Jasper |
| Student number | 4552482 |

| | |
|---|---|
| IDE master(s) | IPD ✔ Dfl SPD |
| 2nd non-IDE master | |
| Individual programme *(date of approval)* | |
| Medisign | ✔ |
| HPM | |

### SUPERVISORY TEAM

Fill in he required information of supervisory team members. If applicable, company mentor is added as 2nd mentor

| | | | |
|---|---|---|---|
| Chair | Conny Bakker | dept./section | SDE, Design for Sustainability |
| mentor | Tamara Hoveling | dept./section | SDE, Design for Sustainability |
| 2nd mentor | Hans Leijen | | |
| client: | Philips | | |
| city: | Eindhoven | country: | Netherlands |
| optional comments | Both the mentor and chair are from the same subsection. But within this subsection they have their own expertises I can use in my graduation. Conny's focus is into circular design methods, while Tamara has expertise in implementing a sustainable approach in medical devices. | | |

! Ensure a heterogeneous team. In case you wish to include team members from the same section, explain why.

! Chair should request the IDE Board of Examiners for approval when a non-IDE mentor is proposed. Include CV and motivation letter.

! 2nd mentor only applies when a client is involved.

### APPROVAL OF CHAIR on PROJECT PROPOSAL / PROJECT BRIEF -> to be filled in **by the Chair** of the supervisory team

Sign for approval (Chair)

Conny Bakker

Digitally signed by Conny Bakker
Date: 2024.03.05 16:49:33 +01'00'

| Name | Conny Bakker | Date | 5 Mar 2024 | Signature | |
|---|---|---|---|---|---|

## CHECK ON STUDY PROGRESS

To be filled in **by SSC E&SA** (Shared Service Centre, Education & Student Affairs), after approval of the project brief by the chair.
The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total _____ EC

Of which, taking conditional requirements into account, can be part of the exam programme _____ EC

| | | |
|---|---|---|
| ★ | **YES** | all 1st year master courses passed |
| | **NO** | missing 1st year courses |

Comments:

Sign for approval (SSC E&SA)

Robin den Braber

Digitaal ondertekend door Robin den Braber
Datum: 2024.03.12 10:15:07 +01'00'

Name Robin den Braber Date 12 mrt 2024 Signature

## APPROVAL OF BOARD OF EXAMINERS IDE on SUPERVISORY TEAM -> to be checked and filled in by IDE's Board of Examiners

Does the composition of the Supervisory Team comply with regulations?

| | | |
|---|---|---|
| **YES** | ★ | Supervisory Team approved |
| **NO** | | Supervisory Team not approved |

Comments:

Based on study progress, students is ...

| | |
|---|---|
| ★ | **ALLOWED** to start the graduation project |
| | **NOT** allowed to start the graduation project |

Comments:

Sign for approval (BoEx)

Monique von Morgen

Digitally signed by Monique von Morgen
Date: 2024.03.13 10:25:36 +01'00'

Name Monique von Morgen Date 13 Mar 2024 Signature

DESIGN FOR our future

TU Delft

# Personal Project Brief – IDE Master Graduation Project

**Name student** Jasper Schuddeboom **Student number** 4,552,482

**PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT**
Complete all fields, keep information clear, specific and concise

**Project title** Circular Design of a heart rate monitoring cable set

*Please state the title of your graduation project (above). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.*

**Introduction**

*Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)*

The healthcare industry is under pressure, due to demographic aging and increasing health standards (Georgiev, 2020). This is while using a high amount of energy and resources (Capolongo et al., 2015). This also results in a lot of waste which is hard to process due to contamination (Ranjbari et al., 2022). It is key to suppress this waste and use of resources. As a business in the healthcare sector, Philips has a responsibility to create the opportunity for hospitals to make a more sustainable choice (Alharbi et al., 2021). Philips is committed to minimizing its impact on the planet within the healthcare sector (Purpose And ESG Commitments | Philips, z.d.).
With this philosophy in mind, Philips is part of the DiCE project. A project in which TU Delft and Philips are working with 18 other partners on the development of circular solutions for digital health devices. One of the projects is to develop a circular concept for medical supplies, in which a case study is conducted for a circularly designed electrocardiogram (ECG) lead set, which is clinically safe, user-friendly, cost-effective and sustainable.
ECGs measure heart activity; ECG lead sets are commonly used in a hospital to connect patients with a monitor. The currently available lead sets are either single-use or multi-use, and the selection is often a dilemma.
The lead set itself is a simple product, but the environment it is used in is rather difficult. This includes legislation (Lappalainen, 2011), and different use scenarios in multiple parts of the hospital. Furthermore, there are different kinds of lead sets with different numbers of leads (Francis, 2016).
Combined this results in an interesting design challenge for this graduation project.

→ *space available for images / figures on next page*

*introduction (continued): space for images*

image / figure 1 ECG Lead set for multi use solutions

image / figure 2 ECG Lead set for single use solutions

# Personal Project Brief – IDE Master Graduation Project

## Problem Definition

*What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.*
*(max 200 words)*

As mentioned earlier the Lead set is available in two options, a single-use and a multi-use option. With sustainability in mind, the multiple-use option sounds obviously better. However, this is not always the preferred option by hospitals due to infection risks. The single-use version is mainly used in the US and the multi-use in Europe. The widespread use contributes to the big waste stream ot of hospitals. Both can be clinically safe with the right procedures and it is a trade-off between infection prevention, user-friendliness, quality, cost and sustainability. It is not clear if and how the wires are cleaned and what happens at the end of life. The expected is that most of them are incinerated. Research is needed to sketch the lifecycle of the ECG leads to see in which areas and in what way the lead set can be made more sustainable. Therefore the following problem definition is formulated.
How can Phillips develop their multiuse ECG leads so that it will result in a lead set that is more sustainable than the current generation while fitting within the different use scenarios?

