# A

# APPENDICES

APRIL 2025

GRADUATION REPORT
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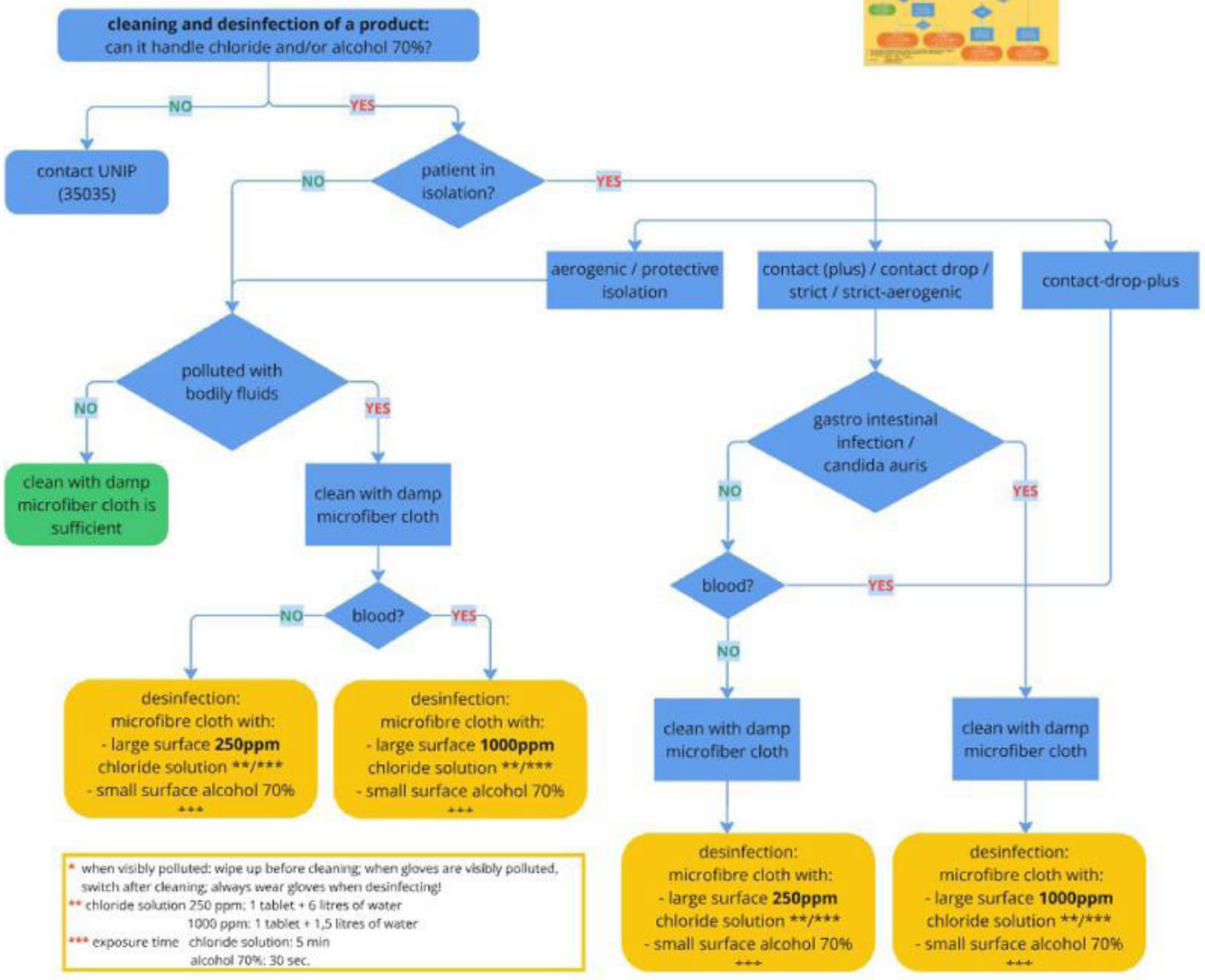
# A / CLEANING PROTOCOL ERASMUS MC

## Erasmus MC cleaning protocol:




## Massimo cleaning protocol:

### Cleaning

To clean the display panel, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.

To clean the outer surface of the oximeter, use a soft cloth dampened with a mild soap and water. Do not allow liquids to enter the interior of the Instrument.

**CAUTIONS:**

- DO NOT AUTOCLAVE, PRESSURE STERILIZE, OR GAS STERILIZE THIS OXIMETER.
- DO NOT SOAK OR IMMERSE THE MONITOR IN ANY LIQUID.
- USE THE CLEANING SOLUTION SPARINGLY. EXCESSIVE SOLUTION CAN FLOW INTO THE MONITOR AND CAUSE DAMAGE TO INTERNAL COMPONENTS.
- DO NOT TOUCH, PRESS, OR RUB THE DISPLAY PANELS WITH ABRASIVE CLEANING COMPOUNDS, INSTRUMENTS, BRUSHES, ROUGH-SURFACE MATERIALS, OR BRING THEM INTO CONTACT WITH ANYTHING THAT COULD SCRATCH THE PANEL.
- DO NOT USE PETROLEUM-BASED OR ACETONE SOLUTIONS, OR OTHER HARSH SOLVENTS, TO CLEAN THE OXIMETER. THESE SUBSTANCES ATTACK THE INSTRUMENT'S MATERIALS AND INSTRUMENT FAILURE CAN RESULT.

Refer to Section 8, *Cleaning and Reuse of Masimo Reusable Sensors and Patient Cables* for cleaning instructions of the sensor and patient cables.

**Cleaning And Reuse Of Masimo Reusable Sensors and Cables**

Reusable sensors and patient cables can be cleaned per the following procedure:

- Remove the sensor from the patient.
- Disconnect the sensor from the patient cable.
- Disconnect the patient cable from the monitor.
- Wipe the entire sensor and/or patient cable clean with a 70% isopropyl alcohol pad.
- Allow to air dry thoroughly before returning it to operation.

**CAUTION:** CAREFULLY ROUTE PATIENT CABLES TO REDUCE THE POSSIBILITY OF PATIENT ENTANGLEMENT OR STRANGULATION.

**Reattachment of Single Use Adhesive Sensors**

- Single use sensors may be reapplied to the same patient if the emitter and detector windows are clear and the adhesive still adheres to the skin.

***NOTE:*** *If the sensor fails to track the pulse consistently, the sensors may be incorrectly positioned. Reposition the sensor or choose a different monitoring site.*

**CAUTION**: DO NOT ATTEMPT TO REPROCESS, RECONDITION OR RECYCLE ANY SENSORS AS THESE PROCESSES MAY DAMAGE THE ELECTRICAL COMPONENTS, POTENTIALLY LEADING TO PATIENT HARM.

Summary:
**display panel:** cotton swab with 70% isopropyl alcohol
**shell (outside surface):** soft cloth dampened with soap & water
**sensors & cables**: pad with 70% isopropyl alcohol

# B / LIFECYCLE ASSESMENT SETUP

This document elaborates on the setup of the Life Cycle Assesment comparing single and reusable pulse oximeters on the Intensive Care Unit of Erasmus MC.

## B.1 Problem Definition

In Dutch hospitals, pulse oximeters have one of the biggest impacts on the environmental footprint of all disposables. In order to design a solution, it is important to identify how big this footprint is, and how design choices can limit this footprint.

Pulse oximeters already exist in both single use as reusable forms, which are both actively used in hospitals. The initial thought is that the reusable pulse oximeter is more sustainable, and a design direction to transition single use to reus able seems logical. However, for the context of Dutch hospitals the environmental benefit of reusable devices is not proven. Therefore, a Life Cycle Assessment comparing these two device types will be performed.

**The functioning of the product system**
To provide continues pulse oximetry measurements for one year.

- ICU: for 3500 patients per year with an average stay of 4,86 days
- Need for 60 reusable sensors to supply the entire ward (in case of full reusable scenario)
- Need for 5000 reusable sensors to supply the entire ward (in case of full single-use scenario)
- Data from ICU (4500 purchased in 2023, 90% use of single use on ward)

**Who**
Monitoring of: non-isolated patients
Handling by: nurses

**What**
A pulse oximeter, comparing a single use product to a reusable variation
Specific products: RD SET DB-I Reusable Soft Sensor and RD SET™ Adt single use sensor

**Where**
Continues patient monitoring, 24 hours daily on the ICU department of Erasmus Medical Center

**How**
Pulse oximeter attached to the fingertip, monitoring through transmissive oximetry.

**Functional unit**
To provide continues pulse oximetry measurements for one year on non-isolated patients on the ICU of Erasmus Medical Center.

**LCA goal**
Comparative analysis of the single vs. multiuse product as well as identification of environmental hotspots, to serve as design input.

**Life Cycle Assessment Modeling**
Life cycle assessment was performed using OpenLCA 2.3.1. and the IDEMAT 2023 database. This database and software were recommended to me by Joost Vogtländer. Ecoinvent database was considered but not recommended, as the EI version 10 was found to have a few big faults. Product specific data was acquired through material identification of Masimo sensors including the RD SET DB-I Reusable Soft Sensor and RD SET™ Adt single use sensor. Ecological Footprint 3.0 (adapted) was used for a detailed impact assessment method, as this assesment method is good for comparing individual impact factors, advised by Joost Vogtländer.

## B.2 Assumptions

- 60 reusable sensors are required to supply the entire ICU, one per bed (50) and 10 extras in storage.
- 5000 single use sensors are required to supply the entire ICU. The purchased amount in 2023 was 3600 sensors, which supplied 90% of the ward.
- The reusable pulse oximeter is only cleaned at patient discharge, using a ¼ of a microfiber cloth and water. This is conform the cleaning protocol of the hospital, for non-isolated patients. As no data was available for the amount of isolated patients, this patient group was excluded.
- The reusable product lifespan was set at 1 year. The manufacturer indicates 2 year lifespan, but this is shortened due to product misuse. This is an estimation as no Erasmus MC data or insight is available about the lifespan of the pulse oximeters in their context.
- The single use pulse oximeters are used for up to a week on the Erasmus MC ICU, afterwards they are replaced with a new one.

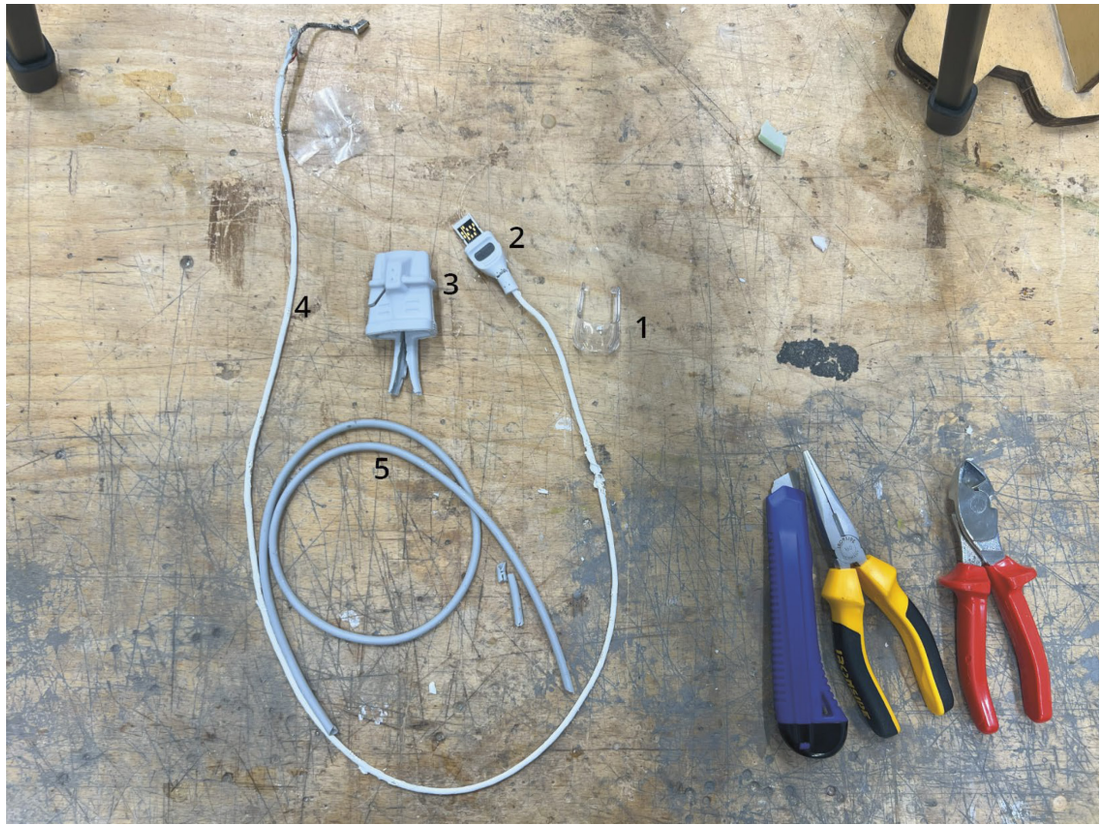
## B.2 Life Cycle Inventory

**Department data**
Beds on the ICU: 50
Amount of patient admissions: 3225
Total amount of treatment days: 15.689
Average patient stay length (days): 4,86
Amount of purchased single use sensors (pcs): 3600

**Bill of materials**
A Bill of Materials of the sensors could not be acquired from the manufacturer, therefore material determination had to be done. Broken sensors were used as to not waste usable sensors. The products were taken apart for a disassembly analysis and afterwards used to determine the main materials of the disassembled part. This was done by looking at the material properties like weight, density, flexibility, feel, suitability of the material in de medical context and burn tests. Within this material breakdown, material waste during production was not included, as this information could not be obtained.
Part numbers refer to the picture under the table.

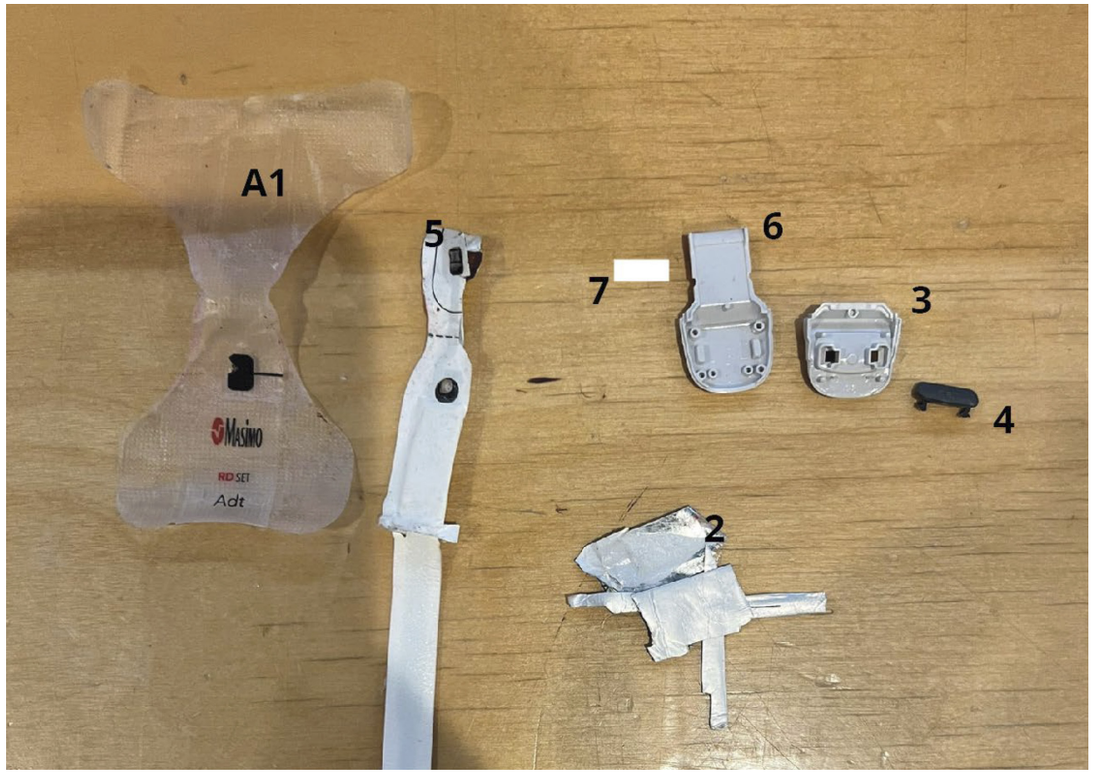
**RD SET DB-I Reusable sensor**

| Part number | Part name | Material | Weight (g) | Production | Notes |
|---|---|---|---|---|---|
| 1 | Clear cable cover | PS | 2,83 g | IM | Sooty flame (quite a lot) takes a little while to light on fire, self extinguishes, bubbles before lighting on fire, leaves hard black char. |
| 2 | Electric cover | TPU | 0,89 | IM | Burn test, slight sutty smoke, melts but is resistant to acetone and more tough to stretch. |
| 3 | Sleeve | silcone rubber (PU) | 15.71 g | IM | Flame test: Lights on fire and creates white ash, self extinguises |
| 4 | Electronics | Mixed: pvs wire cover Hair? Wire? | 20 g | | Weight estimation between materials:<br>4a. Copper (2 parts + heavy)<br>4b PVC (1 part)<br>4c. PC 1 part (injection molded) |
| 5 | Wire sleeve | Silicone rubber (PU) | 9,53 g | Extrusion | Flame test: Lights on fire and creates white ash, self extinguises |
| | Electric cast (hard plastic around electronics) | PC | Included in electronics | IM | |



**RD SER Adt**

| Part number | Part name | Material | Weight (g) | Production | Notes |
|---|---|---|---|---|---|
| 1 | Finger sticker | Low density Polyethyleen (LDPE) with acryl (glue) | 0,59 | Extrusion | |
| 5A | Foam wire cover | Polyethylene foam | 2/3 of electronic weight = 0.59 g | Extrusion | |
| 5B | Electronics | mixed | | | 1/3 copper wire (0.23 g)<br>2/3 foam material (0.59 g) |
| 6,3 | Plastic connector | Polycarbonate PC | 1.68 g | IM | Flame test: does not catch fire, melts, leaves slight black and |
| | | | | | brown residue, smells faintly of fireworks.<br>Float test: sinks. |
| 4 | Set grey | ABS | 0.13 g | IM | Flame test: Does catch fire, self extinguishes, smells a lot of chemicals, black chunk residue<br>Float test: sinks. |
| 2 | Metalic film | Aluminium covered PE | 0.3 g AL<br><br>0.3 g PE | Extrusion | Flame test: burns and shows slight white smoke as it extinguishes, leaves black ball. |
| 7 | Double sided sticker | | 0 g | Extrusion | No weight so not included |



**Packaging material**
Primary reusable
- Cardboard box 0.024 kg Cardboard
- Instruction 0.002 kg virgin paper

Primary disposable
- Pouch
- Clear 0.00183 kg (LDPE 4)(Masimo - Masimo Packaging Labeling, z.d.)
- Label 0.00172 kg (HDPE 2)

Secondary single-use
- https://www.masimo.com/products/sensors/rd-set/
- 0.176 kg cardboard box for 20 pieces
- 8.8 grams of cardboard per single use sensor

**Cleaning procedure**
https://www.vileda-professional.nl/schoonmaakdoeken/poetsdoeken/r-micronsolo-rol
- Roll is 180 towels
- One towel is 25 cm by 32 cm
- One towel is 3.66 grams
- 35% recycled polyester (comprising post-consumer1 PET-bottle waste, certified)
- 15% virgin polyamide
- 50% viscose

Soaked towel is 13.66 grams
- 10 grams of water
- But measured 100 grams of water coming from the tap

In the calculation of the impact of the cleaning wipe, raw material production, wipe manufacturing, water (as a material), transport to end of life and incineration with municipal waste was taken in scope. The transport from manufacturing to hospital was unclear so left out of scope.

**Transport**
The following table shows the estimated transportation distances for the product (parts). Taiwan, Philippines, China and Costa Rica are production and assembly locations, therefore not the full product is transported between these locations. Therefore, an estimation was made for the transportation weight between locations. It was estimated that 1/3 of the product weight is added on in each production phase. After full assembly in Costa Rica, the full product including its packaging is transported.

Only transport over water is taken into account between production facilities, as the exact location of factories is unknown. The production locations are according to Philips' pulse oximeter product journey as well as the Erasmus distribution journey.

