17. APPENDICES content

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Appendix I - List of medical terms

1. **Congenital**: A congenital disorder, or congenital disease, is a condition existing at birth and often before birth, or that develops during the first month of life.
2. **Perioperative**: The perioperative period, less commonly spelled the perioperative period, is the time period describing the duration of a patient's surgical procedure; this commonly includes ward admission, anesthesia, surgery, and recovery. Perioperative generally refers to the three phases of surgery: preoperative, intraoperative, and postoperative.
3. **(Supra) ventricular**: situated or occurring above the ventricles, especially in an atrium or atrioventricular node. A ventricle is a heart chamber.
4. **Post-operative**: The period after the surgical procedure is completed and the patient is on the intensive care to recover from the operation.
5. **Pericardial cavity**: the potential space between the epicardium and the parietal layer of the serous pericardium.
6. **Pericardium**: the fibroserous sac enclosing the heart and the roots of the great vessels.
7. **Saline solution**: Water with 0,9% NaCl
8. **Atrial fibrillation**: Having to do with fibrillating the upper chambers of the heart.
9. **HRQoL**: Health Related Quality of Life
10. **Concor**: In 2000, the Interuniversity Cardiology Institute of the Netherlands and the Netherlands Heart Foundation have taken the initiative to develop a national registry and DNA-bank of patients with congenital heart disease in the Netherlands named CONCOR
11. **Degenerative disorders**: Degenerative disorders involve progressive impairment of both the structure and function of part of the body.
12. **Hematocrit**: level of red blood cells in the blood
13. **Aprotinin**: Medicine to reduce blood loss
14. **CPB**: Cardiopulmonary bypass: A procedure to circulate and oxygenate the blood during heart surgery involving the diversion of blood from the heart and lungs through a heart-lung machine and the return of oxygenated blood to the aorta
15. **BMI**: Body mass index, **BSA**: Body surface area
Appendix II - brainstorm and sketches

This brainstorm was conducted in the AMC hospital with the collaboration of several specialists. Input was gained by people from the instrumentation company, clinically involved people and the perfusion department. The idea behind the brainstorm was to let the attendees think about the problem in a different way they are used to be. The focus was on the look and feel instead of functionality. Eventually functionality became a part of the discussion as well, but with the first thoughts on look and feel different outcomes were collected. The conclusions of the brainstorm are given on the next page. These outcomes acted as an idea box in which new ideas were collected. All ideas were organized, grouped and they helped me coming up with ideas in the next paragraph.
Outcomes Brainstorm

- Storage under the bed could be a good option
- Measure the outflow with a laser to monitor the HCT values
- The product must give a Aston Martin DB9 experience (beautiful and streamlined)
- Wires and cables integrated into the side panels of the bed
- Move the heavy parts as close to the ground to create stability
- Heating element in the, to be designed, saline sack tray.
- Use colors that camouflage the product when attached to the bed
- Empty thorax drain boxes half way the treatment to reduce the size of the boxes
- Get rid of the scale to prevent gravity related errors (bouncy transports and touching the scale) and introduce flow meters.
- Form aspects: One surface, light colors, round edges, no hooks, apple, football, thermos can, electric toothbrush, less is more.
- Ease of use comparable to toys, start and stop button, nothing more.
- Integration with bairhugger (heating element to heat up the patient after surgery)
- NaCl XI bags, design a NaCl bag especially for this application. (future)
- Saline bags in a tray and measure the tray
- Integrate the device in a backpack so a nurse could carry it on her back.
- Levels of integration: Complete (saline, console and outflow) Semi (saline, console + console, outflow), none (console only)
- Wireless data transfer system
- Modular IC bed
- Get rid of the outflow waste
- Integrate a waterbed into the IC bed to get rid of the heating element since the water temperature can be controlled.
APPENDIX III - The Clean Cardiac Surgery Consortium

To start at the very beginning of the project the CCSC will be explained. What is the CCSC and what do they do?

The health care problem at the attention of the CCSC is a consequence of and inherent to cardiac surgery; a growing population of patients with congenital\(^1\) heart disease is facing a future with repetitive surgical interventions, with also repeated and every time increasing hazards due to perioperative\(^2\) complications. In this case surgery means open heart surgery. When facing multiple open heart surgeries it is obvious that this will include high risks on complications.