## Assignment

*This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence) As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:*

*Develop and evaluate a circular design method with the multi-use lead set for Philips as a case study in hospital settings.*

*Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)*

The scope of this project is quite wide at this moment in time. To define the boundaries better I will start early (week 1 or 2) with pitching design directions to the client. These will be explained in one pagers/sketches. The result of these pitches and the following discussion will be the start of my program of requirements and wishes. Thereafter I will do a round of qualitative user research. With interviews and observations of nurses and/or doctors, I can create a picture of the `use phase' of the product. This is important to determine which route the product takes into the collection and end-of-life phase. The DiCE report 2.1 of T. Hoveling included a circular recovery flow chart, with this and the full product life cycle an ideation can be done to come up with ideas to get the Lead set more sustainable. This is a new way of ideation, so for the circular design method I will also include a reflection on what worked and what did not work. The ideas from this session will be converged using weighted objectives to around 5 ideas. These will be developed further using SCAMPER and will need a business case evaluation to get them to around 3 concepts. The choice of the final concept will be together with the client. This concept will then be prototyped and tested in a way that proves the main idea behind the concept.

## Project planning and key moments

*To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a **kick-off meeting**, **mid-term evaluation meeting**, **green light meeting** and **graduation ceremony**. Please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any (for instance because of holidays or parallel course activities).*

*Make sure to attach the full plan to this project brief.*
*The four key moment dates must be filled in below*

| | |
|---|---|
| **Kick off meeting** | 20 feb 2024 |
| **Mid-term evaluation** | 7 mei 2024 |
| **Green light meeting** | 11 juni 2024 |
| **Graduation ceremony** | 9 juli 2024 |

*In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project*

| | |
|---|---|
| Part of project scheduled part-time | |
| For how many project weeks | |
| Number of project days per week | |

Comments:

## Motivation and personal ambitions

*Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).*

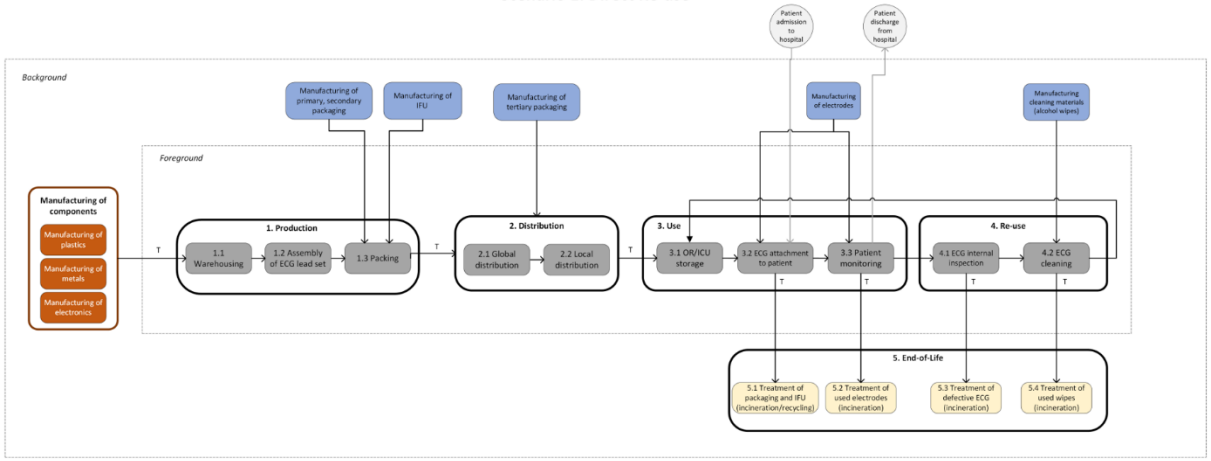
*Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.*
*(200 words max)*

As mentioned in my manage your master plan I loved working with clients and companies. That is why I also am looking forward to doing this project with Phillips. Further I am attracted to the opportunity to make hours internally at Phillips. As I did not manage to do an internship during my master years this will give me some on the job experience. As IPD student I will be more focussed on starting to design new things. This can also become a challenge in this project as it stands more at the beginning of a design process. I will have to start with open minded research without being drawn to ideas or concepts already. Early ideas can help me to be able to determine the scope of the project together with Phillips. These are already starting to form and I will bring sketches with me in the startup meetings. After this it will be important to do a few steps back, a thing I sometimes tend to forget. This will give the opportunity to create a strong basis for the rest of my work.

As this project is at the beginning of a product evaluation, it is not clear what the final result will be. Personally I hope to be able to use my technical knowledge in the second half of the project. A challenge for me will be the research in the early stages of this project. Naturally it is not something that I am good at but with the new method developed and my skills from bachelor and master I will have all the tools to bring this to a good result. I would love to implement the course creative facilitation in this project and in that way co-design with users. This depends on the availability of the users.