**Use**
Reusable cleaning:
- Cleaning once for every (3225) patient
- Every individual sensor (60 in total) was cleaned 53.75 times

The amount of wipes per cleaning was estimated at ¼ wipe per cleaning but is hard to estimate as it can very from 1 to 20 wipes to clean the entire ICU room after patient stay. Difficult to determine how much of these wipes are used for the pulse oximeter alone. On other departments 1 wipe is used to disinfect the 3 vital sensors and 'broodje'. Therefore an estimation of ¼ wipe was also considered for the ICU, this is in line with the Duffy LCA article.

- ¼ wipe per sensor (53.75 times cleaned per year)
- 100 g water per wipe
- 25 g water per sensor

Reusable energy:
- 15689 treatment days per year for 60 sensors
- 261.483 days of continuous monitoring per sensor
- 6275.6 hours per sensor per year
- Average pulse oximeter uses approximately 40 mW of energy. (Baheti & Garudadri, 2009)

| Location (departure) | Location (destination) | Distance (km) | Transport | Product weight |
|---|---|---|---|---|
| Taiwan | Philippines | 885 | Container ship | 1/3 of product |
| Philippines | China | 1330 | Container ship | 2/3 of product |
| China | Costa Rica | 16826 | Container ship | Full product weight |
| Costa Rica | Rotterdam | 9317 | Container ship | Full product weight including packaging |
| Rotterdam | Amsterdam | 95 | Truck with container | Full product weight including packaging |
| Amsterdam | Barendrecht | 97 | Truck with container | Full product weight including packaging |
| Barendrecht | Erasmus MC | 14 | Truck with container | Full product weight including packaging |

Single use cleaning:
/

Single use energy:
- 15689 treatment days per year for 5000 sensors
- 3,1378 days per sensor
- 75,3072 hours per sensor per year
- Average pulse oximeter uses approximately 40 mW of energy. (Baheti & Garudadri, 2009)

As the energy needed to process and store the data could not be estimated, these were left out of scope. Thit energy does not influence the comparison between single and reusable, as they are equal.

**End-of-life**
Because products are disposed of in the general waste on all departments after use, the EOL category of municipality waste incineration is chosen.

The treatment of pathological waste is sometimes restricted to dedicated incinerators, while non-pathological waste is, in some cases, incinerated with other wastes in non-dedicated incinerators e.g. MSWI. (chrome-

extension://efaidnbmnnnibpcajpcglclefindmkaj/https://eippcb.jrc.ec.europa.eu/sites/default/files/2020-03/superseded_wi_bref_0806_0.pdf)

A small part of broken reusable pulse oximeters are discarded in electrical waste, but this is negligible.

Paper and cardboard packaging is collected seperately

- Packaging cardboard (already recycled material): only 3-4 recycling cycles in total (book_LCA) so estimated 2 more recycling cycles. Therefore divide incineration impact by 2
- Paper manual: Virgin paper can be recycled 3-4 times, estimate the lower end so 3 times. Divide incineration weight by 3.

The short distance of EoL transport is assumed to be negligible. The waste is processed in the Netherlands, but exact locations are unknow.

**Calculation**
To perform the calculation. A life cycle process was set up for every life cycle phase of the products (raw material, manufacturing, use, transport and end of life). These phases were all considered for one sensor use over an entire year. Afterwards, to compare the sensors these phases were multiplied by the amount of sensors used for one year, to calculate the impact of the use of the sensors for one year for the entire department.

**Validation**
The final results of the LCA were validated using the Duffy LCA. To do so the amount of cleaning cycles, use of alcohol and higher weight of the single use sensor were temporarily adjusted to match the Duffy article. Doing so, the LCA results showed similar life cycle impact distributions as the Duffy article. Through this validation I concluded that my data was reliable enough to make informed decisions regarding my design.

## B.3 Life Cycle Inventory Philips Nova

**BOM**
The BOM is split up in the reusable and single-use elements.

BOM reusable part

| Part number | Part name | Material | Weight (g) | Volume (mm3) | Production | Notes |
|---|---|---|---|---|---|---|
| 1.1 | Bottom base | PC | 0,22 | 186,56 | Injection molding | |
| 1.2 | Bottom insert | TPU | 0,13 | 111.28 | Injection molding | |
| 1.3 | Click ring | PC | 0,11 | 92.45 | Injection molding | |
| 1.4 | Finger cushion | Silicone rubber | 1,37 | 1224.56 | Injection molding | |
| 1.5 | Top sensor base | PC | 1,92 | 1601.23 | Injection molding | |
| 1.6 | Cable insert base | PC | 0,47 | 391.31 | Injection molding | |
| 1.7 | Cable insert cover | Silicone rubber | 0,36 | 320.70 | Injection molding | |
| 1.8 | Full cover | Silicone rubber | 2,02 | 1799.28 | Injection molding | |
| 1.9 | Wire sleeve | Silicone rubber | 4,765 | | Extrusion | Half the cable length |
| 1.10 | Copper wire | Copper | 5g | | Extrusion | Half the copper weight due to half the cable length |
| 1.11 | Wire cover | PVC | 2,5 g | | Extrusion | Half the weight due to half of cable length |
| 1.12 | Electronics cast | PC | 5 g | | Injection molding | |
| 1.13 | Electric cable cover other end | TPU | 0,89 | | Injection molding | Other end cable cover |
| 1.14 | Nuts and bolts | Stainless steel | 0,7 | | Thread rolling | Total of 2 nuts and 2 screws |
| 1.15 | Box | Recycled cardboard | 24 | | | |
| 1.16 | IFU | Paper | 2 | | | |

Total weight reusable sensor part: 25,455 g

BOM single use part

| Part number | Part name | Material | Weight (g) | Volume (mm3) | Production | Notes |
|---|---|---|---|---|---|---|
| 2.1 | Snap fit top (around wire) | HDPE | 0,13 | 132.43 | Injection molding | |
| 2.2 | Snap fit bottom | HDPE | 0,15 | 157.69 | Injection molding | |
| 2.3 | Sticker | LDPE | 0,59 | | Extrusion | Same size as single use sticker |
| 2.4 | Sticker backing | LDPE | 0,915 | | Extrusion | Half the size of the original sticker wrap |
| 2.5 | Box | Cardboard | 2 | | | |
| 2.6 | | | | | | |

**Transport**
Transport of reusable part is the same as the current reusable product.

Transport single use part is from germany to Erasmus MC (very simple product, so can be produced in europe).

**Packaging**
For the reusable base, the same packaging as the current reusable

The single-use patch has the same box as the current single use, except it is filled with double the amount of stickers, as the stickers are twice as small.

**Use**
- Cleaning: same as current reusable
- 60 sensors estimation (same as reusable)
- 5000 stickers (83 per sensor per jaar

**End-of-life**
Only copper and paper is recycled

Allocate 1/3 of incineration credit to the paper (LCA book)

# C / DISASSEMBLY MAPPING

When considering the 10R's strategy, the value of a product needs to be upheld for as long as possible. A crucial product property for R4-R9, so everything past reuse, is the ease of disassembly. Remanufacturing for example, requires disassembly to acquire the product parts to test and reuse. Simplifying this process will make all R's faster, and therefore more profitable (Soh et al., 2014). To analyse the current ease of disassembly, disassembly maps were created (see figure x). This method combines multiple disassembly strategies, and was created to guide the design process (De Fazio et al., 2021).

## B.1 Disassembly map structure

**Parts**
In the disassembly map product parts are represented as circles, containing a number corresponding to the part. A product part is indicated once completely removed. Some parts come apart as clusters, these are represented as cluster blocks, single component circles containing all product parts, separated by comma's.

The maps can expand in two directions, vertical and horizontal. Maps expanding in the vertical direction are caused by dependent disassembly sequences. This means that the removal of a part requires the removal of the part above it. The lower a part is located in the map, the more steps are required to remove it. The vertical direction of the disassembly map therefore indicates the disassembly depth. More depth generally means a higher disassembly time.

Horizontal map expansion is caused by independent disassembly sequences. In this case, multiple parts can be removed, whether or not the others are removed. There parts then share the same depth level. More horizontal as opposed to vertical expansion results in lower disassembly depths, generally lowering disassembly time.

Sometimes a part can only be removed, after two other independent parts are disassembled. This is indicated using an '&' (De Fazio et al., 2021).

**Actions**
Disassembly actions are depicted as action blocks, located between the product parts. These blocks indicate the tool needed to establish disassembly and the connection type of the part. The colour of the action block shows the required force. Legend in figure x shows the variations (De Fazio et al., 2021).

**Penalties**
Next to action blocks, penalties can be indicated. Penalties show design features that are ideally avoided, as they can cause longer disassembly times, disassembly errors or can interfere with reuse. (De Fazio et al., 2021)

First the reusable sensors will be disassembled and explained. Afterwards two single-use sensors are disassembled. But not compared in as much detail, as the reusable was more inspiring for future redesigns.

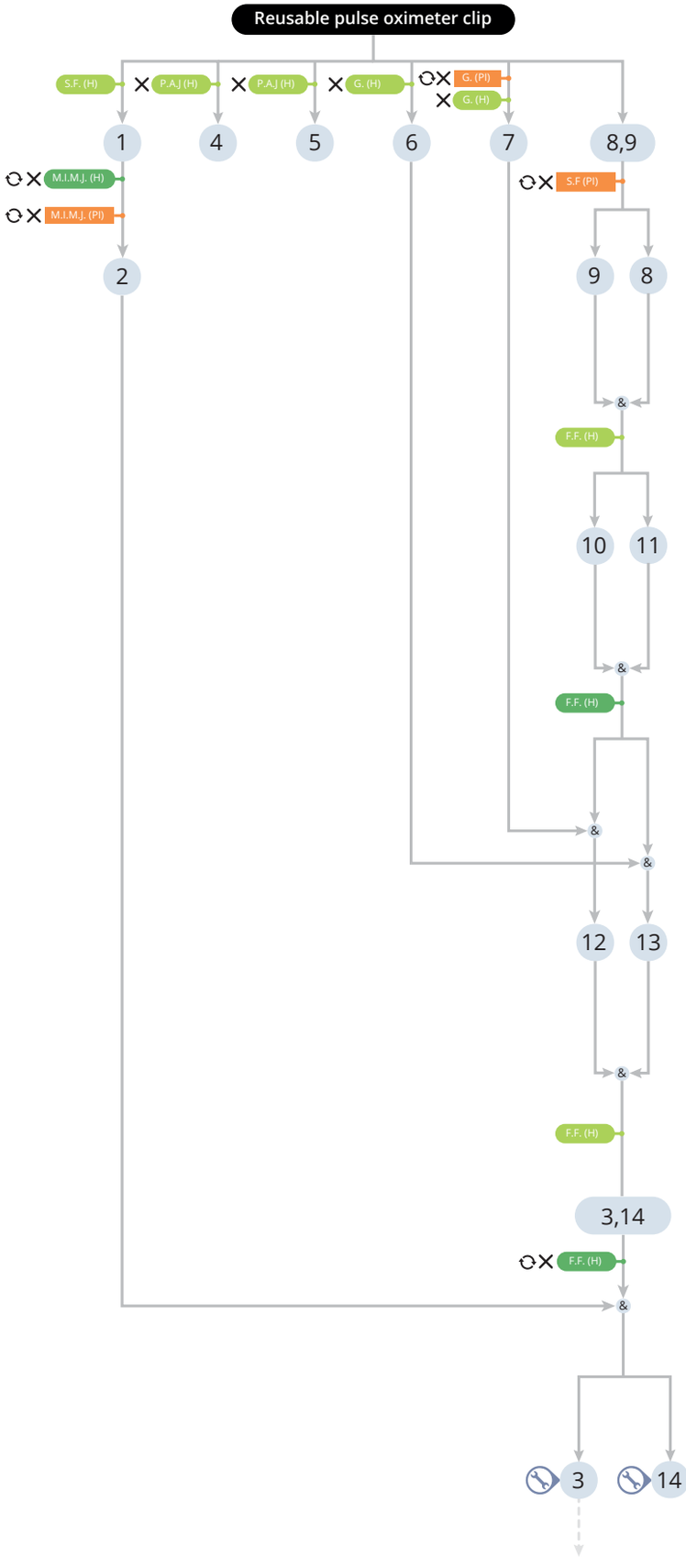
## B.2 Reusable finger clip

The total disassembly of the pulse oximeter clip cost 32 minutes, 14 of which were spent on component 2, the removal of the connector cover. Because of the use of adhesives and multi-part injection moulding, many non-reusable connector penalties are present.

**Connector pin (8,9)**
The main parts, holding together the finger clip were the connector pins 8 and 9. After removing these, the rest of the disassembly of the finger clip (excluding electronics) was straightforward. The pins were held together by a snap-fit. In order to separate part 8 and 9 from each other a high force was required, damaging both parts.

**Finger cushions (6,7)**
The finger cushions are the only component attached using glue. Depending on the amount used, these cushions could be removed without damage, but did leave glue residues on both the cushions and the plastic clips. This would contaminate the purity of the material of both these components, a barrier for high grade recycling

**Electronics (3)**
The electronics are a target component with a failure indication. It received this failure indicator as the electronics are the biggest factor for product failure. If the product lifespan would want to be extended through electronic replacement, this component should be easy to reach. This sensor does not allow component replacement as the electronics are at the highest disassembly depth of 11 and require damaging of other components in on order to reach it. For recycling, the damaging of other component does not have to be a problem. The total disassembly depth of this device is only 4, with a low part count of 5 allowing relatively easy separation of materials for high value recycling. Full disassembly of all individual electronic components, like individual wires and the connector components cast in plastic, was not attempted, but would also not be required for extracting metals from the component for recycling indicate the tool needed to establish disassembly and the connection type of the part. The colour of the action block shows the required force. Legend in figure x shows the variations (De Fazio et al., 2021).





## Type of tool

(H) = Hand
(PI) = Pliers

## Target components

= Failure indicator

## Connectors

S.F. = Snap Fit
F.F. = Friction Fit
M.I.M.J. = Multi-part injection molding joint
(P.A.J.) = Peelable adhesive joint
G. = Glue

## Penalties

= Product manipulation

= Non-reusable connector

**Disassembly action**

| Force intensity | Fastener type | Tool | Action block representation |
|---|---|---|---|
| Force < 5N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |
| 5N < Force < 20N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |

## B.2 Reusable finger clip

The total disassembly of the pulse oximeter sleeve cost 29 minutes, 14 of which were spent on component 2, the removal of the connector cover. Every component except the disassembly of component 1 received the product manipulation and non-reusable connector penalty, not allowing them to be reused in remanufacturing or refurbishment processes.

**Sleeve (3)**
The second most time consuming disassembly component was the silicone sleeve, which cost 8 minutes to remove. As the electronics were injection moulded into the sleeve, it had to be fully cut open using a Stanley knife in order to separate them. Therefore this component received the product manipulation and non-reusable connector penalty.

**Electronics (4)**
For the same reason as the reusable pulse oximeter clip, the electronics are a target component with a failure indication. In order to reach the electronics, all components except part 1 would have to be damaged in order to reach it. The disassembly depth of the electronics is only 5, instead of 11 at the pulse oximeter clip, yet does not take significantly less time to separate. Again, full disassembly of individual electronic components was not attempted.

## B.3 Comparing the reusables

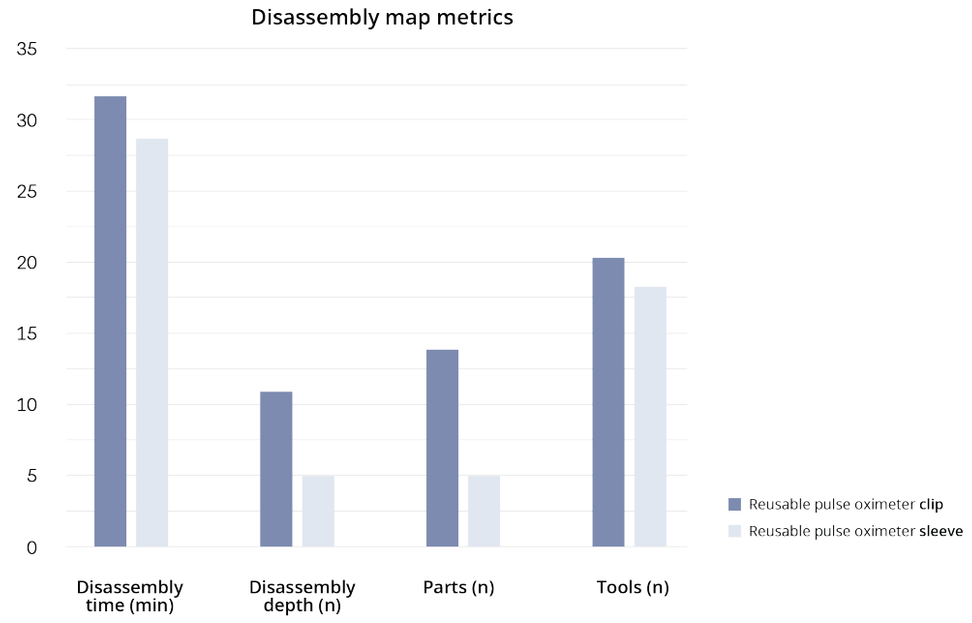
Comparing the two sensors, we can see that the pulse oximeter sleeve has significantly less components as well as lower total disassembly depth. However, this does not significantly lower the disassembly time. This is because the sensors both contain component two, a time consuming part to separate. Alongside this part, the pulse oximeter's sleeve requires a lot of time to disassemble.

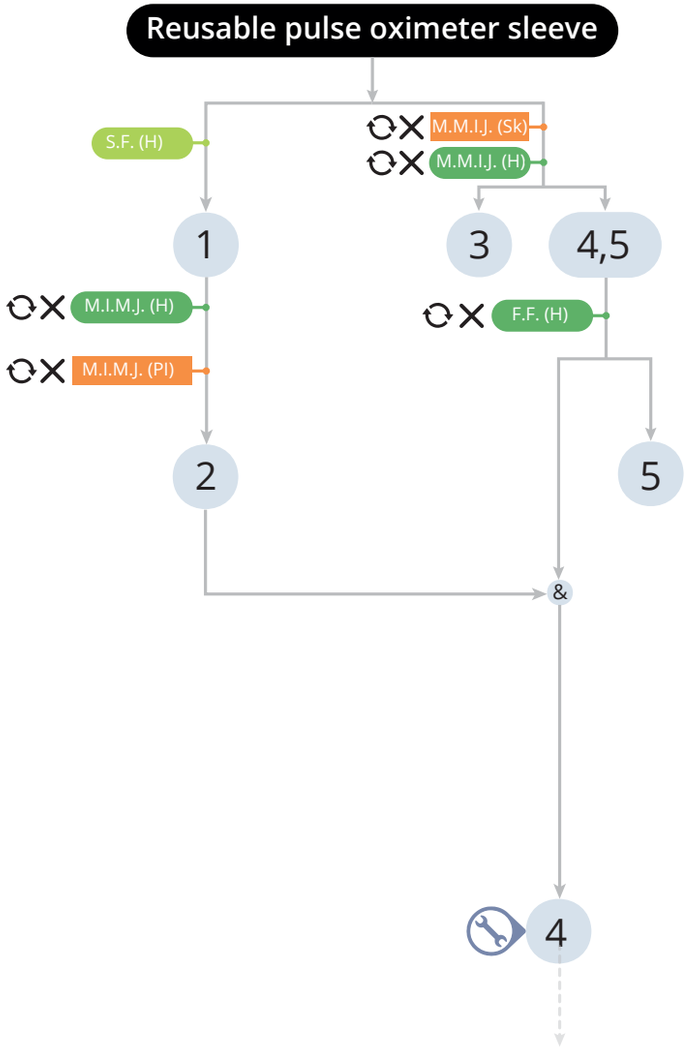
The lower part count does mean, fewer points of possible failure and enhancing durability. It also means less material types, making them easier to sort and recycle at the end of their life.