The CCSC research project focuses on four important complications to which the congenital heart patient is exposed at least one, but probably multiple times during life:

1. (excessive) postoperative blood loss
2. postoperative supraventricular rhythm disturbances\(^3\)
3. the development of pericardial adhesions
4. Post-operative\(^4\) right ventricular function impairment.

The CCSC hypothesizes there is a common determining factor for all these complications, finding its origin in the first; postoperative blood loss and stasis of blood in the pericardial cavity\(^5\).

The CCSC invented a new therapeutic technique, which is continuous postoperative flushing of the pericardial cavity with a saline solution\(^6\) (Postoperative Pericardial Flush), and believe that this can contribute to a cleaner pericardial space, thereby reducing postoperative blood loss, transfusion requirements, atrial fibrillation\(^7\) and postoperative right ventricular function impairment. This will improve the clinical outcome after surgery for congenital heart disease patients with respect to mortality and morbidity, increase HRQoL\(^8\) post cardiac surgery and decrease societal health-care costs.

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\(^1\) Congenital: A congenital disorder, or congenital disease, is a condition existing at birth and often before birth, or that develops during the first month of life.

\(^2\) Perioperative: The perioperative period, less commonly spelled the periooperative period, is the time period describing the duration of a patient’s surgical procedure; this commonly includes ward admission, anesthesia, surgery, and recovery. Perioperative generally refers to the three phases of surgery: preoperative, intraoperative, and postoperative.

\(^3\) (Supra)ventricular: situated or occurring above the ventricles, especially in an atrium or atrioventricular node. A ventricle is a heart chamber.

\(^4\) Post-operative: The period after the surgical procedure is completed and the patient is on the intensive care to recover from the operation.

\(^5\) Pericardial cavity: the potential space between the epicardium and the parietal layer of the serous pericardium. Pericardium: the fibroserous sac enclosing the heart and the roots of the great vessels.

\(^6\) Saline solution: Water with 0,9% NaCl

\(^7\) Atrial fibrillation: Having to do with fibrillating the upper chambers of the heart.

\(^8\) HRQoL: Health Related Quality of Life
After performing a safety and feasibility pilot study in the AMC, this consortium combines the knowledge of three specialized academic institutions to deliver the world’s first proof of principal and proof of concept for the use of postoperative pericardial flush (PPF) by means of a series of controlled randomized trials new technology will be developed to make the therapy safe and ergonomic.

The overall goal of the CCSC is to be able to use this (still to be proven clinically effective) therapeutic technique on children. This will create possibilities to tackle the problems of congenital heart disease patients in a very early state reducing chances on complications.
2.2 The stakeholders

The CCSC consists out of specialists from three universities namely:

Academisch Medisch Centrum (AMC)  
Dep. (Congenital Adult) Thoracic Surgery  
Centrum Voor Aangeboren Hartafwijkingen Amsterdam-Leiden (CAHAL)

Leids Universitair Medisch Centrum (LUMC)  
Dep. (Congenital Paediatric) Thoracic Surgery  
Centrum Voor Aangeboren Hartafwijkingen Amsterdam-Leiden (CAHAL)

Technische Universiteit Delft (TUD)  
Dep. Physical Ergonomics  
Healthcare Programme

In the flowchart the structure of the CCSC is displayed. This complete flowchart can be found in Appendix I.

AMC

The AMC is where the CCSC project mainly takes place. They are able to design prototypes, with the help of the IB (Instrumentation company on site), and test these prototypes without having to get CE certification. A risk analysis is made and if there are no significant risks found by either the medical staff as well as the IB the prototype can be tested in practise. The first development phase, in which the project is now, will therefore takes place within the walls of the AMC to quickly get results and be able to bring the project to the next level.

LUMC

The LUMC is a hospital in which together with the AMC forms the CAHAL. If the prototype is in such a developed phase it has an approved patent and can be tested outside the AMC the LUMC will be a partner in which the CCSC will work with closely.