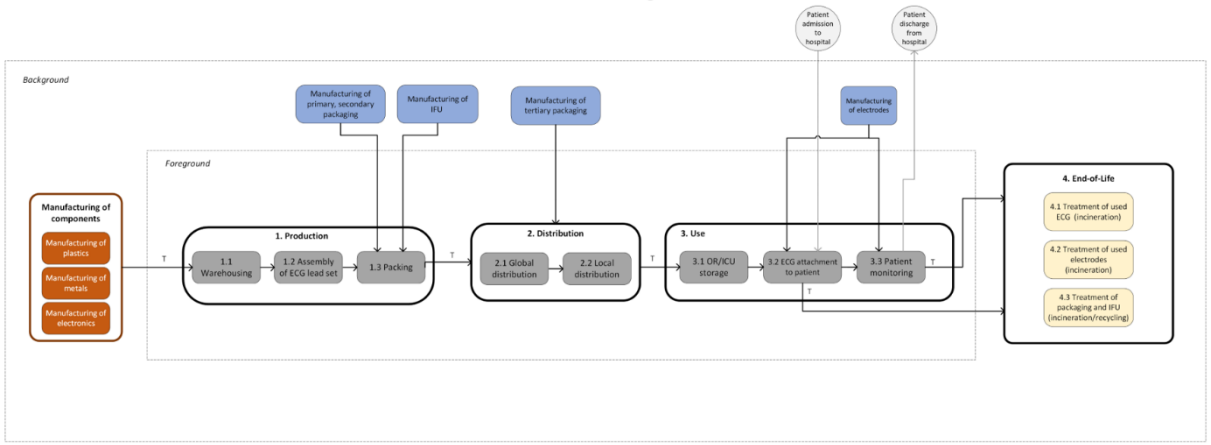
# Appendix B

**Scenario 1: Direct Re-use**



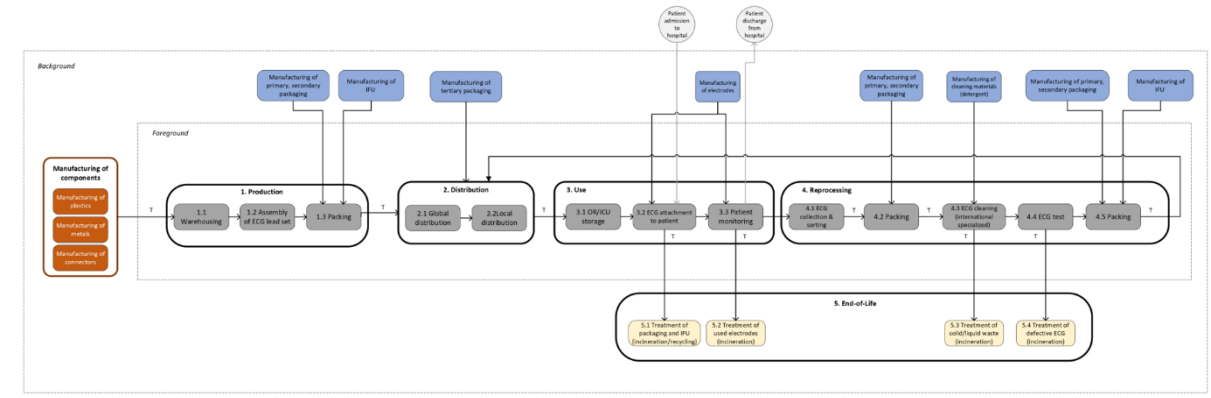

— — System bounderies IFU: Intructions for use. T: Transport.

**Scenario 4: Single use**




— — System bounderies IFU: Intructions for use. T: Transport.

**Scenario 3: International specialized reprocessing**




— — System bounderies IFU: Intructions for use. T: Transport.

## Appendix C

Table of interviews and observations

| Role | Format | Remarks | Datum |
|---|---|---|---|
| CCU EHH Nurse | Interview online | Interview of a couple together. Information learned on use environment ECG Lead set | 17-03-2024 |
| CCU EHH Head Nurse | Interview online | " | 17-03-2024 |
| Nurse Reinier de Graaf Gasthuis CCU | Observations at the CCU and EHH | Tour around two departments with different nurses | |
| Sterilization staff | Observations at the sterilization department | Tour trough the sterilization department and meeting on graduation project | 04-04-2024 |
| LCA Expert Philips | Interview/meeting | | Multiple sessions |
| Product manager USA | Interview online | Midterm feedback meeting | |
| Product manager USA | Interview online | Feedback on proposed design direction | 14-05-2024 |
| Change mangager Philips | Interview/meeting | Interview on implementation of change management | 27-05 |
| Technical product owner ECG Lead set | Interview/meetings online and in person | | Multiple sessions |
| Product engineer ECG Leads | Observations and interview at factory | | 02-05 |
| Sustainability professional Reporting and Analysis | Interview | | 27-03 |