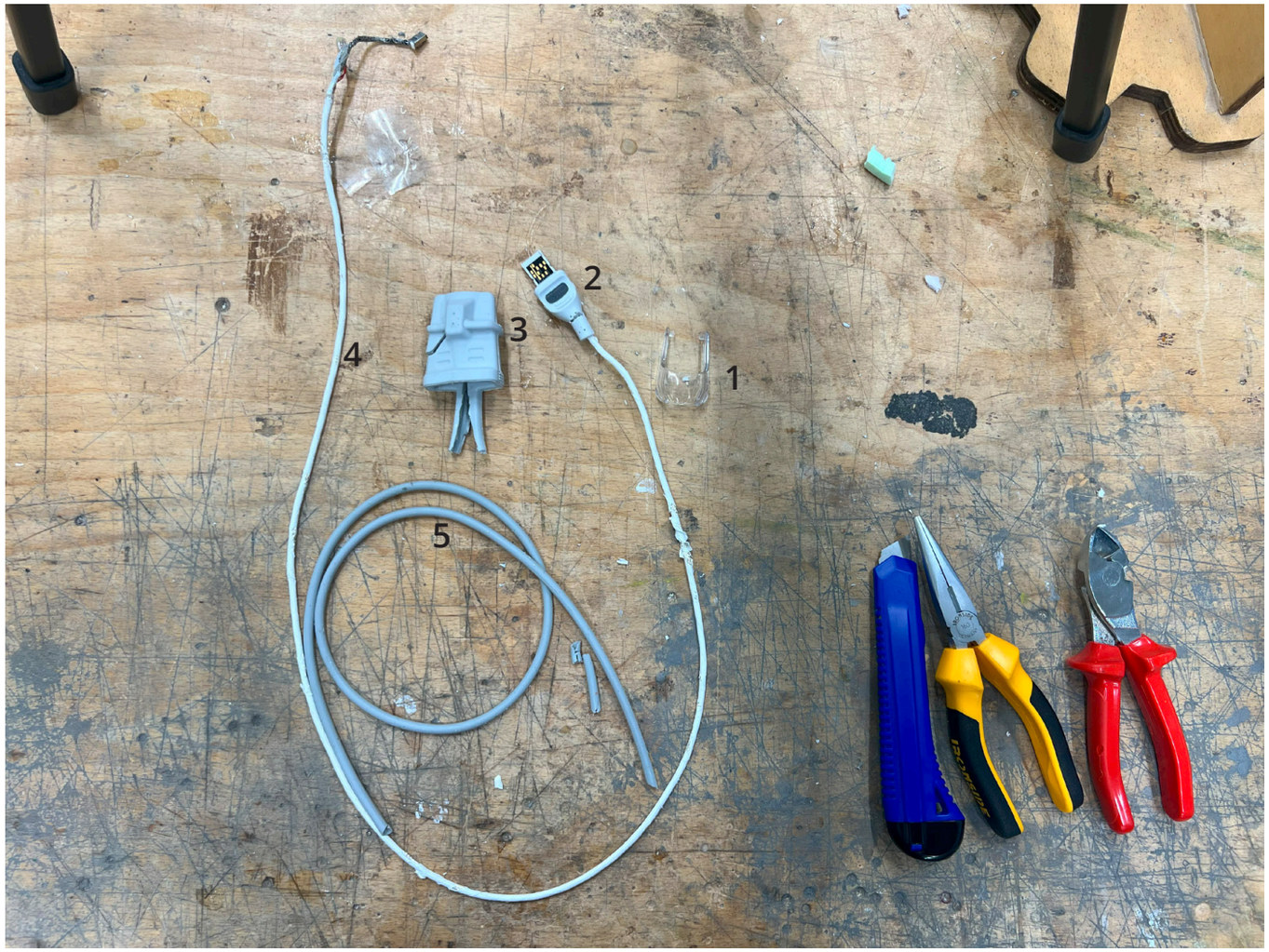
Both sensors have the biggest risk of product failure around the electronics, which is hardest to separate in both cases.

Multi-part injection moulding joints and adhesives like glue complicate disassembly in both sensors as it fuses different material types together.

It can be concluded that neither sensor is designed with ease of disassembly in mind. While this may not be critical in the current product lifecycle, where sensors are incinerated at the end of their life, it becomes important for future redesigns aiming to incorporate circular strategies. Optimizing disassembly through lowered part count and eliminating adhesive and multi-part injection moulding joint types, will be essential to enable repair, refurbishment, and recycling processes effectively (Åkermark, 1997).






### Type of tool
(H) = Hand
(PI) = Pliers
(Sk) = Stanley knive

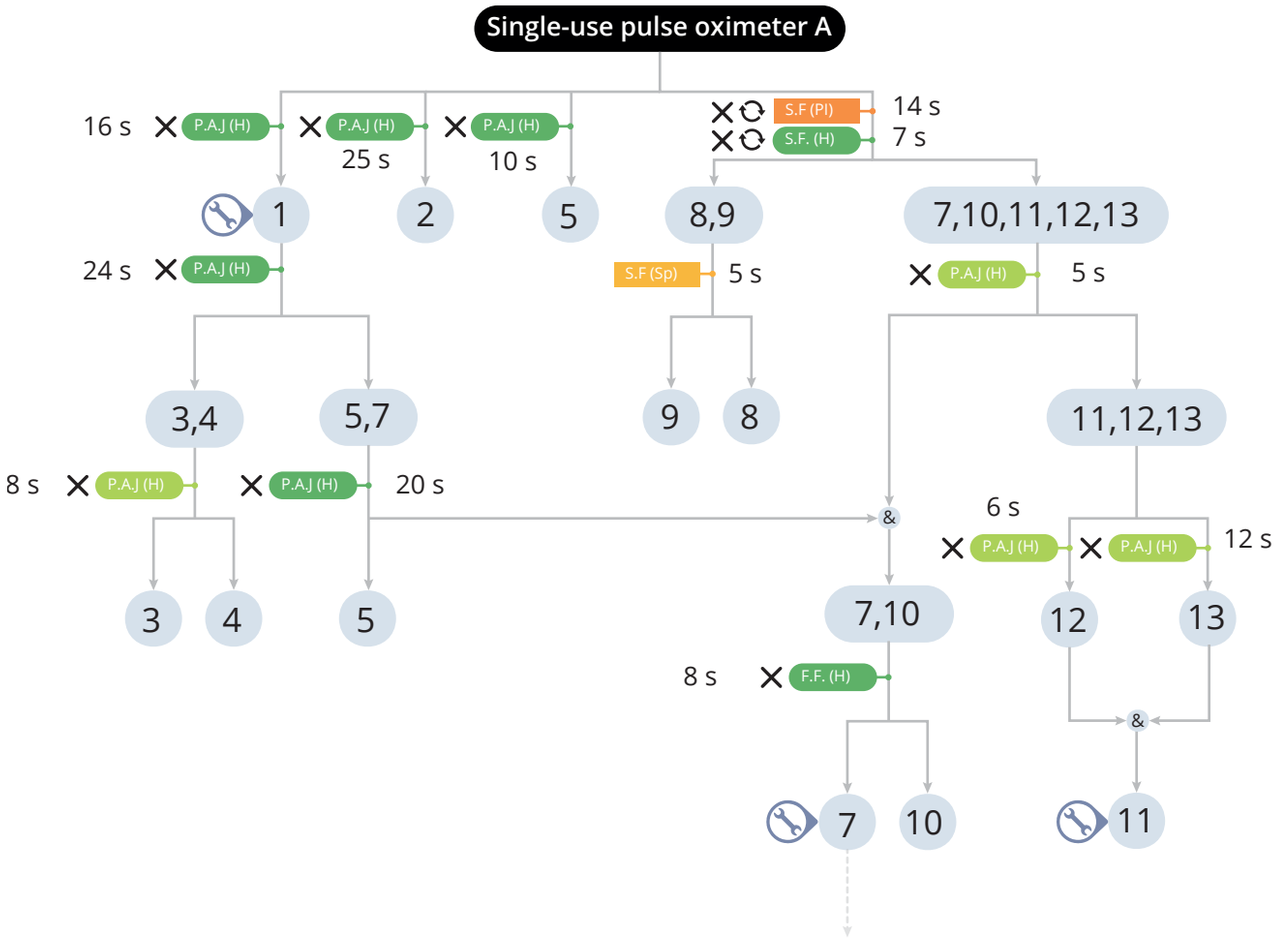
### Connectors
S.F. = Snap Fit
F.F. = Friction Fit
M.I.M.J. = Multi-part injection molding joint

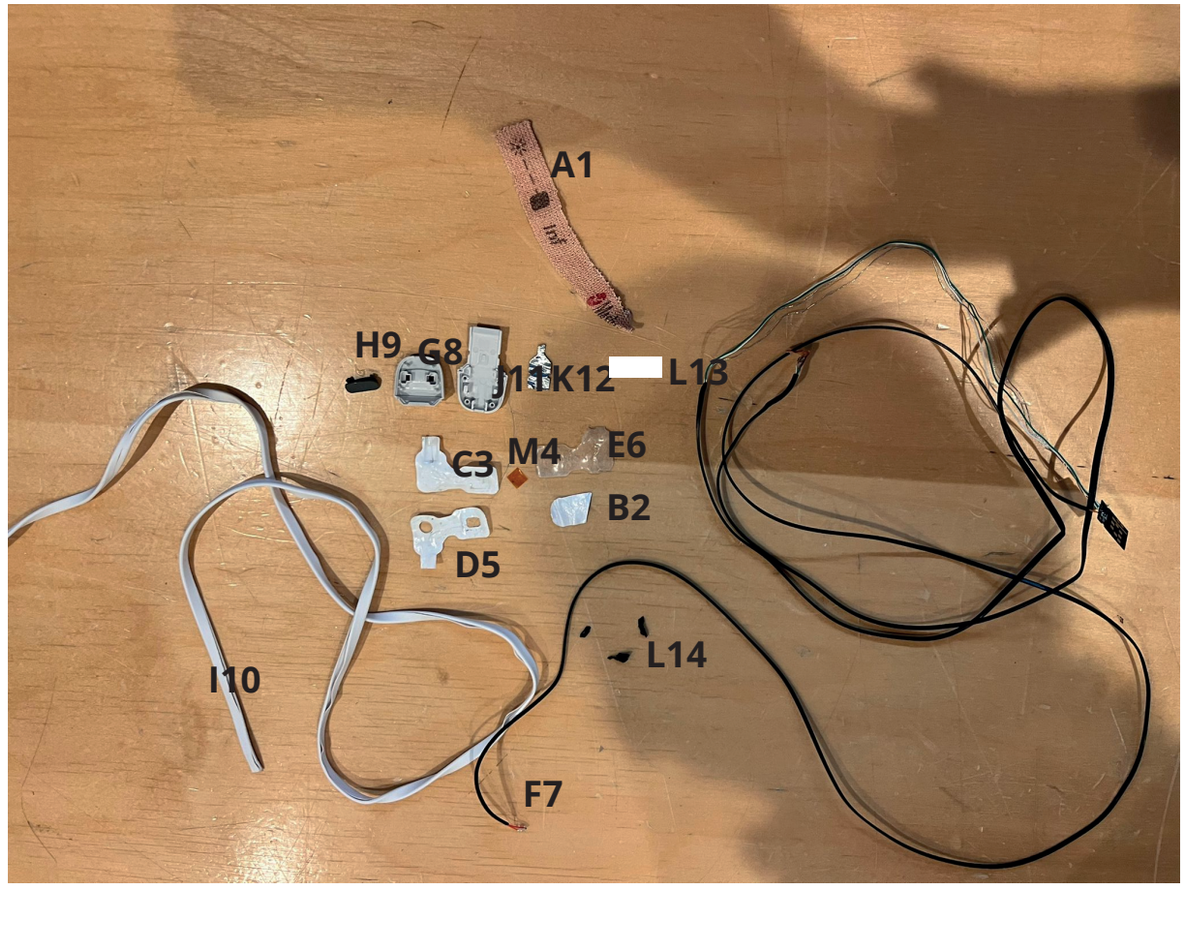
### Target components
= Failure indicator

### Penalties
= Product manipulation
= Non-reusable connector

**Disassembly action**

| Force intensity | Fastener type | Tool | Action block representation |
|---|---|---|---|
| Force < 5N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |
| 5N < Force < 20N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |




## Type of tool

(H) = Hand
(PI) = Pliers

## Target components

= Failure indicator

## Connectors

S.F. = Snap Fit
F.F. = Friction Fit
P.A.J. = Peelable adhesive joint

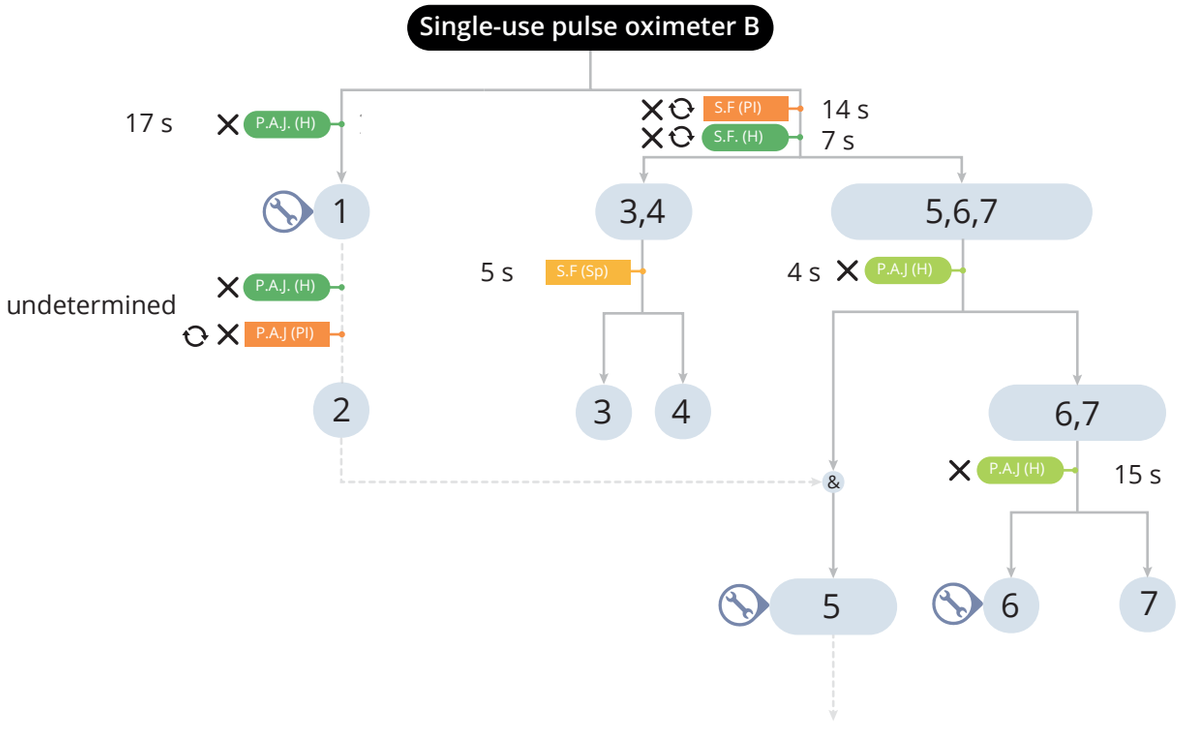
## Penalties

= Product manipulation

= Non-reusable connector

**Disassembly action**

| Force intensity | Fastener type | Tool | Action block representation |
|---|---|---|---|
| Force < 5N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |
| 5N < Force < 20N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |




Part 5 is not fully deconstructed to its electronics, as disassembly was unsuccesful.


## Type of tool

(H) = Hand
(PI) = Pliers

## Target components

= Failure indicator

## Connectors

S.F. = Snap Fit
F.F. = Friction Fit
P.A.J. = Peelable adhesive joint

## Penalties

= Product manipulation

= Non-reusable connector

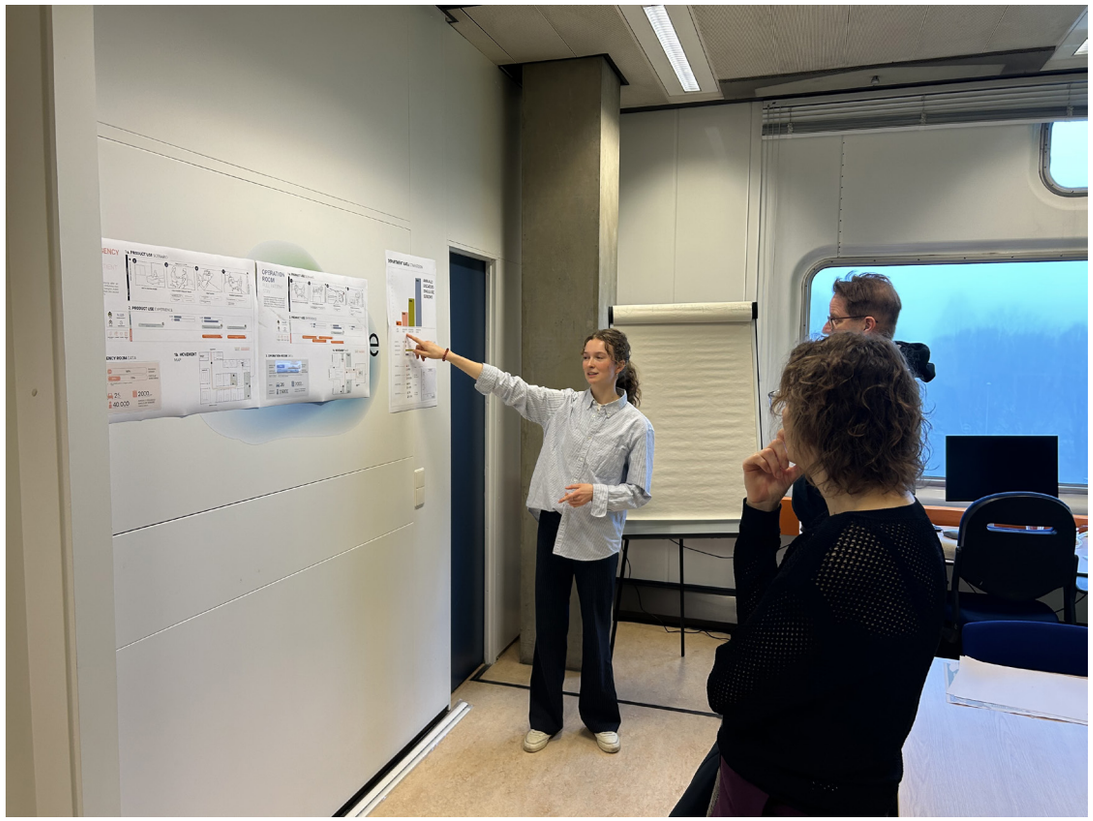
**Disassembly action**

| Force intensity | Fastener type | Tool | Action block representation |
|---|---|---|---|
| Force < 5N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |
| 5N < Force < 20N | Snap fit | Hand | |
| | | Spudger | |
| | Friction fit | Hand | |
| | | Spudger | |

# D / INTERACTION AND DATA MAPS

The following maps were used during a meeting with HCPs and the graduation committee to communicate the problem, and validate my insights.

The meeting was lead by me and started by running through these different user context as well as the data, and finalized by talking about some key insights. During the meeting mistakes were corrected by HCPs and a short brainstorm about solution direction was opened.