TU Delft

The TU Delft is the partner which was contracted to the consortium to bring the prototype to the next level. The current situation of the prototype is explained in the next paragraph “the product”. The TU Delft specialists will mainly focus on improving the product on the level of technology, user experience and interaction as well as creating a solid business plan for the product for a smooth market introduction.
APPENDIX IV – State of art

3.3.3 (Volumetric) Pump
To make sure the saline is pumped through the pericardium a volumetric pump is used. Hereby, the nurse can set a flow rate (500 ml/hour) to ensure the right amount is pumped through the system at the right speed. In the current situation the sacks of saline are hanging on top of the pole so no pumping mechanism is needed to empty the bags, because the gravity force is doing this job. When a redesign of the prototype is considered a pump is maybe needed, because of the different placing of the saline bags. This matter will be discussed in the paragraph “Scope”.

The first picture shows a small venturi system which is able to produce a small vacuum by only needing an airstream. Secondly, the Vacuair is another small vacuum system which can provide a small vacuum. Third and fourth are comparable volumetric pumps. The AMC nowadays uses the Braun volumetric pump which is shown on the right.

3.3.3.1 A vacuum system
In the operating theatre a vacuum is always present but when the patient is transported to the intensive care there could also be a need of a vacuum in case of a changed design. Therefore the small vacuum systems like a venturi pump or the Vacuair could be considered.

3.3.3.2 A volumetric pump
The volumetric pump itself is there in many different formats. In this stadium of the project the volumetric pump which is used by the AMC is advised, but when the need is there to reduce the size of the device a different one could be considered.
APPENDIX V – Literature

3.4 Literature

The use of Aprotinin during surgery greatly reduces the amount of blood loss (Woodman & Harker, 2011) (Alvarez, et al., 1995)

It is very difficult to characterize the bleeding after CPB. There are many variables. The most common factor is the temporary loss of platelet function. However this causes only excessive bleeding at a small amount of patients. (Woodman & Harker, 2011)

It is not recommended to make use of intermittent saline flushing (Zimbudzi, 2013)

Disappointingly, extensive, well-developed guidelines based on current levels of evidence have done little to change clinical practice for different reasons, including a lack of substantial evidence of efficacy, budgetary restrictions, peer pressure, and a difficulty in implementing change to complex, institution-wide processes. (Nalla, Freedman, Hare, & Mazer, 2013)

In several parts of the world the pericardium is left open after cardiac surgery (Dantas, Bastos, & Magnanini, 2010)

Low-dose Aprotinin and a cell saver are effective and comparable methods of blood conservation. Aprotinin helps by decreasing the postoperative drainage, and a cell saver helps by making the patient’s own blood available for transfusion. (tempe, et al., 2001)

3.4.1 Literature outcomes

In this literature research several articles were reviewed and checked for relevant info of this project. It was hard to find specific information about parties who were also developing or doing research in the field of a pericardial flushing device. Therefore, several motivations of improving the operation techniques were found to once more underline the importance of creating this new product. When this technique will be clinically proven to work, children could also be treated and after a few years all other cardiac surgeries are part of the market. This would imply that the potential of the flushing device is enormous.

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9 Aprotinin: Medicine to reduce blood loss
10 CPB: Cardiopulmonary bypass: A procedure to circulate and oxygenate the blood during heart surgery involving the diversion of blood from the heart and lungs through a heart-lung machine and the return of oxygenated blood to the aorta
APPENDIX VI – List of requirements

4. List of requirements

4.1 Technology

1. Hematocrit level needs to be measured in real time and communicated to the device
2. Device needs to have a connection possibility with the intensive care bed.
3. Device should easily be moved around
4. Connection technology, in case of a stand-alone device, should be flexible due to the tilting bed (-15° to 15°)

Wishes

5. Device needs to be compatible with different intensive care beds
6. Device should be modular
7. Volume balance needs to be monitored by means of a flow sensor
8. Volumetric pump needs to be placed below the saline sacks
9. Thorax drain boxes need to be placed as low as possible
10. Saline sacks needs to be placed above the patient to make use of the gravity
11. Technique is integrated into the back of the bed or is replacing the back of the bed.
12. Vital monitor cables can be connected to the system

4.2 Look and Feel

1. Device must have round edges
2. Device should not have small gaps
3. Casing should be semi-transparent

Wishes

4. Device must look beautiful
5. Device is integrated into its environment

4.3 User
6. Interface needs to be visible from different points of view
7. Control panel should be in reach while the user is in a standing position
8. Connecting and disconnecting the device needs to be performed within 1 minute
9. Elements that are not needed during the treatment must be hidden inside the casing
10. Device, when it’s in place, cannot hinder the casual operations around the bed.
11. Device can be moved with a maximum of two persons