## Appendix D

Hospital interview excel doc

| | A | B | C | D |
|---|---|---|---|---|
| 1 | **Language** | | | |
| 2 | Dutch/English/Other | | | |
| 3 | **What is your role?** | | | |
| 4 | Nurse/doctor/medical staff | Procurement | Cleaning / waste management | sterilization department |
| 5 | **What department?** | **What is your process when procuring for a certain product line, in this case the ECG Lead set?** | **What waste/cleaning flows does exist in the hospital?** | **Which products categories go into the sterilization department?** |
| 6 | Surgery / ICU/ EC/ other | open tekst | open tekst | open tekst |
| 7 | **Do you use ECG lead sets in your work?** | **When sourcing ECG lead sets, can you rank your priorities** | **Is there a tracking system for products in the hospital?** | **What types of cleaning and steralization methods are used?** |
| 8 | Yes (if no: go to disposal questions) | request from clinical staff / lowest cost / supplier relation / sustainability | Yes/no | open tekst |
| 9 | **Do you use re-usable or single use lead sets?** | **If sustainability trademarks/ ratings would exist for medical consumables,would that influence procurement decisions** | **How do the contaminated products get to the cleaning department?** | **How are the products send back after cleaning/sterilization to the wards/ICU/OR?** |
| 10 | Single / Multi / Both | yes / maybe / not relevant | open tekst | open tekst |
| 11 | **What is the reason(s)?** | **Do you foresee carbon footprint as a future decision criterium in tenders** | **How are products being sorted?** | **Do problems arize between sterilization and re use of products? If yes please desribe?** |
| 12 | hygiene / cost / convenience / quality | yes / maybe / not relevant | open tekst | no/yes namely... |
| 13 | ***IF MULTI or BOTH:*** | **Do you foresee a need to report on carbon footprint for medical consumables** | **Do non cleanable products and up in the cleanable flow?** | **What product categories would offer opportunities for cleaning / reprocessing in the hospital** |
| 14 | **Do you clean the ECG lead sets?** | yes / maybe / not relevant | yes/no | sugery devices (eg endocutter)/ batteries/ cable sets (eg ECG lead sets)/ wearable sensors/ NIBP cuffs/ SPO2 sensors |
| 15 | yes/no | **If suppliers would offer pay per use cycle for re-usable products, would you consider this option** | **If yes, how are they taken out?** | **What constaints do you see in collection, cleaning processes, testing and packing** |
| 16 | **When do you clean?** | yes / no, because .... | open tekst | open tekst |
| 17 | During use / After each use / Only if contaminated | | **Do you experience problems in waste management related to re-usables?** | |
| 18 | **How do you clean the lead set** | | open tekst | |
| 19 | open tekst | | **What opportunities do you see to collect re-usable materials and reduce products going to waste** | |
| 20 | **How do you experience the cleaning** | | open tekst | |
| 21 | easy to clean / time consuming / difficult to clean / ... | | **What constraints do you see for the collection and logistics of re-usable consumables and devices** | |
| 22 | **Do you pack after cleaning/use?** | | open tekst | |
| 23 | Yes/no | | **What are most important features for these collection** | |
| 24 | **Where do you store after cleaning/use?** | | open tekst | |
| 25 | with the monitor / cabinet / storeroom | | | |
| 26 | **When do you replace for a new set/when do you trow the lead set away?** | | | |
| 27 | contamination /regulation/ broken / total use time / cant find a old one/find the risk to high/other.... | | | |

| | |
|---|---|
| 28 | **How many times do you use a lead set before you trow it away?** |
| 29 | 1-5 times / 5-10 times / 10 - 20 times /more than 20 times |
| 30 | **How do you dispose of the old set after replacement** |
| 31 | Clinical waste / general waste / recycling bin |
| 32 | **When do you use or would you prefer single use lead sets** |
| 33 | open tekst |
| 34 | **How many different collection systems do you use for products on the ward?** |
| 35 | |
| 36 | **And on ECU** |
| 37 | |
| 38 | **And on OR** |
| 39 | |
| 40 | **If a collection and cleaning service for lead sets would exist,** |
| 41 | no thanks, current practice is good enough,<br>Yes, because it will save me time,<br>Yes, because it will reduce infection risk,<br>Yes , because it is more sustainable<br>other: ... |
| 42 | **Would you mind wrapping or packing the leadset for collection** |
| 43 | Yes / No |
| 44 | **Would a collection box near the point of use be feasible?** |
| 45 | Yes / No, space linitations / No, contamination risks / No, other reasons: ... |
| 46 | **What would be maximum acceptable distance to the collection poin** |
| 47 | multiple collection points in the wards, central collection point in the ward, central collection point on a department, central collectiuon points in the hospital |
| 48 | **Would it be possible to combine with other collection points for re-usable products?** |
| 49 | no / yes, with... |
| 50 | **Do you see other opportunities to reduce waste in the application of ECG lead sets** |
| 51 | Reduce packaging /Digital instructions for use / Improve use time of electrodes / other .... |
| 52 | **Do you have frustration points on the ECG Lead set?** |
| 53 | open tekst |
| 54 | **What would you want to change on the ECG Lead sets?** |
| 55 | open tekst |
| 56 | |

## Appendix E

### Life cycle inventory

### SPU

| | what | amount per product | number fu | | total fu | unit | source |
|---|---|---|---|---|---|---|---|
| | *manufacturing* | | | | | | |
| | Full weight | 0,08 | 200 | | 16 | kg | HWP803192141 - Philips 5-Lead SPU ECG Lead Set \| Medline Industries, Inc. |
| | PVC | 0,064 | 200 | | 12,8 | kg | .4 of full weight |
| | copper/tinned copper | 0,016 | 200 | | 3,2 | kg | .6 of full weight |
| | metal forming, elongating | 0,016 | 200 | | 3,2 | kg | R and D manganager Roman |
| | extrusion molding | 0,064 | 200 | | 12,8 | kg | R and D manganager Roman |
| | plating | 0,016 | 200 | | 3,2 | kg | R and D manganager Roman |
| | *transport* | | | | | | |
| | Transport by vrachtwagen | 640 | 200 | 0,08 | 128000 | km | maps |
| | *use* | | | | | | |
| | | | | | | | |
| | *end of life* | | | | | | |
| | incineration | 0,08 | 200 | | 16 | kg | hcwmanagement-factsheet-rfhe.pdf (who.int) |