# **DEPARTMENT DATA** COMPARISON

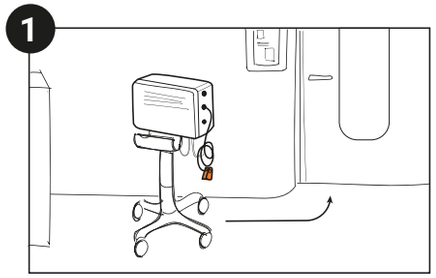
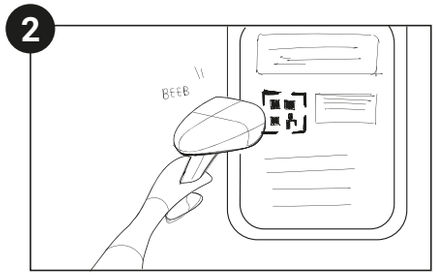
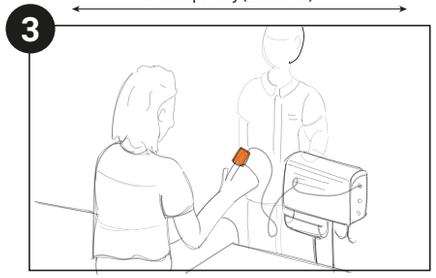
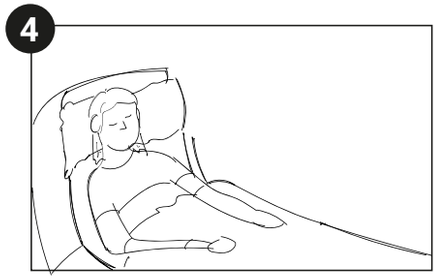
# PULMONARY CLINIC A
## INTERMITTED MONITORING

*95% of pulmonary clinic patients gets monitored through intermitted monitoring, getting checked 1 to 3 times daily. This process is visualised here.*

## 1a. **PRODUCT USE** SCENARIO

PHASES / ACTIONS

1-3 times per day (2 minutes)

| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
|  |  |  |  | NURSE CLEANS MONITOR AFTER PATIENT DISMISSAL |
| ROLL CHECKUP POLE TO PATIENT ROOM | SCAN PATIENT ID | CHECK PATIENT VITAL SIGNS | CONTINUES TREATMENT DAY | |
| A.Log into pole using Erasmus microsection number | A.Scan patient ID on room door or patient wristband | A. Attach blood **pulse oximeter clip, blood pressure** cuff and take **temperature**<br>B. Check if patient SpO2 is represenatative<br>C. Remove sensor<br>D. Roll checkup pole to central hall for next patient checkup | A.Patient data is automatically stored | |

## 2. **PRODUCT USE** EXPERIENCE

NURSE — 0.123 REQUIRED ACCURACY

PATIENT — TIME SENSITIVITY

DEPARTMENT CHANGE · CLEANING · ALARMS · PRODUCT USE

EXPERIENCE

- The checkup pole can take up to a minute to start updistrupting the workflow
- 0.123 (time sensitivity)
- Vital sign checkup can be reassuring for patients

PAIN POINTS

- If finger perfusion is low, finger clip is clipped onto ear : *off label use*
- Pulse oximeter cleaning is frequently skipped

## 3. **PULMONARY CLINIC** INTERMITTED MONITORING DATA

SINGLE USE SENSOR — 0 % — 100% — REUSABLE SENSOR

Reason for reusable: Quick application and removal

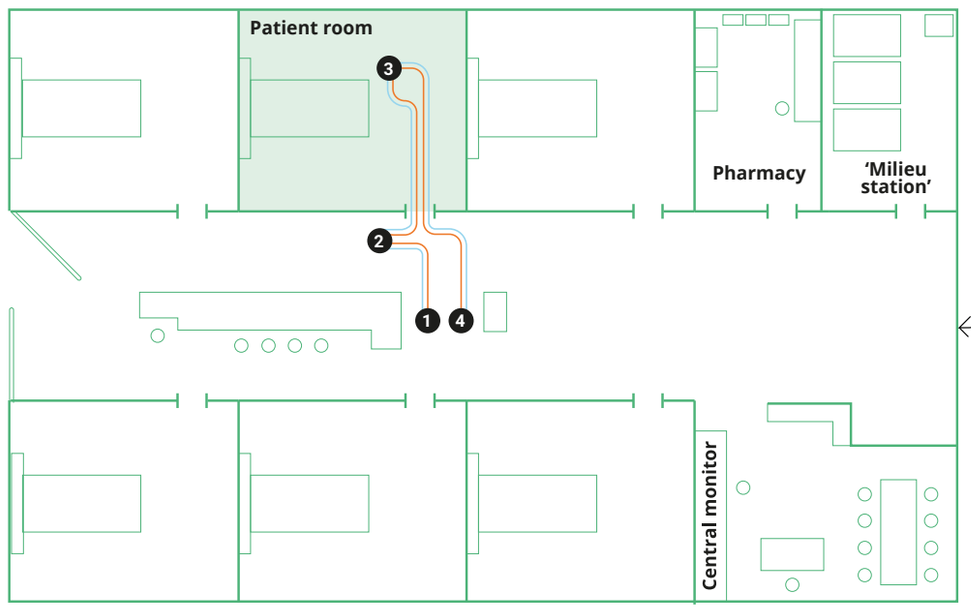
PATIENTS ANNUALLY: 1500

0 pcs — ANNUALLY DISCARDED SINGLE USE SENSORS

## 1b. **MOVEMENT** MAP

NURSE PATH

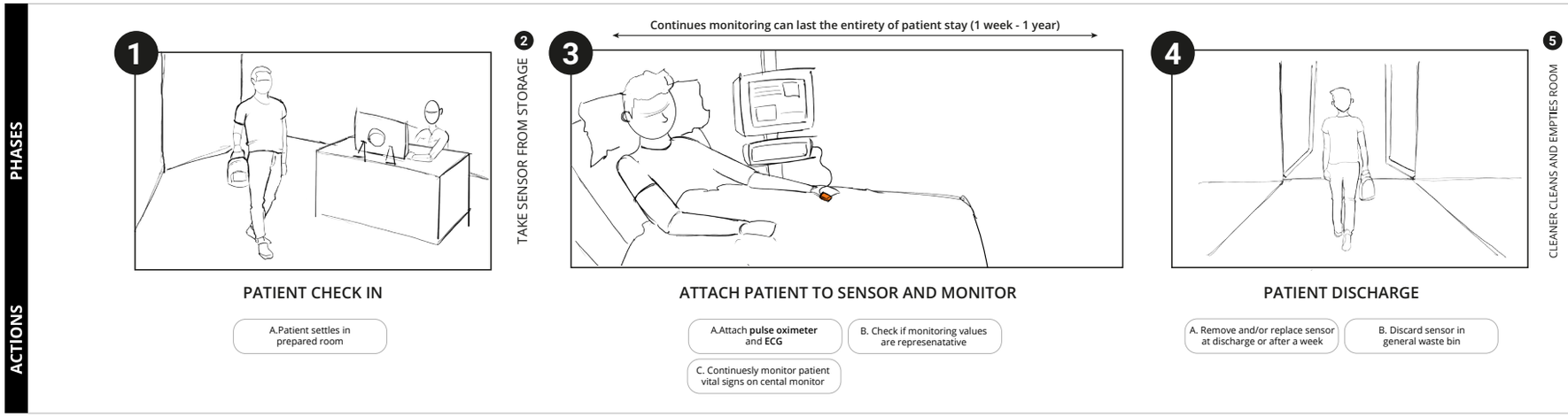
REUSABLE SENSOR PATH



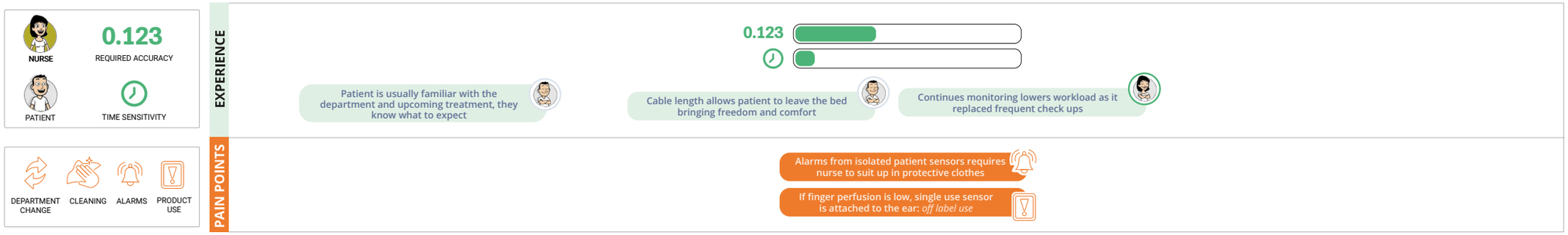
# PULMONARY CLINIC B
## CONTINUOUS MONITORING

*5 to 10% of pulmonary clinic patients gets monitored continuously due to high oxygen administration. This process is visualised here.*

## 1a. **PRODUCT USE** SCENARIO




## 2. **PRODUCT USE** EXPERIENCE




## 3. **PULMONARY CLINIC** CONTINUOUS MONITORING DATA

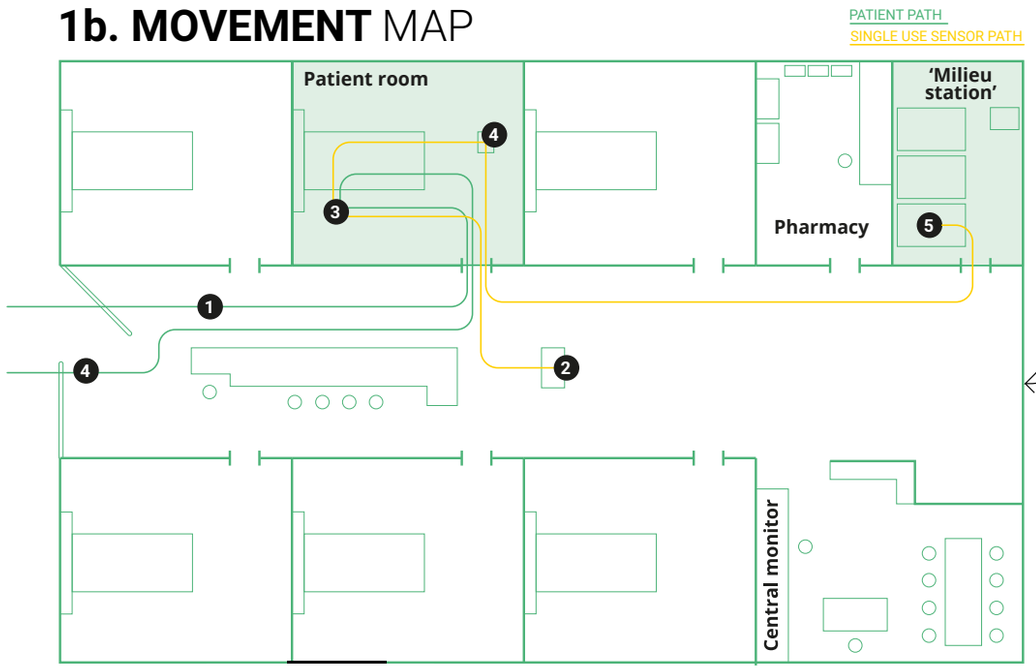
SINGLE USE SENSOR **85%** 15% REUSABLE SENSOR

Reason for single use: Patient comfort: *weight, movement freedom*
Lower risk of nuisance alarms (sensor doesn't move)

PATIENTS ANNUALLY **120**

**600** pcs ANNUALLY DISCARDED SINGLE USE SENSORS

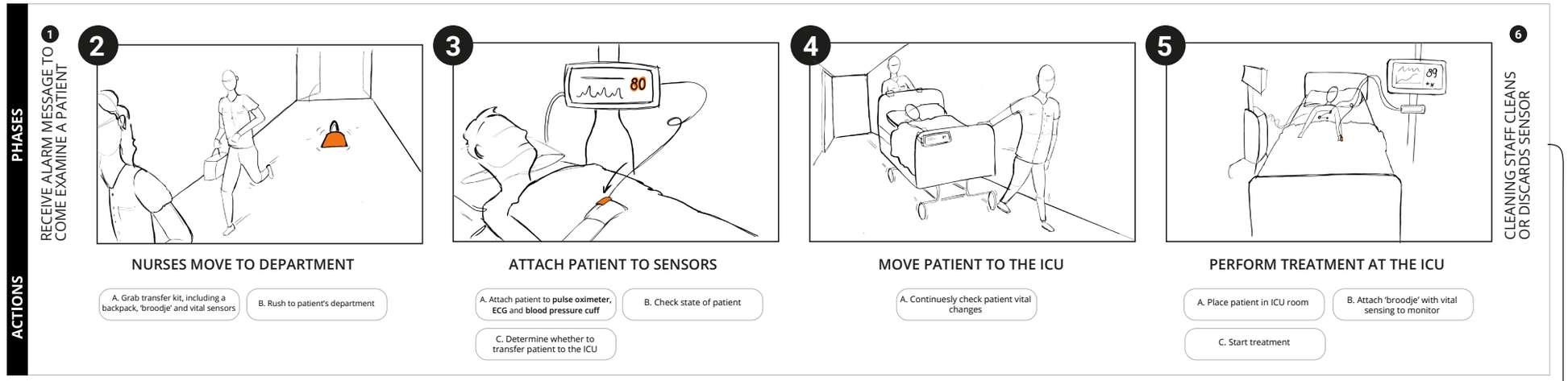
## 1b. **MOVEMENT** MAP



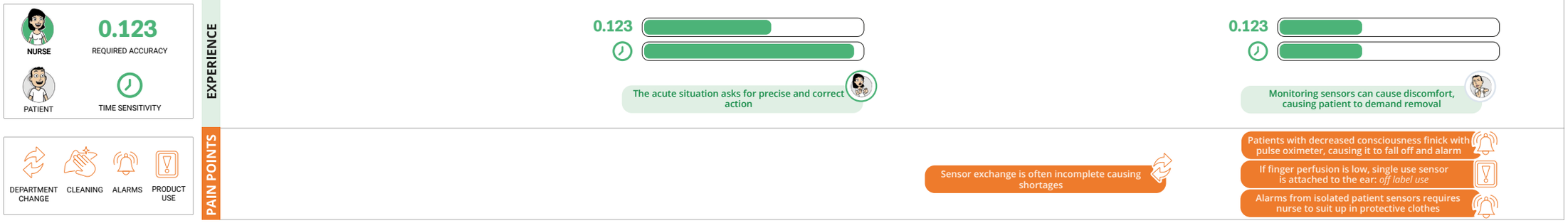
# INTENSIVE CARE UNIT
## PATIENT PICKUP

*ICU patients are always transfered from other departments if patient is in need of more intensive care. This (often) time sensitive transfer is visualised here.*

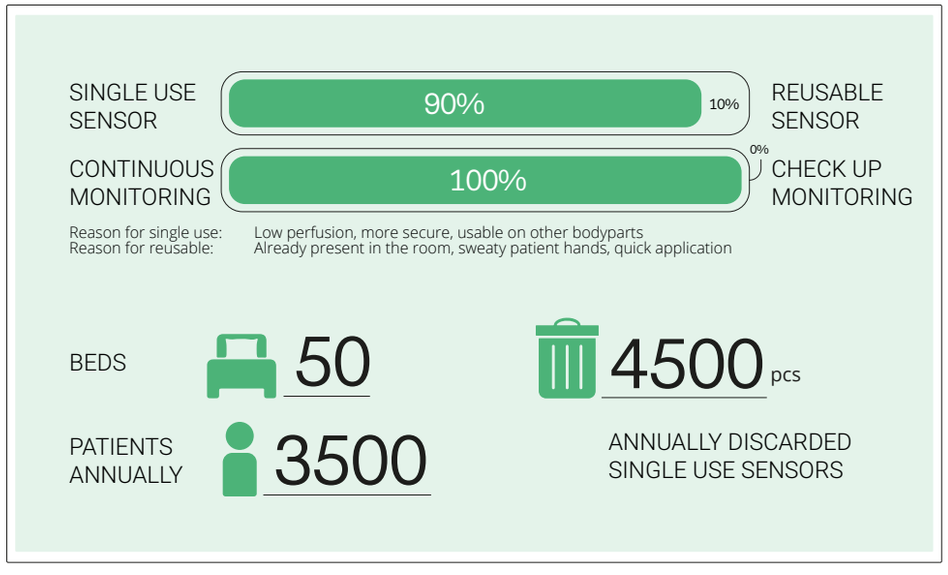
## 1a. **PRODUCT USE** SCENARIO



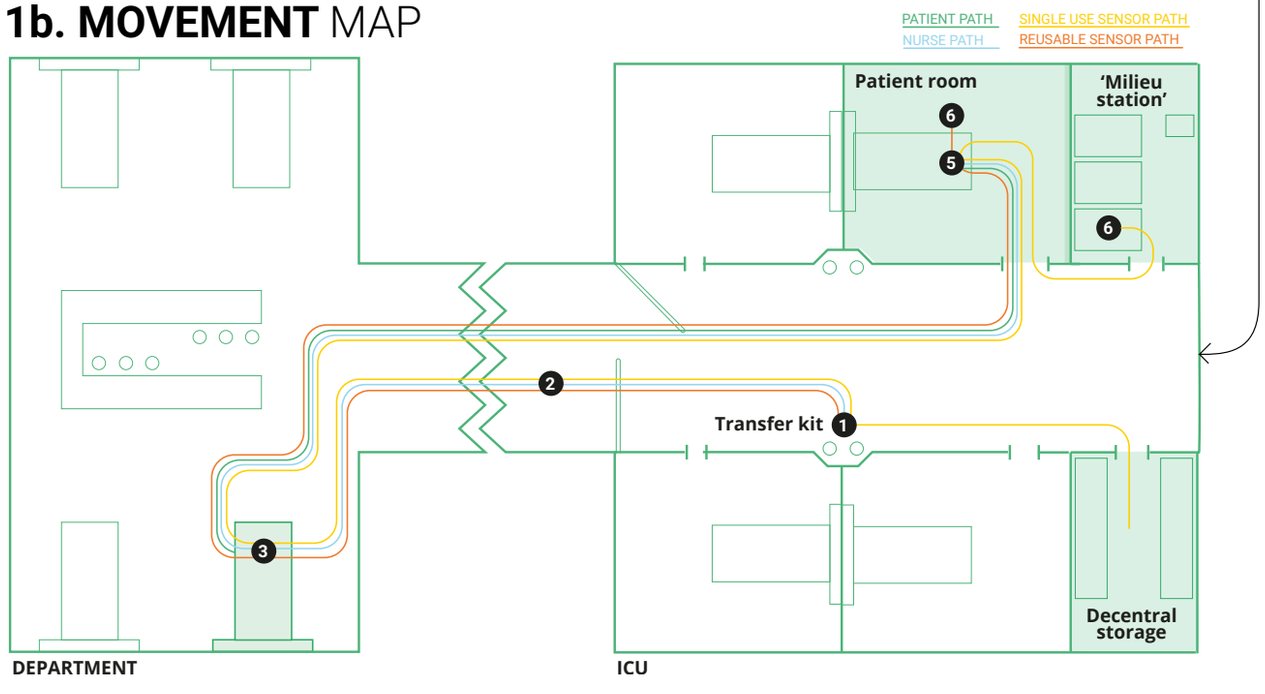

## 2. **PRODUCT USE** EXPERIENCE




## 3. **INTENSIVE CARE UNIT** DATA



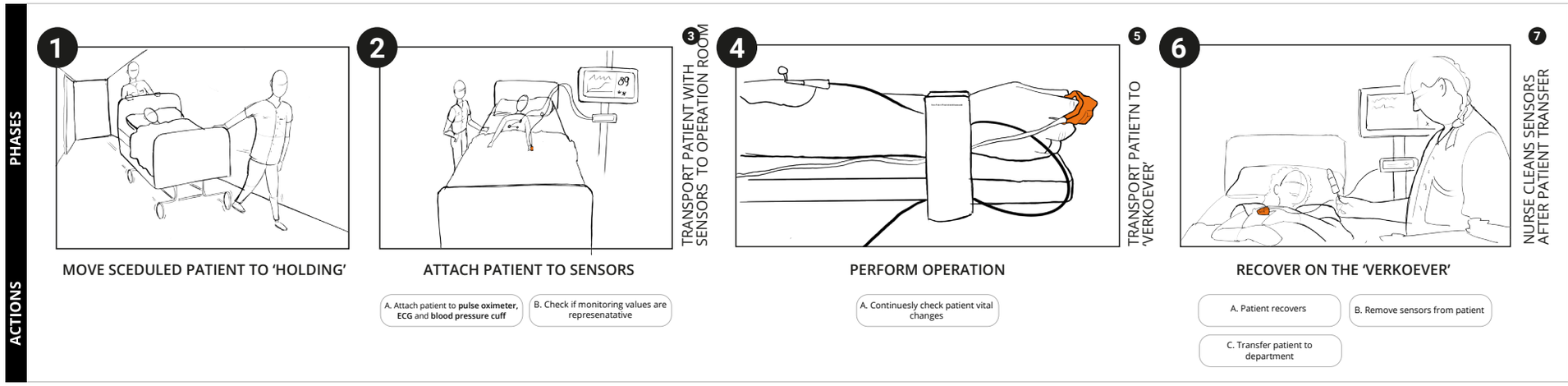

## 1b. **MOVEMENT** MAP



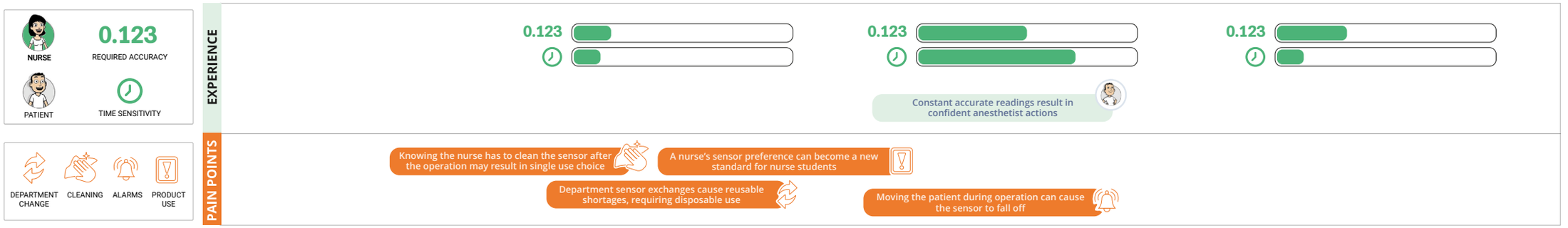
# OPERATING ROOM
## FULL PATIENT STAY

*Most patients undergoing an operation are sceduled in advanced. They are transfered from their department to the OR shortly before intervention, undergo the operation and recover. This process is visualised here.*