Wishes
12. Patient view on the device needs to be blocked as much as possible

4.4 Safety
13. Wires and infusion lines need to be concealed and protected from the environment
14. Product cannot contain sharp edges
15. Product cannot harm someone
16. Device can be taken apart for cleaning reasons
17. Device is splash proof (plant spray on 1 meter distance)

4.5 Dimensions
18. Device cannot exceed the dimensions of the 1st prototype (1731x900x600 (mm))
19. Device cannot protrude at the back of the bed compared to the AMC prototype
20. If placed under the bed it cannot exceed the height of 500 mm because of the height adjustable bed
21. Device cannot exceed the weight limit of 15 kg.
**Wishes**

22. Device needs to be half the height of the 1st prototype
23. Device cannot arise above the back of the bed

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**4.6 Costs**

24. Costs of the device should not exceed the price the customer is willing to pay (will be elaborated in the next phase)

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**Wishes**

25. Body of the device cannot exceed 1000 euros to produce (excluding the devices like sensors etc.)

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**4.7 Materials and production**

26. Basis of the device is made out of a lightweight and strong material
27. Faces that can contact a person are covered with protection strips or soft materials
28. Production methods need to be applicable for small series
APPENDIX VII - Three personas

Mira (32)
Operating nurse
Married with Rogier
8 years of experience

Loves to work in the operating theatre
“There is a very good working atmosphere when performing my job.”

Loves: Neat working space. Nicely arranged working gear.
Hates: the overgrowth of apparatus and wires.
Jeffrey (58)
Cardiac patient
Married to Theresa
Loves his job as sales representative

Is looking forward to
go to his cozy home

Loves: his wife being there for him.
Dislikes: the overcrowded
IC room with beeping apparatus
**Marleen (23)**

Intensive care nurse
Just graduated
Excited to learn

"Working with IC patients is what gives me satisfaction."

"Taking care of patients when they are in a great need of care motivates me to do a great job."

Loves: New technologies, taking the lead.

Hates: Unnecessary complexity, clear information
APPENDIX VIII – IDEA GENERATION
Sketches

The stand-alone laptop based flushing device where everything is integrated into the body of the design. The round shapes will make sure that a friendly and safe look will be perceived. Everything is, as already mentioned, integrated into the body of the device. This will make sure the needed elements are accessible; minimal chance of errors.

Remarkable aspect of this idea is that every aspect is still visible. This will make sure the nurse knows what to do when something goes wrong. Every element is easy accessible. The interface is integrated into the device making it resistant to dirt and fluids, but vulnerable to long repair times because the screen could not easily be replaced if it breaks.

This idea is based on a trolley shape where the whole flushing device floats above the ground when the bed is in a normal position. The nurse positions the trolley at the end of the bed when it is a low position. If the bed is moved in a higher position the trolley will click into the back of the bed. This will make the whole device lift from the ground. Furthermore, easy access is provided by a door.

This idea is based on a bumper shape. It is attached to the frame of the bed replacing the back of the bed. Every aspect is integrated into the body of the idea and anesthesia could also plug in their cables to check the vitals of the patient on the screen of the flushing device also. In this way they have a total overview of the patient’s situation.
This idea is distinguished in waste management as well as in storage. The waste is not collected into the original thorax drain boxes but guided through small chambers of 1 liter where the fluids could be analyzed. Thereafter, the fluids will be guided into a waste bag which could be removed after the treatment. Next, the design of the idea is very open. This will enable multifunctional use of the product.

This U shaped trolley on the bottom can be used in different positions. You can also position the device on the side of the bed enabling the medical staff to use the back of the bed for different purposes. On the bottom the two ends of the U-shape could be extended creating a storage place for the thorax drain boxes.

This idea is based on an infusion pole. The great advantage of an infusion pole is that different elements could be attached without much extra work. The basis of this idea is to make use of a pole where different elements could be attached suiting the patients treatment.
Weight sensors in the slots where the thorax drain boxes could be inserted. The whole set-up could be placed on the ground where this fits the best according to the medical staff. Wire connected for data sharing.
The external outflow measuring unit (described in nr. 10) is placed under the bed. A click mechanism could also be provided to make sure the unit is connected to the bed. It is important to place the drain boxes as low as possible to prevent backflow in case of system failure.