### MPU

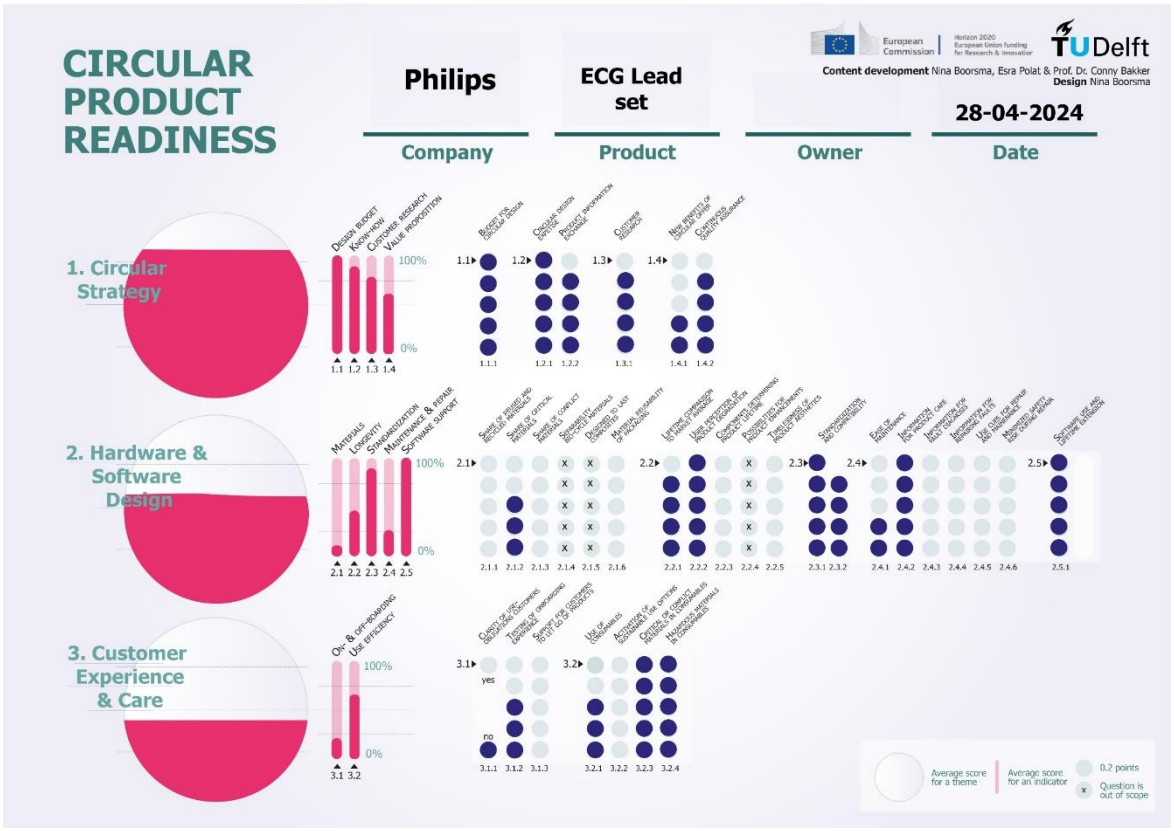
| | what | amount per product | number fu | | total fu | unit | source |
|---|---|---|---|---|---|---|---|
| | *manufacturing* | | | | | | |
| | Full weight | 0,091 | 1 | | 0,091 | kg | weighted |
| | TPU/TPE | 0,0728 | 1 | | 0,0728 | kg | .8 of full weight |
| | copper | 0,0182 | 1 | | 0,0182 | kg | .2 of full weight |
| | metal forming, elongati | 0,0182 | 1 | | 0,0182 | kg | R and D manganager Roman |
| | extrusion molding | 0,0728 | 1 | | 0,0728 | kg | R and D manganager Roman |
| | plating | 0,0182 | 1 | | 0,0182 | kg | R and D manganager Roman |
| | *transport* | | | | | | |
| | Transport by vrachtwa | 640 | 0,091 | | | km/kg | maps |
| | *use* | | | | | | |
| | water | 2 | 200 | | 400 | ltr | observation |
| | *micofiber towl* | 1 | 200 | | 200 | towls | observation |
| | *polyester* | 0,0075 | 200 | | 1,5 | kg | weight of polyester for towels |
| | | | | | | | |
| | *end of life* | | | | | | |
| | incineration | 0,091 | 1 | | 0,091 | kg | hcwmanagement-factsheet-rfhe.pdf (who.int) |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | *Use case 2 30 min wash with 10 lead sets* | | per leadset | per FU | | | Buying a Washer Disinfector, everything you need to know \| STERIS |
| | energy | 5,22 | 0,522 | 200 | 104,4 | MJ | Symbols Used In The Manual: Presentation - Tuttnauer TIVA2 Instructions For Us |
| | water | 50 | 5 | 200 | 1000 | l | tiva2-washer-disinfector-tuttnauer-09-02-21.pdf |
| | enzymatic detergent | 0,05 | 0,005 | 200 | 1 | l | grove schatting, sterk geconcentreerd, vooraad in machine is 0.6 liter |