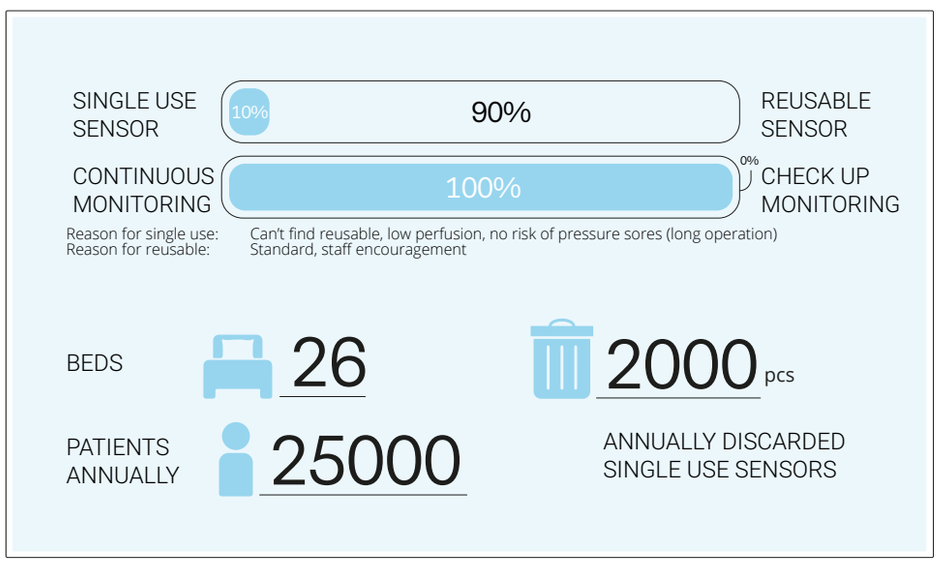
## 1a. **PRODUCT USE** SCENARIO



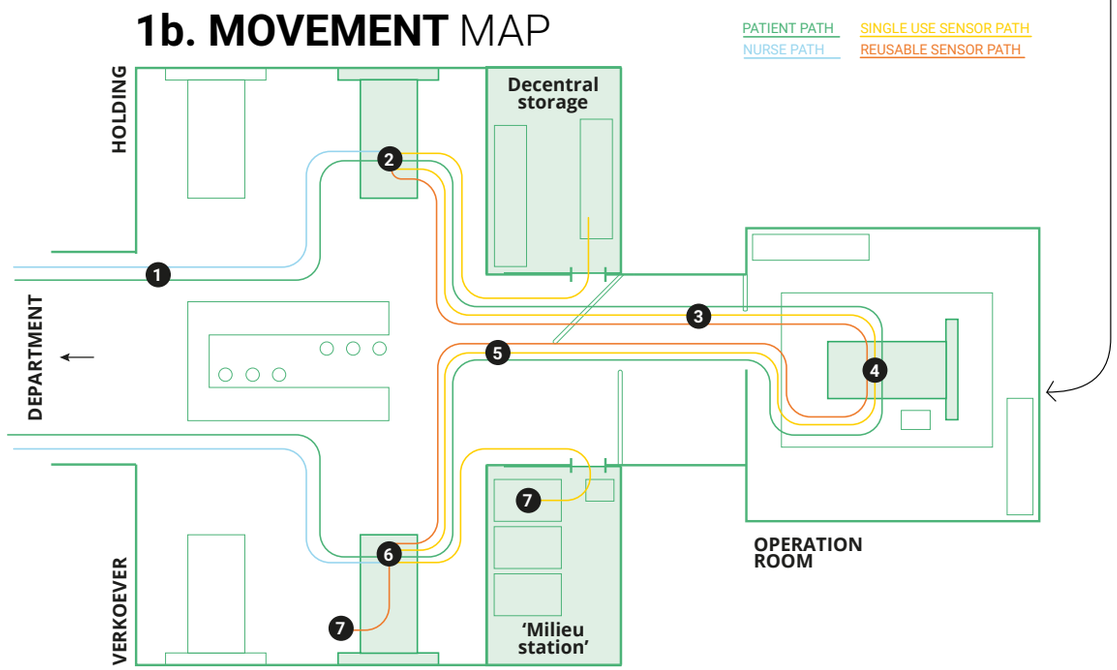

## 2. **PRODUCT USE** EXPERIENCE




## 3. **OPERATION ROOM** DATA



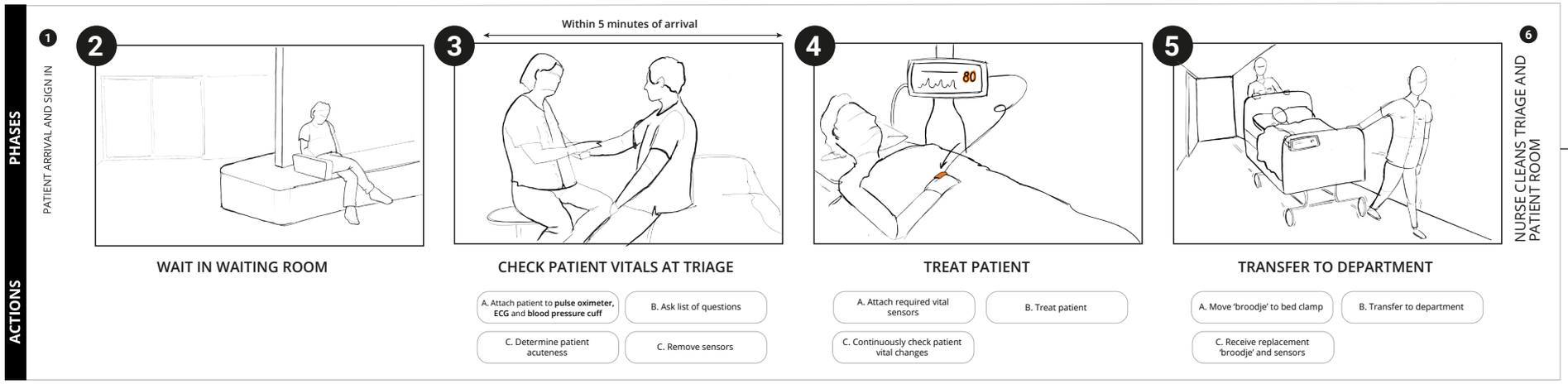

## 1b. **MOVEMENT** MAP



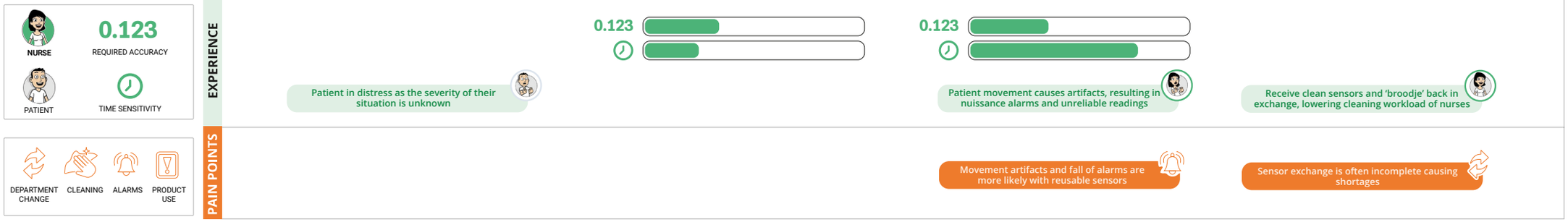
# EMERGENCY ROOM
## FULL PATIENT STAY

*ER patients arrive shortly after an incident. Some arrive by ambulance, most by their own means of transport. A likely patient scenario of from this second group is visualised here.*

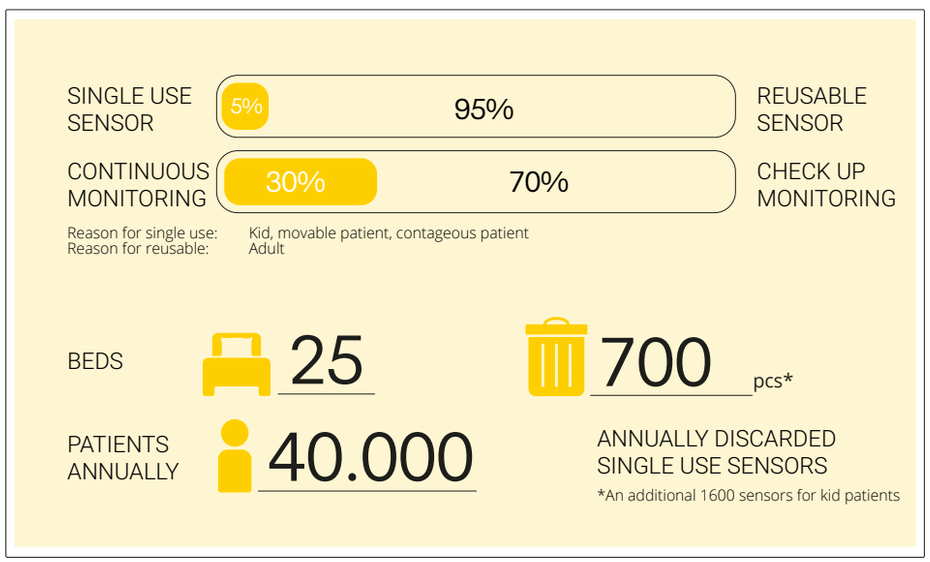
## 1a. **PRODUCT USE** SCENARIO



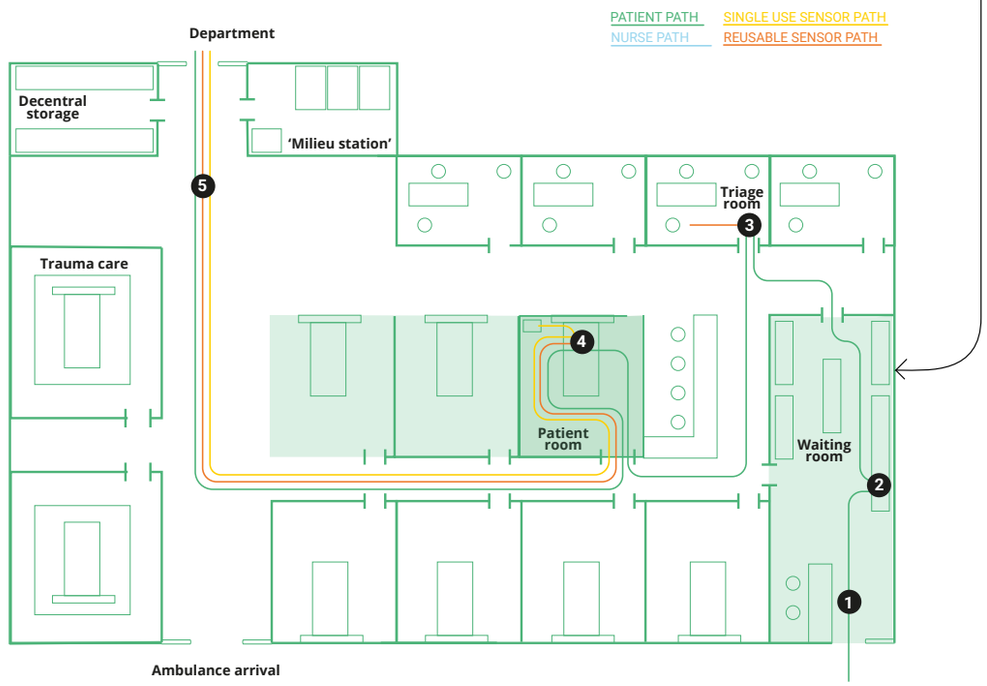

## 2. **PRODUCT USE** EXPERIENCE




## 3. **EMERGENCY ROOM** DATA



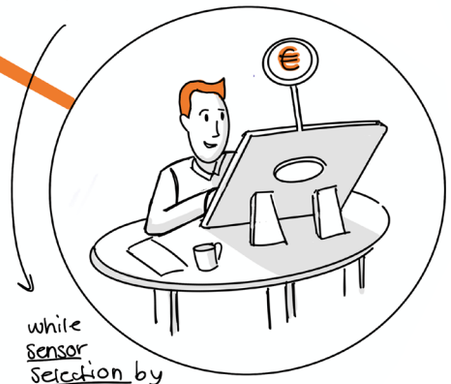

## 1b. **MOVEMENT** MAP



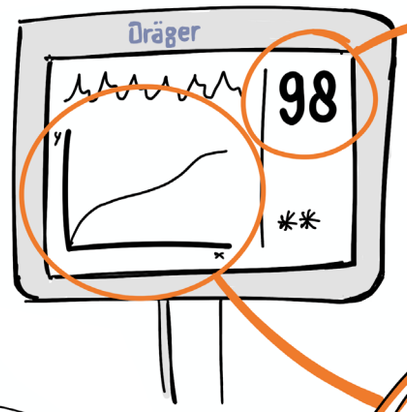
# KEY INSIGHTS


**OFF LABEL USE** can impact the accuracy of measurement data

nurses have low awareness of the impact



while sensor selection by the purchasing department is heavily influenced by accuracy



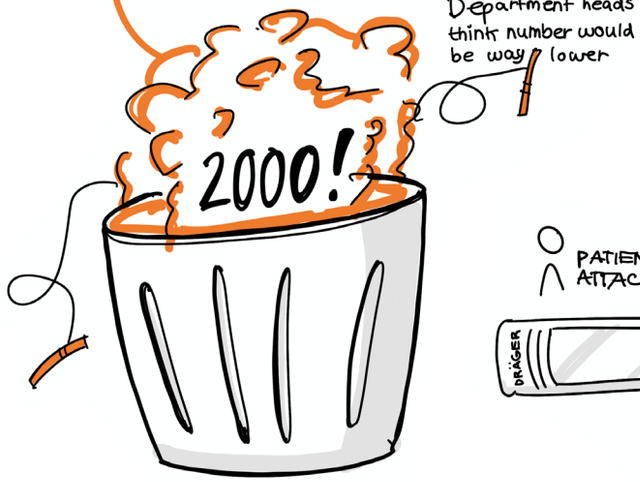

## DATA USE

Value based

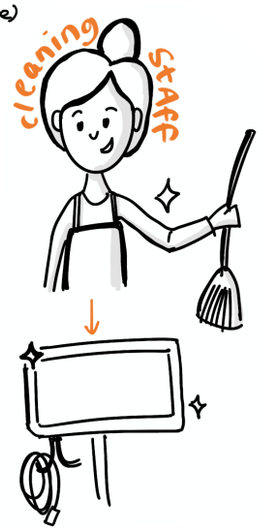
$SpO_2$ data doesn't have to be extremely precise (more about range)

TREND Based changes provoke action

**AWARENESS** about quantity of single use pulse oximeters used is low




Department heads think number would be way lower



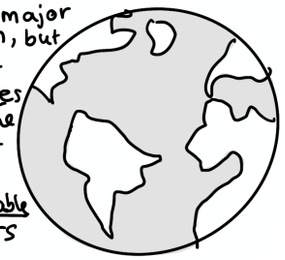


## CLEANING UPKEEP

sensor cleaning is frequently skipped by nurses due to low urgency and time constrains

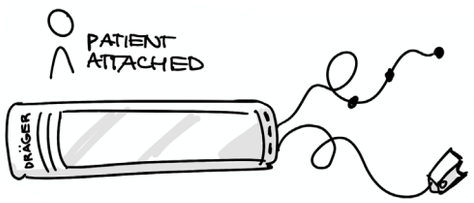
It can also incentivise single use

In Erasmus MC this isn't viewed as a major problem, but for other countries this is the biggest barrier for reusable sensors



## ISOLATED PATIENT ALARMS

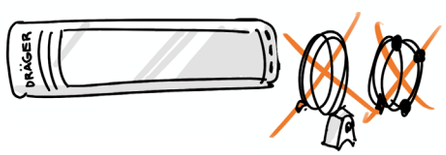
using a reusable sensor can cause more alarms. In isolated patients, having to check the sensor can cause extra trash because of safety wear.




## EXCHANGE PROTOCOL

during department changes products are not always swapped equally.

This can cause shortages of sensors on departments
↳ leading to single use



# E / CREATIVE SESSION

The goal of this creative session is to gain a broad scala of ideas to further develop/integrate into concepts later on. By including more people into the brainstorming process, this will allow more out of the box thinking.

**Who**
The session will be held with 4-6 master design students of the faculty of industrial design engineering. About half of these students are familiar with designing pulse oximeter concepts due to their recently finished 'product now' course. The other half has limited knowledge about pulse oximeters. All designers are familiar with design methods used during this creative session.

**Where**
The creative session will be held at the faculty of industrial design engineering. A private room will be reserved with a big table to seat 6, a screen and wall space to display ideas. As the room is private there will be no limitations to speak freely without disrupting other students.

**When**
The session is planned on 12/02/2025 in the lunch break between 12:00-13:00. The session will last for approximately an hour.

## E.1 Idea generation (30 min)

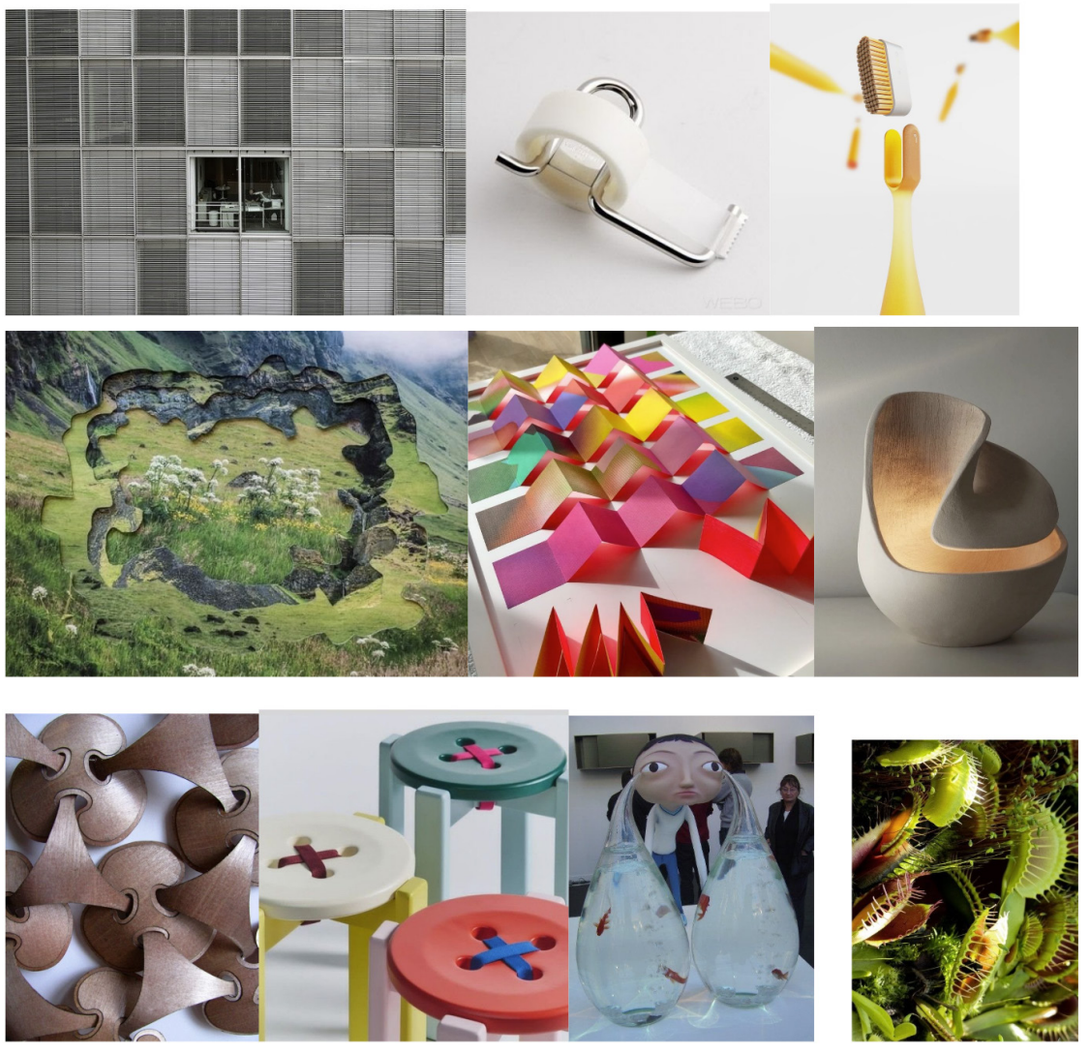
**Method 1: Association (10 min)**
Ideating through association is a design technique that I personally enjoy driving designers to think beyond things they already know. It will take place as follows.