This is an idea where the inflow fluids are combined in a rack with the outflow drain boxes. If the sacks are supported, and not hanging on hooks, they will be less vulnerable for measuring errors due to touching the scale.

The drain box unit consists out of three slots where the drain boxes could be inserted. In this way the scale, to weigh the mass changes, could be integrated in the bottom of the unit instead of making use of the voluminous hanging system. This will make sure the total system could be designed more compact and is less vulnerable for measuring errors.
This concept is based on the idea of replacing the back of the bed by the flushing device. Seen from the patient’s point of view nothing has changed. Hence, when you look at the other side of the bed the complete device becomes visible. The elements are hidden behind a semi-transparent casing which opens to both sides.
This concept is based on the basic idea of placing every element below the bed. This is where the most empty space is. Downside is that it is not easily accessible and replaceable. The whole system can be integrated into the current beds by means of the connection shackle seen below the back of the bed. This shackle clamps around the frame of the bed holding it in place. Two connections are being made on the other side of the concept to make sure it stays in place.
Submarine 1

This concept is based on the idea of a completely self-providing unit. It can stand on its own and only connects by the in- and output lines with the patient. The submarine 1 can be locked to the bed so it stays in place during transport. The wheels can turn 360 degrees so movement will not be hindered.
Suitcase 1

This concept is based on the idea of a replaceable back of the bed. Furthermore, a mobile unit is placed underneath the bed on which the drain boxes could be placed. The suitcase 1 could easily be placed and moved around with the steel grip as shown in the figure. The back of the suitcase 1 will be covered with a semi-transparent material.
This concept is based on the idea of placing every element underneath the bed, except for the electronics. In this way the connections with the bumper 3 could easily be made and another advantage is that the IC staff could also connect their cables of the vitals monitor so this could also be read on the interface of the bumper 3.
This concept is based on the idea of creating a standalone device that also acts as the back of the bed. The submarine 2 is hooked into the back of the bed. In this way the back of the submarine 2 will act as the back of the bed and will stay into place. The elements are logically placed with the saline above the pump.

Figure 6 Submarine 2
APPENDIX IX – Questionnaire user test
User test Adult Intensive Care

User experience questions

1. What are the first five words that pop into your mind when seeing the device?

2. What function do you have in the hospital and does the product address your needs? If no, what can be improved?

3. On what points do you think this design is an improvement and on what points do you think this design is a step back compared to the previous prototype?

User friendliness (geef een score van 1 tot 10 in hoeverre je het eens bent met de steekproef)

1. The device is beautiful
2. I would like to work with the device
3. If I were a patient I would feel safe while treated with this device
4. The device gives me a feeling of peace
5. I think this device is restless
6. I feel safe while using the device
7. I think placing the different reservoirs underneath the bed is logical
8. It would be ideal if every bed has this system
9. It would be ideal if this system is easy to apply on every ICU bed
10. The device is one with the bed. It looks integrated
11. Placing the device on the bed is easy
12. The design without wheels is useful because of the weight space

Comments:...
User test Adult Intensive Care

General

1. What are the first five words that pop into your mind when seeing the device?

2. What function do you have in the hospital and addresses the product your needs? If no, what can be improved?

3. On what points do you think this design is an improvement and on what points do you think this design is a step back compared to the previous prototype?

Look and Feel (geef een score van 1 tot 10. Hoeveel je het eentje beter vindt, de score)

1. The device is beautiful
2. I would like to work with the device
3. If I were a patient I would feel safe while treated with this device
4. The device gives me a feeling of peace
5. I think this device is useful
6. I feel safe while using the device
7. I think placing the different reservoirs underneath the bed is logical
8. It would be ideal if every bed has this system
9. It would be ideal if this system is easy to apply on every ICU-bed
10. The device is one with the bed. It looks integrated.
11. Placing the device on the bed is easy.
12. The design without wheels is useful because of the small space

User friendliness (geef een score van 1 tot 10. Hoeveel je het eentje beter vindt, de score)

1. I think the top of the device provides enough space to place syringes etc.
2. The placing of the handle is logical to me.
3. Installing the device is easy
4. Installing the connection systems for the saline packs is easy
5. Installing the connection systems for the thorax drain box is easy
6. Dismounting the whole system is easy
7. The interface is placed at a logical spot
APPENDIX X – SolidWorks technical drawings

See SolidWorks report