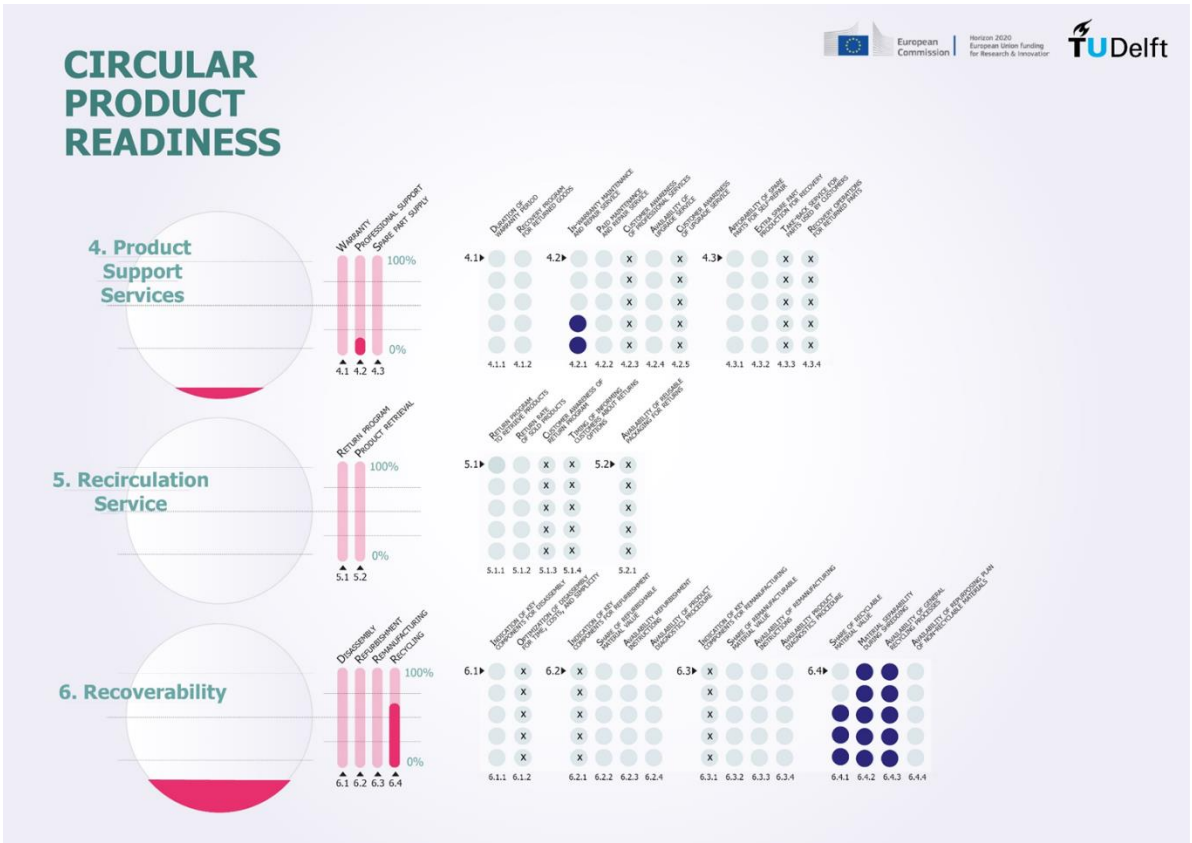
### SPU reprocessed

| | what | amount per product | number fu | | total fu | unit | source |
|---|---|---|---|---|---|---|---|
| | *manufacturing* | | | | | | |
| | Full weight | 0,08 | 50 | | 4 | kg | HWP803192141 - Philips 5-Lead SPU ECG Lead Set \| Medline Industries, Inc. |
| | PVC | 0,064 | 50 | | 3,2 | kg | .4 of full weight |
| | copper/tinned copper | 0,016 | 50 | | 0,8 | kg | .6 of full weight |
| | metal forming, elongating | 0,016 | 50 | | 0,8 | kg | R and D manganager Roman |
| | extrusion molding | 0,064 | 50 | | 3,2 | kg | R and D manganager Roman |
| | plating | 0,016 | 50 | | 0,8 | kg | R and D manganager Roman |
| | *transport* | | | | | | |
| | Transport by vrachtwagen | 640 | 50 | 0,08 | 32000 | km | maps |
| | *use* | | | | | | |
| | mild soap | 0,01 | 200 | | 2 | kg | Stryker reprocessing presentation |
| | microvezel towl | 1 | 200 | | 200 | towels | Stryker reprocessing presentation |
| | Transport by parcel delivery | 200 | 200 | 0,08 | 40000 | km | optimistic guess, 100km one way, from central netherlands to Delft |
| | Repackaging | 0,05 | 200 | | 10 | kg | guestimate, material is probably PE |
| | energy testing | | 200 | | 0 | | no idea |
| | ethylene oxide cleaning | 0,08 | 200 | | 16 | kg | Stryker reprocessing presentation |
| | | | | | | | |
| | *end of life* | | | | | | |
| | incineration | 0,08 | 50 | | 4 | kg | hcwmanagement-factsheet-rfhe.pdf (who.int) |