A brief introduction about pulse oximeters is given, showing the current products and expressing why they need to be secured on the fingertip.

1. The participants are all instructed to ideate on the same questions
   How can you secure something on the fingertip?
2. The participants receive a new plank page.
3. On the screen a powerpoint is visible showing random pictures.

These pictures were generated using a random picture generation website: https://randomwordgenerator.com/picture.php.The chosen pictures were selected to reflect a broad range of themes avoiding visuals of hands.

4. The participants view the picture and get 1 minutes to sketch an idea based on that picture.
5. Afterwards the next picture is shown, this is repeated for 10 pictures



**Method 1: How Can You (10 min)**
A 'How Can You?' Better known as a HKJ is a well known early idea generation method. This will take place as follows.

1. Participants sit around a table
2. Participants each receive an A3 paper with a How Can You question written in the centre of the page. The questions are the following:

- How can you secure something on the fingertip?
- How can you easily apply a product to the fingertip?
- How can you make a product fit different fingertip sizes? x2
- How can you easily clean a pulse oximeter?
- How can you convey product trustworthiness?

3. A timer is set for 2 minutes. The participants start ideating all of the possible answers to the question writing and sketching ideas.
4. After two minutes the pages rotate to the next person.
5. This is repeated until everyone has ideated on every page.

**Discussion (8 min)**
A short discussion moment is implemented for people to share their thoughts on interesting ideas that came up during the HKJ or Association brainstorm. All idea sheets are hung up on the wall and every participant shares (at least) one idea that intrigued them.

## E.2 Concept idea generation (30 min)

**Teamed up ideation (20 min)**
The second phase of the creative session is more focussed on the pulse oximeter, adding in a few more requirements. Participants are shown the current versions of pulse oximeters highlighting two elements, the techpack, including the size and preferred position of the light and detector, and the wire it is attached to. With these essential elements in mind the concept idea development can start. It will take place as follows.

1. Participants are teamed up in groups of 2 or 3.
2. Participants are provided with sketches of hands to draw on top of as well as more blank paper.
3. Participants choose 1-2 ideas (or combined ideas) to draw up into a pulse oximeter concept ideas, taking the wire and techpack into account.
4. Teams have the possibility to try out designs in low-fi prototypes using materials like cardboard, paper and tape.

**Present idea (6 min)**
Every team gets 2 minutes to present their final idea(s) to the group. This finalizes the creative session.

**Wrap up (4 min)**
Thank everyone for their participation.

## E.3 Results

The most important findings were:

<u>Security through contact</u>
Though the current finger sleeve is relatively secure, it does not feel secure as it doesn't have enough contact with the finger area. Therefore, a feeling of more security can be encouraged by increasing the contact surface of the product to the finger

<u>Reusable disposable hybrid risk</u>
A combination of a reusable and disposable part is possible, but might result in a higher likelihood of nurses throwing out the entire product (also the reusable part). This can be discourages through material choice, informative icons etc. A counterargument for this, is that observations in the Erasmus MC have shown that single-use products are frequently stored and reused like reusables.

<u>Study of sex toys</u>
A possible exploration area of sex toys was proposed, as these often have similar material types and sizing mechanisms. A study will be performed to encourage ideation.

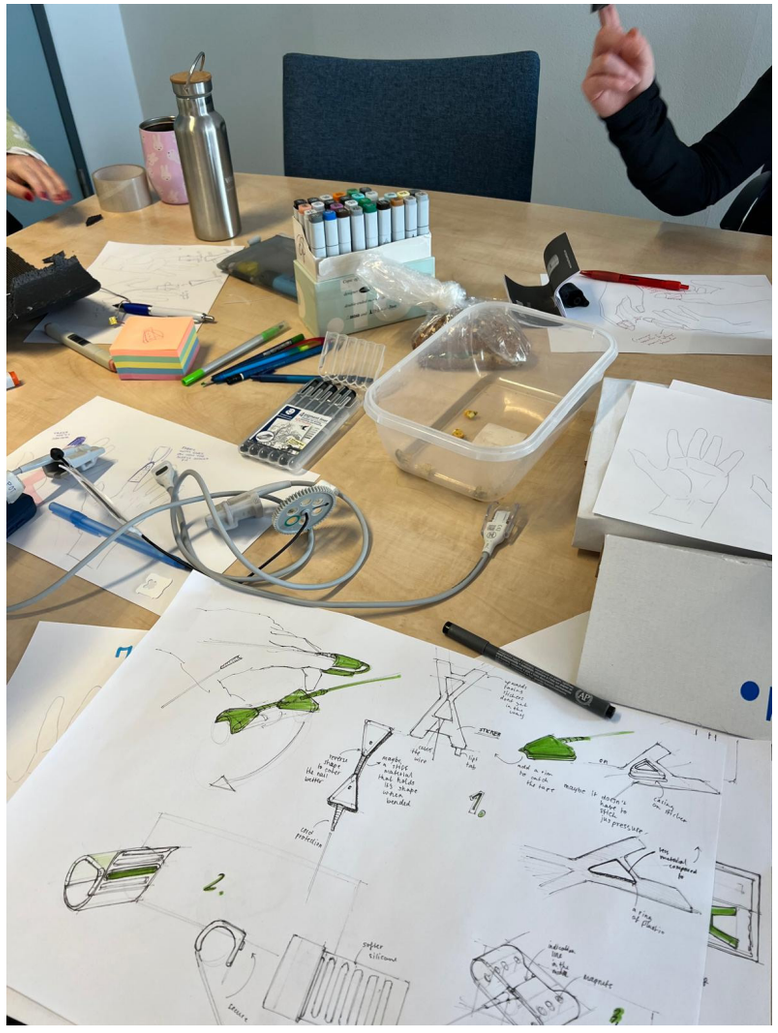
## E.3 Reflection

The creative session on redesigning the pulse oximeter, was insightful and valuable. One of the most positive aspects was the enthusiasm of my fellow students. People were excited to participate, experimenting with materials and contributing ideas. This session was also a great learning opportunity for me, as I often work individually and hesitate to involve fellow students in my design process due to a sense of vulnerability. However, it was encouraging to see how eager everyone was to help and collaborate.

At the beginning, I took on the role of a moderator, managing time, slides, and introductions. As the session progressed, I transitioned into a participant, engaging more actively in discussions. I think this shift created a good balance, starting with structure but later creating a more collaborative, team-like atmosphere.

However, there were also challenges. Many students had prior knowledge of the topic, which seemed to limit their ability to think outside the box. Their awareness of existing requirements made them more cautious in their ideation. As a result, many of the ideas generated were similar to ones I had already considered, so they did not significantly expand my perspective. That said, the most interesting concepts emerged when we engaged in open discussions, rather than strictly following the HKJ technique.

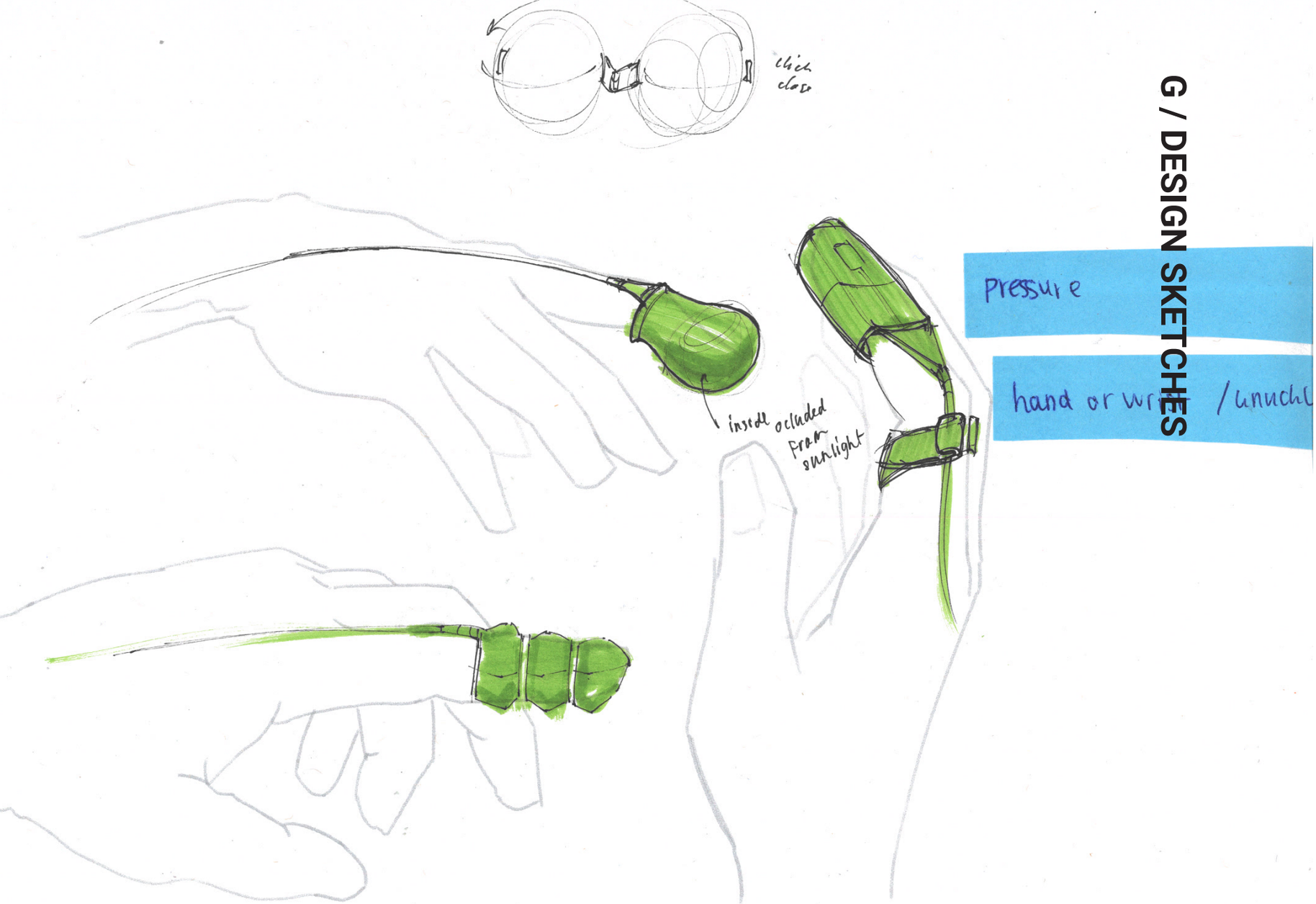
In the future, I would adjust the approach by introducing existing ideas upfront and encouraging participants to modify and expand upon them through discussion and sketching. This might lead to more innovative outcomes and a more dynamic exchange of ideas.