## Appendix F

Circular Product Readiness method result detailed



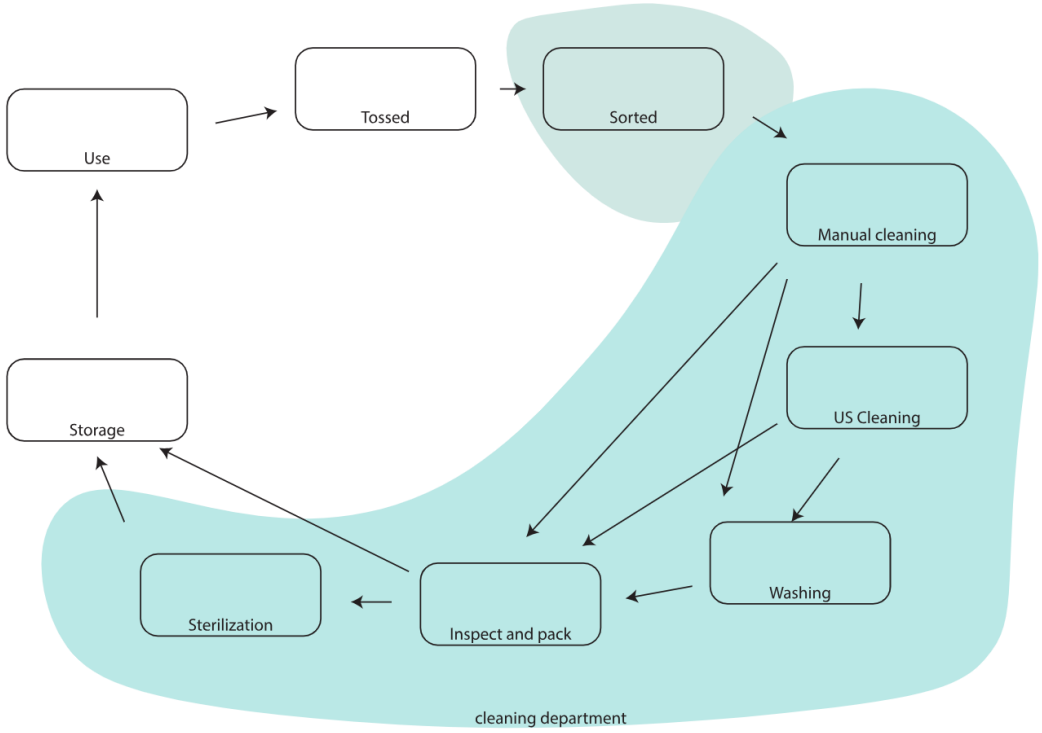



## Appendix G

Sterilization department

Within the sterilization department there are different cleaning flows. The devices get in on the dirty side. There they are checked visually and get a first manual clean. If a lot of blood or fats are present on the devices, they are put through Ultrasonic Cleaning. A cleaning process based on ultrasound waves that creates small implosions on the surface of the devices (Steris Healthcare, 2018).

After the initial cleaning steps, the products go through a washer disinfector machine to the clean side of the sterilization department. Some products are split off here and go directly into storage (eg endoscopes), but most are packed and sent through a sterilization step. With superheated steam the packed products are sterilized within the package and then stored for use. This can be in the sterilization department but also in local storage unit's ad wards.



## Appendix H

**SCAMPER**

## Appendix I

Lead set cleaning agents

### Reusable IntelliVue leadset and trunk cables cleaning and disinfection

| Cleaner, disinfectant* | |
|---|---|
| Accel® TB RTU | ✓ |
| Bacillol® 25 | ✓ |
| Bacillol® AF | ✓ |
| Biguacid Liquid | ✓ |
| Caltech-Dispatch® 5200 Wipes | ✓ |
| Carpe Diem™ Tb Wipes | ✓ |
| Clorox Healthcare® Bleach Germicidal Wipes | ✓ |
| Descogen® Liquid | ✓ |
| Descosept Pur | ✓ |
| Dismozon® Plus | ✓ |
| Hexanios G+R | ✗ |
| Hydrogen peroxide (3%) | ✓ |
| Incidin® Plus | ✗ |
| Isopropyl alcohol (70%) | ✓ |
| Lysoformin® | ✓ |
| Meliseptol® | ✓ |
| Metrex CaviWipes™ | ✓ |
| Microbac® Forte | ✗ |
| Mild soap | ✓ |
| Oxivir® Tb Wipes | ✓ |
| Oxivir® Tb Cleaner Disinfectant | ✓ |
| PDI Sani Cloth® Bleach | ✓ |
| PDI Super Sani Cloth® | ✓ |
| PDI Sani Cloth® PLUS | ✓ |
| PDI Sani Cloth® HB Wipes | ✓ |
| Sodium hypochlorite (bleach) (0.5%) | ✗ |
| Surfanios Citron | ✗ |
| TechSpray® Isopropyl alcohol | ✓ |
| Viraguard® Isopropanol 70% | ✓ |
| Virex® TB RTU | ✗ |

## MX40 reusable lead sets cleaning and disinfection

| Cleaner, disinfectant* | |
|---|---|
| Bacillol® 25 | ✓ |
| Bacillol® AF | ✓ |
| Caltech-Dispatch 5200 | ✗ |
| Chlorine Bleach (1:10 concentration, mixed < 24 hours) | ✓ |
| Cidex Activated Dialdehyde | ✗ |
| Cidex Formula 7 | ✗ |
| Cidex OPA | ✗ |
| Gluteraldehyde | ✗ |
| Hydrogen Peroxide | ✓ |
| Incidin | ✗ |
| Isopropyl alcohol | ✓ |
| Liquid Soap (antibacterial soap) | ✗ |
| Meliseptol® | ✓ |
| Metrex CaviWipes™ | ✓ |
| Metricide | ✗ |
| Omnicide | ✗ |
| Oxivir® Tb Cleaner Disinfectant | ✓ |
| Oxivir® Tb Wipes | ✓ |
| Procide 14 | ✗ |
| Resert XL HLD | ✓ |
| Sani-Cloth® AF | ✗ |
| Sani-Cloth® Bleach Germicidal Disposable Wipes | ✓ |
| Sani-Cloth® HB | ✓ |
| Sani-Cloth® PLUS | ✓ |
| Sani-Cloth® Plus Germicidal Cloths | ✓ |
| Sporox II Sterilizing & Disinfection Solution | ✓ |
| Super Sanicloth | ✓ |
| TechSpray® General Purpose Cleaner | ✓ |
| Viraguard® | ✓ |
| Virex Tb | ✗ |
| Wavicide | ✗ |
| WipesPlus Disinfecting Wipes | ✓ |