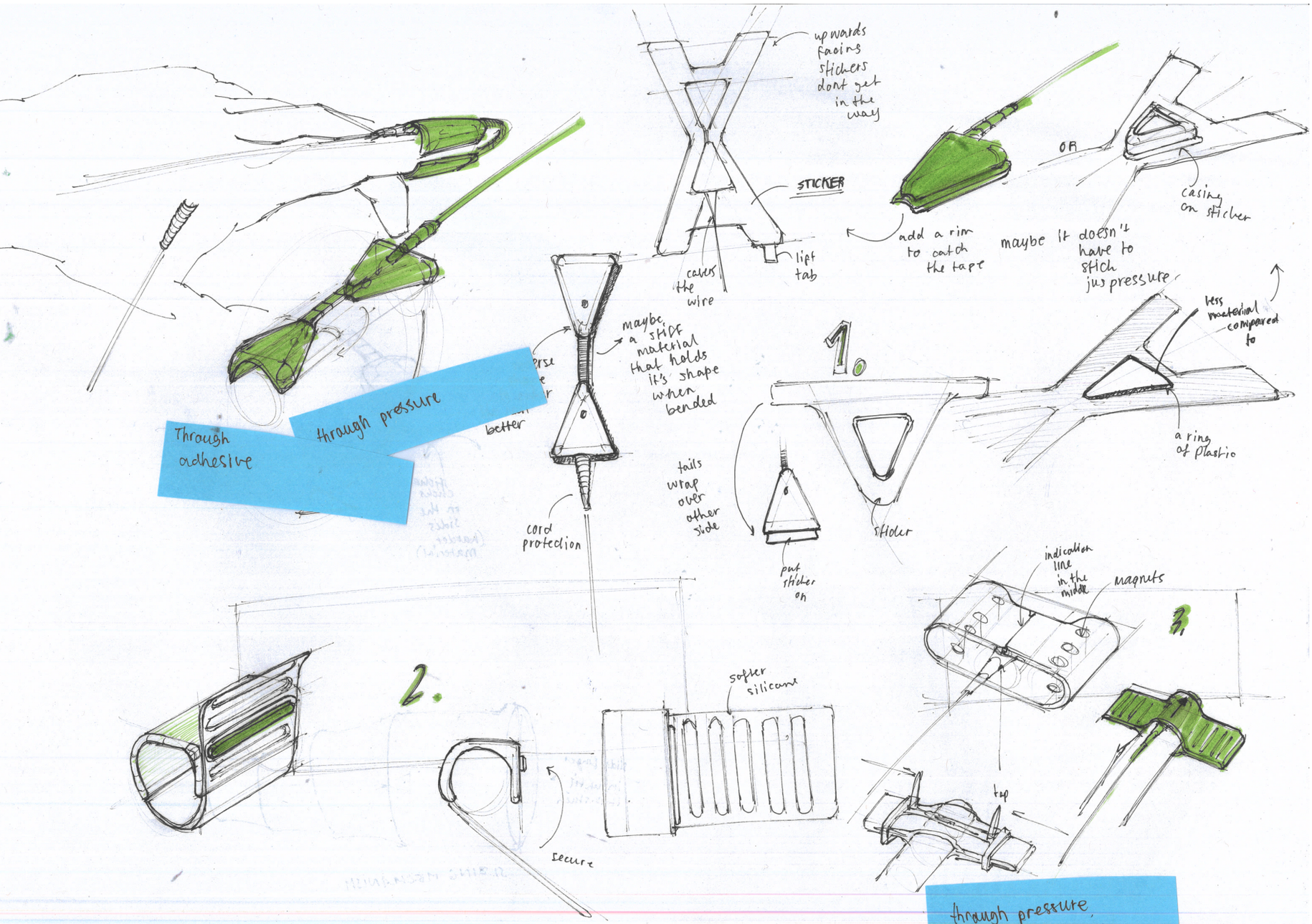


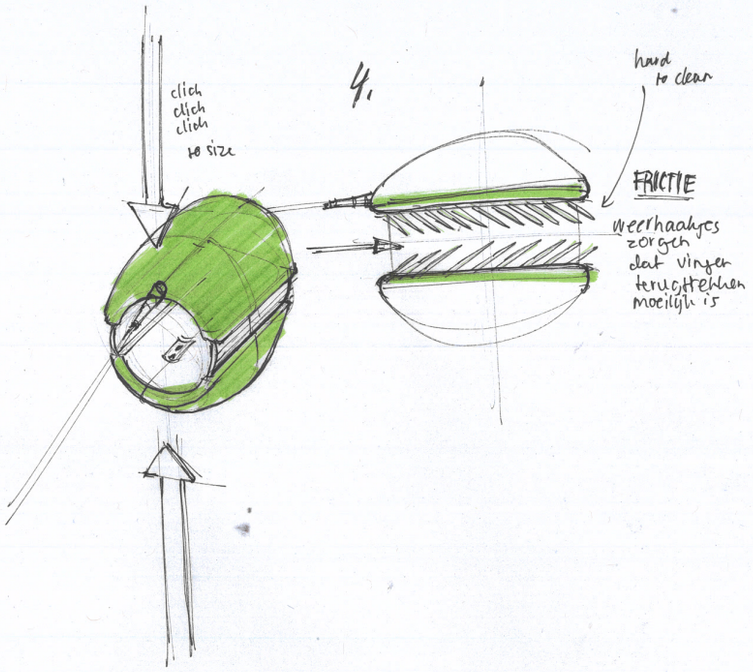
# F / REQUIREMENTS

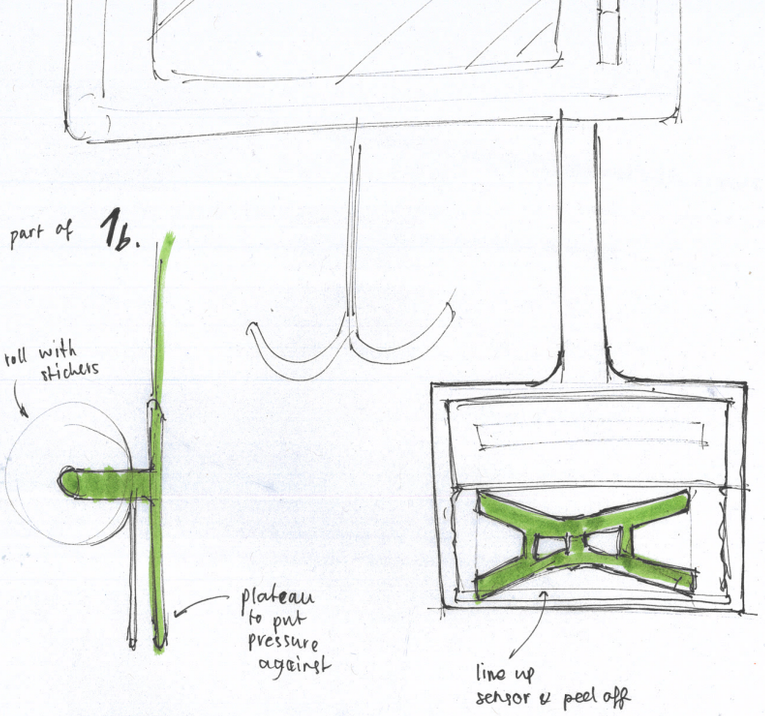
| Category | ID | Requirement | Extra description | Requested by |
|---|---|---|---|---|
| | 1 | System | | |
| Product implementation | S1.1 | Awareness on new product use should be instructed to all nurses over email and posters. | | Nurses Erasmus MC (User test 1) |
| Logistics | S1.2 | The product logisics fits in the sophisticated logisitics system at Erasmus MC | | |
| Logistics | S1.3 | Product is storable in non-sterile central storage unit and drawers | | |
| Logistics | S1.4 | Single-use components should be stored close to the patient's bed | | |
| Product failure | S1.5 | The product is testable using the FLUKE prosim 8 | | MIT EMC |
| Waste handling | S1.6 | No additional waste seperations bins are needed in patient rooms | | As expressed by nurses |
| Usability | S1.7 | The sensor and all its functionalities can be used with monitors from other brands | | requirement in a Tender |
| | | **Product** | | |
| | 2 | **Reusable base** | | |
| Price | R2.1 | The Reusable base costs €30 or less to manufacture | | |
| Fit | R2.2 | The sensor must be used on the 3 middle fingers | | Philips |
| Fit | R2.3 | Sensor has to give access to the fysiological surgical sights | | |
| Fit | R2.4 | Sensor allows finger sizes varying between 14 mm and 20 mm breadth (mm) | 5%-95% of Dutch adults between 20-60 years old (Dined 2004) | |
| Fit | R2.5 | The product has one adult size | | |
| Fit | R2.6 | The material volume on the bottom side of the finger should be minimized. | To increase hand useage freedom of the patient | User test 1 |
| Fit | R2.7 | The detector and infrared light are aligned vertically on the top and buttom of the finger | | |
| Fit | R2.8 | The contact surface between the product and the skin is flush | To safeguard patient comfort and prevent pressure sores | |
| Appearance | R2.9 | The reusable component cannot be white as the main color. | White is associated with single use sensors | User test 1 |
| Appearance | R2.10 | The top and bottom component are assymetrical to avoid confusion about orientation | During the test some people put the product upside down. | User test 1 |
| Appearance | R2.11 | The sensor design communicates technical sophistication, comfort and safety | | |
| Appearance | R2.12 | Any material around the light source or detector has to be black | Avoid light reflection | Steve Philips |
| Usability | R2.13 | The reusable component can be removed while leaving the sticker secured to the finger | This allows patients to remove the sensor when going to the bathroom | User test 1 |
| Usability | R2.14 | The adhesive side of the sticker may not touch the reusable component | As this would require nurses to peel this tape before sensor removal, increasing the risk of the sensor being thrown out with the single use component. | User test 1 |
| Usability | R2.15 | The reusable base can be attached to the patient with one hand | This is a measure of simplicity | |
| Usability | R2.16 | The cable module can only be disassembled by MT staff, and does not come loose by accident | | |
| Cleaning | R2.17 | Cleaning should take the same amount of time or shorter than 70 seconds | The current reusable sensor takes approximately 70 seconds to clean. The new sensor can not take longer. | Student |
| Cleaning | R2.18 | The reusable base avoids dirt collecting ridges for the connection with the patch | | |
| Cleaning & Materials | R2.19 | Sensor materials can withstand water, 250 ppm, 1000 ppm cholide solutions and 70% alcohol without breakdown | Flueds used for decontamination in the Erasmus MC protocol | Erasmus MC |
| Cleaning & Materials | R2.20 | Color of the sensor does not fade to yellow when exposed to contaminates and cleaning agents | heat, sunlight, age, bleach, ammonia, hydrogen peroxide, stool, blood, bile, bodily fluids | Philips |
| Cleaning | R2.21 | The sensor should have as high of an IPX rating as possible | | Philips |
| Manufacturing | R2.22 | No use of Latex, RoHS or REACH materials | | Philips |
| Manufacturing | R2.23 | Reusable element has to be producable in quantities of 20.000 yearly | | |
| Electronics | R2.24 | The electronics should be heavily shielded and withstand defibrillation | | Philips |
| Electronics | R2.25 | Electronics cannot fry the monitor | | Philips |
| Electronics | R2.26 | Sensor cable length is at least 3 m | This allows the patient to move out of the bed, letting the cable reach comfortably across the bed | Pulmonary clinic |
| Electronics | R2.27 | Sensor connection is universal between single and reusable sensors | | Erasmus MC |
| Electronics | R2.28 | The electronics have 9 connection pins | 7 for oxipulse sensing 2 for EEPROM encoding | |
| Electronics | R2.29 | The cable is a removable component | To extend product lifespan the cable can be replaced and sent to recycling | |
| Electronics | R2.30 | *The cable can be secured for testing without full screw attachment* | So you can quickly test whether the cable is the problem | |
| Strength | R2.31 | The product can be able to withstand to be run over by a 400 kg hospital bed | | Philips |
| | 3 | **Single-use patch** | | |
| Price | SP3.1 | The Single-use patch costs €0,10 or less to manufacturing | | Steve Philips 21_02_2024 |
| Usability | Sp3.2 | The adhesive peeling time should be limited to 2 seconds | Similar to the current adhesive peeling time of the single use Masimo Adt sensor | User test 1 |
| Usability | SP3.3 | Adhesive components should be designed to avoid sticking together during and after backing peeling | | User test 1 |
| Usability | SP3.4 | The sticker can be applied to the finger before adding on the reusabel component | This was most intuitive and helpen align the sensor properly | User test 1 |
| Usability | SP3.5 | The design of the patch informs proper aligment | | |
| Usability | SP3.6 | The design of the patch shows what side is the top and which is the bottom | | |
| Technical functioning | SP3.7 | No material may ubstruct the light path beside the finger | | Steve Philips |
| Manufacturing | SP3.8 | Disposable element has to be producable in quantities of 1.800.000 yearly | 1% of global market of disposable pulse oximeters | Steve Philips |
| | 4 | **Traceability** | | |
| Price | T4.1 | The increase in sensor price to accomodate traceability, should not lower purchase attractiveness | | |
| Data | T4.2 | Centralized cleaning cycles should be able to be registered to the pulse oximeter | | |
| Data | T4.3 | Last use location of the pulse oximeters within the hospital should be identifiable digitally by hospital personel | Who should have access to this data? MIT? | |
| Data | T4.4 | Product lifespan should be identifiable by the Medical Technology department to determine coverage by manufacturer warrenty | | MIT |
| Data | T4.5 | Lifespan of sensors at end-of-life should be known to Philips to identify product improvements | During business models like product-as-a-service, extention of end-of-life is in favour of the manufacturer. Reasons for end-of-life are therefore important to identify | |
| Data | T4.6 | The sensor tracks utilization time and frequency | | |
| Data | T4.7 | The sensor tracks maintenance records | | |
| Data | T4.8 | The sensor tracks part cable repair | | |
| Usability | T4.9 | The tracking of utilization time and frequency and last use location can not be obstructed by user error | | |

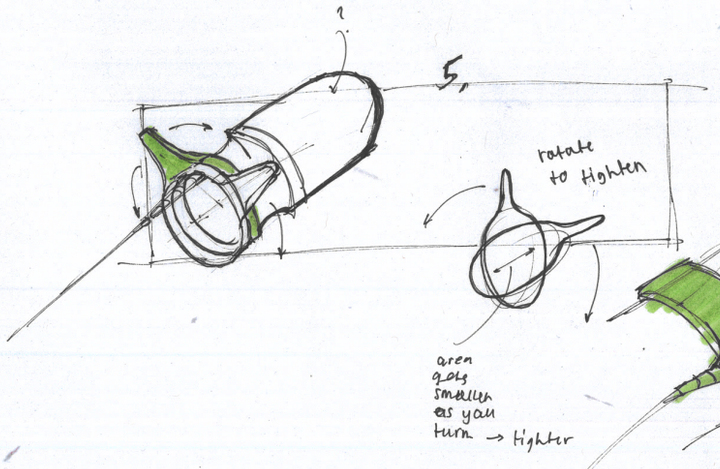
# G / DESIGN SKETCHES

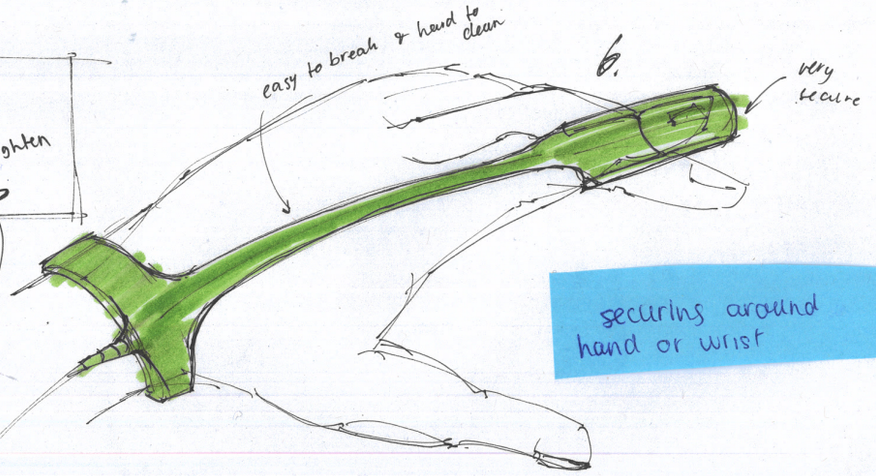


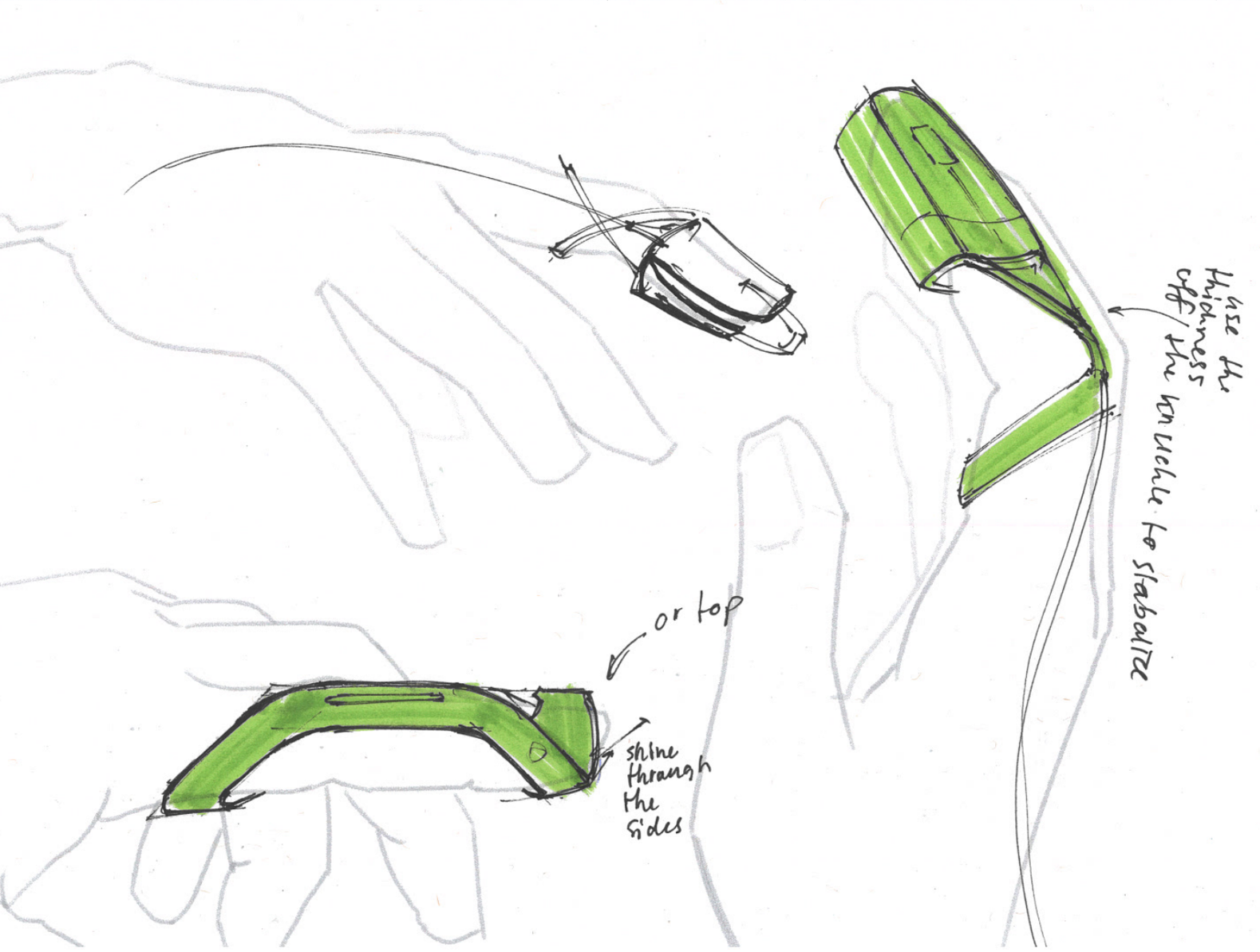




4.
click
click
click
to size
hard to clean
FRICTIE
weerhaakjes zorgen dat vinger terugtrekken moeilijk is


part of 1b.
roll with stickers
plateau to put pressure against
line up sensor & peel off


5.
rotate to tighten
open gets smaller as you turn → tighter


6.
easy to break & hard to clean
very secure
securing around hand or wrist


use the thickness of the velcro to stabalize
or top
shine through the sides

# TO TEST

THROUGH PRESSURE

?

THROUGH ADHESION

hard ring

stiffer

stiffer overwrap

PLAT

THROUGH WRIST OR KNUCKLE SUPPORT

tighter around lower finger

UNDER KNUCKLE

or bendable area

stiffer underwrap

stiff

peel off

around the wrist

magnets or nubs?

nubs pair into rim on bigger fingers

- loose components

A

first add ring around finger than roll forward over clip ring

B.

twist to tighten

- collects dirt in grooves

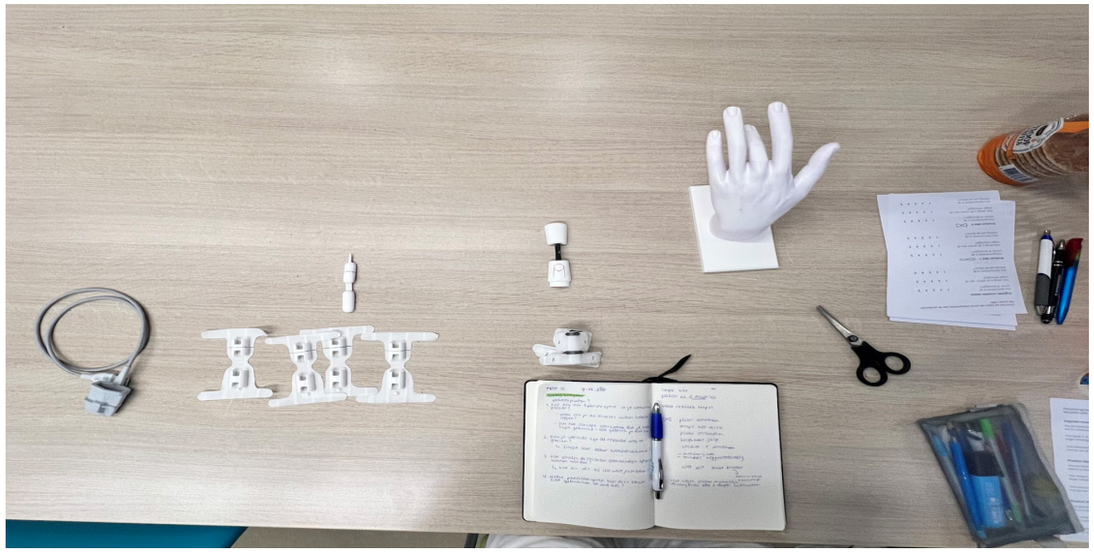
- Big overhang

# H / PROTOTYPE TEST

## H.1 Test plan

**Objective of the Test**
The goal of this test is to gain insight into the user experience and perception of nurses regarding three concepts. The focus is on intuitive usability, sense of security and reliability.

**Test Setup**
- Participants: Healthcare professionals of the ICU and pulmonary clinic department. Most of which are nurses, two doctors and a doctor in training.
- Number of concept ideas: 2 Test, comparing to current reusable finger sleeve
- Method: Hands-on test with think-aloud protocol and ranking scales survey
- Location: On the departments
- Duration per participant: approx. 10 minutes



**Test Setup**
Introduction
- Brief explanation of the test objective and expected duration.
- Clarification that we are testing the concepts, not the participants.
- Encouragement to think aloud while performing tasks.

Hands-on test of concept ideas
- The participant receives the concept and performs the tasks:
    - Applying
    - Removing
- Observation: Note reactions, difficulties, and spontaneous feedback.
- Taking notes on intuitive use, moments of hesitation, and frustrations.
- The following figure shows a picture of the test setup

**Ranking scales survey**
After each concept, the participant completes a short survey with a ranking (on a scale of 1-5) (see below) for:
1. Ease of applying
2. Feeling of security
3. Trustworthiness

Conclusion and Open Feedback
1. What was the most intuitive?
2. Would a hybrid (single and reuse combined) concept fit your workflow?
    - Would you need less additional tape?
    - Would you be tempted to throw out the reusable component?
3. Are there any improvement points or suggestions?
4. What patient (groups) would not be able to use this device?
5. How can these sticker conveniently be stored in the patient room?

**Processing the Results**
- Analyze and compare ranking scale scores between concepts.
- Summarize qualitative feedback and observations.
- Identify patterns and pain points to support further iteration of the concepts.

Omcirkel op basis van jouw interpretatie van de producten het juiste cijfer

**Orginele reusable sleeve**

*Hoe gemakkelijk is de sensor te bevestigen?* 1 2 3 4 5

*Hoe stevig is de sensor aan de vinger bevestigd?* 1 2 3 4 5

*Hoe betrouwbaar is de meting van de sensor?* 1 2 3 4 5

**Product idee 1**

*Hoe gemakkelijk is de sensor te bevestigen?* 1 2 3 4 5

*Hoe stevig is de sensor aan de vinger bevestigd?* 1 2 3 4 5

*Hoe betrouwbaar is de meting van de sensor?* 1 2 3 4 5

**Product idee 2**

*Hoe gemakkelijk is de sensor te bevestigen?* 1 2 3 4 5

*Hoe stevig is de sensor aan de vinger bevestigd?* 1 2 3 4 5

*Hoe betrouwbaar is de meting van de sensor?* 1 2 3 4 5

## H.2 Results

| | Original reusable sleeve | | |
|---|---|---|---|
| | Ease to apply | Security on the finger | Trustworthy reading |
| Healthcare professional 1 | 3 | 2 | 3 |
| Healthcare professional 2 | 4 | 4 | 5 |
| Healthcare professional 3 | 5 | 4 | 3 |
| Healthcare professional 4 | 5 | 1 | 4 |
| Healthcare professional 5 | 5 | 3 | 3 |
| Healthcare professional 6 | 5 | 2 | 3 |
| Healthcare professional 7 | 5 | 2 | 2 |
| Healthcare professional 8 | 5 | 2 | 4 |
| Healthcare professional 9 | 4 | 2 | 3 |
| Average scores | 4,555555556 | 2,444444444 | 3,333333333 |
| Average total score | | 3,444444444 | |

| | Concept idea 1 | | |
|---|---|---|---|
| | Ease to apply | Security on the finger | Trustworthy reading |
| Healthcare professional 1 | 4 | 3 | 3 |
| Healthcare professional 2 | 3 | 5 | 4 |
| Healthcare professional 3 | 3 | 3 | 4 |
| Healthcare professional 4 | 4 | 5 | 5 |
| Healthcare professional 5 | 4 | 4 | 4 |
| Healthcare professional 6 | 3 | 5 | 5 |
| Healthcare professional 7 | 2 | 5 | 5 |
| Healthcare professional 8 | 5 | 4 | 4 |
| Healthcare professional 9 | 4 | 3 | 3 |
| Average scores | 3,555555556 | 4,111111111 | 4,111111111 |
| Average total score | | 3,925925926 | |

| | Concept idea 2 | | |
|---|---|---|---|
| | Ease to apply | Security on the finger | Trustworthy reading |
| Healthcare professional 1 | 5 | 4 | 3 |
| Healthcare professional 2 | 5 | 3 | 4 |
| Healthcare professional 3 | 3 | 5 | 4 |
| Healthcare professional 4 | 5 | 5 | 5 |
| Healthcare professional 5 | 4 | 4 | 4 |
| Healthcare professional 6 | 3 | 5 | 5 |
| Healthcare professional 7 | 3 | 4 | 4 |
| Healthcare professional 8 | 4 | 5 | 4 |
| Healthcare professional 9 | 4 | 3 | 3 |
| Average scores | 4 | 4,222222222 | 4 |
| Average total score | | 4,074074074 | |

The table above shows the results from the filled-out form during test 1.

On overall scores the original reusable ranks the lowest, although it has the highest rating when it comes to 'ease to apply'. The original sleeve is very easy to add onto the fingertip, but this is balanced with a very insecure grip and untrustworthy reading due the products freedom to move. This results in false alarms and errors in the trend reading. These characteristics make the product fit for high stress situations in which a reading a needed very quickly, like an admission to the ICU. Once a situation is settled, this reusable device is often too unstable, uncomfortable and alarm prone to keep on, and is therefore frequently exchanged with a single use sticker.

Concept idea 2 ranks the highest. It has a well distributed score across all three requirements, ease of use, security on the finger and trustworthiness. This prototype was considered easier to apply than concept 1, mostly due to the clicking mechanism as well as the smaller tape area to peel.

Concept 1 ranked lower than 2, though the slide in mechanism was usually understood quicker than the clicking, as it was more visible than the hidden click ridges in concept 2. As the shapes did not hug the finger's shape, but layed on top of it, the concept idea was considered less stable by most.