**Notes:** ✓ Approved cleaner/disinfectant. ✗ Do not use.

Appendix J

| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| 1 | Test leadset forces | | | | | | | |
| 2 | Test 1 0 degrees | | | | | | | |
| 3 | Version 1 | weight (kg) | force (N) | pass/fail | req min | req max | % of min | % of max |
| 4 | | [redacted] | | pass | [redacted] | | 18% | 10% |
| 5 | | | | pass | | | 36% | 20% |
| 6 | | | | pass | | | 54% | 29% |
| 7 | | | | pass | | | 71% | 39% |
| 8 | | | | pass | | | 89% | 49% |
| 9 | | | | fail | | | | |
| 10 | | | | | | | | |
| 11 | Version 2 | weight (kg) | force (N) | pass/fail | req min | req max | % of min | % of max |
| 12 | | [redacted] | | pass | [redacted] | | 18% | 10% |
| 13 | | | | pass | | | 36% | 20% |
| 14 | | | | pass | | | 54% | 29% |
| 15 | | | | pass | | | 71% | 39% |
| 16 | | | | pass | | | 89% | 49% |
| 17 | | | | pass | | | 107% | 59% |
| 18 | | | | pass | | | 125% | 69% |
| 19 | | | | pass | | | 143% | 78% |
| 20 | | | | pass | | | 161% | 88% |
| 21 | | | | pass | | | 178% | 98% |
| 22 | | | | pass | | | 196% | 108% |
| 23 | | | | pass | | | 214% | 118% |
| 24 | | | | fail | | | | |
| 25 | | | | | | | | |
| 26 | Version 2 | weight (kg) | force (N) | pass/fail | req min | req max | % of min | % of max |
| 27 | without mag | [redacted] | | pass | [redacted] | | 18% | 10% |
| 28 | | | | fail | | | | |
| 29 | | | | | | | | |
| 30 | Version 3 | weight (kg) | force (N) | pass/fail | req min | req max | % of min | % of max |
| 31 | | [redacted] | | fail | [redacted] | | | |
| 32 | | | | fail | | | | |
| 33 | | | | pass | | | 4% | 2% |

| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| 1 | Test leadset 45 degrees | | | | | | | |
| 2 | Version 1 | weight (kg) | force (N) | pass/fail | req min | req max | % of min | % of max |
| 3 | | [redacted] | | fail | [redacted] | | | |
| 4 | | | | fail | | | | |
| 5 | | | | pass | | | 16% | 2% |
| 6 | | | | | | | | |
| 7 | Version 2 | weight (kg) | force (N) | pass/fail | req min | req max | % of min | % of max |
| 8 | | [redacted] | | fail | [redacted] | | | |
| 9 | | | | pass | | | 41% | 5% |
| 10 | | | | pass | | | 16% | 2% |
| 11 | | | | | | | | |
| 12 | Version 3 | weight (kg) | force (N) | pass/fail | req min | req max | % of min | % of max |
| 13 | | [redacted] | | fail | [redacted] | | | |
| 14 | | | | fail | | | | |
| 15 | | | | fail | | | | |
| 16 | | | | pass | | | 8% | 1% |

| | A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|---|
| 1 | Test leadset 90 degrees | | | | | | | |
| 2 | Version 1 | weight (kg | force (N) | pass/fail | req min | req max | % of min | % of max |
| 3 | | [redacted] | | fail | [redacted] | | | |
| 4 | | | | fail | | | | |
| 5 | | | | pass | | | 8% | 1% |
| 6 | | | | | | | | |
| 7 | Version 2 | weight (kg | force (N) | pass/fail | req min | req max | % of min | % of max |
| 8 | | [redacted] | | fail | [redacted] | | | |
| 9 | | | | pass | | | 16% | 2% |
| 10 | | | | pass | | | 8% | 1% |
| 11 | | | | | | | | |
| 12 | Version 3 | weight (kg | force (N) | pass/fail | req min | req max | % of min | % of max |
| 13 | | [redacted] | | fail | [redacted] | | | |
| 14 | | | | fail | | | | |
| 15 | | | | fail | | | | |

## Appendix K

Budgetary

| | A | B | C | D | E |
|---|---|---|---|---|---|
| 1 | Cost per FU | | amount | price/st/ltr | total per FU |
| 2 | 200x cleaning | | | | |
| 3 | Cleaning with wipes | | | | |
| 4 | materials: | wipes | 400 | € 0.08 | € 32.00 |
| 5 | | water | 200 | € 0.00 | € 0.40 |
| 6 | | | | | |
| 7 | Time: | Personel 2 min a 35eur/hr: | 6.666667 | € 35.00 | € 233.33 |
| 8 | | | | | |
| 9 | | | **Total** | | € 265.73 |
| 10 | cleaning with tool | | | | |
| 11 | materials: | tool | 1 | € 36.00 | € 36.00 |
| 12 | | cleaning agent mix | 4 | € 10.00 | € 40.00 |
| 13 | | sponges | 10 | € 0.50 | € 5.00 |
| 14 | | wipes | 200 | € 0.08 | € 16.00 |
| 15 | | | | | |
| 16 | Time: | Personel 1:30 min a 35eur/hr: | 5 | € 35.00 | € 175.00 |
| 17 | | | | | |
| 18 | | | **Total** | | € 272.00 |