The extra time it took to apply the hybrid concept ideas compared to the single use was considered negligible, especially as the single use is often applied in non-stressful situations.
The following page shows some pictures of observations of the user tests. The white hand model shows little contrast to the prototypes, which is a consideration for next time.

**Design considerations**
In addition to the scores, the product use was observed and discussed. This resulted in the following design considerations.

- No tape over the reusable component, as this makes it more prone to be thrown out
- Lower the material volume on the bottom of the finger, to give the patient more freedom to use their hand.
- The less tape needs to be peeled the better, as this can be finicky.
- Though more tape did sometimes convey more security
- The curved shape around the top of the finger gives a feeling of security
- The order of first applying the sticker to the finger, then adding the reusable part was considered more intuitive.
- Preferably, the reusable component should be removable while keeping the sticker on.
- Click mechanisms where considered easier and more secure than the slide in mechanism
- Stickers should be stored close to the patient's bed, like the cart in the patient's room.
- White color is considered single-use. So the reusable component should avoid white.
- Making the product asymmetrical prevents confusion about which side goes where.
- Experienced nurses were more likely to correctly apply the concept prototypes compared to inexperienced nurses, as they recognized the single use sensor application in the prototypes.
- Awareness on product use (like not throwing out the reusable component) can be communicated to nurses with use instruction (video) over e-mail alongside product appearance.

**Reflection**
In this test I compared the concept ideas to the reusable finger sleeve. During tests it appeared that the concept idea would not necessarily replace the reusable product, but the single-use one instead, and live alongside the reusable finger sleeve. The reusable could be used in high stress situations, while the concept ideas would be used when stress has subsided, and patient is admitted for a longer period of time (continues measurements). Therefore, the concept ideas should be compared to the single use product as opposed to the reusable finger sleeve.

The scale of trustworthiness in the form was hard for people to understand as they could not experience the use of the product's electronics. Therefore, some people asked how they were supposed to answer it. I answered that they should do it on intuition. What factors were considered to scale the trustworthiness of the product was not completely clear between users. Next time, this scale should be reconsidered or rephrased.

The test was very successful in confirming this concept direction as a desirable one as well as forming a list of design considerations for the next iteration of the design. Nurses were very helpful and the interaction was great.

# I / USABILITY TESTING

## Introduction text

“Thank you for participating in this usability test. Today, we’ll be evaluating the speed and ease of applying different pulse oximeters, including a single-use sensor, a reusable sensor, and a new hybrid prototype. The goal is to identify any usability issues and potential improvements for the prototype.

You’ll be asked to apply each device while we measure the time it takes. We will start by applying the new hybrid design. First I will show you a video instruction on how to use the new design. Afterwards you can try out this design, once to get familiarized, and a than a second time.

The session will take about 10 minutes. If you agree, we may record the test for later analysis. Afterward, you’ll complete a short questionnaire about your experience. Please perform the tasks as you naturally would in a clinical setting, and share any thoughts along the way.

Do you have any questions before we begin?”

## Test plan

**Objective of the Test**
Gather final design improvements and perform a comparitive analysis regarding application speed and cleaning speed of product redesign and existing single use and reusable pulse oximeter

**Limitations**
- Amount of nurses
- Time of nurses (max 5-10 min)
- Amount of stickers (max 2 per person, 10 people)

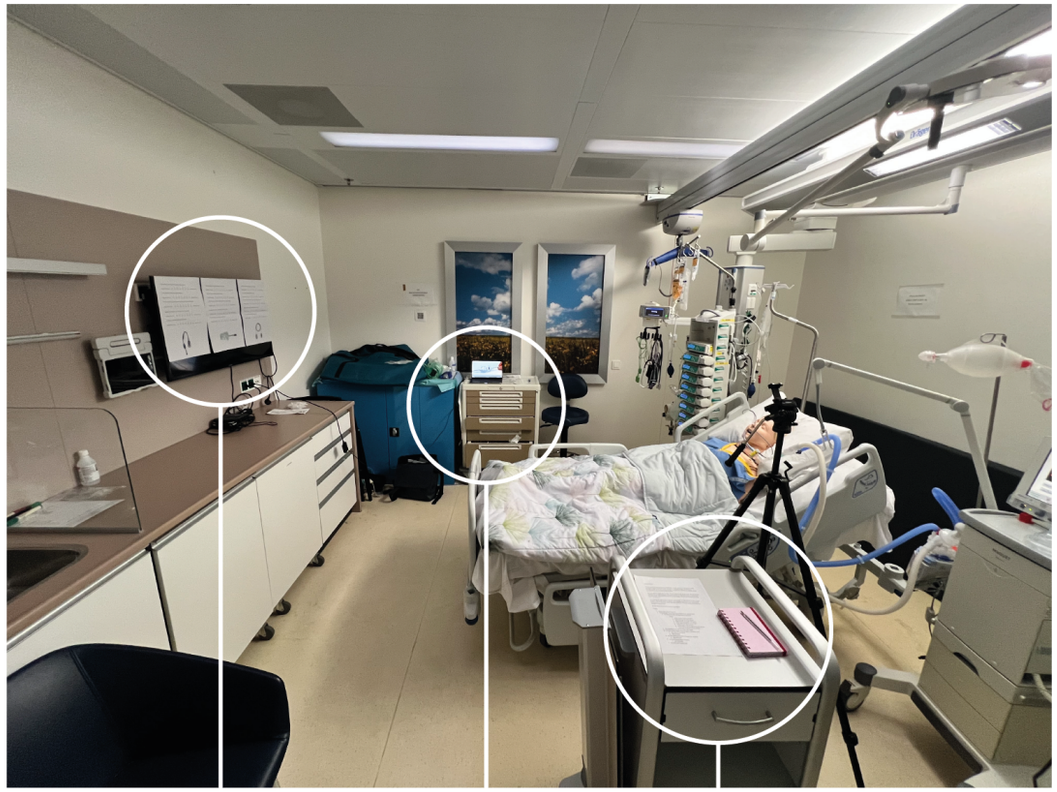
**Test Setup**
1. Show video of intended use
2. Let participant try on their own (real person), guided test (No time pressure, though time is recorded)

Steps:
1. Grab sticker from the drawer
2. Peel backing off of the sticker
3. Align sticker on finger and apply
4. Grab hybrid product from hook
5. Plug product into monitor
6. Click bottom of the hybrid into the sticker
7. Click top of hybrid into the sticker

3. Give feedback on any incorrect user steps
4. Let participant apply product again, optimized test
5. Let the particpant apply a single use product
6. Let participant apply reusable

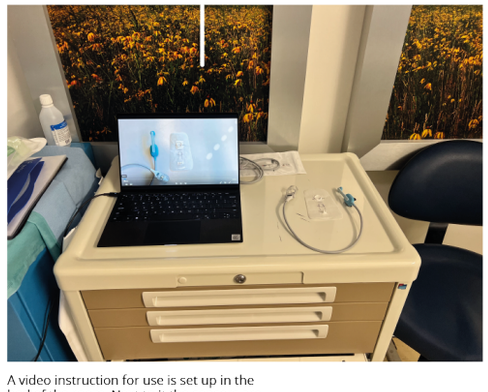
*Note down any observations of user interaction.*

## Test setup



The questionairs are hung on the wall. After the application of all sensors, the questions are answered by rating on a scale of 1-7 by the nurses. This is not filled out but talked through, with follow up questions.

The patient (now a doll, but during the test a student) is positioned in the ICU bed. The camera is set up next to the bed to film the hands of the nurse. Next to the bed I could write down my observations in a notebook.



A video instruction for use is set up in the bed of the room. Next to it the sensors are layed down, so the nurse can see the parts in real life.

## Questionaire

Questionaire inspired by PSSUQ (Post-Study System Usability Questionnaire), with tailored personal questions related comparing the sensors. This questionaire was used to guide an interview, ‘filling it out’ 3 times, one time per sensor type.

**Overall assesment product redesign**

Overall, I am satisfied with how easy it is to use this product

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
|---|---|---|---|---|---|---|---|---|
| Strongly disagree | ○ | ○ | ○ | ○ | ○ | ○ | ○ | Strongly agree |

I was able to complete the tasks and scenarios quickly using this system

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
|---|---|---|---|---|---|---|---|---|
| Strongly disagree | ○ | ○ | ○ | ○ | ○ | ○ | ○ | Strongly agree |

I feel secure that this product will stay in place

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
|---|---|---|---|---|---|---|---|---|
| Strongly disagree | ○ | ○ | ○ | ○ | ○ | ○ | ○ | Strongly agree |

I believe this product to be comfortable for the patient

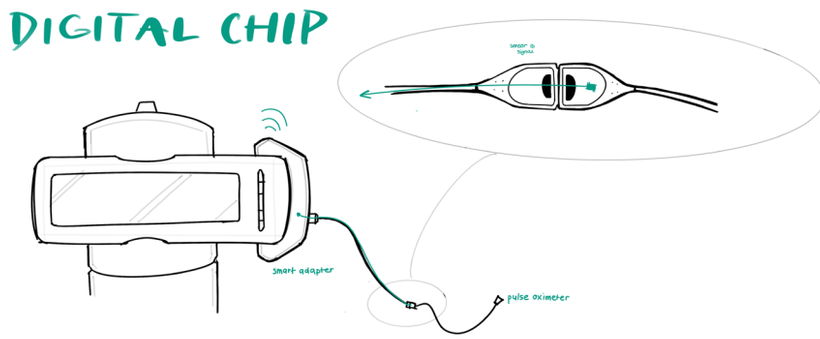
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
|---|---|---|---|---|---|---|---|---|
| Strongly disagree | ○ | ○ | ○ | ○ | ○ | ○ | ○ | Strongly agree |

I believe this product is technologically sophisticated

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
|---|---|---|---|---|---|---|---|---|
| Strongly disagree | ○ | ○ | ○ | ○ | ○ | ○ | ○ | Strongly agree |

# J / TRACEABILITY EXPLORATION

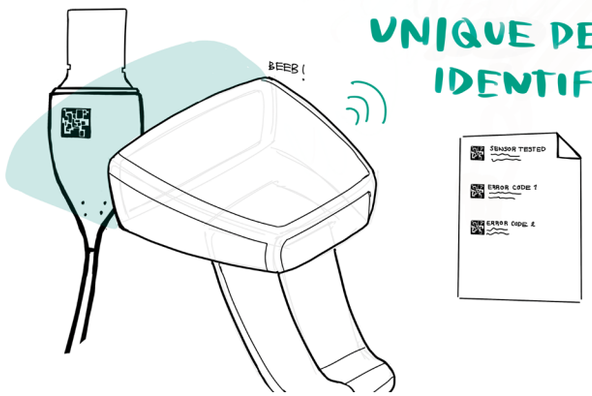
For the traceability system, several technologies were explored and combined. The following figures show an explanation and consiferations for the technologies.




A digital chip (i.e. EEPROM) is an electronic component that can store small amounts of data, like sensor ID. It can transfer this data through wired connection. In combination with a smart adapter, the location and information on product use can be saved to a local server or cloud.

- **No RF interference risk**
- **Cheap**
- **No battery**
- **No location tracking in storage**

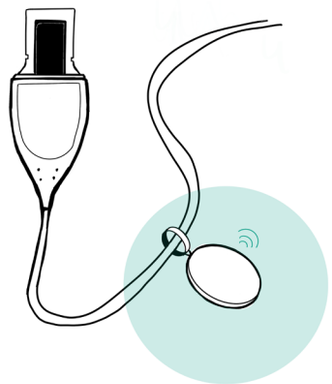
## UNIQUE DEVICE IDENTIFIER




Every medical device is equipped with a UDI that links to regulatory and manufacturer data, but can also be used within a hospital database. In a testing setup i.e. a UDI and error code can be scanned to store the reason for end-of-life in the cloud or local server.

- **Low threshold**
- **No RF interference risk**
- **Requires extra user steps**

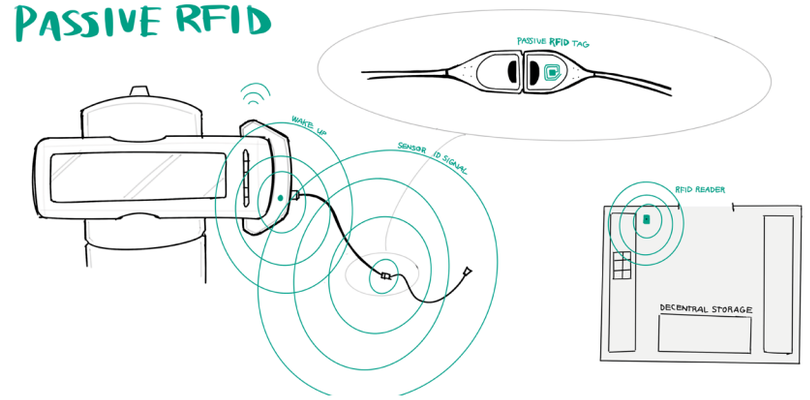
## SMART TAG



A smart tag add-on equipped with GPS and wifi connection can allow real-time location of the sensor throughout the hospital. The smart tag can be connected to the sensor's UDI to save the data to one specific sensor.

- **Low threshold**
- **Battery required**
- **Expensive**

## PASSIVE RFID




A passive RFID can store data like a unique sensor ID. Once the sensor is connected to a monitor (through an adapter) the RFID reader in the adapter sends a signal activating the RFID, which in turn transfers its data. The smart adapter can share location and use info to a local server or cloud

A reader in the storage room can also locate sensors in storage

High-frequency RFID's can reach up to 1.5

- **Cheap**
- **Can track in storage**
- **No battery**
- **Risk of confusing other sensors nearby**
- **Risk of RF interference**

One of the main downsides of the current chosen design, is that when sensors move between departments without being attached to a broodje, the location is not traced. Only the last use location can be viewed. Therefore the implementation of a storage room RFID reader, and RFID tag in the sensor was considered as an addition. When discussing this with Philips, we decided not to include this in the system, as this additional system would quickly surpass the costs of an increased stock of sensors. Therefore, the sensor traceability was kept to last use location, with the recommendation of increasing sensor stock levels in hospitals where this still leads to sensor surplus and shortages.

# 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 | Kuiper |
| Initials | |
| Given name | Fiene |
| Student number | |

IDE master(s) IPD ✓ DfI ☐ 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 | Jan-Carel Diehl | dept./section | SDE/DfS |
| mentor | Sonja Paus-Buzink | dept./section | HCD/AED |
| 2nd mentor | | | |
| client: | Eramus MC within ESCH-R consortium | | |
| city: | Rotterdam | country: | the Netherlands |
| optional comments | | | |

! 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)

Jan-Carel Diehl — Digitally signed by Jan-Carel Diehl Date: 2024.11.19 21:27:39 +01'00'

Name J.C. Diehl Date 19 Nov 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: 2024.11.21 11:38:33 +01'00'

Name Robin den Braber Date 21 nov 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: 2024.11.21 11:59:50 +01'00'

Name Monique von Morgen Date 21 Nov 2024 Signature

# Personal Project Brief – IDE Master Graduation Project

**Name student** Fiene Kuiper **Student number** 4,876,660

## PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT

Complete all fields, keep information clear, specific and concise

**Project title** Reducing the environmental impact of patient monitoring sensors

*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)*

This project focuses on lowering the sustainable impact of the patient vital monitoring sensors in the hospital context (2-3 departments to be determined). Patient monitoring sensors measure a patient's blood oxygen saturation (Oxi Pulse meters), blood pressure and heart rate. Even though multi-use sensors are available in hospitals, a high quantity of single use vital sensors are disposed of yearly. To demonstrate, 515.000 Oxi Pulse sensors are discarded by umc's in the Netherlands alone (Noort, 2024). This shows barriers in lifecycle of the multi-use sensors that need to be researched and tackled, in order to move to a more circular system. Understanding the full product journey is important for designing feasible interventions to tackle these barriers.

Over the past years, awareness on the contribution of the healthcare sector to climate change has grown. The transition toward environmentally viable health systems is perceived as inevitable and necessary (Pereno & Eriksson, 2020). From this growing interest, the ESCH-R ('Evidence-based Strategies to create Circular Hospitals) consortium has emerged (ESCH-R Creating Circular Hospitals Together, z.d.). This interdisciplinary project is a collaboration between Erasmus Medical Center and medical device manufacturers such as Philips. All together we can define the key stakeholders of this thesis as the Erasmus MC, Philips the TU Delft and myself.

Opportunities include: an intrinsic and legislative drive to reduce stakeholders' environmental footprint, existing experience with single- and multi-use sensors, which aids in identifying barriers and enablers, and the potential for significant impact from small improvements in product and system design, given the high volumes of sensors in use.

Limitations may include: slow adoption of redesigns due to the established reliance on disposables and the stringent legislations around product reuse, cleaning, use of sustainable materials etc.

(1) ESCH-R Creating circular hospitals together. (z.d.). ESCH-R Creating Circular Hospitals Together. Geraadpleegd op 12 november 2024, van https://esch-r.org/ (2) Noort, B. (2024). Landelijke Inventarisatie Medische Disposables UMC's. In Nede

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

*introduction (continued): space for images*

image / figure 1 Oxipulse meter single use and reusable sensors

ESCH-R Creating circular hospitals together. (z.d.). ESCH-R Creating Circular Hospitals Together. Geraadpleegd op 12 november 2024, van https://esch-r.org/

Noort, B. (2024). Landelijke Inventarisatie Medische Disposables UMC's. In Nederlandse Federatie van Universitair Medische Centra.

Pereno, A., & Eriksson, D. (2020). A multi-stakeholder perspective on sustainable healthcare: From 2030 onwards. Futures, 122, 102605. https://doi.org/10.1016/j.futures.2020.102605

image / figure 2 sources

# 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)*

In this project I want to develop a solution to decrease the high CO2 emissions and material waste created by patient monitoring sensors. Mapping out the product journey allows me to identifying barriers and enablers of multi- and single-use sensors. A new envisioned sensor lifecyle will be designed with a redesigned sensor to fit this system.

Challenges to tackle in this product and system redesign are:
- Extending the life-in-use of the sensors
- Improving system and product to make the reusable sensor most attractive
- Improving the comfort of the sensors for patients, especially in long-term wear settings
- Balancing the relatively low value of these sensors with potential added costs of their extended life
- Securing the safety of the sensors with relation to pathogen transmission between patients
- Closing the material loop at the end of life by designing for recycling

By gaining progressive insight in the various factors of the complex system and their interaction, i will be able to identify promising directions for solutions. Depending on the outcome I may need to narrow down the design scope to be feasible within the graduation project.

## 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 a patient monitoring sensor system and aligned sensor prototype to lower the environmental footprint of Dutch hospitals.*

*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)*

Methods such as product journey mapping accompanied by (fast-track) Life Cycle Analysis will be used to understand the current system and sustainable impact hotspots. User research through observational studies, as well as interviews will inform on barriers and enablers for a circular system. Analysis on a product level will also be conducted through observational studies and interviews as well as more technical analysis methods such as hotspot- and disassembly mapping.

To redesign the system I aim to set up co-design sessions with multiple stakeholders throughout the lifecycle of the patient monitoring sensors to design and evaluate envisioned product journey scenarios. These scenarios will be compared to each other and the current product journey using (fast-track) Life Cycle Analysis.

In the early stages, product redesigns will be ideated and tested through sketching and scenario evaluation. Later product usability evaluations will be conducted using low- and high fidelity prototypes. These prototypes will be designed for user interaction- and technical testing.

## 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** | 19 nov 2024 |
| **Mid-term evaluation** | 28 jan 2025 |
| **Green light meeting** | 25 mrt 2025 |
| **Graduation ceremony** | 24 apr 2025 |

*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)*

Throughout my studies in Industrial Design Engineering, I have developed a strong interest in medical product design, gaining valuable experience through various projects and courses. I have gained skills in user research, context analysis, technical feasibility, and prototyping. This project excites me as an opportunity to apply this knowledge and deepen my expertise in medical design, with the added insights of working together with Philips to expand my knowledge on the feasibility and viability of implementing design changes.

The opportunity of combining medical design with sustainable solutions is particularly appealing, as I see a critical need for innovation at this intersection. Though I have experience in both fields independently, this project is my first opportunity to address the complex challenges of sustainable medical design.

My ambitions for this project are:
- Gaining experience in systemic design.
- Strengthening stakeholder management skills. Possibly through the creation of a multidisciplinary sounding board group and co-creation sessions.
- Improving my product embodiment design skills through prototyping and collaborating with Philips' engineers.